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Original Article

Chronic insomnia, quality-of-life, and utility scores: Comparison with good sleepers in a cross-sectional international survey

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ABSTRACT

Background: Chronic insomnia has a recognized impact on health-related quality-of-life (HRQoL) but data on utility scores across countries are lacking. The objective of the present study was to assess health related quality of life (HRQoL) and utility scores in individuals from three different countries (USA, France, and Japan), comparing sufferers of chronic insomnia to good sleepers.
Methods: A cross-sectional survey (SLEEPI-i) of 4067 persons in the US (n = 1298; 478 good sleepers and 820 patients with insomnia), France (n = 1858; 998 good sleepers and 860 patients with insomnia) and Japan (n = 911; 506 good sleepers and 405 patients with insomnia). Enrollment and data collection using consumer panels were web-based in the US and France, and gathered via a postal survey in Japan. People with chronic insomnia (>6 months) were selected based on Insomnia Severity Index scores (ISI). Severity of insomnia was assessed using the ISI score and HRQoL was assessed using the self-administered Short-Form SF-36 Health Survey. Utility scores were derived using the algorithm developed by Brazier et al. Multivariate analyses were used to adjust for potential confounding factors.
Results: In all countries, people with chronic insomnia (40% treated) reported lower SF-36 scores in each of eight domains compared with good sleepers ($P < .0001$). Chronic insomnia was associated with significantly lower utility scores compared with good sleepers (mean scores 0.63 versus 0.72 in the US, 0.57 versus 0.67 in France, and 0.67 versus 0.77 in Japan, $P < .0001$).
Conclusions: This survey suggests that chronic insomnia is associated with significant impairment of HRQoL and decreased utilities across the different geographical regions studied.

1. Introduction

Insomnia is defined as difficulty initiating sleep, difficulty maintaining sleep, morning awakening, or sleep that is chronically non-restorative or poor in quality associated with daytime impairment such as fatigue, memory impairment, social or vocational dysfunction, or mood disturbance [1,2]. Chronic insomnia (with a duration of at least 1 month) is the most prevalent sleep disorder in the general population and is reported by 20–30% of adults. It is shown that insomnia increases with age and is more prevalent in women than in men [3–6].

Chronic insomnia not only interferes with an individual's health [2], but also confers a substantial socio-economic burden, given associations with falls and other accidents [7], decreased cognitive functioning, health-related quality of life (HRQoL) [8], increased absenteeism [9,10], and increased utilization of medical resources [10–12]. Yet research on this issue has been limited [2]. Previous studies using the 36-item Short Form Health Survey of the Medical Outcomes Study (SF-36) reported that insomnia was associated with a negative impact across all dimensions of HRQoL, increasing with severity of disease [13–16]. However, to our knowledge, there is no multi-country study of HR-QOL and utilities in insomnia.

The concepts of quality-adjusted life years (QALYS) and utilities are the basis for expressing the burden of disease and evaluating the cost effectiveness of therapeutic interventions. QALYs, the product of the average years of life that remain for the patient

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and the utility of those years based on associated HRQoL, is commonly used for comparative cost effectiveness analyses [18]. Utility measurement is a method of determining an individual's preference for a certain outcome represented by a quantitative score: from perfect health (1) to death (0). Given the importance of understanding common patient characteristics independent of their cultural expression [18–20], and that the prevalence of insomnia varies between countries [21], this cross-sectional survey was performed in the USA, France, and Japan to obtain information relating to HRQoL and utility scores in people with chronic insomnia in different countries.

2. Methods

2.1. Design

SLEEPi (Study Linking European–US–Japanese Economic Perceptions in Insomnia – internet-based) was a cross-sectional, web- and paper-based questionnaire survey in three industrialized countries (the US, France, and Japan).

2.2. Participants

Participants were recruited on-line in the USA and France from the Harris Poll and Ciao (France only) market research panels, consisting of individuals who had voluntarily registered and agreed to regularly complete research surveys on a variety of topics. Between December 2005 and May 2006, individuals were randomly selected to participate in the survey based on pre-registered demographic information (e.g., age, gender, marital status, education level, income level, etc.) and received an e-mail invitation describing the study and providing an individualized web-link to the survey. Individuals initially completed a screening questionnaire and those satisfying the selection criteria were then asked to complete the remainder of the questionnaire. Demographic data used to select a representative sample of each country were based on the 2005 census data of subjects >15 years old (the respective populations of the three countries were USA: 234 934 412 inhabitants, France: 49 498 357, and Japan: 109 221 888 in 2005). A weighting was performed to adjust our sample to the structure of each population at the national level in terms of age, gender, and household economic level. Harris panel participants who qualified and completed the survey received 100 Harris points as an incentive. Ciao respondents received €0.7 for every 5 min spent participating in the survey.

Within the sample for each country, 30% of respondents were to be age 60 years or older, to ensure that the survey captured a sufficient sample of older people, given that insomnia is common in that age group.

In Japan, a postal paper-based survey was used due to the limited size and number of Internet panels in Japan, especially in respect to older members ($\geqslant$60 years). Consequently, respondents were enrolled using the Intage panel, an off-line syndicated consumer panel for which participants were recruited from several sources, including quota samples and random household sampling. A postcard screener was initially mailed to participants, and those satisfying the inclusion criteria were then sent the full survey. A gift certificate (1000 JPY) was offered as an incentive for respondents to complete the full questionnaire. Inclusion and exclusion criteria were then applied to all participants completing the full questionnaire.

Participants were initially screened using the Insomnia Severity Index (ISI) [22], with an inclusion score range of 0–7 for good sleepers (control), 15–28 for non-treated chronic patients with insomnia, and 0–28 for treated chronic patients with insomnia (see below and Fig. 1). Other inclusion criteria for both good sleepers and patients with insomnia were: (1) aged at least 18 years; and (2) ability to read and write English, French, or Japanese (depending on the country of recruitment). Additional criteria for insomnia were assessed with a series of questions and included: (1) fulfilled the International Classification Of Sleep Disorders criteria for insomnia [1] including difficulty initiating or maintaining sleep, early morning waking, or sleep that was chronically non-refreshing or poor in quality (and occurred despite adequate opportunity for sleep), and reported complaints about daytime functioning related to night-time sleep difficulty; and (2) a history of insomnia for at least six months. This duration, rather than at least one month as commonly used to define chronic insomnia, was felt to be preferable for assessing the impact on HRQoL. Exceptionally, we considered that treated patients with insomnia who still presented ICSD complaints of insomnia for more than six months, even if they had an ISI <7, would be included in the group of chronic patients with insomnia.

