Clinical Observation on 90 Cases of High-risk HPV Treated with Lactobacillus Vaginal Capsule Combined with Interferon

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Abstract: Objective: To observe the effect of Lactobacillus vaginal capsule combined with recombinant human interferon α-2b gel in the treatment of patients with high-risk human papilloma virus (HPV) infection. **Method**: 90 patients with confirmed HPV infection who received treatment in our hospital from June 2020 to June 2022 were selected as the study subjects, and patients who received routine treatment in our hospital were selected as controls. The patients were divided into experimental group (n = 45) and control group (n = 45). The experimental group was treated with Lactobacillus vaginal capsule combined with recombinant human interferon α-2b gel, and the control group was treated with recombinant human interferon α-2b gel. The clinical efficacy of the two groups was compared to observe the changes of inflammatory indexes before and after treatment. **Results:** The total effective rate of the experimental group was 100%. The difference was mainly reflected in that the effective rate was 95.55% (43 / 45), which was higher than 8.88% (4 / 45) of the control group, and the difference was statistically significant ($P < 0.05$). The changes of inflammatory indexes after treatment in the two groups were observed, and it was found that TNF-α、 IL-6 and IL-10 in the experimental group were significantly lower than those in the control group ($P < 0.05$). No obvious adverse reactions were observed in the two groups during the treatment period. **Conclusion:** Lactobacillus vaginal capsule combined with recombinant human interferon α-2b gel has a good therapeutic effect on HPV infected patients, and can significantly reduce the level of inflammatory indicators, which is better than recombinant human interferon alone α-2b gel treatment.

1. Introduction

Human papilloma virus (HPV) belongs to the genus A of Papilloma vacuole virus in the Paproavairidae, and presents as a spherical DNA virus. After infection, patients show symptoms such as verruca vulgaris, perinail verruca and genital warts. If not treated in time, it will seriously affect the health of women.

2. Data and Methods

2.1 General Data

88 patients with confirmed HPV infection who were treated in our hospital from June 2020 to June 2022 were selected as the study subjects. They were divided into the experimental group (n = 45) and the control group (n = 45) according to the course of the disease. Inclusion criteria: ① inpatients diagnosed with HPV infection by vaginal examination and pathological analysis; ② patients without other gynecological diseases; ③ volunteer and agree to participate in this study ④ age ≥ 20 years. Exclusion criteria: ① incomplete clinical data; ② with severe organic diseases; ③ have a serious mental history; ④ with malignant tumors of the reproductive system; ⑤ pregnant or lactating patients; ⑥ no contraindications or experimental drugs. The trial was approved by the medical ethics committee of our hospital. The patients were divided into

experimental group (n = 45) and control group (n = 45) according to the course of disease. According to the inclusion and exclusion criteria, a total of 90 cases were included, including 50 males, aged 22-58 years, with an average of 38.45 ± 1.28 years. Among them, a total of 45 patients (control group) received routine treatment, including 25 males, aged 23-58 years, with an average of 38.49 ± 1.36 years. A total of 45 patients (experimental group) were included in the combined trial treatment, with an average age of 38.46 ± 1.35 years (23-58 years). There was no statistical difference between the two groups in general data such as personal basic information, which was comparable.

2.2 Method

The control group was treated with recombinant human interferon α-2b gel, trade name You Jing'an, S20010054, 100000 IU / g: 5g / tube. Before the patients went to bed, after the vulva was fully cleaned in the supine position, the buttocks were properly padded, and the drug pusher was slowly delivered to the posterior fornix of the vagina, and then injected. After completion, take out the propeller 1g / time, 24h / time. On the basis of the control group, the experimental group used Lactobacillus vaginal capsule, trade name: Ding Junsheng, S20030005, 0.25g/5 capsules. Before going to bed, after fully cleaning the vulva, the patients put on a finger cuff and put the product into the deep part of the vagina, one capsule each time, once a day. The two groups were treated for 10 days as a cycle and the continuous treatment lasted 4 cycles. For the patients with HVP after menopause or hysterectomy, the drug was used for 1 cycle, then stopped for 3 days, and then continued for 3 cycles.

2.3 Observation Index

The clinical effects of the two groups were compared. According to the comparison of significant effectiveness, effectiveness and ineffectiveness, ① After 4 cycles of treatment, more than 90% of the patients had HPV negative, and the clinical HPV indicators, symptoms and vaginal secretion contents were significantly improved to be significantly effective; ② More than 70% of the patients were negative for HPV, and the clinical HPV indexes, symptoms and vaginal secretion were improved; ③ No HPV turned negative in the patients, and the symptoms of HPV indicators did not change or even became worse. Formula: total effective rate = (significantly effective + effective) cases / total cases × 100%。

The levels of inflammatory indexes before and after treatment were compared between the two groups.

