significance difference in the efficacy and safety in nucleotide-ide-naïve CHB patients with HIV DNA greater than 6 log10 in the medical center.

PG12 EFFECTIVENESS OF PROBioticS IN IRritablebowel SYndrome: A SYStematic Meta-analYsis

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OBJECTIVES: To investigate the efficacy of probiotics in irritable bowel syndrome (IBS) patients, this meta-analysis was performed. METHODS: The collected data contained twenty-four clinical trials which fifteen were eligible for meta-analysis and nine were reviewed systematically. All studies were randomized placebo-controlled trials in patients with IBS that investigated IBS improvement. Trials were evaluated with Relative Risk (RR) with 95% confidence interval (95% CI). Cochran Q test was used to test heterogeneity with P value 0.05 (P > 0.05). The results were expressed in forest graphs as publication bias indicators. RESULTS: Probiotics reduced pain severity, symptom severity score and induced adequate general symptom improvement. Distension, bloating, and flatulence were not improved after probiotic treatment when compared to placebo. Conclusion: We confirmed the beneficial efficacy of probiotics compared with placebo in IBS patients.

PG13 ESTABLISHMENT OF A HEPATITIS C virus (HCV) COHORT IN A LARGE ISRAELI HMO

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OBJECTIVES: Hepatitis C virus (HCV) affects an estimated 130 million people worldwide and is a major cause of chronic liver disease. Real-world data is needed to better understand the epidemiology of HCV and its complications, as well as treatment patterns and outcomes. The objective of this study is to establish a cohort of HCV carriers in a large health maintenance organization, with comprehensive data on treatment and disease outcomes. METHODS: The HCV cohort will use data available since 1998 from the computerized databases of Maccabi Healthcare Services, the second largest HMO in Israel, with approximately 2 million members. HCV cases are contained twenty-four clinical trials which fifteen were eligible for meta-analysis. Baseline variables were included as covariates in the model. Linearity assumptions were relaxed with the use of restricted cubic splines. Bootstrapping, with 1000 replications, were used in conjunction with estimation of discrimination and calibration. RESULTS: Calibration of the model, assessed graphically, indicated reasonable disagreement, quality-of-life and coping factors on the severity of Crohn’s disease patients. CONCLUSIONS: All of the indicated factors (age, family size, coping skills) had a significant effect on the severity of Crohn’s disease. In addition to prescribing medications, physicians should pay special attention to these factors as part of an overall management plan for their Crohn’s disease patients.

PG14 THE INCIDENCE OF UPPER AND LOWER GASTROINTESTINAL COMPLICATIONS: A RETROSPECTIVE STUDY USING A JAPANESE HEALTH CARE DATABASE

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OBJECTIVES: The objective of this study was to investigate the incidence of complications (bleeding and perforation) with hospitalization from both upper and lower GI tract in Japanese population using a health care claims database (HDB). METHODS: All of the claims data of the patients who have a history of hospitalization due to complications from GI tract between January 2011 and December 2012 were extracted from the HDB which holds about 1.8 million peoples’ claims data under employment-based health insurance. In order to identify upper and lower GI events precisely, we confirmed them when a diagnosis of a GI event in the claims (ICD-10 code) was accompanied by a record of examination and/or endoscopic or surgical treatment relevant to upper and lower GI complications. RESULTS: The total number of person-years at risk was 1.2 million person-years in 2012. The incidence rates in upper and lower GI events were 41 and 41 per 100,000 person-years, respectively. Twenty-one percent of the lower events originated in bleeding from hemorrhoid or related treatments (eg, hemorrhoidectomy). Age–group analyses in the upper vs. lower events, except those from hemorrhoid, were 27 vs. 17, 57 vs. 46 and 104 vs. 104 per 100,000 person-years in 20-39, 40-59, and 60+ years groups, respectively. Data from 2011 were consistent with these observations on the ratio of upper to lower GI events and the age–based incidence distribution. The overall incidence of the 24 week treatment with BOC was 1.4 per 100,000 person-years. This incidence may be useful for identifying and subsequently managing HCV patients at relatively high risk for developing anemia if treated with BOC+PR.

GASTROINTESTINAL DISORDERS – Cost Studies

PG7 BUDGET IMPACT ANALYSIS OF SOfosbuvIr FOR THE TREATMENT OF HEPATITIS C IN THE VENeto REGION, ITALY

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OBJECTIVES: Hepatitis C Virus (HCV) infection is one of the main causes of chronic liver disease worldwide. Sofosbuvir, a nucleotide analog inhibitor of HCV RNA-dependent RNA polymerase, has been approved in Europe for the treatment of chronic hepatitis C genotypes 1-6. This study aims to estimate the budget impact of sofosbuvir in patients who live in the Veneto Region. METHODS: Population data were obtained from a regional survey. The survey was conducted by the Department of Molecular Medicine of Padua University in order to identify the number of patients with advanced stage disease or more rapid disease progression. At the time of this study, the Italian price of sofosbuvir has not been defined so it was estimated that a full 12 week course of sofosbuvir would cost as Swedish price: 42.653 (€81 390) for 48 weeks of treatment. Total costs include costs for other drugs or hospitalization that might be used in combination. RESULTS: In Veneto Region, there are 835 patients with severe Hepatitis C genotype 1 (n=493); genotype 2 (n=94); genotype 3 (n=178); genotype 4 (n=70) and about 110 patients with other genotypes. Therefore, there are 10 patients awaiting liver transplantation and 70 patients with post-transplant recurrence of HCV infection. Therefore, the total estimated expenditure would be about €66 000 000 for all the 1005 patients and about €34 000 000 for the 455 patients (45%) with very high priority to treatment. CONCLUSIONS: High prices for new drugs are a growing concern to payers, given the large number of innovative drugs in development and the limited health care resources. Due to high costs, economic analyses are needed to estimate the budgetary impact for the Regional Health System (RHS) with sofosbuvir.

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OBJECTIVES: To study possible associations and assess the impact of socio-demographic, quality-of-life and coping factors on the severity of Crohn’s disease patients in Israel. METHODS: Consecutive Crohn’s disease patients undergoing clinical follow-up at the Gastroenterology Clinic of the Cleveland Clinic. Incomes: -SF-36 quality-of-life, Ways of Coping, and socio-demographic details. Crohn’s disease severity was measured by Harvey-Bradshaw Index (HBI) expanded to include clinical, physician’s global rating as well as medical surgical complication indicators. Based on these data, a multifactorial model was built using multivariate linear regression. RESULTS: There were altogether 192 patients: 81 (42.2%) men (age 36.8 ± 14.5 years, disease duration 11.4 ± 6.6 years, education 13.7 ± 2.7 years, HBI 7.6 ± 4.9 and 111 (57.8%) women (age 41.4 ± 15.6*, duration 14.0 ± 9.3*, education 14.2 ± 2.8, HBI 8.4 ± 4.6; *p < 0.05 vs. men). The multifactorial model showed the following significant predictors of disease severity: age (beta = −0.250, p = 0.006), number of children (beta = 0.245, p = 0.008), SF-36 General Health score (beta = −0.379, p < 0.01), coping/sense of humor (beta = −0.209, p = 0.011), and coping/acceptance (beta = −0.183, p = 0.024). The model accounted for 29% of explained variance, with Adjusted R² = 0.26. Gender, education and socio-economic status were not predictors of disease severity. CONCLUSIONS: All of the indicated factors (age, family size, coping skills) had a significant effect on the severity of Crohn’s disease. In addition to prescribing medications, physicians should pay special attention to these factors as part of an overall management plan for their Crohn’s disease patients.