HOSPITALIZATIONS FOR GASTROINTESTINAL EVENTS AMONG USERS OF COX 2 INHIBITORS COMPARED WITH TRADITIONAL NON-STEROIDAL ANTI-INFLAMMATORY DRUGS WITH PROTON-PUMP INHIBITORS

Van der Linden MW1, Kuipers E2, Sulem M2, Herings RM1, Gaugris S3

1PHARMO Institute for Drug Outcomes Research, Utrecht, Netherlands, 2Erasmus University Medical Center, Rotterdam, Netherlands, 3PHARMO Institute, Utrecht, Netherlands, 4Merck & Co., Inc, Whitehouse Station, NJ, USA

OBJECTIVE: To compare the rate of hospitalizations for serious upper and lower GI events in patients with increased GI risk taking a Traditional NSAID (tNSAID)+Proton Pump Inhibitor (PPI) or a COX-2 selective inhibitor (Coxib), chronic and acute.

METHODS: From the PHARMO Record Linkage System, including among others linked drug-dispensing and hospital records of approximately three million individuals in The Netherlands, we selected new users of Coxibs or tNSAIDs between January 1, 2000 and December 31, 2004. Eligible patients had ≥1 year history before the 1st NSAID dispensing and ≥1 year follow-up which ended at first hospitalization for serious GI event (the outcome), the last dispensing, or the end of the study period. Chronic users were defined as patients who used any NSAIDs for ≥60 days during the first year of follow-up (n = 58770); other NSAID users were acute users (n = 538,420). Multivariate analysis by Poisson regression adjust for sex, age, duration of follow-up, tNSAID and coxib dose, adherence to NSAIDs or PPIs, gastroprotection, anti-coagulants, acetaminophen, corticosteroids, and cardiovascular disease.

RESULTS: The cohort included 32,953 new tNSAID+PPI users and 80,736 new Coxib users, with main characteristics: mean (±SD) age 58.1 ± 15.5 vs. 56.7 ± 17.5; female 55.3% vs. 62.2%; mean duration of treatment (days): 137 ± 217 vs. 138 ± 179, respectively. Among acute users, adjusted hazard ratios (95% Confidence Interval) of hospitalizations were 0.21 (0.14–0.32) for upper and 0.26 (0.16–0.42) for lower GI events, for Coxib versus tNSAID+PPI users. Among chronic users, adjusted hazard ratios were 0.35 (0.22–0.55) for upper GI and 0.43 (0.25–0.75) for lower GI events, for Coxib versus tNSAID+PPI users. CONCLUSION: Acute and chronic Coxib users had a statistically significantly lower rate of hospitalizations for upper and lower GI events compared to tNSAID+PPI users. Future research is needed to explain these findings, possibly due to prescribing for non-preventive reasons.

GASTROINTESTINAL DISORDERS—Cost Studies

A BRAZILIAN CROSS SECTIONAL STUDY TO EVALUATE HOSPITALIZATION AMONG MODERATE AND SEVERE CROHN’S DISEASE PATIENTS

Araujo G, Fonseca M

Axia Bio Consulting, São Paulo, Brazil

OBJECTIVE: Infliximab improves patient quality of life and is effective to control Crohn’s disease refractory to the standard treatment. It lacks real world Brazilian data demonstrating that this improvement in quality of life and disease control is related to decrease of resource use mainly due to hospitalization. Reducing hospitalization in moderate and severe Crohn’s patients receiving...
infliximab. METHODS: Thirty one gastroenterologists from southeast Brazil prospectively evaluated all their Crohn's disease patients during two months. They used a structured questionnaire specifically developed to evaluate resource use by patients with Crohn's disease. RESULTS: A total of 118 patients with moderate and severe disease were evaluated during 2 months. The patients average age was 30 years and the mean body weight was 62 kg. Fourteen patients were using infliximab. The comparison among infliximab patients and standard care patients showed that 60.6% of the standard care patients needed hospitalization and only 21.4% of the infliximab patients needed hospitalization (p = 0.005). The main reason for hospitalization among the standard care patients was due to anal fistula, and among the infliximab patients, was due to anemia/hemorrhage. CONCLUSION: The use of infliximab in the management of moderate and severe Crohn's disease can be contributive to reduction of the need of hospitalization among these patients.

COST-EFFECTIVENESS OF NATALIZUMAB IN CROHN'S DISEASE PATIENTS WHO HAVE FAILED ANTI-TNF ALPHA THERAPY
Panjabi S1, Niecko T1, Hass SL1, Lacey L1, Spencer MD4
1Elan Pharmaceuticals Inc, South San Francisco, CA, USA, 2Niecko Health Economics, LLC, Escondido, CA, USA, 3LaceySolutions Ltd, Skerries, Co. Dublin, Ireland, 4Elan Pharma, Stevenage, Hertfordshire, UK

