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Research Article

A Study of the Effectiveness of Levonorgestrel Intrauterine System in the Management of Abnormal Uterine Bleeding (AUB) - The Need of the Hour

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A B S T R A C T

Introduction: The incidence of heavy menstrual bleeding is 17.9% to 20% in India. The levonorgestrel intrauterine system (LNG-IUS) has been an effective treatment for any age group.

Aims and Objectives: 1. To know the improvement in menorrhagia after inserting LNG-IUS 2. To compare pretreatment menstrual cycles with post-LNG-IUS cycles 3. To assess the blood loss by PBAC scoring and haemoglobin

Materials And Methods: The study was done in a tertiary centre for a duration of three years. 50 women with abnormal uterine bleeding who fulfilled the inclusion criteria were enrolled in the study and their consent was obtained. History of participants was taken and general and systematic examinations were done along with ultrasonography. LNG-IUS was inserted after menstruation. PBAC score was calculated and compared with the previous cycles. Haemoglobin (Hb) estimation was done and the usefulness of LNG-IUS was noted.

Results: Out of 50 subjects, most were perimenopausal, multiparous women (72%). 36% had a bulky uterus. Endometrial thickness was > 9 mm in 8 women. Dilatation and curettage was done. PBAC score before treatment was 156-200 for 44% of the participants. After the treatment, the PBAC score decreased to 51-70 in 46% of the women. Maximum women used 21-25 pads per cycle before treatment. After treatment, most of the subjects used 10-15 pads per cycle. A decrease in dysmenorrhea was seen in 24% of women. A haemoglobin level of less than 8 gm% was seen in 36% of participants before the treatment. After LNG-IUS, haemoglobin improved by more than 1 gm% in 76% of women.

Conclusion: LNG-IUS is a good treatment for abnormal uterine bleeding. It is as effective as a hysterectomy in patients with dysfunctional uterine bleeding and can decrease the incidence of hysterectomies and the associated complications.

Keywords: Heavy Menstrual Bleeding, Levonorgestrel Intrauterine Device, Effectiveness

Introduction

Abnormal uterine bleeding (AUB) is an important gynaecological problem that affects more than 30% of women at some point in their lives. It can interfere with a women's working capacity and social life. It can also cause anaemia and can lead to no improvement even with continuous iron therapy. Menorrhagia is clinically defined as cyclical bleeding at normal intervals (24-35 days) which is more in amount than calculated by PBAC score or continues for an increased number of days i.e. more than a week, but the diagnosis usually is based on women's perception of her menstrual blood loss and the effect that it has on her daily life. The incidence of heavy menstrual bleeding is 17.9% to 20.0% in developing countries.[1] To classify AUB, PLAM-COEIN was designed to manage patients on a conservative basis (AUB-P: Polyp; AUB-A: Adenomyosis; AUB-L: Leiomyoma; AUB-M: Malignancy and hyperplasia; AUB-C: Coagulopathy; AUB-O: Ovulatory disorders; AUB-E: Endometrial factors; AUB-I: Iatrogenic; and AUB-N: Not classified) and was introduced in 2011 by the International Federation of Gynaecology and Obstetrics (FIGO).[2] The management of heavy menstrual bleeding poses many challenges in the present-day scenario and many medications are utilised for the treatment. Levonorgestrel intrauterine system (LNG-IUS) has been the most effective method even in the puberty age group. It is a T-shaped device which has 52 mg levonorgestrel around the vertical stem. The device releases the hormone at an initial rate of 20 µg/day and declines to a rate of 14 µg/day after 5 years.[3,4] Our objective is to know the usefulness of LNG-IUS in the treatment of heavy menstrual bleeding in middle-aged and perimenopausal women.

