

Original article

Diagnosis of functional constipation: Agreement between Rome III and Rome II criteria and evaluation for the practicality

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OBJECTIVE: To investigate the agreement between Rome III and Rome II criteria for diagnosing functional constipation (FC) and to evaluate the accuracy of each constipation symptom for FC diagnosis.

METHODS: Patients with chronic constipation underwent rigorous biochemical and endoscopic/imaging tests to exclude organic and metabolic diseases. The questionnaires including general information, constipation symptoms, and the most troublesome constipation symptoms were completed in a face-to-face survey. The accuracy of constipation symptoms for FC diagnosis was examined using the likelihood ratio.

RESULTS: Among 184 patients (43 males and 141 females) with chronic constipation, 166 (90.2%) met Rome II criteria and 174 (94.6%) met Rome III criteria for FC, while 166 met both criteria. There was a good

diagnostic agreement between the two sets of criteria, with a kappa value of 0.69 and the overall agreement rate was 95.7% ($P < 0.001$). Based on Rome III criteria, the most accurate symptom for FC diagnosis was sensation of anorectal blockage, followed by straining during defecation and infrequent bowel movements. The most troublesome symptoms reported by patients were lumpy or hard stools, straining during defecation, sensation of incomplete evacuation. More patients indicated that 'the symptoms in the past 3 months' was better than 'those within the past one year' to reflect their constipation (36.7% vs 6.0%, $P < 0.001$).

CONCLUSIONS: There is good agreement between Rome III and Rome II criteria for FC diagnosis. Rome III criteria are more practical than Rome II criteria for Chinese patients.

KEY WORDS: constipation, diagnosis, questionnaires, Rome II criteria, Rome III criteria.

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INTRODUCTION

Functional constipation (FC) is a common functional bowel disorder in clinical practice, manifesting as straining during defecation, lumpy or hard stools and infrequent bowel movements, in the absence of evident organic or structural diseases. Epidemiological survey shows that the prevalence of chronic constipation in the general population of North America is 3.6–16.7%.¹ In the Chinese population, the prevalence of chronic constipation, based on the Rome II criteria is 3.0–11.6%.^{2–5} Persistent constipation adversely affects the patients' mental state and their quality of life,^{6,7} and these patients may seek medical care repeatedly, resulting in a huge waste of medical resources and high medical costs.⁸ Data have shown that different diagnostic criteria may affect the prevalence of constipation observed in epidemiological investigations. For example, in the same population, the prevalence of constipation was 19.2% according to the Rome I diagnostic criteria but 14.0% when Rome II diagnostic criteria were applied.⁹

The Rome III criteria,¹⁰ published in 2006, are internationally recognized the clinical criteria for the diagnosis of irritable bowel syndrome (IBS) and are widely applied in clinical research. The Rome III criteria are also adopted in clinical trials on chronic idiopathic constipation as well as in the epidemiological investigations of chronic constipation.^{11–13} The Rome III criteria were modified based on the Rome II criteria, adjusting the time-frame from 'symptoms occur in >1/4 of defecations for at least 12 weeks, which need not be consecutive, in the preceding 12 months' to 'symptoms onset at least 6 months prior to diagnosis and fulfilled for at least 25% of defecations for the past 3 months', and emphasizing 'loose stools are rarely present without the use of laxatives'. It is still unclear if the adjustment to the diagnostic criteria might affect the clinical diagnosis of FC. In this study, we conducted face-to-face surveys of patients with chronic constipation, in whom organic diseases and metabolic diseases were explicitly excluded, to investigate the agreement between Rome III and Rome II criteria for the diagnosis of FC and to evaluate the accuracy of each constipation symptom for diagnosing FC.

