Volumetric control of whole blood collection in austere environments

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INTRODUCTION: Fresh whole blood transfusions are a powerful tool in prehospital care; however, the lack of equipment such as a scale in field situations frequently leads to collections being under- or overfilled, leading to complications for both patient and physician. This study describes two methods for simple, rapid control of collection bag volume: (1) a length of material to constrict the bag, and (2) folding/clamping the bag.

METHOD: Whole blood collection bags were allowed to fill with saline via gravity. Paracord, zip-tie, beaded cable tie, or tourniquet was placed around the bag at circumferences of 6 to 8.75 inches. A hemostat was used to clamp folds of 1 to 1.5 inches. Several units were drawn during training exercises of the 75th Ranger Regiment with volume controlled by three methods: vision/touch estimation, constriction by paracord, and clamping with hemostat.

RESULTS: Method validation in the Terumo 450-mL bag indicated that paracord, zip-tie, and beaded cable tie lengths of 6.5 inches or clamping 1.25 inches with a hemostat provided accurate filling. The volume variance was significantly lower when using the beaded cable tie. Saline filling time was approximately 2 minutes. With the Fenwal 450-mL bag, the beaded cable tie gave best results; even if incorrectly placed by one/two beads, the volume was still within limits. In training exercises, the use of the cord/clamp greatly reduced the variability; more bags were within limits.

CONCLUSIONS: Both constricting and clamping allow for speed and consistency in blood collection. The use of common cord is appealing, but knot tying induces inevitable variability; a zip/cable tie is easier. Clamping was quicker but susceptible to high variance and bag rupturing. With proper methodological training, appropriate volumes can be obtained in any environment with minimal tools.
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Rapid exsanguination from extremity and noncompressible torso hemorrhage continues to be the leading cause of preventable death on the battlefield.[1,2] Recognizing the need to provide physiologic support until surgical care would be available, the Committee on Tactical Combat Casualty Care (TCCC) recommended the use of blood or blood components at the point-of-injury (POI).[3] To meet this challenge, the 75th Ranger Regiment instituted a protocol using Group O low titer universal donors for fresh whole blood (FWB) transfusions at the POI.[4] Training on whole blood collection and administration has also been introduced during the advanced leaders 'course at Fort Sam Houston, Texas, to enable the noncommissioned officer conventional medic to deliver group-specific FWB during TCCC.

When a whole blood transfusion is required and there are no stored blood units available on site, emergency "buddy transfusions" are performed in which blood is collected and transfused within 6 hours.[5] The Armed Services Blood Program collects 450 mL (±10%) of whole blood during donations (or 585 g total bag mass with lower and upper limits of 526.5 grams and 643.5 g).[6] The Armed Services Blood Program also uses the Genesis blood collection mixer (GenesisBPS, Ramsey, NJ) to aid in determining when a donor bag is full. Scales are not available at the POI owing to logistical issues including a lack of space and power supply. The Joint Theater Trauma System FWB Clinical Practice Guidelines (CPGs) state that a Terumo single blood bag should be filled to a mark on the bag.[6] However, some Terumo blood bags are not available in austere environments owing to specialized storage requirements. The lack of clinical tools and supplies creates a difficult environment for accurately collecting whole blood. Drawing too little blood can cause citrate toxicity once transfused, leading to myocardial depression or coagulopathy,[7] while overfilling can lead to coagulation within the bag from an insufficient ratio of anticoagulant to blood. Unchecked, a collection bag can fill to more than 700 mL of blood, which in addition to being detrimental to the patient, can prove adverse to the donor as undocumented, excessive volumes are removed.

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While in the field, the standard practice of using a bulky scale to determine collection volume is not suitable, and thus simpler methods are needed to reliably collect blood. Current field techniques of estimation include wrapping 9.5 to 11 inches of parachute cord around the waist of the collection bag (a method recommended by manufacturers of blood donation kits, although the length of the cord is manufacturer dependent); observing the appearance of the bag, with dimpling on the edges while lying flat or when holding by the hole from which it hangs; or filling to the point where there is an air/fluid level above the corners of the bag when holding by the hole from which it hangs.

Because of the nebulous nature of these estimation techniques, new methodologies, which underscore the importance of obtaining rapid, accurate measures of blood volume in the field, should be explored. Here, we provide two methods that are simply and quickly executed, that reliably restrict collection to the appropriate volume, and that are cost-effective for large-scale implementation: (1) constricting the center of the collection bag with a length of cord, zip-tie, or tourniquet and (2) folding and clamping a segment of bag material with a hemostat or other clamp.

