Original Article

Validity and Reliability of the Thai Version of Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders

Siajunboriboon S, MD[1], Ngoenmak T, MD[2], Tanpowpong P, MD, MPH[1], Sarawit M, PhD[3], Treepongkaruna S, MD[1]

[1] Department of Pediatrics, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
[2] Department of Pediatrics, Naresuan University Hospital, Naresuan University, Phitsanulok, Thailand
[3] Faculty of Business, Economics and Communications, Naresuan University, Phitsanulok, Thailand

Objectives: To produce the Thai version of the Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents, and assess their validity and reliability.

Materials and Methods: The original English version of Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders, both parent-report and child self-report questionnaires, consisted of 5 sections. The questionnaires were forward translated into Thai. The Thai version was then back translated into English by a professional translator. The original and the back-translated versions were compared and validated using index of item-objective congruence (IOC). Then, reliability tests of the final Thai version were performed with 50 children and 50 parents and analyzed by Cronbach's alpha coefficient. Retest of the questionnaires was evaluated in all subjects and analyzed by intra-class correlation coefficient (ICC).

Results: The IOC of the Thai parent-report and self-report questionnaires were 0.87 and 0.91, respectively. Cronbach's alpha coefficients of the parent-report and self-report questionnaires were 0.94 and 0.96, respectively. The ICC was 0.99 for the parent-report and self-report questionnaires.

Conclusion: The Thai version of the Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents, both parent-report and self-report, provide good validity and good reliability and can be used for research on functional gastrointestinal disorders in Thai children and adolescents.

Keywords: Functional gastrointestinal disorders, Rome criteria, Rome IV, Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders

J Med Assoc Thai 2019;102(Suppl.10): 1-4
Website: http://www.jmatonline.com

Functional gastrointestinal disorders (FGIDs) are defined as chronic or recurrent gastrointestinal symptoms not explained by structural or biochemical abnormalities[1]. FGIDs are very common among infants, children, adolescents and adults[1-7]. In US, 23% of children aged 4 to 18 years have at least one FGID[4] while the study in adolescents has shown the prevalence of 13.9% in Japan[5] and 28.8% in Sri Lanka[6]. Abnormal brain-gut axis has been proposed to cause gut dysfunction and development of FGIDs in combination with many predisposing factors including an early life events, environmental factors, and genetic factors[1].

Although FGIDs are generally a non-life threatening condition, they can cause discomfort and impaired quality of life in the affected children, as well as an anxiety in their parents[4,5,8,9]. There are no specific diagnostic investigations for these disorders; therefore, the diagnosis is usually based on symptoms in combination with excluding potential organic causes using limited investigations. Unfortunately, unnecessary investigations before diagnosing FGIDs are often performed in clinical practice. The Rome criteria provide symptom-based guidelines for diagnosis of FGIDs and can enhance clarity for both clinicians and researchers without excessive investigations. The first international expert consensus for developing the guidelines for the diagnosis of FGIDs in adults was first published in 1994[10] and Rome II which also included criteria for children as the first time in 1998[11], followed by Rome III in 2006[12,13]. In 2016, the most updated version, Rome IV criteria have been developed based on expert consensus as well as an evidence form research studies[14,15]. The major changes of the Rome IV is to include 2 new disorders, functional nausea and functional vomiting, in the FGIDs of children and adolescents[15].

The Questionnaire of Pediatric Gastrointestinal Symptoms (QPGS) have been developed following the Rome criteria to screen FGIDs and serve as case definitions for

Correspondence to:
Treepongkaruna S.
Department of Pediatrics, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand.
Phone: +66-2-2011446
E-mail: supornтr@gmail.com, suporn.tre@mahidol.ac.th

How to cite this article: Siajunboriboon S, Ngoenmak T, Tanpowpong P, Sarawit M, Treepongkaruna S. Validity and Reliability of the Thai Version of Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders. J Med Assoc Thai 2019;102(Suppl.10): 1-4.

epidemiological surveys and in research studies. The Rome III QPGS was translated from original English version into many languages including Thai[16]. Recently, the Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders have been developed by modifying the Rome III QPGS. They have been translated into a Spanish version and validated and then used for an epidemiological survey[17]. However, the Rome IV questionnaires had not been translated into Thai. The authors, therefore, conducted the present study to produce the Thai version of the Rome IV QPGS for child and adolescent and assess its validity and reliability.

Materials and Methods

Questionnaire translation process and validity test

The Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents consist of two report forms, including parent-report form for evaluating children aged 4 to 10 years and self-report form for evaluating adolescents aged 10 to 18 years. There are five sections in the questionnaires: Section A, pain and uncomfortable feelings above the belly button; Section B, bellyaches and abdominal pain around and below the belly button; Section C, bowel movements; Section D, nausea and vomiting; and Section E: other GI symptoms.

