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Intrauterine cleaning after placental delivery at cesarean section: a randomized controlled trial*

Ahizechukwu C. Eke^a, Sheila Drnec^b, Andrea Buras^b, Joanna Woo^b, Denny Martin^b, and Steven Roth^c

^aDivision of Maternal Fetal Medicine, Department of Gynecology and Obstetrics, Johns Hopkins University School of Medicine, Baltimore, MD, USA

^bDivision of General Obstetrics & Gynecology, Michigan State University Women's Health Center, Lansing, MI, USA

^cDivision of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Michigan State University/Sparrow Hospital, Lansing, MI, USA

Abstract

Objective: The objective of this study is to evaluate whether omission of intrauterine cleaning increases intraoperative and postoperative complications among women who deliver via cesarean section.

Methods: We randomized 206 women undergoing primary elective cesarean deliveries to intrauterine cleaning or omission of cleaning. Postpartum endomyometritis rates across groups were the primary outcome. We also examined secondary outcomes. To detect a 20% difference in infection rate between the cleaned and the non-cleaned groups (two-tailed [alpha] = 0.05, [beta] = 0.2), 103 women were required per group. Analysis was by intention-to-treat.

Results: Two hundred and six were randomized as follows: 103 to intrauterine cleaning and 103 to omission of cleaning after placental delivery. There were no statistically significant differences in the rate of endomyometritis between the two groups (2.0% versus 2.9%, RR =0.60; 95% CI 0.40–1.32). There were no statistically significant differences in postpartum hemorrhage rates (5.8% versus 7.7%, RR 0.75; 95% CI 0.6–1.2), hospital readmission rates (2.9 versus 3.8%, RR 0.75; 95% CI 0.5–1.6), time to return of gastrointestinal function, need for repeat surgery, or quantitated blood loss between the two groups.

Conclusions: Our randomized controlled trial provides evidence suggesting that omission of intrauterine cleaning during cesarean deliveries in women at low risk of infection does not increase intraoperative or postoperative complications.

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CONTACT Ahizechukwu C. Eke ahizeeke2nd@yahoo.ca, Division of Maternal Fetal Medicine, Department of Gynecology and Obstetrics, Johns Hopkins University School of Medicine, 660 N Wolfe Street, Phipps 228, Baltimore, MD, USA.

Disclosure statement

The authors did not report any potential conflicts of interest.

Keywords

Intrauterine cleaning; cesarean section; endomyometritis; placental delivery; randomized trial

Introduction

The rate of cesarean delivery has seen a sharp rise in the USA, with more than a million occurring annually [1,2]. The associated increase in complications has created a motivation to reduce perioperative and postoperative morbidity through the use of evidence-based surgical techniques [3–5]. Several randomized controlled trials (RCTs) have assessed the relative safety of specific cesarean section practices, comparing types of cesarean section skin incision [6], creation versus omission of a bladder flap [7,8], different approaches to uterine closure [9], irrigation versus non-irrigation of the abdominal cavity [10], closure versus non-closure of the parietal peritoneum [11], and suture versus staples for skin closure [12].

Intrauterine cleaning at cesarean section – wiping the inner lining of the uterus with a dry laparotomy sponge after placental delivery – is intended to remove blood clots, bits of decidua or membranes within the uterine cavity. It is supported by the rationale that leaving debris in the uterine cavity predisposes patients to postoperative endomyometritis and postpartum hemorrhage [13], but its benefits remain uncertain, as no known RCTs have demonstrated its effectiveness [14–16]. Some obstetricians argue that this procedure is not consistently performed after vaginal deliveries, thereby suggesting that it is unnecessary and inefficient in cesarean sections. Moreover, the process of cleaning the uterus might unintentionally compound infectious risk [17]. Two studies examining intrauterine manipulations at the time of cesarean section have shown that such actions can increase the risk of post-cesarean endomyometritis [13,17]. Nonetheless, the lack of high-quality RCTs specifically assessing intrauterine cleaning complicates efforts to develop specialty-level recommendations regarding this practice. In order to address this issue, we designed a prospective RCT to compare postpartum endomyometritis rates after cleaning versus non-cleaning of the uterus at cesarean section.

