Measuring the effectiveness of hysteroscopic resection of symptomatic cesarean scar defects and its effect on quality of life

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Abstract

Background: Cesarean section (CS) delivery increased to represent more than one third of all deliveries. CS related complications include CS scar defects that result in abnormal uterine bleeding which affect female sexual function and women's quality of life.

Aim: To evaluate the effectiveness of hysteroscopic resection of cesarean scar defects in symptomatic women.

Materials and methods: A randomized clinical trial conducted in the obstetrics and gynecology department of a tertiary hospital. Patients were recruited according to inclusion and exclusion criteria. 70 Patients were allocated into two groups: a study group who had hysteroscopic resection of the scar defect and a control group who were managed expectantly. Patients were assessed for postmenstrual spotting amount and duration. Evaluation of spotting related discomfort and dysmenorrhea was done using a visual analogue scale. Quality of life was evaluated using the Arabic validated SF 36 quality of life questionnaire. Patient satisfaction was measured using a five- point Likert scale.

Results: There was a statistically significant difference between both groups regarding the total number of spotting days post-procedure. The visual analogue scale decreased from 8.37 ± 1.57 and 2.69 ± 1.57 to 3.31 ± 1.76 and 1.43 ± 1.01 for discomfort and dysmenorrhea respectively in the study group. The study group showed significantly increased scores of each component of the quality-of-life questionnaire . Patients' satisfaction was significantly increased in the study group than the control one. The overall satisfaction rate was 74.28%.

Conclusion: Hysteroscopic niche resection resulted in improved patients' symptoms and quality of life.

Key words: niche; resection; postmenstrual bleeding; hysteroscopy.

Synopsis: Caesarean scar defect result in postmenstrual bleeding affecting women's quality of life. Hysteroscopic niche resection considered to be an effective and safe approach for treatment of women with symptomatic niche.

Introduction

Globally, there is an increase in the rate of cesarean section (CS) reaching about 1/3 of all deliveries (1). This attracted the attention towards CS related complications and its effects on women's health (2). Monteguado et al., first described a CS scar defect presented as an anechoic area at the site of the scar and was called "niche" (3). It occurred at an incidence of 24- 69% of cases with previous CS delivery as evaluated by transvaginal ultrasound (4). This resulted in a range of symptoms including pelvic pain, dysmenorrhea, postmenstrual bleeding, and infertility. This was collectively called cesarean scar syndrome (5). About one-third of women with niche complain of abnormal uterine bleeding either in the form of prolonged menstruation or postmenstrual spotting (PS) (6). Hysterectomy was the done to treat such symptoms; however, this is not suitable form women desiring fertility. This led to the adoption of less invasive procedures with the aim to drain menstrual blood and to decrease local production of blood by vessel coagulation. This would be performed laparoscopic resection, hysteroscopic resection or through vaginal repair (7-9). Hysteroscopic resection is less invasive with promising results however it requires sufficing residual myometrium to avoid bladder injury (10). Previous studies reported on symptom improvement (PS) with no data about quality- of- life using validated tools (6, 7, 8, 10). The current study aimed at assessing the effect of hysteroscopic niche resection versus no treatment on patients' symptoms (postmenstrual spotting, pain, and bleeding related discomfort), quality of life, and patient's satisfaction.

Materials and methods

The study was a randomized controlled clinical trial conducted at the Obstetrics and Gynaecology department at a tertiary Hospital from May 2020 to September 2021. The medical ethical committee of the Faculty of Medicine approved the study before commencement and informed consents were obtained from all enrolled patients.

Women were recruited according to predetermined inclusion and exclusion criteria. **Inclusion criteria:** a) age ranged from 18- 45 years, b) previous CS delivery, c) history of postmenstrual spotting (defined as two or more days of intermenstrual spotting or two or more days of brownish discharge at the end of menstrual bleeding when the total period of menstrual bleeding exceeds 7 days) (10) and dysmenorrhea, d) persistent spotting for at least three consecutive months after the last caesarean section, and e) fit for hysteroscopic surgery. **Exclusion criteria:** a) Pregnancy, b) Suspected malignancies, c) Absence of cyclic bleeding periods caused by a levonorgestrel intrauterine device (IUD), continuous oral contraceptives or gonadotropin-releasing hormone (GnRH) agonists, d) Contraindications for spinal or general anesthesia, e) Atypical endometrial cells or cervical dysplasia in cervical cytology, f) Uterine or cervical polyps, g) Submucous fibroids, h) evidence of cervical or pelvic infection, i) communicating hydrosalpinx, j) An irregular cycle (defined as less than 21 days or more than 35 days in duration or where the cycle length varied from month to month by more than 4 days) (11), and k) history of coagulopathy.