PATIENTS AND METHODS

Patients

Patients with chronic constipation who were admitted to the Gastroenterology Clinic of Peking Union

Medical College Hospital (Beijing, China) from March 2009 to October 2010 were recruited in the study. Eligible patients experienced at least two of six constipation symptoms based on the Rome diagnostic criteria, with a disease course of at least 6 months. Routine peripheral blood test, liver and kidney function examinations, plasma glucose, carcinoembryonic antigen (CEA) examination, urine and stool tests including occult blood test, abdominal ultrasound as well as colonoscopy or barium enema examination were performed in all the patients within one year before their enrollment to rule out organic and metabolic diseases. Patients with secondary chronic constipation such as drug-related constipation were excluded. Those meeting the diagnostic criteria for IBS were also excluded from the study. The study was approved by the Institutional Ethics Committee of Peking Union Medical College Hospital.

Questionnaire

The questionnaire included the general information, the disease course, symptoms, degree and frequency of each symptom, and the most troublesome symptom of constipation. We set the questions 'Which of the following symptoms of constipation appeared for at least 12 weeks in the preceding 12 months?' and 'Which of the following symptoms of constipation appeared during at least 25% of defecations in the past 3 months?' where the symptoms on list are straining during defecation, lumpy or hard stools, sensation of anorectal blockage during defecation, sensation of incomplete evacuation, requirement of manual maneuvers to assist defecation (including digital evacuation, support of the pelvic floor and abdominal massage), bowel movement less than 3 times per week, lack of awareness of defecation, unproductive calls (want to but cannot), excessive time on the toilet, and less stool volume on a daily basis. And then, we asked the patients to evaluate which of the following time frames was better to reflect their chronic constipation based on their symptoms: (i) within the past one year (referring to the Rome II criteria); (ii) within the past 3 months (referring to the Rome III criteria); or (iii) the above two are similar. We also asked them to list the three most troublesome constipation symptoms experienced within the past one year and within the past 3 months. The Rome II and Rome III diagnostic criteria were compared according to the patients' responses to the abovementioned questions. The mental state of patients in the past 3 months was evaluated by brief psychosocial questions in the questionnaire.

The questionnaire was completed by face-to-face interview that was conducted by the trained investigators. Written informed consent was obtained from each patient before the surveys, and all the questionnaires were checked by the principal investigator.

Statistical analysis

A database was built using EpiData 3.02 by two independent investigators and the consistency checking was conducted. Once the data were not consistent, the original questionnaire was re-reviewed and the data were corrected. Statistical analyses were performed using SPSS 12.0 (SPSS Inc., Chicago, IL, USA). Continuous data were expressed as mean \pm standard deviation, whereas categorical data were shown as numbers and percentages, respectively. The agreement between the two diagnostic criteria was analyzed using the Cohen's kappa test. McNemar test was used to compare the patients' opinions for the two diagnostic criteria. $P \leq 0.05$ was considered as statistically significant.

The likelihood ratio (LR) is a comprehensive index simultaneously reflecting sensitivity and specificity that is not affected by the prevalence. Based on the Rome III criteria setting as the gold standard for the diagnosis of FC, the positive LR (LR⁺) and negative LR (LR⁻) were calculated for each symptom of constipation to reflect its accuracy in the diagnosis of FC, the patients who did not meet Rome III criteria were divided as the control group. LR⁺ was calculated as sensitivity/(1-specificity), and LR⁻ was calculated as (1-sensitivity)/specificity. Higher values of LR⁺ and smaller values of LR⁻ represented higher diagnostic accuracy.

RESULTS

Baseline characteristics of the patients

A total of 184 patients with chronic constipation met the inclusion criteria and were enrolled in the survey, including 43 males and 141 females with a median age of 49.9 years (range 18.0–80.0 years). The median disease course of constipation in these patients was 8.0 years (range 6 months to 60.0 years).

Agreement of diagnostic rates between Rome III and Rome II diagnostic criteria

Among the 184 patients, 166 (90.2%) patients met the Rome II diagnostic criteria for FC, while 174

Table 1. Diagnostic agreement between Rome III and Rome II criteria for functional constipation (*n*)

		Rome III		Total
		+	-	
Rome II	+	166	0	166
	-	8	10	18
Total		174	10	184

(94.6%) met the Rome III diagnostic criteria, and 166 of them met both criteria. The diagnostic agreement was good between the two criteria, with a κ value of 0.69 (95% CI 0.62–0.76) and the overall agreement rate was 95.7% ($P < 0.001$, Table 1).

Reasons why patients did not meet the diagnostic criteria for FC

Among the 18 patients who did not meet the Rome II diagnostic criteria, 14 lacked of two or more symptoms of constipation lasting for at least 12 weeks (not necessarily consecutive) within the preceding 12 months, while the other 4 exhibited two items of constipation symptoms with a disease course of less than one year. Ten patients did not meet Rome III criteria because they had fewer than two symptoms of constipation during at least 25% of defecations within the past 3 months. And among the 10 patients who meet neither diagnostic criteria, one patient failed to meet Rome II criteria because the disease course was less than one year. Among those who experienced at least two items of constipation symptoms, the frequency of the onset of symptoms did not reach the criteria of 'at least 12 weeks in the preceding 12 months' in 9 patients or 'at least 25% of defecations in the past 3 months' in 10 patients.

The patients' mental states and social conditions such as marital status, occupations, physical labor, educational level and family economic condition did not affect the agreement of the two criteria in the study population (data not shown).

Comparisons of constipation symptoms

The frequency of six constipation symptoms incorporated in the Rome diagnostic criteria was 18.1% to 91.6% in patients who met the Rome II criteria for FC, and 18.4% to 92.0% in those who met the Rome III criteria. The frequency of each symptom and distribution of symptoms were not significantly different between the patients diagnosed using the two criteria (Table 2).

The accuracy of constipation symptoms for the diagnosis of FC

Among the six constipation symptoms incorporated in the Rome diagnostic criteria, sensation of anorectal blockage during defecation had the highest LR⁺, followed by manual maneuvers to assist defecation and bowel movement frequency <3 times per week (Table 3). The symptom with the lowest LR⁻ was straining during defecation, followed by infrequent bowel movements and anorectal blockage. A comprehensive analysis showed that sensation of anorectal blockage, straining during defecation and infrequent bowel movements had the highest accuracy for diagnosing FC, while lumpy or hard stools, sensation of incomplete evacuation, manual maneuvers to assist defecation had the lowest diagnostic accuracy.

The Rome criteria define the manual maneuvers to assist defecation as digital evacuation and support of the pelvic floor. In this study we also listed abdominal massage¹⁴ as a method to facilitate the bowel movement because some Chinese patients believe this is a major and effective method. In our study, 72 patients adopted abdominal massage alone or with digital assistance, which increased the number of manual maneuvers to assist defecation to 92 with LR⁺ of 2.6

Table 2. The symptoms spectra of the patients with functional constipation

Symptoms, n (%)	Rome II (N = 166)	Rome III (N = 174)
Straining during defecation	152 (91.6)	160 (92.0)
Lumpy or hard stools	118 (71.1)	124 (71.3)
Incomplete evacuation	116 (69.9)	120 (69.0)
Anorectal blockage	88 (53.0)	91 (52.3)
Manual maneuvers to assist defecation	30 (18.1)	32 (18.4)
Bowel movement <3 times per week	124 (74.7)	130 (74.7)

Table 3. Accuracy of constipation symptoms for the diagnosis of functional constipation based on the Rome III criteria

Symptoms	Sensitivity, % (95% CI)	Specificity, % (95% CI)	LR ⁺	LR ⁻
Straining during defecation	92.0 (88.0–96.0)	30.0 (1.6–58.4)	1.31	0.27
Lumpy or hard stools	71.3 (64.6–78.0)	40.0 (9.6–70.4)	1.19	0.72
Incomplete evacuation	69.0 (62.1–75.9)	40.0 (9.6–70.4)	1.15	0.78
Anorectal blockage	52.3 (44.9–59.7)	80.0 (55.2–100)	2.62	0.60
Manual maneuvers to assist defecation	18.4 (12.6–24.2)	90.0 (71.4–100)	1.84	0.91
Bowel movement <3 times per week	74.7 (68.2–81.2)	50.0 (19.0–81.0)	1.49	0.51

CI, confidence interval; FC, functional constipation; LR⁺, positive likelihood ratio; LR⁻, negative likelihood ratio.

and LR⁻ of 0.6. Patients adopting massage of anus (*n* = 28) did report they have more severe straining (22 severe and 6 moderate straining), but there was no significant association between these two symptoms (*P* = 0.668).

Patients' opinions for the two diagnostic criteria

Among the 166 patients who met both diagnostic criteria for FC, 95 (57.2%) reported that their symptoms within the preceding 12 months were similar to those within the past 3 months. Sixty-one (36.7%) patients indicated that their symptoms over the past 3 months might better reflect their conditions of constipation, and 10 (6.0%) believed that symptoms over the preceding 12 months might better reflect their illness (McNemar test, *P* < 0.001). These data revealed that the Rome III criteria were more practical than the Rome II criteria considering the patients' opinions for the constipation symptoms evaluation.

The most troublesome constipation symptoms

The most troublesome constipation symptoms were lumpy or hard stools (11.4% in patients met Rome II criteria *vs* 12.1% in patients met Rome III criteria), followed by straining during defecation (10.2% *vs* 10.3%) and sensation of incomplete evacuation (9.0% *vs* 9.8%) in FC patients either diagnosed with Rome II or Rome III criteria. The data of the symptoms which did not be incorporated in Rome diagnostic criteria are not shown.

DISCUSSION

Similar to the epidemiological studies from general populations in China,^{2–4} a heavy skew towards females was also noted in this study. In contrast to those in epidemiological survey, all the participants in this study underwent rigorous biochemical and endoscopic and/or imaging examinations to explicitly exclude the presence of organic and metabolic

diseases, and drug-induced constipation was also ruled out. The results revealed that 90.2% and 94.6% of the patients met the Rome II and III diagnostic criteria for FC, respectively. There was no significant difference in the number of patients qualifying for each diagnosis, indicating the majority of FC patients could be diagnosed with either of the two Rome criteria.

There was good agreement between Rome III and Rome II criteria for diagnosing FC ($\kappa = 0.69$), which is similar to that of an earlier study by Garrigues *et al.*⁹ comparing the diagnostic results for chronic constipation using Rome I and Rome II criteria in the same general population ($\kappa = 0.71$). Another study revealed poor agreement ($\kappa = 0.107$) between Rome II and Rome III criteria for the diagnosis of FC in children,¹⁵ which might be attributed to that investigators used diagnostic criteria that are appropriate for different populations. Their result may also be related to the broad age span of children in that study as well as the characteristics of FC in children and adolescents.

A survey conducted in outpatients with chronic constipation demonstrated that straining during defecation was present in more than 80% of patients and was the symptom with the highest frequency.¹⁶ In a multicenter study in Beijing area, straining during defecation was the most common (74.8%) and most bothersome symptom (61.2%) in outpatients with chronic constipation.¹⁷ In the present study, straining during defecation was the most common among the six constipation symptoms incorporated in the Rome diagnostic criteria, which is consistent with the previous results. It should be pointed out that the participants in this study were individuals with chronic constipation who sought medical care at the Outpatient Clinic of Peking Union Medical College Hospital. Our hospital is the center for diagnosis and treatment of difficult and complicated diseases in China, and that may be the reason why the prevalences of various constipation symptoms in this study were higher than those in other studies. This study compared the spectrum of symptoms in patients diagnosed using Rome II and Rome III criteria, showing no difference in the proportion of various constipation symptoms between FC patients diagnosed with these two diagnostic criteria.

