

White Paper

Primary Care and Sleep Apnea Testing: A Pilot Study for Home Testing with SleepView®

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EXECUTIVE SUMMARY

Obstructive sleep apnea (OSA) is a substantial health problem. Patients with OSA are at significantly higher risk for developing hypertension, diabetes, heart disease, obesity and sudden death. Despite a high prevalence for OSA in all primary care practice populations, too few patients are screened for the disorder and fewer are tested. The gold standard and most common modality for achieving a diagnosis for OSA has traditionally been the in-lab polysomnogram (PSG). Yet, home sleep testing equipment and methodologies have been shown to be of comparable efficacy, are lower cost and can be effectively administered by primary care physicians.

Background

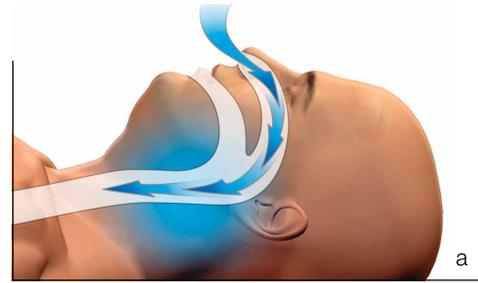
Every day, thousands of patients are seen in primary care offices for routine disease management visits for hypertension, diabetes, heart disease and obesity. To determine how the patient is doing, careful attention is given to the patient's laboratories and physical findings. These indicators include the patient's systolic and diastolic blood pressure numbers, the current hemoglobin A1C levels, changes in cholesterol ratios or elevations in BMI. Optimizing these parameters continues to be the current standard of care for ensuring a favorable clinical outcome. But what about measuring the patient's RDI (respiratory disturbance index), a ratio used to assess severity of OSA? Like poorly controlled common metabolic indicators used for chronic disease management, an abnormally high RDI is strongly linked to adverse outcomes and progression to one or more of the major chronic diseases. It has been established that sufferers of sleep apnea have a 60% increased risk of developing heart failure, a 200% higher likelihood of developing a stroke, 300% increased chance of resistant hypertension and a dramatic 400% increased risk for developing atrial fibrillation.² Taken together, all-cause cardiovascular mortality is nearly twice as high for patients suffering from untreated moderate or severe sleep apnea.²

OSA is a significant health problem that too often goes unrecognized in primary care. Up to 90% of patients with significant sleep apnea remain undiagnosed today. This is unfortunate since patients treated for OSA show lower rates of complications from the associated chronic diseases within the metabolic syndrome.

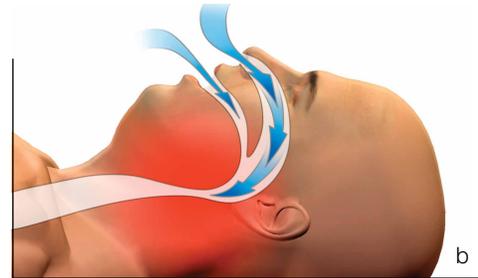
Despite OSA being a largely undiagnosed problem, patients do admit to having problems with their sleep. A study done by James Mold from the University of Oklahoma Health Sciences Center showed that nearly 90% of all adult patients visiting a primary care clinic on any given day are actively experiencing sleep related symptoms. Yet, most fail to discuss their sleep-related symptoms with their physician and therefore are never evaluated for any sleep disorder. Nearly 1/3 of these unidentified and untested patients are actually at high risk for sleep apnea. Studies suggest that a large percentage of high-risk patients will subsequently test positive for OSA in a diagnostic study.

Today, patients of primary care physicians with clinically recognized symptoms of sleep apnea are most often sent to a sleep lab for evaluation. This method has proven to be an excellent work-up pathway for many years. Primary care clinicians know that while at the sleep lab, their patients will likely undergo a full diagnostic polysomnogram study (PSG). If the PSG is positive for OSA, their patients are often provided an immediate and appropriate treatment modality, such as continuous positive airway pressure therapy (CPAP).

But, with the advent of home sleep testing (HST), is prescribing an in-lab PSG now necessary for the majority of primary care patients suspected of OSA? Could the primary care physician rather than



Patients normally have an open airway during sleep, allowing respiration to occur freely.



