and dose adjustment were evaluated up to Week 92 in the long-term extension (LTE) phase of UNIFI. Analysis was conducted in patients who were randomised to receive UST maintenance therapy and continued with UST in LTE. Tests with *p*-value <0.05 were considered statistically significant.

Results: Patients with histological-endoscopic mucosal healing after induction had significantly lower disease activity (partial Mayo score and stool frequency) and a trend for lower inflammation measured by CRP and faecal calprotectin at maintenance Week 44 than those without induction mucosal healing (Table 1). These improvements in disease activity were retained through LTE Week 92, with patients with induction histological-endoscopic mucosal healing showing a continuous reduction of disease activity. Significantly lower disease activity, CRP, and faecal calprotectin were also observed through LTE among patients with histological-endoscopic mucosal healing after UST maintenance compared with those without (Table 1). Patients with histological-endoscopic mucosal healing after induction remained on treatment longer than those without ($p < 0.05$). In addition, patients with histological-endoscopic mucosal healing after induction or maintenance were less likely to receive dose adjustment during LTE, but this association was not statistically significant.

Conclusion: Early macroscopic and microscopic improvement of the mucosa is an indicator of positive long-term clinical outcomes and reductions in inflammatory burden.

Abstract P712

Table 1. Disease activity and inflammation burden of patients with histologic-endoscopic mucosal healing (HEMH) after induction or maintenance therapy compared to those without; Randomized population who received UST maintenance therapy.

	Without HEMH after induction [a, c]	With HEMH after induction [a, c]	p-value [b]	Without HEMH at maintenance Week 44[a]	With HEMH at maintenance Week 44[a]	p-value [b]
N	**172**	**80**		**118**	**142**	
Partial Mayo score						
Week 44	1.91±1.97	1.23±1.84	<0.05	2.68±2.32	0.75±0.84	<0.001
Week 56	1.48±1.41	1.03±1.56	<0.05	1.70±1.57	0.90±1.20	<0.001
Week 68	1.42±1.39	0.98±1.28	<0.05	1.66±1.50	0.92±1.12	<0.001
Week 80	1.45±1.46	0.86±1.28	<0.05	1.55±1.47	1.01±1.34	<0.01
Week 92	1.40±1.37	0.74±1.0	<0.05	1.42±1.34	0.94±1.13	<0.01
Stool frequency						
Week 44	0.98±0.92	0.64±0.84	<0.05	1.23±1.02	0.47±0.60	<0.001
Week 56	0.85±0.78	0.51±0.76	<0.05	0.90±0.81	0.53±0.70	<0.001
Week 68	0.83±0.80	0.56±0.74	<0.05	0.95±0.85	0.55±0.68	<0.001
Week 80	0.81±0.80	0.48±0.73	<0.05	0.84±0.84	0.56±0.72	<0.01
Week 92	0.76±0.76	0.39±0.61	<0.05	0.74±0.74	0.51±0.66	<0.01
CRP (mg/L, log2 transformed)						
Week 44	0.78±1.99	0.43±1.85	ns	1.27±1.88	0.23±1.83	<0.001
Week 56	0.57±2.03	0.42±1.92	ns	0.97±2.06	0.27±1.86	<0.01
Week 68	0.72±2.18	0.38±1.72	ns	1.05±2.01	0.22±1.96	<0.001
Week 80	0.87±2.30	0.31±2.03	ns	1.09±2.22	0.28±2.09	<0.01
Week 92	0.76±2.26	0.29±2.00	ns	0.87±2.16	0.37±2.17	ns
Fecal calprotectin (mg/kg, log2 transformed)						
Week 44	7.72±2.49	6.91±2.25	<0.05	8.94±2.23	6.19±1.84	<0.001
Week 56	7.68±2.53	7.02±2.31	<0.05	8.65±2.40	6.47±2.17	<0.001
Week 68	7.58±2.65	7.18±2.42	ns	8.33±2.57	6.71±2.38	<0.001
Week 80	7.76±2.56	7.39±2.59	ns	8.49±2.36	6.84±2.47	<0.001
Week 92	7.63±2.68	7.43±2.53	ns	8.40±2.54	6.83±2.52	<0.001

a: P-values based on t-test between patients with HEMH and those without; ns: not significant (p>0.05)

b: Values are reported as mean ± standard deviation

c: Induction HEMH irrespective of treatment

P713

Effects of vedolizumab on health-related quality of life, work productivity and patient concerns in patients with ulcerative colitis and Crohn's disease in the UK and Ireland: OCTAVO cohort 2

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Background: Patients with inflammatory bowel disease (IBD) experience substantial impairment in health-related quality of life (HRQoL), therefore HRQoL endpoints are considered important measures of treatment outcome. OCTAVO evaluated the effects of vedolizumab on HRQoL, work productivity and patient concerns in IBD patients in the UK and Ireland.