In order to focus on primary insomnia, exclusion criteria were all co-morbidities which may produce co-morbid insomnia (e.g., chronic pain almost every night; treated major depression or anxiety disorders, alcohol and substance abuse, or other psychiatric illnesses; prostate problems), or risks of sleep disorders other than insomnia such as loud snoring on most nights, difficulty breathing during sleep almost every night, or known sleep apnoea; restless legs on most nights; or circadian sleep disorders such as frequent travel across three or more time zones (jetlag) and night work or rotating shift work.

2.3. Procedure

A questionnaire (see Supplementary Appendix) was developed, and included questions about sleep habits (over the past month, excluding week-ends or vacations), sleep treatments (prescription or non-prescription), education level, employment status, weight and height (to calculate body mass index [BMI]), co-morbidities, use of caffeine, use of alcohol to help sleep, and treatments for insomnia in the last 3 years. The translations were performed from English into French and Japanese by local native speakers and then validated by country-specific focus groups.

2.4. Measures

2.4.1. HRQoL

The SF-36 was used to measure HRQoL in chronic patients with insomnia and good sleepers. The SF-36 is a multipurpose health survey consisting of 36 items, covering eight domains: physical functioning, ten items; limitations due to physical health (role physical), four items; bodily pain, two items; general health perceptions, six items; vitality, four items; social functioning, two items; limitations due to emotional problems (role emotional), three items; and mental health, five items. Scores are expressed on a scale of 0–100 for each domain with higher scores indicative of better health and well being. The SF-36 also yields two summary measures of physical and mental health: the Physical Component Summary (PCS) and Mental Component Summary (MCS). In France and the USA, unadjusted SF-36 domain scores in each group were compared with the general population.

The need to both take account of public-health perspectives and to emphasize patient preferences has led to the development of many health questionnaires and their inclusion as primary and secondary outcome measures in clinical trials [23]. Measurements of HRQoL have, therefore, been extensively used to assess patients' feelings and to organise health care services in the patients' populations [24,25]. The generic, multidimensional 36-item Short-Form Health Survey (SF-36) has been used across a range of populations and disease and treatment groups [26–31]. The advantages of the SF-36 over other similar instruments, particularly its balance between being concise and comprehensive, and its versatility, suit-

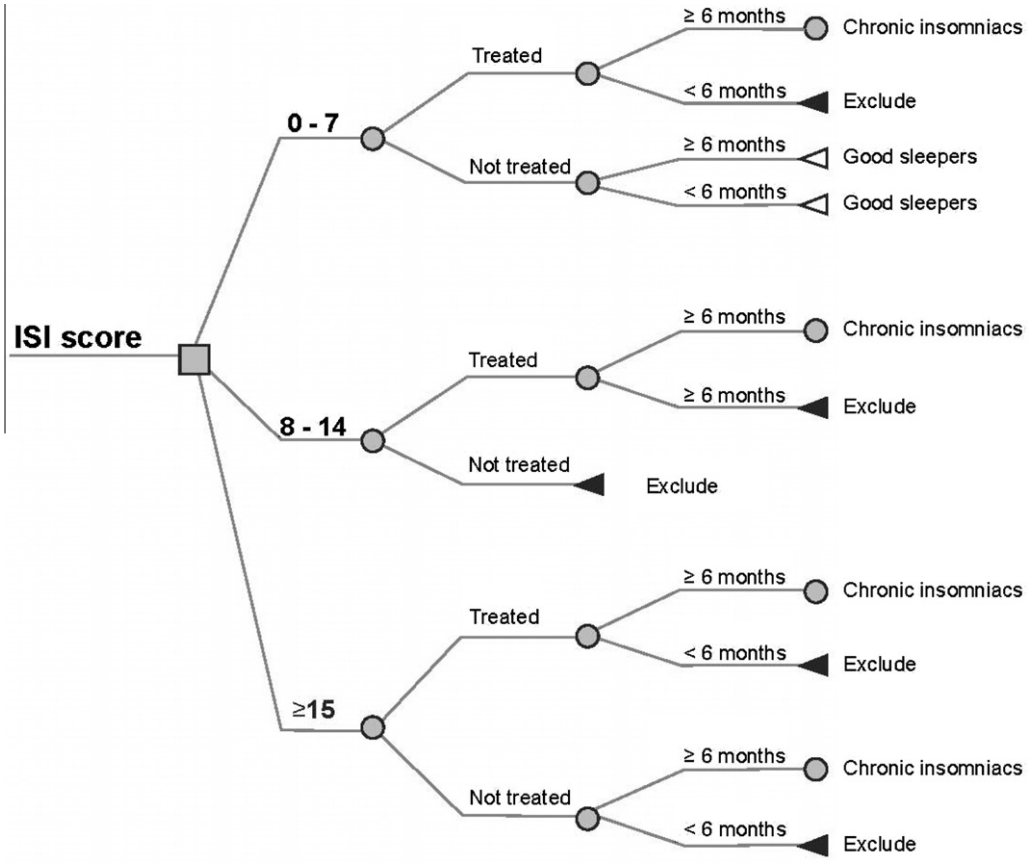

Fig. 1. Method of screening respondents based on their Insomnia Severity Index (ISI) score and treatment group. Legend: the Insomnia Severity Index (ISI) score and clinical information were used to identify individuals with chronic insomnia and to assess its severity [22]. The ISI score focuses on both night- and daytime symptoms of insomnia (insomnia severity, worry about sleep, functional impairment, social concern, and sleep satisfaction). It consists of seven questions with scores ranging from 0 to 28 (the maximum score for questions is 4): a score of 0–7 indicates no clinically significant insomnia (i.e., a good sleeper); 8–14, sub-threshold insomnia; 15–21, moderate insomnia; and 22–28, severe insomnia. Exceptionally, we also included in the chronic insomnia groups patients with treated insomnia who had an ISI <7 but who still complained of chronic insomnia according to the definitions for more than 6 months.

able for self-, interview-, and telephone-administration, have led to its widespread use in many studies' utility scores. Since SF-36 data are multidimensional and the response choices and measured items are not equally important, scores must be transformed into a one-dimensional utility index. To accomplish this, SF-36 data were transformed into a preference-based 6-dimensional health state classification, SF-6D utility scores, using an algorithm developed by Brazier et al. [32]. The algorithm uses a direct approach to derive utility scores from elicited responses of a population using a standard gamble preference method. Originally validated by a UK population, it has been used in France and the US with no significant variation in the weights between countries [33].

