GASTROINTESTINAL COMPLICATIONS INDUCED BY NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID): EPIDEMIOLOGICAL EXTRAPOLATION FOR EUROPE AND ECONOMIC CONSIDERATIONS

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OBJECTIVES: To calculate the dimension of NSAID induced GI complications in Europe because few epidemiologic data exist. To find evidence of treatment patterns and analyse data on the economic burden of NSAID induced GI complications. To assess the economic benefit of ulcer prophylaxis with proton pump inhibitors (PPI). METHODS: Pub Med and Cochrane Library literature research was conducted with defined MESH terms. An epidemiological extrapolation was done to estimate hospitalisation and death cases due to NSAID use in Europe, limited to rheumatoid arthritis (RA) and osteoarthritis (OA) patients. Economic benefit of ulcer prophylaxis was examined on the basis of international cost of illness and cost effectiveness studies.

RESULTS: Eighty-three studies were analysed. Approximately 3 million patients with RA and 17.3 million patients with OA were calculated for Europe. Potential incidence of hospitalisation due to NSAID use was 157933 patients annually with estimated 25222 cases of death. In the UK, total costs for inpatient stay and treatment of complications were about 367.5 million Euros per year. Data from The Netherlands showed that 14% of the costs of all GI complications were due to NSAID use. Across Europe, co-medication studies are rare; in France, co-medication was prescribed in 29.5%, in Spain in 41.6%, and in The Netherlands in 43% of NSAID users. Indirect costs (e.g. loss of productivity) ranged from 20–50% of total costs. CONCLUSION: Compared to our epidemiological extrapolation, much higher hospitalisation and death rates in Europe must be expected because of the wide range of NSAID indications. A lack of outpatient data limits a differentiated calculation of costs for NSAID induced complications. Although guidelines for ulcer prophylaxis do exist in many European countries, daily routine shows an inconsequent application of gastro protective agents. Given the calculated prevalences, prophylactic ulcer care with PPI are recommended.

ECONOMIC EVALUATION OF THE ARTIFICIAL LIVER SUPPORT SYSTEM MARS IN PATIENTS WITH ACUTE-ON-CHRONIC LIVER FAILURE—FINAL RESULTS OF A CLINICAL COHORT TRIAL

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OBJECTIVES: Acute-on-chronic liver failure (ACLF) is a life threatening acute decompensation of a pre-existing chronic liver disease. The artificial liver support system MARS is a new emerging therapeutic option for treatment of ACLF. The medical efficacy of MARS has been demonstrated in first clinical studies. Objective of this study was to determine survival rates, quality of life, direct medical costs and cost-effectiveness. METHODS: In a clinical cohort trial with a prospective follow-up of 3 years and modelling of cost and survival for the remaining lifetime 62 consecutively included ACLF-patients treated with MARS were compared to 87 controls. Survival, health-related quality of life as well as direct medical costs for in- and outpatient treatment from a health care system perspective were determined and by bootstrapping the incremental costs per life year respectively QALY gained were estimated. RESULTS: There were no significant baseline differences between the two groups. Patients treated with MARS had a highly significant better survival (Logrank) with a mean outcome gain of 0.66 years, but bootstrap analysis showed broad confidence intervals (~0.12 to 1.46). The average initial intervention costs for MARS were €14,600 per patient treated. Incremental direct medical costs were €19,946 per patient treated with MARS (CI: 13,308 to 25,429). The mean costs per life-year gained were €29,985, costs per QALY were €43,040. In total, 34% of the bootstrap sample were QALY gained. But bootstrap analysis of CER showed a probability of 34% to be higher than 50,000€ per QALY gained. Further randomized controlled trials investigating the medical efficacy and the cost-effectiveness are recommended.

