

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

Judith A. Owens, MD, MPH*; Carol L. Rosen, MD†; and Jodi A. Mindell, PhD§

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 \pm 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.*

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

From the *Department of Pediatrics and Division of Ambulatory Pediatrics, Brown Medical School, Providence, Rhode Island; †Department of Pediatrics and Divisions of Clinical Epidemiology, Pediatric Neurology, and Pediatric Pulmonology, Case Western Reserve University, Cleveland, Ohio; and §Department of Pediatrics and Division of Pulmonary Medicine, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, and Department of Psychology, Saint Joseph's University, Philadelphia, Pennsylvania. Received for publication Oct 21, 2002; accepted Dec 30, 2002.

Reprint requests to (J.A.O.) Division of Ambulatory Pediatrics, Potter 200, Rhode Island Hospital, 593 Eddy St, Providence, RI 02903. E-mail: Owensleep@aol.com

PEDIATRICS (ISSN 0031 4005). Copyright © 2003 by the American Academy of Pediatrics.

Sleep disturbances in infants, children, and adolescents, particularly bedtime problems and prolonged night wakings, are among the most common and challenging complaints in pediatric practice.¹ Numerous epidemiologic studies of sleep disorders in a variety of pediatric populations have documented high levels of sleep disturbances in children, including difficulty settling and frequent night wakings in up to 40% of infants; bedtime resistance, delayed sleep onset, and disruptive night wakings in 25% to 50% of preschoolers; and bedtime resistance in school-aged children ranging from 15% to 27%.^{2–5} Even higher prevalence rates have been reported in special needs populations, such as children with neurologic impairments, mental retardation, and pervasive developmental disorder and autism,⁶ and in children with a variety of psychiatric (eg, attention-deficit/hyperactivity disorder [ADHD], depression)⁷ and medical conditions (eg, juvenile rheumatoid arthritis, asthma).⁸ A growing body of evidence shows that childhood sleep disturbances may have a wide-ranging impact on children's health; behavior; mood; neurobehavioral parameters such as attention, cognition, and memory; and school performance, as well as on parental stress and family life.^{9–14}

A number of empirically sound and effective behavioral and cognitive/behavioral approaches to the treatment of pediatric insomnia, defined as significant and persistent difficulty in initiating and/or maintaining sleep, have been developed.¹⁵ Although most sleep disturbances in children are managed with behavior therapy alone, pharmacologic intervention or a combination of behavioral and pharmacologic interventions has also been used by both parents and practitioners to treat symptoms of insomnia in children and adolescents. A wide variety of medications have been prescribed or recommended by pediatric practitioners for sleep disturbances in children, including antihistamines, chloral hydrate, barbiturates, phenothiazines, tricyclic antidepressants, benzodiazepines, and α -agonists.¹⁶ In addition, over-the-counter medication such as diphenhydramine and melatonin¹⁶ and herbal preparations¹⁷ are frequently used by parents to treat sleep problems with or without the recommendation of the primary care provider. Pediatric sleep medicine textbooks and reviews of treatment modalities¹⁸ have generally included little information regarding the specifics of pharmacologic treatment options. An empirical basis for the use of these drugs is largely lacking. Few studies have examined the effectiveness of therapy using rigorous techniques such as ran-

domization, placebo control, and blinded participants and providers,¹⁹ and most reports of hypnotic/sedative use in children are case reports or small case series.¹⁶ Furthermore, there are currently no medications labeled for such use in children by the US Food and Drug Administration.

Given these considerations, what is known about actual use in pediatric practice of medications for difficulty initiating and maintaining sleep in children and adolescents? A number of studies from the European literature suggest that even in infants and preschoolers, sleep complaints often dominate the presenting symptoms for which psychotropic medications are prescribed.^{20–26} For example, in one German survey of 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.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.²¹ Another parent-report study from England found that by 18 months, 25% of first-born children had been given sedatives.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.^{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.²⁷

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 neu-

rologists) 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, α -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 drawing for a hand-held organizer 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 usage 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 ($N = 23$), 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 (α -agonists, 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 third 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 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 ≥ 10

years), and experience with ADHD medications for either sleep or daytime behavior problems (Yes/No).

