Construct Validity of the Pediatric Rome III Criteria

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ABSTRACT

Objectives: Functional gastrointestinal disorders (FGIDs) are common. The diagnosis of FGIDs is based on the Rome criteria, a symptom-based diagnostic classification established by expert consensus. There is little evidence of validity for the pediatric Rome III criteria. The construct validity of the criteria, an overarching term that incorporates other forms of validity, has never been assessed. We assessed the construct validity of the Rome III criteria.

Methods: Children from 2 schools in Colombia completed the Questionnaire on Pediatric Gastrointestinal Symptoms at baseline and weekly questionnaires of somatic symptoms and disability for 8 weeks (presence and intensity of gastrointestinal symptoms, nongastrointestinal symptoms, impact on daily activities). A total of 255 children completed at least 6 weekly surveys (2041 surveys).

Results: At baseline, 27.8% children were diagnosed as having an FGID. Prevalence of nausea (Δ 7.8%, 95% confidence interval [CI] 4.46–11.14), constipation (Δ 4.39%, 95% CI 1.79–6.99), diarrhea (Δ 6.69%, 95% CI 3.25–10.13), headache (Δ 7.4%, 95% CI 3.51–11.09), chest pain (Δ 9.04%, 95% CI 5.20–12.88), and limb pain (Δ 4.07%, 95% CI 1.76–6.37) and intensity of nausea (Δ 0.23, 95% CI 0.127–0.333), diarrhea (Δ 0.30, 95% CI 0.211–0.389), abdominal pain (Δ 0.18, 95% CI 0.069–0.291), headache (Δ 0.17, 95% CI 0.091–0.249), and limb pain (Δ 0.30, 95% CI 0.084–0.516) were higher in children with FGIDs ($P < 0.001$). Children with FGIDs had greater interference with daily activities ($P < 0.001$).

Conclusions: Children with a Rome III diagnosis had significantly more gastrointestinal and nongastrointestinal complaints, and greater intensity of symptoms and disability than children without an FGID diagnosis. The study suggests that the Rome III pediatric criteria have adequate construct validity.

Key Words: abdominal pain, functional gastrointestinal disorder, Questionnaire on Pediatric Gastrointestinal Symptoms, Rome III criteria

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Chronic abdominal pain (CAP) is a common complaint in children. A total of 38% of American schoolchildren report abdominal pain each week. One in 4 schoolchildren has persistent abdominal pain lasting >6 weeks (1). The vast majority of children with CAP have a functional gastrointestinal disorder (FGID) (2). There are no biological markers to diagnose FGIDs. The diagnosis of FGIDs is based on the Rome criteria, a symptom-based diagnostic classification established by expert consensus (3,4). The Rome criteria are widely used in clinical practice and research. Despite the widespread use of the Rome criteria, only a few studies have assessed their validity. Studies from Norway and Sri Lanka showed that 70% to 80% of children with CAP and almost 90% of children with an FGID meet the criteria for a specific Rome III diagnosis (5,6). Together, these studies show that the Rome criteria allow characterizing most children with CAP as an FGID and most of the children with an FGID can be given a specific diagnosis. Although important, these studies do not provide evidence of the validity of the criteria. To prove validity, a diagnostic tool has to be reliable and prove to adequately perform in the various categories that establish validity such as construct validity. Construct validity ensures that the tool measures what it is supposed to measure by correlating different variables purported to measure the same concept. Two studies assessed the reliability of the Rome pediatric criteria. One of the studies found fair interrater agreement of diagnosis by pediatric gastroenterologists using the Rome III criteria (7), whereas the other study found poor agreement between the physician clinical diagnosis and the Rome III diagnosis (8). No studies have focused on assessing the construct validity of the Rome criteria. We have conducted the first large prospective pediatric study on the validation of the Rome criteria in schoolchildren. We hypothesized that the Rome III criteria have adequate construct validity. The demonstration of adequate validity of the Rome III pediatric criteria would provide relevance to the criteria and support their use for the diagnosis of FGIDs in children.

