Unlocking Potential

Spectra Optia® Apheresis System Collection Data Drives an Increase in Hematopoietic Stem Cell Yield and CD34+ Collection Efficiency for Sickle Cell Disease Patient Procedures

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Background

- Cell collections via apheresis on sickle cell disease (SCD) patients present many challenges.
- The blood of SCD patients has unique characteristics, making it difficult to separate compared to the blood of non-SCD patients.[1,2]
- These unique characteristics cause cells to separate differently in the blood of SCD patients than in the blood of non-SCD patients.[3,4]
- SCD alters blood viscosity, which affects separation and may require anticoagulant dosing changes.
- As a result, visible clumping of platelets and red blood cells (RBCs) has been reported during SCD procedures on the Spectra Optia Apheresis System.[5]
- Figures 1 and 2 show the correlation between the peripheral blood (PB) CD34+ cell precount and the number of CD34+ cells collected per kilogram via apheresis from mobilized allogeneic (allo) donors and SCD patients.
- This correlation is much stronger for the allogeneic donor population than the SCD population, which makes it difficult to predict hematopoietic stem cell (HSC) collection yields for SCD patients.
- Novel genetic therapies are emerging for SCD that require relatively large numbers of HSCs to be modified.
- Collection of peripheral stem cells by apheresis is significantly more challenging for patients who require multiple days and cycles of collection to achieve the target yield.[2]
- In a study, in some cases, HSC collections resulted in very low yields, preventing patients from receiving cellular therapy.[4]
- Cell collection via apheresis is an inherently variable process, requiring a high level of operator expertise. Reviewing patient, apheresis procedure, and collected product data allows for optimization and improved collected product outcomes.

Figure 1

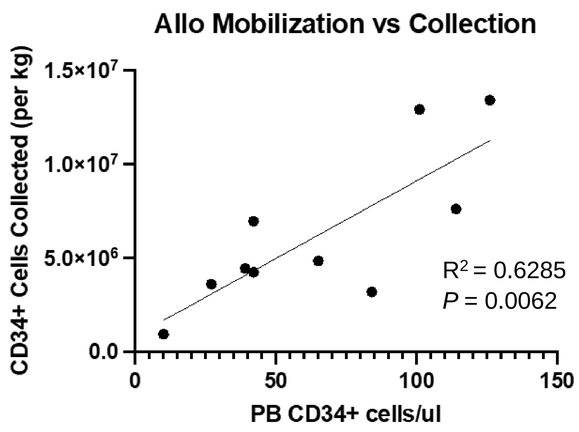
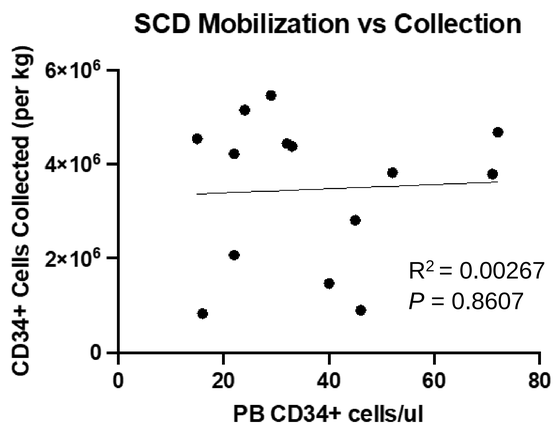


Figure 2



Methods

- A retrospective analysis of 20 continuous mononuclear cell collection (CMNC) procedures completed on SCD patients on the Spectra Optia Apheresis System was conducted to identify opportunities for optimization in future collections.
- Collection procedure data from Spectra Optia devices was reviewed and linked to patient complete blood count and measured product data for each procedure. Terumo Blood and Cell Technologies analysts reviewed various data types from each procedure: for example, blood separation efficacy and interface stability. Procedural issues, including alarms and related pauses and inlet flow rate adjustments, were also reviewed.
- Terumo Blood and Cell Technologies' data analysis findings resulted in optimization suggestions resulted in key actions for subsequent collections: cells were collected from a deeper layer within the buffy coat, and operators carefully managed inlet pump flow rates to minimize access pressure alarms and related pauses.
- CD34+ collection efficiency (CE2) was calculated to track the impact on subsequent cell collection procedures conducted on SCD patients.

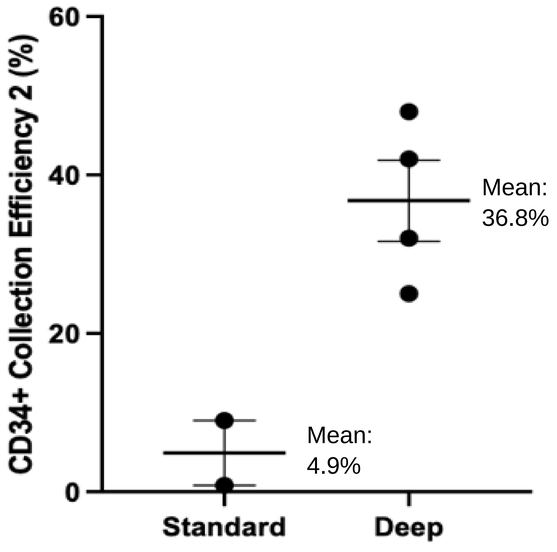
Results

- When optimization suggestions from the Terumo Blood and Cell Technologies analysts were implemented, CD34+ CE2 increased from 4.9% (range: 0.8%-9.0%) for the standard collections to 36.8% (range: 25%-48%) for those collected from a deeper buffy coat layer, as shown in Figure 3.
- The mean CE2 increased significantly ($P = 0.0169$) in the collections where cells were collected from a deeper buffy coat layer than in standard HSC collections.

Conclusion

- Because the SCD patient population is undergoing an increased number of HSC collections for cell and gene therapies, it is critical to ensure collection targets are achieved for these high-stakes procedures and patients.
- Performing data analytics on patient precounts, procedural data, and collected products can help optimize apheresis collection procedures on SCD patients and lead to higher CD34+ CE2.
- Using Terumo Blood and Cell Technologies' data analytics to track and quantify collection performance may help improve outcomes for autologous SCD collections.
- Data analytics can guide operator performance during cell collection procedures and may increase CE2, increasing the chance of success for HSC collections and related gene therapies.

Figure 3



References:

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2. Sharma A, Leonard A, West K, et al. Optimizing hematopoietic stem and progenitor cell apheresis collections from plerixafor-mobilized patients with sickle cell disease. *Br J Haematol*. 2022;198(4):740-744.
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