


# The Effect of Using Rome IV Criteria on the Prevalence of Functional Abdominal Pain Disorders and Functional Constipation among Children of the Western Region of Saudi Arabia

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## Abstract

Functional gastrointestinal disorders are characterized by absence of anatomical and biochemical alterations, and are diagnosed and classified based on symptomatology. We aim to explore the prevalence of functional abdominal pain disorders and Functional constipation using Rome IV criteria. An online questionnaire was distributed randomly via social media targeting the general population of the western region of Saudi Arabia. Parents who have at least 1 child in the age group 3 to 18 years were included. Children with mental disabilities, or any organic gastrointestinal disorder were excluded. Five hundred thirty-two responded and 215 were excluded. The overall prevalence of functional abdominal pain disorders was 3.1%. The prevalence of functional constipation was 4.7%. *Conclusions:* Rome IV criteria seems to give a lower functional abdominal pain prevalence than Rome III, online learning did not seem to affect the prevalence of both disorders, but a family stressor seems to increase functional constipation prevalence.

## Keywords

functional gastrointestinal disorders, COVID-19, Saudi Arabia, Irritable Bowel Syndrome, Pediatric

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## Introduction

Functional gastrointestinal disorders (FGIDs) are a group of disorders that are characterized by the lack of an appreciable alteration from the normal histological, anatomical, and biochemical parameters, and hence are diagnosed and classified based on symptomatology.<sup>1</sup>

The pathophysiology of those disorders is not fully understood.<sup>2</sup> Many theories revolve around the dysfunction of the Brain-gut access, in genetically susceptible individuals along with an early life stressor, leading to a state of autonomic nervous system imbalance (the poly-vagal theory).<sup>3</sup>

Several diagnostic criteria have been proposed by different expert groups, the oldest of which were Apley's, back in 1958.<sup>4-6</sup> More recently the Rome foundation formed by a group of experts proposed symptom-based guidelines and diagnostic criteria that would become the gold-standard in this field.<sup>5,6</sup> With the increasing number of FGIDs studies done over the past

decade; they have updated their criteria (Rome IV) focusing on the most recent available evidence, rather than an expert consensus (as was the case with older Rome versions).<sup>5,6</sup>

The prevalence of FGIDs overall ranges from 9.9% to 29%.<sup>7</sup> The prevalence of adult irritable bowel syndrome (IBS) and functional dyspepsia (FD) in our region are 30.5% and 18%, respectively.<sup>8,9</sup> Most data from our region used Rome III criteria or Apley's for RAP and IBS with a few exceptions.<sup>8-10</sup>

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The economic and social burden of FGIDs cannot be overstated. The estimated direct annual cost of care for FC and IBS in a US study ranged from 1000 to 7000 dollars, with a lower reported quality of life.<sup>11,12</sup> It is estimated that 23% of school-age children with a FGID miss 2-10 days annually in the US and UK.<sup>13,14</sup> A large population based survey from our region showed that chronic abdominal pain in adults was the second most common location of chronic pain in a primary care setting.<sup>15</sup> Another study estimated that 50% of referrals to gastroenterology service are due to a FGID.<sup>1</sup>

This burden is further complicated by the knowledge gap within the primary care setting. An ambulatory practitioner survey in our region showed that only 61% of practitioners were aware of functional constipation definition based on Rome criteria.<sup>16</sup>

Given the disease burden along with this knowledge gap and scarcity of large population-based data on pediatric FGIDs, and more specifically functional abdominal pain disorders (FAPDs) and functional constipation (FC), we aimed to study the prevalence of those 2 groups of disorders in our region. Furthermore, since none of the pediatric studies of FAPDs or FC used Rome IV criteria, we aimed to assess the effect of using those on disease prevalence in comparison to other studies that used older criteria. We also aim to assess the socioeconomic impact as well as COVID-19 impact (distant learning, lockdown, and COVID-19 related death in the family) on the prevalence of FAPDs and FC.

