

TITLE

Double-layered purse string uterine suture employing the French ambulatory cesarean section technique compared with single-layer continuous uterine suture: An ultrasound evaluation randomized trial.

RUNNING TITLE

Purse string uterine suture during cesarean .

AUTHORS

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ABSTRACT

Objective:

To test the hypothesis that compared to single layer continuous uterine suture (SLCUS), a double layered purse string uterine suture (PSUS) significantly reduces cesarean scar defect (CSD) rates, without increasing the perioperative maternal morbidity.

Design : Interventional prospective, randomized study .

Setting: University obstetric units in Tunisia.

Population: 100 pregnant women with an indication of a planned Caesarean.

Methods: Patients were enrolled in 2 groups according to the uterine suture technique: SLCUS or PSUS. A Saline infusion hysterosonography was performed by the same senior obstetrician blinded to the uterine suture technique 6 months after surgery .

Main Outcome measures:

Operative time and Calculated blood loss (CBL) were used for the short time analysis . Uterine and CSD measurements were used for the mid time analysis .

Results :

Despite a few minutes longer operative time in SUS group (7.17 ± 2.31 min Vs. 6.31 ± 3.04 min, $p = 0.028$ in SLCUS group; $p < 10^{-3}$); there was no significant difference in terms of CBL (520 ± 58 in SUS group vs. 536 ± 50 ml in SLCUS group, $p = 0.724$). The medium-term analysis showed a significant decrease in the rate of CSD with the PSUS: 6.66% vs. 40% with SLUCS; $p = 0.002$. Moreover, SLUCS was the leading risk factor for CSD : adjusted OR=6 ;95% CI [0- 1], $p < 10^{-3}$) .

Conclusion :

Compared to single layer continuous suture, purse string uterine suture significantly reduces cesarean scar defect rates, without increasing the perioperative maternal morbidity.

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KEYWORDS

cesarean, uterine Scar, morbidity, delivery, ultrasound .

TWEETABLE ABSTRACT

Compared to single layer continuous suture, purse string uterine suture employing the French ambulatory cesarean section significantly reduces cesarean scar defect rates (6.66% Vs. 40%, $p=0.002$) , without increasing the perioperative maternal morbidity.

INTRODUCTION

The marked increase in the frequency of cesarean section (CS) worldwide warrants the need to address specific complications of this surgery, particularly with regard to subsequent pregnancies.¹ These specific complications are directly related to uterine scar quality.¹

With the rapid development of imaging, including ultrasound, it is now possible to evaluate uterine scar quality in terms of the presence and characteristics of a cesarean scar defect (CSD) or “niche”,^{2,3} which is a uterine scar dehiscence involving myometrial discontinuity.⁴

Several studies have investigated the optimal technique for uterine closure at the time of CS, which largely determines the quality of the uterine scar.⁵ According to recent randomized trials, double-layer sutures appear to be preferable to single-layer sutures.⁶ However, current evidence does not support a specific uterine closure technique for optimal maternal outcomes and to reduce the risk of uterine rupture.^{6,7} Moreover, all investigated techniques have been performed by closing the uterine edges in a horizontal direction.

With the aim of preventing CSD, we introduced a new technique involving a purse string uterine suture (PSUS) in the context of the “French Ambulatory C-Section” (FAUCS)

approach.^{8,9} To date, this uterine suture technique has not been formally evaluated. Therefore, the objective of this study was to test the hypothesis that PSUS would reduce CSD rates without increasing perioperative maternal morbidity compared with single-layer continuous uterine suture (SLCUS).

METHODS

This was a secondary analysis of a prospective, interventional, randomized, controlled study (NCT03741907) comparing the Misgav Ladach CS and the FAUCS, conducted at Mongi Slim University Hospital, La Marsa, Tunisia between August 2018 and April 2019¹⁰. In this secondary analysis (NCT03930134), we compared the short-, mid-, and long-term outcomes of 2 uterine suture techniques: PSUS and SLCUS.

Participants

All pregnant women with a planned CS were prospectively recruited. Women were excluded if they were younger than 18 years of age, declined to participate, had multiple pregnancies, previously received a uterine incision other than a Kerr incision¹¹, delivered preterm (i.e., <37 weeks of gestation), entered into active labor, or underwent emergency surgery before the originally scheduled date (e.g., in case of acute fetal compromise) or by a surgeon not assigned to the study (Figure 1).

