Characteristics of insomnia in a primary care setting: EQUINOX survey of 5293 insomniacs from 10 countries

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A B S T R A C T

Objective: To describe the characteristics of insomnia in primary care physicians’ (PCPs’) practices in 10 countries and to understand how the difficulty of maintaining sleep (DMS) was or was not associated with other insomnia symptoms such as difficulty initiating sleep (DIS), early morning awakenings (EMA) or nonrestorative sleep (NRS) in PCPs patients with insomnia.

Methods: International, noninterventional, cross-sectional, observational survey conducted in a primary care setting in subjects complaining of sleep disturbances in 10 countries. A questionnaire based on DSM-IV and ICSD criteria was administered.

Results: Thirteen thousand one hundred twenty-four subjects were enrolled by 647 physicians; 5293 of them (32.6%) had insomnia and were surveyed. The population was predominantly female (63.9%) with a mean age of 47.8 ± 15.3 years; 39.9% of these patients have already been treated for sleep difficulties. Combination of all types of insomnia symptoms (DIS + DMS + EMA + NRS) was the most frequently reported combination (38.6% of the subjects), while the percentage of subjects presenting with only one type of insomnia symptom (DIS, DMS, EMA or NRS) was very low: 3%, 1.8%, 0.9% and 1.4% respectively. DMS was on average the most commonly reported insomnia symptom (80.2%). Multiple logistic regression showed that DMS, EMA and NRS symptoms were significantly linked with each other and also to other insomnia criteria (sleep satisfaction, sleep quality, sleep duration, number of hours of sleep, frequency of insomnia symptoms, wake up rested / unrested and non restorative sleep).

Conclusions: Patients visiting PCPs with insomnia are likely to present with severe and poly-symptomatic insomnia.

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1. Introduction

Insomnia is a common complaint that can impair patient’s quality of life and daytime functioning. The prevalence of insomnia in the general population of adults has been widely studied in many countries [1–5]. A recent review of the literature covering more than 50 studies of insomnia showed that when consensus definitions of insomnia are used (DSM-IV [6] and ICSD-2 [7]) estimates of prevalence in the general population vary widely, from less than 15% to 25% [8,9], depending on the definition of the characteristics of the population sampled, the regional perceptions and practices regarding sleep disorders.

Consensus definitions are based on subjective assessment made by subjects with complaints of difficulty initiating sleep (DIS), difficulty maintaining sleep (DMS), early morning awakenings (EMA), nonrestorative sleep (NRS) occurring despite adequate opportunity and circumstances for sleep and with daytime impairment reported by the patient [6,7]. These definitions which are used clinically for the diagnosis of insomnia have also been recommended in research by several sleep research groups [10–12].

Several questions regarding the characteristics of insomniacs remain unresolved. One major issue is why even severe insomniacs do not seek professional help to cope with their poor sleep [13] and who does seek help for their insomnia. Surprisingly, few studies have addressed insomnia in general practice [14–17].
Another important issue is to better describe the real complaints of insomnia patients. One paradoxical effect of the adoption of consensus definitions is that it brings a difficulty to exactly understand what a complaint of DIS, DMS, EMA, and NRS means. There is a need for separate analysis of each complaint in order to better characterize the various phenotypes in insomnia.

It has previously been found that the prevalence of insomnia differs, sometimes widely, from one country to another. Ohayon (2005) observed, in a survey on nonrestorative sleep among 25,580 individuals from 7 European countries, that the prevalence seems to follow a North–South line, with the United Kingdom having the highest prevalence and Spain the lowest [3]. These differences were explained by factors such as sleeping habits, climate and the ways different cultures answer questionnaires. Leger and his collaborators (2008) found, in a survey comparing sleep disorders of representative samples of 3962 North Americans, 5005 Europeans and 1165 Japanese, that insomnia was significantly higher in the USA (39%) than in Europe (28%) and Japan (21%) [5].

The EQUINOX (evaluation of daytime quality impairment by nocturnal awakenings in outpatient's experience) survey is an international project aiming the evaluation of the characteristics of various insomnia-related complaints in PCPs’ practices and to compare DMS to other admitted criteria of insomnia [6,7] and then to used descriptions of poor sleep quality.

2. Methods

2.1. Design

This was an international, non-interventional, cross-sectional, observational survey conducted between September 2005 and September 2006 in an out-population of patients consulting in PCP offices. Subjects were systematically interviewed about sleep disturbances during physician’s visit. The insomniacs have only been surveyed. Usual care management of the subject was not modified by the survey.

A central scientific committee composed of five sleep experts (3 from Europe, 2 from the USA) was responsible for advice and recommendations on all scientific aspects of the survey.

In each selected country, a national coordinator was responsible for the coordination of the survey, the respect of time constraints for enrolment and the validation of the local translation of the study documents.

The survey was conducted in accordance with the principles laid by the 18th World Medical Assembly (Helsinki, 1964) and all subsequent amendments and with the guidelines for Good Epidemiological Practice [18].

Each participating country had to locally ensure all necessary regulatory submissions in accordance with local regulations and in particular data protection laws. A written informed consent, translated into local language, was to be obtained from the subjects prior to the interview and the completion of the questionnaire.

The present article is the first of an overall publication program, of which the objectives are to present some specific aspects regarding daytime consequences associated with insomnia. For better comprehension, all the data gathered are not presented here. In subsequent articles, methodological issues and frequency of sleep disturbances will also be more briefly presented; the present article can be referred to for further details.

