

医薬品 研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日 2007. 7. 20	新医薬品等の区分 該当なし	機構処理欄
一般的名称	(製造承認書に記載なし)		研究報告の公表状況	ABC Newsletter. 2007 Jul 6.	公表国	
販売名(企業名)	合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)				米国	
研究報告の概要	<p>○感染症最新情報:マラリア FDAは、初めて認証された米国のマラリア用迅速テスト、Binax NOWマラリア検査の試用を許可した。「マラリアの標準的臨床検査法は、顕微鏡下で血液検体中の寄生虫を特定しなければならず、訓練と経験を要する難しい作業である」とFDAはニュースリリースの中で述べている。「Binax NOW検査は、非常に迅速で使用が簡便である。」全血検体をディップスティックに数滴つけて15分後には結果が得られる。検査結果の確定には、これからもなお標準的顕微鏡検査法を用いなければならない。「米国ではマラリアはまれであるため、医師及び研究所職員は当疾患の診断に慣れていない。Binax NOW検査は、他の臨床検査法と併用した場合、米国でマラリアをより速やかに診断するのに役立つ新たなツールとなる。」とFDA医療機器・放射線保健センターのDaniel Schultz医師は言った。米国外のマラリア流行地域で行った多施設試験において、標準的顕微鏡診断と比較して当該検査の正確度は95%であった。</p>					<p>使用上の注意記載状況・ その他参考事項等</p> <p>合成血「日赤」 照射合成血「日赤」 合成血-LR「日赤」 照射合成血-LR「日赤」</p> <p>血液を介するウイルス、 細菌、原虫等の感染 vCJD等の伝播のリスク</p>
	<p>報告企業の意見</p> <p>FDAは、初めて認証された米国のマラリア用迅速テスト、Binax NOWマラリア検査の試用を許可したとの報告である。</p>	<p>今後の対応</p> <p>日本赤十字社では、輸血感染症対策として問診時に海外渡航歴の有無を確認し、帰国後4週間は献血不適としている。また、マラリア流行地への旅行者または居住経験者の献血を一定期間延期している(1~3年の延期を行うとともに、帰国後マラリアを思わせる症状があった場合は、感染が否定されるまでの間についても献血を見合わせる)。今後も引き続き、マラリア感染に関する新たな知見及び情報の収集、対応に努める。</p>				

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2008 Yellow Book Available in Print and on the CDC Web site

Mexican risk areas for malaria revised

The Centers for Disease Control and Prevention has issued the 2008 edition of Health Information for International Travel (long called "The Yellow Book" for its bright yellow cover). Published every two years as a reference for those who advise international travelers of health risks, the Yellow Book and a related Web site are widely used by the nation's blood centers to identify areas around the globe that CDC considers endemic for malaria.

Revised risk information for malaria includes the following for Mexico: "Risk is limited to areas infrequently visited by travelers including small foci along the Guatemala and Belize borders in the states of Chiapas, Quintana Roo, and Tabasco; rural areas in the states of Nayarit, Oaxaca, Sinaloa; and in an area between 24°N and 28°N latitude, and 106°W and 110°W longitude, which lies in parts of Sonora, Chihuahua, and Durango. No malaria risk exists along the United States-Mexico border. No malaria risk exists in the major resorts along the Pacific and Gulf coasts."

