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Original article

Impact, diagnosis and treatment of restless legs syndrome (RLS) in a primary care population: the REST (RLS epidemiology, symptoms, and treatment) primary care study

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Abstract

Objectives: To assess the frequency, impact, and medical response to the restless legs syndrome (RLS) in a large multi-national primary care population.

Method: Questionnaire surveys of matched patients and primary care physicians (PCPs) in five modern industrialized western countries.

Results: An RLS screening questionnaire was completed by 23,052 patients: 2223 (9.6%) reported weekly RLS symptoms; 1557 of these patients had medical follow-up questionnaires completed both by themselves and by their physician. An RLS sufferer subgroup ($n = 551$) likely warranting treatment was defined as reporting at least twice weekly symptoms with appreciable negative impact on quality of life. A total of 88.4% of RLS sufferers reported at least one sleep-related symptom. Most reported impaired sleep consistent with a diagnosis of insomnia. Out of 551 sufferers, 357 (64.8%) reported consulting a physician about their RLS symptoms, but only 46 of these 357 (12.9%) reported having been given a diagnosis. PCPs reported that 209 (37.9%) RLS sufferers consulted them about RLS symptoms, but only 52 (24.9%) were given an RLS diagnosis. In most countries, sufferers, regardless of diagnosis, were prescribed therapies not known to be effective in RLS.

Conclusions: RLS significantly impairs patients' lives, often by severely disrupting sleep. The marked under-diagnosis and inappropriate treatment of RLS indicates that PCPs need better education about this condition. Recognizing how often disrupted sleep results from RLS should improve diagnosis.

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Keywords: Restless legs syndrome; Quality of life; Primary care; Sleep disturbance; Prevalence; Insomnia

1. Introduction

Restless legs syndrome (RLS) is a sensorimotor disorder [1] characterized by an urge or need to move the limbs, usually associated with abnormal sensations in the legs. These symptoms are worse at rest, are relieved by movement, and mainly occur in the evening and/or at

night [2–4]. RLS was probably first described in the 17th century [5], but modern interest in the condition began with the work of Ekbom in the 1940s [6]. RLS morbidity in patients involves significant sleep disturbance and negative impact on quality of life [7]. The current understanding of the pathophysiology of RLS suggests the involvement of iron metabolism and dopaminergic dysfunction [1,7].

Epidemiological studies indicate that the symptoms of RLS are present in about 5–10% of the general population [8–10]. Despite this high frequency of affected individuals, experience suggests that it is often undiagnosed in those

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who present for treatment [7]. It follows that there is a need to understand more about RLS and how it is likely to present in a medical practice.

The objective of the RLS epidemiology, symptoms, and treatment (REST) Primary Care study was to survey the diagnosis, impact, and treatment of clinically significant symptoms of RLS in an international primary care population. REST Primary Care is the first study to provide a matched view of RLS from both patient and physician perspectives. A unique feature of the study design is the opportunity to compare the responses of physicians and patients to questions on the presentation and management of RLS symptoms within the primary care population.

2. Methods

Primary care centers in the USA and four European countries participated in this study. The goal was to obtain similar numbers of respondents from each country. Data were obtained from 182 primary care physicians (PCPs) and 23,052 patients, as follows: France (59 PCPs/4808 patients); Germany (32/6723); Spain (30/5752); UK (28/2114); USA (33/3655). As practices in France are smaller, more PCPs were selected from France than from other countries. Physicians were recruited from all regions of each country so as to represent the entire population. They were required to be full-time PCPs, who had been practicing for a minimum of 5 years. To facilitate distribution and collection of screening questionnaires, each practice was required to have a secretary/receptionist who could hand them out. In France this was often not possible, so we arranged to have an interviewer sit in the physician's reception to distribute and collect the screening questionnaires. Within the general geographic distribution, we selected preferentially those locations where patients were likely to be better educated and more familiar with completion of written questionnaires.

To avoid bias, PCPs asked to participate in the study were not told that it was a study of RLS. PCPs were informed of the process of the study, but questionnaires were not provided until after they had agreed to participate. Neither the PCP nor the patient (screener and follow-up) questionnaires specifically indicated that this was a study of RLS.

