

To Explore the Efficacy of Fuzheng Jieyu Decoction Combined with Recombinant Human Interferon α 2b Vaginal Effervescent Capsules (Xinfuning) in the Treatment of Cervical HPV Infection

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Abstract: *Objective:* To study the therapeutic effect of Fuzheng Jieyu Decoction combined with recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) on patients with cervical human papillomavirus (HPV) infection. *Methods:* 86 patients with cervical HPV infection who received treatment in our hospital from January 2025 to December 2025 were selected and divided into a combination group and a single drug group using the random number table method, with 43 cases in each group. The single-drug group was treated with recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning), and the combination group was treated with Fuzheng Jieyu Decoction orally on the basis of the single-drug group. The therapeutic effects of the two groups were compared. *Results:* The HPV negative conversion rate and the effective rate of improving cervical inflammation in the combination group were higher than those in the single-drug group. The white blood cell count of cervical secretions and cervical mucosal congestion score after treatment were lower than those of the single-drug group. The vaginal cleanliness was better than that of the single-drug group, and the complication rate was lower than that of the single-drug group ($p < 0.05$). *Conclusion:* Fuzheng Jieyu Decoction combined with recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) can effectively increase the virus negative conversion rate, improve cervical inflammation indicators, and reduce the probability of treatment-related complications in the treatment of cervical HPV infection, which has good clinical application value.

Keywords: Fuzheng Jieyu decoction; Recombinant human interferon α 2b vaginal effervescent capsules; Xinfuning; Cervical HPV infection; Virus negative conversion rate; Cervical inflammation indicators

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1. Introduction

Cervical human papillomavirus (HPV) infection is a common clinical gynecological infectious disease. Persistent infection with high-risk HPV is the main cause of cervical intraepithelial neoplasia and even cervical cancer, which is extremely harmful to female reproductive health. At present, clinical treatment of cervical HPV infection mainly focuses on antiviral and regulating local immunity. Recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning)

are commonly used drugs, which can inhibit viral replication by enhancing local immune function. However, when used alone, the virus negative conversion rate in some patients is not ideal, and the treatment cycle is long^[1,2]. Traditional Chinese medicine classifies cervical HPV infection into the categories of “lead-on disease” and “mild disease”. It is believed that its onset is related to the lack of healthy Qi in the body and the invasion of dampness, poison and turbidity. Treatment needs to be based on the principles of strengthening the body, eliminating evil, detoxifying and transforming filth. Fuzheng Jieyu Decoction, as an empirical prescription of traditional Chinese medicine, has the effects of replenishing Qi and strengthening the spleen, clearing heat and detoxifying, removing dampness and resolving filth, and can regulate the patient's body condition as a whole. Based on this, this study provides a better reference for the clinical treatment of cervical HPV infection by comparatively analyzing the therapeutic effects of Fuzheng Jieyu Decoction combined with recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) and recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) alone.

2. Materials and methods

2.1. General information

86 patients with cervical HPV infection admitted to our hospital from January 2025 to December 2025 were selected as cases and divided into a combination group and a single drug group using the random number table method, with 43 cases in each group. The patients in the combined group were aged 25 to 48 (35.26 ± 4.18) years old; HPV infection type: 43 cases were high-risk type. The patients in the single-drug group were 24 to 49 (35.72 ± 4.05) years old; HPV infection type: high-risk type 43. There was no significant difference in the general information of the two groups of patients ($p > 0.05$), indicating they were comparable.

2.1.1. Inclusion criteria

- (1) Cervical HPV infection confirmed by HPV testing;
- (2) Aged 20 to 50 years old;
- (3) Not receiving relevant antiviral treatment in the past month.

2.1.2. Exclusion criteria

- (1) Combined with cervical cancer and precancerous lesions;
- (2) Severe abnormality of liver and kidney function;
- (3) Allergy to study drugs.

2.2. Method

Both groups of patients started treatment after menstruation. During the treatment period, they were forbidden to have sex and avoid spicy and irritating foods.

2.2.1. Single drug group

Recombinant human interferon α 2b vaginal effervescent capsules were used for treatment. After cleaning the vulva before going to bed, the patient lies on his back and puts the medicine in the posterior fornix of the vagina. Take 1 pill each time (containing 800,000 IU of recombinant human interferon α 2b), once a day. The medication will last for 10 days as one course of treatment. There will be a total of 3 courses of treatment, with an interval of 20 days between each course.

2.2.2. Joint group

On the basis of the treatment of the single drug group, Fuzheng Jieyu Decoction was taken orally.