METHODS

Method Validation Studies in Terumo Collection Bags

Initial proof of concept tests were conducted using a 1-L bag of saline welded to the tubing of a Terumo Teruflex whole blood collection bag (450 mL volume; Terumo BCT, Lakewood, CO) and allowed to fill via gravity (Figure, Supplemental Digital Content 1, http://links.lww.com/TA/A917). The mass of the bag was measured throughout filling with a Midrics I scale (Sartorius, Bohemia, NY); no backflow (as measured by loss of mass) was observed in any sample. The final volume was verified with a graduated cylinder.

To prepare for the constricting cord method, the cord was marked at a specific length (empirically determined to be between 6 and 7 inches for this bag) and tied around the center of the collection bag using a simple knot. The bag was flattened within the confines of the cord so as not to be curving with the cord. Alternatively, one of two plastic ties was marked at the desired length and placed around the collection bag; one was a standard zip-tie (which should be cut off once the collection is complete), and the other was a beaded cable tie that locks into place and can be easily removed. As an additional banding technique, a Velcro-fastening tourniquet (Raptor IV, North American Rescue Products, Inc, Greer, SC) was marked at the appropriate spot and wrapped around the center of the bag. For the clamping method, the bottom of the bag was folded upward for a specific length of overlap (between 1 and 1.5 inches) and subsequently clamped using a locking medical hemostat. After tying or clamping, the saline bag was suspended approximately 18 inches above the surface, and the locking clamp was opened to allow for flow via gravity into the collection bag.

The rate of collection was monitored for each test. These tests were repeated for accuracy ($n \geq 6$ for each).

Minimal Training Laboratory Trials

After determining which measurement for the first set of methods provided the most consistent and accurate outcomes, 12 laboratory technicians were allowed to perform each of three techniques after a brief training session: (1) tying a 6.5-in length of parachute cord around the central short axis, (2) zipping a 6.5 inch zip-tie around the central short axis, and (3) clamping 1.25 inch of bag material with a hemostat and gauze (to protect the bag). Bags were allowed to fill for a specific duration based on doubling the observed filling time in the pilot studies: 6 minutes each for the parachute cord and zip-tie and 4 minutes for the hemostat clamp.

Commercial Solutions on Fenwal Collection Bags

Two additional laboratory studies were conducted using devices supplied by medical kit manufacturers: beaded cable ties and medical wristbands. The Fenwal 450-mL single-blood pack unit bag (currently in use for all Army medics) was evaluated with both devices, and the 500-mL primary container from a sample diversion kit (Fenwal, Lake Zurich, IL) was used with the beaded cable ties. The 450-mL bag required a length of 6.5 inches for the beaded cable tie; collections of saline were done for lengths of 6.25, 6.5, and 6.75 inches ($n = 6$ each). The medical band worked best when affixed at the 7.8-inch hole ($n = 6$); spacing between the holes was too wide to warrant data collection at other lengths beyond a quick observation that the target was not reached. In the 500-mL bag, pilot efforts indicated that a length near 8 inches was required to reach the target fill volume; collections with saline were done with lengths between 7 and 8.75 inches in 0.25-inch increments ($n = 6$ each).

Evaluation of Volumetric Control Methods in Combat Medic Training

During training sessions, special operations combat medics and nonmedic rangers were allowed to choose one of three volumetric control methods (cord tied in a knot, hemostat clamp on bag fold, or estimation by sight/touch) as they practiced FWB transfusions; the resulting donor bags were weighed upon completion of the donation, and these filled bag total masses were recorded rather than actual fill volumes. All trials were completed during medic-specific training under the supervision or direction of a physician. The scales used were chosen from the following: High Precision Digital Kitchen Scale, Z3000-Surge (ZIEIS, Apple Valley, MN), Eat Smart Precision Pro Digital Kitchen Scale (ESKS 01;02;07;08, Healthtools LLC, Mahwah, NJ), Primo Scale (P115, Escali, Burnsville, MN), or Glass Food Scale (3842 N-21, Taylor Precision Products, Oak Brook, IL). All scales were evaluated for accuracy using Precision Steel Balance Scale Calibration Weight Kit (Neewer Technology Ltd, Guangdong, China).