All women who met the predelivery inclusion criteria were invited to participate in the study at their final prenatal visit. Those providing written informed consent were consecutively included in a preliminary participant list managed by an investigator who was not involved in patient care. The women were given a study number on their delivery day in chronological order.

Treatment allocation

Random assignment into the PSUS or SLCUS groups (control group) was performed by an investigator who was not involved in patient care using the Kendall B. B. Smith table.¹² All CSs were performed using the modified Misgav Ladach approach¹³ for the SLCUS group and the FAUCS approach^{8,10} for the PSUS group.

Women and medical residents involved in patient care were blinded to the uterine suture technique before surgery and were informed at discharge. Anesthetists and surgeons were informed of the technique immediately before surgery. Except for the investigators, no one had access to the participant list, postoperative follow-up, or 6-month imaging data.

Uterine suture techniques

All the women had a preoperative and a postoperative (on day 1) blood cell count.

For SLCUS, a holding Vicryl1 suture (Ethicon Inc.) was placed in the left corner to stabilize and define the demarcation of the suture line. A continuous nonlocking stitch began at the right corner and closed the whole thickness of the uterine wall, including the decidual layer, in a cranial/caudal position. For PSUS, a Vicryl 1 suture (Ethicon Inc.) was introduced intramyometrially just above the endometrium with a large round needle (Figure 2a, 2b). The suture started in one corner, proceeded along the upper edge, followed by the lower edge, and returned to the incision point. The subserous layer (Figure 2c) was closed using the same

thread to cover the sparse suture and complete homeostasis while increasing wound thickness.⁸

During surgery, the uterine suture technique and operative time (min) were recorded. All women were discharged within 1 or 2 days after surgery.

Saline infusion hysterosonography

A detailed transvaginal ultrasound examination was planned for all the women 6 months after surgery. All ultrasound exams were performed by 1 senior obstetrician who was blind to the uterine suture technique. Ultrasound exams were performed transvaginally on women in the lithotomy position and with an empty bladder using high-frequency (5–6 MHz) transducers (Samsung Medison UGEO H609).

After disinfection of the cervix and vagina, a flexible 10-gauge diameter catheter without balloon that was purged with isotonic solution was introduced, without the need for anesthesia, into the uterine cavity. The transvaginal probe was introduced after removal of the speculum, and a saline infusion hysterosonography (SIS) with up to 50 cc of isotonic solution was delivered into the uterine cavity at low pressure.

Primary outcome

The primary outcome was the rate of CSD observed 6 months after the surgery. A CSD was defined as an indentation at the site of the CS scar with a depth of at least 2 mm visualized during the SIS³ (Figure 3).

Secondary outcomes

Intraoperative and short-term postoperative outcomes

Operative time was defined as the time in minutes between the start and end of the uterine suture. Calculated blood loss (CBL) was calculated as $BV_M \times \%BV_\Delta$, where BV_M is maternal blood volume and $\%BV_\Delta$ is percent change (i.e., loss) in blood volume. BV_M was calculated by Nadler's formula,¹⁴ and $\%BV_\Delta$ was calculated by Brecher's formula.¹⁵

Mid-term postoperative outcomes

Based on the modified Delphi procedure,³ the following uterine scar and CSD measurements were performed during the SIS 6 months after surgery: CSD measurements consisted of the length, depth, and residual myometrium thickness (RMT), and the adjacent myometrium thickness (AMT) in the sagittal plane (mm), width in the transverse plane (mm), and the healing ratio, which was calculated as RMT/AMT ⁶ (Figure 3). Uterine scar position evaluation used the distance between the external os and the uterine scar in the sagittal plane. (Figure 4). Finally, in cases with no CSD defect, scar thickness, RMT and AMT was equivalent with a healing ratio = 1.

