

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None

ACTIVE INGREDIENT:

Study No: NCT01020890

A cross-sectional study on the prevalence of GERD in primary care patients with upper GI symptoms using the GERD-Q. The Bulgarian GERD-Q Study.

Developmental Phase: Non-Interventional Study

Study Completion Date: 30/04/2010

Date of Report: 07/01/2011

Study type

This is a nationwide, multicenter, descriptive single-visit study of patients with upper gastrointestinal (upper GI) tract symptoms with a 6-month recruitment period.

The aim of the study is not to evaluate the safety and efficacy of medicinal products. The healthcare and treatment, which patients are provided, are in conformity with the common clinical practice.

OBJECTIVES:

The primary objective of the study is to yield data about the number of GERD-patients as a proportion of the patients with upper GI-symptoms, identified through the use of the GERD-questionnaire. The criterion for identifying GERD is score, equal to or greater than 8.

The secondary objectives are to evaluate the number of patients with GERD in relation to their symptoms, estimated on the basis of the questions, asked by the general practitioner, and to compare the results of the two approaches (clinician's assessment of symptoms and GERD-Q).

The information gathered covers 2210 patients. The data were collected by 220 general practitioners from 14 facilities.

The main source of information is the case-report form (CRF). The information was gathered on a single occasion and no additional visits were held, as well as no diagnostic or therapeutic procedures were performed. The CRFs were filled-in on the basis of a single visit to the GP's consulting room, with all the data, necessary for the study, recorded in it. Additionally, the patients filled in the GERD-Q.

Sample size

The sample was formed in keeping with the following procedure: Ten consecutive patients were included – aged above 18, with upper GI complaints, who visited the outpatient consulting room, signed the informed consent and covered the inclusion criteria. Data about the patients' demographics, social, educational and employment status, disease duration and

comorbidities were collected on the basis of their history and personal outpatient records. No additional visits were held, as well as no diagnostic or therapeutic procedures were performed

Primary objective

The aim of the study is to yield data about the distribution of GERD-patients within the population of people with upper GI-symptoms. With regards to this, the primary variable was determined as the number and proportion of people with GERD in the target population. In order to evaluate this number, all patients filled-in the GERD-Q single-handedly. ***A person was considered as having GERD, if the total score was no less than 8.***

Secondary objective

The secondary variable was the number of patients according to the physician's assessment. This assessment was made on the basis of the patient's history and the physical examination. GERD was considered as present in patients with moderate or severe heartburn and acid reflux during at least 2 days in the week, preceding the visit.

METHODS:

The methods of the statistical analysis of the data collected, defined per protocol, were descriptive. These methods do not outstretch the standard statistical approaches.

RESULTS:

Primary objective

The primary objective of this study is to evaluate the prevalence of the GERD patients within the population of people with upper GI-symptoms. The criterion is the questionnaire score, which should be ≥ 8 . The following scores were recorded:

Of 2210 patients studied, 1840 had results of 8 points or higher. This means that 83.3% of the patients were diagnosed as suffering from GERD. The 95% confidence interval (CI) is (81.7%; 84.8 %). This result gives us good reasons to accept that the proportion of patients in the targeted population, suffering from GERD, exceeds 80% - in other words more than 4/5 of these patients actually do suffer from GERD.

Secondary objectives

The secondary objectives are to evaluate the number of patients with GERD in relation to their symptoms, estimated on the basis of the questions, asked by the general practitioner, and to compare the results of the approaches (clinician's assessment of symptoms and GERD-Q). The evaluation was based on the patients' answers about the frequency and severity of two symptoms during the week, preceding the visit. These symptoms were heartburn and acid reflux.

- ✚ In keeping with the diagnostic procedure, the following results were obtained: Of a total of 2210 patients, 1061 are evaluated as suffering from GERD. This equals 48.0% with 95% CI from 45.9% to 50.1%. In other words about one-half of the targeted population is diagnosed as suffering from GERD. This is a considerably smaller number than the one, diagnosed with the use of the questionnaire.***
- ✚ The comparative analysis of the approaches shows that the odds ratio is 6.2. This means that the probability for diagnosing a patient with upper GI***

symptoms as having GERD is about 6 times higher with the use of the GERD-Q. The corresponding 95% CI is (4.6; 8.3).

Patients' characteristics

a) Demographics and social status data:

- ✚ This is a descriptive study, which shows that a big proportion of the patients with upper GI complaints in fact suffer from GERD.
- ✚ The study covers a sample of 2210 patients, which is representative for the Bulgarian population of outpatients with upper GI symptoms.
- ✚ The participants in the study were aged above 18, the prevailing age being above 40 (about 75%). The proportion of women was 57.4%. It could be stated, that the population was dominated by mature women.
- ✚ The body mass index in this population was comparable to the average for the Bulgarian population – both for men and women. For men it was a bit higher than for women (27.0 vs. 25.9).
- ✚ Well-educated people prevailed in the study population. The relative share of people with secondary and tertiary education was just below 95%.
- ✚ The greater proportion of patients were employees (58.8%) or retired, i.e. people, that have been employed (32.1%).

b) Medical history

- ✚ A total of 1103 people or almost half of the participants had other complaints apart from the upper GI symptoms. The most common were arterial hypertension (80.4%), cardiocirculatory diseases (33.5%) and diabetes mellitus (14.1%).
- ✚ The medical history with regards to the upper GI symptoms shows that most commonly the complaints were with duration of more than 1 year (27.5%) and between 1 and 3 months (22.5%). Durations of up to 1 month, from 3 to 6 months and from 6 months to 1 year, were with approximately equal frequencies.
- ✚ The most common complaints were of ulcer of the duodenum (in 6.2%), followed by ulcer of the stomach (in 2.6%) and gastritis (in 2.2%).

c) Dietary habits

- ✚ About one-half of the patients (48.9%) consumed high-fat animal food. The spicy foods were well-presented (38.2%). In 32.7% diet had been recommended for the upper GI complaints.

d) Harmful habits

- ✚ Of the harmful habits the most common one was the regular use of coffee (61.7%). About one-third were smokers (32.4%), and regular alcohol consumption was noted in 20% of the people. About a quarter (24.8%) of the patients did not report any of these harmful habits.

e) Preceding treatment for the upper GI-symptoms

- ✚ 25.9% of the people from the studied population were untreated. About 30% had used baking soda, medicines – just above 60%.
- ✚ Of a total of 1339 patients (60.6% of the whole sample), 56.0 % had used H₂-blocking agents. Antacids had been used in 47.2%, and proton pump inhibitors – in 39.7%. Prokinetik agents had been used in 7.9% of the cases.
- ✚ The most commonly used proton pump inhibitors were omeprazole (67.5%) and lansoprazole (28.6%).

f) Current treatment for the concomitant diseases

- ✚ Just below half of the patients (46.2%) were on concomitant medical therapy. Of them 91.6% were on antihypertensive agents, 22.3% were on lipid-lowering drugs,

and 7.9% were on antidepressants. The relative shares of the other types of medications used were below 3%.

g) *The characteristics of the GERD patients do not differ* from the ones of the people from the common population of outpatients with upper GI-symptoms. All differences are insignificant enough, to be attributed to casual fluctuations. For this reason the characteristics of the common population should be used to describe the population of people, in whom GERD is diagnosed.