Clinical effectiveness of vedolizumab: interim analysis of the Swedish observational study on vedolizumab assessing effectiveness and healthcare resource utilization in patients with Crohn's disease (SVEAH CD)

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Background

Clinical trials may not appropriately reflect real world clinical practice. Therefore, we aimed to assess the clinical effectiveness of vedolizumab in a real world Crohn's disease (CD) cohort.

Methods

This was a prospective, observational, multi-centre cohort study. Eligible patients had active CD and initiated vedolizumab treatment between 1 June 2015 and 19 September 2017 across 21 centers in Sweden.

Data on patients' clinical characteristics, treatment, disease activity and short health scale (SHS) score were recorded at baseline and prospectively, using an electronic Case Record Form, integrated with the Swedish National Quality Registry for IBD (SWIBREG).

Data on patients who had completed 52 weeks of follow-up are presented. The primary outcome at week 52 was clinical remission, defined as a Harvey Bradshaw Index (HBI) <5.

Results

169 CD patients were included. The clinical characteristics of patients (n=104) who completed the 52 week study period are shown in Table 1.

At week 52, 71/104 (68%) were still on treatment with vedolizumab and 45/104 (43%) had achieved clinical remission.

Patients experienced significant improvements in HBI, CRP and SHS at week 52 (Table 2).

Table 1.
Baseline demographics and clinical characteristics of patients with Crohn's disease (n=104) treated with vedolizumab and followed-up for 52 weeks.

Median age at treatment initiation yr. (IQR)	41 (31-52)
Sex; male no. (%)	51 (49)
Median disease duration yr. (IQR)	9 (4-20)
Current smoker no. (%)	12 (11.5)
Location–no. (%)	
Ileal (L1)	17 (16.3)
Colonic (L2)	30 (28.8)
Ileocolonic (L3)	56 (53.8)
Upper Gastrointestinal (L4) only	1 (1)
Behaviour–no. (%)	
Non-stricturing, non-penetrating (B1)	54 (51.9)
Stricturing (B2)	36 (34.6)
Penetrating (B3)	14 (13.5)
Perianal disease–no. (%)	25 (24)
Past anti-TNF therapy – no. (%)	95 (91.3)
Reason for termination of last anti-TNF no. (%)	
Primary non response	19 (20.0)
Secondary loss of response/Intolerance	63 (66.3)
Other reasons	9 (9.5)
Unknown	4 (4.2)

Table 2.
Clinical and biochemical response to vedolizumab

	Baseline median (IQR)	52 weeks median (IQR)	Patients (no)	p-value
Harvey Bradshaw Index	6.0 (3.0-10.0)	3.0 (2.0-5.5)	68	<0.001
C-reactive protein (mg/L)	4.0 (2.0-10.0)	3.0 (1.4-5.0)	67	0.01
Calprotectin (µg/g)	561.0 (139.5-830.0)	232.5 (77.5-464.0)	36	0.09
Short health scale	9.0 (5.0-12.0)	5.0 (3.0-7.5)	68	<0.001

Conclusion

Vedolizumab treated patients represented a treatment-refractory group. Significant improvements in clinical- and inflammatory activity, as well as in quality of life, were observed in patients who continued treatment through to week 52.

Disclosures

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