Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery

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BACKGROUND: Postpartum hemorrhage is the leading cause of maternal mortality in developing countries and the primary cause of one-quarter of all maternal deaths globally. Inaccuracy in estimating blood loss obscures the diagnosis of postpartum hemorrhage and its management.
OBJECTIVE: Our objective was to compare assessment of blood loss using the quantitative Triton system (Gauss Surgical, Inc, Los Altos, CA) with other measures of blood loss in women undergoing cesarean delivery.
STUDY DESIGN: Women scheduled for cesarean deliveries at our facility were included. Intraoperative blood loss was measured using the Triton, which was masked to the clinical team, as well as estimated by the surgeon (subjective estimated blood loss). The relation between the 2 methods (Triton and subjective estimated blood loss) and postoperative hemoglobin as well as delta hemoglobin (postoperative minus preoperative hemoglobin) was determined using the Spearman correlation. Triton measurement and subjective estimated blood loss were compared between women with delta hemoglobin in the upper quartile (cases) vs all other quartiles (control). Prediction of delta hemoglobin in the upper quartile also was evaluated for each method, and the area under the receiver operating characteristic curves was compared.
RESULTS: The trial enrolled 242 patients. The mean blood loss estimated by the Triton device was significantly lower than that estimated by clinical judgment (415.3±260.6 vs 799.6±215.6 mL, $P<.01$). The Triton estimate correlated best with delta hemoglobin. Seventy patients had delta hemoglobin in the upper quartile (delta hemoglobin ≥2). There was a significant difference in the Triton blood loss measurement between cases and controls but no difference with subjective estimated blood loss. Triton, but not subjective estimated blood loss, was predictive of delta hemoglobin ≥2 g/dL (Triton: area under the receiver operating characteristic curve, 0.66; 95% confidence interval, 0.58–0.74; $P<.01$ vs subjective estimated blood loss: area under the receiver operating characteristic curve, 0.53; 95% confidence interval, 0.45–0.61; $P=.45$).
CONCLUSIONS: The Triton system provides a better estimate of blood loss than the visual estimate. Clinical trials to evaluate its benefit are warranted.

Key words: blood transfusion, cesarean delivery, estimated blood loss, postpartum hemorrhage, Triton

According to the World Health Organization, postpartum hemorrhage (PPH) is the leading cause of maternal mortality in developing countries and the primary cause of one-quarter of all maternal deaths globally.[1] PPH constitutes 11% of maternal mortality in the United States, most of which occur within 24 hours of delivery.[2] An estimated blood loss (EBL) ≥1000 mL following cesarean delivery has been used for the definition of PPH.[3] Improving maternal health worldwide is one of the World Health Organization's 8 Millennium Developmental Goals. The prevention and treatment of PPH is an important step toward achieving that goal.[4] Early recognition of PPH is a critical step in the improvement process.

Estimates of blood loss during a delivery are notoriously inaccurate, with underestimation more common than overestimation.[5] The traditional method for estimating blood loss is based on the surgeon's, anesthesiologist's, or nursing staff's subjective assessment. This assessment is influenced by human error, bias, and the presence of large volumes of amniotic fluid, irrigation, or both.[5]

A recent small study (n=50) evaluated and compared the accuracy of visual estimation, quantitative gravimetric, and colorimetric methods in determining cumulative blood loss during cesarean delivery using a validated hemoglobin (Hgb) extraction assay method as the reference standard. The colorimetric system was validated and more accurate than either visual estimation or gravimetric measurement.[6]

The Triton system (Gauss Surgical, Inc, Los Altos, CA) is a novel mobile monitoring platform that uses the Gauss Feature Extraction Technology to compute the hemoglobin mass (mHb) absorbed by surgical sponges from an image, independent of non-sanguineous fluids.[7] Despite being approved by the Food and Drug Administration to estimate blood loss, the Triton system has not been validated in the obstetric population. We hypothesized that the Triton system enables clinicians to prospectively and objectively assess blood loss more accurately than the subjective clinical assessment. Our objective was to compare these 2 methods of evaluating intraoperative blood loss during cesarean delivery.

