



PRACTICE OF EPIDEMIOLOGY

Prevalence of Constipation: Agreement among Several Criteria and Evaluation of the Diagnostic Accuracy of Qualifying Symptoms and Self-reported Definition in a Population-based Survey in Spain

Vicente Garrigues, Consuelo Gálvez, Vicente Ortiz, Marta Ponce, Pilar Nos, and Julio Ponce

From the Gastroenterology Unit, Hospital Universitari La Fe, Valencia, Spain.

Received for publication July 23, 2003; accepted for publication October 13, 2003.

The aims of this study were to estimate the prevalence of chronic constipation and to evaluate the diagnostic accuracy of the symptoms and the self-reported definition of constipation. A cross-sectional survey was conducted in the general community in 1999. A questionnaire comprising 21 items was developed and mailed to a random sample of 489 subjects who were aged between 18 and 65 years and who belonged to a Spanish population. In the 349 subjects (71%) responding to the questionnaire, the prevalence of self-reported constipation was 29.5% (95% confidence interval (CI): 24.9, 34.3) versus 19.2% (95% CI: 15.1, 23.3) and 14.0% (95% CI: 10.4, 17.7) based on Rome I and Rome II criteria, respectively. Agreement was good between self-reported and Rome I criteria (kappa: 0.68) and between Rome I and Rome II criteria (kappa: 0.71), and it was moderate between self-reported and Rome II criteria (kappa: 0.55). Female gender was identified to be a risk factor for constipation; fiber intake and physical exercise were found to be protective factors. Likelihood ratios were higher for the presence of anal blockage and straining and for the absence of hard stools. Chronic constipation is a highly prevalent problem, especially in women. Different prevalence estimates of constipation were observed using different criteria, although agreement between them was acceptable. Anal blockage, straining, and hard stools show the greatest accuracy for the diagnosis of constipation.

colonic diseases; constipation; prevalence

Abbreviation: CI, confidence interval.

Constipation is a frequent problem leading to a great number of medical visits and generating important health care costs as a result of the diagnostic procedures involved, associated medical problems, and treatment with laxatives and herbal remedies. It is therefore important to know the prevalence of constipation, as well as the associated factors involved. However, the constipation prevalence studies conducted to date yield discordant results, with estimates between 2 percent and 34 percent (1–11). This variability does not seem to be the result of sociodemographic differences between the different populations investigated, but rather appears to be attributable to the different criteria used for defining constipation. In this context, most surveys are

based simply on the subject's self-report of constipation or nonconstipation (4–8). Moreover, in many cases, the study samples comprise volunteers or nonrandom samples and are therefore not representative of the general population.

The absence of firm criteria for the diagnosis of digestive functional disorders—the availability and application of which are essential in both clinical practice and for epidemiologic and clinical research—led a group of experts in the 1980s to create committees for establishing consensus on the criteria used to diagnose these problems. These were known as the Rome criteria (12). In 1999, the criteria were modified on the basis of new knowledge gained, and they are now referred to as the Rome II criteria (13).

Correspondence to Dr. Vicente Garrigues, Servicio de Medicina Digestiva, Hospital La Fe, Av. Campanar, 21, 46009 Valencia, Spain (e-mail: garrigues_vic@gva.es).

The Rome II criteria for the diagnosis of chronic constipation differ from the Rome I criteria in that they incorporate two new symptoms to identify individuals with obstructed defecation: anal blockage and manual maneuvers to defecate. In addition, the new criteria exclude subjects presenting with loose stool episodes and irritable bowel syndrome. To date, only one study (10) has evaluated the changes in constipation prevalence resulting from the introduction of the Rome II criteria. Information from European countries is lacking and, moreover, the diagnostic accuracy of the Rome II qualifying symptoms has not been previously evaluated.

With the purpose of determining the importance of chronic constipation as a health problem in our setting and of assessing the changes resulting from introduction of the Rome II criteria, we designed the present cross-sectional epidemiologic survey with the following specific aims: 1) to evaluate the prevalence of chronic constipation on the basis of subject self-report and on Rome I and Rome II criteria; 2) to assess agreement among these criteria; 3) to evaluate the diagnostic accuracy of the self-reported definition and of the symptoms included in the Rome II criteria; and 4) to identify the factors associated with the presence of chronic constipation.

