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MATERNAL-FETAL MEDICINE

Validation of a quantitative system for real-time measurement of postpartum blood loss

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Abstract

Purpose Reliable real-time estimation of blood loss is crucial for the prompt management of postpartum hemorrhage (PPH), which is one of the major obstetric complications worldwide. Our study aims at the validation of feasibility and precision of measured blood loss (MBL) with a quantitative real-time measurement system during (1) vaginal delivery and (2) cesarean section by comparison with a hemoglobin-based formula for blood loss as an objective control. This is the first study to include a reasonable number of patients in an everyday clinical setting.

Methods 921 patients were prospectively enrolled into this study (vaginal delivery: $n=461$, cesarean delivery: $n=460$) at a tertiary care hospital in Switzerland. Blood loss was measured by quantitative fluid collection bags. "Calculated blood loss" (CBL) was determined by modified *Brecher`s* formula based on the drop of hemoglobin after delivery. MBL based on our measurement system was compared to CBL by correlation analysis and stratified by the mode of delivery.

Results During vaginal delivery, MBL as determined by our quantitative measurement system highly correlated with CBL ($p<0.001$, $r=0.683$). This was also true for patients with cesarean deliveries ($p<0.001$, $r=0.402$), however, in a less linear amount. In women with cesarean deliveries, objectively low blood loss tended to be rather overestimated, while objectively high blood loss was more likely underestimated.

Conclusions The technique of real-time measurement of postpartum blood loss after vaginal delivery as presented in this study is practicable, reliable and strongly correlated with the actual blood loss and, therefore, poses an actual improvement in the management of PPH.

Keywords Blood loss measurement · Estimated blood loss · Measured blood loss · Postpartum blood loss · Postpartum hemorrhage · PPH

Introduction

Obstetrical hemorrhage remains one of the main causes for maternal morbidity and mortality over all nations [1]. Maternal hemorrhage accounts for 27.1% of maternal deaths due to obstetric causes worldwide [2, 3]. Identifying women at the early stage of PPH to apply prompt treatment remains challenging as merely visually estimated blood loss, a quick and applicable method in the daily obstetric setting, has been found to be inaccurate [4–6]. Furthermore, adequate and timely management of patients with increased postpartum blood loss with infusion of crystalloid or colloid fluid, coagulation factors and blood products is crucial for the outcome of these women and depends highly on a reliable real-time measurement of blood loss [7]. Beside the consideration of clinical signs and symptoms for PPH, "*The Royal College of Obstetricians and Gynaecologists* (RCOG)" recommends the use of blood collection drapes and suggests the used swabs to be weighed to overcome the inaccuracy of blood loss estimation during delivery [8]. Still, there is uncertainty how to measure postpartum blood loss most accurately, despite its importance for immediate treatment measures. Studies published so far were either clinically impracticable [6] or had a rather small study population [9]. The objective of this prospective study was to validate the measurement of blood loss with quantitative measurement systems during vaginal delivery, and cesarean delivery, by applying a hemoglobin-based, previously standardized formula (modified *Brecher's* formula) for blood loss calculation

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as an objective control [10]. To the best of our knowledge, this is the first study that verifies practicability and precision of the widely used and recommended blood collecting systems in an unselected cohort of women in an everyday setting.

Materials and methods

Study population

This is a secondary analysis of a prospective observational study that investigated risk factors for and management of increased postpartum blood loss at the *University Hospital of Zurich* (PPH-study, ClinicalTrials.govID: NCT02604602). The study population was enrolled from October 2015 to November 2016. Prior to patient recruitment, study approval was given by the "ethics review board of Zurich" (reference number KEK-ZH 2015-0011). Recruitment was conducted by attending obstetricians at the hospital`s outpatient clinic during regular pregnancy check-ups ahead of the patient`s admission to the labor and delivery ward. Pregnant women were enrolled after giving full and informed consent if they met the following inclusion criteria: minimum gestational age of 22 + 0 weeks and initiation of labor (frequent contractions or rupture of membranes) at least 36 h after the first blood withdrawal. Exclusion criteria were comprised bleeding disorders (i.e., known primary coagulopathy or blood-clotting disorders), a patient`s age under 18 and lack of a signed informed consent form. All participants gave written informed consent before study initiation.

