

Thermal balloon endometrial destruction: the outcome of treatment of 117 women followed up for a maximum period of 4 years

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Keywords

balloon catheter, endometrial destruction, menorrhagia, thermal coagulation.

ABSTRACT

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 gonadotrophin-releasing 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 preoperative 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.

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INTRODUCTION

Thermal endometrial destruction by means of a balloon catheter technique, the Cavaterm system (Wallsten Medical S.A., Morges, Switzerland), is a new minimally invasive alternative to hysterectomy as a method of treating menorrhagia.¹ The purpose of this treatment is to achieve reduced menstrual blood loss. Previous reports on the outcome of different balloon techniques have presented results for either a small number of patients or short follow-up periods.^{2–5} Since this is a new technique there is a need for continuous follow up. In the present study, the aim was to report

details of the clinical outcome of the treatment of 117 patients followed for up to 4 years. The objective of the study was also to evaluate the safety of the balloon catheter technique used.

SUBJECTS AND METHODS

During the period August 1993 to December 1996, 117 women, of median age 43.4 years (mean age 43.0, range 25–61), and mean parity 2 (range 0–6), were treated with thermal destruction of the endometrium by means of a balloon catheter, the Cavaterm system. This technique has been described previously.¹ Patients

were treated at the Department of Obstetrics and Gynaecology at the University Hospital in Lund, Sweden. Preliminary results concerning the first 36 women treated have been reported earlier.² The first 60 women, all treated by the authors, were enrolled in a prospective study approved by the Ethics Committee of Lund University. These patients were followed up at 1, 3, 6 and 12 months after treatment, and yearly thereafter. The next 57 patients were treated as a routine procedure by several gynaecologists at the Department. These women were followed up during the second year (10–21 months) after treatment. All follow-up investigations were performed by one of the authors (B.F.).

In 115 patients the indication for treatment was menorrhagia or menometrorrhagia. Menorrhagia is defined subjectively as excessive or prolonged loss of blood on a regular basis,⁶ or objectively as menstrual blood loss of more than 80 mL during a menstrual cycle.⁷ Menorrhagia is sometimes combined with irregular menstruation, i.e. menometrorrhagia. In another two patients the indication for treatment was heavy bleeding during postmenopausal hormone replacement therapy (HRT). Thermal endometrial destruction was given as an alternative to hysterectomy. Most of the women had, without success, tried various pharmacological preparations for the treatment of their menorrhagia, including progestogen-releasing intrauterine devices. Only women who had no future wish for pregnancy and who had no clinical suspicion of genital malignancy were treated.

The severity of menstrual blood loss was assessed subjectively by the patient, and 30 of the first treated patients were asked to collect pads and tampons for objective evaluation of blood loss, as previously published.² Patients were treated on random cycle days. No pretreatment with gonadotrophin-releasing hormone (GnRH) analogues was given. Pretreatment hysteroscopy was not routinely performed. However, a high-resolution vaginal ultrasound examination was done. The size and the location of leiomyomas were recorded. In our first 36 patients we included five patients with submucosal leiomyomas.² Later, based on the preliminary results of the treatment, we recommended that thermal endometrial destruction should not be used to treat women with submucosal leiomyomas.² Nevertheless, after the first 36 women had been treated, two women with known submucosal leiomyomas and another two with diffuse uterine enlargement asked for this treatment instead of hysterectomy.

Before treatment, the haemoglobin concentration in

the blood was analysed. Balloon treatment was preceded by a dilatation and curettage (D&C) to obtain a histopathological diagnosis and to thin the endometrium. Patients were treated if the uterine cavity length was greater than 4 cm or less than 10 cm (in the study of the first 60 patients there was no minimal length and the maximal length was 8 cm). After the first 36 cases, the duration of treatment was reduced from 30 min to 15 min. Patients were treated under general anaesthesia ($n = 95$), spinal anaesthesia ($n = 18$) or local paracervical block ($n = 4$).

