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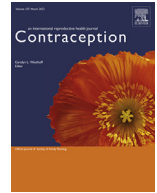
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Original Research Article

Clinical interventions are more accurate than quantitative measurements for defining hemorrhage with dilation and evacuation ☆☆☆★☆☆

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ABSTRACT

Objectives: To assess if quantitative blood loss (QBL) with dilation and evacuation (D&E) procedures correlated with clinically relevant outcomes or hemorrhage.

Study design: We used a de-identified database to review D&E procedures performed at UC Davis Health from April 2019 through March 2020. Surgeons determined QBL during procedures and estimated blood loss, when excessive, during post-procedure recovery. We extracted patient demographic and procedure-related information. We defined clinically relevant bleeding as cases with bleeding-related interventions within 24 hours post-procedure including use of ≥ 2 uterotonics, tranexamic acid administration, cervical injury requiring repair, uterine balloon tamponade, blood transfusion, uterine artery embolization, hospitalization, or return to operating room; the latter 5 criteria defined hemorrhage. We used χ^2 test for trend to evaluate bleeding outcomes.

Results: We evaluated 431 procedures with a mean gestational age of 19 weeks and 3 days. Clinically relevant bleeding outcomes occurred in 6/319 (2%), 15/97 (15%) and 7/12 (58%) patients with total blood loss <250mL, 250–500mL and >500mL, respectively ($p < 0.0001$); 11 had bleeding related to cervical injuries. Hemorrhage occurred in 0, 4/97 (4%) and 5/12 (42%) patients, respectively ($p < 0.0001$). Patients with relevant bleeding outcomes had QBLs ranging from 150–1800mL (median QBL 312.5mL, interquartile range [IQR] 250–550mL) while those without clinically relevant bleeding ranged from 10–900mL (median QBL 150mL, IQR 75–200mL).

Conclusion: Most patients (75%) with clinically relevant bleeding outcomes had QBL ≤ 500 mL. Although higher QBL correlates with clinical interventions, the need for significant interventions rather than a single blood loss amount should be used to define hemorrhage with D&E procedures.

Implications: Clinical hemorrhage is best defined by the necessary clinical interventions required to manage bleeding rather than any quantified amount of blood loss.

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1. Introduction

Hemorrhage is the most common cause of procedural abortion-related mortality, accounting for 41% of deaths at 13 or more weeks gestation based on U.S. data from 1998–2010 [1]. The incidence of hemorrhage with dilation and evacuation (D&E) ranges from 0.9 to 10 per 1,000 cases [2–6]; the wide range is primarily related to the variable definitions across studies. These definitions include both volume references (>250 mL or >500 mL blood loss) and outcomes (e.g., requiring hospitalization or requiring transfusion). These inconsistent definitions make comparisons of incidence, risk factors and treatment difficult. Additionally, esti-

matting blood loss significantly underestimates actual blood loss by about 50% [7]. Accordingly, many studies of hemorrhage incidence are inaccurate. Using measured or quantitative blood loss (QBL) results in a more accurate measurement after abortion procedures and vaginal births [7,8].

The Society of Family Planning (SFP) suggests that a clinically relevant definition of hemorrhage would include both a clinical response to excessive bleeding, such as transfusion or admission, and/or bleeding >500 mL [9]. However, no studies have evaluated the correlation of outcomes or any specific blood loss measurement to bleeding-related morbidity. A hemorrhage definition should consider that all interventions are not clinically equal. For example, a patient that receives multiple uterotonics to manage post-procedure bleeding does not have the same level of morbidity as a patient who requires a uterine artery embolization (UAE). A standard hemorrhage definition would allow for data synthesis for larger analyses in line with the Core Outcomes in Effectiveness Trials (COMET) initiative [10,11] and enable improved research on procedural morbidity and interventions to decrease significant blood loss. We performed this analysis to characterize the relationship between blood loss and interventions for bleeding complications for D&E procedures as a first step at developing an evidence-based hemorrhage definition.

