Measurement of Intraoperative Blood Loss in Pediatric Orthopaedic Patients: Evaluation of a New Method

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Abstract

Introduction: Our goal was to validate a new method of intraoperative blood loss measurement in pediatric patients who undergo orthopaedic surgery.

Methods: We prospectively collected surgical sponges from 55 patients who underwent pediatric posterior spinal fusion, single-event multilevel surgery, or hip reconstruction for measurement of intraoperative blood loss. We enrolled patients if expected estimated blood loss (EBL) was >200 mL. The methods used for blood loss assessment included the Triton sponge scanning system, visual method, gravimetric method, and measured assay (reference) method.

Results: The Triton system calculation of cumulative EBL per patient against the reference method yielded a strong positive linear correlation ($R^2 = 0.88$). A weaker correlation was noted between the gravimetric method and reference EBL ($R^2 = 0.49$). The Triton system had a low bias and narrow limits of agreement relative to the reference method (49 mL; 95% CI, 30 to 68). The gravimetric method had a higher bias and wider limits of agreement (101 mL; 95% CI, 67 to 135). The comparison of visual total EBL against the reference method yielded a notable discrepancy.

Discussion: Estimated blood loss measured using the Triton system correlated better with the reference method than with the gravimetric method. The visual estimation method was found to be inaccurate. Intraoperative use of the Triton system is convenient and precise for monitoring intraoperative blood loss.

No current method exists to practically and accurately measure intraoperative blood loss. The most common method used by surgeons and anesthesiologists is the eyeball method, in which an estimate of blood loss is determined through visual assessment of surgical sponges, suction canisters, and operating room environment, which relies on a discussion between the surgeon and anesthesiologist until a consensus is reached. This method has

been shown by many authors to be inaccurate.[1,2] Various other methods, including the gravimetric method, calculation method, radiometric method, and direct spectrophotometry method, exist to help determine intraoperative blood loss. The direct spectrophotometry method is considered a reasonable "benchmark" for assessment of estimated blood loss (EBL).[3] With this method, intraoperative samples extracted from surgical sponges and suction canisters are measured postoperatively with absorption spectrometry, enabling direct hemoglobin (Hgb) measurement within the samples. Despite improved accuracy over visual estimation, there is still up to a 10% error rate.[4]

However, what all of these methods lack is a practical and accurate real-time intraoperative EBL assessment. For minor procedures in which major blood loss is not expected, accurate measurement is trivial. For procedures in which major blood loss is expected, such as during orthopaedic surgery, allogeneic blood transfusion is often the mainstay for intraoperative and postoperative hemodynamic management, making accurate determination of blood loss a necessity. Blood transfusion carries potential complications, such as transfusion-related infections, hemolytic transfusion reactions, general immunosuppression, volume overload, and transfusion-related acute lung injury.[5-7] In pediatric patients, accurate blood loss measurement is particularly critical, as these patients have a lower hemodynamic reserve compared with adults, and blood volume is determined by patient weight. Inaccurate

EBL assessment leads to a higher likelihood for blood product replacement, which is also dependent on patient weight. Therefore, finding an accurate real-time blood loss measurement method is vital to maintaining the best intraoperative and postoperative care.

A novel FDA-cleared mobile application (Triton system; Gauss Surgical) on a tablet computer (iPad) enables the tablet camera to capture images of surgical sponges and canisters and uses image analysis algorithms and cloud-based machine learning to accurately estimate the Hgb content in real time. This method has been found to be accurate across many sponge types and lighting conditions,[8] as well as to be an accurate determinant of blood loss assessment in adult patients[9] in real time.[10] To date, the device has not been assessed for accuracy in pediatric patients. Our study assesses the accuracy of intraoperative blood loss measurement using the Triton system and those methods that are used mostly in clinical practice, especially the eyeball method (visual estimation) and gravimetric method.

Our hypothesis is that the Triton system is more accurate than the eyeball and gravimetric methods and comparable with the direct spectrophotometric method in determining blood loss in pediatric patients who undergo major orthopaedic surgery.

