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Experience with Levonorgestrel intrauterine system (LNG-IUS) in women with abnormal uterine bleeding (AUB) at tertiary care centre

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Abstract

Aims: To study the acceptability, efficacy and safety of Levonorgestrel intrauterine system (LNG-IUS) among women of reproductive age with abnormal uterine bleeding (AUB) classified according to PALM COEIN at tertiary care institute.

Material and methods: This prospective interventional study was conducted at outpatient and inpatient setup of tertiary care institute of Central India. One hundred fifty women who presented with abnormal uterine bleeding over the period of 2 years, first classified according to PALM COEIN after detailed history, clinical examination and evaluation with PAP smear, transvaginal sonography and hysteroscopic endometrial biopsy. Genital malignancy, genital infection, pregnancy, intramural, subserosal fibroid more than 5 cm, submucosal fibroid (type 0,1 and 2) and uterus size more than 12 weeks, congenital and acquired uterine malformation, not willing for follow up were ruled out. One hundred twenty suitable candidates were counselled for intrauterine LNG-IUS insertion. Out of one hundred twenty candidates, eighty women were consented for LNG-IUS and LNG-IUS was introduced in postmenstrual phase. Four women lost to follow up and remaining seventy six women were followed up at 1, 3, 6 months and 1 year and then bi-annually for total 2 years.

Results: Out of one hundred twenty suitable candidates, total eighty women were enrolled for the LNG -IUS insertion. Out of eighty women, four women lost to follow up and seventy-six women with LNG-IUS followed for next 2 years. Majority (68%) belonged to age group 36-45 years. Majority (62%) had structural abnormalities, fibroid (28%) followed by adenomyosis (20%), endometrial hyperplasia (12%) and polyp (2%). Remaining had ovulatory (30%) and endometrial (8%) dysfunction. Amenorrhea achieved in 42% women at 1 year and in 72% at 2 year of insertion of LNG-IUS. Women with dysmenorrhea had decreased pain at 3 months in 8 % and at 6 months in 14% and absent menses and pain in all patients at 1 year.

Conclusion: Levonorgestrel intrauterine system is a safe and effective option in selected women of reproductive age with abnormal uterine bleeding classified according to PALM COEIN classification and requires regular follow up with device in situ. Decision for hormonal uterine device requires optimal time for proper counselling and sometimes repeated counselling before insertion and during follow up. Women not opting for LNG-IUS require definitive treatment in the form of hysterectomy after multiple medical therapies and not willing for regular follow up with possibility of hysterectomy in future as definitive management.

Keywords: Abnormal uterine bleeding (AUB), PALM COEIN classification, Heavy menstrual bleeding (HMB), levonorgestrel intrauterine system (LNG-IUS), Hysterectomy

Introduction

Abnormal uterine bleeding (AUB) is the bleeding from uterus that is a variation from normal menstruation in regularity, frequency, amount and duration. AUB is the commonest symptom among women presenting in the gynecological outpatient setup accounting for approximately 30% of women in reproductive age group. In 2011, universally accepted FIGO classification system for various causes of AUB i. e. PALM COEIN (Polyp Adenomyosis Leiomyoma Malignancy and Hyperplasia – Coagulopathy Ovulatory Dysfunction Endometrial Iatrogenic; and Not yet classified) classification has been suggested (1). Heavy menstrual bleeding (HMB) replaced old terminology menorrhagia and defined as prolonged (>7 days) or excessive menstrual blood loss greater than or equal to 80 ml per menstrual cycle. Intermenstrual bleeding is the term used in place of old terminology metrorrhagia. Levonorgestrel intrauterine system (LNG-IUS) has become the safe, effective, and acceptable choice of treatment for all variants of PALM COEIN for AUB (2). The LNG-IUS is a hormonal intrauterine device with a polyethylene frame and a steroid reservoir made up of levonorgestrel around the vertical arm. It contains 52 mg of levonorgestrel and releases 20 µg per day for 5 years. It causes initially a local foreign body reaction characterized by an increase in inflammatory cells that usually settles down in 3 months and finally glandular atrophy and stromal decidualization at endometrium. As very few studies (3) had been conducted till date with AUB classified according to PALM-COEIN and our study was conducted to study the acceptability, efficacy and safety of levonorgestrel intrauterine system (LNG-IUS) among women of reproductive age with abnormal uterine bleeding (AUB) classified according to PALM-COEIN at tertiary care centre.