Materials and Methods

Study design

We conducted a single-center, prospective cohort clinical trial. Gauss Surgical Inc supplied the medical devices for this study. The principal investigators (F.S.,

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AJOG at a Glance

Why was the study conducted?

Estimates of blood loss during a delivery are notoriously inaccurate. Traditional methods for estimating blood loss are based on subject assessments by medical practitioners.

Key findings

The Triton system provides a better estimate of blood loss than the visual estimate.

What does this add to what is known?

This study is the first known prospective clinical study to validate the Triton results in an obstetrical population at risk for hemorrhage.

A.S., G.S.) coordinated the study, enrolled the patients, and collected and analyzed the data independently from the device company. The University of Texas Medical Branch's Institutional Review Board approved the protocol, and written informed consent was obtained from all participating subjects. All authors affirm the accuracy and completeness of the data, as well as the study's adherence to the protocol. The study was registered in Clinicaltrials.gov on January 19, 2018.

TABLE 1
Population demographics

	Controls (n=172)	Cases[a] (n=70)	*P* value[b]
Age, y	29 (25–34)	30 (27–35)	.115
Gravidity	3 (2–4)	3 (2–4)	.237
Parity	2 (1–2.5)	1 (1–2)	.128
BMI	33.1 (29.4–38.8)	32.1 (29.4–36.8)	.339
>30	124 (72.1%)	49 (70%)	.744
>35	65 (37.8%)	20 (28.6%)	.173
>40	38 (22.1%)	11 (15.7%)	.263
Race			.010
White	140 (81.4%)	54 (77.1%)	
African American	28 (16.3%)	8 (11.4%)	
Asian	4 (2.3%)	8 (11.4%)	
Hispanic	69 (40.1%)	26 (37.1%)	.668
Triton blood loss, mL	331.5 (222.5–469)	474 (300–642)	.0001
EBL, mL	800 (600–900)	800 (700–900)	.448
Blood transfusion	1 (0.58%)	0	.523
Colloids	1 (0.58%)	1 (1.43%)	.509
Postpartum hemorrhage[c]	11 (6.4%)	8 (11.43%)	.187
Hemorrhagic shock	0	0	
Shock index (bpm/mm Hg)[d]	0.67 (0.59–0.75)	0.73 (0.63–0.83)	.002

Data are presented as n (%) or median (interquartile range).

BMI, body mass index; *EBL*, subjective estimated blood loss.

[a] Cases defined as delta hemoglobin in the upper quartile; [b] Mann–Whitney Wilcoxon rank sum test; Pearson χ^2 test; [c] Defined as EBL ≥1000 mL by provider; [d] Defined as the ratio of heart rate (bpm) to systolic blood pressure (mm Hg).

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

Screening and recruitment

Term pregnant patients scheduled for cesarean deliveries were approached by the principal investigator and study collaborators. Written informed consent was then obtained from patients willing to participate. Patients unwilling or unable to provide consent, incarcerated patients, patients with an intrauterine fetal demise, and patients with placenta previa or placental accreta spectrum were excluded.

Procedures

A complete blood count (CBC) was obtained preoperatively via venous puncture, and the resultant Hgb value was entered into the device. During the cesarean delivery, clinical (EBL) and device (Triton) EBL values were both recorded and saved.

The Triton device used an iPad-based app to capture blood loss collected by surgical sponges and suction canisters in real-time as the procedure was ongoing. EBL was documented at the end of the procedure by the clinicians performing the surgery. Throughout the surgical procedure, Triton blood loss values were masked to the clinical providers by concealing the device readings away from the surgical field. All patients underwent a standardized postpartum CBC on postoperative day 1 at 4:00 AM. Delta hemoglobin (ΔHgb) was calculated as the difference between preoperative Hgb and Hgb on postoperative day 1.