Randomization was factorial and balanced in a 1:1 manner using a computer-generated randomization list, allocating patients into two groups using opaque sealed envelopes that the senior researcher opened after patients' evaluation for eligibility. Each group matched the same baseline characteristics, including women's socio-demographic characteristics (age group, education, occupation, and residency). The control group included **35 women** who were managed expectantly. The study group included 35 women who hysteroscopic resection of the niche. Patients and researchers were aware

of group allocation, but outcome assessors and data analysts were kept blinded.

Eligible women for the study were subjected to the following:

- **History taking** to obtain their socio-demographic characteristics (age, education, occupation, parity, and residency, along with their Menstrual history, Obstetric history, Past History of surgical operations, Operative details of previous cesarean section and Past history of medical disorders.
- **Clinical examination** (Height measurement while the woman is standing, bared foot, the measurements rounded to the nearest 0.5 cm. Weight measurement using a scale. Women were requested to take off any heavy clothing. Weight rounded to the nearest 0.5 Kg. BMI was calculated by dividing the weight in kilograms by the height in meters squared. Women's BMI was classified according to WHO classification (12).
- **Transvaginal ultrasound evaluation**: for diagnosis of niche, by using a Mindray ultrasound machine, model DC-30, 240-270V 50/60Hz, 630VA (Mindray, china). Patients were examined at the end of their menstrual cycle (between day 5 to day 7). The patients were asked to empty the urinary bladder just before the procedure and was put in the lithotomy position. The transducer tip was covered with gel and introduced into protective rubber sheet (condom). The probe tip was covered with a small amount of gel and was gently inserted into the vagina. Niche was defined as a triangular anechoic area at the site of the scar with a depth of at least 2 mm (3).
- The degree of dysmenorrhea and discomfort were determined using a visual analogue scale (VAS). The VAS is a unidirectional measure of the intensity of pain. It is composed of a horizontal scale, 10 cm in length. It is anchored by two verbal pain extremes. An extreme was represented by "no pain" (scored as 0) and the other extreme was represented by "the worst pain ever" (scored as 10). The patients were told to place a mark on the scale that represents the extent of pain they suffer. The score was determined by measuring the distance between the "no pain" extreme and the mark determined by the patient. This gave a range of scores from 0- 100. A higher score indicated a severe pain (13).
- menstrual changes were reported as a) vaginal spotting defined as very slight bleeding that needs no sanitary protection, b) heavy bleeding defined as bleeding that needs sanitary protection, and c) bleeding/ spotting episode defined as one or more successive days with reported blood loss. The number of bleeding/ spotting days, and number of bleeding/ spotting episodes were reported (14). Bleeding was evaluated using a bleeding diary given to each participant after enrollment. Women were instructed to mark a sign ○ for spotting and a sign ● for bleeding days. The usual menstrual bleeding was marked as /. Women were asked to use disposable normal pads and to report the number of pads each day. Heavy menstrual bleeding was defined as increased menstrual blood loss affecting women's physical, social, emotional, and/ or quality of life (15).
- Quality of life was evaluated using the Arabic validated SF-36 health survey questionnaire (16). It yields an 8-scale profile of functional health and well-being scores: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), mental health (MH), and one single item scale on health transition. Score ranges from 0 to 100, with higher score indicating higher level of function

and/or better health and lower score indicating lower level of function and/or bad health (17).

