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Long term real-world effectiveness and safety of upadacitinib in patients with moderate to severe Crohn's disease: A Belgian multi-centric refractory cohort

A. Pavlidi[1], B. Verstockt[2], S. Vieujean[3], V. Desmedt[4], F. Couturier[5], J.F. Rahier[6], F. Baert[7], M. Somers[8], O. Dewit[9], P. Bossuyt[10], A. Hoyois[11], T. Holvoet[12], R. Ouziel[13], B. Willandt[14], G. Lambrecht[15], M. Salame[16], A. Verreth[17], M. Lenfant[2], D. Franchimont[1], A. Cremer[1]
[1]Erasme University Hospital, Department of Gastroenterology, Brussels, Belgium [2]University Hospital Leuven, Department of Gastroenterology, Leuven, Belgium [3]University Hospital CHU of Liège, Department of Gastroenterology, Liège, Belgium [4]University Hospital Gent, Department of Gastroenterology, Gent, Belgium [5]GZA Hospital, Department of Gastroenterology, Antwerp, Belgium [6]CHU UCL Namur site Mont-Godinne, Department of Gastroenterology, Yvoir, Belgium [7]AZ Delta, Department of Gastroenterology, Roeselare, Belgium [8]University Hospital Antwerp, Department of Gastroenterology, Antwerp, Belgium [9]Cliniques Universitaires Saint-Luc, Department of Gastroenterology, Brussels, Belgium [10]Imelda General Hospital, Department of Gastroenterology, Bonheiden, Belgium [11]CHU Saint-Pierre, Department of Gastroenterology, Brussels, Belgium [12]VITAZ Hospital, Department of Gastroenterology, Sint-Niklaas, Belgium [13]CHU Marie Curie, Department of Gastroenterology, Charleroi, Belgium [14]AZ St. Jan Brugge, Department of Gastroenterology, Brugge, Belgium [15]AZ Oostende, Department of Gastroenterology, Oostende, Belgium [16]Centre Hospitalier Régional Haute Senne, Department of Gastroenterology, Soignies, Belgium [17]AZ Voorkempen, Department of Gastroenterology, Malle, Belgium

Background: The therapeutic options for Inflammatory Bowel Disease (IBD) have expanded with the introduction of JAK inhibitors. However, real-world data on upadacitinib (UPA) in patients with moderate to severe Crohn's disease (CD) are scarce. Our aim was to assess the long-term effectiveness and safety of UPA in multi-refractory Belgian patients.

Methods: Data from all patients with active CD initiating UPA between September 2022 and January 2024 were retrospectively collected from 17 Belgian centres. Effectiveness endpoints were evaluated at week 24 and 52. Steroid-free clinical response and remission were defined using the two-component patient-reported outcome. Endoscopic response was defined as a decrease in baseline Simple Endoscopic Score (SES-CD) with ≥50%, and endoscopic remission as SES- CD ≤ 4 or absence of ulcers. Adverse events (AE), treatment discontinuation, CD-related hospitalization and surgery were assessed throughout follow-up. Non-response imputation was applied for clinical evaluation.

Results: A total of 140 patients were included (Table 1) with a median follow-up of 33 weeks (IQR: 3-97). The majority of patients (89%) were exposed to at least 3 biologics. At week 24, 53% and 40% of patients achieved steroid-free clinical response and remission, respectively (Figure 1). At week 52, these numbers were 37% and 29%. Endoscopic data were available in 48/140 patients at week 24, of whom 52% and 27% reached endoscopic response and remission. At week 52, these numbers were 63% and 37%. Of patients with active articular extra-intestinal manifestations at baseline 37% and 34% had a quiescent articular disease by week 24 and 52, respectively. 5 out of 9 patients with active perianal disease at baseline and on UPA by week 52, had persistent perianal active disease. Overall, 66 patients (47%) discontinued UPA during follow-up: 23 due to primary non response, 13 due to secondary loss of response, 16 due to AE, 3 due to patient's choice and 11 due to CD-related surgery. 16 patients required CD-related hospitalization within 52 weeks. AE occurred in 60% of patients (84/140). Of these patients, 11% experienced serious AE of which 2 cardiovascular events: 1 transit ischemic attack and 1 deep venous thrombosis. The most common reported AE were herpes simplex reactivation (5/140), respiratory tract infection (7/140), cutaneous reactions (7/140) and acne (17/140). Only 3 patients had reactivation of herpes zoster infection.