During the period August to November 1997 all the women who had been treated, who had not later had a hysterectomy, either visited the Department of Obstetrics and Gynaecology in Lund or were contacted by telephone. The latter procedure was adopted if the patient had been seen during the last year or if, for practical reasons, she could not come to the Department. At follow up (visit or telephone interview), patients answered a questionnaire. The questions concerned the menstrual cycle: whether or not there was bleeding; the number of days of bleeding; the interval between menses; the date of last menstruation, and subjective assessment of each day's maximal bleeding (minimal, normal, profuse). Women were considered amenorrhoeic if they had experienced their last bleeding 3 months or more before the last follow up. If the woman's daily assessment of bleeding was always 'minimal', her monthly bleeding was considered 'minimal', and if her assessment was 'normal' and less, her monthly bleeding was considered 'normal'. Monthly bleeding was considered 'profuse' if any day was assessed as 'profuse'. Other questions concerned the patient's subjective assessment of satisfaction with the operation (excellent, good, moderate, no improvement); dysmenorrhoea and its intensity before and/or after treatment; use of contraceptives; use of iron supplements before and after the treatment, and the use of HRT after the operation. At the last visit a gynaecological examination was carried out which included transvaginal sonography to measure the endometrial thickness (double layer). During 1997, 90 women were examined at the Department. For these women a comparison was done between the endometrial thickness on that occasion and the maximal subjective bleeding assessment of menstruation prior to that visit. If leiomyomas were observed, they were measured and their location in the uterus noted. Blood samples, for analyses of concentration of haemoglobin and follicle-stimulating hormone (FSH) in serum, were taken at

the last consultation. Patients with FSH values of over 21 U L⁻¹ were considered to be postmenopausal.

In order to identify a possible predictive outcome during the first year after treatment, a comparison was made, for patients followed for 23 months or more, between the patients' subjective maximal bleeding assessments at the 1-year follow up and at the final follow up. The first 60 women treated had been followed for 23–49 months. Three of these underwent a hysterectomy before the 1-year follow-up. Another six women had a hysterectomy after the 1-year follow-up. Therefore, the comparison was made between the bleeding assessments of the remaining 51 women.

The Kruskal–Wallis test and the Mann–Whitney *U* test were used to evaluate endometrial thickness and maximal bleeding assessment. A life-table curve was plotted using the Kaplan–Meier method. The end point was the time for hysterectomy and the time when the patient first assessed her satisfaction with the treatment as 'moderate' or 'not improved'. McNemar's test was used for the comparison of iron medication before and after treatment. Wilcoxon's matched-pair signed rank test was utilized for the comparison of haemoglobin in the blood before and after treatment. Weighted kappa (κ_w) was used for measurement of agreement between subjective maximal bleeding assessment at 1-year follow up and at last follow up.

RESULTS

A total of 117 patients were treated. There were no immediate peroperative complications. The treatment is a day case procedure and 91 patients returned home on the day of treatment. Another 11 women stayed overnight due to tiredness and/or feeling nauseous. The remaining 15 patients stayed overnight for different reasons: intercurrent disease, their home was far away, or if it was late in the evening before they felt well.

Three patients developed postoperative infections. Two patients were considered to have endometritis, which was successfully treated with oral antibiotics, and the third was readmitted to the hospital due to abdominal pain and fever. She was a para 0, who had had tubal surgery because of hydrosalpinges. At transvaginal sonography before thermal destruction of the endometrium remaining hydrosalpinges were seen. She recovered after intravenous treatment with antibiotics.

Up until November 1997, 10 patients had undergone hysterectomy and one patient did not want to be

Table 1 Patients' subjective maximal bleeding assessment at final follow up 10–49 months after treatment, related to the presence of menopause and hormone replacement therapy (HRT) (*n* = 102)*. Patients who had undergone hysterectomy are not included

Bleeding assessment	Postmenopause†		HRT	Total
	Yes	No		
Amenorrhoea	7	10	13	30 (29.4%)
Minimal	2	32	4	38 (37.3%)
Normal	3	23	2	28 (27.4%)
Profuse	0	5	1	6 (5.9%)
Total	12	70	20	102

*FSH concentrations could not be obtained for four patients, bleeding minimally (*n* = 1) and normally (*n* = 3).

