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Effect of Single- versus Double-Layer Uterine Closure during Caesarean Section on Niche Formation and Menstrual Irregularity

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Abstract

Background: The myometrium at the location of the CS (caesarean section) scars, also known as residual myometrium thickness (RMT), is larger after a double-layer uterine closure procedure than following a single-layer one. It may lessen the formation of a niche that is the myometrium's disruption at the location of the scar of the uterus. Gynecological manifestations, obstetric problems in a future pregnancy and birth, and maybe subfertility are linked to thin RMT and a niche. **Objective:** To ascertain if double-layer unlocked closure of the uterus is better than single-layer one in terms of post-menstrual spotting and niche development following a first CS. **Patients and Methods:** In this randomized clinical study, 287 patients were evaluated for qualifying. Of all eligible individuals, 57 patients were excluded from the study based on the inclusion criteria. **Results:** The variation in ages, gestational age, body mass index (BMI), and cesarean section indications between the two assigned groups is statistically insignificant. However, postmenstrual spotting was statistically significantly more common in single-layer group compared to in double-group. The current study revealed ultrasound findings suggestive of niche formation was statistically significantly more common in single-layer group compared to in double-layer group. **Conclusion:** As evident from the current study, it demonstrates the advantages of double-layer unlocked closure of the uterus over single-layer one in terms of post-menstrual spotting and niche development following first-time cs. Thus, we deduced that fewer niches are formed, and fewer menstrual spotting occurs in the presence of double unlocked layers closure. To ascertain the impact of uterus closure method on post-operative niche development and the risk of obstetrics and gynaecological problems, further prospective trials with extended follow-up periods are required.

Keywords

Single-Layer, Double, Caesarean Section, Residual Myometrium Thickness

1. Introduction

Individuals experiencing the long-term morbidity from caesarean scars have grown as a result of the current surge in caesarean births. Recently, there has been a rise in the number of gynaecological symptoms that have been recorded, such as dysmenorrhea, post-menstrual spotting, persistent pelvic discomfort, and dyspareunia after caesarean birth. Additionally, obstetric difficulties like placental insertion anomalies, rupture of the uterus in future pregnancies, and caesarean scar pregnancies have been linked to caesarean scar malformations [1].

Morphology of the caesarean scar may be detected by hysteroscopy, saline infusion sonography (SIS), or ultrasonography. Laparotomies, laparoscopies, or hysteroscopies may all be used to treat scar defects [2].

One of the key elements influencing scars healing might be the surgical method employed for closing the uterine incision after a caesarean birth. The ultimate integrity and appearance of the uterine scars may change depending on whether the uterus is closed in an unlocked or locked manner, and whether it is closed in a single or double layer [3].

However, the best method for closure of the uterus is still unclear, and it's unclear whether using unlocked or locked stitches in the first layer of closing and whether single- or double-layered closure will improve the strength of the wound after caesarean delivery [4].

The safe cut off thickness of scars in uteri after laparoscopic surgery ranges from 1.5 to 3.5 mm; scar thinning at this location increases the risk of rupturing or dehiscence during the following pregnancy. A successful caesarean birth requires the uterine incision to be closed; yet, accurate approximating of the incision margins is rarely guaranteed. This may be the result of edges overlapping, and the thickness of the area of incision is much decreased after remodelling and the healing process [5].

Additionally, the likelihood of inter-surgeon variability is quite significant. The lower segment caesarean section (LSCS) site will be not thin if a suturing technique is developed that guarantees accurate approximating of all layers with zero or very little chance of inters operator variability. Additionally, a scarred uterus repaired in this way should be capable to withstand the stress of labour in the future [4].

Therefore, six-month period following caesarean delivery (CD), we may evaluate the scar using either transvaginal ultrasonic imaging of the uterus or post-natal saline infusion sonohysterography (SIS).

2. Aim of the Work

The purpose of the research is to examine the effects of single-layer and

double-layer unlocked closure of the uterus on post-menstrual spotting and niche development following first-time CS.

3. Patients and Methods

Study Design: Randomized clinical study.

Study Setting: Ain Shams University Maternity Hospital.

