

# Predictive Factors Affecting the Success of a NovaSure Endometrial Ablation

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**Objectives:** Menorrhagia is a common disorder worldwide. It affects approximately 22% of otherwise healthy women. In Hong Kong, 9% of all gynaecology admissions were due to menorrhagia, for which hysterectomy was the main surgical treatment. In 2007, the National Institute for Health and Clinical Excellence guideline recommended endometrial ablation as a treatment option for benign menorrhagia, using second-generation techniques. In this study, patients who received NovaSure endometrial ablation in a local unit in the United Kingdom were analysed. The aim was to identify factors affecting its cost-effectiveness and predict the rate of success, so that the analysis could be applied to the Hong Kong population.

**Methods:** This retrospective study was performed within Poole Hospital, a district general hospital in the United Kingdom. Patients who underwent a NovaSure endometrial ablation for dysfunctional uterine bleeding between July 2009 and June 2010 were included. Several factors that might affect the effectiveness of the procedure were studied in detail. Success rates, failure rates, and amenorrhoea rates were studied after 12 months of follow-up. Success was defined as satisfaction expressed after the procedure and a subjective reduction in menstrual flow. Failure was defined by recourse to subsequent medical or surgical therapy during the same 12 months of follow-up.

**Results:** During the 12-month period, 32 patients underwent a NovaSure endometrial ablation in the unit. Treatment satisfaction and reported reduction in menstrual blood flow was expressed in 84.4% of patients at 12-month follow-up. Amenorrhoea was noted in 17 (53.1%) of the patients. Overall, five (16%) patients warranted extra management, four of whom underwent a hysterectomy. Having a previous Caesarean section was a factor that showed a trend towards failure of a NovaSure ablation, but this result was not statistically significant. All other factors demonstrated no association with outcomes.

**Conclusions:** A history of Caesarean section showed trend towards failure of NovaSure endometrial ablation. The majority of patients were satisfied with the procedure and complication rate was down to 6.3%. Promotion of this technique in Hong Kong may lead to greater patient satisfaction, reduce costs, and minimise hysterectomy rate and outpatient clinic attendance.

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*Keywords: Body mass index; Menorrhagia; Endometrial ablation techniques*

## Introduction

Menorrhagia is a common disorder worldwide. It affects approximately 22% of otherwise healthy and well women<sup>1</sup>. In Hong Kong, 9% of all gynaecology admissions were due to menorrhagia, for which hysterectomy was the main form of surgical treatment. Moreover, 64% of benign abdominal hysterectomies and 65% of benign laparoscopic hysterectomies were performed for menorrhagia<sup>2</sup>. However, since major abdominal procedures confer operative risks and entail a significant recovery period, a large number of patients in Hong Kong opt for medications such as tranexamic acid and hormones. These choices create long-term issues, namely: clinical work load, financial burdens, and prolonged waiting times at outpatient clinics. In 2007 the National Institute for Health and Clinical Excellence (NICE) guideline recommended endometrial ablation to be a possible treatment option for benign menorrhagia prior to

a hysterectomy and second-generation ablation techniques<sup>3</sup>. Compared with hysterectomy and first-generation ablation techniques, second-generation ablation techniques such as NovaSure entail shorter operating times, shorter recovery periods, shorter hospital stays, lower complications rates, and greater patient satisfaction<sup>4</sup>. This technique is suitable for the patients and situations in Hong Kong, since patients can recover quickly and return to work sooner, and the burden of long-term follow-up and waiting times at the clinics can be relieved. Unfortunately however, this technique is not commonly practised in Hong Kong due to a lack of surgeons' expertise.

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In this study, patients who received NovaSure endometrial ablation in a local unit in the United Kingdom have been analysed. The aim was to identify factors that can affect the cost-effectiveness and predict the rate of success, so that the analysis can be applied to population in Hong Kong. It was hoped that the results could aid surgeons to carefully select appropriate patients for the procedure, increase the success rate, and achieve greater patient satisfaction.

## Second-generation Endometrial Ablation

Second-generation endometrial ablation includes NovaSure endometrial ablation, microwave endometrial ablation, and thermal balloon endometrial ablation. In this study, only the NovaSure ablation device was considered.

