



Obstetrics and Gynaecology Cases - Reviews

RESEARCH ARTICLE

Outcome of Novasure Endometrial Ablation in Women with Heavy Menstrual Bleeding with or without Dysmenorrhoea, Including Those with Uterine Cavity Length More Than 6.5 cm

Nader Gad^{1*}, Ashlee Rigby², Alia Vemuri¹ and Mahima Singh³

¹Department of Obstetrics and Gynaecology, Royal Darwin Hospital, Darwin, Australia

²School of Medicine, Flinders University, Adelaide, Australia

³Port Pirie Regional Health Services, Australia

*Corresponding author: Dr. Nader Gad, Consultant & Senior Lecturer, Department of Obstetrician and Gynaecologist, Royal Darwin Hospital, PO BOX 41326, Casuarina - NT0811, Australia, Tel: +61-415-159-150, Fax: +61-8-89-122-505, E-mail: drnadergad@hotmail.com

Abstract

Aim: To assess the outcome of Novasure endometrial ablation procedure in patients with heavy menstrual bleeding, with or without dysmenorrhea including women with uterine cavity length greater than 6.5 cm.

Methods: A retrospective cohort study analysing the outcomes of the procedure in 100 women over a four-year period. The primary outcomes were amenorrhea, reduced menstrual bleeding, persistence of heavy periods and hysterectomy. Success rates were compared with published literature.

Results: The Novasure procedure was performed in 100 women; 91 with uterine cavity length of 4-6.5 cm (group A) and 9 women with uterine cavity length > 6.5 cm (group B). Three women in group A were lost to follow up. Dysmenorrhea was reported in 29 (32.9%) women in group A and in 5 (55.6%) women in group B. In group A the rate of amenorrhea, lighter periods and hysterectomy were 89.8%, 9.1% and 1.1% respectively compared to 55.6%, 22.2% and 22.2% in group B. Two out of the 3 women who required hysterectomy had dysmenorrhea. The failure rate in women presenting with heavy periods without dysmenorrhea was 1/63 (1.59%) compared to 2/34 (5.9%) in women with heavy periods and dysmenorrhea.

Conclusions: The Novasure endometrial ablation procedure is a very effective treatment for heavy menstrual bleeding with and without dysmenorrhea in women who have completed their family. Although the success rate was lower in women with uterine cavity length marginally greater than 6.5 cm, the outcome was still acceptable.

Keywords

Endometrial ablation, Novasure, heavy menstrual bleeding, dysmenorrhea, length of uterine cavity

Introduction

Heavy Menstrual Bleeding (HMB) is a common health problem and may be associated with iron deficiency anaemia affecting the quality of life of many women. Problems of HMB can be more complicated when it is associated with dysmenorrhea. Traditionally, medical management of HMB has been the first line therapy. Unfortunately, many options can be associated with hormonal side effects or lack of efficacy, leading to discontinuation of medical therapy and requirement of surgical interventions [1]. The most common surgical interventions for women who have completed their family are endometrial ablation or a hysterectomy. A hysterectomy will be 100% effective in terms of cessation of blood loss and dysmenorrhea, but it is a substantial, invasive operation, with lengthy recovery time and side effects.

Endometrial ablation involves a wide variety of methods to destroy the basal gland layer of the endometrium under hysteroscopic guidance [2]. The newer "second generation" ablation techniques have been found to involve shorter duration of surgery, less incidence of fluid overload, uterine perforation, cervical lacerations and haematometra, compared to first-generation ablation [3]. Critically, patients receiving ablation with the newer endometrial ablative techniques reported fewer incidence of further surgery or hysterectomy at 10-year follow up [3].