2. Materials and methods

We aimed to identify if any specific QBL with D&E procedures correlated with clinically relevant bleeding outcomes. We hypothesized QBL would not consistently correlate with the need for post-procedure interventions related to bleeding complications. We used the UC Davis Family Planning Division database to query D&E procedures for a 1-year period from April 1, 2019 through March 31, 2020. We chose this time frame as the first year following a switch from using an estimated blood loss (EBL) to a modified quantitative blood loss (mQBL) during abortion procedures. With use of QBL as described for D&E research, a regimented process is used including weighing of the biohazard bag with addition of extra items to account for unmeasured loss [7]. We used a mQBL in which we quantified amniotic fluid removed early in the procedure to subtract from the final estimate, estimated blood loss on gauze and similar drapes based on typical blood in a saturated pad, and measured volume of blood in the collection container after removing fetal parts.

We used the de-identified database to extract patient demographic and procedure-related information. We included all patients, including those with a coagulopathy or using anticoagulation; we only excluded patients that had an urgent D&E prompted by a bleeding complication during pregnancy. Surgeons included Complex Family Planning faculty, fellows or residents with all procedures performed or supervised by 1 of the specialist faculty members. Based on medical history and pregnancy characteristics, physicians assigned a pre-operative bleeding risk assessment (low, medium, or high) based on SFP guidelines (online Appendix 1) [9]. Cervical preparation typically occurred with standardized use of Dilapan-S osmotic dilators placed the day prior to surgery and with occasional use of misoprostol only initiated a few hours prior to the planned procedure, as per our standard practice and described in prior literature [12]. Procedural anesthesia included intravenous propofol, fentanyl and versed. All patients received cervical anesthesia with lidocaine 1% 20 mL with vasopressin 4 units. Additionally, patients at 15 weeks or more gestation considered at moderate or high risk for hemorrhage and all at 18 weeks or more regardless of risk received oxytocin 30 units in 500 mL normal saline intravenously during the procedure [13]. Surgeons did not use prophylactic methylergonovine. Surgeons made individual decisions regarding the need for and type of interventions related to

bleeding based on the clinical scenario. Patients were typically observed in recovery for 1–2 hours post-procedure and nurses notified physicians if they recognized increased vaginal bleeding during observation.

We differentiated cases with clinically relevant bleeding from those with a significant outcome, which should be defined as hemorrhage. We defined clinically relevant bleeding when any of the following interventions occurred related to blood loss within 24 hours post-procedure: use of ≥ 2 uterotonics (not including standard oxytocin infusion), tranexamic acid administration, cervical injury requiring repair, uterine balloon tamponade, UAE, blood transfusion, hospitalization, or return to operating room. We considered hemorrhage as a true complication reflecting the need for uterine balloon tamponade, UAE, blood transfusion, hospitalization, or return to operating room. We included blood loss as mQBL during the procedure and, for patients with excessive bleeding in the recovery room and return to the operating room, all blood loss as described as either estimated or mQBL until completion of the second operating room case. For patients who returned with a bleeding complication after discharge (delayed hemorrhage), we only included the mQBL for their primary procedure in the analysis.

We compared median mQBL for patients with and without clinically relevant bleeding outcomes using Kruskal-Wallis test with pairwise comparisons, χ^2 test for trends, and Fisher exact test, as appropriate, with a $p < 0.05$ considered significant. We used SAS software (Version 9.4) for all analyses. The University of California, Davis Institutional Review Board reviewed the study and considered it exempt.

3. Results

We reviewed 431 D&E procedures performed during the study period of which we excluded 3 who had emergent procedures due to obstetric bleeding. Patient demographics for the remaining 428 patients are presented in Table 1, with a mean gestational age of 19 weeks 3 days and patient ages ranging from 13–46 years. Two (0.5%) patients (D&E mQBL 50 mL and 200 mL) had uncomplicated

Table 1
Characteristics of D&E patients at University of California, Davis from April 2019 through March 2020

Characteristic	Total N=428
Age (y)	28.6 \pm 6.8
BMI (kg/m ²)	29.9 \pm 8.3
>30	172 (40.2%)
Obstetrical history	
Nulliparous	122 (28.5%)
History of vaginal delivery	240 (56.1%)
History of cesarean delivery	117 (27.3%)
History of cesarean deliveries only	66 (15.4%)
Gestational age on procedure day	
< 17w6d	135 (31.5%)
18w0d – 19w6d	87 (20.3%)
20w0d – 21w6d	106 (24.8%)
$\geq 22w0d$	100 (23.4%)
Fetal demise	30 (7.0%)
Bleeding risk assessment ^a	
Low risk	120 (28.0%)
Moderate risk	288 (67.3%)
High risk	18 (4.2%)
Not recorded	2 (0.5%)

w, weeks; d, days.