Demographic and clinical patient data were collected prospectively by the trained study staff and supervised by the attending obstetricians. Data entry was monitored frequently for completeness and accuracy by the trained research personnel.

Within the scope of routine blood draws, blood samples were taken from every enrolled patient on the day of admission for delivery, as well as 24–48 h after delivery. In case of increased blood loss during delivery, additional blood draws were conducted (i.e., in patients with postpartum hemorrhage or low peripartum hemoglobin levels).

Blood loss measurement techniques

During parturition, blood loss was initially estimated visually by obstetricians and midwives. Immediately after clamping the cord at 1 min, the midwife placed a fresh drape underneath the women's pelvis to collect blood. The weight of the drape was regularly checked manually by lifting it. If the weight or visual estimation suggested a significant blood loss, the drape was weighed and replaced by a new one. If the overall weighed blood loss exceeded 300 g, a fluid collection bag with a quantitative scale attached to a drape (Image 1) was placed underneath the patient's pelvis.

Blood loss measurement in cesarean sections was less accurate. The total fluid between hysterotomy and clamping of the baby's cord (being a mixture of amniotic fluid and blood) was collected by a surgical suction pump with a special surgical cloth preventing fluids to drop on the floor. The total amount until this moment was annotated and the proportion of blood estimated visually by the surgeon. Thereafter, additional fluid in the suction pump was attributed completely to blood loss. Fluids from wringed surgical drapes were also measured and attributed completely to blood loss. We did not measure haematocrit in the final blood–amniotic fluid mixture.

Brecher's formula was utilized to calculate blood loss, based on the drop of hemoglobin postpartum. Originally hematocrit-based, Brecher`s formula was modified for the use of hemoglobin levels instead. *Volume of Blood Loss (ml) = CBL (ml) = Estimated Blood Volume (EBV)(ml) x ln (hemoglobin [g/l]/0.33 before delivery/postpartum hemoglobin [g/l]/0.33)* [10]. EBV of the patient was calculated by *Nadler's* formula, based on the patient`s weight, gender and height [11].

Additional blood specimens were taken to overcome falsely high hemoglobin measurements in patients with PPH due to the outstanding volume shift that is delayed after increased blood loss. Likewise, hemoglobin levels from blood specimen taken immediately after intensive fluid infusion therapy in the first hours after a massive bleeding were interpreted with caution as these might be quantified falsely low. In patients experiencing PPH, the clinically most reasonable hemoglobin value usually represents the hemoglobin level 48 h postpartum [12]. Based on this fact and in consideration of the clinical course, in the majority of cases, the hemoglobin level 48 h postpartum was used to calculate ΔHb. However, in case a blood transfusion was needed, the hemoglobin level before transfusion was used.

Statistical analysis

Descriptive statistics were used by displaying demographic and clinical variables of interest (data given in % (*n*) or mean ± SD). Data were tested for normality with Shapiro–Wilk and Kolmogorov–Smirnov test. Since the data were shown to be normally distributed, independent *t* test or Chi-Square test was utilized to test differences between groups (stratification was done based on the mode of delivery).

Pearson correlation was applied to analyze correlations between measured blood loss (MBL) and calculated blood loss (CBL) by Brecher's formula. Therefore, data were stratified by mode of delivery (MOD; vaginal delivery and cesarean section). Values are given as r^2 or mean ± SD if

not indicated otherwise. Further, a Bland–Altman plot was developed to display the agreement between measured and calculated blood loss. Throughout the study, a p value < 0.05 was accepted as significant.

The statistical analyses for this study and data processing were conducted with SPSS (version 22, IBM, USA).

Results

Study population characteristics

For this prospective single center study, 921 patients were enrolled. Table 1 displays relevant patient characteristics of the study population. Patients were stratified based on the mode of delivery (vaginal delivery: $n = 461$; cesarean section: $n = 460$).