Patients who visited the centers (for any reason) over a 2-week enrollment period were asked to complete a screening questionnaire (Table 1) based on standard diagnostic criteria [2,3]. A presumptive diagnosis of RLS required a positive response to the four diagnostic questions of the screening questionnaire ($n = 2564/23,052$; 11.1%). Those with a presumptive diagnosis of RLS who reported symptoms at least once weekly (positive screeners; see Fig. 1) were asked to complete a more detailed questionnaire (patient follow-up questionnaire; $n = 2223/23,052$; 9.6%). This questionnaire included

Table 1

Diagnostic questions used to screen for restless legs syndrome (RLS) and identify frequency of symptoms

1. Do you have, or have you sometimes experienced, recurrent, uncomfortable feelings or sensations in your legs while sitting or lying down?
2. Do you have, or have you sometimes experienced, a recurrent need or urge to move your legs while sitting or lying down?
3. When present, do these uncomfortable feelings or this urge to move become worse when you are resting (either sitting or lying down), than when you are active or moving about?
4. Are these uncomfortable feelings, or this urge to move, worse in the evening or at night, compared with the morning?
5. During the last 12 months, have these uncomfortable feelings or sensations in your legs, or the need to move your legs while sitting or lying down, happened to you on average for one or more nights/days per week?

items confirming the diagnosis and probing demographics, lifestyle, symptom frequency, symptom characteristics, symptom consequences, consultation frequency, and diagnostic and treatment history (Table 2). The PCP for each patient was also asked to independently complete a questionnaire (physician questionnaire) on the screening

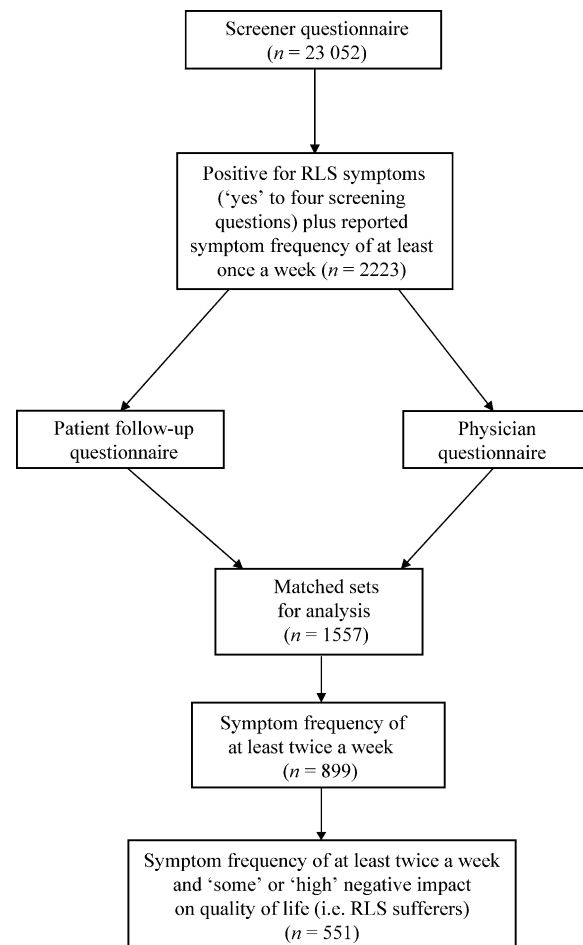


Fig. 1. Definition of the group suffering from restless legs syndrome (RLS). This flow diagram represents the successive stages in screening for RLS and selecting a population of RLS sufferers.

Table 2
Summary of the patient follow-up questionnaire

Questionnaire parts	Description
Part 1: Pre-questionnaire	(i) Do you have, or have you sometimes experienced, recurrent, uncomfortable feelings or sensations in your legs while sitting or lying down? (ii) Do you have, or have you sometimes experienced, a recurrent need or urge to move your legs while sitting or lying down? (iii) When present, do these feelings or movements improve or go away when you get up and walk around, for as long as you are walking? (iv) Plus other questions relating to exercise and whether feelings are more likely to occur when sitting or lying down
Part 2: Personal details	(i) Age (ii) Sex (iii) Employment details (iv) Lifestyle questions (v) Whether discussed symptoms with a doctor or not
Part 3: Symptoms	(i) Age of onset (ii) Frequency (iii) Are the symptoms painful or uncomfortable (iv) Time of day suffer from symptoms (v) Situations when symptoms likely to occur (vi) Parts of the body affected (vii) Symptoms suffered (selected from a list or by writing in other symptoms) and most troublesome symptom (viii) Diagnosis (yes/no: write in diagnosis)
Part 4: Treatment	(i) All treatments used to control symptoms (ii) Whether currently taking a prescription for symptoms or not (iii) Type of treatment taken (iv) Satisfaction with medication
Part 5: Effect of symptoms	(i) Quality of life (ii) Sleep patterns (iii) Sleep on a 'good' night (iv) Sleep on a 'poor' night (v) Statement best describing effect of symptoms

symptoms (Table 3). The PCP was instructed to review the patient's record for the past year in responding to this questionnaire, which was to be completed after the visit when the screening questionnaire was distributed. The PCP questionnaire covered diagnostic impression, previous and current treatment, consultation frequency and history, and specialist referrals.