Study Time: carried out in six months time after protocol approval.

Study Population: Primi-gravida selected for CS attending to Obstetrics and Gynecology clinics and labor ward.

Inclusion Criteria: Primi-gravida, singleton, term after 37 weeks gestation age. Elective caesarean section. Age of 18 - 40 years. Started spontaneous menstruation within six months after delivery. Non lactating, on non-hormonal contraception.

Exclusion Criteria: Patient's refusal to be enrolled in the study. Previous uterine surgery (myomectomy, metroplasty). Women with known causes of menstrual disorders as (Abnormal Uterine Bleeding in the form of premenstrual or postmenstrual spotting, Dysmenorrhea, Amenorrhea). Placenta accreta spectrum during the current pregnancy. Cases associated with poor wound healing as steroid administration or patients with antenatal anemia. Medical conditions as Diabetes mellitus. Risk of endometritis as intraamniotic infection, puerperal sepsis. Postpartum hemorrhage.

Pre-operative assessment: History for demographic data, medical co-morbidities, past surgical procedures (including previous uterine surgeries), known hypersensitivities, and the reason for caesarean delivery.

Clinical examination: General examination: vital data, body-mass index (BMI). Abdominal examination: for previous scars, or hernias. Pelvic examination: Inspection of the vulva, vagina, and perineum. Per vaginal examination to detect cervical changes. Investigations: Routine laboratory and other investigations depending on patient-specific health concerns including complete blood picture. Obstetric ultrasound to evaluate the current pregnancy.

Women were allocated to one of the two groups at random:

***Group A*:** 115 Patients scheduled for CS with Single-layer unlocked uterine closure.

***Group B*:** 115 Patients scheduled for CS with Double-layer unlocked uterine closure.

Each participant provided informed written authorization.

Within an hour following the skin incision, each participant got a prophylactic dosage of antibiotics (2 g intravenously cefazolin sodium). During the procedure, a 20 U iv infusion of oxytocin was given.

For uterine incision closure, for all closures of the uterus, corner sutures will be utilized on each individual using synthetic absorbable suture material (Vicryl 1.0, Ethicon).

Unlocked continuous stitches will be used for both layers of the double-layer

closure of the incision of the uterus, with a significant amount of the myometrium and endometrium incorporated into the first layer. The tissues of serosa and myometrium which was embedded in the first layer will be covered by a continuous running stitch in the second layer.

Uterine closure with unlocking will be given to those in the single-layer group. Starting from one corner of the incision, closure of the uterus will be performed. The incision will be closed with Polyglactin thread (1-0), which covers the endometrial, myometrial, and serosal tissues.

Following childbirth, a call will be made to all participants inviting them to complete a sixth-month assessment in which questions on menstrual processes and any encounters with aberrant symptoms such as dysmenorrhea, postmenstrual spotting, and other irregular bleeding patterns will be asked.

Each participant will be evaluated for postmenstrual bleeding over 3 successive cycles.

In addition, all participants will have transvaginal ultrasonography six months after delivery by the senior staff sonographer at Ain-Shams maternity hospital sonographic unit via Samsung HS60 with frequency 6.6 MHz. All participants will have transvaginal ultrasonography either symptomatic or not (silent niche).

It is recognized that a niche exists when a hypoechogenic area inside the cavity of the endometrium that is at least 2 mm deep in the location where the scar from the caesarean birth is located.

When a niche is detected, its dimensions' depth, length, and width will be established using three-axis measurements, along with its form, residual myometrial thickness and adjacent myometrial thickness.

Primary outcome: Post-menstrual spotting over 3 successive spontaneous menstrual cycles.

Secondary outcomes: Ultrasound findings suggestive of niche formation, dysmennorhea, dyspareunia, premenstrual spotting.

Ethical Considerations

Protocol Approval: The Research Ethical Committee and the Board of Obstetrics and Gynecology Department at Ain Shams University approved the approaches included in this study protocol to guarantee that it adhered to the accepted ethical guidelines regulating research that involve human beings.