METHODS

Conceptual Framework

For the purpose of the present study, we conceptualize that for the Rome III criteria to be valid and relevant, they should be able to differentiate children with dissimilar frequency of symptoms in the 8 weeks following their Rome III criteria–based diagnosis. If the criteria do not measure what they purport to measure, children with and without an FGID diagnosis should have similar gastrointestinal (GI) symptoms. In addition, if children with or without an FGID diagnosis have similar severity of GI symptoms and functional disability in the weeks following the diagnosis, having a Rome criteria diagnosis could be considered irrelevant regardless of their ability to classify children with a specific FGID. Based on these premises, we designed a study aimed at comparing somatic symptoms (GI and non-GI) and functional disability in a mixed cohort of community children with and without FGIDs as per Rome III criteria diagnosis.

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Methods

The present study is the second in a series of investigations conducted by the Functional International Digestive Epidemiological Research Survey group, an international group established to conduct epidemiologic gastroenterological studies in children from Latin America. The first study from our group (9) selected a representative cohort of Colombian schoolchildren of mixed background to assess the prevalence of FGIDs in children. The present study is a nested one conducted in a subgroup of children from the previous study known not to have organic diseases. Families of fourth- and fifth-grade schoolchildren from 2 schools in Pasto (Colombia) were invited to participate in a study that included baseline assessment of the child's health and prospective collection of data. Consenting families provided demographic information (race, marital status, size of household), GI family history, and the child's medical history. The study was approved by local institutional review board and the authorities of each school.

Baseline Data

Children were instructed on the study in a 60-minute PowerPoint presentation conducted in the schools by a member of the research team. Assenting children completed the Spanish version of the Questionnaire on Pediatric Gastrointestinal Symptoms (QPGS) (10,11), an age-appropriate questionnaire to diagnose FGIDs according to the Rome III criteria. Comprehension of the terms in the QPGS by Colombian schoolchildren was ensured before the initiation of the study through 2 focus groups conducted in a large city (Cali) and the city where the study was to be conducted (Pasto). Adequate translation (including reverse translation) and fidelity of the Spanish version of the QPGS-Rome III was established by our local research group according to standard methods (12).

Follow-Up Data

Children completed confidential weekly questionnaires of somatic symptoms and disability for 8 weeks every Friday in their biology class. Surveys consisted of selected questions from the Children's Somatization Inventory (13), a validated and age-appropriate questionnaire. Presence and severity of GI symptoms (abdominal pain, nausea, vomiting, constipation, and diarrhea), comorbid non-GI symptoms (headaches, limb and chest pain), and impact on daily activities were assessed. Symptom severity was graded by a 5-point scale (0 = ''not at all,'' 1 = ''a little,'' 2 = ''some,'' 3 = ''a lot,'' 4 = ''a whole lot'').

External Validity

To ensure external validity of data, the study was conducted in a midsize city of Colombia with a demographic makeup that fairly represents the general population of the country. A private and a public school were selected to ensure socioeconomic diversity.

Statistical Analysis

Mean and standard deviation were calculated for demographics (age, race, marital status, size of household) and symptom status (abdominal pain, nausea, vomiting, constipation, diarrhea, headaches, limb pain, chest pain, and impact on daily activities). Follow-up data from children with a baseline diagnosis of FGIDs according to the Rome criteria were compared with data from children without a baseline diagnosis of FGIDs using the Student *t* test. Data from children with a baseline diagnosis of FGIDs were also analyzed by length of abdominal pain at follow-up (up to 4 weeks and >4 weeks) using the nonparametric Mann-Whitney *U* test. *P* values were 2-sided, and the statistical significance level was defined as $P < 0.05$.

RESULTS

A total of 351 families from a private and a public school in Pasto were invited to participate in the study. A total of 328 (287 from a public school, 41 from a private school; 93.4%) families consented to participate in the study. A total of 63 children (55 from a public school, 8 from a private school) did not participate (no assent 23, teacher refused to participate 39, changed school 1). A total of 255 of 265 eligible children (96.2%) completed at least 6 weekly surveys (232 from a public school and 33 from a private school) (*http://links.lww.com/MPG/A351*). The data of the 10 children (3.8%) who did not complete at least 6 weeks of surveys were not considered for the study (3 FGID and 7 no FGID). A total of 2041 weekly surveys were analyzed. Children in the study were multiracial (160, 60.4%), Hispanic white (94, 35.5%), and Hispanic black (11, 4.1%); had a mean age 9.6 ± 0.7 years (range 8–12); and 152 were girls (57.4%) (Table 1). There was no significant difference in age or sex between included and excluded children.

