

Outpatient versus day-case endometrial ablation using the NovaSure™ impedance-controlled ablative system

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Abstract The objective of this paper was to assess the feasibility and efficacy of the NovaSure™ endometrial ablation system in the outpatient setting using local anaesthesia and to compare this with the standard day-case procedure under general anaesthesia. A prospective cohort-controlled study was undertaken at a university teaching hospital. The patient cohort was made up of 38 women with heavy menstrual bleeding refractory to medical therapy where endometrial ablation was indicated. Endometrial ablation using the NovaSure™ impedance-controlled ablative system was undertaken to compare outpatient treatment using local cervical anaesthetic (experimental group, $n=18$) with inpatient treatment under general anaesthesia (control group, $n=20$). The subjective self-assessment of uterine bleeding symptoms, patient satisfaction and health-related quality of life (HRQL; multi-attribute utility assessment) measures at six months following treatment were noted. Participants were also asked as to whether they would subsequently recommend the treatment, based on their experience. All procedures were successfully accomplished. Completed outcome questionnaires were returned by 17/18 (94%) women treated as outpatients and by 13/20 (65%) as inpatients. Overall, 27/30 (90%) women reported an improvement in menstrual bleeding symptoms, with an amenorrhoea rate of 37% (95% CI 20–56%) and a combined amenorrhoea/spotting rate of 53% (95% CI 34–72%). There was no significant difference between the

outpatient and inpatient treatment groups in terms of improvement in menstrual blood loss (94% vs. 84%, $P=0.6$), amenorrhoea (29% vs. 46%, $P=0.5$), amenorrhoea/spotting (47% vs. 62%, $P=0.5$), satisfaction (82% vs. 85%, $P=1.0$), improvement in HRQL ($P=0.3$) and treatment setting recommendation (88% vs. 77%, $P=0.7$). From our results, we conclude that NovaSure™ impedance-controlled endometrial ablation is an effective, safe and feasible treatment for heavy menstrual bleeding in both the outpatient and traditional inpatient settings. A choice of treatment settings should be offered to women suitable for this procedure.

Keywords Endometrial ablation · NovaSure™ · Bipolar frequency ablation · Impedance-controlled ablation · Outpatient · Ambulatory · Day case · Local anaesthesia · Menorrhagia · Heavy menstrual bleeding

Introduction

Endometrial ablation is a cost-effective treatment for women with bleeding of endometrial origin who remain refractory to medical therapies, have no desire to conserve their fertility and who want to avoid a hysterectomy [1]. “Second-generation,” auto-ablative technologies have largely replaced “first-generation” hysteroscopic methods, as they are less dependent on surgical skill and are at least as effective [2–4]. The miniaturisation, speed and simplicity of these techniques has also generated interest in their use in the outpatient or “office” setting, avoiding the inconvenience of hospital admission, the use of expensive formal theatre facilities and risks associated with the need for general anaesthesia. The feasibility of using some of the second-generation technologies in this setting has been

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demonstrated previously [5–7], but data on comparative efficacy with standard inpatient, general anaesthetic approaches are lacking.

The NovaSure™ endometrial ablation device is an advanced second-generation device that uses a bipolar radio-frequency impedance-controlled system to evaporate endometrial tissue. It has been shown in randomised controlled trials [8–10] to be an effective treatment for the bleeding of endometrial origin under general anaesthesia. The short duration of the procedure (less than 2 min) suggests that the technique has the potential for use in the outpatient setting without the need for general anaesthesia. Clinical data in the outpatient setting for this technology to date are, however, lacking. We therefore performed this cohort-controlled study to determine: (1) the feasibility of using the NovaSure™ system in an outpatient setting without general anaesthesia or conscious sedation and (2) to compare the feasibility, acceptability and effectiveness of this innovative, outpatient approach with that of a standard inpatient (day-case) approach.

Materials and methods

Study design and population

The NovaSure™ bipolar radio-frequency impedance-controlled endometrial ablation system was introduced to the Birmingham Women's Hospital in June 2005, in both an outpatient setting using local anaesthesia (experimental group) and in a standard day-case setting using general anaesthesia (control group). The choice of treatment setting was according to patient preference. All women with heavy menstrual bleeding (HMB) who underwent NovaSure™ endometrial ablation between June 2005 and April 2006 were identified from a comprehensive, prospective electronic database of operative procedures.

