



# The Relationship Between Insomnia and Health-Related Quality of Life in Patients With Chronic Illness

DAVID A. KATZ, MD, MSC, AND COLLEEN A. McHorney, PhD *Madison, Wisconsin, and Indianapolis, Indiana* 

- <u>OBJECTIVES</u> To determine the association between insomnia and health-related quality of life (HRQOL) in patients with chronic illness after accounting for the effects of depression, anxiety, and medical comorbidities.
- <u>STUDY DESIGN</u> We used a cross-sectional analysis of Medical Outcomes Study (MOS) data.
- POPULATION The sample consisted of 3445 patients who completed a self-administered questionnaire and who were given a diagnosis of 1 or more of 5 chronic medical and psychiatric conditions by an MOS clinician. Patients were recruited from the offices of clinicians practicing family medicine, internal medicine, endocrinology, cardiology, and psychiatry in 3 US cities.
- <u>OUTCOMES</u> <u>MEASURED</u> Outcomes were sleep items, health-related quality of life as measured by the Medical Outcomes Study Short Form Health Survey (SF-36), chronic medical comorbidity, depression, and anxiety. Insomnia was defined as the complaint of difficulty initiating or maintaining sleep.
- RESULTS Insomnia was severe in 16% and mild in 34% of study patients. Patients with insomnia demonstrated significant global decrements in HRQOL. Differences between patients with mild insomnia versus no insomnia showed small to medium decrements across SF-36 subscales ranging from 4.1 to 9.3 points (on a scale of 0 to 100); the corresponding decrements for severe insomnia (versus no insomnia) ranged from 12.0 to 23.9 points.
- <u>CONCLUSIONS</u> Insomnia is independently associated with worsened HRQOL to almost the same extent as chronic conditions such as congestive heart failure and clinical depression.
- <u>KEY WORDS</u> Insomnia; sleep disorders; quality of life; SF-36 [non-MeSH]. (*J Fam Pract 2002;* 51:229-235)

Insomnia, one of the most common complaints in primary care practice, affects more than 60 million Americans. Inadequate sleep has been associated

#### KEY POINTS FOR CLINICIANS

- The prevalence of insomnia in patients with chronic medical or psychiatric conditions is high (50% in the current study sample).
- Insomnia is independently associated with worsened health-related quality of life across several domains, especially mental health, vitality, and general health perceptions, even after accounting for the presence of comorbidities.
- Clinicians should not ignore insomnia; identification and appropriate treatment of this disorder in primary care can significantly improve quality of life.

with reduced physical health,<sup>2</sup> subsequent decline in health status, and increased mortality.<sup>3,4</sup> Patients with chronic insomnia are more likely to develop affective disorders.<sup>5,6</sup> Insomnia may worsen somatic symptoms.<sup>7</sup> Recent studies in health maintenance organization enrollees have demonstrated that insomnia is independently associated with significantly greater functional impairment, more days of disability related to health problems, and greater use of medical services.<sup>8,9</sup>

Patients often present to primary care physicians with chronic comorbidities that may adversely affect sleep quality and that may also compromise functional status. While previous investigations have consistently shown decreased functional status in subjects with insomnia, these studies have tended to focus on general population samples, 10-12 health plan

From the Departments of Medicine and Preventive Medicine, University of Wisconsin Medical School, Madison, Wis. (D.A.K.), and the Departments of Internal Medicine and Geriatrics, Regenstrief Institute for Health Care, Indiana University Center for Aging Research, and the Roudebush VAMC, Indiana University School of Medicine, Indianapolis (C.A.M.). The authors report no competing interests. This work was previously presented in part at the annual meeting of the Society of Medical Decision Making, Toronto, Ontario, Canada, Oct. 15, 1996. Reprint requests should be addressed to David Katz, MD, MSc, University of Wisconsin–Madison, WARF Building, Room 707, 610 Walnut St., Madison, WI 53705. E-mail: dak@medicine.wisc.edu.

enrollees, <sup>8,9,13</sup> or volunteers recruited by media advertisement. <sup>14</sup> In addition, most of the studies either lacked detailed assessment of medical or psychiatric comorbidities or did not control for the presence of these comorbidities in the analysis. Thus, our study aims to (1) determine whether insomnia is independently associated with decreased health-related quality of life (HRQOL) in patients with chronic conditions, and (2) compare the decrease in quality of life associated with insomnia with that associated with other chronic conditions.

