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THE EFFECT OF BIPOLAR RADIOFREQUENCY ABLATION (NOVASURE ENDOMETRIAL ABLATION SYSTEM) ON ENDOMETRIAL THICKNESS AND BLEEDING IN PATIENTS WITH PREMENOPAUSAL BLEEDING

By

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ABSTRACT

Background: Ablation of the endometrial lining of the uterus as an alternative to hysterectomy was found to be a less invasive and aggressive method. A large number of clinical trials, as well as retrospective analysis of clinical and financial data, has shown that endometrial ablation allows for a lower morbidity and mortality rate and significantly lower procedure costs. Worldwide, endometrial ablation is increasingly being adopted by the gynecological community.

Objective: To study the effect of bipolar radiofrequency ablation system on endometrial thickness and bleeding in patients with premenopausal bleeding.

Patients and Methods: This was a prospective comparative randomized study including 30 women with premenopausal bleeding not responding to medical treatment performed at Al-Azhar University hospitals and Gamal Abdel Nasser Hospital during the period from April 2016 to October 2018.

Results: The majority of the patients improved (83.3%), 19 of them have complete recovery (63.3%), while 6 cases (20.0%) have minor bleeding, 4 cases (13.3%) have bleeding less before treatment, while only one case has no change.

Conclusion: Bipolar radiofrequency ablation performed under local anaesthetic in the postmenstrual phase is an effective and efficient method of treating the majority of women who wish conservative surgical treatment for heavy menstrual loss.

Keywords: Bipolar radiofrequency ablation, NovaSure endometrial ablation, Endometrial thickness, Premenopausal bleeding.

INTRODUCTION

Menopause is usually a natural change. It can occur earlier in those who smoke tobacco *(Claudio and Michelle, 2010)*. Other causes include surgery that removes either ovaries or some types of chemotherapy. At the physiological level, menopause happens because of a decrease in the ovaries' production of the hormones estrogen and progesterone. While typically not needed, a diagnosis of menopause can be confirmed by measuring hormone levels in the blood or urine *(James, 2017)*.

Specific treatment is not usually needed. Some symptoms, however, may

be improved with treatment. With respect to hot flashes, avoiding smoking, caffeine, and alcohol is often recommended. Sleeping in a cool room and using a fan may help. The following medications may help: menopausal hormone therapy (MHT), clonidine, gabapentin, or selective serotonin reuptake inhibitors *(Krause and Nakajima, 2015)*. Exercise may help with sleeping problems. While MHT was once routinely prescribed, it is now only recommended in those with significant symptoms, as there are concerns about side effects. High-quality evidence for the effectiveness of alternative medicine has not been found. There is a tentative evidence for phytoestrogens *(Oscar et al., 2016)*.

Hysterectomy is currently the leading treatment method for patients symptomatic for menorrhagia. This surgical method of treatment was found to be efficacious, although it is associated with a number of well-known and analyzed serious disadvantages. Hysterectomy has a relatively high morbidity and mortality rate, and direct and indirect costs associated with the procedure are also quite significant *(van derMeij and Emanuel, 2016)*.

Ablation of the endometrial lining of the uterus as an alternative to hysterectomy was found to be a less invasive and aggressive method. A large number of clinical trials, as well as retrospective analysis of clinical and financial data, has shown that endometrial ablation allows for a lower morbidity and mortality rate and significantly lower procedure costs. Worldwide, endometrial ablation is increasingly being adopted by the gynecological community. The risks associated with the hysteroscopic approach are well known and include uterine wall perforation, intravasation of fluid distention media, hyponatremia, enceph alopathy and death. Technical challenges, the need for well-developed hand–eye–foot coordination, potential risks and other drawbacks of this treatment modality do not allow for a successful adoption of this procedure by the vast majority of gynecologists *(Cooper et al., 2011a)*.

The aim of the present work was to study the effect of bipolar radiofrequency ablation system on endometrial thickness and bleeding in patients with premenopausal bleeding.

