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Efficacy of Ulipristal Acetate In Management of Symptomatic Uterine Fibroids : A Retrospective Study

Singh Kalpana^{1*} and Rai Sangeeta²

*1Department of obs. & Gyn. Medical Officer, Sir Sunderlal Hospital, B.H.U , Varanasi, INDIA

²Department of obs. & Gyn. Associate Professor , Institute of Medical Sciences, B.H.U, Varanasi, INDIA

ABSTRACT

Efficacy of ulipristal in management of symptomatic uterine fibroids . A retrospective study done at Banaras Hindu University , patients attending University Employee Health Centre in duration of two years (2016-2018). Ulipristal acetate 5 mg once a day was given to 12 patients complaining of severe menorrhagia, anemia and poor quality of life .Patients in age group of 30yrs to 50yrs received ulipristal acetate. Menorrhagia and anemia were corrected in almost 100% patients and in 4 (33.3%) patients usg findings suggestive of fibroid shrinkage . In spite of good symptomatic improvement, 66.6% patients were not satisfied with the medical management and they want for hysterectomy. ulipristal acetate is very effective drug for symptomatic management of fibroids. Heavy menstrual bleeding is well managed and anemia get corrected on 3 months therapy. Preoperative management of fibroids and postponement of surgery and patient not willing for surgery, in all these cases this medicine is playing an effective role.

KEYWORDS : Ulipristal , uterine fibroids , efficacy.

***Corresponding author**

DR. Kalpana Singh

Medical Officer ,

University Employee Health Care Complex B.H.U , Varanasi

Email :kalpana11dec@yahoo.com

INTRODUCTION

Leiomyomas or fibroids are benign hormone –sensitive tumours of uterine smooth muscle cells , frequently involving point mutations and complex chromosomal rearrangements¹. They occur in about 20%- 40% of women of reproductive age². Heavy menstrual bleeding (HMB), pelvic pressure and pain and reproductive dysfunction are common symptoms that impair women's health and quality of life (QoL)^{3,4}. Surgical interventions , especially hysterectomy , still predominates the treatment strategy⁵. Option of medical therapy are currently limited to preoperative reduction of symptoms related to uterine bleeding and fibroids size .^{6,7} Ulipristal acetate (UPA) is used in preoperative fibroid treatment and also to postpone surgery.⁸

UPA is a selective P receptor modulator (SPRM) that potently modulates P- receptor activity⁹ with proapoptotic / anti proliferative effects on fibroid cells¹⁰. UPA effectively controls HMB and shrinks fibroid. After 3 months course of 5 mg ulipristal once daily , menstruation returns after 4-5 wks but fibroid volume reduction can be sustained for 6 months. Intermittent courses of 3 months UPA treatment with off treatment intervals are a potential option for long term medical management of fibroids.

MATERIALS AND METHODS

A retrospective study done at Banaras Hindu University , in duration of 2 yrs of period (2016-2018). The study done on patients attending university employee health centre . The drug was given to 12 patients of menorrhagia and anemia . The cause of menorrhagia was fibroid. The treatment given them for 3 months to one year as patient desire. As medicine is very costly, so each and every patient could not afford . Some patients took only one course of medicine and few received for 2 to 3 cycles. The age group taking medicine were 30- 45 years . The drug was started from first day of menses and on daily basis 5 mg once a day for continuous 3 months without any gap and then stop the drug and wait for menses . This is the usual course. The patient explained when menses will return after medication , heavy bleeding will occur .

RESULTS

The total no . of patients were 12 . The age group involve between 30- 50 years . Six patients (50%) belong to 41- 45 yers of age group and of middle class. Heavy menstrual bleeding 12 (100%) and anemia were 10 (83%) were main problems. 7 patients (58%) took 2-3 cycles of UPA treatment and only one patient took more than a year . Symptomatic relief occurred in all the patients . Almost 100% get relieved of menorrhagia and anemia and 66% (8) patient relieved from pain abdomen . USG done before starting treatment and after taking treatment showed no increase in size of fibroids , shrinkage in size noticed in 4 patients .

Table 1. Age of patients Years No %

30-35	1	8.33%
36-40	4	33.3%
41-45	6	50%
Above 45	1	8.33%

Table 2. Symptoms of the patients

Menorrhagia	12	100%
Anemia	10	83%
Pain abdomen	4	33%

Four patients (33.3%) were satisfied with medicines but (66.6) 8 patients were unsatisfied . Unsatisfaction of patients were due to high cost of medicines and after stopping the drug , heavy blood flow occur in menses . Majority 8 (66.6%) patients wants surgery , as hysterectomy gives mental satisfaction , that the disease is removed.