Data are presented as *n* (%) or mean \pm standard deviation.

^a see online Appendix 1.

Table 2
Clinically relevant bleeding outcomes for D&E patients at University of California, Davis from April 2019 through March 2020

Gestational age	Bleeding risk assessment	Pre-procedure issues	mQBL (mL) initial procedure	Post-procedure blood loss ^a	Bleeding interventions			
					Cervical injury repair	Uterotonics (doses)	Intrauterine balloon	Other
14w4d	Moderate	Fetal demise	200	N/A	No	2	No	None
15w2d	Moderate	None	300	N/A	No	0	Yes^b	Hospitalization
15w5d	Moderate	Fetal demise	20	1300	No	3	Yes	Return to OR^c, reaspiration, DIC, blood transfusion, ICU admission
17w2d	Low	None	150	N/A	Yes	1	No	None
18w1d	Low	None	210	N/A	Yes	1	No	None
19w6d	Moderate	None	150	N/A	Yes	1	No	None
20w0d	Moderate	None	250	N/A	Yes	1	No	None
20w1d	Moderate	None	250	N/A	No	2	No	None
21w0d	Moderate	Trisomy 21, anomalies	1800	N/A	No	2	No	TXA, UAE
21w0d	High	None	600	N/A	Yes	1	No	None
21w5d	Moderate	Trisomy 21	450	N/A	No	1	Yes	None
21w6d	Moderate	Decompensated alcoholic cirrhosis, thrombocytopenia	550	980	No	2	Yes	Return to OR, reaspiration, TXA, blood and platelet transfusion
21w6d	Moderate	Fetal 45X, anomalies	1635	N/A	No	2	No	Reaspiration, TXA, blood transfusion, vaginal packing, ICU admission
21w6d	Moderate	None	250	N/A	No	2	No	None
22w0d	Moderate	None	200	N/A	No	2	No	None
22w0d	Moderate	Trisomy 21	500	N/A	No	1	Yes	None
22w1d	Moderate	None	400	N/A	Yes	0	No	None
22w3d	Moderate	None	325	N/A	No	2	No	None
22w3d	Moderate	None	300	N/A	No	2	No	None
22w4d	Moderate	None	450	N/A	No	2	No	None
22w4d	Moderate	None	250	N/A	Yes	1	No	None
22w4d	Moderate	None	250	50	Yes	No	No	Return to OR^c
22w4d	Moderate	None	450	N/A	Yes	1	No	None
22w5d	Moderate	Trisomy 21, anomalies	1000	N/A	Yes	1	No	Hospitalization
22w6d	Moderate	Fetal anomalies	250	N/A	No	3	No	None
23w2d	Moderate	None	950	N/A	No	2	No	None
23w6d	Moderate	None	450	N/A	Yes	1	No	None
23w6d	Moderate	Fetal anomalies	200	N/A	No	2	No	None

DIC, disseminated intravascular coagulopathy; ICU, intensive care unit; mQBL, modified quantitative blood loss; OR, operating room; TXA, tranexamic acid; w, weeks; d, days.

Bolded rows have outcomes consistent with hemorrhage.

^a Post-procedure loss includes estimated loss in recovery room and mQBL from second procedure, when applicable.

^b Suspected arteriovenous malformation noted on ultrasound examination prior to procedure.

^c Bleeding during recovery not quantified (reported as soaked pad 60% in 30 minutes), 50 mL post-procedure loss recorded during second procedure; all interventions after return to OR.

procedures and returned to the hospital after discharge with significant bleeding requiring further interventions.

The median mQBL for the study population was 150 mL (interquartile range 75–250 mL). Twenty-eight (6.5%, 95% CI 4.2%–8.9%) patients had clinically relevant bleeding outcomes and 9 (2.1%, 95% CI 0.7%–3.5%) met criteria for hemorrhage, with case details provided in Table 2. Of note, 1 of the patients who required hospitalization was already in the hospital due to liver failure. Eleven patients had bleeding related to cervical injuries requiring repair with mQBL amounts ranging from 150–1000 mL; the other 17 patients had uterine bleeding with mQBL amounts ranging from 200–1800 mL. Clinically relevant bleeding occurred in 2/30 (6.7%, 95% CI 0%–15.6%) patients with IUD and 26/398 patients without IUD (6.6%, 95% CI 4.1%–9.0%).

