

Effectiveness of levonorgestrel-IUD in abnormal uterine bleeding management and users satisfaction

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Abstract:

Background: The prevalence rate of abnormal uterine bleeding (AUB) in India is 17.9% which causes not only psychological and physical discomfort but also has ill effect on health status and quality of life. **Objectives:** To assess the role of levonorgestrel-IUD (LNG-IUD) in management of abnormal uterine bleeding and satisfaction level among women. **Methodology:** Observational, descriptive, retrospective record based study was conducted at tertiary care hospital on 70 women with AUB inserted with levonorgestrel intrauterine device. **Results:** Mean age of women was 43.59 years and commonest age group was 41 to 50 years (43%). Most women (27.14%) had normal uterus on ultrasonography while about one fourth women had adenomyosis (24.29%). Menorrhagia was commonest complaint. At the end of one year, abnormal uterine bleeding was noted in 67.21% women while spotting and heavy menstrual bleeding was noted in 6.56% and 1.64% women respectively. Expulsion rate was 7.14% and removal rate was 5.71%. Mean satisfaction score was 71.2 with highest satisfaction score in adenomyosis and lowest score in women with thick endometrium. **Conclusion:** LNG-IUD had good acceptability with good efficiency, longer duration of action, non-surgical technique, less side effects and good compliance rate. It had offered good satisfaction score in women with different aetiologies of abnormal uterine bleeding. Expulsion rate and removal rates were minimal and could be reduced further with proper selection of cases for LNG-IUD insertion.

Keywords: Mirena, fibroids, adenomyosis, DUB, hysterectomy.

International Federation of Gynaecology and Obstetrics (FIGO) classify causes of abnormal uterine bleeding (AUB) into two groups i.e. non-structural causes are grouped as “COEIN” (coagulopathy; ovulatory dysfunction; endometrial; iatrogenic; and not yet classified) and structural causes are grouped under “PALM” (polyp; adenomyosis; leiomyoma; malignancy and hyperplasia).¹ It is common problem among 7-14% patients coming in the gynaecological OPD which causes not only psychological and physical discomfort but also has ill effect on health status and quality of life.^{2,3} The prevalence rate of AUB in India is 17.9%.⁴

Levonorgestrel intrauterine device (LNG-IUD) is acceptable and efficacious treatment modality over other medical (non-steroidal anti-inflammatory agents, tranexamic acid, combined hormonal contraceptives, cyclic progestins, danazol) and surgical modalities (endometrial ablation / resection or hysterectomy).⁵⁻⁷ LNG-IUD was introduced as contraceptive but it is also useful in heavy menstrual bleeding associated with uterine adenomyosis, uterine fibroids, endometrial hyperplasia and endometriosis.^{8,9} More than 100 countries approved use of it for the treatment of menorrhagia/heavy menstrual bleeding.¹⁰ The LNG-IUS releases 20 µg of levonorgestrel per day and it is a potent blocker of oestrogen activity on the endometrium. It suppresses the endometrium and causes endometrial glandular atrophy as well as thickens the cervical mucus.¹¹

So this study was planned to assess the role of LNG-IUD in management of abnormal uterine bleeding and satisfaction level among women attending gynaecology outpatient department.

Material and methods

An observational, descriptive, retrospective study was conducted at tertiary care hospital in gynaecology out-patient department (OPD). Institutional Ethics Committee (IEC) permission was taken before data collection. Medical case records of last five years (2015-2020) of gynaecology OPD was accessed for information of women with age of 35 years or more attending gynaecology OPD, who were using LNG-IUD for the treatment of abnormal uterine bleeding (AUB). Records of women having known medical disorder such as diabetes mellitus, hypertension, infection and malignancy were not considered for study. Also records with no working contact number or women not willing to respond on telephone were excluded.