Long-term postoperative outcomes

A phone call interview was scheduled for all women 1 year after surgery. During the interview, the women were asked about their reproductive outcomes (e.g., infertility, need for

fertility treatment, pregnancy rate, caesarean scar pregnancy, placenta accreta spectrum disorders, and uterine dehiscence or rupture in subsequent pregnancy) and gynecological symptoms (e.g., postmenstrual spotting, dysmenorrhea, and chronic pelvic pain).

Statistical analyses

All statistical analyses were performed using XLSTAT Addinsoft software. A p-value <0.05 was used as the threshold of statistical significance. The normality distribution of the data was assessed using the Shapiro–Wilk test. Quantitative variables are expressed as mean \pm standard deviation (SD) or medians [75th – 25th percentiles] and were analyzed using Student's t or Mann–Whitney tests. Qualitative variables were expressed as percentages and were analyzed using χ^2 tests. Logistic regression analysis was performed to identify independent risk factors for CSD among all women regardless of their group assignments; for this analysis, a positive event was the visualization of a CSD during the SIS.

RESULTS

The CSs were performed between August 27, 2018 and January 30, 2019. Of the 487 women who underwent a CS during the study period, 169 were planned and assessed for study eligibility. One hundred women were randomized to the PSUS or SLCUS groups and completed the short-term evaluation (Figure 2). There were no significant differences between the groups in epidemiological or obstetric characteristics (Table 1). Despite a longer operative time for uterine suture in the PSUS group (7.17 ± 2.31 min) than in the SLCUS group (6.31 ± 3.04 min, $p = 0.028$), there was no difference between groups in CBL (520 ± 58 vs. 536 ± 50 ml, $p = 0.724$).

The rate of loss to follow-up at the mid-term postoperative evaluation (i.e., 6 months) was 38% despite several phone calls and rescheduling of dates for appointments. Therefore, the SIS was performed on 30 women in each group between May and August 2019. One woman in the PSUS group exhibited a severely retroverted uterus, which prevented introduction of the catheter through the uterine isthmus (Figure 5). The CSD rate was significantly higher in SLCUS group (40%, 12/30) than in PSUS group (6.66%, 2/30; $p = 0.002$). Although uterine scarring level was significantly lower in PSUS group ($p = 0.012$), the obtained scars after purse string suture were significantly thicker (RMT = 6.96 ± 2.55 mm Vs. 4.53 ± 2.09 mm in SLCUS ; $p < 10^{-3}$) with a higher healing ratio (0.97 ± 0.11 Vs 0.8 ± 0.25 , $p = 0.002$) (table 2). Finally, logistic regression showed that SLCUS was the leading risk factor for CSD (adjusted OR=6 ;95% CI [0- 1], $p < 10^{-3}$) Table 3).

The rate of loss to follow-up at the long-term postoperative evaluation (i.e., 1 year) was 16%. Therefore, long-term assessment was performed for 43 women in the PSUS group and 41 women in the SLCUS group.

There were no differences between groups in contraceptive use (41.86% for PSUS vs. 39.02% for SLCUS, $p = 1$), fertility (pregnancy rate, 4.65% for PSUS vs. 0% for SLCUS, $p = 0.47$), or gynecological symptoms (postmenstrual spotting, 9.75% for SLCUS vs. 2.32% for PSUS; $p = 0.11$). Postmenstrual bleeding was reported by only 1 woman who received PSUS with no associated CSD and 4 women who received SLCUS, among who 3 had a CSD.

DISCUSSION

Main Findings

This paper reports the first study comparing PSUS and SLCUS in terms of their short-term uterine incision healing and long-term subsequent fertility and gynecological symptoms. The outcomes of this randomized study support the hypothesis that PSUS reduces the rate of CSD without increasing maternal perioperative morbidity. Despite a longer operative time using the PSUS, there was no significant difference between groups in terms of CBL.

There was a significantly lower rate of CSD in the PSUS group. Moreover, SLCUS was the greatest risk factor for CSD, and uterine scars in the PSUS group were significantly thicker than in the SLCUS group. Together, these outcomes suggest that the PSUS technique allows for better healing of the uterine scar.

Strengths and Limitations

A major strength of this study is its blinded randomized design. Also, excluding cases of emergency CS during labor helped rule out other factors that could influence the healing process. Considering that uterine scar healing is complete after a minimum of 6 months following CS,¹⁶ we respected this delay when performing the SIS. Moreover, the ultrasound examination of the uterine scar was based on the latest international recommendations³ and was performed by an obstetrician blinded to group allocation.