PATIENTS AND METHODS

This prospective comparative randomized study including 30 women with premenopausal bleeding not responding to medical treatment performed at Al-Azhar University hospitals and Gamal Abdel Nasser Hospital during the period from April, 2016 to October , 2018.

All subjects enrolled in the study were asked to give informed written consents after explaining the nature, steps and aim of the study. The approval of Medical Ethics Committee was obtained.

All patients in this study were subjected to the following:

1. Full history taking.
2. CBC and coagulation profile.
3. Ultrasound examination to rule out uterine anomalies.
4. Endometrial thickness more than 12 mm.

5. Endometrial biopsy to be done to rule out malignancy or hyperplasia.
6. Diagnostic hysteroscopy before ablation procedure to rule out any gross pathology.
7. Failed medical treatment to decrease the bleeding.

Inclusion criteria:

- Age between 40-50 years.
- Endometrial thickness 12 mm or more.
- Menorrhagia not responding to medical treatment.
- Endometrial biopsy reveals no malignancy or hyperplasia.
- Women who finished childbearing.

Exclusion criteria:

- Women who still want to get pregnant.
- Patients with urinary or genital tract infection.
- Patients with IUCD.
- Patients with suspects endometrial cancer.
- Intrauterine lesions (polyp or fibroid).
- Endometrial thickness less than 12 mm.

The methods used for identification and construction of the cohorts were previously published *(El-Nashar et al., 2011)*.

Medical diagnoses and surgical interventions for each patient were routinely abstracted and coded according to the Hospital Adaptation of the International Classification of Diseases *(Commission on Professional and Hospital Activities, 1973)*. These computerized indices allow the linkage of medical records from all providers and facilitate the evaluation of disease determinants and outcomes after surgical procedures *(Melton, 1996)*.

Patients were treated with bipolar RFA (NovaSure, Cytyc Surgical Products, Palo Alto, California), a method introduced in 2003 *(Gallinat and Nugent, 2003)*. Before the procedure, all women had a Papanicolaou test, endometrial sampling, pelvic ultrasonography, and office hysteroscopy if structural uterine lesions were suspected. Only women with benign polyps or submucous leiomyomas not distorting the endometrial cavity or less than 2 cm in size were offered endometrial ablation. Removal was by dilation and curettage or ablation in situ.

Baseline data were obtained for each patient, including age, parity, body mass index, pattern of bleeding, presence of dysmenorrhea, uterine length, uterine position, presence of fibroids or polyps, endometrial thickness, and endometrial pathology. Previous operations, including cesarean births and tubal sterilization, were recorded. For procedural data, we noted the type of anesthesia used, total procedural time, balloon fluid volume and pressure for TBA, and the power setting for RFA.

Treatment failure was defined as the need for another ablation procedure or hysterectomy at any point during follow-up, and time to treatment failure was the primary end point for the evaluation of outcome after GEA. Patients with treatment failure were identified by using the relevant International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes; records

were reviewed individually to confirm failure and performance of re-ablation or hysterectomy. To avoid the confounding effect of menopause, the menstrual outcome of primary interest was amenorrhea; this was defined as the documented complete cessation of menstruation that began immediately after GEA and lasted for at least 12 months. Other secondary outcomes included postprocedural change in duration of bleeding, hemoglobin levels, and ferritin levels. Intraprocedural and postprocedural complications were recorded.

Statistical analysis:

Statistical analysis was done by SPSS v20 (IBM©, Chicago, IL, USA). Normality of data (Parametric or not) was checked with Shapiro-Wilks test and histograms and all our data were normally distributed. Quantitative data were presented as range mean and standard deviation (SD) and were compared by student's t- test with ROC curve test if significant and is used to detect sensitivity and specificity. Qualitative data were presented as number. P value <0.05 was considered statistically significant.

