Prevalence of irritable bowel syndrome in the French population according to the Rome I criteria

Gilles BOMMELAER (1), Etienne DORVAL (2), Philippe DENIS (3), Pierre CZERNICHOW (4), Jacques FREXINOS (5), Alain PELC (6), Alain SLAMA (7), Abdelkader EL HASNAOUI (7)

SUMMARY

Background — Irritable bowel syndrome (IBS) is a common functional gastro-intestinal disease. In the absence of specific markers, definition and hence diagnosis depend on clinical presentation. Of the various attempts to set criteria for IBS, the most recent are Rome I and Rome II classifications.

Aims — To estimate in a general population the prevalence of IBS using the modified Rome I criteria, and to investigate sociodemographic criteria, symptoms and management.

Methods — A total of 11,131 people aged 18 years and over, representative of the French population, were surveyed. A diagnostic questionnaire based on the modified Rome I criteria was used to identify IBS sufferers, who were then questioned further about the symptoms and medical management of their IBS.

Results — Of the 5,299 men and 5,832 women interviewed, 445 had IBS according to the Rome I criteria, a prevalence of 4% (95% CI: 3.6%-4.4%). IBS was more frequent in women (5.3%) than in men (2.5%), with a sex ratio (F/M) of 2.3. In 9.1% of sufferers, onset had occurred less than 12 months ago, a yearly incidence of 3.6 per 1,000 of the population. In 32.3% of IBS suffers diarrhoea was predominant, and in 34.6% constipation was predominant. Of IBS sufferers 83.7% had consulted a physician for their condition, and 87.6% had taken medication for their IBS symptoms over the previous 12 months.

Conclusion — The prevalence of IBS observed in this study in France was close to the lower limit in published data (3 to 20%). Our results suggest that the Rome I criteria are not sensitive enough to detect all IBS patients in a population not actively seeking healthcare intervention for the condition. In this regard, the refined classification (Rome II) which was established after our study was carried-out should be evaluated.

RÉSUMÉ

Prévalence du syndrome de l’intestin irritable selon les critères de Rome I dans la population française

Gilles BOMMELAER, Etienne DORVAL, Philippe DENIS, Pierre CZERNICHOW, Jacques FREXINOS, Alain PELC, Alain SLAMA, Abdelkader EL HASNAOUI

Introduction — Le Syndrome de l’Intestin Irritable (SII) est une pathologie fonctionnelle digestive fréquente. En l’absence de marqueurs spécifiques, la définition et le diagnostic de la maladie reposent sur les caractéristiques cliniques. Parmi les nombreuses tentatives de définition, les plus récentes sont les classifications de Rome I et Rome II.

Objectif — Estimer la prévalence du SII en population générale selon les critères de Rome I modifiés et décrire les caractéristiques socio-démographiques, cliniques et la prise en charge des malades.

Méthodes — Une enquête a été réalisée auprès de 11 131 sujets âgés d’au moins 18 ans, représentatifs de la population française. Un questionnaire diagnostique basé sur les critères de Rome I modifiés était utilisé pour identifier les malades souffrant de SII. Ces derniers répondraient ensuite à un questionnaire sur la symptomatologie fonctionnelle et le recours aux soins.

Résultats — Parmi les 5 299 hommes et 5 832 femmes interviewées, 445 avaient un SII selon les critères de Rome I, soit une prévalence de 4% (IC95% : 3.6%-4.4%). Le SII était plus fréquent chez les femmes (5.3 %) que chez les hommes (2.5 %), soit un sex-ratio F/H de 2.3. Chez 9.1 % des sujets atteints de SII, l’ancienneté des troubles était inférieure à 1 an correspondant à une incidence annuelle de 3.6 pour 1 000 habitants. Les troubles du transit étaient à prédominance de diarrhée chez 32.3 % des malades et de constipation chez 34.6 %. Parmi les malades souffrant de SII, 83.7 % avaient consulté un médecin et 87.6 % avaient été traités pour leurs symptômes digestifs au cours des 12 derniers mois.

Conclusion — La prévalence observée dans cette étude approche la borne inférieure des données publiées (3 à 20 %). Nos résultats suggèrent que les critères de Rome I sont peu sensibles et ne permettent pas d’identifier l’ensemble des sujets avec SII n’ayant pas recours aux soins. De ce point de vue, la classification de Rome II publiée après la période de la présente étude, devrait être évaluée.