The Novasure Endometrial Ablation (NEA) system is intended to ablate the endometrial lining of the uterus in premenopausal women with excessive bleeding due to benign causes for whom childbearing is complete. The NEA procedure involves the application of bipolar radiofrequency electrical energy and this procedure is usually performed under general anaesthetic [4]. The NEA device has exceptionally high acceptability of use by gynaecologists (> 98%) [5]. NEA is an effective form of endometrial ablation, with success rates in terms of amenorrhea ranging from 30-75%, depending on length of follow up [6] and very few patients experience menorrhagia at 12 months (3.9%) [7]. Some debate still exists about the best management for women with dysmenorrhea and HMB, especially for those with large uterine cavities. A uterine cavity length of > 10 cm has been found to be associated with higher rates of dysmenorrhea and a higher BMI [8]. Campbell, Monaghan & Parker concluded from a retrospective study that women with longer uterine cavities were less likely to be satisfied with the NEA procedure [9]. However, Lee and Kadra reported that there was no difference in success rates of the use of NEA procedure in terms of uterine length and width and they included participants with a total uterine length up to 12 cm [10]. In addition, endometrial ablation is more successful in achieving amenorrhea, and has higher levels of patient satisfaction in women without dysmenorrhea. Women with dysmenorrhea can benefit from combining endometrial ablation with insertion of a levonorgestrel IUD (Mirena) [11].

The present study aims to evaluate the outcomes of the NEA procedure in women with marginally larger uterine cavity lengths with and without dysmenorrhea.

Method

This is a retrospective review of 100 consecutive patients who underwent NEA for HMB with or without dysmenorrhoea at Darwin Private Hospital in Australia over a four-year period. All procedures were performed by the corresponding author (NG). This study has ethics approval granted by the Medical Advisory Committee of Darwin Private Hospital.

None of the patients received preoperative endometrial preparation. Majority of the patients were admitted as a day procedure and were discharged on the same day except for a few women who were from remote communities and were therefore scheduled for an overnight stay.

Preoperatively, all patients underwent a thorough evaluation including medical history, physical examination and pelvic ultrasound. Women with the following history were not offered NEA: desire for future pregnancy, recent pregnancy-related bleeding, previous endometrial ablation, active pelvic infection, previous upper segment caesarean section and previous trans-

mural myomectomy. Additionally, the following pelvic ultrasound findings were exclusion criteria: congenital abnormality of the uterus, very large uterus due to fibroids, total uterine length > 12 cm, suspected malignant or premalignant endometrial pathology (unless a preoperative endometrial biopsy excluded endometrial hyperplasia or malignancy).

The patients' clinical notes were analysed retrospectively and recorded in a database. The data collected included age, parity, mode of previous births, menstrual bleeding pattern, presence of HMB or dysmenorrhea and pelvic ultrasound findings including size of the uterus and presence of fibroids or polyps. The collected operative findings included the length and width of the uterine cavity and presence of any polyps or submucous fibroids. All women had intraoperative endometrial curettage immediately prior to the ablation. All obtained materials were sent for histological assessment.

Initial postoperative assessments were conducted at 6-12 weeks. Later follow ups for assessments of amenorrhea and other outcomes were conducted through further clinic visits or by telephone contact. Participants were assessed for changes in bleeding pattern including amenorrhea, reduced menstrual bleeding, HMB and dysmenorrhea.

The data were analysed with descriptive statistics to determine the success rate of the procedure of NEA in management of women with heavy periods with or without dysmenorrhoea. Women with cavity length > 6.5 cm were analysed separately. The procedure was considered a failure if the women stated no benefit from the NEA or required hysterectomy for their period problem/s.

Results

The Novasure procedure was performed in 100 consecutive women; 91 with uterine cavity length of 4-6.5 cm (group A) and 9 women with uterine cavity length > 6.5 cm (group B). Of group B, 7 women had a uterine cavity length measuring 7 cm, and 2 participants measured 7.5 cm. Three women were lost to follow up in group A. Patients were referred by their local General Practitioner when different medical treatment failed to treat their HMB. Furthermore, Mirena intrauterine device was not successful in 17% of patients.

Patient characteristics

Table 1 outlines the demographic characteristics of participants in terms of age, obstetric history and gynaecological features including the presence of fibroids and endometrial polyps in both groups. Dysmenorrhea was reported in 32.9% in group A and 55.6% in group B. A total of 10 (10%) women had Mirena IUD inserted intraoperatively. Apart from mild period-like pain, no patients had complications such as uterine perforation, intraoperative haemorrhage, bowel or bladder injury,

Table 1: Patient preoperative and intraoperative demographic characteristics.