After 4 cycles before and after admission, tumor necrosis factor -α （TNF- α）、 Interleukin-6 (IL-6) levels were compared.

After 4 cycles of treatment, the incidence of adverse reactions was compared between the two groups.

2.4 Statistical Method

SPSS 25.0 software was used for statistical analysis, and t-test was used. The counting data were expressed in the rate (%), and $\chi 2$ test, with $P < 0.05$.

3. Results

3.1 Comparison of the Clinical Efficacy of the Two Groups

The total effective rate of the experimental group was 100%, 95.55% (43 / 45), which was higher than that of the control group (8.88% (4 / 45). The difference was statistically significant ($P < 0.05$). See Table 1.

Table 1 Comparison of the Clinical Efficacy of the Two Groups[n(%)]

Index	Experimental group（n=45）	Control group(n=45)	t value	p value
Significant effectiveness	43(95.55)	4(8.88)		

Effectiveness	2(4.44)	41(91.11)	8.839	P<0.001
Ineffectiveness	0（0）	0（0）		
Total effectiveness	45（100%）	45(100%)		

3.2 Comparison of Inflammatory Index Levels between the Two Groups before and after Treatment

There was no significant difference in the TNF -α, levels of IL-6 and IL-10 (P > 0.05). After treatment, TNF-α, the level of IL-6 were lower than that before treatment and the index in the experimental group was lower than that in the control group (P < 0.05). See Table 2.

Table 2 Comparison of TNF -α、IL-6 and IL-10 levels of HPV patients in group 2 (ng / L)

Group	Cases		TNF-α	IL-6	IL-10	t value
Control group	45	Before treatment	201.21±20.62	24.33±4.48	3.82± 1.16	3.45
		After treatment	160.58± 17.21a	17.24± 3.07a	5.35± 1.32a	
Experimental group	45	Before treatment	207.14±20.36	25.04±4.51	3.57± 1.05	
		After treatment	137.29± 16.34ab	14.16± 2.42ab	5.70± 1.02ab	6.26

Note: TNF- α:tumor necrosis factor- α； IL-6: interleukin 6; IL-10: interleukin 10; Compared with that before treatment, aP < 0.05; Compared with the control group after treatment, bP < 0.05

3.3 Comparison of the Incidence of Adverse Reactions between the Two Groups during the Treatment Period

No obvious adverse reactions occurred in the two groups during the treatment period.

Table 4 Four cycles of HPV patients in two groups [cases (%)]

Group	n	Adverse reaction rate
Experimental group	45	2 (4.44)
Control group	45	3 (6.66)
P value		<0.05
T value		2.27

4. Discussion

High-risk HPV infection is often closely related to female cervical cancer. Because HPV gene can realize DNA integration through human path, it will accelerate the apoptosis of basal cells and differentiation layer cells of cervical epithelial cells, which will forcefully block the realization of the cell's own physiological cycle process, resulting in the failure of effective repair of cells at the HPV infected site, and the proto oncogene in cervical cells is activated, and then carcinogenesis [3-4]. The incidence rate of HPV infection in women is increasing rapidly and the age structure is younger. The use of Lactobacillus vaginal capsules can effectively establish the dominant bacterial group of Lactobacillus in the vagina, and through the gradual decomposition of glycogen, the release of acidic products can be satisfied, so as to maintain the acidic environment of the vagina, thereby inhibiting the growth and reproduction of parasitic bacteria in the vagina [5]. While recombinant human interferon α-2b gel is a glycoprotein developed by immune cells against viral infection. It has significant antiviral effect and can effectively inhibit HPV proliferation. In the clinical practice, the single drug use effect of these two drugs is generally. It can be found from the experiment that although the number of ineffective cases is zero, the number of effective drugs in the experimental group reaches 95.55%, while that in the control group is only 8.88%, which can't meet the value of clinical practice and promotion.

In conclusion, Lactobacillus vaginal capsule combined with recombinant human interferon α-2b gel can not only regulate the vaginal flora, thereby improving the dysregulation of vaginal flora, so

as to regain the immune defense force in the vagina, but also effectively inhibit HPV virus, because recombinant human interferon α-2b gel can inhibit virus proliferation and enhance lymphocyte toxicity by binding with specific membrane receptors on the cell surface, and play a significant antiviral role. From the test results, the clinical effect is significant, the inflammatory reaction is effective, and the repair of inflammatory damage is well promoted, so as to improve the clinical symptoms of high-risk HPV patients. It is worthy of clinical application and promotion.

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