

Comparison of different uterine incision closure methods used in cesarean section in terms of postoperative cesarean incision scar thickness and isthmocele formation: a prospective, randomized study

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Objective: In parallel with the increase in cesarean section (CS) rates, the incidence of isthmocele has been increasing. In this study, we aimed to evaluate the effect of four different uterine incision closure techniques (single-layer locked, double-layer locked, single-layer unlocked, and double-layer unlocked) on cesarean scar healing and isthmocele formation by transvaginal ultrasound (TVUS) and saline infusion sonography (SIS). **Materials and methods:** This prospective, randomized study included women who underwent the first, elective, and term cesarean section delivery at the Obstetrics and Gynecology clinic of a tertiary care center between November 2018 and November 2019. A total of 60 patients were divided into four groups including 15 patients in each. Using the TVUS and SIS, the width, depth and length of the CS defect and the thickness of the residual myometrial tissue were measured. **Results:** There was no significant difference in the CS defect measurements and CS defect area among the four groups ($p > 0.05$). The lowest rate of Grade 3 isthmocele was seen in the double-locked group (5%), while the highest rate of isthmocele was seen in the single-unlocked group (35%) ($p > 0.05$). **Conclusion:** No trend of differences was seen in the four subgroups but the sample size is not big enough to draw valid conclusions.

Keywords

Cesarean delivery; Isthmocele; Saline infusion sonography; Uterus closure technique

1. Introduction

The World Health Organization (WHO) advocates that the ideal cesarean section rate should be below 10 to 15% in all societies [1]. Republic of Turkey, Ministry of Health reported that this rate was 57% in 2019, while the primary cesarean rate was 27% [2]. Due to the high rates of cesarean delivery in recent years, long-term adverse consequences have become prevalent [3]. A cesarean scar defect is the thinning and indentation of the myometrium caused by inadequate healing of the myometrium at the site of the hysterotomy. Although it is usually asymptomatic, it can cause unde-

sirable conditions such as abnormal or postmenstrual bleeding, chronic pelvic pain, infertility, placenta accrete or previa, uterine rupture, cesarean scar ectopic pregnancy [4].

CS defect size is thought to play a role in the risk of uterine rupture in subsequent pregnancies [5]. Although the factors implicated in CS defect formation remains to be elucidated, changes in maternal age, uterine position, labor induction, uterine incision closure have been mostly blamed [6]. CS defect morphology can be demonstrated by transvaginal ultrasound (TVUS), saline infusion sonography (SIS) and hysteroscopy [7]. It is of utmost importance to identify the causes of this situation and to tailor strategies to prevent this, if possible. Therefore, the number of the articles in the literature regarding CS defect and treatment preferences has been increasing in recent years. Uterine incision closure technique is also considered an important factor in scar healing and some differences between single-layer and double-layer locked and unlocked techniques have been described for cesarean scar morphology [8].

In the light of these data, we aimed to evaluate the effect of four different uterine incision closure techniques (i.e., single-layer versus double-layer and locked versus unlocked) on cesarean scar healing and isthmocele formation using postpartum TVUS and SIS in pregnant women delivered by the first elective cesarean section.

2. Materials and methods

2.1 Study design and study population

This single-center, prospective, randomized study was conducted at Department of Obstetrics and Gynecology of a tertiary care center between November 2018 and November 2019. The study protocol was approved by the local Ethics Committee (No: 2018/26-21). Prior to study, all patients were informed about the nature of the study and a written informed consent was obtained. The study was conducted in

