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PRACTICAL APPROACHES TO DIABETES AND RELATED DISEASES

A SUPPLEMENT TO DIABETES SELF-MANAGEMENT

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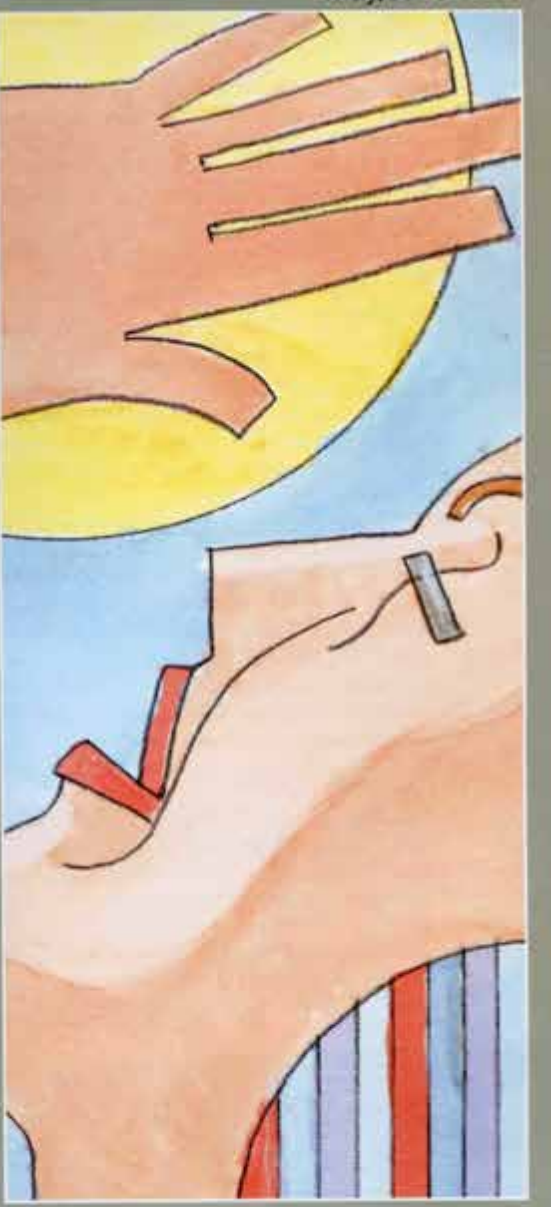

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Alternatives to the Sleep Lab

Viability of Home Testing for Obstructive Sleep Apnea

Liz Seegert, M.A.

A growing body of evidence has made it clear that a strong link exists between Type 2 diabetes and obstructive sleep apnea (OSA). The association demonstrated in numerous studies creates a potential need to screen millions of patients (1–3). Although diabetes can be identified with a blood test, OSA screening is more complex and historically has required testing in a sleep laboratory. However, long wait times, high costs, and lack of accessibility to facilities call for alternative approaches.

Home sleep testing (HST) is a viable option for detecting OSA. Several home monitoring devices have been shown to be as reliable, more cost-effective, and simpler to implement than in-lab screening (4–7). HST can facilitate testing for millions of people with diabetes and OSA by making testing more accessible, thereby reducing health-care costs and use and decreasing rates of morbidity (2, 8, 9).

Although in-lab testing still provides the most accurate monitoring of sleep disorders, the medical literature provides a host of guidance on the effectiveness of HST for specific patient populations, particularly when administered by professionals and coupled with patient follow-up. This article provides an overview of the connection between diabetes and OSA, the classifications of various sleep testing options, cost and reimbursement issues, certification and referral procedures, and the published clinical results of four popular HST devices.

The Connection Between Diabetes and OSA

OSA is characterized by repeated decreases in airflow or by desaturation; that is, apneic or hypopneic episodes (4). Essentially, when a sleeping person stops breathing or does not receive enough air, a reflex reaction causes him or her to wake up to take a breath, thereby disrupting normal sleep patterns. Common symptoms of OSA include loud snoring, frequent waking, and daytime sleepiness.

Recent scientific evidence indicates that sleep irregularities are an important factor in the onset and worsening of a range of glycemic disorders (3, 8). Although it is still uncertain whether diabetes exacerbates OSA or OSA aggravates diabetes, the link between the two is clear (3, 4, 10). Among patients known to have diabetes, nearly one-fourth will also have OSA, and up to 60% may have some form of sleep-disordered breathing (2). Many may have a sleep condition and not even know it. Experts estimate that OSA affects 12 million American adults, yet more than 80% of these individuals remain unaware of their condition (1, 9). In addition to the toll that OSA takes on individual health, the financial burden of untreated OSA is estimated at more than $3.4 billion per year in medical costs (1).

