

Conclusion In its first two years, IBDQIP has shown increased participation and has proved to be a rapid and effective tool to improve IBD services. The project has now merged with the National IBD Audit and will be rolled out to all IBD services in 2014.

Disclosure of Interest None Declared

PTU-080 DEVELOPMENT AND VALIDATION OF THE CROHN'S LIFE IMPACT QUESTIONNAIRE (CLIQ)

doi:10.1136/gutjnl-2013-304907.172

¹J Wilburn, ¹S P McKenna, ¹J Twiss, ²K Kemp, ²S Campbell. ¹Galen Research Ltd;

²Department of Gastroenterology, Manchester Royal Infirmary, Manchester, UK

Introduction Crohn's Disease (CD) is a chronic, inflammatory, autoimmune disorder that substantially impairs patients' physical and emotional well-being. Despite this there is no CD-specific patient-reported outcome measure (PROM) available for determining the efficacy of alternative interventions for the condition. The objective of the study is to develop and validate the first such patient-reported outcome measure. Questionnaire content was derived from 30 qualitative interviews conducted with UK CD patients. Cognitive debriefing interviews conducted with a new sample of 15 CD patients indicated that the draught scales were relevant, clear and easy to use.

Methods A test-retest postal survey was conducted to; identify the final scales, confirm their unidimensionality (by means of Rasch analysis) and to determine reproducibility and construct validity. A subset of the respondents was sent a second questionnaire package 2 weeks after completing the first. The package included the CLIQ, the Nottingham Health Profile (NHP), the Unidimensional Fatigue Impact Scale (U-FIS) and a demographic questionnaire.

Results The questionnaire package was completed by 273 CD patients (34.4% male; aged 16–79 (mean: 43.9; SD 15.1) years). Of these, 107 also completed the second package. Items were removed from the scales that misfit the Rasch model ($\text{Chi}^2 p > 0.05$), were redundant or displayed differential functioning by gender. Rasch analysis confirmed two unidimensional scales ($p < 0.05$); activity limitations (11 items) and QoL (27 items). Internal consistency was good for both scales (0.93 and 0.91) as was test-retest reliability (0.89 and 0.91 respectively). The CLIQ scales were related (as expected) with the NHP section scores and the U-FIS. It was interesting to note that QoL scores were related to both physical and emotional impairments.

Conclusion The CLIQ is the first scientifically rigorous PROM designed specifically for CD patients. It consists of two unidimensional scales with excellent psychometric properties. It should prove to be a valuable tool for evaluating the impact of CD and its treatment on the patients' perspective.

Disclosure of Interest None Declared

PTU-081 ARE WE EXPOSING PATIENTS WITH A MILDLY ELEVATED FAECAL CALPROTECTIN TO UNNECESSARY INVESTIGATIONS?

doi:10.1136/gutjnl-2013-304907.173

¹J P Seenan, ¹F Thomson, ²K Rankin, ²K Smith, ¹D R Gaya. ¹Gastroenterology; ²Biochemistry, Glasgow Royal Infirmary, Glasgow, UK

Introduction Faecal calprotectin (FC) is increasingly used as a non-invasive marker to differentiate irritable bowel syndrome (IBS) from inflammatory bowel disease (IBD). However, it is a non-specific marker of luminal inflammation and false positives are common. We have previously demonstrated a low yield of diagnostic colonoscopy in patients with borderline elevations of FC (50–100 $\mu\text{g/g}$). Higher FC levels (100–200 $\mu\text{g/g}$) often prompt more extensive investigation. We sought to determine the diagnostic yield of endoscopic/radiological investigation in patients

presenting with new lower GI symptoms and a mildly elevated FC (100–200 $\mu\text{g/g}$).

Methods All patients with a faecal calprotectin 100–200 $\mu\text{g/g}$ were identified from our biochemistry laboratory database between September 2009 and September 2011. Patients aged 16 to 50 years attending gastroenterology outpatient clinics with new lower GI symptoms were identified. Patients were excluded if they had a previous FC > 200 $\mu\text{g/g}$, were taking NSAIDs, had known IBD, positive stool cultures or any 'alarm' symptoms. Details of investigations, diagnosis and clinical outcomes were determined electronically from the NHS Greater Glasgow and Clyde Clinical Portal.

Results 163 patients (104 female) were identified who met the inclusion criteria. The mean age was 37.5 years with a mean FC of 146.6 $\mu\text{g/g}$. The primary presenting complaint was diarrhoea in 100 (61.3%) and abdominal pain in 63 (38.7%). Secondary symptoms were abdominal pain (28.2%), diarrhoea (18.4%) and constipation (1.8%). A total of 390 endoscopic, radiological and histological investigations were undertaken in 152 patients with an average of 2.6 investigations per patient. 131 colonoscopies were performed with abnormalities detected in only 23 (17.6%). In patients with a macroscopically normal upper GI endoscopy and colonoscopy, the diagnostic yield of any further investigation was only 7%. The negative predictive value (NPV) of a FC 100–200 $\mu\text{g/g}$ was 86.9% for any pathology and 98.1% for significant luminal pathology (IBD, advanced adenoma or colorectal carcinoma). IBD was the final diagnosis in only 3 (1.8%) of patients while 48.5% were diagnosed as having IBS.

