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## Mirena for AUB(A) and AUB(E): Acceptance and Quality of Life

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### ABSTRACT

Abnormal Uterine Bleeding (AUB) significantly impacts women's quality of life, with heavy and irregular bleeding being common issues. The Levonorgestrel-releasing Intrauterine System (LNG-IUS), such as Mirena, is an effective long-term treatment that reduces menstrual blood loss and regulates cycles, offering an alternative to hysterectomy. Women's acceptance of Mirena depends on its effectiveness, side effects and personal preferences. Understanding their experiences with Mirena, regarding daily life improvements and overall satisfaction is crucial for managing AUB and enhancing patient-centered care. To study the acceptance and quality of living of Mirena Intrauterine Device (IUD) for AUB(A) and AUB(E) among patients with Abnormal Uterine Bleeding. This observational study was conducted among 143 female patients with Abnormal Uterine Bleeding attending the outpatient department of a tertiary care hospital. Institutional ethics committee approval has been obtained. After obtaining informed consent, information was collected regarding acceptance and quality of life with Mirena for AUB(A) and AUB(E) using the WHOQOL-BREF questionnaire from the study participants. In this study, 143 patients came with the history of AUB. Out of which 21 patients agreed for surgery and 122 patients were under conservative medical management. Among them 16 patients had MIRENA for AUB(A) and AUB(E). **CONCLUSION:** Mirena effectively manages AUB by reducing bleeding and improving quality of life, making it a well-accepted alternative to surgical treatments. Enhancing awareness and addressing patient concerns can further improve acceptance and satisfaction with its use.

## INTRODUCTION

Abnormal Uterine Bleeding (AUB) is a prevalent gynaecological condition that significantly impacts women's physical, emotional and social well-being. It encompasses a spectrum of menstrual irregularities, including Heavy Menstrual Bleeding (HMB), intermenstrual bleeding and irregular cycles, often leading to anaemia and diminished Quality of Life (QOL). The International Federation of Gynaecology and Obstetrics (FIGO) classifies AUB into structural (PALM) and non-structural (COEIN) causes. Among these, AUB-A (adenomyosis) and AUB-E (endometrial dysfunction) are particularly challenging due to their complex pathophysiology and the limitations of conventional treatments<sup>[1]</sup>.

Adenomyosis, characterized by the presence of endometrial tissue within the myometrium, often results in HMB and dysmenorrhea. Traditional management strategies, such as hysterectomy, while effective, are invasive and not suitable for women desiring uterine preservation. Similarly, AUB-E, which lacks identifiable structural pathology, poses diagnostic and therapeutic dilemmas. Hormonal therapies, though commonly employed, may have systemic side effects and variable efficacy<sup>[2]</sup>.

The Levonorgestrel-releasing Intrauterine System (LNG-IUS), commercially known as Mirena, has emerged as a promising therapeutic option for AUB. Initially developed for contraception, Mirena delivers a localized dose of levonorgestrel, leading to endometrial suppression and reduced menstrual blood loss. Its efficacy in managing AUB has been substantiated by numerous studies. For instance, a study demonstrated that Mirena significantly reduced endometrial thickness and menstrual volume, leading to improved hemoglobin levels and QoL scores in perimenopausal women with AUB<sup>[3,4]</sup>.

Furthermore, Mirena's role in enhancing QoL extends beyond the physical domain. Research indicates that women using Mirena report improvements in general health, energy levels and emotional well-being. A study highlighted that women using Mirena had higher QoL parameters compared to those using other intrauterine devices or no contraception, with notable improvements in sexual functioning<sup>[5,6]</sup>.

Patient satisfaction is a critical determinant of treatment adherence and success. A multicentric study in India reported that approximately 80% of women using Mirena for AUB were satisfied with the treatment and 73.8% would recommend it to others.<sup>4</sup> Similarly, another study found that 86.66% of women were very satisfied with Mirena, citing significant improvements in bleeding patterns and hemoglobin levels<sup>[6,7]</sup>.

Despite these positive outcomes, the acceptance of Mirena varies among different populations, influenced by factors such as cultural beliefs, awareness and access to healthcare services. Understanding these nuances is essential for optimising patient-centred care. This study aims to evaluate the acceptance and QOL outcomes associated with Mirena use in women with AUB-A and AUB-E. By synthesising current evidence and assessing patient-reported outcomes, we seek to provide insights into the efficacy, safety and acceptability of Mirena as a therapeutic modality for AUB.

