

Rome III Criteria for Functional Gastrointestinal Disorders: Is There a Need for a Better Definition?

Hye-Kyung Jung

Department of Internal Medicine, Ewha Medical Research Institute, Ewha Womans University School of Medicine, Seoul, Korea

Article: Functional gastrointestinal disorders diagnosed by Rome III questionnaire in Korea

Park JM, Choi MG, Cho YK, et al

(*J Neurogastroenterol Motil* 2011;17:279-286)

The reliable diagnosis of functional gastrointestinal disorders (FGIDs) has been shown to be based on researches utilizing the Rome criteria by means of self-reported questionnaires.¹⁻⁴ Rome classification system is essentially based on the symptom clusters that remain consistent across clinical and population groups. The Rome criteria have been modified periodically as new scientific data emerges. Rome foundation has undergone many revisions since its first presentation.

Patients with FGIDs report a wide variety of symptoms affecting different regions of the gastrointestinal (GI) tracts. These symptoms in the GI tract are similar in terms of CNS processing of visceral and somatic signals. However, the FGIDs have accompanied distinct peripheral symptoms that require more specific treatment. The psychiatric agents alone in patients with irritable bowel syndrome (IBS) can not control the diarrhea or constipation.

There are no definitive biomarkers to explain FGIDs and the symptoms that bring patients to physicians. Therefore, symp-

tom-based criteria are used for clinical care and research.³ Symptom-based criteria are used in psychiatry (eg, the Diagnostic and Statistical Manual of Mental Disorders IV) and rheumatology.^{5,6} A critical value of the use of symptom-based diagnostic criteria is related to the ability to define patients' subsets to respond to the clinical trial. The new classification system of Rome III criteria could have important effects on both clinical practice and research. According to the new classification, functional dyspepsia is sub-classified into epigastric pain syndrome and postprandial distress syndrome, based on the presence of meal-related symptoms. IBS is sub-grouped into four categories with the Bristol Stool Scale (BSS). These changes could affect the estimate of prevalence of each subtype and the selection of patients for clinical trials.

The bowel habits in IBS patients show considerable inter- and intra-individual variability,⁷ and it has been common to use the supporting symptom criteria to divide IBS patients into different subgroups based on their predominant bowel pattern. This

Received: June 2, 2011 Revised: June 18, 2011 Accepted: June 19, 2011

© This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

*Correspondence: Hye-Kyung Jung, MD

Department of Internal Medicine, Ewha Womans University Mokdong Hospital, 911-1 Mokdong, Yangcheon-gu, Seoul 158-710, Korea

Tel: +82-2-2650-2874, Fax: +82-2-2655-2874, E-mail: junghk@ewha.ac.kr

Financial support: None.

Conflicts of interest: None.

has been important especially in drug trials, where a positive effect could be expected in one subgroup of patients, whereas side effects in the other subgroups. The study was conducted prospectively in female IBS patients by Rome II criteria to determine the level of agreement between Rome II and Rome III subtypes, and it was quite high (86.5%, kappa 0.79).⁸ The behaviors of Rome II and Rome III subtypes over time were also similar in terms of subtype prevalence and stability. However, in this study, the author analyzed the subtypes of unspecified IBS and mixed IBS into 1 category. In another study with similar setting, the agreement of Rome II and Rome III of IBS subtype was poor and the main disagreement occurred between the alternating IBS in Rome II criteria and mixed IBS with unspecified IBS subtypes in Rome III criteria.⁹ In Rome III questionnaires from the website of Rome foundation, the classification of subtypes of IBS was based on the patients' response to the direct questions in terms of stool form, instead of BSS. In the study conducted from Park et al,¹⁰ the agreement between subtype defined by the self-reporting stool consistency and subtype categorized by the BSS was poor (kappa 0.08).

