OBJECTIVE: To evaluate the safety, feasibility and efficacy of endometrial ablation under local anesthesia.

STUDY DESIGN: A prospective cohort study was performed at the gynecology department of a large teaching hospital. Women with dysfunctional uterine bleeding were included to undergo NovaSure endometrial ablation with paracervical block. We measured the acceptability, pain score (visual analog scale), amenorrhea, and patients’ satisfaction after the procedure.

RESULTS: We treated 33 patients. No complications occurred during the procedure or postoperatively. Of the 33 women, 28 found treatment with NovaSure endometrial ablation acceptable. After 24 hours, 23 of 33 women reported to be pain free, whereas 10 women still had mild pain. Twenty women developed amenorrhea (60.6%) and 13 women hypomenorrhea (39.4%). All women were satisfied with the treatment result and would recommend it to a friend.

CONCLUSION: NovaSure endometrial ablation performed under local anesthesia is a safe, feasible and efficacious procedure.

Keywords: endometrial ablation, menorrhagia, NovaSure, paracervical block.

Menorrhagia is a frequent problem in premenopausal women. Menorrhagia affects 1 in 20 women.1 If the diagnostic workup has shown no abnormalities, the menorrhagia is classified as dysfunctional bleeding. In women with dysfunctional bleeding, endometrial ablation is an effective treatment.2 The NovaSure Endometrial Ablation Device (Cytica, a Hologic Company, Marlborough, Massachusetts) is a bipolar radiofrequency impedance-controlled system to evaporate endometrial tissue.3 In our clinic, the NovaSure was performed from 1998 onward with general anesthesia or regional (spinal) anesthesia. The procedure takes only 1–2 minutes.4 We hypothesized that this short duration of treatment would make this intervention suitable for local anesthesia. We performed a prospective study to assess the feasibility and patient acceptability of NovaSure endometrial ablation in an outpatient setting under local anesthesia.

Materials and Methods

We performed this prospective study in the Máxima Medical Centre (MMC), Veldhoven, the Netherlands, with approval by the institutional review board. The MMC is a teaching hospital with 500

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beds. Women suffering from menorrhagia, as indicated by a pictorial chart with a Higham score of ≥200 points, were eligible for the study. Only women with dysfunctional bleeding were included after evaluation with saline infusion sonohysterography and hysteroscopy verifying that there were no abnormalities. The women had no desire for another child. After being informed about the study, the women gave written informed consent.

In the MMC, endometrial ablation is performed with a NovaSure device. If an ablation treatment of the endometrium was indicated, women were asked if they wanted to undergo the procedure under local anesthesia. The pain score of their menses was noted.

The NovaSure procedure was scheduled at the outpatient clinic. Women were advised to use an oral nonsteroidal antiinflammatory drug (ibuprofen 500 mg) as a painkiller 12 hours and 1 hour before the procedure. A paracervical block with Ultracaine or prilocaine 1% with or without adrenaline was placed. A 12–20 mL amount of the solution was injected just under the epithelium of the cervix, not deeper than 3 mm, at the 2, 5, 7 and 10 o’clock positions.

After placing the paracervical block there was a 3-minute wait time for the anesthetic to take effect before starting the NovaSure procedure. After the NovaSure device was brought into the uterus, suction was applied, the endometrial lining was brought into contact with the electrode array, and the fluid and debris generated during the ablation process were removed. During the procedure, oxygen saturation was monitored by pulse oximeter. The procedure was performed by 1 gynecologist. Four hours after the procedure the patient was advised to take paracetamol 1,000 mg, naproxen 500 mg or Tramal 100 mg.

Visual analog scales (VASs) were used to measure pain when dilating the cervix during the NovaSure procedure and at 4 and 24 hours after the procedure. The VAS is a straight line with the left end of the line representing no pain and the right end of the line representing the worst pain. Patients were asked to mark on the line the painfulness of the procedure.

Follow-up examination was done at 6 weeks after treatment. At this visit the menstruation was scored again on a pictorial chart. Women were also asked whether they would be prepared to undergo the procedure again if needed and whether they would recommend the procedure to a friend.

**Results**

From November 2006 until January 2008, 33 women were included in the study. The mean age was 46.7 years, ranging from 33 to 57 years. The average parity was 2.0, with 3 nulliparas. In all women it was...
feasible to perform the total NovaSure procedure with a paracervical block, and premature termination of the procedure was never needed. Four patients developed a vasovagal reaction during the procedure. The average procedure time was 110 seconds (range, 63–120). The average probe length was 8.5 cm (range, 7–10), the length of the uterine cavity was 4.6 cm (range, 3.5–6 cm) and the intercornual length was 4.1 cm (range, 2.0–4.8 cm).

The median pain score during dilation was 3.0 (range, 1.0–7.0). The median pain score for the entire procedure was 5.1 (range, 0.0–10.0) (Figure 1). After 24 hours, 23 women had a pain score of 0 points, as shown in Figure 2. They all had a lower pain score during menstruation (Figure 3). After 6 weeks, 20 women developed amenorrhea (60.6%) and 13 women hypomenorrhea (39.4%). They were all satisfied with the result. Thirty-one patients found the NovaSure under local anesthetics to be acceptable (94%); only 2 patients would not undergo the procedure again. No complications occurred during the procedure or postoperatively.

Discussion

We used the NovaSure procedure with local anesthesia in 33 patients and found it to be a safe and feasible procedure. In the medical literature almost all endometrial ablation procedures are performed at an outpatient clinic or theater with general or local anesthetics or with paracervical block and intravenous sedation.

One study compared intraoperative and postoperative pain between Gynecare ThermaChoice (Ethicon, Inc., Somerville, New Jersey) endometrial ablation and the NovaSure procedure. The NovaSure system was associated with statistically significantly lower intraoperative and postoperative pain than the ThermaChoice system. Data supported the idea that the NovaSure procedure could become an office-based procedure.

In 2006, hysteroscopic endometrial ablation using the Hydro ThermAblator System (Boston Scientific, Natick, Massachusetts) was performed under paracervical block without local anesthetics or IV sedation. The patients reported mild pain during the procedure, and most found the procedure acceptable. We confirmed this with our study. The percentage of women with amenorrhea after the NovaSure varies from 40% to 60%. The finding of an amenorrhea rate of 60% after 6 weeks corresponds with previous results in the literature.

In summary, we successfully performed endometrial ablation under local anesthesia in our clinic setting, reducing operating room utilization and its associated costs and inconveniences. The results of this study support NovaSure endometrial ablation under local anesthesia as a minimally invasive procedure of choice for women with dysfunctional...
uterine bleeding. It is a safe, feasible and efficacious procedure. Whether the procedure is equally effective as treatment under general anesthesia should be evaluated in a larger clinical trial.

References