

Insomnia Associated with Valerian and Melatonin Usage in the 2002 National Health Interview Survey

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Study Objective: Many people use dietary supplements or herbal products to help them sleep. We analyzed the associations between melatonin use and insomnia and between valerian use and insomnia in a representative sample of the United States population.

Design and Participants: The data reported upon here were collected in the 2002 Alternative Health/Complementary and Alternative Medicine (CAM) Supplement to the National Health Interview Survey. This was a survey of 31,044 personal interviews that constituted an age-representative and socioeconomically representative sample of the civilian noninstitutionalized population of the United States.

Results: Of the survey sample, 5.9% used valerian and 5.2% used melatonin. Of those using valerian, 29.9% endorsed insomnia as 1 reason for

CAM use, and, of melatonin users, 27.5% endorsed insomnia as 1 reason for CAM use. Relatively greater use occurred in individuals under age 60 years. The decision to use such substances was made in consultation with a health care provider less than half of the time.

Conclusions: Large segments of the United States population used valerian or melatonin for insomnia within the year preceding the survey, and usage typically fell outside the purview of the health care system.

Keywords: Valerian, melatonin, herbal

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MANY PEOPLE SEEK TREATMENT FOR INSOMNIA USING ALTERNATIVE AND COMPLEMENTARY MEDICINE. VALERIAN, AN HERBAL PREPARATION DERIVED FROM the root of *valeriana officinalis*, has been suggested to have some, but not unequivocal, efficacy as a sedative/hypnotic in a number of placebo-controlled clinical trials^{1,2} and is widely available throughout the United States as a botanical product unregulated by Food and Drug Administration. Similarly, melatonin, classified as a dietary supplement, has seen widespread use for insomnia. Very little systematically collected data on the use of such substances exist. In this report, we present data on the use of valerian and the use of melatonin, as represented in the National Survey of Complementary and Alternative Medicine (CAM) Use Among Adults: United States, 2002³. This survey was conducted as a part of the 2002 National Health Interview Survey (NHIS), an annual epidemiologic survey conducted under the auspices of the National Center for Health Statistics and the United States Centers for Disease Control and Prevention.

METHODS

In 2002, the National Center for Health Statistics conducted 31,044 computer-assisted personal interviews collecting data on

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usage of CAM in the United States as a supplement to the 2002 NHIS.³ The NHIS is a regularly occurring survey of a representative sample of the civilian noninstitutionalized population of the United States, which collects health and demographic information of all members of a particular household, allowing for proxy responses for adults not home at the time of the interview and for children under 18 years of age. Additionally, more detailed information is obtained on 1 randomly selected adult aged 18 and over and 1 child aged 17 and under. The data reported here represent data derived from this more detailed interview from an adult aged 18 or older. Response rate for the adult supplementary interview was 74.3%. Estimates of usage were age adjusted (18-24, 25-44, 45-65, 65 years and older) for the United States population from 2002 projections based on the 2000 Census and used SUDAAN weighting.⁴ Additional data analyses performed for the purposes of this report used such weighting in nonparametric inferential analyses, which were performed using SAS (SAS, Inc., Cary NC). All data analyzed in this report are available in the public domain and were obtained from the National Center for Health Statistics Web site (<http://www.cdc.gov/nchs/nhis.htm>)

The NHIS survey collected data on whether subjects within the last 12 months had used any of 27 CAM therapeutic modalities. "Therapeutic modalities" were broadly defined and included modalities as diverse as prayer, energy healing, diet-based therapies, tai chi, acupuncture, chiropractic care, and chelation therapy. Of particular interest for this analysis was a single modality category entitled "Nonvitamin, nonmineral, natural products," which was an open-ended question regarding such products. An affirmative answer then led to further questioning, and subjects were presented with a list of 35 different named products, 2 of which were valerian and melatonin. After the interviewer named these substances in total and subjects responded affirmatively to the product(s) that they used (a respondent could use multiple products), respondents were then provided with 74 different conditions (including insomnia) in check-list format that represented the range of conditions for which the products were used. Respondents were allowed to respond to as many of the 74 conditions as they perceived relevant to their usage. The list

of conditions was broad and included conditions as diverse as angina, anxiety/depression, asthma, bronchitis, cancer, diabetes, headache/migraine, hypertension, menopause, joint pain or stiffness, neuropathy, Parkinson disease, dental pain, seizures, stroke, and thyroid problems (see Web site for complete list). No attempt was made by interviewers to link a specific product with a specific condition, i.e., responses could have reflected a single condition treated with multiple substances, multiple conditions treated with a single substance, or any combination thereof. For example, an individual might have mentioned valerian use in conjunction with black cohosh and listed associated conditions such as anxiety/depression, menopause, and insomnia. Within the context of the NHIS Survey, it was impossible to distinguish which specific botanical was used for which specific condition if other conditions or botanicals were mentioned.

