労災疾病臨床研究事業費補助金

職場における腰痛の効果的な治療法等に関する研究

平成27年度　総括・分担研究報告書

主任研究者　松平　浩

平成28年3月

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研究代表者　松平浩　東京大学医学部附属病院22世紀医療センター
運動器疼痛メディカルリサーチ＆マネジメント講座

研究要旨

本研究では、世界的にみてもいまだ克服されていない職場の腰痛対策をテーマに、特に介護看護従事労働者をターゲットとして、疫学的手法を用いたリスク因子の同定、発症予防に役立つ体操や福祉機器および両立支援手法の開発ついての取り組みを、3 年計画で包括的に推進することとした。2年めの主な知見は以下である。

1) 立位におけるアライメントおよび腰部への力学的負荷が腰痛の有訴に与える影響を生体力学的実験にて検証したところ，軽微な不良に伴うと思われる椎間板圧縮力がリスク要因であった.
2) 腰部負担が多い介護労働者の仕事に支障をきたす慢性腰痛の疫学的関連要因を検討したところ、職業性簡易ストレス調査票での身体愁訴が多い、STarT Back スクリーニングツールでハイリスク（心理的要因の領域得点が高い）、TSK-J（恐怖回避思考・行動の点数が高い）が選択された。
3) 英国で慢性腰痛および再発性腰痛の管理として有用とされているボディワークである AT 介入は、腰痛の有無に関わらず腰部負担軽減効果があった。また AT によって介入された姿勢は骨盤が適度に前傾し、腰椎が前弯するとともに胸椎の後弯が減少する理想的な脊椎のS字カーブと想定される良姿勢に近づく結果が得られた。
4) 持ち上げ動作時に squat 法にて骨盤を前傾させるように指示すると、椎間板圧縮力・剪断力とも有意に減少した。
5) 社会福祉法人の介護職に対する簡便な腰椎伸展体操である“これだけ体操”の習慣化は、1年後の腰痛状況を改善した。

最終年度である来年度は、さらに包括的な研究を発展させかつ遂行している研究結果を整理し、職場における効果的な腰痛対策に関する労働安全衛生マネジメントシステム構築を視野に入れた提言を作成する予定である。

A. 研究目的

厚生労働省が公表する「国民生活基礎調査の概要」において，国民の代表的愁訴（有訴者率）が，腰痛（男1位，女2位），肩こり（男2位，女1位）であることはよく知られているが、同じく厚生労働省が公表する業務上疾病発生状況等調査によると、休業4日以上の業務上疾病の発生件数のうち腰痛は、長年に渡り全職業性疾病の約6割を占め第 1 位である。平成 23 年の腰痛全届け出のうち社会福祉施設が 19%を占め、10 年で 2.7 倍という最も顕著な増加となった背景を踏まえ、19 年ぶりに改訂された「職場における腰痛予防対策指針」（平成 25 年、厚生労働省）では、重症心身障害児施設等に限定されていた適用を、福祉・医療等における介護・看護作業全般に拡大し、内容を充実させるに至った。つまり、介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。また世界疾病負担研究にて 289 の疾患や傷

病のうち、腰痛が Years Lived with Disability (YLDs)、つまり健康でない状態で生活する年数を指標とする統計のトップにランクされるなど、社会的損失や健康面への影響の大きい腰痛への対策はグローバルにも重要な課題として位置づけられている。

研究代表者は、一昨年度まで行われた「労災疾病等 13 分野研究」の本分野において世界標準のエビデンスを踏まえつつ独創的な研究を展開し、近年、国際的にも評価される業績を公表してきた（13 分野研究の総括事後評価点数：5 点満点で 4.9)。本研究では、世界的にみてもいまだ克服されていない腰痛対策に関し、臨床専門の医師のみならず産業医学・産業保健、看護、人間工学、福祉工学、統計学といった様々な分野のスペシャリストを分担研究者として招聘し、これまでの主任研究者の実績と研究基盤をさらに発展させた計画を立て、昨年度から取り組んでいる。特に介護看護従事労働者をターゲットとして、疫学的手法を用いたリスク因子の同定、発症予防を目的とした介入法の構築、福祉用具の開発や利用および産業理学療法士によるサポートを基軸とした職業と治療の両立支援法の作成等包括的に推進することとしている。

具体的には、３年計画で以下のサブテーマに基づき遂行する予定とした。①腰痛に関わる実態およびリスクの同定、②予防に有用な福祉機器等の開発、③介護看護従事者への予防介入法とマネジメントシステムの構築、④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発、以上を踏まえた⑤労働安全衛生マネジメントシステム構築を視野に入れた提言作成。

２年目である本年度、推進した研究に関し、上①～④のサブテーマ別に報告する（⑤は最終年度課題であるため今回は省略する)。

B. 研究方法

① 腰痛に関わる実態およびリスクの同定

１）これまでの先行研究では、姿勢観察や分類から、立位姿勢と腰痛との関連は検討されているが、立位姿勢における椎間板圧縮力と腰痛との関連は検討されておらず、立位姿勢の椎間板圧縮力が腰痛に影響を与えるのかは不明である。そこで、本研究では、立位におけるアライメントおよび腰部への力学的負荷が腰痛の有訴に与える影響を明らかにすることを目的に実験を行った。若年男性 67 名を質問紙法により、腰痛有訴群と非有訴群の 2 群に分け、安楽立位姿勢を三次元動作分析装置とスパイナルマウスで計測した。腰痛有訴の有無により t 検定を実施した。ロジスティック回帰分析は、腰痛の有無を従属変数、計測したパラメータを独立変数とし、腰痛の有無へ影響度の高いパラメータを選出した。

２）介護労働者の支障度の高い腰痛に関連する疫学的な心理的関連因子を検討した。石川県内の医療･介護施設 125 か所に調査用紙を送り、本調査研究の趣意に賛同を得た医療・介護施設 95 か所及びそこで働く無作為に選定された 1 施設 20 名を対象とし、腰痛状況を含む多面的な自記式質問紙による横断調査を行った。職場での心理的ストレスの測定は、職業性ストレス簡易調査票を使用した。また、近年、世界的に腰痛の難治化する予後を予想するツールとして注目されている STarT(Subgroup for Targeted Treatment) Back スクリーニングツール日本語版も測定した。さらに、腰痛の最も重要な予後規定因子ともされる恐怖回避思考・行動を TSK-J 短縮版にて測定した。腰痛の程度は 4 段階（grade 0：腰痛無し、grade 1：支障のない腰痛、grade 2：支障はあるが欠勤しなかった腰痛、grade 3：腰痛のため欠勤したことがある）で評価し，grade2 以上かつ 3 ヵ月以上継続した腰痛を重症度の高い腰痛と定義した。統計解析は記述統計と、重症度の高い腰痛との関連要因を検討するためロジスティック回帰を用いた。

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②予防に有用な福祉機器等の開発

1）姿勢改善を目的とした福祉機器の開発を目指し、昨年度は抗力を具備した継手付き体幹装具 Trunk Solution（TS）の開発およびその効果を確認した。しかしながら、今後 TS を改良もしくは姿勢を改善するための機器開発にあったっては、良姿勢の基準が必要となる。英国などでは、慢性および再発性腰痛の管理に有益であることが大規模な無作為比較試験により示されいるアレクサンダーテクニーク(以下 AT)による無駄な筋緊張のない理想的な姿勢へのアプローチが腰痛の改善を目的として取り入れられている。しかし、AT の生理学的、運動学的な機序は不明な点が多く、介入によってどのような立位姿勢や力学的な変化が起こっているかは明らかになっていない。そこで本研究では良姿勢の構築と腰痛管理に有効なボディケアといえる AT 介入での姿勢およびそれに関連する力学的な変化を明らかにすることを目的として実験を行った。対象者は、健常成人男性 11 名、および腰痛有訴者 12 名の合計 23 名とした。実験条件は安楽立位姿勢と AT 介入後の姿勢とし、姿勢パラメータの比較を行った。計測順序は対象者の安楽立位姿勢を計測した後に、資格を有する熟練した AT 教師による 5 分間の介入を行い、AT 介入後の姿勢パラメータを計測し、二元配置分散分析等を行った。

③介護看護従事者への予防介入法とマネジメントシステムの構築

1) 看護領域ではボディメカニクスの理論が普及しており、なるべく介助者の身体の近くで移乗などの介助動作を行うことが推奨されている。これはレバーアームを短くして介助動作を遂行することを意識したもので、これにより腰部負担軽減を目指している。しかし、介助動作時に身体に対象者を近づけることを意識すると介助者の上半身のみが対象者に近づいてしまい、かえって腰部負担を増加させてしまうことがある。そこで我々は身体を近づけるという教示ではなく、“骨盤を前傾させる”という教示を「臍を物体に近づける。」という言葉に変え、今回は基礎的研究として物体の持ち上げ動作時の腰部負担軽減効果を検証した。対象は健常成人男性 10 名とし、三次元動作分析装置、床反力計を使用して持ち上げ動作時の運動学、運動力学的データを計測した。腰部負担の指標は椎間板圧縮力と剪断力を採用した。被験者は 11.3 ㎏に設定された重量物を squat 条件（股関節と膝関節を屈曲）と stoop 条件（股関節を屈曲、膝関節を伸展)、これら 2 つの方法でより骨盤を前傾させるように指示した 2 条件を加えた 4 条件で持ち上げ動作を行った。統計処理は拳上方法の違いと骨盤前傾指示の有無を要因とした繰り返しのある二元配置分散分析反復測定法を用いた。また、通常の条件と骨盤前傾を指示した条件での差は、対応のある t 検定で判定した。さらに、4 条件の中でどの姿勢が最も腰部負担が小さいのかを明らかにする目的で、椎間板圧縮力と剪断力に関する一元配置分散分析反復測定法および多重比較検定(Bonferroni 法)も併せて行うこととした。

2) 主任研究者は、勤務中多忙な介護看護従事者が簡易で即実践できる腰痛予防体操（腰を反らす「これだけ体操」）を、ポピュレーションアプローチとして実践することにより職場の腰痛状況を改善できる可能性を鳥取県の米子こうほうえんで遂行した先行研究で示した。本研究は、同手法を長野県信濃上小地区で実施した研究である。対象であるが、腰痛対策のスペシャリストである我々が、伸展体操プログラムを推進するにあたり妥当であると考える「前かがみ作業」に従事することが多い社会福祉法人の介護士とターゲットとした。具体的には長野県

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信濃上小地区の 3 つの介護福祉施設（依田窪、みまき、ベルポート）のうち 2 施設を積極介入群、1 施設をコントロール群とした。両群間で施設の入居者数、入居者の平均介護度、認知症者の割合、障害の程度の割合、職員の数、性差、年齢に有意差はなかった。積極介入群は、これだけ体操を主とするマニュアルを配布するだけでなく、マニュアルの内容に関する 30 分の講義を受け、さらに参加型形式で業務中の伸展体操を積極的に行う群とした。各施設のファシリデーターと我々の協議により、「これだけ体操」を勤務中に習慣化する仕組みを構築した。対照群は、マニュアルの配布のみとした。

3) 全国 12 労災病院をクラスターとして、A:対照（無介入）、B:「これだけ体操」の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群を実施するため、統計学的な見地を踏まえデザインを行い、ベースライン調査を行った。

④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発

1) 業務上疾病の約 6 割を占める腰痛には、人間工学的要因のみならず心理社会的要因も関与することが科学的根拠のある事項として認識され、さらには正しい情報の提供や周囲の励ます態度などは腰痛を軽快させることが明らかになりつつある。一方、腰痛予防に関しても、特定健診・保健指導で用いられるメール指導による腰痛予防効果の有効性が期待されたため、両立支援手法の新たな手法として産業理学療法士主導で取り組みを構築してきた。その結果、メール指導前後において労働者が各自の職務をどれほど上手にできているかを表す指標である Work Ability Index (WAI) の有意な向上および腰痛に関わる就労状況を含めた予後規定因子である恐怖回避思考の指標である Fear-Avoidance Beliefs Questionnaire (FABQ) の改善傾向を認めるなど、産業理学療法士主導による効果を確認し、本システムを試作した。このシステムは，産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」と命名した。平成 25～26 年度にかけて Compo の試用を行い、平成 27 年度にはその検討の成果をもって Compo を改良しつつ、被験者の登録を開始した。

（倫理面への配慮）

独立行政法人労働者健康福祉機の 12 労災病院、国際医療福祉大学、関西福祉科学大学、東京大学医学部附属病院の倫理審査の承認を得ている．被験者に対してはデータを ID 化して管理するなど個人情報には十分配慮している。

C. 研究結果

① 腰痛に関わる実態およびリスクの同定

1) 非腰痛有訴群、腰痛有訴群のパラメータの比較を対応のない t 検定を用いて行った結果、非腰痛有訴群と腰痛有訴群の身長と体重に有意差は認められなかった。非腰痛有訴群と腰痛有訴群を比較したロジスティック回帰分析の結果、**椎間板圧縮力のみ**有意な変数として選択されオッズ比は 2.3 であった。

2) 調査票は 95 施設，1,704 名より回答を得て、全てを解析対象とした。平均年齢は 40.2 歳(SD 11.7)、 性別は女性が 75.3%であった。多変量ロジスティック回帰の結果、職業性簡易ストレス調査票での**身体愁訴が多い**、STarT Back スクリーニングツールでハイリスク（**心理的要因の領域得点が高い**）、TSK-J（**恐怖回避思考・行動の点数が高い**）が選択された。

②予防に有用な福祉機器等の開発

椎間板圧縮力は AT 介入前後の要因として主効果が認められ、AT 介入後に減少していた。このことから、腰痛の有無に関わらず、AT の介入には腰部負担軽減効果があることが示唆された。

また AT によって介入された姿勢は骨盤が適度に前傾し、腰椎が前弯するとともに胸椎の後弯が減少する理想的な脊椎のＳ字カーブと想定される良姿勢に近づく結果が得られた。

③介護看護従事者への予防介入とマネジメントシステムの構築

1）squat 法にて骨盤を前傾させるように指示すると椎間板圧縮力・剪断力とも有意に減少した。

2）両群併せて 167 名（積極介入群：89 名、対照群：78 名）の介護士をエントリーした。過去１年間に腰痛がなかった割合は 29.9%にとどまり、全体の 10.2%が過去 1 年を総合的に考えて腰痛にため仕事に支障をきたしていた。介入終了後のアウトカム評価は、1 年後に行った自記式調査票への記入を完了した例を対象に分析を行った。ベースライン時での背景情報であるが、年齢、性別、BMI、喫煙習慣に加え、腰痛に対する通院状況、ベースライン時での直近１カ月の腰痛状態（程度）に関し、両群の間に統計的有意差はなかった。自覚的改善度、対策の実行度とも対照群と比較し、「これだけ体操」実施群のほうが統計的に有意に優れていた。また、両群問わず実行度が高いほど腰痛の自覚的改善が得られていた。

3）関東（562 名）、横浜（667 名）、新潟（274 名）、浜松（256 名）、旭（182 名）、大阪（720 名）、関西（674 名）、中国（391 名）、愛媛（193 名）、長崎（285 名）、以上 12 労災病院（施設）をクラスターとし、病床・看護師数、看護師の男女数・平均年齢を割付調整因子とし、コンピューターの乱数表を用い、3 群（4 施設ごと）に無作為割付する非盲検試験を開始した。

A 群は北海道中央、横浜、大阪、浜松の 1,799 名に、B 群は関東、旭、中国、長崎の 1,420 名、C 群は東北、新潟、関西、愛媛の 1,548 名、全体で 4,767 名にアンケートを配布した。全体でアンケート回収数は 3,439 名分で、回収率は 72.1%だった。各群の回収数は A 群 1,319 名、群 1,000 名、C 群 1,120 名であり、回収率はそれぞれ 73.3%、70.4%、72.4%であった。回収したアンケートのうち 58 名に不備があったため解析には 3,381 名分のアンケートを利用した。過去１か月以内に業務に支障を来した腰痛の既往を持つ有病者数は、全体で 272 名（8.0%）であった。この年度末に介入後調査を行った。

④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発

本システムはパソコンでも、携帯電話でも使用可能である。特定の URL を入力し、個別の ID とパスワードでログインする。相談者は担当の指導者へテキストで相談を送信することができ、画像などの種々のファイルも添付可能である。指導者は相談者からの相談内容に応じて返信を行う。相談と指導のやり取りは、システムを通すし、仮名設定を前提とするので、相互の個人情報が開示・他者から確認されることはない。指導者からはアンケートなども一斉送信で容易に実施可能となっており、その結果も CSV でダウンロード可能で、研究事務局で一括管理できる。対象者から相談のあった場合に指導者へ通知されるアラート機能（登録したメールアドレスへシステム上に相談者から連絡のあった場合、リアルタイムに通知される。同様に指導者からシステム上で返信した場合、相談者へリアルタイムに登録したメールアドレスへ通知される）を装備している。現在、Compo を用いた介入研究を実施中である。臨床試験登録システムである UMIN-CTR(UMIN000018450)に 2017 年 7 月 29 日に登録を行い対象者の登録・取入れを開始した（試験名：「産業理学療法指導システム（Compo）による勤労者の腰痛予防効果の検証」).

30 歳から 65 歳までの保健衛生業に従事する者を対象として、Compo を用いて指導を行う群（介入群）と介入を行わない群（対照群）の２群に振り分け、被験者を募集し研究を開始した。

D. 考察

腰痛有訴者の立位姿勢では、非腰痛有訴者と比較し、椎間板圧縮力が増加している可能性が示さ

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れた。これは、軽微な姿勢バランスの乱れや背筋緊張に伴う椎間板への生体力学的負荷の上昇が影響している可能性が考えられる。そして、慢性および再発性腰痛の管理に有益であることが英国での大規模な無作為比較試験により示されいる AT を用いた無駄な筋緊張のない理想的な姿勢へのアプローチは、骨盤を適度に前傾させるなど良好なアライメントを構築することにより、椎間板圧縮力の軽減を主とする腰部負担軽減効果があることが示唆された。我々は、昨年度に報告した腰痛有訴者でも簡便に良姿勢を獲得可能な抗力を具備した継手付き体幹装具 Trunk Solution（TS）を開発しているが、現在、今回の AT 介入研究結果も踏まえて、多様な作業環境に利用できることをめざし、さらなる改良を加えている。

一方、介護従事や荷物拳上作業では、過去の知見により椎間板圧縮力をはじめとする生体力学的な腰部負担が著明に上昇することが示されている。今回、squat 法にて骨盤を前傾させるように指示すると椎間板圧縮力・剪断力ともに小さくなった知見は、基本的な作業姿勢の教育システムを構築するうえで有益と考える。我々は、現在、作業に伴う軽微な腰部負担を検出しバイオフィードバックできる機器およびシステムを開発中であり、来年度には、充実した人間工学的な腰痛予防教育システムを提案できるものと考えている。

しかしながら、職場と家庭を含む日常生活全般で、常に良姿勢を維持することは現実的でなく、止む無く腰痛リスクとなる不良姿勢をとらざるをえないこともあるであろう。主任研究者は、最も簡便で現実的な対策として、以前より“これだけ体操”を考案し、社会福祉法人をはじめとする様々な業種の事業所にこれを普及してきた。今回、先行して成果を得た鳥取の「こうほうえんプロジェクト」の後に追試として行った「信濃上小プロジェクト」でも、これだけ体操普及によるポピュレーションアプローチが腰痛予防に有用なことを示すことができた。この年度末に介入後調査を終える大規模な労災病院看護師プロジェクトでも、その有益性が示されることを期待しているところである。

腰痛のリスクはとしては、人間工学的要因のみならず心理的要因の関与が近年グローバルに重要視されている。今回、横断調査ではあるが、社会福祉法人の介護従事者の仕事に支障をきたしている慢性腰痛と関連する因子として、職業性ストレス簡易調査票における身体症状が多い、STarT Back スクリーニングツールで心理的要因の領域得点が高い、TSK-J による恐怖回避思考・行動の点数が高いことが多変量解析により選択された。職業性ストレス調査票における身体症状の質問には、腰痛以外の症状として“めまい”、“体のふしぶじが痛む”、“頭が重かったり頭痛がする”、“首筋や肩がこる”、“腰が痛い”、“目が疲れる”、“動悸や息切れがする”、“胃腸の具合が悪い”、“食欲がない”、下痢や便秘をする”、“よく眠れない”が該当する。これらは心理的ストレスが脳機能（中脳辺縁系のドパミンシステムなど）や自律神経系機能に影響を与えることによって生じる機能的な症状と想定される。腰痛にも、不良姿勢に伴う椎間板圧縮力の上昇等の腰部へのメカニカルストレスのみならず心理的ストレスによる脳および自律神経系の機能異常を介した筋緊張や局所の動脈でのスパズムが強まって起こるタイプがある可能性も考慮する必要がある。さらに本知見では、STarT Back スクリーニングツールと TSK-J が高いオッズ比を示した。STarT Back スクリーニングツールは５つの質問から構成され、不安と抑うつに関する質問が１問ずつ、恐怖回避思考および近隣概念である痛みへの破局的思考が強いかを問う質問がそれぞれ１問、さらには自己効力感の乏しさともいえる腰痛に関する自覚的な煩わしさの程度で構成されている。TSK は運動器に関する分野において恐怖回避思考を測る世界標準の調査票である。これらは、グローバルには腰痛発症後の予後を規定するツールであることが明らかになっている。

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今回の結果は、日本の介護施設労働者に対しても、先述した椎間板圧縮力を高めない人間工学的対策とともに、健康管理の一環として、恐怖回避思考モデルや心理的ストレスマネジメントの教育を行う必要性があると考えられた。つまり、両者は職場の腰痛対策の車の両輪といえる。

産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」は、前述した知見を含むエビデンスを基盤とした主任研究者の包括的な腰痛対策を、一般産業医や保健師よりも関連知識および実地経験とも豊富な産業理学療法士が効率的に両立支援を遂行するシステムとして立ち上げたものである。今後、遂行中の研究知見等を踏まえた PDCA サイクルにより、洗練された手法にしていきたいと考えている。

E. 結論

●立位におけるアライメントおよび腰部への力学的負荷が腰痛の有訴に与える影響を生体力学的実験にて検証したところ、軽微な不良に伴うと思われる椎間板圧縮力がリスク要因であった。

●腰部負担が多い介護労働者の仕事に支障をきたす慢性腰痛の疫学的関連要因を検討したところ、職業性簡易ストレス調査票での身体愁訴が多い、STarT Back スクリーニングツールでハイリスク（心理的要因の領域得点が高い）、TSK-J（恐怖回避思考・行動の点数が高い）が選択された。

●英国で慢性腰痛および再発性腰痛の管理として有用とされているボディワークである AT 介入は、腰痛の有無に関わらず腰部負担軽減効果があった。また AT によって介入された姿勢は骨盤が適度に前傾し、腰椎が前弯するとともに胸椎の後弯が減少する理想的な脊椎のＳ字カーブと想定される良姿勢に近づく結果が得られた。

●持ち上げ動作時に squat 法にて骨盤を前傾させるように指示すると、椎間板圧縮力・剪断力とも有意に減少した。

●社会福祉法人の介護職に対する簡便な腰椎伸展体操である“これだけ体操”の習慣化は、1 年後の腰痛状況を改善した。

F. 健康危険情報

該当なし

G. 研究発表

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H. 知的財産権の出願・登録状況（予定を含む）

1．特許取得

なし

2．実用新案登録

なし

3．その他

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Ⅱ.分担研究報告

労災疾病臨床研究事業費補助金

分担研究報告書

成人男性における立位姿勢の各関節角度・負担の計測と腰痛の有無に影響を与える要素の特定

研究分担者　岡敬之　東京大学医学部附属病院 22 世紀医療センター
運動器疼痛メディカルリサーチ＆マネジメント講座

研究要旨

これまで，腰痛の発症には，骨，骨格筋，靭帯，軟部組織，神経由来や心理社会的要因，職場環境など，多くの要因が複雑に関連しているといわれており，職場環境において，長時間の立位姿勢は腰痛を発症するリスクファクターになることや，不良姿勢が腰痛に関連することも指摘されている．しかし，これまでは立位姿勢における各関節や脊柱の角度を検討した研究は行われているが，三次元的に身体の姿勢を分析し，腰部に生じる力学的負担を明らかにした研究はない．さらに，これまでの先行研究では，姿勢観察や分類から，立位姿勢と腰痛との関連は検討されているが，立位姿勢における椎間板圧縮力と腰痛との関連は検討されておらず，立位姿勢の椎間板圧縮力が腰痛に影響を与えるのかは不明である．そこで，本研究では，立位におけるアライメントおよび腰部への力学的負荷が腰痛の有訴に与える影響を明らかにすることを目的に実験を行った．対象は，成人男性とし，日常習慣的にとっている安楽立位姿勢の計測を行った．結果として，ロジスティック回帰分析の結果，独立変数として椎間板圧縮力が選ばれた．以上のことから，立位姿勢における椎間板圧縮力の増加は腰痛の有無に影響することが示された．これらのことから，立位姿勢のような小さな腰部負担であっても，腰痛の有訴に影響し，不良姿勢となることで力学的な負担の増加が起こり，腰痛の有訴へ影響すると考えられる．

A. 研究目的

本邦において，腰痛は最も有訴率の高い疾患である．推計では約 2800 万人もの腰痛者が存在すると報告され，70~85%のヒトが人生のうち少なくとも一度は経験するといわれている．また，腰痛は本邦だけではなく欧米においても有訴者数が最大の疾患である．加えて，腰痛は職業関連の疾患のなかで発生頻度が最も高く，主要な休職理由になっているため，腰痛による多大な金銭的，時間的な社会的損失が報告されている．このような背景から，近年，腰痛発症や慢性化のメカニズムを明らかにする多くの試みが行われるようになってきている．

腰痛の発症には，骨，骨格筋，靭帯，軟部組織，神経由来や心理社会的要因，職場環境など，多くの要因が複雑に関連しているといわれており，職場環境において，長時間の立位姿勢は腰痛を発症するリスクファクターになることや，不良姿勢が腰痛に関連することも指摘されている．

立位姿勢と腰痛との関連に着目した研究は，立位姿勢の矢状面や前額面上の二次元の関節角度を計測し分析した結果と腰痛の有訴との関連を検討した研究が行われている．また，椎間板への持続的な圧縮負荷は，椎間板の厚みを減らし，腰痛を引き起こすことが指摘されており，不良姿勢のような腰椎屈曲位や伸展位では，椎間板への圧縮力が不均等となり圧力の高い部分の損傷を引き起こすことが指摘されている．

以上のように不良姿勢と腰痛との関連が指摘されており，いわゆる不良姿勢を想定すると，腰部関節中心と上半身重心位置との距離が離れることで，椎間板への力学的負担が増大することが予想できる．従って，力学的な負荷を考慮すれば，関節への負荷が小さい姿勢が良い姿勢，大きい姿勢が悪い姿勢と考えることができる．

しかし，これまでは立位姿勢における各関節や脊柱の角度を検討した研究は行われているが，三次元的に身体の姿勢を分析し，腰部に生じる力学的負担を明らかにした研究はない．さらに，これまでの先行研究では，姿勢観察や分類から，立位姿勢と腰痛との関連は検討されているが，立位姿勢における椎間板圧縮力と腰痛との関連は検討されておらず，立位姿勢の椎間板圧縮力が腰痛に影響を与えるのかは不明である．そのため，立位姿勢のアライメントや腰部負担などの，どのような運動学，運動力学的要素が腰痛の有訴に影響するのかを明らかにすることができれば，腰痛の改善や予防に対して有用な情報となると考えた．

以上より，本研究では，立位におけるアライメントおよび腰部への力学的負荷が腰痛の有訴に与える影響を明らかにすることを目的に実験を行った．

B. 研究方法

若年男性 67 名(23.9±3.3 歳，172.7±6.2cm，65.2±7.9kg)を対象とした．計測を行うに先立ち，被験者には研究内容を十分に説明し，書面にて研究への同意を得た．本研究では RDQ (Roland-Morris Disability Questionnaire)，Clermont らによって確立された腰痛に関する質問，そして心理社会的要因による腰痛の判別に用いられる keele STarT back scoring tool を用いたスクリーニングによって腰痛有訴者と非腰痛有訴者の判別を実施した．RDQ1 点以上かつ腰痛があると答え，3 ヶ月以上腰痛が続いている対象者を腰痛の訴えがある者と定義し，腰痛有訴者とした．非腰痛有訴者はいずれの設問にも該当しない者とした．また，被験者の除外基準は，keele STarT back scoring tool が 4 点以上の心理社会的腰痛の疑いがある者，下肢症状のある者とした．

計測条件は被験者が習慣的にとっている安楽立位姿勢とした．被験者は片脚ずつ床反力計上に肩幅程度に足を広げて立ち 10 秒間 3 試行の立位姿勢を計測した．目線は 5m 先に設置した目線の高さの目印を見るように指示した．

計測には三次元動作解析装置(VICON)，床反力計(AMTI)，スパイナルマウス(Idiag)を用いた．

三次元動作解析装置で得られたパラメータは，10 秒間の値を平均し，3 試行の値を平均した値を分析に用いた．スパイナルマウスから得られた値は 3 試行の平均値を用いた．関節モーメント，椎間板圧縮力は被験者の体重で除し正規化した．

統計解析は，被験者間の身体特性および非腰痛有訴群と腰痛有訴群の比較には対応のない t 検定を行った．

ロジスティック回帰分析は，腰痛の有無を従属変数，計測したパラメータを独立変数とし，腰痛の有無へ影響度の高いパラメータを選出した．ロジスティック回帰分析を行うに際し，ピアソンの積率相関係数を用いて独立変数間で相関係数が，$|r|>0.9$ の強い相関のある変数がないことを確認した．ロジスティック回帰分析に投入する独立変数の選定は，非腰痛有訴群と腰痛有訴群にて，対応のない t 検定によって，有意な差を認めた変数を用いた．変数選択の方法は尤度比による変数増加法を用いた．いずれも有意水準は 5%とした．

C. 研究結果

非腰痛有訴群，腰痛有訴群のパラメータの比較を対応のない t 検定を用いて行った結果，非腰痛有訴群と腰痛有訴群の身長と体重に有意差は認められなかった．また，今回計測したパラメータでは，椎間板圧縮力，腰部屈伸モーメントが腰痛有訴群で有意に大きかった．非腰痛有訴群と腰痛有訴群の比較では，その他のパラメータに有意差は認められなかった．

ロジスティック回帰分析の結果，椎間板圧縮力のみ変数として選択され，オッズ比は2.308であった．モデル X^2 検定は $P<0.01$ で有意であった．

D. 考察

立位姿勢における椎間板圧縮力が腰痛の有訴に対する影響をロジスティック回帰分析を用いて明らかにすることを目的に解析を行った．

本研究における腰痛有訴者と非腰痛有訴者の分類は RDQ，質問紙の結果より分類した．RDQ が 1 点以上かつ，腰痛の有無に関して腰痛があると答え，腰痛を自覚してから 3 ヶ月以上症状が続いている者を対象とした．除外基準は keele STarT back scoring tool が 4 点以上の心理社会的腰痛が疑われるもの，下肢症状のあるものとした．

RDQ は腰痛による日常生活の障害を問うものであり，質問紙は腰痛の自覚を問うものである．つまり，本研究における腰痛有訴群は，3 ヶ月以上続く腰痛の自覚があり，日常生活になんらかの障害をもつ者となる．

以上の基準より判定した腰痛の有無を従属変数とし，非腰痛有訴群と腰痛有訴群で有意差のあったパラメータである椎間板圧縮力，腰部屈伸モーメントを独立変数として，ロジスティック回帰分析を行った．この方法により単一のパラメータ間の比較でなく，複合的な要因が腰痛に与える影響について調べることができる．ロジスティック回帰分析の結果から，腰痛の有無には椎間板圧縮力が影響することが示唆された．オッズ比から，椎間板圧縮力が 1(N/kg)増えると，腰痛を訴える可能性が約 2.3 倍になることが示された．

本研究で用いた椎間板圧縮力は3軸まわりの腰部モーメントと各モーメントのモーメントアームとの逆数との積により筋張力を推定し，合計した値を用いて算出された．この方法を用いると，いずれの方向の姿勢の崩れに対しても，腰部負担を各軸周りのモーメントの増加として反映することができる．前述した腰痛の有無による比較では椎間板圧縮力だけでなく，腰部屈伸モーメントにも有意差が認められたが，ロジスティック回帰分析では腰部屈伸モーメントは腰痛の有無に影響を与える要素として選択されなかった．これは椎間板圧縮力が単軸のモーメントだけでなく，多軸のモーメントの影響を複合して算出されていることが影響したためと考えられる．先行研究においても，腰痛に関連すると考えられる不良姿勢には, 過度の胸椎後弯, 過度の腰椎前弯など, 様々なパターンがあると報告されている．立位姿勢を保持する戦略や不良姿勢には多様性があるが，最終的には各軸周りのモーメントが複雑に関連することで椎間板圧縮力が増加し，腰痛の有訴に影響していたことが考えられる．

椎間板圧縮力に関して，NIOSH の基準に示されているように大きな腰部負担は不可逆的な損傷をもたらすといわれている．そのため多くの先行研究では重量物の運搬や移乗介助動作など，高負荷な動作の腰部負担に関しての検討がなされてきた．本研究の結果から，腰痛有訴者では非腰痛有訴者に比べて立位時の椎間板圧縮力が大きいこと，小さい負担であっても椎間板圧縮力の増加は腰痛の有訴に影響することが示されたことより，立位時に生じるようなわずかな負担の違いであっても，負担を軽減することが重要であることが示唆された．

E. 結論

立位姿勢における椎間板圧縮力が腰痛の有訴に与える影響を明らかにすること，立位における姿勢変化が椎間板圧縮力の増減に対する影響を明らかにすることを目的とし，本研究を行った．

若年男性の立位姿勢の運動学，運動力学的パラメータを計測した．その値を用いてロジスティック回帰分析を行った結果，立位姿勢における椎間板圧縮力の増加は腰痛の有無に影響することが示された．このことから立位姿勢の椎間板圧縮力が増えることは腰痛の危険因子になることが明らかになった．

これまで，不良姿勢は腰痛との関連が指摘され

ており，先行研究では，いくつかの姿勢が腰痛に関連する姿勢と述べられていた．しかし，先行研究においては，姿勢と腰痛との関連を指摘するのみにとどまり，力学的要素の様子や影響は明らかではなかった．

今回の実験結果より，椎間板圧縮力は腰痛の有無に影響ことが示唆された．

以上のことから，いわゆる不良姿勢になることで，体節の重心と関節中心との距離が離れることにより，力学的な負荷が増加することが考えられる．

先行研究において，重量物の持ち上げや，肥満など，腰部に大きな負担のかかることと，腰痛の発症や増悪との関連が指摘されている．また，椎間板への持続的な力学的負担の増加は障害につながると指摘されている．これらのことから，立位姿勢のような小さな腰部負担であっても，腰痛の有訴に影響し，不良姿勢となることで力学的な負担の増加が起こり，腰痛の有訴へ影響すると考えられる．

F. 健康危険情報

該当なし

G. 研究発表

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H. 知的財産権の出願・登録状況（予定を含む）

1．特許取得
なし

2．実用新案登録
なし

3．その他

労災疾病臨床研究事業費補助金

分担研究報告書

介護施設労働者における重症度の高い腰痛の関連要因の検討

研究分担者　金城大学医療健康学部　小山善子

研究要旨

腰痛は痛みの原因が特定できる「特異的腰痛」と，原因を特定しきれない「非特異的腰痛」に大別される．非特異的腰痛のリスク要因は「重い荷物を持つ」,「姿勢の悪さ」など，腰自体への負担に関わる問題に加え，様々な心理・社会的要因が重要なことが明らかになってきた．我が国における労働災害による死傷者数は，長期的には減少傾向にあるが，保健衛生業では増加している．今回，心理・社会的要因を考慮して介護施設労働者における腰痛の関連要因を検討した．多施設横断研究で介護施設に働く労働者を対象とし，自記式の質問表を使用した．対象となった 1,704 名のうち，重症度の高い腰痛は 205 名（12.0%）に認められた．多変量ロジスティック回帰分析により関連要因を検討し，ストレス要因による身体愁訴，STarT Back スクリーニングツールがハイリスク（心理的要因が強い）,TSK-J（恐怖回避思考が強い）が統計的に有意な結果であり，心理・社会的要因の関与が示唆された．腰痛対策には人間工学的アプローチのみならず，恐怖回避思考を代表とする心理的なアプローチが必要であると考えられた．

A.研究目的

腰痛は病気の名前ではなく，症状の総称である．具体的には助骨縁より下部で，下殿溝より上記に限定的に起こる疼痛や不快感と定義される．その分類は，医師の診察や画像検査で痛みの原因が特定できる「特異的腰痛」と，さまざまな検査をうけても原因を特定しきれない「非特異的腰痛」に大別される．その割合は特異的腰痛については腰痛を理由に医療機関を受診する 10%程度であり，およそ 85%が非特異的腰痛に該当する．

近年，この非特異的腰痛の実態を分析するため，各国の研究者によりさまざまな角度から研究が行われている．その結果，非特異的腰痛のリスク要因は「重い荷物を持つ」,「姿勢の悪さ」など，腰自体への負担に関わる問題に加え，さまざまな心理・社会的な要因（心理的ストレッサー）が重要であることが明らかになってきた．特に難治化する要因の多くが心理・社会的要因である報告もある．我が国でもこうした各国の腰痛研究の結果を踏まえ，考え方が変わりつつあり「腰痛診療ガイドライン 2012」においても疫学に関する最もエビデンスレベルの高い項目として「発症と遷延に心理的因子が関与」が挙げられている．

腰痛は職場に多く，厚生労働省労働基準局調査よると平成 24 年の業務上疾病の発生件数（休業 4 日以上）は，業務上の負傷に起因する疾病者の 84.2%が腰痛（災害性腰痛）と報告されている．その中でも，我が国における労働災害による死傷者数は，長期的には減少傾向にあるが，サービス経済化の進展等に伴い，全産業に占める第三次産業の割合は年々増加している．そのうち，老人介護分野においては，今後一層の高齢化の進展により介護施設労働者の増加が見込まれ，腰痛についてもその増加が懸念されている．

このような背景で，介護施設が増える中，そこで働く介護施設労働者の腰痛対策は喫緊な課題である．厚生労働省では平成 25 年に「職場における腰痛予防対策指針」を改訂し，適用範囲を福祉・医療分野における介護・看護作業全般に広げた．指針には作業管理や作業環境管理のみならず，

健康管理や労働衛生教育が記載されており，心理・社会的要因にも配慮した内容となっている．

そこで我々は，多面的な心理・社会的要因を考慮して介護施設労働者における腰痛の関連要因を検討する研究を実施した．腰痛は一般的な症状であるため本研究では，特に重症度の高い腰痛に注目した．

B. 研究方法

研究デザインは多施設共同横断研究とした．対象は介護施設に働く労働者とし，施設の選定は石川県内の介護施設 125 箇所に調査用紙を郵送して本研究の趣旨に賛同をえた 95 箇所とした．1 施設 20 人を対象とし，無記名の自記式質問表を郵送にて回収した．

調査項目は，個人的要因（性別，年齢，学歴，婚姻），生活習慣（喫煙，運動習慣，睡眠時間，睡眠の質），労働要因（雇用形態，経験年数，職種，労働時間，夜勤の回数），心理・社会的要因（職業性ストレス調査票，日本語版 STarT Back スクリーニングツール，TSK-J）とした．

年代は，“10 代～35 歳未満”，“35 歳以上～50 歳未満“，“50 歳以上”と区分した．学歴は，“中卒・高卒”，“専門学校・高専・短大卒・大学卒・大学院卒”と区分した．婚姻は，“未婚”，“既婚”と区分した．

喫煙は，“現在喫煙”，“現在非喫煙”と区分した．運動習慣は，30 分以上の運動を過去 1 ヵ月に平均週 2 回以上の実施とした．睡眠時間は過去 1 ヵ月の平均で，“5 時間未満”，“5 時間以上 6 時間未満”，“6 時間以上”と区分した．睡眠の質は次の 3 つの質問：①“入眠が 30 分以上”，②“中途覚醒が週 3 回以上”，③“早期覚醒が週 3 回以上”で調査し，該当数を“2 つ以上”，“1 つ”，“0 個”と区分した．

雇用形態は，“正社員”，“正社員以外”と区分した．経験年数は，“1 年未満”，“1 年以上 5 年未満”，“5 年以上”と区分した．職種は，“介護福祉士・ホームヘルパー”，“介護福祉士・ホームヘルパー以外”と区分した．労働時間は過去 1 ヵ月の 1 週間あたりの残業時間を含む労働時間が，“40 時間以内”，“41 時間以上 60 時間以内”，“61 時間以上”と区分した．夜勤の回数は過去 1 ヵ月の 1 週間あたりの回数が，“2 回以上”，“1 回”，“0 回”と区分した．

心理・社会的要因であるストレスの測定は，職業性ストレス調査票を用いた．57 の質問で構成され，①ストレスの原因と考えられる因子，②ストレスによっておこる心身の反応，③ストレス反応に影響を与える他の因子の 3 つの領域に大別され，さらに細かくは 18 の尺度に分類される．得点化は標準化得点法（下図）に沿って，各尺度について状態が一番悪い分類（灰色マーカー部）を“High”，それ以外を“Low”と区分した．

尺度	計算 No.は質問項目得点	男性					女性				
		低い／少い	やや低い／少い	普通	やや高い／多い	高い／多い	低い／少い	やや低い／少い	普通	やや高い／多い	高い／多い
		質問項目合計得点 下段は分布 (n=15, 933)					質問項目合計得点 下段は分布 (n=8, 447)				
【ストレスの原因と考えられる因子】											
心理的な仕事の負担（量）	15-(No.1+No.2+No.3)	3-5	6-7	8-9	10-11	12	3-4	5-6	7-9	10-11	12
		7.2%	18.9%	40.8%	22.7%	10.4%	6.6%	20.4%	51.7%	15.6%	5.8%
心理的な仕事の負担（質）	15-(No.4+No.5+No.6)	3-5	6-7	8-9	10-11	12	3-4	5-6	7-8	9-10	11-12
		4.5%	20.6%	43.4%	25.7%	5.7%	4.9%	17.5%	38.2%	29.1%	10.3%
自覚的な身体的負担度	5-No.7		1	2	3	4		1	2	3	4
			33.8%	39.3%	18.7%	8.2%		37.0%	33.7%	19.7%	9.6%
職場の対人関係でのストレス	10-(No.12+No.13)+No.14	3	4-5	6-7	8-9	10-12	3	4-5	6-7	8-9	10-12
		5.7%	24.8%	47.5%	17.6%	4.5%	7.3%	26.8%	41.0%	18.4%	6.4%
職場環境によるストレス	5-No.15		1	2	3	4	1		2	3	4
			25.1%	38.0%	23.1%	13.8%	17.7%		31.7%	28.8%	21.7%
仕事のコントロール度	15-(No.8+No.9+No.10)	3-4	5-6	7-8	9-10	11-12	3	4-5	6-8	9-10	11-12
		5.4%	16.6%	37.1%	32.4%	8.5%	5.5%	16.0%	48.8%	23.3%	6.3%
技能の活用度	No.11	1	2	3	4		1	2	3	4	
		4.5%	18.2%	49.4%	27.9%		9.1%	26.7%	45.6%	18.6%	
仕事の適性度	5-No.16	1	2	3		4	1	2	3		4
		6.4%	23.3%	54.9%		15.4%	9.3%	25.9%	49.7%		15.1%
働きがい	5-No.17	1	2	3		4	1	2	3		4
		7.3%	24.2%	51.4%		17.0%	13.1%	29.3%	44.5%		13.1%
【ストレスによっておこる心身の反応】											
活気	No.1+No.2+No.3	3	4-5	6-7	8-9	10-12	3	4-5	6-7	8-9	10-12
		10.9%	14.3%	41.6%	24.5%	8.7%	13.4%	19.2%	37.3%	21.3%	8.8%
イライラ感	No.4+No.5+No.6	3	4-5	6-7	8-9	10-12	3	4-5	6-8	9-10	11-12
		10.3%	20.9%	38.2%	22.7%	7.8%	7.6%	18.2%	45.1%	20.3%	8.8%
疲労感	No.7+No.8+No.9	3	4	5-7	8-10	11-12	3	4-5	6-8	9-11	12
		9.7%	12.2%	47.4%	23.3%	7.4%	6.2%	23.2%	40.1%	23.1%	7.4%
不安感	No.10+No.11+No.12	3	4	5-7	8-9	10-12	3	4	5-7	8-10	11-12
		8.3%	14.9%	51.9%	17.8%	7.1%	12.3%	15.6%	44.7%	21.6%	5.8%
抑うつ感	No.13～No.18の合計	6	7-8	9-12	13-16	17-24	6	7-8	9-12	13-17	18-24
		15.1	21.6%	40.6%	16.2%	6.5%	12.40%	18.9%	39.3%	22.3%	7.2%
身体愁訴	No.19～No.29の合計	11	12-15	16-21	22-26	27-44	11-13	14-17	18-23	24-29	30-44
		5.3%	31.0%	40.5%	15.9%	7.4%	8.3%	23.6%	38.6%	21.7%	7.8%
【ストレス反応に影響を与える他の因子】											
上司からのサポート	15-(No.1+No.4+No.7)	3-4	5-6	7-8	9-10	11-12	3	4-5	6-7	8-10	11-12
		6.9%	27.0%	32.8%	24.7%	8.7%	7.5%	22.0%	38.9%	26.7%	4.9%
同僚からのサポート	15-(No.2+No.5+No.8)	3-5	6-7	8-9	10-11	12	3-5	6-7	8-9	10-11	12
		6.1%	32.4%	39.9%	16.3%	5.3%	8.1%	31.3%	35.3%	17.9%	7.4%
家族・友人からのサポート	15-(No.3+No.6+No.9)	3-6	7-8	9	10-11	12	3-6	7-8	9	10-11	12
		6.9%	13.9%	20.3%	28.4%	30.6%	4.4%	10.6%	16.0%	28.6%	40.4%
仕事や生活の満足度	10-(No.1+No.2)	2-3	4	5-6	7	8	2-3	4	5-6	7	8
		5.0%	12.3%	57.2%	17.4%	8.1%	6.4%	15.4%	57.8%	15.4%	5.0%

さらに、近年、世界的に腰痛の難治化する予後を予想するツールとして注目されている STarT(Subgroup for Targeted Treatment) Back スクリーニングツール日本語版も測定した．5 つの質問から構成され，“そうだ”もしくは“とても/極めて”を 1 点として，本ツールを開発した

英国キール大学の推奨に沿って（下頁図が領域得点と呼ばれる心理的要因の設問項目）、領域得点 4 点以上を“High risk”，4 点未満を“Low risk”と区分した．

	そうではない 0	そうだ 1
私のような体の状態の人は、体を動かし活動的であることは決して安全とはいえない	□	□
最近2週間は、心配事が心に浮かぶことが多かった	□	□
私の腰痛はひどく、決して良くならないと思う	□	□
以前は楽しめたことが、最近2週間は楽しめない	□	□
全般的に考えて、ここ2週の間に腰痛をどの程度煩わしく感じましたか？	全然 □ 0　少し □ 0　中等度 □ 0	とても □ 1　極めて □ 1

さらに，腰痛の最も重要な予後規定因子ともされる心理的要因である恐怖回避思考について，TSK-J（下図）にて測定した．11 の質問から構成され，該当するを 1 点として，加算した総得点を 3 分位して，“High”，“Medium”，“Low”とした．

1. 運動すると体を痛めてしまうかもしれないと不安になる
2. 痛みが増すので何もしたくない
3. 私の体には何か非常に悪いところがあると感じている
4. 他の人は私の体の状態のことなど真剣に考えてくれない
5. アクシデント(痛みが起こったきっかけ)のせいで，私は一生痛みが起こりうる体になった
6. 痛みを感じるのは，私の体を痛めたことが原因である
7. 不必要な動作を行わないよう，とにかく気をつけることが，私の痛みを悪化させないためにできる最も確実なことである
8. この強い痛みは私の体に何か非常に悪いことが起こっているからにちがいない
9. 体を痛めないために，痛みを感じたら私は運動をやめる
10. 私はとても体を痛めやすいので，全てのことを普通の人と同じようにできるわけではない
11. 痛みがある時は，誰であっても運動することを強要されるべきではない

腰痛の程度は 4 段階（grade 0：腰痛無し，grade 1：支障のない腰痛，grade 2：支障はあるが欠勤しなかった腰痛，grade 3：腰痛のため欠勤したことがある）で評価し，grade2 以上かつ 3 ヵ月以上継続した腰痛を重症度の高い腰痛と定義した．

統計解析は記述統計と，重症度の高い腰痛との関連要因を検討するためロジスティック回帰を用いた．ロジスティック回帰の結果はオッズ比と 95%信頼区間で示した．まず各要因について重症度の高い腰痛ありをイベントとしたロジスティック回帰にて粗オッズ比を算出した．粗オッズ比の p 値が 0.05 以下の要因について，変数同士の関連性を検討した．独立と思われる要因を用いて，多変量ロジスティック回帰のステップワイズで p 値 0.05 を基準として要因を検討した．全ての解析は両側で有意水準を 0.05 とした．解析ソフトは SAS9.3 を使用した．

C. 研究結果

調査票は 95 施設，1,704 名より回答を得て，全てを解析対象とした．平均年齢は 40.2 歳(SD 11.7)，性別は女性が 75.3%であった．

腰痛の程度は grade 0 が 28.0 %，grade 1 が 55.6%，grade 2 が 13.9 %，grade 3 が 2.5%であった．grade2 以上で 3 ヵ月以上継続した重症度の高い腰痛は 205 名（12.0%）に認められた．

重症度の高い腰痛に関する粗オッズ比を求めた．p 値が 0.05 以下の関連が疑われる要因は，年代，睡眠時間，睡眠の質，職場満足度，心理的な仕事の負担（量），心理的な仕事の負担（質），自覚的な身体的負担度，職場での対人関係のストレス，職場環境によるストレス，仕事の適性度，働きがい，上司からのサポート，活気，イライラ感，疲労感，不安感，抑うつ，身体愁訴，STarT Back スクリーニングツール，TSK-J であった．

変数間の相関係数を算出するとともに，臨床的な見地から，年代，睡眠時間，睡眠の質，職場満足度，心理的な仕事の負担（量），職場での対人関係のストレス，上司からのサポート，身体愁訴，STarT Back スクリーニングツール，TSK-J を独立な変数とした．

多変量ロジスティック回帰の結果，身体愁訴，STarT Back スクリーニングツール，TSK-J が選択され，本研究における重症度の高い腰痛の関連要因とした（下図）．

要因		Odds ratio (95%CI)
身体愁訴	Low	1.00
	High	2.00 (1.43- 2.77)
STarT	Low risk	1.00
	High risk	4.06 (2.67- 6.18)
TSK-J	Low	1.00
	Medium	2.69 (1.37- 5.30)
	High	3.18 (1.65- 6.16)

D. 考察

介護施設労働者における重症度の高い腰痛の関連要因を検討した．対象者の 12.0%に重症度の高い腰痛が認められた．一連の解析の結果，身体愁訴，STarT Back スクリーニングツール，TSK-J

が関連要因として示された．

今回の結果では，職業性ストレス調査票における身体愁訴が高いオッズ比を示した．身体愁訴の質問には“めまい”，“体のふしぶじが痛む”，“頭が重かったり頭痛がする”，“首筋や肩がこる”，“腰が痛い”，“目が疲れる”，“動悸や息切れがする”，“胃腸の具合が悪い”，“食欲がない”，“下痢や便秘をする”，“よく眠れない”が該当する．これらはストレスに伴う自律神経失調様の機能的な症状であり，専門科で器質的な原因が明らかにされない臓器系の症状に加え，運動器系の症状も含まれている．これらは心理的ストレスが脳機能に影響を与えることによって起こってくる症状であり，腰痛にも心理的ストレスによる脳機能の不具合（dysfunction）を介し，筋緊張や局所の動脈でのスパズムが強まって起こるタイプがあるという認識を持っている．心理・社会的要因の強い腰痛では，さまざまな身体化徴候をあわせもつ場合が想定されるため，診療では注意深く問診することが必要であると考えている．

今回の研究では STarT Back スクリーニングツールと TSK-J が高いオッズ比を示した．STarT Back スクリーニングツールは 5 つの質問から構成され，不安と抑うつに関する質問が 1 問ずつ，恐怖回避思考（行動），これと近い概念である痛みへの破局的思考が強いかを問う質問がそれぞれ 1 問，さらには自己効力感の乏しさともいえる患者が自覚的にどのくらい煩わしく感じているかで構成されている．TSK は運動器に関する分野において恐怖回避思考を測る世界標準の調査票である．今回の結果は，重症度の高い腰痛には恐怖回避思考や身体化といった心理的要因が強く関与していることを示している．英国キール大学のグループは，このような標準的な整形外科的治療では改善させることが難しいハイリスクな患者に対して，認知行動療法などを駆使し，早い段階で心理的アプローチを実施したほうがよいと推奨しており，日本の介護施設労働者に対しても今後考慮すべきアプローチかと考えられた．

今回の研究結果を解釈するには，いくつか注意する点がある．一つ目は横断研究であるので因果関係は明らかでない．2 つ目は，この研究では腰痛や疾病について医師により診断されていないことや，欠損値が存在するなど，自記式の質問票を用いていることによる情報バイアスが入っている可能性がある．3 つ目は今回の研究の対象者は石川県の介護施設労働者であるため一般化可能性には限界がある．4 つ目は我々が想定していない要因が重症な腰痛に影響を与えている可能性がある．最後に，この研究ではロジスティック回帰モデルにて要因を検討しているが，このデータにより適合するモデルがある可能性がある．

E. 結論

介護施設労働者において，重症度の高い腰痛には心理的要因の関与が示唆された．

腰痛対策には，人間工学的アプローチのみならず，恐怖回避思考をはじめとする心理的なアプローチが必要であると考えられた．

F. 健康危険情報

該当なし

G. 研究発表

1. 論文発表

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2. 学会発表

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H. 知的財産権の出願・登録状況（予定を含む）

1．特許取得

なし

2．実用新案登録

なし

3．その他

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労災疾病臨床研究事業費補助金

分担研究報告書

アレクサンダーテクニーク介入前後の姿勢変化の計測と分析

研究分担者　高井ゆかり　東京大学大学院医学系研究科、成人看護学

研究要旨

欧米においてはアレクサンダーテクニーク(以下 AT)による姿勢改善が腰痛や頚部痛などの愁訴改善を目的として治療に取り入れられている．しかし，AT の生理学的，運動学的な機序は不明な点が多く，介入によってどのような立位姿勢や力学的な変化が起こっているかは明らかになっていない．そこで本研究では腰痛改善に有効とされる AT の介入による，姿勢変化や力学的な変化を明らかにすることを目的として実験を行った．対象者は，Roland-Morris Disability Questionnaire(RDQ)により分類した，健常成人男性 11 名(RDQ 0 点)，および腰痛有訴者 12 名(RDQ 1 点以上)の合計 23 名とした．実験条件は安楽立位姿勢と AT 介入後の姿勢とし，姿勢パラメータの比較を行った．計測順序は対象者の安楽立位姿勢を計測した後に，AT 教師による 5 分間の介入を行い，AT 介入後の姿勢を計測した．計測した姿勢パラメータを，腰痛の有無を対応のない要因，介入前後を対応のある要因とした，二元配置分散分析を行った結果，椎間板圧縮力は介入前後の要因に主効果が認められ，介入後に減少していた．このことから，腰痛の有無に関わらず，AT の介入には腰部負担軽減効果があることが示唆された．以上より，腰痛改善に有効とされる AT による介入は腰痛有訴者でなくても椎間板圧縮力を軽減できることから，腰痛の治療と予防双方にとって有効である可能性が提示できた．

A.研究目的

腰痛の治療や改善の方法に関しては本邦や欧米においてガイドラインが存在する．腰痛に対する治療介入に関して，日本の腰痛ガイドラインやヨーロッパの腰痛ガイドラインでは，薬物療法や認知行動療法に並び，運動療法が推奨されている．

なかでも運動療法は薬物療法と比較し運動療法の予後がよいことや，認知行動療法を組み合わせた方法は対費用効果が高いと報告されている．運動療法は，筋力強化やストレッチ，動作指導など，内容は多岐にわたる．そのうちのひとつとして，欧米においてはピラティスやアレクサンダーテクニーク(以下 AT)などによる姿勢改善に有効とされる方法が腰痛や頚部痛などの愁訴改善を目的として治療に取り入れられている．AT は 100 年程前にオーストラリアで始まった，心身の不要な使い方を修正することを目的とした体の使い方の技術である．AT の介入は教師による徒手での誘導や声による教示によって行われる．介入は対象者が日常生活や種々の活動において，姿勢保持や動作が，より少ない努力で行えるように誘導を行う．

AT の生理学的，運動学的な機序は不明な点が多いが，先行研究によりさまざまな効果が認められている．特に，慢性腰痛患者を対象とした，Randomized Control Trial（RCT）による大規模な先行研究において，通常の運動指導を行うグループ，マッサージや体操を行うグループに比べ，AT を行ったグループのほうが，腰痛の愁訴が改善し，1 年後も良好な状態が継続したと報告されている．また，AT はマッサージや通常の運動指導に比べて対費用効果も高いとされており，最も

エビデンスの高い姿勢介入の方法として欧米では広く認知されている．このように，AT の腰痛改善効果は明らかであるが，介入によってどのような立位姿勢や力学的な変化が起こっているかは明らかになっていない．そこで我々は腰痛改善に有効とされる AT の介入による，姿勢変化や力学的な変化を明らかにすることができれば，腰痛改善に有効な手段や評価の一助となると考えた．

B. 研究方法

対象者は，成人男性 23 名とした．その 23 名に対して，Roland Morris Disability Questionnaire(RDQ)を聴取し，健常成人男性 11 名(RDQ 0 点), および腰痛有訴者 12 名(RDQ 1 点以上）の 2 群に分けた．

計測を行うに先立ち，被験者には研究内容を十分に説明し，書面にて研究への同意を得た．

計測順序は対象者の安楽立位姿勢を計測した後に，AT 教師による 5 分間の介入を行い，AT 介入後の姿勢を計測した．

AT による介入については，AT 教師養成校の認定を受け，日本アレクサンダーテクニーク協会（Japan Alexander Technique Society）に所属する AT 教師（資格取得後５年）により実施した．AT による介入は声による教示と徒手による姿勢の修正によって行われた．立位姿勢への介入は以下の点を意識して行った．

体の腹側と背側に 2 つの鉛直線をとる．腹側の鉛直線が,「胸鎖関節部」と「脛と足の甲の交わる部位」を通過している．背側の鉛直線は，殿部の最背部を通過させ，その鉛直線よりも「肩甲骨最背部」,「頭部最背部」,「踵最背部」が内側にある．脊椎が屈曲する形で頭部が前に過度に突出していないか，逆に過度に後方に位置づけていないかを確認するこれらを目安にし，上記のようになっていない場合は，徒手で対象者を誘導した．介入時間は 5 分以内とした．AT による介入を行った後は，被験者には介入内容を意識して立位姿勢を保持するよう指示し，通常の立位姿勢の計測と同様に被験者は片脚ずつ床反力計上に肩幅程度に足を広げて立ち 10 秒間 3 試行の立位姿勢を計測した．目線は 5m 先に設置した目線の高さの目印を見るように指示した．AT の有無による計測は介入無し条件の計測後に介入有り条件の計測を行った．

計測には三次元動作解析装置(VICON)，床反力計(AMTI)，スパイナルマウス(Idiag)を用いた．

三次元動作解析装置で得られたパラメータは，10 秒間の値を平均し，3 試行の値を平均した値を分析に用いた．スパイナルマウスから得られた値は 3 試行の平均値を用いた．関節モーメント，椎間板圧縮力は被験者の体重で除し正規化した．

統計解析は，被験者間の身体特性を対応のない t 検定を用いて比較した．

AT 介入前後におけるパラメータの変化の比較を，腰痛の有無を対応のない要因，介入前後を対応のある要因とし，二元配置分散分析を行った．いずれも有意水準は 5%とした．

C. 研究結果

腰痛の有無を対応のない要因，介入前後を対応のある要因とした，二元配置分散分析の結果，椎間板圧縮力は介入前後の要因に主効果が認められ，介入後に減少していた．健常群と腰痛有訴群の間に主効果はなかった．介入後は，両群とも有意に椎間板圧縮力が低下した．交互作用はなかった．3 軸まわりの腰部モーメントの内，腰部伸展モーメントは低下傾向であったが，介入前後の要因に主効果は認められなかった．腰部側屈モーメントには主効果が認められ，介入後に低下していた．腰部回旋モーメントには主効果が認められなかった．いずれの軸周りのモーメントにおいても腰痛の有無の要因で主効果はなく，交互作用は認められなかった．

頭部，体幹と骨盤のアライメントを示す角度は介入前後の要因で頭部屈伸角度，体幹屈伸角度，胸椎，腰椎弯曲角度，骨盤の前傾角度に主効果が認められた．頭部角度は屈曲方向に，体幹角度は

伸展方向に変化した．胸椎後弯角度は減少し，腰椎前弯角度は増加していた．骨盤前傾角度は増加していた．いずれの項目にも腰痛の有無に主効果はなく，交互作用は認められなかった．

D. 考察

AT 介入による姿勢パラメータの変化を明らかにすることを目的に，介入前後の変化を対応のある要因，腰痛の有無を対応のない要因とした二元配置分散分析を行った．その結果，頭部角度，体幹角度，胸椎弯曲角度，腰椎弯曲角度，骨盤角度に介入前後の主効果を認めた．いずれにも腰痛の有無に主効果はなく，交互作用はなかった．

頭部角度は，屈曲傾向を示しており，顎を引くような変化が起こっていた．体幹角度は，伸展方向に変化していた．頭部と体幹において，介入前は頭部伸展，体幹屈曲傾向であるが，介入後はそれぞれ逆方向へ変化しており，両部位の重心が鉛直線上に並ぶような姿勢変化が起きていたと考えられる．胸椎弯曲角度は，介入後は伸展方向へ変化しており，腰椎弯曲角度は，前弯方向へ変化し骨盤角度は前傾方向へと変化していた．これらの変化は体幹を伸展した際に上半身重心が後方へ変位することに対して，上半身の土台である骨盤を前傾させ，身体重心を支持基底面内に留めるために生じた反応であったと考えられる．

また，椎間板圧縮力に AT 介入による主効果を認めた．腰痛の有無に主効果はなく，交互作用はなかった．このことから，腰痛の有無に関わらず，AT の介入には腰部負担軽減効果があることが示唆された．

腰部モーメントに関しては伸展モーメントが減少傾向を示していたが，側屈モーメントのみが有意に減少し，腰部伸展，回旋モーメントについては有意差を認めなかった．腰部側屈モーメントが減少したことから，前額面上の変化が起こったと考えられるが，本研究においては，体幹側屈角度に介入前後の変化を認めなかった．前額面の変化が，頭部や体幹の角度変化に表れなかった理由として，姿勢の個人差が挙げられる．個人によって頭部や体幹が左右どちらかに傾くかは異なる．また，同一の個人であっても頭部と体幹の傾斜の大きさの程度が異なる．そのため，角度変化としては有意な差がなく，腰部以上の位置変化の結果として腰部側屈モーメントの変化が表れたと推察される．また，Cacciatore らは，40 代の腰痛有訴のある女性 1 名に対して，AT の介入を 6 か月間に 20 回実施し，立位姿勢やバランス能力の変化を床反力計とモーションキャプチャーシステムを用いて計測を行った結果，静止立位姿勢における脊柱の側弯が減少したと報告している．今回，計測に用いた 3 次元動作解析装置やスパイナルマウスでは側弯の変化を計測できないが，体幹の側屈角度には変化がみられなかったものの，Cacciatore らが報告したような側弯の変化が起こることで上半身重心の位置の側方変位が修正され，腰部側屈モーメントの変化が起こった可能性も考えられる．

以上を踏まえ，椎間板圧縮力が軽減した理由を考察する．AT の介入によって，頭部角度，体幹角度，胸椎，腰椎弯曲角度，骨盤角度が変化していた．上半身部位の変化は腰部モーメントに影響する．腰部モーメントに関して，側屈モーメントは有意に減少し，伸展モーメントは減少傾向を示していた．つまり，頭部や体幹，骨盤の位置が腰部モーメントの軸である腰椎上に重心が位置するように変化することで腰部モーメントが減少し，椎間板圧縮力が軽減されたと考えられる．

E. 結論

腰痛改善に有効とされる AT の介入による姿勢変化を計測した．その結果，AT の介入は，腰痛の有無にかかわらず，立位姿勢における椎間板圧縮力を軽減することが示された．

また AT による介入は腰痛有訴者でなくても椎間板圧縮力を軽減できることから，腰痛の治療と予防双方にとって有効である可能性が提示できた．

F. 健康危険情報

該当なし

G. 研究発表

1. 論文発表

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2. 学会発表

なし

H. 知的財産権の出願・登録状況（予定を含む）

1．特許取得

なし

2．実用新案登録

なし

3．その他

労災疾病臨床研究事業費補助金

分担研究報告書

持ち上げ動作時の教示が腰部負担に与える影響

研究分担者　勝平純司　国際医療福祉大学小田原保健医療学部

研究要旨

本研究の目的は持ち上げ動作時に骨盤を前傾させるように指示することで腰部負担が軽減するのかを検証すること,squat 法･stoop 法それぞれで骨盤を前傾させる指示を与え，腰部負担のより小さい作業姿勢を明らかにすることとした.対象は健常成人男性 10 名とし，三次元動作分析装置，床反力計を使用して持ち上げ動作時の運動学，運動力学的データを計測した．腰部負担の指標は椎間板圧縮力と剪断力を採用した．被験者は 11.3 kgに設定された重量物を squat 条件（股関節と膝関節を屈曲）と stoop 条件（股関節を屈曲，膝関節を伸展)，これら 2 つの方法でより骨盤を前傾させるように指示した 2 条件を加えた 4 条件で持ち上げ動作を行った．結果として，squat 法では骨盤を前傾させるように指示すると椎間板圧縮力・剪断力ともに小さくなった．この結果から，squat 法で骨盤を前傾させると腰部椎間板圧縮力と剪断力を抑えることができるため，腰痛の予防効果が期待されることが示唆された.

A.研究目的

腰痛は労働時に生じる疾患で最も多いとされており，作業内容では重量物を持ち上げる作業が腰痛を発症する危険性が最も高いといわれている.

持ち上げ動作は股関節と膝関節を屈曲させた姿勢で行う squat 法と股関節を屈曲・膝関節を伸展させて行う stoop 法の 2 つの方法に大きく分けられる．先行研究ではこの 2 つの方法で腰部負担を比較しているものが数多くある．Van Dieën らは squat 法と stoop 法を比較した総説で，この 2 つの動作で腰部負担に大きな差はないとしており，持ち上げ動作時に腰部負担を抑えることができる姿勢は，明確なものが示されていないのが現状である.

持ち上げ動作時の腰部負担は腰部関節中心から重量物重心までの距離が影響するといわれている．このことから，骨盤を前傾させて腰部関節を重量物に近づけた姿勢で作業を行うことで腰部負担を軽減することができると考えられる．しかしながら，実際に骨盤の前後傾についての教示を行い，腰部負担を比較した報告は見当たらない.

そこで，本研究の目的は持ち上げ動作時に骨盤を前傾するように指示することで腰部負担が変化するのか検証すること，squat 法・stoop 法それぞれで骨盤前傾指示を行い，腰部負担の小さい作業姿勢を明らかにすることとした.

B. 研究方法

対象: 健常成人男性 10 名（年齢 20.9±0.5 歳　身長 174.9±4.3 ㎝　体重 64.1±4.8 kg）

計測条件: ①squat 条件（股関節と膝関節を屈曲）②stoop 条件(股関節を屈曲,膝関節を伸展)，③squat 骨盤前傾条件（squat 条件よりも骨盤を前傾させるように指示)，④stoop 骨盤前傾条件（stoop 条件よりも骨盤を前傾させるように指示）の 4 つの条件を設定した.

重量物は 11.3 kgに設定し，被験者の足先から

足長の 1/2 の距離に設置するように統一した．

解析方法：測定機器は三次元動作解析装置 VICON MX（VICON 社製），床反力計（AMTI 社製）4 枚，赤外線カメラ（周波数 100Hz）10 台を用いた．被験者には 45 個の赤外線反射マーカーを貼付し，動作中の椎間板圧縮力，椎間板剪断力，骨盤前傾角度，腰部関節中心と重量物の重心との距離を算出した．椎間板圧縮力と椎間板剪断力は体重で除して正規化した値で比較・検討を行った．

統計処理は拳上方法の違いと骨盤前傾指示の有無を要因とした繰り返しのある二元配置分散分析反復測定法を用いた．また，通常の条件と骨盤前傾を指示した条件での差を判定するために，対応のある t 検定を用いた．さらに，4 条件の中でどの姿勢が最も腰部負担が小さいのかを明らかにするため，椎間板圧縮力と剪断力については一元配置分散分析反復測定法と多重比較検定(Bonferroni 法)を併せて行った．有意水準は 5%とした．

C. 研究結果

図 1 に椎間板圧縮力の結果を示す．二元配置分散分析反復測定法の結果，拳上方法の違いと骨盤前傾指示の有無による交互作用がみられた．対応のある t 検定の結果，椎間板圧縮力は squat 条件よりも squat 骨盤前傾条件で有意に小さくなった．一方，stoop 条件では骨盤前傾指示の有無で有意な差はみられなかった．また，一元配置分散分析と多重比較検定の結果，squat 条件は他の 3 つの条件よりも有意に椎間板圧縮力が大きく，squat 条件以外の 3 つの条件の間に有意差はみられなかった．

図 2 に椎間板剪断力の結果を示す．二元配置分散分析反復測定法の結果，交互作用はみられなかった．また，対応のある t 検定の結果，各条件で骨盤前傾の有無での差はみられなかった．一元配置分散分析と多重比較検定の結果では squat 骨盤前傾条件は他の 3 条件よりも剪断力が有意に小さかった．

図 3 には骨盤の前傾角度を示す．二元配置分散分析反復測定法の結果，拳上方法の違いと骨盤前傾指示の有無による交互作用がみられた．また，対応のある t 検定の結果, squat 条件よりも squat 骨盤前傾条件において骨盤の前傾角度は有意に大きく，stoop 条件と stoop 骨盤前傾条件では有意差はみられなかった．

図 4 には腰部関節中心と重量物重心との距離を示す．二元配置分散分析反復測定法の結果，交互作用はみられなかった．対応のある t 検定の結果では squat 条件よりも squat 骨盤前傾条件においてこの距離は有意に小さく，stoop 条件と stoop 骨盤前傾条件では有意差はみられなかった．

D. 考察

椎間板圧縮力は stoop 法で動作を行った 2 条件で有意差がみられなかった一方で，squat 法では骨盤を前傾するように指示することで有意に減少した．このことから，持ち上げ動作時に骨盤を前傾させる教示を与えることは squat 法で動作を行う際に有効であることが示唆された．

squat 法で骨盤前傾を指示することで椎間板圧縮力が軽減したのは，骨盤前傾角度が有意に増大し，それに伴って腰部関節が前方に移動することで，モーメントアームである腰部関節中心と重量物重心の距離が小さくなったことによると考える．

stoop 法において骨盤前傾による腰部負担の軽減効果が得られなかったのは，stoop 法そのものが骨盤を大きく前傾させる動作のため，骨盤をさらに前傾するように指示しても角度に大きな変化がみられないことや，膝関節伸展位で股関節を屈曲させるため，ハムストリングスなどの大腿後面筋が骨盤の前傾を制限したためであると考える．

今回の結果では squat 骨盤前傾条件と stoop 条件，stoop 骨盤前傾条件の 3 条件で椎間板圧縮力に有意な差はみられなかった．しかし，椎間板剪断力は squat 骨盤前傾条件で他の条件よりも有意

に小さい値を示した．よって，椎間板圧縮力・剪断力ともに小さい値であるsquat法で骨盤を前傾させた姿勢が腰痛予防のために推奨される作業姿勢であるといえる．

E. 結論

squat 法で持ち上げ動作を行う場合，骨盤を前傾させるように意識すると腰部椎間板圧縮力と腰部椎間板剪断力の両方が軽減され，腰痛の軽減効果を期待することができる．労働時の持ち上げ動作によって生じる腰痛は世界中で問題となっており，本研究では労働時に推奨される作業姿勢を明らかにした．今回得られた知見は労働時に生じる腰痛のリスク回避のための一助となると考える．

F. 健康危険情報

該当なし

G. 研究発表

1.論文発表

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2.学会発表

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H. 知的財産権の出願・登録状況(予定を含む)

1. 特許取得
　なし
2. 実用新案登録
　なし
3. その他

労災疾病臨床研究事業費補助金
分担研究報告書

腰痛予防体操の有用性と腰痛体操の集団アプローチの有用性に関する研究

研究分担者　唐司寿一　関東労災病院　整形外科

研究要旨

疫学的アプローチにより生活習慣病予防のための運動を阻害する要因として、運動器の障害、特に腰痛が重要であることが判明したため、その原因別の対策を講じるにあたり、運動器のエキスパートでない現場の指導員が簡便に利用しうる腰痛に対する予防的・治療的体操メニューを考案した。またそれを実行するための集団アプローチを行い、その有用性を検証した。

A.　研究目的

国民生活基礎調査では、腰痛は有訴率、通院率とも常に上位にある。つまり、腰痛は生活習慣痛と言っても過言ではなく、これらにより運動することに支障をきたしている国民は少なくないのではと仮説を立て、本プロジェクトを開始した。

我々が行った約 2 万人に対する全国調査（PACE survey 2009.JP）でも、少なくとも国民の 5 人に 1 人が慢性の痛みを保有しており、部位別では腰痛をはじめとする運動器の痛みが上位を占めている実態が明らかとなった[1]。

一方、平成 20 年から始まった特定健康診査・特定保健指導では生活習慣病の予防が柱であり、栄養管理に加え、運動の推進が重要視されているが、前述したとおり腰痛を代表とする運動器の痛みを保有していたり、肥満者が運動推進中にこれらの障害が発生したりするとついつい安静思考になり、運動器の専門家ではない現場の指導員では積極的な指導は行いづらく、運動推進の継続は難しくなると考えられる。

近年、慢性的な腰痛に対する治療介入として運動療法が有益であることが指摘されている。我々は先行研究として、腰痛の臨床に精通する運動器のエキスパートが提案するスクリーニング質問票（チェックリスト）および腰痛保有者用の治療的体操メニューを作成し、その有用性を検証した。その結果、「前かがみになると腰痛がでる」「座っていると腰痛がでる」「歩いていると腰痛が楽になる」というパターンの被験者が予想通り多く（それぞれ被験者の 6～7 割）、これらの設問に関する被験者のチェックとエキスパート（分担研究者：松平浩）の判定との一致度は高かった。以下に、実際に聴取した結果の分布を示す。

項目		いつもそうである	時々そうである	そうでもない	まったくそうでもな	はっきりしない	合計
		n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)
横になって休んでいても常に腰が痛い	n	1	5	19	7	0	32
	割合(%)	3.1	15.6	59.4	21.9	0.0	100.0
腰痛のために睡眠時間が妨げられる	n	2	6	14	10	0	32
	割合(%)	6.3	18.8	43.8	31.3	0.0	100.0
太ももからふくらはぎや腰にかけての痛みやしびれがある	n	1	17	4	10	0	32
	割合(%)	3.1	53.1	12.5	31.3	0.0	100.0
前かがみになると腰痛がでる	n	8	15	4	3	2	32
	割合(%)	25.0	46.9	12.5	9.4	6.3	100.0
座っていると腰痛がでる	n	4	19	8	0	1	32
	割合(%)	12.5	59.4	25.0	0.0	3.1	100.0
歩いていると腰痛が楽になる	n	4	16	7	2	2	31
	割合(%)	12.5	51.6	22.6	6.5	6.5	100.0
咳やくしゃみをすると腰痛がでる	n	2	9	9	10	2	32
	割合(%)	6.3	28.1	28.1	31.3	6.3	100.0

項目		そうだ	まあそうだ	やや違う	違う	どちらともいえない	合計
		n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)	n 割合(%)
普段腰をそらさないようにしている	n	2	9	10	4	7	32
	割合(%)	6.3	28.1	31.3	12.5	21.9	100.0

指導した伸展エクササイズ（10 分以内の直接指導および指導書の配布）の治療成績は、2 週で約 8 割の被験者が自覚的に改善するなど良好であった。つまり、腰痛治療のスペシャリストである分担研究者が開発した伸展体操プログラムは、腰痛の 3 次予防対策として有益である可能性が高いことを示すことができた[2]。

一方、健康日本２１では、高リスクアプローチと集団アプローチの組み合わせによる推進と、国民の行動変容を支援する環境整備の重要性が示された。つまり、コミュニティを対象とした健康保健活動ではポピュレーションアプローチが有益な方法論と考えられている。ポピュレーションアプローチとは、対象集団全体への働きかけであり、罹患率を左右する要因を制御して危険因子の平均値を下げ、全体の曝露の分布を良い方向に移動させる試みのことで、1985 年に Geoffrey Rose によって提唱された[3]。

ハイリスク集団（腰痛で言えば、腰痛で支障をきたして病院を受診する患者）にアプローチするより、一見健康な集団にアプローチする方がはるかに予防効率がよいという「予防医学パラドックス」に依拠する理論が基盤となっている。ハイリスク者ではない集団に、リスクそのものを軽減させる予防的啓発が重要視される。日常診療、言い換えれば三次予防に追われている臨床医にはない発想である。

本年度の研究目的は、

① **現在腰痛がない人を，再発も含め腰痛を新たに起こさせない対策**

② **軽い腰痛の人には重症化させない対策**

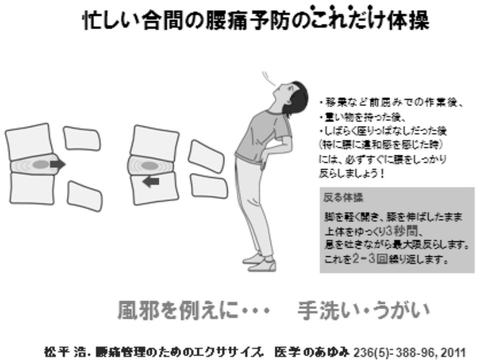
③ **すでに支障度の高い人にはコントロール可能なレベルに戻しかつ支障度の高い腰痛の再発を予防する対策**

つまり 1・2 次予防に重点を置いた 1～3 次予防対策として、シンプルな伸展体操プログラム自体の有用性と、伸展体操プログラム導入における集団アプローチの有用性を検討することである。

B．研究方法

対象であるが、腰痛対策のスペシャリストである分担研究者が、伸展体操プログラムを推進するにあたり妥当である「前かがみ作業」に従事することが多い社会福祉法人の介護士とターゲットとした。具体的には長野県の 3 つの介護福祉施設（依田窪、みまき、ベルポート）のうち 2 施設を積極介入群、1 施設をコントロール群とした。両群間で施設の入居者数、入居者の平均介護度、認知症者の割合、障害の程度の割合、職員の数、性差、年齢に差はなかった。<u>積極介入群</u>は、体操を主とするマニュアルを配布するだけでなく、マニュアルの内容に関する 30 分の講義を受け、さらに参加型形式で業務中の伸展体操を積極的に行う群とした。各施設の担当者と本研究の分担研究者の協議により、<u>予防体操（具体的には立位で腰を反らす‘これだけ体操’）を勤務中に習慣化する仕組みを構築</u>していただいた。<u>対照群</u>は、マニュアルの配布のみとした。尚、本介入研究は、対象とした地域にちなんで「しなのプロジェクト」と名づけた。

以下に、**‘これだけ体操’**の内容を提示する[4]。



シンプルな本体操のコンセプトは、動作・姿勢に依存する、言い換えればメカニカルな要素が明確な場合にターゲットを絞った診断･治療体系の代表であるMcKenzie法（mechanical diagnosis and therapy）の derangement syndrome（椎間板内における髄核の変位に依存するとした腰痛モデル）に基づいている[5]。Derangement syndrome はメカニカルストレスに伴う最もポピュラーな腰痛のサブグループであると考えられ、その中でも最も多いのが、前屈姿勢・作業により誘発される後方 derangement（髄核の後方への移動・陥屯）と想定されるパターンであり、伸展運動により改善しやすい。Zou J らは，立位での動的な MRI による検討により、変性が乏しい椎間板では McKenzie の理論モデル（後方 derangement syndrome のメカニズム）が妥当であることを報告している[6]。

アウトカム評価は、介入直前（ベースライン）と介入開始から 1 年後に自記式調査票を用い行った。主要評価項目は、介入 1 年後の**自覚的改善度**（腰痛の状態は 1 年前と比較し、改善／不変／悪化）及び対策の**自覚的実行度**（実行／未実行）とした。副次的評価として、ベースライン時と介入 1 年後の**腰痛による通院状況の推移**及び **Oswestry Disability Index** (ODI：最小値 0、最大値 100)を評価した[7]。先行研究によると機能障害を伴う腰痛は ODI 値が 12 以上であることから、ODI≧12 である割合も比較した[8]。

（倫理面への配慮）

独立行政法人労働者健康福祉機構関東労災病院医学研究倫理審査の承認を得て推進した。被験者に対してはデータを ID 化して管理するなど個人情報には十分配慮すること、同意後もいつでも同意撤回が可能であること等を説明後、書面での同意を取得した。

C．研究結果

両群併せて 167 名（積極介入群：89 名、対照群：78 名）の介護士をエントリーした。167 名の平均年齢は 37.5 才で、女性が 65 名（81.4%）であった。過去 1 年間に腰痛がなかった割合は 29.9%にとどまり、全体の 10.2%が過去 1 年を総合的に考えて腰痛にため仕事に支障をきたしていた。

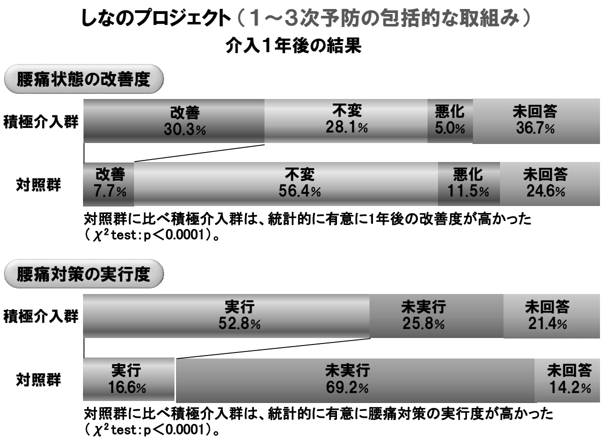
尚、介入終了後のアウトカム評価は、1 年後に行った自記式調査票への記入を完了した例を対象に分析を行った。

以下に、両群における分析対象者のベースライン時での背景情報を示す。年齢、性別、BMI、喫煙習慣に加え、腰痛に対する通院状況、ベースライン時での直近 1 カ月の腰痛状態（程度）、ODI に関し、両群の間に統計的有意差はなかった。

Table 1.

