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ORIGINAL ARTICLE

NovaSure endometrial ablation: a review of 400 cases

Patrick Campbell · Caitriona Monaghan · Michael Parker

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Abstract The objective of this study is to review outcomes and factors predictive of patient satisfaction following NovaSure endometrial ablation in the treatment of menorrhagia. NovaSure endometrial ablation has been established as a safe and effective treatment for menorrhagia. The setting of a hospital that is the biggest user of NovaSure in Ireland, coupled with a stable population, provided a unique opportunity to obtain accurate long-term follow-up data on the largest sample size reported to date. This is a retrospective observational study of 400 women who attended for NovaSure endometrial ablation between December 2006 and December 2009. Information was collected from patient charts and followed up with postal and telephone questionnaires. Statistical analysis was performed using SPSS version 18. The mean age and parity of patients were 44 years and 2.84, respectively. Three hundred and sixty-eight patients underwent the procedure, with an average treatment time of 88 seconds. Eighty-seven percent of patients were satisfied with the procedure, with 59% achieving amenorrhoea. Subsequent hysterectomy was performed in 7.6%. The complication rate was 14% (32 abandoned procedures and 23 in-patient admissions following the procedure). There were no uterine perforations. Women with longer uterine cavities were less likely to be satisfied with the procedure ($p=0.045$). Satisfaction rate at 1-year follow-up was 95%. NovaSure endometrial ablation is a highly effective treatment for menorrhagia. We recommend outpatient follow-up of women with longer cavities as further treatment may be necessary.

P. Campbell (✉) · C. Monaghan · M. Parker
Obstetrics & Gynaecology, Altnagelvin Area Hospital,
Londonderry, Northern Ireland, UK
e-mail: patrickcampbell@doctors.org.uk

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Introduction

One in 20 women aged 30–49 years in the UK consults her GP with menorrhagia each year [1]. NovaSure impedance control system has been established as a safe and effective second-generation technique for the treatment of this condition. [2–4] Five-year follow-up studies have reported amenorrhoea rates of 48–75% [3, 4]. The most commonly reported outcome measures in the current literature are amenorrhoea and hysterectomy rates, with a prospective follow-up of 200 cases representing the largest sample size [5]. Our study of 400 patients represents the largest sample size reported.

Most studies reporting outcomes following NovaSure have had strict inclusion criteria resulting in a selected group of women with normal-sized uterine cavities [2, 6, 7]. We hypothesised that NovaSure may be less effective when treating women with larger uterine cavities. We decided to assess this by examining whether patient satisfaction could be predicted on the basis of uterine cavity length.

NovaSure is primarily performed as a day-case procedure. It is therefore important to be aware of the rate of post-operative in-patient admission. We aimed to assess the number of post-operative admissions, and their indications, in our hospital.

Methods

A retrospective observational study was performed on women who underwent NovaSure endometrial ablation

between December 2006 and December 2009 at a district general hospital in Northern Ireland. Inclusion criteria were simply any woman who was admitted for the procedure during the specified time period. No pre-treatment was given, and there were no exclusion criteria. The standard NovaSure technique was performed under general anaesthesia, as previously reported in the literature [5, 8, 9].

Four hundred patients were identified from theatre logbooks and their charts reviewed. A proforma was used to collect demographic data and procedural data (cavity measurements, time taken and power of the procedure). Cavity length was measured with a uterine sound; cornual width and power were calculated by the NovaSure device. Minor operative complications were classified as failure to complete the procedure or post-operative admission. Major complication was defined as uterine perforation. Outcome measures were amenorrhoea rate and patient satisfaction with the treatment ('yes' or 'no'). The rate of subsequent hysterectomy was determined for patients not satisfied. The post-operative histological data for these patients were examined. Follow-up information was obtained from gynaecology outpatient clinic letters. Those patients not reviewed at clinic were followed up by postal and telephone surveys.

Statistical analysis was performed with SPSS version 18. An independent-samples *t* test was conducted to compare uterine length with patient satisfaction ('yes' or 'no'), and Levene's test confirmed equal variances. Following this statistical test, we subsequently assessed satisfaction rates in women with uterine cavities measuring less than 5 cm, 5 to 6 cm and greater than 6 cm.

