

FEATURE ARTICLES

In Cold Blood

A Feasibility Study on Maintaining, Storing, and Transporting Cold Whole Blood by a Special Forces Unit

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ABSTRACT

Transfusion of blood products at the point of injury is among the most critical interventions for trauma patients. Since WWI, the U.S. Military has been attempting to perfect the methods of transfusion to limit preventable deaths on the battlefield. While whole blood is now universally recognized as the premier blood product and a myriad of guidelines/protocols exist advocating for its use by SOF medics and providers far forward in the deployed setting, there is no cohesive guidance for blood product administration within the Continental United States (CONUS). This is despite recent data demonstrating that accidents are among the leading causes of death in non-deployed Servicemembers. Under current doctrine, only FDA-approved cold-stored whole blood should be used while in the U.S. With this in mind, our unit developed this feasibility study to determine whether a Special Forces Battalion would be able to maintain, store, and transport FDA-approved cold-stored whole blood within appropriate temperature ranges in order to support blood transfusion at the point of injury and treat hemorrhagic shock in the CONUS training environment. This was a very small and simple study. However, it did demonstrate that maintaining appropriate temperature ranges is feasible, even as blood is transported to and from multiple sites of training. This is a critical first step in ensuring that appropriate blood products can be staged with and transported by our well-trained medics and providers supporting SOF training objectives within the U.S.

KEYWORDS: *whole blood; special operations; cold blood*

Introduction

Blood transfusion has been attempted throughout history but typically failed until the early 20th century for a multitude of reasons, including knowledge of ABO typing, blood storage requirements, and the means by which to transfer blood from the donor to the recipient. Several key advances were made in the U.S. in the years leading up to WWII. In 1913 Klimpon and Brown showed that clotting could be delayed in donor blood

by collecting it in paraffin-coated glass cylinders. That same year, Lindemann devised a multiple syringe method, which kept syringes in constant motion from donor to recipient. They also used sharp-pointed metal needles to enter the vein directly through the skin rather than previous methods which exposed the vessel by incision. Later, tubing and stopcock devices simplified the process further. In 1914–1915, the introduction of sodium citrate anticoagulant allowed blood to be stored for days, which ended the need for the donor and recipient to be in the same room. As a result of U.S. involvement in the first European War, innovation in transfusion medicine continued. Shortly after arriving in France, physicians Lee and Robertson developed what many consider the world's first blood bank.¹ During WWII the use of blood plasma, a component of whole blood (WB), emerged as an essential component in treating wounded soldiers.²

Recognizing the impact that blood products could have on preventable deaths, the Armed Services Blood Program (ASBP) was established to help meet the need for blood in the deployed setting. The Vietnam War was the first major engagement in which this program was used and, throughout the conflict, the ASBP collected nearly 1.8 million units of blood in support of warfighters. This was the first time that every unit of WB used to support a war was voluntarily donated by military personnel, their dependents, or civilians employed at military installations, and not through civilian organizations.³

In the years between conflicts, several studies demonstrated that prolonged hemorrhagic hypotension was associated with microvascular injury and marked extracellular fluid deficits. Evidence at the time was thought to show that these deficits could be corrected by isotonic crystalloids in volumes of two to three times the estimated volume of blood loss due to forfeiture of interstitial fluid from the extravascular space. Unfortunately, this treatment trend led to the overuse of crystalloids, and during this time it was common for severely bleeding patients to receive up to 5–10L of crystalloids before any blood product administration.³

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Lessons learned over the next several decades, including through U.S. involvement in the Global War on Terror, demonstrated a shift in focus back to blood products for resuscitation of hemorrhagic shock, with WB emerging as the fluid of choice when it is available.⁴⁻⁷ Typed and matched WB is primary in the non-emergent, hospital setting, though low-titer O type blood is now recognized as the standard of care across the Advanced Trauma Life Support (ATLS) and Joint Trauma System (JTS) protocols for prehospital or emergency trauma care. Product Component therapy at a 1:1:1:1 ratio (packed red blood cells [pRBC], platelets, plasma, CRP) remains an acceptable option when WB is unavailable.^{8,9} Intuitively, as the body loses WB, WB should replace it. This is borne out in current literature as well. However, there are many logistical challenges associated with WB on the battlefield, given the need for either immediate use, or tightly temperature-controlled storage.

The Ranger O Low-Titer (ROLO) program, one well publicized SOF-led initiative, sought to mitigate barriers to WB far forward on the battlefield. ROLO depends on drawing of units of WB from Rangers who have been pre-screened as having low-titer O type blood. For the purposes of this and other Department of Defense (DoD) programs, *low titer* is defined as blood group O, with IgM, anti-A, and anti-B titers <1:256.¹⁰ Under a ROLO protocol, once a massive transfusion scenario takes place, pre-identified Ranger donors serve as a walking blood bank of fresh whole blood (FWB) for purpose of resuscitating critically wounded unit members. This protocol has become highly praised and was recognized by the Army Materiel Command as the individual military winner of the annual Army's Greatest Innovation Award in 2014. It has been effective in saving the lives of combat casualties in at least one documented case, in Wardak Province in 2020.¹¹ Despite the overwhelming success of the ROLO protocol, there are significant barriers to its broad application to all units, even within SOF.

