Predictors of Vedolizumab Treatment Persistence in Bio-Naïve Ulcerative Colitis Patients

Timothy E. Ritter, MD[1]; Harry E. Sarles, MD[2]; Samantha A. Mehta, PharmD[3]; Lucinda Van Anglen, PharmD[3]

[1]GI Alliance, Southlake, Texas; [2]Digestive Health Associates of Texas, Dallas, Texas;
[3]Healix Infusion Therapy, LLC, Sugar Land, Texas.

BACKGROUND

Vedolizumab (VDZ) is increasingly being utilised as first-line biologic therapy for the treatment of inflammatory bowel disease (IBD) in adults, particularly for ulcerative colitis (UC). Identifying a certain subset of bio-naïve UC patients most likely to benefit from VDZ and remain on long-term maintenance therapy is important. The purpose of this study is to evaluate predictors of VDZ treatment persistence at 12 months in real-world clinical practice.

METHODS

- Retrospective review of all adult (≥18 years) bio-naïve UC patients started on VDZ at two large multicentre gastroenterology private practices in the US
- Data collection included baseline demographics, disease duration, VDZ therapy, concomitant conventional agents, any prior IBD-related surgery, IBD-related healthcare resource utilisation (hospitalizations and/or emergency department visits) within 1 year of VDZ initiation, and disease activity scores using the partial Mayo score (pMayo)
  - Clinical response was assessed at 6 weeks and 14 weeks and defined as a pMayo reduction of ≥2 points
- Treatment persistence at 12 months was assessed; patients were divided into two cohorts, those persisting on VDZ at 12 months and those discontinuing VDZ prior to 12 months
- Logistic regression analysis was used to determine predictors associated with persistence

RESULTS

Table 1. Baseline Demographics

	Vedolizumab n=141
Age in years, mean ± SD	44 ± 14.5
Male gender, n (%)	82 (58%)
Charlson Comorbidity Index score ≥3, n (%)	21 (15%)
Disease duration in years, median (IQR)	5.5 (1.6 - 13.3)
Prior IBD-related surgery, n (%)	4 (3%)
IBD-related healthcare resource utilisation within 1 year, n (%)	29 (21%)
Elevated CRP at baseline, n (%)	53 (38%)
Elevated ESR at baseline, n (%)	33 (23%)
pMayo at baseline, median (IQR)	6 (5 - 7)

