شبكة المعلومات الجامعية

بسم اللّه الرحمن الرحيم

شبكة المعلومات الجامعية

التوثيق الالكتروني والميكروفيلم

شبكة المعلومات الجامعية

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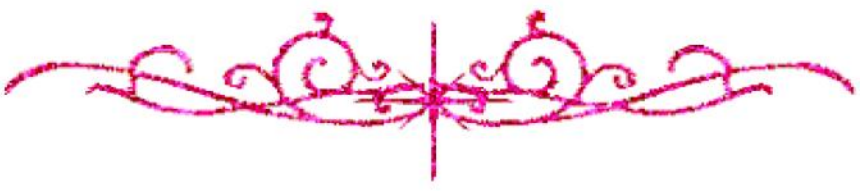

بالرسالة صفحات
لم ترد بالأصل

Hysteroscopic management of a uterine caesarean scar defect (niche) in women with postmenstrual spotting: a randomised controlled trial

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ABSTRACT

Background: Long-term complaints after caesarean section, such as postmenstrual spotting, dysmenorrhea, dyspareunia, or chronic pelvic pain, are frequently described in relation to the presence of a niche. A post-caesarean niche is defined as an indentation in the myometrium at the site of the uterine scar. Two independent prospective cohort studies reported that the presence of a niche after caesarean section increases the risk of postmenstrual spotting for more than 2 days from 15 to 30%. Postmenstrual spotting may be caused by a mechanical outflow problem, with the retention of menstrual blood in a niche, or by the accumulation of blood because of impaired uterine contractions at the site of the niche. Additionally, newly formed fragile vessels in the niche may play a role in the formation of blood or fluid in the niche and uterine cavity.

Objective: The aim of this study was to compare the effectiveness of a hysteroscopic niche resection versus no treatment in women with postmenstrual spotting and a uterine caesarean scar defect.

Methods: This trial is a randomised controlled trial that provides evidence for the (cost) effectiveness of hysteroscopic resection of a niche versus expectant management in women with niche related postmenstrual spotting. It was carried out on 28 cases divided into two equal group. The study was conducted at Ain Shams University on the women reporting postmenstrual spotting after a caesarean section. The primary outcome was the number of days of postmenstrual spotting 6 months after randomization. Secondary outcomes were spotting at the end of menstruation, intermenstrual spotting, dysuria, sonographic niche measurements, and additional therapy. Outcomes were measured at 3 months and, also at 6 months after randomization.

Results: The results of this study show a significant improvement in interventional group after 3 months more than the control group in bleeding micturition characteristics which includes total days of spotting, spotting end of menstruation, intermenstral spotting, discomfort from spotting, dysmenorrhea and daily pain during micturition, after 6 months the two group improved but the interventional group was significantly higher than

control group. Regarding the radiological assessment it was found that there was a significant improvement in intervention group more than the control group after 3 months, also the control group improved after 6 months also, but the intervention groups was significantly higher than the control group.

Conclusion: A hysteroscopic niche resection reduces postmenstrual spotting, and the discomfort from spotting, compared with expectant management after 3 months of follow-up in women with a niche with a residual myometrium of at least 3 mm.

Keywords: Hysteroscopic; niche; postmenstrual spotting

INTRODUCTION

During the past 15 to 20 years, and for a variety of reasons, cesarean section has become a common method of delivery and one of the most frequent surgical procedures. Approximately 40% of deliveries are performed by cesarean section. Women who have two or more children may have repeated cesarean sections during their reproductive years ***(Gurol-Urganci et al., 2013)***.

To date, the long-term effects of this widely used procedure have been poorly studied. In 1995, a study reported pathologic findings in 51 uterine specimens taken from women who underwent hysterectomy because of bleeding abnormalities and low abdominal pain, without the diagnosis of any uterine or hormonal pathology and who had failed several treatment attempts. All of them had previous cesarean section deliveries ***(Hofmeyer et al., 2015)***.

The study described several abnormalities in the specimens in relation to the cesarean scar, such as distortion and widening of the lower uterine segment, congested endometrium above the scar recess, lymphocytic infiltration, and capillary dilation and attributed the preoperative symptoms to these findings ***(De Vaate et al., 2011)***.

In a recent publication using transvaginal ultrasound (TVU) and hysteroscopy we described the presence of a pouch on the low anterior uterine segment in a group of women who had at least one cesarean section delivery and correlated this finding with abnormal uterine bleeding, particularly postmenstrual spotting. Some women are asymptomatic, but others may have gynecologic symptoms such as postmenstrual spotting, prolonged menstruation, continuous brown discharge, chronic pelvic pain, and secondary infertility. These symptoms, taken together, have been closely investigated and are called cesarean scar syndrome ***(Borges et al., 2010)***.