Material and Methods

After taking approval from institutional ethical committee, this prospective interventional study was initiated at tertiary care institute of central India. One hundred fifty Women attended at outpatient and inpatient department with complains of heavy menstrual bleeding, intermentrual bleeding and dysmenorrhea were included after proper history taking, examination and evaluation. Evaluation included PAP smear, transvaginal sonography (TVS), hysteroscopic and histopathological endometrium assessment. Women with active genital infection, suspected pregnancy, genital malignancy, intramural and subserosal fibroid more than 5 cm, submucosal fibroid (type 0,1 and 2) and uterus size more than 12 weeks, congenital and acquired uterine malformation,

not willing for follow up were excluded. Out of one hundred fifty women, one hundred twenty suitable women counselled before LNG-IUS insertion regarding possibility of variable bleeding pattern during initial 3-6 months and scanty and absent menstruation later on. Out of one hundred twenty women, eighty women were opted for LNG-IUS after proper counselling. Out of eighty women, four women lost during follow up. Study involved seventy six women aged between 30 and 50 years and followed up over 2 years period. LNG-IUS was inserted in outpatient setup during postmenstrual phase either when bleeding become less or absent. Women were advised to follow up at 1 month, 3 months, 6 months, 1 year and then biannually till total 2 years. During follow up visits history regarding bleeding pattern, examination and ultrasonography were done.

Results

In our study, initially total eighty women were enrolled and four women lost to follow up. Out of remaining seventy six women, majority (68%) belonged to age group 36-45 years.

Table 1: Distribution of cases according to age

Age (years)	No. of cases
30-35	18 (24%)
36-40	24 (32%)
41-45	27 (36%)
46-50	6 (8%)

Out of seventy six women, majority (61.8%) had structural abnormalities, fibroid (27.6%) followed by adenomyosis (19.8%), endometrial hyperplasia (11.8%) and polyp (2.6%). Remaining had nonstructural causes (38.2%), ovulatory (30.3%) and endometrial (7.9%) dysfunction.

Table 2: Distribution of cases according to PALM COEIN classification.

Cause	No. of cases
Polyps (after removal)	2 (2.6%)
Adenomyosis	15 (19.8%)
Leiomyoma (Fibroids)	21 (27.6%)
Endometrial hyperplasia without atypia	9 (11.8%)
Ovulatory	23 (30.3%)
Endometrial (after exclusion)	6 (7.9 %)

During first 3 months, 56% women had normal or scanty bleeding and after 6 months 58 % had scanty menses. Amenorrhea achieved in 42% women at 1 year and in 72% at 2 years of insertion of LNG-IUS. Women with dysmenorrhea had decreased pain at 3 months in 8 % and at 6 months in 14% and absent menses and pain in all patients in 1 year.

Table 3: Bleeding Pattern with LNG-IUS on Follow up

Bleeding pattern	3 Months	6 months	12 months	24 months
Irregular heavy	18 (24 %)	12 (16%)	8 (10%)	0
Irregular scanty	27 (36%)	32(42%)	22(30%)	3(4%)
Regular normal	3(4%)	2(2%)	0	0
Regular Scanty	12(16%)	12 (16%)	0	0
Absent menses	0	0	32 (42%)	54(72%)
Dysmenorrhoea	9(12%)	4 (6%)	0	0

Failure of LNG-IUS in the form of spontaneous expulsion, need for removal of device, need for hormonal therapy and hysterectomy is seen on follow up in some cases. Spontaneous expulsion is seen in 8% women at 3 months and in 6 % at 6 months. 4% women requested for removal of LNG-IUS at 6 months and 6% at 1 year as they were having irregular heavy bleeding. Three of them advised for hysterectomy.

