

Efficacy of Levonorgestrel Releasing Intrauterine System (Mirena) in Conservative Management of Abnormal Uterine Bleeding

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Abstract: **Background:** To study the efficacy of levonorgestrel intrauterine system (LNG-IUS; Mirena) in conservative management of abnormal uterine bleeding (AUB). **Objective:** To determine the effectiveness of Levonorgestrel releasing intrauterine system (Mirena), in decreasing the menstrual blood loss, dysmenorrhea and dyspareunia at the end of one year after insertion. **Materials & Methodology:** This observational study was carried out on 43 patients done in tertiary care hospital, Rajahmundry over 1 year between 2021 to 2022. A detailed general, systemic, pelvic (to see for Mirena threads), and breasts examination was done at every visit. Follow-up ultrasound was done at every visit to see for Mirena location and if there were any changes in the original pelvic pathology or development of a new pathology like ovarian cysts. Hemoglobin (Hb) estimation was done after 1 year. **Results:** Out of 43 patients studied most common reason for mirena insertion being AUB (53.4%), endometriosis (23.2%), adenomyosis (13.9%) and fibroid uterus (9.30%). Common symptoms for mirena insertion being menorrhagia (62.7%), dysmenorrhea 13 (30.2%) and dyspareunia 3 (6.9%). The majority of women having irregular cycles (74.41%), regular cycles (25.58%). The patterns of bleeding post mirena insertion was shifted to amenorrhea (48.8%) followed by regularized cycle with reduced flow (37.20%) and irregular cycles with reduced flow (13.9%). The major side effect noticed post mirena insertion is weight gain in 55.8% followed by spotting (30.2%), breast tenderness (9.3%) and pelvic pain (4.6%). **Conclusion:** Levonorgestrel-releasing intrauterine system provides an incredible nonsurgical alternative in treatment of abnormal uterine bleeding, adenomyosis, endometriosis, endometrial hyperplasia. Its effects are reversible and it also an effective contraceptive. Side effects are generally mild and most of the times assurance is enough to ensure continuation of device.

Keywords: Abnormal uterine bleeding, mirena, contraceptive, anemia

1. Introduction

One of the most frequent causes of women in the reproductive age group seeking medical attention is abnormal uterine bleeding (AUB). In the absence of a medical condition or pelvic pathology, dysfunctional uterine bleeding accounts for about half of all abnormal bleeding cases. First, it is important to rule out any organic causes and rule out pregnancy. Heavy menstrual flow can be a symptom of structural problems such as leiomyoma or endometrial hyperplasia⁽¹⁾. Although they can also present with menorrhagia, adenomyosis and endometriosis typically appear with dysmenorrhea.

Abnormal uterine bleeding can be managed medically using NSAIDs, tranexamic acid, progesterone, oral contraceptives, GnRh analogues, and Levonorgestrel-releasing intrauterine systems, among other therapeutic options.

A T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) encircling the vertical stem makes up the Mirena LNG-IUS (levonorgestrel-releasing intrauterine system).

Levonorgestrel and silicone are combined to create the reservoir, which is a white or almost white cylinder that holds 52 mg of levonorgestrel in total. A semi-transparent silicone (polydimethylsiloxane) membrane covers the reservoir. The T-body measures 32 mm both horizontally and vertically. The T-polyethylene body's is combined with barium sulphate to make it radiopaque. The vertical stem of the T-loop body's is capped with a monofilament brown polyethylene with removing thread. Along the vertical stem of MIRENA, there are 52 mg of levonorgestrel. After five years, the device's hormone release rate drops to 14 µg/day from its initial rate of 20 µg/day, which is still in the range of effectiveness.

In the uterine cavity, Mirena predominantly has local progestogenic actions. The endometrium undergoes a variety of morphological alterations, such as

- Stromal pseudo decidualization,
- Glandular atrophy,
- Leucocytic infiltration, and
- A reduction in glandular and stromal mitoses.
- Modification of the uterotubal fluid and cervical mucus
- Prevents motility of sperm
- Detrimental effect on sperm activity and motility inside the vaginal tract, which prevents conception.

