Insomnia and Hypnotic Use, Recorded in the Minimum Data Set, as Predictors of Falls and Hip Fractures in Michigan Nursing Homes

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OBJECTIVES: To examine the relationship between insomnia, hypnotic use, falls, and hip fractures in older people.

DESIGN: Secondary analysis of a large, longitudinal, assessment database.

SETTING: Four hundred thirty-seven nursing homes in Michigan.

PARTICIPANTS: Residents aged 65 and older in 2001 with a baseline Minimum Data Set assessment and a follow-up 150 to 210 days later.

MEASUREMENTS: Logistic regression modeled any follow-up report of fall or hip fracture. Predictors were baseline reports of insomnia (previous month) and use of hypnotics (previous week). Potential confounds taken into account included standard measures of functional status, cognitive status, intensity of resource utilization, proximity to death, illness burden, number of medications, emergency room visits, nursing home new admission, age, and sex.

RESULTS: In 34,163 nursing home residents (76% women, mean age ± standard deviation 84 ± 8), hypnotic use did not predict falls (adjusted odds ratio (AOR) = 1.13, 95% confidence interval (CI) = 0.98, 1.30). In contrast, insomnia did predict future falls (AOR = 1.52, 95% CI = 1.38, 1.66). Untreated insomnia (AOR = 1.55, 95% CI = 1.41, 1.71) and hypnotic-treated (unresponsive) insomnia (AOR = 1.32, 95% CI = 1.02, 1.70) predicted more falls than did the absence of insomnia. After adjustment for confounding variables, insomnia and hypnotic use were not associated with subsequent hip fracture.

CONCLUSION: In elderly nursing home residents, insomnia, but not hypnotic use, is associated with a greater risk of subsequent falls. Future studies will need to confirm these findings and determine whether appropriate hypnotic use can protect against future falls. **J Am Geriatr Soc 53:955–962, 2005.**

Key words: insomnia; accidental falls; hip fractures; aged; nursing homes; Minimum Data Set; interRAI

More than one-third of adults aged 65 and older fall each year.[1] In this age group, falls are the leading cause of injury-related deaths[2] and the most common cause of nonfatal injuries and hospital admissions for trauma.[3] About 1% of falls result in hip fractures that cause restricted mobility for 60%, increased functional dependence for 25%, death within 6 months for 25%, and annual medical costs of $2 billion.[4] Among the many causes of falls in older persons are medical conditions, impaired vision and hearing, misuse of assistive devices, environmental factors, and medications.

Of medications commonly used by older persons, psychotropic agents and hypnotics in particular have been implicated as strong risk factors for falls.[5–8] In a community setting, psychotropic or sedative use increased the likelihood of falls by a factor of 28.3 (95% confidence interval (CI) = 3.4–239.4), after controlling for some other risk factors.[9] In comparison, cognitive impairment only increased fall risk by a factor of 5.0 (95% CI = 1.8–13.7) and multiple balance and gait abnormalities by a factor of 1.9 (95% CI = 1.0–3.7). Sedatives can impair posture, reaction time, coordination, protective responses during falls, and cardiovascular reflexes that normally prevent orthostatic hypotension,[10–12] but much of the measured effect of sedative use also may be attributable to unmeasured health conditions and practices common in sedative users—including comorbidities, decreased coordination, cognitive

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dysfunction, impaired mobility, and sedative polypharmacy—rather than to a causative link between single sedative use and falls or hip fracture.[13–15]

Furthermore, most studies that have implicated hypnotics as risk factors for falls and injuries did not explore the possibility that underlying insomnia, rather than medication, could be the main reason for the adverse outcomes.[16] In a community-based cross-sectional survey of 1,526 older adults, insomnia, but not psychoactive medication, was associated with falls within the previous 12 months,[17] although use of psychoactive agents was rare (4%) in this relatively well-educated Silicon Valley community. Neither this study nor others of insomnia or hypnotics in older persons have combined sufficient sample size, adjustment for the large number of potential covariates, and a longitudinal design to confirm that putative risk factors precede outcomes. A better understanding of whether hypnotics, underlying insomnia, both, or neither contribute to falls could inform interventions likely to have substantial effect on the health of institutionalized older people. To address this question, a statewide, government-mandated nursing home database that contains information about sleep, falls, health, and many covariates collected longitudinally at 3-month intervals was used.

