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Evaluation of effects of levonorgestrel releasing intrauterine system in heavy menstrual bleeding

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ABSTRACT

Background: Heavy menstrual bleeding (HMB), is one of the most frequently encountered problem in the gynaecology OPD. It can significantly affect women's quality of life and overburden health-care systems. The Levonorgestrel Releasing Intrauterine System (LNG-IUS) is a highly effective long-acting reversal contraceptive, also useful for controlling HMB and promoted by National Institute for Health and Care Excellence (NICE).

Materials and Methods: This prospective interventional study conducted upon 30 women, with heavy menstrual bleeding, of 30-50 years' age, reporting in the outpatient department of a tertiary health care facility unit "between" January 2018 to June 2019. Women, who met inclusion and exclusion criteria were our study population. Data was collected during follow up at 1^{st}, 3^{rd} and 6^{th} month and all the association were tested by mean, proportion and percentages. Chi-square test was used for comparing categorical result and p-value of less than 0.05 was considered as statistically significant. Calculation was made by using IBM SPSS 26^{th} version of statistical software.

Results: Majority of women were from 40-45 years' age group. Pictorial Blood Loss Assessment Chart (PBAC) score was calculated in 30 women who underwent LNG IUS insertion. There was significant reduction ($p<0.05$) in the mean PBAC score at 3^{rd} and 6^{th} month compared to their initial value after LNG-IUS insertion.

Conclusion: LNG IUS is effective and can be used as first line measure for treatment of HMB.

1. Introduction

Heavy menstrual bleeding (HMB), is one of the most frequently encountered problem reported in the field of gynaecology that can adversely affect women's lives and burden the health-care systems. The National Institute for Health and Care Excellence (NICE) defines HMB as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and marital quality of life (QoL), and which can occur alone or in combination with other symptoms.[1,2] As per quantification of blood loss, i.e. a loss of more than 80 ml of blood per cycle has often been classified as heavy menstrual bleeding. Prevalence of HMB has been reported in 4% to 51% cases, the wide range being due to differences in definition, measurement (objective vs. subjective), and clinical settings. In India the prevalence of HMB has been reported as 17.9%.[3,4]

The Royal College of Obstetricians and Gynaecologists (RCOG) guidelines also advocate an initial nonsurgical management of HMB, with medical therapy such ashormonal pills, tranexamic acid or mefenamic acid or the levonorgestrel-releasing intrauterine system (LNG-IUS).[1]

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The LNG IUS is a well-accepted long-acting reversal contraceptive.[4,5] It bears a plastic frame shaped as a T holding a total of 52 mg of levonorgestrel, which is released at a rate of approximately 20 μg per day. It has been approved for a continuous use for 5 years after which it has to be removed and if desired can be replaced by a new one Further fertility is quickly restored after removal. The LNG-IUS has not been approved for use in women with fibroids distorting the uterine cavity, congenital uterine anomaly, in women with pelvic infection, and in suspected malignancies.[6] The basal endometrial mucosa quickly absorbs levonorgestrel released by the LNG IUS., and may become detectable in plasma, 15 mins after insertion. The LNG targets the endometrium and decreases the menstrual blood loss and pain by uniform suppression of endometrial proliferation and decidualisation of stroma. However there maybe irregular bleeding or spotting during the initial months due to non-responsiveness of endometrium to estrogen. The-side effects fall into two categories: those due to an intrauterine placed device, such as expulsion of the device, cramping lower abdominal pain, dysmenorrhea, irregular bleeding and ectopic pregnancy; and those due to the hormonal content of the device, progestogens. The latter includes weight gain, a sense of bloating and breast tenderness. The main disadvantage of the LNG-IUS is its interference with the normal rhythm of the menstrual cycle, particularly in the first six months,[7] Amenorrhea following a year post insertion has been reported in around 12%.[8]

Developing a well-accepted and effective treatment for HMB in women of reproductive age is a Herculian task and continues to be a challenge because of lack of facilities and awareness in the population and poor compliance with screening and treatment.

Earlier a more invasive approach of doing hysterectomy was practised as a treatment modality for heavy menstrual bleeding patients. These surgical interventions increased costs[9] and also subjected women to the adverse effects of early surgical menopause apart from operative risks.

