

# EFFICACY, SAFETY, PATIENT SATISFACTION, DISCONTINUATION, AND NEED FOR HYSTERECTOMY IN PATIENTS USING MIRENA LNG-IUS AS TREATMENT OF HMB

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## ABSTRACT

**Objective:** To study the efficacy, safety, patient satisfaction, discontinuation and need for hysterectomy in patients using Mirena LNG-IUS as treatment of HMB.

**Material & Methods:** This study was conducted at the department of Gynecology & Obstetrics, Ayub Teaching Hospital from January 2016 to August 2021. All women who opted for Mirena LNG IUS as treatment of heavy menstrual bleeding, or already using Mirena during the study period were included. Data was collected on a structured pro forma and patients were followed initially for one year and then for five years of use of Mirena or till expulsion or discontinuation of use. A total of 88 women with heavy menstrual bleeding who had been inserted MIRENA LNG-IUS were enrolled in the study.

**Results:** Overall 88.1% of Mirena users reported improvement in HMB. Of these, about 36.4% of study participants reported improved menstrual flow during next menstrual cycle, 52.4% had improved / normal menstrual flow within 6 months of Mirena LNG-IUS use, while 7% had their Mirena LNG-IUS removed early due to side effects and only 4.54% failed to respond to Mirena LNG-IUS. Reported common side effects included spotting (25%), Amenorrhea (6%), oligomenorrhea (42%), weight gain (14%), breast pain and heaviness (7%), mood changes not including depression (7%) and depression (7%).

**Conclusion:** Mirena LNG-IUS is an effective, cost-saving non-surgical treatment option for women with heavy menstrual bleeding and should be offered as a preferred treatment option to such women.

**Keywords:** HMB, IUD, LNG-IUS, Mirena, Progestogens, Hysterectomy.

## INTRODUCTION

Heavy menstrual bleeding (HMB) is associated with a number of acute and chronic complications for women and is found in up to one-half of women in reproductive age across the world.

Heavy menstrual bleeding (HMB) has been defined as "excessive menstrual blood loss, which interferes with a woman's physical, social, emotional and/or material quality of life."<sup>1</sup>

Though the amount of blood lost varies from one woman to other, a loss of more than 80 ml of blood during menstruation, a duration of periods longer than a week, or presence of both have been defined as heavy menstrual bleeding.<sup>2</sup> <sup>3</sup> <sup>4</sup> The prevalence of HMB in general population has been reported as ranging from 27.2% to 54% in different national and international studies. The reported prevalence of heavy menstrual bleeding in Pakistani women ranges from 6.7%-48%.<sup>5</sup><sup>6</sup> All menstrual disorders including heavy menstrual bleeding affect the physical, social, mental and financial wellbeing of a woman.<sup>7</sup> <sup>8</sup> <sup>9</sup>

Traditionally the mainstay of treatment for heavy menstrual bleeding has been surgical removal of uterus/hysterectomy.<sup>10</sup> Overall hysterectomy has been reported in as much as 30% of patients with HMB.<sup>11</sup> <sup>12</sup> While hysterectomy has been an effective treatment for heavy menstrual bleeding, but during the last two decades, the focus has gradually shifted towards non-surgical management of heavy menstrual bleeding which is not only cost-effective but also conserves uterus and fertility for patients where possible.<sup>13</sup>

The Mirena-LNG (IUS) is a minimally invasive treatment modality that reduces the heavy menstrual bleeding by as much as 90% due to

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its progestogenic effect on the uterine endometrium. Ever since it was introduced in 1977, published data indicates to its utility as a cost-effective and safe non-surgical treatment modality in the treatment of heavy menstrual bleeding.<sup>14</sup> The use of LNG(IUS) has been associated with an improved and better quality of life for patients with HMB.<sup>15</sup>

The use of Mirena LNG-IUS is gradually increasing in women in low resource countries, though the over-all use of this device is sparse in general population specifically due to its cost.

As far as contraceptive use is concerned, due to the high cost and the presence of cheaper methods of contraception such as barrier methods, oral contraceptive pills and the copper-T device, Mirena is not recommended for the purpose of contraception alone in the general population unless indicated for a medical reason.

This study was conducted with an aim to study the efficacy, safety, patient satisfaction, discontinuation and need for hysterectomy in patients using Mirena as treatment of HMB. In view of paucity of relevant literature from our region, we hoped to find and establish baseline patterns of its effectiveness in our region.

