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## Small bowel perforation after thermoregulated radiofrequency endometrial ablation: a case report

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**Abstract** During the past decades, numerous hysteroscopic ablation techniques have been developed for the treatment of menorrhagia, all conferring relatively comparable success rates and low complication incidences. We here report an unusual, adverse, post-operative, complication of the Vesta thermoregulated radiofrequency endometrial ablation system in a 34-year-old nulliparous woman with dysfunctional uterine bleeding. Fourteen days after the procedure she presented with acute abdominal pain. At laparotomy, a small bowel perforation was identified, and the entire uterus was found to be necrotic, necessitating a total hysterectomy. This is the first report of a severe complication of this endometrial ablation system in the absence of uterine perforation. We propose that minimal myometrial thickness should be taken into consideration to improve the safety of thermoregulated radiofrequency endometrial ablation.

**Keywords** Endometrial ablation · Bowel perforation · Vesta system · Thermal balloon · Radiofrequency

### Introduction

Menorrhagia, defined as monthly periods lasting longer than 7 days or a blood loss volume of more than 80 ml, is a common problem in women of reproductive age [1]. In the

absence of malignancy and uterine cavity abnormalities the first-line approach is drug treatment, including combined oral contraceptives, progestagens, prostaglandin synthetase inhibitors, tranexamic acid, antifibrinolytics and hormone-releasing intra-uterine systems [2, 3]. Second-line treatment is essentially surgical, with dilatation and curettage (D&C) and hysterectomy being most common. D&C often causes temporary improvement, whereas hysterectomy is regarded as a definitive mode of treatment, although it is associated with a higher morbidity rate [4].

In the past three decades various methods of endometrial ablation have been developed. Hysteroscopic techniques, such as laser ablation, endometrial diathermy and resection under direct vision, have demonstrated a relatively good outcome with regard to effectiveness, safety and costs [5, 6]. These techniques require additional specialised training and are not seldom complicated by fluid overload, uterine perforation, infection, haematometra, haemorrhage, thermal injuries and even death [7–9].

In 1994 Neuwirth et al. [10] introduced thermal uterine balloon therapy to address these problems. The success rate and complication profile of thermal balloon therapy compare favourably with hysteroscopic techniques [11–14]. The Vesta system (Vesta Medical, Mountain View, Calif., USA) is a thermoregulated radiofrequency balloon system for endometrial ablation. The device consists of a silicone inflatable electrode carrier inserted into the uterine cavity and a controller to monitor and distribute current from a matched electro-surgical generator. Treatment involves a 3 min or shorter warming-up period and a 4 min treatment phase. The system ensures that correct temperatures are maintained at a stable degree in each area, which prevents over- or undertreatment [15]. It reduces bleeding and gives a long-term outcome equivalent to that of hysteroscopic endometrial ablation [16–18]. The intrinsic advantages of this device over conventional electro-surgical endometrial ablation include (A) stationary electrodes, which decrease the risk of perforation or uneven treatment, (B) a balloon platform, allowing expansion to fit the uterine cavity, (C) the absence of distending fluids and (D) the ability for the procedure to be performed

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under local anaesthesia in an out-patient clinic setting with limited operating time [7, 19].

In the following case report, however, a severe adverse event is described.

### Case report

A 34-year-old nulliparous woman sought specialist advice for dysfunctional uterine bleeding. As a child she had been treated for epilepsy. She had been diagnosed with hyperthyroidism and fibromuscular dysplasia, the latter resulting in recurrent pareses. She was known to have severe cerebral vascular malformations as well. In 1997 she underwent a laparoscopic sterilisation, as her cerebral vascular condition and fibromuscular dysplasia were considered absolute contra-indications for pregnancy. Postoperatively, this procedure had been complicated by left-sided reversible hemiparesis.

No improvement in menorrhagia was achieved with norgestrel acetate 5 mg daily, nor with a combined treatment of diclofenac (150 mg daily) and tranexamic acid (3 g daily). Therefore, it was decided to perform endometrial ablation, as opposed to a hysterectomy, in order to reduce (post-) operative morbidity. For pre-operative endometrial thinning a GnRH-agonist, leuprorelin acetate (Lucrin, Abbott Laboratories, Madrid, Spain), was used.

The cervix was dilated to 9 mm diameter after bilateral paracervical injection of 5 ml lignocaine 2% solution.

