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Original Article

Levofloxacin combined with azithromycin shows greater efficacy in cervicitis treatment compared to azithromycin monotherapy

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Abstract: Objective: To evaluate the efficacy of levofloxacin combined with azithromycin in the treatment of cervicitis and its effect on serum inflammatory markers. Methods: A retrospective analysis was conducted on the clinical records of 102 patients with cervicitis treated at Gansu Provincial Maternity and Child-care Hospital between March 2022 and March 2023. The control group (47 patients) received azithromycin, while the study group (55 patients) was treated with a combination of levofloxacin and azithromycin. Serum levels of tumor necrosis factor-α (TNF-α), interleukin-6 (IL-6), and C-reactive protein (CRP) were measured before treatment and after two weeks. The efficacy, adverse reaction rate, and recurrence of cervicitis over a 6-month follow-up period were analyzed. A multiple logistic regression was performed to identify factors influencing recurrence. Results: Prior to treatment, no significant differences were observed between the two groups in IL-6, TNF-α, or CRP levels (all P>0.05). After treatment, both groups showed significant reductions in these markers (all P<0.0001), with the study group exhibiting more pronounced decreases (P<0.0001). The overall response rate in the study group was significantly higher than that of the control group (P=0.041). No significant difference in the incidence of adverse reactions was found between the groups (P=0.551). The recurrence rate of cervicitis was significantly higher in the control group compared to the study group (P=0.022). Logistic regression analysis identified disease severity (P=0.014, OR: 8.616; CI: 1.543-48.096), post-treatment IL-6 (P=0.003, OR: 17.573; CI: 2.720-113.531), post-treatment CRP (P=0.039, OR: 5.731; CI: 1.089-30.157), and post-treatment TNF-α (P=0.001, OR: 20.547; CI: 3.210-131.518) as independent predictors of recurrence. Conclusion: Levofloxacin combined with azithromycin is more effective than azithromycin monotherapy in treating cervicitis. The combination significantly reduces inflammatory responses and recurrence rates without increasing adverse effects, making it a valuable option for clinical use.

Keywords: Levofloxacin, azithromycin, cervicitis, efficacy, serum inflammatory factors

Introduction

Cervicitis is a common gynecologic condition, particularly prevalent in women of childbearing age [1]. Its clinical manifestations include purulent leukorrhea, tenderness, and cervical hyperemia [2]. In its early stages, cervicitis is often overlooked by patients, but as the disease progresses, it can lead to cervical erosion, polyps, and cysts, significantly affecting quality of life [3, 4].

Current treatment strategies for cervicitis primarily involve antibiotics and topical therapies. Antibiotics target bacterial infections, while topical medications reduce inflammation, but both approaches have limitations, such as antibiotic resistance and incomplete treatment of underlying causes [5]. Macrolides and quinolones are commonly used antibiotics in the treatment of cervicitis [5]. Levofloxacin, a quinolone, has broad-spectrum antibacterial activity against Gram-negative and Gram-positive bac-

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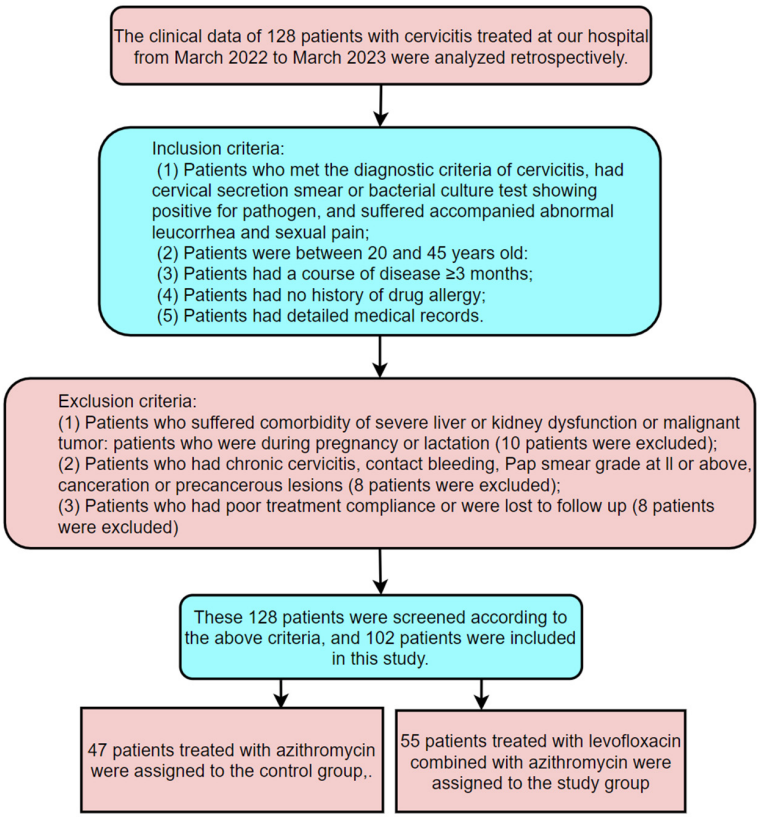

