

Clinical Study on the Treatment of Cervical HPV Infection with Yiqi Chushijiedu Decoction

Xia Wu

Rugao Center for Disease Control and Prevention, Rugao 226500, Jiangsu, China

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Abstract: *Objective:* To analyze the actual effect of Yiqi Chushijiedu Decoction in the treatment of cervical human papillomavirus (HPV) infection. *Methods:* 80 patients with cervical HPV infection were randomly divided into a control group and an observation group, 40 cases each. The control group received conventional therapy, while the observation group received Yiqichushijiedu decoction in addition to conventional therapy. Compare the traditional Chinese medicine syndrome scores, HPV negative conversion, changes in immune function indicators and the probability of adverse reactions between the two groups before and after treatment. *Results:* After treatment, the TCM syndrome score of the observation group was lower than that of the control group, the HPV negative conversion rate was higher than that of the control group, the improvement of immune function was better than that of the control group, and the incidence of adverse reactions was lower than that of the control group. These differences were statistically significant ($p < 0.05$). *Conclusion:* Yiqi Chushi Jiedu Decoction has obvious therapeutic effect on cervical HPV infection. It can improve the clinical symptoms of patients, turn more HPV negative, regulate immune function and has good safety, so it is suitable for clinical promotion.

Keywords: Cervical HPV infection; Yiqi Chushijiedu Decoction; TCM syndrome score; HPV negative conversion rate; Immune function

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1. Introduction

Human papillomavirus (HPV) infection is common worldwide and accounts for a very high proportion of female reproductive system diseases. Relevant studies indicate that approximately 80% of women will be infected with HPV at least once in their lives. There are many HPV subtypes, among which persistent infection with high-risk HPV is the main cause of cervical cancer and precancerous lesions, posing a great threat to women's reproductive health and life safety. It usually takes a long time from infection with high-risk HPV to the development of cervical cancer, which provides opportunities for clinical intervention. If effective treatment can be taken in time during the HPV infection stage to turn HPV negative, the possibility of cervical cancer can be greatly reduced. At present, Western medicine methods for treating cervical HPV infection mainly include drug therapy (such as recombinant human interferon, etc.), physical therapy (such as freezing, laser, microwave, etc.) and surgical treatment (such as cervical ring electrosurgery, etc.)^[1,2]. But these treatments have certain limitations. The effect of drug treatment is limited, and some patients have no response to drugs;

physical therapy may damage the normal tissue of the cervix and affect the physiological functions of the cervix; surgical treatment is suitable for patients with more severe lesions, and may also have the risk of postoperative complications and recurrence. In addition, HPV is easy to relapse after infection, and it is difficult to completely eliminate the virus with conventional treatment. Patients often have to face the problem of recurrence of the disease. In recent years, as people's understanding of traditional Chinese medicine has deepened, the application of traditional Chinese medicine in the treatment of viral infectious diseases has received more and more attention. Traditional Chinese medicine believes that the occurrence of diseases is related to the overall imbalance of the body. During treatment, it focuses on adjusting the balance of Yin and Yang and supporting healthy energy to eliminate disease pathogens. This concept has unique value in the treatment of HPV infection. For cervical HPV infection, traditional Chinese medicine does not have a corresponding disease name, but based on its abnormal vaginal discharge, vaginal discomfort and other symptoms, it is classified into the categories of "leucorrhea disease" and "mast". The core of its pathogenesis is insufficient righteousness, spleen deficiency and misfortune, which leads to endogenous dampness. At the same time, exogenous toxins and dampness combine with each other to invade the lower burner, damage Chongren, and then cause local cervical lesions. Therefore, the treatment should focus on replenishing Qi, strengthening the spleen, removing dampness and detoxification, and achieve the purpose of treatment by enhancing the body's resistance and removing dampness and toxins. Yiqi, Chushi and Jiedu Decoction is a prescription prepared based on the characteristics of this pathogenesis. In the prescription, *astragalus*, *Atractylodes*, etc. can replenish Qi and strengthen the spleen, *Phellodendron*, *Sophora flavescens*, etc. can clear away heat and dehumidify, Smilax, Guanzhong, etc. can detoxify and dissipate stagnation. Multi-flavored medicines work together to both strengthen the body and dispel evil. This study compares the effects of conventional treatment and combined treatment with Yiqi Chushijiedu Decoction, and observes the effect of this prescription on clinical symptoms, virus conversion and immune function in patients with cervical HPV infection, providing more basis for clinical treatment.

