Medication Use in the Treatment of Pediatric Insomnia: Results of a Survey of Community-Based Pediatricians

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ABSTRACT. Objectives. To examine clinical practice patterns, beliefs, and attitudes regarding the use of both nonprescription and prescription medications by community-based pediatricians for children with significant difficulties in initiating and/or maintaining sleep.

Methods. A survey was mailed to 3424 American Academy of Pediatrics members in 6 US cities.

Results. The final sample (n = 671) consisted of practitioners who identified themselves as primary care pediatricians. Three percent ± 7% of visits in the respondents’ practices were for pediatric insomnia, although there was a wide range in the numbers of children identified during a typical 6-month practice period. More than 75% of practitioners had recommended nonprescription medications, and >50% had prescribed a sleep medication. Specific clinical circumstances in which medications were most commonly used were acute pain and travel, followed by children with special needs (mental retardation, autism, and attention-deficit/hyperactivity disorder). Antihistamines were the most commonly reported nonprescription medications for sleep. Melatonin or herbal remedies had been recommended by approximately 15% of the respondents. α-agonists were the most frequently prescribed sleep medications (31%). The likelihood of prescribing medication for sleep was 2- to 4-fold greater in respondents who treated children with attention-deficit/hyperactivity disorder for daytime behavioral problems or nocturnal sleep problems, respectively. Practitioners expressed a range of concerns about sleep medication appropriateness, safety, tolerance, and side effects in children.

Conclusions. The practice of prescribing or recommending sedatives and hypnotics for pediatric insomnia is common among community-based pediatricians, especially among special needs patients. An empirically based approach to the use of these medications is needed. Pediatrics 2003;111:e628–e635. URL: http://www.pediatrics.org/cgi/content/full/111/5/e628; insomnia, sleep disturbances, medications, hypnotics, prescribing practices.

SPECIFIC MEDICATIONS.

[Medications listed here]

ABBREVIATIONS. ADHD, attention-deficit/hyperactivity disorder; OR, odds ratio; CI, confidence interval.

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http://www.pediatrics.org/cgi/content/full/111/5/e628
mecations are prescribed.\textsuperscript{20} Presenting symptoms for which psychotropic medications were also the most common reason for prescribing medications for primary care practitioners, pediatricians, and psychiatrists, sleep disturbances accounted for 35\% of prescriptions for infants up to 1 year of age and were the most common reason for prescribing a drug therapy to infants. Sleep disturbances were also the most common reason for prescribing medications to preschoolers, 23\% of whom were given a drug therapy for sleep disturbances.\textsuperscript{20} In another parent interview study from France, 12\% of primary school children had used a psychoactive drug, most often prescribed for a sleep disturbance, and 39\% of these children had received the medication on a daily basis for 1 to 2 years.\textsuperscript{21} Another parent-report study from England found that by 18 months, 25\% of first-born children had been given sedatives.\textsuperscript{22} Finally, medications have also been used to facilitate sleep in adolescents; in 2 large French surveys, 10\% to 12\% of the respondents reported use of prescription or over-the-counter drugs for sleep disturbances.\textsuperscript{24,25}

Although these results suggest that prescribing hypnotics for sleep complaints is a common practice among both pediatricians and general practitioners, as well as child psychiatrists, it should be noted that there have been no similar epidemiologic studies specifically regarding use of hypnotics/sedatives for childhood sleep disorders in the United States. In an informal chart review (by J.A.O.) of patients who presented to a pediatric sleep clinic in a tertiary care children's hospital, one third of patients who were referred for behavioral sleep problems were currently taking or had been previously treated with pharmacologic agents for sleep, such as diphenhydramine, promethazine, chloral hydrate, clonidine, trazodone, melatonin, and acetaminophen with codeine. Furthermore, a recent survey of sleep knowledge and practices among >600 primary care pediatricians in New England suggested that use of these medications is often inappropriate; 11\% reported “often” using diphenhydramine for night terrors, 25\% reported at least occasionally prescribing hypnotics, and 20\% at least occasionally recommended melatonin specifically for adolescents with inadequate sleep hygiene.\textsuperscript{26}