Statistical Analyses

Statistical analyses were performed with Microsoft Excel and GraphPad Prism. Median fill volumes/masses were calculated for each length in every constriction method along with the 25% and 75% percentile ranges for the median; Kolmogorov-Smirnov tests of normality were conducted on all data sets. Wilcoxon signed rank tests were used to compare median collected volumes/masses to target values. Variances

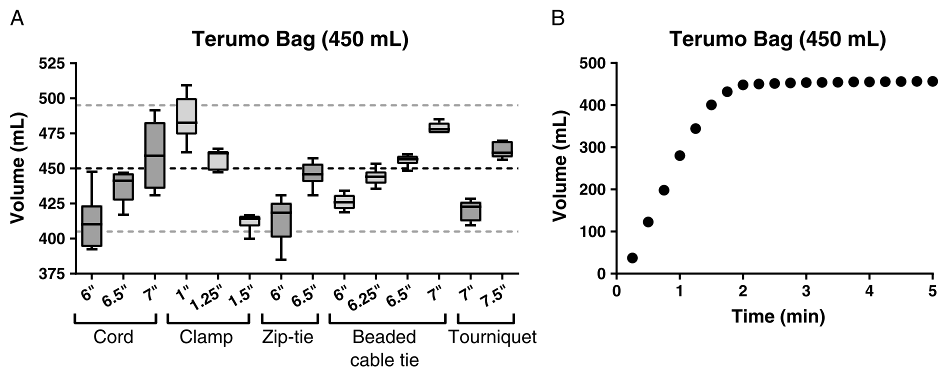

Figure 1. (*A*), Method development studies were conducted using saline to fill a Terumo collection bag; this enabled the determination of which methods and associated measurements provided fill volumes that were within acceptable ranges (target volume shown with *black dashed line* with acceptable minimum and maximum shown with *gray dashed lines*). Box and whisker plots with median volumes and 95% confidence intervals are shown. See Table 1 for descriptive statistics. (*B*) A representative sample's collected saline volume at discrete time points during the collection using the 6.5-inch zip-tie for constriction illustrates diminishing returns; by 2 minutes, the collected volume has gone from 0 to 448.1 mL, while at 5 minutes, it has only climbed to 456.5 mL.

between corresponding methods within an individual trial were measured using the Bartlett test for equal variances. The χ^2 test for independence was used to determine relationships between collection method and categorical level of filling, and contingency data were calculated to determine expected categorical patterns.

RESULTS

This section describes results of two sets of studies. The tests performed in the laboratory using saline as a filling agent are described in three subsections: (1) initial methodological validations using Terumo collection bags, (2) trials with support personnel who were naive to the technique before brief training, and (3) a final set of studies using Fenwal collection bags and best-performing constriction methods. Each of these studies only required a small sample size because of the relatively invariable nature of the methodology. The other set of studies was conducted during the 75th Ranger Regiment medic training in which whole blood was collected into Fenwal bags using one of three volumetric control methods; larger sample sizes were collected because of variability associated with both personnel (primarily trainees) and blood collection procedures (including differences between donors).

Method Validation Studies in Terumo Collection Bags

Multiple methods and variations within those methods were tested for functionality, repeatability, and ease of use. These initial studies showed that the use of a cord, zip-tie, beaded cable tie, tourniquet, or hemostatic clamp all proved to be straightforward; the primary nonquantitative result was that although the clamp seemed to be the easiest method to implement, it had the risk of puncturing the bag and had difficulties with precision and repeatability, since slight deviations in orientation had a large impact. The zip-tie, beaded cable tie, and tourniquet were easier to accurately provide a banding constriction than tying a knot in a cord. Variances for the different lengths within a given method were not found to be statistically different.

For the tied cord around the Terumo collection bag, lengths of 6, 6.5, and 7 inches were tested (n = 5 or more for each); the median collection volume for each was 410.2, 441.2, and 458.9 mL, respectively (Fig. 1A). Data were verified to be distributed normally. Confidence intervals and the Wilcoxon signed rank test were used to evaluate each length's accuracy to the target goal of 450 mL (Table 1). The 6-inch cord resulted in underfilling of some bags. The 6.5- and 7-inch cord lengths resulted in median fill volumes very close to the

TABLE 1. Statistical Results From Proof-of-Concept Trials Indicate Best Constriction Methods via Median Collected Volume and Confidence Intervals

Method	n	Median (mL)	25% Percentile	75% Percentile	CV (%)	*p*
Cord						
6 inches	7	410.2	394.0	423.7	4.61	0.016*
6.5 inches	6	441.2	427.1	446.6	2.64	0.031*
7 inches	5	458.9	435.6	483.0	5.37	0.63
Hemostat						
1 inch	6	482.4	474.2	500.2	3.40	0.031*
1.25 inches	6	460.8	448.4	462.4	1.60	0.16
1.5 inches	6	414.1	408.7	416.3	1.50	0.031*
Standard zip-tie						
6 inches	6	418.4	400.7	425.6	3.97	0.031*
6.5 inches	6	446.0	440.3	453.4	1.99	0.44
Beaded cable tie						
6 inches	6	418.7	421.0	431.2	1.31	0.031*
6.25 inches	6	435.4	439.2	448.0	1.34	0.063
6.5 inches	6	448.5	453.2	459.1	0.91	0.063
7 inches	6	475.2	475.2	482.7	0.81	0.036*
Tourniquet						
7 inches	5	422.6	412.3	426.4	1.81	0.063
7.5 inches	5	461.3	457.9	469.6	1.31	0.063

*Significant at alpha = 0.05 level.

p value calculated from Wilcoxon signed rank test for the hypothesis that each median is significantly different from 450 mL.

