2 Sleep Medicine: Evidence-Based Clinical Practice

J.F. Pagel and G. Vernon Pegram

Introduction

Dysfunctions of sleep, a state in which we each spend 1/3 of our lives, lead to declines in quality of life, diminished waking performance, more frequent illness, as well as increases in disease morbidity and mortality. Recent epidemiological data have emphasized the significant contribution of obstructive sleep apnea (OSA), one of the most physiological disruptive and dangerous sleep-related diagnoses, to pulmonary, cardiac, endocrine, and cognitive diseases [1–4]. The spectrum of sleep disorders mirrors the clinical population of patients in a broad-based practice of primary care [5]. Almost all chronic diseases result in physical or mental discomfort for the patient and consistently induce disturbances in the state of sleep.

In clinical practice, sleep disorders are often only rarely addressed or treated. Despite the high prevalence of sleep disorders in the population and primary care setting, several studies suggest that sleep complaints are under-addressed by physicians. Only one-third of patients with insomnia mention it to their physicians and only 5 % seek treatment [6, 7]. Sleep problems are even more rarely addressed in the pediatric age population. In a review of 50,000 physician patient contacts in family practice and general pediatric clinics, notes mentioning sleep were found in only 123 [8].

These findings are in part a result of the fact that the field of sleep medicine is relatively new with few physicians having expertise or training in the area. Most patients with sleep disturbance receive their medical care in the primary care setting. The evidence exists documenting the importance of the diagnosis and treatment of sleep disorders in primary care practice in reducing morbidity and mortality, improving comorbid disease processes, and improving patient quality of life. This book presents the argument for an evidence-based practice of sleep medicine in primary care.

Sleep Disorders: The Clinical Spectrum

Sleep diagnoses have been variably classified. Sleep quality worsens with age and stress. Sleep disruption occurs in association with psychiatric disorders and is often a component of DSM-based diagnostic criteria. Pregnancy and menopause induce insomnia and sleep disruption. Pediatric sleep disorders are common. Sleep diagnoses are

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divided into six primary categories: insomnias, sleep-related breathing disorders, hypersomnias not otherwise classified, circadian-rhythm sleep disturbance, parasomnias, and sleep-related movement disorders.

The Insomnias

Insomnia is a primary care problem. The specialty of sleep medicine is new with few physicians boarded and trained in the area. Yet in the medical care setting sleep disorders are common. Whereas 30 % of the general population report symptoms of sleep disruption, more than 50 % of primary care patients have sleep complaints [9]. Diagnostically, about 75 million adults have occasional insomnia, whereas 25 million (11–14 % of the population) have an ongoing problem with chronic insomnia [6, 10]. At least 40 % of American adults struggle with occasional insomnia. Those most at risk include women, sometimes because biological changes such as menstrual periods, pregnancy, or menopause may contribute to bouts of insomnia. Older adults report disruptions to their sleep as a result of medical conditions, sleep disorders, or discomfort. They are also more sensitive to environmental stimuli [11, 12].

The insomnias share the complaint of difficulty with sleep initiation, duration, consolidation, or quality associated with daytime functional impairment. The daytime functional impairment in insomnia can be fatigue, impaired memory or concentration, mood disturbance, daytime sleepiness, reduced motivation or energy, tension, headaches, or gastrointestinal symptoms as well as concerns and worries about sleep. In adults, chronic insomnia is associated with impaired social and vocational function and reduced quality of life, and in severe cases may be associated with an increased risk of traffic and work-site accidents as well as psychiatric disorders. In children chronic insomnia is associated with poor school performance.

There is no question that insomnia is a quality-of-life issue. Individuals with chronic insomnia consistently report lower values of quality of life particularly on somatic/physical scales. Chronic insomnia is also associated with higher levels of reported cognitive impairment, increased job absenteeism, psychiatric illness, increased accident risks, and higher health care costs [13]. There is a strong association between insomnia and other illnesses. Chronic insomniacs have an increased risk of depression and anxiety [14]. Recent data have pointed out the association between insomnia and obesity. Sleepless individuals are much more likely to be obese [15]. Chronic insomnia is also associated with increased pain in rheumatic disease with the degree of insomnia on any given night being a predictor of pain intensity the following day [16]. Chronic insomniacs also report a 4.5 times higher incidence of serious accidents and injuries [17]. The American Academy of Sleep Medicine has developed a series of evidence-based criteria for the evaluation and treatment of insomnia [18–20].

