RETROSPECTIVE ANALYSIS OF A PRIOR AUTHORIZATION PROGRAM USING COX-2 INHIBITORS IN A MANAGED CARE POPULATION

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OBJECTIVES: This study examines the patient level factors that play role in initiating the process of prior authorization, and evaluates whether prior authorization (PA) process has an effect on future gastrointestinal (GI) outcomes (e.g. bleeding, peptic ulcer disease (PUD)) in managed care population. METHODS: Patients who encountered a PA system edit for Cox-2 inhibitors during January 1, 2001 to July 31, 2002 were followed up for 1 year post rejection date. Patients were stratified to 2 groups; 1) initiated the process of PA, 2) never initiated the process of PA. Using multivariate logistic regression, significant covariates in predicting future GI bleed or PUD, and applying for PA were identified. Charlson Comorbidity Index (CCI) was calculated for each patient and used in the regression analysis. RESULTS: Those who initiated the PA process were significantly older, had higher CCI, higher total medical and pharmacy costs, and more GI events than those who never applied for a PA. Significant covariates in predicting future GI bleed were aged >65, previous GI bleed or PUD, and higher CCI. In addition to gender similar covariates also predicted future PUD where females were at higher risk of having a PUD. Whether prior authorization process was initiated or not was not a significant factor in predicting future GI event. Patients who are females or age >65, with osteoarthritis, rheumatoid arthritis, previous ulcer or GI bleed event, or high CCI score were more likely to apply for PA. CONCLUSION: PA process appears to select high risk patients to receive Cox-2 inhibitors. Patients who did not apply for PA appear to have similar adjusted future GI event rate than those who applied.

EVALUATING THE GERD SYMPTOM AND MEDICATION QUESTIONNAIRE (GERD-SMQ) IN A CLINICAL TRIAL

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OBJECTIVES: Assess the construct validity of the GERD-SMQ in relation to esophagitis grade severity, symptom severity, and quality of life within a clinical trial. METHODS: The GERD-SMQ was administered to 1722 subjects participating in a multicenter, randomized double-blind clinical trial. Subjects had a history of erosive esophagitis based on an endoscopy (EGD) performed at study entry or a previous EGD within five years. The Modified Hetzel-Dent Grading Scale was used to determine esophagitis grade scores. A 4-point Likert scale was used to assess GERD symptoms and the Gastroesophageal Reflux Disease Symptom Assessment Scale (GSAS) distress domain assessed quality of life (QOL). Logistic regression, using the GERD-SMQ score (based on previous validation using the heartburn + regurgitation + medication subscores) as the independent variable, was performed to test the GERD-SMQ’s degree of association with esophagitis grade and GERD symptoms. ANOVA techniques, using QOL as the independent variable, were employed to test the GERD-SMQ’s degree of association with QOL scores. RESULTS: Results of ordinal logistic regression univariate analyses using esophagitis grade score as the dependent variable showed that as GERD-SMQ score increased by one unit, the odds of having more severe symptoms also increased significantly (OR 1.04, p < 0.05). Using screening symptoms scores as the dependent variable, the odds of having more severe symptoms significantly increased with observed increases in GERD-SMQ scores (OR 1.22, p < 0.0001). Analysis of variance results showed that for every one unit increase in the GSAS distress score, the GERD-SMQ score significantly increased by a factor of 2.39 (p < 0.0001). CONCLUSIONS: Significant relationships exist between the GERD-SMQ score, specific symptoms and clinical severity markers demonstrating that the GERD-SMQ is valuable in the clinical trial setting. Further evaluation of the GERD-SMQ is warranted to determine the use of this questionnaire in patients with symptoms of GERD with or without erosive esophagitis.