	Group A uterine cavity 4-6.5 cm	Group B uterine cavity > 6.5	t	p
	Mean (SD)	Mean (SD)		
Age	44.1 (5.2)	45.0 (6.0)	-0.49	0.53
Parity [*]	2.1 (0.9)	2.6 (1.9)	-1.35	0.015
Preoperative US uterine volume [*]	116.3 (43.8)	206.9 (106.6)	-4.54	< 0.001
Length of uterine cavity (cm) [*]	5.4 (0.6)	7.1 (0.2)	-8.30	0.005
Width of uterine cavity (cm) [*]	4.0 (0.7)	4.4 (0.4)	-1.8	0.048
	N (%)	N (%)	X ²	P
Nulliparous	6 (7.1)	1 (11.1)	0.26	0.61
Vaginal delivery only	61 (69.3)	4 (44.4)	2.27	0.13
Caesarean section	22 (25)	2 (22.2)	2.75	0.43
Heavy menstrual periods only	59 (67.0)	4 (44.4)	1.84	0.18
Heavy menstrual periods and dysmenorrhea	29 (32.9)	5 (55.6)		
Adenomyosis (n = 93)	18 (20.5)	3 (33.3)	1.49	0.49
Previous mirena IUD failure	14 (15.9)	3 (33.3)	1.87	0.17
Mirena IUD insertion or replacement intraoperatively	6 (6.8)	0 (0.0)	0.63	0.43
Mirena IUD replaced intraoperatively	3 (3.4)	1 (11.1)	1.30	0.25
Submucous fibroids [†] (n = 93)	7 (8)	0 (0.0)	0.81	0.37
Fibroids (excluding submucous) (n = 92), [#]	20 (22.7)	5 (55.6)	4.06	0.04
Intrauterine polyps [‡] (n = 93)	10 (11.7)	1 (11.1)	0.005	0.94

^{*}Diagnosed on US or intraoperatively; [#]Diagnosed on preoperative US; [‡]Diagnosed on US or intraoperatively; [†]p = < 0.05.

Table 2: Duration of patient follow up (weeks).

	Number of patients	Patients lost to follow up	Mean follow up duration	SD	t	p
Group A	91	3	75.08	63.34	1.53	< 0.001
Group B	9	0	40.54	24.77		

uterine infection or haematoma. Histology of endometrial samples confirmed that there was no incidence of endometrial hyperplasia or malignancy.

Follow up

The mean duration of follow up for all participants was 72.2 weeks (SD-61.6 weeks); three patients in group A were lost to follow up. Patients in group B had a significantly shorter duration of follow up (75.08 weeks vs. 40.54 weeks; t (1.53), p = 0.001) (Table 2).

Post-ablation tubal sterilisation syndrome

Twenty patients (20%) in total had preoperative Tubal Ligation (TL), three participants had intraoperative TL and a further eight participants had bilateral salpingectomy at the time of NEA. No patient developed post-ablation tubal sterilisation syndrome.

The success and failure rates of Novasure

Of the 97 women who had follow up data available, 84 (86.6%) reported amenorrhea, 10 (10.3%) reported lighter bleeding or spotting and 3 (3.1%) needed to have a hysterectomy. An independent sample t-test reported that uterine cavity length was inversely related to likelihood of achieving amenorrhea (t = 1.06, p = 0.045). A Chi-square test supported this and found that there was a significant difference in amenorrhea in group A (89.8%) compared to group B (55.6%) (X² = 8.34, p = 0.004). Women in group B were more likely to report spotting/light bleeding (22.2%) compared to

group A (9.1%), this was not statistically significant. A total of three (3.1%) women had a hysterectomy following NEA, one from group A and the other 2 from group B. The woman from group A had a cavity length of 5cm, dysmenorrhea and HMB as well as a 2-3 cm submucous fibroid (confirmed on histology) with < 50% projecting into the cavity and required Laparoscopic Assisted Vaginal Hysterectomy (LAVH) post NEA. The two women from group B who needed hysterectomy also had LAVH, they both had an endometrial cavity length of 7 cm. One of them had HMB only and the other one had heavy and painful periods. Histology of the uteri confirmed adenomyosis. Thus, two out of the three women who needed a hysterectomy were in group B, statistically there was a strong association with the larger endometrial cavity and likelihood of hysterectomy (X² = 11.59, p = 0.003). Two out of the 3 women who required hysterectomy had dysmenorrhea; this was not statistically significant. Only one of the three women who needed hysterectomy had a Mirena inserted during the NEA, she had HMB and dysmenorrhea (Table 3).

