THERMAL BALLOON ENDOMETRIAL DESTRUCTION: THE OUTCOME OF TREATMENT OF 117 WOMEN FOLLOWED UP FOR A MAXIMUM PERIOD OF 4 YEARS

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• Objective: To study the long-term results of treatment for menorrhagia involving the thermal destruction of the endometrium by means of a balloon catheter.

Design: Between August 1993 and December 1996, 117 women were treated and, in a prospective study, 116 (99%) of them were followed up with consultations and questionnaires. No pretreatment with gonadotrophinreleasing hormone (GnRH) analogues was given.

Setting: Gynaecology department at a university hospital.

Results: There were no immediate peroperative complications. The success rate after 25 months (range 10-49) was 94%, excluding women with peroperative intracavitary changes

and pretreatment ultrasonographically identified submucosal leiomyomas. Life-table analysis showed that the probability of assessing the treatment as "excellent" or "good" and avoiding hysterectomy over a 49-month period was 81%, and the probability of avoiding hysterectomy over the same time period was 85% when no exclusions were made.

Conclusions: For women with menorrhagia, who have no further wish for pregnancy, this study shows that thermal endometrial destruction by means of the balloon catheter technique is a safe type of day case procedure with a high success rate. Pretreatment examination is important in order to select women well suited for the treatment. A successful result 1 year after treatment implies a successful result in the long term.

OUTCOME OF THE FIRST 220 CASES OF ENDOMETRIAL BALLOON ABLATION USING CAVATERM[™] PLUS

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• The objective of this prospective study was to evaluate the effectiveness of day-case Cavaterm[™] *plus* thermal balloon endometrial ablation in the treatment of therapy-resistant menorrhagia. The study included 220 patients with a mean age of 41 years, mean parity of 2.1 and mean duration of menorrhagia of 3.2 years. A 6-mm diameter Cavaterm[™] *plus* catheter with a silicone balloon at its tip was used. The ablation time was 10 minutes at a temperature of 78 ° C. No procedure-related operative or

immediate postoperative complications were encountered. The mean follow-up period was 19 months (range 6-24 months). The amenorrhoea-hypomenorrhoea rates at the various follow-up periods ranged between 74% and 83%. At the end of follow-up, 83% of patients were satisfied with the procedure. We conclude that Cavaterm[™] *plus* is a safe and effective treatment for menorrhagia and has good patient acceptability.



LONG-TERM RESULTS IN THE TREATMENT OF MENORRHAGIA AND HYPERMENORRHEA WITH A THERMAL BALLOON ENDOMETRIAL **ABLATION TECHNIQUE**

Background and objectives: Evaluation of long-term results using a thermal balloon endometrial ablation technique to treat menorrhagia and hypermenorrhea, considered dysfunctional uterine bleedings.

Methods: A single-arm, prospective study with long-term follow-up of 48 months at the department of obstetrics and gynaecology, University of Kiel, Germany. Following hysteroscopic evaluation of the uterine cavity and fractionated curettage, the Cavaterm endometrial thermal ablation technique was performed on 70 patients over the age of 40 with menorrhagia and hypermenorrhea in whom medical treatment had previously failed. The study included a group of 10 patients with adenomyosis and uterine fibroids.



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Results: In 65 patients, a complete 48-month follow-up evaluation was possible: 58% of patients reported amenorrhea and 33% hypomenorrhea. Nine percent of patients remained eumenorrheic. Fifty percent of the small group with failed indications for the procedure had to undergo a hysterectomy.

Conclusions: The Cavaterm thermal coagulation system in the earlier mode of application (15 minutes at a temperature of 70°C and a pressure of 200 mmHg is a safe and highly effective method of endometrial ablation resulting in a minimal amount of posttreatment menstrual bleeding.

CAVATERM THERMAL BALLOON ENDOMETRIAL ABLATION VERSUS HYSTEROSCOPIC ENDOMETRIAL **RESECTION TO TREAT MENORRHAGIA:** THE FRENCH, MULTICENTER, RANDOMIZED STUDY

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• Study objective: To compare the efficacy and safety of Cavaterm thermal balloon endometrial ablation with hysteroscopic endometrial resection.

Design: Multicenter randomized trial (Canadian Task Force classification I).

Setting: Departments of obstetrics and gynaecology in French university hospitals.

Patients: Fifty-one women with menorrhagia unresponsive to medical treatment.

Interventions: Women were randomized to thermal destruction of the endometrium or to hysteroscopic endometrial resection. Women completed preoperative, 6-, and 12-month postoperative pictorial charts to determine Higham blood loss scores and a satisfaction questionnaire. Operative time, discharge time, complication rate, and resumption of normal activities were evaluated for each group.

Measurements and main results: Amenorrhea rates were 36% (95% CI 19%-56%) and 29%

(95% CI 8%-51%) in the Cavaterm and the endometrial resection groups at 12 months, respectively (ns). Both treatments significantly reduced uterine bleeding. The median decrease in Higham score at 12 months was significantly higher in women treated by Cavaterm (377, range 108-1300) than in women treated by resection (255, range -82 to 555) (p=.006). A subsequent hysterectomy for recurrent bleeding was performed in 2 women, both previously treated by resection. The rate of women reporting good or excellent satisfaction was 89% (95% Cl 72%-98%) in the Cavaterm group and 79% (95% CI 54%-94%) in the resection group at 12 months. Discharge time was significantly lower in women treated by Cavaterm, although postoperative pain at 1 hour was higher. There were no major complications in either group.

Conclusions: Cavaterm 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.