	積極介入群 (n = 89)	対照群 (n = 78)	*P*
年齢	37.5 ± 12.4	37.6 ± 11.6	0.97
女性（%）	74 (83.1)	62 (79.5)	0.56
BMI	22.5 ± 3.8	22.3 ± 3.5	0.74
喫煙習慣（%）	39 (43.8)	37 (47.4)	0.28
腰痛による通院あり（%）	9 (10.1)	16 (20.5)	0.06
直近１ヵ月の腰痛状況			
● 腰痛なし	26 (29.2)	24 (30.8)	
● 腰痛はあるが仕事に支障はない	54 (60.7)	40 (51.3)	0.37
● 腰痛があり仕事に支障がある	4 (4.5)	11 (14.1)	
● 腰痛があり休職を要する	1 (1.1)	1 (1.3)	
ODI	9.8 ± 1.0	11.5 ± 1.1	0.28
ODI ≧ 12	30 (33.7)	32 (41.0)	0.33

次に、主要評価項目の群間比較結果を示す。自覚的改善度、対策の実行度とも対照群と比較し、積極介入群のほうが統計的に有意に優れていた。



また、副次的評価項目とした腰痛による通院状況および ODI を以下に示す。積極介入群では腰痛による医療機関への通院機会は有意に減少していた。また、介入後には ODI≧12 である割合が、積極介入群でコントロール群よりも有意に少なかった。

Table 2.

	積極介入群 (n = 89)	対照群 (n = 78)	*P*
腰痛による通院あり			
介入前（%）	9 (10.1)	16 (20.5)	0.06
介入後（%）	3 (3.4)	12 (15.4)	*0.007
ODI ≧ 12			
介入前（%）	30 (33.7)	32 (41.0)	0.33
介入後（%）	26 (29.2)	37 (47.4)	*0.04

次に、腰痛体操の実行度による腰痛の自覚的改善度を示す。積極介入群、対照群ともに実行度が高いほど腰痛の自覚的改善が得られた。

Table 3. 腰痛体操実行度による自覚的腰痛の変化

実行度		n	改善	不変	悪化
実行	積極介入群（%）	38	22 (57.9)	12 (31.6)	4 (10.5)
	対照群（%）	10	3 (30.0)	7 (70.0)	0 (0)
未実行	積極介入群（%）	17	4 (23.5)	12 (70.6)	1 (7.5)
	対照群（%）	48	3 (6.3)	37 (77.1)	8 (16.7)

D. 考察

本研究での主要な介入は、McKenzie 法（mechanical diagnosis and therapy）の後方 derangement の予防対策である立位で腰を反らす‘これだけ体操’を、勤務中に習慣化する仕組みを構築したことである。対策実行者が、対照群に対して積極介入群では有意に多かったことから仕組みの構築は概ね成功したと思われ、そのことが腰痛状況の改善につながったと解釈できる。腰痛状況の改善には、積極介入群では腰痛による通院状況も有意に改善したことも含まれ、本介入は医療経済的にも有益な効果をもたらしうることが示唆された。また、各群ともに本体操の実行度が高いほど腰痛の

自覚的改善が得られたことから、本体操自体の有効性を示すことができた。

Ｅ．結論

腰痛を抱える対象者に対し、運動器のエキスパートでない現場の指導員が簡便に迷い無く指導できる指針予防的・治療的体操メニューを考案し、その実行のための集団アプローチを行い、その有用性を検証した。

Ｆ．健康危険情報

特記すべき事項なし。

Ｇ．研究発表

投稿中。

Ｈ．知的財産権の出願・登録状況

現時点ではなし。今後、検討予定。

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労災疾病臨床研究事業費補助金

分担研究報告書

介護看護従事者への予防介入とマネジメントシステムの構築に関する研究

研究分担者　三好光太　横浜労災病院　整形外科

研究要旨

厚生労働省調査にて、業務上疾病の発生件数は、腰痛が全職業性疾病の約 6 割を占め第 1 位であること、平成 23 年の腰痛全届け出のうち社会福祉施設で腰痛が顕著な増加を辿っていることなどから介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。

本研究では、産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性に大規模介入比較試験を行い、エビデンスを構築する。

具体的には、全国 12 労災病院をクラスターとして、A:対照（無介入）、B：腰椎伸展体操の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群の無作為比較試験を行う。研究２年目となる本年度は、統計学的な検討に基づいた割付を行い、介入前のベースライン調査を行った。A 群 1,799 名に、B 群 1,420 名、C 群 1,548 名、全体で 4,767 名にアンケートを配布し、全体でアンケート回収数は 3,439 名分で、回収率は 72.1%だった。各群の回収数は A 群 1,319 名、B 群 1,000 名、C 群 1,120 名であり、回収率はそれぞれ 73.3%、70.4%、72.4%であった。

3,381 名分のアンケートを解析した結果、過去 1 か月以内に業務に支障を来した腰痛の既往を持つ有病者数は、全体で 272 名（8.0%）であった。また各群の背景情報には偏りはなかった。

A.研究目的

厚生労働省業務上疾病発生状況等調査にて、腰痛における休業 4 日以上の業務上疾病の発生件数は、全職業性疾病の約 6 割を占め第 1 位となっている。平成 23 年の腰痛全届け出のうち社会福祉施設が 19%を占め、10 年で 2.7 倍という最も顕著な増加となった背景を踏まえ、19 年ぶりに改訂された「職場における腰痛予防対策指針」(平成 25 年、厚生労働省)では、重症心身障害児施設等に限定されていた適用を、福祉・医療等における介護・看護作業全般に拡大し、内容を充実させるに至った。つまり、介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。また世界疾病負担研究にて 289 の疾患や傷病のうち、腰痛が Years Lived with Disability (YLDs)のトップにランクされるなど、社会的損失や健康面への影響の大きい腰痛への対策は global にも重要な課題として位置づけられている。

本研究では、産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性に大規模介入比較試験を行い、エビデンスを構築する。研究２年目となる本年度は、介入前のベースライン調査を行った。

B. 研究方法

国 12 労災病院をクラスターとして、A:対照（無

介入)、B：腰椎伸展体操の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群を実施するため、統計学的な見地を踏まえデザインを行い、ベースライン調査が終了した。

（論理面への配慮）

本研究は、研究対象者の組み入れ前であるが、同意取得やデータは匿名化の方法は確立しており、研究遂行にあたり倫理面での問題はないとの承認を、全国労災病院倫理委員会より得ている。

C. 研究結果

以下の研究プロトコールの通りに、ベースライン調査を実施した。

①施設をクラスターとした無作為比較試験

選択基準:選定された労災病院に勤務する成人（20 歳以上）看護師、本研究の趣旨に賛同し同意を得た者

除外基準：妊婦，あるいは妊娠の疑いがある場合、腰椎伸展により症状が誘発される腰部脊柱管狭窄症と診断されたことがある者、研究の同意を撤回した者

②対照（無介入)、腰椎伸展体操の普及・実践、B の介入+産業理学療法士による腰痛教育・相談の実践の 3 群

③北海道中央（看護師数：156)、東北（407)、関東（562)、横浜（667)、新潟（274)、浜松（256)、旭（182)、大阪（720)、関西（674)、中国（391)、愛媛（193)、長崎（285)、総計 4,767 名。以上 12 労災病院（施設）のをクラスターとし、病床・看護師数、看護師の男女数・平均年齢を割付調整因子とし、コンピューターの乱数表を用い、3 群（4 施設ごと）に無作為割付する非盲検試験を行った。

④A 群は北海道中央、横浜、大阪、浜松の 1,799 名に、B 群は関東、旭、中国、長崎の 1,420 名、C 群は東北、新潟、関西、愛媛の 1,548 名、全体で 4,767 名にアンケートを配布した。全体でアンケート回収数は 3,439 名分で、回収率は 72.1%だった。各群の回収数は A 群 1,319 名、B 群 1,000 名、C 群 1,120 名であり、回収率はそれぞれ 73.3%、70.4%、72.4%であった。

回収したアンケートのうち 58 名に不備があったため解析には 3,381 名分のアンケートを利用した。過去 1 か月以内に業務に支障を来した腰痛の既往を持つ有病者数は、全体で 272 名（8.0%）であった。

⑤本年度はベースライン調査での各群の背景情報に関する検討を行った：

	A 群	B 群	C 群
年齢	35.5 (35.0-36.1)	35.1 (34.5-35.8)	35.5 (34.9-36.1)
性 男性（%）	6.7	5.3	4.2
BMI	21.2 (21.0-21.3)	21.5 (21.3-21.6)	21.1 (20.9-21.3)
STarTBack	1.4 (1.3-1.5)	1.4 (1.3-1.5)	1.4 (1.3-1.5)
StarTBack high risk(%)	2.2	2.8	2.2
FABQ 15 点以上（%）	27.7	30.2	29.6
EQ5D	0.88 (0.87-0.89)	0.87 (0.86-0.88)	0.88 (0.87-0.89)

各群の背景情報の分布は上に示すとおりであり、全ての群で似通った傾向であった。

⑥エンドポイントは以下に示すとおりである。

EQ-5D と腰痛に関わる医療施設での治療日数から概算した医療費から算出した QALY、腰痛の有無および仕事への支障度を勘案した腰痛 grade（重症度）の改善、直近 4 週の腰痛の程度

（Numerical Rating Scale)、腰痛の自覚的改善度、腰痛予防対策の自覚的実行度、腰痛の受診状況、腰痛に対する恐怖回避思考（FABQ 身体)、Kneel Start Back スクリーニングシステムによるリスク、抑うつ（K6)、過去 30 日間の仕事のでき具合（HPQ)、労災病院検診データ[介入期間：1 年]

D. 考察

産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性を検証するために大規模介入比較試験を施行予定である。研究２年目となる本年度は、統計学的な検討に基づいた割付を行い、介入前のベースライン調査を行った。この結果過去１か月以内に業務に支障を来した腰痛の既往を持つ有病者数は、全体で 272 名（8.0%）であり、また各群の背景情報には偏りはなかった。

E. 結論

統計学的な検討に基づいた割付を行い、介入前のベースライン調査を行い、各群の背景情報に偏りがないことを確認した。

F. 健康危険情報

該当なし

G. 研究発表

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2. 学会発表
なし

H. 知的財産権の出願・登録状況（予定を含む）

1．特許取得
なし

2．実用新案登録
なし

3．その他

労災疾病臨床研究事業費補助金
分担研究報告書

腰痛予防への効率的かつ効果的な理学療法介入に関する研究

研究分担者
野村卓生　関西福祉科学大学 保健医療学部 リハビリテーション学科
浅田史成　大阪労災病院 治療就労両立支援センター
高野賢一郎　関西労災病院 治療就労両立支援センター

研究要旨
平成 27 年度においては，1.メール指導を効率的かつ効果的に行うためのシステムの開発ならびに開発したシステムを用いた研究を行う，2.産業理学療法先進国の視察を行う，3.腰痛予防教育教材の作製と普及を行うこと，以上の 3 点を目的とした．結果，1.産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」を開発し研究を開始した（UMIN-CTR: UMIN000018450）．2.産業理学療法先進国の一つであるオーストラリアにおいて視察を行った．3.腰痛予防教育教材として，スクリーンセイバー，動画（映像）の作製を行った．今後，開発した Compo を用いての研究を実施，腰痛予防に対する理学療法の情報を国内外から継続的に収集，作製した腰痛予防教材の普及を行う予定である．

A. 研究目的

我々は過去，理学療法士（指導者）のメール指導による勤労者（相談者）への腰痛予防効果を検証することを目的として，Physical Consultant 研究（PCo 研究）を実施した. 平成 26 年度においては, PCo 研究のデータベースを用いて，介入終了後に指導者および相談者に行ったアンケート結果を分析し，コンピューターや携帯端末機器を利用したより効率的かつ効果的なメール指導のあり方に資する資料を得ることを目的に検討を行った [1)]．PCo 研究では対象者および指導者双方が個人のメールアドレスを使用していたが，相談者は 20 名であったので，研究事務局が指導者および相談者のメール内容の状況把握が可能であった．しかし，大多数の相談者への対応や指導者の育成，対象者と指導者間の個人情報の保護，相談内容とそれに対する指導内容（メールでの指導成果）の蓄積などを考慮するにあたり，専用のシステムの開発が必要と考えられた．また，産業保健分野における理学療法士の育成（例えば，より良い腰痛予防指導を行える理学療法士を育成する）を考える上で，産業理学療法の先進国における理学療法士の教育や研究の実際に関する視察が必要と考えた．さらに，職場における腰痛予防に資するため，腰痛予防教育教材の開発と普及が必要と考えた．

そこで，平成 27 年度においては，1.メール指導を効率的かつ効果的に行うため

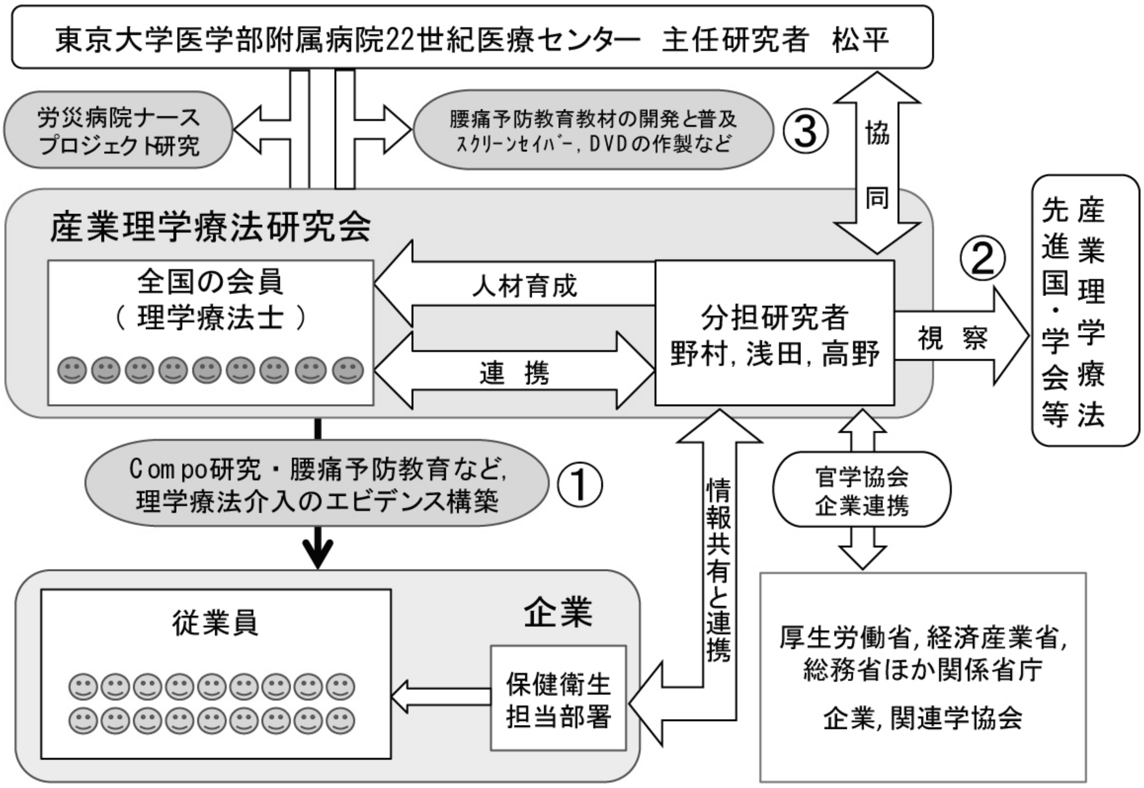

図１．分担研究のシェーマ

のシステムの開発ならびに開発したシステムを用いた研究を行う, 2.産業理学療法先進国の視察を行う, 3.腰痛予防教育教材の開発と普及を行うことを目的とした.

B.　研究方法

我々が労災疾病研究事業費補助金「職場における腰痛の効果的な治療法」で行う分担研究のシェーマを図 1 に示す.

1)　専用のシステムの開発とその効果検証（図１－①）

我々は平成 24 年度に日本理学療法士協会の助成を得て，株式会社 SIGEL（大阪）とともにメール指導を行うシステムのベースを試作した．このシステムは，産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」と命名した．平成 25～26 年度にかけて Compo の試用を行い, 平成 27 年度にはその検討の成果をもって Compo を改良することとした．試作した Compo は，産業理学療法研究内での試用を試み，さらに相談者や指導者が使用しやすいように，本研究の助成を得て改良を行うこととしたまた，Compo の効果検証を行うため, 研究計画を立案し, 研究を実施することとした.

2)　産業理学療法先進国の視察（図１－②）

理学療法士の教育制度について，アメリカでは大学卒業後に約 3 年をかけての大学院教育，オーストラリアでは 4 年制の大学教育で行われるなど一定に統制された高等教育で理学療法士養成を行っている国がある一方，日本では 3 年制の短期大学および専門学校教育, 4 年制の大学

および専門学校教育で理学療法士の養成が行われている．理学療法士が行うことのできる業務範囲については，開業権が認められている国や消炎鎮痛薬の処方が認められる国があるなど，各国で異なるのが実情である[2)]．本研究では，世界理学療法連盟（World Confederation for Physical Therapy，WCPT）において，Network for Occupational Health and Ergonomics[3)]の代表を務める理学療法士のDr. Rose Boucaut氏（南オーストラリア大学）の協力を得て，オーストラリアにおける産業理学療法を視察することとした．

3) 腰痛予防教育教材の作製と普及（図1－③）

平成27年度においては，凸版印刷株式会社（東京）の協力を得て，腰痛予防に関する教育教材としてスクリーンセイバーと動画（映像）を作製することとした．スクリーンセイバーについては，看護師を中心とした保健衛生業に従事する者を対象にして，松平の開発した「これだけ体操」[4)]の実施を促す構成とした．動画（映像）についても同様に保健衛生業に従事する者を対象にして，腰痛の発生を誘引しないことを目的としたトランスファーの技術指導，これだけ体操や体幹の屈曲・伸展・回旋運動などの腰痛予防体操の実施を促す構成とした．スクリーンセイバーおよび動画について，監修は主任研究者の松平が行うこととした．また，動画の作製にあたっては（一社）産業理学療法研究会および大阪労災病院リハビリテーション科の協力を得ることとした．

C. 研究結果

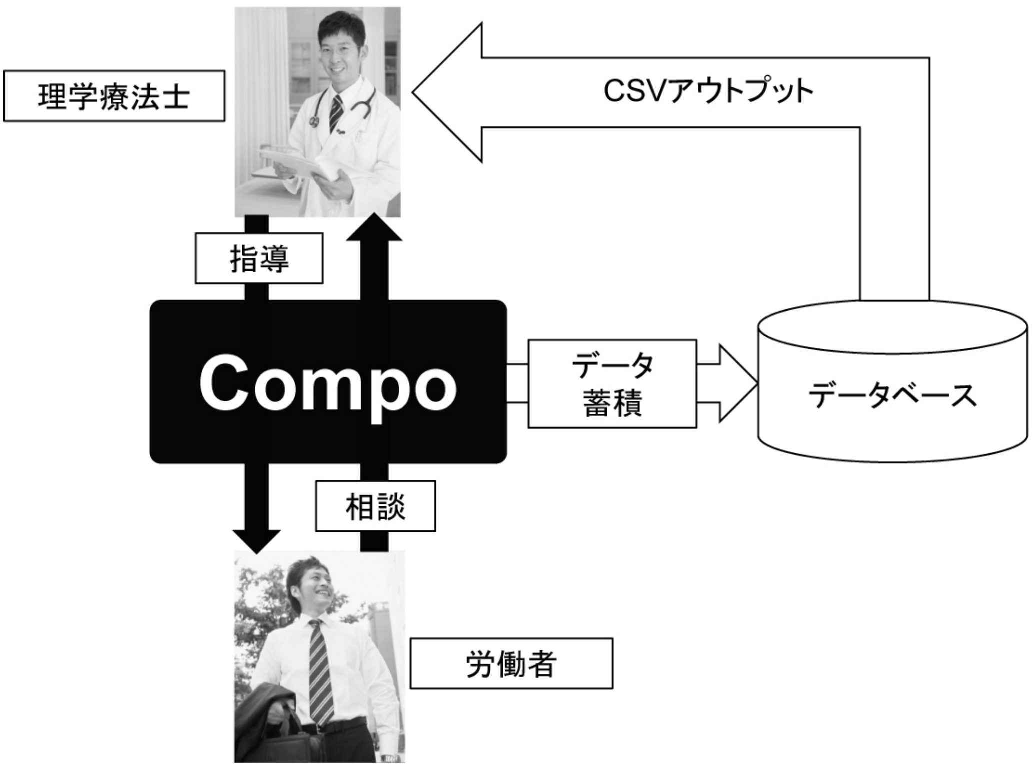

図２．Compoの機能概要

図３．作製したスクリーンセイバー

1) 開発したシステムと効果の検証計画

Compo の機能概要を図 2 に示す．本システムはパソコンでも，携帯電話でも使用可能である．特定の URL を入力し，個別の ID とパスワードでログインする．相談者は担当の指導者へテキストで相談を送信することができ，画像などの種々のファイルも添付可能である．指導者は相談者からの相談内容に応じて返信を行う．相談と指導のやり取りは，システムを通すし，仮名設定を前提とするので，相互の個人情報が開示・他者から確認されることはない．

指導者からはアンケートなども一斉送信で容易に実施可能となっており，その結果も CSV でダウンロード可能で，研究事務局で一括管理できる．対象者から相談のあっ

た場合に指導者へ通知されるアラート機能（登録したメールアドレスへシステム上に相談者から連絡のあった場合，リアルタイムに通知される．同様に指導者からシステム上で返信した場合，相談者へリアルタイムに登録したメールアドレスへ通知される）を装備している．

現在，Compo を用いた介入研究を実施中である．臨床試験登録システムである UMIN-CTR（UMIN000018450）に 2017 年 7 月 29 日に登録を行い対象者の登録・取入れを開始した（試験名：「産業理学療法指導システム（Compo）による勤労者の腰痛予防効果の検証」）．30 歳から 65 歳までの保健衛生業に従事する者を対象として，Compo を用いて指導を行う群（介入群）と介入を行わない群（対照群）の 2 群に振り分け，研究を実施中である．

2) 産業理学療法先進国・学会等の視察

南オーストラリア大学（アデレード）ならびにシドニー大学（シドニー）において，産業理学療法に関する教育，研究，理学療法の実際や理学療法士の役割に関する視察を行った[5)]．南オーストラリア大学理学療法学科では4年次に講義・現場での実習を含め，多くの時間をかけて「産業保健と安全管理（occupational health and safety）」に関する理学療法，理学療法士の役割が教授される．南オーストラリア大学理学療法学科の1学年の定員は100名であり，1学年全体で受講する講義のほか，Tutorialなどは少人数制できめ細かく行われる（Occupational Health and Safetyであれば，当該科目をもつ教員においては，学生は異なるが同じ内容を6回開講する）．例えば，ワイナリーに勤務する勤労者の健康管理と安全対策をテーマにする学生では，そのワイナリーへ実際に何度も出向き，詳細に仕事・作業の内容を調査して問題を抽出する．一連の調査内容を数十枚にわたるレポートにまとめ，学内で他の学生や教員と議論の上，エビデンスをふまえて対策方法を現場の安全管理者や従業員へ提案し議論を行っていた．また，ダムの工事現場においては，労働者の健康管理と安全対策のみならず，近隣の住民の安全対策までを考慮しているのが，日本の理学療法，理学療法士の業務とは次元の異なる点であったことなどが印象的であった．

3) 腰痛予防教育教材の開発と普及

作製したスクリーンセイバー（スライド枚数・全 5 枚）を図 3 に示す．動画（映像，再生時間：46 分 15 秒）については，①腰痛予防に関する基礎的な知識，②腰痛予防のための運動，③様々な状況を想定し，腰痛発生の予防を目指したトランスファー技術の 3 構成とした（図 4）．

D. 考察

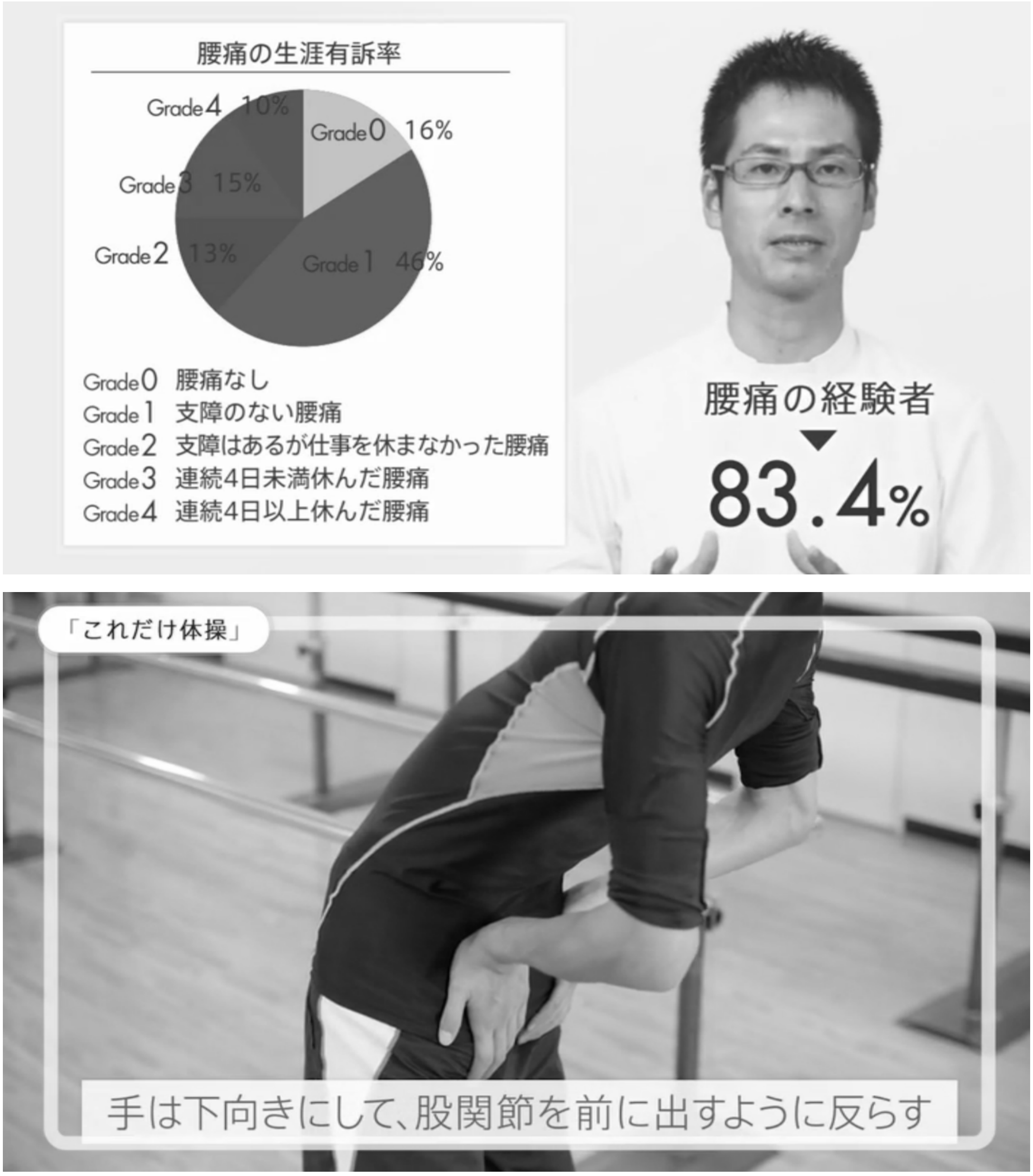

図４．作製した動画

Compo の開発を行ったが，より良い操作性や利便性を向上させるために，さらなる改良が必要と考えている．また，Compo を利用した研究を通して，より効率的・効果的な理学療法介入の在り方を検討していく必要がある．平成 27 年度においては，オーストラリアにおいて産業理学療法に関する視察を行ったが，今後も国内外の情報を継続的に収集していく予定である．作製した腰痛予防教育教材に関しては，インターネットや SNS 等を用いて，より広範囲に現場に普及させていきたいと考えている．また，作製した動画については，DVD 化等も考慮してい

く予定である.

E. 結論

1. 産業理学療法指導システム（Compo）の開発を行い, Compo を用いて腰痛予防を目的とした介入研究を開始した. 今後の研究成果をもとに, Compo の操作性や利便性をさらに向上させ, 職場における腰痛の効果的な予防法の一手段として確立させたいと考えている.
2. 産業理学療法に関する先進国であるオーストラリアにおいて視察を行った. 今後も継続して国内外の情報を収集していく予定である.
3. 腰痛予防のための教育教材について, スクリーンセイバーと動画（映像）を作製した. 今後, 作製した教育教材を広く普及させていく予定である.

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G. 知的財産権の出願・登録状況

1. 特許取得
   なし
2. 実用新案登録
   なし
3. その他
   なし

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Ⅲ. 研究成果の刊行に関する一覧

研究成果の刊行に関する一覧表

【H27.4.1～H28.3.31】

雑誌

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Ⅳ. 研究成果の刊行物・別刷

RESEARCH ARTICLE

Predictive Factors for Subjective Improvement in Lumbar Spinal Stenosis Patients with Nonsurgical Treatment: A 3-Year Prospective Cohort Study

Ko Matsudaira[1], Nobuhiro Hara[2], Hiroyuki Oka[1]*, Junichi Kunogi[3], Takashi Yamazaki[2], Katsushi Takeshita[4], Seichi Atsushi[5], Sakae Tanaka[6]

1 Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical & Research Center, Faculty of Medicine, University of Tokyo, Tokyo, Japan, **2** Department of Orthopaedic Surgery, Musashino Red Cross Hospital, Tokyo, Japan, **3** Department of Spine and Orthopaedic Surgery, Japanese Red Cross Medical Center, Tokyo, Japan, **4** Department of Orthopaedic Surgery, Jichi Medical University, Tochigi, Japan, **5** Department of Orthopaedic Surgery, Mitsui Memorial Hospital, Tokyo, Japan, **6** Department of Orthopaedic Surgery, University of Tokyo, Tokyo, Japan

* okah-tky@umin.ac.jp

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Abstract

Objective

To assess the predictive factors for subjective improvement with nonsurgical treatment in consecutive patients with lumbar spinal stenosis (LSS).

Materials and Methods

Patients with LSS were enrolled from 17 medical centres in Japan. We followed up 274 patients (151 men; mean age, 71 ± 7.4 years) for 3 years. A multivariable logistic regression model was used to assess the predictive factors for subjective symptom improvement with nonsurgical treatment.

Results

In 30% of patients, conservative treatment led to a subjective improvement in the symptoms; in 70% of patients, the symptoms remained unchanged, worsened, or required surgical treatment. The multivariable analysis of predictive factors for subjective improvement with nonsurgical treatment showed that the absence of cauda equina symptoms (only radicular symptoms) had an odds ratio (OR) of 3.31 (95% confidence interval [CI]: 1.50–7.31); absence of degenerative spondylolisthesis/scoliosis had an OR of 2.53 (95% CI: 1.13–5.65); <1-year duration of illness had an OR of 3.81 (95% CI: 1.46–9.98); and hypertension had an OR of 2.09 (95% CI: 0.92–4.78).

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Conclusions

The predictive factors for subjective symptom improvement with nonsurgical treatment in LSS patients were the presence of only radicular symptoms, absence of degenerative spondylolisthesis/scoliosis, and an illness duration of <1 year.

Introduction

Lumbar spinal stenosis (LSS) presents with neurological symptoms, such as numbness, pain, and intermittent claudication, in the lower extremities due to a narrowing of the intervertebral foramen and spinal canal, which serve as a passageway for nerves in the lumbar region.[1] Because of these symptoms, LSS is an important risk factor for decreased quality of life (QOL), particularly in the elderly. Previous epidemiological studies in Japan indicated a prevalence of LSS among people aged ≥70 years of approximately 10%.[2] With the aging society, the number of patients with LSS is predicted to rapidly increase. Thus, LSS is a disease that will be frequently encountered by primary care physicians.

With regard to LSS prognosis, several reports have demonstrated better outcomes with surgery compared with nonsurgical treatments.[3–5] Conversely, various other reports have revealed that, in some patient groups with relatively mild symptoms, the disease's natural course has a favourable prognosis.[6–10] However, patients with mild symptoms were excluded from some studies, and, in other cases, patients with severe symptoms requiring surgery were excluded. Therefore, it is not possible to draw conclusions regarding the natural history of LSS in all patients. To determine which patients have favourable prognoses, studies need to be conducted on a wide range of patients with LSS, regardless of the disease severity and therapeutic methods. However, to the best of our knowledge, no such study has been conducted.

Our hypothesis was that pre-treatment factors, such as duration of illness, types of symptoms, radiographic features, comorbidity, would predict patients' subjective improvement without surgical intervention. The aim of this study was to establish the evidence for favourable prognoses without surgical intervention.

Materials and Methods

Study design

This study was an investigator-initiated observational cohort study conducted at 17 medical centres in Japan, in which a wide variety of treatments, including surgical and conservative methods, were used in the treatment of spinal diseases. This study was approved by institutional review board of University of Tokyo, Tokyo Metropolitan Geriatric Hospital, Hitachi General Hospital, Asama General Hospital, MIshuku Hospital, Musashino Red Cross Hospital, Tokyo Metropolitan Tama Synthesis Medical Center, Japanese Red Cross Medical Center, Tokyo Yamate Medical Center, NTT Medical Center Tokyo, Sanraku Hospital, Kanto Central Hospital, Tokyo Metropolitan Hiroo Hospital, Tokyo Metropolitan Komagome Hospital, Kosei Hospital, Yokohama Rosai Hospital, Toranomon Hospital, and written informed consent was obtained from all participants.

Patient population

Patients with LSS were enrolled from the University of Tokyo Hospital and 17 related facilities between July 2002 and June 2003 based on the following eligibility criteria: aged 50–85 years old and LSS based on the definition of Verbiest [11] (presence of paraesthesia or pain in the lower extremities, buttocks, perineum, or perianal region and magnetic resonance imaging showing the presence of spinal canal stenosis that may explain the patient's symptoms). Based on the pathogenesis, the patient's condition was required to be degenerative acquired stenosis (e.g., spondylosis, spondylolisthesis, or scoliosis), and patients with congenital, developmental, or post-traumatic LSS as well as those who underwent spinal surgery were excluded. The exclusion criteria were also as follows: presence of lumbar disc herniation (i.e., a positive straight leg raise test); arteriosclerosis obliterans (i.e., non-palpable foot arteries); complications causing disorders that interfere with gait, such as those after cerebral infarction or myelopathy; diagnosis of lower extremity symptoms because of peripheral nerve diseases; rheumatoid arthritis or Parkinson's disease; current administration of psychosomatic medicine or outpatient treatment at a psychiatric department; and compensation for damage.

Of the 314 patients that were screened, the study enrolled 274 patients (151 men, 123 women; mean age, 71 years) whose eligibility was guaranteed by a third-party evaluation.

In this study, a database was created by prospectively enrolling patients with LSS, regardless of the disease severity or treatment. Three years later, their prognosis was examined, and the factors that led to a subjective improvement in their symptoms without surgical intervention were assessed.

Study interventions

The treatment choice was made by the patients and physicians of each facility. The therapeutic methods included surgery (i.e., posterior lumbar decompression, posterior lumbar spinal fusion, or anterior lumbar interbody fusion) and nonsurgical methods (i.e., administration of non-steroidal anti-inflammatory drugs or prostaglandin E1 derivatives, exercise therapy, physical therapy, or nerve blocks). There was no limitation to the treatment selection.

Study measures

The following variables were examined at initial enrolment: degree of obesity (body mass index: $\geq$25 or $<$25 kg/m^2), educational background (at least a high school graduate, other), current comorbidities (hypertension, diabetes mellitus), duration of illness ($<$12 months, 12–59 months, or $\geq$60 months), types of symptoms (presence of cauda equina symptoms, at least the presence of bilateral numbness in the lower limbs), and presence of degenerative spondylolisthesis (% slip $\geq$5%) and scoliosis (Cobb angle $\geq$10 degrees) on radiographs. In addition, the Geriatric Depression Scale (GDS)-15, which is the abridged version of the GDS-30, was administered and assigned to tertiles defined by approximate thirds of the score distribution (0–2, 3–6, and $\geq$7) to assess depression.[12]

Three years after enrolment, a self-administered survey was delivered by mail to examine the patients' subjective improvement and determine whether surgery had been performed. In addition, the study centre also contacted survey non-respondents by telephone as an alternative form of contact to increase the response rates. The subjective degree of improvement was based on a 5-point scale, with 1 and 2 points indicating improvement without surgical intervention: 1) the condition has improved a lot; 2) the condition has improved; 3) nothing has changed; 4) the condition has become worse; and 5) the condition has become a lot worse.

Statistical analysis

A multivariable logistic regression model was used to assess the relationship between the candidate variables and patients' subjective improvement without surgical intervention. The following candidate variables were included in the final regression model when $P < 0.10$ in the univariable analysis: age, sex, obesity, educational background, duration of illness, types of symptoms, and the presence of each of degenerative spondylolisthesis/degenerative scoliosis, hypertension, diabetes, and depression (GDS-15). Statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA). A P value < 0.05 was considered to be statistically significant, and all reported P values are two sided.

Results

The 3-year follow-up rate was 67.5% (n = 185). There were no differences in the candidate variables between the 185 patients who completed the follow-up survey and the 89 patients who did not (Table 1).

Nonsurgical treatment resulted in subjective improvements in 56 (30.3%) of the 185 patients, and the condition worsened or did not change in 47 (25.4%) patients. In 82 patients (44.3%), surgery was performed within the 3-year follow-up (Fig 1). The proportion of patients with improvement was not significantly different between the groups (surgical treatment: 51/82, 62.2%; nonsurgical treatment: 57/103, 55.5%; P = 0.28).

The univariable analysis revealed that the duration of illness, types of symptoms, and the presence of each of degenerative spondylolisthesis/scoliosis, hypertension, and depression were significant explanatory variables ($P < 0.10$) (Table 2). The multivariable analysis with these explanatory factors showed that the absence of cauda equina symptoms (only radicular symptoms) had an odds ratio (OR) of 3.31 (95% confidence interval [CI]: 1.50–7.31); absence of degenerative spondylolisthesis/scoliosis had an OR of 2.53 (95% CI: 1.13–5.65); a <1-year duration of illness had an OR of 3.81 (95% CI: 1.46–9.98); and hypertension had an OR of 2.09 (95% CI: 0.92–4.78) (Table 3).

Table 1. Baseline characteristics, compared between the participants with lumbar spinal stenosis who did and did not complete the 3-year follow-up.

	Participants (n = 185)	Drop-outs (n = 89)	P-value
Age (years), mean (SD)	70.7 (7.4)	71.7 (7.6)	0.28
BMI (kg/m^2), mean (SD)	23.4 (3.1)	23.2 (3.1)	0.53
Gender (%)			
Female	77 (41.6)	46 (51.7)	0.12
Educational background			
At least a high school graduate	134 (72.4)	64 (71.9)	0.93
Cauda equina symptoms	78 (42.2)	44 (49.4)	0.26
Degenerative spondylolisthesis/scoliosis	99 (53.5)	47 (47.5)	0.91
Duration of illness (months)			
<12	48 (26.0)	23 (25.8)	0.99
12–59	80 (43.2)	38 (42.7)	
≥60	57 (30.8)	28 (31.5)	
Hypertension	120 (64.9)	57 (64.0)	0.89
GDS score (tertiles)			
0–2	73 (39.5)	27 (30.3)	0.13
3–6	64 (34.6)	29 (32.6)	
≥7	48 (25.9)	33 (37.1)	

BMI, body mass index; SD, standard deviation; GDS, Geriatric Depression Scale
The values are reported as n (%), unless indicated.

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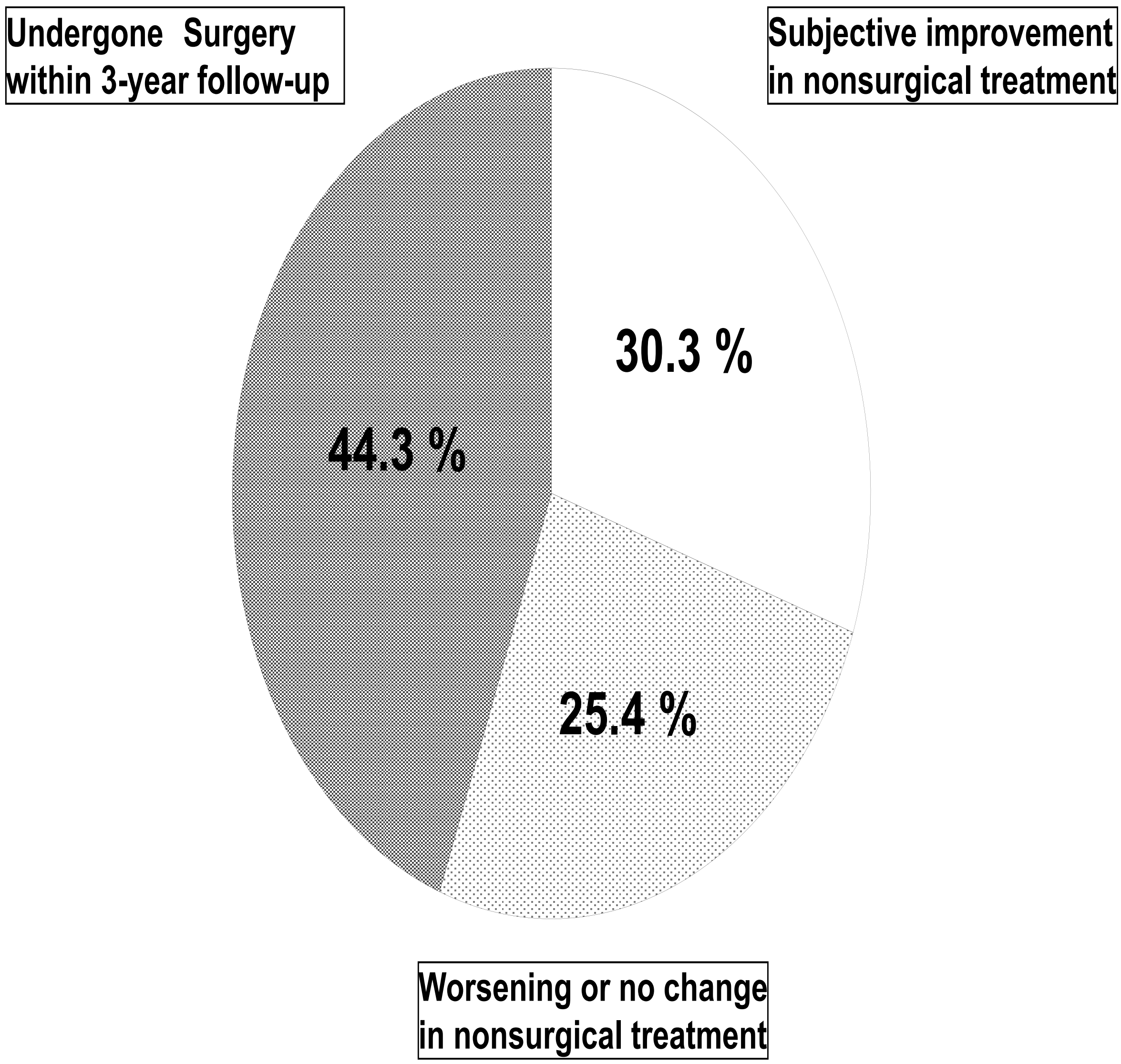

Fig 1. Response to the self-administered survey in 185 patients with lumbar spinal stenosis 3 years after treatment.

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Discussion

In patients with LSS from multiple medical centres and varying levels of disease severity and treatments, nonsurgical treatment resulted in subjective improvement of the symptoms at 3 years after enrolment in 30% of the patients; however, in 70% of the patients, the symptoms

Table 2. Univariable logistic regression analyses for 3-year subjective improvement in lumbar spinal stenosis symptoms through nonsurgical treatment.

Baseline factors	n	Odds ratio(95% CI)	P-value
Age (years)			
<65	40	1.69 (073–3.95)	0.22
65–74	80	1.21 (0.58–2.51)	0.61
≥75	65	1.00	
BMI (kg/m^2)			
<25	129	088 (0.45–1.73)	0.71
≥25	56	1.00	
Gender			
Female	77	1.19 (0.63–2.25)	0.85
Male	108	1.00	
Educational background (at least a high school graduate)			
Yes	134	1.00	
No	51	0.95 (0.47–1.91)	0.88
Cauda equina symptoms			
Yes	78	1.00	
No	107	4.42 (2.10–9.30)	< 0.001
Degenerative spondylolisthesis/degenerative scoliosis			
Yes	86	1.00	
No	99	2.11 (1.10–4.03)	0.03
Duration of illness (months)			
<12	47	3.68 (1.54–8.81)	0.003
12–59	79	1.72 (0.76–3.89)	0.2
≥60	59	1.00	
Hypertension			
Yes	65	1.00	
No	120	1.96 (0.97–3.95)	0.059
GDS score (tertiles)			
0–2	73	2.07 (0.88–4.14)	0.09
3–6	64	1.73 (0.88–4.83)	0.22
≥7	48	1.00	

BMI, body mass index; GDS, Geriatric Depression Scale; CI, confidence interval

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remained unchanged, worsened, or were treated surgically. Multivariable analysis showed that the factors associated with the improvement of subjective symptoms at 3 years after treatment were the presence of only radicular symptoms, the absence of degenerative spondylolisthesis and scoliosis, and an illness duration of <1 year.

The present study was conducted using a large-scale cohort of LSS patients from multiple medical centres, regardless of the disease severity, resulting in more representative data than previous studies. However, the present study did not include patients with very mild symptoms, who tend not to present at hospitals. Therefore, the prognosis may be slightly different from that in patients with more severe LSS. In addition, the degree of improvement of subjective symptoms was used as the measure of improvement; therefore, there may be differences in the actual improvement. However, the LSS severity is often defined on the basis of the intensity of lower extremity pain, and, because there are no well-defined classifications or criteria, the degree of subjective improvement may be closest to the actual degree of improvement. In a

Table 3. Multivariable logistic regression analyses for 3-year subjective improvement in lumbar spinal stenosis symptoms through nonsurgical treatment.

Baseline factors	Odds ratio (95% CI)	P-value
Cauda equina symptoms		
Yes	1.00	
No	3.31 (1.50–7.31)	0.003
Degenerative spondylolisthesis/degenerative scoliosis		
Yes	1.00	
No	2.53 (1.13–5.65)	0.024
Duration of illness (months)		
<12	3.81 (1.46–9.98)	0.007
12–59	1.87 (0.77–4.54)	0.17
≥60	1.00	
Hypertension		
Yes	1.00	
No	2.09 (0.92–4.78)	0.08
GDS score (tertiles)		
0–2	2.05 (0.80–5.25)	0.14
3–6	1.80 (0.70–4.68)	0.23
≥7	1.00	

GDS, Geriatric Depression Scale; CI, confidence interval

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study that compared surgically treated to conservatively treated patients and conducted follow-ups with 19 patients for an average of 31 months, [13] symptoms improved in 30% and remained unchanged in 60% of the conservatively treated patients who did not undergo any procedure. Despite the study's limitations, including its retrospective nature, unknown inclusion criteria for the conservatively treated patients, and small sample size, the rate of improvement was comparable to that of our cohort. Similarly, in a 5-year follow-up with 120 patients in whom conservative treatment was initially effective, an improvement was found in 43% of patients, the symptoms remained unchanged in 17%, and symptoms worsened in 40% at the final follow-up; however, the patients may have had relatively mild initial symptoms.[6] Moreover, in a prospective, randomised comparative study of surgical treatment for LSS, observations at 10 years after treatment in the 18 patients that received conservative treatment (control group) revealed mild pain in 2 patients (11%), moderate/severe pain in 6 patients (33%), and surgical treatment in 9 patients.[14] At the 2-year follow-up of a randomised cohort study with patients without spinal instability who were identified as surgical candidates and randomised to either surgical or conservative treatment, 43% of the patients with conservative treatment had to be re-assigned to the surgery group, while 28.7% reported an improvement in their symptoms.[15] However, because the patients with improved symptoms did not include those who were converted to the surgery group, it is possible that the percentage would be lower than those in the present study if the percentage was calculated in the same manner. Furthermore, the differences in results in these latter two studies, when compared with the present study, may be explained by the fact that the patients were indicated for surgery and may have had more severe conditions. However, in our study, if long-term follow-up was conducted, the percentage of patients with a favourable prognosis would likely decrease.

There are few reported studies regarding the predictive factors for the subjective improvement of LSS. However, Miyamoto et al. reported that the outcomes were favourable in patients with radicular-type symptoms and in those who showed good improvement after the initial treatment, while outcomes were poor in patients with degenerative scoliosis.[6] Based on our experience, the prognosis of patients with radicular type LSS has been favourable; however, the underlying mechanism is not yet known. In the present study, the percentage of patients with cauda equina deficits whose treatment was converted to surgery was 3 times higher than that of patients with only radicular type LSS, which may support our experience. Degenerative scoliosis/spondylolisthesis was also predictive of poor prognosis in the present study; conservative treatment is reportedly less effective against degenerative scoliosis, [16] including at a 2-year follow-up.[17] It is possible that patients who repeatedly develop radiculopathy symptoms because of a susceptibility to physical compression have a poorer prognosis, and their treatment is likely to be converted to surgery. In addition, long illness duration has been associated with poor surgical outcomes in LSS; [18] likewise, our findings showed that, in the natural course of LSS, illness duration $\geq$1 year was also a factor for poor prognosis. A long illness duration likely leads to chronic nerve compression, which may cause oedema or Wallerian degeneration of the affected nerves.[19] Although hypertension was not a significant prognostic factor, it tended to be associated with a poor prognosis. Hypertension is more common in patients with LSS than in controls; [20,21] it causes arteriosclerosis and promotes degenerative changes in the spine and intervertebral discs.[22] Because it can also cause chronic obstructive arteriosclerosis, it may aggravate the prognosis; therefore, further studies are needed to determine if hypertension is related with prognosis in LSS.

This study has several limitations. First, because the follow-up rate was 67%, the presence of non-response bias is possible. Second, we intended to exclude lumbar disc herniation with the use of the straight leg raise test. However, the test was often negative in the elderly, even though they had undergone surgery for lumbar disc herniation. Furthermore, disc herniation is often prevalent in degenerative spine and is a concomitant cause of stenosis.[23] Thus, it was difficult to determine whether the cause of lumbar radiculopathy was lumbar disk herniation or LSS in our population, and it is possible that the influence of disk herniation was underestimated. Third, this study collected data at only a single time point, at 3 years from the date of enrolment. Therefore, the results failed to capture the time course of the disease, the rate of improvement, or requirement for surgical treatment. Additionally, we did not control for the nature, intensity, or duration of surgical or nonsurgical management.

The present study, with a wide range of patients with LSS, provided important findings that have not been reported previously and will aid decision-making regarding LSS treatment. In patients with radicular-type symptoms without degenerative scoliosis or spondylolisthesis and an illness duration of $<$1 year, the prognosis is likely to be favourable; however, in patients with cauda equina symptoms, degenerative scoliosis or spondylolisthesis, and a long disease duration, surgery may need to be proactively considered.

Future long-term follow-up of this cohort should be conducted, potentially with a questionnaire that more accurately measures disease severity and degree of satisfaction, such as the Zurich Claudication Questionnaire developed by Stucki et al., which is currently being used worldwide.[24] Determining the long-term prognosis of LSS may be useful for developing treatment guidelines.

Conclusion

In 30% of 274 patients with LSS, conservative treatment led to a subjective improvement in the symptoms at the 3-year follow-up; however, in 70% of the patients, the symptoms remained unchanged, worsened, or required surgical treatment. The predictive factors for improved subjective symptoms were the presence of only radicular symptoms, the absence of degenerative spondylolisthesis and scoliosis, and an illness duration of $<$1 year.

Supporting Information

S1 File. Supporting information. Dataset of this study.
(XLSX)

Author Contributions

Conceived and designed the experiments: KM HO. Performed the experiments: KM NH JK TY KT SA ST. Analyzed the data: HO. Contributed reagents/materials/analysis tools: KM HO. Wrote the paper: KM NH HO.

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Psychological Detachment from Work during Nonwork Time:
Linear or Curvilinear Relations with Mental Health and Work Engagement?

Akihito SHIMAZU, PhD [1, 2]
Ko MATSUDAIRA, MD, PhD [3, 4]
Jan DE JONGE, PhD [2, 5]
Naoya TOSAKA, BA [1]
Kazuhiro WATANABE, MA[1, 6]
Masaya TAKAHASHI, PhD [7]

[1] Department of Mental Health, The University of Tokyo, Graduate School of Medicine, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

[2] Asia Pacific Centre for Work Health and Safety, University of South Australia, Adelaide, Australia

[3] Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan

[4] Clinical Research Center for Occupational Musculoskeletal Disorders, Kanto Rosai Hospital, 1-1 Kizukisumiyoshicho, Nakahara-ku, Kawasaki 211-8510, Japan

[5] Human Performance Management Group, Department of Industrial Engineering and Innovation Sciences, Eindhoven University of Technology, Eindhoven, The Netherlands

[6] Japan Society for the Promotion of Science, Tokyo, Japan

[7] National Institute of Occupational Safety and Health, 6-21-1, Nagao, Tama-ku, Kawasaki 214-8585, Japan

Address for correspondence: Akihito SHIMAZU, PhD
Department of Mental Health, The University of Tokyo, Graduate School of Medicine,
7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
TEL/FAX: +81-3-5841-3612
e-mail: ashimazu@m.u-tokyo.ac.jp

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Abstract

This study examined whether a higher level of psychological detachment during non-work time is associated with better employee mental health (Hypothesis 1), and examined whether psychological detachment has a curvilinear relation (inverted U-shaped pattern) with work engagement (Hypothesis 2). A large cross-sectional Internet survey was conducted among registered monitors of an Internet survey company in Japan. The questionnaire included scales for psychological detachment, employee mental health, and work engagement as well as for job characteristics and demographic variables as potential confounders. The hypothesized model was tested with moderated structural equation modeling techniques among 2,234 respondents working in the tertiary industries with regular employment. Results showed that psychological detachment had curvilinear relations with mental health as well as with work engagement. Mental health improved when psychological detachment increased from a low to higher levels but did not benefit any further from extremely high levels of psychological detachment. Work engagement showed the highest level at an intermediate level of detachment (inverted U-shaped pattern). Although high psychological detachment may enhance employee mental health, moderate levels of psychological detachment are most beneficial for his or her work engagement.
(184/200 words)

Key words: Psychological detachment; Mental health; Structural equation modeling; Work engagement; Curvilinearity

Introduction

In recent years, scholars have argued that not only on-job experiences (how employees spend their working time) but also off-job experiences (how they spend their private or leisure time) are crucial for understanding employee well-being[1]. More specifically, better knowledge of off-job recovery from the demands experienced during working time is imperative[2]. Recovery can be defined as a process during which individual functional systems that have been called upon during a stressful experience return to their initial, pre-stressor level[3]. Recovery can be regarded a process opposite to the strain process, during which the detrimental effects of stressful situations are alleviated or eliminated. Recovery is also regarded as an explanatory mechanism in the relation between acute stress reactions and chronic health impairment[4]. Certain experiences outside of work can help in alleviating reactions to work demands[5-7]. These so-called recovery experiences consist of psychological detachment, relaxation, mastery, and control[8]. Psychological detachment; i.e., the ability of individuals to mentally "switch off" from work by not doing work-related tasks and not thinking about work during non-work time, is considered the most crucial recovery experience for protecting one's well-being regarding job-related recovery[2, 9].

In the context of respites from work, detachment has been described as an "individual's sense of being away from the work situation" [10]. Psychological detachment has been further characterized as not being involved in work-related activities, such as phone calls, e-mails, or other work-related tasks, during off-work time[8]. Psychological detachment from work extends beyond the pure physical absence from the workplace during off-job time and abstaining from job-related tasks. It implies leaving the workplace behind oneself in psychological terms[11].

The relation between psychological detachment and well-being can be explained by COR theory[12] and the Effort-Recovery Model[3]. Conservation Of Resources (COR) theory asserts that an individual aspires to preserve, protect, and build resources. Resources are characterized as objects, conditions, personal characteristics, or energies that have specific importance for the individual. According to COR theory, stress occurs when individuals are threatened with resource loss, actually lose resources, or fail to gain resources following resource investment. The inability to replenish energy resources may lead to long-term fatigue, which hampers normal functioning in many aspects in daily life, including work. Thus, to recover from stress, individuals have to gain new resources and restore threatened or lost resources. Psychological detachment can contribute to gaining new resources and restore threatened or lost resources.

The Effort-Recovery Model[3] holds that effort expenditure at work leads to load reactions such as fatigue or physiological activation. Load reactions can accumulate and lead to impaired health and well-being, unless individuals can recover from work. By no longer being exposed to job-related demands, load reactions can return to pre-stressor levels, and recovery can occur before the next working period starts. This implies that recovery strategies such as psychological detachment during off-work time can be an opportunity to return to and stabilize at a baseline level. Thus, both the Effort-Recovery Model and COR theory suggest two complementary processes by which recovery occurs. First, it is important to refrain from work demands and to avoid activities that call upon the same functional systems or internal resources as those required at work. Second, gaining new internal resources such as energy, self-efficacy or positive mood will additionally help to restore threatened resources[8].

Previous studies that examined the relation between psychological detachment and well-being have revealed that psychological detachment is positively associated with mental health and negatively associated with job stress and burnout[6, 8, 11, 13, 14]. Therefore, we expect that a higher level of psychological detachment during non-work time will be associated with better mental health (Hypothesis 1).

Regarding positive aspects of employee well-being, the present study focuses on work engagement, which refers to a positive, fulfilling, work-related state of mind that is characterized by vigor, dedication, and absorption[15]. Previous studies have shown that psychological detachment is positively associated with work engagement [16-18], because detachment may contribute to the prevention of continued resource drain and restoration of resources[18]. If employees do not unwind from one's work, depleted resources can lead to low work engagement. Thus, we can assume that low levels of psychological detachment are associated with low work engagement.

However, the relation between psychological detachment and work engagement appears to be more complex. For instance, Shimazu et al.[19] showed a negative relation between these variables, suggesting that switching off mentally during off-job time did not improve work engagement, but rather decreased it. When individuals are highly detached from their jobs during off-job time, they may feel difficulty in "switching on" again in the next morning[14], and they may need more time to mobilize their energy for their job, which results in impaired work engagement.

These findings suggest that (very) low and (very) high levels of psychological detachment will be detrimental to work engagement. As a result, moderate levels of psychological detachment will be associated with the highest levels of work engagement. All these findings imply non-linear rather than linear relations between detachment and work engagement, which is in line with Warr's (1994) assumptions on work [20], mental health and well-being. Accordingly, we expect that psychological detachment will have a curvilinear relation (inverted U-shaped pattern) with work engagement (Hypothesis 2).

Method

Study population

An Internet research company with 1.5 million registered research volunteers aged 20–69 years, was used to conduct a large Internet-based cross-sectional survey on occupation, health and well-being in 2011. We randomly selected 106,250 volunteers from 201,170 monitors, living in three greater metropolitan areas of Japan (23 wards of Tokyo, the City of Osaka, and the City of Nagoya). On March 25, 2011, the selected volunteers were invited to take part in the study via an e-mail containing a link to the survey. Participants received online shopping points as an incentive for participation. In order to prevent double registration, e-mail addresses were checked and a link to the questionnaire was disabled once the survey was completed. On March 31, 2011, the survey was closed when more than five thousand participants responded (a total of 5,860 surveys were collected). Therefore, a specific response rate could not be calculated for this survey.

Our respondents were very close to the people living in 23 wards of Tokyo, the City of Osaka, and the City of Nagoya in terms of mean age (45.2 years in our respondents, 43.9 in Tokyo, 44.8 years in Osaka, and 43.8 years in Nagoya), gender (50.8 % in our respondents, 50.7 % in Tokyo, 51.5 % in Osaka, and 50.7 % in Nagoya), and employment status (46.5 % regular employment in our respondents, 46.1 % in Tokyo, 46.2 % in Osaka, and 50.1 % in Nagoya). However, our respondents had higher educational level (40.9 % undergraduate or higher) than those living in Tokyo (33.2 %), in Osaka (20.8 %), and in Nagoya (26.0 %)[21, 22].

In our respondents, the proportion of respondents working within primary industries (e.g., agriculture, forestry, and fisheries) and secondary industries (e.g., mining, manufacturing, and constructions) was extremely low (0.1% and 7.6% respectively). Therefore, we analyzed responses only from those individuals working in tertiary industries (e.g., transport and postal activity, wholesale and retail trade, accommodations, eating and drinking services, finance and insurance, advertising, education and learning support, and medical, health care and welfare). Individuals with a reported age of either < 20 years or ≥ 65 years, those with non-regular employment, or shift workers were excluded[23, 24, 25]. A total of 2,234 participants were retained and included in the analysis. The mean age of the participants was 41.7 years (SD = 11.3). Of the participants, 63.9% were male, 54.4% were married, 55.9% had a university degree or higher, and 12.2% worked more than 60 hours per week.

Measures

Psychological detachment

Psychological detachment was assessed using the corresponding subscale of the Japanese version of the Recovery Experience Questionnaire[8, 19], consisting of four items (i.e., “I forget about work,” “I don’t think about work at all,” “I distance myself from my work,” and “I get a break from the demands of work”). All items were scored on a five-point Likert scale, ranging from 1 (do not agree at all) to 5 (fully agree). Responses for the 4 items were summed to get a scale score. Cronbach’s alpha coefficient was .86.

Mental health

Mental health was assessed using the corresponding subscale of the SF-36 version 1.2[26-28], consisting of five items (i.e., “Have you been a very nervous person?”, “Have you felt so down in the dumps that nothing could cheer you up?”, “Have you felt calm and peaceful? (reversed) ”, “Have you felt downhearted and blue?”, and “Have you been a happy person? (reversed)”). All items were scored on a six-point Likert scale, ranging from 1 (all of the time) to 6 (none of the time). We used the SF-36 mental health summary score as a measure of mental health (Range: 0-100)[29]. Cronbach’s alpha coefficient was .84.

Work engagement

Work engagement was assessed using the short form of the Utrecht Work Engagement Scale (UWES) [15], which has been validated in Japan[30]. The UWES includes three subscales that reflect the underlying dimensions of engagement: Vigor (3 items; e.g., “At my job, I feel strong and vigorous”), Dedication (3 items; e.g., “I am enthusiastic about my job”), and Absorption (3 items; e.g., “I am immersed in my work”). All items are scored on a seven-point Likert scale ranging from 0 (never) to 6 (always). Responses for the 3 items each were summed to get a scale score. Cronbach’s alpha coefficients were .87 for vigor, .84 for dedication, and .86 for absorption.

Potential confounders

We controlled for two types of potential confounders; i.e., (1) job characteristics and (2) demographic characteristics. Their relation with detachment and our outcome measures is well-established in the literature[4, 9, 11].

Job characteristics were assessed using three scales of the Brief Job Stress Questionnaire (BJSQ[31]): job demands, job control and workplace support. The first two scales consisted of 3 items each, for instance "My job requires working hard" and "I have influence over the pace of my work". Workplace support consisted of 6 items: 3 items for supervisor support and 3 items for coworker support. To receive a more parsimonious model and to avoid multi-collinearity, we combined the two subscales in overall workplace support due to a high bivariate correlation ($r = 0.59$; $p < .001$). All items were scored on a four-point Likert scale, ranging from 1 (disagree) to 4 (agree). Cronbach's alpha coefficients were .81 for job demands, .85 for job control, and .86 for workplace support.

Demographic characteristics such as age, gender, marriage, education, and working hours per week were also included as potential confounders in the questionnaire.

Data analyses

To test the hypotheses, we conducted moderated structural equation modeling (MSEM) analyses, using the AMOS software package[32]. We preferred MSEM to hierarchical regression analyses, because MSEM allows multivariate testing of outcomes, allows assessing and correcting for measurement error, and provides measures of fit of the models under study. We followed the procedure proposed by Mathieu et al.[33] as described by Cortina et al.[34]. Linear psychological detachment and mental health had only one indicator that was the standardized (centered) scale score of the respective factor[33]. The indicator of the latent curvilinear psychological detachment was the squared term of the standardized (centered) scale score of psychological detachment. Work engagement had three indicators (i.e., vigor, dedication, and absorption). Correlation between linear psychological detachment and curvilinear one was constrained to be zero, whereas mental health and work engagement were allowed to correlate. The paths from the latent exogenous factors to their indicators were fixed using the square roots of the scale reliabilities, and the error variances of each indicator were set equal to the product of their variances and 1 minus their reliabilities. See Figure 1 for our hypothesized model. For more details regarding the calculation of the reliability score of the curvilinear term, we refer to Cortina et al.[34].

Figure 1 about here

The fit of the models was assessed with the chi-square statistic, the goodness-of-fit index (GFI), the comparative fit index (CFI), the non-normed fit index (NNFI), and the root-mean-square error of approximation (RMSEA). It is suggested that GFI, CFI, and NNFI values that exceed .90 and RMSEA values as high as .08 are indicative of acceptable fit[35].

Ethics statement

This study was approved by the medical/ethics review board of the Japan Labour Health and Welfare Organization and The University of Tokyo medical department.

Results

Simple statistics

Zero-order correlation coefficients are shown in Table 1. Psychological detachment was positively correlated with mental health (r = .22, p < .001), and negatively correlated with vigor (r = -.04, p < .05), dedication (r = -.06, p < .01), and absorption (r = -.14, p < .001).

Table 1 about here

Results of MSES analyses

Results of the MSEM-analyses showed that the hypothesized model (Model 1) fits to the data (χ^2 (8) = 236.72, p < .001, GFI = .97, NNFI = .93, CFI = .96) although RMSEA value exceeded .08 (RMSEA = .11). In line with Hypothesis 1, linear psychological detachment was positively related to mental health (β = .24, p < .001). As to Hypothesis 2, both linear and curvilinear psychological detachment were negatively related to work engagement (β = -.10, p < .001 and β = -.06, p < .01, respectively).

To ensure that no curvilinear relation existed between psychological detachment and mental health in addition to linear one, we examined the alternative model that adds the path from curvilinear psychological detachment to mental health. The model fit of the alternative model (Model 2: χ^2 (7) = 216.11, p < .001, GFI = .97, NNFI = .92, CFI = .97, RMSEA = .12) was similar to one of the hypothesized model. However, the chi-square difference test, comparing the hypothesized model (Model 1) with the alternative model (Model 2), shows a significant improvement in model fit ($\Delta\chi^2$(1) = 20.61, p < .001). This means that the alternative model (Model 2), including the path from curvilinear psychological detachment to mental health, offers a better account of the data than the hypothesized model (Model 1). Therefore, we decided to adopt the alternative model (Model 2) in further examination.

As can be seen in Figure 2, linear psychological detachment was significantly and positively related to mental health (β = .22, p < .001) whereas curvilinear psychological detachment was also significantly but negatively related to it (β = -.10, p < .001). In addition, both linear and curvilinear psychological detachment were significantly and negatively related to work engagement (β = -.11, p < .001 and β = -.09, p < .01, respectively). Please note that the results regarding the curvilinear relationship between psychological detachment and work engagement were similar in all three sub dimensions of the construct (i.e., vigor, dedication, and absorption).

Figure 2 about here

Regarding the curvilinear relation between psychological detachment and mental health, Figure 3 shows that initially there is a positive relation: more detachment is associated with better mental health. However, at high levels of psychological detachment, the positive relation between psychological detachment and mental health became less prominent, and even seems to disappear. Mental health did not increase further and remained at a high level.

Figure 3 about here

With regard to the curvilinear relation between psychological detachment and work engagement, Figure 4 shows that moderate levels of psychological detachment were associated with the highest levels of work engagement, whereas very low and very high detachment were associated with lower levels of work engagement (i.e., inverted U-shaped pattern).

Figure 4

In a final step, we conducted additional analysis to control for potential confounders (i.e., age, gender, marriage, education, working hours, job demands, job control, and workplace support). Specifically, each control variable was included in the alternative model (Model 2) as a manifest variable simultaneously and was allowed to relate to all variables in the model. After controlling for confounding variables, the path coefficients were virtually the same as those of the alternative model (Model 2), but the model fit decreased (χ^2 (35) = 1538.06, p < .001, GFI = .91, NNFI = .53, CFI = .82, RMSEA = .14). These results indicate that the added relations of the control variables to the model variables were weak. Importantly, many control variables did not significantly affect the structural paths in the model (i.e., 18 out of 48 paths were not statistically significant). Therefore, the control variables were removed from the final model in Figure 2.

Discussion

The aim of this large cross-sectional Internet survey study was to examine whether higher levels of psychological detachment during non-work time would be associated with improved employee mental health (Hypothesis 1). We also examined whether psychological detachment would have a curvilinear relation (i.e., inverted U-shaped pattern) with work engagement (Hypothesis 2). Examination of the curvilinear relation was novel, because prior research on the function of psychological detachment on work engagement is inconsistent in this respect[16-19].

As far as the relation between psychological detachment and mental health is concerned, MSEM revealed that not only linear psychological detachment (β = .22, p < .001) but also curvilinear detachment (β = -.10, p < .001) was significantly related to mental health. This result was contrary to our expectation. Examining Figure 3, the positive relation between psychological detachment and mental health flattened after higher levels of psychological detachment. This pattern of findings suggests that mental health initially improves when people psychologically detach. However, employee mental health does not benefit any further from extremely high levels of psychological detachment. It is important to note that mental health does not suffer at such very high levels of psychological detachment. Although most previous studies showed that higher levels of psychological detachment during non-work time were associated with better employee mental health[6, 8, 11, 13)], our result suggests that the favorable effect of psychological detachment may have an upper limit on mental health, at least among our participants. Future research needs to examine under which conditions and for whom psychological detachment has such a curvilinear relation with mental health.

As to the relation between psychological detachment and work engagement, we also found a curvilinear relation. Moderate levels of psychological detachment were associated with highest levels of work engagement, whereas very low and very high psychological detachment was associated with lower levels of work engagement (i.e., inverted U-shaped pattern). Very low levels of psychological detachment may drain one's resources and inhibit resource restoration, whereas very high levels of psychological detachment may require a longer time to get back into "working mode" in the next morning [9)]. These may negatively impact work engagement, particularly at high levels of detachment. Finally, it is worth noting that the curvilinear relation between psychological detachment and work engagement resembles (albeit at a weaker level) a previously found relation between psychological detachment and job performance in earlier research[14]. Given that both of these are more strictly work-related variables, the current finding may have implications for future research on the topic.

Limitations and suggestions for future research

Next to several strengths such as a large sample size and sufficient study power, there are also several limitations of this study. First, we used self-report survey data. Self-report measures may be biased due to, for example, negative affect. Common method variance might have affected the results, suggesting that the true associations between variables might be weaker than those observed in this study. Although several studies have shown that these influences are not as high as could be expected[36-38], our findings should be replicated using more objective measures (e.g., peer-ratings of mental health and work engagement) in the future.

Second, we used a cross-sectional study design, which precludes making causal inferences. For instance, our data showed that psychological detachment was related to better mental health. This might indicate that more psychological detachment leads to better mental health. It might also be that individuals enjoying better mental health are more likely to detach themselves from their work. Based on the cross-sectional analyses of the current study, it can only be concluded that psychological detachment is related to mental health and well-being. More longitudinal research is needed to uncover the causal sequence in the relation between psychological detachment and its consequences. However, it should be noted that there is a growing body of literature that demonstrates longitudinal effects of psychological detachment on health and well-being, particularly at day-level[39-42]. They support our causal inferences from both theoretical and empirical viewpoints.

Third, our data were collected from people living in three greater metropolitan areas of Japan (23 wards of Tokyo, the City of Osaka, and the City of Nagoya), which requires caution regarding the generalizability of our findings. Our sample may not represent other working populations quite well. Therefore, further studies are necessary to examine whether our results are applicable to workers in local areas.

Fourth, our data were collected via the Internet, which again requires caution regarding the generalizability of our findings. It has been claimed that the socioeconomic and educational status of the average Internet user is usually greater than that of the general population[43)]. Indeed, our participants reported higher educational status than those completing nationwide paper-and-pencil surveys in Japan[44)] and those living in Tokyo, in Osaka, and in Nagoya[21, 22)]. Thus, similar to typical Internet studies, self-selection might be a limitation of the present study.

Finally, psychological detachment did not have much explanation for outcomes in our participants. Specifically, linear and curvilinear psychological detachment explained successively 6 % and 2 % of the variances of mental health and work engagement in Model 2. One possible explanation is that we did not examine the combined effects of psychological detachment and other types of recovery experiences. Until now, only bivariate associations of recovery experiences with outcome variables have mainly been investigated. However, in reality, it is less likely that people use either type of recovery experience exclusively. Rather, they may use various types of recovery experiences simultaneously given the positive correlations among them (e.g., r = .16 - 63 by Sonnentag[8)], and r = .26 - .70 by Shimazu et al.[19)]). Hence, it is important to examine the combined as well as independent associations of each type of recovery experience with well-being in employees. According to COR theory[12], employees using various type of recovery experiences simultaneously are assumed to experience better well-being because multiple recovery experiences may provide more opportunity for recovery from resource loss and for resource gain. Another possible explanation is that we did not consider conditions under which employees use psychological detachment. This suggests the possibility that psychological detachment may not be favorable for everybody and in all situations[45]. For instance, employees who experience their jobs as highly meaningful and enjoyable might find detachment difficult to achieve, but lack of detachment might be less of a problem for such people. Thus, job features might moderate the relation between psychological detachment and well-being. Future research needs to examine the conditions under which psychological detachment can have more favorable effects.

Implications for practice

Our findings have some implications for practice. A first implication is that psychological detachment during non-work time is associated with employee mental health and work engagement *in different ways*.

With regard to employee mental health, higher levels of detachment would facilitate better mental health (although the favorable effect of detachment had limitations). It is important that both organizations and supervisors should support employee detachment by advising that employees be as unavailable as possible (e.g., via e-mail, texting or phone) during their nonwork time. It might be beneficial for workers to detach from work if they do not use their smartphones or tablets for work-related issues during free time [46-48]. However, it might also be possible that checking one's work e-mails helps to detach from work in particular circumstances. For example, if s/he is unsure whether s/he has forgotten to inform a colleague about an important work-related issue, to check the sent box of his/her e-mail account might help him/her thereafter to detach from work. Further research needs to examine whether the use of communication devices such as smartphones or tablets during non-work time can be beneficial or not for one's detachment from work. Organizations and supervisors can also support employee detachment by not initiating work-related communication with their employees during non-work time, thereby allowing detachment to occur[14]. Supervisors can act as role models in this respect by not being available during non-work time. This is particularly important in a country like Japan, because those who are in charge of changing long working culture in Japan are often work addicts themselves[49]. Furthermore, improving working conditions to achieve adequate levels of job demands can be a promising avenue to facilitate psychological detachment because high job demands (e.g., reduce time pressure) can inhibit psychological detachment during off-work time[2].

It is also important for employees who are at risk for workaholism (i.e., working excessively with an obsessive manner[50]) to modify this tendency, since it inhibits psychological detachment[2]. Training programs that focus on time management and problem solving skills might be helpful, because workaholic employees take on more work than they can handle and accept new tasks before completing previous ones[51]. Rational emotive therapy[52] might be also helpful, since workaholic people suffer from the belief that they should be perfect[53].

With regard to work engagement, the relation with psychological detachment is more complex and suggest a different practical implication: Moderate levels of psychological detachment would be associated with the highest levels of work engagement. Although operationalizing the optimal level of psychological detachment seems to be not very easy, it should be noted that thinking about work may not be necessarily negative per se[9, 54)]. Positively reflecting about one's work (e.g., thinking about a recent success or about an inspiring goal) might even improve work engagement, but this thinking should not be too much – there seems to be an upper limit for work reflection. Future research needs to clarify the preferable type and amount of work-related thoughts during off-job time to improve work engagement.

Conclusion

Although higher levels of psychological detachment may enhance employee mental health, it seems that moderate levels of psychological detachment are most beneficial for his or her work engagement. In future, more research is needed to address how, and under which conditions, to attain optimal levels of psychological detachment to achieve both better employee mental health and greater work engagement.

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Table 1. Descriptive statistics for the key study variables (N=2,234)

Variable	Range	Mean	SD	1	2	3	4	5	6	7
1 Age	20-64	41.74	11.31							
2 Gender [a]	0-1	.64	.48	-.10***						
3 Marriage [b]	0-1	.54	.50	-.41***	.31***					
4 Education [c]	0-1	.56	.50	-.08***	-.19***	-.03				
5 Working hours (per week) [d]	0-1	.12	.33	-.06**	-.15***	-.04*	.03			
6 Job demands	3-12	8.20	2.22	-.14***	-.07**	.02	.09***	.26***		
7 Job control	3-12	8.10	2.02	.18***	-.02	-.10***	.00	-.06**	-.16***	
8 Workplace support	6-24	15.20	3.89	-.03	.03	-.05*	-.01	-.01	-.02	.30***
9 Psychological detachment	4-20	13.77	3.53	.01	.06**	.07**	-.05*	-.11***	-.25***	.07***
10 Mental health	0-100	59.93	19.37	.14***	-.04*	-.12***	.03	-.09***	-.22***	.25***
11 Vigor	0-18	6.93	3.67	.20***	.03	-.11***	.01	.01	.01	.31***
12 Dedication	0-18	8.25	3.77	.17***	.05*	-.09***	.01	.05*	.13***	.29***
13 Absorption	0-18	6.97	3.87	.14***	.00	-.08***	.03	.06**	.14***	.27***

Table 1. (continued)

	Variable	8	9	10	11	12
1	Age					
2	Gender [a]					
3	Marriage [b]					
4	Education [c]					
5	Working hours (per week) [d]					
6	Job demands					
7	Job control					
8	Workplace support					
9	Psychological detachment	.05 *				
10	Mental health	.35 ***	.22 ***			
11	Vigor	.30 ***	-.04 *	.31 ***		
12	Dedication	.30 ***	-.06 **	.25 ***	.82 ***	
13	Absorption	.24 ***	-.14 ***	.18 ***	.79 ***	.83 ***

Note: * $p < .05$ ** $p < .01$ *** $p < .001$. SD: Standard Deviation. [a] Gender was coded as 1 (men) and 0 (women). [b] Marriage was coded as 1 (yes) and 0 (no). [c] Education was coded as 1 (university or higher) and 0 (college or lower). [d] Working hours per week was coded as 1 (60 =<) and 0 (< 60).

