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ACCEPTANCE OF MIRENA IN HEAVY MENSTRUAL BLEEDING : A PROSPECTIVE STUDY

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ABSTRACT

The phrase "abnormal uterine bleeding" (AUB) refers to a broad spectrum of irregularities in the menstrual cycle, such as differences in the volume, regularity, frequency, and length of flow outside of pregnancy.

Excessive monthly blood loss, known as heavy menstrual bleeding, has a detrimental effect on a woman's social, physical, emotional, and/or economical well-being. It might show up alone or in combination with other symptoms. First line option includes LNG-IUS, hormonal medications like combined oral contraceptive pills, cyclical progesterons, non-hormonal medications like tranexamic acid, NSAIDS. The T-shaped, MIRENA is a cylindrical device that controls the pace at which hormones are released. It comprises 52 milligrams of levonorgestrel enclosed in a rate-regulating membrane. Initially, levonorgestrel is released at a rate of 20 µg per 24 hours; this drops to 11 µg per 24 hours after five years, yielding an average daily release rate of 14 µg over the device's lifetime. A prospective research was conducted on patients who were enrolled from February 2017 to February 2018 at the gynecology and obstetrics department of Rohilkhand Medical College and Hospital in Bareilly. We made use of the patient's data regarding her menstrual cycle and related adverse effects. It was utilized for follow up of patient. Pictorial Blood Loss Assessment Chart, weight, and hemoglobin were used to measure blood loss during each menstrual cycle in addition to other information.

Keywords: Abnormal uterine bleeding, NSAIDS, MIRENA

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INTRODUCTION

"Abnormal uterine bleeding" (AUB) is a broad term used to characterize abnormalities in the menstrual cycle outside of pregnancy . These irregularities might include variations in the frequency, regularity, length, and volume of flow. [1]. Acute and chronic forms are another classification for it. Excessive bleeding is known as acute AUB, and it needs to be treated immediately to stop more blood loss. An irregular menstrual flow for the bulk of the previous six months is known as chronic AUB. AUB can be acute or chronic, occurring alone or in combination. To categorize the characteristics, the International Federation of Obstetrics and Gynecology (FIGO) developed the terminology PALM-COEIN and irregular uterine bleeding. Whereas COEIN focuses on non-structural problems, PALM explains structural etiologies.

P: Polyp, A: Adenomyosis, L: Leiomyoma, M: Malignancy and hyperplasia, C: Coagulopathy, O: Ovulatory dysfunction, E: Endometrial disorders, I: Iatrogenic, N: Not otherwise classified

Physical conditions such as polyps and leiomyomas, which may not exhibit any symptoms, may not be the main cause of AUB in a patient.[2] Excessive menstrual blood loss can have a detrimental effect on a woman's social, physical, emotional, and/or financial well-being. The symptom may manifest independently or in combination with other signs.

According to 2018 NICE guidelines, hysterectomy is the second line option for treatment of heavy menstrual bleeding. First line option includes LNG-IUS, hormonal medications like combined oral contraceptive pills, cyclical progesterons, non-hormonal medications like tranexamic acid, NSAIDS.[3]

The US and Europe have been selling levonorgestrel-releasing intrauterine devices (LNG-IUS) since 1990. Germany's Bayer Schering Pharma is the company that markets it under the Mirena® name. The rate of hormone release is regulated by this T-shaped, cylindrical device. It has a rate-regulating membrane covering 52 milligrams of levonorgestrel. For a maximum of five years, it offers astonishingly efficient contraception. Levonorgestrel is initially released at a rate of 20 µg per 24 hours; after five years, this drops to 11 µg per 24 hours, giving a total average release rate of 14 µg per day throughout the duration of the cylindrical device's life. The device thins the endometrium, which prevents implantation . It thickens cervical mucus and inhibits endometrial growth, making the environment unfavorable for sperm survival. This impairs motility and capacitation, which stops fertilization. Ovulation suppression is not achieved in most LNG-IUS users because the modest blood levels of absorbed progestin are sufficient to allow for normal ovulation[4]. Mirena is a novel option for treating heavy menstrual bleeding .

AIM AND OBJECTIVES

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AIM:

To assess the awareness and efficacy of Levonorgestrel Intrauterine System (LNG-IUS) in the management of abnormal uterine bleeding(AUB).

