country). Patient inclusion criteria were: C-HCV diagnosis within past 5 years; treated with peginterferon alfa-2a or alfa-2b plus ribavirin combination therapy (PEG2A® or PEG2B®R, respectively); age ≥21 years; no diagnoses of hepatitis B or HIV/AIDS; ≥21 year follow-up post-treatment initiation; no clinical trial participation. Treatment duration and follow-up time was based on the patient level. Published drug prices were used in all cost calculations. RESULTS: Hepatology, gastroenterology, and internal medicine were the predominant physician specialties observed, representing 22%, 30%, and 25%, respectively, of all physicians recruited. A total of 804 patients (160 per country) were identified, of whom 65% were male with mean age of 46 years. More patients initiated PEG2A®R (69%) than PEG2B®R (31%). For both regimens, all major ribavirin doses (800, 1000, and 1200 mg) were seen, representing 36%, 35%, and 22%, respectively, of PEG2A® patients on 800 mg, 1000 mg, and 14%, respectively, of PEG2B®R patients. Mean treatment duration was ∼35 weeks for both PEG2A®R and PEG2B®R, with distribution spikes at 24 and 48 weeks. Treatment compliance was relatively high, with ∼75% of patients completing therapy as planned regardless of regimen. Mean weekly treatment costs ranged from €280 to €350 depending on the ribavirin dose. Mean total regimen costs were estimated at €111,827 and €11,109 per patient for PEG2A®R and PEG2B®R, respectively. CONCLUSIONS: Peginterferon-based regimens, although a mainstay of C-HCV management, are costly. Public health systems bearing the high economic burden of C-HCV treatment should be mindful of these costs when considering formulary access for alternative treatments.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes Studies

PG120

SELECTING CHRONIC CONSTIPATION (CC) CLINICAL TRIAL ENDPOINTS: INCORPORATING THE PATIENT’S VOICE

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OBJECTIVES: 1. Identify a comprehensive set of symptoms for measurement in CC clinical trials. 2. Achieve saturation and provide support for the content validity of the corresponding set of endpoints in accordance with FDA’s PRO guidance. METHODS: Twenty-eight in-depth interviews were conducted in two phases, in different geographic locations, with participants meeting modified Rome II criteria for CC. A semi-structured interview guide was used, beginning with a series of open-ended questions to elicit all relevant symptoms, followed by interviewer probes to fully understand the relationships among the concepts. Multiple rating and ranking methods were used to develop a subset of CC symptoms of greatest importance to patients. For example, participants were asked to identify their most bothersome CC symptoms, as well as those in which they would most like to see an improvement with treatment. RESULTS: When asked to describe their CC symptoms, the patients reported 62 potentially distinct concepts: 12 bowel symptoms, 21 abdominal symptoms, 25 additional physical symptoms, and 4 mental or emotional issues. Patient descriptions of symptoms revealed that symptom terms were highly related and/or could be considered secondary to CC. Results of the subsequent rating and ranking tasks suggest that the concepts of stool frequency, stool consistency, straining, incomplete evacuation, abdominal pain, abdominal discomfort, and bloating were distinct and comprise patients’ most bothersome symptoms. Further, improvements in these symptoms would constitute an improvement in patients’ CC overall, and PRO items addressing these symptoms were found to be correlated. CONCLUSIONS: Patient input is vital to identify the full spectrum of symptoms, and to determine an optimal set of clinical trial endpoints. Interview results suggest that a variety of techniques may be necessary to demonstrate concept saturation and identify those symptoms which accurately represent a functional disorder such as CC.

PG121

CORRESPONDENCE OF MULTIPLE HEALTH OUTCOMES MEASURES IN PATIENTS WITH ULCERATIVE COLITIS

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OBJECTIVES: To understand how multiple health outcomes (HO) instruments could better measure health-related quality of life (HRQoL) and work productivity in ulcerative colitis (UC) patients, we examined interrelations among three HO instruments used in a clinical trial: a generic measure (SF-12v2), a disease specific measure (Shortened Inflammatory Bowel Disease [IBD] Questionnaire [SIBDQ]), and a work productivity measure (Work Productivity and Activity Impairment Questionnaire for UC [WPAI-UC]). METHODS: Mild-to-moderate UC patients received MMX mesalamine daily for 8 weeks in an open-label study. HO was measured at baseline and eight-weeks with generic HRQoL, SIBDQ, and WPAI-UC measures. Convergent validity of IBD-related QoL: bowel symptoms, systemic symptoms, emotional function, and social function. The WPAI-UC measures 4 dimensions of work-related productivity impacted by UC: absenteeism, presenteeism, work impairment, and activity impairment. Repeated-measures ANOVA examined changes in HO scores. Associations among instruments in detecting HO change were assessed by intercorrelations among change scores, and correlations with patient-reported symptoms: bowel movement frequency (BMF) and rectal bleeding severity (RBS). RESULTS: 107 patients completed both assessments. Improvement occurred in 19 of 19 HO scale and summary scores (p < 0.05 for differences), indicating each instrument was responsive to treatment. Correlations indicated moderate associations in the predicted directions for change scores among all three instruments: the average correlation was 0.47 between SF-12v2 and SIBDQ scales, −0.39 between SF-12v2 and WPAI-UC scales, and −0.48 between SIBDQ and WPAI-UC scales. Improvement in scale scores for all measures was moderately correlated with improvement in both BMF and RBS (magnitude of average correlations ranged from 0.29 to 0.47). CONCLUSIONS: Instruments measuring different aspects of HO showed consistent responsiveness to eight-weeks’ treatment with MMX mesalamine in mild-to-moderate UC patients. Similar results obtained using different HO instruments confirm the treatment effect, and also indicate convergent validity among these instruments within this patient population.

PG122

PAIN AFTER LIVER TRANSPLANT: A CROSS SECTIONAL STUDY

PGI31

RESPONSIVENESS TO MMXTM MESALAMINE TREATMENT FOR PATIENTS WITH ULCERATIVE COLITIS

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OBJECTIVES: To conduct a systematic review of studies reporting primary hrQoL data among patients with Hepatitis C and assess implications for adherence, work