European Crohn's and Colitis Organisation

Treatment discontinuation, flares and hospitalisations among biologic-naïve patients with IBD over the first year of treatment: A comparative effectiveness study of vedolizumab versus infliximab

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Disclosures

- **M. Raluy-Callado —** Full-time employee of Evidera, commissioned by Takeda
- **A. Berger —** Full-time employee of Evidera, commissioned by Takeda
- **J. Khalid —** Employee of Takeda International - UK Branch
- **H. Patel —** Employee of Immensity Consulting, Inc., which received funding from Takeda Development Centre Europe Ltd.

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Background and Objective

- Ulcerative colitis (UC) and Crohn's disease (CD) are chronic inflammatory bowel diseases (IBD) characterised by symptoms such as abdominal pain, diarrhoea, gastrointestinal bleeding, and malnutrition
- Both vedolizumab (VDZ), a gut-selective humanised immunoglobulin G1 monoclonal antibody that binds to $\alpha_4\beta_7$ integrin and infliximab (IFX), a IgG1k monoclonal antibody targeting TNFα, are approved for the treatment of adult patients with moderately to severely active UC and CD
- Although the efficacy and safety of both therapies have been well established in clinical trials, there is a lack of long-term, real-world comparative effectiveness data among biologic-naïve patients with IBD who initiate these biologic therapies

OBJECTIVE: To evaluate real-world comparative effectiveness of VDZ versus IFX as a first-line biological therapy for patients with moderate to severe UC or CD

TNFα, tumor necrosis factor alpha.

Methods and Analyses

- A retrospective, observational study was conducted among biologic-naïve patients with IBD who initiated VDZ or IFX between May 2014 and April 2017 from the Explorys Universe database
  - Contains data for 50 million US patients, 16% of the population
- Patients included were
  - Aged ≥18 years
  - With ≥12 months of medical history after therapy initiation
  - Who successfully moved to maintenance therapy (≥3 infusions ≤98 days from therapy initiation and a 4th infusion ≤90 days after the 3rd infusion)
- VDZ initiators were propensity-score (PS) matched to IFX initiators using a caliper width of 0.2 standard deviation of PS[a]
- Study outcomes: Tx discontinuation, all-cause hospitalisation, IBD-related surgery, and use of intravenous CS (flares)
- Kaplan-Meier analysis was used to calculate time to event and incidence rates (per patient-year) with 95% CIs

[a] PS matching variables included age, gender, disease type, prior healthcare utilisation, surgeries, and use of non-biologic therapies.
CD, Crohn's disease; IBD, inflammatory bowel disease; IFX, infliximab; UC, ulcerative colitis; VDZ, vedolizumab; CI, confidence interval.

Demographic and clinical characteristics of PS matched bio-naïve cohorts

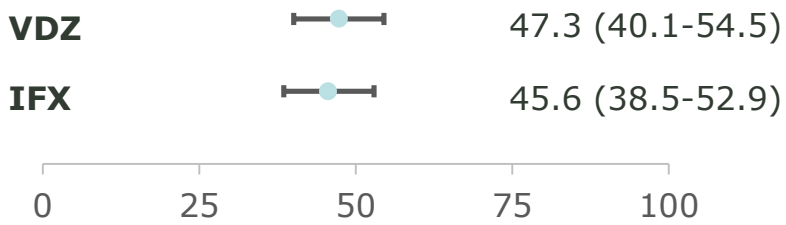
	VDZ n=182	IFX n=182
IBD diagnosis, n (%)	UC = 67 (37) CD = 115 (63)	UC = 76 (42) CD = 106 (58)
Age, mean years (SD)	48.0 (16.0)	50.0 (17.2)
Female sex, %	51.6	53.3
Caucasian, %	90.1	83.5
Median disease duration, y[a] (IQR)	2.7 (1.0–6.6)	2.4 (0.7–6.0)
Prior IBD-related surgery, %[b]	15.4	17.0
Pre-index[c] CS therapy, %	69.2	76.9
Pre-index[c] IM therapy, %	20.9	36.3

[a] (UC or CD) to index date (IQR).
[b] (any time up to index).
[c] "pre-index", defined as the 12-month period immediately preceding index date.
CD, Crohn's disease; CS, corticosteroid; IM, immunosuppressant; IBD, inflammatory bowel disease; IQR, interquartile ratio; PS, propensity-score; SD, standard deviation; UC, ulcerative colitis.

