PWE-047 IMPROVED PATIENT-REPORTED OUTCOMES WITH UPADACITINIB OVER 52 WEEKS IN PATIENTS WITH MODERATE-TO-SEVERE CROHN'S DISEASE

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Introduction Upadacitinib (UPA), a selective JAK1 inhibitor was associated with clinical and endoscopic efficacy over 52 weeks (wks) in patients with moderate–to-severe refractory Crohn's disease (CD) (Sandborn, 2017). This is the first study assessing the long-term effects of UPA on patient-reported outcomes (PROs) in CD.

Methods 52 wk data from the phase 2 CELEST study were analysed for long-term effects of 4 UPA regimens on PROs. Patients (pts) who completed the 16 wk induction period were re-randomised 1:1:1 to receive UPA 3 mg twice daily (BID), 12 mg BID or 24 mg daily (QD) for 36 wks. The 24 mg QD arm was later stopped and a 6 mg BID arm initiated to evaluate an intermediate maintenance dose. Pts completed the Inflammatory Bowel Disease Questionnaire (IBDQ), EuroQol (EQ-5D) and Work Productivity and Activity Impairment (WPAI) PROs at baseline, wk 16, and wk 52. Wk 52 outcomes for pts who received UPA induction therapy and achieved clinical response at wk 16 were assessed. Percentages of pts achieving IBDQ response (minimum clinically important differences $\geq$16-point increase in IBDQ from baseline) and IBDQ remission (IBDQ $\geq$170) at wk 52 were determined using non-responder imputation (NRI). Changes from baseline to wk 52 were calculated using observed cases (OC) and analysis of covariance for IBDQ, EQ-5D visual analogue score (VAS) and WPAI.

Results Among 94 wk-16 clinical responders, a greater proportion of pts in the BID dose groups attained IBDQ response and achieved IBDQ remission at wk 52 than those in the 24 mg QD dose group (Table). Dose-related improvements in mean IBDQ and EQ-5D VAS were observed in the 3 mg, 6 mg and 12 mg BID dose groups at wk 52. At wk 52, improvements in WPAI including reduction of activity impairment and work impairment were numerically greater for the BID dose groups.

Conclusions Maintenance treatment with UPA among wk-16 clinical responders resulted in improved quality of life based on IBDQ, EQ-5D and work productivity over 52 wks. Numerically greater improvements were reported in the pts who received 12 mg BID.

Abstract PWE-047 Table 1 PRO results for wk-16 clinical responders

Mean±SD (n)	UPA 3mg BID N=32	UPA 6mg BID N=14	UPA 12mg BID N=29	UPA 24mg QD N=19
IBDQ at wk 52 (NRI), n (%)				
Remission (IBDQ$\geq$170)	14 (43.8)	7 (50.0)	12 (41.4)	6 (31.6)
Response ($\Delta\geq$16)	14 (43.8)	11 (78.6)	20 (69.0)	6 (31.6)
Mean change from baseline to wk 52 (OC)				
IBDQ	43±44 (n=22)	47±28 (n=13)	71±47 (n=23)	27±53^{+} (n=14)
EQ-5D VAS	18±19 (n=22)	22±17 (n=13)	36±26^{+} (n=22)	9±18* (n=14)
WPAI% activity impairment	−29±32 (n=22)	−26±22 (n=12)	−42±28 (n=21)	−15±27^{+} (n=14)
WPAI% overall work impairment[a]	−23±36 (n=12)	−37±32 (n=5)	−38±35 (n=15)	−21±26 (n=6)

*,+statistically significant at 0.05 and 0.1 level for each group vs 3 mg BID for mean change from baseline [a]Only employed patients

REFERENCE

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PWE-048 ENDOSCOPICALLY-DELIVERED PURASTAT FOR THE TREATMENT OF SEVERE HAEMORRHAGIC RADIATION PROCTOPATHY: A CASE SERIES

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Introduction 30,000 people are treated with pelvic radiotherapy annually in the UK. Rectal bleeding is common following pelvic radiotherapy,one of the main causes being radiation proctopathy (RP). Radiation causes ischaemia and fibrosis,leading to neovascularisation with small friable vessels which are the source of bleeding. 6% develop severe bleeding from RP, leading to anaemia requiring iron +/- blood transfusion. There are very few safe,effective,evidence-based treatments.

Purastat is a haemostatic agent licenced for GI bleeding. It is a self-assembling peptide which forms a molecular mesh in contact with blood,thereby sealing blood vessels. There are numerous studies showing its efficacy and safety in various surgical/endoscopic settings. We report the first data for the use of Purastat for the treatment of RP.

Methods Consecutive patients attending pelvic radiation disease clinic with severe refractory RP were offered treatment with Purastat. This was defined as rectal bleeding into the pan +/- clots +/- anaemia with no response to rectal sucralfate +/- hyperbaric oxygen therapy (HBOT). Purastat was applied endoscopically at 4 weekly intervals up to 4 times. Severity of bleeding was recorded using patient diaries. Severity of RP was graded using the Zinicola score(1).

Results All 13 patients offered Purastat accepted treatment (10 male; 9 prostate, 2 vaginal, 2 rectal; median age 74 years (4–4)). 10 had previously used rectal sucralfate (3 were unable to due to mobility),2 had HBOT and 4 had APC. 3 were on antithrombotics (2 warfarin, 1 aspirin) and 1 had thrombocytopenia. 8 had anaemia at baseline and 9 required intervention (6 oral iron; 5 IV iron; 3 blood transfusion).

