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RESEARCH ARTICLE

Quality of life assessment 6 months after insertion of levonorgestrel – intrauterine system in women with abnormal uterine bleeding at a tertiary care centre

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ABSTRACT

Background: The levonorgestrel- releasing intra uterine system (LNG – IUS) is now used widely for the purpose of noncontraceptive effects for conditions such as menorrhagia and dysmenorrhea. There has been limited literature regarding the effects of LNG – IUS on quality of life caused by dysmenorrhea and menorrhagia due to various gynaecological causes in females. **Objectives:** This study is to assess the frequency of dysmenorrhea and menorrhagia and to evaluate the quality of life and satisfaction in women treated with the (LNG – IUS) in women aged 26 to 55 years. **Methods:** This was a prospective observational study conducted over 1 year from the year 2018 to 2019 in women who were in the age group of 26 to 55 yrs, who have undergone treatment for abnormal uterine bleeding with levonorgestrel releasing intrauterine system, from Department of Obstetrics and Gynaecology, Government Medical College, Thrissur. They were followed up for 6 months. Data was collected using a pre-tested semi-structured interview schedule and analysed using SPSS software to assess the quality of life and patient satisfaction 6months after insertion of LNG–IUS. **Results:** Majority of women (58.8%) included in this study were between 36-45 years. 60.8% had bleeding lasting >7 days and 82.3% had dysmenorrhea. On endometrial sampling, majority (73.7%) of histopathology results came as secretory endometrium. On ultrasonography majority of patients 35.3% had fibroid uterus, 33.3% had thickened endometrium, and 21.6% had adenomyosis. Of the total patients studied, LNG-IUS was inplace in 94.1%, and it was expelled in 3.92%, and 1 patient underwent hysterectomy. After 6 months of insertion of LNG-IUS, 66.7% patients had complete relief of dysmenorrhea while dysmenorrhea reduced in 28.5% of patients. 56.9% had complete alleviation of AUB while bleeding reduced in 33.3%. On assessing patient satisfaction after 6 months of insertion of LNG-IUS, 90.2% were satisfied and they preferred to keep using the device, 92.2% said they would suggest LNG-IUS to others as a treatment option. Regarding general health, 66.7% felt that it was much better after 6 months of insertion of the device. In our study, there was significant improvement in physical functioning, body pain, general health, vitality, social functioning, emotional and mental health, (p value <.01, for each parameter, after 6 months of insertion of LNG –IUS. **Conclusion:** The LNG-IUS is an effective and well-tolerated treatment modality in abnormal uterine bleeding. The Quality of life of women treated with the LNG-IUS is markedly improved, causing high levels of patient satisfaction.

Keywords: LNG IUS, AUB, quality of life, dysmenorrhea.

Abnormal uterine bleeding (AUB) is defined as a change in frequency, duration, or amount of menstrual bleeding. It is a common gynecological complaint that affects 10-30% of reproductive aged women contributes to one-third of all outpatient gynecological visits [1]. The quality of woman's life can be adversely affected by the abnormal uterine bleeding. It can lead to psychological, social, medical, and sexual problems which will need appropriate management. Chronic AUB can also lead to a reduction in work productivity by about 30%. This can have an impact on income [2] and further

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affect her normal functioning.

Heavy menstrual bleeding (HMB) or menorrhagia is menstruation at regular cycle intervals but with excessive flow and duration. Only 50% of the affected women actually seek medical care. But the level of satisfaction, with medical treatment is low [3].

There have been modest modifications in FIGO's system of nomenclature and definitions of AUB [4]. The classification system of causes of AUB is summarised by the acronym 'PALM-COEIN'. It was accepted by FIGO in 2010, and was published in 2011 [5].

The levonorgestrel - releasing intra uterine system (LNG – IUS) is a treatment option for benign lesions causing menorrhagia [6], which is effective and reversible. It is an intrauterine device that releases synthetic progesterone into the endometrial cavity at a rate of 20µg/day. It was developed primarily as a contraceptive device. But now it is used widely for the noncontraceptive effects for menorrhagia and dysmenorrhea due to the continuous progestogenic effect on the endometrium [7].

The LNG –IUS is a T-shaped device composed of a cylinder containing 52 mg of LNG covered by a rate controlling membrane. 20 mcg of levonorgestrel is released every 24 h initially, but decreases to 11 mcg every 24 h by the end of 5 years [8]. The LNG-IUS has been used in treatment of leiomyomata, endometriosis and adenomyosis, due to its effect on the endometrium by suppressing the endometrial glands and an inactive endometrium [9, 10]. The option of levonorgestrel - IUS for menorrhagia was introduced by UK guidelines in 2007 [11]. Pregnancy, pelvic inflammatory disease, lower genital tract infection, undiagnosed abnormal uterine bleeding, uterine anomalies like fibroids distorting the uterine cavity, uterine or cervical malignancy, progestin-dependent neoplasia, including breast cancer, cervical dysplasia, liver dysfunction or hypersensitivity to levonorgestrel or any of the other ingredients in the formulation are contraindications for its use.

