

Research Article

Thermal Balloon Ablation for Dysfunctional Uterine Bleeding among Iranian Patients

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ABSTRACT

Objective: dysfunctional uterine bleeding is a common gynecological condition which affects about 20-30% of premenopausal women. When medical treatments fail to provide adequate relief, surgical interventions, including hysterectomy or destruction of the endometrium, might be considered. The aim of the present study was to determine the menstrual outcomes and the satisfaction level, after thermal balloon endometrial ablation to treat this condition among Iranian patients. **Design classification:** A single-arm prospective study. **Setting:** University teaching hospital. **patients:** 52 patients with dysfunctional uterine bleeding. **Intervention:** Patients underwent endometrial ablation using Cavaterm plus and were followed up for 12 months, Post operatively. **Measurements:** The pictorial blood loss assessment chart score of menstrual cycle, number of days in the cycle, degree of dysmenorrhea, satisfaction from treatment and any complication of treatment were assessed. **Main results:** Eighty-eight percent of patients responded to treatment; the mean number of days of bleeding per month decreased from a mean of 13.6 to 4 days ($p < 0.001$) and the mean amount of bleeding decreased from 535.4 to 38.6 in pictorial blood loss assessment chart ($p < 0.001$). Also 45% of patients became amenorrheic after one year follow up and 88% were satisfied with their treatment. **Conclusions:** Thermal balloon endometrial ablation among our patients showed a similar outcome to previous reported studies. It seems that this method represents an excellent alternative to hysterectomy, with high rate of success, a very low complications rate and high patients satisfaction.

Keywords: Dysfunctional uterine bleeding, endometrial ablation, thermal balloon, pictorial blood loss, Iran.

INTRODUCTION

Dysfunctional uterine bleeding (DUB) is a common gynecological condition that affects about 20-30% of premenopausal women [1, 2]. Although treatment usually starts with medical therapy [3], 60% of patients do not respond satisfactorily to medical treatment and a surgical intervention is required. Hysterectomy is the gold standard surgical approach

in DUB. However, it is accompanied by significant morbidity and a lengthy recovery period. Minimally invasive methods for destroying the endometrium represent a feasible alternative to hysterectomy [4,5].

During the last 30 years from the first use of the neodymium-doped yttrium aluminium garnet (Nd:YAG) laser hysteroscopic photovaporization [6], a variety of ablation procedures have been developed. Currently, there are two generations of these

techniques: hysteroscopic-based and the techniques that do not require hysteroscopy [7,8]. First generation techniques use electrical, thermal or laser energy for destroying endometrium in direct visualization of uterine by hysteroscopy and need a high degree of surgical skill. Second generation non-hysteroscopic techniques are safer, technically easier to perform, have shorter hospital staying and can be performed under local anesthesia. Since 1997, the US food and drug administration (FDA) has approved five global endometrial ablation devices for minimally invasive treatment of uterine bleeding. These methods use a variety of modalities to ablate endometrium, including thermal balloon, circulated hot fluid, cryotherapy, radiofrequency (RF), electrosurgery and microwave energy. These methods have response rate for treatment about 70-90% between studies [8,9]. Thermal balloon endometrial ablation (TBEA) was one of the earliest second generation endometrial ablation techniques. This technique is simple and is associated with less postoperative morbidity and a short recovery period, and good therapeutic efficacy of about 80% [9].

Although at present this method has worldwide use, there are not enough studies to assess its outcomes among Iranian patients [10]. Consequently, the aim of the present study was to evaluate the response rate after a one-year follow-up among Iranian patients who underwent thermal balloon ablation to treat dysfunctional uterine bleeding.

PATIENTS AND METHODS

The present study was a single arm prospective longitudinal study on women with DUB who were referred to the gynecology clinic of Imam Hussein Medical Center, Tehran, Iran, from February 2011 to February 2013. The selected patients had failed to respond to at least 6 months of medical treatment or were unwilling to continue medical therapy and also had decided they did not want any future pregnancy. The study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences, Teheran, Iran. A written informed consent was obtained from all patients before entering the study.

