carry high burden for patients and health services. Therefore, there is a need for an improved non-invasive monitoring method based on a reliable IBD marker, such as calprotectin (CP). Activation of the intestinal immune system during IBD leads to recruitment of neutrophils. CP comprises 60% of cytosol proteins in these cells, thus the amount of CP is proportional to the number of neutrophils and eventually to the degree of the gut inflammation.

Methods: The correlation between routine CalproLab ELISA-based laboratory test for CP and the new point-of-care test (CalproSmart™) was evaluated. The latter consists of a faeces extraction device prefilled with a buffer, a rapid lateral flow test, a support frame and a smartphone application. The study was performed by trained personnel on both fresh and frozen/thawed stool samples from 50 IBD patients during a 2 weeks period. Upon completion of the study, the operator was asked to fill out a survey evaluating design and user experience with the new test.

Results: 93% of the CP values measured by the new CalproSmart™ and the routine ELISA test were in good agreement with each other. The deviation between the measurements was less than 15% for the majority of the samples (67% of the total) and less than 25% for the rest of them. The average sensitivity and specificity of CalproSmart™ was calculated as 93% and 78%, respectively; the average positive and negative predictive values were 87% and 88%, respectively. CP values measured by CalproSmart™ and the routine method were scrutinised for fitting into the correct diagnostic window. This demonstrated that the results of the tests coincide in 100% of the cases when it comes to measuring samples from acute patients (CP level above 500 mg/kg); therefore, there were no false negative results. CalproSmart™ and the routine method placed patients with moderate CP levels into the same category in 73% of the cases and healthy individuals—in 86% of the cases. No 'bleeding through' between the acute and healthy patients category was observed.

Conclusions: CalproSmart™ demonstrated reliability, high degree of accuracy and correlation with the routine test. It received a positive feedback on its design and user experience—in principle, the test can be used even by patients with no previous experience in using smartphone applications. The new test is economically beneficial, it costs about 10- to 30-fold less than the enormous cumulative price of a single day in at a hospital. The test helps to improve compliance, reduce periods of pain and amount of drugs needed due to monitoring of CP.

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Abdominal pain and its relationship with clinical outcomes, biomarker levels, and health-related quality of life in patients with moderate to severe ulcerative colitis: data from U-ACHIEVE, a Phase 2b study of upadacitinib

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Background: Abdominal pain (AP), a common symptom in Crohn's disease, is reported but not thoroughly assessed in patients with ulcerative colitis (UC). We evaluated the impact of AP in UC and its relationship with other clinical outcomes, biomarker levels, and health-related quality of life (HRQOL) in the 8-week induction period of the upadacitinib trial U-ACHIEVE (NCT02819635).

Methods: In the Phase 2b study U-ACHIEVE, we evaluated data from adults with moderate-to-severe UC (adapted Mayo score [Mayo score without Physician Global Assessment] of 5–9 points and endoscopy subscore of 2–3) who randomly received upadacitinib or placebo for 8 weeks. AP (0=none, 1=mild, 2=moderate, 3=severe) was collected in the patient daily diary. Average AP score over the most recent 3 days before study visits was calculated. Impact of AP on HRQOL was assessed by comparing baseline (BL) Inflammatory Bowel Disease Questionnaire (IBDQ) and Short Form 36 Health Survey (SF-36) scores with AP severity. AP scores were calculated for patients in clinical remission and clinical response per adapted Mayo score at Week 8. Correlations between AP and clinical outcomes, HRQOL measures, and biomarker levels were evaluated with Spearman's correlation coefficients at Week 8.

Results: Among 250 patients, 82% reported any level of AP at BL (7% severe, 34% moderate, 41% mild); 8% had no AP; 10% had missing data. A trend was observed that patients with more severe AP had more impaired HRQOL at BL (Table 1). At Week 8, significantly lower AP scores were reported for patients with vs. without clinical remission (0.28 vs. 0.73; $p < .001$); improvement of AP score from BL to Week 8 was significantly greater in patients with vs. without clinical response (–0.94 vs. –0.36; $p < .001$). At Week 8, AP had a moderate to strong correlation with Mayo rectal bleeding subscore, IBDQ, and SF-36 Physical Component Summary scores (Table 2) but a weak correlation with Mayo endoscopic subscore and faecal calprotectin (f-cal).

Conclusions: Over 80% patients with UC reported experiencing AP, with higher AP severity linked to impaired HRQOL. AP was correlated moderately to strongly with HRQOL, clinical response and remission, but weakly correlated to proxy indicators of inflammation (endoscopy subscore and f-cal), inspiring future study on alternative mechanistic explanations for AP relief in UC.

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Systematic assessment of patient self-reported signs, symptoms, and nutrition behaviour

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Background: Symptom-based patient-reported outcomes (PROs) measurements are currently being investigated and re-assessed with the goal to be more appropriate in clinical trials as well as in daily practice. Our objectives were to assess the prevalence of patient-reported signs, symptoms - as collected in traditional disease activity scores for CD and UC/IBDU (labelled as UC), to assess nutrition behaviour of patients and its association with the other PROs.

Methods: We conducted a cross-sectional study among patients enrolled in the Swiss IBD cohort. We collected patient self-reported signs and symptoms, as used in the CDAI and MTWAI activity indexes. In addition, we collected information on needs, reasons, and frequency of diet adaptations. Descriptive statistics included numbers and percentages. Generalised ordered logit regression was used to assess associations between nutrition behaviour and PROs.