**Objectives:** To study the acceptance and quality of living of Mirena intrauterine device (IUD) for AUB(A) & AUB(E) among patients with Abnormal Uterine Bleeding.

## MATERIALS AND METHODS

This is an observational study focused on female patients experiencing Abnormal Uterine Bleeding (AUB). Here's a breakdown of the key components:

- **Study population:** The research involved 143 female patients diagnosed with AUB. This condition can manifest in various forms, characterized by menstrual bleeding that differs from the normal pattern in terms of frequency, duration, or volume
- **Study setting:** The study was conducted in an outpatient department at a tertiary care hospital. Tertiary care hospitals typically offer specialized medical services and cater to complex cases, which adds credibility to the study's context
- **Ethical considerations:** Prior to commencing the study, approval was secured from the institutional ethics committee. This is an essential step in medical research to ensure that the rights and well-being of participants are protected. It indicates that the study adheres to ethical guidelines and standards
- **Informed consent:** Researchers obtained informed consent from all participants. This means that each participant was fully informed about the study's purpose, procedures, risks and benefits before agreeing to take part. Informed consent is a critical requirement in ethical research practices
- **Data collection:** Information was gathered regarding the participants' acceptance of the Mirena device, which is an Intrauterine Device (IUD) used for birth control and management of heavy menstrual bleeding. The study specifically looked at two types of AUB:

- **AUB(A):** Abnormal Uterine Bleeding associated with an anatomical cause.
- **AUB(E):** Abnormal Uterine Bleeding that is primarily due to an endocrinological issue
- **Quality of life assessment:** The study aimed to assess the quality of life of participants using Mirena for managing their AUB. This aspect highlights the importance of understanding how a medical intervention impacts a patient’s overall well-being, beyond just clinical outcomes
- **Methodology:** Data was collected using a semi-structured questionnaire, which allows for both fixed and open-ended responses. This methodology enables researchers to gather quantitative data while also exploring in-depth qualitative insights from participants regarding their experiences with the Mirena device

This study is designed to evaluate the experience of women using Mirena for the treatment of AUB, focusing on two subtypes of the condition, while ensuring ethical standards are maintained throughout the research process. The findings could help inform clinical practices and improve care for women experiencing this common gynecological issue.

**RESULTS AND DISCUSSION**

The above table gives the age distribution of AUB(A) and AUB(E), where most of the patients belong to the age group of 30-39, 50-59 and 40-49, respectively.

Table 1 and 2 gives the age distribution of AUB(A) and AUB(E) and patients with MIRENA, where most of the patients belong to the age group of 40-49 and 30-39 respectively.

Figure 1a and b reveal that a significant majority of patients with Abnormal Uterine Bleeding (AUB), specifically 85.3%, opted for conservative medical management over surgical intervention and 13.1% were MIRENA users. This preference highlights a strong inclination among patients towards less invasive treatment options. Factors influencing this choice likely include concerns about surgical risks, financial constraints, longer recovery periods and individual or cultural preferences that favor non-surgical approaches when effective alternatives are available.

Table 3-6 and Fig. 2-3 from the study findings reveal the changes before and after treatment (LNG-IUS Insertion) using MMAS, SF-36, PBAC and WHOQOL-BREF Scores and also gives the comparison of costs for 5 years.

In this study, a total of 143 patients presented with a condition known as abnormal uterine bleeding (AUB). This condition can manifest as heavy bleeding, prolonged bleeding, or bleeding between menstrual cycles and can be caused by various factors, including hormonal imbalances, fibroids, or other underlying health issues.

Out of these 143 patients, only 21 decided to undergo surgical intervention to address their

Table 1: Age distribution AUB(A) and AUB(E)

| Age distribution (years) | Number ( n=143) | Percentage |
|--------------------------|-----------------|------------|
| 20-29                    | 28              | 19.6       |
| 30-39                    | 41              | 28.7       |
| 40-49                    | 36              | 25.2       |
| 50-59                    | 38              | 26.5       |
| 60-69                    | 0               | 0          |

Table 2: Age Distribution in patients with MIRENA

| Age distribution (years) | Number (n = 16) | Percentage |
|--------------------------|-----------------|------------|
| 20-29                    | 1               | 6.25       |
| 30-39                    | 5               | 31.25      |
| 40-49                    | 10              | 62.5       |
| 50-59                    | 0               | 0          |