#### **MATERIAL AND METHODS**

This study was conducted at the department of Gynecology & Obstetrics, Ayub Teaching Hospital from January 2014 to August 2019. All women who opted for Mirena LNG IUS for heavy menstrual bleeding in this period were included in the study. Data was collected on a structured pro forma and patients were followed initially for one year and then for five years of use of Mirena or till expulsion or discontinuation of use.

A total of 88 women with heavy menstrual bleeding who had been inserted MIRENA LNG-IUS were enrolled in the study after taking an informed consent. The aim and

objectives were also explained to women enrolled in the study. Mirena users were interviewed by using a structured proforma to collect details and they were followed during 1-5 years of duration of use, or up till either expulsion of the Mirena LNG-IUS, discontinuation of use or need for alternate treatment options e.g., surgery.

#### **RESULTS**

The mean age of the patients (n=100) in this study was  $38.65 \pm 5.84$  years as shown in Table No. I. Majority of the patients 50 (50%) belonged to the age group 36-45 years, most of the women were postgraduates 47(47%), doctors by profession 37(37%) and the bulk of study participants 65(65%) belonged to middle socioeconomic status. Almost all the women 89(89%) were multiparous and without any medical or gynecological comorbidity while only 04(4%) women had medical comorbidities and 7(7%) had other gynecological problems like fibroids. Regarding Mirena use, most of the women 73 (73%) had been using Mirena both for contraception and control of HMB. The rest of the Mirena users (23%) used Mirena as a

treatment modality for heavy menstrual bleeding only. Most common side effect among the patients was spotting occurring in 22(22%) of women while 93(93%) patients had no complication with Mirena use. Improvement in HMB was seen in majority of the patients (56%), within 3-6 months, while only 11(11%) patients had no improvement in bleeding as can be viewed in Table No. II.

Overall efficacy of LNG-IUS was >89% in our study, as is illustrated in the Fig No. I and in only 04(4%) patients, hysterectomy had to be performed while in 07 (7%) patients Mirena-LNG IUS had to be removed earlier due to the side effects.

**Table I: Mean age of the patients**

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age of the patient	100	27.00	50.00	38.6500	5.84544

**Table II: Mirena related variables (n=100) Variables Groups**

Indications of Mirena use Contraception &amp; HMB\* HMB only

**Frequency(%age):** 73(73%) 27(27%)

Side effects	No side effect Spotting Depression Weight gain Breast symptoms Mood swings	35(35%) 22(22%) 07(7%) 10(10%) 17(17%) 09(9%)
Complications	No complication Expulsion Vasovagal syncope	93(93%) 05(5%) 02(2%)
Effect on menstrual bleeding	No improvement Improvement within 1 month Improvement within 3-6 months	11(11%) 33(33%) 56(56%)

\*HMB: Heavy menstrual bleeding//

**DISCUSSION:**

Heavy menstrual bleeding is present in more than one third of women worldwide and considering the magnitude of the problem, its management will have long lasting effect on the quality of life (QOL) of women as well as incidence of a related common complication such as Iron Deficiency anemia (IDA).<sup>16, 17</sup>

Classically, HMB is a result of a number of anatomical, physiological, and pathological conditions such as uterine fibroids, endometriosis, coagulation disorders, iatrogenic causes<sup>18</sup> and sometimes the cause of heavy menstrual bleeding remains unknown and it is termed as dysfunctional uterine bleeding or bleeding of endometrial origin.<sup>19, 20</sup>

In the absence of structural or histological abnormality or a small fibroid, which is not distorting the endometrial cavity, medical treatment of HMB is considered as first line management. Although surgical approach to HMB offers a definitive treatment, it is associated with a number of short- and long-term complications;<sup>21,22</sup> including infection, hemorrhage, wound infection, genito-urinary complications e.g., ureteral injury, urinary retention, pelvic organ prolapse and premature ovarian failure.<sup>23, 24</sup>

Evidence has accumulated over the years regarding efficacy of levonorgestrel (LNG) releasing intra-uterine system as a non-surgical, uterus preserving option for treatment of HMB option for HMB, and this mode of treatment has been found superior to other medical treatment options such as NSAIDs, tranexamic acid, and combined oral contraceptive pills both in efficacy and safety.<sup>25</sup>

In the present study, the use of Mirena LNG IUS resulted in normalization of menstrual blood flow in more than one third of patients by next menstrual cycle, while more than half of patients had improvement and normalization of their menstrual blood flows within 6 months after placement of Mirena LNG-IUS.

