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Original Research Article

Levonorgestrel intrauterine system in menorrhagia- an effective and acceptable alternative

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ABSTRACT

Background: To study the efficacy, performance and acceptability of levonorgestrel intrauterine device (LNG-IUS) in treatment of women with menorrhagia.

Methods: This was a descriptive, prospective and observational study conducted over a period of January 2015 to September 2020. Seventy-five (75) women presented with heavy menstrual bleeding having no contraindication for device underwent LNG-IUS insertion after consent. Menstrual pattern, pictorial blood loss assessment chart score (PBAC), rate of acceptability and satisfaction were recorded at 3 months, 6 months, 1, 2 and 3 years after insertion of LNG-IUS.

Results: The most common bleeding pattern at 3 month post-insertion was inter-menstrual spotting followed by infrequent menses, oligomenorrhea and amenorrhea. LNG-IUS caused 45.19% reduction in menstrual blood loss (MBL) at 3 months, 81.48% at 1 year, 91.85% at 2 years and 97% at 3 years. Hemoglobin levels improved from mean baseline 8.9 mg/l to 12.8 mg/l at 3 years. Majority of women were satisfied with this minimally-invasive treatment with continuation rate of 94.66%. No major side-effects were noted.

Conclusions: LNG-IUS is an excellent minimal invasive, highly effective in controlling blood loss and well-tolerated alternative for women with menorrhagia. Its fertility-sparing property makes it an emerging option for young women.

Keywords: Levonorgestrel intrauterine system, Menorrhagia, Pictorial blood loss assessment chart

INTRODUCTION

Abnormal uterine bleeding is the commonest symptom for which women seek gynecologist's consultation. Menorrhagia is a major cause of discomfort, anxiety, anemia and decreased quality of life of women in their child-bearing age. Menorrhagia is defined as greater than 80 ml blood loss per menstrual cycle. The major causes of menorrhagia are ovulatory disorders, primary endometrial disorders, fibroid, adenomyosis, endometriosis or genital malignancies.¹ Nearly 30% of all hysterectomies are performed to alleviate heavy menstrual bleeding (HMB).² Historically, definitive surgical correction has been mainstay of treatment of menorrhagia. But today modern gynecology has trended

towards conservative therapy both for controlling treatment costs and the desire of many women to preserve the uterus.

Levonorgestrel releasing intrauterine system (LNG-IUS), a steroid releasing intrauterine system offers a safe, long-acting and minimally-invasive alternative to traditional medical and surgical treatments of HMB. It is a T-shaped device that releases levonorgestrel directly into the uterine cavity at an initial rate of 20 µg/day up to 5 years. The contraceptive and therapeutic benefits of LNG-IUS stems primarily from its local effects. The major effect on endometrium is that it becomes atrophic and inactive with few glands and scarce mitotic activity.³ It also causes local foreign body reaction characterized by an increase

in inflammatory cells, plasma cells and macrophages. These changes settle down within 3 months of insertion of LNG-IUS. The high contraceptive efficacy is well documented through extensive clinical research.⁴ LNG-IUS also confers important non-contraceptive health benefits like the oral contraceptive pills.⁴

This study aimed to evaluate the efficacy of LNG-IUS in treatment of menorrhagia.

METHODS

Seventy-five (75) women who had menorrhagia were recruited for study from the OPD of Bafna Hospital and Maternity Home, from January 2015 to September 2020. Women were offered the option of LNG-IUS insertion for treatment of HMB after detailed counseling. Informed consent was obtained for each woman prior to procedure. Data was collected prospectively and analyzed.

Inclusion criteria

All women who diagnosed as abnormal uterine bleeding were explained about the procedure in their language and those who agreed to give consent were included in the study.

Exclusion criteria

Active genital tract infections. Severe anemia (Hb≤7mg/l). Pregnancy. Abnormal cervical cytology. Premalignant and malignant endometrial histology. Previous endometrial resection/ablation. Fibroid >3 in number/ >3 cm size/ sub mucosal/ distorting the endometrium. Adnexal tumors. Postmenopausal bleeding. Hypersensitivity to levonorgestrel.

A detailed history of demographic profile, obstetric history, previous IUCD use, any medical and surgical illness along with a detailed menstrual history was noted. Subjective assessment of menstrual blood loss was done with pictorial blood loss assessment chart (PBAC) score. The PBAC score is calculated by multiplying the number of pads used with duration of flow with degree of staining 1, 5 and 20 for slight, moderate and heavily soiled pads respectively. PABC score ≥100 was considered as MBL>80ml and as diagnostic of menorrhagia.

