

severity*10%risk":0.355; coef."moderate severity *10% risk":0.112; coef."severe severity *10% risk":-0.246; coef."mild severity *40% risk":0.165; coef."moderate severity *40% risk":-0.116; coef."severe severity *40% risk": -0.271. **CONCLUSIONS:** The DCE could prove that the included hepatitis C patients have different preferences with respect to the probability of risk relative to the severity of different side-effects. In all significant characteristics the dominance for less severity and less risk could be proven and both aspects were taken into account when making treatment decisions. For the first time compound side-effect attributes have been applied in a preference elicitation method and detected corresponding differences within patient preference measures.

PGI43

HEALTH RELATED QUALITY OF LIFE (HRQL) IN PATIENTS WHO HAVE UNDERGONE COLECTOMY FOR ULCERATIVE COLITIS: IMPACTS OF COMPLICATIONS POST-SURGERY

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OBJECTIVES: Ulcerative colitis (UC) management aims to reduce symptoms associated with the disorder as well as inducing and maintaining remission. Surgery is typically considered in severe or refractory UC patients who have not responded to maximal treatment. This study evaluated HRQL following surgery, along with experience and severity of complications, including those experienced in the longer-term. **METHODS:** UK adult UC patients (n=202) who had undergone bowel surgery completed an online survey including EQ-5D-5L utility assessment, Work Productivity and Activity Impairment (WPAI), Inflammatory Bowel Disease Questionnaire (IBDQ), post-surgical complications, and Female Sexual Function Index (FSFI) or International Index of Erectile Function (IIEF). **RESULTS:** Over 58% of participants were >1 year post-surgery. Mean EQ-5D utility for the overall sample was 0.74. Mean utility was significantly higher in those who reported no complications post-surgery than in those who did (0.90 vs 0.71; p<0.001). The most commonly reported symptoms since surgery were increased fatigue (56%), abdominal pain (42%), and increased stool frequency (31%). Participants with complications had reduced HRQL across bowel symptoms, systemic symptoms, emotional functioning and social functioning IBDQ domains. They also reported more work time missed, greater impairment while working and greater overall impairment of regular activities due to UC than those without complications. Of those responding about sexual function, FSFI scores for 68% of female participants indicated sexual dysfunction and IIEF scores for 52% of male participants indicated at least mild erectile dysfunction. A marked decrease in utility by IBDQ disease severity was observed: those classified as having severe disease had lower scores than those classified as being in remission (0.52 vs 0.88). **CONCLUSIONS:** Although surgery for UC is intended to be curative, IBDQ and EQ-5D data suggest that HRQL may not return to normal levels. These results may be related to severity of ongoing fatigue, bowel and sexual function problems.

PGI44

SYSTEMATIC LITERATURE REVIEW OF HEALTH-RELATED QUALITY OF LIFE IN PATIENTS RECEIVING PARENTERAL NUTRITION

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OBJECTIVES: Short bowel syndrome (SBS) is a rare, complex clinical condition that results from loss of intestinal absorptive capacity. Parenteral nutrition (PN) is often needed to maintain clinical status in patients with SBS. Teduglutide reduces, and in some cases eliminates, patients' dependency on PN. PN is not exclusively used in patients with SBS and, since robust utility data is often difficult to collect for rare conditions due to limited patient numbers, a wider body of published literature reporting a link between PN and health-related quality of life (HRQL) was considered. We assessed if an acceptable body of evidence was available to determine the HRQL impact associated with the use of PN that could support an assessment of the potential impact of reduced PN using teduglutide. **METHODS:** Searches were performed using MEDLINE, MEDLINE In-Process and Cochrane Library. Additionally, hand searches were performed at targeted conferences. Of 2,724 studies screened, 76 met the inclusion criteria: adults receiving PN for longer than 6 months and reported utilities or other HRQL data. **RESULTS:** Patients receiving PN were shown to have lower HRQL than the general population. HRQL was shown to increase at initiation of PN, compared to the pre-PN state. However, discontinuation of PN and intestinal transplantation (ITx) were associated with further improvements in HRQL. Trends associating increased number of PN complications, PN volume and PN frequency with lower HRQL were also identified. **CONCLUSIONS:** Improvements in HRQL achieved by discontinuing PN and ITx suggest that weaning patients with SBS off PN could increase HRQL. These, along with results of an ongoing vignette study in patients with SBS, may allow quantification of the HRQL associated with the use of teduglutide in SBS.