Data were further analyzed in all cases having matched pairs of patient follow-up and physician questionnaires

Table 3
Summary of the physician questionnaire

Questionnaire parts	Description
Part 1: Patient history	(i) How many times has this patient been to see you in the last 12 months? (ii) How many times has the patient seen a specialist in the last 12 months? (iii) Which, if any, of the following conditions has the patient been diagnosed with in the last 12 months? (Select from list) (iv) Medications prescribed for conditions in (iii): write in (v) Drug classes prescribed for conditions diagnosed in last 12 months (select from list) (vi) Estimate of patient's current quality of life
Part 2: Diagnosis. The remaining questions referred specifically to the symptoms forming the RLS diagnostic criteria	(i) Have you discussed these symptoms with the patient before today? (ii) How many times in the last 12 months have you seen the patient about these symptoms? (iii) What impact do these symptoms have on the patient's quality of life? (iv) Tests conducted/requested (v) Secondary care specialists seen (vi) What diagnosis has patient received (write in or tick box for 'none') (vii) Who made the diagnosis?
Part 3: Treatment of symptoms	(i) Have you recommended any non-drug or over-the-counter treatment? (ii) Is the patient currently receiving any prescribed treatment? (iii) Was the treatment first prescribed today? (iv) Details of current treatments prescribed for symptoms

($n = 1557/2223$; 70.0%). From this group, a population of patients (RLS sufferers) was selected who might be most likely to present for treatment of RLS (Fig. 1). These patients were required to have reported symptoms at least twice weekly on the patient follow-up questionnaire ($n = 899/1557$; 57.7%) and also either some or a high negative impact of these symptoms on their quality of life (meeting both criteria $n = 551/1557$; 35.4%). Matching pairs of questionnaires from this final population were used for the analysis.

The differences between groups of subjects were explored with chi-squared statistics for categorical variables and with *t*-tests for quantitative variables.

Considering the total group of patients with a presumptive diagnosis of RLS and symptoms at least once weekly ($n = 2223$), the mean age of the 666 patients without matching pairs of completed questionnaires was compared with that of the group for whom completed matched sets were available. The residual from this latter group ($n = 1557 - 551 = 1006$), those who were not categorized as RLS sufferers, was also compared with the final analysis population ($n = 551$) for age and sex. Age at onset of symptoms was compared between men and women using a *t*-test.

3. Results

3.1. Prevalence of RLS symptoms in a primary care population

The prevalence of any degree of RLS symptoms was 11.1% (2564/23,052) and that for symptoms at least once weekly was 9.6% (2223/23,052). Considering only patients with matched questionnaires, a minimum estimate of the prevalence in those with at least twice-weekly symptoms is 3.9% (899/23,052; Fig. 1) and in those whose symptoms have also appreciable negative impact on quality of life, 2.4% (551/23,052; Fig. 1). Figures for individual countries are given in Table 4.

Because there were 666 patients who lacked matched questionnaires (2223 – 1557), it is appropriate to adjust these values. The mean age of these 666 subjects was no different from the ones with matched questionnaires ($P > 0.05$, *t*-test; because gender was only collected on the follow-up questionnaire, we cannot test for difference in gender). If we assume that the 666 patients without matched questionnaires are affected in the same proportion as the 1557 with matched questionnaires, then the estimated total number with twice-weekly symptoms is $(899/1557) \times 2223 = 1284$, and the estimated total number whose symptoms also had appreciable impact on quality of life is $(551/1557) \times 2223 = 787$. The corresponding

estimates of prevalence increase to 5.6% (1284/23,052) and 3.4% (787/23,052), respectively (see Table 4 for individual country breakdowns).

3.2. Patient demographics

The mean age of the 551 RLS sufferers was significantly greater than that of the whole survey population ($n = 23,052$) (56.6 [SD 15.3] vs. 51.4 [SD 17.6] years; $t = 6.87$; $P < 0.001$). Women comprised 68.1% of the RLS sufferers. The mean ages for men and women in the RLS sufferers group were 56.9 (14.6) and 56.5 (15.7) years, respectively. The mean age of onset of RLS symptoms was 45.8 (16.8) years for the RLS sufferer group as a whole, 48.5 (16.1) years for men and 44.5 (17.1) years for women ($t = 2.58$, $P < 0.01$). Overall, 53.4% of men and 64.8% of women (61.1% overall) reported onset of symptoms at 50 years of age or younger.

3.3. Symptoms

As part of the follow-up questionnaire, patients were asked to identify their symptoms from a set list or by writing in other symptoms. Many of those listed reflected the sensory nature of the diagnostic criteria: 96.7% of RLS sufferers reported at least one sensory symptom; 88.4% reported at least one sleep-related symptom (including one or more of inability to fall asleep, inability to stay asleep, and disturbed sleep), and 43.4% rated a sleep-related symptom as their most troublesome symptom (Fig. 2).

