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An evaluation of the simultaneous use of the levonorgestrel-releasing intrauterine device (LNG-IUS, Mirena®) combined with endometrial ablation in the management of menorrhagia

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The objective of our study was to document the efficacy and possible complications in women who were treated for menorrhagia with the simultaneous use of endometrial ablation and the levonorgestrel-releasing intrauterine device. Women were offered this combined treatment if they complained of menorrhagia and needed contraception. A structured questionnaire was mailed to 150 women who had undergone this combined treatment; 105 (70%) returned a completed questionnaire. The mean duration of follow-up was 25 months (range 6–54 months). Following treatment, 53 women (50.5%) described their periods as being lighter than normal and 49 (46%) had become amenorrhoeic. Overall, 101 (96%) stated that they were satisfied with the treatment. Of the women, 95 (90.5%) said that the treatment had been a 'complete success'; eight (7.6%) 'partly successful' and two women (1.9%) said the treatment had been a 'failure'. One woman subsequently required a hysterectomy. This observational study supports the hypothesis that combined endometrial ablation and insertion of a levonorgestrel-releasing intrauterine device is an effective treatment for menorrhagia and has some advantages when compared with the individual use of these treatments.

Keywords: Ablation, endometrial, levonorgestrel-releasing intrauterine device, menorrhagia

Introduction

Menorrhagia is excessive cyclical menstrual bleeding, classically defined as blood loss of 80 ml or more per cycle (Nilsson and Rybo 1971). In clinical practice however, the volume is estimated based on the patient's description of flooding, the presence of clots, or simply the number of sanitary towels/tampons used per day.

Hysterectomy has long been considered the 'gold standard' in the management of medically refractory menorrhagia. However, in recent years, transcervical resection of the endometrium has become an alternative treatment, having a shorter recovery period and being more cost-effective. More recently, hysteroscopic endometrial resection has been replaced by second generation, non-hysteroscopic techniques. To date, the US Food and Drug Administration has approved five such methods: bipolar radiofrequency ablation, microwave ablation, cryoablation, circulated hot fluid ablation and thermal balloon ablation (McGurgan and O'Donovan 2003). All five have been shown to have a better safety profile and their ease of use is superior to that of hysteroscopic endometrial ablation.

For women wishing to preserve their fertility, the levonorgestrel-releasing intrauterine device (LNG-IUS, Mirena®) has proven to be an effective alternative in the management of menorrhagia. It acts as a long-term contraceptive by inducing atrophy of the endometrial epithelium for more than 5 years. This effect is associated with a significant reduction in menstrual blood loss. Success rates of the levonorgestrel-releasing intrauterine device for the treatment of menorrhagia have been shown to be comparable to the endometrial ablation methods. It has been previously demonstrated that approximately 80% of women who had the levonorgestrel-releasing intrauterine device for menorrhagia, experienced at least a 70% decrease in menstrual blood loss after 2 years (Kaunitz et al. 2010). Because of the ease of insertion and removal, in addition to the favourable side-effect profile, this device is generally considered the most effective first-line agent is the management of menorrhagia. Furthermore, the levonorgestrel-releasing intrauterine device is an effective form of contraception.

Although both endometrial ablation and the levonorgestrel-releasing intrauterine device have been shown to be effective alternatives to hysterectomy in the management of refractory menorrhagia, there are little data in the literature evaluating their combined use.

The objective of our study was to document the efficacy and possible complications in women who were treated for menorrhagia with the simultaneous use of endometrial ablation and the levonorgestrel-releasing intrauterine device.

Methods

We conducted a qualitative questionnaire study to assess the use of endometrial ablation, combined with the simultaneous insertion of the levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. Ethical approval for the study was obtained. A pilot study was done initially to detect any ambiguities in the questionnaire. Based on the findings of this pilot study, the questionnaire was modified.

Women with idiopathic menorrhagia who required contraception were offered treatment if they had completed child-bearing. A structured questionnaire was sent to 150 women who had undergone simultaneous thermal balloon endometrial ablation

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combined with levonorgestrel-releasing intrauterine device insertion from 1 January 2006 to 31 December 2009. The questionnaire was not sent until at least at least 6 months following treatment.

