GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PG127 PREDICTIVE VALUE OF PATIENT-REPORTED OUTCOMES TO MUCOSAL HEALING IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (Colombel J.F., 1Harcourt D., 2Reinicke W., 3Feagan B., 4Marano C., 5Strauss R., 6Johanns J., 7Zhang H., 8Gibson P., 9Collins J., 10Rutgeerts P., 11Sandborn W.)

Methods: Patients with active UC defined by a Mayo score of ≥6, including an endoscopy sub-score of ≥2 were randomized to receive placebo or golimumab (GLM) 200mg/200mg or 400mg/200mg at weeks 0 and 2, respectively. Patient-reported outcomes (PROs) were measured by disease activity (Disease Activity Index [DAI]), Work Productivity and Activity Impairment (WPAI), and PROs were collected from the most recent consecutive 3-day period within the 2 weeks prior to week 6. Responder was defined as normalized stool frequency or no rectal bleeding. Receiver Operating Characteristic (ROC) curve was developed based on different cut-off of combined stool frequency and rectal bleeding scores or no rectal bleeding. Mucosal healing is defined as an endoscopy subscore of the Mayo score of 0 or 1. With ROC curve, a cut-off of 77.1% achieved mucosal healing vs. 32.8% (0-6). Results: At week 0, 99% of patients reported abnormal stool frequency and 86.9% reported rectal bleeding. Among patients who reported no rectal bleeding at week 6, 6.6% achieved mucosal healing compared to 16.0% of patients with rectal bleeding (p=0.006). Similarity, among patients with normalized stool frequency at week 6, 77.1% achieved mucosal healing vs. 32.8% of patients with abnormal stool frequency at week 6 (OR=6.9, p<0.001, PPV=0.77, LR=5.6). Receiver operating characteristic (ROC) curve, a cut-off of ≥3 on a combined stool frequency and rectal bleeding score resulted in a sensitivity of 85% and specificity of 70.6% for predicting mucosal healing at Week 6. Conclusions: Normalized stool frequency and no rectal bleeding are predictors for mucosal healing in patients with UC.

PG128 THE CORRESPONDENCE BETWEEN PATIENT-REPORTED OUTCOME (PRO) INSTRUMENTS AND MUCOSAL HEALING IN ADULT PATIENTS WITH MILD-TO-MODERATE ULCERATIVE COLITIS (UC) RECEIVING SHORT-TERM DAILY TREATMENT WITH MMX MESALAMINE

Yurula JS, 1William MA, 2Johnson LS

1Optum, Lincoln, RI, USA, 2Shire, Wayne, PA, USA, 3Shire Development LLC, Wayne, PA, USA

Objectives: To examine correspondence between PROs with changes in disease activity and treatment in patients with UC. PRO instruments assessed generic health-related quality of life (12-Item Short Form Health Survey (SF-12v2), disease-specific (Shortened Inflammatory Bowel Disease Questionnaire [SIBDQ]), and work-related outcomes (WROs, Work Productivity and Activity Impairment Questionnaire: UC [WPAI:UC]). Methods: Adults with mild-to-moderate UC received MMX mesalamine 4.8 mg/kg/for 8 weeks in an open-label, prospective study (NCT01124149). PROs and a modified UC-Disease Activity Index (UCDAI) that captured several symptoms, including stool frequency (SF) and rectal bleeding severity (RBS), were administered at baseline and Week 8. Spearman coefficients examined associations between changes in PROs and disease activity. Analysis of variance (ANOVA) models tested changes in scores over time, with Cohen's d used to interpret effect sizes. ANOVAs examined PROs across disease activity (quiescent and active) versus quiescent and active UC regarding QoL and productivity loss. Results: There was a decrease in the proportion of proprietary prescriptions was for greater QIs (7%) than previously reported for statins (65%), however, this did not translate to greater savings in total UC. This could be due to the higher average number of prescriptions per year and the higher average QIC per prescription item for statins than for PPIs. Analyzing data for each PFI, we found dramatic decreases in proprietary prescribing (0% to ~1%) within two years following patent expiry of the proprietary form. Conclusions: There was a decrease in the proportion of proprietary prescribing of PPIs in England between 2007 and 2012, with rapid declines following patent expiry of proprietary drugs. This suggests that the BCIV indicator is being met for PPIs as well as for statins.

PG133 PATTERNS OF STEROID AND STEROID SPARING REGIMENS AMONG OLDER INFLAMMATORY BOWEL DISEASE (IBD) PATIENTS WITH CONTRAINDICATIONS TO TUMOR NECROSIS FACTOR ANTAGONISTS (ANT-TNFs)

Johnson RL, 1Bartels C, 2Thorpe C, 3Palta M, 4Weiss J, 5Smith M

1University of Wisconsin-Madison, Madison, WI, USA, 2University of Pittsburgh, Pittsburgh, PA, USA

Objectives: IBD-specific quality measures calling for the use of steroid sparing regimens were underutilized in this cohort. Many older patients have contraindications to anti-TNFs. Our objective was to determine the proportion of anti-TNF users in IBD who were younger, white, receiving any IBD drug class except anti-TNFs, had polypharmacy, more hospitalizations or absence of stroke history had greater odds of receiving steroids. Among steroid recipients, polypharmacy and anti-TNF use were infrequently (anti-TNFs: 19-30 users per 1000 patients each year, 1.2% prevalence) in UC.

PG132 PATTERNING PATTERNS OF TREATMENT, HEALTH CARE RESOURCE UTILIZATION AND COSTS IN UNITED STATES PATIENTS DIAGNOSED WITH CHRONIC HEPATITIS C INFECTION

Le TK, 1Kalinciak A, 2Yuan Y, 3Macaulay D, 4Sorg R, 5Bhurer CR, 6Arunajadai SG, 7Wei J, 8Wu EQ

1Bristol-Myers Squibb, Hopewell, NJ, USA, 2Bristol-Myers Squibb, Princeton, NJ, USA, 3Bristol-Myers Squibb, Mississauga, ON, Canada, 4Analysis Group, Inc., New York, NY, USA, 5Analysis Group, Inc., Boston, MA, USA