

## ORIGINAL ARTICLE

## PATIENT SATISFACTION FOR LEVONORGESTREL INTRAUTERINE SYSTEM AND NORETHISTERONE FOR TREATMENT OF DYSFUNCTIONAL UTERINE BLEEDING

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**Background:** Dysfunctional uterine bleeding (DUB) is a common problem with complex management. It can be quite harrowing for the physicians as in most instances they are unable to pinpoint the cause of abnormal bleeding even after a thorough history and physical examination. Aim was to compare patient satisfaction for Levonorgestrel intra uterine system (LNG-IUS) and Norethisterone for the treatment of Dysfunctional Uterine Bleeding (DUB). It is Descriptive case series conducted in Department Obstetrics and Gynaecology, Shifa International Hospital, Islamabad from September, 2011 to September, 2012. **Methods:** One hundred and nineteen (119) female patients of reproductive age Group with DUB were selected by consecutive sampling. Informed written consent was obtained. A structural patient satisfaction questionnaire (PSQ) was used to collect information regarding age of patients, type of method used for treatment of DUB (Levonorgestrel or Norethisterone), treatment outcome in terms of patient satisfaction scale, and decrease in bleeding after 6 months. **Results:** The mean age of the patients was  $41.03 \pm 4.415$  year ranging from 28–60 years. The mean parity of women in the study was  $3.22 \pm 1.188$  with a range of 1–7. The satisfaction level was significantly ( $p < 0.05$ ) greater (90% versus 20%) in Group A (levonorgestrel-releasing intrauterine system) as compared with Group B (Norethisterone). The blood loss was significantly ( $p < 0.05$ ) decreased in Group A (98%) as compared with Group B (80%). The preference of continuing the method as well as recommendation to a friend was significantly greater in Group A as compared to Group B. **Conclusion:** The levonorgestrel-releasing intrauterine system (LNG-IUS) is a better choice as compared to Norethisterone, for treatment of DUB with 90% patients highly satisfied.

**Keywords:** Levonorgestrel, Norethisterone, patient satisfaction, treatment outcome

### INTRODUCTION

Dysfunctional uterine bleeding is quite a common condition, usually making up about 10% of admissions and 20% of OPD patients.<sup>1</sup> Dysfunctional uterine bleeding (DUB) is a common problem with complex management. It can be quite harrowing for the physicians as in most instances they are unable to pinpoint the cause of abnormal bleeding even after a thorough history and physical examination.<sup>2,3</sup> The management of abnormal bleeding involves a lot of decision making regarding diagnosis and treatment, as a prerogative of the physician, which may not necessarily be based on comprehensive or evidence-based guidelines.<sup>4</sup>

There are a number of treatments available for DUB such as Norethisterone, levonorgestrel releasing Intra Uterine Device, endometrial ablation and hysterectomy, but since none of them is proved to be superior to the others, and as all treatments have their advantages and disadvantages, counselling of patients with DUB is recommended to enable her to choose the treatment options best suiting her condition.<sup>5</sup> A lot of studies have shown Levonorgestrel releasing Intra Uterine Device to be effective for treating DUB and thus resulting in improved patient satisfaction.<sup>6</sup>

Our study was a Descriptive case series for comparison of efficacy of levonorgestrel-releasing intrauterine system (LNG-IUS) and Norethisterone, in terms of patient satisfaction for the treatment of DUB. One hundred and nineteen (119) women with DUB were followed up for 6 months to check the efficacy of use of LNG-IUS and Norethisterone in terms of decrease in amount and duration of bleeding, and patient satisfaction rate. The study was carried out at Gynae Unit, Shifa Hospital, Islamabad from September 2011 to April 2012.

Objective of the study was to compare patient satisfaction and reduction in bleeding for LNG-IUS and Norethisterone oral pill for the treatment of Dysfunctional Uterine Bleeding.

### MATERIAL AND METHODS

This study was conducted in Obstetrics and Gynaecology Department of Shifa International Hospital, from September 2010 to September 2011. Permission was obtained from the Hospital Ethical review committee before the commencement of study. There was no conflict of interest. Informed written consent was obtained prior to the start of the study. One hundred and nineteen patients were selected by consecutive (non-probability) sampling technique using

WHO sample size calculator, where Confidence interval=95%, absolute precision=0.09, P1=96%, P2=21%<sup>7,8</sup>, Sample size=97 (total sample taken as 119 patients to overcome attrition problems) from the Gynaecology Outpatient department. Women with DUB were selected from the Gynaecology OPD and were followed up for six months after being given LNG-IUS or Norethisterone for the decrease in uterine bleeding and patient satisfaction scale. Since the researcher selected the patients by consecutive sampling and they were already allocated the treatment regimes, there was no randomisation or any single blind or double blind technique. That is the reason this study is Descriptive case series and not randomised control trial, and this is a limitation of the study as well. The study included currently married women in the child bearing age, i.e., 18–45 years, so as to minimise the ethical issues as LNG-IUS is an intrauterine device also used for contraceptive purposes. The patients included in the study were those having DUB, parous, no hormonal therapy for the last 3–4 months, no contraindication to IUCD use, no adnexal pathology at clinical and ultrasonographic examination, no malignant or atypical endometrial changes on histology, no malignant liver disease, normal cervical cytology and no known bleeding disorders.