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

TABLE 1. Number of Children With Significant Sleep Problems Seen by an Individual Practitioner in a Typical 6-Month Period†

Age Group (Years)	Mean (\pm SD)	Median	IQR
0–2	51 \pm 127	20	6–50
3–5	20 \pm 60	10	2–20
6–12	9 \pm 34	3	1–10
13+	8 \pm 21	3	1–10
Total	89 \pm 224	42	14–95

SD indicates standard deviation; IQR, interquartile range (25th–75th percentile).

† Data missing from 2 to 3 respondents.

TABLE 2. Sleep Disorders in Which Physicians Reported Medication Use*

Sleep Disorder	Respondents Reporting “Yes” (%)
Insomnia	39
Bedtime struggles/sleep onset delay	38
Delayed sleep-phase/circadian rhythm disturbance	17
Nightwaking	15
Sleepwalking/sleep terrors	11
Restless legs/periodic limb movements	4

* No time frame specified; data missing from 7 to 10 respondents.

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% \pm 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-

TABLE 3. Physicians Reporting Medication Use (Nonprescription or Prescription) for Sleep Problems*

Clinical Circumstances	% of Respondents
Acute pain	54
Travel	45
Mental retardation/developmental delay	45
ADHD	41
Autism/pervasive developmental disorder	38
Mood/anxiety disorder	32
Acute stress (eg, death in the family)	32
Insomnia (but otherwise healthy child)	23
Chronic pain	18
Hospitalization	16
Blind	4

* Data missing from 7 to 11 respondents.

TABLE 4. Reasons That Physicians Might Use Medications to Treat Sleep Problems in Children

Reasons	Respondents Answering "Yes" (%)
"Provides families with needed respite"	55
"Use for 'special needs' children"	52
"Use medication in combination with behavioral treatments"	50
"Use medication if other treatments have failed"	42
"Medications work more quickly than other treatments"	18
"Less time and effort for parents than other treatments"	12
"Medications are more effective than other treatments"	9
"Less time and effort for practitioners than other treatments"	7

TABLE 5. Reasons That Practitioners Might Not Use Medications to Treat Sleep Problems in Children

Reasons	Respondents Answering "Yes" (%)
"Gives parent the wrong message about correct treatment"	68
"Concern about short- or long-term side effects"	54
"Sleep problems needing medication are rare in my practice"	50
"Concern about 'hang-over' event on the following day"	47
"Unsure about the best/appropriate sleep medication to choose"	45
"Development of tolerance or habituation to medications"	44
"Concern about respiratory depression"	36
"Parental nonacceptance of medication"	33
"Lack of data on efficacy"	31
"Concern about off-label use of these medications"	29
"Personal belief against the use of sleep medications in children"	29
"Haven't found medications to be helpful"	15
"Cost of medications"	6

nation with behavioral management strategies. "Gives the wrong message to parents" or "concerns about side effects" were cited by more than half of the practitioners for not using medication. Practitioners expressed a range of concerns about sleep medication safety, tolerance, and side effects in children, although relatively few reported not using medication because of lack of efficacy. However, one half of the respondents reported that their lack of use of hypnotic/sedative medications was related to the low prevalence of significant sleep problems in their practice.

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

TABLE 6. Physicians Reporting at Least 1 Nonprescription Medication Recommendation for Children's Sleep in the Past 6 Months*

Medication	Respondents (%)				
	Age Groups (Years)				
	0-2	3-5	6-12	≥13	Any Age
Antihistamine	48.6	58.2	46.5	34.1	67.9
Combination sleep/pain reliever	15.7	16.9	17.2	20.4	29.2
Melatonin	1.7	7.7	15.4	18.9	24.9
Herbal preparations	13.5	12.7	13.3	15.6	22.2

* Data missing from 9 to 28 respondents, depending on the age group.