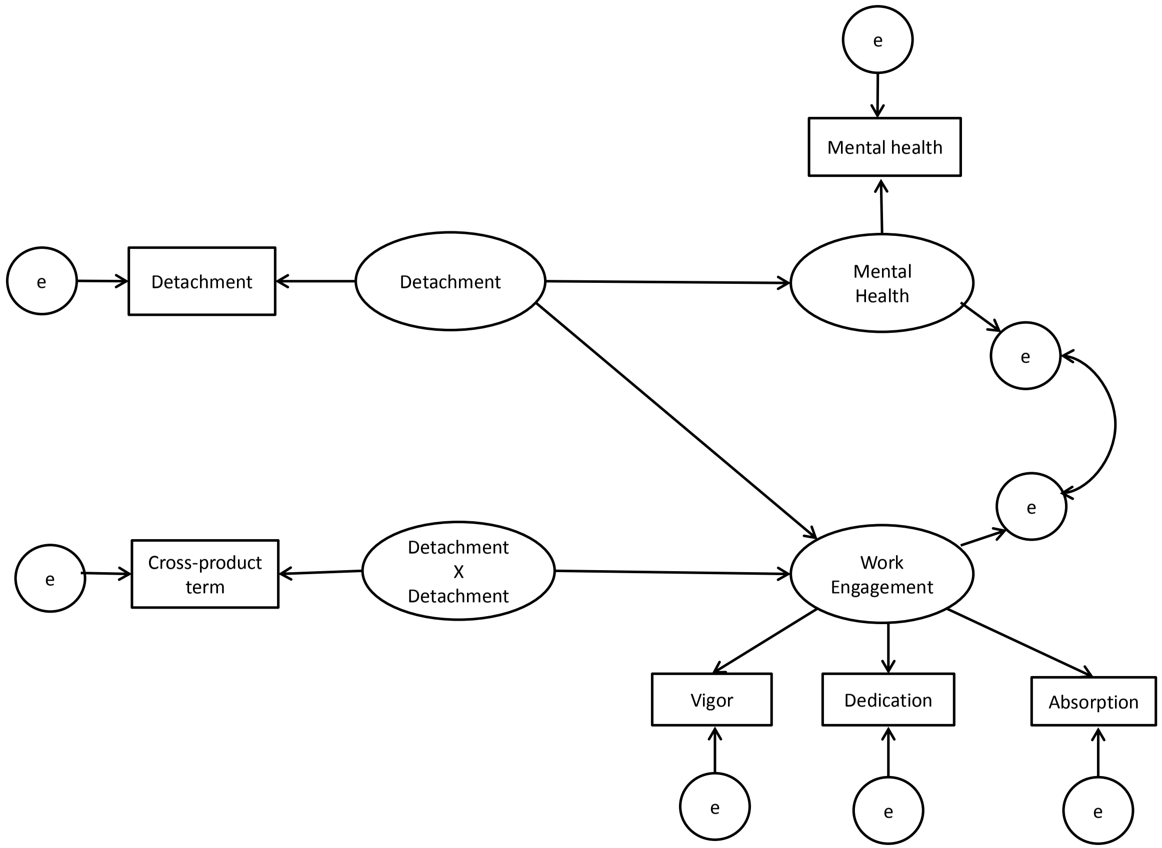

Figure 1. Hypothesized model (Model 1).
Note: e = error.

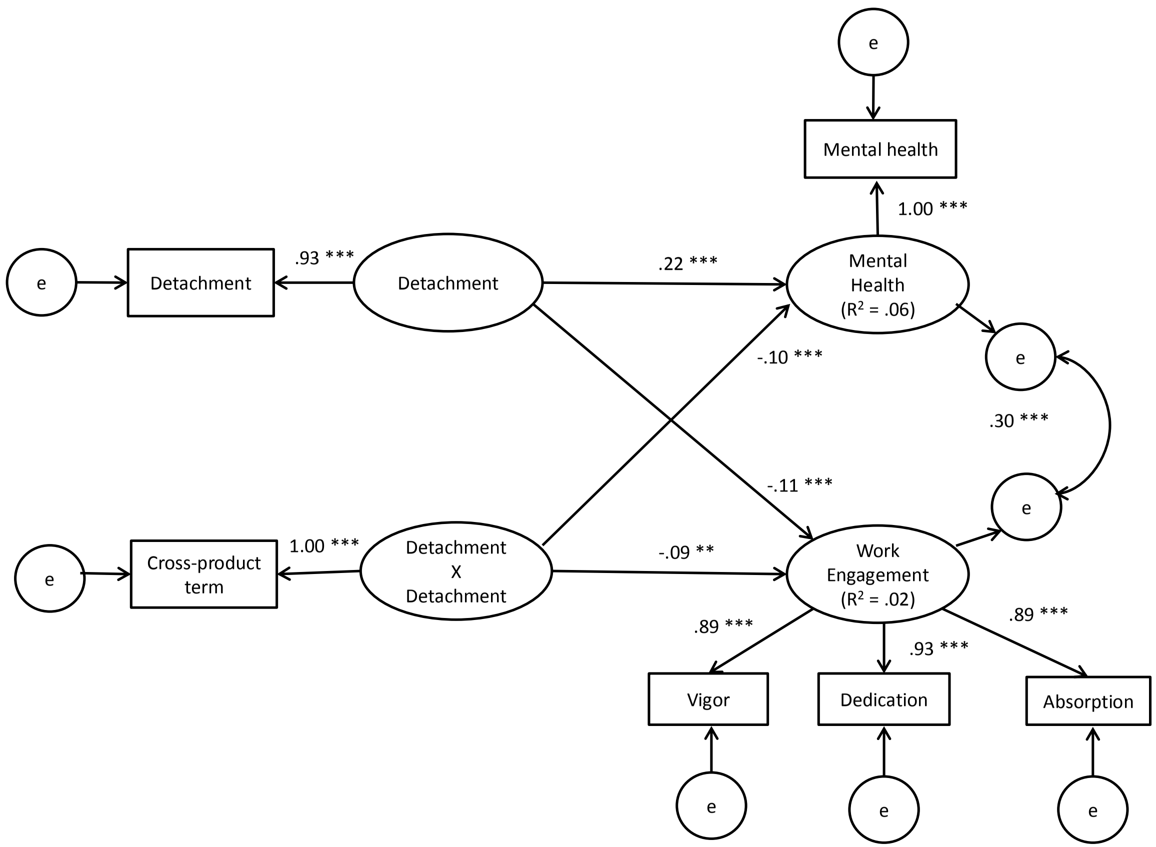

Figure 2. Standardized solution (Maximum Likelihood estimates) of the final (alternative) model (Model 2: N=2,234).

Note: e = error. *** p < .001, ** p < .01, * p < .05.

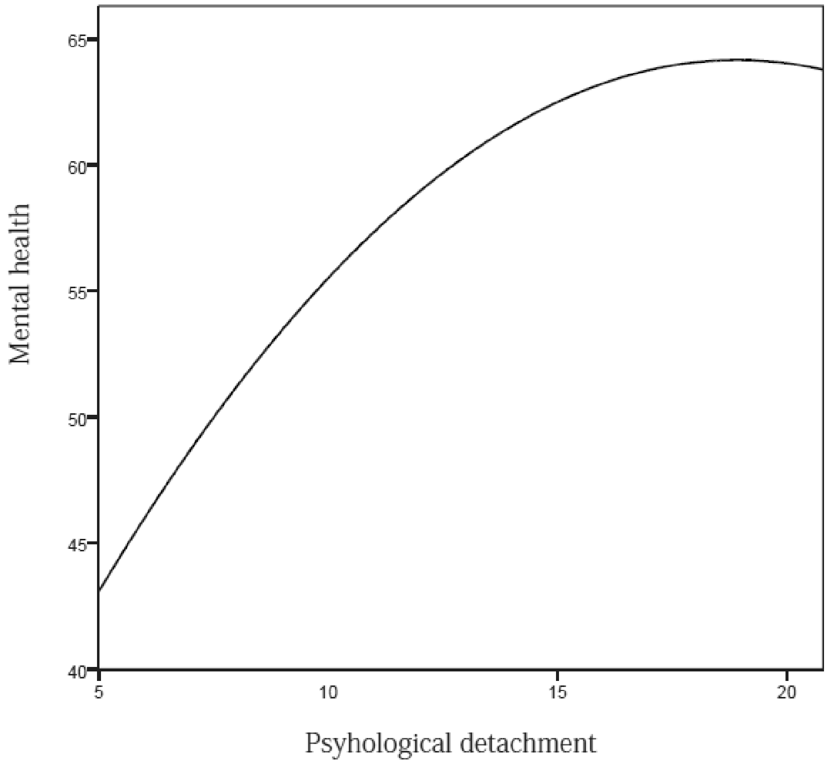

Figure 3. Curve-fitting between psychological detachment and mental health.

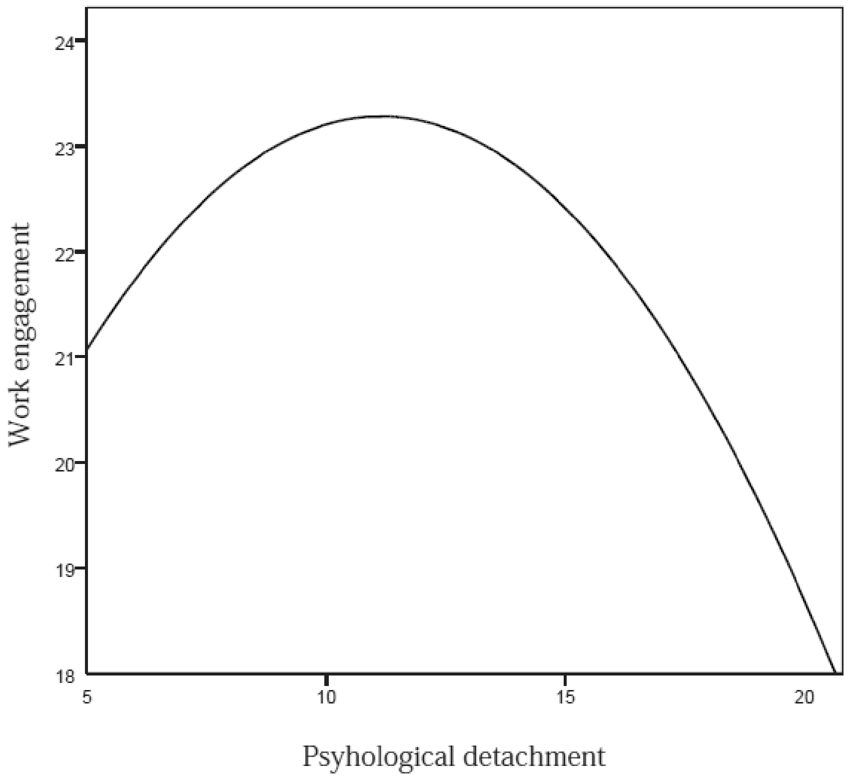

Figure 4. Curve-fitting between psychological detachment and work engagement.

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Potential risk factors for onset of severe neck and shoulder discomfort (Katakori) in Urban Japanese workers

[Authors and affiliations]

Takayuki Sawada[1,2], Ko Matsudaira[3], Yumiko Muto[1], Tadashi Koga[1,4], Masaya Takahashi[5]

[1] Clinical Study Support, Inc., Japan

[2] Department of Public Health, Aichi Medical University, Japan

[3] Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, Faculty of Medicine, the University of Tokyo, Japan

[4] CPC Clinical Trial Hospital, Medipolis Medical Research Institute, Japan

[5] National Institute of Occupational Safety and Health, Japan

[Correspondence]

Takayuki Sawada

Clinical Study Support, Inc., Daiei Bldg., 2F, 1-11-20 Nishiki, Naka-ku, Nagoya 460-0003, Japan

Ph: +81-52-211-2011; Fax: +81-52-211-2012

Email: takayuki_sawada@jp-css.com

[Running title]

Risk factors for onset of severe Katakori

[Abstract]

Katakori is a Japanese word, and there is no clear English translation. Katakori consists of two terms, Kata means neck and shoulder, kori means stiffness. Consequently, Katakori is defined as neck and shoulder discomfort or dull pain. Katakori is a major somatic complaint and has a large impact on workers. To examine the association between onset of severe Katakori and potential risk factors in Japanese workers, a prospective cohort study, entitled “Cultural and Psychosocial Influence on Disability (CUPID)”, was conducted. Self-administered questionnaires were distributed twice: at baseline and 1 year after baseline. Logistic regression was used to explore the risk factors of onset of severe Katakori. Of those 1,398, the incidence of severe Katakori onset after 1 year was 3.0% (42 workers). Being female (adjusted odds ratio: 2.39, 95% confidence interval: 1.18-4.86), short sleep duration (adjusted odds ratio: 2.86, 95% confidence interval: 1.20-6.82) and depressed mood with some issues at work (adjusted odds ratio: 3.11, 95% confidence interval: 1.38-7.03) were significantly associated with onset of severe Katakori. Psychosocial factors as well as gender difference were associated with onset of severe Katakori. We suggest that mental health support at the workplace is important to prevent severe Katakori.

[Key words]

Katakori, Prospective study, Risk factors, Japanese workers, Psychosocial factors

Introduction

Katakori is a Japanese word, and there is no clear English translation. Katakori consists of two terms, Kata means shoulder and kori means stiffness. Consequently, Katakori is defined as discomfort or dull pain caused by muscle stiffness around the back of the head and through the shoulders and/or shoulder blades[1)]. Katakori is usually classified as one of the cervico-omo-brachial syndrome. The symptoms of Katakori are considered to be close to “neck pain” or “chronic nonspecific neck pain” as expressed in the references[2-4)].

Katakori is classified into primary Katakori (essential Katakori) which does not identify any causable disease (organic disorder) and secondary Katakori (symptomatic Katakori) which is caused by disease. Examples of disease which can be the cause of secondary Katakori include cervical spine disease, glenohumeral joint disease, cardiovascular disease, pulmonary disease, eye fatigue, temporomandibular arthrosis, and menopausal syndrome[5, 6)].

The prevalence of Katakori is 6.1% among males and 13.1% among females in Japan[7)], therefore Katakori is a major somatic complaint which is comparable to low back pain and has a large impact on people including workers with subjective symptoms, however, its pathogenesis is still unclear. Furthermore, the association between Katakori and potential risk factors has not been properly assessed in prospective epidemiological research.

There have been reports of several risk factors associated with Katakori: such being female[6-9)], using a Visual Display Terminal (VDT)[6)] and mental health[9, 10)]. These factors have been identified based on the results of cross-sectional studies.

A prospective cohort study, entitled “Cultural and Psychosocial Influence on Disability (CUPID)”, was conducted to explore further the impact of cultural and psychosocial influences on musculoskeletal symptoms and associated disability[11, 12]. A cross-sectional analysis of baseline data shows that being female and depressed mood have been associated with severe Katakori in urban Japanese workers[8]. In this study, using one year of follow-up data, we conducted a continued analysis to examine the association between onset of severe Katakori and potential risk factors in urban Japanese workers. To our knowledge, this was the first longitudinal study assessing the potential risk factors for onset of severe Katakori. In this study, we especially focused on severe Katakori since Katakori is a common symptom among Japanese workers.

Subjects and methods

Data from a 1-year prospective cohort of the CUPID study were used for this analysis. The CUPID study is an international joint research project, which has involved 18 countries. In Japan, ethical approval for the study was obtained from the ethics committees of the University of Tokyo Hospital and review board of the Japan Labour Health and Welfare Organization. All participants provided written informed consent.

The workers around Tokyo including office workers, sales and marketing personnel, transportation workers, and nurses were recruited.

The board of each participating organization was asked to distribute a self-administrated questionnaire along with a cover letter from the study administration office to their workers. Responders were asked to return their completed questionnaires by mail and to provide their names and mailing addresses for direct correspondence from the study administration office for 1-year follow-up purposes.

The original questionnaire used in the CUPID study was translated into Japanese with some newly designed questions for Japanese workers regarding Katakori. The translation equivalence with the original questionnaire was checked through independent back-translation into English. For the participants, the pain area of Katakori was defined as the back of the head and through the shoulders and/or shoulder blades (Fig. 1). At baseline, respondents were asked about the frequency and severity of Katakori they had experienced during the previous month. The frequency of Katakori was assessed on a 6-point scale (1, always; 2, almost always; 3, often; 4, sometimes; 5, seldom; 6, never); the severity of Katakori was measured on an 11-point numerical rating scale (NRS) ranging from 0 (no Katakori) to 10 (severe Katakori). At follow-up, the frequency of Katakori was assessed using three duration periods (1-6 days, 1-2 weeks, or ≥ 2 weeks) and the severity of Katakori was measured by NRS.

In addition, the baseline questionnaire assessed individual characteristics (i.e., age, gender, age at the last educational status, body mass index (BMI), hours of sleep, marital status, regular exercise, smoking habits, visual fatigue, dental therapy, dental bite, and outpatient with articular and spine symptoms), ergonomic work demands (period of current service, working hours per week, VDT use, finger repetition, lifting, driving, standing, and work shift), and psychosocial factors (job satisfaction, job control, inadequate break time at work, worksite support, interpersonal stress at work, and experience of depressed mood with an issue at work). Variables were categorized by the same methods previously used in the CUPID study for Katakori association[8]. Age was categorized as < 30 years, 30-39 years, 40-49 years or ≥ 50 years. BMI was calculated by height and body weight recorded in a questionnaire; BMI ≥ 25 was defined as obesity. Age at the last educational status was categorized as ≤ 19 years or > 19 years; low education was defined as ≤ 19 years. Regular exercise was defined as physical exercise performed more than twice a week for 20 minutes or longer during the previous 12 months. Short sleep duration was defined as an average of < 5 hours. Low experience in current job was defined as < 1 year of current service. Sixty hours of working hours per week was defined as high work demand. VDT was defined as work using the computer display for ≥ 4 hours per shift. Lifting was defined as a work to lift or move ≥ 25 kg (object or person) by hand. Driving was defined as ≥ 4 hours of car or truck driving per shift. Standing was defined as ≥ 4 hours standing per shift. Work shift was defined as irregular work shift such as night shift. To assess the level of job satisfaction, responders were asked, “Considering everything, how satisfied are you with your work?” Answers were the following four choices: “Very satisfied”, “Satisfied”, “Not well satisfied” and “Not satisfied at all”. Low job satisfaction was defined as an answer of “Not well satisfied” or “Not satisfied at all”. To assess the level of job control, responders were asked, “How much control do you have in your work?" These items had four response options: often, sometimes, seldom, and never/almost never. Low job control was defined as an answer of "seldom" or "never/almost never". To assess the level of worksite support, responders were asked, "When you have difficulties in your work, how often do you get help and support from your colleagues or supervisor/manager?" This item had five response options: often, sometimes, seldom, never, and not applicable. Low worksite support was defined as an answer of "seldom" or "never" for worksite support. Depressed mood with some issues at work was defined as experience of that in past 12 months.

The follow-up questionnaire was distributed 1 year after the baseline assessment, and the second questionnaire was sent only to the participants who returned the first one with their written consent of participating. Therefore, those who did not return a questionnaire did not participate in the study any longer.

The outcome of interest was onset of severe Katakori during the 1-year follow-up period. In this study, severe Katakori was defined as frequency more than 2 weeks in the previous month and as severity with NRS more than 7 points at the follow-up. Incidence was calculated for the participants who reported no severe Katakori at baseline, as we defined severe Katakori as frequency more than often and as severity with NRS more than 7 points during the previous month. Participants were excluded from the analysis if they had changed their job.

For statistical analysis, in addition to compiling descriptive statistics, logistic regression was used to explore the associations between risk factors and onset of severe Katakori. Results of logistic regression analyses were summarized by odds ratios (ORs) and the respective 95% confidence intervals (CIs). For the assessment of potential risk factors, crude ORs were initially estimated. Factors with p-values < 0.1 were considered to be potential risk factors. We conducted a multivariate logistic regression analysis using potential risk factors in the model and then using a stepwise selection method in which terms were retained if they reached the 0.05 level of significance. All statistical tests were two-tailed, and conducted with a significance level of 0.05. The software package SAS Release 9.3 (SAS Institute Inc., Cary, NC) was used for statistical analyses.

Results

The baseline questionnaire was distributed to 3,187 participants and was completed by 2,651 participants. The following year, 1,809 participants successfully completed and returned the follow-up questionnaire, thereby yielding a follow-up rate of 68.2%.

Participants (n = 411) were excluded from the analysis if they had severe Katakori at baseline (n = 330) or those who changed their job (n = 81). Thus, a total of 1,398 participants were included in the present analysis (Fig. 2).

Mean (SD: standard deviation) age was 37.3 (10.0) years, of which 1,398 of 73.8% of participants were male. Jobs were nurses (21%), office workers (15%), sales and marketing personnel (21%) and transportation operators (43%). [Table 1] The incidence of onset of severe Katakori in the follow-up period was 3.0% (42 workers), with mean (SD) age of 37.1 (9.0) years. Of those, 50% were males.

To assess the effect of the selected drop-out, the baseline characteristics of patients who were followed up (n = 1,809) and those who dropped-out (n = 842) are calculated. The mean (SD) age was 37.3 (10.0) years and 33.6 (8.5) years, respectively, and the majority were men in both groups (66.0% vs 57.7%). The prevalence of severe Katakori was 18.8% and 21.2%, respectively.

Crude odds ratios of baseline factors for onset of severe Katakori are shown in Table 2. The factors potentially relating to onset of severe Katakori were gender, visual fatigue, sleep duration, inadequate break time, standing, work shift, interpersonal stress and depressed mood with some issues at work. In psychosocial factors, depressed mood with some issues at work was only included, instead of interpersonal stress at work, because of its strong correlation (ρ = 0.4137, $p < 0.0001$). The crude odds ratio of depressed mood with some issues at work was higher than the interpersonal stress at work, thus the higher factor was selected. Because 77%（281/366）of females were nurses, and 87%（255/294）of nurses were defined as irregular work shift, the correlation between female and irregular work shift was strong (ρ = 0.3422, $p < 0.0001$). Previous studies reported that Katakori was associated with females, so “female” was included in multivariate logistic regression analysis.

In the multivariate logistic regression analysis, these six factors were entered into the model. As a result, three potential risk factors were selected (Table 3).

A supplemental analysis was conducted to examine a combined impact of gender and nurses because 77% (281/366) were female nurses. We performed multivariate logistic regression analysis with the main three effects, nurse and interaction of gender and nurse. The adjusted odds ratios of main effects were similar to the main analysis, and the nurse effect as well as the interaction were not statistically significant. Based on these results, we propose three potential risk factors: gender, short sleep duration, and depressed mood with some issues at work which might associate with severe Katakori.

Discussion

To examine the association between onset of severe Katakori and potential risk factors, we conducted analyses using data from the CUPID study among urban workers in Japan. Although the incidence was small, severe Katakori occurred during the 1-year follow-up in some workers who had no or mild symptoms at baseline. A series of analyses showed gender, low sleep or depressed mood with some issues at work as important potential risk factors.

In our results, females showed higher odds (adjusted odds ratio= 2.18) as a potential risk factor for onset of severe Katakori. According to the supplemental analysis, being female is potential risk factor of Katakori as it eliminates the possibility of nurses to affect the main result of this study. Based on these results, this study suggests the association of gender as a potential risk factor of severe Katakori. This finding is similar to those published previously[6, 8, 9)]. We speculate this trend may be attributable to gender differences in muscle strength. Estrogen may also be involved in the pathogenesis of Katakori, although there is no scientific evidence for this assertion. Further studies will be required to explain the reason for gender differences in the manifestation of Katakori.

Being in a depressed frame of mind with some issues at work showed 3.1 times more increased risk of severe Katakori than those who are not. Previous cross-sectional studies suggest the association of Katakori and work stress, which was classified as a psychosocial factor[1, 6]. Krantz et al. have reported that emotional stress and psychologically stressful tasks are associated with increased electrographic activity in the trapezius muscle[13], and Hallman et al. have reported that autonomic imbalance is associated with neck shoulder pain, the Japanese definition of Katakori[14]. We suggest that psychosocial stress can progress to sympathetic and muscle stress, which may lead to the onset of Katakori.

In the present study, we found short sleep duration to be a potential risk factor. Mulligan et al. reported that nocturnal pain was associated with sleep quality, sleep duration, and habitual sleep efficiency in patients with shoulder disorders[15]. Short sleep duration might delay a daily recovery of tissue damage and cause the onset of severe Katakori. In order to ensure an adequate sleep duration, individuals should be responsible in attaining the required sleep duration, and support can be provided by encouraging a non-stressful work environment. In the present study, we had assessed sleep duration only. Further studies are required to explore any association between Katakori and the quality of sleep, including insomnia and other sleep disorders.

Factors identified as potential risk factors in the present study can be explained by Eriksen's hypothesis that head-down and neck flexion positions and/or psychological stress increase the intracellular nitric oxide/oxygen ratio through sympathetic nerve activity, resulting in inhibition of cytochrome oxidase; and then, lactate production would follow activating nociceptive fibers[16].

There were some limitations in this study. First, the generalizability of the findings may be limited. The majority of participants were male, and therefore a broad range of Japanese occupations was not represented. The study cohort was not a representative sample of the entire spectrum of Japanese workers in urban areas. Being female was one of the potential risk factors of Katakori although no interaction effects of gender and nurse were found in our supplemental analysis. However, the majority of females in this study were nurses, and the sample size included in the supplemental analysis may not have been sufficient. Therefore, our results need to be interpreted with care. Second, misclassification, to some extent, is inevitable. Information might be subjective in the decision of Katakori or sicknesses and missing value cannot be avoided due to the nature of a self-assessment survey. Third, drop-out may introduce bias into the data analysis due to the low follow-up rate of this study, although we considered that the baseline characteristics of both the follow-up group and the drop-out group seemed to be similar. Fourth, this study may not cover some unquestioned items which were not involved in the questionnaire. For example, some peculiar characteristics of Japanese may not be addressed by the original CUPID questionnaire regarding stress at work. Also, there were some items which were not involved in the original CUPID questionnaire as follows: disabilities of the arm, shoulder and hand questionnaire scores correlated significantly with depressive symptoms, catastrophic thinking, kinesiophobia, and pain anxiety[17]. The aforementioned behavioral items may need to be included as additional potential risk factors of severe Katakori. At last, a more complicated analysis model might be suitable for further assessment to discover other potential risk factors, instead of the logistic regression models assessed for the present analysis.

In conclusion, being female, short sleep duration and depressed mood with some issues at work were associated with onset of severe Katakori. We suggest that mental health support including the lack of sleep is important to prevent severe Katakori, especially for females.

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[Figure titles and legends]

Fig. 1. Diagram showing pain area for Katakori.

Fig. 2. Flowchart of the sample selection.

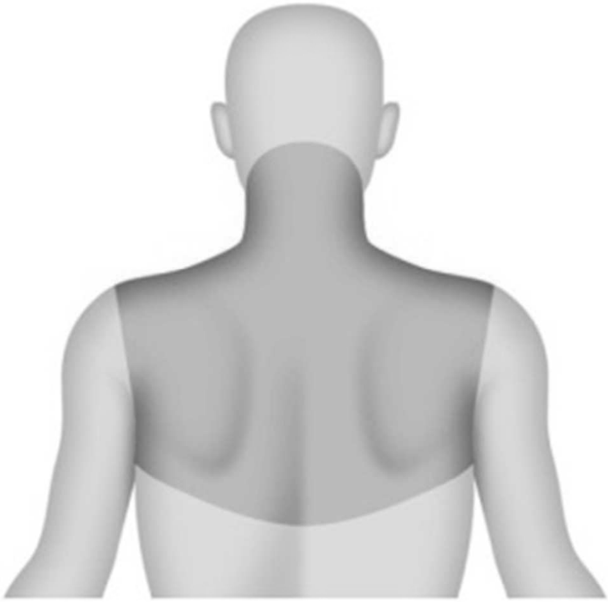

Fig. 1. Diagram showing pain area for Katakori.

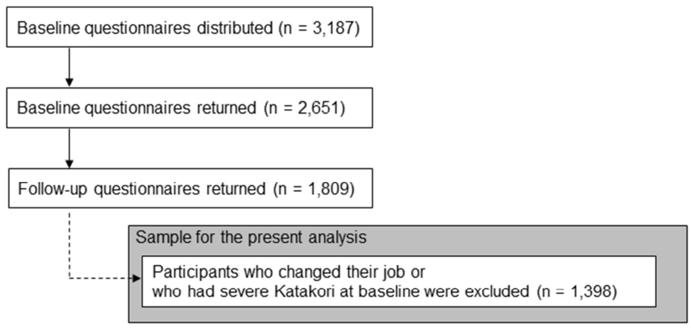

Fig. 2. Flowchart of the sample selection.

[Tables]

Table 1. Characteristics of responders

Characteristics	Severe Katakori	Non-Severe Katakori	Total
N (%)	42 (3.0%)	1356 (97.0%)	1398
Gender			
Male, n (%)	21 (2.0%)	1011 (98.0%)	1032 (73.8%)
Female, n (%)	21 (5.7%)	345 (94.2%)	366 (26.2%)
Age, mean (SD)	37.1 (9.0)	37.3 (10.0)	37.3 (10.0)
Job type			
Transportation operative	15 (2.5%)	585 (97.5%)	600 (43.0%)
Sales/ marketing personnel	5 (1.7%)	289 (98.3%)	294 (21.0%)
Nurse	16 (5.4%)	278 (94.6%)	294 (21.0%)
Office workers	6 (2.8%)	204 (96.7%)	211 (15.1%)

Table 2. Crude odds ratios of the risk factors for onset of severe Katakori

Risk factors	%	Crude odds ratio (95%CI)	p value
Gender			
Male	73.8	1.00	
Female	26.2	2.92(1.58-5.42)	0.001
Age (yr)			
<30	25.5	1.00	
30-39	37.3	1.79(0.74-4.33)	0.197
40-49	22.6	1.64(0.62-4.35)	0.324
≥ 50	14.6	1.51(0.50-4.57)	0.462
Outpatient with articular and spine			
No	97.2	1.00	
Yes	2.8	0.82(0.11-6.14)	0.850
Outpatient with dental therapy			
No	92.7	1.00	
Yes	7.3	1.35(0.47-3.87)	0.537
Wrong dental bite			
No	83.8	1.00	
Yes	16.2	1.76(0.85-3.65)	0.130
Visual fatigue			
No	56.3	1.00	
Yes	43.7	2.20(1.15-4.21)	0.017
BMI			
<25 kg/m^2	84.0	1.00	
≥ 25 kg/m^2	16.0	1.50(0.71-3.19)	0.291
Current smoking			
No	56.4	1.00	
Yew	43.6	1.44(0.78-2.66)	0.245
Age at last educational status **(yr)**			
≥ 20	62.4	1.00	
<19	37.6	0.66(0.33-1.29)	0.221
Regular exercise			
Yes	20.2	1.00	
No	79.8	1.50(0.62-3.60)	0.367
Marital status			
Married	56.4	1.00	
Not married	43.3	1.20(0.65-2.21)	0.568
Sleep duration			
≥ 5 h	56.4	1.00	
<5 h	43.3	2.75(1.24-6.10)	0.013
Experience in current job			
≥ 1 yr	90.6	1.00	
<1 yr	9.4	1.32(0.51-3.42)	0.569
Working hours per week			
Low	59.2	1.00	
High	40.8	0.89(0.47-1.67)	0.715
Inadequate break time at work			
Not inadequate	45.6	1.00	
Inadequate	54.4	3.16(1.50-6.66)	0.003
VDT			
Not VDT	75.3	1.00	
VDT	24.7	1.23(0.62-2.42)	0.557
Finger repetition			
No	77.7	1.00	
Yes	22.3	1.09(0.53-2.25)	0.811

Lifting			
No	47.4	1.00	
Yes	52.6	1.09(0.59-2.03)	0.777
Driving			
No	64.5	1.00	
Yes	35.5	1.01(0.53-1.91)	0.980
Standing			
No	43.1	1.00	
Yes	56.9	1.93(0.98-3.80)	0.058
Work shift			
Regular shift	60.8	1.00	
Irregular shift	39.2	1.73(0.94-3.21)	0.058
Job satisfaction			
Satisfied	43.4	1.00	
Not satisfied	56.6	1.38(0.74-2.57)	0.310
Job control			
Controlled	46.4	1.00	
Not controlled	53.6	0.64(0.35-1.19)	0.528
Worksite support			
Supported	91.3	1.00	
Not supported	8.7	1.15(0.40-3.27)	0.800
Interpersonal stress at work			
Not stressed	51.2	1.00	
Stressed	48.8	1.93(1.02-3.66)	0.045
Depressed mood with some issue at work			
Not feeling depressed	50.0	1.00	
Depressed	50.0	4.15(1.89-9.07)	<0.001

CI: confidence interval.

Table 3. Adjusted odds ratios of risk factors which were significant for onset of severe Katakori

Risk factor	Adjusted odds ratio (95%CI)	p value
Gender		
Male	1.00	
Female	2.39 (1.18 -4.86)	0.016
Sleep duration		
≥ 5 h	1.00	
<5 h	2.86 (1.20 -6.82)	0.018
Depressed mood with some issue at work		
Not feeling depressed	1.00	
Depressed	3.11 (1.38- 7.03)	0.006

CI: confidence interval.

Adjusted by gender, sleep duration and experience of depressed mood with some issue at work

RESEARCH ARTICLE

Risk Factors for Prolonged Treatment of Whiplash-Associated Disorders

Hiroyuki Oka[1]*, Ko Matsudaira[1], Tomoko Fujii[2], Hiroshi Okazaki[2], Yukari Shinkai[3], Yutaka Tsuji[3], Sakae Tanaka[4], Ryuichi Kato[3]

1 Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical & Research Center, Faculty of Medicine, University of Tokyo, Tokyo, Japan, **2** Department of Orthopaedic Surgery, Japan Labour, Health and Welfare Organization, Kanto Rosai Hospital, Kanagawa, Japan, **3** Medical Research Center, JA Kyosai Research Institute, Tokyo, Japan, **4** Department of Orthopaedic Surgery, University of Tokyo, Tokyo, Japan

* okah-tky@umin.ac.jp

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Abstract

Objectives

Whiplash-associated disorders (WAD) are the most common injuries that are associated with car collisions in Japan and many Western countries. However, there is no clear evidence regarding the potential risk factors for poor recovery from WAD. Therefore, we used an online survey of the Japanese population to examine the association between potential risk factors and the persistence of symptoms in individuals with WAD.

Materials and Methods

An online survey was completed by 127,956 participants, including 4,164 participants who had been involved in a traffic collision. A random sample of the collision participants (n = 1,698) were provided with a secondary questionnaire. From among the 974 (57.4%) respondents to the secondary questionnaire, we selected 183 cases (intractable neck pain that was treated over a period of 6 months) and 333 controls (minor neck pain that was treated within 3 months). Multivariable logistic regression analysis was used to evaluate the potential risk factors for prolonged treatment of WAD.

Results

Female sex, the severity of the collision, poor expectations of recovery, victim mentality, dizziness, numbness or pain in the arms, and lower back pain were associated with a poor recovery from WAD.

Conclusions

In the present study, the baseline symptoms (dizziness, numbness or pain in the arms, and lower back pain) had the strongest associations with prolonged treatment for WAD, although the psychological and behavioral factors were also important. These risk

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factors should be considered when evaluating patients who may have the potential for poor outcomes.

Introduction

Whiplash-associated disorders (WAD) are the most common injuries that are associated with car collisions in many Western countries [1] and in Japan [2]. Although the prognosis for WAD is generally favorable, previous studies have found that up to about 20% of patients experience persistent neck pain at 6 months after their injury [3,4]. Unfortunately, this lack of recovery creates personal, economic, and social burdens [1]. To reduce this burden, the number of individuals who develop chronic WAD must be reduced, although it is difficult to predict which patients will experience persistence of their symptoms. However, several prognostic factors have been identified, including sex [5,6], a low level of education [5,6], the severity of the collision [7], expectations of recovery [8], a no-fault claim [7], the presence of dizziness [9], upper extremity numbness or pain [10], and lower back pain [11–13]. Unfortunately, there is no clear evidence regarding the potential risk factors for poor recovery from WAD in the Japanese population. Based on this absence of suitable data, we conducted an online survey of the general Japanese population to identify individuals who had been in a car collision. Using the data from that survey, we examined the associations between the potential risk factors and the persistence of symptoms in individuals with WAD.

Materials and Methods

Sources of data

In 2012, we conducted an online survey to assess the prevalence of WAD in the general population. The participants were recruited through an internet research company that has approximately 1.8 million registered Japanese adult volunteers (20–79 years old). The company's volunteers are representative of the general Japanese population, and were stratified according to sex and age. From among these volunteers, 1,063,083 individuals were randomly selected and invited to participate in this study via an email that contained a unique link to the survey (dated July 1, 2012). Among these invited individuals, only 227,853 were considered effective users, as the research company was unable to exclude the non-users from the invitations due to technical reasons. The participants received points for online shopping as an incentive, and double registration was prevented by reviewing the participant's e-mail address at the beginning of the survey and disabling the link to the questionnaire at the conclusion of the survey. The initial survey was closed when the number of participants reached 127,956 (July 17, 2012). Thus, the response rate for the invitations was not relevant to this survey. This study's design was approved by the ethics review board of Kanto Rosai Hospital.

All participants completed the original questionnaire, which included items regarding their demographical and social characteristics, as well as any traffic collisions that they had experienced. However, for our analysis we only evaluated the questionnaires from participants who had been in a traffic collision (n = 4,164). From among this sample, 1,698 participants were randomly selected to participate in a secondary survey. Among the 974 respondents (57.4%) for the secondary questionnaire, we excluded 44 participants who were not wearing a seatbelt when the collision occurred, as these participants were likely to have sustained serious injuries. From the 930 remaining subjects, we included 183 participants in the cases group (neck pain that was treated over a period of 6 months) and 333 participants in the control group (minor neck pain that was treated within 3 months) (Fig 1). We defined the self-reported presence of WAD in this study as a response to the internet questionnaire that indicated 1) an obvious instance of an injury that was sustained during a rear-end collision, or 2) an established diagnosis of WAD by a medical doctor.

Assessment

The questionnaire evaluated socio-demographic data, age, sex, weight, height, smoking, education level (not college, or college), the severity of the collision (high, or other; high severity was defined as the vehicle's bumpers exhibiting extensive damage after a rear-end collision). Body mass index (BMI; k/m^2) was calculated using the participant's self-reported weight and height. Expectations of recovery were evaluated by asking "Do you expect that your neck pain will be a problem in the next 3 months?", using response categories of "No", "Possibly", "Probably", and "Definitely". Poor expectations of recovery were defined as answers of "Probably" or "Definitely". We also used the question "Did you have any fault in this accident?" to identify participants with a "victim mentality" (i.e., an answer of "no"). The presence of dizziness (yes/no) was evaluated using the question "Did you have any dizziness in the week after this accident?", and numbness or pain in the arms was evaluated using the question "Did you have any numbness or pain in your arms in the week after this accident?" Lower back pain was defined as pain that lasted for >1 day in the area between the lower costal margin and the gluteal folds, regardless of any accompanying radiating pain, and that was not associated with febrile illness, menstruation, or pregnancy [14].

Statistical analysis

The preliminary survey was administered to 10,000 participants for sample size estimation. Our preliminary study revealed that 16 of the 10,000 participants were assigned to the case group. 2) As our dependent variable was binary, we decided to use logistic regression analysis, because we needed a 1:2 case:control ratio. One guideline has suggested that the accurate estimation of discriminant function parameters requires a sample size with at least 20 cases for each independent variable in the logistic regression [15]. Therefore, based on this guideline and our 10 predictor variables, we required 200 cases for our analysis. Thus, the survey was closed at approximately 125,000 participants, although slightly more than 125,000 participants were included, due to technical reasons.

We compared the characteristics of the cases and controls using the chi-square test for categorical variables, and the one-factor analysis of variance for numerical variables. Age, sex, BMI, smoking, education level, severity of collision, poor expectation of recovery, victim mentality, dizziness, numbness or pain in arms, and lower back pain have previously been identified as risk factors for a poor recovery from WAD [5–13]. Therefore, we entered these variables into the multivariable logistic regression model, in order to adjust for potential confounding. The Variance Inflation Factor (VIF) was used to check for multicollinearity in the model. All statistical tests were performed at a significance level of 0.05 (two-sided), and were not adjusted for multiple testing. All data analyses were performed using SAS software (version 9.1.3, SAS Institute Inc., Cary, NC).

Results

Table 1 shows the demographic characteristics of the participants. When we compared the case and control groups, we observed significant differences in the severity of the collision, poor expectations of recovery, dizziness, upper extremity numbness or pain, and lower back pain.

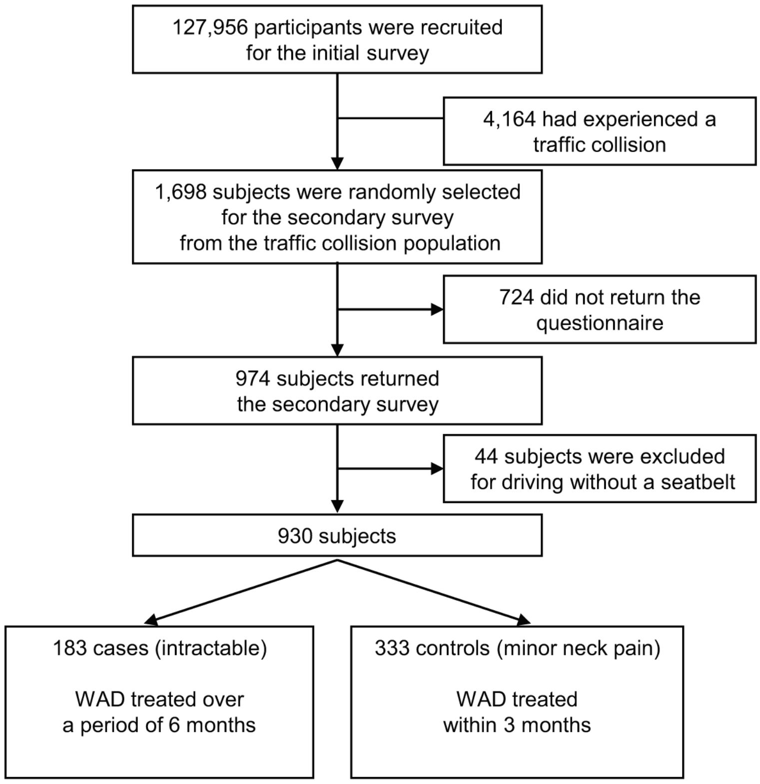

Fig 1. Study flow chart. WAD, whiplash-associated disorders.

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However, no significant differences were observed for age, sex, BMI, smoking, and a low level of education.

Table 2 shows the results from the univariate logistic regression analysis for a poor recovery from WAD. Based on the results of this analysis, we found that female sex, the severity of the collision, poor expectations of recovery, victim mentality, dizziness, numbness or pain in the

Table 1.

	Cases (n = 183)	Controls (n = 333)	p-value
Age, years	44.8 ± 10.3	45.3 ± 11.7	0.6218
Sex, male/female	124/59	242/91	0.2397
BMI, kg/m^2	23.4 ± 4.0	23.0±3.7	0.1971
Smoking (%)	74 (36.6)	128 (38.4)	0.6563
Education level: not college (%)	57 (31.2)	99 (29.7)	0.7373
Severity of collision: high (%)	131 (71.6)	159 (47.9)	<0.0001
Poor expectation of recovery (%)	90 (49.2)	41 (12.3)	<0.0001
Victim mentality (%)	150 (83.0)	253 (76.0)	0.1154
Dizziness (%)	120 (65.6)	94 (28.2)	<0.0001
Numbness or pain in arm (%)	149 (81.4)	170 (51.1)	<0.0001
Low back pain (%)	113 (61.2)	74 (22.2)	<0.0001

BMI, body mass index.

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Table 2.

	Odds ratio	95% CI	p-value
Age, +1 year	1	0.99–1.02	0.6209
Female (vs. male)	1.26	0.85–1.87	0.2417
BMI (+1 kg/m^2)	0.97	0.92–1.02	0.1983
Smoking	0.92	0.64–1.33	0.6566
Education level: not college	1.06	0.72–1.58	0.7376
Severity of collision: high	2.76	1.88–4.08	<0.0001
Poor expectation of recovery	6.89	4.48–10.76	<0.0001
Victim mentality	1.44	0.92–2.28	0.1114
Dizziness	4.84	3.30–7.17	<0.0001
Numbness or pain in arms	4.2	2.76–6.54	<0.0001
Lower back pain	5.65	3.82–4.82	<0.0001

CI, confidence interval; BMI, body mass index.

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arms, and lower back pain were significantly associated with a poor recovery from WAD. Table 3 shows the results from the multivariable logistic regression analysis, after adjusting for the various confounding factors. The VIF values for age, sex, BMI, smoking, education level, severity of collision, poor expectation of recovery, victim mentality, dizziness, numbness or pain in arms, and lower back pain were 1.12, 1.12, 1.14, 1.03, 1.19, 1.17, 1.16, 1.26, 1.23, and 1.24, respectively. However, none of the VIF values exceeded 10, which indicates that there was no collinearity in the model [16]. Based on the results of this model, we found that female sex, the severity of the collision, poor expectations of recovery, victim mentality, dizziness, numbness or pain in the arms, and lower back pain were significantly associated with a poor recovery from WAD.

Discussion

To the best of our knowledge, this is the first study to examine the risk factors that are associated with a prolonged recovery among Japanese patients with WAD. Our final model identified seven risk factors (female sex, the severity of the collision, poor expectations of recovery, victim mentality, presence of dizziness, numbness or pain in the arms, and lower back pain); all of these factors have previously been reported to be independent prognostic factors for recovery from WAD [5–13].

Interestingly, it is not clear which sex is an independent risk factor for poor recovery from WAD, as several studies have reported that female sex was an independent predictor, while others have reported that male sex was an independent predictor. In addition, previous studies have reported that a low level of education was significantly related to a poor recovery [5,6]. However, in the present study, education level was not a significant risk factor for a poor recovery from WAD. Unfortunately, the reasons for these discrepancies between our findings and those of the previous studies are not clear, although they may be related to differences in the populations that were studied.

We also observed that the severity of the collision was an important risk factor for poor recovery from WAD. In this context, a whiplash injury occurs when the force of a rear-end collision “whips” the cervical spine beyond its normal range of motion. Therefore, it is logical that severe car crashes can cause serious damage to the musculoskeletal system, which can result in a poor recovery.

Table 3.

	Odds ratio	95% CI	p-value
Age, +1 year	1	0.98–1.03	0.7577
Female (vs. male)	1.83	1.07–3.17	0.0283
BMI (+1 kg/m^2)	1.07	0.99–1.14	0.0576
Smoking	0.95	0.58–1.57	0.8515
Education level: not college	1.11	0.67–1.85	0.6819
Severity of collision: high	1.97	1.19–3.30	0.0086
Poor expectation of recovery	4.47	2.68–7.53	<0.0001
Victim mentality	3.37	1.76–6.67	0.0002
Dizziness	3.12	1.93–6.00	<0.0001
Numbness or pain in arms	2.56	1.51–4.40	0.0004
Lower back pain	4.77	2.91–7.94	<0.0001

CI, confidence interval; BMI, body mass index.

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After adjusting for the relevant confounders, such as socio-demographic characteristics and symptoms, we observed that poor expectations of recovery and victim mentality were significant risk factors for a poor recovery. Similarly, previous studies have reported that expectations for recovery were an important factor in the prognosis for WAD recovery [5]. Therefore, in addition to understanding these injuries and their clinical symptoms, it is also important to understand the patient's perception of recovery, in order to adequately treat WAD. Furthermore, victim mentality is an aspect of the patient's perception, and may affect their expectations for recovery. This finding indicates that psychological factors have prognostic value for evaluating the risk of prolonged recovery from WAD.

A previous study has reported that dizziness, numbness in the arms, and lower back pain did not decrease within 6 months after the accident, although many other symptoms were transient [13]. Similarly, we observed that these symptoms (dizziness, numbness, and lower back pain) were independent risk factors for a prolonged recovery from WAD. Therefore, it appears that these symptoms are more common in severe cases, which are less likely to experience recovery within 6 months. Furthermore, dizziness, numbness, and lower back pain are known as somatic symptom, and patients who have chronic whiplash also report elevated levels of somatic symptoms in body areas that were not affected by their neck trauma [17, 18]. In this context, the symptoms of functional somatic syndromes are very similar to those of somatization disorder, and the two conditions are thought to be closely related [19–21]. Thus, it is important to consider these signs and symptoms when following-up patients who have experienced whiplash. Furthermore, although the baseline symptoms (dizziness, numbness, and lower back pain) had the strongest associations with prolonged treatment for WAD, the psychological and behavioral factors were also important, and these risk factors should also be considered when evaluating patients who have experienced whiplash.

This study has several limitations. First, due to the cross-sectional design, inferences cannot be made regarding the causality of the relationships. Second, the sample was selected from among internet research volunteers, who may not be representative of the general population of internet users. Third, compared to the general population, our sample contained a higher proportion of people who were living in large cities and who had completed university-level or graduate-level education [22]. Fourth, we surveyed the respondents after their traffic collisions, and it is plausible that some reported symptoms may have been preexisting, rather than caused by the traffic collision. Furthermore, there are other important factors that can affect recovery from WAD, such as coping styles, previous traffic injuries, comorbidities, somatic and psychological pre-injury health, pain intensity and disability, injustice perception, depression and pain-related emotions, social support, personality traits, and post-traumatic stress symptoms. However, these factors were not included because we needed to evaluate the information from at the time of injury as a prognostic factor. Therefore, recall bias may be present, given the interval between the injury and the administration of the validated questionnaires. In addition, we attempted to ensure that the full questionnaire could be completed in 10 min, in order to obtain complete data from the respondents. Unfortunately, the effect of this selection bias on our findings would be difficult to address. Despite these limitations, this study provides useful insight for medical and public health practitioners who treat patients who have experienced whiplash.

Author Contributions

Conceived and designed the experiments: H. Oka KM ST. Performed the experiments: TF H. Okazaki. Analyzed the data: H. Oka KM. Contributed reagents/materials/analysis tools: YS YT RK. Wrote the paper: H. Oka KM.

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Disabling Low Back Pain Associated With Night Shift Duration: Sleep Problems as a Potentiator

Masaya Takahashi, PhD,[1]* Ko Matsudaira, MD, PhD,[2,3] and Akihito Shimazu, PhD[4]

Background *We investigated how night shift duration and sleep problems were jointly associated with disabling low back pain (LBP) among workers in different occupations.*
Methods *An online-survey was conducted regarding work schedules, disabling LBP, sleep problems, and other relevant factors in 5,008 workers who were randomly selected from a market research panel. Multiple logistic regression analyses determined the joint associations of night shift duration (0 [permanent day shift], <8, 8–9.9, 10–15.9, ≥16 hr) and sleep problems (no, yes) with disabling LBP adjusted for potential confounders.*
Results *A night shift ≥16 hr was associated with a significant increase in the likelihood of disabling LBP. The magnitude of this association was elevated when participants perceived sleep problems including both sleep duration and quality.*
Conclusion *Associations between extended night shifts and disabling LBP became stronger in the presence of short or poor quality sleep.* Am. J. Ind. Med. 58:1300–1310, 2015. © 2015 Wiley Periodicals, Inc.

KEY WORDS: musculoskeletal disorders; shift schedules; sleep duration; insomnia symptoms

INTRODUCTION

Low back pain (LBP) represents a major health and safety problem in workplaces worldwide [Driscoll et al., 2014]. The situation is serious in Japan as well, where LBP accounts for approximately 60% of occupational injuries requiring absences of 4 days or more among Japanese workers [Japanese Ministry of Health, Labour and Welfare 2013]. Importantly, this problem affects a wide range of industries: 30% of occupational LBP cases are identified in health care, 19% in commerce, and financial advertising, 15% in manufacturing, 14% in transportation and traffic, 6% in customer entertainment, and 5% in construction.

A number of occupational variables have been found to act as causal or exacerbating factors in LBP [Yassi et al., 2013; Matsudaira et al., 2014]. While the two dominant factors, heavy physical work and high psychosocial demands, have been well recognized, evidence for the effects of other occupational factors is largely limited [da Costa et al., 2010]. Recent research highlights the essential role of work schedules in musculoskeletal disorders (MSDs) [Caruso et al., 2008]. Shift work involving night shifts, in particular, is shown to be a target factor in many cases [Eriksen et al., 2004; Takahashi et al., 2008]. The principal component of its burden relates to night shift duration [Rosa et al., 1997; Ferguson et al., 2012]. Previous studies compared low back problems between 8- and 12-hr night shifts [Yamada et al., 2001; He et al., 2011], or between 8- and 16-hr night shifts [Takahashi et al., 1999] for some selected occupations, mainly health care professionals. Preliminary evidence clearly requires that a more detailed

[1]National Institute of Occupational Safety and Health, Tama-ku, Kawasaki, Japan
[2]Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, Faculty of Medicine, The University of Tokyo, Bunkyo-ku, Tokyo, Japan
[3]Clinical Research Center for Occupational Musculoskeletal Disorders, Kanto Rosai Hospital, Nakahara-ku, Kawasaki, Japan
[4]Department of Mental Health, The University of Tokyo, Graduate School of Medicine, Bunkyo-ku, Tokyo, Japan
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*Correspondence to: Masaya Takahashi, PhD, National Institute of Occupational Safety and Health, 6-21-1, Nagao, Tama-ku, Kawasaki 214-8585, Japan.
E-mail: takaham@h.jniosh.go.jp

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investigation into the association between night shift duration and LBP be undertaken in a more systematic manner, examining a variety of occupations. Increased knowledge about the effects of night shift duration on LBP can facilitate the optimization of shift work so as to minimize issues related to LBP.

Working at night has been linked with unfavorable consequences in the health, safety, and well-being of workers [Caruso, 2014]. Notably, shift work involving night shifts can disturb sleep [Wright et al., 2013; Takahashi 2014]. Recently published findings indicate the close association between sleep problems and pain [Buxton et al., 2012; Finan et al., 2013a]. Musculoskeletal pain, including LBP, can be a source or predictor of insomnia [Tang et al., 2012; Tang et al., 2015]. Conversely, poor quality of sleep is reported to predict the incidence of LBP in healthy workers [Agmon et al., 2014] and to be associated with a subsequent increase in LBP intensity in patients [Alsaadi et al., 2014b]. Prospective evidence demonstrates that disturbed sleep is significantly associated with an elevated risk of sickness absence and disability retirement due to MSDs [Salo et al., 2012; Ropponen et al., 2013]. Moreover, recent efforts have been devoted to clarification of the brain circuits shared by both sleep and pain [Finan et al., 2013b; Koh et al., 2015].

Associations among the three variables—LBP, sleep problems, and night shift duration—are highly complicated, as demonstrated in previous studies on LBP, sleep problems, and a third factor (e.g., job strain and physical activity) [Canivet et al., 2008; Sorensen et al., 2011]. One common approach to clarifying the associations is to determine if sleep problems lie in the causal pathway between night shift duration and LBP. Results obtained will be meaningful in understanding the potential mechanisms for these three factors. Another possible strategy is to examine if sleep problems have moderating effects on the association between night shift duration and LBP. If this association is modified according to the conditions of sleep, such a finding would provide us with novel information about sleep-related options for LBP prevention among night shift workers.

The present study examined how night shift duration and sleep problems were jointly associated with LBP in a sample of workers in different occupations. We hypothesized that a longer night shift would be associated with an increased likelihood of LBP and that this association would be strengthened with sleep problems. Testing these hypotheses has scientific merit, because little data are available for a dose-response relation of night shift duration with LBP, and because interventions to achieve better sleep may be possible for reducing or preventing LBP. Our research also focused on differences in the associations according to subtypes of sleep problems.

METHODS

Participants

The details of participant recruitment have been reported in a previous paper [Matsudaira et al., 2013]. Briefly, potential participants were selected randomly from a market research panel according to the inclusion criteria: age (20–69 years old) and residential area (23 wards of Tokyo, the City of Osaka, and the City of Nagoya). A total of 5,917 workers completed a web-based questionnaire. The final sample was 5,856 participants after exclusion of those who reported age of either below 20 or beyond 65 years old and those who reported working in primary and secondary industries. This study included 5,008 participants who provided their work schedules. The medical/ethics review board of the Japan Labour Health and Welfare Organization reviewed and approved this study.

Measures

Work schedules

Participants were asked if they engaged in permanent day work, rotating shift work involving night shifts, or other shifts. Participants with rotating shift work also responded to a question about the duration of the night shift: <8, 8–9.9, 10–11.9, 12–13.9, 14–15.9, or 16 hr or longer.

Disabling LBP

LBP was assessed with the question, “How would you describe your LBP in the past year?” Response options included (1) no LBP, (2) LBP that did not interfere with work, (3) LBP that interfered with work but no absence from work, and (4) LBP that interfered with work, leading to sick-leave. A diagram with a shaded area was presented to help participants correctly understand the site of the low back. LBP was defined as pain occurring in the area between the lower costal margin and the gluteal folds. LBP must also have lasted more than one day, and occurred regardless of accompanying radiating pain, but it must not be associated merely with febrile illness, menstrual periods, or pregnancy [Dionne et al., 2008]. LBP was classified as disabling if it caused disruption to the job regardless of absence from work (i.e., positive response to the option 3 or 4) [Von Korff et al., 1992]. Disabling LBP was the outcome of interest in this study.

Sleep problems

Sleep problems were evaluated using questions about the quantity and quality of sleep in the past month [Nakata et al., 2005; Takahashi et al., 2008]. Short sleep duration was defined as sleep duration of less than 6 hr. Difficulty initiating sleep was defined as taking more than 30 min to fall asleep. Difficulty maintaining sleep and early morning awakening were defined as nocturnal awakenings or early morning awakenings occurring 3 times or more per week. Insomnia symptoms were considered to be present if the participants reported any of the 3 symptoms of insomnia above.

Covariates

We collected self-reported data on age, gender, employment (permanent, other), occupation (white-collar [managers, professionals, clerical workers, sales workers], blue-collar [service, production, security, transportation, and communications workers], other), main work contents (work with video display terminals [VDT], physically repetitive work, neither), weekly work hours (<40, 40–49, 50–59, ≥60 hr), education (high school or lower, university, or higher), regular exercise (no, yes), smoking status (never smoker, former smoker, current smoker), chronic conditions requiring doctor visits (present, not present), height, and weight. The questionnaire also measured psychosocial work characteristics with the Brief Job Stress Questionnaire [Shimomitsu et al., 2000] for job demand, job control, and worksite (supervisor and coworker) social support.

Statistical Analysis

The duration of a night shift was re-classified as 0 (permanent day work; n = 4,691), <8 (n = 100), 8–9.9 (n = 90), 10–15.9 (n = 82), and ≥16 (n = 45) hr according to its distribution. Associations between night shift duration and the study variables were examined using a chi-square test and analysis of variance. Joint associations of night shift duration and sleep problems with disabling LBP were analyzed using logistic regression models with a reference group of permanent day workers without sleep problems. The first model provided crude odds ratios (ORs) and 95% confidence intervals (CIs) for the joint associations. The second model adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status. The third model further adjusted for psychosocial work characteristics. In addition, tests for linear trend were conducted to examine the dose-response relationship between the categories of night shift duration and disabling LBP. Given the small sample size in each group of shift workers, those four groups were collapsed into a single, shift-working group. Data from the shift work group have been listed in parallel. All statistical analyses were conducted using IBM SPSS Statistics version 20 (IBM Corporation, New York).

RESULTS

Characteristics of Study Sample

As summarized in Table I, both the permanent day workers and the shift workers showed a similar gender ratio, with the majority of men among the groups with night shifts of 8–10 and 10–16 hr. The shift workers engaged in more blue-collar jobs with a higher degree of physically repetitive work compared to the permanent day workers. The shift workers were also younger than the permanent day workers, except for those with a night shift of less than 8 hr.

It should be noted that the 16 hr or longer night shift group reported disabling LBP at a rate almost double (42%) that of the other groups (18–23%; $P < 0.01$). Although the percentage reporting sleep duration of less than 6 hr was comparable among the five groups, the shift groups reported insomnia symptoms more often than the permanent day group. Similar differences were observed for each subtype of insomnia symptoms. The shift group working a night shift of 16 hr or more reported higher job demand ($P < 0.001$) and lower job control ($P < 0.001$) compared to the other groups, while they showed a greater level of worksite social support ($P = 0.019$).

Comparisons between the permanent day group and the shift work group revealed results similar to those obtained from comparisons between the permanent day group and the four groups of shift workers. These two groups, however, showed no significant differences in disabling LBP, early morning awakening, or social support at work.

Disabling LBP Associated With Night Shift Duration by Sleep Problem

Table II indicates that the 16 hr or longer night shift group with short sleep duration was more likely to report disabling LBP. This significant association was observed even after adjusting for several confounding factors (Model 3: OR 4.90, 95%CI 2.18–11.03). The permanent day workers also reported more disabling LBP if they experienced short duration of sleep. However, this association was not statistically significant after adjusting for psychosocial work characteristics. The corresponding tests for linear trend became statistically non-significant in Model 3 ($P = 0.135$). No significant associations were observed between working shifts and disabling LBP in the cases of sleep duration of less than 6 hr or greater than 6 hr.

When insomnia symptoms were present, both the permanent day workers (Model 3: 1.42, 1.20–1.68) and the shift workers who worked at night for 16 hr or longer (6.59, 2.35–18.49) showed statistically significant ORs (Table III, P for linear trend = 0.140). The shift work group also produced a significant association (1.78, 1.13–2.80).

TABLE I. Characteristics of Study Participants

	Day	Duration of a night shift					Shift	
		<8h	8–10 h	10–16 h	≥16 h			
	n (%)	n (%)	n (%)	n (%)	n (%)	P[a]	n (%)	P[b]
Gender								
Men	2378 (51)	51 (51)	66 (73)	60 (73)	26 (58)	0.001	203 (64)	0.001
Women	2313 (49)	49 (49)	24 (27)	22 (27)	19 (42)		114 (36)	
Employment								
Permanent	2410 (51)	32 (32)	55 (61)	55 (67)	39 (87)	0.001	181 (57)	0.048
Others	2281 (49)	68 (68)	35 (39)	27 (33)	6 (13)		136 (43)	
Occupation								
White-collar	3336 (71)	30 (30)	33 (37)	31 (38)	17 (38)	0.001	111 (35)	0.001
Blue-collar	923 (20)	52 (52)	49 (54)	42 (51)	20 (44)		163 (51)	
Others	432 (9)	18 (18)	8 (9)	9 (11)	8 (18)		43 (14)	
Main work contents								
VDT work	2498 (53)	18 (18)	18 (20)	22 (27)	11 (24)	0.001	69 (22)	0.001
Physically repetitive work	885 (19)	44 (44)	49 (54)	38 (46)	20 (44)		151 (48)	
Neither	1308 (28)	38 (38)	23 (26)	22 (27)	14 (31)		97 (31)	
Weekly work hours (hours)								
−40 h	1642 (35)	51 (51)	12 (13)	14 (17)	6 (13)	0.001	83 (26)	0.001
40–49 h	1989 (42)	43 (43)	63 (70)	43 (52)	25 (56)		174 (55)	
50–59 h	655 (14)	4 (4)	13 (14)	12 (15)	8 (18)		37 (12)	
≥60 h	405 (9)	2 (2)	2 (2)	13 (16)	6 (13)		23 (7)	
Education								
High school or lower	2676 (57)	80 (80)	60 (67)	59 (72)	30 (67)	0.001	229 (72)	0.001
University or higher	2003 (43)	20 (20)	30 (33)	23 (28)	15 (33)		88 (28)	
Regular exercise								
No	3610 (77)	78 (78)	71 (79)	62 (76)	29 (64)	0.370	240 (76)	0.611
Yes	1081 (23)	22 (22)	19 (21)	20 (24)	16 (36)		77 (24)	
Smoking								
Non-smoke	2687 (57)	64 (64)	44 (49)	44 (54)	21 (47)	0.029	173 (55)	0.013
Past smoke	845 (18)	12 (12)	12 (13)	14 (17)	6 (13)		44 (14)	
Current smoke	1159 (25)	24 (24)	34 (38)	24 (29)	18 (40)		100 (32)	
Chronic conditions that require doctor visits								
Present	1297 (28)	31 (31)	20 (22)	20 (24)	13 (29)	0.672	84 (26)	0.657
Disabling low back pain	915 (20)	18 (18)	21 (23)	16 (20)	19 (42)	0.004	74 (23)	0.097
Sleep problems								
Sleep duration <6 hours	2062 (44)	44 (44)	39 (43)	42 (51)	25 (56)	0.389	150 (47)	0.243
Insomnia symptoms	1087 (23)	34 (34)	26 (29)	20 (24)	16 (36)	0.001	96 (30)	0.004
Difficulty initiating sleep	827 (18)	23 (23)	23 (26)	15 (18)	14 (31)	0.022	75 (24)	0.007
Difficulty maintaining sleep	328 (7)	17 (17)	10 (11)	7 (9)	5 (11)	0.001	39 (12)	0.004
Early morning awakening	316 (7)	14 (14)	6 (7)	5 (6)	4 (9)	0.028	29 (9)	0.101
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	
Age (years)	44.8 (12.5)	44.8 (14.0)	39.0 (11.6)	40.6 (12.4)	40.0 (11.5)	0.001	41.4 (12.8)	0.001
BMI	22.6 (3.5)	21.7 (3.3)	22.6 (3.6)	22.6 (3.9)	23.3 (3.2)	0.092	22.4 (3.6)	0.495
Job demand	7.7 (2.3)	7.0 (2.4)	8.5 (2.0)	8.7 (2.0)	9.1 (2.3)	0.001	8.2 (2.3)	0.001
Job control	8.0 (2.2)	7.1 (2.2)	7.0 (2.2)	6.8 (2.0)	6.8 (2.3)	0.001	6.9 (2.1)	0.001
Worksite social support	15.1 (4.2)	15.4 (3.5)	14.1 (3.6)	14.4 (3.7)	16.4 (4.1)	0.019	14.9 (3.7)	0.608

Day: Permanent day workers. Shift: All shift workers. BMI: Body mass index.
a. Compared between permanent day workers and 4 groups of shift workers.
b. Compared between permanent day workers and all shift workers.
Statistical significance was tested using chi-square test for categorical data and using analysis of variance for continuous data.

TABLE II. Joint Associations of Night Shift Duration/Shift Work and Sleep Duration of Less Than 6 hr (no, yes) With Disabling Low Back Pain (N = 5,008)

	Disabling LBP		Model 1		Model 2		Model 3	
	n	(%)	OR	95%CI	OR	95%CI	OR	95%CI
Day, n	481	(18.3)	1.00		1.00		1.00	
<8h, n	10	(17.9)	0.97	0.49–1.94	0.96	0.48–1.93	1.01	0.50–2.03
−10h, n	11	(21.6)	1.23	0.63–2.42	1.16	0.59–2.30	1.08	0.55–2.15
−16h, n	10	(25.0)	1.49	0.72–3.07	1.34	0.64–2.78	1.28	0.61–2.66
≥16h, n	5	(25.0)	1.49	0.54–4.12	1.37	0.49–3.81	1.20	0.43–3.39
P for linear trend			0.172		0.287		0.437	
Shift, n	36	(21.6)	1.23	0.84–1.80	1.15	0.78–1.70	1.12	0.75–1.65
Day, y	434	(21.0)	1.19	1.03–1.37	1.16	1.00–1.35	1.12	0.97–1.31
<8 h, y	8	(18.2)	0.99	0.46–2.15	0.95	0.44–2.08	0.95	0.43–2.09
−10 h, y	10	(25.6)	1.54	0.75–3.19	1.32	0.63–2.75	1.18	0.56–2.46
−16 h, y	6	(14.3)	0.75	0.31–1.78	0.66	0.27–1.58	0.58	0.24–1.40
≥16 h, y	14	(56.0)	5.69	2.57–12.62	5.13	2.29–11.49	4.90	2.18–11.03
P for linear trend			0.025		0.097		0.135	
Shift, y	38	(25.3)	1.52	1.04–2.22	1.36	0.92–2.01	1.27	0.86–1.87

n. sleep duration ≥6 h, y. sleep duration <6 h.
Day: Permanent day workers. Shift: All shift workers.
Model 1. Crude.
Model 2. Adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status.
Model 3. Adjusted for Model 2+job demand, job control, and workplace social support

TABLE III. Joint Associations of Night Shift Duration/Shift Work and Insomnia Symptoms (no, yes) With Disabling Low Back Pain (N = 5,008)

	Disabling LBP		Model 1		Model 2		Model 3	
	n	(%)	OR	95%CI	OR	95%CI	OR	95%CI
Day, n	648	(18.0)	1.00		1.00		1.00	
<8 h, n	8	(12.1)	0.63	0.30–1.33	0.64	0.30–1.35	0.67	0.31–1.42
−10 h, n	14	(21.9)	1.28	0.70–2.33	1.20	0.65–2.19	1.10	0.60–2.01
−16 h, n	13	(21.0)	1.22	0.66–2.25	1.12	0.60–2.09	1.06	0.56–1.98
≥16 h, n	9	(31.0)	2.06	0.93–4.55	1.89	0.85–4.21	1.72	0.77–3.86
P for linear trend			0.119		0.281		0.408	
Shift, n	44	(19.9)	1.14	0.81–1.60	1.08	0.76–1.53	1.03	0.73–1.47
Day, y	267	(24.6)	1.49	1.26–1.75	1.46	1.24–1.72	1.42	1.20–1.68
<8 h, y	10	(29.4)	1.91	0.91–4.01	1.81	0.86–3.84	1.83	0.86–3.88
−10 h, y	7	(26.9)	1.69	0.71–4.03	1.49	0.62–3.60	1.41	0.58–3.41
−16 h, y	3	(15.0)	0.81	0.24–2.77	0.66	0.19–2.29	0.59	0.17–2.04
≥16 h, y	10	(62.5)	7.63	2.76–21.08	6.80	2.43–18.97	6.59	2.35–18.49
P for linear trend			0.045		0.078		0.140	
Shift, y	30	(31.3)	2.08	1.34–3.23	1.86	1.19–2.92	1.78	1.13–2.80

n. insomnia symptoms were not present, y. insomnia symptoms were present.
Day: Permanent day workers. Shift: All shift workers.
Model 1. Crude.
Model 2. Adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status.
Model 3. Adjusted for Model 2+job demand, job control, and workplace social support.

As listed in Table IV, the OR for reporting disabling LBP was greater in the 16 hours or more night shift group with difficulty initiating sleep (Model 3: OR 5.35, 95%CI 1.82–15.68, P for linear trend = 0.091) than in those without difficulty initiating sleep (1.99, 0.93–4.24). Even the permanent day group showed a significantly increased OR with difficulty initiating sleep.

Having difficulty maintaining sleep was significantly associated with increased likelihood of reporting disabling LBP among both the permanent day workers and the shift workers, except the 10–16 hr night shift group (Table V). A clear contrast was observed when comparing between the 16 hr or longer night shift group with (Model 3: OR 13.85, P for linear trend = 0.179) and without difficulty maintaining sleep (OR 2.28), though the former's 95%CI was large.

Results for the joint association between night shift duration and early morning awakening (Table VI) were similar to results in terms of difficulty initiating sleep. Specifically, the OR approached significance for disabling LBP in the 16 hr or longer night shift group who experienced early morning awakening (Model 3: OR 9.75, P for linear trend = 0.077), which far exceeded the OR in their counterpart who did not experience early morning awakening (2.36). The permanent day workers who experienced early morning awakening were significantly more likely to report disabling LBP.

If any of the subtypes of insomnia symptoms were present, shift work was significantly associated with disabling LBP (ORs: 1.70–3.49); otherwise, no associations were found to be significant (Tables IV to VI).

DISCUSSION

The present study indicated that an extended night shift, particularly beyond 16 hr, was associated with a significant increase in the likelihood of disabling LBP. The magnitude of this association increased when participants perceived sleep problems. Indeed, in terms of sleep duration, a significantly greater OR for disabling LBP was obtained with sleep of less than 6 hr. In terms of sleep quality, a significantly increased OR was found for cases where insomnia symptoms were reported. Analyses for subtypes of insomnia symptoms revealed varying results. The ORs for disabling LBP were greater among the permanent day group and the 16 or longer hours of night shift group when those groups had difficulty initiating sleep. Similar results were observed for early morning awakening. However, overall increases in the ORs for disabling LBP were found when difficulty maintaining sleep was present. Our data for the shift work group, if they experienced sleep problems, principally reflected the significant results of the 16 hours or longer night shift group, with the exception of short sleep duration.

The present finding of increased disabling LBP associated with a night shift of 16 hr or longer calls for an appropriate design of shift schedules. We have to consider

TABLE IV. Joint Associations of Night Shift Duration/Shift Work and Difficulty Initiating Sleep (no, yes) With Disabling Low Back Pain (N = 5,008)

	Disabling LBP		Model 1		Model 2		Model 3	
	n	(%)	OR	95%CI	OR	95%CI	OR	95%CI
Day, n	720	(18.6)	1.00		1.00		1.00	
<8 h, n	13	(16.9)	0.89	0.49–1.62	0.89	0.48–1.64	0.94	0.51–1.73
−10 h, n	14	(20.9)	1.16	0.64–2.10	1.07	0.59–1.96	1.00	0.55–1.83
−16 h, n	13	(19.4)	1.06	0.57–1.94	0.96	0.52–1.77	0.89	0.48–1.65
≥16 h, n	11	(35.5)	2.41	1.15–5.05	2.22	1.05–4.69	1.99	0.93–4.24
P for linear trend			0.104		0.290		0.453	
Shift, n	51	(21.1)	1.17	0.85–1.61	1.10	0.79–1.53	1.06	0.76–1.47
Day, y	195	(23.6)	1.35	1.13–1.61	1.35	1.12–1.62	1.32	1.10–1.59
<8 h, y	5	(21.7)	1.22	0.45–3.29	1.19	0.44–3.24	1.18	0.43–3.22
−10 h, y	7	(30.4)	1.92	0.79–4.68	1.75	0.71–4.30	1.56	0.63–3.86
−16 h, y	3	(20.0)	1.10	0.31–3.89	0.94	0.26–3.38	0.89	0.25–3.18
≥16h, y	8	(57.1)	5.84	2.02–16.89	5.26	1.80–15.39	5.35	1.82–15.68
P for linear trend			0.038		0.048		0.091	
Shift, y	23	(30.7)	1.94	1.18–3.19	1.78	1.07–2.95	1.70	1.02–2.82

n. difficulty initiating sleep was not present, y. difficulty initiating sleep was present.
Day: Permanent day workers. Shift: All shift workers.
Model 1. Crude.
Model 2. Adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status.
Model 3. Adjusted for Model 2 + job demand, job control, and workplace social support.

TABLE V. Joint Associations of Night Shift Duration/Shift Work and Difficulty Maintaining Sleep (no, yes) With Disabling Low Back Pain (N = 5,008)

	Disabling LBP		Model 1		Model 2		Model 3	
	n	(%)	OR	95%CI	OR	95%CI	OR	95%CI
Day, n	808	(18.5)	1.00		1.00		1.00	
<8 h, n	10	(12.0)	0.61	0.31–1.18	0.60	0.31–1.18	0.62	0.31–1.21
−10 h, n	16	(20.0)	1.10	0.64–1.92	1.02	0.58–1.78	0.94	0.54–1.65
−16 h, n	14	(18.7)	1.01	0.56–1.82	0.92	0.51–1.67	0.88	0.49–1.60
≥16 h, n	15	(37.5)	2.65	1.39–5.05	2.42	1.26–4.66	2.28	1.18–4.41
P for linear trend			0.080		0.223		0.381	
Shift, n	55	(19.8)	1.09	0.80–1.48	1.02	0.75–1.39	0.98	0.72–1.35
Day, y	107	(32.6)	2.14	1.68–2.73	2.02	1.58-2.58	1.92	1.50–2.46
<8 h, y	8	(47.1)	3.93	1.51–10.21	3.70	1.41-9.73	3.96	1.50–10.43
−10 h, y	5	(50.0)	4.42	1.28–15.30	3.59	1.03-12.56	3.59	1.01-12.68
−16 h, y	2	(28.6)	1.77	0.34–9.13	1.32	0.25–6.89	1.00	0.19–5.26
≥16 h, y	4	(80.0)	17.67	1.97–158.34	14.61	1.62–131.67	13.85	1.50–127.83
P for linear trend			0.046		0.171		0.179	
Shift, y	19	(48.7)	4.20	2.23–7.90	3.60	1.90–6.83	3.49	1.83–6.66

n. difficulty maintaining sleep was not present, y. difficulty maintaining sleep was present.
Day: Permanent day workers. Shift: All shift workers.
Model 1. Crude.
Model 2. Adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status.
Model 3. Adjusted for Model 2+job demand, job control, and workplace social support.

multiple characteristics of shift schedules, in addition to shift duration [Ferguson et al., 2012; Harris et al., 2015]. Extension of a night shift would be allowed as long as a variety of conditions inside and outside the workplace are optimized [Knauth, 2007]. Challenges have recently been proposed to the use of a night shift of more than 8 hr in light of workers' health and productivity [Hopcia et al., 2012; Sallinen et al., 2010; Griffiths et al., 2014]. Our data reported

TABLE VI. Joint Associations of Night Shift Duration/Shift Work and Early Morning Awakening (no, yes) With Disabling Low Back Pain (N = 5,008)

	Disabling LBP		Model 1		Model 2		Model 3	
	n	(%)	OR	95%CI	OR	95%CI	OR	95%CI
Day, n	823	(18.8)	1.00		1.00		1.00	
<8 h, n	13	(15.1)	0.77	0.43–1.40	0.76	0.42–1.39	0.78	0.43–1.43
−10 h, n	18	(21.4)	1.18	0.70–2.00	1.08	0.64–1.85	1.00	0.59–1.71
−16 h, n	14	(18.2)	0.96	0.54–1.72	0.86	0.47–1.55	0.81	0.45–1.47
≥16 h, n	16	(39.0)	2.77	1.47–5.21	2.52	1.33–4.79	2.36	1.24–4.51
P for linear trend			0.046		0.178		0.313	
Shift, n	61	(21.2)	1.16	0.87–1.56	1.08	0.80–1.46	1.04	0.76–1.40
Day, y	92	(29.1)	1.76	1.36–2.27	1.65	1.27–2.13	1.59	1.23–2.07
<8h, y	5	(35.7)	2.40	0.80–7.19	2.26	0.75–6.82	2.43	0.80–7.38
−10h, y	3	(50.0)	4.33	0.87–21.48	3.17	0.63–15.88	3.11	0.61–15.93
−16h, y	2	(40.0)	2.89	0.48–17.30	2.36	0.39–14.20	1.80	0.30–10.90
≥16h, y	3	(75.0)	12.99	1.35–124.99	10.36	1.07–100.33	9.75	0.99–95.57
P for linear trend			0.038		0.058		0.077	
Shift, y	13	(44.8)	3.52	1.69–7.34	3.00	1.42–6.30	2.92	1.38v6.19

n. early morning awakening was not present, y. early morning awakening was present.
Day: Permanent day workers. Shift: All shift workers.
Model 1. Crude.
Model 2. Adjusted for age, gender, employment, occupation, main work contents, weekly work hours, education, and smoking status.
Model 3. Adjusted for Model 2+job demand, job control, and workplace social support.

here support this view, requiring critical evaluation of working at night for 16 hours or more to prevent disabling LBP.

The present data highlight the important role of sleep problems in disabling LBP linked to the duration of a night shift. When sleep was short (<6 hr), there was a significantly higher likelihood of disabling LBP. This finding may be due in part to a reduced threshold of pain consequent to sleep restriction, as shown in experimental studies [Ødegård et al., 2015; Roehrs et al., 2012]. If insomnia symptoms existed, similar potentiating effects were evident. These results are consistent with our hypothesis and in turn provide novel insight into the triad: night shift duration, disabling LBP, and sleep problems, given the previously reported dyad of LBP and sleep problems [Finan et al., 2013a; Kelly et al., 2011].

Because of limited evidence on the triad mentioned above and the nature of the present study design, it is difficult to describe how those three variables are associated with each other. Nevertheless, at least two hypotheses can be presented. First, a long night shift may interfere with sleep [Takahashi et al., 2008]; the problems in sleep may then translate into greater LBP. This association is possible, since sleep disturbance can affect the autonomic, neuroendocrine, and neuroimmunologic systems to provoke inflammatory response, delayed recovery of tissue damage, and increased pain sensitivity [Heffner et al., 2011; Garland, 2012; Roehrs et al., 2012; Mertens et al., 2015; Ødegård et al., 2015]. Second, an extended night shift may be associated with higher LBP via increased/prolonged exposure to physical (mechanical) and mental workload during the long period of shift [Katsuhira et al., 2013; Sterud et al., 2013; Coenen et al., 2014]; the elevated level of LBP is likely to impair subsequent sleep. Further research is warranted for better understanding of the complex relationship among night shift duration, disabling LBP, and sleep problems. A cohort study of workers with different lengths of a night shift (e.g., 8, 12, 16 hr) will be needed to test the hypothesis that night shift workers without sleep problems at baseline show night-shift dose-dependent increases in disabling LBP at follow-up if they suffer from sleep problems during the follow-up period. In contrast to this observational strategy, an intervention study can be conducted to examine the hypothesis that participants with different night shift durations who report sleep problems at baseline exhibit dose-dependent decreases in disabling LBP at follow-up after treatments for their sleep problems, compared to after placebo treatments.

When examining differences in the three subtypes of insomnia symptoms, the 16 hr or longer night shift group consistently showed greater ORs for disabling LBP if they experienced any difficulty initiating or maintaining sleep or waking too early from sleep. However, significantly higher ORs were also found in the shift groups working at night for less than 10 hr who reported frequent nocturnal awakenings (OR = 3.59–3.96). The current observation suggests that difficulty maintaining sleep may serve as a potentiating factor for disabling LBP among shift workers. Alternatively, frequent awakenings during sleep could be a target when addressing disabling LBP associated with night shifts.

