

Comparison of the Outcomes of the Conventional Blunt Uterine Expansion Technique to Cephalad-caudad Expansion in Cesarean Section: A Randomized Controlled Trial

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ABSTRACT

Objective: To compare the outcomes of the two techniques of blunt uterine extension.

Materials and methods: A randomized controlled trial was conducted from April to July 2022 after the institutional human ethics committee approval. All pregnant women at or beyond term undergoing cesarean were included. Computer-based randomization was generated. A total of 521 patients were screened. As required, 154 patients were recruited and 77 were equally randomized in the cephalad-caudad (CC) and transverse (TS) expansion groups. The primary outcome was the estimation of unintended intraoperative injuries and drop in the hemoglobin (Hb) level (postoperatively). Secondary outcomes were to determine the postoperative complications.

Results: Higher number of unintended injuries were noted in the TS expansion compared with CC expansion group, 2 (2.6%) vs 1 (1.3%); $p = 1.0$, similar to the unintended uterine artery injury [7 (9.1%) vs 6 (7.8%); $p = 0.7$]; however, both the parameters did not show any statistical difference. A clinically relevant case of significant broad ligament hematoma injury happened in the TS group. Postpartum hemorrhage (PPH) occurred in 4 (5.2%) patients of TS group of which one needed blood transfusion, while none occurred in the CC group. The mean difference in drop of Hb was not significant (TS vs CC, 0.9 ± 1.1 vs 1.0 ± 1.1 ; $p = 0.3$). The mean difference of visual analog scale (VAS) scores was not significant (2.8 ± 1.6 vs 2.5 ± 1.6 ; $p = 0.2$). There were no case of endometritis, fever, or sepsis.

Conclusion: The cephalad-caudad blunt expansion technique is equally safer than the transverse expansion.

Keywords: Cesarean section, Fetomaternal outcomes, Postoperative pain, Postpartum hemorrhage, Uterine expansion technique.

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INTRODUCTION

Cesarean is one of the most widely performed abdominal surgeries all over the world. This surgery helps us to deliver in our best capacity a healthy baby to a healthy mother. The World Health Organization recommends that cesarean deliveries should not exceed 10–15% in any country.¹ Despite a high rate of successful TOLAC being reported in other Asian countries in India.² The overall rate of cesarean delivery reports from 5% to as high as 60.7% with substantially a higher rates of 12.3–40.9% particularly in private sector health facilities.^{3,4} Rising section rates have shown to increase morbidity in the maternal and perinatal population.^{5,6}

This life-saving surgery can pose inherent intraoperative and postoperative complications with short- to long-term morbidities.⁷ Studies with eponymous techniques regarding every step of this surgery have been undertaken vastly. Challenging trials have compared the techniques of abdominal entry, uterine exteriorization and incision, blunt vs sharp uterine extension, uterine closure, abdominal closure, and antibiotic prophylaxis to address conclusive surgical techniques that can reduce morbidity. While most of the procedural steps have been studied in the past, there is an inconclusiveness about a specific step, that is the direction of blunt uterine extension after the standard lower segment uterine incision.

Based on the underlying anatomical factors, postulates have been made that blunt expansion of the uterus in cephalad-caudad (CC) direction is associated with better maternal outcomes when compared with transverse expansion during a cesarean delivery.^{8–10} However, speculations on the potential surgical advantages with this technique are still controversial. In this era of global rise in cesarean

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rates, there is an utmost need to adapt practices that will reduce the maternal and fetal morbidities. This study was conducted to evaluate the effectiveness of a blunt uterine incision expansion in CC compared with transverse direction in reducing intraoperative injuries and blood loss in women who underwent lower segment transverse cesarean delivery.

MATERIALS AND METHODS

The study was a prospective single-blinded randomized controlled trial carried out in the department of obstetrics and gynecology after approval from the Institutional Review Board (IRB) and institutional human ethics committee (IHEC).