Clinically relevant bleeding outcomes occurred in 6/319 (2%), 15/97 (15%) and 7/12 (58%) patients with total blood loss <250 mL, 250–500 mL and >500 mL, respectively ($p < 0.0001$). Hemorrhage occurred in 0, 4/97 (4%) and 5/12 (42%) patients with total blood loss <250 mL, 250–500 mL and >500 mL, respectively

($p < 0.0001$). The study population included two patients with a coagulopathy and 1 using anticoagulation. One patient with a coagulopathy had liver failure due to alcoholic cirrhosis with thrombocytopenia (57,000/mm³) and underwent an initially uncomplicated D&E at 21 weeks 6 days gestation with a mQBL of 550 mL; however, the patient had significant bleeding during recovery necessitating return to the OR (Table 2). The second patient with a coagulopathy (immune thrombocytopenic purpura on chronic prednisone 20 mg daily) had a D&E at 17 week 3 days for intrauterine fetal demise with a mQBL of 175 mL. Pre-procedure, the patient had prolonged partial thromboplastin time and elevated d-dimers, presumed to be related to the demise, and received fresh frozen plasma pre-operatively. The patient using anticoagulation (therapeutic low molecular weight heparin, stopped 36 hours before procedure) had a history of pulmonary embolus in a prior pregnancy and underwent a D&E at 23 weeks 4 days gestation with a mQBL of 500 mL. Neither of the latter two patients had clinically relevant bleeding.

The median mQBL measurements for the 28 patients with and the 400 patients without clinically relevant bleeding are reported

Table 3

Blood loss for 428 patients with and without clinically relevant bleeding with D&E procedures at University of California, Davis from April 2019 through March 2020

	Clinically relevant bleeding ^a n=28	No clinically relevant bleeding n=400	No uterotonics n=335	One uterotonic n=65
mQBL (Median, IQR)	312.5 (250–550) mL	150 (75–200) mL	115 (50–200) mL	200 (150–300) mL
Range	150–1800 mL	10–900 mL	10–550 mL	50–900 mL
p-value ^b	referent	<0.0001	<0.0001	0.0004

IQR, interquartile range; mQBL, modified quantitative blood loss.

^a Required intervention for bleeding within 24 hours post-procedure, including use of ≥ 2 uterotonics (not including standard oxytocin infusion), cervical laceration requiring repair, tranexamic acid administration, uterine balloon tamponade, uterine artery embolization, blood transfusion, hospitalization, or return to operating room.

^b Comparing median mQBL to patients without clinically significant bleeding.

in Table 3. Among patients who received no or 1 uterotonics, median QBLs were 115 mL (IQR 50–200 mL) and 200 mL (IQR 150–300 mL), respectively ($p < 0.0001$). The median mQBL for the 9 patients with hemorrhage was 1000 mL (IQR 450–1530 mL).

Physicians recorded pre-operative bleeding risk assessments for 426 patients and assigned risks as low, moderate and high in 120 (28.2%), 288 (67.6%), and 18 (4.2%) of patients, respectively. The number in each group that experienced clinically relevant bleeding were 2 (1.7%), 25 (8.7%), and 1 (5.6%), respectively (test for trend $p = 0.03$) with no difference between moderate and high-risk patients (Fisher exact test $p = 1.0$).

4. Discussion

Our findings suggest no single amount of blood loss is easily correlated with clinical interventions and hemorrhage. Most patients (21/28 [75%]) requiring additional interventions have QBL ≤ 500 mL. About 40% of patients with blood loss of more than 500 mL had no clinically relevant bleeding outcomes with the procedure, including a patient with mQBL as high as 900 mL. Interestingly, 6/319 (1.9%) patients with a blood loss < 250 mL had a clinically relevant bleeding event. These findings likely reflect quick action by expert surgeons who recognized the clinical situation and intervened to limit the bleeding before the amount was excessive. Unlike the SFP guidelines [9] which suggested that clinical hemorrhage may be defined as both the clinical response to excessive bleeding and/or bleeding more than 500 mL, our study suggests a higher degree of importance to the clinical aspects of this definition and demonstrates that no specific amount of blood loss is independently diagnostic.

