

Fecal Incontinence Diagnosed by the Rome IV Criteria in the United States, Canada, and the United Kingdom

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BACKGROUND & AIMS: The diagnostic criteria for fecal incontinence (FI) were made more restrictive in the Rome IV revision. We aimed to determine the characteristics of FI patients defined by the Rome IV criteria, assess how FI frequency and amount affect quality of life, identify risk factors, and compare prevalence values among countries.

METHODS: We performed an internet-based survey of 5931 subjects in the United States, Canada, and the United Kingdom, from September to December 2015. Subjects were stratified by country, sex, and age. Responders answered questions about diagnosis, health care use, and risk factors. We performed multivariate linear regression analysis to identify risk factors for FI.

RESULTS: FI was reported by 957 subjects (16.1%) but only 196 (3.3%) fulfilled the Rome IV criteria. Frequency of FI was less than twice a month for 672/957 subjects (70.2%) and less than 6 months for 285/957 subjects (29.8%). Quality of life was significantly impaired in all subjects with FI compared to subjects with fecal continence. The strongest risk factors for FI were diarrhea, urgency to defecate, and abdominal pain. FI was more prevalent in the United States than in the United Kingdom. Between-country differences were due to less diarrhea and urgency in the United Kingdom.

CONCLUSIONS: Rome IV FI prevalence is lower than previous estimates because the new criteria exclude many individuals with less frequent or short duration FI. These excluded patients have impaired quality of life. It might be appropriate to make a diagnosis of FI for all patients with FI ≥ 2 times in 3 months and to provide additional information on frequency, duration, and amount of stool lost to assist clinicians in treatment selection.

Keywords: Quality of Life; Risk Factors; Diarrhea; Urgency; Accidental Bowel Leakage.

Q4 Fecal incontinence (FI) is the unintended loss of solid or liquid stool.^{1,2} It occurs in 7%–15% of individuals, with variability caused by the diagnostic criteria used, the age group in which it is studied, and any chronic illnesses present.³ FI has a major impact on health-related quality of life⁴ causing social isolation and increasing the likelihood among older adults of referral to a nursing home.⁵ Changes to the diagnostic criteria for FI are important because it is prevalent and has a large effect on quality of life.

The Rome Foundation recommended diagnostic criteria for FI in 2006 (Rome III criteria)⁶ and revised them in 2016 (Rome IV criteria).⁷ In both cases, FI was defined as multiple episodes of solid or liquid stool

passed into clothes, and accidental loss of flatus was ignored.^{6,7} Rome III and Rome IV identify patients with FI based on the frequency of accidental loss of solid or liquid stool and the duration of the disorder.

For Rome III at least 1 FI event per month is required⁶ but for Rome IV at least twice a month is needed. An unintended consequence of requiring a higher frequency of FI for diagnosis in Rome IV is that

Abbreviations used in this paper: FI, fecal incontinence.

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many people with occasional FI are no longer diagnosed. It is not clear how these individuals should be managed by clinicians, and that is 1 of the reasons for comparing the quality of life in FI defined by different criteria.

The aims of this study were (1) to determine the prevalence of FI by all diagnostic criteria, (2) assess quality of life in each subgroup, (3) identify risk factors for FI, and (4) compare prevalence rates in different countries. These countries were the United States, English-speaking parts of Canada, and the United Kingdom. These comparisons enabled us to determine whether FI is stable across countries and whether risk factors for FI differ among countries.

Methods

This survey methodology and content has been previously described.⁸ A total of 2100 subjects were recruited from Internet registries in the United States, Canada, and the United Kingdom by Qualtrics (Provo, UT). These individuals volunteered to participate in community surveys on a variety of topics, such as market research or politics. In exchange, participants received credits toward the purchase of products. Subjects remained anonymous to the investigators. In this survey, Qualtrics was given quotas of demographic characteristics to match including 50% males; 40% aged 18–39, 40% aged 40–64, and 20% aged 65 or older; and no more than 30% with a college degree. For the United States, participants should include 20% African American and 20% Hispanic. The study invitation and consent form described the survey as a health survey with no mention of gastrointestinal disorders. Subjects were directed to a Web site where they completed questionnaires. Data analysis occurred at the University of North Carolina.

