

Pilot Program Using An Automated Apheresis Device To Reduce Allogeneic Platelet Usage During Cardiac Surgery

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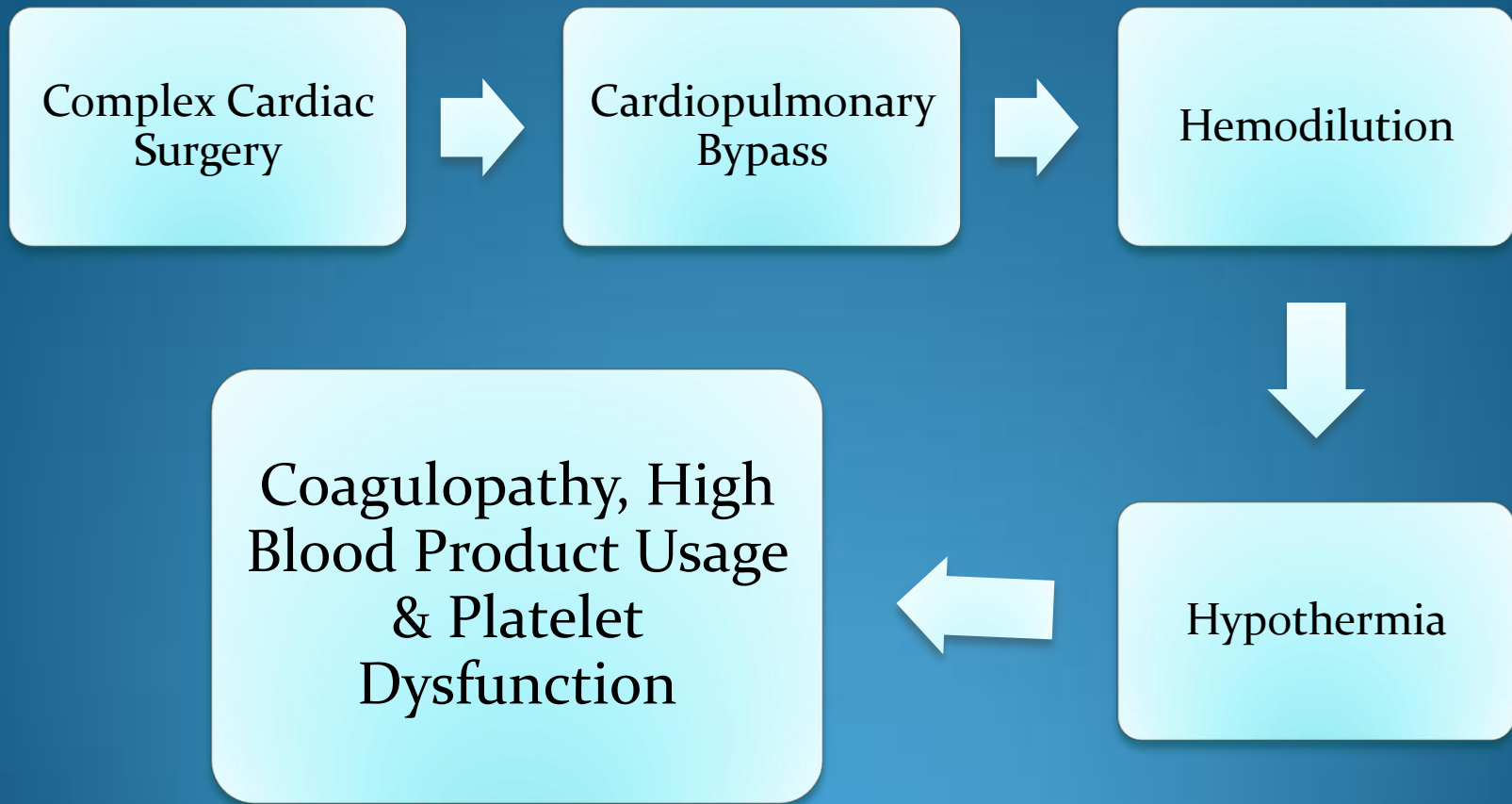
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Disclosure Statement

