

STUDY REPORT SYNOPSIS

Finished product: not applicable

Active ingredient: not applicable

Study No. NIS-GRS-DUM-2010/1

An epidemiological, post marketing observational study to describe symptom control and impact of gastroesophageal reflux disease (GERD) on patients' daily life

Developmental phase: IV (non-interventional study)

Study completion date: 20 Dec 2010

Date of Report: 05 May 2011

OBJECTIVES:

The primary objective of this non-interventional study (NIS) at General Practitioner (GP)-setting was to gather local Serbia-specific epidemiological data in a population of patients with gastroesophageal reflux disease (GERD) with disease duration of ≤ 3 years or newly diagnosed. These epidemiological data included:

- demographic data,
- typical GERD symptoms (indicating frequency and severity of symptoms) and signs,
- treatments for GERD and treatment changes,
- patient's perspective of symptom control as well as impact on daily life assessed using a patient-questionnaire (GIS-GERD Impact Scale).

Secondary objective was to evaluate the added value of a patient questionnaire (GIS-GERD Impact Scale) as a useful tool for the initial and long-term management of GERD patients-determination of the appropriate treatment and evaluation of the response to treatment.

METHODS:

Patients had three study related-visits: visit 1 (baseline), visit 2 (4 weeks after visit 1) and visit 3 (8 weeks after visit 1). At each visit the following tools were used: recording of data in CRF (by investigator) and filling in the Patient's questionnaire-GIS GERD Impact Scale (by patient).

RESULTS:

Demographic data:

The study was conducted in 13 centers with the participation of 91 GPs. They included a total of 828 patients in the study. The average age of patients included in the study was 54.8 years.

From the recorded habits among patients who entered the study the most common is the habit of drinking coffee. Majority of patients considered themselves as exposed to stress (81.7%).

Every 4th patient has a habit of consuming alcohol, while the percentage of active and former smokers was 45.7%.

Typical GERD symptoms/signs:

All GERD symptoms/signs significantly improved at visit 3 vs. visit 1, based on GPs' evaluation of signs/symptoms:

- Number of patients with moderate to severe intensity of **burning sensation in the stomach** from 683 patients (82.5%) at first visit decreased to 43 patients (5.2%) at visit 3 (p<0.001).
- Number of patients who had frequency of more than 2 days in the week **burning sensation in the stomach** decreased from 644 (77.8%) at visit 1 to 54 (6.6%) at visit 3. (p<0.001).
- Number of patients with moderate to severe intensity of **acid regurgitation** was reduced from 608 patients (73.4%) in the first visit to 28 (3.4%) in the third visit (p<0.001).
- Number of patients in which the **acid regurgitation was present more than 2 days during one week** dropped from 559 patients (67.5%) at visit 1 to 25 (2.9%) at visit 3 (p<0.001).
- At visit 1, 727 (88 %) patients felt **gastric pain**, while in the second visit this number decreased to 442 (53%). At visit 1, 169 patients had severe gastric pain, at visit 3 only 2 patients still had severe gastric pain, while 96 (57%) didn't have gastric pain at all. (p<0.001).

Treatments for GERD and treatment changes:

Based on data from baseline visit (visit 1), 558 (67%) out of 827 patients had been already treated for GERD. 269 (32.5%) had not been treated before, 358 patients (43.3%) had been using H₂ blockers before, 305 (36.9%) antacids, while 285 patients (34.5%) had been using proton pump inhibitors (PPI), out of which omeprazole was the most used PPI - by 117 patients (14.1%). 118 patients (14.3%) had a gastroscopy exam done in the previous 6 months, while 709 (85.7%) had no gastroscopy. At visit 3, only 13 patients (1.6%) still used antacids and 20 (2.5%) H₂ blockers.

Patient's questionnaire (GIS-GERD Impact Scale):

All symptoms/signs, as assessed by patients, improved at visit 3 as compared to visit 1.

- At the first visit, 301 (36.3%) out of 828 patients felt **chest pain or pain behind the sternum** often or every day. At visit 3, 42 (68.9%) out of 61 patients who felt pain every day during the first visit, no longer suffered from pain in the chest or behind the sternum (p<0.001)
- Of 370 patients who had the feeling of **burning sensation in the chest or behind the sternum (heartburn)** daily or often, only 10 remained in this category at Visit 3 (p<0.001).
- Out of 320 patients suffering at visit 1 from **problem to have a good night sleep** - daily or often due to GERD, only 16 (1.9%) patients still had this problem (p<0.001) at visit 3.
- Out of 496 patients who at visit 1 **could not eat or drink** what they like daily or often, due to symptoms of GERD, at visit 3 only 38 (18.5%) patients still had this problem (p<0.001).

- Out of 323 patients who at visit 1 were **prevented by GERD symptoms** - daily or often to be fully productive in business and other activities, at visit 3 this kind of problem occurred in only 20 (16.3%) patients ($p < 0.001$).
- Out of 287 patients who had taken **additional medication**, other than recommended by a doctor, every day or often at visit 1, only 15 patients (14.8%) were still taking it ($p < 0.001$) at visit 3.

Global clinical assessment:

Out of 238 patients who had a global clinical assessment (done by investigator) as “severe” at the first visit, 153 (64%) of them were scored “mild” and 73 (31%) “moderate” at the third visit. Out of 828 patients, the global clinical assessment “mild” was attributed to 631 (76.2%) patients, “moderate” to 176 (2.3%) patients, while 21 (2.5%) were categorized as “severe” at the third visit. Wilcoxon-test obtained a statistically significant difference in global clinical assessment of current symptoms of GERD between the first and third visit ($Z = 22,852$; $p < 0.001$).

Investigators’ evaluation of the usefulness of the patient questionnaire GERD Impact Scale (GIS):

At the end of visit 3, investigators (GPs) were asked to answer the question: “How do you rate the importance of GIS in assisting you in determination of the appropriate therapy for your patient and evaluation of the response to therapy?”. Out of 776 patients for whom the answer to this question was available, in 763 (92.2%) patients GPs evaluated the patient questionnaire (GERD Impact Scale - GIS) as a useful tool for the initial and long-term management of GERD patients and determination of the appropriate treatment and evaluation of the response to treatment.