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, α -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 α -agonists for daytime ADHD symptoms 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 respondent also reported prescribing α -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

TABLE 7. Physicians Reporting at Least 1 Prescription Medication Recommendation for Children's Sleep in the Past 6 Months*

Medication	Respondents (%)				
	Age Groups (Years)				
	0-2	3-5	6-12	≥13	Any Age
Alpha agonist (eg, clonidine, guanfacine)	2.0	10.6	27.8	18.9	30.6
Antihistamine (eg, diphenhydramine, hydroxyzine)	15.7	16.9	18.6	15.2	29.1
Antidepressant (eg, SSRIs, tricyclics, trazodone)	–	1.2	7.3	15.1	16.4
Benzodiazepine (eg, clonazepam, diazepam, temazepam)	1.2	2.0	6.5	8.6	11.9
Chloral hydrate	6.7	6.0	5.8	2.3	11.6
Hypnotic (eg, zolpidem, zaleplon)	–	–	1.4	7.9	8.1
Antipsychotic (eg, risperidone)	0.45	1.4	5.0	4.9	7.9
Anticonvulsant (eg, valproex, topiramate)	0.15	0.8	0.9	0.9	1.6
Barbiturate (eg, phenobarbital)	0.6	0.5	0.15	0.45	1.2

* Data missing from 8 to 14 respondents, depending on the age group.
SSRI indicates selective serotonin reuptake inhibitor.

TABLE 8. Duration of Treatment With Medication for Sleep

Medication Type	Typical Duration of Treatment When Sleep Medications are Used (% of Treated Children With Specified Duration of Therapy)		
	<1 Week	1 Week to 1 Month	>1 Month
Nonprescription*	56 ± 43	29 ± 35	10 ± 23
Prescription†	21 ± 35	24 ± 32	47 ± 43

* 181 (28%) of respondents report never using these medications.
† 310 (48%) of respondents report never using these medications.

TABLE 9. Percentage of Respondents Who Prescribed Sleep Medication for at Least 1 Child With ADHD in the Past 6 Months*

Medication	Respondents (%)				
	Age Group (Years)				
	0-2	3-5	6-12	≥13	Any Age
Alpha agonist	.15	8.5	29.6	22.8	31.7
Late-day stimulant	0	5.9	24.7	20.3	26.2
Antihistamine	4.6	11.9	15.3	11.6	18.4
Antidepressant	0.15	1.5	8.8	11.4	12.7

* Data missing from 9 to 17 respondents, depending on the age group.

and 58% had prescribed medication for sleep at least once in the past 6 months of practice. To examine more closely the factors that potentially have an impact on the likelihood of prescribing or recommending medications for pediatric insomnia in practice, we divided the respondents into 2 groups: those who reported "never" using sleep medication (either prescription or nonprescription) in any age group in the past 6 months and those who used sleep medications "at least once" in the past 6 months. Having experience with treating children with ADHD for either nocturnal sleep problems or daytime behavioral problems was strongly associated with sleep medication use in children. After the practitioner's gender, years in practice, previous behavioral specialty training, and frequency of sleep problems seen in the practice were adjusted for, practitioners who used sleep medications for children with ADHD were almost 4 times more likely to prescribe sleep medications to children (odds ratio [OR]: 3.95; 95% confidence interval [CI]: 2.7–5.7; $P < .0001$). Practitioners who treated daytime behavioral problems in chil-

dren with ADHD were more than twice as likely to prescribe sleep medication for children (OR: 2.3; 95% CI: 1.1–4.6; $P = .0256$). 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.³⁰ 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 1995³¹ 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.⁷ 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).^{6,32} 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.³³ 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 soporifics³⁴ 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,³⁵ 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 use of such herbals as valerian root and hops,¹⁷ although the occurrence 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, al-

though 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.³⁶ 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.³⁷ 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.

ACKNOWLEDGMENTS

This study was supported by an unrestricted educational grant from Sanofi-Synthelabo; additional support was provided by the National Institutes of Health to Dr Owens (NIH NHLBI HL 03896) and to Dr Rosen (NIH NHLBI 04426).

