

at 6 months ($p=0.014$). Median IBDQ bowel subset score improved from 41 at baseline to 50 at 6 months ($p<0.0005$). Significant improvement was also found in the median VIQ score from 11 at baseline to 8 at 6 months ($p<0.0005$). The median CTCAE rectum bowel mean score for men improved from 1.4 at baseline to 0.9 at 6 months and for women from 1.4 at baseline to 1.3 at 6 months. Pooling male and female data, the CTCAE mean score significantly improved comparing baseline with 6 month scores ($p=0.001$).

Conclusion GI symptom questionnaire scores significantly improved from baseline to 6 months. This suggests that structured gastroenterological evaluation using an algorithmic approach may improve GI symptoms in this patient group, although a controlled study is necessary to confirm this.

Competing interests None declared.

PTU-148 DOES INVESTIGATING CHRONIC GASTROINTESTINAL SYMPTOMS FOLLOWING PELVIC RADIOTHERAPY IDENTIFY TREATABLE DIAGNOSES?

doi:10.1136/gutjnl-2012-302514c.148

¹C C Henson,* ²J McLaughlin, ²Y Ang, ³C Babbs, ⁴J Crampton, ⁴M Kelly, ³S Lal, ⁵J Limdi, ⁶G Whatley, ¹R Swindell, ¹W Makin, ¹S E Davidson. ¹Christie Hospital, Manchester, UK; ²University of Manchester, Manchester, UK; ³Salford Royal Foundation Trust, Salford, UK; ⁴University Hospital of South Manchester NHS Trust, Manchester, UK; ⁵Pennine Acute Hospitals NHS Trust, Manchester, UK; ⁶Tameside Hospital NHS Foundation Trust, Ashton under Lyne, UK

Introduction 17 000 patients are treated with radical pelvic radiotherapy per year in the UK. Although 50% develop significant chronic gastrointestinal (GI) symptoms, <20% are referred for gastroenterological evaluation. We aimed to determine the causes of GI symptoms in this patient group.

Methods 60 patients with GI symptoms ≥ 6 months after radical pelvic radiotherapy were identified from oncology clinics. Those requiring urgent investigation via the 2-week wait pathway were excluded. Baseline characteristics including demographic data, cancer treatment details and symptoms were collected. Patients were referred for gastroenterological evaluation using an algorithmic approach, which involves the identification of all GI symptoms and investigation for all potential causes for the individual symptoms. Details of investigations and diagnoses were collected.

Results 20 men and 36 women with primary gynaecological (31), urological (17) or lower GI (8) tumours were included, with a median age of 58.5 years (range 26.9–81.8). As part of their cancer treatment 15 patients also had brachytherapy, 28 had chemotherapy and 25 had surgery. Patients presented with multiple GI symptoms (median 8, range 4–16) including frequency (46), urgency (52), loose stool (50), faecal incontinence (40), flatulence (43), bloating/distension (38) and rectal bleeding (29). The median number of investigations per patient was 9 (range 1–17), including routine blood tests (47), coeliac screen (39), breath tests for small bowel bacterial overgrowth (21) and lactose intolerance (16), SeHCAT scans (27) and upper (27) and lower (38) GI endoscopy. Common diagnoses include radiation proctopathy (22) and bile acid mabsorption (12). Some diagnoses are unrelated to previous radiotherapy, for example, diverticulosis (9) and colonic polyps (8). No cause was found for symptoms in seven patients. 25 patients have 2 or more GI diagnoses.

Conclusion Gastroenterological evaluation identifies significant and potentially treatable diagnoses in patients who develop chronic GI symptoms following pelvic radiotherapy. Some findings are incidental and some are unrelated to previous cancer treatment. GI symptoms in these patients have historically been considered “untreatable”. These data suggest that structured gastro-

enterological assessment has the potential to improve outcome by identifying these diagnoses and facilitating focussed treatment.

Competing interests None declared.