Data was collected on a pre structured Performa which included age of the patients, type of the treatment used either Group A (LNG-IUS) or Group B (Norethisterone, 10 mg). The study participants were followed up for 6 months. Outcome data included Participant satisfaction with treatment results and was collected regarding the respondent's experience with the study and the patient satisfaction regarding the particular method for treatment of DUB. Satisfaction rate was recorded using visual analogue scale (VAS) that included score 1–10 rating as: not satisfied (0), mildly satisfied (1–3), moderately satisfied (4–6), highly satisfied (8–10), as well as decrease in blood loss (in percentage on a scale of 1–100%) as judged by patients, method preference and recommendation to friends.

**RESULTS**

A total of 119 patients were included in this Descriptive case series study. The mean age of the patients was a 41.03±4.415 year ranging from 28–60 years (Table-1). There were 27 (22.7%) patients who were illiterate and 92 (77.3%) patients were literate. Majority of the participants had an education level of graduation followed by SSC/F. Sc. level as shown in (Table-2). About 70 (58.3%) participants were house wives followed by 31 (26%) who had private job and 17 (14.2%) who were doing government job. These women had an average monthly income of 58,327±26,239 rupees. The mean height of these women was 5.2±0.3 feet ranging from 4.5–6 feet. The mean parity of women

was 3.22±1.188 with a range of 1–7 (Table-1). In Group A (85/94) 90% of the patients were highly satisfied while (5/25) 20% patients were highly satisfied in Group B. The satisfaction level was significantly greater ( $p<0.05$ ) in Group A (LNG-IUS) as compared with Group B (Norethisterone). The blood loss was significantly decreased (98%,  $p<0.05$ ) in Group A compared to Group B (80%). The preference of continuing the method was significantly greater in Group A 98% compared with Group B (76%). The recommendation to a friend was also significantly high ( $p<0.05$ ) in Group A 98% as compared with Group B 76%. When the patients were inquired about discontinuing the method and go for Hysterectomy, the positive response rate was very low but it was significantly greater ( $p>0.05$ ) in Group B (36%) compared with 4% in Group A (Table-3).

**Table-1: Demographic characteristics of the patients**

Characteristics	n*	Min	Max	Mean±SD
Age	118	28	60	41±4
Parity	116	1	7	3±1
Monthly income (PKR)	55	15,000	100,000	58,327±26,240
Husband monthly income	118	10,000	700,000	203,136±182,016
Total income	26	20,000	700,000	236,538±189,371

\*n was different in different parameters due to missing data

**Table-2: Education level in the patients (n=92)**

Education	Numbers	%
Primary	1	1.08
Matric/F. Sc.	36	39.13
Graduate	47	51.08
Postgraduate	8	8.7

**Table-3: Comparison of different satisfaction parameters in both groups [n(%)]**

Responses	Group A	Group B	Total	p
<b>Are you satisfied with this method?</b>				
Not satisfied ( 0 )	1 (1)	4 (16)	5	0
Mildly satisfied (1–3)	0 (0)	2 (8)	2	
Moderately satisfied (4–6)	8 (9)	14 (56)	22	
Highly satisfied (7–10)	85 (90)	5 (20)	90	
<b>Has there been a decrease in blood loss after start of treatment?</b>				
Yes	93 (99)	20 (80)	113	0
No	1 (1)	5 (20)	6	
<b>Would you prefer to continue this method?</b>				
Yes	93 (99)	19 (76)	112	0
No	1 (1)	6 (24)	7	
<b>Would you recommend this method to your friends?</b>				
Yes	93 (99)	19 (76)	112	0
No	1 (1)	6 (24)	7	
<b>Would you like to undergo hysterectomy if you are not satisfied with this method?</b>				
Yes	4 (4)	9 (36)	13	0
No	90 (96)	16 (64)	106	

Group A: Levonorgestrel intra-uterine system, Group B: Norethisterone tablets

The satisfaction level was significantly ( $p<0.05$ ) greater in Group A as compared with Group B, 90% patients were highly satisfied and only 20% patients were highly satisfied in Group B. The blood loss was significantly ( $p<0.05$ ) decreased in Group A (98%) compared with Group B (80%).

## DISCUSSION

Menstrual disorders are among the major gynaecological problems. A large chunk of the women population lives in villages in Asian countries like India or Pakistan and has no health care facilities available near their home place and they have to move to big cities for treatment.