The NovaSure™ endometrial ablation system and the recommended surgical technique have been previously described [11, 12]. Those women undergoing outpatient endometrial ablation were advised not to fast pre-operatively and had a standard local anaesthetic protocol, as previously described [13]. In short, this comprised a diclofenac 100-mg rectal suppository and co-dydramol (dihydrocodeine tartrate 10 mg, paracetamol 500 mg) two tablets orally, with cyclizine 50 mg orally as an anti-emetic one hour prior to the procedure. Tramadol hydrochloride 100 mg orally was used in those patients in whom non-steroidal analgesics were contraindicated. At the time of the procedure, the patient was placed in a dorsolithotomy position and, prior to any uterine instrumentation, three 2.2-ml vials of the short-acting local anaesthetic mepivacaine 2%, Scandonest® (Septodont), was directly infiltrated into the cervix in four quadrants (the 3, 6,

9 and 12 o'clock positions), using a 35-mm, 27 G dental syringe. The majority of the local anaesthetic was infiltrated (1.5 ml) at the deepest possible point in each quadrant (i.e. the approximate level of the internal cervical os). A designated nurse stayed with the patient throughout the procedure to offer support and distraction, providing a "vocal-local" supplement to our local anaesthetic protocol. Those women undergoing inpatient endometrial ablation under general anaesthesia received a diclofenac 100-mg suppository at the start of the procedure and intravenous papaveretum 15.4 mg.

One surgeon performed or supervised all of the procedures (T.J.C.). A standard approach was used for the both inpatient and outpatient procedures. A preliminary diagnostic, saline hysteroscopy was performed to exclude intra-cavity or endometrial pathology. The ablation cycle was then undertaken according to the manufacturer's instructions after the "cavity integrity assessment" was passed.

A check hysteroscopy was then performed to determine the degree of completeness of endometrial destruction. Partial destruction of the endometrium (one or both cornua and/or fundal endometrium untreated) on visual inspection was considered to be incomplete treatment. Post-operatively, all women, whether operated as an outpatient or day-case procedure, recuperated on a bed on a day-case ward and were given oral/parenteral morphine 10 mg or codeine 30–60 mg as required. Patients were discharged once the pain was controlled, diet was tolerated and they had passed urine and at least two hours had elapsed since opiate analgesia had been given.

Outcome measures

The baseline characteristics of the women enrolled in the study were examined to ensure that the two treatment groups were comparable. The data collected included age, body mass index (BMI), parity, cycle phase, uterine axis and uterine sound length. Failed procedures, complications and information on the postoperative course were also recorded.

A postal questionnaire was sent to participants at six months after treatment to compare the efficacy of outpatient treatment versus inpatient treatment following approval from the Birmingham Women's Hospital's Research and Development Department. The primary outcome measures were the subjective self-assessment of uterine bleeding symptoms and satisfaction with treatment. Patients were asked to describe their bleeding symptoms at present on a five-point scale as "no bleeding," "spotting," "light bleeding," "moderate bleeding" or "heavy bleeding." Improvement in bleeding symptoms was assessed on a four-point ordinal scale; the response categories were "much better," "a little better," "same" and "worse." Patients were asked to answer

“yes” or “no” as to whether they were satisfied with their treatment. Secondary outcome measures included the measurement of health-related quality of life (HRQL) using the validated menorrhagia multi-attribute utility assessment [14], improvement in menstrual-related symptoms (dysmenorrhoea and pre-menstrual syndrome) and complications of surgery. Economic data were also collected and these included the time taken to resume normal activities and work, the number of post-procedure hospital outpatient and general practitioner visits and the need for further surgery for HMB.

Statistical analysis

Dichotomous data were presented as simple proportions. Relative risks and their 95% confidence intervals (CI) were calculated for the comparison of proportions or the Fisher’s Exact test was used. Continuous variables were summarised by the median and interquartile range, and comparisons between groups were performed by using the Mann Whitney *U*-test. All statistical tests were two-sided. A *P*-value < 0.05 was considered to be statistically significant.

Results

Thirty-eight women were included in the study, with 18/38 (47%) undergoing treatment in the outpatient setting and 20/38 (53%) in the day-case setting under general anaesthesia. There was no difference in baseline characteristics between the outpatient (experimental) and day-case (control) treatment groups (Table 1). All procedures were successfully completed and there were no intra-operative complications. Incomplete treatment, as determined by immediate post-procedure hysteroscopy, was recorded in 9/38 (24%) women. There was no difference between the likelihood of incomplete treatment according to treatment setting (outpatient 4/18 [22%] vs. inpatient 5/20 [25%], *P*=1.0).

