

## **To drain or not to drain: intraperitoneal closed-suction drainage placement during cesarean delivery**

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## ABSTRACT

**Introduction:** Intraperitoneal closed suction drains are occasionally placed during cesarean delivery. However, little is known about the possible risks and benefits. This study aims to ascertain the prevalence, associated factors, outcome, and risks of intraperitoneal closed-suction drain placed during cesarean delivery.

**Material and Methods:** A retrospective cohort study of all women undergoing cesarean delivery in a single center from 2005 to 2015. We excluded cases of cesarean hysterectomy and women who had hollow viscus injury. Cesarean deliveries were categorized into two groups based on intraperitoneal drain use: drain+ and drain-. The study aims were to describe: 1. Drain use prevalence; 2. Factors associated with drain use; 3. Interval to relaparotomy due to intraperitoneal bleeding and outcome of drain use; and 4. Unique drain-related adverse outcome. Statistics: Univariate, multivariable, and inverse probability treatment weighting (IPTW) analysis.

**Results:** After applying the inclusion and exclusion criteria, 16 581 (99.3%) cesareans were included. An intraperitoneal drain was used in 1264 (7.6%) cesareans, ranging from 4.4% to 18.8% in women with no and four or more cesareans, respectively. Comparing the drain+ and drain- groups, multivariable analysis revealed that the factors associated with the use of a drain included (OR, 95%CI) uterine rupture (5.14, 3.15-8.38), intrapartum fever (2.65, 1.87-3.75), previous cesareans (2.29, 2.00-2.68), second-stage cesarean (2.21, 1.64-2.74), preterm delivery (1.89, 1.63-2.19), spontaneous onset of labor (1.42, 1.24-1.63), and maternal age greater than 35 years (1.35, 1.19-1.54);  $P < 0.001$  for all. Of the forty-four women (0.27%) who underwent relaparotomy for intraperitoneal bleeding, there were fourteen in the intraperitoneal drain group. Inverse probability treatment weighting analysis demonstrated that median (interquartile range) times (hours) to relaparotomy were significantly shorter in the drain+ group [3.5 (3.3-10.0) vs. 12.5 (7.9-15.6),  $P < 0.001$ ] and that puerperal fever incidence was higher in the drain+ group (2.2% vs. 1.4%,  $P < 0.001$ ). The incidence of relaparotomy to remove a retained drain or drain fragment was 0.48% (6/1264).

**Conclusions:** Drain use in our study resulted in a shorter time to relaparotomy for intraperitoneal hemorrhage. However, it was associated with a higher risk for puerperal fever and a 0.5% risk for relaparotomy for removal of the drain.

**Keywords**

Cesarean section; drain; surgical complications; surgical technique; post-partum care; post-partum hemorrhage; relaparotomy; adverse outcome

**Key message**

Intraperitoneal drain placed during cesarean is used more often in complicated surgeries and is associated with a shorter interval to relaparotomy.

## Introduction

Cesarean delivery is one of the most common surgical procedures performed worldwide.(1) Relaparotomy complicates 0.1% to 1.0% of cesareans, with up to 66% performed for intraperitoneal hemorrhage(2-5).

Intraperitoneal hemorrhage following cesarean is a challenging diagnosis. Diagnostic clues include maternal symptoms and deteriorating vital signs. Physical examination might reveal pallor, abdominal distention, and tenderness. Laboratory findings might include dropping hemoglobin level, low platelets, and abnormal coagulation studies; ultrasound might show free intra-abdominal fluid. The appropriate initial management includes volume resuscitation and blood transfusion. When ongoing intraperitoneal hemorrhage is suspected, return to the operating theater is recommended.(6)

Prophylactic drainage of the abdominal cavity after gastro-intestinal surgery is widely used despite substantial disfavoring evidence(7). Closed-suction drainage systems, such as the Jackson-Pratt (JP) drain, when placed intraperitoneally, can provide an early sign for intraperitoneal hemorrhage. (8) An early alert of intraperitoneal hemorrhage may shorten the time to relaparotomy, hence minimizing morbidity by preventing further blood loss, reducing the need for transfusion, and allowing shorter recovery. Conversely, a drain can aggravate discomfort(9), might be a source of infection, or rarely, require relaparotomy to remove a retained drain or repair a drain incision herniation. Unlike evidence on sub-rectus or subcutaneous wound drains, the literature on intraperitoneal draining in obstetrics is scarce(10). A literature search using Mesh of "Cesarean Section" or "Delivery, Obstetric" and "Drainage" published in the literature on humans between 1990 and 2018 using PubMed revealed 443 publications. These publication titles were read by two authors (LD, HYS) as were all relevant abstracts (n=27) and manuscripts (n=11). Most were case reports of drain-related complications. Two studies were reporting on the incidence of drain use in repeat cesarean delivery(11, 12).