Similar outcomes were observed between VDZ and IFX PS matched bio-naïve cohorts

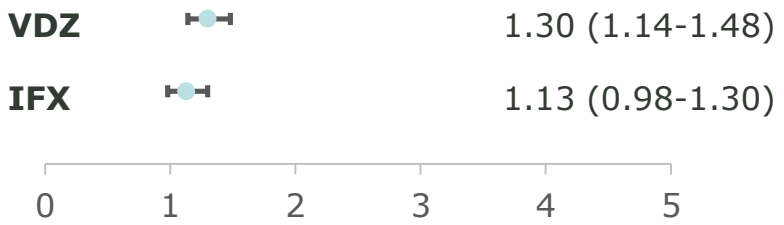
Incident-rates (with 95% CI) and median time to event[a]

Tx discontinuation



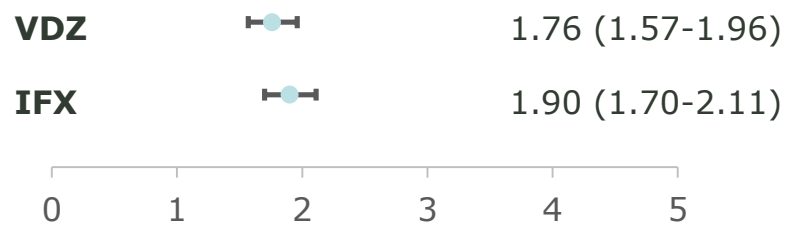
Median (IQR)[a] time to event with VDZ vs IFX:
240 (188-300) vs **244** (207-292)

Use of intravenous steroids (flares)



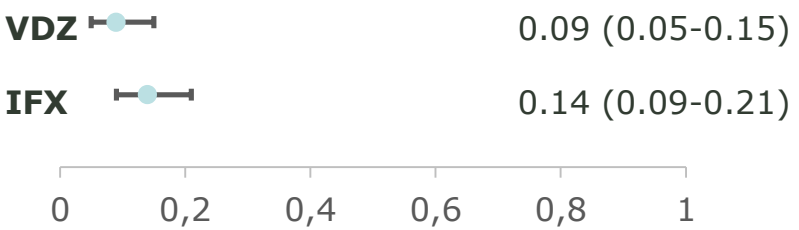
Median (IQR)[a] time to event with VDZ vs IFX:
78 (21-226) vs **88** (35-193)

All-cause hospitalisations



Median (IQR)[a] time to event (VDZ vs IFX):
42 (14-167) vs **54** (18-154)

IBD-related surgery



Median (IQR)[a] time to event (VDZ vs IFX):
250 (177-327) vs **201** (169-232)

[a] Median times were calculated among patients with an event.
[b] Flare defined as the use of intravenous steroids.
IBD, inflammatory bowel disease; IFX, infliximab; IQR, interquartile range; PS, propensity-score; VDZ, vedolizumab.

Conclusions

- Rates of investigated outcomes over the 1-year period following initiation of VDZ therapy were similar to those of patients who began IFX
- Possible trend, although not statistically significant, towards lower incidence of all-cause hospitalisations and surgeries with VDZ therapy. The trend with VDZ was not observed for discontinuation and use of IV steroids (flares)
- A limitation of the study was lack of availability of clinical variables (i.e., disease severity) to control for possible channelling bias
- Future studies should examine a larger cohort of VDZ patients with a longer follow-up period