2.5. Statistical methods and data analysis

The planned recruitment was 1200 individuals per country, comprising 400 good sleepers and 800 patients with insomnia (400 each with onset insomnia or maintenance insomnia). A total of 400 respondents per group was considered sufficient to detect a meaningful minimum difference in effect size of 0.20 in the SF-36 domains with 80% power ($\alpha = 0.05$) [34].

All statistical tests were two-sided with a global level of significance of 5%. Qualitative variables were compared between groups using an χ^2 test, or Fisher's exact test in the case of small expected cell frequency (i.e., <5). Continuous variables were compared using either a *t*-test or an analysis of variance (ANOVA, Fisher test) for more than two groups. If normality conditions were not attained, then non-parametric tests were performed (Mann–Whitney–Wilcoxon test for comparison of two groups or Kruskall–Wallis test for comparisons of more than two groups). To adjust for potential confounding factors, two multivariate regression analyses (ANCOVA) were performed. For the comparison of good sleepers versus chronic patients with insomnia the covariates included age, gender, class, BMI, household income, employment status, smoking status, coffee (caffeine) use, alcohol use, characteristics of insomnia (family history of insomnia, Insomnia Severity Index [ISI] score, duration of insomnia, insomnia treatment), and selected comorbidities or conditions, such as (1) hypertension, (2) diabetes, (3) lung disease, (4) heart disease, (5) digestive problems, (6) arthritis, (7) menopausal problems and (8) metabolic disorders. For the analysis of treated versus non-treated chronic patients with insomnia the same analysis was performed excluding the ISI score as a covariate, as treated patients were assumed to have lower scores. Multivariate models were developed with SAS® (version 9.1, SAS Institute Inc., Cary, NC), using a backward stepwise approach; non-significant variables at the 5% level were excluded.

3. Results

3.1. Population characteristics

Fig. 2 shows the flow of participants in the study. The study population comprised 4067 individuals, of whom 2085 (48.7%) had chronic insomnia; 832 (39.9%) patients with insomnia were currently treated.

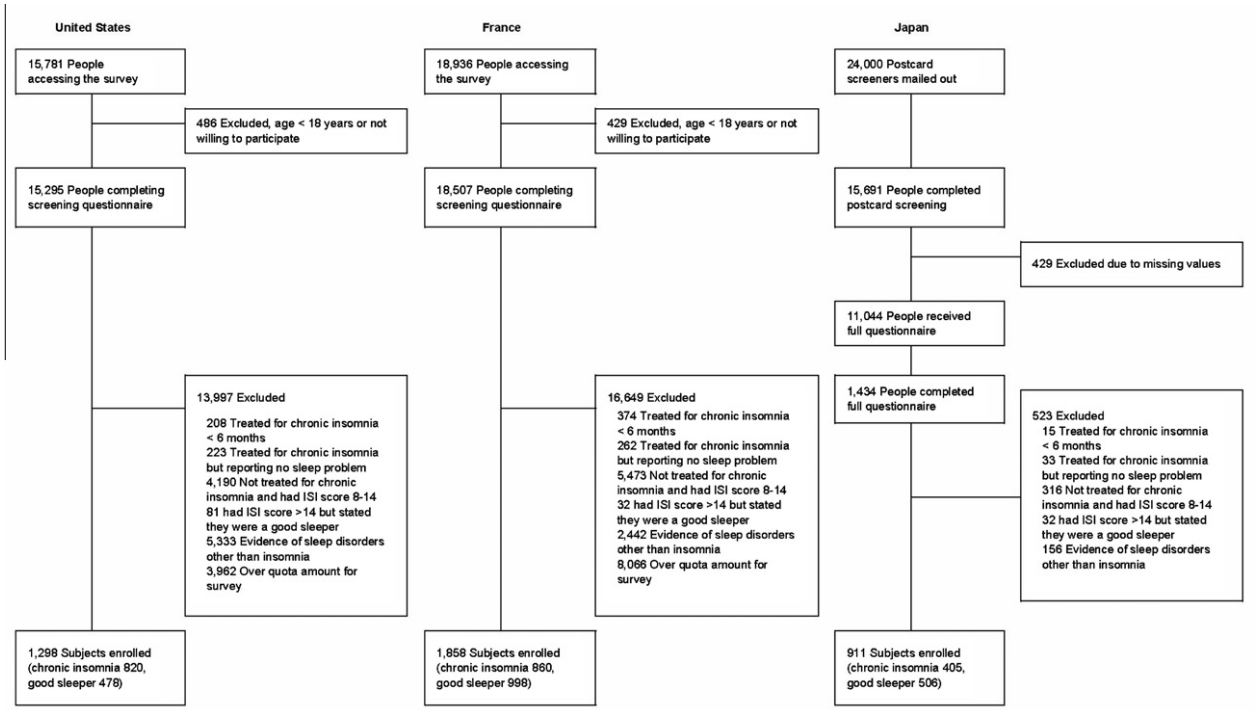

Fig. 2. Participant flow in the study.

Table 1
Demographic and clinical characteristics of good sleepers compared with chronic patients with insomnia.