Obstructive sleep apnea occurs when the airway is repeatedly blocked by relaxed soft tissue in the throat and neck.

the sleep specialist become the primary caregiver responsible for coordinating care including the diagnosis and treatment of routine sleep apnea? Primary care physicians are the primary caregivers for the other chronic disorders in the metabolic syndrome such as diabetes, hypertension and heart disease. It seems natural that OSA could be added to the list of conditions commonly managed by these front line providers.

New technologies on the market for home sleep testing represent an attractive new option for diagnosing sleep apnea outside the sleep lab. Portable monitors designed for the home environment lower the complexity and costs for achieving a reliable diagnosis of OSA. The latest technologies are affordable and can now leverage the diagnostic support of sleep specialists using the Internet. This specialty-assisted model represents an attractive option that allows the primary care physician to take the role of the principal investigator and manager of OSA related conditions.

In recent years, the technology utilized for assessing sleep apnea in the home has made remarkable advances. Some HST devices now fit in the palm of one's hand. One of the most advanced devices on the market is the SleepView® Monitor which is capable of simultaneously measuring seven independent sensor channels during sleep. When compared to the corresponding channels found in a full PSG study, the SleepView® Monitor has been shown to exhibit a high diagnostic correlation for the key indicators of OSA. Developed by Cleveland Medical Devices Inc. (CleveMed), SleepView® has been cleared by the FDA for home studies. SleepView® was designed using the

guidelines provided by the American Academy of Sleep Medicine.

Unlike many other devices, the SleepView® system is integrated with an online service platform (portal) that adds valuable diagnostic functionality. Once the SleepView® Monitor is connected to a portal-enabled computer, the clinician is supported with full test interpretation services. Within the secure HIPAA compliant web-based SleepViewSM Portal, the ordering physician gains the advantage of remote test data validation and review by registered sleep technologists, a highly developed algorithm-assisted test scoring process, test interpretation services by board-certified sleep physicians licensed in the state where the HST took place, online test setup and scheduling, and full study data management utilities. These services are aimed to support the primary care physician in the evaluation and management of patients with sleep disorders.

HST as a preferred method for diagnosing OSA patients is growing. Improvements in accuracy and enhanced remote interpretive support methodologies have increased confidence in HST as a

viable alternative to in-lab PSG in many cases. Most of the major insurance carriers, including The Center for Medicare and Medicaid Services (CMS), have approved the use of HST within ambulatory care offices. Over time, many experts expect home sleep testing to become the most common method for evaluating sleep disordered breathing in low to moderate complexity patients. The advantages seen by payers include lower testing costs, improved patient convenience and improved patient access to reliable diagnostic studies. Enabling the primary care workforce to manage a broader spectrum of health conditions at lower costs to the system is also seen as a favorable outcome for HST. Insurers are also studying the effects widespread home sleep testing may have on reducing the number of patients suffering from major chronic diseases that can be triggered by untreated OSA. Patients with chronic diseases associated with chronic obstructive sleep apnea currently consume the majority of today's dollars.

Testing the SleepView® home sleep test in primary care offices

To demonstrate efficacy and effectiveness of the SleepView® system for diagnosing OSA within a primary care setting, pilot programs were recently completed at four clinical sites. The test site physicians for the SleepView® pilot included:

- Dr. Barrett Tilley of Medical Associates in Fremont, California
- Dr. Rodney Orr of Family Medical Group in Silverton, Oregon
- Dr. Stewart Segal of Lake Zurich Family Treatment Center near Chicago, Illinois
- Dr. Berto Zamora of Z&Z Medical Associates in Dallas, Texas

The goal of establishing the reference accounts was to test three hypotheses regarding the integration of SleepView® home sleep

testing within primary care. The hypotheses were:

- 1. Patients are more willing to complete a home sleep study versus an in-lab polysomnogram.**
- 2. The test is easy to administer for physicians and patients. Primary care physicians can effectively manage the entire testing process. Patients can effectively self-administer a home study with few test failures.**
- 3. HST is effective as a standalone study for OSA disease management including, if necessary, direct CPAP titration without a follow-up PSG study.**

This paper examines the effectiveness of incorporating the SleepView® HST monitor within primary care as an office-based diagnostic study for evaluating patients at-risk for OSA. Three hypotheses regarding integrating HST were tested in a SleepView® pilot study conducted in 2011.

Methods

The reference site physicians and their staff were not informed of these three hypotheses prior to the testing period. Rather, upon receiving a set of SleepView® Monitors, each physician was simply asked to implement home sleep testing as part of their normal care delivery process. They were given training on the Epworth and STOP-BANG screening tests—inventories that are commonly used to identify patients at-risk for OSA. Training was provided on using

the SleepView® Monitor, the secure SleepViewSM Portal and method for providing patient instructions. Each account required just a few hours of training.