Irritable bowel syndrome (IBS) is one of the most common functional gastro-intestinal diseases. IBS remains frustratingly difficult to diagnose with certainty as there are no clear diagnostic markers, probably because no single pathophysiological abnormality clearly separates IBS from either organic gastro-intestinal disease or normal individuals [1]. Diagnosis and definition of IBS are therefore based on clinical presentation, and there have been several attempts to define the way of distinguishing symptoms of IBS from those of organic gastro-intestinal diseases. In 1978, Manning demonstrated that four symptoms were significantly more common in the IBS than in the organic gastro-intestinal disease: abdominal distention, relief of pain on defaecation, more frequent stools with onset of pain, and looser stools with onset of pain [2]. Although Manning’s
criteria have been well accepted, they were shown to be not highly sensitive [3]. An expert working party refined the criteria on the basis of other epidemiologic data and Kruss’ observations which included also the chronicity of symptoms [4]. These diagnostic guidelines are known as Rome I criteria and were published in 1989 [5]. A revised version of Rome I criteria added to the Manning’s list of symptoms that the requirement that certain symptoms should be present for at least 25% of the time [6-8]. These revised criteria have become known as the modified Rome I criteria. A more recent revision of the diagnostic criteria by an expert panel consensus has led to the Rome II criteria [9].

Estimated prevalences of IBS vary widely, and a survey of epidemiological studies found figures from 6.6% up to 21.8% [10]. This variation is unlikely to be due to cultural or racial differences, as studies in one country showed similar diversity in their findings; a big american population-based cross-sectional survey suggested that the prevalence of IBS varies substantially depending on the specific definition of IBS used [11]. In France, Bommelaer et al. and Pauwels et al., using different definitions of the disease, found that prevalence was 13% [12] and 3.4% [13] respectively.

As Rome criteria were established on the basis of an expert panel consensus, it was mostly useful to check their efficacy in selecting IBS patients on a general population survey. The main objective of this study was to estimate the prevalence and incidence of IBS in the French population using the modified Rome I criteria, which were the criteria generally used at the time the study was initiated, in 1999.

Methods

Objectives

The primary objective of this study was to estimate the prevalence and incidence of IBS in the French population using the modified Rome I criteria (table I). Secondary objectives were to examine in detail the clinical characteristics of the condition (including the predominance of diarrhea or constipation), to survey the medical management of IBS, and to define the socio-demographic characteristics of IBS sufferers.

Design, methods and population

This was an observational, cross-sectional study of a representative sample of the overall French population aged 18 years and more. The sample was recruited in six weekly stages; at each stage respondents were selected in order to fulfill a quota in terms of age, sex, region of residence, and educational level.

The study consisted in a two-phase survey. The first phase was conducted using a diagnostic questionnaire (figure 1) based on the modified Rome I criteria (table I), with a representative sample of the overall French population of at least 18 years, in order to identify a sub-sample of patients with IBS and to evaluate the prevalence of IBS in France. The second phase was aimed at describing, in those patients identified during the first phase, the clinical features of the IBS, to assess its impact on their daily living, and to identify the therapeutic management of their disease.

Prior to the study, a two-part pilot phase was carried-out to validate the acceptability of the questionnaires, i.e., to verify whether the way questions were formulated in the two questionnaires to be utilized during the survey was likely to draw satisfactory responses in terms of data management. During the first (qualitative) part, open questions were asked to 10 subjects (6 IBS patients, 4 IBS-free subjects) in order to identify their wording when speaking about their intestinal discomfort. This wording was then utilized, in the second (quantitative) part of this pilot phase, to formulate the questions which were asked to 370 subjects (320 IBS-free subjects, 50 IBS patients) before validating the final version of the questionnaires.

Data were collected in face-to-face interviews conducted by the population-based survey research organisation SOFRES during the period 9th April 1999 to 13th July 1999. A computer system (Computer Assisted Personal Interview — CAPI) was used to identify IBS sufferers by analysis of the diagnostic questionnaires.

The diagnostic questionnaire (figure 1) designed to identify IBS sufferers was based on the modified Rome I criteria (table I), i.e., the recurrent symptoms at least three months per year. Interviewees identified as IBS sufferers answered a second questionnaire about the characteristics of their symptoms and the medical management of their IBS. This clinical questionnaire was based on questions to be answered by yes/no and multiple choice answers verbally cited by the interviewer, with corresponding number of points. The questions were aimed at determining the periodicity of IBS onset, the abdominal pain topography, the IBS duration and history, the medical management of the IBS, the assessment of patients’ quality of life and impact of the IBS on daily living, and finally the assessment of nutritional habits.