Twenty-seven out of 34 (79.4%) women with HMB and dysmenorrhea had achieved amenorrhea and a further 5 (14.7%) reported lighter menstrual bleeding/spotting and 2 (5.9%) needed hysterectomy. In comparison, 63 women with HMB and no dysmenorrhea 57 (90.5%) had amenorrhea, 5 (8%) had spotting and one woman needed a hysterectomy (1.5%). However, the group differences were not statistically significant for women with or without dysmenorrhea in terms of

Table 3: Patient outcome as measured by amenorrhea, reduction in menses and hysterectomy.

	Group A (n = 88)		Group B (n = 9)		Total (n = 97)	
	N	%	N	%	N	%
Amenorrhea	79	89.8	5	55.6	84	86.6
Spotting/light periods	8	9.1	2	22.2	10	10.3
Procedure failed or required hysterectomy	1	1.1	2*	22.2	3	3.1

*One of these 2 women requested to have hysterectomy due persistent dysmenorrhea, in spite of resolution of heavy periods

Table 4: Rate of amenorrhea following NEA in this study in comparison to relevant literature.

Author	Amenorrhea	Women who needed hysterectomy
Clark [12]	14/25 (56.0%)	1/25 (4.0%)
Penninx [13]	35/75 (46.7%)	4/75 (5.3%)
Bongers [14]	34/83 (41.0%)	4/83 (4.8%)
Campbell [10]	217/368 (59.0%)	28/386 (7.6%)
Thiel [15]	100/168 (59.5%)	15/168 (8.9%)
Current study	84/97 (86.6%)	3/97 (3.1%)

amenorrhea ($X^2 = 2.32$, $p = 0.13$) or spotting ($X^2 = 2.07$, $p = 0.35$). Two out of the three women who required a hysterectomy also had dysmenorrhea, but this was not statistically significant ($X^2 = 1.29$, $p = 0.26$).

Intraoperative mirena IUD insertion and dysmenorrhea

A total of 10 women had a Mirena IUD inserted intraoperatively because some patients needed contraception and/or had preoperative dysmenorrhoea. Of these 10 women, Mirena was inserted in 9.5% (6/63) of those with HMB without dysmenorrhea and 11.8% (4/34) of those with dysmenorrhea. There was not a significant relationship between insertion of Mirena IUD and presence of dysmenorrhea ($X^2 = 2.16$, $p = 0.14$). Women who did not have Mirena IUD insertion during NEA procedure were more likely to report amenorrhea at follow up ($n = 69$, 92%), compared to those with Mirena insertion ($n = 15$; 71.4%; $X^2 = 6.35$, $p = 0.01$) (Table 4).

Discussion

Endometrial ablation is a procedure that can improve a range of health outcomes and quality of life for many women experiencing HMB. The NEA method is a safe and effective procedure, with good patient acceptability and beneficial outcomes in terms of amenorrhea, reduction in dysmenorrhea and low rates of failure requiring hysterectomy [7,9].

The overall rate of amenorrhea in the present study was 86.6% and it was even higher in women in group A (89.8%). We report that for women with a uterine cavity length of greater than 6.5 cm (group B), the amenorrhea rate was reduced (55.6%), however this was still comparable with published amenorrhea rates in recent literature [9] (Table 4). In comparison to the relevant literature, one study evaluated the use of NEA in women with total uterine lengths > 10 cm and reported a 51.9% rate of amenorrhea, which is lower than in the present study [15]. The success rate in women with endometrial cavity length 4-6.5 cm, endometrial cavity length more than 6.5 cm and overall was 98.9%, 77.8% and 96.9% respectively.

In total, only 3.1% of the study required a postoperative hysterectomy. Two out of these three women were from the group B with a uterine cavity > 6.5 cm in length, although this group contained only 9 patients. Our study reported a lower rate of hysterectomy (1.1%) in women with a uterine cavity length between 4-6.5 cm compared to published literature (4.0-8.9%) [12,15], however there was a higher rate of hysterectomy when the uterine cavity length was > 6.5 cm (22.2%).