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- h) Changes in the vascular system, including a decrease in mean vascular density and an increase in mean vessel area⁽⁵⁾.
- i) By lowering the pre-ovulatory rise in luteinizing hormone, ovulation is suppressed.

By the end of a year, Mirena was shown to be superior to every other form of medical treatment, and the blood loss had decreased.

In comparison to hysterectomy, mirena was also shown to be more affordable. By employing this hormone-releasing intrauterine device, the surgical morbidity associated with hysterectomy is minimised⁽¹⁰⁾. Although amenorrhea is anticipated in Mirena users, counselling should always cover the drug's benefits, drawbacks, and dangers of withdrawal. When it comes to lowering monthly blood loss, Mirena is highly effective.

Without changing the systemic haemostasis, Mirena affects the haemostatic and fibrinolytic inhibitor systems in menorrhagia-afflicted women⁽³⁾ and shows increased expression of fibrinolytic inhibitors and urokinase-type plasminogen activator in the endometrium⁽⁴⁾.

In women with fibroid-related issues, LNG-IUS:

- Minimises the necessity for surgery;
- Diminishes blood loss;
- Causes an increase in haemoglobin;
- Has no appreciable impact on fibroid volume reduction and uterine size shrinkage.

The reason behind Mirena's effectiveness in treating adenomyosis and endometriosis patients is likely the atrophy of the endometrial glands and significant transformation of the decidua brought on the endometrium by prolonged exposure to progesterones⁽¹²⁾.

For five years, Mirena works as a reliable contraceptive. It is an extremely palatable and quickly reversible method of birth control, with 3-year continuation rates of 75-82%.

2. Material and Methods

This observational study was carried out on 43 patients who had mirena insertion in tertiary care hospital over 1 year between 2021 to 2022. When bleeding had ended, Mirena was inserted post menstrually on days 5, 6, or 7. The patient was informed about the altered bleeding pattern that is known to cause for 3-6 months prior to installation. She received advice on post- insertion amenorrhea.

Except in a few cases where the cervix could not be visualised well, where the cervix was pulled up during a prior caesarean surgery, or in apprehensive patients, it was implanted in the operating room (OT) with only minimum anaesthesia⁽⁶⁾. Upon insertion, the patient was instructed to keep a menstrual calendar for four months, marking the days of spotting or bleeding. The women were contacted for follow-up calls after one month, four months, and then annually (for a maximum of one year), during which time

they were asked how much relief they had experienced from their prior menstrual issues.

Every visit included a thorough general, systemic, pelvic (to check for Mirena threads), and breast examination. Every appointment included a follow-up ultrasound to check the Mirena site and determine whether the initial pelvic pathology had changed or whether any new pathologies, such as ovarian cysts, had emerged⁽⁷⁾. After a year, an estimation of haemoglobin (Hb) was made. Improvement in quality of life and subjective symptomatic relief were used to gauge Mirena's effectiveness.

Inclusion Criteria:

- 1) Married women
- 2) Age group (18-50 yrs)
- 3) With Mirena inserted for Menorrhagia, Endometriosis, Adenomyosis, Fibroid and Endometrial hyperplasia.

Exclusion Criteria:

- 1) Uterine anomaly
- 2) Submucous fibroids distorting the uterine cavity
- 3) Acute pelvic disease
- 4) Liver disease

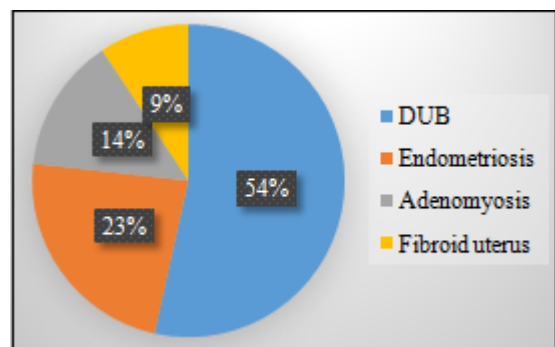


Figure 1: Reason for insertion of Mirena

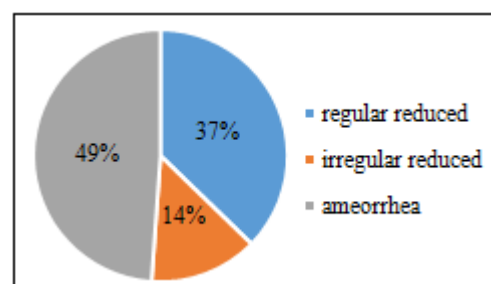
- Most common reason for mirena insertion being DUB accounting upto (53.4%) followed endometriosis of about (23.2%) and least being distributed among adenomyosis (13.9%) and fibroid uterus (9.30%).