The purpose of this study was to evaluate the prevalence, associated factors, complications and outcome associated with intraperitoneal closed-suction drain placed during cesarean delivery.

## Material and Methods

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We conducted a retrospective cohort study of all cesarean deliveries in a single tertiary, university-affiliated medical center between July 2005 and December 2015. We excluded women who required a cesarean hysterectomy, but not those who underwent hysterectomy during relaparotomy. We further excluded women with a hollow viscus injury (i.e., incidental cystotomy, ureterotomy, ureter obstruction, or enterotomy), as these are arguably candidates for routine placement of an intraperitoneal drain due to the nature of the complication. Using these criteria, we aimed to select women whose drain was placed to report an early sign of intraperitoneal bleeding following cesarean delivery.

Data were extracted and de-identified from our computerized database, which includes participants' demographics, procedures, and diagnoses, all of which are updated during the hospital stay.

Our medical center settings have been previously reported.<sup>(13)</sup> In brief: Shaare Zedek Medical Center is a university-affiliated medical center with a large obstetric service. Cesareans are performed either by an attending physician or by a resident who is supervised by a scrub attending physician. Attending physicians performing Cesareans are general obstetricians, maternal-fetal medicine specialists, or other practitioners of board-certified obstetrics/gynecology subspecialties, who were either on call or performed the Cesarean in their private patients. Postoperative and postpartum care routinely is provided by residents who are postgraduate year one or two and is supervised by a maternal-fetal medicine specialist when necessary. The decision regarding discharge is based on maternal medical status. National Health and Drug Insurance plans cover all women for antenatal and peripartum care.

There is no pre-specified protocol for the use of an intraperitoneal closed-suction drain. In our department, the purpose of placing a drain is usually to provide an additional method of hemorrhage monitoring in women who had a difficult cesarean and were considered by the surgeon to be at high risk of bleeding. Therefore, the placement of an intraperitoneal drain depends on the clinical scenario and the senior surgeon's clinical judgment. Additional suturing and hemostatic agents are also available and used in accordance to surgeon discretion. Notwithstanding the lack of protocol for drain placement, the surgical technique for drain placement is similar among surgeons. A generic 10 mm Jackson-Pratt (JP) drainage tube (Biometrix b.v., Gronsveld, The Netherlands) is used. The skin is incised (approximately 10 mm) in the Cesarean intraperitoneal draining

lateral lower quadrant with a scalpel, taking care to avoid the inferior epigastric vessels. The Scarpa's fascia is then punctured with a blunt instrument (such as Mosquito forceps), and the drain is placed inside the intraperitoneal space, attached to the forceps, and pulled out of the abdomen through the incision. Subsequently, the drain is pulled back and forth through the abdominal incision to facilitate eventual removal. The draining end is placed intraperitoneally at the pelvic surgical bed or the Douglas pouch and is secured externally by a silk suture to the skin. After skin closure, the drain is properly dressed and connected to a 100mL suction bulb reservoir. The drain is removed within 24 to 48 hours postoperatively; before removal, any negative pressure is released.

Standard care after Cesarean includes frequent assessment of the women's well-being, vital signs recording, urine output monitoring, repeat blood count on post-operative day number one and physical examinations that is performed by certified obstetric nurses for the first 24 hours using a strict protocol. The monitoring schedule is not altered by the presence of a drain. With any concern, a thorough evaluation is performed by the on-call resident. Such an assessment includes as required a repeat clinical assessment, complete blood count, other pertinent laboratory studies and trans-abdominal ultrasound for assessment of the presence of free peritoneal fluid.