2.2. Physicians

At the beginning the study was proposed to 22 countries around the world (12 in Europe, 5 in Asia and 5 in America) by the sponsor to its affiliates. Out of these, based on the expertise and interest of the World Association of Sleep Medicine (WASM) and of the scientific committee, we selected 15 countries they found important to be represented in the study. Finally, only 10 countries were able to find enough support and expertise to organize the study during the period selected.

The physicians who participated in the survey represented four different continents: Northern Europe was represented by Finland, Sweden and Switzerland; Southern Europe by Greece and Portugal; Northern Africa by Morocco; Central America by Mexico; Middle East by Jordan and Lebanon; and South-East Asia by Philippines.

In all countries, the physicians were mainly general practitioners (GPs) (88%) or internal medicine (9%) and family medicine specialists (3%). Their practice had to be office-based unless this was not consistent with the country’s Health System organization. The sample of the physicians was based on their agreement to participate in the survey and on previous collaboration with the sponsor.

Guidelines have been nationally provided to select a representative sample of GPs based on the statistics of each country regarding age, sex ratio, urban vs. rural practice. These guidelines have been applied in the 10 countries and GPs for each country were represented.

In most of the countries, GPs have been selected to be as representative as possible of the GPs at the national level (according to sociodemographic and geographic statistics).

The procedures for survey initiation for each country (either investigator’s meeting or on-site visits, personnel involved in the survey initiation) and for translation of survey documents are presented in Table 1. The study initiated during an investigator meeting in 8 out of 10 countries.

2.3. Subjects

GPs who agreed to participate in the study had to interview all the patients (above 18 years old) during two consecutive work days of the first week following the survey initiation in the center. For each patient, the GP was asked to fill in an anonymous Patient Log Form with age and sex.

Subjects who were diagnosed as insomniacs were invited to participate in the survey and had to give written informed consent. In order to better assess the characteristics and daytime consequences of insomnia independently of potential side effects of current treatments, those who had been treated by a sleep promoting agent (benzodiazepine receptor agonists, tranquilizers, anxiolytics, anti-depressants, antihistamine and melatonin agonists) in the 4 weeks preceding the survey were excluded.

Insomnia was defined according to the DSM-IV and ICSD-2 definitions [5,6].

- Subjects were selected by the eligibility criteria (see Appendix A): “difficulty initiating sleep, difficulty maintaining sleep, early awakenings, nonrestorative sleep associated with daytime consequences at least 2 times a week for at least one month (but with no sleep promoting agents taken).”

- DSM-IV and ICSD definitions were assessed based on the following items of the sleep questionnaire (see Appendix A):
  1) Presence to one of the items enquiring about sleep symptoms: 1.2, 3 or 4.
  2) Suffering from insomnia symptoms more than 3 nights per week and for more than one month (items 5.1 and 5.2).
  3) Endorsing negative impact (3, 4 or 5) to one of the 9 daytime consequences items.
In addition, the definition of the American Academy of Sleep Medicine (AASM) Working Group was also used for exploratory purposes [19].

2.4. Data collection instruments

In all countries, the survey was conducted using the same instruments, translated into local languages. Data collected on the Patient Log Form included gender, age, presence of sleep disorders, treatment for sleep disorders, and inclusion in the survey. For each subject included in the survey, the physician filled in a questionnaire specifically created for the survey, as the existing sleep questionnaires, usually used in the context of clinical studies, were not judged suitable in primary care practice due to their complexity and time spent to fill out the questionnaire. A sample questionnaire is presented in Appendix A; this questionnaire was translated into local languages. Data collected on psychiatric and other sleep disorder comorbidities.

Table 1
Procedures for survey initiation and translation of documents.

<table>
<thead>
<tr>
<th>Survey initiation</th>
<th>Personnel involved in the survey initiation</th>
<th>Translation of the documents into local language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator’s meetings</td>
<td>On-site visits</td>
<td>National coordinator CRO’s Project Manager</td>
</tr>
<tr>
<td>Finland Yes</td>
<td>Yes</td>
<td>National coordinator CRO’s Project Manager</td>
</tr>
<tr>
<td>Greece No</td>
<td>Yes</td>
<td>Local Clinical Research Associate</td>
</tr>
<tr>
<td>Jordan and Lebanon Yes</td>
<td>Yes</td>
<td>National coordinator</td>
</tr>
<tr>
<td>Morocco Yes</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>Mexico Yes</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>Philippines Yes</td>
<td>–</td>
<td>National coordinator</td>
</tr>
<tr>
<td>Portugal Yes</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>Sweden Yes</td>
<td>–</td>
<td>Clinical Research Associate</td>
</tr>
<tr>
<td>Switzerland No</td>
<td>Yes</td>
<td>National coordinator</td>
</tr>
</tbody>
</table>

CRO: Clinical Research Organization.

3. Comorbidities

Even if comorbidities were not the endpoint of the study, we had, based on our questionnaire, the possibility of evaluating both psychiatric and other sleep disorder comorbidities.

3.1. Psychiatric comorbidities

Psychiatric comorbidities have been assessed both by patients’ feelings and by the practitioner.

- Patients had to rate between 0 (“no”) up to 5 (“very high”) the following items: (Q7) “Do your sleep problems have a negative impact during the day making you feel tense?” (Q9) “Do your sleep problems have a negative impact on your mood during the day, making you feel depressed?” Based on these items we supposed that subjects rating themselves “high” or “very high” in these questions may be considered as having an anxious (Q7) or a depressed (Q9) tendency, respectively.
- Practitioners also had to give their feeling on how they were willing to treat the patients. We assume also that patients treated by anxiolytics were considered anxiety and patients treated by antidepressants were considered depressive.

