



COMPARATIVE STUDY OF LEVONORGESTREL INTRA-UTERINE SYSTEM (LNG-IUS) VERSUS THERMAL BALLOON ENDOMETRIAL ABLATION (TBEA) IN PERI-MENOPAUSAL WOMEN WITH HEAVY MENSTRUAL BLEEDING: A PROSPECTIVE OBSERVATIONAL STUDY.

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ABSTRACT **Background:** To compare the effectiveness of Levonorgestrel Intra-uterine System (LNG-IUS) versus Thermal Balloon Endometrial Ablation in perimenopausal women with Heavy Menstrual Bleeding (HMB).

Methods: A prospective comparative study was conducted in the Department of Obstetrics and Gynaecology at SDM College of Medical Science and Hospital, Dharwad, India. The study included 80 peri-menopausal women with heavy menstrual bleeding, aged between 40 and 55 years, over a period of 2 years. 40 women had undergone TBEA (Thermachoice) and 40 women had LNG-IUS inserted. All patients had undergone trans-vaginal ultrasound, Pap smear, endometrial biopsy, and PBAC (Pictorial Blood loss Assessment Chart) scoring before the treatment. Only those cases with uterine size less than 12 weeks, no submucous fibroid, with negative Pap smear and those with endometrial biopsy negative for malignancy were included. Patients were followed up at intervals of 3 months, 6 months and at 12 months. At each visit, the patients were evaluated for bleeding per vagina, spotting, amenorrhea, pain abdomen, expulsion of LNG-IUS, cycle regularity and PBAC score.

Results: Follow up was possible in 37 women with LNG-IUS and 38 women with TBEA. Both the study groups were statistically comparable in terms of age, parity, PBAC score, and endometrial pattern. On followup, there was no statistically significant difference in the outcome in terms of PBAC score and therapy failure. Student sample t test was used for analysis.

Conclusion: Both LNG-IUS and TBEA are equally effective and safe in the treatment of heavy menstrual bleeding. The choice of treatment should be individualized according to the woman's needs and choice and depending on risk factors.

KEYWORDS : Thermal Balloon Endometrial Ablation, Levonorgestrel Intra-uterine System, heavy menstrual bleeding

INTRODUCTION:

Heavy menstrual bleeding is one of the major and most common complaints presenting to gynecological clinic, accounting for up to 20% of all cases. Heavy menstrual bleeding is often incapacitating and severely affects the quality of life. The common causes for heavy menstrual bleeding are dysfunctional uterine bleeding (DUB), endometrial hyperplasia, fibroids, adenomyosis, polyps, thyroid disorders and lastly endometrial malignancies. The usual protocol for treatment of perimenopausal heavy menstrual bleeding is to perform a trans-vaginal ultrasound scan followed by an endometrial biopsy¹.

First-line treatment for heavy menstrual bleeding is medical management in the form of hormonal and non hormonal medications. But they are less effective, require long term therapy, restricted by poor compliance and unacceptable side effects². As an alternative to medical therapy is the levonorgestrel intrauterine system (LNG-IUS), a contraceptive device that reduces menstrual loss through profound suppression of endometrial growth by local release of progestogen³. Hysterectomy is the definitive treatment when medical therapy fails, is more costly and can cause serious complications in a minority of women⁴. Less invasive alternatives to hysterectomy for the treatment of heavy menstrual bleeding, such as endometrial ablation and the levonorgestrel releasing intrauterine system, have become increasing popular. These treatment modalities result in lesser morbidity, rapid recovery, are cost effective and rarely cause serious complications. Other surgical treatments are also available and include first- and second-generation endometrial ablation that reduces menstrual blood loss (MBL) by destroying the endometrium⁵.

Thermal Balloon Endometrial Ablation (TBEA, Thermachoice) is a minimally invasive day care surgery having a high safety profile. The ablation procedure destroys the endometrium globally and the damaged tissue contracts and develops into a scar. Any endometrium remaining after the ablation is trapped beneath the scar, preventing further bleeding⁶.

The aim of the present study was to compare results of women submitted to LNG-IUS or TBEA for the treatment of HMB after 1-year follow-up using as end points, bleeding patterns and satisfaction rates.