Methods

Local institutional review board approval was obtained for our study. All patients who agreed to participate

in the study provided appropriate preoperative consent. We collected surgical sponges and canisters from pediatric patients who underwent posterior spinal fusion, single-event multilevel surgery, or hip reconstruction for measurement of intraoperative blood loss. We prospectively enrolled patients if expected intraoperative EBL was >200 mL. We included patients if they were aged ≤18 years at the time of surgery to assess the clinical accuracy across all pediatric patient ages. All patient weights were accepted for inclusion if EBL was expected to be >200 mL. Because the patient study population included patients who underwent procedures known to lead to high blood loss, all patient ages and weights were considered, and whether they ultimately experienced the expected amount of blood loss was a factor for study inclusion. The methods used for blood loss assessment included the Triton system (Gauss Surgical), gravimetric method, and spectrophotometric assay (reference) method. The preoperative Hgb level (in grams per deciliter) and information pertaining to intraoperative blood product transfusion, crystalloid infusion, irrigation, and cell salvage were documented. Postoperative blood product needs were not recorded, as this was an assessment of intraoperative accuracy. Standard practices were used throughout the procedures when managing fluids, sponges, and canisters. After each procedure, the visually EBL agreed on by the surgeon and anesthesiologist was recorded. This estimation was done before any gravimetric or Triton

measurements were made to avoid confounding. Following the case, the Triton system was used to measure blood loss on sponges and within canisters. Image analysis was performed using both the standard Triton application and canister application. Immediately after images were obtained using the Triton system, all laparotomy sponges were weighed using a calibrated scale, and the dry weight of the sponges was subtracted to compute the sanguineous fluid mass contained within (gravimetric method). The fluid mass was then computed to volume units, assuming a 1.0 g/mL mean density conversion corresponding to blood loss mixed with irrigation.

The measured spectrophotometric assay (reference method) was determined by direct measurement of the sanguineous effluent extracted from the sponges using a validated extraction method adapted from other methods described in the literature.[3,11-16] To extract and assay sponges, up to 10 sponge samples were collected in the drying chamber of a centrifugal spin dryer (The Laundry Alternative) and 3 L of heparinized normal saline (0.90% NaCl, 1,000 U/mL) was added. The dryer was then operated at 1,600 rpm for 45 seconds of spin cycle, and the drained sanguineous effluent was collected in an externally placed container. Additional spin cycles were performed as necessary to maximize the recovery of blood from the batch of sponges into the soak solution. The mass (in grams) of the drained effluent was calculated using a calibrated weighing scale and converted to volume, assuming a fluid density of 1.0 g/mL. The Hgb concentration (grams per milliliter) of the effluent was measured by sampling a 2-mL aliquot of the solution and using a point-of-care testing device (Hemocue Plasma/Low system) following the manufacturer's instructions. At least two separate measurements of the Hgb were made, and the arithmetic mean of the measurement was calculated. The Hgb mass of each batch of sponges was then calculated as follows: Hgb mass per sponge (in grams) = effluent volume (in milliliters) × mean effluent Hgb concentration (in grams per milliliter), and serial batches were summed. To estimate and apply the recovery rates and inherent bias of the spectrophotometric method performed in this study, the method was characterized in vitro using banked blood deposited in known quantities on sponges and then mechanically re-extracted. Whole blood was reconstituted from anticoagulated packed red blood cells and plasma to 13 and 17 g/dL and mixed with a small volume of 2 M $CaCl_2$ to simulate the effect of clotting and adhesion of blood to sponges observed before the extraction assay. Sixty-four representative sponge samples were created and underwent mechanical extraction. The comparison of recovered versus deposited Hgb values via regression analysis resulted in a linear model (recovered Hgb mass (in grams) = 0.6076 × deposited mass (in grams) − 0.5386; R^2 = 0.93), which was applied to spectrophotometric assay values to correct for bias introduced by clotting and incomplete extraction.

Finally, canisters and cell saver blood waste bags were collected and directly assayed using a Hemocue photometer, and the total blood loss was determined (ie, sponges + canisters + cell saver blood waste bags) for comparison with the documented visual EBL per case.

Because it was desired to show that the Triton method is no better or worse than the spectrophotometric assay (reference) method, an equivalence test was used to compare these methods. The online power calculator from Sealed Envelope, online at www.sealedenvelope.com/power/, was used to calculate the sample size. The equivalence limit used was 200 mL (as deemed reasonably close to the volume of a transfused unit of packed red blood cells), and based on past data collection, the SD was estimated to be 300 mL. An α = 0.025 was used because it is standard for a superiority test to use α = 0.05, and for an equivalence trial, the α is generally set at half of what would be used for a superiority test. Using a power of 80%, the calculated sample size was found to be 48. A Bland-Altman analysis was used to assess the concordance between the Triton method and spectrophotometric method.[17] Limits of agreement were computed as mean ± 1.96 (SD). The Triton method was compared with the gravimetric method and the spectrophotometric assay (reference) method using paired Student p-test. Descriptive statistics for quantitative variables are presented with the mean and SD, including the median when outliers heavily influence the mean. Descriptive statistics for categoric variables are presented with counts and percentages.

