Eficacia clínica de las tabletas vaginales de clotrimazol combinadas con itraconazol en el tratamiento de la vaginitis micótica

Clinical Efficacy of Clotrimazole Vaginal Tablets Combined with Itraconazole in the Treatment of Mycotic Vaginitis

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Resumen
Investigar la eficacia clínica de las tabletas vaginales de clotrimazol combinadas con itraconazol en el tratamiento de la vaginitis micótica. El grupo de control se trató con tabletas vaginales de clotrimazol y el grupo de observación se trató con cápsulas de itraconazol sobre la base del grupo de control. Observe y compare los efectos del tratamiento clínico, las reacciones adversas, la calidad de vida y las tasas de recurrencia en los dos grupos de pacientes. La tasa efectiva en el grupo de observación después del tratamiento fue del 89,80%, que fue significativamente mayor que la del grupo control (67,35%) (P < 0,05). La incidencia de reacciones adversas después del tratamiento en el grupo de observación no fue significativamente diferente de la del grupo control (P > 0,05). La calidad fue significativamente mayor que el grupo control, P < 0,05 (con diferencia estadística); La tasa de recurrencia en el grupo de observación fue menor que en el grupo control (P < 0,05). La aplicación combinada de cápsulas de itraconazol y tabletas vaginales de clotrimazol en el tratamiento de la vaginitis micótica tiene un efecto rápido, un efecto curativo significativo, una baja tasa de recurrencia y mejora efectivamente la calidad de vida de pacientes con vaginitis micótica con garantía confiable de seguridad. Es digno de aplicación clínica y promoción vigorosa.

Palabras clave: tabletas vaginales de clotrimazol; Itraconazol; Vaginitis micótica; Reacciones adversas; Tasa de recurrencia

Abstract
To investigate the clinical efficacy of clotrimazole vaginal tablets combined with itraconazole in the treatment of mycotic vaginitis. The control group was treated with clotrimazole vaginal tablets, and the observation group was treated with itraconazole capsules on the basis of the control group. Observe and compare the clinical treatment effects, adverse reactions, quality of life, and recurrence rates in the two groups of patients. The effective rate in the observation group after treatment was 89.80%, which was significantly higher than that in the control group (67.35%) (P < 0.05). The incidence of adverse reactions after treatment in the observation group was not significantly different from that in the control group (P > 0.05). The quality was significantly higher than the control group, P < 0.05 (with statistical difference); the recurrence rate in the observation group was lower than that in the control group (P < 0.05). The combined application of itraconazole capsules and clotrimazole vaginal tablets in the treatment of mycotic vaginitis has rapid effect, significant curative effect, low recurrence rate, and effectively improves the quality of life of patients with mycotic vaginitis with reliable guarantee of safety. It is worthy of clinical application and vigorous promotion.

Key words: Clotrimazole vaginal tablets; Itraconazole; Fungal vaginitis; Adverse reactions; Recurrence rate

1. Introduction

Mycotic vaginitis is a common vulvovaginal inflammatory disease caused by Candida albicans infection. Its clinical manifestations are pruritus pruritus, increased vaginal discharge, and difficulty urinating, which can easily cause complications such as cervicitis, cervical erosion, tubal ovarian inflammation, and pelvic inflammatory disease. In severe cases, it can lead to premature labor, miscarriage and infertility. According to statistics [1], adult women have a 75% chance of contracting fungal vaginitis, and 30% of pregnant women have candida in their vagina, and the incidence is about 15%. At present, conventional medicine is often used as the main method for clinical treatment of mycotic vaginitis, but it has the disadvantages of low cure rate and high recurrence rate. Therefore, the application of effective clinical protocols to treat mycotic vaginitis has become one of the most urgent medical problems. In order to effectively help patients relieve pain, it is necessary to continuously find effective treatment methods in clinical practice [2]. Through long-term research and clinical
practice, it has been found that the use of clotrimazole vaginal tablets combined with itraconazole in the treatment of mycotic vaginitis has achieved good clinical effects, effectively promoted the recovery of patients and improved their quality of life. This study will focus on the clinical effects of itraconazole capsules and clotrimazole vaginal tablets in the treatment of fungal vaginitis, which are reported as follows.

2. Materials and methods

2.1 Normal information

A total of 98 patients with mycotic vaginitis received by our county hospital from December 2016 to December 2017 were selected as the research subjects.

