The American Insomnia Survey: an epidemiology study of insomnia in subjects with various comorbidities and/or conditions

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ABSTRACT

Introduction: The prevalence of insomnia as a disorder is not well defined. Little is known about the number and patterns of night-time and daytime symptoms, their severity and chronicity, or the associations among those features. Most epidemiological studies of insomnia have failed to either systematically use diagnostic criteria or study insomnia subtypes (onset, maintenance [night-time wakening and waking too early], non-restorative sleep) in sufficient detail and have not documented the relative or joint effects of insomnia subtypes on daytime functioning. The night-time and daytime symptoms as well as the disease burden of primary insomnia and comorbid insomnia have not been compared.

Methods: The American Insomnia Survey (AIS) telephone questionnaire (approximately 40 minutes) has been administered to 11812 respondents from the HealthCore Integrated Research Database™ consisting of a representative sample of subscribers from 14 geographically dispersed US health plans, which allows responses to be linked with medical and pharmacy claims data. The aim is to investigate associations between insomnia and relevant outcomes, including reported daytime impairment, accidents, injuries, lost productivity, and health care utilization. We also examine prevalence and burden of insomnia in subsamples defined by presence of comorbidities identified by ICD–9 codes on medical claims, including COPD, osteoarthritis, hypertension, obstructive sleep apnea, neuropathic pain, diabetes, and GERD.

Results: This presentation describes AIS methods, instrument development and rationale for choice of scales within the instrument, validation against clinician diagnostic interviews, and planned analyses. Overall, and for each comorbidity controlled for severity, we evaluate prevalence and incremental predictive effects of insomnia and its subtypes on functioning among patients. Analyses include examination of diagnostic thresholds for insomnia based on symptom clustering, severity, and correlates with daytime impairment. The study also includes specific analyses of respondents aged over 65 years, a clearly identified population with an increased prevalence of insomnia.

Conclusion: The AIS is a recently completed, large scale, rigorous survey designed to examine the prevalence and impairments associated with insomnia and insomnia subtypes in the USA. First results are reported at the satellite symposium entitled "THE AMERICAN INSOMNIA SURVEY: METHODS AND RESULTS", Tuesday 10 November 2009, WASM 2009, São Paulo, Brazil.

INTRODUCTION

- While insomnia is a considerable health burden,[1] the prevalence of insomnia as a disorder is not well described, neither in the general population, nor in populations with medical comorbidities,[2,3] leading to large variations in prevalence estimates.[2,3]
- The relative burden of primary insomnia versus comorbid insomnia is also poorly understood.
- Little is known about the number and patterns of night-time and daytime symptoms, their severity and chronicity, or associations among those features.
- Insomnia is generally characterized by one or more of three primary night-time symptoms – problems with sleep onset, sleep maintenance (night-time wakening and waking too early), and non-restorative sleep associated with perceived health burden.
- The majority of epidemiological studies of insomnia have failed to study these subtypes in sufficient detail to document their relative or joint associations with negative behavioral or health outcomes.
- Reported here is the methodological design of a recently completed, large-scale, rigorous epidemiological study designed to address these questions.

OBJECTIVES

Primary

- To evaluate the prevalence of insomnia (according to three diagnostic systems), insomnia symptoms, and symptom clusters (e.g. problems with sleep onset, sleep maintenance, night-time awakening, early morning awakening, and non-refreshing sleep) in a representative US population and among respondents with selected comorbid conditions.

Secondary

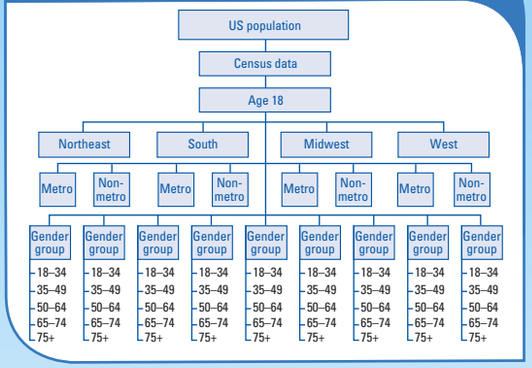
- To evaluate insomnia burden, including:
  - Daytime functioning in the past 30 days
  - Quality of life in the past 30 days
  - Work productivity (lost work days) in the past 28 days
  - Accidents and injury in the past 12 months
  - Healthcare care consumption in the past 12 months
- To characterize specific symptoms and symptoms clusters, demography, comorbidity, treatment patterns, and sleep habits in people with insomnia.

METHODS

Enrollment/sampling

- The study has been conducted in the USA via telephone survey.
- The sampling frame was the HealthCore Integrated Research Database™ of approximately 18 million commercial health plan subscribers. A probability sample of subscribers has been selected to create a stratified sample representative of the US population in terms of census region, urban and rural residence, sex, and age (Figure 1).
- Probability samples of subscribers with selected comorbid conditions have been over-sampled in order to provide sufficient sample size for targeted analyses of each condition.