Several methods were used to ensure data quality: 3 questions from early in the survey were repeated a second time, and a difference of greater than 2 response steps (out of 8) on any of these 3 questions caused the subject to be rejected. We also measured how much time subjects took to complete the survey and eliminated those who were more than 3 times faster than the median for early participants. Also excluded were those who failed either of 2 attention-check questions. Excluded respondents were 5.9%, leaving 5931 for analysis.

Any Internet survey must show that the data are representative. We previously showed that this Internet sample is unbiased by sex, age, race, and education after the Internet provider fills the demographic quotas below. It compares favorably with random telephone surveys or door-to-door or mailed surveys, which are limited by the reluctance of many individuals to respond to unsolicited telephone calls or mail.

What You Need to Know

Background

We aimed to determine the characteristics of FI patients defined by the Rome IV criteria, assess how FI frequency and amount affect quality of life, identify risk factors, and compare prevalence values among countries.

Findings

An internet survey of 6300 United States, Canadian, and British subjects found fecal incontinence in 16.1%, but only 3.3% met Rome IV criteria. Excluded subjects had impaired quality of life.

Implications for Patient Care

It may be appropriate to diagnose FI in all patients with 2 or more incidences in 3 months, and to provide additional information on frequency, duration, and amount of stool lost to assist clinicians in treatment selection.

Survey Questions

The primary questions came from the Rome IV Diagnostic Questionnaire for Adults (86 questions).⁹ FI is diagnosed by 2 questions: (1) In the last 3 months, how often did you have accidental leakage of stool (fecal material)? The minimum frequency for diagnosis was 1 day for Rome III and 2 days for Rome IV. (2) Has it been 6 months or longer since you started having accidental leakage of stool? Rome IV diagnosis required a “yes” response.

The average amount of stool lost was asked. Although not in the diagnostic criteria for FI, “amount” is included because it is often used to select research participants for studies. Possible answers were a small amount (only enough to stain underwear), moderate amount (more than staining but less than a full bowel movement), or large amount (a full bowel movement). The moderate and large volume choices were combined because only 3.6% reported losing a full bowel movement.

Variations in the criteria used to diagnose FI may exclude some subjects who have infrequent or milder forms of FI, and it is important to know if this subgroup has impaired health-related quality of life. The validated Short Form-8 scale includes subscales for a physical component and a mental component of quality of life.¹⁰

Additional psychological symptom scales included questions about how much bowel symptoms concern the subject, how embarrassing those symptoms were, and whether psychological stress made the symptoms worse. The Patient Health Questionnaire-12¹¹ was used as a measure of somatization; it was included because the Brief Symptom Inventory has been shown to predict FI occurrence.¹²

Additional questions on gastrointestinal health history, use of medications, and health care use were based on previous surveys. An international diet questionnaire was constructed by identifying the 10 most common foods eaten globally and asking subjects to report the number of days per week they consumed each food type.

Data Analysis

Sex, age, and education were controlled by the Internet provider. Student *t* tests or chi square tests were used to compare prevalence rates within and between countries. Variability was shown by 95% confidence intervals.

Table 1 shows the impact of changes in the diagnostic criteria on the prevalence of FI followed by the proportion meeting Rome III and Rome IV criteria.

A key aim of the study was to assess the impact of limitations on diagnostic criteria to quality of life. T-tests were used to compare the quality of life in the “never had FI” subgroup with the quality of life in other subgroups with FI.

Independent risk factors were identified by binary logistic regression. Three regression models were used to identify independent predictors of any FI, Rome III FI, and Rome IV FI.

