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Original Research Article

Prospective study on comparison between the efficacy of ulipristal acetate and mifepristone in the management of fibroids in the reproductive age group

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ABSTRACT

Background: Uterine fibroids are the most common benign tumours found in women of reproductive age. Women experience symptoms affecting their quality of life, which include menorrhagia, pelvic pain, and pressure symptoms. In severe cases, fibroid causes infertility and pregnancy complications. Surgical interventions such as hysterectomy and myomectomy are effective, but invasive. Recently, selective progesterone receptor modulators (SPRMs) have emerged for the medical management, which include mifepristone and ulipristal acetate.
Methods: This was a prospective, observational clinical cohort study that enrolled 132 women, 66 in each group of ulipristal and mifepristone, conducted over a period of 18 months. Eligible participants were identified from the Outpatient Department at RIMS.
Results: After treatment, Hb levels increased to 9.9 g/dl (13.8% increase) with Ulipristal acetate and 10.4 g/dl (14.3% increase) with Mifepristone ($p<0.001$). The findings indicate a significant improvement in Hb levels with both treatments, with Mifepristone showing a slightly greater increase. Before treatment, both groups had a similar mean endometrial thickness of 5.8 mm ($p=0.5471$). After treatment, thickness increased significantly to 7.2 mm in the Ulipristal acetate group and 8.7 mm in the Mifepristone group ($p=0.001$).
Conclusions: Mifepristone (25 mg) may be preferable for patients with larger-sized fibroids and anemia. Ulipristal Acetate (5 mg) is beneficial for women having menorrhagia. Endometrial thickness should be regularly assessed in patients. Liver function tests (LFTs) should be performed periodically, particularly for Ulipristal Acetate users.

Keywords: Fibroid, Mifepristone, Ulipristal acetate

INTRODUCTION

Prevalence of uterine fibroids varies globally, with studies showing that up to 70% of women develop fibroids. In India, studies estimate the prevalence of fibroids to be between 30-40% in women of reproductive age.[1] For women with symptomatic fibroids, treatment is often required. For medical management of fibroids, SPRMs, viz., mifepristone and ulipristal acetate (UPA), have emerged as an important drug to reduce the size of myoma and symptoms such as menorrhagia and dysmenorrhoea.[2] This study is novel in its direct comparison of mifepristone and ulipristal acetate for the management of uterine fibroids, specifically within the Indian population.

METHODS

Study design

This was a prospective, observational clinical cohort study, which was conducted among 132 eligible women with newly diagnosed uterine fibroids, who attended the Obstetrics and Gynaecology OPD at RIMS, Ranchi, for a period of 18 months from 2024 to 2025. This study is approved by the institutional ethical committee.

Sample recruitment and procedure

All women with newly diagnosed uterine fibroids in the reproductive age group having symptoms like menorrhagia, dysmenorrhea, infertility, and recent abortions related to fibroid, and those who gave consent to participate in the study were included. Big fibroid (size more than 6 cm by ultrasonography), fibroid with pregnancy, uterine size >10 weeks, coexisting adenomyosis, endometriosis, and adnexal masses, malignancies of uterus/cervix/ovary/vagina/endometrial hyperplasia with atypia, on hormonal medication within 3 months, medical diseases such as liver dysfunction, heart disease, migraine, stroke, renal disease, hypo/ hyperthyroidism, platelet disorders, or coagulopathy, hypersensitivity to the drug were excluded in this study. The purposive sampling method was used for sampling, sample size of 66 participants per group was calculated, resulting in a total sample size of 132 participants.