Aims and Objectives

- To know the improvement in menorrhagia after inserting LNG-IUS
- To compare pretreatment menstrual cycles with post-LNG-IUS insertion cycles
- To assess the blood loss done by PBAC scoring and haemoglobin

Materials and Methods

This was a cross-sectional study done in a tertiary care referral centre - Mamata Medical College and General Hospital, Khammam, Telangana, situated in the periphery, over a period of three years from January 2020 to December 2022. The Institutional Ethics Committee clearance certificate was obtained prior to the study. Among 190 women, 50 women with AUB who fulfilled the inclusion criteria were selected and enrolled in the study. Inclusion criteria were women aged 18-45 years, having heavy menstrual bleeding (as per Table 1) and no associated pelvic diseases, diabetes, hypertension, obesity, or hormonal abnormality. Exclusion criteria were large leiomyomas, endometrial polyps distorting the uterine cavity, huge hydrosalpinges, chocolate cysts of the ovary, tubal pregnancy, and molar pregnancy. In the case of AUB with regular cavity, dilatation and curettage/ pipelle biopsy was done to rule out malignancy. The histopathological examination report was noted. Women with endometrial cancer were also excluded from our study. Informed written consent was obtained from all participants. A detailed history was taken and a general examination was done wherein pallor, icterus, clubbing, pedal oedema and vitals were checked. Cardiovascular and respiratory systems were examined systematically, and abdominopelvic examination was done along with ultrasonography. If the HPE report revealed proliferative endometrium, three cycles of oral progesterone were given for three weeks in the first half of the cycle and in the case of secretory endometrium, it was given in the second half of the cycle for a week and the response was noted. LNG-IUS was inserted after menstruation had stopped, mostly within seven days. It was inserted as an office procedure except for a few women for whom it was inserted in a minor operation theatre under minimal sedation. After insertion, the women were enquired about their menstruation and dysmenorrhoea. PBAC score was calculated and compared with the previous cycles after thirty days. Haemoglobin (Hb) estimation was done 3 months after the insertion. The usefulness of LNG-IUS was noted by improvement in PBAC score and improved haemoglobin status. At the end of the study, the results were analysed with the appropriate statistical methods.

Results

50 women were selected by random sampling method on the basis of the selection criteria.

Table 1.PBAC Score

Pads		
1 Point	For each lightly stained pad	
5 Points	For each moderately stained pad	

20 Points	For each completely saturated pad	
Tampons		
1 Point	For each lightly stained tampon	
5 Points	For each moderately stained tampon	
10 Points	For each completely sturated tampon	
	Clots/ Flooding	
1 point	For each small clot (size of a nickel or indian 50 paise coin	
5 point	For each large clot (size larger than nickel or indian 2 re coin	
5 point	For each episode of flooding	

Most of the study subjects were between 36 and 45 years of age (Table 2).

Table 2.Agewise Distribution of Women

Age (Years)	No. of Women with Menorrhagia	Percentage
18-25	8	16
26-35	12	24
36-45	30	60
Total	50	100

As shown in Table 3, most (72%) of the participants were multiparous women.

Table 3.Paritywise Distribution of Women

Parity	No. of Women with Menorrhagia	Percentage
Unmarried	2	4
Nulliparous	4	8
Para One	8	16
Multipara	36	72
Total	50	100

Out of 50 women, 64% had a normal uterus, 36% had a bulky uterus, 90% had normal adnexa, and 10% presented with small simple ovarian cysts (Table 4). Ultrasonography showed that the endometrial thickness was normal in 84% of the women, and for 8 women, it was more than 9 mm. Diagnostic D&C was done which showed normal endometrium in all women.

Table 4.Distribution of Women as per the Clinical and Ultrasound Findings

Parameter	Findings	No. of Women	Percentage
Uterine size	Normal size	32	64
	Bulky uterus (6-8 weeks)	18	36
	Total	50	100
Adnexal pathology	Normal ovaries	45	90
	Cystic ovaries	5	10
	Total	50	100
Endometrial thickness (mm)	1-5	18	36
	6-9	24	48
	> 9	8	16
	Total	50	100

Most (44%) of the women had PBAC scores between 156 and 200 before treatment, followed by 36% having scores between 126 and 150 (Table 5).

