



## 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 (SLEEP-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.

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## 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 ( $\geq 60$  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-

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