*Abbreviations: CRP, C-reactive protein; ESR, erythrocyte sedimentation rate*

Table 2. Concomitant Conventional Agents

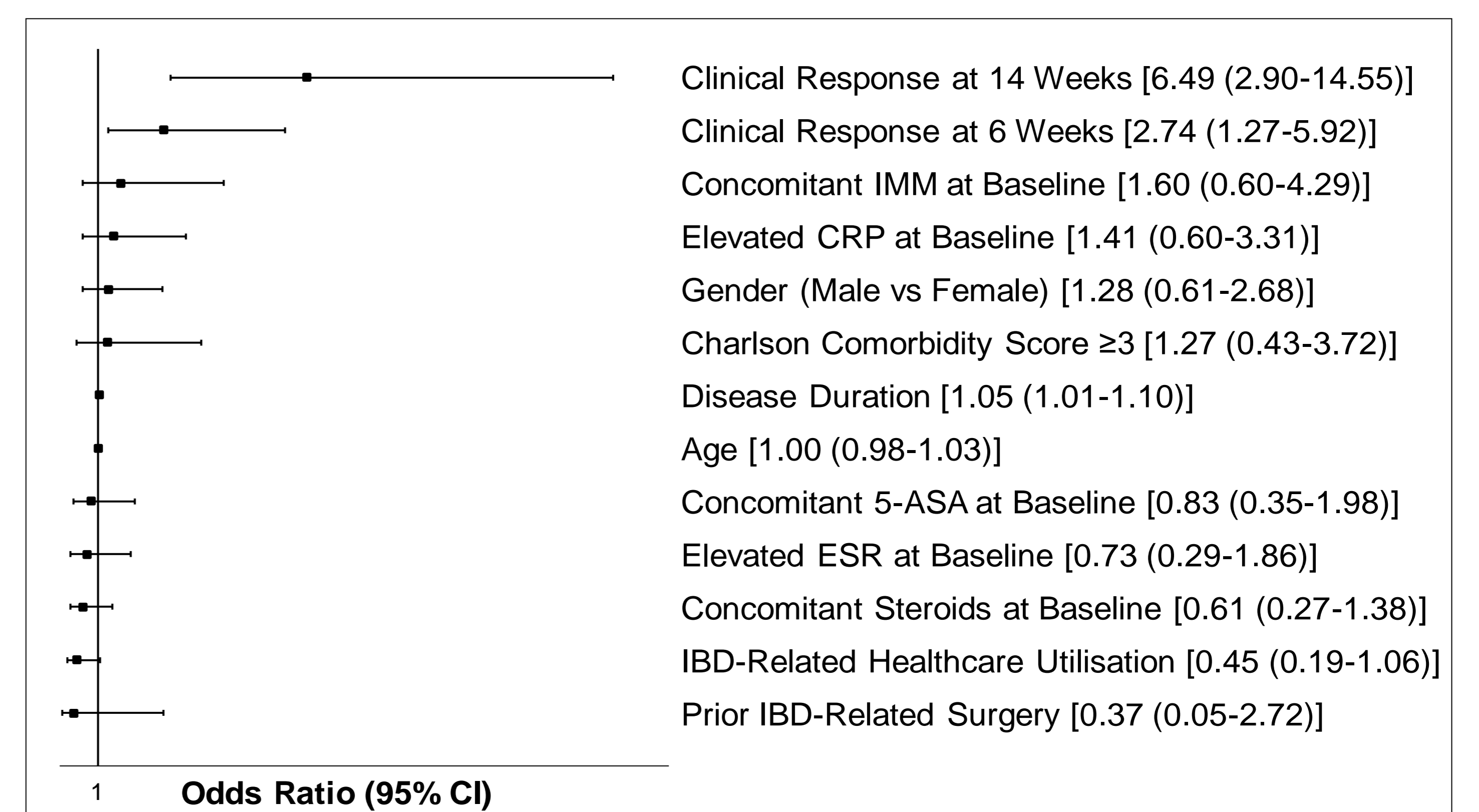|	Vedolizumab n=141
Concomitant conventional agents, n (%)	132 (94%)
Corticosteroids	94 (67%)
Immunomodulators (IMM)	29 (21%)
Aminosalicylates (5-ASA)	105 (74%)
Multiple conventional agents, n (%)	77 (55%)