Other problems associated with cesarean scar defect are a higher risk of complications during subsequent pregnancy, such as dehiscence, placenta previa or accreta and cesarean scar ectopic pregnancy, and difficulty with gynecologic procedures like uterine evacuation, hysteroscopy, and intrauterine-device insertion. The incidence and prevalence of this anatomic defect is unknown; however, this study showed that 82.6% (76/92) of women with this defect complained of abnormal bleeding ***(De Vaate et al., 2011)***.

The presence of fibrotic tissue below the previous cesarean delivery scar (PCDS) defect may impair the drainage of menstrual flow through the cervix, acting like a valve and producing blood accumulation in the pouch, which in turn leads to secondary postmenstrual spotting. We believe that this anatomic defect, secondary to the healing process after a cesarean section surgery, can be repaired by hysteroscopic resection ***(Hofmeyer et al., 2015)***.

AIM OF THE WORK

This study aims to compare the effectiveness of a hysteroscopic niche resection, versus no treatment in women with postmenstrual spotting and a uterine caesarean scar defect.

PATIENTS AND METHODS

This trial is a randomised controlled trial that provides evidence for the (cost) effectiveness of hysteroscopic resection of a niche versus expectant management in women with niche related postmenstrual spotting. It was carried out on 28 cases divided into two equal group. The study was conducted at Ain Shams University on the women reporting postmenstrual spotting after a caesarean section. The primary outcome was the number of days of postmenstrual spotting 6 months after randomization. Secondary outcomes were spotting at the end of menstruation, intermenstrual spotting, dysuria, sonographic niche measurements, and additional therapy. Outcomes were measured at 3 months and, also at 6 months after randomization

Using PASS program, setting alpha error at 5% and power at 80%. Results from previous study ***(Vervoort et al., 2017)*** showed a reduction of 3 days of postmenstrual spotting between the 2 groups with an estimated S.D. of 2.6 days. Based on this, the needed sample is 14 cases per group (28 total).

Patients were enrolled in the study according to the following inclusion criteria: Previous Caesarean section, caesarean scar niche as diagnosed by Transvaginal ultrasound with residual myometrium of ≥3 mm, two or more days of intermenstrual spotting, two or more days of brownish discharge at the end of menstrual bleeding when the total period of menstrual bleeding exceeds 7 days, postmenstrual spotting needed to be present for at least three consecutive months after the last caesarean section, All of these patients were presented within the first 6 months following CS and hence the comparison between hysteroscopic intervention and no intervention.

Patients were excluded from the study according to the following criteria: Pregnancy, suspected malignancies, absence of cyclic bleeding periods Caused by a levonorgestrel intrauterine device (IUD), continuous oral contraceptives or gonadotropin-releasing hormone (GnRH) agonists, atypical endometrial cells or cervical dysplasia in cervical cytology, uterine or cervical polyps, submucosal fibroids, cervical or pelvic infection in the cervical swab, hydrosalpinx that communicates with the uterus, and chest or cardiac conditions contraindicates hysteroscopy.

Randomization:

After taking a informed consent, women were randomly allocated to either hysteroscopic niche resection within 1 month (intervention group) or to expectant management (control group).

Based upon a computer based randomization where the patients were given numbers from 1 to 28 and were randomly allocated to either group. The numbers were put in dark sealed envelops opened by a 3rd party to allocate the patients.

Interventions

Hysteroscopic niche resection (intervention group):

The procedure was done under general anathesia and the patients were in lithotomy position.

Dilatation of the cervix to 9 hegar to allow entrance of the resectoscope.

Distention of the uterus was done using electrolytic solutions as saline or lactated ringer.

The resection was performed under continuous sonographic evaluation. The lower rim of the niche, if prominently visible, was resected as described by ***Fabres et al. (2005) and Chang et al. (2009)*** The niche surface was superficially coagulated with the use of a rollerball.

Expectant management (control group)

Women in the control group were motivated to refrain from an additional intervention for 6 months after randomisation.

They were encouraged to discontinue any hormonal medication during this period that they had used before randomisation. In case women wanted to undergo a hysteroscopic niche resection or to use other additional therapies before 6 months of follow-up, we left the decision up to the gynaecologist and the participant, and participants remained included in the study.

Statistical analysis of the data

Data were fed to the computer using IBM *SPSS software package version 20.0.* Qualitative data were described using number and percent. Comparison between different groups regarding categorical variables was tested using Chi-square test. Quantitative data were described using mean and standard deviation for normally distributed data while abnormally distributed data was expressed using median, minimum and maximum. *For normally distributed data, comparison between two independent population were done using independent t-test while more than two population were analyzed F-test (ANOVA) to be used.* Significance test results are quoted as two-tailed probabilities. Significance of the obtained results was judged at the 5% level.

