

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: Non-drug study

Study No: D9612L00113

A cross-sectional, Canadian, multi-centre study of symptom burden and clinical management in subjects with Gastroesophageal Reflux Disease (GERD)
RANGE: Retrospective ANalysis of GERd

Developmental phase: No phase / Observational

Study Completion Date: May 31, 2008

Date of Report: N/A

OBJECTIVES:

- To estimate the proportion of patients in primary care (PC) setting with Gastroesophageal Reflux Disease (GERD) symptoms
- To evaluate the reason(s) for subject consultation at the Index Visit
- To describe the characteristics of reflux symptoms at the Index Visit
- To describe the type, intensity and frequency of current reflux symptoms at Visit 1
- To describe the impact of reflux symptoms on subjects' daily life by means of the patient reported outcomes (PROs)
- To describe the impact of reflux symptoms on work productivity
- To describe subject satisfaction with treatment
- To describe the treatment utilised by the Primary Care Physician (PCP) to manage upper GI symptoms thought to be reflux related at the Index Visit
- To estimate the proportion of subjects with reflux complications
- To explore the role of initial diagnosis on current symptoms
- To explore subject's willingness to pay for complete symptom relief of gastroesophageal reflux disease (GERD)

METHODS:

This was a cross-sectional study of symptom burden and clinical management of a representative sample of subjects who have attended the PC office with reflux symptoms during a retrospective period of 4 months (Index Visit) and were invited to complete a

health survey questionnaires and partake in a subject-physician/study nurse interview (Visit 1), in order to address the above objectives.

RESULTS:

Due to the descriptive objectives of the study, there were no hypotheses to test with statistical methods to predetermine a needed sample size. Therefore, all variables of interest were summarized for the whole study population descriptively using standard summary statistics.

Demographic and baseline characteristics of subjects (ITT)

Demographic or baseline characteristics		Subjects (n=379)
Demographic characteristics		
Sex (n and % of subjects)	Male	178 (47.0)
	Female	201 (53.0)
Age (years)	N	379
	Mean (SD)	56.9 (15.9)
	Range	19, 96
Race (n and % of subjects)	White	364 (96.0)
	Black or African American	4 (1.1)
	Asian	10 (2.6)
	American Indian or Alaska Native	1 (0.3)

Percentage of subjects with acid related GERD symptom of the total number of patients who visited the participating investigator site during the study period ranged from 0.77% to 13.3% across 14 sites.

The follow-up in asymptomatic patient was the most common reason for primary consultation (42.7%), followed by persistent symptoms (29.3%).

Many subjects recalled having no symptoms in the 7 days prior to Index visit. No heartburn = 36.4%, no acid regurgitation = 46.8% (note: these results are viewed with caution since patients had to recall as far back as 11 months).

Symptoms assessed by subjects at Visit 1 based on the Reflux Disease Questionnaire (RDQ) (6-pt scale (0-5); 1=very mild): Heartburn (overall mean score) = 0.85. Acid Regurgitation (overall mean score) = 0.98

Half (53.6%) of all patients employed lifestyle changes, with the most common being dietary/drinking modification.

Impact on work productivity over the previous 7 days was measured using the Work Productivity and Activity Impairment Questionnaire – GERD (WPAI-GERD): Overall Lost Work Productivity score (WPS) was 8.91%.

Satisfaction score on the Treatment Satisfaction Questionnaire GERD (TSQ-G) at Visit 1 was higher than average with a mean score of 4.35 (maximum score = 6).

Majority of subjects (76%) were prescribed a PPI at the index visit, while 9.2% were prescribed an H2-blocker.

Some subjects experienced GERD complications. Esophagitis (2.6%), Barrett's Esophagus (0.3%), Stricture (0.3%), Other complications (4.5%)

Sleep disturbance appeared to be most frequent extraesophageal symptom, although still mild.

GERD was the most common diagnosis at the primary consultation, although many patients had >1 diagnosis. The vast majority of diagnoses were made based on symptoms (93.7%).

The overall appeal of GERD treatment attributes (part-worth utilities) indicated that patient choices were driven most strongly by 'side effects', then 'sleeping discomfort', then 'episodes during the day', then 'dietary changes' then 'when take GERD meds'.