The uterine cavity depth was measured at 6 cm. The Vesta handset was introduced and advanced until its tip reached the fundus, whereupon the sheath was withdrawn and the silicone carrier was inflated with 10 ml of air. After a warming-up interval, the automatic control unit started the procedure, and the electrodes were kept at 75°C for 4 min, except for the corneal electrodes, which were set at 72°C. No intra-operative complications were noted, and the patient did not experience any significant discomfort throughout the procedure. One day after the intervention she was discharged from the hospital.

Fourteen days later the patient was readmitted to the hospital with acute abdominal pain. The ultrasound demonstrated a small bowel perforation. A laparotomy was performed, and a small defect in the distal part of the ileum was found, located behind the posterior wall of the uterus. The entire uterus appeared necrotic and oedematous. No perforation of the uterus was noticed. After the intestinal defect had been repaired a hysterectomy was performed. The patient subsequently made an uneventful recovery. Histological examination of the uterus revealed several extravasations and traumatic changes of the entire uterine wall. Nevertheless, no uterine perforation could be diagnosed. Microscopic analysis of the myometrium showed loci of fresh haemorrhage, together with ruptured large blood vessels and necrotic tissue, compatible with thermal damage. Hyalinisation of the myometrium adjacent to haemorrhagic regions was noted.

### Comment

We performed an extensive Medline search and checked the Maude website of the American Food and Drug Administration for reports of a similar complication and concluded that this is the first report of a severe complication of thermoregulated radiofrequency endometrial ablation therapy in the absence of uterine perforation.

A large series from the UK and Canada reported an operative complication rate between 2% and 6% for patients undergoing their first hysteroscopic endometrial resection. For repeat resections a complication rate between 9% and 15% was reported [20–22]. After rollerball ablation of the endometrium (without uterine perforation) one case of bowel injury was described [23]. With microwave endometrium ablation, producing a tissue temperature of 95°C, two cases of small bowel perforation have been reported [24]. For balloon therapy the reported complication rate is lower: Dequesne et al. [25] described two patients with haematometra and one with pelvic pain in a group of 187 patients. Corson et al. [19] did not find any immediate complication in their study of 150 patients. One case report of delayed bowel trauma following uterine perforation during an endometrial ablation with the Vesta system was published [26].

When serosal temperatures were monitored using the Vesta system, no significant increases were reported [16]. In studies with the ThermaChoice (Gynecare, Edinburgh, UK) and Cavaterm (Wallsten Medical, Morges, Switzerland) uterine balloons, using the same temperature range as the Vesta system, it was found that the temperature in this technique was not sufficient to cause tissue damage to the uterine serosa. By electron microscopy no influence of heat could be demonstrated beyond a distance of 15 mm from the endometrial surface. The myometrium thickness varied between 15 mm and 25 mm [27–29]. By studying the serosal temperature, and by light and electron microscopic evaluation of the thermal action on the myometrium, Andersen et al. concluded that thermal balloon endometrial ablation only coagulates the myometrium to a depth where full thickness necrosis or injury is unlikely [30].

In the literature the accepted maximum uterine cavity depth for this procedure is 10 cm [19, 27–30]. The minimum depth varies. Meyer et al. described thermal balloon ablations with a uterine cavity depth of 4 cm and no complications [31]. However, in this study, no endometrial thinning regimes had been used as a pre-treatment. Corson et al. [19] excluded two patients because of a too-small uterine cavity depth, which was not described in centimetres. In our patient the uterine cavity depth was 6 cm, which is relatively small. She had used leuprorelin acetate (Lucrin) for endometrial thinning before the treatment. These factors may have contributed indirectly to an increase in the uterine serosal temperature, thereby causing thermal defects of the ileum. The thickness of the uterine wall was not measured preoperatively, as this has not been recommended. This complication has been reported to the manufacturer. The control unit was found

to work properly and had been serviced in accordance with the company's protocols.

This patient suffered from fibromuscular dysplasia, resulting in vascular malformations. Spontaneous perforation of the small bowel has been described in children with this disease [32]. In this case it is highly unlikely that this underlying disorder contributed significantly to the bowel perforation.

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## Conclusion

Thermoregulated radiofrequency endometrial ablation is an excellent tool for gynecologists with little expertise in operative hysteroscopy and confers only minor postoperative complications. Further research is needed to establish the minimum myometrial thickness for thermoregulated radiofrequency endometrial ablation. As with every thermal intra-uterine procedure, doctors should be alert for this complication and inform their patients accordingly.

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