Because of the format of the NHIS survey, we conducted several additional analyses to understand the data collected. Because any particular product was not linked specifically to any given condition within the interview, we examined the population-adjusted weighted usage of the 5 most common substances associated with insomnia mentions in the survey. We also examined another condition for which poor sleep might be expected to have a relatively strong association, anxiety/depression (considered a single condition on the NHIS), and examined its association with valerian use and with melatonin use. A consequence of the NHIS survey methodology is that any association detected between a condition and a particular substance might be spurious, e.g., the reported usage might represent a side effect caused by use of the product, rather than a primarily medicinal usage of the product.

RESULTS

In the NHIS, 5.9% of the respondents reported valerian use at least once in the prior 12 months, and 5.2% of the respondents reported melatonin use at least once in the prior 12 months.³ Of those using valerian, 29.9% (SE = 4.61%) endorsed insomnia as 1 reason for CAM use, and, of melatonin users, 27.5% (SE = 3.93%) endorsed insomnia as a reason for CAM use. A total of 5.8% of the survey sample mentioned insomnia in association with valerian and melatonin use. Population-weighted estimates suggested that more women were valerian users relative to men (ratio 2.6:1) and that more women were melatonin users relative to men (5.5:1). Age effects are shown in Table 1 and suggest that older subjects were less likely to use these substances relative to younger and middle-aged populations. This contrasts with prescription medication for insomnia, of which older adults are higher proportionate users.

Valerian represented the third and melatonin represented the fifth most commonly endorsed herbal products associated with insomnia mentions in the survey. The first, second, and fourth most commonly mentioned herbal products associated with insomnia were echinacea (42.0%, SE = 4.90%), ginseng (34.1%, SE = 4.74%), and ginkgo biloba (29.8%, SE = 4.15%). Their relatively high use in association with insomnia mentions is probably best viewed as iatrogenic to their use for other purposes, as many herbals may confer stimulant effects.⁵

Additional data available in the NHIS Survey included information on how individuals came upon the decision to use particular CAM treatments. In the case of melatonin and in the case of valerian, the proportions of individuals basing their use on the sugges-

Table 1—Population-weighted Use^a of Valerian and Melatonin in Conjunction with Insomnia Mentions as a Function of Age

Age range, y	Valerian, % using	Melatonin, % using
18-40	40.4	38.5
41-60	45.7	45.8
61+	13.9	15.7
Total	100	100

^aPopulation-weighted estimates of percentage of valerian use in conjunction with insomnia mentions and population-weighted estimates of percentage of melatonin use in conjunction with insomnia mentions at least once in the preceding calendar year; estimates used SUDAAN to extrapolate from the NHIS sample (n = 31,044) to the United States population using 2002 population projections based on 2000 United States Census.

tion of a medical professional was low (46% for melatonin users who reported insomnia and 32% for valerian users who reported insomnia). A minority of patients using melatonin (30%) and reporting insomnia opted for this choice because they believed that conventional medicine would not help; for valerian this figure was zero (0%). None of the respondents taking melatonin and none of the respondents taking valerian used these treatments because of the perceived higher cost of prescription medication. Although the NHIS was not specifically geared to examining the usage of alcohol as a hypnotic, available data within the survey suggested that at least moderate use of alcohol within the last month (at least 8 days per month) was less likely to be associated with insomnia. Usage of alcohol was lower for those with insomnia (20.9%) than for those individuals without insomnia (24.5%).