While JTS clinical practice guidelines (CPGs) state that FWB donors have not shown significant decrements in military-relevant task performance following donation,¹⁰ other studies argue that although negative physiological effects on the individual donor are minimal, they claim consensus on the fact that performance is temporarily reduced.¹² In the heat of battle, it is instinctively unfavorable to return Servicemembers who have recently donated blood to a situation where they have a higher likelihood of becoming casualties themselves. If injured, they would begin with the disadvantage of having less blood volume than they would otherwise have had. Moreover, JTS CPGs suggest that, due to the potentially chaotic conditions in which FWB such as ROLO is used, there is an increased risk of transfusion-transmitted infections (e.g., HIV, hepatitis B or C, syphilis), and an increased risk of clerical errors leading to major mismatches. For SOF units structured or immediately supported by platoon or company-sized elements, these costs and considerations might be offset by the size of the available donor pool and accompanying manpower. Though some SOF units are routinely organized into elements of 4–12 Operators, even temporarily removing a portion of the fighting force represents the potential for critical degradation in capability to perform continuing operations.

Special Operations Command (SOCOM) at large has established a Special Operations Low-Titer O Blood (SOLO) program. While this protocol ultimately supports the use of a walking blood bank program with low-titer O whole blood

(similar to ROLO), it also places emphasis on using existing DoD systems to support the drawing, testing, labeling, and storing of blood rather than relying solely on walking blood banks.¹³ The SOLO protocol recognizes that walking blood bank–procured FWB is not an FDA-licensed product and, therefore, should not be thought of as a primary method for meeting CONUS blood needs. It reiterates that walking blood bank FWB has an increased risk to forces when compared to FDA-approved cold whole blood (CWB) due to the latter's risk of transfusion-transmitted infections and increased risk of clerical errors leading to transfusion mismatch.¹⁴

As medics and providers with significant SOF experience, 2/1 SFG(A) Med recognizes that there is rarely a single solution to a complex issue such as point of injury blood transfusion. Unit structure, operational setting, and geographic location will affect medical practice and Commanders' responses to risk. Guidelines from CoTCCC, JTS, SOCOM, and other organizations provide a litany of deployed protocols ranging from obtaining blood/blood products from the ASPB supply, to pre-screened low-titer O type blood drawn as needed, to the establishment of walking blood banks organic to the force. The same is not true for the CONUS environment. Despite current data suggesting that 32% of non-overseas deaths of active-duty Servicemembers occurred due to accidents,¹⁵ there is currently no guidance on storage and transfusion of blood products for SOF elements in the CONUS setting. As a result of this paucity of guidance, very few SOF units routinely carry blood or blood products on training missions within the U.S., regardless of risk level or proximity to definitive care. It is our belief that this has led to training scares and violates the military mantra of “train as you fight.” FWB donated from emergency unit walking blood banks is part of training in Special Operations Combat Medic (SOCM)-producing courses and re-trained and assessed at the refresher and team level; autologous FWB transfusion for the purpose of training is commonplace throughout SOF and beyond. Conversely, proper maintenance, transport, and transfusion of CWB is rarely discussed and exercised, despite its improved safety profile and often improved practicality.

Study purpose

Understanding that walking blood bank procured FWB does not answer the organizational concerns of Special Forces ODA and USSOCOM guidance favoring prioritization of ASBP-supplied, FDA-approved CWB. Also considering additional quality restraints when practicing in the U.S., the medical section at 2/1 SFG(A) developed a feasibility study to determine if the organic capability existed to store and transport CWB to potential points of injury within CONUS. While conducting typical unit training, SOF Operators brought CWB to the training sites where the medics tracked the product's refrigerated lifespan. We hypothesized this capability would be feasible and that demonstrating success would lead to additional studies and pilot programs, facilitate novel methods of blood procurement to mitigate training risk in the CONUS pre-hospital setting, and improve our medics' competence in working with CWB in any setting.

Methods

Three male volunteers aged 25–41 years were selected from 2Bn 1SFG(A) Support Company. Their selection was based on gender, volunteerism, and the criteria that they had not

donated blood in the past 60 days. For the purposes of this study, no blood typing was performed, TTDs were assessed for using only MODs and Genesis (EMR) screening, and there was never a planned protocol for this blood to be transfused autologously or otherwise.