## Methods

This is a cross-sectional online survey-based study targeting the general population of the western region of Saudi Arabia. Questionnaires were designed by google forms and links were shared randomly on social media apps, mainly (WhatsApp<sup>®</sup>). According to global media insights; 26.25 million (71%) of the Saudi population use that app, the most common messaging/social media app used in this region.

**Questionnaire design:** The Questionnaire (sample attached in Supplemental Material) was carefully designed so the answer pathways would lead to fulfillment of Rome IV criteria of 1 or more of the functional abdominal pain disorders as well as functional constipation.<sup>5</sup> Using Google Forms features such as “required to proceed” to make sure no criteria would be left unanswered, yes/no questions for present/absent criteria were designed, and duration questions were used where duration criteria must be fulfilled with the appropriate cutoff points. Subjects that do go through criteria for a FAPD or FC would still continue to go through questions for the other disorders in the questionnaire. Since IBS-C and FC criteria overlap but they are mutually exclusive,

participants that meet both criteria were manually screened for the question that asks whether “pain improves with defecation.” When answered yes, that participant was considered to have FC ONLY, and IBS-C ONLY when the answer was no. Other than this exception, participants can fulfill criteria for more than 1 disorder.

**Inclusions:** This is a public survey. All participants from our region that have at least 1 child between the ages 3 and 18 who have clicked the survey link were included.

**Exclusions:** any child known to have a chronic organic gastrointestinal disorder. Any child with special needs. Any child who’s on daily medications or have a chronic medical condition like Diabetes. In addition, participants who answered yes to chronic abdominal pain question and had 2 or more gastrointestinal (GI) symptoms indicative of a possible organic etiology were also excluded. Those symptoms include weight loss, blood in stools, joint pains or swellings, mouth ulcers, visual symptoms (uveitis), and family history of a GI disorder.

**Data collection:** Information on parental age, marital status, income, occupation, living status, location, child’s age, gender, history of COVID-19 and COVID-19 related death in the family, and perception of distant learning on symptoms were collected in the questionnaire from each participant. In addition; participants were asked whether their child: was ever diagnosed with any medical condition, is on chronic daily medications, is a special needs child, or have symptoms of organic GI disorders.

**Sample size determination:** OpenEpi<sup>®</sup> ver3.0 software was used to estimate our sample size that is representative of our region population of 8.5 million. For confidence level of 99%, and an expected prevalence of 10%; the sample size required is 239. We aimed to obtain at least 500 participants to overcome potential exclusions.

## Statistical Analysis

After proper translation and coding, data obtained was entered into the statistical package for social science software (SPSS<sup>®</sup>) for analysis. Case identification per Rome IV criteria was done using complex operators and logical expressions in the case selection command. The frequency of cases identified for each category and subcategory were expressed in numbers (n) and percentages (%) of the total sample. Then  $\chi^2$  (Fisher’s exact) test was used to measure any association between cases and different categorical variables (marital status, occupation, income, educational level, history of COVID-19 diagnosis, or death in the family), and Spearman’s correlation for continuous variables. A multinomial logistic regression model was used to assess the effect of all