MATERIALS AND METHODS

Study subjects

The study was carried out in Aldaya, a town of 23,425 inhabitants near the city of Valencia, on the Spanish Mediterranean coast. The study sample was extracted from the electoral census, which includes all residents aged more than 18 years, the only inclusion criterion being age (18–65 years). This yielded an eligible population of 15,696 individuals. For an expected prevalence of chronic constipation of 20 percent, a sample size of 375 subjects was estimated to provide a 95 percent confidence interval of plus or minus four percentage points. With an expected response of 75 percent, the global sample required a total of 500 subjects. Systematic, age-stratified sampling was carried out, arbitrarily considering three groups: 18–30 years, 31–50 years, and 51–65 years. A list including all the eligible individuals of the population, arranged in alphabetic order, was prepared for each group. From each list, we then systematically selected the study subjects, selecting one of every 31 (the result of dividing 15,696 by 500). The first subject was selected randomly from among the first 31 individuals of the census, while the following subjects were selected by successively adding 31 to the first number, until reaching the end of the list. In this way, we selected a sample of 506 individuals with age and gender characteristics similar to those of the global eligible population.

Study questionnaire

A questionnaire with 21 items was developed that included the variables needed to define the presence of chronic constipation during the last 12 months, according to the Rome I, Rome II, and subject self-reported criteria. Likewise, we included variables related to the subject's lifestyle, other parameters that could be associated with chronic constipation, and basic sociodemographic variables (see

Appendix). A pilot study was conducted with this questionnaire, administering it to 10 subjects from a sociocultural setting similar to that of the study population. The questionnaire was found to be easy to understand and to answer.

The questionnaires were distributed by mail, starting in April 1999, along with a letter explaining the characteristics and reasons for the study and requesting subject participation. Up to six repeat mailings were made to those subjects who failed to respond; the first, moreover, included a note requesting that the subject inform us if he or she did not wish to participate in the study. Before the last mailing, nonresponders whose telephone number was known were contacted by phone.

Statistical analysis

The prevalences of constipation were calculated, along with the corresponding 95 percent confidence intervals. The agreement between constipation as self-reported by the subject and constipation as defined by Rome I and Rome II criteria was evaluated by the Cohen kappa coefficient with its corresponding 95 percent confidence interval.

The evaluation of the diagnostic accuracy of self-reported constipation was based on the Rome II definition as the "gold standard," and the evaluation of the diagnostic accuracy of each of the symptoms included in the Rome II criteria was based on both the self-reported and the Rome II definitions of the disorder as the gold standard. Because Rome II criteria give the same diagnostic weight to each of the six qualifying symptoms, we considered that a comparison of these symptoms regarding the diagnostic accuracy for chronic constipation (Rome II) could be adequate and useful, by giving information about the weight of each symptom in the final diagnosis. The sensitivity, the specificity, and the positive and negative likelihood ratios, with their corresponding 95 percent confidence intervals, were calculated. The positive likelihood ratio is the probability of a positive test result in subjects with the condition, divided by the probability of a positive result in subjects without the condition, or sensitivity/(1 – specificity). It indicates how much the probability of constipation changes from baseline when a symptom is present. On the other hand, the negative likelihood ratio is the probability of a negative test result when the condition is present, divided by the probability of a negative test result when the condition is absent, or (1 – sensitivity)/specificity. It indicates how much the probability of constipation changes when a symptom is absent. Likelihood ratios must be multiplied by prior probability of constipation (i.e., its prevalence) in each subject in order to know the actual probability of constipation for a present (positive likelihood ratio) or absent (negative likelihood ratio) symptom.

