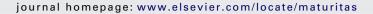
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### **Maturitas**





# Factors relating to insomnia during the menopausal transition as evaluated by the Insomnia Severity Index

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#### ARTICLE INFO

Article history: Received 5 January 2011 Received in revised form 9 February 2011 Accepted 22 February 2011

Keywords: Insomnia Severity Index Insomnia Menopause Climacteric Hot flushes

#### ABSTRACT

*Background:* Although the menopause associates to poor sleep quality, insomnia severity data in the menopausal transition is scarce or lacking.

Objective: To assess insomnia prevalence, severity and related factors in mid-aged women.

Methods: In this cross-sectional study 340 women (40 to 59 years) completed the Insomnia Severity Index (ISI) and a general questionnaire containing personal/partner data. Hot flush presence and intensity was also assessed with the Menopause Rating Scale (MRS).

Results: Median age of the sample was 48.0 years, with 63.5% having lower education and 52.9% being postmenopausal. At the moment of the survey 7.1% were on hormone therapy, 8.2% on phytoestrogens and 2.1% on psychotropic drugs. A 63.8% were abdominally obese (waist circumference > 88 cm) and 65.5% sedentary. According to item 1 of the MRS, 60.9% presented hot flushes, graded in 17.4% as severe-very severe. Regarding the partner (n = 255), erectile dysfunction was present in 23.9%, premature ejaculation 37.6%, 35.3% abused alcohol and 42.4% were faithful. The ISI tool displayed a high internal consistency (alpha Cronbach coefficient = 0.87), identifying 41.5% of women with some degree of insomnia (Total ISI score  $\geq$ 8) further categorized as sub-threshold or mild (32.0%), moderate (7.4%) and severe (2.1%). Multiple linear regression analysis obtained two best fit models predicting total ISI scores, one not including and one including partner data. In the first model, hot flush severity, psychotropic use and sedentarism displayed significant positive correlations with total ISI scores. In the second, hot flush intensity, psychotropic drug use and male erectile dysfunction positively correlated whereas partner faithfulness inversely with ISI scores.

Conclusion: In this mid-aged series insomnia severity was related to female and partner factors; several of which are susceptible of intervention.

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#### 1. Introduction

The menopause is associated with different physiological, behavioral and socio-demographical changes. Progressive decline in estrogen levels are frequently related to vasomotor symptoms, urogenital discomfort, muscle-skeletal limitations, mood alterations and sleep disorders [1–4]. Menopausal women have more sleep disturbances when compared to premenopausal ones [5,6], frequently displaying less than six hours of sleep and reporting more fatigue or difficulty in initiating and maintaining sleep [7]. Under this scenario, there is an increase for short-term (fatigue-

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related accidents) and long-term problems (hypertension, diabetes and cardiovascular disease) [8]. Despite the aforementioned, caution has been recommended not to impute the menopause a causative role for sleeping disorders [9]. In fact, many psychological menopausal symptoms are similar to those related with insomnia (i.e. fatigue, irritability and sleep disruptions) [10]. It has been proposed that menopausal mood changes are due to sleep disruptions caused by hot flushes [11].

Research related to sleep has used different approaches: population based sampling, assessment of sleep disorders in morbid conditions and the use of sophisticated sleep laboratory techniques. Many questionnaires and tools have been designed to assess sleep duration and disorders [12]. However, while some tools lack insomnia severity assessment, others do not meet DSM-IV diagnostic criteria [13]. In this sense, the Insomnia Severity Index (ISI) is a simple, easy to use instrument designed to assess insomnia intensity and concomitantly fulfill DSM-IV sleep disor-

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der criteria [14]. The objective of the present study was to assess insomnia prevalence, severity and related factors in mid-aged women.

#### 2. Materials and methods

#### 2.1. Participants

A cross sectional study was performed during December 2010 at the Enrique C. Sotomayor Obstetrics and Gynecology Hospital, an associated teaching facility of the Medical Faculty of the Universidad Católica de Santiago de Guayaquil, Ecuador. Research aimed at assessing insomnia severity and related factors. Hence, healthy women aged 40–59 years visiting inpatients at the different wards of the Hospital (daily visiting hours: noon to 2 pm) were requested to complete the ISI [14] and a questionnaire containing personal and partner data. Subjects were additionally assessed for hot flush presence and severity using item 1 of the Menopause Rating Scale (MRS) [15]. Sotomayor Hospital is a major referral center providing reproductive healthcare basically to low income women of Guayaquil and surrounding peripheral areas. Women excluded from the study were those refusing participation or were incapable of understanding the items included in the questionnaire.