2. Materials and methods

2.1. General information

80 patients with cervical HPV infection admitted to the hospital in our town from January 2023 to December 2024 were selected and divided into a control group and an observation group of 40 cases each using the random number table method. The age of the control group was 25–50 years old, with an average of (36.5 ± 5.2) years old; the disease duration was 3–18 months, with an average of (8.6 ± 2.5) months. The age of the observation group was 23–48 years old, with an average of (35.8 ± 4.9) years; the duration of the disease was 2–16 months, with an average of (8.2 ± 2.2) months. Comparing the general information of the two groups of patients, the difference was not statistically significant ($p > 0.05$) and can be compared.

2.2. Inclusion criteria

It complies with the diagnostic criteria for HPV infection in the "Expert Consensus on Immune Prevention of Cervical Cancer and Other Human Papilloma Virus-Related Diseases", and is confirmed to be a high-risk HPV infection by HPV-DNA testing. The TCM syndrome differentiation belongs to the syndrome of Qi deficiency, dampness and heat, and dampness and toxin accumulation, and the main symptoms are band The vaginal discharge is heavy, yellow or yellow-green, sticky, smelly, or accompanied by genital itching; secondary symptoms include fatigue, distended lower abdomen, short red urine, loose stools or unpleasantness, light red tongue, yellow and greasy coating, and slippery pulse; age 18–55 years old; the patient signed an informed consent form.

2.3. Exclusion criteria

Complicated with serious heart, liver, kidney and other important organ diseases; women who are pregnant or lactating; allergic to the study drugs; have used immunomodulators or antiviral drugs in the past 3 months; suffer from other sexually

transmitted diseases; have poor compliance and cannot take medications on time or cooperate with follow-up visits.

2.4. Treatment methods

The control group used recombinant human interferon $\alpha 2b$ vaginal effervescent capsules (Xinfuning, 800,000 IU/capsule) for vaginal application, one capsule per night for 3 months. On the basis of the treatment in the control group, the observation group received Yiqi Chushijiedu Decoction, which consisted of 20 g of *Astragalus membranaceus*, 15 g of *Atractylodes macrocephala*, 15 g of *Poria cocos*, 30 g of Coix seed, 10 g of *Phellodendron cypress*, 10 g of *Sophora flavescens*, 15 g of *Sophora sinensis*, 30 g of *Smilax smilax*, 10 g of Guanzhong, and 6 g of licorice. Take 1 dose per day, decoct in water and take 400 mL of juice, take it warmly twice in the morning and evening, and take it continuously for 3 months.

2.5. Observation indicators

The TCM syndrome scores of the two groups of patients were observed before and after treatment, including the amount of vaginal discharge, the color of vaginal discharge, genital itching, fatigue, distension of the lower abdomen, short red urine, loose stools or discomfort, etc., and were scored as 0, 2, 4, and 6 respectively as none, mild, moderate, and severe. score; detect HPV-DNA and calculate the HPV negative conversion rate; use flow cytometry to detect the $CD3^+$, $CD4^+$, and $CD8^+$ levels of T lymphocyte subsets and calculate the $CD4^+/CD8^+$ ratio; record the occurrence of adverse reactions during treatment.

2.6. Statistical methods

SPSS22.0 statistical software was used for data analysis. Measurement data are expressed as $(\bar{x} \pm s)$, and t -test is used for comparison between groups; count data are expressed as rate (%), and χ^2 test is used for comparison between groups. $p < 0.05$ indicates that the difference is statistically significant.

3. Results

3.1. Comparison of TCM syndrome scores between the two groups of patients before and after treatment

The observation group was lower than the control group ($p < 0.05$), see Table 1.

Table 1. Comparison of TCM syndrome scores between the two groups of patients before and after treatment ($\bar{x} \pm s$, points)

Group	n	Before treatment	After treatment
Control group	40	22.56 ± 3.24	15.68 ± 2.87
Observation group	40	22.89 ± 3.41	11.25 ± 2.56
t		0.444	7.285
p		0.658	0.000

3.2. Comparison of HPV negative conversion rates between the two groups of patients

After treatment, the HPV negative conversion rate in the observation group was higher than that in the control group ($p < 0.05$), see Table 2.

Table 2. Comparison of HPV negative conversion rates between two groups of patients [n (%)]

Group	n	Turn negative	Not turned negative	Negative conversion rate
Control group	40	20 (50.00)	20 (50.00)	50.00
Observation group	40	30 (75.00)	10 (25.00)	75.00
χ^2				5.333
<i>p</i>				0.021

3.3. Comparison of immune function indicators between the two groups of patients before and after treatment

After treatment, the CD3⁺, CD4⁺ levels and CD4⁺/CD8⁺ ratio of the two groups of patients were higher than before treatment, and the CD8⁺ level was lower than before treatment. The improvement in the observation group was better than that in the control group ($p < 0.05$), see **Table 3**.

