

Incidence of Adverse Esophageal and Gastric Events in Alendronate Users

Byung-Joo Park, Jon Clouse, Diane Wyosky, Andy Stergachis, Deborah Shatin

¹*Department of Preventive Medicine, Seoul National University College of Medicine,*

²*Center for Health Care Evaluation, United Health Care,*

³*Office of Epidemiology and Biostatistics, Food and Drug Administration,*

⁴*Department of Pharmacy, School of Pharmacy, University of Washington,*

⁵*Department of Epidemiology, School of Public Health and Preventive Medicine, University of Washington,*

We estimated the incidence of the adverse esophageal and gastric events associated with alendronate use. The computerized pharmacy claims records of 12 geographically dispersed managed health plans of United HealthCare Corporation were used to identify 1,321 persons who received a prescription for alendronate. The medical claims data of these individuals were searched for subsequent diagnoses of esophagitis, ulcer of the esophagus, esophageal perforation, gastric ulcer, and gastritis/duodenitis. Thirty-nine persons had an incident esophageal or gastric diagnosis of interest, including 22 with esophagitis, 2 with esophageal ulcer, 1 with gastric ulcer, 15 with gastritis/duodenitis. Five(12.8%) of the 39 patients were hospitalized at the time of their diagnosis. Thirty-seven(94.8%) patients were female. The cumulative incidence rate of esophageal and gastric events for alendronate users was 3.3% in females, 2.0% in males, and 3.2% overall. The incidence density of a diagnosis of esophageal or gastric events was 8.9 per 100 woman-years of exposure. The highest age-specific cumulative incidence was 4.4% in ages 40~49, while the lowest was 2.0% in ages 50~59. Sixteen(41.0%) of the cases had concomitant prescriptions for non-steroidal anti-inflammatory drugs at diagnosis compared with 393(34.0%) of 1,171 alendronate users without a diagnosis of interest($p>0.05$). Five(12.8%) of the 39 patients had concomitant oral systemic corticosteroid prescriptions. These results suggest a high rate of incidence of esophageal and gastric diagnoses associated with the use of alendronate. Further research is needed to assess the possible association between alendronate and adverse upper gastrointestinal events.

KEY WORDS : alendronate ; incidence ; adverse esophageal of gastric effects