- TRIMA Accel[®] Automated Blood Collection System from Caridian BCT was used
- Duke Hospital received support from Caridian BCT in regards to the loan of the equipment & 10 disposable sets
- I, personally, received no monetary incentive. This also applies to all authors listed

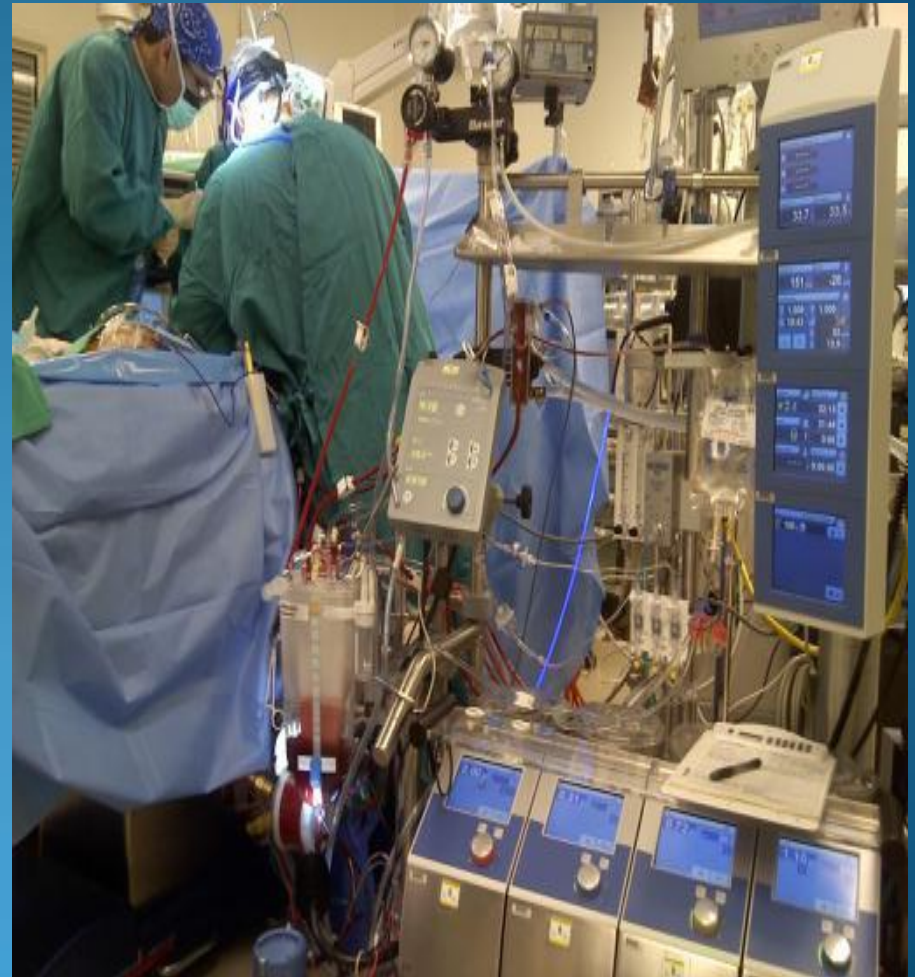
Objective : Why we did it



Harvesting blood components before exposure to CPB provides autologous re-infusion post-CPB

Cardiopulmonary Bypass (CPB)

- Utilized during open heart surgery
- Maintains patient's heart and lung function throughout surgical procedure, allowing surgeon to operate on a bloodless and motionless field



