Endometrial Ablation Therapy in Dysfunctional Uterine Bleeding (DUB), is it the Answer for Safety and Satisfaction?

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Abstract: **Objectives:** This study was done to evaluate 1- the effectiveness and safety of endometrial ablation with thermal balloon (therma choice uterine balloon therapy system – Gynecare) (TBEA) in patients suffering from premonopausal dysfunction uterine bleeding (DUB). 2- Uterine artery pulsitility index "PI" before and after endometrial thermoablation therapy in one year follow up as a marker of the efficacy of therapy in rising the impedance to uterine artery blood flow which may be due to fibrosis in the uterine cavity. 3- Patient satisfaction through one year follow up. **Design:** Prospective study. **Setting:** AlZahraa University hospital, Faculty of Medicine (Girls), Al Azhar University, Al Haram Hospital (for research and treatment, Ministry of health and some private hospitals in Cairo, Egypt. **Method:** Sixty two premenopausal patients with (DUB) were allocated in this study since 2010 to 2013. All patients were submitted to history, examination, pelvic and transvaginal ultrasound (U/S), pap. Smear, diagnostic hysteroscopy and endometrial biopsy. The endometrial therapy using (thermachoice system) was carried out on cycle 3-8. Color Doppler measurements were carried too. Flow waveforms were obtained from the main branch of the uterine arteries on both sides. Doppler flow parameters were used for statistical analysis. The measurements took place before the initiation of treatment, on the first day post operative, 3,6 months and one year after initiation of the study. **Results:** The pulsatility index (PI) was statistically significant higher after endometrial ablation than pretreatment level. The PI was gradually increased throughout the period of follow up at 6 months (2.8±0.9), and 12 months (2.9±0.8), post treatment vs. (1.9±0.4) pretreatment. **Conclusion:** Thermoablation therapy induces a rise in impedance to uterine blood flow which is a good marker for inducing amenorrhea in DUB patients. The procedure was accepted by the patients with a high efficacy rate 90%. The existing evidence suggested that the success rates and complications profile of 3rd generation are low depend on proper patient selection.
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1. Introduction

Dysfunctional uterine bleeding is a common gynecological problem. It is diagnosed by exclusion. It has a significant impact on the health of women[1,2].

Endometrial ablation is a safe and effective treatment for women with DUB. The clinical efficacy of thermal balloon endometrial ablation therapy have been focused on the morphological changes in the endometrium[3,4].

Transvaginal color Doppler ultrasonography can be used to discover the changes affecting uterine hemodynamics[5,6].

Objectives:

1- Prospective study was done to evaluate the effectiveness and safety of the outcome of the therapy by endometrial ablation with thermal balloon (therma choice uterine balloon therapy system – Gynecare) (TBEA) in the patients with premonopausal dysfunction uterine bleeding (DUB). 2- The study compared uterine artery pulsitility index "PI" before and after endometrial thermoablation therapy in one year follow up as a marker of the efficacy of therapy in rising the impedance to uterine artery blood flow which may be due to fibrosis in the uterine cavity. 3- The study evaluated the patient satisfaction through one year follow up.

2. Patients and Methods

Sixty two premenopausal patients with (DUB) were allocated in the study from January 2010 till the end of December 2013. patients were recruited from outpatient clinic at AlZahraa University hospital, Al Haram Hospital for research and treatment and some private hospitals in Egypt. Exclusion criteria are listed in Table 1.

Table (1): Exclusion criteria

Age less than 40 years old,
Uterine sounds > 10 cm,
Endometrial hisotpathologic abnormality
PAP smear cytology
Desire to become pregnant

The pre-treatment gynecologic investigations are shown in Table 2.

Table (2): Pre treatment gynecologic examination

▪ History, gynecologic pelvic examination and breast examination
▪ PAP SMEAR if not recently taken within 6 months
▪ Gynecologic trasnvaginal ultrasonography
▪ Color Doppler examination of uterine arteries on cycle days 3-8
▪ Diagnostic hysteroscopy
▪ Endometrial histopathological analysis

Color Doppler measurements were performed before treatment, 3, 6 and 12 months after initiation of treatment. Also, patients were examined on the first postoperative day.

The measurements were carried out on cycle day 3-8 on basis of two facts: first, clinical outcome of thermal ablation is better with thin endometrium, second, the impedance to uterine blood flow appears stable at that time of the menstrual cycle[7].

Measurements were performed in the morning due to the presence of circadian variation in uterine blood flow impedance[6,7].

Color Doppler study of uterine artery was performed using high resolution real time ultrasonography equipment "Simens Sono-line Elegra" with 6.5 MHZ transducer. Assessment of genital and pelvic organs to rule out any gross pathology. Flow velocity waveforms were obtained from the main uterine artery at the level of the inner cervical os just beside the cervix on both sides. The waveforms were characterized by peak systolic velocity "PF", End diastolic "ED", time –averaged maximum velocity "TAMX" and pulsitility index "PI".