**Table 1.** Baseline Characteristics Overall, and Baseline Characteristics of Subjects with FAPD and FC.

Variable	Overall N = 317 (%)	FAPD N = 10 (%)	P value	FC N = 15 (%)	P value
Living with both parents	297 (94)	7 (70)	<b>.01</b>	15 (100)	.6
Parent age			.5		.6
>40	134 (42)	3 (30)		5 (33)	
31-40	144 (45)	5 (50)		9 (60)	
20-30	39 (12)	2 (20)		1 (6)	
Married	297 (94)	8 (80)	.07	15 (100)	1
Educational level			1		1
Undergraduate	240 (75)	8 (80)		11 (73)	
Occupation			<b>.05</b>		.7
Field work	88 (28)			4 (26)	
Business	116 (36)	4 (40)		4 (26)	
Student/unemployed	87 (27)	6 (60)		6 (40)	
Healthcare	25 (8)			1 (6)	
Monthly income			.3		1
<5000 SAR*	49 (15)	3 (30)		2 (13)	
5000-10000 SAR	79 (25)	1 (10)		4 (26)	
>10000 SAR	111 (35)	3 (30)		5 (33)	
Unanswered	78 (24)	3 (30)		4 (26)	
Child's age			.8		.8
<5	91 (29)	2 (20)		4 (26)	
5-12	174 (55)	6 (60)		8 (53)	
13-18	52 (16)	2 (20)		3 (20)	
Child's gender			.3		.5
Male	156 (49)	3 (30)		6 (40)	
Learning issues			1		.1
Yes	13 (94)	0		2 (13)	
COVID-19 in family			.7		.3
Yes	87 (27)	2 (20)		2 (13)	
COVID-19 death in family			.2		.07
Yes	10 (3)	1 (10)		2 (13)	
Had home lockdown			1		.1
Yes	301 (95)	10 (100)		13 (87)	

P values shown are for Fisher's exact tests for the respective variables in association with FAPD cases versus non-selected cases, and with FC cases versus non-selected cases.

Bold indicates the result is significant.

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variables combined on cases. P values <.05 were considered significant.

## Results

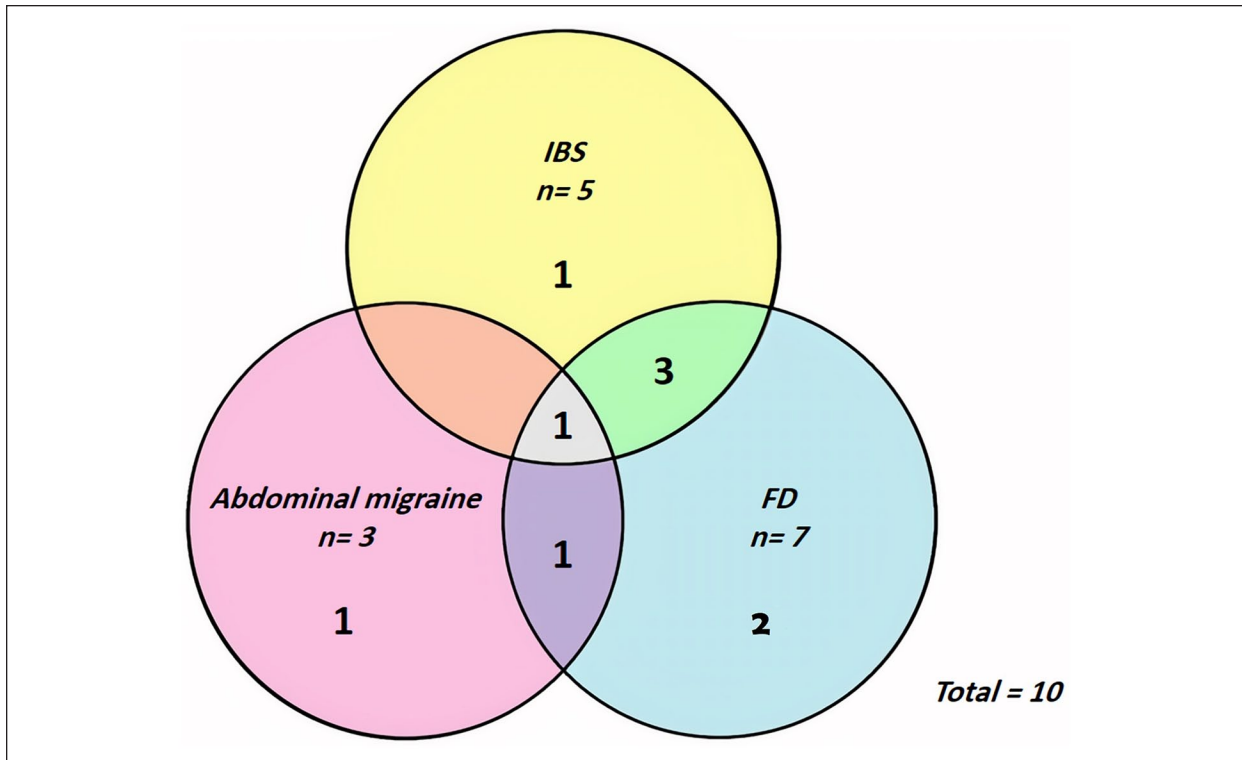
Five hundred thirty-two responded to the questionnaire, and 215 were excluded (review exclusions). The baseline characteristics of the remaining 317 are summarized in Table 1.

