Response and Healthcare Resource Utilization in Inflammatory Bowel Disease Patients Treated with Either Infliximab or Vedolizumab

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Background

Inflammatory bowel disease is associated with significant utilization of healthcare resources over time.[1-5] Both infliximab (IFX) and vedolizumab (VDZ) are FDA-approved for treatment of inflammatory bowel disease (IBD). Much of the published data on clinical outcomes for either IFX or VDZ compare the biologic agent against conventional oral agents rather than alternative biologics, making comparisons of efficacy and safety difficult. Additionally, the impact of specific drug therapy, either conventional or biologic, on overall use of healthcare resources in IBD patients is needed.

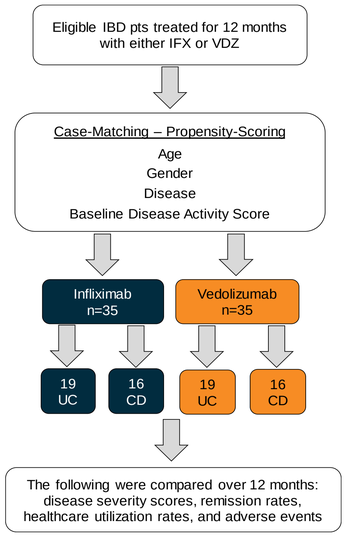
The aim of this study was to assess comparative clinical response and healthcare resource utilization (HRU) in case-matched IBD patients treated with either IFX or VDZ for 12 months.

Methods

We performed a retrospective review of Crohn's disease (CD) and ulcerative colitis (UC) patients who initiated treatment with either IFX or VDZ at a large multicenter, gastroenterology private practice from 2016-2018. Those who persisted on therapy for 12 months were identified. Patients were case-matched 1:1 based on age, gender, diagnosis, and baseline disease severity scores.

- Disease activity was assessed using the partial Mayo (pMayo) for UC patients and the Harvey-Bradshaw Index (mHBI) for CD patients at the following time points: baseline, 3 months, 6 months, and 12 months
- Primary endpoints were changes in disease activity scores at 3, 6, and 12 months compared to baseline, clinical remission rates, and healthcare resource utilization (HRU)
  - Clinical remission was defined by pMayo <2 or mHBI <5
  - HRU was defined as emergency department (ED) visits, and hospitalizations during the 12 months of treatment
- Additionally, adverse drug reactions (ADR), including infections, during the study period were reported
- Descriptive data were reported as frequencies and proportions for categorical variables, and as mean ± standard deviation (SD) or median (interquartile range, IQR) for continuous variables

Study Cohort



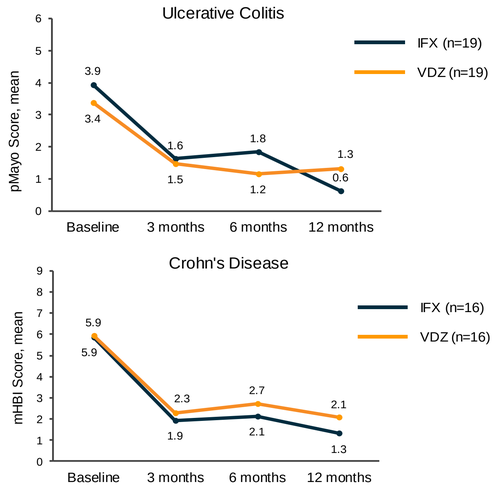
Results

Baseline Demographics

	Infliximab Cohort UC n=19	Infliximab Cohort CD n=16	Vedolizumab Cohort UC n=19	Vedolizumab Cohort CD n=16
Age (yrs), mean±SD	36±21.2	40±18.5	40±13.7	39±16.8
Male gender, n(%)	12 (63%)	7 (44%)	12 (63%)	7 (44%)
Disease duration (yrs), median (IQR)	2 (0.7-9.0)	2 (0.4-11.4)	7 (2.4-15.1)	6 (2.7-13.2)
Bio-naïve, n(%)	15 (79%)	6 (38%)	6 (32%)	4 (25%)
Steriod dependent, n(%)	7 (37%)	1 (6%)	3 (16%)	4 (25%)

Disease Activity Scores

Infliximab vs. Vedolizumab: Disease Activity Scores



- In both UC and CD patients, IFX and VDZ showed comparable reduction in mean disease severity scores within the initial 3 months of therapy
- This reduction persisted over the 12 months of study follow-up