This study has some limitations. We did not investigate the frequency of uterine rupture in subsequent pregnancies. Given uterine rupture is a rare event, occurring in <2% of cases, thousands of participants would be required to detect a possible difference. Furthermore, a substantial amount of evidence has already shown a direct link between CSD and risk of uterine rupture. Other limitations of this study are the relatively small number of patients in each group, particularly due to the high rate of loss to follow-up at the mid-term evaluation. Finally, including women with both primary and repeated CS does not ensure a perfect homogeneity of the study population. Therefore, further clinical randomized studies should be performed to confirm the present findings.

Interpretation

The presence of CSD, RMT, and the healing ratio as analyzed by ultrasound are associated with gynecologic outcomes, uterine scar dehiscence, and uterine rupture, making them surrogate markers of uterine scar healing.^{6,17,18}

The uterine incision closure technique is considered the most important factor for good healing and prevention of CS-related future complications.^{6,19} Thus, surgical techniques that reduce the occurrence of CSD are important for preventing CS-related complications.⁴ With classical uterine closure techniques, the prevalence of uterine incisional defects is reported to be 20%–60% in various studies,^{2,6,20} which is consistent with our 40% rate of CSD in the SLCUS group.

A CSD reflects poor and incomplete healing of part of the hysterotomy. The mechanism underlying this defective healing could be mechanical tension of the lower uterine segment with the use of continuous transverse or horizontal sutures.⁴ Indeed, uterine sutures in a horizontal direction following the Kerr incision do not respect the circumferential involution of the uterus postpartum, which leads to the relaxation of sutures with significant mechanical tension at the corners. This defective/inappropriate apposition of myometrial layers can impair blood perfusion and oxygenation of healing tissue.¹⁹ To reduce mechanical tension in the uterine wall and blood loss, purse-string suturing has been used for removal of myomas during CS.²¹ This type of circumferential suture, described by Turan et al. for closing Kerr incisions at the time of CS,⁴ differs from PSUS in the use of a double-layer circumferential closure. Compared with the classical double-layer continuous locking suture, the Turan technique results in shorter uterine incisions (8.5 cm vs. 3.7 cm) and a lower rate of CSD (60% [39/65] vs. 23.5% [12/51]). The relatively high rates of CSD defects in the Turan et al. study might be due to the short delay before ultrasound examination (i.e., 6 weeks). However, it appears that circumferential or purse string sutures of the uterus are more respectful of the rapid physiological uterine involution postpartum. In the present study, with a minimum delay of 6 months before ultrasound evaluation, PSUS significantly reduced the CSD rate to 6.66%, which is clinically important.

The position of the scar was significantly lower after PSUS than after SLCUS. This could be related to the CS procedure itself, given all CSs in the PSUS group were performed using the FAUCS approach,^{8–10} which is an extraperitoneal left paravesical approach that can lower the uterine incision site by a few millimeters.

Several authors have suggested that a lower uterine incision is a risk factor for incomplete healing of the CS scar.²² However, devising a reproducible sectional plan is difficult, even with elective sections, given the development of the lower uterine segment varies depending on the gestational age of the pregnancy, size of the uterus, effacement of the cervix, and many other factors. Thus, further studies using standardized evaluations of uterine scar position are needed to determine their clinical impact.

CONCLUSION

In conclusion, compared with Single layer continuous uterine suture, purse string uterine suture significantly reduces the rate of CSD without increasing perioperative maternal morbidity.

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CONFLICTS OF INTEREST STATEMENT

The authors have no conflict of interest to declare

CONTRIBUTION TO AUTHORSHIP:

KD : study design, surgeries, ultrasound exams , article writing and editing.

OA: data analysis and article review.

RM: data collection and analysis.

LV: article review.

BS: article review.

DF: Supervision , article review.

AT: Supervision , article review.

ETHICS APPROVAL :

The study protocol was approved by the local hospital ethics committee on January 5th,2019 (reference number 04/19) and was registered at clinicaltrials.gov (NCT03930134). Data collection was performed in compliance with Tunisian laws regarding personal data protection, and all participants provided written informed consent.