Figure 1. Screening and grouping process.

teria, as well as Chlamydia pneumoniae [6, 7]. Azithromycin, a macrolide, inhibits bacterial protein synthesis and reduces mucus production, effectively controlling disease progression [8, 9]. However, monotherapy with antibiotics often yields suboptimal results, requiring prolonged treatment courses that increase the risk of drug resistance and adverse reactions [10, 11].

There are limited studies on the combined use of levofloxacin and azithromycin in cervicitis treatment. This study aimed to evaluate the efficacy of the levofloxacin-azithromycin combination and its effect on serum inflammatory markers, providing a reliable reference for cervicitis therapy. The novelty of this research lies in demonstrating the superior efficacy and lower recurrence rates achieved with combination therapy, while identifying disease severity, post-treatment IL-6, post-treatment CRP, and post-treatment TNF-α as independent factors influencing recurrence.

Materials and methods

Sample selection and criteria

This retrospective study included the records of 128 cervicitis patients treated at Gansu Provincial Maternity and Child-care Hospital between March 2022 and March 2023.

Inclusion criteria: Patients met the diagnostic criteria for cervicitis [12], had a positive cervical secretion smear or bacterial culture for pathogens, exhibited abnormal leucorrhea and sexual pain; patients were aged 20-45 years, had a disease course of ≥3 months; patients had no history of drug allergies, and had complete medical records.

Exclusion criteria: Patients suffered from comorbidities such as severe liver or kidney dysfunction or malignancies; patients were pregnant or lactating; patients had chronic cervicitis, contact bleeding, Pap smear results of grade II or above, cancer, or precancerous lesions; patients had poor treatment compliance or were lost to follow-up.

After screening based on these criteria, 102 patients were included in the study. A total of 47 patients receiving azithromycin were assigned to the control group, while 55 patients receiving levofloxacin combined with azithromycin were assigned to the study group. The screening and grouping process is outlined in **Figure 1**. This study was approved by the Medical Ethics Committee of Gansu Provincial Maternity and Child-care Hospital.

Therapeutic regimen

The control group was treated with oral azithromycin tablets (Tonghua Golden-Horse Pharmaceutical Industry Co., Ltd., SFDA approval no.: H20083813; specification: 0.25 g/tablet) at a dose of 1 g once daily for 2 weeks.

Table 1. Comparison of baseline data

Factor	Study group (n=55)	Control group (n=47)	χ^2	*P* value
Age			0.177	0.674
≥30 years old	20	19		
<30 years old	35	28		
BMI			1.933	0.164
≥23 kg/m^2	31	20		
<23 kg/m^2	24	27		
Course of disease			1.408	0.236
≥1 year	15	18		
<1 year	40	29		
Severity			0.081	0.776
Mild-moderate erosion	42	37		
Severe erosion	13	10		
History of smoking			0.809	0.368
Yes	10	12		
No	45	35		
History of alcoholism			0.790	0.374
Yes	8	10		
No	47	37		
Place of residence			1.585	0.208
Rural area	36	25		
Urban area	19	22		

Note: BMI: Body mass index.

The study group received azithromycin as in the control group, in addition to levofloxacin (Zhejiang Huayuan Pharmaceutical Co., Ltd., SFDA approval no.: H20093894; specification: 0.1 g/capsule) at a dose of 0.3 g twice daily (morning and evening) for 2 weeks. Both groups were followed up for 6 months.

Data collection

Patient data were obtained from the medical record system, including sex, age, body mass index (BMI), disease duration, disease severity, smoking history, alcohol history, place of residence, levels of serum inflammatory factors, treatment efficacy, incidence of adverse reactions, and recurrence of cervicitis within 6 months.