Results

Between April 15, 2014, and July 1, 2015, a total of 55 pediatric patients who underwent posterior spinal fusion, single-event multilevel surgery, or hip reconstruction were enrolled in the study. A total of 781 surgical sponges (Medical Action Industries) were collected for analysis. Other basic demographic data are shown in Table 1. Data on patient age at the time of surgery were not collected. The mean preoperative Hgb level was 13.2 g/dL (range, 9.4 to 16.0 g/dL). The mean sponge count per case was 14.2 (range, 4 to 30). One patient (1.8%) required intraoperative transfusion and 19 patients (34.5%) underwent intraoperative cell saver blood transfusion. For these patients, the average cell saver blood volume returned was 138.6 mL (range, 30 to 320 mL).

When comparing the EBL measurement between the gravimetric method and assay (reference) method,

Table 1

Patient Demographics and Blood Loss Estimates

Weight, kg (range)	42.5 (12.2 to 129.6)
Surgical procedure, PSF	18 (33%)
Other (hip reconstruction and SEMLS)	37 (67%)
Average sponges per case (range)	14.2 (4 to 30)
Average preoperative Hgb (range)	13.2 (9.4 to 16.0)
Average postoperative Hgb (range)	9.6 (4.7 to 16.3)
Average Triton EBL in sponges (mL)	213.7 (23 to 723)
Average gravimetric EBL in sponges (ml)	257.7 (13 to 651)
Average eyeball total EBL (mL)	356.2 (50 to 1,400)
Average assay total EBL (mL)	326.4 (35 to 1,372)

EBL = estimated blood loss, Hgb = hemoglobin, PSF = posterior spinal fusion, SEMLS = single-event multilevel surgery
Patients were included if they were aged ≤18 years at the time of the procedure.

the gravimetric method overestimated blood loss, with a calculated correlation between the two methods of $R^2 = 0.49$ (Figure 1, A). When comparing the EBL measurement between the Triton system and assay method, there was generalized agreement between the two methods. The Triton method had slight overestimation of EBL measurement, but the overall correlation between the two methods was very high ($R^2 = 0.88$) (Figure 1, B). To assess the bias of each method compared with the reference assay method, a Bland-Altman analysis was performed. The bias in the Triton method (49 mL; 95% CI, 30 to 68) was smaller than half of the gravimetric method bias (101 mL; 95% CI, 67 to 135) compared with the reference method, with substantially narrower limits of agreement for the Triton method (Table 2).
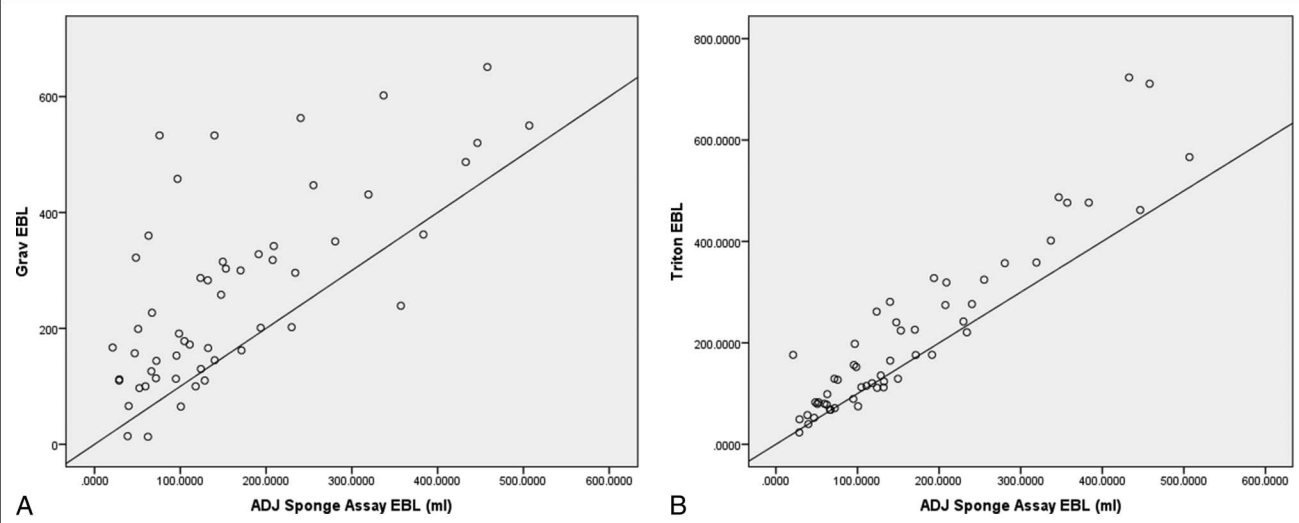
Finally, the visual estimate (ie, sponges, canisters, and cell saver blood waste bags) of the total blood loss was compared with the assay reference method and found to have very little correlation overall, as it tended to overestimate blood loss at lower measured values and underestimate blood loss at high measured values (Figure 2).