†A concentration of FSH in serum of >21 U L⁻¹ indicates that menopause has occurred.

followed up. The results presented below are therefore for the remaining 106 patients. All these patients, except one who visited the Department in March 1997, 12 months after treatment, were contacted during the fall of 1997. The mean follow-up period was 25 months (range 10–49). No repeat thermal endometrial destruction treatment was deemed necessary.

Table 1 shows that 30 of 102 (29.4%) patients became amenorrhoeic. Serum FSH measurements of seven of these women showed menopausal values. The remaining patients, apart from one (one of six women bleeding profusely), reported reduced bleeding of varying degree. Of 70 women who had not had their final menstruation, 42 (60%) were bleeding minimally or were amenorrhoeic at the time of follow-up.

The endometrial thickness in amenorrhoeic women was at the final visit significantly less than that in women bleeding minimally, normally or profusely (all *P* values < 0.001). The *P* value for the difference in endometrial thickness between women bleeding minimally and profusely was 0.009, and between women bleeding normally and profusely it was 0.045. There was no significant difference in endometrial thickness between women bleeding minimally and those bleeding normally (Fig. 1).

Pretreatment leiomyomas (i.e. submucosal, intramural and subserosal) were recorded in 21 women, and it was unclear whether leiomyomas were present in another five women. At the last examination, leiomyomas were seen in 33 women. Three of these, who all had leiomyomas located submucosally, were bleeding profusely.

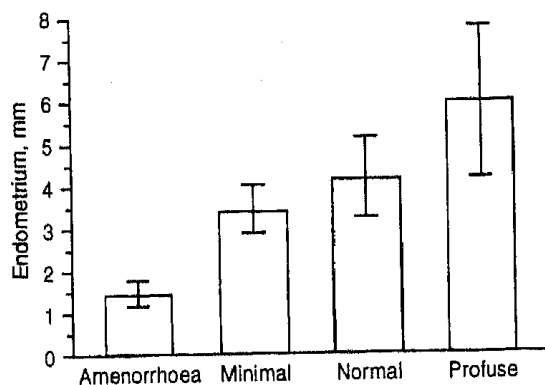


Figure 1 Mean endometrial thickness (95% CI), measured by transvaginal sonography at last examination, during 1997, for women who were amenorrhoeic ($n = 23$), or who assessed their bleeding as minimal ($n = 32$), normal ($n = 28$) or profuse ($n = 7$).

Satisfaction with the treatment was assessed as 'excellent' by 97 women (91.5%). Amongst the remaining nine women, the degree of satisfaction was 'good' in six cases (5.7%) and 'moderate' in two cases (1.9%), and one patient was not improved (0.9%). Six women were bleeding profusely. Besides the woman who was not improved, three women assessed their satisfaction with the treatment as 'excellent' and another two women as 'good'. The life-table curve shows that at 49 months after the first thermal endometrial destruction about 85% of women had undergone no further surgery and 81% of women had undergone no further surgery and assessed their satisfaction with the treatment as 'excellent' or 'good' (Figs 2 and 3).

Before treatment 47/105 of the patients (45%) had been treated with iron supplements because of

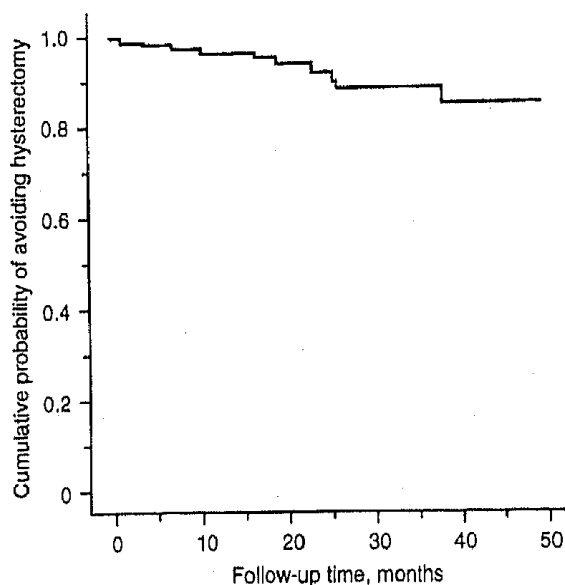


Figure 2 Life-table curve for thermal balloon endometrial destruction patients, with hysterectomy as outcome.

