ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 8, Issue – 3, June - 2025, Page No.: 277 – 281

A Prospective Interventional Study on Efficacy of Mifepristone in The MedicalManagement of Uterine Leiomyomas

[1]Dr. Indira H, Professor and HOD, Department of Obstetrics and Gynaecology, Sri Siddhartha Medical College and Hospital, Tumkur, Karnataka.

[2]Dr. Priyanka Patel, Post Graduate, Department of Obstetrics and Gynaecology, Sri Siddhartha Medical College and Hospital, Tumkur, Karnataka.

[3]Dr. Subhash Choudhary, Post Graduate, Department of Radiology, Mahatma Gandhi hospital, Jaipur.

[4]Dr. Riyaj Ahmed Kalaburgi, Associate Professor/Statistician, Department of Community Medicine, Sri Siddhartha Medical College, Tumkuru, Karnataka.

Corresponding Author: Dr. Indira H, Professor and HOD, Department of Obstetrics and Gynaecology, Sri Siddhartha Medical College and Hospital, Tumkur, Karnataka.

How to citation this article: Dr. Indira H, Dr. Priyanka Patel, Dr. Subhash Choudhary, Dr. Riyaj Ahmed Kalaburgi "A Prospective Interventional Study on Efficacy of Mifepristone in The Medical Management of Uterine Leiomyomas", IJMACR- June - 2025, Volume – 8, Issue - 3, P. No. 277 – 281.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Medical treatment with T. Mifepristone 25mg is an effective method in reducing size, number, volume of myomas and decreasing amount of blood loss, regression of symptoms and decreasing number of surgery.

Objective

- To determine the efficacy of Mifepristone in the medical management ofuterine leiomyomas.
- To assess the need of surgicalmanagement.

Methods: It is a prospective interventional study conducted at Sri Sidharatha Medical Collage, Tumkuru. The effects of Mifepristone 25mg administrations for 3 months was carried out after satisfying inclusion and exclusion criteria, relevant medical history and general physical examination and systemic examination was done. All the patients were subjected to ultrasound abdomen and pelvis to know the location, size, number, volume of myomas and endometrial thickness before the start of treatment

Results: There was a statistically significant increase in Hemoglobin after treatment ($P < 0.001$) and significant reduction in fibroid size post-treatment ($P< 0.001$).

Conclusion: Mifepristone 25mg showed significant reduction in size, volume and improvement in symptoms in a woman with uterine leiomyomas.

Keywords: Mifepristone**,** Leiomyomas, Myoma, Hysterectomy

Introduction

Uterine fibroids are also known as uterine leiomyomas, are the most common beingn monoclonal smooth muscles cell tumors. Uterine fibroids are common in reproductive age group occurring in 20-50% of women with maximum incidence between 35-45 years of age. The exact etiology is debatable, but the risk factors include younger age at menarche, obesity, nulliparity and African race. They are responsible for 27% of gynecological admissions and are the most frequent indication for hysterectomy. Aim was to know the efficacy of medical management with Mifepristrone25mg in a woman with 30-45years of age group. Mifepristone is a synthetic estrange steroid with an anti-progestogen activity. As progesterone is needed for leiomyoma growth, Mifepristone in low dose has been found effective for decreasing the size of myoma and to reduce blood loss. Majority of the women with myomas are asymptomatic. Women with symptomatic fibroids presents with abnormal uterine bleeding, dysmenorrhea, dyspareunia, infertility, pressure symptoms, recurrent pregnancy loss, lower abdominal pain and abdominal enlargement. Management of uterine fibroids depends upon age, symptoms, size and site of fibroid and fertility status. It can be expectant, medical or surgical. Medical therapy includes Nonsteroidal anti-inflammatory drugs, tranexamic acid, gonadotropin-releasing hormone agonists, gonadotropin-releasing hormone antagonists, Anti-progesterone drugs like mifepristone, ulipristal acetate and progesterone releasing intrauterine device [(1)]