PTU-149 CAMBRIDGE-MIAMI RISK ASSESSMENT FOR INTESTINAL TRANSPLANTATION

doi:10.1136/gutjnl-2012-302514c.149

¹C Pither,* ²R Sivaprakasam, ³H Takahashi, ³S Nishida, ²A Butler, ³J Moon, ¹M D Dawwas, ⁴S Gabe, ²N Jamieson, ⁵J Woodward, ⁶E Island, ⁶A Tzakis, ¹S J Middleton. ¹Gastroenterology, Cambridge University, Cambridge, UK; ²Transplantation Surgery, Cambridge University, Cambridge, UK; ³Transplantation Surgery, Department of Surgery, University of Miami School of Medicine, Miami, USA; ⁴Intestinal Failure Unit, St Mark's Academic Centre, London, UK; ⁵Gastroenterology, Cambridge University, Cambridge, UK; ⁶Transplantation Surgery, Department of Surgery, University of Miami School of Medicine, Miami, USA

Introduction The Cambridge-Miami (CaMi) preoperative risk assessment score has been previously validated in a small cohort and accurately predicted the survival after intestinal transplantation. We undertook a further validation in a larger cohort of patients.

Methods Co-morbidity and lost venous access are used as putative preoperative risk factors, each scored 0–3 for severity. Patients (72 adults (M:F, 33:39) received an isolated intestinal graft (27), or a cluster graft including intestine (45).

Results Mean (SD) survival was 1501 (1444) days. The Kaplan–Meier analysis of survival revealed a significant inverse association between survival and CaMi score [logrank test for trend, $p<0.0001$]. Patients were grouped into CaMi scores of 0 and 1, 2 and 3, 4 and 5, 6 and above, and HR [95% CIs] for death (compared to group 0+1) was found to increase as the CaMi score increased; 1.945 [0.7622 to 5.816], 5.075 [3.314 to 36.17] and 13.77 [463.3 to 120100] respectively and was significantly greater than group 0+1 at group 4 +5 ($p<0.0001$).

Conclusion The ability to predict survival from the CaMi score might allow better patient selection, and identify patients for earlier transplantation.

Competing interests None declared.

PTU-150 QUALITY OF LIFE BEFORE AND AFTER INTESTINAL TRANSPLANTATION

doi:10.1136/gutjnl-2012-302514c.150

¹C Pither,* ¹S Duncan, ¹H Tinncknell, ¹C Hanson, ¹B Chukualim, ¹J Woodward, ²A Butler, ¹S Middleton. ¹Gastroenterology, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK; ²Transplant Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

Introduction Survival following intestinal transplantation has substantially improved over the last decade and if this trend continues quality of life (QOL) may be considered as a major indication for transplantation. It is important to establish if QOL can be enhanced by transplantation and whether some aspects are more inclined to improve than others.

Methods QOL was assessed using Short form 36 (SF36) in a cohort of consecutive patients who had either been assessed for, undergone or, were awaiting transplantation. Data were scored using validated criteria for different QOL functions. The statistical package SPSS (IBM) was used to analyse the data.

Results 62 data sets were available, 26 pre-transplant and 36 post-transplant. Grouped data showed significantly better physical function ($p=0.03^*$), social functioning ($p=0.01^*$), general health ($p=0.006^*$) and emotional role limitation ($p=0.02^*$) in the

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

doi:10.1136/gutjnl-2012-302514c.151

¹D S Pearl,* ²A Higginson, ¹A Quine. ¹Gastroenterology, Portsmouth Hospitals NHS Trust, Portsmouth, UK; ²Radiology, Portsmouth Hospitals NHS Trust, Portsmouth, UK

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

doi:10.1136/gutjnl-2012-302514c.152

¹E M Quigley,* ²A J Lembo, ³C Diaz, ³J Fortea, ³M Falques, ⁴S Shiff, ⁴K Shi, ⁴H A Schneier, ⁵J M Johnston. ¹University College Cork, Cork, Ireland; ²Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; ³Almirall, Barcelona, Spain; ⁴Forest Research Institute, Jersey City, New Jersey, USA; ⁵Ironwood Pharmaceuticals, Cambridge, Massachusetts, USA

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.

Competing interests E M Quigley Consultant for: Ironwood Pharmaceuticals, A J Lembo Grant/Research Support from: Ironwood Pharmaceuticals. Consultant for: Ironwood Pharmaceuticals/Salix/Prometheus/Aikermes/Ardelyx/GSK/Theravance, Conflict with: Lecture fees from Ironwood Pharmaceuticals, C Diaz Employee of: