

Evaluation of Clinical Efficiency and Safety of Cefdinir Combined with Ornidazole in the Treatment of Pelvic Inflammatory Disease

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Abstract: *Objective:* To explore the therapeutic value of cefdinir combined with ornidazole in patients with clinical pelvic inflammatory disease, analyze the effect of this combination on disease improvement, and evaluate adverse drug reactions. *Methods:* The case screening time was between May 2024 and March 2026. The selected research subjects were patients with pelvic inflammatory disease who were treated in our hospital. The sample size was 92 cases. They were divided into a control group (ornidazole single drug oral treatment) and an observation group (cefdinir combined with ornidazole oral treatment) of 46 cases each using the random number table method. The treatment efficiency (total effective rate, symptom improvement, inflammatory factors) and safety of each group were compared. *Results:* The total clinical treatment effectiveness of the observation group was significantly higher than that of the control group, and the time for symptom resolution in the observation group was shorter than that of the control group, and the difference was statistically significant ($p < 0.05$); before treatment, the baseline levels of inflammatory factors and hemorrheology indicators in the two groups were similar ($p > 0.05$); after treatment, both groups had all indicators dropped significantly compared with those before treatment, and the decline rate of the observation group was better than that of the control group. The statistical result was $p < 0.05$. The overall incidence of adverse reactions in the observation group was lower than that of the control group, and the adverse reactions were mild and could be relieved on their own. No serious adverse drug events occurred ($p < 0.05$). *Conclusion:* The combined use of cefdinir and ornidazole in the treatment of pelvic inflammatory disease can quickly control clinical symptoms and reduce the body's inflammatory response level. It has few adverse reactions and good tolerability. It is safe and reliable in clinical application and deserves to be actively adopted.

Keywords: Cefdinir; Ornidazole; Pelvic inflammatory disease; Clinical efficiency; Safety

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1. Introduction

Pelvic inflammatory disease is a general term for upper reproductive tract infectious diseases that are highly prevalent in women of childbearing age. The disease is mostly caused by the invasion of endogenous pathogens and exogenous pathogenic bacteria in the reproductive tract into the pelvic cavity. It has clinical characteristics such as protracted disease, repeated attacks, and difficulty in curing^[1]. Failure to receive timely and standardized anti-infective intervention in the acute phase can easily lead to fallopian tube adhesion and blockage and pelvic tissue scarring, which can then induce

long-term complications such as ectopic pregnancy, secondary infertility, and chronic persistent pelvic pain, seriously damaging women's reproductive health and quality of daily life. Pelvic inflammatory disease is mostly a mixed infection pattern of aerobic bacteria and anaerobic bacteria. The antibacterial spectrum coverage of a single antibacterial drug is limited, making it difficult to completely eliminate all kinds of pathogenic bacteria in the pelvic cavity, which is an important reason for the prolongation and recurrence of the disease. Therefore, clinical treatment advocates the use of drug combinations with complementary antimicrobial spectrums to achieve simultaneous coverage of aerobic and anaerobic bacteria and control the progression of infection from the root cause of the disease^[2]. Cefdinir is a third-generation oral cephalosporin antibiotic with high oral bioavailability and strong tissue penetration. It can maintain effective inhibitory concentrations in female pelvic tissue, fallopian tubes and ovarian tissues, and has stable bactericidal and bactericidal activity against common clinical Gram-positive bacteria and Gram-negative pathogenic bacteria^[3]. Ornidazole, as a new generation of nitroimidazole derivatives, is highly sensitive to anaerobic bacteria and trichomonas pathogens, has definite bactericidal effect, and has a stable half-life, and is suitable for the long-term standardized treatment of pelvic anaerobic bacterial infections^[4]. This study set up a randomized controlled trial to clarify the clinical advantages and application value of cefdinir combined with ornidazole in the treatment of pelvic inflammatory disease, and to provide data support for clinical practice.

2. Materials and methods

2.1. General information

The study period is from May 2024 to March 2026. The observation subjects are from patients with pelvic inflammatory disease treated in our hospital. The sample size is 92 cases. The grouping is based on the random number table method, with 46 cases allocated to each group. The age range of the control group is 21 to 50 years old, with an average of $(35.33 \pm 35.33 \pm 5.11)$ years old; the disease duration is 3d to 6 months, with an average disease duration of (3.11 ± 0.48) months; the age range of the observation group is 22 to 50 years old, with an average disease duration of (36.01 ± 5.22) years; the disease duration is 4d to 6 months, with an average disease duration of (3.15 ± 0.49) months. The above two groups of data were analyzed by software and the statistically obtained difference value was insignificant ($p > 0.05$), thus meeting the comparability conditions between groups.

2.1.1. Inclusion criteria

Meet the diagnostic criteria in the "Standards for Diagnosis and Treatment of Pelvic Inflammatory Disease"; age 20 to 50 years old; Disease duration ≤ 6 months, acute attack stage; voluntary participation, all fully informed and signed consent document.