In the present study, participants working a night shift of 16 hr or more (16+h group) reported higher job demand, lower job control, and higher social support at work compared to the other groups (Table I). The fact that the 16+h group showed greater LBP despite increased social support is contradictory to the common notion of increased LBP with low social support [Lang et al., 2012; Lundberg, 2015]. Possibly, the 16+h group may have managed the longer night shift while receiving more support from their supervisors and colleagues.

Our present results need to be considered in view of the study's limitations. As an initial stage of investigation, a cross-sectional design was used in this study to examine the associations among night shift duration, sleep problems, and disabling LBP. Thus, it was not possible to test the temporal relationship of the study variables. The study sample, derived from workers registered with a market research company, was not representative of the general working population in Japan. Hence, particular caution is required in generalizing our findings. Data collection by an online survey also may have caused several types of bias. Clearly, workers without access to the internet are never able to become participants. Potential candidates are less likely to participate in the survey if they suffer from severe LBP. Individuals with long and/or demanding work also tend to miss the opportunity to respond. This sampling bias may have been reflected in the smaller proportion of shift workers (6%, n = 317) in the current study than that reported by the national survey (18%) [Japanese Ministry of Health, Labour and Welfare, 2007]. In particular, the shift group working a night shift of 16 hr or more consisted of only 45 workers. The low number of shift-work participants may have resulted in missed clear dose-response relationships between night shift duration (four categories) and disabling LBP. Tests for linear trend were not found to be statistically significant among the groups with sleep problems ($P = 0.077$–0.179 in Model 3), although consistently increased ORs of disabling LBP were observed for the 16+h group with sleep problems. It was unable to identify the duration of night shift shorter than 16 hours at which the risk of disabling LBP increased in our study. Given the bias and confounding due to the small sample sizes, the joint associations of night shift duration and sleep problems with disabling LBP found here can be taken as selected and preliminary, and less reliable (i.e., wide confidence intervals for the 16+h group). Furthermore, recall time frames were different between sleep problems (the past month) and disabling LBP (the past year). Prevalence has been reported to be higher at 1 year than at one month for both variables [Matsudaira et al., 2011; Morin et al., 2014]. The longer time frame of recall on the sleep scale may have identified more cases, which in turn may have resulted in increased stability of estimates. At the same time, however, an increased possibility of recall error has to be traded off. Alternatively, if disabling LBP was asked to be reported in the frame of the same past month as sleep problems, the risk estimates of the sleep problems might have been attenuated due to fewer cases of disabling LBP than the present ones. It is thus preferable to use the same time frames of recall among the scales employed in the future study. All data were self-reported, and it is desirable to assess sleep using an objective method such as wrist actigraphy, even in a subsample [Schuh-Hofer et al., 2013; Alsaadi et al., 2014a]. Additionally, while our previous study excluded participants who had worked in their current job for less than one year [Matsudaira et al., 2013], the present study did not. The associations reported here were found to be consistent with those obtained from the dataset when we excluded the participants with less than one year of work experience (n = 4,222, data not shown). This fact implies that the current results were not confounded by the effects of those specific participants.

The current findings inform us of some practical implications. First of all, adequate scheduling for shift work involving night shifts should be a priority for LBP protection. There is a debate regarding the cost and benefit of extended night shifts [Smith et al., 1998; Lockley et al., 2004; Ferguson et al., 2012]. However, special care should be exercised when implementing a night shift longer than 8 hours, particularly for occupations characterized by greater levels of biomechanical and psychosocial demands (e.g., health care workers). This recommendation is still valid, assuming that in the present study, shift workers with an 8- to 16-h night shift did not show significant ORs for disabling LBP due to small sample sizes. In addition, various sources of workload need to be reduced as much as possible by active use of ergonomic devices, adequate staffing, and planned napping during the night shift. For health care practices in the workplace, treating sleep problems or promoting sleep health can be a promising strategy to reduce the level of LBP and to protect against the new onset of LBP [Eadie et al., 2013; Finan et al., 2014]. At an organizational level, employers are expected to revise multiple aspects of the work environment to ensure adequate sleep of their employees [Takahashi, 2012].

In conclusion, the present findings suggest that a night shift of 16 hr or longer was associated with a greater risk of disabling LBP and that the increased risk was further elevated among workers experiencing short or poor quality sleep.

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AUTHORS CONTRIBUTION

Conception, design, and data acquisition of this study: Ko Matsudaira; Analysis and interpretation of data: Masaya Takahashi and Ko Matsudaira; Drafting of manuscript: Masaya Takahashi; Critical revision: Masaya Takahashi, Ko Matsudaira, Akihito Shimazu; Final approval of the version to be published: All authors.

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Original Article

Assessment of psychosocial risk factors for the development of non-specific chronic disabling low back pain in Japanese workers—findings from the Japan Epidemiological Research of Occupation-related Back Pain (JOB) study

Ko MATSUDAIRA[1, 2]*, Mika KAWAGUCHI[3], Tatsuya ISOMURA[3, 4], Kyoko INUZUKA[3], Tadashi KOGA[3], Kota MIYOSHI[5] and Hiroaki KONISHI[6]

[1]Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, Faculty of Medicine, The University of Tokyo, Japan
[2]Clinical Research Center for Occupational Musculoskeletal Disorders, Kanto Rosai Hospital, Japan
[3]Clinical Study Support, Inc., Japan
[4]Institute of Medical Science, Tokyo Medical University, Japan
[5]Department of Orthopaedic and Spine Surgery, Yokohama Rosai Hospital, Japan
[6]Department of Orthopaedic Surgery, Nagasaki Rosai Hospital, Japan

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Abstract: To investigate the associations between psychosocial factors and the development of chronic disabling low back pain (LBP) in Japanese workers. A 1 yr prospective cohort of the Japan Epidemiological Research of Occupation-related Back Pain (JOB) study was used. The participants were office workers, nurses, sales/marketing personnel, and manufacturing engineers. Self-administered questionnaires were distributed twice: at baseline and 1 yr after baseline. The outcome of interest was the development of chronic disabling LBP during the 1 yr follow-up period. Incidence was calculated for the participants who experienced disabling LBP during the month prior to baseline. Logistic regression was used to assess risk factors for chronic disabling LBP. Of 5,310 participants responding at baseline (response rate: 86.5%), 3,811 completed the questionnaire at follow-up. Among 171 eligible participants who experienced disabling back pain during the month prior to baseline, 29 (17.0%) developed chronic disabling LBP during the follow-up period. Multivariate logistic regression analysis implied reward to work (not feeling rewarded, OR: 3.62, 95%CI: 1.17–11.19), anxiety (anxious, OR: 2.89, 95%CI: 0.97–8.57), and daily-life satisfaction (not satisfied, ORs: 4.14, 95%CI: 1.18–14.58) were significant. Psychosocial factors are key to the development of chronic disabling LBP in Japanese workers. Psychosocial interventions may reduce the impact of LBP in the workplace.

Key words: Chronic disabling low back pain, Nonspecific low back pain, Psychosocial factors, Risk factors, Japanese workers

*To whom correspondence should be addressed.
E-mail: kohart801@gmail.com

Introduction

Individuals commonly experience low back pain (LBP) at some stage during their life. Most LBP cases are classified as non-specific[1], which is not attributable to any identifiable pathology in the spine[2]. It is well-acknowledged that those who had LBP once tend to have subsequent episodes within a year[3–6], while each LBP episode can be resolved within a few weeks to 3 months[7, 8]. Despite the resolving nature of LBP, a small proportion of individuals with LBP (2–7%) develop chronic pain[8] which persists for 12 wk or longer[2]. In fact, LBP was found to be the leading specific cause of years lived with disability[9]. Not surprisingly, Western research has indicated that LBP, especially chronic LBP entailing disability, accounts for substantial economic loss at the workplace as well as in the healthcare system[2, 10].

An earlier Japanese study reported a lifetime LBP prevalence of over 80%[11]. Not surprisingly, the Ministry of Health, Labour and Welfare of Japan (MHLW) reported that LBP is the first and second most common health complaint in 2013 among Japanese men and women, respectively[12]. Since LBP is common in the Japanese population, the economic loss caused at the workplace and in the healthcare system is presumably as large as in Western countries.

In previous research, individual factors as well as ergonomic factors related to work have been well-investigated. In recent decades, an increasing body of evidence, however, has revealed that psychosocial factors play an important role in chronic non-specific LBP. In particular, distress (i.e., psychological distress, depressive mood, and depressive symptoms)[13, 14], low job satisfaction[14–16], emotional trauma in childhood such as abuse[17], and pain level[18] affect the development of chronic LBP.

Although the proportion of individuals suffering from chronic LBP is small according to Western studies, it is important to identify potential risk factors since the small proportion accounts for large loss. Little, however, is known concerning chronic disabling LBP in relation to psychosocial factors in Japanese workers. The objective of the present study was to investigate the associations between psychosocial factors and the development of chronic disabling LBP in Japanese workers.

Subjects and Methods

Data source

Data were drawn from a 1-yr prospective cohort of the Japan Epidemiological Research of Occupation-related Back Pain (JOB) study. Ethical approval was obtained from the review board of the MLHW. Participants for the JOB study were recruited at 16 local offices of the participating organizations in or near Tokyo. The occupations of the participating workers were diverse (e.g., office workers, nurses, sales/marketing personnel, and manufacturing engineers). Baseline questionnaires were distributed to employees by the board of each participating organization. Participants provided written informed consent and returned completed self-administered questionnaires with their name and mailing address for the purpose of follow-up directly to the study administration office. At a year after the baseline assessment, the follow-up questionnaire was distributed to the participants.

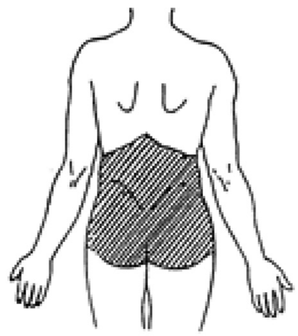

Fig. 1. Diagram showing pain area for low back provided in the baseline and follow-up questionnaires.

The baseline questionnaires contained questions on the presence of LBP, severity of LBP, individual characteristics (e.g., gender, age, obesity, smoking habit), ergonomic work demands (e.g., manual handling at work, frequency of bending, twisting), and work-related psychosocial factors (e.g., interpersonal stress at work, job control, reward to work, depression, somatization). LBP was defined in the questionnaire as pain localized between the costal margin and the inferior gluteal folds[10]. A diagram showing these areas was provided in the questionnaire to facilitate workers' understanding of the LBP area (Fig. 1). To evaluate the severity of LBP, Von Korff's grading[19] was used in the following manner: grade 0 was defined as no LBP; grade 1 as LBP that does not interfere with work; grade 2 as LBP that interferes with work but no absence from work; and grade 3 as LBP that interferes with work, leading to sick-leave. For the assessment of the psychosocial factors, the Brief Job Stress Questionnaire (BJSQ) developed by the MLHW[20, 21] was used. The BJSQ contains 57 questions and assesses 19 work-related stress factors: mental workload both quantitative- and qualitative-wise, physical workload, interpersonal stress at work, workplace environment stress, job control, utilization of skills and expertise, job fitness, reward to work, vigor, anger, fatigue, anxiety, depressed mood, somatic symptoms, supports by supervisors, supports by coworkers, supports by family or friends, and daily-life (work and life) satisfaction. These work-related factors were rated on a 5-point Likert scale ranging from the lowest score of 1 to the highest of 5.

The BJSQ incorporates questions from various standard questionnaires such as the Job Content Questionnaire (JCQ)[22], the National Institute for Occupational Safety and Health (NIOSH)[23], the Profile of Mood States (POMS)[24], the Center for Epidemiologic Studies Depression Scale (CES-D)[25], the State-trait Anxiety Inventory (STAI)[26], the Screener for Somatoform Disorders (SSD)[27] and the Subjective Well-being Inventory (SUBI)[28]. Standardized scores were developed for the 19 individual factors based on the sample of approximately 10,000 Japanese workers. The BJSQ has been shown to have internal consistency reliability and criterion validity with respect to the JCQ and NIOSH[29].

The follow-up questionnaire contained questions about the severity of LBP during the previous year, length of sick-leave because of LBP, medical care seeking, pain duration, and onset pattern. LBP severity was assessed using Von Korff's grading in the same manner as baseline.

Data analysis

The outcome of our interest was the development of chronic disabling LBP during the 1-yr follow-up period. In the present study, chronic disabling LBP was defined if a participant experienced LBP that interfered with work, with or without sick-leave due to LBP, corresponding to grade 2 or 3 in Von Korff's grading, during the month prior to baseline and experienced LBP with the same grades for 3 months or longer during the 1-yr follow-up period. Absence from work is often used as the outcome measurement for disability in Western studies. The present study, however, defined chronic disabling LBP as LBP that interfered with work for 3 months or longer, regardless of sick leave because our early international epidemiological study indicated that the proportion of Japanese workers who both took time off work and did not due to musculoskeletal disorders is almost equal to that of British workers who took time off work from the same reason[30]. This finding may be a result of cultural differences in attitude toward one's work. For this reason, the present study defined chronic disabling LBP as LBP that interfered with work for 3 months or longer, regardless of sick leave.

Incidence was calculated for the participants who experienced disabling LBP (grade 2 or 3) during the month prior to the baseline survey. Participants were excluded from the analysis if they changed their job for reasons other than LBP or developed LBP due to accident, a tumor, including metastasis, infection, or fracture.

For data analysis, the following factors were initially included: (1) individual characteristics, (2) ergonomic work demands, and (3) work-related psychosocial factors. Individual characteristics included age, sex, obesity (body mass index: BMI $\geq$25 kg/m^2), smoking habit (Brinkman index $\geq$400), education, flexibility, hours of sleep, experience at current job, working hours per wk ($\geq$60 h per week of uncontrolled overtime), work shift, emotional trauma in childhood, and pain level (NRS $\geq$8 as painful). Ergonomic work demands included manual handling at work; bending, twisting ($\geq$half of the day as frequent); and hours of desk work ($\geq$half of the day as frequent). Psychosocial factors were assessed with BJSQ. The 5-point Likert scale was reclassified into 2 categories: the "not feeling stressed" category, where low, slightly low, and moderate were combined, and the "feeling stressed" category, where slightly high and high were combined. Pain level was scaled on the Numerical Rating Scale, ranging from 0 to 11.

To assess smoking habit, the Brinkman Index was calculated based on the total number of cigarettes smoked per day multiplied by duration of smoking in year[31]. A Brinkman Index value of 400 or higher indicated that a respondent was a heavy smoker, whereas a value of less than 400 indicated that a respondent was a non-heavy smoker. Workers were defined as flexible if their wrists could reach beyond their knees but without their fingertips touching their ankles, and not flexible if their wrists could not reach beyond their knees[32].

In addition to descriptive statistics, univariate and multivariate logistic regression analyses were conducted to examine the associations between risk factors and the development of chronic disabling LBP. Results of logistic regression analyses were summarized by odds ratios (ORs) and the respective 95% confidence intervals (CI). To assess potential risk factors, crude ORs were initially computed. Subsequently, all factors with $p<0.1$ in univariate logistic regression analyses were entered into the multivariate logistic regression model, significance levels of $p<0.05$ for entry and $p>0.1$ for removal. The stepwise method was used to select variables with statistical significance at $p<0.05$. All tests were 2-tailed. The software package STATA 9.0 (StataCorp, LP, College Station, TX) was used for all statistical analyses.

Results

Baseline characteristics of the follow-up vs. drop-out group

The baseline questionnaire was distributed to 6,140 workers and had a response rate of 86.5% (5,310 workers). Of these participants, 3,811 workers successfully completed and returned 1-yr follow-up questionnaires (follow-up rate: 71.8%).

The characteristics of the 3,811 participants who provided follow-up data (follow-up group) did not appear to be much different from those who did not (drop-out group). The mean [standard deviation (SD)] age of the follow-up group was 42.9 (10.1) yr, compared to 38.0 (10.2) yr in the drop-out group. The majority were men in both groups (80.6% and 82.8%, respectively). The mean (SD) BMI of the follow-up group and drop-out group were similar [23.1 (3.3) and 22.9 (4.1), respectively]. In the follow-up group, 78.6% of the participants engaged in the manual handling of objects <20 kg, or not manually handling any objects at work, 17.8% engaged in manually handling objects ≥20 kg or worked as a caregiver, and data was missing for 3.6%. The respective values for the drop-out group were 75.5%, 18.9%, and 5.6%. In both the follow-up and drop-out groups, the most common occupational fields were office workers engaging in the manual handling of objects <20 kg or not manually handling any objects and nurse engaging in manual handling of objects ≥20 kg or caregiver.

Baseline characteristics of the study participants

Of the 3,811 workers, 171 reported LBP and experiencing work interferences with or without sick-leave during a month prior to baseline (Fig. 2). The mean (SD) age of 171 participants was 41.5 (10.2) yr and the majority were men (n=122; 71.4%). The mean (SD) BMI of the participants was 23.0 (3.6; n=170) kg/m^2. About half of the participants did not engage in manually handling heavy objects at work (n=79; 48.8%). Those workers who manually handled objects of less than 20 kg accounted for 17.9% (n=29) and those who manually handled heavy objects 20 kg or heavier or worked as a caregiver accounted for 33.3% (n=54). Desk work and sales, manufacturing, and nurses were the major occupations in the categories of non-manually handling work, manually handling work of less than 20 kg, and manually handling work of 20 kg or heavier, respectively.

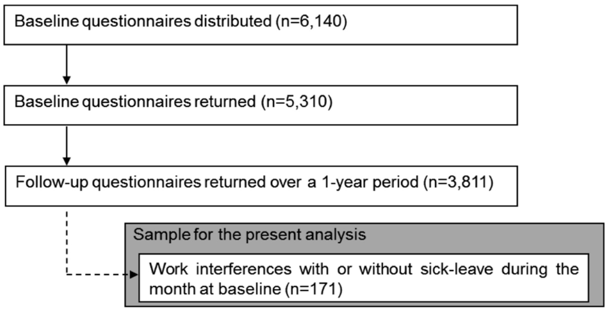

Fig. 2. Flow chart of the sample selection for the present analysis.

Incidence of chronic disabling LBP

Of a total of 171 eligible participants, 29 (17.0%) developed chronic disabling LBP during a year prior to the follow-up period (5 missing cases).

Association between chronic disabling LBP and potential risk factors

Crude and adjusted ORs for the development of chronic disabling LBP and their 95% CIs are shown in Tables 1 and 2. The univariate logistic regression analysis showed that job fitness, reward to work, vigor, anger, fatigue, anxiety, depressed mood, supports by supervisors, daily-life satisfaction, work shift, emotional trauma in childhood, and pain level were potentially associated with the development of chronic disabling LBP (ORs of 2.00–7.93; $p<0.1$ for all) (Table 1). In the multivariate logistic regression analysis, these 12 factors were entered into the model. As a result, 3 psychosocial factors were selected: reward to work (OR: 3.62, 95%CI: 1.17–11.19), anxiety (OR: 2.89, 95%CI: 0.97–8.57), and daily-life satisfaction (OR: 4.14, 95%CI: 1.18–14.58) (Table 2), indicating that a combination of psychosocial factors can play a key role in the development of chronic disabling LBP. A supplemental analysis was conducted to examine a combination effect of psychosocial factors: reward to work and daily-life satisfaction, which were at $p<0.05$ in the multiple logistic regression model (Table 3). Consequently, ORs increased with the level of dissatisfaction in a combination of daily-life satisfaction and reward to work. The results suggested that when both daily-life satisfaction and reward to work were not satisfied with an approximately 8-fold higher risk of developing chronic disabling LBP.

Discussion

Results suggest that exposure to multiple psychosocial factors potentially predisposes the development of

Table 1. Crude odds ratios of baseline factors for chronic disabling LBP

Risk factor	n	%	Odds ratio	95%CI	*p* value
Age (yr)	171				
<40	78	45.6	1.00		
40–49	51	29.8	0.95	0.36–2.48	0.909
≥50	42	24.6	1.17	0.44–3.12	0.746
Sex	171				
Male	122	71.4	1.00		
Female	49	28.7	1.26	0.53–3.03	0.601
Obesity[a]	169				
< BMI 25 kg/m^2	129	76.3	1.00		
≥ BMI 25 kg/m^2 (obesity)	40	23.7	0.85	0.32–2.28	0.748
Smoking habit	153				
Heavy smoker	112	73.2	1.00		
Not heavy smoker	41	26.8	1.80	0.72–4.52	0.211
Education	165				
College/Junior college	105	63.6	1.00		
High school/Junior high school	60	36.4	0.44	0.17–1.18	0.103
Flexibility	162				
Flexibility	98	60.5	1.00		
Not flexible	64	39.5	0.57	0.23–1.41	0.225
Manual handling at work	162				
No manual handling (desk work)	79	48.8	1.00		
Manual handling of <20-kg objects	29	17.9	1.40	0.43–4.50	0.577
Manual handling of ≥20-kg objects or working as a caregiver	54	33.3	1.84	0.72–4.72	0.203
Bending	169				
Not frequent	121	71.6	1.00		
Frequent	48	28.4	1.40	0.58–3.40	0.454
Twisting	168				
Not frequent	140	83.3	1.00		
Frequent	28	16.7	1.24	0.42–3.65	0.690
Hours of desk work	167				
Not frequent	111	66.5	1.00		
Frequent	56	33.5	0.74	0.30–1.81	0.510
Mental workload (quantitative aspect)	170				
Not stressed	66	38.8	1.00		
Stressed	104	61.2	1.08	0.47–2.46	0.859
Mental workload (qualitative aspect)	170				
Not stressed	71	41.8	1.00		
Stressed	99	58.2	0.63	0.28–1.42	0.267
Physical workload	171				
Not stressed	75	43.9	1.00		
Stressed	96	56.1	1.62	0.70–3.73	0.260
Interpersonal stress at work	171				
Not stressed	118	69.0	1.00		
Stressed	53	31.0	1.15	0.49–2.68	0.745
Workplace environment stress	171				
Not stressed	102	59.7	1.00		
Stressed	69	40.4	1.95	0.87–4.38	0.105
Job control	169				
Controlled	4	32.0	1.00		
Not controlled	115	68.1	1.81	0.69–4.79	0.230
Utilization of skills and expertise	170				
Utilization of skills and expertise	131	77.1	1.00		
No utilization of skills and expertise	9	22.9	1.59	0.66–3.85	0.304
Job fitness	171				
Feeling fit	114	66.7	1.00		
Not feeling fit	7	33.3	2.04	0.91–4.60	0.086

Table 1. Continued

Risk factor	n	%	Odds ratio	95%CI	*p* value
Reward to work	171				
Feel rewarded	120	70.2	1.00		
Not feeling rewarded	51	29.8	3.59	1.57–8.20	0.002
Vigor	170				
Vigorous	123	72.4	1.00		
Not vigorous	47	27.7	2.12	0.92–4.88	0.078
Anger	170				
Not angry	75	44.1	1.00		
Angry	95	55.9	2.79	1.12–6.97	0.028
Fatigue	171				
No fatigue	69	40.4	1.00		
Fatigue	102	59.7	2.45	0.98–6.11	0.055
Anxiety	171				
Not anxious	95	55.6	1.00		
Anxious	76	44.4	2.75	1.19–6.35	0.018
Depressed mood	169				
Not feeling depressed	79	46.8	1.00		
Depressed	90	53.3	2.16	0.92–5.08	0.078
Somatic symptoms	168				
Not somatic symptoms	58	34.5	1.00		
Somatic symptoms	110	65.5	1.81	0.72–4.55	0.206
Supports by supervisors	167				
Supported	103	61.7	1.00		
Not supported	64	38.3	2.00	0.88–4.55	0.098
Supports by coworkers	168				
Supported	93	55.4	1.00		
Not supported	75	44.6	0.97	0.43–2.18	0.946
Supports by family or friends	169				
Supported	128	75.7	1.00		
Not supported	41	24.3	1.13	0.44–2.90	0.801
Daily-life satisfaction	171				
Satisfied	96	56.1	1.00		
Not satisfied	75	43.9	4.98	1.99–12.47	0.001
Hours of sleep	168				
≤5 h	151	89.9	1.00		
>5 h	17	10.1	1.56	0.47–5.21	0.466
Experience of current job	171				
<5 yr	55	32.2	1.00		
≥5 yr	116	67.8	1.02	0.43–2.42	0.970
Working hours per wk	171				
<60 h	131	76.6	1.00		
≥60 h	40	23.4	0.63	0.22–1.78	0.385
Work shift	171				
Daytime shift	115	67.3	1.00		
Nighttime shift	56	32.8	2.90	1.28–6.58	0.011
Emotional trauma in childhood	143				
No	136	95.1	1.00		
Yes	7	4.9	7.93	1.64–38.26	0.010
Pain level	155				
Not painful (NRS >8)	140	90.3	1.00		
Painful (NRS ≤8)	15	9.7	4.11	1.31–12.85	0.015

LBP: low back pain; CI: confidence interval; BMI: body mass index; NRS: numerical rating scale.
BMI ≥25 kg/m^2 is defined as obesity in Japan

Table 2. Stepwise logistic regression results of baseline factors for chronic disabling LBP

Risk factor	Odds ratio	95%CI	*p* value
Reward to work			
Feel rewarded	1.00		
Not feeling rewarded	3.62	1.17–11.2	0.025
Anxiety			
Not anxious	1.00		
Anxious	2.89	0.97–8.57	0.056
Daily-life satisfaction			
Satisfied	1.00		
Not satisfied	4.14	1.18–14.58	0.027

LBP: low back pain; CI: confidence interval; BMI: body mass index.

chronic disabling LBP in Japanese workers, especially office workers, nurses, sales/marketing personnel, and manufacturing engineers. Similarly, an increasing body of evidence, mostly in Western countries, has indicated that psychosocial factors affect the development of chronic disabling LBP[13–17].

The present study suggests that exposure to not one, but a combination of psychosocial factors, such as daily-life satisfaction and reward to work, may trigger the development of chronic disabling LBP with an 8-fold increased risk, compared to those who were satisfied with psychosocial aspects. Given that daily-life satisfaction in the BJSQ consists of the extent of being content with not only life, but also work, the results in the present study are consistent with Western studies indicating that job dissatisfaction predisposes the development of chronic disabling LBP[14–16, 33–35]. Another psychosocial factor, reward to work, can also be considered to be relevant to the magnitude in job satisfaction. The association between chronic disabling LBP and a combination of such psychosocial factors may possibly be explained by dysfunction in mesolimbic dopaminergic activity. In recent years, there has been an assumption that exposure to chronic, rather than acute, stress could result in a state of hyperalgesia in the body due to the inhabitation of mesolimbic dopaminergic mechanisms where both pain and pleasure are controlled[36, 37]. Hyperalgesia resulting from chronic stress due to not being content with life and work, for example, may lead to the development of chronic disabling LBP.

In the past, the occupational health of the Japanese worker has mainly focused on an ergonomic approach in the management and prevention of LBP. Consistent with Western studies, the present study suggests, however, that we should be more alert to a psychosocial approach to reduce the risk of developing chronic disabling LBP. Although our earlier prospective study indicated that both ergonomic and work-related psychosocial factors were associated with new-onset of disabling LBP in symptom-free Japanese workers[38], no ergonomic factors seemingly affect the development of chronic disabling LBP in the present study probably because workers who already experienced disabling LBP at baseline were the focus of the present study. The results are consistent with the guidelines stating that the development of chronic pain and disability results more from work-related psychosocial issues than from physical features[34].

There are several limitations to the study. First, generalization of the results of the present study is limited. The majority of the study participants were males. The study cohort was also not a representative sample of all Japanese workers in terms of area as well as range of occupations. Second, the sample size for the present analysis is small. Future research with a larger sample size should be conducted for further identification of potential risk factors of chronic disabling LBP. Third, the context of cognitive and emotional aspects, such as fear-avoidance belief and physician's attitudes, was not considered in the present study despite being known to affect the development of serious disability. As of the time of data collection, scales measuring fear avoidance were not available in the Japanese language. Since the author developed the Japanese versions of the Fear-Avoidance Beliefs Questionnaire (FABQ)[39]

Table 3. Odds ratios for chronic disabling LBP in relation with a combination of daily-life satisfaction and reward to work

Risk factor		Chronic disabling LBP		Odds ratio	95%CI
Daily-life satisfaction	Reward to work	Yes (%)	No (%)		
Satisfied	Feel rewarded	6 (7.7%)	72 (92.3%)	-	-
	Not feeling rewarded	1 (7.7%)	12 (92.3%)	1.00	0.11–9.06
Not satisfied	Feel rewarded	7 (18.9%)	30 (81.1%)	2.80	0.87–9.03
	Not feeling rewarded	15 (39.5%)	23 (60.5%)	7.83	2.72–22.52

LBP: low back pain; CI: confidence interval.

and the Tampa Scale of Kinesiophobia (TSK)[40, 41] after the JOB survey, both are currently available. These scales should also be included in future research. Fourth, misclassification, to some extent, is inevitable. Responses that rely on subjective measurement may be distorted and missing values cannot be avoided due to the nature of a self-assessment survey. Moreover, the possibility for recall bias towards retrospective questions should be kept in mind. Fifth, the present study focuses on the baseline factors affecting the development of chronic disabling LBP under the assumption that workers retained the same status quo as the baseline during the follow-up period. The status in some factors could possibly fluctuate during the period. Such fluctuation in factors was not taken into consideration in the present study. Finally, there may be alternative methods for the selection of potential risk factors prior to conducting multivariate analysis. It should be noted that a more complicated model may offer a better explanation of the data although the results are consistent with Western studies. Further research is needed to identify a full range of potential risk factors for inclusion in future studies.

In conclusion, the present study suggests that psychosocial factors could play a key role in the development of chronic disabling LBP in Japanese workers. Therefore, the occupational health of the Japanese worker should be focused not only on ergonomic interventions but also on psychosocial ones to reduce the impact on the workplace from the repercussions of developing chronic disabling LBP.

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ORIGINAL ARTICLE

Incidence of disability and its associated factors in Japanese men and women: the Longitudinal Cohorts of Motor System Organ (LOCOMO) study

Noriko Yoshimura · Toru Akune · Saeko Fujiwara · Yoko Shimizu · Hideyo Yoshida · Yuji Nishiwaki · Akihiro Sudo · Go Omori · Munehito Yoshida · Hiroshi Shimokata · Takao Suzuki · Shigeyuki Muraki · Hiroyuki Oka · Kozo Nakamura

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Abstract We investigated the incidence of disability and its risk factors in older Japanese adults to establish an evidence-based disability prevention strategy for this population. For this purpose, we used data from the Longitudinal Cohorts of Motor System Organ (LOCOMO) study, initiated in 2008 to integrate information from cohorts in nine communities across Japan: Tokyo (two regions), Wakayama (two regions), Hiroshima, Niigata, Mie, Akita, and Gunma prefectures. We examined the annual occurrence of disability from 8,454 individuals (2,705 men and 5,749 women) aged ≥65 years. The estimated incidence of disability was 3.58/100 person-years (p-y) (men: 3.17/100 p-y; women: 3.78/100 p-y). To determine factors associated with disability, Cox's proportional hazard model was used, with the occurrence of disability as an objective variable and age (+1 year), gender (vs. women), body build (0: normal/overweight range, BMI 18.5–27.5 kg/m^2; 1: emaciation, BMI <18.5 kg/m^2; 2: obesity, BMI >27.5 kg/m^2), and regional differences (0: rural areas including Wakayama, Niigata, Mie, Akita, and Gunma vs. 1: urban areas including Tokyo and Hiroshima) as explanatory variables. Age, body build, and regional difference significantly influenced the occurrence of disability (age, +1 year: hazard ratio 1.13, 95 % confidence interval 1.12–1.15, $p < 0.001$; body build, vs. emaciation: 1.24, 1.01–1.53, $p = 0.041$; body build, vs. obesity: 1.36, 1.08–1.71, $p = 0.009$; residence, vs. living in rural areas: 1.59, 1.37–1.85, $p < 0.001$). We concluded that higher age,

N. Yoshimura (✉) · H. Oka
Department of Joint Disease Research, 22nd Century Medical and Research Center, Graduate School of Medicine, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan
e-mail: yoshimuran-ort@h.u-tokyo.ac.jp

T. Akune · S. Muraki
Department of Clinical Motor System Medicine, 22nd Century Medical and Research Center, Graduate School of Medicine, University of Tokyo, Tokyo, Japan

S. Fujiwara
Hiroshima Atomic Bomb Causality Council, Hiroshima, Japan

Y. Shimizu · H. Yoshida
Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan

Y. Nishiwaki
Department of Environmental and Occupational Health, School of Medicine, Toho University, Tokyo, Japan

A. Sudo
Department of Orthopaedic Surgery, Mie University Graduate School of Medicine, Mie, Japan

G. Omori
Center for Transdisciplinary Research, Institute for Research Promotion, Niigata University, Niigata, Japan

M. Yoshida
Department of Orthopedic Surgery, School of Medicine, Wakayama Medical University, Wakayama, Japan

H. Shimokata
Graduate School of Nutritional Sciences, Nagoya University of Arts and Sciences, Aichi, Japan

T. Suzuki
National Center for Geriatrics and Gerontology, Aichi, Japan

K. Nakamura
National Rehabilitation Center for Persons with Disabilities, Saitama, Japan

both emaciation and obesity, and living in rural areas would be risk factors for the occurrence of disability.

Keywords Nation-wide population-based cohort study · Epidemiology · Incidence · Disability · Body build

Introduction

In Japan, the proportion of the population aged 65 years or older has increased rapidly over the years. In 1950, 1985, 2005, and 2010, this proportion was 4.9, 10.3, 19.9, and 23.0 %, respectively [1]. Further, this proportion is estimated to reach 30.1 % in 2024 and 39.0 % in 2051 [2]. The rapid aging of Japanese society, unprecedented in world history, has led to an increase in the number of disabled elderly individuals requiring support or long-term care. The Japanese government initiated the national long-term care insurance system in April 2000 in adherence with the Long-Term Care Insurance Act [3]. The aim of the national long-term care insurance system was to certify the level of care needed by elderly adults and to provide suitable care services to them according to the levels of their long-term care needs. According to the recent National Livelihood Survey by the Ministry of Health, Labour and Welfare in Japan, the number of elderly individuals certified as needing care services increases annually, having reached 5 million in 2011 [4].

However, few prospective, longitudinal, and cross-national studies have been carried out to inform the development of a prevention strategy against disability. To establish evidence-based prevention strategies, it is critically important to accumulate epidemiologic evidence, including the incidence of disability, and identify its risk factors. However, few studies have attempted to estimate the incidence of the disability and its risk factors by using population-based cohorts. In addition, to identify the incidence of disability, a study should have a large number of subjects. Further, to determine regional differences in epidemiological indices, a survey of cohorts across Japan is required.

The Longitudinal Cohorts of Motor System Organ (LOCOMO) study was initiated in 2008, through a grant from Japan's Ministry of Health, Labour and Welfare, for the prevention of knee pain, back pain, bone fractures, and subsequent disability. It aimed to integrate data gathered from cohorts from 2000 onwards and follow-up surveys from 2006 onwards, using a unified questionnaire, with an ultimate goal being the prevention of musculoskeletal diseases. The present study specifically aims at using LOCOMO data, which is based on the long-term care insurance system, to investigate the occurrence of disability in order to clarify its incidence and risk factors, especially in terms of body build and regional differences.

Materials and methods

Participants were residents of nine communities located in Tokyo (two regions: Tokyo-1, principal investigators (PIs): Shigeyuki Muraki, Toru Akune, Noriko Yoshimura, Kozo Nakamura; Tokyo-2, PIs: Yoko Shimizu, Hideyo Yoshida, Takao Suzuki), Wakayama [two regions: Wakayama-1 (mountainous region) and Wakayama-2 (coastal region), PIs: Noriko Yoshimura, Munehito Yoshida], Hiroshima (PI: Saeko Fujiwara), Niigata (PI: Go Omori), Mie (PI: Akihiro Sudo), Akita (PI: Hideyo Yoshida), and Gunma (PI: Yuji Nishiwaki) prefectures [5]. Figure 1 shows the location of each cohort in Japan.

Disability in the present study was defined as 'cases requiring long-term care', as determined by the long-term care insurance system. The procedure for identifying these cases is as follows: (1) each municipality establishes a long-term care approval board consisting of clinical experts, physicians, and specialists at the Division of Health and Welfare in each municipal office; (2) The long-term care approval board investigates the insured person by using an interviewer-administered questionnaire consisting of 82 items regarding mental and physical conditions, and makes a screening judgement based on the opinion of a regular doctor; (3) 'Cases requiring long-term care' are determined according to standards for long-term care certification that are uniformly and objectively applied nationwide [6].

In order to identify the incidence of disability, data were collected from participants aged 65 years and older within the above-mentioned cohorts. In Japan, most individuals certified as 'cases requiring long-term care' are 65 years and older. Table 1 shows the number of subjects per region, as well as the data obtained within the first year of the observation. The smallest cohort consisted of 239 subjects, residing in Mie, while the largest consisted of 1,758, who resided in Gunma.

The earliest baseline data were collected in 2000 in Hiroshima, while the latest were obtained in 2008 in Tokyo-2. The cohorts were subsequently followed until 2012. Data regarding participants' deaths, changes of residence, and occurrence or non-occurrence of certified disability were gathered annually from public health centres of the participating municipalities. As an index of body build, baseline data on participants' height and weight were collected, and used to calculate body mass index (BMI, kg/m^2). Participants were classified as follows: normal or overweight (BMI = 18.5–27.5), obese (BMI >27.5), or emaciated (BMI <18.5). These cut-off points were determined according to a WHO report [7]. From 2008 onwards, follow-up data was obtained using the unified questionnaire.

All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo (nos. 1264 and 1326), the Tokyo Metropolitan Institute of Gerontology

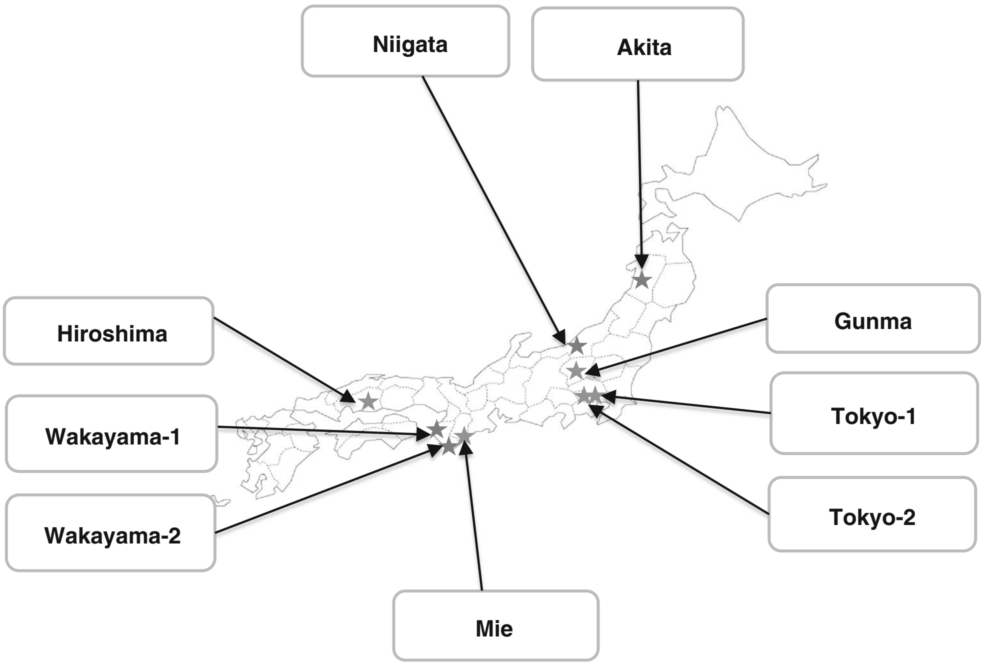

Fig. 1 Location of nine regions from which the study cohorts were selected

Table 1 Number of subjects classified by regions of each cohort

Region	Start year	Total	Men	Women
Tokyo-1	2005	1,332	461	871
Tokyo-2	2008	1,453	59	1,394
Wakayama-1 (Mountainous)	2005	610	239	371
Wakayama-2 (Coastal)	2006	357	129	228
Hiroshima	2000	1,341	351	990
Niigata	2007	805	343	462
Mie	2001	239	95	144
Akita	2006	559	223	336
Gunma	2005	1,758	805	953
Total		8,454	2,705	5,749

(no. 5), Wakayama (no. 373), the Radiation Effects Research Foundation (RP 03-89), Niigata University (no. 446), Mie University (nos. 837 and 139), Keio University (no. 16–20), and the National Center for Geriatrics and Gerontology (no. 249). Careful consideration was given to ensure the safety of the participants during all of the study procedures.

Statistical analysis

All statistical analyses were performed using STATA (STATA Corp., College Station, Texas, USA). Differences in proportions were compared using the chi-squared test. Differences in continuous variables were tested using an analysis of variance (ANOVA) with Scheffe's least significant difference test for post-hoc pairwise comparisons. To test the association between the occurrence of disability and other variables, Cox's proportional hazard regression analysis was used. Hazard ratios (HRs) were estimated using the occurrence of disability as an objective variable (0: non-occurrence, 1: occurrence) and the following explanatory variables: age (± 1 year), gender (vs. female), body build (0: normal and overweight vs. 1: emaciation vs. 2: obesity), and regional differences (0: rural areas, including Wakayama-1, Wakayama-2, Niigata, Mie, Akita, and Gunma vs. 1: urban areas, including Tokyo-1, Tokyo-2, and Hiroshima). All p values and 95 % confidence intervals (CI) of two-sided analyses are presented.

Results

Table 2 shows the number of participants classified by age and gender. The majority of participants were 75–79 years old; two-thirds of the participants were women.

Selected characteristics of the study population, including age, height, weight, and BMI, are shown in Table 3. The mean values of age, height, and weight were significantly greater in women than in men ($p < 0.001$), but BMI did not significantly differ between men and women ($p = 0.479$).

The estimated incidence of disability is shown in Fig. 2. In total, the incidence of disability among individuals aged 65 years and older was 3.58/100 person-years (p-y) (p-y; men: 3.17/100 p-y; women: 3.78/100 p-y). The incidence of disability was 0.83/100 p-y, 1.70/100 p-y, 3.00/100 p-y,

Table 2 Number of subjects classified by age and gender

Age strata (years)	Total (%)	Men (%)	Women (%)
65–69	1,390 (16.4)	555 (20.5)	835 (14.5)
70–74	1,704 (20.2)	668 (24.7)	1,036 (18.0)
75–79	2,923 (34.6)	812 (30.0)	2,111 (36.7)
80–84	1,810 (21.4)	463 (17.1)	1,347 (23.4)
≥85	627 (7.4)	207 (7.7)	420 (7.3)
Total	8,454 (100.0)	2,705 (100.0)	5,749 (100.0)

Table 3 Baseline characteristics of subjects classified by age and gender

Variables	Men	Women	*p* (men vs. women)
Age (years)	75.3 (6.4)	76.5 (6.0)	<0.001
Height (cm)	160.5 (6.5)	147.7 (6.1)	<0.001
Weight (kg)	58.7 (9.1)	49.8 (8.4)	<0.001
BMI (kg/m^2)	22.7 (2.9)	22.8 (3.5)	0.479
Living in rural area (%)	84.8	58.5	<0.001

Values are represented as mean (standard deviation)

BMI body mass index

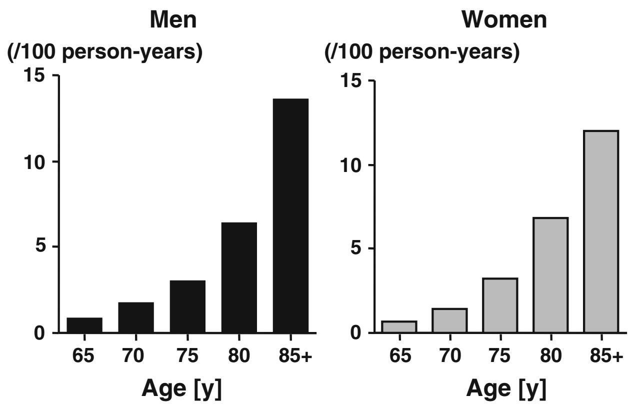

Fig. 2 Incidence of disability according to age and gender

6.36/100 p-y, and 13.54/100 p-y in 65–69-, 70–74-, 75–79-, 80–84-, and ≥85-year-old men, respectively. In women, the incidence of disability was 0.71/100 p-y, 1.40/100 p-y, 3.25/100 p-y, 6.85/100 p-y, and 12.01/100 p-y in the age ranges of 65–69, 70–74, 75–79, 80–84, and 85 or more years, respectively (Table 4).

Cox's proportional hazard regression analysis showed that occurrence of disability was significantly influenced by age, body build, and regional differences, but not gender (age, +1 years: hazard ratio 1.13, 95 % confidence interval 1.12–1.15, $p < 0.001$; sex, vs. female: 1.13, 0.97–1.31, $p = 0.125$; body build: emaciation: 1.24, 1.01–1.53, $p = 0.041$; body build; obesity: 1.36, 1.08–1.71, $p = 0.009$; residence, vs. living in rural areas: 1.59, 1.37–1.85, $p < 0.001$).

Discussion

Using the data of the LOCOMO study, we determined the incidence of disability and identified age, emaciation, obesity, and residence in rural areas as risk factors for the occurrence of disability. More specifically, we integrated data collected from subjects aged 65 and older in individual cohorts established in nine regions across Japan to determine the incidence of disability in the specified regions. We found an association between various risk factors and disability; these include age, emaciation, and obesity, as well as residence in rural areas.

The LOCOMO study was the first nation-wide prospective study to track a large number of the subjects from several population-based cohorts. The LOCOMO study aimed to integrate information from these cohorts, to prevent musculoskeletal diseases and subsequent disability. The data shed light on the prevalence and characteristics of targeted clinical symptoms such as knee pain or lumbar pain, or defined diseases such as knee osteoarthritis (KOA), lumbar spondylosis (LS), and osteoporosis (OP), as well as their prognosis in reference to either mortality or chances of developing a disability. In the present study, we also

Table 4 Hazard ratios (HRs) of potential risk factors for the occurrence and non-occurrence of disability

Disability (occurrence vs. non-occurrence)

Explanatory variable	Reference	HR	95 % confidence interval	*p*
Age (years)	+1 year	1.13	1.12–1.15	<0.001***
Gender	0: men, 1: women	1.13	0.97–1.31	0.125
Body build	0: 18.5 ≤ BMI ≤ 27.5, 1: BMI < 18.5	1.24	1.01–1.53	0.041*
	0: 18.5 ≤ BMI ≤ 27.5, 2: BMI >27.5	1.36	1.08–1.71	0.009**
Type of residential area	0: urban area, 1: rural area	1.59	1.37–1.85	<0.001***

BMI body mass index

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

compared the above-mentioned symptoms, diseases, and prognoses between regions.

The overall incidence of disability among individuals aged 65 years and older was 3.58/100 person-years. When results from the present study are applied to the total age-sex distribution derived from the Japanese census in 2010 [1], it could be assumed that 1,110,000 people (410,000 men and 700,000 women) aged 65 years and older are newly affected by disability and require support. It has been reported that the total number of subjects who were certified as needing care increases annually [4]; however, few of these reports estimate the number of newly certified cases through a population-based cohort. Clarifying the incidence of disability and its risk factors was viewed as the first step toward preventing its occurrence.

Emaciation and obesity were both identified as risk factors for disability; thus, there appears to be a U-shaped association between BMI and disability as well as between BMI and mortality [8, 9]. According to the recent National Livelihood Survey, the leading cause of disabilities that require support and long-term care is cardiovascular disease (CVD), followed by dementia, senility, osteoarthrosis, and fractures [4]. Obesity is an established risk factor for chronic diseases, including hypertension, dyslipidemia, and diabetes mellitus, which increase the risk for CVD [10]; in turn, CVD causes ADL-related disabilities in older adults. In addition, numerous reports have shown an association between overweight or obesity and KOA [11–17]. In previous reports, we found a significant association between BMI and not only the presence of KOA, but also the occurrence and progression of KOA [18, 19]. In addition, emaciation is an established risk factor for OP and OP-related fractures [20]. OP might be related to low nutrition due to chronic wasting diseases.

The current study also found an association between living in a rural area and the occurrence of disability. There have been reports of regional differences in the certification rate of disability in Japan. For instance, Kobayashi reported a prefectural difference in the certification rate of disability, which was particularly prominent among individuals aged 75 years and older at lower nursing care levels in the long-term care insurance system [21]. In addition, Shimizutani et al. [22] pointed out that the financial condition of the insurer influenced the certification rate of disability. Further, Nakamura found that the certification of lower care levels was influenced by social and/or individual factors, such as the type of service provider, the application rate, and number of medical treatment recipients. However, certification of advanced nursing care levels was influenced by CVD and lifestyle-related diseases [23].

Other than differences in the social backgrounds of individuals in each prefecture, we posited that regional differences (rural or urban) in the occurrence of disability might be due to differences in the frequency of diseases and ailments that cause disability in each area. The prevalence of musculoskeletal diseases, such as KOA and LS, differs among mountainous, coastal, and urban areas [24]. Evidence also exists for regional differences in the incidence of hip fractures [25–27]. It was also found that mortality and incidence of ischemic stroke, which is related to CVD, was higher in the northeastern than in the southwestern part of Japan [28]. However, there is currently no information on regional differences in dementia prevalence and incidence in Japan. In general, differences in the frequency of diseases causing disability might influence regional differences in disability rates. In relation to this, in a future study on follow-up data from the LOCOMO study, it might be necessary to collect information on the prevalence and frequency of diseases that cause disability, such as musculoskeletal diseases, CVD, and dementia. This future study should also attempt to clarify mutual associations among risk factors for disability, so as to inform the development of measures for its primary prevention.

Despite its contribution to existing knowledge, the present study has several limitations. First, its sample does not truly represent the entire Japanese population, because our cohorts were not drawn from the northernmost and southernmost parts of Japan (e.g., Okinawa prefecture or Hokkaido prefecture). This limitation must be taken into consideration, especially when determining the generalisability of the results. However, the LOCOMO study is the first large-scale, population-based prospective study with approximately 9,000 participants aged 65 years and older. Second, data collected from the cohorts were not uniform, as certain information was obtained from some participants, but not others. For example, the X-ray examinations of subjects' knees were performed in Tokyo-1, Wakayama-1, Wakayama-2, Niigata, and Mie; lumbar spine X-ray examinations were performed in Tokyo-1, Wakayama-1, Wakayama-2, Hiroshima, and Mie. Therefore, we could not evaluate the presence or absence of KOA, LS, or OP as a possible cause of disability by using the data of the entire LOCOMO study. Further investigation following the integration of information on musculoskeletal disorders would enable us to evaluate all the factors that are associated with disability.

Nevertheless, our study has several strengths. As mentioned above, the large sample size is the study's biggest strength. The second strength is that we collected data from nine cohorts across Japan, which enabled us to compare regional differences in the incidence of disability. In addition, the variety of measures and assessments used in this study enabled us to collect a substantial amount of detailed information. However, given the fact that not all of the measures were administered in all cohorts, regional selection bias in the analysis should be considered when interpreting the results.

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Conflict of interest All authors declare no conflicts of interest.

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ORIGINAL ARTICLE

Does osteophytosis at the knee predict health-related quality of life decline? A 3-year follow-up of the ROAD study

Shigeyuki Muraki · Toru Akune · Keiji Nagata · Yuyu Ishimoto · Munehito Yoshida · Fumiaki Tokimura · Sakae Tanaka · Hiroshi Kawaguchi · Kozo Nakamura · Hiroyuki Oka · Noriko Yoshimura

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Abstract The objective of the present longitudinal study was to clarify whether osteophytosis and joint space narrowing predict quality of life (QOL) decline using a longitudinal population-based cohort of the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study. The present study analyzed 1,525 participants who completed the radiographic examination at baseline and questionnaires regarding QOL at a 3-year follow-up (546 men and 979 women; mean age, 67.0±11.0 years). This study examined the associations of osteophyte area (OPA) and minimum joint space width (mJSW) in the medial compartment of the knee at baseline with pain and physical functional disability measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). OPA and mJSW in the medial compartment of the knee were measured using a knee osteoarthritis (OA) computer-aided diagnosis system. Overall, OPA independently predicted physical functional disability after 3 years of follow-up. When analyzed in men and women separately, OPA, rather than mJSW, was an independent predictor for pain and physical functional disability after 3 years of follow-up in men. OPA, rather than mJSW, also predicted worsening of pain in men during the 3-year follow-up, whereas in women, mJSW, rather than OPA, predicted worsening of pain. In conclusion, the present longitudinal study using a large-scale population from the ROAD study found gender differences in the association of osteophytosis and joint space narrowing with pain and physical functional disability.

Keywords Epidemiology · Longitudinal Studies · Osteoarthritis · Pain · WOMAC

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S. Muraki (✉) · T. Akune
Department of Clinical Motor System Medicine, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Hongo 7-3-1, Bunkyo-ku, Tokyo 113-8655, Japan
e-mail: murakis-ort@h.u-tokyo.ac.jp

K. Nagata · Y. Ishimoto · M. Yoshida
Department of Orthopaedic Surgery, Wakayama Medical University, Wakayama, Japan

F. Tokimura
Department of Orthopaedic Surgery, Tokyo Metropolitan Geriatric Medical Center, Tokyo, Japan

S. Tanaka · H. Kawaguchi
Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, Tokyo, Japan

K. Nakamura
National Rehabilitation Center for Persons with Disabilities, Saitama, Japan

H. Oka · N. Yoshimura
Department of Joint Disease Research, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan

Introduction

Knee osteoarthritis (OA) is a major public health issue causing chronic pain and disability [1–3]. The prevalence of radiographically confirmed knee OA is high in Japan [4], with 25,300,000 persons aged 40 years and older estimated to experience radiographic knee OA [5]. According to the recent Japanese National Livelihood Survey of the Ministry of Health, Labour and Welfare, osteoarthritis is ranked fourth among diseases that cause disabilities that subsequently require support with activities of daily living [6].

The principal clinical symptoms of knee OA are pain and physical functional disability [7], but the correlation of these symptoms with radiographic severity of knee OA is controversial [4, 8–10]. In terms of disease-specific scales for estimating pain and physical functional disability due to knee OA, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) has been used for Caucasians [11] and Asians [12, 13], although these reports were not population-based studies. Furthermore, there is little information on the impact of knee OA on incident pain and physical functional disability using WOMAC in Japan, although reports from a population survey suggest that the disease pattern differs among races [14–16].

Knee OA is characterized by the pathological features of osteophytosis and joint space narrowing, but there is controversy regarding the importance of osteophytes. Nevertheless, hand and hip joint researchers and clinicians have argued that separate radiographic features should be recorded and may be more meaningful than overall composite scores such as the Kellgren-Lawrence (KL) scale [17]. Furthermore, a previous study showed that osteophytes performed better as a primary diagnostic feature than joint space narrowing in cross-sectional knee OA epidemiologic studies [18]. However, most conventional systems for grading radiographic severity have been categorical grades, such as KL grading [19], which is unable to assess osteophytosis and joint space narrowing individually. Several studies have shown that knee OA had a strong effect on quality of life (QOL) [13, 20–22], but in these studies, knee OA was defined by categorical grades such as KL score or American College of Rheumatology grade, total knee arthroplasty, and self-administered questionnaires. In addition, osteophytosis and joint space narrowing were separately evaluated using a radiographic atlas of individual features published by the Osteoarthritis Research Society International in 1995 [23] and revised in 2007 [24]. However, the grading is still limited in reproducibility and sensitivity due to the subjective judgment of individual observers and the categorical classification into four grade scales (0–3). To overcome this problem, osteophyte area (OPA) or joint space width should be evaluated using a fully automatic system [25].

The objective of this study was to clarify whether osteophytosis and joint space narrowing at the knee independently predict decline of QOL measured by WOMAC pain and physical function score during a 3-year follow-up among Japanese men and women using a fully automatic system to measure OPA and joint space width in the longitudinal, population-based cohort from the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study.

Materials and methods

Study sample The ROAD study is a nationwide prospective study designed to establish epidemiologic indices for the evaluation of clinical evidence to allow for the development of disease-modifying treatments for bone and joint disorders (with OA and osteoporosis as the representative bone and joint diseases). The ROAD study consists of population-based cohorts in several Japanese communities. A detailed profile of the ROAD study has been published previously [4, 5, 26]; therefore, only a brief summary is provided here. To date, the ROAD study has completed the creation of a baseline database including clinical and genetic information for 3,040 inhabitants (1,061 men and 1,979 women) ranging in age from 23 to 95 years (mean, 70.6 years). Participants were recruited from resident registration listings in three communities: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a seacoast region in Taiji, Wakayama. All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology. Anthropometric measurements, including height and weight and body mass index (BMI) (weight [kg]/height^2 [m^2]), were calculated. Grip strength was measured on bilateral sides using a TOEI LIGHT handgrip dynamometer (TOEI LIGHT CO., LTD, Saitama, Japan), and the better measurement was used to characterize maximum muscle strength.

Radiographic assessment All participants underwent radiographic examination of both knees using an anterior-posterior view with weight-bearing and foot map positioning by experienced radiological technologists. The beam was positioned parallel to the floor with no angle and aimed at the joint space. We used fluoroscopic guidance with an anterior-posterior X-ray beam to properly visualize the joint space and to centralize the patella over the lower end of the femur. The images were downloaded into Digital Imaging and Communication in Medicine (DICOM) format files. A single experienced orthopedist (S.M.) read the knee radiographs without knowledge of participant clinical status using the KL radiographic atlas for overall knee radiographic grades [19]. Knee OA was defined as KL ≥2. Medial compartment minimum joint space width (mJSW) and medial tibial OPA were measured with the knee osteoarthritis computer-aided diagnosis (KOACAD) system bilaterally. The knee with the least mJSW was defined as the designated knee for each participant. The KOACAD system has been previously described in detail [25, 27, 28]. The KOACAD system is a fully automatic system capable of quantifying the major features of knee OA on standard radiographs. This system allows for objective, accurate, and simple assessment of the structural severity of knee OA in general clinical practice. The KOACAD system was programmed to measure OPA at the medial tibia and mJSW in the medial and lateral compartments using digitized knee radiographs. The KOACAD system was applied to the DICOM data by the experienced orthopedist who developed this system (H.O.), and there is strong reliability for this measurement [25]. Reference values for OPA and mJSW by gender and age strata in Japan using the KOACAD system have been published previously [28]. Lateral OA was defined as being present when a knee had a KL grade ≥2 [19] and lateral joint space narrowing score ≥1 on a 0–3 scale according to the Osteoarthritis Research Society International atlas [24].

Instruments All 3,040 subjects were invited to attend a follow-up interview between 2008 and 2010. We used the WOMAC at the follow-up study to evaluate QOL. The WOMAC is a 24-item OA-specific index consisting of three domains: pain, stiffness, and physical function. Each of these 24 items is graded on either a 5-point Likert scale or a 100-mm visual analog scale [11, 29]. The Likert scale (version LK 3.0) was used in the present study. The domain score ranges from 0 to 20 for pain, 0 to 8 for stiffness, and 0 to 68 for physical function. Japanese versions of the WOMAC have also been validated [30].

Statistical analysis Differences in age, height, weight, BMI, grip strength, OPA, mJSW, and WOMAC scores between men and women were examined using a non-paired student *t* test. The associations of mJSW and OPA with pain and physical functional disability after 3 years were determined by using multiple regression analysis after adjustment for age, BMI, gender, grip strength, and pain score at baseline; after adjustment for age, BMI, gender, grip strength, and physical function score at baseline, respectively, in the overall population; and after adjustment for age, BMI, grip strength, and pain score at baseline and after adjustment for age, BMI, grip strength, and physical function score at baseline, respectively, in men and women. In addition, to determine the independent association of OPA and mJSW with pain and physical function scores, multiple regression analysis was used with age, BMI, gender, grip strength, pain score at baseline, OPA, and mJSW and with age, BMI, gender, grip strength, physical function score at baseline, OPA, and mJSW, respectively, as explanatory variables in the overall population, and with age, BMI, grip strength, pain score at baseline, OPA, and mJSW and with age, BMI, grip strength, physical function score at baseline, OPA, and mJSW, respectively, as explanatory variables in men and women. We classified men and women separately into three groups based on grip strength: <20, ≥20 to <30, and ≥30 and examined the associations of BMI, OPA, and mJSW with pain, using multiple regression analysis with age, BMI, OPA, mJSW, and pain score at baseline as explanatory variables. We also calculated changes of scores as follows: "scores at follow-up−scores at baseline" and determined the association of OPA and mJSW with changes of pain and physical function scores after adjustment for age, BMI, gender, grip strength, and pain score at baseline; after adjustment for age, BMI, gender, grip strength, and physical function score at baseline, respectively, in the overall population; and after adjustment for age, BMI, grip strength, and pain score at baseline and after adjustment for age, BMI, grip strength, and physical function score at baseline, respectively, in men and women. In addition, to determine independent associations of OPA and mJSW with changes of pain and physical function scores, multiple regression analysis was used with age, BMI, gender, grip strength, pain score at baseline, OPA, and mJSW and with age, BMI, gender, grip strength, physical function score at baseline, OPA, and mJSW, respectively, as explanatory variables in the overall population and with age, BMI, grip strength, pain score at baseline, OPA, and mJSW and with age, BMI, grip strength, physical function score at baseline, OPA, and mJSW, respectively, as explanatory variables in men and women. Data analyses were performed using SAS version 9.0 (SAS Institute Inc., Cary, NC).

Results

Of the 3,040 subjects in the baseline study in 2005–2007, 125 had died by the time of the review 3 years later, 123 did not participate in the follow-up study due to bad health, 69 had moved away, 83 declined the invitation to attend the follow-up study, and 155 did not participate in the follow-up study for other reasons. Among the 2,485 subjects who did participate in the follow-up study, we excluded 39 subjects younger than 40 years at baseline. Those participating in the follow-up study were younger than those who did not survive or who did not participate for other reasons (responders 68.6 years, non-responders 75.1 years; $P<0.0001$). The follow-up study participants also were significantly more likely to be women (responders 66.3 % women, non-responders 61.8 % women; $P=0.03$) and were significantly more likely to have knee OA at the baseline examination than either those who did not survive to follow-up or those who did not participate for other reasons (responders 51.5 %, non-responders 60.9 %; $P<0.0001$). Among them, 1,578 subjects provided complete questionnaires of WOMAC both at baseline and follow-up. We excluded 3 subjects who did not undergo plain radiography at the knee and 17 subjects who underwent total knee arthroplasty before the follow-up study. We also excluded 12 subjects whose X-rays were too obscure to measure mJSW and OPA and 21 subjects who had lateral knee OA, leaving a total of 1,525 subjects (546 men and 979 women). The mean duration between baseline and follow-up was 3.3±0.6 years.

Characteristics of the 1,525 participants in the present study are shown in Table 1. BMI was higher in men than women. The prevalence of knee OA was significantly higher in women than men. The OPA was significantly larger and mJSW was significantly narrower in women than men. The WOMAC pain score was similar in men and women, whereas the WOMAC physical function score was worse in women than men, both at baseline and follow-up.

Table 1 Characteristics of subjects

	Overall	Men	Women	*p* value
N	1,525	546	979	
Age (years)	67.0±11.0	68.2±10.7	66.3±11.1	0.001
Height (cm)	155.3±8.8	163.3±6.4	150.8±6.4	<0.0001
Weight (kg)	55.5±10.4	62.2±10.3	51.8±8.5	<0.0001
BMI (kg/m^2)	22.9±3.3	23.3±3.1	22.7±3.3	0.0027
Grip strength (kg)	27.2±9.4	35.4±8.7	22.7±6.4	<0.0001
Knee OA (%)	48.8	38.5	54.5	<0.0001
OPA (mm^2)	3.56±8.43	1.79±5.47	4.54±9.56	<0.0001
mJSW (mm)	2.67±0.94	2.99±0.88	2.50±0.92	<0.0001
WOMAC at baseline				
Pain	1.13±2.20	1.03±2.06	1.18±2.27	0.1753
Physical function	3.05±6.68	2.59±5.74	3.30±7.14	0.0328
WOMAC at follow-up				
Pain	1.82±2.81	1.74±2.69	1.87±2.88	0.3881
Physical function	5.56±9.61	4.79±8.34	5.99±10.22	0.0137

Knee OA was defined as Kellgren-Lawrence grade ≥2 at baseline; except where otherwise indicated, the values at baseline was shown

BMI body mass index, *OA* osteoarthritis, *OPA* osteophyte area, *mJSW* minimum joint space width, *WOMAC* Western Ontario and McMaster Universities Osteoarthritis Index

First, we analyzed the associations of age, BMI, and grip strength with WOMAC pain and physical function scores in men and women (Table 2). Age and grip strength were significantly associated with pain and physical function in men and women, while BMI was significantly associated with pain and physical function in women, but not in men.

Multiple regression analysis after adjustment for age, BMI, grip strength, and pain score at baseline showed that, overall, OPA and mJSW were significant predictors for pain (Table 3). To assess whether OPA and mJSW independently predicted pain, we used multiple regression analysis with age, BMI, grip strength, pain score at baseline, OPA, and mJSW as explanatory variables and found that the association of OPA with pain score after 3 years disappeared, whereas mJSW was an independent predictor for pain after 3 years. When analyzed in men and women, separately, OPA was an independent predictor for pain in men, but mJSW was not. In women, mJSW was an independent predictor for pain, but OPA was not.

In terms of physical function, multiple regression analysis after adjustment for age, BMI, grip strength, and physical function score at baseline showed that OPA and mJSW were significant predictors for physical functional disability (Table 4). To assess whether OPA and mJSW independently predicted physical functional disability, we used multiple regression analysis with age, BMI, grip strength, physical function score at baseline, OPA, and mJSW as explanatory variables and found that OPA and mJSW were independent predictors for physical functional disability. When analyzed in men and women separately, OPA was an independent predictor for physical functional disability in men, but mJSW was not. In women, mJSW was an independent predictor for physical functional disability, but OPA was not.

To clarify the association of OPA, mJSW, and BMI with pain according to muscle strength, men and women were separated into three groups based on grip strength: <20, ≥20 to <30, and ≥30 and the associations of BMI, OPA, and mJSW with pain were examined, using multiple regression analysis with age, BMI, OPA, mJSW, and pain score at baseline as explanatory variables (Supplementary Table 1). In women with grip strength <20, mJSW was significantly associated with pain and BMI tended to be associated with pain, but OPA was not. In men with grip strength <20, BMI, OPA, and mJSW were not significantly associated with pain, likely because only nine men had a grip strength <20. In women with grip strength ≥20 to <30, mJSW and BMI was significantly associated with pain, while OPA was not. In men with grip strength ≥20 to <30, BMI was significantly associated with pain, while OPA and mJSW were not. In men and women with grip strength >30, OPA was significantly associated with pain, while mJSW and BMI were not. We also

Table 2 Effect of age, BMI, and grip strength at baseline on WOMAC pain and physical function scores after 3 years

	Pain		Physical function	
	Regression coefficient (95 % CI)	*P* value	Regression coefficient (95 % CI)	*P* value
Men				
Age (years)	0.05 (0.03 to 0.07)	<0.0001	0.23 (0.17 to 0.29)	<0.0001
BMI (kg/m^2)	0.05 (−0.02 to 0.12)	0.1616	0.17 (−0.06 to 0.39)	0.1459
Grip strength (kg)	−0.05 (−0.07 to −0.02)	0.0003	−0.26 (−0.34 to −0.19)	<0.0001
Women				
Age (years)	0.06 (0.05 to 0.08)	<0.0001	0.33 (0.28 to 0.39)	<0.0001
BMI (kg/m^2)	0.20 (0.14 to 0.25)	<0.0001	0.66 (0.47 to 0.85)	<0.0001
Grip strength (kg)	−0.10 (−0.12 to −0.07)	<0.0001	−0.44 (−0.54 to −0.35)	<0.0001

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, *CI* confidence interval, *BMI* body mass index

Table 3 Effect of OPA and mJSW at baseline on WOMAC pain scores after 3 years

	Crude regression coefficient[b] (95 % CI)	P value	Adjusted regression coefficient[a] (95 % CI)	*P* value	Adjusted regression coefficient[b] (95 % CI)	*P* value	Standardized beta
Overall							
OPA (mm^2)	0.08 (0.06 to 0.09)	<0.0001	0.02 (0.006 to 0.04)	0.0051	0.01 (−0.003 to 0.03)	0.1036	0.04
mJSW (mm)	−0.76 (−0.90 to −0.61)	<0.0001	−0.30 (−0.44 to −0.16)	<0.0001	−0.26 (−0.41 to −0.12)	0.0005	−0.09
Men							
OPA (mm^2)	0.09 (0.04 to 0.13)	<0.0001	0.05 (0.01 to 0.08)	0.0078	0.05 (0.01 to 0.09)	0.0127	0.1
mJSW (mm)	−0.45 (−0.71 to −0.20)	0.0005	−0.11 (−0.33 to 0.12)	0.3466	0.02 (−0.22 to 0.27)	0.8574	0.007
Women							
OPA (mm^2)	0.08 (0.06 to 0.09)	<0.0001	0.02 (−0.0008 to 0.03)	0.0623	0.006 (−0.01 to 0.02)	0.4789	0.02
mJSW (mm)	−0.96 (−1.15 to −0.78)	<0.0001	−0.41 (−0.58 to −0.23)	<0.0001	−0.39 (−0.57 to −0.20)	<0.0001	−0.12

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, *CI* confidence interval, *OPA* osteophyte area, *mJSW* minimum joint space width

[a] Adjusted regression coefficients for pain scores were calculated by multiple regression analysis after adjustment for age, BMI, gender, grip strength, and pain score at baseline in the overall population and after adjustment for age, BMI, grip strength, and pain score at baseline in men and women

[b] Adjusted regression coefficients for pain scores were calculated by multiple regression analysis with age, BMI, gender, grip strength, pain score at baseline, OPA, and mJSW as explanatory variables in the overall population and with age, BMI, grip strength, pain score at baseline, OPA, and mJSW as explanatory variables in men and women

examined the association of OPA, mJSW, and BMI with physical function disability according to muscle strength (Supplementary Table 2). Results were similar to findings for pain.

To examine whether OPA and mJSW predicted worsening of pain during the 3-year follow-up, we calculated differences of the WOMAC pain scores between baseline and follow-up (Table 5). In the overall population, mJSW was a significant predictor for worsening of pain after adjustment for age, BMI, gender, and pain score at baseline, whereas OPA was not. When analyzed in men and women separately, OPA was a significant predictor for worsening of pain in men, whereas mJSW was a significant predictor for worsening of pain in women.

We also examined whether OPA and mJSW predicted worsening of physical functional disability during the 3-year follow-up (Table 6). In the overall population, OPA and mJSW were significant predictors for worsening of physical functional disability after adjustment for age, BMI, gender, grip strength, and physical function score at baseline. To

Table 4 Effect of OPA and mJSW at baseline on WOMAC physical function scores after 3 years

	Crude regression coefficient[b] (95 % CI)	*P* value	Adjusted regression coefficient[a] (95 % CI)	*P* value	Adjusted regression coefficient[b] (95 % CI)	*P* value	Standardized beta
Overall							
OPA (mm^2)	0.34 (0.29 to 0.40)	<0.0001	0.09 (0.04 to 0.14)	0.0002	0.05 (0.0004 to 0.10)	0.0480	0.04
mJSW (mm)	−3.24 (−3.73 to −2.75)	<0.0001	−1.36 (−1.80 to −0.92)	<0.0001	−1.22 (−1.68 to −0.76)	<0.0001	−0.12
Men							
OPA (mm^2)	0.35 (0.23 to 0.48)	<0.0001	0.19 (0.08 to 0.30)	0.0008	0.14 (0.02 to 0.26)	0.0204	0.09
mJSW (mm)	−2.21 (−2.99 to −1.44)	<0.0001	−1.07 (−1.77 to −0.37)	0.0027	−0.69 (−1.46 to 0.07)	0.0758	−0.07
Women							
OPA (mm^2)	0.34 (0.27 to 0.40)	<0.0001	0.06 (0.009 to 0.12)	0.0225	0.03 (−0.03 to 0.08)	0.3305	0.03
mJSW (mm)	−3.86 (−4.51 to −3.20)	<0.0001	−1.49 (−2.05 to −0.92)	<0.0001	−1.41 (−2.00 to −0.82)	<0.0001	−0.13

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, *CI* confidence interval, *OPA* osteophyte area, *mJSW* minimum joint space width

[a] Adjusted regression coefficients for physical function score were calculated by multiple regression analysis after adjustment for age, BMI, gender, grip strength, and physical function score at baseline in the overall population and after adjustment for age, BMI, grip strength, and physical function score at baseline in men and women

[b] Adjusted regression coefficients for physical function score were calculated by multiple regression analysis with age, BMI, gender, grip strength, physical function score at baseline, OPA, and mJSW as explanatory variables in the overall population and with age, BMI, grip strength, physical function score at baseline, OPA, and mJSW as explanatory variables in men and women

examine whether OPA and mJSW independently predicted worsening of physical functional disability, we used multiple regression analysis with age, BMI, gender, grip strength, physical function score at baseline, OPA, and mJSW as explanatory variables and found that mJSW was an independent predictor for worsening of physical functional disability, but the significant association of OPA disappeared. When analyzed in men and women separately, after adjustment for age, BMI, grip strength, and physical function scores at baseline, OPA and mJSW were significant predictors for worsening of physical functional disability in men; in women, mJSW was a significant predictor for worsening of physical functional disability, but OPA was not. To examine whether OPA and mJSW independently predicted worsening of physical functional disability in men, we used multiple regression analysis with age, BMI, grip strength, physical function score at baseline, OPA, and mJSW as explanatory variables and found that the significant association of OPA and mJSW with worsening in physical function disappeared.

Discussion

This is the first large-scale study to examine whether osteophytosis and joint space narrowing independently predict QOL decline measured by WOMAC pain and physical function score in a longitudinal model. In addition, osteophytosis and joint space narrowing were estimated not by categorical grade but by continuous values such as OPA and mJSW at the knee. In the present study, OPA, rather than mJSW, was an independent predictor for pain and physical functional disability after 3 years of follow-up in men. OPA, rather than mJSW, also predicted worsening of pain in men during the 3-year follow-up, whereas mJSW, rather than OPA, predicted worsening of pain in women.

Previous studies have shown that knee OA has a strong effect on QOL [13, 20–22]; however, the knee OA was defined by KL grade or other categorical methods. KL grade is the most conventional system to grade radiographic severity of knee OA, but in this categorical system, osteophyte formation and joint space narrowing are not assessed separately. Thus, we cannot clarify whether osteophytosis and joint space narrowing have distinct effects on QOL. In addition, our previous cross-sectional study showed that osteophytosis was not strongly related to joint space narrowing on plain radiographs [31]. Furthermore, our experimental mouse model for OA identified a cartilage-specific molecule, carminerin, that regulates osteophytosis without affecting joint cartilage destruction during OA progression [32, 33]. This accumulating evidence indicates that osteophytosis and joint space narrowing may have distinct etiologic mechanisms and their progression may be neither constant nor proportional. Thus, to examine factors associated with knee OA, these two OA features should be assessed separately. Furthermore, because categorical methods are statistically less powerful than continuous methods, the association between knee OA and QOL might have been underestimated in previous studies. In addition, most studies regarding the association of knee OA with QOL were cross-sectional designs; thus, a causal relationship could not be clarified. So far, the role of the osteophytes in OA is controversial, with several researchers believing that osteophytes are merely a reflection of age and not associated with any of the clinical symptoms of OA, though few reported data support or refute this argument. This study was the first longitudinal model to report that osteophytosis, rather than mJSW, predicted QOL decline in men.

Table 5 Effect of OPA and mJSW at baseline on worsening of WOMAC pain scores after 3 years

	Crude regression coefficient[a] (95 % CI)	*P* value	Adjusted regression coefficient (95 % CI)	*P* value
Overall				
OPA (mm^2)	0.01 (−0.004 to 0.03)	0.1443	–	–
mJSW (mm)	−0.16 (−0.29 to −0.03)	0.0132	−0.30 (−0.44 to −0.16)	<0.0001
Men				
OPA (mm^2)	0.04 (0.006 to 0.08)	0.0209	0.05 (0.01 to 0.08)	0.0078
mJSW (mm)	−0.06 (−0.28 to 0.15)	0.5684	–	–
Women				
OPA (mm^2)	0.006 (−0.01 to 0.02)	0.4880	–	–
mJSW (mm)	−0.24 (−0.41 to −0.07)	0.006	−0.41 (−0.58 to −0.23)	<0.0001

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, *CI* confidence interval, *OPA* osteophyte area, *mJSW* minimum joint space width

[a] Adjusted regression coefficients for change of scores were calculated by multiple regression analysis after adjustment for age, BMI, gender, grip strength, and pain score at baseline in the overall population and after adjustment for age, BMI, grip strength, and pain score at baseline in men and women

Table 6 Effect of OPA and mJSW at baseline on worsening of WOMAC physical function scores after 3 years

	Crude regression coefficient[b] (95 % CI)	*P* value	Adjusted regression coefficient[a] (95 % CI)	*P* value	Adjusted regression coefficient[b] (95 % CI)	*P* value	Standardized beta
Overall							
OPA (mm^2)	0.10 (0.05 to 0.14)	<0.0001	0.05 (0.002 to 0.10)	0.0393	0.01 (−0.04 to 0.06)	0.6078	0.01
mJSW (mm)	−1.44 (−1.84 to −1.04)	<0.0001	−1.14 (−1.58 to −0.69)	<0.0001	−1.10 (−1.57 to −0.63)	<0.0001	−0.14
Men							
OPA (mm^2)	0.18 (0.07 to 0.29)	0.0012	0.14 (0.03 to 0.26)	0.012	0.10 (−0.02 to 0.23)	0.1095	0.08
mJSW (mm)	−1.27 (−1.95 to 0.59)	0.0003	−0.93 (−1.65 to −0.21)	0.0113	−0.66 (−1.45 to 0.13)	0.1021	−0.08
Women							
OPA (mm^2)	0.08 (0.03 to 0.13)	0.0024	0.03 (−0.02 to 0.09)	0.2521	–	–	–
mJSW (mm)	−1.58 (−2.10 to −1.05)	<0.0001	−1.25 (−1.82 to −0.68)	<0.0001	–	–	

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index, *CI* confidence interval, *OPA* osteophyte area, *mJSW* minimum joint space width

[a] Adjusted regression coefficients for changes in physical function scores were calculated by multiple regression analysis after adjustment for age, BMI, gender, grip strength, and physical function score at baseline overall and after adjustment for age, BMI, grip strength, and physical function score at baseline in men and women

[b] Adjusted regression coefficients for changes in physical function scores were calculated by multiple regression analysis with age, BMI, gender, grip strength, OPA, mJSW, and physical function score at baseline as overall explanatory variables and with age, BMI, grip strength, OPA, mJSW, and physical function score at baseline as explanatory variables in men

The association of osteophytosis with QOL may be complex. Osteophytes may not have any primary effect themselves but rather serve as markers for factors that strongly affect QOL decline. First, osteophytosis appears to start from activation of periosteal layers, with initial generation of chondrophytes and subsequent calcification to real osteophytes. The process is probably an adaptive reaction of the joint to cope with joint instability, and thus, OPA may indicate the severity of joint instability [34], which might lead to pain and physical functional disability, particularly in men. In addition, it is possible that osteophytosis is strongly associated with patellofemoral disease [35], which is associated with knee pain [36]. This is an area where further research would be useful. Nevertheless, our results indicate that the presence or absence of osteophytosis, rather than joint space narrowing, is an appropriate method to predict QOL decline in men.

The present study revealed gender differences in the associations of osteophytosis and joint space narrowing with pain and physical functional disability. Joint space narrowing was an independent predictor for QOL decline measured by WOMAC pain and physical function scores in women, but not in men. Our previous cross-sectional study also showed that the odds ratio of knee pain for KL grade 3 or 4 knee OA was approximately twice as high in women as in men [4]. Considering the definition of KL grade [19], this finding may indicate that joint space narrowing is more strongly associated with pain in women than men. At the same time, osteophytosis is an independent predictor for QOL decline measured by the WOMAC pain and physical function scores in men, but not in women. As mentioned above, osteophytosis may represent joint instability or patellofemoral disease, which may be more strongly associated with pain and physical function than joint space narrowing due to cartilage loss in men. These findings may be partly explained by the lower muscle mass in women compared with men. Previous reports have shown that muscle mass is also associated with QOL [37, 38]. BMI also has different effect on QOL between men and women. To clarify the effect of muscle strength on the association of OPA, mJSW, and BMI with QOL, we classified subjects according to grip strength and examined the association of OPA, mJSW, and BMI with WOMAC pain score. In both men and women with strong muscle strength, OPA was associated with pain rather than mJSW or BMI, whereas in those with weaker muscle strength, mJSW and BMI were associated with pain rather than OPA. We also examined the association of OPA, mJSW, and BMI with WOMAC physical function score according to grip strength, and results were similar to those for pain. This means that muscle strength, rather than gender itself, may affect differences between men and women in the association of mJSW and OPA with QOL.