## METHODS

We conducted a cross-sectional analysis of data from the Medical Outcomes Study (MOS), an observational study of health outcomes for patients with chronic medical and psychiatric conditions. <sup>15-21</sup>

## Sample and Data Collection

Study participants were English-speaking adults who had had an office visit with 1 of 523 clinicians trained in family practice, general internal medicine, cardiology, endocrinology, psychiatry, or clinical psychology during 9-day screening periods held from February to November 1986. Patients who were eligible for inclusion in the MOS baseline panel completed questionnaires addressing general health status (the Medical Outcomes Study Short Form Health Survey [SF-36]), alcohol use, exercise, and sleep.

Data from standardized physician-completed forms were used to identify patients with 5 index conditions: hypertension, diabetes, congestive heart failure, recent myocardial infarction, and depression.15-20 We identified patients with depression using a short form of the Center for Epidemiologic Studies—Depression (CES-D) Scale<sup>22</sup> and then used the National Institute of Mental Health Diagnostic Interview Schedule (DIS) to assess its severity. 18,22 The definition of current depressive disorder was based on Diagnostic and Statistical Manual, 3rd ed. (DSM-III), criteria for lifetime major depression or dysthymia during the previous 12 months (DSM-IV was unavailable at the time of the MOS). Patients with depressive symptoms who did not satisfy this definition were considered to have subthreshold depression.<sup>23</sup>

### Measures of HRQOL

The SF-36 is a 36-item generic quality-of-life measure that assesses 8 domains: (1) physical functioning; (2) role limitation due to physical health problems (role physical); (3) bodily pain; (4) general health perceptions; (5) vitality; (6) social functioning; (7) role limitations due to emotional health problems (role emotional); and (8) mental health.<sup>24-26</sup> Physical function

and role physical scales best distinguish between groups differing in severity of chronic medical conditions and have the purest interpretation with regard to physical health; mental health and role-emotional scales best distinguish between groups differing in severity of psychiatric disorders and have the purest interpretation with regard to mental health. Social function, vitality, and general health perception scales measure both physical and mental health status.<sup>24</sup> All health measures were scored on scales of 0 to 100, with higher scores indicating better health.

### Measures of Sleep

Insomnia was defined as the complaint of initiating or maintaining sleep (CIMS) using a 6-point categorical scale, with responses ranging from "all of the time" to "never." Mild insomnia was defined by responses to 2 of the MOS sleep items indicating difficulty in initiating or maintaining sleep over the prior 4 weeks "some" or "a good bit" of the time; severe insomnia was defined by difficulty "most" or "all" of the time (see Table W1, available at www.jfponline.com). By inquiring about sleep over the prior 4 weeks, the 2-item measure of *DSM-III* captures key elements of the *DSM-IV* definition<sup>28</sup> and is similar to definitions used in other epidemiologic investigations of insomnia.<sup>29,30</sup>

The measure provides a simple tool for the identification of chronic insomnia in busy primary care practice. In addition, the validity of this 2-item categorical measure is supported by excellent concordance between this measure and a continuous 5-item measure of insomnia (details available on request from the author). The 2-item measure, it is important to note, does not include the *DSM-IV* item pertaining to impairment of daytime functioning, as this item is closely related to the dependent variables of interest in this study.

