Use of Rome criteria for the diagnosis of irritable bowel syndrome in primary care: a survey among European countries

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Background and objectives The majority of patients with irritable bowel syndrome (IBS) are diagnosed and treated in primary care. The aim of this study was to investigate the implementation of the Rome criteria in daily primary care clinical practice and adherence of general practitioners (GPs) to recommended diagnostic approaches for IBS.

Patients and methods A survey consisting of 18 questions was distributed across 11 European countries and was used to assess GPs’ diagnostic approach of IBS, the use of Rome criteria in daily practice and GPs’ perspective on the aetiology of the disorder.

Results Overall, 185 GPs completed the survey. In daily clinical practice, 32% of GPs reported that they usually make a positive diagnosis on the basis of symptoms only, whereas 36% of GPs reported regular use of the Rome criteria to diagnose IBS. Furthermore, 62% of the respondents reported that they applied additional diagnostics, such as blood tests, 31% found it necessary to perform endoscopy to make a positive diagnosis of IBS and 29% referred patients with IBS to a specialist. Psychological factors were the most frequently selected potential aetiological factor of IBS (88% of GPs). Overall, 52% of GPs reported systematically including questions on psychological symptoms in the assessment of history of IBS.

Conclusion Only about one-third of GPs regularly used the Rome criteria to diagnose IBS. In daily primary care practice, IBS largely remains a diagnosis of exclusion. This has implications in terms of GPs’ specialty training and questions the applicability of IBS guidelines in daily care, which advocate an early, positive, symptom-based diagnosis. Eur J Gastroenterol Hepatol 00:000-000

Keywords: diagnosis, general practitioner, irritable bowel syndrome, primary care, Rome criteria

Introduction

Irritable bowel syndrome (IBS) is a prevalent functional gastrointestinal (GI) disorder characterized by chronic recurrent abdominal pain and altered bowel habits. It affects around 10% of the population globally [1]. Although IBS may lead to significant quality-of-life impairment in affected patients, only a minority of patients with IBS seek medical assistance and most of those who do are managed in primary care [1–3]. IBS is a symptom-based diagnosis and making a positive diagnosis is challenging. Recently updated Rome IV criteria have been published, which can be used to make a positive diagnosis on the basis of symptoms in the absence of ‘red flags’ [4,5]. These criteria indicate that for the diagnosis of IBS, recurrent abdominal pain has to be present on average at least 1 day a week in the last 3 months, associated with at least two of the following: (i) related to defecation, (ii) associated with change in frequency and/or (iii) consistency of stool [4]. Alarm symptoms or red flags that should trigger a physician to exclude organic disorders are unexplained weight loss, severe progressive worsening of symptoms, nocturnal diarrhoea, rectal blood loss or melena, anaemia, symptom onset at older than 50 years of age and a family history of organic GI disorders [3]. Routine diagnostic testing has been shown to have a generally low yield in patients who fulfil symptom-based criteria for IBS without alarm symptoms [6,7]. Guidelines generally advise patients with IBS to be managed in primary care without additional invasive diagnostic procedures when alarm symptoms are absent [8]. Nevertheless, in everyday practice, many health care providers approach IBS as a diagnosis by exclusion [9,10]. A significant proportion of patients with IBS are referred to secondary care for further diagnostics to exclude organic causes [2]. This approach is, to some extent, supported by studies indicating that the symptom-based criteria do not provide optimal diagnostic performance in the exclusion of organic disease in patients suspected of having IBS [11,12]. However, when considering the high pretest probability
The questionnaire was sent to GPs in 11 European countries, selected on the basis of geographical cardinal directions, that is, north (Sweden, Norway, Estonia), east (Poland, Czech Republic), south (Greece, Italy, Spain) and west (the Netherlands, the UK). Random selection of GPs per country was not possible because of differences in primary care systems and the lack of contact information of all GPs per country. Therefore, in every country, a researcher who was familiar with the country’s primary care system sent the questionnaire by e-mail to 50–100 GPs pragmatically selected to represent the diversity of GPs in that country on the basis of the geographical region, type of practice, involvement in teaching, location of the practice and experience of the physician. The selection of GPs to be contacted was performed by each country representative separately per country. GPs received two reminders.

Statistical methods

Data analyses were carried out using IBM SPSS Statistics, version 22.0 (IBM Statistics for Windows, Armonk, New York, USA). Correlations between the categorical survey data were tested using Spearman’s rank-order correlation. Regional differences and differences between types of practices were assessed using the Pearson $\chi^2$-test.

Results

One hundred and eighty five GPs completed the questionnaire. The baseline characteristics are presented in Table 1.