The Yellow Book home page is: wwwn.cdc.gov/travel/contentYellowBook.aspx

INFECTIOUS DISEASE UPDATES

vCJD

Cambridge-based ProMetic BioSciences Ltd (PBL) has announced a \$1.7 million deal to develop its proprietary prion-binding ligands, with a prominent European plasma fractionator. The ligand technology will be used to minimize the risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD), the human form of "mad cow disease," by plasma-derived products. The technology, developed by Pathogen Removal and Diagnostic Technologies (PRDT), a collaboration with the American Red Cross, is the prion capture element of the P-Capt prion reduction filter used for the treatment of red blood cell concentrate. It will be utilized in a program to bind and remove any abnormal prion protein – PrP^{sc}, the agent responsible for vCJD – that might be present in donor plasma. "Although the risk of cross infection is relatively low after the establishment of treatment protocols, the filter provides an extra level of safety due to the absence of a commercially available diagnostic test for detection of the blood-borne form of the vCJD agent," ProMetic said. ProMetic President & CEO Pierre Laurin said: "The efficacy of PRDT's technology in combating the risk of transmission of vCJD in transfusion blood is already established and the P-Capt filter is approved for treatment of red blood cell concentrate. Its application to increase the safety of plasma and plasma derivatives is an obvious extension of the use of this technology." As part of the program, PBL will manufacture and validate an affinity capture material comprising the PRDT ligand, attached to synthetic resin particles. "While for competitive reasons we are not disclosing the name of PBL's partner in this agreement, we are delighted to open a significant new market opportunity for PRDT's technology," Mr. Laurin said. (Source: Business Weekly (UK), 7/4/07)

MALARIA

The Food and Drug Administration has cleared for laboratory use the first authorized US rapid test for malaria – the Binax NOW Malaria Test. "Standard laboratory tests for malaria require identifying parasites in a blood sample under a microscope, a difficult task that requires training and experience," FDA said in a news release. "The Binax NOW test is significantly faster and easier to use." Results are available in 15 minutes after a few drops of whole blood are placed on a dipstick. The test parasites. Results still must be confirmed using

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INFECTIOUS DISEASE UPDATES (continued from page 19)

standard microscopic evaluation. "Since malaria is uncommon in the US, clinicians and lab personnel may not be accustomed to diagnosing this disease," said Daniel Schultz, MD, director of FDA's Center for Devices and Radiological Health. "When used in combination with other laboratory tests, the Binax NOW test provides an additional tool to help them diagnose this disease faster in the United States." The assay was 95 percent accurate compared with standard microscopic diagnosis in a multi-center study outside the United States in areas where malaria is prevalent. The test is manufactured by Binax Inc., a subsidiary of Inverness Medical Innovations Inc. of Scarborough, Maine. (Source: FDA News, 6/26/07)

SARS

An international team of investigators has identified the first human antibodies that can neutralize different strains of the virus responsible for outbreaks of severe acute respiratory syndrome (SARS). The researchers, from the National Institutes of Health and elsewhere, used a mouse model and *in vitro* assays to test the neutralizing activity of the antibodies. Their findings appear in the July 2, 2007, early online edition of the *Proceedings of the National Academy of Sciences*. The study is important because it is unlikely that the viral strain that caused the outbreak in people in 2002 still exists in nature. "What we need to prove for any vaccine, therapeutic, antibody, or drug is that it is effective not only against the strain of SARS virus isolated from people, but also against a variety of animal strains, because animals will be a likely source for re-emergence of the SARS virus," the researchers said. The discovery of two effective antibodies has the advantage that a newly emergent variation of the SARS coronavirus might be insensitive to neutralization with one, but still susceptible to the other. "Our results demonstrate novel potential antibody-based therapeutics against SARS that could be used alone or in combination ... these human antibodies could be also used for diagnosis and as research reagents in the development of vaccines and inhibitors," the authors said. Citation: Zhu Z *et al*. Potent cross-reactive neutralization of SARS coronavirus isolates by human monoclonal antibodies. *Proc Natl Acad Sci USA* 2007;104, No. 27 [E-pub July 3, 2007]

WEST NILE VIRUS

A Winnipeg, Manitoba-area blood donor is the first human case of West Nile virus (WNV) this year in Canada. The individual tested positive by mini-pool NAT after a June 19 blood donation at Canadian Blood Services and tested positive by mini-pool NAT. Initial reports indicate that the individual now has mild symptoms. Further investigation is underway to confirm when and where exposure may have taken place. The earliest human exposures to WNV identified in Manitoba were in mid-June 2006. While Canadian health officials are not predicting that an epidemic will occur this summer, they are finding more *Culex tarsalis* mosquitoes, which carry WNV, and the numbers are soaring early in the season. In June 2006, just two *C. tarsalis* mosquitoes were found in the Winnipeg area. This year the *C. tarsalis* number jumped to 389. The rising numbers prompted officials in Winnipeg to order fogging trucks to conduct mass sprayings of malathion to help control the insect population. In 2006, 151 human cases of West Nile virus were reported across Canada: 39 in Alberta; 19 in Saskatchewan; 50 in Manitoba; 42 in Ontario and one in Québec. (Source: Manitoba Office of the Chief Officer of Health, 6/21/07; CTV.ca, 7/2/07)