#### Measures of Potential Confounders

We used an indicator of poverty by dichotomizing per capita household income (in 1985 dollars) at a cut-off point of 200% of the poverty level. Alcohol and smoking status were assessed with a 3-point scale: no history of use, past user, or current user. Frequency of exercise was assessed with the question, "How often do you exercise?" on a 6-point Likert-type scale, with responses ranging from "daily or almost daily" to "almost never or never." Subjects were overweight if body mass index (BMI) exceeded 25 and obese if BMI exceeded 30.31.32

We identified 16 common medical conditions comorbid to the index conditions by using data from the MOS standardized health examination. Data on

TABLE 1

/ariable	No Insomnia (N = 1583)	Mild Insomnia (N = 1145)	Severe Insomnia (N = 540)
<b>Demographics</b> Age, mean (SD)	53.8 (15)	54.8 (16)	53.1 (17)
Gender (% male)*	44	35	27
Race (% nonwhite)*	18	22	26
ncome, mean adjusted 1985 nousehold dollars*	\$24,649	\$22,376	\$19,506
Education, years mean)*	13.7	13.2	12.7
Employed (%)*	59	49	43
Married (%)*	62	58	51
Clinical conditions, % Hypertension* Congestive heart	66	59	49
ailure*	4	7	9
Myocardial nfarction†	3	4	2
Diabetes mellitus type 1 or 2)†	20	16	17
Clinical depression*	9	15	32
Subthreshold depression*	17	27	29
Mean number of comorbidities*	1.2	1.5	1.8

medications were excluded because they do not reflect contemporary patterns of medication use and because of collinearity between medication and comorbidity variables already in the model.

## Statistical Analysis

We used multiple linear regression to identify the association between insomnia and HRQOL. We adjusted for sociodemographic characteristics, health habits, index conditions, severity of index conditions, <sup>19</sup> a count of the 16 medical comorbidities, <sup>34</sup> and study location. To account for the potentially nonlinear relationship between age and HRQOL, we included 3 dummy variables for age: 40 to 55 years, 56 to 65 years, and older than 65 years (age younger than 40 years was the holdout category). Similarly, we included dummy variables for education (less than 12 years or exactly 12 years; more than 12 years was the holdout category) and exercise (at least 4 times a week or less than once a week; 1 to 3 times a week was the holdout category).

We report the average deviation in HRQOL values for mild and severe insomnia and for 2 comparison conditions: clinical depression and congestive heart failure (CHF). These conditions were selected because they are representative of conditions with predominant effects on physical functioning (CHF) and mental health (depression).<sup>17,24,25</sup> The average deviation in HRQOL is represented by the regression coefficients corresponding to the terms for these conditions in each HRQOL model.<sup>17</sup> Because all patients in the current study had at least 1 of the 5 physician-identified conditions, we used the subgroup of patients with mild hypertension<sup>19</sup> and without insomnia as the reference group.

We also performed a subset analysis of 2197 patients who had completed a screening version of the DIS for anxiety disorders (generalized anxiety disorder, phobia, or panic disorder) at the baseline health evaluation. In this patient subset, we constructed a series of regression models and examined the change in average deviation in HRQOL associated with insomnia with the addition of groups of covariates (sociodemographics, health habits, medical conditions, depression, and anxiety) to a base model including only insomnia and study location variables.

We also examined whether our results were robust by using logistic regression. Because most of the dependent variables are highly skewed (and thus may not satisfy the distributional assumptions of linear regression), we dichotomized each dependent variable as categorical (lowest tertile versus middle and upper ter-

tiles) and determined the odds ratios for mild and severe insomnia associated with the lowest tertile of each HRQOL measure. Because we assessed the significance of both mild and severe insomnia in 8 different HRQOL domains, we used the Bonferroni correction to adjust for multiple comparisons (only *P* values ≥.003 were considered statistically significant).

Finally, we checked for selected 2-way interaction terms to determine whether the association between insomnia and HRQOL differed significantly by age, gender, race, education, and burden of comorbidity.<sup>28,35,36</sup>

## RESULTS

Baesd on our definition of insomnia, 16% of study patients had severe insomnia and 34% had mild insomnia. Patients with mild and severe insomnia were more likely to be female, nonwhite, poor, unemployed, and unmarried. They were also more likely to have clinical (or subthreshold) depression, congestive heart failure, and a greater number of medical comorbidities (Table 1).

