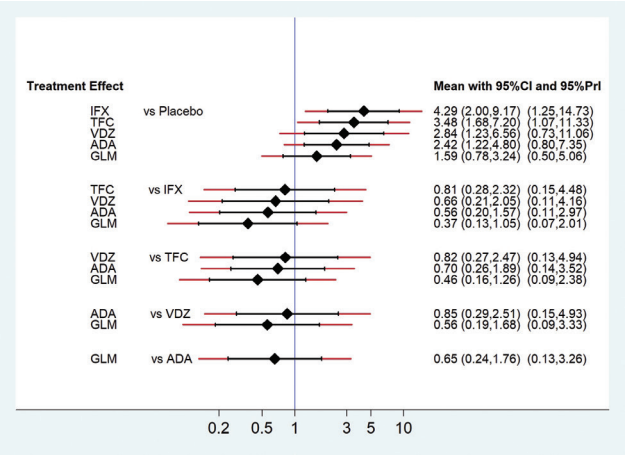

Steroid-free remission. The black lines represent the confidence intervals (CIs) for summary OR for each comparison and the red lines the predictive intervals (PrIs). An OR >1 favours the first intervention and an OR < 1 favours the second.

Conclusions: Very low-quality evidence support efficacy of all interventions but golimumab for steroid-free remission. In anti-TNF experienced patients, sparse data suggest that there is no effective treatment.

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Calprotectin does not add accuracy to PRO2 for prediction of continuous clinical response in moderate-to-severe ulcerative colitis patients treated with golimumab

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Background: Stool frequency and rectal bleeding are major patient-reported outcomes (PRO2) in ulcerative colitis (UC). The STRIDE consensus recommends monitoring of UC activity by PRO2 and endoscopy, while faecal calprotectin (CP) is not a treatment target.[1] We investigated the association of PRO2 alone and in combination with CP with continuous clinical response (CCR) in the PURSUIT-maintenance (-M) trial.[2]

Methods: This analysis included 456 patients who responded to golimumab induction therapies, and were randomised in the PURSUIT-M trial through week 54. Logistic regression was used to assess the association of PRO2 and faecal CP concentration with CCR. The accuracy of predictors of CCR was assessed through area under the receiver-operating characteristic curve (AUC), which ranges from 0 (low) to 1 (high accuracy). The ability to predict CCR was assessed by comparing AUC between a model with and without the predictor. PRO2 was assessed every 4 weeks and CP was assessed at weeks 0, 30, and 54. From time of loss of response (LOR), the baseline PRO2 (week 0 of induction) was imputed, assigning non-CCR status to patients with LOR. CP values at week 0 were carried forward through week 26, and from week 30 through week 50. The actual 4-weekly (partial) Mayo clinical response (PMS) was introduced in the model as ±1 if the PRO2 assessment date was earlier/later than the date of LOR. The model thus was: CCR = PRO2 + $\log_{10}$ (CP) ± PMS.

Results: The CCR prediction model that included PRO2, CP, and PMS was highly associated with CCR, and accuracy (AUC) increased through week 54 (Table). The model was mostly driven by PRO2, as noted when assessing the accuracy (AUC) of PRO2 alone. In contrast, CP alone and the prediction model without PRO2 had a lower accuracy for prediction of CCR. Finally, the model without CP had similar accuracy (AUC) for prediction of CCR compared with the complete model (that included CP).

Visit	No. of Patients with LOR	AUC					Model with PRO2, CP, and PMS	
		CP	PRO2	Model without PRO2	Model without CP	Model with PRO2, CP, and PMS	Sensitivity	Specificity
Week 0	0	0.5791	0.5401	0.5879	0.5632	0.6028	0.28351	0.83206
Week 30	191	0.6915	0.8608	0.6966	0.8674	0.8756	0.82474	0.75191
Week 54	227	0.6428	0.9307	0.6506	0.9353	0.9365	0.88144	0.87405

Conclusions: This PURSUIT-M post hoc analysis suggests that CP does not provide added predictive value beyond that of PRO2 alone in predicting CCR in UC patients.

References

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Number needed to treat to achieve clinical response at week 8 along with response or remission at week 52 with ustekinumab treatment vs. placebo from the phase 3 UNITI Crohn's disease studies, by population

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Background: UNITI-1 and -2 and IM-UNITI were multicentre, randomised, double-blind, PBO-controlled Phase 3 studies to evaluate safety and efficacy of ustekinumab (UST) in adults with moderate–severe active Crohn's disease (CDAI 220-450). Number needed to treat (NNT) is a useful measure, where lower values indicate greater effectiveness in achieving a specific end point. Because NNT calculations are PBO subtracted, randomised withdrawal studies can be a challenge vs. pure treat-through designs, but continuation of induction PBO patients on SC PBO maintenance provides opportunity to assess a true PBO comparison for attaining induction response and either response or remission at 1 year in the UNITI program.

Methods: Patients with inadequate response or intolerance to TNF antagonists (UNITI1, *n* = 741) or to conventional therapy (UNITI2, *n* = 27) were randomised 1:1:1 to 130 mg or ~6 mg/kg UST or PBO IV at week 0. Patients who had clinical response to UST 8 weeks later (100 patients CDAI reduction) were re-randomised in IM-UNITI to SC PBO or UST 90 mg q12w or q8w for 44 more weeks (1 year total treatment; *n* = 388). Because responders to PBO induction continued on SC PBO in blinded fashion, per protocol, a treat-through analysis was used to calculate response and remission (CDAI < 150) rates at 1 year, among induction responders to PBO or ~6 mg/kg (approved induction dose) followed by continued PBO or UST SC maintenance, respectively. To calculate NNT, induction week 8 response rates were multiplied by appropriate maintenance week 44 response