Histologically, fibroids are benign neoplasms composed of disordered smooth-muscle cells buried in abundant quantities of extracellular matrix. The precise molecular basis of leiomyoma pathogenesis is unknown, the importance of 17β-estradiol (E2) and progesterone (P4) in the etiology of Uterine leiomyomata is well established. Estrogen is believed to be very important in the pathogenesis of a leiomyoma; however, only progesterone induces mitotic activity in these tumors. [(2)]

Material and Methods

The study was carried out as a prospective interventional study, the effects of Mifepristone 25mg administrations for 3 months was carried out after satisfying inclusion and exclusion criteria. An informed consent was obtained from all the participants enrolled in the study. After enrollment, relevant medical history and general physical examination and systemic examination was done. All the patients were subjected to ultrasound abdomen and pelvis to know the location, size number, volume of myomas and endometrial thickness before the start of treatment. After 3months of Mifepristrone 25mg, cases were followed up for the next 5months. The outcome measures was analysed using appropriate statistical methods with regard to change in volume and number of leiomyomas and the regression of symptoms.

Objective

- To determine the efficacy of Mifepristone in the medical management of uterine leiomyomas.
- To assess the need of surgical management.

Inclusion Criteria's

1) Patients of age >18years
2) Symptomatic patients diagnosed with fibroid with size <5cm

3) Patients willing for ultrasound examination during follow-up.

Exclusion Criteria

1. Adenomyosis
2. Endometriosis
3. Adnexal masses
4. Liver or renal dysfunction
5. Current genital infection
6. Hormonal medication taken within 3months
7. Fibroids >5cm or > 12weeks size on Per abdomen
8. Endometrial hyperplasia with atypia
9. Women desiring pregnancy or already pregnant
10. Pelvic Inflammatory Disease
11. Uterine Malignancy
12. Patients who are lost to follow up.

Result

Table 1: Age Distribution

Age in years	Frequency	Percent
30-35	8	18.2
36-40	17	38.6
41-45	15	34.1
46-50	4	9.1
Total	44	100.0

The age distribution of a sample population comprising 44 individuals. Age Group with 30–35 years included 8 individuals (18.2%) indicating a relatively smaller representation of younger participants. Age Group between 36–40 years include highest frequency 17 individuals which represents 38.6% of the sample. Age Group between 41–45 years is the second highest which include 15 individuals (34.1%). Age Group 46–50 years include 4 individuals (9.1%). The age distribution is skewed towards the middle-aged group (36–45 years), which is the key demographic relevant to the study.

Table 2: Location of Fibroid Determination by Ultrasonography

USG	Frequency	Percent
Intramural	29	65.9
Submucosal	4	9.1
Subserosal	11	25.0
Total	44	100.0

Intramural leiomyomas was found in 29 individuals accounting for 65.9% of the total sample indicating intramural fibroids the most predominant type. Subserosal Fibroids was seen in 11 individuals accounting for 25.0%. Submucosal Fibroids was observed in 4 individuals accounting 9.1% of total sample size. This suggests a lower prevalence of fibroids impacting the endometrial cavity and may have implications on management, as these are more often associated with abnormal uterine bleeding and fertility issues.

Table 3: Statistical Measures of Quantitative Variables:

	Mean±SD	Median (Inter Quartile Range)	Minimum	Maximum
AGE	39.9±4.1	40.0 (36.5-43.0)	30	47
PULSE	80.3±8.5	82.0 (72.5-86.0)	68	98
SBP	116.0±8.9	118.0 (110.0-120.0)	100	132
DBP	78.6+9.0	78.0 (70.0-86.0)	60	98
RR	18.5±1.5	19.0 (18.0-19.0)	16	22
SPO2	98.1±1.0	98.0 (98.0-99.0)	95	100
TSH	2.7±0.7	2.8 (2.1-3.1)	1.2	4.1

The Mean age was 39.9 ± 4.1 years, with a median of 40 years (IQR: 36.5–43). The participants were between 30 and 47 years of age, indicating a relatively middle-aged cohort. Mean pulse was 80.3 ± 8.5 bpm, with a median of 82 bpm (IQR: 72.5–86) reflecting normal resting heart rates.