We found a significant independent association between insomnia and HRQOL, even after we had statistically controlled for sociodemographic characteristics, health habits, BMI, medical comorbidities, and the presence of clinical and subthreshold depression. All covariates were forced into each HRQOL model simultaneously. Insomnia showed the strongest associations with mental health, vitality, and social subscales (based on the Wald statistic).

Relative to patients without insomnia, increased severity of insomnia was associated with a progressively greater deviation in HRQOL (Table 2). The decreases in HRQOL observed for mild and severe insomnia were pervasive across all SF-36 domains and were similar when the sample was restricted to those patients seen by a primary care clinician (family physician or general internist, n = 2463) (Table W2 at www.jfponline.com). The magnitude of the average deviation in physical function for severe insomnia was comparable with that observed for CHF; similarly, the average deviation in the mental health domain for severe insomnia was about 60% that observed for clinical depression.

Mild and severe insomnia were associated with diminished HRQOL across all SF-36 domains using logistic regression (relative to patients without insomnia); however, the magnitude of associations for subscales differed somewhat. In these analyses, the adjusted odds ratios for mild and severe insomnia

TABLE 2

were greatest for mental health (3.5 and 10.2, respectively), vitality (2.4 and 7.4, respectively), and general health perceptions (2.0 and 5.1, respectively). Other subscale results are available on request from the author.

The incremental effect of controlling for chronic medical conditions, depression, and anxiety on the decrements in HRQOL associated with insomnia is demonstrated in Table 3 for selected domains. Addition of medical variables reduces the strength of association between insomnia and physical function by 28% and 28%, vitality by 17% and 18%, and mental health by 12% and 12% (for mild and severe insomnia, respectively). Subsequent addition of depression and anxiety variables reduces the strength of association between insomnia and mental health by 33% and 38%, vitality by 18% and 23%, and physical function by 11% and 10% (for mild and severe insomnia, respectively). Even after accounting for depression and anxiety, both mild and severe insomnia account for significantly decreased HRQOL in this subset analysis.

In tests of interactions, the association between insomnia and HRQOL was similar across age, gender, race, education, and comorbidity (≥3 versus <3 comorbid conditions). Of a total of 64 interaction terms across all SF-36 subscales, only 3 were statistically significant and no consistent pattern was observed; this is what would be expected by chance alone.

AVERAGE DEVIATION IN HEALTH-RELATED QUALITY OF LIFE (HRQOL) DOMAINS ASSOCIATED WITH INSOMNIA IN THE MEDICAL OUTCOMES STUDY CROSS-SECTIONAL SAMPLE (N=3445)

		Average Deviation From Reference Group*				
	Average Score of Reference Group	Mild Insomnia	Severe Insomnia	Congestive Heart Failure	Clinical Depression	
Physical function	80.8	-4.1 (0.8)†	-12.0 (1.1)†	-14.8 (1.7)†	-4.8 (1.3)†	
Role, physical	69.5	-8.9 (1.4)†	-23.9 (1.9)†	-13.1 (2.8)†	-16.0 (2.2)†	
Pain	76.1	-4.9 (0.9)†	-15.2 (1.1)†	1.8 (1.7)	-8.9 (1.3)†	
General health percepti	on 65.1	-5.6 (0.8)†	-12.6 (1.0)†	-11.2 (1.5)†	-8.7 (1.2)†	
Vitality	64.0	-7.2 (0.7)†	-16.0 (1.0)†	-7.5 (1.5)†	-13.0 (1.2)†	
Social	90.3	-5.6 (0.8)†	-15.7 (1.1)†	-6.4 (1.6)†	-22.6 (1.3)†	
Role, emotional	80.8	-9.3 (1.4)†	-18.7 (1.9)†	-3.5 (2.8)	-31.6 (2.2)†	
Mental health	80.0	-6.6 (0.6)†	-14.6 (0.8)†	0.5 (1.2)	-24.6 (1.0)†	

NOTE: Average deviations in HRQOL for a chronic medical condition (congestive heart failure) and a chronic psychiatric condition (clinical depression) are provided for comparison.