Participants' Consent: Prior to enrolment, Participants must provide their agreement for participation in the clinical trial following being fully informed about its purpose, scope, and potential implications. They also have the option of withdrawing from the study at any time, for any reason. A permission form (in Arabic) with all necessary components should be reviewed by the patient and signed by both the patient and the data provider with a dated official signature. In the event that the patient is not literate, the written permission form was conveyed verbally to her in front of an unbiased witness. This witness ought to sign a formal, dated document with the patient's legally accepted signature substitute (such as a fingerprint or stamp). With data confidentiality ensured, the lead investigator kept the original signed permission documents.

***Data Confidentiality*:** Hospital numbers were recorded in the Case Record Forms. The investigator maintained a confidential patient identification list (patients' numbers with the corresponding patients' names) to enable record identification.

Data management

All research data gathered for the study belongs to the university. The main investigator for this study assumed responsibility for gathering, organizing, and disseminating the research data. The proposed research included data from the subjects being assessed for postmenopausal bleeding and transvaginal ultrasound at Ain Shams maternity hospital. The final dataset included self-reported demographic data from the interviews with the participants and radiological data about the presence of scar niche from the ultrasound provided. The final dataset from this investigation was unidentified before being made available for distribution and was handled, processed, and kept in a safe setting. We only provided access to the data and related documentation to users under the terms of a data-sharing agreement, which include the following: 1) a promise to utilize the data solely for study and not determine any specific participant; 2) a promise to secure the information utilizing suitable computer technological advances; and 3) a promise to eliminate or return the data following analyzes are finished.

Statistical analysis:

The statistical software for social sciences, edition 23.0 (SPSS Inc., Chicago, IL, USA), was used to evaluate the data that was collected. The ranges and mean ± standard deviation have been utilized to show the quantitative data. Qualitative parameters were also shown as percentages and numbers. Data were examined for normalcy utilizing the Shapiro-Wilk and Kolmogorov-Smirnov tests.

We conducted the subsequent tests: When analyzing two means, the independent-samples t-test of significance was employed. Mann Whitney U test: used in non-parametric data for two-group comparisons. The Chi-square test was used to compare groups based on qualitative data. The accepted margin of error was set at 5%, while the confidence interval was established at 95%. Thus, the following P-value was deemed significant: Probability (P-value): A P-value of less than 0.05 was deemed significant. P-values less than 0.001 were regarded as highly significant. P-values greater than 0.05 were regarded as insignificant.

4. Results

Table 1 and Figure 1 revealed that: No statistically significant variation among the groups study as regard age, BMI and Time from last section.

Table 2 showed that: Myometrial thickness in the isthmus uteri was statistically significantly thinner in Single group compared to in Double group. Ultrasound findings suggestive of niche formation, dysmenorrhea, postmenstrual spotting and dysparunia were statistically significantly more frequent in Single group than in Double group. No statistical significant variation among the studied groups regarding premenstrual spotting.

Table 1. Demographic characteristics among the study groups.

Characteristics	Single layer (Total = 115)	Double layer (Total = 115)	P-value
Age (years)	27.4 ± 5.7	26.4 ± 5.4	^0.173
BMI (kg/m^2)	28.3 ± 1.9	28.2 ± 2.4	^0.715
Time of start of follow up from cesarean section (months)	5.3 ± 0.7	5.5 ± 0.7	^0.157

Data presented as Mean ± SD. BMI: Body mass index. ^Independent t-test.

