FROZEN AND DEGLYCEROLIZED RED BLOOD CELLS

CLINICAL PRACTICE GUIDELINE (CPG) TRAINING

Joint Trauma System Trauma Care Educational Program

Disclosure/Disclaimer

- No financial disclosures
- The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army or Air Force Medical Department, the U.S. Army or Air Force Office of the Surgeon General, or the Department of Defense or the U.S. Government.

Purpose

- These slides are based on the JTS Frozen and Deglycerolized Red Blood Cells CPG which guidelines for the use of frozen deglycerolized red blood cells (DRBCs) in combat theater.
- Date of CPG publication: 11 Jul 2016
- JTS CPGs are evidence-based guidelines developed by subject matter experts in the military and civilian communities. CPGs are compiled from DoD Trauma Registry data, health data abstracted from patient records and after action reports.
- Information contained in this presentation is only a guideline and not a substitute for clinical judgment.

Agenda

- Summary
- Background
- Clinical Use of DRBCs
- Documentation
- Performance Improvement (PI) Monitoring
- References
- Appendices
- Contributors

Summary

- FDA-approved DRBCs are typically used at Role 2 and higher Medical Treatment Facilities (MTFs) but could be used in the pre-hospital setting after thawing and deglycerolization if appropriately transported.
- Previously frozen deglycerolized red blood cells (DRBCs) can be used interchangeably with liquid-stored red blood cells in transfusions.
- Sep 2023 update: clarification of deglycerolization process of one blood unit on an Automated Cell Processor-215.

Background

- DRBCs are derived from 450-500 mL of whole blood through a multistep process.
  - The red blood cell components are separated and frozen in a cryoprotectant (40% w/v glycerol.)
  - The frozen red blood cells (RBCs) are stored at minus 65°C or colder for up to 10 years.
  - Once thawed for use, the blood is washed to deglycerolize creating the DRBCs.

Background

- Frozen blood has been in use since 1956 and is FDA approved for transfusion for up to 14 days when processed on the Haemonetics Automated Cell Processor ACP215.
  - When using multiple ACP215s, maximal throughput from initial thawing to unit release/availability can average up to 1 U every 2-3 hours per device.
- FDA-approved DRBCs are typically used at Role 2 or higher medical treatment facilities but can be used in the prehospital setting.
- No statistically significant difference in outcomes or transfusion-related complications have been identified.

Background

Massive Transfusion with DRBC compared to Standard Massive Transfusion

	p value	
Overall Mortality	0.241	63 cases/63 controls matched for age, ISS, total RBC within 24 hours, patient category, gender
Complications	**p value**	
Transfusion Reaction	N/A	No cases in sample
Coagulopathy	0.271	63 cases/63 controls matched for age, ISS, total RBC within 24 hours, patient category, gender, initial base deficit, initial temperature, initial INR
Renal Failure	0.57	60 cases/60 controls matched for age, ISS, total RBC within 24 hours, patient category, gender, extremity injury
DVT	0.753	23 cases/23 controls matched for age, ISS, total RBC within 24 hours, patient category, gender, extremity injury
Respiratory Failure	N/A	No cases in sample
Sixty-three patients in Afghanistan were identified between Jan 10 - Sep 11 as having a massive transfusion which included deglycerolized blood (DRBC). A control population of 525 patients with non-DRBC massive transfusion from the same time period and theater was found in the DoD Trauma Registry (DoDTR) to provide comparison of overall mortality.		
CONCLUSION: With the data available, there appears to be no statistical difference in mortality outcome in theater for patients receiving deglycerolized blood (DRBC) as part of a massive transfusion when compared to patients receiving no DRBC as part of a massive transfusion. Additionally, there seems to be no significant difference between massive transfusions with DRBC and without DRBC in the development of complications for transfusion reaction, coagulopathy, renal failure, deep vein thrombosis (DVT), or respiratory failure.		
Completed 23 March 2012		

Clinical Use of DRBCs

- The primary indication for the use of DRBCs is to supplement liquid RBCs during surge periods of increased transfusion requirements.
- DRBCs may be used in lieu of liquid-stored RBCs for all RBC transfusion requirements including massive transfusions.
- The physician may order use of DRBCs, but in practice the medical treatment facility will use DRBCs and liquid-stored RBCs interchangeably.

