

ORIGINAL RESEARCH

Efficacy of recombinant human interferon α -2b combined with cervical loop electrosurgical excision procedure in the treatment of cervical precancerous lesions

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Abstract

Background: This study explores the efficacy of combining recombinant human interferon α -2b with the cervical loop electrosurgical excision procedure (LEEP) in the treatment of cervical precancerous lesions. **Methods:** Clinical data from 100 patients treated for cervical precancerous lesions at our hospital from January 2021 to January 2023 were retrospectively analyzed. Patients were divided into two groups based on treatment method: an experimental group (50 cases) and a control group (50 cases). The control group received LEEP using a high-frequency electric knife, while the experimental group was treated with LEEP combined with recombinant human interferon α -2b gel. The differences in efficacy between the two groups were compared. **Results:** The experimental group demonstrated a significantly higher overall effective rate compared to the control group ($p < 0.05$). There was no significant difference in the incidence of surgical complications between the two groups ($p > 0.05$). At 6 months and 1 year after surgery, the experimental group exhibited a lower recurrence rate and a higher clearance rate of high-risk human papillomavirus (HR-HPV) compared to the control group ($p < 0.05$). Three months after treatment, the scores for environment, social relationships, physiology and psychology in the experimental group were significantly higher than those in the control group ($p < 0.001$). **Conclusions:** Combining LEEP with recombinant human interferon α -2b in patients with cervical precancerous lesions effectively eliminates HPV, improves quality of life, reduces complications and recurrence and is safe for medication.

Keywords

Cervical loop electrosurgical excision procedure; Cervical precancerous lesion; Recombinant human interferon α -2b

1. Introduction

Cervical precancerous lesions mainly refer to abnormal changes occurring in female reproductive system, primarily affecting the squamous epithelium of the cervix. These lesions are predominantly caused by persistent infection of high-risk human papillomavirus (HR-HPV), posing significant carcinogenic risks [1, 2]. Clinical symptoms mainly include vaginal contact bleeding and increased secretions, commonly observed in women aged 25–35, which threaten both physical and mental health [3]. Given the potential progression of cervical precancerous lesions to cervical cancer, timely and effective treatment is essential for improving patient prognosis [4]. Currently, surgical interventions are the predominant treatment for cervical precancerous lesions, with multiple methods available. The loop electrosurgical excisional procedure (LEEP), often performed under colposcopic guidance, is a widely adopted

technique for ensuring more precise excision. However, as the development of cervical precancerous lesions is closely associated with human papillomavirus (HPV) infection, surgical treatment alone does not eliminate the risk of HPV re-infection [5, 6]. Consequently, antiviral medications are frequently combined with surgical approaches to reduce HPV re-infection rates. Recombinant human interferon α -2b, a broad-spectrum antiviral drug, has been shown to effectively inhibit viral replication and aid in clearing the virus in infected patients [7].

Combined therapy plays a significant role in the treatment of cervical precancerous lesions in women, leading to improved prognosis and clinical outcomes of cervical-related diseases. This approach is essential for enhancing women's reproductive health. The present research contributes to our understanding of cervical diseases, highlighting the necessity of addressing these conditions to improve women's health and overall quality of life. Such improvements enable women to work and

live healthily, thereby supporting population growth and the healthy development of future generations. Therefore, this study analyzed 100 cases of patients with cervical precancerous lesions to investigate the clinical significance of combining recombinant human interferon α -2b with LEEP.

2. Materials and methods

2.1 General information

Based on previous studies, we hypothesize that the complication rate in the experimental group can be reduced by 30%. Assuming a significance level of 0.05 and a power of 0.8, it is estimated that each group will require 43 patients. Considering a dropout rate of 15%, a total of 50 patients per group will be recruited. Therefore, the study will include 100 patients in total. Clinical data of 100 patients treated for cervical precancerous lesions at our hospital from January 2021 to January 2023 were retrospectively collected. The patients were divided into an experimental group (50 cases) and a control group (50 cases) based on the treatment method.

