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Section 4: Clinical Pharmacy Services

EFFECTIVENESS AND SAFETY OF INTRAVENOUS USTEKINUMAB INTENSIFICATION IN CROHN'S DISEASE WITH LOSS OF RESPONSE OR PARTIAL RESPONSE TO SUBCUTANEOUS THERAPY

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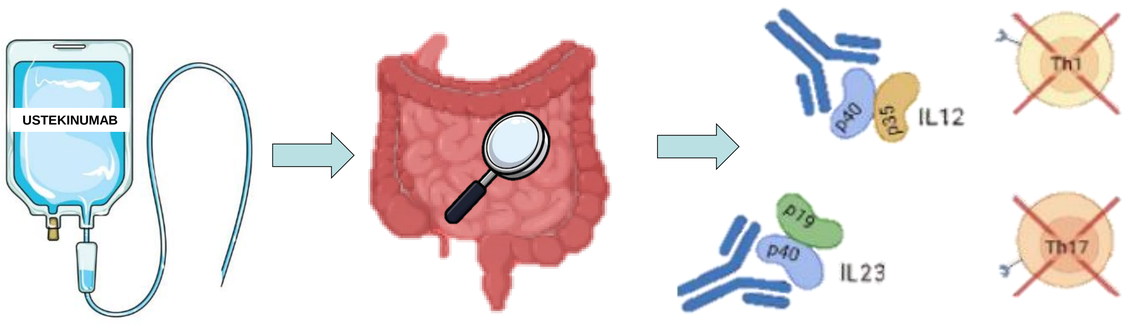
OBJECTIVES

To evaluate the effectiveness and safety of treatment intensification with intravenous ustekinumab in adults with CD and loss of response to the standard subcutaneous regimen.



BACKGROUND AND IMPORTANCE

Ustekinumab is a fully human IgG1 monoclonal antibody targeting the IL-12/IL-23 p40 subunit, utilized for the treatment of both Crohn's disease (CD) and ulcerative colitis (UC). It has demonstrated efficacy in inducing and maintaining remission in moderate-to-severe CD. However, some patients eventually experience a loss of response and exacerbation of CD symptoms. The effectiveness of ustekinumab intensification as salvage therapy is well-documented; nevertheless, there is currently limited evidence regarding its intravenous administration every six weeks.

MATERIALS AND METHODS

Single-centre, descriptive, retrospective study including CD patients who intensified ustekinumab treatment to receive 130 mg intravenously every 4-6 weeks from January 2020 to August 2022.

The clinical remission rate (defined as a Harvey-Bradshaw index (HBI)<5) at 12, 24 and 52 weeks and the early clinical response rate (defined as a reduction in HBI by ≥3 points or by a 30% from baseline) at 12 weeks were analysed. The evolution of inflammatory laboratory parameters such as C-reactive protein (CRP) and faecal calprotectin (FC) was assessed. Adverse effects developed during the follow-up period were collected.

RESULTS

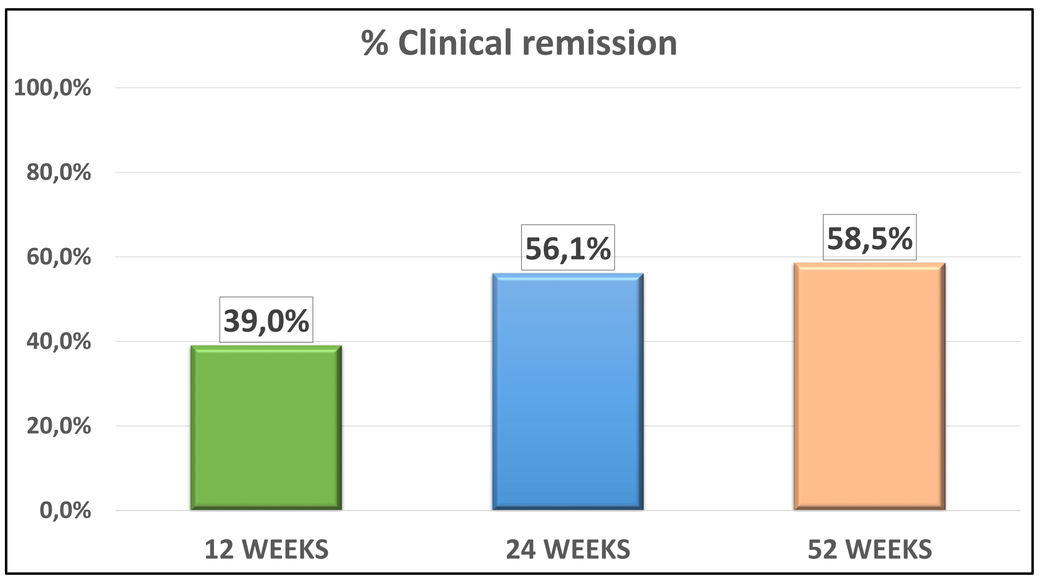
We included 41 patients who intensify subcutaneous ustekinumab every 8 weeks to 130 mg/Kg intravenous infusion every 6 weeks. No serious adverse effects were reported and no patient discontinued treatment due to adverse effects.

VARIABLE	N=41
Age at intensification (years, Md, IQR)	44,9 (37,8 – 59,6)
Male (n,%)	25 (61,0%)
Disease progression (years, Md, IQR)	16,6 (8,1 – 22,3)
Localization (Montreal) (n, %)	
▪ Ileal (L1)	17 (41,5%)
▪ Colonic (L2)	0
▪ Ileo-colonic (L3)	22 (53,7%)
Behavior (Montreal) (n, %)	
▪ Inflammatory (B1)	10 (24,4%)
▪ Stricturing (B2)	18 (43,9%)
▪ Penetrating (B3)	13 (31,7%)
Perianal Crohn's disease (Montreal) (n, %)	19 (46,3%)
Previous intestinal resection (n,%)	32 (78,0%)
Previous therapy (n,%)	
• Thiopurines	30 (73,2%)
• Methotrexate	5 (12,2%)
• 1 Anti-TNF	13 (31,7%)
• 2 Anti-TNF	20 (48.8%)
• 3 Anti-TNF	6 (14.6%)
• Vedolizumab	6 (14.6%)
• Other therapies	2 (4,9%)

Table 1. Description of the study population

Time on ustekinumab before IV intensification (months, Md, IQR)	19,6 (10,8 – 31,3)
Harvey-Bradshaw Index at intensification (Md, IQR)	6 (5 – 9)
CRP at intensification mg/L (Md, IQR)	7 (3 -- 15)
Faecal calprotectin at intensification, µg/g (Md, IQR)	253,5 (106,3 – 587,3)
Co-immunosuppressant (n,%)	4 (9,8%)
Early response rate at week 12 (n, %)	18 (58,1%)
Steroid free clinical remission at week 12 (n, %)	16 (39,0%)
Steroid free clinical remission at week 52 (n, %)	24 (58,5%)

Table 2. Clinial basal and effectiveness variables



Graphic 1. Rate of clinical remission achieved at different times

CONCLUSION AND RELEVANCE

Intravenous ustekinumab 130 mg every 4-6 weeks improves CD inflammatory activity in patients with loss of response or partial response to the standard subcutaneous regimen.

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