**The Rome IV criteria for diagnosing functional dyspepsia are no superior to the Rome III and potential Asia criteria**

Dyspepsia is a clinical syndrome originating from the upper gastrointestinal tract[1, 2]. Dyspepsia is present in approximately 20% of global general population[3, 4] and represents about a third of those who seek health care[5]. And dyspepsia can be subdivided into two subgroups: functional dyspepsia (FD) and organic dyspepsia. FD is defined as recurrent or chronic functional symptoms that are thought to originate from gastroduodenal without any structural abnormalities[6, 7]. And due to the constant visits and continuous medications use, dyspeptic symptoms caused substantial socioeconomic burden[8, 9], and negatively affect the quality of daily life and caused significant economic losses[10-13].

The Rome diagnostic criteria for FD required a duration of 6 months or more. However, most experts in the FD consensus in Asia believed that 6 months or more was too long as the diagnostic criteria for the Asian population. A Japanese study found that most patients with dyspepsia seek their first medical care within six months[14]. Among the experts participating in the formulation of FD consensus in Asia, 68% of them believed that the duration of dyspepsia should be set at 3 months[15]. There was still a lack of relevant research data in China, and further research was needed.

Ford et al. evaluated the effectiveness of Rome III criteria, Rome II criteria and broad definition in diagnosing functional dyspepsia[16]. However, the diagnostic efficacy of the Rome IV criteria for FD was still unclear, hence further assessments on the Rome IV criteria were needed. The aim of this study was to validate the Rome IV criteria for FD. We also compared the effectiveness of the Rome IV criteria in evaluating FD with the Rome III criteria and the Asia criteria, as well as the effectiveness of the Rome IV criteria in evaluating EPS and PDS.

Research purpose and design:

A cross-sectional study was conducted to evaluate the accuracy of the Rome IV criteria in identifying patients with functional dyspepsia (FD) and compared the differences between the Rome IV, Rome III and potential Asia criteria in identifying patients with FD. All patients who were satisfied with the inclusion criteria and exclusion criteria in the department of our hospital and the Affiliated Hospital of Northwest University received investigation. The study was conducted in the gastroenterology clinics of the Second Affiliated Hospital of Xi’an Jiaotong University and the Affiliated Hospital of Northwest University.

Inclusion criteria:

1. aged ≥ 18 years ;

2. discomfort was characterized by the presence of one or more symptoms that included bothersome postprandial fullness, bothersome early satiation, bothersome epigastric pain, or bothersome epigastric burning, and symptoms had to be present for at least 3 months;

3. patients visited the gastroenterology clinics and completed upper GI endoscopy and epigastric ultrasounds at the same visit during the study period;

4. routine blood tests and liver function tests were conducted at any time after the onset of dyspeptic symptoms.

Exclusion criteria:

1. history of diagnosed organic upper GI diseases which can explain dyspeptic symptoms, such as esophagitis, gastric ulcer and duodenal ulcer etc.;

2. pregnant or lactating;

3. history of major abdominal surgery;

4. severe neuropsychiatric disease or severe liver, kidney or respiratory disease;

5. pancreaticobiliary disease or metabolic disease (thyroid dysfunction, diabetes), liver dysfunction;

6. steroids or nonsteroidal anti-inflammatory drugs were currently used;

7. the main symptoms were related to reflux (acid regurgitation and posterior sternal burning);

8. declined to participate in this study.

Informed consent:

This study is a cross-sectional study to evaluate the accuracy of the Rome IV criteria in identifying patients with FD . The related information is used only to evaluate the value of the Rome IV standard for the identifying of FD. The personal information will be treated in a cryptic manner and given a code that distinguishes it from other individuals to mark the patients. No personal information will be disclosed in any report or publication related to the study, and therefore no harm will be caused to the patients mentally or physically. And we have applied for exemption of subject's informed consent.

Follow-up:

This study is a cross-sectional study, from March 2018 to January 2019, patient went to the gastroenterology clinics of the Second Affiliated Hospital of Xi’an Jiaotong University and the Affiliated Hospital of Northwest University who met the inclusion criteria and exclusion criteria were included in the study, and we obtained relevant information through a clinic visit and telephone consultation. Patients were followed up by telephone to collect information if we were unable to perform outpatient consultations.

Data collection：

1. Basic demographic data: name, age, height, weight, gender, marriage;

2. Dyspeptic information: dyspeptic symptoms, duration, frequency per week;

3. Lifestyle habits: spicy foods, smoking, drinking, sleep quality, daily exercise time;

4. Examination results: [Helicobacter pylori](javascript:;), upper abdominal B ultrasound, gastroscopy;

5. Family history, and outpatient cost information.

Statistical analysis：

EpiData3.1 software was used to input data, the statistical analyses were performed using EmpowerStats and SPSS 20.0 (IBM Corp., Armonk, New York, USA). The sensitivity (95% CI), specificity (95% CI), positive predictive values (95% CI), negative predictive values (95% CI), positive LR (95% CI), and negative LR (95% CI) were calculated within a Microsoft Excel spreadsheet. P <0.05 was considered statistically significant. Prism 6.0 to draw the analysis diagram.

Research significance：

To evaluate the accuracy of the Rome IV criteria in identifying patients with FD.

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