Table 1: Clinical characteristics of the study population

Features	Cephalad-caudad group (n = 77)	Transversal group (n = 77)	p-value
Age (years) ^b	27.07 ± 4.0	28.07 ± 4.1	0.156
Gestational age (weeks) ^a			
34–36 weeks	10 (12.7%)	6 (7.8%)	0.270
At or beyond 36 weeks	67 (87.3%)	71 (92.2%)	
Parity			
Primi para	40 (51.9%)	42 (54.5%)	0.420
Multi para	37 (48.1%)	35 (45.5%)	
Indications for CS ^a			
CPD	12 (15.6%)	8 (10.4%)	0.830
Fetal distress	22 (28.6%)	23 (29.9%)	
Previous LSCS in labor	24 (31.2%)	23 (29.9%)	
Thick MSL			
Failed induction	5 (6.5%)	9 (11.7%)	
Other absolute Indications	6 (7.8%)	7 (9.1%)	
Indications	8 (10.4%)	7 (9.1%)	
Type of surgery ^a			
Elective LSCS	32 (41.5%)	37 (48.0%)	0.650
Emergency LSCS	45 (58.4%)	40 (51.9%)	
Preoperative Hb level (mg/dL) ^b	11.07 ± 1.43	11.51 ± 1.34	0.05

^aValues are presented as number (%), compared with a Chi-square; ^bValues are presented as mean ± SD compared with independent t-test

Study was registered in the Clinical Trials Registry, India with reference number CTRI/2022/03/041552 following which the data collection began from April 2022 till July 2022. All pregnant women of age 18 years and above, at 34 weeks or later periods of gestation who underwent an elective or emergency cesarean section presenting in stable condition were screened. Women with severe anemia, HELLP syndrome, coagulation disorders, placenta previa, morbidly adherent placenta, fibroid complicating pregnancy, uterine rupture, and uterine anomaly were excluded. For sample size calculation, we used the study by Ozcan et al.¹¹ By assuming $\alpha = 0.1$ (10%) and a power of the study as 80%, the minimum sample size per group was estimated as 77 with a total sample of 154. Being a tertiary care loss to follow up till discharge was not anticipated. Randomization was computer generated. After exclusion preoperatively and intraoperatively, allocation was done in block randomization manner until total minimal sample size was reached (154) as depicted in Table 1. Designated-on-call duty persons assigned participants into two groups: the intervention group (cephalad-caudad group) and the control group (transversal group) based on the sealed envelope. The operating surgeons were the on-call obstetrician in charge or final residents under direct supervision of seniors on calls.

Preoperative hemoglobin was sent for all the patients. All patients received antibiotic prophylaxis and surgeries were performed under spinal anesthesia as decided by the anesthesia team. Skin preparation was done with betadine solution. In all the units, following standard surgical steps were followed. Joel Cohen skin incision was given. Sharp or blunt dissection was done on a case-by-case basis till the peritoneal cavity. Bladder flap was created. A lower segment sharp transverse uterine incision of 1–2 cm was made. The incision was expanded further using the surgeon's two

