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Background: This analysis of the HARIR study explored disease characteristics, treatment and outcomes of patients (pts) with diseases including Crohn's disease (CD) or ulcerative colitis (UC) treated with biologics in clinical practice where data are limited: North Africa, the Middle East and Western Asia.

Methods: HARIR was a prospective, observational, multicentre, cohort, phase 4 study (NCT03006198). This analysis included adult pts with CD or UC who were starting infliximab, golimumab or ustekinumab (study period: March 2016–December 2018; terminated early). Pts needed to be previously untreated with study drugs or received ≤2 biologics prior to enrolment. Treatment was at physician's discretion. Pts were followed for 1 year or until study withdrawal (amended from 2 years); pts who stopped the study due to study termination were considered to have completed the study. For CD, the main efficacy outcomes were Crohn's Disease Activity Index (CDAI) treatment response, remission and change from baseline of inflammatory Bowel Disease Questionnaire (IBDQ). Adverse events (AEs) and serious AEs (SAEs) were recorded.

Results: A total of 86 pts with CD or UD from Algeria, Egypt, Kuwait, Qatar and Saudi Arabia were enrolled; 56 pts completed the study. Target enrolment was achieved for CD but was 1 pt short for UC. Mean (SD) age was 32.7 (11.5) years for CD and 29.6 (9.4) years for UC. Most pts with CD and UC had not previously received biologics (CD: 95.2%, 59/62; UC: 66.7%, 16/24). All pts with CD and UC received infliximab. Investigators noted lack of access to study drug and concomitant treatments as limiting factors for enrolment. Immunosuppressant use was low; methotrexate was used by 1 pt with UC prior to study treatment and azathioprine or mycophenolate mofetil were used by 19.4% (12/62) of pts with CD and 24.0% (6/25) of pts with UC during the study. At Month 3, 29.2% (14/48) of pts with CD had a positive treatment response (CDAI score ≥70 to ≥25% versus baseline; Figure). The percentage of pts with CD in clinical remission was 53.8% (28/52) at baseline and 70.8% (34/48) at Month 3 (Figure). Mean (SD) IBDQ score increased by 11.3 (39.6%) points from baseline to Month 3 (Figure). Overall, pt numbers were too low to analyse outcomes for CD after Month 3 and over the study duration for UC. In CD and UC, respectively, AEs were reported by 25.8% (16/62) and 37.5% (9/24) of pts and SAEs were reported by 12.9% (8/62) and 16.7% (4/24) of pts.

Conclusion: Infliximab treatment was well tolerated, and a moderate clinical response was observed for this Middle Eastern and Northern African population. Limited accessibility to biologics and concomitant treatments in these countries restricted conduct of the study.

P575

Nutrition and Inflammatory Bowel Disease – a nationwide survey of patients, gastroenterologists and dietitians

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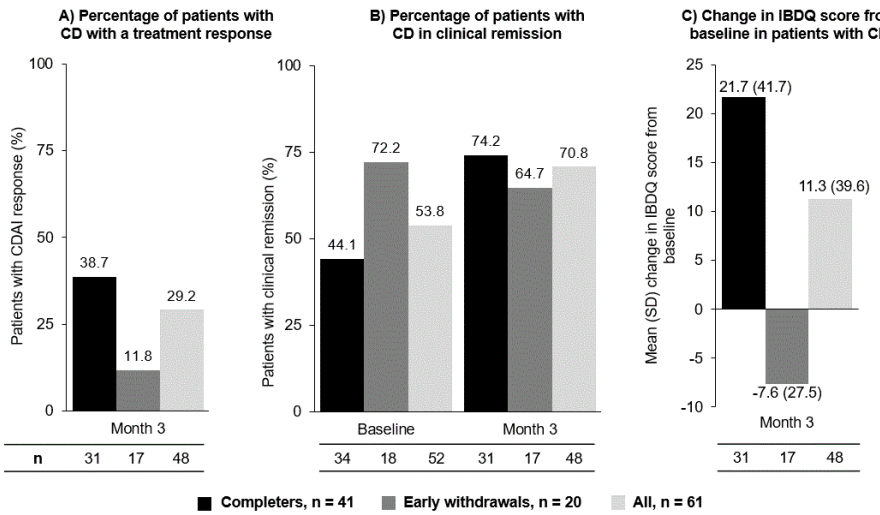
Background: Literature indicates that Inflammatory Bowel Disease (IBD) patients (pts), who are at high risk of malnutrition, often adjust their diet following diagnosis and wish to receive specialised nutrition advice from their healthcare team. Dietitians (DTs) are health professionals (HPs) with specialist nutrition expertise. Our aim was to assess nutrition advice provided by different HPs.

Methods: Electronic surveys were disseminated to New Zealand IBD pts, DTs and gastroenterologists (GIs) asking about experience of, and practice providing, IBD nutrition advice. DTs and GIs were asked which nutrition interventions they recommend. DTs

Abstract P574



Intent-to-treat analysis set for effectiveness (n = 61); CDAI response was defined as CDAI score of ≥70 and ≥25% compared with the baseline; clinical remission was defined as CDAI score <150; the IBDQ score ranges from 32 to 224, with a higher score indicating better health-related quality of life.
CDAI, CD activity score; IBDQ, Inflammatory Bowel Disease Questionnaire; SD, standard deviation.

responded separately for Crohn's disease (CD) and Ulcerative Colitis (UC) while GIs responded about IBD pts as a group.

Results: Surveys were completed by 407 pts, 79 DTs and 40 GIs.

Almost all (97%) GIs report their IBD pts ask about nutrition and 95% said they provide nutrition advice. DTs and GIs commonly recommended specific diets: modified fibre, high protein/energy and low fermentable carbohydrate diets, with occasional use of some other diet regimes (Table 1).

