Does the low prevalence of bacterial contamination in random platelet concentrates justify the use of preventive measures?

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¹Instituto Pasquini de Hemoterapia e Hematologia, Curitiba, PR, Brazil ²Universidade Federal do Paraná - UFPR, Curitiba, PR, Brazil Despite the growing advancement of transfusion medicine, bacterial contamination of blood components still represents a serious risk to recipients and is currently the leading cause of adverse effects⁽¹⁾ and the second leading cause of death related to blood transfusions⁽²⁾.

It is estimated that the risk of sepsis related to platelet transfusions is 1:12.000, with a mortality rate of 26%. The rates are further increased when transfusions of platelet concentrates are obtained from multiple donors⁽³⁾. Currently the Ordinance no 1353 of June 13, 2011 is in force in Brazil; this regulation determines that 75% or more of blood products must comply with the established quality and sterility standards⁽⁴⁾.

Given the importance of microbiological control in blood banks, the present study aimed to analyze the prevalence of positive bacterial cultures in random platelet concentrates (RPC) obtained in the period from November 2010 to April 2011 in the Instituto Pasquini de Hemoterapia e Hematologia in Curitiba, Brazil. A retrospective observational study was conducted of 409 reports of bacterial cultures on RPC, which represented a total of 3183 donations.

It is recommended that a patient requiring a platelet transfusion receives one unit for every 10 kg body weight. The Instituto Pasquini has standardized eight units of RPC for all patients except for surgical and pediatric patients. The material is prepared in a laminar flow hood with prior irradiation of germicidal light for 15 minutes. After, the eight units of RPC are transferred to a 600 mL pouch, from which 10 mL are removed for blood cultures (BacT / Alert ® 3D, bioMérieux, USA) using a previously validated method⁽⁵⁾.

A culture in January 2011 was positive (Table 1), showing a growth of coagulase-negative *Staphylococcus*. This represented 1.25% of the cultures performed in January 2011 and 0.24% in the period from November 2010 to April 2011. As at least one unit of this pool was contaminated, this represents 0.15% of random platelet donors of January, and is thus well within the parameters established by Ordinance no 1353 for the sterility of blood components which determines a level of sterility higher than 75%.

Month	Donations n	Cultures n	Positive n	Negative n
December 2010	691	87	-	87
January 2011	645	80	1	79
February 2011	397	53	-	53
March 2011	621	80	-	80
April 2011	563	74	-	74
Total	3183	409	1	408

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The authors declare no competing financial interest.

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The rate of minimal bacterial contamination was 1:3183 donations which corresponds to 0.03%. In the United States it is estimated that bacterial contamination of random platelets is 1 in every 3000 units⁽⁶⁾, with transfusion-related septicemia occurring in 1 of every 20,000 transfusions⁽⁷⁾.

The most frequently agents related to platelet concentrates are gram-positive *coccus*, *Staphylococcus spp* and *Streptococcus spp*⁽⁸⁾. Ordinance n° 1353 is not specific about the sterility of RPC, unlike the Board Resolution (RDC) n° 153 of July 2004, repealed in December 2010, which stipulated a sterility of platelet concentrates greater than 99.5%⁽⁹⁾.

Despite the low prevalence of bacterial contamination in RPC demonstrated in this study, it is of paramount importance to adopt preventive measures that can ensure safety in blood transfusions, because RPC are used in large quantities and their administration is intravenous which facilitates the

development of pathogens, especially in debilitated patients. Thus, a strict quality control, coupled with highly sensitive techniques would allow the correct identification of bacteria in blood products, and may contribute to reduce transfusion accidents.

References

- Brecher ME, Hay SN. Bacterial contamination of blood components. Clin Microbiol Rev. 2005;18(1):195–204.
- Campos TC, Pedroso CD, Dantas SC, Pinheiro FC, Costa LF, Pereira AF, et al. Monitorização da contaminação bacteriana em concentrados de plaquetas randômicas – Experiência de um banco de sangue [Abstract 696]. Rev Bras Hematol Hemoter. 2009; 31(5): 276.
- Razouk FH, Reiche EM. Caracterização, produção e indicação clínica dos principais hemocomponentes. Rev Bras Hematol Hemoter. 2004;26(2):126-34.
- Agência Nacional de Vigilância Sanitária. Portaria nº 1.353, de 13 de Junho de 2011. Aprova o Regulamento Técnico de Procedimentos Hemoterápicos [Internet]. Brasília: ANVISA; 2011. [cited 2012 Jun 21]. Available from: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2011/ prt1353_13_06_2011.html

- Magalhães GL, Pelisson M, Colluço AG, Koti AN, Gelinski JR, Saito M, et al. Validação do sistema BactAlert utilizado para controle microbiológico de hemocomponentes no Hemocentro Regional de Londrina [Abstract 750]. Rev Bras Hematol Hemoter. 2009;31(5):291.
- Fiebig EW, Busch MP. Infectious disease screening. In: Roback JD. Combs MR. Grossman BJ, Hillyer CD, editors. Technical Manual. 16th ed. Bethesda: AABB; 2008. p. 241-82.
- Mendrone AJ. Terapia transfusional no transplante de células-tronco hematopoeticas. In: Voltarelli JC, Pasquini R, Ortega ET. Transplante de células-tronco. São Paulo: Atheneu; 2009. p 653-75.
- Rodrigues MC, Almeida DR. Avaliação de análises microbiológicas de hemocomponentes [Abstract 984]. Rev Bras Hematol Hemoter. 2011;33(2):408.
- 9. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Resolução RDC n.153, de 14 de junho de 2004. Determina o Regulamento Técnico para os procedimentos hemoterápicos, incluindo a coleta, o processamento, a testagem, o armazenamento, o transporte, o controle de qualidade e o uso humano de sangue, e seus componentes, obtidos do sangue venoso, do cordão umbilical, da placenta e da medula óssea [Internet]. Brasilia, MS: 2004. [cited 2011 Sept 15]. Available from: http://portal.saude.gov.br/portal/arquivos/pdf/resolucao_153_2004.pdf

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