West Nile Virus was detected for the first time last month in sentinel chickens in Puerto Rico. The chickens were in four separate habitats in rural and urban areas. Seroconversion for WNV was detected by a chicken specific MAC-ELISA in seven sentinel chickens in four pens (one wetland, one mangrove forest, and two evergreen forests) from a sample drawn on June 4, 2007 and from another 21 chickens on June 11 in 11 out of the 12 pens, covering all types of habitats, including rural and urban areas. Puerto Rican health officials now are testing mosquitoes captured around the positive pen areas in an attempt to isolate the virus and the Puerto Rico Department of Health (PRHD) has alerted the population to take prevention measures. The Centers for Disease Control and Prevention and PRDH have conducted routine island-wide human surveillance for WNV since late 2002. To date, no human cases of WNV infection have been reported in Puerto Rico. More active surveillance now has been initiated. (Source: ProMed Digest, 7/3/07) ♦

医薬品 研究報告 調査報告書

識別番号・報告回数		報告日	第一報入手日 2007. 6. 30	新医薬品等の区分 該当なし	機構処理欄
一般的名称	(製造承認書に記載なし)		研究報告の公表状況	T.Y. Kim, International Society of Blood Transfusion 17th Regional Congress, Europe; 2007 Jun. 23-27; Madrid.	公表国
販売名(企業名)	合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)				韓国
研究報告の概要	<p>○韓国におけるマラリアPCRを用いたマラリア遡及プログラム 背景: マラリアは世界的に重大な感染症であり、主にハマダラカの刺咬により伝播するが、輸血によっても伝播する可能性がある。 目的: 韓国はマラリア流行地域ではないが、近年一部の地域(特に韓国北部)で三日熱マラリアが多発している。我々は、供血後にマラリア感染の診断を受けた供血者の保管血液検体を調べ、輸血によるマラリア感染の発生について調査した。 方法: 韓国疾病対策予防センター(KCDC)が、全国の病院や保健所からマラリア感染の報告を収集した。診断前6ヶ月間以内に供血を行ったマラリア患者の保管検体を選定しPCRを実施した。結果が陽性の場合、PCR陽性の血液成分を輸血された全受血者の血液検体入手し、末梢血塗抹標本(PBS)、マラリア抗原・抗体検査、PCR及びnested PCRで検査した。 結果: 2005年5月～2006年8月の期間に、合計2,056名の患者に三日熱マラリアの感染が確認された。このうち、46名(2.2%)に診断前直近6ヶ月以内の供血歴があった。この46名の供血回数は51回であった。保管血液検体51のうち、マラリアPCR陽性となったのは4名の供血者由来の5検体であった。PCR陽性となった供血後マラリアと診断されるまでの期間は、3～149日(中央値48日)であった。この5つの供血血液由来の7製剤(pRBC5製剤、PC2製剤)が7名の受血者に輸血されていた。pRBC製剤は供血から7～30日後、PC製剤は供血から2日後に輸血されていた。受血者7名のうち、1名はnested PCRでマラリア感染が認められた。残り6名の検査結果はいずれも陰性であった。 結論: マラリア遡及プログラムにより、1名の受血者に輸血によるマラリア伝播が確認された。PCRに基づくマラリア遡及調査は、輸血によるマラリア伝播の特定に役立つ。</p>				<p>使用上の注意記載状況・ その他参考事項等</p> <p>合成血「日赤」 照射合成血「日赤」 合成血-LR「日赤」 照射合成血-LR「日赤」</p> <p>血液を介するウイルス、 細菌、原虫等の感染 vCJD等の伝播のリスク</p>
	<p>報告企業の意見</p> <p>韓国のマラリア遡及プログラムにより、2005年5月～2006年8月の期間で1名の受血者に輸血によるマラリア伝播が確認されたとの報告である。</p>	<p>今後の対応</p> <p>日本赤十字社では、輸血感染症対策として問診時に海外渡航歴の有無を確認し、帰国後4週間は献血不適としている。また、韓国のうちソウルより北の地域、江原道、京畿道をマラリア流行地(B地域)として、旅行者または居住経験者の献血を一定期間延期している(1～3年の延期を行うとともに、帰国後マラリアを思わせる症状があった場合は、感染が否定されるまでの間についても献血を見合わせる)。今後も引き続き、マラリア感染に関する新たな知見及び情報の収集、対応に努める。</p>			

