別紙様式第2-1

No. 34

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
				2005. 9. 26	該当なし	

一般的名称	人全血液	研究報告の公表状況	藤巻克通, 宮崎拓也, 小原澤英之, 山路聡, 池田多聞, 斎藤聡, 金森平和, 石ヶ坪良明. 第67回日本血液学会総会・第47回日本臨床血液学会総会; 2005 Sep 17-19; 横浜.	公表国
販売名(企業名)	人全血液CPD「日赤」(日本赤十字社) 照射人全血液CPD「日赤」(日本赤十字社)			日本

研究報告の概要

○HBs抗体陽性患者における同種造血幹細胞移植後のHBウイルスのreactivation

【目的】HBsAg陰性でHBsAb陽性の場合、HBの既感染として同種造血幹細胞移植患者では特別な配慮は不要とされている。しかし、最近、上記の患者において移植1年程度経過してからHBウイルスのreactivationを来たし、死亡に至る症例の報告もある。最近5年間で6例のHBsAg陰性でHBsAb陽性患者の移植を施行しているがそのうち1例が移植後15ヶ月で劇症B型肝炎を発症したので報告する。

【対象】2000年1月から2004年12月までに同種造血幹細胞移植を受けた72症例のうち、移植前HBsAg陰性でHBsAb陽性患者6例。

【結果】男性4例、女性2例。年齢中央値57歳(33-62歳)。原疾患はAML4例、MDS1例、CML1例。移植前処置は骨髄破壊的前処置2例、骨髄非破壊的前処置4例。6例とも移植前HBsAg陰性、HBsAb陽性。HBcAbは5例で陽性、1例で陰性。このうち、56歳男性でMDSに対して骨髄破壊的前処置を施行し、慢性GVHDに対してPSL10mg、tacrolimus1mg使用中の患者で移植15ヶ月にHBsAg陽性劇症B型肝炎を発症した。血漿交換療法等施行するも肝不全で死亡した。

【考察】移植前HBsAg陰性でHBsAb陽性患者に同種造血幹細胞移植を施行する場合、prospectiveにHBウイルスをモニタリングする必要があると考えられる。

報告企業の意見	今後の対応
HBsAg陰性でHBsAb陽性患者が、同種造血幹細胞移植後15ヶ月で劇症B型肝炎を発症したとの報告である。輸血後HBV感染症の調査には、免疫状態の変化による再活性化など輸血以外の要因について考慮する必要がある。	HBV感染の新たな伝播ルート等について、今後も情報の収集に努める。

使用上の注意記載状況・その他参考事項等

人全血液CPD「日赤」
照射人全血液CPD「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

WS-4-4　化学療法および造血細胞移植療法実施後にB型肝炎ウイルスの再活性化を生じた、HBs抗原陰性症例の検討
HB virus reactivation in HBs antigen-negative patients after chemotherapy and HSCT

○広瀬　貴之、今井　洋介、石黒　卓朗、張　高明（新潟県立がんセンター 内科）
TAKAYUKI HIROSE, YOUSUKE IMAI, TAKUROU ISHIGURO, TAKAAKI CHOU

当科において、化学療法および造血細胞移植療法実施後に、重篤なB型肝炎を生じた症例を複数例経験した。いずれの症例も治療前のHBs抗原は陰性であり、治療経過中に投与された輸血製剤を介した感染や院内感染による伝播は否定的であった。これらの症例の中にはHBs抗体およびHBc抗体の陽性者が存在することが判明しており、免疫状態の変動にともないB型肝炎ウイルス(HBV)の再活性化が生じたことが推察される。肝移植においては、HBc抗体陽性のドナーから移植を受けたレシピエントでは高率にHBVの感染が成立することが以前から知られている。つまりHBc抗体陽性のHBV既往感染例からはHBV遺伝子が完全に排除されておらず、微量の増殖が続いているもののHBs抗体の存在によって沈静化が維持されている状態であり、宿主の免疫状態によっては再燃しうると考えられる。以上をふまえ、当科では治療開始前に可能な症例においてHBs抗原、HBs抗体、HBc抗体を測定し、HBc抗体が高力価陽性(10.0 S/CO以上)の症例には抗ウイルス薬(Lamivudine)を化学療法開始当初から併用する方針を検討しており、文献的考察も含め報告を行う。

別紙様式第2-1

No. 25

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
				2005. 10. 14	該当なし	

一般的名称	人全血液	研究報告の公表状況	CDC. Available from: URL: http://www.cdc.gov/ncidod/dvbid/westnile/qa/transfusion.htm	公表国
販売名(企業名)	人全血液CPD「日赤」(日本赤十字社) 照射人全血液CPD「日赤」(日本赤十字社)			米国

