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Original article

Prevalence of bacterial contamination in platelet concentrates at the National Center of Blood Transfusion (Mexico)

Prévalence de la contamination bactérienne dans les concentrés de plaquettes au Centre national de transfusion sanguine (Mexique)

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Abstract

Objectives. – Most common bacterial sepsis associated with transfusion is caused by contaminated Platelet Concentrates (PC). The screening of PC to detect bacterial contamination is obligatory in Mexico, and it is carried out in quality control programs. In Mexico, the identification and molecular characterization of bacterial contaminants to detect contamination sources have not been implemented due to high costs; however, it is an actual current need.
Material and methods. – One hundred PC were randomly selected and microbiologically analyzed. This sample size corresponds to 1% of the PC obtained by the National Center of Blood Transfusion (NCBT) in Mexico City according to the Official Mexican Standard NOM-253-SSA1-2012. Additionally, molecular biology tests were implemented in order to identify the possible contamination sources.
Results. – Nine of the 100 PC analyzed (9%) showed bacterial contamination; analysis of the nucleotide sequences revealed the presence of characteristic microbiota from donor skin and soil. Diverse clonal relationship between the strains was identified in *Staphylococcus epidermidis.*
Conclusion. – Detection of contaminants associated with environmental and skin flora, shows the need to implement measures in the process of disinfecting skin at the site of phlebotomy and cleaning each of the areas involved in blood collection.
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Keywords: Bacteria; Platelet concentrates; Blood bank; Contamination; Quality control

Résumé

Objectifs. – La plus commune septicité bactérienne associée à la transfusion est causée par des concentrés plaquettaires contaminés (CP). Le dépistage de CP pour détecter la contamination bactérienne est obligatoire au Mexique et il est effectué dans des programmes de contrôle de qualité. L'identification et la caractérisation moléculaire des polluants bactériens pour détecter les sources de contamination n'ont pas été mises en œuvre au Mexique, à cause des hauts coûts; cependant c'est un besoin actuel réel.
Matériels et méthodes. – Cent CP ont été aléatoirement choisis et microbiologiquement analysés. Cette taille de l'échantillon correspond à 1 % des CP obtenus du Centre national de transfusion de sang (NCBT) au Mexique, d'après la Norme officielle mexicaine NOM-253-SSA1-2012. Également, des tests de biologie moléculaire ont été mis en œuvre pour identifier les sources de contamination possibles.

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Résultats. – Neuf sur 100 CP analysés (9 %) ont montré la contamination bactérienne ; l'analyse des ordres nucléotides a révélé la présence de microbiote caractéristique de la peau du donneur et du sol. Une relation clonale diverse entre les souches a été identifiée dans *Staphylococcus epidermidis*.
Conclusion. – La détection de polluants associés à l'environnement et à la flore cutanée montre le besoin de mettre en œuvre des mesures dans le procédé de désinfection de la peau au site de phlébotomie et de nettoyer chacune des zones impliquées dans la collecte de sang.
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Mots clés : Bactéries ; Concentrés plaquettaires ; Banque du sang ; Contamination ; Contrôle qualité

1. Introduction

Due to the mandatory introduction of screening tests for the detection of virus in blood donors that has been achieved during the last decades, a significant reduction in the transmission of viral infections related to transfusion has been reached; however, reports of bacterial infections related to this same process continue [1]. The most common bacterial sepsis associated with transfusion is caused by contaminated Platelet Concentrates (PC) more than by Red Blood Cells (RBC) since bacteria grow mainly at the temperature in which PC bags are stored ($22 \pm 2\,^{\circ}C$), creating an excellent medium for their proliferation [2]. The Federal Drug Administration (FDA) reported that in the period between 2005 and 2009, bacterial infections were the third cause of transfusion-related deaths [3]. In contrast to virus detection, detection of bacterial contamination in blood components is under consideration or has already been implemented in many countries, both in Europe and in North America [4]. In some cases it has been unsatisfactory regarding the risks of sampling error and the long periods of time to get the results [5]. Possible sources of contamination of PC include flora from donors' skin, asymptomatic donors, devices used in blood collection and environmental flora [5,6]. It has been previously shown that, in most positive cultures, bacterial contamination is the result of contamination with the resident skin microbiota when performing venipuncture [7,8]. This cross-sectional study reports the prevalence of microbial contamination in PC in a Mexican Blood Bank. One hundred PC were randomly selected, these correspond to 1% of the blood components obtained from the National Center of Blood Transfusion (NCBT). The aforementioned according to the Official Mexican Standard NOM-253-SSA1-2012, "For the disposal of human blood and blood components for therapeutic purposes", in Section 8 "Processing, preservation, expiry date and quality control of blood units and blood components" [9]. In addition, Enterobacterial Repetitive Intergenic Consensus, based on Polymerase Chain Reaction (ERIC-PCR) assays for typing the isolated bacteria, was performed in order to clonally discriminate between strains identified in PC bags. The aim of this work is to guide the staff involved in the process of phlebotomy and blood fractionation with evidence about the importance of good manufacturing practices in blood banks.

2. Material and methods

2.1. Platelet concentrates preparation in the NCBT's blood bank

Platelet Concentrates containing 55 ± 5 mL were routinely obtained after the fractionation of whole blood of voluntary donors, in donation campaigns in the metropolitan area of Mexico City. Collection bags (Teruflex® Terumo Hatagaya, Shibuya, Japan; containing CPDA-1 solution) were used. PC were obtained by centrifugation at 22 °C in a J6-M1 Centrifuge (Beckman, Coulter, California, USA) before the sixth hour of collection. The fractionation and removal of the buffy coat was performed by using a T-ACE II Automatic Component Extractor (Terumo, New Jersey, USA). Individual PC bags were stored under continuous agitation before microbiological control.

2.2. Sampling platelet concentrates

Using simple random sampling techniques, a sample size of 100 PC bags was analyzed. This sample size corresponds to 1% of the PC obtained from the National Center of Blood Transfusion (NCBT). This is according to the Official Mexican Standard NOM-253-SSA1-2012, "For the disposal of human blood and blood components for therapeutic purposes". PC were obtained from October to December 2014; the inclusion criteria for selecting the PC bags were: obtained before six hours after blood collection, expiry date (between one to five days post-blood fractionation), storage under standard conditions in blood bank (shaking at 100 rpm at 22 °C), negative infectious markers (HIV, HCV, HBV, Chagas, Syphilis and *Brucella*) and no visual evidence of bacterial contamination. The PC bags were transported at room temperature to the NCBT's Research Department for subsequent analysis.

2.3. Non-selective enrichment of microbial contaminants in the BacT/ALERT 3D automated system

All PC bags samplings were carried out under aseptic conditions (prior sanitation with ethanol 70%) in a laminar flow cabinet type 2. Twenty milliliters of each PC bag were obtained by puncture with a hypodermic syringe; subsequently, 10 mL were directly inoculated into the BacT/ALERT 3D:

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