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# Patient Reported Health-related Quality of Life in Co-morbid Insomnia: Results from a Survey of Primary Care Patients in the United States

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## Abstract

**Background:** This study attempts to establish the incremental burden of co-morbid Insomnia in an indigent and underserved population among patients with other primary Chronic diagnoses.

**Methods:** Adult patients with primary chronic diseases were categorized for co-morbid Insomnia using the Insomnia Severity Index (ISI). One-way ANOVA and regression were conducted to assess group differences in SF-36 domain scores and independent associations between insomnia and HRQL, adjusting for inherent differences.

**Results:** 962 respondents were categorized as: 230 "Insomnia" and 732 "No Insomnia". Patients with insomnia had worse mean Physical Component Summary (PCS) and Mental Component Summary (MCS) scores across most disease categories. Patients with insomnia had lower scores in all of the SF-36 scales for all disease groups except OAD.

**Conclusion:** Findings suggest a strong association of poverty levels with increase in sleep problems - especially among women, and make a case for treating co-morbid insomnia independently of the primary condition.

**Keywords:** Co-morbid insomnia; Health-related quality of life; SF-36; Primary care; survey

## Background

Insomnia is acknowledged to be the most widespread sleep complaint globally [1,2] with almost half of the patients in primary care or general practice settings experiencing some form of the condition [3]. These findings are particularly relevant for individuals from disadvantaged socio-demographic and socio-economic groups, as differences in sleep and sleep disparities (ameliorable differences) may place these groups at increased risk of poor health outcomes [4]. Research has shown that past and present economic difficulties are strongly associated with current complaints of insomnia [5].

It has also been suggested that 75% of such insomnia cases are co-morbid with other "primary" illnesses [6,7]. As such, co-morbid insomnia is seldom treated actively in the primary care setting. The condition is often left to resolve on its own with improvement in the primary condition with which it co-exists. Patients also tend to report insomnia symptoms often only as a casual or a "by-the-way" complaint resulting in an inadequate appreciation of the problem and its impact on the quality of life – both by the physician and the patient [8,9].

Studies [3,5,8] conducted in general populations have demonstrated Health-Related Quality of Life (HRQL) impairments resulting from insomnia. However, owing to the inconsistent definition of the condition, problems associated with falling or staying asleep have been loosely defined and reported, as insomnia, thus potentially overestimating its actual prevalence. Additionally, there has been no documentation of the incremental burden imposed by insomnia over and above the impairment caused by a primary condition in actual routine treatment settings such as in a primary care clinic utilizing a standardized method of classifying patients' symptoms as not having or having insomnia.

Findings of independent association of insomnia with HRQL, especially in real-world patients treated in routine settings, may enhance awareness of the poor HRQL patients experience and highlight the need to identify and treat this condition, more actively. It is possible that co-morbid insomnia 'incrementally' impacts HRQL to the extent that may or may not be resolved with the treatment of the "primary" disorder with which insomnia co-exists.

This study attempts to address the existing gap in the literature by comparing HRQL among patients with and without insomnia who sought care for other conditions in the primary care setting in West Virginia – a medically underserved and economically challenged state. With almost 1 in 5 citizens in poverty, West Virginia ranks among the poorest states in the country [10]. West Virginia ranked 46 out of all US states in overall assessment of health and did even worse in specific health concern areas such as diabetes, smoking, and obesity [11]. The state also ranks 49th in health status and reports the poorest mental health rank in the nation [10]. About 18% of the adult population in West Virginia could not afford to see a primary care physician, compared to a national average of 13% [11].

Given such access issues, and the relatively lesser perceived acuity of independent insomnia complaints, co-morbid insomnia was identified using the validated Insomnia Severity Index (ISI) [12] instrument developed as a screening tool for categorizing patients as suffering

from insomnia symptoms or not, and with established validity for such use in routine primary care settings.

To further establish the incremental burden of such insomnia in a relatively indigent and underserved population, the objective of this study was to compare Health-Related Quality Of Life (HRQL) among patients with and without insomnia in patients who were diagnosed with various chronic conditions that are commonly encountered in the primary care setting.

## Methods

The study was approved by the West Virginia University Institutional Review Board.

Patients were included in the study if they had treatment within six months prior to the beginning of the study at the Clark K. Sleeth Family Medicine Center of West Virginia University Hospitals, Morgantown, WV for one of the following chronic diseases (based on ICD-9 CM diagnosis codes): cardiovascular (CVD), diabetes (D), gastrointestinal (GI), musculoskeletal (MS), and obstructive airways (OAD) and were between 18 and 64 years of age. Between May and June of 2007 data were collected from the identified patients using a mailed survey that included the Medical Outcomes Study (MOS) Short Form 36 (SF-36) questionnaire [13]. The one month recall version (v2) was utilized. The SF-36 calculates scores for eight domains of HRQL and also presents two component summary scores. Based on its wide usage as a generic HRQL measure, the SF-36 allows comparisons across conditions and populations.

