on therapy used more health care resources and were more costly during the 12-month observation period.

PGI24

BURDEN OF GASTROESOPHAGEAL REFLUX DISEASE AMONG PATIENTS WITH PERSISTENT SYMPTOMS DESPITE PROTON PUMP INHIBITOR THERAPY: AN OBSERVATIONAL STUDY IN FRANCE

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OBJECTIVES: Proton pump inhibitors (PPIs) are the treatment of choice for gastro-esophageal reflux disease (GERD), yet many patients experience persistent symptoms. To date, the burden of illness (BoI) among partial responders to PPI treatment is not well understood. **METHODS:** REMAIN-France was a multicentre, 12-month prospective study of adults with GERD who were newly identified as partial responders to optimised PPI treatment. BoI was evaluated at baseline, 3, 6, 9 and 12 months via patient-completed questionnaires, including the Reflux Symptom Questionnaire with 7-day recall (RESQ-7). Medical evaluations were completed at baseline, 6 and 12 months. Healthcare consumption was evaluated in terms of visits to a primary care physician (PCP) and gastroenterologist, number of endoscopies and days on prescribed GERD medication. All analyses were descriptive. **RESULTS:** A total of 262 patients were enrolled (mean age, 54y; 40.5% men), the majority of whom (n=226, 86%) completed the 12-month study. Using the RESQ-7 questionnaire, 32% of patients reported severe symptoms and 48% reported daily symptoms at baseline despite PPI treatment. Whilst continuing to receive prescribed GERD medication (most commonly daily PPIs), symptoms remained burdensome at 6 and 12 months and indicated a positive relationship with impaired quality of life (SF-36, EQ-5D) and decreased work productivity (WPAI-GERD). Between baseline and 6 months, the mean number of visits to a PCP and gastroenterologist among all patients was 1.9 and 0.5, respectively. For 7-12 months' follow up the corresponding figures were 1.8 and 0.4, respectively. A total of 12 patients (4.6%) underwent endoscopy in the first 6 months of follow-up; thereafter, 10 patients (3.9%) underwent endoscopy between 7 and 12 months. **CONCLUSIONS:** In French patients with GERD who have persistent symptoms despite PPI therapy, the symptom burden is substantial and a positive relationship with impaired quality of life and decreased work productivity is indicated. Supported by AstraZeneca R&D, Mölndal, Sweden.

PGI25

CHRONIC HEPATITIS C (CHC) RELATED FLU-LIKE SYMPTOMS; DEVELOPMENT OF A PATIENT REPORT OUTCOME (PRO) MEASURE AND RESULTS FROM PILOT EFFICACY STUDIES

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OBJECTIVES: Flu-like symptoms (pyrexia, chills, myalgia and arthralgia) are experienced by 30%-50% of chronic hepatitis C (CHC) patients undergoing combination interferon and ribavirin (RBV) treatment and are often cited as reasons for discontinuation. To track these symptoms, the Hepatitis Physical Symptom Severity Diary (HPSS-D), was developed. **METHODS:** Four items from the HPSS-D comprise the Flu-Like Symptom Index (Index): fever, chills, muscle aches/pain, and joint pain. Response options ranged from 0 (no symptoms) to 10 (worst symptom/problem) over the past 24 hours. The diary was completed for 7 consecutive days at baseline and weeks 4, 8 and 12. Data from two Phase 2b studies of treatment-naïve patients comparing pegIFNalpha2a/RBV (peg-alfa) to peg-INF Lambda/RBV (peg-lambda) and peg-alfa to peg-alfa and direct acting antiviral were combined. Measurement properties were assessed. Mean and change scores and proportions of patients reporting flu-like symptoms were calculated. **RESULTS:** Measurement properties of the Index were supported with test-retest ICC value of 0.85, Cronbach's alpha range: 0.73-0.81, low to moderate construct validity [range: 0.23-0.63], and demonstrated known groups validity (based on physician-reported flu symptoms). Responsiveness coefficients suggested a small to medium effect (SES=0.40; SRM=0.39). MIDs were 2.5-3.0 points. Mean Index scores at week 12 for the peg-alfa group (N=36) increased from baseline by 2.39 ± 4.95 versus 0.83 ± 5.05 for peg-lambda patients (N=26). The percentage reporting any flu-like symptoms was significantly higher for peg-alfa (75%) versus peg-lambda patients (27%) at week 12, ($p<0.001$), despite similar baseline rates. Fewer peg-lambda versus peg-alfa patients (50% versus 82%) experienced clinically significant worsening of flu-like symptoms. **CONCLUSIONS:** PRO measures are important parameters to gauge patients' experience with treatment, providing systematic assessment of treatment benefit and side effects. This new Flu-Like Symptom Index from the HPSS-D demonstrated adequate measurement properties and detected lower intensity and frequency of flu-like symptoms for peg-lambda versus peg-alfa patients.