Baseline Data

At baseline, 71 of 255 (27.8%) children were diagnosed as having an FGID according to the Rome III criteria. Of them, 38 (14.9%) had functional constipation, 13 (5.1%) irritable bowel syndrome, 6 (2.4%) functional abdominal pain syndrome, 6 (2.4%) functional dyspepsia, 4 (1.6%) abdominal migraine, and 3 (1.2%) nonretentive fecal incontinence.

Follow-Up Data

GI Symptoms

Children who had a baseline diagnosis of FGIDs reported a weekly average prevalence of nausea $28.80\% \pm 12.59\%$, constipation $25.00\% \pm 8.41\%$, diarrhea $28.77\% \pm 13.22\%$, abdominal pain $21.80\% \pm 10.89\%$, and vomiting $15.31\% \pm 8.49\%$ (Table 2). Children diagnosed as having FGID had a weekly average intensity of nausea 1.79 ± 0.25, constipation 1.90 ± 0.27, diarrhea 1.90 ± 0.27, abdominal pain 1.91 ± 0.27, and vomiting 1.82 ± 0.53 on the 5-point Likert scale (Table 3).

Non-GI Symptoms

Children who had a baseline Rome III criteria diagnosis of FGIDs reported a weekly average prevalence of headaches $36.26\% \pm 14.25\%$, chest pain $33.61\% \pm 15.62\%$, and limb pain $18.83\% \pm 10.32\%$ (Table 2), and an average intensity of headaches 1.85 ± 0.16, chest pain 1.64 ± 0.22, and limb pain 1.87 ± 0.22 on the 5-point Likert scale (Table 3).

Disability

Children who had a baseline Rome III criteria diagnosis of FGIDs reported that their symptoms frequently interfered with common daily activities. There was a weekly average of interference with school ($20.05\% \pm 5.65\%$), play ($25.90\% \pm 10.27\%$), sleep ($7.46\% \pm 5.69\%$), and sports ($12.23\% \pm 5.65\%$) (Table 4).

FGIDs Versus Non-FGIDs

Children with a Rome III diagnosis had significantly more complaints than children without an FGID diagnosis. The prevalence

TABLE 1. Demographics

	Total, n = 265	FGID, n = 74	No FGID, n = 191	P
Age, y ± SD	9.6 ± 0.7	9.9 ± 0.7	9.5 ± 0.7	
Range	8–12	8–12	8–11	
Sex, n (%)				
Female	152 (57.4)	39 (52.7)	113 (59.2)	0.34
Male	113 (42.6)	35 (47.3)	78 (40.8)	
Race, n (%)				
Multiracial	160 (60.4)	48 (64.9)	112 (58.6)	0.35
Hispanic white	94 (35.5)	24 (32.4)	70 (36.7)	
Hispanic black	11 (4.1)	2 (2.7)	9 (4.7)	
School type, n (%)				
Public	232 (87.6)	64 (86.5)	168 (88.0)	0.74
Private	33 (12.4)	10 (13.5)	23 (12.0)	
Family structure, n (%)				
Nuclear family	201 (75.9)	60 (81.1)	141 (73.8)	0.22
Single-parent household	64 (24.1)	14 (18.9)	50 (26.2)	
Only child, n (%)				
No	183 (69.1)	54 (73.0)	129 (67.5)	0.39
Yes	82 (30.9)	20 (27.0)	62 (32.5)	
Family history of FGIDs, n (%)				
No	192 (72.4)	47 (63.5)	145 (75.9)	0.04
Yes	73 (27.6)	27 (36.5)	46 (24.1)	