Routine investigations included hemogram, sugars, coagulation profile, thyroid function test, gynecological examination. Trans-vaginal sonography was done to evaluate possible cause of menorrhagia like fibroid, adenomyosis, endometrial polyps and endometrial cysts. Cervical cytology and endometrial sampling was done to rule out cervical or endometrial neoplasia. All women had negative pregnancy test prior to insertion of LNG-IUS.

LNG-IUS insertion was done post-menstrual within 7 days under i.v. sedation. Patient were observed for any

immediate complications and then discharged. After the procedure patient was advised to keep record of the menstrual flow including the number of pads, duration and amount of staining using the PBAC charts. These records were evaluated in subsequent visits along with hemoglobin levels at 3 months, 6 months, 1 year, 2 years and 3 years.

Also, patient satisfaction was recorded on a scale 0-5 with; 0 as 'least satisfied' and 5 as 'most satisfied'. Parameters like general well-being, mental health, effect of menstrual blood loss, adverse effects and overall acceptability were assessed.

The primary outcome included reduction in menstrual blood loss, decrease in dysmenorrhea, incidence of side-effects and improvement in hemoglobin levels. The secondary outcome was to assess patient satisfaction, acceptability and continuation rate of LNG-IUS for heavy menstrual bleeding.

RESULTS

In our study, 75 women between 21 to 50 years of age underwent LNG-IUS insertion for menorrhagia and were systematically followed up at regular interval of time. The mean age of participants is 39.53 years. Although majority of women were above 40 years, younger women also showed interest in using this safe, reversible and fertility sparing device (Figure 1).

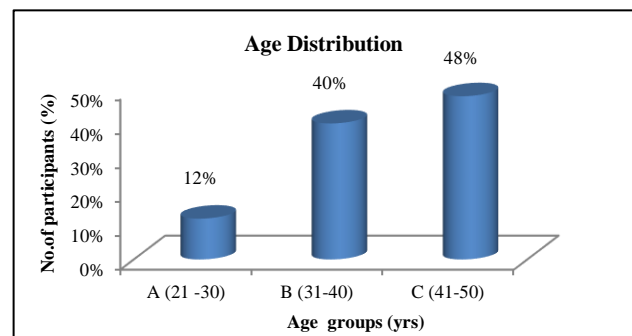


Figure 1: Age distribution.

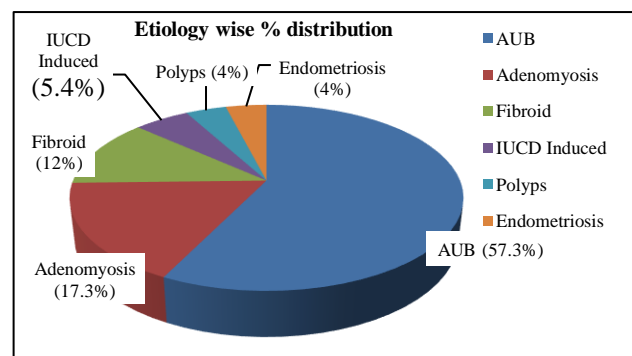


Figure 2: Etiology of menorrhagia.

Abnormal uterine bleeding (AUB) 57.3% (43) was found to be the single most common indication of HMB followed by adenomyosis 17.3% (13), fibroid 12% (9), endometriosis 4% (3) and endometrial polyps 4% (n=3). Previous copper IUCD-induced menorrhagia 5.3% (3) was an emerging group who sought for LNG-IUS as an option for their contraceptive needs along with HMB problem due to traditional IUCD use (Figure 2).

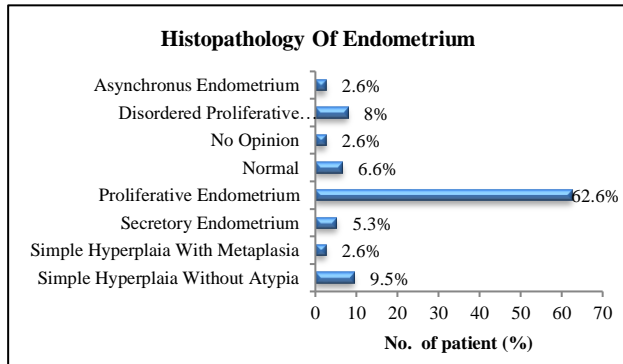


Figure 3: Histopathology of endometrium.