Given the paucity of data on US pediatric practices regarding use of medication for sleep, the purpose of this study was to examine the use of pharmacotherapy for sleep problems by primary care pediatricians and subspecialty pediatricians (including behavioral and developmental pediatricians and pediatric neuropsychiatrists) in the community. The first goal was to examine the target populations, indications, and types and frequency of medications prescribed or recommended for sleep problems in infants, children, and adolescents, including: 1) over-the-counter medications such as antihistamines, melatonin, and herbal remedies and 2) prescription medications such as hypnotics, antidepressants, benzodiazepines, \(\alpha\)-agonists, and other psychotropic medications. The second goal of this study was to examine beliefs and attitudes of practicing pediatricians regarding medication use for sleep problems in children. Information regarding practitioners’ use of psychotropic medication for ADHD was also assessed for comparison purposes.

METHODS

Participants and Procedure

The Pediatric Sleep Medication Survey (available by request from the authors) was sent to a sample of 3424 area pediatricians during a 2-month period in winter 2001 with a second mailing \(- 6\) weeks later. The sample consisted of American Academy of Pediatrics members practicing within either a 75-mile radius of Philadelphia or a 100-mile radius of Atlanta, Cleveland, Dallas, Providence, or San Diego. The survey was completed anonymously, and the participants were offered the opportunity to be included in a second mailing for a hand-organized as an incentive for participation. The study was approved by the institutional review boards at each of the 3 sponsoring institutions.

Instrument

The survey was developed by the authors based on a review of the current literature regarding use of and prescribing practices for hypnotics and sedatives in children. On the basis of feedback from a panel of academic pediatricians and pilot testing in small groups of local practicing pediatricians (\(N = 25\)), minor modifications were made to the instrument, primarily in wording and format, to enhance clarity. The final questionnaire consisted of 4 sections: 1) the sleep and medication section included questions regarding the prevalence of sleep problems (defined as “significant difficulty falling and/or staying asleep”) in the respondents’ practice, the types of sleep problems and clinical situations for which respondents typically recommend or prescribe sleep medications, and reasons for and against recommending or prescribing medications for sleep problems in practice; 2) the practice section asked participants to indicate the number of patients in the past 6 months for whom they had recommended (over-the-counter antihistamines, pain reliever combinations, herbal preparations, etc) or prescribed specific classes of medications (antihistamines, antidepressants, etc) for 4 different age groups (0–2 years, 3–5 years, 6–12 years, and >13 years), as well as the average duration of therapy for both over-the-counter and prescription sleep medications recommended; 3) the section focused on participants’ prescribing practices regarding medication for children with ADHD using a similar format, to provide a standard of comparison for the use of other psychotropic medications in practice; and 4) the final demographics section included questions regarding the participants’ medical training, practice type, and other demographic information.

Data Analysis

Questionnaire response data were summarized as mean \(\pm\) standard deviation scores or median or interquartile ranges when distributions were highly skewed. Univariate analyses and multiple regression analyses were used to examine the effects of practitioner characteristics on medication use for sleep problems in children when use of sleep medication was the primary dependent outcome variable. Frequency of sleep problems in the practice was the primary independent variable. The relationship between the independent and dependent variables was adjusted for key covariates that made intuitive sense: practitioners’ gender, previous training in a behavioral specialty (Yes/No), years in practice (<10 or \(\geq 10\) years), and subspecialty pediatricians (primary care vs subspecialty).
RESULTS

After 2 mailings, a total of 840 of 3424 (25% response rate) surveys were returned. The final sample (n = 671) was restricted to primary care practitioners who identified their practice as >50% primary care pediatrics. Fifty-eight surveys were returned blank because the practitioners were no longer in active practice, and 114 respondents were primarily engaged in subspecialty practices and thus eliminated from the final sample. Respondents characteristics were as follows: 55% female, 84% white, 14% black, 2% Asian, 5% Hispanic, and 65% younger than 50 years. Thirty-one percent of the respondents had been in practice for <10 years, 35% for 10 to 20 years, and 35% for >20 years. Eighty-eight percent were community-based physicians (group, health maintenance organization, or community health practices), with the remainder reporting a university or university-affiliated practice. Practice environments were mostly suburban (67%), with a smaller percentage urban (27%), and rural (8%). The median number of patients seen by the respondents per week for any concerns was 110 (interquartile range: 90–150).