Half of the pts (52%) had seen a DT for advice and 31% had received nutrition advice from other HPs, commonly their GI, general practitioner or IBD nurse. Some patients (13%) received nutrition advice from other practitioners: nutritionist, naturopath, other medical doctors, counsellor, cannabis practitioner, integrated health professional, osteopath and herbalist.

Patients frequently received general nutrition advice and specific diet advice including various strict exclusion diets and herbal, probiotic and vitamin/mineral supplements from DTs and non-DT HPs (Table 1). No DTs or GIs recommended low carb, high fat, sugar free or ketogenic diets in IBD, which were recommended to pts by other HPs.

Table 1. Nutrition interventions recommended by DTs and GIs compared with advice pts recall receiving from DTs and other HPs.

	Nutrition interventions DTs and GIs recommend			Nutrition recommendations pts received	
	DTs		GIs %	From DTs %	From other HPs %
	CD %	UC %			
Exclusive enteral nutrition	Children 21	9	51	18	9
	Adults 38	7			
Partial enteral nutrition (2+ meals/day)	26	7	27	9	4
High protein/calorie supplement drinks	91	88	81	40	19
Vitamin/mineral supplements	45	39	65	10	20
General nutrition advice	90	89	86	52	52
Trial specific diet	76	70	62	53	42
Natural products/supplements	12	14	16	5	10
Other	10	5	3	12	14

Conclusion: Pts with IBD often ask for nutrition advice but only half had seen a DT. The advice given by HPs (medical and non-medical) varies and it appears that this high-risk group of pts is not always offered advice with evidence of scientific benefit in pts with IBD. Pts would benefit from greater access to DTs with IBD expertise.

P576

Ustekinumab levels correlate with induction fecal calprotectin drop-slope and discriminate the need for intensification at week 52 in Crohn's Disease patients.

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Background: Ustekinumab (UST) intensification during Crohn's Disease (CD) treatment is becoming common in clinical practice. Little is known about early intensification maintenance regimens and their drug levels utility in discriminating CD-response and the need for further intensification. We aim to analyze UST levels' evolution in an intensified maintenance regimen, their capacity to discriminate response according to inflammatory parameters and indicate the need for further intensification.

Methods: This is a retrospective study with 43 moderate/severe active CD patients (Harvey-Bradshaw Index [HBI] ≥4 and Fecal Calprotectin [FC] >250 µg/g) who received UST induction treatment (induction dose of 6mg/kg IV, plus dose of 90mg SC at week 8). Patients received maintenance treatment (90mg SC/8 weeks) and were followed for 52 weeks. They were classified according to the response obtained at the first year in **responders** (**R**), HBI <3 and FC <200µg/g; **non-responders** (**NR**), HBI ≥4 and FC >250µg/g; and **intensification group** (**IG**), partially responders that needed UST intensification to every 4 weeks. HBI, FC, C-Reactive Protein (CRP), and UST levels data were collected at baseline (w0), week 8 (w8), week 16 (w16), and 52 weeks (w52) of maintenance. IG was followed 12–26 weeks after intensification (aI).

Results: Half of the patients (48.8%) were male. Most of them (97.7%) have received previous anti-TNF-α treatment (53.49% ≥2 anti-TNF-α). Patients' median age at the moment of starting UST was 51 (37.5, 58.5) years. Median disease duration was 11 (7.5, 23) years. Location of disease was ileal in 30% of patients and ileocolic in 53%. One-third of patients suffered perianal disease, and 41 % were smokers. The only demographic factor associated with non-response was ileocolic location.

Table 1 shows the evolution of inflammatory parameters and UST levels according to the response. A Pearson correlation (r=0.62) between higher FC drop (baseline-w16) and higher drug levels at w16 was observed. The evolution of biological markers discriminates NR during induction; however, neither biological markers nor UST level can distinguish between R and those who will need intensification. R shows higher UST levels at w52 compared to IG. IG showed a significant increase of UST levels (mean of 5.39 points) and a substantial drop of FC and HBI (mean of 115.62 and 2.27 points, respectively) after intensification. Those patients reported clinical improvement; however, they could not reach a FC <250µg/g, which could need a more extended period to decrease.

Abstract P576

	UST LEVELS (µg/ml)				FC (µg/g)				CRP (mg/l)				HBI		
	w8	w16	w52	aI	w0	w16	w52	aI	w0	w16	w52	aI	w0	w52	aI
R (n=15)	13.36 (10.1)	2.19 (1.2)	4.37 (2.21)	___	923.3 (670.4)	180.1* (129.7)	159.1* (167.71)	___	4.34 (4.3)	2.49* (1.6)	1.06* (0.64)	___	6.37 (3.6)	1.6* (2)	___
NR (n=15)	8.47 (9.48)	3.07 (2.71)	___	___	1708.06 (1095.2)	1401.6 (976.3)	___	___	10.66 (8.85)	18.95 (17.8)	___	___	8.14 (6.5)	7.31 (5)	___
IG (n=13)	11.63 (9.75)	2.42 (0.97)	2.23 + (0.84)	7.61 ^ (3.1)	1013.2 (450.9)	493.7* (407.12)	554.7 (529.69)	366.5^ (421.8)	10.15 (17.4)	7.23 (9.48)	5.72 (8.15)	4.28 (4.22)	7.69 (2.98)	4.5 (2.3)	2.3^ (1.3)

Table 1 - data: mean (SD); * p <0.05 w16 or w52 *vs.* w0 in same group and parameter; + p <0.05 R *vs.* IG w52; ^ p <0.05 IG w52 *vs.* aI.