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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	新医薬品等の区分	機構処理欄
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研究報告の概要

○輸血用血液製剤の病原体不活化についての欧州の見解
血液、血液成分および血漿由来製剤の安全性および有効性の向上は、現在も重要な問題である。医療技術の進歩と寿命の延長に伴い、血液需要は増加し続けている。現在、供血者の選別によって、輸血用血液製剤の安全性が確保されているが、ウイルス、細菌、寄生虫感染の残存リスクに加えて、新たなウイルスによる感染の危険が存在する。化学的、光化学的なゲノム修飾による病原体不活化は、広範囲の病原体に対応する予防的アプローチである。多くの不活化技術が利用され、血漿由来製剤の不活化に成功した。有機溶媒・界面活性剤とメチレンブルーを用いた方法はヨーロッパの多くの国で利用され、副作用の発生もなく製剤の安全性を向上させているが、赤血球と血小板製剤(PC)には適用できない。アモトサレン(Intercept)、リボフラビン(Mirasol)を用いた新しい方法は、CEマークを受けヨーロッパで導入されている。MirasolはPCおよび血漿用に開発されており、赤血球にも適用される可能性がある。血小板減少症患者を対象としたMirasol PCの第III相臨床試験の結果は、近いうちに報告される予定である。Intercept PCは、ヨーロッパの複数施設で既に15,000単位以上が輸血されている。フランスでは、レユニオン島でチクングニヤウイルスの流行時(2006年)に、またマルティニークとグアドループ-ギアナではデングおよびシャーガス病対策として導入された。アルザス(不活化のパイロット実施地域)では、Intercept PCが2006年5月に、Intercept血漿が2007年7月に導入された。2008年1月時点で、Intercept PCは22,000本以上、Intercept血漿は8,000本が輸血された。Intercept PCの臨床的止血効果は従来の未処理PCと同等(血小板量同等)であり、輸血副作用は約50%減少した。Intercept血漿は、貯留保管を経た血漿の現行適応症に対して使用され、有効性は同等であった。2007年のトロントのコンセンサス会議では、すべての輸血用血液製剤の不活化完全実施を求める声明が発表された。将来、全ての輸血用血液製剤の不活化を可能とするべきである。

報告企業の意見	今後の対応
輸血用血液製剤の病原体不活化について、ヨーロッパでは有機溶媒・界面活性剤、メチレンブルー、アモトサレン、リボフラビンなどを用いた方法が開発され、フランスのアルザス地方ではこれを導入し、3万本の使用実績が報告された。	日本赤十字社では8項目の安全対策の一つとして、不活化技術の導入について、各不活化技術の効果、血液成分への影響、製造作業への影響などについて評価検討を行っている。厚生労働省の薬事・食品衛生審議会へ不活化技術導入にかかる基本的考え方を報告したところである。

使用上の注意記載状況・その他参考事項等

合成血-LR「日赤」
照射合成血-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

JRC2008T-037

Monday: Parallel Sessions S1 – Pathogen Reduction/ Inactivation

2A-S01-01

PATHOGEN REDUCTION: AN AMERICAN VIEW

Klein H
NIH, Bethesda, MD, USA

Blood transfusion is extremely safe in the United States. The risks of known viral infections are now so low that they must be calculated from donor data rather than measured directly. Nevertheless, measures for interdicting bacterial contamination remain imperfect, a variety of known pathogens, including viruses and parasites, are not screened out of the blood supply, and the risk of emerging infections transmitted by blood remains a concern of the public, the regulatory agencies, and the medical establishment. Following the HIV epidemic of the early 1980's, the plasma fractionation industry adopted pathogen reduction technology and has improved the process continuously; no transmission of major pathogens has since been reported when proper validated plasma fraction production has been performed, and transmission of some newly recognized agents, such as West Nile virus has been prevented. The blood collection services and the regulatory agencies have remained wedded to the reactive strategy of surveillance, screening, and testing as an approach to new infectious threats. The result has been an accepted disease burden prior to introduction of screening methods and a continued loss of blood donors. Barriers to adopting pathogen reduction technology include concerns about product safety, reduced therapeutic dose, absence of a single technique to treat all blood components, recognition that no technology inactivates all pathogens, and the added cost and complexity of the inactivation process. In January 2008, the Advisory Committee on Blood Safety and Availability recommended to the US Secretary of Health and Human Services that the potential benefits of pathogen reduction warrant a commitment and concerted effort to add this technology as a broadly applicable safeguard to the nation's blood supply. Pathogen reduction was seen as a pro-active and pre-emptive strategy to address the residual risk of known agents and to prevent emerging agents from becoming transfusion risks. The Committee recognized that to achieve this goal, government, industry, blood organizations, and public stakeholders must work in concert to commit the required financial and technical resources.