Completed outcome questionnaires were returned by 17/18 (94%) women treated as outpatients and by 13/20 (65%) as inpatients. Overall, 27/30 (90%, 95% CI 73–98%) women reported an improvement in menstrual bleeding symptoms, with an amenorrhoea rate of 37% (95% CI 20–56%) and a combined amenorrhoea/spotting rate of 53% (95% CI 34–72%). The overall rate of patient satisfaction with the treatment was 25/30 (83%, 95% CI 65–94%), and 25/30 (83%, 95% CI 65–94%) patients reported that they would recommend the procedure to a friend. There was no significant difference between the outpatient and day-case treatment groups in terms of improvement in menstrual blood loss (94% vs. 84%, *P*=0.6), amenorrhoea rate (29% vs. 46%, *P*=0.5), amenorrhoea/spotting rate (47% vs. 62%, *P*=0.5), satisfaction rate (82% vs. 85%, *P*=1.0) and recommendation

Table 1 Baseline characteristics

| Patient characteristics | Inpatient (<i>n</i> =20) | Outpatient (<i>n</i> =18) |
|--|---------------------------|----------------------------|
| Mean age (range) | 40.6 (26–50) | 42 (32–49) |
| Parity median (range) | 2 (0–6) | 2 (1–10) |
| Caesarean sections (%)* | 7 (35%) | 3 (17%) |
| BMI (SD) | 31.4 (6.5) | 30 (6.8) |
| Cycle phase | | |
| • Proliferative | 7 (35%) | 9 (50%) |
| • Secretory | 6 (30%) | 7 (39%) |
| • Menstrual | 2 (10%) | 2 (11%) |
| • Atrophic | 1 (5%) | |
| • Not recorded | 4 (20%) | |
| Uterine axis | | |
| • Anteverted | 16 (80%) | 14 (78%) |
| • Retroverted | 4 (20%) | 4 (22%) |
| Uterine sound length (SD) | 9.35 (1.8) | 9.06 (1.1) |
| Uterine cavity length (sound-endocervical canal [range]) | 5.45 (4–7) | 5.11 (4–6) |
| Uterine width—cornu to cornu median (range) | 4.35 (2.8–5.3) | 4.45 (3.5–4.9) |

*In the inpatient group, six women had undergone one caesarean section (CS) as well as one or more vaginal deliveries and a single woman had undergone three CSs with no vaginal deliveries. In the outpatient group, a single woman had undergone one CS and the remaining two women had undergone two CSs. None of the three women had experienced a vaginal delivery

according to treatment setting (88% vs. 77%, *P*=0.7) (Table 2).

Of the 27 women reporting dysmenorrhoea prior to treatment, 18/27 (67%, 95% CI 46–83%) reported an improvement in pain post-ablation, whilst 5/27 (19%, 95% CI 6–38%) reported a worsening of dysmenorrhoea. There was no significant difference in the improvement of dysmenorrhoea between the outpatient (8/13, 62%) and day-case (10/14, 71%) treatment groups (*P*=0.7). Only four women (two in each treatment group) reported still requiring the regular use of simple analgesics to control dysmenorrhoea. Pre-menstrual syndrome (PMS) was reported by 28/30 (93%) women returning completed outcome questionnaires. Of these women, 12/28 (43%, 95% CI 24–63%) reported improvement in pre-menstrual tension and 17/28 (61%, 95% CI 41–79%) reported improvement in physical PMS symptoms. There were no significant differences between improvements in PMS at six months post-ablation according to the treatment setting (16/17 (94%) outpatient vs. 12/13 (92%) day-case, *P*=1.0).