研究報告の概要

○ウエストナイルウイルスQ&A、輸血・臓器提供・供血時のスクリーニングについて
Q. (5番目)供血時のNATによって輸血による感染のリスクは大幅に下がったが、臓器移植時の検査はどう違うのか？
A. (a)時間、(b)検査の種類、(c)潜在的な生物学的相違を考慮しなければならない。
(a)時間は臓器提供において最も重要な要素である。
(b)NATは臓器提供においては未だに有効性が立証されていない。
(c)IgM抗体陽性の場合はWNVは輸血によって感染しないことがわかっており、輸血による感染が成立した例はすべて低力価のウイルス血症でIgM抗体は陰性だった。今回の臓器移植による感染例(文献番号:JRC2005T-105で報告)は、固形臓器の移植による感染はIgM、IgG陽性でNAT陰性の場合も起こる可能性があることを示唆している。ヒトおよび動物の実験的データでは、ウイルス血症の消失後(つまり、血中にウイルスが存在しない)もWNVが臓器に残存する可能性があることを示唆している。このことから、供血血液に行っているNAT以外の新たな検査が必要になるようなシナリオが考えられるだろう。

報告企業の意見	今後の対応
固形臓器の移植においては、ウエストナイルウイルス感染はIgM、IgG陽性でNAT陰性の場合も起こる可能性があるとの報告である。	輸血によるWNV感染リスクを防止するため、国の指示(平成16年7月13日付薬食発第0713008 号「ウエストナイルウイルス等の輸入感染症対策に係る採血禁止期間の変更について」)により帰国(入国)後4週間の供血を禁止している。また、WNV感染の発生に備え、平成17年10月25日付血液対策課発事務連絡に基づき、緊急対応の準備を進めている。

使用上の注意記載状況・その他参考事項等

人全血液CPD「日赤」
照射人全血液CPD「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

(2)

MedDRA/J Ver.8.1J

West Nile Virus Basics
·Avoid Mosquito Bites
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PDF (254 KB/77 pages)

Esta página en Español

West Nile Virus Home > FAQ Index > Blood Transfusions and Organ Donations

New! West Nile Virus Infections in Organ Transplant Recipients --- New York and Pennsylvania, August--September, 2005.

Questions and Answers

Please use the menu below to jump to a topic:

West Nile Virus Topics: go

Blood Transfusion, Organ Donation and Blood Donation Screening Information

NEW! Questions related to West Nile Virus Infections in Organ Transplant Recipients --- New York and Pennsylvania, August--September, 2005. MMWR Dispatch, October 5, 2005

Q. How were these cases identified?
A. After unexplained neurological illnesses resulted in two organ recipients from one donor, serum and plasma collected from the donor were retrieved and tested. The samples tested positive for WNV IgM and IgG antibodies, but were negative for WNV RNA by PCR.

Q: How was the organ donor infected?
A. It is likely that the organ donor was infected by the bite of an infected mosquito, as he was reported to have spent time outdoors and infected mosquitoes were collected from a site near the person' s home approximately 10 days before he died.

Q. What is the current protocol for testing donor or organs before a transplant is conducted?
A. Organ donors are screened to identify infectious risks on the basis of national organ-procurement standards. Screening of all organ donors with WNV NAT is not currently required or routinely performed for several reasons: 1) NAT is only available through an "Investigational New Drug" applications for blood screening at this time; 2) the length of turnaround time to obtain WNV NAT testing, and 3) the unproven test performance in the organ-donation setting. National guidelines for organ-donor screening are continuously reevaluated by the Health Resources and Services Administration in consultation with FDA, CDC, and organ-procurement organizations.

Q. Which agencies regulate transplant and blood issues?
A. The US Health Resources and Services Administration (HRSA) and Centers for Medicare and Medicaid Services (CMS) have oversight over organ procurement and transplantation, while the Food and Drug Administration (FDA) regulates tissue and blood.

Q. You have stated that the system of testing donated blood for WNV by nucleic acid-amplification test (NAT) has markedly reduced the risk of transfusion transmission. How is the testing of organs before transplantation different?
A. There are several issues to consider: (a) time, (b) type of test and (c) potential biological differences.

(a) Time is a critical factor in organ donation; one analysis suggested that WNV NAT screening might result in a net loss of years of life among certain types of potential transplant recipients because screening might exclude healthy donors from an already limited donor pool. The time pressure to test and process donated blood is not as extreme.