Menstrual irregularity is the most common side effect associated with the LNG-IUS. Amenorrhea [12] is a reason for discontinuation in 25% of women. Irregular spotting and pelvic inflammatory disease are the other side effects [13, 14]. Systemic absorption, though less can lead to undesirable side effects such as ovarian cysts, acne, weight gain, depression and decreased libido. However, the overall tolerance of the device is good. There has been limited literature regarding the effects of LNG – IUS on quality of life in women suffering from AUB, due to various gynaecological causes. There are very few such reported studies from Kerala. This study is to assess the frequency of AUB and to evaluate the quality of life and satisfaction in women aged 26 to 55 years treated with the LNG – IUS.

Methodology

This study is a hospital based prospective observational study. Females in the age group of 26 to 55 yrs who have undergone treatment for abnormal uterine bleeding with levonorgestrel releasing intrauterine system in Government Medical College, Thrissur over a period of one year (2018 to 2019) were selected for this study and followed up for 6 months with their consent.

Inclusion criteria -

1. Females in the age group of 26 to 55 years having abnormal uterine bleeding treated with Levonorgestrel releasing intra uterine system who give consent for the study.

Exclusion criteria -

2. Confirmed or suspected cases of malignancy of uterus, ovaries or breast.
3. History of behavioural or psychiatric disorders.
4. Pelvic inflammatory diseases or history of pelvic inflammatory diseases.
5. Medical contraindications for hormonal therapy.

A detailed history was taken including age, socio-economic status, parity, marital status, and educational status of the patient. Patients were interviewed and asked about the abnormal bleeding pattern, the duration of bleeding, any history of passage of clots, no of pads changed per day and about any history of dysmenorrhea. The ultrasonography report and endometrial sampling if done, the results were collected. Reduction of dysmenorrhea and reduction in bleeding was assessed by using a self expression questionnaire in the follow up visits classified into scales – no reduction, increased, reduced, completely alleviated as compared to the period before IUD insertion. Each volunteer is compared with herself before and after insertion of LNG-IUS. Patient satisfaction is assessed by satisfaction questionnaire - 1) are you satisfied with IUD insertion, 2) do you prefer keep using the device, 3) do you want to suggest the IUD to the others.

Quality of life (QoL) is assessed by SF36 questionnaire. The Short Form 36 Health Survey questionnaire (SF-36) is used to indicate the health status of particular populations, to help with service planning and to measure the impact of clinical and social interventions. The SF-36 is a 36 item scale, which measures eight domains of health status: physical functioning (10 items); physical role limitations (four items); bodily pain (two items); general health perceptions (five items); energy/vitality (four items); social functioning (two items); emotional role limitations (three items) and mental health (five items). A scoring algorithm is used to convert the raw scores into the eight dimensions listed above. The scores are transformed to range from zero where the respondent has the worst possible health to 100 where the respondent is in the best possible health. Quality of life is assessed at the time of insertion of LNG-IUS and after 6 months of insertion of LNG-IUS. To assess improvement in quality of life, the absolute and percentage increments versus baseline were determined at each visit.

Results are expressed as numbers, percentages, mean and standard deviations for categorical data. The scores corresponding to each of the scales and the global score were calculated. The mean is reported. To assess improvement in QoL, the absolute and percentage increments versus baseline were determined at each visit. Paired t test done to assess the improvement in QoL.

Results

Majority, 30 women (58.8%) included in this study were between 36-45 years, 18(35.3%) were between 46 to 55 yrs and 3(2.8%) were between 26 to 35 years. According to the educational status of those patients studied majority, i.e. 39 patients (76.5%) studied upto plus-ten/degree/diploma, and 12 patients (23.5%) studied upto school level, no uneducated females were there. Majority of patients 45(88.2%) belonged to above poverty line while 6 patients (11.8%) belonged to below poverty line. 41 were having a parity between 1-3 (80.4%), 9 patients had parity more than 3(17.6%).there was only 1 nullipara (2%).

Among the patients under study 31 patients (60.8%) had bleeding lasting >7 days and 20 patients had bleeding 4 to 6 days (39.2%). 42 patients (82.3%) had dysmenorrhea, while 9 had no dysmenorrhea (17.7%). 45 patients (88.2%) had history of passage of clots, while 6 (11.8%) did not had history of passage of clots.

Among 51 patients studied 38 patients (74.5%) underwent endometrial sampling. Majority of histopathology results came as secretory endometrium 28 patients (73.7%), for 5 patients (13.2%) came as disordered proliferative endometrium, for 3 patients (7.9%) results came as proliferative endometrium and in 2 cases (5.3%) result was benign endometrial polyp.