Diagnosis of irritable bowel syndrome

Thirteen questions were related to the diagnosis of IBS (Table 2). In their daily practice, 32% of the 185 GPs usually made a positive diagnosis of IBS on the basis of symptoms only, half of which were based on the Rome criteria. Overall, 36% used the Rome criteria regularly, whereas 39% did not use these to diagnose IBS. Furthermore, 45% of GPs who indicated that they used the Rome criteria regularly applied laboratory tests or endoscopy as well before making the diagnosis. Overall, 62% of GPs performed laboratory blood tests to rule out organic causes and 31% indicated that endoscopy was required before making a definite diagnosis of IBS. In addition, most GPs (75%) could order a colonoscopy without referral to a specialist, which was not country dependent, and furthermore, did not significantly correlate to the previous question on the need for endoscopy before making a positive diagnosis of IBS.

Referral of potential patients with irritable bowel syndrome by the general practitioner

Questions on referral of potential patients with IBS are presented in Table 3. Of the 185 GPs, 25% indicated that they were not confident in making the diagnosis of IBS without referral to a GI specialist. In line with this, 29% indicated that they made a referral to a specialist in secondary care to confirm the diagnosis of IBS. These answers correlated significantly (Spearman’s $\rho = 0.52$, $P < 0.001$).
Table 2. Diagnosis of irritable bowel syndrome

<table>
<thead>
<tr>
<th>Total number of responders: 185 Agree (%)</th>
<th>Neutral (%)</th>
<th>Disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In my clinical practice I usually make a positive diagnosis of IBS based on symptoms only</td>
<td>32</td>
<td>28</td>
</tr>
<tr>
<td>My specialist colleagues advise me to make a positive diagnosis of IBS based on symptoms</td>
<td>26</td>
<td>31</td>
</tr>
<tr>
<td>I use the Rome criteria to make a positive diagnosis of IBS</td>
<td>36</td>
<td>25</td>
</tr>
<tr>
<td>I routinely use laboratory blood tests in diagnosing IBS to rule out other organic causes</td>
<td>62</td>
<td>14</td>
</tr>
<tr>
<td>I believe that colonoscopy or sigmoidoscopy is necessary to make a diagnosis of IBS</td>
<td>31</td>
<td>24</td>
</tr>
<tr>
<td>I can directly order a colonoscopy or sigmoidoscopy as a general practitioner</td>
<td>75</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3. Referral of patients with irritable bowel syndrome by the general practitioner

<table>
<thead>
<tr>
<th>Total number of responders: 185</th>
<th>Agree (%)</th>
<th>Neutral (%)</th>
<th>Disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not confident in making the diagnosis of IBS without referral to a GI specialist</td>
<td>25</td>
<td>16</td>
<td>59</td>
</tr>
<tr>
<td>To confirm a diagnosis of IBS I usually make a referral to a specialist in secondary care</td>
<td>29</td>
<td>21</td>
<td>50</td>
</tr>
<tr>
<td>My specialist colleagues hospital care usually order a colonoscopy or sigmoidoscopy before making a diagnosis of IBS</td>
<td>65</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>I trust a secondary care specialist’s diagnosis of IBS, even when no lower GI investigation has been done</td>
<td>44</td>
<td>26</td>
<td>30</td>
</tr>
<tr>
<td>I am under pressure to limit referrals to secondary care specialists</td>
<td>21</td>
<td>27</td>
<td>52</td>
</tr>
</tbody>
</table>

Fig. 1. Aetiology of irritable bowel syndrome according to the general practitioners (GPs) included (three answers provided by each GP). GI, gastrointestinal; IBS, irritable bowel syndrome.

About two-third of GPs (65%) indicated that specialists in secondary care usually perform endoscopic investigations before making the diagnosis of IBS. Only 44% of the GPs indicated that they trusted the diagnosis of IBS made by a specialist colleague if no endoscopy was performed. At the same time, 21% felt under pressure to limit referrals to a specialist.

Regional differences and differences between types of practices

Differences between geographical regions in Europe (Table 1) were assessed (P < 0.05 provided) as this could not be done for individual countries because of small sample numbers. In the western region, most GPs usually made a positive diagnosis of IBS on the basis of symptoms only, that is, 49% (P = 0.04 vs. north, P = 0.02 vs. east) compared with 43% in the southern and 24% in the northern and eastern countries. However, the Rome criteria were regularly applied by 22% GPs in both the western (P = 0.03 vs. east, P = 0.01 vs. south) and the northern regions (P = 0.01 vs. south), whereas this was higher for eastern and southern countries, that is, 42 and 73%, respectively (P = 0.02 east vs. south). The percentage of GPs who performed laboratory blood tests to rule out organic causes was 74, 62, 35 and 64% for north (P = 0.02 vs. east, P = 0.01 vs. south), east (P = 0.02 vs. south, P = 0.04 vs. west), south (P = 0.01 vs. west) and west, respectively. The number of GPs who indicated that endoscopy was needed before making a definite diagnosis of IBS was 31, 39, 23 and 22% for north, east (P = 0.02 vs. south, P = 0.03 vs. west), south and west, respectively. It has to be noted that the southern region is represented by only 23 GPs. Differences with respect to referral of potential patients with IBS to a specialist were not statistically significant.