All patient-level data related to diagnoses and age were extracted from patient records by clinic staff under the supervision of the head of the clinic. The authors had access only to de-identified data based on alphanumeric codes which the clinic had assigned to individual patients. Authors were blinded to the actual identity of these patients.

Survey packets were mailed out to 2,190 patients satisfying the eligibility criteria. A cover letter explaining the purpose of the survey and a follow-up reminder card was mailed after 7-10 days of the first mailing to increase response rate. Three weeks after the initial mailing a second round of mailing to non-respondents was made. Data collection for the first phase was stopped three weeks after the second round of mailing.

Patients diagnosed with psychiatric conditions (e.g., depression) or other sleep disorders (e.g., obstructive sleep apnea) were not included a priori owing to potential for confounding. Determination of the presence of depression was based on ICD-9 codes assigned to the patients during their visit(s) in the six months prior to the date of the survey.

The Insomnia Severity Index (ISI) was used as a screening tool to categorize patients as suffering from insomnia symptoms or not based on the questionnaire's established validity for such use [12]. Based on the scores generated by this questionnaire, a cut-off score of [14] was used to categorize patients as having insomnia or not. This cut-off was based on the recommendation of the developer of the instrument. Scores below [15] represented either sub-threshold insomnia or the absence of insomnia and respondents having such scores were classified as 'non-insomnia patients'. However, scores from [16] and upwards were considered to be indicative of having insomnia with progressively higher scores (22 onwards) representing a more severe condition.

A set of questions seeking socio-demographic and medication use information was also incorporated. Information was collected on height, weight, race, gender, family income, and education. Given their particular relevance to sleep hygiene, questions about certain health behaviors such as alcohol intake and exercise habits were also included. In order to control for confounding owing to the presence of depressive symptoms at the time of the survey, the Center for Epidemiologic Studies for Depression Scale (CESD) was employed [14]. Scores of [15,16] and higher on this scale have been found to be indicative of depressive symptoms.

### Statistical Analyses

Mean scores in each of the eight SF-36 domains and the two summary scores [Physical Component Summary (PCS) and Mental Component Summary (MCS)] were calculated for respondents identified as not having or having insomnia across the five different disease groups. Comparisons using the effect size as suggested by Cohen were also made to check whether or not these differences were just "statistically" different or had some clinical significance associated with them. Irrespective of the sign, the effect size is an indicator of the impact of insomnia on the quality of life: trivial when it ranges between 0 and 0.2, mild between 0.2 and 0.5, moderate between 0.5 and 0.8, and relevant for values >0.8. Group differences in SF-36 domain scores were analyzed using an analysis of variance (general linear modeling technique) method. Regression models were built using SAS (v9) to assess independent associations between insomnia and HRQL, after statistically controlling for socio-demographic characteristics, health habits, BMI, number of medical conditions, and the presence of depressive symptoms. SF-36 scores between two patient groups with and without insomnia were compared. The variables that were found to have meaningful associations with HRQL in studies of insomnia were controlled for as covariates. While continuous variables were retained, categorical variables were recoded to include the most relevant levels of each variable in the final model in the interest of model parsimony. The variables and their respective levels included in the final model are presented in Table 2.

For missing data, list-wise deletion was adopted and missing data points were not imputed. This was mainly due to two reasons. First, simple mean imputation, the recommended method (half rule) for treating missing data for the SF-36 (the most comprehensive HRQL instrument used in the survey questionnaire) is appropriate in cases where a respondent has answered at least 50% of the questions (for even number of questions) and at least one more than half the total number of questions (for odd number of questions). However, in the case of the current survey, most non-responses arose from patients missing sections altogether when turning pages over. Second, literature supports investigation into causes when data on a particular item are missing for more than 3 to 4 per cent of the respondents. In the current study data was missing for less than 4 per cent of the respondents on almost all variables (except "income") and were not expected to bias parameter estimates, especially in view of the large sample size obtained. Since more than 7% of the respondents had missing data on the "income" variable, it was dropped from statistical analyses. Based on the significant positive non-parametric correlation between 'income' and 'education', and since 'education' had more complete data than income, 'education' was retained in the analyses. To account for the potentially non-linear relationship between age and HRQL, age was collected as a continuous variable but categorized into groups: 18-39 years, and 40-64 years.