### FAPDs

Twenty-three answered yes to chronic abdominal pain (7.3%). Out of whom 5 met criteria for irritable bowel syndrome (IBS), and 3 of those had IBS-C. Four cases

out of the 5 also met criteria for functional dyspepsia (FD), while 1/4 also met criteria of abdominal migraine. Seven cases met criteria for FD (specifically post-prandial distress subtype), 4 out of them also met criteria for IBS, while 1/4 also met criteria for abdominal migraine. Three cases met criteria for abdominal migraine, and 2 of them also met criteria for FD, while 1/2 met criteria for IBS. The breakdown of FAPD subtype is illustrated in Figure 1. No cases met criteria for “functional abdominal pain not otherwise specified” subtype in our study. Collectively, there were 10/317=(**3.1%**) cases that did meet criteria for one or more of the FAPDs. Their baseline characteristics are summarized in Table 1.

Living with both parents was significantly associated with FAPD (P=.019). Similarly parental occupation



**Figure 1.** Diagrammatic summary of the number of cases for each isolated FAPD subtype, along with the overlapping cases. Abbreviations: FD, functional dyspepsia; IBS, irritable bowel syndrome.

was significantly associated with FAPD ( $P=.05$ ). Otherwise, there was no statistical significant association between FAPDs and any of the individual independent variables including: marital status, parental age, parental educational level, parental occupation, monthly income, child's age and gender, and learning issues. Table 1 summarizes Fisher's exact test  $P$  values for each variable.

A binomial logistic regression model combining all independent variables showed no statistical association with the diagnosis of a functional abdominal pain disorder but was very close (final model fitting  $\chi^2=30$ ,  $P=.056$ ). It should be noted however that the likelihood ratio for occupation was statistically significantly associated with FAPD in the model ( $\chi^2=11$ ,  $P=.009$ ). In addition, FAPD cases were less likely to be living with both parents by 97% (odds ratio 0.027,  $P=.03$ ).

Distant learning doesn't seem to affect FAPDs symptoms (symptoms before and after COVID-19 pandemic) based on parental perception (Fisher's exact=1.6,  $P=.6$ ).

## FC

Forty-three (13.5%) answered yes to having chronic constipation. Fifteen cases (4.7%) did meet criteria for functional constipation. There was no statistically significant

association between FC and any of the individual independent variables including: marital status, parental age, parental educational level, parental occupation, monthly income, child's age and gender, and learning issues. Table 1 summarizes Fisher's exact test  $P$  values for each variable.

A binomial logistic regression model combining all independent variables showed no statistical association with the diagnosis of functional constipation ( $\chi^2=18$ ,  $P=.54$ ). It should be noted however that within the logistic regression model, a COVID-19 death in the family was significantly associated with the diagnosis of FC (odds ratio 10,  $P=.02$ ). The likelihood ratio of having a COVID-19 related death in the family with the diagnosis of FC is 4  $P=.03$  in the same model.

Distant learning doesn't seem to affect FC symptoms (symptoms before and after COVID-19 pandemic) based on parental perception (Fisher's exact=1.6,  $P=.5$ ).

In summary: The prevalence of FAPDs was 3.1%, and the prevalence of FC was 4.7%.