Conclusion In adult patients under 50 years old presenting with new lower GI symptoms, the NPV of a FC between 100 and 200 $\mu\text{g/g}$ in excluding significant organic GI disease is high. Patients are often extensively investigated yet the overall diagnostic yield is very low and the majority of these patients have functional disease. We suggest that the manufacturer's FC cut off of 50 $\mu\text{g/g}$ of stool is too low for utilisation in clinical practise and often results in unnecessary, invasive investigations.

Disclosure of Interest None Declared

PTU-082 FAECAL INCONTINENCE IN INFLAMMATORY BOWEL DISEASE: WE DON'T ASK AND THEY DON'T TELL

doi:10.1136/gutjnl-2013-304907.174

¹J Duncan, ¹G Sebeos-Rogers, ²O Poole-Wilson, ³C To, ⁴J B Canavan, ¹V Kariyawasam, ¹M Ward, ¹R Goel, ¹K Patel, ¹A Stanton, ¹M Sastrillo, ¹S Anderson, ¹K Taylor, ¹J Sanderson, ¹P Irving. ¹Gastroenterology, Guy's & St Thomas' NHS Foundation Trust; ²South London Healthcare Trust, London, UK; ³Australian National University, Canberra, Australia; ⁴Kings College London, London, UK

Introduction The deleterious effect of faecal incontinence (FI) on quality of life (QOL) is well documented. People with FI experience stigma, embarrassment and social exclusion, and report adverse effects on activities and relationships. Restoration of continence is associated with improvement in QOL. Diarrhoea is associated with increased prevalence of FI and, therefore, people with inflammatory bowel disease (IBD) are at risk.

Methods To investigate how frequently health care professionals (HCPs) assess FI in a cohort of patients with IBD we performed a cross sectional survey of 380 adults attending a tertiary referral IBD clinic. Patient surveys were: the validated ICIQ-B questionnaire, detailing frequency and severity of bowel pattern, control and quality of life; and the non-validated Bowel Leakage Questionnaire, detailing any prior interventions by health care professionals. Demographics of age, gender, diagnosis, Montreal classification, St Mark's Continence Score and disease activity were also recorded. Data was entered into a database and analysed using SPSS statistical package.

Results 229/380 (60%) had Crohn's Disease (CD) and 180/380 (47%) were female. Median age was 38 years (IQR:31–50) with a median disease duration of 8.7 years (3.4–15.1). 343/380 (90%) had

experienced incontinence of flatus or faeces while 255/380 (67%) reported FI. Only 136/380 (36%) had been asked about FI during an encounter with a HCP. Of the people who had been asked about FI, the vast majority had been asked in IBD clinics (130/136, 96%). Fewer enquiries were made by HCPs in a primary care setting with 42/136 (31%) people having been asked by a family doctor and 12/136 (9%) by a practise nurse. A minority of patients spontaneously volunteered information about incontinence to a healthcare professional (146/380, 39%). Of the people who had discussed continence issues with a HCP, 55 (38%) were offered specific advice or referral for treatment. Those who volunteered information regarding continence had worse ICIQ-B control scores (9 (6–14) vs 3 (1–8), $p < 0.0001$) and quality of life scores (16 (11–20) vs 9 [6–14], $p < 0.0001$), reflecting greater burden of disease.

Conclusion Faecal incontinence is common in IBD. It is both under-reported by patients and under-recognised by healthcare professionals. Because symptoms and QOL can be significantly improved with appropriate intervention, HCPs need to enquire about FI as part of routine assessment.

Disclosure of Interest None Declared

Liver

PTU-083 BILIARY MICRORNA MARKERS IN BILE AID THE DIAGNOSIS OF CHOLANGIOCARCINOMA AT ERCP

doi:10.1136/gutjnl-2013-304907.175

^{1,2}A Zabron, ²A Frampton, ³J Krell, ³J Stebbing, ³L Castellano, ¹S Khan, ²L Jiao. ¹Hepatology and Gastroenterology Section, Department of Medicine; ²HPB Surgical Unit, Department of Surgery and Cancer; ³Division of Oncology, Department of Surgery and Cancer, Imperial College, London, UK

Introduction Cholangiocarcinoma (CCA) is a primary biliary ductal cancer which is often difficult to diagnose and which carries a poor prognosis. New diagnostic tests are urgently needed to improve patient outcome. Bile is a rich source of potential novel biomarkers for CCA, due to its intimate proximity to the malignant lesion. However, there are no biliary biomarkers for CCA currently available.