An evaluation was made of the association of self-reported constipation and constipation defined by the Rome II criteria with nine independent variables: gender, age (18–30, 31–50, and 51–65 years), educational level (basic/primary/secondary-higher), the amount of dietary fiber (low/medium/high), physical exercise (never/sometimes/habitually), the consumption of nonsteroidal antiinflammatory drugs (yes/no), anxiolytic medication (yes/no), calcium antagonists (yes/no), and female hormone-based drugs (yes/

TABLE 1. Prevalence of constipation by diagnostic criteria and demographic characteristics, Aldaya, Spain, 1999

	No.	%	Self-reported		Rome I		Rome II	
			%	95% CI*	%	95% CI	%	95% CI
Overall	349		29.5	24.7, 34.3	19.2	15.1, 23.3	14.0	10.4, 17.7
Gender								
Female	182	52.1	40.1	33.0, 47.2	28.6	22.0, 35.1	22.0	16.0, 28.0
Male	167	47.9	18.0	12.1, 23.8	9.0	4.6, 13.3	5.5	2.5, 10.0
Age (years)								
18–30	120	34.4	29.2	21.0, 37.3	21.7	14.3, 29.0	13.3	7.3, 19.4
31–50	154	44.1	29.2	22.0, 36.4	18.2	12.1, 24.3	14.3	8.7, 19.8
51–65	75	21.5	30.7	20.5, 42.4	17.3	9.6, 27.8	14.7	6.6, 22.7
Educational level†								
Basic	153	43.8	31.4	24.0, 38.7	21.6	15.1, 28.1	15.0	9.4, 20.7
Primary	92	26.4	26.4	17.3, 35.4	15.2	7.9, 22.6	13.0	6.2, 19.9
Secondary/higher	99	28.4	30.3	21.3, 39.4	20.2	12.3, 28.1	14.1	7.3, 21.0

* CI, confidence interval.

† Five subjects did not respond to the question on educational level.

no). Logistic regression analysis was performed controlling for all of the independent variables.

Ethical considerations

The study was approved by our institutional medical director and by local authorities of the town of Aldaya. Spanish regulations about the management of personal data were fulfilled at all times.

RESULTS

A total of 506 questionnaires were mailed. Of these, 17 were returned because of change of address, thus leaving a sample of 489 individuals. A total of 349 subjects replied (71.4 percent). Table 1 shows the demographic characteristics of the responders, which were very similar to those of the study sample.

Prevalence of constipation

Table 1 shows the prevalence of constipation, overall and stratified according to the demographic characteristics. The prevalence of self-reported constipation was 29.5 percent (95 percent confidence interval (CI): 24.7, 34.3) versus 19.2 percent (95 percent CI: 15.1, 23.3) according to the Rome I criteria and 14.0 percent (95 percent CI: 10.4, 17.7) according to the Rome II definition. With regard to including individuals with loose stools among the Rome II criteria, the prevalence of constipation reached 21.2 percent (95 percent CI: 16.9, 25.5). The prevalence of constipation was significantly greater among women according to all criteria, but no significant differences were apparent according to age or educational level.

Agreement among the different diagnostic criteria

Agreement between the self-reported and Rome I criteria was good (kappa: 0.68, 95 percent CI: 0.59, 0.77) and similar to that obtained between the Rome I and II criteria (kappa: 0.71, 95 percent CI: 0.61, 0.81). In contrast, agreement between the self-reported and Rome II criteria was moderate (kappa: 0.55, 95 percent CI: 0.44, 0.65) (table 2).

TABLE 2. Concordance among different diagnostic criteria for constipation, Spain, 1999

	Rome I criteria*		
	+	–	Total
Self-reported criteria*			
+	64	39	103
–	3	243	246
Total	67	282	349
	Rome II criteria†		
	+	–	Total
Self-reported criteria†			
+	48	55	103
–	1	245	246
Total	49	300	349
	Rome II criteria‡		
	+	–	Total
Rome I criteria‡			
+	44	23	67
–	5	277	282
Total	49	300	349

* kappa: 0.68, 95% confidence interval: 0.59, 0.77.

† kappa: 0.55, 95% confidence interval: 0.44, 0.65.

‡ kappa: 0.71, 95% confidence interval: 0.61, 0.81.