COMPARATIVE EFFICACY OF PARIET (RABEPRAZOLE): LESSONS FROM CLAIMS DATA

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OBJECTIVES: Pariet (rabeprazole) was introduced at a substantial price discount to existing, branded proton pump inhibitors (PPIs) in Canada. Therefore, there may have been a perception of comparative reduced efficacy with Pariet, in part because Pariet is generally dosed at two tablets daily, compared to one unit daily for other PPIs. The objective was to conduct individual claims data descriptive analyses to identify differences in patterns of use indicative of reduced efficacy or selection of patients. METHODS: Individual claims data were obtained for Ontario, Canada. PPI claims were followed backward in time to determine if the patient had received a different PPI, an H2 antagonist or neither therapy previously (minimum time period, twelve months). This could suggest selection bias for naïve patients versus treatment-experienced patients. PPI claims were followed forward in time to determine if there were subsequent claims for a different PPI, an H2 antagonist, or neither. This proxy measure was interpreted as a lack of efficacy requiring therapy switches. RESULTS: Pariet users were equally likely as other PPI users to have had no claims for another PPI or H2 in the previous twelve months (74% PPI market overall, 70% Pariet). The proportion of patients who subsequently switched therapy increased as the duration of follow-up increased. Overall, Pariet users were most likely to have no subsequent claims for another PPI or an H2 antagonist compared to other PPIs (59% overall market, 71% Pariet users). CONCLUSION: Claims data do not support that Pariet has different efficacy from other PPIs or is used differently.

HEALTH-STATE UTILITIES IN LIVER DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Health-state utilities are essential for cost-effectiveness analysis, and few estimates exist for liver disease in the literature. Our aim was to conduct a systematic review of health-state utilities in liver disease, and to estimate utilities for various liver disease states for a large UK Department of Health study. METHODS: Articles were included in the systematic review if health-state utility tools were used to estimate utility or if they
were estimated by expert opinion. If two or more studies estimated utility for a similar disease state then a meta-analysis was carried out to pool the variance weighted mean estimates.

RESULTS: Twenty-eight studies measured utilities of liver diseases or disease states. Only nine of these studies were eligible for meta-analysis for four health states in chronic liver disease patients (compensated cirrhosis, decompensated cirrhosis, pre-liver transplant and post-liver transplant) and three in Hepatitis C patients (compensated cirrhosis, decompensated cirrhosis and post-liver transplant). The pooled mean estimates in chronic liver disease and hepatitis C patients with compensated cirrhosis were 0.87 (95% CI 0.62 to 1.12) and 0.83 (95% CI 0.68 to 0.99) respectively. For decompensated cirrhosis they were 0.68 (95% CI 0.40 to 0.95) and 0.73 (95% CI 0.50 to 0.97). For post-liver transplant, the estimates were 0.70 (95% CI 0.40 to 1.01) and 0.76 (95% CI 0.52 to 1.01) respectively. Pre-liver transplant patients with chronic liver disease had a utility estimate of 0.57 (95% CI 0.28 to 0.87).

CONCLUSIONS: We have estimated summaries of patient utilities for the major states of chronic liver disease and hepatitis C, and created a valuable liver disease-based utility resource for researchers and policy makers.

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ARE ADULTS MORE AVERSE TO TREATMENT RISKS FOR THEIR CHILDREN THAN THEY ARE FOR THEMSELVES?

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OBJECTIVE: Compare maximum acceptable risk (MAR) of treatment-related serious adverse events (SAE) between adult Crohn's disease (CD) patients and parents of children with CD. Information on benefit-risk tradeoffs may aid clinicians and regulatory agencies in their decision-making.

METHODS: An online panel of adult CD patients and parents of children with CD completed a series of choice-format conjoint tradeoff tasks. The treatment attributes included daily symptom severity and activity limitations, the potential for serious disease complications, the time between flare-ups, oral steroid use, and varying levels of three SAE mortality risks: serious infection, progressive multifocal leukoencephalopathy (PML) and lymphoma. The annual MAR was calculated for 15 SAE-clinical benefit combinations (3 SAEs X 5 levels of clinical improvement from a severe or moderate CD state).

RESULTS: A total of 357 adult patients and 105 parents completed the survey. Improvements in daily symptom severity were the most important factor in treatment preferences. Higher MAR (greater risk acceptance) was observed for tradeoff tasks involving higher levels of clinical benefit. Compared to adult patients, parents were willing to accept a greater SAE risk for alleviation of severe CD symptoms (for 7 of 9 SAE vs. clinical benefit combinations), but were less willing to accept SAE risk for improvement of moderate CD symptoms (for 6 of 6 combinations).

CONCLUSIONS: Medical interventions carry risks of adverse outcomes that must be evaluated against their clinical benefits. Adult patients and parents of children with CD indicated they are willing to accept defined mortality risks in exchange for clinical efficacy. While parents were more willing to accept higher SAE risks for improvement of severe CD symptoms, patients were willing to accept higher risks for improvement of moderate CD symptoms.