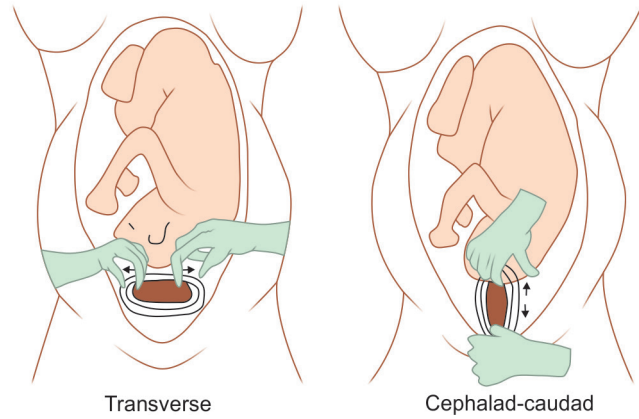


Fig. 1: Transverse and cephalad-caudad uterine expansion

forefingers based on the assessment of required space for the delivery of the fetus. In the interventional group, this blunt expansion was directed in the CC manner in the midline while in the control group, the pull was transverse from medial to lateral direction as depicted in the Figure 1. Following delivery of the baby, placenta was extracted in a controlled manner, uterus was exteriorized, uterine closure was done in double layer. After ensuring hemostasis and mop counts, subsequently, the peritoneal and abdominal layers were closed. To prevent atony, which is a common surgical complication in cesarean, 5 units of oxytocin as slow intravenous followed by 20 units of oxytocin in 1000 cc normal saline infusion was given to all the patients postoperatively on continuum. For pain relief, all patients were given paracetamol (500 mg) as required (every 6 hourly) as the standard postoperative analgesic drug.

The primary outcome was to determine the frequency of unintended uterine artery injuries, uterine tissue extensions and the drop in hemoglobin (Hb) at 24 hours post-surgery in both the groups. Secondary outcomes were the estimation and comparison of the postpartum hemorrhage (PPH), the need for blood transfusion and postoperative morbidity in terms of pain, fever, infection, or wound gape. For maintaining objectivity in the reporting, unintended uterine artery/tissue extensions/injuries were considered as any wall defect that required additional surgical sutures to repair and/or stop bleeding. Postoperative morbidity was defined as a temperature of 38°C or more on two separate occasions at 24 hours apart (excluding the first 24 hours) of surgery or wound discharge of any form or wound gape of any depth. VAS scoring was assessed at 12th and 24 hours postoperatively once the patient was weaned from anesthetic drugs of surgery. Postoperative Hb level was repeated after 24 hours. All women were followed up till their discharge. The data were collected from the operative notes, daily patient notes, and the hospital information management system.

Statistical analysis was performed using SPSS software (version 17.0; SPSS Inc, Chicago, IL). Continuous variables were summarized with mean ± standard deviation (SD) while categorical variations were expressed by frequency and percentage (%). The student t-test and Chi-square test was used for continuous and categorical variables within the group respectively. Differences in continuous variables between two groups was analyzed using the independent t-test. Proportions were compared with the use of the Fisher exact test. Statistical significance was set at $p < 0.1$. The RCT was reported following the CONSORT statement.¹²

Table 2: Primary outcomes

Parameters	Cephalad-caudad group (n = 77)	Transversal group (n = 77)	p-value
Unintended uterine artery injury ^a	6 (7.8%)	7 (9.1%)	1.00
Unintended uterine tissue extension ^a	1 (1.3%)	2 (2.6%)	1.00
Hemoglobin difference (mg/dL) (preoperative–postoperative level)	0.9 ± 1.1	1.0 ± 1.1	0.33

^aValues are presented as number (%); ^bValues are presented as mean ± SD

Table 3: Secondary analysis

Parameters	Cephalad-caudad group (n = 77)	Transversal group (n = 77)	p-value
PPH ^a	0 (0.0%)	4 (5.2%)	NA
Blood transfusion ^a	0 (0.0%)	1 (1.3%)	NA
VAS score at 12 hours ^b	5.38 ± 1.18	5.4 ± 1.34	0.001
VAS score at 24 hours ^b	2.86 ± 1.34	2.66 ± 1.14	0.001
Difference in VAS scores ^b	2.519 ± 1.659	2.805 ± 1.647	0.280

^aValues presented as number (%); ^bValues are presented as mean ± SD

RESULTS

This study was conducted to compare the outcomes between the technique of expanding the uterine incision either in cephalad or in transverse direction. Complications of surgery are related to the procedural steps practiced. In this RCT, we intended to compare the intraoperative complications, primarily uterine artery injury and uterine tissues extensions with further secondary analysis of the postoperative morbidity between the two techniques. All patients were similar in both groups with respect to maternal clinical characteristics and demographics as depicted in Table 1.