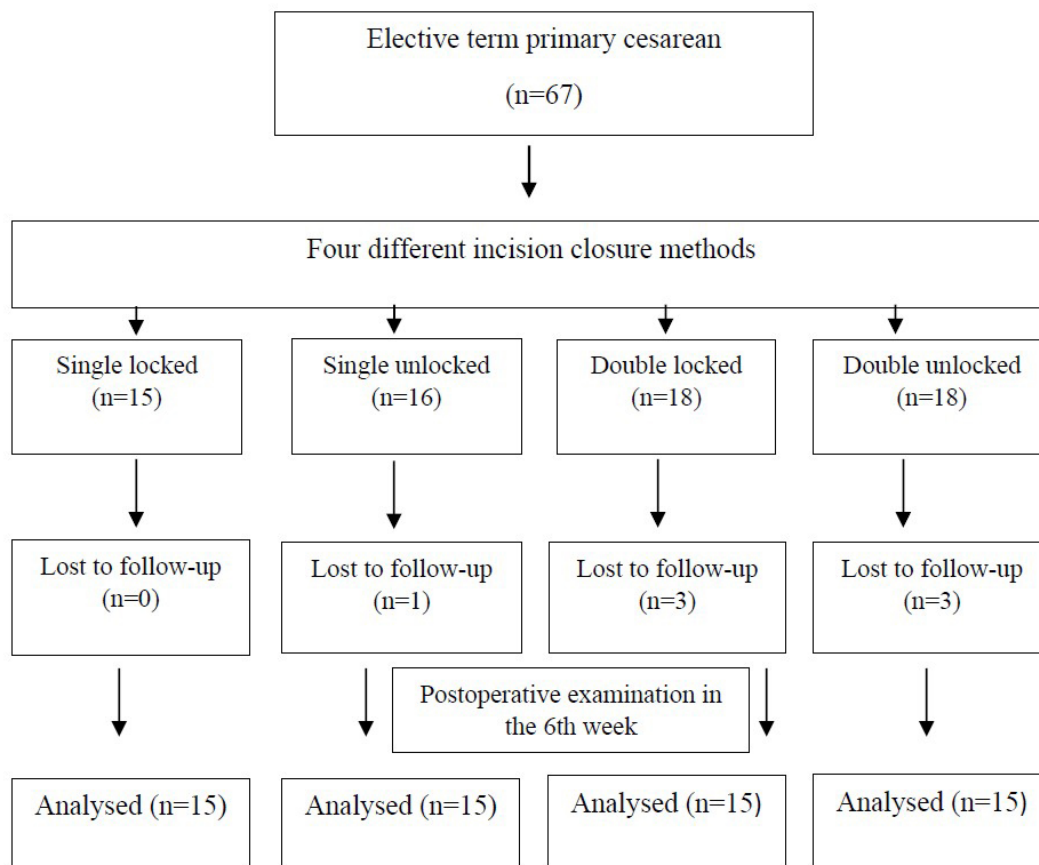


Fig. 1. Study flow chart.

accordance with the principles of the Declaration of Helsinki.

Patients with their first cesarean section between the ages of 18 and 40 years with a term pregnancy, who agreed to attend to the control visit at six weeks postpartum, and patients whose prenatal and follow-up data were complete in the patient file were included. Those under 37 weeks of gestation, with labor (having active contractions with cervical patency of 4 to 5 cm or more), having placenta previa, previous uterine surgery, a diagnosis of immune system disorder such as insulin-dependent diabetes mellitus, or those who did not attend to follow-up were excluded from the study. All patients were evaluated by SIS and TVUS at six weeks in the postpartum period.

2.2 Randomization and allocation

A total of 67 patients were randomized using the simple random number generator. All patients were operated using the traditional Pfannenstiel-Kerr method. Totally, 60 patients who met the inclusion criteria were included in the study. The patients were divided into four groups including 15 in each group. The first group was applied with the single-layer locked, the second group with the single-layer unlocked, the third group with the double-layer locked, and the fourth group with the double-layer unlocked incision closure technique. The study flow chart is shown in Fig. 1.