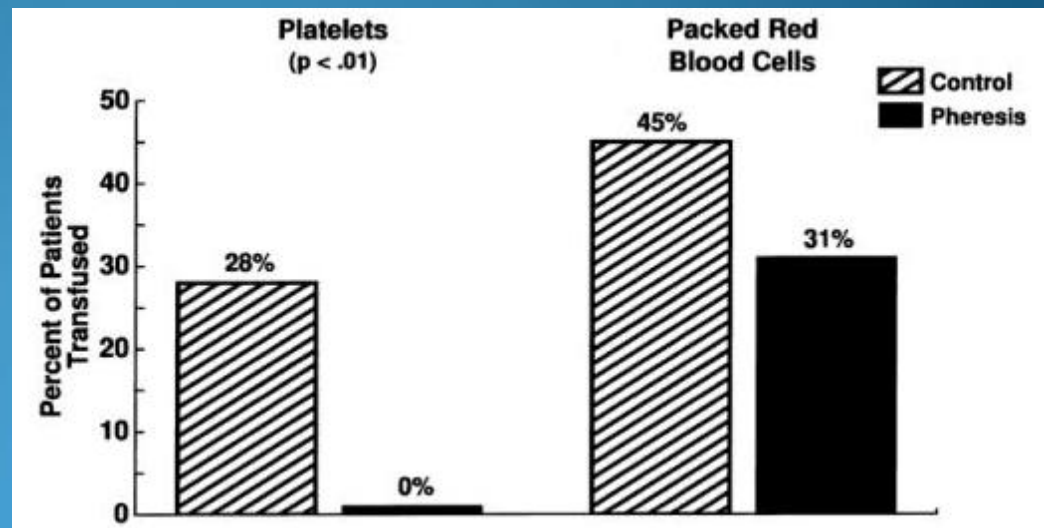
Disruption of Coagulation & Platelet Function

- Inflammatory mediators are activated with contact of a foreign surface (CPB circuit)
 - Activation of coagulation cascade – intrinsic pathway
- Heparinization
- Hypothermia
- Hemodilution
- Invasive surgical procedure – extrinsic pathway
- Platelet adhesion/aggregation
 - CPB oxygenator – sequestration of platelets
 - Decreases platelet count
 - Potentially as much as 20-65% . And typically returns to normal within 24 hours
 - As much as 58% of PLTs in circulation have impaired function.

