Abstract PTU-059 Table

Hospitalization and Colectomy Rates in ULTRA 1 and 2: Week 8 ADA Responders

	ADA		PBO			
Patients	n/PYs at Risk	IR (n/PYs at Risk)	n/PYs at Risk	IR (n/PYs at Risk)	RR (ADA/PBO)	P-Value
All-cause hospitalisation	46/260.4	0.18	58/222.3	0.26	0.68	.047[a]
UC-related hospitalisation	29/266.5	0.11	49/223.6	0.22	0.50	.002[a]
Colectomy	6/271.9	0.02	11/231.7	0.05	0.46	.122[a]
Hospitalizations	E/PYs	IR (E/PYs)	E/PYs	IR (E/PYs)	RR(ADA/PBO)	
All-cause	55/272.7	0.20	71/232.8	0.31	0.65	.021[b]
UC-related	32/272.7	0.12	59/232.8	0.25	0.48	< 0.001b

IR, incidence rate; PYs at Risk, time at risk in patient years; n, number of patients with event; E, total number of events; RR, relative risk.
[a]Z-score and normal approximations.
[b]Poisson regression with time offset.

M. Skup Shareholder of: AbbVie, Employee of: AbbVie, M. Yang Shareholder of: AbbVie, Employee of: AbbVie, A. Lazar Shareholder of: AbbVie, Employee of: AbbVie, R. Thakkar Shareholder of: AbbVie, Employee of: AbbVie, J. Chao Shareholder of: AbbVie, Employee of: AbbVie, P. Mulani Shareholder of: AbbVie, Employee of: AbbVie

REFERENCES

1. Feagan BG, *et al.* Presentation OP209, UEGW, Stockholm, Sweden. October 22–26, 2011.
2. Miettinen O. *Am J Epidemiol.* 1976; 103:226–35.

PTU-060 PHENOTYPIC CHARACTERISATION OF INFLAMMATORY BOWEL DISEASE IN SOUTH ASIANS IN THE UNITED KINGDOM-INSIGHTS INTO A SHIFTING LANDSCAPE

doi:10.1136/gutjnl-2013-304907.152

[1,*]C Boyd, [1]J K Limdi. [1]*Department of Gastroenterology, Pennine Acute Hospitals NHS Trust, Manchester, UK*

Introduction The aetiology of inflammatory bowel disease (IBD) remains elusive. The increasing incidence of IBD in developing countries and immigrant populations appears to outpace what genetic influences alone could instigate. There is a relative dearth of literature on the phenotypic characteristics of South Asian immigrant populations. The aim of our study was to define the clinical phenotype of IBD in South Asians in North-West England.

Methods We conducted a retrospective study of 102 patients of South Asian origin attending IBD clinics at our hospital. Clinical data including demographics, disease characteristics (Montreal classification), treatment and blood results were obtained using electronic case records.

Results Of 106 patients reviewed, 55 were male. The median age was 38 years (range 16–80) and mean disease duration was 9.5 years. Seventy-six patients had ulcerative colitis (UC) and 30 had Crohn's disease (CD). Five patients were current or ex smokers (4.7%). Seventeen patients had extra-intestinal manifestations of IBD (16.0%). Of UC patients 37 had pancolitis, 34 left sided disease and 5 had proctitis. Of patients with CD, 3 had ileal disease, 11 colonic disease and 16 had ileocolonic disease. Five CD patients had stricturing disease, 10 had penetrating disease (6 also stricturing) and 15 had non-penetrating, non-stricturing disease. Perianal disease was noted in 3 at diagnosis and in 5 subsequently. Eighty four patients received steroids, topical steroids (31), 5-ASA (99), topical 5-ASA (31), azathioprine (56), 6- mercaptopurine (4), cyclosporine (2), methotrexate (10), infliximab (21) and adalimumab (10). Fifty eight patients received at least one immunomodulatory therapy with the median time to use being 12 months (range 0–276 months). Thirteen patients (7 CD, 3 UC) required surgery (3 total colectomy, 10 subtotal). Mean time to surgery was 4 years (range 0–13 years). Seventeen patients had disease progression leading to Montreal reclassification (median time 60 months; range 1–216 months).

Conclusion We noted a higher prevalence of UC with predominantly pancolonic disease and a significant proportion of CD with penetrating or stricturing disease. The majority of patients required immunomodulatory therapy. Epidemiologic insights from such populations may provide further clues in defining an aetiological paradigm for IBD and should form an important area of further research. A case control study exploring differences is underway at our institution.