Discussion and Summary

The current method of choice for surgeons and anesthesiologists for intraoperative EBL determination is the "eyeball" or visual estimation method, which relies on a discussion between the surgeon and anesthesiologist at the conclusion of a case.

Figure 1

A, Graph showing estimated blood loss (EBL) in sponges: the gravimetric method versus the assay (measured) method ($R^2 = 0.49$). **B**, Graph showing EBL in sponges: the Triton scanning estimation versus the assay (measured) method ($R^2 = 0.88$). ADJ, adjusted.

The visualization method requires suppositions dependent on blood loss found in suction canisters, surgical sponges, surgical drapes/surgical gowns, and the operating room environment (ie, operating room floor).[18] This method has been found to be inaccurate for estimating blood loss in many studies[11,19-25] that show that physicians underestimate blood loss in high blood loss situations and overestimate in low blood loss situations.[9,11,18]

Accurate EBL assessment is necessary for proper patient care in both intraoperative and postoperative settings. Proper critical care includes blood volume management and determination for blood product replacement and is therefore highly dependent on an accurate assessment of EBL. This initiative is especially important in pediatric patients who have a lower hemodynamic reserve compared with adults and because blood volume is dependent on weight. The decision for blood product replacement needs to be based on the most accurate data to obviate the associated complication risk.[5-7]

To improve the inaccurate results of visual estimates of blood loss, other blood loss assessment methods have been developed, including the gravimetric, calculation, radiometric, and spectrophotometric methods. The gravimetric method was first described by Wangensteen[26] and depends on weighing surgical sponges before and after surgical use. Estimated blood loss is determined by assessing the weight difference before and after use, with every gram of weight equivocal to 1 mL of blood loss. This method is inexpensive, simple, and practical for measuring EBL[27] but neither precise nor accurate.[25] The calculation method uses various predetermined mathematical formulas that incorporate variables, such as blood volume and preoperative and postoperative hematocrit levels, to calculate EBL.[21] In a setting such as the intensive care unit,

calculations may be readily made but become more time intensive and laborious in the operative room. Surgeons are not privy to the proper information in real time and depend on anesthesiologists to perform the calculations, which may not always be shared in a timely fashion or even understood by surgeons who do not normally use calculation-based methods to determine blood loss. The radiometric method is an accurate method for determination of EBL but requires assessment of hemodilution with radioactive-tagged red blood cells and therefore is time/labor intensive and determined postoperatively. The spectrophotometric method using absorbance spectrophotometry can be considered a reasonable benchmark

Table 2

Performance Comparison of the Triton System Versus the Gravimetric Method Relative to a Reference Standard (Assay)

Statistical Category	Triton System	Gravimetric Method
Bias (95% CI), mL	49 (30 to 68)	101 (67 to 135)
Upper limit of agreement (95% CI), mL	176 (157 to 195)	329 (295 to 363)
Lower limit of agreement (95% CI), mL	−78 (−97 to −59)	−126 (−160 to −92)
SD (differences), mL	65	116