## Results

Altogether 1,020 responses (out of 2,190 mailed the survey packets) were received within the study cut-off date resulting in a response rate of 46.58%. Based on 962 respondents who answered questions in the ISI, 230 patients were classified as "Insomnia" and 732 patients as "No Insomnia" groups, respectively.

| Disease Group | No Insomnia | Insomnia n = 230 |
|---|---|---|
| Cardiovascular disease group (CVD) | 466(77.7%) | 134(22.3%) |
| Diabetes group (D) | 169(71.0%) | 69(29.0%) |
| Musculoskeletal disease group (MS) | 56(28.9%) | 138(71.1%) |
| Obstructive disease group (OAD) | 56(32.4%) | 117(67.6%) |
| Gastrointestinal disease (GI) | 30(26.8%) | 82(73.2%) |
| Total n | 732 | 230 |
| Please note: Numbers in the columns do not add up to 100% as several patients had multiple conditions<br>CVD = Cardiovascular disease group<br>D = Diabetes group<br>MS = Musculoskeletal disease<br>OAD = Obstructive airways disease<br>GI = Gastrointestinal disease | | |

**Table 1:** Number and proportion of respondents with and without insomnia in each disease group

Table 1 describes the distribution of insomnia across various disease groups based on the ISI. While the overall prevalence across all disease groups combined was 24% (230/962) this estimate varied considerably when prevalence was studied separately in the individual disease groups. The disease group that reported the highest prevalence of insomnia was the GI group (73%) followed by the MS (71%) and the OAD (68%) groups. Almost 29% of patients with diabetes and 22% patients with CVD reported having insomnia.

A comparison of demographic characteristics revealed that the "Insomnia" and "No Insomnia" groups were significantly different on all characteristics except age and race. A higher proportion in the "Insomnia" group compared to the "No Insomnia" group was female (66.1% vs. 53.4), with annual household income < $ 50,000 per annum (74.3% vs. 46.5%), without college degree (77.3% vs. 58.6%), not married at the time of survey (50% vs. 29.2%), not employed (55.7% vs. 23.9%), obese (54.3% vs. 44.9%), with two medical conditions (37.8% vs. 25.1%) and with depressive symptoms per the CESD (94.3% vs. 46.6%). A majority (58.7% vs. 43.4%) had no history of alcohol use. The distribution of demographic characteristics across the two groups is shown in Table 2. Table 3 shows the average differences (associated with insomnia) in HRQL (as measured by SF-36) domains compared with the no-insomnia group in the study cross-sectional sample after controlling for socio-demographic characteristics, health habits, BMI, number of medical conditions, and the presence of depressive symptoms.

| Demographic Characteristics | No Insomnia n = 732 | Insomnia n = 230 | p-value |
|---|---|---|---|
| Age | | | |
| 18-39 | 124 (16.9%) | 44 (19.1%) | 0.5128 |
| 40-64 | 589 (80.5%) | 184 (80%) | |
| Race (White, %) | 676 (92.3%) | 216 (93.9%) | 0.6156 |
| Gender* (Female, %) | 391 (53.4%) | 152 (66.1%) | 0.0012 |
| Household Income* | | | |
| $25,000 or less | 135 (18.4%) | 116 (50.4%) | <.0001 |
| $25,001 – 50,000 | 206 (28.1%) | 55 (23.9%) | |
| $50,001 – 75,000 | 175 (23.9%) | 26 (11.3%) | |
| More than 75,000 | 160 (21.9%) | 24(10.4%) | |
| Education* | | | |
| Some high school or less | 258 (35.2%) | 125 (54.3%) | <.0001 |
| Some college | 171 (23.4%) | 53 (23.0%) | |
| College graduate | 291 (39.8%) | 48 (20.9%) | |
| Marital status* | | | |
| Currently Married | 518 (70.8%) | 115 (50.0%) | <.0001 |

| | | | |
|---|---|---|---|
| Not currently married | 123 (16.8%) | 81 (35.2%) | |
| Never married | 74 (10.1%) | 30 (13.0%) | |
| Employment Status* | | | |
| Employed full-time | 490 (66.9%) | 84 (36.5%) | <.0001 |
| Employed part-time | 50 (6.8%) | 15 (6.5%) | |
| Not employed | 175 (23.9%) | 128 (55.7%) | |
| Alcohol Use* | | | |
| No history of use | 318 (43.4%) | 135 (58.7%) | <.0001 |
| Current user | 400(54.6%) | 93(40.4%) | |
| BMI* | | | |
| Underweight | 3(0.4%) | 3(1.3%) | 0.0179 |
| Normal | 116(15.8%) | 20(8.7%) | |
| Overweight | 184(25.1%) | 61(26.5%) | |
| Obese | 329(44.9%) | 125(54.3%) | |
| Exercise* | | | |
| Little/none | 64(8.7%) | 41(17.8%) | 0.0005 |
| Some | 491(67.1%) | 144(19.7%) | |
| Regular | 164(22.4%) | 42(18.3%) | |
| Medical Conditions* | | | |
| 1 | 520 (71.0%) | 130 (56.5%) | <.0001 |
| 2 | 184 (25.1%) | 87 (37.8%) | |
| 3 | 28 (3.8%) | 11(4.8%) | |
| 4 | 0 (0.0%) | 2 (0.9%) | |
| Depressive Symptoms* | | | |
| NOT present | 391(53.4%) | 13(5.7%) | <.0001 |
| Present | 341(46.6%) | 217(94.3%) | |