2.1.2. Exclusion criteria

Those with clear allergies to the study drugs; pregnant and lactating women; those with other acute and chronic gynecological diseases; those with mental or cognitive disorders; those who voluntarily stopped taking the drug midway, were lost to follow-up, or were unable to complete the course of treatment.

2.2. Method

Both groups of patients were given symptomatic intervention: appropriate bed rest in the acute phase, a light diet and avoid spicy stimulation, and sexual intercourse was strictly prohibited during the treatment period; patients with high fever were given physical cooling treatment, and symptomatic antipyretic treatment was given when the body temperature exceeded 38.5°C ; patients with severe abdominal pain were given routine symptomatic antispasmodic and analgesic support, and the basic intervention period was set to 14 days.

The control group was given orally administered ornidazole dispersible tablets alone, 0.5 g/tablet, 0.5 g each time,

once a day in the morning and evening, with warm water after meals, for 14 consecutive days.

On the basis of ornidazole, the observation group also received cefdinir dispersible tablets for oral administration, with a specification of 0.1 g/tablet, 0.1 g each time, 3 times a day, after three meals. The usage, dosage and course of treatment of ornidazole were consistent with those of the control group, and the entire course of medication was standardized for 14 days.

The two groups were uniformly educated during the medication: it is strictly forbidden to drink alcohol and consume alcoholic foods and preparations throughout the medication and within 7 days after stopping the medication to avoid disulfiram-like adverse reactions; it is strictly forbidden to increase or decrease the dosage without authorization, or interrupt the treatment course; blood routine and liver and kidney functions are regularly monitored, and physical discomfort after medication is closely observed.

2.3. Observation indicators

Judgment of clinical efficacy: Markedly effective means the complete disappearance of all symptoms, no tenderness in the uterus and appendages during gynecological examination, and pelvic ultrasound indicating complete absorption of effusion and inflammatory masses; effective means that subjective symptoms have been alleviated, gynecological signs have been further improved, the volume of pelvic effusion and masses has been reduced by $\geq 70\%$, and laboratory indicators have basically returned to normal; ineffective means that the above-mentioned effectiveness standards have not been met. Calculation is always efficient.

The time required for the four core symptoms of lower abdominal pain, lumbosacral pain, abnormal leucorrhea, and fever to achieve significant relief or complete resolution was recorded and compared between the two groups.

5 mL of fasting venous blood was collected before treatment and in the morning after 14 days of treatment. After serum separation, enzyme-linked immunosorbent assay was used to uniformly detect serum levels of interleukin-1 (IL-1), C-reactive protein (CRP), and tumor necrosis factor- α (TNF- α).

Adverse reactions such as gastrointestinal discomfort, dizziness and headache, skin rash and itching that occurred during the medication were recorded throughout the two groups, and the total incidence rate between the groups was calculated.

2.4. Statistical methods

The data entry software is SPSS25.0 statistics. The description of qualitative data is presented as “n (%)” and verified with χ^2 ; the quantitative data is presented as “($\bar{x} \pm s$)” and verified with t. If $p < 0.05$, the obtained difference value has research significance.

3. Results

3.1. Comparison of clinical efficacy

The overall efficiency achieved by the treatment of the patients in the observation group was higher than that of the control group, and the difference evaluation value $p < 0.05$, **Table 1**.

Table 1. Comparison of clinical efficacy (n, %)

Group	n	Effective	Valid	Invalid	Always efficient
Observation group	46	37	8	1	45 (97.83)
Control group	46	30	9	7	39 (84.78)
χ^2	-	-	-	-	4.929
p	-	-	-	-	0.026

3.2. Comparison of clinical symptom relief time

The duration of relief of relevant symptoms in the observation group was shorter than that in the control group, and the difference was statistically significant ($p < 0.05$), **Table 2**.

Table 2. Comparison of clinical symptom relief time ($\bar{x} \pm s$, d)

Group	n	Lower abdominal pain relief	Lumbosacral pain relief	Abnormal relief of leucorrhea	Fever relief
Observation group	46	3.62 ± 1.03	4.08 ± 1.44	3.97 ± 1.28	1.25 ± 0.37
Control group	46	5.29 ± 1.84	7.11 ± 2.07	7.05 ± 2.19	3.22 ± 0.53
<i>t</i>	-	5.371	8.149	8.235	20.671
<i>p</i>	-	< 0.001	< 0.001	< 0.001	< 0.001

3.3. Comparison of serum inflammatory factor levels

There was no significant difference in the levels of various inflammatory factors between the two groups before treatment ($p > 0.05$); after treatment, the indicators in both groups were lower than before treatment, and the decrease in the observation group was more prominent. The difference between the groups was meaningful ($p < 0.05$), **Table 3**.

