A Case Review: Collection of Hematopoietic Cells from a Baby under 10kg

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Disclosures:

- I work as a per diem Clinical Specialist for TerumoBCT.
  I train Optia New User/TPE/RBCX protocols
Objectives

• Background
• Case review
• Conclusions
Introduction

• Lurie uses Optia MNC procedure for peripheral blood stem cell harvests and donor lymphocytes for infusion since January 2015. Previously used the Cobe AutoPBSC

• accustomed to collecting a concentrated product from babies

• Use central venous access catheters (CVC) for babies

• SOP to process TBV x 4 regardless of counts

• Peripheral blood pre-CD34 is collected but not resulted until late in the collection so is useful in planning the 2^{nd} day collection if necessary or as a validation of good/poor yield
MNC collection procedure using Optia

- Sets up based on lab data entered by the operator
- Hct sets the plasma pump to set the interface
- WBC and platelet count or buffy coat thickness determines the collection preference (CP) and controls the collect pump
- We do not make any changes to the CP AKA “the scoop” of the buffy coat to fill the collect chamber
- We use same day lab values for accuracy
Lurie sets Optia to prompt when ECV reaches 15% of patient ETBV

- This suggests need for a blood or albumin prime
- Lurie rule of thumb:
  - Patients who are less < 20 kg
  - or have lower hematocrit <25% with a low weight we might blood prime
- Optia accounts for the blood prime based of the values we’ve entered: 250ml for blood prime with PRBC unit with Hct averaging 60%
- Chart illustrates the likely increase of our patient’s Hct by 1-6%. We plan to remove some of these red cells with our harvested product.
- If Optia has trouble setting the interface and alarms or you don’t see a red cell layer which you know needs to be high enough to accumulate buffy coat
- Same inverse relationship to adjust interface as Cobe.
  - If interface needs to be higher, the Hct needs to be lowered
  - If interface needs to be lower, the Hct needs to be higher
What is meant by interface: Cell separation is based on the weight and size of the cells.

plasma

Buffy coat

Red cells
Case Review:

- 14 month old baby with neuroblastoma post 2 cycles of chemotherapy
  - 78cm
  - 9.5Kg
  - ETBV = 712ml
  - WBC=59.5, Hgb/Hct=8.9/27%, platelets=512K (large)
    - Lymphocytes=0, monocytes=5, neutrophils=94
  - PBCD34+ =91 (unknown at starting time)
  - Pre-ionized calcium=1.46 mM range of 1.08 - 1.34 mM (pt on TPN overnight)
  - 9Fr Bard tunneled dual lumen existing line for chemo/TPN
  - Mobilization: GCSF 10mcg/kg daily beginning 4 days prior to Day1 of harvest
  - Target cell dose = 6 x 10⁶ CD34+/kg
Case Review (continued):

- Blood prime with 250ml PRBC (include blood warmer)
- AC ratio of 12:1 using ACD-A
- Minimum Inlet rate of 10 ml/min (achieved by increasing AC infusion rate)
- AC infusion rate of 1.2 ml/min/L TBV—Caution mode
- Administer slow infusion of calcium gluconate to maintain level
  - Start at 20 ml/hour = 37.6 mg/hour
  - Cardiac monitor with BP every 15 minutes
  - Re-checked calcium periodically
- Collect pump at 0.9 ml/min
- Collection Preference of 20 (high platelet and WBC)
Wait to see a red cell interface with buffy coat

• Some return pressure alarms in the first few minutes baby repositioned in mom’s arms then adequate functioning lines

• If we couldn’t get baby to calm and cooperate we would medicate (Tylenol, Benadryl, Ativan, Versed)
  • A very active baby can cause lines to fold. Stopping and starting effects the interface. Steady flow= steady interface and the best scoop of buffy coat into the chamber.

• We waited approximately 30 minutes before we could see it build and start “filling chamber” at 300ml (expectation 300-500ml)
Wait to fill the chamber and collect

• Can feel like an eternity
• Based on volume processed not time
• Based on counts so it could take 500-2000ml before the first harvest
• With babies this can be nerve-racking because the flow rates are so slow at 10ml/minute
What *should* I see in the collect line and the chamber?

