AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None
ACTIVE INGREDIENT:

Study No: NCT01432392
A PROSPECTIVE, OBSERVATIONAL STUDY TO DESCRIBE SYMPTOM CONTROL AND IMPACT ON DAILY LIFE IN PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Developmental Phase: Non-Interventional Study
Study Completion Date: 06/04/2012
Date of Report: 05/03/2013

Study type

This was a national, multicenter, non-interventional study in which no additional diagnostic or monitoring procedures were applied to the patients. The aim was to describe symptom control and the impact of GERD on the patients' daily life. The patients were followed for a maximum of 12 weeks, with 3 visits total: Visit 1 (enrolment), Visit 2 (4 to 6 weeks after Visit 1), and Visit 3 (8 to 12 weeks after Visit 1).

OBJECTIVES:
Primary Objective

- The study aimed to evaluate the impact of GERD management in a primary care setting on symptom control and daily life in currently symptomatic patients with GERD, using the GERD-Q and a clinical symptom assessment. The following data were evaluated:
    - Demographics
    - Typical GERD symptoms (with frequency and severity of symptoms)
    - Prescribed treatments for GERD and treatment changes
    - From a patient's perspective, symptom control and impact on daily life were described using the GERD-Q

Secondary objective

- To evaluate the added value of GERD-Q as a useful tool for the initial and long-term management of GERD patients; i.e., determination of the appropriate treatment and evaluation of the response to treatment.

METHODS:

It was planned to recruit 1000 patients in 10 centers by 100 general practitioners (GPs). Each GP was expected to recruit an average of 10 patients.

All patients participating in the study were treated for GERD according to current practice [GERD Diagnostic and Therapeutic Algorythm (Consensus) of Bulgarian GE Society, 2010] and according to the instructions in the scientific leaflet of the prescribed medicinal product.

Diagnosis and Main Criteria for Inclusion: Patients were males and females aged 18 years and over with known or newly diagnosed GERD. Patients had typical symptoms of GERD, such as heartburn and/or regurgitation within 2 days prior to the start of the study and had a GERD-Q score ≥8 in the absence of proton-pump inhibitor (PPI) treatment. All patients were not receiving PPI treatment at the time of enrollment.

Patient receiving treatment with acetylsalicylic acid (ASA), non-steroidal anti-inflammatory drugs (NSAIDs), or COX-2 inhibitors within 2 weeks prior to the start of the study were not eligible to participate as were any patients with a history of surgical intervention of the esophagus, stomach, or duodenum. Females of childbearing potential were not pregnant or nursing and were using reliable contraception.

Evaluations: Typical GERD symptoms (heartburn, acid regurgitation, dysphagia, and epigastric pain) were assessed by the investigator in terms of intensity using a 4 point scale (0=none, 1=mild, 2=moderate, and 3=severe). Symptom frequency was measured as the number of days symptoms were present in the 7 days prior to each visit.

The initial prescribed treatment, as well as any change in GERD treatment since the last visit (which included any changes to the dose, stopping treatment, switching treatments, or use of 'on demand' treatments) was recorded.

Throughout this study the GERD-Q was used to collect patient reported outcomes (PRO) in order to describe symptom control and to evaluate the impact of symptoms on the patient's daily life.

Patients were asked to reflect on the symptoms they had experienced over the preceding week. Scores ranging from 0 to 3 were applied for the positive predictors and from 3 to 0 (reversed order, where 3 = none) for negative predictors. The GERD-Q score was calculated as the sum of these scores, giving a total score ranging from 0 to 18.

A secondary objective was to evaluate the added value of GERD-Q as a useful tool for the initial and long-term management of GERD patients; i.e., it's usefulness for determining the appropriate treatment and evaluation of the response to treatment.

Statistical Methods: The percent change from Visit 1 to Visit 2 for each symptom in terms of severity and frequency was calculated in order to describe symptom control from a clinical perspective. The percentage of patients requiring alteration of their treatment and the percentage of patientя with treatment discontinuation at Visit 2 was calculated.
Changes in GERD-Q scores from Visit 1 to Visit 2 were calculated.