The questionnaire translation process and validity test were performed following the guidelines of the Rome committee[18]. The English questionnaires were forward translated into the Thai language by 2 Thai pediatric gastroenterologists independently (PT and TN). Both Thai versions were reconciled by another pediatric gastroenterologist (ST). Then, the final Thai version was back-translated into English by a professional translator (MS) who was a native English speaker and linguistic expert. Two experts in English compared item-by-item on the dimension of literal translation and compared interpretation between the original English and the back-translation versions. The content validity of the Thai version of the instrument was examined. The index of item-objective congruence (IOC) was assessed to evaluate validity. The completed Thai questionnaires were then pilot tested with a few volunteers (children, adolescents, and parents) for clarity and ease of understanding. Further revisions were made to the final Thai version of the Rome IV questionnaires after discussion with the experts in pediatric FGIDs and general pediatrics.

Reliability testing

The authors recruited 50 children (aged 10 to 18 years) with or without GI symptoms and 50 parents at the outpatient clinic and in-patient wards at Department of Pediatrics, Faculty of Medicine Ramathibodi Hospital. None of the patients had serious acute or chronic illness. The questionnaires were answered by parents for children aged 4 to 10 years old and self-answered by children aged more than 10 years. Cronbach's alpha coefficients were then analyzed for evaluation of internal consistency. To retest, all subjects answered the same questionnaire within 2 weeks from the first test. The interval time of 2 weeks was considered a reasonable compromise between memory of subjects and clinical changes[19]. There was no drop-out during this process. The stability of the Thai questionnaires was analyzed, using the intra-class correlation coefficient (ICC). The study was approved by the Ethics Committee of the Faculty of Medicine Ramathibodi Hospital.

Statistical analysis

The STATA program, version 16, was used for statistical analysis. Data were expressed as mean, and analyzed by Item-objective congruence (IOC) for evaluation of content validity, and Cronbach's alpha coefficient and ICC for evaluation of reliability. IOC was calculated from total scores of agreement of two experts in each item. Acceptable IOC was between 0.5 to 1.0[19]. Internal consistency was interpreted as acceptable and excellent when Cronbach's alpha coefficients were >0.7 and >0.9, respectively[20]. ICC was interpreted as poor (ICC <0.5), moderate (0.5 $\leq$ ICC <0.75), good (0.75 $\leq$ICC $\leq$0.9), and excellent (ICC >0.9)[21].

Results

The mean age of children in parent reporting group and in self-reporting group was 6.3$\pm$1.6 years and 14.1$\pm$2.4 years, respectively. The IOC was 0.87 for parent-report and 0.91 for self-report questionnaires, which both indicated high validity. The Cronbach's alpha coefficients were 0.94 for the parent-report and 0.96 for the self-report questionnaires. In addition, the ICC was 0.99 for both parent-report and 0.98 for self-report questionnaires. The reliability of each section of the questionnaires is shown in Table 1.

Discussion

The Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders serve as screening tools and are adopted in FGIDs research in children. Cross-cultural research needs to adapt to the individual culture and is comprehended differently depending on the countries while maintaining the meaning and intent of the original items[18]. Translation is the common procedure for cross-cultural research. For the language validity of the Thai version, the translation process was performed according to guidelines of the Rome committee[18].

Our report is the first study which purposed to develop the Thai version of Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders. The content validity of the Thai version was established from expert opinions, showing good validity for both parent-report and self-report forms.

The present study also showed that Thai version had excellent reliability. The internal consistency of the questionnaires was determined by Cronbach's alpha coefficient which showed 0.94 for the parent-report and 0.96 for the self-report questionnaires. Cronbach's alpha coefficient of above 0.9 is considered excellent internal consistency[20]. In addition, the test-retest method was performed. The ICC was determined through the test-retest analysis and an ICC above 0.75 is considered excellent

Table 1. Summary of reliability of the Thai version of the Rome IV questionnaire

	Parent-report (n = 50)		Self-report (n = 50)	
	Cronbach's alpha	ICC (95% CI)	Cronbach's alpha	ICC (95% CI)
Total	0.94	0.99 (0.98 to 0.99)	0.96	0.99 (0.99 to 1.00)
Section A: Pain and uncomfortable feelings above the belly button	0.69	0.98 (0.97 to 1.00)	0.70	0.99 (0.98 to 0.99)
Section B: Bellyaches and abdominal pain around and below the belly button	0.82	0.99 (0.99 to 1.00)	0.89	0.99 (0.99 to 1.00)
Section C: Bowel movements	0.86	0.99 (0.98 to 1.00)	0.76	0.99 (0.98 to 1.00)
Section D: Nausea and vomiting	0.91	1.00	0.97	0.99 (0.98 to 1.00)
Section E: Other symptoms	0.70	0.97 (0.93 to 1.0)	0.78	0.99 (0.98 to 1.00)

ICC = intra-class correlation coefficient

stability[21]. The ICC coefficients of parent-report and self-report questionnaires were 0.99. Therefore, the Thai questionnaire had excellent reliability.

Our study has some limitations. The data were collected only among patients in Ramathibodi Hospital, limiting generalizability to Thai children and parents. This limitation may result in different understanding and interpretation for other regions depending on variation in the culture of population.

Conclusion

The Thai version of the Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents are established with good validity and reliability and can be used as a tool in research studies on FGIDs in Thai children and adolescents.