MicroRNAs (miRNAs) are key post-transcriptional regulators, and influence tumorigenesis. Studies on cell lines and tissue have identified several potential miRNA signatures for CCA, and recently miR-9 was identified as elevated in bile from CCA compared with benign disease¹.

In this study we aimed to measure specific miRNA expression in bile from patients with CCA, gallstone disease and pancreatic adenocarcinoma (PA) and to assess their performance in differentiating these causes of biliary obstruction.

Methods Bile was collected at endoscopic retrograde cholangiopancreatography (ERCP) from patients with CCA (n = 6), PA (n = 10) and gallstones (n = 8; benign control). Bile was prepared as previously described¹ and total RNA was isolated using TRIzol (Invitrogen, Paisley, UK). Quantitative real-time reverse-transcription polymerase chain reaction (RT-qPCR) was performed using Taqman mature miRNA primers and probes (Applied Biosystems, Cheshire, UK). Expression of oncomiR-21, miR-155 and miR-106a was measured. Cycle passing threshold (Ct) was recorded and normalised to RNU6B expression. Relative expression was calculated as $2^{Ct_{miRNA} - Ct_{RNU6B}}$. PCR reactions were carried out in duplicate.

Results MiR-106a and oncomiR-21 were highly expressed in bile from patients with CCA compared to those with gallstones. MiR-155 was not significantly upregulated in malignancy. In discriminating CCA from benign disease, miR-106a had sensitivity and specificity of 83.3% [95% CI 36–100] and 88% [95% CI 47–100] respectively, with an AUC of 0.83 (cut-off level > 6.05). OncomiR-21 was also upregulated in the bile of both tumour types, but was not

as reliable. Neither miRNA discriminated significantly between PA and CCA.

Conclusion MiRNA can be reliably isolated from bile pellets. Both miR-106a and oncomiR-21 are potential novel biliary biomarkers for CCA, and could improve differentiation of benign from malignant disease at ERCP. Further work is required to validate these findings in a larger cohort and against other disease groups, and to investigate possible correlations between miRNA profile and disease course.

Disclosure of Interest None Declared

REFERENCE

- Shigehara K, Yokomuro S, Ishibashi O, *et al.* Real-time PCR-based analysis of the human bile microRNAome identifies miR-9 as a potential diagnostic biomarker for biliary tract cancer. *PLoS one*. 2011; 6(8):e23584.

PTU-084 TREATMENT OF HEPATITIS C THROUGH AN IN-PRISON SPECIALIST CLINIC

doi:10.1136/gutjnl-2013-304907.176

¹A Shalabi, ¹A G Lim, ¹L T Tan. ¹Gastroenterology, Epsom and St. Helier University Hospitals NHS Trust, Epsom, UK

Introduction There is a high prevalence of hepatitis C virus (HCV) among inmates in UK prisons. Treatment of prisoners in hospital clinics proved to be logistically complex and expensive and resulted in high levels of treatment failures. Our aim was to establish specialist hepatitis C treatment clinics entirely within prison facilities and to evaluate their efficacy.

Methods Clinics were established in two prisons, HMP High Down (Capacity of 1103 inmates) and HMP Downview (capacity of 364 inmates) and run twice a month. The specialist team collaborated with the prison healthcare team to diagnose, investigate and treat HCV entirely within the prison setting. Link nurses would refer inmates with positive antibodies for further investigation including detailed virology and ultrasound scan. Suitable patients were offered treatment and monitored for progress and side effects.

Results 163 inmates with an average age of 40 were referred to the clinic. 62.6% were females and 37.4% were males. 73 patients received genotyping, 50.68% were genotype 1, 43.84% were genotype 3, 2.74% were genotype 2 and 2.74% were genotype 4. Out of the patients who completed treatment data is available on 58%. To date, 85% of patients who completed treatment tested negative after completion of treatment (EOT). 100% of patients who received follow-up testing achieved a sustained viral response (SVR) at 6 months. 9.5% of patients withdrew from treatment because they left prison. 1 patient withdrew as a result of side-effects (severe thrombocytopenia).

Conclusion An in-prison treatment service reduced the number of failed attendances at our hospital service. We were very successful in completing therapy for patients serving longer sentences in prison with good eradication rates. As the prison population is mobile, more effective collaboration between different prisons and community teams are needed to improve treatment and follow up of HCV infected prisoners.

Disclosure of Interest None Declared

REFERENCES

- Department of Health. Hepatitis C Strategy for England, 2002. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4059510.pdf (accessed 21 October 2012).
- Skipper C, Guy JM, Parkes J, Roderick P, Rosenberg WM. Evaluation of a prison outreach clinic for the diagnosis and prevention of hepatitis C: implications for the national strategy. *Gut* 2003; 52: 1500–1504.
- Vescio MF, Longo B, Babudieri S, Strinini G, Carbonara S, Rezza G, Monarca R. Correlates of hepatitis C virus seropositivity in prison inmates: a meta-analysis. *J Epidemiol Community Health* 2008; 62: 305–313.