OBJECTIVES: To assess symptoms reported by IBS-C patients through exploratory open-ended questions in two phase 3 clinical trials. **METHODS:** Prior to answering a daily symptom diary, patients were asked to list bothersome symptoms of IBS-C in an open-ended manner at the pre-treatment visit. At the randomization visit, patients were asked to list any additional bothersome symptoms of IBS-C that were not assessed during the prior two weeks. The data at both time points for randomized patients were analyzed using ATLAS.ti. Codes were developed using patients' verbatim words. Frequency counts of symptoms were tabulated. Results were compared with symptoms reported from four focus groups with IBS-C patients (n = 32). **RESULTS:** Across trials, 1496/1610 (92.9%) and 603/1610 (37.5%) patients provided responses at the pre-treatment and randomization visit, respectively. The ten bothersome symptoms of IBS-C listed by patients most frequently at the pre-treatment visit were: bloating (76.1%), cramping (39.0%), gas (31.6%), constipation (29.1%), abdominal pain (24.8%), pain (general) (21.1%), fullness (20.0%), straining (14.4%), pain (stomach) (13.4%), and UBM (13.1%). Out of the patients reporting additional symptoms at randomization, the five most frequently listed bothersome symptoms were: gas (23.1%), bloating (14.1%), cramping (12.9%), fullness (11.6%), and nausea (11.6%). Only two of these symptoms identified at the randomization visit were not assessed during the trial: gas and nausea. The symptoms most frequently reported by patients in the trial were reported during the focus groups. **CONCLUSIONS:** This method of data collection provided insight on IBS-C patient perspective. Adult IBS-C patients experience many bothersome symptoms, including both abdominal and bowel symptoms. The results from this analysis confirm the comprehensiveness of four focus groups conducted with IBS-C patients and provides evidence that across different IBS-C patient groups the type of abdominal and bowel symptoms reported by patients is consistent.

PGI21

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH MILD-TO-MODERATE ULCERATIVE COLITIS BEFORE AND AFTER 8 WEEKS' TREATMENT WITH MULTI-MATRIX MESALAMINE: COMPARISON WITH 2009 GENERAL POPULATION NORMS IN THE UNITED STATES

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OBJECTIVES: Ulcerative colitis (UC) is a chronic inflammatory disease of the large intestine and rectum. Symptoms such as abdominal pain, diarrhea, and the persistent urge to defecate can impair UC patients' physical and socio-psychological well-being. This study examined the magnitude of this impairment, and the degree to which treatment improved health-related quality of life (HRQL), of mild-to-moderate UC patients relative to a US general population sample. **METHODS:** Short-Form (SF)-12v2 baseline and endpoint scores were collected from a multicenter, open-label study in which patients with active mild-to-moderate UC received multi-matrix (MMX) mesalamine 2.4–4.8g/day QD for 8 weeks. Patients were compared with a 2009 US general population sample derived from an Internet-based survey administered to a representative national sample of adults. The normative sample was matched to the age and sex of the patient sample using least squares regression. Analysis of variance models tested for significant differences between UC patients' mean scores and normative sample's estimated scores at each time. Group comparisons on physical and mental summary scores (PCS and MCS, respectively) relative to established minimally significant differences (MID) of 3 points identified clinically meaningful group differences. **RESULTS:** Baseline SF-12v2 scores for UC patients were significantly below the matched general population on 7 of 8 subscales (all $P<0.01$ except for mental health, $P>0.05$) and on both summary measures (PCS: 45.4 vs. 50.4, $P<0.001$; MCS: 47.3 vs. 49.4, $P<0.05$). Sample differences for PCS scores but not MCS scores exceeded the established MID. At 8 weeks, SF-12v2 scores of the treated UC patients were either statistically equivalent to or exceeded norm scores. **CONCLUSIONS:** Active UC negatively impacted almost all dimensions of HRQL; the burden in physical health dimension was larger than the burden in mental health. Eight weeks of daily MMX mesalamine treatment improved patients to "normal" levels of functioning and well-being.

PGI22

CONCORDANCE AMONG MULTIPLE HEALTH OUTCOMES MEASURES IN RESPONSIVENESS TO MULTI-MATRIX MESALAMINE MAINTENANCE TREATMENT FOR PATIENTS WITH QUIESCENT ULCERATIVE COLITIS

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OBJECTIVES: To understand the correspondence across measures of patient-reported outcomes (PRO) in quiescent ulcerative colitis (UC) patients, we examined the responsiveness to treatment, sensitivity to disease activity, and inter-associations among measures of generic and disease-specific health-related quality of life (HRQL) and work-related outcomes. **METHODS:** Patients with UC in quiescence (defined by a lack of rectal bleeding and normal frequency of defecation) received 2.4 g/day multi-matrix (MMX) mesalamine daily for 12 months in a multicenter, prospective, open-label study. PROs were administered at baseline, 6 months, and 12 months. The Short Form (SF)-12v2 measured generic HRQL, the shortened Inflammatory Bowel Disease Questionnaire (SIBDQ) measured IBD-specific HRQL, and the Work Productivity and Activity Impairment Questionnaire for UC (WPAI: UC) measured absenteeism and work productivity. Repeated-measures ANOVAs examined changes in scores over time. Associations among instruments were assessed by inter-subscale correlations. Sensitivity to disease activity was assessed using ANCOVA models to compare PRO endpoint scores between recurrent and non-recurrent patients (recurrence is defined as 4 or more bowel movements/day above normal, and evidence of urgency, abdominal pain or rectal bleeding). Data were collected at baseline, Month 6, and Month 12/early withdrawal. **RESULTS:** 198 patients were enrolled at baseline. In quiescent patients, no changes in any PRO instrument subscale occurred over time (all $p>0.10$). Overall, small to moderate inter-subscale correlations were found across all instruments: average correlations were 0.37 between SF-12v2 and SIBDQ subscales, −0.33 between SF-12v2 and WPAI:UC subscales, and −0.43 between SIBDQ and WPAI:UC subscales. Most subscales demonstrated statistically worse outcomes for patients with recurrent UC. **CONCLUSIONS:** In quiescent UC patients, instruments measuring different outcomes associated with UC showed stability during 12-month maintenance treatment with MMX mesalamine. The strength of inter-scale correlations and the finding of similar sensitivity to clinical outcomes indicate convergent validity among these instruments within this patient population.