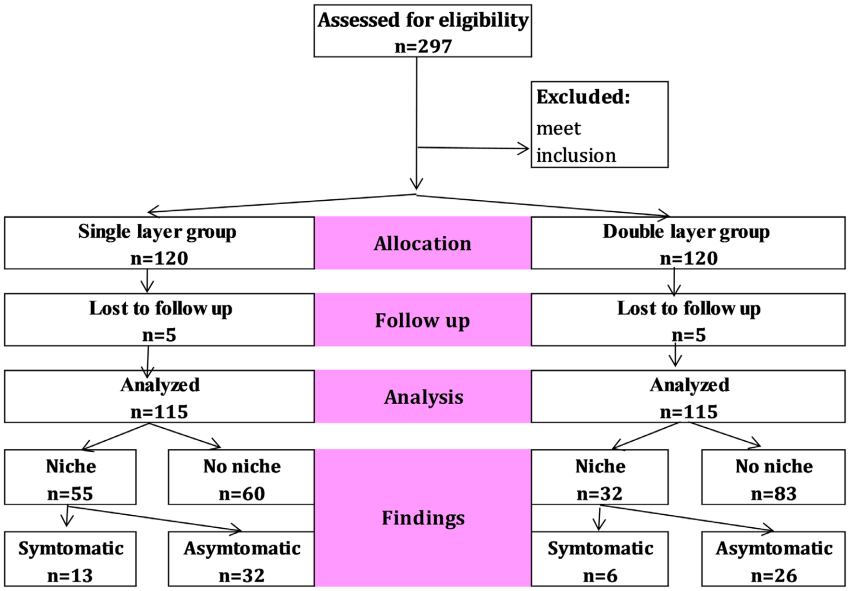

Figure 1. Flow chart of the studied cases.

Table 2. Niche detection and symptoms among the study groups.

Measures	Single layer (Total = 115)	Double layer (Total = 115)	p-value	Relative effect	
				RR	95% CI
Niche	55 (47.8%)	32 (27.8%)	#0.002*	1.72	1.21 - 2.44
Postmenstrual spotting	19 (16.5%)	5 (4.3%)	#0.003*	3.80	1.47 - 9.83
Postmenstrual spotting	17 (14.8%)	4 (3.5%)	#0.003*	4.25	1.48 - 12.24
Dysparunia	17 (14.8%)	6 (5.2%)	#0.016*	2.83	1.16 - 6.93
	Total = 55	Total = 32			
Dysmenorrhea	18 (32.7%)	3 (9.4%)	#0.014*	1.11	3.49 - 10.94
Premenstrual spotting	3 (3.6%)	2 (6.3%)	§0.623	0.09	0.58 - 3.93
Dysmenorrhea	17 (30.9%)	1 (3.1%)	#0.002*	1.38	9.89 - 70.86
Dysparunia	15 (27.3%)	2 (6.3%)	#0.017*	1.07	4.36 - 17.87
Silent niche	32 (58.2%)	26 (81.3%)	#0.028*	0.72	0.54 - 0.95

#Chi square test. ^Independent t-test. RR: Relative rate. SE: Standard error. CI: Confidence interval. Relative effect: effect in Single group relative to that in Double group. *Significant.

Table 3. Niche characteristics in cases with detected niche among the study groups.

Characteristics		Single layer (Total = 55)	Double layer (Total = 32)	P-value	Relative effect	
Shape	Semicircular	29 (52.7%)	18 (56.3%)	#0.714	NA	NA
	Triangular	18 (32.7%)	8 (25.0%)			
	Droplet	8 (14.6%)	6 (18.8%)			
					Mean ± SE	95% CI
Length (mm)		4.1 ± 1.0	5.6 ± 1.0	^<0.001*	−1.4 ± 0.2	−1.9 - −1.0
Depth (mm)		5.5 ± 1.4	4.7 ± 1.2	^0.009*	0.8 ± 0.3	0.2–1.4
Width (mm)		3.7 ± 0.9	4.7 ± 0.8	^<0.001*	−1.0 ± 0.2	−1.4 - −0.7
Residual myometrial thickness (mm)		4.0 ± 1.0	5.6 ± 1.2	^<0.001*	−1.6 ± 0.2	−2.1 - −1.1
Adjacent myometrial thickness (mm)		9.5 ± 1.2	10.3 ± 1.3	^0.009*	−0.8 ± 0.3	−1.3 - −0.2
Residual myometrial thickness ratio		43.0 ± 10.7	54.9 ± 10.7	^<0.001*	−12.0 ± 2.4	−16.7 - −7.2

§Fisher's Exact test. #Chi square test. test. ^Independent t-test. SE: Standard error. CI: Confidence interval. Relative effect: effect in Single group relative to that in Double group. NA: Not applicable. *Significant.

Table 3 revealed: No statistical significant variation among the studied groups as regard number and shape of detected niche. Width, length, depth, RMT, adjacent thickness of the myometrium and residual myometrial thickness ratio of the detected niche were statistically significantly decreased in Single group compared to in Double group.

