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Original Article

Clinical Characteristics of Elderly Patients with Refractory Gastroesophageal Reflux Disease☆

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SUMMARY

Background: Gastroesophageal reflux disease (GERD) is a common upper gastrointestinal disease, and almost 30% of GERD patients do not respond well to proton pump inhibitor (PPI) therapy. The aim of this study is to evaluate the clinical characteristics of elderly GERD patients who either respond to or resist PPI therapy.

Methods: A total of 198 patients (75.9 ± 6.4 years, 73.7% males) with GERD receiving PPI treatment were enrolled in this study. Enrolled patients were requested to complete a questionnaire and a personal interview concerning their demographics, comorbidities, symptoms, and endoscopic findings.

Results: Among the 198 enrolled patients, 135 responded to PPI once or twice daily (Group R), while 63 failed to respond to PPI twice daily (Group F). Cross-group differences were detected for body mass index ($p = 0.042$), family status ($p = 0.028$), depression (0.7% vs. 7.9%, $p = 0.03$), compliance (77% vs. 60%, $p = 0.015$), and hiatal hernia (6.7% vs. 17.5%, $p = 0.019$).

Conclusion: PPI failure appears to be significantly influenced by body mass index, family status, depression, compliance, and hiatal hernia of GERD patients.

1. Introduction

Gastroesophageal reflux disease (GERD) is a chronic and common upper gastrointestinal disease, the incidence of which in European and American countries is in the range of 10–20%[1]. Several studies have demonstrated that over 40% of the US adult population report GERD-related symptoms at least once a month and 20% once a week[2–4]. In China, the prevalence of GERD symptoms is about 9%[5]. Although not a life-threatening disease, GERD has a significant impact on patients' health and quality of life.

At present, proton pump inhibitors (PPIs) still represent the cornerstone of treatment for both erosive esophagitis (EE) healing and symptom relief. However, studies have shown that up to 40% of GERD patients reported either partial or complete lack of response of their symptoms to a standard PPI dose once or twice daily[6].

When PPI therapy failed, physicians are often inclined to increase the dose of PPI or change to an alternative for symptomatic relief. However, this therapeutic strategy frequently results in a less satisfactory symptomatic relief, and the majority of patients continue to experience GERD symptoms. To explore the underlying mechanisms that are accounted for PPI failure, a lot of research has been carried out and several mechanisms have been proposed, including lifestyle, adherence to and compliance with treatment, esophageal hypersensitivity, ultrastructural and functional changes in the esophageal epithelium, etc[6]. However, only a few studies have focused on elderly GERD patients. As a special population, elderly patients show a lack of typical reflux symptoms and are more likely to suffer from severe diseases and esophagal complications. Moreover, some available treatments for GERD may be more dangerous to the elderly patients[7]. In this study, we compared the clinical characteristics of elderly GERD patients who failed to

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respond to PPI twice daily with those who responded to PPI at least once daily.

2. Materials and methods

2.1. Patients

GERD patients who had received PPI (omeprazole/esomeprazole 20 mg, lansoprazole 30 mg, rabeprazole 10 mg, or pantoprazole 40 mg) once or twice daily for at least 3 months were enrolled in this study. Prior to PPI treatment, patients reported at least three incidences of heartburn or acid regurgitation per week.

Patients were then categorized into two groups: those who responded to PPI once and/or twice daily (Group R) and those who failed to respond to PPI twice daily (Group F). Group R patients reported that their heartburn and acid regurgitation symptoms were relieved, the EE was downgraded by one or more level regardless of symptoms, or the time of pathological acid reflux was decreased by $\geq$30% regardless of symptoms after receiving PPI treatment once or twice a day for the past 3 months. However, Group F patients continued to suffer from heartburn and acid regurgitation at least three times a week for the past 3 months, the EE was unimproved or exacerbated regardless of symptoms, or the time of pathological acid reflux was decreased by <30% regardless of symptoms despite receiving PPI twice daily.