2.1.1 Inclusion criteria

(1) It complies with the diagnostic criteria of the 4th edition of Obstetrics and Gynecology [2];
(2) Using the hanging drop method to confirm the diagnosis of vaginal discharge;
(3) Clinical symptoms of increased vaginal discharge and burning vulva;
(4) All patients gave informed consent;
(5) Age 65 years and older, gender is not limited;

2.1.2 Exclusion criteria

(1) Have allergic reactions to itraconazole and clotrimazole;
(2) History of diabetes, liver and kidney blood system diseases;
(3) Mixed vaginal infections;
(4) Poor compliance, unable to cooperate with investigation and research.

2.1.3 Patient grouping

The patients in this group were randomly divided into observation group and control group, with 49 cases in each group. The age of the observation group was between 21 and 60 years, with an average age of (40.51 ± 4.37) years; the course of disease was from 3 months to 4 years, with an average of (2.13 ± 1.07) years; the age of the control group was between 23 and 57 years, with an average age (40.19 ± 4.52) years old; course of disease was 5 months to 4 years, with an average course of (2.29 ± 1.15) years. Comparison of general information such as age and course of disease between the two groups was not statistically significant (P> 0.05) and was comparable.

2.2 Treatment methods

Instruct patients to maintain vulvar hygiene, and perform NaHCO3 solution cleanup on the vulva and vagina of all patients during non-menstrual periods. The control group was given clotrimazole vaginal tablets. Methods: Before going to bed, put 1 (0.5g) clotrimazole vaginal tablets in the depth of its vagina (6-9cm) and continue to apply it for 1 week. On the basis of the above control group, the observation group was treated with itraconazole capsules, itraconazole capsules, orally, 0.1 g / times, 2 times a day for 1 week.

2.3 Observation indicators

2.3.1 Efficacy Evaluation

(1) Clinical efficacy: The patient's clinical symptoms completely disappeared, and a vaginal discharge examination showed a negative result for cure;
(2) The clinical symptoms and signs of the patient basically disappeared, and the vaginal secretion examination showed a positive effect.
(3) The clinical symptoms and signs of the patient have disappeared, and a vaginal discharge examination shows a positive result;
(4) Ineffectiveness means no improvement in clinical symptoms and signs, or even signs of deterioration.

2.3.2 Incidence of adverse reactions

The patients were followed up for 3 months, and the adverse reactions such as loss of appetite, nausea and vulvar allergy after treatment were recorded and compared between the two groups of patients.

2.3.3 The recurrence rates of patients after treatment were compared

2.3.4 Quality of Life

SF-36 (Quality of Life Scale) was used to evaluate the quality of life of all the subjects, including a total of 6 functions. The higher the score, the higher the quality of life.
2.4 Statistical method

SPSS 19.0 software was used to analyze the measurement data using (x ± s) and t test. The data were described using "rate" and c2 test. When P <0.05, the difference was statistically significant.

3. Results

3.1 Comparison of clinical efficacy

After treatment, the total effective rate in the observation group was 89.80%, which was higher than the control group by 67.35%. The difference was statistically significant (P <0.05). See Table 1 for details.

<p>| Table 1. Comparison of clinical treatment effect between two groups of patients (%) |
|------------------------------------------|-------------------|-------------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>As for r Marked effect</th>
<th>Effective</th>
<th>Invalid</th>
<th>Total effective rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>49</td>
<td>23 (46.94)</td>
<td>21</td>
<td>4 (8.61)</td>
<td>1 (2.04)</td>
</tr>
<tr>
<td>Control group</td>
<td>49</td>
<td>18 (36.73)</td>
<td>15</td>
<td>11 (22.45)</td>
<td>5 (10.20)</td>
</tr>
</tbody>
</table>

3.2 Comparison of adverse reactions

In the observation group, 1 case of vulvar allergy, 3 cases of loss of appetite, 4 adverse reactions, accounting for 8.16%; 4 cases of vulvar allergies in the control group, 1 case of nausea, 5 adverse reactions, accounting for 10.20%. The incidence of adverse reactions was not significantly different from that of the control group (P> 0.05). The above-mentioned adverse reactions subsided on their own after 1-2 days of discontinuation, as shown in Table 2.

<p>| Table 2. Comparison of adverse reactions after treatment between two groups of patients (%) |
|------------------------------------------|-------------------|-------------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>Vulvar allergy</th>
<th>Nausea</th>
<th>Loss of appetite</th>
<th>Incidence of adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>49</td>
<td>1 (2.04)</td>
<td>0 (0.00)</td>
<td>3 (6.12)</td>
<td>4 (8.16)</td>
</tr>
<tr>
<td>Control group</td>
<td>49</td>
<td>4 (8.16)</td>
<td>1 (2.04)</td>
<td>0 (0.00)</td>
<td>5 (10.20)</td>
</tr>
</tbody>
</table>