RESULTS

This study was conducted on 30 women with premenopausal bleeding not responding to medical treatment. The age ranged from 40-50 years with a mean of 45.2±3.44, regarding the parity the majority of the patients had 3 parity, while 10 cases had 1 para and 2 were two para. Distribution of the studied patients group regarding body mass index, 12 patients (40.0%) had normal weight, while 13 cases 43.3% was overweight, and 5 cases was obese, the body mass index was ranged from 21.0-31.8 with a mean of 26.24±3.54. Distribution of the studied patients group regarding dysmenorrhea and previous cesarean delivery, only 4 cases (13.3%) had dysmenorrhea, 12 patients had previous cesarean delivery. Distribution of the studied patients group regarding duration of bleeding (days), the majority of the patients had duration of bleeding less than 10 days while 7 cases (23.3%) had duration more than 10 days, the duration of bleeding was ranged from 6-15 day with a mean of 8.10±2.17 **(Table 1)**.

Table (1): Distribution of the studied patients group regarding age, parity, body mass index, dysmenorrhea and previous cesarean delivery and duration of bleeding (days)

Group / Parameters	Number	Percent
Age		
40-45	17	56.7
45-50	13	43.3
Range	40 - 50	
Mean	45.2	
S.D.	3.44	
Parity		
1	10	33.3
2	6	20.0
3	14	46.7
Body mass index		
Normal weight	12	40.0
Over weight	13	43.3
Obese	5	16.7
Range	21.0-31.8	
Mean	26.24	
S.D.	3.54	
Dysmenorrhea		
Yes	4	13.3
No	26	86.7
Previous Cesarean delivery		
Yes	12	40.0
No	18	60.0
Duration of bleeding		
<10 days	23	76.7
>10 days	7	23.3
Range	6-15	
Mean	8.10	
S.D.	2.17	

Comparison between pre and post endometrial thickness, before treatment the endometrial thickness was ranged from 12.2-18.6 with a mean of 15.74±1.89 and decreased significantly after treatment to range 52-8.5 with a mean of 6.67±0.97, there was a highly significant decrease in endometrial thickness after treatment ($p < 0.05$).

Comparison between pre and post Bleeding score, the bleeding score before treatment was ranged from 16-35 with a mean of 25.97±5.40, after treatment the bleeding score was ranged from 7-12 with a mean of 9.60±1.87, there was a significant decrease in bleeding score after treatment more than before treatment ($p < 0.05$).

Comparison between pre and post hemoglobin and hematocrit, the hemoglobin level before treatment was ranged from 6.5-11.2 with a mean of 8.58±1.31 and increased significantly after treatment to be 3.77±0.31, there was a significant increase in hemoglobin level after treatment ($p < 0.05$). Regarding hematocrit before treatment the mean value was 31.56±4.82, while after treatment the mean value of hematocrit was 42.28±6.32, there was a significant increase in hematocrit after treatment ($p < 0.05$) **(Table 2)**.

Table (2): Comparison between pre and post endometrial thickness, bleeding score and Hb & Ht

Groups / Parameters	Before treatment	After treatment
Endometrial thickness		
Range	12.2-18.6	5.2-8.5
Mean	15.84	6.67
S.D.	1.89	0.97
T	8.16	
p	0.001*	
Bleeding score		
Range	16-35	7-12
Mean	25.97	9.60
S.D.	5.40	1.87
T	6.25	
p	0.001*	
Hb		
Range	6.5-11.2	3.2-4.2
Mean	8.58	3.77
S.D.	1.31	0.31
T	7.25	
p	0.001*	
Ht		
Range	23.92-41.216	31.6-52.6
Mean	31.56	42.28
S.D.	4.82	6.32
T	8.16	
p	0.001*	

Comparison between pre and post RBCs and platelet, the mean RBCs before treatment was ranged from 3.2-4.2 with a mean of 3.770.31, and increased significantly after treatment to be 4.51±0.50, there was a significant increase in RBCs after treatment ($p < 0.05$). The platelet before treatment was ranged from 91-219 with a mean of 153.57±41.07, there was no change after treatment in platelet count to be 140.37±33.52 ($p > 0.05$).