Figure 1. Probability sample derived to reflect demographic distribution of the United States



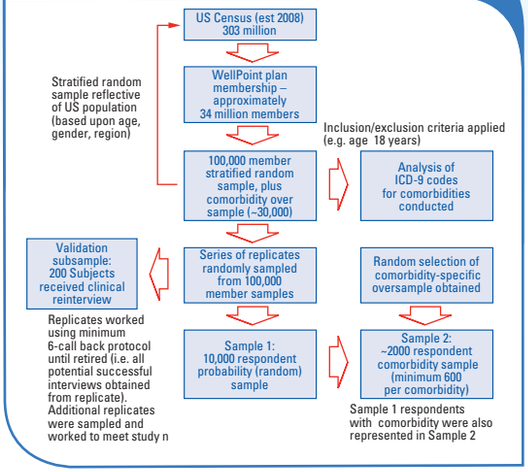
Sample 1: random probability sample

- Inclusion criteria:
  - ≥18 years of age
  - Willing and able to provide verbal informed consent
  - Fluent in English
  - 12 months continuous enrollment in WellPoint health plan
  - Available home telephone number
  - Member of WellPoint health plan on date of completed survey
- Exclusion criteria:
  - Plan members without a recorded home telephone number or those unable to answer a telephone questionnaire for reasons related to health (e.g. hearing impairment, hospitalization), cognitive impairment, or language fluency

Sample 2: comorbidity oversample

- Inclusion criteria:
  - Presence of at least one selected comorbidity as per ICD-9 code from the health plan (diabetes mellitus, neuropathic pain, osteoarthritis, gastroesophageal reflux disease, high blood pressure, chronic obstructive pulmonary disease, sleep apnea), and/or
  - Presence of one of 2 conditions: elderly (aged ≥65), or obesity (BMI ≥30)

Figure 2. Participant enrollment/sampling in the American Insomnia Survey



Analyses

- *Clinical reappraisal*

  Insomnia disorder diagnosis obtained by telephone survey was validated against blinded sleep medicine clinician interviews of a probability sub-sample of survey respondents, over-sampling those classified in the survey as having insomnia.
- *Prevalence of insomnia disorder and its associated impairment according to 3 different diagnostic systems*

  Insomnia disorder prevalence was determined according to 3 diagnostic systems (DSM-IV-TR, ICD-9, Research Diagnostic Criteria) and described by age; comorbidities; impairment; and days out of role.
- *Prevalence of insomnia symptoms and subtypes in multivariate profiles*

  Prevalence by meeting any diagnostic system, including symptom subtypes, were examined along with data on clinical significance of these subtypes as they related to impairment, lost productivity and related cost.
- *Implications of changing symptom severity thresholds*

  The thresholds that determined clinically significant insomnia were defined and an assessment was conducted on the effect of thresholds (number of days per week in which the following symptoms were experienced; number of awakenings, sleep onset latency, WASO, or severity of non-restorative sleep) on prevalence estimates. Correlates of insomnia symptoms with other burden measures (days out of role, daytime sleepiness) were also examined.
- *Healthcare cost/utilization by people with insomnia*

  Economic burden was determined by linking survey data with health care claims to estimate the difference in mean healthcare utilization and cost between insomnia and no insomnia (e.g. control) cohorts over the prior 12 month period. Inpatient (acute), outpatient/emergency and prescription medication costs were included.

THE AIS INSTRUMENTS

All respondents

Respondents participating in the 40-minute interview were administered the following:

- Introductory module
- Employment module
- Composite International Diagnostic Interview (CIDI) Injury Series (6.1)
- Sleep questionnaire (developed by the study authors)
- Modified Berlin Questionnaire – sleep apnea screening
- Restless Legs Syndrome Questionnaire, simplified
- Fatigue Severity Scale (FSS) of sleep disorders
- Epworth Sleepiness Scale
- Substance/alcohol abuses assessment
- WHO-DAS D1 Series - Understanding and Communicating
- Generalized Anxiety Disorder (GAD)-7
- Short-form Heath Survey (SF-12)
- Sheehan Disability Scale
- Demography Module
- Quick Inventory of Depressive Symptomatology (QIDS), modified

Elderly respondents

- Modified Fredricks[4] scale of functional status and activities of daily living administered to those no longer employed.
- The Resnick Fall Risk Assessment questionnaire

Respondents with comorbidities

The following condition-specific instruments were administered to respondents with the selected comorbid conditions:

- Chronic Obstructive Pulmonary Disease – Eisner COPD Severity Score
- Sleep apnea – Berlin Questionnaire
- Osteoarthritis – Western Ontario and McMaster Universities Index of Osteo- arthritis (WOMAC)
- Hypertension – Severity Of High Blood Pressure (BP) Questionnaire
- Diabetes – Severity Of Diabetes Questionnaire
- Neuropathic pain – Chronic Pain Grading Scale, modified
- Gastroesophageal Reflux Disease – Nocturnal GERD Symptom Scale
- Obesity – Body Mass Index (BMI)
- Generalized Anxiety Disorder – GAD-7 assessment
- Depressive symptoms – Quick Inventory of Depressive Symptoms (QIDS), modified

RESULTS

- Enrollment of respondents is complete.
- Data analysis and presentation are in progress.

SUMMARY

- The AIS compares insomnia disorder prevalence data according to three commonly used diagnostic systems.
- The AIS provides a description of the number and patterns of night-time and daytime insomnia symptoms in the general population, their severity and chronicity, and associations among those features in the general population. Additionally, AIS provides an estimate of the overall burden of insomnia with and without comorbidity.
- The study advances our understanding of insomnia by examining subtypes (sleep-onset, maintenance [night-time awakening and waking too early], non-restorative sleep) in sufficient detail to document their relative and joint effects on behavioral, health and economic outcomes.
- The AIS examines the relative burden of primary insomnia versus comorbid insomnia, and the impact of insomnia symptom severity thresholds on burden.

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