Records of 70 women fulfilling above inclusion and exclusion criteria were examined. From records, information about age of women; onset, duration and progress of AUB; date of LNG-IUD insertion, pre-treatment ultrasonographic findings of uterus was collected. Also, information of occurrence of complaints like spotting, amenorrhea, heavy menstrual bleeding, irregular cycles, expulsion and removal of LNG-IUD etc. at 3, 6 and 12 months following treatment were recorded. After this satisfaction levels among LNG-IUD user was assessed through telephonic interview with the help of 0 to 100 point Likert's scale. Informed consent was taken from all women before recording their response. Confidentiality about identity of cases was maintained. Standard operating definitions and protocols were formulated beforehand and followed throughout the study period.¹¹

Data collected from medical records and responses from women were recorded in Microsoft Excel 2007 and analysed with SPSS v.16 software. Descriptive statistics like frequency, proportions, mean and standard deviation were used. Data tables and graphs were used at appropriate places to summarize the data.

Results

Study conducted on 70 women in whom levonorgestrel intrauterine device (LNG-IUD) was inserted for the complaint of abnormal uterine bleeding. As mentioned in figure 1, out of 70, highest number of women were of age 41 to 45 years (n=30, 43%) followed by women of age group 35 to 45 years (37%) and 46 to 50 years (20%). Mean age of study participants was 43.59 ± 7.25 years.

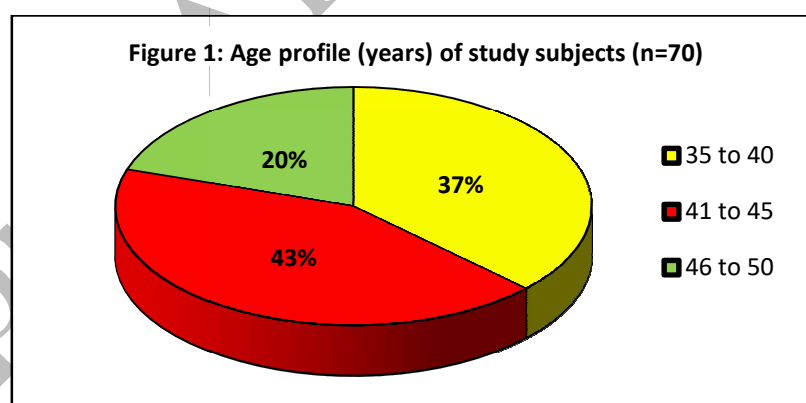


Figure 1: Age profile (years) of study subjects (n=70).

Pre-treatment symptoms and etiological profile based on ultra-sonographic findings shown in table 1. Out of 70 women, 58.57% had menorrhagia followed by post-menopausal bleeding (15.71%), dysmenorrhea in addition to menorrhagia (14.29%) and menometrorrhagia (11.43%). Most women (27.14%) had normal uterus on ultrasonography while about one fourth women had adenomyosis (24.29%), 21.43% had thickened endometrium, 18.57% had fibroids and 8.57% had endometriosis.

Changes or clinical improvement in bleeding complaint is shown table 2. There were 70 cases at commencement of study which reduced to 68, 65 and 61 at 3rd, 6th and 12th month follow-up visits due to LNG-IUD removal or expulsion. Abnormal uterine bleeding was reduced in 23.53% women at 3rd month follow-up visit. This proportion of women was increased to 49.23% and 67.21% patients at 6th month and 12th month, respectively. Spotting was present in 60.29% women which was reduced to 30.77% and 6.56% women at 6th month and 12th month, respectively. Amenorrhea was seen in 1.47%, 15.38% and 24.59% women at 3rd, 6th and 12th month follow-up visits. Complaint of heavy menstrual bleeding was found in 14.71% cases. This proportion was reduced to 4.62% and 1.64% at 6th month and 12th month, respectively.

