Poster D0382

Comparison of Surgery Rates in Biologic-Naïve Patients with Crohn's Disease Who Were Treated with Vedolizumab or Ustekinumab: Findings from SOJOURN

Michelle Vu,[1] Sabyasachi Ghosh,[2*] Kandavadivu Umashankar,[2*] Benjamin Chastek,[1] Ninfa Candela,[2] Laura Weber,[1] Christina Landis[1]

[1]Optum, Eden Prairie, MN, USA; [2]Takeda Pharmaceuticals U.S.A., Inc., Lexington, MA, USA

*These authors were affiliated with Takeda Pharmaceuticals U.S.A., Inc. at the time of the study

Background

- Crohn's disease (CD) is a chronic inflammatory bowel disease characterized by skip lesions and transmural inflammation that can affect any region of the gastrointestinal tract[1,2]
- Patients with CD who have an inadequate response or nonadherence to medical treatments and those who develop disease complications, including strictures and fistulas, may require surgery[3]
- Surgery rates among patients with CD have declined in recent years, owing in part to advances in medical treatment;[4,5] however, the cumulative risk of first major abdominal surgery (intestinal resection) within 10 years of diagnosis remains as high as 26.2%[6]
- Most data on surgery rates are from patients receiving an anti-tumor necrosis factor α treatment,[7-10] with little known about the impact of vedolizumab or ustekinumab on CD-related surgery

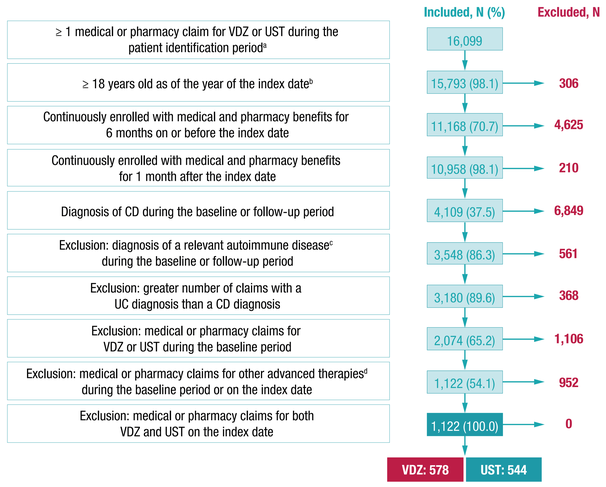
Aim

- The aim of the SOJOURN (Surgery rate cOmparison between treatment JOURNey with ustekinumab and vedolizumab in biologic-naïve CD patients) study was to compare the hazard rate and incidence of first CD-related surgery following initiation of treatment with vedolizumab and ustekinumab in biologic-naïve patients with CD

Methods

- SOJOURN was a retrospective, observational cohort study conducted using de-identified medical and pharmacy claims data from the Optum® Research Database
- Adult patients with at least one medical or pharmacy claim for vedolizumab or ustekinumab during the patient identification period (January 1, 2018, to December 31, 2019) and who met the selection criteria were included in the analysis (**Figure 1**)

Figure 1. Patient selection criteria



CD, Crohn's disease; UC, ulcerative colitis; UST, ustekinumab; VDZ, vedolizumab.
[a]January 1, 2018, to December 31, 2019. [b]The index date was defined as the first medical or pharmacy claim for VDZ or UST during the patient identification period. [c]Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, hidradenitis suppurativa, or noninfectious uveitis. [d]Other advanced therapies approved for the treatment of CD or UC.

- The index date was defined as the date of the first medical or pharmacy claim for vedolizumab or ustekinumab during the patient identification period
- The variable follow-up period started on the day after the index date and ended on whichever occurred first of discontinuation, switching, initiation of combination biologic treatment, disenrollment, surgery event, or the end of the study period
- The primary endpoint of the study was CD-related surgery
  - Kaplan–Meier analysis was used to estimate the time to first CD-related surgery on biologic treatment and a log-rank test was used to determine whether the distributions for the treatment groups were different
  - The hazard ratios and incidence rate ratios of CD-related surgery were compared between the vedolizumab and ustekinumab cohorts, after controlling for covariates, using a Cox proportional hazards model and a Poisson regression model, respectively