NovaSure endometrial ablation utilises radiofrequency to ablate the endometrium. It consists of an impedance controlled system with a single ablation device and a radiofrequency controller<sup>5</sup>.

### *NovaSure Radiofrequency Controller*

The controller is a constant power output generator with a maximum power delivery of 180 Watts. It automatically calculates the output power based on uterine cavity length and width. The length of the uterine cavity is assessed during uterine sounding, while the width is calculated as the device expands in the cavity (cornu-to-cornu distance).

A vacuum pump is built into the controller and generates a continuous suction during the ablation cycle. Suction allows removal of liquid components such as blood and saline within the uterine cavity and maintains a close apposition of the uterine walls to the bipolar electrode. The device also has a safety feature called cavity integrity assessment system. It is designed to detect uterine perforations and prevent energy delivery to the organs in the abdominal cavity. This is achieved by monitoring the CO<sub>2</sub> pressure within the uterine cavity. After the device is inserted and deployed in the uterine cavity, CO<sub>2</sub> is delivered into the cavity at a safe flow rate and pressure. If a pressure of 50 mm Hg can be maintained for a period of 4 seconds, radiofrequency ablation proceeds. If there is a leakage of CO<sub>2</sub> during the procedure, the system automatically terminates the ablation immediately.

### *NovaSure Endometrial Ablation Device*

The NovaSure device consists of a single-use bipolar electrode gold-plated mesh mounted on an

expandable and flexible frame. After the deployment, the electrode mesh conforms to the shape of the uterine cavity. The system uses tissue impedance (electrical resistance) as a modality to control the depth of ablation. During ablation of the endometrium, impedance is low due to a high concentration of saline in endometrial tissue. The endometrium is thus vapourised and evacuated from the uterine cavity by suction. As the ablation progresses into the myometrium, tissue impedance rapidly rises due to the much lower concentration of saline. The ablation cycle stops automatically when tissue impedance reaches 50 Ohms. From the specific configuration of the electrode, the ablation depth in the cornua and lower uterine segment does not exceed 2 mm and reaches a maximum of 5-7 mm in the mid-body of the uterus.

In the United Kingdom, this device is gaining in popularity due to its high success rates, ease of use, and short operating time<sup>6</sup>. Multiple studies have shown encouraging results. Success defined as subjective reduction of heavy-to-normal bleeding has been observed in 75 to 95% of patients. Of these patients, 69 to 75% become amenorrhoeic at 12 months<sup>7</sup>, 18 months<sup>4</sup> and 5 years<sup>8</sup>. In all cases, operating times ranged from 45 to 120 seconds as the device stopped ablating automatically at 120 seconds.

The cost of performing a NovaSure ablation is comparable to that of a hysterectomy when all costs including anaesthetics and hospital stay are included (3000 pounds for NovaSure vs. 5400 pounds for an abdominal hysterectomy<sup>9</sup>). It is reasonable to assume that NovaSure ablation is more cost-effective as it requires a shorter hospital stay. However, hysterectomy was shown to be more cost-effective based on using an incremental cost per quality-adjusted life year (QALY) of 1440 pounds compared to 970 pounds per additional QALY year for NovaSure<sup>10</sup>. Those dissatisfied after their NovaSure endometrial ablation eventually undergo a hysterectomy and this reduces the cost-effectiveness of using this device.

NovaSure ablation can also reduce outpatient attendance numbers compared with using long-term medical treatment. After a successful procedure, only one outpatient appointment is usually necessary over the next 5 years, mainly to ensure patient satisfaction and possible recurrence. This amounts to an 80% reduction in outpatient attendance compared with persons receiving medical management and yearly follow-ups.