450-mL mark (and all within the acceptable range), but the median volume following 6.5-inch length constriction was shown to be significantly different from 450 mL, while the 7 inch length constriction was not significantly different. This discrepancy is reflective of the larger interquartile range coefficient of variation in the 7-inch cord test.

With the hemostat clamp, folds of 1, 1.25, and 1.5 inches were made at the bottom of the bag and clamped in place before filling (n = 6 for each). Larger fold lengths reduced the available filling volume; the median collection volumes for the 1-, 1.25-, and 1.5-inch clamped folds were 482.4, 460.8, and 414.1 mL, respectively (Fig. 1A). Data were not found to be distributed normally in the 1.25-inch folded samples (four of the six data points were tightly clustered), but it was the only fold length that resulted in a filling volume, which was not significantly different from 450 mL (Table 1). Variance was very low for all three of these measures, illustrating the tight volume control a clamping technique offers when performed carefully.

The use of a zip-tie was very similar to that of a tied cord, except that the application process was much quicker. Median fill volumes with 6- and 6.5-inch zip-tie lengths were 414.6 and 445.8 mL, respectively (Fig. 1A). Data were distributed normally (n = 6 for each). One bag was underfilled with the 6-inch zip-tie length, while all 6.5-inch zip-tie wrapped bags were within the acceptable range. The median was significantly different from 450 mL for 6 inches, while a length of 6.5 inches was consistently accurate (Table 1).

The beaded cable tie was affixed in the same manner as the zip-tie. Because of the precise nature of the manufacturing of these devices and the resultant low variability with their use, fill volumes with four distinct cord lengths were observed to determine which was best. Median fill volumes for 6-, 6.25-, 6.5-, and 7-inch lengths were 418.7, 435.4, 448.5, and 475.2 mL, respectively (Fig. 1A). Data were distributed normally (n = 6 for each). Each of these lengths resulted fill volumes within the acceptable range, although only the 6.25- and 6.5-inch lengths had median fill volumes, which were not significantly different from the target of 450 mL (Table 1).

Longer lengths of 7 and 7.5 inches were used with the tourniquet to accommodate the effects of the wider band (compared to cord or zip-tie), which provides additional constriction. Median fill volumes for 7- and 7.5-inch tourniquet bindings were 420.0 and 463.2 mL, respectively (Fig. 1A). Data were distributed normally; both medians were significantly different from the target 450-mL volume, although *p* values for both were only slightly above the 0.05 level (Table 1). No bags were under- or overfilled with either 7- or 7.5-inch lengths.

While the numerical results may not exactly match those that would be obtained from an actual blood donation (incorporating pressure and viscosity), the time of saline filling was carefully documented during the 6.5-inch zip-tie trials (representative sample shown in Fig. 1B); these data shed light on the point of diminishing returns during collection, and future studies should be conducted with whole blood under the various constriction methods to determine an appropriate collection time, which is both sufficient to fill the bag and short enough to accommodate the timely need. The rapid rate of filling over the first 2 minutes of the artificial collection suggests that increased pressure is not required to fill a constricted bag.

Minimal Training Laboratory Trials

The use of unaffiliated laboratory technicians enabled us to observe the constriction and filling process as conducted by minimally trained individuals. Personnel were briefly instructed on how to apply the individual devices and then allowed to perform the following methods: 6.5-inch length of parachute cord around the center of the bag's short axis, 6.5-inch zip-tie length in the same fashion, and 1.25 inches of material at the bottom of the bag folded up and clamped with a hemostat (n = 12 for each method). Median fill volumes for cord, zip-tie, and