Research protocol of the study was reviewed and approved by the Scientific and Research Committee of the Enrique C. Sotomayor Hospital. All participants were informed about the research (its purpose and used tools) and written consent obtained.

#### 2.2. Sample size calculation

This was based on the fact that 59.9% of mid-aged women present sleeping problems [16]. Hence a minimal sample of 251 subjects was calculated considering that the hospital covers for an estimated population of 5000 women aged 40–59 and assuming a 55% insomnia prevalence with a 6% desired precision and a 95% confidence interval.

#### 2.3. General data questionnaire

#### 2.3.1. Female data

Female data included: age (years), parity, menopausal status (pre, peri or postmenopausal), marital status, educational level (years), accessed healthcare system (free-minimal cost or paid), smoking habit (current, sometime, non-smoker), partner status (yes/no), church attendance, history of sexual abuse, psychiatric consultation and the use of drugs: psychotropics or hormone therapy [HT]/phytoestrogens for the menopause. Women were asked about how they perceived their health status and that of their partner. Those (men or women) capable of performing daily routine activities were defined as healthy. Sedentarism was defined if subjects carried out less than 15 min of physical activity twice a week [17]. Waist circumference was measured with subjects in standing position at the end of a normal breath expiration using a Gulick measuring tape placed horizontally around the abdomen at level of iliac crest. Abdominal obesity was defined as a waist circumference >88 cm [18].

Menopausal status was defined as: premenopausal (regular menses), perimenopausal (menstrual irregularities >7 days from their normal cycle) and postmenopausal (no more menses in the last 12 months) [19]. Those with bilateral oophorectomy were defined as postmenopausal. For statistical purposes hysterectomized women were considered as a separate group.

#### 2.3.2. Partner data

Information regarding the partner was obtained from women and included: age, educational level, health status, faithfulness and the presence of alcoholism and sexual dysfunction (erectile dysfunction or premature ejaculation). Definitions for insufficient education (men and women), alcoholism, erectile dysfunction and premature ejaculation have previously been described [20].

#### 2.4. Instruments

#### 2.4.1. Menopause Rating Scale (MRS)

The Menopause Rating Scale (MRS) was used to assess hot flush presence and severity. This scale is a menopause specific health related quality of life instrument composed of 11 items grouped into three subscales: somatic, psychological and urogenital [15]. Item one of the somatic subscale was used to assess hot flushes and grade them from 0 (not present) to 4 (1 = mild; 2 = moderate; 3 = severe; 4 = very severe).

#### 2.4.2. The Insomnia Severity Index (ISI)

The ISI is a brief, reliable, validated self-reporting instrument that yields a quantitative index of perceived insomnia severity [14]. The tool comprises 7 items targeting sleep disturbance severity, sleep related satisfaction and the degree of daytime functional impairment, impairment perception and distress and concern related to the sleeping problem. Each item is rated on a 5-point Likert scale (0–4) and summed up to provide a total score ranging from 0 to 28. Higher scores reveal more severe insomnia. Scores may be categorized as: 0–7 (no clinically significant insomnia) or 8–28 (some degree of insomnia). The latter was further divided into: 8–14 (sub-threshold insomnia or mild); 15–21 (moderate insomnia) and 22–28 (severe insomnia) [14].

#### 2.5. Statistical analysis

Analysis was performed using statistical software: EPI-INFO 6.04 (Centers for Disease Control, Atlanta, Ga., USA; WHO, Basel, Switzerland) and SPSS 10.0 (Version for Windows, SPSS, Chicago IL, USA). Data are expressed as medians, interquartile ranges, percentages, beta coefficients and confidence intervals. The Kolmogorov Smirnov test was used to determine normality of data distribution. According to this, continuous non parametric data were compared using the Mann Whitney test (two independent samples) or the Kruskal Wallis test (various independent samples). Chi-square and Fisher's exact tests were used to compare percentages with Yate's correction performed when applicable. Internal consistency of the ISI tool was assessed computing alpha Cronbach coefficients.

Multiple linear regression analysis was performed to obtain two best models predicting total ISI scores (insomnia severity), one with and one without partner data. Independent variables were entered into each model using a stepwise procedure. Potential interaction variables were also entered during model construction. Both final best fit models were validated with a scatter graph model using studentized residues and predictive values obtained within each model. For all calculations a p value of <0.05 was considered as statistically significant.

#### 3. Results

During the study period a total of 355 women were invited to participate. Refusal rate was 4.2% (15/355) which left 340 complete surveys for analysis. Characteristics of surveyed women and their partners are shown in Table 1 (binomial data only). Median [interquartile range = IQR] age, educational level and parity was 48.0 [9] years, 8 [6] years and 3 [2], respectively. A 63.5% had less

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