The thermal balloon systems used were either Thermachoice® (Gynecare Inc., Menlo Park, CA, USA) or Thermablate® (Indoman Ltd, Ireland). The levonorgestrel-releasing intrauterine device (Mirena®; Schering Healthcare, UK) was inserted immediately after thermal balloon ablation.

All procedures were performed as day-cases under general anaesthesia. A hysteroscopy and endometrial biopsy were done prior to performing the thermal balloon endometrial ablation.

The primary objective of the review was to ascertain amenorrhoea and hypomenorrhoea rates following treatment. Secondary objectives were to look at the effect of the treatment on dysmenorrhoea as well as the side-effect profile of the simultaneous treatments.

Results

Of the 150 women who underwent simultaneous thermal balloon endometrial ablation combined with levonorgestrel-releasing intrauterine device insertion, 105 (70%) returned a completed questionnaire. The thermal balloon systems used were either Thermachoice® in 72 (69.6%) patients or Thermablate® in 33 (31.4%). The mean age was 43 years (range 33–44), mean parity 2.27 (range 0–4) and mean endometrial cavity length 9 .04 (range 8–12). The mean duration of follow-up was 25 months (range 6–54). All patients were discharged on the day of treatment and none were readmitted because of complications of the treatment. No patient became pregnant following treatment.

Following treatment, 53 women (50.5%) described their periods as being lighter than normal and 49 (46%) had become amenorrhoeic. Two patients stated that their bleeding was unchanged and one patient stated that her menstrual bleeding had become heavier after treatment.

Before treatment, 87 women complained of dysmenorrhoea. Following treatment, 73 (84%) of these reported that their pain had either gone or improved; nine (10.3%) had not noticed any change and five (5.7%) reported that their menstruation-related abdominal pain had become worse. One woman developed new onset dysmenorrhoea following treatment.

Following treatment, 60 (57.1%) stated that their weight had remained unchanged, 30 (28.6%) stated that their weight had increased and 15 (14.3%) stated that they had lost weight since undergoing treatment.

When asked about breast tenderness, 75 (71.4%) women complained of this before treatment. Following treatment, this had disappeared in 24 (32%); improved in 30 (40%); remained unchanged in 16 (21.3%) and had become worse in five (6.7%). Breast tenderness was reported as a new symptom by six of the 30 (20%) women, who said that they did not have breast tenderness before treatment.

Overall, 101 (96%) stated that they were satisfied with the treatment; 95 (90.5%) considered that the treatment had been a 'complete success'; eight (7.6%) 'partly successful' and two women (1.9%) said that the treatment had been a 'failure'. Two women expelled the levonorgestrel-releasing intrauterine device within 1 week after insertion. Six women (5.7%) had the levonorgestrel-releasing intrauterine device removed soon after insertion: two women stated weight gain as their reason for having it removed; three described severe mood disturbance and one woman felt that the device was causing headaches.

Two women required further treatment for their menorrhagia. One woman had a vaginal hysterectomy and one woman underwent a second endometrial ablation.

Discussion

Both endometrial ablation and the levonorgestrel-releasing intrauterine device are now accepted as effective treatments in the management of women with menorrhagia and both treatments are now considered as better options than hysterectomy in the absence of significant pathology.

Endometrial ablation is less invasive than a hysterectomy and aims to treat menorrhagia by selectively destroying the endometrium, while preserving the uterus. Kleijn et al. (2008) demonstrated that amenorrhoea rates at 5 years after balloon endometrial ablation are in the region of 32%. El-Nashar et al. (2009) recently demonstrated that success rates of endometrial ablation are highly dependent on a number of factors, particularly age, uterine cavity length and endometrial thickness. Although that study demonstrated that the prediction of amenorrhoea following treatment was variable, depending on a number of factors, the overall amenorrhoea rate was 23%, which was lower than that of previously published reports (Abbott et al. 2003; Bongers et al. 2004). A Cochrane review (Lethaby et al. 2010) reported that 86% of women described an improvement in bleeding within 1 year following treatment with first and second generation endometrial ablation techniques. Overall, 71% women stated that they were satisfied with treatment at both year 1 and year 2 following treatment.