## Methods

This retrospective study was performed within Poole

Hospital, a district general hospital in the United Kingdom. Patients who underwent a NovaSure endometrial ablation for dysfunctional uterine bleeding between July 2009 and June 2010 were included. The patients all had the criteria necessary for endometrial ablation suggested by NICE<sup>3</sup>, including uterus of <10 weeks' gravid size, uterine fibroids of <3 cm in size, and no known structural or histological abnormalities. In this context, structural abnormalities included bicornuate uterus, uterine didelphys, or septated uterus. The presence of an endometrial polyp of <3 cm was not considered as exclusion criteria based on the fact that Sabbah and Desaulniers<sup>7</sup> found that their presence did not alter the outcome. The procedures were performed as day cases under general anaesthesia by a single qualified surgeon, hence minimising discrepancies between surgical techniques and assessments. All patients received a thorough clinical examination, a cervical smear, contraceptive advice, and hysteroscopy prior to the procedure. None of the patients received preoperative preparation of their endometrium.

A self-designed proforma (Appendix 1) was used to obtain information through each patient's hospital records at the 12-month follow-up. Success rates, failure rates, and amenorrhoea rates were studied. Outcome was assessed mainly by the patient's perception of their menstruations compared with their preoperative periods; the procedure was deemed a success if the menstrual bleeding was arrested, subjectively reduced or returned to normal. However, postoperatively all patients also received a simple menstruation record chart to document their menstruation flow (Appendix 2) with the aim of identifying those with persistent menorrhagia. Failure was defined as

having subsequent medical or surgical therapy at the same 12-month follow-up either due to (a) persisting heavy blood loss interfering with their physical, social, emotional, and material quality of life as per NICE guideline<sup>3</sup> or (b) persisting menstruation constantly marked as excessive in the menstrual record chart.

Putative factors that might affect the effectiveness of the procedure were studied in detail. These included patient age, body mass index (BMI), parity, previous Caesarean section, regularity of periods prior to procedure, time interval between last menstrual period and date of procedure, uterine dimensions (length and width provided during NovaSure procedure), and abnormal pre-procedure findings on hysteroscopy. The duration of the procedure (in seconds) was also studied as patients in whom it was longer might be associated with a larger cavity and warrant subsequent management.

Pearson Chi-square tests were performed on all factors individually; a p value of <0.05 was considered statistically significant.

Data on hospital admission for menorrhagia in the year 2011 were also looked at within Queen Elizabeth Hospital in Hong Kong. The aim was to generate approximate figures as to how many patients would be suitable for NovaSure (using the guidelines from NICE<sup>3</sup>) and how the procedure might affect the department as a whole if implemented.

## Results

During the 12-month period, 32 patients underwent

**Table. Results of NovaSure endometrial ablation (n=32)**

Results	Successful cases (n=27)	Failures (n=5)	p Value
No. of patients	27 (84.4%)	5 (15.6%)	-
Mean age (years)	42.6	39.2	0.696
Mean body mass index (kg/m <sup>2</sup> )	26.9	26.2	0.134
Mean parity	1.9	2.8	0.514
≥1 Previous Caesarean section	11.1%	40.0%	0.102
Regular periods	48.1%	40.0%	0.737
Mean No. of days from the last menstrual period to the day of the procedure	13.8	11.6	0.743
Abnormal findings on hysteroscopy	3.7%	20.0%	0.167
Mean uterine length (cm)	4.8	4.8	0.873
Mean uterine width (cm)	3.8	3.8	0.960
Mean duration of procedure (seconds)	86.0	95.8	0.604

a NovaSure endometrial ablation in the unit. All their medical and procedural records were available and all attended follow-up at 12 months post-procedure.

Of the 32 patients, 27 (84.4%) expressed satisfaction with their treatment and reported reduction in menstrual blood flow at the 12-month follow-up. Amenorrhoea was noted in 17 (53.1%) of these 32 patients. Overall, five (16%) of them received extra management and were classified as failures. Four of these five patients subsequently underwent hysterectomy and one patient (3%) received medical treatment in the form of Depo-Provera. Of the 32 patients, two (6%) developed endometritis postoperatively and were treated with antibiotics. There were no other postoperative complications.

The detailed results are shown in the Table. All 32 patients had a hysteroscopy prior to the procedure, but only two had an endometrial polyp, neither of which was resected at the time of procedure. One of these patients was deemed to have a successful outcome while the other received extra management.

