Original Article

Comparing Cesarean Scar Defect Incidence After Locked and Unlocked Repair Methods Among Primiparous Patients: A Randomized Double-Blinded Trial

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Abstract

Objective: To compare residual myometrial thickness (RMT) and cesarean scar defect (CSD) development after cesarean section using double-layer locked and unlocked closure techniques.

Materials and methods: We conducted a randomized double-blinded trial comparing double-layer locked and unlocked uterine closure techniques following cesarean section in primiparous women. The locked technique involved continuous suturing of the full myometrial thickness in the first layer, followed by back-and-forth needle maneuvering on both sides of the incision for the second layer. The unlocked method included running suturing of two-thirds of the myometrial thickness in the first layer, followed by suturing the upper half of the myometrial thickness in the second layer. Transvaginal ultrasonography was performed one year post-cesarean section, with RMT as the primary outcome and scar depth and width as secondary outcomes. Independent t-test and Chi-square test were utilized for statistical analysis.

Results: All 30 patients from the locked and 26 from the unlocked group in the follow-up were diagnosed with CSD (scar depth>2mm). The mean RMT for the unlocked and locked groups were 4.44±1.07mm and 4.12±0.48mm, respectively, showing no significant difference (p =0.14). There was also no significant difference in mean scar width between the locked and unlocked groups (3.68±1.44mm vs. 3.95±1.00mm, p =0.42). However, the mean scar depth was higher in the unlocked group (3.77±1.11 mm vs. 3.16±1.1mm, p =0.04).

Conclusion: We have found no significant differences in the RMT and CSD prevalence between two-layered locked and unlocked uterine closure techniques, while the scar depth was greater in the unlocked group. Nonetheless, future randomized trials implementing larger sample sizes are required to precisely compare the outcomes of the double-layer locked and unlocked uterine suturing techniques.

Keywords: Cesarean Section; Myometrium; Scar; Ultrasonography

Introduction

Cesarean section (CS) is the most prevalent major surgical procedure worldwide and its global prevalence has surged from 7% in 1990 to the current rate of 21% (1). This upward trajectory is primarily

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attributed to non-medically necessary CS procedures, frequently driven by maternal requests (2). Performing CS without certain medical indications is associated with an increased risk of different short-term and long-term maternal complications, posing significant health threats (3). Short-term complications following the CS include wound infection, wound dehiscence and reoperation, intensive care unit (ICU) admission, blood transfusion, hysterectomy, and even mortality (3, 4). Meanwhile, long-term sequels of CS encompass chronic pelvic pain, dyspareunia, dysmenorrhea, postmenstrual spotting, and infertility (5, 6). Moreover, it heightens the risk of abnormal placentation, ectopic pregnancies, stillbirth, and preterm births in subsequent pregnancies (5, 7).

One emerging delayed complication following the CS is the cesarean scar defect (CSD), also known as isthmocele, which is a pouch-like structure formed at the scar site of the previous CS on the anterior uterine wall (8, 9). CSD results from inadequate myometrial repair during CS, often indicated by reduced residual myometrial thickness (RMT) at the scar site in ultrasonographic examination (10). Studies have shown up to a 70% prevalence of CSD following the first CS (10). Despite its high prevalence, most cases remain asymptomatic, but around 30% of patients may experience symptoms such as abnormal uterine bleeding (AUB), dysmenorrhea, dyspareunia, chronic pelvic pain, and secondary infertility (11-13). Moreover, CSD is associated with significant obstetric complications in subsequent pregnancies, including placenta previa, placenta accreta, scar dehiscence, uterine rupture, and cesarean scar ectopic pregnancy (11, 14).

