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Short communication

Effectiveness of bipolar impedance controlled radiofrequency (NovaSure) endometrial ablation for the treatment of menorrhagia in Hong Kong Chinese women[☆]

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ABSTRACT

Objective: Bipolar impedance controlled radiofrequency endometrial ablation is a valuable treatment options for menorrhagia. We examined the short term outcomes of Hong Kong Chinese women undergone this procedure.

Material: All patients who underwent this procedure at Queen Elizabeth Hospital, Hong Kong during January 2013 to August 2016. Method this is a prospective cohort study where the menstruation status among the selected patients was questioned at each 6 monthly follow-up after the procedure. A validated MIQ (menorrhagia impact questionnaire) was sent to assess quality of life before and after the procedure. **Result:** 44 patients underwent the procedure. 77.4% had reduced or minimal bleeding with 19.4% achieving amenorrhoea. 96.77% were found to have reduced bleeding or amenorrhoeic at 3 months; 96.3% at 6 months, 95.83% at 12 months; 95.45% at 18 months; 100% at 24 and 36 months of follow up. Endometritis occurred in 9.7%. No case required blood transfusion or other surgical management post-operatively. Improvement in all aspects of MIQ was seen when compared post-operative scores to pre-operative scores ($p < 0.01$). 100% claimed improvement in menstruation and 87.1% suggested they would recommend the procedure to family and friends.

Conclusions: Bipolar impedance controlled radiofrequency endometrial ablation appears to be an effective method for managing menorrhagia amongst Chinese women in Hong Kong.

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Introduction

Approximately 9% of all gynaecological admissions in Hong Kong were due to menorrhagia.¹ Amongst this population, medical treatment is generally preferred and when surgical management deemed necessary, hysterectomy is usually the preferred choice. However, when compared to an endometrial ablation procedure, medication such as tranexamic acid or hormonal treatment are less effective while a hysterectomy (regardless whether it is done

abdominally, vaginally, laparoscopically or via robotic assisted), is associated with more complications, longer hospital stay, longer recovery period and longer operative time.²

In 2007, the NICE (National Institution for Health Care and Excellence) Institution recommended endometrial ablation to be a choice of management for benign menorrhagia prior to a hysterectomy. This recommendation remained despite the recommendation was updated in 2016.³ Both NICE³ and Cochrane review⁴ suggested second generation endometrial ablation in particular the bipolar impedance controlled radiofrequency technique to be ablation method of choice as these procedures are as effective for treating menorrhagia, less time consuming and more likely to be done in an outpatient settings compared to the gold standard first generation techniques such as transcervical resection of the endometrium.

Our department adopted the bipolar impedance controlled radiofrequency endometrial ablation technique as an alternative

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management of menorrhagia. This technique was chosen as a result of the NICE and Cochrane recommendations and available specialized expertise. In this study we aim to examine the effectiveness of the bipolar impedance controlled radiofrequency endometrial ablation in the treatment of menorrhagia amongst the Hong Kong population.

Method

Since 2013, our hospital introduced the bipolar impedance controlled radiofrequency endometrial ablation for the management of menorrhagia. All the patients who underwent this procedure during the period of January 2013–August 2016 were included in the study. After their respective operations, all patients would have been given a follow up appointment 3 months post-operatively. Subsequent follow up appointments were at the attending doctors and or patient's discretion but usually on a 6 monthly basis. Those patients who did not have subsequent follow up appointment at all or those who only had a single follow up less than 3 months after the operation were excluded.

Amongst the included patients, details of the procedure (such as uterus size, pathology, procedure time) were collected retrospectively using computerized hospital data system (CDARS) with accurate data entered by the surgeons. Operative time was measured when the patient was anaesthetized until the completion of the operation. It included the time for positioning of patient, cleaning, draping and setting up equipment as well as diagnostic hysteroscopy, dilatation and curettage which were performed to all patients prior to the endometrial ablation.

