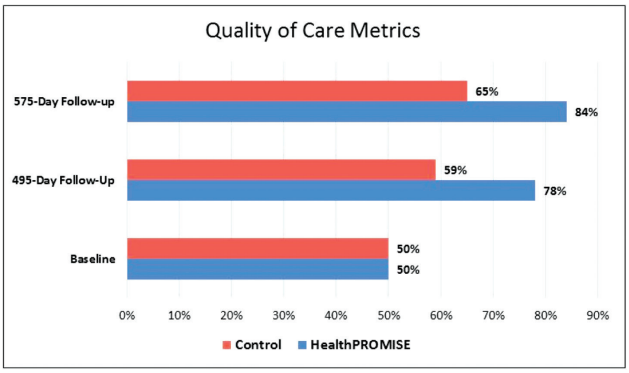

Figure 2. Change in percentage of patients meeting eligible QOC metrics at 495 days from baseline (+9 pp control vs. +28 pp HealthPROMISE, $p < 0.01$) and at 575 days from baseline (+15 ppt control vs. +34 ppt HealthPROMISE, $p < 0.01$).

Conclusions: A significant improvement in QOC was observed among patients using HealthPROMISE. IBD patients engaging with HealthPROMISE reported more equitable participation in their care decision-making process, and showed improved health outcomes. Digital health interventions and IBD remote monitoring can address gaps in QOC, increase patient engagement, and improve health outcomes.

DOP070

Development and pilot of an index to identify young people with inflammatory bowel disease at risk of psychological morbidity

R.T. Lees[1]*, A.J. Brooks[1], G. Rowse[2], P. Narula[3], P. Norman[4], A.J. Lobo[1]

[1]*Sheffield Teaching Hospitals, Department of Gastroenterology, Sheffield, UK,* [2]*University of Sheffield, Clinical Psychology Unit, Sheffield, UK,* [3]*Sheffield Children's Hospital, Gastroenterology Department, Sheffield, UK,* [4]*University of Sheffield, Department of Psychology, Sheffield, UK*

Background: Young People (YP) living with inflammatory bowel disease (IBD) are at an increased risk of psychological morbidity. There is growing interest in risk factor stratification in psychological screening as a means of implementing the European Crohn's and Colitis Organisation psychological screening recommendations. This study aimed to develop a novel index to predict future anxiety and depression: IBD Risk Assessment PsychologicalmorbIDity (IBD-RAPID) for use in 16–24 year olds.

Methods: An initial 30-item version, IBD-RAPID-30, was developed from evidence obtained in: (1) systematic review of psychological morbidity risk factors in YP with IBD; (2) original research into the illness perceptions of YP with IBD; (3) risk factors for psychological morbidity in YP with other chronic diseases. Following expert review of IBD-RAPID-30 through focus groups, a revised 35-item version was developed: IBD-RAPID-35. YP aged 16–24 years with a confirmed diagnosis of IBD were then recruited for a pilot study from the following; (1) local paediatric and adult IBD centres; (2) existing research database of YP with IBD (3) web-based recruitment advertised through Twitter and several IBD charitable organisations. Participants completed IBD-RAPID-35, Hospital Anxiety and Depression Scale (HADS), Inflammatory Bowel Disease Questionnaire (IBDQ), an adapted acceptability questionnaire and recorded their future disclosure preferences.

Results: Sixty-five participants were recruited. Participants had a median age of 22 years (16–24) with 38 females (58%). 36 had a diagnosis of Crohn's disease (55%), 21 ulcerative colitis (32%), 8 unknown (12%). Sixty-two (97%) participants were willing to repeat the survey at future time points, with 94% finding it either "easy" or "very easy" to complete. The emotional representations of IBD items were most strongly associated with anxiety ($r = 0.687$, $p < 0.0001$) and depression ($r = 0.580$, $p < 0.0001$) scores. Items related to general well-being ($r = 0.567$), hopelessness ($r = 0.515$), and availability of someone to confide in ($r = 0.504$) were significantly associated with depression sub-scale scores (all $p < 0.0001$). Participants were most willing to allow an IBD nurse specialist (89%) or IBD consultant (87%) to view their IBD-RAPID-35 responses, with general practitioner the least frequent named response (55%).

