Real-world Effectiveness and Onset of Action of Vedolizumab as a First-line Biologic in Biologic-Naïve Patients With Ulcerative Colitis

Poster P2571

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Background

- In a prior analysis, we found that second-line anti-tumor necrosis factor α (TNFα) treatments can be used following vedolizumab as a first-line biologic in patients with ulcerative colitis (UC) without concerns about their effectiveness[1]
- However, in patients with UC, additional data is needed to demonstrate the real-world effectiveness of vedolizumab as a first-line biologic, particularly for the onset of action, because there remains a perception that vedolizumab is slower to act than other targeted inflammatory bowel disease therapies[2]

Aim

- This exploratory endpoint analysis aimed to evaluate the effectiveness and onset of action of vedolizumab as a first-line biologic in a real-world cohort of biologic-naïve patients with UC

Methods

- The study included patients aged 18 years or older with moderate to severe UC who were treated at a large, multicenter, private gastroenterology practice in Texas, USA
- Eligible patients were biologic-naïve before receiving vedolizumab as a first-line biologic between January 1, 2018 and May 31, 2020; the study index period was January 1, 2018 to December 31, 2021. The index date for each patient was the date of their first vedolizumab infusion
- The primary endpoint was the proportion of patients who discontinued vedolizumab as a first-line biologic and had a clinical response (defined as ≥ 2-point reduction in partial Mayo score from baseline) to second-line anti-TNFα treatment at 3, 6, 9, and 12 months after initiating second-line treatment; these results have been reported previously[1]
- Key exploratory endpoints were the proportion of patients with clinical remission (partial Mayo score < 2) and the proportion of patients with corticosteroid-free clinical remission (clinical remission and no longer receiving corticosteroids) at 3, 6, 9, and 12 months after initiating vedolizumab as a first-line biologic
- The onset of action of vedolizumab was assessed using partial Mayo scores (a decrease of ≥ 1 point in rectal bleeding or ≥ 1 point in stool frequency from baseline) at weeks 2 and 6

Results

- Baseline demographics and disease characteristics of 260 patients with UC who received vedolizumab as a first-line biologic during the index period are shown in **Table 1**
- Treatment characteristics for vedolizumab as a first-line biologic are shown in **Table 2**
  - At baseline, 158 patients (60.8%) were receiving a corticosteroid
  - 72 patients (27.7%) discontinued treatment within 12 months of initiation. Secondary loss of response to treatment was the most frequent reason for discontinuation
- The proportion of patients who had clinical remission and corticosteroid-free clinical remission with vedolizumab as a first-line biologic is shown in **Figure 1**
  - Evaluation of partial Mayo scores revealed that some enrolled patients had mild disease at baseline
  - Of the 188 patients who continued to receive vedolizumab at 12 months, 149 (79.3%) had clinical remission
  - At 12 months, 52.3% of patients who continued to receive vedolizumab and were receiving a corticosteroid at baseline had corticosteroid-free clinical remission
- The results of a multivariable analysis of factors influencing the odds of having clinical remission 12 months after initiating treatment with vedolizumab as a first-line biologic are shown in **Figure 2**
  - Being in remission and having mild disease severity at baseline had odds ratios of 3.46 and 5.71, respectively, for clinical remission at 12 months
- Onset of action was observed by week 6 in 87.2% of patients with moderate or severe disease; 49.6% had a response to vedolizumab within 2 weeks of initiation (**Figure 3**)

Table 1. Baseline demographic and disease characteristics of patients who received vedolizumab as a first-line biologic

Demographic or disease characteristic	Vedolizumab as a first-line biologic[a] N = 260
Age	
Age, years, mean (SD)	42.6 (15.7)
Age category, n (%)	
18–34 years	90 (34.6)
35–64 years	148 (56.9)
≥ 65 years	22 (8.5)
Sex, n (%)	
Male	143 (55.0)
Female	117 (45.0)
Smoking status, n (%)	
Never smoked	192 (73.8)
Former smoker	54 (20.8)
Current smoker	14 (5.4)
Other characteristics, median (IQR)	
Body mass index, kg/m^2	25.9 (22.1–29.4)
Charlson comorbidity index score	0 (0–1)
Time from diagnosis to receiving vedolizumab, years	3.2 (0.9–9.1)
Time from vedolizumab referral to induction, days	32.0 (18.0–48.0)
Duration of vedolizumab treatment during 12-month follow-up, months	12.0 (9.6–12.0)

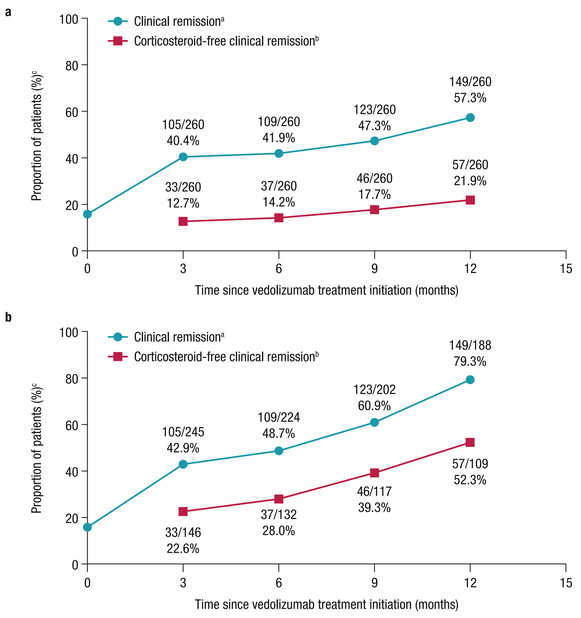
IQR, interquartile range; SD, standard deviation.
[a]Patients were biologic-naïve and received vedolizumab as a first-line biologic but may have received prior conventional therapy.