Prior studies have identified several risk factors for CSD, with multiple CS being the most prevalent (11, 15). Additionally, factors such as CS performed after more than 5 hours of labor or cervical dilatation exceeding 5 cm, lower uterine incision during CS, obstetrical complications in pregnancy, and pelvic adhesions have been associated with an increased risk of CSD (10, 16). Putting these risk factors aside, recent studies have searched for the potential effects of different uterine suturing techniques on CSD incidence. Some studies reported a higher CSD incidence in patients who receive endometrial suturing following CS (17), some others found no significant difference in CSD incidence between patients with and without endometrial suturing (18). Also, a meta-analysis revealed that single-layer myometrium closure during CS significantly increases the risk of CSD compared to double-layer closure (19). However, there is conflicting evidence on the impact of different closure techniques, with some studies showing lower CSD rates after unlocked double-layer closure (20) and others found no significant differences between locked and unlocked closure methods (21, 22).

Given the prevalence and significance of CSD-related complications, it is crucial to employ specific approaches during CS to mitigate its occurrence. This study aims to address the limited research on the relationship between CS closure techniques and post-operative CSD incidence by comparing locked and unlocked uterine closure methods.

Materials and methods

Study design and ethical considerations: We conducted a randomized double-blinded trial conducted from April 1, 2021, to April 1, 2023, to compare the RMT and CSD incidence following the double-layer locked and unlocked suturing. Eligible primiparous patients who were candidates for CS from April 1, 2021, to April 1, 2022, were recruited and were followed one year following the surgery. This study was conducted in accordance with the principles of the Declaration of Helsinki (23). All participants provided informed verbal and written consent prior to their inclusion in the study. Measures were taken to ensure the anonymity and confidentiality of patient information. Written consent was obtained from all participants for the publication of any potentially identifiable data. This study received approval from the ethics committee and Institutional Review Board of Tehran University of Medical Sciences on March 3, 2021 (ethics code: IR.TUMS.IKHC.REC.1399.523).

The protocol of this trial was retrospectively registered in the Iranian Registry of Clinical Trials (IRCT), a Primary Registry in the World Health Organization (WHO) Registry Network, under a registration code of IRCT20231028059887N1 (available at https://irct.behdasht.gov.ir/trial/73431). Furthermore, we followed the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting the findings of our study (24).

Study Population: Study inclusion criteria were as follows: (a) primiparous term pregnant women in their third trimester, (b) eligible for primary CS, (c) possessing a normal pre-pregnancy body mass index (BMI), (d) lacking pre-pregnancy medical conditions, (e) free from major pregnancy complications like

gestational hypertension, preeclampsia, eclampsia, and gestational diabetes mellitus, (f) not in the latent phase of labor, (g) presenting with a fetal head station of zero or higher (-3, -2, -1, and 0), and (h) no history of prior lower uterine segment surgery.

Exclusion criteria encompassed: (a) extension of the CS incision during the procedure, (b) pregnancy during 1 year following the CS, (c) patient unwillingness, or (d) patient non-cooperation.

Sample size calculation: The sample size for our study was determined based on a prior investigation conducted by Roberge et al. in 2016 (20). Using the mean RMT values reported for patients undergoing double-layer locked and unlocked uterine closure techniques, and considering an 80% power, a significance level of 0.05, and an estimation ratio of 1:1, we calculated a sample size of 54. Accounting for a 10% attrition rate, we arrived at a final calculated sample size of 60 for our research, with 30 patients allocated to each group.

Randomization and blinding: Patients were randomly assigned to either the "locked" or "unlocked" uterine closure methods using a random block allocation method with a block size of four. Specifically, for every block of four patients enrolled, two were allocated to the locked technique and two to the unlocked technique. The random allocation sequences were crafted by an experienced epidemiologist at the center, while an obstetrics and gynecology resident was responsible for enrolling participants and assigning them to their respective interventions. The allocation sequence was concealed using sequentially numbered, sealed, opaque envelopes. Surgeons were informed of each patient's assignment before the operation by providing them with the respective sealed envelope. Both patients and the examiner conducting ultrasonographic assessments were blinded to the surgical closure approach assignments.

