citated with each health state, followed by micro-costing of the results. Costs were calculated according to Portuguese official databases. Only direct health costs were applied and were assumed to be constant, and if not treated. The incremental cost and effectiveness of treatment was estimated as the difference between actual events and the assumed longstanding disease state. The individual patient data regarding age, gender, and duration of and response to treatment was used to estimate cost of follow-up CHC, and QALYs.

METHODS: Incremental cost effectiveness ratio (ICER) and 95% bootstrap confidence interval (CI) were calculated, and probabilistic sensitivity analysis (PSA) was done for assumptions on the distribution of uncertain data. Conservative assumptions were used throughout the analysis. RESULTS: There were a total of 1378 patients (median age 68 yr; range 65–80 yr). 1005 patients had hepatitis C virus type 1 (72.9%), and 1269 had a high viral load (92.1%). A plateau count of <100,000/mm3 was found in 152 patients (11.0%), 100,000–150,000/mm3 in 541 patients (39.3%), and >150,000/mm3 in 655 patients (47.5%). 1106 patients completed the planned treatment (80%). The mean viral load was lower in the subgroup of patients who did not have any expansion of height of hospital stay (LOS) and extra medical costs. METHODS: We analyze the relationship between variations in antimicrobial prophylaxis (AMP) and extra medical costs in surgical patients with colorectal malignancies. Utilizing profiling administrative data, we analyzed 161 admitted patients between 2007 and 2009 at a university hospital. To reassess the patient charts at random on a AMP strategy, the control group (112) and the case group (49). Most patients from both groups were appropriately given AMP agents consistent with the guidelines of infection-related associations. RESULTS: The LOS of the control group (24.6 ± 12.1 days) was shorter than the case (44 ± 29 days). Hospitalization charge of the control group (15130 ± 3930 USD) was lower than that of the case (23130 ± 1212) (p < 0.05). Furthermore, 73 cases of the control group were given on the day of surgery till the first postoperative day, and 39 cases were given to the second and third postoperative days. LOS of the former (22.7 ± 9.5 days) was shorter than that of the latter (23.8 ± 15.5) (p < 0.05). CONCLUSIONS: AMP agents in our hospital were found to generally given according to the recommended guidelines. It is important for the hospital administrators to quantify the additional costs on top of the above diagnosis in order to properly deal with infection control and hospital management.

Gastrointestinal Disorders – Patient-Reported Outcomes & Preference-Based Studies

PG123 ECONOMIC IMPACT OF MEDICATION ADHESION AND PERSISTENCE IN THE TREATMENT OF ULCERATIVE COLITIS IN CANADA: ANALYSES WITH THE RAMQ DATABASE

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OBJECTIVES: The aim of this study was to assess adhesion and persistence to mesalamine treatment in ulcerative colitis (UC), and to evaluate the impact on health care resource utilization and cost from a Canadian health care system perspective. METHODS: A retrospective prescription and medical claims analysis was conducted using a random sample of UC patients with no diagnosis of Crohn’s disease who were initiated on an oral mesalamine formulation from January 2005 to December 2009. Treatment adherence (medication possession ratio [MPR]) and persistence were calculated over a 1-year period after index prescription. To evaluate the economic impact of non-adherence and non-persistence, total and all-cause costs of physician visits, emergency visits, and hospitalizations were estimated. Statistical comparisons, based on adherence and persistence, were made using the chi-square test for proportions and Student’s t-test or the F-test from one-way ANOVA for means. Statistical significance was p < 0.05. RESULTS: A sample of 1681 patients was obtained. The mean age of new oral mesalamine users was 53.3 years (SD = 17.8), with a similar proportion of males and females. At month 12, 27.7% of patients had a MPR ≥80%, and 45.5% of patients were persistent on treatment. Over the 12-month period, there was a statistically significant difference in total health care resource utilization and costs (US$4357.70 versus US$3758.81, p = 0.007, adjusted) in favor of more adherent patients. Adherence and persistence to oral mesalamine for the treatment of UC was relatively poor in this patient cohort. Furthermore, patients who were non-persistent for investigation in a real-world setting. METHODS: PEG-IFN + RBV-treated CHC patients 65-years or older were analyzed. All registered patients received antiviral treatment, and were assumed to be appropriate given AMP agents consistent with the guidelines of infection-related associations. RESULTS: The mean viral load was lower in the subgroup of patients who did not have any expansion of height of hospital stay (LOS) and extra medical costs. METHODS: We analyze the relationship between variations in antimicrobial prophylaxis (AMP) and extra medical costs in surgical patients with colorectal malignancies. Utilizing profiling administrative data, we analyzed 161 admitted patients between 2007 and 2009 at a university hospital. To reassess the patient charts at random on a AMP strategy, the control group (112) and the case group (49). Most patients from both groups were appropriately given AMP agents consistent with the guidelines of infection-related associations. RESULTS: The LOS of the control group (24.6 ± 12.1 days) was shorter than the case (44 ± 29 days). Hospitalization charge of the control group (15130 ± 3930 USD) was lower than that of the case (23130 ± 1212) (p < 0.05). Furthermore, 73 cases of the control group were given on the day of surgery till the first postoperative day, and 39 cases were given to the second and third postoperative days. LOS of the former (22.7 ± 9.5 days) was shorter than that of the latter (23.8 ± 15.5) (p < 0.05). CONCLUSIONS: AMP agents in our hospital were found to generally given according to the recommended guidelines. It is important for the hospital administrators to quantify the additional costs on top of the above diagnosis in order to properly deal with infection control and hospital management.