The LR reflects the contribution of each constipation symptom in the diagnostic criteria to the final diagnosis of chronic constipation.⁹ Considering the LR in this study, the sensation of anorectal blockage during def-

ecation contributed the most accurate value among the six constipation symptoms incorporated the Rome III criteria of FC, followed by straining during defecation and infrequent bowel movements. This is consistent with the previous results that used Rome II as the gold standard and showed that the sensation of anorectal blockage and straining during defecation had the greatest accuracy for the diagnosis of chronic constipation.^{9,18} Previous studies also revealed that manual maneuvers to assist defecation was the least valuable symptom in the diagnosis for chronic constipation.⁹ In Garrigues *et al.*'s survey, the questionnaire emphasized the need to massage the anus or vagina to complete defecation. In our survey, the definition of manual maneuvers was more detailed. Anal or vaginal massage was less common in Chinese patients, either limited with massage anus/vagina and support of pelvic floor or extended abdominal massage as manual maneuvers did not reduce LR⁺ of this symptom for FC diagnosis. We did not pay more attention to the relation between defecation habits (i.e. sitting or squatting on toilets) and the constipation symptoms. It should be noted that previous studies detected chronic constipation in the general population using different criteria, and our study only included patients with FC, in whom organic diseases were excluded. The results may better reflect the situation of patients with FC and objectively evaluate the Rome criteria. Some investigators believe that different clusters of constipation symptoms suggest different pathophysiological mechanisms of constipation. For example, prominent straining, sensation of anorectal blockage during defecation, requirement of manual maneuvers to assist defecation, and feeling of incomplete evacuation suggest the presence of anorectal dysfunction in patients;¹⁹ and reduced number of bowel movements and lumpy or dry stools suggest a delay of colonic transit in patients.^{20,21} In this study, in only some patients gastrointestinal transit time was evaluated and anorectal manometry was performed. Therefore, the relationship between FC symptom clusters and the pathophysiological classification could not be analyzed.

The Rome criteria for diagnosing FC are based on symptomatology. The proportion of these patients is of significant importance for us to well understand the advantages of the Rome III diagnostic criteria. Although the prevalence of lumpy or hard stools was not the highest among all the symptoms and it had the lowest LR⁺ and a high LR⁻, patients perceived it to be the most troublesome symptom among the six constipation symptoms incorporated in Rome diagnostic criteria. This result indicated the physicians

should pay sufficient attention to stool form and the patients' perception of constipation during the treatment, which might improve the patient's satisfaction with treatment. In this study we also found that, among all of the constipation symptoms including those not incorporated in Rome diagnostic criteria, unproductive calls and a lack of awareness of defecate are the top two among the most troublesome constipation symptoms perceived by patients (data not shown).

In this study, specific questions were set in the questionnaire to collect patients' opinions on the two sets of diagnostic criteria. Rome III criteria emphasized on a shortened course of disease and the frequency of recent symptoms and were deemed more practical than the Rome II diagnostic criteria for patients who sought medical cares. Although *Rome III: The Functional Gastrointestinal Disorders (Chinese version)* accurately translated the Rome II and Rome III diagnostic criteria, the statement that 'symptoms occur in >1/4 of defecations for at least 12 weeks, which need not be consecutive, in the preceding 12 months' in the Rome II criteria is difficult for clinicians and patients to understand.

Although Rome II criteria for FC have been abandoned for more than 7 years, this study may still be helpful for physicians to understand the Rome criteria for FC, optimize the therapy for this disease in clinical practice and to apply the diagnostic criteria in epidemiological and pathophysiological studies with flexibility. Furthermore, it might be referred as an evidence for Rome IV criteria process, which is going to be released by 2016. The following limitations are worth noting in this study. The number of patients who did not meet the Rome III criteria for FC was too small to be the control group for LR calculation, and we did not enroll the individuals without constipation as negative control group. The limitations of the design might have affected the accuracy of the specificity of symptoms and LR.

In conclusion, there was good diagnostic agreement between symptom-based Rome II and Rome III diagnostic criteria for FC. Sensation of anorectal blockage, straining during defecation and infrequent bowel movements are of great accuracy for the diagnosis of FC. And more patients considered that Rome III diagnostic criteria might better reflect their constipation condition, indicating that Rome III criteria are more practical than the Rome II criteria.

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