The impact of processing less blood with the Therakos™ Cellex® Photopheresis System for pediatric patients

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- Apheresis program started in June 2014
- Physician, program coordinators, and nurses
- Extracorporeal photopheresis used for graft-vs-host disease in bone marrow transplant patients
- Potential for solid organ transplant rejection
- As of February 2015, 8 patients have been treated with over 240 individual treatments
Mechanism of Action

• Lymphocyte apoptosis
• Immunomodulatory effect
  – Modulation of dendritic cells
  – Alterations in cytokines
  – Induction of regulatory T-lymphocytes
Therakos™ Cellex® Photopheresis System

• Newest generation
• Single, integrated, closed system
• Reduced risk of infection, cross-contamination, and patient re-infusion errors
• Decreased processing time to 1.5 hours
• Whole blood processing amount defaults to 1500 mL
• Amount based on historical data using the first (UVAR) and second generation (UVAR XTS) discontinuous system, which collected ~1500 mL after 3-6 collection cycles
Therakos™ Cellex® Photopheresis System
Treatments

• Treatment dosing and intervals have not changed significantly in 25 years
• Most regimens include 2-3 treatments per week on a weekly basis, followed by a taper
Adults vs Pediatrics

- Regimens are based on adult data
  - Limited studies in pediatrics
  - No randomized controlled studies
  - Children and adults are different
    - Differences in body size, weight, and blood volume
Overview

There is evidence that ECP provides clinical benefits as a second line therapy in acute and chronic GVHD, but there is still so much to learn...
Areas of Interest in Pediatrics

- Treatment schedules
- Whole blood processing amounts
- Changes in Biomarkers
- Prognostic factors
Where did we begin?

- Whole blood processing amounts in pediatrics
- A small number of pediatric apheresis teams decrease whole blood processing amount in smaller patients
- PCH policy
  - 1500 mL WBP for patients > 20 kg
  - 1250 mL patients 15-20 kg
  - 1000 mL for patients < 15 kg
Methods

• Retrospective review
• Patients treated from June to October 2014
• Quality control data
  – A pre-treatment CBC w/ diff obtained from the patient
  – CBC w/ diff obtained from the treatment bag prior to photopheresis
• Percentage of cells treated and cell fold enrichment was calculated for WBC, lymphocytes, and monocytes
• Independent T-test was performed to evaluate statistical significance

## Results

<table>
<thead>
<tr>
<th>Groups</th>
<th>1250 mL</th>
<th>1500 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Treatments</td>
<td>56 (43%)</td>
<td>75 (57%)</td>
</tr>
<tr>
<td>Mean WBP</td>
<td>1199 mL</td>
<td>1443 mL</td>
</tr>
</tbody>
</table>
Results

Cell Fold Enrichment

- WBC (p=0.524)
  - 1250 mL: 3.6
  - 1500 mL: 3.4

- Lymphocytes (p=0.555)
  - 1250 mL: 5.8
  - 1500 mL: 6.6

- Monocytes (p=0.023)
  - 1250 mL: 5.7
  - 1500 mL: 8.8
Results

Percent of cells treated

- WBC (p=0.000): 50% for 1250 mL and 18% for 1500 mL
- Lymphocyte (p=0.001): 76% for both 1250 mL and 1500 mL
- Monocyte (p=0.002): 74% for 1250 mL and 43% for 1500 mL
Discussion

• In terms of cell fold enrichment, increased WBP results in more efficient monocyte fold enrichment and possibly in lymphocytes enrichment
Discussion

• Despite greater fold enrichment in the 1500 mL group, targeting 1250 mL in pediatric patients resulted in a greater percent of cells being treated
Discussion

• If an adequate ECP treatment is related to the amount of cells processed, then being able to maintain an equal or greater percentage of cells treated would suggest that lower volumes processed can still allow an adequate treatment in smaller patients
Future Research

• Clinical correlation between decreased whole blood processing volumes and patient response
• Evaluating laboratory findings before, during, and after ECP treatments to identify other ways to evaluate successful ECP treatments
• Further evaluation of ECP in GvHD to determine prognostic factors and pretreatment probability of success
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