Intervention: Patients were randomly assigned to one of two groups: "locked" or "unlocked" uterine closure methods. In the locked group, a two-layer closure was performed, including a first continuous layer encompassing the endometrium and myometrium, and a second layer which is achieved by maneuvering the needle in a back-and-forth trajectory on the myometrium on both sides of the incision (Figure 1). While, in the unlocked group, a two-layer closure, comprising an initial continuous unlocked suture that encompasses the endometrium and approximately two-thirds of the inner myometrium and a secondary unlocked suture, targeting the upper half of the myometrium was performed (Figure 1). It is noteworthy that the endometrium was included in the suturing of the first layer in both groups. Cesarean incision closure in both groups was performed using VICRYL® 1.0 sutures.

Study measures and outcomes: At the baseline, data regarding the participants' age, gravidity, indications for CS, BMI, gestational age, cervical dilatation at the time of cesarean section, and fetal head station were recorded. Subsequently, one year after the surgery, all patients underwent transvaginal ultrasonographic examination in the dorsal lithotomy position after emptying their bladders. We designated RMT as the primary outcome of our study, with scar depth and width considered secondary outcomes.

The scar on the uterine surface was identified in the sagittal view, and parameters including scar width, scar depth (vertical distance between the base and apex of the defect), and RMT were measured (Figure 2). Furthermore, in accordance with findings from previous research, patients with scar depth exceeding 2 mm were diagnosed with a CSD (25), and patients with RMT lower than 2.5 mm were diagnosed with a large CSD (26).

Statistical analysis: Statistical analysis was performed using the Statistical Package of Social Science Software (SPSS, version 25, IBM Company, Armonk, NY, USA).

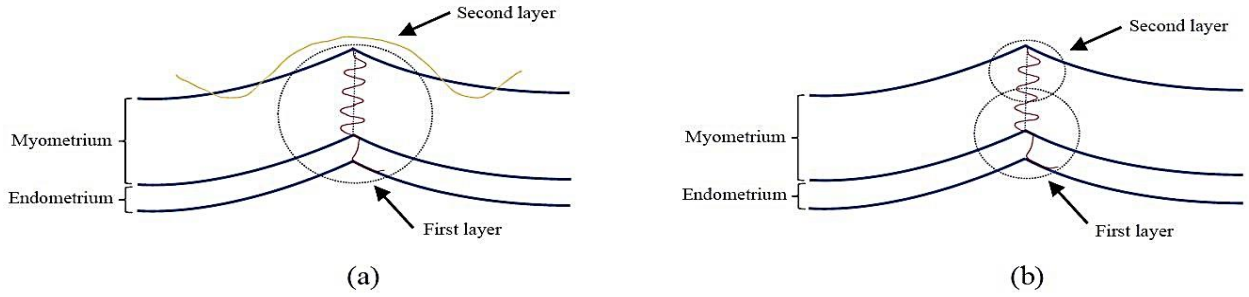

Figure 1: Illustration of implemented suturing techniques in the (a) locked and (b) unlocked groups

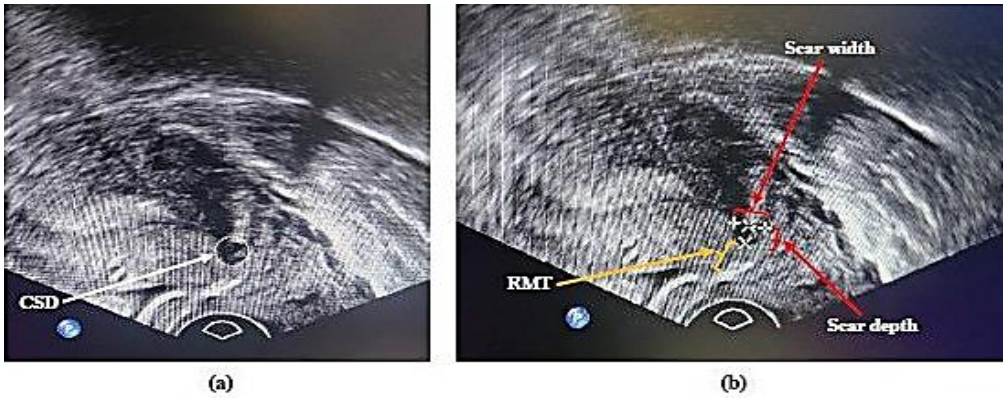

Figure 2: Transvaginal ultrasonographic view of (a) CSD, and (b) measurement of the RMT, scar width, and scar depth

Categorical variables were reported as numbers (%), and continuous variables were reported as mean ± standard deviation (SD). The Chi-square test was used for analyzing two groups of categorical data between the groups. Also, the independent t-test was employed to analyze the differences in continuous variables between the groups. In addition, before interpreting the results of the independent t-tests, Levene's test was conducted to assess the homogeneity of variances. The statistical significance level was set at p-value < 0.05 for all analyses.