(b) Additionally, NAT has not yet been proven as an effective test in the organ-donation setting—it is not known at this time that it would prove as useful as it has in identifying blood donations that pose a risk.

(c) It has been learned through limited retrospective studies that transfused viremic donations di not transmit WNV infection if IgM antibody was present, and investigation of all 30 cases of WNV

transmitted by blood transfusion documented to date indicated that the donors' viremias can be of low titer and that all resulted from IgM antibody-negative donations. This instance of organ-transplant-associated WNV transmission suggests that transmission through solid organ transplantation can occur from donors with IgM and IgG antibodies and without detectable nucleic acid by PCR in their serum. Experimental evidence in humans and animals suggests that WNV might persist in organs after clearance of viremia (e.g.., when virus is no longer circulating in the bloodstream.) This would present a different scenario, requiring different testing, than the case of NAT testing of donated blood.

Q. Is there testing available that would have been able to identify the risk of WNV infection before the organs were transplanted?
A. It is currently unknown whether NAT would have detected West Nile virus in this donor.

Q. What will be done to follow up these cases, and to reduce the risk of WNV infection through transplanted organs in the future?
A. Clinicians should be aware that transplant-associated infectious disease transmission can occur and should be vigilant for unexpected outcomes in transplant recipients, particularly when they occur in clusters.

Cases of suspected WNV infection through organ transplant should be reported promptly to local and state health departments and CDC.

We will continue the evaluation of the blood donor to the organ donor to look for evidence of WNV infection, and the evaluation of the organ donor serum. When done with our investigation, HRSA, CMS, FDA, CDC, state and city authorities and organ procurement organizations will be working together closely to see if evidence in these cases might be used to develop protocols to reduce risks of WNV infection associated with transplanted organs.

Q. What type of treatment is being given to the organ recipients? Is that treatment available to other people with WNV disease?
A. The organ recipients were treated with Omr-IgG-am, an intravenous immunoglobulin product with high-titered neutralizing antibody to WNV available through a Food and Drug Administration (FDA)-approved IND compassionate release protocol. No proven effective treatment or prophylaxis for WNV infection exists; a randomized placebo-controlled, double-blind trial of Omr-IgG-am is underway, and more information on participation can be obtained at http://www.clinicaltrials.gov/show/NCT00068055

Information on other randomized placebo-controlled, double-blind trials for WNV infection is also available at http://www.cdc.gov/ncidod/dvbid/westnile/clinicalTrials.htm

Guidance related to donated organs, and the use of screening and diagnostic tests for West Nile virus was issued January 9, 2004 and is posted on the website of the Organ Procurement and Transplantation Network.

Publications concerning WNV and blood donations/transfusion-associated cases:

- Transfusion Complications PDF (70KB/5 pages), West Nile Virus blood transfusion-related infection despite nucleic acid testing, December 2004.
- West Nile Virus Screening of Blood Donations and Transfusion-Associated Transmission, MMWR Dispatch April 9, 2004.
- Detection of West Nile Virus in Blood Donations---United States, 2003, MMWR Dispatch September 18, 2003.

For General Information about Screening of Blood Donations for WNV, click here.

General Information on Screening of Blood Donations for WNV

Q. What is being done to reduce the risk of transfusion-related West Nile virus transmission?
A.All blood banks in the United States have been screening blood donors and donations for West Nile virus since 2003.

State and local public health departments report cases of West Nile virus infection in patients who have received blood transfusions during the 4 weeks before they got sick to the blood collection agency that collected the donation. Health departments also report this information to CDC through ArboNET, the national database where information about cases of West Nile virus is kept.

In addition, cases of West Nile virus infection in people who donated blood in the 2 weeks preceding illness onset should also be reported to CDC and blood collection agencies where the sick person donated blood. The blood collection agencies destroy potentially infectious units of blood.

Q. How does the blood screening test protect people from WNV?
A. The blood screening methods allow blood banks to destroy potentially infectious blood before it is given to anyone.

In addition, public health departments and blood banks cooperate to identify and destroy blood products (if necessary) from donors who develop a West Nile viral illness after they give blood. If someone becomes ill after a transfusion, blood banks destroy the blood products taken from the donor of the transfused blood. Prompt reporting of these cases helps facilitate withdrawal of potentially infected blood components.

Q. Should people avoid donating blood?
A. No. There is no risk of of being infected by West Nile virus through giving blood. Blood saves lives and is always needed, especially during the summer months. Because donating blood is safe, we encourage blood donation now and in the future. We also encourage all donors to truthfully answer the questions asked by the blood bank to make sure they are fit to donate on a given day.