The general status of the menstruation (either amenorrhoea, minimal, same or worsened) was asked at each follow up and these were also retrospectively collected through the CDARS system. pre-operative haemoglobin, post-operative haemoglobin within 6 months of follow up and difference between pre-operative and post-operative haemoglobin were also investigated.

To review their menstrual status, MIQ (menorrhagia impact questionnaire) were sent to each patient by post with a stamped returned envelope. The Menorrhagia Impact Questionnaire (MIQ) is 6 points questionnaire measuring the patient's quality of life whilst suffering from menorrhagia (Fig. 1). This is a validated disease-specific patient-reported outcome (PRO) questionnaire assessing the influence of heavy menstrual bleeding on quality of life.⁵ Each patient was given 2 MIQ questionnaires, one to investigate patient's quality of life before the endometrial ablation and one for investigating patient's quality of life after the endometrial ablation. Within the post-procedure questionnaire, the questions were the same as those as pre-procedure (Fig. 1). However, an addition question— 'Would you recommend this procedure to your friends and family?' was asked to determine their satisfaction to the procedure. Those who failed to reply after 8 weeks since questionnaire distributions were further excluded from the study.

Demographics data, operation details and general outcome at follow up were all documented. All other results were statistically analysed using the Statistical Package for the Social Sciences (SPSS). Statistical significance is represented by p values that were calculated using Wilcoxon test was used whilst comparing components of the pre and post-operative MIQ. 95% confidence interval were used and a value of $p < 0.05$ to be considered to be statistically significant.

All the patients were consented for completing and returning of the MIQ questionnaire and the study was approved by the ethics committee at Queen Elizabeth Hospital, Hong Kong.

Results

During January 2013–August 2016, a total of 44 patients underwent a bipolar impedance controlled radiofrequency endometrial ablation (NovaSure). Amongst the 44 patients, one patient passed away due to other medical conditions and hence excluded. Amongst the remaining 43 patients, 12 did not return the MIQ questionnaire hence resulting in 31 patients included in the study and a response rate of 72.1%. All patients had at least one follow up which was at least 3 months after the procedure being performed.

Demographics and procedural details are listed in Table 1. On average the operation time including cleaning, draping, position of patient, diagnostic hysteroscopy, dilatation curettage and endometrial ablation was 17.5 min. This particularly result derived from 26 patients only as 5 patients had multiple operations such as laparoscopic ovarian cystectomy hence they were excluded from this particular part of the study. Post-procedural hysteroscopy assessment of the percentage of cavity being ablated reached 100% ablation in 24 patients (77.42%), 90% in 3 patients (9.68%), 80% in 2 patients (6.45%) and 70% in 2 remaining patients (6.45%). However these were subjective assessment by the performing surgeon through the hysteroscope.

27 of the 31 patients had pre-operative single intravenous injection of augmentin and metronidazole to prevent infection. Endometritis accounted for 3 out of 31 patients (9.68%) however amongst those who had antibiotics cover, only 2 of 27 patients (7.41%) developed post-operative endometritis as complications compared to 1 of 4 (25%) for those who wasn't given. There were no other complications otherwise in all patients (Table 1).

All 31 patients had haemoglobin checked before their procedure. However, only 22 patients had post-procedural haemoglobin checked at least 3 months after procedure. Post-operatively, none of the patients needed iron or any other supplements for anaemia and none of the patients needed further transfusions or surgery for management of menorrhagia subsequently. The average pre-operative haemoglobin was 10.55 g/dl while post-operative average was 12.56. The average difference between pre and post-operative haemoglobin was +2.01 (range -0.7 to 3.8) g/dl which was statistically significant ($p < 0.01$) (Table 1).

