

The prevalence, patterns and impact of irritable bowel syndrome: an international survey of 40 000 subjects

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SUMMARY

Aim: To determine the prevalence, symptom pattern and impact of the irritable bowel syndrome, across eight European countries, using a standardized methodology.

Methods: A community survey of 41 984 individuals was performed using quota sampling and random digit telephone dialling to identify those with diagnosed irritable bowel syndrome or those meeting diagnostic criteria, followed by in-depth interviews.

Results: The overall prevalence was 11.5% (6.2–12%); 9.6% had current symptoms, 4.8% had been formally diagnosed and a further 2.9%, 4.2% and 6.5% met the Rome II, Rome I or Manning criteria, respectively. Bowel habit classification varied by criteria: 63% had an 'alternating' bowel habit by Rome II vs. 21% by self-

report. On average, 69% reported symptoms lasting for 1 h, twice daily, for 7 days a month. Irritable bowel syndrome sufferers reported more peptic ulcer (13% vs. 6%), reflux (21% vs. 7%) and appendectomy (17% vs. 11%), but not hysterectomy, cholecystectomy or bladder procedures. Ninety per cent had consulted in primary care and 17% in hospital; 69% had used medication. Irritable bowel syndrome substantially interfered with lifestyle and caused absenteeism.

Conclusions: Irritable bowel syndrome is common with major effects on lifestyle and health care. The majority of cases are undiagnosed and the prevalence varies strikingly between countries. Diagnostic criteria are associated with varying prevalences and bowel habit sub-types. This limits their utility in clinical practice and the transferability of research findings using them.

INTRODUCTION

Irritable bowel syndrome, a functional gastrointestinal disorder, is a recognized symptom complex with abdominal pain and disturbed bowel action. It leads to a substantial reduction in the quality of life, accompanied by considerable socio-economic and psychological consequences,^{1–4} and represents a major proportion of gastrointestinal workload in both primary and second-

ary care.⁵ Current data indicate a community prevalence of between 3% and 22%,^{6–9} with wide variations between countries, ranging from 3.5% in Iran to 30% in Nigeria. The health-seeking behaviour of sufferers also varies, with 10–50% seeking medical attention in most countries.^{1, 8}

However, these data are drawn from independent studies, using varying methodologies and diagnostic criteria; in particular, there is a paucity of data comparing European countries. This information is important in order to define more precisely the size of the problem for health care planning and to ascertain whether international differences are real or apparent.

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Three main sets of diagnostic criteria have been developed for use in irritable bowel syndrome. The Manning criteria are based on the relief of pain on bowel movement, more frequent stools with the onset of pain, looser stools with the onset of pain and abdominal distension and associated mucous passage and feelings of incomplete evacuation.¹⁰ The Rome I¹¹ and the later Rome II¹² criteria are more refined, and include the duration of symptoms within their definitions — some have argued that the Rome II criteria are too restrictive. The application of these different sets of criteria poses problems for prevalence studies. Furthermore, in the setting of the consulting room, a more pragmatic approach to diagnosis is usually adopted using clinical judgement rather than specific criteria.⁵

The aim of this study was to ascertain the prevalence, pattern of symptoms and effect on health, lifestyle and resource use of irritable bowel syndrome across Europe, using a standardized methodological approach on a large scale. We aimed to ascertain diagnostic rates without reference to specific criteria, as well as by using the Manning, Rome I and Rome II criteria. This would allow us to compare normal clinical practice with the more standardized criteria-based diagnosis. By seeking direct responses from sufferers, we also aimed to ascertain the extent of the applicability of the criteria in clinical practice.

METHOD

Survey methodology

We used a market research approach of telephone interviewing to gather data. The attraction of this is that it enables data to be collected from geographically scattered samples more quickly than by fixed interviewing, and avoids the limitations of postal surveys. Telephone interviewing from a central source also allows close supervision and control and avoids cluster sampling, a problem of multiple, fixed-site surveys. This technique also has the capacity to contact large numbers of people more readily.