CI = confidence interval; FGID = functional gastrointestinal disorder; OR = odds ratio; SD = standard deviation.

of nausea (Δ 7.8%, 95% confidence interval [CI] 4.46–11.14), constipation (Δ 4.39%, 95% CI 1.79–6.99), diarrhea (Δ 6.69%, 95% CI 3.25–10.13), headache (Δ 7.4%, 95% CI 3.51–11.09), chest pain (Δ 9.04%, 95% CI 5.20–12.88), and limb pain (Δ 4.07%, 95% CI 1.76–6.37) was significantly higher ($P < 0.001$) in children with a Rome III diagnosis at baseline. Complaints of abdominal pain showed a trend toward a higher prevalence in the FGID group ($P = 0.065$). There was no difference in complaints of vomiting between both groups ($P = 0.99$) (Table 2).

Children with a Rome III diagnosis had significantly higher intensity of somatic complaints than children without an FGID diagnosis. The intensity of nausea (Δ 0.23, 95% CI 0.127–0.333), diarrhea (Δ 0.30, 95% CI 0.211–0.389), abdominal pain (Δ 0.18, 95% CI 0.069–0.291), headache (Δ 0.17, 95% CI 0.091–0.249), and limb pain (Δ 0.30, 95% CI 0.084–0.516) was significantly higher ($P < 0.001$) in the FGID group than in children without an FGID at baseline. The intensity of constipation, vomiting, and chest pain was not significantly different (Table 3). Children with FGID had significantly greater interference with daily activities than children who did not have a baseline diagnosis of FGIDs ($P < 0.001$) (Table 4).

Length of Abdominal Pain

Only 15 of 265 (5.7%) children reported abdominal pain for >4 weeks; 7 of them had FGID at baseline (9.9% of all children with FGIDs vs 4.4% of all children without FGIDs; $P = 0.08$). A subanalysis of abdominal pain intensity and disabilities in the subgroup of children who had baseline FGIDs and reported persistent abdominal pain for a period greater or shorter than 4 weeks revealed significantly higher intensity of abdominal pain and disabilities in those who reported pain for >4 weeks. Children who had abdominal pain for >4 weeks had greater abdominal pain intensity than children who reported pain for <4 weeks (2.15 ± 0.81 vs 1.62 ± 0.90; $P = 0.001$). Degree of interference with daily activities was significantly higher for school (3.40 ± 2.69 vs 1.20 ± 1.65; $P = 0.0495$) and gym class (2.71 ± 2.84 vs 0.70 ± 1.20; $P = 0.0001$) in children who had >4 weeks of abdominal pain compared with that in children with <4 weeks of abdominal pain.

TABLE 2. Prevalence of gastrointestinal symptoms in children with and without a baseline diagnosis of functional gastrointestinal disorders

	Total, n = 255	FGID, n = 71	No FGID, n = 184	P, 95% CI (Δ%)
Gastrointestinal symptoms				
Nausea	23.18 ± 11.89	28.80 ± 12.59	21.00 ± 11.94	<0.001 (4.46–11.14)
Constipation	21.85 ± 9.44	25.00 ± 8.41	20.61 ± 9.84	<0.001 (1.79–6.99)
Diarrhea	23.95 ± 12.19	28.77 ± 13.22	22.08 ± 12.23	<0.001 (3.25–10.13)
Abdominal pain	19.91 ± 9.80	21.80 ± 10.89	19.17 ± 9.86	0.065 (−0.16 to 5.42)
Vomiting	15.30 ± 8.22	15.31 ± 8.49	15.30 ± 8.87	0.99 (−2.40 to 2.42)
Extraintestinal symptoms				
Headache	31.00 ± 13.63	36.26 ± 14.25	28.96 ± 13.59	<0.001 (3.51–11.09)
Chest pain	27.10 ± 13.73	33.61 ± 15.62	24.57 ± 13.26	<0.001 (5.20–12.88)
Limb pain	15.91 ± 8.03	18.83 ± 10.32	14.77 ± 7.50	<0.001 (1.76–6.37)

Values expressed as X ± standard deviation, %. CI = confidence interval; FGID = functional gastrointestinal disorder.

