response to bowel cleansing products, and to assess the psychometric and scaling properties of the new measure. METHODS: Instrument content was derived via qualitative interviews conducted with patients in the UK. Face and content validity were assessed via patient cognitive-debriefing interviews. Psychometric and scaling properties were assessed via a survey. Patients completed the BOCLIR and demographic questions prior to colonoscopy. Item response theory (Rasch analysis) was employed for item reduction and unidimensionality. Internal consistency and construct validity (association of BOCLIR scores with known factors) were also assessed. RESULTS: Qualitative interviews (n = 40/58% M) highlighted key areas of patient concern as: satisfaction with the bowel cleanser, impairments (adverse events) and activity limitations. A draft questionnaire was constructed comprising three scales addressing these areas. Cognitive-debriefing interviews (n = 1963% M) demonstrated BOCLIR’s acceptability, relevance, clarity and ease of completion. Survey sample: n = 166/52% M, mean age 34.3 SD 15.2 years. Application of Rasch analysis removed misfitting or redundant items. Final scales fit the Rasch model as indicated by non-significant $\chi^2$ p-values (p > 0.13 for all scales), confirming unidimensionality. Cronbach’s alpha coefficients were high indicating good internal consistency; Satisfaction 0.84, Impairments 0.77, Activities 0.94. There were significant differences in BOCLIR scores between patients based on their willingness to use the product in future and on ease of drinking the full preparation (p < 0.01). For Impairments and Activities scales significant differences were also observed between patients dependent on how well they felt and satisfaction with the preparation (p < 0.001). CONCLUSIONS: The BOCLIR is a new questionnaire comprised of unidimensional scales (satisfaction, impairments and activities) with good psychometric and scaling properties. The BOCLIR will allow accurate assessment of patients’ response to bowel cleansing preparations.

QUALITY OF LIFE (HEALTH-RELATED UTILITY) IN ADULTS WITH ULCERATIVE COLITIS IN REMISSION VS. MILD/ MODERATE AND SEVERE RELAPSE: FINDINGS FROM THE PODIUM STUDY

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OBJECTIVES: Ulcerative colitis (UC) is a chronic inflammatory condition characterised by remission and relapse. Although UC disease severity is a strong predictor of quality of life, the impact of disease relapse on health-related utility compared to remission has never been characterised. It has been found that at 12 months, 71% of subjects remained in remission on once daily mesalazine (Pentasa; 1x2g) vs. 59% in twice-daily mesalazine (2x1g), p = 0.024, using Kaplan Meier analysis (Diggsn, 2007). METHODS: The purpose of this study was to examine quality of life by estimating changes in health-related utility associated with transition from a remitting to relapsing states in adults with established UC. Data were analysed from the Phase-3 PODIUM trial (Pentasa Once Daily In Ulcerative colitis for Maintenance of remission). Patients were classified into the following disease states at baseline and at 12 months based on their UC disease activity index (UC-DAI): remission, $\geq$2; mild/moderate relapse, 3–8; and severe relapse, $>9$. Health utility was estimated by Monte Carlo bootstrap simulation using a response mapping algorithm to predict EQ-5D domain response from UC-DAI item scores and applying the UK tariff for preference based utility.

RESULTS: Evaluable data were available for 359 patients, 53% of whom were male, with a mean age at screening of 48 years (SD $\pm$ 15). At baseline, all patients were in remission and had a mean EQ-5D index of 0.945 (SD $\pm$ 0.023). At 12 months, 73.8% of patients remained in remission, 22.6% were in mild/moderate relapse, and 3.6% were in severe relapse. There were no baseline differences between patients relapsing or remitting at 12 months; however, significant differences in utility emerged at 12 months. For patients in remission at 12-months, their mean utility was 0.940 units (95%CI 0.937–0.943), whilst for mild/moderate relapsing cases their mean utility was 0.775 units (95%CI 0.751–0.800) and 0.660 units (95%CI 0.595–0.725) for those in severe relapse (p < 0.001). CONCLUSIONS: Patients with relapsing UC showed considerable decrease in health-related utility consistent with disease severity. Patients in mild/moderate relapse had health-related utility comparable to those with cardiac dysrhythmia (0.774) or gout (0.771), whilst severe relapsing patients had similar disutility to those with emphysema (0.663) or renal failure (0.651). Maintenance treatments that prolong the UC remission phase are likely to have substantial benefits on health related utility.

FURTHER VALIDATION OF THE GASTROINTESTINAL SHORT FORM QUESTIONNAIRE (GSFQ) IN THE SPANISH POPULATION

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OBJECTIVES: Additional validity evidences have been gathered to support the adequacy of the Gastrointestinal Short Form Questionnaire (GSFQ) adapted to (Iberian) Spanish culture. The GSFQ questionnaire is a specific HRQoL instrument which measures the impact of Gastroesophageal Reflux Disease (GERD) symptoms. If the GSFQ is to be a valid measure of patient’s HRQoL it should be possible to stratify and discriminate patients using the questionnaire score as criteria. METHODS: A national representative sample of GERD patients was selected, stratified by gender, age (<45, $\geq$45 years) and GERD severity (0-I, II-IV Savary-Miller score) for validation purposes. Age, gender, BMI, GERD diagnose, GERD severity, associated comorbidities and risk factors were recorded. GSFQ, EuroQol, and the corresponding Visual Analogue Scale (VAS) were answered by patients. A semantic reduction of reported comorbidities was carried out to attain a final clustering of pathologies. Using the GSFQ score as a continuous independent criteria, several segmentation models were studied with different sets of predictive variables.CHAID and CR&T tree growing algorithms were used. Obtained stratum profiles were further explored on non-significant variables in the search of multicolinearity and surrogates. RESULTS: A total of 3997 patients were recruited by 490 clinicians. Mean age was 49 ($\pm$14.4) years and 48.4% were women. Reported comorbidities were clustered in 6 antecedents and 15 concomitant pathologies. Although hypertension was the most frequent comorbidity (15.8%) only a small relation with other pathologies was found (mainly with Diabetes, Dyslipemia, Osteoarthritis and Hypercholesterolemia). The best stratification predictor of mean GSFQ score was the EQ-5D utility score. GERD severity, EQ-5D VAS QoL, alcohol consumption, tabaquism, age, carbonic beverage consumption depression and Osteoarthritis were also significant predictors at different tree levels. CONCLUSIONS: The Spanish version of the GSFQ is sensitive to differences between patients with respect to HRQoL, comorbidities and several risk factors. Surprisingly, some risk factors which had no simple direct effect on GSFQ scores were significant in combination with other segmentation criteria at lower tree levels.