The aim of the study was to know the efficacy of LNG-IUS in terms of reduction of blood loss and to estimate the prevalence of side effects following the device insertion.

2. Materials and Methods

All women between the ages of 30 to 50 years', reporting to the outpatient department of a tertiary care hospital between January 2018 to June 2019 were included in the study. It is a prospective interventional study of women with heavy menstrual bleeding (HMB). Study participants were those women meeting inclusion and exclusion criteria.

The Institutional Ethics Committee approved the study, and the study was performed in accordance with its recommendations and that of Helsinki Declaration of 1975 that was revised in 2013 and informed consent was taken prior to study from each individual. All the selected women had undergone LNG IUS insertion as a part of management for HMB.

2.1. Inclusion criteria

Women between 30 and 50 years' age with heavy menstrual bleeding (HMB) with or without associated dysmenorrhoea and/or histologically proven benign endometrial hyperplasia or adenomyosis or endometriosis were selected for study. Women with fibroid uterus of less than 12 weeks' size of pregnant uterus and/or not distorting endometrial cavity or women unsuitable for surgery due to medical or surgical cause was also included within our study sample.

2.2. Exclusion criteria

Women with pelvic inflammatory disease, pregnancy or suspected genital malignancy or presence of uterine fibroid of more than 5 cm size or submucosal myoma were excluded from study. Women who had abnormal cervical cytology or endometrial hyperplasia, chronic hepatic disease or coagulopathy detected during study were also excluded from the study.

All willing woman for study, of 30 to 50 years' age with complaint of heavy menstrual bleeding (HMB), who came to outpatient department of gynaecology of tertiary care hospital were put under relevant history taking, clinical examination and investigations. The investigations include serum bilirubin, liver enzymes, thyroid stimulating hormones (TSH), coagulation profiles and peripheral blood smear, complete haemogram. All women of our study were put under transvaginal sonography (TVS) to assess endometrial thickness, Pap smear and endometrial sampling taken to exclude malignancy. Women, who met the inclusion and exclusion criteria was recruited for our study. Informed consent was taken before inserting LNG IUS. The device was inserted in immediate post menstrual phase and was continued for five years. For our study, data was collected in pre-structured proforma before device insertion and then at 1^{st} postmenstrual month, 3^{rd} month and 6^{th} month. Data were collected from the responses on validated questionnaires from each study participant during each visit, regarding menstrual blood loss, relief from symptoms, palpation of thread and other related complaint, if any.

Transvaginal sonography was performed after insertion of LNG IUS in each study participant and the women were put under transvaginal sonography to assess the position of the device and endometrial thickness to compare with the data with value of pre-insertion.

On each follow up visit, semi quantitative assessment of menstrual blood loss was done by using the PBAC (Pictorial Blood Loss Assessment Chart).[3] The PBAC score was calculated by assigning a score of 1, 5 or 20 respectively to a lightly, moderately or fully soaked sanitary pad, and a score of 1 or 5, respectively, for the small or large clots.

The degree of disturbance caused by their menstrual bleeding, pain and/or both, on the general wellbeing and physical activity was assessed by using an instrument named as visual analogue scale (VAS). The VAS is a subjective measure for acute and chronic pain. The scores are recorded by making a handwriting mark on a 10 cm line that represents a continuum between 'no pain' to 'worst pain'. Their response closely indicates the effects of uterine bleeding or menstrual pain on normal life, without distinguishing between the two.[10](Figure 2)

Our study variables were age, parity, aetiological factors, PBAC score and VAS score. Collected data were entered in MS Excel and were analysed by using of IBM SPSS version 26^{th} statistical software. These data were computed in table format in percentages and proportions. Findings were measured at 95% confidence level and Pearson's Chi-Squared test was used for non-parametric data to see the significance level where p-value<0.05.