The cost and health care utilization data have been calculated for the common sleep disorders including insomnia and OSA. The annual direct costs of insomnia in the USA include $1.97 billion for medications and $11.96 billion for health care services. Indirect costs include decreased productivity, higher accident rate, increased absenteeism, and increased comorbidity with total annual cost estimates ranging from $30 to $107.5 billion [10, 21].

Insomnia as a symptom often arises secondary to underlying medical conditions, mental disorders, and other sleep diagnoses. Diagnosing insomnia can be a complex task as the origin of a patient's insomnia is often multifactorial. Life stressors, concomitant illness, family, and social structure can precipitate symptomatic insomnia. The primary care physician often has a more complete knowledge of these factors than the polysomnographic oriented subspecialist. Healthy sleep is under assault by the stressful culture in which we live. The primary care physician is in the ideal position to define the cause of the sleep–wake disturbance in a patient with insomnia. Like diet and exercise, sleep disruption and insomnia are lifestyle issues for which primary care physicians are best suited to address. Evidence-based criteria for the evaluation and treatment of insomnia are summarized in Tables 2.1, 2.2, and 2.3 [18–20, 22].

Table 2.1 Evidenced-based symptom and diagnostic correlates for chronic insomnia

Chronic insomnia leads to poorer self-rated quality of life	A	Multiple large retrospective cohort studies
Chronic insomnia leads to increased health care cost for affected patients	A	Multiple large retrospective cohort studies
Chronic insomnia predisposes an individual to mood disorder/depression	B	Large retrospective cohort study, longitudinal prospective study
Chronic insomnia is associated with decreased work productivity and increased time missed from work and/or school	B	Multiple small retrospective studies with consistent findings
Chronic insomnia leads to drug and alcohol abuse	C	Significant associated variables in adult and adolescent populations
Chronic insomnia leads to obesity	C	Small retrospective studies
Chronic insomnia is associated with an increase in automobile accidents	C	Retrospective review
Chronic insomnia is associated with an increase in mortality in geriatric patients	C	One large retrospective study
Chronic insomnia is associated with increased pain complaints in chronic pain patients	C	Retrospective review

The Sleep-Related Breathing Disorders

The sleep-related breathing disorders include both those occurring secondary to obstruction of the airway resulting in continued breathing effort but inadequate ventilation (OSA) and the central sleep apnea syndromes in which respiratory effort is diminished or absent because of central nervous system or cardiac dysfunction. OSA occurs at high frequency in the primary care clinic population. It is one of the most physiological disruptive and dangerous sleep-related diagnoses, affecting at least one of every five adults in some populations [4]. As many as 18 million Americans suffer from sleep apnea. It is more common among men, those who snore, are overweight, and have high blood pressure or physical abnormalities in their upper airways [8].

Table 2.2 Evidenced based recommendations for the diagnosis and treatment of insomnia

The evaluation of chronic insomnia does not require polysomnographic evaluation except when associated with other sleep-associated diseases such as OSA or PLMD	B	Consensus guidelines, usual practice, disease-oriented evidence, prospective diagnostic cohort study
Drug treatment of chronic insomnia leads to improvements in associated sleep states and daytime performance	B	Retrospective cohort and case control studies with good follow-up
Drug treatment of chronic insomnia with newer medications can be maintained for a long term without loss of efficacy and without negative effects	B	Large prospective study (drug company)
Behavioral treatment of chronic insomnia leads to improvements in associated sleep states and daytime performance	C	Consensus guidelines, usual practice

Table 2.3 Evidence-based criteria for sleep testing in patients with insomnia

Full attended polysomnography indications		
(a) Suspected sleep-related breathing disorders	A	Prospective diagnostic cohort studies
(b) Patients with systolic or diastolic heart failure not responding to optimal medical management	A	Standard of care
(c) Diagnosing restless leg syndrome/periodic limb movement disorder	C	Disease-oriented evidence
(d) Diagnosing insomnia in patients not responding to behavioral or medical therapy	C	Consensus guidelines
Limited PSG for the diagnosis of sleep disorders	B	Lower initial procedure cost in patients potentially with breathing disturbance