We did not include blood loss estimates that occurred in the recovery room for uncomplicated patients or additional loss after repeat procedures because the goal was to assess if a specific volume correlated with clinical interventions to define hemorrhage. Including these values would not have changed the conclusions and only increased the blood loss amounts for uncomplicated patients. We note that our mQBL amounts are lower than those reported with strict QBL assessments [7], which may imply that we underestimated actual blood loss in all patients. We used a mQBL process in clinical practice which is less time consuming while approximating the most important steps of the regimented QBL process. However, our lower blood loss amounts could also be explained by our use of prophylactic intravenous oxytocin which significantly decreases blood loss with D&E procedures [13] and was not used by the investigators that performed prior QBL assessments [7].

Surgeons typically provide early intervention when increased bleeding is present to prevent clinically significant bleeding, most notably uterotonics. We only included use of two uterotonic agents as indicative of clinically significant bleeding because 1 agent would imply some early bleeding for which treatment prevented the need for any further interventions. In our series, 65 (15.2%) patients received 1 uterotonic (typically methylergonovine) without

any other interventions and mQBL totals ranging from 50–900 mL. Whereas recent data suggests that prophylactic methylergonovine may result in worse bleeding outcomes [14], our findings suggest that use when clinically indicated appears to be a reasonable option.

We found no correlation of increased clinically relevant bleeding outcomes in patients with predicted high as compared to moderate bleeding risk. Surgeons did not do anything different for moderate- and high-risk patients other than obtaining different labs and cross-matching blood in advance. However, it is possible that in clinical practice, we behaved differently to prevent bleeding more in this high-risk group. It is also possible that patients with multiple moderate risk factors could be at higher risk than those with 1 risk factor, an assessment outside the scope of this report. These results suggest that further research is needed to reevaluate factors that predict significant bleeding with D&E procedures to optimize pre-procedure use of resources such as crossmatching and laboratory testing.

Our D&E clinically relevant bleeding rate was 65 per 1,000 cases and our hemorrhage rate was 21 per 1,000 cases. The difference in these rates reflects that bleeding interventions during D&E represent a spectrum and the term hemorrhage should truly reflect a significant outcome, as we define in our series as uterine balloon tamponade, UAE, blood transfusion, hospitalization, or return to operating room. Our hemorrhage rate is higher than the range of 0.9 to 10 per 1,000 cases reported in the literature [2–6], which may reflect a high-risk population referred to our center or, perhaps, a more realistic rate in contemporary practice. The SFP definition [9] of hemorrhage would include all of our clinically relevant bleeding cases plus an additional 5 patients with QBL > 500 mL who did not have any clinically relevant bleeding outcomes, resulting in an even higher rate of 77 per 1,000 cases. These numbers reflect the importance of recognizing a gradation of bleeding outcomes with D&E from none to clinically relevant bleeding to hemorrhage.

Our findings are limited by the small number of patients with relevant bleeding outcomes meaning our results can be considered exploratory at best; a larger sample may demonstrate a clearer correlation of blood loss amounts and clinical interventions and outcomes related to hemorrhage. Although our data may support new definitions for clinically relevant bleeding and hemorrhage, our results related to amount of blood loss and hemorrhage rates may only be generalizable to other referral centers like ours. Additionally, measurements of continued blood loss outside of the operative room were accounted for by using EBL rather than QBL, which makes finding the true total amount of blood loss difficult to achieve. However, because patients with this excessive bleeding had a blood loss of 1,000 mL or more and required multiple interventions to treat, this estimation does not likely alter the overall findings. Lastly, the electronic medical record did not consistently reflect race and ethnicity so we felt we could not accurately include these patient characteristics.

Our outcomes reflect real life scenarios with surgeons making individual decisions regarding the need for and type of interventions related to bleeding based on the clinical situation. Clinical hemorrhage may be best defined within the collective symptomatic profile of the patient, which could include symptoms and vital sign changes as well as the clinician's response to bleeding rather than any quantified amount of blood loss. Continuing to gather data using clinical outcomes may enable development of more accurate guidelines and additional interventions to decrease significant blood loss.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.contraception.2022.11.005](https://doi.org/10.1016/j.contraception.2022.11.005).

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