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SUPPORTING INFORMATION LEGENDS

1- Dataset

2- Consort checklist

TABLES

Table 1. Patient characteristics.

Characteristic	SLCUS ^a	PSUS ^a	Statistic ^b	p ^c	R ^{2d}	Raw p
Weight (kg)	82.95 ± 14.08	79.52 ± 11.93	1.741 (1,98)	1.000	0.018	0.190
Height (m)	1.61 ± 0.05	1.62 ± 0.05	0.065 (1,98)	1.000	0.000	0.799
Body mass index	31.79 ± 4.34	30.42 ± 3.75	2.758 (1,98)	0.900	0.027	0.100
Age (years)	33.86 ± 0.75	32.80 ± 0.77	0.975 (1,98)	1.000	0.010	0.326
Gestation (weeks)	39.08 ± 0.10	39.14 ± 0.10	0.185 (1,98)	1.000	0.002	0.668
Hematocrit	33.82 ± 3.49	33.68 ± 3.45	0.040 (1,98)	1.000	0.000	0.841

Gravidity	2.5 ± 0.5	2.5 ± -2	0.231 (1)	1.000	0.018	0.631
Parity	2 ± 1	2 ± 0.5	1.730 (1)	1.000	0.002	0.188
Prior CS	1 ± 1/0	1 ± -0.25/0	0.628 (2)	1.000	0.007	0.730

^aMean ± SD for weight, height, body mass index, age, gestation, and preoperative hematocrit; median ± 75th and 25th percentiles for gravidity, parity, and prior CS

^bF (df_{numerator},df_{denominator}) for weight, height, body mass index, age, gestation, and preoperative hematocrit; χ^2 (df) for gravidity, parity, and prior CS.

^cHolm adjusted for family wise error rate, nine simultaneous tests.

^dNagelkerke's pseudo R².

Table 2. Scar measurements comparison.

Ultrasound measure	PSUS	SLCUS	P value
External Os – Scar distance (mm) (mean ± SD)	29.63±5.09	32.61 ± 4.02	0.012
RMT (mm) (mean ± SD)	6.96 ±2.55	4.53 ± 2.09	0.000
Healing Ratio (mean ± SD)	0.97 ± 0.116	0.8 ± 0.25	0.002
Defect length (mm) (mean ± SD)	0.453 ± 1.76	1.75 ± 2.2	0.017
Defect depth (mm) (mean ± SD)	0.237 ± 0.90	1.337 ± 1.84	0.005
Defect width (mm) (mean ± SD)	0.37 ± 1.52	2.93 ± 4.06	0.002

Table 3. Risk factors for uterine scar defects: results of logistic regression.

Variables	Univariate analysis Odds ratio [95% confidence interval]	Multivariate analysis Adjusted Odds ratio [95% confidence interval]
P value		
Maternal age	1 [0.9- 1]	0 [0-0]
Number of uterine scars	2 [1-5]	2 [0-1]
SLCUS	8 [1-41]	6 [0-1]
Birth weight	1 [1-1]	1 [-1-0]
Distance from scar to external os	1 [1-1]	0 [-1-0]
Position of the uterus	3 [0-141]	0[0-1]

LEGEND OF FIGURES

Figure 1. CONSORT flow diagram.

Figure 2. Purse String Uterine Suture technique.

(a, b) Intramyometrial layer. (c) Subserous layer.

Figure 3. Ultrasound measurement of Cesarean Scar Defect. (a,b) Sagittal view: length (black arrow and 1) and depth (dotted arrow and 2). (c,d) Sagittal view: AMT (dotted arrow) and RMT (black arrow). (e,f) Transverse view: width. (g,h) Sagittal view: distance between CSD and external os.

Figure 4. Ultrasound measurements of uterine scar. (a, b) Sagittal view. Distance between uterine scar and external os.

Figure 5. Purse string uterine suture outcomes. (a) Sagittal view of a hypoechoic scar in front of the vesicovaginal fold with no defect. (b) Sagittal view of a retroverted uterus and intact hypoechoic uterine scar. (c) Transverse view of an intact uterine scar.