Of the sleep disorders, OSA is the best studied from a cost-effect, epidemiological, and evidence-based perspective. The associated morbidity, mortality, comorbidities, and quality-of-life effects are well researched and described. Adult OSA has a long-term and clear association with obesity and daytime cognitive impairment (i.e., daytime sleepiness) that has been shown to lead to an increase in motor vehicular accidents in untreated patients. Subjects with apnea–hypopnea index (AHI) of greater than 10 have a 6.3 times odds of having a traffic accident compared with 152 case-matched control with AHI less than 10 [23]. Recent epidemiological studies that have cross-matched sleep apnea evaluation with long-term prospective cardiovascular risk studies have served to point out the consistent and strong association between OSA and essential hypertension. Odds of hypertension increase with increasing severity of apnea in a graded dose response fashion, with an odds ratio of 1.27 for hypertension in group with AHI greater than 30 against the nonapnic grouping with an AHI of less than 5 [24]. Research supports the association between OSA and increased mortality, congestive heart failure (both right- and left-sided), myocardial infarction, and cerebral vascular accidents [25]. Evidence is slightly less clear or under development for the association of adult OSA with diabetes and metabolic syndrome [26]. Cardiac arrhythmias (bradycardia, atrial fibrillation, and ventricular tachycardia) are often seen in polysomnography (PSG) studies of OSA patients. Recent studies have emphasized the clinical significance of the association between atrial fibrillation and untreated OSA [27].

The pathophysiology and clinical presentation of pediatric OSA differ from those of adult OSA. In pediatric patients OSA is most clearly associated with poor school performance. In first graders performing at the bottom 10 % of grade level, more than 20 % have OSA. Of the children, all children who had tonsillar-adenectomy (T&A) surgery improved their grades, and the others stayed the same [28]. Studies also support the association of pediatric OSA with failure to thrive, enuresis, and learning disability. Studies have been contradictorily addressing the association of pediatric OSA with obesity and attention-deficit/hyperactivity disorder with strong associations occurring in specific patient populations and not in other clinically defined settings [29].

OSA: Cost and Health Care Utilization

The costs of untreated sleep apnea have been addressed in several studies. In 238 consecutive OSA patients studied in 1999, the mean annual medical cost was $2,720 per patient before diagnosis compared with age, body mass index, and gender-matched controls [30]. Patients with OSAS use health care resources at higher rates than control subjects for years before diagnosis. Of all comorbid diagnoses, significantly increased utilization is found for cardiovascular disease and hypertension in patients with OSA [27]. For the 10 years before OSA diagnosis in 1999, patients with OSA had yearly claims of $3,872 per patient compared with matched control claims of $1,969 per patient. There was a rise in health care costs each year before diagnosis with initial data suggesting that after diagnosis yearly claims were halved. By the time patients were finally diagnosed for sleep apnea, they had already been heavy users of health services for several years [31]. In Canada hospital stays are 1.27 days per patient per year, 1 year before OSA diagnosis, and 53 days per patient per year, 1 year after diagnosis. These differences were only seen in those patients adhering to treatment with no difference between patients and controls for non-adherers [32]. In pediatric OSA there are also suggestions for increased health care utilization with a 226 % increase in health care utilization 1 year before evaluation, more hospital days, more drug use, and more visits to ER with the severity of OSA correlating directly to total annual cost independent of age [33] (Table 2.4).

Table 2.4 Evidence-based associations of obstructive sleep apnea (OSA)