Results

Participants: A total of 91 patients underwent initial screening, and subsequently, 70 of them met the eligibility criteria for inclusion in the study. These eligible participants were randomly assigned to either the locked group (n = 35) or the unlocked group (n = 35). Fourteen patients, five from the locked group and nine from the unlocked group, were dropped out of the study. Among them, twelve patients declined participation in the one-year follow-up visits, while two patients required an extension of the CS incision during surgery (Figure 3). Consequently, 56 patients successfully completed the study and were included in the final analysis.

There were no significant differences between the study groups in their age, pre-pregnancy BMI, indications for CS, gravidity, gestational age, cervical dilatation, and fetal head station (p > 0.05).

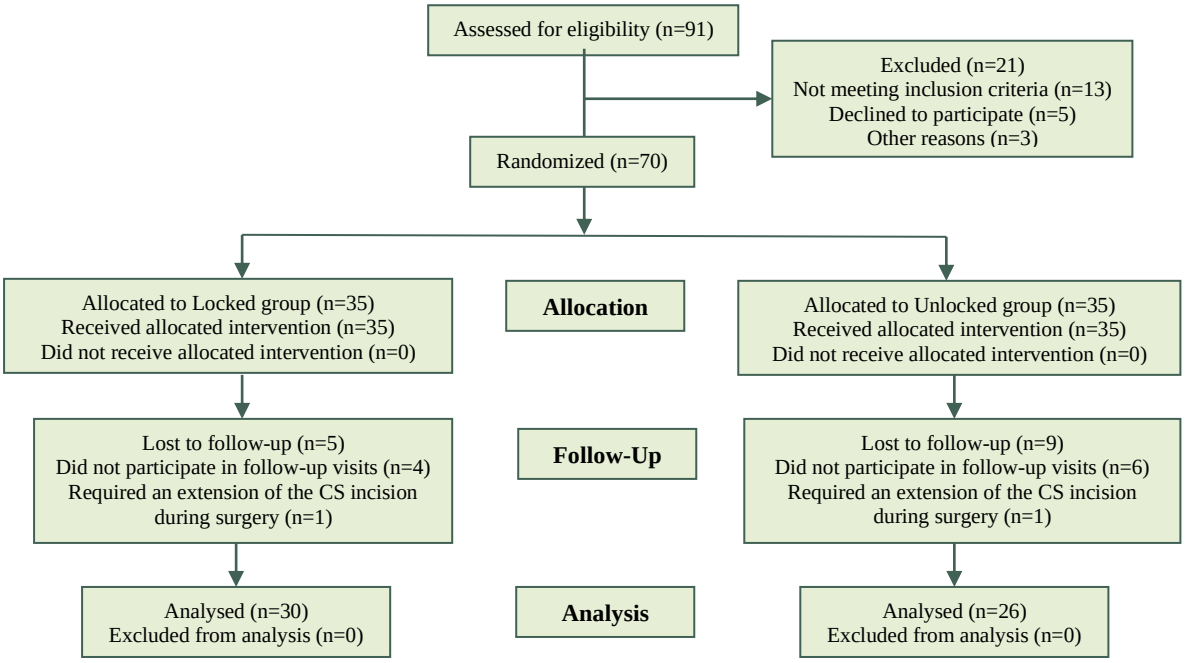

Figure 3: Flow diagram of the process of participant selection based on the CONSORT 2010 guideline

More detailed information regarding the baseline characteristics of the study participants is available in Table 1.