The mean duration of the procedure was 86.0 seconds in the successful group and 95.8 seconds in the failure group ( $p=0.604$ ). While the device was set to automatically turn off at 120 seconds, none of the devices in the failure group reached that limit, but three did so in the successful group.

In Queen Elizabeth Hospital, Hong Kong, there were 368 admissions for menorrhagia caused either by dysfunctional uterine bleeding or fibroids in 2011. Notably, 126 (35%) of these patients met the criteria for NovaSure (uterus <10 weeks' gravid size, <3 cm fibroids, and no structural or histological abnormalities); 108 (30%) of them were aged  $\geq 40$  years and likely to have completed having their family.

## Discussion

In this study, success was defined as a satisfactory return to normal bleeding, reduction in menstrual bleeding, or arrested bleeding. Failure was defined as requiring further management after a NovaSure endometrial ablation. Follow-up of 12 months was chosen because of limited numbers of procedures performed beyond that time and it was suggested that majority of failed cases underwent hysterectomy within 24 months of the procedure<sup>11</sup>. The data indicated a success rate of 84.4% and an amenorrhoea rate of 53.1% at the 12 months' post-procedure follow. This was comparable to other reports. There was a failure rate

of 15.6% and a subsequently hysterectomy rate of 12.5%; these findings were also consistent with other studies where hysterectomy rates after NovaSure ablation ranged between 3.8% and 13.4%<sup>8,12-16</sup>.

The complication rate of 6.3% was also comparable to a large NovaSure study by Campbell et al<sup>17</sup>, who described a postoperative complication of 6% after reviewing 400 cases. This was much less than the complication rates after a hysterectomy (40.6%<sup>18</sup>) and after first-generation endometrial ablation (10.9%<sup>18</sup>).

Previously, a similar study by Shavell et al<sup>15</sup> looked at several similar factors that might affect the success rate of second-generation endometrial ablations (including NovaSure). It showed that women undergoing hysterectomy subsequent to endometrial ablation were younger at the time of ablation and were more likely to have had a prior Caesarean section. There was no difference in terms of gravidity, parity, endometrial thickness, or presence of uterine fibroids. However, this was a study of second-generation endometrial ablation as a whole, and not specifically directed at NovaSure.

In this NovaSure-specific retrospective study, patient age and parity did not show any trend towards more successful procedures, and was in line with what was mentioned by Shavell et al<sup>15</sup>, particularly with respect to NovaSure ablation. Performance of the procedure at particular times of the menstrual cycle that could affect endometrial thickness also did not show any obvious effects on outcomes. Akin to Shavell et al's<sup>15</sup> data suggesting a trend towards a subsequent hysterectomy if patients had a scar from a previous Caesarean procedure also yielded no particular trend.

Gemer et al<sup>19</sup> showed that presence of endometrial polyps did not lead to any trend or statistical significance in the success of endometrial ablation. Our data further confirmed this finding. Fakih et al<sup>20</sup> suggested a trend towards failure and higher rate of hysterectomy following a NovaSure ablation if patients' BMI was over 34 kg/m<sup>2</sup>, but a similar trend was not confirmed in this study.

NovaSure was always used for a uterus of <12 cm in length, and the maximum procedure duration of 120 seconds. Between the successful and failure group, results showed no significant difference in the mean length and width of the uterus found during the uterine assessment process of the NovaSure. One can also assume that a larger uterine cavity takes longer to ablate and was more likely

to fail than when applied to small cavities. This might be even more important if the procedure was to be stopped by the device's maximum procedure duration of 120 seconds, regardless of whether the entire endometrium was ablated. However our results showed no difference in operating times in relation to successful outcomes, and our three patients who had the maximum duration (120 seconds) procedures all had successful outcomes. This suggests that unless the uterine cavity was more than 12 cm in length, a longer duration of the procedure and even a larger-sized uterus does not predict the outcome of NovaSure ablation.