5. Discussion

Ultrasound may be used to evaluate the integrity of the caesarean scar and forecast potential scar pregnancy issues such as rupture of the uterus or implanting on a scar. These days, it is possible to evaluate several ultrasonographic characteristics to show scar weakening [6].

In addition to causing dysmenorrhea, pelvic discomfort, or postmenstrual bleeding, isthmocele could additionally result in an area of chronic inflammation that reduces fertility due to retained blood from menstruation [7].

The field of long-term complications associated with the existence of a CD scar in the uterus has grown over the recent past. These complications include rupture or dehiscence of the CD scar, placentas that adhere morbidly, and caesarean scar pregnancies [8].

A substantial amount of research demonstrates a high correlation between menstruation abnormalities, infertility, and placental diseases and ultrasono-

graphic scar defects and RMT [9].

Following a caesarean surgery, a meta-analysis was done, and the LUS thickness was suggested as a predictor of rupture of the uterus for vaginal delivery [10].

Scar morphology appears to be a determining factor in the likelihood of scar-related problems, with the existence of a niche in the CD scar being the primary factor [11].

The most significant factor in the development of a CD deficit or niche seems to be the surgical methods used to close uterine incisions [12].

We have shown a strong correlation between post-menstrual spotting in those who have had a prior Caesarean section and the existence of a niche as detected by TVS.

In regard to the niche, a number of theories have been put out to explain the aetiology of bleeding diseases. Post-menstrual spotting is thought to result from the retention of blood from menstruation in the niche, that is periodically evacuated following the bulk of the monthly flow has stopped, perhaps accounting for irregular bleeding from the uterus.

According to Thurmond, the muscles in the uterus surrounding the scar may not be contracting well, which might be the cause of this problem. Furthermore, the fibrotic tissue underneath the niche can hinder the cervix's ability to eliminate menstrual flow.

The lack of confirmation of our hypothesis on the potential relationship between abnormal bleeding from the uterus and the depth and shape of the niche might be attributed to the inadequate group size for testing these secondary outcome factors.

In this prospective study, 287 patients were evaluated for eligibility. Of all eligible participants, 57 patients were excluded from the study based on the inclusion criteria.

This study was performed on 230 primigravida (115 in single-layer group and 115 in double-layer group) with full-term pregnancy that had CD and assessment of uterine scar following 6 months of delivery by transvaginal ultrasound.

The main purpose of our research is to contrast the impact of single-layer unlocked machine versus double-layer closure on niche formation and menstrual irregularities, while performing TVUS in patients underwent lower segment cesarean section 6 months ago, The term "niche" describes the myometrium's hypoechoic region in the isthmus, or lower uterine portion, where it ends at the scar from a prior caesarean incision. The scar in the uterus's sagittal transsection was found using TVS, and we evaluated: post menstrual spotting as a primary outcome and niche presence by TVUS, premenstrual spotting, dyspareunia, dysmenorrhea as secondary outcomes.

The variation in age, gestational age, BMI, and cesarean section indications between the two assigned groups is statistically insignificant.

However, postmenstrual spotting was statistically significantly more common in Single group compared to in Double group.

The current study revealed Ultrasound findings suggestive of niche formation was statistically significantly more common in Single group compared to in Double group.

These results were in concordance with the data reported by *Khamees* which reported that only 30% of patients who had double layer closure method had the emergence of a niche, while 65% of patients who underwent single layer approach showed this occurrence which was statistically significant.

There is insufficient power in this experiment to show statistically significant differences between the two procedures in terms of blood loss, extra hemostatic sutures needed, or operating time.

Roberge assessed the effects of three uterine closure procedures following CD on uterine scar healing, which is consistent with our findings. The uterus scars were closed using one of three methods: an unlocked single-layer, a double-layer with the first layer locked and the decidua included, or a double-layer with the first layer unlocked and the decidua excluded. They discovered that double-layer closure with an unlocked initial layer was substantially linked to thicker RMT, a higher recovery ratio, and less niche development than single-layer closure. On the other hand, there was no statistically significant difference between single-layer closure and double-layer closure with locked initial layer in terms of niche creation, RMT, or recovery ratio.