Conclusions: IBD-RAPID-35 is highly acceptable for use in 16–24 year olds with IBD. A longitudinal study is feasible, which would allow the identification of items with the strongest predictive ability, with the intention of developing a shortened, clinically acceptable risk index. Further studies are needed to assess the benefit of early identification and subsequent intervention in this population.

DOP071

Tight control with adalimumab-based treatment is associated with improved quality of life outcomes in patients with moderate to severely active Crohn's disease: data from CALM

R. Panaccione[1]*, J.-F. Colombel[2], P. Bossuyt[3], F. Baert[4], T. Vanasek[5], A. Danalioglu[6], G. Novacek[7], A. Armuzzi[8], W. Reinisch[7], E. Neimark[9], J. Petersson[9], A.M. Robinson[9], R.B. Thakkar[9], N. Chen[9], M. Skup[9], W.-J. Lee[9], G. D'Haens[10]

[1]*University of Calgary, Calgary, Canada,* [2]*Icahn School of Medicine at Mount Sinai, New York, USA,* [3]*Imelda General Hospital, Bonheiden, Belgium,* [4]*AZ Delta Roeselare-Menen, Roeselare-Menen, Belgium,* [5]*Hepato-Gastroenterologie HK, s.r.o., Hradec Králové, Czech Republic,* [6]*Bezmialem Vakif University, Istanbul, Turkey,* [7]*Medical University of Vienna, Vienna, Austria,* [8]*Presidio Columbus, Fondazione Policlinico Gemelli Università Cattolica, Rome, Italy,* [9]*AbbVie Inc., North Chicago, USA,* [10]*IBD Unit, Academic Medical Center, Amsterdam, The Netherlands*

Background: The Phase 3 CALM study demonstrated that tight control (TC) of inflammation based on biomarkers led to superior clinical outcomes including endoscopic and deep remission in patients with moderate to severe Crohn's disease (CD) compared with standard clinical management (CM).[1] Quality of life outcomes were analysed in this study.

Methods: Adult patients who were immunomodulator and biologic-naïve with active CD were treated with a prednisone burst and taper for ≤8 weeks, and randomised 1:1 to TC or CM at week 0. Patients received up to four treatment options (TOs) administered in a stepwise manner based on pre-defined success criteria: TO1=no treatment; TO2=160/80 mg adalimumab (ADA) weeks 0/2, then 40 mg every other week; TO3=ADA 40 mg weekly; TO4=ADA 40 mg weekly + azathioprine 2.5 mg/kg/day. The following outcomes and the values change from baseline (BL) were assessed at weeks 12, 24, 36 and 48: Inflammatory Bowel Disease Questionnaire (IBDQ), SF-36 Physical Component Summary Score (SF-36 PCS) and Mental Summary Score (SF-36 MCS), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Patient Health Questionnaire-9 (PHQ-9) and Work Productivity and Activity Impairment (WPAI)

questionnaire. IBDQ response (ΔIBDQ≥16 from BL) and remission (IBDQ>170) were assessed at weeks 12, 24, 36 and 48. Mixed models were used to estimate the difference in improvement (i.e., change from BL) between TC and CM over 48 weeks and at each visit; logistic regression was used to assess IBDQ response/remission.

Results: In total, 244 patients were randomised. BL characteristics and outcome values were similar between groups. At week 48, significantly more patients in TC vs. CM had an IBDQ response and were in IBDQ remission (Table 1).

Over the course of the study, average improvement (outcome values change from BL) were significantly greater in TC vs. CM for IBDQ, SF-36 PCS, SF-36 MCS, FACIT-F, PHQ-9 and daily activity impairment; and was numerically greater for work time missed, impairment while working, and overall work impairment (Table 2).

Conclusions: Compared with CM, TC with an ADA-based strategy was associated with normalisation of CD symptoms as well as significant improvement in general and disease-specific quality of life, fatigue and depression.

Reference

1. Colombel, *et al. Lancet* 2017.

DOP072

Achieving biochemical remission with adalimumab therapy using therapeutic drug monitoring: Results of a large prospective Crohn's disease cohort

N. Plevris, P. Jenkinson, C.S. Chuah, M. Lyons, R. Hall, G. Jones, E. Watson, I. Arnott, C. Lees

NHS Lothian, Gastroenterology, Edinburgh, UK

Background: Adalimumab (ADA) is a well-established treatment for Crohn's disease (CD). Despite this limited data are available regarding the relationship of serum ADA levels, and antibodies to ADA (ATA) with clinical outcomes.