On histopathological examination of endometrial samples 62.6% (47) patients had proliferative endometrium, 5.3% (4) with secretory endometrium and 9.3% (7) with simple hyperplasia without atypia (Figure 3).

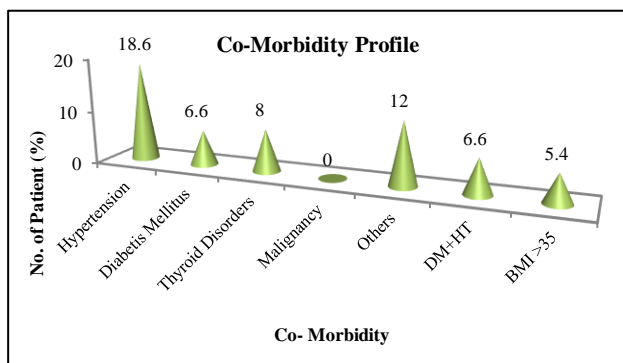


Figure 4: Co-morbidity profile of the participants.

The Co-morbidity profile of the participants is given in Figure 4. Other co-morbidities like Bronchial asthma, Ischemic heart disease, SLE, sarcoidosis, chronic renal disease, chronic liver disease, thalassemia trait were seen in 12% of participants.

Table 1: Number of patients (n) and duration of follow-up (months/year).

Follow up duration	Sample size (n)	Excluded from F/U
3 months	75	3 expulsion
6 months	72	1 removal
1 year	60	-
2 years	43	-
3/3+ years	31	-

The number of participants who follow up as an ongoing process is shown in Table 1. Three (4%) patients had spontaneous expulsion of the device at 3-4 months and one (1.3%) patient requested removal at end of 6 months for persistent irregular bleeding. These women later underwent hysterectomy and were excluded from further follow up.

Menstrual blood loss pattern was observed at 3 months, 6 months, 1 year, 2 years and 3 years and found that intermenstrual spotting was most common pattern at 3 months 50.6% (38) which drastically reduced to as low as 3% (1) at 3 year use. At end of 3 years follow-up 80.6% (25) became amenorrhic and 12.9% (4) had infrequent scanty menses (Figure 5).

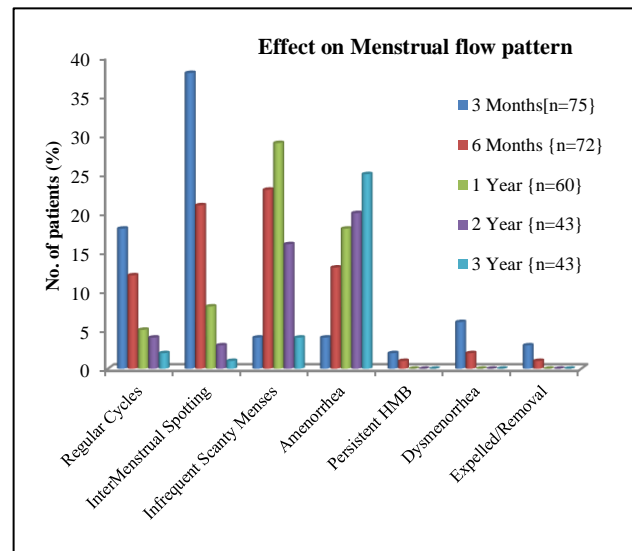


Figure 5: Effect on menstrual flow pattern.

Our study had statistically significant improvement in hemoglobin (Hb) levels. The mean pre-insertion Hb level was 8.95 mg/l, at 1 year 10.2 mg/l, at 2 year 11.4 mg/l and at 3 year 12.8 mg/l (Figure 6).

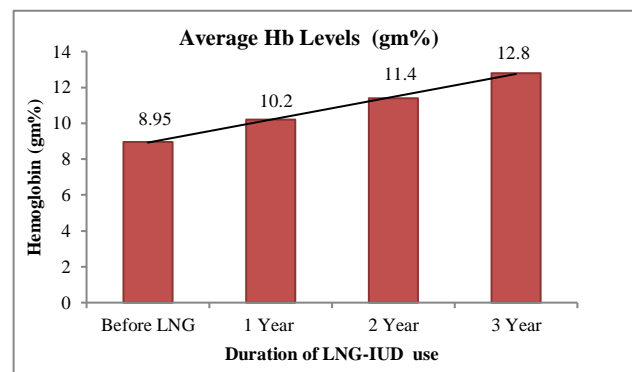


Figure 6: Effect on hemoglobin levels (gm%).