A total of 60 studies were accomplished during the five-month pilot study (see Table 1 below).

| | Lake Zurich | Silverton | Fremont | ZZ Medical |
|--|-----------------|---------------|-----------------|-----------------|
| Subjects (N) | 18 | 20 | 12 | 10 |
| Gender (M,F) | 14,4 | 8,12 | 11,1 | 9,1 |
| Age (mean ± sd) | 54.6 ± 14.2 yrs | 49.2 ± 11 yrs | 50.1 ± 11.1 yrs | 51.5 ± 13.9 yrs |
| BMI (mean ± sd) | 30.1 ± 8 | 33.5 ± 6.7 | 28.7 ± 5.9 | 37.8 ± 11.3 |
| RDI (mean ± sd) | 16.9 ± 14.2 | 11.95 ± 10.5 | 29.6 ± 27.4 | 28.3 ± 26.12 |
| ESS (mean ± sd) | 7 ± 4.1 | 12 ± 4.8 | 7.4 ± 7.2 | 10 ± 6.5 |
| Total rec. time (mean ± sd) | 400 ± 120 min | 410 ± 102 min | 329 ± 107 min | 353 ± 92.7 min |
| Number of OSA positive | 14 | 17 | 9 | 8 |
| Number of OSA negative | 3 | 3 | 2 | 2 |
| Number of inconclusive HST | 1 | 0 | 1 | 0 |
| Turnaround time for Specialist Report (avg.) | 1.2 days | 1.35 days | 1.6 days | 2.8 days |

Table 1: Summary of Reference Account HST Activity

Results

The results of the five-month study demonstrated that the three hypotheses were confirmed at all four test sites. We will discuss each hypothesis in more detail below.

Hypothesis #1

Patients are more willing to participate in diagnostic study using HST as compared to in-lab PSG.

Discussion

Until recently, PSG was the only clinical test available to determine the presence, type, and severity of OSA. Yet,

the practice of evaluating symptomatic patients via a sleep lab referral for a PSG study is problematic for many patients. It is anticipated that nearly 30% of patients scheduled for an in-lab polysomnogram fail to show up on the test night. Some refuse to go for cost reasons, others cite the inconvenience and still others may be in denial or choose not to go after the typical multi-week delay between test scheduling and PSG administration. Home sleep testing represents

a new alternative for achieving a reliable diagnostic study that may mitigate some of these concerns.

The first hypothesis of the pilot project was to determine if primary care physicians could more effectively encourage their at-risk patient to have the home SleepView® test over an in-lab PSG.

Results for hypothesis #1

The four SleepView® pilot sites demonstrated that a large majority of patients identified as at-risk for OSA by their physicians were willing to complete a home study. For most of the physicians, this response differed from their past experiences of referring patients for in-lab PSG. Simply stated, arranging a home sleep study was an easier task than convincing patients to go to the sleep lab. The reasons cited by the physicians for increased patient willingness to conduct an HST over PSG can be summarized in three areas—significant cost savings for the patient, added convenience of testing at home, and immediate testing capability of HST (versus waiting several weeks for an in-lab PSG).

Dr. Orr and his colleagues commented that the cost savings found with HST over PSG was especially important in achieving a sleep diagnostic study on their patients. Dr. Orr's office completed 20 studies during their pilot. Several in the home study cohort had previously refused an in-lab PSG. According to Dr. Orr, "The simple convenience of HST takes a backseat to the affordability of diagnostic testing."

The physician's ability to order a home sleep study on the very night of the office visit proved to be a valuable asset. With the ability to achieve a diagnostic study immediately after identifying an at-risk individual, more patients agreed to be tested. As stated by Dr. Segal, "The simple words, 'we can test you tonight at your own home' as opposed to 'we can test you in two weeks at the sleep lab' proved to be highly influential in getting the patients to agree to a test." He continued, "When I said those words about having the test done immediately and at home, fewer patients objected."

All the physicians found their existing and ongoing relationship was a useful asset for encouraging home testing. All the physicians felt that having the diagnostic study available within their office, as compared to the less familiar sleep lab, lowered the resistance to completing a study. Dr. Tilley noted, "The biggest advantage with the SleepView® program is that I have another way to gain important clinical information on my patients right from my office. My patients gain because they learn of their clinical situation regarding sleep apnea from the person they have a trusting relationship with—their primary care physician."