**Table 2:** Distribution of demographic characteristics across the insomnia and no-insomnia groups

| | HRQL Domain | Avg. Score (No Insomnia) | S.E | Avg. Score (Insomnia) | S.E | Avg. Diff from Ref Grp | SD | Effect size | P-val |
|---|---|---|---|---|---|---|---|---|---|
| CVD | Physical Functioning | 67.3 | 4.0 | 55.9 | 4.2 | -11.4 | 29.3 | 0.4 | <.0001 |
| | Role, Physical | 70.2 | 4.4 | 54.4 | 4.7 | -15.8 | 31.7 | 0.5 | <.0001 |
| | Pain | 59.4 | 4.1 | 42.0 | 4.3 | -17.4 | 25.8 | 0.7 | <.0001 |
| | General Health Perception | 57.4 | 3.7 | 46.0 | 3.9 | -11.4 | 24.8 | 0.5 | <.0001 |
| | Vitality | 59.2 | 3.4 | 45.9 | 3.6 | -13.3 | 23.0 | 0.6 | <.0001 |
| | Social Functioning | 79.8 | 3.7 | 61.9 | 3.9 | -18.0 | 27.8 | 0.6 | <.0001 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Role, Emotional | 81.9 | 3.9 | 67.1 | 4.2 | -14.7 | 27.2 | 0.5 | <.0001 |
| | Mental Health | 72.5 | 3.0 | 61.6 | 3.2 | -10.9 | 19.9 | 0.5 | <.0001 |
| | PCS | 43.4 | 1.7 | 37.7 | 1.8 | -5.6 | 11.8 | 0.5 | <.0001 |
| | MCS | 50.5 | 1.8 | 43.6 | 1.9 | -6.9 | 11.7 | 0.6 | <.0001 |
| Diabetes | Physical Functioning | 71.7 | 3.8 | 58.3 | 5.2 | -13.4 | 32.3 | 0.4 | 0.0021 |
| | Role, Physical | 73.4 | 4.3 | 56.3 | 6.0 | -17.1 | 34.1 | 0.5 | 0.0006 |
| | Pain | 64.7 | 4.0 | 48.2 | 5.4 | -16.5 | 27.8 | 0.6 | 0.0003 |
| | General Health Perception | 53.3 | 3.3 | 43.5 | 4.4 | -9.8 | 24.1 | 0.4 | 0.0070 |
| | Vitality | 53.5 | 3.2 | 44.4 | 4.4 | -9.0 | 23.8 | 0.4 | 0.0126 |
| | Social Functioning | 75.3 | 3.7 | 54.9 | 5.1 | -20.4 | 31.6 | 0.6 | <.0001 |
| | Role, Emotional | 80.3 | 3.9 | 59.3 | 5.4 | -21.0 | 29.3 | 0.7 | <.0001 |
| | Mental Health | 70.9 | 3.0 | 57.9 | 4.1 | -13.1 | 21.9 | 0.6 | 0.0001 |
| | PCS | 45.0 | 1.7 | 40.3 | 2.3 | -4.7 | 12.6 | 0.4 | 0.0135 |
| | MCS | 48.0 | 1.8 | 40.2 | 2.4 | -7.8 | 12.7 | 0.6 | 0.0001 |
| MS | Physical Functioning | 53.1 | 6.4 | 42.5 | 6.5 | -10.5 | 28.7 | 0.4 | 0.0308 |
| | Role, Physical | 62.2 | 8.2 | 44.1 | 8.4 | -18.1 | 30.5 | 0.6 | 0.0009 |
| | Pain | 53.2 | 6.9 | 33.0 | 7.1 | -20.2 | 24.8 | 0.8 | <.0001 |
| | General Health Perception | 51.0 | 5.7 | 36.8 | 5.8 | -14.2 | 24.0 | 0.6 | 0.0011 |
| | Vitality | 49.2 | 6.0 | 31.8 | 6.1 | -17.4 | 22.4 | 0.8 | <.0001 |
| | Social Functioning | 96.8 | 5.6 | 68.0 | 5.8 | -28.8 | 30.3 | 1.0 | <.0001 |
| | Role, Emotional | 82.7 | 7.5 | 71.1 | 7.7 | -11.6 | 27.6 | 0.4 | 0.0201 |
| | Mental Health | 76.1 | 5.9 | 60.4 | 6.0 | -15.7 | 21.2 | 0.7 | <.0001 |
| | PCS | 36.9 | 3.1 | 31.2 | 3.2 | -5.7 | 11.1 | 0.5 | 0.0062 |
| | MCS | 53.6 | 3.3 | 44.8 | 3.4 | -8.8 | 12.2 | 0.7 | <.0001 |
| OAD | Physical Functioning | 70.9 | 7.4 | 67.6 | 7.9 | -3.3 | 31.7 | 0.1 | 0.5308 |
| | Role, Physical | 70.2 | 7.0 | 64.7 | 7.4 | -5.5 | 32.0 | 0.2 | 0.2652 |
| | Pain | 57.1 | 6.9 | 48.2 | 7.3 | -8.9 | 27.9 | 0.3 | 0.0668 |
| | General Health Perception | 57.9 | 6.0 | 47.6 | 6.3 | -10.3 | 25.2 | 0.4 | 0.0148 |
| | Vitality | 50.7 | 5.5 | 46.7 | 5.8 | -4.0 | 22.9 | 0.2 | 0.3016 |
| | Social Functioning | 79.2 | 6.5 | 70.3 | 6.9 | -8.9 | 29.8 | 0.3 | 0.0552 |
| | Role, Emotional | 78.8 | 7.3 | 76.6 | 7.7 | -2.2 | 29.4 | 0.1 | 0.6656 |
| | Mental Health | 69.5 | 5.8 | 56.1 | 6.1 | -13.3 | 22.5 | 0.6 | 0.0013 |
| | PCS | 44.2 | 2.9 | 42.1 | 3.1 | -2.1 | 12.3 | 0.2 | 0.3184 |
| | MCS | 48.1 | 3.3 | 43.0 | 3.5 | -5.0 | 13.0 | 0.4 | 0.0330 |
| GI | Physical Functioning | 71.2 | 6.8 | 52.7 | 7.2 | -18.4 | 29.6 | 0.6 | 0.0013 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Role, Physical | 72.1 | 7.0 | 57.7 | 7.4 | -14.5 | 30.6 | 0.5 | 0.0122 |
| | Pain | 68.3 | 7.0 | 43.9 | 7.4 | -24.4 | 23.7 | 1.0 | <.0001 |
| | General Health Perception | 71.5 | 6.2 | 53.9 | 6.5 | -17.6 | 25.7 | 0.7 | 0.0007 |
| | Vitality | 65.9 | 5.9 | 40.0 | 6.2 | -25.9 | 25.4 | 1.0 | <.0001 |
| | Social Functioning | 90.1 | 7.0 | 62.1 | 7.3 | -28.0 | 27.7 | 1.0 | <.0001 |
| | Role, Emotional | 88.0 | 6.9 | 57.4 | 7.3 | -30.6 | 28.3 | 1.1 | <.0001 |
| | Mental Health | 81.3 | 5.8 | 52.5 | 6.2 | -28.8 | 22.4 | 1.3 | <.0001 |
| | PCS | 45.9 | 2.5 | 41.0 | 2.6 | -4.9 | 10.8 | 0.5 | 0.0188 |