TABLE 3. Accuracy of the symptoms included in the Rome II criteria for the diagnosis of constipation, considering the self-reported definition as the "gold standard," Spain, 1999

	Sensitivity (%)		Specificity (%)		LR+*		LR-*	
	Value	95% CI*	Value	95% CI	Value	95% CI	Value	95% CI
Straining	56	47, 66	99	89, 100	56	4.27, ∞	0.44	0.33, 0.59
Hard stools	64	55, 73	96	94, 99	16	9.2, 73	0.38	0.27, 0.48
Incomplete evacuation	30	21, 39	98	97, 100	15	7, ∞	0.71	0.61, 0.81
Anal blockage	48	38, 57	100	99, 100	∞	38, ∞	0.52	0.43, 0.63
Manual maneuvers	23	15, 31	97	95, 99	7.7	3.0, 31.0	0.79	0.70, 0.89
<3 defecations per week	22	14, 30	98	96, 100	11	3.5, ∞	0.80	0.70, 0.90

* LR+, positive likelihood ratio (probability of a positive answer when constipation is present divided by the probability of a positive answer when constipation is absent); LR-, negative likelihood ratio (probability of a negative answer when constipation is present divided by the probability of a negative answer when constipation is absent); CI, confidence interval.

Of the subjects who considered themselves to be constipated ($n = 103$), 62 percent satisfied the Rome I criteria and 47 percent satisfied the Rome II criteria. Only 4 percent of the individuals who satisfied the Rome I constipation criteria and 2 percent of those who met the Rome II criteria did not consider themselves to be constipated.

Evaluation of diagnostic accuracy

Table 3 shows the values of the sensitivity, the specificity, and the positive and negative likelihood ratios for each of the symptoms included in the Rome II criteria, considering self-reported constipation as the gold standard. Table 4 shows the values of these parameters for self-reported constipation and for each of the symptoms included in the Rome II criteria, considering the Rome II definition as the gold standard.

The highest positive likelihood ratios according to both criteria of constipation, that is, self-reported and Rome II, were for anal blockage and straining; and the lowest, for manual maneuvers. The best negative likelihood ratio was

reached by hard stools; and the worst, by manual maneuvers and frequency of defecation. Self-reported constipation showed a good positive likelihood ratio and an excellent negative likelihood ratio (table 4).

Factors associated with the presence of constipation

On evaluating the relation of the different independent variables to the presence of self-reported constipation, we found that the only factor to be positively associated was female gender (table 5). Women were 2.9 times (95 percent CI: 1.68, 4.98) more likely to self-report constipation compared with men. In the analysis of the relation of these factors to constipation as defined by the Rome II criteria, an increased frequency of constipation was noted among women, while the disorder was significantly less common among subjects who consumed a medium amount of dietary fiber and in those who performed physical exercise occasionally or habitually (table 5).

TABLE 4. Accuracy of the self-reported constipation criterion and of the symptoms included in the Rome II criteria for the diagnosis of constipation, considering the Rome II definition as the "gold standard," Spain, 1999

	Sensitivity (%)		Specificity (%)		LR+*		LR-*	
	Value	95% CI*	Value	95% CI	Value	95% CI	Value	95% CI
Self-reported constipation	98	94, 100	82	77, 86	5.4	4.1, 7.1	0.02	0, 0.08
Straining	84	72, 94	94	91, 96	14	8.0, 23.5	0.17	0.06, 0.30
Hard stools	92	84, 100	90	87, 93	9.2	6.5, 14.3	0.09	0, 0.19
Incomplete evacuation	43	29, 57	95	93, 98	8.6	4.1, 28.5	0.59	0.43, 0.77
Anal blockage	71	59, 84	95	93, 97	14.2	8.4, 28	0.30	0.16, 0.43
Manual maneuvers	29	16, 41	94	92, 97	4.8	2.0, 13.7	0.77	0.63, 0.91
<3 defecations per week	31	18, 43	96	93, 98	7.8	2.6, 21.5	0.71	0.59, 0.91

* LR+, positive likelihood ratio (probability of a positive answer when constipation is present divided by the probability of a positive answer when constipation is absent); LR-, negative likelihood ratio (probability of a negative answer when constipation is present divided by the probability of a negative answer when constipation is absent); CI, confidence interval.

TABLE 5. Independent variables associated with the presence of constipation, Spain, 1999

	Total (no.)	With constipation		Odds ratio*	95% CI†	<i>p</i> value
		No.	%			
Self-reported constipation						
Gender						
Male	167	30	18.0	Referent		
Female	182	73	40.1	2.90	1.68, 4.98	0.0001
Functional constipation (Rome II)						
Gender						
Male	167	9	5.5	Referent		
Female	182	40	22.0	4.58	1.98, 10.60	0.0004
Fiber intake						
Low	52	10	19.2	Referent		
Medium	230	25	10.9	0.38	0.15, 0.96	0.04
High	67	14	20.9	1.05	0.35, 3.17	0.93
Physical exercise						
Never	112	26	23.2	Referent		
Sometimes	156	17	10.9	0.43	0.20, 0.89	0.02
Habitually	81	6	7.4	0.31	0.11, 0.87	0.03

* Odds ratios are adjusted for all of the independent variables.

