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Original Research Article

Utility of the Bladder Flap at Cesarean Delivery: A Randomized Controlled Trial

Subhra Bharti[1], Anjali Suman[2], Joydeb Mukherjee[3], Miss Jeny[4]

[1]PGT 3rd Year, Department of Obstetrics & Gynaecology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India

[2]PGT 3rd Year, Department of Obstetrics & Gynaecology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India

[3]Professor & HOD, Department of Obstetrics & Gynaecology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India

[4]Assistant Professor, Department of Obstetrics & Gynaecology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India

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Corresponding author: Dr. Subhra Bharti

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Abstract

Objective: To assess the implications of doing a lower segment caesarean delivery without performing the bladder flap creation step. Specific objectives: Total operating time is a primary outcome measure (from skin incision to closure of the skin). Secondary outcome measures include time from skin incision to delivery, time from skin incision to fascial closure, blood loss, hematuria, dysuria, retention of urine, febrile morbidity, analgesic use, hospital days, wound infection, newborn outcomes, and readmissions. [Time frames: On the first post-op day and during the four-week post-op visit].

Method: We randomly assigned the development of the bladder flap (n = 130) or its omission (n = 120) in 250 women undergoing primary and repeat caesarean births at 30 weeks of gestation or more. Other abdominal surgeries outside caesarean deliveries were prohibited, as were planned vertical uterine incisions and emergency caesarean deliveries. Total operational time served as the main result indicator. Secondary outcomes included urinary tract infection, endometritis, bladder injury, incision-to-delivery and incision-to-fascial closure times, estimated blood loss, postoperative microhematuria, discomfort, and hospital days. The intention-to-treat premise guided the analysis.

Result: There was no change in the overall operating time (50 [range 17-123] minutes compared with 50 [range 15 - 177] minutes; P=0.20), although the median skin incision to delivery interval was shorter with the bladder flap removed (8 [range 0- 42] compared with 11 [range 3-71] minutes. There were no bladder injuries in either group, and there were no notable differences in endometritis, estimated blood loss, change in haemoglobin level, postoperative microhematuria, postoperative discomfort, hospital days, or urinary tract infection.

Conclusion: The bladder flap does not result in an increase in intraoperative or postoperative problems after first or subsequent caesarean births. Time from incision until delivery is reduced, but overall operating time seems to remain constant.

Keywords: Caesarean Delivery, Bladder Flap, Delivery.

Introduction

The most frequent major surgical procedure carried out during pregnancy is a Caesarean birth. The overall caesarean delivery rate in India was around 20.0% in 2019–2020 (up from 9.5% in 2005–2006), and the most recent trends point to a rate of about 35%. Surgery-related problems such bladder hematoma, infection, and bladder damage as well as long-term consequences like adhesion formation are likely to rise along with this rate [1].

There is still controversy about whether bladder creation is a required step in the common caesarean delivery process despite several research evaluating the technical aspects of the procedure. There is no evidence to support the claim that bladder flap creation makes it simple to reach the lower uterine section and prevents bladder injury in retrospective or randomised studies. [2]

Contrarily, some research revealed that the construction of a bladder flap lengthens the duration of surgery and may raise the risk of postoperative adhesion formation, infection, and bladder injury during a subsequent caesarean section. Employing evidence-based strategies to maximise outcomes and reduce complications is necessary given the increase in caesarean sections [3].

Due to its submucosal tissue composition and lack of arteries, the vesico-uterine space (VUS) following caesarean section (CS) can be easily dissected and sutured during surgical treatment of the bladder flap (BF) in primary CS. In contrast, submesothelial fibrosis altered the VUS in the repeat CS, making the surgical management of BF more challenging and potentially challenging. When the visceral peritoneum (VP) is sutured, any retroperitoneal fluid produced in the abdominal cavity (BF) cannot drain into the peritoneum and may cause a bladder flap hematoma or abscess, or, if the damage is severe, it may lead to post-CS broad-ligament edoema, hematomas, or abscesses [4].

In order to investigate the claim that skipping the bladder flap during primary and repeat caesarean deliveries reduces operating time without noticeably raising intraoperative and postoperative problems, we undertook a randomised controlled trial.