CI = confidence interval

Figure 2
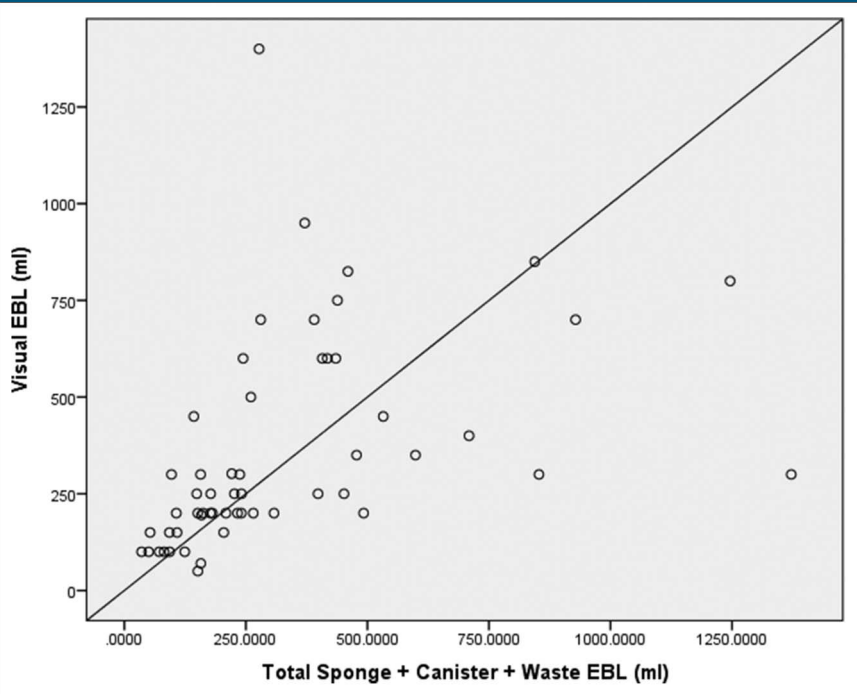
Graph showing the correlation of the visual estimate of the total blood loss with the assay (measured) method. The visual method overestimates blood loss at lower measured values and underestimates blood loss at higher measured values. EBL = estimated blood loss

for assessment of blood loss but can practically only be done post-operatively.[3,11] Furthermore, although the spectrophotometric method is accepted as a standard reference method, there is a reported error range of up to 10%.[4]

The Triton system aims at alleviating the problems associated with these other measurement methods. It is easy to use, does not require any time-consuming calculations or blood sample preparation, and can be performed in real time by circulating operating room staff. Many studies have found the Triton system to be highly accurate and correlative with the benchmark spectrophotometric method in adult patients.[8-10] The results from this analysis in the pediatric population reflect similar results. The correlation between the Triton tablet method and the benchmark spectrophotometric technique in pediatric patients (0.88) was closer to that determined in the in vitro study by Konig et al[8] (0.92), the adult surgical study by Holmes et al[9] (0.93), and the real-time adult orthopaedic study by Sharareh et al[10] (0.92). Similar to these studies, there was a low bias with narrow limits of agreement for the Triton method compared with the assay reference method. Although not as great as the fivefold difference between gravimetric and Triton methods found by Holmes et al,[9] this study found a two-fold discrepancy in accuracy between these methods. This is the first study in the literature to demonstrate the accuracy of determination of EBL by the Triton tablet system in pediatric surgery.

One weakness of the current study is that for every method other than visual estimation, all patient blood loss samples were evaluated postoperatively. This procedure may have decreased accuracy by allowing blood in surgical sponges to clot and/or evaporate, thus potentially underestimating blood loss in the comparison gravimetric and laboratory methods. Also, because samples were not assessed in real time, there was no accounting for environmental blood loss (ie, blood on the floor) that may have been observed at the time sponges were collected. Another weakness is that the accepted benchmark assay method also has an inherent error rate, and comparison with this method can impart decreased accuracy.

Strengths of the current study include an appropriate preoperative power analysis with a uniform method for obtaining samples in a distinct and specific patient population who undergo procedures leading to high blood loss (ie, pediatric orthopaedic surgery). This method helps minimize variability and bias in the overall results and may be more applicable to clinical practice. It should also be noted that at lower blood volumes of EBL, the Triton application more closely correlates with the reference method than at higher volumes. This fact suggests that in smaller patients in whom higher levels of blood loss are more clinically important, the Triton application may be particularly helpful in determining proper blood management intraoperatively and postoperatively.

In conclusion, the Triton tablet method was found to be highly correlative and accurate in estimating intraoperative blood loss in pediatric orthopaedic surgery patients. Accurate EBL determination may result in more appropriate blood product usage and minimize side effects related to blood product replacement.

References

Levels of evidence are described in the table of contents. In this article, references 11, 12, and 13 are level I studies. References 2, 5, 8, 9, 10, 18, and 19 are level II studies. References 1, 3, 4, 6, 15, 20, 21, 22, 24, and 25 are level III studies. References 16, 23, 26, and 27 are level IV studies. References 7, 14, and 17 are level V studies.

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