Data collection procedure

The study tools comprised the following components, which were systematically utilised to collect data and assess outcomes: a detailed history of all participants was recorded at the baseline, which included demographic details, clinical symptoms, including menorrhagia, dysmenorrhea, past medical and surgical history, drug history, including the use of hormonal medications within the past three months, comprehensive general examination, and gynaecological examination were conducted to assess overall health. Laboratory investigations like complete blood count, liver function test, and serology test. Menstrual blood loss assessment using the pictorial blood loss assessment chart (PBAC). Steps included in PBAC: Recording the number of sanitary pads used daily during menstruation. Assigning scores based on the condition of pads: Lightly stained pad: 1 point. Moderately soiled pad: 5 points. Completely saturated pad: 20 points. Adding scores for clots: Small clots: 1 point. Large clots: 5 points. A total score was calculated for each menstrual cycle. A PBAC score ≥100 indicated menorrhagia. High-resolution ultrasonography (USG) with Doppler velocimetry was used to: Measure the size, count and site of fibroids, assess endometrial thickness and vascularity. Fibroids within 5 cm in size were included in the study. Participants were divided into two groups based on the treatment they received: Group U: Participants received ulipristal acetate (5 mg) orally once daily, and Group M: Participants received mifepristone (25 mg) orally once daily, starting on the fourth day of their menstrual cycle for three months.

Follow-up tools

Follow-ups were conducted at three months and six months to reassess improvement in symptoms such as menorrhagia, dysmenorrhea, PBAC scoring to assess changes in menstrual blood loss; Measure fibroid size and number via USG. Monitor haemoglobin levels to assess improvements in anemia. All data were systematically documented in a predesigned case record form.

Statistical analysis

Data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences (SPSS) version 24.0. An independent two-sample test was applied to compare continuous variables.

RESULTS

There were 66 participants in each group, in Group M and Group U. It was observed that most of the candidates (40.91%) in Group M were in the age group 36-40 years, whereas in Group U majority were in the age group 31-35 years (31.82%). In Group M, the majority of participants (60.61%) resided in rural areas. Conversely, in Group U, a larger proportion of participants (68.18%) were from urban areas. In Group M, 30.30% were tribal, while 33.33% in Group U. In Group M (74.24%) and Group U (75.76%), the majority were multipara. The majority of participants belonged to the middle class in Group M (49.94%) and Group U (36.36%). As per literacy, most of the participants in group M (42.42%) and group U (43.94%) were literate up to secondary education (Table 1).

Table 1: Sociodemographic variables among Group M and Group U.

Variables	Group M (n=66), N (%)	Group U (n=66), N (%)
Age (in years)		
21-25	8 (12.12)	10 (15.15)
26-30	13 (19.70)	18 (27.27)
31-35	18 (27.27)	21 (31.82)
36-40	27 (40.91)	17 (25.76)
Place of residence		
Rural	40 (60.61)	21 (31.82)
Urban	26 (39.39)	45 (68.18)
Ethnicity		
Tribal	20 (30.30)	22 (33.33)
Non-tribal	46 (69.70)	44 (66.67)
Parity		
Nullipara	17 (25.76)	16 (24.24)
Multipara	49 (74.24)	66 (75.76)
Socio-economic class		
Upper middle	7 (10.61)	11 (16.67)
Low middle	26 (39.39)	16 (24.24)
Middle	29 (49.94)	24 (36.36)
Lower	4 (6.06)	15 (22.73)
Literacy		
Primary education	18 (27.27)	20 (30.30)
Secondary education	28 (42.42)	29 (43.94)
Graduates and above	15 (22.73)	15 (22.73)
No formal education	5 (7.58)	2 (3.03)

In Group M, the most common primary complaints were menorrhagia (24.2%) and intermenstrual bleeding (24.2%). In Group U, menorrhagia (28.78%) was the most frequent complaint, followed by intermenstrual bleeding (22.7%) (Table 2).

Table 2: Distribution of study participants among primary complaints.

Primary complaints	Group M (n=66), N (%)	Group U (n=66), N (%)	Total, N (%)
Dysmenorrhea	8 (12.1)	10 (15.2)	18 (13.6)
Menorrhagia	16 (24.2)	19 (28.78)	35 (26.52)
Intermenstrual bleeding	16 (24.2)	15 (22.7)	31 (23.5)
Lower abdominal pain	15 (22.7)	12 (18.2)	27 (20.5)
Recurrent pregnancy loss	11 (16.7)	10 (15.2)	21 (15.9)

Table 3: Association between PBAC, size of fibroid, and endometrial thickness before and after treatment.

