



IMPACT OF DOUBLE LAYER UNLOCKED SUTURE VS SINGLE LAYER LOCKED SUTURE IN PREVENTION OF CAESAREAN SCAR ISTHMOCELE – RANDOMISED CONTROLLED TRIAL AT A TERTIARY CARE CENTRE IN MAHARASHTRA.

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ABSTRACT

Background: The increasing rates of cesarean sections (CS) have led to a rise in complications such as cesarean scar defects, which can manifest as niches or thinning of the residual myometrium, potentially resulting in postmenstrual spotting, chronic pelvic pain, and other serious conditions. Optimal uterine closure techniques are critical for preventing these defects, but evidence comparing single-layer locked versus double-layer unlocked sutures is limited. Thus, the current study was conducted to assess compare the impact of single layer locked versus double layer unlocked suture.

Methodology: This randomized controlled trial was conducted at a tertiary care center over 18 months, enrolling 300 women undergoing their first cesarean section. Participants were randomly assigned to either single-layer locked sutures (Group A) or double-layer unlocked sutures (Group B). Follow-up was performed at six months using transvaginal sonography to assess the presence of cesarean scar defects and residual myometrial thickness.

Results: Group A demonstrated a higher need for additional sutures, increased bleeding rates, and a greater need for blood transfusions compared to Group B. At the six-month follow-up, Group A had a higher incidence of niches, significantly lower residual myometrial thickness, and narrower adjacent myometrial thickness compared to Group B. These findings align with other studies suggesting that double-layer unlocked sutures may provide better outcomes.

Conclusion: The double-layer unlocked suture technique is more effective than the single-layer locked technique in preventing cesarean scar isthmocele and promoting better uterine scar healing. It resulted in lower prevalence and narrower width of niches, better preservation of residual myometrial thickness, and greater adjacent myometrial thickness, making it a preferable choice for cesarean deliveries.

KEYWORDS: Cesarean delivery, Uterine scar, Niche development, Single layer, Double layer, Suturing technique

INTRODUCTION

The rising rates of global cesarean deliveries promotes increasing number of women are at risk of associated complications. The short-term issues like bleeding and infection are common, there are also significant long-term risk including uterine rupture, dehiscence, cesarean scar defects, cesarean scar pregnancies and placental adhesion anomalies [1]. A cesarean scar defect occurs when the myometrium thins and indents due to inadequate healing at the site of a cesarean incision. While often asymptomatic, it can lead to complications such as abnormal or postmenstrual bleeding, chronic pelvic pain, infertility, placenta accreta or previa, uterine rupture, and cesarean scar ectopic pregnancy [4].

The prevalence of cesarean scar defects varies from 19% to 61% after a single cesarean and can reach up to 100% in women who have had three cesareans. These figures may be underestimated, as many women are asymptomatic, and there is a lack of awareness among healthcare practitioners [2]. The morphology of a cesarean scar can be assessed using hysteroscopy, saline infusion sonography (SIS), or ultrasonography. Treatment of scar defects may involve laparotomy, laparoscopy, or hysteroscopy [5].

Cesarean scar defect (CSD) formation has been linked to various perioperative factors, including the level of the uterine incision, the indication for the cesarean section, the duration of labor, cervical dilation before the cesarean, the closure technique, the presence of adhesions, and a retroverted uterus [3]. Optimal uterine closure, involving both surgical technique and suture material, is crucial for improved scar healing. However, there remains limited evidence on the most effective uterine closure technique to prevent cesarean scar defects [6].

The optimal method for uterine closure remains uncertain, particularly regarding the use of unlocked versus locked stitches in the first layer and whether single- or double-layer closure enhances wound strength after a cesarean delivery. Thus, the current study was conducted to assess compare the impact of single layer locked versus double layer unlocked suture.

MATERIALS AND METHODOLOGY

The current randomized controlled trial was conducted in the tertiary care center, Akola. The study was carried out over a duration of 18 months. Prior to initiating the study, the written informed consent was taken from all the patients. A total of 300 patients were included.

The study enrolled patients with primary C- section selected through random sampling method and were randomly assign to either single- layer or double-layer uterine closure using delayed absorbable polygalactin (Vicryl No. 1).

The study included women aged 18 or older, delivering via cesarean section at over 37 weeks of gestation, undergoing their first cesarean, and who provided informed consent and agreed to participate.

Participants with a history of previous uterine hysterotomy, such as a cesarean section or myomectomy, known uterine anomalies, active labor, bleeding disorders, maternal connective tissue disorders, and cesarean delivery before 37 weeks of gestation were excluded from the study.

