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

OBJECTIVES: BURDEN OF GASTROESOPHAGEAL REFUX 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, observational study with patients with GERD treated with PPIs for >4 weeks for symptoms suggestive of GERD. A total of 1,030 patients met inclusion criteria and were followed in the first 6 months and then every 6 months for up to 12 months. The study was approved by the relevant ethics committees in each country. RESULTS: BoI was assessed in the 1,030 patients. Overall, 759 patients completed the study. The BoI was calculated as the sum of four dimensions: physical health, emotional health, social health, and work productivity. The BoI was higher in patients with persistent symptoms than in those without persistent symptoms. CONCLUSIONS: The BoI of GERD patients is substantial, and the burden is higher in patients with persistent symptoms than in those without persistent symptoms. This study highlights the need for new treatments for GERD that can provide better symptom control and reduce the BoI.


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OBJECTIVES: To develop and validate a clinically useful instrument for assessing the impact of gastrointestinal symptoms (GIS) 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 was developed and its reliability and feasibility, and validity (content and construct) were proven. At second, an observational, prospective, multicentre study, the Mypaciente 2, was designed to assess the test-retest reliability and the sensitivity to change (AAR). SOT patients aged 18–75 who were 12–24 months before and suffering from GI, were evaluated at baseline, 1–2 weeks and 3 months after baseline. Data recorded: age, sex, SOT type, acute allograft rejection (AAC), GI etiology, Clinical and Patient global Impression scale (CGI-SIGIT and CGI-QOL), and depression. The percentage of patients with persistent symptoms was significantly higher for patients with persistent symptoms than for patients without persistent symptoms. 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.

PG57 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 was 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 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 H/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 H/AIDS (8.1% vs. 2.4%), an anxiety disorder (56.3% vs. 22.9%), and depression (48.9% vs. 10.8%) (p<0.01) than patients without sleep disturbances. After controlling for potential confounders, anxiety disorder (OR=2.4; 95% CI=1.6-3.6) and depression (OR=2.9; 95% CI=1.9-4.4) were significantly associated with patients with sleep disturbances. Conclusively, 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.

PG128 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), and what factors are associated with such disturbances. METHODS: This analysis examined the 12-month maintenance phase of a two-phase, multicenter, open-label study, during which patients with quiescent UC and active symptoms were maintained in remission with MMX mesalamine 2.4 g/day. 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, extraintestinal symptoms, emotional well-being, and daily living. SIBDQ domains and total score over time were assessed using repeated-measures analysis of variance. Results confirmed that disease-specific HRQoL was significantly higher at all time points compared to the baseline assessment. A significant reduction in the SIBDQ domains and total score over time was observed 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.