医薬品 研究報告 調査報告書

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研究報告の概要

○輸血を介したバベシア症の伝播:FDAに届けられた最近の死亡報告

背景:バベシア症は輸血を介した伝播リスクが知られているが、認可されたスクリーニング法は存在しない。本試験は、FDAに報告されたバベシア関連輸血事象の重症度と特徴について、最近の輸血関連バベシア症死亡報告と生物学的製品逸脱報告サマリー(BPDRs)に焦点を当て検討した。

方法:過去10年間にFDAに報告された3つのFDA調査システム(採血および輸血死亡報告、MedWatchプログラム、BPDRs)のデータを収集した。

結果:輸血感染バベシア症死亡報告は1998年の1例以降しばらく無かったが、2006年1月～10月にはFDAに5例が報告された。受血者は関連血液製剤の輸血から4～7週間後に発症し、全員が*Babesia microti*に感染していた。過去10年間のバベシア症関連のBPDRsは68件であり、近年この報告が増加傾向にあることは、当該寄生虫による輸血関連リスクが増加していることを示している。

結論:最近の死亡報告は、増加中のBPDRsと合わせて、稀な輸血後合併症であるバベシア症のリスク増大を明らかにした。発熱を呈した受血者にはバベシア症の可能性があることを医師が認識することにより、効果的治療のための迅速な診断を容易にし、また、残存する血液製剤を差止める検査の実施が促進されると考える。バベシア症供血者および輸血関連事象の報告は、FDAによるリスク範囲の評価、公衆衛生上の感染制御対策の一助となる。

報告企業の意見	今後の対応
FDAに報告されたバベシア関連輸血事象の重症度と特徴について、最近の輸血関連バベシア症死亡報告と生物学的製品逸脱報告サマリーに焦点を当て検討した結果、近年、当該寄生虫による輸血関連リスクが増加していることを示しているとの報告である。	今後も引き続き、新興・再興感染症の発生状況等に関する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

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

SP246

Quantitative Real-time PCR Assay for *Trypanosoma cruzi*

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Background: *Trypanosoma cruzi* infects about 18 million people, and results in 50,000 deaths from Chagas disease annually, primarily in Latin America. Latin American blood donors in the US may harbor chronic *T. cruzi* infection and be potential reservoir of *T. cruzi* transmission by blood transfusion. US blood centers began donor screening for *T. cruzi* antibody (Ab) in early 2007 and have identified hundreds of seropos blood donors. Our objective was to develop a sensitive assay for *T. cruzi* parasite detection and quantitation in whole blood (WB) samples from seropos donors. The assay is also needed for studies of *T. cruzi* transfusion-transmission and disease pathogenesis. **Methods:** Trypomastigotes of *T. cruzi*, grown in culture, were harvested, counted, and spiked into fresh WB to create samples containing 8, 4, 2, and 1 parasite/20 mL WB. Lysis of parasites was performed by adding 20 mL of Guanidium-EDTA lysis buffer (6M Guanidine HCl with 0.2M EDTA, pH8.0) to 20 mL WB and vortexing. The lysed WB was heated at 100C for 15 mins to disentangle minicircle kinetoplast DNA present at ~10,000 copies/parasite. Total DNA was prepared from 0.4 mL of the lysate by precipitating hemoglobin and inhibitors: Parasitic DNA was captured by *T. cruzi* specific oligonucleotide probes bound to magnetic beads. After being eluted from the beads, parasite DNA was amplified by real-time (RT)-PCR with SyBr green dye & an optimized buffer system using a *T. cruzi* kinetoplast DNA specific primer pair (Tc-121/Tc-S36). **Results:** Table summarizes RT-PCR results for 5 replicate amplifications of the spiked dilution series. A single parasite in 20 mL WB gave strong signal (~10 cycles below 45-cycle cutoff) & good precision quantitation of up to 8 parasites. We tested 27 coded specimens from *T. cruzi* Ab-reactive donors: 2/7 RIPA(+) and 0/20 RIPA(–) donors tested PCR(+); the 2 pos donors had ~1 parasite/20 mL WB. **Conclusion:** We can detect single *T. cruzi* parasites in 20 mL WB with this sensitive quantitative RT-PCR assay. Additional *T. cruzi* seropos donor blood samples from the US, Argentina, Honduras & Brazil are being collected for analysis.