On assessing the results of ultrasonography majority of patients i.e. 35.3% had fibroid uterus, 33.3% had thickened endometrium, 21.6% had adenomyosis and 17.6% had features suggestive of endometriosis (table 1).

Table 1: Percentage distribution of the sample according to USG findings

USG findings	Number	Percentage
Thickened endometrium	17	33.3
Adenomyosis	11	21.6
Fibroid uterus	18	35.3
Endometriosis	9	17.6

Majority of patients with AUB who underwent treatment with LNG – IUS had no comorbidities (68.6%). 7 patients (13.7%) had hypothyroidism. 6 of them had (11.8%) had hypertension and 3 were (5.9%) diabetic.

Of the total 51 patients studied, LNG-IUS was inplace in 48 patients (94.1%), and it was expelled in 2 patients (3.92%), and 1 patient underwent hysterectomy (1.96%), after 6 months of insertion. Majority of patients (42) had dysmenorrhea, in those patients after 6 months of insertion of LNG-IUS 28 (66.7%) patients had complete relief of dysmenorrhea. While dysmenorrhea reduced in 12(28.5%) patients. 2 patients had persistent dysmenorrhea at the end of 6 months. Of the total 51 patients 29(56.9%) had complete allevation of AUB, bleeding reduced in 17 (33.3%) while 5 patients (9.8%) had no reduction in bleeding at the end of 6 months.

Table 2: Descriptive statistics for quality of life and patient satisfaction before insertion of LNG – IUS.

Parameters	Mean	SD	Median	Minimum	Maximum
Physical functioning	65.6	5.2	66.7	36.7	66.7
Role - physical	47.9	10.1	50.0	0.0	50.0
Body pain	64.2	9.3	61.7	34.2	75.0
General health	43.0	5.8	44.0	20.0	56.0
Vitality	47.7	6.7	50.0	29.2	62.5
Social functioning	62.3	10.6	60.0	40.0	80.0
Role emotion	49.0	7.2	50.0	0.0	50.0
Mental health	62.1	9.3	66.7	43.3	76.7

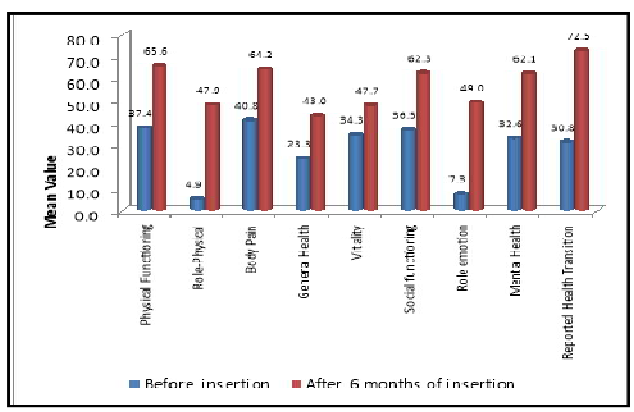

Figure 1: Effectiveness of quality of life and patient satisfaction before and after insertion of LNG –IUS.

Quality of life was assessed in 28 patients at the time of insertion of LNG IUS and take as baseline (table 2). Quality of life assessed after 6 months of insertion, there was significant improvement in physical functioning, body pain, general health ,vitality, social functioning and emotional and mental health, after 6 months of insertion of LNG –IUS compared to before insertion of LNG-IUS (table 3, figure 1). In this study on assessing patient satisfaction after 6 months of insertion of LNG-IUS of the total 51 patients studied 46(90.2%) were satisfied with LNG-IUS and they preferred to keep using the device, 47(92.2%) opined that they will suggest LNG-IUS to others as a treatment option.

Table 3: Effectiveness of quality of life and patient satisfaction before and after insertion of LNG–IUS

Quality of life	Stage	Mean	SD	N	Mean difference	Paired t	P value
Physical functioning	Before insertion	37.4	6.3	48	28.3	23.82	p<0.01
	After 6 months of insertion	65.6	5.2	48			
Role -physical	Before insertion	4.9	9.6	48	43.0	22.68	p<0.01
	After 6 months of insertion	47.9	10.1	48			
Body pain	Before insertion	40.8	7.5	48	23.4	15.62	p<0.01
	After 6 months of insertion	64.2	9.3	48			
General health	Before insertion	23.3	5.0	48	19.7	17.14	p<0.01
	After 6 months of insertion	43.0	5.8	48			
Vitality	Before insertion	34.3	4.8	48	13.4	11.12	p<0.01
	After 6 months of insertion	47.7	6.7	48			
Social functioning	Before insertion	36.5	7.9	48	25.8	12.82	p<0.01
	After 6 months of insertion	62.3	10.6	48			
Role emotion	Before insertion	7.3	13.7	48	41.7	19.26	p<0.01
	After 6 months of insertion	49.0	7.2	48			
Mental health	Before insertion	32.6	11.1	48	29.5	13.17	p<0.01
	After 6 months of insertion	62.1	9.3	48			

Of the total 48 patients studied, all were asked for the general health 1yr before the time of insertion of LNG IUS and after 6 months (table 4). At the time of insertion 26 patients (54.2%) answered that their health was the same one year before and 22 patients (45.8%) opined that it was somewhat worse than 1year ago. No one answered that their health was much better than one year ago or somewhat better than one year ago.