The abdominal pain topography was established using a 9-zone graphical illustration of the abdomen which allowed patients to indicate the painful region: right hypochondrium, epigastrium, left hypochondrium, right and left para-umbilical regions, umbilical region, right and left iliac fossae, and hypogastrium.

Intensity of pain was assessed according to a verbal 5-degree rating scale (1 = very mild, 2 = mild, 3 = moderate, 4 = severe, 5 = extreme).

Statistical analysis

Data management and statistical analysis were carried out using the statistical analysis software package Statistical Analysis System (SAS). Descriptive statistics included frequency distributions, means, medians and standard deviations. Two-tailed statistical tests were conducted with the significance level set at 5%. The overall prevalence of IBS, prevalence in sub-populations

<table>
<thead>
<tr>
<th>Table I. — Modified Rome I criteria used for the diagnostic questionnaire.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critères de Rome I modifiés, utilisés pour la constitution du questionnaire diagnostique.</td>
</tr>
<tr>
<td>At least three months of recurrent symptoms of:</td>
</tr>
<tr>
<td>1. Abdominal pain or discomfort relieved with defecation, or associated with a change in stool frequency, or associated with a change in stool consistency and</td>
</tr>
<tr>
<td>— altered stool frequency</td>
</tr>
<tr>
<td>— altered stool form</td>
</tr>
<tr>
<td>— altered stool passage</td>
</tr>
<tr>
<td>— passage of mucus</td>
</tr>
<tr>
<td>— bloating or distension</td>
</tr>
<tr>
<td>2. Two or more of the following on at least 25% of occasions or days:</td>
</tr>
</tbody>
</table>

**Abbreviation: IBS** : Irritable Bowel Syndrome

**Statistical analysis**

Data management and statistical analysis were carried out using the statistical analysis software package Statistical Analysis System (SAS). Descriptive statistics included frequency distributions, means, medians and standard deviations. Two-tailed statistical tests were conducted with the significance level set at 5%. The overall prevalence of IBS, prevalence in sub-populations
and prevalence of the various clinical presentations were estimated from the corresponding frequencies in the sample. The incidence of IBS was estimated from the proportion of patients whose symptoms had begun within the previous 12 months.

### Results

#### Population sample

A total of 11,131 subjects aged 18 years and more were interviewed: 5,299 men (47.6%) and 5,832 women (52.4%). Comparison with data from the French national statistical office (Institut National de la Statistique et des Etudes Economiques — INSEE) [14], showed that the study population was representative of the French population as a whole in terms of age, sex, regional distribution and socio-professional category.

#### Prevalence and incidence of IBS

The prevalence of IBS in the whole population surveyed was estimated to be 4.0%, with women more likely to be affected than men in the ratio 2.3:1 (table II). The annual incidence of the disease was estimated to be 3.6 cases per 1,000 of the population. Prevalence and incidence did not vary significantly across the age groups, educational levels, community size, or regions.

Of the 445 IBS patients identified by the diagnostic questionnaire, 351 (79%) agreed to respond to the second questionnaire about the characteristics of symptoms and the medical management. Responders tended to be younger than non-responders (table III).

The type of transit disorder, classified as “predominant diarrhoea”, “predominant constipation”, “alternating diarrhoea/constipation” according to the patient’s evaluation, was distributed in equal thirds across the total population (table IV). However, as it can be seen in table IV, analysis by sex showed differences in presentation: in women, constipation predominance was more prevalent than diarrhea predominance, whilst in men diarrhea predominance was more frequent than constipation predominance. In contrast, there was no difference between men and women in the proportion of sufferers reporting alternating diarrhea and constipation.
reported suffering daily during their periods of discomfort. Moderate, severe, and extreme pain, respectively, and 20% reported moderate to extreme intensity: 43.8%, 35.2%, and 5.2% reported 43.3%). Location of IBS pain varied considerably. The areas in which pain was most frequently reported were the hypogastrium (53.8%), the umbilical (36.5%) and para-umbilical (right: 19.4%, left: 17.9%) regions, and the iliac fossae (right: 42.7%, left: 53.8%), the umbilical (36.5%) and para-umbilical (right: 19.4%, left: 17.9%) regions, and the iliac fossae (right: 42.7%, left: 43.3%).