In our study, no major adverse side-effects were observed (Figure 7).

Patient education, counselling and re-enforcement at subsequent visits have led to the continuation of use and regular follow up of the patients. Figure 8 shows satisfaction score among the users over the time. At 3 months satisfaction score >4 was seen in 64% which further improved to 93% after 1 year and 96.7% at 3 years.

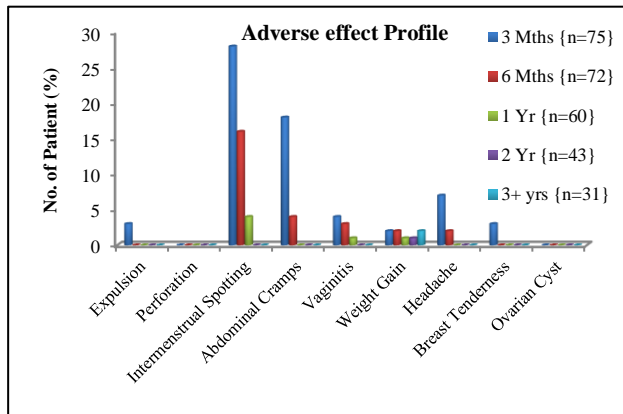


Figure 7: Adverse effect profile.

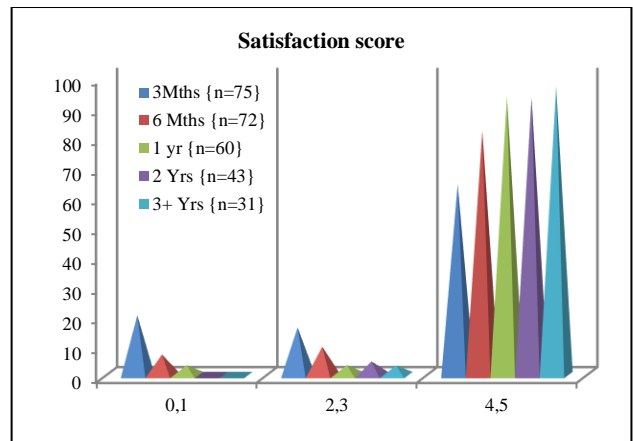


Figure 8: Satisfaction score.

Comparison with various studies available in literature, yielded similar results as ours. Comparison was done in following aspects: 1) Percent (%) reduction in menstrual blood flow (MBF) (Figure 9). 2) Adverse effect/complication comparison (Table 2). 3) Continuation score and satisfaction score (Table 3).

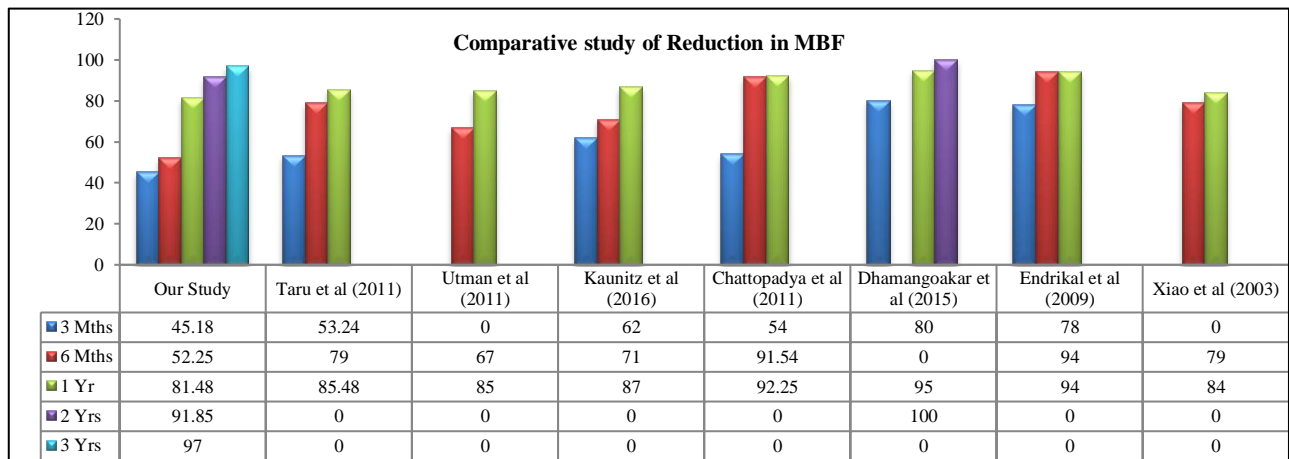


Figure 9: Comparison of reduction in menstrual blood flow (MBF).

