Impact of irritable bowel syndrome (IBS) on health-related quality of life (HRQOL)

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SUMMARY
Aims — To assess the impact of irritable bowel syndrome (IBS) on patient-reported health-related quality of life (HRQOL).
Methods — Two HRQOL instruments were administered by telephone interviews to a sample of 253 IBS French patients recruited from the general population. IBS was diagnosed according to the Manning, Rome I and Rome II criteria. Patients with organic diseases were excluded from the study. A generic instrument, the Short Form 36 (SF-36), and an IBS disease-specific instrument, the IBSQOL, were used.
Results — Patients with IBS had statistically significant (P < 0.05) lower scores for all SF-36 QOL domains compared with the general French population. Women (N = 192) reported significantly (P < 0.05) poorer HRQOL on both the SF-36 and the IBSQOL scores than men (N = 61) for all domains except energy on the SF-36 and the sleep on the IBSQOL. HRQOL deteriorated with time since onset of IBS symptoms for some domains such as diet. For both instruments, a positive correlation was observed between low scores and intensity of pain and discomfort. IBS patients with a predominance of diarrhea (N = 72) exhibited significantly greater impairment of HRQOL in the emotional domain than IBS persons with constipation predominance (N = 65) (P<0.05).
Conclusion — IBS has a significant impact on HRQOL of patients. In addition, specific characteristics such as gender, symptom severity and time since onset of symptoms are predictive of more impaired health-related quality of life.

Introduction
Irritable Bowel Syndrome (IBS) is an important public health problem, owing both to the high prevalence of this chronic condition and its impact on the patient’s quality-of-life (QOL). IBS is characterized by the often-associated presence of abdominal pain, intestinal disorders (diarrhea, constipation or alternation of the two), and abdominal bloating [1]. Symptoms may continue intermittently. The prevalence of the IBS is high, varying greatly between different surveys, depending on the more or less restrictive diagnostic criteria that are used. Using the diagnostic criteria generally applied for clinical research but not often used in daily practice, such as the Manning or the Rome criteria, the prevalence of this functional pathology is situated between 3 and 20% [2-4].
IBS is a chronic disorder; when monitored regularly, only 5% of patients remain symptom-free five years after symptom onset [5]. Though not life threatening, the chronic nature of the characteristic symptoms of IBS can have a strong impact on the patient’s QOL interfering with the different dimensions of daily living [6]. Leisure activities, work, travel, and social relationships are all affected by IBS [7] and often more so than in other diseases. It has been reported that the QOL of patients with IBS is not as good as that of patients with other gastrointestinal diseases, such as gastroesophageal reflux disease, or other chronic diseases such as asthma or migraine [8].

Considering these observations, it is particularly important in IBS to evaluate the patient’s perceived state of health. QOL can be assessed in two manners: globally using a generic QOL scale developed for the general population, or more specifically using a specific scale developed within the framework of the disease under study [9]. While the first approach allows comparison with healthy subjects or with patients presenting other symptoms, the second has the advantage of better taking into consideration the manifestations of illness and their causes in order to obtain a more precise assessment of treatment-related changes in the patient’s health status. It should also be noted that other factors related to the social environment - for example the cultural connotation of symptoms, facility of access to health care, or the nature of treatments undertaken [1] - can be determinant in the way IBS affects QOL. The goals of this investigation were to evaluate the impact of the disease on health-related QOL (HRQOL) of IBS patients recruited from the general population in France and to look for characteristic clinical and sociodemographic features which could affect the HRQOL of the population studied.

**Patients and methods**

**Population studied**

A sample from the general population aged 18 years and older was stratified by age and sex. Two series of investigations were conducted: the first involved 8,221 people representative of the French population (quota method) and the second a group of 1,475 people. Among the 9,696 people in the sample population, 280 were recognized as having IBS. IBS was identified with a screening questionnaire based on three selection algorithms: the Manning criteria according to the version used by Talley et al. [2,10], the Rome I criteria [3] and the Rome II criteria [4]. Organic diseases that would exclude the diagnosis of IBS (ulcerative colitis, Crohn’s disease, diverticulitis, colorectal cancer) were ruled out. In addition, 280 subjects fulfilling Rome II criteria were identified according to the following definition: for a cumulative period of three months or more during the previous twelve months, presence of abdominal pain or discomfort and responding to the symptomatic features described by the Manning and/or the Rome I and/or Rome II criteria. Of these 280 IBS subjects, 253 completed the HRQOL questionnaires (90.4%). Physicians specialized in gastroenterology or internal medicine interviewed these subjects by telephone between February and April 2000. The patient selection method and the investigation protocol have been described in detail elsewhere [11].

