Cardio Sleep Review

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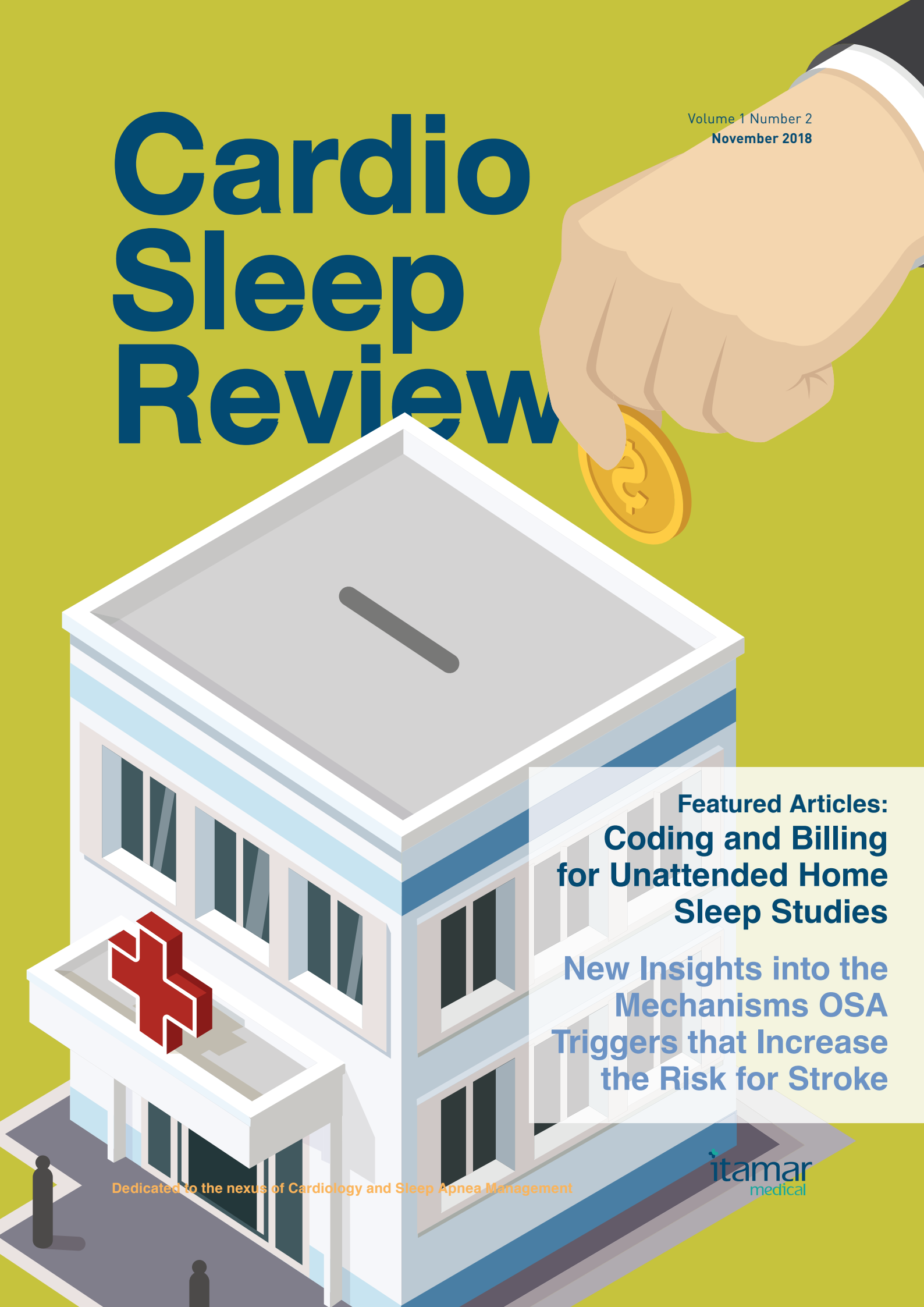

Featured Articles:

Coding and Billing for Unattended Home Sleep Studies

New Insights into the Mechanisms OSA Triggers that Increase the Risk for Stroke

Dedicated to the nexus of Cardiology and Sleep Apnea Management

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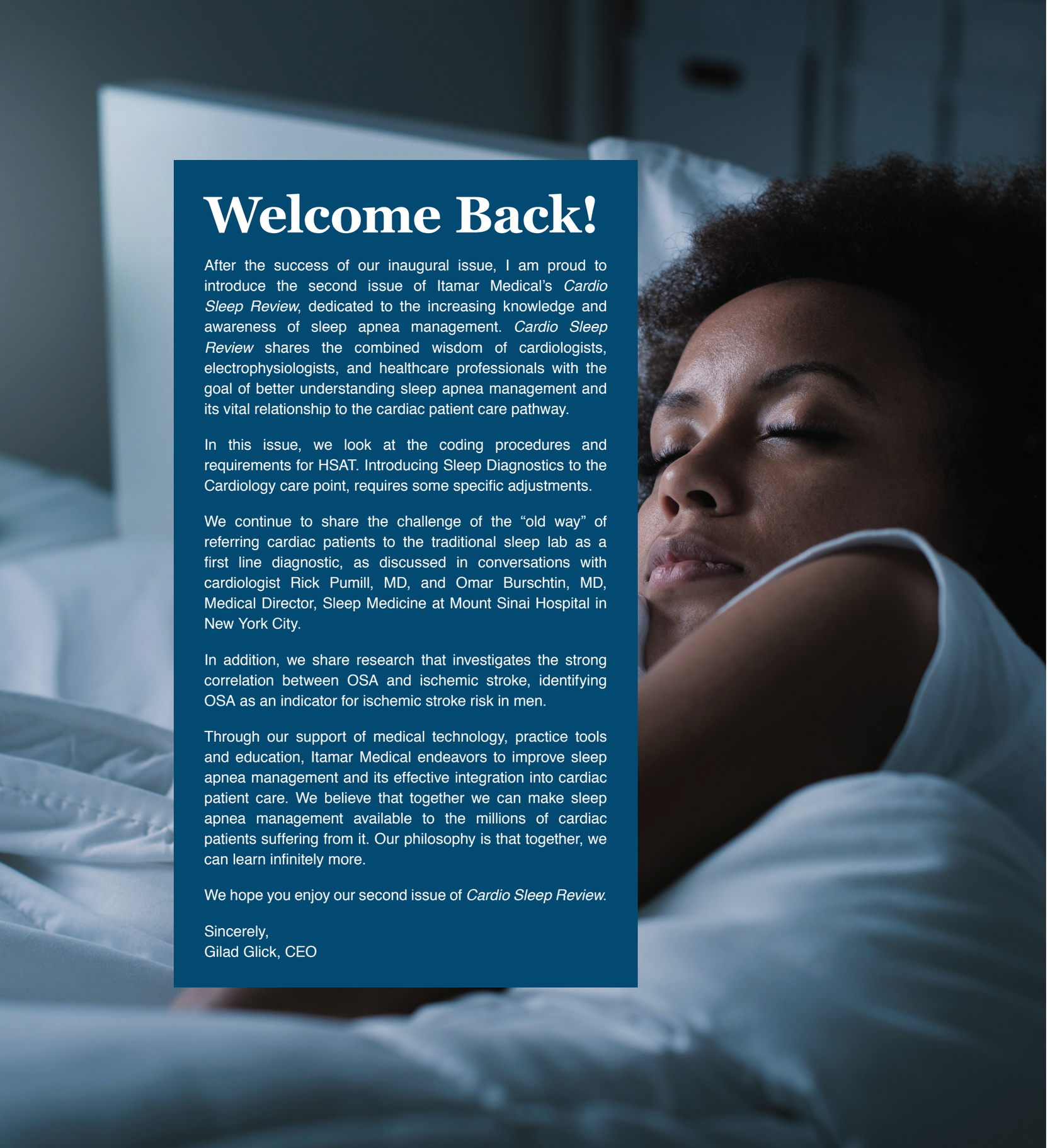

Welcome Back!