Each patient had preoperative routine history and physical examination performed, while Pap smear, pelvic ultrasonography and endometrial sampling were carried out and beta-hCG levels were determined. Exclusion criteria were: inflammatory disease, abnormal cervical cytology, suspected or abnormal endometrial pathology, a history of classical caesarian delivery or myomectomy or any major

uterine surgery, any kind of uterine abnormality or intrauterine pathology (for example polyps or intrauterine fibroids sized >3 cm) and any ovarian disease for which hysterectomy was appropriate. Based on the Cavaterm plus (Pnn Medical SA, Morges, Switzerland) manufacturer's instructions, any condition associated with a myometrium thickness less than 12 mm, uterine cavity length less than 4 cm or more than 10 cm (from isthmus to fundus) and cervical canal length of more than 6 cm were also excluded. Menstrual status was defined according to pictorial blood loss assessment chart (PBAC) [11], and the level of dysmenorrhea was graded in four groups [12]. Procedures were carried out on random menstrual cycle days and based on anesthesiologist's preference patients underwent the proper kind of anesthesia. After preparation of the Cavaterm plus catheter (Pnn Medical SA, Morges, Switzerland) according to the manufacturer's instructions, the balloon was inflated with glucose 5% until a pressure of 230 ± 10 mm/Hg was reached and this pressure was maintained throughout the entire procedure. Then, the fluid was heated up to a temperature of 75°C and maintained for 10 minutes. Patients were discharged one day after the procedure. At follow-up visits 3, 6, and 12 months post operatively the PBAC score of menstrual cycle, number of days in each cycle, degree of dysmenorrhea, satisfaction from treatment and any complication after treatment were assessed. Success of treatment was defined as elimination of menses or reduction of flow to normal range (PBAC < 100).

Data were analyzed using SPSS version 21.0 statistical software (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.). Data work-up described the frequency (percent), mean \pm SD, and range. To evaluate the difference before and after ablation surgery, the Wilcoxon test was used. Changes within groups were evaluated using repeated measure analysis of variance and Friedman test. P-values less than 0.05 were considered as statistically significant.

The sample size calculation was performed to have a 95% power in predicting the response rate to treatment with assumption of 80% response based on previous studies. Based on this calculation the number of patients required to enter the study was calculated to be 52 patients.

RESULTS

In this study, 52 patients were treated with Cavaterm plus (Pnn Medical SA, Morges, Switzerland) thermal

balloon ablation and no case of balloon failure was recorded. Baseline characteristics of patients and procedure variants are summarized in Table 1. Seventy one percent of the cases had a past medical history of chronic disease (e.g. hypertension, diabetes, ischemic heart disease and hypothyroidism), while 46% had a previous caesarian section.

Most procedures were performed under general anesthesia (84%). After treatment, the volume (Figure 1), and the number of days of bleeding per month decreased significantly, from a mean of 13.6 to 4 days (P<0.001). Only 45% of patients became amenorrheic. Table 2 summarizes the before and after treatment comparison of dysmenorrhea levels.

Table 1: Baseline characteristics of the patients (n=52)

Parameter	Mean	SD	Minimum	Maximum
Age	43.5	5.7	30	57
BMI	29.4	6.0	19	52
Parity	2.63	1.14	0	7
Base line PBAC	535	639	40	3700
Base line days of menstruation	13.7	5.8	3	30
Base line Hb	11.1	1.5	6.6	13.8

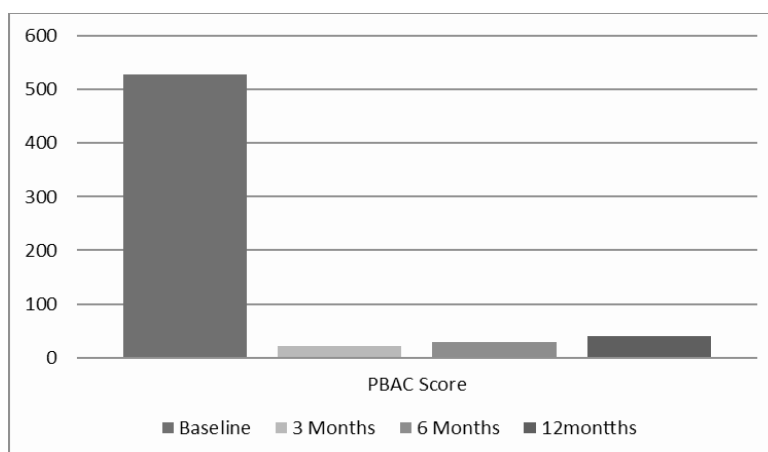


Figure 1: The trend for the volume bleeding before and after the treatment based on PBAC