2.3 Surgical technique

All operations were performed by a single surgery team including four obstetrics and gynecology specialists. Following randomization, the technique to be used was explained to the surgeon. Routine skin cleaning was performed with povidone-iodine before the operation. Prophylactic antibiotic therapy was given with cefazolin sodium 1 g. The type of anesthesia (general or regional) was left to the discretion of the anesthesia team. In all patients, the Pfannenstiel incision was used. Fascia was opened transversely by sharp dissection and the peritoneum was opened bluntly. The bladder peritoneum was pushed, creating a bladder flap and, then, the uterus was opened through a Kerr incision. Following the delivery of the fetus, four different closure techniques were applied for closure of the uterus according to the groups. The fascia was closed continuously without locking. The skin was sutured subcutaneously.

2.4 Outcome measurements

Data including age, weight, height, body mass index, gestational week, repair time of the uterus, number of additional sutures (defined as requirement of three or more sutures after uterine incision), total operation time, operation-related complications, and time to discharge were recorded.

CS defect measurements were performed at six weeks postpartum as follows: The cervix was visualized by placing a speculum in the vagina in the gynecological position and cleaned with an antiseptic solution. A sterile small flexible cannula was passed through the cervical canal (Nasogastric feeding catheter No: 6 Bıçakcılar Medical Devices, Istanbul, Turkey). After the speculum was removed, the uterine cavity was started to be filled with saline under TVUSG. Three-dimensional Voluson™ E8 (GE Healthcare, Tokyo, Japan) ultrasound system was used. Three-dimensional images were obtained with TVUSG, when the CS defect was most prominent. The width, depth and length of the CS defect and the thickness of the remaining myometrial tissue were measured using recorded images. The degree of the niche was calculated based on the height and base width of the CS defect and the existing niche area (Figs. 2,3,4,5). Since the Isthmocol shape is similar to isosceles triangle, the area can be calculated with $\text{base} \times \text{height} / 2$ formula [9]. Based on the ultrasound measurements, isthmoceles were classified into three grades as described previously: Grade 1, less than 15 mm^2 ; Grade 2, between 16 to 25 mm^2 ; and Grade 3, larger than 25 mm^2 [9]. Grade of the isthmoceles was determined by calculating the niche area. All measurements were performed by a single surgeon who was blind to group allocation using the same ultrasound device.

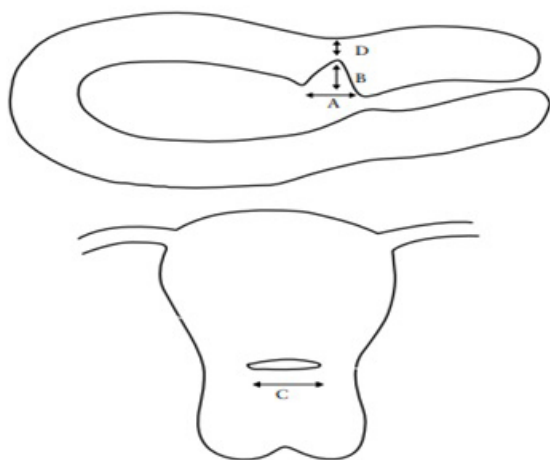


Fig. 2. Schematic view of measurements by TVUS. (A) Niche width. (B) Niche depth. (C) Niche length. (D) Thickness of the residual myometrium.

2.5 Statistical analysis

Statistical analysis was performed using the SPSS version 24.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean \pm standard deviation (SD) or number and frequency, where applicable. The Student *t*-test was used to compare quantitative data. Chi-square test and Fisher exact test were used to compare normally distributed continuous variables. A *p* value of <0.05 was considered statistically significant with 95% confidence interval.

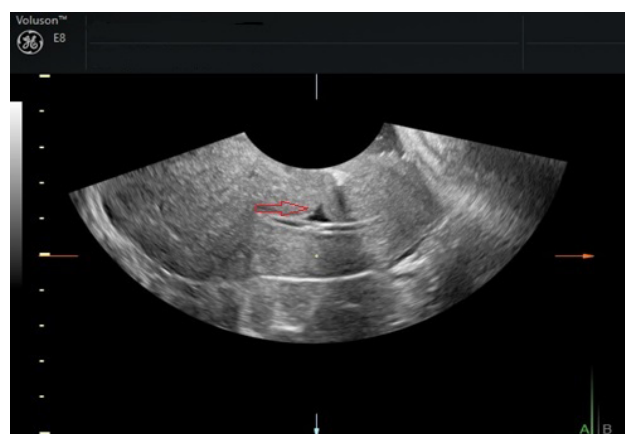


Fig. 3. Isthmocol in the sagittal plane by 3D TVUS with SIS.