In this study, it was postulated that excluding results from patients with a raised BMI and those who had a previous Caesarean section, the success rate and cost-effectiveness might be improved. However, a recent study<sup>21</sup> suggested that failure and amenorrhoea rates after radiofrequency or balloon thermal ablation were not different in patients with or without a Caesarean scar. Besides, due to the increasing rate of Caesarean sections and subjects with high BMIs among the general population, excluding such patients might lead to very limited use of NovaSure ablation. Hence, with good counselling a previous Caesarean scar should not be deterrent.

A Hong Kong local study has suggested that even first-generation endometrial ablation can be successful in management of menorrhagia, with 96% of patients avoiding a second operation, 86% satisfied after 4 years of follow-up, and a complication rate of 9% (mainly excessive fluid absorption and endometritis)<sup>2</sup>. These results are comparable to other studies worldwide and to our study. To date, second-generation devices such as NovaSure are not in common use in Hong Kong and only minimal local data are available. After reviewing admission data, we deduced that 30 to 35% of patients admitted for menorrhagia could benefit from NovaSure ablation. Conceivably, overall benefits may be even greater, as not all patients with menorrhagia need to be admitted to undergo the procedure.

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Given that studies suggest that NovaSure is as effective as first-generation endometrial ablation and yields better amenorrhoea rates (41% vs. 35%), reduced complication rates (6% vs. 9%), and much reduced procedure times (4 minutes vs. 24 minutes<sup>22</sup>), it appears to offer several advantages. In addition, NovaSure endometrial ablation entails a potential reduction in costs, hysterectomy rates, and outpatient attendances.

Limitations of this study include the small sample size, and only 12 instead of 24 months when most hysterectomies for failed ablation are performed. Ideally, a prospective study with a larger sample size and the use of a more standardised post-procedure measuring scale for menorrhagia and outcome should have been used. Owing to possible difference in demographic features between Hong Kong and the United Kingdom population, a study specifically directed to patients in Hong Kong may also be appropriate.

## Conclusions

According to our study findings, age, BMI, parity, a history of Caesarean section, regularity of menstruation, abnormalities on hysteroscopy, and mean procedure duration had no effect on the success rate of NovaSure endometrial ablation. The main criteria for the procedure remain those suggested by NICE<sup>3</sup>. The majority of patients were satisfied with the procedure and complication rate was low. Promotion of this technique in Hong Kong may lead to better patient satisfaction, reduction of costs, as well as hysterectomy and outpatient attendance rates.

## Declaration

We declare that we have no conflict of interest to disclose.

## Appendices

Additional material related to this article can be found on the HKJGOM website. Please go to <<http://www.hkjgom.org>>, search for the appropriate article, and click on Full Text (PDF).

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## Appendix 1. The self-designed proforma

NOVASURE Ablation Data Proforma Proforma No. \_\_\_\_\_

Patient's details:

Age \_\_\_\_\_ BMI \_\_\_\_\_

Parity \_\_\_\_\_ No. of vaginal delivery \_\_\_\_\_ No. of previous Caesarean sections 0 1 2 >2

Smear up to date? Y / N      Family complete: Y / N

Contraception:      Contraception discussed? Y / N

Symptoms and pre-op findings

1) Menorrhagia: none      mild      moderate      heavy

2) Periods regular? Y / N

3) Last menstrual period – days prior to procedure: \_\_\_\_\_

4) Scan normal? Y / N

Findings if not normal:

5) Lower segment thickness (if applicable): \_\_\_\_\_

6) Histology Y / N

Findings:

7) Examination findings: Normal / Abnormal

Details:

Op findings:

10) Pre-op hysteroscopy: Normal / Abnormal

Details:

11) Cavity details and op time:

length: \_\_\_\_\_ width: \_\_\_\_\_

Time for NovaSure to complete: <2 mins (duration: \_\_\_\_\_ ) / >2 mins

12) Post-op hysteroscopy – Results Uniform / Partial

Follow-up 12 months

13) Complications: Y / N      Details: \_\_\_\_\_

14) Periods? Y / N

15) Periods reduced / no difference / worst

16) Further management required? Y / N

Details: \_\_\_\_\_

**Appendix 2. Menstruation record chart**

Please fill in the dates of menstruation and vaginal bleeding:

spotting			normal			excessive		
							X	
				X			X	
	X			X			X	

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31