Characteristics	US		France		Japan	
	Good sleepers (n = 478)	Chronic insomnia (n = 820)	Good sleepers (n = 998)	Chronic insomnia (n = 860)	Good sleepers (n = 506)	Chronic insomnia (n = 405)
ISI score	3.5 ± 2.3	16.7 ± 4.7[a]	3.6 ± 2.2	16.4 ± 3.8[a]	2.8 ± 2.1	16.3 ± 4.0[a]
Age, mean ± SD, y	54.3 ± 16.5	50.0 ± 15.9[a]	52.3 ± 15.9	43.7 ± 15.9[a]	47.8 ± 16.7	52.4 ± 15.1[a]
Over 60 y, No. (%)	244 (51.0)	285 (34.8)[a]	530 (53.1)	224 (26.0)[a]	138 (27.3)	158 (39.0)[a]
Females, No. (%)	218 (45.6)	553 (67.4)[a]	268 (26.9)	549 (63.8)[a]	252 (49.8)	276 (68.1)[a]
Race, No. (%)						
Caucasian	439 (91.8)	746 (91.0)	–	–	–	–
Black	9 (1.9)	10 (1.2)	–	–	–	–
Other	30 (6.3)	64 (7.8)	–	–	–	–
BMI, mean ± SD, kg/m^2	28.8 ± 7.1	28.4 ± 7.4	26.3 ± 5.6	25.1 ± 5.4[a]	22.2 ± 2.9	21.7 ± 2.9
Obese >29.9 kg/m^2, No. (%)	174 (36.4)	271 (33.0)	166 (16.6)	121 (14.1)	7 (1.4)	4 (1.0)
Alcohol to help sleep, No. (%)	23 (4.8)	71 (8.7)[a]	23 (2.3)	52 (6.0)[a]	65 (12.8)	118 (29.1)[a]
Duration of insomnia (years), mean ± SD	1.4 ± 3.7	8.1 ± 10.3[a]	1.3 ± 5.1	6.6 ± 9.0[a]	0.4 ± 1.5	4.4 ± 5.0[a]
Smokers and recent quitters, No. (%)	108 (22.6)	258 (31.5)[a]	208 (20.8)	284 (33.0)[a]	118 (23.3)	83 (20.5)
Intake of caffeinated drinks, mean ± SD[b]	2.4 ± 2.3	2.4 ± 2.7	2.4 ± 2.3	2.5 ± 2.4	2.1 ± 2.0	2.2 ± 1.9
Receiving insomnia treatment, No. (%)	–	387 (47.2)	–	243 (28.3)	–	202 (49.9)
High level education, No. (%)[c]	117 (24.5)	165 (20.1)	400 (40.1)	226 (26.3)	–	–
Full or part time employment, No. (%)	254 (53.1)	421 (51.3)	457 (45.8)	477 (55.5) [a]	311 (61.5)	202 (49.9) [a]
Charity work, No. (%)	63 (13.2)	108 (13.2)	201 (20.1)	92 (10.7) [a]	14 (2.8)	16 (4.0)

Abbreviations: ISI = Insomnia Severity Index; n = number; SD = standard deviation; % = percentage; y = years; BMI = body mass index.
–Insufficient data or calculation not applicable.
[a] Indicates P<.05 by t-test, good sleepers versus chronic patients with insomnia within each country.
[b] Number of cups or cans per day.
[c] Equivalent to reaching graduate school level in the USA and Baccalauréat plus 4 or over in France.

Demographic and clinical characteristics of participants with chronic insomnia and good sleepers are summarized by country in Table 1. The proportion of older respondents (>60 years) with chronic insomnia was higher in the US and Japanese cohorts (35% and 39%, respectively) than the French cohort (26%). Participants with chronic insomnia were younger than good sleepers in France and the US (mean age 44 and 50 years, versus 52 and 54 years), but older in Japan (52 versus 48 years), and there was a majority of women (64–68%). Those with chronic insomnia reported sleeping problems for an average of 8 years in the US,

Table 2
Demographic and clinical characteristics of respondents with chronic insomnia, treated versus not treated.

Characteristic	US		France		Japan	
	Treated (*n* = 387)	Not-treated (*n* = 433)	Treated (*n* = 243)	Not-treated (*n* = 617)	Treated (*n* = 202)	Not-treated (*n* = 203)
ISI score	14.9 ± 5.5	18.4 ± 3.1[a]	13.8 ± 5.1	17.4 ± 2.4[a]	15.3 ± 5.0	17.3 ± 2.3[a]
Age, mean ± SD, y	53.9 ± 15.5	46.5 ± 15.5[a]	55.0 ± 14.4	39.2 ± 14.1[a]	59.4 ± 12.2	45.3 ± 14.3[a]
Over 60 y, No. (%)	173 (44.7)	112 (25.9)[a]	133 (54.7)	91 (14.7)[a]	118 (58.4)	40 (19.7)[a]
Females, No. (%)	246 (63.6)	307 (70.9)[a]	146 (60.1)	403 (65.3)	160 (79.2)	116 (57.1)[a]
Race, No. (%)						
Caucasian	362 (93.5)	384 (88.7)	–	–	–	–
Black	2 (0.5)	8 (1.8)	–	–	–	–
Other	23 (3.9)	41 (9.5)	–	–	–	–
BMI, mean ± SD, kg/m^2	28.0 ± 7.0	28.8 ± 7.7	25.3 ± 4.5	25.0 ± 5.7	21.5 ± 3.0	22.0 ± 2.8
Obese >29.9 kg/m^2, No. (%)	109 (28.2)	162 (37.4)	33 (13.6)	88 (14.3)	2 (1)	2 (1)
Alcohol to help sleep, No. (%)	30 (7.8)	41 (9.5)	9 (3.7)	43 (7)	47 (23.3)	71 (35.0)[a]
Smokers and recent quitters, No. (%)	96 (24.8)	162 (37.4)[a]	64 (26.3)	220 (35.7)[a]	26 (12.9)	57 (28.1)[a]
Intake of caffeinated drinks, mean ± SD[b]	2.1 ± 2.6	2.6 ± 2.7[a]	1.9 ± 1.8	2.7 ± 2.6[a]	1.9 ± 1.6	2.5 ± 2.1[a]
High level education, No. (%)[c]	92 (23.8)	73 (16.9)	64 (26.3)	162 (26.3)	N/A	N/A
Full or part time employment, No. (%)	178 (46.0)	243 (56.1)[a]	75 (30.9)	402 (65.2)[a]	81 (40.1)	121 (59.6)[a]
Charity work, No. (%)	57 (14.7)	51 (11.8)[a]	48 (19.8)	44 (7.1)[a]	12 (5.9)	4 (2.0)[a]
Current treatments, No. (%)						
- At least one benzodiazepine	107 (27.6)	–	96 (39.5)	–	94 (46.5)	–
- At least one z-drug[d]	194 (50.1)	–	116 (47.7)	–	49 (24.3)	–
- Other	122 (31.5)	–	63 (25.9)	–	74 (36.6)	–
Past treatment (in the three last years), No. (%)	137 (35.4)	147 (33.9)	78 (32.1)	151 (24.5)	69 (34.2)	28 (13.8)
P-value		NS		.02		<.0001
Duration of insomnia (years), mean ± SD	8.1 ± 9.4	8.1 ± 11.0	8.7 ± 10.8	5.8 ± 8.1	4.6 ± 4.6	4.2 ± 5.3
P-value		NS		<.0001		.003

Abbreviations: NS, non-significant; ISI = Insomnia Severity Index; *n* = number; SD = standard deviation; % = percentage; y = years; BMI = body mass index.
– Insufficient data or calculation not applicable.
[a] Indicates $P < .05$ by *t*-test for comparison of treated versus non-treated chronic patients with insomnia within each country.
[b] Number of cups or cans per day.
[c] Equivalent to reaching graduate school level in the USA and Baccalauréat plus 4 or over in France.
[d] Non-benzodiazepine GABA-receptor agonists (zolpidem, zopiclone or zaleplon).