There is a limitation in the present study. We did not include other weight-bearing joints that can have OA, such as hip OA, in the analysis, although such disorders may also affect QOL decline. However, the prevalence of KL grade 3 or 4 hip OA is 1.4 and 3.5 % in Japanese men and women [39], respectively, which is much less than the prevalence of KL grade 3 or 4 knee OA (13.5 and 24.6 % in Japanese men and women, respectively) [4]. Thus, it is possible that hip OA would not strongly affect the results of the present study.

In conclusion, the present longitudinal study using a large-scale population from the ROAD study revealed that osteophytosis is a predictor for QOL decline in men. We also revealed gender differences in the association of osteophytosis and joint space narrowing with QOL decline. Future studies, along with longitudinal surveys in the ROAD study, will help further the understanding of osteophytosis and joint space narrowing mechanisms at the knee and their relationship with QOL.

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ORIGINAL ARTICLE

Serum levels of 25-hydroxyvitamin D and the occurrence of musculoskeletal diseases: a 3-year follow-up to the road study

N. Yoshimura · S. Muraki · H. Oka · K. Nakamura · H. Kawaguchi · S. Tanaka · T. Akune

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Abstract

Summary Assessment of serum 25-hydroxyvitamin D levels in association with the occurrence of musculoskeletal diseases using a population-based cohort study design revealed that serum 25-hydroxyvitamin D levels could predict the occurrence of osteoporosis at the femoral neck within 3 years, but not the occurrence of knee osteoarthritis or lumbar spondylosis.

Introduction The aim of this study is to clarify the association between serum 25-hydroxyvitamin D (25D) levels and occurrence of osteoporosis and osteoarthritis in the general population.

Methods The Research on Osteoarthritis/Osteoporosis Against Disability study, a large-scale population-based cohort study, was performed during 2005–2007. Serum 25D levels were measured in 1,683 participants. Of these, 1,384 individuals (81.9 %) completed a second follow-up survey 3 years later. Osteoporosis was defined according to World Health Organization criteria, in which osteoporosis is diagnosed by T-scores of bone mineral density (BMD) that are 2.5 standard deviations (SD) less than normal BMD. Knee osteoarthritis and lumbar spondylosis were defined as Kellgren–Lawrence grade ≥2, using paired X-ray films. Cumulative incidences were determined according to changes in measurements using World Health Organization criteria for osteoporosis or Kellgren–Lawrence grades for osteoarthritis between the baseline and second survey.

Results The mean (SD) serum 25D level of the 1,384 participants in both surveys was 23.4 ng/mL (6.5). The annual cumulative incidences of osteoporosis at L2–4 and the femoral neck were 0.76 and 1.83 %/year, respectively. The incidences of knee osteoarthritis and lumbar spondylosis were 3.3 and 11.4 %/year, respectively. After adjusting for potential associated factors, logistic regression analyses revealed that the odds ratio for the occurrence of femoral neck osteoporosis significantly decreased as serum 25D levels increased (+1 SD; odds ratio 0.67; 95 % confidence interval 0.49–0.92; $p=0.014$).

Conclusions Higher serum 25D levels may prevent the occurrence of osteoporosis at the femoral neck, but not knee osteoarthritis, lumbar spondylosis, or osteoporosis at L2–4.

Keywords 25-Hydroxyvitamin D · Epidemiology · Incidence · Osteoarthritis · Osteoporosis · Population-based cohort study

N. Yoshimura (✉) · H. Oka
Department of Joint Disease Research, 22nd Century Medical and Research Center, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan
e-mail: YOSHIMURAN-ORT@h.u-tokyo.ac.jp

S. Muraki
Department of Clinical Motor System Medicine, 22nd Century Medical and Research Center, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan

K. Nakamura · T. Akune
National Rehabilitation Center for Persons with Disabilities, 1, Namiki 4-chome, Tokorozawa City, Saitama Prefecture 359-8555, Japan

H. Kawaguchi
JCHO Tokyo Shinjuku Medical Center, 5-1, Tsukudo-cho, Shinjyuku-ku, Tokyo 162-8542, Japan

S. Tanaka
Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan

Introduction

As the average age of the human population is rapidly increasing, the development of methods to prevent musculoskeletal disorders that impair activities of daily life (ADLs) and quality of life (QOL) in the elderly has become an urgent need. Osteoporosis and osteoarthritis are major bone and joint health problems that cause impairment of ADL and QOL among the elderly and lead to increased morbidity and mortality in this population. The recent National Livelihood Survey performed by the Ministry of Health, Labour and Welfare in Japan [1] found that arthritis is ranked fourth, and falls and osteoporotic fractures are fifth among the diseases that cause disabilities requiring support and long-term care. Therefore, developing approaches to prevent osteoporosis and osteoarthritis could reduce the impairment of ADL and QOL and subsequent disabilities among the elderly.

Vitamin D influences bone quality and is important in maintaining bone density [2, 3]. A number of studies have reported an association between inadequate vitamin D intake and osteoporosis [4–7]. In contrast, no clear association has been found between vitamin D and osteoarthritis. An association between low levels of 25-hydroxyvitamin D (25D) and prevalent hip osteoarthritis was observed in cross-sectional studies [8, 9]. In addition, it has been shown that low serum 25D levels increased the risk of knee osteoarthritis progression [10] and incident hip joint space narrowing [11]. However, it has also been reported that serum 25D levels did not predict joint space narrowing or loss of cartilage volume of the knee [12] or clinically diagnosed knee or hip osteoarthritis [13].

In the present study, we performed a population-based cohort survey using the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study cohorts. The second ROAD survey, a 3-year follow-up survey that repeated the baseline examinations performed in the original ROAD study, has been completed. The aim of our study was to determine whether vitamin D inadequacy affects the occurrence of musculoskeletal diseases, including osteoporosis, knee osteoarthritis, and lumbar spondylosis.

Methods

Study participants

The present study was performed using the ROAD study cohorts established in 2005. The ROAD study is a national, prospective study of osteoarthritis that is made up of population-based cohorts from several communities in Japan. Details of the cohort profile have been reported elsewhere [14, 15]. In brief, between 2005 and 2007, a baseline database was created that included clinical and genetic information for 3,040 residents (1,061 men, 1,979 women; mean age, 70.3 years (SD 11.0), 71.0 years (10.7) in men, 69.9 years (11.2) in women) of Japan. The subjects were recruited from resident registration listings in three communities with different characteristics: 1,350 subjects from an urban region in Itabashi, Tokyo; 864 subjects from a mountainous region in Hidakagawa, Wakayama; and 826 subjects from a coastal region in Taiji, Wakayama. In the present study, we enrolled all 1,690 subjects (596 men, 1,094 women; mean age 65.2 years (12.0), 66.3 years (11.7) in men, 64.7 years (12.1) in women) from the mountainous and coastal regions who participated in the ROAD study. Bone mineral density (BMD) measurements and blood and urinary examinations were performed on the participants from the mountainous region and the coastal region.

The study participants provided written informed consent. The study was conducted with the approval of the ethics committees of the University of Tokyo (no. 1264 and no. 1326) and the University of Wakayama Medical University (no. 373).

Baseline assessment

Interviewer-administered questionnaire

Participants completed an interviewer-administered questionnaire that consisted of questions related to lifestyle, including occupation, smoking habits, alcohol consumption, family history, medical history, physical activity, reproductive history, and health-related QOL.

Dietary assessment

A brief diet history questionnaire (BDHQ) was administered to assess the diet of the participants, and nutrient intakes from the preceding month were determined. The BDHQ is a four-page structured questionnaire that includes questions about the frequency of consumption of 80 principal foods. The serving sizes of the foods are described as normal portions that are the standard weight and volume of servings commonly consumed by the general Japanese population. The BDHQ was modified from a comprehensive, 16-page validated self-administered diet history questionnaire [16]. A total of 141 variables, including dietary energy and nutrient intakes, were calculated using an ad hoc computer algorithm for the BDHQ. Detailed explanations accompanied each questionnaire. Well-trained interviewers clarified any unclear sections of the questionnaire, which was completed by the participants at their leisure.

Anthropometric measurements and medical history

Anthropometric measurements, including height and weight, were measured in all participants. Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared. Handgrip strength was measured using a Toei Light handgrip dynamometer (Toei Light Co., Ltd., Saitama, Japan). Both hands were tested and the larger value used to determine the maximum muscle strength of the subject. Experienced orthopedic surgeons collected medical information about pain, swelling, and range of motion of the knee.

Blood and urinary examinations

Samples were collected between the end of October and the middle of January from participants in the mountainous and coastal areas. All blood and urine samples were extracted between 09:00 and 15:00. After blood samples were centrifuged, the sera and urine samples were immediately placed on dry ice and transferred to a deep freezer within 24 h. Samples were stored at −80 °C until assayed.

Serum levels of 25D were measured using a radioimmunoassay with a ^{125}I-labeled tracer (DiaSorin, Stillwater, MN, USA) [17]. Intact parathyroid hormone (iPTH) levels were measured using an electrochemiluminescence immunoassay (Roche Diagnostics GmbH, Manheim, Germany). Serum N-terminal propeptide of type I procollagen (PINP), a marker of bone formation, was measured using a radioimmunoassay (Orion Diagnostics, Espoo, Finland). Urinary levels of β-isomerized C-terminal telopeptide cross-links of type I collagen (β-CTX), a marker of bone resorption, were determined using an enzyme-linked immunosorbent assay (Fujirebio, Inc., Tokyo, Japan). Urinary β-CTX values were standardized to urinary creatinine concentrations.

BMD examination

Lumbar spine and proximal femur BMD values were determined using dual-energy X-ray absorptiometry (DXA; Hologic Discovery; Hologic, Waltham, MA, USA)

X-ray examination

Plain radiographs of the lumbar spine in the anteroposterior and lateral views and both knees in the anteroposterior view with weight bearing and foot map positioning were obtained.

Three-year follow-up

Between 2008 and 2010, the 1,690 participants were invited to participate in the 3-year follow-up of the ROAD survey, which repeated the baseline examinations.

Definition of osteoporosis and osteoarthritis

Osteoporosis was defined according to World Health Organization criteria; osteoporosis was diagnosed when BMD T-scores were lower than peak bone mass by 2.5 standard deviations (SD) [18]. The mean (SD) for the L2–4 BMD in young adult men and women, as measured by the Hologic DXA in Japan, is 1.011 g/cm^2 (0.119) [19]. Therefore, osteoporosis of the lumbar spine was defined as an L2–4 BMD <0.714 g/cm^2. The mean (SD) BMDs of the femoral neck in young adult men and women are 0.863 g/cm^2 (0.127) and 0.787 g/cm^2 (0.109), respectively [19]. Therefore, osteoporosis at the femoral neck in men and women was defined as a femoral neck BMD <0.546 and <0.515 g/cm^2, respectively.

Knee and lumbar radiographs were read by a single experienced orthopedist who was blinded to participants' clinical status and were categorized using the Kellgren–Lawrence grading scale [20]: grade 0, normal; grade 1, slight osteophytes; grade 2, definite osteophytes; grade 3, disk space narrowing with large osteophytes; and grade 4, bone sclerosis, disk space narrowing, and large osteophytes. In the present study, a subject with at least one knee and at least one lumbar spine with a Kellgren–Lawrence grade ≥2 was defined as having radiographic knee osteoarthritis and lumbar spondylosis, respectively. When a different grade was assigned to each knee, the participant was classified to the higher grade. To examine intra-observer variability of Kellgren–Lawrence grading, 100 randomly selected radiographs of the knee were scored by the same observer 1 month after the initial reading. To determine inter-observer variability, 100 radiographs were scored by two experienced orthopedic surgeons using the same atlas. The Kellgren–Lawrence grade (0–4) intra- and inter-variabilities were confirmed by kappa analysis to be sufficient for assessment (κ=0.86 and κ=0.80, respectively).

Incidence of osteoporosis and osteoarthritis

Cumulative incidence of osteoporosis and osteoarthritis was determined on the basis of changes in measurements between the baseline and second survey. A new case of osteoporosis was identified if an individual's BMD values at baseline were not indicative of osteoporosis, but at follow-up, BMD T-scores were lower than peak bone mass by 2.5 SD. A new case of radiographic knee osteoarthritis was identified if the Kellgren–Lawrence grade at baseline was <2 for both knees and one or both knees were assigned a grade ≥2 at follow-up. A new case of radiographic lumbar spondylosis was identified if the Kellgren–Lawrence grade at baseline was <2 for all lumbar spines and at least one spine was assigned a grade ≥2 at follow-up.

Statistical analysis

All statistical analyses were performed using STATA statistical software (STATA Corp., College Station, TX, USA). Differences in proportions were compared using the chi-squared test. Differences in continuous variables were tested for significance using analysis of variance for comparisons among multiple groups or Scheffe's least significant difference test for pairs of groups.

Logistic regression analysis was used to test the association between serum levels of 25D and the occurrence of osteoporosis at L2–4, osteoporosis in the femoral neck, knee osteoarthritis, and lumbar spondylosis. In the analysis, we used the occurrence of musculoskeletal diseases, such as osteoporosis, knee osteoarthritis, and lumbar spondylosis, as the objective variable and serum levels of 25D (ng/mL, +1 SD) as an explanatory variable, after adjusting for age (+1 year), sex (0, men; 1, women), BMI (+1 kg/m^2), and regional differences (0, mountainous area; 1, coastal area). In addition, we adjusted for factors associated with serum levels of 25D that were identified previously [21]: month of examination (0, October, November, or December; 1, January), smoking (0, never; 1, current), alcohol consumption (0, never; 1, current), serum levels of iPTH (0, <65 pg/mL; 1, ≥65 pg/mL), and total energy from daily amount of intake (+100 kcal/day) and vitamin D (+10 μg/day), calculated based on the BDHQ questionnaire. Furthermore, we adjusted for potential risk factors, including variables regarding exercise, past history, and pain that showed a significant ($p<0.05$) association with the occurrence of each musculoskeletal disease in the simple linear analysis.

Results

Eligible participants

Of the 1,690 study participants, 25D levels were measured at baseline in 1,683 individuals (595 men, 1,088 women; mean age 65.3 years [12.0], 66.3 years [11.7] in men, 64.7 years [12.1] in women). A total of 1,384 individuals (81.9 %; 466 men, 918 women; mean age 66.8 years [11.8], 67.8 years [11.6] in men, 66.4 years [11.8] in women) completed the second follow-up survey that included BMD measurements and X-ray radiography. A total of 251 individuals (14.9 %; 104 men, 147 women) dropped out of the follow-up study. The reasons for the dropouts were as follows: 40 individuals (27 men, 13 women) died, 97 individuals (32 men, 65 women) were ill, 16 individuals (5 men, 11 women) moved away, 8 individuals (4 men, 4 women) were absent, 51 (24 men, 27 women) declined to participate in the second survey, and 39 (12 men, 27 women) had other reasons for not participating in the second survey, including lack of response to the invitation. In addition, 55 individuals (3.3 %; 26 men, 29 women) participated in the second survey, but not all measurements were obtained.

Annual incidence of musculoskeletal diseases

In order to estimate cumulative incidence of osteoporosis and osteoarthritis, participants who had previously been diagnosed with osteoporosis and osteoarthritis at baseline were excluded from the estimation for the incidence of each musculoskeletal disease. Of the 1,384 participants who completed both the baseline and follow-up surveys, 204 individuals who had been diagnosed with osteoporosis at L2–4 or who had been prescribed medication for the treatment of osteoporosis at baseline were excluded. Thus, cumulative incidence of osteoporosis at L2–4 was estimated using data from 1,179 participants. Similarly, cumulative incidence for osteoporosis of the femoral neck, knee osteoarthritis, and lumbar spondylosis was estimated using data from 1,187; 728; and 530 participants, respectively (Table 1).

In those participants who completed both the baseline and follow-up surveys, the annual cumulative incidence of osteoporosis of the lumbar spine and femoral neck was estimated to be 0.76 and 1.83 %/year, respectively. The annual cumulative incidence of knee osteoarthritis and lumbar spondylosis was estimated as 3.3 and 11.4 %/year, respectively. The age and sex distribution of the incidence for each musculoskeletal disease is shown in Fig. 1.

Baseline characteristics of participants and occurrence of musculoskeletal diseases during 3-year follow-up periods

The measured baseline characteristics of the study participants, including serum levels of 25D; anthropometric measurements; lifestyle factors such as residence, smoking, alcohol consumption, and exercise; and medical history of fractures, hip pain, and knee pain, are shown in Table 1.

Serum 25D values categorized according to the occurrence or non-occurrence of musculoskeletal diseases are shown in Table 1. The mean levels of serum 25D were significantly lower in the subjects with femoral neck osteoporosis than those who did not develop femoral neck osteoporosis ($p=0.0088$). In contrast, serum 25D levels did not differ significantly between the groups with or without the occurrence of osteoporosis at L2–4 ($p=0.16$). Serum 25D levels were higher in subjects with knee osteoarthritis and lumbar spondylosis when compared to those who did not have knee osteoarthritis or lumbar spondylosis, although there were no significant differences (knee osteoarthritis, $p=0.15$; lumbar spondylosis, $p=0.10$).

When the osteoporosis at L2–4 occurrence group was compared to the non-occurrence group, participants in the occurrence group tended to have lower BMI ($p=0.031$), were more likely to be women ($p=0.011$), and did not exercise frequently ($p=0.017$). Serum PINP and urinary β-CTX and CTX-II levels were significantly higher in the osteoporosis at L2–4 group than in the non-occurrence group (PINP, $p=0.0001$; β-CTX, $p=0.004$; CTX-II, $p=0.006$). Serum levels

Table 1 Comparison of baseline characteristics of individuals with occurrence or non-occurrence of musculoskeletal diseases during the 3-year follow-up period

	Population at risk (*n*=1,179)			Population at risk (*n*=1,187)			Population at risk (*n*=728)			Population at risk (*n*=530)		
	Occurrence (*n*=27)	Non-occurrence (*n*=1,152)	*p* (Occurrence vs non-occurrence)	Occurrence (*n*=65)	Non-occurrence (*n*=1,122)	*P* (Occurrence vs non-occurrence)	Occurrence (*n*=71)	Non-occurrence (*n*=657)	*P* (Occurrence vs non-occurrence	Occurrence (*n*=182)	Non-occurrence (*n*=348)	*P* (Occurrence vs non-occurrence)
Means (standard deviations) of serum levels of 25D (ng/mL)	21.7 (5.3)	23.5 (6.6)	0.1556	21.4 (5.5)	23.6 (5.5)	0.0088**	24.2 (6.5)	23.0 (6.6)	0.1493	23.1 (6.5)	22.1 (6.1)	0.1033
Mean values (standard deviations) of selected characteristics												
Age (year)	66.8 (8.9)	62.4 (11.8)	0.06	70.2 (9.0)	61.9 (11.5)	<0.0001***	67.3 (8.2)	58.2 (11.8)	<0.0001***	63.2 (10.8)	56.8 (12.5)	0.0059**
Height (cm)	151.9 (7.8)	157.0 (8.6)	0.0022**	151.4 (6.7)	157.2 (8.7)	<0.0001***	153.9 (8.6)	158.8 (8.6)	<0.0001***	154.3 (9.2)	155.2 (7.9)	0.26
Weight (kg)	50.6 (7.4)	57.7 (10.3)	0.0004***	49.0 (6.4)	58.1 (10.3)	<0.0001***	56.0 (8.8)	56.8 (11.0)	0.56	54.9 (9.7)	53.6 (9.5)	0.15
BMI (kg/m^2)	22.0 (3.0)	23.4 (3.3)	0.0312*	21.5 (3.2)	23.5 (3.3)	<0.0001***	23.6 (2.9)	22.4 (3.2)	0.0035**	23.0 (3.2)	22.2 (3.3)	0.0107*
Frequency of selected characteristics (%)												
Female sex	85.2	61.0	0.011*	84.6	60.6	<0.001***	74.7	58.6	0.009**	71.4	83.1	0.002**
Residing in a coastal area	48.2	56.4	0.39	52.3	56.4	0.52	70.8	56.3	0.012*	42.3	61.5	<0.001***
Current smoking habit (more than once a month)	3.9	13.7	0.15	5.0	13.8	0.05	7.1	16.9	0.034*	14.4	9.8	0.12
Current alcohol consumption (more than once a month)	40.7	44.3	0.71	20.3	45.0	<0.001***	64.8	52.1	0.041*	61.5	60.7	0.85
Regularly walking outside (less than once a week, including job)	11.5	21.3	0.23	19.7	20.2	0.92	29.0	23.0	0.27	22.9	22.7	0.940
Regularly exercising outdoors (football, tennis, baseball, golf, etc.) after graduation from the last school	0.0	17.6	0.017*	7.7	18.1	0.032*	7.0	19.9	<0.001***	12.6	13.5	0.780
History of osteoporotic fractures (hip, spine [clinical, symptomatic], shoulder, wrist)	7.4	2.9	0.17	2.5	4.6	0.30	7.0	2.0	0.009**	5.0	2.9	0.220
Visited the doctor owing to pain in the hip	0.0	4.5	0.32	4.08	3.83	0.93	5.7	4.3	0.67	2.6	5.3	0.230
Visited the doctor owing to pain in either knee	19.1	22.9	0.68	26.4	22.4	0.50	25.9	11.7	0.002**	25.9	17.9	0.050*
Month of examination (January)	22.2	26.8	0.59	32.3	26.2	0.28	42.3	23.1	<0.001***	43.4	26.7	<0.001***
Mean values (standard deviation) of serum and urinary biochemical markers												
Serum levels of iPTH (pg/mL)	40.6 (14.5)	40.7 (31.5)	0.99	43.4 (14.9)	40.9 (38.3)	0.6	40.8 (18.3)	42.0 (46.6)	0.83	41.5 (28.4)	42.4 (49.3)	0.83
Serum levels of PINP (µg/L)	76.1 (21.9)	56.1 (25.4)	0.0001***	73.5 (28.7)	56.5 (26.1)	<0.0001***	59.0 (26.9)	56.3 (27.2)	0.43	59.0 (27.1)	59.2 (28.2)	0.94
Urinary levels of β-CTX (µg/mmol Cr)	245.1 (90.4)	176.4 (121.9)	0.0037**	269.5 (138.6)	176.9 (124.4)	<0.0001***	199.7 (130.2)	170.8 (113.0)	0.0452*	2,11.9 (157.7)	193.6 (134.7)	0.17

Table 1 (continued)

	Population at risk (n=1,179)			Population at risk (n=1,187)			Population at risk (n=728)			Population at risk (n=530)		
	Occurrence	Non-occurrence	P	Occurrence	Non-occurrence	P	Occurrence	Non-occurrence	P	Occurrence	Non-occurrence	P
	(n=27)	(n=1,152)	(Occurrence vs non-occurrence)	(n=65)	(n=1,122)	(Occurrence vs non-occurrence)	(n=71)	(n=657)	(Occurrence vs non-occurrence)	(n=182)	(n=348)	(Occurrence vs non-occurrence)
Urinary levels of CTX-II (μg/mmol Cr)	327.4 (568.9)	224.8 (173.3)	0.0060**	248.9 (126.3)	223.1 (193.0)	0.29	237.5 (175.0)	189.3 (135.2)	0.0059**	207.6 (138.4)	193.6 (154.5)	0.31
Means (standard deviations) of daily nutrition intake												
Total energy (kcal/day)	1,778.1 (458.6)	1,980.9 (600.0)	0.08	1,800.2 (535.3)	1,982.5 (597.4)	0.0172*	1,963.6 (631.4)	1,964.9 (595.4)	0.99	1,945.9 (581.3)	1,815.9 (489.3)	0.0069**
Vitamin D (μg/day)	18.8 (9.3)	20.4 (12.5)	0.51	20.7 (11.0)	20.3 (12.5)	0.77	23.9 (12.3)	18.5 (11.7)	0.0003***	19.6 (11.0)	18.0 (11.3)	0.12

N number of subjects, *KL* Kellgren–Lawrence grade, *BMI* body mass index, *25D* 25-hydroxyvitamin D, *iPTH* intact parathyroid hormone, *PINP* procollagen type I N-terminal propeptide, *β-CTX* β-isomerized C-terminal telopeptide cross-links of type I collagen, *CTX-II* C-terminal cross-linked telopeptide type II collagen

*$p<0.05$; **$p<0.01$; ***$p<0.001$

of iPTH were not significantly associated with osteoporosis at L2–4.

When the osteoporosis at the femoral neck occurrence group was compared to the non-occurrence group, the participants who had osteoporosis at the femoral neck tended to be older ($p<0.0001$), tended to have lower BMI ($p\leq0.0001$), were more likely to be female ($p\leq0.001$), did not consume alcohol regularly ($p<0.001$), did not exercise regularly ($p=0.032$), and consumed less calories ($p=0.017$) than those in the non-occurrence group. Serum PINP and urinary β-CTX levels were significantly higher in the participants with osteoporosis at the femoral neck than in those who did not have osteoporosis at the femoral neck ($p<0.0001$). Serum levels of iPTH and urinary levels of CTX-II were not significantly associated with osteoporosis at the femoral neck.

When participants in the knee osteoarthritis occurrence group were compared to those who did not have knee osteoarthritis, those with knee osteoarthritis were older, had a higher BMI, were less likely to be female, resided in a coastal area, smoked less, consumed more alcohol, exercised less regularly, were more likely to have a history of osteoporotic fractures, and were more likely to have a history of medical visits because of knee pain. In addition, vitamin D levels were significantly higher in the participants with knee osteoarthritis than those in the non-occurrence group ($p=0.0003$). Although iPTH and PINP serum levels did not differ between the occurrence and non-occurrence groups, urinary β-CTX and CTX-II levels were significantly higher in the knee osteoarthritis occurrence group than those in the non-occurrence group (β-CTX, $p=0.045$; CTX-II, $p=0.006$).

Participants with lumbar spondylosis were older, had a higher BMI, were less likely to be female, and were more likely to have a history of past pain in either knee than the participants in the non-occurrence group. Although iPTH, PINP, β-CTX, and CTX-II levels were not different between those with lumbar spondylosis and those without, total daily energy intake was higher in the lumbar spondylosis group than in the non-occurrence group.

Logistic regression analysis between the occurrence of musculoskeletal disease and serum 25D levels

Logistic regression analysis was performed with the occurrence of musculoskeletal diseases, including osteoporosis, knee osteoarthritis, and lumbar spondylosis, as the objective variable and serum 25D levels (ng/mL, +1 SD) as the explanatory variable, after adjusting for age (+1 year), sex (0, men; 1, women), BMI (+1 kg/m^2), and regional differences (0, mountainous area; 1, coastal area). In addition, adjustments were made for factors previously shown to be associated with serum levels of 25D [20], including month of examination

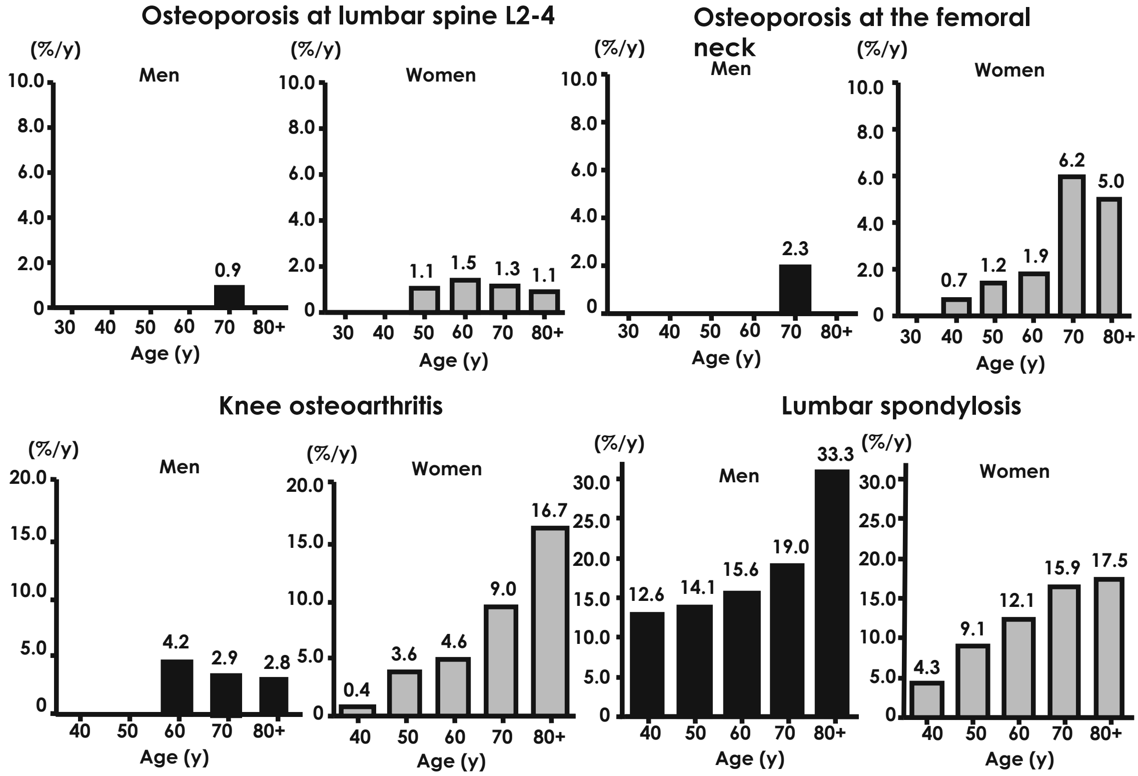

Fig. 1 Cumulative incidence (%/year) of musculoskeletal diseases (osteoporosis at the lumbar spine, osteoporosis at the femoral neck, osteoarthritis of the knee, and lumbar spondylosis) stratified by age and sex

(0, October, November, or December; 1, January), smoking (0, never; 1, current), alcohol consumption (0, never; 1, current), serum iPTH levels (0, <65 pg/mL; 1, ≥65 pg/mL), total daily energy intake (+100 kcal/day), and vitamin D (+10 μg/day) calculated according to responses on the BDHQ questionnaire. Furthermore, we adjusted for potential risk factors that showed a significant ($p<0.05$) association with the occurrence of each musculoskeletal disease in the simple linear analysis described in Table 2. Selected potential factors in each analysis were as follows: osteoporosis at L2–4, regularly exercising outdoors (0, yes; 1, no), serum levels of PINP (+1 SD), and urinary levels of β-CTX (+1 SD) and CTX-II (+1 SD); osteoporosis at femoral neck, regularly exercising outdoors (0, yes; 1, no), and urinary levels of β-CTX (+1 SD) and CTX-II (+1 SD); knee osteoarthritis, regularly exercising outdoors (0, yes; 1, no), history of osteoporotic fractures (0, no; 1, yes), history of knee pain (0, no; 1, yes), and urinary levels of β-CTX (+1 SD) and CTX-II (+1 SD); and lumbar spondylosis, history of knee pain (0, no; 1, yes).

After adjusting for potential risk factors, serum 25D levels were significantly associated with the occurrence of osteoporosis at the femoral neck (odds ratio 0.67; 95 % confidence interval 0.49–0.92; $p=0.014$). However, serum 25D levels were not significantly associated with the occurrence of knee osteoarthritis, lumbar spondylosis, or osteoporosis at L2–4.

Discussion

In the present study, using information from the population-based cohort ROAD study, we estimated the incidence of osteoporosis at L2–4 and at the femoral neck and found that higher serum 25D levels decreased the risk of future occurrence of osteoporosis at the femoral neck, but not the risk of osteoporosis at L2–4 or osteoarthritis, including knee osteoarthritis and lumbar spondylosis.

Previously, we have estimated the age–sex stratified cumulative incidence of knee osteoarthritis and lumbar spondylosis in the Japanese population, using the ROAD study of more than 2,200 subjects who participated at baseline and at the 3-year follow-up study and for whom paired radiographs and complete pain histories were obtained [22, 23]. In contrast, there are few reports estimating the incidence of osteoporosis diagnosed by BMD in the Japanese population [24, 25]. In the present study, we established the population-based cohorts of the ROAD study in identical areas to the previous studies and performed a baseline study between 2005 and 2007 and a follow-up study between 2008 and 2010. Using the data of 1,384 participants from both the baseline and follow-up studies, we estimated the annual cumulative incidence of osteoporosis at the spine L2–4 and at the femoral neck to be 0.76 and 1.83 %/year, respectively. Using the total age and sex

Table 2 Odds ratios of serum 25-hydroxyvitamin D levels influencing the occurrence of musculoskeletal diseases during the 3-year follow-up periods

		Occurrence of osteoporosis at the lumbar spine L2–4			Occurrence of osteoporosis at the femoral neck			Occurrence of knee osteoarthritis			Occurrence of lumbar spondylosis		
Explanatory variables	Reference (at the baseline)	OR	95 % CI	*p*	OR	95 % CI	*p*	OR	95 % CI	*p*	OR	95 % CI	*p*
Serum levels of 25D (ng/mL)	+1 SD	0.87	0.569–1.319	0.504	0.67	0.49–0.92	0.014*	1.23	0.90–1.69	0.198	1.01	0.81–1.28	0.900
Adjusted factors													
Age (year)	+1 year	1.05	1.00–1.09	0.043*	1.11	1.07–1.15	<0.001***	1.10	1.06–1.14	<0.001***	1.04	1.02–1.06	0.001**
Sex	0, men; 1, women	2.74	0.74–10.22	0.132	3.23	1.21–8.61	0.019*	3.24	1.24–8.45	0.016*	0.65	0.34–1.25	0.196
BMI	0, 18.5–27.5 vs 1, <18.5	3.65	0.96–14.34	0.064	8.89	3.33–23.77	<0.001***	1.00[a]	–	–	0.07	0.09–0.51	0.009**
	0, 18.5–27.5 vs 1, >27.5	0.41	0.05–3.17	0.394	0.15	0.02–1.17	0.071	2.29	0.80–6.58	0.125	2.17	1.06–4.45	0.033*
Month of examination	0, October, November, December vs 1, January	0.59	0.20–1.72	0.333	1.59	0.74–3.40	0.234	1.78	0.79–4.02	0.163	1.22	0.70–2.14	0.482
Residing region	0, mountainous area; 1, coastal area	0.71	0.28–1.81	0.467	1.69	0.80–3.58	0.171	1.18	0.53–2.64	0.688	0.71	0.42–1.20	0.197
Smoking	0, ex or never smoker; 1, current smoker	0.47	0.06–3.98	0.491	0.68	0.16–2.84	0.594	1.01	0.27–3.79	0.987	1.28	0.59–2.77	0.529
Alcohol consumption	0, ex or never drinker; 1, current drinker	1.64	0.68–3.94	0.271	0.72	0.34–1.54	0.396	0.83	0.40–1.70	0.604	0.83	0.50–1.37	0.459
Serum levels of iPTH (pg/mL)	0, <65 pg/mL; 1, ≥65 pg/mL	0.39	0.05–3.07	0.371	0.65	0.18–2.41	0.521	1.88	0.65–5.44	0.245	1.88	0.81–4.37	0.145
Total energy from daily food (kcal/day)	+100 kcal	1.00	0.90–1.11	0.991	0.93	0.86–1.01	0.101	1.01	0.94–1.08	0.768	1.04	0.98–1.10	0.179
Vitamin D from daily food (μg/day)	+10 μg	0.84	0.53–1.35	0.479	1.14	0.85–1.54	0.377	1.25	0.94–1.65	0.123	0.94	0.75–1.20	0.636
Selected adjusted factors													
Regularly exercising outdoors	0, yes; 1, no	1.00[a]	–	–	1.15	0.35–3.80	0.819	1.53	0.46–5.03	0.485	–	–	–
History of osteoporotic fractures	0, no; 1, yes	–	–	–	–	–	–	1.95	0.54–7.07	0.311	–	–	–
History of knee pain	0, no; 1, yes	–	–	–	–	–	–	1.84	0.87–3.92	0.111	1.11	0.75–1.20	0.636
Serum levels of PINP (μg/L)	+1 SD	1.51	1.00–2.26	0.040*	1.36	1.01–1.82	0.044*	–	–	–	–	–	–
Urinary levels of β-CTX (μg/mmol Cr)	+1 SD	1.05	0.69–1.61	0.802	1.18	0.91–1.51	0.206	0.76	0.512–1.13	0.176	–	–	–
Urinary levels of CTX-II (μg/mmol Cr)	+1 SD	1.09	0.83–1.44	0.528	–	–	–	1.41	0.96–2.07	0.076	–	–	–

OR odds ratio, *95 % CI* 95 % confidence interval, *25D* 25-hydroxyvitamin D, *BMI* body mass index, *iPTH* intact parathyroid hormone, *PINP* procollagen type I N-terminal propeptide, *β-CTX* β-isomerized C-terminal telopeptide cross-links of type I collagen, *CTX-II* C-terminal cross-linked telopeptide type II collagen

*$p<0.05$; **$p<0.01$; ***$p<0.001$

[a] Omitted from the model

population distributions from the Japanese 2010 census [26], our results indicate that approximately 450,000 people (50,000 men and 400,000 women) aged ≥40 years are affected by osteoporosis at L2–4 and that approximately 1,180,000 people (130,000 men and 1,050,000 women) aged ≥40 years are affected by osteoporosis at the femoral neck.

An association between inadequate vitamin D and osteoporosis has been reported previously. Deficiency of vitamin D results in decreased bone mineralization and secondary hyperparathyroidism and increased cortical bone loss and has been linked to the pathogenesis of osteoporosis and hip fractures [2, 3]. In addition, vitamin D supplementation may help to decrease fractures and falls [27, 28]. In a primary care cohort study of 1,470 postmenopausal Japanese women, there were trends of decreasing incidence of proximal femur and long bone fractures as serum 25D levels increased [29]. However, there are few reports that have assessed the predictive ability of serum 25D levels and the occurrence of osteoporosis itself. In the present study, we confirmed that higher serum 25D levels are associated with the prevention of osteoporosis occurrence, especially at the femoral neck.

There is conflicting information about the association of vitamin D and the occurrence of osteoarthritis. Few longitudinal studies have identified vitamin D deficiency as a risk factor for occurrence or progression of osteoarthritis. Specifically, Lane et al. reported that an increased risk of hip joint space narrowing is associated with low baseline serum 25D levels [11]. McAlindon et al. reported that an increased risk of knee osteoarthritis progression is associated with a low vitamin D intake or low serum 25D levels [10]. Bergink et al. reported that low dietary vitamin D intake increases the risk of progression of radiographic knee osteoarthritis [30]. In addition, cross-sectional studies have shown an association between low 25D levels and prevalent hip osteoarthritis [8, 9]. However, it has also been reported that low serum 25D levels do not increase the incidence of knee osteoarthritis. Felson et al. reported, using data from the Framingham Osteoarthritis Study cohort, that vitamin D status is unrelated to the risk of joint space or cartilage loss in knee osteoarthritis [12]. In addition, Kostari et al. followed a population of 805 subjects who participated in national health examination surveys held in 1978–1980 and 2000–2001 and found no significant association between serum 25D levels and the risk of incident knee or hip osteoarthritis [13]. Our study found no association between serum 25D levels and incident knee osteoarthritis. In addition, although no reports have examined the association between 25D and onset of lumbar spondylosis, we found no association between 25D and incident lumbar spondylosis.

In our previous report examining the association of vitamin D and musculoskeletal diseases at baseline [21], we found that the prevalence of osteoporosis at the L2–4 or at the femoral neck tended to be highest in the vitamin D deficiency group, followed by the vitamin D insufficiency and normal groups, although the groups did not differ significantly. The prevalence of knee osteoarthritis and lumbar spondylosis did not differ between vitamin D levels. In the present follow-up study using the same population, we found that higher levels of serum 25D prevented the occurrence of osteoporosis at the femoral neck, but not knee osteoarthritis or lumbar spondylosis, after adjusting for associated factors. This is the first study to confirm the association between 25D levels and the occurrence of musculoskeletal disorders, using the same population. Therefore, we concluded that the serum 25D levels would be useful in assessing the risk of future osteoporosis, but not the risk of future osteoarthritis.

There are several limitations to this study. First, although the ROAD study includes a large number of participants, these participants may not be representative of the general population. To address this, we compared the anthropometric measurements and smoking frequency and alcohol consumption between the study participants and the general Japanese population. No significant differences were found, with the exception that male ROAD study participants aged 70–74 years were significantly smaller than the overall Japanese population ($p<0.05$) [14]. This difference should be considered when evaluating potential risk factors for men aged 70–74 years. Second, we used Kellgren–Lawrence grade ≥2 as a criterion for the diagnosis of knee osteoarthritis and lumbar spondylosis. The Kellgren–Lawrence scale is a categorical index in which grade 2 is defined as definite osteophytes and grade 3 is defined as disk space narrowing with large osteophytes. Based on this scale, it would be difficult to evaluate osteophytosis and joint space narrowing separately. Thus, all cases of joint space narrowing, with and without the presence of osteophytosis, are categorized into the grade 3. Therefore, to evaluate the severity of knee osteoarthritis using quantitative parameters, a knee osteoarthritis computer-assisted diagnostic system [31] measuring minimum joint space width and area of osteophytosis is under development. In addition, a lumbar spondylosis computer-assisted diagnostic system is also under development. These systems will provide further accuracy in determining the association between the components of osteoarthritis including joint space and osteophytes and serum levels of 25D for early prevention of osteoarthritis. Finally, the measurement of the 25D level in the present study was measured on a single occasion. Thus, we could not exclude the effect of incidental life changes of participants, such as holidays or dietary changes that occurred around the examination date. Owing to budget and lack of manpower, we could not perform recurrent measurements of serum 25D levels to minimize fluctuations in 25D levels due to the effect of environmental factors. However, the large number of participants of the study means that the individual variance in serum 25D levels is diluted.

Importantly, the strength of the present study is that the participation rate in the follow-up survey was very high (81.9 %).

In conclusion, the present study revealed that serum 25D levels could predict the occurrence of osteoporosis at the femoral neck within 3 years, but not the occurrence of knee osteoarthritis or lumbar spondylosis. Raising serum 25D levels may be useful in the prevention of osteoporosis occurrence in the near future.

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Conflicts of interest Noriko Yoshimura, Shigeyuki Muraki, Hiroyuki Oka, Kozo Nakamura, Hiroshi Kawaguchi, Sakae Tanaka, and Toru Akune declare that they have no conflict of interest.

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ORIGINAL ARTICLE

Prevalence of diffuse idiopathic skeletal hyperostosis (DISH) of the whole spine and its association with lumbar spondylosis and knee osteoarthritis: the ROAD study

Ryohei Kagotani · Munehito Yoshida · Shigeyuki Muraki · Hiroyuki Oka · Hiroshi Hashizume · Hiroshi Yamada · Yoshio Enyo · Keiji Nagata · Yuyu Ishimoto · Masatoshi Teraguchi · Sakae Tanaka · Kozo Nakamura · Hiroshi Kawaguchi · Toru Akune · Noriko Yoshimura

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Abstract We aimed to assess the prevalence of diffuse idiopathic skeletal hyperostosis (DISH) and its association with lumbar spondylosis (LS) and knee osteoarthritis (KOA) using a population-based cohort study entitled Research on Osteoarthritis/osteoporosis Against Disability (ROAD). In the baseline ROAD study, which was performed between 2005 and 2007, 1,690 participants in mountainous and coastal areas underwent anthropometric measurements and radiographic examinations of the whole spine (cervical, thoracic, and lumbar) and both knees. They also completed an interviewer-administered questionnaire. Presence of DISH was diagnosed according to Resnick criteria, and LS and KOA were defined as Kellgren-Lawrence (KL) grade ≥3. Among the 1,690 participants, whole-spine radiographs of 1,647 individuals (97.5 %; 573 men, 1,074 women; mean age, 65.3 years) were evaluated. Prevalence of DISH was 10.8 % (men 22.0 %, women 4.8 %), and was significantly higher in older participants (presence of DISH 72.3 years, absence of DISH 64.4 years) and mainly distributed at the thoracic spine (88.7 %). Logistic regression analysis revealed that presence of DISH was significantly associated with older age [+1 year, odds ratio (OR): 1.06, 95 % confidence interval (CI): 1.03–1.14], male sex (OR: 5.55, 95 % CI: 3.57–8.63), higher body mass index (+1 kg/m^2, OR: 1.08, 95 % CI: 1.02–1.14), presence of LS (KL2 vs KL0: 1, OR: 5.50, 95 % CI: 2.81–10.8) (KL ≥3 vs KL0: 1, OR: 4.09, 95 % CI: 2.08–8.03), and presence of KOA (KL ≥3 vs KL0: 1, OR: 1.89, 95 % CI: 1.14–3.10) after adjusting for smoking, alcohol consumption, and residential area (mountainous vs coastal). This cross-sectional population-based study clarified the prevalence of DISH in general inhabitants and its significant association with LS and severe KOA.

Keywords Prevalence · Diffuse idiopathic skeletal hyperostosis · Knee osteoarthritis · Lumbar spondylosis · ROAD study

R. Kagotani · M. Yoshida (✉) · H. Hashizume · H. Yamada · Y. Enyo · K. Nagata · Y. Ishimoto · M. Teraguchi
Department of Orthopaedic Surgery, Wakayama Medical University, 811-1 Kimiidera, Wakayama 641-8509, Japan
e-mail: yoshimunenoriko@yahoo.co.jp

S. Muraki · T. Akune
Department of Clinical Motor System Medicine, 22nd Century Medical and Research Centre, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

H. Oka · N. Yoshimura
Department of Joint Disease Research, 22nd Century Medical and Research Centre, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

S. Tanaka · H. Kawaguchi
Department of Orthopaedic Surgery, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

K. Nakamura
Rehabilitation Services Bureau, National Rehabilitation Centre for Persons with Disabilities, Tokorozawa, Japan

Introduction

Diffuse idiopathic skeletal hyperostosis (DISH) is characterised by calcification and ossification of soft tissue such as entheses and joint capsules [1]. Resnick and Niwayama specifically defined DISH as the radiographic finding of calcification or ossification along the anterolateral aspects of at least 4 contiguous vertebral levels (across 3 disc spaces), with relative preservation of disc height in the involved vertebral segments and without degenerative disc disease [2]. In 1998, Mata and co-workers [3] developed a scoring system such that the presence of DISH could be assessed reproducibly. This system scores individuals who fulfill the Resnick criteria by numerically classifying each vertebral level based on the amount of ossification and whether partial or complete bridging of the disc space is present [3].

Although some reports have indicated a significant association between DISH and ossification of the posterior longitudinal ligament (OPLL) [4–7], DISH is thought to be an asymptomatic condition in many affected individuals; however, several clinical symptoms have been described including pain, limited range of spinal motion, and increased susceptibility to unstable spinal fractures after trivial trauma [8]. In addition, dysphagia and airway obstruction at the cervical levels [8, 9], as well as radiculopathy and spinal injury after spinal fracture [10–12], have been reported as clinical manifestations of DISH.

Although the condition is recognised in many parts of the world [13–20], there are relatively few population-based studies concerning its prevalence. Such data are important in order to characterise the burden of the disease. In addition, regarding its characteristics, several epidemiologic studies have reported that DISH is observed mainly in the elderly, and that prevalence increases with age [18, 19]. Men are affected by DISH much more frequently than women [20]. Although metabolic disturbance is hypothesised to be a factor [21, 22], the aetiology of the condition remains unknown.

Based on the definition of DISH as the radiographic finding of calcification or ossification, it appears that the condition might be associated with osteoarthritis (OA) of the spine. The severity of OA, as observed on radiography, was determined according to Kellgren-Lawrence (KL) grading as follows [23]: KL0, normal; KL1, slight osteophytes; KL2, definite osteophytes; KL3, joint or intervertebral space narrowing with large osteophytes; and KL4, bone sclerosis, joint or intervertebral space narrowing, and large osteophytes. KL2 is commonly used as the diagnostic criterion for lumbar spondylosis (LS) or OA at other sites. Thus, LS—defined as KL2 (defined as the definite presence of osteophytes)—could easily be associated with DISH. However, there are few reports to confirm the association between DISH and severe LS with the criterion of KL3 (defined as the presence of intervertebral space narrowing) or KL4 (defined as the presence of bone sclerosis). In addition, there are few reports to clarify the association between DISH and OA at other sites, such as the knees.

We conducted a survey, known as the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study, using a population-based cohortto determine the prevalence of DISH using lateral whole-spine radiography in recently examined subjects, which included men and women in Japan. Another aim of our study was to clarify the association of DISH with LS and knee osteoarthritis (KOA) based on KL grade.

Materials and methods

Outline of the ROAD study

We conducted the present study using the cohorts established in 2005 for the ROAD study—a nationwide, prospective study of OA comprising population-based cohorts in several communities in Japan. Details of the cohort profile have been reported elsewhere [24, 25]. Briefly, from 2005 to 2007, we developed a baseline database that included clinical and genetic information of 3,040 residents of Japan (1,061 men, 1,979 women) with a mean age of 70.3 (SD, 11) years [men: 71 (SD, 10.7) years, women: 69.9 (SD, 11.2) years]. Subjects were recruited from resident registration listings in three communities with different characteristics: 1,350 subjects (465 men, 885 women) from an urban region in Itabashi, Tokyo; 864 (319 men, 545 women) from a mountainous region in Hidakagawa, Wakayama; and 826 (277 men, 549 women) from a coastal region in Taiji, Wakayama.

Participants completed an interviewer-administered questionnaire of 400 items that included lifestyle information, such as occupation, smoking habits, alcohol consumption, family history, medical history, physical activity, reproductive variables, and health-related quality of life. The questionnaire was prepared by modifying the questionnaire used in the Osteoporotic Fractures in Men Study (MrOS) [26]; some new items also were added to the modified questionnaire. Participants were asked whether they took prescription medication daily or nearly every day (no = 0, yes = 1). If the participants did not know the reason for the prescribed medication, they were asked to bring their medication to the medical doctor (NY).

Anthropometric measurements, including height (cm), body weight (kg), arm span (cm), bilateral grip strength (kg), and body mass index (BMI, kg/m^2) were recorded for each patient. Medical information was recorded by experienced orthopaedic surgeons on systematic, local, and mental status, including information on back, knee, and hip pain; swelling and range of motion of the joints; and patellar and Achilles tendon reflexes.

Eligible subjects of the present study

In the ROAD study, radiographic examination of the thoracic spine was performed only in subjects in mountainous and coastal regions. These subjects also underwent blood and urinary examinations. In the present study, among 1,690 subjects (596 men, 1,094 women) in mountainous and coastal regions in the ROAD study, we excluded 43 whose radiograph quality was so poor that it was difficult to observe the sites of thoracic–lumbar junction and lumbosacral junction; thus, we analysed 1,647 participants (573 men, 1,074 women) ranging in age from 23 to 94 years (mean: 65.3 years, men: 66.3 years, women: 64.7 years).

Study participants provided written informed consent, and the study was approved by the ethics committees of the University of Wakayama Medical University (No. 373) and the University of Tokyo (No. 1264 and No. 1326).

Radiographic assessment

Plain radiographs of the cervical, thoracic, and lumbar spine in the anteroposterior and lateral views, and bilateral knees in the anteroposterior view with weight-bearing and foot-map positioning were obtained. DISH was diagnosed according to the following criteria, defined by Resnick and Niwayama [2]: (1) flowing ossification along the lateral aspect of at least 4 contiguous vertebral bodies, (2) relative preservation of intervertebral disc height in the involved segments, and (3) absence of epiphyseal joint bony enclosing and sacroiliac joint erosion. In the assessment of lateral radiographs, since it was difficult to read the C7/Th1 to T3/4 vertebral levels, 'whole spine' in the present study implies radiographs assessed from the C0/1 to C6/7, Th4/5 to Th12/L1, and L1/L2 to L5/S1 levels.

The radiographic severity of OA was determined according to the above-mentioned KL grade [20]. Radiographs of each site (i.e., vertebrae and knees) were examined by a single experienced orthopaedic surgeon (SM) who was blinded to the participants' clinical status. In the present study, the maximum grade, diagnosed in at least 1 intervertebral level of the lumbar spine or at least 1 knee joint, was regarded as the subject's KL grade.

Statistical analysis

All statistical analyses were performed using STATA statistical software (STATA Corp., College Station, TX, USA). Differences in proportions were compared using the Chi-square test. Differences in continuous variables were tested for significance using analysis of variance for comparisons among multiple groups or Scheffe's least significant difference test for pairs of groups.

To test the association between the presence of DISH and LS and/or KOA, we used logistic regression analysis. In the analysis, we used presence of DISH as the objective variable (absence = 0, presence = 1), and severity of prevalent LS (KL0, 1 = 0 vs. KL2 = 1; KL0, 1 = 0 vs. KL3 or 4 = 2) and KOA (KL0, 1 = 0 vs. KL2 = 1; KL0, 1 = 0 vs. KL3 or 4 = 2) as explanatory variables, in addition to basic characteristics such as age (+1 year), sex (men = 1, women = 0), BMI (+1 kg/m^2), and regional differences (mountainous area = 0, coastal area = 1). Other potential associated factors were selected with significant or marginal ($p < 0.1$) association with DISH status in a simple linear analysis. The selected explanatory variables for logistic regression analysis are described in the Results section.

Results

Prevalence of DISH was 10.8 % (men: 22.0 %, women: 4.8 %), and was significantly higher in men than in women. Figure 1 shows the prevalence of DISH according to age and sex. Prevalence increased with age in both men and women. Prevalence in subjects classified by age-strata—<50, 50–59, 60–69, 70–79, and ≥80 years—was 1.8, 11.7, 15.4, 32.6, and 39.6 % in men, and 0.7, 1.5, 3.5, 7.6, and 11.8 % in women, respectively.

Table 1 shows the baseline characteristics of the 1,647 participants with and without DISH. In total, subjects with DISH tended to be older, taller, heavier, and have higher BMI than those without DISH ($p < 0.0001$). In the comparison classified by sex, age was significantly higher in those with DISH in both men and women ($p < 0.0001$). In women, mean weight and BMI were significantly higher in those with DISH than in those without DISH (weight: $p < 0.05$, BMI: $p < 0.0001$).

Prevalence of DISH was lower in individuals residing in a coastal area. Individuals with DISH had a higher frequency of smoking and alcohol consumption ($p < 0.05$). The difference in the residing area was significantly observed in men. However, in the comparison classified by sex, differences in smoking and drinking were diluted (Table 1).

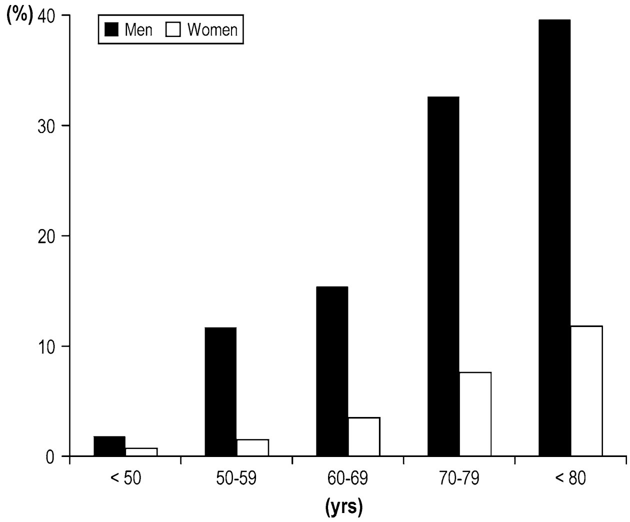

Fig. 1 Prevalence of diffuse idiopathic skeletal hyperostosis (DISH) according to sex and age

Table 1 Mean values (standard deviations) of the anthropometric measurements and the prevalence of lifestyle factors for the participants classified by presence or absence of DISH

	Total ($n = 1647$)			Men ($n = 573$)			Women ($n = 1074$)		
	DISH (−) $n = 1470$	DISH (+) $n = 177$	p	DISH (−) $n = 447$	DISH (+) $n = 126$	p	DISH (−) $n = 1023$	DISH (+) $n = 51$	p
Age (years)	64.4 (12.1)	72.3 (8.4)	<0.0001***	64.6 (12.1)	72.4 (8.2)	<0.0001***	64.3 (12.2)	71.9 (8.8)	<0.0001***
Height (cm)	154.7 (9.2)	158.6 (8.8)	<0.0001***	163.7 (7.3)	162.5 (6.7)	0.0918	150.8 (7.0)	148.9 (5.5)	0.0589
Weight (kg)	55.9 (10.6)	60.1 (10.5)	<0.0001***	62.3 (11.0)	62.1 (10.0)	0.8806	51.9 (8.8)	55.0 (10.3)	0.0126*
BMI (kg/m^2)	22.9 (3.4)	23.8 (3.3)	0.0005***	23.2 (3.2)	23.5 (2.9)	0.3378	22.8 (3.4)	24.7 (3.9)	0.0001***
Residing in the coastal area (%)	50.48	40.11	0.009**	50.3	35.7	0.004**	50.5	51.0	0.951
Current smoking habit (regularly, ≥1 month) (%)	11.9	21.3	<0.001***	29.9	29.0	0.858	3.8	2.0	0.506
Current alcohol consumption (regularly, ≥1 month) (%)	38.7	48.0	0.017*	68.5	61.1	0.122	25.7	15.7	0.108
Presence of LS (KL grade ≥2) (%)	59.1	93.8	<0.001***	72.0	94.4	<0.001***	53.4	92.2	<0.001***
Presence of LS (KL grade ≥3) (%)	35.6	48.0	0.001**	35.4	45.2	0.043*	35.7	54.9	0.005**
Presence of KOA (KL grade ≥2) (%)	48.2	65.5	<0.001***	35.5	58.7	<0.001***	53.8	83.3	<0.001***
Presence of KOA (KL grade ≥3) (%)	18.4	34.5	<0.001***	11.0	27.0	<0.001***	21.7	54.2	<0.001***

DISH diffuse idiopathic skeletal hyperostosis, *BMI* body mass index, *LS* lumbar spondylosis, *KOA* knee osteoarthritis, *KL grade* Kellgren-Lawrence grade

DISH (−) absence of DISH, *DISH (+)* presence of DISH

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 1 also shows the prevalence of LS and KOA defined by KL grade ≥2 and grade ≥3, according to DISH status. In total, the prevalence of LS was higher in those with DISH than in those without DISH ($p = 0.001$). A similar tendency was observed in the prevalence of KOA ($p < 0.001$). This tendency also was noted in the comparison classified by sex.

We classified subjects with DISH into 4 types: (1) cervical, ossification along the lateral aspect of at least 4 contiguous vertebral bodies only in the cervical region (C0/1–C6/7); (2) thoracic, ossification along the lateral aspect of at least 4 contiguous vertebral bodies only in the thoracic region (Th4/5–Th12/L1); (3) lumbar, ossification along the lateral aspect of at least 4 contiguous vertebral bodies only in the lumbar region (L1/2–L5/S1); and (4) diffuse, ossification along the lateral aspect of at least 4 contiguous vertebral bodies in more than 2 regions or through more than 2 regions. Table 2 shows the prevalence of DISH classified by location in the spine. A total of 89 % was shown to be thoracic, whereas the remaining was diffuse; there were no subjects with cervical-type or lumbar-type DISH.

Figure 2 shows the distribution of DISH classified by vertebral level (Th4/5–LS/S1). Among diffuse-type DISH, although 2 subjects had ossification in the cervical region, the cervical site is excluded from the figure. Figure 2 shows that ossification was observed mainly in the middle-lower thoracic sites (Th7/8–Th9/10).

Logistic regression analysis was performed with DISH as the objective variable, LS and KOA as explanatory variables, and patient characteristics including age, sex, BMI, regional differences, smoking, and alcohol consumption as potential risk factors. Presence of DISH was significantly associated with presence of LS (KL2 vs KL0: 1, KL ≥3 vs KL0: 1) and KOA (KL ≥3 vs KL0: 1). Among other potential associated factors, older age, male sex, and higher BMI remained as significantly associated with the presence of DISH (Table 3).

Table 2 Number (proportion, %) of DISH (+) patients classified by spinal ossification site

Type of DISH	Total	Men	Women
Cervical type	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Thoracic type	157 (88.7 %)	111 (88.1 %)	46 (90.2 %)
Lumbar type	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Diffuse type	20 (11.3 %)	15 (11.9 %)	5 (9.8 %)
Total	177 (100.0 %)	126 (100.0 %)	51 (100.0 %)

Cervical type: Ossification along the lateral aspect of at least four contiguous vertebral bodies existing only in the cervical region (C0/1–C6/7)

Thoracic type: Ossification along the lateral aspect of at least four contiguous vertebral bodies existing only in the thoracic region (Th4/5–Th12/L1)

Lumbar type: Ossification along the lateral aspect of at least four contiguous vertebral bodies existing only in the lumbar region (L1/2–L5/S1)

Diffuse type: Ossification along the lateral aspect of at least four contiguous vertebral bodies existing in more than 2 regions or through more than 2 regions

Finally, to clarify the association of DISH with LS and KOA, we performed logistic regression analysis using DISH as an objective variable, LS and KOA as explanatory variables, and patient characteristics including age, sex, BMI, regional differences, smoking, and alcohol consumption as potential risk factors. Presence of DISH was significantly associated with presence of LS (KL2 vs KL0: 1, KL ≥3 vs KL0: 1) and KOA (KL ≥3 vs KL0: 1) independently (Table 4).

Discussion

In the present study, using lateral whole-spine radiographs of recently examined population-based samples, we estimated that the prevalence of DISH was one-tenth of the population, which consisted of participants from the ROAD study. The subjects with DISH tended to be older and had bigger body build than those without DISH. In addition, DISH was observed more frequently in men than

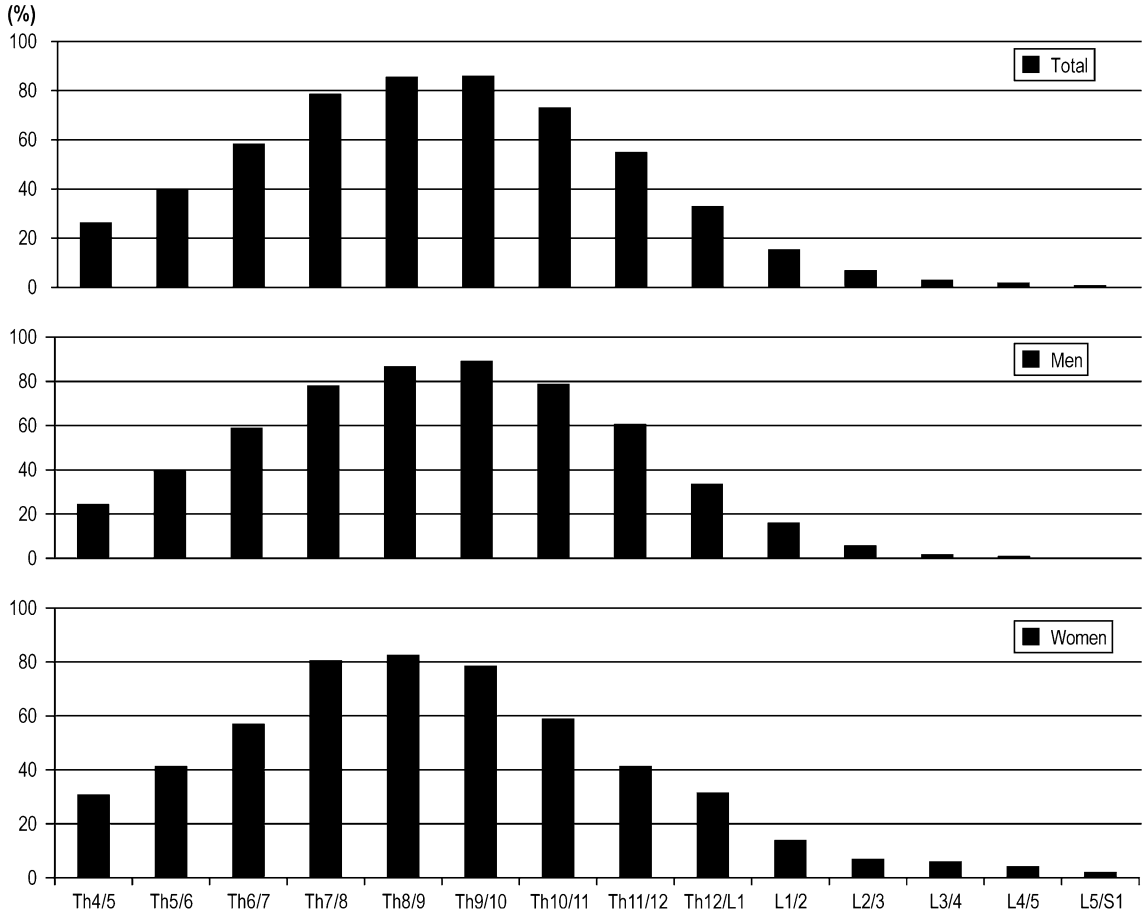

Fig. 2 Prevalence of diffuse idiopathic skeletal hyperostosis (DISH) in each vertebral level, classified by sex

Table 3 Odds ratios of lumbar spondylosis or knee osteoarthritis, and potentially associated factors for the presence of DISH vs. absence of DISH

Explanatory variables	Category	OR	95 % CI	*p*
Lumbar spondylosis				
Presence of LS	0: KL grade = 0, 1, 1: KL grade = 2	5.80	2.97–11.3	<0.001***
	0: KL grade = 0, 1, 2: KL grade ≥3	4.54	2.34–8.84	<0.001***
Age (years)	+1 year	1.07	1.05–1.09	<0.001***
Gender	1: men, 0: women	4.61	3.05–6.99	<0.001***
Region	0: mountainous area, 1: coastal area	0.88	0.61–1.26	0.475
BMI (kg/m^2)	+1 kg/m^2	1.11	1.05–1.17	<0.001***
Smoking	0: ex or never smoker, 1: current smoker	1.65	1.04–2.63	0.034*
Alcohol consumption	0: ex or never drinker, 1: current drinker	0.82	0.56–1.22	0.329
Knee osteoarthritis				
Presence of KOA	0: KL grade = 0, 1, 1: KL grade = 2	1.34	0.85–2.10	0.211
	0: KL grade = 0, 1, 2: KL grade ≥3	2.15	1.32–3.52	0.002**
Age (years)	+1 year	1.07	1.04–1.09	<0.001***
Gender	1: men, 0: women	6.90	4.48–10.6	<0.001***
Region	0: mountainous area, 1: coastal area	0.95	0.65–1.37	0.771
BMI (kg/m^2)	+1 kg/m^2	1.09	1.03–1.15	0.002**
Smoking	0: ex or never smoker, 1: current smoker	1.52	0.95–2.42	0.079
Alcohol consumption	0: ex or never drinker, 1: current drinker	0.85	0.58–1.26	0.431

DISH diffuse idiopathic skeletal hyperostosis, *BMI* body mass index, *LS* lumbar spondylosis, *KOA* knee osteoarthritis, *KL grade* Kellgren-Lawrence grade

OR odds ratios, *95 % CI* 95 % confidence interval

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 4 Odds ratios of lumbar spondylosis and knee osteoarthritis, and potentially associated factors for the presence of DISH vs. absence of DISH

Explanatory variables	Category	OR	95 % CI	*p*
Presence of LS (KL grade = 2)	vs. KL grade = 0, 1	5.50	2.81–10.8	<0.001***
Presence of LS (KL grade ≥3)	vs. KL grade = 0, 1	4.09	2.08–8.03	<0.001***
Presence of KOA (KL grade = 2)	vs. KL grade = 0, 1	1.22	0.77–1.92	0.404
Presence of KOA (KL grade≥ 3)	vs. KL grade = 0, 1	1.89	1.14–3.10	0.013**
Age (years)	+1 year	1.06	1.03–1.14	<0.001***
Gender	1: men, 0: women	5.55	3.57–8.63	<0.001***
Region	0: mountainous area, 1: coastal area	0.88	0.60–1.29	0.522
BMI (kg/m^2)	+1 kg/m^2	1.08	1.02–1.14	0.008**
Smoking	0: ex or never smoker, 1: current smoker	1.59	1.00–2.55	0.052
Alcohol consumption	0: ex or never drinker, 1: current drinker	0.81	0.54–1.21	0.298

DISH diffuse idiopathic skeletal hyperostosis, *BMI* body mass index, *LS* lumbar spondylosis, *KOA* knee osteoarthritis, *KL grade* Kellgren-Lawrence grade

OR odds ratios, *95 % CI* 95 % confidence interval

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

in women, and the most common site was the thoracic vertebrae. Presence of DISH was significantly associated with the presence of KOA and LS, after adjusting for potential associated factors.

There have been several epidemiologic studies on DISH in many parts of the world [12–19]. The results indicate that DISH is observed mainly in men and the elderly; prevalence increases with age, and it is distributed mostly in the thoracic spine. These results are supported by the results of the present study. However, there are considerable differences in the prevalence. Weinfeld et al. [20] reported that genetic or hereditary differences are important predisposing factors for DISH. Their previous study involved patients from ethnic populations, including 667 white, 144 black, 72 Native American, 11 Hispanic, and 30 Asian patients. They showed that the Asian, black, and Native American populations had a remarkably lower prevalence of DISH; however, their study population was small. In a recent study, Kim et al. [18] reported that race influences the prevalence of DISH. Their prevalence of DISH was 5.4 % in men and 0.8 % in women aged over 80 years in a Korean population, which is remarkably lower than the prevalence in our study, despite the similar race. Our prevalence was similarly high as the white population in Weinfield's report. Therefore, it is believed that genetic factors influence the prevalence of DISH more than race.

The present study clarified that most cases of DISH were observed in the thoracic vertebrae. There were no cases of DISH located in only the cervical or lumbar region. All cases of DISH in the cervical region were categorised as diffuse-type. Even if subjects were categorised into diffuse-type DISH, thoracic vertebrae were found to be the most affected. In addition, among the thoracic vertebrae, we found the predilection site to be the middle thoracic vertebrae (Th7–Th9). Holton et al. [27] reported that the distribution of the lowest level of DISH in 298 male subjects aged $\geq$65 years was 38 % in the thoracic region, 49 % in the thoracolumbar region, and 13 % in the lumbar region. It is interesting that DISH has predilection sites, which might be due to anatomic alignment of the vertebrae. For example, the middle thoracic vertebrae are likely to be affected by compressive mechanical stress because the Th8 is located nearly at the top in physiologic kyphosis. DISH originates mainly from the thoracic spine and extends to the cervical and/or lumbar spine by mechanical stress. In the present cross-sectional study, we could not evaluate whether DISH tends to occur in the thoracic vertebrae and then forms in the lumbar spine secondarily; however, we were able to follow-up on the ROAD study and clarify the disease course of thoracic DISH.

Regarding the definition of DISH, it might be easy to imagine that LS, defined by KL2 (defined as radiographically definite osteophytes), is associated with DISH. However, there are few reports to confirm the association between DISH and severe LS with the criterion of KL3 or 4. In the present study, we confirmed the significant association between DISH and LS, not only with the criterion of KL2, but also with KL $\geq$3. In addition, there are few reports to clarify the association between DISH and OA of other sites. In the present study, we also confirmed the significant association between DISH and KOA. In fact, the OR of the presence of DISH for KOA significantly increased according to the severity of KOA. The effects of LS and KOA coexisted independently. This result suggests that DISH and OA might be in a similar vein of disease, for example, the so-called 'bone proliferative group'. There have been several reports regarding the association between DISH and OPLL [4–7]. Resnick et al. [4] described 4 patients with coexisting DISH and cervical OPLL, and found OPLL in 50 % of 74 additional patients with DISH after reviewing their cervical spine radiographs. However, there has been no report on the association of DISH and OA; thus the etiology of ossification might not be similar to that of OA. Therefore, with only the results of the present study, we cannot definitely claim that DISH and OA are in a similar disease group, even though DISH tends to have similar associated factors, such as age, overweight (bigger BMI), and mechanical stress, as OA.

Another hypothesis is that there might be hidden associated factors that might affect both DISH and OA. We considered risk factors for metabolic syndrome as potential confounders. Several constitutional and metabolic abnormalities have been reported to be associated with DISH including obesity, large waist circumference, hypertension, diabetes mellitus, hyperinsulinemia, dyslipidemia, and hyperuricemia [21, 28–30]. In addition, both LS and KOA are well known to be associated with obesity [31]. We have already reported on the presence of hypertension and impaired glucose tolerance, and shown that the accumulation of metabolic risk factors is associated with the presence and occurrence of KOA [32, 33]. In addition, we found that current smoking, a known risk factor for cardiovascular disease as well as metabolic risk factors, was significantly associated with DISH. These findings may indicate that DISH is a candidate surrogate index for metabolic risk factors as a predictor of OA, or vice versa. We could not evaluate this hypothesis at present, but we would clarify the association including the causal relationships between DISH, OA, and metabolic risk factors in a further study.

Alternatively, we considered associated factors for inflammation or cartilage metabolic turnover as potential confounders between DISH and OA. These factors might coexist as risk factors for DISH and OA. Thus, there might be a direct or indirect pathway between DISH and OA via hidden associated factors, which should be investigated in a further study.

This study has several limitations. First, although the ROAD study includes a large number of participants, these subjects may not truly represent the general population. To address this, we compared the anthropometric measurements and frequencies of smoking and alcohol consumption between study participants and the general Japanese population; no significant differences were found, with the exception that male ROAD study participants aged 70–74 years were significantly smaller in terms of body structure than the overall Japanese population ($p < 0.05$)

[25]. This difference should be considered when evaluating potential risk factors in men aged 70–74 years; factors such as body build, particularly greater weight, are known to be associated with LS and KOA. Therefore, our results may be an underestimation of the prevalence of these conditions. Second, in the present study, we used only the data of the baseline study. Thus, we were not able to confirm a causal relationship between DISH status and other associated factors, as mentioned above. Nevertheless, we have performed a follow-up study, so we will be able to clarify the causal relationship between DISH status and OA in the near future. Third, this study could not evaluate the cervicothoracic junction (C7–Th4) because we assessed only radiographs. Although most cases of DISH existed in the inferior thoracic spine, as Fig. 2 shows, the lack of findings in the C7/C1–Th3/Th4 levels might have underestimated the prevalence of DISH. To evaluate the cervicothoracic junction, it would be necessary to use computed tomography or magnetic resonance imaging of the whole spine, which appeared impossible to perform on more than 1,600 subjects. Fourth, LS defined by KL2 may have been included in cases of DISH, but there is no method to confirm the overlap of the presence of DISH and LS of KL2 using the radiographic diagnostic criteria. DISH is observed mainly in the thoracic region, and only the diffuse type expands partly into the lumbar region. Therefore, there is a small possibility that LS of KL2 might be contaminated into DISH. Finally, in the present study, we could not evaluate other sites of OA besides the knee and lumbar spine, such as the hands or hip. To evaluate DISH and other sites of OA, we should evaluate the presence or occurrence of OA at other sites in a further study.

In conclusion, in the present population-based study, we found that the prevalence of DISH was 10.8 % in the overall population. Prevalence was significantly higher in older subjects, and mainly distributed at the thoracic spine. Logistic regression analysis revealed that the presence of DISH was significantly associated with older age, male sex, higher BMI, and presence of severe KOA.

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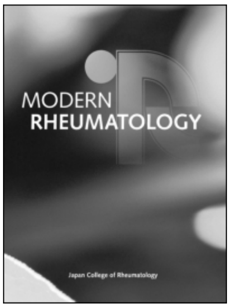

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ORIGINAL ARTICLE

The effect of cartilage degeneration on ultrasound speed in human articular cartilage

Satoru Ohashi[1,2], Isao Ohnishi[1], Hiroyuki Oka[3], Takuya Matsumoto[1], Masahiko Bessho[1], Kozo Nakamura[1], and Sakae Tanaka[1]

[1]*Department of Sensory & Motor System Medicine, Faculty of Medicine, The University of Tokyo, Tokyo, Japan,* [2]*Department of Orthopaedic Surgery, Sagamihara Hospital, National Hospital Organization, Sagamihara, Japan, and* [3]*Department of Joint Disease Research, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan*

Abstract

Objectives: We investigated the effect of cartilage degeneration on ultrasound speed in human articular cartilage *in vitro*.
Methods: Ultrasound speed was calculated by the time-of-flight method for 22 femoral condyle osteochondral blocks obtained from osteoarthritis patients. In parallel, histological evaluation of specimens was performed using the modified Mankin and OARSI scores.
Results: The mean ultrasound speed was 1757 ± 109 m/s. Ultrasound speed showed significant negative correlation with OARSI score, and a decreasing tendency with high Mankin scores. Good correlation was found between the optically measured and the calculated cartilage thickness.
Conclusion: Our results show that articular cartilage degeneration has relatively little influence on ultrasound speed. In addition, morphological evaluation of articular cartilage using a preset value of ultrasound speed seems to offer relatively accurate results.

Keywords

Cartilage degeneration, Cartilage thickness, Osteoarthritis, Ultrasonography, Ultrasound speed

History

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Introduction

Osteoarthritis (OA) of the knee is a condition characterized by morphological, biochemical, molecular, and biomechanical changes in both cells and the extracellular matrix, resulting in softening, fibrillation, ulceration, and eventual loss of articular cartilage [1]. In clinical practice, plain radiography is typically used to evaluate the stage of OA [2,3]. However, this method does not allow direct imaging of the cartilage, because it only evaluates the distance between the femoral and tibial bone surfaces, and the presence of osteophytes and sclerosis of the subchondral bone. Direct imaging of cartilage has been achieved using magnetic resonance imaging (MRI), which allows morphological evaluation of articular cartilage, including the determination of cartilage thickness and volume [4], and identification of cartilage degeneration [5].

In addition to MRI, ultrasonography has also been investigated for applications allowing the direct evaluation of articular cartilage, including degenerative changes in cartilage [6] and cartilage surface roughness [7]. Ultrasonography was also used in previous investigations to visualize articular cartilage and evaluate cartilage thickness, either directly on the surface of cartilage [8,9] or percutaneously [10–12]. In these studies, the set-up speed value of the diagnostic ultrasound device (1540 m/s) was used for the calculation of cartilage thickness [13]. Theoretically, however, for quantification of cartilage thickness or volume using ultrasonography, the actual ultrasound speed in each articular cartilage should be measured, since the speed of sound might differ among tissues, and thus affect the calculations [14].

Studies have been performed in articular cartilage to investigate the effect of degeneration and other factors on ultrasound speed, mostly using animal samples [15]. These studies have shown that the speed of sound in cartilage can be affected by composition [16,17], material properties [17,18], or mechanical strain [19–21], as well as by orientation of collagen fibrils [22] or anisotropy [23] of articular cartilage. Cartilage ultrasound speed can also be affected by external factors, such as the ultrasound beam angle against the cartilage surface [24], and temperature or saline concentration [23].

Some studies have investigated ultrasound speed in human articular cartilage. Based on experimental results on bovine cartilage and the results of a previous study on human cartilage, Toyras et al. [17] performed simulations investigating the relationship between the speed of sound, cartilage thickness, and the error in dynamic modulus; they suggested that a constant speed of sound can be utilized to obtain a clinically acceptable accuracy for cartilage thickness and modulus. However, relatively variable mean values for ultrasound speed have been reported in human articular cartilage (1658 m/s [25], 1892 m/s [26], ca. 1580 m/s [20]). In bovine cartilage, ultrasound speed decreases as the cartilage degenerates through chemical treatment [17]. In addition, ultrasound speed in cartilage of OA patients was reported to be lower than in normal cartilage [25]. Since it would be difficult to measure a patient-specific value of ultrasound speed in cartilage and apply this value for each patient during clinical morphological

Correspondence to: Satoru Ohashi, Department of Sensory & Motor System Medicine, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan and Department of Orthopaedic Surgery, Sagamihara Hospital, National Hospital Organization, 18-1 Sakura-dai, Minami-ku, Sagamihara, Kanagawa 252-0315, Japan. Tel: +81 427428311. Fax: +81 427425314.
E-mail: soohashi-tky@umin.ac.jp

evaluation of cartilage, the relationship between ultrasound speed and the degree of degeneration in human cartilage warrants further investigation.

The aim of this study was to perform measurements of ultrasound speed, histologically score the degeneration in human cartilage samples, and to investigate the correlation between cartilage degeneration and ultrasound speed, in order to investigate the feasibility of using a constant value of speed in morphological evaluation of articular cartilage by ultrasound.

Methods

Cartilage sample preparation

All procedures used in this investigation were approved by the institutional review board at our university. Subjects comprised 11 OA patients who planned to undergo total knee arthroplasty and provided written informed consent prior to participation in the study. All the patients were female, with an average age of 73.2 ± 8.0 years (range: 56–83 years). Pre-operation plain radiographs showed that the Kellgren–Lawrence score [27] of all the patients was grade 4. Osteochondral blocks removed from the medial and lateral femoral condyles during operation were wrapped in gauze moistened with normal saline, packed in plastic bags, manually degassed, hermetically sealed, and stored at $-60\,^{\circ}$C. A total number of 22 osteochondral blocks from femoral condyles were acquired from the patients through operations. On the day of the experiment, the osteochondral samples were thawed in normal saline solution (Otsuka Pharmaceutical, Tokyo, Japan) at room temperature ($20\,^{\circ}$C). Osteochondral blocks from the femoral condyle were trimmed by a band saw (SWD-250; Fuijiwara Sangyo, Miki, Japan), achieving a surface size of approximately 18 mm $\times$ 18 mm for cartilage samples. Trimming was performed to obtain a sample containing sufficient quantities of cartilage for the acoustic and microscopic measurements, preferably from the part of the block closest to the weight-bearing area. Samples were then fixed on a custom-made acryl sample holder (30 mm $\times$ 30 mm $\times$ 13 mm; Murai & Co., Tokyo, Japan) with resin (GC-Ostron; GC Corporation, Tokyo, Japan) (Figure 1). During preparation, samples were continuously cooled at $20\,^{\circ}$C and moistened using normal saline solution.