Clinical Use of DRBCs

Each unit of DRBCs:

- Should be considered equivalent to a fresh unit of RBCs.
- Have a 14-day shelf-life upon deglycerolization.
- Contain more than 80% of the RBCs present in the original unit of blood.
- Provides the same physiologic benefits as liquid RBCs.
- Carries the same expectation for post-transfusion survival as liquid-stored RBCs.
- Contains significantly lower concentrations of proteins associated with non-hemolytic transfusion reactions.

Clinical Use of DRBCs

- Thawing and deglycerolization are time-consuming processes.
  - Takes at least 35 minutes to thaw.
  - Takes 60 minutes to deglycerolize one unit in the ACP215.
- In periods of predictable operational requirements, it may be prudent to pre-thaw and deglycerolize several units to avoid the preparation delay.

Documentation

- Clinical documentation for a frozen and deglycerolized transfusion is the same as for a liquid transfusion. In addition:
- The laboratory will establish and maintain a process to document DRBC transfusions in a manner that will facilitate future evaluation of receipts. Documented items should include at least:
  - Blood component identified
  - Date of blood component received in frozen state
  - Date of thaw/deglycerolization/additive process and resulting expiration date
  - Casualty identifiers
  - Date of transfusion
  - Transfusion indication
  - Transfusion reaction/outcome

PI Monitoring

- Intent (Expected Outcomes)

  All patients who receive DRBC transfusions have accurate documentation in the medical record of the quantity of transfused blood and any transfusion-related adverse events.

- Performance/Adherence Measures

  In patients who were transfused DRBCs, there was accurate documentation in the medical record as to the quantity of blood transfused and any transfusion-related adverse events.

- Data Source
  - Patient Record
  - DoDTR
  - CENTCOM blood bank logs
  - Theater Medical Data Store

References

1. Emergency War Surgery Handbook, Fourth United States Revision, 2013, Borden Institute, US Army Medical Department and School, Ft. Sam Houston, Texas.
2. Glycerolization and deglycerolization of red blood cells in a closed system using the Haemonetics ACP215, Naval Blood Research Laboratory, C. Robert Valeri, http://www.nbrl.org/SOP/ACP215/ACP215All.html
3. Hampton DA, Wiles C, Fabricant LJ, Kiraly L, Differding J, Underwood S, Le D, Watters J, Schreiber MA. Cryopreserved red blood cells are superior to standard liquid red blood cells. J Trauma Acute Care Surg. 2014 Jul;77(1):20-7; discussion 26-7. PMID:24977750
4. Fabricant L, Kiraly L, Wiles C, Differding J, Underwood S, Deloughery T, Schreiber M. Cryopreserved deglycerolized blood is safe and achieves superior tissue oxygenation compared with refrigerated red blood cells: a prospective randomized pilot study. J Trauma Acute Care Surg. 2013 Feb;74(2):371-6; discussion 3767. PMID:23354227

Appendices

- **Appendix A**: Massive Transfusion with DRBC Compared to Standard Massive Transfusion
- **Appendix B**: Additional Information Regarding Off-label Uses in CPGs

Contributors

- LTC Andrew Cap, MC, USA
- LTC John Badloe, MC, Netherlands
- LTC Thomas Woolley, UK
- MAJ Nicolas Prat, MC, France
- COL (ret) Richard Gonzales, MC, USA
- LTC (ret) Wilbur Malloy, MC, USA
- LTC Audra Taylor, MC, USA
- LTC Jason Corley, MC, USA
- Heather Pidcoke, MD, PhD
- LTC Michael Reade, MC, Australia
- COL Martin Schreiber

Slides: Lt Col Andrew Hall, USAF, MC

Photos are part of the JTS image library unless otherwise noted.