Q. Should people avoid getting blood transfusions or organ transplants?
A. No. About 4.5 million people receive blood or blood products annually. The benefits of receiving needed transfusions or transplants outweigh the potential risk for West Nile virus infection. However, doctors and their patients who need blood transfusions or organ transplants should be aware of the risk for West Nile virus infection.

Q. If a person had a West Nile virus infection in the past, can they still donate blood?
A. Yes. West Nile virus infections do not last very long. The virus is in the blood for a very short time. People fight the virus and usually get rid of it in a few days. To get rid of the virus, they develop antibodies against it. Antibodies keep people from getting a West Nile virus infection again.

People who have been diagnosed with West Nile virus confirmed by positive laboratory testing should not be allowed to donate blood for 120 days from the start of their symptoms or their laboratory diagnosis, whichever is later. If there are no symptoms to suggest a West Nile virus illness, a positive West Nile virus antibody test result alone should not be grounds for refusing a blood donation.

Q. If I recently had a transfusion or transplant, should I be concerned about getting West Nile virus?
A. You should be aware of the potential risk for West Nile virus infection and the need to monitor your health. If you have symptoms of West Nile virus or other concerns you should contact your physician. If a patient who recently received a blood transfusion or organ transplantation develops a West Nile virus infection, that does not necessarily mean that the transfusion/transplantation was the source of infection.

Q. How can a person test positive for WNV infection at a blood bank, but not be considered a "case" by CDC?
A. A WNV "case" is a person who has become ill and been confirmed to have WNV infection. This infection might be either West Nile Fever, a mild illness with fever, or West Nile encephalitis or meningitis, more severe illnesses. Blood donors who do not become ill and do not develop symptoms are counted in a separate category because they are not considered "cases."

For more information on human cases, disease surveillance, and a map of cases, go to http://www.cdc.gov/ncidod/dvbid/westnile/surv&control.htm.

Q. What happens to the blood collected from donors that test positive for WNV?
A. When a unit of blood is identified as possibly infected with WNV by initial screening, it is removed from the blood supply. If the confirmation process reveals that the unit is NOT actually infected, the remaining blood products may be used.

Q. Is there enough blood to meet the needs of hospitals?
A. Although there is always an increased demand for blood products during summer months, only a relatively few units of blood will be removed from the blood supply.

Blood donations usually decrease in summer. Despite the recently identified problems with

receiving infectious blood, it is still safe to donate blood. CDC encourages people who can donate to consider making a donation during summer months to help ensure adequate blood supplies for all who need them.

Q. If someone who is donating blood at the same time that I do tests positive for WNV, can I catch it from them?
A. No. WNV is generally transmitted through the bite of an infected mosquito. You cannot get infected with WNV from contact with an infected person. For more information, see the Transmission page.

Q. If a blood bank does not use my blood because it tests positive for WNV, does this mean I'm going to get sick?
A. Probably not. What this means is that you have WNV in your blood, so you have been recently bitten by an infected mosquito. Most infected people do not become ill at all and only a very small number develop West Nile fever or more serious disease. It is thought that you will have immunity from WNV for a long period after becoming infected, possibly for life. For more information, visit the Transmission page.

Q. Will the blood bank notify me if my blood tests positive for WNV?
A. Blood banks will contact donors who may have a WNV infection. A subsequent blood sample will be requested in order to help confirm the infection. We thank you in advance for your cooperation in protecting the national blood supply, and helping to validate the tests that are being used.

Q. What do I need to do if my blood tests positive for WNV?
A. If you learn from a blood bank that your blood was likely infected with WNV you may be requested to give another blood sample to help confirm the infection.

Most WNV infections do not cause any symptoms, and do not require any medical attention. There is nothing in particular that you need to do because of the infection. It is also likely that you have antibodies to prevent you from getting sick with WNV in the future. If you were infected with WNV, this does tell you that there is a risk of infection in your area, and it is important for the rest of your family to protect themselves from mosquito bites.

Of course if you do feel ill you should consult your health care provider.