PGI45

TRANSLATABILITY ASSESSMENT AND LINGUISTIC VALIDATION OF THE PATIENT-REPORTED OUTCOME INSTRUMENT FOR IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D PRO)

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OBJECTIVES: Following the 2009 FDA Guidance, a new PRO instrument was developed to support endpoints in multinational clinical trials assessing IBS with diarrhea (IBS-D) symptom severity. Our objective was to assess the translatability of the IBS-D PRO instrument into ten languages, and subsequently perform a cultural adaptation/linguistic validation of the questionnaire into US Spanish and Japanese.]

METHODS: Translatability assessments of the US English version of the IBS-D PRO were performed by experienced PRO translators who were native speakers of each target language and currently residing in-country. Languages included: Chinese (China); Dutch (Netherlands); French (Belgium); German (Germany); Japanese (Japan); Polish (Poland); Portuguese (Brazil); Russian (Russia); Spanish (Mexico); and Spanish (US). The project team assessed the instrument to identify potential linguistic and/or cultural adaptation issues. After the identified issues were resolved, the instrument was translated into Spanish (US) and Japanese through a process of two forward translations, one reconciled translation, and one back translation. The project team reviewed the translated versions before the instruments were evaluated by cognitive debriefing interviews (CDIs) with samples of five Spanish (US) and five Japanese IBS-D patients. **RESULTS:** A few linguistic and cultural adaptation concerns were identified during the translatability assessment as requiring minor revisions: mainly the presentation of dates/times and word structure. During the CDIs, two out of five Spanish respondents misunderstood the term "bowel movement" to mean only diarrhea in the Spanish version. Consequently, the term was changed from "movimiento intestinal" to "evacuaciones." None of the Japanese respondents identified issues with the Japanese version. **CONCLUSIONS:** The translatability of the IBS-D PRO instrument into ten target languages was confirmed, with only minor changes made to the translations of the instrument. The translation and linguistic validation into Spanish (US) and Japanese provide evidence that this instrument can be used in multinational trials and clinical settings.

PGI46

DEVELOPMENT OF A VALIDATED QUESTIONNAIRE EVALUATING THE BURDEN OF THE HAEMORRHOIDAL DISEASE AND ANAL FISSURE (HEMO-FISS)

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OBJECTIVES: The haemorrhoidal disease is a frequent and chronic illness. The anal fissure is the second reason of proctologic medical visits. At the moment, there is only a clinical score measuring the grade of the haemorrhoids, but the impact of the disease on the patients' quality of life is not evaluated. The objective of this study is to validate a specific questionnaire to evaluate the burden of the haemorrhoidal disease and anal fissure (HEMO-FISS) on the patients' daily life. **METHODS:** The questionnaire HEMO-FISS, including 38 questions, has been submitted to patients suffering from a haemorrhoidal disease or an anal fissure and, consulting a participating proctologist in France during the study period (2012-2014). The psychometric properties were evaluated by testing the acceptability, construct validity and reliability. A principal component analysis (PCA) using Varimax rotation, a Spearman correlation coefficient with SF-12 and PGWBI and a multi-trait analysis (MTA) were conducted to assess the construct validity of the questionnaire. The reliability was evaluated using Cronbach's alpha coefficient (CAC). Backward Cronbach alpha curves (BCAC) were drawn. **RESULTS:** A total of 256 patients were included in the study. Following the factor analysis, four dimensions were defined: physical disorders, psychology, troubles defecating and sexuality. The number of questions was reduced from 38 to 28. Item reduction was based on MTA and BCAC. A strong correlation was observed between SF-12 and the dimensions regarding physical disorders (with PCS) and psychology (with MCS). The Cronbach's coefficient (all > 0.7) reflected a good internal consistency of the different dimensions of the questionnaire. **CONCLUSIONS:** The questionnaire HEMO-FISS displays good properties to evaluate the burden of haemorrhoids and anal fissures. Consecutive to this preliminary validation, a graded response model (GRM) will be developed to precise the unidimensionality of each dimensions.