RESULTS, CONTINUED

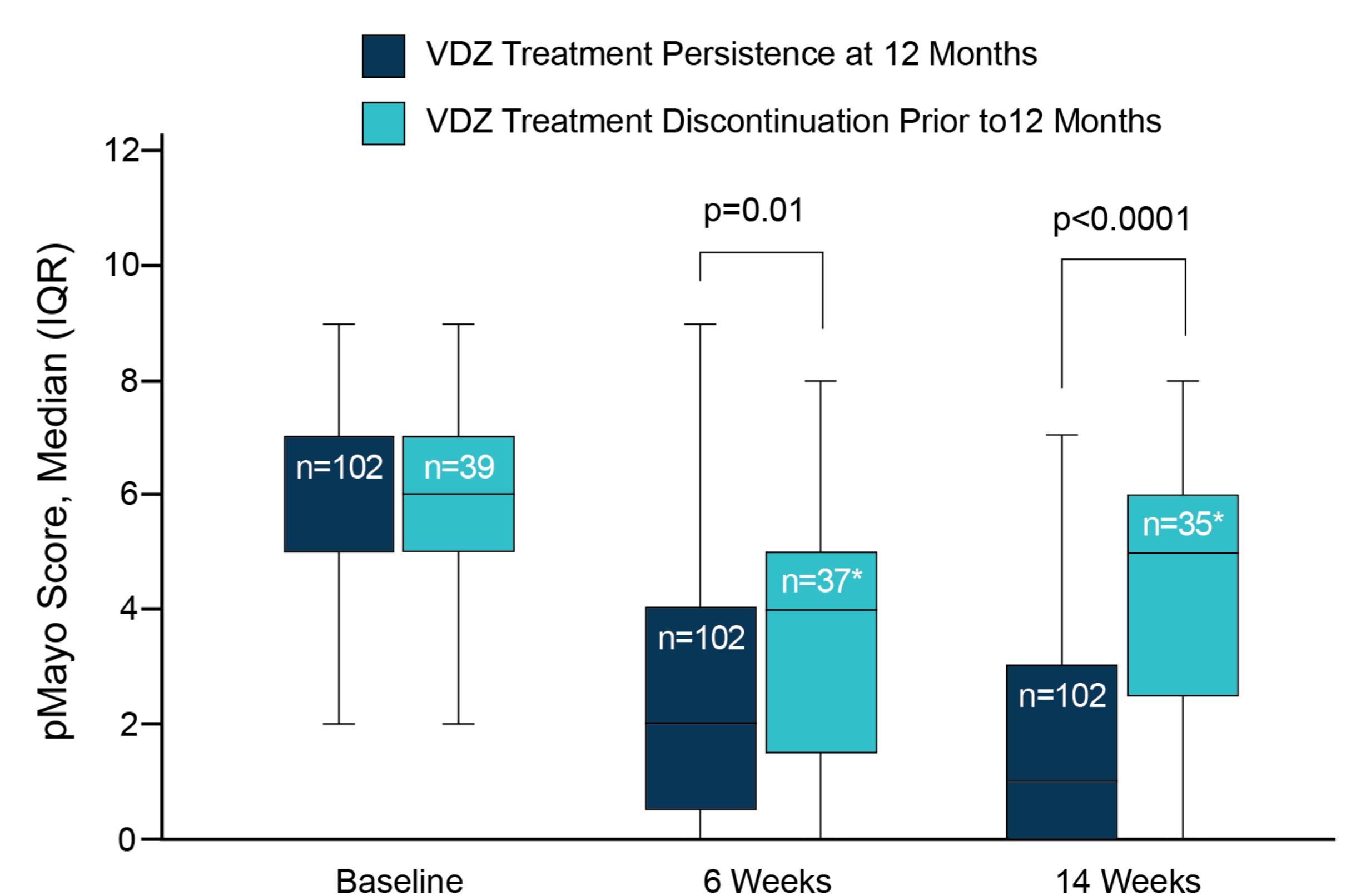**Figure 1.** VDZ Treatment Persistence at 12 Months