Table 3 Symptomatic improvement

Menorrhagia	12	100%
Anemia	12	100%
Pain lower abdomen	8	66%
USG – Finding (fibroid volume / shrinkage)	4	33%

Table 4 : treatment

Duration of

< 6 months	4	33%
6-12 months	7	58%
>12 months	1	8%

Table 5 Patients Satisfaction

Satisfied	4	33%
Unsatisfied	8	66%

DISCUSSION

This study was done to know the efficacy of ulipristal in medical management of uterine fibroids. Most of the patients relieved after taking single course of therapy, but actual aim was to postpone the surgery. As menorrhagia is improved, quality life of patients improved in terms of health, pain relief, anxiety and depression. There is immediate improvement in menorrhagia as most of patient reviews amenorrhic, during the course of treatment. During the off-treatment period fibroid related symptoms may reappear but magnitude of bleeding reduces after each cycle. Size of fibroids reduces after 3 cycles of drug on usg finding, which is a reversible change.

The role of UPA in postponement of surgery and improvement in quality of life is more beneficial, so that future surgery can be planned. The introduction of UPA will modify the use of surgery in different ways:

1. In case of myoma class 0,1 and 2 symptomatic fibroids > 2 cm distorting the uterine cavity and wishing to preserve their fertility, with myoma reduction, UPA may make hysteroscopic myomectomy procedure easy and reduce the number of two-step procedure, so an alternative to hysteroscopic myomectomy.
2. Women with multiple symptomatic fibroids (class 2-5) wishes to preserve their fertility.
3. Women with a few class 5 or 6 large myomas could be treated with UPA preoperatively to present laparoscopic myomectomy instead of laparotomy.
4. Perimenopausal women with heavy menstrual bleeding who are unwilling to undergo surgery.

Currently, UPA is authorized for preoperative treatment for fibroids for a cycle of 3 months which can be repeated once. Due to reverse of symptoms, most of the patients want surgery at the end of therapy.

As such, no long term treatment of fibroids, approved. GnRH analogues, mifepristone, and progestins are used. Limitation of our study, no long term treatment effects are known till date. The cost of medicine is also one of the major factor in our country, as maximum patients cannot afford. 50% patients were not satisfied due to reverse of symptoms and went for surgery.

CONCLUSION

UPA 5 mg daily treatment course for 3 months and repeated cycles, can improve QOL of patients and postponement of surgery. This proving UPA a good drug for medical management of fibroids.

REFERENCES

1. Mehine, M., Kaasinen, E., Mäkinen, N., Katainen, R., Kämpjärvi, K., Pitkänen, E. et al. Characterization of uterine leiomyomas by whole-genome sequencing. *N Engl J Med.* 2013; 369: 43–5
 2. Wallach, E.E. and Vlahos, N.F. Uterine myomas: an overview of development, clinical features, and management. *Obstet Gynecol.* 2004; 104: 393–406
 3. Stewart, E.A. Uterine fibroids. *Lancet.* 2001; 357: 293–298
 4. Donnez, J. and Jadoul, P. What are the implications of myomas on fertility? A need for a debate?. *Hum Reprod.* 2002; 17: 1424–1430
 5. Stewart, E.A. Uterine fibroids and evidence-based medicine—not an oxymoron. *N Engl J Med.* 2012; 366: 471–473
 6. Donnez, J., Schrurs, B., Gillerot, S., Sandow, J., and Clerckx, F. Treatment of uterine fibroids with implants of gonadotropin-releasing hormone agonist: assessment by hystero-graphy. *Fertil Steril.* 1989; 51: 947–950
 7. Lethaby, A. and Vollenhoven, B. Fibroids (uterine myomatosis, leiomyomas). *Clin Evid (Online).* 2011;2011: 0814
 8. Zapata, L.B., Whiteman, M.K., Tepper, N.K., Jamieson, D.J., Marchbanks, P.A., and Curtis, K.M. Intrauterine device use among women with uterine fibroids: a systematic review. *Contraception.* 2010; 82: 41–55
 9. Melis, G.B., Piras, B., Marotto, M.F., Orrù, M.M., Maricosu, G., Pilloni, M. et al. Pharmacokinetic evaluation of ulipristal acetate for uterine leiomyoma treatment. *Expert Opin Drug Metab Toxicol.* 2012;8: 901–908
 10. Gainer, E.E. and Ulmann, A. Pharmacologic properties of CDB(VA)-2914. *Steroids.* 2003; 68: 1005–1011
 11. Horak, P., Mara, M., Dundr, P., Kubinova, K., Kuzel, D., Hudecek, R. et al. Effect of a selective progesterone receptor modulator on induction of apoptosis in uterine fibroids in vivo. *Int J Endocrinol.* 2012; 2012: 436174.
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