Table 2: Pattern of bleeding before & after one year of insertion of Mirena – Regular

Before

| Regular cycles | n | % |
|----------------|----|-------|
| No | 32 | 74.41 |
| Yes | 11 | 25.58 |

After



- The majority of women are having irregular cycles i.e 74.41% and those with regular cycles are 25.58 %
- The patterns of bleeding post mirena insertion was shifted to amenorrhea accounting upto 48.8% majorly followed by regularized cycle and reduced flow of about 37.20% followed by irregular cycles with reduced flow of 13.9%

Table 3: Symptoms before insertion of Mirena

| Indication | n | % |
|--------------|----|------|
| Menorrhagia | 27 | 62.7 |
| Dysmenorrhea | 13 | 30.2 |
| Dyspareunia | 03 | 6.9 |

- The major symptom for mirena insertion being menorrhagia about 27 (62.7%) followed by dysmenorrhea 13(30.2 %) and least for dyspareunia 3 (6.9%).

Table 4: Haemoglobin before and one year after insertion of Mirena

| Preinsertion | Mean±SD |
|-----------------------|----------|
| Hb (gm%) | 9.4±2.4 |
| Hb after 1 year (gm%) | 11.5±2.3 |

- The relation of haemoglobin prior mirena and post mirena insertion an year follow up showed a standard increase of about 2.1 gm to 2.4 gm of haemoglobin .

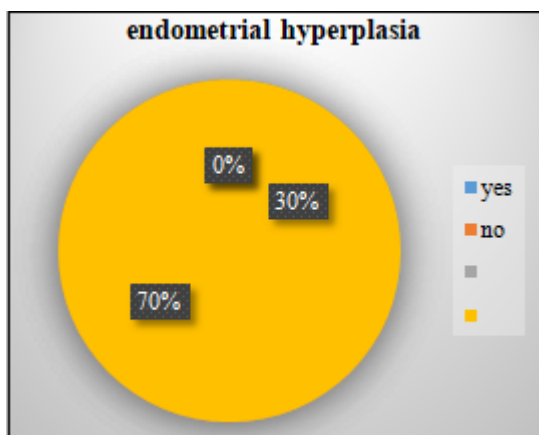


Figure 3: Number of patients with a histopathological diagnosis of Endometrial Hyperplasia

Ultrasound – 75.6% of patients who had insertion of Mirena had a screening ultrasound. Endometrial biopsy- Only 23.3% of patients had an endometrial biopsy done, for evaluation.

- The patients who underwent endometrial biopsy were 10 (23.3 %) among them a majority of 70 % are reported to have normal endometrium and about 30% are having endometrial hyperplasia normal

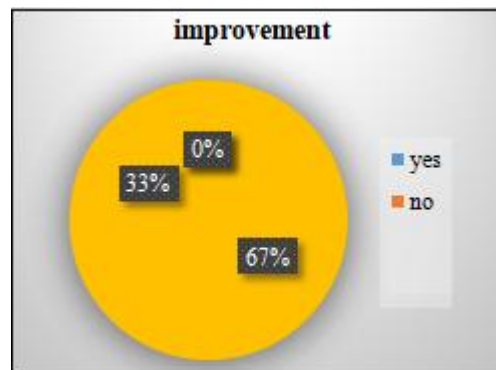


Figure 4: Women who had Improvement of symptoms after one year of insertion of Mirena

- The majority of women 29 members (67.4%) post mirena insertion had a symptomatic relief , while the rest 14 members (32.5%) still persisted with symptoms .