Inclusion criteria: (1) Clinically HPV-positive, confirmed as cervical precancerous lesions through colposcopy biopsy; (2) Undergoing LEEP for the first time; (3) Suitable for surgical treatment with complete clinical data; (4) Signed informed consent.

Exclusion criteria: (1) Abnormal immune system or coagulation disorders; (2) Severe chronic internal diseases; (3) Combined severe heart, lung or other organ dysfunction; (4) Accompanied by uterine bleeding or pelvic inflammation; (5) History of mental illness or combined cognitive and communication disorders.

2.2 Methods

The control group received high-frequency electric knife LEEP treatment under colposcopic assistance. Preoperatively, patients underwent routine blood tests, and the surgery was performed 3–7 days after menstrual clearance. Vaginal cleaning with 0.5% povidone-iodine was conducted 1–3 days before surgery, and sexual intercourse was prohibited for 7 days prior. Patients were positioned in the lithotomy position to fully expose the cervix and vulva, which were disinfected with povidone-iodine. Local anesthesia was administered using 1% lidocaine. Following anesthesia, the cervix was fully exposed with a speculum, the lesion area on the cervix was marked with iodine, and the lesion margins and transformation zone type were observed using a colposcope. The LEEP electrode was rotated clockwise from the outer edge of the iodine-negative area 3–5 mm outside the lesion, excising the cervical lesion along with 2–3 cm of surrounding normal tissue to a depth of 15–25 mm. This ensured the specimen's integrity and minimizing contact time between the electrode and the cervix. Hemostasis was achieved through electrocoagulation, followed by a pathological examination of the lesion. Postoperative care included anti-infection treatment, maintaining vulval cleanliness and prohibiting sexual intercourse and bathing for 14 days.

The experimental group received LEEP combined with recombinant human interferon α -2b gel. LEEP surgical proce-

dures were performed using the same method as in the control group. Based on the patient's pathological results, the medication was initiated after basic wound healing (more than 10 days and within 1 month after surgery). Recombinant human interferon α -2b gel was applied to the posterior vaginal fornix before bedtime and then smeared onto the wound site. This was done once a day, using 100,000 U each time, with a one-week break during the menstrual period. The treatment continued for three months.

2.3 Observation indicators

(1) Clinical efficacy: After 3 months of medication, the efficacy of both groups was evaluated. Significant effect: post-treatment, the cervix is smooth, and the wound surface disappears; Effective: post-treatment, the cervix is relatively smooth, with a reduction in wound area by $\geq 75\%$; Ineffective: post-treatment, the cervix remains rough, with a reduction in wound area $< 75\%$ [8]. The efficacy rate is defined as: patients having a smooth cervix and no visible lesions after treatment, or patients with a relatively smooth cervix and a reduction in the area of lesions of $\geq 75\%$ after treatment. The treatment efficiency rate = (number of significantly effective cases + number of effective cases)/total number of cases $\times 100\%$. (2) Incidence of surgical complications: mainly includes scab shedding bleeding, infection and urinary retention. (3) Recurrence and HR-HPV conversion: all patients were followed up for one year, comparing the 6-month and one-year recurrence rates and HR-HPV conversion rates between the two groups. Cervical samples were collected, and HPV testing was performed using the hybrid HR-HPV nucleic acid testing kit produced in China (referred to as the HPV testing kit). This *in vitro* detection reagent is based on real-time quantitative Polymerase Chain Reaction (PCR) and is designed for detecting high-risk (HR) HPV-DNA.