Ninety-nine percent of the respondents had completed pediatric training, and 19% had additional subspecialty training. The percentage of respondents who had subspecialty training in behaviorally oriented subspecialties (developmental/behavioral pediatrics, adolescent medicine, child psychiatry, pediatric neurology) was 7%. Forty-two percent reported an academic appointment at a medical school with the majority (88%) self-identified as “clinical” faculty rather than “academic” faculty.

Frequency of Sleep Problems

There was a wide range in the numbers (mean and median) of children identified by respondents in their individual practices with significant problems falling asleep or staying asleep during a typical 6-month practice period (Table 1). The number of children with significant sleep problems seen in a 6-month period was greatest in the infant/toddler group (median: 20 children; 57% of the median total across age groups), decreased with age, but remained consistent among the older children (median: 9 and 8 children among school-aged children and adolescents, respectively). Using each practitioner’s estimate of the total number of patients with sleep problems across all 4 age groups seen in 6 months as the numerator and using each practitioners’ estimates of the average number of children seen per week (multiplied by 24) in their own practice for any concerns as the denominator, on average an estimated 3% ± 7% of practice visits overall were for significant sleep problems.

Insomnia and bedtime struggles/sleep onset delay were the most commonly identified sleep disorders for which practitioners had recommended either nonprescription or prescription medications (Table 2). Relatively few had used medication for more medically based sleep disorders, such as delayed sleep phase/circadian rhythm disturbances and restless legs syndrome. The specific clinical circumstances in which the respondents reported recommending nonprescription medications or prescribing medications for difficulty falling and/or staying asleep in children are summarized in Table 3. The most commonly endorsed clinical circumstances were acute pain and travel, followed by children with special needs (mental retardation, autism, and ADHD). More than one third of the respondents also endorsed using sleep medications in the setting of acute or chronic (mood disorders) emotional stress.

Beliefs and Attitudes About Sleep Medication

Practitioners endorsed a variety of reasons cited for either “using” or “not using” medications to treat significant sleep problems (Tables 4 and 5). “Respite for families” and “special needs children” were reported by more than one half of the respondents as a rationale for medication use. Half of the respondents also endorsed using medication primarily in combi-
Clinical Practices Regarding Specific Medications

Tables 6 and 7 summarize physicians’ use of various nonprescription and prescription medications for sleep problems in children. Over-the-counter antihistamines were the most commonly reported nonprescription medication for sleep, used by more than two thirds of practitioners, varying from 34% to 58% depending on the age group; combination pain relievers containing a sedating antihistamine were less commonly recommended across all age groups (29%). Melatonin was rarely used in toddlers or preschool children (1%–8%) but was more frequently recommended for school-aged children and adolescents (15%–19%); use of herbal preparations such as valerian root or chamomile teas was endorsed equally across age groups (13%–15%).

Of all prescription medications, ß-agonists were the mostly commonly prescribed medications overall and also the most frequently prescribed medications for school-aged children and adolescents, followed by antihistamines and antidepressants. Other classes of medications, such as benzodiazepines, hypnotics, or other neurologic or psychiatric medications, were much less likely to be used for pediatric sleep problems. However, more than one quarter (28%) and almost half (48%) of practitioners reported “never” using nonprescription or prescription medication, respectively, for children’s sleep problems (Table 6 and 7). Finally, in terms of duration of use (Table 8), there was a clear distinction between use of nonprescription and prescription medications; over-the-counter medications were much more likely to be used for short periods of time (<1 week), whereas prescription medications were more likely to be used long term (longer than 1 month).