METHODS

Subjects and Database

Data for this study were obtained from assessments of all residents of nursing home facilities in Michigan that qualify for federal funding under Medicare or Medicaid. In compliance with the Omnibus Reconciliation Act of 1987, these residents are assessed at least four times each year using the Long-Term Care Facility Resident Assessment Instrument, a comprehensive, standardized assessment instrument that includes the Minimum Data Set (MDS). The MDS includes 350 items on demographics; health conditions; cognitive, physical, emotional, and social functioning; medical diagnoses; therapies; treatments; and medication use. Full assessments occur at admission, when significant changes in health status occur, and at least annually. Quarterly assessments that cover fewer items occur approximately every 90 days after admission. Trained assessors at each facility use all available sources of information (e.g., the resident, facility staff, resident's physician, and medical chart) to determine the most appropriate response for each assessment item. The University of Michigan medical institutional review board approved use of the Michigan MDS data for the purposes of this research.

For this analysis, the sample includes all nursing home residents, both newly admitted and long-stay, aged 65 and older who had a full assessment in 2001 (January 1, 2001, to December 31, 2001) and a follow-up assessment approximately 6 months (150–210 days) later. When more than one full assessment in 2001 was available, the earliest assessment was used. By these criteria, there were 34,163 available subjects (Figure 1).

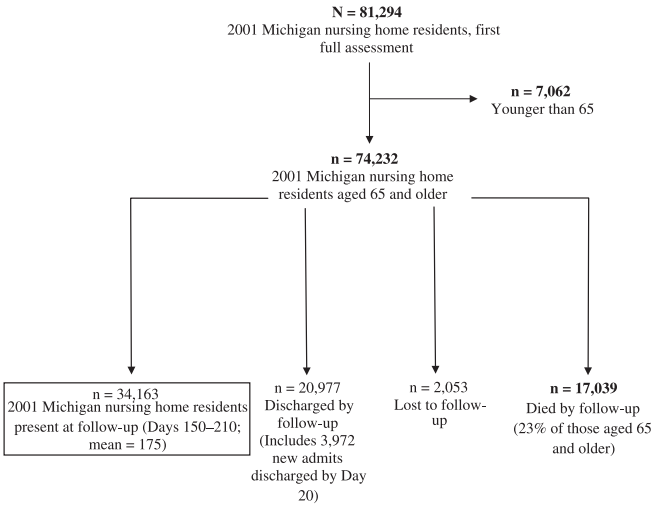

Figure 1. Identification of the 34,163 subjects whose data were used for this study.

Measures

The Resident Assessment Instrument/Minimum Data Set 2.0 (RAI/MDS 2.0) was designed to improve care planning and therefore covers a broad range of domains, including physical and cognitive function, continence, mood, medical diagnoses and conditions, activity patterns, medications, and changes in physical status. Five items from the MDS were used: insomnia (E1k), hypnotic use (O4d), hip fracture (J4c), falls in previous 30 days (J4a), and falls in previous 31 to 180 days (J4b). Since implementation in 1991, the items included in the MDS have performed well in tests of reliability and validity,[18] as have scales derived from the MDS items. Several reliability studies have examined interobserver reproducibility, which is the agreement between two assessors who independently evaluate the same resident.[18–21] Spearman-Brown intraclass correlation coefficients for each section of the MDS between contemporaneous ratings by two research nurses range from 0.46 to 0.78.[22] Reproducibilities for the independent variables used in the present analysis were 0.53 for insomnia; 0.62 for hypnotic use, 0.70 for hip fracture, 0.66 for falls in previous 30 days, and 0.69 for falls in previous 31 to 180 days (Morris JN, personal communication, 2004). A recent large-scale reliability trial of the MDS, with more than 5,700 dual assessments performed by facility staff during routine operation and research assessors in six states and 219 facilities, demonstrated average to good reliability.[23]