Comparison between pre and post Prothrombin time (sec.), PTT (sec.) and Bleeding time (min.), the mean prothrombin time before treatment was 15.79±2.47 and after treatment increase without any significant to be 16.70±2.82, PTT before treatment was 62.39±13.81 sec, and after treatment was 68.53±9.20, there was no significant difference between before and after treatment ($p > 0.05$), bleeding time before treatment was 6.41±2.02 and after treatment was 6.01±1.60 min, no significant change in bleeding time after treatment ($p > 0.05$) **(Table 3)**.

Table (3): Comparison between pre and post RBCs, platelet, Prothrombin time (sec.), PTT (sec.) and Bleeding time (min.)

Groups / Parameters	Before treatment	After treatment	T p
RBCs			
Range	3.2-4.2	3.2-5.3	4.65
Mean	3.77	4.51	0.001*
S.D.	0.31	0.50	
Platelet			
Range	91-219	90-210	0.081
Mean	153.57	140.37	
S.D.	41.07	33.52	
Prothrombin time (sec.)			
Range	12-20.8	12-21	0.094
Mean	15.79	16.70	
S.D.	2.47	2.82	
PTT (sec.)			
Range	42.2-85.8	50.6-79.9	0.064
Mean	62.39	68.53	
S.D.	13.81	9.20	
Bleeding time (min.)			
Range	3.3-9.5	3.5-9.5	0.197
Mean	6.41	6.01	
S.D.	2.02	1.60	

Distribution of the studied patients regarding the net results after treatment, the majority of the patients was improved (83.3%), 19 of them was complete recovery (63.3%) while 6 cases (20.0%) had minor bleeding, 4 cases (13.3%) had bleeding less before treatment, while only one case had no change.

Distribution of the studied patients regarding their satisfaction after treatment, the majority of the patients was satisfied (70.0%), while 5 cases was neutral feeling, 4 cases show unsatisfied **(Table 4)**.

Table (4): Distribution of the studied patients regarding the net results and satisfaction after treatment

Groups / Parameters	Number	Percent
Complete recovery	19	63.3
Minor bleeding	6	20.0
Bleeding less before treatment	4	13.3
No change	1	3.3
Very satisfied	6	20.0
Satisfied	15	50.0
Neutral	5	16.7
Unsatisfied	3	10.0
Very unsatisfied	1	3.3

DISCUSSION

Menstrual disorders are common and account for 33% of referrals to gynecological practice *(Coulter et al., 2010)*. The perceived loss of excessive blood during menstruation causes 5% of women aged 20–39 years to consult their gynecologist each year *(Vessey et al., 2012)*. This problem has a significant impact on the health of the individual woman and on health care systems since its treatment is estimated to account for 1% of total health care costs. In over 50% of cases, no cause is found and the diagnosis of dysfunctional uterine bleeding (DUB) is made. Endometrial ablation provides safe and effective treatment for women with DUB *(Coulter et al., 2010)*.

The first-line of treatment of heavy menstrual bleeding is medical treatment with either tranexam acid, oral contraceptives or levonorgestrel-releasing intrauterine device. If the treatment fails, the next option is either hysterectomy or endometrial ablation. Sometimes women do not want to have intrauterine device for personal reasons; in our long-term study only 37% of women had tried treatment of HMB with LNG-IUS. Patients presenting with menorrhagia are typically 35 years or older, and many of them have gone through tubal ligation for birth control, and may thus be reluctant to use LNG-IUS to treat bleeding. Hysterectomy is a definitive solution, but it is a major operation with possible major complications. If a woman has a normal uterus which does not descend, the mode of hysterectomy is usually laparoscopic hysterectomy, which has a total complication rate of 15.4% and major complication rate of 4.3% *(Brummer et al., 2011)*.

Endometrial ablation refers to a number of minimally invasive surgical procedures designed to treat AUB, which is defined as changes in frequency of menses, duration of flow, or amount of blood loss. EA consists of targeted destruction or removal of the endothelial surface of the uterine cavity in selected women who have no desire for future fertility. The procedure was designed to treat heavy menstrual bleeding refractory to medical therapy and not caused by structural uterine pathology. It is a less invasive alternative to hysterectomy *(Cooper et al., 2011b)*.