Using a standard 18Gx1 ¼ safety IV catheter and saline lock, 3 units of FWB were drawn from the three subjects. Blood was collected and stored in Fenwal Blood-Pack Unit bags. Each unit consists of a primary container with 63mL of citrate-phosphate-dextrose (CPD) solution containing 1.66g sodium citrate (dihydrate) USP, 1.61g dextrose (monohydrate) USP, 188mg citric acid (anhydrous) USP, 140mg monobasic sodium phosphate (monohydrate) USP (lot number FM24B20022 EXP Date 27 February). The alkalinity of pH may have been adjusted with sodium hydroxide. Each collection bag was filled to between 440–450mL weighed on a digital scale (Taylor, Oak Brook, IL) at the time of collection. Each unit was drawn at 1020hrs on 31 October 2024 and put into one of two cold storage containers. Units 1 and 2 were brought down from room temperature and then 9.2°C starting at 1100hrs on 31 October 2024 and reached a storage temperature of 3.1°C by 1500hrs that same day.

For the storage and cooling of units 1 and 2, a SO-LOW environmental Equipment Laboratory Refrigerator was used, and temperatures were measured using a LabQuest 3 digital laboratory thermometer (Vernier, Beaverton, OR). Temperature was maintained between 1.7 and 6°C inside the refrigerator. Unit 1 was also established as the test unit which would be transported in a portable cooling/storage container by designated 18Ds conducting training off site. The portable storage container used was BloodBoxx Tactical (Safeguard Medical Huntersville, NC) and temperatures were maintained between 4 and 6°C while outside the refrigerator.

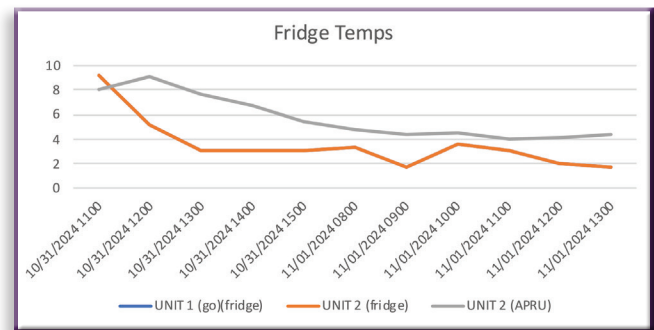
Temperatures were monitored the entire time using the same LabQuest 3 digital laboratory thermometer. Units were then returned to the SO-LOW refrigerator upon completion of training. Unit 3 was brought down from room temperature to 8°C

and ultimately reached and held a temperature of 5.4°C from 1100–1500hrs on 31 October 2024 using a APRU 6L Autonomous Portable Refrigeration Unit (Delta Development Team, Tucson, AZ). Unit 3 was held in the APRU for the duration of testing at a constant temperature between 4.1 and 4.7°C. On day 1 of testing, all temperatures were recorded every hour from 1100 until 1500hrs ensuring all units reached the appropriate storage range. On each following day, all temperatures were recorded at 0800, 1300, and 1500hrs. When unit 1 was taken out for training, it was placed in the BloodBoxx and monitored every hour on the hour until it was returned to the SO-LOW refrigerator. Data were collected on all units to include temperature, times, and methods of storage. Additionally, the APRU inherently records and reports internal temperature continuously, including if power is lost, indicating that the unit is no longer at the desired temperature range.

Results

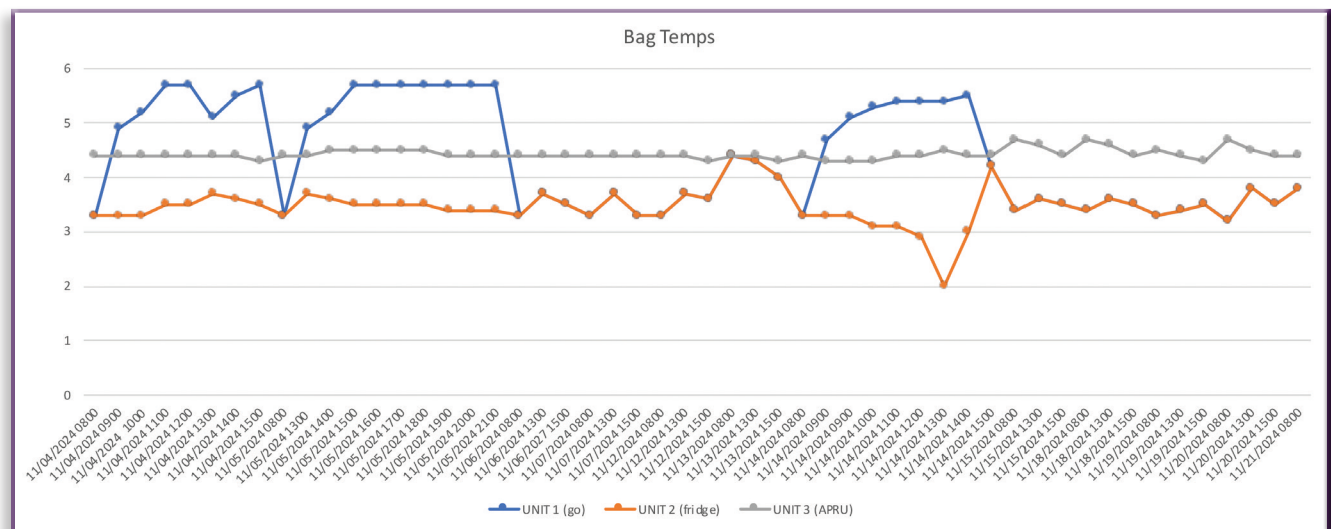
At no point during the testing did any unit of blood leave the desired temperature range above 6°C. Unit 1, while it was in the BloodBoxx at training sites, did have temperature elevations exceeding the temperature of the other two units, which were in powered containers, though it never reached a temperature greater than 6°C (Figures 1 and 2).