Table 1: Symptoms and USG profile of study participants			
Parameters		Frequency	Percentage
Symptoms (N=70)	Menorrhagia	41	58.57
	Menometrorrhagia	8	11.43
	Post-menopausal bleeding	11	15.71
	Menorrhagia+Dysmenorrhea	10	14.29
USG findings (N=70)	Normal	19	27.14
	Fibroids	13	18.57
	Thick Endometrium	15	21.43
	Endometriosis	6	8.57
	Adenomyosis	17	24.29

Table 2: Menstrual cycle (bleeding) changes in follow up visits						
Menstrual cycle (bleeding)	3 months (N=68)		6 months (N=65)		12 months (N=61)	
	No.	%	No.	%	No.	%
Reduced bleeding	16	23.53	32	49.23	41	67.21
Spotting	41	60.29	20	30.77	4	6.56
Amenorrhoea	1	1.47	10	15.38	15	24.59
Heavy menstrual bleeding	10	14.71	3	4.62	1	1.64

Expulsion or removal rate of LNG-IUD is shown in table 3 which also highlight treatment modalities in such cases. Among 70 women, expulsion rate was 7.14% and removal rate was 5.71%. Expulsion of LNG-IUD was found in 2 women each by 3rd and 6th month follow-up visits and one by 12th month follow-up visit. Due to consistent heavy bleeding and/or irregular menstrual cycle, spotting, LNG-IUD was removed in 4 women. Out of these 9 women in whom LNG-IUD failed, 6(8.57%) underwent hysterectomy, 2 had hormonal therapy and 1 underwent endometrial ablation.

Table 3: Status of levonorgestrel intrauterine devices and treatment modalities in failure cases			
LNG-IUD		Number	Percentage
Status of levonorgestrel intrauterine devices	Expelled	5	7.14
	Removed	4	5.71
	At place	61	87.14
Treatment modalities in patients in whom LNG-IUD failed (removed/expelled)	Hysterectomy	6	8.57
	Endometrial ablation	1	1.43
	Hormonal therapy	2	2.86

Figure 2, highlights patient satisfaction score among cases with different aetiologies. Women with thick endometrium had least satisfaction scores (57) while women with adenomyosis (83), normal USG findings (79), fibroids (73) and endometriosis (64) had comparatively good level of satisfaction with LNG-IUDs. Average score was 71.2.

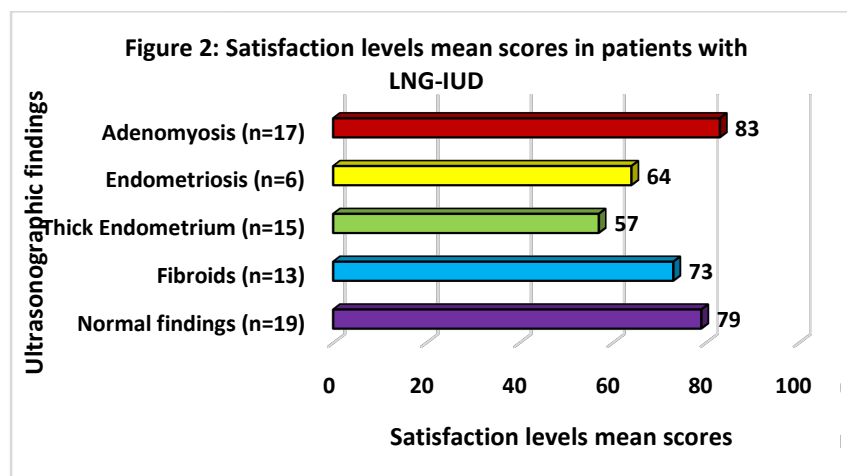


Figure 2: Satisfaction levels mean scores in patients with LNG-IUD.

Discussion

Women of peri-menopausal age group have high prevalence of abnormal uterine bleeding which may lead to moderate to severe anaemia. In the past, oral contraceptive pills and progesterone only mini pills were useful treatment modalities but now a days levonorgestrel intrauterine devices are preferred method having improved compliance.¹² Previous study done by Stewart et al¹³ reported high mean level blood loss due to combined oral contraceptives pills, oral progestogens, danazol, non-steroidal anti-inflammatory drugs and tranexamic acid as compared to LNG-IUD. In current study average age of study participants was 43.59 years and was belonged to 41 to 50 years of age group (43%). Mansukhani et al¹⁴ reported 35 to 40 years as commonest age group while Desai et al¹⁵ reported concurrent findings with present study. Vasudeva et al¹² reported lower mean age (33.28 ± 3.49 years) as compared to present study findings (43.59 years).