Results

Four hundred women were included in the study. Thirty-two procedures (8%) were not completed. Data were analysed on the remaining 368 patients. There were no missing data.

The mean age and parity were 44 years (range, 29–58 years) and 2.84 (range, 0–7), respectively. Cavity length ranged from 3.5 to 9.5 cm (mean 5.6 cm), and cornual width ranged from 2.5 to 5.2 cm (mean 4.1 cm). The mean time to complete the procedure was 88 s (range, 37 to 120 s).

The majority of the abandoned cases (28/32) were due to patient factors such as a uterine cavity that was too large or too small. Other rare causes included a sub-septate uterus, cervical stenosis and a lax cervix. The remaining four abandoned cases were due to mechanical failure of the NovaSure device. Hysteroscopy was performed in 16/32 cases with no confirmed uterine perforations. During the same operative session, thermal balloon ablation was performed in 11 cases and one patient had a Mirena coil inserted. Subsequent hysterectomy was performed in 13 patients. Of the remaining patients, five had no further treatment and two patients underwent successful repeat NovaSure endometrial ablation at a later date.

Three hundred and twenty-one women (87%) were satisfied with the procedure, and the overall amenorrhoea rate was 59% (217/368 cases). Of the 47 women not satisfied with the procedure, subsequent hysterectomy was performed in 28 cases—22 for menorrhagia and 6 for dysmenorrhoea—giving a total hysterectomy rate of 7.6%. Post-operative histological data were available on 21 of the 28 patients revealing ten cases of benign leiomyomas, two cases of adenomyosis, two benign endometrial polyps and one case of FIGO stage 1A endometrial carcinoma. The remaining six women had normal uteri (Fig. 1).

Twenty-three patients (6%) required post-operative in-patient admission from the day-case unit following the procedure. The most common indications for admission were pain (11 cases) and nausea (6 cases). Other indications were hypotension, dizziness and vasovagal episodes. Of the 368 women in whom the procedure was completed, there were no major intra-operative or post-operative complications. The overall complication rate, including failure to complete the procedure and requirement for post-operative admission, was 14% (55/400 cases).

Follow-up information was obtained from 172 patients reviewed at the gynaecology outpatient clinic. A postal questionnaire was delivered to the remaining 196 patients of whom 100 responded (59% response rate). The remaining patients were contacted by telephone. Follow-up data, which ranged from 4 months to 3 years, were available in 100% of cases. Long-term follow-up data (>1 year) were available mainly from those women who responded to the postal and telephone surveys. In this group, the satisfaction rate was 95% (135/142 women) at 1 year following the procedure and 91% (59/65 women) at 2 years (Fig. 2).

There was a statistically significant difference when uterine length was compared with patient satisfaction ($p = 0.045$) indicating that women with longer uterine cavities were more likely to be unsatisfied with the procedure. Further analysis revealed women with cavities less than 5 cm (147 patients) were satisfied in 91% of cases. Women with cavities measuring 5–6 cm (114 patients) had a satisfaction rate of 86%, and those with cavities greater than 6 cm (107 patients) were satisfied in 83% of cases.

Discussion

Many studies have published convincing evidence to confirm the safety and efficacy of NovaSure endometrial