2A-S01-02

EUROPEAN VIEW ABOUT PATHOGEN INACTIVATION IN LABILE BLOOD PRODUCTS

Cazenave JP
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Increased safety and efficiency of blood, blood components and drugs derived from plasma remain a major concern. Blood transfusion in Europe is tightly regulated. The demand for blood has continually increased as health care and life expectancy have increased. The safety of labile blood products [red blood cell concentrates (RBCC), platelet concentrates (PC) and plasma] is currently ensured by medical and biological donor selection measures. Nonetheless, in addition to the residual risk of viral, bacterial and parasitic infection, there is the emerging danger associated with new viruses. PI based on chemical or photochemical genomic modifications is a broad-spectrum and pro-active approach. A number of PI techniques have been use with success to inactivate plasma derived products. The solvent-detergent (SD) and the methylene blue (MB) methods are used in many countries in Europe, increasing the safety of the products and without side effects. Unfortunately, SD and PI technologies cannot be applied to RBCC and PC. New PI methods, amotosalen (Intercept, Cerus) and riboflavin (Mirasol, Gambro) have received CE marking and are being implemented in Europe. A PI process (Mirasol PRT, Gambro) is being developed for PC, plasma and possibly RBCC, using riboflavin, UV and visible light. The procedure inactivates a wide range of pathogens. Toxicity is reduced. A phase III clinical study to evaluate the efficacy and safety of Mirasol PC in thrombocytopenic patients is to be reported. Amotosalen hydrochloride and UVA (Intercept, Cerus) inactivate a broad spectrum of pathogens in PC and plasma. Intercept PC (both apheresis and buffy-coat derived) have been implemented in several centres in Europe (more than 15, 000 units transfused). In France Intercept PC have been implemented during an epidemic of Chikungunya virus in the Ile de la Réunion in 2006 and in EFS-Martinique and EFS-Guadeloupe-Guyane in 2007 (dengue and Chagas disease). EFS-Alsace, a pilot region, has introduced Intercept PI for PC (40% apheresis and 60% buffy coat derived PC, about 15 000 units/year) in May 2006 and Intercept PI for plasma (about 15 000 units/year) in July 2007. The distribution of both products is universal to patients. As of January 2008 more than 22 000 Intercept PC and 8,000 Intercept plasma have been transfused. For all patients, clinical haemostasis provided by Intercept PC is equivalent (same platelet dose) to conventional non treated PC and transfusion adverse reactions are reduced by about 50%. Intercept plasma has been used for current indications with equivalent effects as quarantine plasma. Inactivation of RBCC is a major undertaking. The use of FRALE S-303 (Cerus) is in the more advanced stage of development. In 2007, the Consensus Conference of Toronto concluded with statements that will guide the ultimate implementation of PI for all labile blood products: (1) active surveillance cannot account for the risk of an emerging transfusion-transmitted pathogen; (2) such risks require a proactive approach; (3) PI should be implemented when feasible and safe methods are available; and (4) costs and benefits should be assessed. Universal inactivation of all labile blood products should be possible in future.