Method

This study compared the outcomes of the standard caesarean birth method with and without the bladder flap. It was a randomised controlled trial. The MGM Medical College & LSK hospital committee gave their approval to the study.

The investigation was carried out at MGM Medical College & LSK hospital in Kishanganj, Bihar. Women who underwent a primary or subsequent caesarean section at 30 weeks or more of gestation were eligible. Women enduring planned vertical uterine incisions, emergency caesarean deliveries, and previous laparotomies in addition to caesarean deliveries were not included. The research nurse or other members of the research team approached eligible patients who were scheduled for caesarean deliveries to obtain their permission to take part in the study. Consent was requested for patients who were not scheduled after it was decided to conduct a caesarean delivery. Utilizing computer-generated random numbers cloaked in opaque envelopes, enrolled patients were classified into primary and repeat caesarean births and randomly assigned to the bladder flap group or no bladder flap group. The patients' group assignment was concealed from them. They were never informed whether they were assigned to the bladder flap group or the no bladder flap group throughout the procedure or the follow-up. Additionally, they were not told if the assigned treatment was actually carried out.

The surgeon opened a sealed envelope carrying the patient's allocation and randomization number before going into the operating room. The only difference between the two groups' caesarean delivery methods was whether the bladder flap was present or not. Without dissection or the creation of a bladder flap, a low-transverse uterine incision was performed about 2 cm above the vesico-uterine peritoneal fold in the group without bladder flaps. Patients underwent the procedure according to their allocation unless the surgeon felt that the alternative technique was medically required based on intraoperative findings.

Incision time, delivery time, fascial closure time, skin closure time, the type of uterine incision, the development or omission of the bladder flap, and any intraoperative problems were all recorded by the circulating nurse on a data collecting form. From the patients' charts, the study nurse retrieved demographic data as well as antepartum, intrapartum, and birth details.

Prior to having their indwelling Foley catheter removed on the first postoperative day, participants were asked to rate their level of pain on a scale of 0 (no pain) to 10 (worst pain). Prior to its removal, a urine sample was taken directly through the Foley catheter and examined for microhematuria using dipsticks. To determine changes in haemoglobin, preoperative and postoperative haemoglobin levels were tested and compared.

Patients were contacted by the study nurse by telephone 4 weeks after surgery to inquire about their postoperative course, including pain score (0–10), infection symptoms, and trips to the ER or doctor's office for postoperative problems. Clean void urine samples were taken and examined for blood, leukocyte esterase, and nitrite with dipsticks at the patients' 4-week postpartum appointments. For samples suspected of harbouring a urinary tract infection, reflex urine cultures were carried out.

An independent, three-member data safety and monitoring board conducted one planned interim study after evaluating half of the patients experiencing repeat caesarean deliveries because there had never been any published data on omitting the bladder flap during repeat caesarean deliveries. The interim analysis was not done by any of the investigators. The O'Brien-Fleming stopping bounds were used to determine the significance threshold for the interim analysis [5].

Intention-to-treat analysis was used, where patients were evaluated in the groups to which they were randomly allocated regardless of whether the prescribed procedure was carried out. With the proper use of the unpaired Student t-test for normally distributed continuous variables, the 2 test or Fisher exact test for categorical variables, selected baseline characteristics and the majority of outcome measures were compared between the two groups. The Kolmogorov-Smirnov test was used to determine if continuous variables were normally distributed or not, and the results were logarithmically converted.

Using the Mann-Whitney U test, data that were not normally distributed even after logarithmic adjustment were compared.

Using a linear regression model with an interaction term, we investigated the impact of the primary or repeat caesarean delivery and the presence or absence of the bladder flap on the overall operating time. We conducted a combined study of both initial and repeat caesarean deliveries in the absence of a significant interaction. Additionally, we carried out a predetermined stratified analysis for initial and subsequent caesarean deliveries. We regarded tests with a P=0.046 as significant in order to take the interim analysis into consideration. Stata 11 was used to conduct the analysis.