Scales derived within selected domains of the MDS demonstrate concurrent validity through high correlation with other frequently used measures. For example, the Cognitive Performance Scale,[24] derived from the MDS, correlates highly with the Folstein Mini-Mental State Examination[25] and the Albert Test of Severe Impairment.[26] In addition, a national evaluation of the full RAI system demonstrated the system's effectiveness in care improvement; after implementation of the RAI, falls were reduced,[27–30] which suggests criterion validity. The RAI/MDS is a resource for research as well as for care planning;[31] as of April 2004, Medline indexed 527 articles that used the MDS.

Explanatory Variables and Potential Confounders

Potential effects of insomnia and hypnotic use on falls and hip fractures were studied, after adjustment for a number of

general health status indicators. All explanatory variables and potential confounders were obtained from the baseline MDS assessment. Residents with insomnia/change in usual sleep pattern on any of the preceding 30 days were coded as having insomnia. Residents who had received a hypnotic medication during the previous 7 days were coded as using a hypnotic. Hypnotics as defined by the MDS 2.0 User's Manual[32] included aprobarbital, flurazepam, quazepam, triazolam, pentobarbital, ethchlorvynol, estazolam, temazepam and secobarbital, although any drug considered to be a hypnotic would be coded as a hypnotic, regardless of the indication, as recommended by the Centers for Medicare and Medicaid Services when it revised the MDS 2.0 nursing home manual in 2001 (Belleville-Taylor P, personal communications, 2004). Additional drugs in this classification may be determined by consulting a drug reference source such as the U.S. Pharmacopeia Formulary, the Physician's Desk Reference, or the Merck Index; zolpidem and zaleplon are classified as hypnotics in these sources. Note that a hypnotic used off label for another purpose would still be coded as a hypnotic, whereas a drug not classified as a hypnotic (e.g., an anxiolytic) would not be coded as a hypnotic, even if intended to promote sleep.

Fifty-four percent of the residents who had received a hypnotic in the previous week received it on five or more days. Other fall-related resident characteristics (resident age, sex, functional and cognitive status, intensity of resource utilization, burden of illness, number of medications taken, emergency department visits, and new admission) were controlled for. Functional status (ability in locomotion, transferring, toileting, and eating) was measured using the activity of daily living hierarchy scale,[33] cognitive status (memory, decision making, understanding) using the Cognitive Performance Scale,[24] intensity of resource utilization using the Resource Utilization Group (RUG)-III category and Case Mix Index,[34] burden of illness using the Changes in Health, End-stage disease and Symptoms and Signs scale[35] and the Personal Severity Score (unpublished data), polypharmacy using the number of medications taken, and recent changes in health status using any emergency department visit in the previous 90 days not resulting in admission to the hospital and admission to the nursing home.

Outcome Measures

Two outcomes were examined—falls and hip fractures—that occurred in the 6 months between the baseline and follow-up assessments. Both were coded from the follow-up assessment. A fall was coded if the resident had fallen in the previous 30 days or in the previous 31 to 180 days. A hip fracture was coded if a hip fracture occurred in the previous 180 days.

Analysis

Within the sample of 2,001 Michigan nursing home residents aged 65 and older who had a 6-month follow-up, the data were checked for completeness. In the few cases in which a value was missing for one independent variable but present for all others, the most common value (discrete variables) or the mean (continuous variables) was imputed. The Pearson chi-square test was then used for discrete variables and the Student *t* test for continuous variables to examine the bivariate (unadjusted) associations between outcome variables, explanatory variables, and potential confounders. To examine the effect of insomnia, hypnotic use, and both insomnia and hypnotic use after controlling for confounding, multivariate logistic regression models were created. The combined effect of insomnia and hypnotic use on falls and hip fracture was evaluated using a four-categorical variable representing insomnia without hypnotic use, insomnia despite hypnotic use, hypnotic use without current insomnia, and neither insomnia nor hypnotic use. Relationships between explanatory and confounding variables and outcomes were considered significant when $P < .05$. Three potential confounders—vision, Personal Severity Index, and Case Mix Index—were significant in bivariate but not in multivariate models. Therefore, these variables were removed from subsequent logistic regression models.