Outcomes

The ΔHgb results were categorized into quartiles, and patients whose ΔHgb was in the upper quartile were considered as having increased blood loss (cases). Controls were patients whose ΔHgb was in the lower 2 quartiles. Triton measurement and EBL were compared between women with ΔHgb in the upper quartile (cases) vs all other quartiles

(control). For the primary analysis, blood loss using EBL estimates vs Triton estimates was compared between cases and controls. A distinct receiver operating characteristic (ROC) curve was generated to predict ΔHgb, transfusion administration, colloid resuscitation, PPH (defined as blood loss ≥1000 mL by clinical providers), shock index (SI [bpm/mm Hg]; ratio of heart rate to systolic blood pressure), and hemorrhagic shock (defined as massive blood loss associated with hypotension, tachycardia, oliguria, tachypnea, and mental status changes ascertained by clinical providers).

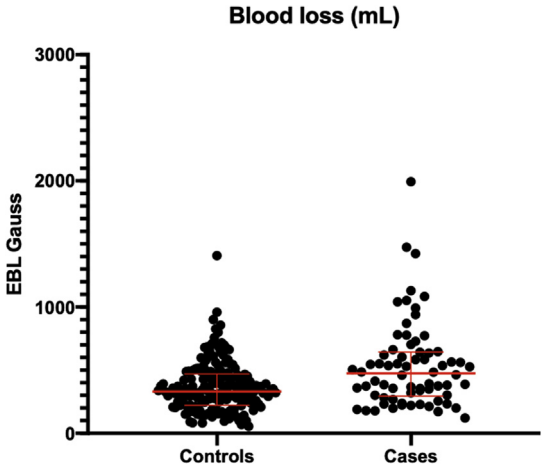
The study coordinators abstracted data from the medical records, including patient demographics, preoperative and postoperative Hgb/hematocrit, EBL- and Triton-estimated blood loss, as well as relevant outcomes.

Statistical analysis

Normality was tested by the Kurtosis method. For parametric data with a normal distribution, an unpaired *t* test was used. The Wilcoxon and Mann−Whitney rank sum tests were used for nonparametric data without a normal distribution. A χ^2 test or Fisher exact test was used for categorical data. A *P* value <.05 was considered statistically significant. Statistical analyses were performed using STATA 15 software (StataCorp, College Station, TX) and GraphPad Prism version 8.0.0 for Mac (GraphPad Software, San Diego, CA). Data were reported as mean ± standard error of the mean or median with interquartile range as appropriate. We calculated the Spearman correlation coefficient (r) for the assessed blood loss by each method (Triton and EBL) and postoperative Hgb, as well as ΔHgb. ROC curves were generated, and areas under the curve (AUCs) were calculated for prediction of ΔHgb in the upper quartile (ΔHgb > 2 mg/dL).

In a published study of 50 patients undergoing cesarean delivery, the mean blood loss measured using the Triton System was 555.8 mL with a standard deviation of 317 mL.[6] We estimated that a minimum sample of 220 women was needed to provide a power of 80% with an alpha level of 0.05 and a 25% effect size. We planned to enroll 242 patients to account for up to 10% missing data or loss to follow-up.

FIGURE 1
Triton measurements



Scatter plot showing the distribution of blood loss between cases and controls as determined by the Triton device (*P*=.0001).

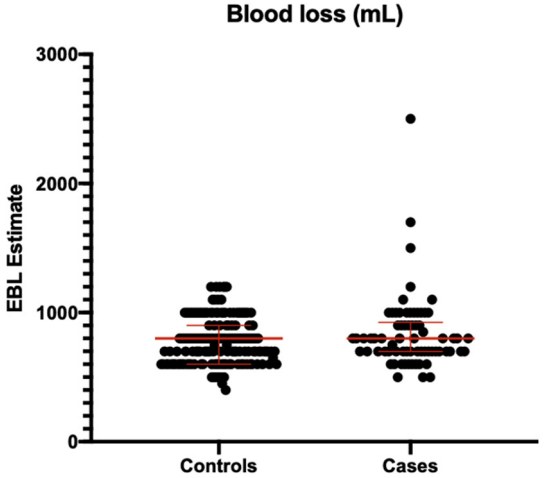
EBL, estimated blood loss.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