**Table 3:** Average differences (associated with insomnia) in HRQL (as measured by SF-36) domains compared with the no-insomnia group.

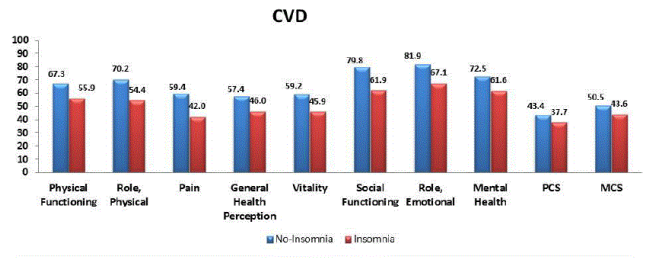


**Figure 1:** Average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in primary care patients with CVD (based on ICD-9 codes)

SF-36 data was available for 197 of the 230 (85.6%) patients in the "Insomnia" group and for 663 out of 732 (90.6%) in the "No Insomnia" group. The mean component and summary measure scores in the two groups i.e. "Insomnia" and "No insomnia" across the various disease categories are shown in Figures 1-5. The figures show the average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in the study cross-sectional sample after controlling for socio-demographic characteristics, health habits, BMI, number of medical conditions, and the presence of depressive symptoms.

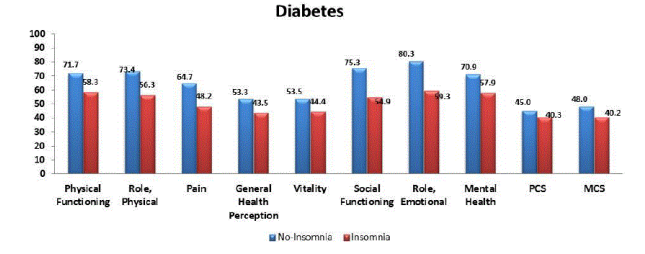


**Figure 2:** Average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in primary care patients with Diabetes (based on ICD-9 codes)