Mean SBP was 116.0 ± 8.9 mmHg, with a median of 118 mmHg (IQR: 110–120). Minimum and maximum values were 100 and 132 mmHg, respectively, consistent

with normotension in most participants. Mean DBP was 78.6 ± 9.0 mmHg, with a median of 78 mmHg (IQR: 70–86) indicating normal physiological limits.

The mean respiratory rate was 18.5 ± 1.5 breaths/min, with a median of 19 (IQR: 18.0–19.0). The values ranged from 16 to 22 breaths/min, within the normal adult range.

Mean oxygen saturation was 98.1 ± 1.0%, with a median of 98% (IQR: 98.0–99.0). The range of 95–100% suggests adequate oxygenation in most cases.

The mean TSH was 2.7 ± 0.7 µIU/mL, with a median of 2.8 (IQR: 2.1–3.1). The levels ranged from 1.2 to 4.1 µIU/mL, suggesting most values fall within normal reference limits

Table 4: Pre And Post Comparsion of Hb % And Fibroid Size

Parameter		Mean	Std. Deviation	Paired Mean Differences	t-value	P-value
Hb%	Before	10.35	1.07	-0.673	-6.090	<0.001
	After	11.03	1.09			
Fibroid Size	Before	740.50	554.99	510.405	7.375	<0.001
	After	230.10	186.12			

There was a statistically significant increase in Hb% after treatment ($p < 0.001$).

The rise in hemoglobin levels indicates improved hematological status, likely due to reduced amount of blood loss. There was a highly significant reduction in fibroid size post-treatment ($p < 0.001$).

Overall both Hb% increased and fibroid size decreased significantly after the intervention. These results collectively support the clinical effectiveness of the treatment administered in improving patient outcomes.

Discussion

The study comprising 44 subjects, the majority of participants were between 36–45 years of age, with a mean age of 39.9 years, indicating fibroid are most prevalent in women in their late reproductive to perimenopausal age group.

On ultrasonography, intramural fibroids were the most common type (65.9%), followed by subserosal (25%) and submucosal (9.1%) showed statistically significant reduction in volume of fibroid (<0.001). Similarly in a study conducted by Diancui Zhang (2021), Concluded that Patients with uterine leiomyoma with Low-dose mifepristone can reduce uterine leiomyoma volume, reduce adverse. Another study conducted by Dr. Bharati maheshwari (2020) concluded that at the end of 3 months, there was significant reduction in the amount of menorrhagia, dysmenorrhea, abdominal pain, uterine and fibroid volume and improvement in haemoglobin level. Study conducted by Ojaswini yadav (2023) concluded that treatment with 25mg mifepristone daily for 3months, effectively controls bleeding, reduces fibroid volume ameliorates pain and abnormal bleeding, improves hemoglobin.

Vital parameters such as pulse rate, blood pressure, respiratory rate, and oxygen saturation were within normal physiological ranges in most participants. Notably, the mean TSH level was 2.7 µIU/mL, suggesting that thyroid dysfunction was not a contributing factor in this cohort.

Conclusion

Mifepristone offers a valuable non-surgical option for symptomatic management of uterine fibroids, particularly in patients seeking fertility preservation or candidates not fit for surgery. However, its long-term use is limited due to concerns about endometrial hyperplasia.

The early identification and treatment of uterine fibroids can lead to substantial therapeutic benefits, reduce disease burden, and potentially prevent complications related to anemia and mass effects. Further studies with

larger sample sizes and long-term follow-up are recommended to validate and expand upon these findings.

Reference

1. Ojaswini yadav, Amrita Rao, International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2023 Sep; 12(9):2741-2745
2. European Journal of Obstetrics & Gynecology and Reproductive Biology. Volume 303, December 2024, 302-309
3. Gupta, Meeta; Jamwal, Narita; Sabharwal, Sumeet; Sobti, Shalini. A prospective interventional study to evaluate the effects of medical therapy (Mifepristone 25 mg) on the management of uterine fibroids. Journal of Family Medicine and Primary Care 9(7):p 3230-3235, July 2020
4. Saba Rani, Arati Biswas. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2023 Apr;12(4):888-892