**HRQOL instruments**

Two HRQOL instruments were used: a generic scale, the SF-36 (Short Form 36), and a disease-specific scale, the IBSQOL (Irritable Bowel Syndrome Quality of Life). A validated version of the SF-36 was used (IQOLA SF-36 – V1.3-Oct. 1994, New England Medical Center Hospitals, Inc). This SF-36 measures eight domains of QOL: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, general health. The questionnaire has two to ten items for each of these domains. In addition to these eight domains, the SF-36 has a supplementary item relating to the perception of changes in the state of health in comparison with the preceding year [12-17]. For the disease-specific scale, we used the IBSQOL, originally developed in English, adapted to a culturally-specific French version. This scale contains 40 items measuring nine domains: emotional health, mental health, sleep, energy, physical functioning, physical role, diet, sexual relations, and social role [18]. For both scales, responses referred to the patient’s situation during the four preceding weeks (except for the special comparative item on the SF-36). The responses to items for the different domains were first recoded then scored according to the system described for each scale. QOL scores varied from 0 (very poor QOL) to 100 (excellent QOL).

**Data analysis**

A descriptive analysis of the demographic, social and clinical characteristics of the patients, as well as QOL scores, was performed first. Then, finer analyses were carried out by age, sex, and symptom duration and severity to search for factors having a determinant effect on QOL in the population studied. QOL scores from the SF-36 were crossed with IBS severity criteria. Disease severity was defined from time since symptom onset, intensity and frequency of abdominal pain, as well as the number of symptoms reported by the patient. The symptoms retained for analysis corresponded to the list of symptoms that were used to identify patients suffering from IBS: pain or abdominal discomfort attenuated by defecation, very frequent bowel movements or inversely very infrequent passage of stools, change in stool consistency; difficulty in evacuating fecal matter; reported presence of mucus in stools; bloated feeling. Student’s t test was used to search for significant differences between means. Two thresholds of significance were retained: 5:100 and 1:1000. SAS V8.00 for Windows™ was used for the statistical analysis.

**Results**

**Population**

Of the 253 subjects investigated, 76% were women and 24% were men, average age 48.3 years (range: 18 - 86 years). 96% of the subjects fulfilled the Manning criteria for IBS as given by the version used by Talley et al. [10], 83.4% Rome I criteria, and 45.9% Rome II criteria. No significant difference was observed between the men and the women. Symptoms were noted as far back as ten years for 36% of the interviewed subjects. The new cases (symptoms for less than one year) accounted for 16% of the patients. The main characteristics of patients are presented in figure 1. Using the definitions proposed by the Rome II criteria [4], 28.5% of subjects had diarrhea predominance symptoms and 25.7% constipation predominance. Diarrhea predominance was found more in men than women, and inversely constipation predominance more in women than men. About 6% of patients had two symptoms or less, 40% three or four symptoms and 54% five symptoms or more. The responses corresponded to the patient’s self-reported situation during the four weeks preceding the investigation. Close to 80% of the studied population reported abdominal pain (65.6% of the men and 82.3% of the women). Pain was “severe” or “very severe” for 46% of these patients and “mild to moderate” for 42%.

**Impact of IBS on Quality of Life**

**SF-36 score**

IBS subjects reported very significantly lower SF-36 QOL scores for all domains (P < 0.001, figure 1) in comparison with a sex- and age-matched general population published by Leplege et al. [19, 20]. Except for the energy domain, the SF-36 QOL scores were significantly lower for women than for men (P < 0.001 for physical functioning, physical role and emotional well-being, and P < 0.05 for the other domains) (figure 2). No age-related trends were observed, but subjects aged over

**ABBREVIATIONS:**

IBS : Irritable bowel syndrome
HRS QOL : Health-related quality of life

64 years (N = 55) had lower QOL scores than the younger subjects (except for the social role domain) with scores of less than 50 for half of the domains. SF-36 scores are presented by predominant transit disorders in figure 3. QOL was better among subjects with constipation predominance (N = 65) compared with those with diarrhea predominance (N = 72) but the difference was not statistically significant. QOL scores of subjects presenting alternating diarrhea - constipation were very similar to those of subjects with diarrhea predominance.