Methodology

This interventional RCT involves the random allocation of patients to either a single-layer locking or a double-layer unlocking suturing technique.

Group A consisted of patients with single layer locking sutures while **Group B** consist of double layer unlocking sutures.

The surgical procedures involved Pfannenstiel abdominal incisions and Kerr techniques for uterine incisions. After delivering the baby, the size of the Kerr uterine incision was measured with a sterile ruler just before closure. Uterine closure was then performed using the single-layer closure which involves continuous running locked sutures or double-layer closure, where the first layer consists of continuous unlocked sutures including the endometrial layer, and the second layer consists of

continuous unlocked sutures that imbricate the first layer, a No. 1 Vicryl suture was used to transversely pass through the inner myometrium-decidua line for the first layer, followed by a continuous parallel transverse pass through the outer myometrium-visceral peritoneum line, forming a purse-string closure.

All surgeries were performed by the same surgeon (EY), using Polyglycolic Vicryl No. 1 sutures for uterine closure, with additional hemostatic sutures applied as needed for bleeding.

Follow-up was taken after six months to evaluate for uterine myometrium defects (isthmocele) using transvaginal sonography. All participants were scheduled for a follow-up visit at the tertiary care centre 6 months after surgery. While there is no universally accepted gold standard method for diagnosis, transvaginal sonography (TVS) is commonly employed.

Statistical analysis:

Statistical analysis was conducted using SPSS version 24.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were presented as mean ± standard deviation (SD) or as number and frequency, as appropriate. The Student's t-test was employed for comparing quantitative data, while the chi-square test and Fisher's exact test were used for comparing normally distributed continuous variables. A p-value of <0.05 was considered statistically significant, with a 95% confidence interval.

RESULTS

Table-1: Demographic characteristics in the study groups

Variables	Group A	Group B	P-value
	Mean ± SD	Mean ± SD	
Age	32.8 ± 5.2	33.9 ± 6.3	0.1002
BMI	27.17 ± 5.3	28.55 ± 5.7	0.03

Group A had a mean age of 32.8 ± 5.2 years and BMI of 27.17 ± 5.3, while Group B had a mean age of 33.9 ± 6.3 years and BMI of 28.55 ± 5.7. Age difference was not significant (p=0.1002), but BMI difference was significant (p=0.03).

Table-2: Maternal and obstetric baseline characteristics of the participants in each Study group

Variables	Group A	Group B	P-value
	Mean ± SD/N/ (%)	Mean ± SD/N/ (%)	
Nulliparity	110 (73.33%)	115 (76.67%)	0.74
Multiparity with primi caesarean	40 (26.67%)	35 (23.33%)	0.56
Gestational age at delivery	42.1 ± 3.1	42.3 ± 3	0.57
Comorbidities			
Diabetes mellitus	15(5.4%)	11(7.3%)	0.56
Hypertension in pregnancy	12(8%)	11(7.3%)	0.79
Emergent caesarean			
Not in labour	65 (43.33%)	40(26.7%)	0.01
Latent labour	61 (40.67%)	39(26%)	0.03

Group A and Group B showed no significant differences in nulliparity, multiparity with prior Caesarean, gestational age, or comorbidities like diabetes and hypertension (p-values > 0.5). However, Group A had significantly more emergent Caesareans not in labor (43.33% vs. 26.7%, p=0.01) and in latent labor (40.67% vs. 26%, p=0.03).

Table-3: Post-operative findings

Findings	Group-A	Group-B	P-value
	Mean ± SD/N/ (%)	Mean ± SD/N/ (%)	
Haemoglobin (mg/dL) on day 2	11.31 ± 2.25	12.26 ± 3.24	0.003
Fever	26 (17.33%)	15 (10.00%)	0.08
Wound gap	23 (15.33%)	12 (8.00%)	0.06
Need for transfusion	21(14.00%)	10(6.67%)	0.04
Return to theatre	18(12.00%)	8(5.33%)	0.04
Hospital stay (days)	4.26 ± 1.29	1.23 ± 0.78	<0.0001

Group A had significantly lower hemoglobin levels on day 2 (11.31 ± 2.25 vs. 12.26 ± 3.24, p=0.003) and a higher need for transfusion (14% vs. 6.67%, p=0.04) and return to theatre (12% vs. 5.33%, p=0.04) compared to Group B. Differences in fever and wound gap rates were not significant (p=0.08 and p=0.06, respectively).