OBJECTIVES:

1. To determine how many women with abnormal uterine bleeding adopt the Levonorgestrel Intrauterine System (LNG-IUS).
2. To study the efficacy of Levonorgestrel Intrauterine System among women with AUB.
3. To study the side effects with Levonorgestrel Intrauterine System among women with AUB.

MATERIALS AND METHODS

A prospective study was carried out in the department of gynaecology and obstetrics of Rohilkhand Medical College and Hospital, Bareilly. Fifty patients were enrolled from February 2017 to February 2018. These fifty patients with LNG-IUS/ MIRENA insertion were selected who fulfilled the inclusion and exclusion criteria after taking proper verbal and written consent. We took detailed history followed by examination just prior to Mirena insertion. Also, urine pregnancy test was done in each case to rule out pregnancy. Then, a transvaginal ultrasound which was followed by Pap smear and endometrial biopsy by Pipelle method was done in each patient. After menstruation, Mirena was implanted as an outpatient procedure. The patient was followed up with once a week initially, and then once a month after that. The patient's record of their menstrual cycle and any related adverse effects was utilized to monitor their progress. The quantity of blood loss and other parameters were evaluated using a pictorial blood loss assessment chart, weight, and hemoglobin.

Inclusion criteria:

1. A sexually active age women of 20 to 50 years
2. No known illnesses such as cancer, diabetes mellitus, hypertension, or infections.
3. No organic genital tract illnesses .
4. Not aiming to become pregnant for at least a year .

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Exclusion criteria:

1. Individuals with infections of the genital tract
2. Being pregnant
3. Liver disorders
4. Coagulation issues
5. Atypical endometrial hyperplasia or cancer; uterine size >12 weeks
6. Abnormalities related to cervical cells.

RESULTS

In our study, 50 women with irregular bleeding patterns, whose mean age was 36.4±0.6 years, were included. Eighty-six percent (86%)of the women were in the age group of thirty to fifty. Sixty-four percent(64%) of the patients complained of excessive menstrual bleeding, sixteen percent(16%) had fibroid uterus, ten percent(10%) had endometriosis, and eight percent(8%)had adenomyosis.

Table 1: Age wise distribution of cases

AGE	NO. OF PATIENTS	PERCENTAGE
21-30	6	12%
31-40	24	48%
41-50	19	38%
51-60	1	2%
TOTAL	50	100%

Patients were followed monthly to assess the various effects of MIRENA like bleeding pattern, amenorrhea, pelvic pain, satisfaction with the device. It was observed that after 3 months interval, 22% patients achieved normal menstrual cycle, 24% still had irregular heavy menses. For 24% of patients, heavy menstrual bleeding was the most prevalent problem during the first three months; after six months, this figure decreased to 14%, and after a year, it was 0%. After a year of use, 10% of women had very little menstrual flow and 72% had amenorrhea. After three months, dysmenorrhea affected 32% of the patients; by the end of a year, that number had dropped to 8%. After one complete year of use 90% subjects were s with the device.

Table 2: Approach to cases of heavy menstrual bleeding

DIAGNOSIS		NUMBER	PERCENTAGE
HMB	HMB IN < 40 YRS	21	42%
	HMB IN > 40 YRS ,CONSERVATIVE MANAGEMENT	12	24%
FIBROID		8	16%

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ENDOMETRIOSIS	5	10%
ADENOMYOSIS	4	8%

In our study, after 3 months, 4% experienced expulsion of the device. 32% women complained of post insertion pain after 3 months of the device but gradually over months, pain settled. After 1 year of follow up, only 4% experienced irregular heavy menstrual cycles. 90% were satisfied with the device.

Table 3: Follow up effects on intervals

DIAGNOSIS	3 MONTHS	6 MONTHS	12 MONTHS
Irregular heavy menses	12	7	2
Irregular spotting	7	3	2
Normal menses	11	4	4
Scanty menstrual flow	1	14	5
Amenorrhea	0	6	36
Dysmenorrhea	16	6	4
Satisfied with device	24	34	45
Device removed by itself	2	0	0

TABLE 4: FOLLOW UP SIDE EFFECTS

SIDE EFFECTS	AFTER 3 MONTHS	AFTER 6 MONTHS	AFTER 12 MONTHS
IRREGULAR HEAVY MENSES	12	7	2

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IRREGULAR SPOTTING	7	3	2
EXPULSION	2	0	0
POST INSERTION PAIN	16	2	0

DISCUSSION:

A woman's daily life is greatly impacted by heavy menstrual flow. Similar to the findings of Singh K et al.'s[5] study from 2015, which included 69% of instances with excessive menstrual bleeding with no known reason, 66% of our patients also had this condition.