The overall reduced bleeding rate was 77.42% with amenorrhoea reached in 19.35% of patients hence a combined reduction in bleeding or amenorrhoea rate of 96.77% (Table 1). All 31 patients were seen at least 3 months after their procedure. 30 patients (96.77%) had either reduced or minimal bleeding or amenorrhoea with one patient experienced no change in her symptoms (3.23%). Subsequently 27 patients had follow up at least 6 months after their procedure, improvement in menstruation occurred in 26 (96.3%) of patients; 24 patients had at least 12 months follow up after their procedure with improvement to 23 (95.83%) of patients; 22 patients had follow up at least 18 months since the operation with improvement occurred in 21 patients (95.45%); 7 patients had follow up at least 24 months after procedure while 2 patients had follow up at least 36 months after procedure each showed 100% improvement to her initial symptoms (Table 2).

Significant improvements were found across the MIQ items (Table 3). For MIQ item one – perception of amount of blood loss – Pre-procedure scored an average of 3.68 which would have categorized between a scale 3 (heavy menstruation) and scale 4 (very heavy). After the procedure, the average score improved to an average of 1.52 where 1 is light and 2 is moderate ($p < 0.01$). For MIQ item 2 – limitations in work outside or inside home – pre-operative score of 3.52 (3 being moderately affected and 4 being quite affected) dropped to 2.03 (2 – slightly affected) after the procedure ($p < 0.01$). For MIQ item 3 – limitations in physical activities – pre-operative score of 4.42 represent somewhere

MENORRHAGIA IMPACT QUESTIONNAIRE –

MIQ 1 – Perception of amount of blood loss

During your most recent menstrual period *before / after* the procedure, your blood loss was :

1. Light 2. Moderate 3. Heavy 4. Very heavy

MIQ 2 – Limitations in work outside or inside home

During your most recent menstrual period *before / after* the procedure, how much did your bleeding limit your work outside or inside the home:

1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely

MIQ 3 – Limitations in physical activities

During your most recent menstrual period *before / after* the procedure, how much did your bleeding limit you in your social or leisure activity?

1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely

MIQ 4 – Limitations in social or leisure activities

During your most recent menstrual period *before / after* the procedure, how much did your bleeding limit you in your physical activity?

1. Not at all 2. Slightly 3. Moderately 4. Quite a bit 5. Extremely

MIQ 5 – All activities that were limited by excessive bleeding

Please Mark 'X' all activities that were limited by bleeding during your recent menstrual period *before / after* the procedure

- Walking travelling / vacation Standing Home management
 Climbing stairs Leisure Squatting / Bending down Sports
 Exercise Child care Gardening Shopping Others:

MIQ 6 (6a/6b) – Assessment of change in blood loss

Compare to your normal menstrual period, would you say your blood loss *after* the operation was (Choose one of the following):

0 about the same

1 – Better

- Almost the same, hardly worse at all (1)
 A little better (2)
 Somewhat better (3)
 An average amount better (4)
 A good deal better (5)
 A great deal better (6)
 A very great deal better (7)

2 – worse

- Almost the same, hardly better at all (1)
 A little worse (2)
 Somewhat worse (3)
 An average amount worst (4)
 A good deal worse (5)
 A great deal worse (6)
 A very great deal worse (7)

MIQ 6c – Meaningfulness of perceived change in blood loss

Was this a meaningful or important change for you? (Choose one of the following):

- Yes No

Additional question for post procedure

Would you recommend this procedure to your friends and family? (Choose one of the following):

- Yes No

Fig. 1. Menorrhagia impact questionnaire – MIQ.

Table 1

Patient's demographics and procedure details.