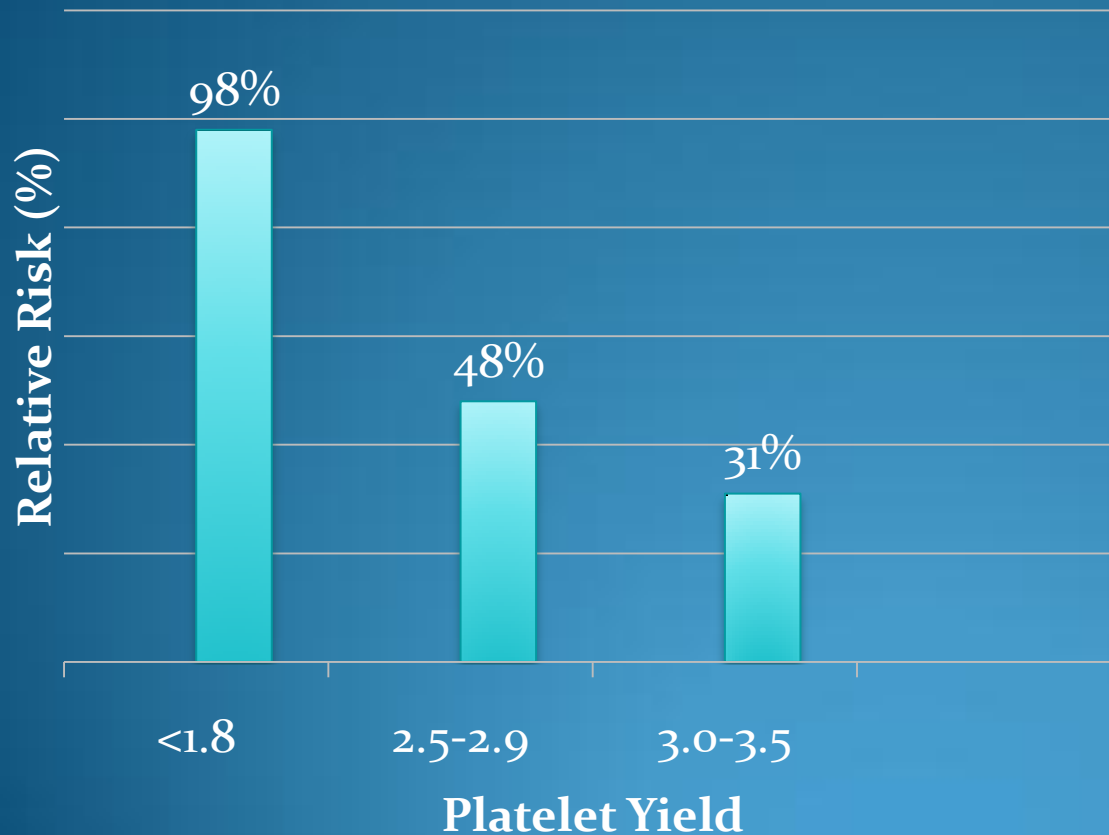
Other Studies

- 54 cardiac surgery patients studied
- 8 of 29 (28%) patients in the control group received PLTs
- 0 of 26 (0%) patients in PRP group received PLTs
- Statistically significant
 - $P < 0.01$

Mean PLT yield 6.2 ± 2.1 units



Relative Risk of Receiving Allogeneic Blood Transfusion



Cochrane Meta Analysis
Results – Review of PRP for
Minimizing Peri-Op
Allogeneic Blood Transfusion

1589 patients

22 trials

Demonstrates a higher PLT
yield may result in a lower
relative risk of receiving
allogeneic transfusions

Statistically significant ($p = 0.05$)

Apheresis Patient Selection



- Undergoing complex cardiac surgery
- Platelet (PLT) count $> 200 \times 10^9/L$
- Hematocrit (HCT) $> 32\%$
- INR within normal range
- No anti-platelet medication
 - With exception to ASA 81 mg

Apheresis Procedure Selection

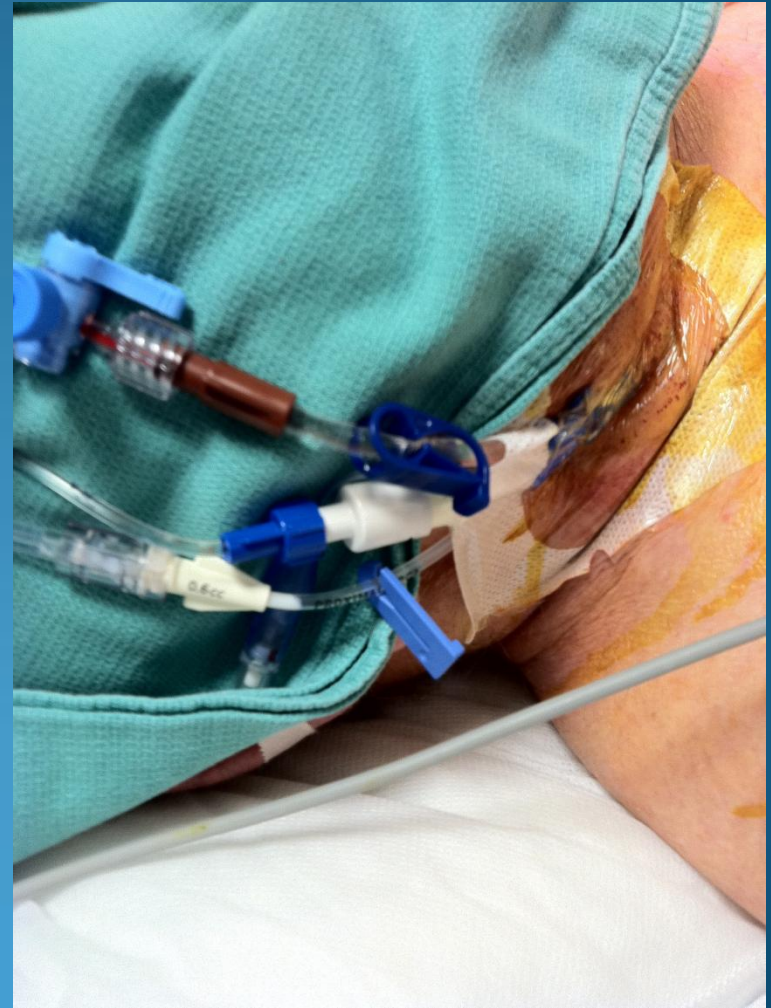
- Based upon data entered
 - Height, weight, sex, HCT, PLT count
- Choose procedure that allows for :
 - Maximal PLT yield
 - We tired to achieve a yield of at least 4.0
 - Collection time less than 60 minutes