In general, the experience of our physicians verified that achieving a diagnostic study for OSA was improved by the incorporation of SleepView® into their care delivery process. None of the physicians encountered much resistance by their patients when asked to directly participate with a self-administered monitor at home. While anecdotal, we believe the pilot supported the hypothesis that HST with SleepView® markedly improved patients' participation in OSA evaluation when compared to in-lab PSG.

Hypothesis #2 (Part 1)

The test is easy to administer for physicians and patients.

Part 1- The physicians can effectively manage the testing process.

Discussion

Unlike existing medical devices used in their primary care settings, the SleepView® had features and a workflow that were initially unfamiliar to the pilot physicians and office staff. Most medical devices in the market today (such as the ECG, spirometer, and Holter monitor) utilize an internal computer algorithm that produces an immediate diagnostic report after the sensor data is acquired.

The SleepView® device employs a new and more rigorous process for analyzing the sensor data. Rather than relying on an isolated algorithm resident in the device or on the attached computer,

SleepView® incorporates an online portal system that extends the diagnostics process to remotely situated sleep specialists. With SleepView®, registered sleep technologist scoring and board-certified physician interpretation is provided for every study. This virtualized support mechanism is unlike any other office-based study our physicians had previously encountered.

When the patient completes a test, the monitor is returned to the physician's office where the data is uploaded to a secure SleepViewSM Portal. A registered sleep technologist reviews the multiple sensor waveforms and validates the quality and length of every overnight study. If deemed scoreable—a preliminary report is generated with the help of a sophisticated scoring algorithm. This report is forwarded to an in-state board-certified sleep physician for final review. The physician reviews the waveform data and records an official electronically signed diagnosis within the portal. This final report is then sent to the primary care physician for review with the patient.

This Internet-enabled workflow for SleepView® required new skills for the pilot physicians. As a result, it was necessary to test how well such a process could be integrated within the routine of a typical medical office. Would the process prove to be overly cumbersome?

How difficult was it to transfer the monitor data to the portal system?

Results for hypothesis #2 (Part 1)

The results of the pilot demonstrated that all the sites became quickly adept at managing the new device data workflow requirements. Each of the four offices had little difficulty ordering tests online, setting up their monitors for each patient study and downloading completed reports from the SleepViewSM Portal. Most physicians found the process to be easy to follow and quite effective. In fact, several physicians commented that the portal is one of the best features of the SleepView® system. One physician commented "It was like getting a sleep physician consult without having to send the patient." Another commented on the high confidence he experienced regarding the diagnostic credibility and reliability of the process.

During the pilot, the four pilot sites completed a total of 60 studies (Table 1), all of which utilized the process described above. The studies were uploaded to the portal were scored and interpreted within the SleepView® system. Results show that only 2 out of 60 studies (3.3%) were inconclusive and required an-lab PSG for confirmation (80% positive OSA, 16.7% negative OSA). The average turnaround from time of data upload to when the primary care physician received a final report was between 1.2 and 2.8 days for each office.

The pilot confirmed that the physicians and their staff had little difficulty with the workflow requirements of SleepView® and were pleased with the turnaround time and diagnostic expert support provided by the portal.

Hypothesis #2 (Part 2)

The test is easy to administer for physicians and patients.

Part 2- Patients can effectively self-administer their home study with few test failures.

Discussion

During an in-lab polysomogram, a staff of sleep technicians manage the sensor hook-up and monitor the nighttime study. The staff corrects any test-related issues that arise during the overnight recording period. With home sleep testing, these tasks are left for the patient to administer. While SleepView® is certainly less complicated than a PSG, it was important to verify that patients were able to successfully complete a diagnostic SleepView® study without direct supervision by medical staff.