RESULTS

Descriptive statistics and item identifiers for outcomes, baseline explanatory variables, demographics, and other potential confounding variables are shown in Table 1 for the study sample and those excluded for lack of follow-up data. The study sample largely reflects long-term nursing home residents, whereas those without a 6-month follow-up were likely to have been in the nursing home for post-acute, rehabilitation, or terminal care. Accordingly, the excluded sample was more likely to have been recently admitted to the nursing home, to have had an emergency room visit, and have higher burden of illness; those excluded used more medications, were less able to balance well, and were more functionally impaired. Insomnia and hypnotic use were more frequent in the excluded sample. Alternatively, the study sample had a greater proportion of women and was, on average, 2 years older, more cognitively impaired, more visually impaired, and more likely to be in a clinically intense RUG-III category.

Of the 34,163 subjects in this study, 14,661 (42.9%) were reported to have fallen in the 6-month period (mean of 174 days) between their baseline and follow-up evaluations, whereas 841 (2.5%) were reported to have sustained a hip fracture. Almost all (90.3%) of the subjects who sustained a hip fracture in the follow-up period experienced at least one fall (chi-square = 796.54, $P < .001$). Moderate insomnia (occurring on 1 to 5 nights per week) was reported in 1,872 (5.5%) subjects, and severe insomnia ($\geq$6 nights per week) in 277 (0.81%). Hypnotic use was reported in 882 (2.6%) of the subjects. As expected, insomnia (moderate or severe) was strongly associated with hypnotic use (chi-square = 852.97, $P < .001$); 11.3% of moderate insomniacs used some hypnotic, as did 17.3% of severe insomniacs.

In the following, falls and hip fractures are described separately. Table 2 shows the bivariate (unadjusted) relationship between each explanatory, demographic, and potential confounding variable and each outcome variable. Increasing age, unsteady balance, use of more medications, and recent changes in health status as reflected in recent nursing home admission, a recent emergency department visit, and increased burden of illness each increased the likelihood of fall or hip fracture. Risk of fall or hip fracture

Table 1. Outcomes, Explanatory Variables, Demographics, and Other Potential Confounders for the Study Sample and for Excluded Subjects

Variable	MDS Item	Definition	Included Older People (n = 34,163)	Excluded Older People (n = 39,982)	*P*-value
Outcome variables (at follow-up), n (%)					
Falls	J4a, J4b	≥1 in previous 180 days	14,661 (42.9)	Unknown	N.A.
Hip fracture	J4c	≥1 in previous 180 days	841 (2.5)	Unknown	N.A.
Explanatory variables (at baseline), %					
Insomnia	E1k	Within previous 30 days	6.3	10.5	<.001
Hypnotic use	O4d	At least once in previous 7 days	2.6	6.9	<.001
Demographics					
Age, mean ± SD	AA3		84.2 ± 7.7	82.6 ± 7.7	<.001
Women, %	AA2		76.5	66.6	<.001
Potential confounders (at baseline)					
Activities of daily living hierarchy scale, %	G1eA, G1hA, G1iA, G1jA	Mildly impaired (0,1,2)	31.5	30.9	<.001
		Moderately impaired (3,4)	39.6	34.6	
		Severely impaired (5,6)	28.8	34.6	
Cognitive Performance Scale, %	B2a, B4, C4	Mildly impaired (0,1)	22.7	46.9	<.001
		Moderately impaired (2,3,4)	60.9	42.6	
		Severely impaired (5)	8.8	4.7	
		Very severely impaired (6)	7.6	5.9	
RUG III Categorization, %	H2c, H2e, H2f, H2g	Reduced physical function	20.9	56.9	<.001
		Behavioral problems	5.0	11.8	
		Impaired cognition	5.9	7.8	
		Clinically complex	18.3	10.8	
		Special care	16.9	3.2	
		Intensive services, %	0.6	0.2	
		Special rehabilitation, %	32.4	9.3	
Case mix index, mean ± SD	H2c, H2e, H2f, H2g	Ratio of RUG III category hours of care to average hours of care	1.04 ± 0.61	1.66 ± 0.69	<.001
Burden of illness, mean ± SD	B6, G9, J1b-d, J1l, J1o, J5c, K3a, K4	Changes in Health, End-stage disease, and Signs and Symptoms score (0–6)	1.09 ± 1.08	1.82 ± 1.13	<.001
Personal Severity Index, %	A3, B4, B5e, G1bA, G1eA, G1hA, G1Ja, E1c, E1g, H1a, J5a–c, K3a, M2a, M2b, Q2	Above mortality threshold (5)	39.3	44.9	<.001
Vision, %	D1, D2a, D2b	Impaired	42.7	31.8	<.001
Balance test, %	G3a	Unsteady, needs support,	87.9	93.2	<.001
Polypharmacy, mean ± SD	O1	Medications	8.3 ± 4.2	9.6 ± 4.5	<.001
Emergency room visit, %	P6	1 in previous 90 days	6.4	10.3	<.001
Admission to nursing home, %	AA8a	Within previous 90 days	23.3	42.3	<.001