Adult OSA	Obesity	A	Consistent systemic meta-analyses
	Cognitive impairment (daytime sleepiness)	A	Consistent systemic meta-analyses
	Motor vehicular accidents	A	Consistent systemic meta-analyses
	Hypertension	A	Cross-sectional analysis of prospective cohort studies, consistent systemic meta-analyses
	Increased mortality	B	Retrospective cohort studies
	Congestive heart failure (right and left sided)	B	Cross-sectional analysis of prospective cohort studies, inconsistent systemic meta-analyses
	Coronary artery disease	B	Cross-sectional analysis of prospective cohort studies, retrospective diagnostic cohort study
	Cerebral vascular accidents	B	Cross-sectional analysis of prospective cohort studies, retrospective cohort study
	Metabolic syndrome	B	Cross-sectional analysis of prospective cohort studies, retrospective cohort studies
	Atrial fibrillation	B	Multiple retrospective cohort studies, and treatment follow-up studies
	Diabetes	C	Retrospective cohort studies
	Other cardiac arrhythmias	C	Case series, usual practice
Pediatric OSA	Poor school performance	B	Multiple retrospective cohort studies
	Enuresis	C	Retrospective cohort studies
	Failure to thrive	C	Case series, usual practice
	Learning disability	C	Retrospective cohort studies
	Obesity	C	Retrospective cohort studies
	Attention-deficit/hyperactivity disorder	C	Inconsistent retrospective cohort studies

The Cost-Effectiveness of CPAP Therapy for OSA

In OSA patients there is reduced hospitalization with cardiovascular and pulmonary disease in OSA patients on nasal content-positive airway pressure (CPAP) treatment [32]. CPAP treatment reduces the need for acute hospital admission owing to cardiovascular and pulmonary disease in patients with OSAS. For the 2 years before and 2 years after CPAP use in CPAP users, 413 hospital days were utilized before treatment and 54 hospital days after treatment. In OSA CPAP non-users these findings were 137 hospital days before treatment and 188 days after treatment. This reduction of concomitant health care consumption should be taken into consideration when assessing the cost–benefit evaluation of CPAP therapy [34].

Hypersomnias Not Otherwise Classified

In the modern fast-paced world, an adequate level of alertness is required for well-being and performance. This diagnostic category includes a group of diagnoses sharing the primary characteristic of inducing significant daytime sleepiness. These diagnoses have significant effects on waking performance and therefore morbidity and mortality. The National Health and Safety Administration (NHTSA) in 1999 estimated 1.5 % of 100,000 police-reported crashes, and 4 % of all traffic crash fatalities involved drowsiness and fatigue as principal causes. Beyond the personal and social loss associated with these accidents, the NHTSA in 1994 estimated cost at $83,000 lifetime per fatality, resulting in a total of $12.5 billion with

85 % of cost from workplace loss and loss of productivity [35].

The clinically significant sleep disorders that induce daytime sleepiness occur at lower frequency than OSA in the general population. These diagnoses generally require multiple sleep latency testing (MSLT) for diagnosis, an objective test measuring an individual's tendency to fall asleep in quiet situation [36]. Narcolepsy is the most common of the neurological diseases inducing severe daytime sleepiness, present in 1/2,000 individuals in the general population.

Circadian Rhythm Sleep Disorders

The biological clock for sleeping is based in part on the circadian rhythm of sleep and wake propensity. Chronic sleep disturbance can result from disruptions in this system or from misalignments between an individual's circadian rhythm and the 24-h social or physical environment. Delayed sleep-phase syndrome is symptomatic in 7–16 % of adolescents. Shift work disrupts normal sleep patterns for approximately 20 % of the population. At least 10 % of individuals evaluated in sleep laboratories for chronic insomnia have a definite circadian component to their disorder [8].

Parasomnias

Parasomnias are undesirable physical events or experiences that occur during entry into sleep, within sleep, or during arousals from sleep. Parasomnias encompass sleep-related movements, autonomic motor system functioning, behaviors, perceptions, emotions, and dreaming. These are sleep-related behaviors and experiences in which the sleeper has no conscious deliberate control. Parasomnias become clinical diagnoses when associated with sleep disruption, nocturnal injuries, waking psychosocial effects, and adverse health effects. Parasomnias are classified based on sleep stage of origin into the disorders of arousal occurring out of deep sleep (stages 3 and 4), those associated with rapid eye movement sleep (REMS), and a grouping including less well-defined diagnoses with unclear sleep stage association.

Some of the sleep-associated parasomnias are common but of unclear or variable clinical significance. The arousal disorders of somnambulism and 4 % of pediatric patients. Enuresis is present in 15–20 % of 5-year-old children declining to 1–2 % in young adulthood. Recurrent nightmares occur in 15–40 % of normal adolescents and may be present in up to 50 % of traumatized immigrant communities reflecting a high incidence of post-traumatic stress disorder present in these populations. REMS behavior disorder occurs in 0.38–0.5 % of the population [37].

