Management of gastro-esophageal reflux disease in primary care. Results from an observational study of 2 474 patients

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SUMMARY
Objective — The aim of the present study was to describe the management of gastro-esophageal reflux disease (GERD) by primary care physicians (PCPs).

Methods — This prospective survey was conducted in patients with suspected or previously diagnosed GERD. PCPs completed questionnaires at first consultation (M0) and at a 3-month follow-up visit (M3).

Results — 2 474 patients were available for analysis at M0 and 1 993 at M3. GERD was the reason for consultation in 84% of patients; 33% were consulting about reflux symptoms for the first time. Symptoms occurred once daily in 55% of patients and were considered very disruptive or incapacitating by 51%. Upper gastrointestinal endoscopy was performed at any time in 57% of patients and at M0 in 20%. Only 48% of demands for endoscopy agreed with current recommendations and this rate was not influenced by PCP training in the previous 6 months. Lifestyle measures were recommended in 95% of patients at M0. Proton pump inhibitors were prescribed in 98%, to be taken “on-demand” in 22-57% depending on symptom frequency. Therapeutic management was considered as very satisfactory by 81% of patients.

Conclusions — GERD managed in primary care is severe, leading to expensive, but effective diagnostic investigations and treatments. Agreement with recommendations for endoscopy is poor.

Introduction
Gastro-esophageal reflux disease (GERD) is highly prevalent and is estimated from the presence of typical symptoms, to affect 20-40% of adults [1-3]. Atypical manifestations of GERD, such as respiratory or cardiac symptoms, complicate estimates of prevalence as some patients may remain undiagnosed. Although usually limited to symptoms and non-severe esophagitis, GERD can also induce complications such as stricture, ulceration and bleeding [4, 5]. Moreover, 10-15% of patients with GERD show evidence of Barrett esophagus, a metaplastic alteration that is known to increase the risk of malignancy [5, 6]. In addition to the direct medical cost of GERD, there are indirect costs to society, from, for example, reduced productivity or absence from work [7, 8], which can exceed the cost of diagnosis or treatment.

Such a prevalent and potentially costly disease requires that the treatment goals of improving patients’ quality of life through symptom relief and preventing the risk of complications are achieved through an optimal use of resources. A key feature of GERD management concerns the cost of diagnosing GERD, particularly the use of diagnostic tests versus the empirical approach of GERD therapy trials [9]. It is recommended that upper gastrointestinal (GI) endoscopy should only be considered in cases where the diagnosis remains unclear or when alarm symptoms suggest the possibility of complications or other diseases [9]. For the therapeutic management of GERD, a strategy using proton…
Patients and methods

Study design and patients

We conducted an observational study in which patients were recruited through PCPs randomly selected from those listed by the Institut de la Communication Medicale (ICOMED) and stratified by geographical location. During the first 5 months of the study, PCPs were required to recruit chronologically the first four patients who satisfied the entry criteria: i.e., any patient aged over 18 years with either suspected GERD or previously diagnosed GERD with symptoms requiring specific management and a follow-up visit.

Upon entry to the study (M0), the PCP completed a questionnaire using answers given by each patient and all reports available. Items included: (1) previous diseases of the patient; (2) the patient’s reasons for consultation; (3) the type, duration and frequency of GERD symptoms and associated symptoms; (3) the diagnostic tests previously used and those prescribed by the PCP; (4) lifestyle interventions and treatments previously used and those prescribed by the PCP at the time of the consultation. A follow-up visit was planned 3 months later (M3) when a similar questionnaire, which also included data on the results of the management planned at M0, was completed. During the study, PCPs followed their usual practice of patient care and the questionnaires were designed to have as little impact as possible on the management of patients. Each patient received information on the design, data handling and aims of the study. The study was conducted in accordance with the declaration of Helsinki and approved by the national ethic committee (CNOM).

