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Thermal endometrial ablation in dysfunctional uterine bleeding: an economic comparison of bipolar ablation and balloon ablation

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Abstract *Objective:* A bipolar radio-frequency impedance-controlled endometrial ablation system is more effective than balloon ablation in the treatment of dysfunctional uterine bleeding. The aim of the present study was to compare the costs of both treatments, and to perform a cost-effectiveness analysis. *Study design:* An economic evaluation was set up alongside a randomised clinical trial comparing bipolar radio-frequency endometrial ablation and balloon ablation in 126 patients with dysfunctional uterine bleeding. Data on resources used for treatment and lost production time were prospectively collected, and costs of both treatments were calculated. *Results:* Mean direct medical costs per patient were €1638 for bipolar ablation and €1545 for thermal balloon ablation with a mean difference of €93 (95% CI €45–140, *P*-value 0.01). Mean indirect medical costs were just over €200 in each group. Incorporation of the costs of post-ablation hysterectomies resulted in mean costs of €2006 and €2053 in the balloon group (*P*-value 0.01). In the balloon group, the cost per satisfied patient was €2333 compared to €2112 in the bipolar group. Similarly, in the bipolar group the cost per amenorrhoeic patient

was €4361 and in the balloon group €12831. *Conclusions:* The direct costs of bipolar ablation were higher than the costs of balloon ablation. However, after inclusion of the retreatment costs, bipolar ablation was less expensive than balloon ablation.

Keywords Menorrhagia · Dysfunctional uterine bleeding · Endometrial ablation · Economic analysis · Cost-effectiveness

Introduction

Excessive menstruation is a frequent problem in premenopausal women. Menorrhagia can be caused by intracavitary abnormalities, but it also occurs in women without such abnormalities. Women with periodic uterine blood loss of >80 ml and a normal uterine cavity are said to have dysfunctional uterine bleeding. Ablation of the endometrium is an effective treatment in women with dysfunctional uterine bleeding [1–3].

We have previously reported on a randomised clinical trial comparing a bipolar radio-frequency impedance-controlled endometrial ablation system and thermal balloon ablation, which are both second generation endometrial ablation devices. At one-year follow-up, amenorrhoea rates were 43% (34/83) in the bipolar group and 8% (3/43) in the balloon group (Relative Risk (RR) 0.17, 95% confidence interval (CI) 0.06–0.52). Moreover, 12 months after the start of treatment 90% of the patients in the bipolar group were satisfied with the result of the treatment versus 79% in the balloon group (RR 0.46, 95% CI 0.1–1.1). We concluded that the bipolar ablation system was more effective than balloon ablation in the treatment of dysfunctional uterine bleeding.

In view of these data, we feel that the bipolar system should be the ablation treatment of choice in women with dysfunctional uterine bleeding, if the costs of this treatment are acceptable. In our randomised clinical trial, we also collected data on the use of resources for

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both treatments. The aim of the present paper was to report on the costs of both treatments, and to perform a cost-effectiveness analysis.

Materials and methods

Women with dysfunctional uterine bleeding, indicated on a pictorial chart with a Higham score of 150 points or more, were eligible for the trial [4]. The study was performed at the Máxima Medical Centre in Veldhoven, The Netherlands, between November 1st 1999 and July 1st 2001. All participants gave written informed consent before enrolment. Saline infusion sonography or diagnostic hysteroscopy were required to confirm a normal uterine cavity with histological benign endometrium and a uterine depth of between 6 and 11 cm. All women had to have a normal pap smear, a negative chlamydia test of the cervix, and a premenopausal follicular stimulating hormone (FSH)-level of less than 40 IU/l. Exclusion criteria were documented as coagulopathies, patients treated with anticoagulants, a desire to preserve fertility, and prior uterine surgery (except low segment caesarean section).

After a patient had given this consent, she was scheduled for surgical intervention. Randomisation was performed in the operating theatre by one of the authors (MB) just before the beginning of treatment. The randomisation sequence was computer-generated, and in order to conceal the allocation, opaque sealed envelopes were used. Patients and investigating doctors were unaware of the result of the randomisation, and remained uninformed of the ablation method used during the study. The ratio of women allocated to bipolar radio-frequency ablation to women allocated to balloon ablation was 2:1. The reason for the 2:1 ratio was to enable rapid information to be obtained on the performance of the new bipolar radio-frequency technique.