## Discussion

The worldwide pooled prevalence of functional abdominal pain disorders from a large meta-analysis is 13.5%.<sup>17</sup> The prevalence varies significantly based on different

regions and ranges from as low as 1.6% to as high as 41.2%.<sup>17</sup> Studies that used Rome III (in comparison to Rome IV) criteria tended to have a relatively higher prevalence.<sup>17,18</sup> Our prevalence although seems somewhat on the lower end relative to other regions might have underestimated the real prevalence. Telmesani previously reported a prevalence of as high as 17% in our region, although his study was mainly focused on middle school and high school kids from 1 school, and both *H-pylori* positive and negative subjects were included.<sup>10</sup> Moreover, he used Appley criteria to define “recurrent abdominal pain” which are less strict than the Rome IV criteria.<sup>4,5,10</sup> An adult study from the central region of Saudi Arabia again showed a much higher prevalence of 30.5%, albeit Rome III criteria were used.<sup>9</sup> The prevalence of functional abdominal pain disorders does seem to be affected by which criteria are used.<sup>8,17,18</sup> As mentioned previously; the prevalence seems to be lower when Rome IV instead of III criteria are used, since Rome IV criteria are stricter.<sup>5,6,17,18</sup> It is well known that using a higher threshold for a diagnostic test (eg, stricter diagnostic criteria) for a given medical condition commonly results in a higher specificity and a lower sensitivity and vice versa.<sup>19</sup> Disease prevalence also affects those interactions.<sup>20</sup> Since they are usually inversely proportional; the optimal diagnostic threshold to balance sensitivity and specificity that is pre-determined by clinicians relies on factors such as how serious a condition’s long term sequelae are (if the diagnosis is missed for example, hence sensitivity would be prioritized over specificity).<sup>19</sup> FGIDs overall and FAPDs are generally benign with no known long-term sequelae besides the increased likelihood of adult FGIDs.<sup>5,21</sup> Furthermore, when a given diagnosis relies heavily on subjective data (as is the case with FGIDs) it tends to have a significant inter-provider variability; thus necessitating a higher specificity and “stricter” diagnostic criteria, in order to ameliorate the diagnostic variability.<sup>5</sup>

FAPDs used to be a diagnosis of exclusion until Rome IV criteria came out.<sup>5</sup> The Rome IV expert committee deliberately removed that designation and instead used “after careful evaluation of other etiologies” in their criteria, in order to reduce unnecessary testing.<sup>5</sup> In pediatric patients with prolonged abdominal pain and absence of “red flags,” the decision to pursue further testing becomes challenging considering the low prevalence of FAPDs in our region. Furthermore, *H-pylori* and celiac disease incidences are 3.2% and 27.4%, respectively; 2 common examples of organic gastrointestinal disorders that do share clinical features of FAPDs.<sup>10,22</sup> In a prospective study, the diagnostic yield of upper endoscopy in pediatric patients with chronic abdominal pain was 38%.<sup>23</sup> In Telmesani’s study; up to

72% of recurrent abdominal pain cases had a positive *H-pylori* test.<sup>10</sup> But again, this was one of the reasons why the expert committee chose much stricter criteria in Rome IV (to avoid over diagnosis of FAPDs).<sup>5</sup>

Functional Constipation pooled prevalence is estimated to be around 9.5% based on a large meta-analysis.<sup>24</sup> Similar to FAPDs, the prevalence seems to have a wide range based on different geographic locations.<sup>24</sup> Our prevalence seems comparable to the lower end of the range studies, even though those studies used Rome III criteria.<sup>24</sup> Unlike the case with FAPDs, Rome IV criteria for FC were largely unchanged from Rome III criteria.<sup>5,6,25</sup> An adult study from the central region showed a prevalence of 4.4% although validated criteria (eg, Rome) were not used.<sup>26</sup> The prevalence of constipation as an isolated symptom could be much higher.<sup>27</sup> The relationship of dietary habits including fiber intake with FC is controversial.<sup>28-30</sup> It can be argued that FC is in fact a true chronic GI disorder with a mechanistic pathophysiology involving rectal desensitization to distension, resulting in a sustained rather than an intermittent and direct response to dietary and lifestyle habits seen in isolated constipation as a symptom.<sup>5,31</sup> This also reiterates the importance of having highly specific diagnostic criteria to distinguish the former from the latter.<sup>5</sup>

FGIDs and more specifically functional abdominal pain disorders tend to overlap with one another, and in many instances, patients may exhibit features of more than 1 disorder simultaneously.<sup>5,32,33</sup> This was clearly demonstrated in our data where the majority did meet at least one other functional abdominal pain disorder or functional constipation in addition to their primary FAPD.