For the purpose of this study, we assigned each cesarean to one of two groups: drain positive (drain+) women who underwent a cesarean and in whom an intraperitoneal closed-suction drain was placed, and drain negative (drain-), women who underwent cesarean and an intraperitoneal drain was not placed.

Adverse maternal outcomes studied were the following: relaparotomy due to intraperitoneal hemorrhage, relaparotomy due to drain-related complications, hemoglobin drop greater than 4 gr/dL, packed red blood cells transfusion, puerperal fever (defined as temperature of 38.0°C /100.4°F or higher on two measurements, exclusive of the first 24 hours postoperatively(14)), prolonged maternal hospitalization (length of stay  $\geq$  10 days) and readmission to hospital (within 42 days postoperatively).(15)

Study aims were to ascertain 1. The prevalence of drain use. 2. Factors associated with drain use. 3. Interval to relaparotomy and outcomes associated with the use of a drain 4. Unique drain-related adverse outcome.

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### *Statistical Analyses*

The demographic and obstetric characteristics of women who had a drain placed were compared with those of women who did not have a drain placed using  $\chi^2$  or Fisher's exact test for categorical variables and Student's unpaired t-test or Mann-Whitney U-test for continuous variables. For dichotomous variables, percent were reported. For continuous variables, mean and standard deviation (SD), or median and interquartile ranges (IQR) were reported. All tests are two-tailed. In order to better characterize the factors associated with the placement of a drain, multivariate logistic regression models were devised adjusting for participants' demographics and comorbidities: maternal age, parity, previous cesareans, multiple pregnancy, gestational diabetes mellitus, hypertensive disorder, elective cesarean, vertex presentation, intrapartum fever (temperature > 38.0°C /100.4°F), second-stage cesarean(16), and preterm delivery. Odds ratio (OR) and 95% confidence intervals (CI) are reported. A p-value below 0.05 was considered statistically significant.

Given the rare occurrence of relaparotomy after cesarean, our ability to perform multivariate analyses to account for confounding by indication bias(17) was limited, hence we decided to use the inverse propensity score weighting method in order to create a bigger "pseudo-population" in which the treatment (drain placement) is independent of the measured confounders. The propensity score was estimated with multivariable logistic regression for intraperitoneal drain placement. Drain placement probability included pretreatment clinical and historical variables potentially associated with drain placement. We tested several models; the final model included: age, number of previous cesareans, uterine rupture, multiple pregnancy, nulliparity, vertex presentation, and gestational age. The goodness-of-fit of the propensity score model was evaluated with the Hosmer–Lemeshow test. Baseline and post-inverse probability treatment weighting (IPTW) adjustment balance between covariates were assessed using standardized mean differences. Variables were considered balanced if the standardized mean difference was <10%.

In this method, each woman receives a score that is estimated using a logistic regression model and is defined as the probability to receive the treatment conditional on pre-treatment covariates (i.e., the propensity score). Women with equal propensity scores will, on average, have similar pre-treatment covariate values, thus adjusting for propensity score allows for unbiased estimation of treatment effect. Furthermore, Cesarean intraperitoneal draining



through the artificial increase of the study population, one is not limited by the number of covariates in relation to the number of clinical outcomes events. We chose to incorporate the propensity scores into a treatment effect model using inverse probability treatment weighting. This assures that the contributions of treatment and control women are equal and no women's data are left out due to a mismatch in propensity scores. This method generates a pseudo-population in which each covariate combination is perfectly balanced between women and controls.

Analyses were carried out using SPSS software package version 22.0 (IBM, Armonk, NY, USA).

### *Ethical approval*

The Shaare Zedek Medical Center ethical committee approved the study protocol #0195-15.

## **Results**

### *Prevalence*

During the study period, there were a total of 16 699 cesareans. We excluded 62 women who underwent a primary cesarean hysterectomy (0.4%) and further excluded 56 women (0.3%) with hollow viscus injuries, leaving 16 581 (99.3%) women for analysis. A drain was used in 1264 cesareans; thus, the prevalence was 7.6% (Fig. 1). The rate of drain usage was proportional to the number of previous cesareans: 4.4%, 9.5%, 12.4%, 15.2% and 18.8% in women with no and up to four or more cesareans, respectively.