The International Diabetes Federation Taskforce on Epidemiology and Prevention, Healthy People 2020, and other organizations have called for improved management and cross-screening of both diabetes and OSA (1, 10, 11).

American Academy of Sleep Medicine Monitoring Guidelines

Considering this critical need to test patients for OSA, it is important to understand the categories of testing options available as described by the American Academy of Sleep Medicine (AASM).

Laboratory polysomnography. The reliability of in-lab sleep testing with polysomnography (PSG) makes it the gold standard in diagnosis. PSG should be performed when home screening is not feasible because of age, infirmity, or comorbid conditions. Additionally, patients with suspected sleep disorders other than OSA, or those who test negative for OSA but still exhibit clinical symptoms, may benefit from an in-lab PSG evaluation (4, 12). However, although PSG provides excellent clinical accuracy, it is costly and available facilities are few, which can result in delayed diagnosis.

Home sleep testing. The AASM has determined that under its clinical guidelines, HST can be considered as reliable and accurate as PSG conducted in sleep labs (4, 12). Specifically, HST can be incorporated into a broad program of patient assessment and management if conducted under the supervision of a certified sleep specialist (12). Patients with a high pretest probability of moderate to severe OSA make the most appropriate candidates.

Types of monitoring devices. The AASM provides specific parameters for using sleep-monitoring devices. Type I, or sleep-lab–based PSG, requires a technician and monitors at least seven channels, which include the following: heart rate, airflow, respiration, oxygen saturation, brain activity, and eye and muscle movements. Type II monitoring is approved for home use; it measures the same variables as Type I and provides accurate analysis but can be complex to set up in a home environment (6, 13).

Type III and IV monitors are the most commonly used in the home setting. They do not determine sleep stages or disruption, but infer the respiratory disturbance index (RDI) and/or apnea–hypopnea index (AHI). Type III devices measure four to seven channels. Type IV devices record one or more variables (4, 14).

Cost and Reimbursement

Despite the widespread adoption of standard AASM classifications, the American Medical Association (AMA) has recently indicated that it is moving away from this system, following the rapid introduction of new devices that are not neatly categorized. Instead, the AMA has endorsed the broader transaction codes (T-codes) for reimbursement purposes (6). However, the Centers for Medicare and Medicaid Services (CMS) continues to use the older G-codes, based on the AASM's four categories.

In fact, CMS recently announced that it will pay for the treatment of OSA diagnosed by Type IV devices that use at least three channels (15), opening the door for physicians to use HST for more patients. Because private carriers generally follow CMS' lead, they will likely use similar payment guidelines for home sleep testing reimbursement. Several of the country's largest insurance carriers already provide reimbursement for home sleep testing, and other payers are modifying their coverage to align with CMS guidelines and take advantage of cost savings. The cost differential is substantial: Lab-based PSG can cost $1,600 to $5,000, while in-home testing averages $300 (8).

Test Administration

A comprehensive pretest evaluation by a trained physician helps to determine whether a patient qualifies for home sleep testing. The Portable Monitoring Task Force of the AASM calls for clinical monitoring to be conducted only by a board-certified sleep specialist, trained technologist, or practitioner who meets sleep medicine certification criteria (12). This requirement ensures that the person administering the test has the skill set needed to understand symptoms, interpret results, and place data within the framework of the patient's medical history. A skilled technician or provider directly applies the sensors or educates the patient on their placement.

In the United States, the American Board of Internal Medicine administers the Sleep Medicine Certification Program for its physicians, as well as for those accredited by the American Board of Family Medicine, the American Board of Pediatrics, the American Board of Psychiatry and Neurology, and the American Board of Otolaryngology. The certification normally involves at least 12 months of specialty training and/or practice and is recognized by the American Board of Medical Specialties (16).

AASM recommends that primary-care physicians and endocrinologists not certified in sleep medicine refer patients who have a history of snoring, apneic episodes, or excessive daytime sleepiness to sleep specialists. Use of the Epworth Sleepiness Scale and/or Berlin Questionnaire, in addition to a clinical examination, will help to document pretest probability for OSA and determine the need for referral (1).

Type III and IV Devices for Home Testing

For patients who quality for home sleep testing, there are several devices on the market that have demonstrated effectiveness in clinical trials.

