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Uterine Thermal Balloon Ablation versus Hysteroscopic Endometrial Resection in Treatment of Menorrhagia

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Abstract

Study design: A randomized clinical prospective comparative study.

Setting: The study was conducted in the Department of Obstetrics and Gynecology, between May 2010 and August 2012.

Objective: To compare the efficacy and safety of a uterine thermal balloon system with hysteroscopic endometrial resection in the treatment of selected cases of menorrhagia.

Patients and methods: The study comprised seventy premenopausal women with persistent intractable menorrhagia, selected under strict inclusion criteria. Patients were randomized into two equal groups of 35 patients each. Patients of the first group were treated by uterine thermal balloon system (35 patients), while those of the other group were treated by hysteroscopic endometrial resection (35 patients). Quantification of pre-procedural and post-procedural menstrual blood was defined by pad count and self-assessment. Twelve-month follow-up data were presented on all women and compared statistically.

Results: Twelve-month results indicated that both techniques significantly reduced menstrual blood flow with no clinically significant difference between the two groups. Success rates, as reflected by percent of patients who returned to normal bleeding or less, were comparable being 82.8% for the balloon group and 91.4% for the resection group. Procedural time was reduced significantly in the uterine balloon therapy group. Intra-operative complications occurred in three (8.5%) of the hysteroscopic resection patients, whereas no intra-operative complications occurred in the thermal balloon group.

Conclusion: Uterine thermal balloon therapy is as efficacious as hysteroscopic resection in the treatment of selected cases of menorrhagia. Further studies are needed to confirm this conclusion.

Keywords: Menorrhagia; Thermal balloon; Resectoscope; Hysteroscopic ablation

Introduction

Menorrhagia is a common problem in women of reproductive age. This disorder often exists in the absence of organic lesions of the endometrium and continues to be the underlying reason for more than one-third of the hysterectomies performed annually in the United States [1]. Over the last three decades, hysteroscopic endometrial ablation has proven to be a cost-effective and patients accepted it as a surgical alternative to hysterectomy [2-4]. Clinical efficacy of ablation compared with hysterectomy has been documented [5]. However, success rate for ablation is optimized after weeks of preoperative medical regimens aimed at thinning the endometrium and the techniques requires extensive hysteroscopic training [6]. In addition, general anesthesia is usually necessary and unique intra-operative complications result from hemorrhage, uterine perforation, and intravascular fluid overload from distention media [7,8]. Uterine thermal balloon therapy was developed in an effort to simplify the ablative procedure and to provide efficient treatment that parallels traditional hysteroscopic modalities.

Aim of the work

This work was designed to compare the efficacy and safety of a uterine thermal balloon system with hysteroscopic resection ablation in the treatment of selected cases of menorrhagia.

Patients and Methods

This work was conducted in the Department of Obstetrics and Gynecology, between May 2010 and August 2012. 70 women were enrolled in a clinical trial comparing the effectiveness of a uterine thermal balloon system (ThermaChoice, Gynecare Inc., Menlo Park, CA) to hysteroscopic endometrial resection ablation in the treatment of selected cases of menorrhagia. Patients who met entry criteria were randomized to either the hysteroscopy or the uterine balloon group in a 1:1 allocation ratio (35 patients each) by the generation of a random numbers table.

Participants were required to be at least 40 years old, and have a documented history of 3 months of intractable (failed medical therapy) persistent menorrhagia. All patients were unwilling or unable to continue medical therapy of menorrhagia and were candidates for either endometrial ablation or hysterectomy. Women with uterine leiomyomata, atypical endometrial hyperplasia, or adenocarcinoma, cavity length greater than 12 cm and those wishing to maintain fertility were excluded. Suspected pelvic infection, endometriosis, and adnexal pathology were also absolute exclusion criteria. Patients with history of previous cesarean section were not included in the study. None of the patients had previously undergone endometrial ablation.

Institutional review board approval and informed consent were

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taken. It was emphasized during the informed consent process that these modalities of treatment were designed to reduce menstrual flow, not necessarily to eliminate it. All patients had their detailed history taken. Each patient showed normal physical examination, pelvic ultrasound, and diagnostic office hysteroscopy. Endometrial biopsy results from within the previous 6 months were obtained. A normal Papanicolaou smear within the preceding year was also required.

There are several methods for menstrual blood quantification [9,10]. In our work prospective documentation of bleeding patterns was achieved by asking he patients to report number of pads used per day and number of days of flow per cycle. These data were written in special score sheet forms given to the patients assigned for trial entry. All patients were assessed postoperatively at 3, 6, and 12 months. They were queried as to menstrual volume and frequency, side effects, and need for further therapy. Accurate documentation of the score sheet forms given to each patient was a must for continuation of enrollment of the patient in the study.