3. Results

Out of thirty women, 60% belonged to the age group of 40-45 years followed by 20.0% in the age group of 35- 40 years, 13.3% in the age group > 45 years and least in the age group of 30-35 years (6.7%). The mean age of presentation being 41.3 years. The maximum women were belonging from parity two (76.7%) and least from parity three (6.6%). (Table 1)

The majority of patients 16/30 (53.3%) of our study, presented with HMB alone prior to LNG IUS insertion, followed by 30.0% presenting with both HMB with dysmenorrhea. Most of the patients of dysfunctional uterine bleeding (DUB) 17/30 (56.7%) had normal size uterus. In our study, 7/30 (23.3%) women were diagnosed with myoma uteri, single or multiple small intramural and/or subserosal myoma (<5 cm). There was no evidence of submucosal myomas and 5/30 (16.7%) were diagnosed as having adenomyosis in our study group. (Table 2)

All women were given education regarding counting of pads and noting down of pad soakage as per PBAC chart score. The mean PBAC score at the first visit prior to insertion was 195.33±13.5, with maximum 19/30 (63.3%) women having a score was in between 150-200. In our study, there was significant (p-value<0.05) reduction in the mean PBAC score at 3^{rd} and 6^{th} months after LNG-IUS insertion in comparison to the pre-insertion value. (Table 3)

During the course of follow up, the mean haemoglobin concentration of 8.9g/dl was at preinsertion, that increased by 14.6% at 3 months and 19.1 % at 6 months. Similarly, the tool VAS score was used for subjective measurement of pain. The score improved from 7.3 to 4.6 at 3 months and 2.8 at 6 months, emphasizing on the acceptability of the LNG IUS. The endometrial thickness also showed a reduction from a mean of 8.5 mm to 7.4 at the end of 3^{rd} month and then 5.3mm at the end of 6 months. (Table 3)

At the 1^{st} month 18/30 (60.0%) women presented with irregular spotting, got reduced to 14/30 (46.7%) at 3 months and 2/30 (6.7%) at 6 months, it however remained the most common complaint of patients throughout this study. In our study, five women (16.7%) resumed normal menses at the end of 1^{st} month, 10/30 (33.3%) at the end of 3^{rd} months. and nearly 14/30 (46.7%) at 6^{th} months. At the end of 6^{th} months 2/30 (6.7%) achieved amenorrhea. (Table 4)

Most common side effect 18/30 (60.0%) was irregular spotting at first visit, and 14/30 (46.7%) at 3^{rd} months and in 2/30 (6.7%) at 6^{th} months. This was followed by lower abdominal cramps and heavy menstrual bleeding. Only one woman throughout the study complained of breast heaviness and 2 patients expelled the LNG IUS during the period of study. (Figure 1)

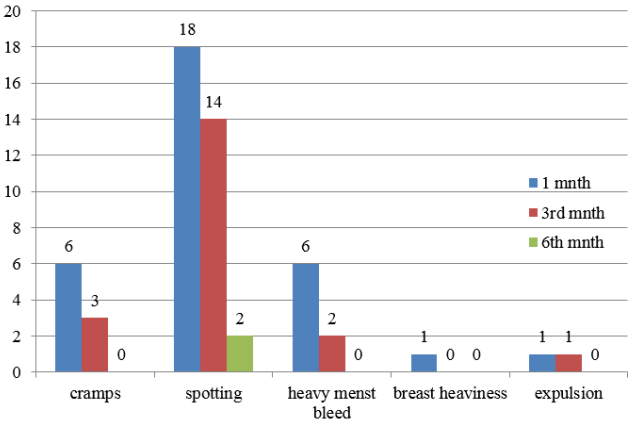

Fig. 1: Common side effects during follow up.

4. Discussion

Heavy menstrual bleeding (HMB) is a commonly encountered symptom, that has enormous effect on day to day life of a woman and adds to substantial health care expenditure required to combat the problem. This prospective interventional study on 30 women with symptoms of HMB with or without dysmenorrhea, fulfilling the stringent inclusion and exclusion criteria were undertaken with intent to study the effect, efficacy, acceptability and side effects of LNG IUS in heavy menstrual bleeding. The results and statistical analysis of obtained data have reconfirmed the efficacy and acceptability of the LNG IUS in a setting of HMB with or without dysmenorrhea.

