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Original Research Article

Mirena: a novel alternative to hysterectomy

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ABSTRACT

Background: To study the awareness and efficacy of Mirena (Levonorgestrel intrauterine system) in treatment of abnormal uterine bleeding.

Methods: A prospective analytical study was conducted from January 2012 to June 2018 at Smt. Kashibai Navale medical college and general hospital, Pune, Maharashtra, India. Total 30 women between age of 35 to 45 yrs age were included in the study. Mirena was inserted post-menstrually in the operation room under sedation was done. The women were called for follow-up after 1 month, then 4 months, and then yearly (for maximum 2 years); and asked regarding the relief they have obtained from the antecedent menstrual complaints.

Results: At end of study, Overall satisfaction rate among women was 76.67% and decrease menstrual blood flow observed in 20 (74.07%) cases. Most common side effect observed was irregular menses in 6 (22.22%) cases. Hysterectomy was required in 3 (11.11%) cases.

Conclusions: Menorrhagia is a common gynaecologic problem often needing hysterectomy. The LNG-IUS reduces bleeding in women with menorrhagia due to benign causes. The patient acceptance and satisfaction is high. Main problem is irregular bleeding especially for the first 3 months after insertion. If the patients can be counseled before insertion, continuation rates for LNG-IUS are high. It has the potential to replace hysterectomy as treatment of choice in certain patients.

Keywords: Abnormal uterine bleeding, Endometrial hyperplasia, Levonorgestrel intrauterine system, Mirena

INTRODUCTION

Heavy menstrual bleeding (HMB) is a common problem evident in gynaecological out-patient department. Heavy menstrual bleeding is clinically defined as greater than or equal to 80 mL of blood loss per menstrual cycle.¹ Its prevalence is 9 to 14% in women of reproductive age group.² In India, the reported prevalence is around 17.9%.³ It often leads to iron deficiency anaemia and affects both personal as well as social quality of life. Nearly 30% of all hysterectomies are performed to alleviate heavy menstrual bleeding.⁴ Historically, surgical

treatment was considered to be the definitive management of HMB.

But modern gynaecology aims towards preservation of uterus. A wide variety of medications, both hormonal and non hormonal are available to reduce heavy menstrual bleeding but there is considerable variation in practice and uncertainty about the most appropriate therapy. It was found that progesterone or progestogen-releasing intrauterine systems, which were initially introduced as contraceptives were associated with reduction in menstrual blood loss.⁵ Progestasert was the first

hormonally impregnated device releasing 65µg of progesterone per day; it required re-insertion approximately yearly but was discontinued in 2001.

Soon Mirena was introduced as a long-acting reversible contraceptive method. It has T-shaped polyethylene frame with a steroid reservoir (hormone elastomer core) made of a mixture of levonorgestrel and silicone (polydimethylsiloxane), containing a total of 52 mg levonorgestrel around the vertical stem. The device releases the hormone at an initial rate of 20 µg/day and declines to a rate of 14µg after 5 years, which is still in the range of clinical effectiveness.⁶ Local intrauterine delivery of levonorgestrel (LNG) results in extensive decidualization of endometrial stromal cells, atrophy of the glandular and surface epithelium, and changes in vascular morphology (suppression of spiral artery formation and presence of large dilated vessels) along with down-regulation of sex steroid receptors in all cellular components.⁷

Our aim was to study the awareness and efficacy of LNG - IUS (Levonorgestrel intrauterine system) in treatment of abnormal uterine bleeding.

METHODS

A prospective analytical study was conducted from January 2012 to June 2018 at Smt. Kashibai Navale medical college and general hospital, Pune, Maharashtra, India.

Total 30 women between age of 35 -45 yrs age were included in the study.

Inclusion criteria

- Self motivated
- Willing to bear cost
- Associated comorbid condition like uncontrolled diabetes mellitus and hypertension who were unfit for surgery.

Exclusion criteria

- Uterine size > 12 weeks
- Distorted uterine cavity
- Endometrial or cervical carcinoma
- Pregnancy
- Acute pelvic inflammatory disease
- Genital bleeding of unknown etiology
- Liver disease.

Cases were evaluated by hemogram, transvaginal and transabdominal sonography. Endometrial biopsy was done to rule out endometrial carcinoma. Mirena was inserted post-menstrually in the operation room under sedation was done. The women were called for follow-up after 1 month, then 4 months, and then yearly (for

maximum 2 years); and asked regarding the relief they have obtained from the antecedent menstrual complaints.

Statistical analysis

Data was analysed using SPSS software.

RESULTS

The profiles of findings have been shown in Table 1. 43.3% of the population had endometrial hyperplasia findings followed by 33% with findings of adenomyosis. 20% of the patients had fibroid. One patient (3.3%) had endometriosis.