7 years in France, and 4 years in Japan. Similar proportions of obese subjects were observed among those with chronic insomnia and good sleepers, although in France the mean BMI for patients with insomnia was lower than for good sleepers ($P < .0001$). Participants with chronic insomnia generally drank more alcohol to help them sleep ($P < .01$), and in France and the US were more likely to be smokers ($P < .01$). Caffeine use was similar among those with chronic insomnia and good sleepers.

As shown in Table 2 treated patients with insomnia were older than those not treated. Benzodiazepines were the most frequent prescription drugs in Japan (47%), whereas in France and the US use of non-benzodiazepine benzodiazepine-receptor agonists (zolpidem, zopiclone, or zaleplon [US only]) were most frequently reported (48% and 50%, respectively). Even in the absence of current treatment, a sizable proportion of participants (between 14% in Japan and 34% in the US) had received some form of treatment in the past three years.

3.2. HRQoL and utility scores

After adjustment for significant demographic and clinical covariates, data from all countries showed that chronic insomnia was associated with significantly lower SF-36 scores in all domains compared with good sleepers ($P < .05$) (Fig. 3a and Table 1 in the Supplementary Appendix). Similarly, the two summary measures (MCS and PCS) were lower in those with chronic insomnia ($P < .0001$). Chronic insomnia was also associated with significantly lower ($P < .0001$) utility scores compared with good sleepers (mean scores 0.63 versus 0.72 in the US, 0.57 versus 0.67 in France and 0.67 versus 0.77 in Japan) (Fig. 4).

Treatment of chronic insomnia was associated with higher HRQoL scores, although this varied in extent between countries (Fig. 3b and Table 2 in the Supplementary Appendix). In the US and France, treatment was also associated with significantly higher MCS ($P < .0001$) and utility scores ($P < .005$), although there was no observed difference in the physical components between treated and untreated individuals. In Japan there was no significant difference in any of the SF-36 dimensions or utility scores observed for treated versus untreated individuals.

4. Discussion

The results of this study are consistent with prior observations [13–16] that chronic insomnia is associated with impairment in HRQoL and lower utility scores ($P < .0001$ in each country) compared with good sleepers. Across all three countries, people with chronic insomnia (including those receiving treatment) reported lower SF-36 scores in each of eight domains compared with good sleepers ($P < .0001$), with greatest impact on the vitality, social functioning, role-emotional, and mental health dimensions. The unadjusted SF-36 scores were comparable with previously reported findings from France and the US that used paper-based questionnaires or telephone interviews [13,14,34], confirming the reliability of the HRQoL measures obtained from this internet-based study. Furthermore, the unadjusted SF-36 scores for individuals with chronic insomnia were comparable with those reported in patients with other chronic conditions previously shown to impact HRQoL [35,36], such as congestive cardiac failure, diabetes, and major depression.

HRQoL has been used in these major chronic diseases and public health issues to reflect both the feelings of patients and the health care services use in the general population. Our study clearly demonstrates that chronic insomnia has an impact on HRQol, in three different continents, independent of the geographical origin of the patient and independent of its sociodemographical characteristics. These results strongly support the concept that insomnia is not only a single night symptom, but a severe disease whose impact may be

