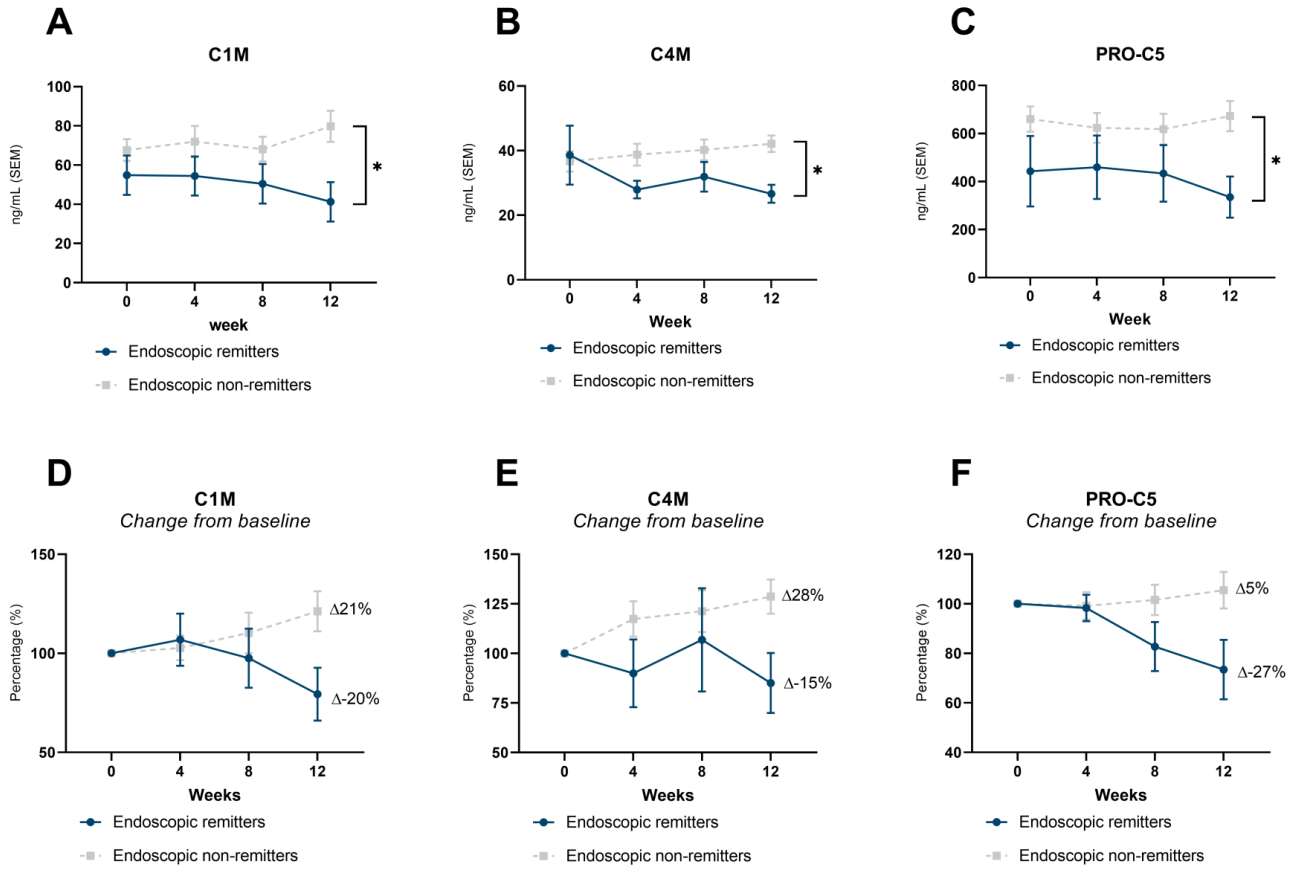
Abstract P516



(centrally read) was used to evaluate disease activity. Remission was defined as a SES-CD≤4 score at week 12. 54 CD patients completed the 12-week induction phase. Serum biomarkers measured by competitive ELISA se included C1M, C3M, C4M, PRO-C3, PRO-C4, PRO-C5 at baseline, week 4, week 8 and week 12. Spearman rho correlation was applied to evaluate the association with biomarkers and SES-CD score.

Results: Seven patients (11%) achieved a SES-CD≤4 at week 12. At baseline and at week 12 the biomarkers, C1M (baseline: r=0.36, P=0.005; wk12: r=0.47, P=0.0007), C3M (baseline: r=0.46, P=0.0002; wk12: r=0.28, P=0.047), C4M (baseline: r=0.40, P=0.002; wk12: r=0.36, P=0.011) PRO-C4 (baseline: r=0.36, P=0.004; wk12: r=0.35, P=0.013), and PRO-C5 (baseline: r=0.30, P=0.022) correlated with SES-CD (table 1). Remitters at baseline showed a numerically lower serum levels of C1M (54ng/mL vs. 65ng/mL), C3M (14.7ng/mL vs. 16.5ng/mL), PRO-C4 (241ng/mL vs. 299ng/mL) and PRO-C5 (442ng/mL vs. 660ng/mL) compared to non-remitters. The biomarkers C1M (P<0.05), C4M (P<0.05) and PRO-C5 (P<0.05) were significantly suppressed in remitters at week 12 compared to non-remitters (figure 1). The same biomarkers also demonstrated sustained suppression of serum concentrations at week 4, 8 and 12 (C1M: 21.6% decrease from baseline at week 12; C4M: 15% decrease from baseline at week 12; PRO-C5: 26.6% decrease from baseline at week 12) in remitters compared to non-remitters.