Medication for ADHD and Sleep

Most of the respondents reported prescribing a variety of medications for daytime symptoms of ADHD across age groups. In terms of stimulant medications, 55% had prescribed these at least once in 3- to 5-year-olds, 92% in school-aged children, and 86% in adolescents within the past 6 months. Thirty-seven percent and 29% had prescribed ß-agonists specifically for sleep problems in school-aged children and adolescents, respectively, whereas 22% and 28% had prescribed antidepressants at least once in the same 2 groups. Almost 30% of respondents also reported prescribing ß-agonists specifically for sleep problems in school-aged children and adolescents with ADHD, and >20% had prescribed late-day stimulants in this setting (Table 9). Other medications, such as antihistamines or antidepressants, were used less frequently.

Analysis of Prescribing Practices

Seventy-seven percent of respondents had recommended over-the-counter medications at least once...
who treated daytime behavioral problems in children (OR: 3.95; 95% CI: 2.0–4.8; P < .0001). Finally, practitioners with >10 years in practice were more likely to prescribe medication (OR: 1.6; 95% CI: 1.1–2.3; P = .0164). Similar relationships were seen for use of over-the-counter sleep medications (OR: 3.1; 95% CI: 2.0–4.8; P < .0001 for practitioners who treated sleep problems in ADHD; OR: 2.4; 95% CI: 1.3–4.5; P = .0078 for those who treated daytime behavioral problems in ADHD).

**DISCUSSION**

The results of this study suggest that the use of both prescription and nonprescription medications for pediatric insomnia is a relatively common practice among community-based pediatricians in the United States and seems to fall into 2 general patterns: short-term “situational use” (travel, acute pain, acute stress) of nonprescription medications and longer-term, more chronic use of prescription drugs in high-risk populations, such as children with neurologic impairment, developmental delays, psychiatric conditions, and ADHD. A substantial minority (23%) also reported using medication in otherwise healthy children with significant difficulty falling or staying asleep. It is interesting that there was comparatively little reported use of any medications for sleep either in the setting of medical conditions (chronic pain, hospitalization) or with more “organically based” sleep disorders (circadian rhythm disturbances, restless legs syndrome, periodic limb movements), despite that sleep problems have been reported to be significant and medications potentially effective in these situations.28,29

Because our survey and study design did not link medication use to specific sleep diagnoses, we are able to make only some general statements about the process of clinical decision making that determines the probability and appropriateness of sleep medication use in practice. In theory, a number of variables may potentially have an impact on the decision of whether to use medication; these include patient variables (age, presence of comorbid psychiatric, developmental, or acute medical conditions), parent/family variables (educational level, parenting skills, household composition, parental stress level and...
caregiver exhaustion, previous experience with and acceptability of pharmacologic treatment to family), provider/practice setting variables (initial presentation to a primary care physician vs subspecialist such as developmental/behavioral pediatrician or pediatric neurologist), provider familiarity with behavioral treatment strategies, time and reimbursement issues, cultural/societal variables (acceptance of psychotropic use in children, acceptance of alternative therapies, ethical considerations), and characteristics of the clinical situation (type and severity of sleep problem: duration, frequency, daytime impairment; previous failed attempts at conventional behavioral therapy). Overall, the more than three quarters of the practitioners in this study who did recommend over-the-counter medications and the more than one half who prescribed sedatives and hypnotics seemed to be conservative in their approach to the use of these drugs in practice and expressed concern about a variety of potential negative effects. The respondents in this study clearly perceived that stress on families, particularly on high-risk families, resulting from significant sleep disturbances in a child is a legitimate rationale for the use of sleep medications. At the same time, they tended to endorse the use of these medications only in combination with behavioral therapy and/or when other treatment modalities had failed, and expressed concern about sending inappropriate messages to parents, presumably regarding a “quick fix” approach implied with the use of medications. In addition to concerns about safety (short- and long-term side effects), respondents reported uncertainty about their ability to make appropriate medication choices and lack of information about the medications in general.