† CI, confidence interval.

DISCUSSION

The present study investigates the prevalence of constipation in a selected sample of the Spanish population. The study sample was identified by a stratified systematic random sample, thereby reducing selection bias. Many epidemiologic studies to date involve sample selection based on volunteers recruited from populations, occupational groups, commercial databases, and student populations (7, 9, 11, 14, 15), increasing the risk of selection bias, or based on physician-delivered questionnaires or hospital diagnoses upon admission (6, 16, 17), thereby increasing the risk of information bias. The response rate, 71.4 percent, is sufficiently high to consider the data representative of the target population. On the other hand, the selected population is a restricted sample of the Mediterranean area, so our data must be considered an approximation of the prevalence of constipation in Spain.

The prevalence of constipation was high for each of the definitions of constipation considered and varied by definition. The self-reported criterion of constipation was the definition for which the highest constipation prevalence was recorded (29.5 percent), followed by the Rome I and Rome II criteria (19.2 percent and 14.0 percent, respectively). These results are similar to those published elsewhere (7, 8) and are practically identical to those obtained in the only study evaluating the prevalence of constipation based on the Rome II criteria to date (10). Talley et al. (3) obtained a considerably lower prevalence of self-reported constipation, 12.5 percent, which increased to 16 percent when individuals who used laxatives were included. The prevalence of constipation was significantly greater in women, as has also been noted in most of the studies published to date (3, 5, 6, 10).

For all definitions of constipation, the observed prevalence of the disorder was similar in the different age groups, as has already been reported elsewhere (8, 10). However, Talley et al. (3) found that functional constipation, but not outlet delay or self-reported constipation, was associated with age, being more frequent in the age group 30–39 years.

The lesser prevalence of constipation observed on applying the Rome II criteria versus the Rome I criteria is attributable to the exclusion of those individuals presenting loose stools or diarrhea. According to Pare et al. (10), this could constitute an excessively restrictive criterion, by excluding those individuals who in fact suffer altered quality of life because of chronic constipation. Perhaps for this reason the observed agreement was good between self-reported constipation and the Rome I criteria but only moderate between the former and the Rome II definition, thus supporting the idea that the latter may be too restrictive.

The agreement obtained between the two objective constipation criteria (Rome I and Rome II) was good. This is explained by the fact that the Rome II definition constitutes a modification rather than a major change in the original Rome I criteria. Accordingly, variations in prevalence between the two criteria are lower than in the case of other functional disorders, such as irritable bowel syndrome (18). Pare et al. (10) also reported good agreement on constipation between Rome I and Rome II criteria (kappa: 0.71). However, the agreement between self-reported constipation and the Rome I and Rome II criteria was lower in the study by Pare et al. (10) than in our study, despite the fact that the constipation prevalences in their study and our own are very similar.

In our study, 96 percent and 98 percent of the individuals who met the Rome I and Rome II criteria for constipation, respectively, considered themselves to be constipated. In contrast, Talley et al. (3) found that only 21 percent of the subjects with functional constipation according to the Rome I criteria considered themselves to be constipated, although this percentage increased to 45 percent on including those subjects who referred to an alternating bowel habit. A possible explanation for this discrepancy is the low prevalence of self-reported constipation in the study by Talley et al. (3), as noted earlier. Several differences between the two studies, in addition to possible geographic variations, might explain the discrepancy in the self-reported constipation rate. In the study by Talley et al., subjects were selected from extensive indices based on clinical and histologic diagnoses and surgical procedures, including over 95 percent of local residents but not from the general population; only subjects between 30 and 64 years were included; 30 percent of the population in the study by Talley et al. was rural, as opposed to our exclusively urban population; and an equal proportion of men and women was selected.

Using the Rome II definition as the gold standard for constipation, we found that self-reported constipation offered excellent sensitivity and negative likelihood ratio, thus making it a good criterion for assessing the absence of constipation in the general population. However, the positive likelihood ratio was not as good; as a result, its clinical usefulness in identifying individuals with constipation defined by objective criteria is more limited.