Results

250 women in total were enrolled between March 2020 and May 2021. There were 130

patients in the bladder flap group and 120 in the no bladder flap group after one lady in the bladder flap group was lost to follow-up. A bladder flap was given to 115 (82.3%) of the 130 patients who were assigned to the bladder flap group, but not to 15 (17.5%). Scar tissue (n = 10), the requirement for a vertical uterine incision (n = 2), and other factors (n = 8) were cited as justifications for not doing the bladder flap. The bladder flap was absent in 102 (89.1%) of the 120 women assigned to the no bladder flap group, while it was present in 18 (11.1%) of them. Scar tissue was the most frequent cause (n = 7).

Regarding baseline demographic, pregnancy, and operational features, women assigned to the bladder flap or no bladder flap group were comparable. In particular, the primary surgeon's level of experience was evenly distributed between the two groups. Each group's patients had primary caesarean births in around half the cases. Cesarean deliveries were most frequently performed for reasons including elective repetition, failure to progress, foetal intolerance of labour, and malpresentation. These were split between the two groups equally. Low transverse deliveries by caesarean section were the majority, and staples were most frequently used to seal the skin.

We offer the combined analysis' findings because we found no significant interactions between the bladder flap's inclusion or exclusion and the initial or repeat caesarean delivery, as well as no significant impact sizes for either stratum of caesarean delivery type (primary and repeat caesarean deliveries). Women assigned to the no bladder flap group had a shorter median time (8 [range 0- 42] compared with 11 [range 3-71] minutes) from the skin incision to delivery than those assigned to the bladder flap group [Table1].

Table 1: Surgery Duration and Results in Women Having First and Subsequent Cesarean Deliveries

Surgical Time and Outcome	Bladder Flap	Non-Bladder Flap	P-Values
Total operating time (min)	50 (15-177)	50 (17-123)	0.20
Incision-to-delivery time (min)	11 (3-71)	8(0-40)	0.03
Incision-to-fascial closure time (min)	41 (13-170)	37 (11-115)	0.11
Estimated blood loss (mL)	*700 (300-2,500)*	*700 (200-1000)*	*0.07*
Change in hemoglobin (g/dL)	-1.5 (-4.3 to 1.1)	-1.6(-6.4 to 1.4)	0.73
Bladder injury	1	1	-
Microhematuria	48 (44.4)	57 (54.6)	0.13
First postoperative day	2 (2.8)	1 (2.1)	0.93
Pain score (0–10)	2 (1-8)	3 (1-11)	0.68
First postoperative day	2 (1-6)	1 (2.1)	0.74
Endometritis	2 (2.2)	3 (3.1)	0.71
Days hospitalized	3 (1-34)	3 (1-34)	0.70
Urinary tract infection	2 (0.7)	1 (1.5)	0.60

The median total operating time was the same for both groups (50 [range 17-123] minutes as opposed to 50 [range 15-177] minutes; P=0.20). No one in either group sustained a bladder injury, and there were no differences in estimated blood loss (700 [range 200-1,000] compared with 700 [range 300-2,500] mL), change in haemoglobin level (1.6 [range 6.4 to 1.4] compared with 1.5 [range 4.3 to 1.1] g/dL), postoperative day 1 microhematuria (54.6% compared with 44.4%; P=0.13), postoperative day 1 pain score (median 3 [range 1 –11] compared with 2 [range 1 – 8]; P=0.68), hospital days (median 3 [range 1–34] compared with 3 [range 1–34];

P=0.70), endometritis (3.1% compared with 2.2%; P=0.71), or urinary tract infection (1.5% compared with 0.7%;P=0.60). At 4 weeks postpartum, there were no appreciable differences in the pain score or the microhematuria.

Similar results were found when analysis was divided into first-time or repeat caesarean deliveries, with the exception of the incision-to-delivery time, which was considerably shorter in the group with no bladder flap among first-time but not among repeat caesarean deliveries.

Discussion

While the total operating time remained unchanged, we discovered that skipping the bladder flap during a caesarean delivery was related with a shorter incision to delivery time. Additionally, we did not see a corresponding rise in intraoperative or postoperative problems.

The only other published randomised research on the short-term effects of skipping the bladder flap during caesarean birth found benefits, including a shorter time from incision to delivery, less time spent operating overall, and less blood loss, microhematuria, and analgesic need [6]. The only white women who underwent primary caesarean deliveries were included in that study. Because we enrolled individuals from a wider range of backgrounds and covered both main and repeat caesarean deliveries, our findings may be more broadly applicable. We were also able to determine if removing the bladder flap has different advantages or disadvantages for main and recurrent caesarean deliveries by including both caesarean deliveries. Our study's randomised design, which produced two groups with similar baseline characteristics, is one of its other strong points. The primary outcome's follow-up was meticulous, with only one patient going unfollowed.