- (1) Drug composition

20 g of *Astragalus membranaceus*, 15 g of *Codonopsis pilosula*, 12 g of *Atractylodes macrocephala*, 15 g of *Poria cocos*, 15 g of honeysuckle, 12 g of *Forsythia suspensa*, 15 g of dandelion, 12 g of soybean root, 20 g of coix seed, 10 g of plantain (fried), 12 g of angelica root, and 6 g of licorice.

(2) Decoction method

Soak the above medicinal materials in water for 30 minutes, boil over high heat, then reduce to low heat and decoct for 30 minutes, and take about 300 mL of concoction; add appropriate amount of water to the medicinal residue, boil over high heat, then decoct over low heat for 20 minutes, take about 200 mL of concoction, and mix the two concoctions evenly. One dose per day, taken warmly twice in the morning and evening, 250 mL each time, for 10 consecutive days as one course of treatment, a total of 3 courses of treatment, started simultaneously with vaginal medication, and the interval between courses is consistent with the single-drug group.

(3) Precautions

Observe the patient for nausea, diarrhea and other discomforts during the medication. If any obvious adverse reactions occur, suspend the medication and adjust the prescription in a timely manner.

2.3. Observation indicators

The HPV negative conversion rate and cervical inflammation improvement rate after 3 courses of treatment were compared between the two groups; cervical inflammation indicators (cervical secretion white blood cell count, cervical mucosal congestion score, vaginal cleanliness) before and after treatment; and the incidence of complications (vaginal burning, vulvar itching, gastrointestinal discomfort) during treatment.

Determination of HPV negative conversion: HPV test after treatment shows that the viral load is < 1.0 RLU/CO; effective rate of improvement of cervical inflammation: cure (cervical mucosal congestion and edema completely disappear, secretion white blood cell count returns to normal, vaginal cleanliness I degree) + markedly effective (cervical mucosal congestion and edema are significantly reduced, secretion white blood cell count is reduced by $\geq 50\%$ compared with before treatment, vaginal cleanliness II degree) + effective (cervical mucosal congestion and edema are alleviated, secretion white blood cell count is reduced compared with before treatment) 20% to 49% less, vaginal cleanliness degree II to III) as a proportion of the total number of cases; cervical mucosal congestion degree score: 0 points (no congestion), 1 point (mild congestion, congestion range $< 1/3$ of the cervical area), 2 points (moderate congestion, The congestion range is $1/3\text{--}2/3$ of the cervical area), 3 points (severe congestion, the congestion range is $> 2/3$ of the cervical area); vaginal cleanliness: degree I (normal), degree II (mild inflammation), degree III (moderate inflammation), degree IV (severe inflammation).

2.4. Statistical methods

Data were analyzed using SPSS24.0. *t*-test for measurement data; χ^2 test for count data. $p < 0.05$ represents significant difference.

3. Results

3.1. Comparison of the HPV negative conversion rate and the effective rate of improving cervical inflammation between the two groups

The HPV negative conversion rate and the effective rate of improving cervical inflammation in the combination group were higher than those in the single-drug group ($p < 0.05$), see **Table 1**.

Table 1. Comparison of HPV negative conversion rate and effectiveness in improving cervical inflammation between the two groups [n (%)]

Group	n	HPV negative	Cervical inflammation is effectively improved
Joint group	43	30 (69.77)	39 (90.70)
Single drug group	43	20 (46.51)	31 (72.09)
χ^2		4.778	4.914
<i>p</i>		0.029	0.027

3.2. Comparison of cervical inflammation indicators between the two groups before and after treatment

After treatment, the white blood cell count of cervical secretions and cervical mucosal congestion score in the combination group were lower than those in the single-drug group, and the vaginal cleanliness was better than that in the single-drug group ($p < 0.05$), see **Table 2**.

Table 2. Comparison of cervical inflammation indicators between the two groups before and after treatment ($\bar{x} \pm s$)

Group	Cervical secretion white blood cell count (units/HP)		Cervical mucosal congestion score (points)		Vaginal cleanliness (degree)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Joint group (43)	18.62 \pm 3.25	6.35 \pm 1.58	2.15 \pm 0.42	0.68 \pm 0.21	3.02 \pm 0.35	1.52 \pm 0.28
Single drug group (43)	18.45 \pm 3.18	11.26 \pm 2.34	2.20 \pm 0.40	1.35 \pm 0.30	3.05 \pm 0.32	2.36 \pm 0.30
<i>t</i>	0.245	11.403	0.565	11.998	0.415	13.423
<i>p</i>	0.807	0.000	0.573	0.000	0.679	0.000

3.3. Comparison of the incidence of complications between the two groups during treatment

The incidence of complications during treatment in the combination group was lower than that of the single-drug group ($p < 0.05$), see **Table 3**.

