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Hysteroscopic Resection of Caesarean Scar Defect (Niche) in Women with Postmenstrual Spotting: A Randomized Controlled Trial

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ABSTRACT

Background: Interest in the possible long-term morbidity of CS scars has increased because to the rising CS rate. Hysteroscopic niche resection is the least intrusive surgical procedure. Only a small number of studies have documented hysteroscopic resections thus far. There have been no documented problems, and success rates in reducing postmenstrual spotting that are high.

Objective: This study aimed to compare women who experienced postmenstrual spotting to control patients who received no intervention, the efficacy of a hysteroscopic resection of a post-cesarean scar defect (CSD) (niche).

Patients and methods: This was a randomized controlled trial that had been performed in Early Cancer Detection and Gynecological Endoscopy Unit in Ain Shams University Maternity Hospital, and in Menoufia University Hospital, during the period from May 2020 to February 2022.

Results: There was highly significant difference between both groups regarding their clinical improvement in the form of absence of postmenstrual spotting after first menstrual cycle of randomization, 77.8% of cases improved after one month of operation, the percentage increased to 88.9% in the second month of follow up. Only one patient (3.7%) still had minimal spotting after three months of operation and randomization. There was significant relation between postoperative improvement and niche depth postoperatively among the study group. Improved cases had significantly smaller niche depth than the non-improved cases with niche depth less than 6.5 mm as shown by ROC curve (P value 0.005). **Conclusion:** Hysteroscopic resection of CSD (niche) was a safe and successful procedure, particularly in women with residual myometrial thickness (RMT) more than 4 mm.

Keywords: CS niche, Post-menstrual spotting, Hysteroscopic resection.

INTRODUCTION

The existence of a Cesarean scar niche is commonly linked to long-term issues following a CS, including post-menstrual spotting, dysmenorrhea, dyspareunia, or persistent pelvic discomfort [(1)]. A depression in the myometrium at the location of the uterine scar that is deeper than 3 mm is known as a post-Caesarean niche [(2)]. According to **Van der Voet *et al.*** [(1)] almost 60% of women who had a CS had a myometrial disruption in the uterine scar visible on saline or gel infusion sonography. A niche is a disturbance or "defect" of this kind [[1]]. Mechanical outflow issues that result in the retention of menstrual blood in the Cesarean niche or blood buildup due to decreased uterine contractions at the niche site are two possible causes of postmenstrual spotting [(3)].

Infertility, dysmenorrhea, pelvic discomfort, postmenstrual spotting, abnormal uterine bleeding (AUB), and other complications have recently been connected to CSDs. Furthermore, it has been documented that women with CSD have uterine rupture, placenta accreta, placenta previa, scar dehiscence, and ectopic pregnancy in CSDs [(2)]. For patients who have had prior CS, US is a trustworthy technique for determining the thickness of the lower uterine segment (LUS) and the integrity of the scar. The most accurate method with the highest sensitivity and specificity for measuring the thickness of the LUS's muscle layer is transvaginal 3D ultrasonography [(4)].

The most common technique for detecting CSD is transvaginal ultrasound without contrast, but saline instillation sonohysterography (SIS) offers a clearer delineation and is a quick, less invasive procedure that can be done in a doctor's office without causing any discomfort to the patient. Its overall accuracy is 96% [(5)]. Various techniques have been devised to heal the CS niche, including hysteroscopic, laparoscopic, and laparoscopic aided vaginal niche resections [(6)]. The least invasive of these procedures is a hysteroscopic niche resection, but it necessitates a thick enough residual myometrium between the niche and the bladder to shield it from damage [(7)].

There are two approaches to execute a hysteroscopic niche resection: Either the lower rim of the niche, which is closest to the external cervical os, can be resected to facilitate menstrual outflow, or both the lower and upper rims can be removed [(8)]. In the absence of problems following hysteroscopic CSD resection, prior cohort studies found that 80–90% of women experienced less postmenstrual spotting and 97% experienced less discomfort [(3, 9)].