3.3 Comparison of recurrence rates

There was 1 patient with recurrence in the observation group with a recurrence rate of 2.04%; 7 cases in the control group with a recurrence rate of 14.29%. The recurrence rate in the observation group was significantly lower than that in the control group (P <0.05). See Table 3.

| Table 3. Comparison of recurrence rates after treatment between two groups of patients (%) |
|------------------------------------------|-------------------|-----------------|-----------------|-----------------|-----------------|
| Group                     | Number of cases | Number of relapses | Recurrence rate(%) |
|---------------------------|-----------------|-------------------|-------------------|-----------------|-----------------|
| Observation group         | 49              | 1                 | 2.04              |
| Control group             | 49              | 7                 | 14.29             |

3.4 Comparison of quality of life between the two groups

Quality of life score: P> 0.05 (no statistical difference) between the two groups before treatment; the observation group was significantly higher than the control group after treatment, P <0.05 (with statistical difference).

<p>| Table 4: Comparison of quality of life between two groups of patients (x±s) |
|------------------------------------------|-------------------|-------------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>Before treatment (points)</th>
<th>After treatment (points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>49</td>
<td>43.26±8.14</td>
<td>79.62±12.62</td>
</tr>
<tr>
<td>Control group</td>
<td>49</td>
<td>43.33±8.12</td>
<td>54.26±9.22</td>
</tr>
<tr>
<td>t</td>
<td>/</td>
<td>0.043</td>
<td>11.358</td>
</tr>
<tr>
<td>P</td>
<td>/</td>
<td>0.966</td>
<td>0.000</td>
</tr>
</tbody>
</table>

4. Discussion

Mycotic vaginitis is one of the common female diseases, also known as candidal vaginitis, and its causes are related to the abuse of antibiotics, diabetes, the use of large doses of estrogen, long-term use of
imunosuppressants, and indirect exposure to infection. Related experts believe that [3], the pathogenesis of mycotic vaginitis is that Candida has an adhesion effect on host cells, which can colonize and invade it, and then form pseudohyphae or germs [4]; when pseudohyphae or germs are formed, it can use the nutrients obtained from the host cells for its own growth. In addition, the fungus can secrete a variety of proteolytic enzymes that are invasive to the host cells to help them adhere to the epithelial cells. This severely damages the tissue of epithelial cells; the fungus has the property of activating the path adjacent to complement, which in turn causes allergy to be released from the path adjacent to complement, causing patients with local vasodilation, local edema, and inflammatory cell infiltration. At present, the clinical treatment of this disease is based on topical medication, but the prolonged administration will cause discomfort in the gastrointestinal tract. Therefore, it is difficult to achieve the desired effect. Medical research shows [5] that the use of comprehensive and combined medications can avoid liver and gastrointestinal damage to patients, reduce adverse reactions, and significantly improve clinical results.

Some studies suggest that at present, it is generally believed that the occurrence of mycotic vaginitis is closely related to pregnancy, sexual transmission, gastrointestinal diseases, human cell-mediated immune mechanisms, diabetes, and abuse of antibiotics. The main clinical characteristics of patients are Difficulty urinating, increased vaginal discharge, itching of the vulva, etc. If the disease is not treated promptly or the method is inappropriate, it can easily cause complications such as pelvic inflammatory disease, fallopian tube inflammation, cervical erosion, and cervicitis. Abortion and premature birth [6-7]. Drug therapy is currently the main method for clinical treatment of mycotic vaginitis, but single drug treatment is not effective. Therefore, clinical trials are currently being conducted to treat patients with a combination of drugs. Clotrimazole vaginal tablets have a significant antibacterial effect, which can effectively adjust the vaginal PH value of the patient, weaken the adhesion of Candida to vaginal epithelial cells, reduce the activity of Candida, and achieve the purpose of sterilization. Itraconazole capsule is a broad-spectrum antifungal drug, which has the advantages of broad-spectrum, high efficiency, low toxicity, good lipophilicity, and can selectively inhibit ergosterol synthesis in cell membranes and fungal demethylases, and can effectively inhibit Superficial fungi are produced to kill effective fungi. The combination of itraconazole capsules and clotrimazole vaginal tablets can synergistically relieve the symptoms of leucorrhea and itching in patients. The study showed that the total clinical effectiveness and quality of life in the observation group were significantly higher than those in the control group, P <0.05; the incidence of adverse reactions in the two groups was compared with P> 0.05. In the study of Chen Rui’e [8], the total effective observation group and the control group were 89.80% and 67.35%, respectively, P <0.05, which is consistent with the results of this study, indicating that the combination of itraconazole capsules and clotrimazole vaginal tablets is fungal. The effectiveness and safety in the treatment of vaginitis should be the ideal treatment for patients with fungal vaginitis [9-10].

