

Efficacy and Safety of Vedolizumab with Glucocorticoids vs Infliximab in Severe Ulcerative Colitis: A Retrospective Study

Chenfei Zhang¹, Xiaoling Huang¹, Mailidan Maimaitiniyazi¹, Tingwei Zhou²

¹Xinjiang Uygur Autonomous Region People's Hospital, Urumqi, Xinjiang, People's Republic of China; ²Wenzhou Medical University, Wenzhou, Zhejiang, 325000, People's Republic of China

Correspondence: Xiaoling Huang, Email Huangxiaolingzyf@sina.com

Objective: To compare the efficacy and safety of vedolizumab plus glucocorticoids versus infliximab in severe ulcerative colitis for optimized treatment selection.

Methods: Patients admitted to the Department of Gastroenterology of Xinjiang Uygur Autonomous Region People's Hospital with confirmed diagnosis of ulcerative colitis from January 2020 to December 2022 were collected, and according to the biologics used, the patients were divided into Vedolizumab combined with glucocorticoids group (n = 23) and infliximab group (n = 23). Clinically relevant indicators of the patients were retrospectively analyzed.

Results: The difference between the basic information of the two groups of patients before treatment was not significant ($p > 0.05$). WBC 30 weeks, ESR (6 weeks, 30 weeks), ALB 30 weeks, Hb (6 weeks, 14 weeks, 30 weeks) of the difference between the groups was statistically significant ($p < 0.05$). WBC, CRP, ESR, ALB, Hb were tested by ANOVA, the differences between groups were statistically significant ($p < 0.05$). Comparison of the incidence of various complications between the two groups of patients, the difference was not significant ($p > 0.05$). The clinical response rate, clinical remission rate and mucosal healing rate of the 2 groups were statistically analyzed in terms of treatment effects at weeks 6, 14 and 30, respectively. Comparison between the groups showed that the differences in clinical response rate at week 6, clinical remission rate and endoscopic remission rate at week 30 and at weeks 14 and 30 were not statistically significant ($p > 0.05$); at weeks 14 and 30, the clinical response rate of group A was better than that of group B, and the differences were statistically significant ($p < 0.05$). At week 14, the clinical remission rate of group A was better than that of group B, and the difference was statistically significant ($p < 0.05$).

Conclusion: Vedolizumab and infliximab are effective for severe UC, but vedolizumab with glucocorticoids outperforms infliximab in clinical response, remission, and long-term outcomes.

Keywords: ulcerative colitis, vedolizumab, glucocorticoid, infliximab, efficacy

Introduction

Ulcerative colitis (UC) is a chronic non-specific inflammatory bowel disease (IBD) characterized by chronic intestinal inflammation with a typical course of relapse and remission. The pathogenesis of IBD has not yet been clarified, and it is currently believed to be related to genetic susceptibility, epithelial barrier defects, immune dysregulation, infections and environmental factors. Clinical symptoms mainly include abdominal pain, diarrhea, and mucopurulent blood stools.¹ In recent years, the incidence and prevalence of IBD in western developed countries have stabilized, but the incidence in Asia, Eastern Europe, Africa and South America has been increasing.² With the rapid development of China's economy, people's living standards have been improving, and their needs and concerns for health have been increasing. At the same time, the popularization and promotion of gastroenteroscopy has led to a year-on-year increase in the consultation rate of IBD patients, and the incidence and prevalence of IBD in China have shown a significant upward trend in recent years. The total number of such patients in China was about 350,000 in 2005–2014, and it is expected that the number of such



patients will reach 1.5 million cases by 2025.³ At present, the definitive diagnosis of UC mainly relies on a combination of factors such as patient symptoms, clinical signs, laboratory tests, electronic endoscopy, and histopathologic biopsy.

