Take One – Get Two: Automated Red Blood Cell Collection

While the demand for blood donations is rising, basically due to an aging population and increasing invasive procedures, the pool of blood donors is shrinking, partly because of stricter donor criteria. Thus, in times of shortages of blood supply, there is a need for new solutions to improve blood availability, to ensure that only desired compounds are collected and that there is no ‘lesion of collection’. The automated component collection system ALYX, for example, doubles productivity of each donor by allowing blood center to gather two units of red blood cells from one single eligible volunteer in just one procedure lasting less than half an hour. The simple formula behind the new method: Take one (donor) – get two (leukoreduced red blood cell units), i.e. donate once for two blood units while staying in a state of isovolemia. Even though automation has conquered almost every section of the industrialized world, most donor blood is drawn and processed manually. But manual collection has several disadvantages, since the volume may vary, leading to variable amounts of red blood cells in the final product. The same centrifuges in use also influence the content of red blood cells. Moreover, additional factors such as temperature, methods applied, preincubation and choice of filters have an impact on the results of the reduction in leukocytes and the number of red blood cells in the final product. The missing link in the evolution of ‘blood collection’ might well be the automated component collection system ALYX (fig. 1). This innovative and portable automated device provides a controlled manufacturing process and is designed for the collection of multiple blood components from one eligible donor. The system enables the operator to collect either two units of red blood cells (RBCs) from a single. Anticoagulant (ACD-A) and additive solutions (SAG-M) as well as filters are integrated in each tray of the functional sets, only saline solution has to be hooked up separately.

Single-Venous Access and Isovolemia

The single-needle-collection process includes blood taking and reinfusions and an integrated automated depletion of leukocytes. During the draw phase whole blood is collected, anticoagulants are added and the centrifuge separates the anticoagulated blood into its two components – blood plasma and red blood cells. The red blood cells remain in the system, while the rest of the blood components along with saline solution is being pumped back into the donor during the first return phase. Therefore, the donors stay in a state of isovolemia during the whole procedure. The last drawing cycle is adapted to collect only the amount of blood needed to reach the red blood cell target volume. Advantages of ALYX are: Standardized volume of the final product with a consistent content of red blood cells and a standardized efficient depletion of leukocytes.

Apheresis Double-Dose RBC Donation Versus Standard RBC Donation

ALYX acceptance in clinical trials was high, indicating that donors were comfortable with the single-needle procedure. These findings were supported by new data presented by Thomas Hundhausen, Oldenburg, Germany, who compared short-term donor safety and quality of ALYX donations (n = 36) to standard RBC donations (n = 43) in the same donors. Donors in this trial, however, included only men who were, except for 3 first-time donors, experienced apheresis donors. Hundhausen pointed out. Donor selection took place according to current German guidelines, the additional donor safety for the ALYX donation included a body weight of at least 60 kg and a minimum height of 170 cm in males. Vital and laboratory parameters of the donors were recorded before and after donation and were also checked during collection with the ALYX system. The target volume of the donations was 360 ml. Average procedure time was 25 ± 4 minutes and filtration lasted only about 6 minutes. After the blood donations, all donors were asked to fill out questionnaires. The results revealed that ALYX acceptance was high: Out of 36 donors, 34 would donate with ALYX on a regular basis, 1 donor was undecided, 1 would not donate again with the new system, because he felt physically weak for more than one day. Two men reported a prolonged mild physical weakness. Apart from a mild vagovagal reaction in one donor at the time of venipuncture, which was not related to the apheresis procedure, no side effects requiring medical attention were reported. Vital parameters such as blood pressure and heart rate of the donors were within normal range before and after ALYX 2RBC collections as well as pre- and post-standard blood donations. After ALYX 2RBC donations, WBCs were marginally lower than before, whereas platelet counts seemed virtually unchanged (fig. 2).

49-Day Storage Data

RBC quality parameters during 49 days of storage were obtained. All products passed sterility testing on day 49. Even though ALYX RBCs had a slightly lower pH-value at the end of the storage period and a larger total protein concentration than standard RBC concentrates, they are highly standardized and in this respect superior to the standard RBC concentrates they were compared with.

ALYX – Highly Accepted Among Donors

Hundhausen concluded that the donation of two red blood cell units with the new automated component collection system is feasible, safe and effective in the selected donor population (n = 36). 94% of the donors would donate with the innovative system on a regular basis. Procedure-related side effects of ALYX were comparable to standard (platelet) apheresis. Hundhausen emphasized. According to the speaker, the ALYX RBCs easily fulfilled current German quality
All It Takes Is 27 Minutes!