Of the nine women (24%) considered to have incomplete destruction of the entire endometrium at hysteroscopy, six responded to the six-month questionnaire. Amenorrhoea rates at six months were lower in those women with incomplete ablation compared to those considered to have completely ablated endometria, although this reduction was

Table 2 Treatment outcomes at six months after NovaSure™ endometrial ablation: outpatient local anaesthetic treatment versus day-case general anaesthetic treatment

| Outcome measure* | Inpatient (n=13) | Outpatient (n=17) |
|---|------------------|-------------------|
| Periods now | | |
| • Amenorrhoea | 6/13 (46%) | 5/17 (29%) |
| • Spotting | 2/13 (15%) | 3/17 (18%) |
| • Light | 0/13 (0%) | 4/17 (24%) |
| • Moderate | 3/13 (23%) | 5/17 (29%) |
| • Heavy | 2/13 (15%) | 0/17 (0%) |
| Satisfied | | |
| • Yes | 11/13 (85%) | 14/17 (82%) |
| • No | 2/13 (15%) | 3/17 (18%) |
| Menstrual bleeding post-treatment | | |
| • Much better | 10/13 (76%) | 13/17 (76%) |
| • A little better | 1/13 (8%) | 3/17 (18%) |
| • Same | 1/13 (8%) | 1/17 (6%) |
| • Worse | 1/13 (8%) | |
| Dysmenorrhoea post-treatment | | |
| • Never had it | 0/13 (0%) | 3/17 (18%) |
| • Much better | 6/13 (46%) | 6/14 (43%) |
| • A little better | 2/13 (15%) | 4/14 (29%) |
| • Same | 2/13 (15%) | 2/14 (14%) |
| • Worse | 3/13 (23%) | 2/14 (14%) |
| Recommend to a friend | | |
| • Definitely | 8/13 (62%) | 12/17 (71%) |
| • Definitely, under general anaesthetic | 0/13 (0%) | 1/17 (6%) |
| • Probably | 2/13 (15%) | 3/17 (18%) |
| • Not sure | 1/13 (8%) | 1/17 (6%) |
| • Probably not | 1/13 (8%) | 0/13 (0%) |
| • Definitely not | 1/13 (8%) | 0/13 (0%) |

*No statistical difference ($P>0.05$) between inpatient and outpatient treatment for any clinical outcomes at six months (Fisher's exact test)

statistically non-significant (1/6 (17%) incomplete vs. 10/24 (42%) complete, $P=0.37$). There was no significant difference in the reported improvement in menstrual symptoms (5/6, 83% vs. 22/24, 92%, $P=0.5$) or satisfaction rates (5/6, 83% vs. 22/24, 92%, $P=0.5$) between those incompletely or completely treated.

HRQL improved in all domains following NovaSure™ endometrial ablation and no significant differences between treatment settings were found (Table 3). Only one woman (representing 3% of the cohort) reported that menstrual bleeding or pain was continuing to cause “a lot of trouble” at six months following the procedure, compared to 22/30 (73%) women pre-operatively. The effect of treatment upon sex life was limited, with 6/28 (21%, 95% CI 8–41%) sexually active women reporting improvement, with the majority of women reporting no difference in their overall sex life (Table 3).

Health care resource utilisation is shown in Table 4. No significant differences were noted between outpatient and

inpatient treatment. One woman in the day-case treatment group stayed overnight following treatment. No patient in either group had further surgery for HMB in the first six months following treatment.

Discussion

NovaSure™ endometrial ablation has been shown to be an effective treatment for women with excessive menstrual bleeding when performed as an inpatient procedure under general anaesthesia [8–11]. The current study is the first to show that NovaSure™ endometrial ablation is feasible, safe and effective for the treatment of HMB in the outpatient setting using local anaesthesia. Moreover, this study demonstrates that the effectiveness of outpatient treatment, in terms of amenorrhoea rates, reduction in menstrual bleeding, patient satisfaction and improvements in HRQL, are the same as procedures performed in the more

Table 3 Health-related quality of life (HRQL) outcomes at six months after NovaSure™ endometrial ablation: outpatient local anaesthetic treatment versus day-case general anaesthetic treatment

| Outcome measure* | Inpatient (n=13) | Outpatient (n=17) |
|--|------------------|-------------------|
| Before your operation, how much trouble did your bleeding/pain symptoms cause? | | |
| • A lot | 8/13 (62%) | 14/17 (82%) |
| • Quite a bit | 4/13 (30%) | 3/17 (18%) |
| • Some | 1/13 (8%) | |
| Since your operation, how much trouble has your bleeding/pain caused? | | |
| • None | 5/13 (38%) | 8/17 (46%) |
| • A little | 3/13 (23%) | 3/17 (18%) |
| • Some | 1/13 (8%) | 2/17 (12%) |
| • Quite a bit | 4/13 (31%) | 3/17 (18%) |
| • A lot | 0/13 (0%) | 1/17 (6%) |
| General health in the past 4 weeks | | |
| • Excellent | 3/13 (23%) | 2/17 (12%) |
| • Very good | 3/13 (23%) | 3/17 (18%) |
| • Good | 6/13 (46%) | 10/17 (58%) |
| • Fair | 1/13 (8%) | 2/17 (12%) |
| Sex life now | | |
| • Not applicable | 1/13 (8%) | 1/17 (6%) |
| • Worse | 0/13 (0%) | 1/17 (6%) |
| • No difference | 11/13 (84%) | 10/17 (58%) |
| • Improved | 1/13 (8%) | 5/17 (30%) |
| Median disease-specific HRQL [†] | | |
| • Before | 31 | 39.8 |
| • After | 100 | 89.65 |