(4) Quality of life: Evaluated using the World Health Organization Quality of Life-BREF (WHOQOL-BREF) [9] before surgery and 3 months after medication. The scale consists of 26 items, with the first two questions being overall evaluations, and the other 24 questions systematically asking individuals about their subjective feelings about their quality of life and health status in four areas: physiology, psychology, social relationships, and environment before and after treatment. The number of items in each field varies, including psychology (6 items), physiology (7 items), social relations (3 items) and environment (8 items). Each item has 5 options and is scored on a scale of 1–5, with each field scoring between 4–20 points. The scoring methods for the four domains are as follows: scores are scored positively, and the total score is directly proportional to the quality of life. Physiological field (phys) = $4 \times [(6 - Q3) + (6 - Q4) + Q10 + Q15 + Q16 + Q17 + Q18]/7$; Psychological field = $4 \times [Q5 + Q6 + Q7 + Q11 + Q19 + (6 - Q26)]/6$; Environmental domain = $4 \times (Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25)/8$; Social relations field (social) = $4 \times (Q20 + Q21 + Q22)/3$. Detailed information is shown in Table 1.

TABLE 1. Content of the WHOQOL-BREF scale.

Field
I. Physiology field
1. Pain and discomfort
3. Sleep and rest
4. Action capability
5. Activity of daily living
6. The dependence on drugs and medical means
7. Working ability
II. Psychological field
8. Positive feeling
10. Self-respect
11. Body and appearance
12. Negative feelings
13. Spiritual pillar
III. Social field
14. Personal relationship
15. The satisfaction of the social support required
16. Sexual life
IV. Environmental field
18. Housing environment
19. Source of finance
20. Medical services and social security: access to and quality
21. Opportunities to acquire new information, knowledge and skills
22. Participation opportunity and participation degree in leisure and recreational activities
23. Environmental conditions (pollution/noise/traffic/climate)
24. Transportation condition

2.4 Statistical methods

The collected data were analyzed using SPSS 21.0 statistical software (IBM, Armonk, NY, USA) and GraphPad Prism 8.0.2 (GraphPad Software, Inc, San Diego, CA, USA). Normally distributed continuous data are expressed as ($\bar{x} \pm s$), with independent samples *t*-test used for inter-group comparisons and paired samples *t*-test for intra-group comparisons. For data with skewed distributions or unequal variances, the Mann-Whitney U test was applied, and results are presented as median (M) and interquartile range (IQR) (P25, P75). Categorical variables are presented as counts and percentages (%), with inter-group comparisons using the chi-square test or Fisher's exact test. A *p*-value of < 0.05 indicates statistical significance. Chi-square tests can be used when the sample size is large and the expected frequency in each cell is greater than or equal to 5. Fisher's exact test should be used when the sample size is small or when the expected frequency in any cell is less than 5, particularly in 2×2 tables.

3. Results

3.1 Main results

3.1.1 General information

The general information of both groups is shown in Table 2, with comparable data ($p > 0.05$).

TABLE 2. Comparison of general information between two groups.

Variables	Experimental group (n = 50)	Control group (n = 50)	χ^2/t	<i>p</i>
Age (yr)	40.35 \pm 3.67	40.54 \pm 3.88	0.251	0.802
Disease course (mon)	4.57 \pm 0.95	4.80 \pm 1.10	1.160	0.249

3.1.2 Comparison of treatment efficacy

The total efficacy rate in the experimental group was significantly higher than that in the control group ($p < 0.05$) (Table 3).

3.1.3 Incidence of complications

The difference in the incidence of surgical complications of the two groups was not significant ($p > 0.05$) (Table 4).

TABLE 3. Comparison of patient efficacy in the two groups (n (%)).

Efficacy	Experimental group (n = 50)	Control group (n = 50)	χ^2	<i>p</i>
Significant effect	31 (62.00)	23 (46.00)		
Effective	17 (34.00)	19 (38.00)		
Ineffective	2 (4.00)	8 (16.00)		
Total effective rate	48 (96.00)	42 (84.00)	4.000	0.046

TABLE 4. Comparison of the complications (n (%)).

Complications	Experimental group (n = 50)	Control group (n = 50)	χ^2	<i>p</i>
Scab shedding bleeding	1 (2.00)	1 (2.00)		
Infection	1 (2.00)	2 (4.00)		
Urinary retention	0	0		
Total	2 (4.00)	3 (6.00)	0.211	0.646

3.1.4 Recurrence and HR-HPV conversion

At 6 months and 1 year after surgery, the recurrence rate in the experimental group was lower than the control group, and the HR-HPV conversion rate was higher than the control group ($p < 0.05$) (Table 5).