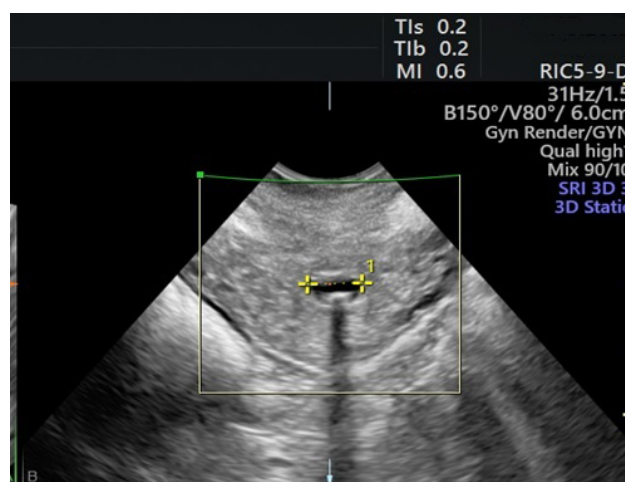


Fig. 4. Cesarean scar niche length in transvers plane by 3D TVUS with SIS.



Fig. 5. Isthmocol and residual myometrium in sagittal plane by 3D TVUS with SIS.

3. Results

In this study, a total of 60 pregnant women who underwent the first, elective and term cesarean delivery were included. The cesarean delivery indications were cephalopelvic disproportion in 19 (28%), abnormal presentation

Table 1. Demographic characteristics of patient groups.

	Single-unlocked (n = 16)	Single-locked (n = 15)	Double-unlocked (n = 18)	Double-locked (n = 18)	p
Age (year)	29.25	28.50	30.15	30.08	ns
Height (cm)	160.20	159.40	163.30	162.50	ns
Weight (kg)	74.37	78.75	74.47	76.77	ns
BMI (kg/m ²)	28.40	27.50	28.60	29.40	ns
Gravida	1.43	1.17	1.11	1.72	ns
Parity	0.31	0.71	0.26	0.93	ns
Abort	0.12	0.28	0.36	0.38	ns
Smoke	1	1	2	1	ns

BMI, body mass index; ns, not significant ($p > 0.05$).

Table 2. Cesarean operation times of patient groups.

	N	Mean	±SD	Min	Max
Single-unlocked	16	25.6875	3.71876	21.00	35.00
Single-locked	15	24.3571	3.24884	20.00	32.00
Double-unlocked	18	24.5789	1.70996	21.00	28.00
Double-locked	18	24.4444	1.88562	21.00	28.00

Table 3. Additional sutures of patient groups.

	N	Additional suture	p
Single-unlocked	16	0	ns
Single-locked	15	2	ns
Double-unlocked	18	0	ns
Double-locked	18	0	ns

ns, not significant ($p > 0.05$).

in 22 (33%), fetal anomaly in 12 (18%), fetal distress in seven (10.5%), and macrosomia in seven (10.5%) macrosomia. There was no significant difference between the age, height, weight, body mass index, obstetric history, and smoking and alcohol use among the groups (Table 1).

The data regarding cesarean operations were similar among the groups. The operation times were comparable, indicating no statistically significant difference (Table 2). None of the groups required blood transfusion during and after the operation. There was no significant difference in terms of the use of additional sutures and blood transfusion among the groups ($p > 0.05$ for both) (Table 3).

At the postoperative sixth week, 60 patients were scheduled for a follow-up visit for the evaluation of the CS defect depth, width and length, and residual myometrial thickness was measured.

There was no significant difference in the CS defect measurements and CS defect area among the four groups ($p > 0.05$) (Tables 4 and 5). The lowest rate of Grade 3 isthmocele was seen in the double-locked group (5%), while the highest rate of isthmocele was seen in the single-unlocked group (35%) ($p > 0.05$) (Table 4).

4. Discussion

In recent years, the number of cesarean operations has been gradually increasing, leading to many adverse conse-

quences and complications with high morbidity and mortality rates, such as uterine rupture, preterm labor, and placental adhesion anomalies, which have been reported particularly in subsequent pregnancies due to the failure of the cesarean scar [10, 11]. Researchers have currently investigated the ways to reduce these risks and compared the uterine incision closure techniques [12, 13]. In the present study, we compared four different incision closure techniques. At the postoperative sixth week, we observed no significant differences in the CS defect measurements and defect areas among the groups.

In a retrospective cohort study including 149 women undergoing elective cesarean delivery, Glavind *et al.* [14] examined CS defect length, width, depth and residual myometrial thickness in 68 women with single-layer closure and 81 women with double-layer closure. The authors found that the CS defect length was greater in women with single-layer closure than those with double-layer closure (6.8 mm *vs.* 5.6 mm, respectively). However, there was no significant difference in the other measurements. In the current study, we performed single-layer locked, single-layer unlocked, double-layer locked, and double-layer unlocked incision closure techniques. We found no significant difference in the CS defect length among the groups. However, unlike the study of Glavind *et al.* [14], our sample size is relatively small.

In another prospective, randomized study comparing the effects of single- and double-layer suturing techniques on healing of the uterine scar following cesarean delivery, Sevkett *et al.* [15] applied single-layer technique to 18 women and double-layer technique in 18 women. At six months, residual myometrial thickness and CS defect depth were measured using SIS. Markers of uterine scar healing were defined as the healing ratio and residual myometrial thickness covering the defect. Residual myometrial thickness was significantly higher in the double-layer technique than the single-layer technique (9.95 mm *vs.* 7.53 mm). The healing ratio was also significantly higher in the double-layer technique. In a prospective study of Hayakawa *et al.* [16], single-layer versus double-layer interrupted sutures and a novel method developed by the authors were compared. A total of 137 women who underwent first cesarean delivery (between 26 and 41 weeks of gestation) were assessed using TVUS at one

Table 4. CS defect sizes of patient groups.

CS defect	Single-unlocked (n = 15)	Single locked (n = 15)	Double-unlocked (n = 15)	Double-locked (n = 15)	p
Grade 1	4 (25%)	8 (55%)	5 (35%)	11 (75%)	ns
Grade 2	6 (40%)	3 (20%)	6 (40%)	3 (20%)	ns
Grade 3	5 (35%)	4 (25%)	4 (25%)	1 (5%)	ns

Data are given in number and frequency, unless otherwise stated. ns, not significant ($p > 0.05$).

Table 5. CS defect measurements of patient groups.

	Scar width	Scar depth	Scar length	Residual myometrium thickness	p
Single-unlocked (n = 15)	6.19 ± 2.15	4.59 ± 1.68	9.14 ± 2.11	7.61 ± 2.52	ns
Single-locked (n = 15)	4.91 ± 1.32	4.26 ± 1.85	7.78 ± 1.92	7.46 ± 1.74	ns
Double-unlocked (n = 15)	5.13 ± 2.18	4.22 ± 1.83	9.42 ± 6.78	8.12 ± 1.82	ns
Double-locked (n = 15)	4.35 ± 1.54	3.68 ± 1.83	7.91 ± 2.74	7.78 ± 1.81	ns

Data are given in mean ± standard deviation, unless otherwise stated. ns, not significant ($p > 0.05$).

month after surgery and appearance of lower uterine scars were evaluated. The first group was applied single-layer interrupted myometrium suture, the second group was applied double-layer interrupted myometrium suture, and the third group was applied a novel method consisting of continuous suture with decidual closure, followed by interrupted myometrium suture in which the endometrial layer was permanently unlocked and the remaining myometrial tissue was repaired. During regular postpartum visit on 30th to 38th day of surgery, residual myometrial and scar defect measurements were performed using the TVUS. The authors reported that the rate of wedge defects was significantly higher in the single-layer unlocked technique than the other two techniques. Multiple regression analysis showed that increasing gestational week at the time of delivery, multiple pregnancy, premature rupture of membranes, and preeclampsia were associated with an increased risk of wedge defects.