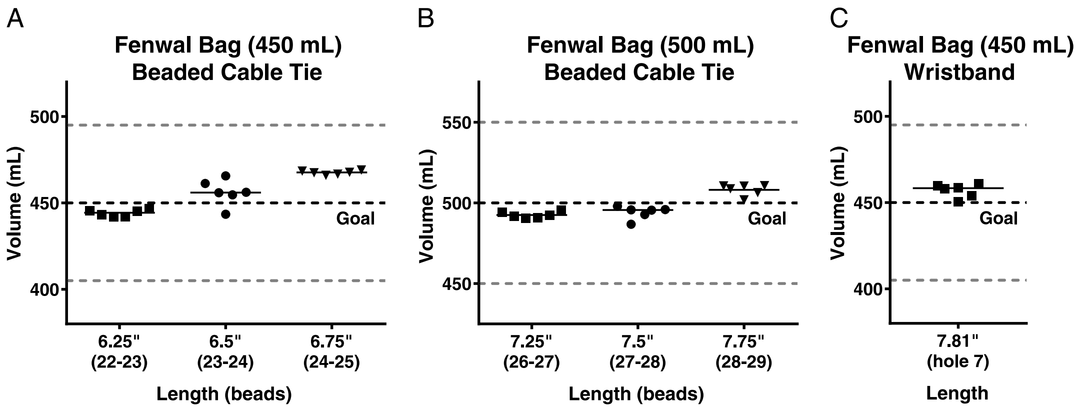

Figure 2. Laboratory trials using the Fenwal collection bags constricted by the beaded cable ties as the best method from initial studies were conducted to determine the appropriate measurements for the actual product used by the medic in the field. (*A*) A 450-mL *collection bag* required a 6.5-inch length of *cable* (between Beads 23 and 24) to properly constrict the bag. The variance was low, and adjacent bead *lengths* of 6.25 and 6.75 inches both resulted in acceptable volumes, indicating that even a minor mistake in the measurement (as might be common under high stress) would not result in a poor blood collection. (*B*) Similarly, the 500-mL collection bag was tested with the beaded cable tie, and while lengths between 7 and 8.75 inches resulted in acceptable median collection volumes, a length of 7.5 in. (between Beads 27 and 28) resulted in the median closest to the target volume (only 7.25, 7.5, and 7.75 inches shown). (*C*) An acceptable collection volume was found when the plastic *wristband* was snapped in the seventh hole (approximately 7.81-inch length).

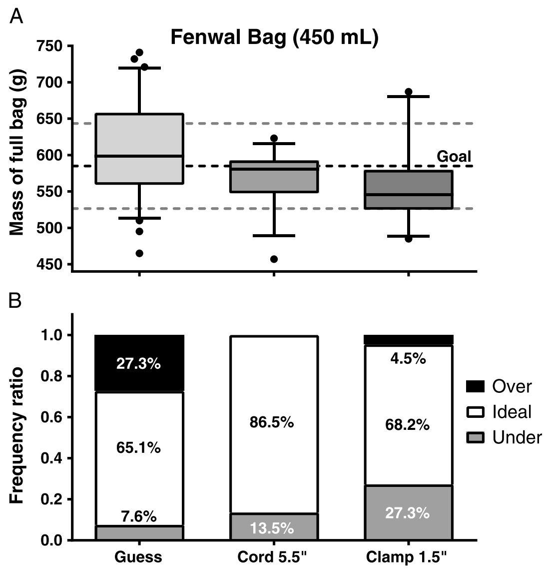

Figure 3. (*A*) Blood collection during training sessions with Army Rangers was conducted using three methods: tied cord, hemostat clamp, and the guess method, where the trainee stopped collection with his/her judgment as to when the bag seemed full (using touch and sight). Masses of the full bags were recorded rather than actual fill volumes. The variance with the guess method was large, with several over- and underfilled bags, although the median mass was close to the target. The cord provided an accurate median mass, but several bags were underfilled. The *clamp* produced a greater degree of underfilling. *Box and whisker plots* with median volume and 95% confidence intervals are shown. Table 2 shows descriptive statistics. (*B*) Observed frequency ratios of fill volume categories from rangers' medic training trials. The cord method had no overfilled bags and the best percentage of bags within the acceptable range, while the clamp method had a large fraction of underfilled bags. Table 3 shows actual values observed in the trial versus those expected under these ratios.

hemostat were 468.5, 463, and 455.1 mL, respectively (Figure, Supplemental Digital Content 2, http://links.lww.com/TA/A918). With these three techniques, there were no overfilled bags; there was one occurrence of underfilling in the 1.25-inch clamped fold. Variances in each group were determined to not be significantly different, but the zip-tie seemed to be the most repeatable (coefficient of variation = 3.11%). None of the three techniques was demonstrated to result in a median fill volume statistically different from 450 mL (Table, Supplemental Digital Content 3, http://links.lww.com/TA/A919).

