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Effect of Single layer versus Double Layer Suturing on Healing of cesarean Uterine Scar: A Randomized controlled trial

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Abstract

Objective: Closing the uterine incision is a crucial aspect of a cesarean section. Therefore, it is essential to use a resilient surgical method that can withstand the pressure of subsequent labor. We aimed to assess the impact of single versus double-layer closure on residual myometrial thickness following cesarean section.

Methods: This randomized controlled trial was conducted on 60 pregnant women scheduled for elective cesarean section at the operative theater of Ain Shams University Maternity Hospital from February to August 2021. We randomized the patients into two groups (30 in the single-layer group and 30 in the double-layer group) and had undergone cesarean delivery. The study evaluated their uterine scars using saline infusion sonography (SIS) three months after delivery.

Results: No significant differences were observed between the two groups regarding hemoglobin drop, blood loss, procedure time, blood transfusion, and postoperative complications. However, the thickness of the residual myometrium covering the defect was significantly lower in the double-layer closure group compared to the single-layer closure group (4.70 ± 0.95 vs. 5.30 ± 1.15, respectively, P = 0.032).

Conclusion: The single-layer unlocked closure is recommended over the double layer due to better uterine scar healing and higher RMT.

Key words: Layer suturing, caesarean, uterine scar

Introduction

It has been observed that a higher number of patients are experiencing long-term health problems due to cesarean scars, caused by the recent increase in cesarean deliveries. Some of the gynecologic issues that are being documented more frequently in recent years include postmenstrual spotting, dysmenorrhea, chronic pelvic discomfort, and dyspareunia

following cesarean delivery. Furthermore, obstetric problems such as cesarean scar pregnancies, incorrect placental implantation, and uterine rupture in subsequent pregnancies have also been linked to cesarean scar defects[1].

The method used to close the uterine incision during a cesarean delivery can significantly affect the healing of the scar. Whether the uterus is locked or unlocked, and whether it is closed in a single or double layer, may impact the final appearance and integrity of the uterine scar[2].

With ultrasound, saline infusion sonography (SIS), or hysteroscopy, morphological anomalies of the cesarean scar may be seen. The scar defect may be fixed by performing a laparotomy, laparoscopy, or hysteroscopy[3].

After a cesarean delivery, a transvaginal ultrasound or postnatal saline infusion sonohysterography can be used to evaluate the scar. These approaches increase the identification of endometrial pathology and improve endometrial visualization. The closure method of uterine incision - single-layer vs. double-layer - is gaining attention for its effect on the likelihood of uterine rupture[4].

The uterine closure technique after cesarean delivery is still unclear. Surgeon variability may occur and affect the outcome. The best method for closure and suture type to increase wound strength is unknown[5].

The study aims to assess the thickness of the residual myometrium, measured three months postoperatively, in women who underwent primary cesarean delivery using two different uterine closure techniques.

Methods

This randomized controlled trial was conducted on 60 pregnant women scheduled for elective cesarean section at the operative theater of Ain Shams University Maternity Hospital from August 2022 to February 2023. The study protocol gained the approval of the OB/GYN scientific council and the ethical approval of the Faculty of Medicine Ain Shams University (FMASU MS 568/2022), which is in accordance with the Declaration of Helsinki. The study was registered in Pan-African clinical trials.

Inclusion criteria

Women with singleton, viable pregnancies with term pregnancy ≥ 37 weeks of gestation underwent primary cesarean section were enrolled.

Exclusion criteria

The following groups of women were excluded from the study: those who had undergone previous uterine surgeries such as myomectomy, hysterotomy or metroplasty; pregnant women who declined to participate; women with maternal disease; those carrying multiple pregnancies; those who experienced postpartum hemorrhage or puerperal sepsis; women diagnosed with chorioamnionitis; and those diagnosed with placenta accreta spectrum during the current pregnancy.

The study's primary outcome was the thickness of the residual myometrium, measured three months postoperatively, in women who underwent primary cesarean delivery using two different uterine closure techniques.

Secondary outcomes included operation time, need for extra hemostatic sutures, blood transfusion, bladder injury, ICU admission, wound infection, hospital stay, postoperative fever, secondary postpartum hemorrhage, and blood loss by allowable blood loss(ABL) formula.

ABL = weight kg * age sex factor (65ml/ kg)*initial HGB(g/dl)-final HGB(g/dl) / initial HGB (g/dl)[8]

Sample Size Justification

The text discusses a randomization table for a convenience sample of women candidates for a ce-

sarean section. Khamees (2018) found a significant difference in the mean thickness of the residual myometrium between the two groups, with an effect size of 1.97. To identify a large effect size (0.8) with a sample size of 30 cases per group, a two-independent samples t-test can be used with a threshold of significance of 0.05. To account for dropouts, the sample size was increased by 20%[4].

Randomization, Allocation and concealment

To ensure equal opportunity for every patient meeting the inclusion criteria, a computer-based program (using www.randomization.com) randomly assigned 30 patients to each of the two groups. The randomization process was guided by a table of random members using sequentially sealed opaque envelopes. The study randomly assigned women using a computer-generated sheet with MedCalc version 13. The group allocations were placed in 60 envelopes, which were numbered serially and put in a box. When a patient arrived, the first envelope was opened, and the patient was allocated accordingly.

Study procedures

Pregnant women planning elective lower CS were enrolled in the study. After explaining the purpose, risks, and complications, informed written consent was obtained.

All participants will be subjected to:

History taking included personal and obstetric history, chronic medical conditions, surgeries, contraception, and menstrual history. General and abdominal examinations were conducted, along with a vaginal exam to check for cervical changes, rupture of membranes, and cervical polyps or fibroids.

Investigations

Required lab tests include CBC, coagulation profile, RH, blood group, viral markers, liver and kidney function tests, and a random blood sugar test. Additionally, all participants underwent a basic ultrasound examination to evaluate fetal life, fetal parameters, amniotic fluid, and placental location.

Women were divided into two groups (A and B). Group A had a double-layer unlocked closure of their uterine incision, while group B had a single-layer unlocked closure. Synthetic absorbable thread was used for all sutures. In group B, a holding stitch stabilized the right corner and the uterine wall (except decidua) was sutured using a single-layer continuous unlocked stitch.

Patients were randomly assigned to a double-layer closure during surgery. The technique involved continuous unlocked suturing of the uterine incision in two layers, and additional sutures for hemostasis might be added as required. The surgical technique included in situ closure of the uterus, parietal peritonization, approximation of the rectus musculature, and closing of the subcutaneous space.

Patients received antibiotics and oxytocin during the cesarean delivery. They started breastfeeding with the help of a nurse. Discharged within two days and scheduled for follow-up after three months.

Saline-infused sonohysterography (SIS)

The SIS examinations were conducted using a covered ultrasound vaginal probe with a frequency of 7MHz, specifically the Voluson 730 Expert model from GE Medical Systems in Zipf, Austria. All examinations were performed after the woman's menstrual cycle, with an empty bladder, while lying on her back. The woman also had a wedge-shaped hard cushion placed under her lower back and pelvis during the examination[6].

A soft catheter was inserted into the uterus through the cervix, while a transvaginal ultrasound transducer was inserted into the vagina. The catheter introduced saline into the uterus, and pictures of the inside of the uterus were captured before and after the saline injection to see the uterine lining. The scar area was

magnified, and the measurements were taken[7,8].

Residual myometrial thickness was measured in all women who underwent saline sonohysterography, while the sonographer and the database administrator remained blinded to the intervention allocation.

Postoperatively, the two groups were subjected to

Follow-up of the vital data, urine output, assessment for postpartum hemorrhage or puerperal sepsis and hemoglobin percentage 24h after the operation.

During a medical examination, a triangular hypoechoic or anechoic filling defect was found under the bladder break that measured less than 2 mm. After delivery, the medical team gathered additional information such as whether the vesicouterine and parietal peritoneum were closed, if additional sutures were needed, and the length of the procedure.

Statistical Analysis

The statistical analysis was done using SAS 9.1, and a single statistician guarded the randomization code until the database was locked. Fisher's exact and chi-square association tests were used to analyze categorical data. In contrast, the Wilcoxon rank sum test and the two-tailed unpaired Student t-test were used for quantitative data. The analysis was the last intended, and P 0.05 was used to determine statistical significance. Relative risks and 95% confidence intervals were reported for the primary and secondary outcomes, using intent-to-treat for all studies.

Results

Our results show that most of our patients are under the age of 30, with the mean Age of the patients in group A being 27.57 ± 5.17 years vs. 26.17 ± 5.29 in group B. Most of them are overweight, with a BMI of 28.43 ± 0.57kg/m2 vs. 28.33 ± 0.99 in group B. Most patients were Primigravida in both groups (60% vs. 50%), and most had CS near full term (39.00 ± 1.29 vs. 38.97 ± 1.13 weeks). There is no statistically significant difference between groups A and B regarding maternal age, body mass index (BMI), parity, and gestational age (GA) of the studied patients (Table 1).

The preoperative Hb was 10.92 ± 1.13gm/dl in group A vs. 10.83 ± 0.98 in group B, reflecting that most patients had mild anemia (<11gm/dl). The postoperative difference in Hb was -0.97 ± 0.60 gm in group A vs-1.25 ± 0.70 in group B. There is no statistically significant difference between groups A and B regarding hemoglobin drop (Table 2).