No pretreatment endometrial thinning regimens were used; however, ablation was timed to be performed in the early follicular phase of the cycle (day 4-6). To reduce postoperative cramping, all patients received indomethacin 100 mg rectal suppository immediately after the procedure. All patients were operated under general anesthesia. Before ablation by either technique, a 3-minute curettage using a 5-mm suction curette was completed.

The uterine thermal balloon system (ThermaChoice; Gynecare, Inc.; Menol Park, CA) consists of a 16-cm-long catheter 4.5 mm in diameter. At its distal ends is attached a latex balloon that houses a heating element. The controller unit monitors, displays, and regulates preset intra-balloon pressure, temperature, and duration of treatment. For safety, the device automatically deactivates when pressure falls below 45 mm Hg or rises above 210 mm Hg. Optimum starting balloon pressure and treatment times were established (160-180 mm Hg/8 min) at the beginning of each procedure.

Patients were prepared and draped in the dorso-lithotomy position. Size, shape, and position of the uterus were determined by pelvic examination. Cervical dilatation, if necessary, to 5 mm and a 3-minutes suction curettage was done. The uterine balloon catheter was inserted through the cervix into the uterus and the balloon was filled with sterile fluid until the pressure reached 160-180 mm Hg. A heating element inside the balloon raised the temperature to 87 ± 0.5°C and maintained it for 8 minutes. The control unit continuously monitors and displays catheter pressure, regulates fluid temperature, and controls therapy time throughout the procedure. To ensure patient safety, if any of the preset parameters were exceeded, the heating element was automatically deactivated and the procedure was immediately terminated. When the control unit signaled that treatment was complete, the balloon was deflated and the catheter was withdrawn and discarded.

Hysteroscopic endometrial resection was performed using standard hysteroscopic equipment. Low viscosity (1.5% glycine) media were used to distend and irrigate the uterus. The absorption of fluid was monitored continuously. Electrosurgical current specifications, hysteroscopic instruments, and techniques were as preferred and used most commonly by the surgeon. All patients recovered were discharged the day of the procedure. At 3, 6 and 12 months after the procedure, a repeat physical examination was performed. Patients also presented their monthly forms describing amount of menstrual flow.

Statistical Analysis

Prior calculations indicated that a sample size of 35 subjects in each treatment arm would provide enough power and confidence to detect difference between both techniques. Data were collected and coded then entered into an IBM compatible computer, using the SPSS version 12 for Windows. Entered data were checked for accuracy then for normality, using Kolmogorov-Smirnov and Shapiro-Wilk tests.

Quantitative variables were expressed as median, mean and standard deviation. Independent samples *t*-test was used as a parametric test of significance for comparison between two sample means, after performing the Levene's test for equality of variances. Independent samples Mann-Whitney's U-test (or Z-test) was used as a nonparametric test of significance for comparison between two sample medians. All comparisons were two tailed, with a P value less than 0.05

Paired *t* test, χ^2 probabilities, and a repeated measures analysis of variance were used in appropriate cases to compare the demographics and outcomes of the two treatments groups. All tests were done at 5% level of significance.

Results

The demographic data and gynecologic history of the 70 patients who completed 12-month follow-up indicated no significant differences in age, body mass index, duration of menorrhagia, and uterine criteria between women treated by either balloon or endometrial resection (Table 1). Mean age was 45 years, with the women averaging a 10-year history of menorrhagia.

There were no intra-operative complications in the thermal balloon group. However, we appreciated three intra-operative complications in the hysteroscopy group (8.5%), two cases with fluid overload, and one patient with cervical lacerations.

Postoperatively, three cases of endometritis were attributed to the balloon therapy group (8.5%). All cases responded to oral antibiotic therapy. As for the hysteroscopy group, there were three women who experienced delayed adverse events (8.5%): two developed endometritis (resolved with oral antibiotics), and one had symptomatic hematometra (resolved with D&C).

Item	Balloon (n=35)			Hysteroscopy (n=35)		
	Mean (± SD)	Range	n (%)	Mean (± SD)	Range	n (%)
Age (y)	46.4 (4.9)	40-52		44.6 (5.2)	40-49	
Body mass index (kg/m^2)	30.7 (6.6)	25.2-40.3		32.1 (7.3)	28.1-49.6	
Years with menorrhagia	9.4 (7.3)	2-12.0		10.4 (7.9)	1.4-10.4	
Uterine criteria: Cavity depth (cm)	10.4 (1.0)	4.0-10.5		11.1 (1.2)	6.0 – 12.0	
Anteverted			28 (80)			30 (85.7)
Retroverted			7 (20)			5 (14.3)

SD = standard deviation

Table 1: Patients' demographics.