Despite the high incidence of women having dysmenorrhea in our study 35.1% (34/97), we reported a high success rate. The overall success rate was 96.9 (94/97) and for women with both heavy and painful periods it was 94.1% (32/34). Mirena IUD was inserted in only 10.3% (10/97) of all patients, 9.5% in group A and 11.8% in group B. Dysmenorrhoea was reported in the only woman in group A who needed hysterectomy. In addition, one of the two women in group B who required a hysterectomy also reported dysmenorrhea and had Mirena IUD inserted during the NEA procedure. Thus, in our study the failure rate was 3.1% in women with heavy periods only and 5.9% in women with heavy and painful periods. Our finding compares favourably with a recent study comparing outcome of NEA alone versus NEA and Mirena IUD insertion in women with HMB and dysmenorrhea which reported that only one woman who had NEA and Mirena insertion had hysterectomy but 24% of women who had NEA alone needed hysterectomy [11].

We acknowledge the limitations of our study being retrospective, short period of follow up and the relatively small number of patients, especially in the group of women with marginally large uteri.

Conclusion

This single-sited and single-surgeon retrospective study demonstrated that NEA is an effective method of endometrial ablation in women with heavy periods. In addition, it has an acceptable success rate in women with heavy periods and dysmenorrhoea and those with marginally large uteri with a uterine cavity length up to 7.5 cm.

Disclosure

None of the authors have any disclosures.

References

1. Maybin JA, Critchley HO (2016) Medical management of heavy menstrual bleeding. *Womens Health (Lond)* 12: 27-34.
2. Lethaby A, Hickey M, Garry R, Penninx J (2009) Endometrial resection/ablation techniques for heavy menstrual bleeding. *Cochrane Database Syst Rev*.
3. Daniels JP, Middleton LJ, Champaneria R, Khan KS, Cooper K, et al. (2012) Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. *BMJ* 344: e2564.
4. Sharp HT (2006) Assessment of new technology in the treatment of idiopathic menorrhagia and uterine leiomyomata. *Obstetrics Gynecology* 108: 990-1003.
5. Pollock W, Jamieson W (2002) Next-generation NovaSure® device for endometrial ablation: assessing ease-of-use among physicians. *Int J Womens Health* 4: 109-113.
6. Gimpelson RJ (2014) Ten-year literature review of global endometrial ablation with the NovaSure® device. *Int J Womens Health* 6: 269-280.
7. Gallinat A, Nugent W (2002) NovaSure impedance-controlled system for endometrial ablation. *J Am Assoc Gynecol Laparosc* 9: 283-289.
8. Goldstuck N (2012) Assessment of uterine cavity size and shape: A systematic review addressing relevance to intrauterine procedures and events. *Afr J Reprod Health* 16: 130-139.
9. Campbell P, Monaghan C, Parker M (2012) NovaSure endometrial ablation: A review of 400 cases. *Gynecol Surg* 9: 73-76.
10. Lee MMH, Khadra M (2013) Predictive factors affecting the success of a Novasure endometrial ablation. *Hong Kong J Gynaecol Obstet Midwifery* 13: 108-113.
11. Papadakis EP, El-Nashar SA, Laughlin-Tommaso SK, Shazly SA, Hopkins MR, et al. (2015) Combined endometrial ablation and levonorgestrel intrauterine system use in women with dysmenorrhea and heavy menstrual bleeding: novel approach for challenging cases. *J Minim Invasive Gynecol* 22: 1203-1207.
12. Clark TJ, Samuel N, Malick S, Middleton LJ, Daniels J, et al. (2011) Bipolar radiofrequency compared with thermal balloon endometrial ablation in the office: A randomized controlled trial. *Obstet Gynecol* 117: 109-118.
13. Penninx JP, Mol BW, Engels R, Van Rumste MM, Kleijn C, et al. (2010) Bipolar radiofrequency endometrial ablation compared with hydrothermablation for dysfunctional uterine bleeding: A randomized controlled trial. *Obstet Gynecol* 116: 819-826.
14. Bongers MY, Bourdrez P, Mol BW, Heintz AP, Brölmann HA (2004) Randomised controlled trial of bipolar radio-frequency endometrial ablation and balloon endometrial ablation. *BJOG* 111: 1095-1102.
15. Thiel JA, Briggs MM, Pohlman S, Rattray D (2014) Evaluation of the novasure endometrial ablation procedure in women with uterine cavity length over 10 cm. *J Obstet Gynaecol Can* 36: 491-497.