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Research Article Endometrial Ablation for Dysfunctional Uterine Bleeding in Low-Resource Settings: A Randomized Controlled Trial

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Abstract

Background and Objective: Dysfunctional uterine bleeding (DUB) affects nearly half of those women with abnormal uterine bleeding which has a negative impact on patient's health related quality of life (HRQoL). Endometrial ablation used as an alternative to hysterectomy in dysfunctional uterine bleeding. The objective of this study was to compare the efficacy and safety profile of bipolar resectoscopic endometrial ablation (REA) and non-resectoscopic endometrial ablation modalities (NREA) i.e., (thermal ablation by modified Foley's catheter and chemical ablation using TCA. **Materials and Methods:** This open-label randomized controlled prospective study conducted in the Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Egypt during the period from May, 2016 to May, 2019. The study included 150 women with refractory DUB which was randomly allocated as follow: Fifty were assigned to bipolar hysteroscope (versapoint), 50 were assigned to thermal group and 50 were assigned to chemical group. The 1ry outcome was operative time, complications and menstrual changes along 6 months follow up. The 2ry outcome was HRQoL and patient satisfaction. **Results:** There was significant shorter operative time, hospital stay and more rapid return to daily and sexual activity in thermal and chemical group than hysteroscopic group. There was no significant difference between 3 groups as regard complications, menstrual changes, amenorrhea rate and failure rate along the duration of follow up. **Conclusion:** Both thermal and chemical methods of endometrial ablation were as effective as REA in the management of DUB and had a significant shorter operative time and shorter hospital stay with more rapid return to daily and sexual activity. Chemical endometrial ablation can be performed without general anaesthesia especially for highly risk patients and in low resource settings.

Key words: Dysfunctional uterine bleeding, endometrial ablation, resectoscopic endometrial ablation, thermal ablation, trichloroacetic acid

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Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Abnormal uterine bleeding is a common gynaecologic complaint that affects up to 30% of reproductive-aged women with highest incidence in premenopausal age¹. Dysfunctional uterine bleeding (DUB) is diagnosed after exclusion of pregnancy, structural abnormalities of genital tract, general or endocrinological diseases according to "PALM-COEIN" FIGO classification².

DUB affects nearly half of those women with abnormal uterine bleeding and has a significant negative impact on patient's health related quality of life. Medical treatment of DUB includes antifibrinolytic drugs, nonsteroidal anti-inflammatory drugs, combined oral contraceptives, progestagens, danazol, GnRH agonists, progestin releasing IUD, etc. However, these regimens are associated with high recurrence rate after discontinuation of treatment³. Most of those women undergo hysterectomy after failure of medical treatment. Although, hysterectomy is obviously 100% effective in stopping bleeding but it associated with significant complications as well as social and economic costs⁴.

Endometrium ablation (EA) with destruction of the endometrium using minimally invasive procedures is alternative to hysterectomy. They involve using electrocautery, laser, microwaves, radio frequency waves, hot saline, thermal balloon or chemical agents e.g., formalin, silver-nitrate and trichloroacetic acid⁵.

The so-called 'first-generation' techniques (resection, laser and roller ball) considered "the gold standard". However, despite their efficacy, they have a number of drawbacks. They require a skilled hysteroscopic surgeon, with risk of uterine perforation and fluid overload⁶.

This led to the introduction of the second-generation methods e.g. (thermal, chemical and microwave endometrial ablation) to overcome these drawbacks⁷.

One of the first generation techniques of EA is bipolar (versapoint) resectoscope which can be used with physiological saline as a distention medium, thus reducing the harmful effect of fluid overload with monopolar resectoscope. Thermal balloon is one of the second generation techniques of EA which has been used for many years and has demonstrated similar efficacy to first generation procedures with fewer adverse effects. Trichloroacetic acid is topically corrosive chemical agent that denatures tissue proteins and causes chemical cauterization of the affected tissues without systemic effect⁸⁻¹⁰.

The aim of this randomized prospective study was to compare 3 endometrial ablation modalities i.e., bipolar

resectoscope, thermal balloon and trichloroacetic acid in the management of perimenopausal patients with dysfunctional uterine bleeding.

MATERIALS AND METHODS

This open-label randomized controlled study was conducted in the Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Egypt during the period from May, 2016 to May, 2019. The study included 150 patients who underwent endometrial ablation due to DUB. DUB was defined subjectively as heavy menstrual bleeding either regular or irregular due to increase in the amount and/or duration of menstrual loss in the absence of organic disease of genital tract.