Outcome measures

Main outcome measures: Serum inflammatory factors: Fasting venous blood samples (3 mL) were collected from each patient before treatment and 2 weeks after treatment. The samples were centrifuged at 3,000 rpm for 10 minutes to separate serum. Interleukin-6 (IL-6) and tumor necrosis factor-α (TNF-α) levels were measured using chemiluminescence kits (IL-6: Derong Medical Technology Co., Ltd., Hunan, China; TNF-α: Tarcine BioMed (Hong Kong) Limited, Hongkong, China). C-reactive protein (CRP) levels were determined by immunoturbidimetry (Nanjing Institute of Environmental Biotechnology, Nanjing, China).

Efficacy: Treatment efficacy was evaluated based on established criteria [12].

Markedly effective: Complete resolution of symptoms such as pruritus vulvae, cervical erosion, edema, and abnormal leukorrhea, with normal cervical morphology and negative pathogen test results.

Effective: Significant symptom improvement with normal cervical morphology and negative or weakly positive pathogen test results.

Ineffective: No improvement or worsening of symptoms after treatment.

Overall response rate = [(markedly effective cases + effective cases)/total cases] × 100%.

Factors influencing recurrence: Multiple logistic regression analysis was used to identify factors affecting recurrence.

Secondary outcome measures: Baseline data: The general baseline characteristics of patients were analyzed. Adverse reactions: Recorded adverse reactions during treatment included nausea, vomiting, diarrhea, and anorexia. Recurrence rate: 2 weeks after treatment, patients were followed up for 6 months to observe for recurrence.

Statistical analyses

Data were analyzed using SPSS 20.0, with GraphPad 8 used for visualization. Continuous

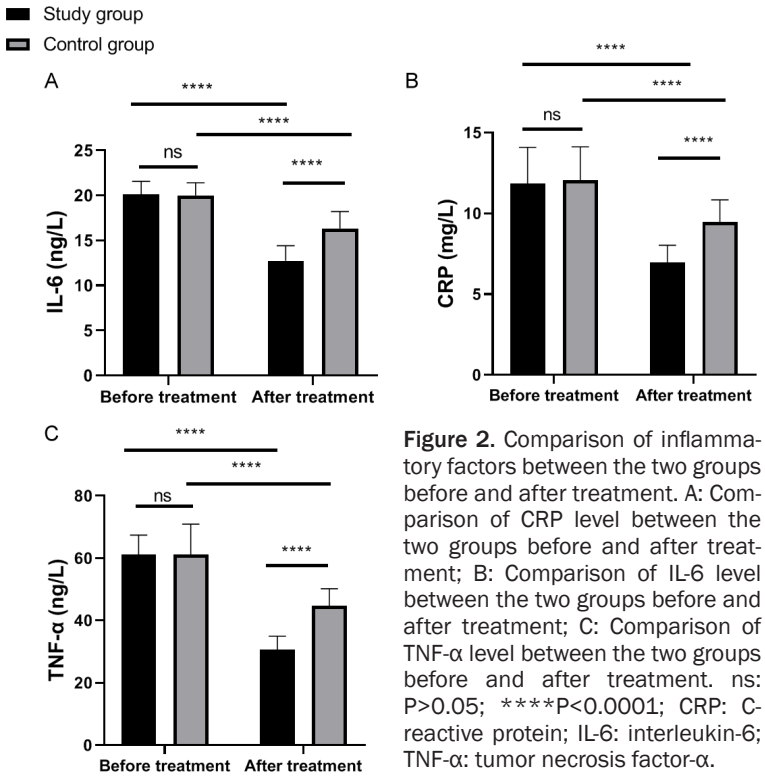

Figure 2. Comparison of inflammatory factors between the two groups before and after treatment. A: Comparison of CRP level between the two groups before and after treatment; B: Comparison of IL-6 level between the two groups before and after treatment; C: Comparison of TNF-α level between the two groups before and after treatment. ns: P>0.05; ****P<0.0001; CRP: C-reactive protein; IL-6: interleukin-6; TNF-α: tumor necrosis factor-α.