Second-generation endometrial ablation techniques have now been used for over 8 years and have demonstrated similar efficacy to first-generation endometrial ablation procedures *(Amso et al., 2010)*. The aim of this study was to compare the effectiveness and acceptability of two second-generation ablation procedures, the Cavaterm ™ Thermal Ablation System (Cavaterm) and the NovaSure™ Impedance Controlled Endometrial Ablation System (NovaSure), in a double-blind, randomized trial.

In this study, age ranged from 40-50 years, the parity ranged from 1-3, the body mass index 40.0% of the patients had previous cesarean delivery, the endometrial thickness before treatment was at least 12 mm, and significantly decreased after treatment.

The literature regarding EA in patients with previous CS consists primarily of small retrospective cohorts studies. For resectoscopic EA, there are generally no restrictions following previous CS.

However, caution should be exercised over the CS scar as myometrial thinning may predispose it to perforation or thermal injury. For a patient with previous transmural myomectomy, obtaining adequate visualization of the cavity using a pressure pump should allow for safe treatment *(Oscar et al., 2016)*.

In our study the bleeding score significantly decreased after treatment to be 9.60±1.87, from pre-operative bleeding score (25.97±5.40). This result was an agreement with study carried by *Jack et al. (2010)*. The generalizability of the results are enhanced by the avoidance of entry criteria based on menstrual blood scores or predetermined uterine cavity regularity, while 69% of eligible patients referred for MEA would consider treatment under local anesthetics *(Wallage et al., 2013)*.

In our study, the complete improved patients was 83.3%, while only one case failed, Treatment failure was defined as the need for another ablation procedure or hysterectomy at any point during follow-up, and time to treatment failure was the primary end point for the evaluation of outcome after GEA. Patients with treatment failure were identified by using the relevant International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes; records were reviewed individually to confirm failure and performance of re-ablation or hysterectomy. To avoid the confounding effect of menopause, the menstrual outcome of primary interest was amenorrhea; this was defined as the documented complete cessation of menstruation that began immediately after GEA and lasted for at least 12 months. Other secondary outcomes included postprocedural change in duration of bleeding, hemoglobin levels, and ferritin levels. Intraprocedural and postprocedural complications were recorded.

In other study, they observed no significant differences in treatment failure rates between RFA and TBA (cumulative failure rate of 9% for RFA and 12% for TBA). The similar likelihood of treatment failure was unchanged after adjusting for known confounders of treatment failure, including age, parity, pretreatment dysmenorrhea, and history of tubal ligation *(Abbott and Colleagues, 2011)*.

In agreement with our study, in another study the overall “success” of the Cavaterm group was high, with 100% of women reporting eumenorrhea or better at 12-month follow-up. The amenorrhea rate in this group was significantly lower than in the NovaSure group, although the hypomenorrhea rate was significantly greater and the combined rates show no difference between the groups. The overall improvement in menstrual function is highly significant, and the difference between amenorrhea and spotting does not appear to affect either patient satisfaction, which is universally high for this procedure, or quality of life, which is improved.

It is essential that equipment failure be reported, as malfunction of the device or generator carries with it significant cost for disposable items and may require either retreatment at a later time or immediate treatment by an alternate method. In this study, equipment problems were encountered in 11% of the Cavaterm group and 8% of the NovaSure group. These problems did not seem to

have a marked clinical effect in the Cavaterm group, although they contributed to poor outcomes for women in the NovaSure group. Other randomized trials using MEA and VestaDUB have reported a similar equipment failure rate of 3% and 4%, respectively *(Corson et al., 2010).*

The results of the previous study indicate that there is a significant improvement in menstrual status with both of these treatments. There is a significantly greater amenorrhea rate in the NovaSure group compared with the Cavaterm group. There is a significant improvement in quality of life for both techniques, with NovaSure providing better results compared with Cavaterm. Patient satisfaction is high with both techniques, with reintervention rates comparable to those reported in other published data. Equipment failure and problems must be considered as a factor for the second generation endometrial ablation procedures, with an associated implication for clinical and cost-effectiveness outcomes. These excellent short-term results need to be followed up in the longer term to ensure that the results are maintained *(Corson et al., 2010).*