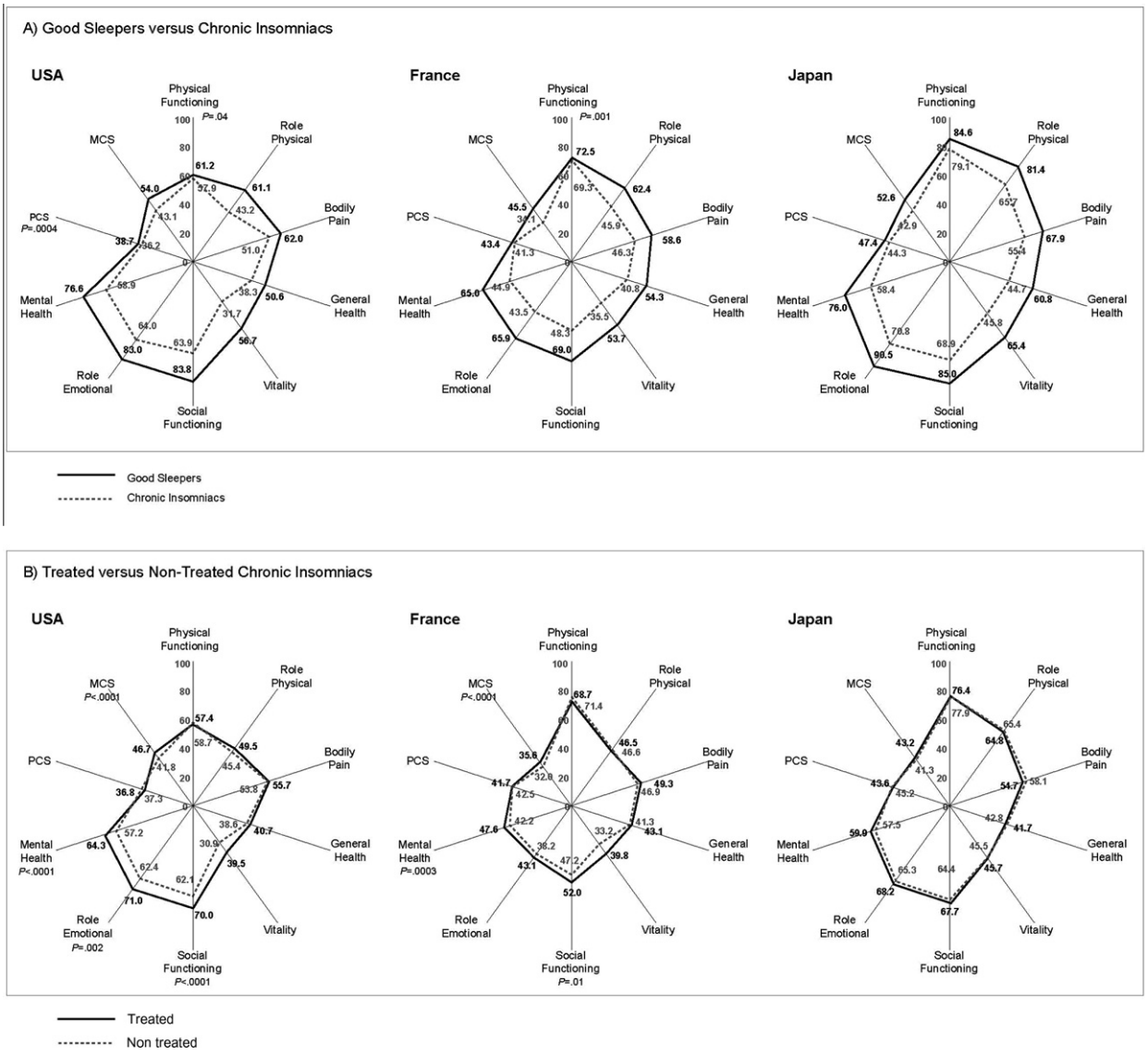

Fig. 3. Distribution of the different subscales of the SF-36 for each of the three countries. *P*-value <.0001 for difference between good sleepers and chronic patients with insomnia in each dimension of SF-36 except where highlighted. Abbreviations: PCS, Physical Component Summary; MCS, Mental Component Summary. Statistically significant *P*-values for difference between treated and non-treated chronic insomniacs in each dimension of SF-36 are highlighted.

compared to diabetes and major depression [1,2,35,36]. Moreover, treating insomnia appears, according to our results, to have a significant impact on HRQol except in Japan.

Thus, treatment of insomnia was associated with higher utility scores compared with those observed in individuals not treated in France and the US, although in Japan none of the SF-36 components (and hence utility scores) differed significantly between treated and non-treated individuals. The shorter duration of insomnia in the Japanese sample, cultural differences, or predominant medication used may partly explain this difference, but no conclusion can be drawn as this study was not designed to study treatment effect.

Limited information is available on utility scores for individuals with chronic insomnia. A search of published literature indicated two studies, one each conducted in the UK and US [17,37], although the derivation of health utility values varied. Morgan et al. [17] evaluated the cost utility of providing cognitive behavioral therapy for insomnia to long-term ($\geqslant$1 month) hypnotic users with chronic sleep problems recruited from general practice in the UK. Utility scores were derived from SF-36 responses using the first generation multi attribute utility approach developed by Brazier et al. [32]. The health utility score associated with chronic insomnia was 0.65. The second study [37] used a different indirect transformation algorithm proposed by Nichol et al. [38] to assign the utilities of subjects with insomnia versus those without insomnia using published SF-36 scores from a study [39] involving 3445 patients in SC, USA. Adjustment was made for the difference in SF-36 scores between those with mild, severe, or no insomnia by statistically controlling for differences in sociodemographic characteristics, health habits, index conditions (and severity), comorbidities, and location. In patients with insomnia most, or all of the time the utility score was 0.76 compared with 0.84 in good sleepers. Thus, the utility scores reported from chronic patients with insomnia in our study (0.63 in the US, 0.57 in France, and 0.67 in Japan) compare with those reported by Morgan et al. [17]. Although they are lower than those reported in the other study [37] the difference in utilities between good sleepers and patients with insomnia is similar. Differences in the utility scores observed in these studies can be partially explained by variations in the approaches used to derive a utility index from the HRQoL measures. It is noteworthy that characteristics of chronic patients with insomnia in our study were generally similar to those in each of these study populations [17,38]. We are, however, unaware of

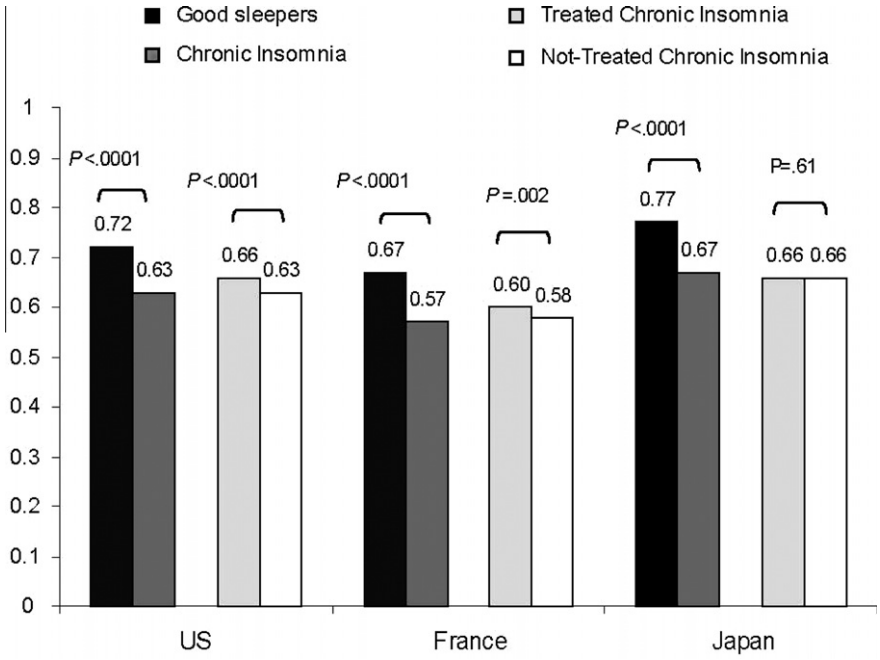

Fig. 4. Utility scores for good sleepers versus chronic insomniacs and treated versus non-treated chronic insomniacs summarized by country.

any other studies reporting utility scores across several countries using the same instrument.