To provide a broader frame of reference for melatonin use and for valerian use and insomnia mentions in the NHIS Survey, we examined their usage in relation to another condition that might be expected to covary with insomnia to an appreciable extent, anxiety/depression. Consistent with their usage throughout the survey, echinacea (37.9%, SE = 3.69%), ginseng (35.9%, SE = 4.01%), and ginkgo biloba (32.7%, SE = 3.84%) showed high rates of use in association with anxiety/depression. Usage of valerian (23.4%, SE = 3.55%) and usage of melatonin (13.9%, SE = 2.93%) were lower than those estimates derived in conjunction with insomnia mentions, implying that respondents did not make major use of these products as self-initiated treatments for anxiety/depression.

DISCUSSION

Within the United States, usage of CAM is rising dramatically. From 1990 to 1997, the proportion of the population employing such treatments for any health conditions rose from 33.8% to 42.1%.^{6,7} These surveys also suggested increased usage in all types of CAM for the treatment of insomnia, with figures increasing from 20.4% (in 1990) to 26.4% (in 1997). However, the surveys did not provide estimates for the usage of valerian and usage of melatonin per se.

Within the limitations of the NHIS methodology, the usage of valerian and the usage of melatonin appear to be relatively high. Specific data on valerian usage and on melatonin usage in general populations are relatively scarce. The 1995 National Sleep Foun-

dation Poll⁸ reported a relatively low use of melatonin (2%-4%) for disturbed sleep relative to over-the-counter sleep medications (19%-35%). In Washington state, 2.6% of cervical cancer survivors used melatonin, relative to 1.5% of cancer-free controls 4 or more days per week.⁹ One report showed that valerian was used by 2.5% of presurgical patients at 5 California hospitals, but time and duration of use were unclear in this study.¹⁰

There are a number of non-mutually exclusive reasons why usage estimates derived from the 2002 NHIS Survey are considerably higher than those derived from these previous studies. First, as reported by Eisenberg et al,^{6,7} the upwelling of interest throughout the 1990s in alternative treatments may represent a secular trend for greater use of herbal preparations and dietary supplements for a variety of conditions (including insomnia), a phenomenon still better captured by the relative recency of the 2002 survey. Secondly (and not incompatible with the aforementioned possibility), the tremendous public interest in sleep disorders and their attendant morbidities may have led to greater awareness of poor sleep as an issue detrimental to health and well-being and a condition necessitating treatment. Thirdly, it is possible that the higher estimates reflect the specific format of the NHIS questions, which collapsed frequent and infrequent use of such substances over a broad 12-month window. Because many of the previous surveys employed a window of usage shorter than the 12 months in the NHIS Survey, it remains possible that this variation in methodology contributed to the lower figures in these studies. A final reason could be that the large number of participants accessed and the more accurate reflection of the race, age, and education composition of the United States may have led to more stable and valid estimates of use otherwise underestimated by previous survey methodologies not using the census-weighted format of the NHIS.

Although relatively uncommon, potential adverse reactions and overdoses to melatonin use^{11,12} and valerian use¹³⁻¹⁶ have been reported, though valerian has been reported to have minimal impact on any of the major cytochrome P450 pathways.^{17,18} Because the usage of valerian and melatonin in the current survey is higher than in previous surveys,⁸⁻¹⁰ this raises potential concern for usage that is largely unreported to medical professionals. A substantial database has demonstrated interactions of many herbals/botanicals with chemotherapy agents,¹⁹ oral health,²⁰ conventional psychotropics and cardiovascular medications,^{5,21} preoperative and postoperative care,^{10,22,23} and diabetes and seizure medications.²¹ Additionally, within the United States, both valerian and melatonin are considered dietary supplements under the 1994 Dietary Supplement and Health Education Act, in essence regulating their production, distribution, advertising, and sale under food law, rather than drug law. The quality of many valerian and melatonin products purchased in the United States has been shown to be suspect in meeting label claims.^{24,25} On the other hand, Canada represents a far stricter approach to the regulation of botanicals and supplements under the aegis of the relatively recent creation of an Office of Natural Health Products, the mandate of which is to oversee standardization of the manufacturing, labeling, packaging, and adverse-event reporting for all such products.²⁶ Canadian regulations contrast with the less stringent controls within the purview of Dietary Supplement and Health Education Act, which allow for claims affecting only "function and structure" but disallow claims affecting disease processes. Because large proportions of individuals self-mediate with valerian and melatonin,

the practicing sleep medicine specialist should be aware of the unregulated sources of these products and of the potential for drug interactions.

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