4. Other sleep disorders

Patients were interviewed by the following items: (Q11) “Have you ever been told that you suffer from: snoring loudly, sleep disorders (SBD), restless legs syndrome (RLS)?” The definition of RLS according to the international criteria was written to allow better comprehension of the disease. Medical comorbidities were not assessed.

4.1. Statistical methods

Data collected were sent and analyzed in a single independent statistical center. All statistical analyses were performed at the 5% significance level using 2-sided test or 2-sided confidence intervals. At the exception of those performed on the screening log, all the analyses involved the population defined as all patients included in the study without any major violations such as age < 18 years, absence of sleep disorders, treatment by a sleep promoting agent (whatever its class) in the previous 4 weeks, missing data to questions 1 to 4 of the “Sleep Questionnaire,” and at least one of the nine questions of the Day After Questionnaire missing (Q2 “impact on working activities” must be answered by worker patients). Comparisons between groups of sleep disturbances were made using student t-test or Mann–Whitney non-parametric test.
for continuous data and Chi-square test or Fisher exact test for categorical data.

For each sleep disturbance, one multiple logistic regression was performed in order to identify the associative variables associated with the most DMS, DIS, EMA and NRS. The decision criterion was Wald Chi-square test, and stepping was stopped when there were no further candidate variables that enter the model at the 5% significance level. Data collection, validation procedures and data quality control ensured the quality of the study database.

5. Results

5.1. Populations

A total of 13,124 subjects were enrolled by 647 physicians. The highest percentages of subjects entered in the Patient Log Form were from Mexico (n = 3021; 23%), Morocco (n = 2476; 18%), and Finland (n = 1782; 14%). In this population of subjects consulting their physicians during a period of two consecutive working days, the prevalence of non-medically treated insomnia was 42% (5544 subjects); these subjects completed the sleep questionnaire. Another 15.6% of the subjects were treated insomniacs who were not included in the survey.

Of these 5544, we finally retained 5293 for analysis (in 28 subjects informed consent was not available; 224 had either major deviations or missing data and were excluded). The number of participants per country is presented in Table 2. The study has been designed to have a representative sample of patients (and therefore of insomniacs) who were visiting GPs. Compared to the non-insomniacs, insomniacs were elder (45 years old vs. 35 years old; p < 0.001) and the sex ratio was predominantly female (65% of the insomniacs vs. 60% of the non-insomniacs; p < 0.001).

5.2. Socio-demographic characteristics

The population of subjects included in the survey analyses was predominantly female (63.9%, from 50% in Jordan to 70.3% in Portugal) with a mean age of 47.9 ± 15.3 years (from 43.1 ± 14.2 in Jordan to 60.5 ± 15.2 in Greece), and 45.3% of the subjects were older than 50 years. Mean body weight was 70.9 ± 14.5 kg (from 59.5 ± 11.4 in the Philippines to 76.7 ± 16.7 in Finland) with 55.7% of the subjects having a body mass index superior or equal to 25 kg/m² (Table 3).

The majority of subjects lived at home with other people (90.6%) in urban or suburban area (86.1%). Half of the worker subjects had a full time employment (50.0%, from 30.6% in Greece to 75.5% in Finland), only 12.8% were shift workers (from 5.5% in Greece to 28.9% in Finland), 44.7% considered their environment as noisy (from 13.4% in Sweden to 76.4% in Mexico), 52.6% considered him/herself a morning person (from 31.5% in Jordan to 66.8% in Mexico) and 56.5% had a driver’s license (from 33.8% in Morocco to 85% in Finland) (Table 3).

The most relevant differences between countries were observed for the following socio-demographic characteristics. 1) Age: the percentages of subjects older than 50 years were higher in European countries, ranging from 42.9 to 75.6 years compared to other countries (ranging from 29.3 to 44.1 years of age); 2) living at home with other people: the percentages of subjects living with other people were lower in European countries, ranging from 70.0 to 94.3% compared to other countries (ranging from 93.2 to 95.9%); 3) employment: the percentage of subjects full time employed was higher in Finland (75.5%) and Portugal (69.1%) than other countries (ranging from 30.6% to 52.6%); 4) residence: the percentages of subjects living in rural area were higher in Sweden (33.8%), Portugal (32.4%) and Jordan (42.3%) compared to other countries (ranging from 1.6% to 25.9%); 5) noisy environment: the percentages of subjects living in a noisy environment were lower in European countries, ranging from 14.2% to 33.7% compared to other countries (ranging from 36.0% to 76.4%); 6) driver’s license: the percentages of subjects having a driver’s license were higher in Northern Europe (Finland 85.0%, Sweden 84.3% and Switzerland 84.5%) compared to other countries (ranging from 33.8% to 72.0%).

5.3. Characteristics of insomnia symptoms

All 5293 individuals had insomnia according to the definitions mentioned previously: 78.6% with DSM-IV criteria for insomnia (APA, 2000), 98.3% with the American Academy of Sleep Medicine (AASM) definition criteria (AASM, Edinger, 2004), and 76.9% according to both criteria.