After the success of our inaugural issue, I am proud to introduce the second issue of Itamar Medical's *Cardio Sleep Review*, dedicated to the increasing knowledge and awareness of sleep apnea management. *Cardio Sleep Review* shares the combined wisdom of cardiologists, electrophysiologists, and healthcare professionals with the goal of better understanding sleep apnea management and its vital relationship to the cardiac patient care pathway.

In this issue, we look at the coding procedures and requirements for HSAT. Introducing Sleep Diagnostics to the Cardiology care point, requires some specific adjustments.

We continue to share the challenge of the "old way" of referring cardiac patients to the traditional sleep lab as a first line diagnostic, as discussed in conversations with cardiologist Rick Pumill, MD, and Omar Burschtin, MD, Medical Director, Sleep Medicine at Mount Sinai Hospital in New York City.

In addition, we share research that investigates the strong correlation between OSA and ischemic stroke, identifying OSA as an indicator for ischemic stroke risk in men.

Through our support of medical technology, practice tools and education, Itamar Medical endeavors to improve sleep apnea management and its effective integration into cardiac patient care. We believe that together we can make sleep apnea management available to the millions of cardiac patients suffering from it. Our philosophy is that together, we can learn infinitely more.

We hope you enjoy our second issue of *Cardio Sleep Review*.

Sincerely,
Gilad Glick, CEO

Table of Contents

Cardio Sleep Review
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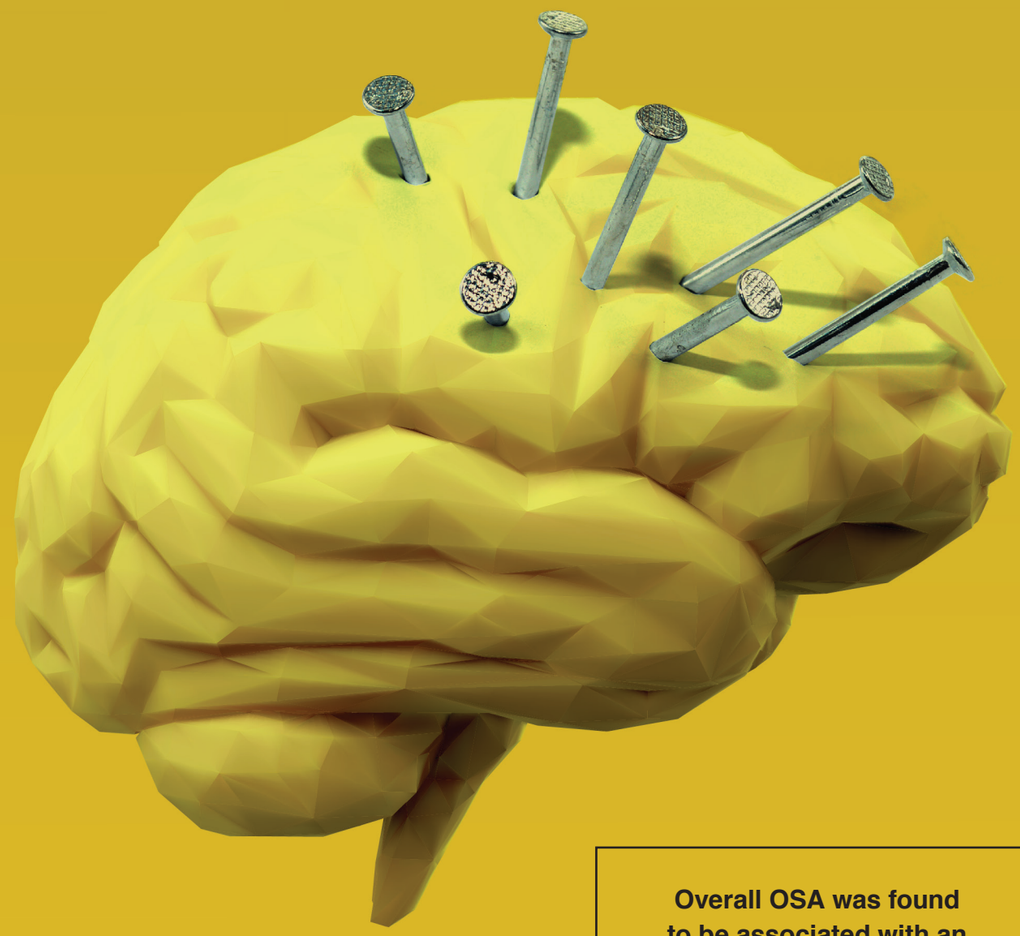
New Insights on the Mechanisms OSA Triggers that Increase Risk of Stroke