Disclosure of Interest None Declared

PTU-061 VITAMIN D DEFICIENCY IS WIDELY PREVALENT IN SOUTH ASIAN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

doi:10.1136/gutjnl-2013-304907.153

[1,*]C Boyd, [1]J K Limdi. [1]*Department of Gastroenterology, Pennine Acute Hospitals NHS Trust, Manchester, UK*

Introduction There has been resurgent interest in recent years in the pro-hormone vitamin D in its role and plausible effects on immune regulation and inflammatory bowel disease (IBD). We postulated a wide prevalence of vitamin D deficiency in South Asian patients with implications for the control of their IBD. The aim of our study was to review vitamin D assessment in a South Asian IBD cohort.

Methods We conducted a retrospective review of 102 South Asian patients attending IBD clinics in our institution. Clinical data including demographics, disease characteristics (Montreal classification) and therapy were obtained from electronic record review. Serum 25-hydroxyvitamin D (25-OHD) concentrations were recorded in all patients tested and in all having serial measurements.

Results Of 106 patients reviewed, 55 were male. The median age was 38 years (range 16–80) and mean disease duration was 9.5 years. Seventy-six patients had ulcerative colitis (UC) and 30 had Crohn's disease (CD). Five patients were current or ex smokers (4.7%). Vitamin D status was assessed in 52 patients (49%), 26 had serial measurements. Median 25-OHD was 10.25 (range 3.3–44.4). Fifty one patients had levels < 25 ng/ml consistent with deficiency and all 52 had insufficient levels < 50 ng/ml. Of the patients with deficiency 35 had UC and 16 had CD. Of the UC patients, 18 had pancolitis, 13 had left sided disease and 4 proctitis. Of the CD patients 5 had penetrating disease and 4 had stricturing disease. Forty-three of the deficient patients had received

steroids and 29 received immunomodulatory therapy (27 azathioprine, 3 methotrexate, 1 cyclosporin, 2 6MP, 10 infliximab, 6 adalimumab). Seven deficient patients (4 CD, 3 UC) required a colectomy and the mean 25-OHD level in this group was 10.7 (range 4.0–20.1 ng/ml). Mean time to surgery was 3.6 years (range 0–8 years). Of the CD patients 1 had a subtotal colectomy, 3 had hemicolectomy and of the UC patients 2 had subtotal colectomy and 1 had total colectomy.

Conclusion There was a high prevalence of Vitamin D deficiency although assessment was suboptimal and probably reflective of a wider experience. Patients with vitamin D deficiency appeared to have a more aggressive disease course. The role of vitamin D in IBD is a science in evolution underpinning exciting implications for research. Meanwhile vitamin D deficiency is under-recognised and consequently undertreated with likely implications for adequate disease control in this potentially vulnerable group.

Disclosure of Interest None Declared

PTU-062 VALUE OF MRI IN PREDICTING SEVERE OUTCOME IN SMALL BOWEL CROHN'S DISEASE

doi:10.1136/gutjnl-2013-304907.154

[1,*]C Rutter, [1]S Bhatt, [2]I Sequeiros, [2]P Burn, [1]P D Thomas. *[1]Gastroenterology; [2]Radiology, Taunton and Somerset NHS Foundation Trust, Taunton, UK*

Introduction The optimal approach to managing terminal ileal (TI) Crohn's disease remains to be defined. It is unclear at what stage surgery or biological therapy should be offered and current clinical and biochemical parameters offer poor prediction of disease course. Small bowel MRI scanning (SBMRI) has been correlated with endoscopic and histological disease severity in Crohn's disease and may offer better global assessment of the extent and severity of disease. We aimed to determine which MRI features might predict the need for surgery or biological therapy.

Methods 48 sequential patients with Crohn's disease who underwent SBMRI in a 20 month period to Feb 2011 were identified from a radiological database. 8 patients were excluded due to predominant colonic disease. All remaining 40 patients had confirmed isolated TI disease. Standard management with escalation of therapy via immunomodulors, biological agents and surgery based on clinical follow up was applied. Patients were followed for a minimum of 2 years after the initial MRI. MRI scanning was performed using oral fluid load, IV buscopan, T1/2 axial, coronal and dynamic post contrast sequences. The images were reviewed by a radiologist blinded to outcome of cases and key abnormal features recorded (mesenteric abnormalities, wall thickness > 6 mm, disease extent > 15 cm or proximal dilatation > 25 mm). Patients were then divided into 2 groups, those requiring biological therapy or surgery (severe) and those managed with 5ASA or immunomodulators alone (non severe).

