Endometrial Thermal Balloon Ablation with the ThermaChoice System: Effect of Intrauterine Pressure and Duration of Treatment

George A. Vilos, M.D., Fatma A. Aletebi, M.D., and Mamdoh A. Eskandar, M.D.

Abstract

Study Objective. *To determine the safety and efficacy of thermal balloon therapy under variable intrauterine pressures and durations of treatment.*
Design. *Retrospective cohort study. (Canadian Task Force classification II-1).*
Setting. *University-affiliated teaching hospital.*
Patients. *Sixty-six women with menorrhagia.*
Intervention. *Eighteen patients were treated with the ThermaChoice thermal balloon system for 8 minutes at 80 to 150 mm Hg pressure, 15 were treated for 8 minutes at 151 to 180 mm Hg, and 33 were treated for 12 to 16 minutes at 151 to 180 mm Hg.*
Measurements and Main Results. *No intraoperative complications occurred and postoperative morbidity was minimal. At 12 to 24 months follow-up, persistent menorrhagia was reported in 56% of women treated at 80 to 150 mm Hg compared with 20% treated at 151 to 180 mm Hg for 8 minutes ($p = 0.01$), and in 24% treated for 12 to 16 minutes at 151 to 180 mm Hg ($p = 0.1$).*
Conclusion. *Thermal balloon endometrial ablation is a safe and effective treatment for menorrhagia. Balloon pressure greater than 150 mm Hg increased the effectiveness of treatment. Success was not affected or influenced by increasing the duration of treatment from 8 to 12 minutes or more.*

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Menorrhagia is a common problem, with a worldwide prevalence as high as 19% in women of reproductive age.[1] It can cause discomfort and disrupt life, and its impact on women's social, economic, and psychologic well-being can be severe. During the past decade endometrial ablation proved to be an effective alternative to hysterectomy. Worldwide experience indicates that the success rate of hysteroscopic endometrial ablation is in the range of 70% to 90%.[2–4] Although the procedure is effective and is associated with reduced morbidity, mortality, hospitalization, convalescence, and health care cost compared with hysterectomy, it requires additional training and surgical expertise involving a significant learning curve.[5,6] Furthermore, the operative complication rate ranged from 6% for patients undergoing their first endometrial ablation to 15% for repeat procedures.[7–9]

A thermal uterine balloon system was introduced and evaluated to minimize these potential risks and complications[10–12] and proved to be safe as well as

From the Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology and Infertility, St. Joseph's Health Center, University of Western Ontario, London, Ontario, Canada (all authors).

Address reprint requests to George A. Vilos, M.D., Department of Obstetrics and Gynecology, St. Joseph's Health Center, 268 Grosvenor Street, London, Ontario, Canada N6A 4V2; fax 519 646 6256.

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effective in properly selected women with menorrhagia.[13–19] The natural capacity of the uterus is reached at approximately 170 to 180 mm Hg, and intrauterine balloon pressure may have been a contributing factor in treatment outcome.[12] Most studies indicate that 8 minutes of treatment is safe as well as effective; however, the effect of increasing the duration of treatment from 8 to 12 and 16 minutes has not been determined. Therefore, we investigated the safety and efficacy of thermal balloon therapy under variable intrauterine pressures and duration of treatment.

Materials and Methods

Between June 1995 and June 1998, 66 women (age 26–60 yrs, mean 39 ± 6 yrs) were treated for menorrhagia using a thermal balloon endometrial ablation system (ThermaChoice; Gynecare Inc., Menlo Park, CA). Forty-eight (72%) were multiparous, 8 (12%) were primiparous, and 10 (15%) were nulliparous. Institutional review board approval was obtained, and all women gave informed consent. Each patient had preoperative routine history and physical examination, and negative cervical Papanicolaou smear, pelvic sonogram, and endometrial biopsy.

Operative Procedure

Twenty women requested general anesthesia, 43 had neuroleptic anesthesia and paracervical block, 2 had neuroleptic anesthesia only, and 1 had paracervical block only. The size, shape, and position of the uterus were determined by pelvic examination. The cervix was grasped with a tenaculum, paracervical block was performed when indicated, and the cervix was dilated to 5 mm. A 5-mm, rigid diagnostic hysteroscope was introduced and the cavity was distended with Ringer's lactate solution and evaluated.