Apheresis Patient Access

Anesthesiologist accesses patients right internal jugular (IJ) and places a large bore multiple access catheter (MAC)

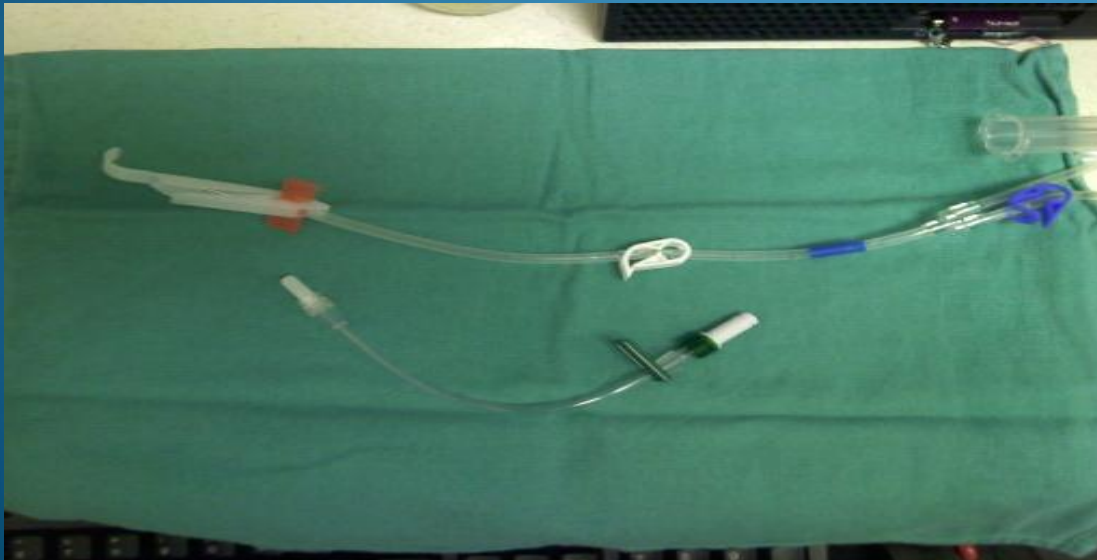
Routine procedure for cardiac surgery



Apheresis Tubing Kit Modification

Use 7" standard bore catheter extension set

Splice extension onto tubing kit, removing the needle and adding a male connection



Apheresis Data Collection

- Patient Information
 - Height, weight, HCT, PLT count
- Product Information
 - Predicted PLT yield, plasma volume, run time
- Transfusion Information
 - Units received in OR
 - Units received post-op

Duke University Medical Center CASE# _____

Apheresis Procedure Record

Surgeon:		Case:	
Provider:		Access 1:	Access 2:

Donor Information

Date		Sex (M/F)	
Patient		Height (cm)	
Patient ID		Weight (kg)	
Serial Number	1T00660	TBV (ml)	
Blood Type	NA	Hgb / Hct	
Time Started		Platelet Pre-count	

Supply Information

	Manufacturer	Lot Number	Expiration Date
Disposable Set	CardinalBCT		
ACD-A	Medsep		
AS-3	CardinalBCT		
Saline			

Run Information

	Platelet Yield (x 10 ¹¹)	Plasma Vol. (ml)	RBC Vol. (ml)	Run Time (min)
Initial Prediction				
Adjusted Values				
Adjusted Values				

End of Run Summary

Total AC Used (ml)		Post Hematocrit (%)	
End of Run Time		AC to Donor (ml)	
Length of Run (min)		Blood Volume Processed (ml)	
Platelet Post-count X 1000/ μ L		Total Saline Used (ml)	

	Total Volume (ml)	Yield (x10 ¹¹)	Volume of AC in product (ml)
Platelet			
Plasma		N/A	
RBC		N/A	

