Of the 217 assessments 109 were in SCCAI defined remission, 95 were in PRO2 defined remission and the two were highly contingent (\(p<0.0001\)). The sensitivity and specificity of disease activity assessments made with PRO2 vs SCCAI were 0.85 and 0.98, respectively. The positive and negative predictive values were 0.98 and 0.87, respectively.

**Conclusions** The PRO2 performs well when validated against an established clinical disease activity index (SCCAI), quality of life assessments and biochemical markers of disease activity. PRO2 assessments have the benefit of being more rapid to administer (comprising of only 2 items) than SCCAI (6 items), whilst providing similar and accurate evaluations of remission status.

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**P144** THERAPEUTIC THRESHOLDS FOR GOLIMUMAB SERUM CONCENTRATIONS DURING INDUCTION AND MAINTENANCE: RESULTS FROM THE GO-LEVEL STUDY

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**Introduction** The exposure-response relationship associated with the use of golimumab for UC was demonstrated in the PURSUIT trial. Significant associations between serum golimumab concentrations (SGC) and favourable outcomes were observed during both induction and maintenance therapy. However, data regarding the optimal therapeutic SGC threshold is limited and therefore, recent AGA guidance made no recommendation in this regard.

**Methods** GO-LEVEL was an open label, phase IV, investigator-initiated study (NCT03124121) which included a prospective cohort of UC patients commencing golimumab induction therapy, as well as a cross-sectional cohort receiving maintenance treatment (>18 weeks from initiation).

Patients commencing induction all had disease activity objectively confirmed and were evaluated at weeks 6, 10 and 14. Patients receiving maintenance therapy were recruited either at the point of flare, or during stable remission. Clinical disease activity was evaluated using SCCAI and PRO2, and biochemical activity using FC and CRP. Combined clinical-biochemical remission was defined as SCCAI less than 3 and FC less than 250 ug/g.

SGC and anti-golimumab antibodies (ADA) were measured using a drug sensitive ELISA (LISATRACKER, Theradiag).

Mann-Whitney U was used to compare groups, ROC curve analysis to identify therapeutic thresholds, Spearman’s rank coefficient (\(r_s\)) for correlations and Cochrane-Armitage test for quartile data.

**Results** Thirty-nine patients were included in the induction cohort, of whom 15 (38%) achieved combined remission at week 6. The median SGC of those in combined remission was significantly higher (3.0 vs 2.1 ug/ml, respectively, \(p=0.003\)). ROC curve analysis demonstrates 2.4 ug/ml as the optimal therapeutic threshold to achieve combined remission (sensitivity 0.73, specificity 0.66, AUC 0.71).

SGC quartile analyses (figure 1) demonstrated significant trends to higher rates of combined remission with greater exposure during both induction (\(p=0.01\)) and maintenance (\(p=0.01\)).

No AGA were detected in either cohort.

**Conclusions** GO-LEVEL offers further evidence of the exposure-response relationship with golimumab. Clinicians may consider using therapeutic drug monitoring to optimise golimumab dosing aiming to achieve our suggested SGC therapeutic thresholds of 3.8 ug/ml at week 6 and 2.4 ug/ml during maintenance.

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**P145** BIOLOGICS ARE INFERIOR TO SURGERY IN ISOLATED INTERNAL PENETRATING CROHN’S DISEASE: A SINGLE CENTRE EXPERIENCE

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**Introduction** 50% of patents with Crohn’s disease (CD) develop fistulae, resulting in significant morbidity. Isolated internal penetrating CD (IPCD), without enterocutaneous manifestations, is the second most prevalent fistulating phenotype after perianal CD (Schwartz et al., 2019) yet the management