As our hospital is a teaching hospital where the residents perform the CS, the duration of CS was 73.53 ± 10.46 minutes in group A vs 76.13 ± 8.10 in group B. Only one patient in group A had a blood transfusion preoperatively to elevate the Hb level. The blood loss was comparable in both groups (508.33 ± 130.04 ml in group A vs 511.67 ± 110.39 ml in group B). No statistically significant difference between groups A and B regarding the studied patients' blood loss, procedure time, and blood transfusion (Table 3).

There is an absence of postoperative complications in the study populations, such as post-operative fever, ICU admission, postoperative hospital stays, wound infection, bladder injury, and postpartum hemorrhage (Table 4).

It is clear that the RMT was more remarkable in group B (5.30 ± 1.15) compared to group A (4.70 ± 0.95), and this difference was statistically significant (P- value 0.032) (Table 5).

Discussion

Our results and their interpretation

The current study revealed that single-layer closure results in a significantly higher residual myometrial thickness than double-layer closure. No significant differences were observed between the two groups regarding hemoglobin drop, blood loss, procedure time, blood transfusion, and postoperative

Table 1. Demographic characteristics of the study population.

		GROUP A NO. = 30	GROUP B NO. = 30	TEST VALUE	P-VALUE	SIG.
Age (years)	***Mean ± SD***	27.57 ± 5.17	26.17 ± 5.29	1.037•	0.304	NS
	Range	19 – 43	19 – 40			
BMI	***Mean ± SD***	28.43 ± 0.57	28.33 ± 0.99	0.478•	0.634	NS
	Range	28 – 30	24 – 30			
Parity	***PG***	18 (60.0%)	15 (50.0%)	2.173*	0.537	NS
	P1	4 (13.3%)	6 (20.0%)			
	P2	5 (16.7%)	3 (10.0%)			
	>= P3	3 (10.0%)	6 (20.0%)			
	Median (IQR)	0 (0 – 2)	0.5 (0 – 2)	-0.813≠	0.416	NS
	Range	0 – 4	0 – 7			
Abortion	***No***	12 (66.7%)	16 (84.2%)	1.546*	0.214	NS
	Yes	6 (33.3%)	3 (15.8%)			
GA (weeks)	***Mean ± SD***	39.00 ± 1.29	38.97 ± 1.13	0.107•	0.915	NS
	Range	37 – 41	37 – 41			

Table 2. Hemoglobin drop in the study population.

		GROUP A NO. = 30	GROUP B NO. = 30	TEST VALUE	P-VALUE	SIG.
Pre-operative hemoglobin	***Mean ± SD***	10.92 ± 1.13	10.83 ± 0.98	0.329•	0.743	NS
	Range	8.5 – 13	9 – 12.5			
Postoperative hemoglobin	***Mean ± SD***	9.96 ± 1.23	9.59 ± 1.02	1.273•	0.208	NS
	Range	7.8 – 12.5	7.5 – 11.4			
Paired t-test	***t***	-8.847	-9.746			
	P-value	<0.001	<0.001			
Difference	***Mean ± SD***	-0.97 ± 0.60	-1.25 ± 0.70	-1.663•	0.102	NS

Table 3. Characteristics of the intervention to the groups.

		GROUP A NO. = 30	GROUP B NO. = 30	TEST VALUE	P-VALUE	SIG.
Procedure time (min.)	***Mean ± SD***	73.53 ± 10.46	76.13 ± 8.10	-1.076•	0.286	NS
	Range	60 – 90	65 – 88			
Total blood loss (ml)	***Mean ± SD***	508.33 ± 130.04	511.67 ± 110.39	-0.026•	0.872	NS
	Range	50 – 700	150 - 650			
Blood transfusion	***No***	29 (96.7%)	30 (100.0%)	1.017*	0.313	NS
	Yes	1 (3.3%)	0 (0.0%)			

Table 4. Postoperative course.

		TOTAL NO. = 60
Postoperative hemoglobin	Mean ± SD	9.77 ± 1.13
	Range	7.5 – 12.5
ICU admission	No	60 (100.0%)
Hospital stay (days)	Mean ± SD	1.58 ± 0.81
	Range	1 – 3
Postoperative fever	No	60 (100.0%)
Wound infection	No	60 (100.0%)
TVUS after 3 months (mm)	Mean ± SD	5.00 ± 1.09
	Range	3 – 8
Bladder injury	No	60 (100.0%)
Post partum hemorrhage	No	60 (100.0%)

complications. However, the thickness of the residual myometrium covering the defect was significantly lower in the double-layer closure group compared to the single-layer closure group (4.70 ± 0.95 vs. 5.30 ± 1.15, respectively, P = 0.032).

The comparison of our results to other studies.

Stegwee et al. (2021) found that single-layer uterine closure is more economical than double-layer uterine closure and reported long-term reproductive outcomes to support this finding[9].