3.2 Secondary results

3 months after medication, the scores for environment, social relationships, physiology, and psychology in the experimental group were significantly higher than the control group ($p < 0.05$) (Table 6).

4. Discussion

The study results indicate that the overall efficacy rate of the experimental group is significantly higher than that of the control group, with minimal differences in the incidence of complications between the two groups. Six months and one year post-surgery, the recurrence rate in the experimental group is lower than that in the control group and the HR-HPV negativity rate is higher in the experimental group. Additionally, three months after treatment, the experimental group's scores in environmental, social relationships, physiological and psychological assessments are significantly higher than those of the control group.

Cervical precancerous lesions are prevalent gynecological conditions frequently associated with early sexual activity and HPV infection, which can lead to chronic inflammation of the cervix. Repeated stimulation can cause abnormal proliferation of cervical epithelial cells, eventually resulting in cervical precancerous lesions [10]. Colposcopy-assisted LEEP utilizes ultra-high-frequency low-pressure technology to effectively excise large, deep lesions, allowing for complete removal with minimal trauma and ease of operation [11]. However, clinical practice has shown that surgical excision alone cannot completely eradicate HPV infection, necessitating the use of adjunctive antiviral medication to reduce recurrence rates [12].

Recombinant human interferon α -2b can modulate estrogen and progesterone levels, improve the vaginal environment,

promote cervical wound healing, shorten the duration of vaginal discharge, alleviate clinical symptoms, and expedite post-operative recovery through enhanced repair and regeneration [13, 14]. This study indicates that the total efficacy rate in the experimental group was significantly higher than in the control group, suggesting that recombinant human interferon α -2b combined with LEEP is effective in treating cervical precancerous lesions. This combination therapy can lead to disappearance of symptoms or significant improvement, yielding definitive therapeutic effects. The effectiveness of LEEP lies in its underlying mechanism in which the high-frequency electric knife generates high-frequency waves at the electrode tip effectively excising the diseased area while simultaneously controlling disease progression without causing pathological damage to surrounding tissues [15]. Although LEEP demonstrates efficacy in the treatment of cervical precancerous lesions, it does not adequately address persistent HPV infection and has a high postoperative recurrence rate, which may adversely affect patient prognosis. Hence, combined drug therapy is often chosen in clinical settings [16]. Recombinant human interferon α -2b is a multifunctional polypeptide that enhances immune function by regulating macrophage phagocytic capacity, thereby inhibiting the proliferation of cervical neoplastic cells and boosting antiviral and anti-infective capabilities [17]. In combination therapy, recombinant human interferon α -2b rapidly dissolves and decomposes in the posterior fornix of the vagina, allowing close contact with target tissues. By binding to interferon receptors, it activates relevant genes within target cells, promoting the synthesis and secretion of antiviral proteins. This process inhibits the production of HPV viral proteins, as well as the replication and transcription of nucleic acids, reducing tumor marker levels, enhancing immune cell functionality, regulating hormone levels, maintaining vaginal environmental balance, promoting wound healing and restoring immune function. Additionally, it alleviates surgical wound edema, promotes epithelial cell proliferation and accelerates the healing of injured tissues. Therefore, LEEP combined with recombinant human interferon α -2b not only effectively removes the diseased area but also enhances the body's antiviral and anti-infective

TABLE 5. Comparison of recurrence and HR-HPV conversion (n (%)).

Prognosis	Experimental group (n = 50)	Control group (n = 50)	χ^2	<i>p</i>
Recurrence rate				
6 mon	1 (2.00)	8 (16.00)	5.983	0.014
1 yr	2 (4.00)	10 (20.00)	59.278	<0.001
Negative turning rate of HR-HPV				
6 mon	42 (84.00)	33 (66.00)	4.320	0.038
1 yr	45 (90.00)	36 (72.00)	5.263	0.022

TABLE 6. Comparison of quality of life ($\bar{x} \pm s$, score).

