Factors Associated with Breakthrough Symptoms and OTC Use Among GERD Patients in a Real-World Setting

Introduction

**Gastroesophageal reflux disease (GERD) is a common, chronic condition primarily associated with heartburn and acid reflux.**

- Patients are at increased risk of esophageal reflux disease damage and complications (including Barrett's esophagus and adenocarcinoma) if heartburn is not properly managed.

**Physician Questionnaire**

- Practice profile
- Knowledge of dosing directions for PPIs
- Physician-patient relationship/communication

**Patient Questionnaire**

- Use of any concurrent OTC medications to treat GERD
- Frequency of breakthrough symptoms
- Knowledge: How did patients receive their PPI prescription?
- Physician advice for PPI dosing

**Covariates**

- Concomitant OTC use and presence of breakthrough symptoms

**Variables**

- Patient demographics: age, gender, race, body mass index (BMI), smoking status, concomitant medications, health status
- Practice profile: practice size, primary care vs. specialty care, patient chart review in the United States from Dec 2010 - June 2011.

**Methods**


**Objective**

- To identify patient factors associated with 1) use of OTC medications for GERD and 2) experience of breakthrough symptoms among prescription PPI users.

**Study Design**


**Participants**

- A national representative sample of primary care physicians (PCPs) and gastroenterologists (GIs) treating GERD patients who met certain inclusion criteria were recruited:
  - Currently managing at least 10023 patients diagnosed with GERD for PPIs, respectively; and
  - Must have prescribed a PPI for GERD to at least 4 patients for PPIs, respectively.

**Patient Characteristics**

- All Patients
- Symptomatic, Non-Erosive: 278 (55%) 108 (54%) 170 (56%)
- Erosive (Erosive Esophagitis, EE): 80 (16%) 33 (17%) 47 (16%)
- Unknown: 143 (29%) 58 (29%) 85 (28%)
- Age, median (IQR): 51 years (42–61) 37% male, 81% Caucasian, 38% with college degree, and 47% patient-physician relationship/communication.

**Results**

- Overall, 27% of patients were enrolled in the study with mean age 51 years, 37% males, 81% Caucasian, 38% with college degree, and 47% patient-physician relationship/communication.

**Breakthrough Symptoms**

- Seventy-three percent of patients reported experiencing ≥1 breakthrough symptoms.

**Adjusted Models**

- Drug class effects (reference OME) 0.50 (95% CI: 0.39–0.64) and obesity (versus OME) 0.57 (95% CI: 0.46–0.70) were less likely to report breakthrough symptoms among OTC users.

**Conclusions**

- Even with the use of prescription PPIs for the treatment of GERD, approximately 48% of patients utilized OTC medications to treat GERD and 73% continued to experience breakthrough symptoms, although few patients experienced symptoms once a week or more.

- This study suggests that higher patient adherence to medication adherence may be associated with fewer breakthrough symptoms.

**Limitations**

- This study was limited to GERD patients who were taking one prescription PPI at the time of analysis and did not include patients who were treated with over the counter PPIs alone or any other combination of GERD treatment options.

- A large proportion of patients reported OTC use for GERD after stepwise selection: Breakthrough symptoms (OR: 5.11: 95% CI: 3.07-8.50).

**References**


**Acknowledgments**

- This study was sponsored by Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA; Pharmerit International, Bethesda, MD, USA; and Medical Data Analytics, Parsippany, NJ, USA.

**Figure 1** Breakthrough Symptoms and Frequency – All Patients

**Table 1** Comparison Analysis and Factors Potentially Predicting Use of OTC for GERD Among All Patients

**Table 2** Comparison Analysis and Factors Potentially Predicting Use of OTC for GERD Among Symptomatic, Non-Erosive Patients

**Table 3** Comparison Analysis and Factors Potentially Predicting Use of OTC for GERD Among Erosive (EE) Esophagitis Patients