The ablation treatments were performed in both arms by one gynaecologist (MB). Patients received no medical pre-treatment, and the ablation was not timed in the menstrual cycle. All patients had Naproxen 250 mg 12 h and 1 h before treatment. The methods of treatment have been described earlier (Chapter 7). In short, the bipolar endometrial ablation system consists of a generator and a disposable NovaSure device (Novacept, Palo Alto, CA, USA). The NovaSure radio-frequency generator is a constant power output generator with a maximum energy delivery of 180 W. The device consists of a single use, conformable bipolar electrode mesh, mounted on an expandable frame that can create a confluent lesion involving the entire interior surface area, within the cavity of the uterus.

The balloon ablation system (ThermaChoice I Gynecare, Somerville, NJ, USA) consists of a generator and a balloon catheter [5]. The balloon is inserted into the uterine cavity. A thermistor in the balloon is used to raise the temperature of the fluid to 87 °C (170 °F) for a period of 8 min, while maintaining the pressure of the balloon at 170 mmHg or higher. Endometrial thinning

was performed by aspiration curettage prior to the balloon treatment procedure [6].

Follow-up visits were carried out at the outpatient clinic at three, six and 12 month intervals after the initial treatment. At these, the patients were seen by a doctor who was unaware of the treatment that had been performed. At each visit, the presence of amenorrhoea was registered, and patients expressed their satisfaction with the treatment result. Levels of satisfaction were categorised as completely satisfied, satisfied, doubtfully satisfied or not satisfied. Furthermore, it was noted as to whether a reintervention had been performed, or whether a patient had started using oral contraceptives.

After treatment of 44 patients, a technical failure in the bipolar generator was discovered. No analysis of results was performed until the reason for the error was established. The precise moment at which the error occurred was not known, although it was clear that during the first five bipolar radio-frequency treatment procedures, the generator had worked properly.

Costs

The mean costs of each treatment were calculated by multiplying used resources and resource unit prices. Standardised unit costs were calculated for the Máxima medical centre. A distinction was made between costs of medical interventions (direct costs) and costs resulting from productivity losses (indirect or time costs) [7]. Resource utilisation was assessed using individual data in the case record forms. Resources counted were: duration of surgical procedure, days of day-care, extra hospital stay from the moment of randomisation in days, visits to the outpatient clinic, repeat ablation and hysterectomy. Each patient was sent a questionnaire concerning professional and non-professional domiciliary care, transportation costs, use of sanitary towels, visits to the general practitioner, and productivity loss. Trial specific resource utilization and associated costs were excluded from the analysis.

Resource unit prices reflected: unit costs for staff, materials, equipment, housing, depreciation, and overheads, the latter both at department level and at hospital level. Unit prices were calculated for all medical resources accounted for. Since in the Dutch health care system the hospitals bill the patient's insurance company and they are managed on a non-profit basis, the calculated costs are an appropriate measure of the societal cost of direct medical care.

Prices were calculated and reported in European Euros (€). Since all costs were realised approximately 12 months after treatment, a correction for differential timing of economic costs was not performed. Direct costs were calculated using data from all of the patients included in the trial, whereas calculation of total costs was limited to those patients who completed the questionnaire. The CI around the mean costs of each treatment and around the difference in costs were obtained

using a bootstrap sampling procedure [8]. For this purpose, 2000 random samples with replacement were drawn from the distribution of total costs in the two treatment groups.

Cost-effectiveness

In the cost-effectiveness analysis, we used satisfaction with treatment result and the number of amenorrhoeic patients as measures of the effectiveness of the ablative treatments. We calculated the cost per patient satisfied with the treatment result after one year, and the cost per amenorrhoeic patient after one year.

Sensitivity analysis

Sensitivity analysis was performed to explore the effect of plausible changes in key variables on the results of the cost analysis. Key variables considered were: effectiveness of the bipolar treatment, cost of the bipolar device and the time the generator had been in use, the number of hysterectomies due to dissatisfaction with the treatment result, and the number of ablative procedures performed per year at the centre. The latter factor might be important, since the high cost of the hardware might affect the cost per treatment if the number of procedures per year is relatively low.