Table 1. Baseline characteristics of patients with CD

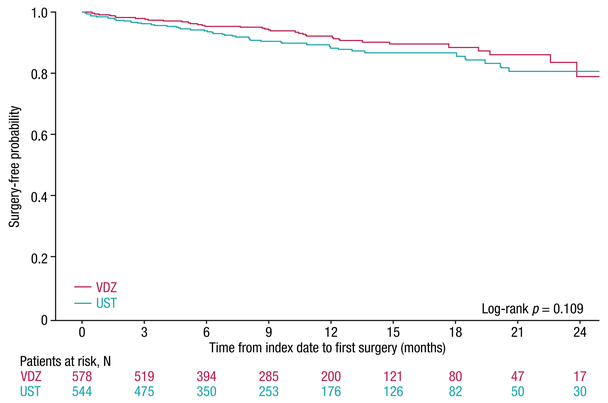
	Total N = 1,122	Vedolizumab N = 578	Ustekinumab N = 544	*p* value
Demographics				
Age, years				
Mean (SD)	47.8 (16.7)	49.8 (17.7)	45.8 (15.3)	< 0.001
Sex, N (%)				0.971
Male	508 (45.3)	262 (45.3)	246 (45.2)	
Female	614 (54.7)	316 (54.7)	298 (54.8)	
Race/ethnicity, N (%)				0.702
White	881 (78.5)	449 (77.7)	432 (79.4)	0.481
African American/Black	91 (8.1)	49 (8.5)	42 (7.7)	0.643
Hispanic	67 (6.0)	35 (6.1)	32 (5.9)	0.903
Asian	27 (2.4)	17 (2.9)	10 (1.8)	0.228
Unknown/uncoded	22 (2.0)	9 (1.6)	13 (2.4)	0.315
No socioeconomic status information	34 (3.0)	19 (3.3)	15 (2.8)	0.605
Insurance type, N (%)				< 0.001
Commercial	832 (74.2)	393 (68.0)	439 (80.7)	
Medicare	290 (25.8)	185 (32.0)	105 (19.3)	
Clinical characteristics				
Baseline CCI score				
Mean (SD)	0.65 (1.3)	0.76 (1.4)	0.53 (1.2)	0.004
Median (Q1–Q3)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	
CD-related hospitalization, N (%)	233 (20.8)	128 (22.1)	105 (19.3)	0.241
CD-related surgery, N (%)	93 (8.3)	39 (6.7)	54 (9.9)	0.054
Disease characteristics, N (%)				
Perianal/severe rectal disease	77 (6.9)	31 (5.4)	46 (8.5)	0.041
Abscess	85 (7.6)	40 (6.9)	45 (8.3)	0.392
Fistula/fistulizing disease	182 (16.2)	74 (12.8)	108 (19.9)	0.001
Stricture/stricturing disease	3 (0.3)	1 (0.2)	2 (0.4)	0.528
Anemia, N (%)	214 (19.1)	102 (17.6)	112 (20.6)	0.210
Use of corticosteroids, N (%)				
0–14 days	562 (50.1)	275 (47.6)	287 (52.8)	0.083
15–30 days	121 (10.8)	61 (10.6)	60 (11.0)	0.797
31–60 days	183 (16.3)	105 (18.2)	78 (14.3)	0.083
≥ 61 days	256 (22.8)	137 (23.7)	119 (21.9)	0.466

CCI, Charlson Comorbidity Index; CD, Crohn's disease; Q, quartile; SD, standard deviation.

Results

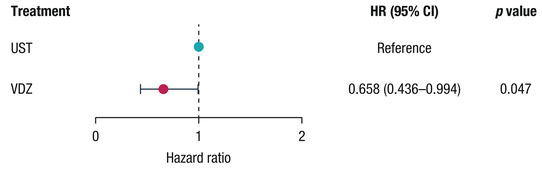
- After applying the eligibility criteria, 1,122 biologic-naïve patients with CD were identified, of whom 578 and 544 were treated with vedolizumab and ustekinumab, respectively (**Figure 1**)
- Patients in the vedolizumab group were on average older and had a greater mean Charlson Comorbidity Index score than patients who received ustekinumab. A greater proportion of patients in the vedolizumab group were insured by Medicare than those in the ustekinumab group (**Table 1**)
- The unadjusted incidence of CD-related surgery was lower for vedolizumab (0.0069 surgeries per patient-month) than ustekinumab (0.0093 surgeries per patient-month); however, this difference was not statistically significant (rate ratio, 0.743; $p = 0.150$)
- There was no statistically significant difference between the time to first CD-related surgery survival curves for vedolizumab and ustekinumab 2 years after the index date (log-rank $p = 0.109$; **Figure 2**)
- After adjusting for covariates, vedolizumab was associated with a 34.2% lower hazard rate of CD-related surgery than ustekinumab ($p = 0.047$; **Figure 3**)
- The CD-related surgery rate was 34.5% lower among patients who received vedolizumab than those who received ustekinumab after adjusting for covariates ($p = 0.044$; **Figure 4**)