Table 2: Comparison of adverse effects.

Study (n = no. of participants)	Expulsion	Perforation	Irregular bleeding	Abdominal cramps	Vaginitis	Weight gain	Headache	Breast tenderness	Ovarian cyst
Our study 2020 (n=75)	4	0	37.3	24	5.3	2.6	9.3	3	0
Taru et al 2011⁵ (n=70)	4.2	0	30	20	6.1	3	7.69	0	0
Utman et al⁶ 2011 (n=60)	10	0	13	0	3.33	0	0	0	0
Sushil et al 2005¹² (n=40)	0	0	22	0	0	5	0	0	0
Kriplani et al 2007¹³ (n=63)	0	0	71	38	33.3	30.5	13.3	0	0
Kaunitz et al 2010⁷ (n=82)	5	0	0	0	11	0	10	0	0
Chattopadyay et al⁸ 2011 (n=42)	2.38	0	28.5	4.76	0	0	0	0	0
Reid et al¹⁴ 2005 (n=25)	16	0	44	32	0	2.6	40	24	24

Table 3: Comparison of continuation rate and satisfaction score in various studies.

	Our study	Taru et al ⁵	Utman et al ⁶	Kaunitz et al ⁷	Chattopadhyay et al ⁸	Dhamagaonkar et al ⁹	Endrikat et al ¹⁰	Reid et al ¹⁴
Continuation rate	94.66	88.58	80	96	88.1	87.14	95	84
Satisfaction rate	96.7	94.54	80	85	96.3	91.42	85	82

DISCUSSION

In the present study we found that LNG-IUS was an effective and simple alternative for treatment of menorrhagia. Our findings further proved the efficacy of LNG-IUS in treatment of menorrhagia as in other similar studies.⁵⁻¹¹ In this study women with AUB, fibroid, adenomyosis, endometriosis, endometrial polyps and previous copper IUCD-induced menorrhagia were included. Figure 9 shows comparison of reduction in menstrual blood flow found in various studies. All groups showed decreased blood loss and eventually improved hemoglobin status and quality of life. In present study dysmenorrhea was relieved in the women with adenomyosis and endometriosis.

With LNG-IUS local endometrial concentration of levonorgestrel is high and uniform as compared to blood concentration leading to lesser side-effects. Table 2 presents the comparison of occurrence of various adverse side-effects in our and other studies.^{5-8,12-14}

Table 3 shows comparison of the continuation rate and satisfaction rate in our and other studies.^{5-10,14} At the end of 3 years 94.66% of participants continued the use of LNG-IUS with a satisfaction score of 96.7%.

LNG-IUS has significant positive impact on quality of life in form of improved hemoglobin levels within 6 months of use. LNG-IUS is also a very good alternative for women who have HMB and desire contraception as in previous copper IUCD-induced menorrhagia group in our study.¹⁵ LNG-IUS is useful in treating HMB in obese women.¹⁶ LNG-IUS is safer option in women with prior surgeries like cesarean and myomectomies. LNG-IUS is beneficial in treatment of diverse causes of HMB like fibroid, adenomyosis, endometriosis, endometrial hyperplasia.¹⁷

CONCLUSION

LNG-IUS can be an excellent alternative to medical and surgical treatment modalities for menorrhagia. It drastically reduces the amount of menstrual blood loss within few months of insertion along with improvement in hemoglobin levels. LNG-IUS truly meets the effectiveness and tolerability criteria for being considered as a first choice of treatment option for women with menorrhagia. Side-effects are generally mild and often needs only assurance for continuation of treatment. Due to its reversible and fertility sparing quality it is an emerging option for young women.

LNG-IUS provides a safe, non-surgical, reversible, fertility- sparing, acceptable and cost-effective option in management of menorrhagia.

Future scope

An unopposed estrogen is an important risk factor for developing atypical hyperplasia and endometrial cancer.¹⁸ Progesterone counters this effect and local intrauterine progesterone releasing device can be explored as primary therapy for complex atypical hyperplasia and early endometrial cancer. The local atrophic action, reduced mitotic and glandular activity of LNG-IUS can cause regression of histological changes in the endometrium with advantage of preserving uterus in young women who have not completed child-bearing.^{19,20}

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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