Correlation of measured blood loss with calculated blood loss for vaginal deliveries

MBL during vaginal delivery [mean 469.3 ml (± 413.6 ml)], achieved by our quantitative measurement system, was correlated with CBL [mean 516.7 ml (± 532.1 ml)]. A high correlation of $r = 0.683$ ($p < 0.001$) was found and is visualized in Fig. 1. The calculated overall mean difference in blood loss between both techniques was found to be 47.3 ml (± 391.7 ml). Bland–Altman plots show the agreement between both blood loss measurement techniques in vaginal deliveries (Fig. 2a) and cesarean sections (Fig. 2b). The plots reveal that values have the tendency to accumulate near the horizontal line of mean difference, suggesting a good agreement between MBL and CBL.

Correlation of measured blood loss with calculated blood loss for cesarean sections

Measurement of blood loss in patients with a cesarean section [mean 560.4 ml (± 249.9 ml)] correlated with the CBL [479.3 ml (± 435.7 ml)], $r = 0.402$, $p < 0.001$. However, this correlation was not as strong as for vaginal deliveries (Fig. 1). According to the scatter plot (Fig. 1), objectively low blood loss rather tended to be overestimated. In contrary, high blood loss was rather underestimated. The overall mean difference for blood loss estimation between both used techniques in cesarean sections was shown to be 81.1 ml (± 405.9).

Table 1 Patient characteristics

	Vaginal delivery $N = 461$	Cesarean section $N = 460$
Feto-maternal characteristics		
Age (years)	31.8 ± 4.9	33.8 ± 5.2
Gestational age (days)	278.1 ± 9.2	268.3 ± 14.1
Parity	1.6 ± 0.9	1.7 ± 0.8
Multipara	42.1% (194)	51.3% (236)
Body mass index (kg/m^2)	23.1 ± 4.5	24.3 ± 5.3
Fetal count	1 ± 0.1	1.1 ± 0.3
Multiple fetus pregnancy	0.9% (4)	7.4% (34)
Placenta previa	0%	2.4% (11)
Vasa previa	0%	0.2% (1)
Perinatal characteristics		
Induction of labor	38.8% (179)	13.9% (64)
Second stage labor duration (minutes)	76.1 ± 66.1	152.5 ± 79.9
Epidural/spinal anesthesia	43.65% (201)	97.2% (447)
Unplanned cesarean section	0%	34.8% (160)
Cervical tear	0.2% (1)	0.2% (1)
Retained placenta	3.9% (18)	0.2% (1)
Morbidly adherent placenta	0.2% (1)	0.7% (3)
Incomplete placenta	4.1% (19)	0.2% (1)
Uterine atony	7.4% (43)	2.4% (11)
Preterm birth (< 37wks gestational age)	9% (2)	10.2% (47)

This table shows the distribution of general feto-maternal and perinatal characteristics, stratified by mode of delivery of our patient cohort [data given in % (n) or mean ± SD]