Interestingly, Park et al¹⁰ also reported that the substantial proportion of functional dyspepsia (18.3%) was not classified into subgroup, such as epigastric pain syndrome or postprandial distress syndrome. They applied the different symptom frequency in functional dyspepsia and its subtypes, which was proposed by Rome foundation with detailed questionnaires and criteria (<http://www.romecriteria.org/>). Rome foundation recommended the "at least" weekly symptoms in the definition of functional dyspepsia, but more frequent symptoms for the definition of subtypes. However, each definition might be applied with the same symptom frequency. Rome foundation conducted a validation study of the Rome III criteria and the questionnaire designed by the questionnaire subcommittee, however, it is not clear whether this controversy comes from simple technical error or not. Rome foundation has to clarify this issue because subgrouping of each item of FGIDs might be important to the clinical applications and research work.

In the present study, the prevalence of epigastric pain syndrome was low, as being 5% of functional dyspepsia. The authors explained that these feature could be influenced by the difficulty in understanding between heartburn and epigastric burning in Korean. However, if the author clearly documented the reliability or validation work of questionnaire, it might have been more easily accessed whether this discrepancy came from socio-cultural difference or not. The cross-cultural translation is a process

which looks at both language and cultural adaptation issues in the process of preparing a study instrument for use in another culture and geographical region. It challenges to develop that new valid method retaining the meaning and intent of the original instrument which would be culturally relevant and comprehensible. In Japanese dyspeptic patients, 81.3% of the patients with functional dyspepsia had postprandial distress syndrome and 56.1% had epigastric pain syndrome and the overlap of these subtypes was significant.¹¹

In conclusion, the study conducted by Park et al¹⁰ explored the features of FGIDs by Rome III criteria in diverse samples from primary and tertiary hospitals in Korea. The half of subjected patients with GI symptoms has FGIDs. Authors raised some ambiguous issues in subtype of functional dyspepsia and IBS by Rome III criteria. Discussions for Rome IV have commenced, but we must allow sufficient time for the accumulation of evidences to justify meaningful changes.

References

1. Management of dyspepsia: report of a working party. *Lancet* 1988;1:576-579.
2. Talley NJ, Stanghellini V, Heading RC, Koch KL, Malagelada JR, Tytgat GN. Functional gastroduodenal disorders. *Gut* 1999;45 (suppl 2):II37-II42.
3. Drossman DA. The functional gastrointestinal disorders and the Rome III process. *Gastroenterology* 2006;130:1377-1390.
4. Tack J, Talley NJ, Camilleri M, et al. Functional gastroduodenal disorders. *Gastroenterology* 2006;130:1466-1479.
5. Zimmerman M, Chelminski I, Young D. On the threshold of disorder: a study of the impact of the DSM-IV clinical significance criterion on diagnosing depressive and anxiety in clinical practice. *J Clin Psychiatry* 2004;65:1400-1405.
6. Lembo T, Naliboff B, Munakata J, et al. Symptoms and visceral perception in patients with pain predominant irritable bowel syndrome. *Am J Gastroenterol* 1999;94:1320-1326.
7. Mearin F, Baró E, Roset M, Badía X, Zárate N, Pérez I. Clinical patterns over time in irritable bowel syndrome: symptom instability and severity variability. *Am J Gastroenterol* 2004;99:113-121.
8. Dorn SD, Morris CB, Hu Y, et al. Irritable bowel syndrome subtypes defined by Rome II and Rome III criteria are similar. *J Clin Gastroenterol* 2009;43:214-220.
9. Ersryd A, Posserud I, Abrahamsson H, Simrén M. Subtyping the irritable bowel syndrome by predominant bowel habit: Rome II versus Rome III. *Aliment Pharmacol Ther* 2007;26:953-961.
10. Park JM, Choi MG, Cho YK, et al. Functional gastrointestinal disorders diagnosed by Rome III questionnaire in Korea. *J Neurogastroenterol Motil* 2011;17:279-286.
11. Manabe N, Haruma K. Diagnosis and treatment of dyspeptic patients in Japan. *J Gastroenterol Hepatol* 2011;26(suppl 3):27-31.