Thirty women having a mean parity of 2 with a mean age of presentation being 41.3 years were included in the study. More than half of the patients (57.0%) were diagnosed with DUB while 23.3% showed fibroid uterus, fibroids being subserosal or intramural but less than 5cm in size and not distorting the cavity. Another 16.7% were suffering from adenomyosis and lastly 3.3% were presented

Table 1: Distribution of age and parity of the patients

Age group (in years)	Number	Percentage (%)	Mean
30-35	2	6.7	
35-40	6	20.0	
40-45	18	60.0	41.3
>45	4	13.3	
Total	30	100	
Parity of patients			
1	5	16.7	
2	23	76.7	2
3	2	6.6	
Total	30	100.0	

Table 2: Distribution of symptoms and aetiological factors

On initial visit of patients		Number	Percentage (%)
Symptoms	HMB only	16	53.3
	Dysmenorrhea only	5	16.7
	HMB + Dysmenorrhea	9	30.0
	Total	30	100.0
Aetiological factors	DUB	17	56.7
	Adenomyosis	5	16.7
	Endometriosis	1	3.3
	Fibroid	7	23.3
	Total	30	100.0

HMB= Heavy Menstrual Bleeding, DUB= Dysfunctional Uterine Bleeding.

Table 3: Distribution of patients according to PBAC Scoring

PBAC score		Number (N=30)	Percentage (%)	Mean ± S.D.	Changes in other parameters		
On initial visit	100-150	3	10.0	195.33 ± 13.5	Haemoglobin (gm/dl)	VAS Score	Endometrial thickness (mm)
	150-200	19	63.3				
	>200	8	26.7				
PBAC score		Mean ± S.D.	Percentages (%) of reduction	p-value			
During follow up	Initial visit	195.33± 13.5	–	–	8.9	7.3	8.5
	1st month	171.76±7	13.7	0.06	–	–	–
	3rd month	52±3.7	74.5	0.002	10.2	4.6	7.4
	6th month	37.8±2.7	81.3	0.001	10.6	2.8	5.3

PBAC= Pictorial Blood Loss Assessment Chart, VAS Score= visual analogue scale, S.D.= Standard Deviation

Table 4: Effect of LNG IUS on menstrual pattern

Menstrual pattern	Irregular heavy menses	Irregular spotting	Normal menses	Scanty menstrual flow	Amenorrhoea
1^{st} month	7(23.3%)	18(60.0%)	5(16.7%)	0	0
3^{rd} month	2(6.7%)	14(46.7%)	10(33.3%)	3(10.0%)	0
6^{th} month	0	2(6.7%)	14(46.7%)	10(33.3%)	2(6.7%)

LNG IUS: Levonorgestrel Releasing Intrauterine System

Table 5: Different studies of Menstrual bleeding pattern during follow up patients after LNG IUS insertion.

Different studies	No. of patients	PBAC pattern during follow up			
		Initial visit	3^{rd} month	6^{th} months	12 months
Fedele ENT et al.[11]	25	211	48	43	44
Grigorieve et al.[12]	67	97	32	21	16
Mercorio et al.[13]	19	310	186	155	96
Barrington et al.[14]	25	107	—	31	—
Reid et al.[4]	25	240	49	25	—
Rauramo et al.[15]	30	261	—	—	7
Scolov D et al.[16]	102	231.7	40.18	20.84	17.58
Present study	30	195.33	52	37.8	—