The women were chosen according to the following criteria:

Patients 40 years age or older with no desire for further pregnancy with refractory abnormal uterine bleeding and failed both hormonal treatment (for a minimum of 3-6 months) and endometrial curettage. Patients with uterine cavity exceeding 10 cm, endometrial histopathological patterns with atypia obtained by endometrial curetting, associated uterine pathology e.g., polyp, adenomyosis, leiomyoma, uterine cavity malformations and malignancy or other pelvic pathology such as prolapse, ovarian mass or endometriosis or known history of coagulopathy or bleeding disorders were excluded from the study.

The study proposal was approved by the Institutional Review Board of Faculty of Medicine, Zagazig University, Egypt. Written informed consent was taken from all participants after explanation of the method used in management regarding the benefits and possible risks.

Full history taking, general and pelvic clinical examination were done to exclude clinically detectable organic lesions. Transvaginal ultrasonography (TVUS) to exclude organic lesions, assess uterine dimensions and shape and measure endometrial thickness. Laboratory investigations (complete blood picture, blood sugar, coagulation profile were done to screen for generalized hemorrhagic disorders, kidney and liver functions) and ECG were done.

Patients were randomly allocated in a ratio of 1:1:1 using online software (http://www.randomization.com) by independent personnel into 3 groups according to management methods as follow: 50 patients managed by hysteroscopic endometrial resection, 50 patients managed by thermal balloon ablation and 50 patients managed by TCA.

Techniques: Firstly, if endometrial thickness>4 mm prethinning of endometrium by medical treatment (Norethisterone acetate 5 mg tab. twice daily for 4 weeks) which was followed by withdrawal bleeding reducing endometrial thickness then endometrial ablation would start immediately in post menstrual period.

Bipolar resectoscopic endometrial resection: General anesthesia was used in all patients, A vaginal speculum was inserted and the cervix was cleaned with povidone iodine and grasped with a vulsellum then the cervix was dilated up to 10 Hegar's dilator. A continuous flow resectoscope "Karl Storz, Germany". with a telescope 4 mm in diameter and a viewing angle of 30° with light source "Xenon XL-A 300". The distention media was saline 0.9% which was controlled by Hysteromat[™] 3700. The resectoscope was, then, introduced through the cervix and adequate panoramic view of the uterine cavity was obtained. Both cornu were first coagulated using the roller-ball electrode and coagulation current of 80-120 watts then, the remainder of the endometrium was systematically resected using a Versapoint and a blended current of 80-120 watts. The depth of resection was judged by the landmark of the circular myometrial fibers. If at any time vision became dim, the procedure was stopped immediately.

Thermal balloon endometrial ablation: 18 French Foley's catheter was modified via cutting its distal part leaving 5 mm beyond it to be coapted with the fundus of the uterus after its insertion. The modified Foley's catheter was then inserted using a sponge forceps, the vagina was protected from thermal injury using vaginal packing. Then boiled saline (15-30 mL) was injected by 20 mL syringe through the catheter, the balloon was left in place for 2.5 min, then the saline was aspirated as its temperature became lower, then repeat the injection again three times.

Trichloroacetic acid (TCA) endometrial ablation: General anesthesia was used only according to the patient request otherwise it was an office procedure. After proper covering of the cervix and vagina with a piece of cotton to protect them from the probable leakage of trichloroacetic acid. A cotton swab applicator (which was lengthened by its attachment to the long tube of IUD using silk plast) dipped in 95% TCA.

Painting of the endometrial walls by TCA would be started from the fundus downward till the internal os from side to side for both the anterior and posterior walls. The procedure would be repeated for 3 times in the same sitting.

Follow up: Pulse, blood pressure, vaginal bleeding and abdominal pain were monitored with special attention paid to clinical signs of fluid overload. Patients were asked to come to the hospital 2 weeks later for follow up of the postoperative adverse effects.

Criteria of evaluation Operative data:

- Operative time
- Amount of saline used and fluid deficit
- Intraoperative and immediate postoperative complications
- Adverse effects within the 2 postoperative weeks

Menstrual changes: Standardized questionnaire was used at all appointments exploring the menstrual pattern. Patients were asked to grade changes in the amount of bleeding according to the following scale; better (amenorrhea, hypomenorrhea and eumenorrhea), worse, or unchanged.

HRQoL assessment: The questionnaire of HRQoL included questions about the consequences of HMB affecting physical health, psychological health, social/family life and work/daily routine for the patients at the end of the follow up period. This questionnaire was evaluated by the visual analogue scale VAS i.e., "0, much worse" and "10, much better" at opposite ends and the mid point representing "5, no change" of HRQoL.