5-Aminosalicylate (5-ASA) (mesalazine, oxalazine, etc.), glucocorticoids (hydrocortisone, dexamethasone, prednisone, etc.) and immunosuppressants (azathioprine, methotrexate, etc.) are the traditional medications used in the treatment of UC,⁴ and despite the efficacy obtained, all of the above medications have a high number of limitations on their use or adverse effects, for example, glucocorticoid hormones can cause medically derived Cushing syndrome face and posture, osteonecrosis, lower limb swelling, easy bleeding tendency, concurrent infections, substance metabolism and water-salt metabolism disorders, etc., and discontinuation syndrome has been seen after stopping the drug.⁵ Mesalazine can cause transaminase elevation, hepatitis, hepatic fibrosis and even hepatic necrosis.⁶ Immunosuppressants can cause patients to be susceptible to infections and cancer, which in turn makes them intolerable.⁷ Immunosuppressive drugs include azathioprine and methotrexate, but their immunosuppressive effects lack specificity, and the side effects of long-term use may lead to intolerance and discontinuation. The application of biologics is gradually increasing, and anti-tumor necrosis factor- α (TNF- α) has the most numerous and widespread applications, mainly including infliximab, adalimumab and golimumab.⁸ TNF- α antagonists are the choice when conventional treatment and immunosuppressive agents are ineffective, and they are the first-line therapeutic option for severe UC. In China, infliximab is used to treat patients who are ineffective or hormone-dependent on conventional therapies, but 15%–36% of patients experience primary non-response during induction therapy,^{9,10} and 30%–40% of patients who are initially effective on induction therapy progressively lose their response as the duration of the drug is increased.¹¹ Integrin is a transmembrane receptor on the cell surface that consists of α and β subunits. Integrin antagonists include Vedolizumab, etrolizumab, etc. Vedolizumab was approved by the State Drug Administration in March 2020 to be marketed in China and was officially commercially available in China in November of the same year. It brings more choices for patients with UC in China. Due to its intestinal selective nature, Vedolizumab is more advantageous in terms of safety for long-term maintenance therapy¹² and has a lower rate of immunogenicity, even when restarted after interruption of therapy.¹³

For severe UC, glucocorticosteroids have been one of the most important drugs for conservative treatment. Since their widespread clinical use in the 1850s, they have made it possible to reduce the case-fatality rate of severe UC, especially acute severe UC, from 75% reported in 1933 to 7% in 1955, and now it has been reduced to about 1%, which has greatly improved the disease prognosis. However, some patients respond poorly to glucocorticoids, with an overall effective rate of about 65%. In severe UC, glucocorticoids are often necessary for symptomatic relief, but because of the many toxic side effects of glucocorticoids, the drug cannot be used for maintenance therapy. Rationale for Combination Therapy: The complementary mechanisms of Vedolizumab and glucocorticoids provide a strong biological basis for their combined use. While glucocorticoids rapidly suppress systemic inflammation through broad-spectrum immunosuppression, Vedolizumab selectively targets $\alpha 4\beta 7$ integrins to inhibit gut-specific lymphocyte trafficking¹⁴. This dual-action approach may address both acute flare management and long-term mucosal healing. Preclinical models demonstrate that Vedolizumab's gut-selective action minimizes systemic immunosuppression, potentially mitigating glucocorticoid-related complications.¹⁵ Emerging clinical evidence suggests synergistic efficacy: a Phase III trial (GEMINI I) reported enhanced response rates when Vedolizumab was initiated alongside corticosteroids compared to monotherapy (68% vs 53% at week 6).¹⁶

This study investigates whether vedolizumab-glucocorticoid combination therapy for severe UC synergizes therapeutic advantages while minimizing individual drug limitations, potentially enhancing clinical response/remission rates and reducing relapse. We retrospectively analyzed 46 patients from Xinjiang Uygur Autonomous Region People's Hospital receiving either vedolizumab + glucocorticoids or infliximab monotherapy, systematically comparing efficacy outcomes to optimize biologic selection strategies in Chinese UC management.

Subjects and Methods

Design Retrospective Study

Time and Location

The trial was completed from January 2020 to December 2022 in the Department of Gastroenterology, Xinjiang Uygur Autonomous Region People's Hospital.

Inclusion Criteria

① The patients' clinical symptoms, endoscopic manifestations, pathologic and laboratory indices were in accordance with the Chinese Guidelines for the Diagnosis and Treatment of Ulcerative Colitis (2023);¹⁷ ② Age > 18 years; ③ patients with severe UC. ④ patients were treated for the first time ⑤ passed by the Ethics Committee of Xinjiang Uygur Autonomous Region People's Hospital, NO: **KY20241201105**. All study subjects had signed an informed consent for drug use.

Exclusion Criteria

① people with combined digestive system diseases and other inflammatory bowel diseases. ② Those who have contraindications to the drugs in this study. ③ Those with incomplete data of this study. ④ Those who have incomplete data of this study. ⑤ Those who use other antibacterial drugs. ⑥ Those with abnormal liver or kidney function. ⑦ Those with autoimmune diseases. ⑧ Malignant tumors. Those with poor compliance. ⑩ pregnant and lactating women.