### *Associated factors*

Maternal, pregnancy and delivery demographics are presented in Table 1. Multivariable logistic analysis revealed that the following factors were significantly associated with the use of a drain: uterine rupture (OR 5.14, 95%CI 3.15-8.38,  $P<0.001$ ), intrapartum fever (OR 2.65, 95%CI 1.87-3.75,  $P<0.001$ ), previous cesareans (OR 2.29, 95%CI 2.00-2.68,  $P<0.001$ ), second-stage cesarean (OR 2.21, 95%CI 1.64-2.74,  $P<0.001$ ), preterm delivery (OR 1.89, 95%CI 1.63-2.19,  $P<0.001$ ), spontaneous onset of labor (OR 1.42, 95%CI 1.24-1.63,  $P<0.001$ ), and maternal age greater than 35 years (OR 1.35, 95%CI 1.19-1.54,  $P<0.001$ ).

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In order to test the effect of each additional cesarean on the risk of having a drain placed in the following cesarean, multivariable logistic analysis was performed with the subgroup of women undergoing a primary cesarean as the comparison group. Regression modeling demonstrated that the odds ratio for drain use increased with each additional previous cesarean from OR of 1.76 (95%CI 1.47-2.12) with one previous cesarean to OR of 4.46 (95%CI 3.37-5.91) with four or more previous cesareans ( $P<0.001$ ) (Fig. 2).

#### *Interval to relaparotomy and outcome of drain use*

Forty-four women underwent relaparotomy for intraperitoneal hemorrhage, none of which had an inherited or acquired bleeding disorder. Rates of relaparotomy due to hemorrhage differed significantly between groups: 0.2% (30/15 317) in the drain- group vs. 1.1% (14/1264) in the drain+ group ( $P<0.001$ ). The median time to relaparotomy was significantly shorter in the drain+ group [4.8 hours (IQR 3.5-11.3) vs. 12.5 hours (IQR 7.9-15.8),  $p=0.009$ ] (Fig. 3). All adverse maternal outcomes occurred more frequently in the drain+ group, aside from puerperal fever which occurred at similar rates (Table 2).

The standardized mean differences before and after covariate balancing with the inverse probability treatment weighting method are illustrated in Supplementary Figure 1. The propensity score model showed appropriate goodness of fit (Hosmer–Lemeshow  $P=0.29$ ). The median time to relaparotomy was 3.5 hours (IQR 3.3-10.0) in the drain+ group and 12.5 hours (IQR 7.9-15.6) in the drain- group ( $P<0.001$ ). Using this analysis, puerperal fever was higher in the drain+ group (2.2% vs. 1.4%,  $P<0.001$ ) (Table 3).

#### *Unique drain-related adverse outcome*

Relaparotomy to remove a retained drain or drain fragment occurred in 0.48% of women in the drain+ group (6/1264). In all six cases, a kink or inadvertent drain entrapment by a suture was the reason for drain or drain fragment retention. None of these surgeries was complicated by intraperitoneal hemorrhage. We did not encounter any cases of drain incision hernia during the follow-up period (42 days postoperatively).

## **Discussion**

In this large retrospective cohort study, we show that intraperitoneal drain was used in 7.7% of cesarean deliveries, ranging from 4.4% in primary cesareans, up to Cesarean intraperitoneal draining

18.8% in women with four or more previous cesareans. The rate of drain use was higher in the more technically challenging cesareans, eg, repeat surgery and second stage cesarean. Other factors associated with the use of a drain include uterine rupture, intrapartum fever, preterm delivery, spontaneous labor, and advanced maternal age. It is clear that the drain+ group differed both in women population and surgery characteristics. Furthermore, in cesareans where a drain was used, adverse maternal outcomes were more prevalent, hence drain use may serve as an indicator of a more complicated case. Drain usage was indeed associated with a higher rate of a relaparotomy, and it provided an early alert of ongoing intraperitoneal hemorrhage, resulting in a shorter interval to relaparotomy. A clear and unique disadvantage of drain usage is the necessity for relaparotomy for drain or drain fragment removal, which was encountered in 1/200 cases.

Two previous studies found the prevalence of intraperitoneal drain use in fourth and fifth cesarean deliveries to be 9.8% (12/122)(11) and 21.8% (329/1506)(12), which is somewhat similar to the rate of 18.8% according to our findings.