SD = standard deviation; RUG = Resource Utilization Group.

increased with functional and cognitive impairment, until impairment became severe; this curvilinear pattern is visible in the greater risks associated with moderate than with severe impairment in functional status, cognitive impairment, and RUG-III category. Vision problems likewise increased the risk of falling and hip fracture only for residents capable of independent locomotion. All explanatory and confounding variables are related to each outcome variable at $P<.05$.

Table 3 reports the relationships between falls and hip fractures and hypnotic use, insomnia, and combinations of hypnotic use and insomnia. All these associations were adjusted for the demographic and confounding variables listed in Table 2. Additional exploratory adjustment (not shown)

Table 2. Unadjusted Relationship of Explanatory, Demographic, and Potential Confounding Variables to Outcome Variables for the Study Sample (N = 34,163)

Variable	n	Falls	Hip Fracture
		Odds Ratio (95% Confidence Interval)	
Explanatory			
Insomnia			
Yes	2,149	1.90 (1.74–2.07)	1.45 (1.14–1.85)
No	32,014	Ref	Ref
Hypnotic use			
Yes	882	1.29 (1.13–1.48)	1.46 (1.01–2.10)
No	33,281	Ref	Ref
Insomnia, hypnotic use	259	1.54 (1.21–1.97)	1.65 (0.87–3.12)
Insomnia, no hypnotic use	1,890	1.96 (1.79–2.16)	1.44 (1.11–1.87)
No insomnia, hypnotic use	623	1.27 (1.08–1.49)	1.43 (0.92–2.23)
No insomnia, no hypnotic use	31,391	Ref	Ref
Demographics			
Age			
65–75	4,489	Ref	Ref
76–85	13,125	1.25 (1.17–1.34)	1.50 (1.17–1.92)
86–95	14,095	1.39 (1.30–1.49)	1.52 (1.19–1.95)
≥96	2,454	1.38 (1.25–1.53)	1.56 (1.12–2.18)
Sex			
Female	26,137	0.80 (0.76–0.84)	1.30 (1.10–1.55)
Male	8,026	Ref	Ref
Potential confounders			
Activities of daily living hierarchy			
Mildly impaired (0,1,2)	1,830	Ref	Ref
Moderately impaired (3,4)	13,543	2.10 (1.89–2.33)	2.54 (1.60–4.05)
Severely impaired (5,6)	9,844	1.07 (0.96–1.20)	2.63 (1.64–4.20)
Cognitive Performance Scale			
Mildly impaired (0,1)	7,755	Ref	Ref
Moderately impaired (2,3,4)	5,289	1.39 (1.30–1.50)	0.84 (0.68–1.03)
Severely impaired (5)	3,015	1.70 (1.57–1.86)	0.71 (0.55–0.94)
Very severely impaired (6)	2,594	0.55 (0.49–0.60)	0.23 (0.14–0.36)
Resource Utilization Group III categorization			
Reduced physical function	7,152	Ref	Ref
Behavioral problems	1,702	0.78 (0.71–0.87)	0.80 (0.63–1.01)
Impaired cognition	2,026	0.39 (0.35–0.43)	0.42 (0.32–0.56)
Clinically complex	6,236	0.55 (0.52–0.59)	0.16 (0.12–0.21)
Special care	5,776	0.82 (0.77–0.88)	0.24 (0.19–0.30)
Intensive services	194	0.60 (0.45–0.80)	0.24 (0.08–0.75)
Special rehabilitation	11,077	0.45 (0.43–0.48)	0.14 (0.11–0.17)
Case Mix Index	34,163	1.19 (1.10–1.14)	37.34 (34.89–39.97)