Market research methodologies using telephone contacts are commonplace in commercial settings and have been proven to be feasible and accurate in health research.^{13–16} The data quality is considered to be comparable to that obtained by face-to-face interviews and, in some situations, more valid. For accurate and valid data collection, samples must be

representative, with adequate response rates. Problems related to households without telephones, unlisted numbers and refusals can be overcome with appropriate sampling and weighting for requisite groups of the population. It is considered that the response rate from telephone surveys is only marginally less than that from face-to-face surveys, where up to 60–70% of those approached fail to respond. Much of the data required for the calculation of sample sizes is based on previous face-to-face surveys where patterns of telephone ownership have been determined. This survey was carried out by The Sample Surveys Research Group, West Malling, UK, commissioned by Novartis Pharmaceuticals.

In order to enhance representativeness, quota sampling was applied in terms of age and gender commensurate with each country's profile. A random digit dialling technique was used to further enhance representativeness. This relied on previous determination of whether the dialled number was residential by cross-checking with databases of businesses and mobile numbers. The methodology took into account that more than 90% of households in Europe have a telephone and that approximately 25% are unlisted. Random digit dialling sampling enabled numbers in each country to be assigned a probability of selection. A random initial sample was drawn from all known listings using a 1 in *n* sampling interval, across all dialling exchanges. An algorithm was then employed to randomize the last two digits, thus ensuring the inclusion of unlisted numbers. To maximize data efficiency, numbers were pre-screened for a valid dialling tone and re-checked to exclude published business listings.

On the assumption of a prevalence rate of 5–10%, to reach 250–500 irritable bowel syndrome sufferers in each country, it was estimated that 5000 targeted respondents would be needed in each country, necessitating 40 000 individually targeted contact calls. Target groups for age were: 18–34 years, 35–54 years and over 55 years. Corrections were applied to the data collected to ensure that age and gender mirrored the profiles of the individual countries. This was undertaken on more closely defined bands, e.g. males aged 18–24 years, males aged 25–34 years. The target of 5000 respondents was consistent across the countries; as country populations varied, the aggregated prevalence figure was adjusted. This did not have any effect on the

prevalence rates of individual countries where no adjustment was required.

The questionnaires: development and application

The study was performed in two phases. Firstly, a screening questionnaire was used. This took approximately 5 min and was designed to identify subjects already diagnosed with irritable bowel syndrome (formally diagnosed) and to elicit information which identified non-diagnosed irritable bowel syndrome sufferers according to the Manning, Rome I and Rome II criteria. To avoid directing responses, the questionnaire was presented as part of a general health project and subjects were asked if they had been diagnosed with any of a range of conditions including irritable bowel syndrome and other gastrointestinal complaints. The questionnaire consisted of 18 questions with stems and multiple responses; questions were skipped depending on various answers.

In the second phase, subjects who were identified as having irritable bowel syndrome, either formally diagnosed or not formally diagnosed, were invited to an in-depth interview about their irritable bowel syndrome, general health factors, lifestyle and the impact of irritable bowel syndrome on their lives. Details were also sought on co-morbidity, therapy use and consultation patterns. Thus, three groups of respondents were obtained: those with formally diagnosed irritable bowel syndrome, those who had irritable bowel syndrome which had not been formally diagnosed, and a comparator group identified from the first phase who did not have irritable bowel syndrome. Those who had symptoms of irritable bowel syndrome within the previous 12 months were identified as current sufferers.

The questionnaires were developed initially with input from primary and secondary care clinicians in the UK and lay people. The English version of the first questionnaire was subjected to five stages of piloting and testing, including respondent validation. The questionnaire was then translated for each of the countries in which it was to be used, and further validation was conducted using clinicians and lay individuals in each country. The locally derived and adapted questionnaire was again tested using the telephone interview technique in each country; in all, 1040 subject-to-subject and telephone interviews were conducted during the development process.

Setting and subjects

The study was carried out in the following countries — UK, France, Germany, Italy, Holland, Belgium, Spain and Switzerland — amongst subjects aged 18 years or over. Those previously diagnosed with Crohn's disease, ulcerative colitis, coeliac disease, diverticulitis, peptic ulcer or colon cancer were excluded from the results because of possible overlap with irritable bowel syndrome symptoms.