Materials and methods

The study reported here was conducted at a single institution: Michigan State University/Sparrow Hospital in Lansing, MI, a high-volume obstetric center with regional catchment for complex cases requiring neonatal intensive care unit availability. Our protocol was approved by the Michigan State University/Sparrow Hospital Institutional Review Board (protocol # 14–459) and carried out from June 2014 through July 2015 (registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study?term=NCT02152735&rank=1), #NCT02152735). Eligible participants were women with singleton or multiple pregnancies, in vertex or breech presentation with intact membranes presenting to the labor and delivery suite for planned elective cesarean delivery. Women were not eligible if they had conditions that predisposed them to endomyometritis prior to cesarean delivery, including preterm premature rupture of the fetal membranes, prolonged rupture of membranes prior to cesarean section, diagnosed chorioamnionitis prior to cesarean section,

uncontrolled diabetes mellitus, chronic steroid therapy use, and immunosuppressive disorders (e.g. HIV infection).

After written informed consent was obtained, eligible participants were randomly assigned in a 1:1 ratio to receive either intrauterine cleaning or non-cleaning of the uterine cavity after placental delivery at cesarean section. Permuted block randomization with varying block sizes was used to stratify randomization. The assignment sequence was generated using SAS software, version 9.2 (SAS Institute, Cary, NC); whereby the sequences were secured and available only to the system manager. The randomization list was managed and maintained by designated nursing staff. Only the four designated surgeons (A. E., S. D., A. B., and J. W.) for this study knew the group to which participating women were allocated. All other investigators, study participants, operating room staff, and anesthesiologists were blinded to group allocation.

Per routine cesarean section operative management at the labor and delivery unit of Michigan State University/Sparrow Hospital, both groups were standardized with respect to all other cesarean section techniques. The following steps represent our standard procedures for scheduled, non-emergent cesarean sections. Before cesarean section, patients are prepped, draped, and placed in the left lateral tilt position to displace the uterus. A foley catheter is inserted and preoperative antibiotics are administered (1–2 g cefazolin intravenous). A time out is always completed. A Pfannenstiel skin incision is used. The fascia is incised in the midline and the incision is extended bilaterally in a blunt fashion. The rectus muscles are separated in the midline and the abdominal cavity is entered bluntly. The uterus is palpated for rotation, after which a bladder blade is placed. The lower uterine segment is scored in the midline in a transverse fashion, and the hysterotomy is extended in a cranial-caudad fashion. Bladder flaps are not routinely created. The hysterotomy closure is usually performed in two layers using 0 monocryl suture. The fascia is closed with 0 PDS suture in a running fashion. The subcutaneous tissue is inspected for pinpoint bleeding and cauterized as necessary. The subcutaneous tissue is closed if it is greater than 2 cm in depth. The skin is reapproximated using a subcuticular technique and a 4/0 monocryl suture. The incision is subsequently dressed and clots are expressed from the patient's vagina. Women with a cefazolin allergy receive 900 mg clindamycin and a 1.5 mg/kg of gentamycin instead of 1–2 g cefazolin.

Intraoperatively, participants randomized to cleaning had their uterine cavities cleaned with a dry laparotomy sponge after delivery of the placenta. Per standard protocol, the uterus was explored with one hand holding the sponge, while the other hand was placed on the fundus to stabilize the uterus. Participants randomized to non-cleaning did not have any manipulation of their uterine cavities after complete delivery of the placenta. The placenta was inspected after delivery to ensure that it was complete, including the membranes. Postoperative management was the same for both groups. Vital signs (blood pressure, pulse rate, and temperature) and uterine tone were monitored every 15 min for 2 h, and then every 4 h in line with the guidelines for active management. The foley catheter was removed on postoperative day 1. The patient care staff (including physicians) responsible for collection of patient reported symptoms were blinded to group randomization. Examination of the surgical incision, notation of return of gastrointestinal function, and a complete blood count

were standard orders for the first postoperative day. Data were abstracted from the medical records of all study participants during the hospitalization and up to 6 weeks postpartum to assess for any morbidities. Participants were contacted immediately after delivery and at 2, 4, and 6 weeks postdelivery. They were asked standardized questions to determine whether there were any symptoms not captured by medical record abstraction (e.g. symptoms of endomyometritis, emergency department visits, and hospital readmissions).