Results for hypothesis #2 (Part 2)

A total of 67 studies were conducted; 60 scorable studies (89.6%) and 7 unscorable studies (10.4%). Studies deemed scoreable were often due to sensor misplacement. However, it is clear that the number of test failures diminished greatly after the first four studies were completed. We attribute this significant improvement in performance of SleepView® to better familiarity with the equipment and enhanced training techniques employed for patients. The failure rate for tests completed after the initial 4 studies was just 7.8% (Table 2).

| Pilot Site | Total Test | Failed tests first 4 patients | Failed tests thereafter |
|-------------|------------|-------------------------------|-------------------------|
| Lake Zurich | 18 | 0 (0%) | 1 (6.7%) |
| ZZ Medical | 12 | 1 (25%) | 1 (12.5%) |
| Fremont | 15 | 1 (25%) | 2 (18.2%) |
| Silverton | 21 | 1 (25%) | 0 (0%) |
| TOTAL | 67 | 3 (18.8%) | 4 (7.8%) |

Table 2: Test Failure Data

With over 92% of patients achieving successful studies at the end of the reference account study period, we determined that patient-directed home sleep testing with SleepView® is a valid and reliable diagnostic modality for OSA. For the two reference accounts where the most studies were performed (Lake Zurich and Silverton), the failure rate after the first 4 tests dropped to 3.1%. There were no failures during the last four studies of the pilot.

Hypothesis #3

HST is effective as a standalone study for OSA disease management including, if necessary, direct CPAP titration without a follow-up PSG study.

Discussion

An issue raised about home sleep studies in the past has been the concern that the clinical data generated from a patient self-

administered test would be insufficient to impact therapeutic decisions. If each patient found to have OSA on HST requires a subsequent PSG to confirm the diagnosis, its value as a cost saving and effective diagnostic tool would be marginalized. A goal of the pilot study was to determine if a patient diagnosed with OSA on HST could be effectively managed and treated without the frequent requirement of a follow-up in-lab PSG evaluation.

Results for hypothesis #3

The results demonstrated that HST is an effective diagnostic modality for clinical decision-making, including the initiation of CPAP (Continuous Positive Airway Pressure) therapy. As mentioned before, the majority of tests (80%) performed at the pilot sites confirmed the presence of OSA, 16.7% negative and only 3.3% that required a repeat in-lab evaluation. The pilot clearly demonstrated that the vast majority of HST studies were of sufficient quality for full clinical decision making without the need for repeat in-lab testing.

| Therapy | Number | Percentage |
|------------------------------|--------|------------|
| CPAP Titration | 25 | 52.0% |
| Lifestyle/Obesity Management | 5 | 10.4% |
| Oral Appliance Therapy | 3 | 6.3% |
| Referral to ENT Specialist | 3 | 6.3% |
| Referral to Sleep Lab | 1 | 2.1% |
| No Therapy | 4 | 8.3% |
| Unknown/Undisclosed | 7 | 14.6% |

Table 4: Therapeutic Choice Summary

* CPAP Titrations done at local sleep labs

The physicians diagnosed a total of 48 patients with OSA during the pilot study. About half were subsequently prescribed CPAP therapy (see Table 4). All the patients receiving CPAP were referred to their local sleep lab for titration. This decision was an independent choice by each provider. No therapeutic guidance was provided by the study organizers. 12 percent were provided primary care directed weight loss and lifestyle modification counseling while 8 percent were referred to specialists for additional care. This included one referral for tonsillectomy.

The capability of initiating CPAP therapy directly from HST without a subsequent in-lab PSG can lower the overall cost of care for patients. Exact reimbursement payments for this pilot are not available; however, if one uses CMS national average reimbursement rates, the pilot would demonstrate at 70.4% reduction in diagnostic testing costs to the patient and insurer. This amounted to \$29,334 savings for the near 60 patients tested (see Table 5).

The efficiency gains and cost savings of HST over PSG in this pilot study were key findings of the SleepView® pilot. With recent studies indicating a similar outcome for patients treated with Automatic

PAP (APAP) machine versus conventional CPAP, the cost savings for therapy would be even greater had the patients in this study progressed directly to APAP therapy as opposed to in-lab CPAP titration.

| Venue - Traditional diagnosis | Cost per Test (CMS national rate) | Number of Studies | Total Expenses |
|--|-----------------------------------|-------------------|----------------|
| Sleep Lab PSG | \$694.14 | 60 | \$41,648 |
| Venue - HST | Cost per Test (CMS national rate) | Number of Studies | Total Expense |
| SleepView® HST | \$182.11 | 60 | \$10,926 |
| Inconclusive HST that require in-lab PSG | \$694.14 | 2 | \$1,388 |
| TOTAL | 0 | 0 | \$12,314 |
| Total Savings | | | \$29,334 |
| Percentage Savings | | | 70.4% |

Table 5: Cost Savings Analysis

In addition to CPAP therapy, the primary care physicians in the study found that sleep diagnostics using SleepView® was a natural fit within their comprehensive chronic disease management programs. While CPAP therapy was the therapy of choice for many of the patients diagnosed with OSA, on several occasions the physicians preferred less invasive therapies such as referral to ENT for oral surgery consideration, referral to a dentist for oral appliance fitting or weight loss and exercise programs. The breadth of therapy options exercised by the PCP in our pilot confirms the successful role of the PCP as a care coordinator for OSA management. The physicians in the pilot program found that their interventions for newly diagnosed OSA were synergistic with their treatments for other chronic diseases, such as diabetes and hypertension.