What is already known on this topic?

The questionnaires for pediatric gastrointestinal disorders using diagnostic Rome criteria are useful for screening functional GI disorders in children and serve as case definitions for epidemiological surveys and in research studies. The Rome IV questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents have recently been developed.

What this study adds?

Thai version of the Rome IV Diagnostic Questionnaires for Pediatric Gastrointestinal Disorders for children and adolescents are established with good validity and reliability and can be used as a tool in research studies on FGIDs in Thai children and adolescents.

Acknowledgements

The authors acknowledge the Rome Foundation for the permission for translation the Rome IV questionnaires, and Dr. Kunlawat Thadanipon, MD, MSc, Division of Clinical Epidemiology and Biostatistics, Faculty of Medicine Ramathibodi Hospital for his assistance in the statistical analysis.

Potential conflicts of interest

The authors declare no conflicts of interest.

References

1. Drossman DA. Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features and Rome IV. Gastroenterology 2016;150:1262-79.
2. Iacono G, Merolla R, D'Amico D, Bonci E, Cavataio F, Di Prima L, et al. Gastrointestinal symptoms in infancy: a population-based prospective study. Dig Liver Dis 2005;37:432-8.
3. Miele E, Simeone D, Marino A, Greco L, Auricchio R, Novek SJ, et al. Functional gastrointestinal disorders in children: an Italian prospective survey. Pediatrics 2004;114:73-8.
4. Lewis ML, Palsson OS, Whitehead WE, van Tilburg MAL. Prevalence of functional gastrointestinal disorders in children and adolescents. J Pediatr 2016;177:39-43.
5. Sagawa T, Okamura S, Kakizaki S, Zhang Y, Morita K, Mori M. Functional gastrointestinal disorders in adolescents and quality of school life. J Gastroenterol Hepatol 2013;28:285-90.
6. Devanarayana NM, Adhikari C, Pannala W, Rajindrajith S. Prevalence of functional gastrointestinal diseases in a cohort of Sri Lankan adolescents: comparison between Rome II and Rome III criteria. J Trop Pediatr 2011;57:34-9.
7. Saps M, Nichols-Vinueza DX, Rosen JM, Velasco-Benitez CA. Prevalence of functional gastrointestinal disorders in Colombian school children. J Pediatr 2014;164:542-5.
8. Tarbell SE, Li BU. Health-related quality of life in children and adolescents with cyclic vomiting syndrome: a comparison with published data on youth with irritable bowel syndrome and organic gastrointestinal disorders. J Pediatr 2013;163:493-7.
9. Campo JV, Bridge J, Ehmann M, Altman S, Lucas A, Birmaher B, et al. Recurrent abdominal pain, anxiety, and depression in primary care. Pediatrics 2004;113:817-24.

10. Drossman DA, Richter JE, Talley NJ, Thompson WG, Corazziari E, Whitehead WE. The functional gastrointestinal disorders: Diagnosis, pathophysiology and treatment: a multinational consensus. McLean, VA: Degnon Associates; 1994.
11. Rasquin-Weber A, Hyman PE, Cucchiara S, Fleisher DR, Hyams JS, Milla PJ, et al. Childhood functional gastrointestinal disorders. Gut 1999;45 Suppl 2:II60-8.
12. Hyman PE, Milla PJ, Benninga MA, Davidson GP, Fleisher DF, Taminiau J. Childhood functional gastrointestinal disorders: neonate/toddler. Gastroenterology 2006;130:1519-26.
13. Rasquin A, Di Lorenzo C, Forbes D, Guiraldes E, Hyams JS, Staiano A, et al. Childhood functional gastrointestinal disorders: child/adolescent. Gastroenterology 2006;130:1527-37.
14. Benninga MA, Nurko S, Faure C, Hyman PE, St. James Roberts I, Schechter NL. Childhood functional gastrointestinal disorders: neonate/toddler. Gastroenterology 2016;150:1443-55.
15. Hyams JS, Di Lorenzo C, Saps M, Shulman RJ, Staiano A, van Tilburg M. Childhood functional gastrointestinal disorders: child/ adolescents. Gastroenterology 2016;150: 1456-68.
16. Ngoenmak T, Yimyam P, Treepongkaruna S. Reliability and validity of thai version ROME III questionnaire for children with functional gastrointestinal disorders. J Med Assoc Thai 2013;96:790-3.
17. Saps M, Velasco-Benitez CA, Langshaw AH, Ramirez-Hernandez CR. Prevalence of functional gastrointestinal disorders in children and adolescents: comparison between Rome III and Rome IV criteria. J Pediatr 2018;199:212-6.
18. Sperber AD. Translation and validation of study instruments for cross-cultural research. Gastroenterology 2004;126:S124-S128.
19. Turner RC, Carlson L. Indexes of item-objective congruence for multidimensional items. Int J Testing 2003;3:163-71.
20. Tavakol M, Dennick R. Making sense of Cronbach's alpha. Int J Med Educ 2011;2:53-5.
21. Koo TK, Li MY. A Guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016;15:155-63.