The use of the Rome criteria did not differ significantly on the basis of type of practice. When comparing GPs involved in any kind of teaching compared with those who are not, the use of the Rome criteria did not differ significantly (i.e. 38 vs. 25%, respectively, P = 0.53). Also, no differences were found for urban versus rural practices (P = 0.47).

Psychological factors

Two questions in the survey assessed the focus on psychological symptoms in the medical history of IBS patients. As shown in Fig. 1, the majority of GPs considered psychological factors such as stress, anxiety or depression to be an important contributing factor in the aetiology of IBS. Overall, 52% of the GPs indicated that they always included questions related to psychological comorbidity in their assessment of history when considering IBS a diagnostic possibility. In all, 47% included these questions only when they assume that psychological issues could be a contributing factor for that specific patient. With respect to questions of a possible history of sexual abuse, only 2% of GPs included such a question in the assessment of the medical history when considering IBS.

Aetiology of irritable bowel syndrome according to the general practitioners and the relation to psychological symptoms

The most important GP-perceived aetiological factors of IBS are presented in Fig. 1.
Discussion

This survey, conducted among 185 GPs from 11 countries across Europe, showed remarkable discrepancies between the recommendations of the Rome committee for the diagnosis of IBS and daily clinical practice in primary care.

A diagnosis, further tests and/or referral to a specialist

The diagnosis of IBS is made on the basis of symptoms and making a positive diagnosis can be challenging as typical features are not discriminative and accurate biomarkers in daily clinical practice are lacking [15,16]. Guidelines emphasize that IBS is not a diagnosis of exclusion and encourage physicians to make a positive diagnosis on the basis of symptom criteria in the absence of red flags [4]. It should be noted that serological tests for coeliac disease are considered useful in patients with diarrhea-predominant IBS on the basis of the increased pretest probability of coeliac disease [7]. Differences in the diagnostic approach related to IBS subtype have not been assessed in the present study.

Most patients with IBS are treated in primary care and therefore GPs need to be familiar with the Rome criteria [1,2]. In the present study, the use of the Rome criteria in primary care was assessed without specification on any version of the criteria, but the survey was conducted when the Rome III criteria were the current ones [5]. Notably, our survey showed that only about one-third (i.e. 36%) of the participating GPs regularly used the Rome criteria in daily clinical practice and that about two-third (62%) usually performed additional investigations before making a positive diagnosis of IBS. Furthermore, one-third of the GPs indicated that they considered endoscopy essential for a definite diagnosis of IBS and a comparable percentage usually referred patients to a specialist to confirm the diagnosis. Most GPs reported being involved in some form of teaching. Therefore, the nonadherence to guidelines with respect to IBS diagnosis may have implications in terms of GPs’ training.

In line with our findings, previous data from Europe and the US showed that more than two-thirds of primary and secondary care clinicians only diagnose IBS after excluding organic disease, instead of making a positive symptom-based diagnosis [9,10,17]. Furthermore, Bijkerk et al. [18] reported that out of 142 patients with IBS diagnosed by a GP, only 18% fulfilled the Rome II criteria. These findings are consistent over the years, which may give rise to questions on the appropriateness and applicability of guidelines, which advocate an early, positive, symptom-based diagnosis in daily practice for IBS [19]. In any case, our findings suggest that implementation of guidelines for IBS could be improved in primary care. In this way, the percentage of endoscopies and referrals could be reduced, probably improving the cost-effectiveness of health care. In a recent study, Flik and colleagues have shown that health care costs of patients with IBS in primary care increase significantly in the 3 years after the diagnosis by an additional 486 Euro annually. These costs were significantly higher for patients with IBS referred to secondary care, with an additional 2328 Euro annually [2]. Hence, referral of potential IBS should be restricted to patients with alarm symptoms or in case of diagnostic uncertainty.

Pressures towards tests and referral of patients

The need to be certain of the diagnosis because of fear of missing severe conditions, such as colorectal cancer, or cause delay, may place pressure on GPs [19,20]. Furthermore, a second opinion can be a powerful aid to reduce pressure from patients whose symptoms are not responding to primary care management and/or to increase patient satisfaction. Interestingly, although GPs are encouraged to make a positive, symptom-based diagnosis, our findings indicate that when patients are referred, specialists mostly perform further tests, including colonoscopies. This mixed message may reduce the applicability of the current guidelines in primary care.