- Participants received preoperative preparation including vaginal administration of 2 tablets misoprostol (Misotac, Segma pharmaceuticals, Egypt) 3 hours before surgery to soften the cervix.
- Hysteroscopy was performed only in the study group following these steps: a) Under spinal anesthesia, patients were placed in the lithotomy position and the vulva was sterilized, b) Painting and draping of towels with support of both legs, c) Bladder evacuation through urethral metal catheter, d) Examination under general anesthesia (EUA) to determine position of uterus (AVF or RVF) and bimanual examination of adnexa, e) Holding the cervix by multi toothed volsullum, and f) Introduction of the hysteroscope. In cases with insufficient dilatation, mechanical dilatation using Hegar dilator was done.
- The endocervical canal was seen then the uterine cavity was visualized, both tubal ostia were seen then the scar defect can be seen & visualized. Operative hysteroscopy was performed using a 9-mm resectoscope (Karl Storz), unipolar electrical current, and sorbitol-mannitol solution as a medium of distension. We performed a resection of the inferior edge of the defect using a cutting loop and pure cutting current to remove the flap of fibrotic tissue. Complete removal of the scar tissue was done using a resectoscopic loop until the muscular tissue below was evident. The base of the pouch was treated by electrocauterization with a roller-ball 3- mm. The operation was conducted under visual examination (7, 18).
- After the surgery, participants were observed in the inpatient ward for 2 hours to avoid surgical complications or those associated with anesthesia. Participants were evaluated at the outpatient clinic at 3 months after the surgery for assessing improvement of symptoms. Quality of life was evaluated again after surgery.
- Patient satisfaction was measured using a Likert scale from 1 to 5, corresponding to extremely dissatisfied, dissatisfied, neutral, satisfied and extremely satisfied.
- The control group was instructed to follow an expectant management which entailed continuing any medication used to control the symptoms (hemostatic drugs) for three months. Then, quality of life and patient satisfaction were evaluated.

Primary outcome measure was the effectiveness of hysteroscopic resection of niche compared to expectant management in the form of postmenstrual bleeding episodes and its duration. Secondary outcome measures were evaluation of the quality of life and patient satisfaction.

Ethical approval: This study was conducted after approval of the research ethics committee of the faculty of medicine, Suez Canal University, on 19th September 2018 with a number of 3578#.

Sample size

Sample size was calculated according to the following equation (19)

$$n = \left[\frac{Z_{\alpha/2} + Z_{\beta}}{P_1 - P_2}\right]^2 (p_1 q_1 + p_2 q_2)$$

Where:

- n= sample size
- $Z\alpha/2 = 1.96$ (The critical value that divides the central 95% of the Z distribution from the 5% in the tail)
- $Z\beta = 0.84$ (The critical value that separates the lower 20% of the Z distribution from the upper 80%)
- P1 = Prevalence/proportion of prolonged postmenstrual bleeding after operation = 33.3% (20)

- P2 = Prevalence/proportion of success of procedure = 66.67% (20)
- q = 1-p

According to the previous equation, the sample size was equal to 35 subjects after the addition of a 10% drop-out rate for each group, giving a total sample size of 70 subjects.

Statistical analysis: The data were coded, organized and the final study results was stated using the SPSS (statistical package for social sciences) version 20 and data was presented through tables. As appropriate numerical data was expressed as mean with or without SD and categorical data was expressed as number %. Student T test was used to test statistical significance of continuous variable between two groups, while chi-square test was used for categorical variables. Statistical significance was considered at P-value < 0.05 and highly significance at P-value < 0.01.

Results

Seventy- six women were eligible for the study. Six women refused to participate leaving a total of 70 women allocated to the study and control group (Figure 1).

Table 1 showed that there were no statistically significant differences between the means of the study groups' ages, body mass indices, parities, previous CSs and times since last CSs. Smoking, Parity and previous CS frequency distributions did not show statistically significant differences between the study groups.

Of note, all cases in the study group still had postmenstrual bleeding/spotting after the procedure. There was a statistically significant decrease between both control and study groups regarding total number of spotting days post-procedure (p value < 0.001) (Table 2).

The VAS score decreased from 8.37 ± 1.57 and 2.69 ± 1.57 to 3.31 ± 1.76 and 1.43 ± 1.01 for discomfort and dysmenorrhea respectively in the study group (p value <0.001 and 0.001, respectively) (Table 3).

The study group showed significantly increased scores of each component of the quality-of-life questionnaire as well as the total score after the operation (Table 4). Patients' satisfaction was significantly increased in the study group than the control one (2.8 ± 0.53 and 1.57 ± 0.61, respectively, p value <0.001). The overall satisfaction rate was 74.28%.