A number of features of the analysis strengthen our findings. Patients included in the survey underwent an extensive screening process using the same protocol in each country and a standardized insomnia measure (ISI score, see Fig. 1) to ensure that the requirements for the target population were met. Overall, more than 30% of patients were older than 60 years. HRQoL was evaluated using a valid, reliable, and widely used measure (SF-36), which is relevant to clinical practice. Multiple regression techniques were used to account for significant demographic and clinical covariates, in particular arthritis and other co-morbidities, age, breathing problems, and alcohol use, that may have influenced the change in SF-36 and utility scores.

We do, however, acknowledge a number of limitations to the study. Firstly, as a result of problems with recruitment, the full sample population was not achieved in Japan (911 included vs. 1200 planned). It is, however, unlikely that recruitment of the specified sample would have substantially changed the overall findings of our analysis in this country. Additionally, in France, <30% of participants were elderly (>60 years). However, sampling requirements for 30% of respondents to be 60 years or older were based on statistical power and not on population statistics, as only 7–26% of the population in the three countries studied are within this age group [40–42,31–33].

Secondly, there was sampling bias in the selection of participants. In France and the US, selection from existing on-line panels is likely to have led to exclusion of individuals from deprived socioeconomic backgrounds without computer access. Furthermore, it is possible that the panels in each country may not have been representative of the adult population. This is exemplified by the low proportion of non-Caucasians included in the US (Table 1). While respondents enrolled using the Harris panel were included via a quota system that includes a sufficient number of participants based on age, gender, and socioeconomic status, it is not certain whether these participants are truly representative of a chronic insomnia population. To account for this potential imbalance, multivariate analysis was used to adjust for factors that may potentially reduce the impact of individual variables.

Thirdly, the interviewing technique (i.e., internet, telephone, or postal questionnaires) may impact on the responses of subjects and be associated with recall bias. A postal survey was used in Japan in an attempt to take account of cultural sensitivities regarding discussion of insomnia. While it is recognized that this may have influenced the results, it is not possible to determine what effect can be attributed to the means of data collection versus other factors. It is noted that the internet survey results were generally similar to those reported in other paper based surveys [13,14,34], indicating that web-based surveys appear to be an appropriate method for collecting HRQoL data. However, considering that participants with chronic insomnia were younger than good sleepers in France and the US (mean age 44 and 50 years, versus 52 and 54 years) but older in Japan (52 versus 48 years), it may be possibly related to this bias. The respondents in France and in the US may have been younger than expected due to the fact that internet users are generally younger than non-users. Finally, only those subjects with chronic insomnia not associated with known common disorders were selected, to exclude other causes of insomnia which may contaminate utility value calculations.

Finally, we understand that the translation of rating scales and cultural interpretations of certain scale items might have a potential impact on the outcome. The need to adapt sleep-screening tools for use in cross-cultural settings is a highly relevant issue in international studies like ours. However, accepted procedures for translating and adapting existing measures such as SF-36 and the items used for the definition of insomnia have been uniformly and consistently incorporated in epidemiologic studies, resulting in an improving homogeneity [1,2,22,35]. However, we acknowledge the limitations of interviewing such different countries with the same questions, which may refer to culturally different approaches in the three countries.

In conclusion, the results of our study confirm that chronic insomnia is associated with significant impairment of both physical and mental dimensions of HR-QOL, and that this impairment is similar across the countries studied. The difference in utility scores between good sleepers and chronic patients with insomnia is also very similar across countries.

Author contributions

Pr. Léger had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design
Léger, Morin, Uchiyama, Kobayashi, Cure, Walsh.
Acquisition of data
Cure, Hakimi
Analysis and interpretation of data
Léger, Morin, Uchiyama, Cure, Walsh.
Drafting of the manuscript
Léger, Hakimi.
Critical revision of the manuscript for important intellectual content
Léger, Morin, Uchiyama, Cure, Walsh.
Statistical expertise
Cure.
Obtained funding
Hakimi.
Administrative, technical, or material support
Hakimi, Cure.
Study supervision
Léger, Cure.

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Pr. Léger reports that he has received honoraria from Sanofi Aventis as scientific advisor. Dr. Morin reports that he has received honoraria and/or Grant support from Sanofi Aventis as scientific advisor. Dr. Uchiyama reports that he has received honoraria and/or Grant support from Sanofi Aventis as scientific advisor. Dr. Hakimi, reports that he was an employee of Sanofi-Aventis. Ms. Cure reports that she has received Grant support from Sanofi-Aventis. Dr. Walsh reports that his institution has received research support from: Pfizer, Merck & Co., Somaxon, Evotec, Actelion, Vanda, Neurogen, Sanofi-Aventis, Ventus, Respironics, and Jazz Pharmaceuticals; and he has provided consulting services to: Pfizer, Sanofi-Aventis, Cephalon, Schering-Plough/Organon, Neurocrine, Takeda America, Actelion, Sepracor, Jazz, Respironics, Transcept, Neurogen, GlaxoSmithKline, Somaxon, Eli Lilly, Evotec, Merck, Kingsdown, Vanda, Ventus, and Somnus.

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Role of the sponsor

Sanofi-Aventis employees worked collaboratively with the investigators in designing the study and interpreting the data and were involved in the conduct of the study, including the collection, management, and initial analysis of the data. Sanofi-Aventis employees provided comments on the manuscript, but the writing committee made final decisions on the interpretation of study results and contents of the manuscript.

Previous presentation

Preliminary data was presented at the 14th Annual Conference of the International Society for Quality of Life Research, October 10–13, 2007, Toronto, ON, Canada.

Conflict of interest

The ICMJE Uniform Disclosure Form for Potential Conflict of interest associated with this article can be viewed by clicking on the following link: doi:10.1016/j.sleep.2011.03.020.