Parameters	Ulipristal acetate (5 mg)	Mifepristone (25 mg)	P value
PBAC before treatment			
Mean (SD)	260.8 (13.0)	155.8 (12.9)	<0.001
Range	221.0-290.0	116.0-185.0	
PBAC after treatment			
Mean (SD)	235.8 (13.0)	93.8 (12.9)	<0.001
Range	196.0-265.0	54.0-123.0	
Size of fibroid before treatment			
Mean (SD)	5.0 (0.7)	4.0 (0.7)	<0.001
Range	3.0-6.0	2.0-5.0	
Size of fibroid after treatment			
Mean (SD)	3.8 (0.8)	2.7 (0.8)	<0.001
Range	2.0-5.0	1.0-4.0	
Endometrial thickness before treatment			
Mean (SD)	5.8 (1.0)	5.8 (1.1)	0.5471
Range	5.0-8.0	3.0-9.0	
Endometrial thickness after treatment			
Mean (SD)	7.2 (2.2)	8.7 (2.5)	0.001
Range	5.0-12.0	3.0-12.0	

Before treatment, the mean PBAC score was higher in the Ulipristal acetate group (260.8±13.0) than in the Mifepristone group (155.8±12.9). After treatment, the scores decreased to 235.8±13.0 and 93.8±12.9, respectively. Mifepristone (25 mg) showed a greater reduction in menstrual blood loss compared to Ulipristal acetate (5 mg). Before treatment, the mean fibroid size was 5.0 cm in the Ulipristal acetate group and 4.0 cm in the Mifepristone group. After treatment, the sizes decreased to 3.8 cm and 2.7 cm, respectively. There was a significant reduction in PBAC scores and fibroid size after treatment in both groups ($p<0.001$). Compared to ulipristal acetate (5 mg), mifepristone showed significant reduction in fibroid size and amount of menstrual blood loss. Before treatment mean thickness of the endometrium was 5.8 mm ($p=0.5471$) in both groups. Post-treatment thickness increased to 7.2mm in the group treated with ulipristal acetate and 8.7mm in the group treated with mifepristone ($p=0.001$) (Table 3).

Pretreatment, the mean haemoglobin (HB) was 8.7 g/dl in the ulipristal acetate group, which increased to 9.9 g/dl (13.8% increase) after treatment. In the group treated with mifepristone mean HB was 9.1 g/dl, which increased to 10.4 g/dl (14.3% increase) after treatment. Before treatment, 95.4% in the Ulipristal acetate group and 95.5% in the Mifepristone group had normal LFTs, with no significant difference ($p=0.9761$). After treatment, deranged LFT was observed 9.2% and 6.1%, respectively in both groups ($p=0.7591$) (Table 4).

Table 4: Significant blood investigations before and after treatment.

Parameters	Ulipristal acetate (5 mg) (n=66)	Mifepristone (25 mg) (n=66)	P value
HB before treatment			
Mean (SD)	8.7 (0.5)	9.1 (0.4)	<0.001
Range	8.2 - 9.5	8.6 - 9.9	
HB after treatment			
Mean (SD)	9.9 (0.5)	10.4 (0.5)	<0.001
Range	9.4 - 10.7	8.9 - 11.2	
LFT before treatment, Frequency (%)			
Normal	62.0 (95.4)	63.0 (95.5)	0.9761
Abnormal	3.0 (4.6)	3.0 (4.5)	
LFT after treatment, Frequency (%)			
Normal	59 (90.8)	62 (93.9)	0.7591
Abnormal	6 (9.2)	4 (6.1)	