Table III

<table>
<thead>
<tr>
<th>Age range</th>
<th>Responders</th>
<th>Non-responders</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>n = 351</td>
<td>94</td>
</tr>
<tr>
<td>18-24 years</td>
<td>n (%)</td>
<td>44 (12.5)</td>
</tr>
<tr>
<td>25-34 years</td>
<td>n (%)</td>
<td>81 (23.1)</td>
</tr>
<tr>
<td>35-49 years</td>
<td>n (%)</td>
<td>96 (27.4)</td>
</tr>
<tr>
<td>50 years and over</td>
<td>n (%)</td>
<td>130 (37.0)</td>
</tr>
</tbody>
</table>

Time since IBS onset

Almost 70% of sufferers had experienced IBS symptoms for at least three years, of whom 42% reported at least ten years and 28% 3-10 years of symptom history. In 21.4% of IBS patients, symptoms were reported with a 1-3 years duration and in 9.1% of IBS sufferers symptoms had emerged in the course of the previous year (incident cases).

IBS symptoms

Location of IBS pain varied considerably. The areas in which pain was most frequently reported were the hypogastrium (53.8%), the umbilical (36.5%) and para-umbilical (right: 19.4%, left: 17.9%) regions, and the iliac fossae (right: 42.7%, left: 43.3%).

Over 80% of respondents considered the pain to be of moderate to extreme intensity: 43.8%, 35.2%, and 5.2% reported moderate, severe, and extreme pain, respectively, and 20% reported suffering daily during their periods of discomfort.

Table IV

| Predominant constipation n (%) | 100 (42.0) |
| Alternating diarrhoea and constipation n (%) | 75 (31.5) |
| Predominant diarrhoea n (%) | 63 (26.5) |

Management of IBS

Approximately 27% of patients declared previous hospitalisation in the past for their intestinal disorders, with a mean number of 2.2 hospitalisations including those necessary to conduct complementary investigations. Recourse to medical treatment was frequent amongst IBS sufferers, and 83.7% had previously consulted a physician for their intestinal disorders. Within the 12 months prior to the study, 70% had seen a general practitioner (mean annual frequency of visits: 6); other specialists consulted included gastroenterologists for 26% of the patients and gynaecologists for 25% of the women (mean annual frequency of visits: 2, and 2.4, respectively), and hospital doctors were consulted by 14.5% (mean frequency of visits: 3). There was no significant difference between the types of physician treating the disease as a function of disease duration. Complementary investigations were conducted during this period in two thirds of patients, consisting mainly of abdominal ultrasound (41%), barium enema (36%), colonoscopy (32%) and stool examination (30%). Intestinal disorders required medical treatment in 87.6% of sufferers, who used a mean of 1.8 ± 1.3 medications during the year preceding the study. No significant difference between men and women was noted on this item. Over two-thirds of sufferers took medication only during periods of discomfort and
18% took medication continuously. The main types of medication reported were antacids and antiflatulents followed by antidiarhoeals, laxatives, and antispasmodics (table V).

**Discussion**

In 1996, Drossman et al. surveyed the results of epidemiological studies conducted in North America and Europe on the prevalence of IBS [10]. The authors of the survey pointed out that some of the studies were not representative of the overall population, in that they over-represented racial minorities. However, this could not explain the range of results. A more recent retrospective survey showed a small degree of overlap between self-reported patients suffering from IBS and those identified by the Rome I and Manning criteria, with 50.6% of self-reporters having IBS according to Manning criteria, and only 31.8% having IBS according to Rome I criteria [16].

The present study shows a 4.0% prevalence of IBS, a prevalence lower than in any of the surveys discussed by Drossman et al. [10] and only a little above Pouwel’s low estimate of 3.4% [13]. However, the result is in agreement with the surveys based on large cohort of subjects published by Hahn et al. which used the Rome I criteria and found that 3% of the US population suffered from IBS [15] and by Boyce et al. which found 4.4% of IBS prevalence in the Australian population according to the Rome I criteria [17]. The sample used in the present study is a very large one, twice as large as the sample in the biggest survey cited by Drossman et al., and has been shown to be representative of the French population as a whole. The high frequency with which the sufferers identified in this study had recourse to physicians or other practitioners (87.6%) indicates that the diagnostic criteria used are picking up mainly the more severe IBS cases. Some surveys suggest that no more than 33% of IBS sufferers consult their physician [18]. Those who do seek help are the most severely affected: Heaton et al. found that the likelihood of an IBS sufferer consulting a physician was directly proportional to the severity of the condition, or that the Rome I criteria for defining IBS are too restrictive. A validation study of the Rome I criteria showed a sensitivity of 63%, a specificity of 100%, a positive predictive value of 100% and a negative predictive value of 76% [21]. The present study seems to confirm that the Rome I criteria are not sufficiently sensitive to pick up all those in the population who suffer from IBS.