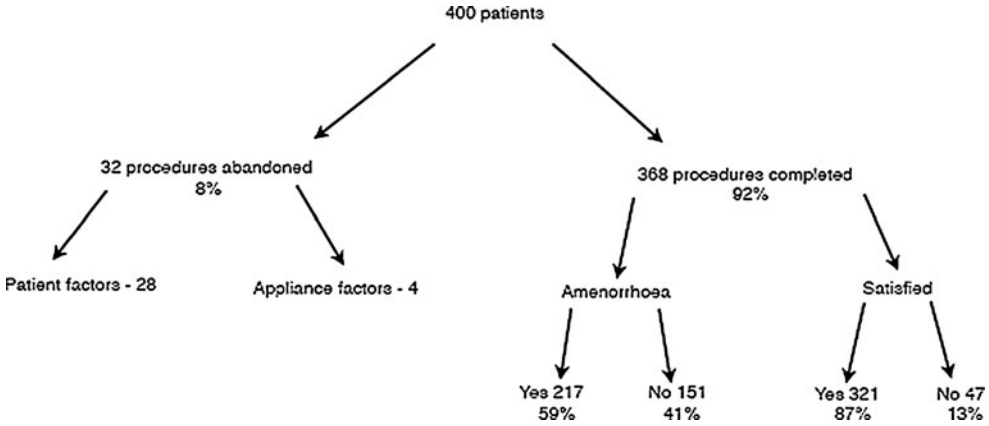

Fig. 1 Flow diagram summarising patient outcomes following NovaSure endometrial ablation

ablation in the treatment of menorrhagia. A recent survey reported that less than 10% of gynaecologists in the UK use the NovaSure device as their first choice endometrial ablative technique [10]. We were fortunate to be based in a Hospital where all seven consultants use NovaSure as their first choice endometrial ablative technique. In fact, our Hospital is the largest user of NovaSure in Ireland. This permitted a review of a large sample size over a relatively short time period. Follow-up data were achievable on all patients (100%), given that the local population is stable with minimal migration. Long-term follow-up greater than 1 year following the procedure was available in 56% of cases. Our results represent the largest sample size reported to date. Our findings of 59% amenorrhoea, 87% satisfaction and 7.6% hysterectomy rate are comparable with previous studies [4, 5, 8], suggesting that our sample is likely to be representative.

The overall complication rate of 14% was due to failure to complete the procedure (32 cases) or post-operative admission for symptom control (23 cases). There were no major complications such as uterine perforation. These findings are similar to those published by Cooper et al. [11] who reported a 13% complication rate with no perforations. Bongers et al. [6] reported no complications. It is possible that such a low complication rate in this study was the result of excluding abandoned procedures as complications and the use of strict inclusion criteria to ensure normal cavities. Given the retrospective nature of our study, we cannot confirm that patients underwent ultrasound assessment prior to treatment with NovaSure.

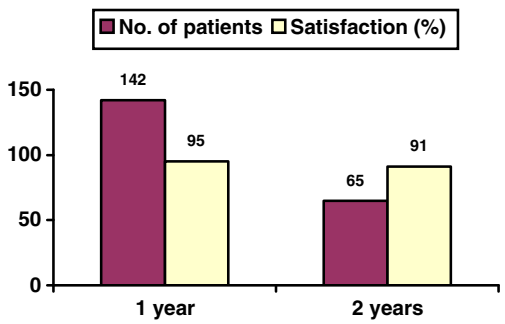

Fig. 2 Long-term follow-up of satisfaction rates following NovaSure endometrial ablation

Statistical analysis revealed an inverse relationship between cavity length and overall patient satisfaction ($p=0.045$). Further analysis revealed women with cavities less than 5 cm were satisfied in 91% of cases and those women with cavities measuring 5–6 cm and greater than 6 cm had satisfaction rates of 86% and 83%, respectively. These findings are supported by a recent study that reported an association between amenorrhoea and a total uterine length of less than 9 cm [12]. We propose that assessment of cavity length at the time of the procedure could be used as a measure of identifying those patients who are less likely to be satisfied. We recommend that patients with longer cavities may benefit from a post-operative review, as further treatment may be necessary.

We found that 6% of our patients required post-operative in-patient admission following the procedure. We considered that the administration of general anaesthesia might have accounted for many of the indications for admission, such as nausea, hypotension and vasovagal episodes. The recent advances in performing NovaSure under local anaesthesia [13], however, have comparable rates of post-operative in-patient admission (7%) [14].

Conclusion

This study highlights the effectiveness of NovaSure in the ‘real life’ setting of a district general hospital rather than a highly selected study population group. The results of our study reaffirm the place of NovaSure as a safe and effective treatment modality for women with menorrhagia.

Declaration of interest The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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