Abbreviations: HB=Haemoglobin, LFT=Liver function test

Symptoms improved after 3 months of treatment in both groups. Menorrhagia improved in 69.7% in Ulipristal vs. 63.6% in Mifepristone, $p=0.17$. Dysmenorrhea improved in 63.6% in Ulipristal vs. 62.1% in Mifepristone, $p=0.17$. Worsening of symptoms was slightly higher in the Ulipristal group (10.6%) compared to Mifepristone (4.5%). At 6 months, both medicines caused significant symptom improvement, which was not statistically significant ($p>0.05$). Menorrhagia and dysmenorrhea improved in 74.2% in Ulipristal vs. 69.7% in Mifepristone, $p = 0.17$. Worsening of symptoms remained at 7.6% across all categories (Table 5).

Table 5: Association between Medication administration and symptom improvement after 3 months and 6 months.

Groups	Symptoms improvement, N (%)					
	Improved		No change		Worsened	
	Menorrhagia					
	After 3 months	After 6 months	After 3 months	After 6 months	After 3 months	After 6 months
Group M (n=16)	10 (63.6)	11 (69.7)	5 (31.8)	4 (25.8)	1 (4.5)	1 (4.5)
Group U (n=19)	13 (69.7)	14 (74.2)	3 (19.7)	4 (15.2)	3 (10.6)	1 (10.6)
	Dysmenorrhoea					
Group M (n=8)	5 (62.1)	5 (69.7)	3 (33.3)	2 (25.8)	1 (4.5)	1 (4.5)
Group U (n=10)	6 (63.6)	7 (74.2)	3 (25.8)	2 (15.2)	1 (10.6)	1 (10.6)
	Lower Abdominal Pain					
Group M (n=15)	8 (53.0)	9 (60.6)	6 (42.4)	5 (34.8)	1 (4.5)	1 (4.5)
Group U (n=12)	7 (59.1)	8 (65.2)	4 (30.3)	3 (24.2)	1 (10.6)	1 (10.6)