The primary outcome for this study was the proportion of postpartum endomyometritis development among the participants. Strict criteria were used for diagnosis. A patient was diagnosed with endomyometritis if she had an oral temperature >38 degrees centigrade (100.4 F) after the 1st 24 h following cesarean, and either (1) fundal tenderness greater than expected, or (2) foul smelling or purulent lochia. Endomyometritis was diagnosed only if other causes for the patients' symptoms and signs were not identified. A diagnosis of endomyometritis met criteria for initiating treatment with antibiotics. Secondary outcomes were the occurrence of postpartum hemorrhage, presence of retained products of conception, quantitative blood loss volume, mean surgical time, length of hospital stay, time until return of gastrointestinal function, need for repeat surgery, and hospital readmission rate. Return of bowel function was defined by the presence of bowel sounds on abdominal auscultation, or passage of flatus whichever came first. As noted above, postoperative rounding physicians were blinded to group assignment to avoid assessment bias. The primary and secondary outcomes were adjudicated by an expert committee whose members were unaware of the group assignments and were not involved in the care of patients.

We calculated the sample size for this study *a priori* based on prior data from an independent pilot study done at Michigan State University/Sparrow hospital – *Intrapartum practices after placental delivery at cesarean section; a retrospective chart review of a single institutional experience* – which determined primary outcome rates of endomyometritis at 1.7% for the women assigned to intrauterine cleaning and 1.8% for the non-cleaned group. To detect a 20% difference in infectious morbidity between the cleaned and the non-cleaned groups (two-tailed $[\alpha] = 0.05$, $[\beta] = 0.2$) with an allocation ratio of 1:1 and a 10% anticipated protocol deviation as well as a 1% loss to follow-up, 103 women were required per group. Analysis was by intention-to-treat.

Two interim analyses were performed and reviewed by the data and safety monitoring board of Michigan State University/Sparrow hospital. They utilized the Lan–DeMets spending function with O'Brien–Fleming-type boundaries to consider early termination of the trial at the first and second interim analyses, respectively. The unit of analysis was the individual woman. The first interim analysis included data from the first 80 women who underwent randomization, and the second included data from the first 160 women who underwent randomization. The trial was allowed to continue to completion.

Data analysis was performed using Stata 13 (Stata Corp, College Station, TX). Categorical variables were compared by χ^2 or Fisher exact test as appropriate and continuous variables were compared by *t*-test or non-parametric Wilcoxon ranksum test for data that were not normally distributed. *p* values were two sided and $p < .05$ was considered significant.

Results

Of the 312 women who were screened for eligibility, 58 did not meet inclusion criteria and 48 declined participation (Figure 1). From June 2014 through July 2015, 206 women were randomized to either the intervention (i.e. intrauterine cleaning) or its control (i.e. non-cleaning). It is their data that form the basis for this report. All charts were reviewed for readmissions and complications in the 6-week postoperative term. Two percent of the patients ($N = 4$) were evaluated at two, four, and 6 weeks postoperation by telephone interview only, whereas the majority of the women —98% (202/206) – were evaluated with a combination of in-person follow-up visits and phone interviews. There were comparable follow-up rates in the cleaned and non-cleaned groups (98% compared with 99%, $p = .58$).

We noted similar demographic and obstetric characteristics between the intrauterine cleaning and non-cleaning groups, as summarized in Table 1. Age, gestational age at cesarean delivery, smoking status, body mass index (BMI), rate of preterm cesarean section for medical indications, rates of primary and repeat cesarean sections, and rates of hypertensive disease and diabetes mellitus in the index pregnancy were similar (Table 1).

There were no statistically significant differences in the primary outcome – incidence of postpartum endomyometritis – between the cleaned and non-cleaned groups (2.0% compared with 2.9%, RR 0.6, 95% CI 0.4–1.3), Table 2. Similarly, there were no statistically significant differences in the secondary outcomes, including mean surgical time (51.7 versus 50.3 min; $p = .62$), quantitative blood loss volume (820 ml versus 819 ml; $p = .53$), length of hospital stay (3 versus 3 d; $p = .67$), and return of gastrointestinal function (1.1 versus 1.0 d; $p = .71$). Furthermore, the rates of postpartum hemorrhage (5.8% versus 7.7%, RR 0.75, 95% CI 0.6–1.2), repeat surgery (0.97% versus 0.97%, RR 1, 95% CI 0.6–1.7), retained products of conception (0.97% versus 0.97%, RR 1, 95% CI 0.8–1.7), and hospital readmission after cesarean section (2.9% versus 3.8%, RR 0.75, 95% CI 0.5–1.6) were similar between both groups (Table 2).

