Defining Insomnia: The Role of Quantitative Criteria

Comment on Lineberger MD; Carney CE; Edinger JD et al. Defining insomnia: quantitative criteria for insomnia severity and frequency. SLEEP 2006;29(4): 479-485.

Thomas Roth, PhD; Christopher Drake, PhD

Henry Ford Hospital Sleep Center, Detroit, MI

THE STUDY BY LINEBERGER ET AL1 AND OTHER SIMILAR STUDIES2-4 ADDRESS A CRITICAL ISSUE IN OUR UNDERSTANDING AND TREATMENT OF INSOMNIA. Specifically, this paper aims to define the most sensitive and specific frequency and severity criteria needed for a diagnosis of insomnia. To accomplish this task, these investigators used a 2-week sleep diary probing a variety of quantitative sleep endpoints (e.g., sleep latency, total sleep time, wake after sleep onset) in a group of subjects with primary insomnia, as well as in controls. Not surprisingly, the investigators did not find a level of severity, frequency, or a combination of the 2 that is differentially superior in terms of both sensitivity and specificity. As might be expected, as severity criteria increased, sensitivity went down and specificity went up. This lack of a clear cut point for diagnostic criteria is not surprising and is common in a variety of disorders such as depression, hypercholesterolemia, and sleep apnea. This lack of a clear cut point simply suggests that the pathology is on a continuum, and the cutoff needs to be defined by the relative importance of sensitivity and specificity.

To restate the question, what is the relative value of a treatment in terms of both safety and efficacy relative to the morbidity associated with not treating the disorder? In the area of insomnia, it seems that the data suggest we should be moving in the direction of greater sensitivity. Insomnia has been shown to be a significant risk factor for the development of major depression in several prospective studies,5-8 and there are now preliminary data suggesting that treatment of insomnia may reduce depression severity.9 Suicidality is also associated with insomnia symptoms,10,11 although causal links have not been established. Serious accidents and falls in the elderly have been linked to insomnia, independent of medication use,12 supporting an additional and important morbidity of this disorder. Finally, quality of life is significantly reduced in insomniacs and is comparable with other chronic medical conditions.13,14 In parallel with morbidity findings in insomnia, there are data on more effective treatment. Recent work in the area of cognitive behavioral therapy has demonstrated that there are less complex, but still efficacious, behavioral treatments that make cognitive behavioral therapy of insomnia more available to a broader range of patients.15,16 In terms of pharmacologic management of insomnia, recent research has witnessed the development of medications that are safer in terms of both appropriate pharmacokinetics and binding sites and regarding long-term efficacy. Clearly, insomnia has significant morbidity, and safe and effective treatments are broadly available. An alternative position might argue that, even with safer treatments available, unnecessary treatment of insomnia in the absence of a demonstration of clinical benefit represents excessive use of healthcare resources. Clearly, data on the value of treatment in less severe insomnias, especially in terms of improvement in insomnia-related morbidity, is needed before one can define when appropriate therapeutic interventions should be initiated.

The diagnostic criteria for insomnia, both in terms of research diagnostic criteria17 and the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition,18 require a negative daytime consequence associated with the disturbance. The question arises as to whether having a severity or frequency criterion in defining the presence or absence of insomnia should be an important component of the diagnosis. Many investigators, as well as clinicians, believe that the clearest indication for the treatment of insomnia relates to the degree of functional impairment. In fact, it is this impairment that differentiates insomnia from “disturbed sleep.” There is 1 study that has demonstrated that the difference between insomniacs volunteering for research versus those seeking clinical attention relates to functional issues rather than nocturnal sleep characteristics.4 Thus, along with the evolution of diagnostic criteria for insomnia has come the incorporation of a functional impairment component to complement the nocturnal criteria as a way to enhance specificity and sensitivity in the identification of cases.

The results of the study by Lineberger and colleagues is also very interesting in that they demonstrate that mean sleep diary data across 2 weeks is as effective in insomnia detection as is looking at individual diary nights for frequency and or severity of sleep disturbance. Clearly, these data reject the often speculated idea that average sleep characteristics do not capture the nature of insomnia to the degree that nightly diary data do. More broadly, this study raises the question of what are the appropriate data source or sources to diagnose insomnia? Historically, clinicians and researchers have utilized 3 sources of information to diagnose insomnia. The first is a sleep history in which both quantitative and qualitative information about sleep and waking

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Address correspondence to: Dr. Christopher Drake, Pulmonary/Sleep Center, Henry Ford Hospital Sleep Center, 2799 West Grand Blvd., CFP-3, Detroit, MI 48202; Tel: (313) 916-4455; Fax: (313) 916-8167; E-mail: cdrake1@hfhs.org

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function are assessed from the patient’s perspective. Often, a second source is the use of sleep diaries over a period of time (typically 2 weeks), in which an estimate of nightly sleep is collected. Finally, in the sleep field we are able to measure sleep “objectively” via polysomnography. In a classic study, Carskadon and colleagues compared data from history, post-sleep questionnaires, and polysomnography and demonstrated that one frequently obtains contradictory estimates of sleep depending on which assay is used (e.g., overestimation of sleep latency by patient estimates compared with polysomnography). In that same vein, when clinical trials of insomnia treatment are performed, the inclusion criteria in terms of difficulty with sleep vary depending on the assay of sleep utilized. For example, when patient estimates are used, either history or sleep diary, the definition of difficulty falling asleep is typically set at a mean of 30 minutes, sometimes without regard to the weekly frequency of meeting this criterion. In contrast, most polysomnography trials, especially pharmacologic trials, use a cutoff of 20 minutes for latency to persistent sleep. Interestingly, in many trials, all of the criteria from each of these domains of assessment (history, diary, and polysomnography) are necessary for inclusion. In these trials, it very common to find that subjects meeting the patient-report criteria of 30 minutes fail to meet the polysomnography requirement of 20 minutes. Thus, not only do these assays of sleep provide different types of information about various aspects of the sleep disturbance (e.g., severity, frequency, chronicity), but there are systematic differences in estimates of severity, with the polysomnogram providing the most conservative estimate.

In the sleep field, we are fortunate in that we can measure sleep “objectively” as well as from patient estimates. Whereas many individuals ponder which is more important, an alternative is to consider them all important and ask the question of what one possible approach is to use a sleep history inquiring about various aspects of nocturnal and diurnal function as the primary diagnostic tool. The challenge then becomes to develop clinically relevant cutoffs for these various endpoints to make the diagnosis. This would make sense because the definition of insomnia is symptom based, and, hence, patient information is the most appropriate source for diagnostic information. Specifically, information about “difficulty” with falling asleep or staying asleep, rather than patient estimates of how long these parameters are, should be the primary diagnostic criteria. In contrast, estimates of nightly sleep from either sleep diaries or polysomnography may serve as appropriate measures of severity and treatment efficacy rather than provide diagnostic information.

The paper by Lineberger and colleagues is a significant contribution to the literature in that it both answers and raises important questions regarding the nature of insomnia. The important findings of mean values not being superior to individual night data for diagnostic purposes and the absence of clear severity or frequency cutoffs for insomnia diagnosis provide important new information. However, it makes us further question the relative importance of sensitivity versus specificity in insomnia diagnosis and leads us to ask what sources of information should be considered for what specific purpose when making the diagnosis and managing the disorder.

REFERENCES