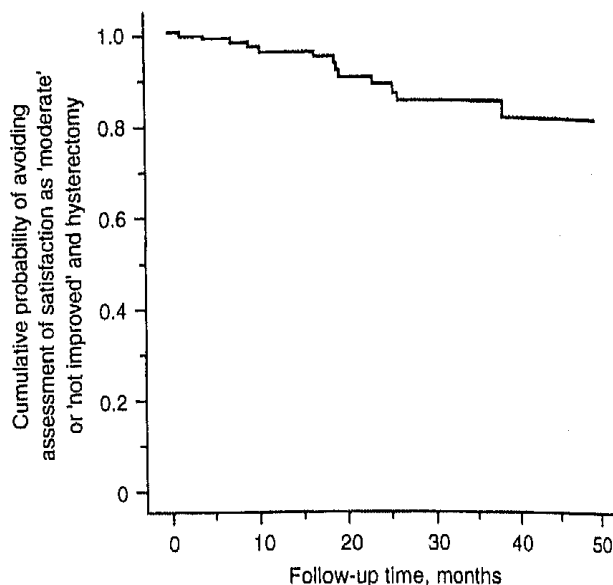


Figure 3 Life-table curve for thermal balloon endometrial destruction patients, with assessment of satisfaction with treatment as 'moderate' or 'not improved', or hysterectomy as outcome.

anaemia. After treatment, five women continued taking this medication: two, who were both amenorrhoeic, because they felt tired, and three on account of gastrointestinal disease. In 98 women, who had their haemoglobin concentration in the blood measured both before and after treatment, the haemoglobin concentration in the blood was significantly higher after treatment ($P < 0.001$).

Pretreatment dysmenorrhoea was reported by 74/103 patients (72%). Of these, 21 were amenorrhoeic at follow up. Of the remaining 53 women, 16 reported no dysmenorrhoea, 13 reported reduced severity, 12 reported no change, and another 12 reported increasingly severe dysmenorrhoea postoperatively. Eight women developed dysmenorrhoea after treatment.

A total of 94/106 women were either using contraceptives ($n = 19$), were sterilized before ($n = 30$) or at the time of treatment ($n = 5$), had a sterilized partner ($n = 13$), had a history of infertility ($n = 4$), did not have a partner ($n = 1$) or were amenorrhoeic ($n = 22$). Of 19 women who used contraceptives, 17 used condoms with varying regularity, one woman used a diaphragm and the other used the mini-pill. Consequently, 12 of 106 women (11%) had no protection against pregnancy. During the 4 years thermal endometrial destruction was performed, one pregnancy has been recorded, 22 months after treatment (Table 2). This pregnancy was diagnosed when the woman had a miscarriage 5–6 weeks after the previous menstruation. She was undergoing anticoagulation therapy on account of an artificial heart

Table 2 Details of hysterectomies performed after thermal endometrial destruction by means of a balloon catheter, between August 1993 and November 1997 ($n = 10$)

Patient no.	Months after treatment	Pretreatment leiomyoma, location*	Indication for hysterectomy	Histopathological diagnosis
33	1	No	Premalignant cells at D&C	No remaining atypical cells
6	4	No	Menorrhagia	Pedunculated leiomyoma
15	7	No	Menorrhagia	Septum
115	8	Yes, diffuse enlargement	Menorrhagia	Adenomyosis; leiomyoma
23	16	Yes, submucosal†	Menorrhagia	Pedunculated and other leiomyoma
42	18	No	Pain	Haematometra
56	23	Yes, intramural	Menorrhagia‡	Leiomyoma; regressive chorionic villi
3	25	No	Pain	Haematometra
18	26	Yes, submucosal	Menorrhagia	Adenomyosis; leiomyoma
10	37	No	Menorrhagia	Leiomyoma

*Results concerning leiomyomas and their location at transvaginal ultrasonography, performed prior to endometrial destruction.