Basic Information

Forty-six patients were included in this study and were divided into 2 groups according to the different drug methods used: ① Vedolizumab combined with glucocorticoids group (Group A): 23 cases, 10 men and 13 women, age 47.609 ± 13.305 years. Body mass index (BMI) 21.820 ± 3.013 kg/m². Comorbidities: hypertension 6 cases, coronary heart disease 4 cases, diabetes mellitus 6 cases. ② infliximab group (Group B): 23 cases, 11 males and 12 females, age 45.957 ± 16.494 years. Body mass index (BMI) 21.831 ± 3.448 kg/m². Three cases of hypertension, 3 cases of coronary heart disease, 8 cases of diabetes. There was no statistically significant difference between the two groups when comparing their general information before treatment ($p > 0.05$).

Drug Treatment Regimen

Of the 46 subjects, 23 received Vedolizumab in combination with glucocorticoids in the group (Group A), with the standard treatment regimen of 1 dose each at weeks 0, 2, and 6, and every 8 weeks thereafter, for a treatment cycle of 22 weeks, all at a dose of 300 mg. Patients who developed secondary loss of response were treated with pharmacologic intensification with infusions of Vedolizumab 300 mg every 4 weeks to improve clinical response. Glucocorticoids were prednisone acetate tablets 0.75 mg/kg once/day orally, decreasing by 5 mg weekly until discontinuation. The remaining 23 received the intravenous infliximab group, which was administered by intravenous infusion at weeks 0, 2, and 6 and every 8 weeks thereafter, with the possibility of shortening the treatment interval for intensification to 4-week intervals, if necessary, if an inadequate clinical response occurs during treatment.

Observation Indicators

General Information

Collect indicators such as age, gender, body mass index (BMI), hypertension, coronary artery disease, diabetes mellitus, history of smoking, history of alcohol consumption, erythrocyte sedimentation rate (ESR), C-reactive protein, leukocytes, erythrocytes, platelets, and hemoglobin through the electronic medical record system. The laboratory parameters involved in this study are normal within the standard range of the World Health Organization (WHO).

Index Related to Efficacy

Ulcerative colitis endoscopic index of severity (UCEIS), Mayo scoring system for ulcerative colitis activity (Mayo) and the complication rate.

- (1) Ulcerative colitis endoscopic index of severity, UCEIS: This scoring system is mentioned in the Chinese Expert Guidelines for Diagnosis and Treatment of Inflammatory Bowel Disease by Digestive Endoscopic Techniques,¹⁴ where the observations are more clearly defined and scored according to different degrees of severity, which is well-defined and reflects the degree of the disease more accurately. The correlation between endoscopic scores and disease activity was verified, with low inter-observer variability, and is recommended for use in a variety of clinical studies and can be used for efficacy monitoring and mid- and long-term prognostic assessment.

(2) Mayo scoring system for ulcerative colitis activity.¹⁴ A sum of scores ≤ 2 and no single subitem > 1 was considered remission, 3–5 was considered mildly active, 6–10 was moderately active, and 11–12 was severely active. Patients were classified as clinically responding to treatment with $\geq 30\%$ decrease in Mayo score from baseline or a decrease of ≥ 3 points and a decrease of ≥ 1 point in blood in stool score or 0 or 1 in this category. A score of ≤ 2 and no single subscale score > 1 was considered clinical remission.

Serological Indicators

Erythrocyte sedimentation rate (ESR), C-reactive protein, leukocytes, erythrocytes, platelets, and hemoglobin at weeks 0, 6, 14, and 30.

Adverse Reaction

Record adverse drug reactions during treatment, mainly including mouth ulcers, arthralgia, and dyspepsia.

Statistical Methods

The data analysis in this study was conducted using SPSS26.0 software. Continuous data distributions were represented by $\bar{x} \pm s$, and differential analysis was performed based on the pre-test application of one-way ANOVA or non-parametric rank-sum tests; categorical data were analyzed using χ^2 test/fisher exact probability method to examine differences between groups. For follow-up time effects and inter-group differences of serological indicators, repeated measures analysis was used. Under the premise of overall differences, Bonferroni method was employed to correct for multiple comparisons at the significance level α for pairwise comparisons between groups. A corrected $P < 0.05$ was considered statistically significant, with $\alpha = 0.05$.

Results

Analysis of the Number of Participants

Forty-six patients with severe active UC were included, and they were divided into 2 groups according to medication, 23 patients with vedolizumab combined with glucocorticoids (group A) and 23 patients with infliximab (group B), all of whom were entered into the outcome analysis with no dropout data.

Experimental Flow Chart the Flow Chart of the Two Groupings is Shown in Figure 1

Baseline data comparison between the two groups preoperative age, gender, body mass index (BMI), hypertension, coronary heart disease, diabetes mellitus, history of smoking, history of alcohol consumption, erythrocyte sedimentation rate, C-reactive protein, leukocytes, erythrocytes, platelets, hemoglobin, Mayo score and UCEIS score of the two groups of patients were compared, and the difference was not significant ($p > 0.05$), as shown in Table 1.