The last aim was to compare FI prevalence among countries and identify variables that could explain differences in FI prevalence. Logistic regression was used to identify independent risk factors. Variables were considered to be significant predictors if their inclusion as a covariate eliminated differences among countries in the prevalence of any FI in the last 3 months.

The study was reviewed by the University of North Carolina Institutional Review Board and determined not to require institutional review because all data were anonymous. There were no risks for participants. All authors had access to the study data and reviewed and approved the final manuscript.

Results

The samples were balanced (less than 2% difference between countries) in sex and age because of quota

sampling. On education, US subjects were less likely to have post-graduate or professional training than Canadian or UK subjects ($P < .05$).

Race accounted for the greatest differences between countries. In the United States, quota-controlled sampling led to 20.2% for blacks, which was significantly higher than Canada and the United Kingdom ($P < .01$). Canada had significantly more Asians than the United States or United Kingdom ($P < .01$). FI was not significantly related to race within any country.

Prevalence Rates for Fecal Incontinence by Different Rome Definitions

There were 957 subjects (16.1%) with FI who reported at least 1 episode of FI in the last 3 months (Table 1). Rome III requires at least 1 episode of FI per month for 3 months, and 412 subjects (6.9%) met this criterion. Rome IV FI requires at least 2 FI episodes per month for 6 months, and 196 subjects (3.3%) met this criterion.

Figure 1 shows that age and sex had a significant impact on FI prevalence, and these 2 variables interacted; over age 40, females had more FI than males, but at age 40 or younger, males had more FI than females. The interaction between age group and gender was significant ($F [2,5920] = 6.131$; $P = .002$). When the dependent variable was changed to any FI in the last 3 months, the data were similar and the interaction was significant ($F [2,5920] = 3.834$; $P = .022$).

Quality of Life

Quality of life declines with each increase in frequency of FI, but the largest difference is between “never had FI” and “FI once per month or less” (Figure 2) ($P < .01$).

Subjects were also asked how much stool was usually lost. Subjects who reported that “soiling or staining underwear only” was typical for them had significantly worse quality of life (45.2 compared with 50.1 for physical component; 45.0 compared with 49.8 for the mental component of quality of life with FI). Losing more

Table 1. Prevalence of FI by Country^a

	United States	Canada	United Kingdom	All cases
Any FI in last 3 mo	17.5% (n = 341) CI, 16%–19% ^b	17.6% (n = 350) CI, 16%–19%	13.3% (n = 266) CI, 12%–15% ^b	16.1% (n = 957) CI, 15%–17%
Rome III FI	8.3% (n = 162) CI, 7%–10% ^b	6.8% (n = 136) CI, 6%–8%	5.7% (n = 114) CI, 5%–7% ^b	6.9% (n = 412) CI, 6%–8%
Rome IV FI	4.2% (n = 81) CI, 3%–5% ^b	3.1% (n = 61) CI, 2%–4%	2.7% (n = 54) CI, 2%–3% ^b	3.3% (n = 196) CI, 3%–4%

CI, confidence interval; FI, fecal incontinence.

^aIn each cell: percent of country sample, number of subjects.

^bBolded numbers are significantly different between the United States and the United Kingdom at $P < .05$.

