databases from 1990–June 2007 were systematically searched for RCTs evaluating the efficacy of PPIs on nighttime symptoms in adults with GERD. Methodological and clinical homogeneity across studies was explored. Methodological diversity or differences in study quality evaluated by Jadad score (ranging from 1 = low to 5 = high) and clinical diversity in nighttime criteria used for patient enrollment, nighttime outcomes measured, and the nighttime definition used were explored. RESULTS: Thirty-two RCTs compared the efficacy of PPI with placebo only (n = 7), H2-receptor antagonist only (n = 12), another PPI only (n = 11) or both placebo and H2-receptor antagonist (n = 2) in controlling nighttime GERD. The majority of studies (n = 28) were of high methodological quality (Jadad score of at least 3 points). Source of data collection was patient daily diaries across all studies. Criteria for enrolling nighttime GERD patients (frequency and/or severity of nighttime symptoms) lacked consistency. Nighttime heartburn measures varied from percentage of patients without heartburn (n = 18), percentage of heartburn-free nights (n = 13), heartburn score (n = 11) or time to heartburn relief (n = 6). Most studies assessed efficacy at eight weeks or less; only three studies measured the long-term efficacy of PPI. However, very few nighttime heartburn measures assessed the same timeframe. The time window for the nighttime symptom assessment was reported in only three studies and was not based on specific hours but on sleep/posture (retiring/lying down to sleep). CONCLUSION: RCTs of PPI therapy in nighttime GERD are of high methodological quality. However, presence of clinical heterogeneity across trials in enrollment criteria, outcomes, and timeframes minimizes the possibility of performing meta-analysis.

PGI2
HOSPITALIZATIONS FOR GASTROINTESTINAL EVENTS AMONG USERS OF COX 2 INHIBITORS COMPARED WITH TRADITIONAL NON-STEROIDAL ANTI-INFLAMMATORY DRUGS WITH PROTON-PUMP INHIBITORS
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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 adjusted for sex, age, duration of follow-up, tNSAID and coxib dose, adherence to NSAIDs or PPIs, gastroprotection, anticoagulants, acetaminophen, corticosteroids, and cardiovascular disease. RESULTS: The cohort included 32,953 new tNSAIDs+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% Cofidence 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 tNSAIDs+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 tNSAIDs+PPI users. CONCLUSION: Acute and chronic Coxib users had a statistically significantly lower rate of hospitalizations for upper and lower GI events compared to tNSAIDs+PPI users. Future research is needed to explain these findings, possibly due to prescribing for non-preventive reasons.

GASTROINTESTINAL DISORDERS—Cost Studies

PGI3
COST OF PATIENT CARE IN PATIENTS WITH ULCERATIVE COLITIS IN BRAZIL: PUBLIC HEALTH PERSPECTIVE
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OBJECTIVE: Ulcerative colitis (UC) is a chronic condition that affects young adults in their economically productive years. Because of its long duration, UC causes high use of health services and high lifetime costs for medical care. The aim of this study was to measure the annual costs of patients with UC from the Brazilian public health perspective and to identify potentially relevant determinants of costs. METHODS: Thirty-one gastroenterologists from southeast Brazil prospectively evaluated all their UC patients during two months. They used a structured questionnaire specifically developed to evaluate resource use by patients with ulcerative colitis. Costs of medical services (diagnostics and treatment) were considered as well as costs of medication. Resource use was valued using government reimbursement for hospital services and government tender prices drugs. RESULTS: A total of 175 patients were evaluated. The mean annual cost of one CD patient was R$1945.06, including medication, physian, laboratory, diagnostic, hospitalization and surgery costs. Medication, hospitalization, surgery and diagnostic procedures accounted respectively for 95%, 3%, 1%, and 1% of the total annual costs. Mesalazine was the most used drug to initiate UC’s treatment (58%). There was no statistical difference between the costs of the patients treated with mesalazine and sulfasalazine. Due to differences in the mean dosage of theses drugs, mesalazine daily cost is lower than sulfasalazine. CONCLUSION: This is the first time that UC treatment costs have been demonstrated from the Brazilian public health perspective. Although mesalazine is deemed to be more expensive than sulfasalazine and considering that there was no statistical difference in total costs among patients taking mesalazine and sulfasalazine, and that medications represent more than 90% of total UC treatment annual costs in the public Brazilian health care system, the use of mesalazine may represent a reduction factor in the financial resource expenditure for the treatment of UC.

PGI4
A BRAZILIAN CROSS SECTIONAL STUDY TO EVALUATE HOSPITALIZATION AMONG MODERATE AND SEVERE CROHN’S DISEASE PATIENTS
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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 reduction in moderate and severe Crohn disease patients receiving