CAPA analysis of clotted red cell unit detected during leukodepletion process: Importance of quality check on blood collection monitors

Sir,

To ensure thorough anticoagulation of blood, its proper mixing with blood is essential during the whole blood (WB) collection process. Proper ratio of blood to anticoagulant and mixing are essential to prevent the start of blood coagulation process and to achieve standardized WB and its components, subsequently. This process can have critical consequences not only for the immediate quality of the resulting components but also for their long-term quality during storage. Blood collection monitors/mixers (BCM) are available and widely used to optimize WB collection process having set up alerts and intuitive instructions to guide the user throughout the draw process, with the view panel for easy viewing during donation. Regular quality check of equipment is must to prevent adverse event during any process.

At our center, an average of 90 blood units (WB) are collected every day in the 450 ml citrate-phosphate-dextrose with saline-adenine-glucose-mannitol triple blood bag system (Compoflex; Fresenius Kabi, Germany) using BCM having auto mixing and auto clamping facility (Hemolight plus, Fresenius Kabi, Germany). We practice universal leukodepletion within 72 h of WB collection using separate laboratory leukodepletion filters (BioR 01 max BBS, Fresenius Kabi, Germany) for red cells and platelets using sterile connecting device (Compo Dock, Fresenius Kabi, Germany). We came across a red cell unit with a huge clot in the bag measuring 8 cm × 7 cm during the leukodepletion process on day 2 of blood collection [Figure 1]. The clot was surprisingly missed during the collection and separation process. Bag was segregated, and other products of the same unit were identified and quarantined. Blood culture of red cell unit and its components was done. BCM are checked weekly for volume limitation and agitations per minute using standard calibrated weights and stopwatch respectively. On corrective and preventive action analysis, it was found that red cell unit was prepared from a WB donation from a 29-year-old first time male donor with the weight 83 kg, who completed the donation process (donor-in to donor-out) within 20 min. All the five BCMs installed in the blood donor collection room were checked for movements and volume limitation and found that one of them was defective in agitation process with 15 agitation/min while the normal range of agitation was 28-32/min; which led to incomplete mixing of anticoagulant to WB while there was no problem in auto clamping [Figure 2]. This particular collection was collected on the malfunctioning BCM. This problem was encountered for the first time; defective BCM was replaced by the alternate one till the problem was rectified by the company engineer. Culture of red cell unit and its components was sterile.

Clots and fibrin strands in the blood units result from the activation of the clotting processes and can be a mixture of clotting proteins (including fibrin) and platelets. However, clots in the unit may also indicate bacterial contamination. In our case, clot formed was most likely due to the activation of clotting process as culture of red cell unit and its components was sterile. The necessary citrate concentration for prevention of activation process is much lower, but because of the risk of inadequate mixing and the biological variation of coagulation capacity among donors, a much higher concentration (1:14) is used.[1-3] If the citrate is not completely mixed with the blood immediately, during the blood collection process there will be inadequate anticoagulation and clump(s) formation which lead to loss of labile coagulation factors, loss of quality of platelets or even complete coagulation of the unit (clotted unit). Mixing devices are widely used to facilitate proper mixing of collected blood and anticoagulant to a similar level as that obtained by manual mixing. Regular quality control check of each BCM is must to ensure proper mixing of anticoagulant and blood to yield good quality products. De Korte *et al.* also suggest that most blood-mixing devices fail to mix efficiently at normal and low bleeding rates.[3] Quality control of BCM must include agitation counts for proper mixing using stopwatch and weighing the known standard weights for ensuring the volume limitations. Normal limits for the agitation should be 28-32/min while ±2% variation in weight is allowed.[4]

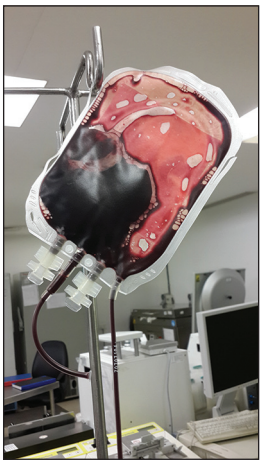

Figure 1: Extraordinary large clot detected during the leukodepletion process

Figure 2: Blood collection mixer

Ravi C. Dara, Aseem Kumar Tiwari, Dinesh Arora, Ganesh Rawat, Vimarsh Raina[1]

Department of Transfusion Medicine and [1]Department of Transfusion Medicine and Laboratory Services, Medanta-the Medicity, Gurgaon, Haryana, India

Correspondence to: Dr. Aseem Kumar Tiwari, Department of Transfusion Medicine, Medanta-The Medicity, Sector-38, Gurgaon - 122 001, Haryana, India.
E-mail: aseem.tiwari@medanta.org

References

1. Prowse C, Waterston YG, Dawes J, Farrugia A. Studies on the procurement of blood coagulation factor VIII *in vitro* studies on blood components prepared in half-strength citrate anticoagulant. Vox Sang 1987;52:257-64.
2. Högman CF, Eriksson L, Gong J, Högman AB, Vikholm K, Debrauwere J, *et al*. Half-strength citrate CPD combined with a new additive solution for improved storage of red blood cells suitable for clinical use. Vox Sang 1993;65:271-8.
3. De Korte D, Veldman HA. Automated blood-mixing devices still fail to mix at low bleeding rates. Vox Sang 2001;80:34-9.
4. Operator Manual, Hemolight Plus. Germany: Fresenius Kabi Deutschland GmbH; 2006.

Access this article online	
Website: www. ajts. org	**Quick Response Code:**
DOI: 10.4103/0973-6247.162732	