PGI23

WORK PRODUCTIVITY AMONG GENOTYPE 1 HEPATITIS C VIRUS (HCV) TREATMENT-NAÏVE PATIENTS RECEIVING TELAPREVIR-BASED TREATMENT REGIMENS: RESULTS FROM ADVANCE AND ILLUMINATE STUDIES

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OBJECTIVES: ADVANCE and ILLUMINATE, phase 3 studies, evaluated efficacy and safety of telaprevir (T)/peginterferon alfa-2a/ribavirin (PR) for genotype 1 HCV treatment-naïve patients. ADVANCE patients were randomized to 8 or 12 weeks of T/placebo plus PR (24 or 48 weeks) or PR (48 weeks). ILLUMINATE patients received T plus PR for 12 weeks; those with extended rapid virologic response (eRVR+) were randomized to 24- or 48-week total treatment. We report on the patient self-reported impact of telaprevir-based regimens on work productivity. **METHODS:** The five-item Work Productivity Questionnaire (WPQ) was administered to patients (N=932) at day 1, and weeks 4, 12, 24, 36, 48 and 72 (assessed previous 4 weeks). WPQ responses were tabulated at each timepoint by treatment group using descriptive statistics. **RESULTS:** At baseline, days missed from work (mean, SD) due to HCV or its treatment ranged from 0.8 (3.6) to 1.1 (4.4) days across treatment groups (ADVANCE), and from 0.6 (3.1) to 0.7 (3.3) (eRVR+ groups, ILLUMINATE) and increased 4-5 fold by week 12 in ADVANCE and ILLUMINATE. Compared to baseline, more patients reported working shorter hours and being less productive by week 12 in ADVANCE and in ILLUMINATE eRVR+ groups. At week 48, days missed from work approached baseline levels in telaprevir treatment groups (1.1 [4.9] T12PR; 1.0 [4.7] T8PR) but not in PR (1.9 [6.3]); in ILLUMINATE corresponding values were 0.1 (0.5) in T12PR24 and 0.8 (2.3) in T12PR48. After week 12, other work productivity measures improved earlier in telaprevir-based groups versus PR (ADVANCE), and in T12PR24 versus T12PR48 in ILLUMINATE (eRVR+). **CONCLUSIONS:** Among genotype 1 HCV treatment-naïve patients, work productivity decreased during the first twelve weeks of therapy in all treatment arms. Work productivity, however, returned to pre-treatment levels earlier in patients who received telaprevir-based regimens compared with PR and in those patients who received shorter treatment duration.

PGI24

DOES UTILITY OR CAPABILITY MATTER FOR IRRITABLE BOWEL SYNDROME? - A PRELIMINARY QUALITATIVE STUDY ON TAIWANESE PATIENTS

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OBJECTIVES: Irritable bowel syndrome (IBS) is a relapsing, chronic functional gastrointestinal disorder with continuous nuisance bowel symptoms leading to long-term disturbances on quality of life (QoL). Various conventional and innovative gastrointestinal drugs are available for the symptomatic control of IBS. However, it is uneasy to justify cost-effectiveness of IBS treatments due to the unspecific symptoms, a disparity of QoL measurements and a lack of clear association between functioning and QoL. This preliminary used a qualitative approach to explore the impacts of IBS on patients and explore underlying attributes to QoL. **METHODS:** Semi-structure interviews were conducted at a medical center in southern Taiwan from July 2010 to December 2010. Outpatients with defined diagnosis of IBS and receiving medical treatment were invited to participate, and a topic guide was used to ensure systematic coverage of attributes related to QoL. The interviews were audiotaped and transcribed verbatim for framework analysis. **RESULTS:** The most disturbing symptoms for 29 participants were recurrent abdominal pain or discomfort, which affect the efficiency of work or study. In addition, the frequent bowel movements reduce patient's willingness to participate in social activities and jeopardize their interpersonal relationship. Moreover, repeated inspections and medical visits during follow-ups also raise patients' further concerns and worries on health. Unsatisfied symptoms control was commonly stated by participants and alternative managements such as homeopathic remedies, traditional Chinese medicines, sports, and diet modifications were tried and considered being ineffective. Some participants with uncontrolled symptoms acknowledged their failure in adhering to medical treatment due to the concerns of adverse drug reactions. **CONCLUSIONS:** For patients with potentially moderate to severe IBS and consistent medical treatments, the functional impairment was still tolerable yet intangible (anxiety, worries) and social stress may have greater impacts on QoL. Therefore, a capability approach may work better than the utility and functioning QoL measure.