PATIENTS AND METHODS

The study is a randomized controlled experiment that took place between May 2020 and February 2022 at the Early Cancer Detection and Gynecological Endoscopy Units of Ain Shams University Maternity Hospital and Menoufia University Hospital in Egypt.

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Participants/eligibility criteria: Women who had postmenstrual spotting following a CS and whose sonohysterography revealed a niche with at least 4 mm of residual myometrium.

Postmenstrual spotting was defined as two or more days of intermenstrual spotting or, if the overall duration of the menstrual flow exceeded seven days, as two or more days of brownish discharge immediately following the menstrual period. The brownish discharge is regarded as normal if the time is less than seven days. As part of the standard diagnostic procedure, saline (SIS) has been administered to these ladies in order to determine the cause of the bleeding.

Exclusion criteria: A residual myometrium of less than 4 mm at sonohysterography, age under 18, pregnancy, a (suspected) cancer, contraindications for spinal or general anesthesia, uterine or cervical polyps, submucosal fibroids, atypical endometrial cells, cervical dysplasia, cervical or pelvic infection, hydrosalpinx that communicates with the uterus, an irregular cycle (>35 days or intercycle variation of 2 weeks or more) were all excluded.

Transvaginal sonography and saline infusion sonohysterography were used to measure the niche before a woman was included in the research.

The measurements were made in the sagittal plane, where the greatest niche is visible, and in the transversal plane, where the niche is largest, meaning that the remaining myometrium is the thinnest.
The niche's form, depth, and remaining myometrium will all be noted. Given the expected risk of bladder injury or perforation with a smaller residual myometrium, a niche must be at least 3 mm deep and the remaining myometrium must be at least 4 mm in one of the planes after SIS in order to be included (Figures 1 & 2). Eligible women were randomly assigned to either the study group, which involved hysteroscopic resection of the niche, or the control group, which had no intervention.

Figure (1): 2D ultra-sonographic appearance of cesarean scar niche.

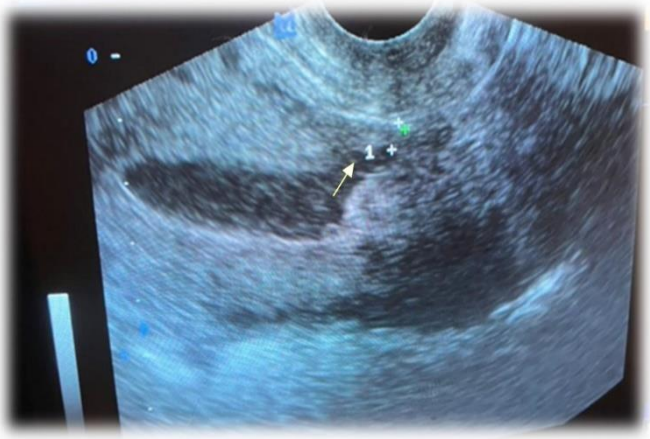

Figure (2): View of cesarean scar niche by Saline infusion sonohysterography.

Each patient had a thorough history taken, a general examination, and a local examination at the time of randomization, all of which were documented in their file. To capture all specialty traits, transvaginal sonography was performed for each subject.

Hysteroscopic niche resection intervention group: Regular preoperative laboratory tests, such as total blood counts, liver and kidney functions, coagulation profiles, and viral markers (HBVsAg, HCV-ab, and HIV-ab), were performed on the 27 patients who were assigned for hysteroscopic niche resection. Routine COVID-19 infection screening.