GERD-Q scores for each dimension were correlated with the clinical judgment, symptom scores, and evaluation by the investigator.

RESULTS:

Subject Disposition and Demography: A total of 1000 patients were enrolled into the study and attended study Visit 1. A total of 984 patients attended study Visit 2, and 944 patients attended study Visit 3. Therefore, 94.4% of patients completed all 3 evaluations in the study.

There were more female patients (58.7%) than males (41.3%). Mean age was 53.0 years (range: 18 to 88 years). Mean height was 168.77 cm (range: 145 to 198 cm), and mean weight was 74.98 kg (range: 40 to 160 kg). Overall, the majority of patients had GERD for more than 1 month. The most frequently reported duration of prior GERD symptoms was >1 year (39.0%).

Treatment and Dosing: At Visit 1, the most frequently prescribed GERD treatment was PPIs, for 96.4% of patients. The most commonly prescribed PPI at Visit 1 was esomeprazole (732 patients, 73.2%). This remained relatively unchanged throughout the study (714 patients, 75.6%, at Visit 3). Overall, throughout the course of the study, nearly half of all patients (44.2%) changed their treatment regimen. However, less than 7% of patients switched to another treatment at Visits 2 or 3.

The mean total daily dose of GERD medication was approximately 35 mg/day throughout the study, ranging from 10 to 120 mg/day. The mean number of weeks for which the GERD medication was prescribed was 5.2 throughout the study, ranging from 1 to 16 weeks. At Visit 1, 1.7% of patients were taking GERD medication only on demand and not in a daily regimen. This proportion increased slightly at Visit 2 to 2.1% and at Visit 3 to 3.2%.

Results: The GERD symptoms of heartburn, acid regurgitation, dysphagia, and epigastric pain were evaluated at each study visit. At each visit, the patient reported the occurrence and severity of symptoms from the previous 7 days.

At Visit 1, the most frequently reported number of days with heartburn for the previous week was 3 to 4 (40.2%) and the most frequently reported severity was moderate (57.0%). At Visit 2, frequency had decreased to 1 to 2 days (46.8%) and severity was mostly mild (51.5%). At Visit 3, the majority of patients reported no heartburn in the previous week (approximately 60% for both number of days=none and severity=none).

At Visit 1, the most frequently reported number of days with acid regurgitation for the previous week was 3 to 4 (41.3%) and the most frequently reported severity was moderate (59.6%). At Visit 2, frequency had decreased to 1 to 2 days (50.1%) and severity was mostly mild (53.4%). At Visit 3, the majority of patients reported no acid regurgitation in the previous week (approximately 65% for both number of days=none and severity=none).

At Visit 1, the most frequently reported number of days with dysphagia for the previous week was none (34.5%) and the most frequently reported severity was none (34.8%). However, 27.5% of patients reported 1 to days of dysphagia, mostly mild in severity (34.0%). At Visit 2, frequency was 0 days for the majority of patients (66.1%) and severity was none (65.7%). The number of patients reporting dysphagia of 1 to 2 days duration remained approximately

27%. At Visit 3, the majority of patients reporting no dysphagia in the previous week increased to approximately 87% (for both number of days=none and severity=none).

At Visit 1, the most frequently reported number of days with epigastric pain for the previous week was none (34.5%). However, 27.5% of patients reported 1 to days of epigastric pain and 22.1% reported 3 to 4 days. The most frequently reported severities were mild (36.5%) and moderate (34.4%). At Visit 2, frequency was 0 days for the majority of patients (66.1%) and severity was none (52.2%). The number of patients reporting epigastric pain of 1 to 2 days duration remained approximately 27%. At Visit 3, the majority of patients reporting no epigastric pain in the previous week increased to 87.5%.

At Visit 1, GERD-related symptoms were considered to be moderate for the majority of patients (65.0%). At Visit 2, the majority of patients were considered to have mild symptoms (73.3%) and at Visit 3, this majority had increased to 90.3%.

The clinicians were asked at Visits 2 and 3 if the GERD-Q was useful in finding the appropriate GERD treatment for the patient. At both assessments, the majority of clinicians (approximately 98%) responded 'yes'.