Table 3. Comparison of serum inflammatory factor levels ($\bar{x} \pm s$)

Group	n	IL-1 (pg/mL)		CRP (mg/L)		TNF- α (pg/mL)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	46	45.15 ± 6.87	20.44 ± 2.32	38.55 ± 5.22	10.13 ± 1.05	32.44 ± 6.99	11.55 ± 2.04
Control group	46	45.77 ± 6.74	33.08 ± 3.33	38.84 ± 5.66	16.22 ± 2.99	32.51 ± 6.81	18.45 ± 3.36
<i>t</i>	-	0.437	21.123	0.255	13.034	0.049	11.905
<i>p</i>	-	0.663	< 0.001	0.799	< 0.001	0.961	< 0.001

3.4. Medication safety comparison

The incidence of adverse reactions in the observation group was lower than that in the control group ($p < 0.05$), **Table 4**.

Table 4. Medication safety comparison (n, %)

Group	n	Gastrointestinal discomfort	Dizziness and headache	Skin rash itching	Incidence of adverse reactions
Observation group	46	1	1	0	2 (4.35)
Control group	46	4	3	2	9 (19.57)
χ^2	-	-	-	-	5.059
<i>p</i>	-	-	-	-	0.024

4. Discussion

The core of pelvic inflammatory disease is the invasion of exogenous or endogenous pathogens into the female pelvic reproductive tract, which induces local acute inflammatory exudation, tissue congestion and edema, and inflammatory cell infiltration. Long-term chronic inflammatory stimulation can cause pelvic microcirculation stasis, tissue adhesion hyperplasia, and form typical symptoms such as persistent lower abdominal pain, lumbosacral distension, and abnormal

leucorrhea. The etiological characteristics of this disease are mainly mixed infection by aerobic bacteria and anaerobic bacteria. A single antibiotic can only cover part of the pathogenic bacteria, making it difficult to completely control the infection process and easily turning into a chronic and recurring state. Therefore, clinical treatment advocates the use of a combined anti-infection regimen with complementary action mechanisms and superimposed antibacterial spectrum^[5].

The mechanism of action of cefdinir is to inhibit bacterial cell wall synthesis. It has a strong antibacterial effect on gram-positive bacteria such as *Streptococcus* and *Staphylococcus* and gram-negative bacteria such as *Escherichia coli* and *Klebsiella*. It has stable oral absorption and strong tissue permeability. It can maintain an effective inhibitory concentration in the target tissue of the female pelvic cavity and can effectively eliminate aerobic pathogenic bacteria in the pelvic cavity^[6]. Ornidazole can act on the nucleic acid substances of anaerobic bacteria in an anaerobic environment, destroying the bacterial DNA replication and transcription process. It has a definite bactericidal effect on dominant anaerobic bacteria such as *Bacteroides fragilis* and *Peptostreptococcus* in the pelvic area. The blood drug concentration is stable, and it is suitable for the standardized treatment of pelvic inflammatory disease. The combination of the two drugs can achieve complementary antibacterial spectrum, cover aerobic bacteria and anaerobic bacteria simultaneously, fit the onset characteristics of mixed pelvic inflammatory infection, and block the progression of infection from the etiological level^[7].

This study shows that the total effective rate of the observation group is much higher than that of the single-drug control group, and the time for related symptoms to subside is shortened, confirming that cefdinir combined with ornidazole can control clinical symptoms faster and improve the overall treatment effect. The reason is that combined medication can kill various pathogenic bacteria in the pelvic cavity at multiple targets, quickly reduce local inflammatory exudation and tissue edema, relieve pelvic peritoneal and adnexal traction stimulation, thereby accelerating the recovery of clinical symptoms and reducing the probability of the disease becoming chronic^[8]. The level of inflammatory factors can objectively reflect the degree of inflammation activation in the body. CRP is a classic clinical acute phase reaction protein, and its serum concentration is positively correlated with the severity of inflammation. TNF- α and IL-1, as important pro-inflammatory mediators, can mediate the accumulation and infiltration of inflammatory cells and amplify the local inflammatory damage response^[9]. In this study, inflammatory factors were down-regulated in both groups after treatment, and the decrease was more significant in the observation group, suggesting that the combined regimen can more effectively suppress the body's excessive inflammatory response, block the inflammatory cascade amplification effect, and reduce persistent inflammatory damage to pelvic tissue.

Medication safety is an important consideration in clinical selection of combination regimens. The incidence of adverse reactions in the observation group was lower, and they were all transient manifestations and could recover spontaneously after stopping the drug. There was no serious organ function damage or severe allergic reaction. It is suggested that the combination of cefdinir and ornidazole will not superimpose the increase in toxic and side effects, and the drug is well tolerated. At the same time, strict alcohol prohibition and education in clinical medication can effectively avoid severe disulfiram-like reactions and further ensure the safety of clinical medication^[10].

Based on the above, the treatment of pelvic inflammatory disease with cefdinir combined with ornidazole can significantly improve the overall efficacy, shorten the recovery time of symptoms, effectively reduce the expression levels of pro-inflammatory factors in the body, and the overall drug safety and patient tolerance are high, which is worthy of clinical reference.

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Disclosure statement

The author declares no conflict of interest.

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