After the balloon catheter was tested for leaks, it was inserted transcervically to touch the fundus. It was inflated with 5% dextrose in water until intrauterine pressure stabilized. Pressure-volume curves were plotted by incremental infusions of 1 ml of fluid and recording intrauterine pressure in nine patients to determine the natural capacity of the uterus, which was reached at approximately 170 to 180 mm Hg (Figure 1). The heater was activated to maintain intraballoon temperature at 87° ± 2° C. Eighteen women were treated for 8 minutes at 80 to 150 mm Hg, 15 for 8 minutes at 151 to 180 mm Hg, and 33 patients for 12 to 16 minutes at 151 to 180 mm Hg. No

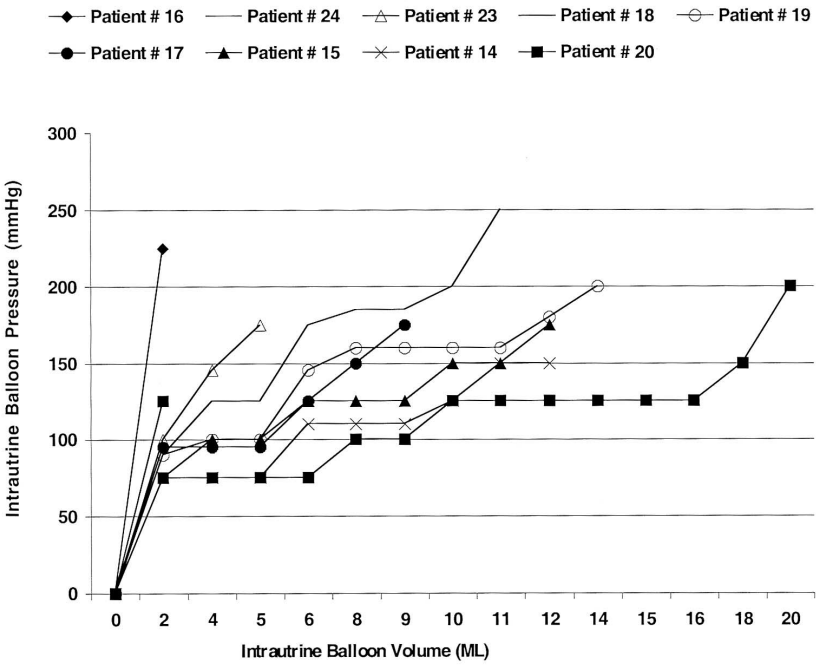

FIGURE 1. Pressure-volume curves for nine patients. The balloon was inflated in 1-ml increments of 5% dextrose in water solution.

intraoperative complications occurred, and postoperative morbidity was minimal.

Patients were evaluated in the recovery room, discharged within 4 hours, and interviewed by telephone within 24 hours to inquire about postoperative complications and adverse events. They were reviewed at 3, 6, 12, and 24 months after the procedure to assess menstrual patterns, degree of dysmenorrhea, adverse events, and need for further therapy. Treatment success was defined as reduction in blood flow from menorrhagia to eumenorrhea or less.

Statistical analysis included Fisher's exact test to compare groups and logistic regression to assess other variables that might have influenced the success or failure of the procedure.

Results

Success was defined by patient and physician as reduction in blood flow from menorrhagia to eumenorrhea (≤10 pads/day for <5 days), hypomenorrhea (≤3 pads/day), and amenorrhea. At 12- to 24-month follow-up persistent menorrhagia was reported by 56% of patients treated at 80 to 150 mm Hg compared with 20% treated at 151 to 180 mm Hg for 8 minutes ($p = 0.01$). The success of treatment was not affected or influenced by increasing the duration of treatment from 8 to 12 minutes or more ($p = 0.1$). Pressure-specific postoperative bleeding patterns were as follows: for the first 18 women who were treated for 8 minutes at 80 to 150 mm Hg, amenorrhea zero, hypomenorrhea 5, eumenorrhea 3, and menorrhagia 10; for the next 15 patients treated for 8 minutes at 150 to 180 mm Hg, amenorrhea 2, hypomenorrhea 10, eumenorrhea zero, and menorrhagia 3; for the last 33 patients treated for 12 to 16 minutes at 151 to 180 mm Hg, amenorrhea 5, hypomenorrhea 11, eumenorrhea 9, and menorrhagia 8.

