

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: N/A

Study No: NIS-GKR-DUM-2008/1

Prevalence of EED and Quality of Life Evaluated by Gastroesophageal Reflux Disease (GERD)-Q in Korean GERD Patients (**Preedom**)

Developmental phase: Marketed

Study Completion Date: 2008-02-13

Date of Report: 2010-01-25

OBJECTIVES:

Primary objective

- ✓ The primary variable is the total rate of GERD patients who had EED symptom and effect on their quality of life

Secondary objectives

- ✓ The secondary variable is the comparison of the EED symptom frequency in ERD and NERD patients.

METHODS:

This non-interventional observational study protocol was reviewed in accordance with the standard procedures of AstraZeneca.

The purpose of this study was to evaluate prevalence rate of EES (Extra-Esophageal symptoms), symptom distribution and quality of life on GERD patients (Gastro-Esophageal Reflux Disease) by using GERDQ (Gastroesophageal Reflux Disease Questionnaire) survey among GERD patients who have classical symptoms of heartburn and acid regurgitation. .

Our study conducted survey towards 1,712 GERD patients enrolled by 123 doctors of 64 local hospitals and clinics.

RESULTS:

Demographics

As a result of investigating gender of all the participants, the number of female was 949 (55.43%) and male was 763 (44.57%). The average age was 50.3 ± 14.0 and the group of 50s showed high est rate of 460 (26.87%). The average BMI was 50.30 ± 13.95 Kg/m² and participants below 25 Kg/m² were 1,239 (72.37%) the most. In the survey of smoking, non-smoking group rated the high

est rate of 971 (56.72%), the current-smoking group was 412 (24.07%) and past-smoking group was 329 (19.63%). As a result of stomach endoscope in GERD patients, 697 (47.7%) patients showed erosive ERD (Esophageal reflux disease).

Prevalence and evaluation of QoL

We have analyzed symptom occurrence frequency of 12 questions in total.

Most frequent occurring symptom that appeared in 1,346 (79.67%) GERD patients was acid regurgitation which included in the GERD positive prediction factor. As a result of evaluating prevalence rate of sleeping disturbance, 701 patients (40.95%) experienced sleeping disturbance due to GERD symptoms.

Total 1,253 (73.19%) patients have experienced stomach burn in the pitch of the stomach as the most frequent occurrence symptom in EES. Table 3 summarized information of occurrence frequency of each symptom.

Table 1. Prevalence of overall EESs by various factors

		N (%)
Gender	Male	763 (44.57)
	Female	949 (55.43)
Age	Mean ± SD (year)	50.30 ± 13.95
	Min-Max	20 ~ 80
	20 ~29	139 (8.12)
	30 ~ 39	284 (16.59)
	40 ~ 49	353 (20.62)
	50 ~ 59	460 (26.87)
	60 ~ 69	315 (18.40)
70 ~	161 (9.40)	
BMI	Mean ± SD (Kg/m ²)	23.32 ± 3.01
	Min-Max	14.03 ~ 38.41
	< 25 Kg/m ²	1,239 (72.37)
	25~27.5 Kg/m ²	336 (19.63)
≥ 27.5Kg/m ²	137 (8.00)	
Smoking	Current smoker	412 (24.07)
	Ex-smoker	329 (19.22)
	Non-smoker	971 (56.72)
GFS	NERD	1015 (59.29)
	ERD	697 (40.71)

Table 4 showed summary information about occurrence frequency of each category in the survey by classifying ERD and NERD via endoscope test results. Including sleeping disturbance ($p < 0.001$), occurrence frequency in ERD patients was higher in all symptoms.

Subgroup analysis

As a result of prevalence rate of EES among GERD patients for last 7 days, 1,545 (90.25%) patients experienced at least one of EES symptoms.

As evaluating EES prevalence rate by gender, age, smoking issue, BMI and endoscope results to analyze related factor of prevalence rate in EES, there was no factor showing significant differences sub-group analysis.