\*These values correspond to the coefficients for insomnia and comparison conditions in HRQQL regression models, which are statistically controlled for demographic factors, health habits, obesity, other chronic conditions, disease severity, and study location; standard errors are in parentheses. All HRQQL values are scored on a scale of 0 to 100. The reference group (N = 1073) is defined as patients with mild hypertension (and no other tracer conditions) and no insomnia. For example, patients with severe insomnia at baseline experienced a 12.0-point decrement in physical functioning (on average) compared with the reference group.

†P < 001.

TABLE 3 =

# THE EFFECT OF ADDING SPECIFIC VARIABLE GROUPS ON THE AVERAGE DEVIATION IN HEALTH-RELATED QUALITY OF LIFE (HRQQL) DOMAINS ASSOCIATED WITH INSOMNIA AT BASELINE

	Physical Function		Vitality		Mental Health	
Model	Mild Insomnia	Severe Insomnia	Mild Insomnia	Severe Insomnia	Mild Insomnia	Severe Insomnia
(1) Insomnia only*	-9.6	-18.5	-11.5	-23.8	-10.2	-23.7
(2) Insomnia + sociodemographics†	-8.0	-16.3	-10.7	-22.0	-9.9	-21.9
(3) Insomnia + sociodemographics +						
health habits‡	-7.5	-15.1	-10.3	-21.1	-9.7	-21.5
(4) Insomnia + sociodemographics						
+ health habits + medical§	-5.4	-10.9	-8.5	-17.3	-8.5	-19.0
(5) Insomnia + sociodemographics +						
health habits + medical + depressionII	-4.9	10.1	-7.4	-14.7	-6.3	-13.7
(6) Model 5 + anxiety¶	-4.8	-9.8	-7.0	-13.4	-5.7	-11.7
Adjusted R <sup>2</sup> (model 5)	0.3	7	0.3	31	0.4	49

NOTE: Analysis sample is limited to those patients who completed a screening evaluation for anxiety disorders (n = 2197).

## DISCUSSION

Physicians often ignore sleep disorders such as insomnia in clinical practice, in part because of increasing time constraints and because of poor preparation to deal with sleep disorders.37,38 The National Commission on Sleep Disorders Research (NCSDR) reviewed 10,000 medical records from 9 family practice clinics, finding only 123 records that contained a note about the patient's sleep; not a single record suggested an effective response to the patient's sleep complaint.1 Ignoring insomnia can have major implications for public health, however. Insomnia increases the risk of occupational injury and traffic accidents; a recent study concluded that driving while sleepy was at least as dangerous as the risk of driving under the influence of alcohol.39 Similarly, a 1991 national survey showed that respondents with chronic insomnia are more likely to feel sleepy when driving, to have impaired concentration, and to have problems in accomplishing daily tasks.10

Our results extend the results of previous investigations by demonstrating that insomnia is independently associated with a significant decrease in overall quality of life for patients with chronic illness. The magnitude of this decrease for severe insomnia is comparable with that observed for chronic conditions such as CHF and clinical depression. We found that such decrements worsened with increased levels of sleep disturbance and that these decreased values persisted

even after accounting for medical comorbidity, depression, and anxiety. These findings are similar to the results of a recent population-based investigation, in which insomnia was associated with global decreases in HRQOL, even after excluding subjects who met *DSM-IV* criteria for depression or anxiety.<sup>12</sup>

Another possible explanation for the negative association between insomnia and HRQOL is that patients with insomnia overreport functional impairment in a systematic fashion. This phenomenon has been described in depressed patients as "negative thinking bias," 40 and it is possible that insomnia also leads to biased reporting. While it is difficult to rule this out, analyses of the health care behavior of patients with insomnia provides indirect evidence of the functional impairment of these patients, as measured by their increased use of medical and mental health services. 89,13

# Limitations

The limitations of our study deserve comment. First, the MOS included a select group of physicians and their patients who agreed to participate in a comprehensive study of medical care. That the MOS sampled only patients with 5 chronic conditions who were insured and had a continuous relationship with a provider in 3 large urban areas limits the ability to generalize. Noteworthy, however, is that the prevalence of mild or severe insomnia in the MOS sample (50%) was comparable with that reported in a recent

<sup>\*</sup> Includes mild and severe insomnia. Average deviations are statistically significant at the P<.001 level for all models. Note that in the main analysis (Table 2),

all variables, including terms for insomnia and potential confounders, were forced into each HRQOL model simultaneously. †Sociodemographic variables include age, sex, race, education, income, and marital status.