The percentages of subjects presenting at least one type of insomnia symptom were high in all the subgroups evaluated: 78.0% of the subjects presented with DIS (from 54.5% in Finland to 98.1 in Jordan), 80.2% with DMS (from 75.2% in Greece to 86.7% in the Philippines), 66.9% with EMA (from 55.2% in Finland to 78% in the Philippines), and 78.6% had NRS (from 66.6% in Sweden to 92.6% in Jordan) (Table 4, Fig. 1). Overall, it seemed that insomnia symptoms were slightly less frequently reported in Northern European countries compared to other countries. Conversely, the percentage of subjects presenting with one type of insomnia symptom only (either DIS, DMS, EMA or NRS) was low: 3%, 1.8%, 0.9%, and 1.4%, respectively (Fig. 2). Most frequently, the subjects presented various combinations of insomnia symptoms. Combination of all types of sleep disorders, i.e., DIS + DMS + EMA + NRS, was the most frequently reported by 38.60% of the subjects (Fig. 2).

In Northern European countries (Finland, Sweden and Switzerland) DMS was more frequent than other insomnia symptoms (Fig. 1). In Middle Eastern countries (Lebanon and Jordan) DIS had the highest frequency among all the countries (98.1% of subjects in Jordan) and was the most frequently reported insomnia symptom. EMA was less frequent than other insomnia symptoms in Southern European countries (Greece and Portugal) and in Morocco.

Insomnia symptoms were reported more than 3 nights per week for 65.2% of the population (from 60.7% in Switzerland to 76.7% in Lebanon). For 81.1% of the population, insomnia symptoms were reported for more than one month (from 62.9% in Philippines to 93.2% in Finland). Snoring loudly was reported in 44.3% of the population (from 27.2% in Switzerland to 56.8% in Mexico) and SBD in 10.2% of the population (from 3.7% in Portugal to 27.8% in Jordan) (Table 5).
5.4. Psychiatric and sleep problem comorbidities

Seventy-nine percent of subjects rated high or very high on feeling tense during the daytime and 64% on feeling depressed. Moreover, 22.7% of insomniacs received anxiolytics, and 22% antidepressants.

In all, 10% of insomniacs said they had been diagnosed with SBD and 20% with RLS. This rate varies from country to country (Table 5).

In Table 7, we have presented the distribution of comorbid psychiatric (feeling tense or depressed) and other sleep problems (SBD, RLS) as a function of insomnia symptoms. Logistic regressions, using χ² systematically, found that comorbidities had a significant influence on the distribution of sleep disturbances. Feeling...
moderately or severely depressed or tense increased significantly (p < 0.0001) the presence of associated sleep disturbances (DIS + DMS + EMA + NRS).

Snoring loudly, SBD and RLS already diagnosed at the time of the study were reported by 44.3%, 10.5% and 21.7% of the subjects, respectively.

SBD is less frequent in DIS but more frequent in associated sleep disturbances (DIS + DMS + EMA + NRS) (p < 0.0001). RLS had a small but significant impact on the prevalence of associated sleep disturbances (DIS + DMS + EMA + NRS) (p < 0.02).

5.5. Associative variables

The results of the univariate analysis looking for associative variables associated with the presence of each type of insomnia symptoms are presented in Table 6.

For each individual criterion of insomnia symptoms (DIS, DMS, EMA and NRS), the other subjective descriptions of sleep (sleep satisfaction, sleep quality, sleep duration, number of hours of sleep, frequency of insomnia symptoms, wake up rested / unrested) were identified as associative variables; there were also variables related to geographic localization and employment (except for NRS). Unlike in subjects with DIS, noisy environment, morningness/eveningness chronotype, time in bed and residence (rural/urban) were not different in subjects with or without DMS. Subjects with DMS were mostly male, older, a higher rate thought they slept less than 5 h, and frequency of sleep disturbances was higher than the other insomnia symptoms.

Those with EMA were not significantly influenced by residence, living with other people, or gender. Patients suffering from EMA were older and were assessed as staying in bed longer (> 7 h) and having more frequently insufficient sleep than the other insomnia symptoms.

Employment and gender did not explain the complaint of NRS. But patients said they woke up feeling unrested, they rated insufficient sleep the highest and they had worse sleep satisfaction than others patients suffering from other insomnia symptoms.

Finally, age and gender did not influence DIS but they were less satisfied with their sleep and more frequently had short sleep duration (<5 hours) than other sleep complaints.

BMI, shift work and drinking alcohol to get to sleep were not significantly associated with one particular insomnia criterion.

Table 5
Insomnia frequency and comorbidities (snoring loudly, SBD and RLS) based on subjective reports. % = percentage by country. N = 5293.

<table>
<thead>
<tr>
<th></th>
<th>Finland</th>
<th>Sweden</th>
<th>Switzerland</th>
<th>Greece</th>
<th>Portugal</th>
<th>Jordan</th>
<th>Lebanon</th>
<th>Mexico</th>
<th>Morocco</th>
<th>Philippines</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td><strong>Frequency of insomnia</strong></td>
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<td></td>
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</tr>
<tr>
<td>More than 3 nights per week (%)</td>
<td>65.9</td>
<td>69.2</td>
<td>60.7</td>
<td>67.7</td>
<td>72.8</td>
<td>70.7</td>
<td>76.7</td>
<td>62.3</td>
<td>64.3</td>
<td>61.2</td>
<td>65.2</td>
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<tr>
<td><strong>History of insomnia</strong></td>
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<tr>
<td>For more than one month (%)</td>
<td>93.2</td>
<td>92.0</td>
<td>88.9</td>
<td>79.1</td>
<td>82.4</td>
<td>76.0</td>
<td>87.3</td>
<td>77.9</td>
<td>80.2</td>
<td>62.9</td>
<td>81.1</td>
</tr>
<tr>
<td>Snoring loudly (%)</td>
<td>51.8</td>
<td>48.3</td>
<td>27.2</td>
<td>38.2</td>
<td>40.5</td>
<td>35.2</td>
<td>34.7</td>
<td>56.8</td>
<td>32.9</td>
<td>48.7</td>
<td>44.3</td>
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<tr>
<td>SBD (%)</td>
<td>15.9</td>
<td>9.2</td>
<td>6.8</td>
<td>7.8</td>
<td>3.7</td>
<td>27.8</td>
<td>6.3</td>
<td>8.9</td>
<td>15.3</td>
<td>7.2</td>
<td>10.2</td>
</tr>
<tr>
<td>RLS (%)</td>
<td>29.6</td>
<td>19.2</td>
<td>10.8</td>
<td>21.4</td>
<td>11.3</td>
<td>25.9</td>
<td>20.4</td>
<td>22.3</td>
<td>20.9</td>
<td>15.2</td>
<td>20.1</td>
</tr>
</tbody>
</table>