Methods: OCTAVO is an ongoing multicentre, observational study to evaluate the impact of vedolizumab on two cohorts. Cohort 1 examined the impact of vedolizumab on concomitant medications compared with anti-TNFs in biologic naïve patients with ulcerative colitis (UC). Cohort 2 was non-comparative and observed changes in patient reported outcomes (PROs) in patients with UC and Crohn's disease (CD) prescribed vedolizumab at any point in the treatment pathway. PROs are assessed by Short Inflammatory Bowel Disease Questionnaire (SIBDQ), IBD-Control-8 (IBD-C-8), Work Productivity and Activity Impairment (WAPI) and Rating Form of IBD Patient Concerns (RFIPC). PROs are collected prospectively at baseline, Week 14, 6 months and 12 months post-initiation via online questionnaires. The results of an interim analysis of Week 14 PROs for patients aged ≥18 years newly initiated on vedolizumab enrolled across 7 hospital sites in Cohort 2 are reported here.

Results: Sixty-one patients (21 CD, 40 UC; 51% male) were recruited, with a median age of 39.0 (IQR 32.0–55.0); and median disease duration of 9.6 years (IQR 1.7–17.2) for CD and 5.6 years (IQR 1.3–17.4) for UC. Mean total SIBDQ scores at Week 14 were: 45.2 for CD; 50.0 for UC. Scores increased by 8.5 points in CD patients and 10.2 points in UC patients in the first 14 weeks of the study. Similarly, improvements in IBD-C-8, WPAI-UC/CD sub-scores and RFIPC were observed in both CD and UC (Table 1).

Table 1. PROs at baseline and week 14

	Crohn's Disease (n=21)		Ulcerative Colitis (n=40)	
	Baseline	Week 14	Baseline	Week 14
SIBDQ Total Score (mean, range 10-70)	36.7	45.2	39.8	50.0
IBD-C-8 (mean, range 0-16)	5.5	8.8	7.0	11.1
WPAI-UC/CD (%, mean)				
- Absenteeism	23	16	19	16
- Presenteeism	43	38	42	29
- Overall Work Impairment	48	40	48	33
- Activity Impairment	50	49	43	32
RFIPC Total Score (mean, range 0-100)	59.0	44.3	58.5	44.5

Conclusion: Vedolizumab treatment was associated with meaningful improvements in PROs at Week 14. Improvements were seen across all measures (SIBDQ, IBD-C-8, WPAI-CD/UC and RFIPC) and were similar between CD and UC. Further investigation of vedolizumab on PROs in the real world is required to assess impact in the longer-term, the full analysis of OCTAVO at months 6 and 12 will help to provide this.

P714

Real-world effectiveness of vedolizumab in ulcerative colitis: Week 52 results from the Swedish multi-centre, prospective, observational SVEAH UC study

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Background: Clinical trials may not readily reflect clinical practice. We aimed to assess the clinical effectiveness of vedolizumab in a real-world cohort of patients with ulcerative colitis (UC).

Methods: This is a prospective, observational, multi-centre cohort study. Eligible patients had active UC confirmed by a Mayo endoscopic subscore ≥2 at initiation of vedolizumab and had started treatment from 1/6/2015. Exclusion criteria included concurrent participation in a clinical trial in which UC treatment is dictated and contraindications to vedolizumab. All patients provided a written consent. Data on clinical characteristics, treatment patterns, disease activity and the short health scale were recorded at baseline and prospectively, using an electronic Case Record Form, integrated with the Swedish National Quality Registry for IBD (SWIBREG). The primary outcomes were A) clinical response, defined as a decrease in partial Mayo score of ≥2 and a reduction of ≥25 % from baseline, with a decrease ≥1 on the rectal bleeding score or an absolute rectal bleeding score of 0 or 1, at week 12 and B) clinical remission, defined as a partial Mayo score <2, at week 52. Continuous data are presented as median (interquartile range). Differences between baseline and follow-up visits were assessed by the Wilcoxon-signed rank test.

Results: In total, 117 eligible UC patients were included during the study period 1/6/2015 to 2/6/2018. Clinical and demographical characteristics of patients are shown in Table 1; 101/117 (86%) patients had failed prior anti-TNF therapy. The drug persistence rate was 106/117 (91%) at 12 weeks and 79/117 (68%) at 52 weeks. The clinical response rate at 12 weeks was 59/117 (50%) and the clinical remission rate at 52 weeks was 57/117 (49%). Altogether, 35/117 (30%) had an endoscopic Mayo score ≤1 at 12 weeks and 41/117 (35%) at 52 weeks. However, data on endoscopy were not available for 42 vedolizumab treated patients at 12 weeks and 30 at 52 weeks. Among patients who continued vedolizumab, the median partial Mayo score decreased from 4 (3–5) at baseline to 1 (0–2) at