In view of the technical failure in the bipolar generator (discovered after inclusion of 44 patients), we also performed a cost-effectiveness analysis in which we used data from the patients that were randomised after the failure was corrected.

Results

Patients

Between November 1st 1999 and July 1st 2001, 126 women were included in the trial, of which 83 were

allocated to the bipolar group, and 43 to the balloon group. Table 1 shows the baseline characteristics of the two groups. There were more patients with a retroverted uterus in the bipolar group (16% vs. 9%), but otherwise the two groups were comparable.

One patient that had already been randomised to the bipolar treatment panicked in the operating room and refrained from the ablative treatment. One year later she had not been treated. Her menstrual blood loss was still heavy but she wanted no further treatment. There were no complications during treatment in both arms of the study. Four patients had a hysterectomy in the bipolar group and four in the balloon group (RR 0.47, 95% CI 0.07–3.3).

Resource units used for each treatment and their prices are presented in Table 2. Whilst the mean duration of the bipolar procedure was 9.0 min (range 5–32 min), treatment with the balloon procedure lasted 14 min on average (range 9–40-min). In both groups, one patient had to be admitted to the hospital overnight due to pain and nausea after the treatment. In the bipolar group there were three patients in whom two disposable devices were required, whereas this was the case in one patient in the balloon group.

The questionnaire on domiciliary care and productivity loss was returned by 83 patients (66%). There were no significant differences between responders and non-responders with respect to baseline characteristics or treatment allocation between the two groups. In the group allocated to bipolar ablation, 16 patients (20%) had domiciliary care from friends or family after one year, whereas in the group allocated to thermal balloon ablation, four patients (9%) had domiciliary care from friends or family. The mean duration of help was 6.6 h in the bipolar group versus 4.9 h in the balloon group. Out of the 52 responders in the bipolar group, there were 34 (66%) who used sanitary towels in the first year after treatment, as compared to 28 out of 31 (90%) in the balloon group.

The costs of the bipolar device were €850 per piece, as compared to €735 in the balloon group. The costs of the

Table 1 Baseline characteristics

	Bipolar group (<i>N</i> = 83)	Balloon group (<i>N</i> = 43)
Age (years) (mean, SD)	42.6 (4.9)	43.1 (3.8)
Duration of menstruation (days) (mean, SD)	7.7 (2.5)	8.1 (2.2)
Number of patients with clots (%)	76 (92%)	38 (88%)
Duration of clots (days) (mean, SD)	3.5 (2.0)	3.3 (2.0)
Pictorial chart (median, min, max)	515 (150–3401)	660 (188–3220)
Dysmenorrhoea		
Moderate	17 (21%)	13 (30%)
Severe	34 (41%)	16 (37%)
Uterus		
Anteverted	49 (60%)	33 (77%)
Midposition	10 (12%)	4 (9%)
Retroverted	13 (16%)	4 (9%)
Missing	10 (12%)	2 (5%)
Haemoglobin (mmol/L) (mean, SD)	8.0 (0.83)	7.9 (0.90)
FSH (IU/L) (mean, SD)	6.5 (3.5)	6.1 (4.3)

Table 2 Average use of resources needed for bipolar ablation and thermal balloon ablation

	Unit price (Euro)	Bipolar group (n = 83)	Costs for bipolar group (Euro)	Balloon group (n = 43)	Costs for balloon group (Euro)
Duration of surgical procedure (min)		8.9 ^a		14.4 ^a	
Duration of theatre time	8.7 min ⁻¹	30.9 ^a	259.4	36.4 ^a	319.2
Cost of gynaecologist			98		98
Device (hardware)	15,000/8000		60		32
Device (disposable)	850/735	86 ^b	880.7	44 ^b	752.1
Day care	302	83 ^b	302	43 ^b	302
Admission to hospital	143	1 ^b	1.4	1 ^b	3.3
Outpatient visits	29	1.24	36.0	1.33	38.4
<i>Direct costs</i>			1638		1545
Data from questionnaire		(n = 52)		(n = 31)	
Sanitary towels	5.0 per month	34 (66%)	19.7	28 (90%)	33.5
Lost labour procedure (mean number of days)	64	1.0	63.9	1.2	78.0
Lost labour outpatient visit	20	1.24	24.8	1.33	26.5
Visits to general practitioner	23	0.57	13.3	0.73	16.7
Domiciliary care from family/friends	15	6.88 ^c	103.2	4.94 ^c	74.1
<i>Indirect costs</i>			225		229
Total costs			1862		1774
Hysterectomy	3000	4 ^b	144	4 ^b	279
			2006		2053