When patients were stratified by preoperative Group B *Streptococcus* (GBS) status, there were no differences in the primary outcome of postpartum endomyometritis rates between women who were GBS positive and those who were GBS negative prior to cesarean delivery ($p = .43$) (Table 3).

Discussion

We found the rate of postpartum endomyometritis to be 2.0% in the treatment group and 2.9% in the control group. There are few prospective studies that have examined the true incidence of post cesarean endomyometritis in women with intact membranes prior to cesarean delivery [18,19]. Andrews et al. showed that bacterial colonization of the chorioamnion in women with intact membranes being delivered by cesarean is a significant, independent predictor of subsequent endomyometritis [18]. In a Cochrane systematic review by Smaill et al., postpartum endomyometritis was estimated to occur in 11% of cesarean sections performed after the onset of labor and 1.7% of those performed electively in patients who received antibiotic prophylaxis within 60 min of initial skin incision [20]. Due

to the low incidence of endomyometritis in women undergoing elective cesarean sections with intact membranes and without labor, there has been debate about the benefit of prophylactic antibiotics in this circumstance. A meta-analysis of four studies found that antibiotic prophylaxis in these group of patients resulted in a decrease in postoperative fever (RR 0.25; 95% CI 0.14–0.44) and endomyometritis (RR 0.05; 95% CI 0.01–0.38) in women undergoing elective cesarean sections with intact membranes [21]. Collectively, these data support the use of prophylactic antibiotics in all women undergoing cesarean section. Our findings reported here contribute to this literature by additionally suggesting that intrauterine cleaning can be safely omitted in women at low risk of infection undergoing cesarean sections with intact membranes without increasing the risk of postpartum endomyometritis.

Colonization with GBS has been shown to be an independent risk factor for endometrial infection, significantly increasing the risk of postpartum endometritis development [22,23]. Studies have demonstrated that GBS can be transmitted from mother to infant, even in the absence of labor [22]. In a retrospective case–control study, Olsen et al. found that 7.7% of women who developed endomyometritis within 30 d after low transverse cesarean section were colonized by GBS (124/1605 study participants), a statistically significant result [22]. However, in our trial, there were no statistically significant differences between endomyometritis rates in GBS positive and negative women (Table 3). It is possible that we did not detect an increased risk of endomyometritis associated with GBS colonization due to our universal use of intrapartum antibiotic prophylaxis, as antibiotic prophylaxis during cesarean sections provides coverage for most gram-positive and negative organisms. Also, all women studied in this trial had intact membranes, which further reduces the risk of GBS-mediated endomyometritis for GBS positive women relative to having ruptured membranes prior to cesarean section [24,25].

Of the secondary outcomes, there were no statistically significant differences between the cleaning and non-cleaning groups. Interestingly, there was a trend towards an increased risk of postpartum hemorrhage in women randomized to the cleaned group compared with those in the non-cleaned group (eight women in the cleaned group versus six in the non-cleaned group). It is well documented that excessive blood loss (>1500 mL) is an independent risk factor for postpartum endomyometritis at the time of cesarean section. Hence, it has been suggested that with blood loss greater than 1500 mL, an additional dose of prophylactic antibiotic should be given [26]. Although some studies have noted statistically significantly greater blood loss volumes and surgical site infection rates after intrauterine manipulations at cesarean sections [27,13], this was not a statistically significant finding in our study.

Our study has several strengths. First, it was a prospective randomized controlled trial, which is the gold standard for evaluating the effectiveness of medical interventions. Second, we ensured that the same surgeons performed all of the cesarean sections, and followed consistent surgical methods. There was strict adherence to appropriate skin preparation procedures (including hair clipping as opposed to shaving), effective antisepsis, and maintenance of sterile surgical fields. Third, we used very strict criteria for diagnosis of endomyometritis to promote consistency and objectivity in diagnosis. Fourth, there was a high rate of follow up; most of which was done through a combination of in-person postpartum visits and telephone interviews (98%). The remaining patients (2%) were

followed with telephone encounters only. Although these patients may not have had documentation of complications following surgery (e.g. endomyometritis), Whitby et al. previously showed a high negative predictive value (98.2%) for excluding postoperative infections in patients who underwent telephone interviews within 6 weeks after surgery as compared with those who underwent medical examinations [28]. No patients interviewed by telephone in the current study had findings suggestive of endomyometritis.

