Original Article

A Hospital-Based Retrospective Study to Compare the Clinical and Endoscopic Effectiveness of Vedolizumab (VDZ) and Infliximab (IFX) in Biologic-Naïve Patients with Ulcerative Colitis at a Tertiary Care Centre

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Abstract

Background: The symptoms of ulcerative colitis (UC), a chronic inflammatory bowel illness, include tenesmus, hematochezia, and stomach pain. Globally, the incidence of UC has been increasing, especially in recently industrialized countries. Anti-TNF medications have significantly changed how moderate-to-severe UC is treated. In a retrospective, real-world, single-center study with a 52-week follow-up (FU), we assessed the efficacy of IFX and VDZ in two nearly identical cohorts of biologic-naïve patients with moderate-to-severe UC. **Material and Methods:** This was a hospital-based retrospective comparative observational study conducted at our tertiary care teaching hospital between January 2021 and December 2025. Data was obtained from hospital medical records department and pharmacy databases. The study duration was 6 months, including protocol approval, data collection, analysis, and report preparation. Participants were divided into two groups: Those receiving Vedolizumab (VDZ) were included in Group 1, while those getting Infliximab (IFX) were included in Group 2. Adult patients with ulcerative colitis who were not exposed to advanced therapies (biologics or small molecules) and who had at least the induction doses of VDZ or IFX administered intravenously (IV) in accordance with the standard induction protocol at 0, 2, and 6 weeks, followed by maintenance every 8 weeks. A 300 mg dose of VDZ and a 5 mg/kg dose of IFX were given. Patients who stopped therapy before week 52 because of primary non-response, subsequent loss of response, adverse events, or the requirement for surgery were included in the mean follow-up calculation. **Results:** We included 30 patients on IFX, 30 on VDZ, and 60 biologic-naïve patients based on the inclusion and exclusion criteria. Before the propensity score was applied, the mean age at diagnosis was higher in the VDZ than in the IFX group (mean age 48.5 vs. 36.8, p=0.001), but the propensity score analysis did not support this. At the end of follow-up (FU), 76.6% and 30% of patients on VDZ and IFX, respectively, achieved the primary end goal of clinical response (CR) ($p<0.05$*; OR:6.725; 95% CI 2.346–16.253). Additionally, the VDZ group had a greater response rate (80% vs. 53.3% for IFX, $p<0.05$*). There was a significant difference ($p<0.05$*) in the percentage of main non-response between the IFX group (30%) and the VDZ group (10%). The secondary response loss was comparable ($p>0.05$). **Conclusion:** For the majority of the predetermined goals (CR, persistence in therapy, clinical response at the end of induction, steroid-free remission, and requirement for optimization), VDZ outperformed IFX as a first-line treatment in biologic-naïve patients with UC in this retrospective real-life study.

Keywords: Ulcerative colitis (UC), infliximab (IFX), vedolizumab (VDZ), Partial mayo score (PMS), Clinical Response (CR).

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Introduction

Ulcerative colitis (UC) is a chronic inflammatory illness of the intestine that shows symptoms like stomach pain, hematochezia and tenesmus.[1] The mucosa of the colon is affected by ulcerative colitis (UC), a chronic, progressive inflammatory disease caused by the immune system. Periods of remission and relapses are the clinical features of this illness.[2,3] The prevalence of UC has been rising worldwide, particularly in recently industrialized nations. This has resulted in more hospitalizations, lower quality of life, and higher healthcare expenses, especially in moderate-to-severe cases.