TABLE 3. Intensity of symptoms in children with and without a baseline diagnosis of functional gastrointestinal disorders

	Total, n = 255	FGID, n = 71	No FGID, n = 184	*P*, 95% CI (ΔX)
Gastrointestinal symptoms				
Nausea	1.65 ± 0.19	1.79 ± 0.25	1.56 ± 0.15	<0.001 (0.127–0.333)
Constipation	1.72 ± 0.11	1.90 ± 0.27	1.63 ± 0.80	0.171 (−0.1212 to 0.661)
Diarrhea	1.68 ± 0.14	1.87 ± 0.22	1.57 ± 0.13	<0.001 (0.211–0.389)
Abdominal pain	1.78 ± 0.16	1.91 ± 0.27	1.73 ± 0.13	0.002 (0.069–0.291)
Vomiting	1.70 ± 0.23	1.82 ± 0.53	1.65 ± 0.21	0.155 (−0.057 to 0.397)
Extraintestinal symptoms				
Headache	1.74 ± 0.16	1.85 ± 0.16	1.68 ± 0.17	<0.001 (0.091–0.249)
Chest pain	1.63 ± 0.16	1.64 ± 0.22	1.63 ± 0.10	0.79 (−0.066 to 0.086)
Limb pain	1.68 ± 0.14	1.87 ± 0.22	1.57 ± 0.13	<0.001 (0.084–0.516)

Values expressed as X ± standard deviation. CI = confidence interval; FGID = functional gastrointestinal disorder.

DISCUSSION

Previous studies have shown that the questions of the QPGS have adequate content validity (fairly represent what they are supposed to measure) (2,10,11). Based on the results of these studies that provided certainty of the adequacy of the diagnostic tool recommended by the Rome committee to establish diagnosis, we embarked on the ambitious project of further validating the Rome III criteria. Our study demonstrated for the first time that the Rome III criteria have adequate construct validity, an overarching term that incorporates other forms of validity.

Schoolchildren who were diagnosed as having FGIDs at baseline had significantly higher prevalence and intensity of most symptoms in 8 weeks of follow-up than children without FGIDs at baseline. Children who met criteria for FGID had a significantly higher prevalence of nausea, constipation, diarrhea, headache, chest pain, and limb pain. There was also a significantly higher intensity of nausea, diarrhea, abdominal pain, headaches, and limb pain among children with FGIDs. Thus, children with FGIDs had significantly greater prevalence, significantly greater intensity, or both for each of the symptoms than children without FGIDs. Regardless of the statistical significance of the data, children without FGID had lower prevalence and intensity in all of the somatic symptoms than children who had a diagnosis of an FGID. Moreover, there was greater interference with sleep, play, social interaction, and school in children who were diagnosed as having a FGID at entry. These findings demonstrate that the relevance of establishing a Rome criteria diagnosis exceeds the time of initial diagnosis and has prognostic implications.

Previous school studies by our group have shown that abdominal pain is greatly prevalent among schoolchildren (1). The results of the present study confirm our previous findings. We found a high prevalence and severity of abdominal pain and other somatic complaints in children in both groups, in those meeting criteria for an FGID and those who did not meet Rome criteria. Children not meeting criteria for FGID had an average of abdominal pain of almost 20% during the 8 weeks of follow-up, which was not significantly different from the average prevalence found in children who had FGIDs. Despite the high frequency of abdominal pain in both groups, children with abdominal pain who were diagnosed as having an FGID had greater severity of symptoms (intensity and disability) than children who had abdominal pain but did not have an FGID. This suggests that in the presence of common pediatric symptoms, completing a brief survey (QPGS) and applying the Rome criteria may help identify children with a more worrisome prognosis who may benefit from further intervention. In view of the high number of children with somatic complaints and the scarcity of resources to care for these children, the Rome criteria may constitute a valuable triage tool for pediatricians and gastroenterologists. Children with an FGID diagnosis without red flags to suggest an organic disease can be educated, reassured, and treated knowing that under these circumstances testing is of limited value (14). Increased awareness of the QPGS and the paucity of data to justify routine testing in all children with FGID may result in a more rational approach to health care. Education of school nurses in the application of the QPGS may help institute early secondary preventive programs focused at children at high disability risk. Headache is the most common somatic complaint in schoolchildren (1). Children with FGIDs had more prevalent and severe headache. It is likely that a subset of these children seek consultation for headache to a non-gastroenterology specialist who is unlikely to use the Rome diagnostic criteria. Increasing the use of the QPGS by other specialists could provide a unique opportunity for comprehensive education and referral to a gastroenterology specialist in cases of severe symptoms.

