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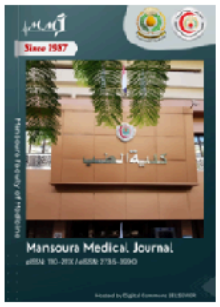

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ENDOMETRIAL THERMAL BALLOON FOR TREATMENT OF IDIOPATHIC MENORRHAGIA: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Study design : A prospective, observational clinical study.

Setting : It was conducted at the department of obstetrics and gynecology

Timing; starting on May 2005, till September 2006.

Objective : To evaluate the safety and efficacy of endometrial thermal balloon ablation in women with menorrhagia.

Patient and methods : The study included 80 women suffering from idiopathic menorrhagia to assign them for endometrial ablation or hysterectomy. The balloon catheter was placed through the cervix and after inflation in the endometrial cavity with 5% dextrose, was heated to 78±5 C°. All women had single 8-minute session. Patients was followed up at 3,6 and 12 months visits.

Results : Endometrial thermal balloon ablation procedure lead to significant decrease in menstrual flow and duration ($P<0.05$). Success rate recorded ranged from 89.5% to 90.9%. No intraoperative complications occurred, whole minor postoperative morbidity occurred in 5% of patients.

Conclusion : Thermal balloon endometrial ablation is a potentially safe and effective technique as hysterecto-

my alternative. Larger studies and follow up are required to substantiate this impression.

Key words : menorrhagia, endometrial ablation, thermal balloon, hysterectomy alternative

INTRODUCTION

Menorrhagia is the most common type of abnormal uterine bleeding, characterized by heavy and prolonged menstrual bleeding, it can have a negative impact on a woman's life style with a specific cause is identified in less than 50 percent of affected women.1 Hysterectomy guarantees amenorrhea in all women, but is costly and has a significant impact on health related quality of life immediately after surgery.2 serious operative complications occur in approximately 7% of patients treated by hysteroscopic ablation.10 Several transcervical endometrial ablation methods have been used for the treatment of menorrhagia. Transcervical resection of the endometrium, endometrial laser ablation, and hot fluid balloon ablation have all shown to be effective alternatives to hysterectomy.3,4 As each treatment has its own potential advantages and disadvantages, it is difficult to choose and advise the best individual treatment for excessive menstrual bleeding. This study has been carried out to evaluate the safety effectiveness and success of thermal balloon ablation in women with menorrhagia.

PATIENT AND METHODS

This prospective study was conducted in the department of Obstetrics and Gynecology, between May, 2005 and September, 2006. 80 women (aged 38-54 years, mean 46±6 years) underwent endometrial ablation for menorrhagia with a thermal balloon system and were followed up for at least one year later. These patients had failed medical therapy with progestins or were unwilling or unable to continue medical therapy. All patients had their detailed history taken. Each patient showed normal physical examination, pelvic ultrasound, hysterosalpingogram or diagnostic hysteroscopy. All patients had documented benign endometrial histology without atypia within the previous 6 months. A normal papanicolaou smear within the preceding year was also required. Women with submucous fibroids, pol-

yps, premalignant lesions, cavity length greater than 12 cm or wishing to retain their fertility were excluded. Suspected pelvic infection, endometriosis, and adnexal pathology and coagulation profile defect were also absolute exclusion criteria. Patients with history of uterine scar were not included in the study. No patient had previously undergone endometrial ablation. Written informed consent was taken from each patient with explanation that this modality of management was designed to reduce menstrual flow, not necessarily to eliminate it. Pre-treatment endometrial thinning regimens varied and included follicular phase timing, uterine curettage, and hormonal manipulation. Details of such treatment protocols have been previously described.(11,12,13) Number of pads used per day, and number of days of flow per cycle were ascertained. The uterine thermal balloon system (Therma Choice; Gynecare, Inc.; Menol Park, CA) consists of a 16 cm-long catheter 4.5 mm in diameter. At its distal end 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 mmHg or rises above 210 mmHg. Optimum starting balloon pressure and treatment times were established (160-180 mmHg/8min) at the beginning of each procedure.(13) Patients were prepared and draped in the dorso-lithotomy position. Size, shape, and position of the uterus were determined by bimanual examination. Length of uterine cavity was documented by uterine sound. After paracervical block with 1% lidocaine and 1-200,000 epinephrine, the cervix was dilated, if necessary, to 5mm and the uterine balloon catheter inserted through the cervix into the uterine cavity. The balloon was filled with sterile fluid until the pressure reached 160-180mmHg. A heating element inside the balloon raised the temperature to 87±0.5 c^{o} and maintained it for 8 min. 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 are 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. All patients received indomethacin 100 mg by rectum to decrease post-procedure cramping and pain. All patients were discharged within 4 hours of the procedure and were assessed postoperatively at 3,6 and 12 months about menstrual volume, frequency, side effects and need for further therapy. Success of the procedure was defined as reduction in blood flow from menorrhagia to eumenorrhea or less. Patients who failed to post their data accurately in the follow up visits were considered as lost to follow up and were excluded from the statistical evaluation for post-treatment follow up.