The SF-36 QOL scores were crossed with the following criteria of IBS severity: time since symptom onset, number of symptoms, frequency of abdominal pain, intensity of abdominal pain during the last four weeks. Search for a typical pattern of SF-36 scores as a function of time since symptom onset was unsuccessful. Analyzing the SF-36 scores by number of reported symptoms (considering symptoms used to define IBS) showed that, for five of the eight domains, scores were significantly higher (P ≤ 0.05) for subjects reporting one or two symptoms than subjects reporting five symptoms or more (figure 4). QOL scores were lower among subjects with permanent abdominal pain in comparison with those reporting intermittent pain. Nevertheless, only two domains, physical pain and general health, exhibited a significant difference (P ≤ 0.05). Lower QOL scores seemed to be correlated with the intensity of pain or abdominal discomfort. Considering two categories of patients according to the severity of pain experienced during the last four weeks (severe and very severe, N = 91 patients, versus mild to moderate, N = 107 patients), one observes that for five of the eight SF-36 domains, the QOL scores were significantly higher (P < 0.05) among subjects with mild to moderate pain (figure 5). Analysis by disease classification (Manning, Rome I, Rome II) revealed very little difference, probably because of the similarity of the definitions used.

**IBSQOL score**

The IBSQOL scores showed that, with the exception of the sleep domain, HRQOL was significantly poorer (P < 0.05) in women than men (figure 6) but that no age-related trends could be noted. Similarly, with the exception of the emotional health domain, there was no significant difference in the IBSQOL scores between the different types of IBS. The general pattern however was that subjects with diarrhea predominance had more altered QOL than the individuals with constipation predominance, except for physical functioning and sexual relations (figure 7). Here again it was noted that the QOL scores were similar for subjects presenting alternating diarrhea and constipation and those with diarrhea predominance.

Generally speaking, the analyses based on the criteria of severity of the IBS showed that deterioration of QOL of a given individual seemed to be associated with the severity of the IBS itself, the association being more or less apparent depending on the criterion studied. When analyzed by time since onset of
the reported symptom, the IBSQOL scores were significantly lower (P < 0.05) among subjects with IBS for five years or more (N = 139) than individuals who had IBS for less than five years (N = 112); this was true for two domains of the IBSQOL: physical functioning and diet. When analyzed by number of symptoms, the IBSQOL scores (figure 8) suggest globally that the more the individuals presented symptoms, the more their QOL declined. This was particularly apparent for three domains (emotional health, energy, social role) for which the QOL scores of the subjects reporting five symptoms or more were significantly (P < 0.05) lower than those of individuals reporting two symptoms or less. In addition, the subjects with permanent abdominal pain had, as a whole, lower QOL scores than those with intermittent pain. Nevertheless, a significant difference (P≤0.05) was observed only for two domains of the IBSQOL scale: emotional health and social role. On the other hand, with the exception of the mental health domain, all of the QOL scores were significantly higher for individuals who reported mild to moderate pain or abdominal discomfort during the four weeks preceding the investigation (N = 107) compared with those reporting severe or very severe pain or discomfort (N = 91) (figure 9). It was also observed that when pain or abdominal discomfort was considered very severe (N = 16), QOL scores were lower than in the presence of less severe pain or discomfort, particularly for the dimension “diet”. Again no differences were found between the different definitions of IBS considered.

**Fig. 5** – SF-36 scores by intensity of abdominal pain reported in two groups (severe-very severe vs mild-moderate).

**Scores SF-36 selon l’intensité des douleurs abdominales regroupées en 2 classes (extrême-forte vs modérée-légère).**

**Fig. 6** – IBSQOL scores by sex.

**Scores IBSQOL selon le sexe.**

**Fig. 7** – IBSQOL scores by characteristic bowel movement.

**Scores IBSQOL selon les caractéristiques des troubles du transit.**

**Fig. 8** – IBSQOL scores by number of symptoms.

**Scores IBSQOL selon le nombre de symtômes.**

**Discussion**

This investigation shows that IBS subjects recruitment from the general population in France have HRQOL scores, measured with the generic QOL scale SF-36, which are significantly lower (P < 0.001) than those of the general population. This result is in agreement with reports from American and other European studies [21-25]. This impact on QOL among IBS patients is greater than observed in individuals with other chronic conditions [8, 25]. Our results showed that IBS has a greater impact on QOL than obesity since QOL scores for all domains except physical function and physical role were lower in our IBS subjects compared to a sample of obese subjects (body mass index ≥ 30) [26]. This comparison should nevertheless be considered with caution since the age and sex distributions were different in the two populations. Except for the domains energy/fatigue of the SF-36 and sleep of the IBSQOL, QOL scores were significantly lower in women than men (P < 0.05). A study recently carried out in France by Coffer et al. on a sample of 858 IBS patients (Rome II criteria) attending gastroenterology consultations, showed similar differences between men and women whose QOL was measured with a specific instrument, the Gastrointestinal Quality of Life Index (GIQLI) [27].