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Poster Session

6.3 Blood safety - transfusion transmitted disease (TTD) - parasites

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MALARIA LOOKBACK PROGRAM USING MALARIA-PCR IN KOREA

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Background: Malaria is a major communicable disease worldwide and mainly transmitted by the bite of infected Anopheles mosquitoes. But, malaria can be transmitted by blood transfusion.

Aims: Korea is not endemic area of malaria. Recently, Plasmodium vivax infection frequently occurred in some area, especially a north part of Korea. We investigated the stored blood samples of blood donors who were diagnosed as malaria infection after blood donations to evaluate the occurrence of transfusion-transmitted malaria infection.

Method: Korea center for disease control and prevention (KCDC) collected the reports of malaria infection from the hospitals or public health care centers nationwide. The stored blood samples of malaria patients who had donated blood within 6 months before diagnosis of malaria were selected. KCDC performed malaria-PCR for above selected blood samples. If the results of PCR for stored blood samples were positive, we obtained the blood samples of all recipients who had received PCR-positive blood components and performed peripheral blood smear(PBS) including thin and thick smear, malaria antigen and antibody, PCR and nested PCR for detection of malaria infection.

Results: Between May 2005 and Aug 2006, a total 2056 patients were confirmed to be Plasmodium vivax infection. Among 2056 patients with malaria, 46 patients (2.2%) had the history of blood donations within 6 months before the diagnosis of malaria. The number of blood donation for 46 patients was 51. Among 51 stored blood samples, five stored blood samples, which were originated from four donors had positive result of malaria PCR. The duration from first donation of PCR-positive blood to the diagnosis of malaria was 3-149 days (median 48 days). Seven blood components [five of packed red blood cell (pRBC), two of platelet concentration (PC)] were derived from five donated blood and given to seven recipients. Among PCR-positive blood components, PCR-positive pRBC were given to the recipients 7-30 days after blood donation and PC were given 2 days after blood donation. Among seven recipients who received PCR-positive blood components, only one recipient was proven to become infected with malaria using nested-PCR of malaria. The results of PBS, malaria antibody and antigen, PCR, and nested-PCR for other six recipients were all negative.

Conclusion: One recipient was documented as transfusion-transmitted malaria infection by malaria lookback program. Malaria lookback program-based on malaria PCR is useful to identify transfusion-transmitted malaria infection.

