Thermal balloon ablation versus endometrial resection for the treatment of abnormal uterine bleeding

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This study compares the clinical efficacy and safety of a thermal uterine balloon system with hysteroscopic endometrial resection in the treatment of dysfunctional uterine bleeding. In all, 147 women were treated by two experienced gynaecological surgeons: one performed 73 thermal balloon ablations and the other 74 endometrial resections between November 1994 and April 1998. The inclusion criteria were similar in both groups. The operative time was reduced significantly with the uterine balloon technique. There were no intra-operative complications in either group and no postoperative morbidities were minimal and not statistically different. Multivariate analysis noted two prognostic factors associated with failures: retroverted uterus with thermal balloon ablation and age under 43 years with endometrial resection. The overall success rate did not differ significantly between the two groups 83.0 ± 5% for balloon ablation and 76.3 ± 6% for endometrial resection. Uterine balloon ablation appears to be as efficacious as endometrial resection. The former is much easier to perform, making the technique readily reproducible, especially by those with limited expertise in hysteroscopic surgery, and thus more widely applicable and safer.

Key words: endometrial resection/menorrhagia/uterine balloon therapy

Introduction

Menorrhagia is a common disorder for many reproductive age women, with significant impact on their medical, social, economic, and psychological well-being (Lalonde, 1994). The worldwide prevalence is reported to be as high as 19% (Snowden and Christian, 1983). This disorder often exists in the absence of organic lesions of the endometrium in the perimenopause. Later, in the post-menopausal period, the problem of excessive uterine bleeding affects women receiving hormonal replacement treatment.

Traditionally, the first-line treatment is medical in menstruating women and discontinuation of hormonal replacement in the menopausal. Except for gonadotrophin-releasing hormone agonists (GnRHa), the various medications generally employed (progestogens, combined oral contraceptives, prostaglandin synthetase inhibitors, antifibrinolytics or danazol) do not achieve amenorrhea, but can reduce menstrual bleeding by 25–80% (Shaw, 1994). Moreover, medical therapy may be fraught with side-effects and symptoms of menorrhagia invariably return once therapy is stopped. Second-line therapies include the surgical approaches of dilatation and curettage, hysteroscopy, and/or hysterectomy. In a randomized study, it was shown (Cooper, 1997) that medical treatment was less effective than hysteroscopic endometrial resection. The Royal College of Obstetricians and Gynaecologists (RCOG) reported that 42% of hysterectomies in the UK are performed for dysfunctional uterine bleeding (RCOG, 1996). Dilatation and curettage is a temporary treatment with limited efficacy (Grimes, 1982; Shaw, 1994) and the patient would be better served by operative hysterectomy. In fact, data indicate that hysteroscopic endometrial resection or ablation with Nd Yag laser and electrocoagulation appear to be the procedures of choice for the control of menorrhagia. Worldwide, a 70–90% success rate has been demonstrated using hysteroscopic endometrial resection or ablation (Garry et al., 1995; O’Connor and Magos, 1996). Hysteroscopic surgery is effective and is associated with less morbidity and mortality, shorter hospitalization and convalescence when compared with hysterectomy. However, it requires additional specialized training and surgical expertise, and involves a significant learning curve (Davis, 1989). Moreover, serious complications may occur, including fluid overload, uterine perforation, infection, haemorrhage, thermal injuries, and even death. In a series of 525 patients treated with hysteroscopic endometrial resection, an operative complication rate of 6% was reported for patients undergoing their first procedure and of 15% for repeat procedures (O’Connor and Magos, 1996). In the Mistlestoe study (Overton et al., 1997) comprising 10 686 women treated with endometrial ablation performed by 690 different surgeons and by different methods, the complication rate was 4.4%. The Roller-Ball and Nd Yag laser techniques had a lower complication rate than endometrial resection.

In the interests of overcoming many of these disadvantages and risks, a thermal uterine balloon therapy system was introduced (Nevi, et al., 1994). This has since been evaluated in several clinical studies of endometrial destruction (Singer et al., 1994; Vilos et al., 1996; Amso et al., 1998). These results indicate that the balloon ablation procedure requires skills similar to those necessary for inserting an intrauterine device.

The purpose of this study was to compare two conservative surgical approaches in the management of abnormal uterine bleeding: thermal uterine balloon ablation versus endometrial...
resection, which is the technique commonly used in France. We compared the safety and the efficacy of the two techniques and attempted to identify the factors influencing outcome. All balloon ablations were done by a skilled gynaecological surgeon (H.F.) and the endometrial resections by a pioneer in hysteroscopic surgery (J.H.).

Materials and methods

Patient selection
Between November 1994 and April 1998, 73 women were enrolled in a prospective study of a thermal uterine balloon system (TheraChoice Gyneecare, Inc, Menlo Park, CA, USA). The control group was selected from examination of the records of patients undergoing resection (n = 74) and treated during the same period by endometrial ablation for abnormal uterine bleeding. Institutional review board approval was obtained for this study. All patients gave informed consent.