Table 2. Treatment characteristics for patients who received vedolizumab as a first-line biologic

Treatment characteristic	Vedolizumab as a first-line biologic[a] N = 260
Dose, median	300 mg
Dose frequency	Q8W
Dose escalation, n (%)	
Increased dose	0
Increased frequency	40 (15.4)
Discontinued vedolizumab after dose escalation	28 (10.8)
Concurrent medication,[b] n (%)	
5-ASA only	74 (28.5)
Immunomodulator only	7 (2.7)
5-ASA + immunomodulator	5 (1.9)
Corticosteroid only	52 (20.0)
Corticosteroid + 5-ASA	95 (36.5)
Corticosteroid + immunomodulator	4 (1.5)
Corticosteroid + 5-ASA + immunomodulator	7 (2.7)
Any corticosteroid[c]	158 (60.8)
Discontinuation characteristics	
Discontinued vedolizumab, n (%)	72 (27.7)
Time to discontinuation, months, median (IQR)	6.0 (3.3–10.8)
Reason for discontinuation,[d] n (%)	
Primary nonresponse	5 (6.9)
Secondary loss of response	29 (40.3)
Transfer of care	13 (18.1)
Lost to follow-up	9 (12.5)
Competing medical problem	6 (8.3)

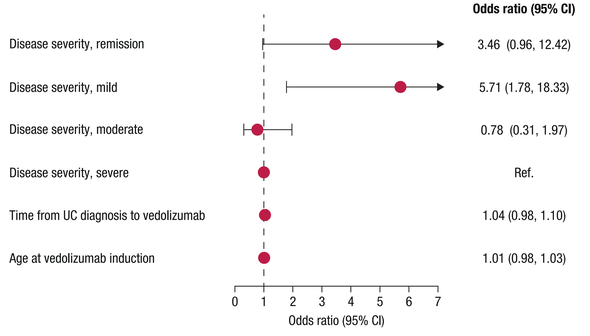
5-ASA, 5-aminosalicylic acid; IQR, interquartile range; Q8W, every 8 weeks; SD, standard deviation.
[a]Vedolizumab treatment characteristics in all patients who were biologic-naïve and received vedolizumab as a first-line biologic. [b]Concurrent medications being used when vedolizumab was initiated as a first-line biologic. [c]Any patients who were receiving a corticosteroid alone or in combination with 5-ASA or an immunomodulator. [d]Patients who discontinued first-line vedolizumab. The table includes categories that had more than five patients.

Figure 1. Clinical remission and corticosteroid-free clinical remission among a) all patients who received vedolizumab as a first-line biologic treatment and b) those who continued to receive vedolizumab at each time point



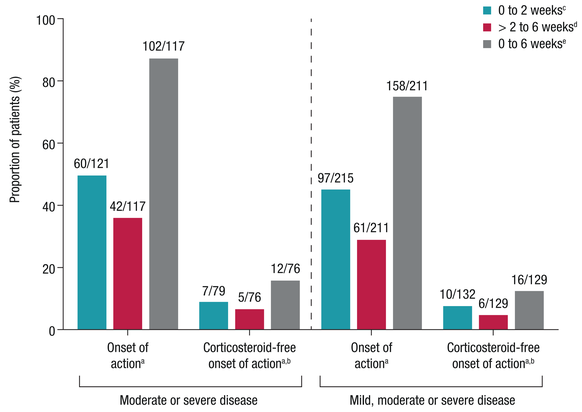
[a]Partial Mayo score < 2. [b]Partial Mayo score < 2 and not receiving a corticosteroid at time of assessment. [c]For clinical remission, the denominator (N) is the total number of patients who continued to receive vedolizumab at each time point. For corticosteroid-free clinical remission, the denominator (N) is the total number of patients who were receiving a corticosteroid at baseline and continued to receive vedolizumab at each time point.

Figure 2. Multivariable analysis of factors that influence the odds of having clinical remission 12 months after initiating vedolizumab as a first-line biologic



The reference group for comparison were those patients with severe disease at baseline.
CI, confidence interval; Ref., reference; UC, ulcerative colitis.

Figure 3. Onset of action of vedolizumab as a first-line biologic



[a]Partial Mayo score decrease of ≥ 1 point in rectal bleeding or ≥ 1 point in stool frequency from baseline as assessed at week 2 or week 6. [b]Patients who were not receiving a concurrent corticosteroid at each time point. [c]Patients with onset of action at week 2. Denominator excludes patients who discontinued or were lost to follow-up. [d]Patients without onset of action at week 2 and with onset of action at week 6. Denominator excludes patients who discontinued or were lost to follow-up. [e]All patients with onset of action by week 6. Denominator excludes patients who discontinued or were lost to follow-up at week 6.

Summary and Conclusions

- **These real-world data show that, for up to 12 months after initiating treatment, a high proportion of previously biologic-naïve patients with UC had remission after receiving vedolizumab as a first-line biologic**
- **Importantly, the data indicate that the onset of action of vedolizumab is typically observed within 6 weeks for most patients; approximately 50% of patients with moderate or severe disease experienced improvement in symptoms within 2 weeks of vedolizumab initiation**

References

1. Anyanwu PA, et al. *Gastroenterology.* 2024;166(5):S1147-1148. 2. Shim HH, et al. *JGH Open.* 2018;2(5):223-234.

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