Research Design and Methods Used to Evaluate Apheresis Instrumentation and Techniques

Edwin A Burgstaler MT,HP (ASCP)
Associate Professor of Laboratory Medicine and Pathology
Mayo Clinic
Rochester, MN

ASFA & WAA Joint Conference
April, 2014
Conflict of Interest

• Consulting work for Fenwal Inc.

• Consulting work for TerumoBCT
My Background

- Started in the Blood Bank as reference lab technologist in 1975
- Worked with the IBM cell washer
- Recruited to apheresis in 1977
- Worked with Charcoal Affinity Column in 1977
- Named Apheresis Developmental Technologist in 1978
- First paper as first author in 1980
- First written and oral abstract as first author in 1982
- Evaluations were written up as abstracts and then papers
- Named Development Tech Coordinator in 2007
- Develop evaluations, comparisons, new techniques
- Oversee clinical trials
Research Considerations
Select a Project Topic

- Potential benefits?
- Potential problems or adverse effects?
- Is it feasible?
- Will there be support?
- Resources required?
- IRB approval?
- Financial considerations?
- Time requirements?
- Has it already been done?
Possible Projects
New Machines

• Photopheresis: Blood Cell Recovery and Reaction Incidence

• Evaluation of Haemonetics MCS Apheresis System for Platelet Yields and WBC Content

• Fenwal Amicus Plateletapheresis-Platelet Yields, Processing Times and WBC content
New Techniques

• Rapid Return to Shorten Intermittent Flow Apheresis Procedures

• 3 Hour vs. 4 Hour Peripheral Blood Stem Cell Collections Using Three Apheresis systems

• Use of Manual Color Monitoring to Enhance Hematopoietic Progenitor Cell collection on the Fenwal Amicus
Comparison of Instruments

• Therapeutic Plasma Exchange - a Paired Comparison of Fresenius AS104 vs. COBE Spectra

• Paired Comparison of Gambro Trima Accel vs. Fenwal Amicus Single Needle Plateletapheresis

• Comparison of Hematopoietic Progenitor Cell Collections Using COBE Spectra version 7 vs. Fenwal Amicus version 3.1 for Patients with Amyloidosis
Comparisons of Techniques

- Comparison of Four Systems in Cholesterol and Plasma Protein Removal
- Photopheresis-Comparison of Single Access vs. Double Access
- 3 Hour vs. 4 Hour Peripheral Blood Stem Cell Collection Using Three Apheresis systems
Modifications of Procedures

- Use of Manual Color Monitoring to Enhance Hematopoietic Progenitor Cell Collection on the Fenwal Amicus
- Concentration Changes to Increase Plateletapheresis Yields while Collecting Mandated Additional Bacteriological Samples
- Improving Anticoagulant Delivery of the Fenwal CS3000 by Shortening the Pump Tubing
Secondary Topics from Clinical Trials

- LAK Cell Generation; Comparison of Ficoll-Hypaque versus Light Spin
- Multiple Blood Product Collection by Apheresis with the Amicus Cell Separator
Reactions

• Photopheresis: Blood Cell Recovery and Reaction Incidence
Our Experience

• Use of the Fenwal CS3000 Plus for Collection of Mononuclear Cells for Dendritic Cell Based Immunotherapy

• In House Equipment Maintenance and Repair Saves Money
Study of Donor or Patient Populations
Research Considerations

Techniques

• Scientific Method

• Type of Study

• Other Considerations
Techniques – Scientific Method

• Define the problem or issue
• Background
• Develop a hypothesis or goal
• Materials and methods
  - Number (N)
  - Statistical methods
  - CE1 vs. CE2
• Results
• Discussion
  - Interpret the results
  - Compare to others
  - Items not covered
• Conclusion
Techniques – Type of Study

- Prospective vs. retrospective
- Paired vs. unpaired
- Randomized vs. not randomized
- Overview
- Administrative
- Evidence based care
Techniques – other considerations

• Co-investigators
  - Physician
  - Statistician
  - Experts

• Interest to others
Example of a Study
Analysis of An Award Winning Abstract Study

Topic

Paired Randomized Prospective Study of Plateletapheresis Using Fenwal Amicus versus COBE Spectra Leukoreduction System
Analysis of An Award Winning Abstract Study
Define the Problem

- Need leukoreduced platelets
- Want high yield of platelets
- Would like double products
- Shortest procedure possible
Analysis of An Award Winning Abstract Study

Background

• Spectra LRS system was new, but established
• Amicus was very new
• Wanted to compare the new systems
Hypothesis (Objectives)

Compare Amicus to Spectra LRS in regard to:

- Platelet yield
- Double product incidence
- Leukoreduction rate
- Processing time
Analysis of An Award Winning Abstract Study