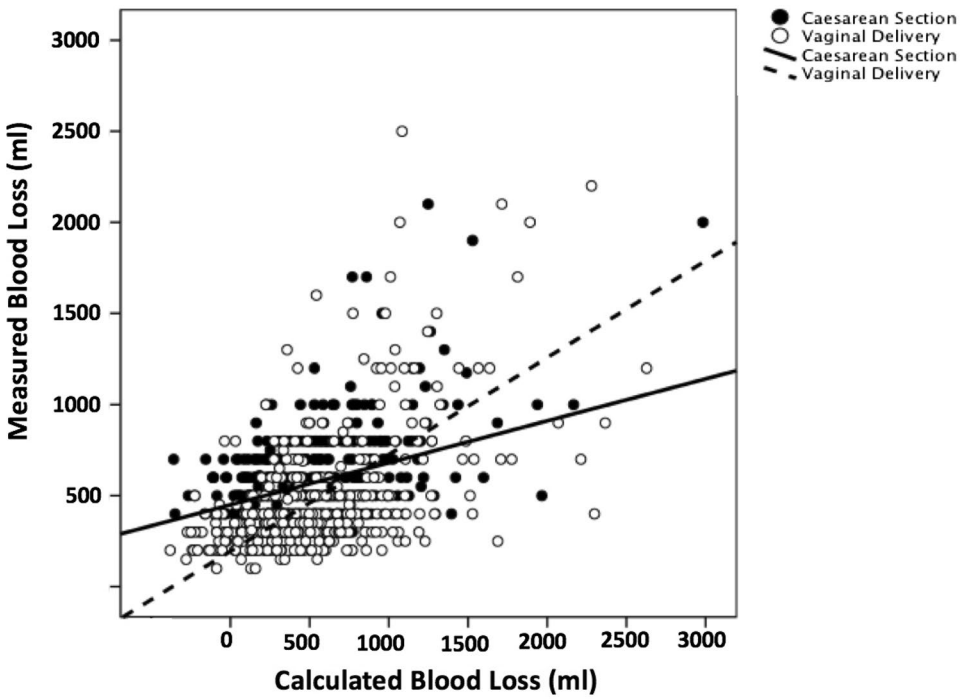

Fig. 1 Scatter Plot for Correlation of MBL and CBL. The scatter plot displays a positive correlation of measured blood loss (MBL) with calculated blood loss (CBL) for vaginal deliveries ($r = 0.683$, $p < 0.001$; mean difference of 47.3 ml), as well as for cesarean sections ($r = 0.402$, $p < 0.001$; mean difference of 81.1 ml). Data were shown to be normally distributed; Pearson correlation was applied to analyze correlation between MBL and CBL, stratified by mode of delivery. $p < 0.05$ was accepted as statistically significant

