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Oral Presentations

O.03 Gastrointestinal and Thromboembolic Events with Etoricoxib: Case Series from a Prescription-Event Monitoring (PEM) Study in England

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Background: In clinical practice, patients prescribed selective cyclo-oxygenase (COX)-2 inhibitors ('coxibs') still experience gastrointestinal (GI) adverse events. The increased risk of thromboembolic (TE) cardiovascular (CV) events may also be a class effect. Channelling of patients with pre-existing CV morbidity into these drugs may contribute to these observations. The DSRU has monitored the safety of etoricoxib during the post-marketing period in England, using the observational cohort technique of PEM.

Objectives: To identify and describe cases of GI (perforations/bleeds) and TE events reported during the PEM study of etoricoxib.

Methods: A retrospective review of GI and TE events reported during the PEM study of etoricoxib (conducted in England May 2002 - Mar 2003). Exposure data were derived from dispensed prescriptions written by primary care physicians; outcome data (including information on selected GI and TE risk factors) from questionnaires posted to prescribers ≥ 9 months after the date of the first prescription for each patient. Reports of events of interest were identified from the PEM database. Patient characteristics and risk factors were summarised.

Results: In the PEM study (N = 12 665), 89 cases (0.7%) of GI (perforations/bleeds) (3 fatal) and 47 cases (0.4%) of TE events (7 fatal) were identified during treatment (+ ≤1 month of stopping), with no reports of Pulmonary Embolism. For GI events: the median age was 74 yrs (IQR 63, 78; n = 86); 60% female; the most frequent prescribing indication was osteoarthritis (55%, n = 47/85); median time to onset was 118 days (IQR 24,216; n = 81); of 89 cases, 39% (n = 35) had no GI risk factors reported whilst 52% (n = 46) had 3 or more. For TE events: the median age for was 76 yrs (IQR 67, 81; n = 42); 60% female; the most frequent prescribing indication was osteoarthritis (67%, n = 28/42); median time to onset 79 days (IQR 32,194; n = 47); of 47 cases, 34% (n = 16) had no CV risk factors reported whilst 43% (n=20) had 3 or more.

Conclusions: GI (perforations/bleeds) and TE events were uncommonly reported and were more likely to occur in patients with 3 or more relevant risk factors. Results of this study should be taken into account together with data from other studies in assessing the benefit-risk profile of this product.