RESULTS

The study was conducted at Ain Shams University, women reporting postmenstrual spotting after a caesarean section.

Table (1): Comparison between the two studied groups regarding demographic data.

	Group I Intervention group	Group II Control group	t-test	P
Age				
Range	28-38	29-38	0.985	0.3613
Mean	32.71	32.29		
S.D.	3.12	3.20		
BMI				
Range	23.5-31.7	23.7-31.3	1.21	0.1261
Mean	28.02	26.93		
S.D.	2.67	2.25		

t-test = student t-test P was significant if ≤ 0.05

Table (1) shows comparison between the two studied groups regarding demographic data. Age in group I ranged from 28-38 with mean value 32.71±3.12 and in group II ranged from 29-38 with mean value 32.29±3.20. BMI in group I ranged from 23.5-31.7 with mean value 28.02±2.67 and in group II ranged from 23.7-31.3 with mean value 26.93±2.25. There was no statistical significant difference between the two studied groups regarding demographic data ($P > 0.05$).

Table (2): Comparison between the two studied groups regarding basic clinical and maternal data.

	Group I Intervention group	Group II Control group	t-test	P
Parity				
Range	1-3	1-3	1.254	0.1812
Mean	2.21	1.93		
S.D.	0.80	0.83		
No. of CS.				
Range	1-3	1-3	1.254	0.1812
Mean	2.21	1.93		
S.D.	0.80	0.83		
Time since last CS (days)				
Range	65-163	59-158	0.968	0.2803
Mean	103.8	101.4		
S.D.	9.93	7.91		
Previous history of uterine surgery (other than C.S.)				
Range	0-1	0-1	0.887	0.3586
Mean	0.50	0.43		
S.D.	0.52	0.51		

Table (2) shows comparison between the two studied groups regarding basic clinical and maternal data. There was no statistical significant difference between the two studied groups regarding basic clinical and maternal data ($P > 0.05$).

Table (3): Comparison between the two studied groups regarding Bleeding characteristics and pain during micturition at base line.

	Group I Intervention group	Group II Control group	t-test	P
Duration of bleeding complaints (months)				
Range	14-41	12-41	0.914	0.3955
Mean	27.93	26.93		
S.D.	9.18	10.54		
Total days of spotting				
Range	5-12	5-12	0.897	0.3210
Mean	8.43	8.86		
S.D.	2.53	2.28		
Spotting end of menstruation				
Range	3-10	3-10	1.21	0.1748
Mean	7.21	6.43		
S.D.	2.01	2.34		
Intermenstrual spotting				
Range	0-5	0-5	0.811	0.5000
Mean	2.29	2.29		
S.D.	1.68	1.59		
Discomfort from spotting (0–10)				
Range	6.1-9	6-8.6	1.85	0.06
Mean	7.69	7.21		
S.D.	0.84	0.72		
Dysmenorrhea (0–10)				
Range	3.1-7.9	2-7.9	1.66	0.0549
Mean	5.51	4.41		
S.D.	1.73	1.76		
Daily pain during micturition				
Range	5-9	5-9	0.84	0.1976
Mean	6.79	7.21		
S.D.	1.12	1.48		

Table (3) shows comparison between the two studied groups regarding Bleeding characteristics at base line. There was no statistical significant difference between the two studied groups regarding Bleeding characteristics at base line ($P > 0.05$).

Table (4): Comparison between the two studied groups regarding ultrasound findings prior to the study.

	Group I Intervention group	Group II Control group	t-test	P
Residual myometrium (mm)				
Range	3.4-6.5	3.3-6.6	0.945	0.3628
Mean	4.59	4.74		
S.D.	0.95	1.17		
Depth niche (mm)				
Range	4.2-7.7	4.5-7.4	1.87	0.0612
Mean	6.22	5.62		
S.D.	1.06	0.92		
Intrauterine fluid	7-10	7-10		0.3763

Range Mean S.D.	8.29 1.14	8.14 1.23	0.985	

Table (4) shows comparison between the two studied groups regarding ultrasound findings prior to the study. There was no statistical significant difference between the two studied groups regarding ultrasound findings prior to the study (P > 0.05).

Table (5): Comparison between the two studied groups regarding Bleeding characteristics and pain during micturition after 3 months.