6. Discussion

This study was to our knowledge one of the largest performed on insomnia in primary care. Other studies conducted in the general population usually found a prevalence of insomnia around 15–25% [1–5, 8, 20]. However, few of them have been performed in primary care. The prevalence of sleep disorder complaints in PCPs reported here was higher than that found in general populations: 42%, with another 15.6% of patients who had already been treated at the moment of the study. These results were higher than the 33% of insomnia complaints found by Alattar et al. in a 1395 sample of patients in North Carolina, USA [14] and the 32.3% of patients with insomnia found by Kushida et al. in a sample of 1249
adult patients who were interviewed in a primary care physician practice in Moscow, Idaho (USA) [15]. Moreover, it is important to remember that one eligibility criterion for entering the survey was the absence of hypnotics treatment in the previous 4 weeks, which drastically underestimates the rate of treated insomniacs in our survey. We acknowledge that patients who did not use treatments may be more severe than patients under treatment. However, nontreated patients have been selected in order to better assess the characteristics and daytime consequences of insomnia, independently of potential current treatment side effects.

This higher prevalence of insomnia in Primary Care may be explained by psychiatric or other sleep comorbidities (which prompted patients to consult their GP) but also for sociodemographic characteristics. For example, we found a high percentage of women (63.9%) and an average age (47.9 ± 15.3 years) in insomnia patients, which is consistent with the literature: insomnia is usually increased in females and in insomnia symptoms that increase with age, but not necessarily insomnia diagnoses [1–5,8,9]. Medical comorbidities were not strictly assessed in this study. In a large study in multiple countries, we had to limit the

Table 6
Variables associated with the presence of sleep disturbances (difference between the subgroups with and without sleep disturbance - p values). OR = odds ratio; NS: Not Significant; NA: Not Applicable; DIS: Difficulty initiating sleep; DMS: Difficulty maintaining sleep; EMA: Early morning awakening; NRS: non restorative sleep; ± means only or with.

<table>
<thead>
<tr>
<th>Country cluster (Northern Europe)</th>
<th>DIS (n = 3970)</th>
<th>DMS (n = 4080)</th>
<th>EMA (n = 3402)</th>
<th>NRS (n = 4004)</th>
<th>All symptoms (n = 1964)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (CI 95%)</td>
<td>OR (CI 95%)</td>
<td>OR (CI 95%)</td>
<td>OR (CI 95%)</td>
<td>OR (CI 95%)</td>
</tr>
<tr>
<td>Asia pacific</td>
<td>4.3 (3.0–6.0)</td>
<td>1.9 (1.3–2.7)</td>
<td>0.9 (0.7–1.1)</td>
<td>1.1 (0.9–1.4)</td>
<td>1.2 (1.1–1.7)</td>
</tr>
<tr>
<td>Southern Europe</td>
<td>2.3 (1.8–2.8)</td>
<td>1.0 (0.8–1.2)</td>
<td>1.0 (0.8–1.2)</td>
<td>1.0 (0.8–1.2)</td>
<td>1.0 (0.8–1.2)</td>
</tr>
<tr>
<td>Middle East</td>
<td>4.7 (2.8–7.9)</td>
<td>1.1 (0.8–1.8)</td>
<td>1.3 (1.2–1.7)</td>
<td>1.3 (1.1–1.7)</td>
<td>1.4 (1.2–1.7)</td>
</tr>
<tr>
<td>Central America</td>
<td>2.5 (2.0–3.1)</td>
<td>1.0 (0.8–1.2)</td>
<td>1.2 (0.96–1.4)</td>
<td>0.8 (0.7–1.1)</td>
<td>1.4 (1.2–2.2)</td>
</tr>
<tr>
<td>Northern Africa</td>
<td>2.4 (1.9–3.0)</td>
<td>1.0 (0.8–1.2)</td>
<td>1.2 (0.96–1.4)</td>
<td>0.8 (0.7–1.1)</td>
<td>1.4 (1.2–2.2)</td>
</tr>
<tr>
<td>Age (years) (&lt;50)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥65</td>
<td>1.5 (1.2–1.8)</td>
<td>1.8 (1.5–2.3)</td>
<td>0.8 (0.7–1.0)</td>
<td>1.3 (1.1–1.6)</td>
<td></td>
</tr>
<tr>
<td>[50–65]</td>
<td>1.3 (1.1–1.6)</td>
<td>1.4 (1.2–1.6)</td>
<td>0.8 (0.7–0.9)</td>
<td>1.0 (0.9–1.1)</td>
<td></td>
</tr>
<tr>
<td>Sleep satisfaction (Somewhat satisfactory or unsatisfactory)</td>
<td>1.8 (1.4–2.3)</td>
<td>1.7 (1.2–2.4)</td>
<td>1.5 (1.0–2.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep quality (Somewhat good or not good)</td>
<td>1.6 (1.2–2.1)</td>
<td>1.5 (1.2–2.0)</td>
<td>1.5 (1.2–2.1)</td>
<td>2.0 (1.4–2.9)</td>
<td></td>
</tr>
<tr>
<td>Sleep duration (Insufficient)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very sufficient or sufficient</td>
<td>1.6 (1.3–1.9)</td>
<td>1.6 (1.3–2.0)</td>
<td>1.9 (1.5–2.3)</td>
<td>2.2 (1.8–2.9)</td>
<td></td>
</tr>
<tr>
<td>Wake up rested/unrested</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Somewhat rested or unrested)</td>
<td>1.8 (1.5–2.0)</td>
<td>2.0 (1.5–2.7)</td>
<td>1.4 (1.0–1.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender (female)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.3 (0.6–0.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noisy environment (NO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.4 (1.1–1.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of sleep disturbance (&lt;3 nights/week)</td>
<td>1.3 (1.1–1.6)</td>
<td>1.3 (1.1–1.5)</td>
<td>1.3 (1.1–1.5)</td>
<td>1.3 (1.1–1.5)</td>
<td>1.3 (1.1–1.5)</td>
</tr>
<tr>
<td>Number of hours you think you sleep (&gt;5 h)</td>
<td>1.6 (1.4–2.0)</td>
<td>1.3 (1.1–1.6)</td>
<td>1.4 (1.2–1.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5 h</td>
<td>1.6 (1.3–1.9)</td>
<td>1.6 (1.2–2.0)</td>
<td>2.2 (1.8–2.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration in bed (≥7 h)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep apnea (NO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.4 (1.1–1.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 7
Distribution of co-morbid psychiatric (feel tense, feel depressed) and medical (sleep apnea, restless legs syndrome) conditions as a function of insomnia symptoms in subjects with at least one sleep symptom and nonrestorative sleep (NRS) n = 3300.

