

Is thermal balloon ablation in women with previous cesarean delivery successful?

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Background/aim: Endometrial ablation is used to treat heavy menstrual bleeding in women who do not respond to standard therapy. This study aimed to compare treatment success in women with previous cesarean delivery and vaginal delivery who were subjected to thermal balloon ablation.

Materials and methods: This cohort study enrolled women with symptoms of heavy menstrual bleeding who had major health problems and were considered as high-risk patients for hysterectomy. Patients were divided into two groups, vaginal delivery and cesarean section (C-section). Thermal balloon ablation was performed under general or regional anesthesia on days 3–5 of the menstrual cycle. Treatment success was compared between the two groups at 12 months.

Results: This study involved 63 women with a mean age of 44.14 ± 6.56 years. Of these, 33 patients (54.1%) had a history of cesarean section and revealed positive results (69.7%) after 1 year of treatment. Age ≤ 45 years and uterine length < 9 cm were significantly associated with treatment success in women with a previous C-section.

Conclusion: Thermal balloon ablation is a possible therapeutic option to treat menorrhagia occurring as a result of benign causes in women with previous C-section deliveries. The results are particularly successful in younger women with shorter uterine depth.

Key words: Thermal ablation, cesarean section, bleeding, amenorrhea

1. Introduction

Endometrial ablation is a minimally invasive procedure to treat heavy menstrual bleeding (HMB) in women who do not respond to standard therapy (1,2). Thermal balloon ablation (TBA) was the first method of global endometrial ablation (GEA) (3), which includes four kinds of devices: ThermaChoice, Menotreat, Cavaterm, and Thermablate (1). TBA is approved by the US Food and Drug Administration (FDA) for women with menorrhagia in whom childbearing is complete (1,4). NovaSure radiofrequency endometrial ablation and chemical ablation of endometrium with trichloroacetic acid are other widely used methods for ablation (5,6). Many studies have been published on the effectiveness and safety of this approach (2–4,7–10) compared to the first generation of endometrial ablation techniques (11,12); however, certain severe complications associated with TBA, such as hemorrhage, hematometra, uterine perforation, sepsis,

thermal bowel injury, admission to the intensive care unit, adnexal necrosis, need for laparotomy, and even death in women who underwent C-section for delivery, were reported by the FDA Manufacturer and User Facility Device Experience database (13). Bouzari et al. reported many intraoperative or postoperative complications in patients who were treated with endometrial ablation by thermal balloon and hysteroscopy resection (14). Patients with a history of previous C-section may be inappropriate candidates for these procedures because the hysterectomy repair site is thin in some of these patients (13). Cavaterm plus (Wallsten Medical SA, Morges, Switzerland) TBA is different from the older version and it requires less cervical dilatation, utilizes higher balloon pressure (230–240 mmHg), and runs for a shorter treatment cycle of 10 min (15).

To the best of our knowledge, few studies have investigated TBA in women with previous C-section

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deliveries (4,16). The estimated complication rate was 5.6 per 1000 patients.

The database has also raised doubt about the use of TBA in patients with a history of C-section delivery (4). No study has examined the predictors of treatment success in women with previous cesarean delivery. This study aimed to compare amenorrhea and treatment success (amenorrhea or hypomenorrhea) at 12 months between women with previous cesarean delivery and women with vaginal delivery who were treated by Cavaterm plus, and to estimate the association between patient factors and primary outcomes by developing and validating predicting models.

2. Materials and methods

This retrospective cohort study was approved by the ethics committee of Babol University of Medical Sciences in order to survey all women with HMB at Ayatollah Rouhani and Emam Hossein Hospitals between January 2012 and December 2013. All women reported major health problems and were considered as high-risk patients for hysterectomy. These patients had delivered children previously and agreed to undergo endometrial ablation. After obtaining informed consent from the patients, their demographic and medical data were collected. Before the procedure, all women underwent pelvic ultrasonography and endometrial biopsy. Exclusion criteria included intracavity pathology (fibroids or polyps), congenital uterine anomaly, uterine cavity less than 4 cm, active urinary tract and pelvic infection, presence of coagulopathies, use of anticoagulants, desire to preserve fertility, history of surgery (myomectomy), endometrial ablation, and classical C-section.

Cavaterm plus (Wallsten Medical SA, Morges, Switzerland) TBA was carried out under general or regional anesthesia on days 3–5 of the menstrual cycle. The cervix was dilated to 6 mm using Hegar dilators, when necessary. After purging the air from the Cavaterm plus system, the catheter end was inserted through the cervix into the fundus of the uterus and the balloon was inflated with 5% glucose until a pressure of 230 (\pm 10) mmHg was achieved. Fluid circulation was followed by heating. The ablation time started on achieving a temperature of 75 °C. Treatment lasted for 10 min with the temperature stabilized at 78 °C (17).

The Postoperative Pictorial Blood Assessment Chart (PBAC) Scoring System was used to record the size of clots/flooding row on the relevant day. This method records the number of tampons or towels used and the degree to which they are stained with blood. A score of 100 and above indicated that the women suffered from HMB, whereas a score of 0 revealed “amenorrhea” (18). Primary outcomes included amenorrhea and treatment

success (amenorrhea or hypomenorrhea) at 12 months posttreatment, whereas secondary outcomes were patient satisfaction and estimation of the association between patient factors and primary outcomes by developing and validating predicting models.

Medical records were reviewed for intraoperative and postoperative complications including fluid overload, hematometra, uterine rupture, and laceration of cervix. In addition, women completed the health status questionnaire on amenorrhea, reduction of menstrual flow, and postoperative heavy bleeding at 12 months posttreatment.

3. Statistical analysis

After dividing the patients into two groups (vaginal delivery or C-section), the collected data were coded, entered into version 18 of SPSS, and analyzed with t-test and chi-square test. Risk adjustments were performed using regression models. Furthermore, P values less than 0.05 were considered statistically significant.

4. Results

The study involved 63 women with a mean age of 44.14 \pm 6.56 years, suffering from HMB, who were subjected to TBA from January 2012 to December 2013. Patients with previous C-section revealed a 69.7% success rate after 1 year of treatment (amenorrhea alone or with hypomenorrhea). Two of the patients were nulligravid and were excluded from the study. Patients were divided into two groups (vaginal delivery or C-section). Of the total, 33 patients (54.1%) revealed a history of C-section. These patients had a history of one or more cesarean deliveries: one patient had four previous C-sections and was a 45-year-old woman, gravida 5 para 5, BMI = 33 kg/m². Twelve months after TBA, she reported hypomenorrhea. Table 1 shows the clinical characteristics of cases and controls. There were several differences between case and control subjects, so that the mean value of preoperative dysmenorrhea, and the uterine length and cervical length between the two groups were statistically significant (respectively: P = 0.04, P = 0.01, and P = 0.03).

Age \leq 45 years (adjusted OR 3.26, 95% CI 1.03–10.34) was significantly associated with amenorrhea in women with a previous C-section. Age \leq 45 years (adjusted OR 4.83, 95% CI 1.51–20.32) and uterine length < 9 cm (adjusted OR 13.68, 95% CI 1.34–150.00) were significantly associated with treatment success (amenorrhea or hypomenorrhea) in women with a previous C-section (Table 2). No complications were observed during and after TBA.

5. Discussion

In this study, age \leq 45 years and uterine length < 9 cm were significantly associated with treatment success of TBA in

Table 1. Clinical characteristics of cases and controls.

Characteristic	Patients without previous CS (NVD) (n = 28)	Patients with previous CS (n = 33)	P-value
Age, years (mean \pm SD)	45.64 \pm 6.43	42.79 \pm 6.65	0.09
Parity (mean \pm SD)	2.79 \pm 1.16	2.91 \pm 0.87	0.64
BMI, kg/m ² (mean \pm SD)	30.97 \pm 6.94	29.64 \pm 5.52	0.40
Score of bleeding (PBAC)	432.46 \pm 263.32	420.79 \pm 224.50	0.85
Score of bleeding (PBAC) after 1 year	39.50 \pm 53.60	32.61 \pm 45.70	0.59
Preoperative dysmenorrhea, n (%)	20 (71.4)	15 (45.5)	0.04
History of tubal ligation, n (%)	11 (39.3)	17 (51.5)	0.34
Operation time (min), (mean \pm SD)	11.96 \pm 2.09	12.24 \pm 2.06	0.60
Hemoglobin (g/dL), (mean \pm SD)	10.94 \pm 1.31	10.93 \pm 1.27	0.97
Uterine length (from the external hole of the cervix to the end of the uterus fundus), cm (mean \pm SD)	10.79 \pm 1.51	11.83 \pm 1.83	0.01
Depth of uterus, cm (mean \pm SD)	6.95 \pm 1.54	7.39 \pm 1.98	0.33
Cervical length, cm (mean \pm SD)	3.84 \pm 0.79	4.59 \pm 1.68	0.03
Endometrial thickness, mm (mean \pm SD)	4.71 \pm 1.88	4.73 \pm 2.05	0.98
Amenorrhea rate at 12 months, n (%)	11 (39.3)	16 (48.5)	0.47
Success of treatment, n (%)	19 (67.9)	23 (69.7)	0.87
Pathology			
Endometrial proliferative	12 (42.9)	10 (30.3)	0.06
Endometrial secretory	7 (25)	14 (42.4)	
Polyps	5 (17.9)	9 (27.3)	
Pill effect	4 (14.3)	0	
The reasons why patients underwent thermal balloon ablation			
Heart disease + diabetic	14 (50)	6 (18.2)	0.02
Heart disease + hypertension	5 (17.9)	7 (21.2)	
No response to treatment	8 (28.6)	12 (36.4)	
Unwillingness of the patient	1 (3.6)	8 (24.2)	