Conclusion: Biomarkers of tissue remodeling correlated with the SES-CD scores of CD patients treated with mongersen. Patients s who achieved remission based on endoscopic criteria showing greater suppression of these biomarkers relative to non-remitters. Collectively, these data suggest that biomarkers of tissue remodeling may be useful to monitoring disease activity and mucosal changes in CD patients.

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One year effectiveness and safety of ustekinumab in Ulcerative Colitis: a multicentre real-world study from Italy.

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Table 1. Outcomes at different time-points in follow-up. Numbers (percentages); AEs = adverse events,

	Baseline n= 68	8 weeks n= 66	24 weeks n = 60	52 weeks n = 38
Steroid-free remission; n (%)	-	13 (20) missing data:2	18 (30) missing data:1	19 (50) missing data:0
Response; n (%)	-	29 (44) missing data:1	32 (53) missing data:0	12 (32) missing data:0
AEs overall; n (%)	-	0	0	1 (3)
Discontinuation of treatment (overall); n (%) Primary failure Secondary failure AEs	-	0 0 0 0	1(2) 0 1 0	6 (16) 0 5 1

Abstract P517

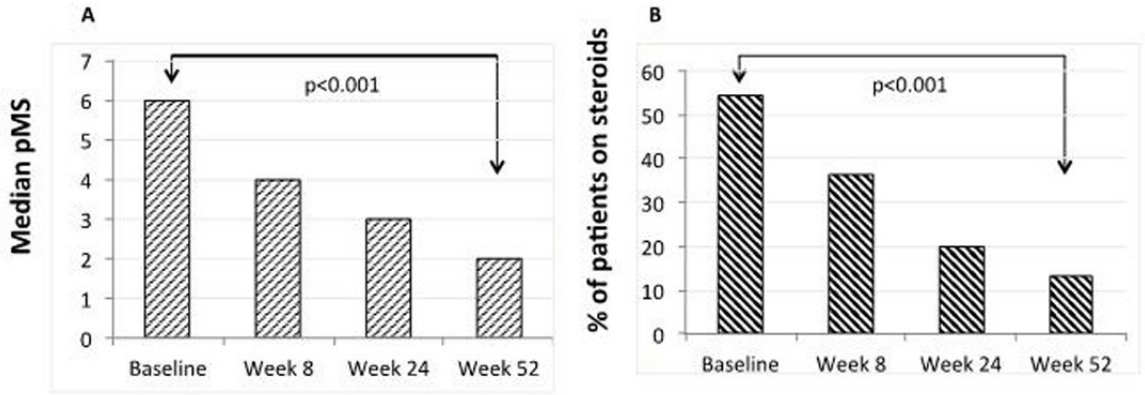

Figure 1: Reduction of the partial Mayo-score (pMS) (panel A) and of steroid use (panel B) during follow-up in UC patients treated with ustekinumab.

Background: Efficacy and safety of ustekinumab for the treatment of Ulcerative colitis (UC) has been demonstrated in phase III clinical trials, but real world data are scarce. The aim of this study was to assess effectiveness and safety of ustekinumab in an Italian cohort of UC patients.

Methods: Data of patients with UC who started using ustekinumab were collected. Primary endpoint was steroid-free clinical remission at 24 and 52 weeks of therapy. Secondary endpoints were: treatment response, endoscopic remission, treatment persistence at 12 months and safety.

Results: A total of 68 patients (males 63.2 %; mean age (SD) 31 years (14.5)) were included. All patients were biologics experienced. At 24 and 52 weeks, 32 % and 50 % of patients achieved steroid-free clinical remission, 85% and 81% had clinical response, respectively. (**Table 1**) At the end of follow-up there were a significant reduction of pMS from baseline (p<0.001) and of steroid use (p<0.001) (**Figure 1**). Of the available endoscopies at 12 months (18/38), 22.2% showed mucosal healing. The probability to persist in therapy with ustekinumab after 12 months of treatment was of 89.7 %. Only one adverse event occurred (diagnosis of an hypophysis adenoma). No patients required colectomy.

Conclusion: Data from our small real-life cohort of treatment-refractory UC patients suggest satisfactory effectiveness of ustekinumab and an excellent safety. More data assessing mucosal healing after one year of treatment are needed

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Compliance with Faecal calprotectin home testing as standard during COVID-19 pandemic compared to laboratory based testing pre-COVID.

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Background: Faecal calprotectin (FC) testing has become a standard non-invasive tool to monitor disease control in Inflammatory Bowel Disease (IBD)(1). Reported patient compliance with submitting samples for hospital testing has been as low as 35% (2). We aimed to evaluate patient compliance with rapid home faecal calprotectin testing kits compared to hospital based testing in our university teaching hospital.

Methods: 100 patients with a diagnosis of IBD for at least 1 year and attended IBD clinic between January 2019 and August 2020 were selected. Our laboratory ceased performing FC testing in late March and we introduced home testing (BÜHLMANN IBD doc). 50 patients who were, pre-pandemic, requested to bring a stool sample to the laboratory for hospital-based ELISA testing were randomly selected. We compared these to 50 random patients who had a home-based FC testing. Patients who were supplied with home testing kits received training from IBD nurses as well as on-line training materials. Data was collated retrospectively. Compliance was recorded if result was documented within 6 weeks of request.

Results: Prior to the introduction of home testing, only 52% of the patients' sampled complied with hospital-based testing. This compared to a 70% compliance rate, when home testing was requested (Figure 1).

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