

Effect of Mifepristone in the Treatment of Uterine Leiomyoma

Diancui Zhang¹, Peipei Sun², Tongzhen Zhao^{2*}

¹Health Management Center, Binzhou Municipal Hospital of Traditional Chinese Medicine, Binzhou, Shandong Province, 256600, China

²Department of Oncology, Binzhou Municipal Hospital of Traditional Chinese Medicine, Binzhou, Shandong Province, 256600, China

*Corresponding author: byfywlq@sina.com

Abstract: To study the effect of mifepristone in the treatment of uterine leiomyoma. **Methods :** 80 cases of uterine leiomyoma treated in our hospital from August 2019 to August 2020, All patients were treated with mifepristone. It was divided into two groups by random number table, Study group A given low dose (12.50 mg/d), Study group B high dose (25.00 mg/d), The changes of serum hormone levels (follicle stimulating hormone (FSH), luteinizing hormone (LH), progesterin (P), estrogen (E2)) and uterine leiomyoma volume were compared between the two groups, The adverse reactions of the two groups were compared. **Results:** Before treatment, Comparison of FSH, LH, P, E2 level and uterine leiomyoma volume between the two groups, and the difference was not statistically significant ($P>0.05$). After three months of continuous treatment, FSH, LH, P, E2 level, uterine leiomyoma volume was lower than before treatment, The FSH, LH, P, E2 level of the A group was lower than that of the B group, difference was statistically significant ($P<0.05$); After three months of continuous treatment, The volume of hysteromyoma in the A group compared with the B group, (b) The difference was not statistically significant ($P>0.05$); The incidence of adverse reactions in the A group was lower than that in the B group, difference was statistically significant ($P<0.05$). **Conclusion:** Patients with uterine leiomyoma are treated with drugs, Low-dose mifepristone can reduce serum hormone levels, promote uterine leiomyoma volume reduction, reduce adverse drug reactions, The application value is remarkable.

Keywords: Uterine Leiomyoma, Serum Hormone, Mifepristone, Low Dose.

Uterine leiomyoma is a common benign gynecologic tumor, causing menstrual disorders, frequent urination and other clinical symptoms, affecting the normal life of patients[1]In the treatment of uterine leiomyoma, we need to regulate the level of serum hormones and inhibit the mechanism of promoting the growth of uterine leiomyoma due to the levels of progesterone and estrogen[2-3]Mifepristone, as an antagonist of progesterone receptor, antagonizes the binding of progesterone to the receptor, thus inhibiting the growth of uterine leiomyoma and reducing the volume of uterine leiomyoma[4-5]In order to evaluate the value of mifepristone in clinical application, 80 cases of uterine leiomyoma treated in our hospital were studied.

1. Information and Methodology

1.1 General information

From August 2019 to August 2020, 80 patients with uterine leiomyoma were selected. Inclusion criteria: meet the diagnostic criteria of uterine leiomyoma; With mifepristone, Sign the consent, Continuous drug treatment for 3 months. Exclusion criteria: combined drug allergy; With mental illness, No clinical medication coordination ability. This study was approved by the Hospital Ethics Committee. The 80 patients were divided into two groups by a random number table, Study A group aged 26~46, Average (34.52±3.03) years, Study B group aged 24~48, average (34.60±3.05) years. There was no significant difference in general data between the two groups.

1.2 Method

The two groups were treated with mifepristone, the A group was given low dose (12.50 mg/d), the B group was given high dose (25.00 mg/d), oral medication after menstrual period, continuous treatment for 3 months.

1.3 Observation Indicators

the changes of serum hormone levels (follicle-stimulating hormone (FSH), luteinizing hormone (LH), progesterone (P), estrogen (E2)), uterine leiomyoma volume were compared between the two groups before and after 3 months of continuous treatment. adverse reactions occurred in the two groups after medication.

1.4 Statistical Analysis

Statistical software SPSS24.0 was used for data analysis and statistical processing, measurement data (serum hormone level, uterine leiomyoma volume) were t tested, counting data (incidence of adverse reactions) were χ^2 tested, the statistical significance was expressed as $P < 0.05$.

2. Fruit

2.1 Comparison of serum hormone levels and uterine leiomyoma volume before and after 3 months of continuous treatment

There was no significant difference in FSH、LH、P、E2 level and uterine leiomyoma volume between the two groups before treatment ($P > 0.05$). the FSH、LH、P、E2 level and uterine leiomyoma volume of the two groups were lower than that of the study group before treatment after 3 months of continuous treatment. the FSH、LH、P、E2 level of the study group was lower than that of the study B group, the difference was statistically significant ($P < 0.05$). See table 1.

Table 1 Comparison of serum hormone levels and uterine leiomyoma volume before and after 3 months of continuous treatment ($\pm \bar{x}$)

Group	FSH (mIU/mL)		t	P	LH (mIU/mL)		t	P
	Pre-treatment	After 3 months of treatment			Pre-treatment	After 3 months of treatment		
Study Group A (n=40)	19.62±6.23	8.47±2.32	14.413	< 0.05	21.82±4.23	11.32±2.73	13.191	< 0.05
Study Group B (n=40)	19.58±6.27	10.87±2.48	12.860	< 0.05	21.76±4.20	12.66±3.04	11.101	< 0.05
t	0.029	4.470	-	-	0.064	2.074	-	-
P	>0.05	<0.05	-	-	>0.05	<0.05	-	-