3.4. Impact of RLS symptoms

RLS sufferers reported that when symptoms occurred, these produced a marked impact on sleep: 68.6% reported taking more than 30 min to get to sleep (Fig. 3a; generally regarded as pathological [11]); and 60.1% reported waking three or more times per night (Fig. 3b). A majority of sufferers (335/551; 60.8%) reported that they lacked 'energy' when experiencing RLS symptoms; 60.1% (331/551) found it 'difficult to sit still or relax'; 57.2% (315/551) stated that their daily activities were disturbed; 53.9% (297/551) reported a tendency to become 'depressed/low'; and 49.7% (274/551) believed the symptoms adversely affected their concentration the next day.

When sufferers were asked about the overall impact of RLS symptoms on their quality of life, 36.3% (200/551) reported high negative impact and 63.7% (351/551) reported some negative impact.

3.5. Diagnosed conditions

Before responding to questions about the specific RLS symptoms, the PCPs were asked to pick from a list all of the diagnoses that they had given the patient within the previous year. PCPs reported that they had diagnosed

Table 4
Prevalence of RLS with different criteria for entire sample and individual country samples

Population sample	RLS at any frequency (%)	RLS at least weekly (%)	RLS sufferers (%) ^a
France ($n = 4808$)	7.4	5.0	2.1
Germany ($n = 6723$)	11.4	7.9	3.7
Spain ($n = 5752$)	5.5	3.6	1.9
UK ($n = 2114$)	14.2	11.3	5.6
USA ($n = 3655$)	13.3	11.3	5.8
Whole sample ($n = 23052$)	9.6	7.1	3.4

^a Subjects reporting at least twice-weekly RLS with moderate or severe impact on quality of life. Adjusted for subjects without matched questionnaires (see Section 3.1).

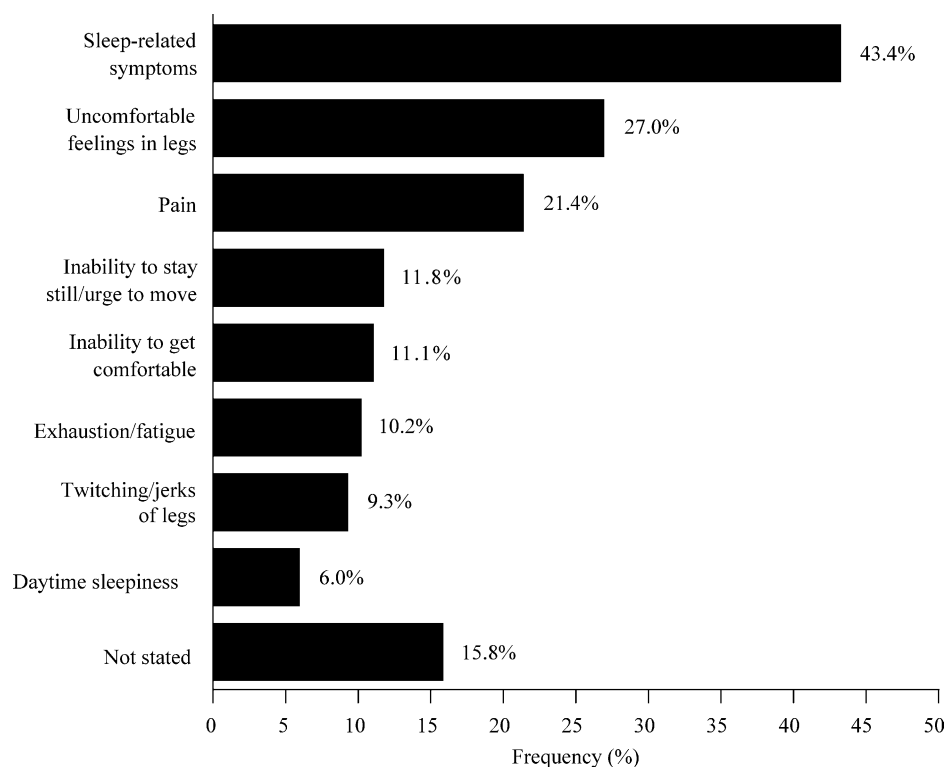


Fig. 2. Symptoms of restless legs syndrome (RLS) considered most troublesome by RLS sufferer group. Some respondents endorsed more than one option.

a wide range of medical conditions in the last 12 months. Those diagnosed at a frequency of 10% or more are listed in Table 5 for both RLS sufferers and those with at least weekly RLS symptoms and matched patient and physician questionnaires who did not meet the severity criteria defining RLS sufferers. The most commonly diagnosed conditions were back pain, depressed mood/depression, hypertension, insomnia/sleeping disorder, and anxiety. Those diagnoses that were most closely related to severity of RLS symptoms were depressed mood/depression, insomnia, and neuropathy, but every one of the diagnoses was more frequently made in the RLS sufferer group. A diagnosis of RLS was significantly more likely to be made in those with more severe symptoms of the syndrome (13.6% in the RLS sufferer group compared with 7.7% in those with weekly RLS symptoms and matched questionnaires who did not meet the severity criteria for sufferers; $P < 0.001$).

