COST-EFFECTIVENESS OF INTERFERON-FREE THERAPY FOR HEPATITIS C IN GERMANY - AN APPLICATION OF THE EFFICIENCY FRONTIER APPROACH

Gisel G1, Gitz G1, Mahlich JCT2, Repp H1

1Institute of Public Health, University of Zürich, Switzerland; 2Center for Health Economics, University Medical Center Hamburg-Eppendorf, Germany

OBJECTIVES: The objective of this study was to evaluate the cost-effectiveness of Sofosbuvir and Ribavirin for interferon-free treatment for hepatitis C genotype 1 infection. We modelled a lifetime perspective and a graphical model with disease progression stages of treatment success and recurrence as endpoints. We studied data from published clinical trials and assessed the efficiency frontier method, which was suggested by German Institute for Quality and Efficiency in Health Care for cost-effectiveness analysis in Germany.

CONCLUSIONS: The efficiency frontier method was used to estimate the long-term cost of HCV therapy. The analysis modeled independent cohorts of GT1 HCV patients over a lifetime horizon with annual cycles from a US payer perspective. Life expectancy was assessed based on previously published natural history model. Direct medical costs (in 2014 prices and discounted at 3% per year) were obtained from the published literature. Efficacy and safety data were obtained from published clinical trials. SVR rates were stratified by patient treatment history, cirrhosis status, and sub-genotype, where available. Long-term cost per SRV for a patient segment was calculated by dividing total cost of HCV over patient’s lifetime by the mean SVR rate in that patient segment. RESULTS: The long-term cost per SRV with Sofosbuvir and Ribavirin for 24 weeks of treatment was $52,717 (95% CI: $49,715 – $55,719) and $87,332 to $125,748 in GT1b treatment-naïve patients (12-week). Long-term cost per SRV with Sofosbuvir and Ribavirin without ribavirin and standard of care in the US, including sofosbuvir plus simprevir (SOF+SMV) and sofosbuvir plus peg-interferon and ribavirin (SOF+PR), among patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection. METHODS: A Markov cost-effectiveness model was used to estimate the long-term cost of HCV therapy. The analysis was conducted using Microsoft Excel and the Markov model was modeled on the German Institute for Quality and Efficiency in Health Care: a decision-analytic model of the natural history of hepatitis C infection in patients with GT1a and GT1b HCV genotype.

PG126 USING THE MEDICARE CLAIMS DATABASE TO UNDERSTAND THE ECONOMIC BURDEN OF LIVER DISEASE: A CASE STUDY OF HEPATITIS C

Wu S1, Sainioh P1, Mallow PJ2, Falconi L1, Gunningberg C1

1CITI Clinical Trial and Consulting Services, Raleigh, NC, USA; 2Harvard University, Cambridge, MA, USA

OBJECTIVES: Hepatitis encaphalopathy (HE) is a major complication of liver disease and is becoming more problematic in an aging population with cirrhosis. Medicare is a United States (US) government-sponsored health insurance program that guarantees access to healthcare for all individuals 65 or older, or who are younger with disability. The objective of this study was to estimate the national healthcare expenditures of patients with HE from a Medicare perspective. METHODS: Inpatient, Outpatient, and Master Beneficiary Research Identifiable Files (RBIs) from the Medicare 5% Sample were utilized for this study. Medicare 5% Sample is a nationally representative sample of healthcare claims data for the Medicare population. RBIs include procedure codes, diagnosis codes, reimbursement, and demographic information. To determine the costs of HE treatment, the primary diagnosis code of HE during an inpatient hospitalization. Healthcare utilization/expenses for inpatient (IP) and outpatient (OP) procedures for the calendar year 2012 were estimated overall and by age cohort: ≤50, 51–64, 65–74, ≥75. RESULTS: A total of 1,113 patients were identified with HE in 2012 (47% were male; 27% of the patients were ≤62 years of age while 11% were ≥75 years. The common chronic liver disease was hypertension (75%) and 41% had renal failure. The mean number of visits to an IP and OP was 1 and 1.68, respectively and varied across age cohorts 14.6 in the ≤62 cohort to 10.7 in the 83+ cohort. p < 0.001. For patients who had an IP visit the mean length of stay was 5.9 days. Mean inpatient expenditures ranged from $25,364 to $58,625 with the highest expenditures in the ≤62 cohort. CONCLUSIONS: HE is a growing problem in the US and becoming increasingly costly condition for the Medicare population.

GASTROINTESTINAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PG128 PREDICTORS OF HEALTH-RELATED UTILITY WEIGHTS IN A CONSECUTIVE COHORT OF REAL-WORLD CROHN’S DISEASE PATIENTS IN ISRAEL

Greenberg D1, Vardi H1, Schwartz D2, Friger M1, Sarid O1, Slomian-Nevo V3, Odes S1

1Ben-Gurion University of the Negev, Beer Sheva, Israel, 2Soroka Medical Center, Beer Sheva, Israel

OBJECTIVES: The objective of this study was to determine the predictors of health-related utility weights in a consecutive cohort of real-world CD patients. METHODS: Patients enrolled in an ongoing socio-economic study of CD in the Israeli adult patient population completed the self-administered SF-36 questionnaire and were assessed for their current clinical status, including the Harvey-Bradshaw Index (HBI) of disease severity. Patients were classified into one of the four disease states: disease remission (HBI<5); mild disease (HBI 5–7); moderate disease (HBI 8–16), and severe disease (HBI>16). RESULTS: A total of 1,113 patients were included in this analysis. The mean age was 37.8 (± 14.2) years, 14.5 (±8.2) years of education, and 11.8 (±8.0) years elapsed since first diagnosis. The average HBI values were in remission disease (HBI≤2), 121 moderate and 25 severe disease. The SF-6D utility weights were correlated with the HBI (r=−0.44; p<0.0001). The mean utility weights for each disease state were as follows: disease remission: 0.720 (±0.143); mild disease: 0.700 (±0.123); moderate disease: 0.603 (±0.109); severe disease: 0.531 (±0.135); p<0.001. The significant predictors of utility weights in a multivariable regression analysis were the HBI (β=-0.236; p=0.001), years of education (β=0.106; p=0.034), and time since diagnosis (β=0.150; p<0.001) (β=-0.246). CONCLUSIONS: CD patients suffer from a deprived quality of life even in the remission and mild stages of the disease. Utility weights for these patients were generally lower as compared to values used in published cost-effectiveness analyses. These values should be considered when assessing the value for money of future interventions for CD.

PG129 PSYCHOMETRIC VALIDATION OF THE DYSPHAGIA SYMPTOM QUESTIONNAIRE IN EOSINOPHILIC ESOPHAGITIS PATIENTS TREATED WITH ORAL BUDENOSIDE SUSPENSION

Hudson J1, Evans CP2, Phillips E1, Hill M3

1Clinical Outcomes Solutions, Tucson, AZ, USA; 2Endpoint Outcomes, Boston, MA, USA; 3Meritage Pharma Inc, San Diego, CA, USA

OBJECTIVES: Eosinophilic Esophagitis (EE) is an inflammatory disorder that can have an impact on quality of life in individuals. The psychometric properties of the Dysphagia Symptom Questionnaire (DSQ) were assessed in a Phase 2, randomized, double-blind, placebo controlled study of oral budesonide suspension with an open-label extension program. METHODS: The evaluation focused on three items of the DSQ. Psychometric data were analyzed against the FDA guidance and included item level analysis as well as score validation including floor/ceiling items, current test validity and known group's method. RESULTS: Among all subjects (n=72), 76% reported worst score at baseline, with only 4% reporting floor/ceiling items. Test-retest reliability, responsiveness, and calculation of minimal important differences (MID). RESULTS: Patients were 69% male, 62% age ≥18, 95% white. Test-retest correlation (Pearson R) was strong (r=0.89). Internal consistency (Cronbach’s α) for all items (range 6.5-8.6%). There was strong item discrimination with 98.1% of patients indicating dysphagia in the quartile of DSQ scores. Physician’s global ratings of severity and EE symptom scores were consistent with monotonically increasing DSQ scores. Anchor-based MIDs were 6.1 ‘a little better’ and 11.3 ‘better’, respectively. CONCLUSIONS: The DSQ is a reliable and valid measure able to clinically discriminate patients along the continuum of dysphagia severity.

