GASTROINTESTINAL DISORDERS— Clinical Outcomes Studies

PGI1

COMORBIDITIES DURING THE YEAR FOLLOWING DIAGNOSIS FOR PERSONS WITH AND WITHOUT GERD USING THE AGENCY FOR HEALTH RESEARCH AND QUALITY (AHRQ) 261 SPECIFIC CATEGORIES

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OBJECTIVES: Evaluate the prevalence and costs of selected comorbidities in GERD patients using a systematic approach. **METHODS:** An employer database query of >300,000 US employees from 2001–2005 to identify subjects with GERD ICD9s and a cohort without GERD (Control). For each GERD subject 10 control patients were matched using logistic regression and propensity scores from demographic differences, region, and the Charlson Comorbidity Index Score. Analysis focused on the 12 months post-diagnosis (Dx). Direct medical cost data were inflated to constant dollars and assigned based on ICD9 codes from the AHRQ's 261 Specific Categories. Prevalence rates were based on persons within the cohort with claims for each category. Average costs for each category were calculated for the entire cohort. Prevalence comparisons used z-scores of log odds ratios (Woolf method), and the average cost comparisons used Sattherthwaite t-tests. **RESULTS:** Data were available for 11,653 GERD and 116,530 matched controls. Differences between cases with GERD and controls are presented as: (% prevalence in GERD: % prevalence in controls, $ cost in GERD: $ cost in controls). Gastrointestinal disorders: Abdominal pain (27.3% GERD : 6.8% Control, $165 GERD : $32 Control); Gastritis + duodenitis (15.2% : 1.0%, $87 : $5); GI hemorrhage (6.6% : 1.8%, $37 : $9); Stomach/duodenum disorders (5.4% : 0.5%, $17 : $1); Noninfectious gastroenteritis (5.0% : 1.6% $19 : $5); Biliary tract disease (3.9% : 0.7%, $150 : $25); Gastroduodenal ulcer (2.5% : 0.2%, $11 : $1); Other GI disorders (30.8% : 3.6%, $116 : $13); Respiratory disorders: Upper respiratory infections (31.5% : 18.0%, $64 : $23); Asthma (6.9% : 2.8%, $23 : $7); COPD+bronchiectasis (4.9% : 2.4%, $10 : $6); Other upper respiratory disease (21.0% : 8.5%, $79 : $24); Other lower respiratory disease (17.6% : 6.8%, $52 : $19); Other disorders: Nonspecific chest pain (18.8% : 6.2%, $163 : $46); Nutrit/endocrine/metabolic (8.6% : 3.3%, $159 : $23); Thyroid disorders (8.0% : 4.8%, $31 : $12). All costs and prevalence of comorbidities were higher in the GERD cohort compared to controls ($P < 0.05$). **CONCLUSION:** Patients with GERD have more prevalent conditions than subjects without GERD. From an insurer's perspective, this increased burden for GERD sufferers is also associated with higher costs.

PGI2

BIOLOGICAL AGENTS FOR THE MANAGEMENT OF CROHN'S DISEASE IN ADULTS: A SYSTEMATIC REVIEW, META-ANALYSIS AND MULTIPLE TREATMENT COMPARISON

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OBJECTIVES: To conduct a systematic review of the clinical effectiveness of biological agents in adult Crohn's disease (CD), a meta-analysis of treatment effect, and an indirect comparison of individual therapies. **METHODS:** Searches were conducted to identify RCTs assessing efficacy of monoclonal antibodies to TNF (infliximab, certolizumab pegol and adalimumab), interferon (fontolizumab) and a selective adhesion molecule inhibitor (natalizumab) in adult CD. A meta-analysis, applying the Mantel-Haenszel test, was used to estimate the pooled odds ratio for all agents (versus placebo), assuming a fixed effects model. Indirect comparisons among treatments, for remission (CDAI < 150) at the end of the induction and maintenance phases, were made by use of a Bayesian analysis of indirect evidence for multiple treatments. **RESULTS:** Fifteen studies were identified; 1 for fontolizumab; 2 each for certolizumab and adalimumab; 3 for natalizumab and 7 for infliximab. These were categorised broadly into: (1) single and (2) multiple dose induction studies with placebo control group; maintenance studies without placebo control group after (3) single and (4) multiple dose induction; and (5) maintenance studies with placebo control group after multiple dose induction. Biological agents were superior to placebo at the end of induction (pooled OR = 1.61, 95%CI 1.22–2.13; heterogeneity I^2 = 0%, 95%CI 0%-64%). End of maintenance studies were deemed too heterogeneous (I^2 = 89%, 95%CI 62%-95%) for analysis. The multiple treatment comparison analysis suggested that at the end of induction, the probability that infliximab is best is 77% (SD 42%); fontolizumab 21% (41%); certolizumab and natalizumab 1%. For maintenance, the probability that adalimumab is best is 60% (SD 49%); infliximab 33% (47%); natalizumab 7% (25%); certolizumab <1%. **CONCLUSION:** Several agents have shown superiority to placebo in moderate-to-severe CD. Head-to-head trial data for rival agents are lacking but a multiple treatment comparison analysis (acknowledging the limitations) failed to identify an individual agent as dominant for both induction and maintenance end-points.

PGI3

CONSTIPATION IN PERSONS RECEIVING HOSPICE CARE: PRELIMINARY ESTIMATES

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OBJECTIVES: Pain at the end of life is common and often suboptimally treated, though treatment of pain can also result in adverse events. One of these adverse events is constipation, which can interfere with pain management, health-related quality of life, and result in avoidable medical resource use. The epidemiology of constipation in persons at the end of life remains incompletely described, thus we sought to determine the prevalence and severity of constipation among persons receiving hospice care in the United States from 2000 to 2004. **METHODS:** Data for this study were obtained from excelleRx, Inc., a national provider of pharmaceutical services to US hospices. Patient-level information included primary diagnosis (by ICD-9 code), type of hospice care received, constipation intensity, and prescription of opioid analgesics. Constipation intensity during the previous 24 hours was assessed by hospice nurses using a 0–10 numeric rating scale (NRS; 0 = none, 10 = worst) at admission and periodically during hospice care. **RESULTS:** During the study period, 347,555 discharged or deceased persons received hospice services; 55% of these persons were female, 87% were Caucasian, and mean age was 75 years. Constipation was assessed at least once for 180,239 (45%) individuals, an average of 3 times per person. Overall, mean intensity of constipation was mild, though moderate and severe constipation was reported by 29,132 (8%) and 13,748 (4%) of persons, respectively. Among individuals who reported severe constipation at least once, 67% had a primary diagnosis of cancer. **CONCLUSION:** Moderate to severe constipation was reported at