Materials and Methods

Results compared:
• Platelet yield
• Collection efficiency
• Collection rate
• Processing times
• White blood cell content
Parameters:

- 20 donors
- Randomized as to order of donation
- Once per week
- Pre and Post PLT counts
- Settings currently in use
- Target yields currently in use
- The counting methods currently in use for both
- Statistics will be used for significance
Analysis of An Award Winning Abstract Study

Results

• Pre and Post PLT Counts
• Volume of blood processed
• Processing rates (ml/min)
• PLT yields
• Percent $\geq 3.0 \times 10^9$ PLT
• Percent $\geq 6.0 \times 10^9$ PLT
• Platelet collection efficiency
• Collection rates (PLT $\times 10^{11}$/min)
• Processing times
• WBC content
Analysis of An Award Winning Abstract Study

Conclusions

Both systems had:

- Consistently leukoreduced products ($<5 \times 10^6 \text{WBC}$)
- Comparable processing times

Amicus was significantly higher than Spectra LRS:

- Platelet yield
- Collection efficiency
- Collection rate
- More double products (not significant)
Example of an Abstract
PAIRIED RANDOMIZED PROSPECTIVE STUDY OF PLATELET-
APHERESIS USING FENWAL AMICUS VERSUS COBE
SPECTRA LEUKOREDUCTION SYSTEM VERSION 5. EA
Burgstaler, AA Pineda. Mayo Clinic, Rochester, MN.

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Example of Another Abstract
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PLERIXAFOR PLUS G-CSF MOBILIZATION RESULTS IN SIMILAR CD34+ CELLS TO TOTAL NUCLEATED CELLS RATIO AND NUMBER OF FREEZER BAGS AS G-CSF ONLY

Author Block:
Edwin A Burgstaler, MT, HP(ASCP), Justin D Kreuter, MD, Jeffrey L Winters, MD, Mayo Clinic, Rochester, MN, USA.

Background: Tanhehco et. al recently reported that plerixafor plus G-CSF (P+G) mobilization resulted in a lower ratio of CD34+ cells to total nucleated cells (TNC) and significantly higher number of freezer bags than chemotherapy plus G-CSF mobilization. We performed a retrospective review of P+G versus G-CSF only (G) mobilization, comparing the proportion of CD34+ cells to TNC, freezer bags required, CD34+ cell yields, and content of other cells.

Materials and Methods: Thirty consecutive patients (each group) were compared per collection and per infusion of 4-5x10^6/kg CD34+ cells. Mobilization was started with 4 days of G-CSF only. If the pre CD34+ cell count was <10 cells/μL for a single transplant (4-5x10^6/kg CD34+ cells) or <20 cells/μL for a double or triple transplant (8 or 12 x10^6/kg), P+G was initiated and collections started the next day. Patient diagnosis included plasma cell malignancy, lymphoma, and acute promyelocytic leukemia. Number of transplants planned were (P+G/G) 1/1 three, 14/13 two, and 15/16 one. The Fenwal Amicus version 3.1 was used for all collections, 5 hour endpoint, whole blood flow rates 65-90 ml/min. MNC offset settings were 1.5 or 2.3 and RBC offset was >5 ml. Median volume processed (minus anticoagulant) was not significantly different, 15.9L P+G, 16.0 L G. Infusion doses were 4-5x10^6/kg per transplant. Freezing concentration was 300x10^6 cells/ml. Estimated number of bags was determined by dividing the cryoprotected product volume by 90 ml.

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Collections

<table>
<thead>
<tr>
<th>CD34+ x10^6</th>
<th>MNC %</th>
<th>MNC x10^9</th>
<th>GranX x10^9</th>
<th>WBC x10^9</th>
<th>RBC x10^9</th>
<th>PLT x10^11</th>
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<td>80</td>
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Infusions

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s = significant  prop = proportion of CD34+ x10^6/TNCC x10^6
The mean number of collections to reach the prospective targets were: (P+G/G) 12/13, 8 = 2.1/1.7, 5 = 1.8/1.8 and 4 = 2.8/1.9. The mean number of collections to reach a target of 4-5x10^6/kg were: P+G/G 1.7/1.5.

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The mean number of collections to reach the prospective targets were: (P+G) 12/2/3; 6 = 2.1/1.7; 5 = 1.8/1.8 and 4 = 2.8/1.9. The mean number of collections to reach a target of 4-5 x 10^6/kg were: P+G 1.7/1.5.