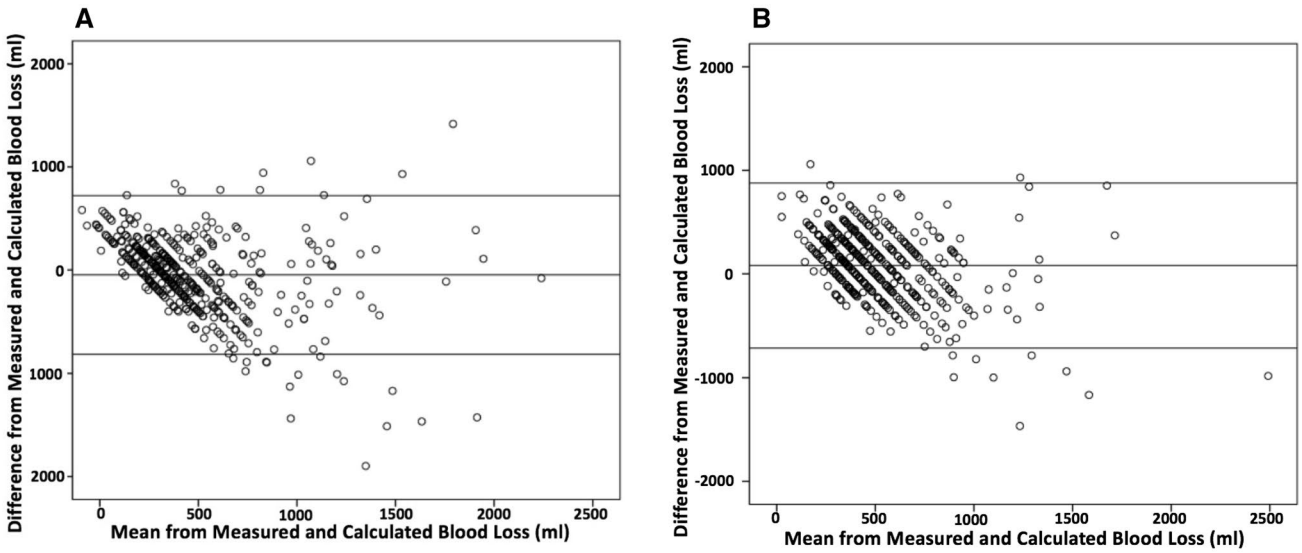

Fig. 2 Bland–Altman Plot for Blood Measurement Techniques in Vaginal Deliveries (2A) and Cesarean sections (2B). The Bland–Altman plots show the agreement between both blood loss measurement techniques (measured and calculated blood loss), the x-axis displaying the mean of both techniques and the y-axis showing the difference between the two measurements. The mean difference of all patients is represented as a horizontal line (standard deviations are the outermost horizontal lines of the plot). The plot reveals that values have the tendency to accumulate near the horizontal line of mean difference, suggesting a good agreement between measured and calculated blood loss. The calculated overall mean difference in blood loss between both techniques was found to be significantly different, measuring 47.3 ml (±391.7 ml) for vaginal deliveries, and 81.1 ml (±405.9) for cesarean sections ($p < 0.001$)

Accuracy of blood loss measurement in vaginal deliveries versus cesarean sections

We compared the difference of measured and calculated blood loss in vaginal deliveries with cesarean sections. This analysis demonstrated that measured and calculated blood loss correlated significantly better in vaginal deliveries than in cesarean sections (47.3 ml vs. 81.1 ml, $p < 0.001$).

Discussion

Currently, there is no reliable clinical standard for estimation of obstetrical bleeding during delivery. The lack of an appropriate blood loss measurement may lead to delayed PPH treatment with the underlying complications [8]. Research has consistently demonstrated the inaccuracy of visual blood loss estimation [4, 5, 13–15]. In this study, we accomplished a validation of our institute`s blood loss measurement technique, involving frequent weighing of bloody drapes or cloths and the application of a quantitative measuring bag attached to a drape for vaginal deliveries (Image 1), and surgical fluid collection bags, connected to a suction tube for cesarean deliveries. Measured blood loss during both vaginal deliveries as well as during cesarean sections showed a strong correlation with the calculated blood loss (Fig. 1).

Accuracy of blood loss calculation was examined in a review authored by Schorn et al. [6]. Photospectometry was regarded as the most precise method, however, being too expensive and complicated for the daily use in clinics [6]. Patel et al. compared a small subset of photospectometry measurement results ($n = 10$) with the accuracy of blood loss measurement by a similar blood collection bag as it was used in our study setting. Even though they showed that in comparison to spectrometry measurements, the blood collection estimate rather overestimated the obstetrical blood loss, the correlation between both methods was still strong [9]. Based on these study results, the recommendations for prevention and management of postpartum hemorrhage include a combination of a gravimetric method and measurement with a blood collection bag, as visual blood loss estimation was shown to be inaccurate [8]. This present study supports the given recommendation with a larger patient sample size of prospectively collected data in a daily obstetric setting.

In this study, the CBL was determined by modified *Brecher's* formula, which integrated the pre- and postdelivery hemoglobin levels, aimed at a more precise blood measurement and served as an internal control for our study. This formula has been used frequently for blood loss estimation and is a common basis for more advanced blood estimation formulas, especially in the field of orthopedic surgery transfusion research [10, 16, 17]. More accurate methods, such as tagged red blood cells, have not been applied since we found it impracticable in our obstetric setting. We demonstrated that the difference in mean blood loss measurement between MBL and CBL for vaginal deliveries accounted for 47.3 ml and for cesarean sections for 81.1 ml. We attribute the better agreement between blood loss measurement methods in vaginal births to the inaccuracy of blood loss measurement in cesarean sections due to an inevitable mixing of amniotic fluid with the bleeding from the hysterotomy before the neonate is born. In vaginal deliveries, on the contrary, heavy bleeding in most cases begins only after the delivery of the neonate when a fresh drape has already been placed and additional amniotic fluid will be implausible to emerge. The scatter plot (Fig. 1) also visualizes the tendency of blood loss underestimation in cesarean sections with higher amounts of blood loss, which is in line with findings of a previous study by Larsson et al. [13]. Further, Duthie et al. demonstrated that estimated blood loss in cesarean sections showed the tendency of being too low when the blood loss exceeded 600 ml [18], which goes along with our results as well.