This trial also had limitations. First, this study was a single center trial, and therefore the limitations of single center trials apply (i.e. the potential for limited external validity of our findings, which may not be generalizable to a broader population of pregnant women) [29]. Additionally, although our study was adequately powered with respect to its primary outcome of interest, a larger sample size may have facilitated detection of more subtle differences within our secondary outcomes and subgroup analyses. Another limitation of this study was our inability to blind the surgeons. However, the physicians examining the patients postoperatively (different from those who performed the cesarean sections) were blinded to the treatment allocation, as were the individuals performing data collection.

In conclusion, our study does not support routine cleaning of the uterine cavity after placental delivery in women at low risk of intrauterine infection undergoing scheduled elective cesarean delivery. Intrauterine cleaning after cesarean placental delivery may have its benefits, but there is insufficient evidence to recommend its routine use. As evidence-based medicine continues to compel modifications in our most common major obstetric procedure – cesarean section, well-articulated national guidelines are needed to assist providers in the minimization of postoperative morbidity.

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Figure 1.
CONSORT flow diagram for the uterine cleaning randomized controlled trial showing algorithm of randomization. *N* represents the number of women.

Table 1.

Patient demographics.

Characteristic	Cleaning (N = 103)		Non-cleaning (N = 103)		p value
	27.5 ± 4.18		28.3 ± 4.73		.43
Nulliparity (n)	24	23.3%	26	25.2%	.37
Gestational age (weeks)	39 ± 0.15		39 ± 0.27		.75
Smoking (n)	17	16.5%	19	16%	.64
^a BMI (mean)	29.9	(24.8–37.3)	30.2	(24.1–37.1)	.71
Primary cesarean section	24	23.3%	21	20.3%	.63
Repeat cesarean section	79	76.7%	82	79.6%	.48
Hypertensive disease	18	17.4%	20	19.4%	.56
Diabetes mellitus	23	22.3%	21	20.4%	.28
Preterm cesarean (<37 wks)	24	23.3%	19	18.4%	.91
Caucasian ethnicity	75	72.8%	77	74.8%	.78

^aBMI: body mass index; Wks: weeks. Data presented in the table are mean ± standard deviation, mean (range), or n (%) unless otherwise specified. *p* was > .05 for all comparisons.

Table 2.
Primary outcome (postpartum endomyometritis) and secondary outcome incidences across treatment groups.

Outcome	Cleaning (N = 103)	No cleaning (N = 103)	p value	RR (95% CI)
Postpartum endomyometritis	2	3	.43	0.60 (0.4–1.3)
Preoperative hematocrit	30.6 ± 3.37	30.9 ± 3.82	.38	–
Postoperative hematocrit	28.3 ± 3.34	28.5 ± 3.84	.56	–
Quantitative blood loss	820 ± 297.4	819 ± 276.5	.53	–
Length of hospital stay	3 ± 0.18	3 ± 0.20	.67	–
Return of GI function ^a	1.1 ± 0.2	1.0 ± 0.3	.71	–
Length of surgery	51.7 ± 16.9	50.3 ± 17.4	.62	–
Repeat surgery	1	1	.97%	1.0 (0.6–1.7)
Hospital readmission rate	3	4	.29%	0.75 (0.5–1.6)
Retained products	1	1	.97%	1.0 (0.8–1.7)
Postpartum hemorrhage	6	8	.58%	0.75 (0.6–1.2)

^aGI: gastrointestinal; RR: relative risk. Data presented in the table are mean ± standard deviation, mean (range), or n (%) unless otherwise specified. *p* was > .05 for all comparisons.

Table 3.

Group B Streptococcus status across treatment groups.

Characteristics of study participants based on study assignment			
Variable	Cleaning (N = 103)	Non-cleaning (N = 103)	p value
Group B Streptococcus positive (%)			
Yes	32	34	.43
No	71	69	.47
Unknown	0	0	0

Data presented in the table are *n* (%) unless otherwise specified. *p* was > .05 for all comparisons.