3.6. Consultation rates for RLS symptoms

A majority (357/551; 64.8%) of the RLS sufferers reported consulting a physician about their symptoms during the last 12 months (Table 6). This number was higher than the number for whom the PCP had recorded a consultation about symptoms of RLS (209/551; 37.9%), but may have included patients who consulted physicians other than their PCPs. There were 26 cases where the physician reported a previous consultation, but the patient

did not (five of which resulted in a diagnosis of RLS) and 172 where the patient reported a consultation but the physician did not. In four cases, the physician provided no information about previous consultations.

In addition to PCPs, patients reported that they had consulted a variety of secondary care specialists. The specialties consulted varied markedly between countries (Table 7), but overall neurologists, vascular specialists, and rheumatologists were most common and were among the three most common specialties in four of five countries. In three countries, cardiologists were also included in the most common group while sleep specialists were only included in the USA.

3.7. Diagnosis rates

Approximately half of RLS sufferers who reported consultations for their symptoms (207/357; 58.0%) reported receiving any diagnosis for them (Table 6). Those physicians who stated that a consultation had taken place with sufferers to discuss their symptoms ($n = 209$) were more likely to report a diagnosis for these symptoms (162/209; 77.5%). PCP responses to a question about what diagnosis had been given for the symptoms of RLS indicated that of the 209 RLS sufferers with a physician's diagnosis for their symptoms, a minority (52/209 or 24.9%) was given a diagnosis of RLS (Table 8). Other diagnoses by the physician included varicose veins/venous disorder

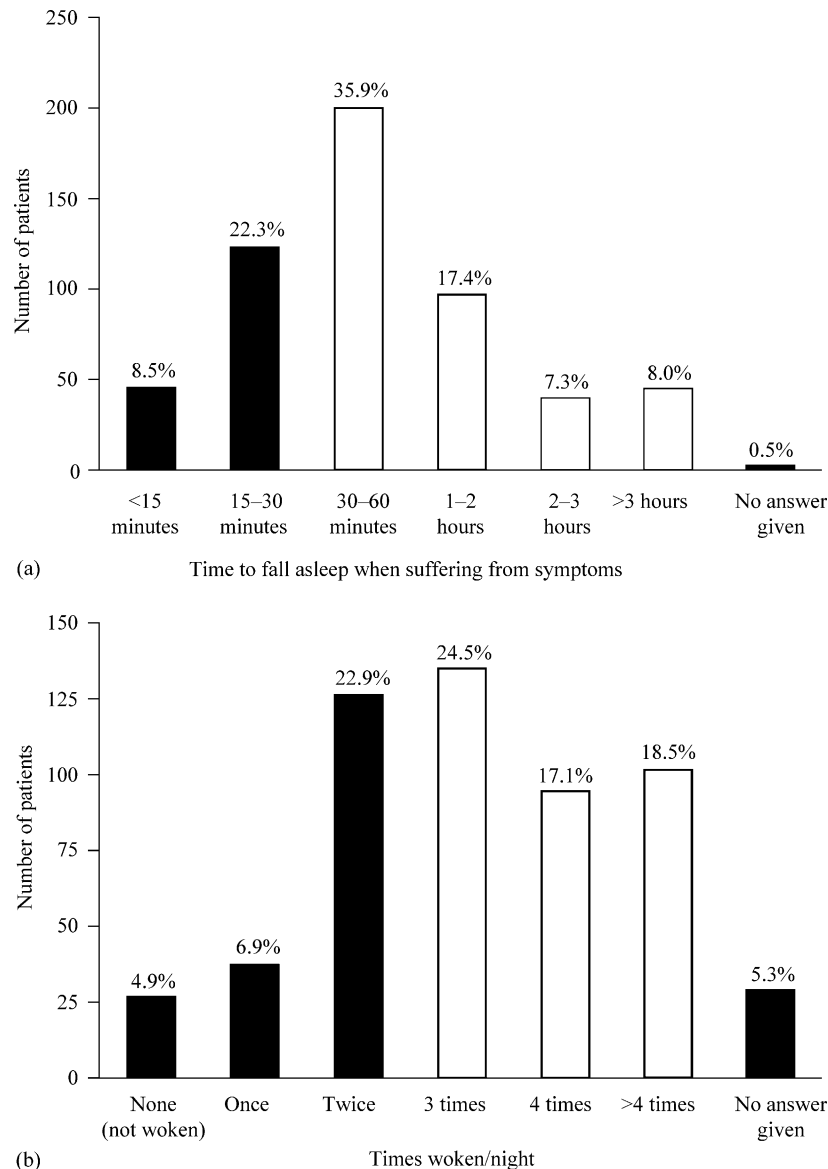


Fig. 3. Effect of restless legs syndrome (RLS) symptoms on (a) reported time to get to sleep and (b) number of reported wakings per night. Figures obtained from RLS sufferer group reporting on nights when bothered by symptoms. Unshaded bars indicate those in the range considered abnormal and representing insomnia.