Overall OSA was found to be associated with an approximately three-fold increased risk of ischemic stroke in men.

By Efrat Magidov
Scientific Consultant

Stroke, sometimes referred to as a "brain attack," is a medical emergency and a leading cause of death around the world. It occurs when the blood supply to a part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients. Such deficit can happen when a blood vessel in the brain bursts (hemorrhagic stroke) or, more commonly, when a blockage develops (ischemic stroke). If not treated immediately, brain cells begin to die within minutes, resulting in serious disability or death.

Sleep-disordered breathing (SDB), especially in its most common form — obstructive sleep apnea (OSA) — has been associated with increased risk for ischemic stroke. Recently, a large prospective cohort study followed 5422 individuals without a history of stroke for a median of 8.7 years.[1] Chances of ischemic stroke in men were shown to be increased with OSA severity (as measured by apnea-hypopnea index [AHI]), even after adjustment for potential confounders (adjusted hazard ratio [HR] 2.86, 95% CI 1.10-7.39). Overall OSA was found to be associated with an approximately three-fold increased risk of ischemic stroke in men, resonating with findings from previous studies that demonstrated a four- to six-fold higher prevalence of OSA in stroke patients.[2] Moreover, it has been shown that treatment of OSA decreases mortality and improves functional recovery after stroke.[3]

This strong connection between OSA and stroke is not surprising considering that OSA may affect all major risk factors of stroke: hypertension, hyperlipidemia, hypoxemia, diabetes and atrial fibrillation. However, the underlying mechanisms by which OSA increases the risk, independent of these traditional risk factors, have not been established. Nevertheless, some notable attempts to suggest a causal mechanism have been made. Two such mechanisms are decreased cerebral blood flow velocity and hypercoagulability and inflammation.

DECREASED CEREBRAL BLOOD FLOW VELOCITY

Ordinarily, the brain regulates its blood flow to meet its own metabolic needs, even in the face of changes in blood pressure, a process known as cerebral autoregulation. The repeated surges and drops in blood pressure, oxygen level and blood flow during numerous apnea episodes each night, reduce the brain's ability to regulate these functions. This mechanism was demonstrated by a study conducted at Yale Center for Sleep Medicine;[4] 48 subjects, 22 diagnosed with OSA (AHI≥30) and 26 controls (AHI<5), free of cerebrovascular and active coronary artery disease, participated in this study. Cerebral autoregulation was examined by measuring cerebral artery blood flow velocity (CBFV) and arterial blood pressure during orthostatic hypotension and recovery as well as during 5% CO2 inhalation. The findings showed that patients with OSA have decreased CBFV at baseline compared to controls (8±3 vs. 55±2 cm/s; P<0.05, respectively) and delayed cerebrovascular compensatory response to changes in blood pressure (CBFV: 0.06±0.02 vs. 0.20±0.06 cm/s-