Table 4: Percentage distribution of general health changes

Compared to one year ago, how would you rate your health in general now?	Before LNG-IUS			6 months after LNG -IUS		
	Response	Frequency	Percentage	Response	Frequency	Percentage
	Much better	0	0	Much better	32	66.7
	Somewhat better	0	0	Somewhat better	14	29.2
	About the same	26	54.2	About the same	2	4.2
	Somewhat worse	22	45.8	Somewhat worse	0	0
	Much worse	0	0	Much worse	0	0

While 6 months after insertion of LNG-IUS 32 patients (66.7%) opined that their health was much better and 14(29.2%) answered that it was somewhat better and 2(4.2%) answered that it was same compared to one year ago.

Discussion

Majority of women (58.8%) included in this study were between 36-45 years, which was comparable to a study by Talukdar B et al in which most of the patients were between 40 and 45 years of age [15]. Majority i.e. 76.5% studied were well educated which is comparable to a study by Ramazanzadeh F et al, 67.5% patients in the study had education above high school diploma [16].

On endometrial sampling, majority of histopathology results came as secretory endometrium which was in contrast to a study by Pratibha et al, which showed majority had proliferative endometrium (23.5%) followed by secretory endometrium (18.2%) [17]. On assessing the results of ultrasonography majority of patients 35.3% had fibroid uterus which was comparable to a study by Talukudar B et al[15] which showed most of them had (45.63%) fibroid uterus.

Of the total patients studied, LNG-IUS was inplace in 94.1% and it was expelled in 3.92% and 1 patient underwent hysterectomy (1.96%). Expulsion of the device has been reported to occur in as many as 5% of cases [18]. Large cohort studies have estimated the rate of device expulsion to be 0% per year for nulliparous women and 0.2% for parous women[19]. The expulsion rate was comparable to the study by Gabriele et al [20].

Of the total 51 patients studied 42 had dysmenorrhea, in those patients after 6 months of insertion of LNG-IUS, 66.7% patients had complete relief of dysmenorrhea. While dysmenorrhea reduced in 28.5% of patients. 2 patients had persistent dysmenorrhea at the end of 6 months. This was comparable to the findings of Kelekci et al in his study [21]. Of the total 51 patients 56.9% had complete alleviation of AUB, bleeding reduced in 33.3% while 9.8% had no reduction in bleeding similar to the study by Kriplani et al [22].

In this study on assessing patient satisfaction after 6 months of insertion of LNG-IUS of the total 51 patients studied 90.2% were satisfied with LNG-IUS and they preferred to keep using the device, 92.2% said they would suggest LNG-IUS to others as a treatment option. This was comparable to the study by Nina Mansukhani et al [23]. In our study, there was significant improvement in physical functioning, body pain, general health, vitality, social functioning and emotional and mental health, after 6 months of insertion of LNG – IUS compared to before comparable to the study by Hurskainen et al [24]. A retrospective cohort study by Georgy et al, showed significant improvement in quality of life 6 months and 1 year [25].

Of the total 48 patients studied, all were asked for the general health 1yr before, at the time of insertion and after 6 months. At the time of insertion, 54.2% answered that it was the same and 45.8% said that it was somewhat worse than 1year ago, no one answered much better than one year ago or somewhat better than one year ago. While 6 months after insertion of LNG-IUS 66.7% answered as much better and 29.2% answered somewhat better and 4.2% answered about the same compared to one year ago. The results were similar to the study by Lete et al [26].

Conclusion

In this study 56.9% patients with AUB had complete allevation of AUB and bleeding reduced in 33.3% patients 6 months after insertion of LNG-IUS and 66.7% patients had complete relief of dysmenorrhea. 90.2% were satisfied with LNG-IUS and they prefer to keep using the device. 92.2%will suggest LNG-IUS to others as a treatment option. Majority had a significant improvement in quality of life 6 months after insertion of LNG-IUS. On assessing the general health, 66.7% had general health much better than 1year ago after insertion of LNG -IUS.

The LNG-IUS is an effective and well-tolerated treatment modality in abnormal uterine bleeding. There is a marked improvement in the quality of life of women treated with the LNG-IUS which yields high levels of patient satisfaction.

Conflict of interest: None. **Disclaimer:** Nil.

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