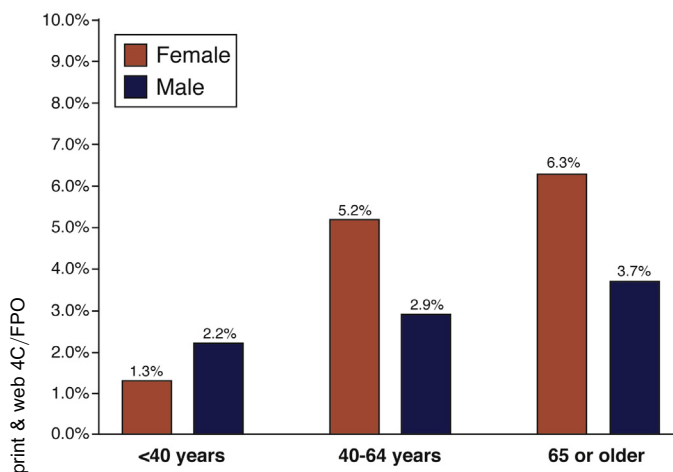


Figure 1. Effects of age and sex on the prevalence of FI. FI was diagnosed by the Rome IV criteria. These data include approximately equal numbers of subjects from the United States, Canada, and the United Kingdom. In subjects less than 40 years of age, females (red bars) had significantly ($P < .05$) less FI than males (blue bars), but after age 40, females had more FI than males ($P < .05$).

solid or liquid stool significantly increased the impact of FI on quality of life.

Independent Risk Factors for Fecal Incontinence

The significant independent predictors of any FI (Table 2) were gender (more prevalent in females than males), age (most prevalent in the oldest group), hard or lumpy stools, loose or watery stools, urgency to defecate, abdominal pain, psychological stress affecting bowel function, and self-ratings of poor health. There were 941 cases with any FI in the sample, and 23.7% of them were identified by these predictors. The Nagelkerke R-Square was 0.281.

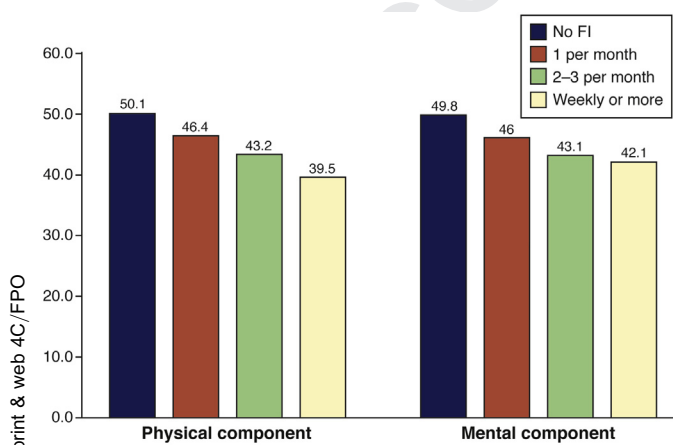


Figure 2. FI prevalence causes decreased physical and mental components of quality of life on the Short Form-8 scale. Confidence intervals are small, and all pairs of bars are significantly different at $P < .001$.

There were 412 Rome III FI patients of whom 18.7% were identified by these predictor variables. Nagelkerke R-Square was 0.310. The predictor variables were the same as any FI except for gender.

For Rome IV there were 196 patients with FI of whom 12.8% were identified by the predictor variables. The Nagelkerke R-Square was 0.305. The predictor variables were the same as Rome III except for abdominal pain and self-rating of poor health.

Between-Country Differences in Fecal Incontinence

The prevalence of any FI was greater in the United States (17.5% for any FI, 8.3% for Rome III, and 4.2% for Rome IV) compared with the United Kingdom (13.3%, 5.7%, and 2.7). Canada was intermediate.

Race and ethnicity were not correlated with FI in any country, but the questions for race and ethnicity differed among countries. To control for this, prevalence rates among countries were compared for white subjects only, and the between-country differences in FI remained significant. To identify factors that could explain between-country differences in any FI, logistic regression was used to identify variables that separated countries ($P < .05$), correlated with FI at $r \geq .2$, and eliminated between-country differences in FI prevalence when these covariates were entered. Only 2 variables met these criteria: the sensation of urgency before FI, and reports of frequent diarrhea. A similar outcome was found for predicting Rome III and Rome IV FI.