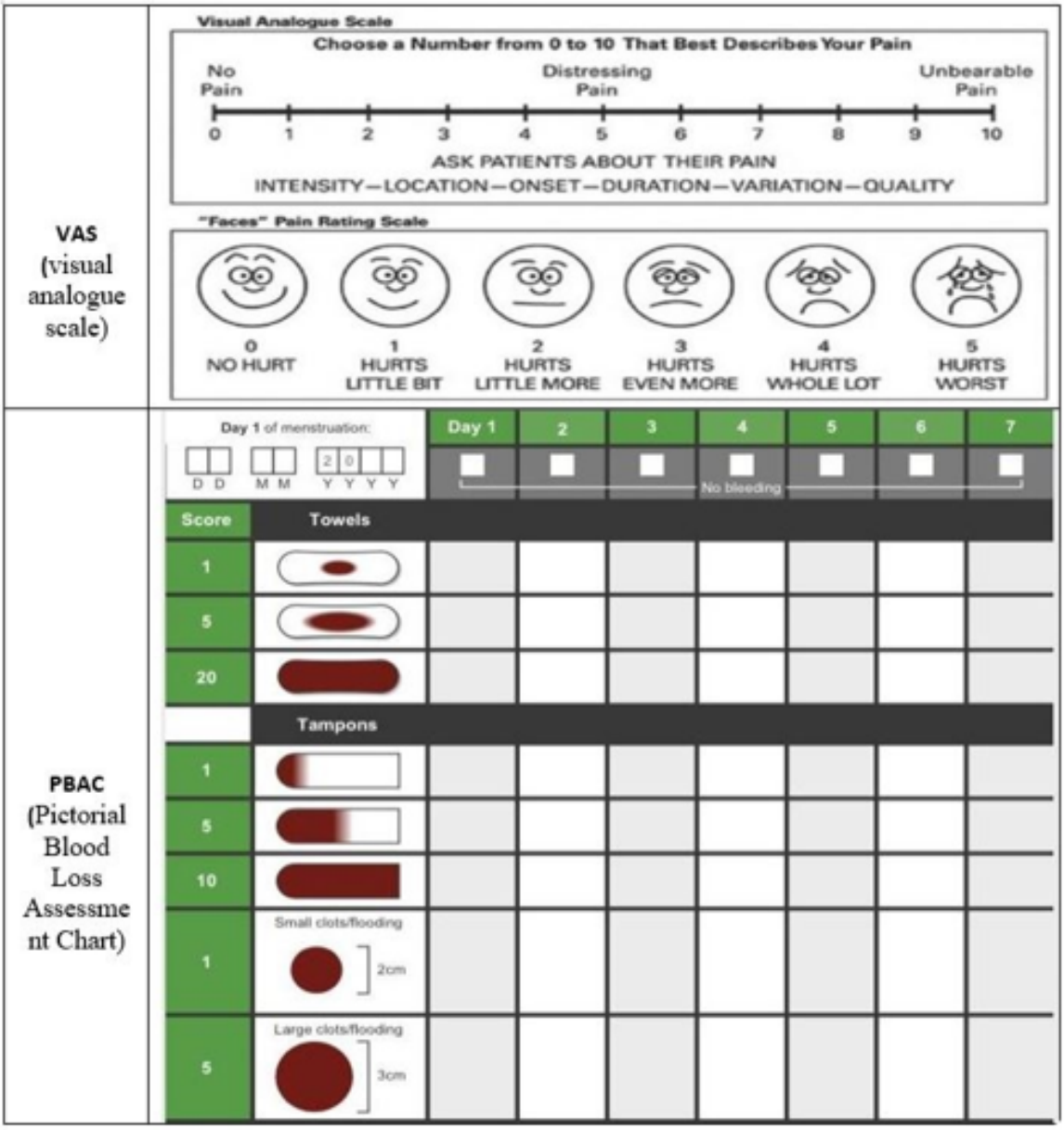

Fig. 2: Visual analogue scale (VAS) and PBAC scale objectively estimate menstrual blood loss and diagnose menorrhagia if PBAC score >100

with endometriosis. Similar age distribution, mean age of presentation and parity was seen in various other studies like the large randomised study by J. Gupta et al[17] for the ECLIPSE Trial collaborative group and Park DS et al.[18] A study by Singh K et al,[19] named "Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding" had 69.0% cases of DUB, 14.3% with fibroid uterus, 10.0% patients with adenomyosis and remaining 7% had endometriosis.

In this study menstrual blood loss (MBL) has been assessed by using the PBAC chart that was initially documented by Higham et al.[20] The validated graphical scoring system made it more reliable and objective tool for quantitative measurement of menstrual blood loss as described by Zakherah MS et al.[21] The mean initial PBAC score in this study was found to be 195.33, that was significantly declined at 3^{rd} and 6^{th} months after LNG IUS insertion, this was found to be in accordance with the work of various authors.

Although, there is less consistency in the average value of the PBAC in studies conducted by different authors to assess usefulness and accuracy of LNG IUS, partly due to the fact that the method depends on the subjective assessment, various researchers had described the effectiveness of the device to decrease the menstrual blood loss in different gynaecological conditions within the first year of treatment. Moreover, the effect was observed in almost all patients after LNG IUS insertion, both in cases of DUB, and in cases of menorrhagia associated with fibroids or adenomyosis, as shown in the studies of Grigorieva et al[12] and Mercorio et al.[13] Our findings are in line with numerous previous publications of LNG IUS to investigate the therapeutic effect on heavy menstrual blood loss.(Table 5)

