AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

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

Study No: NIS-GKR-DUM-2009-1
***MIGHT* study** **The clinical significance of minimal change in reflux esophagitis based on the Gastroesophageal Reflux Disease Questionnaire (GerdQ)**

Developmental phase: Marketed
Study Completion Date: 2009-09-23
Date of Report: 2009-11-24

OBJECTIVES:

This study wanted to define the endoscopic findings of minimal change that is significant to clinical significant reflux esophagitis. Through this, it wanted to estimate the applicability of minimal change findings of reflux esophagitis to the clinic.

Primary Objective

Primary objective of this study was to investigate significant minimal change endoscopic finding of reflux esophagitis diagnosis.

Secondary Objective

Secondary objective was to establish the probability model of diagnosing gastroesophageal reflux disease based on minimal change endoscopic findings through definition of significant minimal change endoscopic findings of gastroesophageal reflux disease diagnosis.

METHODS:

Design

Non-interventional, cross-sectional, multi-center study

The Number of Subject

The target patients' number was 1,500 subjects from domestic medical centres.

Population

Patients who had shown the reflux esophageal minimal change in the endoscopic finding

Inclusion criteria

Patients should meet the following inclusion criteria to participate in this study.

1. Age ≥ 20 years old patients who consent to revealing their medical information and be able to respond to questionnaires regarding the symptom

2. Patients who had shown the reflux esophageal minimal change in the endoscopic finding: the reflux esophagitis minimal change is defined as below findings that is reported over 0.4 of interobserver degree of agreement (κ value)
   A. Erythema: shown the flare in the gastroesophageal junction or lower esophagus
   B. Indistinctness or blurring of mucosal junction: unclear boundary of gastroesophageal junction
   C. Friability: shown a friable finding like a contact bleeding of gastroesophageal junction mucosa
   D.Decreased vascularity: vascularity decreased in the lower oesophagus or gastroesophageal junction
   E. White turbid discoloration: shown the white turbid discoloration or exudate in the lower oesophagus or gastroesophageal junction mucosa
   - G. Edema and/or accentuation of mucosal folds: shown the mucosal edema in the ga stroesophageal junction or sentinel fold

Exclusion criteria

1. Patients who had shown the mucosal break or barrett esophagus at gastric mucosal barrier or lower oesophagus in endoscopic findings
2. Patient with a diagnosis of gastroesophageal reflux disease and who have received medication treatment
3. Patient who had received H2-receptor antagonists, prostaglandin, PPI, NSAIDs or asp irin, high dose steroid and anticoagulants for at least 5 consecutive days in the 4-week period immediately preceding the diagnostic endoscopy
4. Patients with a history of operation due to gastrointestinal disease
5. Patients with malignancy
6. Patients with at least moderate degree of systemic disease (ischemic heart disease, chronic renal failure, chronic heart failure, chronic obstructive pulmonary disease, liver cirrhosis, chronic pancreatitis, diabetes mellitus, hypertension by controlled antihypertensive agent, acute infectious disease)
7. Female patients who are pregnant or breast feeding
8. Patient with alcoholism
9. Patients in participation of other clinical trial

Result variables

- The significant minimal change endoscopic finding for gastroesophageal reflux disease diagnosis.
- Gender, Ages, Height, Weight, Smoking
- GerdQ (gastro-oesophageal disease(GERD) symptom questionnaire)

Statistical Analysis

(1) Analysis and comparison of rate of patients who were able to diagnose as gastroesophageal reflux disease based on the GERD-Q about each of 6 minimal change endoscopic finding

(2) Analysis of endoscopic change finding which was shown the most intense relevance with gastroesophageal reflux disease diagnosis of 6 minimal change endoscopic finding using the logistic regression analysis

(3) Construction and gastroesophageal reflux disease predictive model in minimal change endoscopic finding using the logistic regression analysis

TIME SCHEDULE

Overall Study Design and Flow Chart

The protocol of this study was reviewed in accordance with the SOP of AstraZeneca Korea.

The study was performed the upper endoscope during 4 months and the questionnaire for gastroesophageal reflux disease diagnosis was administered to the patients who shown the minimal change of reflux esophagitis. The study tried to estimate the diagnostic significance of gastroesophageal reflux disease of minimal change endoscopic finding.

RESULTS:

A total of 1456 patients participated in this study, of whom 1445 were included in the analysis set. 11 patients were excluded from the analysis set because they did not meet the inclusion and/or exclusion criteria.

Of 1445 patients in the analysis set, 662(45.8%) were males and 783(54.2%) were females and the mean age was 50 years.

643 (44.5%) were categorized in the GERD group based on the GerdQ. No significant differences in clinical characteristics were found between the GERD and non-GERD groups, except in age and height. Blurring of the Z-line (50.4%) and erythema (45.7%) were the most common endoscopic findings of minimal changes in this study. Just one (16.7%, edema or fold accentuation) of the six findings was significantly more common in the GERD group compared with the non-GERD group (16.0% vs. 11.5%, P=0.01). Using more than one endoscopic finding was not more useful for identifying GERD than using just one endoscopic finding (44.3% vs. 44.7%, $P > 0.05$).