MATERIAL AND METHODS

The prospective comparative study was conducted between March 2014 and March 2016, in the Department of Obstetrics and Gynecology at Shri Dharmasthala Manjunatheshwara College of Medical Science and Hospital, Dharwad, India. 80 peri-menopausal women, aged between 40 to 55 years, with complaints of heavy menstrual bleeding (HMB) were included in the study. 40 women underwent TBEA (Thermachoice) and 40 women had LNG-IUS inserted. This study was approved by the Research Ethics Committee of the college and a written and informed consent was obtained from the patients before the procedure.

Inclusion criteria consisted of heavy menstrual bleeding refractory to medical treatment, uterine size less than 12 weeks gravid uterus size, no obvious cervical or vaginal pathology, a negative pap smear and an endometrial biopsy negative for malignancy. Patients with congenital or acquired uterine anomalies, intra-mural or sub-serous fibroid of size 3 cm or more, sub-mucous fibroid distorting the cavity, acute pelvic inflammatory disease, genital bleeding of unknown etiology were excluded from the study.

At recruitment a detailed clinical history was taken. We estimated the amount of blood loss using a similar methodology of PBAC (Pictorial Blood Assessment Chart) as described by Higham et al⁷. Detailed clinical examination including general, systemic, pelvic and examination of breast was done. Pap smear of each patient was taken. A trans-vaginal ultrasound with 7.5 MHz transducer probe was used for the study. Endometrial biopsy was done in all patients after obtaining consent. On follow up visit, the endometrial biopsy report was reviewed. The various endometrial patterns observed are shown in table 1. The women were explained both the treatment modalities and the patients were allowed to choose the modality of treatment.

Table 1: Endometrial pattern in women with Heavy Menstrual Bleeding included in the study:

Pattern	Proliferative endometrium	Simple hyperplasia without atypia	Complex hyperplasia without atypia	Menstrual endometrium	Secretory endometrium	Pill endometrium
LNG-IUS	2	17	2	9	7	3
TBEA	3	16	2	8	8	3

Before including the women for the study, both the groups were compared in terms of demographic data, menstrual patterns, endometrial patterns and PBAC score to rule out sample bias. Independent sample t test was used and the result is shown in table 2.

Table 2: Baseline characteristics of the patients with HMB treated with the LNG-IUS (n=40) or TBEA (n=40)

Characteristics	LNG-IUS	TBEA	p value
Age	39yrs	38.125yrs	0.09
Parity	1.825	2.175	0.11
PBAC Score	218.1+56.9	197.1+56.7	0.12
Uterine size	8.0 cms	7.61 cms	0.12

All procedures were initiated during the first 10 days of a menstrual cycle. Insertion of the LNG-IUS was performed in the outpatient department in accordance with the manufacturer's instructions. TBEA was performed with the San Thermo uterine balloon therapy system under general anesthesia in the operating room. The thermal balloon was placed in the uterine cavity and then inflated with distilled water. The fluid inside the thermal balloon was heated to 87°C and intrauterine pressure was maintained at 160-180 mm Hg for 8 min. The balloon was deflated and removed after the procedure was complete, the full procedure requiring about 15 to 20 minutes.

Patients were followed up at intervals of 3 months, 6 months and at 12 months. At each visit, the patients were evaluated for bleeding per vagina, spotting, amenorrhea, pain abdomen, expulsion of LNG-IUS, cycle regularity and PBAC score. Treatment was considered to have failed when blood loss increased and in these cases, patients were offered a hysterectomy as definitive treatment. The hysterectomy rates and perceived clinical improvement of the groups were analyzed.

Statistical analysis was performed using the software Statistical Package for the Social Sciences version 18.0 (SPSS, Inc., Chicago, IL, USA). Statistical analysis was performed using the Independent sample t test. Significance level was established as p value of less than 0.05.

In the LNG-IUS group, out of 40 women, 3 women were lost to follow up, whereas in TBEA group, 2 women were lost for follow up (Fig 1).