Reducing inflammation and symptoms, maintaining remission, and promoting endoscopic repair are the three basic goals of UC treatment. Therefore, a more stringent course of treatment is required.[4] Conventional treatments, including azathioprine, prednisone and 5-aminosalicylate (5-ASA), are usually used to treat UC. However, a significant proportion of patients are non-responders or intolerant to conventional therapy, hence novel medications aimed at different therapeutic targets are needed to meet an unmet clinical need.[5] Since the approval of the first biological drugs, such as

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infliximab (IFX), regulators have approved UC care has transformed over the last 20 years with early diagnosis, objective therapeutic targets, improved disease monitoring and growing use of biologic therapies.[4,6] The management of moderate-to-severe UC has been drastically changed by anti-TNF medications. They not only help many patients to recover their mucosa but also cut the rates of hospitalisation and colectomy dramatically.[7] Newly authorized compounds and modes of action include anti-integrins, interleukin inhibitors and Janus kinase (JAK) inhibitors, among others.6,8. Current recommendations are to treat patients with severe disease or failure of traditional treatments with biologic therapy early.[6]

Vedolizumab (VDZ) is one of a class of anti-integrin monoclonal antibodies that specifically target the α4β7 integrin expressed on the surface of circulating lymphocytes and inhibit its interaction with the adhesion MAdCAM-1 receptor expressed on the intestinal vasculature's endothelial cells. This reduces the recruitment of inflammatory cells across the mucosal layers and downregulates trans-endothelial leukocyte trafficking.[9] However, much of the latter data is derived from retrospective research containing individuals already treated with various therapies including anti-TNFα, and real-life comparison trials with biologic naive patients are scarce.

We conducted a retrospective, real-world, single-center trial with a 52-week follow-up (FU) to evaluate the effectiveness of VDZ and IFX in two nearly identical cohorts of patients with moderate-to-severe UC who were biologic-naïve.

Materials and Methods

This was a hospital-based retrospective comparative observational study. The study was conducted at our tertiary care teaching hospital after approval of Institutional Ethics Committee. Data was obtained from hospital medical records department and pharmacy databases. The study duration was 6 months, including protocol approval, data collection, analysis, and report preparation. Retrospective data was collected for patients treated between January 2021 and December 2025. Participants were divided into two groups: Group 1 included patients receiving Vedolizumab (VDZ) and group 2 incorporated patients receiving Infliximab (IFX)

Adult patients with UC who receive at least induction doses of VDZ or IFX intravenously (IV) in accordance with the conventional induction regimen at 0, 2, and 6 weeks, with maintenance every 8 weeks, and who are not exposed to advanced therapy (biologics or small molecules). 300 mg VDZ and 5 mg/kg IFX were administered. The major drivers in the biologic choice were the physicians' level of confidence and their perceptions about the safety and efficacy of the two drugs.

Inclusion and Exclusion Criteria

The criteria for inclusion were as follows: (1) patients with a confirmed diagnosis of UC who were bio-naïve 10; (2) patients treated with either VDZ or IFX; (3) patients with mild activity but refractory to conventional medications or moderate-to-severe activity based on the Mayo score; and (4) patients who were at least eighteen years old.

The following were the exclusion criteria: (1) Individuals who have previously received Janus kinase inhibitors or biologic agents. (2) Indeterminate colitis or Crohn's disease diagnosis. (3) Unfinished medical records. (4) Concurrent severe systemic disease that influences outcome evaluation.

Data Collection: Patient records were identified using hospital medical records, electronic database and biologic therapy registry. Demographic variables, dietary practices, smoking and alcohol use, disease duration, patient-reported symptoms, disease location per Montreal Classification, disease activity measured by Mayo score, medication history, endoscopic findings, laboratory results (C-reactive protein (CRP) and albumin (ALB)), treatment protocols, and adverse events (AEs) were documented utilizing a prestructured case record form. Week 52 was designated as the follow-up (FU) end. Patients who stopped therapy before week 52 because of primary non-response, subsequent loss of response, adverse events, or the requirement for surgery were included in the mean follow-up calculation. At every infusion, the Partial Mayo Score (PMS) was determined. Trough levels of the medication were measured, and endoscopic activity was reexamined using recto-sigmoidoscopy when required in situations of inadequate response or deteriorating clinical conditions. When the doctor thought it essential, steroids or immune suppressants were administered during the FU. It was also mentioned that a medicine switch or dose optimization was required.

Statistical analysis: The mean and standard deviation, or the median and interquartile range for continuous data, were used to define patient characteristics. The proportions of the categorical variables were compared using Fisher's test or the $\chi 2$. Quantitative variables were compared using either the student's t-test or its non-parametric equivalents.