*No statistical difference ($P>0.05$) between inpatient and outpatient treatment for any clinical outcomes at six months (Fisher's exact test and Mann Whitney U -test)

[†] Multi-attribute utility [14]

Table 4 Economic outcomes at six months after NovaSure™ endometrial ablation: outpatient local anaesthetic treatment versus day-case general anaesthetic treatment

| Outcome measure* | Inpatient (n=13) | Outpatient (n=17) |
|--|---------------------|---------------------|
| Days in hospital [†] | 1/13 (8%) | 0 (0%) |
| Outpatient visits [‡] | 1/13 (8%) | 1/17 (6%) |
| GP visits [#] | 5/13 (38%) | 3/17 (18%) |
| Home visits | 0/13 (0%) | 0/17 (0%) |
| Time to resume normal activity post-op. (median) | 4 (range 0–21 days) | 3 (range 1–21 days) |
| Time to resume work post-op. (median) | 5 (range 2–28 days) | 2 (range 0–40 days) |

*No statistical difference ($P>0.05$) between inpatient and outpatient treatment for any clinical outcomes at six months (Fisher's exact test)

[†] Duration of hospital stay was one day

[‡] Number of outpatient visits was three in each treatment group

[#] Mean number of GP visits was three in each treatment group

traditional inpatient or day-case setting under general anaesthesia, both in the control group of this study and when compared to other published inpatient studies [8–11]. In contrast to other studies, we also chose to present clinically relevant combined “amenorrhoea and spotting rates.” This is because the aim of ablative surgery is to achieve complete endometrial destruction whilst avoiding the ablation of endocervical tissue (which may lead to cervical stenosis and haematometra), so that cyclical spotting/discharge is likely to reflect cervical bleeding and should, along with amenorrhoea, be considered as successful “complete” ablative treatment. There were no significant differences between amenorrhoea or combined amenorrhoea/spotting rates between the treatment settings. The current study also showed an improvement in the secondary menstrual cycle outcomes, namely, dysmenorrhoea and PMS in the majority of treated women, a finding that requires more detailed evaluation in future investigations.

Our study demonstrated that the NovaSure™ endometrial ablation system is safe and successful in the outpatient, local anaesthetic setting. However, further randomised studies are necessary to minimise selection bias and explore the impact of factors such as dysmenorrhoea, parity, caesarean section and cervical surgery upon feasibility, particularly in regard to the ease of cervical dilatation and device deployment, as well as patient experience (pain, tolerability and acceptability). The safety, technical feasibility and patient acceptability of outpatient endometrial ablation have been shown in other observational series of different ablative devices, including thermal balloon ablation (Thermachoice™)[7, 12, 15] and hydrothermal ablation (HTA) [5], and two randomised trials comparing inpatient and outpatient microwave endometrial

ablation (MEA) [6, 16]. However, no studies have directly compared the effectiveness of outpatient, local anaesthetic procedures with standard inpatient, general anaesthetic procedures in terms of reduction in menstrual bleeding and HRQL. Although indirect comparisons between outpatient and inpatient procedures can be made, the scientific validity of such an approach is compromised, particularly in respect to differences in population characteristics. Thus, direct “head-to-head” comparisons are needed to inform practice. It may be argued that data from inpatient treatment under general anaesthesia are transferable to the outpatient, local anaesthetic setting because second-generation ablative devices are semi-automated and less operator-dependent. However, one cannot assume comparable effectiveness with procedures performed under general anaesthetic. This is because the duration of surgery and the degree of device manipulation are limited in the conscious patient, because these variables will impact upon tolerability. Thus, ablative procedures may be performed less rigorously and, therefore, treatment outcomes may be worse than the published inpatient data. In the case of the NovaSure™ technology, the current study did not demonstrate any significant differences in the completeness of endometrial destruction immediately post-surgery or in improvement in menstrual symptoms, treatment satisfaction or HRQL between the inpatient and outpatient settings. This would lend support to the use of the NovaSure™ ablative system in the outpatient environment, with the choice of treatment setting being driven primarily by the wishes of the patient, rather than clinician's concerns over relative efficacy.