	# of *T. cruzi* Spiked into 20 mL Whole Blood				
n = 5	8	4	2	1	0
Mean Cp (±STD)	31.4 (±0.5)	32.64 (±0.1)	33.48 (±.01)	15.18 (±–0.0)	>45

A one unit change in Cp in a real-time PCR assay is expected to equate to an ~ doubling of parasite load. Our assay performs as expected in the range of 1-8 parasites.

Disclosure of Conflict of Interest

Tzong-Hae Lee, Ester Sabino, Lani Montalvo, Li Wen, Daniel Chafets, Brian Custer, Michael P. Busch, for the Retrovirus Epidemiology Donor Studies-II (REDS-II): Nothing to Disclose

SP247

Screening for *Trypanosoma cruzi* in the Blood Donor Setting

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Background: Our blood donor center recently began testing for antibodies to the agent that causes Chagas' Disease (*Trypanosoma cruzi*). We reviewed incidence among our current blood donor population and all look-back cases to determine if there were any reports of transfusion-transmitted *Trypanosoma cruzi*. **Methods:** At our center all allogeneic and autologous donations were tested for antibodies to *T. cruzi* using a US Food and Drug Administration licensed enzyme immunoassay (EIA) methodology. Those donations that were repeat reactive (RR) on EIA were sent for an unlicensed confirmatory radioimmunoprecipitation assay (RIPA). In accordance with AABB Association Bulletin 06-08 donors RR on EIA were indefinitely deferred and notified of results. Look-back was performed on those donors who tested RIPA positive and included all electronic donor records available. **Results:** From 7/30/07-3/15/08 222,059 donations (212,505 whole blood, 7,520 autologous, 2,034 directed and of which 51,298 were first-time donors) were tested by EIA for anti-*T. cruzi*. 16/222,059 (0.007%) donations were EIA RR donations. Confirmatory RIPA results were as follows: 7/16 (43.75%) or 7/222,059 (0.003%) were positive and 9/16 (56.25%) were negative. 2/7 (28.6%) or 2/51,298 (0.004%) RIPA positive results were from first-time donors. Look-back was performed on the 5 RIPA positive repeat donors and involved 75 transfusable blood components (70 were transfused, 2 discarded and 3 no information was provided). There were no reports of recipients of the 70 transfused blood components testing reactive for antibodies to *T. cruzi*. **Conclusions:** At our blood center, the introduction of testing for *T. cruzi* prevented transfusion of a small number of units that confirmed positive for the presence of antibodies. Look-back revealed no reports of transfusion-transmission of *T. cruzi* from previously donated untested units.