Results

From March 2018 to November 2018, a total of 260 women were screened. Two hundred forty-two women provided consented and were enrolled in the

FIGURE 2
Clinical blood loss estimates

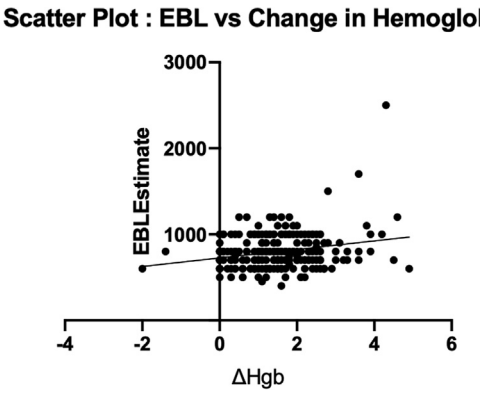


Scatter plot showing the distribution of blood loss between cases and controls as determined by the clinical estimation method (*P*=.448).

EBL, estimated blood loss.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

FIGURE 3
Scatter plot, subjective blood loss



Shown is the distribution of blood loss estimate in relation to change in hemoglobin.

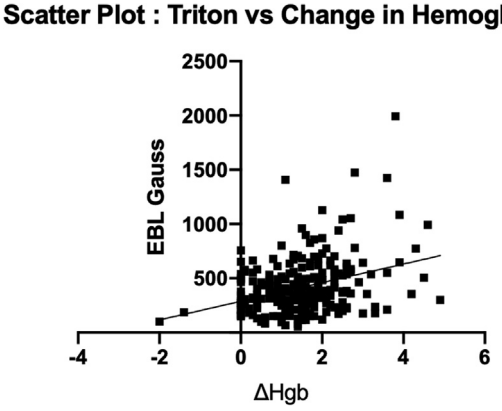
EBL, estimated blood loss.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

study. We did not have any missing data or loss to follow-up. Demographic data are summarized in Table 1. Seventy patients (cases) had ΔHgb in the upper quartile (ΔHgb ≥2 g/dL), whereas 172 patients (controls) had ΔHgb in the lower 2 quartiles (ΔHgb <2 g/dL). No significant difference between the 2 groups was seen in terms of maternal age, gravidity, parity, body mass index, and ethnicity. Most women underwent scheduled cesarean delivery and were young, multiparous, obese, and white Hispanic patients.

Rates of PPH (blood loss ≥1000 mL by clinical providers) (11.4% [8/70] vs 6.4% [11/172]; P=.187), administration of blood products (0% [0/70] vs 0.58% [1/172]; P=.523), and colloid administration (1.43% [1/70] vs 0.58% [1/172]; P=.509) did not differ between cases and controls.

FIGURE 4
Scatter plot, Triton



Shown is the distribution of Triton blood loss in relation to change in hemoglobin.

EBL, estimated blood loss; *ΔHgb*, delta hemoglobin.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

The blood loss assessed with the Triton was significantly lower than that estimated by EBL (415.3 ± 260.6 mL vs 799.6 ± 215.6 mL, P<.01; Mann−Whitney rank sum test). SI (0.73 [0.63−0.83] vs 0.67 [0.59−0.75]; P<.01) and Triton blood loss (474 [300−642] mL vs 331.5 [222−469] mL; P<.01) were significantly different between cases and controls (Figure 1 and Table 1). No significant difference was seen in EBL between cases and controls (800 [700−900] mL vs 800 [600−900] mL; P=.448; Figure 2). Figures 3 and 4 illustrate the distribution of blood loss in both methods in comparison with change in Hgb. We calculated the Spearman correlation coefficient (r) to measure the strength of association between ΔHgb and EBL blood loss as well as ΔHgb and Triton blood loss (Table 2). The Spearman r for the relation between blood loss by Triton and ΔHgb and postoperative Hgb were greater than the ones for EBL (Table 2).

