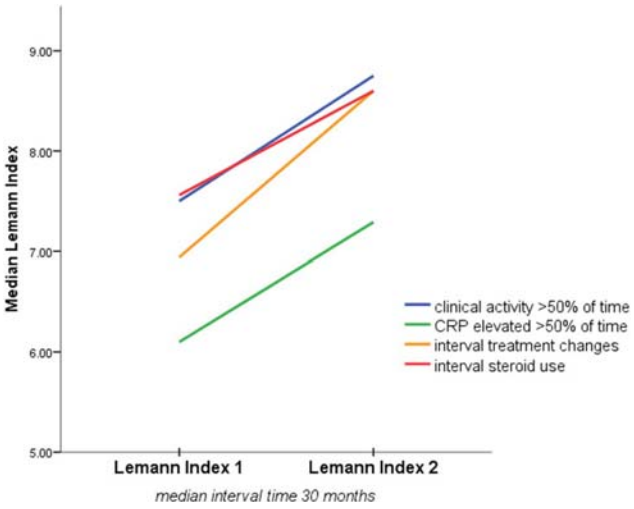

Figure 1. Lemann Index in Crohn's disease patients at 2 time points.

(DLI=2.2, z=3.309, p=0.001) and significant changes in treatment (DLI=2.2, z=2.418, p=0.016) during the interval period (Wilcoxon signed-rank test, Figure 1).

Conclusions: Our results show that ongoing Crohn's disease activity as indicated by persistent symptomatic disease, persistent CRP elevation, frequent steroid use and changes in treatment is associated with progressive bowel damage.

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Fecal calprotectin accurately predicts symptomatic relapse in children and adolescents with inflammatory bowel disease in clinical remission

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Background: In children and adolescents with inflammatory bowel disease (IBD) in clinical remission, it is difficult to predict when a relapse will occur. Reliable data on the value of biomarkers of inflammation for predicting relapse in these young patients are lacking. Therefore, we aimed to investigate the predictive value of fecal calprotectin (FC) and CRP for symptomatic relapse in pediatric IBD in clinical remission.

Methods: In this cross-sectional cohort study, patients aged <18 years with Crohn's disease or ulcerative colitis in clinical remission ≥3 months were included. At baseline, clinical and biochemical disease activity were assessed using the abbreviated-Pediatric Crohn's Disease Activity Index (aPCDAI) or Pediatric Ulcerative Colitis Activity Index (PUCAI), and FC and CRP, respectively. Clinical remission was defined as an aPCDAI or PUCAI <10. Disease course over the subsequent 12 months was retrospectively assessed. Symptomatic relapse was defined as an aPCDAI or PUCAI score ≥10, with the need for treatment intensification. Multivariate Cox regression analysis was performed to evaluate whether FC and CRP were independent predictors for symptomatic relapse.

Results: In total, 114 patients in clinical remission were included (56% males; median age 14.9 years). Baseline FC level was higher in patients that developed a relapse compared to patients without symptomatic relapse (median 367 μg/g vs. 117μg/g, p=0.014). FC level was an independent predictor for symptomatic relapse within 6 months from baseline (HR per 100μg/g: 1.15 [95% CI: 1.06–1.24], p<0.001), corresponding to a 15% increase in the probability of relapse per 100 μg/g increment, with fair predictive accuracy (AUC: 0.77, p<0.001). The optimal FC cut-off was 350 μg/g, with a sensitivity and specificity of 76% and 78%, respectively.

Baseline CRP level did not differ between patients with or without symptomatic relapse. CRP level was an independent predictor for symptomatic relapse within 6 months from baseline (HR per 1mg/L: 1.10 [95% CI: 1.01–1.19], p=0.025), corresponding to a 10% increase in the probability of relapse per 1 1mg/L increment, with poor predictive accuracy (AUC: 0.67, p=0.036). The optimal CRP cut-off was 0.6 mg/L, with a sensitivity and specificity of 88% and 38%, respectively.

Conclusions: Levels of FC and CRP were both independent predictors of symptomatic relapse in pediatric IBD in clinical remission, with superior predictive test characteristics of FC. High FC levels at routine measurement justify careful disease monitoring and evaluation of current treatment.

P298
Comparison between clinical and patient-reported symptoms among Crohn's disease and ulcerative colitis patients

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Background: There is no symptom-based patient-reported outcomes (PRO) measurement available in IBD. Disease scores contain a mixture of PRO and physician's observations and have shown serious limitations in clinical trials. Comparison between healthcare professionals (HCP) and patient (P) reports on scores' items is a first step toward disease scores refinement. In our IBD cohort study, we were able to collect P and HCP-reported symptoms independently. We assessed the agreement between both measures, and tested the correlation between the general well-being item (GWB) and two health-related quality of life (HRQoL) measures.

Methods: Between 2012 and 2015, we collected CDAI and MTWAI items 1) during follow-up medical visits, 2) through P self-reported follow-up questionnaire, except lab values. We compared items independently reported by HCP and P, stratified by diagnostic and Δt HCP-P reports. We calculated the Cohen's kappa (κ) statistic for agreement. A quadratic weight was applied for more severely serious disagreements. For EIM & complications, we computed a pooled κ based on the average between observed and expected probability of agreement over sub-items. A pooled κ was computed to summarize agreement over all examined variables. We also collected SF-36 and IBDQ scores. Pearson correlation coefficients r were calculated between both scores and GWB reports of HCP and P.