Inclusion in the study required that women be 40 years of age or older (excepting for two patients in each group who had a serious medical contraindication for pregnancy in addition to menorrhagia). The indication for treatment in both groups was excessive menstrual blood loss that was quantified by the number of pads used per cycle. The premenopausal women in these series had either failed medical therapy with progestins or were unwilling or unable to carry on with medical treatment. The post-menopausal patients were not willing to discontinue hormonal replacement therapy.

Women with submucous fibroids, polyps, premalignant lesions, a uterine cavity measuring >12 cm in length, or those of reproductive age wishing to retain fertility were excluded. Each patient had a routine history taken and underwent a routine physical examination, as well as a PAP smear, pelvic sonogram, and a hysteroscopic evaluation. All of the patients had documented benign endometrial histology without atypia. None of the patients, in either group, received pretreatment for endometrial thinning and procedures were not scheduled to coincide with a specific time of the cycle. The operating time was measured from the initiation of anaesthesia to the end of the procedure. All patients were monitored for peroperative and postoperative morbidity.

Choice of anaesthesia
One hour prior to the initiation of the procedure irrespective of the type of anaesthesia, the patients received non-steroidal anti-inflammatory drugs orally (except for two patients, who had a contraindication) and 1 g of paracetamol intravenously. This drug regimen was used to alleviate anxiety, pain, and/or cramping during the procedure. The duration of action of these medications was 6 h. The same medication was repeated as necessary during the immediate postoperative period, in the event of persistent uterine cramps.

All endometrial resections were done under general anaesthesia. For the patients in the balloon group, the type of anaesthesia was not dictated in the protocol and was left up to the patient, anaesthetist and surgeon to determine. Local anaesthesia was used when it was medically necessary or when the patient desired this form of anaesthesia, provided she demonstrated her ability to relax by good toleration of the pelvic examination and the diagnostic hysteroscopy which was performed without anaesthesia.

Local anaesthesia was achieved by the establishment of a parametrical block with 1% lignocaine HCl and epinephrine 1:200 000 (20 ml) diluted 1:20 with normal saline. A total of 40 ml was used per patient: 5 ml of the solution was injected into each of four points of the cervix corresponding to 01.00, 05.00, 07.00, and 11.00 h on a clock face. The cervix was then grasped with a tenaculum and 5 ml of the solution was injected into each of the following sites in the isthmus, corresponding to 02.00 and 10.00 on a clock face, and into each of the uterosacral ligaments (1 cm depth). A time of 3-5 min was allowed to elapse for the anaesthetic to take effect before starting the procedure.

Equipment and operative technique
The TheraChoice™ uterine balloon therapy system consisted of a 16 cm long, 4.5 mm diameter catheter with a latex balloon at its distal end which housed a heating element. The controller unit monitored, displayed and controlled the preset intra-balloon pressure, temperature, and duration of treatment. For safety, the device automatically deactivated when the pressure fell below 45 mmHg or rose above 200 mmHg.

The patients were placed in the dorsolotomony position in the procedure room. The bladder was not catheterized and when necessary the cervix was dilated to 5.5 mm. The balloon was inserted transcervically to touch the fundus, and then was inflated with 5% dextrose in water (typically 10–15 ml) until the intrauterine pressure stabilized between 150–170 mmHg. The heater was then activated and it maintained the intra-balloon temperature at 87 ± 5°C. An effective therapy cycle was 8 min in duration, based on previous in-vitro and in-vivo studies, and this typically resulted in a 0.4–0.6 cm depth of tissue coagulation (Neuvirth et al., 1994).

Endometrial resection was performed using standard hysteroscopic equipment, and a previously described technique (Salat-Baroux and Hamou, 1996). Low viscosity (1.5% glycine) medium was used for uterine distention. The fluid balance was monitored continuously.

Neither group of patients received routine antibiotic prophylaxis and in both groups, the patients were discharged on the day of the procedure.

Follow-up
The patients in the balloon group were contacted by phone 3, 6 and 12 months postoperatively and annually thereafter. Their postoperative follow-up varied between 3 and 44 months. Those in the resection group were called once: their follow-up varied from 3 to 36 months. During the telephone interview, we attempted to ascertain the characteristics of the menstrual flow, the number of pads used per cycle and the degree of dysmenorrhea, and the need for any further therapy was assessed.

Statistical analysis
The primary end-point was defined as elimination of menses (amenorrhea) or a significant reduction of flow compared with normal (eumenorrhea) or less than normal (hypomenorrhea). The secondary end-point was the disappearance of dysmenorrhea, when present before the procedure.

The analysis was done after the first patient completed 44 months of follow-up. The significance of the differences between groups in categorical variables was tested with the Chi square test. Student’s t-test was used to determine the significance of the differences between groups in continuous variables. Life-table analysis was based on a technique in which time to failure was the dependent variable, which made it possible to use all of the available information about the participants for as long as they had been followed up. The Kaplan-Meier survival curves were used to describe the ‘survival’ distributions of the two treatments (balloon and resection), and the differences were tested with Mantel-Cox (log-rank) statistics. The Cox proportional hazards model was applied in order to analyse the simultaneous relationships between event failure and the possible covariates and to study the influence of prognostic factors on the appearance of failure. Failed