RESULTS

Interviews attained

Of a total of 41 984 interviews completed, each country accounted for the following number of respondents: UK, 5999; France, 5033; Germany, 5002; Italy, 5082; Holland, 5463; Belgium, 5229; Spain, 5097; Switzerland, 5079 (from a total of 116 752 randomly dialled calls).

The first interview identified 3880 individuals (range between countries, 317–768) as having irritable bowel syndrome, comprising those who had been formally diagnosed ($n = 1961$) and those who had not but were identified using the Manning (2658), Rome I (1072) and Rome II (1203) criteria, with many who overlapped by criteria. Of these, 2633 (68%; range between countries, 218–480) agreed to the second interview and 1838 (47.4% of the original number) eventually participated (range between countries, 171–326; male/female ratio, 48 : 52).

The prevalence of diagnosed and non-diagnosed irritable bowel syndrome

The overall adjusted prevalence of irritable bowel syndrome (formally diagnosed and not formally diagnosed) across the eight European countries was 11.5% (Figures 1 and 2). This comprised 9.6% of those with current symptoms (i.e. within the previous 12 months) and 1.9% with previous symptoms. Those with current irritable bowel syndrome further comprised those who had been formally diagnosed (2.8%) and those who had not been formally diagnosed (6.8%). The average European prevalence for formally diagnosed irritable bowel syndrome (comprising those with current symptoms and no current symptoms), adjusted for variations in population size between countries, was 4.8%, ranging

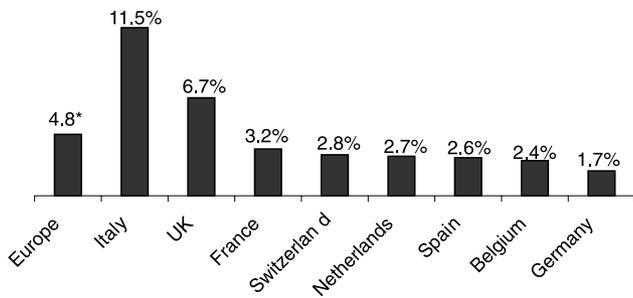


Figure 1. The prevalence of formally diagnosed irritable bowel syndrome in Europe ($n = 41\ 984$ respondents). *Adjusted for variations in population sizes between countries.

individually from 11.5% in Italy to 1.7% in Germany. The total prevalence rates for formally diagnosed and not formally diagnosed current irritable bowel syndrome ranged from 12.0% in Italy and the UK to 6.2% in The Netherlands. The proportion of formally diagnosed vs. not formally diagnosed current irritable bowel syndrome sufferers varied between countries: in the UK and Italy, this was approximately 50%; in the other countries, the majority of subjects had not been formally diagnosed.

The age/sex distribution of current irritable bowel syndrome sufferers (formally diagnosed and not formally diagnosed)

Most subjects (63%) were female. The total prevalence was 9.6% in 41 984 respondents; males comprised 7.1% and females 12%. The prevalence by age was: 18–34 years, 12.2%; 35–54 years, 9.9%; 55 years or over, 7%.

Symptoms and match with diagnostic criteria

The chief symptoms experienced by irritable bowel syndrome sufferers were abdominal pain (88%), bloat-

ing (80%), trapped wind (66%), tiredness (60%), diarrhoea (59%), tightness of clothing (58%), constipation (53%) and heartburn (47%).

Respondents who did not have a formal diagnosis of irritable bowel syndrome were asked about symptoms from a checklist. Overall, 6.8% were noted to have irritable bowel syndrome consistent with any of the Manning, Rome I or Rome II criteria. However, there were variations in the diagnostic rates from the criteria: 6.5% conformed to the Manning criteria, 4.2% to the Rome I criteria and 2.9% to the Rome II criteria. These discrepancies were reflected in differences in the way in which respondents self-classified their symptoms as constipation- or diarrhoea-predominant or alternating, compared with the definitions elicited using the Rome II criteria. The difference in classification was most marked for the alternating sub-type: the Rome II criteria classified 63% of current sufferers as alternating, whereas only 21% of respondents classified themselves in this way; 18% fell into the 'don't know' category (Table 1).