Other studies which have compared different criteria for identifying IBS have shown that the Rome I criteria identified the smallest number of sufferers. Surveys using the Manning criteria have resulted in estimates of prevalence nearly three times as great as those using the Rome I criteria [11, 15]. This disparity suggests that, either the broad term IBS applies to more than one condition, or that the Rome I criteria for defining IBS are too restrictive. A validation study of the Rome I criteria showed a sensitivity of 63%, a specificity of 100%, a positive predictive value of 100% and a negative predictive value of 76% [21]. The present study confirms that the Rome I criteria are not sufficiently sensitive to pick up all those in the population who suffer from IBS.

The study confirmed as widely reported in the literature [15] that the prevalence of IBS is greater in women and showed that the three subtypes of IBS, those in which constipation predominated, diarrhea predominated, and those in which the two transit disorders alternated, were equally frequent. The study confirmed

**Table V. – Medication taken for intestinal disorders in the preceding 12 months.**

<table>
<thead>
<tr>
<th>Type of medication</th>
<th>%</th>
<th>95 % CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antacids/antiflatulants</td>
<td>41.9</td>
<td>36.0%-47.8%</td>
</tr>
<tr>
<td>Antidiarhoeals</td>
<td>35.7</td>
<td>30.0%-41.4%</td>
</tr>
<tr>
<td>Laxatives</td>
<td>34.6</td>
<td>28.9%-40.2%</td>
</tr>
<tr>
<td>Antispasmodics</td>
<td>29.8</td>
<td>24.3%-35.2%</td>
</tr>
<tr>
<td>Prokinetics</td>
<td>15.4</td>
<td>11.1%-19.7%</td>
</tr>
<tr>
<td>Miscellaneous drugs (herbal teas, homeopathics)</td>
<td>8.5</td>
<td>5.1%-11.8%</td>
</tr>
<tr>
<td>Anti-ulcer drugs</td>
<td>7.4</td>
<td>4.3%-10.5%</td>
</tr>
<tr>
<td>Non narcotic analgesics</td>
<td>6.3</td>
<td>3.4%-9.1%</td>
</tr>
<tr>
<td>Cholecystaggreges</td>
<td>2.2</td>
<td>0.5%-4.0%</td>
</tr>
<tr>
<td>Tranquillisers</td>
<td>1.8</td>
<td>0.2%-3.4%</td>
</tr>
</tbody>
</table>
that IBS is a chronic condition: the majority of sufferers identified in this study had experienced symptoms for at least three years, and 40% for ten or more. Although the location of the pain varied, the majority of the sample found it moderate to extreme in intensity, and 20% reported suffering on a daily basis. Other symptoms were also common: feelings of gassiness or bloating, and an urgent need to defecate were reported by over 80% of respondents.

The amount of discomfort and the frequent use of healthcare resources, such as recourse to physicians, use of medication, and hospitalisations revealed by this study demonstrates that IBS is a major cause of morbidity in the general population and presents a substantial cost to society as a whole and, specifically, to healthcare providers. Accurate diagnosis is difficult and it is therefore important to apply criteria which identify IBS sufferers as accurately as possible and reduce the likelihood of unnecessary tests and treatment and their related cost.

In conclusion, the Rome I criteria identified only a small proportion, 4%, of the French population as suffering from IBS. Previous studies have suggested that there is a large population with symptoms consistent with a diagnosis of IBS, but which do not fit Rome I criteria. Moreover, a descriptive pragmatic survey [22] showed the widespread prevalence of functional digestive symptoms affecting 28 million French people, of whom more than 12.2 million (27% of French population) claimed to be inconvenienced by their symptoms. Impact on public health is undoubtedly greater than the estimates derived from studies designed in accordance with conventional nosological categories. We argue that use of the Rome I criteria will miss a large proportion of IBS sufferers in the community. However, as the condition is identified by symptoms, the Rome I and Rome II initiatives give highly specific symptom-based classifications of great importance, particularly for use in clinical trials. Further initiatives are needed to define the criteria with optimal sensitivity and specificity to detect all IBS patients in a population not actively seeking healthcare intervention for the condition.

REFERENCES

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