As for menstrual disorders like DUB patient has to undergo not only a number of investigations, but also has to be on the long waiting lists for months because of the burden on the hospital theatres. Substantial costs are incurred due to a long convalescence in both hospital and at home.<sup>7</sup>

The number of women with DUB who require hysterectomy may be reduced by the increasing use of second-generation endometrial ablative devices, levonorgestrel intrauterine system and possibly uterine arterial embolisation.<sup>9</sup> LNG-IUS was developed in Finland during the 1980s and licensed for contraception in 1990. Worldwide, the number of current LNG-IUS users is more than 4 million, and the US food and drug administration approved the LNG-IUS for use as a contraceptive in 2001.<sup>10</sup>

Norethisterone (15 mg) daily from days 5–26 of the menstrual cycle, or injected long-acting progestogens act as the third line management technique for DUB.<sup>11</sup> Norethisterone prevents proliferation of the endometrium and it also acts as a contraceptive in a dose of 15 mg daily on days 5–26 of the cycle. Unwanted outcomes are weight gain, bloating, breast tenderness, headaches, acne; depression.<sup>12</sup> The quality of life of women suffering from menorrhagia is impaired in many respects. Excessive bleeding and pain, or both, may impose severe constraints on their professional, social, and family activities.<sup>13</sup>

Our study results showed that the satisfaction level was significantly greater in Group A as compared with Group B. Usually NSAIDs are the first line of defence, oral combined contraceptive pills and Norethisterone make up as 2<sup>nd</sup> and 3<sup>rd</sup> line of treatment but a lot of studies have shown LNG-IUS has proved to be of good use for treatment of DUB, and patient satisfaction is better when this treatment modality is used. A prospective study involving 50 women recruited from District general hospital in south Wales indicated that LNG-IUS represents an effective non-surgical treatment for DUB.<sup>12</sup> Many women scheduled for hysterectomy as the final treatment for menorrhagia might still prefer a conservative alternative.<sup>15</sup> Dysfunctional uterine bleeding, with both anovulatory and, less commonly, ovulatory causes, occurs during the childbearing years. It is a diagnosis of exclusion and is made only after pregnancy, iatrogenic causes, systemic

conditions, and obvious genital tract pathology have been ruled out.<sup>16</sup> Medical management for Dysfunctional uterine bleeding is preferred for DUB treatment.<sup>17</sup> Hysterectomy carries a significant risk of morbidity and mortality. A viable alternative should be available to alleviate heavy menstrual flow and, consequently, improve the quality of life in women with menorrhagia.<sup>17</sup> A recent Cochrane Review showed that the treatment by Norethisterone resulted in a significant reduction in menstrual blood loss but that women found the treatment less acceptable than intrauterine levonorgestrel.<sup>12</sup>

The results in our study also showed that there was significant reduction of blood loss in Group A (98%) as compared with Group B (80%) after 6 months of treatment.

The results of a meta-analysis showed the use of the LNG-IUS could significantly reduce menstrual blood loss (range 74–97%) in women with confirmed menorrhagia.<sup>7</sup> The LNG-IUS compares well to other medical therapies. The mean menstrual blood loss reduction at 6 months and 12 months was higher with the LNG IUS reducing blood loss by 96% compared to 21% with flurbiprofen and 44% with Tranexamic acid.<sup>8</sup> The results of a non-comparative study showed a reduction of menstrual blood loss of 86% in menorrhagic women in only 3 months and a further reduction to 97% 12 months after insertion of the device.<sup>18</sup>

Our Results showed that the preference of continuing the method was significantly greater in Group A as compared with Group B. The recommendation to a friend was also significant ( $p < 0.05$ ) in Group A as compared with Group B. LNG-IUS was originally developed for contraception, but many studies have shown its ability to decrease the amount and duration of normal menstrual flow.<sup>19</sup>

In our study, when the patients were inquired about discontinuing the method and go for Hysterectomy, the positive response rate was very low but it was significantly ( $p < 0.05$ ) greater in Group B as compared with Groups A. A multiple number of studies have shown that LNG-IUS is as equally effective in improving quality of life and psychological wellbeing as hysterectomy.<sup>20,21</sup> The reversibility of treatment with LNG-IUS, its contraceptive efficacy and the opportunity it provides to maintain future fertility will make it an attractive alternative to ablation therapy even if other devices do prove to be more effective than thermal balloon ablation.<sup>22</sup> A study done in New Zealand in 2006 found that there are equivalent results with LN-IUS and thermal balloon ablation.<sup>7</sup>

There are different social and cultural aspects incorporated into the realm of the

reproductive health for women and multiple factors play their role in accessing modern reproductive health technologies. Efforts should be made to translate recent advances in Reproductive health technology from laboratory to service sector for improving women's over all reproductive health.<sup>23</sup> Counselling is imperative before use of any one method for treatment.

The biggest limitation for our study was that we could not have a randomised control trial as randomization of patients or, single or double blind techniques could not be employed. The sample size was small in our study and we had a time constraint.

## CONCLUSION

The LNG-IUS is a better choice as compared to Norethisterone, for treatment of DUB comprising of 90% high satisfaction rate for patients.

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