Upon counselling, patients were given advise for MIRENA insertion and were followed up for effects and side effects. After 3 months, 22% achieved normal menses, none achieved amenorrhea, 40% still had menstrual irregularities, 48% were satisfied with the device, 32% experienced post insertion pain which is in lines with the study done by Singh K et al[5] where 20% achieved normal menstrual cycles, 57.5% were satisfied with the device, none achieved amenorrhea, 22.5% experienced post insertion pain but menstrual irregularities were seen in 70% patients. There is also similarity with the study conducted by Kriplani et al[8] where heavy menstrual bleeding was cured in 77.7% subjects during first 3 months and in all the subjects at the end of three years.

In our study, after 6 months, 20% had menstrual irregularities, 8% achieved normal menses, 28% had scanty menstrual blood flow, 12% achieved amenorrhea, 12% faced dysmenorrhea, 14% still had irregular heavy menses, 4% faced post insertion pain which is similar to study by Singh K et al[5] where 13.89% had menstrual irregularities, 13% experienced amenorrhea, 8.3% had irregular heavy menses while none faced post insertion pain. 16.7% achieved normal menses unlike 8% in our study which is different from study conducted by Singh K et al[5]. Results were in lines to study conducted by Garg et al[6] where 10% had absence of menstruation , 40%

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had decreased flow, 20% had scanty bleeding and only 6.66% had irregular bleeding which was heavy in amount.

In our study, by the end of one year, majority of the subjects experienced relief from dysmenorrhea, that is, 92% while 76.6% were relieved of dysmenorrhea in study by Garg et al[6].

In our study, after 1 year of follow up, 90% were satisfied with the device, 72% achieved amenorrhea, 8% achieved normal menstrual cycles, 4% had irregular heavy menses while none had post insertion pain which is similar to study by Singh K et al[5] where after one year of follow up 92.5% were satisfied with the device, 81.5% achieved amenorrhea while one experienced irregular heavy menses or post insertion pain. By the end of one complete year, 90% of patients had developed absence of menstruation in study conducted by Garg et al[6]. In a research by Yazbeck et al.[7], 86.1% of female patients with dysfunctional bleeding were satisfied with the levonorgestrel intrauterine system therapy; this finding is comparable to our study, in which 90% of participants expressed satisfaction with the device after a full year of use.

CONCLUSION

LNG-IUS is a safe, efficient, and socially acceptable treatment for severe menstrual bleeding. It may be a suitable option instead of a hysterectomy since excessive menstrual bleeding might have many benign causes. It is linked to a higher satisfaction rate and fewer side effects. Throughout the entire reproductive years, LNG-IUS is a viable treatment option that facilitates a seamless menopausal transition. Thus, having a hysterectomy for an unwarranted reason should be avoided.

REFERENCES

1. Fraser IS, Critchley HO, Munro MG, Broder M. Can we achieve international agreement on terminologies and definitions used to describe abnormalities of menstrual bleeding? Hum Reprod. 2007 Mar;22(3):635-43.

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2. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 557: Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. Obstet Gynecol. 2013 Apr;121(4):891-6.

3. Belli AM. Heavy menstrual bleeding (NICE clinical guideline 44). Natl Inst Health Clin Excel. 2007 Jan.

4. Beatty MN, Blumenthal PD. The levonorgestrel-releasing intrauterine system: safety, efficacy, and patient acceptability. Therapeutics and clinical risk management. 2009;5:561.

5. Singh K, Bharati G, Prasad D, Kumari S. Role of levonorgestrel releasing intrauterine device in management of heavy menstrual bleeding: a conservative approach. Int J Reprod Contracept Obstet Gynecol. 2017;6(2):631-5.

6. Garg S, Soni A. A Non- surgical lifeline for Abnormal uterine bleeding (AUB) - the LNG IUS. Ind J Obstet Gynecol Res. 2016;3(1):23-27.

7. Yazbeck C, Omnes S, Lavenu VMC, Madelenat P. Levonorgestrel-releasing intrauterine system in the treatment of dysfunctional uterine bleeding: A French multicenter study. Gynecol Obstet Fertil. 2006;34:906-13.

8. Kriplani A, Singh BM, Lal S, Agarwal N. Efficacy, acceptability and side effects of the levonorgestrel intrauterine system for menorrhagia. Int J Gynaecol Obstet. 2007;97(3):190-4.