Demographics and procedure details					
Age		Range 39–53		Average 46.26 years	
Type of Anaesthesia used		29 – General		93.54%	
		1 – Local		3.23%	
		1 – spinal		3.23%	
Diagnostic hysteroscopy findings		20 – normal		64.52%	
		11 – other pathology		35.48%	
		– 7 submucosal fibroids <3 cm			
		– 4 endometrial polyps			
Pathology (uterine currettings)		31 benign		100%	
Cavity width		Range 4–6.5 cm		Average 4.16 cm	
Cavity length		Range 2.8–5.0 m		Average 5.55 cm	
Ablation time		Range 45–120 s		Average 78.16 s	
Operation time (n = 26, 5 were done in conjunction with other operations)		Range 10–20 min (including diagnostic hysteroscopy, dilatation and curettage, cleaning, draping and position of patient)		Average 17.5 min	
Post-procedure hysteroscopy findings (Objective)		100% cavity ablation – 24		77.42%	
		90% cavity ablation – 3		9.68%	
		80% cavity ablation – 2		6.45%	
		70% cavity ablation – 2		6.45%	
Antibiotic usage pre-operatively (single IV injection of augmentin and metronidazole)		Yes – 27		87.1%	
		No – 4		12.9%	
Complication (total)		3 – all PID		9.68%	
Complications without antibiotics usage		1 of 4		25%	
Complications with antibiotics usage		2 of 27		7.41%	
Overall reduction in blood loss		24 of 31		77.42%	
Amenorrhoea		6 of 31		19.35%	
Reduced, minimal or no periods after procedure		30 of 31		96.77%	
Require blood transfusion for management of menorrhagia after procedure		0 of 31		0%	
Require further surgical procedure for management of menorrhagia		0 of 31		0%	
Average haemoglobin before and after procedure					
	Pre-procedure average	Post-procedure average	Difference pre and post-procedure Hb	Average change in Hb pre and post-procedure	P value
Haemoglobin level (n = 22)	10.55	12.56 g/l	–0.7 to 3.8	+2.01	<0.01

Table 2

Post-procedural menstruation status.

Outcome of menorrhagia procedure	At 3 months N = 31	At 6 months N = 27	At 12 months N = 24	At 18 months N = 22	At 24 months N = 7	At 36 months N = 2	Overall N = 31
No period	6	5	5	6	4	1	6 (19.35%)
Minimal or reduced period	24	21	18	15	3	1	24 (77.42%)
No change	1	1	1	1	0	0	1 (3.23%)
Worsened	0	0	0	0	0	0	0 (0%)
Overall improvement (reduced, minimal or no bleeding)	30 (96.77%)	26 (96.30%)	23 (95.83%)	21 (95.45%)	7 (100%)	2 (100%)	30 (96.77%)

Table 3

Post-procedural Menorrhagia Impact Questionnaire (MIQ) Scores.

	Pre-procedure average	Post-procedure average	P value
MIQ 1 – Perception of amount of blood loss	3.68	1.52	<0.01
MIQ 2 – Limitations in work outside or inside home	3.52	2.03	<0.01
MIQ 3 – Limitations in physical activities	4.42	2.19	<0.01
MIQ 4 – Limitations in social or leisure activities	3.97	2.19	<0.01
MIQ 5 – All activities that were limited by excessive bleeding	5.94	1.29	<0.01
	Improvement after procedure	No improvement after procedure	
MIQ 6 a/b – Assessment of change in blood loss	31 (100%) Meaningful – Yes	0 (0%) Meaningful – No	
MIQ 6 c – Meaningfulness of perceived change in blood loss	26 (83.9%) Yes	No – 5 (16.1%) NO	
Would you recommend the procedure	27 (87.1%)	4 (12.9%)	

between quite a bit to extremely affected. This is compared to the average score of 2.19 (where 2 – slightly affected) after the procedure ($p < 0.01$). For MIQ 4 – limitations to social and leisure activities, pre-operative score of 3.97 (where 4 suggest quite a bit affected) were reduced to 2.19 (where 2 – slightly affected) after the operation ($p < 0.01$).

Item 5 of the MIQ involved patients to describe all their daily activities that were limited by excessive bleeding. They were given a choice of 8 items and a space to fill in additional activities they think was affected. Pre-operatively, the 31 patients on average had 5.94 numbers of daily activities limited by excessive bleeding. After the procedure, this average dropped to 1.29 numbers of daily activities. This was statistically significant ($p < 0.01$) (Table 3).