Data analysis

To allow observation of different treatments for GERD, a sample size of 3 600 patients was planned. This entailed a sample of 900 PCPs, assuming a maximum of four patients per PCP. The consistency and quality of data were assured by data checking and audit of 2.5% of the PCPs assuming a maximum of four patients per PCP. The consistency and quality of data were assured by data checking and audit of 2.5% of the PCPs assuming a maximum of four patients per PCP. The consistency and quality of data were assured by data checking and audit of 2.5% of the PCPs assuming a maximum of four patients per PCP. The consistency and quality of data were assured by data checking and audit of 2.5% of the PCPs assuming a maximum of four patients per PCP. The consistency and quality of data were assured by data checking and audit of 2.5% of the PCPs assuming a maximum of four patients per PCP.

To identify the specific management decided by PCPs in this study, concordance between diagnostic recommendations and practice was assessed in the subgroup of patients consulting for the first time for reflux symptoms. Using the completed questionnaires, we identified, according to the last French consensus conference [11], patients who definitely required an upper GI endoscopy (defined as the presence of an alarm sign such as weight loss, dysphagia, oedema or anaemia, or age > 50 years) and patients who could be managed without upper GI endoscopy (absence of definite indication, age < 50 years, typical symptoms and no previous GERD treatment). Crude percentages of agreement between recommendations and practice were calculated and significance was estimated using K statistics. A subgroup analysis was performed in PCP that had followed a specific postgraduate course on GERD during the 6 months preceding the study, whatever the content and the method used for this training.

Results

Patient disposition and demographics

A total of 871 PCPs received study documentation, and 696 (80%) reported at least one patient. Of the 2 699 patients originally reported, 225 did not fulfil the entry criteria or were enrolled too late. Therefore, 2 474 patients (92%) were included in the analysis at M0. Among these patients, 1 993 (81%) were available for follow-up at M3. Patients’ median age at inclusion was 54 years (range 18-95) with 1 516 patients over 50 years old. The male to female ratio was 1:1.

Patients and symptoms at inclusion

GERD was the main reason for consulting in 84% of patients at the inclusion visit. This was the first consultation for GERD for 33% of patients, 21% had consulted because of a scheduled follow-up and 46% because of relapse or worsening of GERD symptoms. The median duration of GERD symptoms at inclusion was 12 months (range 1-636 months).

The prevalence of typical and atypical symptoms of GERD, and associated manifestations are listed in table I. Typical GERD symptoms (heartburn and/or epigastric burning) were present in 96% of patients and dyspeptic symptoms were present in 25% Alarm symptoms were present in 19% of patients. Symptoms occurred at least once a day in 55% of patients. They were present mostly during the day in 29% of patients, mostly at night in 25%, and without any predominance in 46%. GERD symptoms were considered to be very disruptive or incapacitating by 51% of patients.

Diagnostic investigations

Prior to M0, 53% of patients had undergone upper GI endoscopy with a mean of 1.6 ± 0.9 endoscopies per patient. Less than 5% had pH-metry and/or manometry. The GERD diagnosis was supported by symptoms in 95% of patients, by endoscopy in 40%, and was made after a consultation with a specialist in 35%. At M0, an upper GI endoscopy was prescribed in 20% of patients (mostly via consultation with a gastroenterologist), pH-metry in 2.5% and manometry in 1% of patients.

Overall, 57% of patients had been referred for an upper GI endoscopy since the beginning of GERD symptoms. The reasons were diagnosis (60%), persistence or relapse of symptoms (35%) or alarm signs (5%). The endoscopy was normal in 66% of patients, showed esophagitis in 27% and a complication in 7% (mainly Barrett esophagus).

The concordance between observed and recommended practice when referring for upper GI endoscopy in newly consulting patients is shown in table II. Only 48% of cases matched with the recommendations: endoscopy was performed when recommended in 26% and not performed when not recommended in 82% of cases. The coefficient K was very low (0.07) confirming the absence of a statistical link between the recommendation for endoscopy and clinical practice. Concordance was not affected by any specific reason for endoscopy: 26% of concordance for age > 50 years and 33% for the presence of alarm signs. The level of concordance was not significantly affected by participation of PCPs in a postgraduate course on GERD management during the 6 months preceding the study (table II).