Burden of illness (Changes in Health, End-stage disease, and Signs and Symptoms)			
Low predicted mortality (0)	12,342	Ref	Ref
Some predicted mortality (1–6)	21,285	1.64 (1.57–1.72)	3.35 (2.76–4.06)
Personal Severity Index			
Below mortality threshold (0–4)	20,754	Ref	Ref
Above mortality threshold (≥5)	13,409	0.93 (0.89–0.97)	1.36 (1.19–1.56)
Vision			
Impaired	14,545	0.94 (0.90–0.99)	0.75 (0.65–0.86)
Not impaired	19,521	Ref	Ref
Balance test			
Unsteady/needs support	4,134	1.18 (1.11–1.26)	1.56 (1.21–2.00)
Steady	29,994	Ref	Ref
Polypharmacy (medications)			
0	275	Ref	Ref
1–5	8,736	1.46 (1.13–1.89)	1.62 (0.51–5.10)
6–10	16,236	1.74 (1.35–2.25)	2.28 (0.73–7.14)
11–15	7,307	1.75 (1.35–2.27)	2.81 (0.90–8.85)

(*Continued*)

Table 2. (Contd.)

Variable	n	Falls	Hip Fracture
		Odds Ratio (95% Confidence Interval)	
16–25	1,579	1.55 (1.18–2.04)	3.89 (1.21–12.5)
≥26	30	1.47 (0.68–3.18)	6.48 (1.04–40.41)
Emergency department visit			
Yes	2,200	1.48 (1.35–1.61)	1.57 (1.24–1.98)
No	31,949		
Admission to nursing home			
Yes	7,953	1.86 (1.77–1.96)	2.06 (1.78–2.37)
No	26,210		

Ref = reference.

for the following specific medical comorbidities had essentially no effect on model results: cerebrovascular disease, dementia, hypertension, hypotension, seizure disorder, atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, chronic obstructive pulmonary disease, hemiplegia, renal failure, diabetes mellitus, human immunodeficiency virus, and cancer.

Falls

In a bivariate model, baseline hypnotic use predicted a 29% greater risk and baseline insomnia predicted a 90% greater risk for future falls (odds ratios of 1.29 and 1.90, respectively, Table 2). After adjustment for age, sex, and all other potential confounders listed in Table 1, hypnotic use did not predict a significantly greater risk for future falls, whereas insomnia at baseline still predicted a 52% greater risk (Table 3).

In comparison with subjects with no baseline insomnia or hypnotic use, insomniacs who took no hypnotics had an adjusted 55% greater risk for future falls ($P < .001$). Similarly, subjects reported to have insomnia despite use of hypnotics had a 32% greater risk for future falls ($P = .03$). In contrast, subjects who took hypnotics but did not have concurrent insomnia had no significantly greater risk for future falls ($P = .22$).

Dose-Response Relationship

Subjects reported to have moderate insomnia (1–5 nights per week) at baseline were 47% more likely to fall in the follow-up period (odds ratio (OR) = 1.4, 95% CI = 1.33, 1.63) than those with no insomnia. Subjects reported to have severe insomnia (≥6 nights per week) were 86% more likely to experience future falls (adjusted OR = 1.86, 95% CI = 1.44, 2.39).