Boerma et al. (2018) conducted a clinical experiment but failed to show any benefit of double-layer closure over single-layer closure in reducing postmenstrual spotting after the first cesarean section[10].

Moreover, Dodd et al. (2014) found that closure of a single-layer uterine incision was associated with a reduction in mean blood loss, operation time, postoperative pain prevalence, and length of hospital stay[11].

According to Khamees et al. (2018), the single-layer method resulted in a higher occurrence of niche appearance in 65% of patients compared to those who underwent the double-layer closer with only 30%. However, this contradicts our findings. Unfortunately, the experiment did not have the power to establish significant differences between the two procedures regarding blood loss or operating time[4].

In a study conducted by Roberge et al. (2012), the researchers investigated the impact of three different methods of uterine closure on the healing of uterine scars following a cesarean delivery. The three methods were locked single-layer closure with the decidua, double-layer closure with a locked first layer including the decidua, and double-layer closure with an unlocked first layer omitting the decidua. The study followed up on 81 participants and found that double-layer closure with an unlocked first layer was significantly associated with thicker RMT (residual myometrial thickness) in comparison to single-layer locked closure (3.8 ± 1.6 mm vs 6.1 ± 2.2 mm; P<.001). However, double-layer closure with a locked first layer did not exhibit a significant difference in the RMT compared to single-layer locked closure (4.8 ± 1.3 mm; P =.032)[12].

In a study conducted by Sevket et al. (2014), 36 patients who underwent a cesarean delivery were compared based on the closure method of their

Table 5. Impact of closure techniques on the residual myometrial thickness.

SALINE INFUSION SONOGRAPHY AFTER 3 MONTHS (MM)	GROUP A NO. = 30	GROUP B NO. = 30	TEST VALUE	P-VALUE	SIG.
Mean ± SD	4.70 ± 0.95	5.30 ± 1.15	-2.202•	0.032	S
Range	3 – 6	4 – 8			

uterine scar, single-layered or double-layered, six months after the surgery. The study evaluated the cesarean scars visible on saline infusion sonography. The thickness of the anterior and myometrial layers above the scar defect was measured. The research found that after a double-layer closure, the residual myometrial thickness was 9.95 ± 1.94 mm, whereas, after a single-layer closure, it was 7.53 ± 2.54 mm. The difference was statistically significant (P = 0.005). Unlike our study, this study assessed the residual myometrial thickness over a more extended period[13].

During their prospective cross-sectional study measuring cesarean scar after single-layer and double-layer hysterotomy closures, Teknir et al. (2018) observed no difference in the size of the uterine scar seen on SIS 3 months post-surgery[1].

In a clinical trial conducted by Qayum et al. (2021), it was found that the Double-Layer Uterine Closure method had higher residual myometrial thickness and lower incidence of dysmenorrhea as compared to the Single-Layer Uterine Closure method for Cesarean Section Scar. However, the Single-Layer Closure method had the advantage of quicker processing time. The study concluded that both techniques had similar amounts of blood loss, hospital stays, risks for maternal infections, readmission rates, and chances for uterine rupture or dehiscence[14].

Furthermore, obstetric problems such as cesarean scar pregnancies, incorrect placental implantation, and uterine rupture in subsequent pregnancies have also been linked to cesarean scar defects[1].

Clinical implications of the study: We encourage all Obstetricians, especially juniors, to perform the single-layer closure of the uterus during CS.

Strengths and limitations of the study: The strength of our research is the appropriate methodology and proper randomization. The limitations of our study are the relatively small number of patients and the fact that it is a single-center study, which could lead to a statistical bias.

Recommendations for further studies: Larger numbers of patients are needed, and we recommend similar studies to be multi-centric for better results

Conclusion

Single-layer uterine closure is better than double-layer closure for uterine scar healing and residual myometrial thickness (RMT).

Authors Contribution

Mohamed H. Salama: Conception & Design of Study, Data Collection, Data Analysis & Interpretation, Responsible Surgeon or Imager, Statistical Analysis

Sabry S. Mohamed: Conception & Design of Study, Data Collection, Data Analysis & Interpretation, Statistical Analysis

Sara A. Hamad: Conception & Design of Study, Data Collection, Manuscript Preparation

Ahmed M. Zeinhom: Conception & Design of Study, Data Collection, Data Analysis & Interpretation, Manuscript Preparation, Patient Recruitment

Funding

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Study registration

The study was registered in the Pan-African Clinical Trial

Disclosure of Interest

The authors declare no conflict of interest.

Ethics Approval

Following local regulations, the protocol gained ethical and research approval from the Faculty of Medicine Ain Shams University FMASU MS 568/2022.

Informed Consent

All patients gave their informed consent after

explaining the whole procedure

We Confirm that all methods were performed according to the relevant guidelines and regulations according to the Declaration of Helsinki.

Data Sharing

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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