The main reason the Rome IV expert committee subclassified FAPDs is for research and clinical purposes.<sup>5</sup> While treatment approach might differ only slightly, one could argue whether subclassifying FAPDs is of clinical value; given the considerable overlap in clinical features, general treatment approach and long-term outcomes.<sup>5,21</sup>

The relationship of FGIDs and FAPDs to psychiatric diagnoses ranging from depression to anxiety disorders is well described in the literature.<sup>34,35</sup> It is not clear whether psychiatric illnesses directly affect the brain-gut axis and increase the susceptibility of those patients to a FGID, or those 2 groups of disorders simply coexist in the same patient populations with a possible common inciting event such as an early life stressor as well as a genetic predisposition.<sup>2,33,36</sup> In our cohort, while we haven’t specifically examined the incidence of concomitant psychiatric disorders; we aimed to examine the psychological impact of distant learning and mandatory home lockdowns (as life stressors) among others, during



the 2019/2020 COVID-19 pandemic on the prevalence of FAPDs and FC. Interestingly, we found a potentially higher prevalence of FC in those that experienced a family death due to COVID-19. This is in line with other studies that showed an increased prevalence in association with a severe illness in the family.<sup>24,37</sup> In addition to living with a single parent, we also found a potential link of parental occupation to FAPD but not FC prevalence. Our plausible explanation is that non-healthcare worker parents perceive FAPDs as being from an organic etiology and would more likely seek medical therapies and hence pay more attention to their children's symptoms as opposed to healthcare worker parents who might discount such symptoms as being normal occurrences. This has been corroborated by a study by Sood et al, where most parents perceived FAPDs as being due to physical and not psychosocial causes, and therefore would be more accepting to medical therapy over cognitive behavioral therapy.<sup>38</sup>

The strengths of the current study include a decent sample size, and the use of the more recently published Rome IV criteria. Only a handful of population-based studies have used Rome IV criteria thus far. The study was limited by the slight confusion that may have arisen from translating Rome IV criteria into questions in the native (Arabic) language of our population. The exclusion of patients who are on chronic daily medications or with a chronic illness including organic GI diagnoses might have overlooked some FAPD and FC in those populations as organic and functional disorders can certainly coexist.<sup>5</sup>

## Conclusions

The prevalence of FAPDs and FC in our population is similar to that of other regions, albeit on the lower end of the range. Rome IV criteria seemed to give a lower FAPD but not FC prevalence since it is considered somewhat stricter than Rome III for the former but not the latter. Distant/online learning did not seem to affect the prevalence of FAPDs or FC, but a family stressor seems to increase FC prevalence.

## Author Contributions

AK: Contributed to conceptualization and study design; questionnaire design; data acquisition; data analysis; manuscript drafting; and gave the approval of the final manuscript.

GA: Contributed to conceptualization and study design; questionnaire design; data acquisition; manuscript drafting; and gave the approval of the final manuscript.

SB: Contributed to conceptualization and study design; questionnaire design; data acquisition; and gave the approval of the final manuscript.

MA: Contributed to conceptualization and study design; questionnaire design; data acquisition; and gave the approval of the final manuscript.

DB: Contributed to conceptualization and study design; questionnaire design; data acquisition; and gave the approval of the final manuscript.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Research Ethics and Consent

This research was approved by the institutional review board (ref# HAPO-02-K-012-2020-10-474). Written consent was obtained from each participant prior to participation (please review Supplemental Material).

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## Supplemental Material

Supplemental material for this article is available online.

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