Hip Fractures

In bivariate models, baseline hypnotic use predicted a 46% greater risk of future hip fracture, and baseline insomnia predicted a 45% greater risk (Table 2). After adjustment for age, sex, and all other potential confounders listed in Table 1, baseline hypnotic use, insomnia, and combinations of the two failed to predict future hip fracture (Table 3).

DISCUSSION

This statewide study of older Michigan nursing home residents shows that, after adjustment for a wide range of possible confounding variables, insomnia, but not hypnotic use, is associated with subsequent falls. The data raise the question of whether hypnotic use had a protective effect; nursing home residents who took hypnotics but did not have insomnia showed no greater risk of falls, perhaps because the condition was well treated. These findings derive from a study unique in size, sample representativeness, longitudinal design, and strength of controls for potential confounders. The sample composition minimizes selection bias. Longitudinal design ensured that measured insomnia and hypnotic use preceded falls and hip fractures. Adjustment for multiple potential confounds rendered nonsignificant the association between hypnotics and falls but did not eliminate the association between insomnia and falls. Furthermore, insomnia predicted future falls in a dose-dependent manner.

These data are among the first to suggest that current hypnotics may not make a major contribution to falls, or hip fractures, in institutionalized older people. Previous studies that reported such associations may not have adjusted effectively for multiple confounders, assessed whether insomnia is a key confounder, or used a longitudinal research design. Another difference between this study and older ones may be that the latter enrolled subjects using primarily benzodiazepines. More recently released nonbenzodiazepine hypnotics, such as zolpidem and zaleplon, have short half-lives and may have less cognitive effect than older medications.[36] Perhaps in part for this reason, the fully adjusted models suggest that, when insomnia is not an active problem, patients on hypnotics have no increased risk for falls. These data could support the speculation that reduction of insomnia using short-acting, nonbenzodiazepine hypnotics may actually reduce the risk for subsequent falls.

There are several possible mechanisms by which insomnia could increase the risk of falls. Sleep loss causes excessive daytime sleepiness, cognitive dysfunction, and decreased psychomotor performance. Reaction time is particularly sensitive.[37,38] Studies of falls in older persons have implicated small changes in the velocity of lower extremity muscle contractions.[39] Similar delays in response to an

Table 3. Adjusted Associations Between Baseline Explanatory Variables and 6-Month Outcome Variables (N = 34,163 Subjects)

Explanatory Variable	Observations n	Falls		Hip Fracture	
		Odds Ratio (95% Confidence Interval)			
Insomnia					
Yes	2,149	1.52	(1.38–1.66)	0.99	(0.77–1.26)
No	32,014	Ref		Ref	
Hypnotic use					
Yes	882	1.13	(0.98–1.30)	0.85	(0.58–1.22)
No	33,281	Ref		Ref	
Insomnia, hypnotic use	259	1.32	(1.02–1.70)	0.92	(0.48–1.76)
Insomnia, no hypnotic use	1,890	1.55	(1.41–1.71)	0.99	(0.76–1.30)
No insomnia, hypnotic use	623	1.11	(0.94–1.31)	0.81	(0.52–1.27)
No insomnia, no hypnotic use	31,391	Ref		Ref	

Note: These models controlled for age, sex, functional status, cognitive status, intensity of resource utilization, burden of illness, number of medications taken, emergency department visits, and new admission.
Ref = reference.

imminent fall could arise from slowed danger perception, response calculation, or motor command generation. Studies in occupational or emergency department settings show that sleep problems and decreased sleep often precede traumatic accidents.[39,41] Excessive daytime sleepiness is a major cause of motor vehicle crashes, in part because of psychomotor impairment rivaling that seen with alcohol intoxication.[42] However, simpler reasons also may explain an effect of insomnia on fall risk; for example, insomnia could cause falls in older people because it increases the likelihood of nocturnal ambulation.[17]

The data from the current study do not implicate hypnotic use as a risk factor for hip fracture. Whereas lack of sufficient statistical power has been blamed for failure in other studies to prove an effect of fall prevention intervention on serious injury, including hip fracture,[43] the current study had a sample size adequate to detect these relationships if present. Hypnotic use is only marginally related to hip fracture even on a bivariate basis; when insomnia is included in any model of hypnotic use, neither falls nor hip fractures are related to hypnotic use. These results support the inference that insomnia drives the association between hypnotic use and falls.