Sleep-Related Movement Disorders

More than 12 million people in this country experience unpleasant, tingling, creeping feelings in their legs during sleep or inactivity as a symptom of a disorder called restless leg syndrome. This neurological movement disorder causes an uncontrollable urge to move and to relieve the sensations in the legs. As a result, sleep is either disrupted and people sleep poorly, become sleep deprived, and experience daytime sleepiness [38–40].

The Diagnostic Evaluation of Sleep Disorders

The diagnosis of the insomnias, the circadian-rhythm sleep disturbances, and the movement disorders of sleep are primarily based on a sleep history and physical. However, in order to diagnosis and manage many of the common sleep disorders, sleep physicians routinely utilize diagnostic tests for evaluation of the patient. The results of these tests can provide useful information that the primary care physician can utilize in providing optimal care for patients [41–43].

Sleep laboratory testing can be expensive, and alternative approaches are now often utilized. The sleep-related breathing disorders are now commonly initially evaluated using home screening tests (HSTs). This approach has been shown to be particularly useful in younger patients without comorbid diagnoses [44]. Limited PSGs including fewer recording channels cannot determine whether the patient is actually asleep during the recording, and in patients with insomnia, and those with ongoing psychiatric problems, the number of respiratory events (apneas and hypopneas) per hour will be lower than actually present due to the large amount of recording time that will be in wake. Periodic limb movements and arousals from events such as parasomnias are not recorded by HSTs. Most home screeners differentiate poorly between obstructive and central apnea that often requires a different approach to treatment. Patients who may have central apnea including those with a history of CHF, post-ICU patients, those with a history of significant cardiovascular, pulmonary, or CNS disease, those with development abnormalities, those being treated with opiates, the extreme elderly, and those living at elevations above 6,500 ft generally require full PSG for evaluation. Used across the board, incomplete recordings are obtained in 20 % of studies [44, 45]. The hypersomnias generally require both PSG and MSLT for diagnostic evaluation and assessment of daytime sleepiness.

PSG is the recording of multiple physiological signals during sleep. The standard PSG recording montage includes channels of electroencephalography (EEG), electrooculogram (EOG), and chin electromyelogram (EMG) that are required for sleep staging as well as recordings of respiratory effort, airflow, pulse oximetry, snoring, sleep position, ECG, leg EMG, and video monitoring. Additional channels are sometimes utilized including end-tidal or transcutaneous CO_2 and additional EEG channels if potential nocturnal seizure disorders are being evaluated. In evaluating the sleep-related breathing disorders, a split night protocol is often utilized in which a therapeutic treatment or "titration" portion of the PSG is added after at least 120 min of diagnostic sleep time. During the titration, C-PAP, Bi-PAP, and oxygen are utilized in an attempt to eliminate or reduce respiratory events and restore normal sleep. The PSG report is scored by a sleep technologist and interpreted by a sleep medicine physician. The PSG interpretation that you receive should include data as to sleep architecture, respiratory parameters, periodic limb movements, a description of any parasomnia or seizure activity, ECG abnormalities, and the results and appropriate setting of any titration attempted during the night of study. Autotitrating pap systems are tolerated well by some patients; however, these systems have minimal diagnostic capacity and can report inappropriate settings for misdiagnosed patients and patients with central apnea and/or nasal congestion or mouth leaks on pap therapy [46].

Daytime sleepiness is generally evaluated through MSLT that includes four to five opportunities to nap in the sleep laboratory after a full-night PSG under standard conditions with EEG, EOG, and EMG monitored, so that sleep and REMS onset can be determined. MSLT reports should include average or mean latency to sleep, and the number of sleep-onset REMS periods recorded (a diagnostic criteria for narcolepsy). The maintenance of wakefulness test is similar to the MSLT. For this procedure, the patient attempts to maintain wakefulness when monitored for appropriate testing periods to assess the patient's ability to maintain wakefulness during the day.