Concurrent conditions and previous surgery

A comparison between irritable bowel syndrome sufferers and those without irritable bowel syndrome yielded a higher prevalence of concurrent conditions in sufferers (values in parentheses refer to non-sufferers): gastro-oesophageal reflux disease, 21% (7%); peptic ulcer, 13% (6%); dyspepsia, 13% (4%); depression, 25% (9%); asthma, 13% (7%) [but similar for diabetes: 6% (5%)]. A similar comparison for previous surgery yielded a higher rate of appendectomy in irritable bowel syndrome sufferers (17% vs. 11%), but similar rates for hysterectomy (5% vs. 4%), cholecystectomy (3% vs. 2%), herniorrhaphy (3% vs. 2%), ovarian surgery (2%

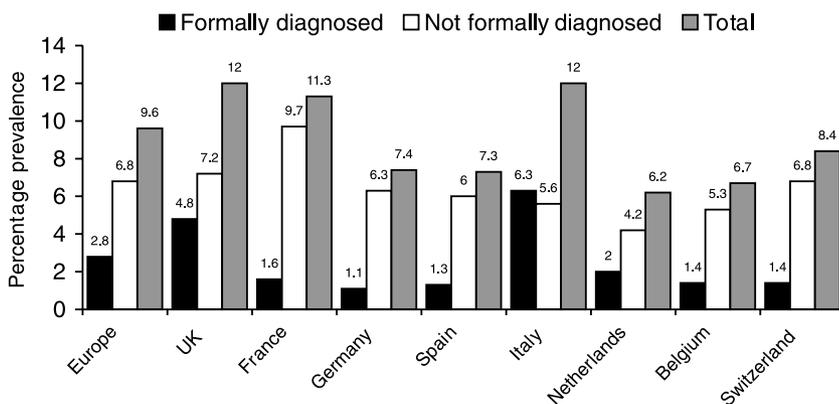


Figure 2. The prevalence of current irritable bowel syndrome by country in Europe.

Table 1. Sub-typing of irritable bowel syndrome: current sufferers

	Rome II (%)	Respondent classification (%)
Constipation-predominant	16	34
Diarrhoea-predominant	21	27
Alternating/both	63	21
Don't know		18

vs. 1%), laparoscopy (1% vs. 1%) and bladder surgery (1% vs. 1%).

The duration and patterns of symptoms

Of those formally diagnosed as having irritable bowel syndrome, 40% had been diagnosed more than 10 years ago, 43% 2–10 years ago, 7% 1–2 years ago and 10% within the last year.

From the in-depth interviews with subjects with current irritable bowel syndrome, 40% reported having symptoms for 1–3 days per month, 29% for 4–9 days, 17% for 10–20 days, 8% for more than 21 days and 6% were unsure. On average, symptoms were experienced for 7 days per month. The average number of bouts on an affected day was two, each bout lasting an hour. Amongst those who had been formally diagnosed, the last symptoms occurred in 59% within the last 12 months, in 25% 1–5 years previously and in the rest prior to that.

Irritable bowel syndrome: impact on health, lifestyle and sickness days

Respondents were asked about the extent to which their general state of health affected their lives. Overall, 78% of irritable bowel syndrome sufferers reported that their general state of health affected their lives, compared with 60% of those who did not have irritable bowel syndrome (Figure 3). Compared with those who did not suffer from irritable bowel syndrome, more respondents (24% vs. 17%) reported that their lives were affected to a 'very large' or 'large' extent, and 52% vs. 40% to 'some' extent. Specific factors which impinged upon their lifestyles were diet, concentration, long journeys, physical appearance, the ability to eat out, the ability to lead a 'normal' life and sex and physical relationships; in all of these categories, sufferers were more likely to report problems than non-sufferers.