Comparison of the Follow-Up Points in the Two Groups

WBC 30 weeks, ESR 6 weeks, 30 weeks, ALB 30 weeks, Hb 6 weeks, 14 weeks, 30 weeks by t -test $p < 0.05$, the difference between the groups was statistically significant ($p < 0.05$). WBC, CRP, ESR, ALB, Hb by ANOVA test $p < 0.05$, the difference between the groups was statistically significant ($p < 0.05$). See Table 2 and Figure 2.

Comparison of the Incidence of Adverse Effects Between the Two Groups

Indicators of adverse reactions such as dyspepsia, arthralgia and oral ulcers were compared between the two groups, and the differences were not significant ($p > 0.05$), and in terms of the overall incidence of adverse reactions, although the incidence of adverse reactions in group B (34.783%) was higher than that in group A (17.391%), the p value of the chi-square test (0.179) was greater than 0.05, so it could not be concluded that there was a significant difference between the two groups in terms of the overall adverse reaction incidence rate was significantly different. See Table 3 for details.

Treatment Effects Were Compared Between the Two Groups

The clinical response rate increased to 82.60% in group A and 52.17% in group B at 14 weeks, at which point there was a significant difference between the two groups ($\chi^2 = 4.847$, $p = 0.028$), suggesting that group A performed better than

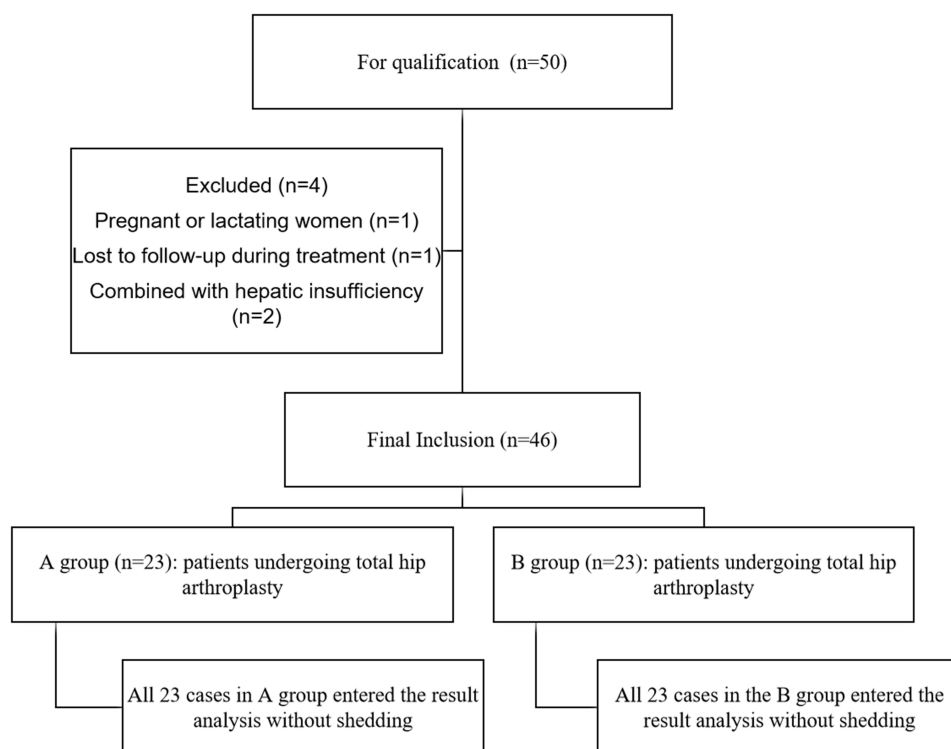


Figure 1 Flow chart of test grouping.

group B in terms of clinical response at this time point. At 30 weeks, the clinical response rate reached 91.30% in group A and 56.52% in group B, a highly significant difference between the two groups ($\chi^2 = 7.216$, $p = 0.007$), further indicating that group A performed better than group B in terms of clinical response over time. Clinical remission rate at 14 weeks, the clinical remission rate was 56.52% in group A and 21.73% in group B. The difference between the two