Follow-up ultrasonographic findings: Patients were followed up at an average of 371.22 ± 40.78 days post-surgery. As illustrated in Table 2, there were no significant differences in the mean RMT and scar width between the locked and unlocked groups (p = 0.14 and 0.42, respectively). However, the mean scar depth was notably greater in the unlocked group, measuring 3.77 ± 1.21 mm compared to 3.16 ± 1.11 mm in the locked group (p = 0.04).

Moreover, all of the 56 patients had a scar depth greater than 2 mm and were diagnosed with CSD. In addition, only one patient from the locked group had a RMT of 2.4 mm and was diagnosed to have a large CSD.

Discussion

Based on our findings, there was no significant difference between the two closure techniques of two-layer locked and unlocked suturing in the post-operative RMT, scar width, and CSD incidence. However, the scar depth was significantly higher in the unlocked group.

Previous research demonstrated that larger CSDs are associated with more pronounced clinical symptoms (27). The proposed mechanism for postmenstrual spotting and pelvic pain associated with CSD is the accumulation of blood in the pouch, microvascular disruption, and production at the site of small vessels (27). The severity of these symptoms may be proportional to the size of the defect, with larger defects trapping more blood and potentially leading to long-term postmenstrual spotting (27). Therefore, employing a uterine closure approach that enhances myometrial support at the scar site not only has the potential to reduce the risk of CSD occurrence but may also alleviate CSD-related symptoms in affected patients.

Growing evidence suggests that techniques used for uterine closure during CS may influence the repair of the uterine scar and RMT at the scar site (10). A recent systematic review found that single-layer uterine closure is associated with an increased risk of CSD occurrence compared to double-layer closure technique (28). Single-layer closure appears to result in weaker myometrial support (thinner RMT) at the CS scar site, although there is no difference between the two techniques in the rate of uterine rupture occurrence (29, 30). While most studies have focused on single-layer or double-layer closure methods, less attention has been given to locked or unlocked techniques. Yasmin et al. (2011) found no significant difference in the risk of uterine rupture between two-layer locked and unlocked closure techniques (31). However, the locked method was associated with weaker myometrial support at the scar site (31).

Table 1: Baseline characteristics of the study participants[a]

Variable		Group		p-value
		Locked (n=30)	Unlocked (n=26)	
Age, y		26.06 ± 4.44	27.69 ± 4.85	0.19[b]
Pre-pregnancy BMI		21.5 ± 1.9	21.7 ± 1.9	0.72[b]
Indication for CS	Late deceleration	13 (43.3)	15 (57.7)	
	Fetal tachycardia	4 (13.3)	5 (19.2)	
	Breech position	5 (16.7)	2 (7.7)	0.13[c]
	Meconium staining	3 (10)	2 (7.7)	
	Lack of labor progress	5 (16.7)	0 (0)	
	HIV positive	0 (0)	2 (7.7)	
Gravidity	1	25 (83.3)	24 (92.3)	0.18[c]
	2	5 (16.7)	1 (3.8)	
	≥ 3	0 (0)	1 (3.8)	
Gestational age, w		38.5 ± 0.7	38.9 ± 1.1	0.06[b]
Cervical dilatation, mm		7.9 ± 1.7	7.8 ± 1.8	0.87[b]
Fetal head station	-3	10 (33.3)	5 (19.2)	
	-2	10 (33.3)	9 (34.6)	0.61[c]
	-1	6 (20)	6 (23.1)	
	0	4 (13.3)	6 (23.1)	

BMI: Body mass index, CS: Cesarean section, HIV: Human immunodeficiency virus, mm: Millimeters, w: Weeks, y: Years.
a. Categorical data are presented in numbers (percentage) and continuous variables as mean ± standard deviation.
b. Independent t-test, c. Chi-square test

Table 2: Findings of the ultrasonographic examination of the patients, one year after the surgery