ROC curve analysis showed that Triton, but not EBL, was predictive of ΔHgb >2 (Triton AUC, 0.66; 95% CI, 0.58−0.74; P<.01 vs EBL AUC, 0.53, 95% CI, 0.45−0.61; P=.45; Table 3 and Figure 5). Table 3 summarizes the predictive parameters for the best cutoff for each method.

Discussion

Principal findings

The Triton device was easy to use, intuitive, safe, and did not malfunction. Its accuracy in predicting a Hgb drop and its ability to provide real-time blood loss data as each data point is obtained highlights the potential usefulness of the Triton device for intraoperative monitoring. This will potentially allow earlier intervention instead of waiting for postoperative CBC results or blood loss estimates at the end of the case.

Results

For this study, we used a drop of Hgb from baseline to postoperation in the upper quartile as a surrogate for excess bleeding. The excess bleeding between cases and controls

was confirmed by a significantly greater SI in the cases compared with controls. An SI cutoff of 0.9 has been shown to be predictive of maternal death, intensive care unit admission, severe end-organ failure, and or maternal morbidities. We found that Triton, compared with EBL, was more predictive of a drop of Hgb in the upper quartile (ΔHgb $\geq$2 g/dL), with better sensitivity, specificity, and greater positive likelihood ratio. Our multivariate analysis showed that ΔHgb and postoperative Hgb correlated best with the Triton device but not with EBL estimate of blood loss.

TABLE 2
Spearman correlation coefficient (r)

	ΔHgb		Postoperative Hgb	
	Correlation coefficient	*P* value	Correlation coefficient	*P* value
Triton	0.26	<.0001	−0.18	.003
EBL	0.13	.03	−0.009	.17
SI	0.17	.007	−0.036	.57

ΔHgb, delta hemoglobin; *EBL*, subjective estimated blood loss; *Hgb*, hemoglobin; *SI*, shock index; *Triton*, objective estimated blood loss by Triton device.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

Clinical implications

The Triton device performs image analysis and uses cloud-based machine-learning models to quantify mHb on surgical sponges in real time. The same technology also can be used to measure the Hgb content of fluid collected in suction canisters during surgery.[8] In 2014, Konig et al[9] showed that blood loss monitoring using the Triton system is accurate in assessing mHb on surgical sponges across a range of ambient light conditions, sponge saturation, and saline contamination. The study suggested that the use of such a tool in general surgery, obstetrics, orthopedics, and cardiac surgery would significantly improve the accuracy of blood loss estimates. Another study, by Holmes et al,[10] showed that this novel mobile monitoring system provides an accurate measurement of mHb on surgical sponges, as compared with manual rinsing measurements, and is significantly more accurate than the gravimetric method.

Obstetricians are more inclined to overestimate blood loss due to blood contamination with amniotic fluid and irrigation fluid, which in turn leads to larger volumes in suction canisters and more soaked lap sponges. Overestimation of blood loss may cause surgeons to order unnecessary blood work and expose their patients to unnecessary medications and blood transfusions. In contrast, underestimation may lead to a delay in evaluation and treatment.[7] Accurate estimation of blood loss in real time would change the timing of medical interventions to control the bleeding.

Research implications

Maternal hemorrhage is a major cause of maternal comorbidity and mortality,[3] emphasizing the need for early detection and management of such a serious condition. Despite implementing simulations and didactic training, centers around the United States still struggle to identify and treat maternal hemorrhage.[11,12] The Triton system is approved by the Food and Drug Administration, and its accuracy is supported by several studies.[7] While this study found that the Triton system provides a better assessment of blood loss, clinical trials to evaluate its benefit are warranted.

Strengths and limitations

This study is the first known prospective clinical study to validate the Triton results in an obstetrical population at risk for hemorrhage. The strengths of our study include a large sample size, adequate power, and prespecified outcomes and analyses. We had 100% enrollment rate and no loss to follow-up.