Table 1 Comparison of the Preoperative General Data Between the Two Groups

Items	A Group (n = 23)	B Group (n = 23)	χ^2/t	p
Age $\bar{X} \pm s$	47.609 \pm 13.305	45.957 \pm 16.494	0.366	0.716
Sex (n, male/female)	10/13	11/12	0.088	0.767
BMI (kg/m^2 $\bar{X} \pm s$)	21.820 \pm 3.013	21.831 \pm 3.448	-0.011	0.991
Basic disease (n/%)				
Hypertension	6/26.087	3/13.043	1.243	0.265
Coronary disease	4/17.391	3/13.043	0.168	0.681
Diabetes	6/26.087	8/34.783	0.411	0.522
Smoking	2/8.696	1/4.348	0.357	0.550
Drinking	3/13.043	1/4.348	1.095	0.295
Inspection index				
ESR	38.435 \pm 19.354	33.000 \pm 23.139	0.845	0.403
CRP	46.153 \pm 53.683	19.764 \pm 36.711	1.903	0.064
WBC	9.475 \pm 3.578	8.736 \pm 3.330	0.709	0.482
RBC	4.256 \pm 0.630	4.143 \pm 0.757	t0.539	0.593
PLT	390.304 \pm 158.413	383.609 \pm 130.445	0.153	0.879
Hb	104.174 \pm 25.155	101.913 \pm 24.029	0.305	0.762

(Continued)

Table 1 (Continued).

Items	A Group (n = 23)	B Group (n = 23)	χ^2/t	<i>p</i>
Mayo score/scores			2.242	0.134
Mild (3–5)	0	0		
Moderate (6–10)	16/69.565	11/47.826		
Severe (11–12)	7/30.435	12/52.174		
UCEIS score/scores			2.685	0.261
Mild (1–3)	7/30.435	4/17.391		
Moderate (4–6)	11/47.826	9/39.130		
Severe (7–8)	5/21.739	10/43.478		

Abbreviations: BMI, Body mass index = weight/height²Eqn; mean \pm standard deviation; n, sample size; ESR, erythrocyte sedimentation Rate; CRP, C-reactive protein; WBC, white blood cell; RBC, red blood cell; PLT, platelet; Hb, hemoglobin.

Table 2 Comparison of Serological Parameters Between Subjects Before and After Treatment

Items	Group	0 week	6 week	14 week	30 week	<i>F</i>	<i>p</i>
WBC ($\times 10^9/L$)	A group	8.71 \pm 1.22	6.82 \pm 1.22	5.74 \pm 1.15	4.57 \pm 0.93	52.624	<0.001
	B group	8.68 \pm 0.78	7.11 \pm 0.66	5.95 \pm 0.42	5.07 \pm 0.44	148.792	<0.001
	<i>t</i>	0.112	−0.981	−0.776	−2.276		
	<i>p</i>	0.911	0.332	0.442	0.028		
CRP (mg/L)	A group	39.06 \pm 5.55	30.04 \pm 5.13	16.97 \pm 4.16	6.21 \pm 3.11	217.867	<0.001
	B group	38.59 \pm 5.03	28.86 \pm 2.74	18.58 \pm 0.34	6.03 \pm 2.55	434.468	<0.001
	<i>t</i>	0.296	0.958	−1.808	0.207		
	<i>p</i>	0.768	0.343	0.084	0.837		
ESR (mm/h)	A group	56.66 \pm 6.07	42.63 \pm 2.70	19.63 \pm 4.12	6.26 \pm 2.22	680.769	<0.001
	B group	54.91 \pm 1.69	40.31 \pm 1.34	19.31 \pm 1.56	7.49 \pm 0.96	4902.06	<0.001
	<i>t</i>	1.303	3.590	0.337	−2.389		
	<i>p</i>	0.199	<0.001	0.738	0.023		
ALB (g/L)	A group	33.63 \pm 3.51	40.86 \pm 2.10	44.18 \pm 1.11	50.86 \pm 4.26	124.860	<0.001
	B group	32.53 \pm 1.46	40.45 \pm 2.44	43.72 \pm 2.08	48.15 \pm 2.16	223.248	<0.001
	<i>t</i>	1.368	0.598	0.911	2.665		
	<i>p</i>	0.178	0.553	0.367	0.012		
Hb (g/L)	A group	104.62 \pm 3.86	112.32 \pm 2.70	121.31 \pm 7.33	129.51 \pm 7.25	79.861	<0.001
	B group	107.06 \pm 4.43	114.49 \pm 3.26	116.95 \pm 4.81	124.26 \pm 5.14	55.385	<0.001
	<i>t</i>	−1.944	−2.403	2.332	2.773		
	<i>p</i>	0.058	0.021	0.024	0.008		

Note: The continuous value was given as the mean and the standard deviation.