FIGURE 1 Unit temperature, first 26 hours.



*Due to units 1 (blue) and 2 (orange) being measured in the same SO-LOW Laboratory Refrigerator, the temperature graph for each is obscured by the other.

FIGURE 2 Unit temperature, duration of study.



*Unit 1 experienced the greatest ranges in temperature variation, this correlates with the times at which it was removed from the SO-LOW Refrigerator and placed in the storage container. At points where the blue line cannot be visualized, it is obscured by the graph of unit 2 and so was at the same temperature as the APRU.

Discussion

This was a very small, simple study using only three units of non-typed, non-ASBP drawn WB from non-screened volunteer donors, conducted simply to determine whether maintaining CWB/blood products at appropriate temperatures with equipment organic to a Special Forces battalion was feasible during transportation to potential locations of injury throughout the shelf-life of the storage bag.

As expected, there were variations in temperatures for those bags removed from fixed (electronically powered) refrigeration units, but no incidents that would have led to “wasting” of products. This study demonstrates an internal validity of our ability to appropriately manage cold blood if procured. Additional blood storage devices in the form of APRUs, Blood-Boxx, and purpose-built blood refrigerators will be required if these findings are to be expanded and applied at a larger scale.

The process of procuring FDA-approved WB products for real-world use during training emergencies in the U.S. is the next significant hurdle. Coordination for scheduling blood donation events at the unit level and as well as coordination with local ASBPs will be required to support this advancement of care. An ancillary, but advantageous outcome may be an increased supply of the unfortunately depleted supplies of donor blood for Armed Service Blood Banks (ASBB) at large and contingency blood supplies also throughout the multiple combatant commands they support. As it stands today, multiple regulatory processes overseen by the FDA, ASBP, and other governing bodies limit the ability of blood products that go unused by SOF units to be rotated back into the military hospitals’ use cycle. For clarity, if a hospital or donation center issues blood to a SOF unit, they must consider it “wasted” since they will not be allowed to accept its return under most circumstances. As hospitals and blood banks are charged with ensuring the best use of this scarce resource, this may serve as a barrier to routine issuing of WB to SOF Operators. With this study demonstrating the ability of SOF medics to store and handle blood at appropriate temperatures throughout its shelf-life, and the subsequent development of a pilot program between Armed Services Blood Bank Center – Pacific Northwest and 2nd Bn 1st SFG(A) to incentivize donations and implement continuous access to CWB at JBLM, it is our hope that a discussion can be initiated about allowing hospitals to accept unused blood back from SOF units and, by extension, further remove some of the barriers in access to CWB at the point of injury in CONUS training environments.

Conclusion

The results show there were no cases of mishandling or requirement to waste blood products prematurely due to temperatures falling outside of appropriate ranges. This demonstrates the feasibility of maintaining CWB and other cold-stored blood products at the operational level in SOF, which brings us one step closer to putting this life-saving treatment in the hands of our well-trained medics and providers at the point of injury for use on severely injured Operators at training events in CONUS.

Disclosures

The authors have indicated they have no financial relationships relevant to this article to disclose.

Disclaimer

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Inside this Issue:

- › FEATURE ARTICLES: Maintaining, Storing, and Transporting Cold Whole Blood
- › fNIRS-differentiated Marksmanship Performance
- › Double-Trunk Mask for Efficient Oxygen Delivery
- › A Review of JSOM Articles on Ultrasound Use by SOCM
- › End-user Assessment of i-view
- › Arctic or Extreme Cold Casualty Care Considerations
- › IN BRIEF: Tool to Evaluate Tactical Combat Casualty Care in the Cold
- › CASE REPORTS: Intraoral Neuroprosthesis for PTSD-Associated Nocturnal Behavior Disorder
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