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

PG124
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 gastroesophageal 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 of adult patients with GERD who were prescribed PPIs and declared as partial responders to optimized PPI treatment. BoI was assessed at baseline, 3, 6, 9 and 12 months via patient-completed questionnaires, including the Reflux Symptom Questionnaire with 7-day recall (RESEQ-7). Medical evaluations were completed at baseline, 6 and 12 months. Healthcare consumption was evaluated in terms of visits, hospitalizations, and planned and unplanned medical care. BoI was calculated. RESULTS: A total of 262 patients were enrolled (mean age, 54.9 years; 40.5% men), the majority of whom (n=238, 89%) completed the 12-month study. Using the RESEQ-7 questionnaire, the BoI was high at baseline and throughout the study period. BoI was significantly higher in patients with persistent GERD compared to those with resolved or milder symptoms at baseline despite PPI treatment. Whilst continuing to receive prescribed PPI medication, symptoms remained burdensome at 6 and 12 months and indicated a positive relationship with impaired quality of life (SF-12). The percentage reporting any flu-like symptoms was significantly higher (p<0.001) than patients with no sleep disturbances. After controlling for potential confounders, anxiety disorder (OR 2.2; 95% CI 1.4-3.4), depression (OR 2.0; 95% CI 1.3-3.0) and decreased participation in social activities (OR 1.8; 95% CI 1.1-2.8) were significantly associated with increased BoI. 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 supported. Supported by AstraZeneca R&D, Mölndal, Sweden.

PG125
CHRONIC HEPATITIS C (CHC) RELATED FLU-LIKE SYMPTOMS: DEVELOPMENT OF A PATIENT REPORTED 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 (FSI). Mean FSI scores were calculated as weekly items were added up. RESULTS: The mean FSI score was 5.5 (range: 0-21 at baseline, 5.1 at week 12). The FSI scores were significantly lower in the only patients who achieved SVR compared to the patients who did not achieve SVR. CONCLUSIONS: The FSI can be a useful measure of flu-like symptoms in CHC treatment trials and can be used to ascertain the impact of treating flu-like symptoms.

PG126
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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 100 SOT patients (SIGIT-QoL). The second phase 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. RESULTS: In the initial 100 patients aged 18-70, who reported 2-24 months before and suffering from GIS, were evaluated 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-SiGli and PGI-SiGli) and the 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: A total of 155 GIS (range: 0-4) were identified (61.4% females) to whom median age was 56.29(11.6) years, time since transplantation was 12.31(6.74) months and 22.4% suffered AAR. At baseline, SIGIT-QoL® scores: 51.11(2.15) showed an impact on patients’ HRQol. That diminished 3 months later: 50.82(3.00). SIGIT-QoL® test-retest reliability was adequate (ICC: 0.740-0.895). A high moderate effect size (d=0.59) was found. Moreover, MID of 4.2 points in total scores were found (F4,233=16.917.p<0.001 and F4,224=25.138.p<0.001). Finally, a cut-off point (55.00) was estimated (AUC=0.846.p<0.001; sensitivity=0.755; specificity=0.713; negative likelihood ratio=0.290; positive likelihood ratio=2.76). CONCLUSIONS: The SIGIT-QoL® is a feasible (average completion time lower than 6.5 minutes), reliable and valid instrument for assessing the impact of GIS symptoms on SOT patients.

PG127
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 difficulties 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%) (p<0.05) than patients with no sleep disturbances. After controlling for potential confounders, anxiety disorder (OR 4.0; 95% CI 2.6-6.1) and depression (OR 5.1; 95% CI 2.6-9.9) were the only significant predictors of sleep disturbances (p<0.01). 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=-5.0; p<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.

PG128
DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH QUINSECT ULCERTATIVE 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, multicentre, open-label study, during which patients with quiescent UC were treated with 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, extraintestinal symptoms, and depression. 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 current and non-current 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.