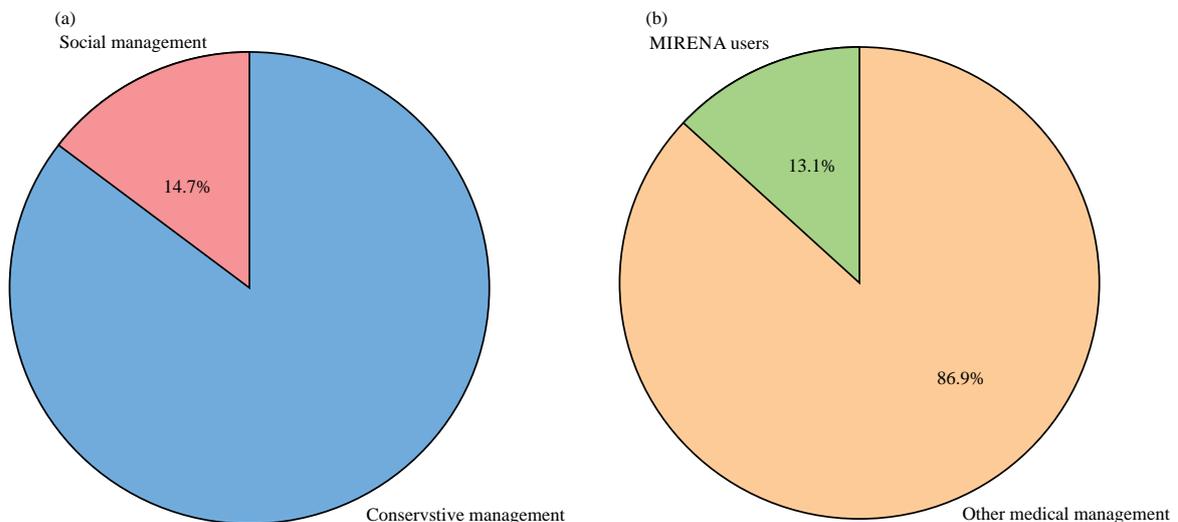


Fig. 1(a-b): Treatment choices and conservative management breakdown among AUB patients (a) Treatment choice among AUB patients and (b) Conservative management breakdown

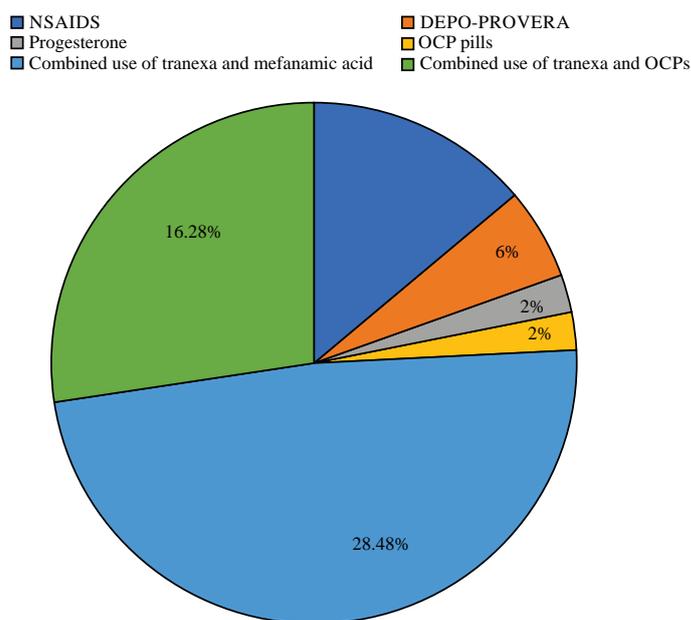


Fig. 2: Conservative management breakdown among AUB patients

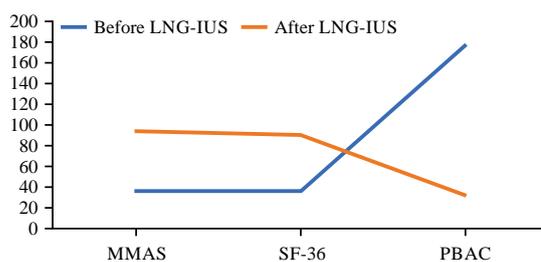


Fig. 3: Line diagram depicting the changes in different score means before and after LNG-IUS insertion