Variable	Group	Mean ± SD (Range)	p-value	Mean differences (95% CI)
RMT, mm	Locked (n = 30)	4.44 ± 1.07 (2.44-7.68)	0.14	-0.32 (-0.76-0.11)
	Unlocked (n = 26)	4.12 ± 0.48 (3.10-5.20)		
Scar depth, mm	Locked (n = 30)	3.16 ± 1.11 (2.00-6.97)	0.04	0.61 (0.01-1.21)
	Unlocked (n = 26)	3.77 ± 1.21 (2.30-6.50)		
Scar width, mm	Locked (n = 30)	3.68 ± 1.44 (1.58-6.90)	0.42	0.26 (-0.40-0.94)
	Unlocked (n = 26)	3.95 ± 1.00 (2.30-6.20)		

CI: Confidence interval, mm: Millimeters, SD: Standard deviation

Roberge et al. (2011) showed that single-layer locked closure of the uterus increased the risk of uterine rupture in patients attempting a trial of labor compared to double-layer unlocked closure (32). Although, there was no significant difference between single-layer unlocked and double-layer closure techniques (32). While there is an evident lack of knowledge regarding the myometrial thickness differences following each double-layer locked and unlocked layers, there seems a trend for better myometrial outcomes following the unlocked closure technique among the previous studies.

Our findings were consistent with the results of a randomized controlled trial by Bamber et al. (2017), indicating that the uterine double-layer closure approaches (both locked and unlocked) do not significantly affect the occurrence rate of CSD or the scar site RMT in patients (33). It is noteworthy that in this study, similar to ours, the endometrial layer was included in the first layer of the suturing in both locked and unlocked groups (33). This suturing technique appears to potentially impact myometrial support at the CSD site. Gezer et al. (2024) demonstrated that uterine closure following cesarean section with the inclusion of endometrial suturing is associated with significantly higher CSD development and intermenstrual spotting compared to closure without endometrial suturing (33). In a related study, Roberge et al. (2016) compared RMT following cesarean section in double-layer locked suturing with the first layer including endometrial thickness and double-layer unlocked suturing with the first layer excluding endometrial thickness (20). In contrast to our findings, they observed significantly higher RMT at the cesarean scar site in patients with unlocked suturing compared to the locked group (20). Overall, these data suggest that the inclusion or exclusion of the endometrium during uterine closure may be a more critical factor than the locked or unlocked suturing technique and may be more associated with better myometrial support at the cesarean scar site. This underscores the need for future research to determine the precise effects of suturing methods (locked and unlocked), as well as the inclusion or exclusion of the endometrium in uterine closure, on the occurrence of CSD and myometrial support.

Our study has several limitations that may affect the generalizability of its findings. These limitations are primarily linked to the small sample size. Additionally, our study lacked long-term follow-up, and we did not assess the long-term complications of CSD, such as AUB, dysmenorrhea, pelvic pain, and uterine rupture during subsequent pregnancies. Another limitation is that we did not conduct ultrasonographic examinations of patients at a consistent, predefined phase of their menstrual cycle, which can affect the generalizability of our sonographic findings.

It is important to highlight that the disparity in suturing techniques between our study groups extended beyond merely being locked or unlocked in the first layer. Additionally, there were differences in the amount of myometrial thickness included in both suturing layers. This complexity suggests caution in attributing observed findings solely to locked or unlocked techniques. It underscores the necessity for future research to employ identical amounts of myometrium in suturing to establish the precise effects of locking or unlocking suturing on the incidence of CSD. These limitations emphasize the pressing need for future studies, implementing improved designs and larger samples, to reach more reliable findings concerning the clinical outcomes of uterine closure utilizing the locked and unlocked suturing techniques.

Conclusion

Collectively, the incidence of CSD and scar site RMT in our study were not significantly different following the double-layer locked and double-layer unlocked uterine closure techniques, while the scar depth was

greater in the unlocked group. These findings suggest that neither of these techniques has significant advantages over others in resulting in better myometrial support following the cesarean section. However, considering the potential effects of the mentioned limitations of our study, there is still a need for further larger randomized trials with more standardized and homogeneous designs to reach a conclusion in this regard.

Conflict of Interests

Authors declare no conflict of interests.

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