It is documented that the inducing mechanisms of mycotic vaginitis include abuse of antibiotics, diabetes, human cell-mediated immune mechanisms, gastrointestinal diseases, sexual transmission, and pregnancy. The pathogenic mechanism of mycotic vaginitis includes the following: one is the candida colonization and invasion due to the candida's adhesion to the main cells of the human body, and the candida germ and candida pseudohyphae are formed after the candida adheres to the main cells; The formation of Candida pseudomyycin can provide sufficient nutrition for the development of Candida cells. The third is that Candida can secrete proteolytic enzymes. This proteolytic enzyme is invasive and can help Candida to adhere to skin cell tissues. It has damaging effects. Fourthly, Candida can activate the AP pathway. The AP pathway can produce a substance called minomycin, which can cause patients with local vasodilation, local edema, and inflammatory cell infiltration.

Mycotic vaginitis is a common infectious disease in adult women. In the past, mycotic vaginitis was mostly based on clinical treatment with topical medications. Excessive medication time could easily cause gastrointestinal reactions in the users, which is not suitable for long-term medication. Candida exists in a symbiotic form in patients. Under appropriate circumstances, Candida can form hyphae, causing vaginal skin capsules to fall and vaginal candida infection.

In related studies, the combination of itraconazole capsules and clotrimazole vaginal tablets showed a total effective rate of 97.7% in the study group and 72.7% in the control group, with significant differences and statistical significance (P <0.05). It can be seen that itraconazole and clotrimazole are better treatment drugs for fungal vaginitis. Itraconazole capsules contain an antibacterial drug and have strong inhibitory effects on ergot fungus cells. In previous research reports, itraconazole capsules have many advantages in clinical use, short treatment course, quick results, economy, and no side effects. Therefore, itraconazole, a relatively mature drug, was selected in this study. Clotrimazole vaginal tablets are mainly synthesized from candida ergot alcohol substances, which can change the composition of candida cells in the body, inhibit fungal cells, and even cause fungal death. Therefore, itching symptoms of fungal vaginitis can be eliminated[11].

The lactobacillus component in clotrimazole vaginal tablets can improve the fungicidal ability of clotrimazole vaginal tablets. When the solubility of acidic substances increases, acidic substances and lactobacillus can cooperate with antibacterial. Clotrimazole vaginal tablets can be used for vaginitis. Clinical
treatment. Clotrimazole vaginal tablets have a high bactericidal concentration and a long retention period, usually 3 to 4 days, in order to maintain the normal physiological environment of the patient's vagina. Clotrimazole vaginal tablets have little side effects in clinical treatment, only need to be used once, and they are convenient to use and can be accepted by most patients. Clotrimazole vaginal tablet drug placement work can be completed in the clinic, there are no drug management issues[12-13].

Itraconazole capsule is a broad-spectrum antifungal drug. It has good lipophilicity and keratophilic characteristics, which can ensure that the vaginal mucosa and other parts can obtain a higher concentration of the drug. In addition, the drug can effectively inhibit superficial fungi, so it can effectively kill harmful fungi. Clotrimazole vaginal tablets are formulated with lactic acid and have strong antibacterial effects. The mechanism of action is that the drug can maintain the balance of vaginal PH value in patients, reduce the adhesion of Candida to vaginal epithelial cells, and thus the activity of Candida is affected. Inhibit, so as to achieve the purpose of sterilization[14]. At the same time, clotrimazole vaginal tablets can change the permeability of cell membranes and disrupt the fungal biological metabolism. Related research shows that the combination of itraconazole capsules and clotrimazole vaginal tablets for the treatment of fungal vaginitis is complementary and the clinical effect is more significant. The results of this study show that the total clinical effective rate of the observation group after treatment was 89.80% significantly higher than that of the control group at 67.35%; the improvement of adverse reactions in the observation group was not statistically significant compared with the control group[15-16]; the recurrence rate in the observation group after treatment was significantly lower than Control group. It shows that the clinical application of itraconazole capsules and clotrimazole vaginal tablets in the treatment of mycotic vaginitis can effectively reduce the recurrence rate of patients, improve the efficiency of clinical treatment, and achieve the purpose of completely curing mycotic vaginitis[17].

5. Conclusion

The combined application of itraconazole capsules and clotrimazole vaginal tablets in the treatment of mycotic vaginitis has a fast and effective effect, a low recurrence rate, and effectively improves the quality of life of patients with mycotic vaginitis, with a reliable guarantee of safety. It is worthy of clinical application and vigorous promotion.

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References