<table>
<thead>
<tr>
<th>Psychiatric and sleep comorbidities</th>
<th>Sleep disturbances</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DIS ± NRS</td>
<td>DMS ± NRS</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>SBD</td>
<td>30</td>
<td>6.7</td>
</tr>
<tr>
<td>No</td>
<td>417</td>
<td>93.3</td>
</tr>
<tr>
<td>RLS</td>
<td>77</td>
<td>17.2</td>
</tr>
<tr>
<td>No</td>
<td>370</td>
<td>82.8</td>
</tr>
<tr>
<td>Feel tensed</td>
<td>308</td>
<td>68.4</td>
</tr>
<tr>
<td>Absent/Mild</td>
<td>142</td>
<td>31.6</td>
</tr>
<tr>
<td>Feel depressed</td>
<td>239</td>
<td>53.1</td>
</tr>
<tr>
<td>Absent/Mild</td>
<td>211</td>
<td>46.9</td>
</tr>
</tbody>
</table>
number of questions to maintain a certain quality level. Here, we observed that all the patients visiting each GP during two following days filled out the questionnaire. However, we had to limit the length of the questionnaire, and assessment all the comorbidities with validated questionnaires was finally not retained. We used parts of the questionnaire to approach the assessment of psychiatric comorbidities and other sleep disorders associated with the impact of sleep. There are documented data establishing the longitudinal link between insomnia and depression [24–26].

In our study, we did not check stress, anxiety or depression as possible factors associated. However, we enquired about possible severe repercussions of insomnia on “feeling tense,” “irritable” or “depressed” and found that these repercussions were associated with the following variables: DMS, EMA, but not with DIS. Moreover, we found that 22% of insomniacs (treated by antidepressants) had some kind of depression and 32.7% (treated by anxiolytics) would be anxious. These rates of comorbid psychiatric insomnia are consistent with those from the literature [5,7,18,19]. Similarly, the percentages of insomniacs who reported they have been diagnosed with sleep apnea (10%) and RLS (20%) are also consistent with previously published papers. This approach allows us (imperfectly but quite precisely) to calculate the respective influence of these comorbidities on insomniacs’ symptoms (see Table 7), leading us to comment that psychiatric comorbidities had a significant influence on the presence of insomnia in primary care. Patients who feel tense or depressed or treated by GPs with antidepressants or anxiolytics had more severe and associated symptoms than other patients. Mental disorders are significantly associated with sleep complaints, a finding that is consistent with previous studies [3,5,8,14,21,27]. However, we acknowledge that a semi-constructed interview would have been more appropriate to assess psychiatric disease in a smaller group of patients and that it is not possible to confirm psychiatric diseases based only on subjective assessments.

Due to the selection process, physicians were selected as statistically representative of the GPs of their country. One limitation is that the two consecutive working days we retained could have been not representative of ordinary days of practice. However, each physician screened an average of 20 patients over these two days, which seemed reasonable in order to get an idea of their average clinical activity. We found that insomniacs selected were older (45 years old vs. 35 years old; p < 0.001) and more predominately female (65% vs. 60%) than the noninsomniacs (p < 0.001), which is consistent with the literature, i.e., insomnia increases with age and is more frequent in females.

One limitation of this study is that the presence of other sleep disorders, including SDB and RLS, is based on subjective reports. This could be influenced by the relative availability of sleep medicine in the various countries as well as the well-documented under-diagnosis of these disorders. To clarify this point, Table 5 describes the percentage of insomniacs who reported they have been diagnosed with SDB and RLS in each country. For RLS, it varies from 10.8% in Switzerland to 29.6% in Finland and for SDB, from 3.7% in Portugal to 27.8% in Jordan.