Discussion

In this random sample survey of 3 English language countries, we asked subjects to describe their experience of FI in terms of frequency, duration, and usual amount of stool lost. The overall prevalence of FI is 16.1% based on any report of an episode of FI in the last 3 months. The Rome III criteria exclude fewer subjects and identify 6.9% as having FI. The Rome IV criteria identify only 3.3% of the population because limiting FI to individuals with a frequency of twice a month and a duration of 6 months or longer excludes many. The Rome IV criteria exclude 4 out of every 5 individuals with occasional FI from an FI diagnosis.

The estimates for Rome III prevalence are consistent with estimates in other large community samples. Prevalence varies from 8%¹ to 15%² depending on the diagnostic criteria used, the age of the subjects selected, and comorbid diagnoses. These data have the advantages of drawing from large random samples of subjects and well-balanced age groups and sex distribution making it easier to assess the impact of modifications to the diagnostic criteria on prevalence rates.

Data from clinics may give higher estimates of the prevalence of FI than these community samples. In

Table 2. Logistic Regression to Identify Independent Predictors of FI^a

Variable	Any FI		Rome III FI		Rome IV FI	
	Wald	Significance	Wald	Significance	Wald	Significance
Sex	13.601	0.000	1.080	0.299	0.324	0.569
Age	110.565	0.000	64.194	0.000	62.394	0.000
Education	1.120	0.290	0.230	0.632	0.101	0.751
Hard/lumpy stools	7.343	0.007	9.379	0.002	10.547	0.001
Loose/watery stools	76.480	0.000	61.491	0.000	20.486	0.000
Urgency	134.405	0.000	84.805	0.000	46.481	0.000
Abdominal pain	13.168	0.000	20.111	0.000	1.139	0.286
Irritable bowel syndrome	2.780	0.095	3.428	0.064	1.887	0.170
Diabetes mellitus	3.235	0.072	0.380	0.538	0.810	0.368
Anxiety medication weekly	1.450	0.229	0.696	0.404	0.001	0.978
Depression medication weekly	3.305	0.069	1.348	0.246	2.073	0.150
Psychological stress	50.596	0.000	19.182	0.000	18.451	0.000
Self-rating of health	8.929	0.003	7.041	0.008	0.321	0.571

FI, fecal incontinence.

^aWald coefficients adjust for all other variables in the model; they are bolded if significant at $P < .05$.

patients with neurologic disorders, such as dementia¹³ and spinal cord injury,¹⁴ FI prevalence is elevated. In patients with urinary incontinence, inflammatory bowel disease,¹⁵ diabetes mellitus,¹⁶ and a history of pelvic surgery,¹⁷ prevalence rates are also higher.

Quality of Life Impact of Fecal Incontinence

The restrictive criteria of Rome IV leave many people who have infrequent FI with no diagnosis or treatment guideline. To determine whether these more restrictive criteria for FI diagnosis are helpful, we investigated the association of symptoms with impairment in quality of life. As the frequency of FI increases, quality of life declines, but the largest difference is between continence and having any FI. Similar effects are seen for the effect of duration of FI symptoms and amount of stool lost (ie, the presence of any FI has more impact on quality of life than differences in duration or amount of stool lost). More than half of people with FI (56.9%) have it less often than monthly, and 29.8% of the 957 people with any FI have had FI symptoms for less than 6 months. These individuals with short-term FI have a quality of life impact similar to subjects with long-term FI, suggesting that they might be equally in need of treatment. This raises questions about the appropriateness of the restrictive criteria used to diagnose FI in the Rome IV questionnaire.

In the small group who fulfilled all the criteria for Rome IV FI, most (70.4%; 138/196 subjects) report that their FI episodes usually consist of soiling of underwear. This subgroup would not be included in some clinical research studies that require loss of measurable amount of solid or liquid stool.