All patients' clinical data including their demographics, comorbidities, medications, symptoms, compliance with treatment (if patients took the PPI daily), and adherence to treatment (if patients took the PPI before a meal) were collected via a questionnaire, and their endoscopic findings were also recorded.

2.1.1. Inclusion criteria

Patients who were older than 65 years and had typical symptoms of heartburn and acid regurgitation, or were definitely diagnosed with EE by endoscopy or nonerosive reflux disease by 24-hour gastroesophageal pH monitoring test despite typical symptoms were included.

2.1.2. Exclusion criteria

Patients who had a history of gastric or esophageal surgery or peptic ulcer, and were unable to fulfill the questionnaire or provide the information requested by the protocol were excluded.

This study was approved by the medical ethics committee of the Chinese PLA General Hospital, Beijing, China.

2.2. Procedure

Patients meeting the inclusion criteria were requested to fill up a questionnaire with data regarding their demographics, comorbidities, medications, and symptoms related to GERD, and were interviewed about their compliance with treatment (if patients took the PPI daily) and adherence to treatment (if patients took the PPI before a meal).

2.3. Demographics

All patients enrolled in this study completed a questionnaire with information regarding age, sex, weight, height, body mass index (BMI), family status (single, married, divorced, or widowed), and current smoking and alcohol-drinking status. BMI was calculated using each individual's weight and height. The patients' comorbidities, such as hypertension, diabetes mellitus, chronic obstructive pulmonary disease, ischemic heart disease, renal failure, depression, *Helicobacter pylori* infection, and asthma, were also recorded, together with their medications.

2.4. Evaluation of GERD-related symptoms

Patients' atypical reflux symptoms, such as chest pain, epigastric pain, cough, sleep disturbance, abdominal distension, and dysphagia were recorded.

2.5. Compliance with and adherence to therapy

Patients were interviewed whether they took PPI according to the prescribed dose in the past 3 months. Compliance was assessed by asking the patients whether they kept taking the PPI at the prescribed dose during the past 3 months. Adherence was evaluated by confirming whether the patients took the PPI half an hour before a meal or not. Patients who took the PPI with or after a meal were considered to be nonadherent, while those who did not take PPI at the prescribed dose were considered to be noncompliant.

2.6. Endoscopic findings

Patients' upper endoscopic findings were needed to evaluate the degree of esophageal mucosal breaks and the presence of hiatal hernia. The degree of esophageal mucosal breaks was categorized according to the Los Angeles classification, which is presented in Table 1.

2.7. Statistical methods

SPSS 20.0 statistical analysis software (IBM SPSS Statistics, Armonk, New York, United States) was used for data analysis. Continuous variables, such as age, weight, and height, were reported as mean $\pm$ standard deviation. Normality of distribution of continuous variables was assessed using the Kolmogorov–Smirnov test (cutoff at $p = 0.05$). Continuous variables were compared between groups using independent-samples t test. Categorical variables were expressed in frequency (%). The comparison of categorical variables between groups used the chi-square test. Multiple logistic regression was used to model variables. Odds ratios were estimated with 95% confidence intervals. All tests were two sided and considered significant at $p < 0.05$.

3. Results

3.1. Demographics

A total of 261 patients with GERD were recruited, while 63 patients were lost to follow up. Ultimately, a total of 198 patients meeting the inclusion criteria were included in the study; of them, 135 fully responded to PPI once or twice daily (Group R) and 63 failed to respond to PPI twice daily (Group F).

Patients' characteristics are listed in Table 2. The mean age of the patients was 75.9 $\pm$ 6.4 years and male patients accounted for

Table 1
Los Angeles classification of esophagitis.

Grade A	One (or more) mucosal break no longer than 5 mm that does not extend between the tops of two mucosal folds
Grade B	One (or more) mucosal break more than 5 mm long that does not extend between the tops of two mucosal folds
Grade C	One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but involves <75% of the circumference
Grade D	One (or more) mucosal break that involves at least 75% of the esophageal circumference