Table 3. Comparison of the incidence of complications between the two groups during treatment [n (%)]

Group	n	Vaginal burning	Itching of the vulva	Gastrointestinal discomfort	Overall incidence
Joint group	43	1 (2.33)	1 (2.33)	1 (2.33)	3 (6.98)
Single drug group	43	3 (6.98)	3 (6.98)	5 (11.63)	11 (25.58)
χ^2					5.460
<i>p</i>					0.019

4. Discussion

Cervical HPV infection is a common infectious disease in the female reproductive system, and its prevention and treatment has always been a key topic in gynecological clinical research. The HPV virus mainly replicates by infecting cervical epithelial cells and integrating into the host genome. The ability of the body's immune system to clear the virus is a

key factor in determining the outcome of the infection. Most people with normal immunity can clear the virus on their own within 1 to 2 years. However, those with low immunity or immune dysfunction are prone to developing persistent infections, thereby increasing the risk of cervical lesions. The core mechanism of recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) currently commonly used in clinical practice is that through local administration, interferon α 2b acts directly on the cervical infection site, activating the activity of local macrophages, T lymphocytes and other immune cells, enhancing the body's ability to recognize and clear HPV viruses. It can also inhibit the activity of viral DNA polymerase and prevent virus replication and spread. However, clinical practice has found that when this drug is used alone, the virus negative conversion rate in some patients is often less than 50% due to factors such as poor overall immune status of the body, excessive viral load, or chronic inflammatory stimulation. Moreover, local vaginal irritation symptoms are prone to occur after treatment, affecting patients' treatment compliance^[3,4].

Traditional Chinese medicine theory has a unique system for understanding cervical HPV infection, which closely relates the occurrence of the disease to the imbalance of "righteous energy" and "evil energy". "Good Qi exists within, and evil cannot be removed; where evil gathers, its Qi must be deficient." Patients with cervical HPV infection often suffer from damaged spleen and kidney functions due to long-term fatigue, emotional disorders, improper diet, etc. If the spleen is not healthy, dampness and turbidity will arise internally, and kidney Qi will be deficient and the defense will not be solid. The dampness and turbidity from the outside (HPV virus) will interact with each other, infect the uterus, and erode the cervix, thus causing abnormal vaginal discharge, cervical inflammation and other diseases. Therefore, TCM treatment of cervical HPV infection needs to follow the principle of "strengthening the body without retaining evil, dispelling evil without damaging the body", and while strengthening the body's righteousness, it can eliminate the evil of dampness, poison and turbidity in the lower burner. The Fuzheng Jieyu Decoction used in this study is based on this treatment idea. In the formula, *Astragalus*, *Codonopsis*, *Atractylodes*, and *Poria* are the king herbs. Astragalus nourishes Qi and raises yang, consolidates the surface and relieves sweating. *Codonopsis ginseng* nourishes the middle Qi, strengthens the spleen and lungs, *Atractylodes* strengthens the spleen and removes dampness, replenishes Qi and consolidates the surface, and *Poria cocos* strengthens the spleen, exudes dampness, calms the heart, and calms the mind. The combination of these four drugs can significantly enhance the effectiveness of the treatment. The functions of the spleen and kidneys improve the overall health of the body and lay the foundation for eliminating viruses; honeysuckle, forsythia, dandelion, and soybean are the ministerial drugs. Honeysuckle clears away heat and detoxifies, evacuates wind-heat, Forsythia clears away heat and detoxifies, reduces swelling and dissipates stagnation, dandelion clears away heat and detoxifies, diuresis and removes stagnation, and soybean grass clears away heat and detoxifies, eliminates carbuncle and expels pus. All four medicines have strong effects. It has the power of clearing away heat and detoxification, which can specifically remove the evils of dampness, poison and turbidity in the lower burner, and inhibit the activity of viruses; *Coix* and *Plantago* are used as adjuvant medicines. It has the property of clearing away heat and detoxifying to avoid damage to the spleen and stomach; *Angelica sinensis* can nourish blood, activate blood circulation, regulate menstruation and relieve pain, which can improve local blood circulation in the cervix and promote inflammation repair. Licorice harmonizes various medicines and moderates the properties of the medicine. The whole prescription has the effects of replenishing Qi and strengthening the spleen, clearing away heat and detoxification, removing dampness and removing filth, and achieves the organic unity of "strengthening" and "eliminating evil"^[5,6].