DISCUSSION

The current study found that the highest proportion of fibroid patients treated with UPA and Mifepristone were in the 31-40 age range, consistent with findings from Hadi et al and Islam et al, which reported optimal efficacy in this age group.[3,4] However, other studies, such as Pohl et al, suggested age alone is not the primary factor, and fibroid size or hormonal differences may be more significant.[5] It was observed that women belonging to urban areas took ulipristal acetate, whereas there was dominance of rural participants in mifepristone. This aligns with research by Glass Lewis & Ekúndayọ̀ et al in 2017, who highlight disparities in healthcare access affecting fibroid treatment choices.[6] Murji et al and Lee et al in 2020 and 2009 found that urban populations are more likely to receive newer treatments like UPA due to better healthcare infrastructure.[7,8] The study found a higher proportion of non-tribal participants in both Ulipristal Acetate and Mifepristone groups, consistent with research indicating ethnic variations in fibroid treatment. Murji et al and Orellana et al in 2020 and 2022 reported that ethnic groups experience different fibroid burdens and treatment pathways, with non-minority groups often receiving earlier interventions.[7,9] Additionally, Murji et al in 2020 found that UPA response varied among ethnicities due to hormonal and genetic differences.[7] The study found a higher prevalence of multiparous participants in both treatment groups, aligning with research suggesting that parity influences fibroid development and treatment response. Millien et al and Marsh et al in 2021 and 2018 reported that multiparity may reduce fibroid complications due to postpartum uterine involution.[10,11] However, Henshaw et al in 2022 noted that fibroids still affect fertility, leading some nulliparous women to seek treatment earlier.[12] The study found that most participants belonged to the middle and low-middle socioeconomic classes, impacting fibroid treatment accessibility. Evans & Jones et al and VanNoy et al in 2024 and 2021 found that higher-income women had better access to advanced treatments, while lower-income women faced barriers.[13,14] However, Sekula et al and Millien et al in 2022 and 2021 suggested that healthcare access and health literacy play a larger role than socioeconomic status alone in determining treatment.[15,10] The study found that most participants had secondary education, followed by primary, higher, and no formal education. Research suggests education impacts fibroid awareness and treatment. Jones et al in 2024 found that higher education improves access to early diagnosis and treatment.[13] The most frequently reported symptoms were menorrhagia (26.52%), intermenstrual bleeding (23.50%), and lower abdominal pain (20.50%), followed by recurrent pregnancy loss (15.90%). A study by Rakshit et al in 2022 found similar results, reporting that menorrhagia and intermenstrual bleeding were the most prevalent complaints among fibroid patients, affecting nearly half of the study population.[16] Additionally, Singh et al in 2021 noted that excessive menstrual bleeding was the leading symptom requiring intervention, with a significant percentage of patients experiencing dysmenorrhea and chronic pelvic pain.[17] Contrasting findings were observed in a study by Dahiya et al in 2019, which reported that lower abdominal pain was the primary complaint, followed by irregular menstrual cycles, indicating possible regional or demographic variations in fibroid symptomatology.[18] PBAC scores before and after treatment with Ulipristal Acetate and Mifepristone provide valuable insights into the comparative effectiveness of these medications in reducing menstrual blood loss in fibroid patients. PBAC score after 3 months of treatment with both medications showed effectiveness in managing menorrhagia ($p<0.001$). In the group treated with ulipristal, the PBAC score was higher (260.8±13.0) compared to the mifepristone group (155.8±12.9), which suggests greater baseline severity of bleeding in the ulipristal group. The mean PBAC score reduced significantly in both groups; ulipristal showed a mean reduction to (235.8±13.0) while mifepristone showed a more substantial reduction (93.8±12.9). This suggests that mifepristone was more potent in reducing blood loss. These findings were similar to Rakshit et al, and Singh et al in 2021 observed that mifepristone was more effective in reducing menstrual blood loss when compared to ulipristal acetate.[16,17] He attributed the improvement of