Discussion

Postmenstrual bleeding was present in both groups with durations reaching 9 days. This was explained by several causes such as accumulated menstrual blood in the caesarean scar defect with intermittent discharge after cessation of menstruation, failure to drain menstrual blood adequately because of fibrotic tissue presence below the scar defect, and the formation of new fragile vessels causing in situ accumulation of blood (7, 21). Hysteroscopic resection of the niche resulted in improved patients' symptoms (postmenstrual bleeding, pain, and discomfort). This agreed with the results reported previously (7, 10, 18, and 22). This would be rendered to resection of the lower margin of the niche and cauterization of the bleeding fragile vessels in its base improving menstrual blood drainage and decreasing formation of blood after the menstruation stops.

Pain and discomfort were decreased significantly after niche resection. Another study reported a significant reduction in suprapubic pelvic pain (23). According to a previously published systematic review (6), pain resolved in 97% of patients after hysteroscopic- resection (23, 24, 25); however, methods of pain assessment were not mentioned. Discomfort was not decreased significantly in another study (10). This was explained by persistent postmenstrual

bleeding despite the decrease in its duration.

The overall satisfaction rate was 74.28%. This agreed with the results reported previously where 79.66% of the participants reported a satisfactory symptom relief (26) while another one reported increased satisfaction from 2.10 ± 1.05 to 3.53 ± 1.41 ($p<0.01$) (27). A systematic review reported a satisfaction rate of 87% due to relief of bleeding symptoms (6). This study reported a significant improvement in all aspects of the quality- of- life questionnaire as well as the total score. However; this was not evaluated using a validated tool in previous studies (6). A study reported on the QOL after hysteroscopic resection of the niche declared no improvement in the QOL among the study and control groups (10). This would be rendered to the ultrasound findings after the operation where the depth of the niche and the myometrial thickness showed no difference between both groups and within the two groups compared to baseline data. Also, 55% of women allocated in the intervention group had their operation 2- 3 months after allocation. This would result in improper evaluation of the data obtained at 3 months later. Additionally, the duration of bleeding in the control group was prolonged (10 days) with marked improvement with medical treatment which would underestimate the effect of their study.

Strength and limitations

This study evaluated the QOL after surgery using a validated tool. The small sample size is a limitation. Long term follow up would be more conclusive. We did not recruit women with infertility. Postoperative ultrasound evaluation of the scar defect was not done. Blinding was not possible for the patients and the surgeons. We recruited patients with small niche and residual myometrium > 3 mm which might limit the generalizability of results.

Conclusion

Hysteroscopic resection of cesarean scar defects resulted in improved patients' symptoms as well as their QOL.

References

1. Adewuyi EO, Auta A, Khanal V, Samson J, Yun Zhao. Cesarean delivery in Nigeria: prevalence and associated factors—a population-based cross-sectional study BMJ Open 2019; 17: 9(6).
2. Chen H, Tan D. Cesarean Section or Natural Childbirth? Cesarean Birth May Damage Your Health. Front. Psychol. 2019; 10: 351.
3. Monteagudo A, Carreno C, Timor-Tritsch IE. Saline infusion sonohysterography in nonpregnant women with previous cesarean delivery: the "niche" in the scar. JUM; 2001; 20 (10); 1105-1115.
4. Bamberg C, Hinkson L, Dudenhausen LW, Bujak V, Kalache KD, Henrich W. Longitudinal transvaginal ultrasound evaluation of cesarean scar niche incidence and depth in the first two years after single- or double-layer uterotomy closure: a randomized controlled trial. AOGS; 2017; 96 (12); 1484-1489.
5. Dosedla E, Calda P. Outcomes of Laparoscopic Treatment in Women with Cesarean Scar Syndrome. Med Sci Monit. 2017; 23:4061-4066.
6. van der Voet LF, Vervoort AJ, Veersema S, BijdeVaate AJ, Brölmann HAM, Huirne JAF. Minimally invasive therapy for gynaecological symptoms related to a niche in the caesarean scar: a systematic review. BJOG 2014; 121: 145– 156.
7. Fabres C, Arriagada P, Fernandez C, Mackenna A, Zegers F, Fernandez E. Surgical treatment and follow-up of women with intermenstrual bleeding due to cesarean section scar defect. J Minim Invasive Gynecol 2005;12:25–8.