Statistical analysis: Results were recorded, tabulated and subjected for statistical analysis using SPSS and analysed using frequency tables, Fisher's exact test and Chi-squared test, the data were presented as mean values for normal distributed data and as median values for skewed data. The p-value < 0.05 was considered significant.

RESULTS

The study included 150 women with refractory DUB which was randomly allocated as follow: Fifty were assigned to bipolar hysteroscope (versapoint), 50 were assigned to thermal group and 50 were assigned to chemical group.

Preoperative criteria and patients' characteristics: Patients in the 3 groups were comparable in age $(44.9\pm4.8, 45.7\pm5.1, 46.5\pm4.5)$ years, parity, BMI, uterine length and in preoperative Hb concentration in g/dL with no significant differences between them (p>0.05) as shown in Table 1.

Table 1: Patients characteristics of the studied 3 groups

Variables	Hysteroscopic	Thermal	Chemical	F-value	p-value
Age	44.9±4.8	45.7±5.1	46.5±4.5	1.38	0.25 ^{ns}
Parity	3.0±1.9	3.2±1.5	3.6 ± 1.4	1.79	0.17 ^{ns}
BMI	29.1±7.8	30.3±8.5	30.9±8.4	0.61	0.54 ^{ns}
Uterine length sounding (cm)	8.4±1.5	8.5 ± 1.3	8.2±0.8	0.76	0.46 ^{ns}
Preoperative Hb concentration (g/dL)	10.4±0.3	10.6 ± 0.5	10.4±0.8	2.04	0.13 ^{ns}

nsNon significant, p-value>0.05

Table 2: Preoperative endometrial criteria of the studied 3 groups

Variables	Hysteroscopic	Thermal	Chemical	F-value	χ^2	p-value
Endometrial thickness (mm)	9.0±3.3	8.8±3.0	8.6±2.7	2.06		0.12 ^{ns}
Endometrial pathology						
Simple or complex endometrial hyperplasia without atypia	40 (80%)	35 (70%)	34 (68%)		2.08	0.35 ^{ns}
Atrophic endometrium	5 (10%)	8 (16%)	10 (20%)		1.95	0.37 ^{ns}
Disordered proliferative endometrium	5 (10%)	7 (14%)	6 (12%)		0.38	0.82 ^{ns}

Table 3: Operative data

	Hysteroscopic	Thermal	Chemical			
Variables	(n = 50)	(n = 50)	(n = 50)	χ^2	F-value	p-value
Anaesthesia						,
General	50 (100%)	50 (100%)	6 (12%)	12.5	98.3	0.001 ^{HS}
Without	0	0	44 (88%)			
Time of procedure (min)	31±12	12.2±5.3	10.4±4.1			0.001 ^{HS}
Complications						
Bleeding	2 (4%)	0	0			
Bowel injury	0	0	0			
Bladder injury	0	0	0			
Perforation	0	0	0			
Fluid overload	1 (2%)	0	0			
Thermal injury	0	1 (2%)	0			
Chemical injury	0	0	2 (4%)			

HSHighly significant

Table 4: Duration of hospital stay and return to daily activities

Variables	Hysteroscopic	Thermal	Chemical	F-value	p-value
Hospital stay (h)	10.3±8.0	6.3±1.7	4.6±0.8	42.2	0.03*
Return to daily activities (days)	7.0 ± 2.7	3.9 ± 2.4	2.0 ± 1.3	37.2	0.04*
Resumption of sexual activity (days)	14.8±6.7	11.8±6.6	6.9 ± 4.7	35.6	0.02*

^{*}Significant values

Moreover, Table 2 showed that there was no significant difference in endometrial thickness in mm between the 3 groups $(9.0\pm3.3,~8.8\pm3.0,~8.6\pm2.7)$ and also the endometrial pathology were comparable and (90,84 and 80%) of patients in REA, thermal and chemical groups respectively were candidate for prethinning of the endometrium.

Operative data: Table 3 showed the operative data including anaesthesia in the 3 groups, there were 44 patients in the chemical group were not given anaesthesia because there was no need for cervical dilatation under general anaesthesia as the applicator used for chemical ablation was of 3 mm diameter, in contrast with patients in hysteroscopic and thermal groups all of them were given anaesthesia. As regard

the time of procedure in "min.", the operative time was highly significantly shorter in thermal (12.2 \pm 5.3) and chemical (10.4 \pm 4.1) groups than REA group (31 \pm 12) (p-value = 0.001). Regarding complications, 2 patients were complicated by vaginal bleeding and one patient have fluid overload in REA group, while one patient had thermal injury in thermal group and 2 patients had chemical injury in chemical group.