Treatments

Lifestyle measures were advised at the inclusion (M0) and at the follow-up (M3) visits in 95% and 100% of patients,
Results of management

At the M3 follow-up visit, 47% of patients were free from any reflux symptoms (figure 2). The pattern of symptoms over the day was unchanged, as the proportion of patients with predominantly daytime symptoms remained almost equal to those with predominantly night-time symptoms. More striking were the decreases in the frequency and the severity of GERD symptoms (figure 2). The proportion of patients with daily symptoms dropped from 55% at M0 to 5% at M3 (P < 0.01) and those considering their symptoms very disruptive or incapacitating dropped from 51% at M0 to 18% at M3 (P < 0.001). The frequency of heartburn dropped from a mean of 4.5 ± 2.3 days per week in the 7 days before M0, to 0.7 ± 1.4 days in the 7 days before M3 (P < 0.001). Finally, 80% of patients reported that their symptoms were very much improved since M0, whereas only 1% said that their symptoms had not improved at all and 81% of patients were very satisfied with their treatment.

Discussion

Several sets of guidelines that offer recommendations for diagnostic and therapeutic management of GERD have been published [9-11]. The level of adherence to these guidelines is not, however, well known. In this study, we followed patients with GERD for the 3 months after they consulted their PCP, during which time their symptoms, diagnostic tests and treatment were assessed. The results show a low level of agreement with recommendations for diagnostic testing, but a good level of agreement with therapeutic recommendations leading to a strong improvement in patients’ GERD symptom relief.

The study was designed to be as representative of real-life as possible, hence the use of a geographically stratified sample of PCPs across France who routinely managed patients with GERD. To further reduce bias, patients were not selected by the PCP, but the first four eligible patients were included chronologically from when they had decided to consult their PCP. Additionally, questionnaires were designed to avoid suggesting any diagnosis or therapeutic approach.

The results from this study emphasize the severity of GERD symptoms experienced by patients when consulting their PCP. At M0, 55% of patients experienced symptoms every day, and 51% considered their symptoms to have a serious affect on their general health. The proportion of patients in this study with endoscopic lesions or GERD complications was comparatively high for patients seen by PCPs and similar to that seen in specialized settings [21]. These results agree with previous studies showing that many people live with GERD symptoms for several years, self-medicating with antacids, before consulting their PCP [22]. It is, however likely that our study was biased toward patients with severe forms of GERD as PCPs were asked to include only those patients who required a specific management of reflux symptoms. Therefore, patients with minor or very intermittent symptoms that did not require explorations, specific treatment or only self-medication were not included in the present work. This bias probably explains the discrepancy between our results and those recently published [23] concerning the frequency of daily symptoms of GERD (15% vs 55% in our study).

Over half of the patients had been referred for diagnostic upper GI endoscopy for GERD symptoms either before or during the 3-month period of this study. However, when patients’ records were compared against guidelines, endoscopy appears to have been widely misapplied, with referrals appropriate in only 48% of cases. The majority of errors arose from not using endoscopy when indicated: where endoscopy was indicated only 26% of patients had undergone endoscopy compared with 82% of patients not undergoing endoscopy, in agreement with recommendations, when there was an absence of indication. As we only included patients consulting for the first time in this analysis, these findings reflect the decision of the PCP, without interference from other specialized or non-specialized physicians. Participation in a specific postgraduate course on GERD during the 6 months preceding this study did not appear to improve the performance of PCPs in terms of appropriateness of endoscopy referral. Although the content and the method of the training respectively (table III). Postural and dietary changes were the most frequently recommended lifestyle measures.

Drugs prescribed before inclusion, at the inclusion visit and at the follow-up visit are listed in table IV. Drug prescriptions at M3 were very similar to those at M0, with most patients receiving a PPI at both visits. Alginates, antacids and prokinetics were rarely prescribed; H2-receptor antagonists or combinations of two drugs were almost never prescribed. Prescribing was not influenced by the frequency of GERD symptoms. On-demand treatment was used in 22-57% of patients according to the frequency of GERD symptoms. On-demand treatment was almost never prescribed. Prescribing was not influenced by the frequency of GERD symptoms. On-demand treatment was used in 22-57% of patients according to the frequency of GERD symptoms.