Results: 2427 reports could be evaluated (Δt: 537<1 month, 390 1–2, 1500 2–6), referring to 1385 patients (52% females, 58% CD). The best overall κ was found at Δt 1–2 months, moderate for number of stools/wk and antidiarrheal treatment (AT) in CD, moderate

Abstract P298 – Table 1. Cohen's Kappa scores for GI-P agreement among activity index items (0–0.2: very low, 0.2–0.4: low, 0.4–0.6: moderate, 0.6–0.8: high, 0.8–1: perfect).

	Δt					
CD	**<1**	**1-2**	**2-3**	**3-4**	**4-5**	**5-6**
Nb soft stool during last week	**0.457**	**0.484**	**0.500**	0.357	**0.469**	**0.444**
Abdominal pain	0.265	0.363	0.336	0.318	0.385	0.288
General well-being	0.161	0.338	0.222	0.240	0.268	0.355
Antidiarrheal treatment	0.292	**0.441**	0.288	0.166	0.186	0.125
EIM & complications	0.379	0.382	0.252	0.309	0.180	0.265
Overall	*0.336*	*0.423*	*0.370*	*0.297*	*0.355*	*0.351*
UC						
Noctural diarrhea	0.281	**0.749**	0.318	0.378	0.317	**0.438**
Bloody stools	0.243	**0.540**	0.284	0.256	0.240	0.217
Fecal incontinence	0.252	0.055	0.250	0.268	0.177	0.312
Abdominal pain	0.378	0.366	0.147	0.302	0.218	0.378
General well-being	0.316	0.201	0.340	0.318	0.198	0.304
Antidiarrheal treatment	0.255	0.069	0.360	0.284	**0.427**	0.202
Overall	*0.296*	*0.325*	*0.298*	*0.309*	*0.264*	*0.316*

to good for nocturnal diarrhea and bloody stools in UC. Agreement on GWB was low to very low. P-reported GWB were well correlated with IBDQ (CD: r=0.65, UC: r=0.67), SF-36 physical (PCS) (CD: r=0.52, UC: r=0.58) an SF-36 mental (MCS) component scores (CD: r=0.47, UC: r=0.46). Correlation of PCS resp. IBQD with HCP-reported CD-GBW was moderate at Δt <1 and 2–3 months (r=–0.45 and –0.53, resp. –0.43 and –0.48), but correlation with MCS remained low (r<0.40) whatever Δt. For UC, HCP-reported GBW moderately correlated with IBDQ at Δt<1 and 1–2 months (r=–0.48 and –0.47), but was low when Δt >2. Correlation with PCS and MCS remained low whatever Δt.

Conclusions: The agreement was low for many scores' items, except two per disease. Among scores' items with high weight, eg CDAI AT or GWB, agreement was surprisingly low. P-GWB correlated with HRQoL scores better than HCP, especially for scores related to mental or emotional aspects.

P299
Identification of a prognostic biomarker able to predict ulcerative colitis patients that will not respond to standard therapy

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Background: Ulcerative Colitis (UC) is associated with high rate of morbidity and disability. There is an urgent unmet need to identify a specific biomarker that early in the disease course select suitable patients for appropriate therapy, avoiding thereby unnecessary step-up therapies and patients'disability due to prolonged inflammation. Recently, we showed that aberrant glycosylation of T cells plays a crucial role in UC pathogenesis [1,2]. We herein studied whether this molecular marker is able to predict therapy response in UC patients, early in disease course.

Methods: 131 formalin fixed paraffin-embedded colonic biopsies collected at the time of diagnosis from 131 UC patients were analyzed by immunohistochemistry in order to evaluate the expression of our biomarker (glycosylation levels in intestinal T cells). The relationship between biomarker expression and clinicopathological/therapeutic features of UC patients was analyzed. ROC curves were performed and the predictive value of the biomarker in the response to therapy was determined.

Results: Univariate analysis showed that our biomarker is able to predict patients' therapeutic outcome, early in disease course, by distinguishing patients that will display a stable disease course (always under 5-ASA) from those that will step-up therapy. High levels of biomarker expression, at/near to diagnosis can predict 78% (Negative Predictive Value - NPV) of the patients that will display a good disease course (always under 5ASA; p<0.05). When the biomarker is analyzed in severe UC patients (MayoE 3) at diagnosis, the sensitivity of the biomarker increase (from 46% to 64%), in which low levels of biomarker are able to predict 78% (Postive Predictive Value - PPV) of the UC patients that will step-up therapy to biologics (with bad disease course). Multivariate analysis revealed that only our biomarker and C Reactive Protein are shown to be independent predictors of non-response to standard therapy (5ASA; corticosteroids; immunomodulators). Interestingly, the ROC curve (AUC=0.714, p=0.001) revealed a powerful effect of both molecular parameters when analyzed together, suggesting an additive value in the prediction of the failure to standard therapy. This additive predictive effect was stronger when analyzed in severe patients (MayoE 3) in which the association of both biomarkers is able to predict 70% of the UC patients (PPV), early in the disease course, that will not respond to standard therapy.

Conclusions: Our results reveal a potential novel molecular tool in the prediction of failure to standard therapy in UC patients with promising prognostic value to be included in the algorithm of the therapy-decision making of UC patients.

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P300
Illness perceptions and coping with health-related quality of life in patients with inflammatory bowel disease

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