VASM position regarding use of Portable Monitoring (PM) in diagnosis of Obstructive Sleep Apnea (OSA)

Introduction

PM is an emerging technology in the diagnosis of OSA. It is an appropriate alternative to in-laboratory polysomnogram (PSG) in carefully selected patients who have a moderate to high clinical likelihood of OSA and absence of significant comorbid conditions. It has been studied recently mostly in Veterans Administration settings, where long delays of 6 months or more to see a sleep specialist or get a sleep study were encountered. Objective data to date that support the use of PM has been obtained in the setting of comprehensive sleep programs integrated with thorough clinical evaluations by trained sleep specialists who understand the limitations of the tests and are prepared to manage the evaluation process and integrate results into a meaningful treatment plan. In most of the studies, specially trained technicians applied the sensors, resulting in much less data loss (7% of studies) as compared to that when patients apply the sensors independently at home (33% of studies).[1] In some studies, the technician directly educated the patient on sensor application. The raw data in these studies was reviewed by a trained sleep professional to ensure validity of test results. These steps are important to avoid poor clinical outcomes in patients with sleep apnea, such as failure to diagnose properly (both false positive and false negative test results) and non-adherence to treatment. It has been demonstrated that treatment outcomes are superior in patients evaluated and treated in comprehensive sleep programs when compared to those who are not. [2]

There are standards for PM established by the American Academy of Sleep Medicine to ensure proper utilization of this technology[3]. However, in Virginia there has been a recent proliferation of devices and increasingly aggressive marketing of these devices by the manufacturers to non-sleep professionals, with encouragement of practices that do not meet these standards, driven by profit motivation. A large HMO is aggressively promoting use of the devices for its participants while bypassing a thorough clinical evaluation (a "simple clinical survey" is suggested) and the instructions for application of sensors are sent in

the mail. Many devices entering the community do not meet appropriate technical standards. Some do not allow data to be reviewed by a sleep specialist trained in interpreting the results. Some promote that data review by a trained sleep professional is possible, but unnecessary. (Some have such high cost per study for testing materials that providers opt to omit the sleep specialist's services to maximize profit after overhead, and no physician reviews the raw data.) Some providers are charging cash as though the service is not covered by insurance. Studies are being requested without a thorough sleep evaluation, and in patients without high pretest probabilities or with comorbid conditions that need attended polysomnography to evaluate properly. These practices will result in both false positive and false negative results, poorer patient outcomes, and in the long run are not cost efficient due to inappropriate ordering of tests on a large scale.

In many states, standards are in place to ensure that this new technology is not abused. The Virginia Academy of Sleep Medicine hereby proposes standards also be implemented in our state for the benefit of our citizens. Virginia has ready availability of sleep medicine expertise including AASM accredited sleep centers, board certified sleep medicine specialists, and polysomnographic technologists who will soon be licensed by the state. We have the resources to ensure appropriate use of this technology.

The Virginia Academy of Sleep Medicine, in accord with the American Academy of Sleep Medicine standards for Out of Center Sleep Testing (OCST)[4] proposes the following **Guidelines** for use of portable monitoring for the diagnosis of sleep apnea in the state of Virginia:

Indications:

1. PM may be used as an alternative to polysomnography for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. Portable monitoring is not appropriate for the diagnosis of OSA in patients with significant co-morbid medical conditions that may degrade the accuracy of PM, including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, and congestive heart failure. In lab PSG remains the standard for patients with significant co-morbid medical disorders.

2. PM is not appropriate for the diagnostic evaluation of OSA in patients suspected of other sleep disorders, including central sleep apnea, PLM

(periodic limb movement) disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy.

3. PM is not appropriate for general screening of asymptomatic populations.

4. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness.

5. PM may be indicated to monitor the response to non-CPAP treatments for OSA, including oral appliances, upper airway surgery, and weight loss.

Technology for PM

1. The PM equipment must meet the minimum definitions described in at least one of the CPT codes 95800, 95801, or 95806:

    - 95800 Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg by airflow or peripheral arterial tone), and sleep time.

    - 95801 Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis, (eg by airflow or peripheral arterial tone)

    - 95806 Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg thoracoabdominal movement)

2. Technical personnel must be appropriately trained and supervised, and, and where required by law, licensed to perform sensor application and/or patient education to assure the patient's safety and understanding of the test.

Data Acquisition, Scoring and Reporting

1. PM reports must include at minimum: RDI (estimate of apneas and hypopneas per unit time), evaluation of oxygen saturation during recoding period; recording duration of test, and technical adequacy of test.