Table 3: Treatment Approaches Among Patients with Abnormal Uterine Bleeding (AUB)

| Category                          | Number of Patients         | Percentage (%)                                       |
|-----------------------------------|----------------------------|--|
| Total patients with AUB (n=143)   | AUB(A) = 75<br>AUB(E) = 68 | AUB(A) = 52%<br>AUB(E) = 47%                         |
| Opted for surgical management     | 21                         | 14.7%  |
| Opted for conservative management | 122                        | 85.3%  |
| Using MIRENA IUD                  | 16                         | 11.2% (of total) / 13.1% (of conservatively managed) |
| Other medical management          | 106                        | 74.1% (of total) / 86.9% (of conservatively managed) |

Table 4: Changes in MMAS, SF-36 and PBAC scores before and after LNG-IUS Insertion

| Measure | Before treatment | After treatment | Mean change | t-value | p-value |
|---------|------------------|-----------------|-------------|---------|---------|
| MMAS    | 36.73±8.11       | 93.72±9.24      | +56.99      | 45.30   | <0.001  |
| SF-36   | 35.33±7.82       | 90.54±8.36      | +55.21      | 44.98   | <0.001  |
| PBAC    | 176.36±28.02     | 32.19±14.67     | -144.16     | -50.49  | <0.001  |

Table 5: WHOQOL-BREF Score before and after treatment

| Group             | Before treatment | After treatment | Mean change | t-value | p-value |
|-------------------|------------------|-----------------|-------------|---------|---------|
| Control (n = 61)  | 69.23±8.37       | 82.09±10.47     | +12.86      | ≈ 7.50  | <0.001  |
| Research (n = 61) | 69.18±8.42       | 102.25±11.01    | +33.07      | ≈ 18.65 | <0.001  |
| t-value           | 0.027            | ≈ 10.38         |             |         |         |
| p-value           | 0.979            | < 0.001         |             |         |         |

Table 6: Comparison of costs - 5 years

| Mirena   | Tranexamic acid | Hysterectomy        |
|----------|-----------------|---------------------|
| Rs. 5000 | Rs. 20,500      | Rs.50,000 to 1 Lakh |

approaches can include hormone therapy, medications to control bleeding, or lifestyle changes to improve overall health.

symptoms. The remaining 122 patients opted for conservative management, which typically involves medical treatment rather than surgery. Conservative

Among the patients who were under conservative medical management, 16 were using MIRENA, which is a type of Intrauterine Device (IUD) that releases the

hormone levonorgestrel. MIRENA is often used to treat AUB by thinning the uterine lining and reducing menstrual flow. The use of MIRENA is specifically targeted at patients experiencing AUB related to various causes, helping to alleviate symptoms effectively while avoiding the need for surgical procedures.

Overall, the study highlights the options available for managing AUB, emphasizing that while some patients may require surgery, many can achieve satisfactory outcomes with medical management, including the use of devices like MIRENA.

**Effective management of AUB:** Abnormal uterine bleeding is a condition that can significantly impact a woman's quality of life, causing discomfort, embarrassment and health concerns. Mirena helps in managing AUB by gradually thinning the uterine lining and reducing menstrual blood loss. This makes it a viable option for women looking for non-surgical methods to control their bleeding<sup>[8,9]</sup>.

**Improving quality of life:** By effectively reducing bleeding episodes, Mirena can lead to improved daily functioning and emotional well-being for women experiencing AUB. Many users report fewer menstrual cramps, less fatigue and a decrease in the need for excessive sanitary products, which can enhance overall quality of life<sup>[10-14]</sup>.

**Alternative to Surgical Treatments:** Traditionally, women with severe AUB might have been advised to consider surgical interventions such as endometrial ablation or hysterectomy. The advent of Mirena offers a less invasive alternative that can be just as effective. This is particularly appealing to women who wish to avoid the potential complications or recovery times associated with surgical procedures<sup>[15-16]</sup>.

**Enhancing awareness:** The text suggests that increasing awareness about Mirena and its benefits is crucial. Many women may not be aware of the options available to them or might have misconceptions about the IUD. Educational efforts could include discussions with healthcare providers and informational resources that clarify how Mirena works, its benefits and any potential side effects<sup>[17-18]</sup>.

**Addressing patient concerns:** Patient satisfaction with any medical treatment often depends on how well their concerns and questions are addressed. This could include discussing how Mirena might affect hormonal balance, what side effects to expect and the effectiveness of the device in managing AUB. Open communication can lead to better-informed patients who feel more confident in their treatment choices<sup>[19]</sup>.