Table I. – Prevalence of GERD symptoms and associated manifestations at inclusion (M0) and the 3-month follow-up visit (M3).

<table>
<thead>
<tr>
<th>GI symptoms</th>
<th>M0</th>
<th>M3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epigastric pain/burning</td>
<td>1 840 (74%)</td>
<td>238 (12%)</td>
</tr>
<tr>
<td>Heartburn</td>
<td>1 731 (70%)</td>
<td>229 (12%)</td>
</tr>
<tr>
<td>Acid regurgitation</td>
<td>1 558 (63%)</td>
<td>154 (8%)</td>
</tr>
<tr>
<td>Erythrosis</td>
<td>1 039 (42%)</td>
<td>180 (9%)</td>
</tr>
<tr>
<td>Flatulence</td>
<td>723 (29%)</td>
<td>228 (11%)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>585 (24%)</td>
<td>105 (5%)</td>
</tr>
<tr>
<td>Feeling of gastric fullness</td>
<td>483 (20%)</td>
<td>120 (6%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>426 (17%)</td>
<td>62 (3%)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>415 (17%)</td>
<td>45 (2%)</td>
</tr>
<tr>
<td>Non-acid regurgitation</td>
<td>174 (7%)</td>
<td>90 (5%)</td>
</tr>
<tr>
<td>Odynophagia</td>
<td>131 (5%)</td>
<td>4 (0.2%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>126 (5%)</td>
<td>6 (0.3%)</td>
</tr>
<tr>
<td>GI bleeding</td>
<td>26 (1%)</td>
<td>2 (0.1%)</td>
</tr>
<tr>
<td>Non-digestive symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear, nose and throat</td>
<td>411 (17%)</td>
<td>59 (3%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>275 (11%)</td>
<td>51 (2%)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>130 (5%)</td>
<td>26 (1%)</td>
</tr>
<tr>
<td>General symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General deterioration</td>
<td>127 (5%)</td>
<td>16 (1%)</td>
</tr>
<tr>
<td>Weight loss</td>
<td>121 (5%)</td>
<td>15 (1%)</td>
</tr>
<tr>
<td>Anaemia</td>
<td>28 (1%)</td>
<td>2 (0.1%)</td>
</tr>
</tbody>
</table>

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were probably heterogeneous, our results are in agreement with previous findings that show that passive methods of disseminating recommended practice, such as publication in professional journals, rarely leads to changes in professional behaviour [24, 25]. We know that more interactive methods are necessary to improve physician behaviour, such as small group discussions and the use of case studies, in conjunction with reminders, audit and feedback [26]. The validity of the recommendations for use within PCP practice may also be questioned, even though the consensus document used in the present study was formulated by a multidisciplinary group that included PCPs [11]. Additional studies are needed to investigate the reasons why recommendations were not followed.

Modifications to diet and lifestyle remained widely used in this study, despite the poor efficacy of these measures [9]. Although there is little conclusive evidence that patients benefit from common lifestyle interventions, such as raising the head of the bed or changing eating habits, PCPs still appear to recommend their use or, at least, do not dissuade patients from their use. It could be speculated that patient quality of life would actually increase if these measures were discontinued, as the chances of any improvement in GERD is far outweighed by the inconvenience and annoyance caused to the patient. In this aspect, it is noteworthy that almost all patients used these measures in the present study, but still required drug prescription.

There was consistency amongst PCPs in the choice of medication prescribed for GERD. PPIs were by far the most common prescription with 98% of patients receiving this class of drug at M0. This is in-line with current guidelines, which recommend prescribing an optimal acid-control therapy as first-line treatment [9-11]. The proportion of patients using antacids/alginates declined substantially after the first consultation. The decline in the use of H2-receptor antagonists was also notable between the pre-inclusion and the M0 visits. It was also clear from their prescribing habits, that the PCPs involved in this study had fully integrated the use of on-demand PPI therapy, even if most publications describing this type of management were more recent than the last French consensus conference [27-30]. This modality of prescription was, as expected, correlated with the frequency of symptoms (i.e. used more often when symptoms were intermittent than when continuous) and more frequently used at the 3-month follow-up visit than at the inclusion visit. Overall our results suggest many PCPs have chosen a strategy with a PPI as the first step of treatment, followed by step-down to a PPI on demand depending on symptom frequency.