PGI47

NUTRITIONAL ASPECTS AND DISINFORMATION IN LIVER DISEASE: A QUESTIONNAIRE-BASED SURVEY IN ITALIAN PATIENTS

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OBJECTIVES: The study focused on a secondary aspect of liver diseases, never investigated in Italy so far. The study purpose was in fact to obtain the patients' perception about the role of nutrition during the disease phases and in general for liver welfare, with the final aim of understanding the importance given to nutrition by patients and the current disinformation to be possibly tackled. **METHODS:** EpaC is the most important Italian NGO for hepatopathic patients. An anonymous web-based questionnaire was published on the association website www.epac.it. It was composed of multiple choice and open questions investigating the general info of the patient, health state, and opinions/perceptions about nutritional aspects. **RESULTS:** 483 patients participated the survey. The profile of participants was assessed concerning sex, age, health condition, presence of cirrhosis. Mean age was 52.9 (min 24 - max 80), 60% males, 76% HCV-positive, 15% cirrhotic. 99% knew alcohol can damage the liver and 86% answered that any alcohol quantity is potentially harmful (79% do not assume alcohol and 62% go on after being cured). Besides alcohol, other foods believed to be harmful to liver are all fried foods, salami, sugar and sweets, meat (in particular red meat), cheeses (above all fat cheeses). Although in low percentages, 5% and 13% respectively consider vegetables and fruit as harmful. Moreover, 53% think a vegan/vegetarian diet is essential, but 81% would like to have a specialist nutritional advice. **CONCLUSIONS:** Considering that nutritional aspects are important in everybody's life, they are particularly relevant in case of liver disease. The results shown express patients' degree of knowledge about these aspects and highlights that a certain disinformation is widespread. The results also point out liver-suffering patients' need to receive clinicians' evidence-based advice/information on nutrition and lifestyle as part of the routine counselling and to develop an educational campaign on nutrition for hepatopathic patients.

PGI48

HEALTH-RELATED QUALITY OF LIFE, WORK PRODUCTIVITY, AND DAILY ACTIVITY AMONG A SAMPLE OF COMMERCIALY INSURED PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION OR CHRONIC CONSTIPATION IN THE UNITED STATES

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OBJECTIVES: To assess the impact of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) on health-related quality of life (HRQOL), work and daily activity among US commercially-insured patients. **METHODS:** Consenting survey-eligible patients ≥ 18 years identified from the HealthCore Integrated Research Database completed a cross-sectional survey. IBS-C cases that had ≥ 1 IBS claim and either ≥ 2 constipation claims or ≥ 1 constipation claim and ≥ 1 constipation-related pharmacy claim and CC cases that had ≥ 2 constipation claims ≥ 90 days apart or ≥ 1 constipation claim and ≥ 1 constipation-related pharmacy claim ≥ 90 days apart were included. Controls were matched on age, gender, region, plan type and insurance status. Only cases meeting and controls not meeting modified Rome III criteria completed the survey. Short Form-12 v2 physical component summary (PCS) and mental component summary (MCS) [range: 0-100; US normative mean=50] and EuroQol-5D (EQ-5D; range: 0=death to 1=perfect health) assessed HRQOL. Work Productivity and Activity Impairment Questionnaire (General Health version) assessed absenteeism, presenteeism and daily activities (higher percentages indicate greater impairment). Indirect costs were calculated based on overall work productivity loss (absenteeism+presenteeism) using the human capital method. **RESULTS:** Among 354 respondents (177 IBS-C/CC cases, 177 controls; mean age 46 \pm 15 years; 86% female; 66% employed), mean PCS and MCS scores were lower for cases versus controls (mean differences: 8.9 (p<0.01), 6.8 (p<0.01), respectively). EQ-5D mean utility score was lower among cases versus controls (0.7 versus 0.9; p<0.01). Cases also had greater overall work productivity loss (28% versus 12%; p<0.01) and activity impairment (39% versus 15%; p<0.01). Estimated indirect costs were \$108 higher per employed respondent/week for cases versus controls (p<0.01). **CONCLUSIONS:** IBS-C/CC patients reported lower HRQOL and greater impairments in work and daily activity compared with matched controls. Treatments that effectively manage IBS-C/CC symptoms may improve these outcomes in IBS-C/CC patients.

