Efficacy and safety of ustekinumab in patients with moderate to severe Crohn’s disease: a real world study in Brazil

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BACKGROUND & AIMS

- Ustekinumab (UST): fully human monoclonal antibody against IL-12/23 associated with clinical response and maintained a higher rate of response than placebo in Crohn’s disease (CD). UST was approved in Brazil in November 2017.
- Real world data regarding efficacy and safety to UST in CD is lacking in Brazil.
- We report our experience of UST use in patients with moderate to severe CD.

METHODS

- An open-label prospective not controlled study, eleven academic medical centers
- Clinical response (HBI decrease ≥ 3); clinical remission (HBI ≤ 3) (baseline to week 56).
- C-reactive protein (CRP) from baseline and at week 48
- Ethical approval: 3.335.068/2019. Statistical analysis: Data presented “As observed”.

RESULTS

Characteristics (baseline)  N=161
Age (years) (IQR) 38.2 (18-83)
Female, n (%) 89 (55.3)
Smokers, n (%) 26 (16.2)
Anemia, n (%) 85 (55.5)
Previous surgeries, n (%) 94 (58.4)
Perianal disease, n (%) 75 (46.6)
Disease duration [y] (IQR) 10.3 (1-36)
0-2 years, n (%) 16 (9.9)
3-5 years, n (%) 36 (22.4)
6-10 years, n (%) 45 (28)
>10 years, n (%) 64 (40)
Previous exposure to anti-TNF n=138 (85.7%)
One biological, n (%) 44 (32)
Two biologicals, n (%) 78 (56.5)
Three biologicals, n (%) 16 (11.5)
Naive to biological therapy, n (%) 23 (14.3)
Extra intestinal manifestations, n (%) 61 (38)
Fecal calprotectin (mg/kg) n=90 1173 (19-600)
Mean C-reactive protein (CRP) (mg/L) 213 (0.08-125)
Mean HBI (IQR) 10.1 (2-19)

Montreal Classification  N=161
A1 (<16yo), n (%) 21 (13)
A2 (17-40yo), n (%) 116 (72)
A3 (>40yo), n (%) 24 (15)
L1 (ileal), n (%) 47 (29.2)
L2 (colon), n (%) 24 (14.9)
L3 (ileo-colonic), n (%) 90 (55.9)
B1 (Inflammatory), n (%) 47 (29.2)
B2/B3 (non-inflammatory), n (%) 114 (70.8)

Comparison OR [IC 95%], P-value
Location (L3 vs L2) 0.77 [0.64-0.92], <0.01
Location (L3 vs L1) 0.83 [0.91-0.99], 0.04
Behavior (B1 vs B2/B3) 1.22 [1.05-1.42], 0.01
Disease duration (0-2y vs >2y) 1.23 [1.05-1.44], <0.01
Prior biologic exposure (no vs yes) 1.28 [1.12-1.45], <0.01
0 vs 1 biologic 1.17 [0.99-1.38], 0.06
0 vs 2 or more biologics 1.33 [1.14-1.56], <0.01
Perianal disease (no vs yes) 1.15 [0.97-1.37], 0.10
Previous surgeries (no vs yes) 1.16 [0.99-1.36], 0.07

CONCLUSIONS

UST therapy was successful for inducing and maintaining of clinical remission and improving laboratory biomarkers of disease activity in patients with moderate to severe CD and who were refractory to anti-TNF therapy. Both UST induction and maintenance regimens until week 56 were overall well tolerated. These results support a favorable safety and efficacy profile.