Analyzing the change in the pattern of menstrual bleeding after LNG IUS insertion, our study showed that in 33.3% of women at the end of 3 months and 46.7% at the end of 6 months had reverted to normal menses. In addition, further reduction of PBAC score leading to scanty menstrual flow was observed in another 33.3% after 6 months. At the end of 6 months 2 women (6.7%) became amenorrhic. In similar study by Singh K et al,[19] it was found that in first 3 months, normal menstrual cycle achieved by 20.0% patients, and 44.44% had scanty menstrual flow at 6 months and 81.5% became amenorrhoic after use of 1 year. In their study, there was spontaneous expulsion of the device in 5.0% women within their first 3 menstrual cycles. In a study by Seeru G. et al,[22] at six months' post LNG IUS insertion 10.0% had amenorrhea, 40.0% had irregular spotting and 20.0% had scanty regular bleeding. By the end of 12 months in this group 90.0% of women developed amenorrhea. In present study 16.6% patients reported dysmenorrhoea. All got relieved at the end of 6 months from dysmenorrhoea. Our study shows an improvement in the mean VAS score from 7.3 at the initiation of treatment to 2.8 at the end of 6^{th} months. In the study conducted by Sheng J[23] it was found that VAS score of dysmenorrhoea dropped continuously and significantly from base line score of 77.91±14.7 to 11.8±17.9 after 6 months of LNG IUS use. A similar Taiwanese study by Park DJ,[18] showed a mean VAS score for dysmenorrhea remarkably reduced from 5.81±2.96 to 2.86±2.8 after 3 months. Parallel to reduction in menstrual blood loss an increase in haemoglobin levels and a decrease in endometrial thickness has been observed. During the course of follow up, the mean haemoglobin concentration of 8.9gm/dl at pre-insertion increased by 10.2gm/dl at 3 months and 10.6gm/dl at 6 months. Endometrial thickness also showed a significant reduction from a mean of 8.5 mm to 7.4 and then 5.3mm at 6 months. A study by Mawet M,[24] showed a statistically significant rise of haemoglobin by 0.9 gm/dl post LNG IUS insertion; and a decrease in mean endometrial thickness from 12.2±4.8 to 4.5±2.7 at the end of one year of follow up. In an another study, Endrikat J et al[25] also showed a similar improvement in haemoglobin levels after 3 months and 1 year. Even though the spotting reduced progressively over time, but was still encountered occasionally in 11 patients (10.48%) at the end of 6 months of the study. Study by Park DS et al,[18] showed a similar side effects profile with vaginal spotting occurring in 58.3%, and 10.4% requiring premature removal, whereas 3.75% (n=18) expelled the LNG IUS spontaneously.

In our study, overall level of satisfaction was very high in all patients after the end of third month onwards.

User acceptability and satisfaction was directly associated with the amount of awareness and information provided to the patients regarding the various adverse effects such as menstrual irregularities, pelvic inflammatory diseases and pregnancy. Backman T et al[26] demonstrated in their study that acceptability of the device and satisfaction with the treatment modality was especially high amongst the women who were well counselled regarding the possibility of amenorrhea and initial side effects.

Our study has certain limitations, the study population was small in number and there was absence of control group. Despite the limitation, our study establishes usefulness of LNG IUS to control heavy menstrual bleeding of women.

5. Conclusion

This study provides evidence of the efficacy of LNG-IUS in management of this magnanimous problem that gynaecologists treat on a regular basis. Although there are limitations in the body of literature on this symptom, this study reconfirms significant reduction in both the objective and subjective discomforting symptoms of heavy menstrual blood loss. Hysterectomy remains a definitive cure but associated with several drawbacks of major surgical procedures and surgical menopause. Even the uterus, sparing conservative operative techniques, is also associated

with certain risks related to the procedures. LNG-IUS is a safe, effective and acceptable mode of treatment for heavy menstrual bleeding. It can be a treatment of choice as an alternative to hysterectomy for heavy menstrual bleeding due to benign conditions and it can help in smooth transition to menopause.

6. Acknowledgement

None.

7. Authors' Contributions

All authors exclusively contributed in this work and read and approved the final manuscript.

8. Declaration of Patient Consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

9. Source of Funding

None.

10. Conflicts of Interest

There is no conflict of interest.

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