PGI49

MODELS OF THE IMPACT OF MAJOR LIVER DISEASES ON EQ-5D VISUAL ANALOGUE SCALE AND UTILITY-INDEX: CONVERGENCES AND DIVERGENCES

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OBJECTIVES: Liver diseases (LDs) can reduce health-related quality-of-life (HRQoL), with an important impact on the burden of LDs. Our aim was to analyze the impact of the major LDs on EQ-5D Visual Analogue Scale (VAS) and utility-index (UI) through different regression models, using HRQoL of the general population as a reference. **METHODS:** HRQoL data were measured using the EQ-5D-3L in a sample of patients with 9 major LDs enrolled during 2011-2012 in a multicenter study conducted in the most populated region of Italy, Lombardy. Such data were added to those recorded in 2013 on a representative sample of Lombardy general population. Relationships between the outcomes of interest (VAS and UI) and LDs were explored through ordinary least squares (OLS) and Tobit regression, that accounts for ceiling effect, adjusting for age and gender. Goodness-of-fit was assessed through R2 (OLS) and pseudo-R2(Tobit). **RESULTS:** The sample included 9,817 subjects (3,017 with LDs). OLS and Tobit regressions performed similarly on VAS (R2:0.13,pseudo-R2:0.12) and estimated the largest and significant HRQoL reduction in patients with decompensated cirrhosis (DC), followed by those with autoimmune hepatitis (AIH) and hepatocellular carcinoma (HCC). As for UI, the Tobit model performed better than OLS regression (R2:0.11,pseudo-R2:0.15), with the highest decrease estimated in patients with DC, followed by those with HCC and compensated cirrhosis. **CONCLUSIONS:** The Tobit model performed slightly better than OLS regression on the UI, but not on VAS, maybe due to a stronger ceiling effect in UI. This distributional difference mirrors different data-generation mechanisms: UI is derived from the EQ-5D-3L domains, while VAS is reported by patients. Therefore, VAS and UI might capture different aspects of HRQoL, as supported by our results, that show how the same LD can be differently associated with VAS and UI (e.g.: AIH seemed to have an impact on VAS only, while HCC on UI only).

PGI50

LIFE QUALITY OF YOUNG ADULT PATIENTS WITH INFLAMMABLE BOWEL DISEASE

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OBJECTIVES: The number of patients over 19 years with registered inflammable bowel disease which has non-infectious origin is duplicated in the last 16 years (KSH 2013). Our aim is to get a picture about the different dimensions of life quality in the course of the chronic disease. **METHODS:** Cross-sectional, quantitative examination was carried out between 15.07.2014 and 31.12.2014 at the Clinical Centre of the University of Pécs. Patients with M Crohn and ulcerative colitis between the age of 18 and 46 were selected with non-randomized, convenience sampling method. For data collection we used standard questionnaires (Illness Intrusiveness Rating Scale, IBDQ, Coloplast life quality questionnaire) and questions about demographic data (N=103). We used Microsoft Excel 2013 software to carry out descriptive statistics, two-sample t-test and χ^2 -test (p<0.05). **RESULTS:** The age of the patients were between 31.03 \pm 8.18. Illness Intrusiveness Rating Scale (the effect of the disease on role efficiency) was evaluated more unfavourable by the patients with ulcerative colitis (p<0.05). Average life quality is not affected by gender (p=0.21), marital status (p=0.15), te type of the disease (p=0.77), and employment status (p=0.75).

Patients with stoma evaluated their life quality only with 42.33 points from the overall 80. **CONCLUSIONS:** Patients with intestinal diseases are defatigable, and have abdominal problems frequently. In case of ulcerative colitis the burden of disease is higher, life quality is less favourable. Stoma negatively affects life quality. The residence is significantly affected by the disease burden and quality of life.

PGI51

THE DEMOGRAPHIC ASPECTS OF TURKISH CHRONIC HEPATITIS C PATIENTS AND THE TREATMENT INITIATION FROM A PHYSICIAN'S & PATIENT'S POINT OF VIEW. FIRST INTERIM ANALYSIS OF TURKISH DATA FROM MOSAIC STUDY (AN INTERNATIONAL MULTICENTER PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE EPIDEMIOLOGY, HUMANISTIC AND ECONOMIC OUTCOMES OF TREATMENT FOR CHRONIC HEPATITIS C VIRUS)