(12.4%), back/spinal injury or problem (11.0%), diabetic neuropathy (7.7%) and depression (5.3%).

Forty-nine of the 551 RLS sufferers indicated that they had received a diagnosis of RLS. In 35 out of these 49 cases (71.4%), physicians indicated that they had made an RLS diagnosis. In the remaining 14 cases, the physician reported a non-RLS diagnosis in 10 cases, but gave no diagnosis in four cases. In 17 cases, the physician diagnosed RLS for these symptoms but the RLS sufferer did not report receiving the diagnosis.

3.8. Treatments for RLS symptoms

Medications prescribed for RLS symptoms in patients in the RLS sufferer group are listed in Table 9 from both the patient and physician perspectives. Both groups listed

a wide variety of medications. It is notable that while L-dopa is the most commonly prescribed medication for patients with a diagnosis of RLS, all but one of these sufferers (from the patient's perspective) were treated in Germany, where an L-dopa-based medication is approved for the treatment of RLS.

4. Discussion

The REST Primary Care study indicates that RLS is a common cause of sleep disruption that usually remains undiagnosed in primary care. Even when diagnosed, RLS is often not appropriately treated. These results highlight the need for education to make physicians more aware of how RLS presents and how it is diagnosed as well as

Table 5
Conditions commonly diagnosed during the last 12 months in patients with symptoms of RLS

Conditions diagnosed by physician (n = 1557)	RLS sufferers (n = 551) (%)	Other respondents with at least weekly RLS symptoms (n = 1006) (%)	Statistical significance (chi-square test)
Back pain	34.8	28.8	*
Depressed mood/depression	26.9	16.2	***
Hypertension	26.1	24.6	–
Insomnia/sleeping disorder	26.0	16.5	***
Anxiety	23.2	20.2	–
Arthritis	21.8	15.1	**
Nocturnal cramps	19.8	13.6	**
Obesity	17.1	13.1	*
Cardiovascular disease	16.2	13.1	–
Fatigue	14.3	13.4	–
RLS	13.6	7.7	***
Neuropathy/radiculopathy	12.0	5.2	***

*** $P < 0.001$; ** $P < 0.01$; * $P < 0.05$; –, not significant ($P > 0.05$).

Table 6
Consultation and diagnosis rates for RLS symptoms among RLS sufferers: patient and physician perspectives

	Patient perspective, n/N (%)	Physician perspective, n/N (%)
<i>Consultation</i>		
Patients consulting for RLS symptoms	357/551 (64.8)	209/551 (37.9)
<i>Diagnosis</i>		
Any diagnosis for RLS symptoms	207/357 (58.0)	162/209 (77.5)
RLS diagnosis	46/357 (12.9)	52/209 (24.9)
Other diagnosis	161/357 (45.1)	110/209 (52.6)

Table 7
Specialists consulted about RLS symptoms by country: patient perspective

Type of specialist	France (n = 70) (%)	Germany (n = 174) (%)	Spain (n = 75) (%)	UK (n = 83) (%)	USA (n = 149) (%)	Overall (n = 551) (%)
Neurologist	5.7	17.2	9.3	3.6	15.4	12.2
Phlebologist/vascular surgeon	20.0	11.5	10.7	3.6	1.3	8.5
Rheumatologist	15.7	5.7	10.7	1.2	6.7	7.3
Cardiologist	12.9	5.7	0.0	3.6	4.7	5.3
Psychiatrist	10.0	2.3	5.3	1.2	4.7	4.2
Sleep specialist	1.4	5.2	2.7	2.4	6.0	4.2
Diabetologist	1.4	3.4	1.3	0.0	4.0	2.5
Endocrinologist	4.3	1.7	5.3	0.0	2.0	2.4
Pulmonologist	1.4	2.9	0.0	1.2	2.0	1.8
Nephrologist	0.0	1.7	0.0	0.0	2.0	1.1
Geriatrician	0.0	1.7	1.3	0.0	0.7	0.9

The three most frequently consulted specialties in each country are in bold (n is the number of RLS sufferers in each country and overall).

the medications established to be most effective for its treatment. REST Primary Care is the first profile study of RLS to collect data on the condition from both the patient and physician perspective. An attempt was made to reduce biases in PCP selection and reporting by only disclosing the focus of the study after PCPs agreed to undertake the process. Because the study investigated several thousand patients in each of the five countries, the results are not restricted to any particular locale and are broadly representative of the situation in developed western countries. To make it clinically relevant, we focused on patients with relatively frequent and troublesome symptoms, that is, the group most likely to seek medical help for the condition.