Table 4: Failure of LNG-IUS on Follow up

Parameters	3 months	6 months	12 months	24 months
Expulsion of device	6 (8%)	4 (6%)	0	0
Removal of device	0	3 (4%)	4 (6%)	0
Need for Hormonal therapy	18 (24%)	12 (16%)	8 (10%)	0
Need for Hystrectomy	0	0	3 (4%)	0

Discussion

Abnormal uterine bleeding (AUB) is the commonest reason for women seeking a gynecologist consultation. FIGO approved PALM COEIN classification of AUB had made easy to understand the etiology for AUB (1). LNG-IUS being a progestogen intrauterine device causing uniform suppression of endometrium and thus useful in HMB and dysmenorrhea associated with various etiology of AUB.

Medical management of AUB is a challenge due to poor compliance, side effects, cost, troublesome breakthrough bleeding and actual failures (2). Hysterectomy is the definitive treatment, but it is a major surgical procedure and has significant anatomical, urological, sexual, psychological and emotional sequel and high cost of the procedure (3). According to Value study, a survey of outcomes of 37,000 hysterectomies, operative and postoperative complication was reported in 3.5% and 9% cases. Postoperative mortality was 0.38/1000 patients and psychological implication was seen in 35-45% patients (4).

LNG-IUS is a cost effective option for all patients of AUB, can be offered to all variants of PALM COEIN, before taking a decision for hysterectomy (2). Ever since its launch in 1977, the LNG-IUS has steadily been replacing medication and surgery as a satisfactory management option for women with AUB. A constant search for a suitable alternative to hysterectomy showed that this minimally invasive treatment modality could indeed be a one-stop answer to AUB (5). Despite all of the evident benefits of the LNG-IUS, the utilization rates remain quite low in the developing countries. To overcome those factors, cost and design of LNG-IUS had been modified by various manufacturing companies. During this study, I realized even after proper counselling, women ask for definitive treatment in the form of hysterectomy. Factor responsible for asking for hysterectomy was women needs definitive treatment after so much medications hormonal as well as nonhormonal. This realizes, LNG-IUS can be the one stop answer to all forms of AUB. However proper counselling before insertion emphasizing more on variable bleeding pattern for initial 3-6 months can help to make decision in favor of LNG-IUS.

In our study, on follow up most of the women (76%) continued its use and were satisfied with the relief of HMB and dysmenorrhea. Their quality of life including physical, social, psychological and sexual had been improved. In the first 3 months, 56% had scanty or normal flow with relief of dysmenorrhea in 40% women. Amenorrhoea is seen in 42% women after 1 year and in 72% in 2 years. Spontaneous expulsion of device is seen in 8% and 6% women at 3 and 6 months follow up respectively. 4% women requested for removal of LNG-IUS at 6 months and 6 % at 1 year as they were having irregular heavy bleeding. Two (4%) of them need the hysterectomy.

Singh K et al study (6) included 42 patients with HMB showed amenorrhoea in 81%in 1 year, 5% expulsion in 3 months, significant improvement in QOL, dysmenorrhoea and Hb level.

Dhamangaonkar et al study (7) included 70 women between age 30-55 years with AUB and showed 80% decrease in HMB at 4 months and 95% at 1 year, 100% amenorrhoea at 2 years, significant reduction in dysmenorrhoea . Hysterectomy could be avoided in most of the women. LNG IUS was beneficial in the treatment of fibroid, endometriosis, adenomyosis and

endometrial hyperplasia. LNG-IUS found superior to medical treatment and hysterectomy and considered excellent fertility sparing device.

According to Cochrane review,The levonorgestrel-releasing intrauterine device (LNG IUS) is more effective than oral medication as a treatment for heavy menstrual bleeding (HMB). It is associated with a greater reduction in HMB, improved quality of life and appears to be more acceptable long term but is associated with more minor adverse effects than oral therapy. When compared to endometrial ablation, it is not clear whether the LNG IUS offers any benefits with regard to reduced HMB and satisfaction rates and quality of life measures were similar. Some minor adverse effects were more common with the LNG IUS but it appeared to be more cost effective than endometrial ablation techniques. The LNG IUS was less effective than hysterectomy in reducing HMB. Both treatments improved quality of life but the LNG IUS appeared more cost effective than hysterectomy for up to 10 years after treatment (8).