102/141 (72%)
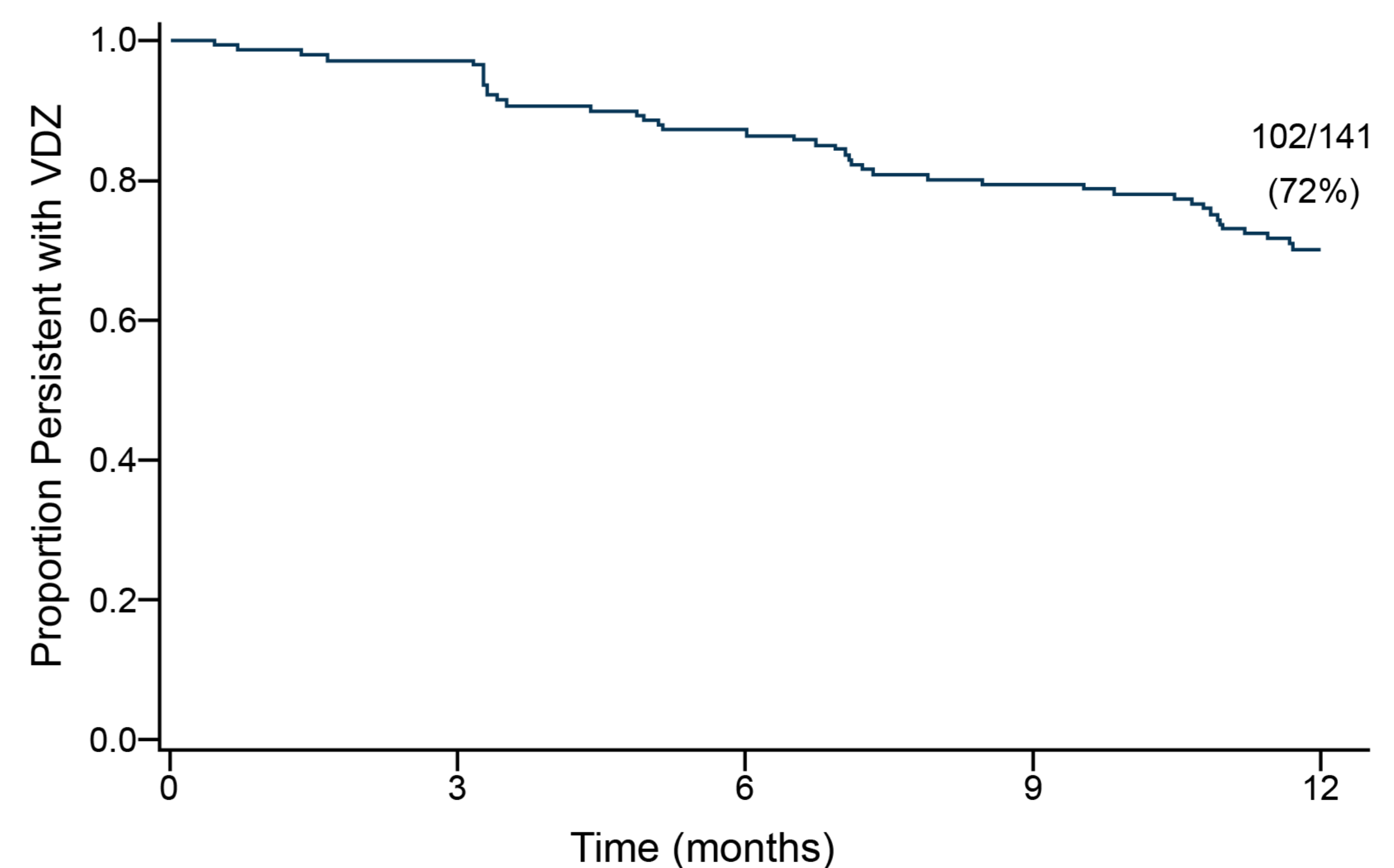
- VDZ treatment persistence at 12 months was observed in 102 (72%) patients
- Amongst 39 patients who discontinued VDZ prior to 12 months, reasons included lack or loss of response in 35 (90%), anti-drug antibodies in 3 (8%), and intolerance in 1 (3%)

Figure 2. Predictors of VDZ Treatment Persistence at 12 Months

Clinical Response at 14 Weeks [6.49 (2.90-14.55)]
Clinical Response at 6 Weeks [2.74 (1.27-5.92)]
Concomitant IMM at Baseline [1.60 (0.60-4.29)]
Elevated CRP at Baseline [1.41 (0.60-3.31)]
Gender (Male vs Female) [1.28 (0.61-2.68)]
Charlson Comorbidity Score ≥3 [1.27 (0.43-3.72)]
Disease Duration [1.05 (1.01-1.10)]
Age [1.00 (0.98-1.03)]
Concomitant 5-ASA at Baseline [0.83 (0.35-1.98)]
Elevated ESR at Baseline [0.73 (0.29-1.86)]
Concomitant Steroids at Baseline [0.61 (0.27-1.38)]
IBD-Related Healthcare Utilisation [0.45 (0.19-1.06)]
Prior IBD-Related Surgery [0.37 (0.05-2.72)]

Odds Ratio (95% CI)

- The only factors associated with VDZ treatment persistence at 12 months were clinical response at 6 and 14 weeks

Figure 3. Disease Activity Scores Based on Treatment Persistence at 12 Months

VDZ Treatment Persistence at 12 Months
VDZ Treatment Discontinuation Prior to 12 Months

p=0.01   p<0.0001

n=102 n=39
n=102 n=37*
n=102 n=35*

Baseline   6 Weeks   14 Weeks

*Disease activity scores not included for patients with VDZ discontinuations <6 weeks (n=2) and <14 weeks (n=4)

- Patients who remained on VDZ at 12 months had significantly lower disease activity scores at 6 and 14 weeks than those who discontinued VDZ prior to 12 months

CONCLUSIONS

Treatment persistence at 12 months occurred in 72% of bio-naïve ulcerative colitis patients treated with vedolizumab in a real-world clinical practice setting. The only factors associated with vedolizumab treatment persistence at 12 months were clinical response at 6 and 14 weeks. Response to induction may be used to predict those who will remain on maintenance therapy for greater than 12 months.