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Evaluation of a New Automated Red Cell Exchange Procedure in Routine Use

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Purpose: Red Blood Cell Exchange (RBCx) is used to remove abnormal or excess red blood cells (RBCs) from patients and exchanging them for healthy donor RBCs and/or crystalloid or colloid solutions to maintain fluid balance. The removal of abnormal RBCs and replacement with healthy donor RBCs is used in the treatment of patients with complications of sickle cell disease (SCD) to lower the percentage of hemoglobin S (HbS) present in the body and prevent stroke. In 2016, a new CE marked device became available for automated red cell exchange, the AMICUS Separator with software version 5.1 (Fresenius Kabi, Lake Zurich, IL, USA). The procedure was evaluated by measuring fraction of cells remaining (FCR) accuracy and end hematocrit (Hct) accuracy in adult patients.

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Methods: Between November 2016 and January 2017, 35 procedures were executed using the RBC depletion/exchange procedure on AMICUS to treat SCD patients to prevent iterative vaso-occlusive crisis, and treat 4 patients with history of stroke (20 male, 15 female). For the depletion phase, 10 procedures used albumin as the non-cellular replacement fluid (RF), 16 procedures used hydroxyethylstarch, and 9 procedures used saline to initially decrease the patient's Hct to the programmed depletion Hct. In all procedures, packed RBCs in storage solution with an average Hct of 55% or 58% were used as RF for the exchange portion of the procedure. Blood samples were taken before and after the procedure to measure cell counts, Hct and HbS. The machine settings, adverse events and procedure results were documented for each procedure.

Results: In all procedures the HbS level decreased from a median 46.1% (16.2 - 85.3%) to 16.8% (4.5 - 42.1%) resulting in a median achieved FCR of 33.3% (21.8 - 63.1%) compared to the median target FCR of 33% (23 - 55%). The median starting patient Hct was 27.1% (22.0 - 40.6%) and the median end patient Hct was 28.0% (24.0 - 36.0%). The median target end Hct was 28% (24 - 35%). The end Hct difference from target to actual had a median difference of 0.30 (-4.1 - 6.8%). One non-device related adverse event was reported where the patient experienced a drop in blood pressure and a bolus of hydroxyethylstarch was given after the procedure was terminated.

Conclusion: AMICUS was found to be safe and effective in treating SCD patients using the RBCx procedure. AMICUS was able to accurately reduce the level of HbS to reach the desired FCR while effectively reaching the target end Hct for the patient population.

Source: Sanderson F, Kanouni T, Bouhya S, Poullin P. Evaluation of a new automated red cell exchange procedure in routine use. In: Proceedings from the International society for Apheresis; May 17-20, 2017; Copenhagen, Denmark. Abstract #36.

Note: The Amicus RBCx System is CE marked for distribution in the EU. It is not FDA cleared for marketing in the United States of America.

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