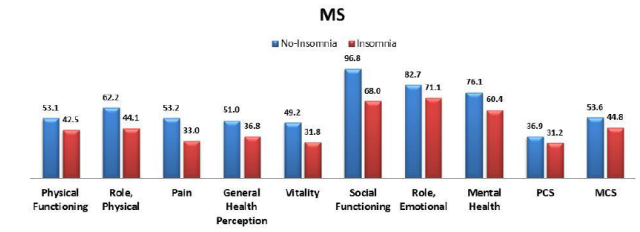


**Figure 3:** Average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in primary care patients with MS (based on ICD-9 codes)

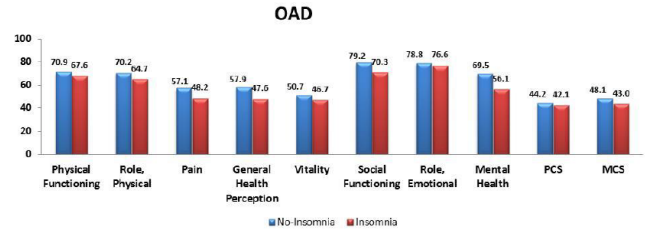


**Figure 4:** Average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in primary care patients with OAD (based on ICD-9 codes)

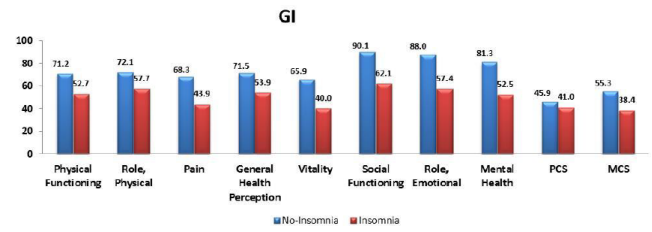


**Figure 5:** Average differences (associated with insomnia) in HRQL domains (as measured by SF-36) compared with the no-insomnia group in primary care patients with GI (based on ICD-9 codes)

The SF-36 scores revealed that patients with insomnia had worse mean Physical Component Summary (PCS) and Mental Component Summary (MCS) scores when compared to the group without insomnia across the various disease categories. Such differences were generally statistically significant ($p<0.05$). In addition, scores for patients with insomnia were statistically significantly lower than those of patients without insomnia in all of the SF-36 scales. Exceptions were seen in the OAD group where only the general health perception and mental health domains scores were significantly lower for the insomnia group compared to the no insomnia group. Effect sizes for the differences in component summary and individual domain scores ranged from 0.4 to 1.0, thereby showing that these differences were also meaningful. Thus a statistically significant independent relationship between insomnia and HRQL generally remained after controlling for the relevant covariates. Therefore, our analysis indicates that insomnia is associated with an independent decrease in HRQL.

## Discussion

Results of this study suggest that using the ISI there was an overall 24% prevalence of insomnia in the sample of primary care patients surveyed with varying prevalence across the different disease conditions. Surveys of clinical populations have revealed a range of estimates. A World Health Organization (WHO) study conducted across 15 different countries revealed an average of 27% of patients in primary health care clinics as suffering from sleep problems, comparable to the 24% found in this study [15]. Another study of 286 patients carried out in the United States of patients in primary care clinics found almost 69% of patients reporting occasional insomnia with 19% reporting chronic insomnia [16]. Yet another survey of managed care enrollees found that 34% of patients reported insomnia symptoms during an office visit [17]. According to several reports, in patients consulting for various complaints at primary care clinics, the prevalence of insomnia may range between 30% for occasional insomnia to 10% for chronic insomnia [18,19]. Estimates have varied depending upon the sample studied, and the level of stringency employed with respect to the definition of insomnia. For example, some studies considered even a single night's sleeping difficulty as insomnia while some required the symptoms to have been present for a few weeks before being considered as insomnia. In view of the above findings and the fact that the current study is a self-administered survey of a general practice population, a 24% prevalence rate seems reasonable.

About half of all patients in the insomnia group in our study had a household income of less than $25,000 (50.4% vs. 18.4%; $p<0.001$). Also, more than half the patients in the insomnia group were less educated (54.3% vs. 35.2%; $p<0.001$) and unemployed (55.7% vs. 23.9%; $p<0.001$). These social indicators of chronic poverty seem to suggest a strong association of poverty levels with increase in sleep problems. Thus, our study supports prior research that has demonstrated that lower socioeconomic status was generally associated with increased likelihood of sleep problems. One study had also found that low and very low food security, were also consistently associated with sleep symptoms even after adjustment of other socio demographic variables. The same study concluded that those in poverty are more likely to experience sleep problems than those not in poverty, and those with household income less than $20,000 were more likely to report multiple sleep disordered symptoms consistent with our findings [4].

Our study found that a significantly greater proportion of patients (66.1% vs. 53.4%, $p=0.0012$) in the insomnia group were women – suggesting an association of female gender with higher rates of co-morbid insomnia. Similarly, earlier research has also shown that complaints of insomnia at least once a week were reported by 25% of women and 21% of men. Childhood economic difficulties showed associations with complaints of insomnia among both women (OR 1.52; 95% CI 1.31–1.76) and men (OR 2.25; 95% CI 1.67–3.02) even after full adjustments of other demographic differences. Also current economic difficulties remained associated with complaints of insomnia, but only among women (OR 1.65; 95% CI 1.41–1.93) [5].