Table 3. Comparison of immune function indicators between the two groups of patients before and after treatment ($\bar{x} \pm s$)

Group	CD3 ⁺ (%)		CD4 ⁺ (%)		CD8 ⁺ (%)		CD4 ⁺ /CD8 ⁺	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	62.35 ± 5.12	66.58 ± 5.43	35.26 ± 4.35	38.52 ± 4.68	30.18 ± 3.56	28.24 ± 3.25	1.17 ± 0.21	1.36 ± 0.24
Observation group	62.68 ± 5.23	71.26 ± 5.87	35.51 ± 4.42	42.63 ± 5.02	30.32 ± 3.61	25.36 ± 2.98	1.18 ± 0.22	1.68 ± 0.28
<i>t</i>	2.878	3.702	0.255	3.787	0.175	4.131	0.208	5.488
<i>p</i>	0.005	0.000	0.799	0.000	0.862	0.000	0.836	0.000

3.4. Comparison of adverse reactions between the two groups of patients

During the treatment period, the incidence of adverse reactions in the observation group was lower than that in the control group, but the difference was not statistically significant ($p > 0.05$), see **Table 4**.

Table 4. Comparison of the occurrence of adverse reactions between the two groups of patients [n (%)]

Group	n	Vaginal burning sensation	Stomach ache	Nausea	Abdominal bloating	Overall incidence
Control group	40	3 (7.50)	2 (5.00)	0 (0.00)	0 (0.00)	5 (12.50)
Observation group	40	0 (0.00)	0 (0.00)	1 (2.50)	1 (2.50)	2 (5.00)
χ^2						0.626
<i>p</i>						0.429

4. Discussion

Cervical HPV infection is the main causative factor of cervical cancer, and its prevention and treatment has always been the focus of clinical research. Although Western medicine treatments can improve the condition to a certain extent, they have problems such as poor efficacy, easy recurrence, and possible damage to cervical tissue. Traditional Chinese medicine starts from a holistic concept and has unique advantages in the treatment of HPV infection. Astragalus is a royal medicine

in the prescription of the Yiqi Chushijiedu Decoction used in this study. It is sweet and warm in nature and returns to the spleen and lung meridian. It has the functions of nourishing Qi and raising Yang, consolidating the surface and stopping sweating, diuresis and reducing swelling. It can greatly replenish vitality, enhance the body's immunity, thereby strengthening the body and eliminating evil^[3,4]. *Atractylodes macrocephala*, *Poria cocos*, and coix seed are used together as ministerial drugs. *Atractylodes* can invigorate the spleen and Qi, dry dampness and diuresis; *Poria cocos* can diuretic and dampness, strengthen the spleen and calm the heart; coix seed can diuretic and dampness, strengthen the spleen and stop diarrhea, remove paralysis, expel pus, detoxify and disperse stagnation. The combination of these three medicines can enhance the power of spleen and dehumidification, cut off the source of dampness evil, and assist astragalus to strengthen the body. *Cortex Phellodendron*, *Sophora flavescens*, *Cortex Sophorae*, *Smilax smilax*, and Guanzhong are adjuvants. *Cortex Phellodendron* can clear away heat and dampness, purge fire and detoxify; *Sophora flavescens* can clear away heat and dampness, kill insects and relieve itching; *Cortex Cortex* has the effects of clearing away heat and detoxification, eliminating carbuncle and pus, removing blood stasis and relieving pain. *Smilax Poria* can detoxify, dehumidify, and relieve joints; Guanzhong can clear away heat and detoxify, cool blood, stop bleeding, and kill insects. When used together, these drugs can clear away heat and dehumidify, detoxify and dissipate stagnation, and get rid of pathogenic factors^[5,6]. Licorice is an herbal medicine that can reconcile various medicines. It can also nourish the spleen and replenish Qi, moisten the lungs and relieve cough, clear away heat and detoxify. The entire formula is carefully formulated to both strengthen the body and remove evil spirits, and jointly achieve the effect of replenishing Qi, removing dampness and detoxifying. Judging from the results of this study, the TCM syndrome scores of the observation group after treatment were significantly lower than those of the control group, which shows that Yiqi Chushijiedu Decoction can more effectively improve patients' clinical symptoms such as heavy vaginal discharge, thick yellow color, itching of the genitals, and fatigue. This is because the medicines in the prescription can improve the patient's systemic condition by replenishing Qi and strengthening the spleen, and enhance the body's transportation and transformation functions, thereby alleviating the endogenous dampness evil. At the same time, the medicines for clearing away heat, dehumidification and detoxification can directly target the local dampness evil, eliminate inflammation and relieve symptoms. For example, the Qi-enhancing drugs such as *Astragalus* and *Atractylodes* in the prescription can improve the patient's energy and spirit and improve the symptoms of mental fatigue; the heat-clearing and dampness-clearing drugs such as *Cortex Phellodendron* and *Sophora flavescens* can relieve symptoms such as thick yellow matter in vaginal discharge and vaginal itching. Clinical observation found that after taking this prescription for 2 weeks, most patients' vaginal abnormalities were significantly improved, and their vaginal itching symptoms were reduced. This is closely related to the mild effect of traditional Chinese medicine and its local and overall characteristics.