The thermal balloon ablation system "thermachoice" consists of a 16 cm long and 4.5 mm diameter catheter with a latex end, which houses a heating element. The catheter is connected to a control unit. Which monitors, displays and adjusts intrauterine balloon pressure, temperature and duration of treatment. The catheter was inserted transcervically to touch the uterine fundus. The balloon was filled with a variable volume of 5% dextrose/water until the intrauterine pressure stabilized between 160-180 mmHg. The fluid was heated to approximately 87◦C after which the treatment lasted 8 minutes and the catheter was removed. The operation was performed under general anesthesia. Women were discharged home on the first postoperative day and reviewed in the out patient clinic at three, six and twelve months. Color Doppler measurements were repeated at each visit.

3. Results.

Table (3): The clinical parameter of the patients.

Variables	Study group (No= 62) Mean ± SD
Age (years)	44.4 ± 4.4
Parity	3.3 ± 1.2
BMI (kg/m^2)	27.9 ± 6.8
Bleeding days	8.8 ± 2.7
Cycle length (days)	24.2 ± 3.1
Cavity length (cm)	9 ± 0.7

Data concerning the Doppler flow parameters of the uterine artery are presented in table 2. In the study group, there were statistically significant rise in blood flow waveforms in uterine artery Doppler after 6 months and 12 months when compared to pretreatment values.

The procedure was accepted by 90% of the patients.

The end diastolic velocity (ED) had decreased at 6 months [5±3.2 vs 8.8±3.5, P= 0.01], at 12 months [4.8±3.0 vs 8.8 ±3.5, P= 0.001].

The time – averaged maximum velocity (TAMX) had also decreased at 6 months [15.3±3.6 VS 19.8±4.5, P= 0.01], at 12 months [14.9 ±2.4 VS 19.8 ±4.5, P=0.01].

The pulsatiliy index (PI) had increased at 6 months [2.8±0.9 VS 2.1 ±0.5, P= 0.03], at 12 months [2.9±0.8 VS 2.1±0.5, P= 0.03].

Table (4): Uterine artery Doppler flow parameters for the study group (No=62).

	Pretreatment	First day	Sig.	3 months	Sig.	6 months	Sig.	12 months	Sig.
PS velocity Cm/S	46.5 ± 12.3	50.3 ± 15.2	NS	43.6 ± 12.8	NS	41.2 ± 12.5	NS	44.3 ± 11.6	NS
ED velocity CM/S	8.8 ± 3.5	9.1 ± 3.6	NS	7.4 ± 3.8	NS	5.0 ± 3.2	0.011	4.8 ± 3.0	0.001
TAMX cm/S	19.8 ± 4.5	20.1 ± 6.0	NS	17.7 ± 6.4	NS	15.3 ± 3.6	0.012	14.9 ± 2.4	0.011
PI cm/S	2.1 ± 0.5	2.0 ± 0.6	NS	2.3 ± 0.8	NS	2.8 ± 0.9	0.033	2.9 ± 0.8	0.032

Data presented as Mean±SD P< 0.05 significant, P> 0.05 non significant

Table (4): Effect of treatment on the nature of bleeding.

Variables	**Study group (No=62)**	
	No.	**%**
Amenorrhea	56	90.3
Hypomenorrhea	6	9.7
Eumenorrhea	0	0
Menorrhagia	0	0

4. Discussion

Therma-choice balloon system is one of the second generation of ablation techniques which was approved by FDA[8]. The greater the fibrosis of the uterine cavity after thermal balloon therapy, the better prognosis[9-11]. Transvaginal Doppler ultrasound provides a non invasive method used to study the uterine hemodynamics changes after endometrial thermoablation[7,12].

The current study found that no changes in uterine artery blood flow 3 months after initiation of the study. The pulsatility index (PI) had increased significantly 6 months after the operation when compared to pretreatment levels. The increase was maintained at 12 months. 90.3% of the patients had a menorrhea and 9.7% of them hypomenorrhea.

Previous studies found that the rise in impedance may be due to fibrosis in uterine cavity caused by thermal ablation[12-17].

The current study results suggest that tissue fibrosis affects uterine hemodynamics. The increase in impedance appears due to decrease in blood flow during diastole. The end diastolic velocity was decreased whereas the peak systolic velocity remained unchanged. This may be due to destruction of distal end of uterine vasculature, caused by thermal balloon endometrial ablation.

Fergusson *et al*. (2013) found that endometrial resection and ablation offers an alternative to hysterectomy as a surgical treatment for heavy menstrual bleeding. Both procedures are effective and satisfaction rates are high. Although hysterectomy is associated with longer operation time (particularly for the laparoscopic route), a longer recovery period and higher rates of postoperative complications, it offers permanent relief from heavy menstrual bleeding. The initial cost of endometrial destruction is significantly lower than that of hysterectomy, but because retreatment is often necessary, the cost difference narrows over time.

Smithling *et al*. (2014) found the preoperative bleeding pattern did not appear to affect failure rates or the need for gynecological procedures after endometrial ablation.

Conclusion

Thermoablation therapy induces a rise in impedance to uterine blood flow which is a good marker for inducing amenorrhea in DUB patients. The procedure was accepted by the patients with a high efficacy rate 90%. The existing evidence suggested that the success rates and complications profile of 3rd generation are low depend on proper patient selection.

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