Results

We enrolled 60 biologic-naïve patients based on inclusion and exclusion criteria, of which 30 were on IFX and 30 on VDZ. Gender, disease extension, duration of illness, severity at the start of biological therapy (mean PMS and its sub-scores, endoscopic activity, CRP and albumin at baseline), and drugs used at T0 were all homogenous across the two groups. The mean age at diagnosis was greater in the VDZ group than in the IFX group prior to the application of the propensity score (mean age 48.5 vs. 36.8, p=0.001), but this was not verified after propensity score analysis. [Table 1].

76.6% and 30% of patients on VDZ and IFX, respectively, met the primary end point of clinical response (CR) at the end of FU ($p<0.05$*; OR: 6.725; 95% CI 2.346–16.253). Additionally, the VDZ group had a greater response rate (80% vs. 53.3%f or IFX, $p<0.05$*). There was a significant difference ($p<0.05$*) between the two groups, with the IFX group having a larger percentage of primary non-response (30%) compared to VDZ (10%). Table 2 shows that secondary loss of responsiveness was comparable ($p>0.05$).

Table 1: Clinical characteristics of the study populations.

		IFX (n=30)	VDZ (n=30)	P value
Mean age of diagnosis (±STD)		36.8 (±12.7)	48.5 (±13.5)	0.001***
Male, n (%), female, n (%)		20 (66.6%); 10 (33.3%)	16 (53.3%); 14 (46.6%)	>0.05
UC extension, n (%)	Proctitis	2 (6.66%)	0 (0%)	>0.05
	Left sided	13 (43.3%)	16 (53.3%)	>0.05
	Extended	15(50%)	14 (46.6%)	>0.05
Duration of disease in years, mean ± STD		9.3 (±8.27)	8.5 (±8.34)	>0.05
Partial mayo score (PMS) at T0, mean ± STD		5.27 (±1.84)	4.93 (±1.96)	>0.05
Mild UC (PMS 2–4), n (%)		9 (30%)	10 (33.33%)	>0.05
Moderate UC (PMS 5–7), n (%)		18 (60%)	18 (60%)	1.000
Severe UC (PMS >7), n (%)		3 (10%)	2 (6.66%)	>0.05
CRP, mean ± STD		1.57 (±2.34)	1.8 (±2.37)	>0.05
Albumin value, mean ± STD		3.82±0.56	3.48±0.72	>0.05
5-ASA use, n (%)		13 (43.33%)	13 (43.33%)	1.000
Steroid use, n (%)		12 (40%)	17 (56.66%)	>0.05
Thiopurine use, n (%)		7 (23.33%)	6 (20%)	>0.05
COMBO with thiopurine for 6 months, n (%)		6 (18%)	5 (16.66%)	>0.05

Table 2: Main results obtained comparing Infliximab (IFX) and Vedolizumab (VDZ) in naïve patients with Ulcerative Colitis.

	IFX (n=30)	VDZ (n=30)	P value
Duration of clinical FU, mean (weeks)	38	46	>0.05
Subjects in CR at the end of FU, n (%)	9 (30%)	23 (76.6%)	<0.05*
Drug persistency at the end of FU, n (%)	16 (53.3%)	24 (80%)	<0.05*
Subjects who achieved CR at the end of FU	14	20	>0.05
Time to obtain CR (weeks, median)	8.6	12.9	.0.05
Response at the end of induction, n (%)	16 (53.3%)	24 (80%)	<0.05*
Need for optimization, n (%)	17 (56.6%)	8 (26.6%)	<0.05*
Primary non-response	9 (30%)	3 (10%)	<0.05*
Secondary loss of response (immunogenic or not)	2 (6.66%)	3 (10%)	>0.05
Adverse events, n (%)	4 (13.3%)	1 (3.3%)	>0.05

* $p < 0.05$ (Statistically significant), ** $p < 0.01$ (Highly statistically significant), *** $p < 0.001$ (Extremely statistically significant)

Discussion

When choosing advanced treatment for CD patients who have not reacted to steroids and/or traditional immunomodulators, there are significant implications for maximizing long-term treatment success for specific patients.[4] Biologic-naïve UC patients have not yet been adequately studied in relation to anti-TNF and anti-integrins. The VDZ group's older age was the only factor influencing treatment choice. Thus, despite being retrospective and non-randomized, this study looked for important confounders in two well-matched populations.

