

Outcome of Impedance Bipolar Radiofrequency Ablation (Novasure) for the Management of Heavy Menstrual Bleeding in Women with Scarred Uterus

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Abstract

Objective: To see if the presence of uterine scar(s) in women with heavy menstrual bleeding (HMB) can affect the outcome of Novasure endometrial ablation.

Design: A retrospective study

Material and Methods: A retrospective case note review of women with HMB who had Novasure endometrial ablation from November 2015 till December 2018 at South Tyneside Hospital, South Shields, UK.

Results: 26 women with HMB and scarred uterus were included in the study. Data regarding procedure completion, complications, hospital stay, success rate and failure of procedure necessitating hysterectomy was obtained. The majority of the patients had one C/S, 5 had two, one had 3 and two had 4 previous C/S scars. The procedure was completed in 84% of cases. Success rate was 68% (15/22) in the scarred uterus group and 32% (31.8%) (7/22) needed hysterectomy due to continuing heavy periods or pain. One woman in the scarred uterus group had uterine perforation (3.8%) needing overnight admission, all the rest of cases were done as a day procedure. A third (7/22)(32%) of women required a hysterectomy for persistent heavy bleeding or pelvic pain, all were with previous one C/S. The histology of the removed uterus confirmed leiomyomas with or without adenomyosis in all the cases explaining the possible cause of failed Novasure ablation.

Conclusion: Novasure ablation is effective and safe with high completion rate in women with HMB having scarred uterus regardless of the number of C/S scars they have. Caution should be taken when selecting patients having uterine fibroids/adenomyosis as the success rate might decline.

Keywords: Novasure; Ablation; Scarred Uterus

Introduction

Heavy menstrual bleeding (HMB) is a common gynaecological problem affecting around 20% of women of reproductive age. It has a major effect on women's physical, social and emotional wellbeing. HMB has as a major adverse effect on the quality of life of many women which accounts for around 15% of all secondary care gynaecological referrals in the UK (NICE 2018) [1]. In the early 1980s, 60% of women were estimated to have a hysterectomy as the first-line management for HMB in the UK, which has dramatically declined due to the availability of the marina IUS and first/second generation endometrial ablation techniques [2,3].

The management of HMB is divided into hormonal, non-hormonal treatment and surgical intervention in the form of endometrial ablation/resection and hysterectomy [1]. Most women following failed medical treatment including the mirena IUS opt to have endometrial ablation or resection. Recent Cochrane review showed that randomised controlled trials failed to provide conclusive evidence regarding the relative safety and efficacy of first- and second-generation endometrial ablation methods in women with HMB. In addition to the very low certainty evidence to suggest no overall difference in the incidence of amenorrhoea at one year between the two approaches [4]. There was no apparent differences between 1st and 2nd generation methods in women's satisfaction, inability to work, quality of life or requirement for further surgery. However; first generation methods were associated with more fluid overload, perforation, cervical laceration and hematomata with the second-generation methods associated with more equipment failure, cramping and abdominal pain. Second generation ablation methods are associated with shorter operative times and are performed more often under local rather than general anaesthesia [5].

According to the recently published Cochrane review on the comparison of the effectiveness and safety of two different surgical methods for heavy menstrual bleeding namely ablation/resection and hysterectomy: Endometrial resection and ablation offers

an alternative to hysterectomy as a surgical treatment for HMB. Both are effective with high satisfaction. Although hysterectomy offers permanent and immediate relief from HMB, it is associated with a longer operating time and recovery period with higher rate of post-operative complications such as sepsis, blood transfusion and haematoma. Cost is lower with endometrial destruction but, because retreatment is often necessary, the cost difference narrows over time [6].

The impedance bipolar radiofrequency ablation (Novasure) is a second-generation non-resectoscopic technique which has been used since more than 15 years with over 2.5 million women treated. It is found to be quick and simple with no pre-treatment required and it can be done at any time during the menstrual cycle. It is easier to learn and perform, with less complications and shorter operation time compared to other ablative techniques. It utilises unique patented technology to deliver customised ablation to each patient. It has a favourable safety profile with low rates of reintervention and high patient satisfaction. Its rates of amenorrhoea and reduction in heavy menstrual bleeding were found to be consistently higher compared to other second-generation ablation devices with a satisfaction rate reaching over 90% and amenorrhoea at 12 months reaching over 55% [7].