Diagnostic hysteroscopy: It was performed using a 2.9 mm telescope (Karl Storz GmbH and Co, Tuttlingen, Germany) and a continuous flow sheath with saline infusion as distention media. The participants were placed in the lithotomy position and the hysteroscopic examination was performed using the vaginoscopic approach as an office procedure without the use of a tenaculum or cervical dilatation. The internal os was the starting point for the uterine cavity's exploration, which then moved systematically to assess the scar from the prior Cesarean surgery and look for signs of CSD. The operation was then performed in an ambulatory environment while under spinal or general anesthesia. Following cervical os dilatation to Hegar 9 mm, a 9 mm resectoscope (Karl Storz GmbH and Co, Tuttlingen, Germany) was used to execute the hysteroscopic resection in a systematic manner, as detailed below. Glycine fluid has been employed as a distension medium for monopolar current and 0.9% NaCl for bipolar current. Hysteroscopy has been used to assess the niche, and standardized traits have been recorded. If the distal edge of the fetal CS niche is clearly visible, it has been removed, and the surface of the niche has been superficially coagulated. It is OK to lose no more than 1000 milliliters of glycine or 2000 milliliters of NaCl. Each patient's surgical results, including surgical steps, complications, and length of hospital stay after surgery, have been documented. Patients have been released the same day after an uncomplicated operation.

Control group (expectant management): For the first three months following the study's commencement, the control group did not receive any extra interventions. During this time, patients are advised to abstain from using oral contraceptives and/or medications as they did before to randomization.

Sample size justification: Sample size n = [DEFF X Np (1-p)] / [($d^2/Z^2_{1-\alpha/2}$ X (N-1) + p X (1-p)]
The sample size was calculated using the MedCalc® version 12.3.0.0 tool, a statistical calculator that relies on a 95% confidence interval and 80% research power with a 5% α error.

Ethical approval: The Ethics and Research Committee of the Obst. & Gyn. Dep. Faculty of Medicine, Menoufia University approved the study (No. 4/2020OBSGN05). After receiving all of the information, each woman signed her consent. The Helsinki Declaration was followed throughout the course of the investigation.

Statistical analysis

The results were statistically examined using SPSS 26.0, and two types of statistical analyses were performed. Descriptive data were presented as numbers (No.), percentages (%), and mean ± SD. Analytic statistics, for example, Student's t-test is a significance test used to compare quantitative variables between two groups of regularly distributed data, whereas Mann Whitney test was used to compare quantitative variables between two groups of non-normal distribution data. The paired t test was allowed for the comparison of various readings of regularly distributed data in the same group (for example, before and after treatment), whereas the Wilcoxon test was used to compare different readings of non-normally distributed data in the same group. The X^2-test was employed to examine the relationship between qualitative factors. Fischer's exact test was used if the predicted number of cells was fewer than five. A two-sided P-value of ≤ 0.05 indicated statistical significance.

RESULTS

Sixty-five patients have been approached in this study eleven cases were excluded due to sudden occurrence of pregnancy in two cases and the rest nine cases due to other gynecological conditions e.g. polyp or myoma. Then 54 cases were allocated and randomized into two groups group **1** (study group) included 27 cases underwent hysteroscopic resection of Cesarean scar niche and group **2** (control group) included 27 women as control cases without intervention (**Figure 3**).