Results The characteristic of the two groups is shown in the table. Means given unless stated.

Abstract PTU-062 Table

	n	Age	CDAI at MRI	CRP at MRI	Years post diagnosis	Previous surgery (%)	Immunomodulator use (%)
A Non severe	20	36	77	19	9.9	45	45
B Severe	20	42	120	30	9.8	45	75

6/20 patients in the non-severe group (A) had two or more adverse radiological features compared with 12/20 in the severe (B) group ($p = 0.06$). However, only 3/20 patients had lumen > 25 mm or extent > 15 cm in A compared with 15/20 in B ($p < 0.001$). Wall thickness and mesenteric involvement were not associated with a severe outcome. Disease extent and proximal luminal diameter were significantly associated with surgery ($p = 0.02$ and $p = 0.0001$). 85% of patients who eventually required surgery had either proximal lumen > 25 mm or disease extent > 15 cm.

Conclusion Two or more adverse radiological MRI features are associated with with the need for surgery or biological therapy. Small bowel dilatation > 25 mm proximal to the disease segment and disease extent > 15 cm are particularly associated with the need for surgery. These MRI findings may be helpful in deciding appropriate longer term strategies for managing these patients.

Disclosure of Interest None Declared

PTU-063 ASSESSMENT OF SLEEP IMPAIRMENT IN PATIENTS WITH CROHN'S DISEASE: RESULTS FROM THE USTEKINUMAB CERTIFI STUDY

doi:10.1136/gutjnl-2013-304907.155

[1,*]C Gasink, [1]D Chan, [1]L-L Gao, [2]B Schenkel, [3]C Han. [1]Janssen R&D, LLC, [2]Janssen Scientific Affairs, LLC, Spring House, [3]Janssen Pharmaceutical Services, Malvern, United States

Introduction To describe the extent of sleep impairment reported in CERTIFI (Ph2 evaluating UST in inducing & maintaining clinical response & remisison)using Jenkins Sleep Evaluation Questionnaire (JSEQ) & establish a clinically meaningful improvement threshold for JSEQ.

Methods Pts with moderate-to-severe CD(CDAI ≥220 & ≤450) who had previously failed or were intolerant to ≥1 anti-TNF were randomised to PBO/UST induction at wk0. Primary endpt was clinical response (≥100-pt reduction in CDAI from BL) at wk6. Sleep impairment assessed using JSEQ (total score 0–20; higher scores indicate greater sleep impairment) at BL&wk6. Relationships between BL sleep impairment, clinical disease activity (CDAI), & HRQoL impact(IBDQ) evaluated using Pearson correlation. Clinically meaningful improvement threshold of JSEQ was established with the anchor-based [clinical response by reduction in CDAI of ≥70-pt or clinically meaningful improvement (≥16-pt) in IBDQ] & distribution-based (change by one-half of the standard deviation [SD] of BL JSEQ score) methods. Prop of pts who achieved clinically meaningful improvements in JSEQ at wk6 was determined & compared.

Results At BL,both grps(n = 526) experienced similar degree of moderate sleep impairment, with JSEQ scores (mean±SD) of 11.0 ± 4.30(PBO)&11.0 ± 4.59(UST),resp. About 60% were "waking up feeling tired and worn out"; about 30–35% of pts had trouble falling asleep, staying asleep,& woke up several times during the night for 15–30 days in the previous month. At BL, JSEQ was correlated with CDAI ($r = 0.19$, $p < 0.0001$)&IBDQ($r = -0.39$, $p < 0.0001$). Using the anchor-based method, pts who achieved vs didn't achieve clinically meaningful improvements in CDAI or IBDQ at wk6 vs BL, reported improvements(mean±SD)from BL in JSEQ of –2.52 ± 4.43vs-0.58 ± 3.51 & –2.68 ± 4.16vs-0.16 ± 3.45, resp. Using distribution-based method, the JSEQ clinically meaningful improvement threshold was 2.25(SDof BL JSEQ = 4.50). 2 potential thresholds for clinically meaningful improvement in JSEQ (eg. reduction of > 2 or > 3 points from BL JSEQ score at wk6) were derived. More pts who received UST induction achieved both thresholds at wk6(Table).

Abstract PTU-063 Table

Treatment Group	Improvement in Total JSEQ > 2 at Wk6	Improvement in Total JSEQ > 3 at Wk6
PBO (n = 130)	26.2%	18.5%
UST combined (n = 390)	34.6% (p = 0.084)	27.2% (p = 0.048)
Absolute difference between UST and PBO	+8.5% for UST	+8.7% for UST