In a randomized-controlled study by Bamberg *et al.* [17], 435 patients who underwent cesarean delivery were examined. Of these patients, 40% were applied the single-layer locked, 32% the single-unlocked, and 43% the double-layer technique. Using the TVUS, CS defect depth and niche area measurements were calculated at six weeks and at six to 24 months postoperatively. In this study, the authors found no significant difference in the cesarean scar depth and niche area measurements among the three groups at both time points. In a review including 21 studies, Bij de Vaate *et al.* [18] examined the link between a niche and abnormal uterine bleeding. Potential risk factors in terms of isthmocele formation were found to be the use of single-layer technique, multiple cesarean sections, and retroverted uterus. Postmenstrual spotting was the most common symptom. The authors concluded that there was no significant difference in the isthmocele formation between the closure techniques. In our study, however, pelvic pain was the most common symptom probably due to the fact that the patients were evaluated at six weeks postoperatively in our study.

Furthermore, in their prospective, longitudinal study including 60 pregnant women, Ceci *et al.* [19] compared two different single-layer sutures by TVUS and hysteroscopy. The patients were divided into two groups. The uterine incision was closed using the locked continuous single-layer sutures in the first group and using the single-layer interrupted sutures in the second group. Cesarean scar defect was greater in the first group than the second group (6.2 mm² vs. 4.6 mm²). The authors concluded that locked continuous sutures resulted in a larger defect probably due to a greater ischemic effect on the uterine tissue.

In a systematic review and meta-analysis, Di Spiezio Sardo *et al.* [20] analyzed nine randomized-controlled studies including 3,969 participants. In five studies comparing single-layer and double-layer technique, CS defect was observed more frequently with the double-layer technique, although it did not reach statistical significance. In addition, in five studies, residual myometrial thickness was significantly lower with the single-layer technique. The discrepancy between the results can be attributed to the use of different techniques, uterine positions, and ultrasound technologies in the included studies. Additionally, as there is no consensus on definition of the scar healing time, different time points were used for the postoperative evaluation. In our study, we analyzed the CS defect at six weeks after cesarean delivery. Unlike the findings of Di Spiezio Sardo *et al.* [20], we found no significant differences between the locked versus unlocked and single-layer versus double-layer incision closure techniques in terms of the cesarean scar depth, width, length and residual myometrial thickness.

In addition to the surgical technique, the surgery itself is a risk factor. Surgery may trigger the development of isthmocele through many factors such as inflammation, tissue ischemia, tissue manipulation and insufficient hemostasis [21].

The main limitations of the present study are the relatively small sample size and short follow-up. The main strengths of this study are its prospective, randomized design, homogeneous study population, and the use of a valid randomization method to examine the effect of the technique on isth-

mocele formation. Nevertheless, further large-scale, long-term, prospective, randomized-controlled studies are needed to draw a firm conclusion.

5. Conclusions

In conclusion, no trend of differences was seen in the four subgroups but the sample size is not big enough to draw valid conclusions. A much larger RCT with adequate power to detect relevant differences is required to draw any definitive conclusions.

Author contributions

Aİ Conception and design of study, acquisition of data, analysis and/or interpretation of data, drafting the manuscript. SK Acquisition of data, interpretation of data, drafting the manuscript. OED Conception and design of study. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study protocol was approved by the local Ethics Committee (No: 2018/26-21). Prior to study, all patients were informed about the nature of the study and a written informed consent was obtained. The study was conducted in accordance with the principles of the Declaration of Helsinki.

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Conflict of interest

The authors declare no conflict of interest.

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