Luigi Antoniazzi, Madrid, Spain, also emphasized that ALYX meets the European guidelines and then talked about the US experience. 7 blood centers in several American states (NY, LA, TX, MN, FL, OK) participated in a trial in which a minimum of 50 procedures were completed at each site. 36% of the collections were achieved in fixed sites, while 64% took place in a mobile setting. Antoniazzi said that needle-in-to-needle-out donation time for a target collection of 360 ml varied between 20 and 40 minutes, the average being 27 minutes. At the same time, he pointed out that donation times are expected to drop as operator proficiency with the ALYX system increases. Talking about product quality, the speaker mentioned that the mean hemoglobin value was 54.6 g per unit and the mean RBC volume 157.6 ml per unit, thus fulfilling the pre-requisites for the final component (mean hemoglobin ≥ 51 g per unit or 153 ml packed red cell volume per unit). The leukoreduction results also showed that all (100%) units fulfilled the criteria. Reduction time was 6 minutes and 58 seconds, also meeting target settings (<10 minutes).

Positive Operator and Donor Feedback

The operators’ evaluation was based on 30 surveys ranging from 1 to 5 (1 being ‘very negative’ and 5 being ‘very positive’). The average rating for operating the system was 4.7, the overall experience on the ALYX collection system was 4.6. Training effectiveness was measured by operator skill demonstrations and post-evaluation questionnaires. The results showed that all (100%) operators observed (n = 27) could complete the four key steps after their fifth procedure and all could load the kit in less than 5 minutes. All responses rated 4.5 or better on a scale of 1 to 5, the average rating being 4.7.

Donors were also asked to complete a survey at the end of the procedure, and the donation experience on the ALYX system received an average rating (based on 317 donor surveys) of 4.6. The overall length of the procedure rated 4.4 and the level of comfort during blood collection was 4.6. Compared to other apheresis donations, the ALYX experience was rated 4.6 both in donors with apheresis experience (n = 93) as well as donors with auto RBC experience (n = 42), Antoniazzi pointed out.

Analysis of Stored Blood and Donor Data in ZRC Collections

Gert Matthes, Leipzig, Germany, talked about interim data of a study (Matthes et al. 2003, poster DGTI 2003) focussing on automated collection of double unit red cell concentrates (RCCs) from one donor and on quality parameters during 42 days of storage as well as in vivo regeneration up to 120 days post donation. In 23 donors, 20 automated double unit red cell collection procedures were performed; 3 procedures had to be stopped. Almost two thirds of the donors were men, 13% were first time donors, 87% were experienced (39% whole-blood donors, 48% apheresis donors). The male donors all met the requirements for whole-blood donation and fulfilled further eligibility criteria for donor safety such as Hct ≥ 40%, Hb ≥ 13.5 g/dl, body weight ≥ 60 kg and height >170 cm. For women, prerequisites were as follows: Hct > 40%, Hb ≥ 13.5 g/dl, ≥ 70 kg, > 168 cm. All donors were volume-supplemented with a mean of 420 ml saline solution. So far, only 70-day data are available, the speaker said. Immediately after donation there was an Hb loss of 20.2 ± 5.2%, reduced to 14.1 ± 6.1% on day 1 and to 4.3 ± 10.4% on day 42. Men and women regenerate their loss in RBCs differently, Matthes said. While male donors reach a level of 13.5 g Hb/dl within 14 days, it takes 42 days for female donors to reach 12.5 g Hb/dl, he explained. Donor safety was maintained during the procedure, and all pre/post procedure vital signs were within clinically acceptable limits. The results revealed no serious or severe adverse events during or after apheresis.

Rheology

Moreover, double-unit RCC storage data collected with the ALYX system, using ACD-A anticoagulant and SAG-M additive solution for storage, showed an acceptable quality of RBCs (also maintaining deformability for a reasonable period of time), and were at least as good as manually collected RCC or even better, Matthes concluded.

Take-Home Message

ALYX fulfills the quality standard of Europe and the United States of America, secures a constant quality of blood products, increases efficiency of the blood collection process and at the same time maintains donor safety.

Source

‘ALYX Component Collection System’ meeting, held in Innsbruck, Austria, September 17, 2003 at the 36th congress of the DGTI (Deutschen Gesellschaft für Transfusionsmedizin und Immunhämatologie e.V.) Organized by Baxter GmbH, Germany.

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