In our study, more accurate symptoms to confirm the presence of constipation were anal blockage and straining, and the more accurate symptom to rule out constipation was the absence of hard stools. Similarly, straining and hard stools were highly associated with the presence of constipation in a multinational study reported by Talley et al. (19). Manual maneuvers had the poorest accuracy for diagnosing constipation. The accuracy of the symptoms of constipation has been analyzed by Koch et al. (20), who concluded that symptoms are not useful for differentiation among the pathophysiologic subtypes of constipation.

In the multivariate analysis, female gender was related to the presence of any definition of constipation. In the case of constipation defined by the Rome II criteria, two other variables were also seen to be associated: dietary fiber intake and physical exercise. In our study, consumption of a medium amount of fiber constituted a protective factor against constipation as defined by the Rome II criteria. However, high fiber intake did not show any protective effect, perhaps because some of these subjects could be taking fiber when they were in fact suffering from constipation. Dietary fiber is known to exert a beneficial effect upon constipation as a result of its fecal bolus mass-incrementing effect, water retention properties, increase in colon bacteria, and gas production (21), with an acceleration of colon transit (22). However, earlier studies have reported no relation between fiber consumption and constipation (23, 24). Only Everhart et al. (5) found low fiber intake in males to constitute a risk factor for constipation, while high intake in women exerted a protective effect. These differences may be explained by the fact that, in the same way as in our study, quantification of

the amount of fiber is based on the subject's opinion and is therefore subjective. Physical exercise was found to be a protective factor against constipation as defined by the Rome II criteria, this being in agreement with earlier studies in which physical inactivity was found to constitute a risk factor for constipation (11, 25). In contrast, other authors have reported no relation between physical exercise and constipation (26, 27).

In conclusion, constipation is seen to be highly prevalent in our selected Spanish Mediterranean population, especially in women. The self-perception of constipation is greater than that determined by objective criteria. The Rome II definition allows the diagnosis of individuals with stool obstruction, though the exclusion of individuals with loose stools or diarrhea may be too restrictive for the diagnosis of chronic constipation. Anal blockage, straining, and hard stools show the greatest accuracy for the diagnosis of constipation.

ACKNOWLEDGMENTS

Supported by a grant from the Sociedad Española de Patología Digestiva and in part by a grant from the Instituto de Salud Carlos III (c03/02).

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3. Indicate your educational level.
4. Indicate your job.
5. Indicate the amount of fiber in your diet: low/medium/high.
6. How often do you perform physical exercise? Never/sometimes/habitually.
7. Indicate which drugs you are taking.
8. Have you felt constipated? Yes/no.
9. Do you strain during a bowel movement?
10. Do you feel an incomplete emptying sensation after a bowel movement?
11. How often are your stools hard?
12. Do you feel a blockage in the anus that makes it difficult to pass the stool?
13. Do you need to press around the anus or vagina to complete a bowel movement?
14. Do you spend more than 10 minutes on the toilet to pass the stools?
15. How many bowel movements do you usually have each week?
16. Do you take oral laxatives?
17. Do you need to use suppositories to have bowel movements?
18. Do you need to use enemas to have bowel movements?
19. Have you visited a doctor because of constipation? Yes/no.
20. Have you presented with abdominal pain more than six times this past year? Yes/no.
21. Have you presented with loose or watery stools? Yes/no.

Questions 5–21 referred to the last 12 months. For questions 9–14, four answers were offered: never, sometimes (<25 percent of the time), often (≥25 percent of the time), and always. For questions 16–18, four answers were offered: never, fewer than once a week, one or more times a week, and every day.

Functional constipation (Rome I criteria) comprises the following: two or more of four criteria (questions 9–11 (answer = often or always) and fewer than three bowel movements a week) or fewer than two bowel movements a week as the sole criterion.

Functional constipation (Rome II criteria) comprises the following: two or more of six criteria (questions 9–13 (answer = often or always) and fewer than three bowel movements a week) or “no” as the answer to question 21.

APPENDIX

The following items appear on the questionnaire mailed to subjects.

1. Indicate your age.
2. Indicate your gender.