Table 5.Distribution of Women according to PBAC Scoring before LNG-IUS

PBAC Scoring	No. of Women	Percentage
101-125	7	14
126-150	18	36
151-155	3	6
156-200	22	44
Total	50	100

Table 6 shows that after treatment, the PBAC scores of 46% of participants came down to the 51-70 range.

Table 6.Distribution of Women according to PBAC Scoring after LNG-IUS

PBAC Scoring	No. of Women	Percentage
30-40	8	16
41-50	9	18
51-60	12	24
61-70	11	22
71-80	5	10
> 80	5	10
Total	50	100

Maximum (44%) subjects used 21-25 pads per cycle before treatment, while after treatment, most (56%) of the subjects used 10-15 pads per cycle (Table 7).

Table 7.Number of Pads Used Before and After Insertion of LNG-IUS

No. of Pads Used Per Cycle	Before Treatment	Percentage	After Treatment	Percentage
< 10	-	-	2	4
10-15	4	8	28	56
16-20	18	36	16	32
21-25	22	44	3	6
25-30	6	12	1	2
Total	50	100	50	100

Table 8 shows that 36% of women had haemoglobin less than 8 gm% before LNG-IUS insertion.

Table 8.Distribution of Women as per Their Haemoglobin Levels Before LNG-IUS Insertion

Haemoglobin (gm%)	No. of Women	Percentage
< 8	18	36
8-10	24	48
> 10	8	16
Total	50	100

Table 9 shows the improvement in haemoglobin after the insertion of LNG-IUS and iron therapy. It was seen that after the treatment, haemoglobin improved by more than 1 gm% for 76% of the participants.

Table 9.Improvement in Haemoglobin Levels of Participants After LNG-IUS Insertion

Haemoglobin Increase (gm%)	No. of Women	Percentage
< 1	12	24
1-2	20	40
2-3	10	20
> 3	8	16
Total	50	100

Table 10.Effect of LNG-IUS on Pain during Menstruation

Pain	No. of Women	Percentage
Better	12	24
Same	20	40
AUB without dysmenorrhoea	18	36
Total	50	100

Out of 32 women, only 24% showed a decrease in dysmenorrhea (Table 10).

Table 11.Side Effects of LNG-IUS Experienced by the Participants

Side Effects	No. of Women	Percentage
Menorrhagia	3	6
Pain abdomen	2	4

White discharge per vagina	1	2
Expulsion	2	4
Without side effects	42	84
Total	50	100

6 women had minimal side effects and 2 of them had expulsion (Table 11).

84% of the women were satisfied with LNG-IUS (Table 12).

Table 12.Status of Satisfaction of Women with LNG-IUS

Satisfaction	No. of Women	Percentage
Satisfied	42	84
Unsatisfied	8	16
Total	50	100

Table 13.Effect of LNG-IUS on Women's Satisfaction and Acceptability

Acceptability	No. of Women	Percentage
Acceptable	37	74
Not acceptable	13	26
Total	50	100

Only 74% of the women continued with LNG-IUS (Table 13); others discontinued because of relative side effects and the persistence of dysmenorrhoea among a few women. 10% of those who were not willing to continue with LNG-IUS had their uteruses removed.

Discussion

50 women were selected by random sampling method on the basis of selection criteria. 60% of them were between 36 and 45 years of age (perimenopausal period). 72% of the respondents were multiparous women. LNG-IUS was inserted for the treatment of heavy menstrual bleeding. A recent Cochrane review published in 2015 by Lethaby et al. concluded that LNG-IUS is more useful than oral medications like a combined oral contraceptive pill with oestrogen and progesterone, local vasoconstrictors and non-steroidal anti-inflammatory drugs like mefenamic acid, and progesterone preparations like medroxyprogesterone acetate and norethindrone acetate, as a treatment for abnormal uterine bleeding and it definitely reduces menstrual bleeding to a large extent and thus improves the quality of life. It is more acceptable in the long term since the efficacy lasts for more than five years. It is associated with negligible adverse effects as compared to oral therapy.[5] The Cochrane review identified LNG-IUS to be better than oral medication in the treatment of abnormal uterine bleeding and associated it with greater reduction in menstrual bleeding and improvement in quality of life which was comparable to our study.