CONCLUSION

Bipolar radiofrequency ablation performed under local anaesthetic in the postmenstrual phase is an effective and efficient method of treating the majority of women who wish conservative surgical treatment for heavy menstrual loss. Treatment post-menses avoid the unpleasant side effects and significant costs of drug preparation. The technique is rapid, achieving both high satisfaction and acceptability rates, while also achieving menstrual outcomes and rates of further surgery unmatched by other endometrial ablative techniques. There are demonstrable lower cost to the health service and also the potential benefit of releasing valuable operating theatre time and personnel for other operations, which require these facilities.

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تأثير الترددات ثنائية القطبين لإستئصال بطانة الرحم (جهازالنوفاشور) على سمك بطانة الرحم والنزيف فى المرضى الذين يعانون من نزيف قبل انقطاع الطمث

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خلفيـــة البحـــث: إستئصـــال بطانـــة الـــرحم كبـــديل لاستئصـــال الـــرحم أقـــل تـــوغلاً وشـــدة. وإستئصـــال بطانـــة الـــرحم يســـمح بمعـــدلات مراضـــة ووفيـــات أقـــل وتكـــاليف إجـــراء أقـــل بشـــكل ملحـــوظ. فـــي جميـــع أنحـــاء العـــالم، ويـــتم إعتمـــاد استئصال بطانة الرحم بشكل متزايد من قبل مجتمع أمراض النساء.

الهـــدف مـــن البحـــث: دراســـة تـــأثير التـــرددات ثنائيـــة القطبـــين لإستئصـــال بطانـــة الـــرحم (جهازالنوفاشـــور) علـــى ســـمك بطانـــة الـــرحم والنزيـــف فـــى المرضـــى الـــذين يعـــانون مـــن نزيـــف قبـــل انقطـــاع الطمـــث بعـــد توضـــيح خطوات الدراسه للمرضى وأخذ موافقة كتابية.

المريضـــات وطريقـــة البحـــث: أجريـــت هـــذه الدراســـة علـــى 30 ســـيدة يعـــانون مـــن نزيـــف قبـــل انقطـــاع الطمـــث ممـــن يتوافـــدن علـــى عيـــادات امـــراض النســـاء بمستشـــفيات جامعـــة الازهـــر. وقـــد اجريـــت هـــذة الدراســـة فـــى الفتـــرة مـــن ابريل 2016 الى اكتوبر 2018.

نتـــائج البحـــث: تعمـــل التـــرددات ثنائيـــة القطبـــين لإستئصـــال بطانـــة الـــرحم (جهازالنوفاشـــور) وبشـــكل جيـــد علـــى ســـمك بطانـــة الـــرحم والنزيـــف وخفـــض حـــدة مضـــاعفاتها وبالتـــالى تخفـــيض نســـب المضـــاعفات المتعلقـــة بـــالنزيف الرحمـــى وزيـــادة ســـمك بطانـــة الـــرحم, وقـــد كانـــت نســـبة التحســـن 83% بـــين الحـــالات حيـــث وصـــل عـــدد حـــالات الشـــفاء التـــام الـــى 19 حالـــة بنســـبة 63%

بينما يوجد 6حالات تعانى من معدل نزيف بسيط بنسبة 20%, بينما يوجد4 حالات لديهم نزيف لكن اقل مما كان قبل الخضوع للدراسة, وتبقى حالة وحيدة لم يظهر عليها اى تاثر.

الاستنتاج: تخصيص أبحاث لاحقه تجرى فاعلياتها على عدد أكبر من المرضى وتوسيع دائرة البحث لتشمل طرقا أخرى من أجل الوصول إلى أعلى مستويات النجاح فى علاج النزيف المهبلى وبمضاعفات أقل.

الكلمات الدالة : الترددات ثنائية القطبين – إستصال بطانة الرحم – سمك بطانة الرحم – نزيف قبل إنقطاع الطمث .