2A-S01-03

A RANDOMIZED, CONTROLLED, 2-PERIOD CROSSOVER STUDY OF RECOVERY AND LIFESPAN OF RADIOLABELED AUTOLOGOUS 35-DAY-OLD RED BLOOD CELLS PREPARED WITH A MODIFIED S-303 TREATMENT FOR PATHOGEN INACTIVATION

Cancelas JA[1], Dumont L[2], Herschel L[2], Roger J[2], Rugg N[1], Garratty G[3], Arndt P[3], Propst M[4], Laurence L[4], Sundin D[4], AuBuchon J[2]
[1]*University of Cincinnati, Cincinnati, USA* [2]*Dartmouth-Hitchcock Medical Center, Lebanon, USA* [3]*American Red Cross Blood Services, Pomona, USA* [4]*Cerus Corporation, Concord, USA*

Background: The S-303 Treatment System for Red Blood Cell concentrates (RBC) developed by Cerus Corporation uses S-303, a frangible anchor-linker-effector compound, to irreversibly inactivate contaminating bacteria, viruses, protozoa, and leukocytes. Following observations of antibodies specific for S-303 treated RBCs in a Phase three trial the treatment process was modified to reduce S 303 binding to treated RBCs.
Aims: The present study was conducted to evaluate recovery/lifespan of 35-day old autologous RBCs, prepared with the modified S-303 process.
Study Design: This was a proof-of-concept, radiolabeled, crossover Phase I study conducted in 28 healthy subjects (10 male, 18 female). The study was divided into three periods: Screening and enrollment, Treatment Period 1, and Treatment Period 2. In each treatment period, subjects underwent autologous blood donation on Day 0 and infusion of double-label (51Cr/99mTc) autologous RBCs on Day 35. All whole blood units were processed into AS-3 solution, and leukocyte reduced. In random sequence, one unit (Test) from each subject was treated with the modified pathogen inactivation process (0.2 mM S-303 and 20 mM GSH) and stored at 4°C for 35 day. The other unit (Control) was prepared as conventional RBC and stored at 4°C for 35 day. Following infusion, blood samples were obtained over a 24 hour period (for single and double radio-isotope determinations of post-transfusion recovery). Additional samples were collected for 35 day post-infusion to determine lifespan. Biochemical assessments of study units (e.g. ATP, 2,3-DPG, PCV) were performed on days 0 and 35 of storage. Crossmatch reactivity to S303 treated RBC was conducted during the study using conventional gel cards.

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番号 13

医薬品
医薬部外品　　研究報告　調査報告書
化粧品

識別番号・報告回数			報告日	第一報入手日 2008 年 8 月 27 日	新医薬品等の区分 該当なし	厚生労働省処理欄
一般的名称	①乾燥抗 HBs 人免疫グロブリン ②ポリエチレングリコール処理抗 HBs 人免疫グロブリン		研究報告の公表状況	ProMED/20080826.2660	公表国 中国	
販売名 (企業名)	①ヘブスブリン（ベネシス） ②静注用ヘブスブリンーIH（ベネシス）					

研究報告の概要

中国の新しい研究が、狂犬病感染が劇的に急増していることを報告した。この報告によると、中国のいくつかの省においてヒトの狂犬病の症例数が、2000 年以降急に跳ね上がったという。
報告者らが調査したのは、中国保健省のサーベイランス・データベースから得た、1990 年 1 月から 2007 年 7 月までの 22,527 のヒト狂犬病症例のデータである。報告者らは、ヒトの狂犬病は 1990-1996 年に下火になり、このときはわずか 159 の症例が報告されただけであったが、この数字は、2006 年に 3,279 症例に跳ね上がったことを見出した。
さらに、狂犬病に遭遇する頻度が多いのは、中国の南西部および南部の省、特に人口密度の高い地域であることを見出した。
報告者の 1 人は、「狂犬病流行のこの 4 つの省では、イヌの狂犬病を排除する厳しい強制的措置が欠けているか、またはヒトへ投与する最新技術による細胞培養の狂犬病ワクチンがないのです」と述べた。報告者らによると、最も影響が大きかった広東省では、患者の 62.5%が、受けた傷への適切な治療を受けておらず、92.5%が曝露後に十分なワクチン接種を受けていなかったという。また 91.25%が抗狂犬病免疫グロブリンの投与を受けなかった。
この報告者らは、現在の狂犬病の管理プログラムを、監督を強化することによって改善し、これによって地方と政府との人的交流を改善し、狂犬病への意識を高め、都市の計画立案と開発を変更してヒトと動物とのふれ合いのバランスを図るべきであると勧告している。
（本研究は in press であり、"Rabies trend in China (1990-2007) and post-exposure prophylaxis in the Guangdong province" と題され、BMC Infectious Diseases に掲載される予定である。）