Despite the clear merits of the Rome III criteria demonstrated by the present study, the analysis of the data also calls for a thorough review of some of their criteria. The Rome III criteria require weekly presence of pain for 8 weeks to establish a diagnosis of an abdominal pain–associated FGID. Only 1 child in the study reported abdominal pain in all weeks of the study. This would suggest that all children who were initially diagnosed as having an FGID resolved their FGID, an unlikely scenario in view of the persistent disability found in children who were initially diagnosed

TABLE 4. Interference with daily activities

	Total, n = 255	FGID, n = 71	No FGID, n = 184	*P*, 95% CI (Δ%)
Play	19.90 ± 5.60	25.90 ± 10.27	17.53 ± 4.18	<0.001 (6.59–10.15)
School	14.50 ± 3.23	20.05 ± 5.65	12.36 ± 3.43	<0.001 (6.54–8.84)
Sports and activities	7.76 ± 3.43	12.23 ± 5.65	6.01 ± 2.92	<0.001 (5.15–7.29)
Sleeping	3.85 ± 3.79	7.46 ± 5.69	2.45 ± 3.35	<0.001 (3.87–6.15)

Values expressed as X ± standard deviation, %. CI = confidence interval; FGID = functional gastrointestinal disorder.

as having FGIDs. An alternative explanation is that children who reported having abdominal pain every single week for the previous 8 weeks at time of initial completion of the QPGS may have not had symptoms every week, but had pain in most of the weeks. We have previously shown that children recall of abdominal pain is not greatly accurate (15). Children likely respond that they had pain every week for the past 2 months even if the pain was not present in some of the weeks. Whether the new edition of the Rome criteria should continue to require the presence of symptoms in every week or most of the weeks is a matter of debate. We have found that only a few children had abdominal pain for >4 weeks and that those children with >4 weeks of abdominal pain at follow-up had more intense abdominal pain and disability than children who had <4 weeks of abdominal pain. Although the results of the present study do not suffice to suggest a change in criteria from 8 to 4 weeks of symptoms to establish an FGID diagnosis, our data provide valuable information to consider the flexibilization of such a strict criterion.

Some of the strengths of our study include the prospective design, low attrition rate, use of standardized and validated questionnaires, and assurance of comprehension of the questionnaires by the children. The school-based setting of our studies enhances external validity and minimizes selection bias of patients. Variations in prevalence of symptoms throughout the different weeks of the study suggest careful completion of data by children because random completion would likely result in similar prevalence of symptoms throughout the study. Limitations of the study included lack of information on environmental and psychosocial factors that could explain the variation in prevalence of symptoms found in the present study. The design of our study does not allow us to definitively rule out the presence of an organic GI disorder in some of our patients. Although parents completed questionnaires on their child's symptoms and medical history, we cannot ensure that the information provided by the parents was accurate because patients' charts were not reviewed. The size of our sample does not allow obtaining conclusive information on the exact duration of symptoms that is most likely associated with greater intensity and disability. Although this was a diverse and carefully selected population that represents the socioeconomic and demographic spectrum of Colombian children, we cannot ensure that the results of the present study can be extrapolated to all children in Colombia.

CONCLUSIONS

We found that children with a diagnosis of FGIDs at baseline have higher prevalence, intensity, and disability at follow-up than children who were not diagnosed as having FGIDs according to the Rome III criteria. The study suggests that the Rome III pediatric criteria have adequate construct validity. Future studies should further validate the criteria and establish the length of persisting abdominal pain that is more likely associated with more severe symptoms.

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