In contrast to patients who were on steroids at baseline, our findings indicated that VDZ surpassed IFX regarding the clinical response rate at the conclusion of the induction period, clinical remission at the end of follow-up, medication adherence, need for optimization, and steroid-free remission. Comparable results were observed in a recent multicenter real-world study conducted in Italy. Eleven. Macaluso et al. established that at week 52, VDZ surpassed Adalimumab (ADA) and Golimumab (GOL) in achieving steroid-free remission, with rates of 51.5%, 32.4%, and 29.4% for VDZ, ADA, and GOL, respectively. Eleven Regretfully, IFX was left out of the analysis in this study.

The efficacy outcomes align with findings from further real-world, retrospective studies.[12,13] This includes propensity score-matched observational data from anti-TNFα-naive individuals within the VICTORY consortium (showing no significant disparity between vedolizumab and infliximab in achieving clinical remission, steroid-free clinical remission, or endoscopic remission) and the principal EVOLVE study (which encompasses real-world data for infliximab and alternative anti-TNFα therapies).[12,14]

The examination of treatment adherence rates indicated a tendency for increased rates in the vedolizumab group compared to the infliximab group over time, yet this tendency did not reach statistical significance at the 12-month mark, potentially attributable to the limited sample size in this unadjusted analysis. These results corresponded with the VICTORY observational cohort study involving 1266 patients with CD (n = 659) treated from May 2014 to December 2017; the incidence of non-infectious serious adverse events was markedly lower with vedolizumab than with anti-TNFα therapy (OR 0.072; 95% CI, 0.012–0.242), while no significant differences were observed between the vedolizumab and anti-TNFα groups regarding serious infections (OR 1.183; 95% CI, 0.519–1.806).[12]

By the end of the induction period, VDZ demonstrated a markedly superior clinical response (CR) relative to IFX (VDZ 80% vs. IFX 53.3%, p<0.05*). Helwig et al,[15] conducted a retrospective investigation comparing the clinical remission rates of 57 patients treated with IFX, ADA, or GOL to 76 patients treated with VDZ. At week 26, the clinical response rates were recorded at 31.5% for anti-TNFα and 50.1% for VDZ among the biologic-naïve sample of 40 anti-TNFα patients and 22 VDZ patients. The variation was not statistically meaningful, but it was numerically greater in patients receiving VDZ treatment. In a bidirectional cohort examination, Alamneni et al. found analogous response rates in UC patients receiving IFX and 32 with VDZ (n = 18 and 13 naïve, respectively), with VDZ

demonstrating enhanced performance in patients previously exposed to anti-TNFα. However, there were exceedingly few patients who qualified.[16]

Guidi et al. prospectively examined the impact of VDZ trough levels at the end of induction in predicting medication persistency and related clinical benefit at 6, 14, 22, and 54 weeks in 59 patients with UC, 81.4% of whom were treated to one or more anti-TNFαagents.[17]

Medication optimization was utilized for participants in the GETAID investigation who faced either primary non-response or later loss of response over a 52-week follow-up period.[18] Among them, 30% achieved a complete response and 41% attained a clinical response.[18] In our research, VDZ drug optimization was exclusively based on clinical criteria; conversely, IFX optimization was based on clinical criteria in addition to trough levels. The disparity was statistically significant (VDZ 26.6% vs. IFX 56.6%, $p<0.05$*), and VDZ necessitated less adjustment compared to IFX.

Conclusion

In this retrospective observational trial, VDZ surpassed IFX as a primary treatment in biologic-naïve individuals with UC across the majority of established endpoints (CR, therapy persistence, clinical response at the conclusion of induction, steroid-free remission, and necessity for optimization). To substantiate these findings and facilitate the ideal positioning of the existing UC therapy, additional prospective and comparative studies are necessary.

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Conflicts of interest

There are no conflicts of interest.

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