Procedure time was significantly less for the thermal balloon group, mean 15.5 ± 3.5, (range 15-20), compared with mean operative time of 30.5 ± 8.6 (range 24-37) minutes in the hysteroscopic resection group (p<0.05). Intra-operative bleeding indicated by hemoglobin drop post-operatively was higher among the hysteroscopy group, yet the difference was not significant statically. Hospital stay after operation was longer in hysteroscopy group than the balloon group, and the difference was statistically significant (Table 2).

During the 1-year follow-up, 9 out of 70 patients included in the study needed further management. Five of these patients had a 50% reduction in their bleeding flow after initial treatment, yet they were dissatisfied with the results. Three hysteroscopic resection patients underwent hysterectomy due to persistent bleeding. Four hysterectomies were performed in the balloon therapy group due to persistent bleeding, and another two patients had repeated balloon therapy for the same reason.

There was significant reduction in the menstrual flow after treatment as evidenced by reduction in number of pads/day, days/cycle, and pads/cycle in both groups (Tables 3 and 4). However, the difference between both groups was not statistically significant. The success rates, defined as percent of patients who had eumenorrhea or less 12 months after treatment, were 82.8% for the thermal balloon group and 91.4% for the hysteroscopy group. Success rates were clinically comparable and not statistically different among the two groups (Table 4). Furthermore, repeated measures analysis of variance demonstrated no difference between the two treatment arms in bleeding pattern variability at 3, 6, and 12 months after the procedure. The patients who suffered from persistent menorrhagia after treatment were considered as failures, and were destined for hysterectomy or repeat thermal ablation as mentioned above (Table 5). A significant greater percentage of women in the hysteroscopy group (40.0%) compared with the uterine balloon therapy group (20.0%) were amenorrheic at their 12-month follow up (p<0.05). Percent of patients with hypomenorrhea, eumenorrhea, and menorrhagia (failed treatment) in both treatment arms of the study were comparable.

Discussion

After medical therapy is deemed unsuccessful in the treatment of dysfunctional uterine bleeding, attempts at curative D&C often fail and frequently are only temporary solutions [11]. Hysterectomy, although curative, may be associated with a 40% morbidity rate and a mortality rate approaching 10 per 10,000 procedures performed for non-obstetric and benign causes [12]. As a result, other surgical alternatives for menorrhagia have been developed since Magos et al. [13], and DeCherney and Polan [14] initially used cryosurgery and hysteroscopy to ablate the endometrium. Uterine thermal balloon

Item	Thermal balloon group		Hysteroscopic resection group		*p*
	Mean ± SD	Range	Mean ± SD	Range	
Operative time	15.5 ± 3.5	15-20	30.5 ± 8.6	24-37	$p < 0.05$*
Hb drop %	0.8 ± 0.3	0.2-0.9	1.2 ± 1	0.5-1.6	$p > 0.05$
Hospital stay hours	8 ± 2	6-10	14 ± 8	8-20	$p < 0.05$*

*significant

Table 2: Operative findings in study groups.

Flow	Pretreatment		Post-treatment (last follow-up)	
	Mean ± SD	Range	Mean ± SD	Range
Pads/day (n=35)	12 ± 2.5[a]	7-17	4.5 ± 2.3[a]	0-10
Days/cycle (n=35)	11.2 ± 5.7[b]	7-24	4.3 ± 2.3[b]	0-12
Pads/cycle (n=35)	134.4.0 ± 48.0[c]	24-224	26.4 ± 20.8[c]	0-72

[n]=number of patients on whom both pretreatment and post treatment data were available
[a]=p<0.0001; [b]=p<0.0001
[c]=p<0.0001

Table 3: Menstrual flow before and after treatment in thermal balloon group.

Flow	Pretreatment		Post-treatment (last follow-up)	
	Mean ± SD	Range	Mean ± SD	Range
Pads/day (n = 35)	11.6 ± 2.3[a]	9-19	5.0 ± 1.5[a]	0-11
Days/cycle (n=35)	12.4 ± 4.4[b]	9-26	4.0 ± 2.9[b]	0-10
Pads/cycle (n = 35)	143.8 ± 50.0[c]	28-213	24.2 ± 22.8[c]	0-78

n=number of patients on whom pretreatment and post treatment data were available
[a]=p<0.0001; [b]=p<0.0001
[c]=p<0.0001

Table 4: Menstrual flow before and after treatment in hysteroscopy group.

Bleeding pattern	Number & (%) of Thermal balloon patients	Number and (%) of hysteroscopic resection Patients	*p* value
Amenorrhea or Light spotting	7 (20.0)	14 (40.0)	$p < 0.05$*
Hypomenorrhea	8 (22.8)	9 (25.7)	$p > 0.05$
Eumenorrhea	14 (40.0)	9 (25.7)	$p > 0.05$
Menorrhagia	6 (17.1)	3 (8.6)	$p > 0.05$
Success rate	82.8%	91.4	$p > 0.05$

*=Significant; n=35 patients for each group

Table 5: Post-treatment bleeding patterns in both groups at 12-month's visit.

therapy was developed in an effort to simplify the ablative procedure provide efficacy that parallels traditional hysteroscopic modalities [15].