Acoustic measurements

Acoustic measurements were performed using a custom-made apparatus (Figure 1). The acryl holder with the human osteochondral block affixed was positioned in a water tank containing normal saline ($20\,^{\circ}$C), so that the cartilage surface faced upward. A stage underneath, with three micrometers (accuracy, 10 μm), allowed horizontal movement of the sample. Two micrometers, perpendicular to each other in the horizontal plane, were used for position adjustment by linear movement (*x*- and *y*-axes). The third micrometer enabled circular movement in the horizontal plane (rotation movement in the *x–y*-plane). An ultrasound transducer was placed over the sample in the water tank, and the holder of the transducer had a *z*-adjustment device so that the distance between the cartilage surface and the transducer could be kept at the transducer focus distance (2.5″=63.5 mm).

Ultrasound measurements were performed using the A-mode pulse-echo method and a focused non-contact ultrasound transducer (V311-SU; Olympus NDT, Waltham, MA) (center frequency = 7.3 MHz, 3.4–11.2 MHz, −3 dB; transducer tip diameter = 16 mm; element diameter = 13 mm; radius of curvature = 63.5 mm). Acoustic pulses were excited electrically using a pulser/receiver board (NDT-5800; Olympus NDT). Echoes of the transmitted pulse were recorded with the transducer and pulser/receiver board. A bandpass filter (1.0–20.0 MHz) was used to enhance the ultrasound signal-to-noise ratio. The signal was digitized at a 1000-MHz sampling frequency using an oscilloscope (DPO4034; Tektronix Japan, Tokyo, Japan).

For acoustic measurements, the edges and the center point of the 30 mm $\times$ 30 mm acryl sample holder surface were first identified by moving the stage horizontally under the fixed ultrasound beam. The cartilage surface was then scanned with the ultrasound transducer by moving the stage to identify the top cartilage surface point (point C) (Figure 2). The ultrasound beam was, theoretically, perpendicular to the cartilage surface at this point, as the cartilage of the femoral condyle has a convex surface. After identifying the coordinates for this point as (a, b), two additional points at 1 mm apart on each side of this point were set as radiofrequency signal acquisition points, along with point *C*. The *x–y* coordinates of the two points were thus (a+1, b), (a−1, b) using units of 1 mm.

RF signals at these three points were acquired and output from the oscilloscope device as comma-separated values data. Time of flight was measured in each sample using the peak envelope method previously described [28] (Figure 3). The envelope of each RF signal was calculated using a Hilbert transform [29]. Peaks of the envelope signal were attributed to reflections occurring at the cartilage surface and at the cartilage-bone interface. Time of flight was defined as the duration (Δt) between peaks, corresponding to the travel time of the ultrasound pulse back and forth between the cartilage surface and the cartilage-bone interface of the specimen.

Microscopic optical thickness measurement and calculation of ultrasound speed

In order to measure cartilage thickness, direct optical measurement using microscopy was performed on a cross-section of the sample. The acryl holder with the osteochondral sample was attached to the holding arm of a diamond saw device (Minitom; Struers, Cleveland, OH) such that the saw blade was vertical to the holder top surface, that is, vertical to the *x-y* plane of the sample coordinates and parallel to the *y*-axis. By adjusting the position of the arm within an accuracy of 10 μm, cut planes were created, each containing 3 RF signal acquisition points. Subsequently, each cut sample was mounted on a glass slide and covered with a cover glass after dripping normal saline onto the sample surface, to keep the cartilage moist and inhibit deformation due to drying during measurement.

Cartilage thickness [4] was measured using an optical measuring microscope (×30 magnification) (MM-400; Nikon, Tokyo, Japan) containing an eyepiece with adjustable crosshairs, and an adjustable stage system (MHS 2 $\times$ 2; Nikon) (Figure 4). With the optical measuring microscope and the stage, the center point of the sample holder could be identified by measuring the distance from both edges of the sample holder, and then the RF signal acquisition points could be determined in a similar manner. The microscope could also align the sides of the sample holder, which were parallel to the direction of the ultrasound beam in RF signal acquisition, to the direction of thickness measurement. After these adjustments, cartilage thickness (d_C) along the beam direction was measured at each RF acquisition point, and the speed of sound in cartilage (SOS_C) at each point was calculated as follows:

$$SOS_C = \frac{2d_C}{\Delta t}. \quad (1)$$

Histological evaluation

Each osteochondral sample was fixed in 4% paraformaldehyde phosphate buffer solution (Wako Pure Chemical Industries, Osaka,

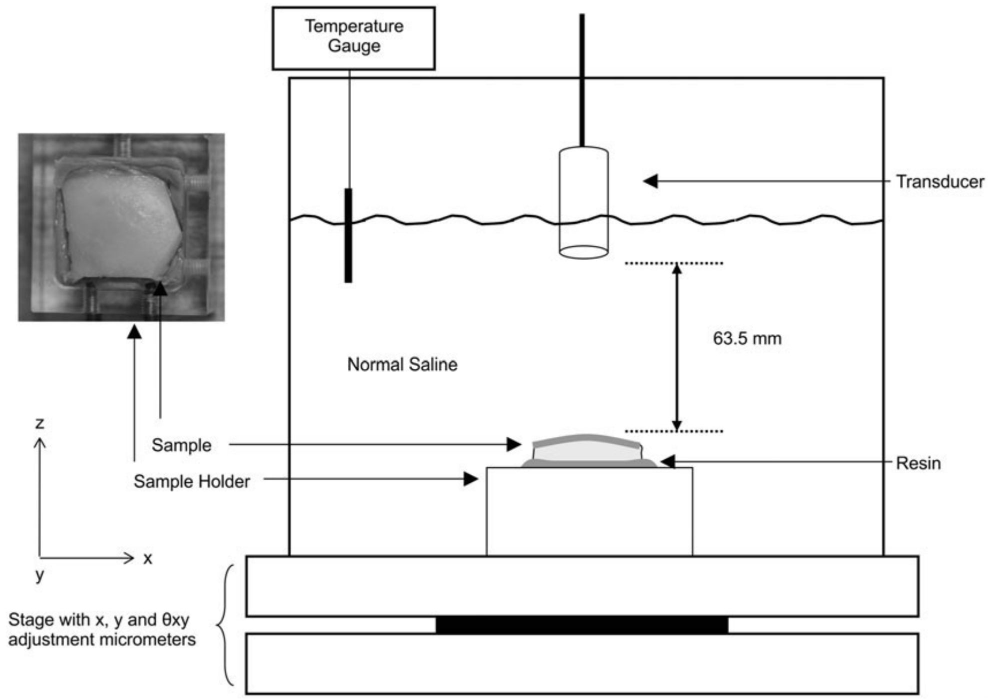

Figure 1. Custom-made apparatus for acoustic measurements. A human cartilage sample with subchondral bone was immersed in normal saline and fixed on the sample holder by resin. The water tank has a stage underneath with three micrometers (*x*-, *y*- directions and rotation movement in the *x*–*y* plane) to allow horizontal movement of the sample.

Japan) for 4 days, followed by decalcification with Plank-Rychlo's Solution composed of 0.3 M aluminum chloride, 3% hydrochloric acid, and 5% formic acid for 36 h. After decalcification, all specimens were dehydrated with ethanol, embedded in paraffin and sectioned by microtome with a thickness of 4 μm. Fast Green and Safranin O stainings were performed, and specimens were histologically evaluated using the modified Mankin score [30,31] and the Osteoarthritis Research Society International (OARSI) score [32] by two well-experienced examiners (Tables 1 and 2) (Figure 5). Histological evaluation was carried out twice by each examiner with an interval of two weeks and the mean score was used for statistical analysis.

Statistical analysis

SOS_C was defined as the mean ultrasound speed of the three acoustic measurement points in each sample. In order to assess the reliability of the histological evaluation, intraclass correlation coefficients (ICCs) comparing the first and second histological scores of each examiner were evaluated for intraobserver reliability. In addition, ICC calculation and linear regression analysis were performed to assess interobserver reliability, comparing the mean of the first and second histological scores of the specimens between the two examiners.

Spearman's rank correlation coefficient between SOS_C and the histological scores of the first examiner's first scoring as well as the correlation coefficient between SOS_C and d_C were calculated to investigate the influence of cartilage degeneration and cartilage thickness on ultrasound speed. Correlation analysis was also performed between d_C and histological scores to investigate the degree of confounding between them. In addition, to investigate the feasibility of using a preset value of ultrasound speed in thickness measurements of articular cartilage using ultrasound, linear regression analysis and Bland–Altman plot analysis were performed between optical thickness measurement values

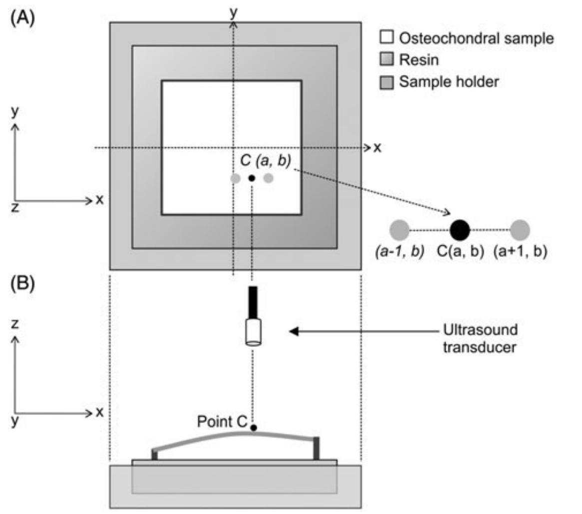

Figure 2. (A) The cartilage surface point closest to the transducer (point *C*) was acoustically identified. (B) With point *C* as the center point, radiofrequency signals were acquired at three points, each 1 mm apart. Units in the figure are 1 mm.

(d_C-optical) and thickness values calculated from time of flight using the average ultrasound speed of this study (d_C-US).

Statistical analysis was performed using IBM SPSS Statistics version 21.0 software (IBM, Armonk, NY), and results were considered significant for values of $p < 0.05$.

Results

In all RF signals, peaks of the reflected ultrasound wave envelopes from the cartilage surface and the cartilage-bone interface were clear enough to be identified. The mean SOS_C of all articular

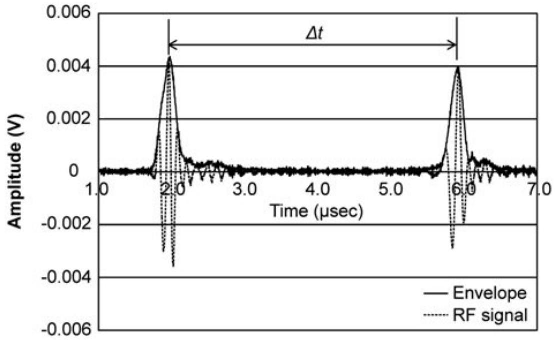

Figure 3. The graph shows an example of the radiofrequency [30] signal wave and the envelope wave calculated from the RF signal. Time of flight (Δt) was defined as the duration between peaks of the envelope wave.

cartilage samples was 1757 ± 109 m/s. The mean standard deviation calculated from the standard deviation of the three-point ultrasound speed values of individual samples was 55.2 m/s. The mean coefficient of variance calculated from each sample's SOS_C and standard deviation of the three-point ultrasound speed values was 3.2%.

ICCs for intraobserver reliability of examiner 1 and examiner 2 were 0.888 [95% confidence interval (CI), 0.753–0.952] and 0.914 (95% CI, 0.807–0.963) [overall, 0.904 (95% CI, 0.832–0.947)] for the modified Mankin score, and 0.927 (95% CI, 0.834–0.969) and 0.945 (95% CI, 0.874–0.977) [overall, 0.935 (95% CI, 0.885–0.964)] for the OARSI score, respectively. ICCs for interobserver reliability were 0.717 (95% CI, 0.438–0.871) for the modified Mankin score, and 0.965 (95% CI, 0.919–0.985) for the OARSI score. Significant linear correlation was noted between the histological scores of the two examiners by linear regression analysis ($r = 0.783$; root mean square error, 1.87; $p < 0.01$; slope, 1.24 for the modified Mankin score and $r = 0.967$; root mean square error, 0.310; $p < 0.01$; slope, 1.05 for the OARSI score).

The scatter plots for SOS_C and histological scores are shown as Figure 6. SOS_C showed a decreasing tendency with high modified Mankin scores ($r = -0.330$; $p = 0.134$), and significantly correlated with the OARSI score ($r = -0.483$; $p < 0.05$). In addition, SOS_C showed a significant positive correlation with cartilage thickness ($r = 0.484$, $p < 0.05$). There were no significant correlations between cartilage thickness and the modified Mankin score ($r = -0.253$; $p = 0.256$) or OARSI score ($r = -0.420$; $p = 0.052$).

Using the average SOS_C value, linear regression analysis showed a significant correlation between cartilage thickness measured optically and cartilage thickness calculated by time of flight (Figure 7A) ($r = 0.959$; root mean square error, 0.194 mm; $p < 0.01$; slope, 1.053). Bland–Altman plots showed a mean difference of 0.0478 mm with a standard deviation of 0.188 mm between d_C-optical and d_C-US (Figure 7B).

Discussion

Several studies have measured ultrasound speed in human articular cartilage, reporting a relatively wide range of values (1658 and 1581 m/s for normal and OA femoral cartilage, respectively [25]; 1892 m/s for the ankle joint and hip joint cartilage of one patient [26]; and ca. 1580 m/s for patellar cartilage [20]). Since cartilage degeneration has been reported to influence ultrasound speed in articular cartilage in animal studies, degeneration might be one of the reasons behind the observed differences [17,33]. We performed ultrasound speed measurements in human articular cartilage and investigated the influence of cartilage degeneration on ultrasound speed. As a result, we obtained a mean ultrasound speed of 1757 m/s, which is comparable to values reported for human articular cartilage in a previous study [26], but is higher than measurements in two other studies [20,25], including one conducted on femoral cartilage. A possible reason accounting for this discrepancy could be swelling of the cartilage during cross-sectioning. Moreover, the cartilage sample preparation steps, such as freezing, storage, thawing, and immersion in saline, could also have contributed to the discrepancy. Although we confirmed that cartilage thickness did not change after cross-sectioning, by covering the cross-section surface with a cover glass and performing the same procedures on all the samples, we cannot exclude the possibility that swelling of the cartilage during cross-sectioning, or change of propagation properties through sample preparation, might have occurred, resulting in higher ultrasound speed values.

Since we wanted to evaluate the reliability of our method on human cartilage, we performed cartilage thickness measurements by acquisition of RF signals at three points. The mean standard deviation and the mean coefficient of variance calculated for each osteochondral sample were relatively low (55.2 m/s and 3.2%, respectively) compared with the coefficient of variance of this method published for animal cartilage (3.4% for a 6-month-old pig and 6.4% for a 3-year-old pig) [28]. However, although we validated the accuracy of the cartilage thickness measurements by cross-sectioning using the custom-made devices described in a previous study involving micro-CT [28], it would be ideal to use a less invasive method, such as the needle probe method [33–35] or the custom-made ultrasound probe method [20,21], with which more ultrasound speed measurement points can be acquired and SOS_C could be more accurate.

Ultrasound speed showed a significant negative correlation with OARSI scores used for the histological evaluation, decreasing with higher degrees of cartilage degeneration. The present study is the first to report these findings in human cartilage samples. Ultrasound speed also decreased with cartilage degeneration assessed by the modified Mankin score, although the trend was not significant. The trend between the ultrasound speed and cartilage degeneration was compatible with results of previous studies on animal cartilage [17,33]. Treatment of bovine articular cartilage with trypsin for 4 h, resulting in the digestion of proteoglycan and minor cleavage of collagen, decreased ultrasound speed [33]. In bovine articular cartilage samples obtained from different locations, ultrasound speed decreased with Mankin score and water content but increased with uronic acid and hydroxyproline levels [17]. Nevertheless, a constant speed of sound was suggested to provide a clinically acceptable accuracy for cartilage thickness (error: 7.8%) in that study.

Several factors could have affected ultrasound speed in the present study. Uronic acid and hydroxyproline levels have been reported to be lower in degenerated cartilage than in normal cartilage [36]. Amide I-rich areas in the superficial layer and carbohydrate-rich areas in the whole layer have been observed to be decreased in the human OA samples [37]. These factors might have caused changes in the acoustic properties of cartilage with age, as was also observed in a study using rat articular cartilage [38].

Instead of evaluating individual components of cartilage degeneration, we performed histological scoring, in order to ensure that we investigate the overall effect of cartilage degeneration on ultrasound speed. Mankin score has been previously reported to negatively correlate with the uronic acid and hyaluronic acid content of articular cartilage [39]. In the present study, however, the OARSI score showed a better correlation with ultrasound speed than the modified Mankin score, which we believe is an interesting finding of the two different histological

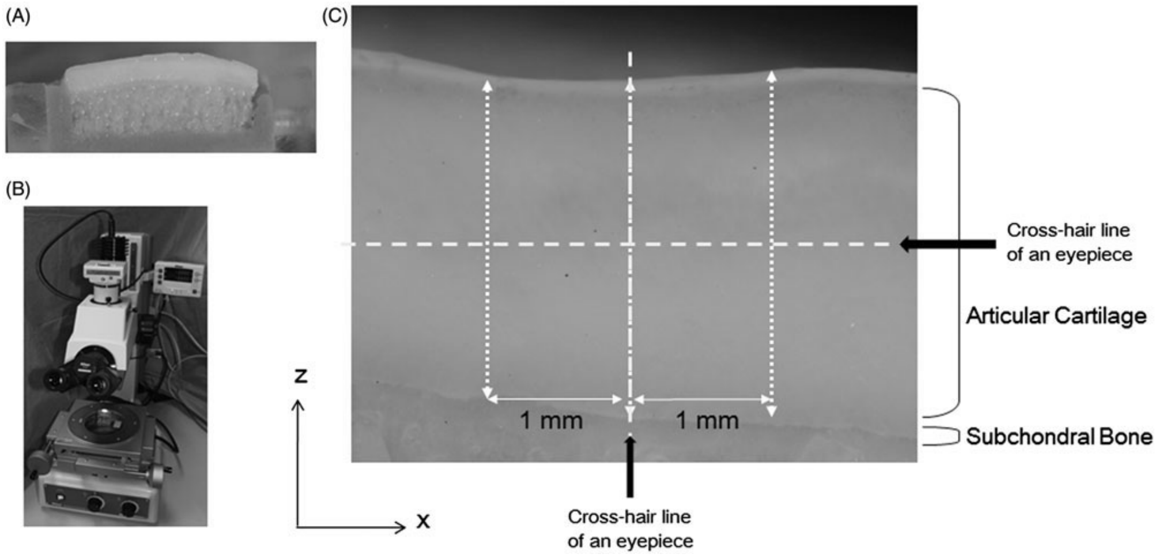

Figure 4. Images showing cartilage thickness measurement using a microscope. After registration of the RF signal acquisition points on the articular cartilage, the cut plane was created (A), containing three measurement points (B). Cartilage thickness was measured optically using a microscope (C) at the RF signal acquisition points.

Table 1. Modified Mankin score.

		Grade
I	Structure	
	Normal	0
	Surface irregularities	1
	Pannus and surface irregularities	2
	Clefts to transitional zone	3
	Clefts to radial zone	4
	Clefts to calcified zone	5
	Complete disorganization	6
II	Cells	
	Normal	0
	Diffuse hypercellularity	1
	Cloning	2
	Hypocellularity	3
III	Safranin-O staining	
	Normal	0
	Slight reduction	1
	Moderate reduction	2
	Severe reduction	3
	No dye noted	4

evaluations. A possible reason for this discrepancy could be that the OARSI score comprises not only a qualitative evaluation of articular cartilage, but also evaluation of morphological damage, a feature of advanced cartilage degeneration. In contrast, the modified Mankin score does not contain evaluation of morphological change and captures relatively early degenerative changes of articular cartilage. Indeed, we found that ultrasound speed showed a significant positive correlation with cartilage thickness, and that cartilage thickness did not correlate with the histological scores. We assume that not only cartilage degeneration, but also cartilage wear, which generally occurs in advanced OA, could have influenced the ultrasound speed. However, articular cartilage thickness can differ even between healthy individuals [40]. Thus, we assumed that cartilage wear or decrease in cartilage thickness could not be quantified in the patients in the present study because the original cartilage thickness (i.e. before OA had started) is unknown in each patient, and the positive correlation between the ultrasound speed and cartilage thickness in this study did not prove the correlation between ultrasound speed and cartilage wear.

In the present study, we found that both the modified Mankin score and the OARSI score were precise and reliable, as judged by intraobserver and interobserver reliability values, corroborating the findings of previous studies [31,41–43]. The correlation coefficient between the two scoring systems was 0.942 ($p < 0.001$), but ICCs for both intraobserver reliability and interobserver reliability were lower for the modified Mankin score than for the OARSI score. The OARSI score covers a relatively wide range of cartilage change, from early to advanced degeneration, while the modified Mankin score evaluates relatively early degenerative changes of articular cartilage. Thus, samples showing advanced degeneration might have resulted in a lower reliability for the modified Mankin score.

In a study using animal cartilage samples [17], a constant speed of sound was shown to provide a clinically acceptable accuracy for cartilage thickness. In addition, a good correlation ($r = 0.78$) was observed between the cartilage thickness calculated acoustically and the thickness measured optically in a study using human osteochondral samples [25]. Our results show an even better correlation ($r = 0.959$) between these values, although this might be due to differences in patient populations. Ultrasound intensity of the cartilage surface has been reported to significantly decrease as degeneration or OA develops, both in animals and in humans, and is suggested to have the potential to detect early osteoarthritic changes at the preclinical stage [37]. In the present study, ultrasound speed had a significant correlation with the OARSI score but not with the modified Mankin score. In addition, since it is technically difficult to measure the ultrasound speed in cartilage and apply this value for each patient during clinical morphological evaluation of cartilage, using a specific preset value of ultrasound speed seems justifiable based on our findings.

An MRI study on OA patients with OARSI grade 1, 2, and 3 medial joint space narrowing (JSN) has shown a reduced cartilage thickness (with differences of 0.190, 0.630, and 1.560 mm in the respective groups) in weight-bearing medial femorotibial compartments compared to cartilage in knees without JSN [44]. In addition, the mean annual loss of cartilage thickness in the center of the medial femoral condyle was over 0.180 mm in the grade 2 and 3 patient groups [45]. Clinical morphological evaluation of

Table 2. OARSI score.

Grade (key feature)	Subgrade
Grade 0: surface intact, cartilage morphology intact	No subgrade
Grade 1: surface intact	1.0 Cells Intact
	1.5 Cell death
Grade 2: surface discontinuity	2.0 Fibrillation through superficial zone
	2.5 Surface abrasion with matrix loss within superficial zone
Grade 3: vertical fissures (clefts)	3.0 Simple fissures
	3.5 Branched/complex fissures
Grade 4: erosion	4.0 Superficial zone delamination
	4.5 Mid zone excavation
Grade 5: denudation	5.0 Bone surface intact
	5.5 Reparative tissue surface present
Grade 6: deformation	6.0 Joint margin osteophytes
	6.5 Joint margin and central osteophytes

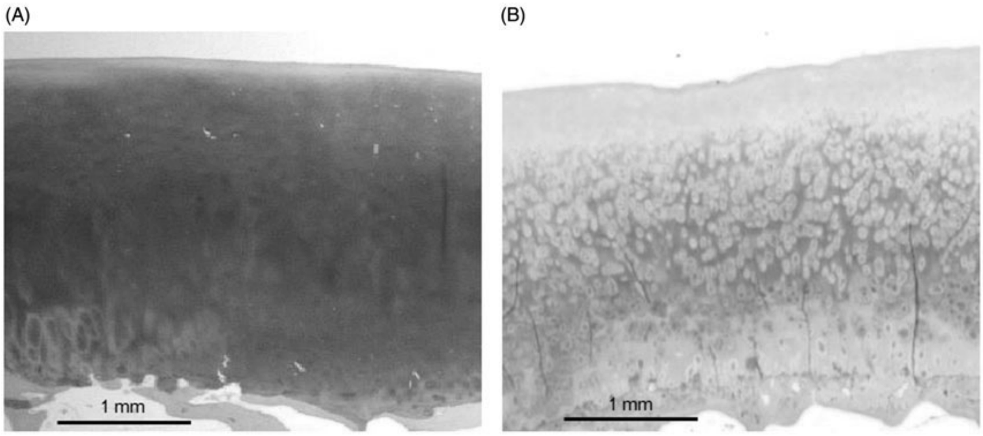

Figure 5. Representative images of histological sections stained with Fast Green and Safranin O. (A) Relatively healthy cartilage exhibits slight reduction in Safranin O staining. Histological scores were graded as 2 based on the modified Mankin score and 1 based on the OARSI score. (B) Moderately degenerated cartilage exhibits pannus/surface irregularities, diffuse hypercellularity, and moderate reduction in Safranin O staining. Histological scores were graded as 5 based on the modified Mankin score and 2.5 based on the OARSI score.

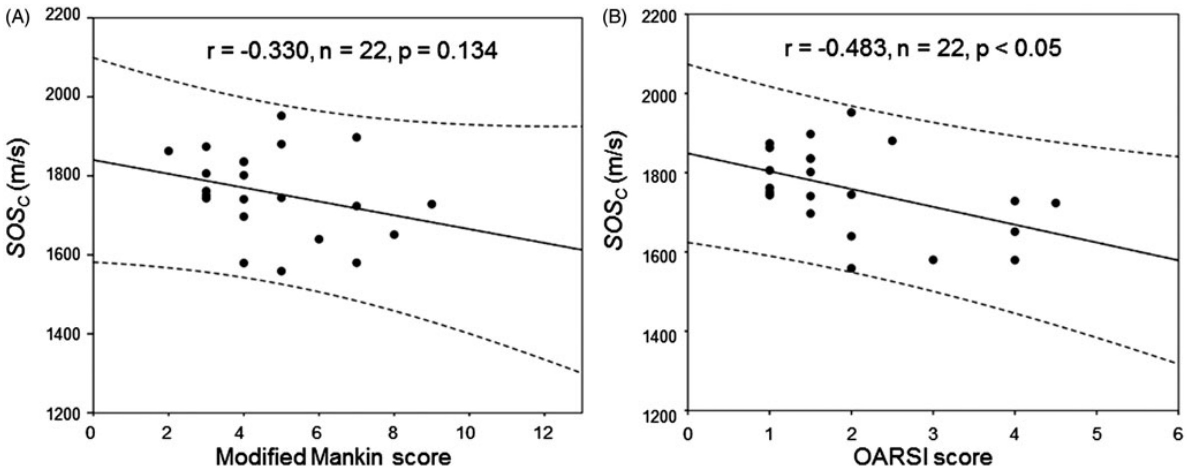

Figure 6. Scatter plots of ultrasound speed (SOS_C) and histological scores. (A) Modified Mankin score; (B) OARSI score. Spearman's rank correlation coefficients (*r*) are shown. The regression line and the 95% CIs for the population (dashes) are also shown.

articular cartilage using ultrasound is performed either percutaneously [46,47] or arthroscopically [48,49]. The ultrasound frequency used in our study is relatively close to the ultrasound frequency used clinically (5–15 MHz), and we believe that our results could be applied to both percutaneous and arthroscopic evaluation of cartilage thickness. The mean and standard deviation (0.0478 ± 0.188 mm) of the differences between ultrasonic and optical thickness in the present study assures that cartilage

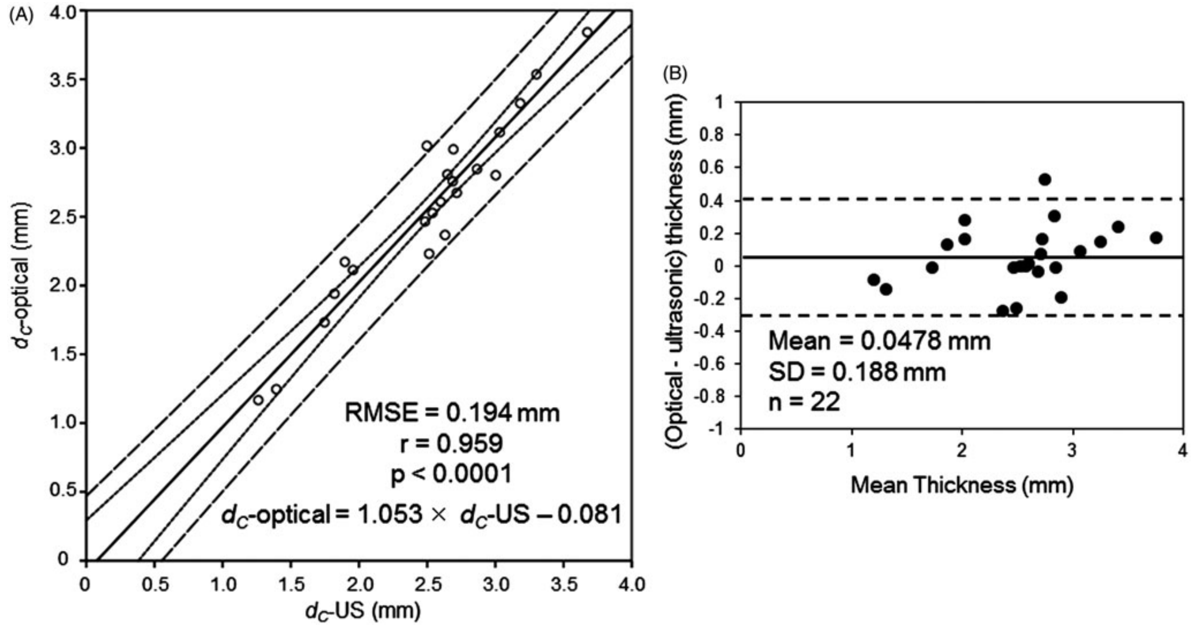

Figure 7. (A) Correlations between optical thickness measurement values (d_C-optical) and thickness values calculated using the average ultrasound speed (d_C-US). The 95% CIs for regression (short dashes) and the population (long dashes) are shown. Root mean square errors (RMSE) and Pearson's correlation coefficients (r) are also shown. (B) Bland–Altman plot analysis of the difference in d_C-optical and d_C-US compared with the mean thickness of d_C-optical and d_C-US. The line corresponding to the mean difference of d_C-optical and d_C-US and lines for mean $\pm 1.96 \times$ SD (dashes) are shown.

evaluation using a specific ultrasound speed can detect clinically important differences or changes in articular cartilage thickness, considering the results of the past MRI studies.

We are aware of several limitations of our study that will require further exploration. First, we were able to collect specimens only from OA patients who underwent total joint arthroplasty. Although we performed measurements on samples with various degrees of degeneration, from relatively normal areas to degenerated lesions on the femoral condyles, probably none of the samples could be considered fully normal cartilage in this study. Ideally, normal cartilage samples are acquired from cadavers without OA of the knee. Second, we performed evaluation only on samples acquired from the knees, but not from other joints. In animal studies, ultrasound speed could differ among samples obtained from different sites [17,50]. Thus, our results cannot be automatically extrapolated to ultrasonic evaluation of cartilage of other joints, although we assume that the effect of degeneration on ultrasound speed will be similar. Finally, we did not perform a biochemical evaluation of cartilage degeneration. As mentioned before, our aim was to investigate the overall effect of cartilage degeneration on ultrasound speed. Nevertheless, performing biochemical evaluations could reveal which component of the cartilage affects ultrasound speed.

The present study has several strengths. To our knowledge, this is the first study investigating the effect of the degree of cartilage degeneration on ultrasound speed using human samples. We believe that a relatively broad range of samples, representing different degrees of degeneration, was covered in our study and that the findings of the present study support the usage of a preset ultrasound speed value in clinical morphological evaluations of cartilage. In conclusion, our results show that cartilage degeneration has relatively little influence on ultrasound speed in articular cartilage. In addition, morphological evaluation of articular cartilage using a preset value of ultrasound speed seems to offer relatively accurate values of cartilage thickness.

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Conflict of interest

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ORIGINAL ARTICLE

Association between new indices in the locomotive syndrome risk test and decline in mobility: third survey of the ROAD study

Noriko Yoshimura[1] · Shigeyuki Muraki[2] · Hiroyuki Oka[3] · Sakae Tanaka[4] · Toru Ogata[5] · Hiroshi Kawaguchi[6] · Toru Akune[5] · Kozo Nakamura[5]

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Abstract
Background We aimed to clarify the association between new indices in a locomotive syndrome risk test and decline in mobility.
Methods In the third survey of the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study, data on the indices were obtained from 1575 subjects (513 men, 1062 women) of the 1721 participants in mountainous and coastal areas. As outcome measures for decline in mobility, we used the five-times-sit-to-stand test (FTSST) and walking speed with cutoff values of 12 s and 0.8 m/s, respectively.
Results We first estimated the prevalence of the indices in locomotive syndrome risk test stage 1, including two-step test score <1.3, difficulty with one-leg standing from a 40-cm-high seat in the stand-up test, and 25-question GLFS score ≥7, which were found to be 57.4, 40.6, and 22.6 %, respectively. Next, we investigated the prevalence of the indices in locomotive syndrome risk test stage 2, including two-step test score <1.1, difficulty with standing from a 20-cm-high seat using both legs in the stand-up test, and 25-question GLFS score ≥16, which were found to be 21.1, 7.9, and 10.6 %, respectively. Logistic regression analysis using slow FTSST time or slow walking speed as the objective factor, and presence or absence of indices as the independent factor, after adjusting for confounders, showed all three indices in both stages 1 and 2 were significantly and independently associated with immobility. Finally, we clarified the risk of immobility according to an increasing number of indices in both stages 1 and 2 and found that the odds ratio for both slow FTSST time and slow walking speed increased exponentially.
Conclusion We found that the three indices independently predicted immobility and that accumulation of indices increased the risk of immobility exponentially.

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✉ Noriko Yoshimura
yoshimuran-ort@h.u-tokyo.ac.jp

1 Department of Joint Disease Research, 22nd Century Medical and Research Center, The University of Tokyo, Hongo 7-3-1, Bunkyo-ku, Tokyo 113-8655, Japan

2 Department of Clinical Motor System Medicine, 22nd Century Medical and Research Center, The University of Tokyo, Tokyo 113-8655, Japan

3 Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, The University of Tokyo, Tokyo 113-8655, Japan

4 Department of Orthopaedic Surgery, Sensory and Motor System Medicine, Graduate School of Medicine, The University of Tokyo, Tokyo 113-8655, Japan

5 National Rehabilitation Center for Persons with Disabilities, Saitama 359-0042, Japan

6 JCHO Tokyo Shinjuku Medical Center, Tokyo 162-8542, Japan

Introduction

According to the most recent National Livelihood Survey by the Ministry of Health, Labour, and Welfare in Japan, osteoporotic fracture and falls is ranked fourth and osteoarthritis is ranked fifth among conditions that cause disability and subsequently require support with regard to activities of daily living [1]. Given the increasing proportion of elderly individuals in the Japanese population, a comprehensive and evidence-based prevention strategy for musculoskeletal diseases is urgently required. In 2007, the Japanese Orthopaedic Association (JOA) proposed that the term "locomotive syndrome" should be adopted to designate a condition requiring nursing care, or being at risk of developing such a condition, because of a decline in mobility resulting from a disorder of the locomotive system, which consists of bones, joints, muscles, and nerves [2]. Weakness of such locomotive components causes difficulty in mobility—defined as the ability to stand, walk, run, climb stairs, and perform other physical functions essential to daily life.

As candidate indices to assess the risk of locomotive syndrome, in 2013, the JOA proposed the following three tests: two-step test, stand-up test, and 25-question geriatric locomotive function scale (GLFS) [3]. With regard to the stand-up test, more than 50 % of subjects younger than 70 years old can stand up on one leg from a 40-cm-high seat [3]. The 25-question GLFS has already been assessed regarding its sensitivity and specificity for prediction of disability and was assigned a cutoff value of 16 by Seichi et al. [4]. However, there is little information regarding reference and/or cutoff values for the two-step test.

Recently, the JOA determined clinical decision limits of these three indices for assessing risk of locomotive syndrome [5]. In their proposal, clinical decision limits were established in two stages as follows:

Stage 1:

1. Two-step test score <1.3.
2. Difficulty with one-leg standing from a 40-cm-high seat in the stand-up test (either leg).
3. 25-question GLFS score ≥7.

When a subject meets any of the above-mentioned conditions, he/she is diagnosed as starting to decline in mobility.

Stage 2:

1. Two-step test score <1.1.
2. Difficulty with standing from a 20-cm-high seat using both legs in the stand-up test.
3. A 25-question GLFS score ≥16.

When a subject meets any of the above-mentioned conditions, he/she is diagnosed as progressing to a decline in mobility.

However, no report has evaluated such indices using data of the general population. From 2005 to 2007, we started a large-scale, population-based cohort investigation entitled the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study, consisting of 3040 participants in three communities located in urban, mountainous, and coastal areas. Following the baseline study, we performed a second survey in the same communities from October 2008 to January 2010, followed by a third survey from October 2012 to December 2013. In the third survey, participants completed the two-step test, stand-up test, and 25-question GLFS. In the present report, using data from the third survey of the ROAD study, we assessed the usefulness of these new indices for predicting immobility, which causes subsequent disability.

Participants and methods

Participants

Measurements were obtained from participants of the third survey of the ROAD study. The ROAD study, which began in 2005, is a nationwide prospective study comprising population-based cohorts established in several communities in Japan. Recruitment methods for this study have been described in detail elsewhere [6, 7]. To date, we have created a baseline database including clinical and genetic information of 3040 inhabitants (1061 men; 1979 women) aged 23–95 years who were recruited from listings of resident registrations in three communities. All participants provided written informed consent, and the study was conducted with approval from the ethics committees of the participating institutions.

The third survey of the ROAD study began in 2012 and was completed in 2013. All participants in the baseline study and second survey were invited to participate in the third survey. Besides former participants, inhabitants aged ≥40 years who were willing to attend the ROAD survey performed in 2012–2013 also were included as participants in the third survey. As a result, a total of 2566 (837 men, 1729 women; urban area, 845 individuals; mountainous area, 769 individuals; coastal area, 952 individuals) residents participated in the third survey.

In the present study, we used data from 1575 subjects (513 men; 1062 women) who completed the stand-up test, two-step test, and 25-question GLFS for disability among all 1721 participants in mountainous and coastal areas in the third survey.

At the third survey, participants completed an interviewer-administered questionnaire. Five interviewers, who had been trained by an expert (NY), were provided for this study. The questionnaire consisted of 200 items that included lifestyle information, such as primary occupation, smoking habits, alcohol consumption, physical activity, medical history, and prescription medication. Anthropometric measurements included height (cm), weight (kg), body mass index [BMI, weight (kg)/height (m)^2], and hand grip strength (kg).

Indices for risk of decline in mobility resulting from locomotive syndrome

In the present study, participants performed the following tests for assessment of decline in mobility.

Two-step test

This test measures the stride length to assess walking ability, including muscle strength, balance, and flexibility of the lower limbs. The two-step test was performed using the following procedure [3, 8, 9]: (1) subjects determined the starting line and stood with the toes of both feet behind it; (2) subjects were instructed to take two long steps (as long as possible) and then align both feet; (3) the length of the two steps from the starting line to the tips of the subject's toes where he/she stopped was measured. The two-step test score was calculated using the following formula: length of the two steps (cm) $\div$ height (cm).

Stand-up test

This test assesses leg strength by having the subject stand up on one or both legs from a specified height. After preparation of four seats of different heights—40, 30, 20, and 10 cm—the subject stood up from each seat (in descending height order), first with both legs then with one leg. If the subject could stand up without leaning back to gain momentum and maintain the posture for 3 s, then he/she was diagnosed as having passed that height level [3, 9]. In the present study, if the subject was unable to stand up on one leg (right or left) from a height of 40 cm, then his/her stand-up test was considered failed.

The 25-Question GLFS

As mentioned above, the 25-question GLFS was developed by Seichi et al. [4]. It is a self-administered, comprehensive measure, consisting of 25 items that include four questions regarding pain during the last month, 16 questions regarding activities of daily living during the last month, three questions regarding social functions, and two questions regarding mental health status during the last month. These 25 items are graded with a five-point scale, from no impairment (0 points) to severe impairment (4 points), and then arithmetically added to produce a total score (minimum = 0, maximum = 100). Thus, a higher score is associated with worse locomotive function. Validity of the scale has been assessed, and a cutoff point of 16 was determined to have the highest sensitivity and specificity for indication of disability resulting from locomotive syndrome [3, 4].

Indices for decline in mobility resulting from locomotive syndrome

Because the present study utilized a cross-sectional design, not a longitudinal follow-up design, we could not evaluate the ability of the stand-up test or two-step test for prediction of disability resulting from locomotive syndrome. Therefore, in the present study, we used the following outcome measures as indices for decline in mobility.

Five-times-sit-to-stand test

There are several reports that inability to rise from a chair five times within a determined time is associated with increased disability and morbidity [10–12]. We have also reported that the longer the standing time is, the higher the incidence of disability [13]. The five-times-sit-to-stand test (FTSST) was performed according to the following procedure: (1) using a straight-back chair with a solid seat, participants were asked to sit on the chair with their arms folded across their chest; (2) participants were instructed to stand up and sit down as quickly as possible five times, keeping their arms folded across their chest; (3) the time when the participant stood for the fifth time was measured. In the present study, we used a cutoff value of 12 s to indicate a decline in mobility [14].

The 6-m walking time

As another outcome measure for decline in mobility, participants walked a 6-m course at their usual speed. The method of measurement of walking time was identical to that performed in the large-scale cohort study entitled Osteoporotic Fractures in Men (MrOS), which started prior to the ROAD study [15]. In the present study, we used a cutoff value of 0.8 m/s to indicate a decline in mobility [16].

In the present study, among the above-mentioned indices, mean scores and SDs for the two-step test were calculated according to participants' sex and age strata (<40, 40s, 50s, 60s, 70s, and $\geq$80 years). Then, we estimated the prevalence of each index in stages 1 and 2. Finally, we assessed the association between the cumulative number of indices and decline in mobility using multivariate analysis.

Statistical analysis

All statistical analyses were performed using STATA statistical software (STATA, College Station, TX, USA). Differences in proportions were compared using the chi-square test. The significance of differences in continuous variables was evaluated using analysis of variance for comparisons among multiple groups or Scheffe's least significant difference test for pairs of groups. All p values and 95 % confidence intervals are two-sided. A p value of <0.05 was considered statistically significant.

Logistic regression analysis was used to test the association of each factor with the presence or absence of a decline in mobility. In the analysis, we used presence of immobility according to the FTSST time (>12 s = 1; ≤12 s = 0) and usual walking speed (<0.8 m/s = 1; ≥0.8 m/s = 0) as the objective variable, and presence or absence of new indices in stages 1 and 2 as explanatory variables, after adjusting for age (+1 year), sex (men = 0, women = 1), BMI (+1 kg/m^2), and regional difference (mountainous area = 0; coastal area = 1). Other factors were considered in the multivariate model after simple linear analysis; those used as explanatory factors are described in "Results."

Results

Summary characteristics, including age and BMI of the participants, are shown in Table 1. Two-thirds of the 1575 participants were women, and the mean age of women participants was 1 year less than that of men participants; however, this difference was not significant. By contrast, there was a significant difference in BMI between sexes ($p < 0.0001$). Table 1 also shows the age and sex distributions of mean FTSST time and walking speed. Both values tended to be significantly slower in participants aged in their 70s and 80s in both men and women, and there were no significant differences between sexes. Table 1 also shows the age and sex distributions of mean two-step test scores. Mean two-step test score was 1.25 (SD 0.20) in men and 1.23 (SD 0.21) in women; this difference was significant ($p < 0.0001$). Age differences indicated that the two-step test score was significantly lower according to age in both men and women ($p < 0.05$).

First, the prevalence of the indices in stage 1 and their association with decline in mobility described by slow FTSST time and slow walking speed were assessed (Table 2). Overall, the prevalence of two-step test score <1.3, difficulty with one-leg standing from a 40-cm-high seat in the stand-up test, and 25-question GLFS score ≥7 were 57.4, 40.6, and 22.6 %, respectively.

Prevalence of two-step test score <1.3 in subjects aged in their 30s and younger, 40s, 50s, 60s, 70s, and 80 years and older were 17.0, 28.5, 32.6, 51.5, 76.2, and 90.0 %, respectively, indicating that the prevalence increased according to age; even in subjects aged in their 40s and 50s, the prevalence was more than 30 %. Prevalence of subjects who could not stand with one leg from a 40-cm-high seat who were aged in their 30s and younger, 40s, 50s,

Table 1 Mean (SD) values for age, body mass index (BMI), five-times-sit-to-stand test (FTSST) time, walking speed, and two-step test score of participants classified by age and sex

Age strata (years)	n	Age (years)	BMI (kg/m^2)	FTSST time (s)	Walking speed (m/s)	Two-step test score
Men						
<40	23	32.8 (4.8)	24.5 (3.3)	6.96 (1.33)	1.26 (0.22)	1.49 (0.14)
40–49	38	44.7 (3.1)	25.4 (5.1)	6.79 (2.41)	1.25 (0.25)	1.41 (0.15)
50–59	82	55.2 (2.5)	24.2 (3.3)	7.11 (1.47)	1.25 (0.26)	1.36 (0.13)[a]
60–69	137	64.3 (2.7)	23.8 (3.4)	8.10 (2.51)	1.16 (0.26)	1.29 (0.15)[ab]
70–79	139	74.3 (2.8)	23.4 (2.9)	8.72 (2.18)[bc]	1.02 (0.24)[abcd]	1.20 (0.16)[abcd]
≥80	94	83.8 (3.1)	22.3 (3.0)	11.48 (4.72)[abcde]	0.81 (0.28)[abcde]	1.06 (0.22)[abcde]
Total	513	66.2 (13.7)	23.6 (3.4)	8.57 (3.17)	1.08 (0.30)	1.25 (0.20)
Women						
<40	36	34.4 (4.8)	20.7 (3.0)	7.11 (1.26)	1.28 (0.17)	1.40 (0.14)
40–49	85	44.9 (2.9)	21.9 (3.2)	7.19 (1.64)	1.25 (0.22)	1.35 (0.11)
50–59	195	54.7 (2.9)	23.0 (4.1)	7.10 (1.94)	1.26 (0.22)	1.35 (0.13)
60–69	309	64.7 (2.9)	22.8 (3.4)	7.90 (2.31)	1.18 (0.23)[c]	1.28 (0.18)[abc]
70–79	303	74.3 (2.9)	23.3 (3.3)	9.44 (3.57)[abcd]	1.02 (0.28)[abcd]	1.16 (0.18)[abcd]
≥80	134	83.1 (3.0)	22.0 (3.4)	11.89 (4.60)[abcde]	0.75 (0.28)[abcde]	0.97 (0.23)[abcde]
Total	1062	65.3 (12.6)	22.7 (3.5)	8.58 (3.31)	1.11 (0.30)	1.23 (0.21)

[a] Significantly different ($p < 0.05$) from values of those aged <40 years

[b] Significantly different ($p < 0.05$) from values of those aged in their 40s

[c] Significantly different ($p < 0.05$) from values of those aged in their 50s

[d] Significantly different ($p < 0.05$) from values of those aged in their 60s

[e] Significantly different ($p < 0.05$) from values of those aged in their 70s

Table 2 Prevalence of indices in the locomotive syndrome risk test (stage 1): two-step test score <1.3, difficulty with one-leg standing from 40-cm-high seat in the stand-up test (either leg), and 25-question geriatric locomotive function scale (GLFS) score ≥7 in participants classified by age and sex

Age strata (years)	Age (years) mean (SD)	Two-step test score <1.3 (%)	Difficulty with one-leg standing from 40-cm-high seat (either leg) (%)	25-question GLFS score ≥7 (%)
Men				
<40	32.8 (4.8)	13.0	4.4	4.4
40–49	44.7 (3.1)	21.1	15.8	10.8
50–59	55.2 (2.5)	34.6	15.9	7.4
60–69	64.3 (2.7)	49.3	30.7	12.0
70–79	74.3 (2.8)	71.7	47.8	19.9
≥80	83.8 (3.1)	84.6	78.0	44.0
Total	66.2 (13.7)	55.6	39.1	18.8
Women				
<40	34.4 (4.8)	19.4	11.1	0.0
40–49	44.9 (2.9)	31.8	12.9	8.3
50–59	54.7 (2.9)	31.8	23.6	13.0
60–69	64.7 (2.9)	52.4	33.9	19.7
70–79	74.3 (2.9)	78.3	56.2	31.6
≥80	83.1 (3.0)	93.8	78.1	54.3
Total	65.3 (12.6)	58.2	41.3	24.5*

* Significantly different ($p < 0.05$) from values of men

Table 3 Effect of presence of indices in the locomotive syndrome risk test (stage 1) for decline in mobility described by slow five-times-sit-to-stand test (FTSST) time and slow walking speed

Indices for decline in mobility	Reference	OR (95 % CI)	*p* value
FTSST time >12 s			
Two-step test score <1.3	Yes vs. no	3.28 (1.81–5.97)	<0.001
Difficulty with one-leg standing from 40-cm-high seat (either leg)	Yes vs. no	1.78 (1.17–2.69)	0.007
25-question GLFS score ≥7	Yes vs. no	2.51 (1.73–3.62)	<0.001
Walking speed <0.8 m/s			
Two-step test score <1.3	Yes vs. no	4.24 (2.18–8.22)	<0.001
Difficulty with one-leg standing from 40-cm-high seat (either leg)	Yes vs. no	2.01 (1.35–3.16)	0.001
25-question GLFS score ≥7	Yes vs. no	2.65 (1.82–3.86)	<0.001

After adjusting for age, sex, body mass index, and regional difference. Presence or absence of indices for stage 1 also was mutually adjusted
CI confidence interval, *GLFS* geriatric locomotive function scale, *OR* odds ratio

60s, 70s, and 80 years and older were 8.5, 13.8, 21.3, 32.9, 53.5, and 78.1 %, respectively, indicating that the prevalence increased according to age, similar to the two-step test; even in subjects aged in their 40s and 50s, the prevalence was around 20 %. Prevalence of 25-question GLFS score ≥7 in participants aged in their 30s and younger, 40s, 50s, 60s, 70s, and 80 years and older were 1.7, 9.1, 11.4, 17.4, 27.9, and 50.0 %, respectively, indicating the overall prevalence was lower than that of the other two indices, but it increased synergistically in those in their 80s and older. Regarding the sex difference of the indices in stage 1, although there were no significant differences between men and women with regard to two-step test score <1.3 and difficulty with one-leg standing from a 40-cm-high seat in the stand-up test, the prevalence of 25-question GLFS score ≥7 in women was significantly higher than that in men ($p < 0.05$).

Table 3 shows the results of logistic regression analysis using immobility described by slow FTSST time or slow walking speed as the objective factor and the presence or absence of new indices in stage 1 for a decline in mobility as explanatory factors, after adjusting for age (+1 year), sex (men = 0; women = 1), BMI (+1 kg/m^2), and regional difference (mountainous area = 0; coastal area = 1). The analysis revealed that all three indices in stage 1 independently predicted immobility described by both slow FTSST time and slow walking speed.

Table 4 shows the association between accumulation of the indices in stage 1 and decline in mobility described by slow FTSST time or slow walking speed, after adjusting for age (+1 year), sex (men = 0; women = 1), BMI (+1 kg/m^2), and regional difference (mountainous area = 0; coastal area = 1). The analysis revealed that according to an increasing number of indices, the odds ratio of both slow FTSST time and slow walking speed increased exponentially.

Table 4 Effect of accumulation of indices (stage 1) for decline in mobility

No. of indices	OR (95 % CI)	*p* value
Five-times-sit-to-stand test time >12 s		
0 = reference	1.0	–
1	2.19 (0.98–4.87)	0.055
2	2.90 (1.30–6.47)	0.009
3	11.59 (5.18–25.93)	<0.001
Walking speed <0.8 m/s		
0 = reference	1.0	–
1	5.73 (1.71–19.16)	0.005
2	9.82 (2.96–32.52)	<0.001
3	32.21 (9.64–107.7)	<0.001

After adjusting for age, sex, body mass index, and regional difference

CI confidence interval, *OR* odds ratio

Next, the prevalence of the indices in stage 2 and their association with decline in mobility described by a slow FTSST time and slow walking speed were assessed (Table 5). Overall, the prevalence of two-step test score <1.1, difficulty with standing from a 20-cm-high seat using both legs in the stand-up test, and 25-question GLFS score ≥16 were 21.1, 7.9, and 10.6 %, respectively.

Prevalence of two-step test score <1.1 in subjects aged in their 30s and younger, 40s, 50s, 60s, 70s, and 80 years and older were 0.0, 1.6, 3.3, 11.3, 28.4, and 65.8 %, respectively, indicating that the prevalence was less than 5 % in those aged in their 50s and younger, around 10 % in those aged in their 60s, but more than 50 % in those aged 80 years and older. Prevalence of subjects who could not stand from a 20-cm-high seat using both legs who were aged in their 30 s and younger, 40s, 50s, 60s, 70s, and 80 years and older were 0.0, 0.8, 0.7, 5.0, 9.9, and 25.1 %, respectively, indicating that the prevalence was less than 5 % in those aged in their 60s and younger, around 10 % in those aged in their 70s, but dramatically increased in those aged 80 years and older. Prevalence of 25-question GLFS score ≥16 in participants aged in their 30s and younger, 40s, 50s, 60s, 70s, and 80 years and older were 0.0, 1.7, 3.3, 5.0, 12.9, and

Table 5 Prevalence of indices in the locomotive syndrome risk test (stage 2): two-step test score <1.1, difficulty with standing from 20-cm-high seat using both legs in the stand-up test, and 25-question geriatric locomotive function scale (GLFS) score ≥16 in participants classified by age and sex

Age strata (years)	Age, mean (SD) years	Two-step test score <1.1 (%)	Difficulty with standing from 20-cm-high seat (%)	25-question GLFS score ≥16 (%)
Men				
<40	32.8 (4.8)	0.0	0.0	0.0
40–49	44.7 (3.1)	2.6	2.6	0.0
50–59	55.2 (2.5)	3.7	0.0	1.2
60–69	64.3 (2.7)	8.8	3.7	6.0
70–79	74.3 (2.8)	23.9	2.9	8.1
≥80	83.8 (3.1)	58.2	16.5	27.5
Total	66.2 (13.7)	20.1	4.9	9.0
Women				
<40	34.4 (4.8)	0.0	0.0	0.0
40–49	44.9 (2.9)	1.2	0.0	2.4
50–59	54.7 (2.9)	3.1	1.0	4.2
60–69	64.7 (2.9)	12.4	5.5	4.6
70–79	74.3 (2.9)	30.4	13.1	15.1
≥80	83.1 (3.0)	71.1	31.3	39.4
Total	65.3 (12.6)	21.6	9.4*	11.4

* Significantly different ($p < 0.01$) from values of men

Table 6 Effect of presence of indices in the locomotive syndrome risk test (stage 2) for decline in mobility described by slow five-times-sit-to-stand test (FTSST) time and slow walking speed

Indices for decline in mobility	Reference	OR (95 % CI)	*p* value
FTSST time >12 s			
Two-step test score <1.1	Yes vs. no	3.03 (1.97–4.66)	<0.001
Difficulty with standing from 20-cm-high seat %	Yes vs. no	5.87 (3.48–9.89)	<0.001
25-question GLFS score ≥16	Yes vs. no	2.83 (1.77–4.54)	<0.001
Walking speed <0.8 m/s			
Two-step test score <1.1	Yes vs. no	4.19 (2.75–6.39)	<0.001
Difficulty with standing from 20-cm-high seat %	Yes vs. no	3.40 (1.99–5.82)	<0.001
25-question GLFS score ≥16	Yes vs. no	3.49 (2.15–5.65)	<0.001

After adjusting for age, sex, body mass index, and regional difference. Presence or absence of indices for stage 2 also was mutually adjusted

CI confidence interval, *GLFS* geriatric locomotive function scale, *OR* odds ratio

34.4 %, respectively, indicating that the overall prevalence increased according to age; the prevalence was less than 5 % in subjects aged in their 60s and younger, around 10 % in those aged in their 70s, but dramatically increased in those aged 80 years and older. Regarding the sex difference of the indices in stage 2, although there were no significant differences between men and women with regard to two-step test score <1.1 and 25-question GLFS score ≥16, the prevalence of difficulty with standing from a 20-cm-high seat using both legs in the stand-up test in women was significantly higher than that in men ($p < 0.01$).

Table 6 shows the results of logistic regression analysis using immobility described by a slow FTSST time or slow walking speed as the objective factor and the presence or absence of new indices in stage 2 for decline in mobility as explanatory factors, after adjusting for age (+1 year), sex (men = 0; women = 1), BMI (+1 kg/m^2), and regional difference (mountainous area = 0; coastal area = 1). The analysis revealed that all three indices in stage 2 independently predicted immobility described by both a slow FTSST time and slow walking speed. The odds ratios of all indices in stage 2 for slow FTSST time and slow walking speed were greater than those of all indices in stage 1.

Table 7 shows the association between accumulation of the indices in stage 2 and decline in mobility described by slow FTSST time or slow walking speed, after adjusting for age (+1 year), sex (men = 0; women = 1), BMI (+1 kg/m^2), and regional difference (mountainous area = 0; coastal area = 1). The analysis revealed that according to an increasing number of indices, the odds ratio of both slow FTSST time and slow walking speed increased exponentially. The odds ratios of accumulation of the indices in stage 2 for slow FTSST time and slow walking speed were greater than those of accumulation of the indices in stage 1.

Table 7 Effect of accumulation of new indices (stage 2) for decline in mobility

No. of new indices	OR (95 % CI)	*p* value
Five-times-sit-to-stand test time >12 s		
0 = reference	1.0	–
1	2.99 (1.85–4.84)	<0.001
2	12.35 (7.08–21.54)	<0.001
3	46.87 (19.37–113.45)	<0.001
Walking speed <0.8 m/s		
0 = reference	1.0	–
1	3.50 (2.19–5.59)	<0.001
2	12.52 (7.08–22.13)	<0.001
3	61.93 (24.92–153.87)	<0.001

After adjusting for age, sex, body mass index, and regional difference

CI confidence interval, *OR* odds ratio

Discussion

In the present study, we clarified the associations of three new indices for immobility, including the two-step test, stand-up test, and 25-question GLFS, represented by slow FTSST time and slow walking speed. We first tested the associations among the three indices by using the clinical decision limits for locomotive syndrome risk test stage 1. Next, we tested the three indices in stage 2. We clarified the age and sex distributions of the prevalence of these three indices and found that the three indices in both stages 1 and 2 significantly and independently predicted a decline in mobility and that the accumulation of such indices increased the risk of immobility exponentially.

First, we used both FTSST time and 6-m walking speed as outcome measures of immobility. As mentioned in "Methods", these two indices are both regarded as predictors for morbidity and disability [10–12, 16]. In the ROAD study, we reported that the longer the standing time, the higher the incidence of disability [13] and that slow walking speed was also a predictor for the occurrence of disability [13]. Although we could not clarify the direct associations between these new indices and occurrence of disability because this study design was cross-sectional, these surrogate indices could help predict disability in the near future. Therefore, if we could clarify the significant associations between these new indices and FTSST time and 6-m walking speed, we might clarify the ability to predict disability indirectly. Based on this hypothesis, we used cutoff values of 12 s for FTSST time [13] and 0.8 m/s for 6-m walking speed [16].

The two-step test was developed to assess walking ability, including muscle strength, balance, and flexibility of the lower limbs. This test was first developed by Muranaga and Hirano in 2003 [3, 8]. They compared two-step test scores of 108 healthy volunteers (38 men, 70 women; mean age 59.0 years) with those of 108 hospital outpatients (56 men, 52 women; mean age 60.3 years) and found that the two-step test score was significantly associated with the risk of falling and degree of independence in daily life [7]. In the present study, we clarified mean two-step test scores in participants classified by age and sex and found mean scores of 2.07 in men and 1.87 in women. Scores of men were significantly higher than those of women, and age differences indicated that scores were significantly lower according to age in both men and women. These age and sex tendencies are consistent with those reported in a previous study [3].

Regarding the prevalence of the indices in locomotive syndrome risk test stages 1 and 2, we found that all prevalences increased with age. However, the distribution of each index seemed to differ. In stage 1, the prevalence was highest for a two-step test score <1.3, followed by difficulty with one-leg standing from a 40-cm-high seat in the stand-up test and 25-question GLFS score ≥7. By contrast, in stage 2, the prevalence also was highest for a two-step test score <1.1, but the prevalence of a 25-question GLFS score ≥16 was higher than that of difficulty with standing from a 20-cm-high seat using both legs in the stand-up test. The different age distributions of these three indices in both stages 1 and 2 might be conducive to their mutually independent associations with immobility. Our result that these three indices in both stages 1 and 2 independently predicted immobility shows that all three are important for predicting immobility. Furthermore, because these indices independently predicted immobility, risk severity may be classified by a positive number of indices present. In fact, in our study, accumulation of indices increased the risk of immobility exponentially, especially accumulation of indices in stage 2, which suggests the possibility of categorizing the severity of risk for immobility, such as 0, normal; 1, mild; 2, moderate; 3, severe.

With regard to the 25-question GLFS, there might be some concern that it is too cumbersome for older people to answer 25 questions. Seichi et al. also proposed a short version of the test using only five questions with a cutoff score of ≥6, on behalf of a 25-question GLFS score ≥16. They selected five questions from the 25-question GLFS using the Akaike information criterion (AIC) [17–19]. They determined that a cutoff score of 6 had the lowest AIC value, representing the model with the best fit, and finally concluded that the five-question GLFS can be applied as a rapid self-check tool for locomotive syndrome [4]. We compared the results of 1535 individuals who completed both the 25-question GLFS and five-question GLFS. Supplementary Table 1 shows that these two indices (five-question GLFS and 25-question GLFS) have a strong association (sensitivity 0.859; specificity 0.985). This result shows the possibility of using the five-question GLFS instead of the 25-question GLFS as a rapid-check tool for the prediction of immobility.

There are several limitations in the present study. First, as mentioned above, our study assessed the usefulness of three indices in locomotive syndrome risk test stages 1 and 2 for predicting immobility using FTSST time and walking speed as outcome variables. Although there has been significant evidence regarding these outcome measures, such as slow FTSST time and slow walking speed, and disability [8, 10–13, 16], including our report, the direct associations of these new indices and occurrence of disability are unclear. The proposal of these new indices was published in 2013 [3], so there was not enough time to observe future occurrence of disability in our cohort. Therefore, we should continue to observe our cohort and assess the ability of such indices to predict disability directly. Second, although the ROAD study includes a large number of participants, these participants do not truly represent the general population, since the subjects in the present study were recruited from only two areas. However, we have already confirmed the representativeness of the participants of the ROAD baseline study to the Japanese population by comparing anthropometric measurements and frequencies of smoking and alcohol consumption between participants and the general Japanese population [5]. Values for the general population were obtained from the 2005 National Health and Nutrition Survey conducted by the Ministry of Health, Labour and Welfare in Japan [20]. Regarding anthropometric measurements, we found no significant differences between our participants and the total Japanese population, except that men participants aged 70–74 years in the ROAD study were significantly smaller in terms of body structure than the overall population ($p < 0.05$). In addition, proportions of current smokers and current drinkers were significantly higher in the general Japanese population than in the study population [5], suggesting that participants of the ROAD study have healthier lifestyles than the general population. This "healthy" selection bias should be taken into consideration when using reference values obtained in the ROAD study.

In conclusion, we have assessed whether the proposed clinical decision limits of the indices in locomotive syndrome risk test stages 1 and 2 could predict immobility represented by a slow FTSST time and slow walking speed using data from a population-based cohort of the third survey of the ROAD study. We found that all the indices in the locomotive syndrome risk test—the two-step test, stand-up test, and 25-question GLFS—could significantly and independently predict a decline in mobility and that the accumulation of such indices increased the risk of immobility exponentially.

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Conflict of interest No conflicts of interest have been declared by the authors.

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Prevalence of radiographic hip osteoarthritis and its association with hip pain in Japanese men and women: the ROAD study

T. Iidaka †, S. Muraki ‡ *, T. Akune §, H. Oka ||, R. Kodama ¶, S. Tanaka ¶, H. Kawaguchi #, K. Nakamura §, N. Yoshimura †

† Department of Joint Disease Research, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
‡ Department of Clinical Motor System Medicine, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
§ National Rehabilitation Center for Persons with Disabilities, Saitama, Japan
|| Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
¶ Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, Tokyo, Japan
# Department of Orthopaedic Surgery, Japan Community Healthcare Organization Tokyo Shinjuku Medical Center, Tokyo, Japan

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SUMMARY

Objective: Although hip osteoarthritis (OA) is a major cause of hip pain and disability in elderly people, few epidemiologic studies have been performed. We investigated the prevalence of radiographic hip OA and its association with hip pain in Japanese men and women using a large-scale population of a nationwide cohort study, Research on Osteoarthritis/osteoporosis Against Disability (ROAD).

Methods: From the baseline survey of the ROAD study, 2975 participants (1043 men and 1932 women), aged 23–94 years (mean 70.2 years), living in urban, mountainous, and coastal communities were analyzed. The radiographic severity at both hips was determined by the Kellgren/Lawrence (K/L) grading system. Radiographic hip OA was defined as $K/L \geq 2$, and severe radiographic hip OA as $K/L \geq 3$.

Results: The crude prevalence of radiographic hip OA was 18.2% and 14.3% in men and women, respectively, that of severe radiographic hip OA was 1.34% and 2.54%, and that of symptomatic $K/L \geq 2$ OA was 0.29% and 0.99%, respectively. The crude prevalence of hip OA, including severe OA, was not age-dependent in men or women. Male sex was a risk factor for radiographic hip OA, whereas female sex was a risk factor for severe radiographic hip OA and hip pain. Compared with $K/L = 0/1$, hip pain was significantly associated with $K/L \geq 3$, but not with $K/L = 2$.

Conclusion: The present cross-sectional study revealed the prevalence of radiographic hip OA and severe hip OA in Japanese men and women. Hip pain was strongly associated with $K/L \geq 3$.

Introduction

Hip osteoarthritis (OA) is a major public health issue causing chronic disability of elderly people in most developed countries[1,2]. Despite the urgent need for strategies to prevent and treat this condition, epidemiologic data on hip OA are sparse. The reported prevalence of radiographic hip OA differs considerably among previous population-based epidemiologic studies[1,3–8]. This may be due to limitations in sample size or variability in age, ethnicity, and radiologic acquisition. In particular, previous studies suggested that the prevalence of OA at other sites, such as the knee, differed among races. In addition, anthropometric measurements and environmental situations vary substantially in different countries. Thus findings in Caucasians cannot be applied to different ethnic groups. In Japan, our previous study in 1998 was the only population-based study to examine the prevalence of hip OA. With the aging population, there have been dramatic changes in number of elderly people; this aging may have affected the prevalence of hip OA. To the best of our knowledge, no population-based cohort studies for hip OA have been performed in Japan since our previous study.

* Address correspondence and reprint requests to: S. Muraki, Department of Clinical Motor System Medicine, 22nd Century Medical & Research Center, Faculty of Medicine, The University of Tokyo, Hongo 7-3-1, Bunkyo-ku, Tokyo 113-8655, Japan. Tel: 81-3-5800-9178; Fax: 81-3-5800-9179.
E-mail address: murakis-ort@h.u-tokyo.ac.jp (S. Muraki).

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Hip pain is the principal clinical symptom of hip OA[9], but the reported prevalence of hip pain and symptomatic hip OA also differs among previous population-based epidemiologic studies[1,5–8]. In addition the impact of hip OA on pain remains controversial.

With the goal of establishing epidemiologic indices to evaluate clinical evidence for the development of disease-modifying treatment, we set up a large-scale nationwide cohort study for bone and joint disease called ROAD (Research on Osteoarthritis/osteoporosis Against Disability) in 2005. We have to date created a baseline database with detailed clinical and genetic information on three population-based cohorts in urban, mountainous, and coastal communities of Japan.

The objective of this study was to examine the prevalence of radiographic hip OA as well as hip pain and symptomatic hip OA by gender and age strata in Japanese men and women in a large-scale, population-based cohort from the ROAD study. We also examined the association of the severity of hip OA with the presence of hip pain.

Subjects and methods

The ROAD study is a nationwide prospective study of bone and joint diseases (with osteoarthritis and osteoporosis as the representative bone and joint diseases) constituting population-based cohorts established in several communities in Japan. As a detailed profile of the ROAD study has already been described elsewhere[10–12], a brief summary is provided here. From 2005 to 2007, we created a baseline database that included clinical and genetic information for 3040 inhabitants (1061 men, 1979 women) in the age range of 23–95 years (mean 70.6 years), recruited from listings of resident registrations in three communities: an urban region in Itabashi, Tokyo, with a population of 529,400/32 km^2 with 0.1, 25, and 75% of jobs in the primary industry (agriculture, forestry, fishing, and mining), the secondary industry (manufacturing and construction), and the tertiary industry (service industry), respectively, and residents $\geq$65 years constituted 19.1% of the population; a mountainous region in Hidakagawa, Wakayama, with a population of 11,300/330 km^2 with 29, 24, and 47% of jobs in the three industries above, and 30.5% were $\geq$65 years; and a coastal region in Taiji, Wakayama, with a population of 3500/6 km^2 with 13, 18, and 69% of jobs in the three industries, and those $\geq$65 years accounted for 34.9% of the total. Participants in the urban region were recruited from a cohort study[13] in which the participants were randomly drawn from the Itabashi-ward residents register database, and the response rate in the age groups of $\geq$60 years was 75.6%. Participants in the mountainous and coastal regions were recruited from listings of resident registration and the response rates in the age group of $\geq$40 years were 57.3% and 33.1%, respectively. However, those inhabitants aged <60 years in the urban region and <40 years in the mountainous and coastal regions who were interested in participating in the study were invited to be examined. The inclusion criteria, apart from residence in the communities mentioned above, were the ability to walk to the survey site, report data, and understand and sign an informed consent form. All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Geriatric Medical Center.

Participants completed an interviewer-administered questionnaire of 400 items that included lifestyle information such as smoking habits, alcohol consumption, family history, medical history, and previous hip injury history. Anthropometric measurements included height and weight, from which the body mass index (BMI) (weight [kg]/height [m^2]) was calculated. Furthermore, all participants were interviewed by well-experienced orthopedists regarding pain in both hips, who asked “Have you experienced right hip pain on most days in the past month, in addition to now?” and “Have you experienced left hip pain on most days in the past month, in addition to now?” Subjects who answered “yes” were defined as having hip pain. We defined an individual as having hip pain if at least one of the hip joints was affected.

Radiographic assessment

All participants underwent radiographic examination of both hips using an anteroposterior view with weight-bearing and feet internally rotated. Fluoroscopic guidance with a horizontal anteroposterior X-ray beam was used to properly visualize the joint space. Hip radiographs at baseline were read without knowledge of the participant's clinical status by a single, well-experienced orthopedist (TI), and the Kellgren/Lawrence (K/L) grade was defined using the K/L radiographic atlas for overall hip radiographic grades[14]. In the K/L grading system, radiographs are scored from grade 0 to grade 4, with higher grades being associated with more severe OA. To evaluate intraobserver variability of K/L grading, 100 randomly selected radiographs of the hip were scored by the same observer more than 1 month after the first reading. One hundred other radiographs were also scored by two experienced orthopedic surgeons (TI and SM) using the same atlas for interobserver variability. The intra- and intervariabilities evaluated for K/L grade (0–4) were confirmed by kappa analysis to be sufficient for assessment ($\kappa = 0.87$ and $\kappa = 0.85$, respectively).

Radiographic hip OA was defined as a K/L radiographic severity grade $\geq$2 (i.e., presence of at least probable joint space narrowing [JSN] in either the superolateral or superomedial hip joint, as well as presence of an osteophyte) and severe radiographic hip OA was defined as K/L $\geq$ 3. We defined an individual as having radiographic hip OA if at least one of the hip joints was affected. In addition, symptomatic hip OA was defined as having hip pain with corresponding radiographic OA in the same hip. Prevalence of total prevalence of hip OA (%) = (total number of subjects who were diagnosed as radiographic hip OA/total subjects who participated in the X-ray examination) $\times$ 100.

Individuals who had undergone a total hip arthroplasty (THA) were defined as having severe radiographic hip OA in that joint ($n = 13$ subjects; 18 hips). However at the time of analysis of the association with hip pain, we excluded all subjects who had undergone a THA.

Statistical analysis

Odds ratios (ORs) and 95% confidence intervals (95% CIs) are provided. Differences of age and BMI between men and women were examined by non-paired *t*-test. Differences in age, height, weight, and BMI among the urban, mountainous, and coastal communities were determined using one-way analysis of covariance and Tukey's honestly significant difference test. We used the chi square test to compare the prevalence of radiographic hip OA between men and women. Association of prevalence with age was determined by logistic-regression analysis after adjustment for BMI. Association of the variables such as age, BMI, gender, and community with radiographic hip OA was evaluated by multivariate logistic-regression analysis. Logistic-regression analyses were used to estimate OR and the associated 95% CI of K/L = 2 and K/L $\geq$ 3 hip OA for pain compared with K/L = 0/1 after adjustment for age, BMI, and community. Data analyses were performed using SAS version 11.0 (SAS Institute Inc., Cary, NC).

Results

Characteristics of participants

Of the 3040 subjects in the present study, 62 (2.0%) did not undergo plain radiography, 1 (0.03%) had just experienced bilateral hip fractures, and 2 (0.07%) could not read; these subjects were excluded. The remaining 2975 subjects (95.8%) (1043 men and 1932 women), aged 23–94 years (mean 70.2 years), were included in this study (Table I). Men were significantly older than women in the overall population and in the urban population. Although the coastal residents tended to show higher body height and weight than residents in the other two communities, BMI was comparable among the three communities.

Prevalence of radiographic hip OA, hip pain, and symptomatic hip OA

Table II shows the prevalence of radiographic hip OA, severe radiographic hip OA, including unilateral and bilateral hip OA, hip pain, and symptomatic hip OA in the overall population and subgroups classified by gender and community. In the overall population, the prevalence of radiographic hip OA was 15.7%, severe radiographic hip OA was 2.12%, and that of hip pain was 1.86%. The prevalence of K/L ≥ 2 and K/L ≥ 3 symptomatic hip OA was 0.75% and 0.64%. The prevalence of radiographic hip OA was significantly higher in men than in women, but that of severe radiographic hip OA, hip pain, and symptomatic hip OA was significantly higher in women than in men. The prevalence of radiographic hip OA and hip pain were not significantly associated with age in either gender [Fig. 1]. Table II also shows the prevalence of radiographic hip OA classified by the regions. In the urban region, the prevalence of K/L ≥ 2 hip OA was 9.4% in men and 6.0% in women, respectively, and that of K/L ≥ 3 was 0.89% and 2.13%, respectively. In the mountainous region, the prevalence of K/L ≥ 2 hip OA was 16.4% in men and 16.1% in women, respectively, and that of K/L ≥ 3 was 0.63% and 2.59%, respectively. In the coastal region, the prevalence of K/L ≥ 2 hip OA was 34.7% in men and 25.4% in women, respectively, and that of K/L ≥ 3 was 2.89% and 3.11%, respectively. In the urban and mountainous regions, the prevalence of K/L ≥ 2 hip OA was significantly higher in men than in women, and in the coastal region, the prevalence of K/L ≥ 3 hip OA was significantly higher in women than in men.

Characteristics of participants classified by presence or absence of hip OA and hip pain

Mean age of subjects with and without radiographic hip OA was 70.4 ± 10.4 and 70.2 ± 11.2 years, respectively ($P = 0.68$). Mean age of subjects with and without severe radiographic hip OA was 72.5 ± 9.3 and 70.1 ± 11.1 years, respectively ($P = 0.05$), and that of subjects with and without hip pain was 67.6 ± 13.6 and 70.2 ± 11.1 years, respectively ($P = 0.16$).

Association of radiographic hip OA with hip pain

Table III shows the association of age, BMI, gender, and community with radiographic hip OA, severe radiographic hip OA, and hip pain. BMI was classified as normal (18.5 ≤ BMI < 25.0), thin (BMI < 18.5), obesity (25.0 ≤ BMI < 27.5), and high obesity (BMI ≥ 27.5). BMI ≥ 27.5, female sex, and community were significantly associated with radiographic hip OA. Female sex and coastal community were significantly associated with severe radiographic hip OA. Only female sex was significantly associated with hip pain. We then determined independent associated factors using a multiple logistic regression analysis that included the above significant

Table I
Characteristics of participants

	Men				Women			
	Overall	Urban	Mountainous	Coastal	Overall	Urban	Mountainous	Coastal
Number of subjects	1043	449	317	277	1932	845	540	547
Age (years)	71.0 ± 10.7	77.2 ± 4.2	69.5 ± 9.1†	62.6 ± 13.2†	69.8 ± 11.3*	76.3 ± 5.0*	68.6 ± 10.4†	60.8 ± 12.5†
Height (cm)	162.5 ± 6.7	161.3 ± 5.9	161.3 ± 6.9	165.8 ± 6.8†	149.8 ± 6.5*	148.6 ± 5.6*	148.2 ± 6.7*	153.2 ± 6.2*,†
Weight (kg)	61.3 ± 10.0	60.1 ± 8.7	60.0 ± 10.2	64.8 ± 11.0†	51.5 ± 8.6*	50.7 ± 8.4*	50.5 ± 8.6*	53.5 ± 8.8*,†
BMI (kg/m^2)	23.2 ± 3.1	23.1 ± 2.9	23.0 ± 3.0	23.5 ± 3.4	22.9 ± 3.5*	23.0 ± 3.5	23.0 ± 3.3	22.8 ± 3.6*

Data are means ± SD.
BMI, body mass index.
* $P < 0.05$ vs men in the corresponding group by non-paired t-test.
† $P < 0.05$ vs urban residents in the corresponding group by Tukey's honestly significant difference test.

Table II
Number (percentage) of participants with radiographic hip osteoarthritis, hip pain, and their combination

	Total ($n = 2975$)	Men ($n = 1043$)				Women ($n = 1932$)			
		Overall	Urban	Mountainous	Coastal	Overall	Urban	Mountainous	Coastal
K/L ≥ 2 hip OA									
Total	467 (15.7)	190 (18.2)	42 (9.4)	52 (16.4)	96 (34.7)	277 (14.3)*	51 (6.0)*	87 (16.1)	139 (25.4)*
Unilateral	278 (9.3)	103 (9.9)	29 (6.5)	30 (9.5)	44 (15.9)	175 (9.1)	36 (4.3)	55 (10.2)	84 (15.4)
Bilateral	189 (6.4)	87 (8.4)	13 (2.9)	22 (7.1)	52 (19.0)	102 (5.3)*	15 (1.8)	32 (6.0)	55 (10.1)*
K/L ≥ 3 hip OA									
Total	63 (2.12)	14 (1.34)	4 (0.89)	2 (0.63)	8 (2.89)	49 (2.54)*	18 (2.13)	14 (2.59)*	17 (3.11)
Unilateral	37 (1.24)	7 (0.67)	2 (0.45)	1 (0.32)	4 (1.44)	30 (1.55)*	13 (1.54)	10 (1.85)	7 (1.28)
Bilateral	26 (0.88)	7 (0.68)	2 (0.45)	1 (0.32)	4 (1.46)	19 (0.99)	5 (0.60)	4 (0.75)	10 (1.84)
Hip pain	55 (1.86)	6 (0.58)	3 (0.68)	0	3 (1.08)	49 (2.56)*	23 (2.77)*	11 (2.05)*	15 (2.75)
Symptomatic hip OA									
K/L ≥ 2	22 (0.75)	3 (0.29)	1 (0.23)	0	2 (0.72)	19 (0.99)*	8 (0.96)	5 (0.93)	6 (1.10)
K/L ≥ 3	19 (0.64)	2 (0.20)	1 (0.23)	0	1 (0.36)	17 (0.89)*	6 (0.72)	5 (0.93)	6 (1.10)

* $P < 0.05$ vs men in the corresponding group by chi-squared test.