Methods: We performed a prospective cross-sectional study to investigate the association of serum ADA levels and ATA on clinical outcomes. Inclusion criteria were a diagnosis of CD and minimum of 12 weeks therapy. Patients were written to in advance of their next clinic visit and advised to omit their ADA dose if due within 72 h from their appointment. Serum ADA levels / ATA, CRP and faecal calprotectin (FC) were simultaneously collected at clinic. Biochemical remission was defined as FC < 200 µg/g in addition to CRP < 5 mg/l.

Results: At the time of testing, 259 patients were on ADA maintenance therapy (of 356 who had ever received ADA). A total of 195 samples were available for analysis from 178 patients; matched FC and CRP was available for 142/195. Median duration of ADA therapy was 2.4 years (IQR 1.2–4.3) with 37/178 (20.8%) patients receiving concomitant immunosuppression. Median ADA levels were higher in patients receiving weekly (n = 55) (14.0 µg/ml, 8.0–17.4) vs. fortnightly dosing (n = 123) (11.0 µg/ml, 7.0–14.5, p = 0.0095). 29/178 (16.3%) patients were positive for ATA. A clear negative correlation was observed between ADA levels and ATA (Spearman's r = –0.567, p < 0.0001). Median ADA levels were 11.0 µg/ml (8.0–14.9), 4.2 µg/ml (2.0–6.0) and 0.0 µg/ml (0.0–2.0) at ATA of < 25 AU/ml, 25–50 AU/ml and >50 AU/ml, respectively (p < 0.0001). Patients in biochemical remission (n = 64/142; 45.1%) had significantly higher ADA levels (12.0 µg/ml, 9.0–14.7) than those with active disease (8.9 µg/ml, 5.0–13.2, p = 0.0003). ROC

Abstract DOP071 **Table 1. IBDQ remission and IBDQ response**

	Week 12			Week 24			Week 36			Week 48		
	TC	CM	p*	TC	CM	p*	TC	CM	p*	TC	CM	p*
IBDQ remission (IBDQ>170), %	47.5	36.1	**0.03**	54.1	43.4	0.14	51.6	39.3	0.08	50.8	36.1	**0.03**
IBDQ response (ΔIBDQ≥16), %	70.4	56.9	0.06	64.0	53.9	0.23	60.5	50.0	0.22	55.2	40.3	**0.04**

* p value based on logistic regression models adjusting for BL IBDQ, BL screening smoking status and BL weight.

Abstract DOP071 **Table 2. Mean difference in improvement for TC versus CM by visit**

	Difference between TC vs CM in outcome values change from BL				Average difference over 48 weeks (TC-CM)
Outcome measures	Wk 12 (TC-CM)	Wk 24 (TC-CM)	Wk 36 (TC-CM)	Wk 48 (TC-CM)	
IBDQ, mean	10.04*	8.14	11.20*	10.59*	9.90*
SF36 PCS	1.99	2.00	3.01*	2.11	2.25*
SF36 MCS	3.26*	3.28*	3.94*	4.23*	3.61*
FACIT-Fatigue	3.82*	4.04*	5.19*	4.73*	4.37*
PHQ-9†	-1.22*	-1.43*	-1.95*	-1.88*	-1.57*
WPAI†					
Work time missed‡	-3.59%	-5.05%	-6.90%	-1.16%	-4.31%
Impairment while working‡	-5.34%	-6.04%	-7.51%	-6.35%	-6.24%
Overall work impairment‡	-7.36%	-6.67%	-10.42%	-3.80%	-7.23%
Daily activity impairment	-6.10%	-5.07%	-6.70%	-8.27%*	-6.40%*

* p value <0.05, using mixed models accounting for longitudinal measures, BL smoking status, BL weight and corresponding BL outcome values.

† A higher value of PHQ-9 represents a higher level of depression; a higher value of WPAI represents a higher percentage of work productivity affected.

‡ Answered by patients who were employed (~50% of the population).