The results of our study suggest that the QOL of patients is significantly more impaired with increasing intensity of pain or
abdominal discomfort. Similarly, we observed that QOL tended to deteriorate with increasing number of symptoms. This result is in agreement with Coffin et al. who demonstrated a significant correlation between symptom intensity and deterioration of QOL [27]. In a study conducted in the United States among 126 IBS patients, Hahn et al. also found a strong relation between the severity of patient-perceived disorders and the degradation of QOL [21]. These authors did not observe any significant differences between the patients presenting mild and moderate symptoms. Nevertheless, subjects who reported their symptoms as severe or very severe had a very poor QOL compared with those who reported their symptoms as moderate. This relationship was observed for six of the nine domains of the IBSQOL: emotional health, mental health, energy, physical functioning, physical role, social role). Symptoms related to altered bowel habit - constipation or diarrhea - did not seem to be determinant. Nevertheless, subjects with diarrhea predominance tended to have lower QOL scores than the other patients on the two considered scales. It was previously reported that an increase in the frequency of bowel movements is associated with a more marked deterioration of QOL [28]. Similarly, Coffin et al. observed that the subjects with a diarrhea profile had a greater deterioration of their QOL [27].

A comparison of our IBSQOL scores with those of a study conducted among American and English populations shows that globally for the majority of the domains the perceived QOL in our sample of French subjects was significantly better than observed in the samples of English or American subjects [21]. This result could be explained in part by the origin of the subjects; American and English IBS subjects were recruited through associations of patients while our sample of patients was recruited from the general population. Likewise, the method used to administer the questionnaires in our study (telephone interview) may have caused an underestimation of the QOL scores. In addition, the proportion of women and the average age of the patients were higher in the study by Hahn et al.

It should be recalled that data for the present study were collected by telephone interview. This method may have introduced a bias in the responses obtained for an instrument initially designed to be self-administered. In order to minimize this potential bias, interviewers were first trained then monitored to ensure they used good elocution during the interviews, did not influence the patient responses, left the patients respond freely without adding pressure, and did not reformulate the questions into wordings other than the ones presented in the two scales used. Moreover, the results obtained were in close agreement with earlier studies so that it would be reasonable to assume that the administration methodology had little or no impact on the results. Additional studies should be undertaken to check this point.

Finally, depression and anxiety are frequently observed among IBS patients, notably those with more severe conditions [29]. The domains of emotional well-being and mental health appear to have been the most strongly impaired in our study, exhibiting greater deterioration with increasing symptom severity. As suggested by other studies [30], these psychological states could well affect patient-perceived health status, but such patterns were not considered in our study.

In conclusion, IBS has a strong impact on HRQOL as demonstrated by the scores observed with the two generic and specific QOL instruments considered. Specific characteristics such as female gender, symptom severity, and time since symptom onset are associated with lower QOL.

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**Fig. 9** – IBSQOL scores by intensity of abdominal pain reported in two groups (severe-very severe vs mild-moderate).

Scores IBSQOL selon l’intensité des douleurs abdominales regroupée en classes (« extrême-forte » vs « modérée- légère »).

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**Table I.** – Main characteristics of the study population.

<table>
<thead>
<tr>
<th>Characteristic symptoms (%)</th>
<th>Men (N = 61)</th>
<th>Women (N = 192)</th>
<th>All (N = 253)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time since onset of symptoms (%)</td>
<td>47.6</td>
<td>48.5</td>
<td>48.3</td>
</tr>
<tr>
<td>More than 10 years</td>
<td>29.5</td>
<td>38.0</td>
<td>36.0</td>
</tr>
<tr>
<td>5 to 10 years</td>
<td>24.6</td>
<td>17.2</td>
<td>18.9</td>
</tr>
<tr>
<td>1 to 5 years</td>
<td>29.5</td>
<td>27.6</td>
<td>28.1</td>
</tr>
<tr>
<td>Less than 1 year</td>
<td>16.4</td>
<td>16.2</td>
<td>16.2</td>
</tr>
<tr>
<td>Not reported</td>
<td>-</td>
<td>1.0</td>
<td>0.8</td>
</tr>
</tbody>
</table>

| Frequency of abdominal pain (%) | 77.0 | 74.5 | 75.1 |
| Frequency of episodes (%) | N = 47 | N = 143 | N = 190 |
| Less than one episode per month | 76.6 | 72.0 | 73.2 |
| About one episode every three months | 17.0 | 17.5 | 17.4 |
| About one episode every six months | - | 1.4 | 1.1 |
| Median duration of an episode in days (SD)* | 16.3 (31.3) | 13.1 (13.1) | 13.9 (19.3) |

* SD: standard deviation.
REFERENCES

15. Ware JE. How to score the revised MOS Short Form health scales (SF-36). Boston, MA: The Health Institute, New England Medical Center Hospitals, 1988.