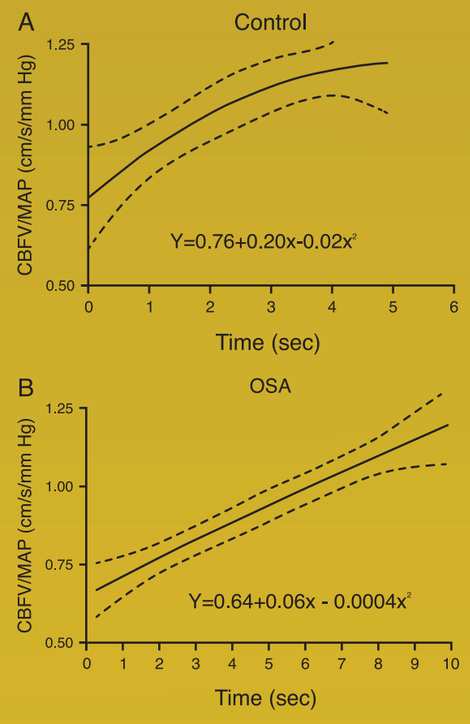


Figure 1: Rate of change of vascular conductance in response to orthostatic hypotension as a measure of cerebral autoregulation. The OSA patients (B) had significantly lower compensatory rate (the slope of CBFV/MAP/time) (P<0.05) and longer time course than the control (A).

2·mmHg-1; P<0.05, figure 1). These perturbations may increase the risk of cerebral ischemia during obstructive apnea.

HYPERCOAGULABILITY AND INFLAMMATION

Another suggested mechanism relates to the hypercoagulability and increased platelet aggregation related to OSA, which in turn increase risk of blood vessels' blockage. This mechanism was recently demonstrated by a group of researchers at Soroka Clinical Research Center, Soroka University Medical Center, Beer-Sheva, Israel.[5] 43 patients underwent a nocturnal respiratory assessment during the first 48 hours after stroke symptoms onset. In addition, serum samples were obtained from all the study participants on the first morning after their admission in order to track the concentration of some proinflammatory and procoagulant factors. Almost 90% of the patients had SDB (AHI>5) with 51% diagnosed with OSA (AHI ≥15), strengthening previous findings of high prevalence of SDB in patients with stroke. As the mechanism predicted, AHI was found to be correlated with indicators of inflammation and coagulability: IL-6 (ρ=0.37, P=0.02) and PAI-1 (ρ=0.31, P=0.07). PAI-1 was negatively correlated with a saturation nadir (ρ=−0.47, P=0.005) and positively correlated with a desaturation index (ρ=0.41, P=0.02). PAI-1 (pg/mL) was significantly higher in patients with an AHI≥15; mean of 176.64±74.52 versus 98.48±52.58 pg/mL, P=0.003 (Figure 2A). IL-6 (pg/mL, 6.64±5.27 versus 3.14±2.05, P=0.006, Figure 2B) and TNF (pg/mL, 6.39±5.00 versus 3.57±1.87, P=0.022, Figure 2C) were similar.