8. Donnez O, Jadoul P, Squifflet J, Donnez J. Laparoscopic repair of wide and deep uterine scar dehiscence after cesarean section. Fertil Steril 2008;89:974–80.
9. Tahara M, Shimizu T, Shimoura H. Preliminary report of treatment with oral contraceptive pills for intermenstrual vaginal bleeding secondary to a cesarean section scar. Fertil Steril 2006;86:477–9.
10. Vervoort AJMW, van der Voet LF, Hehenkamp WJK, Thurkow AL, van Kesteren PJM, Quartero H et al. Hysteroscopic resection of a uterine caesarean scar defect (niche) in women with postmenstrual spotting: a randomised controlled trial. BJOG 2018; 125: 326–334.
11. Treloar AE. Menstrual cyclicity and the pre-menopause. Maturitas 1981;3:249–64.
12. WHO (1998) 'Executive Summary of the Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.', Archives of internal medicine, 158(17): 1855–1867.
13. Hawker GA, Mian S, Kendzerska T, French M. Measures of Adult Pain. Arthritis Care & Research 2011;63(11):240–252.
14. Belsey EM, Machin D, d'Arcangues C. The analysis of vaginal bleeding patterns induced by fertility regulating methods. World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction. Contraception 1986; 34:253–260
15. National institute for Health and Care Excellence (NICE) Heavy menstrual bleeding: Assessment and management 2018: 4 -18.
16. Guermazi M, Allouch C, Yahia M, Huissa TBA, Ghorbel S, Damak J, et al. Translation in Arabic, adaptation and validation of the SF-36 Health Survey for use in Tunisia, Annals of Physical and Rehabilitation Medicine 2012; 55(6): 388-403.
17. Brazier JE, Harper R, Jones NM, Cathain A, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. BMJ, 305 (6846) (1992), pp. 160-164
18. Chang Y, Tsai EM, Long CY, Lee CL, Kay N. Resectoscopic treatment combined with sonohysterographic evaluation of women with postmenstrual bleeding as a result of previous cesarean delivery scar defects. Am J Obstet Gynecol 2009;200 (4):370.e 1–4
19. Dawson B, Trapp RG. Basic & Clinical Biostatistics. 4th edition, 2004; New York; Lange Medical Books basic science /McGraw-Hill; page 438.
20. Xu H, Yang M, Zhang X, Wang Q, Yi X, Ding J, et al. Efficacy of caesarean scar defect repair in improving postmenstrual bleeding and factors associated with poor effect. Journal of Obstetrics and Gynaecology; 2017; 37(8), 1076–1081.
21. Thurmond AS, Harvey WJ, Smith SA. Cesarean section scar as a cause of abnormal vaginal bleeding: diagnosis by sonohysterography. J Ultrasound Med 1999;18:13–6.
22. Wang CJ, Huang HJ, Chao A, Lin YP, Pan YJ, Horng SG. Challenges in the transvaginal management of abnormal uterine bleeding secondary to cesarean section scar defect. Eur J Obstet Gynecol Reprod Biol ;2011; 154(2):218–222.
23. Gubbini G, Centini G, Nascetti D, Marra E, Moncini I, Bruni L, et al. Surgical hysteroscopic treatment of cesarean-induced isthmocele in restoring fertility: a prospective study. J Minim Invasive Gynecol; 2011; 18(2):234–237.
24. Luo L, Niu G, Wang Q, Xie HZ, Yao SZ. Vaginal repair of cesarean section scar diverticula. J Minim Invasive Gynecol 2012; 19:454–8.
25. Florio P, Gubbini G, Marra E, Dores D, Nascetti D, Bruni L, et al. A retrospective

case-control study comparing hysteroscopic resection versus hormonal modulation in treating menstrual disorders due to isthmocele. Gynecol Endocrinol 2011;27:434–8.

26. Cohen SB, Bouaziz J, Bar On A, Orvieto R. Fertility success rates in patients with secondary infertility and symptomatic cesarean scar niche undergoing hysteroscopic niche resection, Gynecological Endocrinology, 2020;36(10):912-916.

27. Zhu Q, He X, Jiang L, Liang G, Zhu C, Pan H, et al. Effectiveness of hysteroscopic resection of a uterine caesarean niche can be predicted: a prospective cohort study. Scientific Reports 2020 ;10(1):17424.

Figure 1: flow diagram of the study