4.1. Prevalence estimate of RLS symptoms

The four diagnostic questions in the screening questionnaire were based on the standard diagnostic criteria for RLS [2,3]. These four questions were validated in a prior study in a PCP population and had a sensitivity of 82.3% and specificity of 89.9% [12] in a validation study performed in one North American PCP practice located in an ethnically homogenous (Caucasian) practice in Idaho. In this study we found that 11.1% of the sample met the diagnostic criteria with any frequency, 9.6% had weekly symptoms, and 5.6% had twice-weekly symptoms. These frequencies are somewhat lower than those in the Idaho study, but are closer if a minimum frequency of symptoms is required (e.g. RLS at any frequency, 11.1 vs. 24.0% in Idaho or at weekly frequency, 9.6 vs. 15.3% in Idaho). A number of differences may have contributed to this result. First, the Idaho community was relatively homogenous and most of its members had North European origins. Second, it was not necessarily as representative as our general result, based on a single practice as opposed to the many practices utilized in the current study. Finally, the study members in Idaho were fully aware of the aim

Table 8

Diagnosis given by physicians for symptoms of RLS to those individuals in the RLS sufferer group reported by the physician to have consulted about their symptoms

Diagnosed by physician	Diagnosis, <i>n</i> (<i>N</i> = 209) (%)
RLS	52 (24.9)
Varicose veins/venous disorder	26 (12.4)
Damage/problem with lower spine/lumbar region	23 (11.0)
Diabetic neuropathy	16 (7.7)
Depression	11 (5.3)
Myalgia	9 (4.3)
Neuropathy/radiculopathy	8 (3.8)

of their study and this might have led to increased numbers of positive responses.

Our results are also similar to those in large population studies using similar questionnaires. Phillips et al. [8] used a frequency criterion of at least five nights per month to define persons with symptoms of ‘restless legs’ in their study of the general population in Kentucky, USA. They reported a very similar prevalence of 10.0% for those with symptoms of RLS at least weekly. Other studies in the general population using the current diagnostic criteria have found prevalences in a similar range [9,10,13]. Because our sample was drawn from those seeking medical attention, it might likely include a higher fraction of individuals who report having RLS symptoms. In a companion study, which included all of the countries investigated in this report (Allen et al., unpublished observation), we have found that overall prevalence rates are lower, that 7.2% rather than 11.1% report symptoms at any frequency. Thus, it is likely that our estimates may be somewhat higher than would be true of a general population that includes those not seeking medical care.

However, even considering that our prevalence figures may be somewhat increased from the general population and that our study includes at least some individuals who

obtained ‘false positive’ diagnoses for RLS, the validity of our questionnaire indicates that a substantial percentage of individuals have RLS and suffer from its symptoms.

4.2. Estimate of patients likely to require treatment for RLS

We selected a group of patients to analyze in detail who had RLS symptoms likely to require medical management (RLS sufferers: those with symptoms at least twice a week and with appreciable negative impact on quality of life). We estimate this group to make up over 3% of the population presenting to a PCP. The Idaho primary care study found that a quite similar portion of those with RLS had clinically significant symptoms. They identified a group with symptoms that occurred three times or more a week but requiring only a mild or greater impact. This group had a prevalence of 6.0% compared with our RLS sufferer prevalence of 3.4%. These RLS sufferers experience both sensory and sleep-related symptoms. The sensory symptoms form part of the standard diagnostic criteria for RLS but sleep-related symptoms can also aid the clinical diagnosis of RLS. High percentages of those with moderate or severe RLS reported taking > 30 min to get to sleep (a widely used indicator of insomnia [11]) and waking more than three times per night when suffering from RLS symptoms. Similar results were reported by Montplaisir et al. [14], who studied 133 patients diagnosed with RLS by the criteria of the International RLS Study Group and found that 85% complained of difficulty falling asleep and/or staying asleep.