Disclosure of Conflict of Interest

Richard Gammon, Michael Pratt: Nothing to Disclose

TTID 2: Tideborne Disease, CJD

SP248

A Fatal Case of Transfusion-Transmitted Babesiosis in the State of Delaware

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Background: Babesiosis is an emerging zoonotic disease caused by intraerythrocytic protozoa. Although the disease is usually transmitted by tick bite, there has been an increase in the number of transfusion-transmitted cases reported. This report describes a fatal case of transfusion-transmitted babesiosis in Delaware. **Case Report:** The patient was a 43-year-old Caucasian woman with history of transfusion-dependent Diamond-Blackfan Syndrome, hepatitis C, pulmonary hypertension and splenectomy. She had been receiving two units of RBCs every 2 weeks. She presented on 1/9/08 with fever, chills, cough and fatigue, and was treated with antibiotics initially for presumptive pneumonia. Examination of the peripheral blood smears revealed numerous intraerythrocytic ring forms, consistent with Babesia. The diagnosis of babesiosis was confirmed by positive polymerase chain reaction (PCR) for B. microti DNA and high titer of antibody to B. microti (1:2048). Despite aggressive therapy including Clindamycin and Quinine, the patient's condition rapidly deteriorated with multi-system organ failure and she expired 3 days after admission. The patient resided in Delaware and had no history of tick bites or recent travel history outside Delaware. Thirteen implicated donors were subsequently tested for B. microti. All tested donors were negative by PCR for B. microti. However, one of them had a significantly elevated B. microti antibody titer (1:1024). This donor resides in New Jersey and had recently traveled to Rhode Island. The donor has no known history of tick bites or flu-like symptoms within the past 2 years. The donor has not been diagnosed with Babesiosis, Lyme's disease or Ehrlichiosis, and has never received a blood transfusion. The implicated unit was donated on 8/8/07, frozen, and transfused as a deglycerolized unit on 11/27/07, 6 weeks prior to development of the patient's symptoms. **Conclusion:** This case emphasizes the need to review peripheral blood smears in febrile, immunocompromised patients who have been recently transfused. Prompt recognition and treatment are important, as Babesia infections can be severe or fatal in splenectomized and/or immunocompromised patients. It also illustrates the need for better strategies, including more sensitive, specific and rapid screening tests, to prevent transfusion-transmitted babesiosis.

Disclosure of Conflict of Interest

Yong Zhao, Ken Love, Scott Hall, Frank Beardell: Nothing to Disclose

SP249

Babesiosis Transmission through Blood Transfusion: Recent Fatality Reports Received by FDA

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Background: Babesiosis is a known transfusion-transmitted disease risk, with no licensed donor screening assay. There are estimates that 70 transfusion-transmitted cases have occurred from 1979 through 2007. This research evaluated the magnitude and characteristics of Babesia-related transfusion events reported to the Food and Drug Administration (FDA) with focus on the recent transfusion-related babesiosis fatality reports and a

summary of Biological Product Deviation Reports (BPDRs) submitted to the FDA. **Methods:** Data were collected by querying three FDA surveillance systems for reports received within the past decade: Blood Collection and Transfusion Fatality Reporting, the MedWatch. Program, and BPDRs. **Results:** Between January and October 2006, the FDA received five transfusion-related babesiosis fatality reports after only one prior report in 1998. Recipients presented with symptoms 4 to 7 weeks after transfusion of implicated blood units, and all were infected with Babesia microti. No MedWatch report was received; however 68 Babesia-related BPDRs over the past decade, with increasing numbers in more recent years, suggest a rising risk for transfusion-transmission from this parasite. **Conclusions:** The recent fatality reports, along with growing numbers of BPDRs, underscore babesiosis as a rare post-transfusion complication whose risk may be increasing. Enhanced clinician awareness of the possibility of babesiosis in febrile transfusion recipients may facilitate prompt diagnosis with more effective treatment and timely investigations to interdict extant infected units. Reporting of babesiosis donor and transfusion-related events assists the FDA in assessing the scope of the risk and developing appropriate public health control measures. Disclaimer: The findings and conclusions in this abstract have not been formally disseminated by the Food and Drug Administration and should not be construed to represent any Agency determination or policy.