Quality of life item	Experimental group (n = 50)	Control group (n = 50)	<i>t</i>	<i>p</i>
Environment				
Before surgery	5.24 ± 1.60	5.22 ± 1.42	0.066	0.947
3 months after medication	13.82 ± 2.59	10.28 ± 2.12	7.475	<0.001
Social relations				
Before surgery	5.50 ± 1.45	5.34 ± 1.36	0.569	0.571
3 months after medication	12.06 ± 2.53	9.42 ± 1.82	5.996	<0.001
Physiology				
Before surgery	5.44 ± 1.13	5.50 ± 1.23	0.254	0.800
3 months after medication	13.82 ± 2.65	10.42 ± 2.44	6.675	<0.001
Psychology				
Before surgery	6.24 ± 2.12	6.46 ± 2.27	0.501	0.617
3 months after medication	15.58 ± 2.44	11.34 ± 2.45	8.674	<0.001

abilities, addressing the shortcomings of surgery alone and thereby further improving clinical treatment outcomes. In the study conducted by Đurović Srđan at the Genesis Gynecology Specialty Hospital in Novi Sad, cervical loop electrosurgical excision was performed on 150 patients. Group A included 87 patients diagnosed with cervical intraepithelial neoplasia, while Group B comprised 63 patients with benign cervical lesions. The results indicated that 16 patients (20.7%) in Group A experienced complications, compared to 4 patients (6.4%) in Group B. The absolute risk of complications was 18.39% in Group A and 6.34% in Group B. The relative risk of complications was 2.9, suggesting that women in Group A had a threefold higher risk of complications than those in Group B. This data supports the use of loop electrosurgical excision as the preferred method for treating cervical dysplasia, demonstrating favorable therapeutic outcomes and a lower incidence of complications. The study by Noppames S also confirms the efficacy of cervical loop electrosurgical excision (LEEP) in treating high-grade cervical precancerous lesions. These findings further validate the significant effectiveness of LEEP in managing cervical precancerous conditions.

No significant difference in the incidence of complications was observed between the two groups, indicating that LEEP combined with Recombinant Human Interferon α -2b interferon results in better prognosis and low complications, thereby demonstrating good safety. The high-heat principle of LEEP enhances surgical precision, facilitating accurate

excision of lesions while minimizing damage to surrounding tissues [18]. Both groups underwent identical surgical procedures leading to no notable difference in complication rates. At 6 months and 1 year post-surgery, the experimental group exhibited a lower recurrence rate and a higher HR-HPV conversion rate compared to the control group, indicating that this combined therapy effectively clears HPV and prevents reinfection. This efficacy is attributed to the high-frequency electric waves and electrode knife used in colposcopy-assisted LEEP, which directly excise lesion tissue. Ultrahigh-frequency electric waves create a thermal energy field on the metal wire, transforming cellular water into steam upon contact with the cervix, thereby achieving electrocautery, excision and hemostasis. The high heat also induces necrosis in residual lesions. By selecting appropriate excision loops based on individual differences, LEEP accurately controls excision depth and scope, leading to more thorough excision than conventional methods ultimately reducing recurrence rates [19]. Furthermore, recombinant human interferon α -2b effectively clears HPV, thereby reducing recurrence rates. Interferons possess broad-spectrum antiviral functions. Upon entry into the body, recombinant human interferon α -2b directly activates antiviral-related genes within cells, inhibits viral gene expression, and reduces viral load. It also acts on deeper tissues, inducing the benign transformation of cervical precancerous cells and gradually restoring them to normal, thereby lowering recurrence rates [20, 21]. In a study by Ding

Wei's, 178 patients with cervical intraepithelial neoplasia (CIN) combined with high-risk HPV positivity were divided into a study group ($n = 89$) and a control group ($n = 88$). The control group received treatment with recombinant human interferon α -2b, while the study group received traditional Chinese medicine in addition to the treatment received by the control group. After treatment, the study group exhibited a significantly reduced recurrence rate and a significantly increased HPV negativity rate. These findings suggest that the combination of traditional Chinese medicine and recombinant human interferon α -2b can effectively enhance the HPV negativity rate, reduce cervical erosion, and improve patients' immunity, outperforming the use of interferon alone. These results are consistent with those of the current study.