Duration of hospital stay and return to daily and sexual activities: Table 4 showed that there was significant shorter hospital stay in hours and more rapid return to daily $(3.9\pm2.4, 2\pm1.3 \text{ vs. }7\pm2.7)$ days and sexual activity $(11.8\pm6.6, 6.9\pm4.7 \text{ vs. }14.8\pm6.7)$ days in thermal and chemical group vs. hysteroscopic group (p<0.05).

Table 5: Clinical outcome after 6 months follow up

	Hysteroscopic ($n = 50$)		Thermal (n = 50)		Chemical (n	Chemical (n = 50)		
Variables	Number	Percentage	Number	Percentage	Number	Percentage	χ^2	p-value
Eumenorrhea	7	14	8	16	8	16	0.103	0.95
Hypomenorrhea	8	16	8	16	7	14	0.103	0.95
Amenorrhea	30	60	28	56	28	56	0.218	0.897
Worse	1	2	1	2	1	2	0.000	1.00
Unchanged	4	8	5	10	6	12	0.440	0.801

Table 6: Patient satisfaction at the end of the follow up period

	Hysteroscopi	Hysteroscopic		Thermal		Chemical		
Variables	Number	Percentage	Number	Percentage	Number	Percentage	χ^2	p-value
Satisfied	43	86	41	82	40	80	0.65	0.72
Not satisfied	7	14	9	18	10	20		

Table 7: Impact of endometrial ablation procedures on HRQoL scores before and 6 months after the procedures

Variables	Hysteroscopic	Thermal	Chemical	p-value
Before procedure	3.0±2.6	2.6±2.9	2.2±2.5	0.12
After procedure	8.3 ± 1.2	8.5 ± 1.6	8.2 ± 1.4	0.33

Menstrual changes and clinical outcome: Menstrual changes and clinical outcome presented in Table 5 and showed no significant difference between the 3 groups as regard menstrual changes, amenorrhea rate that occurred in (60, 56 and 56%) of patients in REA, thermal and chemical groups respectively and worsening of bleeding affect one patient in each group along the 6 months of follow up.

HRQoL and patient satisfaction: Table 6 showed no significant difference between the 3 groups as regard patient satisfaction that range between 86, 82 and 80% in REA, thermal and chemical groups respectively. Moreover, Impact of endometrial ablative procedures on HRQoL scores before and 6 months after the procedures presented in Table 7 and showed increase in the HRQoL scores from $(3.0\pm2.6, 2.6\pm2.9, 2.2\pm2.5)$ to $(8.3\pm1.2, 8.5\pm1.6, 8.2\pm1.4)$ 6 months post-procedure in the 3 groups with no significant difference between them.

DISCUSSION

The study offered a good treatment option in management of dysfunctional uterine bleeding (DUB), the problem that has a negative impact on women's quality of life. Hysterectomy is considered a definitive treatment but with high cost and a risk of intraoperative and postoperative complications. Endometrial ablation offers a cheaper, effective alternative with faster recovery as concluded by a recent systematic review comparing endometrial ablation and hysterectomy¹¹.

This randomized prospective study was performed to compare the efficacy and safety profile of bipolar resectoscopic endometrial ablation (REA) and non-resectoscopic endometrial ablation modalities (NREA) i.e., (thermal ablation by modified Foley's catheter and chemical ablation using trichloroacetic acid) as a possible alternative in low resource settings. Such thermal and chemical methods of endometrial ablation could offer a simple, good, effective, cheaper alternative for REA in the management of DUB with a good impact on HRQoL.

Regarding the preoperative criteria and patients characteristics including age, parity, BMI, uterine length (cm), hemoglobin concentration (g/dL) there were no significant difference between the 3 groups (Table 1). Also the 3 groups were comparable in this study as regard Preoperative endometrial criteria (endometrial thickness and pathology) as showed in (Table 2). This means that all cases of the 3 groups were matched to avoid bias of the results.

In this study, there was no significant difference between each group (45, 42 and 40) in REA, thermal and chemical groups respectively regarding the number of cases who were candidate for prethinning of endometrium (Table 2). Laberge *et al.*⁶ reported that endometrial thinning can be used to facilitate endometrial ablation especially in REA to decrease irrigant fluid absorption and operative time than no thinning. They added that endometrial thinning lead to higher amenorrhea rate and patient satisfaction than no thinning.

Medical treatment used in this study for endometrial thinning was Norethisterone acetate 5 mg bid. For 4 weeks. Bradley¹² used GnRH agonist and D and C before different modalities of global endometrial ablation while Kucukozkan *et al.*¹³ used TCA for endometrial ablation for 90 cases dividing them into 3 groups, in group "1" cases underwent D and C before ablation, in group"2" cases were administered danazol before ablation and in group "3" cases received goserelin acetate.