LNG-IUS is a first line medical management for endometrial hyperplasia without atypia recommended by Green Top guidelines (RCOG-BSGE February, 2016, updated in 2017) (9). LNG-IUS is the first-line treatment after counseling about the risks of underlying malignancy or disease progression in women with endometrial hyperplasia with atypia desirous of fertility preservation. Hysterectomy should be offered after completion of family. LNG-IUS is also recommended during HRT to protect endometrium.

According to FOGSI- Good clinical practice recommendations (10) for AUB-PALM, LNG-IUS is recommended as first line treatment for benign polyps, adenomyosis desiring fertility but not immediate conception, intramural and subserous leiomyoma where immediate conception is not required and in endometrial hyperplasia without atypia. In AUB-COEIN, LNG-IUS is second line treatment of choice in coagulopathy, first line treatment in AUB-O and E where COC is contraindicated, in AUB-I after change of agent and in AUB-N where women desire contraception.

Conclusion

This study was conducted to understand the role of LNG-IUS in various causes of AUB, classified by FIGO as PALM-COEIN. We found that LNG-IUS must be considered as first line therapy in majority of AUB cases before directly taking decision for hysterectomy. Pre-insertion counseling regarding possibility of variable bleeding pattern during initial 3-6 months and scanty or absent menstruation later on, helps in compliance of women on LNG-IUS. Cost of LNG-IUS has been reduced markedly as compare to initial years, making it is a cost-effective option for all women. Modifications in size and design also made easier insertion can be done even in OPD setup and possibility of expulsion has been reduced. Hysterectomy is being done routinely for majority of AUB cases especially after completion of family, LNG-IUS should be considered as first choice in such women after proper counseling and selection of cases before going for hysterectomy.

LNG-IUS is a safe and cost-effective option for women of reproductive age with AUB classified according to PALM COEIN.

Reference

1. Munro MG, Critchley HO, Broder MS, et al. FIGO working group on menstrual disorders. FIGO classification system. (PALM-COEIN) for causes

of AUB in non gravid women of reproductive age. Int J Gynaecol Obstet. 2011; 113:3–13.

2. Anipindi G, Vani I. Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding: A safe and effective option for all PALM COEIN variants. IAIM, 2017; 4(12): 127-131
3. Garg S, Soni A. A Non-surgical lifeline for Abnormal uterine bleeding (AUB)—the LNG IUS. Ind J ObstetGynecol Res. 2016;3(1):23–7.
4. McPherson K, Metcalfe MA, Herbert A, Maresh M, Casbard A, Hargreaves J, et al. Severe complications of hysterectomy: The VALUE study. BJOG, 2004; 111(7): 688-94.
5. Nayar J, Nair S, George N. Is LNG-IUS the One - Stop Answer to AUB?. J. Obs and Gyn of Ind.2018;68(4):253-7.
6. Singh K, Bharati G, Prasad D, et al. Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding: a conservative approach. Int J Reprod Contracept Obstet Gynecol. 2017;6:631–5.
7. Dhamangaonkar PC, Anuradha K, Saxena A. Levonorgestrel intra uterine system(Mirena): an emerging tool for conservative treatment of abnormal uterine bleeding. J Midlife Health. 2015;6(1):26–30. doi:10.4103/0976/7800153615.
8. Lethaby A, Hussain M,Rishworth JR, Rees MC. Progesterone or progesterone-releasing-intrauterine systems for heavy menstrual bleeding. Cochrane Database Syst Rev.2015; 30(4):CD002126.doi:10.1002/14651858.
9. Endometrial hyperplasia management of (green top guideline no.67) joint guideline of RCOG/BSGE published in February 2016 and updated in February 2017.
10. AUB-FOGSI-GCPR Summary of Recommendations.www.fogsi.org/wp-contēnt/uploads/2016/06/AUB-FOGSI-GCPR-Summary-of-recommendations.pdf.