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ORIGINAL ARTICLE

J. W. Barrington · F. Bano · M. Swart · J. Montgomery

Patient outcomes following an endometrial thermal balloon ablation (thermochoice) procedure for menorrhagia in a day surgery unit

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Abstract This study was carried out to assess the efficacy, complication rate and acceptability of endometrial thermal balloon ablation in a District General Hospital in the South West of England.

Keywords Endometrial thermal balloon ablation · Menorrhagia · Gynaecology

Introduction

Heavy menstrual bleeding or menorrhagia is a common deliberating symptom for women. It is estimated that 1 in 20 women aged 30–44 years will consult their general practitioner each year with menorrhagia, which accounts for 12% of all gynaecological referrals in the United Kingdom [1]. Although the initial recommended management is medical, these guidelines are often not followed, and recent evidence suggests that only 58% of women receive such treatment before referral to a specialist [2]. However, medical treatment is often unsuccessful, and surgery may offer the only permanent cure.

Once referred, 60% of women will have a hysterectomy within 5 years [3]. The rate of hysterectomy is approximately 52,000 women per annum in the United Kingdom, of which the majority (82%) are performed abdominally [4]. Approximately half of these hysterectomies can be expected to be performed for menorrhagia [5].

However, hysterectomy is a medical procedure with a recognised morbidity and mortality [6]. Alternative techniques have therefore been developed to try to reduce the symptoms of menorrhagia in a simple, safe and equally effective manner. Laser endometrial ablation was first developed in 1981 [7], followed by electro-surgical techniques such as trans-cervical resection of the endometrium (TCRE) in the mid 1980s. Although successful, TCRE does require specialist surgical skills and training, and it has associated complications including cerebral oedema [8], uterine perforation, haemorrhage and even death [9].

Newer second generation ablative techniques have therefore been developed [10], but are not widespread, and it is suggested that they account for only 2,000 out of an estimated 16,000 endometrial ablative procedures per annum in the United Kingdom [11]. They are, however, much safer and are suitable for use by all general gynaecologists. This study was therefore carried out to assess the efficacy, complication rate and acceptability of endometrial thermal balloon ablation in a District General Hospital in the South West of England.

Materials and methods

In our study, 212 women who underwent a thermal endometrial balloon procedure (Thermochoice I: Gynecare) in the Day Surgery Unit at our Hospital between 1 November 1998 and 26 April 2002 were recruited into the study. All women were given intravenous sedation with Propofol (Diprivan: AstraZeneca) and intravenous Tenoxicam (Mobiflex: Roche), and Remifentanil (Ultiva: Elan) was also given for analgesia. In addition, a para-cervical block using up to 20 ml of 2% bupivacaine hydrochloride (Marcaine: AstraZeneca) was given to selected patients. A routine Thermochoice procedure was then carried out at 87°C for 8 min with the intrauterine pressure between 140 and 200 mmHg.

The women were followed up by a detailed questionnaire at between 6 and 24 months postoperatively. The women were asked their opinion on the preoperative information they were given, the length of time to resume day-to-day activities and the length of time taken to return to work. They were also asked about the level of postoperative pain and the perception of their problem with respect to the severity of pain and bleeding preoperatively compared with postoperatively. The women were asked if they were satisfied with their operation and whether they would recommend the procedure to a friend. The results were analysed independently by the Clinical Effectiveness Department at our hospital. In addition, the patient's

J. W. Barrington (✉) · F. Bano
Department of Obstetrics and Gynaecology,
Torbay Hospital,
Torquay, Devon, TQ2 7AA, UK
e-mail: julian.barrington@nhs.net
Tel.: +44-1803-654647

M. Swart · J. Montgomery
Department of Anaesthetics,
Torbay Hospital,
Devon, UK

hospital notes were examined for demography and the indication for surgery.