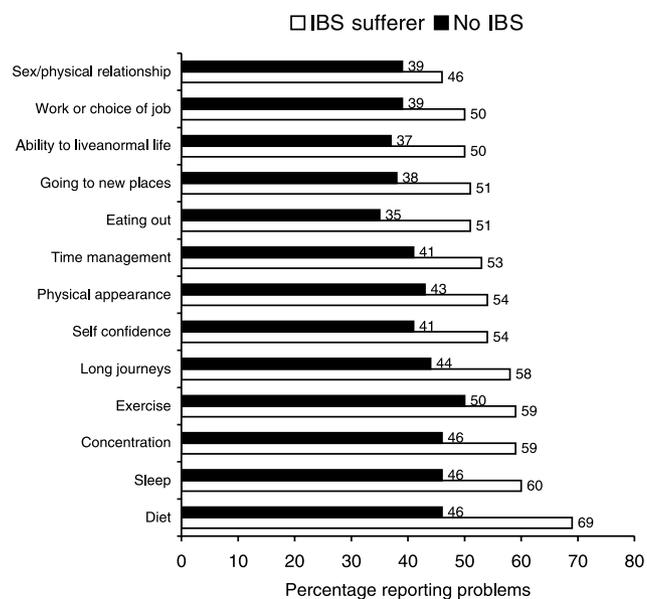


Figure 3. Impact on lifestyle: irritable bowel syndrome and non-irritable bowel syndrome respondents (percentage reporting a negative effect).

In addition, irritable bowel syndrome sufferers reported having more sickness days off work in the previous 12 months: overall, they spent 3.9 days in bed (corresponding figure for non-sufferers, 2.7 days), 5.5 days sick off work (3.1 days), 8.4 days seeing a doctor or nurse (5.2 days) and 10.2 days when work activities had to be cut short (4.8 days). Of those who had formally diagnosed irritable bowel syndrome, 96% had shared information about their problem with others, but only 10% had told their employer about it. Of those formally diagnosed, 60% felt that their condition would be with them for life and that they had a real medical condition.

Consultations and use of health services

Of all the European irritable bowel syndrome sufferers, 17% had been seen in a hospital (as out-patients or as admissions) about their condition, 7% in the last 12 months, and 5% had been to hospital more than once. The types of health professionals consulted varied, but a general practitioner or a primary care physician had seen 90% of those formally diagnosed. Also, of those formally diagnosed 19% had been given the diagnosis on their first visit and 56% after 1–5 further visits to a clinician.

However, 37% of those who had not been formally diagnosed had not consulted a health professional about

Table 2. Type of clinician seen about irritable bowel syndrome at any stage: percentage of subjects with current symptoms

	Formally diagnosed (%)	Not formally diagnosed (%)
Seen no-one		37
GP/primary care physician	90	55
Gastroenterologist	28	12
Gynaecologist	6	6
Other hospital specialist	26	9

GP, general practitioner.

irritable bowel syndrome; the chief reasons cited were 'symptoms not serious enough' (72%) or 'learnt to live with it', 'too busy', 'don't like going to the doctor' (17%) (Table 2).

Treatments used and their perceived effectiveness

Of all sufferers with current symptoms, 69% had taken some form of therapy. Of those formally diagnosed, 50% had taken a prescription therapy, compared with 30% who had not been formally diagnosed; in contrast, 26% of the former had taken non-prescription products compared with 35% of the latter. Equal proportions in each category (19%) had tried what they regarded as 'natural remedies'. Daily medication was taken by 19% of those formally diagnosed, compared with 13% of those not formally diagnosed; 53% in each group reported taking a product intermittently only when having symptoms, and 27% and 33%, respectively, reported taking no products of any sort.

The respondents' perceptions of the effectiveness of the treatments they used varied. Asked to categorize the extent of overall satisfaction, 38% said they were 'completely' or 'very' satisfied, 47% 'somewhat' satisfied and 15% 'not very' or 'not at all' satisfied. In terms of specific symptoms, the following proportions of irritable bowel syndrome sufferers reported complete relief with their treatments: abdominal pain, 24%; bloating, 11%; heartburn, 24%; trapped wind, 12%; diarrhoea, 17%; constipation, 15%; tightness of clothing, 9%; tiredness, 4%.