Finalized Constriction Configurations in Fenwal Bags

As part of the final laboratory tests, the Fenwal collection bags were constricted with the beaded cable ties, thus matching the best outcome from early trials with the bags supplied to the US Army medics. With beaded cable ties, Fenwal 450-mL bag fill volumes were measured at 6.25, 6.5, and 6.75 inches (n = 6 each) and demonstrated very low variance (Fig. 2A). All three lengths resulted in volumes within the acceptable limits, indicating that even in high-stress situations, setting the constriction to either side of the 6.5-inch segment of the cable tie will not be the cause of a poor blood draw.

Similarly, the Fenwal 500-mL bags were constricted with the beaded cable tie at lengths ranging from 7 to 8.75 inches (n = 6 each), with lengths of 7.25, 7.5, and 7.75 inches falling closest to the target; 7.5 inches resulted in a median that was closest to the target volume (495.6 mL; Fig. 2B). Very low variance was observed, with all three lengths resulting in fill volumes within acceptable limits.

At the end of the study, one additional solution was explored by constricting with a plastic snapping wristband. When affixed around the 450-mL Fenwal bag using the hole that gave a length of approximately 7.81 inches, the median fill volume (458.4 mL) was closest to the target goal with a low degree of variance (n = 6; Fig. 2C).

Combat Medic Training Trials

In training sessions with combat medics and nonmedic rangers, three blood collection procedures using Fenwal bags were attempted: (1) guessing based on visual and touch cues (n = 66), (2) use of a 5.5-inch parachute cord tied around the central short axis of the bag (n = 37), and (3) a hemostat clamp on a 1.5-inch fold at the bottom of the bag (n = 22).

Data for the guess and clamp measurements were normally distributed, but the 5.5-inch cord (shorter than the determined optimal length from laboratory trials) resulted in some skewing toward underfilled bags (Fig. 3A). Blood bag masses obtained using the cord method had lower variance than the guess or clamp methods (Table 2).

Despite the medians of these methods (598.5 g for guess method, 581.0 g for 5.5-inch cord, and 545.5 g for 1.5-inch clamped fold) falling close to the target of 585-g total bag mass, each was determined to be significantly different from that goal (Table 2). Of note, the 5.5-inch cord seemed to have a very accurate median collection mass (581.0 g), but the 95% confidence interval for that method ranged from 554.9 to 580.2, falling below the target of 585 g; this was due to the non-normal distribution of the data from that method.

Blood bags with total mass under 526.5 g after collection are considered underfilled; bags greater than 643.5 g are overfilled. In light of these constraints, it makes sense to conduct a nonparametric approach to the analysis. The blood bag mass data was partitioned into three categories for fill level (over, under, or ideal) and three categories for blood bag collection procedure (guess, cord, or clamp) as seen in Table 3. Calculated frequency ratios for each category from this trial are illustrated

TABLE 2. Statistics were Collected From Bag Filling Trials With Combat Medics and Nonmedic Rangers Using Three Methods

Method	n	Median (g)	25% Percentile	75% Percentile	CV (%)	*p*
Guess	66	598.5	559.3	741.0	10.23	0.031*
Cord, 5.5 inches	37	581.0	547.5	592.5	6.68	0.031*
Hemostat, 1.5 inches	22	545.5	525.0	579.5	8.19	0.008*

*Significant at the alpha = .05 level.

The variance with the guess method was large, while the cord method had an accurate median but was skewed toward underfilling in its distribution. *p* values calculated from Wilcoxon signed rank test for the hypothesis that the median is significantly different than 585 g.

TABLE 3. Fill Levels From Rangers' Medic Training That Were Observed Are Compared to Expected Values Calculated From χ^2 Expectation Tests

	Blood Bag Collection Procedure					
	Guess		Cord		Clamp	
	Observed	Expected	Observed	Expected	Observed	Expected
Over	18	10.03	0	5.62	1	3.34
Ideal	43	47.52	32	26.64	15	15.84
Under	5	8.45	5	4.74	6	2.82

The χ^2 test of independence showed that the relationship between collection procedure and fill level category was significant; $\chi^2(4, n = 125) = 20.17$, $p = 0.0005$. For the guessing method, more bags were overfilled and underfilled than expected; for the clamp and cord methods, there were more overfilled bags than expected but fewer underfilled bags than expectation showed.

in Figure 3B. The χ^2 test of independence was performed to examine the relation between blood bag collection procedure and fill category, and the relation between these variables was significant, χ^2 (4; n = 125) = 20.17, $p = 0.0005$. The largest contributor to the χ^2 statistic was the guess method, which had a larger than expected proportion of overfilled bags. The clamp method contributed more than expected to the underfilled category. The cord method contributed less than expected to the overfill category and more than expected to the ideal category.