<sup>‡</sup>Health habits include alcohol use, smoking status, and exercise frequency.

<sup>§</sup>Medical variables include medical tracer conditions (hypertension, myocardial infarction, congestive heart failure, diabetes mellitus), including severity status, number of comorbid medical conditions (see text), and obesity.

Il Depression variables include current depressive disorder and subthreshold depression.

<sup>¶</sup>Anxiety variable is defined as any anxiety disorder (generalized anxiety disorder, phobia, or panic disorder) over the previous 12 months.

study of managed-care enrollees (46%).9

Second, this analysis is based on cross-sectional data. We cannot rule out the possibility that decreased quality of life leads to insomnia (ie, reverse causality). The causal relation of insomnia to diminished HRQOL is supported by longitudinal data suggesting that insomnia is an important precursor of depression.<sup>5,41</sup> Alternatively, insomnia may partially mediate the effect of chronic conditions such as CHF on HRQOL. Indeed, prior work has shown that worsening of chronic conditions tends to be associated with worsening of insomnia during follow-up, and vice versa.<sup>42</sup>

Third, sleep problems were assessed by self-report. No attempt was made to validate our findings with polysomnographic measurements. Polysomnography has limited value in the evaluation of insomnia; many self-identified insomniacs do not show objective sleep abnormalities on polysomnography<sup>13</sup> and tend to have high night-to-night variability in the quality of their sleep.<sup>44</sup> Indeed, some discrepancies may exist between self-reported sleep and laboratory data.<sup>45,46</sup> Data obtained from MOS patients regarding other measures of sleep (including total sleep time, sleep latency, and adequacy of sleep) appear to verify the existence of sleep problems.<sup>42</sup>

Fourth, the definition of depression was based on *DSM-III* criteria, which differ somewhat from those of *DSM-IV*. We note, however, that the primary emphasis in revising the *DSM-III* criteria for these conditions was to improve discrimination between major depression and dysthymia,<sup>47</sup> for both of which our analysis controlled. In addition, the diagnostic criteria for major depression and dysthymia incorporate sleep disturbance; thus, adjustment for depression would tend to reduce the estimated association between insomnia and HRQOL (as confirmed in Table 3).

Interpretation of the above findings should account for the nature of the study sample. Because all patients in the study sample had chronic conditions, average deviations in HRQOL scores were computed relative to the group with mild hypertension and without insomnia (reference group). Because even mild hypertension and its treatment may have an impact on several HRQOL domains, the associations between insomnia and HRQOL in the current study would probably have been even stronger if the reference group comprised patients with no chronic conditions.

While depression and insomnia (one of the diagnostic criteria for depression) overlap considerably, pharmacologic and behavioral approaches, including light therapy<sup>49-52</sup> and exercise,<sup>53</sup> have potential to significantly lessen the burden of chronic insomnia

and its effect on HRQOL.<sup>54</sup> In addition, clinicians should identify (and treat, if possible) predisposing conditions associated with insomnia.<sup>28,36,42</sup> Finally, future clinical trials involving treatment of insomnia should incorporate measures, such as the SF-36, that can detect clinically meaningful effects of insomnia on HRQOL in addition to standard laboratory and self-reported measures of sleep disturbance.

## CONCLUSIONS

Even after accounting for the presence of chronic medical comorbidities, depression, and anxiety, insomnia is associated with significantly worsened HRQOL, particularly in the domains of mental health, vitality, and general health perceptions. By identifying and treating chronic insomnia, including any predisposing conditions that may perpetuate insomnia, clinicians can significantly improve the quality of life of patients with chronic illness.

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