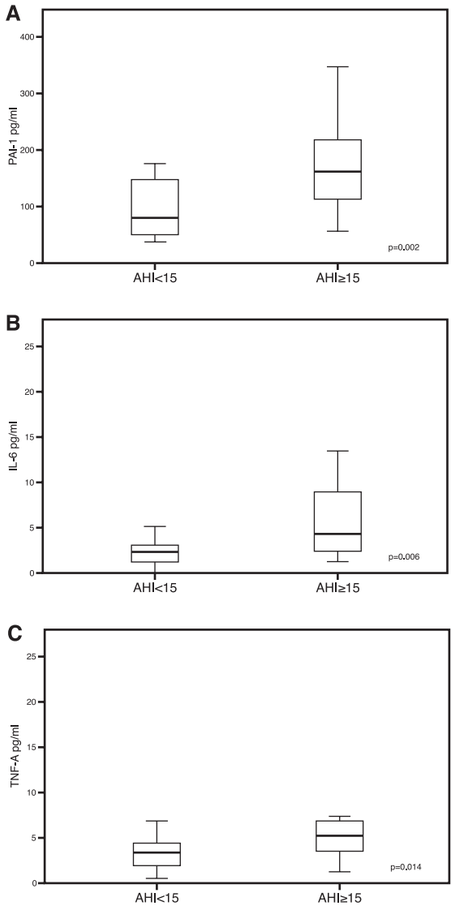


Figure 2: A, Plasminogen activator inhibitor-1 (PAI-1) levels stratified by apnea-hypopnea index (AHI). PAI-1 concentration (pg/mL) was significantly higher in serum drawn from patients with AHI≥15 than in patients with AHI<15. B, Interleukin-6 (IL-6) levels stratified by AHI. IL-6 concentration (pg/mL) was significantly higher in serum drawn from patients with AHI≥15. C, Tumor necrosis factor (TNF)-α levels stratified by AHI. TNF concentration (pg/mL) was significantly higher in serum drawn from patients with AHI≥15. Horizontal lines represent median values; the upper and lower box limits indicate the 25th and 75th percentile; whiskers represent the 10th and 90th percentiles.

The clinical importance of the last described study goes beyond the mechanism demonstration—it was the first time the respiratory assessment in stroke patients was evaluated using WatchPAT. Since WatchPAT technology is easily used as a bed-side measure in the acute post-stroke period and enables rapid diagnosis and therapeutic recommendations, it's ideal for the improvement of secondary prevention. ■

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"PAMS": New Service Offers Remote Personal Coach to CPAP Users and Increases Compliance Significantly

By William Hardy, RRT, Mark Aloia, PhD., Christy Stitt, MS, Jeff Jasko, MS
Philips Respironics Health Tech

INTRODUCTION

A major challenge for electrophysiologists nowadays is a persistently high 1-year AFib recurrence despite treatment by cardioversion, catheter ablation or drugs. Often a repeat ablation is necessary to treat AFib efficiently, and AFib may still recur despite these additional interventions. Electrophysiologists were concerned about a group of patients who seemed refractory to maintenance of sinus rhythm despite aggressive therapy.

In recent years, multiple published studies linked untreated sleep apnea with substantial increases in the rate of AFIB recurrence—practically telling us that the common 20% - 40% recurrence rate has two groups: those with Sleep Apnea, about half the patients, with a much higher rate of AFib recurrence and the other half, without Sleep Apnea, with lower rate.

Moreover, when patients with confirmed OSA complied properly with CPAP Sleep Apnea treatment, ablation success rates improved to match those among non-apnea sufferers in all AFib types.

Dr. Andrea Natale, showed that Sleep Apnea was an independent predictor for PVAI failure, and that treatment with CPAP improved PVAI success rates. Patients not treated with CPAP in addition to having higher prevalence of non-PV triggers were 8 times more likely to fail ablation.[1]

A broader landmark study was published by Dr. Fein, Dr. Anter and colleagues. These authors found that AFib-free survival rate among patients with CPAP-treated OSA was similar to a group of patients without OSA (71.9% vs. 36.7%; p = 0.01). AFib recurrence following PVI in CPAP-nonuser patients was significantly higher (HR: 2.4, p < 0.02) and similar to that of OSA patients managed medically without ablation (HR: 2.1, p = 0.68).[2]

1. Dimpi Patel el al. "Safety and Efficacy of Pulmonary Vein Antral Isolation in Patients With Obstructive Sleep Apnea" Circulation Arrhy and Electro, 2010 **2.** Fein AS, Anter E., et al. Treatment of obstructive sleep apnea reduces the risk of atrial fibrillation recurrence after catheter ablation. J Am Coll Cardiol. 2013; 62:300-305.

What if every OSA patient had a dedicated, personal coach to help educate, motivate and manage their use of PAP therapy?

Adjusting to PAP therapy is a behavior change which can be challenging, and sometimes emotional, for OSA patients. Philips Respironics initiated PAMS program which delivers a dedicated, personalized sleep coaching service that provides a structured and consistent approach to post-setup PAP patient follow up. PAMS sleep coaches and licensed respiratory therapists engage with patients early, and follow their progress to increase adherence rates, days therapy used, and hours per night therapy used, by encouraging behavior change using Motivational Enhancement Techniques, educating patients on the treatment of obstructive sleep apnea using positive airway pressure, supporting patients using a wide variety of the most common masks for PAP treatment.