As shown in Figure 3B, using the cord method led to the highest percentage of bags in the ideal category—86.5% versus 65.1% for guess and 68.2% for clamp methods, suggesting that the cord method was the most reliable of the three.

DISCUSSION

There are concerns with both overfilling and underfilling the donor bag. Overfilling can cause coagulation within the donor bag, which could cause flow issues and, even with a 170- to 260-μm filter, potential for thromboembolism. Underfilling is a lesser concern; citrate toxicity is rare with a single transfused unit, and careful monitoring of blood calcium levels should be in place during massive transfusion protocols.[8]

Laboratory tests using these methods showed that there was low variance in fill volume in most cases; variance in rangers' medic training trials was attributed to trainee inaccuracies rather than inherent methodological problems. This indicates the importance of ensuring proper training and including premeasured tools to avoid user error.

Even with careful marking, tying paracord around the bag precisely proved to be difficult; medics suggested the use of a marked zip-tie. This method was more reliable; agitation (as specified by clinical practice guidelines) ensured that the blood was filling evenly in the bags. In laboratory trials, the plastic tie methods (including zip-tie, beaded cable tie, and snapping wristband) were the best performing solutions. The zip-tie is faster to operate and has no risk of slipping, although it is more difficult to remove; the beaded cable tie offers the benefits of locking into place with easy unlocking after a collection, but has a small risk of slipping out of place. The beaded cable tie also has the added benefit of being easily premarked on one or two consecutive beads so that the user knows exactly where to place the lock. The plastic wristband has the benefit of being easy to manufacture with only a single hole for snapping, making it impossible to misalign, but depending on the material can stretch as the bag fills resulting in some variance.

The clamping method, while easier to implement than tying a cord, had the added risk of perforating the bag, particularly if the hemostat had teeth. In trials, medics suggested the use of gauze to prevent any metal from contacting the bag. However, the variance with this method was higher, indicating that small differences in the placement of the clamp could result in significantly different collection volumes.

Use of the tourniquet was easy and could be fine-tuned in training to be accurate, but it is likely that scenarios requiring a buddy transfusion will also necessitate the use of a tourniquet; this device should be saved for its originally intended purpose.

Our tests with minimally trained personnel show that constricting the center of the 450-mL bags at a 6.5-inch circumference is an easy, efficient, and reliable method for controlling the collection volume when a scale is not available (Figure, Supplemental Digital Content 4, http://links.lww.com/TA/A920). The method functions simply by reducing the total available volume within the bag under standard gravity flow pressure. While both constriction and clamping methods are effective, there are some key differences. The cord method proved to be more reliable in achieving the acceptable range of blood volume. Tying with a cord requires more preparation time (somewhat mitigated with the use of the zip-tie or beaded cable tie), but these materials should already be available to any soldier. Clamping is quicker to set up, but the equipment to clamp the bag would not be as widely available and poses the risk of rupturing the collection bag if handled particularly roughly (although in testing the bags proved very durable with only one puncture event).

The degree of underfilling observed in both the cord and clamp trials with the rangers' trainees leads to two primary conclusions. First, the exact measurements to best accommodate the ideal volume must be rigorously determined for each technique, device, and bag type. Second, training with the chosen methods should include not only the accurate application of the device, but also the required time to fill with the device in place. The filling time study highlighted in Figure 1B should be replicated for blood rather than saline solution with a minimum fill time determined empirically. The constriction methods may also differentially affect the pressure required to fill the bag for blood with its higher viscosity, and adjustments may be needed to ensure appropriate filling.

The administration of blood or blood components in the prehospital combat setting may be as important to saving lives in combat as quick evacuation to a surgeon,[9] but it certainly does not replace surgery or the importance of rapid evacuation. Several prospective and retrospective studies have demonstrated the benefits of FWB,[10–13] although there are limited data on FWB in the prehospital setting. However, data clearly support the usage of blood components before hospital.[14–17] By ensuring that prehospital providers and medics are able to accurately determine when a blood donation bag is adequately full, the usage of FWB can be expanded, ensuring that more lives could be saved.

AUTHORSHIP

M.A.M. designed the study, collected, analyzed, and interpreted data, reviewed the literature, and wrote the manuscript. A.D.F. designed the study, collected data, reviewed the literature, and wrote the manuscript. G.C.P. collected and analyzed data and performed a critical review of the manuscript. E.A.M. designed the study, interpreted data, and performed a critical review of the manuscript. W.B.M. analyzed and interpreted data. W.B.K. collected data. S.C.N. contributed to the writing and performed a critical review of the manuscript. A.P.C. designed the study, interpreted data, reviewed the literature, contributed to the writing, and performed a critical review of the manuscript.