The higher prevalence of insomnia symptoms seen in patients with musculoskeletal diagnoses (including ICD-9 codes that are related to pain) may be explained by the vicious cycle of pain, and insomnia. Pain and immobility may worsen sleeping difficulties at night. While pain may disrupt sleep, poor sleep may lower pain threshold and contribute to increased daytime perception of pain. As such, pain and insomnia have been suggested to go hand in hand [20,21]. It is not surprising then that almost three-fifths of the patients with MS problems involving pain screened positive for insomnia symptoms in the current study. Again, gastrointestinal disease (such as peptic ulcer disease and gastro esophageal reflux disease) has been found to be associated with insomnia. Given symptoms of these conditions include nigh time heartburn and irritable bowel this association is to be expected.

Sleep disorders have been reported in patients with diabetes, too. The occurrence of obesity as a common risk factor for both diabetes and obstructive sleep apnea and disruption of central nervous system regulation leading to periodic breathing (a form of respiratory dysfunction), have been suggested as possible explanations. Sleep and breathing disorders are hypothesized to be causally linked to the onset of type 2 diabetes [22]. West Virginia has among the worst obesity and diabetes rankings in the country, therefore that a substantial proportion of patients with diabetes screened positive for insomnia in the current study is not surprising.

West Virginians also rank among the states with the poorest cardiovascular health in the nation. As such, cardiovascular disease (including ischemic heart disease, nocturnal angina, congestive heart failure), chronic obstructive pulmonary disease, bronchial asthma, dyspnea, and hypertension can cause pain, immobility, and difficulty breathing during the day which may lead to difficulties with sleeping at night [20,21]. This is expected to manifest in diminished HRQL among patients with primary CVD diagnoses.

The OAD group in the current study included patients with ICD-9 codes that represented diagnoses made for mainly COPD, asthma, and for other respiratory conditions that could be classified as "obstructive airways diseases". The prevalence of insomnia in these patients has been reported to be quite high [23]. Since difficulty with breathing may exacerbate night-time symptoms, interference with sleep may be a logical sequel in people with respiratory symptoms. This problem may be further worsened by the presence of sleep apnea a condition common in obese individuals. The primary care sample being obese (BMI>30), a high prevalence of insomnia symptoms seems very likely. As mentioned earlier, literature supports the idea that obesity may be linked to insomnia. However, although the relative prevalence compared to other patients is high - it is less than that reported in exclusively COPD patients. This may be for two reasons: there is a mix of patients (with a variety of disorders in OAD not restricted to just COPD) and also patients in the primary care setting may not be very 'severe' in their disease – or would otherwise have been referred to specialist clinics.

In addition to the co-morbid disorders themselves causing insomnia problems, side effects due to drug treatment of the disorders also may contribute to insomnia. A variety of drugs are reported to cause increased wakefulness and poor-quality sleep. These include corticosteroids, beta-blockers, calcium-channel blockers, diuretics, and bronchodilators [23]. It is understandable, therefore, that various treatments for hypertension and obstructive airway diseases (where prescriptions for the above mentioned drugs are very common) may be associated with insomnia and patients with these diagnoses therefore screened positive for insomnia.

In this study it was seen that co-morbid insomnia adversely impacted all domains of functioning and HRQL, with such impact being significant in the presence of various primary disease conditions. All domains in the CVD, MS and GI and D groups demonstrated significantly greater impairment owing to the presence of insomnia (as evidenced by moderate to relevant effect sizes). Only a few of the domain scores on the SF-36 were unchanged owing to the presence of co-morbid insomnia in the OAD group.

Similar findings have been reported by other studies that measured the impact of insomnia on HRQL in various clinical and general population settings. Two studies comparing quality of life of patients with insomnia with those of healthy controls in one, and with patients with chronic conditions in the other, revealed all domains to be significantly impaired in people with insomnia [24,25]. In yet another study based in a general practice setting, the secondary insomnia group was found to have significantly worse scores than either the primary insomnia group or those without insomnia on six of the eight SF-36 domains [26]. Analysis of quality of life in people with chronic insomnia versus those with congestive heart failure or depression showed that people with severe insomnia had quality-of-life impairments that were at least as severe as those for people with congestive heart failure, with people with insomnia reporting impairments in their quality of life across all the domains [24]. In the current study all the eight domains in most patients (except in the OAD group) have been shown to be impaired ranging from mild to relevant effect sizes. While this could have been the effect of using a different questionnaire to identify patients with insomnia resulting in the more "serious" patients having been identified, such results may also reflect better power generated from a bigger sample to be able to detect differences. Since the summary measure scores on the SF-36 are made up of component scores it was reasonably anticipated that summary measures will differ between the two groups across the various disease categories. A higher prevalence of insomnia was found in women in the current study, corroborating existing literature which supports a higher prevalence of insomnia in females [27,28].