Logistic regression analyses of the entire group of patients are summarized in Tables 1 and 2. Intrauterine balloon pressure was the only significant factor that affected the odds of success ($p = 0.01$). When pressure was controlled at 151 to 180 mm Hg, the patient's age, parity, uterine volume, and therapy with pretreatment thinning agents did not significantly affect the odds of success of the procedure.

TABLE 1. Logistic Regression Analysis of Possible Factors Affecting Odds of Success

Factor	Probability of Success (p)
Patient age	0.14
Intrauterine volume	0.62
Treatment duration	0.74
Intrauterine balloon pressure	0.01[a]

TABLE 2. Logistic Regression Analysis of All Possible Factors Affecting Odds of Success with Intrauterine Balloon Pressure 151–180 mm Hg

Factor	Probability of Success (p)
Patient age	0.08
Patient parity	0.90
Intrauterine volume	0.90
Treatment duration	0.70
Pretreatment thinning	0.30

Discussion

Success rates for thermal balloon ablation range between 80% and 90%, with substantial decrease in duration of menstrual flow. Many factors contribute to the success of the procedure, including high intrauterine balloon pressure, increasing patient age, and small uterine cavity.[13–19]

In this study efficacy improved with higher balloon pressure. At higher pressures the endometrium is flattened and thinned out, and tighter balloon contact with the uterine wall may allow greater local thermal injury and higher degree of endomyometrial coagulation and fibrosis. The greater the degree of fibrosis of the uterine cavity after balloon endometrial destruction by thermal coagulation, the better the effect on menstrual blood loss.

To determine the natural capacity of the uterus we performed pressure-volume curves by incremental infusions of small volume of 5% dextrose in water. The natural uterine capacity was reached at 170 to 180 mm Hg. Attempts to infuse even a small portion of fluid after this pressure would induce uterine contractions and large increases in intrauterine pressure. It is likely that, at natural capacity, the uterus assumes a more spheric shape, allowing good contact of the balloon with endometrium, and decreases blood circulation into the area, allowing deeper and more uniform energy distribution.

The effects of blood flow, balloon pressure, and blood vessel damage were studied in a geometric model of the uterus. The model predicted that higher

intraballoon pressures (>166 mm Hg) strangulate endomyometrial capillary vessels by local stress, allowing deeper penetration of thermal coagulation and necrosis.[20]

One might think that increasing the duration of treatment from 8 to12 to 16 minutes would result in deeper endomyometrial coagulation and fibrosis, which might give significantly higher success rate. However, the results of this study indicate that this results in no substantial improvement in outcome. Eight minutes seems to be the most appropriate duration, and it has been adopted as standard protocol for ThermaChoice uterine balloon therapy. Using this protocol, a prospective, randomized, comparative clinical trial of ThermaChoice versus rollerball electrocoagulation showed that the two procedures were equally effective in treating menorrhagia.[15,16]

One possible mechanism for this phenomenon is that the uterus with its intact blood supply behaves like a car radiator (heat sink). The temperature measured in various areas on the surface of the uterus reached steady state after 5 minutes and never exceeded 38° C after 8 and up to 16 minutes of treatment.[21,22] A steady-state plateau of 67° C was reached at approximately 5 minutes, indicating that longer treatment may not significantly affect clinical results.[19]

If the car radiator analogy is correct, strategies may be developed to decrease blood circulation through the uterus during balloon therapy and thus improve outcomes. A possible mechanism that might achieve this is injection of vasopressor agents such as vasopressin or epinephrine into the cervix and lower uterine segment before balloon insertion. A more logical approach might be to treat patients with a gonadotropin-releasing hormone agonist for 4 to 8 weeks before ThermaChoice treatment. These agents decrease blood circulation through the uterus by decreasing blood vessel diameter and increasing vascular resistance.[23–25] Preliminary results from a continuing clinical trial support this hypothesis (GA Vilos, unpublished results).

In conclusion, thermal endometrial ablation is a safe and effective treatment for menorrhagia. It requires similar skills to those of inserting an intrauterine contraceptive device and it can be easily mastered. Balloon pressure over 150 mm Hg increased the effectiveness of treatment. Clinical results were not affected or influenced by increasing the duration of treatment from 8 to 12 minutes.

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