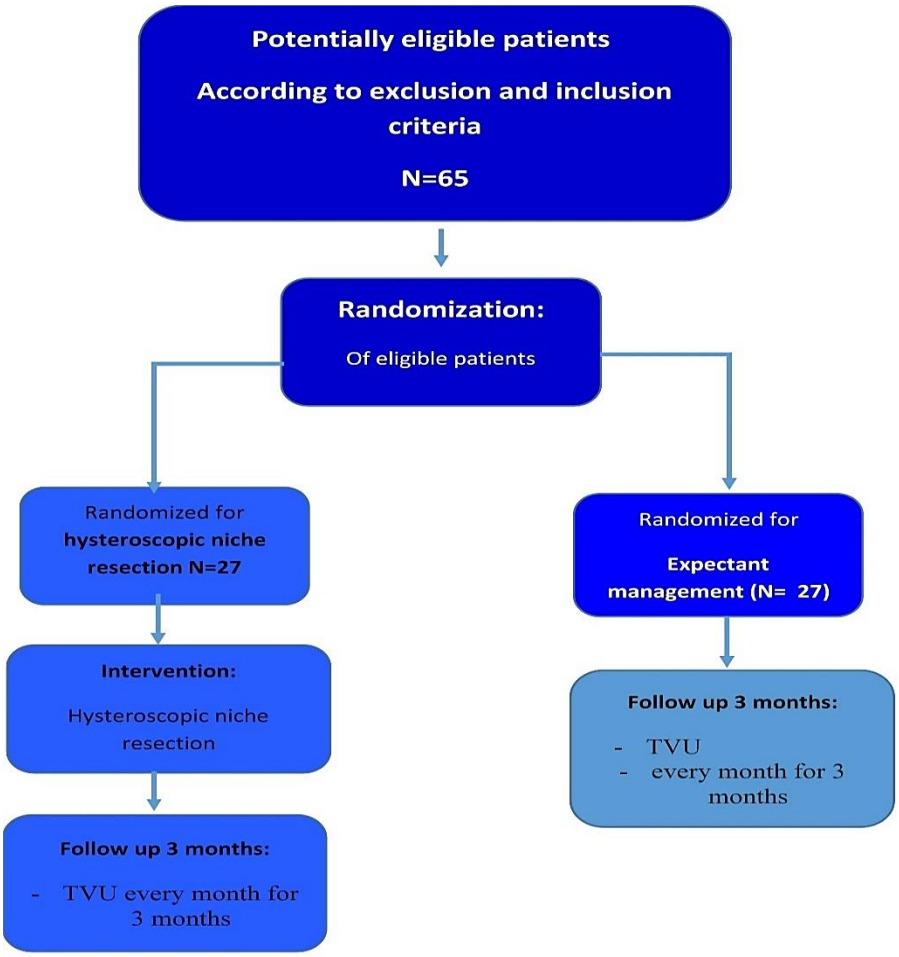

Figure (3): Flow chart.

There was no statistically significant difference between both groups regarding their age, weight, time since last CS and number of previous CS or miscarriage (P value >0.05) (Table 1).

Table (1): Demographic data of the studied patients (N=54):

Variables	Cases (N=27)	Controls (N=27)	t-test	P value
Age / years Mean ±SD (Min – Max)	 31.4±4.45 20 – 39	 31.8±4.32 20 – 39	0.279	0.781
Weight (KG) Mean ±SD Min – Max	 71.8±4.76 63 – 81	 72.7±4.71 63 – 81	0.747	0.458
Time since last C.S Mean ±SD Min – Max	 2.81±1.46 6months – 7 years	 2.94±1.52 6months – 7 years	0.319	0.751
Previous miss carriage Mean ±SD Min – Max	 0.85±1.51 0 - 7	 1.07±1.49 0 – 7	0.544	0.589
Number of previous C.S Mean ±SD Min – Max	 2.29±0.95 1 - 4	 2.22±0.89 1 – 4	0.295	0.769

There was no significant difference between both groups regarding their main presenting complaint (P value >0.05) which was spotting and infertility 48.1% followed by postmenstrual spotting 56.3%, spotting and infertility and pelvic pain present in only one patient (1.9%) and spotting & recurrent implantation failure present in two patients (3.70%) (Table 2).

Table (2): Main presenting complains among the studied patients (N=54):

Variables	Cases (N=27)		Controls (N=27)		Total		X^2	P value
	No.	%	No.	%	No.	%		
Main presenting complains								
• Post menstrual spotting	11	40.7	14	51.9	25	46.3		
• Spotting and infertility	14	51.9	12	44.4	26	48.1	1.51	0.679
• Spotting, infertility and pelvic pain	1	3.70	0	0.00	1	1.90		
• Spotting & recurrent implantation failure	1	3.70	1	3.70	2	3.70		

There was no significant difference between cases and controls regarding hormonal treatment (P value 0.05). Total 88.9% of the studied groups had hormonal treatment and only 11.1% don't have treatment (Table 3).

Table (3): Hormonal treatment among the studied patients (N=54):

Variables	Cases (N=27)		Controls (N=27)		Total		X^2	P value
	No.	%	No.	%	No.	%		
Hormonal treatment								
Yes	25	92.6	23	85.2	48	88.9	0.750	0.386
No	2	7.40	4	14.8	6	11.1		

Diagnosis of Cesarean scar niche was through transvaginal 2D or 3D ultrasonography in 29.6 % and saline infusion sonohysterography in most of patients (70.4%) (Table 4).