Sleep testing provides a wealth of useful information for the physician involved in the treatment of the patient's sleep disorder. The primary care physician able to understand the data and interpretation from a high-quality PSG will find much information useful in patient care. The management of diabetes, hypertension, and congestive heart failure are core aspects of primary care medicine. These disorders as well as the childhood behavioral disorders have significant relationships with the disease processes addressed in sleep medicine. Sleep laboratory testing can be utilized as an objective insight into the patient's pulmonary, cardiac, neurological, endocrine, cognitive, and psychiatric status. Evidence-based testing indications are summarized in Table 2.5.

Table 2.5 Evidence-based criteria for sleep testing for OSA

Attended split night polysomnography indications		
(a) The diagnosis of sleep-related breathing disorders	A	Standard of care
(b) Positive airway pressure titration	A	Standard of care
(c) Pre- and postoperative evaluation of patients having surgery for obstructive sleep apnea	A	Standard of care
(d) Evaluation of patients being treated for OSA with persistent symptoms	A	High-quality cohort studies
(e) Patients with systolic or diastolic heart failure not responding to optimal medical management	A	Prospective diagnostic cohort studies
Treatment with PAP systems leads to reduced symptoms of sleepiness, increased quality of life, and lower blood pressure	A	Meta-analysis of retrospective cohort studies (standard of care)
Non-attended limited HST for the diagnosis of sleep-related breathing disorders	B	Retrospective cohort and case control studies with good follow-up (developing as standard of care)
Autotitrating PAP for treating obstructive sleep apnea	B	Case control studies with good follow-up
Multiple sleep latency testing indications		
(a) Assessing daytime sleepiness	B	Meta-analysis, usual practice, usual practice, disease-oriented evidence
Maintenance of wakefulness testing to assess daytime sleepiness	C	Disease-oriented evidence, usual practice

Conclusion

The field of sleep medicine has shown remarkable growth in the last decades. The number of board-certified sleep physicians has grown from under 500 to more than 3,000 in the last 15 years. Yet the overwhelming majority of individuals that suffer from disorders of sleep and wakefulness are undiagnosed and untreated. Primary care physicians have training and experience in the full extent of medical and psychiatric illness affecting patients with sleep disorders. They often have close relationships with their patients and an awareness and understanding of the bio-psycho-social context in which their patients live. These are advantages that the primary care physician has over the specialist in the diagnosis and management of patients with sleep disorders. The physician with training in sleep and an understanding of appropriately utilized testing procedures can utilize current evidence-based knowledge in the field to provide high-quality sleep medicine in primary care practice.

Case Example #1: Suspected Sleep Apnea

Introduction: Pt is a 23-year-old male referred by Vocational Rehab for evaluation of fatigue, snoring, and observations of breath holding during sleep. He reports difficulty concentrating at work and falling asleep in the afternoon if he was not active. He reports sleeping for approximately 8–9 h at night and had no difficulty getting up at the alarm in the morning.

Case Description: Height 5′6″. Weight 328 lb. He had moderate intake of caffeine, no alcohol, and no tobacco. His Epworth Sleepiness Scale 1 s 7/24 which is mild/moderately sleepy. Other than morbid obesity, his physical exam was unremarkable. His blood pressure is 160/95 mmHg in the office. Last BP recorded 3 years ago was 145/85. At that time pt weighed 276 lb. He has no significant medical problems or family history suggestive of sleep disorders.

In light of a weight gain of 52 lb, and developing hypertension, overnight PSG was performed due to suspected sleep

(continued)

apnea. The study showed sleep efficiency of 92 % and relatively mild sleep apnea with an index of 9.5/hour of sleep and SaO_2 of 92 %, and relatively mild myoclonus with index of 12/hour of sleep. His RDI (respiratory disturbance index including snoring-associated arousals) is 14.6/hour. EKG showed a 19 beat run of ventricular tachycardia.

Discussion: An exercise and dietary program including salt reduction is prescribed, and follow-up reevaluation of BP is scheduled. Given his obesity and hypertension with a component of apnea, daytime sleepiness, an abnormal EKG, and a sleep study consistent with a diagnosis of OSA presenting in part as upper airway resistance syndrome (UARS), a trial with CPAP is scheduled. Weight loss in a patient with morbid obesity is very important but often difficult to achieve for a patient with active apnea without treatment of that apnea. No daytime passing-out spells are reported; however, cardiology referral for the run of ventricular tachycardia is recommended.

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