Novel management of fibroid with Ulipristal

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Original Research Article

ABSTRACT

Introduction: Fibroid with heavy menstrual bleeding and pain in pre and perimenopause women to reduce it, in reproductive women to relieve symptoms in infertility and in preoperative conditions to reduce size of fibroid, now a days medical therapy is available.

Aim: To determine effectiveness and safety of Ulipristal in symptomatic fibroid by assessing reduction in heavy menstrual bleeding, pain, reduction in size of the fibroid and improvement in activity score

Materials and Methods: This is a Prospective study. Women between 20-45 years both unmarried and married attending gynaec OPD of Saveetha Medical College and hospital with fibroid with symptoms of heavy menstrual bleeding, pain abdomen during period, with Infertility were recruited after ethical Clarence and informed consent. Study was conducted from September 2018 to Dec 2018 first week. Menstrual blood loss was assessed with pictorial blood loss chart (PBAC) and pain was assessed with short form Mc Gill pain questionnaire pain score. After routine investigation including LFT, USG abdomen and Pelvis were done for all subject and mapping of fibroid were done pretreatment and every month and at the end of treatment. Women were given 10 mgs Ulipristal once daily for 13 weeks. Post treatment investigations and USG were repeated.

Results: Women age group between 30-40 years were 86.5%, 20-25 were 6.66% and Nulliparous were 6.66%. Pretreatment 66.66% had PBAC score of 130 and above. None of the women had PBAC <100 before treatment. After 13 weeks treatment Perimenopause women 13.33 % developed amenorrhea. 20% women had PBAC score <100, PBAC score 100-110, in 63.33% of women, PBAC between 111-120 score in 3.33% PABC score between 120 and above were Nil. Fibroid volume reduced between >25 to <50% in 53.33% of size and volume and 10% fibroid disappeared. There is considerable improvement in pain score with p value of 0.0001 and activity score significantly improved with p value of 0.0001.

Conclusions: In all age groups commonest gynaec condition is Fibroid. In the study Ulipristal resulted in, improvement in heavy menstrual bleeding ,pain and considerable reduction in size of the fibroid and thereby improved quality of life

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1. Introduction

Fibroids although benign, are commonly associated with abnormal uterine bleeding Murji A et al.¹ In some women it is asymptomatic but it is the leading cause of hysterectomy. Conversely women do experience symptoms. The most common are increase in menstrual bleeding, known as menorrhagia, sometimes with blood clots, sometimes causes pelvic pain, painful menstruation, infertility, pressure on the bladder, which may cause frequent urination and a sense of urgency to urinate and, rarely, the inability to urinate; pressure on the rectum, resulting in constipation, pelvic pressure, “feeling full” in the lower abdomen, lower abdominal pain. Fibroid can increase up to umbilicus, and/ pelvic mass discovered during a physical examination. Previously it is most preferred therapy was surgery. Now Medical therapy is preferred in symptomatic fibroid, to relieve symptoms in infertility, and in pre and peri
Ulipristal acetate. Jacques Donnez et al. 

bleeding was controlled in 92% of the women who received

assess the reduction in size of fibroid. At the end of 13

every month for symptoms and USG was repeated to

10mgs per day for 13 weeks. Women were evaluated at the

Sonologist was blinded about the study. Women were

fibroid(size, volume, number, situation) and endometrial

after routine investigation including LFT, USG abdomen

2D USG by the Sonologist. Improvement in anaemia was

menopause women, in preoperative conditions to reduce

this oral medication can be used before surgery

to reduce size so that blood loss during surgery will be

and transfusion of blood during surgery will be less

Ulipristal reduces bleeding and achieves amenorrhea. J.

Simon W.H. Catherino et al2 Oral medical management

fibroid is selective progesterone receptor modulator -

Ulipristal acetate (UPA). Simon James et al3 menstrual

bleeding was controlled in 92% of the women who received

10 mg of Ulipristal acetate. Jacques Donnez et al.4 Stated

that other medical therapies like GnRH agonist for fibroids

have limitations. GnRH agonists cause side effects such

as hot flashes and atrophic vaginitis, osteoporosis that

may reduce adherence to therapy and require add back

therapy but Ulipristal is well tolerated Simon JA et al.5

Ulipristal acetate can effectively control bleeding, pain and

reduce fibroid volume, and restore QoL in patients with

symptomatic fibroids Jacques Donnez et al.6 It eliminates

the need for surgery or postpones surgery and has efficacy

equivalent to surgery and cheaper alternative

2. Aim

To determine effectiveness of Ulipristal in symptomatic

fibroid by assessing reduction in heavy menstrual bleeding,

pain and improvement in activity score.

To determine effectiveness of Ulipristal in symptomatic

fibroid by assessing fibroid size number and volume or its

disappearance and to determine its efficacy

3. Materials and Methods

Prospective study conducted at Saveetha Medical College

and hospital Gynaec outpatient Department. Study was

conducted from September 2018 to Dec 2018 first week.