Table (4): Diagnosis of niche among the studied patients (N=54)

Diagnostic methods	Cases (N=27)		Controls (N=27)		Total (N=54)	
	No.	%	No.	%	No.	%
• Transvaginal US and 3D ultrasonography	9	33.3	7	25.9	16	29.6
• Transvaginal US and saline infusion sonohysterography	18	66.7	20	74.1	38	70.4

First post-operative ultrasound revealed that operation succeeded in 77.8% of patients and only 6 patients (22.2%) still have small niche (Table 5).

Table (5): First post-operative ultrasound finding among the study group (N=27):

Studied variables	Cases (N=27)	
	No.	%
US		
Small niche	6	22.2
No niche	21	77.8

There was highly significant difference between both groups regarding their clinical improvement in the form of absence of postmenstrual spotting after first menstrual cycle of randomization, 77.8% of cases improved after one month of operation, the percentage increased to 88.9% in the second month of follow up. Only one patient (3.7%) still had minimal spotting after three months of operation and randomization (Table 6).

Table (6): Post-operative improvement among the studied groups (N=54):

Variables	Cases (N=27)		Controls (N=27)		X^2	P value
	No.	%	No.	%		
First month						
Improved	21	77.8	0	0.00	54.0	**0.001****
Minimal spotting	6	22.2	0	0.00		
No improvement	0	0.00	27	100		
Second month						
Improved	24	88.9	0	0.00	54.0	**0.001****
Minimal spotting	3	11.1	0	0.00		
No improvement	0	0.00	27	100		
Third month						
Improved	26	96.3	0	0.00	54.0	**0.001****
Minimal spotting	1	3.70	0	0.00		
No improvement	0	0.00	27	100		

There was significant relation between postoperative improvement and niche depth postoperatively among the study group. Improved cases had significantly smaller niche depth than the non-improved cases with niche depth less than 6.5 mm as shown by ROC curve (P value 0.005) (Figure 4).

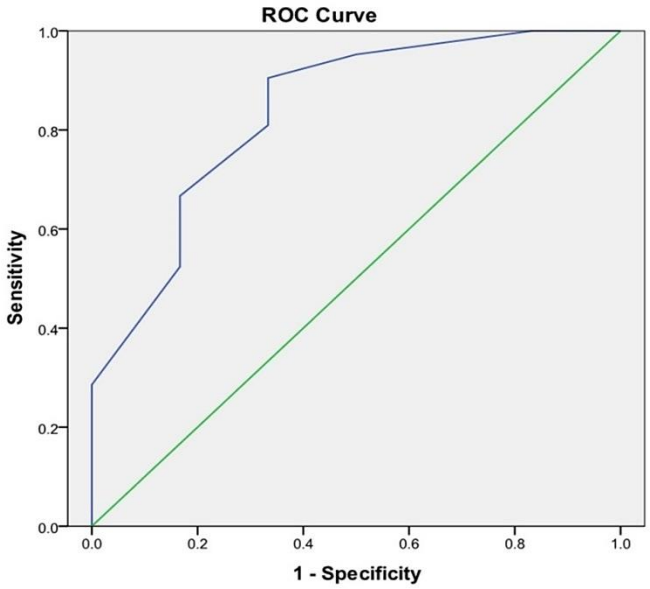

Figure (4): Niche depth lower than 6.5 had sensitivity 90% in detection of improvement of cases postoperatively**.**

DISCUSSION

We recently learned that bleeding problems are linked to niches in the CS uterine scar. About 20% of women have postmenstrual spotting following a CS [(4)]. To lessen these problems, a number of cutting-edge surgical techniques have been devised, such as vaginal, laparoscopic, or hysteroscopic repair of the CS niche [(6)].

It's critical to understand that not every niche results in symptoms. In our study, we found that niche depth more than 3 mm diagnosed with saline infusion sonohysterography is considered significant. Niches without symptoms shouldn't be addressed because treatment should only be used to lessen symptoms [(3)].