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References

[1] American Academy of Sleep Medicine. International classification of sleep disorders, 2nd ed.: diagnostic and coding manual. Westchester, IL: American Academy of Sleep Medicine, 2005. American Academy of Sleep Medicine, 2005.
[2] National Institutes of Health. National Institutes of Health State of the Science Conference statement on Manifestations and Management of Chronic Insomnia in Adults, June 13–15, 2005. Sleep 2005;28:1049–57.
[3] Martin SA, Aikens JE, Chervin RD. Toward cost-effectiveness analysis in the diagnosis and treatment of insomnia. Sleep Med Rev 2004;8:63–72.
[4] Ohayon MM. From wakefulness to excessive sleepiness: what we know and still need to know. Sleep Med Rev 2008;12:129–41.
[5] Léger D, Poursain B, Neubauer D, Uchiyama M. An international survey of sleeping problems in the general population. Curr Med Res Opin 2008;24:307–17.
[6] Ohayon M, Lemoine P. Sleep and insomnia markers in the general population. Encephale 2004;30:135–40.
[7] Brassington GS, King AC, Bliwise DL. Sleep problems as a risk factor for falls in a sample of community-dwelling adults aged 64–99 years. J Am Geriatr Soc 2000;48:1234–40.
[8] Moul DE, Nofzinger EA, Pilkonis PA, et al. Symptom reports in severe chronic insomnia. Sleep 2002;25:553–63.
[9] Léger D, Massuel MA, Metlaine A. Professional correlates of insomnia. Sleep 2006;29:171–8.
[10] Daley M, Morin CM, Leblanc M, Gregoire JP, Savard J. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. Sleep 2009;32:55–64.
[11] Léger D, Guilleminault C, Bader G, Levy E, Paillard M. Medical and socio-professional impact of insomnia. Sleep 2002;25:625–9.
[12] Ozminkowski RJ, Wang S, Walsh JK. The direct and indirect costs of untreated insomnia in adults in the United States. Sleep 2007;30:263–73.
[13] Zammit GK, Weiner J, Damato N, Sillup GP, McMillan CA. Quality of life in people with insomnia. Sleep 1999;22:S379–85.
[14] Léger D, Scheuermaier K, Philip P, Paillard M, Guilleminault C. SF-36: evaluation of quality of life in severe and mild insomniacs compared with good sleepers. Psychosom Med 2001;63:49–55.
[15] Léger D, Scheuermaier K, Raffray T, et al. HD-16: a new quality of life instrument specifically designed for insomnia. Sleep Med 2005;6:191–8.
[16] Hatoum HT, Kong SX, Kania CM, Wong JM, Mendelson WB. Insomnia, health-related quality of life and healthcare resource consumption. A study of managed-care organisation enrollees. Pharmacoeconomics 1998;14:629–37.
[17] Morgan K, Dixon S, Mathers N, Thompson J, Tomeny M. Psychological treatment for insomnia in the regulation of long-term hypnotic drug use. Health Technol Assess 2004;8:iii–68.
[18] Gold MR, Siegel JE, Russell LB, et al. Cost-effectiveness in health and medicine. New York, NY: Oxford University Press; 1996.
[19] Furukawa TA, Streiner DL, Azuma H, Higuchi T, Kamijima K, Kanba S, et al. Cross-cultural equivalence in depression assessment: Japan–Europe–North American study. Acta Psychiatr Scand 2005;112:279–85.
[20] Ohayon MM. Prevalence and correlates of nonrestorative sleep complaints. Arch Intern Med 2005;165:35–41.
[21] Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. Sleep Med Rev 2002;6:97–111.
[22] Bastien CH, Vallieres A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med 2001;2:297–307.
[23] Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of life measurements. JAMA 1994;272:619–26.
[24] McHorney CA. Measuring and monitoring general health status in elderly persons: practical and methodological issues in using the SF-36 Health Survey. Gerontologist 1996;36:571–83.
[25] Ware Jr JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–83.
[26] Cumming RG, Salkeld G, Thomas M, Szonyi G. Prospective study of the impact of fear of falling on activities of daily living, SF-36 scores, and nursing home admission. J Gerontol A Biol Sci Med Sci 2000;55:M299–305.
[27] Kroenke K, West SL, Swindle R, Gilsenan A, Eckert GJ, Dolor R, et al. Similar effectiveness of paroxetine, fluoxetine, and sertraline in primary care: a randomized trial. JAMA 2001;286:2947–55.

[28] Cohen HJ, Feussner JR, Weinberger M, Carnes M, Hamdy RC, Hsieh F, et al. A controlled trial of inpatient and outpatient geriatric evaluation and management. N Engl J Med 2002;346:905–12.
[29] Hobart JC, Williams LS, Moran K, Thompson AJ. Quality of life measurement after stroke: uses and abuses of the SF-36. Stroke 2002;33:1348–56.
[30] Edelman D, Olsen MK, Dudley TK, Harris AC, Oddone EZ. Impact of diabetes screening on quality of life. Diabetes Care 2002;25:1022–6.
[31] Baker F, Haffer SC, Denniston M. Health-related quality of life of cancer and noncancer patients in medicare managed care. Cancer 2003;97:674–81.
[32] Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. J Health Econ 2002;21:271–92.
[33] Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. Berlin: Springer; 1988.
[34] Léger D, Cure S, Amand C, Gilloteau I, Walsh JK. Can health-related quality of life measures obtained from online samples be considered reliable? Results from a multicountry survey in chronic insomnia. 2007 International Society for Quality of Life Research meeting abstracts [http://www.isoqol.org/2007mtgabstracts.pdf]. Qual Life Res Suppl, A-86, Abstract #1655.
[35] Leplege A, Ecosse E, Verdier A, Perneger TV. The French SF-36 Health Survey: translation, cultural adaptation and preliminary psychometric evaluation. J Clin Epidemiol 1998;51:1013–23.
[36] Ware JE, Kosinski M. SF-36 physical and mental health summary scales: a manual for users of version 1. 2nd ed. Lincoln, RI: Quality Metric incorporated; 2001. SF-36 2001.
[37] Botteman MF, Ozminkowski RJ, Wang S, Pashos CL, Schaefer K, Foley DJ. Cost effectiveness of long-term treatment with eszopiclone for primary insomnia in adults: a decision analytical model. CNS Drugs 2007;21:319–34.
[38] Nichol MB, Sengupta N, Globe DR. Evaluating quality-adjusted life years: estimation of the health utility index (HUI2) from the SF-36. Med Decis Making 2001;21:105–12.
[39] Katz DA, McHorney CA. The relationship between insomnia and health-related quality of life in patients with chronic illness. J Fam Pract 2002;51:229–35.
[40] National Sleep Foundation. <http://www.sleepfoundation.org/>; 2009 [accessed 13.02.09].
[41] US Census Bureau. <http://www.census.gov/>; 2009 [accessed 13.02.09].
[42] l'Institut national d'études démographiques <http://www.ined.fr>; 2009 [accessed 13.02.9].