Table 1

Group	P (nmol/L)		t	P	E2(Pmol/L)		t	P
	Pre-treatment	After 3 months of treatment			Pre-treatment	After 3 months of treatment		
Study Group A (n=40)	18.47±3.23	6.31±1.27	22.159	< 0.05	342.38±21.02	148.82±23.73	38.616	< 0.05
Study Group B (n=40)	18.53±3.30	6.89±1.31	20.734	< 0.05	341.88±21.25	159.72±24.03	35.915	< 0.05
t	0.082	2.010	-	-	0.106	2.041	-	-
P	>0.05	<0.05	-	-	>0.05	<0.05	-	-

Table 1

Group	mm of uterine leiomyoma ³		t	P
	Pre-treatment	After 3 months of treatment		
Study Group A (n=40)	90.21±6.23	39.23±3.20	40.036	<0.05
Study Group B (n=40)	90.42±6.18	40.72±4.27	41.846	<0.05
t	0.151	1.766	-	-
P	>0.05	>0.05	-	-

2.2 Comparison of adverse reaction rates between two groups

The incidence of adverse reactions in the A group was lower than that in the B group ($P < 0.05$). See table 2.

Table 2 Comparison of adverse reaction rates between the two groups [n(%)]

Group	Fatigue	Gross	Abdominal distension	Sweat	Rash rash	Incidence
Study Group A (n=40)	1(2.50)	1(2.50)	0(0.00)	1(2.50)	0(0.00)	3(7.50)
Study Group B (n=40)	3(7.50)	2(5.00)	2(5.00)	2(5.00)	1(2.50)	10(25.00)
χ^2	-	-	-	-	-	4.510
P	-	-	-	-	-	<0.05

3. Analysis and discussion

Uterine leiomyoma is mostly benign tumor, it belongs to hormone-dependent tumor, the growth of uterine leiomyoma is related to the hormone level of the body, and the serum progesterone and estrogen in patients with uterine leiomyoma are significantly higher than the normal value[6-7]Mifepristone is a common drug in the treatment of uterine leiomyoma, which can antagonize the binding of progesterone to the receptor and reduce the serum hormone level[8-9]A comparison of the therapeutic effects of mifepristone with 12.50 mg/d、25.00mg/d doses based on different doses of mifepristone showed that the serum hormone levels of patients were significantly reduced under both doses, and the volume of uterine leiomyoma was significantly reduced after 3 months of continuous treatment, while the low dose regimen was more effective and the decrease of serum hormone levels was higher. This shows that mifepristone acts as a progesterone receptor antagonist, which has a significant effect on the treatment of uterine leiomyoma, reducing the volume of uterine leiomyoma and reducing serum hormone level, and the effect of low dose medication is more significant. On the other hand, comparing the adverse reactions of the two groups, the results showed that the incidence of adverse reactions was low under low dose, which indicated that taking progesterone receptor antagonists for a long time would have some side effects, but it could reduce the side effects and improve the safety of drug use under the premise of reducing the dosage of drugs[10].

In general, in clinical drug therapy, mifepristone has significant therapeutic effect, can promote the volume reduction of uterine leiomyoma, and can significantly reduce serum hormone level under low dose medication. And the drug safety is higher, more clinical application value.

References

- [1] Zhang Dinghong, Wang Hongli. Comparison of clinical efficacy of different doses of mifepristone in the treatment of uterine leiomyoma [J]. *Chinese Journal of Family Planning* 28(11):1821-1823.
- [2] Bai Xue, Zhang Jinzhi, Zhao Liwu, Liu Yan. Efficacy and safety of different doses of mifepristone in the treatment of patients with functional uterine bleeding during menopause [J].; and *China Maternal and Child Health Care*, 2019, 34(21):4978-4980.
- [3] Ren Ping. Effect of mifepristone combined with myomectomy on the level of cytokines and sex hormones in patients with uterine leiomyoma [J].; and *Shanxi Medical Journal*, 2019, 48(22):2741-2744.
- [4] Lei Jinfeng. Comparative observation on the efficacy of different doses of mifepristone in patients with uterine leiomyoma and its effect on estrogen and progesterone levels [J].; and *Capital Food and Medicine*, 2019, 26(22):77-78.
- [5] Zhang Jian, Reina, Xue Xiuzhen. Effect of Guizhi Fuling Pill combined with mifepristone on clinical efficacy and serum sex hormone level in patients with uterine leiomyoma [J].]1 *Exploration of Rational Drug Use in China*, 2020, 17(11):39-42.
- [6] Zhang Lizhen. Clinical efficacy and safety of Guizhi Fuling capsule combined with mifepristone in the treatment of uterine leiomyoma [J].]1 *Capital Food and Medicine* 27(03):102.
- [7] Gao Qiong. Clinical Observation on Menopause Induced by Different Dosage of Mifepristone in Perimenopausal Uterine Myoma [J]. *Chinese and Foreign Women's Health Research*, 2020(01):49-50.
- [8] Feng Yuanyuan, Zhao Zixiong. Clinical efficacy of laparoscopic surgery combined with low dose

mifepristone in the treatment of endometriosis with infertility [J].1 Exploration of rational Drug Use in China ,2020,17(02):48-53.

[9] Arora D,Chawla Jaya,Kochar S P S,Sharma J C.A randomized control trial to assess efficacy of Mifepristone in medical management of uterine fibroid.[J]. Medical journal,Armed Forces India, 2017,73(3).

[10] Liu Chongdong, Lu Qi, Qu Hong, Geng Li, Bian Meilu, Huang Minli, Wang Huilan, Zhang Youzhong, Wen Zeqing, Zheng Shurong, Zhang Zhenyu.Different dosages of mifepristone versus enantone to treat uterine fibroids:A multicenter randomized controlled trial.[J]. Medicine, 2017, 96(7).