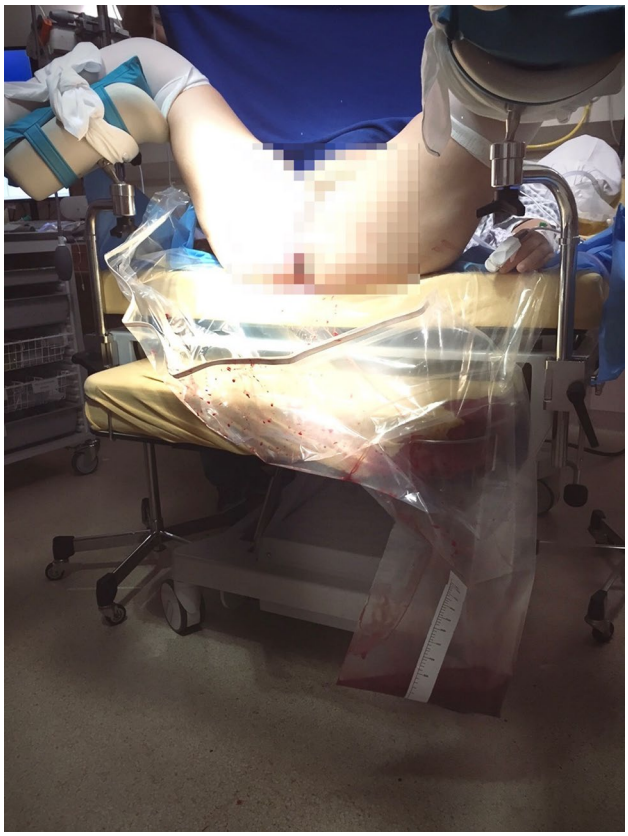

Image 1 Fluid collection bag with a quantitative scale for blood loss measurement in vaginal deliveries

A major strength of this study, conducted in a tertiary care hospital, is the prospective data collection. It is well known that hemoglobin concentrations right after bleeding can be measured too high and in contrary hemoglobin concentrations immediately after rigorous fluid administration may be quantified too low. Therefore, the most appropriate value for every individual was chosen, typically the hemoglobin value, 48 h after delivery, however, considering the clinical course such as administration of blood transfusions.

To our understanding, the obstetrical blood loss measurement on our institution's labor and delivery ward is a reliable real-time measure and allows for a direct PPH treatment in patients with vaginal deliveries. Formulas for blood loss, such as *Brecher's* formula, provide a basis for an internal validation of MBL but are not applicable in the clinical setting as they can only be used after the receipt of the postpartum hemoglobin level, which is far too late for patients with an acute bleeding. For the clinical management of PPH, still experienced by about 6% of women, it is relevant to have a reliable real-time estimation of blood loss [19]. This is the basis for timely PPH treatment with adequate volume and coagulation management. An approved PPH prevention and treatment flow are crucial as well, as accurate blood loss estimation alone does not necessarily lead to improved outcomes [20]. However, clinical PPH symptoms can occur rather late in young women, who remain hemodynamically stable for a long time period even while experiencing PPH. It is known that delayed PPH management ("*too late, too little*") can lead to less favorable outcomes [8]. The importance of this finding has been emphasized again in a recent publication [21]. The authors claim that reliable measurement of blood loss would present a significant challenge for blood loss threshold-based diagnosis and that until today no evaluation method has been used broadly for precise blood loss measurement. To our best knowledge, we are the first to show that real-time measurement of blood loss is feasible and accurate.

We conclude that first, this study supports our assumption that reliable real-time obstetric blood loss measurement for vaginal deliveries is possible and can be achieved by the blood measurement techniques which are applied on our institution's labor and delivery ward, as well as in many hospitals worldwide. Second, the actual blood loss for uncomplicated cesarean deliveries with low blood loss tends to be overestimated and contrariwise the blood loss for cesarean sections with a high blood loss shows a trend to underestimation. The latter finding should call attention, as the majority of obstetricians might have to improve their blood measurement skills during cesarean deliveries.

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Author contributions MKK: data management, data analysis, manuscript writing. RB: data collection. RZ: project development. DF: data collection. CH: protocol development, data management, manuscript editing.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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