Findings from this study must be interpreted with caution. This two-wave observational design does not allow strong causal inference, such as might derive from a prospective randomized clinical trial or even from a multiwave observational study that follows hypnotic use and insomnia in specific individuals. Large population studies based on secondary data from routine administrative sources often include variables of interest that are not validated against criterion-standard measures or for which no criterion standards exist.[5] In this case, insomnia, hypnotic use, falls, and hip fractures were all ascertained using single MDS items that have not specifically been validated against other criterion-standard measures. Also, unintentional preferential coding for insomnia could have occurred when nursing home staff knew that individuals used hypnotics. Fortunately, the item about insomnia precedes that about hypnotics and is located in a different section, which would reduce the likelihood of this bias.

There are several interpretation questions associated with the use of MDS data. MDS data are recorded in compliance with specific definitions; understanding these definitions aids in interpretation of these findings. In the MDS, insomnia is a symptom rather than a diagnosis, and the many different causes for insomnia could have divergent relationships with falls or hip fractures. As defined using the MDS 2.0 User's Manual, insomnia is defined as "difficulties falling asleep, waking up too early and being unable to fall back asleep."[31] Although insomnia can be classified into primary and secondary insomnia, and primary insomnia can further be classified as intrinsic (endogenous) and extrinsic (reactive to a specific trigger), the MDS does not distinguish between these forms, permitting several possible causal mechanisms. Also, insomnia has the weakest reliability of the study variables. Still, when insomnia is coded, it seems to have an important effect on falls and hip fractures. Furthermore, the medications identified as hypnotics on the MDS and hence in this study do not include other medications that may be prescribed for those with sleep difficulties, such as diphenhydramine and trazodone. Therefore, these conclusions are restricted to medications classified as hypnotics.

Use of MDS data also raises timing issues. Hypnotic use and insomnia were only available from the first assessment and not during the entire follow-up period. In some cases, hypnotic use or insomnia may have been started or stopped during the 6-month follow-up period and would not be reflected in MDS records. Such potential discontinuity could have affected the precision of the analyses, but is unlikely to have affected a sufficiently large portion of the sample to affect the robust basic relationships reported. If hypnotic use were discontinued because of fall-related indications (such as daytime sedation or unsteadiness), the inference that hypnotics can be used successfully in this population will be overstated. Inferences on the benefits of insomnia reduction would be unaffected.

The mechanisms by which insomnia could contribute to falls were not explored in this study, although none of the many covariates tested, such as overall burden of illness or intensity of resource utilization, appears to be a sufficiently

strong intermediary variable to eliminate the primary relationship. The lack of association between hypnotics and falls results from adjustment for potential confounders; in reality these variables may act as important intermediary variables in a causal pathway. For example, if hypnotic use increases fall risk only through impairment of locomotion, then adjustment for locomotion performance could have obscured the effect of hypnotics. Until the pathophysiology of falls in older people is better understood, optimal choices of covariates in such models will be challenging.

Despite these limitations, findings from this study have important implications for future research and possibly for clinical practice. In the nursing home setting, untreated insomnia may be a more important problem than previously recognized. Although nonpharmacological treatments for insomnia are usually preferable to hypnotics (unpublished data), the data from the current study raise the question of whether effective use of selected hypnotics, including short-acting nonbenzodiazepine hypnotics, also may reduce fall risk. Future research should address this hypothesis more directly and should include institutionalized older people, for whom insomnia and falls may be particularly prevalent causes of medical morbidity.

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