Table 2. Comparison of efficacy between the two groups [n (%)]

	Markedly effective	Effective	Ineffective	Overall response rate
Study group (n=55)	33 (60.00)	18 (32.73)	4 (7.27)	51 (92.73)
Control group (n=47)	24 (51.06)	13 (27.66)	10 (21.28)	37 (78.72)
χ^2	0.821	0.308	4.197	4.197
P value	0.365	0.579	0.041	0.041

Table 3. Comparison of adverse reactions in the two groups [n (%)]

	Nausea and vomiting	Diarrhea	Anorexia	Total adverse reaction
Study group (n=55)	2 (3.64)	1 (1.82)	2 (3.64)	5 (9.10)
Control group (n=47)	2 (4.26)	3 (6.38)	1 (2.13)	6 (12.77)
χ^2	0.026	1.402	0.202	0.356
P value	0.873	0.237	0.653	0.551

Table 4. Comparison of recurrence rate in the two groups [n (%)]

Group	Recurrence
Study group (n=55)	4 (7.27)
Control group (n=47)	11 (23.40)
χ^2	5.258
P value	0.022

data were normally distributed and expressed as mean ± standard deviation (SD). Inter-group and intra-group comparisons were performed using independent-samples t-test and paired t-test, respectively. Categorical data were presented as cases (%), analyzed with the chi-square test (χ^2). Multiple logistic regression was used to analyze factors influencing recurrence, with binary outcomes (cervicitis recurrence) examined based on clinical relevance. Models were built using backward elimination, and predictor significance was assessed using odds ratios (OR) and *p*-values. A *p*-value of <0.05 indicated significance.

Results

Comparison of baseline data

The control and study groups showed no significant differences in age, disease duration, severity, history of alcoholism, body mass index (BMI), smoking history, or place of residence (all P>0.05, **Table 1**).

Comparison of inflammatory factors

Prior to therapy, IL-6, CRP, and TNF-α levels were comparable between the two groups (all P>0.05). After therapy, these levels decreased significantly in both groups (all P<0.0001), with the study group showing a more pronounced reduction (P<0.05, **Figure 2**).

Comparison of efficacy

The study group exhibited a significantly higher overall response rate compared to the control group (P=0.041, **Table 2**).

Table 5. Univariate analysis of factors influencing patient recurrence of cervicitis

	Recurrence group (n=15)	Non-recurrence group (n=87)	χ^2/t	P
Age			1.470	0.225
≥30 years old	8	32		
<30 years old	7	55		
BMI			0.703	0.402
≥23 kg/m^2	9	42		
<23 kg/m^2	6	45		
Course of disease			6.142	0.013
≥1 year	9	24		
<1 year	6	63		
Severity			14.121	<0.001
Mild-moderate erosion	6	73		
Severe erosion	9	14		
Post-treatment IL-6 (ng/L)	17.32±1.89	12.74±1.66	11.24	<0.001
Post-treatment CRP (mg/L)	10.48±1.36	6.87±1.06	11.31	<0.001
Post-treatment TNF-α (ng/L)	45.82±5.48	28.55±4.42	15.30	<0.001
History of smoking			1.439	0.230
Yes	5	17		
No	10	70		
History of alcoholism			0.985	0.321
Yes	4	14		
No	11	73		
Place of residence			0.345	0.557
Rural area	10	51		
Urban area	5	36		

Notes: CRP: C-reactive protein; IL-6: interleukin-6; TNF-α: tumor necrosis factor-α.

Table 6. Assignment

	Assignment
Course of disease	<1 year =0, ≥1 year =1
Severity	Mild-moderate erosion =0, severe erosion =1
Post-treatment IL-6	<13.7 =0, ≥13.7 =1
Post-treatment CRP	<7.46 =0, ≥7.46 =1
Post-treatment TNF-α	<32 =0, ≥32 =1
Recurrence	No recurrence =0, recurrence =1

Notes: CRP: C-reactive protein; IL-6: interleukin-6; TNF-α: tumor necrosis factor-α.

Comparison of adverse reactions

There was no significant difference between the two groups in terms of the overall incidence of adverse reactions (P=0.551, **Table 3**).

Comparison of recurrence rate

Six months after treatment, the control group had a significantly higher recurrence rate compared to the study group (P=0.022, **Table 4**).

Analysis of risk factors for cervicitis recurrence

Patients were classified into a recurrence group (n=15) and a non-recurrence group (n=87) based on their recurrence status. Univariate analysis identified disease duration, severity, and post-treatment levels of IL-6, CRP, and TNF-α as factors influencing recurrence (**Table 5**). These variables were assigned values (**Table 6**) and subjected to multivariate analysis. Logistic regression revealed that disease severity (P=0.014, OR: 8.616; CI: 1.543-48.096), post-treatment IL-6 (P=0.003, OR: 17.573; CI: 2.720-113.531), post-treatment CRP (P=0.039, OR: 5.731; CI: 1.089-30.157), and post-treatment TNF-α (P=0.001, OR: 20.547; CI: 3.210-