An additional reason, cited by half of the respondents, for not recommending or using sedatives and hypnotics in children was the perception that “significant” sleep problems were rarely encountered in their own practice. In addition, there seemed to be little direct relationship between the number of patients with sleep problems in a practice and the likelihood of medication use, despite considerable variability in the frequency of sleep problems across practices. The implication is that practitioners tend to make choices about medication use on the basis of the types and clinical significance of sleep problems encountered and that clinical practice regarding medication use is not driven simply by the volume of sleep patients seen. Somewhat surprising, previous subspecialty training in a behavioral specialty such as developmental/behavioral pediatrics or pediatric neurology also did not seem to have an impact on clinical practice regarding sleep medication use, suggesting that relatively more experience with and knowledge of behavioral issues does not affect the likelihood of medication use. More experienced practitioners (those in practice for a longer period of time), however, did seem to be more likely to use medication.

The relationship found in this study between sleep problems in ADHD and use of medications for sleep problems in general was particularly striking and suggests that insomnia in children with ADHD is a major contributor to the use of hypnotics/sedatives in clinical practice. In particular, the high prevalence of α-agonist use among school-aged children reported in this study was most likely related to sleep onset problems in children with ADHD. It seems that practitioners frequently choose medications such as clonidine and guanfacine to address sleep problems in this population, despite the relative lack of empirical evidence and the potential risks attached to the use of these drugs in the treatment of ADHD-related sleep problems. Our results are also supported by those of a recent study that examined the prevalence of psychotropic medication use in preschool children ages 2 to 4 years and utilization trends over 5 years from 1991 to 1995 in which the rate of increase was greatest for clonidine prescriptions (6.8- to 28.2-fold increase in prescription prevalence). The authors of that study speculated that the use of clonidine for treatment of insomnia associated with either ADHD itself or secondary to stimulant treatment may have contributed to this dramatic increase.

An additional concern regarding the use of sleep medications in ADHD in clinical practice is that results of a number of empirical studies of sleep architecture, sleep patterns and behaviors, and sleep disturbances in children with ADHD compared with children without ADHD have been mixed and, at times, contradictory. It is overall safe to say that although most parental report studies have reported increased sleep problems, including difficulty falling asleep, night wakings, and restless sleep in children with ADHD, most of the “objective” studies using polysomnography or actigraphy have failed to find consistent significant differences in sleep architecture and patterns between children with ADHD and controls. However, the cause of the sleep disturbance in a given child with ADHD is likely to be highly variable across individuals and may range from primary sleep disorders (obstructive sleep apnea syndrome, periodic limb movement disorder, delayed sleep phase syndrome, etc) presenting with or exacerbating underlying “ADHD” symptoms, to sleep onset delay associated with comorbid oppositional defiant disorder or psychostimulant “ rebound.” Thus, the failure of some studies to find group differences in sleep between children with ADHD and controls may not be relevant to many of the clinical situations encountered in actual practice. In any event, the results of this study suggest that sleep disturbances in children with ADHD, whatever the cause, are perceived by parents and practitioners to be a major clinical concern, often prompting the use of psychotropic medications to address them.

Children with neurodevelopmental disorders and sleep disturbances also clearly pose a management challenge for practitioners and families, both in this study and in general. Not only is the prevalence of sleep problems significantly increased in these children (estimated to be 70%–80% in children with severe mental retardation and autism/pervasive developmental disorder, for example), but sleep disturbances frequently become chronic (persisting in one half to two thirds in 1 study of 200 children with severe mental retardation). The negative effects of...
sleep disturbances are also often magnified in these high-risk populations; for example, chronic sleep difficulties in neurologically impaired children are a major reason for placement in a residential facility. Furthermore, because of cognitive and physical limitations, often limited alternative treatment options are available to these children and families, and thus medication may assume more of the role of a primary therapeutic modality.