^a Operation time in minutes ^b Absolute numbers ^c Price per day professional domiciliary care ^d Including €10 transportation costs. Values are mean numbers unless stated otherwise

hardware for the bipolar system were €15,000, versus €8000 for the balloon system. With 50 ablative procedures per year, and a system lifetime of five years, this gives a cost of €60 per treatment in the bipolar group and €32 in the balloon group. The costs per lost day of labour were set at €64 [9].

The mean direct costs per patient allocated to the bipolar group were €1638 (Table 2). The mean direct costs in patients allocated to balloon ablation were €1545. The mean difference between both groups was €93 (95% CI €45–€140, *P*-value 0.01). The mean indirect costs were €225 and €229, respectively (*P*-value 0.91). The mean total costs for the bipolar group were €1863 and for the balloon group €1774.

The amenorrhoea rates were 43% in the bipolar group and 8% in the balloon group. This resulted in a cost-effectiveness ratio of €4335 per amenorrhoeic patient in the bipolar group versus €22,175 in the balloon group (Table 3). The satisfaction rates of 90% in the bipolar group and 79% in the balloon group resulted in cost-effectiveness ratios of €1820 per satisfied patient in the bipolar group versus €1956 per satisfied patient in the balloon group (Table 3). Sensitivity analysis did not alter the outcome of the analysis.

At the one-year follow-up, four patients in each group underwent a hysterectomy. Due to this interventions, the mean total cost per patient increased to €2006 in the bipolar group and €2053 in the balloon group, whereas the number of satisfied patients rose to 95% in the bipolar group and 88% in the balloon group. The cost-effectiveness ratios became €2112 in the bipolar group and €2333 in the balloon group.

After excluding the 44 patients that were included before the defect in the bipolar generator was detected, the mean total costs were €1845 in the bipolar group

versus €1774 in the balloon group, a marginal change compared to the costs for the whole group. After excluding the bipolar procedures performed with the defective bipolar generator, the satisfaction rates in the bipolar group increased to 94% and the amenorrhoeic patients to 55%. In the bipolar group, the costs per amenorrhoeic patient dropped to €1972, whereas the costs per satisfied patient dropped to €1371.

Discussion

This study compared the costs of a bipolar endometrial ablation system with those of balloon ablation in the treatment of dysfunctional uterine bleeding. We found statistically significantly higher direct and total costs after the one year follow-up for the bipolar ablation compared to the balloon ablation, although the economic relevance of the difference was only marginal, with this difference being only €88 for the total cost. If the hysterectomy patients were included in the calculation, the costs of the balloon ablation were higher than the bipolar ablation. With respect to amenorrhoea and with respect to patient satisfaction, the cost-effectiveness was significantly better in the bipolar group compared to the balloon group.

In the Dutch health care system, costs of health care are paid by insurance companies (private or government-owned companies). The hospitals provide care to the patients and subsequently bill the insurance company. However, since the billing statements are not based on actual cost calculations, they do not represent real costs. Therefore, we calculated the real costs that had to be made to perform endometrial ablation in patients with dysfunctional uterine bleeding.

Table 3 Cost-effectiveness of ablative treatments

	Bipolar ablation	Balloon ablation
Result of initial treatment		
Amenorrhoeic patients	43%	8%
Satisfied patients	90%	79%
Direct medical costs	1.638	1.545
Direct medical costs per amenorrhoeic patient	3.809	19.313
Direct medical costs per satisfied patient	1.820	1.956
Total costs	1.862	1.774
Total costs per amenorrhoeic patient	4.335	22.175
Total costs per satisfied patient	2.071	2.246
Result of treatment strategy in the first year		
Amenorrhoeic patients (including hysterectomy)	46%	16%
Satisfied patients (including hysterectomy)	95%	88%
Costs after one year (including hysterectomy)	2.006	2.053
Total costs per amenorrhoeic patient	4.361	12.831
Total costs per satisfied patient	2.112	2.333

One of the cost variables considered was the number of ablative procedures performed per year at the centre. 50 ablations a year seems a realistic estimate. The costs of a specific ablation depend on the costs of the device and on the costs of the generator. The lifetime of the generator might be important, since the high costs of the hardware might affect the costs per treatment when the number of procedures per year is relatively low. We assumed that the generator would be in use for five years, which resulted in hardware costs for the bipolar device of €60, compared to €32 in the balloon group. Thus, these relative low hardware costs of the devices will result in only a limited impact from the number of procedures per year on the cost-effectiveness. Varying the number of procedures per year to 25 or 100 did not alter the outcome of the analysis.