This study also helped update and reinforce past knowledge with more recent information, specifically showing that most domains on SF-36 were adversely impacted in patients experiencing co-morbid insomnia.

## Limitations

Results of the current study should be interpreted with consideration of certain potential limitations. First, although the screening instrument was validated in a population of primary care patients, the lack of an appropriate sleep disorder diagnostic assessment could be an important limitation of the study. While ICD-9 codes based on clinician diagnoses would have been the most reliable method of identifying patients with insomnia, this method could not be used because secondary insomnia is seldom reported as the reason for a clinic visit (only being mentioned casually as a problem, and it is rarely diagnosed by clinicians as a separate stand-alone condition (unlike "primary insomnia" brought to the physician's attention by the patient), and therefore not ascribed a "diagnosis code" very frequently. The use of well-validated and reliable measures was expected to take care of poor recall and self-report biases, especially with respect to sleep characteristics. However, in spite of such measures there may have been some bias associated with the self-report and therefore with the estimates. Second, given the cross-sectional design of the study, no causal relationships between insomnia and HRQL can be concluded. Third, there could have been patients who may not have had a diagnosis of insomnia, but occult diagnoses such as sleep apnea may have been the underlying cause of insomnia, which in turn might have overestimated some of the results. Fourth, since no stratification was done on severity levels of the diagnoses included in the disease groups the potential differential relationships between insomnia and the primary condition could not be assessed. Finally, the respondents were a convenience sample of patients from the outpatient clinics of a university hospital, limiting the generalizability of the study findings to other settings.

## Conclusions

In conclusion, this study emphasizes the significant burden of co-morbid insomnia in primary care settings that care for the underserved and economically disadvantaged populations. Research from different studies, including from this one, has demonstrated the adverse medical, socio-demographic and socioeconomic impact of insomnia. The burden of insomnia may include costs directly related to the problem, its diagnosis and treatment (e.g., outpatient visits, sleep recordings, medications, etc.), indirect costs resulting from productivity and workplace losses due to disease and treatment-related morbidity and mortality (for e.g., diminished professional activity, absenteeism, alcohol and substance abuse, accidents, etc.), and intangible costs in the form of impairments on health status and health-related quality of life, family relationships, and social life. Although it is not possible to calculate the monetary value of the humanistic burden imposed by the condition, the intangible costs in the form of quality of life impairments on health status, family relationships, and social life are expected to be substantial. These may be owing to a wide range of adverse consequences of insomnia such as impairment of cognitive functioning, suboptimal daytime functioning,

and decreased social functioning. Related to this, is the development of somatic disorders like alcoholism, and smoking which result in further deterioration of HRQL and serve as risk factors for other chronic illnesses [29,30].

Based on the independent incremental effect of insomnia, this study makes a case for treating the condition on its own merit, rather than as a symptom of other chronic conditions. It is important to consider more regular identification, diagnosis, and treatment of the condition in the primary care setting, not just to alleviate the burden from the disease itself but to prevent development of other related adverse consequences as mentioned above.

Measurement of health-related quality of life (now discussed under the rubric "patient-reported outcomes") is critical to the management of a symptom-driven condition like insomnia. Documenting differences and estimating the relative burden of different medical conditions with and without insomnia in primary care patients can help determine the scope and extent of insomnia treatment while treating the other conditions. Such an understanding can lend rationale to treatment guidelines and help evaluate whether the routinely used interventions exert a clearly positive influence on patient health-related quality of life. Benchmarks in health-related quality of life levels of comparable populations of patients (with one group having insomnia and the other free of insomnia) available from this research can serve in setting reference standards for practitioners, and help evaluate influence of medications or other treatments on patient reported outcomes. Normative data from such otherwise comparable populations are not available in the literature [31]. Subjective patient reports (describing health-related quality of life burden) are especially useful in conditions where objective physiological/clinical markers are either non-existent (e.g., pain), difficult to obtain (e.g., insomnia), or are not completely reliable (e.g., insomnia). Insomnia is diagnosed mainly by subjective reporting of symptoms and treatment effectiveness is also primarily dependent on patient reports. Although polysomnography and wrist actigraphy have been employed in some studies their extensive use are limited by the high costs, associated complexity with their use, and inconclusive validity. Consequently, patient reported outcomes play a pivotal role in the diagnosis and treatment of insomnia.

Thus, findings from the current study not only help understand the influence of co-morbid insomnia on HRQL, but are also be useful in setting population reference standards for HRQL in primary care patients with secondary co-morbid insomnia, especially in the new clinical paradigm where functional problems, emotional status, and other aspects of health-related quality of life are playing an increasing role in treatment choices and in assessing the effectiveness of treatments [32-36].

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