- Peanut butter or salmon color filling the chamber
- No evidence of clumping along the interface
- A flicker in the collect line
- Possible snowflakes coming up from the chamber that do not clump in the reservoir
  
  ➢ We’re happy because we believe we’re in the buffy coat layer and platelets are being sent back to the patient
Collecting MNCs!

- We collect the first chamber at 544ml
- Assess by using the Colorgram against the collect line
  - We like the 3rd color nearing the middle
- Assess the color is your product
  - Too light or too dark could indicate intercellular contamination, increased volume, decreased purity
- It looks right... dark salmon color with a hue of optimism that there is an abundance of stem cells in the bag (still no pbCD34+ count)
Case events, a closer look

• Optia/AIM sets up the interface after a few inlet/return pressure alarms while trying to settle baby

• Started filling the chamber at 300ml

• 1st collection phase at 544 ml at the first hour mark
  • Checked Ionized calcium after 1.5 hours = 1.4 mM
  • Decreased calcium to 15ml/hour = 28.2mg/hr

• 2nd collection phase at 443 ml 50 minutes after the 1st or at hour 2

• This seems too soon and not enough volume processed...
Alarm! Red blood cells were detected too soon... What do I do?

• Uh Oh- Alarms and screaming baby all at once!
• RBC detected too soon at 334ml and only 30 minutes since previous collection
• Read the screen for possible reasons and actions
  • The interface looks like its in the correct position
  • Patient data is entered correctly
  • Increase the CP? Make it lighter?
    • Our WBC and platelet counts were high.
    • Risk: collecting too many platelets, donor platelet loss
    • Benefit: decreased red cell contamination
Troubleshooting the alarm

• Read the screen for possible reasons and actions (continued)
  • Packing factor is >20
  • Patient condition
    • Patient looks stable
    • The baby is crying and agitated; press continue
    • Maybe the interface needed to be paused to settle

• 3rd collection phase initiated by the system

• Optia proceeded to harvest at 334ml

• Color looked darker possibly 5%
Another alarm!

- “Red blood cells still seen too soon”
  - RBC detected too soon at 414 ml and 50 minutes since previous collection
    - Changed CP from 20 to 30
- Collection phase at 524ml at hour 3+
  - Ionized calcium after 3.5 hours = 1.43
- Collection phase at 648ml at hour 4+
- Added volume to be processed to 2900 ml
- Final collection phase at 556 ml
Case timeline

- Harvest at 544ml
- Harvest at 443ml
- Red cells seen too soon
- Harvest at 334ml
- Cells still seen too soon at 414ml
- Harvest at 524ml
- Harvest at 648ml
- Harvest at 556ml

- Data entry ok
- No changes
- CP increased to 30
- Added TBVP to 2900ml
Results: Harvest completed

• Processed 4x TBV (2876ml) over 314 minutes or 5.25 hours
• 120ml collected (no plasma)
• Fluid balance= +148
• Side effects: None
  • Lowest BP=93/45 appropriate for age & while asleep at hour 3.5
  • HR 150 when upset after waking up from nap
  • Ionized calcium WNL for patient
• Yield = 12.5 x 10^6 CD34+/kg
Hind sight is 20/20: What should we have done differently?

- Change CP with first alarm from 20 to 30
- Skip 3rd harvest (at 334ml)
  - Return chamber to patient
  - Flush chamber to patient to clear lingering red cells
- Lengthen time to collect volume to 600-700ml
  - Reduce overall harvest volume to < 100ml
  - Extra high platelet count might crowd the buffy coat layer and push into white cell layer
  - By allowing more volume to be processed to fill the chamber with WBC this could push the platelets out and back to the patient to reduce platelet loss
- Get a result for PB-CD34+ early to calculate TBVP and not extend
Conclusions

• Challenges
  • High platelet count over 500,000
  • High WBC count with high percent monocytes
• Alarm suggesting to change CP with the 3rd harvest phase was unexpected due to high counts discussed above
  • Likely to cause too deep of a scoop into the red cell layer
  • Likely to have contributed to a product Hct 9%
  • Likely had undesirable amount of stem cells
• Overall collection was successful for autologous stem cell rescue with plenty of extra cells for 2-3 transplants allowing for growth since cell dose is based on recipient’s weight