AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A
ACTIVE INGREDIENT: N/A

Study No: NIS-GMY-DUM-2009/1
DIAGNOSIS AND RESPONSE TO TREATMENT USING A RELIABLE GERD QUESTIONNAIRE (GERDQ)- AN "IN-CLINICAL PRACTICE" STUDY IN PRIMARY CARE IN MALAYSIA

Developmental Phase: July 2009 – November 2009
Study Completion Date: 16 November 2009
Date of Report: 18 November 2010

OBJECTIVES:

Primary

- To determine the applicability and utility of GERD Q in the diagnosis of GERD and assessment of treatment response.

Secondary

- To identify and assess the proportion of patients whose quality of life has been impacted by GERD
- To assess and monitor the treatment response of patients diagnosed with GERD
- To assess and compare the efficacy of treatment according to GERD Q.
- To assess and compare the safety and tolerability of various treatments used after diagnosis of GERD by GERD Q.

METHODS:

Doctors in primary care practice were invited to take part in the study. Each doctor was requested to recruit consecutively 5-10 patients whom they have diagnosed to have GERD based on their own clinical interview. Patients of either gender between the ages of 18-79 years of age were eligible to be recruited. Patients who were regularly taking medications for their GERD symptoms were excluded from the study.

Each patient filled in the simple questionnaire. Basically it consists of 3 sections. Section A has 2 questions specifically enquiring about the frequency of heartburn and regurgitation symptoms over the preceding 1 week. In both these questions for the benefit of the patient, the description of both symptoms was "spelt out". These 2 symptoms were considered positive predictors for GERD. A score of 0-3 was given according to the frequency per week.

In Section B, symptoms of epigastric pain and nausea were asked for and in the third section, patients were asked if their symptoms of heartburn and "regurgitation" disturb their sleep. As these symptoms were considered negative predictors for GERD, score of 3-0 was given according to the frequency per week.

Section C enquires whether patients took additional medications (antacids) on their own for relief of symptoms. For all these questions, a score of 0-3 was given according to the frequency per week. A maximum cumulative total of 18 can be obtained. A score of 0-7 indicated a low likelihood of GERD (probability of 50% or lower) whereas a score of ≥ 8 indicated that GERD was likely (probability of at least 80%). For patients GERDQ score ≥ 8, sub score on impact of symptoms of < 3 indicated "inconvenient GERD whereas a score of ≥ 3 indicated "disrupting GERD".

The patient's demographic data including their height and weight were recorded. Body mass index (BMI was defined according to WHO criteria modified to Asian standards 0-22.9kg/m2- normal, 23.0-24.9kg/m2- overweight, 25.0-29.9 kg/m2- obese and ≥ 30.0 kg/m2- severe obesity.

Patients were then prescribed a course of medications according to the clinical practice of the doctor. Patients were seen 4 weeks later by the same doctor and filled in the GERDQ a second time.

The proportion of patients with scores of 2-3 and more (considered troublesome) were also compared. Individual scores for heartburn, regurgitation and questions in the impact item >1 after treatment were considered as "needing an alteration in treatment".

RESULTS:

Two hundred and fifty patients were recruited for the study from 32 primary care clinics in Kuala Lumpur from June to August 2009. The mean age (± S.D.) of patients was 44.8± 12.4 years with a male:female ratio of 130:120. The mean BMI (± S.D.) of patients was 24.9 ± 5.1. The distribution of BMI were as follows: normal- 94 (37.6%), overweight- 50 (20.0%), obese- 66 (26.4%), grossly obese -40 (16%) (Table 1).

Table 1: Basic demography of patients (n=250)

	N (%)
Mean age ± S.D.	44.8± 12.4 years
Gender- M:F	130:120
Ethnicity	
Malay	71 (28.4%)
Chinese	131 (52.4%)
Indian	40 (16.0%)
Others	8 (3.2%)
Mean BMI ± S.D.	24.9 ± 5.1

Based on the questionnaire, 221 of 250 (88.4%) of patients were considered to have a high likelihood of GERD (baseline score > 7). Of the 221 GERD patients, 137 (62.0%) were considered to have "inconvenient" GERD while 84 (38%) disruptive GERD (Table 2).

Table 2: Proportion of patients and GERDQ scores before and after treatment (n=250)

	Before treatment	After Treatment	P value
Low Likelihood of GERD (score 0-7)	29 (11.6%)	162 (64.8%)	<0.001
High Likelihood GERD (score 8- 18)	221 (88.4%)	88 (35.2%)	
Inconvenient GERD (Total impact score <3)	85 (38.5%)*	69 (78.4%)#	<0.001[a]
Disrupting GERD (Total impact score ≥ 3)	136 (61.5)*	19 (21.6%)#	

*out of 221

out of 88

[a] Proportion of inconvenient vs. disruptive GERD

Two hundred and forty eight of 250 (99.2%) patients received a 4 week course of PPIs and 2 (0.8%) patients H2 antagonists. The types of PPI used are as shown in Table 3. All patients returned for the follow-up visit at Week 4. The proportion of patients with GERDQ score ≥ 8 had decreased significantly from 88.4% to 35.2% (p<0.001).

Table 3: Types of PPI used (n=248)

PPI	Frequency	Percent
Omeprazole (all types)	85	34.0
Nexium/esomeprazole	88	35.2
Controloc/pantoprazole	7	2.8
Prevacid/lansoprazole	66	26.4
Pariet/rabeprazole	4	1.6

Following treatment, 88 (35.2%) patients had GERDQ scores ≥ 8. This was significantly lower compared to pre-treatment (p<0.001). 69 ((78.4%) had inconvenient and 19 (21.6%) had disrupting GERD. The proportion of patients with disrupting (vs. inconvenient GERD) had also decreased from 61.5% to 21.6% (p=<0.001).

The proportion of patients with scores of 2-3 for heartburn, regurgitation, sleep disturbance and use of additional medications (who are considered "needing treatment alteration") were: 31 (12.4%), 28 (11.2%), 20 (8.0%) and 22 (8.8%) respectively (Table 4). Compared to pre-treatment the improvement was highly statistically significant for all these 4 items (p<0.001). However, by definition, a total of 101 (40.4%) patients had at least one score in these 4 items >1 who were considered needing treatment alteration in the form of additional medication, increased dosage or increased treatment duration.

Table 4: Proportion of patients with frequency of symptoms ≥2 days per week before and after treatment (n=250)

	Before treatment	After Treatment	P value
Heartburn	203 (81.2%)	31 (12.4%)	<0.001
Regurgitation	169 (67.6%)	28 (11.2%)	<0.001
Sleep disturbance	146 (58.4%)	20 (8.0%)	<0.001
Use of additional medications	106 (42.2%)	22 (8.8%)	<0.001