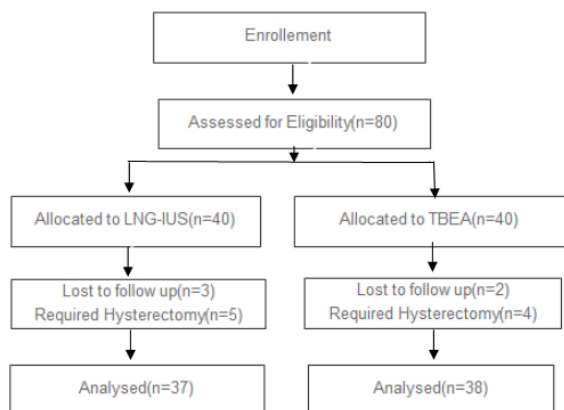


Fig 1 : Flowchart diagram of the study population of patients with heavy menstrual bleeding treated either with the LNG-IUS (n=40) or TBEA (n=40)

At 12 month follow up, the mean PBAC scores are shown in table 3. There was no statistically significant difference between the outcomes in both the treatment modalities.

Table 3: Evaluation of PBAC in patients with heavy uterine bleeding before and 1 year after treatment with the LNG-IUS or TBEA.

	LNG-IUS	TBEA	t value	p value
At recruitment	218.1+56.9	197.1+56.7	1.582	0.12
After 12 months	46.9+73.6	28.3+56.9	1.203	0.23

In the LNG-IUS group, spontaneous expulsion of IUS was noted in 6 women, and they were offered hysterectomy. In the TBEA group, out of 38 women, 4 women had failure of therapy. All 4 women underwent hysterectomy.

DISCUSSION

Treatment options for heavy menstrual bleeding include medications or surgery. LNG-IUS, Endometrial ablation and hysterectomy are all effective in reducing menstrual blood loss, hysterectomy being more effective. But hysterectomy is associated with longer operating time, hospital stay, recovery time and increased morbidity. LNG-IUS and endometrial ablation are uterus conserving procedures which are safe, acceptable, equally effective, with lesser morbidity^{4,8}.

Both the treatments compared in this study are well established for the treatment of heavy menstrual bleeding, with no definitive evidence showing the best method. In a randomized control trial of forty four women after failed medical treatment, TBEA appeared to offer better health status function and was more acceptable than LNG-IUS⁹.

Whereas few other trials comparing these two treatment modalities, concluded LNG-IUS to be more effective in reducing PBAC scores, although there were no significant differences between either treatment in quality of life, patient satisfaction or the number of women requesting an alternative treatment^{10,11,12}.

In the trial conducted by Agnaldo L et al, had the longest follow up period of 5 years. They followed up 30 women with LNG IUS and 28 women with TBEA showed at the end of 5 years LNG –IUS users had higher efficacy and satisfaction rates compared to TBEA¹³.

The results of the meta-analysis of 7 RCTs involving 467 patients suggest that the LNG-IUS may be more effective in reducing PBAC Scores and affordable than TBEA as a long-term treatment (24 months) for HMB¹⁴.

According to the study conducted by Julian W. Barrington et al, both thermal balloon ablation and the LNG-IUS are useful additions with equivalent therapeutic effects in the treatment of menorrhagia¹⁵.

Based on the systemic review and meta-analysis including 360 women the efficacy of the levonorgestrel intrauterine system in the management of heavy menstrual bleeding appears to have similar therapeutic effects to that of endometrial ablation up to 2 years after treatment.¹⁶

Our study showed that both Levonorgestrel- Intrauterine System and Thermal Balloon Endometrial Ablation are equally effective in the treatment of heavy menstrual bleeding. Though the sample size was less there were no selection bias and outcome was comparable in both the groups. The learning curve for thermal balloon ablation is short, technically simple, minimally invasive and does not require expertise in hysteroscopic surgery. The Mirena insertion can be carried out by general practitioners as well as specialists in obstetrics and gynaecology.

CONCLUSION

Both LNG-IUS and TBEA are equally effective and safe in the treatment of heavy menstrual bleeding. The choice of treatment should be individualized according to the women's needs and choice and depending on risk factors. Both are cost effective modalities when compared to hysterectomy, with no added risk associated with a major surgery.

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