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DISCLOSURE

The authors declare no conflicts of interest.

REFERENCES

1. Eastridge BJ, Mabry RL, Seguin P, Cantrell J, Tops T, Uribe P, Mallett O, Zubko T, Oetjen-Gerdes L, Rasmussen TE, et al. Death on the battlefield (2001–2011): implications for the future of combat casualty care. *J Trauma Acute Care Surg*. 2012;73(6 Suppl 5):S431–S437.
2. Bellamy RF. The causes of death in conventional land warfare: implications for combat casualty care research. *Mil Med*. 1984;149(2):55–62.
3. Tactical Combat Casualty Care Guidelines for Medical Personnel 2017 [January 31, 2017]. Available from: http://cotccc.com. Accessed April 12, 2017.
4. Fisher AD, Miles EA, Cap AP, Strandenes G, Kane SF. Tactical damage control resuscitation. *Mil Med*. 2015;180(8):869–875.
5. Strandenes G, De Pasquale M, Cap AP, Hervig TA, Kristoffersen EK, Hickey M, Cordova C, Berseus O, Eliassen HS, Fisher L, et al. Emergency whole-blood use in the field: a simplified protocol for collection and transfusion. *Shock*. 2014;41(Suppl 1):76–83.
6. Joint Trauma System, United States Army Institute of Surgical Research. Fresh whole blood transfusion [October 24, 2012]. Available from: http://www.usaisr.amedd.army.mil/cpgs.html. Accessed April 12, 2017.
7. Sihler KC, Napolitano LM. Complications of massive transfusion. *Chest*. 2010;137(1):209–220.
8. Giancarelli A, Birrer KL, Alban RF, Hobbs BP, Liu-DeRyke X. Hypocalcemia in trauma patients receiving massive transfusion. *J Surg Res*. 2016;202(1):182–187.
9. Kotwal RS, Howard JT, Orman JA, Tarpey BW, Bailey JA, Champion HR, Mabry RL, Holcomb JB, Gross KR. The effect of a golden hour policy on the morbidity and mortality of combat casualties. *JAMA Surg*. 2016;151(1):15–24.
10. Nessen SC, Eastridge BJ, Cronk D, Craig RM, Berséus O, Ellison R, Remick K, Seery J, Shah A, Spinella PC. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. *Transfusion*. 2013;53:107S–113S.
11. Garcia Hejl C, Martinaud C, Macarez R, Sill J, Le Golvan A, Dulou R, Longin Roche C, De Rudnicki S. The implementation of a multinational "walking blood bank" in a combat zone: the experience of a health service team deployed to a medical treatment facility in Afghanistan. *J Trauma Acute Care Surg*. 2015;78(5):949–954.
12. Spinella PC, Perkins JG, Grathwohl KW, Beekley AC, Holcomb JB. Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries. *J Trauma*. 2009;66(Suppl 4):S69–S76.
13. Perkins JG, Cap AP, Spinella PC, Shorr AF, Beekley AC, Grathwohl KW, Rentas FJ, Wade CE, Holcomb JB, 31st Combat Support Hospital Research G. Comparison of platelet transfusion as fresh whole blood versus apheresis platelets for massively transfused combat trauma patients (CME). *Transfusion*. 2011;51(2):242–252.
14. Glassberg E, Nadler R, Rasmussen TE, Abramovich A, Erlich T, Blackbourne LH, Kreiss Y. Point-of-injury use of reconstituted freeze dried plasma as a resuscitative fluid: a special report for prehospital trauma care. *J Trauma Acute Care Surg*. 2013;75(2 Suppl 2):S111–S114.
15. Kim BD, Zielinski MD, Jenkins DH, Schiller HJ, Berns KS, Zietlow SP. The effects of prehospital plasma on patients with injury: a prehospital plasma resuscitation. *J Trauma Acute Care Surg*. 2012;73(2 Suppl 1):S49–S53.
16. Brown JB, Sperry JL, Fombona A, Billiar TR, Peitzman AB, Guyette FX. Pre-trauma center red blood cell transfusion is associated with improved early outcomes in air medical trauma patients. *J Am Coll Surg*. 2015;220(5):797–808.
17. Brown JB, Cohen MJ, Minei JP, Maier RV, West MA, Billiar TR, Peitzman AB, Moore EE, Cuschieri J, Sperry JL, et al. Pretrauma center red blood cell transfusion is associated with reduced mortality and coagulopathy in severely injured patients with blunt trauma. *Ann Surg*. 2015;261(5):997–1005.