Patients were only monitored for problems for the first four weeks after surgery. The long-term implications of leaving out the bladder flap were not examined in this study, despite the fact that it is an improvement over the last study's reporting of outcomes only up until hospital release [6]. We hypothesise that there will be less adhesions if tissue is separated in a natural plane as opposed to traumatically forming a bladder flap. This is in line with findings from a recent study by Malvasi et al. [7], which showed that removing the bladder flap reduced adhesions and submesothelial fibrosis during a subsequent caesarean delivery. We intend to monitor the trial participants' outcomes in terms of adhesions and labour trial outcomes in order to evaluate the long-term implications of removing the bladder flap.

Patients will be evaluated for the length of the future surgery as well as the location and severity of intraperitoneal adhesions if they have a repeat caesarean delivery in our hospital within the following four years.

Last but not least, neither our study nor the other experiment [6] had the necessary power to determine the impact of eliminating the bladder flap on bladder injury. Although there were no occurrences of bladder injury, a disproportionately high sample size would be needed to detect any differences due to the low prevalence of bladder injury following caesarean delivery [6,8,9]. Other studies, however, have suggested that difficulties producing the bladder flap—rather than its absence—is a risk factor for bladder damage after caesarean birth [8, 9].

It is worth noting that operating time was chosen as the main result. For a study analysing the impact of skipping a step that is predicted to be unnecessary but not necessarily advantageous or detrimental, it can be challenging to choose a suitable short-term primary outcome. However, it is not biologically conceivable to link the development or omission of the bladder flap to the majority of these outcomes at caesarean delivery, even though it would have been useful to evaluate the influence

of doing so on considerable intraoperative and postoperative morbidity. In the near term, bladder injury that could be directly connected to the bladder flap during caesarean birth happens infrequently, and we would need an impractically huge sample size to identify any differences.

In order to test our hypothesis that eliminating the bladder flap will shorten operating time without raising difficulties, we chose operating time as the major short-term outcome. Reduced postoperative complications following caesarean delivery have been linked to shorter operating times. [10] A difference in median duration, a summary statistic that can conceal significant variability and heterogeneity in subpopulations, accounts for the 2-minute difference in duration that we observed in our study. [11]

It should be noted that the recorded incision-to-delivery times were extremely diverse, with maximum values in the bladder flap and no bladder flap groups being 42 and 71 minutes, respectively. This suggests that for certain patients, the actual duration differences may be significantly larger. In contrast to the prior trial6, we found no variations in the overall operating times. This might be due to the numerous factors that can affect total operating time as well as the large range in total operating times found in our study. There was a wide range of operating times because our study was carried out in a teaching hospital and caesarean births were carried out by surgeons with different levels of experience. Even after logarithmic adjustment, these were not normally distributed, preventing the use of parametric statistical approaches for analysis and making it more challenging to identify significant differences. Additionally, we observed a substantial crossover effect in which 11.0% of patients randomly assigned to the bladder flap group did not have a bladder flap whereas 17.6% of patients randomly assigned to the no bladder flap group did. As a result, our findings would be more likely to support the null hypothesis of no difference.

When women were considered "as treated," however, our findings remained unaltered. In our study, women's average BMI was over 41, with 88.3% of them being obese (BMI more than 31). The higher BMI of the women in our study may have increased the overall length of surgery and diminished the impact of skipping the bladder flap, whereas BMI was not reported in the prior trial [6].

Conclusion

The results of this randomised controlled trial suggest that skipping the bladder flap during primary and repeat caesarean deliveries does not result in an increase in intraoperative or postoperative complications, despite the fact that the study was not powered to detect differences in rare outcomes like bladder injury. It might reduce the time from the skin incision until delivery, if only by a median of 2 minutes. In the absence of a clear justification for bladder dissection, these findings, along with those from a different study that suggested greater adhesions, may be used to challenge the practice of producing the bladder flap routinely after caesarean deliveries.

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