In terms of HPV negative conversion rate, the observation group was higher than the control group. This may be because Yiqi Chushijiedu Decoction can not only directly inhibit HPV virus replication, but also enhance the body's ability to clear the virus by regulating the body's immune function. Modern pharmacological research shows that drugs such as *Astragalus* and *Atractylodes* have immune-regulating effects, can promote lymphocyte proliferation, and enhance the body's cellular immunity and humoral immunity. Drugs such as *Smilax Poria* and Guanzhong have antiviral activity and can inhibit the nucleic acid synthesis of the HPV virus, thereby reduce the HPV load and increasing the negative conversion rate. *Astragalus* polysaccharides in *Astragalus* can promote the proliferation and differentiation of T lymphocytes, enhance the body's immune response, and help eliminate HPV viruses. When treating viral infectious diseases, Yiqijiedu prescriptions can exert antiviral effects through multiple ways, not only directly acting on the virus, but also indirectly inhibiting viral replication by improving the host's immune status^[7].

The immune function index results showed that after treatment, the observation group's CD3⁺, CD4⁺ levels and CD4⁺/CD8⁺ ratio increased more than the control group, and the CD8⁺ level also decreased more than the control group. CD3⁺ represents total T lymphocytes, CD4⁺ helper T lymphocytes can assist other immune cells to function, CD8⁺ cytotoxic T lymphocytes can kill target cells, and the CD4⁺/CD8⁺ ratio can reflect the immune balance of the body. Yiqi Chushijiedu Decoction restores the balance of the body's immune function by regulating T lymphocyte subpopulations, enhances

immune surveillance and immune clearance capabilities, and better fights HPV infection. This further illustrates that the mechanism of action of this prescription in treating HPV infection is closely related to regulating immune function. In clinical practice, patients with low immune function are often more susceptible to persistent HPV infection, and regulating immune function through traditional Chinese medicine can fundamentally improve patients' antiviral ability. This is also an important reason why the observation group has a higher HPV negative conversion rate.

In terms of safety, the incidence of adverse reactions in both groups was relatively low, and there was no significant difference. This shows that Yiqi Deshi Jiedu Decoction is safe during the treatment process, is well tolerated by patients, and will not cause obvious adverse reactions to patients, which provides guarantee for its long-term clinical application. The adverse reactions in the control group were mainly related to the vaginal administration of interferon, manifesting as local irritation symptoms; the adverse reactions in the observation group were mild gastrointestinal discomfort, which may be related to the bitter and cold nature of some drugs, but the symptoms were mild and did not affect the progress of the treatment, and would be relieved after adjusting the medication time (such as taking it after meals). The Yiqichushijiedu Decoction in this study is a pure traditional Chinese medicine preparation. It not only has significant curative effect, but can also avoid damage to cervical tissue caused by physical therapy, reflecting the characteristics and advantages of traditional Chinese medicine treatment. For young patients with fertility needs, this non-invasive and effective treatment method is more acceptable and can protect their reproductive function while treating the disease.

In addition, traditional Chinese medicine treatment focuses on individualized adjustment. In practical applications, the Yiqichushijiedu Decoction can be added or subtracted according to the patient's specific symptoms. For example, patients with large vaginal discharge and obvious odor can add *Houttuynia cordata* and dandelion to enhance the power of clearing away heat and detoxification; patients with obvious symptoms of fatigue and fatigue can increase the dosage of *astragalus* or add *Codonopsis pilosula* to strengthen the effect of replenishing Qi; patients with obvious lower abdominal distension can add Motherwort and *Salvia miltiorrhiza* to activate blood circulation and remove blood stasis. This kind of flexible addition and subtraction can further improve the pertinence of treatment and better adapt to the condition characteristics of different patients, which is also the advantage of traditional Chinese medicine treatment.

In summary, Yiqi Chushijiedu Decoction has significant efficacy in treating cervical HPV infection. It can effectively improve patients' clinical symptoms, increase the rate of HPV negative conversion, regulate immune function, and is highly safe. It provides a safe and effective method for the treatment of cervical HPV infection and is worthy of clinical promotion and application.

About the author

Wu Xia (1981-), female, Han nationality, native of Rugao, Jiangsu, with a bachelor's degree, is currently an attending physician in TCM gynecology, and works at the Rugao Center for Disease Control and Prevention. Her research interests include pelvic inflammatory disease, vaginitis, cervical cancer, ovarian tumors and other TCM gynecological related diseases.

Disclosure statement

The author declares no conflict of interest.

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