We achieved comparable success rates of 82.8% and 91.4% in the thermal balloon and the hysteroscopic resection groups respectively. Those rates were consistent across the three occasions of follow up in the first year. Statistically significant differences were found between pre-treatment and post-treatment menstrual flow and duration at 3, 6 and 12 months visits after treatment in both treatments' arms ($p<0.05$). Our results were comparable to those obtained by Meyer et al. [16] who recorded success rates of 80.2% to 84.3% for the balloon and ablation groups respectively together with significant reduction in menstrual flow and duration before and after treatment ($p<0.0001$). The higher success rates recorded in other studies, reaching up to 97% in some centers, might be attributed to pretreatment use of endometrial thinning agents and the longer periods of follow up (3 years) considered in these studies [15,17-19]. Although the length of post-ablation follow-up in this study is limited to 12 months, such improvements in menstrual bleeding in other ablative studies appear to be sustained for 3 years and longer.

In a study conducted by Brun et al. [20] Amenorrhea rates were 36% (95% CI 19%-56%) and 29% (95% CI 8%-51%) in the thermal balloon and the endometrial resection groups at 12 months, respectively. Both treatments significantly reduced uterine bleeding. The median decrease in Higham score (menstrual blood loss) at 12 months was significantly higher in women treated by thermal balloon than in women treated by resection. However they concluded that thermal balloon ablation was as effective as hysteroscopic endometrial resection to treat menorrhagia, both resulting in a significant reduction in menstrual blood loss and high patient satisfaction. This conclusion is similar to our study outcome.

Success was defined as subjective reduction of menses to eumenorrhea or less and did not specifically address patients' levels of satisfaction. Physicians have to set patient expectations appropriately regarding different therapies for the reduction of menstrual flow. In our study, five of the nine women who suffered continued menorrhagia remained dissatisfied with their bleeding pattern despite an average reduction of 50% after initial treatment, hence, they requested further management.

Age is more important than type of procedure in predicting subsequent hysterectomy after endometrial ablation. Women undergoing endometrial ablation at younger than 40 years of age are at elevated risk of hysterectomy, and rather than plateauing within several years of endometrial ablation, hysterectomy risk continues to increase through 8 years of follow-up [21]. We recorded intra-operative complications in 8.5% of the roller ball patients. No intra-operative complications were recorded in the balloon group. Delayed complications were recorded in 8.5% of patients in both groups. Those figures are comparable to those of recorded by Meyer et al. [16] The American Association of Laparoscopists has reported a complication rate of 4.4% for operative hysteroscopy [22]. However, several authors have documented complication rates ranging from 5 to 10% in their studies [23-25].

In this study the primary endpoint for efficacy was the reduction of menstrual bleeding to normal flow or less. Although postoperative amenorrhea was significantly higher in the hysteroscopic ablation group, this was not determined to be a key endpoint because patients undergoing any form of endometrial ablation should not anticipate this result. The primary consideration for most menorrhagic women is to be returned to normal flow or less. Patients expecting amenorrhea as an outcome should choose hysterectomy, as this is the only procedure that can guarantee such a result. In fact, while amenorrhea rates were statistically higher among the hysteroscopic ablation patients, no statistical difference was noted between the two groups as regards hypomenorrhea or eumenorrhea.

In a study conducted by EL-Nashar et al. [26], they described predictors of treatment failure. Factors participating in failure of ablation included: age younger than 45 years; parity of 5 or greater; prior tubal ligation; and history of dysmenorrheal [26]. General anesthesia regimen was dictated in the protocol, to target the results of the operative techniques per say and to unify the inclusion criteria. The uterine thermal balloon therapy, however, could be totally performed under paracervical block, an advantage that may lower the number of intra-operative complications and reduce the cost to patients [27].

Conclusion

The uterine thermal balloon system is as effective as hysteroscopic roller ball ablation in the management of menorrhagia. As for safety, this study demonstrated that, uterine balloon therapy is at least as safe as hysteroscopic rollerball ablative therapy, if not safer. The simplicity and efficacy of the uterine thermal balloon system, as well as the advantages that the procedure holds in terms of reducing operating time, choice of anesthesia, efficacy, and relative safety makes widespread adoption of the technique likely. A reduction in the number of hysterectomies performed annually for dysfunctional uterine bleeding would lead to reductions in treatment costs and patient morbidity. Further studies with wider scale of recruited patients would provide more solid evidence.

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