General anaesthesia was used in all cases of both resectoscopic and thermal groups and 6 cases only in the chemical group due to patients request (Table 3). This was highly significant in the chemical group which make it the method of choice for poor surgical candidates. Also, Kucukozkan *et al.*¹³ did not use general anaesthesia during chemical endometrial ablation but only paracervical block to obtain biopsy.

There was highly significant shorter operative time (min) of NREA techniques (chemical 10.4 ± 4.1 and thermal 12.2 ± 5.3) than REA technique (31 ± 12), this was due to easier techniques of NREA methods (Table 3) this is in accordance with Brun *et al.*¹⁴, who found significant shorter operative time (min) during CavatermTM thermal balloon endometrial ablation than REA in menorrhagia patients (11.5 ± 4.2 vs. 29.4 ± 6.2 , respectively). This disagreed with Mencaglia *et al.*⁸ who recorded shorter mean operative time (min) during bipolar REA (13.2 ± 2.3) which may be due to high experience of the surgeon with advanced equipments and technique in addition to smaller uterine cavities and proper prethinning of endometrium by GnRH analogue before the procedure.

There were no major complications in each group and no significant difference between each other (Table 3). Laberge *et al.*⁶ reported that both REA and NREA are safe procedures with low complication rates.

The duration of hospital stay in (h) was longer in REA group than thermal and chemical groups (10.3 \pm 2.1, 6.3 \pm 1.7 and 4.6 ± 0.8), respectively (Table 4), which was attributed to shorter operative time, less intra operative blood loss and shorter duration of pain in both thermal and chemical groups The duration to return to routine daily activity was significantly shorter in NREA than REA group i.e., return to daily activities in (days) was earlier in thermal (3.9 \pm 2.4) and chemical (2 ± 1.3) than REA (7 ± 2.7) . Also, there was significant difference as regard the resumption of sexual activity in (days) between REA and NREA (p<0.05). Lethaby et al. 15 found that patients recovered early when they treated by NREA than REA. All 3 modalities of EA Significantly reduced uterine bleeding in REA group there was 90% success rate vs. 10% failure rate, in NREA groups there were 88 vs. 12% and 86 vs. 14% in thermal and chemical groups, respectively (Table 5), Regarding to treatment or clinical failure and the subsequent further surgical intervention by hysterectomy after endometrial ablation procedures there was no significant difference between REA and NREA (10 vs. 12% and 14% in REA vs. thermal and chemical groups respectively). Brun et al.14 reported that treatment failure incidence was (7 and 12% in Cavaterm and resectoscopic groups respectively) after 1year follow up.

All 3 modalities of endometrial ablation had a good impact on HRQoL at the end of the follow up period and there was no significant difference between the scores of three groups $(8.3\pm1.2, 8.5\pm1.6 \text{ and } 8.2\pm1.4)$ in REA, thermal and chemical groups respectively as shown in Table 7.

Lethaby *et al.*¹⁵ searched 25 randomized controlled trials (RCT) from cochrane menstrual disorders register and concluded that there is no superiority of a particular technique of endometrial ablation in the pair wise comparisons between the newer "blind" techniques (second-generation) with the gold standard hysteroscopic ablative techniques (first-generation) and added that no significant differences in the improvement of heavy menstrual bleeding (HMB) (12 RCTs), patient satisfaction and HRQoL (11 RCTs).

One of the limitations of the present study is that patients and investigators were not blinded to the treatment after randomization. However it provides a cost effective, reasonable means for comparing 3 different modalities of endometrial ablation in treating womens with dysfunctional uterine bleeding.

CONCLUSION

The study compared the efficacy and safety profile of bipolar resectoscopic endometrial ablation (REA) and non-resectoscopic endometrial ablation modalities (NREA) i.e., (thermal ablation by modified Foley's catheter and chemical ablation using trichloroacetic acid) as a possible alternative in the management of DUB in low resource settings and concluded that both thermal and chemical methods of endometrial ablation were as effective as REA and had a good impact on HRQoL, with shorter operative time and shorter hospital stay with more rapid return to daily and sexual activity.

SIGNIFICANCE STATEMENT

This study showed that thermal ablation by modified Foley's catheter and chemical ablation using trichloroacetic acid can be used in management of DUB in low resource settings being as effective as REA with the advantages of being more simple, cheaper, requiring less experience. This study will help the researchers and clinician to carefully balance the risk-benefit and cost-effectiveness of different methods of management of DUB.

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