The cost of the operating room was derived from the costs of anaesthesiologists and operating room staff, overhead costs, management staff, operation room housing, and number of days used. A mean bipolar procedure lasted 9 min compared to 14 min for a balloon procedure. The time needed for anaesthesia, to prepare patients and to change patients was fixed at 22 min. As a consequence, eight bipolar procedures can be performed in 4 h operating time, as compared to 6.5 balloon ablations. This resulted in costs of €259 for a bipolar ablation and €319 for a balloon ablation. Other authors have reported a procedure time for bipolar procedure of 4.2 min, which is even shorter than the 9 min reported in the present study [3]. This can lead to an extra reduction in the cost of the bipolar procedure.

Our study was limited to cost of the initial treatment and to a relatively short period of follow-up of 12 months. Cost of reintervention is an important additional issue in the economic evaluation of the treatment of dysfunctional uterine bleeding. For instance, in the comparison between bipolar ablation and balloon ablation, bipolar ablation had a significant higher satisfaction and amenorrhoea rate compared to balloon ablation, which may result in a lower reintervention rate, thus making the bipolar method a less

expensive strategy. A longer follow-up will be needed to shed further light on reintervention rates and additional costs in both strategies.

Previous studies have suggested that ablation often reduces costs considerably compared to hysterectomy [10–13]. The key long-term resource cost, however, is the retreatment rate of women in the ablation group. In the Bristol randomised trial that compared endometrial resection versus hysterectomy, the total costs of resection were 53% of the costs of hysterectomy after four months, whereas that percentage had increased to 71% at a mean follow-up of 2.2 years [12, 13]. An important issue is whether this cost gap will narrow further, but previous studies have demonstrated that retreatment rates do not increase significantly two years after the initial procedure [1]. It is likely that the cost advantage of endometrial ablation over (abdominal) hysterectomy will remain, whatever the period of follow-up.

However, the crucial issue to consider is the relative cost-effectiveness of treatments of dysfunctional uterine bleeding, which requires not only an assessment of costs but also of benefits. Therefore, we calculated the costs of bipolar and balloon ablation in relation to amenorrhoea and satisfaction. Figure 1a shows the costs of both strategies compared to the percentage of patients with amenorrhoea at one year of follow-up. Figure 1b also shows the costs for both strategies, but instead compared to the percentage of satisfied patients.

In Fig. 1a and b, we also incorporated data from the study of Hurskainen et al [14], who has previously reported on the cost-effectiveness of the levonorgestrel-releasing IUD and hysterectomy in the treatment of menorrhagia. To facilitate this comparison, we used the lower estimate of productivity loss reported in the Finnish study (for the IUD group €1227 and for the hysterectomy group €3067).

From Fig. 1a, it can be seen that the percentage of patients with amenorrhoea after one year is comparable in the IUD strategy and the bipolar ablation groups. The balloon ablation is inferior to the other two strategies, with a far lower percentage of patients being amenorrhoeic at a cost similar to that of the bipolar