Many of the consequences of RLS identified by the patients could be related to sleep disruption; for example, lack of energy and lack of concentration in the following day. The impact of RLS symptoms on sleep may also explain the reported association between RLS and reduced general health status [8–10,15]. Sleep-related symptoms are likely to be a major presenting feature when patients consult a physician about the symptoms of RLS, and hence

Table 9

Medications prescribed most frequently for the treatment of RLS symptoms in patients in the RLS sufferer group with and without a diagnosis of RLS: physician and patient perspectives

	Patients with a diagnosis other than RLS, <i>n</i> (%)		Patients with a diagnosis of RLS, <i>n</i> (%)	
	Patient perspective (<i>N</i> = 161)	Physician perspective (<i>N</i> = 110)	Patient perspective (<i>N</i> = 46)	Physician perspective (<i>N</i> = 52)
Thiocolchicoside	11 (6.8)	10 (9.1)	0 (0.0)	0 (0.0)
Diclofenac	15 (9.3)	9 (8.2)	1 (2.2)	1 (1.9)
Paracetamol	12 (7.4)	9 (8.2)	0 (0.0)	1 (1.9)
Gabapentin	8 (5.0)	7 (6.4)	0 (0.0)	4 (7.7)
Quinine bisulphate	1 (0.6)	6 (5.5)	0 (0.0)	1 (1.9)
Clonazepam	2 (1.2)	5 (4.5)	6 (13.0)	3 (5.8)
L-dopa ^a	3 (1.8)	1 (0.9)	20 (43.5)	23 (44.2)
Trazodone	0 (0.0)	0 (0.0)	1 (2.2)	2 (3.8)

^a Includes Restex[®], indicated for the treatment of RLS in Germany.

RLS should be specifically explored as a possible diagnosis when patients complain of difficulties in getting to sleep and frequent awakening during the night.

The other clinical criterion for inclusion in the RLS sufferers group was self-reported impact of symptoms on quality of life, again set at a level likely to be clinically relevant. Over 35% of the sufferer group considered the symptoms of RLS to have a substantial negative impact on their quality of life. Rothdach et al. [16] also investigated the impact of RLS on quality of life. They found significant differences ($P = 0.03$) in Short Form (SF)-36 mental health scores between elderly people with and without symptoms of RLS. Similarly, the companion REST general population study found that RLS sufferers have SF-36 scores significantly below age- and gender-adjusted population norms and comparable to those of patients with other chronic medical conditions (Allen et al., submitted).

Many of the RLS sufferers in this study were not diagnosed or given accepted medical treatment for RLS [17], which may likely have resulted in continued distress for the patient and possible repeat consultations and/or specialist referral. Patients reported by PCPs to have been given some diagnosis received a wide range of prescribed medications, including preparations for gout (thiocolchicoside), cramps (quinine), analgesics, anti-inflammatory drugs, and benzodiazepines. Many of these medications are not appropriate first-line treatments for the symptoms of RLS.

Treatment standards for RLS have indicated that a number of drug classes can be useful in RLS [17], including opioids, dopaminergic agents, and anticonvulsants. Recently published, updated standards have focused only on dopaminergic agents [18].

In particular, controlled studies have shown that dopaminergic medications improve both the sensory and motor symptoms of RLS in most patients [19–25]. Indeed, response to treatment with dopaminergic agents has recently been proposed as a supportive feature in the clinical diagnosis of RLS [3]. In the REST Primary Care study, dopaminergic therapy was prescribed for a number of patients (Table 9); all but one of these patients were in Germany, where an L-dopa-based therapy is approved for the treatment of RLS. Most countries have no licensed therapies available for the treatment of symptoms of RLS. However, the usefulness of L-dopa may be limited because it is associated with a high frequency of symptom augmentation [26]. It is likely that a wider recognition of effective treatments would improve the management of RLS by PCPs.

4.3. Comparison of patient and physician perspectives

An important feature of the design of the REST Primary Care study is the opportunity to compare responses to the patient questionnaire with data supplied by the PCPs from their records. There were discrepancies between the patient

and physician views of RLS consultation, diagnosis, and treatment. Physicians reported consultations and diagnoses that patients did not and vice versa. RLS sufferers recorded more consultations about RLS symptoms than did PCPs, but, given the phrasing of the question, the RLS sufferers may have been remembering consultations with other physicians. This group had frequent specialty consultations other than PCP visits. The differences between patients and PCPs may reflect misunderstandings by the patient, difficulty in describing sensory symptoms, a failure of the physician to recognize the diagnostic criteria of RLS due to low awareness of the condition, inadequate information supplied by the physician, or possibly deficiencies in the physicians' records.

5. Conclusions

In conclusion, the results of the REST Primary Care study suggest that RLS is a major cause of sleep disturbance among patients visiting PCPs in western Europe and the USA. The data reported here support the view that moderately severe symptoms of RLS causing appreciable distress are present in about 3% of patients visiting a PCP, but RLS often remains undiagnosed. Awareness of the condition appears to be low as shown by the wide range of diagnoses given to those with symptoms of RLS and by the low rate of diagnosis of RLS. Diagnosis rates could be improved by making the diagnostic criteria for RLS better known and having physicians consider RLS in the differential diagnosis of patients with sleep disorders that involve long sleep latency and frequent waking during the night. It will also be important for those making the diagnosis to be aware of current effective treatment options to alleviate the substantial impairment of quality of life that many of the RLS sufferers reported.

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