報告企業の意見	今後の対応
中国における狂犬病が 2006 年に急増したとの報告である。 血漿分画製剤からの狂犬病ウイルス伝播の事例は報告されていない。また、万一原料血漿に狂犬病ウイルスが混入したとしても、BVDをモデルウイルスとしたウイルスバリデーション試験成績から、本剤の製造工程において十分に不活化・除去されると考えている。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。

使用上の注意記載状況・その他参考事項等

代表として静注用ヘブスブリンーIH の記載を示す。
2. 重要な基本的注意
(1) 本剤の原材料となる血液については、HBs抗原、抗HCV抗体、抗HIV-1抗体、抗HIV-2抗体陰性で、かつALT（GPT）値でスクリーニングを実施している。更に、プールした試験血漿については、HIV-1、HBV及びHCVについて核酸増幅検査(NAT)を実施し、適合した血漿を本剤の製造に使用しているが、当該NATの検出限界以下のウイルスが混入している可能性が常に存在する。本剤は、以上の検査に適合した高力価の抗HBs抗体を含有する血漿を原料として、Cohnの低温エタノール分画で得た画分からポリエチレングリコール4000処理、DEAEセファデックス処理等により抗HBs人免疫グロブリンを濃縮・精製した製剤であり、ウイルス不活化・除去を目的として、製造工程において60℃、10時間の液状加熱処理及びろ過膜処理（ナノフィルトレーション）を施しているが、投与に際しては、次の点に十分注意すること。

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Subject PRO/AH/EDR> Rabies - China: increased incidence

RABIES - CHINA: INCREASED INCIDENCE
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A ProMED-mail post
<http://www.promedmail.org>
ProMED-mail is a program of the
International Society for Infectious Diseases
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Date: Fri 22 Aug 2008
Source: Science Daily [edited]
<http://www.sciencedaily.com/releases/2008/08/080820194839.htm>

A new Chinese study has reported a dramatic spike in rabies infections. The research shows that in some provinces of China the number of human rabies cases has jumped since the new millennium.

Jia-Hai Lu, from the School of Public Health at Sun Yat-Sen University, China, led a team of researchers who studied the rabies trend in China between 1990 and 2007. Lu describes how things have changed in the last 8 years: "In China, human rabies was largely under control during the years 1990-1996, via nation-wide rabies vaccination programmes. Since the end of the century, however, cases of human rabies have jumped high enough to trigger a warning sign for control and prevention."

Rabies, an infection of the nervous system transmitted by animal bites, causes over 50 000 deaths each year around the world. During recent years, most of the research on control of rabies has concentrated on the development of post-exposure prophylaxis (preventative treatment -- in this case, preventing the worsening of an infection). According to the researchers, "The use of human and equine rabies immunoglobulins (HRIG/ERIG) has saved the lives of countless patients who would have died if treated with vaccine alone. However, both products are often in short supply worldwide and are virtually unaffordable in developing countries." [See ProMED post 20080826.2659 Announcements (03): Rabies vaccine supply limited - USA (CDC)].

Data from 22 527 human rabies cases from January 1990 to July 2007 were obtained from a surveillance database from the Ministry of Health of China. The authors found that human rabies was under control from 1990 to 1996, when only 159 cases of rabies were reported, but this figure had leapt to 3279 cases in 2006.

The authors found that rabies was most frequently encountered in the southwestern and southern territories of China, especially in highly populated areas. Lu said, "The 4 rabies-endemic provinces lacked strictly enforced measures to eliminate dog rabies or an ample supply

of modern cell culture rabies vaccines for humans." Most of the patients were children or teenagers, and most contracted the disease after being bitten by a dog, usually on the head and neck. According to the authors, "In the worst-affected province, Guangdong, 62.5 percent of patients did not receive proper treatment on their wounds, 92.5 percent did not receive adequate post-exposure vaccination, and 91.25 percent did not receive any anti-rabies immunoglobulin."

The authors recommend that the current rabies control programme be improved by increasing supervision, improving the interaction between local and national authorities, increasing rabies awareness, and altering urban planning and development to balance the interaction between humans and animals.