REFERENCES

1. Glaze D, Rosen C, Owens J. Towards a practical definition of pediatric insomnia. *Curr Ther Res.* 2002;63(suppl B):B4–B17
2. Richman N. A community survey of characteristics of one- to two-year-olds with sleep disruptions. *J Am Acad Child Psychiatry.* 1981;20:281–291
3. Blader JC, Koplewicz HS, Abikoff H, Foley C. Sleep problems of elementary school children: a community survey. *Arch Pediatr Adolesc Med.* 1997;151:473–480
4. Owens JA, Spirito A, McGuinn M, et al. Sleep habits and sleep disturbance in elementary school-aged children. *J Dev Behav Pediatr.* 2000;21:27–36
5. Owens J, Palermo T, Rosen C. Overview of current management of sleep disturbances in children: II. Behavioral interventions. *Curr Ther Res.* 2002;63(suppl B):B38–B52
6. Quine L. Sleep problems in children with mental handicap. *J Ment Defic Res.* 1991;35:269–290
7. Corkum P, Tannock R, Moldofsky H. Sleep disturbances in children with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry.* 1998;37:637–646
8. Rosen C, Owens J, Scher M, Glaze D. Pharmacotherapy for pediatric sleep disturbances: current patterns of use and target population for controlled clinical trials. *Curr Ther Res.* 2002;63(suppl B):B53–B66
9. Mindell JA. Sleep disorders in children. *Health Psychol.* 1993;12:151–162
10. Dahl RE. The impact of inadequate sleep on children's daytime cognitive function. *Semin Pediatr Neurol.* 1996;3:44–50
11. Randazzo AC, Muehlbach MJ, Schweitzer PK, Walsh JK. Cognitive function following acute sleep restriction in children ages 10–14. *Sleep.* 1998;21:861–868
12. Wiggs L, Stores G. Behavioural treatment for sleep problems in children with severe learning disabilities and challenging daytime behaviour: effect on daytime behaviour. *J Child Psychol Psychiatry.* 1999;40:627–635
13. Lavigne JV, Arend R, Rosenbaum D, et al. Sleep and behavior problems among preschoolers. *J Dev Behav Pediatr.* 1999;20:164–169
14. Sadeh A, Gruber R, Raviv A. Sleep, neurobehavioral functioning, and behavior problems in school-age children. *Child Dev.* 2002;73:405–417
15. Mindell JA. Empirically supported treatments in pediatric psychology: bedtime refusal and night wakings in young children. *J Pediatr Psychol.* 1999;24:465–481
16. Reed MD, Findling RL. Overview of current management of sleep disturbances in children: I—pharmacotherapy. *Curr Ther Res.* 2002;63(suppl B):B18–B37
17. Gyllenhaal C, Merritt S, Peterson S, Block K, Gochenour T. Efficacy and safety of herbal stimulants and sedatives in sleep disorders. *Sleep Med Rev.* 2000;4:229–251
18. Owens JL, France KG, Wiggs L. Behavioural and cognitive-behavioural interventions for sleep disorders in infants and children: a review. *Sleep Med Rev.* 1999;3:281–302
19. Ramchandani P, Wiggs L, Webb V, Stores G. A systematic review of treatments for settling problems and night waking in young children. *BMJ.* 2000;320:209–213
20. Trott GE, Badura F, Wirth S, et al. [Self-assessment of prescribing behavior of psychotropic drugs for children and adolescence. Results of a survey of established physicians]. *Psychiatr Prax.* 1995;22:235–239
21. Kopferschmitt J, Meyer P, Jaeger A, Mantz JM, Roos M. [Sleep disorders and use of psychotropic drugs in 6-year-old children]. *Rev Epidemiol Sante Publique.* 1992;40:467–471
22. Ounsted MK, Hendrick AM. The first-born child: patterns of development. *Dev Med Child Neurol.* 1977;19:446–453
23. Adams S. Prescribing of psychotropic drugs to children and adolescents. *BMJ.* 1991;302:217
24. Patois E, Valatz JL, Alperovitch A. Prevalence of sleep and wakefulness disorders in high school students at the Academy of Lyon. *Rev Epidemiol Sante Publique.* 1993;41:383–388
25. Ledoux S, Choquet M, Manfredi R. Self-reported use of drugs for sleep or distress among French adolescents. *J Adolesc Health.* 1994;15:495–502
26. McNicholas F. Psychotropic prescribing practices of paediatricians in the UK. *Child Care Health Dev.* 2001;27:497–508
27. Owens JA. The practice of pediatric sleep medicine: results of a community survey. *Pediatrics.* 2001;108(3). Available at: www.pediatrics.org/cgi/content/full/108/3/e51
28. Walters AS, Mandelbaum DE, Lewin DS, Kugler S, England SJ, Miller M. Dopaminergic therapy in children with restless legs/periodic limb movements in sleep and ADHD. Dopaminergic Therapy Study Group. *Pediatr Neurol.* 2000;22:182–186
29. Stores G. Sleep-wake function in children with neurodevelopmental and psychiatric disorders. *Semin Pediatr Neurol.* 2001;8:188–197
30. Hunt RD, Hoehn R, Stephens KJ, Riley W, Osten C. Clinical patterns of ADHD: a treatment model based on brain functioning. *Compr Ther.* 1994;20:106–112
31. Zito JM, Safer DJ, dosReis S, Gardner JF, Boles M, Lynch F. Trends in the prescribing of psychotropic medications to preschoolers. *JAMA.* 2000;283:1025–1030
32. Stores G. Sleep studies in children with a mental handicap. *J Child Psychol Psychiatry.* 1992;33:1303–1317
33. Espezel H, Jan J. The use of melatonin to treat sleep-wake-rhythm disorders in children who are visually impaired. *J Vis Impair Blind.* 1996;90:34–50
34. Russo RM, Gururaj VJ, Allen JE. The effectiveness of diphenhydramine HCl in pediatric sleep disorders. *J Clin Pharmacol.* 1976;16:284–288
35. Jan MM. Melatonin for the treatment of handicapped children with severe sleep disorders. *Pediatr Neurol.* 2000;23:229–232
36. Gadow KD. Pediatric psychopharmacology: a review of recent research. *J Child Psychol Psychiatry.* 1992;33:153–195
37. Dahl RE. The pharmacologic treatment of sleep disorders. *Psychiatr Clin North Am.* 1992;15:161–178