Table 7. Multivariable logistic regression analysis

Factor	B	S.E.	Wals	df	Sig.	Exp (B)	95% C.I. for EXP (B)	
							Lower limit	Upper limit
Course of disease	0.256	0.917	0.078	1	0.780	1.291	0.214	7.783
Severity	2.154	0.877	6.025	1	0.014	8.616	1.543	48.096
Post-treatment IL-6	2.866	0.952	9.067	1	0.003	17.573	2.720	113.531
Post-treatment CRP	1.746	0.847	4.246	1	0.039	5.731	1.089	30.157
Post-treatment TNF-α	3.023	0.947	10.184	1	0.001	20.547	3.210	131.518

Notes: CRP: C-reactive protein; IL-6: interleukin-6; TNF-α: tumor necrosis factor-α.

131.518) were independent risk factors for recurrence (**Table 7**).

Discussion

In recent years, changes in lifestyle habits and increased work-related stress have led to a rising incidence of cervicitis [13]. However, due to the personal sensitivity of the disease site and insufficient patient awareness, the condition often progresses unchecked, possibly leading to infertility or malignancy, posing a serious threat to patients' health and well-being [14, 15]. Cervicitis is commonly treated with medications, particularly antibiotics [16]. Azithromycin, a widely used antibiotic, is often employed to treat urogenital infections. However, the efficacy of azithromycin alone is often unsatisfactory, and prolonged use may disrupt the vaginal microbiota [17]. Levofloxacin, a broad-spectrum antibiotic with potent antibacterial activity, has shown enhanced therapeutic effects when combined with azithromycin, as indicated by previous research [18]. This study investigates the efficacy of the combined treatment for cervicitis and its effects on serum inflammatory factors.

CRP and TNF-α levels in cervicitis patients are reportedly higher compared to healthy individuals [19]. IL-6, a multifunctional inflammatory cytokine, plays a crucial role in the inflammatory response. Elevated IL-6 levels can cause inflammatory damage, hindering recovery [20]. CRP, a reactive protein released during inflammation, is a common marker for infection evaluation [21]. TNF-α has dual functions: it regulates immune function and combats inflammation, but excessive production can aggravate inflammation and cause tissue damage [22]. In this study, IL-6, TNF-α, and CRP levels significantly decreased in both groups after treatment, with the study group showing more substantial reductions. These findings suggest that levofloxacin combined with azithromycin effectively lowers serum IL-6, CRP, and TNF-α levels, thereby reducing inflammation and promoting cervical recovery. The study group also had a significantly higher overall response rate compared to the control group, while the incidence of adverse reactions was similar between the two groups. This indicates that levofloxacin combined with azithromycin is more effective than azithromycin alone in treating cervicitis without increasing adverse reactions. The enhanced bioavailability of the combination therapy may explain this improved efficacy. Owais et al. [23] demonstrated that azithromycin and levofloxacin have a favorable synergistic effect on extensively drug-resistant Klebsiella pneumoniae, without antagonistic interactions, supporting the results of this study.

The study also included a 6-month follow-up, showing a significantly lower recurrence rate of cervicitis in the study group. This suggests that the combination of levofloxacin and azithromycin synergistically inhibits bacterial reproduction, effectively eliminates pathogens, and reduces recurrence.

Moreover, the study identified factors influencing cervicitis recurrence, revealing that disease severity, as well as post-treatment IL-6, CRP, and TNF-α levels, were independent predictors of recurrence. Cervicitis severity may be related to pathogen load and the strength of the inflammatory response. More severe cases may leave a residual infection or inflammation after treatment, increasing recurrence risk [24]. Post-treatment IL-6 and CRP levels reflect the degree of inflammation and treatment efficacy [25]. Elevated levels of these markers may indicate persistent inflammation or an inadequate immune response, raising the likelihood of recurrence. High post-treatment TNF-α lev-

els may also indicate an abnormal immune response associated with recurrence.

This study has some limitations. The relatively small sample size may have introduced bias into the conclusions. Additionally, long-term patient outcomes were not tracked, so the impact of levofloxacin plus azithromycin on long-term prognosis remains unknown. Further studies with larger sample sizes and extended follow-up are necessary to provide more comprehensive and convincing evidence about combination therapy for cervicitis.

In conclusion, levofloxacin combined with azithromycin is more effective than azithromycin alone in treating cervicitis. The combination significantly reduces inflammation and recurrence rates without increasing adverse reactions, making it a promising treatment option.

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Disclosure of conflict of interest

None.

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