The levonorgestrel-releasing intrauterine device is a commonly used treatment for women with menorrhagia due to its favourable cost and side-effect profile, in addition to its ease of insertion and removal. It is particularly useful in women who wish to preserve their fertility, as its effects are easily and quickly reversed. Crosignani et al. (1997) reported that amenorrhoea or hypomenorrhoea 12 months after insertion of levonorgestrel-releasing intrauterine system was reported by 65% of women. It decreases menstrual blood loss and has a positive effect on the symptoms of dysmenorrhoea. Furthermore, the levonorgestrel-releasing intrauterine device offers very reliable contraception to women who have the device inserted to treat menorrhagia. However, one of the disadvantages of the levonorgestrel-releasing intrauterine system is that a proportion of women experience prolonged irregular light bleeding following insertion of the device. This has been reported to affect up to 32% of women, by Baldaszti et al. (2003) and is a common reason for a woman to request removal of the device.

One of the disadvantages of endometrial ablation is that it cannot be considered as having a reliable contraceptive effect. Most women referred for treatment of menorrhagia have completed their family and usually require reliable contraception. When endometrial resection was first introduced, it was recommended that women undergoing this procedure should have a simultaneous tubal ligation. This is not considered necessary with second and third generation endometrial ablation procedures. Indeed, the simultaneous use of laparoscopic tubal ligation for women undergoing endometrial ablation would significantly increase both the surgical risks and cost of the procedure.

The combined use of endometrial ablation and the levonorgestrel-releasing intrauterine device offers a potential solution for the woman with menorrhagia who needs reliable contraception. There are little published data on the efficacy and potential problems of this combined therapeutic modality. Maia et al. (2003) reported on the use the combined use of the levonorgestrel-releasing intrauterine device and endometrial resection in women treated for adenomyosis. Amenorrhoea rates were reported as significantly higher in the women who had combined treatment compared to those who had endometrial resection alone.

Although amenorrhoea is not the primary endpoint by which success is measured in the management of women with menorrhagia, it is associated with very high patient satisfaction rates. In our study, the combined use of thermal balloon endometrial ablation and insertion of a levonorgestrel-releasing intrauterine device resulted in an amenorrhoea rate of almost 47%. This is significantly higher when compared with amenorrhoea rates when endometrial ablation or the levonorgestrel-releasing intrauterine device are used separately (Kaunitz et al. 2010; El-Nashar et al. 2009).

When discussing treatment options for menorrhagia, it is not uncommon for women to express reservations when offered a levonorgestrel-releasing intrauterine device. This is because many women believe that the use of this device is associated with weight gain and a high rate of breast tenderness. Kittelsen and Istre (1998) found that weight gain was reported in 15% of women using the levonorgestrel-releasing intrauterine device. In our study, 28% of women felt that their weight had increased since they had been treated. This study is not designed to allow us to make any statement as to the possible links between weight gain and treatment.

Breast tenderness following the use of the levonorgestrel-releasing intrauterine device has been reported in 11–36% of users (French et al. 2010; Kittelsen and Istre 1998). In our study, *de novo* breast tenderness was reported in 20% of women, although 72% of those who complained of breast tenderness before treatment reported that it had improved or disappeared.

Dysmenorrhoea has been considered as a relative contraindication to the use of endometrial resection and ablation on the basis that it may be caused by adenomyosis. Even if all of the endometrium is removed from the uterine cavity and the woman becomes amenorrhoeic, in the presence of adenomyosis, it is likely that dysmenorrhoea will persist following treatment. In our study, dysmenorrhoea was reported in 34% of women prior to treatment. Following endometrial ablation combined with insertion of the levonorgestrel-releasing intrauterine system, 79% reported an improvement in dysmenorrhoea. This effect is more likely to be attributable to the hormonal effect of the levonorgestrel-releasing intrauterine system.

One of the measures of success of this combined treatment is the need for further treatment. Of the 105 women included in our study, only two women required further treatment; one of these had a hysterectomy for persistent menorrhagia, the other had a second endometrial ablation. In the study by El-Nashar et al. (2009), 45 women (5%) subsequently had a hysterectomy following endometrial ablation alone.

In conclusion, this observational study supports the hypothesis that combined endometrial ablation and insertion of a levonorgestrel-releasing intrauterine device is an efficacious treatment for menorrhagia and has some advantages compared to the individual use of these treatments. A randomised control trial is necessary to confirm this observation.

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