Q. What kind of test is used to test donated blood?
A. During the 2002 WNV epidemic, the blood-banking industry, FDA, and CDC worked together closely to identify WNV transmission to humans through blood transfusion and organ donation. These screening tests identify whether West Nile virus is present in the blood. The tests being used for the blood supply are still being validated by all the agencies involved.
If the test is positive, the blood from this donation is removed from the blood supply. To validate these new tests, further testing is done. In some cases, the screening test result may be a "false positive", and blood banks are taking a cautious approach to avoid future WNV transmission by transfusion. For more information, consult the FDA WNV Web page at http://www.fda.gov/oc/opacom/hottopics/westnile.html.
These blood-screening tests are different than the already validated tests that are used to diagnose WNV infections among ill people who are not donors. Among people who are not donors, we use tests that identify antibodies (proteins in the blood that help fight infection) that are produced by the body in response to a WNV infection.

Q. Can I get tested for WNV at my doctor's office with the blood test that blood banks are using?
A. No. The tests being used at blood banks are new and not licensed by the FDA for routine screening purposes. These tests are being used only at blood banks. If your health care provider suspects you may have WNV illness he/she can send a sample of your blood to a private laboratory or to the state health department for testing for antibodies.

Q. Are all U.S. blood centers testing the blood they collect for WNV?
A. Yes. Screening is going on in every U.S. civilian blood center, including Alaska and Hawaii and Puerto Rico.

Guidance related to donated organs, and the use of screening and diagnostic tests for West Nile virus was issued January 9, 2004 and is posted on the website of the Organ Procurement and Transplantation Network.

The most recent information on West Nile Virus Screening of Blood Donations and Transfusion-Associated Transmission is found in the update of the MMWR Dispatch Apri

9, 2004.

Also, **Detection of West Nile Virus in Blood Donations -- United States, 2003** is found in the MMWR Dispatch September 18, 2003.

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別紙様式第2-1

No. 26

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
				2005. 10. 3	該当なし	

一般的名称	人全血液	研究報告の公表状況	ProMED. 20050928-0040, 2005 Sep. 27. 情報源:[1]Weekly Epidemiological Bulletin, (37th Epidemiological Week, 11-17 Sep 2005), 2005 Sep 17. [2]Yahoo News, Singapore, 2005 Sep 26. [3]CNN News, Atlanta, US, 2005 Sep 27. [4]INQ7 Net News, Malaysia, 2005 Sep 26.	公表国 [1]ベネズエラ [2]シンガポール [3]マルチニーク島 [4]マレーシア
販売名(企業名)	人全血液CPD「日赤」(日本赤十字社) 照射人全血液CPD「日赤」(日本赤十字社)			

研究報告の概要

○デング熱/デング出血熱最新状況、2005年

・ベネズエラでは、9月11日～17日の間にデング熱患者1282名が診断され、内72名がデング出血熱だった(5.6%)。デング熱/出血熱比は17対1だった。死亡患者は発生しなかった。前週の統計に比べ患者数は4.8%減少したが、患者数も流行レベルに相当する。2005年の患者数累計は27820名で、前年同時期に比べ23.3%増加し、内6.1%が出血熱だった(1694名)。デング熱/出血熱比は15対1だった。累積の罹患率は人口10万人当たり104.7例となる。1,2,3および4型ウイルスが感染循環している。報告された全患者のうち15歳未満が51.8%を占め、次いで15歳～24歳が20.9%となっている。

・シンガポール保健省は、同国史上最悪のデング熱流行による死亡患者数は11例に増加し、患者総数も11000例に迫ると発表した。当局は媒介蚊発生源撲滅キャンペーンを行っているが、9月26日には週当たりの新規患者数が過去最多を記録した。

・カリブ海のフランス領マルチニーク島当局は9月26日、デング熱/出血熱により2名が死亡し、これまでに6000名以上が感染したと発表した。同島の医師は、9月中旬以来新規患者の発生が週当たり約1000名に増加したと指摘した。60名以上が入院したが、そのうちの3名は重症のデング出血熱であった。同島の北にあるフランス領グアドループでも、8月初旬以来患者700名が報告され、毎週新規患者約100名が発生している。感染の拡大を防止するため、当局は水溜まりの撲滅キャンペーンを強化している。

・マレーシアでは、9月26日、双子を妊娠した女性がデング熱で死亡した。この患者は、今年Penan州で3例目、全国では70例目の死亡患者に当たる。南部のNegeri Sembilan州では、これまでに住民5人がデング熱のため死亡し、先週患者42名以上が確認されたが、これは前の週に比べて2倍増である。

報告企業の意見	今後の対応
ベネズエラ、シンガポール、マルチニーク島、マレーシアでデング熱が流行しているとの報告である。	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。問診でデング熱の既往があった場合には、治癒後1ヶ月間献血不可としている。今後も引き続き情報の収集に努める。

使用上の注意記載状況・その他参考事項等

人全血液CPD「日赤」
照射人全血液CPD「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