医薬品 研究報告 調査報告書

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一般的名称	新鮮凍結人血漿		研究報告の公表状況	公表国 Nomura T, Fujimoto T, Ebisutani C, Horiguchi H, Ando S. Jpn J Infect Dis. 2007 Jul;60(4):241-3.		日本
販売名(企業名)	新鮮凍結血漿「日赤」(日本赤十字社) 新鮮凍結血漿-LR「日赤」(日本赤十字社)					
研究報告の概要 179	<p>○淡路島の日本紅斑熱死亡例について 日本紅斑熱は、1984年に初めて報告されて以来、わが国におけるリケッチア感染症の中で重要な位置を占めている。淡路島南部の諭鶴羽山系は、<i>Rickettsia japonica</i>の好発地域の一つである。急速に進行し、DIC、消化管出血により死亡した日本紅斑熱症を報告する。 77歳男性、2005年9月2日より食欲低下、翌日より下腿に皮疹が出現、5日に38.7℃の高熱、歩行障害、構音障害が出現し、7日に症状が悪化したために受診した。自宅の畑には出ているが、特に山林には出入りしていなかった。両下腿の皮膚に7mm大紅斑が散在、右肩前面にダニ刺し口があった。入院時検査で血小板減少、軽度の肝障害と脱水を認め、CRP20.34mg/dlと著明な上昇を認めた。リケッチア感染症による肝機能障害、DICを疑い、ミノサイクリン200mg/日、ヘパリン1万単位/日、また脱水に対し補液を開始した。第2病日9月8日にはCRP17.7mg/dlとなり、炎症所見と肝酵素も改善傾向にあったが、9日急速に血圧低下、赤色凝血塊混じりの下血を繰り返す、全身皮膚にも紫斑が出現、その後心停止、死亡した。病理解剖の結果、両側胸水と胃～大腸粘膜からのoozing様出血を認めた。初診時のEDTA採血よりDNAを抽出し、PCR、nested-PCRを実施したところ、塩基配列は<i>R. japonica</i>と100%一致した。血清中の<i>R. japonica</i> IgGおよびIgM抗体価は、間接蛍光抗体法でIgG 320倍、IgM 80倍であった。 発疹性の発熱疾患であるリケッチア感染症は、わが国ではつつが虫病と日本紅斑熱が知られている。臨床症状からの鑑別は困難だが、発生時期や発生場所により疫学的な鑑別がある程度可能である。この症例では刺し口、発疹、発熱と3主徴がそろい、発症時期、発症地より日本紅斑熱を疑い、速やかにミノサイクリン投与を開始し、一時的に改善を認めたもののDICによる出血傾向により不幸な転帰をとった。 日本紅斑熱患者の2/3は50歳以上で比較的高齢者に多い疾患である。これは疾患感受性によるものというより、山村部の高齢化という環境要因が強いと考えられる。近年日本紅斑熱は増加傾向にあり、中山間地域の高齢化のため、今後も日本紅斑熱による重症例、死亡例は増加することが考えられる。医療従事者への啓発、検査の普及、同時に一般住民に対する注意勧告が必要と考える。</p>					使用上の注意記載状況・ その他参考事項等 新鮮凍結血漿「日赤」 新鮮凍結血漿-LR「日赤」 血液を介するウイルス、 細菌、原虫等の感染 vCJD等の伝播のリスク
	報告企業の意見			今後の対応		
淡路島で、急速に進行し、DIC、消化管出血により死亡した日本紅斑熱の症例報告である。			今後も情報の収集に努める。			

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Laboratory and Epidemiology Communications

The First Fatal Case of Japanese Spotted Fever Confirmed by Serological and Microbiological Tests in Awaji Island, Japan

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Japanese spotted fever is an important rickettsial disease in Japan (1). Japanese spotted fever was first reported by Mahara et al. (2,3) in 1984 in Anan City, Tokushima Prefecture, Japan. Since then, cases of Japanese spotted fever have been reported in many regions of the country. Yuzuruha Mountain in Awaji Island (Figure 1) is one of the areas heavily contaminated with *Rickettsia japonica*, and Japanese spotted

fever cases are reported every summer in this area (4). In the present report, we describe the first fatal case of Japanese spotted fever confirmed by serological and microbiological methods.

A 77-year-old male recognized loss of appetite as the initial symptom on September 2, 2005, which is defined as day 1 of his illness. Rash appeared on the lower thighs on day 2, and a high fever of 38.7°C, dysarthria, and gait disorder on day 4. The patient visited Awaji hospital on day 6, because the symptoms had worsened. The patient claimed that he had worked on farmland, but had not visited a forested area before he developed the illness. He was alert on arrival at the

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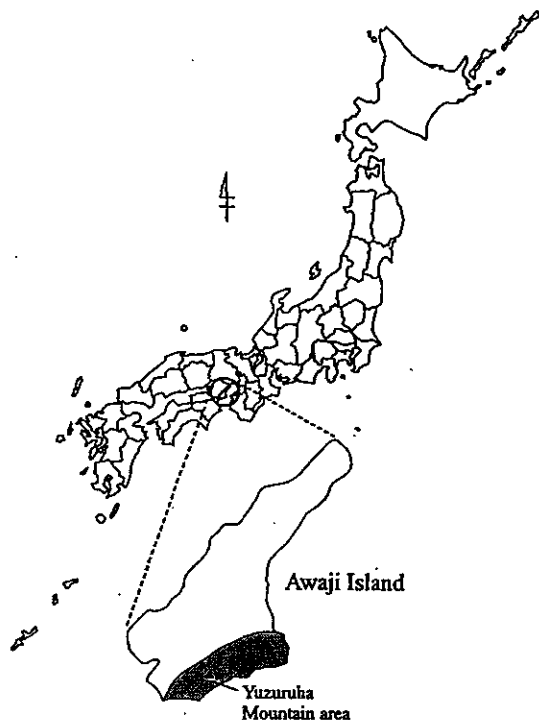