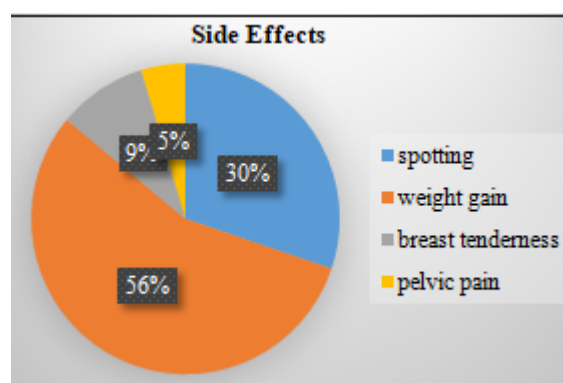


Figure 5: Side effects reported by women after insertion of Mirena.

- The major side effect noticed post mirena insertion is weight gain in 24 patients of the study i.e. (55.8%) followed by spotting in about 13 patients (30.2 %) and breast tenderness in 4 patients (9.3 %) and the least being pelvic pain in 2 patients (4.6%).

3. Discussion

- Both ovulatory and anovulatory menstruation is referred to as abnormal uterine bleeding. 10% to 30% of women in the reproductive age range and about 50% of women in the perimenopausal age range experience abnormal uterine bleeding⁽⁸⁾. The average menstrual cycle lasts for 28 days on average, lasts 4 days on average, and results in a blood loss of 30 to 40 ml per cycle.
- Mirena has been demonstrated in numerous studies to be more successful than oral progestogens, antifibrinolytics, and contraceptive tablets in treating heavy menstrual bleeding⁽⁹⁾

The following are the findings from this study's follow-up of patients who had Mirena implants between 2021 and 2022.

- Mirena insertions were made in 52 patients all, although only 43 individuals could be followed
- Most common reason for mirena insertion being DUB accounting upto (53.4%) followed endometriosis of about (23.2%) and least being distributed among adenomyosis (13.9%) and fibroid uterus (9.30%).

- In 62.7% of cases and in 30% of cases, menorrhagia and dysmenorrhea were the main symptoms respectively.
- In our study only 6.9% of patients complained of dyspareunia compared to Kingman CE study showed 2.1%.
- The mean Hb% in our study increased significantly from about 2.1 to 2.4gm% compared to the study done by Journal mid-life health , which is 1.4 to 1.8gm%.
- Among the patients, 75% underwent ultrasound examinations, while 23.3% underwent endometrial biopsies, only 3 of which revealed endometrial hyperplasia.
- With Mirena, 86% of patients experienced symptomatic improvement, and the median time it took for improvement to be observed was 5.3 months. 48.8% of women reported having amenorrhea, while about 37.2% bled frequently but less frequently.
- The most common complaint of women in our study is abnormal uterine bleeding which is similar to the complaint in many other studies.
- The majority of women 29 members (67.4%) post mirena insertion had a symptomatic relief , while the rest 14 members (32.5%) still persisted with symptoms
- Minor side effects like partner threads, occasional spotting, and chronic symptoms were reasons for dislike. Yet except from one woman who had Mirena removed because of recurrent leukorrhea, none of them needed to be removed.
- The Mirena removal was mainly due to leukorrhea compared to study done by Blackman

T is irregular menstruation & pelvic pain⁸

The most common adverse reaction following mirena insertion was weight increase in 24 of the study participants, or 55.8% of them. This was followed by spotting in roughly 13 (30.2%), breast soreness in 4 (9.3%), and pelvic pain in 2 (4.6%).

4. Conclusions

Mirena has been found to be more effective than hysterectomy and other medical treatment. It offers good patient compliance and satisfaction. Reduced menstrual blood flow and improved anaemia are two benefits of LNG-IUS. Those who are obese can also utilise it without risk. For females with AUB who want to use contraception, it is also a very good solution. Women who have had previous abdominal procedures, such as caesarean sections or myomectomy, are safe to use it. Uterine fibroid, endometriosis, adenomyosis, and endometrial hyperplasia can all be successfully treated with LNG-IUS. The majority of the time, assurance is sufficient to ensure that the device will continue to work despite any minor side effects. LNG-IUS was found to be more cost-effective and to produce superior health-related quality of life results than hysterectomy.

The study came to the conclusion that the menorrhagia treatment option Mirena, a levonorgestrel-releasing intrauterine system, offers an amazing nonsurgical alternative that is reversible and spares fertility.

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