Results

One hundred fifty-eight replies were received, which represents a 75% response rate, and 98% of the women received some form of preoperative information: the majority received both verbal and written information (Fig. 1). The main indication for surgery was menorrhagia after failed medical treatment (Fig. 2). Twenty-eight women (13.2%) were admitted from the Day Surgery Unit for a variety of reasons including pain (*n*=12), nausea/vomiting (*n*=5), dizziness (*n*=4), feeling unwell (*n*=2), drowsiness (*n*=1), bleeding (*n*=1), inability to mobilise (*n*=1), inability to void (*n*=1) with one reason unknown. Of the women, 73% did not need to contact their GP within 7 days of surgery; of the 27% who did, 10% of consultations were for pain, 9% for pain and bleeding and 8% for bleeding problems. Fifty percent of the women were able to resume normal activities within 3 days; a further 27% resumed normal activities within a week. Of the women, 23% took longer than a week to return to normal activities. Eighty-one percent of the women were employed outside the home; the return to employment was largely due to the type or nature of their job with women with sedentary jobs returning the soonest (Table 1).

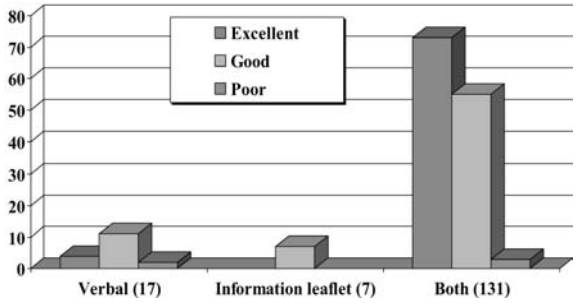

Fig. 1 Type and quality of information received

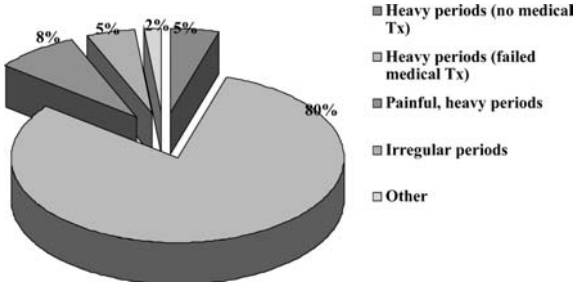

Fig. 2 Indications for surgery

The amount of menstrual loss as perceived by the majority of women was reduced by the procedure and this effect persisted over the follow-up period (Table 2). However, this table does not accurately reflect the improvement in bleeding patterns on an individual basis, which is therefore shown in Table 3. A similar improvement was seen when the pre- and postoperative degrees of dysmenorrhoea were compared (Tables 4, 5). Overall, 82% of women would recommend the procedure to a friend.

No further treatment was required by 111 (70%) of the women (Fig. 3): 19 (12%) were prescribed oral medication including anti-fibrinolytics, 6 women (4%) subsequently had a levonorgestrel intra uterine system [LNG-

Table 3 Individual comparison of severity of bleeding

Light > none	1
Light > light	3
Light > moderate	1
Moderate > none	3
Moderate > moderate	1
Heavy > none	51
Heavy > light	49
Heavy > moderate	30
Heavy > heavy	12
Heavy > variable	6

Table 1 Return to employment

	Desk/seated (*n*=41)	Light physical (*n*=57)	Heavy physical (*n*=28)
Within 7 days	29	35	16
8–14 days	9	14	5
15+ days	3	8	7

Table 2 Overall comparison of severity of bleeding

	6 months (*n*=20)		7–9 months (*n*=11)		10–12 months (*n*=5)		13–24 months (*n*=55)		24+ months (*n*=67)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Light		4	1	3			3	19	1	26
Moderate	1	6		2		2	1	11	2	11
Heavy	19	2	10	1	5	2	51	4	64	3
None		7		5		1		18		24
Variable		1						3		2

