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. Half of the IBS-C patients were not assessed during the prior two weeks. The data at both time points for random- ized patients were analyzed using ATLAS.ti. Codes were developed using patients’ verbatim words. Frequency counts of symptoms were tabulated. Results were com- pared to a 2009 US general population sample derived from an Internet-based survey administered to a representative national sample of adults. The normative sit- uation was to which treatment improved health-related quality of life (HRQL), of mild-to-mod- erate UC patients were analyzed using ATLAS.ti. Codes were developed using patients’ verbatim words. Frequency counts of symptoms were tabulated. Results were com- pared to 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 sub- scales demonstrated statistically worse outcomes for patients with recurrent UC. CONCLUSIONS: In quiescent UC patients, instruments measuring different out- comes associated with UC showed stability during 12-month maintenance treat- ment 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.

PG12 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 (RBV) for genotype 1 HCV treatment-naïve patients. ADVANCE patients were randomized to 8 or 12 weeks of T+placebo plus RBV (24 or 48 weeks) or RBV (48 weeks). ILLUMINATE patients received 7 p+h+RBV for 12 weeks; those with extended rapid virologic response (EVR+) were randomized to 24- or 48-week total treatment. We report on the patient self-re- ported impact of telaprevir-based regimens on work productivity. METHODOLOGY: The five-item Work Productivity Questionnaire (WPQ) was administered to patients (N=932) at day 1, and weeks 4, 12, 24, 48, 72 and 108 (assessed previously 4 weeks). WPQ scores were tabulated at each timepoint by treatment group using de- scriptive 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) (eVR+ groups, ILLUMINATE) and in- creased 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 eVR+ groups. At week 48, days missed from work approached baseline levels in telaprevir treatment groups (1.4 [4.9] T2PR1, 1.0 [4.7] T2PR) but not in FR (1.9 [6.3]). In ILLUMINATE corresponding values were 0.1 (3.0) T1PR1, 0.8 (3.2) T1PR4 and 0.8 (3.2) T1PR48. After week 12, other work productivity measures improved earlier in telaprevir-based groups versus FR (ADVANCE), and in T12PR24 versus T12PR48 in ILLUMINATE (eVR+). CONCLUSIONS: Among geno- type 1 HCV treatment-naïve patients, work productivity decreased during the first twelve weeks of therapy in all treatment arms. Work productivity, however, re- turned to pre-treatment levels earlier in patients who received telaprevir-based regimens compared with FR and in those patients who received shorter treatment duration.

PG24 DOES UTILITY OR CAPABILITY MATTER FOR IRITABLE BOWEL SYNDROME? - A PRELIMINARY QUALITATIVE STUDY ON TAIWANESE PATIENTS

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OBJECTIVES: Irritable bowel syndrome (IBS) is a complex and 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 un-specific symptom disparity of QoL measures 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-structured 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 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 treatment effect. Concluded that IBS symptomatology was associated with coping strategies and alternative mechanisms such as homeopathic remedies, traditional Chinese medicines, sports, and diet modifications were tried and considered being ineffec- tive. 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 consist- ent medical treatments, the functional impairment was still tolerable yet intan- gible (anxiety, worries) and social stress may have greater impacts on QoL. There- fore, a capability approach may work better than the utility and functioning QoL measure.