

Reliability and Validity of Thai Version ROME III Questionnaire for Children with Functional Gastrointestinal Disorders

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Background: The ROME III diagnostic questionnaire for pediatric functional gastrointestinal disorders (FGIDs) is widely accepted as an essential tool for the diagnosis of FGIDs in children and as a research tool. However, the questionnaire has not been translated into Thai.

Objective: To transpose the ROME III diagnostic questionnaire and to determine its validity and reliability in the Thai cultural setting.

Material and Method: The original English ROME III diagnostic questionnaire, composed of 71 items, was translated into Thai following permission from the ROME foundation. The ROME III questionnaire, Thai version was then translated back to English by a bi-lingual expert. The original English and the back-translation versions were compared and the validity was analyzed using Index of Item-Objective Congruence (IOC). Finally, the Thai questionnaire was tested with 50 healthy school-children aged four to 15 years old who had no serious illness. The questionnaire was answered by parents for children aged four to 10 years, and self-answered by children aged over 10 years. The reliability was evaluated by Cronbach's alpha coefficient.

Results: Item to item comparison between the original English and the back-translation versions valued by IOC was 0.94, which indicated high validity. The Cronbach's alpha coefficient of the overall 71 items was 0.98, which indicated high reliability. Moreover, the alpha of reliability for self-report and parent-report was 0.96 and 0.97 respectively.

Conclusion: The ROME III diagnostic questionnaire in Thai is valid and reliable for the diagnosis of FGIDs in Thai children.

Keywords: ROME III, Questionnaires, Functional gastrointestinal disorders

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Functional gastrointestinal disorders (FGIDs) are common in children and adolescents. The cross-sectional survey conducted in 427 adolescents aged 12-16 years in a semi-urban school in Sri Lanka using a validated self-administered questionnaire according to Rome III criteria showed a prevalence of 29% for FGIDs. They were abdominal-pain-related FGIDs (13.8%), functional constipation (4.2%), aerophagia (6.3%), adolescent rumination syndrome (4%), cyclic vomiting syndrome (0.5%) and non-retentive fecal incontinence (0.2%)⁽¹⁾. One Italian study revealed that 28-46% of school-age children complained of

abdominal pain each week. Organic causes were identified in only 10% of these children while most of them had FGIDs⁽²⁾.

Children with FGIDs have no specific structural, biochemical, and metabolic abnormalities, however, they could have a long absence from school resulting in impaired quality of life^(3,4). Diagnosis of FGIDs require an exclusion of organic causes, on the other hand, unnecessary diagnostic testing before diagnosis should be avoided^(3,4). In 1999, an international committee of pediatricians established the ROME II diagnostic criteria for FGIDs in childhood and adolescence^(5,6), and the ROME III criteria were further modified in 2006^(7,8). According to the ROME III criteria, FGIDs in children includes abdominal-pain related FGIDs (classified as functional dyspepsia, irritable bowel syndrome, chronic functional abdominal pain, and abdominal migraine), functional constipation,

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non-retentive fecal incontinence, aerophagia, cyclic vomiting syndrome, and adolescent rumination syndrome^(7,9). The English version of the ROME III diagnostic questionnaire has been translated into many languages and this have been validated for the diagnosis of childhood FGIDs and serves as essential tools for research studies and clinical practice⁽¹⁰⁾. However, the questionnaires have not been translated into the Thai language. The authors therefore, conducted the present study to validate the Thai version of ROME III diagnostic questionnaire. The Thai version of ROME III diagnostic questionnaire available to access from www.Theromefoundation.org contact to Rome Foundation Translation project: Ami D. Sperber. MD. MSPH.

Statistical analysis: mean, Mann-Whitney U test, alpha-coefficient, index of item-objective congruence.

Material and Method

Questionnaire translation process and validity test

Permission to translate into Thai and use the ROME III questionnaire was sought and granted by the ROME foundation. Forward translation of the original ROME III questionnaire into Thai were produced by two Thai pediatric gastroenterologists (TN and PY) independently and was finalized by another pediatric gastroenterologists (ST). The final Thai version was then back-translated into English by a professional translator who was a native English speaker and fluent in Thai. Item to item comparison between the original English and the backward translation versions was independently performed by the two experts in English. The validity was assessed by the index of item-objective congruence. Finally, a meeting with these experts was convened to arrive at a consensus for the final Thai version of the questionnaire.

Reliability testing

This present work was approved by the institutional ethics committee of Naresuan University. After informed consents by children and/or parents, the Thai questionnaire was tested in 50 children aged four to 15 years, at Rojanawit School and Chalermkwansatree School, Phitsanulok province who had no serious illness. The questionnaire was answered by parents for children aged four to 10 years old, and self-answered by children aged over 10 years. The answers of the Thai questionnaire were analyzed using Cronbach's alpha coefficient.

Results

The ROME III questionnaire is composed of four parts: Part A seeks information about pain and uncomfortable feelings above the umbilicus. Part B is for pain and uncomfortable feelings around and below the umbilicus. Part C is about bowel movements. Finally, part D is about other symptoms. Item to item comparison and the validity analysis assessed by index of item-objective congruence was 0.94.