Figure 2. Kaplan–Meier curve for time to first CD-related surgery on biologic treatment



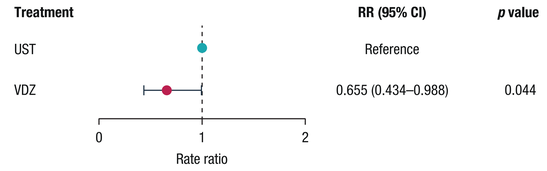
CD, Crohn's disease; UST, ustekinumab; VDZ, vedolizumab.

Figure 3. Adjusted hazard ratios for CD-related surgery



Cox proportional hazards model adjusted for sex, age, insurance type, race/ethnicity, CCI score, CD-related hospitalization, and presence of abscess, anemia, and corticosteroid use at baseline.
CCI, Charlson Comorbidity Index; CD, Crohn's disease; CI, confidence interval; HR, hazard ratio; UST, ustekinumab; VDZ, vedolizumab.

Figure 4. Adjusted rate ratios for CD-related surgery



Poisson regression model adjusted for sex, age, insurance type, race/ethnicity, CCI score, CD-related hospitalization, and presence of abscess, anemia, and corticosteroid use at baseline.
CCI, Charlson Comorbidity Index; CD, Crohn's disease; CI, confidence interval; RR, rate ratio; UST, ustekinumab; VDZ, vedolizumab.

Summary and Conclusions

- **The results of this real-world study suggest that vedolizumab is associated with a lower rate of CD-related surgery than ustekinumab**
- **These findings provide insight into the comparative outcomes of vedolizumab and ustekinumab as first-line biologics for CD and may help to inform clinicians' choice and positioning of biologics**

References

1. Veauthier B, et al. *Am Fam Physician.* 2018;98:661-669.
2. Feuerstein JD, et al. *Mayo Clin Proc.* 2017;92:1088-1103.
3. Lightner AL, et al. *Dis Colon Rectum.* 2020;63:1028-1052.
4. Ma C, et al. *Am J Gastroenterol.* 2017;112:1840.
5. Frolkis AD, et al. *Gastroenterology.* 2013;145:996-1006.
6. Tsai L, et al. *Clin Gastroenterol Hepatol.* 2021;19:2031-2045.e11.
7. Lichtenstein GR, et al. *Am J Gastroenterol.* 2004;99:91-96.
8. Lichtenstein GR, et al. *Gastroenterology.* 2005;128:862-869.
9. Murthy SK, et al. *Gut.* 2020;69:274-282.
10. Guasch M, et al. *J Crohns Colitis.* 2018;12:S301-S302.

Acknowledgments

This study was sponsored by Takeda Pharmaceuticals U.S.A., Inc. Medical writing support was provided by Cerys Evans PhD of PharmaGenesis Cardiff, Cardiff, UK, and funded by Takeda Pharmaceuticals U.S.A., Inc.

Disclosures

Michelle Vu: employee and stockholder of Optum. Benjamin Chastek, Laura Weber, and Christina Landis: employees of Optum. Sabyasachi Ghosh: former employee of Takeda Pharmaceuticals U.S.A., Inc. and holds stock or stock options. Kandavadivu Umashankar: former employee of University of Illinois, Chicago, IL, USA, supported by a Takeda Pharmaceuticals U.S.A., Inc. fellowship at the time of the study. Ninfa Candela: employee of Takeda Pharmaceuticals U.S.A., Inc. and holds stock or stock options.

Presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting, October 21–26, 2022, Charlotte Convention Center, Charlotte, NC, USA and Virtual