

Study on the Efficacy of Low-Dose Mifepristone in the Treatment of Endometriosis

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Abstract: *Objective:* To explore and analyze the efficacy of low-dose mifepristone in the treatment of endometriosis. *Methods:* 56 patients with endometriosis who were diagnosed and treated in the gynecology department of the People's Hospital of Danyang between August 2020 to December 2022 were recruited and divided into the study group (n = 28) and control group (n = 28). The study group was treated with low-dose mifepristone, and the control group was treated with regular-dose mifepristone. The effective rate of medication, hormone levels, bone density, and adverse reactions were compared between the groups. *Results:* There was a statistically significant difference (P < 0.05) in the effective rates of medication between the groups (P > 0.05); after treatment, the hormone levels in the study group were significantly better than those in the control group (P < 0.05). Before treatment, there was no significant difference in bone mineral density between the groups (P > 0.05); after treatment, bone density in the study group was higher than that in the control group (P < 0.05). *Conclusion:* Low-dose mifepristone has a significant curative effect in the treatment of endometriosis, the hormone level and bone density are better, and there are few adverse drug reactions. This treatment is worthy of widespread promotion and application.

Keywords: Low-dose mifepristone; Endometriosis; Treatment

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1. Introduction

Endometriosis (EMT) is a disease caused by the growth of endometrial tissue in an abnormal position ^[1]. The ectopic endometrium usually invades the pelvic organs, the most common sites are the ovaries, and the main symptom is progressively aggravated secondary dysmenorrhea ^[2]. Mifepristone is a drug used to terminate embryonic development and can guide decidual shedding. After entering the body, the drug can combine with progesterone to stop the growth of the endometrium ^[3]. There is some ambiguity in the use of mifepristone. It has been reported in the literature that low-dose mifepristone has a better curative effect and safety can be controlled ^[4]. This article aims to study and analyze the efficacy of low-dose mifepristone in the treatment of endometriosis.

2. Materials and methods

2.1. General information

56 patients with endometriosis who were diagnosed and treated in the gynecology department of the People's Hospital of Danyang between August 2020 to December 2022 were recruited and divided into the study group (n = 28) and the control group (n = 28). The age of the study group was between 22 and 31 years old with an average age of 26.14 ± 1.27 years old, the menstrual cycle was 23 to 32 days with an average of 27.21 ± 1.36 days, the number of menstrual days was 3 to 7 days with an average of 5.01 ± 0.33 days. The control group was between 23 and 31 years old with an average age of 26.22 ± 1.29 years old; the menstrual cycle was 22 to 32 days and the average menstrual cycle was 27.52 ± 1.32 days; menstrual days were 4 to 7 days with an average of 5.21 ± 0.27 days. The comparison of general information showed no statistical significance (P > 0.05).

Inclusion criteria included: (1) Patients who meet the diagnosis of endometriosis; (2) Patients with informed consent; (3) The patient was treated with mifepristone for the first time; and (4) Patients with good compliance.

Exclusion criteria included: (1) Patients with malignant tumors; (2) Patients with blood system diseases; and (3) Patients with mental illness.

2.2. Methods

The control group was treated with conventional doses of mifepristone (12.5 mg), administered on the 5th day of menstrual cramps, and continued for 6 months.

The study group received low-dose mifepristone treatment (6.25 mg), administered on the 5th day of menstrual cramps, and continued for 6 months.

2.3. Observation indicators

The observation indicators of this study included:

- (1) Compare the effectiveness of medication between groups, including markedly effective (no symptoms and signs), effective (mild symptoms and signs), and ineffective (no improvement in symptoms and signs).
- (2) Hormone levels were compared between groups, including FSH (follicle-stimulating hormone), LH (gonadotropin), and E2 (estradiol hormone).
- (3) Bone density was compared between groups.
- (4) Adverse reactions between price comparison groups included nausea, dizziness, low back pain, and rash.

2.4. Statistical analysis

SPSS 21.0 statistical software was selected to process and analyze the data, the count data were expressed by the number of cases (*n*) and percentage (%), the x^2 test was implemented, the measurement data were expressed by the mean \pm standard deviation (SD), and the *t*-test was implemented, P < 0.05 were considered statistically significant.

3. Results

3.1. Comparing the effective rate of the study group and the control group

Table 1 showed that there was a statistically significant difference in the effective rates of medication between the study group and the control group (P < 0.05).

Group	Number of cases	Markedly effective	Effective	Ineffective	Total effective rate	
Study group	28	21 (75.00)	7 (25.00)	0 (0.00)	28 (100.00)	
Control group	28	15 (53.57)	12 (48.86)	1 (3.57)	27 (85.71)	
x^2 value	-	-	-	-	4.3077	
P value	-	-	-	-	0.0379	

Table 1. The comparison of effective rates between groups [n (%)]

3.2. Comparison of hormone levels between the study group and the control group

Before treatment, the levels of FSH, LH, E2, and other hormones were compared between the groups, and there was no statistically significant difference (P > 0.05); after treatment, the levels of FSH, LH, E2, and other hormones in the study group were significantly better than those in the control group (P < 0.05). See **Table 2** for details.