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

Judith A. Owens, Carol L. Rosen and Jodi A. Mindell

Pediatrics 2003;111:e628

DOI: 10.1542/peds.111.5.e628

Updated Information & Services

including high resolution figures, can be found at:
<http://pediatrics.aappublications.org/content/111/5/e628>

References

This article cites 36 articles, 2 of which you can access for free at:
<http://pediatrics.aappublications.org/content/111/5/e628#BIBL>

Subspecialty Collections

This article, along with others on similar topics, appears in the following collection(s):
Developmental/Behavioral Pediatrics
http://www.aappublications.org/cgi/collection/development:behavioral_issues_sub
Growth/Development Milestones
http://www.aappublications.org/cgi/collection/growth:development_milestones_sub
Pharmacology
http://www.aappublications.org/cgi/collection/pharmacology_sub
Therapeutics
http://www.aappublications.org/cgi/collection/therapeutics_sub

Permissions & Licensing

Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
<http://www.aappublications.org/site/misc/Permissions.xhtml>

Reprints

Information about ordering reprints can be found online:
<http://www.aappublications.org/site/misc/reprints.xhtml>

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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

Judith A. Owens, Carol L. Rosen and Jodi A. Mindell

Pediatrics 2003;111;e628

DOI: 10.1542/peds.111.5.e628

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://pediatrics.aappublications.org/content/111/5/e628>

Pediatrics is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. Pediatrics is owned, published, and trademarked by the American Academy of Pediatrics, 345 Park Avenue, Itasca, Illinois, 60143. Copyright © 2003 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 1073-0397.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