Abbreviations: ESR, erythrocyte sedimentation Rate; CRP, C-reactive protein; WBC, white blood cell; PLT, platelet; Hb, hemoglobin; ALB, albumin;

groups was significant ($\chi^2 = 5.841$, $p = 0.016$), indicating that group A performed better than group B in terms of clinical remission. The difference in endoscopic remission rate between the two groups at each follow-up point was not significant ($p > 0.05$). In summary, in terms of clinical response rate, Group A performed better than Group B overall and the difference over time was more obvious; in terms of clinical remission rate, Group A was better than Group B in the early stage, but the gap narrowed in the later stage; in terms of endoscopic remission rate, the difference between the two groups was always insignificant. For details, see [Table 4](#) and [Figure 3](#).

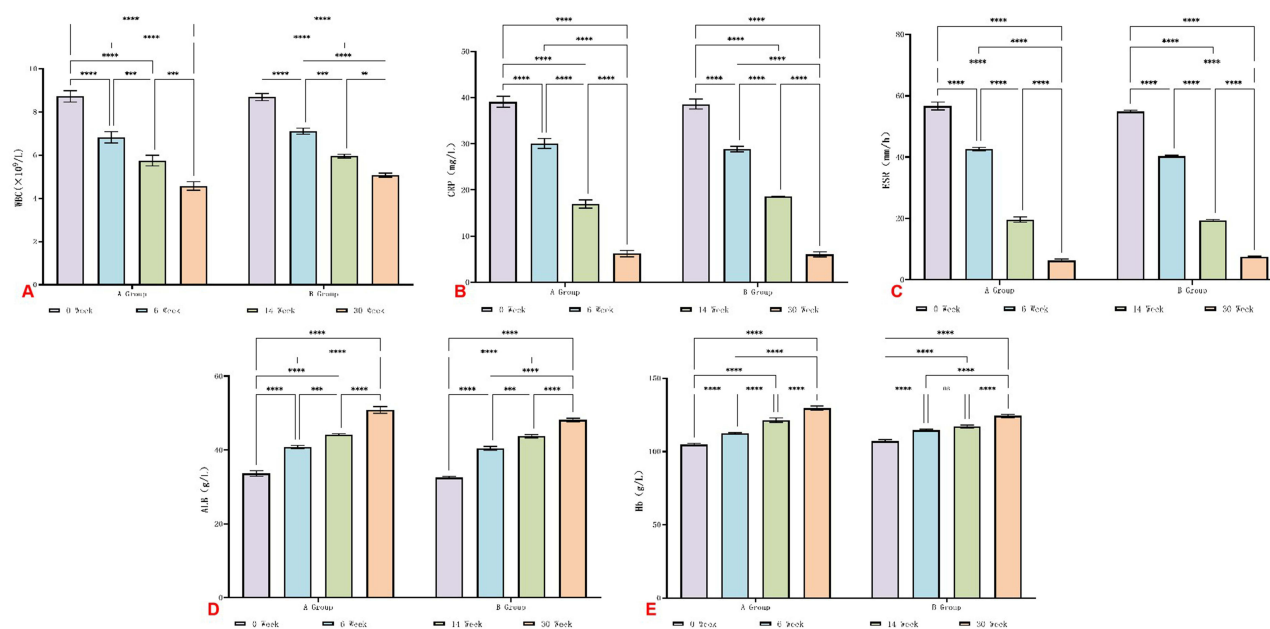


Figure 2 Comparison of serological parameters between subjects before and after treatment.
Notes: A. White blood cell; B. C-reactive protein; C. Hematocrit; D. Albumin; E. Hemoglobin.

Discussion

Summary of Evidence

The etiology of UC has not yet been fully clarified, and treatment in the past mainly focused on symptomatic treatment of its clinical symptoms such as diarrhea, abdominal pain and blood in stools, with the aim of inducing remission and maintaining the therapeutic effect, which is usually a lengthy treatment process. However, in recent years, the treatment concept has changed, and the goal of clinical treatment has shifted more to early intervention, which is no longer only satisfied with clinical relief on the basis of controlling the clinical symptoms, but also pursues mucosal healing, so as to reduce the rate of surgery and hospitalization of patients, reduce the risk of deterioration of the condition, prevent and treat various complications, and thus improve the quality of life of patients.^{18–22} At the same time, comprehensive and individualized treatment plans will be adopted according to the type of UC, severity and extent of lesion involvement to achieve the best therapeutic effect.