Not surprisingly, insomnia in Primary Care seems to be more severe than insomnia in the general population; subjects rarely showed a single insomnia symptom: 3.0% for DIS, 1.8% for DMS, 0.5% for EMA, 1.4% for NRS. In contrast, 38.6% were associated with the 4 factors contributing to insomnia and 70.7% had DIS + DMS + EMA with or without NRS. Kushida et al. also found severe insomnia with 14.1% of the sample experiencing insomnia on a nightly basis [15]. Conversely, studies performed in the general population with a larger amount of subjects often only had one sleep complaint. Leger et al. found that 67% of insomniacs of the general population in Western Europe, 52% in USA and 52% in Japan had only one sleep complaint reported [5]. Kim et al. (2000) also found in a 3030 subjects sample representative from the general population of Japan that 8.3% of subjects had DIS only, 15% DMS and 8% EMA. NRS sleep was not assessed [21]. Finally, Soldatos et al. also found in an international survey collected the same day from 35,227 subjects from 10 countries representing all the continents, that DIS was the only complaint in 12.1% of subjects and DMS in 20.8% [4].

Another possibility is that there is high comorbidity between insomnia symptoms. Therefore, knowing that probably more than half of the subjects have more than 1 insomnia symptom, it is not surprising there is so little difference between each insomnia symptom. It may therefore be hypothesized that the combination of sleep complaints drives the insomnia patient to the GP. Very few insomniac patients even with severe symptoms consult a practitioner [13–22]. Pires et al. showed that only 12.5% of the Brazilian insomniacs in 1987 and even less (10.8%) in 1995 sought medical help for their sleep problems or informed their physician of sleep problems during the evaluation of other problems [2]. In a study carried out in the USA in five managed care organizations, Hatoum et al. indicated that only 0.9% of US patients consulted physicians for sleep problems [23]. Of those, only 11.6% were taking prescription medications specifically for sleep problems and 21.4% were taking over-the-counter products.

Another interesting finding in this study is the interrelationships between insomnia symptoms in Primary Care, as we previously observed through the vast majority of patients (Table 2). We also showed that each of the DMS, EMA and NRS symptoms were significantly linked to each other (Table 6). DIS alone is not associated significantly with DMS and EMA but was associated with NRS. Moreover, subjective assessments such as sleep satisfaction, sleep quality and sleep duration were also significantly associated with all the insomnia criteria. This is not enough to question the validity of consensual insomnia definitions and working sleep research groups [5,6,10,11], but it questions how the association of two or more single criteria would be representative of severe insomnia. Nonrestorative sleep (NRS) is, with regard to this debate, particularly representative. In the sample, we found that NRS was strongly associated with all other insomnia criteria. Ohayon (2005) had already shown in a sample of 25,580 Europeans that NRS was more likely to affect the active classes of the population and was also associated with excessive daytime sleepiness (a third of NRS subjects reported excessive daytime sleepiness compared to one-tenth for other subjects with insomnia), mood swings and cognitive impairment [3]. Kim et al. also analyzed the factors associated with each symptom of insomnia and found that in individuals who were psychologically stressed and being unable to cope with stress were significantly associated with DIS, DMS and EMA and explained most of the effects of other socio-demographic variables [21].

A major strength of this study is conducting the same protocol in ten countries, with different cultures from the Mediterranean countries of Europe, Middle Eastern countries (Greece, Portugal, Lebanon and Morocco), northern countries (Switzerland and Finland), Mexico (Central America), and the Philippines (Asia). International studies on sleep rhythms and complaints have been recommended by the World Health Organization [28] and for some of these countries (Lebanon, Morocco, Philippines) there were no data available in the recent international literature. In this study, however, we are aware that some countries were much more represented than others: Finland, Morocco, and Mexico. This may have influenced the global results, as Lebanon (58 patients) is very symbolic. Nevertheless, these three countries were also from three very different parts of the world (North Europe, South America, North Africa) so one cannot deny the wealth of its multicultural assessment of insomnia.

Cultural differences in sleep disorders have sometimes been explained by the awareness of the general population, by the education of GPs or by economical evolutions (Soldatos 2005, Pires 2007, Leger 2008). In this survey, we found that employment, noisy
environment, morning vs. evening chronotype, gender, age and residence are independent variables associated with sleep disturbances. These aspects will be developed more extensively in future papers.

7. Conclusion

Our study found that insomnia is a very common complaint in primary care all around the world and that insomniacs who visit PCPs seem to have more severe symptoms than those complaining of insomnia in the general population. This may convince GPs to systematically enquire about sleep disorders when patients are visiting even for another purpose, as more than one-third of their patients have well established insomnia.

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Appendix A

ELIGIBILITY CRITERIA

- Age ≥ 18
- Signed his/her informed consent
- Sleep disorders*
- Sleep promoting agents intake within one month prior to this visit, including OTC medication such as melatonin or diphenhydramine

* Sleep disorders are defined as difficulty initiating sleep, difficulty maintaining sleep, early awakenings, non-restorative sleep with daytime consequences, at least 2 times a week for at least one month.