**Improvement in acceptance and satisfaction:** By enhancing awareness and addressing concerns, healthcare providers can help improve how well Mirena is accepted among patients. The goal is to ensure that women feel empowered in their health decisions, leading to higher satisfaction rates with the treatment they choose<sup>[20]</sup>.

Despite the preference for conservative management, the use of MIRENA, a levonorgestrel-releasing intrauterine system, remained relatively low. Only 16 out of the 122 patients (13.1%) who chose medical management utilized MIRENA. This limited adoption is noteworthy given the device's proven effectiveness in reducing menstrual blood loss, controlling symptoms of AUB and improving quality of life. Possible reasons for this underuse include a general lack of awareness among patients, misconceptions or fear surrounding intrauterine devices and issues related to cost, availability, or healthcare provider recommendation patterns<sup>[15-17,20]</sup>.

The results suggest a clear opportunity to increase the adoption of MIRENA among eligible patients. As an effective and minimally invasive alternative to surgical intervention, MIRENA has the potential to significantly improve patient outcomes. Enhanced patient education and proactive provider involvement could play a pivotal role in bridging the gap between clinical efficacy and real-world usage. When patients are well-informed about their options, they are more likely to choose interventions that align with both their medical needs and personal preferences<sup>[21-22]</sup>.

The data also highlights the importance of awareness campaigns focused on the benefits and safety profile of MIRENA. Educating patients through counselling sessions, informational materials, or community health programs could dispel common myths and alleviate concerns about hormonal effects or potential side effects. Furthermore, balanced discussions between patients and healthcare providers about the range of available treatment options including both medical and surgical approaches can facilitate more informed and confident decision-making<sup>[20]</sup>.

While conservative methods were favoured, the study also demonstrates that surgical intervention remains a necessary and appropriate option for a subset of patients (14.7%). These cases likely involve individuals with severe or persistent symptoms unresponsive to medical therapies, or those with structural abnormalities such as large fibroids that warrant more definitive treatment. Additionally, some patients may opt for surgery after carefully weighing all options and considering their long-term health goals. Thus, while non-surgical methods are highly effective for many, surgical management continues to have an essential role in comprehensive AUB care<sup>[19-22]</sup>.

The study analysis supports the robust findings reported by Agarwal *et al.*<sup>[23]</sup> showing substantial improvement in both quality of life and bleeding control following LNG-IUS insertion. The MMAS and SF-36 scores increased by 56.99 and 55.21 points, respectively, indicating significant improvements in both disease-specific and general health-related quality of life. The PBAC score decreased by 144.16, demonstrating strong efficacy in reducing menstrual blood loss. These findings align with previous studies such as the ECLIPSE trial and other international cohorts, which have consistently found LNG-IUS to be as effective as, or superior to, surgical interventions for HMB management in selected patients. Given its non-invasive nature, lower complication risk and cost-effectiveness, LNG-IUS should be considered a frontline therapy, especially in settings with limited access to surgical care. This study shows that among 143 individuals clinical improvements would likely be observed even in smaller study populations or local clinic settings, reinforcing the generalizability of these outcomes<sup>[23-26]</sup>.

The study highlights that medical management is the preferred approach for AUB, with MIRENA being a valuable yet underutilised option. There's significant potential to improve patient outcomes by enhancing access, education and support for the use of MIRENA and similar treatments.

## CONCLUSION

The study results show that Mirena is a highly effective, non-surgical option for managing Abnormal Uterine Bleeding (AUB), significantly enhancing women's quality of life. By prioritizing education and open communication, healthcare providers can help improve acceptance and satisfaction with this treatment among patients dealing with AUB.

## STRENGTHS AND LIMITATIONS

This study highlights the treatment preferences of patients with Abnormal Uterine Bleeding (AUB), showing a strong preference for conservative, non-surgical management. It emphasizes the effectiveness of MIRENA, a hormone-releasing intrauterine device, as an alternative to surgery. The findings reveal gaps in awareness and the need for improved patient education, providing healthcare providers with data-driven guidance for better decision-making and treatment satisfaction. This study results does not account for local population variability, adherence differences, or unmeasured confounders. However, limitations include a small sample of MIRENA users, lack of long-term follow-up data and the omission of socioeconomic and cultural factors that could impact treatment choices. Additionally, reliance on patient-reported preferences may introduce selection bias.

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