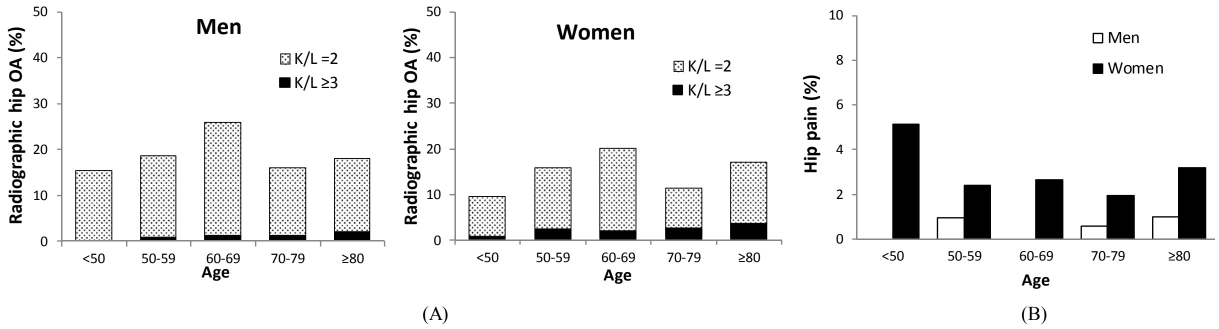

Fig. 1. (A) Prevalence (percentage) of subjects with radiographic hip osteoarthritis in each age stratum (<50, 50–59, 60–69, 70–79, ≥80). (B) Prevalence (percentage) of subjects overall with hip pain in each age stratum.

factors in the univariate model. The results were similar to the crude odds ratios.

When we considered hip pain in 5891 hips, we evaluated the association between K/L grade and hip pain in the designated hip. Figure 2 shows the percentage of subjects with hip pain in subgroups classified by radiographic hip OA severity: K/L = 0/1, K/L = 2, and K/L ≥ 3. In the overall population, the percentage of K/L = 0/1 was 0.75% (0.17% in men and 1.05% in women, respectively), that of K/L = 2 was 0.71% (0.78% and 0.64%, respectively), and that of K/L ≥ 3 was 36.2% (11.1% and 45.1%, respectively). In the urban community, the percentage of K/L = 0/1 was 0.79% (0.24% in men and 1.07% in women, respectively), that of K/L = 2 was 2.17% (0% and 4.65%, respectively), and that of K/L ≥ 3 was 42.1% (25.0% and 46.7%, respectively). In the mountainous community, the percentage of K/L = 0/1 was 0.40% (0% in men and 0.63% in women, respectively), that of K/L = 2 was 0%, and that of K/L ≥ 3 was 33.3% (0% and 40.0%, respectively). In the coastal community, the percentage of K/L = 0/1 was 1.08% (0.25% in men and 1.45% in women, respectively), that of K/L = 2 was 0.66% (1.47% and 0%, respectively), and that of K/L ≥ 3 was 34.4% (9.1% and 47.6%, respectively). Although the percentage with pain was positively correlated with radiographic severity, the difference between K/L = 2 and K/L ≥ 3 appeared to be greater than that between K/L = 0/1 and K/L = 2 in the overall population and all communities. Compared with K/L = 0/1, the OR of K/L ≥ 3 hip OA for hip pain was high, whereas that of K/L = 2 was not significantly associated with hip pain, even after adjustment for age, BMI, and community (Table IV).

Discussion

This is the first large-scale, population-based study to examine the prevalence of radiographic hip OA in Japanese men and women. We found that 15.7% of subjects had radiographic hip OA, 2.12% of subjects had severe radiographic hip OA, and 0.75% of subjects had symptomatic hip OA in at least one hip. We also examined the relation between the prevalence of radiographic hip OA, sex, and age. The present study showed factors associated with hip OA and the association of hip OA with hip pain.

Few studies have examined the prevalence of radiographic hip OA in Japan[3,15]. In 2000, Inoue *et al.* estimated the prevalence of K/L ≥ 3 hip OA among Japanese aged 20–79 years to be 1.4% in men and 3.5% in women, but their subjects were patients who underwent intravenous urography, who may not be representative of a general Japanese population. To the best of our knowledge, our previous study was the only population-based study to estimate the prevalence of hip OA among Japanese subjects; results showed that the prevalence of Croft grade ≥3 hip OA was 0% in men and 2% (95% CI 0.04–4.0) in women aged 60–79 years, but this study was published in 1998[3,16]. Because of the increasing number of elderly subjects in Japan, it is likely that these data have changed since our previous study. Furthermore, in Japan, previous studies showed only the prevalence of severe radiographic hip OA, but the prevalence of radiographic hip OA (e.g., K/L ≥ 2) was not reported. In the present study, we examined the prevalence of radiographic hip OA and severe radiographic hip OA using a large-scale, population-

Table III
Association factor for radiographic hip osteoarthritis and hip pain*

	Radiographic hip OA						Hip pain	
	K/L grade ≥2			K/L grade ≥3				
	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)
Age (+1 years)	–	1.00 (0.99–1.01)	–	–	0.98 (0.95–1.004)	–	–	1.02 (0.996–1.04)
BMI (kg/m^2)								
18.5≤, <25.0	297 (14.9)	Reference	Reference	37 (1.86)	Reference	–	33 (1.66)	Reference
<18.5	28 (13.1)	0.86 (0.56–1.28)	0.80 (0.51–1.22)	5 (2.34)	1.26 (0.43–2.97)	–	5 (2.34)	1.42 (0.48–3.36)
25.0≤, <27.5	74 (16.3)	1.11 (0.83–1.45)	1.09 (0.81–1.45)	9 (1.98)	1.07 (0.48–2.13)	–	12 (2.64)	1.61 (0.79–3.05)
≥27.5	66 (23.0)	1.70 (1.25–2.29)	1.83 (1.32–2.51)	10 (3.48)	1.91 (0.89–3.73)	–	5 (1.75)	1.06 (0.36–2.50)
Sex								
Men	189 (18.2)	Reference	Reference	13 (1.25)	Reference	Reference	6 (0.58)	Reference
Women	276 (14.5)	0.76 (0.62–0.93)	0.76 (0.62–0.95)	48 (2.51)	2.03 (1.13–3.92)	2.11 (1.17–4.09)	49 (2.57)	4.53 (2.09–11.85)
Community								
Urban	91 (7.18)	Reference	Reference	20 (1.58)	Reference	Reference	26 (2.06)	Reference
Mountainous	139 (16.2)	2.51 (1.90–3.32)	3.45 (2.59–4.62)	16 (1.87)	1.19 (0.60–2.30)	1.62 (0.81–3.19)	11 (1.29)	0.62 (0.29–1.23)
Coastal	235 (28.6)	5.16 (3.99–6.74)	10.08 (7.48–13.68)	25 (3.04)	1.95 (1.08–3.58)	3.47 (1.78–6.74)	18 (2.19)	1.07 (0.57–1.95)

* Adjusted odds ratios (ORs) were calculated by multiple logistic regression analysis after adjustment for all other variables in addition to regions. We show all variables we analyzed in the present study. K/L = Kellgren/Lawrence; 95%CI = 95% confidence interval; BMI = body mass index.

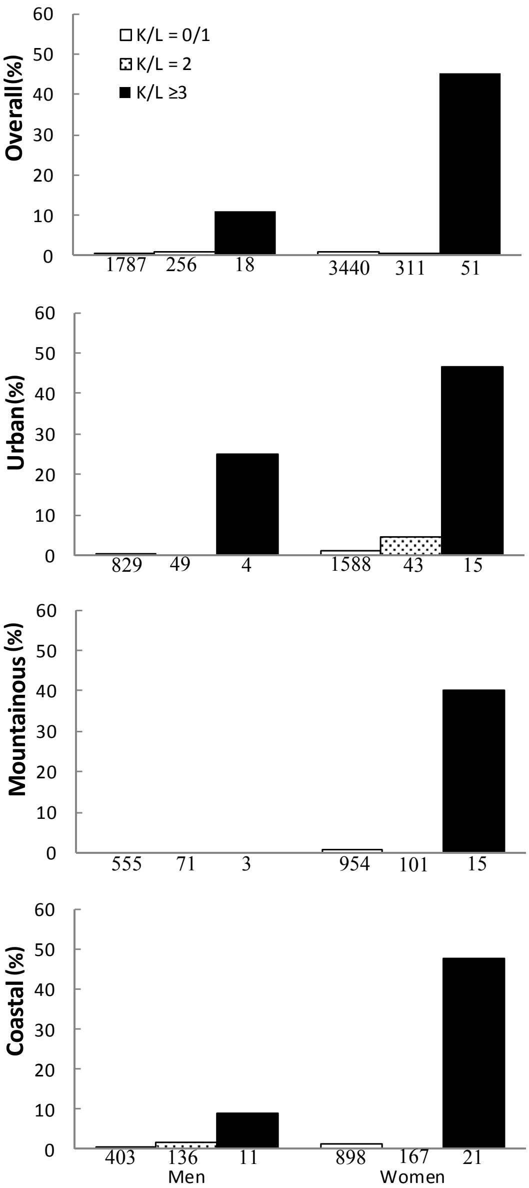

Fig. 2. Proportion (percentage) of subjects with hip pain in each subgroup classified by K/L grade in the overall population and communities. The number of subjects in each subgroup is shown under the bars. K/L, Kellgren/Lawrence.

based study and found that the prevalence of radiographic hip OA was 18.2% in men and 14.3% in women.

Although strict comparisons may be limited because the definitions of hip OA differ among studies and interobserver reliability for categorical methods is not good, the prevalence of hip OA in the present study is much lower than that seen in studies of Caucasians. In the Framingham study, the prevalence of K/L $\geq$ 2 hip OA was 24.7% (95% CI 20.6–28.7) and 13.6% (95%CI 10.7–16.5) in men and women, respectively[8]. The Johnston County prevalence study, a prevalence survey of a rural community in the United States, reported that the prevalence of K/L $\geq$ 2 hip OA was 27.6% (95%CI 26.3–28.9) and that of severe radiographic hip OA was 2.5% (95%CI 2.2–3.0)[6]; African Americans had a higher prevalence of hip OA than Caucasians. In the Rotterdam study, the prevalence of K/L $\geq$ 2 hip OA was 15.0% and that of K/L $\geq$ 3 hip OA was 4.3%[1]. In contrast, in a Beijing study, the prevalence of radiographic hip OA was 1.1% in men and 0.9% in women, which are similar or lower than values in the present study[7]. It is thought that the prevalence of hip OA is low in Asia[3,7,15,17,18], and that of severe radiographic hip OA is lower in Asians than in Caucasians; however, the presence of radiographic hip OA was not as low in the present study. These findings suggest that some ethnic factors may affect hip OA.

In the present study, coastal residency was significantly associated with radiographic hip OA, including severe radiographic hip OA, even after adjustment for age and BMI, indicating the involvement of environmental factors like nutrition or occupation. Both rural community backgrounds and farming have long been documented to be risk factors for hip OA. In England and India, rural male farmers were shown to have a higher risk of hip OA compared to rural male non-farmers[19,20]. The principle industries in the coastal residency are farming and fishing, which demand physical activity and repetitive laborious use of the hip joints, which may partly explain the higher prevalence of hip OA in the coastal region. We also found that the prevalence of radiographic hip OA was not associated with age in either gender. In the Copenhagen study, the prevalence of radiographic hip OA was age-dependent in both genders[4], whereas in the Beijing study, it slightly increased with age in men, but it did not increase with age in women[7]. These findings may also indicate a distinct etiology of hip OA among races. In addition, we also found that the prevalence of lumbar spondylosis (LS) and knee OA was significantly associated with age in the ROAD study[10,21], which may indicate that the etiology of hip OA may be different from that of LS and knee OA.

The association of gender with hip OA is controversial. Several studies in Caucasians showed that radiographic hip OA was more prevalent in men than in women[8,22], whereas in the Johnston County study and Rotterdam study, it was more prevalent in women than in men[1,6]. Previous studies in Japan showed that hip OA was significantly more prevalent in women than in men[3,15]. In the present study, interestingly, radiographic hip OA was more prevalent in men than in women, whereas, severe radiographic hip OA was more prevalent in women. In addition, the prevalence of radiographic hip OA was much higher than that of severe radiographic hip OA in the present study. This may be because a greater number of subjects in this study had osteophytosis than JSN. We have reported that osteophytosis of the lumbar spine was more

Table IV
Association of Kellgren/Lawrence grade with hip pain*

	Overall			Men			Women		
	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)
K/L grade									
0/1	39 (0.75)	Reference	Reference	3 (0.17)	Reference	Reference	36 (1.05)	Reference	Reference
2	4 (0.71)	0.9 (0.28–2.35)	1.36 (0.40–3.53)	2 (0.78)	4.68 (0.61–28.38)	4.50 (0.53–31.15)	2 (0.64)	0.6 (0.10–2.01)	0.79 (0.13–2.68)
≥3	25 (37.3)	80 (43.7–141.9)	123.4 (62.1–250.5)	2 (11.1)	74.3 (9.33–478.6)	57.3 (6.06–476.9)	23 (46.9)	83 (43.4–160.3)	129.1 (61.7–279.4)

We show all variables we analyzed in the present study. K/L = Kellgren/Lawrence; 95%CI = 95% confidence interval; BMI = body mass index.
* Adjusted odds ratios (ORs) were calculated by multiple logistic regression analysis after adjustment for age, BMI and communities.

prevalent in elderly Japanese men in the ROAD study[21]. In Japan, it appears that osteophytosis is more common in men than women[23,24]. However, this may indicate that the etiology of hip OA may be different from that of LS, because of the prevalence and the association were different between hip OA and LS. BMI was associated with radiographic hip OA, but not with severe radiographic hip OA in the present study. Several studies have reported that obesity has a low association with hip OA[7,18], whereas a multi-institutional study in Japan showed that obesity was a major cause for hip OA in women[25]. The discrepancy regarding the effect of obesity on hip OA may partly explain the distinct prevalence of various severities of hip OA[26].

Like the prevalence of severe radiographic hip OA, that of hip pain and symptomatic hip OA were low in both genders in the present study compared with previous studies, which showed that prevalence of hip pain was 7–40%, and that of symptomatic hip OA was 3–11%[1,5–8]. The present study also showed that the percentage of subjects with hip pain was less than 1% in subjects with K/L = 0/1 and 2, whereas it was more than 10% in men and more than 40% in women with K/L $\geq$ 3 hip OA. Furthermore, the OR of K/L $\geq$ 3 hip OA for hip pain was approximately 80 in both genders, which is much higher that of knee OA for knee pain in our previous study (K/L $\geq$ 3, OR 8.55, 95% CI 5.00–14.84 vs K/L = 0/1)[10]. This finding suggests that the prevalence of severe radiographic hip OA, hip pain, and symptomatic hip OA is low, but the association of hip pain with hip OA is much stronger than that for the knee.

Although the prevalence of radiographic hip OA was much higher than that of severe radiographic hip OA in the present study, the prevalence of symptomatic K/L $\geq$ 2 and K/L $\geq$ 3 hip OA was very low, and the difference in prevalence rates was small (0.75% and 0.64%, respectively). This finding indicates that subjects with K/L = 2 hip OA mostly did not have hip pain. This finding suggests that JSN, rather than osteophytosis, was associated with hip pain. We think that it is important to clarify the association of hip OA and hip pain to examine the prevalence of both K/L $\geq$ 2 and K/L $\geq$ 3.

There are several limitations to this study. First, regarding the selection bias of all participants of the ROAD study, we have already confirmed that participants of the ROAD study are representative of the Japanese population after comparison of anthropometric measurements and frequency of smoking and alcohol drinking between the participants and the general Japanese population. Thus, the values for the general population were obtained from the report on the 2005 National Health and Nutrition Survey conducted by the Ministry of Health, Labour and Welfare, Japan. No significant differences were identified between our participants and the total Japanese population, except that the male participants aged 70–74 years in the ROAD study were significantly smaller in terms of body structure than the overall Japanese population[12]. Unfortunately, we could not avoid the difference in the selection methods used in the three areas including the urban area, and both mountainous and coastal areas, performed during surveys in the ROAD study. Therefore, although coastal residency was significantly associated with radiographic hip OA in the present study, this factor might be affected by selection bias. Second, in the present report, we described the prevalence of hip OA with no mention of acetabular dysplasia.

In conclusion, this cross-sectional study using a large-scale population from the ROAD study clarified the prevalence of radiographic hip OA in Japanese men and women. The prevalence of radiographic hip OA was significantly higher in men than in women, but that of severe radiographic hip OA was significantly higher in women than in men and was not age-dependent in either gender. In addition, hip pain was strongly associated with K/L $\geq$ 3 hip OA. Further progress, along with continued longitudinal surveys of the ROAD study, will elucidate the backgrounds of hip OA and its relation with hip pain.

Author contributions

All authors have made substantial contributions to all three of the following sections:

(1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data;
(2) drafting the article or revising it critically for important intellectual content; and
(3) final approval of the version to be submitted.

Conflict of interests

There are no conflicts of interest.

Role of funding source

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Spine

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CERVICAL SPINE

Efficacy of Posterior Segmental Decompression Surgery for Pincer Mechanism in Cervical Spondylotic Myelopathy: A Retrospective Case-controlled Study Using Propensity Score Matching

Akihito Minamide, MD, PhD,* Munehito Yoshida, MD, PhD,* Hiroshi Yamada, MD, PhD,* Hiroshi Hashizume, MD, PhD,* Yukihiro Nakagawa, MD, PhD,* Hideto Nishi, MD, PhD,* Hiroshi Iwasaki, MD, PhD,* Shunji Tsutsui, MD, PhD,* Otohiro Okada, MD, PhD,* Sae Okada, MD,* and Hiroyuki Oka, MD, PhD†

Study Design. Retrospective case-controlled study using propensity score matching.

Objective. We aimed to evaluate the efficacy of cervical microendoscopic laminoplasty (CMEL) of the articular segment in patients with cervical spondylotic myelopathy (CSM) by comparing the clinical results of CMEL with conventional expansive laminoplasty (ELAP) for CSM.

Summary of Background Data. A total of 259 patients undergoing CMEL or ELAP surgery for CSM at authors' institute were reviewed.

Methods. The patients were matched according to calculated propensity scores in a logistic regression model adjusted for age, sex, and preoperative severity of disorders and divided into the CMEL and ELAP groups. All patients were followed postoperatively for more than 2 years. The preoperative and 2-year follow-up evaluations included neurological assessment (Japanese Orthopaedic Association [JOA] score), recovery rates, the JOA Cervical Myelopathy Evaluation Questionnaire (JOACMEQ), axial pain (visual analog scale), and the Short Form 36 questionnaire (SF-36).

Results. There were 71 patients in each group (47 males and 24 females each). The mean ages of the CMEL and ELAP groups were 63.8 and 62.8 years, respectively. There was no significant difference in the preoperative JOA score between groups. The mean numbers of surgically affected levels in the ELAP and CMEL groups were 3.2 and 1.8 discs, respectively ($P \leq 0.05$). The groups exhibited similar recoveries of JOA, JOACMEQ, and SF-36 scores postoperatively. Sagittal alignment was maintained in both groups. However, postoperative neck axial complaints were significantly reduced in the CMEL group.

Conclusion. CMEL may be a useful and effective surgical procedure for CSM, providing similar results as ELAP. CMEL for CSM is indicated for posterior decompression of the articular segment along with a pincer mechanism. This minimally invasive technique may have potential advantages compared with conventional ELAP, and may provide an alternative surgical option.

Key words: articular segment, cervical laminoplasty, cervical spine, cervical spondylotic myelopathy, clinical outcome, endoscopic spinal surgery, minimum invasive surgery, pincer mechanism, propensity score matching, retrospective case-controlled study.

Level of Evidence: 4

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From the *Department of Orthopaedic Surgery, Wakayama Medical University, Wakayama, Japan; and †Department of Medical Research and Management for Musculoskeletal Pain, 22nd Century Medical and Research Center, The University of Tokyo Hospital, Tokyo, Japan.

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Address correspondence and reprint requests to Akihito Minamide, MD, PhD, Department of Orthopaedic Surgery, Wakayama Medical University, 811–1 Kimiidera, Wakayama City, Wakayama 641–8510, Japan; E-mail: minamide@wakayama-med.ac.jp

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Cervical expansive laminoplasty (ELAP) for cervical myelopathy is a posterior decompression surgery that is reported to have favorable results.[1–9] However, some problems after conventional expansive laminectomy or laminoplasty have also been reported due to damage to the cervical posterior soft tissues including muscles and ligaments,[5,10–15] including persistent axial pain, restriction of neck motion, and loss of lordotic curvature. For the treatment of multisegment cervical myelopathy, the posterior arches of the cervical vertebrae and attached deep extensor muscles are extensively compromised by consecutive laminectomy or laminoplasty throughout the affected levels.

Endoscopic surgery poses several challenges for endoscopic surgeons, particularly in terms of mastering hand-eye coordination. After training in live animal and cadaver surgery was introduced, technical progress has reduced some postoperative morbidities such as dural tear, neural deficit, *etc.*[16] Microendoscopic decompressive techniques were recently developed and applied to various spine pathologies including lumbar spinal stenosis and cervical radiculopathy and myelopathy.[1,4,7,9,13,16–21] Over 3000 patients with lumbar spinal canal stenosis have undergone microendoscopic decompression surgery at the authors' institution. The authors have performed cervical microendoscopic laminoplasty (CMEL) as a minimally invasive strategy for cervical posterior decompression surgery of the articular segment with a pincer mechanism.[21] This procedure is also a spinal cord decompression procedure that maintains the posterior structures.

Therefore, in the present study, we aimed to evaluate the efficacy of CMEL for the articular segment with pincer mechanism in patients with cervical spondylotic myelopathy (CSM) by comparing the clinical results of CMEL with conventional ELAP for patients with CSM.

MATERIALS AND METHODS

Study Design

This retrospective case-control study of the clinical outcomes of CMEL and ELAP for the treatment of CSM used the propensity score matching method.[22] A one-to-one matching analysis was performed between patients who underwent ELAP and CMEL on the basis of the estimated propensity scores of each patient.

CMEL Technique

First, the patient is secured in a Mayfield headholder and is turned to the prone position. The neck is fixed in a neutral position. The operator generally stands on the side of the approach, usually the left, with the video monitors opposite him/her. Under fluoroscopic guidance held lateral to the patient, the targeting level is marked on the side of the approach. A skin incision approximately 16-mm long is made at the spinal level to be decompressed. After splitting into the paravertebral muscles, a set of serial dilators from the METRx endoscopic system (Medtronic Sofamor Danek, Memphis, TN) is passed to gently dilate the cervical musculature. The tubular retractor lies on the lamina and facet joints, and is tilted to parallel to the intervertebral disc (Figure 1A). The endoscope is then attached to the tubular retractor. With the bony edges well visualized, the interlaminar space and medial edge of the fact complex are confirmed.

To begin the partial laminectomy, a high-speed drill with a long curved endoscopic bit (*e.g.*, Midas-Rex Legend; Medtronic, Fort Worth, TX) is used to thin the lamina to near the attachment of the ligamentum flavum. The endoscope is then swung medially to obtain a contralateral view (Figure 1B). After the basement of spinal process is drilled, the laminotomy is performed using a long curved high-speed drill with an endoscopic bit. Thus, the laminotomy is performed with the drilling and tunneling of the internal plate of the lamina through the spinal canal side. The scope is rotated to a lateral position to make use of its 25° viewing angle. As a result of these maneuvers, an excellent viewing angle of approximately 60° to 75° is usually obtained with good contralateral visualization.

The superior attachment of the ligamentum flavum is exposed, and the procedure is then continued to the superior portion of the inferior lamina. The inferior attachment of the ligamentum flavum is subsequently exposed. It is important to continue the contralateral procedure without removing the ligamentum flavum in order to protect the spinal cord.

When the spinal cord is completely decompressed, the floated ligamentum flavum is observed (Figure 1C). The ligamentum flavum is subsequently completely removed, revealing the dural pulsation (Figure 1D). When decompression surgery is required for an adjacent level, the tubular retractor is inclined cranially or caudally. Then, the same procedure is repeated at the adjacent level (Figures 1E, 2A–C). For cases requiring operation of more than 3 levels, another skin incision is added. For example, in a case of C3–C7 CMEL, the skin incisions are made at the C4 and C6 levels. A drain is placed at each level to prevent postoperative epidural hematoma. Finally, the tubular retractor and endoscope are removed, and the fascia and skin are closed using standard techniques.

Patient Population

This study was approved by the institutional review board of the authors' institution. Between 2004 and December 2011, consecutive patients diagnosed with CSM were enrolled. All patients presented with symptoms of cervical myelopathy, such as clumsiness, numbness of the upper and lower extremities, gait disturbance, and urinary disturbance. Cervical spinal cord compression was confirmed by magnetic resonance imaging (MRI), myelography and postmyelography computed tomography. The exclusion criteria were cervical myelopathy with tumor, trauma, ossification of the posterior longitudinal ligament, rheumatoid arthritis, pyogenic spondylitis, destructive spondyloarthropathies, and other combined spinal lesion.

A total of 259 patients underwent posterior decompression surgery using either CMEL[21] (Figure 1) or conventional cervical ELAP (French-door[23]or open-door type[24]) at the authors' institution. Postoperatively, the use of a neck brace was left to the patients' discretion. All patients were followed postoperatively for more than 2 years.

Assessment

Neurological evaluation and recovery rates were assessed postoperatively by using Hirabayashi's method with the

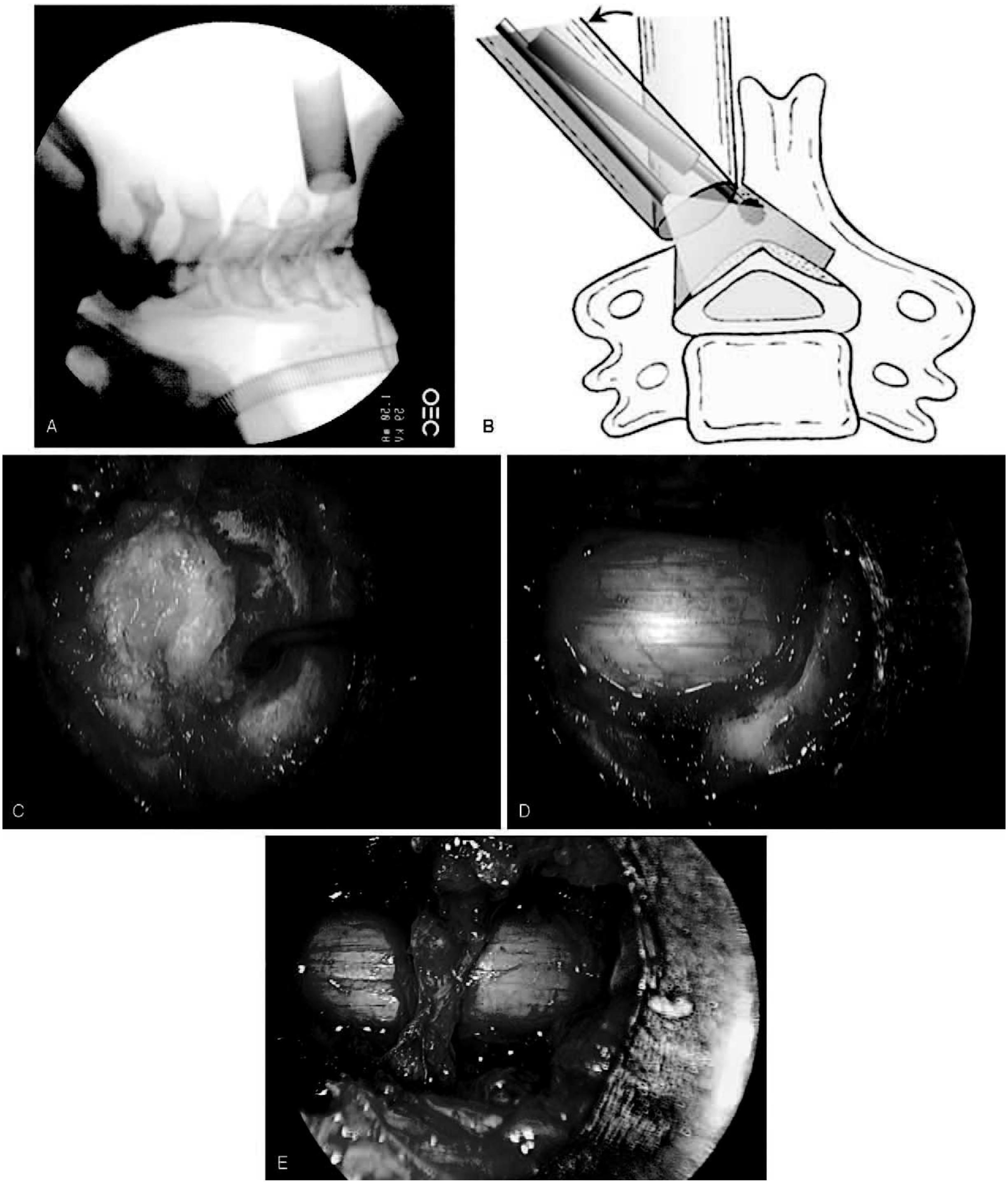

Figure 1. Cervical microendoscopic laminoplasty (CMEL) procedure. **(A)** The tubular retractor lies on the lamina and facet joints, and is tilted parallel to the intervertebral disc. The decompression surgery is performed using a high-speed air drill. **(B)** The hemilaminectomy is performed on the approaching side, followed by the laminotomy on the contralateral side done. Finally, the expansive laminotomy is completed to enlarge the spinal canal. **(C)** When the spinal cord is completely decompressed from all attachments of the ligamentum flavum, the floated ligamentum flavum is observed. **(D)** When the ligamentum flavum is completely removed, the ural pulsation is observed. The decompression is performed until the lateral edge of dural tube. **(E)** For an adjacent level, the tubular retractor is inclined cranially or caudally, and the above procedure is repeated.

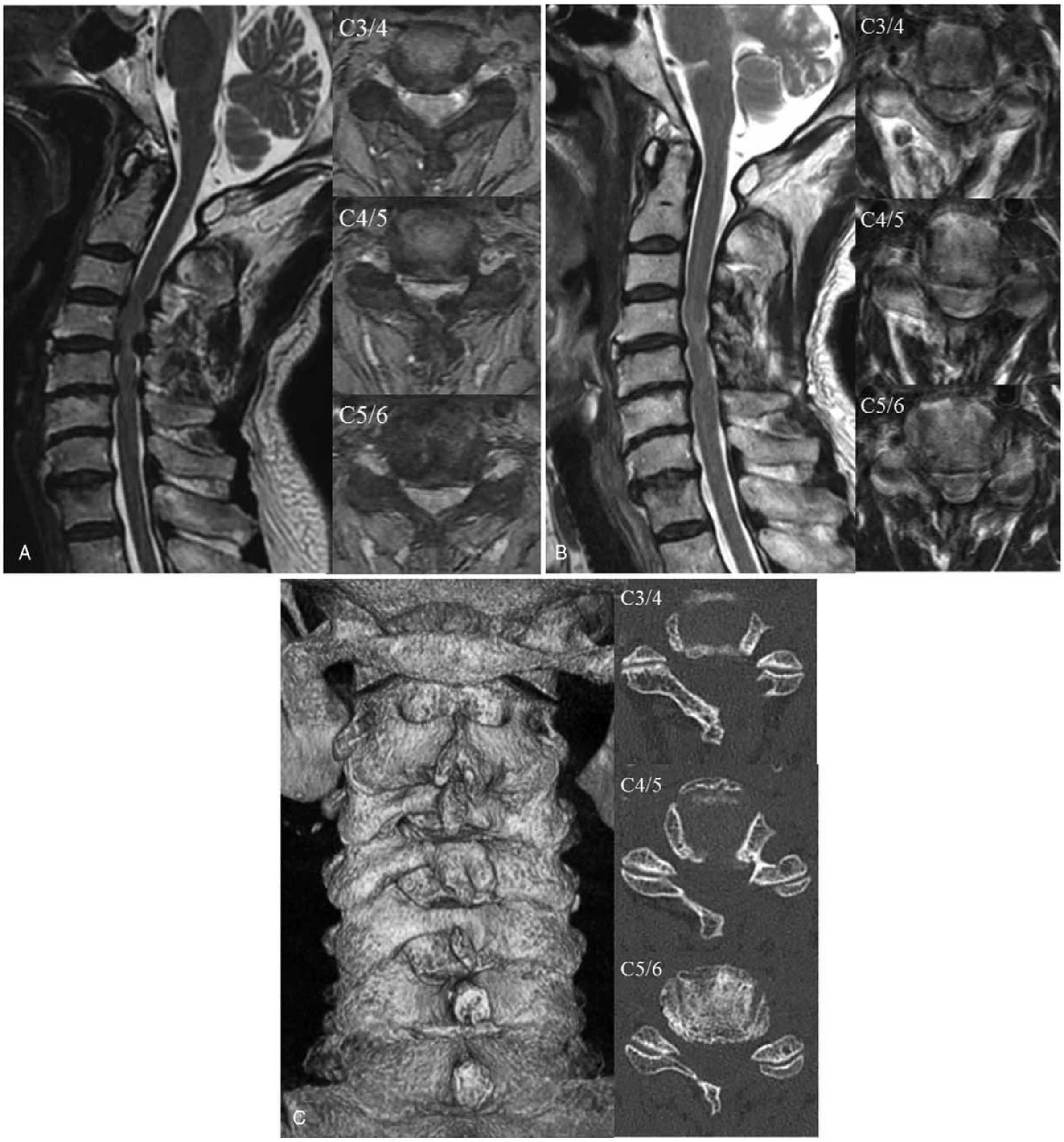

Figure 2. Illustrative case. A 74-yr-old female with cervical spondylotic myelopathy presented with clumsiness, numbness in the hands, crutch walking owing to spasticity, and urinary disturbance. **(A)** MRI showing spinal cord compression with spondylosis at the C3–C4, C4–C5, and C5–C6 levels, particularly severe spinal cord compression due to calcification of ligamentum flavum at C4–C5. The patient underwent CMEL from the C3–C6 levels. Her JOA score improved from 12 points preoperatively to 16 points 2 yr postoperatively. **(B, C)** MRI and CT yr postoperatively showing the success of spinal cord decompression. Axial images also show the successfully decompressed spinal cord at each level. By the unilateral approach, the partial hemilaminectomy and the laminotomy on the contralateral side are done at each level.

criteria proposed by the Japanese Orthopaedic Association scoring system (JOA score, maximum score: 17 points),[25] the JOA Cervical Myelopathy Evaluation Questionnaire (JOACMEQ),[26] the visual analog scale (VAS) for the assessment of axial pain, and the Short Form 36 (SF-36) survey. On the basis of JOACMEQ severity score points pre- and postoperatively, we investigated the effectiveness of treatment for cervical spine function, upper extremity function, lower extremity function, bladder function, and QOL. As for patient evaluations, we judged a treatment as effective when either of the following conditions was met: (1) postoperative score was increased by 20 or more compared with preoperative score or (2) preoperative score less than 90 reached 90 or more postoperatively. Furthermore, the effective rate of a group was calculated by dividing the number of subjects for whom treatment was judged as effective by the number obtained by subtracting the number of subjects with scores of 90 or more before surgery that remained 90 or

TABLE 1. Characteristics of Each Group on Matching by the Calculated Propensity Score

	ELAP*	CMEL†	P‡
Patients	71	71	
Sex	Male 47, female 24	Male 47, female 24	0.645
Age	63.8 ± 11.7	62.8 ± 13.7	0.96
Preoperative JOA§	10.1 ± 2.4	10.2 ± 2.6	<0.0001
Surgical levels¶	3.2 ± 0.6	1.8 ± 0.8	

*Conventional cervical expansive laminoplasty.
†Cervical microendoscopic laminoplasty.
‡$P < 0.05$ is statistically significant.
§Japanese Orthopaedic Association scoring system (JOA); full score 17 points.
¶The number of surgically affected levels.

more postoperatively from the total number of subjects constituting a group. Lateral radiographs were taken in the neutral position preoperatively and 2-years postoperatively. The lordotic angle was determined to be between the C2 and C7 angles at the neutral position using Cobb method.

Statistical Analysis

A one-to-one matching analysis was performed between the ELAP and CMEL groups on the basis of the estimated propensity scores of each patient. The propensity score approach addresses the selection bias inherent to retrospective observational studies, in which outcomes can reflect a lack of comparability in treatment groups rather than the actual effects of treatment.[22]

The matching procedure matched cases in the 2 groups according to the similarity of their propensity scores. A nearest-neighbor matching procedure was used, with the restriction that the propensities matched had to be within 0.05 units of each other. The application of propensity score matching involves the estimation of the propensity score followed by the matching of patients according to their estimated propensity score and comparison of outcomes in matched patients. To estimate the propensity score, we fitted a logistic regression model for the receipt of ELAP as a function of patient demographic factors including age, sex, and preoperative JOA score.

Demographic items were compared between surgical methods preoperatively and at the 2-year follow-up. Student *t* test was used to compare preoperative and postoperative recovery rates as well as JOA, JOACMEQ, VAS, and SF-36 scores between the CMEL and ELAP groups. All statistical analyses were performed using SPSS version 20.0 (SPSS Inc., Chicago, IL). The level of significance was set at $P < 0.05$.

RESULTS

There were 71 patients each in the CMEL and ELAP groups; each group comprised 47 males and 24 females. The mean ages at surgery in the ELAP and CMEL groups were 63.8 ± 11.7 and 62.8 ± 13.7 years, respectively ($P > 0.05$). The mean number of surgical levels involved in the ELAP and CMEL groups were 3.2 and 1.8, respectively ($P < 0.05$). The mean preoperative JOA scores in the ELAP and CMEL groups were 10.1 ± 2.4 and 10.2 ± 2.6 points, respectively ($P > 0.05$) (Table 1). The mean hospital stay was significantly shorter in the CMEL group than the ELAP group ($P < 0.01$) (Table 1). The mean recovery rates in the ELAP and CMEL groups were 56.3 ± 22.2% and 58.2 ± 23.7%, respectively; there was no significant difference in the JOA recovery rate between groups ($P = 0.35$) (Table 2).

Regarding perioperative complications, 1 patient each in the ELAP and CMEL groups had C5 nerve root palsy postoperatively and 2 patients developed postoperative epidural

TABLE 2. Clinical Outcomes on Each Surgical Procedure at the 2-yr Follow-up

	ELAP*	CMEL†	P‡
JOA§	13.9 ± 2.1	14.1 ± 1.9	0.485
JOA recovery rate	56.3 ± 22.2	62.8 ± 13.7	0.349
VAS¶	42.8 ± 32.4	24.5 ± 25.6	0.001
Satisfaction‖	7.8 ± 2.1	8.5 ± 1.8	0.036

*Conventional cervical expansive laminoplasty.
†Cervical microendoscopic laminoplasty.
‡$P < 0.05$ is statistically significant.
§Japanese Orthopaedic Association scoring system (JOA); full score 17 points.
¶Visual analogue scale for axial symptoms; full scale 100 mm.
‖Satisfaction for each surgery; full scale 10 points.

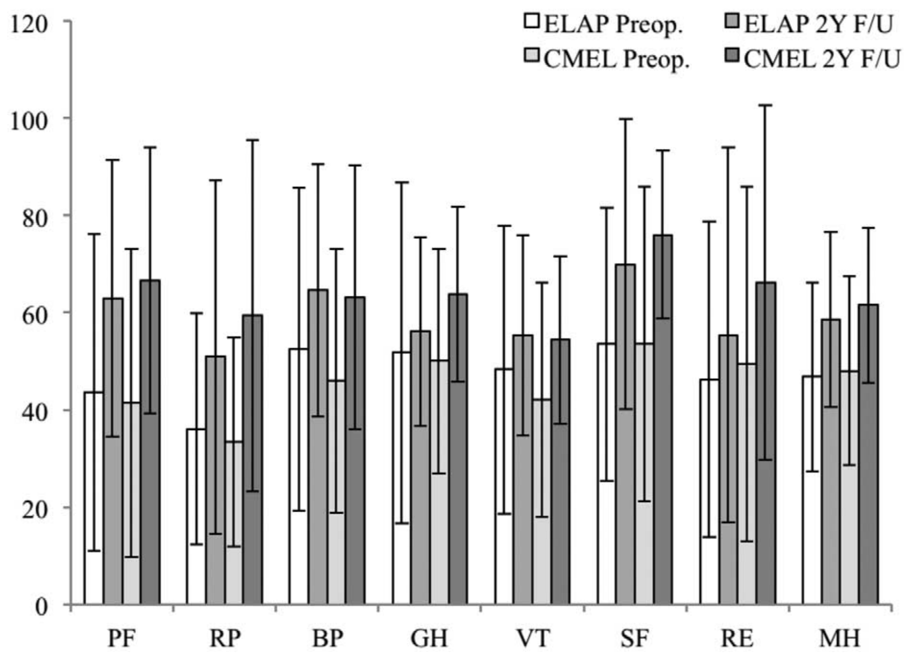

Figure 3. SF-36 scores. There were no significant differences in any subscale (physical functioning [PF], role physical [RP], bodily pain [BP], social functioning 1 [SF], general health perceptions [GH], vitality [VT], role emotional [RE], and mental health [MH]) between the CMEL and ELAP groups. (Preop: preoperatively, 2Y F/U: 2-yr follow-up).

hematoma in the CMEL group. All patients improved as a result of conservative treatment and had returned to daily life at the final follow-up. The VAS score for axial symptoms at the 2-year follow-up was significantly lower in the CMEL group than the ELAP group ($P = 0.001$) (Table 2). Regarding the JOACMEQ and SF-36 scores, there were no significant differences in any subscale between groups ($P > 0.05$) (Figure 3) (Table 3). The score on the patient satisfaction scale (scored on 10 points) was significantly higher in the CMEL group than the ELAP group ($P = 0.036$) (Table 2).

In the ELAP group, the mean lordotic angle was 8.9° preoperatively and 9.1° at the 2-year follow-up (Table 4); that in the CMEL group was 12.3° preoperatively and 13.6° at the 2-year follow-up. There were no significant differences in the lordotic angle pre- and postoperatively between groups ($P > 0.05$). 2 patients each in the ELAP and CMEL groups had local kyphosis that was greater than 13°[27]; 1 patient each in both groups exhibited improved local kyphosis after surgery, whereas the other patients still had kyphosis. The recovery rate was 36.4% in the ELAP group and 39.1% in the CMEL group. With regard to changes in the alignment of the lateral neutral position, 2 patients each in the ELAP and CMEL groups presented with preoperative lordosis that changed to kyphosis at the 2-year follow-up. Similarly, 8 (11.3%) and 4 (4.2%) of 71 patients in the ELAP and CMEL groups, respectively, exhibited an increase in the lordotic angle greater than10°. This suggests CMEL maintained lordosis better than ELAP.

DISCUSSION

Axial symptoms after cervical ELAP have recently been reported[10–14]; the frequency of such symptoms is reported to be 3 times that following cervical anterior interbody fusion.[10] Postoperative complications including persistent axial pain remain unresolved. Therefore, various modifications of surgical techniques as well as early neck mobilization have been developed for conventional cervical laminoplasty to prevent such morbidities.[23,28]

TABLE 3. Effective Rate of JOACMEQ* in Each Group

JOACMEQ*	ELAP† (%)	CMEL‡ (%)	P§
Cervical spine function	47.5	56.4	0.405
Upper extremity function	46.3	48.1	0.834
Lower extremity function	45.5	44.9	0.835
Bladder function	46.3	45.5	0.836
Quality of life	45.7	43.5	0.845

*Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire.
†Conventional cervical expansive laminoplasty.
‡Cervical microendoscopic laminoplasty.
§$P < 0.05$ is statistically significant.

TABLE 4. Between C2 and C7 Angle at the Neutral Position Using Cobb Method on Lateral Radiograph

	ELAP*	CMEL†	*P*‡
Preoperation	8.9 ± 10.7	12.3 ± 10.7	0.069
2-yr follow-up	9.1 ± 9.8	13.6 ± 10.6	0.011

*Conventional cervical expansive laminoplasty.
†Cervical microendoscopic laminoplasty.
‡$P < 0.05$ is statistically significant.

Intraoperative damage to the cervical posterior soft tissues including muscles and ligaments is reported to be one of the causes for these complications. Accordingly, the authors have been applying CMEL as a minimally invasive strategy for cervical posterior decompression surgery for cervical myelopathy.[21] This microendoscopic procedure involves a small skin incision that splits into the paravertebral muscles. CMEL also involves the combination of endoscopic hemilaminectomy and laminotomy. Compared with the conventional technique, endoscopic surgery substantially differs with respect to the influence on the soft tissues (Figure 4). In this study, the VAS scores for the assessment of axial pain indicate that CMEL resulted in less damage to the cervical soft tissues than ELAP. This difference is due to the smaller skin incision and less damage to the soft tissues, including muscle, incurred by the minimally invasive CMEL technique.

The main indication for CMEL is myelopathy with posterior factors such as calcification or ossification of the ligamentum flavum and degenerative spondylosis with a pincer mechanism.[29–31] The procedure extends the adaptation for CSM to multiple levels. In patients with CSM, this was possible with the decompression of the articular segment (Figure 5 A,B). This procedure can achieve the posterior decompression of the spinal cord associated with CSM by the decompression of the articular segment. The surgical procedures of this concept for posterior decompression include the segmental partial laminectomy and skip laminectomy.[27,32] However, the indication for articular segment decompression is limited to the cervical myelopathies excluding developmental spinal canal stenosis and spinal canal stenosis with severe anterior factors such as severe ossification of the posterior longitudinal ligament. Compared with the conventional laminoplasty technique, CMEL limits the enlarged area of the spinal canal because of the laminotomy technique. The posterior shift of the spinal cord with ELAP was thought to be necessary for patients with ossification of the posterior longitudinal ligament.[2,3] CMEL is indicated for the posterior decompression of the articular segment when the posterior indentation of the spinal cord is recognized with or without anterior compression of a bony spur and a degenerative bulging disc.

In this study, the surgical disc levels differed between the 2 groups, although there was no difference in the surgical selection criteria for the patients with CSM. Endoscopic surgery poses several challenges for endoscopic surgeons, particularly in terms of mastering hand-eye coordination. The CMEL surgery also has a learning curve. Therefore, the decision for the use of either ELAP or CMEL as the surgical method for patients with CSM was made as per the operator's discretion. Moreover, based on the general concept of the posterior shift of the spinal cord with ELAP, ELAP at C3–C5, C3–C6, or C3–C7 was performed even in patients with CSM in whom the main lesion responsible was located at 1 or 2 disc levels; for example, a patient with CSM

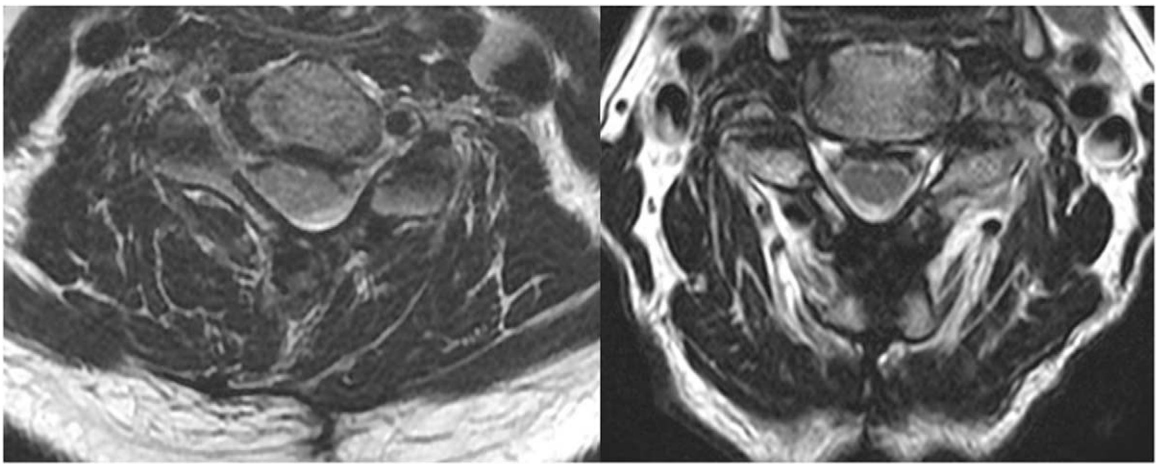

Figure 4. Influence of surgical techniques on soft tissues. The influence of endoscopic surgery (left) on the soft tissues differs substantially from that of conventional laminoplasty (right). MRI shows no changes of fatty degeneration in the paravertebral muscles after CMEL.

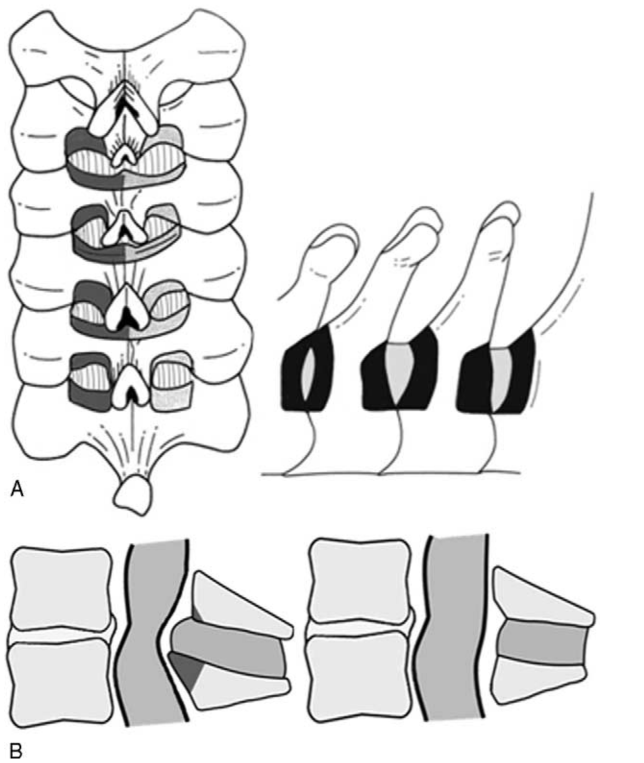

Figure 5. The microendoscopic procedure extends adaptation for patients of CSM. **(A)** Drilling and tunneling are performed from the inferior edge of the upper lamina to the superior edge of the lower lamina. The interlaminar space is enlarged until the attachment of the ligamentum flavum. **(B)** The ligamentum flavum is removed, and the spinal cord is decompressed, resulting in successful decompression of the articular segment.

with 1 lesion at the C4–C5 level underwent C3–C5 ELAP surgery, whereas a patient with CSM with 2 lesions at the C4–C5 and C5–C6 levels underwent C3–C6 ELAP surgery. However, CEL surgery was performed at the affected levels alone. Thus, it is possible that there may be another factor correlated with the decompression of the articular segment, besides the posterior shift of the spinal cord in CSM, unlike that in clinical conditions such as the ossification of the posterior longitudinal ligament.

The results of this study show that CMEL for CSM achieved a similar clinical outcome as ELAP with respect to the JOA, JOACMEQ, and SF-36 scores. Moreover, CMEL preserved the sagittal alignment of the cervical spine. This may indicate posterior decompression was sufficiently achieved and that the pincer mechanism was resolved. In addition to the recovery of spinal cord function, the invasion to the extensor musculature in the CMEL group may reduce postoperative axial neck pain.

The major limitation of this study is its retrospective case-control design with the use of propensity score matching, and the fact that it was not a randomized controlled trial, which would have been more desirable. The propensity score was estimated using preoperative clinical severity, which did not include imaging factors such as the stages of stenosis. Regardless, this study provides preliminary findings of this new surgical procedure, because the results indicate CMEL for CSM may have some advantages compared with laminoplasty. Nevertheless, further studies are required to clarify the efficacy and safety of this procedure.

In conclusion, this study indicates the clinical outcomes of CMEL for patients with CSM are similar to those of conventional laminoplasty. Posterior decompression of the articular segment with a pincer mechanism in CMEL can be indicated for patients with CSM. This minimally invasive technique may have potential advantages compared with conventional ELAP, and may provide an alternative surgical option.

➢ Key Points

- ❑ Compression of the cervical spinal cord in cervical spondylotic myelopathy (CSM) consists of a pincer mechanism due to bulging discs and a hypertrophied ligamentum flavum.
- ❑ Cervical microendoscopic laminoplasty (CMEL), in which the interlaminar space is enlarged until the attachment of the ligamentum flavum, which is then removed, exhibited comparable clinical outcomes as conventional expansive laminoplasty (ELAP) according to propensity score matching analysis.
- ❑ Posterior decompression of the cervical spinal cord in CSM is sufficient to remove the elements of the articular segment, such as the ligamentum flavum and the superior or inferior edge of the lamina.
- ❑ CMEL is promising for reducing postoperative neck and shoulder complaints caused by ELAP-induced soft-tissue damage.

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RESEARCH ARTICLE

Comparison of the Japanese Orthopaedic Association (JOA) Score and Modified JOA (mJOA) Score for the Assessment of Cervical Myelopathy: A Multicenter Observational Study

So Kato[1]*, Yasushi Oshima[1], Hiroyuki Oka[1], Hirotaka Chikuda[1], Yujiro Takeshita[2], Kota Miyoshi[2], Naohiro Kawamura[3], Kazuhiro Masuda[3], Junichi Kunogi[3], Rentaro Okazaki[4], Seiichi Azuma[4], Nobuhiro Hara[5], Sakae Tanaka[1], Katsushi Takeshita[1]

1 Department of Orthopaedic Surgery, the University of Tokyo, Tokyo, Japan, **2** Department of Orthopaedic Surgery, Yokohama Rosai Hospital, Yokohama, Japan, **3** Department of Spine and Orthopaedic Surgery, Japanese Red Cross Medical Center, Tokyo, Japan, **4** Department of Orthopaedic Surgery, Saitama Red Cross Hospital, Saitama, Japan, **5** Department of Orthopaedic Surgery, Musashino Red Cross Hospital, Musashino, Japan

* skatou-tky@umin.org

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Abstract

Objectives

The Japanese Orthopaedic Association (JOA) score is widely used to assess the severity of clinical symptoms in patients with cervical compressive myelopathy, particularly in East Asian countries. In contrast, modified versions of the JOA score are currently accepted as the standard tool for assessment in Western countries. The objective of the present study is to compare these scales and clarify their differences and interchangeability and verify their validity by comparing them to other outcome measures.

Materials and Methods

Five institutions participated in this prospective multicenter observational study. The JOA and modified JOA (mJOA) proposed by Benzel were recorded preoperatively and at three months postoperatively in patients with cervical compressive myelopathy who underwent decompression surgery. Patient reported outcome (PRO) measures, including Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ), the Short Form-12 (SF-12) and the Neck Disability Index (NDI), were also recorded. The preoperative JOA score and mJOA score were compared to each other and the PRO values. A Bland-Altman analysis was performed to investigate their limits of agreement.

Results

A total of ninety-two patients were included. The correlation coefficient (Spearman's rho) between the JOA and mJOA was 0.87. In contrast, the correlations between JOA/mJOA and the other PRO values were moderate (|rho| = 0.03 – 0.51). The correlation coefficient of the recovery rate between the JOA and mJOA was 0.75. The Bland-Altman analyses showed that limits of agreement were 3.6 to -1.2 for the total score, and 55.1% to -68.8% for the recovery rates.

Conclusions

In the present study, the JOA score and the mJOA score showed good correlation with each other in terms of their total scores and recovery rates. Previous studies using the JOA can be interpreted based on the mJOA; however it is not ideal to use them interchangeably. The validity of both scores was demonstrated by comparing these values to the PRO values.

Introduction

Cervical compressive myelopathy is a common disorder that frequently results in impairment of a patient's motor, sensory and bladder function. Several scales that measure severity of physical disability have been developed to assess a patient's pre- and post-treatment condition and the effectiveness of intervention. For example, the Japanese Orthopaedic Association (JOA) score was developed by the JOA in 1975. Since then, it has become one of the most frequently used outcome measures to evaluate functional status in patients with cervical myelopathy. Furthermore, and the concept of "recovery rate," advocated by Hirabayashi et al., has been widely accepted as an outcome measure [1]. Currently, the revised version of the JOA score (1994), which includes an assessment of the shoulder and elbow function, is the most frequently used [2, 3].

One of the drawbacks of the JOA score is that it evaluates the degree of motor dysfunction by assessing a patient's ability to use chopsticks. The use of chopsticks is limited to East Asian cultures including Japanese, Korean, Chinese and Vietnamese populations. The issues associated with using questionnaires related to cultural differences in eating methods have already been reported [4, 5]. Although chopsticks are now more widely used for eating, even in Western cultures, questionnaires using chopsticks cannot be readily applied to those who have not used them, or who do not use them regularly. Therefore, the adaptation of the JOA score to a Western population requires translation as well as modification [6]. Currently, there are three different kinds of so-called "modified JOA (mJOA) scores" [7–9]. However, the translation of these scores has not been validated and the scoring structure and content of evaluation items are substantially different. Despite their differences, the JOA score and the various modified scales are frequently confused with each other, and mistakenly discussed as being the same. Few comparisons of these scales have been made in the literature and few studies have assessed the validity of these scores. This causes confusion about which scale should be used in a certain population, and prevents us from comparing results of studies that used different modifications of the JOA score.

Therefore, it is very important to compare the properties of the JOA score and the mJOA score for the assessment of cervical myelopathy; the JOA score and the mJOA score. The objective of this study is to investigate the differences in and interchangeability of the JOA score and the mJOA score and to examine the validity of these scales by assessing correlations with other patient-reported outcome measures.

Materials and Methods

The study protocol was approved by the institutional review board of the Clinical Research Support Center of the University of Tokyo Hospital. In order to secure a sufficient number of participants, we called for volunteers from our research group, "The University of Tokyo Spine Group," and recruited five medical center institutions to participate in this prospective multicenter observational study. Ten surgeons in total were involved in this study. All eligible patients provided their written informed consent to participate in this study. All patients who underwent surgery for cervical compressive myelopathy between April 2013 and March 2014 were enrolled. Those with systemic diseases, including neurological disorders and rheumatoid arthritis, that could potentially affect motor function were excluded. Preoperatively, the surgeons recorded the following two scores.

JOA score (Table A in S1 File) [2, 3]

We used the latest version of the JOA score in Japanese. This scale consists of six domain scores (motor dysfunction in the upper extremities, motor dysfunction in the lower extremities, sensory function in the upper extremities, sensory function in the trunk, sensory function in the lower extremities, and bladder function), scaled from 0 to 4, 4, 2, 2, 2, and 3, respectively, with the minimum total score being 0 and the maximum total score being 17. Yonenobu et al. defined the myelopathy severity as mild if the JOA score is larger than 13, as moderate if the JOA score ranges from 9 to 13 and as severe if the JOA score is less than 9 [3]. Motor function in the fingers was assessed based on the ability to use chopsticks and button clothing. Keller et al. published the modified version in German [9, 10]. The authors did not mention the use of cutlery, but rather simply used the term "fine motor function" for the assessment of motor function in the upper extremities. The score proposed by Chiles et al. is similar, although the authors mentioned the use of a knife and fork [8]. The recovery rate was calculated according to the following formula (Hirabayashi method): Recovery rate (%) = (postoperative JOA −preoperative JOA) / (17 [full score]—preoperative JOA) × 100 [1].

Modified JOA score (Benzel et al.) (Table B in S1 File) [7]

This scale is the most commonly used among the so-called "mJOA" scores. Its scoring system differs from that of the original JOA in that it assesses only motor dysfunction in the upper and lower extremities, sensory function in the upper extremities, and bladder function, and does not include a scale for sensory function in the trunk and lower extremities. Each scale ranges from 0 to 7, 5, 3, and 3, respectively, with a total score of 0 to 18. Fehlings et al. defined the severity of myelopathy as mild if the mJOA score is 15 or larger, moderate if the mJOA score ranges from 12 to 14 or severe if the mJOA score is less than 12 [11]. This scale focused on the use of a spoon instead of chopsticks to evaluate motor function in the upper extremities. The recovery rate is calculated using the same formula as that applied for the original JOA, changing the full score from 17 to 18.

The differences between these scores are summarized in Table 1. The JOA score allocates 8 out of 17 (47%) points of the total score to motor function, while the mJOA score allocates 12 out of 18 (67%) points of the total score to motor function. These two scores were determined by the responsible surgeons at each institution. In addition to these scores, the Japanese Orthopaedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) [12], Short Form-12 (SF-12) [13] and the Neck Disability Index (NDI) [14] were recorded as patient reported outcome (PRO) measurements. These scales were completed by the patients in the form of questionnaires. The postoperative scores were recorded whenever possible at follow-up visits performed three months after surgery.

Table 1. A summary of the differences between the JOA score and modified JOA score.

	Structure							Assessment of MU
	MU	ML	SU+	ST	SL	BL	Total	
JOA [3]	4	4	2	2	2	3	17	Chopsticks
Modified JOA [7]	5	7	3	N/A	N/A	3	18	Spoon

JOA: Japanese Orthopaedic Association score, MU: motor function in the upper extremities, ML: motor function in the lower extremities, SU: sensory function in the upper extremities, ST: sensory function in the trunk, SL: sensory function in the lower extremities, BL: bladder function, N/A: not applicable

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The preoperative JOA and mJOA scores in each domain were compared with each other. The total scores were also compared with each other and to the PRO measurements. Furthermore, we compared the JOA and mJOA after dichotomizing the patients according to severity of motor function by the median of the JOA motor function scores. A prediction formula for the mJOA score was created using the JOA to enable direct comparisons between studies using these scores by converting the scores. We plotted the individual difference between the mJOA total score and the JOA total score (mJOA–JOA) against the average between the mJOA and JOA scores using a Bland–Altman plot. Bland-Altman analyses are now widely used for comparing two methods of measurement [15–19]. According to Bland and Altman, the limits of agreement can be estimated as the mean between duplicate measurements (the bias) ±1.96 SD, where the SD is the standard deviation of all of the paired differences [20]. This means that 95% of the differences will lie between these limits. Provided that differences within these lines are not clinically important, we could use the two measurement methods interchangeably. Although the minimally clinical important difference (MCID) of the JOA or mJOA has not been established, experts have argued that a difference of at least two points of mJOA is clinically important [21]. Therefore, the limits of agreement below 2 suggests the interchangeability of the two scores in the present study. Finally, among the patients whose postoperative scores at three months were available, the recovery rates for the JOA and mJOA scores were compared, and a Bland-Altman analysis was performed.

All analyses were carried out using the IBM SPSS Statistics Version 19 software package (SPSS, Inc., Somers, NY, USA). Correlations between the scores were analyzed by calculating the Spearman's rank correlation coefficient rho. P-values less than 0.05 were considered to be significant in all statistical tests. We defined the strength of the correlation according to the general guideline (rho $\geq$ 0.70: very strong, $\geq$ 0.50: strong, $\geq$ 0.30: moderate, $\geq$ 0.10: weak) [22].

Results

Ninety-two patients were included in the study. One patient whose bladder function could not be assessed due to anuria resulting from chronic renal failure was excluded. The mean age was 63.3 years (standard deviation: 12.9). The most common diagnosis indicated for surgery was cervical spondylotic myelopathy (58 patients), followed by ossification of the posterior longitudinal ligament (28 patients) and cervical disc herniation (six patients).

Comparisons of the scores in each domain

The correlations between the JOA and mJOA scores in each domain were strong to very strong, with correlation coefficients of 0.84 for motor function in the upper extremities ($p < 0.001$), 0.93 for motor function in the lower extremities ($p < 0.001$), 0.67 for sensory function in the upper extremities ($p < 0.001$) and 0.89 for bladder function ($p < 0.001$). The correlation

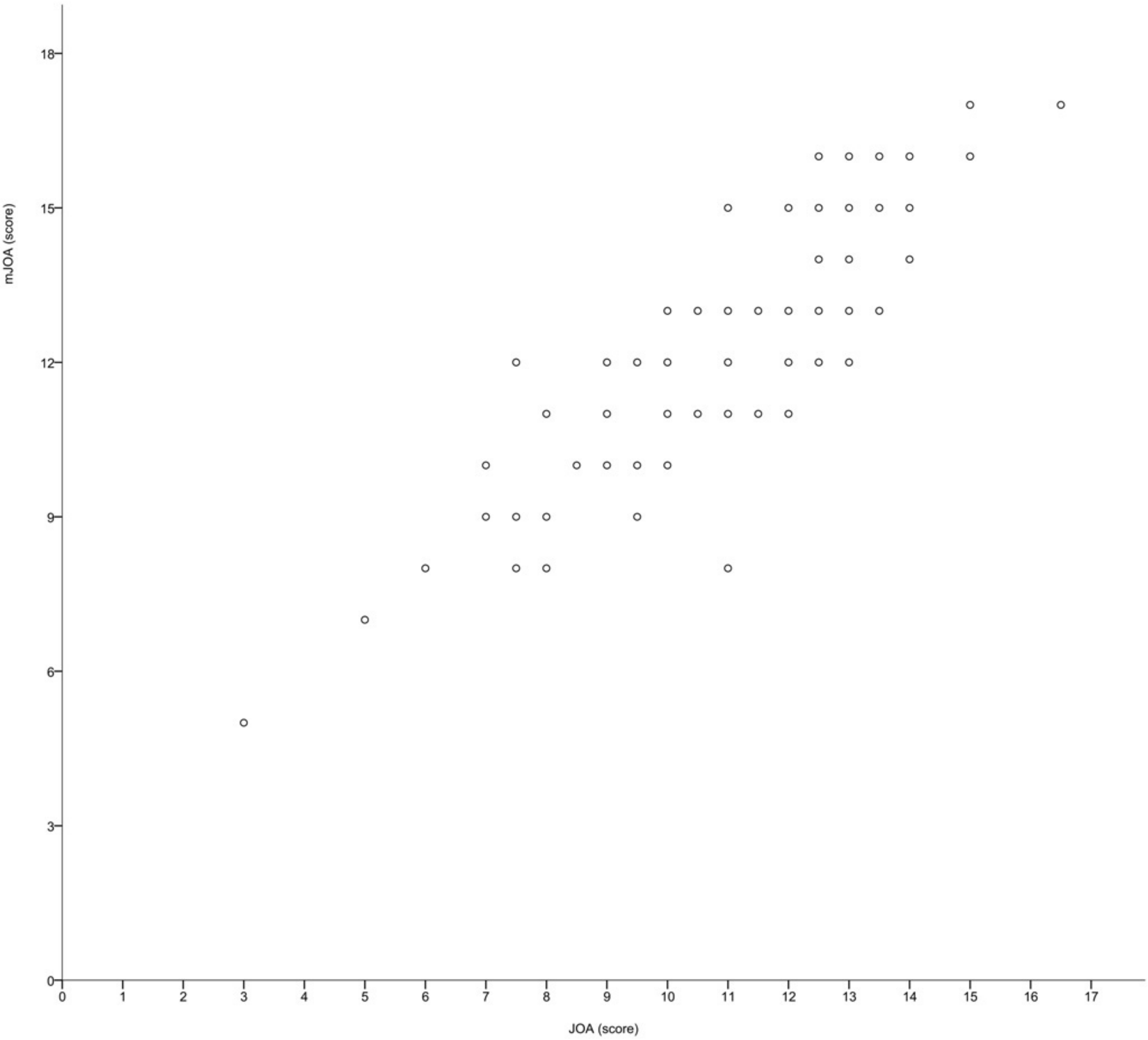

Fig 1. Scatterplot of the total scores for the JOA and mJOA scores (n = 92).

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between the total scores for motor function (the sum of the scores for the upper and lower extremities) was also very strong (rho = 0.90, $p < 0.001$).

Total score

The mean preoperative JOA score was 11.2 (range: 3.0–16.5, standard deviation: 2.5), whereas the mean mJOA score was 12.4 (range: 5–17, standard deviation: 2.5). A scatterplot of the JOA and mJOA scores is shown in Fig 1, and the correlations between the preoperative scores are summarized in Table 2. The JOA and mJOA scores were very strongly correlated with each other (rho = 0.87, $p < 0.001$). The median of the JOA motor function scores was 5. The correlation was found to be weaker in those with a motor function score less than 5 (n = 37,

Table 2. Correlations between the preoperative total scores among the JOA, modified JOA, JOACMEQ QOL score, SF-12 PCS, MCS and NDI (n = 92).

	JOA	Modified JOA	JOACMEQ QOL	SF-12 PCS	SF-12 MCS	NDI
JOA	1	0.87*	0.41*	0.50*	-0.05	-0.50*
Modified JOA		1	0.41*	0.47*	0.03	-0.51*
JOACMEQ			1	0.29*	0.40*	-0.66*
SF-12 PCS				1	-0.29*	-0.47*
SF-12 MCS					1	-0.17
NDI						1

* Statistical significance

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rho = 0.64) than in those with milder motor dysfunction (n = 55, rho = 0.77). On the other hand, the correlations between the JOA/mJOA scores and the other PRO values were not as strong. JOACMEQ QOL score, SF-12 PCS and NDI showed moderate correlations (|rho|: 0.41–0.51), whereas SF-12 MCS did not (|rho|: 0.03–0.05). While the very strong correlation between the JOA and mJOA scores demonstrates convergent validity, the moderate correlation with other PRO values suggests divergent validity. We created a prediction formula to calculate the total scores for the mJOA from the score of the JOA using linear regression analysis. The result is as follows:

$$\text{mJOA total} = 2.39 + 0.89 \times (\text{JOA total})$$

The R^2 of this equation was 0.78.

A Bland–Altman plot showing the differences between the two scores (mJOA–JOA) plotted against the mean of the two scores is shown in Fig 2. The mean difference between the two scores (the bias) was 1.2 (95% confidence interval: 0.9–1.5, standard deviation: 1.21). The upper and lower limits of agreement were 3.6 and -1.2, respectively. This range was well above the threshold we set based on an assumed MCID [21]; from this result, we were able to conclude that it is not ideal to interchange the JOA and mJOA.

Recovery rate (RR)

In 65 patients (71%) followed at three months postoperatively, the recovery rates were calculated using the Hirabayashi method and compared with each other. The mean JOA recovery rate was 45.1% (range: -33%– 100%, standard deviation: 30.8%), whereas the mean mJOA recovery rate was 38.2% (range: -200%– 100%, standard deviation: 43.0%). A scatterplot of the recovery rates for the JOA and mJOA is shown in Fig 3. In this figure, one outlier whose JOA RR was 0 and mJOA RR was -2.0 (deterioration), was omitted. Their correlations were very strong (rho: 0.75, p <0.001). In two cases, one scale showed recovery while the other showed deterioration. Both of these patients had urinary symptoms. We created a prediction formula to calculate the mJOA RR from the JOA RR using linear regression analysis. The result is as follows:

$$\text{mJOA RR} = -0.05 + 0.95 \times (\text{JOA RR})$$

The R^2 value of this equation was 0.46.

A Bland–Altman plot showing the differences between the two recovery rates plotted against the mean of the two recovery rates is shown in Fig 4. The mean bias was -6.9% (95% confidence interval: -14.7%– 1.0%, standard deviation: 31.6%). The upper and lower limits of

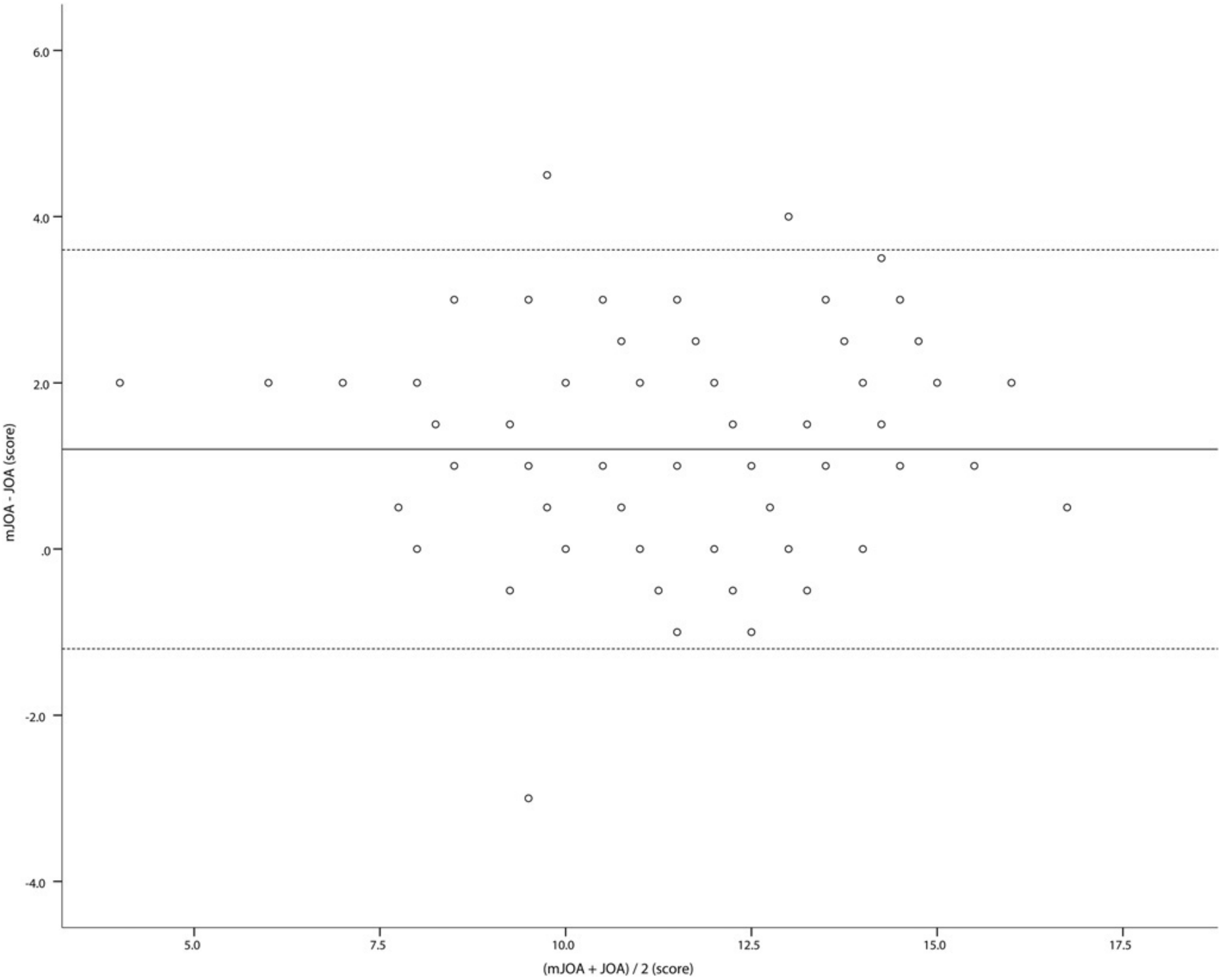

Fig 2. A Bland–Altman plot comparing the JOA and mJOA scores. The bias is shown as a solid line, and the upper and lower limits of agreement are shown as broken lines.

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agreement were 55.1% and -68.8%, respectively. This range is also substantial enough to consider that it is not ideal to interchange the recovery rates of the JOA and mJOA.

Discussion

There are two major findings in the present study. First, the domain and total scores of the JOA and mJOA were strongly correlated with each other. In addition, although the total scores and the recovery rates of the mJOA can be accurately predicted by the conversion formulas using the JOA score and its recovery rate, the Bland-Altman analyses showed they are not interchangeable. Second, the validity of the two types of JOA scores was demonstrated in comparisons with the PRO values.

No previous studies have directly compared the JOA and its modifications. The present study showed that the domain scores of the JOA and mJOA are strongly correlated, although the scoring structures of these scales differ in many domains, and the linearity of the scale is

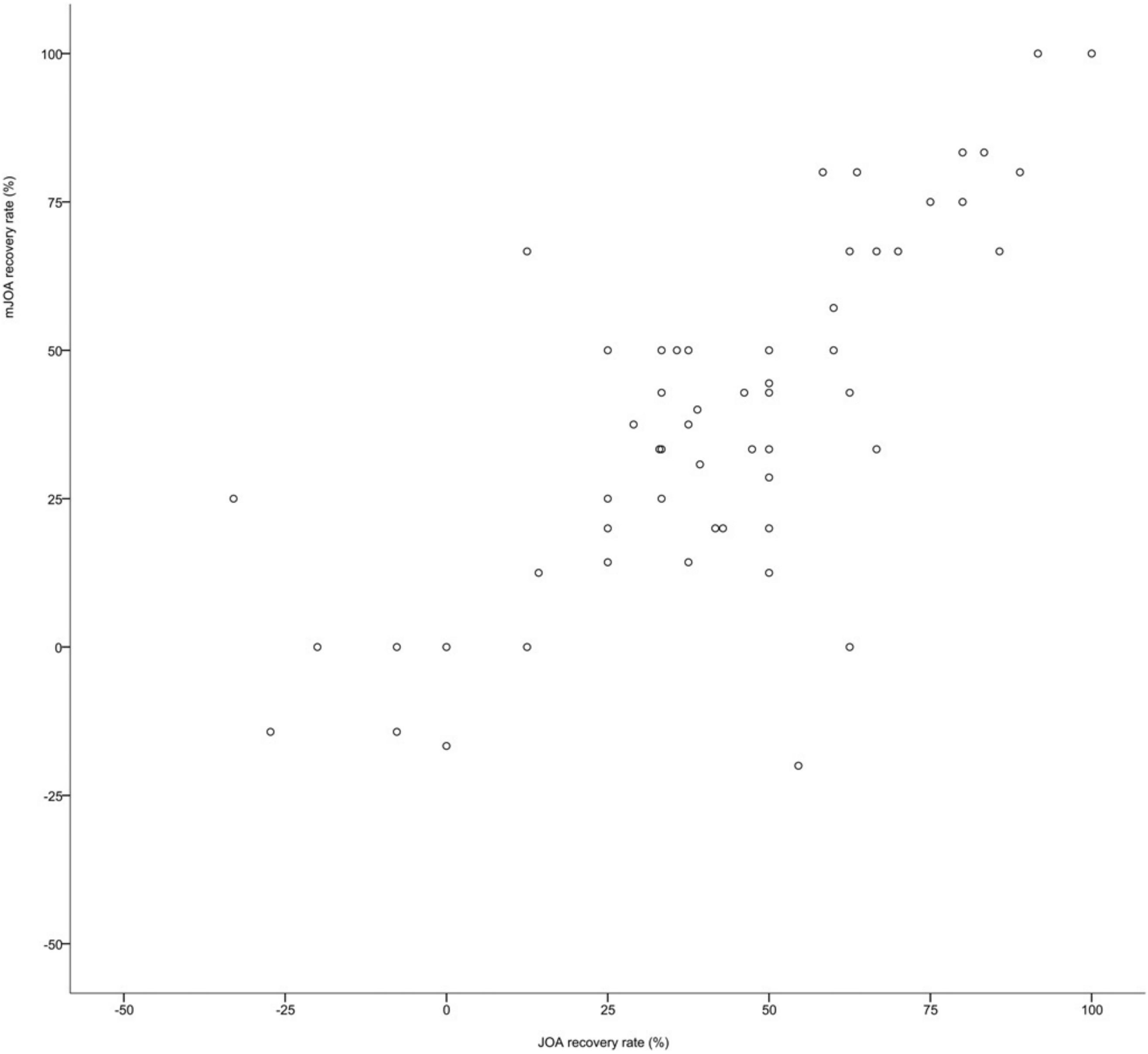

Fig 3. Scatterplot of the recovery rates for the JOA and mJOA scores. This figure includes only cases with a recovery rate from -1.0 to +1.0. Only two outliers were omitted (n = 63).