OBJECTIVE: To compare the cost-effectiveness (CE) of natalizumab (NAT) to FDA-approved tumor-necrosis factor alpha inhibitors (anti-TNFα) in Crohn's disease (CD). METHODS: Decision analysis was used to model treatment for patients with moderate-to-severe CD (Crohn's Disease Activity Index scores ≥220 and <450). Patients are assumed to have failed treatment with corticosteroids, immunomodulators, and anti-TNFα therapy. The model includes an induction phase followed by a two year maintenance phase comparing NAT 300 mg, infliximab (INF) 5 mg/kg or 10 mg/kg, and adalimumab (ADA) 40 mg every other week or weekly. At the end of induction and each of the four six-month maintenance cycles, patients enter one of three efficacy states (remission, response, nonresponse) that are estimated from phase III clinical studies and NAT clinical data. Total costs associated with each comparator agent are composed from published pharmacy and medical costs derived from published price lists and analyses of CD claims from a database assembled by Health Benchmarks International. Drug costs for INF and ADA were weighted by dose based upon the distribution observed in published phase IV studies. RESULTS: Over the two year maintenance period, NAT patients on average were estimated to be in remission for 0.41 years versus 0.22 and 0.26 for those receiving INF and ADA, respectively. Average total costs over induction and maintenance were predicted to be $62,377 (NAT), $55,195 (INF), and $56,654 (ADA). NAT was associated with 13% and 10% increases in total cost compared to INF and ADA, but resulted in 86% and 57% increases in remission duration over the comparators, respectively. The CE ratio for NAT relative to ADA and INF remained insensitive to increases in NAT-related costs (up to $36,000) or decreases in NAT efficacy (up to −25%). CONCLUSION: This model, based on estimates from the available published literature, projected NAT to be the most cost-effective treatment alternative for patients who had failed prior anti-TNFα therapy.

COST-EFFECTIVENESS RECOMBINANT FACTOR VIIa USE IN ORTHOTOPIC LIVER TRANSPLANT
Schoenhaus B, Awdishu L, Daniels C
University of California at San Diego, San Diego, CA, USA

OBJECTIVE: Recombinant factor VIIa, an expensive coagulation factor, was previously utilized pre-operatively at UC San Diego Medical Center (UCSDMC) to reduce blood loss during Orthotopic Liver Transplant (OLT). Recent large randomized, controlled clinical trials have demonstrated a lack of efficacy and a potential risk of thromboembolic complications. As a result, use of recombinant factor VIIa for bleeding prophylaxis in OLT was discouraged due to compromised cost-effectiveness. This change in practice warranted validation through pharmacoeconomic outcomes research. METHODS: A single-center, retrospective review was performed to determine if the change in UCSDMC OLT guidelines resulted in negative outcomes. The primary outcome measure was the volume of blood products required during OLT. Secondary outcomes included total cost of care, operating room time, LOS, and thromboembolic events. RESULTS: 119 liver transplant recipients were included in the analysis. There was no significant difference in the primary outcome of blood product requirement. Patients receiving factor VIIa failed to demonstrate any statistically significant reduction in need for PRBC 13.8 vs 13.4 units (p = 0.9), FFP 11.3 vs 15.6 (p = 0.2), or PLT 4 vs 6.6 (p = 0.08) when compared to controls. The secondary outcome measurements also failed to reach statistical significance, including LOS 23 vs 15 days (p = 0.17), blood costs (p = 0.92), surgical costs (p = 0.69), and total cost of care (p = 0.15). Two patients developed hepatic artery thrombosis in the treatment group compared to one patient in the control group. As measured by the Scientific Registry of Transplant Recipients (SRTR), no significant changes in liver transplant patient or graft survival were noted. An 83% reduction average recombinant factor VIIa use for reduction of blood product requirements in OLT has not been demonstrated to be cost-effective and may be associated with a risk of thromboembolic events.

COST EFFECTIVENESS ANALYSIS OF HELICOBACTER PYLORI SCREENING IN PREVENTION OF GASTRIC CANCER IN CHINESE
Xie F1, Luo N2, Blackhouse G1, Goeree RA1, Lee HP2
1McMaster University, Hamilton, ON, Canada, 2National University of Singapore, Singapore, Singapore

OBJECTIVE: Associated with no screening, H. pylori serology screening, and the 13C-Urea breath test (UBT) for gastric cancer in Chinese. METHODS: A Markov model simulation was carried out in Singaporean Chinese at age of 40 years (n = 478,500) from the perspective of public health care providers. The main outcome measures were costs, number of gastric cancer cases prevented, life years saved, quality-adjusted life years (QALYs) gained from the screening age to death, and incremental cost-effectiveness ratios (ICERs), which were compared among the three strategies. The uncertainty surrounding ICERs was addressed by scenario analyses and probabilistic sensitivity analysis using Monte Carlo simulation. RESULTS: The ICER of serology screening versus no screening was $23,881 per QALY gained (95% confidence interval (95% CI): $5700 to $120,000). The ICER of UBT versus no screening was $3,602 per QALY gained (95% CI: $16,000 to $230,000). ICER of UBT versus serology screening was $470,000 per QALY gained, for which almost all random samples of the ICERS distributed above