Intraoperative primary outcome as given in Table 2 showed that unintended uterine artery injury occurred in 6 (7.8%) patients in CC group compared with 7 (9.1%) patients in transverse group ($p = 0.7$). There was 1 (1.3%) unintended uterine tissue extension in the CC group while 2 (2.6%) in the transverse group ($p = 1.0$). Statistically, there were no differences found regarding the above outcomes between both the groups. Significant drop in hemoglobin was observed in both the groups; however, on comparison, the mean difference in hemoglobin levels showed no difference between CC and TS group, respectively (0.9 ± 1.1 vs 1.0 ± 1.1 ; 95% CI, -0.52 to 0.18 ; $p = 0.3$). Postpartum hemorrhage occurred in 4 (5.2%) patients of transverse group of which one needed blood transfusion while no PPH was documented in CC group ($p = 0.1$).

Postoperatively, all patients were stable. Parameters for secondary outcome analysis are depicted in Table 3. VAS scoring for surgical site pain was significantly reduced postoperatively in each group at 24 hours (CC vs TS; 2.86 ± 1.3 vs 2.66 ± 1.1) compared with the scores at 12 hours (5.38 ± 1.1 vs 5.47 ± 1.3) postoperatively ($p < 0.1$). On comparison, the mean difference in VAS score however showed no significant difference between CC compared with TS group (2.86 ± 1.3 vs 2.66 ± 1.1 ; $p = 0.2$). In no case, hysterectomy or bowel injuries occurred. All the patients got discharged on

average at day 3–5 postoperatively. Out of 154, 14 (9.09%) women showed significant growth in the urine culture. However, no wound discharge/gape was recorded.

DISCUSSION

Rise in cesarean section rates has invariably risen the morbidity associated with the procedure in both mother and the baby. Ever since then studies have been undertaken to address the complications rooting from this surgery. Regarding short-term outcomes, the CORONIS trial recommended that clinicians can use whichever surgical technique they prefer when choices come down to the following five interventional pairs: 1. blunt vs sharp abdominal entry; 2. exteriorization vs intra-abdominal uterine repair; 3. single vs double-layer closure of the uterus; 4. closure vs non-closure of the peritoneum; and 5. chromic catgut vs polyglactin-910 for uterine closure. A Cochrane systematic review also recommends that blunt dissection is better in reducing the risk of requiring blood transfusion (1,345 women; RR 0.24; 95% CI, 0.09–0.62) when compared with sharp dissection.⁷ However, with regards to the direction of pull to expand the uterine incision in the lower segment is a step less discussed upon.

There is a general practice of extending the uterus laterally. Many also claims the direction to be a curve upwards. From what we know about the anatomy of the lower uterine segment (LUS), it is that this site is characteristically abundant in elastic tissue but poor in blood vessel density. The thinner muscle bundles in the LUS runs around the axis of the uterus in concentric manner making it the ideal site for uterine incision during a CS.⁸ The LUS is expected to be formed around 28 weeks and by term, it is fully formed. Traditional technique observed to be in practice (almost in all cases in our institute and other teaching institutes-confirmed by recalls) is the transverse expansion. Potential disadvantage with this technique is that the maximum traction force remains at the lateral edges which can allow uncontrolled extension laterally if the pull is swept too far even if unintentional, posing a higher likelihood of extension of the incision into the uterine vessels.¹⁰

When the incision extension is in the vertical direction the peak force magnitude tends to create a force feedback mechanism along the midline. This constraint can generate resistance for further tissue extension at the lateral margins of the uterus in a controlled manner.¹³ Since the difference in myometrial thickness has been observed to affect the rate of complications the uterine extension direction as a surgical step becomes imperative to be optimized.¹⁴