Disclosure of Conflict of Interest

Diane Gubernot, Charles Lucey, Karen Lee, Gilliam Conley, Leslie Holness, Robert Wise: Nothing to Disclose

SP250

Evaluation of Candidate Reentry Proposals for *Babesia microti* Infection

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Background: B. microti (Bm) is a tick-borne rbc parasite which can be transmitted by transfusion from chronically infected donors. Implication in transfusion babesiosis (TB) or clinical babesiosis (CB) requires permanent donor deferral. As part of a multi-year longitudinal research study in New England, Bm seropositive blood donors are deferred despite apparent clearance of infection in many cases. We evaluated several candidate donor reentry proposals (Schemes) that also may be applicable to donors with CB or implicated in TB. **Methods:** Consenting blood donors were screened by IFA for Bm (positive ≥1:64) using retention tubes (index sample). Consenting positive donors agreed to provide subsequent samples at 1-2 month intervals which were screened by IFA and nested- or RT-PCR. 18 donors were released from study before 1 year after 3 consecutive negative bleeds. 45 donors dropped out and could not be evaluated. Study data were used to evaluate 4 potential reentry Schemes based on the initial PCR result (<12 week after the initial IFA) and on the first IFA and PCR result ≥11 months following the index sample (Table 1). Reentry failure was defined as a PCR positive samples following successful reentry. **Results:** 76/139 donors completed 1 year or more of follow-up and were eligible for assessment using the four candidate reentry Schemes (Table 2). All 43 eligible donors with IFA titers ≤1:128 after the index sample could be reentered. Only 21/33 (64%) donors with 1 or more IFA titers >1:128 after the index sample could be reentered. Requiring all IFA titers to be ≤1:128 would eliminate only 1/3 Scheme failures, but would require multiple donor samples. Requiring 2 rather than 1 year wait after the seropositive screen would eliminate the observed Scheme failures in all cases. However, this could not be fully assessed because of limited follow-up. **Conclusion:** Reentry for Bm is feasible using approaches similar to other TTD markers. Evaluated Schemes could reenter a significant portion of donors; however, there was a small, but unacceptable failure rate. In addition, 18 donors released from the study before a year could also be considered for reentry, but there was no follow-up to assess this approach. Sampling beyond 1 year may be required to develop an acceptable reentry Scheme. Such a Scheme could be useful for donor management if Bm screening is implemented, and could allow reentry of donors implicated in TB or recovered CB.

TABLE 1. Reentry schemes

#	Initial IFA	Initial PCR	IFA 1 Year	PCR 1 Year	Other PCR
1a	≥1:64	Neg	≤1:128	Neg	All Neg
1b	≥1:64	Neg	≤1:128	Neg	Any
2a	≥1:64	Pos or NA	≤1:128	Neg	All Neg
2b	≥1:64	Pos or NA	≤1:128	Neg	Any

TABLE 2. Evaluation of reentry schemes

Reentry scheme	1a	1b	2a	2b
Eligible initially	116	116	139	139
Followed 1 year	55	55	76	76
Reentered	42	47	55	64
% reentered	76%	85%	72%	84%
Scheme failures*	2	3	2	3

* PCR positive samples following successful reentry

Disclosure of Conflict of Interest

Ritchard Cable, Stephanie Johnson, Laura Tonnetti: Nothing to Disclose
David Leiby: Not Specified

SP251

Seasonal and Geographic Distribution of *Babesia microti* Seroprevalence in Connecticut Blood Donors: 2006 and 2007

S Johnson[1] (tonnettil@usa.redcross.org), R Cable[2], D Leiby[3], E V Tassell[4], L Tonnetti[3]. *[1]American Red Cross, Farmington, CT; [2]American Red Cross Blood Services, New England Div, Farmington, CT;[3]American Red Cross, Rockville, MD;[4]Farmington.*