In our study, there was no statistically significant difference between both groups regarding their age, weight, time since last CS and number of previous CS or miscarriage (P value >0.05). There was no significant difference between both groups regarding their main presenting complaint (P value > 0.05), which was spotting and infertility 51.9% followed by postmenstrual spotting 40.7%, Spotting and infertility and pelvic pain present in only one patient (3.70%) and spotting & recurrent implantation failure present in two patients (3.70%).

By cutting off the niche's margins, surgical hysteroscopy allows for the correction of the anatomical defect and prevents menstrual blood from building up. Furthermore, cauterization of the CSD pouch results in scar retraction and decreases in-situ blood generation and inflammatory factor release. According to some authors' uncontrolled studies, these hysteroscopic treatments appear to be beneficial in alleviating the symptoms of CSD, and in most cases, they even result in the remission of the AUB [(10)]. At the moment, hysteroscopic niche resection is the least intrusive surgical procedure. Only a few numbers of studies have documented hysteroscopic resections. There have been no documented problems, and success rates in reducing postmenstrual spotting [(3, 4, 10)]. Thus, it is evident that our findings align with those of earlier research.

It is crucial to keep in mind that the surgical procedure is not immune to problems, even though we did not record any following hysteroscopic resection of CSD (niche) in our research. In addition to the usual hazards associated with hysteroscopy, it should be mentioned that the myometrium above the niche is thinner in these situations, suggesting a higher chance of perforation and consequent vascular, bladder, or bowel damage.

In current study, there was significant relation between postoperative improvement and niche depth postoperatively among the study group. Improved cases had significantly smaller niche depth than the non-improved cases with niche depth less than 6.5 mm as shown by ROC curve (P value 0.005).

It is advised to measure the RMT above the niche in order to reduce the possibility of bladder damage and uterine perforation. Patients with an RMT less than 4 mm were excluded from our study, even though **Tanimura *et al.*** [(11)] recommended a cutoff limit of safety of 2.5 mm. In these situations, a laparoscopic procedure was used to make the adjustment. The cutoff point of the RMT that was safe and advised for the hysteroscopic repair of the niche was less controversial at the time we started our investigation.

According to **Laganà *et al.*** [(12)] who stated that the laparoscopic method is recommended to lower the risk of perforation when the myometrial thickness is less than 3 mm. This is the cut-off, or limit, that we now employ. Furthermore, it is particularly crucial to prevent excessive myometrial resection in individuals with secondary infertility who anticipate becoming pregnant in the future and have hysteroscopic resection surgery. The objective in these situations will be to conceive, and the danger of uterine rupture is increased by exceedingly thin remaining myometrium [(10)].

Therefore, as laparoscopic correction also encourages the restoration of myometrial thickness, it is the suggested approach for patients seeking pregnancy and having an RMT < 3 mm, According to our study's findings, the optimal RMT cutoff point for hysteroscopically correcting CSD with greater safety and the best reported decrease in spotting days and discomfort in favor of hysteroscopic niche resection in our trial was 4 mm, with niche depth less than 6.5 mm, taken into consideration in symptomatic women after surgical improvement. This is not a choice for women who genuinely want to get pregnant or who have hormone contraindications [(13, 14)]. We also found that

niche with depth more than 6.5 mm carry less chance for improvement of spotting after surgical correction hysterocopically.

LIMITATIONS

The unknown impact of a hysteroscopic niche resection on the likelihood of scar rupture during delivery, pregnancy implantation involving the scar and associated morbidly adherent placenta, or cervical incompetence in subsequent pregnancies is taken into consideration. Furthermore, the control group had a notably high number of women who withdrew right after randomization or who were lost to follow-up, making it impossible to quantify the reproductive result. This included the one-year follow-up of patients who reported secondary infertility. This needs to be taken into account.

CONCLUSION

Therefore, we recommend that more study be conducted to show the effectiveness of hysteroscopic therapy of symptomatic CSD. In women with symptomatic niches, Hysteroscopic resection of CSD appears to be useful in resolving pelvic discomfort and postmenstrual AUB (spotting). It was challenging to follow up patients who had secondary infertility for a full year, and some of them were lost.

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