PGI2

CHANGES IN PRESCRIPTIONS DISPENSED ON PROTON PUMP INHIBITORS (PPIS) FOLLOWING NEW RESTRICTIONS FOR REIMBURSEMENT – A NATIONWIDE NORWEGIAN PRESCRIPTION DATABASE STUDY

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OBJECTIVES: To assess the changes in PPI prescriptions dispensed after the introduction of new reimbursement policy from February 1, 2007. The intention of the new policy was to reduce costs by shifting patients from esomeprazole to lansoprazole, omeprazole or pantoprazole. New patients should not start on esomeprazole and ongoing esomeprazole patients should shift to a different PPI. Esomeprazole could be used upfront in severe cases or after having tried a different PPI first. **METHODS:** The Norwegian Prescription Database (NorPD) contains data on all prescriptions dispensed making it possible to follow each individual over time. All PPI prescriptions dispensed from January 1, 2004 to January 31, 2008 were analysed. **RESULTS:** For patients using esomeprazole before February 1, 2007 and having a new PPI prescription dispensed the year after (n = 79781), 64% continued on esomeprazole and 36% changed to a different PPI. In the latter group 57%, 20% and 23% shifted to pantoprazole, lansoprazole or omeprazole, respectively. 27%, 23% and 21% of those who shifted from esomeprazole to pantoprazole, lansoprazole or omeprazole, respectively, shifted back to esomeprazole again. The overall figure was 25%. For patients starting on PPI treatment during the year after February 1, 2007 (n = 32479), 42% started with pantoprazole, 16% with omeprazole, 19% with lansoprazole and 23% with esomeprazole. Seven percent in the group of new PPI users shifted to a second PPI. There was a profound drop in new prescriptions dispensed for esomeprazole from 57% during the last quarter before the introduction, to 26%, 24%, 22% and 20% during the four quarters after introduction. **CONCLUSIONS:** The new reimbursement policy for PPIs has led to significant changes in the pattern of prescription dispensed. The policy was easier to implement for new patients starting on PPI treatment compared to a compulsory shift for patients on ongoing esomeprazole treatment.

PGI3

RISK OF UPPER GASTROINTESTINAL ADVERSE EVENTS AND THE EFFECT OF ACID-SUPPRESSIVE THERAPY IN PATIENTS RECEIVING ACETYLSALICYLIC ACID FOR CARDIOVASCULAR RISK MANAGEMENT

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OBJECTIVES: Minimizing the risk of upper gastrointestinal (GI) adverse events (AEs), which may compromise patient compliance with low-dose acetylsalicylic acid (LDASA) therapy, is an important part of cardiovascular (CV) risk management. Using data from the AstraZeneca ARIADNE database we assessed the risk of upper GI AEs (including peptic ulcer disease, esophagitis and dyspepsia) and the benefits of acid-suppressive therapy with proton pump inhibitors (PPIs) in patients taking LDASA for CV risk management. **METHODS:** The ARIADNE database was created by Astra (now AstraZeneca) to store safety-related clinical study data. For this analysis, data on elderly patients with mild hypertension were extracted. During the follow-up period (mean 3.7y), patients received antihypertensive therapy (hydrochlorothiazide, plus an angiotensin II receptor antagonist or placebo) and other treatments required for their individual care. Among patients without a history of upper GI AEs (n = 4539), Cox proportional hazard models were used to estimate the relative risk (RR; adjusted for age, sex, and body mass index) of upper GI AEs associated with concomitant use of LDASA and in relation to when PPI therapy was commenced. **RESULTS:** Overall, 1191 patients (26.2%) received LDASA during the study (with or without concomitant acid-suppressive therapy). There was a trend towards an increased risk of upper GI AEs in current LDASA users (RR, 1.27; 95% confidence interval [CI]: 0.95, 1.71). Within the subgroup using LDASA and PPIs (n = 138, 11.6%) the RR of upper GI AEs was 5.41 (95% CI: 3.43, 8.53) when LDASA therapy was initiated before the start of PPI therapy. Adding LDASA to an existing PPI treatment protected against an increased risk of GI AEs. **CONCLUSIONS:** These data suggest that the risk of upper GI AEs is high in elderly patients receiving LDASA for CV risk management, and that PPIs confer a protective effect against upper GI AEs in these at-risk individuals.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI4