The results of intraoperative complications in our study showed less number of unintended uterine artery injuries in the cephalad group compared with the transverse group [6 (7.8%) vs 7 (9.1%) ($p = 0.7$)] and similarly less number of uterine tissue extension 1 (1.3%) vs 2 (2.6%) ($p = 1.0$) in the respective groups. This finding was similar to the RCT done by Morales et al.⁹ which reported the uterine vessel injury did not reach statistical significance (839; CC vs transverse: 3.54% vs 6.28%; OR 0.55; 95% CI, 0.28–1.05; $p = 0.09$). Although unlike our study, the study reports the unintended extension of the uterine incision (10.35% vs 16.18%; OR, 0.6; 95% CI, 0.4–0.9; $p = 0.01$) to be of statistical significance. This could have been an attribute of excluding previous cesarean cases in their study which were included in our study in view of pragmatism that higher proportion of previous section cases being encountered.^{6,15}

The study of Morales reported no difference in decrease in Hb between the groups (CC: 1.1 ± 0.9 vs TS: 1.2 ± 1.1 ; $p = 0.34$) which was similar to our study with CC as 0.9 ± 1.1 and in TS group as $1.0 \pm$

1.1; $p = 0.33$. Similar conclusion regarding drop in Hb were reported in a study by Sukanda as 0.6 (0.75) vs 0.5 (0.68) ($p = 0.2$) and Selin 1.26 ± 0.76 vs 1.44 ± 0.86 ($p = 0.1$).^{9,16} However, a meta-analysis by Xodo S et al. reported that women randomized in the CC group significantly had lower Hb drop [mean deviation (MD) -0.26 gm/dL; 95% CI, -0.37 to -0.14], unintended extension (4.8% vs 8.9%; 95% CI, 0.30–0.88) and uterine vessels injury (1.5% vs 2.8%; 95% CI, 0.20–0.84) unlike in our study. The final data of this meta-analysis were pooled from only two RCTs. One RCT was by Ozcan et al. (54 vs 56) that enrolled singletons at term without severe medical conditions. The result variation could be due to the smaller number of sample sizes. Also as mentioned in the study, all the surgeries were performed by the same team with four surgeons, while in our study, surgeries were performed by experienced consultants as well as residents. Another RCT was by Cromi et al. (405 vs 406), wherein inclusion of moderate preterm cesarean (30 weeks of gestation) could be a plausible risk for increased blood loss due to thick LUS. The multivariable regression of the study reported the statistically significant number of macrosomia as an independent attribute for more blood loss. Macrosomia is a known associated risk factor for unsuccessful VBAC and higher complications in cesarean.^{16,17} Only one case of macrosomia was documented in our study.

Widely accepted definition of PPH is quoted as mean blood loss of 1000 mL. Blood loss of >1500 mL and need for transfusion has also been used as an alternate indicator of PPH estimation.¹⁸ PPH (estimated by quantitative gravimetric method) in our study occurred in 4 (5.2%) patients in TS group while none in CC group ($p = 0.1$) similar to the meta-analysis where no statistical significance was found in the incidence of blood loss >1000 mL (1.2% vs 3.0%; RR 0.41, 95% CI, 0.14–1.18).¹¹ Cromi et al. reported blood loss of >1500 mL significantly higher in the TS group, compared with the CC group (2.0% vs 0.2%; $p = 0.0$).¹⁰ In clinical practice, the tendency is to underestimate true blood loss with rate of errors being higher where the total blood loss is greater.^{19,20} The need for transfusion, in our study, was documented for one patient of TS group with no statistical significance, similar to the report of Dikmen S study (CC vs TS: 0 vs 2; $p = 0.1$) and the Morales et al. (CC vs TS: 0.9% vs 1.79%; OR 0.55; 95% $p = 0.51$).