ABSTRACT

Telehealth has generated interest in the effort to increase patient adherence to continuous positive airway pressure (CPAP) therapy, as well as reduce the time necessary to reach adherence. A structured patient management program, the Patient Adherence Management Service (PAMS), is a telehealth service that includes the use of personal sleep coaches and respiratory therapists to conduct motivational interviewing, therapy education and support for patients new to PAP therapy. A retrospective analysis involving new patients from three (3) durable medical equipment (DME) providers (N= 4,383) who were managed in the PAMS program and a control group consisting of new PAP patients not participating in the PAMS program (N= 54,455) from the Philips Respironics' EncoreAnywhere database was conducted to identify differences in adherence rates, hours of use, and time to reach the CMS definition of CPAP compliance. The analysis revealed that 79.5% of new PAP patients in the PAMS program achieved the CMS definition of CPAP adherence within 90 days, compared to 63.1% in a standard care control group. Further, the same structured patient adherence management program resulted in 65.6% and 74.8% adherence rates at 30 days and 60 days respectively, compared to 50% and 59.2% of patients in the control group ($p < 0.001$ for both analyses). Patients included in the PAMS program showed improved adherence rates, higher hours of use, and faster time to meeting the compliance guidelines compared to patients receiving standard care. A structured, consistent approach to patient outreach, coaching, motivation and education is related to better patient therapy adherence and increased use of PAP therapy.

BACKGROUND

Adherence to CPAP is less than optimal and can be influenced by patient and disease characteristics, therapy titration procedures, therapy technology and side effects, and psychological and social factors.[1] Adherence to CPAP can be low even in the carefully controlled setting of a clinical trial[2] and has been observed to decline over time with and without structured interventions to improve it.[3]

Several interventions to improve adherence have been evaluated. One study suggested the use of hypnotics during CPAP titration may improve adherence in the first 6 weeks of treatment[4] and another study showed a benefit in adherence when a hypnotic was used for the first two weeks of treatment[5]. Monitoring adherence remotely and contacting patients to address issues (persistent high mask leak, poor adherence, and high residual AHI or high auto-CPAP pressure) resulted in higher adherence than waiting for the patient to come in for clinic visits.[6] Another study used a structured, interactive voice response system to improve CPAP adherence.[7] A recent review paper suggested five steps to maximizing adherence: assessing patient readiness, setting goals and engaging and empowering the patient in their care, maximizing experiences early in the course of treatment, and implementing a planned, proactive, well thought out follow up program.[8] Additionally, involving patients in healthcare decision making improved adherence to medication in patients with asthma.[9]

In an effort to identify an efficient means for increasing patient adherence with CPAP therapy, an evaluation of a structured patient adherence management program, PAMS, for patients with OSA that utilizes telemedicine to affect motivation, therapy education, and coaching, was undertaken. The aim of the study was to compare adherence in a large cohort of patients in the structured patient adherence management program to a random sampling of non-program patients who initiated treatment in the same timeframe.

		Mean	± Standard Deviation	Median	p-value*
Adherence, All Days (Hours/Night)	Control Group	4.4	2.7	4.8	p<0.001
	Adherence Management Group	5.3	2.4	5.6	
Adherence, Days Used (Hours/Night)	Control Group	5.2	2.5	5.6	p<0.001
	Adherence Management Group	5.8	2.1	6.0	
Percent of Days Used	Control Group	74.0	32.8	90.3	p<0.001
	Adherence Management Group	86.2	22.7	96.8	
Percent of Days with ≥ 4 hours of use	Control Group	57.6	36.2	67.7	p<0.001
	Adherence Management Group	70.2	30.8	80.6	