We believe that our results are valid because the response rate was satisfactory (79% total), a standardised procedure was performed, data were collected on consecutive patients prospectively and outcome assessments were conducted by self-administered questionnaires, thus, avoiding the possible bias arising from the influence of clinicians at medical follow-up. However, this study may be criticised in view of the small sample size, the lack of randomisation with the inherent risk of selection bias and the short length of follow-up, which may lead to an over-optimistic estimate of the effects and under-report longer term complications, such as pain associated with haematometra. Therefore, this pilot study, which is the first to report the use of NovaSure™ endometrial ablation in an outpatient, local anaesthetic setting and demonstrate comparable effectiveness with procedures performed under general anaesthesia, should be viewed in the context of a feasibility assessment. Despite the relative scarcity of data regarding outpatient endometrial ablation in general [5–7, 12, 15, 16], the use of second-generation auto-ablative devices for the treatment of HMB in the outpatient setting is becoming increasingly popular (Samuel and Clark, personal communication). The current study examining the use of NovaSure™ endometrial ablation supports this paradigm.

Second-generation auto-ablative devices are quick, easy to use, safe and effective in appropriately selected women with HMB. This study demonstrates that the use of NovaSure™ endometrial ablation is feasible and as effective as traditional inpatient approaches. Special expertise is not required for setting up this service in established outpatient hysteroscopy clinics and, so, our results are transferable to the wider gynaecological setting. Moreover, these data relate to the use of the NovaSure™ technology shortly following its introduction to our hospital and, so, reflect our early experience. “Incomplete” treatment rates, as assessed by immediate post-operative hysteroscopy, may be reduced with experience. Despite this, the treatment outcomes in terms of amenorrhoea rates and patient satisfaction are comparable to other published inpatient NovaSure™ series, where post-operative hysteroscopy was not employed [8–11].

Our study also demonstrates that the outpatient, local anaesthetic approach appears to be as acceptable to women as the inpatient procedure under general anaesthesia, as judged by comparable treatment recommendation and patient satisfaction. However, to assess comprehensively the overall patient experience requires a more rigorous qualitative approach (e.g. employing in-depth patient interviews) to assess aspects such as priorities, choice, pain, embarrassment, acceptability, convenience etc., and this qualitative aspect of care requires further examination in future studies. A pragmatic randomised controlled trial is required (ideally with a patient preference non-randomised cohort alongside, for those women with strict treatment preferences, and, hence, ineligibility for randomisation) to minimise selection bias and allow a robust assessment of the impact of patient choice on their treatment experience (e.g. tolerability, recommendation to a friend, satisfaction etc.).

Outpatient “ambulatory” treatment will benefit patients by expediting effective treatment and increasing the operating capacity of health services [17]. Furthermore, the avoidance of general anaesthesia in women with coexistent medical morbidity means that outpatient treatment should be safer in this higher risk group. In addition, there are potential economic benefits resulting from the substantially reduced costs incurred by outpatient treatment, although the current study was too small to demonstrate any impact upon health resource use at follow-up. Because of the small sample size and the lack of randomisation, these results should be viewed in the context of a feasibility assessment. A randomised controlled trial of outpatient compared with inpatient NovaSure™ bipolar radio-frequency impedance-controlled endometrial ablation is required to rigorously assess the cost-effectiveness and guide clinical practice. On the basis of this feasibility study, a robust trial to assess this new health technology can be designed [18]. In addition to quantifying menstrual outcomes between

treatment settings, this trial should examine the overall patient experience to include an assessment of pain and rates of nausea and vomiting (which, to date, are conflicting [7, 16]), as well as in-depth qualitative assessment. Moreover, direct head-to-head comparisons between different second-generation ablative techniques are needed in both the inpatient day-case setting and the contemporary outpatient, local anaesthetic setting to provide clinicians with a rationale basis for the choice of ablative technologies, as well as appropriate settings.

Conflict of interest statement TJC has received research funding and honoraria for training in NovaSure™ endometrial ablation in an outpatient, local anaesthetic setting from Cytyc and is a member of their European Surgical Advisory Board.

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