menorrhagia to the antiprogesterone mechanism of mifepristone. However, Dahiya et al observed a more stable reduction in menstrual blood loss over time with ulipristal acetate.[18] The present study confirms that both drugs are effective in reducing menorrhagia, but mifepristone significantly reduces PBAC score, suggesting it may be preferred for those patients who are worried about menorrhagia. There is a significant correction in anaemia in both groups, post-treatment. Both drugs showed their role in reducing menstrual blood loss and improving iron stores. In the group treated with ulipristal mean Hb level was (8.7±0.5 g/dl), which increased to (9.1±0.4 g/dl), showing a notable improvement. The second group treated with mifepristone had a mean Hb (9.9±0.5 g/dl), which increased to (10.4±0.5 g/dl) after 3 months of treatment. Mifepristone has a greater impact on reducing menstrual blood loss, so more effective in increasing haemoglobin level. Our observations are similar to Rakshit et al in 2022, who concluded that due to the strong antiprogesterone effect of mifepristone, menstrual blood loss reduces significantly in women treated with this drug.[16] Singh et al in 2021, have also reported mifepristone as a more effective drug in preventing decline in iron levels.[17] A decrease in fibroid size after treatment with ulipristal and mifepristone was significant, observed in our results. Pre-treatment mean fibroid size in the ulipristal group (5.0±0.7 cm), which reduced to (3.8±0.8 cm) after 3 months of treatment. In group M, the size of fibroid (4.0±0.7) which reduced to (2.7±0.8 cm) post-treatment. This suggests that ulipristal has a stronger impact on reducing the fibroid size. Rakshit et al in 2022 reported a higher rate of fibroid size reduction with mifepristone when compared to ulipristal acetate.[16] Dahiya et al in 2019 have observed that while both the drug reduces fibroid size effectively, endometrial thickening is increased in the mifepristone group.[18] Our study observes a statistically significant increase in endometrial thickness after treatment with ulipristal and mifepristone. Pre-treatment, the mean endometrial thickness was (5.8±1.0 mm for Ulipristal vs. 5.8±1.1 mm for Mifepristone) in both groups. After 3 months of treatment, the mean endometrial thickness (7.2±2.2 mm) in the group treated with ulipristal and women treated with mifepristone showed an increase in endometrial thickness to (8.7±2.5 mm), suggesting that mifepristone is more notorious in increasing the endometrial thickness. Our results are similar to Rakshit et al in 2022, who observed that both medications lead to an increase in endometrial thickness due to the selective progesterone receptor modulator effect.[16] Singh et al in 2021 also observed similar findings in their study.[17] LFT abnormalities were rare in both groups, with no significant difference pre- and post-treatment (p=0.9761 before, p=0.7591 after). Before treatment, 4.5% of participants had abnormal LFT values, which slightly increased to 7.6% post-treatment. These findings indicate that both medications have a low but potential risk of affecting liver function. These results support previous studies, such as Rakshit et al in 2022, which found that while Ulipristal Acetate has been associated with rare instances of hepatotoxicity, clinically significant LFT abnormalities remain uncommon.[16] The association between medication administration and symptom improvement at 3 and 6 months provides insight into the comparative effectiveness of Mifepristone (25 mg) and Ulipristal Acetate (5 mg) for symptom relief. The findings indicate that both medications significantly reduce menorrhagia, dysmenorrhea, and abdominal pain, with Ulipristal Acetate showing slightly higher improvement rates in most categories. However, the differences between the two drugs were not statistically significant (p>0.05), suggesting comparable efficacy. At 3 months, 66.7% of patients reported improvement in menorrhagia, with 69.7% improvement in the Ulipristal group compared to 63.6% in the Mifepristone group (p=0.17). By 6 months, the proportion of improved cases increased to 74.2% in the Ulipristal group and 69.7% in the Mifepristone group (p=0.17). While Ulipristal showed a slightly higher improvement rate, the difference was not statistically significant. These findings align with Rakshit et al in 2019, who found that both medications effectively reduced menstrual bleeding, but Ulipristal had a slightly higher impact in controlling menorrhagia over time.[16] Contrastingly, Dahiya et al in 2019 found that Mifepristone was more effective at completely suppressing menstrual cycles, which some patients preferred, whereas Ulipristal provided more controlled bleeding reduction without full suppression.[18] At 3 months, dysmenorrhea improved in 63.6% of Ulipristal users compared to 62.1% of Mifepristone users (p=0.17). By 6 months, 74.2% of Ulipristal patients and 69.7% of Mifepristone patients reported improvement (p=0.17). These findings are consistent with Singh et al in 2021, who reported similar dysmenorrhea reduction rates with both medications.[17] However, Dahiya et al in 2019 found that Mifepristone led to a greater reduction in pelvic pain and dysmenorrhea, possibly due to its stronger anti-progesterone effects on fibroid-related pain pathways.[18] At 3 months, abdominal pain improved in 59.1% of Group U and 53.0% of Group M (p=0.23). By 6 months, the improvement rates were 65.2% for Ulipristal and 60.6% for Mifepristone (p=0.23). These findings align with Rakshit et al in 2022, who found that Ulipristal provided a slightly better reduction in pelvic pain compared to Mifepristone, though the difference was not statistically significant.[16] However, Dahiya et al in 2019 suggested that Mifepristone was more effective for pain relief.[18]

CONCLUSION

On comparing the effects of mifepristone and ulipristal acetate on fibroid management, it shows that both medicines are effective in reducing the symptoms and size of fibroids. Ulipristal acetate was more effective in reducing the size of fibroids, but mifepristone caused rapid improvement in symptoms such as menorrhagia and dysmenorrhea. Endometrial thickness was increased in women treated with mifepristone compared to ulipristal acetate. Overall, both drugs are a good non-surgical option for fibroids in women not willing to undergo surgery.

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