TNF- α is an inflammatory cytokine that plays an important role in active inflammation associated with IBD.²³ Increased TNF- α induces cell proliferation, differentiation, and leads to up-regulation of endothelial adhesion molecules in order to increase the transport of immune cells to the site of inflammation.^{24,25} Infliximab is a heterodimeric chimeric IgG1 monoclonal antibody that specifically binds to soluble and membrane-bound TNF- α , thereby inhibiting the immune and inflammatory responses induced by TNF- α . The migration of lymphocytes to the gastrointestinal tract in IBD is accomplished by the interaction between integrins on the surface of lymphocytes and intestinal endothelial ligands. Integrins are composed of two subunits, α and β , and a total of 24 specific integrins are known through the inter-combination of 18 α -subunits and 8 β -subunits. Those relevant to the gastrointestinal tract include $\alpha 2\beta 2$, $\alpha 4\beta 1$, and $\alpha 4\beta 7$. Integrin $\alpha 4\beta 7$ specifically binds to VCAM-1 in the intestinal mucosal address in cell adhesion molecule-1 (MAdCAM-1) and mucosal address to regulate lymphocyte

Table 3 Comparison of the Adverse Effects in Both Groups (n/%)

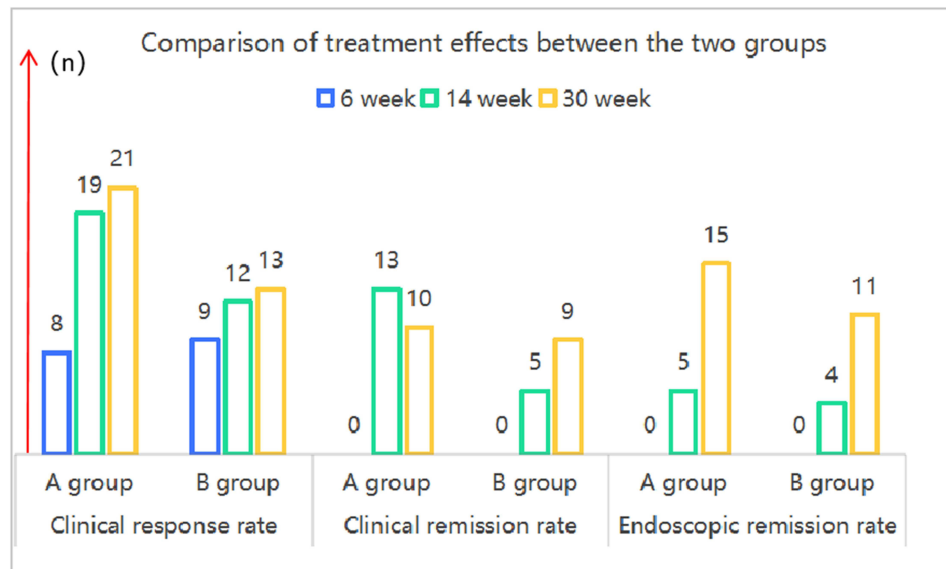
Group	Cacoehyilia	Arthralgia	Dental Ulcer	Sum
A group	1(4.34)	1(4.34)	2(8.69)	4(17.39)
B group	3(13.04)	2(8.69)	3(13.04)	8(34.78)
χ^2	1.095	0.357	0.224	1.804
<i>p</i>	0.295	0.550	0.636	0.179

Table 4 The Treatment Effect Comparison Between the Two Groups (n/%)

Items	Group	n	6	14 week	30 week
Clinical response rate	A group	23	8(34.78)	19(82.60)	21(91.30)
	B group	23	9(39.13)	12(52.17)	13(56.52)
	χ^2		0.093	4.847	7.216
	<i>p</i>		0.760	0.028	0.007
Clinical remission rate	A group	23	0 (0)	13(56.52)	10(43.47)
	B group	23	0 (0)	5(21.73)	9(39.13)
	χ^2			5.841	0.090
	<i>p</i>			0.016	0.765
Endoscopic remission rate	A group	23	0 (0)	5(21.73)	15(65.21)
	B group	23	0 (0)	4(17.39)	11(47.82)
	χ^2			0.138	1.415
	<i>p</i>			0.710	0.234

migration, thereby mediating lymphocyte translocation to intestinal tissues.²⁶ Vedolizumab is a humanized integrin antagonist that can bind specifically to the integrin $\alpha 4\beta 7$ on the surface of targeted memory T lymphocytes, preventing the interaction between this type of lymphocytes and MAdCAM-1 and inhibiting their transfer to the inflammatory sites in the gastrointestinal tract, thus reducing intestinal inflammation to achieve therapeutic effects.²⁷

In the present study, 46 patients with severe UC were selected for observation. The results of the study showed that Vedolizumab combined with glucocorticoids in the analysis of the changes in WBC count, Hb, CRP, ESR and ALB showed that the subjects in the 2 groups gained significant improvement in all serological indices after treatment, but the differences were statistically significant when compared at all time points. The results suggest that Vedolizumab in combination with glucocorticoids group better improves patients' serologic indices and final symptomatic outcomes but can more rapidly relieve clinical symptoms.