Fig. 1. Location of Yuzuruha Mountain area in Awaji Island.

hospital. At the first visit, other general findings included a height 160 cm, weight 50 kg, body temperature 36.4°C, blood pressure 102/58 mm Hg, pulse rate 86/min and regular, and SpO₂ 97%. There were no abnormal findings in the chest region, and neither abdominal mass nor hepatosplenomegaly was palpable. Lymph node swelling was not found. No neurological abnormality was observed. Diffuse erythema of 7 mm in diameter was present on each bilateral lower thigh, and a bite mark (eschar) of a tick was evident on his anterior right shoulder.

Laboratory data were as follows: red blood cell count $4.48 \times 10^6/\mu\text{l}$, Hb 13.8 g/dl, Ht 39.1%, white blood cell count $12,500/\mu\text{l}$, platelet count $52,000/\mu\text{l}$ – thrombocytopenia observed, FDP 54 $\mu\text{g/ml}$, suggesting concurrent DIC. Mild hepatopathy and dehydration and a marked elevation of CRP at 20.34 mg/dl were observed. Weil-Felix reaction was negative: OX19<1:80, OX2<1:20, and OXK<1:20. Blood sugar level was elevated at 462 mg/dl and HbA1c 6.7%. As an underlying disease, concurrent diabetes was suspected based on the high blood sugar level. Findings from diagnostic imaging were noncontributory.

Because of the presence of an eschar and rash, it was suspected that liver dysfunction and DIC were due to rickettsial infection. Minocycline 200 mg/day, heparin 10,000 units/day, and fluid replacement for dehydration were started for treatment. On day 7, the 2nd day of hospitalization, CRP decreased to 17.7 mg/dl. Physical findings of inflammation started to improve and liver enzyme levels started to normalize. On day 8, blood pressure was 84/48 mm Hg, showing a rapid decline. Thereafter, the patient had repeated bloody stool mixed with red blood clots, and purpura appeared over the entire body. The patient eventually had cardiac arrest and death was confirmed on the same day. The autopsy demonstrated bilateral pleural effusion and oozing hemorrhage from the mucous membranes of the stomach to the large intestine.

DNA was extracted from the blood in EDTA collected at the initial examination. PCR (5) was performed with the R1-

R2 primer combination to detect spotted fever group rickettsia, and a 2nd PCR was then performed using the Rj5-Rj10 primer combination, which specifically amplifies *R. japonica*. Agarose electrophoresis detected the target size of 357 bp as the amplified product. The nucleotide sequence of the amplified product was analyzed by direct sequencing. The nucleotide sequence matched 100% with that of *R. japonica* (GenBank accession no. U83442). Serum IgG and IgM antibody titers were examined against *R. japonica* by indirect immunofluorescence assay. The IgG and IgM titers were 1:320 and 1:80, respectively.

Tsutsugamushi disease and Japanese spotted fever are two diseases caused by rickettsial infection in Japan (1). Within Awaji Island, these diseases occur in different regions: tsutsugamushi disease in the northern part of the island and Japanese spotted fever in the southern Yuzuruha Mountain area (4). This is probably due to the different distribution of the respective vectors. There have been several cases of either disease annually. It is very difficult to differentiate these two diseases based on clinical symptoms, but they can be epidemiologically differentiated to some degree based on the time of year and the geographical location in which they occur. The patient in this study presented all 3 of the major signs for rickettsial infection, eschar, rash, and fever. The patient was clinically suspected to have Japanese spotted fever, according to the time and location of the incidence. Therefore, minocycline administration was started promptly, and the patient's conditions temporarily improved. However, the patient died from hemorrhaging manifestation.