Hematoma is a collection of clotted blood within organ, tissue, or body space. Hematoma formation (19.17%) is one of the significant complications related to cesarean section next only to infections (56.16%).²¹ The Morales study reported broad ligament hematoma as a separate entity to quantify the severity of the tear (CC vs TS: 4.0% vs 6.28%; OR 0.62; 95% CI, 0.33–1.16; $p = 0.17$). Although their study observed the trend to be higher in the transverse group, the statistics did not have a significant difference similar to our study where one case of broad ligament hematoma occurred in the transverse group. Lesser case in our study could be the subjectivity regarding the size and the clinical relevance of hematoma among surgeons to document it.

Surgical site pain was the major complaint apart from difficulty in breastfeeding. It remains a vital component of postoperative care but only few RCTs compare both the techniques and comments upon postoperative pain. In Ozcan study, although pain was evaluated by the faces pain rating scale (FPRS) 24 hours after surgery, the scores between the groups were not of statistical significance (CC vs TS: 4.6 ± 1.8 vs 5.1 ± 1.8 ; $p = 0.2$), similar to the findings in the mean difference of VAS score in our study, CC vs TS (2.5 ± 1.6 vs 2.8 ± 1.6 ; $p = 0.2$). Despite analgesia cover the primary surgical site, pain scores at 12 hours postoperative were higher in both the groups (CC and TS; 5.38 ± 1.1 and 5.47 ± 1.3 ; $p = 0.6$).

However, pain reduced significantly by 24 hours (hrs) in both the groups. Annika et al. conducted a survey after a cesarean birth and reported the median VAS rating of 6 during the first 24 hours after surgery. This study showed that in 62%, breastfeeding and the new born care were negatively affected to a large extent by postoperative pain during the first 24 hours.²²

Long-term effects of LSCS have been analyzed in questionnaires by 220 patients (90.2% answered) reporting chronic pain as a significant problem in 5.9% of patients with an incidence of persistent pain of 4.2% at 1 year.^{23,24} Optimal pain management still needs to be of higher quality to facilitate faster recovery, ideal breastfeeding, infant care, and better bonding with the child.

The Ozcan study states evaluating postoperative morbidity although the nature of cases is not described clearly. While not any of the RCT in this field mentions the postoperative complication, our study documented 14 out of 154 women with significant growth in urine culture, 5 (6.4%) in CC and 9 (11.6%) in TS group ($p = 0.2$). Appropriate antibiotics were administered.

Strengths in our study was that high-risk groups were included. Surgeries were performed by different levels of experienced surgeons suggesting that the technique is simple and replicable. Based on the results, emphasis can be made on the implementation and adapting the technique into daily practice. The strictly controlled variables, specified definition for unintended uterine extension with no drop out of the participants were other strong points.

Limitation in our study could be the intraoperative blood loss estimation. Although this information was documented, we decided not to highlight as the management depends on the symptoms and the Hb levels plus the PPH cases were part of the analysis. Other limitations could be the duration and additional suture used in the surgery. Due to preferential differences among the surgeons in the peritoneal closure and the inclusion of sterilization steps in a significant number of cases, it was decided to avoid the cumbersome calculations.

Despite the technique being equally effective and rather showing better outcomes, there is reluctance in the teaching of vertical expansion technique. Our study depicts that this technique can be practiced by surgeon of any experience and still provide significant outcomes. Postulates that myometrium fibers accumulating at incision ends in the conventional lateral extension technique increasing the risk of sacculation-type defects in the uterine wall while prevented by vertical pull are advantages that need evaluation. Determining long-term effects and the outcomes in high-risk pregnancies in future studies could optimize surgical decision-making.

CONCLUSION

The smallest significant reduction in the morbidities with the use of equally safer, potentially more beneficial techniques in combination to other standard established techniques could improve health, health services and policies to a large extent. In view of clinically relevant advantages and the anticipated future benefits of the technique the CC expansion should be brought back to practice, especially in institutes nurturing future surgeons as the technique is simple and can be safely performed with non-inferior outcomes.

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