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not guaranteed. It is of note that the mJOA score exhibited a very strong correlation with the JOA score, despite that the mJOA lacks scores for sensory function in the trunk and lower extremities. This finding may be due to the fact that severe sensory disturbances in the trunk or lower extremities are relatively rare in operative candidates for cervical myelopathy. The correlation between the scores for the sensory function in the upper extremities was lower than that for the other domains. This result may be explained by the exaggerated construct differences in which the JOA has two points and the mJOA has three points. The correlation in the subjects with severer motor dysfunction was weaker. This finding is also understandable given that the mJOA score gives a higher proportion to the motor function score. In the two patients with

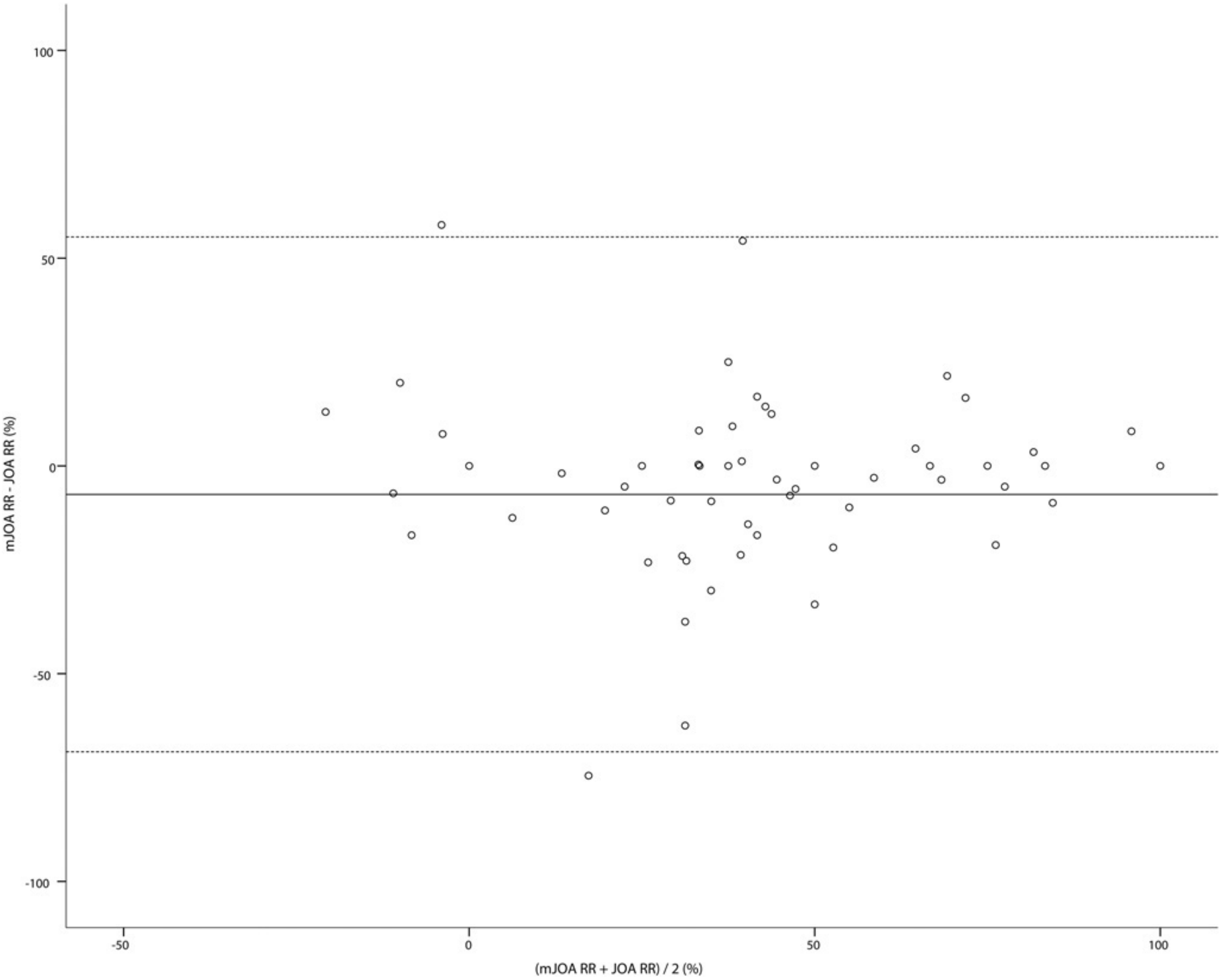

Fig 4. A Bland–Altman plot comparing the JOA and mJOA recovery rates. The bias is shown as a solid line, and the upper and lower limits of agreement are shown as broken lines.

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urinary symptoms, the recovery was not properly reflected in one scale. The bladder function score in the JOA tended to be exaggerated because the JOA criteria are more complicated than those of the mJOA. For example, the sense of urinary retention can lead to the patients receiving a score of 1, and this symptom is very common even in the elderly generation without myelopathy. These comparisons did not lead us to conclude that one scale had significant advantages over the other, and any of them can be used as desired based on the patients' cultural background. The mJOA would be more easily accepted for Asian populations, since many of them now use a spoon, than would the JOA for Western populations, although no validated translations in Asian languages exist, and this would be an obstacle for raters who do not understand English. Using our conversion formulas, it is possible to interpret the results of previous studies that used the mJOA according to the original JOA score. For example, if a study set a certain cut-off point to evaluate the effectiveness of a treatment using the recovery rate, we speculate that the evaluation might be slightly stricter when using the mJOA instead of the JOA.

The present study showed that the scores for the mJOA and JOA are strongly correlated; however, Anscombe suggested that data with nearly identical simple statistical properties may appear very different when graphed [23]. A further understanding of the relationship between the mJOA and JOA scores can be achieved by looking at the differences between the two methods plotted against the mean score for each subject. We therefore examined the two seemingly compatible scores using Bland-Altman plots. Although Bland-Altman analyses were originally developed to make comparisons of two methods using the same scale, many authors have since applied this technique to the comparisons of two different scales [16, 19]. The range of the JOA score and mJOA score differ slightly (0–17 vs. 0–18), but very few patients in the present study achieved a nearly full score, which theoretically maximizes the difference between the two scales. Since a Bland-Altman analysis is the best method for visualizing errors and because there are no alternatives, we believe that the application of this method to the present dataset is acceptable. In Fig 2, the error appears unbiased, as differences are spread evenly and randomly above and below zero points. We examined the agreement between these two methods by looking at the spread of differences. The variability between the two methods is reflected by the limits of agreement, which were substantial in the present study. Based on this difference, a patient can easily be categorized into different groups of severity by both the JOA and mJOA.

While the criterion validity of the JOA score has been discussed by comparing it to the results of multiple other scales, including the Cooper myelopathy scale (CMS) [10, 24], European myelopathy scale (EMS) [10, 25] and Short Form-36 (SF-36) PCS [26, 27], few studies have discussed the validation of mJOA based on comparisons of these scores with the PRO values [28]. The mJOA score has been compared with the Nurick grade [29–31], NDI and SF-36 [31]. We measured the concurrent validity by performing comparisons to the JOACMEQ, SF-12 and NDI. In the present study, we used the SF-12 instead of the SF-36 because the summary scores for the SF-12 have been shown to mirror those of the SF-36 [13]. All of these results suggest divergent validity. The PRO forms are completed by the patients, as opposed to the JOA and mJOA, and these scales are substantially affected by the patients quality of life. Meanwhile, the JOA and mJOA are more disease-specific for cervical myelopathy and likely measure a different construct. These results are in accordance with the findings of the study by Kopjar et al. that validated the mJOA score [31].

There are some limitations associated with the present study. First, the rate of follow-up was not as high as expected. Many patients dropped out after the surgery as they were satisfied with their postoperative results. Therefore, the analysis of the recovery rate may have been biased. Second, because the assessment for the JOA score and mJOA were produced in different languages, the translational validity was not verified. Finally, the inter-observer reliability and test-retest reliability were not investigated in the present study. However, the inter- and intra- observer reliability of the JOA is reported to be high [3]. The inter-observer reliability of the mJOA has also been reported to be high [32], although this finding should be interpreted with caution since a translated version of the scale was used in this study. Unfortunately, the test-retest reliability of the mJOA has not yet been established. Further studies may make it possible to compare the properties of these scores.

Conclusion

In conclusion, the mJOA score is very strongly correlated with the JOA, and previous studies using the JOA can be interpreted based on the mJOA based on this speculation, especially by using the conversion formulas advocated in this report. However, the Bland-Altman analysis revealed that it is not ideal to use these scoring systems interchangeably.

Supporting Information

S1 Dataset. Dataset of the outcomes in the participants.
(XLSX)

S1 File. Table A, Japanese Orthopaedic Association Score (English translation) [3]. **Table B,** Modified Japanese Orthopaedic Association Score [7].
(DOCX)

Author Contributions

Conceived and designed the experiments: SK YO KT. Performed the experiments: SK YO YT Kazuhiro. Masuda NK Kota. Miyoshi JK RO SA NH. Analyzed the data: SK HO. Contributed reagents/materials/analysis tools: SK. Wrote the paper: SK YO HO KT HC ST.

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Clinical Study

Elevated levels of phosphorylated neurofilament heavy subunit in the cerebrospinal fluid of patients with lumbar spinal stenosis: preliminary findings

Junichi Ohya, MD[a], Hirotaka Chikuda, MD, PhD[a,*], So Kato, MD[a], Kentaro Hayakawa, MD, PhD[a], Hiroyuki Oka, MD[a], Katsushi Takeshita, MD, PhD[a], Sakae Tanaka, MD, PhD[a], Toru Ogata, MD, PhD[b]

[a]*Department of Orthopaedic Surgery, The University of Tokyo, 7-3-1 Hongo, Tokyo 113-8655, Japan*
[b]*Department of Rehabilitation for the Movement Functions, Research Institute, National Rehabilitation Center for Persons with Disabilities, 4-1, Namiki, Tokorozawa, Saitama, Japan*

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Abstract

BACKGROUND CONTEXT: The phosphorylated neurofilament heavy subunit (pNfH) is an axon fiber structural protein that is released into the cerebrospinal fluid (CSF) after nerve damage. Although the previous studies have reported elevated CSF levels of pNfH in various neurological diseases, including amyotrophic lateral sclerosis, these levels have not been examined in patients with spinal stenosis.
PURPOSE: The purpose of this study was to investigate the CSF levels of pNfH in patients with lumbar spinal stenosis (LSS) and to examine the relationship between CSF levels of pNfH and the severity of LSS.
STUDY DESIGN: This is a prospective observational study.
PATIENT SAMPLE: We included consecutive patients with LSS who were undergoing myelography for preoperative evaluation. The CSF samples from patients with idiopathic scoliosis were used as the controls.
OUTCOME MEASURES: Physiological measures: CSF levels of pNfH were measured using an enzyme-linked immunosorbent assay. The Zurich Claudication Questionnaire (ZCQ) and the Numerical Rating Scale (NRS) for sciatic pain were used to assess the clinical severity of LSS, and patients were grouped into tertiles according to their symptom severity and pain grading. Axial magnetic resonance imaging was used to evaluate the morphological severity of LSS, and patients were classified into three groups based on their morphological grading (using the CSF/rootlet ratio).
METHODS: Analysis of variance was used to examine the relationship between the CSF levels of pNfH and the severity of LSS.
RESULTS: Thirty-three patients with LSS were included (13 men and 20 women and mean age 73.2 [range 58–88] years). Most patients (n=32) were positive for pNfH in their CSF (mean 1,344 [149–9,250] pg/mL), whereas all control subjects were negative for pNfH in their CSF.

FDA device/drug status: Not applicable.

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* Corresponding author. Department of Orthopaedic Surgery, Sensory and Motor System Medicine, Surgical Sciences, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan. Tel.: (81) 3-3815-5411; fax: (81) 3-3818-4082.

E-mail address: chikuda-tky@umin.ac.jp (H. Chikuda)

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Regarding the association with clinical severity, patients in the third tertiles of ZCQ and NRS tended to have higher levels of pNfH compared with the other groups. There was no association between the CSF level of pNfH and the morphological severity of LSS.

CONCLUSIONS: This study detected elevated pNfH levels in the CSF of patients with LSS. Patients with severe clinical symptoms were more likely to exhibit high levels of pNfH. Our results indicate the potential usefulness of pNfH as a biomarker for compressive spinal disorders.

Keywords: Phosphorylated neurofilament heavy subunit; Cerebrospinal fluid; Lumbar spinal stenosis; Outcome; Diagnosis; Biomarker

Introduction

Lumbar spinal stenosis (LSS) is a common clinical condition among elderly patients and is now the most common diagnosis for patients 65 years and older who require spinal surgery [1]. Although surgical treatment of LSS generally produces favorable outcomes, 20% to 30% of patients who undergo surgery are dissatisfied with the results because of residual symptoms [2–5]. Despite the importance of surgical treatment, its indication typically relies on an individual patient's symptoms, as imaging results do not always accurately reflect the severity of the disease [6–9]. Therefore, given the lack of objective indicators of LSS severity, an optimal timing for surgical treatment of LSS has not been established.

The phosphorylated neurofilament heavy subunit (pNfH) is a type of neurofilament that is involved in maintaining the structure and size of neurons and in conducting nerve impulses along the axons [10]. After the destruction of neural tissue, significant amounts of pNfH are released into the cerebrospinal fluid (CSF). Previous studies have reported that the CSF levels of pNfH were elevated in various neurological disorders, including amyotrophic lateral sclerosis [11], multiple sclerosis [12], Guillain-Barre syndrome [13], and aneurysmal subarachnoid hemorrhage [14]. Given the relative stability of pNfH in CSF [15], it is considered as a good candidate molecule for monitoring the magnitude of neural damage [16]. For instance, a high pNfH level in both the CSF and serum indicates a poor prognosis in patients with amyotrophic lateral sclerosis (ALS) [11]. However, despite the potential usefulness of pNfH as a biomarker, no study has examined the CSF levels of pNfH in patients with spinal stenosis. Therefore, the purpose of this study was to investigate the CSF levels of pNfH in patients with LSS and to examine the relationship between pNfH levels and the severity of LSS.

Materials and methods

Data source

We included patients with LSS who were undergoing myelography for preoperative evaluation between April 2013 and March 2014. Our institution routinely performs preoperative myelography as a part of our evaluation for LSS patients with multilevel stenosis or spondylolisthesis, and this technique is used to determine the appropriate surgical procedure. Patients with concomitant spinal stenosis at other regions (ie, cervical or thoracic spine) (n=7) or previous spinal surgery (n=4) were excluded from the analysis. The CSF of patients with idiopathic scoliosis, who had no neurological symptoms, was used as the control. Written informed consent was obtained from each patient, and the study was approved by the Institutional Review Board of the University of Tokyo.

Measurement of pNfH

Two milliliters of each patient's CSF were collected at the time of the myelography. The pNfH assay was carried out using a commercially available enzyme-linked immunosorbent assay kit (Human Phosphorylated Neurofilament H ELISA; BioVendor, Modrice, Czech Republic), as previously described [17]. Levels of pNfH that were less than the limit of detection (less than 70 pg/mL) were considered as negative results.

Clinical and magnetic resonance imaging evaluation

The Zurich Claudication Questionnaire (ZCQ) [18] and Numerical Rating Scale (NRS) for sciatic pain were used to assess the clinical severity of LSS. Patients were categorized into tertiles based on the results of the ZCQ and NRS tools. Axial magnetic resonance imaging (MRI) was used to evaluate the morphological severity of LSS, and patients were classified into three groups based on their morphological grading, using the CSF/rootlet ratio (as previously described) [19]. In Group A/B, the rootlets could be recognized, and CSF was present, giving the sac a grainy appearance. In Group C, no rootlets could be recognized, the dural sac produced a homogenous gray signal with no visible CSF signal, and posterior epidural fat was present. In Group D, there was no posterior epidural fat, and no rootlets could be recognized.

Statistical analyses

All statistical analyses were performed by using JMP Pro 10 (SAS Institute, Cary, NC, USA). We used analysis of variance to compare the pNfH levels from each group. The threshold for significance was p value less than .05.

Results

This study included 33 patients with LSS who underwent preoperative myelography (13 men and 20 women and mean age 73.2 [range 58–88] years), and all but one were positive for pNfH in the CSF (Table). The mean CSF level of pNfH in these patients was 1,344 (range 149–9,250) pg/mL (Fig. 1), and all the 21 control subjects were negative for pNfH in their CSF. The sensitivity and specificity of pNfH presence as a predictor of LSS were 97% and 100%, respectively. There was no correlation between the CSF level of pNfH and age ($\rho=0.10$, $p=.61$).

Of the 32 patients with CSF positive for pNfH, 21 completed the ZCQ. Patients were categorized into tertiles according to symptom severity: six patients in Tertile 1 (score less than 21), seven in Tertile 2 (score=21 or 22), and eight in Tertile 3 (score greater than 22). Patients in the third tertile were more likely to have higher CSF levels of pNfH compared with the remaining groups, although this result was not statistically significant ($p=.18$) (Fig. 2).

Regarding sciatic pain, 19 patients were categorized into tertiles according to NRS severity: 4 patients in Tertile 1 (score 0–5), 7 in Tertile 2 (6 or 7), and 8 in Tertile 3 (8–10). Patients in the third tertile were more likely to have higher CSF levels of pNfH compared with the remaining groups, although this result was not statistically significant ($p=.36$) (Fig. 3).

With the exception of one patient, most patients with a pacemaker underwent MRI (n=31). We categorized these patients into 3 groups based on the extent of their stenosis: 9 patients in Group A/B (mild stenosis), 14 in Group C (moderate stenosis), and 8 in Group D (severe stenosis). There was no significant difference in the CSF levels of pNfH among the three groups ($p=.65$) (Fig. 4).

Discussion

This pilot study had three main findings. First, the vast majority of CSF samples from patients with LSS were positive for pNfH, and CSF samples from the control subjects were all negative for pNfH. Second, patients with severe clinical symptoms (as assessed by ZCQ or NRS) tended to have higher CSF levels of pNfH. Third, there was no association between the pNfH levels and the morphological severity of stenosis, as determined by axial MRI.

The high sensitivity (97%) and specificity (100%) of pNfH presence indicate that pNfH may be a useful tool for diagnosing LSS. There was no association between age and CSF levels of pNfH, which agree with the findings of a previous study [20]. We further investigated the association between pNfH and the severity of LSS and found that patients with severe symptoms (as measured by ZCQ or NRS) tended to have higher CSF levels of pNfH. In contrast, there was no association between the pNfH levels and the morphological severity of spinal stenosis, as assessed by MRI. Although the mechanisms by which pNfH increases in the CSF on entrapment neuropathy, such as LSS, are unclear, disturbances in the axonal structure (axonotmesis) or impaired axonal transport of cytoskeletal molecules (pNfH) may result in the secretion of pNfH from neurons, whereas their cell bodies in the lumber spinal cord remain alive. Therefore, we assume that the elevation of pNfH may reflect the state of the axons more directly than the MR images. As in other neurodegenerative diseases, our results suggest that pNfH can provide objective information on clinical severity in patients with LSS, which MRI findings are unable to do [6–9].

The clinical implication of the absolute value of pNfH remains to be examined. Currently, there are several commercial products of enzyme-linked immunosorbent

EVIDENCE & METHODS

Context
The phosphorylated neurofilament heavy subunit (pNfH) is an axon fiber structural protein that is a potential marker for nerve damage. The authors present information regarding the capacity for pNfH to be used as a tool in the evaluation of patients with spinal stenosis.

Contribution
This study included 33 patients with spinal stenosis who were referred for myelography and subsequently had pNfH levels analyzed in their CSF. Results were compared against CSF samples from patients with AIS. Patients with spinal stenosis had detectable levels of pNfH as compared to nondetectable levels in those with AIS. There seemed to be some correlation between pNfH levels and severity of stenosis symptoms, although not with the anatomical severity of compression itself.

Implications
The results suggest the pNfH may prove to be a viable biomarker for spinal stenosis. As the authors recognize, this research can only be viewed as preliminary and may be confounded by limitations associated with the patient sample and its clinical context. The specificity of this biomarker relative to spinal stenosis, and as compared to other neurological disorders, will likely define the real utility of the metric going forward.

—*The Editors*

Table
Patient demographics for the LSS and control groups

Patient	Age (y)	Sex	CSF level of pNfH (pg/mL)
LSS group			
1	84	F	973
2	78	M	1,650
3	74	F	476
4	68	F	1,060
5	76	M	1,000
6	65	F	266
7	80	F	615
8	71	M	480
9	72	M	2,380
10	74	F	1,700
11	70	F	1,680
12	78	M	293
13	79	M	1,250
14	60	F	1,110
15	69	M	740
16	85	M	369
17	71	F	739
18	88	F	277
19	58	M	951
20	70	F	881
21	65	F	172
22	68	M	Negative
23	65	F	342
24	72	M	3,790
25	78	F	538
26	64	F	149
27	72	F	997
28	83	M	784
29	79	F	9,250
30	82	F	937
31	75	F	5,610
32	77	F	884
33	65	M	665
Control group			
1	10	F	Negative
2	14	F	Negative
3	23	M	Negative
4	19	F	Negative
5	15	F	Negative
6	12	F	Negative
7	27	F	Negative
8	16	M	Negative
9	19	F	Negative
10	13	F	Negative
11	20	M	Negative
12	15	M	Negative
13	12	F	Negative
14	19	M	Negative
15	12	F	Negative
16	15	F	Negative
17	13	F	Negative
18	15	M	Negative
19	21	F	Negative
20	13	F	Negative
21	11	F	Negative

CSF, cerebrospinal fluid; F, female; LSS, lumbar spinal stenosis; M, male; pNfH, phosphorylated neurofilament heavy subunit.

Note: Negative results for the CSF level of pNfH indicate that the level was less than the limit of detection (70 pg/mL).

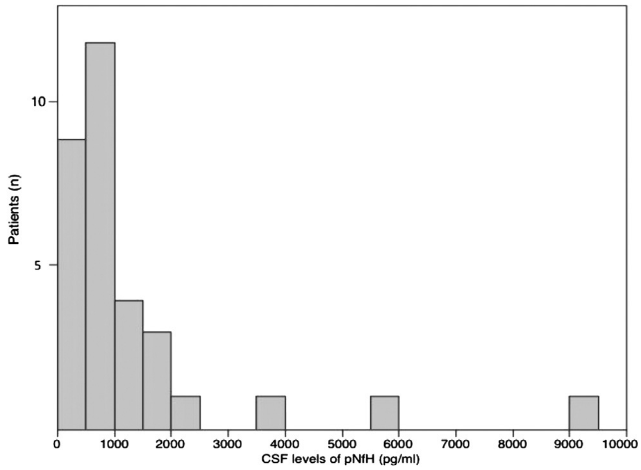

Fig. 1. A histogram of the cerebrospinal fluid (CSF) levels of the phosphorylated neurofilament heavy subunit (pNfH).

assay–based pNfH detection systems available only for experimental use. Boylan et al. [11] reported that the median pNfH in the CSF of ALS patients was 4,380 pg/mL in their case series [11]. Although this value is slightly higher in ALS than in our LSS group (mean 1.344 pg/mL), it should be noted that the difference in manufactural products for the measurement of pNfH between their study and our present study may have had an influence on the absolute value. Further recognition of pNfH as a diagnostic tool will provide an opportunity for the establishment of more standardized measuring methods.

There were three limitations that are relevant to this study. First, the sample size of this study was quite small. Although the present study indicates that there is an

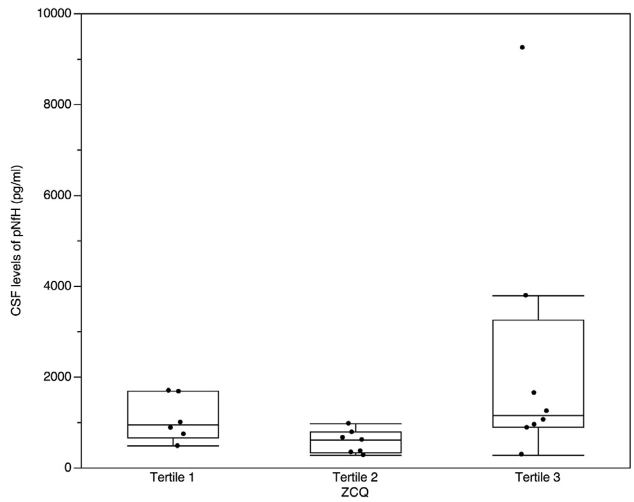

Fig. 2. The association between cerebrospinal fluid (CSF) levels of phosphorylated neurofilament heavy subunit (pNfH) and symptom severity grading. ZCQ, Zurich Claudication Questionnaire.

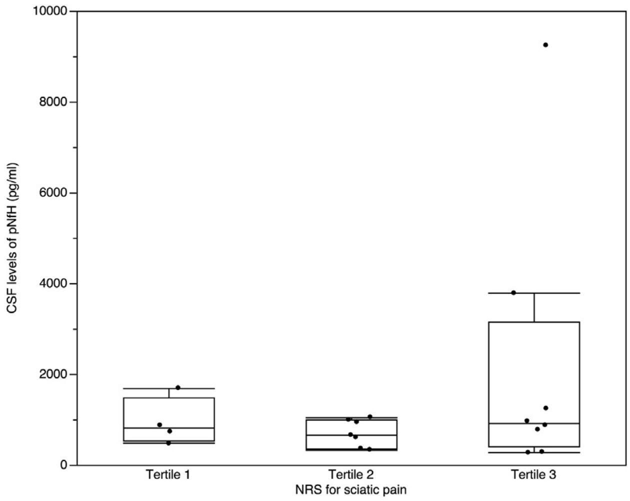

Fig. 3. The association between cerebrospinal fluid (CSF) levels of phosphorylated neurofilament heavy subunit (pNfH) and pain grading. NRS, Numerical Rating Scale.

association between the CSF levels of pNfH and the clinical severity of LSS, further research is needed to confirm our findings. Second, there may be a selection bias affecting the study population, as we only examined patients who underwent preoperative evaluation. Further research among patients with less severe disease would provide additional information. Third, we only performed a single measurement of pNfH for each patient; therefore, repeated measurements may be warranted in the future research.

In conclusion, this study is the first to describe the elevated CSF levels of pNfH in patients with compressive spinal stenosis. Our results indicate that pNfH is a promising biomarker candidate for preoperative evaluation of LSS patients. The use of pNfH in future clinical practice may have a significant positive effect on the management of LSS patients.

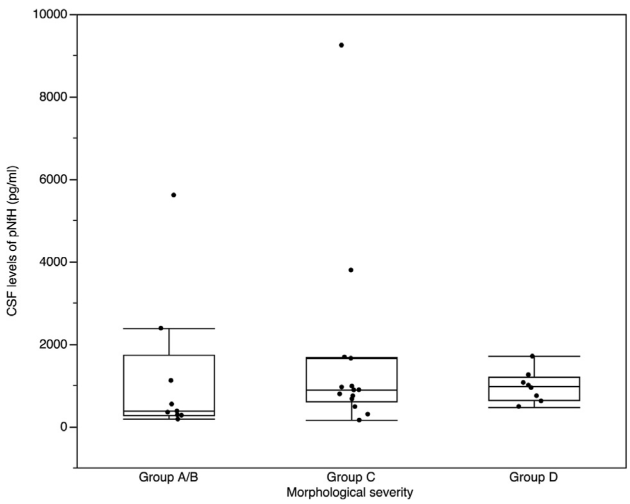

Fig. 4. The association between cerebrospinal fluid (CSF) levels of phosphorylated neurofilament heavy subunit (pNfH) and morphological severity.

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Ⅴ.資　料

「医療・介護職場における腰痛の状況と

職場の心理社会的要因の関連性に関する調査研究」調査票

Ⅰ.あてはまる番号を○で囲んでください。

１．あなたの性別・年齢　　　　（１）男、　（２）女　　　　＿＿＿＿＿歳
２．教育歴　（１）中学卒　（２）高校卒　（３）専門学校・高専・短大卒
　　　　　　（４）大学卒　（５）大学院卒
３．現在の結婚の有無　　（１）有　　　（２）無
４．同居している家族　　（１）実父・実母、舅・姑　　（２）祖父母、義祖父母
　　　　　　　　　　　　（３）兄弟・姉妹、義兄弟・姉妹
　　　　　　　　　　　　（４）子供　①いる（　　　人）　②いない
　　　　　　　　　　　　　　　　　③小学生以下のお子様と同居していますか
　　　　　　　　　　　　　　　　　（ⅰはい、ⅱいいえ）
　　　　　　　　　　　　（５）一人生活　　　（６）単身赴任
５．あなたの雇用形態　　（１）正社員　（２）契約社員　（３）嘱託社員
　　　　　　　　　　（４）派遣社員　（５）臨時・アルバイト（６）その他（　　　）
６．これまでに合計１００本以上または６か月以上たばこをすった経験がありますか
　　（１）はい（１日平均＿＿＿＿本　約＿＿＿＿年間）
　　　　この１か月間に毎日、時々たばこを吸っていますか
　　　　　（１）はい　　（２）いいえ
　　（２）いいえ
７．この１か月、定期的に１回３０分以上の運動（ウオーキングを含む）していますか
　　（１）はい（①平均週２回以上　　②平均週１回　　③週１回はできていない）
　　（２）いいえ
８．現在、通院されている病気はありますか
　　（１）腰痛　（２）腰椎椎間板ヘルニア（坐骨神経痛を伴うもの）
　　（３）生活習慣病関連　（①高血圧　②糖尿病　③高脂血症　④痛風　⑤その他）
　　（４）メンタルヘルス不調
　　（５）その他（　　　　　　　　　　　　　　　　　　　　）
９．この１か月間の平均睡眠時間
　（１）５時間未満　　（２）５時間以上６時間未満　　（３）６時間以上７時未満
　（４）７時間以上８時間未満　（５）８時間以上９時間未満　（６）９時間以上
１０．看護・介護業務の通算での経験年数はどれくらいですか
　　（１）１年未満　　（２）１年以上～２年未満　（３）２年以上～５年未満
　　（４）５年以上～１０年未満　　（５）１０年以上～２０年未満
　　（６）２０年以上
１１．最近１か月間での１週間当たりの労働時間（残業時間も含む）はどれくらいですか

（１）1~34 時間　（２）35 時間~40 時間　（３）41 時間~50 時間
（４）51 時間~60 時間　（５）61 時間~65 時間　（６）66 時間～70 時間
（７）71 時間以上

１２．現在の職場に満足していますか
（１）充分満足している　（２）少し満足している　（３）どちらでもない
（４）あまり満足していない　（５）全然感じていない

１３．あなたの職種
（１）看護福祉士（有資格）（２）ホームヘルパー（1～3 級）（３）ケアワーカー（無資格）（４）看護師・保健師　（５）ＰＴ／ＯＴ　（６）その他（　　）

Ⅱ．この１ヶ月における勤務の状況について

1-1. 早出は週に何回ありましたか？	a. 0 回　b. 1 回　c. 2 回　d. 3 回　e. その他_____回
2. 早出は________時から________時まで	
3. 早出では，およそ________名の利用者を________名で介護 （例，およそ________名の利用者を________名で介護）	
2-1. 日勤は週に何回ありましたか？	a. 0 回　b. 1 回　c. 2 回　d. 3 回　e. その他_____回
2. 日勤は________時から________時まで	
3. 日勤では，およそ________名の利用者を________名で介護	
3-1. 遅出は週に何回ありましたか？	a. 0 回　b. 1 回　c. 2 回　d. 3 回　e. その他_____回
2. 遅出は________時から________時まで	
3. 遅出では，およそ________名の利用者を________名で介護	

夜勤以外の勤務（早出，日勤，遅出）でふだん経験する仕事の負荷は，平均するとどのくらいですか？

	とても軽い				まあまあ				とても重い
1. 身体を動かしたり，体力を使うなど，身体に受ける負荷	1	2	3	4	5	6	7	8	9
2. 注意を集中したり，判断するなど，頭脳に受ける負荷	1	2	3	4	5	6	7	8	9
3. 時間的プレッシャー	1	2	3	4	5	6	7	8	9
4. 緊張が高まったり，神経を張り詰めるなど，感情に受ける負荷	1	2	3	4	5	6	7	8	9

4-1. 夜勤は週に何回ありましたか？	a. 0 回　b. 1 回　c. 2 回　d. 3 回　e. その他_____回
2. 夜勤は________時から________時まで	
3. 夜勤では，およそ________名の利用者を________名で介護	

4. 夜勤中にとる仮眠の長さは，およそ________分
5. 夜勤中に仮眠をとれたのは，夜勤________回のうち 1 回

夜勤でふだん経験する仕事の負荷は，平均するとどのくらいですか？

	とても軽い				まあまあ				とても重い
1. 身体を動かしたり，体力を使うなど，身体に受ける負荷	1	2	3	4	5	6	7	8	9
2. 注意を集中したり，判断するなど，頭脳に受ける負荷	1	2	3	4	5	6	7	8	9
3. 時間的プレッシャー	1	2	3	4	5	6	7	8	9
4. 緊張が高まったり，神経を張り詰めるなど，感情に受ける負荷	1	2	3	4	5	6	7	8	9

Ⅲ. 経験年数について

1. 介護職として働いているのは現在を含めて　合計で________年________ヶ月
2. 交代勤務で働いているのは現在を含めて　合計で________年________ヶ月

Ⅳ. 次の質問で該当するところにチエックしてください

		そう思わない	そう思う
1	私のような体の状態の人は、体を動かしたり活動的であることは決して安全とはいえない	0	1
2	最近 2 週間は、心配事が心に浮かぶことが多かった	0	1
3	私の腰痛はひどく、決して良くならないと感じる	0	1
4	以前は楽しめたことが、最近 2 週間は楽しめない	0	1

		全然	少し	中等度	とても	極めて
5	全般的に考えて、ここ 2 週間の間に腰痛をどの程度煩わしく感じましたか	0	0	0	1	1

Ｖ．自分に当てはまるところの□にチェックしてください。

（１） 仕事の負担度

	そうだ	まあそうだ	やや違う	違う
1非常にたくさんの仕事をしなければならない	①□	②□	③□	④□
2時間内に仕事が処理しきれない	①□	②□	③□	④□
3一生懸命働かなければならない	①□	②□	③□	④□
4かなり注意を集中する必要がある	①□	②□	③□	④□
5高度の知識や技術が必要な難しい仕事だ	①□	②□	③□	④□
6勤務時間中はいつも仕事のことを考えていなければならない	①□	②□	③□	④□
7体をよく使う仕事だ	①□	②□	③□	④□

（２） 仕事のコントロール度

	そうだ	まあそうだ	やや違う	違う
1自分のペースで仕事ができる	①□	②□	③□	④□
2自分で仕事の順番・やり方を決めることができる	①□	②□	③□	④□
3職場の仕事の方針に自分の意見を反映できる	①□	②□	③□	④□

（３） 職場の対人関係

そうだ　まあそうだ　やや違う　違う

1私の部署内で意見の食い違いがある	①□	②□	③□	④□
2私の部署と他の部署とはうまが合わない	①□	②□	③□	④□
3私の職場の雰囲気は友好的である	①□	②□	③□	④□

（４） 技能の活用度

	そうだ	まあそうだ	やや違う	違う
1自分の技能や知識を仕事で使うことが少ない	①□	②□	③□	④□

（５） 職場の環境

1私の職場の作業環境(騒音、照明、温度、換気など)はよくない	①□	②□	③□	④□

（６） 仕事への適正度・働きがい

1仕事の内容は自分に合っている	①□	②□	③□	④□
2働きがいのある仕事だ	①□	②□	③□	④□

（７） 職場の支援度

非常に　かなり　多少　全くない

次の人たちとどのくらい気軽に話ができますか

1上司	①□	②□	③□	④□
2職場の同僚	①□	②□	③□	④□

あなたが困った時、次の人たちはどのくらい頼りになりますか

3上司	①□	②□	③□	④□
4職場の同僚	①□	②□	③□	④□

あなたの個人的な問題を相談したら、次の人たちはどれくらい聞いてくれますか

5上司	①□	②□	③□	④□
6職場の同僚	①□	②□	③□	④□

Ⅵ. 最近１か月間のあなたの状態についてうかがいます。もっともあてはまるものに〇をつけてください。

	殆どなかった	時々あった	しばしばあった	殆どいつもあった
① 活気がわいてくる	1	2	3	4
② 元気がいっぱいだ	1	2	3	4
③ 生き生きする	1	2	3	4
④ 怒りを感じる	1	2	3	4
⑤ 内心腹立たしい	1	2	3	4
⑥ イライラしている	1	2	3	4
⑦ ひどく疲れた	1	2	3	4
⑧ へとへとだ	1	2	3	4
⑨ だるい	1	2	3	4
⑩ 気が張りつめている	1	2	3	4
⑪ 不安だ	1	2	3	4
⑫ 落ち着かない	1	2	3	4
⑬ 憂うつだ	1	2	3	4
⑭ 何をするのも面倒だ	1	2	3	4
⑮ 物事に集中できない	1	2	3	4
⑯ 気分が晴れない	1	2	3	4
⑰ 仕事が手につかない	1	2	3	4
⑱ 悲しいと感じる	1	2	3	4
⑲ めまいがする	1	2	3	4
⑳ 体のふしぶしが痛む	1	2	3	4
㉑頭が重かったり頭痛がする	1	2	3	4

㉒首筋や肩がこる	1	2	3	4
㉓腰が痛い	1	2	3	4
㉔目が疲れる	1	2	3	4
㉕動悸や息切れがする	1	2	3	4
㉖胃腸の具合が悪い	1	2	3	4
㉗食欲がない	1	2	3	4
㉘便秘や下痢をする	1	2	3	4
㉙よく眠れない	1	2	3	4

Ⅶ. 腰痛の状況

腰痛（下図の灰色部分に 1 日以上続いた痛みで，脚（あし）の痛み･しびれを伴った腰痛も含む，ただし，生理や妊娠に伴った腰痛や風邪で熱がある時に感じた腰痛は除く）についてお聞きします。過去 1 か月を総合すると，あなたの腰痛は以下のどの状態でしたか？最もあてはまるものを選んでください

1. 腰痛を伴うことはなかった
2. 腰痛を伴うことはあったが、仕事に支障をきたすことはなかった
3. 腰痛のため仕事に支障をきたしたこともあったが，欠勤（休職）はしなかった
4. 腰痛のため欠勤（休職）をしたことがある

⇒２，３，４に回答（腰痛あり）とした方にお聞きします。

・腰痛を患ってから３か月以上たっていますか？→　はい、　いいえ

・腰痛のため、連続して４日以上休んだ経験はありますか→

ある、　ない

・今までに経験された腰痛で、発症からよくなるまでにかかった時間が最も長かったものはどれくらいですか

１．２週間未満　２．２週間以上~1 か月未満　３．１か月以上～3 か月未満　４．３か月以上~半年未満　５．半年以上～1 年未満　６．１年以上~3 年未満　７．３年以上

・腰痛のために医療機関を受診しましたか（複数回答可）

① 整形外科　②整形外科以外の病院　③接骨院　④マッサージ院　⑤鍼灸院　⑥カイロプラクティック　⑦その他　⑧受診したことはない

Ⅷ. 睡眠について

過去 1 ヶ月の睡眠についてお聞きします。あてはまる番号に○をつけてください。（交代勤務の方は日勤のときの夜間の睡眠を考えて，お答えください。）

1. ふだん，夜に何時間眠りますか？					
a. 5 時間未満	b. 5 時間	c. 6 時間	d. 7 時間	e. 8 時間	f. 9 時間以上
2. ふだん，布団に入ってから眠るまでにどのくらい時間がかかりますか？					
a. 10 分以内	b. 11〜30 分	c. 31〜59 分	d. 1〜2 時間	e. 2 時間以上	
3. 就寝中に途中で目が覚めて，眠りにつけないことはどのくらいありますか？					
a. ほとんどない	b. 年数回	c. 月 1 回以上	d. 週 1〜2 回	e. 週 3 回以上	f. ほぼ毎日
4. 朝早く目が覚めて，そのあと，眠れないことはどのくらいありますか？					
a. ほとんどない	b. 年数回	c. 月 1 回以上	d. 週 1〜2 回	e. 週 3 回以上	f. ほぼ毎日
5. 朝起きた時，疲れを感じることはどのくらいありますか？					
a. ほとんどない	b. 年数回	c. 月 1 回以上	d. 週 1〜2 回	e. 週 3 回以上	f. ほぼ毎日
6. 仕事中に，居眠りしそうなほど強い眠気を感じることはどのくらいありますか？					
a. ほとんどない	b. 年数回	c. 月 1 回以上	d. 週 1〜2 回	e. 週 3 回以上	f. ほぼ毎日

Ⅸ.あなたの考えや気持ちとして最もよく当てはまる数字に○をつけてください

	少しもそう思わない	そう思わない	そう思う	強くそう思う
運動すると体を痛めてしまうかもしれないと不安になる	1	2	3	4
痛みが増すので何もしたくない	1	2	3	4
私の体には何か非常に悪いところがあると感じている	1	2	3	4
他の人は私の体の状態のことなど真剣に考えてくれない	1	2	3	4
アクシデント（痛みが起こったきっかけのせいで、私の一生痛みが起こりうる体になった	1	2	3	4
痛みを感じるのは、私の体を痛めたことが原因である	1	2	3	4
不必要な動作を行わないよう、とにかく気を付けることが、私の痛みを悪化させないためにできる最も確実なことである	1	2	3	4

この強い痛みは私の体に何か非常に悪いことが起こっているからに違いない	1	2	3	4
体を痛めないために、痛みを感じたら私は運動をやめる	1	2	3	4
私はとても体を痛めやすいので、すべてのことを普通の人と同じようにできるわけでない	1	2	3	4
痛みがある時は、誰であっても運動することを強要されるべきでない	1	2	3	4

X．最近のあなたの最近の健康状態についてお聞きします。

最もあてはまる数字に○をつけてください。

１． 気分や健康状態は：

１　よかった　　２　いつもと変わらない　３　悪かった　４　非常に悪かった

（2～11 は１　全くなかった　２　あまりなかった　３　あった　４　たびたびあった）

２．疲労回復剤を飲みたいと思ったことは：	1	2	3	4
３．元気なく疲れを感じたことは：	1	2	3	4
４．病気だと感じたことは：	1	2	3	4
５．頭痛がしたことは：	1	2	3	4
６．頭が重いように感じたことは：	1	2	3	4
７．人前で倒れるのではという不安があったことは：	1	2	3	4
８．からだがほてったり、寒気がしたことは：	1	2	3	4
９．よく汗をかくことは：	1	2	3	4
10. 朝早く目が覚めて眠れないことは：	1	2	3	4
11. 朝起きた時、すっきりしないと感じたことは：	1	2	3	4

12. いつもより元気ではつらつとしていたことが：

１　たびたびあった　２　いつもと変わらなかった　３　元気がなかった

４　全く元気がなかった

（13～15 は１　全くなかった　２　あまりなかった　３　あった　４　たびたびあった）

13. 夜中に目を覚まして、よく眠れなかった日は：　1　2　3　4
14. 夜中に目をさますことは：　1　2　3　4
15. 落ち着かなくて眠れない夜を過ごしたことは：　1　2　3　4

（16～17 は 1 たびたびあった 2 いつもと変わらなかった 3 なかった 4 全くなかった）

16. いつもより忙しく活動的な生活を送ることが：　1　2　3　4
17. いつもよりすべてがうまくいっていると感じることが：1　2　3　4
18. 毎日している仕事は：
　1　非常にうまくいった　2　いつもと変わらなかった　3　うまくいかなかった
　4　まったくうまくいかなかった

（19～20 は 1 できた　2 いつもと変わらなかった　3 できなかった　4 全くできなかった）

19. いつもより容易に物事を決めることが：　1　2　3　4
20. いつもより日常生活を楽しく送ることが：　1　2　3　4
21. たいして理由がないのに、何かが怖くなったり、取り乱したりすることは：
　1　全くなかった　2　あまりなかった　3　あった　4　たびたびあった

（22~23 は 1 全くなかった　2 いつもと変わりなかった　3 あった　4 たびたびあった）

22. いつもよりいろいろなことを重荷と感じたことは：　1　2　3　4
23. いつもより気が重くて憂うつになることは：　1　2　3　4

(24～27 は 1　全くなかった　2　あまりなかった　3　あった　4 たびたびあった)

24. 自信を失ったことは：　1　2　3　4
25. 人生に全く望みを失ったと感じたことは：　1　2　3　4
26. 不安を感じ、緊張したことは：　1　2　3　4
27. 生きていることに意味がないと感じたことは：　1　2　3　4
28. この世から消えてしまいたいと感じたことは：
1　全くなかった　2　なかった　3　一瞬あった　4　たびたびあった
29. 死んだほうがましだと考えたことは
　1　全くなかった　2　あまりなかった　3　あった　4　たびたびあった
30. 自殺しようと考えたことが：
　1　全くなかった　2　なかった　3　一瞬あった　4　たびたびあった

アンケートご協力いただきまして、本当にありがとうございました。

厚生労働省労災疾病臨床研究事業
「職場における腰痛の効果的な治療法等に関する研究」

労災病院ナースプロジェクト

－腰痛とその関連情報を把握するためのアンケート（初年度）－

平成　　年　　月　　日

まず、あなたの基本的な背景や生活習慣についてお聞きします。以下、1～13の設問に関し、数字を記入されるか、該当するものに☑をつけて下さい。

1 職員番号 [　　　　　　　　　　]　**2 年齢** [　　　　] 歳　**3 性別** □男・□女

4 身長 [　　　　] cm　**5 体重** [　　　　] kg　**6** □病棟勤務・□外来勤務・□その他

7 たばこを吸いますか？

□①吸わない　□②以前に吸っていたが現在はやめている　□③吸う

8 この1ヵ月間での1週間あたりの労働時間（残業時間も含みます）を教えてください

□①40時間未満　□②40～50時間未満　□③50～60時間未満
□④60時間以上

9 看護業務の通算での経験年数はどれくらいですか？

□①1年未満　□②1年以上、2年未満　□③2年以上、5年未満
□④5年以上、10年未満　□⑤10年以上、20年未満　□⑥20年以上

10 夜勤はありますか？

□①はい　□②いいえ

11 管理職ですか？

□①はい　□②いいえ

12 現在、通院されている疾患（しっかん）（病気）や愁訴（しゅうそ）（症状）はありますか？

□①ない　□②1つある　□③2つある　□④3つ以上ある

⇒②～④（1つ以上ある）とした方にお聞きします。該当するものに☑して下さい（複数回答可）。

□腰痛　□腰椎椎間板（ようついついかんばん）ヘルニア　□腰部脊柱管狭窄症（ようぶせきちゅうかんきょうさくしょう）
□生活習慣病関連（高血圧、糖尿病、高脂血症、痛風など）　□メンタルヘルスの不調
□その他（　　　　　　　　　　　　　　　　　　　　）

女性の方にお聞きします。

13 現在、妊娠していますか？

□①はい　□②いいえ

14 あなたの腰痛の状態についてうかがいます。
□には、最もあてはまる項目の一つだけにチェックしてください。

腰痛とは、右図に示す部分に1日以上は続いた痛みで、脚の痛み・しびれを伴ったものを含めて考えてください。ただし、生理や妊娠、風邪で熱があるときに感じる腰痛は除きます。腰痛が最近ない方も必ずお答え下さい。

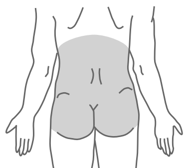


図. 腰痛の部位

1 過去1年間で、ぎっくり腰を含む腰痛全般、あるいは腰椎椎間板ヘルニアのため、医療施設（病院、診療所・クリニック、接骨院などの民間治療は含みません）へ通院、または入院した経験はありますか？

はい／いいえ

→はいの方　恐れ入りますが、①通院した日数を教えてください　________日

②入院した日数を教えてください　________日

＊日数が、ゼロの場合は、0とご記入ください

2 過去1年のあなたの腰痛をふり返ると、以下のどの状態でしたか？

□0 腰痛はなかった
□1 腰痛はあったが、仕事に支障はなかった
□2 腰痛のため仕事に支障をきたしたこともあったが、休職はしなかった
□3 腰痛のため休職したことがある（________日）

3 最近4週のあなたの腰痛状態を総合すると、以下のどの状態でしたか？

□0 腰痛はなかった
□1 腰痛はあったが、仕事に支障はなかった
□2 腰痛のため仕事に支障をきたしたこともあったが、休職はしなかった
□3 腰痛のため休職したことがある

⇒1、2、3に回答（腰痛あり）とした方にお聞きします。

A 腰痛を患ってから3カ月以上経ってますか？

□①はい　□②いいえ

B 腰痛がある頻度はどのくらいですか？

□①ほぼ毎日　□②週2日以上　□③週1日以内

4 最近４週間であった腰痛（しびれを含む）を総合的に考えて、痛みの強さを以下の数字から選んで○をつけてください。０を全く痛みのない状態、10を想像しうる最悪の痛みと考えてお答えください。

まったく痛みのない状態　……　想像しうる最悪の痛み

0　1　2　3　4　5　6　7　8　9　10

5 1年後、あなたの腰痛は、日々の生活や活動をするうえで問題になっていると思いますか？

□①問題にならない　□②おそらく問題にならない
□③おそらく問題になる　□④確実に問題になる

15 **過去３０日の間にどれくらいの頻度で次のことがありましたか。最もあてはまる数字に○をつけてください。**

	全くない	少しだけ	ときどき	たいてい	いつも
1. 神経過敏に感じた。	0	1	2	3	4
2. 絶望的だと感じた。	0	1	2	3	4
3. そわそわ、落ちつかなく感じた。	0	1	2	3	4
4. 気分が沈み込んで、何が起こっても気が晴れないように感じた。	0	1	2	3	4
5. 何をするのも骨折りだと感じた。	0	1	2	3	4
6. 自分は価値のない人間だと感じた。	0	1	2	3	4

16 **過去３０日間のあなたの全般的な仕事の出来具合は何点で表せますか？あなたの仕事を他の誰かがやって最悪だった時の出来を０点、一番仕事が出来る人がやった場合を１０点とした時、あなたの出来は何点で表されますか？ 最もあてはまる番号に○をつけてください。**

最低										最高
0	1	2	3	4	5	6	7	8	9	10

17 **次に、ここ2週の間のことを考えて、次のそれぞれの質問に対するあなたの回答に印（☑）を記入してください。**

	そうではない 0	そうだ 1
ここ２週の間、*腰痛が足のほうにも広がることがあった*	☐	☐
ここ２週の間、*肩や首*にも痛みを感じることがあった	☐	☐
腰痛のため、*短い距離*しか歩いていない	☐	☐
最近２週間は、腰痛のため、いつもより*ゆっくり着がえ*をした	☐	☐
私のような体の状態の人は、体を動かし活動的であることは決して安全とはいえない	☐	☐
*心配事*が心に浮かぶことが多かった	☐	☐
私の*腰痛は*ひどく、決して良くならないと思う	☐	☐
以前は楽しめたことが、最近は*楽しめない*	☐	☐

全般的に考えて、ここ2週の間に腰痛をどの程度煩(わずら)わしく感じましたか？

全然	少し	中等度	とても	極めて
☐	☐	☐	☐	☐
0	0	0	1	1

18 以下は、腰痛に関する考え方についての質問です。それぞれの質問について、<u>身体の動作</u>（前屈(まえかが)みになる、持ち上げる、歩く、運転するなど）があなたの腰痛にどれだけ影響するか、もしくは影響する可能性があるか、0から6のなかで、<u>最もあてはまる数字に一つだけ○をつけてください</u>。

	全くそう思わない	・・・・		どちらともいえない	・・・・		全くそのとおりである
1. 身体の動作は、私の腰の痛みを悪化させる	0	1	2	3	4	5	6
2. 身体の動作は、私の腰に悪い影響を与えるかもしれない	0	1	2	3	4	5	6
3. 私の腰痛を悪化させる（悪化させるかもしれない）ような身体の動作をすべきでない	0	1	2	3	4	5	6
4. 私の腰痛を悪化させる（悪化させるかもしれない）ような身体の動作はできない	0	1	2	3	4	5	6

19 最後に、あなたの総合的な健康状態についてお聞きします。以下のそれぞれの質問であなた自身の<u>今日の健康状態</u>をもっともよくあらわしているものを1～3のうちひとつ選び、番号に○を付けて下さい。

1 移動の程度についてお聞きします

1. 私は歩き回るのに問題はない
2. 私は歩き回るのにいくらか問題がある
3. 私はベッド（床）に寝たきりである

2 身の回りの管理についてお聞きします

1. 私は身の回りの管理に問題はない
2. 私は洗面や着替えを自分でするのにいくらか問題がある
3. 私は洗面や着替えを自分でできない

3 ふだんの生活（例：仕事、勉強、家族、余暇活動）についてお聞きします

1. 私はふだんの活動を行うのに問題はない
2. 私はふだんの活動を行うのにいくらの問題がある
3. 私はふだんの活動を行うことができない

4 痛み／不快感についてお聞きします

1. 私は痛みや不快感はない
2. 私は中程度の痛みや不快感がある
3. 私はひどい痛みや不快感がある

5 不安／ふさぎ込みについてお聞きします

1. 私は不安でもふさぎ込んでもいない
2. 私は中程度に不安あるいはふさぎ込んでいる
3. 私はひどく不安あるいはふさぎ込んでいる

＊＊＊ ご協力ありがとうございました。<u>ご記入漏れ</u>がないかを確認ください。 ＊＊＊

厚生労働省労災疾病臨床研究事業
「職場における腰痛の効果的な治療法等に関する研究」

労災病院ナースプロジェクト

－腰痛とその関連情報を把握するためのアンケート（半年後）－

お名前＿＿＿＿＿＿＿＿＿＿＿＿　　職員番号＿＿＿＿＿＿＿＿＿＿＿＿

1 あなたの腰痛の状態についてうかがいます。もっともあてはまる項目の□に一つだけチェックしてください。

腰痛とは、右図に示す部分に1日以上は続いた痛みで、脚（あし）の痛み・しびれを伴ったものを含めて考えてください。ただし、生理や妊娠、風邪で熱があるときに感じる腰痛は除きます。腰痛が最近ない方も必ずお答え下さい。

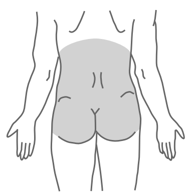


図. 腰痛の部位

1 過去半年間で、ぎっくり腰を含む腰痛全般、あるいは腰椎椎間板ヘルニアのため、医療施設（病院、診療所・クリニック、接骨院などの民間治療は含みません）へ通院、または入院した経験はありますか？

はい／いいえ

→はいの方　恐れ入りますが、①通院した日数を教えてください　＿＿＿＿日

②入院した日数を教えてください　＿＿＿＿日

＊日数が、ゼロの場合は、0とご記入ください

2 過去半年のあなたの腰痛をふり返ると、以下のどの状態でしたか？

- □0 腰痛はなかった
- □1 腰痛はあったが、仕事に支障はなかった
- □2 腰痛のため仕事に支障をきたしたこともあったが、休職はしなかった
- □3 腰痛のため休職したことがある（＿＿＿＿日）

3 最近4週のあなたの腰痛状態を総合すると、以下のどの状態でしたか？

- □0 腰痛はなかった
- □1 腰痛はあったが、仕事に支障はなかった
- □2 腰痛のため仕事に支障をきたしたこともあったが、休職はしなかった
- □3 腰痛のため休職したことがある

⇒1、2、3に回答（腰痛あり）とした方にお聞きします。

A 腰痛を患ってから3カ月以上経ってますか？

□①はい　□②いいえ

B 腰痛がある頻度はどのくらいですか？

□①ほぼ毎日　□②週2日以上　□③週1日以内

4 最近４週間であった腰痛（しびれを含む）を総合的に考えて、痛みの強さを以下の数字から選んで◯をつけてください。0を全く痛みのない状態、10を想像しうる最悪の痛みと考えてお答えください。

まったく痛みのない状態										想像しうる最悪の痛み
0	1	2	3	4	5	6	7	8	9	10

5 あなたの腰痛の状態は、初回のアンケート記入時（半年前）と比較し、どうなりましたか？

□①完全によくなった　□②大変改善した　□③少し改善した　□④変わらない
□⑤少し悪くなった　□⑥大変悪くなった　□⑦今までになく悪くなった
□⑧腰痛はなかったのでわからない

6 あなた自身、この半年間、体操をはじめとする腰痛予防対策をどのくらい実行しましたか？

□①実行できた　□②まあ実行できた　□③あまり実行しなかった
□④ほとんど実行しなかった

2 以下は、腰痛に関する考え方についての質問です。それぞれの質問について、身体の動作（前屈(まえかが)みになる、持ち上げる、歩く、運転するなど）があなたの腰痛にどれだけ影響するか、もしくは影響する可能性があるか、0から6のなかで、最もあてはまる数字に一つだけ◯をつけてください。

	全くそう思わない	・・・・		どちらともいえない	・・・・		全くそのとおりである
1. 身体の動作は、私の腰の痛みを悪化させる	0	1	2	3	4	5	6
2. 身体の動作は、私の腰に悪い影響を与えるかもしれない	0	1	2	3	4	5	6
3. 私の腰痛を悪化させる（悪化させるかもしれない）ような身体の動作をすべきでない	0	1	2	3	4	5	6
4. 私の腰痛を悪化させる（悪化させるかもしれない）ような身体の動作はできない	0	1	2	3	4	5	6

3 過去３０日間のあなたの全般的な仕事の出来具合は何点で表せますか？あなたの仕事を他の誰かがやって最悪だった時の出来を0点、一番仕事が出来る人がやった場合を１０点とした時、あなたの出来は何点で表されますか？ 最もあてはまる番号に◯をつけてください。

最低										最高
0	1	2	3	4	5	6	7	8	9	10

4 あなたの総合的な健康状態についてお聞きします。以下のそれぞれの質問であなた自身の<u>今日の健康状態</u>をもっともよくあらわしているものを1～3のうちひとつ選び、番号に○を付けて下さい。

1 移動の程度についてお聞きします

1. 私は歩き回るのに問題はない
2. 私は歩き回るのにいくらか問題がある
3. 私はベッド（床）に寝たきりである

2 身の回りの管理についてお聞きします

1. 私は身の回りの管理に問題はない
2. 私は洗面や着替えを自分でするのにいくらか問題がある
3. 私は洗面や着替えを自分でできない

3 ふだんの生活（例：仕事、勉強、家族、余暇活動）についてお聞きします

1. 私はふだんの活動を行うのに問題はない
2. 私はふだんの活動を行うのにいくらの問題がある
3. 私はふだんの活動を行うことができない

4 痛み／不快感についてお聞きします

1. 私は痛みや不快感はない
2. 私は中程度の痛みや不快感がある
3. 私はひどい痛みや不快感がある

5 不安／ふさぎ込みについてお聞きします

1. 私は不安でもふさぎ込んでもいない
2. 私は中程度に不安あるいはふさぎ込んでいる
3. 私はひどく不安あるいはふさぎ込んでいる

5 <u>現在</u>、通院されている疾患（しっかん）（病気）や愁訴（しゅうそ）（症状）はありますか？

□①ない　□②1つある　□③2つある　□④3つ以上ある

⇒②～④（1つ以上ある）とした方にお聞きします。該当するものに☑して下さい（複数回答可）。

□腰痛　□腰椎椎間板（ようついついかんばん）ヘルニア　□腰部脊柱管狭窄症（ようぶせきちゅうかんきょうさくしょう）

□生活習慣病関連（高血圧、糖尿病、高脂血症、痛風など）　□メンタルヘルスの不調

□その他（　　　　　　　　　　　　　　　　　　　　）

＊＊＊ ご協力ありがとうございました。<u>ご記入漏れ</u>がないかを確認ください。 ＊＊＊

あなたは大丈夫？ L4/5の腰痛借金！

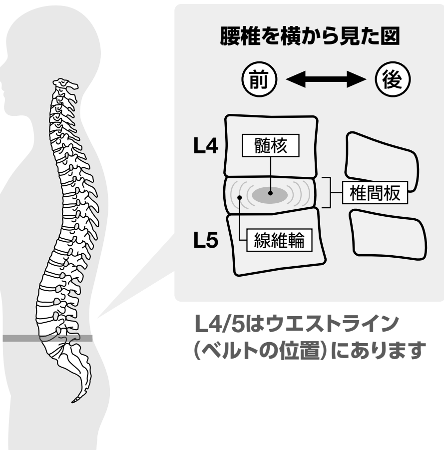
「これだけ体操」ですぐに返済！

一番負担がかかるのは、4番目と5番目の腰骨の間（L4/5椎間板）なのです！

腰痛借金って、なんですか？

●腰痛借金の無い状態

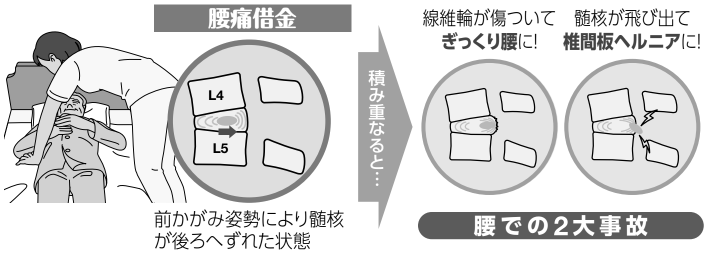
背骨と背骨にはさまれた椎間板の中には、ゼリー状の髄核（ずいかく）という物質があります。
髄核は線維輪（せんいりん）という硬い組織に囲まれており、通常、椎間板の中央に位置しています。
そして、これが腰痛借金の無い状態です。



L4/5はウエストライン（ベルトの位置）にあります

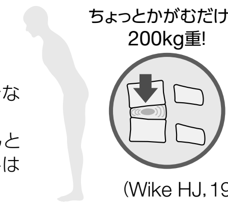
●腰痛借金と、腰痛借金が呼び込む2大事故

髄核は、通常は椎間板の中央にありますが、前かがみでの仕事を続けていると後ろ（背中側）に移動します。これが腰痛借金のある状態です。
この腰痛借金が積み重なると、髄核が後ろへずれっぱなしとなり、ぎっくり腰やヘルニアといった腰での2大事故が起きる可能性が高くなってしまうのです。



ちょっとした不良姿勢に忍び寄る腰痛借金の魔の手?!

椎間板には、普段の何気ない動作でも思いのほか大きな力が加わっています。
少し前へかがむだけでも、L4/5の椎間板にはなんと200kg重もの力が加わっており、腰痛借金の魔の手はちょっとした不良姿勢にも忍び寄っているのです。



（Wike HJ, 1999）

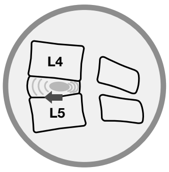
借金はその場で返済！ 「これだけ体操」で腰痛予防！

●どうやるの？

息を吐きながら、3秒間（1〜2回）腰を反らすだけ

手の指先を下にしてお尻に当て、骨盤を前へ押し出すイメージで腰の下のほう（骨盤のすぐ上）ともものの付け根を同時にストレッチします。

腰痛借金の返済



後ろにずれた髄核を、腰を反らして元の位置に戻す

このときは中止！

痛みがお尻から太もも以下に響く場合は中止し、整形外科医にご相談ください。

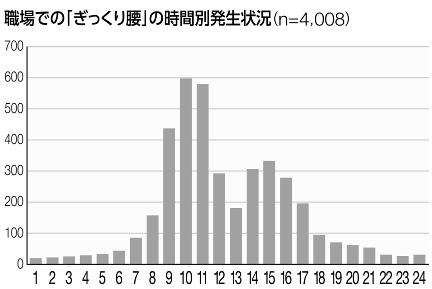
●効果はあるの？

はい、「これだけ体操」を実践し続けた介護施設では、実施しなかった施設に比べ、明らかに「腰痛持ち」が少なくなったという結果が得られています。

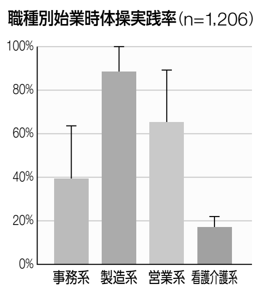
（Matsudaira K, 2015）

●いつやればいいの？

職場でのぎっくり腰は、身体反応の低下している午前中、次に昼休憩後の14〜15時に発生しやすいことがわかっています。一方、職場の始業時体操実施率をみると、他業種に比べ介護・看護系が著しく低いことが報告されています。



（厚生労働省, 2013）



（高野, 2015）

以上のことから、「これだけ体操」は、次のように行うとよいでしょう。

STEP 1 朝の始業時に毎日みんなで実施（朝の貯金）
STEP 2 各自、昼休憩時に実施（昼の貯金）
STEP 3 作業に応じて、その都度、腰痛借金をチャラにする！

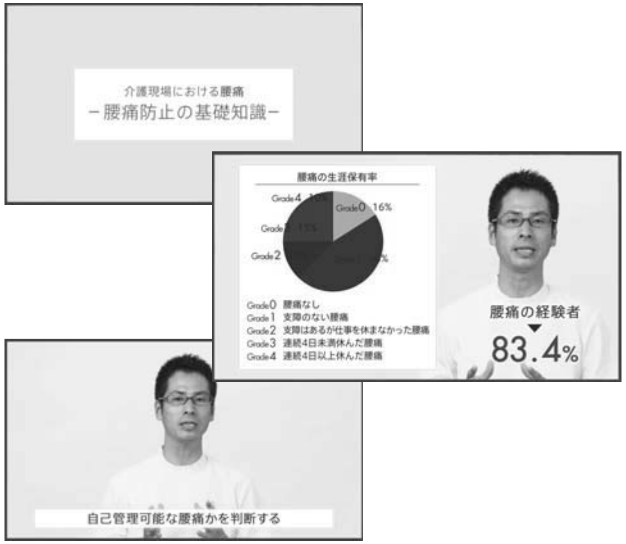
「産業理学療法士」による両立支援の参考資料

「大阪労災病院 -介護技術を紹介する-」　シナリオ.1

2015.7.21

SCENE	VISUAL	ACTION	COMMENT	MEMO
MENU				
#OP		T.　腰痛。その対処法… (タイトル差し替え)		
#1	 	□浅田氏 顔出し T. 大阪労災病院 理学療法士 浅田史成	浅田. 社会福祉施設で働く看護師や介護士の多くが腰痛に悩んでいます。 また最近増えてきている家族による介護、特に老老介護でも多くの方が腰痛に悩まされています。 腰痛発生の原因は主に対象者の車いすからベッドへの移乗動作、つまりトランスファーにあります。 介護施設に就職するにあたり一定の研修を積んでおられますが、無理な持ち上げで腰を痛メルコとが多くまだまだトランスファーの技術に問題がある方が多いようです。 今回は、対象者と介護者の体格に会わせたトランスファーの方法をご紹介します。 これを見て、仲間同士で練習し、自信をつけてからチャレンジしてください。 ポイントに注意して実施すればスムーズなトランスファーができ、今までとは違う容易な介助を体験出来るはずです。	

<table>
<tr><th>SCENE</th><th>VISUAL</th><th>ACTION</th><th>COMMENT</th><th>MEMO</th></tr>
<tr><td>#2</td><td></td><td></td><td>T. このDVDは 1.腰痛の基礎知識 2.運動療法の実際 3.トランスファーの実技 の3部門で構成されています。
どこから見ていただいても構いません。
3.トランスファーの実技は、トランスファーの準備・トランスファーの注意点・トランスファーの実際から構成されています。

※ スーパーにて挿入（NA.無し予定）</td><td></td></tr>
<tr><td>#3</td><td>


</td><td>T. 腰痛。その対処法…
腰痛防止の基礎知識

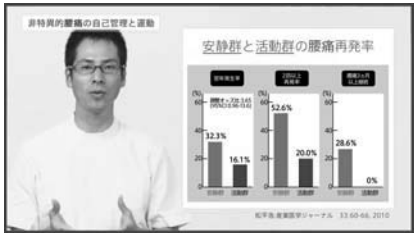
G. 腰痛の生涯保有率
T. 腰痛の経験者▶83.4%
G. 腰痛の生涯保有率
（0~3に留めるときはグリーンに）
T. 自己管理可能な腰痛かを判断する
T. TRIAGE トリアージ

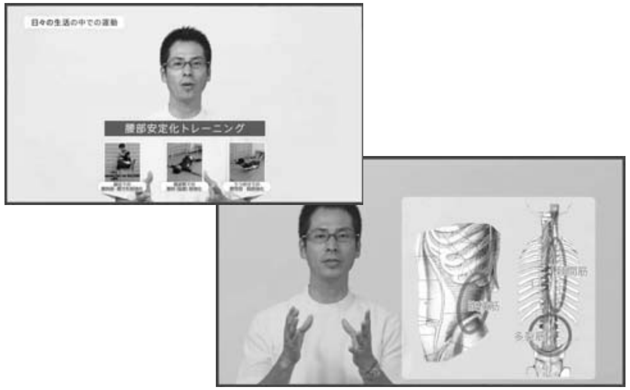
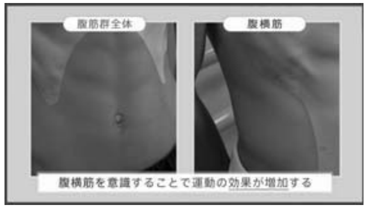
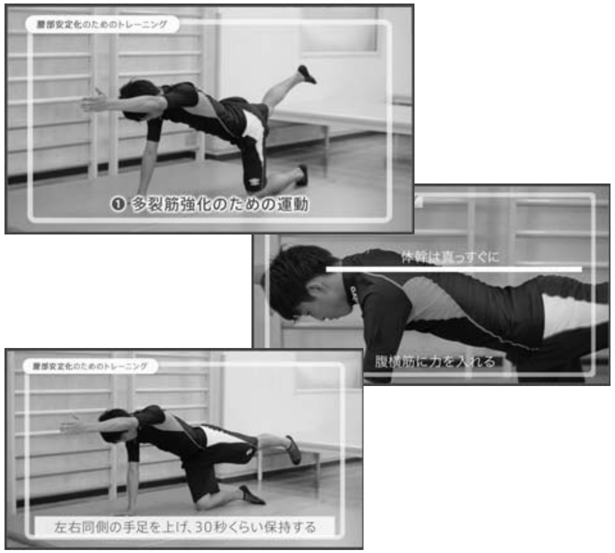
T. 自己管理可能な腰痛かどうかの目安

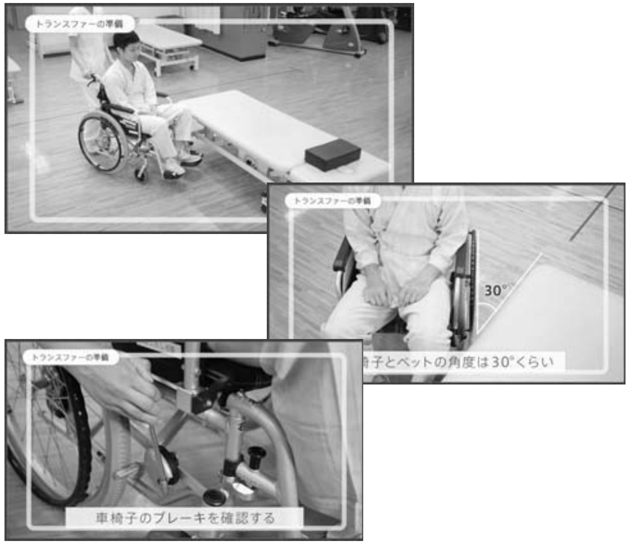
T. 自己管理してはいけない腰痛
T. RED FLAG SIGN</td><td>浅田. 腰痛」は私たち現代社会に生きる者にとって非常に身近な病気です。
こちらをご覧ください。腰痛の程度を「腰痛なし」「生活に支障のない程度の腰痛」「支障はあるが休むほどではない腰痛」「四日未満の休みが必要な腰痛」「四日以上の休みが必要な腰痛」の5っのグレードに分けると、生涯のうちで腰痛を経験したことがある人の割合は全体の80%を超えています。 私たちの腰痛予防の定義としては、このグラフのグレード0から3に留めることを目標にしています。

ところで、私たちは腰に痛みを感じたときどうすればいいのでしょうか?
まずは、自分の症状を把握し「自己管理が可能なのかどうかを正しく判断する」つまり腰痛をトリアージする必要があります。

始めに自己管理してはいけない腰痛の症状を紹介します。
1つ目は、転倒や転落など、外傷後の痛みで日常の生活に支障が出る場合。
2つ目は普通の姿勢でじっとしていても痛みを感じ楽な姿勢が無い状態。
3つ目は強い痛みが臀部から膝より下まで放散する場合。
4つ目は会陰部周囲のしびれや灼熱感、あるいは尿が出づらいことがある場合。
5つ目は足の脱力がある。例えば踵歩き片足で出来にくい場合です。</td><td>1’28”</td></tr>
</table>

SCENE	VISUAL	ACTION	COMMENT	MEMO
	 	G. 安静群と活動群の腰痛再発率 I. 痛みのコントロール （細分化→最後は「痛みのコントロール」部分のみに）	浅田. このグラフを見てください、適度な活動を指示された方よりも安静を指示された方の方が腰痛腰痛が再発しやすく慢性化に陥りやすいのです。 このことからも分かるように腰痛の管理は、正しい情報と知識を元に自身の腰痛と向き合い自発的に適度な運動や活動を続けながら痛みをコントロールし徐々に回復に近づけていく。 これが理想の腰痛管理方法なのです。 さて、この後は腰痛の管理には欠かせない適度な運動。その運動療法の方法について詳しく紹介していきたいと思います。	
	   	T. 腰痛。その対処法… 運動療法の実際 T. ❶不良な姿勢をとった後の対策 I. 髄核の移動 （Ai素材手配中） I. これだけ体操と髄核の移動	浅田. ここでは、運動療法についてご紹介しましょう。 社会福祉施設で働く看護師や介護士の皆さんは、日々の仕事の様々なシーンに応じて腰痛の原因になりうる色々な動きや姿勢をとっています。 私たちはそんな忙しい方達が手軽に実践出来るように運動療法を「TPO」によって使い分ける3つの種類に分けてみました。 一つ目は「不良な姿勢を取った後の対策」です。 例えば、介護の仕事中、着替えの補助やトランスファーなどで、前屈みの姿勢が続いてしまうと髄核が後方へ移動してしまい椎間板に痛みを感じてしまうことがあります。 そんなときは、上体を反らして髄核をもとの位置に戻しましょう。 この体操をこれを「これだけ体操」と言います。	12’06”

SCENE	VISUAL	ACTION	COMMENT	MEMO
#19		T. 腰部安定化トレーニング 腹斜筋・腰方形筋強化　腹斜筋強化　腰背部・臀筋強化 I. 深部の筋肉 (コメントのタイミングに合わせたい) T. 鍛えたい筋肉を意識することで効果を増加させる	浅田. 最後に紹介するのは、腰を安定させるための筋力を鍛えるためのトレーニングです。 腰、つまり腰椎はいろいろな筋肉によって支えられています。　腹筋や背筋はもちろんですが、特に体の深部にある小さな筋、腹横筋・深部多裂筋・棘間筋を鍛えることで、腰をより安定させることが出来ます。　そうすれば労働による疲労に耐えることが出来る強い腰回りを作ることが出来るのです。 まずは、この腹横筋・深部多裂筋を意識してみましょう。	23′55″
#20-1		T. 腹筋群全体を意識する T. 腹横筋を意識する T. 腹横筋を意識することで運動の効果が増加する	NA. このように、腹筋群全体を意識するのは簡単です。 次にお臍を凹ませる感じで下腹部に力を入れ腹横筋を直接感じてみてください。 この部分です。 この腹横筋を意識しながら、これから紹介する運動をしてみてください。	24′42″
#20-2		T. 腰部安定化のためのトレーニング T. ❶多裂筋強化のためのトレーニング T. 体幹は真っすぐに(ラインを黄色統一) T. 腹横筋に力を入れる T. 左右同側の手足を上げ30秒間くらい保持する	NA. 四つ這いでお腹を凹ませ左右反対の手足を体幹の高さまで上げ30秒間保持してください。 反対の手足も…このとき腹横筋を意識し体幹を真っすぐな状態に保つように心がけてください。 先ほどの運動が出来たかたは、次に左右同側の手足を上げる運動にも挑戦してみてください。	25′08″

SCENE	VISUAL	ACTION	COMMENT	MEMO
#21-2		T. 車いすの角度は30°程度 (ラインは黄色統一) T. ブレーキの確認 T. フットレストを開く T. アームレストを取り外す	NA.　まず車いすをベッドの横に据えます。 このときベッドに対して車いすの角度は30度くらいが適当でしょう。 その後、車いすのブレーキをしっかりかけてください。 そして、フットレストを邪魔にならないようにしっかり開きましょう。 アームレストが取り外せるものは外した方がよりスムーズな移乗出来るでしょう。	30'15"
#21-3		T. 体幹を前方へ移動 T. 足を移動後の位置に近づけておく T. 足の角度を調節	NA.　次に、対象者の体幹を座面の前方へ移動します。 臀部を片方づつ前にずらしましょう。 そして、対象者の足を出来るだけ移動後の位置に近づけておきます。 このとき対象者の足の角度も最終肢位に近づけておきましょう。	
#21-4		T. 膝折れ防止ロックをする (31'19" ×膝をロックする) T. 片足のロック・両足のロック	NA.　対象者の膝が折れないようお互いが痛くない位置を探して、自分の足でしっかり固定します。 ロックする足は両足でも片足でも、状況に応じて使い分けましょう。	

SCENE	VISUAL	ACTION	COMMENT	MEMO
#23-1		T. 間違ったトランスファー T. 腰に負担がかかる T. 正解 T. 体を前に引っ張るように	NA.　1っ目は、車いすからベッドへの移動の時、対象者の上体を上に持ち上げるとその体重が直接介助者にかかり腰を痛める原因となります。 このときは、対象者の体を前に引っ張るような感覚で移動させるよう心がけましょう。	33’07”
#23-2		T. 間違ったトランスファー T. 保持バランスが悪くなる T. 体が離れている T. 支持出来ていない T. 正解 T. 必ず３点で支持する	NA.　2っ目は、３点支持についてです。 この場合、介助者の体が対象者から離れすぎているため、２点でしか支えられておらず不安定であり、介助者に負荷がかかります。 介助者は対象者にしっかり体を寄せて、必3点で体を支えるようにしましょう。	
#23-3		T. 間違ったトランスファー T. 前傾姿勢がとれていない T. 腰に負担がかかる T. 正解 T. 対象者の前傾姿勢がとれている	NA.　3っ目は、体がしっかり前傾していません。 車いすからベッドへの移動のときは利用者の上体をしっかり前傾させないと、介護者の腰に必要以上の付加がかかり腰痛の原因になります。 移動のときは、利用者の上体をしっかり前傾させましょう。	
#23-4		T. 間違ったトランスファー T. 膝折れ防止のロックができていない T. 膝のロックを確認する T. 正解 T. 膝のロックを確認する	NA.　4っ目は、膝折れ防止のロックが出来ていません。 これが出来ていないとバランスがとりづらくなるので介助者に突然付加がかかり、事故や腰痛につながります。 移動の時は、必ず自分の足で対象者の膝をロック出来ているか確認しましょう。	

SCENE	VISUAL	ACTION	COMMENT	MEMO
#24-5		T. ❸介護者が前傾しないトランスファー T. 3点でしっかり支持する T. 骨盤をあてる T. 解除しやすければ下から腋を支えてもよい T. 引っ張るように重心を後ろへ T. 下半身を中心に回転する	NA. 次は「介護者が前傾姿勢をとらないときのトランスファー」です。 まず、対象者の両腋を両手で固定したうえで介助者の骨盤を対象者の鎖骨周辺に当てて3点固定をします。 このとき、両腋を支える手は上からまわしても下からまわしてもかまいません。後で解除しやすいほうを選んでください。 NA. そのままの姿勢で介助者が重心を後方にずらしていくと、対象者は前傾姿勢になり自然と臀部が持ち上がります。 その後、介助者は自分の下半身を中心に回転し、対象者を移動させ座らせます。 それでは、もう一度確認しておきましょう。	38’29”
#24-6		T. ❹対象者が後ろに反りかえる場合のトランスファー T. 片腕で腋を支える T. 下方向から腋を支える T. 頸部をロックするように抱える	NA. 次は「対象者が後ろに反りかえる場合のトランスファー」です。 介助者は右手で対象者の腋を支え、左腕を使って対象者の上体が反りかえらず前傾姿勢を保てるように頸部をロックするように抱えます。	39’32”

SCENE	VISUAL	ACTION	COMMENT	MEMO
#24-10		T. 前側の膝をロックする T. 対象者が前に落ちないように手をまわす T. 前側の手でズボンを把持する T. ズボンを把持する手で移動動作をコントロールする	NA.　まず、対象者の前側の膝に膝折れ防止のロックをします。 次に、対象者の上体に「たすきがけ」の要領で腕をまわし、前方へずり落ちないように支えます。 そして開いている方の手で対象者のズボンの後ろ側を持ち、前傾させると同時に自分の重心も前方に移動させます。 対象者の臀部が浮き上がるので、ズボンを掴んでいる手で体の向きを回転させるように移動させます。 それでは、もう一度、動きを確認しておきましょう。	
#25		T. ノーリフトのポリシー 押す・引く・持ち上げる・ねじる・運ぶなどの介護動作を人力のみで行うことを禁止し、対象者の自立度を考慮した介護機器使用による多乗介護を推奨すること。	浅田. このDVDの冒頭でもお話ししましたが… 介助に関しては、人力で対象者を持ち上げないノーリフトが基本ポリシーです。 しかし、どうしてもノーリフト介助が出来ない場合には、その時々の環境に合わせたいろいろなトランスファーの方法を使い分けることで介助者に掛かる負担を軽減することが出来ます。 とは言え、医療介護の仕事は、体を使った重労働であることは変わりません。	45'07"

Compo　機能一覧

No.	分類	機能名	概要	一般ユーザー	管理者
1	アンケート	アンケート表示	配信されたアンケートを一覧表示する。	○	○
2		アンケート回答	配信されたアンケートに回答する。	○	○
3		アンケートテンプレート管理	アンケートのテンプレートの追加・修正・削除・配信を行う。		○
4		アラートメール設定	アンケート配信時にアラートメールの設定を行う。		○
5		アンケート回答状況表示	アンケートの回答状況を表示する。		○
6		未回答者への督促	アンケート未回答者への督促を送信する		○
7		アンケート回答結果表示	アンケートの回答結果を表示する。		○
8		アンケート回答結果出力	アンケートの回答結果をCSVファイルへ出力する。		○
9	相談	相談	相談の新規登録、回答確認、コメントの更新を行う	○	
10		相談表示（一般ユーザー）	自身の相談履歴を一覧表示する。	○	
11		相談表示（管理者）	自身宛の相談を一覧表示する。		○
12		相談回答	自分宛の相談を一覧より確認し、回答する。		○
13		相談終了	相談を終了する	○	○
14		全相談参照	全相談を参照する。		○
15	管理	ユーザプロフィール登録	自分の本名、ニックネーム、パスワード、メールアドレス、携帯メールアドレス等の情報を登録する。	○	○
16		マスタメンテナンス（ユーザー管理）	ユーザーの新規追加、変更、削除を行う。		○
17		マスタメンテナンス（グループ管理）	グループの新規追加、変更、削除を行う。		○
18		マスタメンテナンス（メンターグループ管理）	メンターグループ（相談者と相談先の紐付）の追加、変更、削除を行う。		○