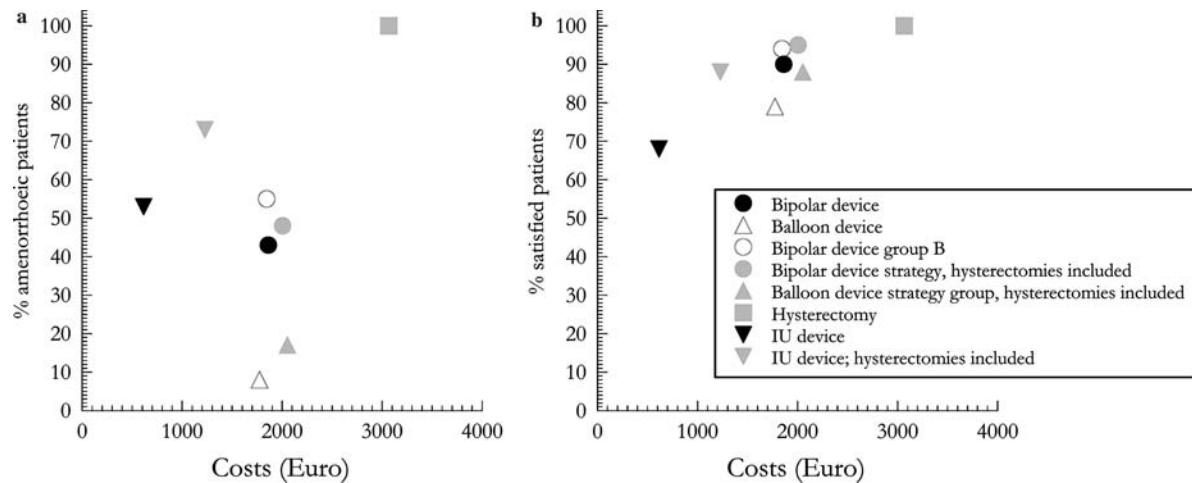


Fig. 1a–b Cost-effectiveness of the evaluated strategies (in terms of amenorrhoea, **a**, and satisfaction, **b**), together with the cost-effectiveness of hysterectomy and a levonorgestrel-releasing device.

Data on the two latter treatments were obtained from Hurskainen et al [14]. Bipolar B group consist of patients who were randomised after the failure with the NovaSure generator had been corrected

ablation. Figure 1b shows that the satisfaction rates after bipolar ablation were slightly better at 12 months follow-up than the satisfaction rates after balloon ablation, and that the cost-effectiveness ratios were comparable. A satisfaction rate was not reported in the Finnish study. We assumed that the 68% of the patients who had their IUD in situ at one year of follow-up were satisfied with their treatment, whereas the remaining 32% were not. Taking into account the cost of the hysterectomies that were performed in 20% of the patients in the IUD group, the cost-effectiveness ratio became comparable to that of the ablative strategies reported in our study. Figure 1a and b also show that hysterectomy is not cost-effective as a first choice treatment compared to either a levonorgestrel-releasing device or thermal ablation.

In the Finnish study, no distinction was made between vaginal, abdominal, or laparoscopic hysterectomy. The vaginal hysterectomy reduces hospital stay compared to abdominal hysterectomy, whereas the duration of the surgical procedure of a vaginal hysterectomy is shorter than the duration of a laparoscopically-assisted hysterectomy (LAVH) [15]. An economic evaluation comparing LAVH and abdominal hysterectomy showed LAVH to be significantly more expensive [16]. These two studies support the conclusion that the vaginal hysterectomy is the most cost-effective route for hysterectomy. As far as we know, a comparison of the cost of vaginal hysterectomy with those of abdominal hysterectomy and LAVH has not been performed. Theoretically, an uncomplicated vaginal hysterectomy can result in a day-care hospital admittance and will substantially reduce the costs. However, Fig. 1b shows that hysterectomy will be cost-effective if this major operation does not cost more than €2000.

The potential for second generation ablation techniques to be performed under local anaesthesia can generate a considerable cost advantage. This approach

will save costs, because an expensive operating theatre, with its equipment and trained staff, is not necessary at the outpatient clinic. The operation time for bipolar radio-frequency endometrial ablation was almost half that of the balloon procedure. This may be an important advantage in an outpatient setting, even though a cervical dilation of up to 7.5 mm is necessary to perform the bipolar technique, and no cervical dilation is needed for balloon ablation. Balloon ablation has been performed under local anaesthesia [17]. Only 61% of the patients would be happy to undertake the procedure again under local anaesthesia, which is a rather low percentage. Future research on the acceptability and costs of bipolar ablation as an outpatient procedure should be performed.

In conclusion, the direct costs of bipolar ablation were higher than balloon ablation. However, when the costs of retreatment were factored in, the bipolar ablation was found to be less expensive than the balloon ablation. Subgroup analysis showed higher cost-effectiveness per satisfied and amenorrhoeic patient for the bipolar group than for the balloon group.

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