STATISTICAL ANALYSIS

Statistical analysis was performed using student t test for parametric continuous variables, and the χ^2 test was appropriate for categorical variables. The SPSS program (SPSS Corporation, Chicago, IL, USA) were used for statistical analysis. Probability below 0.05 was considered the cutoff for statistical significance.

Uterine character of 80 women enrolled in the study was demonstrated at table (1). Table (2) showed methods of pre-procedure uterine preparation in which 32 procedure done at the days 4-6 of follicular phase, 8 procedures were preceded by curettage, while 36 patients received danazole 400 mg/day for one month before the procedure and only 4 patients prepared by GnRH agonist before treatment. Data of menstrual flow were available from 76 women (95%) at 3 months, 72 women (90%) at 6 months, and from 44 women (55%) at one year after the procedure. Table (3) showed pre-procedure and post-procedure pad counts and days of cycle from women on whom data were available till the last (1-year) post-treatment visit (n=44). Blood flow reduction was statistically significant ($p<0.0001$). Table (4) showed the change in bleeding pattern at 3,6, and 12 months after the procedure.

Table (1): Uterine characters of the study group.

Uterine character	No (%) of patients	Mean±SD	Range
Anteverted	56 (70)	-	-
Retroverted	8 (10)	-	-
Axial	16 (20)	-	-
Length of cavity (cm)	-	8.0±1.5	6-12

Table (2): Pre-procedure uterine preparation.

	Early follicular phase*	D&C	Preoperative Danazole (400 mg/day)	GnRH agonist
No and % of patients	32 (40)	8 (10)	36 (45)	4 (5)

*Days 4-6 of the cycle

Table (3): Menstrual flow before and after the procedure at 1 year follow up.

Flow	Pre-treatment		Post-treatment (last follow-up)	
	Mean±SD	Range	Mean±SD	Range
Pads/day (n=44)	9±2.5*	5-17	4.0±2.5*	0-12
Cycle pads (n=44)	82.0±48.0*	20-215	24.4±22.8*	0-86
Days/cycle (n=44)	10.6±6.4*	7-28	4.0±2.6*	0-14

n=Number of patients on whom both pre-treatment and post-treatment data were available.
* =$p<0.0001$

Table (4): follow up bleeding pattern.

Bleeding pattern	Follow up at 3 months (n=76)	Follow up at 6 months (n=72)	Follow up at 12 months (n=44)
Amenorhea	21 (27.7)	19 (26.4)	11 (25.0)
Hypomenorhea	20 (26.3)	20 (27.8)	12 (27.3)
Eumenorhea	27 (35.5)	26 (36.1)	17 (38.6)
Menorhagia	8 (10.5)	7 (9.7)	4 (9.1)
Success rate	89.5%	90.3%	90.9%

n=number of available patients.

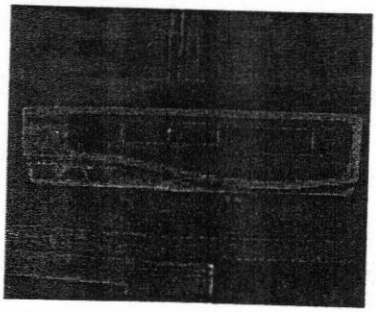

Fig. 1 : Thermal balloon system .

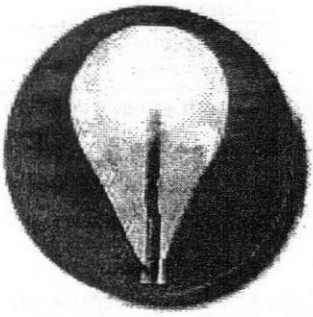

Fig. 2 : Thermachoice; Gynecare .