Table 4 Overall comparison of severity of dysmenorrhoea

	6 months (*n*=20)		7–9 months (*n*=11)		10–12 months (*n*=5)		13–24 months (*n*=55)		24+ months (*n*=67)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Mild	2	7	4	9		2	6	24	8	33
Moderate	13	5	1		2	1	8	10	3	21
Severe	4	4		1	1	1	14	8	23	9
None	9	3	6	1	2	1	25	8	31	2
Variable	1	1					2	4	2	1

Table 5 Individual comparison of severity of dysmenorrhoea

No pain > no pain	17	Moderate > severe	2
No pain > mild	1	Severe > none	24
No pain > moderate	2	Severe > mild	18
Mild > none	15	Severe > moderate	15
Mild > mild	2	Severe > severe	14
Moderate > none	17	Severe > variable	2
Moderate > mild	16	Variable > variable	4
Moderate > moderate	7	Variable > none	1

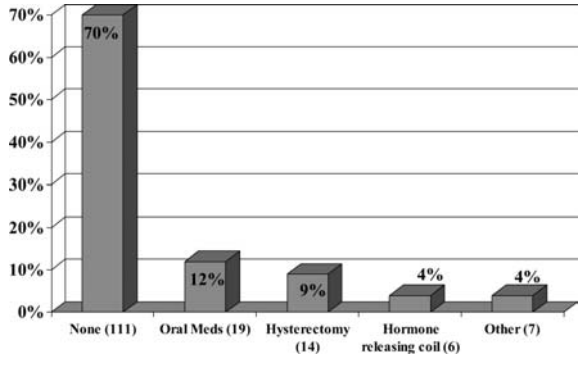

Fig. 3 Further treatment

IUS] (Mirena: Schering) inserted, 14 women (9%) subsequently underwent a hysterectomy, and the outcome of 7 women (4%) were unknown. To resolve any bias in the study, the medical records of the 54 non-responders were examined: 11 women (21%) had undergone a hysterectomy to our knowledge and 11 women failed to attend for follow-up. The remaining 32 women who attended for follow up were pleased with the results of surgery at 3 months (*n*=13), 6 months (*n*=4), 12 months (*n*=7) and 24 months (*n*=2), with no improvement noted at 3 months in 3 women and at 12 months in 2 women.

Discussion

This study has shown Thermochoice to be highly effective in the management of menorrhagia with a high rate of patient satisfaction. It is uncertain whether the newer Thermochoice II/III devices will improve the efficacy rates, although better convection of heat transmission might be expected to do so. Although amenorrhoea rates are often considered the main indicator for successful surgery, we feel that a return to an acceptable bleeding pattern is more relevant in clinical practice. In that respect, although the amenorrhoea rate was 34.8%, the return to normal menstruation was increased to 93.4%, which is comparable to other studies [12, 13]. A major difference between this and other studies was whether to repeat the ablation for non-responders. We felt that repeat ablation was not warranted, and this is reflected in continued use of medical therapy including the LNG-IUS for this group of women. Although this policy might be expected to reflect an increased hysterectomy rate, our rate of 11.8% is comparable to other studies, which suggests a second attempt at medical therapy is warranted. The complications were similar to those described in a large multicentre series with no major sequelae [14]. This is despite the majority of procedures being carried out by junior medical staff with or without consultant staff supervision. This reflects that little training is required and the procedure can be delegated to a junior member of the surgical team.

The cost implications of hysterectomy to the National Health Service are enormous. It has been estimated that if all hysterectomies were replaced by second-generation endometrial ablation, there is a potential saving of £32 million/annum. Although these cost figures are unrealistic, it gives an indication where resources could be redeployed [11]. These savings could be increased further if second generation endometrial ablation is carried out in the outpatient department rather than in the operating theatre with its increased costs [15, 16].

In conclusion, this study has shown that women presenting with heavy menstrual loss refractory to medical therapy should be considered for second-generation endometrial ablation techniques before resorting to hysterectomy.

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