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AmiCORE Apheresis System

Improvements of Platelet Yields and Collection Efficiency in a New Apheresis System During Evaluation by Optimizing Device Parameters

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Background: Institutional Quality Assurance (QA) program requires any new equipment in the facility to be evaluated for performance before putting them into routine use. AmiCORE Apheresis System is a new generation of continuous-flow centrifugation apheresis device, which uses a one-time use, single-needle disposable kit with ACD-A, as the anticoagulant and saline volume replacement for single-dose platelets (SDP) and double-dose platelets (DDP). During the initial evaluation of the AmiCORE (Fresenius Kabi AG, Germany) it was found that the platelet yields and collection efficiency were sub-optimal. The manufacturer was apprised and they in turn made changes to the parameter settings of the device for improving the Operational Performance (OP).

Improvements of Platelet Yields and Collection Efficiency in a New Apheresis System During Evaluation by Optimizing Device Parameters (continued)

Aims: The aim of the study was to evaluate the OP before and after the "device parameters optimization" by the manufacturer.

Methods: All donors were healthy and met the statuary donation criteria. Each donor was given 1000 mg oral calcium just prior to the procedure as part of institutional Standard Operating Procedure (SOP) and adverse reactions, if any, were noted. The device was set up with the basic default settings of 8:1 whole blood: anticoagulant ratio, a citrate infusion rate of 1.25mg/kg/min, inlet flow rate of 100 ml/min and return flow rate of 120 ml/min. 15 consecutive SDP procedures were performed with a target yield of 3.5×10^{11}. OP data of these procedures was collected and analyzed. This included donor pre-and post-donation platelet counts, red-cell and plasma loss, volume of whole blood processed, collection time, flow rates and platelet product quality characteristics (actual platelet yield, swirling, pH and residual WBC count). Primary performance parameters such as Platelet Yield, Actual vs. Targeted (A: T) ratio and Collection Efficiency were assessed.
As these parameter results were sub-optimal, the manufacturer was informed of the results along with the data. The manufacturer analyzed the submitted data as well as the data downloaded from the device. In order to optimize the device performance, they made three changes in the machine; Set-point, Yield Adjuster and Input Hematocrit. Another 15 SDP procedures were performed with the same target platelet yield of 3.5×10^{11}. OP data of these procedures was also collected and analyzed as done for the earlier procedures.

Results: Primary performance of the device was similar pre- and post-optimization except for Platelet Yield, ratio of Actual vs. Targeted yield and CE. Donor vitals and procedure details did not vary with statistical significance. Device optimization did change the Platelet Yield, A: T ratio and Collection Efficiency in a statistically significant manner. Platelet Yield was 2.77×10^{11} and 3.88×10^{11} pre- and post-optimization, respectively a percent increase of 40.4% with a p-value of 0.00027.
A: T was 0.791 and 1.110 pre- and post-optimization, respectively a percent increase of 40.4% with a p-value of 0.00027. Collection Efficiency was 56.7% and 76.5% pre- and post-optimization, respectively a percent increase of 34.8% with a p-value of 0.00064.

Summary/Conclusions: This study shows how initial operational qualification of equipment as part of a QA program and partnership with the manufacturer can play an important role in the successful implementation of new devices for an institution.

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