DISCUSSION

In this study, endometrial thermal balloon ablation was done for 80 women had severe menorrhagia as evidenced by mean pad counts as well as self-assessment of bleeding pattern. We achieved success rate of 89.5% to 90.9% which is constant across the follow up period at 3,6, and 12 months visits after treatment. Statistically significant difference was found between pre-treatment and post-treatment menstrual flow and duration from women on whom data were available till the last (1-year) post-treatment visit ($p<0.0001$). Our results were comparable to those obtained by others.[6,8,9,16] Also, a randomized controlled trial[12] found that the endometrial ablation system is as good as Nd:YAG laser when used for treatment of dysfunctional uterine bleeding. Many centers were documenting success rate of 70% to 97% for hysteroscopic treatment of menorrhagia, regardless of energy modality or technique.[20] In contrast to ours, success rate was low as 57% only as reported in study[7], that concluded only 28 patients. Only 8 women (10% of the study population underwent a second surgical procedure due to continued menorrhagia; two patients within 6 months postprocedure, and 6 patients at 1 year or more afterwards. The second surgical interference was either abdominal hysterectomy done for 6 patients, or repeat balloon abla-

tion for 2 patients. Success was defined as subjective reduction of menses to eumenorrhea or less and did not specifically address. Patients' levels of satisfaction, as some suggested.[5] Physicians have to set patient expectations appropriately regarding this and other therapies for the reduction of menstrual flow. Despite an average reduction of 45% in 3 of the 8 women who requested repeat management due to continuous menorrhagia, they remained unsatisfied with their bleeding pattern. However' some authors,[17,19] reported that patient satisfaction rate has been shown to be significantly higher in thermal destruction compared to hysteroscopy transcervical endometrial resection for menorrhagia with shorter operative time. Difficulties reported by other authors [14,15] when trying to assess menstrual volume accurately by pad count, however, to overcome this problem, patients who failed to post their data accurately in the follow up visits were excluded and considered as lost to follow up. Although one must assume that women lost to follow up could represent later treatment failure, results in 90% of patients at sex months and in 55% at 12 months are highly encouraging. In this study, no complications were recorded during procedures. 4 women had hematoma that was successfully treated with uterine sounding in the clinic. This finding in agreement to others.[12,18,24,25] A multicenter, prospective, randomized study, [21] comparing thermal balloon ablation with endometrial resection for the treatment of abnormal uterine bleeding, found no intra-operative complications and minimal postoperative morbidities. With no intra-operative complications and minor post-procedure complications rate similar to that reported for other ablative treatment methods,[23] it is likely that the safety profile of the device would lead to rapid acceptance by patients and physicians. The current study demonstrated that no significant impact was made by any endometrial-thinning regimen. It is possible that, this was due to insufficient statistical power, hence it needs further evaluation. If adequate balloon inflation is able to compress even a thick endometrial linning, it may be possible to avoid pre-operative thinning regimens,[22] which are expensive and can have side effects.

CONCLUSION

Thermal balloon ablation of the endometrium seems to be available treatment option for menorrhagia, its simplicity, efficacy, and relative safety makes wide spread adoption of the technique likely. Larger studies with longer follow-up periods are required to substantiate this impression.

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"علاج حالات النزف الرحمى باستخدام البالون الحرارى الرحمى : دراسة سريرية"

د/محمد زكى ، د/عمرو الفيومى

يعد النزف الرحمى من أكثر المشاكل الصحية شيوعا بين النساء و قد اجريت هذه الدراسة لتحديد مدى فاعلية و درجة أمان البالون الحرارى الرحمى فى علاج بعض هذه الحالات .

أجريت هذه الدراسة فى قسم النساء و التوليد فى الفترة من يناير ٢٠٠٥ وحتى يونيو ٢٠٠٦ . حيث اشتملت الدراسة على ٨٠ سيدة تعانين من النزف الرحمى فى ميعاد الدورة الشهرية مع انتظام شكل الرحم و كان حجم الرحم١٢سم أو أقل وذلك بعد استبعاد اية شبهة لوجود أورام بالرحم. وقد تم استخدام جهاز البالون الحرارى الرحمى وفقا لبرنامج التشغيل المحدد لعلاج جميع الحالات تحت التخدير الموضعى .ولم تحدث اية مضاعفات اثناء جلسات العلاج. وتراوحت نسبة نجاح العلاج بين ٨٩ر٥% الى ٩٠ر٩% وكانت هذة النسبة ثابتة تقريبا طوال فترة المتابعة التى استمرت سنة كاملة فى ٥٥% من الحالات . وعلية فقد استنتجنا ان علاج حالات النزف الرحمى باستخدام البالون الحرارى الرحمى هو علاج فعال وآمن اذا فشل العلاج الطبى بالعقاقير وذلك كوسيلة بديلة عن عملية استئصال الرحم . كما ننصح باستخدامة على عدد حالات اكثر وزيادة فترة المتابعة لتاكيد ذلك الاستنتاج.