women with a previous C-section and symptoms of HMB. No complications were observed during and after TBA.

Gangadharan et al. argued that ablation can be an alternative treatment without complication for women with menorrhagia and a history of one or more cesarean deliveries; as in this study, none of the patients with a history of C-section required dilatation and curettage following ablation. With a mean age of 43.3 years and previous cesarean delivery and length of uterine cavity of 7.6 cm, these patients were similar to those in the present study (4).

Patients with a previous cesarean history, a mean age of 42.39 years, and a mean parity of 2.51 participated in Khanand et al.'s study, and uterine rupture during endometrial ablation was observed in only 1.2% of them. They concluded that endometrial ablation has the same

efficiency and safety in women with and without previous cesarean delivery (16).

In a case report by Rooney and Cholhan, they described a vesico-uterine fistula after endometrial ablation in a 54-year-old woman with three previous C-sections (19).

Peeters et al. reported that previous cesarean delivery is not associated with an increased risk of failure of endometrial ablation; however, dysmenorrhea, a submucous myoma, and like our study, longer uterine depth are. Menstrual bleeding, sterilization, and age were not associated with failure of ablation, as in women who underwent a hysterectomy for persistent menorrhagia after an ablation (20).

Hector et al. evaluated the safety of thermal balloon endometrial ablation in 41 patients who had had prior low transverse CS with mean uterine scar thickness of

Table 2. Preoperative predictors of amenorrhea and success of treatment (amenorrhea or hypomenorrhea) after TBA in patients with previous caesarian section.

Predictors	Adjusted analyses (amenorrhea or hypomenorrhea) The success of the treatment		Adjusted analyses (amenorrhea 1 year)	
	Multivariable OR (95% CI)	P	Multivariable OR (95% CI)	P
Age ≤ 45 years	6.34 (1.338–30.041)	0.020	3.832(1.170–12.549)	0.026
Body mass index ≤ 30 kg/m ²	1.503 (0.361–6.251)	0.575	1.292 (0.351–4.755)	0.700
Tubal ligation	3.037 (0.637–14.470)	0.163	0.701 (0.205–2.401)	0.572
Preoperative dysmenorrhea	1.915 (0.400–9.159)	0.416	3.327 (0.791–13.997)	0.101
Preoperative bleeding > 7 days	0.300 (0.050–1.801)	0.188	0.284 (0.070–1.147)	0.077
Regular bleeding	0.577 (0.106–3.149)	0.525	0.777 (0.155–3.887)	0.759
Depth of uterus (uterine length < 9), cm (mean ±SD)	15.352 (1.318–178.759)	0.029	1.778 (0.416–7.592)	0.437
Cervical length, cm (mean ± SD)	0.721 (0.422–1.232)	0.231	0.797 (0.501–1.268)	0.338

OR, odds ratio; CI, confidence interval

12.3 mm. Mean thickness decreased as the number of CS increased. No vesicouterine fistulas, uterine perforations, or even serious adverse events were observed up to 6 months after the ablation (21).

In conclusion, TBA is a suitable therapeutic option for treating menorrhagia occurring as a result of benign causes in women with previous cesarean deliveries, particularly younger women with smaller uterine depth.

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