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OBJECTIVES: Chronic Hepatitis C Virus (HCV) infection negatively impacts the patient's quality of life. Interferon (IFN) based therapy has been the standard of care for many years yet antiviral therapy of HCV has rapidly evolved since the introduction of direct acting antivirals (DAA). This report is based on Turkish Mosaic Study. The objective is to characterize patients with chronic HCV and assess the impact of IFN-containing treatment on health related quality of life, work related productivity and activities of daily living and health care utilization. **METHODS:** MOSAIC is an international prospective multicenter observational study that is conducted in 20 countries. Consecutive patients with chronic HCV who initiated an IFN based treatment within 12 weeks were followed for 48 weeks. Patient characteristics, co-morbidities, treatment history, HCV genotype and clinical status were recorded. The response type recorded for previous treatment as null response, relapse, discontinued and partial response. **RESULTS:** Ninety one of 152 patients were treatment naïve, and the 61 were treatment experienced. Relapse was the dominating response type (50%). GT1 patient ratio was 65,8%, non GT1 patient was 5,9%, and 28% of patients were unknown at the date of the report. 42.8% of patients were male, the mean age was 55.1. The physicians have not recommended treatment for 73.6% of patients, and 16.4% of patients rejected the treatment. The leading reasons for physicians and the patients were "waiting for IFN-free treatment option" is followed by "presumed tolerability issue". **CONCLUSIONS:** IFN based therapy has been the standard of care for CHC infection for many years yet the antiviral treatment paradigm of HCV has rapidly evolved since the introduction of IFN-free direct acting antivirals. Higher efficacy with less side effects seems to improving the standard of care.

GASTROINTESTINAL DISORDERS - Health Care Use & Policy Studies

PGI52

DIAGNOSIS AND MANAGEMENT OF MODERATE-TO-SEVERE IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN GERMANY: RESULTS FROM THE IBS-C STUDY

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OBJECTIVES: This is the first study to assess the diagnostic and therapeutic management of moderate-to-severe IBS-C in six European countries (France, Germany, Italy, Spain, Sweden and UK). Here we present the diagnosis and management results from Germany. **METHODS:** Observational 12-month study (6 months retrospective and 6 months prospective) in patients diagnosed with IBS-C (Rome-III criteria) in the last five years and moderate-to-severe disease severity at inclusion (IBS-Symptom Severity Scale (IBS-SSS) score ≥ 175). One of the main objectives was to determine healthcare resource utilisation (HRU) and costs prior to and after an active phase of the disease. **RESULTS:** 102 patients were included (43% severe, mean age [±SD] 47.6 \pm 18.1 years old, 83.3% female). Mean time since diagnosis: 4.6 \pm 8.4 years; mean symptom duration: 15.0 \pm 16.9 years. Diagnostic procedures since the onset of symptoms were highly variable: the most common were colonoscopies(78.4%), blood tests (65.7%), and abdominal ultrasounds(62.7%). The main associated comorbidities were insomnia(31.4%), hypertension(28.4%), chronic pain (27.5%), depression(27.5%), and gastroesophageal reflux disease (GERD; 27.5%). 66.7% of patients had an average of 4.0 \pm 2.5 diagnostic tests during follow-up and 71.6% took prescription drugs (54.9% for IBS-C). The most common medication groups were laxatives (35.6%), prokinetics (23.3%), antispasmodics (15.1%), and analgesics (11.0%). Overall, 69.6% of patients took non-prescription drugs for their IBS-C (32.4% laxatives and 19.6% herbal medicine) and 27.5% of patients sought complementary therapies. Overall, improvement in symptom severity (IBS-SSS total score \pm SD) was observed between baseline (288.3 \pm 78.8) and the 6-month visit (228.1 \pm 9.1). **CONCLUSIONS:** Patients with moderate-to-severe IBS-C often remain undiagnosed for over 10 years and undergo a variety of diagnostic procedures. Chronic comorbidities are frequent. Despite a high use of both prescription and non-prescription drugs, mean symptom severity did improve but remained "moderate" overall.

PGI53

CLINICAL CHARACTERISTICS AND PATTERNS OF CARE AMONG PATIENTS WITH GENOTYPE 1 (G1) HEPATITIS C VIRUS IN EUROPE (EU)

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OBJECTIVES: Assess clinical characteristics and patterns of care among patients with G1 Hepatitis C virus (HCV) in EU. **METHODS:** A multi-center retrospective chart-review study of HCV patients was conducted in the EU (France/Germany/Italy/Spain/UK) in 4Q2014 to collect de-identified data on diagnosis, clinical