Conclusion: In this real-world cohort of highly refractory CD patients, UPA effectively induced both steroid-free clinical remission and endoscopic remission by week 52. UPA was relatively well tolerated with respect to adverse events.

Figure(s)/Table(s): see next page

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Table 1: Baseline characteristics of all included patients	
All patients= 140	
Sex, female, n (%)	80 (57%)
Age at initiation of UPA, years, median [IQR]	40 [14-70]
Disease duration, years, median [IQR]	13 [0-45]
Smoking status, n (%)	
Never	70 (50%)
Current	31 (22%)
Previous	25 (18%)
Unknown	14 (10%)
Age at diagnosis, n (%)	
≤16 years (A1)	28 (20%)
17-40 (A2)	89 (64%)
>40 years (A3)	23 (16%)
Disease location, n (%)	
Ileal (L1)	32 (23%)
Colon (L2)	25 (18%)
Ileocolonic (L3)	83 (59%)
Upper gastrointestinal involvement (L4)	22 (16%)
Disease behaviour, n (%)	
Non-stricturing, non-penetrating (B1)	73 (52%)
Stricturing (B2)	45 (32%)
Penetrating (B3)	21 (15%)
Perianal disease (p), n (%)	53 (38%)
Prior exposition to ≥3 biologics, n (%)	125 (89%)
Prior CD-related surgery, n (%)	82 (59%)

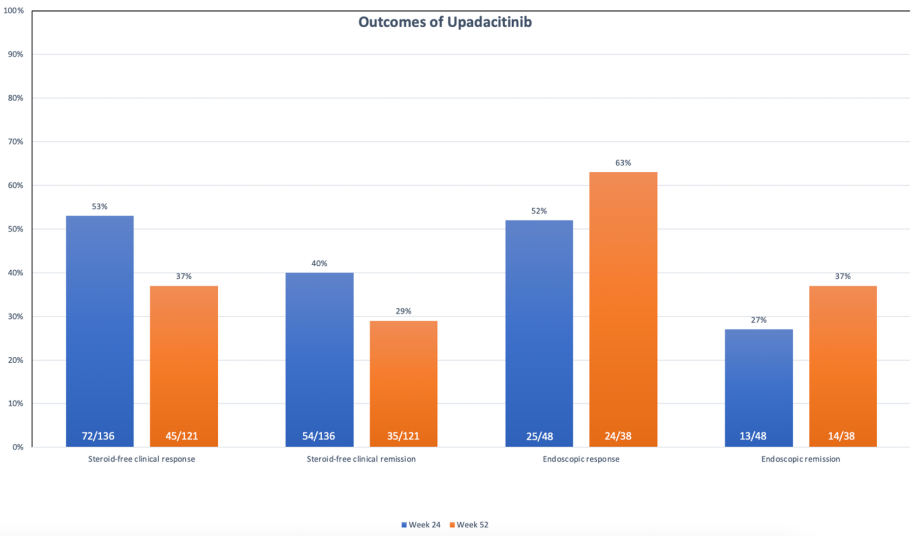

Figure 1: **Evaluation of effectiveness outcomes of Upadacitinib at week 24 and 52.** *Definitions: -Clinical remission: average daily Stool Frequency score (SF) ≤ 2.8 AND average daily Abdominal Pain Score (APS) ≤ 1 AND both not worse than baseline. -Clinical response: ≥ 30% decrease in average daily SF and/or ≥ 30% decrease in average daily AP score and both not worse than baseline. -Endoscopic remission: Simple Endoscopic Score (SES- CD) ≤ 4 or absence of ulcers. -Endoscopic response: ≥ 50% decrease in SES-CD compared to baseline.*

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