Table 2: The comparison of dysmenorrhea levels before and after treatment

		Baseline	3 M	6 M	1year	P-value
Dysmenorrhea	G0	17.3%	88.2%	90%	90%	0.000
	G1	32.7%	5.9%	5.6%	5.6%	
	G2	44.2%	3.9%	3.9%	3.9%	
	G3	5.8%	2%	-	-	

*Friedman test, (n=52)

In total, the success rate of treatment was 88.5% at one-year follow-up. No intraoperative or postoperative major complications or morbidities were encountered.

A problem that affected the majority of the patients was vaginal discharge after ablation (82.7%), with a mean duration of 19.8±16.3 days. The mean duration

for resuming normal home activity was 1.5 ± 0.8 days, while the mean duration until normal professional activity was 3.7 ± 2.6 days. A total of 88% of patients were satisfied with their treatment results after one year.

DISCUSSION

The findings of this investigation support the previous findings indicating that hysterectomy can be avoided by ablation of the endometrium [5,7] and also the effectiveness of TBEA for the control of DUB [13]. The success rate of the present study (88.5%) was comparable with other studies which have used this method for destroying the endometrium [14-25] (Table 3).

Table 3: The results of previous studies regarding the success rate

Studies	Year	Country	Number	Device brand	Age	f/u	Response	Amenorrhea	Future surgery	Satisfaction
Amso, et al. [18]	2003	Multi center	187	THERMACHOICE	40.6	4-6y	86%	47%	24%	-
Lok, et al. [19]	2003	China	72	THERMACHOICE	44.9	3y	82%	9.7%	13%	-
El-Toukhy, et al. [16]	2004	UK	220	Cavaterm	41	19m	74-83%	39%	15%	83%
Andersson, et al. [20]	2007	Sweden	56	THERMACHOICE	46	31m	81%	26%	8%	-
Ahonkallio et al. [21]	2008	Finland	172	All brand	42	63m	68%	14%	24%	76%
Pai, et al. [22]	2009	India	156	THERMACHOICE	41	1-5y	76-92%	30-60%	12.7%	90%
Varma, et al. [23]	2010	UK	102	THERMACHOICE	41	30m	78%	29%	19%	-
Silva-Filho, et al. [24]	2012	Brazil	28	THERMACHOICE	43.4	5y	65%	-	24%	80%
Hrazdirová, et al. [25]	2009	Prague	92	THERMACHOICE	41.6	10y	-	38%-63%	14%	-

Also, our results indicated a higher rate of success in comparison to other methods for the ablation of the endometrium [9, 10, 26, 29, 30]. However, because the base line characteristics of the cases were similar our high success rate might be justified by a short follow-up period (Table 3).

In addition, the effectiveness of TBEA in ameliorating patient menstrual cycle irregularities in the present study has been objectivized by comparing the PBAC score and the total days of bleeding per month, but some of the previous studies have just used terms like menorrhagia or metrorrhagia to report their results with no quantization of bleeding.

Most patients in the present study showed an average level of dysmenorrhea, and the level of pain during the menses was decreased similar to other studies [8,23].

Also similar to the results of the previous studies [27-31], assessing the adverse effects, this procedure had

no major complication such as uterine perforation, heavy blood loss or thermal injuries, and no morbidity was reported. Therefore, this method is simple to use and no specific surgical skills are required with the only important condition for its success being proper patients selection [27-31]. Also, the recovery period have been reported to be shorter than in the case of hysterectomy. Consecutively, the satisfaction rate from TBEA has been high [15,18,19,21, 26]. The main limitation of the present study was the small number of patients compared to similar studies. At present, the TBEA procedure is not very popular in Iran and for this reason its efficacy was unknown among our practitioners, which explains why the sample size was small and the duration of follow-up was relatively short.

CONCLUSIONS

Thermal balloon endometrial ablation among our patients showed a similar outcome to previous reported studies. It seems that this method represents

an excellent alternative to hysterectomy, with high rate of success, a very low complications rate and high patients satisfaction.

CONFLICT OF INTEREST

The authors have no conflict of interest with the subject matter of the present study.

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