NUMBER-NEEDED-TO-TREAT (NNT) ANALYSIS: REMISSION RATES FOR ADALIMUMAB VS. INFLIXIMAB IN CROHN'S DISEASE

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OBJECTIVES: To compare NNTs for infliximab 5-mg/kg vs. adalimumab 40-mg every-other-week (eow) therapies, matching the 2 patient populations at baseline using statistical methods. **METHODS:** Remission rates for infliximab and placebo in ACCENT I (Week-2 responders) and adalimumab and placebo in CHARM (Week-4 responders) were used. Because of the difference in CDAI scores at baseline between the 2 trials, unmatched and matched comparisons were made. Matching excluded CHARM patients with CDAI >400 and weighted remaining CHARM data for equal baseline median and 25th and 75th percentile CDAI scores, as well as mean sex and median age characteristics, with ACCENT I patients. Remission NNTs for Weeks 30/26 and 54/56 were calculated, as well as weighted 56-week average remission rates. Cost per remitter was compared using indicated dosages and assuming complete therapy adherence. Adalimumab's indicated dosing equates to 32 doses/56 weeks. Infliximab's indicated dosing equates to 9 infusions/56 weeks. 2008 wholesale acquisition costs (WAC) were $603.6/100 mg of infliximab and $692.47/40 mg of adalimumab. Administration cost per infliximab infusion was assumed to be $239.49. Patient weight of 70 kg and ½-vial per infusion waste were also assumed. **RESULTS:** At 30 weeks, the infliximab NNT was 5.56; at 26 weeks, the adalimumab unmatched and matched NNTs were 4.34 and 3.86. At 54 weeks, the infliximab NNT was 6.80; at 56 weeks the adalimumab unmatched and matched NNTs were 4.12 and 3.72. 56-week average for the infliximab NNT was 5.92, whereas adalimumab unmatched and matched averaged NNTs were 4.83 and 4.77. Over 56 weeks, costs per patient were $23,885 for infliximab and $22,159 for adalimumab. Average costs per additional remitter were $141,399, $107,028, and $105,698 for infliximab, unmatched adalimumab, and matched adalimumab. **CONCLUSIONS:** Based on matched and unmatched comparisons of data from CHARM and ACCENT I, adalimumab had better efficacy and cost profiles than infliximab.

PGI5

PUBLISHED COST-EFFECTIVENESS RESULTS FOR CHRONIC HEPATITIS B AND C – A COMPARATIVE ANALYSIS

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OBJECTIVES: Each year, cost-effectiveness studies are published in the area of Hepatitis B and Hepatitis C that have varying results. The current abstract aims to analyze and compare the cost-effectiveness results for Chronic Hepatitis B and C across the different countries of publication in order to identify characteristics that can be used across analyses for future studies. **METHODS:** A systematic literature review of the last five years, English only, was conducted using PubMed. Article titles were reviewed by two independent reviewers in order to create a refined list for analysis. The inclusion criterion for analysis was studies related to medications; publications related to vaccination or prevention programs were not included in the analysis. Data from the finalized list of articles was then extracted. For comparison and analysis purposes, all results were converted to 2008 currency values and then to 2008 US Dollars using the Purchasing Power Parities (PPP) rate published by OECD. Lastly, Incremental Cost Effectiveness Ratios (ICER) were compared for either Hepatitis B or Hepatitis C. **RESULTS:** A total of about 40 publications from different countries were included in the comparative analysis. The results reported (incremental cost per QALY or life year gained) varied from $142 (reported in a study from China) to over $100,000 in some cases. Applying the PPP helped in the comparison of results, but conclusions regarding commonalities (such as time horizon, comparators, target groups etc.) among results across studies, countries and drugs prescribed could not be made. **CONCLUSIONS:** Utilizing international cost-effectiveness analyses could facilitate the comparison among results generated by these studies. The use of international cost-effectiveness analyses could also allow information to be obtained about additional products and international experience; however these analyses should not serve as a gold standard in health economics.

PGI6

COST EFFECTIVENESS ANALYSIS OF ANTI-TNF-ALPHA; DRUGS FOR REFRACTORY ULCERATIVE COLITIS

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OBJECTIVES: To evaluate cost-effectiveness of infliximab and adalimumab for patients with refractory moderate-to-severe active ulcerative colitis (UC) in Canada. **METHODS:** A four-health state Markov model was constructed to compare cost-effectiveness of three management strategies: A) usual care without anti-tumor necrosis factor á (anti-TNF-á); B) 5 mg/kg infliximab for responders and adalimumab for nonresponders; and C) 5 mg/kg infliximab for responders, 10 mg/kg infliximab for those lost their response in the maintenance stage, and adalimumab for nonresponders to the initial therapy. ACT1 and ACT2 randomized clinical trials were two main sources of clinical parameters. The primary outcome measure was the incremental cost-effectiveness ratio (ICER) between the strategies. Both deterministic and probabilistic sensitivity analyses were performed. **RESULTS:** In the base case analysis, The ICER was $381,133/QALY for the strategy B versus the strategy A and $609,390/QALY for the strategy C versus the strategy A. The strategy C was dominated by the strategy B. The ICERs were sensitive to the remission rates, early surgery rate, and utility values. When the willingness to pay (WTP) was less than $150,000/QALY, the probability of the strategy A being the optimal strategy was 1.0. The probability of strategy B being optimal was 0.5 when the WTP increased to $400,000/QALY. The probability of the strategy C being the optimal strategy was very low despite the wide range of WTP values. **CONCLUSIONS:** Although infliximab and adalimumab demonstrated clinical benefits over standard treatment in patients with refractory UC, the cost-effectiveness of these treatments are not attractive due to significantly higher costs in Canada.