

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.

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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% know 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.