Out of 50 women, 64% had a normal uterus, 36% had a bulky uterus, 90% were found to have normal adnexa, and 10% had small simple ovarian cysts. Ultrasonography showed that the endometrial thickness in 84% of subjects was normal. Eight women had ET > 9 mm in our study. The histologic diagnosis of endometrial hyperplasia was reinterpreted in relation to the World Health Organization classification, grouping them into 1) hyperplastic endometrium with atypia and 2) hyperplastic endometrium without atypia group.[6] Diagnostic D&C was done among the subjects and we classified reports according to the WHO guidelines. All women who had normal endometrium and hyperplastic endometrium without atypical cells were given the option of LNG-IUS.

Nine randomised trials involving a total of 783 women who had LNG-IUS insertion were compared with women treated with non-hormonal and hormonal methods. It showed that LNG-IUS resulted in a greater reduction in menstrual-blood loss at 3-12 months of follow-up.[7] We followed up on the participants for up to three months. Most (44%) of the women had PBAC scores between 156 and 200 before treatment, followed by 36% with scores ranging between 126 and 150. After the treatment, for 46% of participants, the PBAC scores decreased to 50-70. Maximum subjects (44%) used 21-25 pads per cycle before treatment, which decreased to 10-15 pads per cycle after treatment used by 56% of participants. Kriplani et al. studied the efficacy, acceptability, and side effects of LNG-IUS when used for abnormal uterine bleeding and concluded that it is an effective and well-accepted treatment in the management of heavy menstrual bleeding since it is inserted one time as an outpatient basis and the patients can go home on the same day. A significant decrease in the mean number of bleeding days was observed at 1-month follow-up among women with menorrhagia, and the decrease continued as the treatment duration increased because of oligomenorrhoea followed by amenorrhoea due to the effect of levonorgestrel.[8] These results were similar to those of our study.

Out of 50 women, only 24% showed a decrease in dysmenorrhea. 36% of women had haemoglobin less than 8 gm%. After insertion of LNG-IUS and oral iron therapy, haemoglobin improved by more than 1 gm% for 76% of subjects. A similar increase in haemoglobin was seen in a study done by Gunes et al.[9] on the effect of levonorgestrel intrauterine system on uterine myomas and Xiao et al.[10] in their study on the therapeutic effects of the levonorgestrel-releasing intrauterine system in the treatment of idiopathic menorrhagia.

We had six women with minimal side effects and two of them had expulsion. The side effects of LNG-IUS which included pain with insertion, risk of expulsion, irregular bleeding or spotting, headaches, pelvic pain, breast tenderness, and ovarian cysts were seen in a study by Lethaby A. Though 84% of women were satisfied, only 74% of them continued using LNG-IUS. Other women discontinued the treatment because of relative side effects and the persistence of dysmenorrhoea among a few women. Similar results were found in a study done by Irving et al.[11] LNG-IUS had more efficacy in reducing menstrual blood flow (94% in the LNG-IUS group and 87% in the oral norethisterone group). In the same study, only 22% of women continued treatment in the norethisterone group compared to 76% of women who continued using LNG-IUS. 10% of women were not willing to continue using LNG-IUS, and hence their uteruses were removed. Lahteenmaki et al.[12] conducted a randomised trial to assess LNG-IUS as a conservative alternative to hysterectomy in the treatment of abnormal uterine bleeding. Their study concluded that LNG-IUS was a good alternative to hysterectomy in the treatment of menorrhagia which was comparable to our study. Hence, we recommend that LNG-IUS should be considered before hysterectomy or any other invasive treatment provided the uterine cavity is regular and endometrial carcinoma is excluded.

Conclusion

LNG-IUS is a good treatment option for women with abnormal uterine bleeding. It is equally effective as a hysterectomy in improving heavy menstrual bleeding in patients with dysfunctional uterine bleeding and can decrease the incidence of hysterectomies and the associated complications.

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Conflict of Interest: None

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