Table 2. Prevalence of overall EESs by various factors

		EES(+)		EES(-)		p-value*
		N	(%)	N	(%)	
	Overall	1545	(90.25)	167	(9.75)	
Gender	Male	688	(90.17)	75	(9.83)	0.9253
	Female	857	(90.31)	92	(9.69)	
Smoking	Smoker	366	(88.83)	46	(11.17)	0.2682
	Non-smoker(Including Ex-smoker)	1179	(90.69)	121	(9.31)	
Age	Age<50	751	(90.26)	81	(9.74)	0.9793
	Age≥50	794	(90.23)	86	(9.77)	
BMI	BMI<25kg/m ²	1124	(90.72)	115	(9.28)	0.2857
	BMI≥25kg/m ²	421	(89.01)	52	(10.99)	
Presence of ERD	NERD	913	(89.95)	102	(10.05)	0.6201
	ERD	632	(90.67)	65	(9.33)	

*Chi-square test

Table 3. Frequency of each symptoms in Questionnaire

	1~7 days		No symptom	
	N	(%)	N	(%)
How often do you feel the heart burn behind the breast bone?	1351	(78.91)	361	(21.09)
How often do you have the symptoms of regurgitation (acid or food) up to esophagus or mouth (acid regurgitation)?	1364	(79.67)	348	(20.33)
How often do you feel the pain in the upper abdomen (a pitch of stomach)?	1217	(71.09)	495	(28.91)
How often do you feel nausea (vomiting)?	890	(51.99)	822	(48.01)
How often do you have trouble in good-nights sleep due to symptoms of heart burn (Question no.1) or acid regurgitation (Question no.2)?	701	(40.95)	1011	(59.05)
Have you ever taken additional medication like Anti-acid (Miranta and Armagel) not followed by doctor's prescription due to heartburn (Question no.1) or acid regurgitation (Question no.2)?	646	(37.73)	1066	(62.27)
How often do you feel the stomach burn in the pitch of stomach?	1253	(73.19)	459	(26.81)
How often do you cough?	547	(31.95)	1165	(68.05)
How often do you hear the sound of wheezing (symptoms of asthma) in your throat?	297	(17.35)	1415	(82.65)
How often do you feel globus in your throat?	886	(51.75)	826	(48.25)
How often do you experience hoarse voice?	415	(24.24)	1297	(75.76)
How often do you have chest pain (pleurodynia)?	829	(48.42)	883	(51.58)

Table 4. Frequency of each symptoms in Questionnaire by GFS results

		1~7 days N (%)	No symptom N (%)	p-value*
How often do you feel the heart burn behind the breast bone?	NERD	764 (75.27)	251 (24.73)	<.0001
	ERD	587 (84.22)	110 (15.78)	
How often do you have the symptoms of regurgitation (acid or food) up to esophagus or mouth (acid regurgitation)?	NERD	787 (77.54)	228 (22.46)	0.0081
	ERD	577 (82.78)	120 (17.22)	
How often do you feel the pain in the upper abdomen (a pitch of stomach)?	NERD	683 (67.29)	332 (32.71)	<.0001
	ERD	534 (76.61)	163 (23.39)	
How often do you feel nausea (vomiting)?	NERD	503 (49.56)	512 (50.44)	0.0152
	ERD	387 (55.52)	310 (44.48)	
How often do you have trouble in good-nights sleep due to symptoms of heart burn (Question no.1) or acid regurgitation (Question no.2)?	NERD	356 (35.07)	659 (64.93)	<.0001
	ERD	345 (49.50)	352 (50.50)	
Have you ever taken additional medication like Anti-acid (Miranta and Armagel) not followed by doctor's prescription due to heartburn (Question no.1) or acid regurgitation (Question no.2)?	NERD	327 (32.22)	688 (67.78)	<.0001
	ERD	319 (45.77)	378 (54.23)	
How often do you feel the stomach burn in the pitch of stomach?	NERD	718 (70.74)	297 (29.26)	0.0058
	ERD	535 (76.76)	162 (23.24)	
How often do you cough?	NERD	288 (28.37)	727 (71.63)	0.0001
	ERD	259 (37.16)	438 (62.84)	
How often do you hear the sound of wheezing (symptoms of asthma) in your throat?	NERD	134 (13.20)	881 (86.80)	<.0001
	ERD	163 (23.39)	534 (76.61)	
How often do you feel globus in your throat?	NERD	505 (49.75)	510 (50.25)	0.0459
	ERD	381 (54.66)	316 (45.34)	
How often do you experience hoarse voice?	NERD	217 (21.38)	798 (78.62)	0.0009
	ERD	198 (28.41)	499 (71.59)	
How often do you have chest pain (pleurodynia)?	NERD	461 (45.42)	554 (54.58)	0.0027
	ERD	368 (52.80)	329 (47.20)	