ARES. The apnea risk evaluation system (ARES™) is a Type III device that compares extremely well with in-lab PSG (7, 17). ARES measures blood oxygen saturation, pulse rate, airflow and respiratory effort, snoring levels,

head movement, and head position using a monitor attached to the patient's forehead, pulse oximetry, a small microphone, and an accelerometer. Raw data are uploaded to the manufacturer's Web site and analyzed with a proprietary algorithm to rule in OSA. A physician can also manually score the data. Studies have shown ARES to be a viable, lower-cost alternative to traditional PSG (7).

Westbrook and associates (17) evaluated the accuracy of the ARES in two sleep centers and in participants' homes compared with in-lab PSG. ARES detected OSA and accurately estimated its severity in subjects in a non-laboratory setting. Researchers found the device's automated scoring capability a huge cost advantage compared with attended PSG. They anticipated that costs would be one-half to one-third lower for two nights of ARES monitoring as compared with traditional nighttime PSG (17).

A later investigation by Westbrook and colleagues (7) matched results from ARES and another Type III monitoring device, NovaSom, with PSG. Both HST devices provided accurate and effective results comparable to traditional PSG in the study cohort (7, 17). To and associates (18) found similar results in a validation study conducted among patients in Hong Kong. The sensitivity and specificity of ARES resulted in a high predictive value for patients with moderate to severe OSA. The authors suggested that ARES would be most appropriate among individuals who already present with symptoms.

ApneaLink. The ApneaLink™ is a Type IV device that has shown high sensitivity and specificity for subjects with moderate to severe OSA compared with those referred to a sleep center (12, 16). This single-channel device measures airflow through a nasal cannula attached to a pressure transducer. It provides an AHI based on recording time and analyzes data through its own software, or provides raw information to the physician for rescoring. In a study of adults with Type 2 diabetes, ApneaLink was found to be a highly sensitive and specific clinical tool; results were consistent with previous comparisons to PSG (14).

Erman and coauthors (9) found similar outcomes when comparing AHI from the ApneaLink with sleep-lab PSG in a study of 59 patients with Type 2 diabetes. The investigators concluded that the device could recognize significant levels of sleep apnea, if present. Using the ApneaLink or similar devices may lead to increased opportunities for evaluation of OSA in patients with moderate to severe disease and improve care, treatment, overall health, and quality of life for these patients (9).

Watch-Pat100. The Watch-Pat100 is a self-contained Type IV device worn on the wrist. It uses a noninvasive finger-mounted probe to measure peripheral arterial tone, oxygen saturation, and heart rate. An actigraph records sleep–wake states (13). In the first study of its kind to validate the device in home environments with a general population sample, the Watch-Pat100 demonstrated reasonable accuracy compared with simultaneous unattended PSG. Zou and colleagues (13) found a strong correlation between indices of AHI, RDI, and oxygen desaturation. They concluded that the Watch-Pat100 fulfills a clinical need for simplified home recording techniques for OSA (13). The manufacturer recently introduced an updated device, which measures additional channels.

Holter oximetry. Holter oximetry combines two assessment tools—an electrocardiogram and a pulse oximeter—into one Type IV device. It provides physicians with a timeline in 30-second intervals of either "normal" or "sleep-disordered breathing" and an AHI. Several studies have found that the combined recordings accurately evaluated suspected OSA in patients at home.

Heneghan and coauthors (19) compared Holter oximetry with both PSG and with stand-alone oximetry. Both oximetry systems used the same pattern-recognition process that detects decreases in oxygen saturation typical of OSA. Holter oximetry compared well with in-lab PSG analysis, identifying all episodes of sleep-disordered breathing for every subject, although with less sensitivity than PSG. Holter oximetry also proved superior to the oximetry-only system because it could continue to analyze data regardless of pulse oximeter signal limitations. The investigators concluded that this system could offer multiple benefits for assessing sleep apnea in the general population and in specific patient groups (19). Finally, Stern and associates (20) noted that Holter oximetry has an extremely simple setup and represents an exciting new model of OSA screening in the unattended home setting.

Summary

Given the mounting evidence that sleep disorders seriously affect blood glucose regulation, studies suggest that patients with diabetes, in particular, may benefit from HST to better manage the condition (2, 3, 5). It has also been found that many patients suffering from OSA have diabetes or prediabetes. Promptly cross-screening more patients in these populations will help meet several Healthy People 2020 and other global public-health objectives. Home monitoring devices present a viable alternative for initial screening of many suspected cases of OSA (3), potentially reducing medical costs, improving glycemic control, and mitigating life-threatening complications.

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