2. Scoring personnel should be sleep technicians, sleep technicians with board certification, respiratory therapists with sleep disorders specialist certification, or electroneurodiagnostic technicians with additional sleep certification.

3. Equipment must provide an RDI based on measures that approximate an AHI based on full polysomnography. Equipment must also measure oxygen saturation and heart rate and meet the criteria for the codes designated above and meet the criteria for the above codes. Equipment must allow for the display of raw data for manual scoring or editing.

4. If computer assisted scoring of PM recordings is used, it must be reviewed and edited for accuracy by a board certified sleep physician.

5. The board certified sleep physician interpreting a PM study must conduct an epoch by epoch review of the entire raw data recording for every study interpreted. The review of the data must assure that the quality of the recording and the scoring of sleep and associated events is sufficient to allow for interpretation. Signed attestation of this review must be kept in the patient record in the form of a signature or on the report of the test.

Patient Evaluation and Care

1. Patient Management. A follow up in person visit with a physician, nurse practitioner, or physician assistant must be performed on all patients undergoing PM to discuss the results of the test and treatment options. Appropriate follow-up for patients who require continued management must be available from the testing entity or by referral.

Options for treatment of OSA found during PM may include:

a) Referral to a comprehensive sleep center for a PAP (positive airway pressure) titration or split night study;
b) APAP (autotitrating positive airway pressure) home trial, and
c) Determination of an alternate to PAP therapy.

2. Post-test follow up and management. Technical failures due to equipment malfunction must be documented and the study repeated. In center polysomnography must be recommended in cases where PM fails to establish the diagnosis of OSA in patients with a high pretest probability.

3. Documenting patient evaluation and management. Medical staff must document ongoing evaluation and management of patients with sleep disorders. This documentation must be part of the patient's medical record.

4. PAP titration or therapy initiated must be conducted in accordance with the standards described in the current AASM practice parameters.

5. Patients being treated with fixed CPAP on the basis of APAP must have clinical follow up within 30 days of initiation of therapy. If symptoms do not resolve or if treatment does not appear effective, a standard attended PAP titration must be performed. If the patient does not accept or adhere to therapy following an APAP trial, they must have an evaluation with a sleep specialist.

6. Patients prescribed positive airway pressure treatment must be offered a follow-up appointment within 12 weeks of treatment initiation. Assessment must include a measurement of treatment use and clinical response, done by direct patient inquiry, office visit, telephone inquiry, or downloaded compliance data from the patient's machine.

Ethical Statement

Clinicians should not charge or collect excessive fees.[5] In relation to PM, this precludes clinicians participating with insurance plans from collecting payment in advance from insured patients that exceeds what insurance would contractually pay with the intent of circumventing contractual payment. The clinician may not inform the patient that this service is "not covered" when it is. There should not be misuse of codes such as 95806 which include interpretation payment when no qualified physician has reviewed the raw data to be accurately signing their name to a computer-generated interpretation.

Summary

PM is an emerging technology in the diagnosis of OSA that can be useful if ordered and interpreted correctly. It also has the potential for abuse if standards for use are overlooked due to lack of expertise or drive for financial gain, and we are seeing this already in Virginia. All studies supporting its use were done within comprehensive sleep programs where recognition of test limitations and resources to ensure proper diagnosis and follow up were available. We recommend that home sleep testing in Virginia be performed in accordance with

AASM standards, including (1)appropriate selection of patients with high pretest probability of sleep apnea in the absence of comorbid conditions, (2) that the patient's sensor application be done or instructed by an appropriately trained technician, (3) that an appropriately trained technician score the data, or review autoscored data, (4)that all raw data be reviewed and an interpretation done by a board certified or board eligible sleep physician. We further suggest standards for follow up care and patient education that are paramount to successful therapy for OSA. Conventional polysomnography is recommended for patients who test negative but have a high pretest probability of OSA, and on patients who do not respond to therapy that was based on PM results. Early referral to a sleep specialist is encouraged if there are difficulties encountered in patient management to improve therapy outcomes.

We have the resources in Virginia to ensure quality care for our citizens with obstructive sleep apnea, and steps need to be taken to minimize abuse of available technology and failure to diagnose and treat appropriately and within ethical standards.

References:

1. Golpe R et al. Home sleep studies in the assessment of sleep apnea/hypopnea syndrome. Chest 2002.

2. Parthasarathy, S, Journal of Clinical Sleep Medicine, 2006

3. Standards for Accreditation of Out of Center sleep Testing (OCST) in Adult Patients, AASM website 2011

4. Code of Medical Ethics of the American Medical Association, section 6.05.