Current study reported menorrhagia in 58.57% cases and post-menopausal bleeding in 15.71% cases while study done by Mansukhani et al¹⁴ reported menorrhagia in 77% cases followed by 13% cases of dysmenorrhea, menometrorrhagia (9%) and post-menopausal bleeding (1%). Inclusion of post-menopausal women in current study may be a reason behind this observed difference. Menorrhagia in 47% and 33% women of fibroid and dysfunctional uterine bleeding group reported by Gupta et al¹⁶, respectively. Robinson et al¹⁷ and Dhamangaonkar et al¹⁸ reported similar study findings. Forty four percent had normal USG findings, 40% had fibroid, 37% had adenomyosis, and 5% had endometrial cyst in study done by Dhamangaonkar et al¹⁸ which differed from findings of current study. Fibroid and adenomyosis present in almost 43% cases in current study which explained menorrhagia as most common symptoms. But Desai et al¹⁵ reported different findings for endometrial dysfunction (75% cases), fibroid (2.5%), adenomyosis (10%) cases and endometrial hyperplasia (2.5% cases). Mansukhani et al¹⁴ in their multicentric study reported concurrent study findings.

In present study, 70 women who had inserted with LNG-IUD were followed-up till 1 year with first, second and third follow-up visits on 3rd, 6th and 12th month. It was seen that complaint of abnormal bleeding, heavy menstrual bleeding and spotting had resolved in subsequent follow up visits. At the end of one-year, abnormal uterine bleeding was noted in 67.21% women while spotting and heavy menstrual bleeding were noted in 6.56% and 1.64% women respectively. Desai et al¹⁵ reported, spotting and amenorrhea in 32.5% and 22.5% women which slightly differs from present study findings. Haimovich et al¹⁹ reported in their study on endometrial hyperplasia that 50% reduction occurred in bleeding at 3 months and 100% reduction in bleeding at 2 years. Dhamangaonkar et al¹⁸ reported, amenorrhea, heavy bleeding and spotting in 73.3%, 2.2% and 25% women at the end of one year. Mansukhani et al¹⁴ also reported comparable findings with present study. Zapata et al²⁰ reported, many women with LNG IUD inserted for uterine fibroids were having reduced blood loss after insertion. Socolov et al²¹ achieved oligomenorrhea in 96% patients by 1 year in menorrhagia due to fibroids. They also reported 89% of women with fibroids considered LNG IUS as a good treatment. Cho et al²² reported a finding on adenomyosis, 23% patients had amenorrhea by 12 months considering LNG-IUD as an alternative to hysterectomy in adenomyosis.

In a study done by Desai et al¹⁵, expulsion rate was 10% and removal rate was 5%. They also reported hysterectomy was most common treatment modality for failure cases. Masukhani et al¹⁴ reported expulsion in 7.5% cases and removal in 10% cases. Lower expulsion (7.14%) and removal rate (5.71%) were reported in present study. In current study, out of 5 expulsion 4 occurred by 6 months and one by 12 month while in 4 women, device was removed due to heavy menstrual bleeding and/or persistence of problems. In current study, mean satisfaction score was 71.2 with highest satisfaction score in adenomyosis (83) and lowest score in women with thick endometrium (57). Studies done by Chattopadhyay et al²³ and Kriplani et al²⁴ reported mean satisfaction score of 96.3% and 95.2%, respectively. Gupta et al¹⁶ and Mansukhani et al¹⁴ reported 80% satisfaction score each in their studies. Comparable findings were reported by Mansukhani et al¹⁴.

Conclusion

Levonorgestrel-IUD offered good symptomatic improvement in abnormal uterine bleeding in women above the age of 35 years to post-menopausal women. Expulsion rate and removal rates were minimal and could be reduced further with proper selection of cases for LNG-IUD insertion. LNG-IUD had good acceptability with good efficiency, longer duration of action, non-surgical technique, less side effects and good compliance rate. It had offered good satisfaction score in women with different aetiologies of abnormal uterine bleeding.

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