Pre-Harvest Ca:	Post-Harvest Ca:	Total CaCl given:	
On CPB Platelet:	Post-Harvest Hb:		

Comments/Alarms

Additional Transfusion Needs:

	PRBC	FFP	Cryo	Platelets	Other
In OR					
24hrs Post-Op					

Apheresis Product ID/Storage

- Product Identification
 - Labeled with patient ID label (armband)
 - Date/time of collection
 - Volume/yield
- Storage of Products
 - Products remain at head of the bed near Anesthesia for duration of procedure so it is readily available post-CPB

Our Results

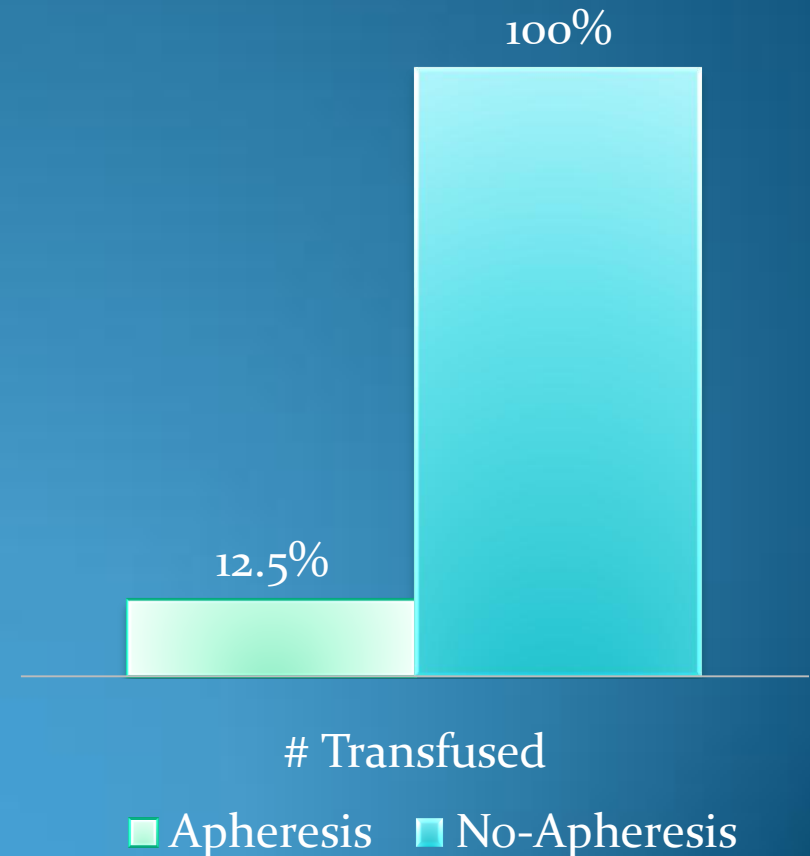
Procedure #	Actual Run Time (min)	Predicted PLT Yield ($\times 10^{11}$)	Actual PLT Yield ($\times 10^{11}$)	Actual Plasma (ml)
1	58	6.0	6.0	513
2	43	8.0	8.0	267
3	42	7.0	7.0	356
4	57	4.0	4.0	618
5	63	7.0	6.5	213
6	58	5.0	5.0	629
7	56	6.0	6.0	406
8	88	6.0	6.0	511
Mean (SD)	58 (14)	6.1 (1.2)	6.1 (1.2)	439 (155)

10 total procedures in pilot program

2 not completed (system test error, leak detection) and not included

Our Results: Allogeneic Transfusions

- Of the 8 apheresis procedures completed, only 1 patient required 1 allogeneic PLT transfusion
- Compare to 8 similar procedures, which apheresis was not used, all patients not only received allogeneic PLTs but multiple allogeneic PLT transfusions (mean 3.0 doses)



Conclusion

- Based upon our initial results, intra-operative collection of autologous platelets/plasma appears to be safe and feasible in this patient population
- Provides an additional blood conservation option
- Additional studies are needed to verify initial findings and demonstrate reproducibility & significance

References

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