Over all efficacy in our study was > 90%, failure of Mirena LNG-IUS was seen in only 4.54% patients, while another 4.54% of the users discontinued using LNG-IUS due to its side effects specifically irregular per vaginal spotting. The efficacy of LNG-IUS in HMB has been reported by Eralil GJ e'tal, in a study from India. They studied 70 women with HMB who used LNG-IUS and the outcome was determined by the Menorrhagia Multi-Attribute Scale (MMAS).<sup>26</sup>

Eralil GJ e'tal reported that 6% patients needed hysterectomy while our results showed 4.54% patients having hysterectomy. These findings are more or less similar to our results.

Similar results have been reported elsewhere in literature. Chi C e, tal, reported a case series of women with inherited bleeding disorders and HMB treated with LNG-IUS who showed an improvement in quality of life and median concentration of hemoglobin in 36 women who received LNG-IUS. The median duration of LNG-IUS use was 33 months in this study.<sup>27</sup> On the other hand; the median use of LNG-IUS use in our study was 38 months (4-58 months).

Overall, patient compliance with Mirena LNG-IUS was >95% in our study. Though we did not use a standardized tool to determine the quality of life after insertion of the device, the general attitude, continuation of LNG-IUS (95%) and efficacy of treatment (90%), favored the trend towards effectiveness of the device. NICE (national institute of clinical excellence) in its evidence review of HMB, 2018, reported discontinuation of LNG-IUS treatment in 7 trials but this was due to adverse

effects and most of these women did not find treatment effective. Similarly expulsion of LNG-IUS was seen in 1 out of 25 users (4%) mainly due to chlamydial endometritis not responding to treatment.<sup>28</sup> This discontinuation rate and expulsion risk was comparable to that reported by our study.

Similar reports were published by Chi and colleagues who reported that the use of LNG-IUS in patients with heavy menstrual bleeding resulted in improvement in a number of hematological indices such as hemoglobin, ferritin, reduction in the assessment scores made with the help of PBAC (pictorial blood assessment chart) and quality of life.

A randomized trial by Busfield R e'tal which compared thermal balloon ablation devices with LNG-IUS devices for heavy menstrual bleeding reported no difference between the two in terms of outcomes; however, the use of both was associated with improved quality of life.<sup>29</sup>

Interestingly, it has been reported that the improvement in quality of life as a result of LNG-IUS insertion is comparable to that following endometrial thermal ablation or hysterectomy, in addition to cost-effectiveness.<sup>30</sup>

No national studies were found that focused on cost-effectiveness of Mirena MNG-IUS in patients with heavy menstrual bleeding. There is a misconception in our setup that Mirena LNG-IUS is expensive and therefore is not a preferred treatment option for many. While it is true, most of our study participants were working women who could afford this treatment option and therefore, opted for it. LNG-IUS devices are known for additional benefits in addition to cost-effectiveness such as increased duration of symptom free months and contribution to quality-adjusted life months.<sup>31</sup>

Though hysterectomy has been reported as a cost-effective treatment by S Bhattacharya e'tal but none of the studies he quoted preferred hysterectomy to LNG-IUS due to invasiveness of procedure and increased risk of complications<sup>32</sup>

Masud A e'tal from Pakistan reported that the use of LNG-IUS was associated with increased patient satisfaction, improvement in hematological parameters such as hemoglobin, reduction in number of sanitary pads used in a menstrual cycle and a reduction in blood loss.<sup>33</sup> Similarly, a number of other local studies by Ara S e'tal and Ashraf MN e'tal have reported that the use of LNG-IUS was associated with reduction in menstrual blood loss, early stoppage of menstruation, reduction in number of sanitary pads used in a menstrual cycle and improvement in hemoglobin levels.<sup>34</sup>

Our results in terms of patient satisfaction and normalization of menstrual blood flow are not different from these studies. More than 85% of our study participants had their menstrual blood flow "normalized" within 6 months after insertion of the LNG-IUS.

To sum up, LNG-IUS is an effective non-surgical treatment option for patients with heavy menstrual bleeding and should be offered as the preferred first line treatment option to women who wish to preserve fertility, despite its increased one-time cost.

This study is not without its limitations. The LNG-IUS was not compared with other non-surgical treatment options for heavy menstrual bleeding. Standardized questionnaires were not used for assessment of patient satisfaction. Despite these limitations, we feel that the results are promising for patients wishing to avoid hysterectomy and preserve their fertility.

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