The case fatality ratio of rickettsiosis by the spotted fever group is low. Rocky Mountain spotted fever has an exceptionally high case fatality rate of 3.7% (6). Kodama et al. (7) reported the first fatal case of Japanese spotted fever in 2001 in Awaji Island, but they did not confirm *Rickettsia* infection serologically. The patient in the present report was an elderly person. Although diabetes mellitus was not observed in his medical history, diabetes was thought to be the underlying disease according to the elevated blood sugar level and a high level of HbA1c. Therefore, it is likely that the patient was in an immunocompromised state, and this condition was one of the factors which contributed to the fatal outcome. For those who are old and predicted to have poor prognosis, steroid therapy has been reported to be effective, and the use of an antibacterial agent of the new quinolone group should be considered in combination with minocycline from the start of the treatment (1).

There is no gender difference in the reported cases of Japanese spotted fever. People of all age groups can be affected, but two-thirds of the patients are 50 years old or older. This is probably due to the strong social activity of the elderly people in the mountain village, rather than disease sensitivity. In recent years, the numbers of Japanese spotted fever cases have been increasing (8). Considering the increase in the percentage of the elderly population in semi-mountainous areas in Japan, it is likely that severe and fatal cases of Japanese spotted fever will increase in the future. On the other hand, healthcare providers are not provided enough information regarding this disease. Further, specific serodiagnostic tests and PCR are not widely used. Therefore, it is important to facilitate the use of these diagnostic techniques, and to provide the general residents with sufficient information concerning this disease.

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医薬品 研究報告 調査報告書

識別番号・報告回数		報告日	第一報入手日 2007. 8. 24	新医薬品等の区分 該当なし	機構処理欄
一般的名称	新鮮凍結人血漿	研究報告の公表状況	朝鮮日報. 2007 Aug 21.	公表国 韓国	
販売名(企業名)	新鮮凍結血漿「日赤」(日本赤十字社) 新鮮凍結血漿-LR「日赤」(日本赤十字社)				
研究報告の概要	<p>○韓国でツツガムシ病患者急増 このところ、ツツガムシ病の患者が急増している。8月20日、疾病管理本部の発表によると、2002年に1,919人だったツツガムシ病の患者数が、04年は4,698人、06年には6,420人に増加したことが分かった。1993年末に法定伝染病に指定されて以来、患者数は実に25倍以上増加した。 ツツガムシ病は、主に9月以降、ツツガムシ菌に感染したツツガムシ(ダニの一種)の幼虫に刺されることにより感染する。10日間程度の潜伏期を経ると、突然高熱が発生し、目の充血、頭痛、筋肉痛、発疹などの症状が現れる。また、刺口がただれ、黒いかさぶたとなる場合もある。ツツガムシという名前は、ダニを意味する日本語(恙虫)に由来する。 サムスンソウル病院感染内科のペク・ギョンラン教授は、「抗生物質で比較的容易に治療できるが、初期症状が風邪と似ているため、適切な治療を受けずにそのまま放置すると、心不全や肺炎で死亡する危険性もある。秋にひどい風邪の症状が現れ、虫に刺された所があったり発疹が出たりした場合には、直ちに病院で治療を受けたほうがよい」と話した。 疾病管理本部伝染病監視チームのパク・ヘギョン研究員は、ツツガムシ病患者が増加したことに対し、「最近、伝染病管理が強化され、患者が確実に報告されるようになった上、温暖化によりダニの活動期間が長くなったためと思われる」と話した。ツツガムシ病は、農村に住む人たちが感染することが多かったが、最近では登山などアウトドア活動が活発になったことを受け、一般の患者も増えている。 ツツガムシ病を予防するには、ダニに刺されないよう長袖の服を着たり、靴下を履くなど皮膚の露出を最大限抑えなければならない。また秋に入り野外に出る際は、草地に直接座ったり、草むらで用を足したりすることは控えなければならない。</p>				使用上の注意記載状況・ その他参考事項等
	報告企業の意見	今後の対応	<p>韓国疾病管理本部の発表によると、2002年に1,919人だったツツガムシ病の患者数が、04年は4,698人、06年には6,420人に増加したとの報告である。</p> <p>今後も情報の収集に努める。</p>		

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