Conclusions: The P+G mobilization did result in significantly higher pre procedure MNC counts and the collections had significantly higher yields of MNC, particularly lymphocytes than G mobilization. However, the proportions of CD34+ cells to TNC and number of freezer bags were equivalent. G mobilization did contain more CD34+ cells, but this may be due to P+G mobilization being used only in poor mobilizers.
Conclusions

Title:
PLERIXAFOR PLUS G-CSF MOBILIZATION RESULTS IN SIMILAR CD34+ CELLS TO TOTAL NUCLEATED CELLS RATIO AND NUMBER OF FREEZER BAGS AS G-CSF ONLY

Author Block:
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Body:
Background: Tanheheco et. al recently reported that plerixafor plus G-CSF (P+G) mobilization resulted in a lower ratio of CD34+ cells to total nucleated cells (TNC) and significantly higher number of freezer bags than chemotherapy plus G-CSF mobilization. We performed a retrospective review of P+G versus G-CSF only (G) mobilization, comparing the proportion of CD34+ cells to TNC, freezer bags required, CD34+ cell yields, and content of other cells.

Materials and Methods: Thirty consecutive patients (each group) were compared per collection and per infusion of 4-5 x 10^6/kg CD34+ cells. Mobilization was started with 4 days of G-CSF only. If the pre CD34+ cell count was <10 cells/ul for a single transplant (4-5 x 10^6/kg CD34+ cells) or <20 cells/ul for a double or triple transplant (8 or 12 x 10^6/kg), P+G was initiated and collections started the next day. Patient diagnosis included plasma cell malignancy, lymphoma, and acute promyelocytic leukemia. Number of transplants planned were (P+G/G) 1/1, 14/13 two, and 15/16 one. The Fenwal Amicus version 3.1 was used for all collections, 5 hour endpoint, whole blood flow rates 65-90 ml/min. MNC offset settings were 1.5 or 2.3 and RBC offset was >5 ml. Median volume processed (minus anticoagulant) was not significantly different, 15.9L P+G, 16.0 L G. Infusion doses were 4-5 x 10^9/kg per transplant. Freeze concentration was 300 x 10^9 cells/ml. Estimated number of bags was determined by dividing the cryoprotected product volume by 90 ml.

Results: Median pre procedure MNC counts were significantly higher for P+G 7.4 vs 5.1 x 10^9/L. Other pre procedure counts were similar: (P+G/G) WBC 50.2 vs 44.1 x 10^9/L, HCT 35.36, and PLT 157 vs 168 x 10^9/L. 64 and 55 collections were performed for the P+G and G groups, respectively. The median percent of lymphocytes in the collections was significantly higher for P+G (38%) than G (30%). The median collection yields are presented in the collection table and the infusion doses in the infusion table.

<table>
<thead>
<tr>
<th>Collections</th>
<th>CD34+ x 10^6</th>
<th>MNC %</th>
<th>MNC x 10^9</th>
<th>Granx x 10^9</th>
<th>WBC x 10^9</th>
<th>RBC/mL</th>
<th>PLT x 10^11</th>
</tr>
</thead>
<tbody>
<tr>
<td>P+G</td>
<td>234.2</td>
<td>80</td>
<td>47.7</td>
<td>13.5</td>
<td>63.5</td>
<td>30</td>
<td>2.0</td>
</tr>
<tr>
<td>G</td>
<td>346.7 s</td>
<td>70 s</td>
<td>37.9 s</td>
<td>14.6</td>
<td>53.5 s</td>
<td>28 s</td>
<td>1.3 s</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infusions</th>
<th>CD34+ x 10^6</th>
<th>WBC x 10^9</th>
<th>Prop %</th>
<th>Bags</th>
<th>Granx x 10^9</th>
<th>MNC x 10^9</th>
<th>Lymx x 10^9</th>
</tr>
</thead>
<tbody>
<tr>
<td>P+G</td>
<td>397.9</td>
<td>79.1</td>
<td>0.57</td>
<td>3</td>
<td>26.7</td>
<td>92.7</td>
<td>30.6</td>
</tr>
<tr>
<td>G</td>
<td>408.1</td>
<td>65.8</td>
<td>0.61</td>
<td>3</td>
<td>23.2</td>
<td>69.5 s</td>
<td>24.4 s</td>
</tr>
</tbody>
</table>

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The mean number of collections to reach the prospective targets were: (P+G/G) 12=2/3, 8 = 2/1.7, 5 = 1.8/1.8 and 4 = 2/1.9. The mean number of collections to reach a target of 4-5 x 10^9/kg were: P+G/G 1.7/1.5.

Conclusions: The P+G mobilization did result in significantly higher pre procedure MNC counts and the collections had significantly higher yields of MNC -- particularly lymphocytes than G mobilization. However, the proportions of CD34+ cells to TNC and number of freezer bags were equivalent. G mobilization did contain more CD34+ cells, but this may be due to P+G mobilization being used only in poor mobilizers.
Research Design and Methods

Conclusions

- Investigate opportunities
- Determine resources
- Perform the research
- Prepare abstracts
- Write the manuscripts