In our cohort, intraperitoneal drains were more frequently used in 'complicated cases' such as high order cesarean or those with longer operative time. Using an inverse probability treatment weighting model, we were able to show that the drain use itself, independent of other factors, was associated with a shorter interval to relaparotomy. Nevertheless, we cannot adjust for factors such as medical staff concern for women who underwent a 'complicated surgery', or for their clinical decisions.

The higher incidence of relaparotomy in the drain+ group may be explained by the higher incidence of drain use in the more 'complicated cesareans.' It may be argued that monitoring drain output and the visualization of blood through the drain is a form of confirmation bias that leads caregivers toward performing relaparotomy. However, this argument is disproved given the higher rate of bleeding and blood transfusion in the drain+ group. Surgical re-exploration for retrieval of a drain or drain fragment is a frustrating complication caused by inadvertent trapping or kinking of the tube during abdominal wall closure.(18, 19) Additionally, there are concerns about retrograde infection with drain use.(20) Our raw data analysis shows that intraperitoneal drain use was not associated with an increased rate of puerperal fever. Nonetheless, when we use the propensity score analysis to match the populations, it appears that placement of an intraperitoneal drain is associated with an increased risk of puerperal fever. This might

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be due to a complex interaction reflecting the higher risk for puerperal fever in the more technically challenging surgeries.

Currently, data are lacking to enable us to devise a rigid protocol for the use of an intraperitoneal drain during cesarean deliveries, and thus the use of a drain is subject to the experience of individual surgeons. Until controlled trials provide robust evidence, the use of an intraperitoneal drain depends on operator preferences. Obstetricians need to understand the possible benefits and morbidity associated with intraperitoneal drains, bearing in mind that drains have been shown to lack clear benefit or even to be harmful in various abdominal surgeries.(21) Most importantly, drains are not a substitute for meticulous surgical technique, and should only be used once hemorrhage control is satisfactory. Our findings suggest that drains should not be routinely used all Cesareans and even at complicated cases the benefit is not certain.

Our study has several strengths, particularly its originality and the use of a large dataset, updated in real-time and later validated. Limitations include the retrospective nature of the study and the lack of a structured protocol governing drain usage. Furthermore, based on our analysis of associated factors and outcomes it is clear that the two groups (drain+ and drain-) are not comparable since the drain group will inevitably include cases in which intraoperative difficulty had occurred. Our findings may not be generalizable to other settings. Our data lack information on body mass index (BMI), which is a known confounder of adverse cesarean outcome(22). We also do not hold validated information on gestational weight gain, lifestyle and other behavioural factors, all of which could effect our findings. Additionally, we have not included clinical information on the women's well-being, caregiver impressions, and vital signs, which all play an essential role in the decision for relaparotomy. Any of these clinical parameters might have led to shorter relaparotomy interval. It is impossible to account for these in a retrospective study. Another important limitation is that the number of relaparotomy procedures performed is small. Nevertheless, by using the propensity score and the inverse probability method, we have mitigated the inherent difference between the groups, thus rendering our results valid, and establishing an important first step towards the planning of future studies to evaluate the role of the intraperitoneal drain during cesarean section. Finally, relaparotomy findings and post-operative outcome are not reported in the current study. This is because in our experience, surgical findings are often unspecific with no apparent

bleeding vessel to be identified. Nevertheless, the number of blood units transfused represents the amount of blood loss and hence outcome.

## Conclusions

In conclusion, our study shows that intraperitoneal drain is used in 7.7% of cesarean deliveries and that there are specific obstetric and surgical factors associated with its use. There is an increased risk of adverse maternal outcomes when a drain is used. Hence, the use of a drain may be viewed as a marker for a complicated cesarean. Drain use is associated with a higher risk for relaparotomy, but the interval to relaparotomy is shorter. Additionally, the use of a drain may necessitate relaparotomy solely to remove the drain. Therefore, the risks and benefits of drain use should be considered prior to utilization. Pending future prospective trials that will shed light on the benefits and risks of intraperitoneal drain use, the decision to use a drain should be based on careful consideration of its potential risks and benefits.

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## List of abbreviations:

Confidence intervals (CI); inverse probability treatment weighting (IPTW); interquartile ranges (IQR); Jackson-Pratt (JP); Odds ratio (OR); standard deviation (SD).

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