There is (only very scarce data) to indicate the effect of having a scarred uterus on the outcome and performance of endometrial ablation [8], however; there are no previous data on the outcome of novasure ablation in women with HMB and scarred uterus, hence this study was conducted.

Objective

To identify if the presence of caesarean section scar (s) can affect the outcome of women with HMB undergoing novasure endometrial ablation.

Design

A retrospective case review

Material and Methods

A retrospective case note review study was conducted from Nov 2015- Dec 2018 at South Tyneside Hospital on all women with HMB who underwent novasure endometrial ablation who had scarred uterus. Ethical committee approval was not required for this study being a retrospective case review study. Data regarding procedure details, complications and follow up indicating success and failure of the procedure was obtained in addition to information indicating the need for further surgery for failed cases.

Results

26 women with HMB and scarred uterus were included in the study. Data regarding procedure completion, complications, hospital stay, success rate and failure of procedure necessitating hysterectomy was obtained. Age ranged between 32-53 and parity ranged from 1-4, Table 1. 18/26 (69%) had one C/S, 5 had two, one had 3 and two had 4 previous C/S scars. 84% (22/26) of women with scarred uterus, the procedure was completed, the rest of which it was abandoned due to: small sized cavity (1 case), patulous os (1 case), uterine perforation (1 case) or machine problem (1case), Table 1. Procedure success was evaluated at 6 and 12 months follow up appointments. Women with complete amenorrhoea and /or satisfactory reduction in menstrual flow at 12 months appointment with no significant pelvic pain were considered to have a successful novasure ablation. Success rate was found in 68% of cases and failed in the rest who needed hysterectomy due to continuing heavy periods or cyclical pelvic pain, Table 1. All the failed cases had one C/S. One case of uterine perforation was recorded who stayed overnight, all the rest of cases were done as a day procedure. The histology of the removed uterus confirmed leiomyomas with or without adenomyosis in all the cases explaining the possible cause of failed Novasure ablation.

Scarred uterus with HMB (N=26)	Previous 1 CS N=18	Previous 2 CS N=5	Previous 3 CS N=1	Previous 4 CS N=2
Completed procedure N=22	14 (4 abandoned)	5	1	2
Age (32-53)	Mean 40+-8	Mean 43+-9	44	53,46
Parity 1-4	1-4	2-4	3	4
Operation time in minutes	10-18	11-16	17	11,18
Complications	1 perforation/ abandoned	0	0	0
Successful procedure 15/22 (68%)	7/14	5	1	2
Failed 7/22 (32%) procedure/hysterectomy	7/14	0	0	0

Table 1: Study of Heavy Menstrual Bleeding (HMB) and scarred uterus

Discussion

Prognostic factors for the success of endometrial ablation for the treatment of HMB were published before with thermal balloon ablation, indicating young age, retroverted uterus, increased endometrial thickness and prolonged menstruation were associated with an increased risk of treatment failure [9].

The presence of a CS scar and its associated effect on the outcome of endometrial ablation was not directly tested before. A study comparing failed and successful endometrial ablative techniques and then identify how many women in each group had a scarred uterus found the outcome to be comparable. It concluded that previous caesarean delivery is not associated with an increased risk of failure of endometrial ablation, however; dysmenorrhoea, the presence of submucous myoma and longer uterine depth were associated with higher failure rate [8].

Success rate of novasure endometrial ablation was not previously tested against the presence of uterine scar (s). In this study despite its small sample size and being retrospective, which could limit its outcome, we found that the number of uterine scars did not affect the outcome of endometrial ablation, operation time and complication rate and procedure completion. However; most cases had one previous CS scar. The presence of uterine scar (s) did not affect the outcome of novasure ablation. It has been reported that late onset endometrial ablation failure (LOEAF) can be presented by recurrence of heavy menstrual bleeding, cyclical/chronic pelvic pain and can be affected by young age and submucous leiomyoma and accounts for around 25% of these cases ending in hysterectomy [10-13]. This study also advised good patient selection before deciding endometrial ablation for the management of HMB [10-13].

Conclusion

Novasure endometrial ablation is a safe procedure for the management of HMB in women with scarred uterus regardless of the number of scars they have with a high completion and success rates. However; a cautious approach should be taken in selection of patients especially in women with uterine fibroids and adenomyosis as success rate might decline necessitating hysterectomy.

Author Disclosure Statement

We have no commercial associations that might create a conflict of interest in connection with submitted manuscripts to disclose.

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