Table 1: Cases included in study.

Type of case	Number of cases
Endometrial hyperplasia (AUB-E)	13
Adenomyosis (AUB-A)	10
Uterine fibroid (AUB-L)	6
Endometriosis	1

There was loss to follow up of 3 cases out of 30 (10%). 4 women (13.33%) were already aware about Mirena as a treatment option for abnormal uterine bleeding. There was decrease menstrual blood flow in 20 (74.07%) cases. Mirena had a satisfaction rate of 76.67%.

Table 2: Adverse effects of Mirena.

Adverse effect	Number of cases
Irregular menses	6 (22.22%)
Lower backache	3 (11.11%)
Vaginal discharge	2 (7.40%)
Dyspareunia	1 (3.70%)

Most common adverse effect observed was irregular menses in 6 (22.22%) cases. Other adverse effects included low back ache (3 cases), vaginal discharge (2 cases) and dyspareunia (1 case). No perforation was observed during insertion (Table 2).

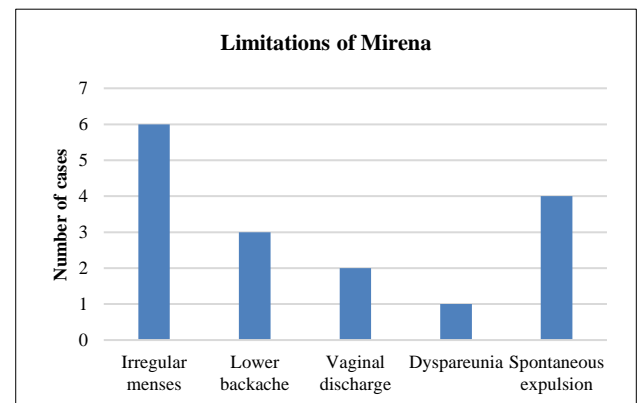


Figure 1: Limitations of Mirena.

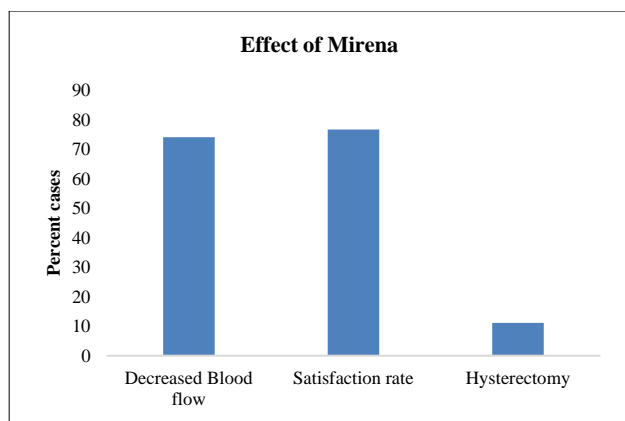


Figure 2: Effect of Mirena.

Spontaneous expulsion of Mirena was observed in 4 (14.81%) cases (Figure 1). Hysterectomy was required in 3 (11.11%) cases. Out of these, hysterectomy was performed following spontaneous expulsion in 2 cases of endometrial hyperplasia. 1 case of multiple uterine fibroids required manual removal of Mirena followed by hysterectomy due to no improvement of symptoms (Figure 2).

DISCUSSION

Heavy menstrual bleeding is a subjective finding, but interferes significantly with a woman's day to day life. Various studies have shown Mirena to be more effective in heavy menstrual bleeding than antifibrinolytics, oral progestogens, and oral contraceptive pills.^{8,9} It has been recommended as treatment of first choice for heavy menstrual bleeding as per NICE guidelines.¹⁰

In a study by Dhamangaonkar et al, Mirena decreased mean blood loss by 80% within 4 months and 95% within 1 year, which was comparable to that observed by us (74.07% cases).¹¹ The rate of hysterectomy varies between 5 - 10% in various studies, while it was 11.11% in our study.^{12,13}

Irregular menstrual cycle was a major adverse effect observed in 22.22% cases. Similar results were noted in a study performed by Vasudeva et al, and Ozdegirmenci et al.^{14,15} Mirena was even found effective in various gynaecologic pathologies, especially endometrial hyperplasia and adenomyosis with significant improvement of symptoms in these cases. The expulsion rate of Mirena was also found to be low. Overall satisfaction rate among women was 76.67%.

CONCLUSION

Menorrhagia is a common gynaecologic problem often needing hysterectomy. The LNG-IUS reduces bleeding in women with menorrhagia due to benign causes. The patient acceptance and satisfaction is high. Main problem is irregular bleeding especially for the first 3 months after

insertion. If the patients can be counseled before insertion, continuation rates for LNG-IUS are high. It has the potential to replace hysterectomy as treatment of choice in certain patients.

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