**Figure 3** Comparison of the treatment effects between the two groups.

Notes: Clinical Response Rate: The proportion of patients achieving predefined criteria for significant symptomatic improvement following treatment. Assessment: Typically quantified by reductions in clinical symptom scores (eg, modified Mayo score). Clinical Remission Rate: The proportion of patients attaining complete or near-complete resolution of symptoms post-treatment. Assessment: Requires meeting strict thresholds (eg, Mayo score ≤ 2 with all subscores ≤ 1), signifying transition to an inactive disease state. This represents the primary short-term treatment goal and correlates directly with improved quality of life. Endoscopic Remission Rate: The proportion of patients demonstrating complete or near-complete healing of mucosal inflammation confirmed by colonoscopy. Assessment: Defined by achieving specific thresholds on endoscopic scoring systems (eg, Mayo endoscopic subscore ≤ 1 or UCEIS score ≤ 1).

A meta-analysis included 6 studies totaling 2830 patients with IBD to assess the safety of long-term use of Vedolizumab. The results showed that: 1. The probability of adverse events and serious adverse events was lower in the Vedolizumab group than in the placebo group. Long-term treatment with Vedolizumab did not increase the probability of adverse events. 2. The incidence of infections was lower in the Vedolizumab group than in the placebo group (63.5/100 person-years versus 82.9/100 person-years). Very few patients (<1%) withdrew from treatment due to infection. 3. Infusion-related reactions (IRR) as defined by the investigators occurred in $\leq 5\%$ of patients receiving Vedolizumab, with the majority of IRRs being mild to moderate and rarely resulting in discontinuation of the drug. 4. A total of 18 patients developed tumors, which were not statistically different from the placebo group difference. The incidence of tumors was similar to that of other IBD populations.²⁸ Another network meta-analysis of 29 studies (23 head-to-head RCTs) evaluating the efficacy and safety of biologics and small molecules currently used for the treatment of UC showed that Vedolizumab ranked the lowest in adverse events and serious adverse events and had the best safety outcomes among the drugs.^{29,30}

The main adverse reactions of Vedolizumab include dyspepsia, allergic reaction and oral ulcer. In this study, 1 case of dyspepsia, 1 case of allergic reaction and 2 cases of oral ulcer occurred in Group A, with an incidence rate of 17.39%. In group B, 3 cases of dyspepsia, 2 cases of allergic reaction and 3 cases of oral ulcer occurred, with an incidence rate of 34.78%. The difference between the two was not statistically significant. The statistical significant difference between group A and group B adverse events does not prevent the use of Vedolizumab because Vedolizumab has lesser adverse events and increased safety outcomes. In the reported studies, the majority of patients receiving Vedolizumab had mild-to-moderate infection severity, and very few patients (<1%) discontinued treatment due to infection. Vedolizumab has a relatively high safety profile compared to infliximab monoclonal antibodies, adalimumab monoclonal antibodies and golimumab monoclonal antibodies, and its specific action in the gut avoids systemic immunosuppressive reactions.³¹

Limitations of the Article

① This trial is a retrospective study, so there may be the possibility of loss of data or failure to record data in time, which may bias the results, but the research team to which the authors belonged strictly and carefully recorded the postoperative outcome indicators of each group to maximize the completeness of the experimental data; ② The sample size of the inclusion of the relatively small, statistically insufficient efficacy of the reporting of bias, and the results of this study need further, multicenter, prospective studies to further elucidate the relationship between clinical outcomes. The results of this study require further multicenter, prospective studies to further elucidate the relationship between clinical outcomes.

Conclusion

Both Vedolizumab and infliximab have been widely used in the treatment of patients with UC, and both have good efficacy in patients with severe UC. However, Vedolizumab in combination with glucocorticoids is superior to infliximab in terms of clinical response and clinical remission, and the combination therapy also helps to improve the long-term prognosis of patients.

Data Sharing Statement

To compare the efficacy and safety of vedolizumab plus glucocorticoids versus infliximab in severe ulcerative colitis for optimized treatment selection, so the dataset analyzed in this study is not publicly available but is available to the corresponding author on reasonable request.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

We confirm that all experiments were performed in accordance with the Declaration of Helsinki. The study was approved by the Ethical Committee of the Xinjiang Uygur Autonomous Region People's Hospital, NO. KY20241201105. Each patient provided written informed consent before participating in the study.

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Disclosure

The authors report no conflicts of interest in this work.

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