Median number of Purastat treatments was 3 (–). There was a reduction in median episodes of rectal bleeding (bleeding into the pan, n= 11) from 12 (–7) 7 days prior to the 1st treatment to 4 (–5) 7 days prior to the 2nd treatment. Endoscopic grade improved in 8 patients, with no change in 4 and an increase in 1,all of whom are awaiting a 3rd treatment. Mean haemoglobin at baseline,mid-treatment and after treatment was 111, 107 and 119 g/L respectively. There were no complications.

Conclusions Even in this cohort of the most severe cases of RP, there was an improvement in rectal bleeding and endoscopic grade. It is crucial that further data are obtained in a randomised controlled trial to determine the safety and efficacy of Purastat in this patient group to address this ongoing

significant area of unmet clinical need and reduce associated morbidity and healthcare costs.

REFERENCE

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PWE-049 ASSESSMENT OF RESPONSE AND TOLERANCE TO ORAL IRON SUPPLEMENTS IN PATIENTS WITH ANAEMIA

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Introduction Iron deficiency anaemia (IDA) is associated with "classical" signs and symptoms such as pallor and koilonychia. Tolerance to oral iron supplements is variable.

Aim We recorded the classical signs and symptoms of iron deficiency in patients presenting to 2 week wait IDA clinic. We also assessed patients' tolerance to oral iron supplements and subjective response.

Patients and methods Patients referred to our iron deficiency clinic were assessed for symptoms and signs of iron deficiency using a proforma. All patients were started on oral ferrous sulphate 200 mg twice daily. Clinical response and tolerability were assessed at 1 and 3 months.

Results There were 336 patients with iron deficiency anaemia and 58 patients with other types of anaemia, mainly anaemia of chronic disease. There were no differences in baseline characteristics between the two groups.

In patients with IDA, the most frequent symptoms of iron deficiency were pallor (42.9%), hair loss (16.4%), less commonly ridges (3.0%), glossitis (1.5%), koilonychia (0.9%) or cheilosis (0.6%). Patients responded to iron supplements and reported reduction in fatigue. Most frequently reported side effects related to oral iron supplements were black stools (66.8%), diarrhoea (20.0%), constipation (20.6%), pruritus (20.0%), abdominal discomfort (20.0%) and nausea (11.1%). 11.1% patients with IDA required dose adjustment or intravenous supplements.

Interestingly, patients in the group of "other" types of anaemia presented symptoms of iron deficiency. Side effects or oral iron supplements were also similar. (See Table below for detail.) 15.5% of patients required dose reduction or intravenous supplements. However, here was only little response in blood test results although subjective fatigue score improved.

Conclusion Iron supplements are well tolerated in patients with anaemia. Their use in patients with no evidence of iron deficiency however is of modest clinical benefit.

Abstract PWE-049 Table 1

	Iron Deficiency Anaemia n 336		Other types of anaemia n 58		
Symptoms of iron deficiency	144 (43.0%)		33 (36.0%)		
Pallor n (%)	55 (16.5%)		15 (16.3%)		NS
Hair loss n (%)	10 (3.0%)		3 (3.3%)		
Ridges n (%)	5 (1.5%)		1 (1.1%)		
Glossitis n (%)	3 (0.9%)		1 (1.1%)		
Koilonychia n (%)	2 (0.6%)		1 (1.1%)		
Cheilosis n (%)					
Side effects on oral iron	133 (66.8%)		43 (74.1%)		
supplements Black stools n (%)	40 (20.0%)		15 (26.0%)		NS
Diarrhoea n (%)	41 (20.6%)		13 (22.4%)		
Constipation n (%)	40 (20.0%)		14 (24.0%)		
Pruritus n (%)	40 (20.0%)		9 (15.5%)		
Abdominal discomfort n (%)	22 (11.1%)		6 (10.3%)		
Nausea n (%)					
Improvement in fatigue Liskert	Baseline	At 3 months	Baseline	At 3 months	
scale (mean)	48.2	61.4	50.0	58.6	NS
Improvement in Haemoglobin (g/	Baseline	At 3 months	Baseline	At 3 months	
dL) Haemoglobin g/dL (mean)	109.1	129.2	109.0	118.4	

n (total number of patients), NS not significative

PWE-050 ESTABLISHING THE NORMAL FAECAL METABOLOME THROUGH ANALYSIS OF VOLATILE ORGANIC COMPOUNDS FROM HEALTHY ADULTS

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Introduction Volatile organic compounds (VOCs) are produced in the faeces through the action of the microbiome on gut contents. Specific changes in faecal VOCs are associated with disease such as colon cancer[1], IBS[2] and IBD[3]. Their role in health is not clearly defined. VOCs can be analysed using analytical techniques such as gas chromatography – mass spectroscopy (GC-MS). In order to interpret abnormal VOC profiles in disease states, we must have a better understanding of what is normal.

Method Data from 10 faecal VOC studies carried out in our lab, between 2015 and 2018, involving 91 healthy participants were amalgamated. All samples were collected and stored in the same conditions, samples were analysed by headspace GC-MS using our optimised protocol[4]. Spectral analysis was performed with Automated Mass Spectral Deconvolution and Identification System (AMDIS) and the National Institute of Standards and Technology (NIST). Further data processing was carried out using Metab in R, Microsoft Excel and Metaboanalyst.

Abstract PWE-050 Table 1 VOCs found in >90% of samples

(4R)-1-methyl-4-prop-1-en-2-ylcyclohexene
2-methylbutanal
2-methylbutanoic acid
3-methylbutanal
3-methylbutanoic acid
3-methylsulfanylpropanal
4-methylphenol
6-methylhept-5-en-2-one
Heptan-2-one
Nonan-2-one
Pentanoic acid
Phenol
Propanoic acid