†The pedunculated leiomyoma was assumed to be a submucosal leiomyoma.

‡The patient was undergoing anticoagulation therapy on account of a mechanical heart valve. After treatment she was bleeding normally until a miscarriage (5–6 weeks after the last menstruation) at 22 months after treatment.

valve and this might have contributed to her profuse bleeding during the miscarriage. No postoperative malignancies have been found.

There is moderate agreement, $\kappa_w = 0.487$, between the results of patients' maximal bleeding assessment at 1 year and at 23–49 months after treatment (Table 3). Six women, who had a hysterectomy after the 1-year follow up but before 23–49 months after treatment were, at 1 year after treatment, bleeding minimally ($n = 2$), normally ($n = 3$) or profusely ($n = 1$).

Table 3 Patients followed up for more than 23 months ($n = 51$) after balloon thermal endometrial destruction. Their subjective maximal bleeding assessments at the 1-year follow-up and at the final follow up are given.* Hysterectomies are not included

Final follow up (23–49 months after treatment)					
Bleeding assessment					
		Amenorrhoea	Minimal	Normal	Profuse Total
<i>1-year follow-up</i>					
Bleeding assessment					
Amenorrhoea	10	2	0	0	12
Minimal	6	14	2	1	23
Normal	2	4	7	1	14
Profuse	1	0	1	0	2
Total	19	20	10	2	51

*There is moderate agreement, $\kappa_w = 0.487$, between the results at 1 year and at 23–49 months after treatment.

Hysterectomies

During the follow-up period, 10 hysterectomies were performed. Further details can be found in Table 2. Two patients underwent a hysterectomy because of pain caused by haematometra. Six of seven women, who had their uteri extirpated on account of menorrhagia, had histopathologically diagnosed leiomyomas. Four of these leiomyomas were seen at transvaginal sonography before treatment. A fifth woman who had a hysterectomy at 37 months post-treatment had a leiomyoma which was seen growing at follow ups but had not been seen before treatment. The sixth woman (who underwent hysterectomy 4 months after treatment) had a pedunculated leiomyoma which was not identified before treatment. Instead, it was interpreted as a thick (18 mm, double layer) endometrium at transvaginal ultrasonography.

DISCUSSION

Minimally invasive methods as alternatives to hysterectomy have become increasingly popular for the treatment of dysfunctional uterine bleeding. Our study, using the balloon thermal endometrial destruction technique, is the most extensive study reported so far and has the longest follow up from a single centre. Only one of 117 women has not been followed up. The employment of different modes of exclusion affects the outcome only marginally, as seen in Table 4. The success rate after a mean follow-up time of 25 months

Table 4 Thermal endometrial destruction: success rates, at final follow-up, for 'successfully treated' women ($n = 103$)* when employing different modes of exclusion

Mode of exclusion	Success rate	
	<i>n</i>	%
None	103/116	89
Intracavitary uterine changes ($n = 4$)	103/112	92
Intracavitary uterine changes ($n = 4$) and submucosal leiomyomas seen at pretreatment ultrasonography ($n = 2$)	103/110	94

*Of 117 women treated, 116 were followed up. Two women assessed their satisfaction with the treatment as 'moderate' and one as 'no improvement' at final follow up, and 10 hysterectomies were performed before the final follow up.

(range 10–49) was 94%, excluding women with preoperative intracavitary changes and submucosal leiomyomas which were ultrasonographically identified before treatment. The cumulative probability of being satisfied and of avoiding hysterectomy 49 months after treatment is 81% when no women are excluded, and the probability of avoiding hysterectomy is 85%. An alternative endometrial ablation method, neodymium: yttrium aluminium garnet (Nd: YAG) laser ablation, has a cumulative probability of 79% of avoiding hysterectomy 6.5 years after treatment.⁸ Another alternative, transcervical resection of the endometrium (TCRE), has a success rate of 80% after 5 years, when success is defined as women who are 'satisfied' (hysterectomies included)⁹ and no further surgery having been needed.¹⁰ The success of the treatment in our study is also evident from the significantly diminished use of iron medication after treatment and the improvement in haemoglobin concentration in the blood.