	Group I Intervention group	**Group II Control group**	**t-test**	**P**
Total days of spotting				
Range	5-8	6-12	3.25	0.0052*
Mean	6.43	8.36		
S.D.	1.28	2.27		
Spotting end of menstruation				
Range	2-7	3-10	2.87	0.0138*
Mean	4.79	6.29		
S.D.	1.63	1.77		
Intermenstrual spotting				
Range	0-1	0-5	4.01	0.0003*
Mean	0.57	2.36		
S.D.	0.51	1.65		
Discomfort from spotting (0–10)			4.25	0.0001*
Range	0-4	6-9		
Mean	1.63	7.70		
S.D.	1.41	0.86		
Dysmenorrhea (0–10)				
Range	1.1-3.5	2.1-8	5.11	0.0001*
Mean	2.28	5.02		
S.D.	0.78	1.55		
Daily pain during micturition				0.0001*
Range	2-6	5-9		
Mean	3.71	6.79	5.31	
S.D.	1.33	1.58		

Table (5) shows comparison between the two studied groups regarding Bleeding characteristics after 3 months. There was statistical significant difference between the two studied groups regarding total days of spotting, spotting end of menstruation, intermenstrual spotting, discomfort from spotting (0–10) and daily pain during micturition (P < 0.05).

Table (6): Comparison between the two studied groups regarding ultrasound findings after 3 months.

	Group I Intervention	**Group II Control**	**t-test**	**P**

	group	group		
Residual myometrium(mm)				
Range	0-2.1	3.6-6.5	6.01	0.00001*
Mean	1.44	5.08		
S.D.	0.53	1.07		
Depth niche (mm)				
Range	1.4-4.1	4.4-7.6	6.00	0.00001*
Mean	2.20	6.28		
S.D.	0.81	0.98		
Intrauterine fluid				
Range	1-4	7-10	7.01	0.00001*
Mean	2.64	8.71		
S.D.	0.84	1.27		

Table (6) shows comparison between the two studied groups regarding ultrasound findings after 3 months. Residual myometrium in group I ranged from 0-2.1 with mean value 1.44±0.53 and in group II ranged from 3.6-6.5 with mean value 5.08±1.07. Depth niche in group I ranged from 1.4-4.1 with mean value 2.20±0.81 and in group II ranged from 4.4-7.6 with mean value 6.28±0.98. Intrauterine fluid in group I ranged from 1-4 with mean value 2.64±0.84 and in group II ranged from 7-10 with mean value 8.71±1.27. There was highly statistical significant difference between the two studied groups regarding ultrasound findings after 3 months ($P < 0.05$).

Table (7): Comparison between the two studied groups regarding Bleeding characteristics and pain during micturition after 6 months.

	Group I Intervention group	Group II Control group	t-test	P
Total days of spotting				
Range	4-7	5-8	2.365	0.0249*
Mean	5.79	6.64		
S.D.	1.12	1.08		
Spotting end of menstruation				
Range	2-6	3-7	4.11	0.0086*
Mean	3.79	5.29		
S.D.	1.63	1.49		
Intermenstrual spotting				
Range	0-1	0-3	2.98	0.0158*
Mean	0.43	1.21		
S.D.	0.51	1.19		
Discomfort from spotting (0–10)				
Range	0-3	1.2-3.9	2.14	0.0250*
Mean	1.76	2.48		
S.D.	0.83	1.01		
Dysmenorrhea (0–10)				
Range	0-1.6	0.7-4.5	5.21	0.0001*
Mean	1.00	2.83		
S.D.	0.51	1.41		
Daily pain during micturition	2-4	3-7		0.0001*
Range	2.93	5.21		

Mean S.D.	0.92	1.12	6.25	

Table (7) shows comparison between the two studied groups regarding Bleeding characteristics after 6 months. There was statistically significant difference between the two studied groups regarding total days of spotting, spotting end of menstruation, intermenstrual spotting, discomfort from spotting, dysmenorrhea and daily pain during micturition ($P < 0.0.5$) while there was no statistical significant difference regarding duration of bleeding complaints ($P > 0.05$).

Table (8): Comparison between the two studied groups regarding ultrasound findings after 6 months.

	Group I Intervention group	**Group II Control group**	**t-test**	**P**
Residual myometrium (mm) Range Mean S.D.	 0-2.5 1.52 0.72	 4-6.6 5.61 0.77	 7.11	 0.0001*
Depth niche (mm) Range Mean S.D.	 1.2-3.2 2.33 0.53	 3.9-7 5.34 1.12	 6.25	 0.0001*
Intrauterine fluid Range Mean S.D.	 0-3 1.00 0.88	 6-9 7.86 0.95	 7.07	 0.0001*

Table (8) shows comparison between the two studied groups regarding ultrasound findings after 6 months. Residual myometrium in group I ranged from 0-2.5 with mean value 1.52±0.72 and in group II ranged from 4.6.6 with mean value 5.61±0.77. Depth niche in group I ranged from 1.2-3.2 with mean value 2.33±0.53 and in group II ranged from 3.9-7 with mean value 5.34±1.12. Intrauterine fluid in group I ranged from 0-3 with mean value 1.00±0.88 and in group II ranged from 6-9 with mean value 7.86±0.95. There was statistical significant difference between the two studied groups regarding ultrasound findings after 6 months ($P < 0.05$).