** If one of these boxes is ticked, the subject cannot be enrolled in the survey

SOCIODEMOCRAPHIC CHARACTERISTICS

1. Gender:  □ Male  □ Female
2. Age (years): □□□□
3. Height: □□□□□ cm
4. Weight: □□□□□ kg
5. Do you live with other people: □ Yes  □ No
   If yes, Number of persons living with you at home: □□□□
   Number of children under 6-year old: □□
6. Employment: □ Full time  □ Part time  □ Unemployed/retired
7. Are you a shift worker? □ Yes*  □ No
   *If yes, □ Regular  □ Irregular
8. Residence: □ Rural  □ Suburban  □ Urban
9. Noisy environment: □ Yes  □ No
10. Do you consider yourself to be: □ a morning person  □ an evening person  □ cannot say
11. Do you have a driving licence? □ Yes  □ No
**SLEEP QUESTIONNAIRE**

1. Do you have difficulty falling asleep?  
   [ ] Yes  [ ] No  [ ] Most Troublesome (tick only 1 box)

2. Do you wake-up during the night with difficulties getting back to sleep?  
   [ ] Yes  [ ] No  [ ] Most Troublesome (tick only 1 box)

3. Do you wake-up too early in the morning without possibility to get back to sleep?  
   [ ] Yes  [ ] No  [ ] Most Troublesome (tick only 1 box)

4. Do you find your sleep is not restoring?  
   *(i.e: feeling unrested even if the duration of your sleep is normal)*  
   [ ] Yes  [ ] No  [ ] Most Troublesome (tick only 1 box)  
   NA

5. *If yes to any of the 4 previous questions, do you have these sleep problems:

   5.1 [ ] ≤ 3 nights per week or [ ] More than 3 nights per week

   5.2 [ ] For ≤ to one month or [ ] For more than one month

6. In general, when you wake-up, are you *(please refer to the completion guidelines for detailed rating):*

   Completely rested  [ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  Completely unrested

7. Sleep satisfaction: in general, do you find your sleep is *(please refer to the completion guidelines for detailed rating):*

   Completely satisfactory  [ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  Completely unsatisfactory

8. Sleep quality: do you feel that your sleep quality is *(please refer to the completion guidelines for detailed rating):*

   Excellent  [ ] 0  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  Dreadful

9. Do you consider your sleep duration *(please refer to the completion guidelines for detailed rating):*

   Very sufficient  [ ] 0  [ ] 1  [ ] 2  [ ] 3  Very insufficient

10. During working days:

   10.1 At what time do you go to sleep?  
       [ ] 11:00 H [ ] 11:00 mn

   10.2 At what time do you wake up in the morning?  
       [ ] 11:00 H [ ] 11:00 mn

   10.3 How many hours do you think you sleep at night on average?  
       [ ] 11:00 H [ ] 11:00 mn

   10.4 Do you regularly take nap?  [ ] Yes*  [ ] No  *If yes, average duration/day:  [ ] 11:00 H [ ] 11:00 mn

11. Have you ever been told that you suffer from:

   - [ ] Snoring loudy
   - [ ] Sleep apnea
   - [ ] Restless legs syndrome*

   * Restless legs syndrome should be suspected if patient experiences(ed) any of the following item:
     - Recurrent uncomfortable feelings or sensations in your legs while sitting or lying down,
     - Recurrent need or urge to move your legs while sitting or lying down,
     - When present, uncomfortable feelings or urge to move become worse while sitting or lying down than when active or moving about,
     - When present, uncomfortable feelings or urge to move are worse in the evening or at night, compared with the morning.

12. Do you take herbal preparations or use alcoholic beverages to help you to sleep?  [ ] None

   If any, please specify:
   < than once a month  < than once a week  1 to 3 times a week  4 to 5 times a week  everyday or almost

   Herbal preparation  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5

   Alcohol  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5
"DAY AFTER" QUESTIONNAIRE

Regarding the "day after" activities / tasks at work or at home, how would you rate the following items (from 0: "No" up to 5: "Very High"):

1. Do your sleep problems have globally a negative impact on your daily activities? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
2. Do your sleep problems have a negative impact on your work activities? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
3. Do your sleep problems have a negative impact on your relationships with other persons? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
4. Do your sleep problems have a negative impact on your leisure activities? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
5. Do your sleep problems have a negative impact on your memory capability? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
6. Do your sleep problems have a negative impact on your concentration capability? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
7. Do your sleep problems have a negative impact on your mood during the day, making you feel tense? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
8. Do your sleep problems have a negative impact on your mood during the day, making you feel irritable? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5
9. Do your sleep problems have a negative impact on your mood during the day, making you feel depressed? □ 0 □ 1 □ 2 □ 3 □ 4 □ 5

In the past 6 months:

10. How many hospitalizations could be related to your sleep problems? ___ ___ ___
11. How many doctor visits could be related to your sleep problems? ___ ___ ___
12. How many sick days could be related to your sleep problems? ___ ___ ___

In the past 12 months:

13. How many times have you fallen asleep while a driver without car accident? ___ ___ ___
14. How many car accidents while a driver could be related to your sleepiness? ___ ___ ___
15. How many accidents at home could be related to your sleepiness? ___ ___ ___
16. How many accidents at work could be related to your sleepiness? ___ ___ ___

SLEEP PROBLEMS MANAGEMENT

How do you plan to manage the sleep problems of your patient? Yes No

1. Cognitive behavioural therapy □ □
2. Prescription of (tick all boxes that apply):
   2.1 Natural products □ □
   2.2 Sleeping pills □ □
   If yes, specify: □ short acting □ moderate acting □ long acting
   2.3 Anxiolytic □ □
   2.4 Antidepressant medication □ □
   2.5 Other drugs □ □
3. Have you planned a follow-up visit for the sleep problems of your patient? □ □
4. Will you refer your patient to a sleep specialist? □ □
References