Background: *Babesia microti* is an intraerythrocytic parasite, transmitted by *Ixodes* ticks, that is found throughout the northeastern United States. *B. microti* is also transmitted by blood transfusion, with over 70 cases reported to date. Individuals exposed to the parasite may develop babesiosis, a potentially life threatening illness. Those at greatest risk for developing serious disease include asplenic, elderly and immunocompromised individuals. Our blood center has been studying the presence of antibodies to *B. microti* in Connecticut blood donors since 1999. The purpose of this analysis is to provide data, and highlight the need, for the development of methods for screening the blood supply to improve blood safety. **Methods:** Consenting blood donors are tested at select blood drives. A donor is considered seropositive when they test positive for *B. microti* antibodies by IFA (≥1:64). Beginning in 2006 testing was conducted year round and included blood drives in all eight counties of Connecticut. **Results:** Seropositive individuals were identified in every county (Table 1), although the two southeastern counties (Middlesex and New London) each had significantly higher seroprevalence rates when compared to the remaining six counties ($p < 0.05$ for both). Seropositive individuals were identified in every month and seroprevalence varied month to month but there was no apparent seasonal pattern. **Conclusions:** Seroprevalence of *B. microti* in Connecticut varies significantly by county, but every county had substantial seroprevalence, 0.4% or greater seropositive rate (40/10,000 donors). Seropositive donors were identified in every month of the year. Based on these results, using seasonal or geographic exclusion criteria to interdict *Babesia* from the blood supply would be an ineffective approach. These data support the need for developing efficient methods for screening the blood supply for *Babesia*, and thereby improving blood safety.

TABLE 1. 2006 & 2007

County	# Tested	# Positive	Seroprevalence per 10,000 Donors
Fairfield	1631	10	61
Hartford	2609	17	65
Litchfield	375	2	53
Middlesex	654	10	153
New Haven	1521	10	66
New London	1062	19	179
Tolland	418	3	72
Windham	252	1	40

Disclosure of Conflict of Interest

Stephanie Johnson, Ritchard Cable, Eric Van Tassell, Laura Tonnetti: Nothing to Disclose
David Leiby: Not Specified

SP252

Transfusion Transmitted Babesiosis in an ITP Patient: A Case Report

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Our case is a 79 years old male who presented to Danbury Hospital Emergency Department (ED) complaining of fever and chills that started a few hours earlier. The patient was discharged 2 weeks prior following a Clostridium difficile (C. difficile) infection. On physical examination the patient

医薬品 研究報告 調査報告書

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				2008. 12. 16	該当なし	

一般的名称	新鮮凍結人血漿	研究報告の公表状況	Benjamin RJ, Kline L, Dy BA, Kennedy J, Pisciotto P, Sapatnekar S, Mercado R, Eder AF. Transfusion. 2008 Nov;48(11):2348-55. Epub 2008 Jul 22.	公表国
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)			米国

研究報告の概要

○全血由来血小板の細菌汚染:米国赤十字(ARC)の初流血除去および保存前プール培養検査の導入
背景:全血由来血小板(WBP)輸血後の細菌性敗血症は、現在も患者にとって大きなリスクであり、これは細菌汚染の抑制あるいは検出するための実用的、効果的な方法がないことが主な原因である。我々は、WBPと初流血除去後のプール全血由来血小板(PSP)の敗血症性反応リスクおよび細菌培養結果について報告する。
試験デザインおよび方法:Acrodose PLシステム(Pall Medical)で調べた製品適合および品質管理(QC)について、4つの地域血液センターにて評価を行った。細菌汚染リスクは、報告されたWBPによる敗血症性輸血反応の調査および自動化細菌検出システム培養(BacT/ALERT 3D, bioMérieux)を用いた白血球除去PSPの好気QC培養により評価した。
結果:PSP実施前(2003年1月～2006年12月)には2,535,043単位のWBPが供給され、死亡2例を含む敗血症性反応20例の報告があった(敗血症性反応:100万あたり7.9[1:126,752]、死亡:100万あたり0.79[1:1,267,522])。2006年10月にPSPが導入され製品適合率は99.6%となり、1プールあたりのPLT数は平均4.0×10^{11}であった。実施トライアル中に初流血除去技術を用いた全血採血セットが導入され、PSP細菌培養の確定陽性率は100万あたり2,111(1:474)から965(1:1036)に減少した(オッズ比0.46;95%信頼区間0.22～0.95)。供給されたPSP 25,936単位による敗血症性反応は報告されなかった。
結論:初流血除去および細菌培養は、WBP輸血の細菌リスクを低減させる有効な方法である。PSPの細菌汚染率は、同等の培養プロトコールを用いたARCの現在のアフェレーシスPLTの5.8倍であると評価された。