PGI26

EVALUATING THE IMPACT OF GASTROINTESTINAL EPISODES ON THE HEALTH-RELATED QUALITY OF LIFE OF SOLID ORGAN TRANSPLANT RECIPIENTS: VALIDATION OF THE SIGIT-QOL® QUESTIONNAIRE – THE MYPACIENTE 1 & 2 STUDIES

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OBJECTIVES: To develop and validate a clinically useful instrument for assessing the impact of gastrointestinal symptoms (GI) on the health-related quality of life (HRQoL) of solid organ transplant (SOT) patients (kidney, liver, heart or lung). **METHODS:** Two phases: the Mypaciente-1 study was an epidemiological, cross-sectional, multicentre study in which the SIGIT-QoL® questionnaire (17 items) was developed and its reliability, feasibility and validity (content and construct) were proven. At second, an observational, prospective, multicentre study, the Mypaciente-2, was implemented to assess the test-retest reliability and the sensitivity to change of the SIGIT-QoL®. SOT patients aged≥18, who had received the graft 3-24 months before and suffering from GI, were evaluate at baseline, 1-2 weeks and 3 months after baseline. Data recorded: age, sex, SOT type, acute allograft rejection (AAR), GI etiology, Clinical and Patient global Impression scale (CGI-SI&GI and PGI-SI&GI) and the SIGIT-QoL® (range: 0-maximum impact to 68-minimum disruption). Intraclass correlation (ICC), differences between baseline and last visit (Wilcoxon test), effect size (Cohen's d), the minimal important difference –MID- (using CGI & PGI as anchors in General Linear Models) and the cut-off score (ROC analysis) were calculated. **RESULTS:** In the Mypaciente-2 study 277 SOT patients (61.4% males) were included. Mean age (SD) was 52.69(11.65) years, time since transplantation was 12.31(6.74) months and 22.4% suffered AAR. At baseline, SIGIT-QoL® scores: 51.21(11.25) showed an impact on patients' HRQoL that diminished 3 months later: 57.40(8.38;$p<0.001$). SIGIT-QoL® test-retest reliability was adequate (ICC=0.740-0.895). A high-moderate effect size (d=-0.590) was found. Moreover, MID of 4.2 points in total scores were found ($F4,223=16.917, p<0.001$ and $F4,224=25.138, p<0.001$). Finally, a cut-off point (55.00 points) was estimated (AUC=0.846,$p<0.001$; sensitivity=0.793; specificity=0.713; negative likelihood ratio=0.290; positive likelihood ratio=2.762). **CONCLUSIONS:** The SIGIT-QoL® is a feasible (average completion time lower than 6.5 minutes), reliable and valid instrument for assessing the impact of GI symptoms on SOT patients.

PGI27

SLEEP DISTURBANCE AND QUALITY OF LIFE AMONG HEPATITIS C INFECTED INDIVIDUALS

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OBJECTIVES: Hepatitis C virus (HCV) infection is associated with fatigue, anxiety, and depression. Little is known, however, about the effect of sleep disturbances on health-related quality of life (HRQoL), and what factors are associated with such disturbances. **METHODS:** This study is based on data from the EU National Health and Wellness Survey (N=57,805), a cross-sectional database representative of the adult EU population. Patients who reported being diagnosed with HCV by a physician and provided household income and body weight information were included for analysis (N=301). Patients who reported experiencing insomnia or sleep difficulty symptoms in the past year (n=135) were compared with patients who did not experience such symptoms (n=166). Sleep group membership was predicted with a logistic regression model, while mental and physical HRQoL (SF-12) were predicted with multiple regression models. Covariates included age, gender, marital status, education, income, employment, BMI, exercise and smoking habits, alcohol use, and physician diagnosed HIV/AIDS, hepatitis B, anxiety disorder, and depression. **RESULTS:** HCV patients with sleep disturbances were significantly younger (48.8 vs. 51.7) and more likely to be diagnosed with HIV/AIDS (8.1% vs. 2.4%), an anxiety disorder (56.3% vs. 22.9%), and depression (48.9% vs. 10.8%) (ps<0.05) than patients with no sleep disturbances. After controlling for potential confounders, anxiety disorder (OR=2.2) and depression (OR=5.1) were the only significant predictors of sleep disturbances (ps<0.05). SF-12 mental HRQoL scores were significantly associated with age (b=0.2), anxiety disorder (b= -5.7), depression (b= -5.9), and sleep disturbances (b= -5.1, ps<0.05). SF-12 physical HRQoL scores, however, were not associated with sleep disturbance. **CONCLUSIONS:** Despite the strong association of anxiety disorder and depression with sleep disturbances among HCV-infected individuals, sleep disturbances had an independent and significant effect on mental HRQoL in this population. The results suggest effective treatment of disturbed sleep may improve the quality of life of HCV patients.

PGI28

DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH QUIESCENT ULCERATIVE COLITIS: EFFECTS OF ONE YEAR MAINTENANCE TREATMENT WITH MMX MESALAMINE

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OBJECTIVES: Active ulcerative colitis (UC) negatively impacts patients' health-related quality of life (HRQoL); thus a fundamental goal of treatment is to achieve and maintain disease remission. The current analysis examines how long-term maintenance treatment with a multi-matrix (MMX) oral formulation of mesalamine impacted disease-specific HRQoL in patients with quiescent UC. **METHODS:** This analysis examined the 12-month maintenance phase of a two-phase, multicenter, open-label study, during which patients with quiescent UC at baseline received MMX mesalamine 2.4 g/day QD. Disease-specific HRQoL was measured at baseline, six-month, and twelve-month (endpoint) visits using the Shortened Inflammatory Bowel Disease Questionnaire (SIBDQ), which measures 4 domains: bowel symptoms, systemic symptoms, emotional function and social function. Changes in SIBDQ domains and total score over time were assessed using repeated-measures analysis of variance. Correspondence between disease-specific HRQoL and disease activity was assessed using analysis of covariance to compare SIBDQ scores at month 12 between clinically recurrent and non-recurrent patients while controlling for age, gender, and BMI. **RESULTS:** Data were collected from 203, 144, and 157 patients at baseline, 6-month, and 12-month/early withdrawal visits, respectively.