For a reliability test, the questionnaires were answered by the parents of 23 children and 27 children answered the questionnaires by themselves. The mean age of children for parent reporting was 6.76 ± 2.13 years and for children self-reporting, it was 14.9 ± 1.1 years. All children stayed with the parent who answered the questionnaires. The alpha of reliability for parts A, B, C, and D was 0.99, 0.99, 0.84, and 0.74, respectively. The overall Cronbach's alpha for the total of 71 questionnaire items was 0.97. Moreover, the alpha of reliability of self-report and parent-report groups was 0.96, 0.97 accordingly.

Discussion

The ROME III questionnaire serves as a tool for the diagnosis of FGIDs in children by using symptom-based parameters. It was designed as a research instrument to classify gastrointestinal and other symptoms into diagnostic groups defined by the Pediatric ROME III criteria. The ROME III questionnaire has been translated into 11 languages, including Thai, and it has been widely used for research studies for FGIDs in many countries. For example, the studies for abdominal pain related FGIDs in Italy⁽²⁾ and Norway⁽¹¹⁾. In the Netherlands⁽¹²⁾, the questionnaire was used for a study of functional constipation in obese children. Translation is a commonly used method for preparing instruments for cross-cultural research. Cross-cultural research has specific methodological problems, most relating to translation quality and the comparability of results in different cultural and ethnic groups^(13,14). The challenge is to adapt it in a culturally relevant and comprehensible form while maintaining the meaning and intent of the original items. Therefore, the translation process must be appropriated and the validation process must be carefully performed. Our translation process followed the Rome Foundation recommendation, as described by Sperber et al^(14,15).

The present study has shown that the Thai ROME III questionnaire has a high validity with the IOC of 0.94. Moreover, the content reliability was proved for both parent-report and self-report versions.

Although the questionnaire was valid and reliable, the small amount of samples from two different schools may result lacking of data variety. Other factors that could affect a validity and reliability of the questionnaire are using wording and translation that are interpreted differently depending on region and culture of the population.

Furthermore, the Thai ROME III diagnostic questionnaire has been approved by the ROME Foundation and is available at www.romecriteria.org/translations/transrequest.cfm by submitting an online request form.

In conclusion, the Thai ROME III diagnostic questionnaire for the diagnosis of FGIDs in children has been successfully validated, has proven to be reliable, and can thus be used as a routine tool in pediatric research and assessments.

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Potential conflicts of interest

None.

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ประเมินความน่าเชื่อถือและความเที่ยงตรงของแบบสอบถาม ROME III ฉบับภาษาไทย

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ภูมิหลัง: แบบสอบถาม ROME III เป็นแบบสอบถามที่นำมาใช้ในการประเมินอาการผิดปกติของระบบทางเดินอาหารที่ไม่มีโรคทางกายที่เป็นสาเหตุ (functional gastrointestinal disorders, FGIDs) ในเด็ก และถือได้ว่าเป็นเครื่องมือที่สำคัญในการศึกษา อย่างไรก็ตามปัจจุบันยังไม่มีแบบสอบถาม ROME III ฉบับภาษาไทย

วัตถุประสงค์: เพื่อประเมินความน่าเชื่อถือและความเที่ยงตรงของแบบสอบถาม ROME III ฉบับภาษาไทย

วัสดุและวิธีการ: ดัชนีฉบับภาษาอังกฤษของแบบสอบถาม ROME III ซึ่งประกอบไปด้วย 4 ส่วนหลัก (A, B, C และ D), 71 คำถามได้นำมาแปลเป็นฉบับภาษาไทยโดยรับอนุญาตจาก ROME foundation จากนั้นจึงมีการแปลกลับจากฉบับภาษาไทยเป็นภาษาอังกฤษโดยผู้เชี่ยวชาญสองภาษา นำแบบสอบถามภาษาอังกฤษต้นฉบับ และแบบสอบถามฉบับแปลกลับมาเปรียบเทียบกัน และหาค่าความเที่ยงตรงด้วยวิธีทางสถิติคือ Index of Item-Objective Congruence (IOC) ต่อจากนั้น แบบสอบถาม ROME III ภาษาไทยฉบับสมบูรณ์ได้ถูกนำไปทดสอบกับเด็กนักเรียนทั้งหมด 50 คน อายุในช่วง 4-15 ปี และไม่มีโรคประจำตัวที่รุนแรง ประเมินค่าความน่าเชื่อถือด้วย Cronbach's alpha coefficient

ผลการศึกษา: ความเที่ยงตรงของแบบสอบถามฉบับภาษาไทยและฉบับแปลกลับเป็นภาษาอังกฤษโดย IOC เท่ากับ 0.94 ซึ่งถือได้ว่าเป็นความเที่ยงตรงมาก ค่า Cronbach's alpha coefficient ของแบบสอบถามทั้งหมดเท่ากับ 0.98 แสดงให้เห็นว่าแบบสอบถามนี้มีมีความน่าเชื่อถือมาก ค่า Cronbach's alpha coefficient ของแบบสอบถามที่เด็กตอบด้วยตนเองและที่ตอบโดยผู้ปกครองเท่ากับ 0.96 และ 0.97 ตามลำดับ

สรุป: แบบสอบถาม ROME III ฉบับภาษาไทยมีความเที่ยงตรงและความน่าเชื่อถือสำหรับใช้วินิจฉัย FGIDs ในเด็กไทย