PG129 SELF-REPORTED HEALTH STATUS OF PATIENTS WITH CHRONIC HEPATITIS B IN CHINA

Guo Y1, Zhang M2, Zhang S3, Shang H4, Han T5, Guo Y6, Wang X7, Liu J8, Bo Q9, Wang X3, Jia F1

1Saw Swee Hock School of Public Health, National University of Singapore, Singapore, Singapore; 2The Sixth People’s Hospital of Shenyang, Shenyang, China, 3Hepatology Hospital of Jilin Province, Jilin, China, 4Yenan Provincial People’s Hospital, Zhangzhou, China, 5Tianjin 3rd Central Hospital, Tianjin, China, 6The 3rd People’s Hospital of Taiyuan, Taiyuan, China, 7Bristol-Myers Squibb, Shanghai, China, 8GCP ClinPlus Co., Ltd., Beijing, China, 9Beijing Friendship Hospital, Capital Medical University, Beijing, China

OBJECTIVES: To study the variations in self-reported health status of mainland Chinese patients with chronic hepatitis B (CHB) prior to initiating nucleotide analogues treatment. METHODS: This study was part of the EVOLVE study, an ongoing observational clinical study of NUs for treating CHB patients with or without compensated cirrhosis in China. All patients underwent a background assessment for liver function and inflammatory tests, histologic, lifestyle, health status (using the EQ-5D-3L questionnaire), and socio-economic status was obtained from medical records or personal interviews. Variations in self-reported health problems and global health were analyzed with logistic and linear regression models, respectively. RESULTS: In total, 3,343 NUA naïve CHB patients enrolled in 63 hospitals across China (mean age 36 years; male: 73%; HBeAg positive: 61%; compensated cirrhosis: 20%). 2% were included in this analysis. Among those, less than 2% reported problems in mobility.
OBJECTIVES: Patients with Clostridium difficile infection (CDI) can experience long- lasting sequelae due to chronic disease state. Debilitating this, a health-related quality of life (HRQL) instrument specific for patients with CDI does not exist. The goal of this study was to develop and validate a disease specific instrument to assess HRQL in patients with CDI.

METHODS: A systematic literature review was conducted to identify HRQL questions and gastrointestinal disease (n=13) related to CDI HRQL. Removing duplicate questions and using direct patient (n=10) or clinician (n=10) interviews, a 36-item instrument was developed. Ten geriatrician and 30 patient interviews were conducted. The final version of the Cdiff36 was assessed for internal consistency in general health, functional health and quality of life domains.

RESULTS: SF-36 scores were significantly higher in healthy controls (72±22) compared to patients with CDI (54±12) or patients with CDI (43±17); p<0.05 each vs. the control. The final version of the Cdiff36 contained six domains: daily activities (6 items), anxiety (3 items), diet (3 items), sleep (2 items), discomfort (6 items), health perception (6 items), dyspepsia (2 items), relationship (2 items), and social interaction (3 items). Cdiff36 scores correlated significantly based on recurrence vs. primary CDI as well as time since last episode (p<0.05, each). Cdiff36 scales also correlated significantly with the SF-36. CONCLUSIONS: The properties of the Cdiff36 make it appropriate to assess changes over time in HRQL in patients with CDI. Future language translations and validation will be required for global use of the Cdiff36.

PG32

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PG34

DO PHYSICIANS CHANGE THEIR PRESCRIPTIONS IN RESPONSE TO FINANCIAL INCENTIVES?

Han E1, Park S2

1Yonsei University, Incheon, South Korea, 2Korea Institute of Health and Social Affairs, Seoul, South Korea

OBJECTIVES - We assessed the impact on prescription behaviors and drug expenditures of an outpatient prescription incentive program in South Korea that provides financial incentives to primary care physicians for less prescription of medicines with high drug expenditures. METHODS - We focused on drugs for ulcer or gastro-esophageal reflux disease. National Health Insurance claims data for years 2009–2012 were extracted from 1,625 clinics. A clinic-level random effects model was used. Removing duplicate questions and using direct patient interviews, a 36-item instrument was developed. Despite the difference from baseline to EOT did not reach statistical significance for either MCS (p-value=0.105) or MCS (p-value=0.063). At PT week 24, mean changes from baseline were 2.4±1.9 in PCS and 2.6±0.99 in MCS in the RBV group, and 2.3±0.05 in PCS and 2.5±0.94 in MCS in the non-RBV group. CONCLUSIONS: At the end of 12-week treatment in PEARL-IV, the addition of RBV to the interferon-free all-oral OBV/PTV/ r+DSV regimen did not have a significant impact on patient HRQL in treatment-naive patients. Physical Component Summary (MCS) scores for both treatment groups showed similar improvement over baseline.