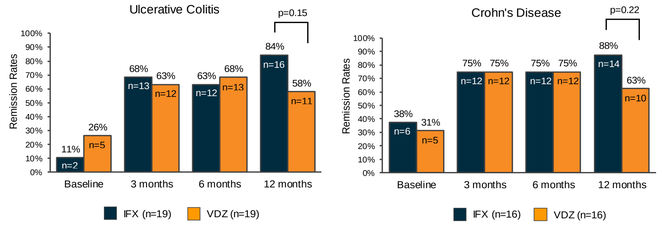
Infliximab vs. Vedolizumab: Disease Activity Score Categories

Disease		Number of Patients Baseline	3 Mo	6 Mo	12 Mo
CD*	**Infliximab**				
	Remission	6	12	12	14
	Mild	6	3	4	2
	Moderate	4	1	0	0
	Vedolizumab				
	Remission	5	12	12	10
	Mild	8	3	3	6
	Moderate	3	1	1	0
UC	**Infliximab**				
	Remission	2	13	12	16
	Mild	10	2	3	3
	Moderate	5	4	3	0
	Severe	2	0	1	0
	Vedolizumab				
	Remission	5	12	13	11
	Mild	9	5	5	6
	Moderate	4	2	1	2
	Severe	1	0	0	0

* No CD patients had severe disease at baseline through 12 months of biologic therapy

- The majority of patients progressed to remission or mild disease activity score categories over the course of 12 months of biologic therapy

Remission Rates

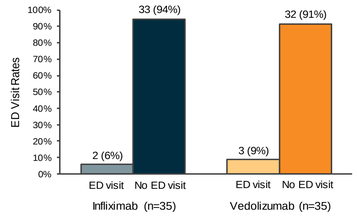


- There was no significant difference between remission rates for IFX and VDZ at 12 months of biologic therapy

Healthcare Resource Utilization

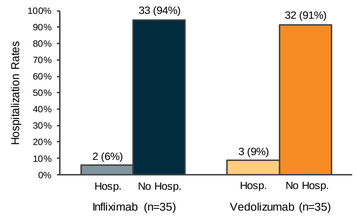
- Overall rates of ED visits and hospitalizations were low across the cohort. Two (6%) IFX patients and 3 (9%) VDZ patients accounted for all healthcare resource utilization.

ED Visits



- There were a total of 9 ED in 5 patients; 100% were IBD-related, all for acute exacerbations
- 1 patient in each cohort had 3 ED visits each

Hospitalizations



- There were a total of 5 hospitalizations in 5 patients; of these, 60% were IBD-related
- One IBD-related hospitalization resulted in hemicolectomy (VDZ-CD patient)
- No patients had multiple hospitalizations

Adverse Events

	Infliximab Cohort UC n=19	Infliximab Cohort CD n=16	Vedolizumab Cohort UC n=19	Vedolizumab Cohort CD n=16
Infections				
Upper respiratory	4	2	3	1
Otitis media	1	1	-	-
Other infections*	-	-	2	2
Other				
Infusion Reaction†	4	1	2	6
Arthralgia	-	3	3	-

*Other infections included abdominal abscess (n=1), C. difficile (n=1), herpes (n=1) and skin & soft tissue infection (n=1)

†Infusion reactions included headache (n=3), blurred vision (n=3), itching (n=3), fever (n=3), and chest tightness (n=1)

- A total of 16 adverse events occurred in 14 (40%) IFX patients and 19 adverse events occurred in 8 (23%) VDZ patients

Discussion

- We performed a case-matched cohort study based on propensity scores comparing long-term (12-month) treatment of IBD with either IFX or VDZ.
- In both UC and CD patients, IFX and VDZ therapy produced similar reductions in disease activity and remission rates at 12 months of biologic therapy.
- Healthcare resource utilization was low and, again, we observed no differences between IFX and VDZ-treated patients.
  - 5 patients (2 IFX-UC, 3 VDZ-CD) went to the ED a total of 9 times, all for IBD-related issues.
  - These same 5 patients represented the only hospitalizations.
- Adverse events were similar in both groups.
  - Overall adverse events occurred in 14 IFX patients, compared to 8 VDZ patients.
  - Infections were the leading cause of adverse events, which accounted for 8 in each group.
- While the study cohort may be biased to those patients who were maintained on treatment with IFX or VDZ for at least 12 months, our comparison of IFX to VDZ indicated no differences in terms of disease activity, remission rates, associated healthcare resource utilization, and adverse events.

Conclusions

- The data demonstrate similarity with use of infliximab or vedolizumab over a 12-month period in treatment of both CD and UC.
- Although the number of case-matched patients in this study is small and the population is limited to responders, overall healthcare resource utilization was noticeably low in this cohort.
- Further study is warranted to provide real-world use comparing infliximab and vedolizumab in the management of IBD patients.

References

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