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」
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報告企業の意見	今後の対応
全血由来血小板の細菌汚染リスクを低減させるためには、初流血除去および細菌培養によるスクリーニングが有効な方法であるとの報告である。	日本赤十字社では、輸血による細菌感染予防対策として、すべての輸血用血液製剤を対象に保存前白血球除去及び初流血除去を導入している。さらに、輸血情報リーフレット等により細菌感染やウイルス感染について医療機関へ情報提供し注意を喚起しているほか、細菌感染が疑われる場合の対応を周知している。今後も細菌やウイルスの検出や不活化する方策について情報の収集に努める。

BLOOD COMPONENTS

Bacterial contamination of whole blood–derived platelets: the introduction of sample diversion and prestorage pooling with culture testing in the American Red Cross

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BACKGROUND: Bacterial sepsis following whole blood–derived platelet (WBP) transfusion has remained a substantial patient risk, primarily due to a lack of practical and effective means to limit or detect bacterial contamination. We describe the risk of reported septic reactions to WBPs and the introduction of prestorage-pooled whole blood–derived platelets (PSPs) collected using initial sample diversion and cultured for bacterial contamination.

STUDY DESIGN AND METHODS: Product qualification and quality control (QC) testing with the Acrodose PL system (Pall Medical) were evaluated in four regional blood centers. Bacterial contamination risk was assessed by review of reported septic transfusion reactions to WBPs and by aerobic QC culture of leukoreduced PSPs utilizing automated microbial detection system cultures (BacT/ALERT 3D, bioMérieux).

RESULTS: Before implementing PSPs (January 2003-December 2006), we distributed 2,535,043 WBP units and received 20 reports of septic reactions including 2 fatalities (7.9 per million [1:126,752] reactions and 0.79 per million [1:1,267,522] fatalities). In October 2006, PSPs were effectively implemented with a product qualification success rate of 99.6 percent and a mean yield of 4.0×10^{11} platelets (PLTs) per pool. Whole blood collection sets with sample diversion technology were introduced during the operational trial and decreased the rate of confirmed-positive bacterial culture of PSPs from 2111 (1:474) to 965 (1:1036) per million (odds ratio, 0.46; 95% confidence interval, 0.22-0.95). No septic reactions to PSPs were reported (25,936 PSP units distributed).

CONCLUSION: Sample diversion and bacterial culture are effective methods to reduce bacterial risk with WBP transfusion. Bacterial contamination of PSPs was assessed at 5.8-fold our current rate for apheresis PLTs utilizing comparable culture protocols.

The introduction of the Food and Drug Administration (FDA)-approved Acrodose PL system (Pall Medical, East Hills, NY) for producing prestorage-pooled, leukoreduced whole blood–derived platelets (PSPs) now offers the possibility of quality control (QC) bacterial culture testing of whole blood–derived platelets (WBP) at the blood center, utilizing either the eBDS (Pall Medical) or the BacT/ALERT 3D (bioMérieux, Durham, NC) culture systems.[1,2] In addition to providing a means to screen WBPs, the Acrodose PL system offers the potential advantages of eliminating the time and labor needed for point-of-issue pooling at the hospital transfusion service and reducing outdate rates, because PSPs do not evoke a 4-hour outdate after pooling. PSPs, however, carry a disadvantage that confirmed-positive and indeterminate culture results lead to the discard of not only the final pooled product, but also to the retrieval and discard of all the associated red blood cell (RBC) and plasma products from the original whole blood

ABBREVIATIONS: PSP(s) = prestorage-pooled whole blood–derived platelet(s); WBP(s) = whole blood–derived platelet(s).

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