DISCUSSION

This study confirmed the feasibility of using proven market research methodology to conduct a large-scale clinical survey. By setting a target for the number of

respondents required, it was possible to circumvent some of the problems associated with low response rates in conventional surveys. The technique enabled data to be collected successfully from multiple locations using a standardized approach. Theoretical problems existed in terms of representativeness, for example in relation to unlisted and non-telephone holders, non-co-operative responders and the sensitive nature of the enquiries. However, the design compensated for these factors by targeting sub-groups, and respondent validity was enhanced by the two-stage enquiry process which avoided detailed questions in the first interview. The results were necessarily based on the respondents' perceptions and recollections and we believe them to be at least as accurate and reliable as those obtained from a conventional survey, with the added advantage of centrally audited quality.

The overall prevalence of irritable bowel syndrome across Europe was 11.5%, with 9.6% of these having current symptoms. There was a striking difference in the prevalence of current irritable bowel syndrome between individual countries, ranging from 6.2% to 12%, and a large difference between those with current symptoms who had been formally diagnosed (2.8%) and those who had not (6.8%).

The larger number of formally diagnosed cases in some countries accounts for the higher prevalence in those countries. This suggests that, in some countries, doctors may be more reluctant to diagnose the condition or that patients with irritable bowel syndrome do not consult so often. Another possibility is that this is a function of the way in which patients perceive their symptoms and present to a clinician, or the interpretation and labelling of the symptoms by the clinicians. However, there was no consistency in the results depending on whether countries had a primary care-based entry into the health system (e.g. UK, Holland) or those into mixed or secondary care entry systems (e.g. Germany, France). When the values for subjects who had not been formally diagnosed were considered on their own, there was still some variation, suggesting that there might be a true difference between countries. It may be of interest in the future to attempt to correlate these findings with the cultural and dietary habits in various countries.

The study reflected impressions about the variations in diagnostic rates obtained using the Manning, Rome I and Rome II criteria.¹⁷ Not unexpectedly, the highest overall prevalence was obtained with the Manning criteria (6.5%), followed by the Rome I (4.2%) and

Rome II (2.9%) criteria. A feature of the Rome II classification is the sub-division of sufferers into either diarrhoea-predominant or constipation-predominant categories. In this study, the majority (63%) of those to whom the Rome II criteria were applied did not fit into these categories, and they reported an alternating bowel movement pattern. Furthermore, there was a discrepancy between the responses obtained on direct questioning of the respondents and the Rome II categorization; indeed, 18% were unable to state which category they fell into. These findings call into question the applicability of the Rome II criteria for clinical practice, and the generalizability to all irritable bowel syndrome patients of trial results using this classification.

The study highlighted the considerable impact of irritable bowel syndrome upon sufferers' health and lifestyle. Irritable bowel syndrome was confirmed as a long-lasting, recurring disorder, with 40% having been diagnosed for 10 years or more, and 59% of these experiencing current symptoms. Nearly 70% had symptoms for 1–9 days per month, and sufferers reported a greater impact on their general health and lifestyle than non-sufferers. A hitherto, possibly underrated, symptom was the preponderance of tiredness (reported by 60%). Levels of co-morbidity tended to be higher, particularly for dyspepsia, reflux and depression, and 17% had been seen in hospital for their irritable bowel syndrome. The study highlighted some of the differences between consulters and non-consulters, inferring that consultation was related to the perceived seriousness of symptoms, and also that a high proportion of all current sufferers (69%) had tried some form of therapy. Sufferers' responses highlighted the current lack of efficacious remedies;¹⁸ overall satisfaction with therapies was 38%, a figure strikingly close to the placebo response rate in most studies of functional problems.

The results of this study confirm some previous observations in irritable bowel syndrome and introduce some new perspectives which should help health care planning in this therapeutic area.

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