Do the Rome IV criteria succeed in separating a group of individuals with more severe FI who may be in greater need of medical care? Yes, they do this

because quality of life is correlated with the severity of FI. However, the criteria also have negative consequences; the largest effect of FI on quality of life exists for having any FI, even if it occurs less than once a month and is of short duration. These subjects with milder forms of FI may benefit from treatment. Our results suggest that FI should be diagnosed in any individual who reports 2 or more episodes of fecal soiling in the past 3 months (2 episodes are required to avoid diagnosing FI in an individual with diarrhea caused by food-borne infection). This more inclusive diagnosis should be accompanied by information on the frequency, duration, and amount of fecal soiling because these characteristics may guide clinicians to the best treatment for individual patients.

Risk Factors for Fecal Incontinence

The multivariate regression analyses to assess risk factors were robust because nearly 6000 participants were surveyed. FI was more prevalent in older subjects, those with urge sensations preceding defecation, loose or watery stools, hard or lumpy stools, abdominal pain, physician diagnoses of irritable bowel syndrome or diabetes mellitus, and those reporting greater effects of psychological stress on bowel function. Female subjects have a higher prevalence of FI than males, which agrees with many previous reports.¹⁸ Unlike some previous studies,¹ no association of FI diagnosis with the use of antianxiety medications or years of education was found.

Abdominal pain was a risk factor for FI independent of irritable bowel syndrome diagnosis. The role of abdominal pain in FI is unknown, but it may identify patients with comorbid neurologic or other illnesses that predispose to FI.³

Different Rates of Fecal Incontinence Between Countries

The prevalence of Rome IV–defined FI was significantly greater in the United States than in the United Kingdom, with the rate in Canada being intermediate. In contrast, the rate of any FI was significantly higher in both the United States and Canada compared with the United Kingdom. These differences were unrelated to race and ethnicity because an analysis limited to white subjects showed the same differences among the United States, Canada, and the United Kingdom. When tested for possible variables that could explain between-country differences, the only variables found were urge sensations before defecation and loose or watery stools. These variables eliminated between-country differences in prevalence when entered individually or together, and differences in these rates among countries may therefore account for the national prevalence differences observed.

Study Limitations

This study has limitations. First, subjects with dementia were not included in the survey because that subpopulation is not accessible via the Internet. Because both dementia and FI increase as people grow older, we may have underestimated the prevalence of FI. Second, anal incontinence was not assessed because there was no question on flatus. This will be addressed in an upcoming study. Third, several potential risk factors, such as body weight,³ urinary incontinence, mobility impairment,³ and pelvic floor muscle injuries,⁵ were not measured and may be associated with FI. Fourth, all questions were retrospective, and it is unknown whether subjects who answered that their FI episodes were “usually” soiling, ever had solid or liquid stool losses that could influence the success of a treatment for FI. Future studies should include a prospective assessment to estimate variability in symptoms. Finally, FI is embarrassing to discuss with others and this may lead to underestimates even when the survey is anonymous.

Recommendations to Clinicians

This study draws attention to the variability in the presentation of FI by showing that more than half of individuals with FI have it less than monthly and two-thirds have it for less than 6 months. Severity of FI is associated with greater quality of life impact. Some of these individuals may benefit from conservative treatments, but everyone with FI has a significant quality of life impact and may require medical diagnosis and management guidelines.

This study supports the following recommendations: (1) Redefine FI by identifying all individuals with FI 2 or more times in 3 months whether or not they meet a frequency or duration criteria. Always report additional

information on the frequency, duration, and amount of stool lost to help clinicians select the best treatment. (2) Develop algorithms for treating FI based on the apparent severity of the disorder. Conservative measures are easily taught and may be helpful to many individuals if appropriately targeted.¹⁹ (3) Screen for FI in all patients with diarrhea and urgency because those individuals are more likely to have FI. (4) In clinical care, identify the causes of diarrhea and urge sensation to see if they are modifiable. (5) Identify FI patients who have abdominal pain to understand the reasons for this association and the implications for treatment.

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Conflicts of interest

The authors disclose no conflicts. Q2

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