Regarding specific medications, we again can comment only about the frequency of use in relation to what is known about these drugs, not about the appropriateness of specific choices made by the respondents in a given clinical situation. Not surprising, over-the-counter antihistamines were the most commonly recommended of all medications in all age groups, presumably because of their familiarity to practitioners and acceptability to parents; prescription antihistamines were also frequently used. It has been shown, however, that although generally safe, these medications are weak and often ineffective soporifics and may cause paradoxical central nervous system excitation. After the α-agonists, the next most frequently used medication was melatonin, largely because of the increased use in older children and adolescents. Melatonin has been specifically suggested for the treatment of circadian rhythm disorders (delayed sleep-phase syndrome) especially in children with developmental delay, but its role in the treatment of pediatric insomnia in otherwise healthy children is uncertain. Herbal preparations were used with nearly equal frequency across age groups; a number of largely European studies show some empirical support for the frequency of use of such herbals as valerian root and hops, although the occurrence of serious side effects such as the outbreak of eosinophilia myalgia related to L-tryptophan use several years ago raises concerns about possible safety issues. Other medications, such as antidepressants, benzodiazepines, and chloral hydrate, were used much less frequently overall. The most commonly prescribed hypnotics in adults, zolpidem and zaleplon, were used by just 8% of the respondents. With the exception of chloral hydrate, all of these medications were also much more likely to be prescribed for adolescents.

There are a number of important limitations to this study that may have an impact on the generalizability of the results and deserve comment. First, although we attempted to obtain a national sample by conducting mailings in different regions around the country, the respondents may not have been representative of community-based physicians in the United States as a whole, particularly because all of the original sample were by definition American Academy of Pediatrics members and not all practicing pediatricians. Second, the data were collected in a retrospective 6-month recall, self-report format that limited the accuracy of reported patient and prescription numbers and may have resulted in data being heavily skewed by the responding practitioners’ biases. Recognizing the skewness of the data, both mean and median values were used to describe the sample. Furthermore, our response rate, although commensurate with many other physician surveys, was clearly low, and, because of the study design, we were unable to obtain information on the nonresponders. Therefore, these data could potentially underrepresent the extent of medication use for sleep disturbances if, for example, any perceived stigma associated with psychotropic medication use in children made it less likely that practitioners who are more frequent medication users would respond to the survey. Similarly, this perception might have led those who did respond to underestimate the extent of their prescribing practices. Alternatively, practitioners who are less interested in or knowledgeable about sleep issues and/or who are less likely to recognize and treat these disorders in their practices may also have been less likely to respond to a survey on pediatric sleep practices. Finally, physician surveys cannot provide an accurate assessment of parent- or child-initiated use of over-the-counter medications, a potentially important additional source of overall sleep medication use in pediatrics.

CONCLUSIONS

The results of this study suggest that many pediatricians do perceive a need for and do recommend and prescribe sedatives and hypnotics for pediatric insomnia in clinical practice but that practitioners generally lack confidence in the currently available medication options and express many reservations, particularly given the absence of clinical guidelines, for the use of these drugs in children. Although recently there has been some interest expressed by pharmaceutical companies in developing pediatric formulations of hypnotic medications for use in children, pediatric sleep disturbances have been identified in the past as one of the most poorly researched areas in pediatric psychopharmacology. Sound clinical practice at all levels is still hampered by the fact there remains a significant lack of knowledge concerning the efficacy, tolerability, and safety profiles of soporific drugs in children. If standards of practice for the use of these pharmacologic agents are to be developed eventually, then it clearly will be important for the pediatric community to advocate for additional research. In the meantime, it seems to be reasonable to consider developing a set of clinical experience-based general guidelines for primary care physicians regarding the diagnostically driven use of medication as an adjunct in the treatment of pediatric sleep disorders, as well as indications, target populations, and parameters for their use, based on the information that is currently available.

Finally, the findings of this study present an opportunity to advocate for additional education of pediatric practitioners regarding the diagnosis and management of sleep disorders in children in general. It should be emphasized that insomnia neither is synonymous with the diagnosis of a specific sleep disorder nor specifies cause, and there are multiple possible causes for the same constellation of symptoms. Because the use of a diagnostic framework in assessing sleep problems in children often provides insight into causative factors, the accurate diagnosis of a sleep disturbance combined with a thorough
assessment of the impact of the sleep disturbance on the child’s health and daily functioning is the key to providing a rationale for the use of any intervention strategies, including behavioral treatment and pharmacologic management. Thus, expanded educational efforts at all training and practice levels regarding the underlying causative factors, clinical presentation, and differential diagnosis of sleep disorders in infants, children, and adolescents should clearly be a goal for the pediatric community.

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