Table-4: Distribution according to caesarean deliveries in each group (Intraoperative findings)

Variables	Group A	Group B	P-value
	No of cases (%)	No of cases (%)	
Need for additional suture	74(49.33%)	50(33.33%)	0.03
Median duration of uterine closure, min	9 (2-10)	4.5(1-10)	0.16
Median operation time (min)	45 (20-50)	30 (20-50)	0.08
Rate of bleeding >1000mL	1900 (800-2800)	1500 (1000-2500)	<0.05

Group A had a higher need for additional sutures (49.33% vs. 33.33%, p=0.03) and a median rate of bleeding >1000mL that was significantly higher than Group B (1900 vs. 1500, p<0.05). Median durations of uterine closure and operation time were not significantly different (p=0.16 and p=0.08, respectively).

Table-5: Follow up at six month with the help of tvs

Outcomes	Group A	Group B	P-value
Presence of niche [depth ,width]	87 (58.00%)	62 (41.33%)	0.04
Residual myometrial thickness [mm] depth	1.7 (0-1.0)	4.1 (0-6.5)	<0.05
Median width of niche with tvs, mm	5.3 (0-7.1)	3.7 (0-6.9)	<0.05
Median Residual myometrial thickness as proportion to myometrium thickness	9.8 (4.0-20)	15.3 (2-25)	<0.05
Median adjacent myometrial thickness, mm	11.8 (7.1- 21)	18 (5.2-22.8)	<0.05

At six-month follow-up, Group A had a higher incidence of niches (58% vs. 41.33%, p=0.04) and significantly lower residual myometrial thickness, both in depth and proportion, as well as narrower adjacent myometrial thickness compared to Group B (all p<0.05).

DISCUSSION

In recent years, research has increasingly focused on complications following cesarean sections, such as the development of niches or thinning of the residual myometrium at the site of the previous cesarean section, along with related symptoms. Both thinning of the residual myometrium and the presence of niches have been associated with postmenstrual spotting [7,8].

The present study compared two suture techniques: Group A, which used single-layer locked sutures, and Group B, which used double-layer unlocked sutures. The aim was to determine which technique offers better outcomes in preventing isthmocele formation and improving overall uterine scar healing. There were no significant differences in age or BMI between the two groups. This were consistent with findings from the research carried out by **Yıldız E et al. [9]**, **Sumigama S et al. [10]**, **Alper E et al. [11]**, and **Hosseini R et al. [12]**

Group A required more additional sutures compared to Group B and had a significantly higher median bleeding rate (>1000 mL) than Group B. In another study conducted by, **Sumigama S et al. [10]** reported postoperative genital bleeding in one case, severe blood loss (>1500 mL) in eight cases, and blood transfusions in two cases. Contrary to the findings of the current study by **E Khamees R et al. [13]**, found no significant difference in bleeding rates between the groups.

At the six-month follow-up, Group A exhibited a higher incidence of niches and significantly lower residual myometrial thickness, both in depth and proportion, as well as a narrower adjacent myometrial thickness compared to Group B.

These findings were in line with the study by **Turan GA et al. [14]** which reported significantly lower niche thickness and thinning percentages in Group B. **Yılmaz Baran Ş et al. [15]** found similar median distances between the niche and the external cervical os for both single- and double-layer closures, while **Incedere A et al. [16]** noted no significant differences in cesarean scar defect measurements or areas at the sixth postoperative week.

Moreover, **Bujold et al. [17]** found that single-layer closure increased the risk of uterine rupture by more than twofold compared to double-layer closure, indicating that single-layer closure adversely affects uterine scar healing, leading to thinning and/or weakness of the scar and inadequate strength to withstand labor stresses. **Tekiner et al. [18]** also reported no significant differences between single- and double-layer uterine closures based on niche assessments at three months post-operation. The study was limited by its single-center design, which may affect generalizability, and a follow-up period of six months, which may not capture long-term outcomes. Although the sample size was adequate, larger multicentric studies are needed for more robust data. Additionally, potential residual biases and unassessed outcomes like long-term reproductive health should be considered.

CONCLUSION

Based on the study's findings, the double-layer unlocked suture technique (Group B) proved superior to the single-layer locked suture technique (Group A) in preventing cesarean scar isthmocele. The double-layer technique was associated with a lower prevalence and narrower width of niches, better preservation of residual myometrial thickness, and greater adjacent myometrial thickness. This indicate that the double-layer unlocked suture technique is more effective in promoting uterine scar healing and reducing niche formation, making it a preferable choice for cesarean deliveries.

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