

post-transplant group. Paired pre and post-operative data were available for eight patients: function scores improved significantly for general health ( $p=0.04^{**}$ ). Improvements in physical function, social functioning, emotional role limitations, energy/fatigue, emotional well-being and pain were seen but this did not reach statistical significance. Physical role limitation was the only function to decline. Of the eight pairs, two patients had significantly better overall scores post transplant ( $p=0.02$ ,  $p=0.01^{**}$ ) and four had improved overall scores not reaching statistical significance. \*independent T test \*\*Wilcoxon signed rank.

**Conclusion** In this small experience there was an overall trend for better quality of life after transplantation, but certain QOL parameters appear to improve more than others. If quality of life is to be an indication for transplantation it will be important to select patients on the basis of quality of life parameters that are known to improve after transplantation. Longer term and larger studies are required.

**Competing interests** None declared.

### PTU-151 SMALL BOWEL ULTRASOUND: DIAGNOSTIC YIELD IN ESTABLISHED SMALL BOWEL CROHN'S DISEASE

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**Introduction** Crohn's disease is an intestinal inflammatory disorder which frequently involves the small intestine. Accurate localisation of disease is important to direct targeted therapy. Video capsule endoscopy (VCE) has revolutionised clinical assessment of small intestinal Crohn's disease. Small bowel ultrasound (SB USS) is a rapid, inexpensive, interactive and non-invasive alternative method for assessing small bowel Crohn's disease, which is in routine use only at selected UK institutions. We evaluated the diagnostic yield of SB USS in VCE determined Crohn's disease.

**Methods** A retrospective assessment of patients who had undergone VCE in 2008–2010 was carried out. Patients investigated for suspected small bowel Crohn's disease, or who had findings of small bowel Crohn's on VCE were included, if they had also had a SB USS within 12 months. VCE findings were graded as mild (aphthous ulcers only), moderate (aphthous ulcers with mucosal distortion) or severe (aphthous ulcers with mucosal distortion and strictures/stenosis). SB USS was graded positive or negative for small bowel Crohn's disease. Both assessments were single operator. Either investigation could predate the other. Results were expressed as sensitivity, specificity, positive and negative predictive value (PPV and NPV) of SB USS compared with VCE for detection of small bowel Crohn's. Sub-analysis of SB USS findings for VCE-defined severity of small bowel Crohn's disease was carried out.

**Results** 196 VCE procedures were reviewed, of which 22 fulfilled the inclusion criteria. 10 patients had SB Crohn's on VCE; this was detected in four patients by SB USS (sensitivity 40%). 12 patients had no evidence of SB Crohn's on VCE; none of these had SB USS findings of Crohn's disease (specificity 100%). Of 18 patients with no evidence of SB Crohn's on SB USS, VCE findings of Crohn's disease were apparent in 6 patients (negative predictive value 67%); however, all patients with positive findings of Crohn's disease on SB USS had evidence of SB Crohn's on VCE (positive predictive value 100%). Sub-analysis for severity of inflammation on VCE was carried out. Of four patients with positive findings at SB USS, 3 were severe and one moderate on VCE. One patient with severe Crohn's on VCE was missed by SB USS; however, the patient's body habitus was unfavourable.

**Conclusion** SB USS has excellent positive predictive value (100%) and specificity (100%) for detection of SB Crohn's disease, with only

moderate negative predictive value (67%). In addition, all detected cases were moderate or severe, which may complicate VCE. It therefore seems a safe, quick, relatively cheap initial investigation in expert hands, which may obviate more costly, invasive investigations. A prospective evaluation of these diagnostic modalities should be carried out.

**Competing interests** None declared.

### PTU-152 SIGNIFICANT IMPROVEMENTS IN ABDOMINAL PAIN AND BOWEL SYMPTOMS IN A PHASE 3 TRIAL OF LINACLOTIDE IN PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C): A EUROPEAN PERSPECTIVE

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**Introduction** Linaclotide, a minimally absorbed guanylate cyclase-C agonist, was evaluated in a Phase 3 trial. To fulfil EMA submission requirements, the efficacy, safety and effects of withdrawal of linaclotide 290 µg in patients with IBS-C were assessed.

**Methods** In a randomised, double-blind, placebo (PBO)-controlled trial, IBS-C patients (modified Rome II criteria), with an average of <3 complete spontaneous bowel movements (CSBM)/week (wk), ≤5 spontaneous bowel movements (SBM)/wk and abdominal pain ≥3 (0–10 scale) during a 2-wk baseline period, received oral, once-daily linaclotide or PBO for a 12-wk treatment period (TP). In a 4-wk randomised withdrawal period (RWP), linaclotide-treated patients were re-randomised to receive linaclotide or PBO, and PBO-treated patients to receive linaclotide.

**Results** 800 patients (median age 44; female 90.5%) received linaclotide (n=405) or PBO (n=395). For the first co-primary parameter (≥30% reduction from baseline in mean abdominal pain or discomfort score for ≥6 of the 1st 12 wks with neither score worsening), 54.8% of linaclotide-treated patients and 41.8% of PBO-treated patients responded ( $p=0.0002$ ). For the second co-primary parameter (patients "considerably relieved"/"completely relieved" on the weekly degree-of-relief of IBS symptoms question for ≥6 of the 1st 12 wks), 37.0% of linaclotide-treated patients and 18.5% of PBO-treated patients responded ( $p<0.0001$ ). Linaclotide significantly improved all secondary parameters (including CSBM frequency rate, stool consistency, bloating and severity of straining) vs PBO (except wk 12 EQ-5D VAS;  $p=0.06$ ). Improvements occurred in wk 1 and were sustained throughout the TP. During the RWP, patients continuing linaclotide had sustained efficacy in abdominal pain/discomfort response and IBS degree-of-relief response, and patients switched to PBO had symptom recurrence to the level of PBO during treatment. In patients initially treated with PBO and switched to linaclotide, abdominal pain improved to the level of linaclotide patients during the TP. Similar trends were seen in other abdominal/bowel parameters. Diarrhoea was the most common AE, causing discontinuation in 5.7% of linaclotide-treated patients and 0.3% of PBO-treated patients.

**Conclusion** In patients with IBS-C, linaclotide significantly improved all primary and secondary abdominal pain and bowel symptom parameters with no evidence of rebound on stopping treatment.

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