Similar findings were seen in a retrospective cohort research conducted by Glavind *et al*., whereby women with single-versus double-layer closures were contrasted with respect to TVUS of RMT, scarring niche depth, breadth, and length, and thicknesses of myometrium close to the scar. Compared to women with single-layer closure, those with double-layer closure had considerably greater RMT [13].

In a study conducted by Sevket *et al*., 36 individuals who had their uterine scars closed either single-layeredly or double-layeredly six months after the caesarean birth were contrasted for the visible scars on SIS. Both the anterior myometrial thickness at the defect level and the myometrial thickness above the scar defect were determined. Compared to the single-layer closure group, the double-layer closure group had statistically substantially greater healing ratios and RMT [5].

We discovered that no variation was existed in niche development and RMT among the two groups at the time of discharge and five months postpartum, which is contrasted to what Bennich *et al.* revealed. They proposed that when an unlocked approach is employed, niche development and RMT are not affected by double-layer closure of a Caesarean uterine incision as contrasted with single-layer closure [6].

In a prospective cross-sectional study evaluating cesarean scar after single- and double-layer hysterotomy closure, Teknir *et al.* revealed no effect on the size of the uterine scar defect detected on SIS either TVUS 3-month period following the first caesarean delivery [1].

Strengths and limitations of the study:

The findings of our study are as follows: 1) the population was homogeneous, consisting of Caucasian individuals with comparable socioeconomic circumstances who had a primary caesarean delivery, were not in labour, had a normal BMI, and had not had prior uterine surgeries, thereby excluding any possible impact of cervical dilatation; 2) the uterine scarring was assessed following a sufficient amount of time had passed to ensure full healing, and the measuring of niche development and RMT was carried out by an independent sonographer that was blinded to the allocations of interventions, indicating very high internal validity.

An additional benefit of this research is that it only included individuals who had their first uterus surgeries, and it assessed their scar at the six-month mark after surgery, giving the scar sufficient time to heal.

The outcome measure is the most significant restriction. Post-menstrual spotting is a subjective aspect that the patient presents, and there is no clear way to evaluate it.

A primary limitation of the research is the rate of dropouts. Furthermore, we are unable to generalise the results of our experiment to caesarean sections done on women who are not yet in labour or who are in the early stages of labour. Under the second scenario, the extremely thin myometrium of the low uterine segment that is usually found in advanced labour may make such a double-layer method impractical or less beneficial.

Implications for practice and future research:

According to our findings, a little modification to the caesarean sections uterine closure method may promote the healing of uterine scars and may lower the risk of serious obstetric issues associated with uterine scar abnormalities. The best and most economical method may be used once the study's findings are known to lessen niche formation-related issues like premenstrual spotting, dyspareunia, dysmenorrhea, and post-menstrual spotting. This won't be challenging since, following the experiment, many gynaecologists and residents are already acquainted with the procedure, which is straightforward to understand. Women ought to be aware of the possibility of developing a niche and the possibility that it might result in symptoms or issues in later life, particularly for a planned CS.

To the greatest extent of our comprehension, the recommendations on detailed uterine niche assessment are meant to serve as a fundamental, useful guide for gynaecologists, ultrasound investigators, and researchers, with the goal of standardising the measurement of niches in non-pregnant women. Nevertheless, we have noticed a number of knowledge gaps related to niche measurement, which call for additional research. These include the ideal depth cut-off value for identifying various niche sizes, as well as the ideal RMT cut-off values and ratios of depth/RMT or RMT/AMT to determine a niche's therapeutic significance.

6. Conclusion

The results of this research demonstrate that, in contrast to single-layer un-

locked uterine closure, the double-layer one is better in terms of post-menstrual spotting and niche development following a first CS. Thus, we deduced that fewer niches are formed and fewer menstrual spotting occurs in the presence of double unlocked layers' closure. To ascertain the impact of uterine closure method on postoperative niche development and the risk of obstetrics and gynaecological problems, further prospective trials with extended follow-up periods are required.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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