Reference

Han Si, Zhong-Min Guo, Yuan-Tao Hao, Yu-Ge Liu, Ding-Mei Zhang, Shao-Qi Rao, and Jia-Hai Lu: Rabies trend in China (1990-2007) and post-exposure prophylaxis in the Guangdong province. BMC Infectious Diseases, (in press) [available at <http://www.biomedcentral.com/content/pdf/1471-2334-8-113.pdf>].

Adapted from materials provided by BMC Infectious Diseases (<http://www.biomedcentral.com/bmcinfectdis/>) via EurekAlert!, a service of AAAS (<http://www.eurekalert.org>).

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[It is useful to read the full article, not so much for the summary of incidence trends or methods but to fully appreciate the application of potential control mechanisms. The authors emphasize the need for improved availability and timely application of anti-rabies biologicals and the undertaking of dog vaccination programs for the control of rabies in dogs as critical elements for success in reducing the rate of occurrence of rabies in China. Such strategies have worked in other countries around the world and have even previously worked in China in the 1990s. The failure of effective dog vaccination programs in China is a step back.

CDC's (US Centers for Disease Control and Prevention) Advisory Council on the subject agrees with the importance of vaccination in dogs in the following introduction:

"As a result of improved canine vaccination programs and stray animal control, a marked decrease in domestic animal rabies cases in the United States occurred after World War II. This decline led to a substantial decrease in indigenously acquired rabies among humans. In 1946, a total of 8384 indigenous rabies cases were reported among dogs and 33 cases in humans. In 2006, a total of 79 cases of rabies were reported in domestic dogs, none of which was attributed to enzootic dog-to-dog transmission, and 3 cases were reported in

humans. The infectious sources of the 79 cases in dogs were wildlife reservoirs or dogs that were translocated from localities where canine rabies virus variants still circulate. None of the 2006 human rabies cases was acquired from indigenous domestic animals. Thus, the likelihood of human exposure to a rabid domestic animal in the United States has decreased substantially."

See "Human Rabies Prevention – United States, 2008, Recommendations of the Advisory Committee on Immunization Practices" at <http://www.cdc.gov/mmwr/pdf/rr/rr57e507.pdf>.

WHO's introduction to their section on rabies from the "WHO recommended standards and strategies for surveillance, prevention, and control of communicable diseases" includes 3 main control strategies: post-exposure prophylaxis, pre-exposure immunization in high risk groups, and control of the disease in dogs.

WHO provides further information in the introduction as follows:
"Rabies is a vaccine-preventable disease, and it is still a significant public health problem in many countries of Asia and Africa, even though safe, effective vaccines for both human and veterinary use exist. Most of the 55 000 deaths from rabies reported annually around the world occur in Asia and Africa, and most of the victims are children: 30–50 percent of the reported cases of rabies — and therefore deaths — occur in children under 15 years of age. The main route of transmission is the bite of rabid dogs. Most of the children who die from rabies were not treated or did not receive adequate post-exposure treatment. Although the efficacy and safety of modern cell culture vaccines have been recognized, some Asian countries still produce and use nervous tissue vaccines, which are less effective, require repeated visits to the hospital, and often have severe side-effects. Moreover, these patients do not receive the necessary rabies immunoglobulin, because of a perennial global shortage and because of its high price, so that it is unaffordable in countries where canine rabies is endemic.

"Due to complete absence of any successful medical treatment for clinical rabies and the horrific nature of the disease, most rabies victims die at home rather than being admitted to a hospital in abysmal conditions. These circumstances add to the notorious lack of surveillance data. Underestimating the health implications of rabies leads many high ranking decision-makers in public health and animal health to perceive rabies as a rare disease of humans resulting from a bite of an economically unimportant animal (the dog). Therefore, rabies usually falls between 2 stools and is not dealt with appropriately either by the Ministry of Health or the Ministry of Agriculture."
See "Human and Animal Rabies" at <http://www.who.int/rabies/en/>. – Mod.PC]

[see also:
Rabies, canine – China: compulsory vaccination 20080120.0254
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Rabies, human, canine – China (02) 20070725.2390