Perhaps the most illustrative reference account for the successful incorporation of OSA management within primary care was found with Dr. Tilley. He found managing OSA within primary care to be a natural extension of his practice. Dr. Tilley, "I know my patients' lifestyle issues, their problems, and support systems and can therefore make a more significant impact on initiating a best therapeutic approach—one tailored for each patient. Many times, this involves a weight loss program, something I frequently use with my diabetic and hypertensive patients. With the family physician involved in home sleep testing, he argued that the patient benefits greatly by having a consistent and cost effective management plan for all their conditions." He continued, "I see OSA as being analogous to those other disorders; that is why family docs need to be doing this."

Once diagnosed with OSA using SleepView®, Dr. Tilley found that his management of the patient was improved as compared to his previous experiences following referrals to the local sleep lab. Instead of immediately resorting to therapy with CPAP, Dr. Tilley

chose to counsel his patients on the significance and meaning of the test results before he began discussing or initiating any type of therapy. He informed them of their many options, including weight loss, oral appliance therapy or CPAP. His more severe OSA patients, those who were unlikely to benefit from conservative treatment, were immediately directed towards the sleep lab for initiation of CPAP therapy. Most of the study physicians were pleased to find that their local sleep lab was willing to proceed to CPAP titration from the HST data without requiring the patient undergo second PSG study.

With such success by our pilot physicians for managing the post-test therapy for OSA, it was determined that SleepView® is a reliable and accurate monitor suitable for driving therapeutic choices within the PCP practice. The concern that many patients would require subsequent PSG evaluations before therapy was mitigated by the study outcomes. These primary care physicians also demonstrated that the diagnosis and management of OSA is a natural extension of their practice and is synergistic to the management of other diseases within the metabolic syndrome.

Conclusion

The proven association of OSA with the disorders of the metabolic syndrome, sudden cardiac death, and motor vehicle accidents makes this disorder a serious health concern. With up to 90% of OSA patients remaining undiagnosed today, improvements are urgently needed in identifying and formally diagnosing those at risk.

After reviewing the results of this pilot study, we feel that home sleep testing with SleepView® is a step in the right direction towards improving patient care related to sleep apnea. Our study has found that patients are easier to convince to undergo a sleep study and are thus more likely to be tested. With 93% successful studies in hand, it was shown that patients can also effectively self-administer the at-home testing process. Physicians and their staff have also demonstrated proficiency in implementing SleepView® into their care delivery and were fully capable of managing the data and workflow found within the SleepViewSM Portal. In addition, the remarkable success achieved we observed in our primary care physicians prescribing therapy directly from a home study provides solid evidence that SleepView® is a reliable and accurate diagnostic solution.

The pilot also demonstrated significant cost advantages to the healthcare system with 70% lower diagnostic costs of care for patients found to have OSA. We also found that sleep apnea diagnostics and management is a natural extension of the existing primary care disease management programs, especially for those disorders found within the metabolic syndrome such as diabetes, hypertension, obesity and heart disease.

Yet, as we conclude, it is important to note that sleep labs continue to

have an extremely important role in the overall management of OSA, even those that are diagnosed within a primary care setting. Many patients, diagnosed by their primary care physician with moderate to severe apnea on HST, require referral to sleep specialists for initiation of CPAP therapy. In many cases in this pilot study, the SleepView® patients who required CPAP were sent to a local sleep lab for initiation of their therapy. Thus, the incorporation of home sleep testing in the primary care setting, while reliably diagnostic and cost effective, still requires tertiary sleep lab support in many ways.

The incorporation of HST within primary care should be viewed not as a replacement for sleep lab but rather as an efficient and effective ancillary method for diagnosing and initiating care management for sleep disorders. Perhaps enabling our primary care physicians with the new capabilities afforded by SleepView®, more patients will receive the care they need and reduce their risks for other chronic disease states.

End Notes

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