Three months post-medication, the experimental group showed significantly higher scores in environment, social relationships, physiology and psychology compared to the control group. This finding indicates that the combination of LEEP and recombinant human interferon α -2b is relatively safe. This therapy markedly improves patient symptoms, promotes HPV seroconversion, achieves definitive therapeutic effects, reduces HPV viral load, and enhances patients' postoperative quality of life. The mechanism underlying these effects involve the use of high-frequency electric waves generated at the tip of metal wire during LEEP, producing instantaneous high heat upon contact with lesion tissue. This process causes intracellular water to form steam waves, rapidly excising lesion tissue and causing irreversible tissue denaturation and shedding. Simultaneously, this technique achieves hemostasis, improves local cervical circulation, reduces stress response and bleeding and accelerates postoperative recovery. However, LEEP alone cannot effectively inhibit and treat HPV infection; thus, recombinant human interferon α -2b plays a crucial role in the combined therapy. The vaginal effervescent tablets of recombinant human interferon α -2b regulate hormone levels, promote cervical epithelial tissue repair, exhibit good tissue permeability, act on deep lesion tissues, inhibit pathogen proliferation, promote HPV seroconversion, alleviate symptoms and enhance therapeutic effects. Additionally, recombinant human interferon α -2b enhances immune function and antiviral capability while inhibiting cell proliferation. When placed in the vaginal fornix, it distributes evenly, ensuring localized drug efficacy by inhibiting viral replication and transcription, reducing HPV viral load, and preventing progression to cervical cancer. Symptom relief and lower HPV viral loads upon reexamination boost patients' confidence in their treatment, thereby improving their postoperative quality of life. The combined therapy presented in this study offers both theoretical reference and practical significance for the treatment of cervical precancerous lesions.

This study has several limitations. Firstly, the sample size is relatively small, and the examination of general information such as patients' underlying health conditions is insufficient. The limited sample size and single-center design may restrict the generalizability of the findings. Secondly, there is a lack of relevant research concerning factors affecting patient recurrence rates. Supplementing data analysis in this area would help to further understand the impact of the two different

methods on patients' recurrence. Finally, the risk factors influencing postoperative complications have not been thoroughly explored; therefore, supplementary analyses should be conducted to further improve surgical and clinical management. Future research should include large sample sizes, diverse patient groups, multi-center studies and consideration of the risk factors for postoperative complications. Additionally, increasing volume of data and discussions related to patient recurrence will help improve the accuracy and comprehensiveness of the research results.

5. Conclusions

In summary, LEEP combined with recombinant human interferon α -2b demonstrates significant clinical effectiveness in the treatment of cervical intraepithelial neoplasia. This combination not only enhances treatment efficacy but also improves quality of life, reduces the incidence of complications and postoperative recurrence rate, and increases HPV negativity rate. The use of cervical loop electrosurgical excision in conjunction with interferon for treatment of precancerous lesions has shown promising results, providing a valuable reference for clinical application. Healthcare professionals should widely advocate this combined therapy to maximize treatment efficiency. However, this study is subject to certain limitations, including a relatively small sample size and insufficient investigation into patients' underlying health conditions and general demographic information. Furthermore, there exists a gap in research concerning the factors influencing the recurrence rate in patients. Future studies should include larger sample sizes and conduct multicenter randomized trials to improve the accuracy and comprehensiveness of the research findings.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

JZ—designed the study and carried them out. JZ, CLL, WZC, JG, WM, YAW and HX—supervised the data collection; prepared the manuscript for publication and reviewed the draft of the manuscript. JZ, CLL, WZC, JG and WM—analyzed the data; JZ, CLL, WZC and JG—interpreted the data. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Beijing Luhe Hospital, Capital Medical University (Approval no. 2021-LHKY-129-01). Written informed consents were obtained from legally authorized representatives for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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