Table 2. The comparison of hormone levels between groups before and after treatment (mean \pm SD)

Group	Number of cases	FSH (IU/L)		LH (IU/L)		E2 (pmol/L)	
		Before	After	Before	After	Before	After
Study group	28	4.37 ± 0.42	4.26 ± 0.54	6.95 ± 0.55	6.91 ± 0.42	$599.41 \pm \\20.58$	$570.45 \pm \\ 20.24$
Control group	28	4.38 ± 0.43	3.97 ± 0.47	6.96 ± 0.65	6.57 ± 0.52	$599.68 \pm \\20.63$	$587.24 \pm \\20.53$
<i>t</i> value	-	0.0880	2.1435	0.9507	2.6915	0.0490	3.0817
P value	-	0.9302	0.0366	0.0621	0.0094	0.9611	0.0032

3.3. Comparison of bone mineral density between the study group and the control group

There was no significant difference in bone mineral density between the groups (P > 0.05) before treatment; after treatment, bone density in the study group was higher than that in the control group (P < 0.05). See **Table 3** for details.

Table 3. The bone density comparison between groups before and after treatment (mean \pm SD)

Course	Number of cases	Bone density			
Group		Before treatment	After treatment		
Study group	28	0.48 ± 0.02	0.48 ± 0.01		
Control group	28	0.49 ± 0.03	0.47 ± 0.01		
<i>t</i> value	-	1.4675	3.7416		
P value	-	0.1480	0.0004		

3.4. Comparison of adverse reactions between the study group and the control group

Table 4 showed that the incidence of adverse reactions in the study group was significantly lower than that in the control group (P < 0.05).

Group	Number of cases	Nausea	Dizziness	Low back pain	Rash	Total incidence
Study group	28	1 (3.57)	0 (0.00)	0 (0.00)	0 (0.00)	1 (3.57)
Control group	28	2 (7.14)	3 (10.71)	1 (3.57)	1 (3.57)	7 (25.00)
x^2 value	-	-	-	-	-	5.2500
P value	-	-	-	-	-	0.0219

Table 4. The comparison of adverse reactions between groups [n (%)]

4. Discussion

Endometriosis is a very common gynecological disease that occurs mainly in women of childbearing age. In recent years, the prevalence of this disease has been gradually increasing ^[5,6]. The endometrium is originally a part of the uterine cavity, and there is a certain period of shedding, which is also known as menstruation. Under the influence of some factors, the endometrium will grow outside the uterine cavity, thereby causing endometriosis ^[7,8]. At present, the pathogenesis of endometriosis has not yet been clarified. At this stage, it is believed that hormone levels and autoimmune diseases are the causes of its occurrence. Dysmenorrhea is the main presenting symptom and is categorized under secondary dysmenorrhea. As the disease progresses, dysmenorrhea will aggravate, which will then lead to menstrual disorders, infertility, abdominal pain, and other symptoms ^[9,10]. Endometriosis can be treated with drugs and surgery. Mifepristone is a progesterone receptor antagonist, which is widely used in the fields of terminating pregnancy and resisting implantation of fertilized eggs ^[11]. This drug is a prescription drug that needs to be used under the guidance of a doctor and can be used in the treatment of endometriosis ^[12]. Mifepristone can inhibit the growth of ectopic endometrium, resist the growth and reproduction of endometrium in abnormal positions, and induce the degeneration of ectopic endometrium (^{13]}. In the treatment, there is some ambiguity in the effect of different doses of mifepristone. After research, it is found that the effect of low-dose mifepristone in the treatment of endometriosis is more ideal ^[14].

The experimental results are as follows: after comparing the effective rates of medication between the study group and the control group, there was a statistically significant difference (P < 0.05). The effects of different doses of mifepristone in the treatment of endometriosis have certain clinical value. There is a difference between the efficacy of low-dose medication and the effect of conventional-dose medication. Low-dose medication can be used in treatment to reduce the concentration of medication. Before treatment, the levels of FSH, LH, E2, and other hormones were compared between the groups, and there was no statistically significant difference (P > 0.05); after treatment, the levels of FSH, LH, E2, and other hormones in the study group were significantly better than those in the control group (P < 0.05). Mifepristone has a certain control effect on the periodic ovulation of the ovary and can regulate the nerve center, hinder the development of follicles, and induce ectopic endometrial degeneration. Low-dose medication has little effect on the endocrine level, and the fluctuation of the patient's hormone level is not very large, while the conventional dose of treatment, with a large amount of medication, can cause changes in the hormone level. Before treatment, there was no significant difference in bone mineral density between the groups (P > 0.05); after treatment, bone density in the study group was higher than that in the control group (P < 0.05). After research, it was found that mifepristone can affect bone density, especially in patients who take a large amount of drugs, the change in bone density will be very significant. Taking low doses of mifepristone, its impact on bone density can be minimized, and will not even have an effect. The incidence of adverse reactions in the study group was significantly lower than that in the control group (P < 0.05). Hence, small doses can reduce drug metabolism in the body, reduce adverse drug reactions, and further improve the safety of treatment^[15].

In summary, the effect of low-dose mifepristone in the treatment of endometriosis has been affirmed, and its therapeutic effect is no different from that of conventional doses. The hormone level and bone density are relatively stable, and there are few adverse reactions. This treatment regimen is recommended for broad application.

Disclosure statement

The author declares no conflict of interest.

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