Item 6 of the MIQ assess the global change in blood loss for the patient after the procedure. All 31 patients (100%) found improvement in the procedure where 83.9% found the change in menstrual pattern meaningful or important to their daily lives (Table 3).

Finally amongst the final question added to the MIQ, 27 of the 31 (87.1%) patients suggest they would recommend the procedure to family and friends if they suffered the same conditions suggested a high rate of patient satisfaction (Table 3).

When results were further investigated into those with fibroids < 3 cm ($n = 7$), all patients were satisfied with reduction or minimal bleeding after at least 6 months follow up. All 7 patients also felt they would recommend to procedure to friends and family if they had similar menorrhagia condition.

Discussions

Bipolar impedance controlled radiofrequency endometrial ablation is an established form of endometrial ablation technique used to treat menorrhagia worldwide. Menorrhagia remains the major indication of its use especially if it fails to be managed by medication or intrauterine device. However the procedure is contraindicated when the patient still possess fertility wish; has underlying pregnancy; existing endometrial hyperplasia; suspected malignancy; underlying endometritis; uterus size larger than 12 cm or larger than its fan shaped electrode gold plate mesh which measured maximally with an uterine cavity length of 6.5 cm and cornual to cornual width of 5.5 cm. Success of the procedure remains similar if submucosal fibroid is less than 3 cm while successful cases has been reported in those with underlying adenomyosis which some suggested as a contraindication for the procedure.

One of the longest available data with 7 years follow up reported reduced uterine bleeding in 98% and amenorrhoea in up to 75–97% patients.⁶ A more recent report of pooled data included 3 single armed study and 7 RCTs regarding outcomes of bipolar impedance controlled radiofrequency ablation at 12 months after the procedure. Objective and subjective amenorrhoea rate was 47.6% amongst 732 patients, a success rate of 85% and a patient satisfaction rate of 93.7% out of 515 and 430 patients respectively.⁷ With majority of our patients having followed up at 6 and 12 months after procedure, reduced menstruation rate of 96.3% at 6 months and 95.83% at 12 months were comparable. Satisfaction rates where patient will recommend the operation to their families and friends were 87.1% which is in keeping with the reported findings. Our amenorrhoea

rate of 18.15% at 6 months and 20.83% at 12 months were below the reported rates. Reason for this is uncertain but it is clear that success from an endometrial ablation procedure does not rely on the ethnicity.

Our pre and post-procedure haemoglobin showed there was significant improvement on anaemia amongst our patients. The MIQ results not only showed significant improvement in menstrual bleeding, it showed improved overall lifestyle in general, by reducing the limitations in work activities, physical activities, social activities and general activities caused by the pre-operative heavy menstrual loss.

In terms of complications, our overall complication rate of 7.41% after pre-operative antibiotics use was comparable to the 6% quoted by a larger study involving similar procedures.⁸ One study reported complications rates for hysterectomy differ depending on whether they were performed through the abdominal approach (19.2%), vaginal approach (15.4%) or laparoscopic approach (11.7%),⁹ but in all cases, the complication rates remains higher than those of an endometrial ablation.

The total number of patients investigated remains to be the main limitation of this study. A larger number of patients with longer follow up periods will be more beneficial. Despite this limitation, the findings of this study indicated that bipolar impedance controlled radiofrequency endometrial ablation possess a safe and important role in menorrhagia management within the Hong Kong population. Future prospective study with larger population and longer follow up time will better reflect on the effectiveness of this technique on the treatment of menorrhagia amongst the population in Hong Kong.

Conclusion

Bipolar impedance controlled radiofrequency endometrial ablation appears to be a clinically effective method with a low complication rates for treating menorrhagia amongst the Hong Kong Chinese population. Physicians and patients should be made aware of such method hence reducing the need of hysterectomy.

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