In this survey, we did not ask whether patients were more likely to be investigated or referred if they fell into certain categories, for example, the older age groups or patients with psychological symptoms. This may have skewed the overall findings in terms of the relatively high referral rates that we found. Furthermore, patients who do not respond to therapy are usually managed differently from those who improve after treatment. Therefore, GPs might send the patient for further evaluation not on the first diagnosis, but later.

Psychological factors in the diagnosis of irritable bowel syndrome

The majority (i.e. 88%) of GPs pointed to psychological factors as the most important aetiopathological mechanism, followed by visceral hypersensitivity and altered gut motility. Half of the 185 GPs indicated that they included in their assessment of history questions on psychological symptoms. Anxiety and depression are commonly occurring comorbidities in IBS, but are not present in the majority of patients. The reported prevalence of clinically relevant symptoms of depression and anxiety in IBS varies between 20 and 40% [21–25] compared with 4–10% in the general population [25–27]. It has to be noted that these data are mostly based on hospital settings rather than primary care. Furthermore, patients with functional GI disorders in combination with comorbid psychiatric conditions are more often referred to somatic specialists than those without. These comorbidities are associated with increased GI symptom severity and a greater illness burden in patients with IBS, which may explain referrals to somatic consultants [28,29]. Physicians should assess whether clinically relevant anxiety or depressive symptoms are present, in particular, as adequate treatment of psychological comorbidity may be useful in improving GI symptoms [30].

For most gastroenterologists, the understanding of the IBS pathophysiology is changing, with a shift towards a multifactorial biological approach with acknowledgement of psychological factors as important modulators of symptom generation in a subgroup of patients [31–33]. However, most primary care physicians tend to view IBS as an abdominal expression of medically unexplained physical symptoms [28,34]. A disparity between patient and GP perception on the nature, severity and consequences of IBS is common in daily practice and may lead to patient dissatisfaction [35]. This dissatisfaction has also been related to limited information of the explanation of IBS provided by the physician, among others with respect
to aetiology [18,36–38]. The mismatch in expectations may negatively impact IBS disease outcome [35]. As the effect of therapies in IBS is low to moderate, improved education of patients could lead to a better understanding of their symptoms and to the development of more effective coping strategies. Therefore, accurate understanding of the nature of IBS is crucial for care givers. A recent review by Hungin et al. [39] integrates the current knowledge including pathophysiological changes, psychological distress, symptom perception and disease cognition in IBS in a model for clinicians to be used in daily clinical practice. The transfer of this knowledge to patients with IBS in an understandable, comprehensive way may improve the outcome of IBS in affected patients. Furthermore, better subgroup stratification of patients with IBS in the future could lead to more personalized somatic or psychological therapies [18,38].

**Study limitations**

Every country representative in the 11 European countries has used available databases of GPs to select a number of physicians for the survey. Although care was taken to approach GPs with different backgrounds, possible selection biases cannot be excluded. A high proportion of the participating GPs were involved in teaching and as a result may be more up to date on diagnostic criteria and guidelines, although differences in the use of Rome criteria were not statistically significant. Furthermore, one could also speculate that GPs with specific interest or expertise in this topic were more likely to respond to the survey. Nonresponders might have been those who were less interested in IBS and less familiar with current guidelines and diagnostic criteria. Differences in years of experience between GPs may influence the way in which they diagnose IBS in daily practice; however, we have not assessed this parameter in the present study. The response categories of some questions included the possibility of ‘neutral’, next to ‘agree’ and ‘disagree’, which could be interpreted in different ways. Differences between countries were not tested because of small sample numbers and differences between geographical regions should be interpreted with care for this reason.

**Conclusion**

This survey among primary care physicians in Europe showed that only about one-third of GPs regularly used the Rome criteria to diagnose IBS and that IBS largely remains a diagnosis of exclusion in daily clinical practice. This has implications in terms of GPs’ specialty training and it questions the applicability of current IBS guidelines, which advocate an early, positive, symptom-based diagnosis. As previous studies have shown negative medical and financial consequences of unnecessary diagnostic testing in the target population, efforts should be made to improve diagnosis by closer adherence to IBS guidelines.

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Z.M. co-designed and carried out the study and wrote the manuscript, D.J., A.M. and J.M. co-designed and supervised the study, P.H., J.K., C.L. and N.W. were involved in the selection of questions and data interpretation, and K.A.W., M.P. and V.L. were involved in data collection and interpretation. All authors reviewed the manuscript and approved the final version.

**Conflicts of interest**

There are no conflicts of interest.

**References**