Judging from the results of this study, the HPV negative conversion rate in the combination group (69.77%) was significantly higher than that in the single-drug group (46.51%). This data difference fully reflects the advantages of integrated traditional Chinese and Western medicine treatment. From an analysis of the mechanism of action, recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) directly target the HPV virus through local immune regulation and antiviral effects, while Fuzheng Jieyu Decoction improves the patient's physical condition from an overall perspective. On the one hand, the Qi-tonifying and spleen-tonifying medicinal materials in the prescription, such as *Astragalus membranaceus* and *Codonopsis pilosula*, can enhance the body's cellular and humoral immune functions, increase the proportion of $CD4^+$ T lymphocytes in peripheral blood, natural killer cell activity and other immune indicators, and provide a good systemic immune environment for local antiviral treatment; on the other hand, the active

ingredients in heat-clearing and detoxifying medicinal materials such as honeysuckle and dandelion (such as chlorogenic acid, forsythin, typhus sterol, etc.), has been confirmed by modern pharmacological research to have certain antiviral and anti-inflammatory effects. It can inhibit the expression of HPV virus E6 and E7 oncogenes, reduce virus damage to cervical epithelial cells, and at the same time reduce the local inflammatory response of the cervix, reduce the levels of inflammatory factors (such as interleukin-6, tumor necrosis factor- α), and create a favorable local microenvironment for virus clearance. When the two are used in combination, they form a synergistic mode of “local antiviral + systemic immunity regulation + local inflammation relief”. Compared with the use of recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) alone, which only focuses on local treatment, it can play a role in multiple links and multiple targets, thereby significantly increasing the virus negative conversion rate.

In terms of improvement of cervical inflammation, the effective rate of the combination group (90.70%) was significantly higher than that of the single-drug group (72.09%). After treatment, the white blood cell count of the cervical secretions of the combination group (6.35 ± 1.58 cells/HP) and the cervical mucosal congestion score (0.68 ± 0.21 points) were lower than the single-drug group (11.26 ± 2.34 pieces/HP, 1.35 ± 0.30 points), and the vaginal cleanliness (1.52 ± 0.28 degrees) was better than the single-drug group (2.36 ± 0.30 degrees), which is closely related to the functions of Fuzheng Jieyu Decoction in removing dampness, reducing filth, promoting blood circulation and repairing. The persistence of cervical inflammation will not only affect the local immune function of the cervix, but also provide a suitable environment for persistent infection of the HPV virus. The angelica in Fuzheng Jieyu Decoction can improve the local microcirculation of the cervix, promote the absorption of inflammatory exudates, and accelerate the repair of damaged mucosa; osmotic medicinal materials such as coix seed and psyllium seed can reduce cervical secretions, reduce the white blood cell count in the secretions, and slow down cervical inflammation. It can relieve symptoms such as increased leucorrhea and odor; heat-clearing and detoxifying herbs can inhibit the growth of local bacteria, mycoplasma and other pathogenic microorganisms on the cervix, and prevent mixed infections from aggravating inflammation. They cooperate with the local anti-inflammatory effect of recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) (by inhibiting the infiltration of inflammatory cells and reducing the release of inflammatory mediators) to jointly promote the regression of cervical inflammation. In clinical practice, some patients with cervical HPV infection often experience symptoms such as abnormal vaginal discharge and contact bleeding due to cervical inflammation, which seriously affects the quality of life. The advantages of integrated traditional Chinese and Western medicine treatment in improving these clinical symptoms and inflammatory indicators can also further improve patients' treatment compliance and provide guarantee for the completion of the entire treatment course^[7,8].

Treatment safety is an important consideration when selecting clinical treatment options. In this study, the incidence of complications in the combination group (6.98%) was significantly lower than that in the single-drug group (25.58%), and the complications were mainly mild vaginal burning and gastrointestinal discomfort. There were no serious adverse reactions, indicating that the combination of traditional Chinese and Western medicine treatment has good safety. Among the complications in the single-drug group, local irritation symptoms such as vaginal burning and vulvar itching were more common, which is related to the possible irritation of the vaginal mucosa after local administration of recombinant human interferon α 2b effervescent vaginal capsules (Xinfuning); while in the combination group, after Fuzheng Jieyu Decoction was added, the spleen and stomach herbs such as *Atractylodes macrocephala*, *Poria cocos*, and licorice in the prescription could enhance the spleen and stomach function. It can reduce the irritation of drugs to the gastrointestinal tract and reduce the incidence of gastrointestinal discomforts such as nausea and diarrhea. At the same time, Qi-tonifying medicinal materials such as *astragalus* and *Codonopsis pilosula* can enhance the body's tolerance to drugs and reduce mucosal irritation caused by excessive local immune responses caused by interferons, thereby reducing the risk of local vaginal discomfort symptoms^[9,10].

In summary, Fuzheng Jieyu Decoction combined with recombinant human interferon α 2b vaginal effervescent capsules (Xinfuning) treats cervical HPV infection. By complementing the advantages of traditional Chinese and Western medicine, it shows significant advantages in increasing the virus negative conversion rate, improving cervical

inflammation indicators, and reducing the incidence of complications.

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Disclosure statement

The authors declare no conflict of interest.

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