Our study also has some limitations. Since this was a prospective cohort study, knowledge of exposure status may have biased classification of the outcome. Despite being masked, surgeons were aware that the patient was in a study and that the blood loss was assessed using a device. We suspect that this may have resulted in more attention to the EBL than would have been the case in routine clinical practice. Another limitation of this study is that it investigated a patient population having surgical blood losses mostly within the normal range and excluded patients at greater risk of intraoperative bleeding, such as those with placenta previas and accretas. The study was not powered to study those groups of patients. However, it would be safe to assume that in these cases, there

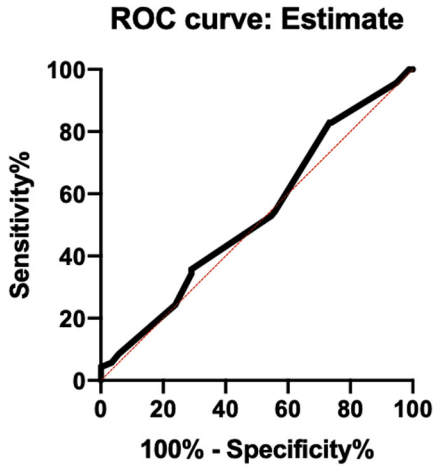
TABLE 3
Parameters for predicting hemoglobin change in the upper quartile by EBL vs Triton

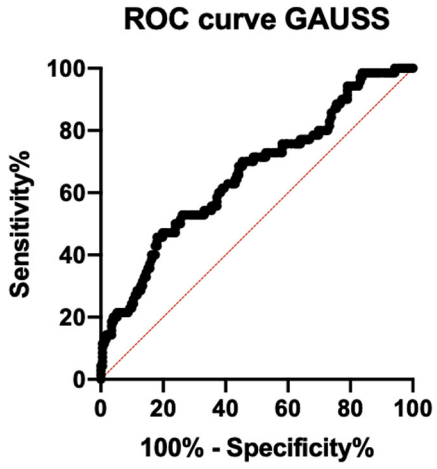
	Best cut off, mL	Sensitivity	Specificity	LR	AUC (95% CI)
EBL	≥775	52.86%	45.35%	0.96	0.53 (0.45−0.61)
Triton	≥375	61.43%	61.05%	1.577	0.66 (0.58−0.74)

AUC, area under the curve; *CI*, confidence interval; *EBL*, subjective estimated blood loss; *LR*, likelihood ratio; *Triton*, objective estimated blood loss by Triton device.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

FIGURE 5
Triton vs EBL hemoglobin change





ROC curves for predicting hemoglobin change in the upper quartile using EBL vs Triton.

EBL, subjective estimated blood loss; *ROC*, receiver operating characteristic; *Triton*, objective estimated blood loss by Triton device.

Saoud et al. Validation of a new method to assess estimated blood loss in the obstetric population undergoing cesarean delivery. Am J Obstet Gynecol 2019.

will be more sponges and more filled canisters with an even better performance of the Triton device compared with visual estimation.

Even though the Triton, compared with EBL, was more predictive of a drop of Hgb in the upper quartile (ΔHgb $\geq$2 g/dL), the blood loss measured (475 cc for cases vs 332 cc for controls) is much less than the current definition of PPH. Thus, the current definition of PPH ($\geq$1000 cc) would not apply to this technology. Moreover, carrying out a study in a single institution limits the generalizability of our findings.

Conclusions

This is the first prospective cohort study evaluating a novel device for objectively estimating blood loss in real time, a device that is not affected by a surgeon's expertise or level of training. Based on our findings, the Triton system will ultimately lead to proper and timely implementation of obstetric hemorrhage protocols and hopefully better maternal outcomes. ■

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Clinical trial registration: Clinicaltrials.gov; Date of registration: Jan. 19, 2018; date of first enrollment: Mar. 1, 2018; https://clinicaltrials.gov/ct2/show/NCT03404375.

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