The frequency of heartburn acid regurgitation and epigastric pain reduced markedly from the first to the last visit, but only 53% of patients were completely free from symptoms at their final visit. Those who did continue to suffer symptoms found that the frequency was much lessened, with only 5% of patients experiencing symptoms every day. This translated into a lower burden of illness, although 18% of patients still considered their symptoms to be very disruptive or incapacitating at the 3-month follow-up visit. Our study, therefore, confirms that PPIs do not completely abolish symptoms of GERD in a significant fraction of

Table III. – Lifestyle measures recommended by PCPs at the inclusion visit (M0) and at the 3-month follow-up visit (M3).

Mesures hygiéno-diététiques recommandées par les médecins généralistes, à la visite d’inclusion (M0) et à la visite de suivi à 3 mois (M3).

<table>
<thead>
<tr>
<th>Measure</th>
<th>M0 N = 2474</th>
<th>M3 N = 1993</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raising the head of the bed</td>
<td>1 810 (73%)</td>
<td>1 306 (66%)</td>
</tr>
<tr>
<td>Low fat diet</td>
<td>1 727 (70%)</td>
<td>1 266 (64%)</td>
</tr>
<tr>
<td>Stopping/reducing smoking</td>
<td>595 (24%)</td>
<td>456 (23%)</td>
</tr>
<tr>
<td>Stopping/reducing alcohol consumption</td>
<td>750 (30%)</td>
<td>556 (28%)</td>
</tr>
<tr>
<td>Weight loss</td>
<td>1 164 (47%)</td>
<td>881 (44%)</td>
</tr>
<tr>
<td>Reducing medicine use</td>
<td>410 (17%)</td>
<td>283 (14%)</td>
</tr>
<tr>
<td>Total</td>
<td>2 342 (95%)</td>
<td>1 993 (100%)</td>
</tr>
</tbody>
</table>

Table IV. – Drugs prescribed before the study, at the inclusion visit (M0) and at the 3-month follow-up visit (M3).

Médicaments prescrits avant l’étude, à la visite d’inclusion (M0) et à la visite de suivi à 3 mois (M3).

<table>
<thead>
<tr>
<th>Drug</th>
<th>Pre-study N = 2474</th>
<th>M0 N = 2474</th>
<th>M3 N = 1993</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proton pump inhibitor</td>
<td>1 018 (62%)</td>
<td>2 436 (99%)</td>
<td>1 706 (99%)</td>
</tr>
<tr>
<td>Antacids/alginates</td>
<td>474 (29%)</td>
<td>96 (4%)</td>
<td>66 (4%)</td>
</tr>
<tr>
<td>Prokinetics</td>
<td>82 (5%)</td>
<td>65 (3%)</td>
<td>39 (2%)</td>
</tr>
<tr>
<td>H2 receptor antagonists</td>
<td>168 (10%)</td>
<td>9 (0.4%)</td>
<td>6 (0.3%)</td>
</tr>
<tr>
<td>Others or drug combinations</td>
<td>29 (2%)</td>
<td>19 (0.8%)</td>
<td>9 (0.5%)</td>
</tr>
</tbody>
</table>
patients [31, 32], but reduce the severity and burden in almost all patients.

In conclusion, this observational study of 2 474 patients with GERD, who were selected using a geographically stratified cross section of PCPs in France, showed severe reflux symptoms among patients consulting in primary care. Compliance of PCPs with recommendations over the diagnostic use of upper GI endoscopy was low, with an under use of this procedure. PCPs used PPIs as the initial treatment, with many subsequently using a step-down approach with a PPI taken on demand. Further studies are needed to understand the reasons for these discrepancies and to ultimately improve compliance with, and relevance of, recommendations in general medicine.

ACKNOWLEDGEMENTS - The authors thank the physicians who participated in the data collection and AstraZeneca who sponsored this study.

RÉFÉRENCES