Women between 20- 45 years both unmarried and married

attending gynaec OPD with fibroid with symptoms of heavy

menstrual bleeding (HMB), pain abdomen during period,

with Infertility were recruited after ethical Clarence and

informed consent. Monthly blood loss was assessed with

pic torial blood loss chart (PBAC) and pain was assessed

by short form Mc Gill pain questionnaire pain score.

were assessed at the end of the study. Women were followed up

for drug-free up to 12 weeks

3.1. Inclusion criteria

Women in a ge group between 20 - 45 years, both

married and unmarried with fibroid both symptomatic &

asymptomatic with infertility and perimenopause women

with Pictorial blood loss score more than 100 and Fibroid

size 3cm - 10cm were included

3.2. Exclusion criteria

Women with Liver disease, renal disorders, with comorbid

medical conditions with breast carcinoma and genital

malignancy, with ovarian cyst, with large fibroid polyp,

with endometrial hyperplasia, not willing for the study were

excluded from the study

4. Results

Statistical Analysis was done by mean, percentage analysis

and pair T test for Pre and Post treatment analysis with p

value of < 0.05 statistic carried out at an confidence interval

of 95 % shows the standard deviation.

In the study maximum 36.6% age group were between 36

-40years followed by y 26.6% between 31-35 years, 23.30%

between 26 -30years, minimum between 20-25 were 6. 66%

and 41-45 years were 6.66% (Figure 1) Nulliparous women

in the study were 6.66% and 93.6% were multiparous.

Predominant symptoms among the women were heavy

menstrual blood loss and was assessed by Pictorial blood

loss score and 66.66% had PBAC of 130 and above 20%

had PBAC between 121 - 130, PBAC of 120-111 in 6.6%

and 41-45 were 6.66% (Figure 1) None of the women had

PBAC <100. After treatment perimenopausal women who

had h eavy menstrual loss, bleeding was reduced within

15 - 20 days and 13.33% women went in for Amenorrhea.

After 13 weeks treatment women 20% women had PBAC

score <100 , PBAC score 100-110 in 6 33.3% of women,

PBAC between 111 -120 score in 3.33% PABC score 120

and above were Nil. There is appreciable improvement in

reduction in menstrual blood loss (Figure 2) Hb level was

increased to 12 gm in 53.3% women and in 40% above

9gm (Figure 3). In the study pain during periods was the

next complaint. Pain was assessed by short form Mc Gill
pain questionnaire pain score was based on pain nature like excruciating, horrible, distressing and discomfort and mild. There is considerable improvement in pain during periods after treatment with a p value of 0.001 (Table 1). In the study fibroid volume reduction > 25% in 23.33% of women, between > 25 to < 50% in 53.33% of women > 50% in 13.33% women and in 10% of women fibroid disappeared when fibroid size was 3 cm which was sustained during follow-up (Figure 3). In the study no evidence of significant changes in endometrial thickness seen in USG or laboratory results during the course of treatment. Activity score was assessed by Physical functioning, Role limitations due to physical health, Role limitations due to emotional problems, Energy/fatigue, Emotional well-being, social functioning. Study results showed activity score for the various quality factor had improved considerably after treatment as evidenced by the P value 0.0001. (Table ??) There was no adverse reaction during the study period and during the follow-up. Side effects like headache and breast tenderness was reported by in 6.66% of women.

**Fig. 1:** Age Distribution

**Fig. 2:** Menstrual blood loss before and after treatment

**Fig. 3:** Hb level increased after treatment

**Fig. 4:** Percentage of Fibroid size and volume reduction after treatment

5. **Discussion**

In the study major complaint among women were heavy menstrual blood loss which was scored by PBAC. Study conducted by Jacques Donnez and Olivier Donnez control of bleeding seen > 80% and PBAC score from > 200 reduced to < 100 at the end of second course but in the study reduction in PBAC score was seen in 86.6%. Study by Jacques Donnez et al. median reduction in size of fibroid volume after 5 gs and at the end of 10 mgs Ulipristal was 54% and 58% but in the study 53.33% reduction between > 25% to 50% size and volume and in 10% fibroid disappeared. In the study head ache and breast tenderness were reported. In the study no changes in endometrial thickness similar to Jacques Donnez M.D, Olivier Donnez, M.D. Dace Matule, M.D et al. In the study there was sufficient improvement in quality of life due to reduction in size and marked improvement in with a p value of 0.001. Jacques Donnez, Guillaume E Courtoy, Olivier Donne et al. In his review article and his key message stated that Ulipristal acetate significantly reduces fibroid size and controls bleeding and improves quality of life, which is similar to the study. Jacques Donnez Marie-Madeleine et al. stated that Fibroids are highly prevalent and leads to high health burden and has an impact on their quality of life and has economic impact. As current treatment mostly surgical there is need for new options. In the study fibroid was treated effectively with 10 mgs Ulipristal for 13 weeks.
which is similar to the statement by Donnez J, Dolmans M et al.\(^\text{10}\) that SPRMs such as Ulipristal are proven to treat fibroid effectively. In the study perimenopausal women Ulipristal arrested bleeding and in few women lead to amenorrhea, hence most perimenopausal women prefer Ulipristal than surgery. Singh SS\(^\text{(11)}\) concluded that Ulipristal may decrease the incidence of surgical and other modality of treatment.

### 6. Conclusions

Ulipristal was efficient in controlling heavy menstrual bleeding and amenorrhea was developed in perimenopausal women. There was reduction in fibroid volume and disappearance of fibroid in few women which was sustained during follow-up. Pain during periods and quality of life was considerably improved. During treatment there was no adverse reaction and very few side effects were noticed. Ulipristal can be an alternative to surgery Hence results of the study concluded that Ulipristal is both effective and safe for fibroid treatment. It is a novel therapy for fibroid management.

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#### 7. Study funded

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#### 7.1. Conflict of interest

None.

### References


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