In our study, two women had preoperatively diagnosed submucosal leiomyomas/diffuse uterine enlargement. One of these women was treated before it became apparent that balloon thermal destruction of the endometrium was not suitable when women had submucosal leiomyomas. We do not now recommend this treatment for women with submucosal leiomyomas. Pretreatment examination is important. Although we did not use hysteroscopy routinely before treatment we wrongly included only three women. This might have been avoided if hysteroscopy had been employed. We now recommend pretreatment hysteroscopy or saline infusion sonography, when in doubt after transvaginal sonography.¹¹ Also, haematometra should

perhaps be treated by cervical sounding instead of hysterectomy.¹²

It is inevitable that some patients will reach the menopause during the follow-up period. In this study, 20/102 women (20%) were using HRT at follow up. These results are comparable with those from a study of long-term follow up after resection.⁹ In our study, another 12/102 women (12%) were postmenopausal at the final follow up, as seen from FSH measurements. Some women in the perimenopause are presumably included in this group. The perimenopausal period is a time during which postmenopausal levels of FSH may be seen, despite continued menstrual bleeding.¹³

The mean age at treatment with minimally invasive methods for menorrhagia is approximately the same with different methods.^{8–10} It can therefore be assumed that approximately the same percentage of patients will reach the menopause, irrespective of the endometrial destruction method used.

An absolute contraindication for balloon thermal endometrial destruction is a desire for future pregnancy. Nevertheless, it is not impossible to become pregnant after this treatment. One woman in this study had a pregnancy which ended in an early miscarriage. We estimate that 11% had the potential to become pregnant during the study period. It is difficult to draw conclusions regarding the risk of pregnancy in this small group of women without contraception. Some authors recommend sterilization at transcervical endometrial resection.¹⁴ Concerning balloon thermal endometrial destruction, our opinion is that recommendations regarding the use of contraceptives after treatment, or sterilization, must be made in each specific case.

In this study, the effect on dysmenorrhoea is variable, although it may be concluded that thermal endometrial destruction does not increase the percentage of patients with dysmenorrhoea.

Adenomyosis is one of the reasons for treatment failure. Another is leiomyomas not seen before the treatment which start to grow, as well as leiomyomas not located submucosally at the time of treatment which, after treatment, grow towards the uterine cavity. None of these reasons for failure can be foreseen. In this study, seven women in the first 36 women treated had a hysterectomy. In the following 81 women who were treated, only three had a hysterectomy. One of the reasons for this discrepancy is that, after the first 36 women had been treated, women who had intracavitary leiomyomas or submucosal leiomyomas were not recommended to have this treatment.

In a previous study,¹¹ we have seen that the greater the degree of fibrosis of the uterine cavity after balloon endometrial destruction, the better seemed the effect on menorrhagia. Though in this study measurement of endometrial thickness was done on arbitrary cycle days, the endometrial thickness was significantly less in amenorrhoeic women than in women who were bleeding. Therefore, if the endometrium at transvaginal sonography at follow up is very thin, it may be assumed that the results of the treatment are good. Since there is at least moderate agreement between 1-year and final success rates, the former could perhaps be used to predict the latter. Final success would then be expected following success at 1 year postoperatively.

The masking of the development of endometrial cancer following endometrial destruction has been discussed. In a review of endometrial malignancies after endometrial ablation it was found that, for endometrial cancer, pre-existing endometrial hyperplasia was a common factor.¹⁵ Perhaps patients with hyperplasia in the uterus, diagnosed at D&C preceding the treatment, should be followed extra carefully. If pathological endometrium is present, this is presumably indicated through abnormal uterine bleeding. If this happens, patients should be thoroughly examined as usual in the case of abnormal bleeding. If the bleeding area is closed, i.e. blood can not pass through the cervix, pain will probably develop, as in the two cases of haematometra in this study.

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