*Independent-Samples t-test

Table 1: Adherence Analysis

METHODS

In this retrospective, observational analysis, we evaluated patients from three (3) durable medical equipment (DME) providers who participated in the PAMS program. Elements of the program included the use of a modem to transmit real time therapy information to a secure database (EncoreAnywhere, Philips Respironics, USA) and a team of "CPAP Sleep Coaches" and Respiratory Therapists who reviewed the therapy equipment and followed a defined patient outreach protocol that identified patient issues and either resolved or escalated the issues to a health care provider. The DME set up the patient's device initially and entered patient data in EncoreAnywhere. The CPAP Sleep Coach contacted the participant within the first 5 days of starting treatment as noted in EncoreAnywhere to identify device or other therapy issues. For patients who were struggling with therapy, motivational interviewing techniques[10] focused on the importance of using therapy, confidence in using therapy, and self-efficacy. Subsequent CPAP Sleep Coach contacts were dictated by a structured outreach protocol and with guidance from a proprietary algorithm and the level of adherence presented by the patient. Patients who opted out of therapy, required a prescription change, who could not be contacted, were not using therapy, or who had health issues were referred back to their DME or physician.

Patients included in the analysis were either in the adherence management program or were randomly selected from the EncoreAnywhere database. The control group was randomly selected from EncoreAnywhere and their adherence data were analyzed based on the first day of therapy data in EncoreAnywhere. For this group, the first day of treatment dates were matched to the first day of treatment dates of the PAMS program patients. To be included in the analysis, all patients had to have patient records in EncoreAnywhere for at least 90 days.

STATISTICAL METHODS

Continuous endpoints were compared between the control group and adherence management groups using an independent-samples t-test. Average adherence statistics could only be examined at the 30-day interval, because the wireless modems used to transmit patient usage data to EncoreAnywhere were deactivated for participants who met the CMS adherence criteria by that time point. The Fisher's Exact test compared the percentage of participants achieving CMS adherence at several intervals, ranging from 21–90 days. Statistical comparisons were considered significant at $p < 0.05$.

RESULTS

In the PAMS structured adherence management program, there were 4,383 patients who had at least 90 days of data and were contacted within the first five days of being set up in EncoreAnywhere. A control group of 54,455 patients with at least 90 days of data was identified from EncoreAnywhere. All patients initiated treatment between March of 2013 and December of 2014.

Adherence at 30 days was significantly higher in the PAMS group with respect to average hours of use on all days (5.3 ± 2.4 vs. 4.4 ± 2.7 hrs./night, $p < 0.001$), on days used, percent of days used and days with four or more hours of use (Table 1).

	% Meeting CMS Criteria at:			
	21 days	30 days	60 days	90 days
Control Group	15.3%	50.0%	59.2%	63.1%
Adherence Management Group	21.8%	65.6%	74.8%	79.5%
p Value*	p<0.001	p<0.001	p<0.001	p<0.001

*Fisher's Exact Test

Table 2: CMS Adherence Analysis

Adherence data were analyzed to determine the proportion of participants in each group who meet adherence requirements implemented by the Center for Medicare Services (CMS). Adherence was analyzed at 21, 30, 60, and 90 days of treatment for both groups to determine the proportion of participants who averaged at least 4 hours of use per night on at least 70% of the nights (Table 2). At each interval, the PAMS group had a greater proportion of patients who met the CMS requirements for adequate adherence.

DISCUSSION

In this large cohort of patients, adherence was significantly higher with a structured program that proactively contacted all patients and continued to contact patients based upon their adherence compared to patients receiving standard care. Follow up in the first week of treatment, assessing treatment outcomes and immediate resolution of therapy issues have been associated with higher levels of adherence.[11] The PAMS program includes all of these elements. Another adherence program that included promoting self-efficacy and providing patient education[12] resulted in greater adherence than standard care. Adherence in this study is similar to that reported in an evaluation of group social cognitive therapy focusing on goal setting, treatment outcomes and coping.[13] The difference in adherence is similar to another structured program that provided educational intervention by phone.[14]

The consistent and significant differences in the measures of adherence and the significantly higher rates of reaching CMS adherence requirements demonstrate that patients in a triaged, proactive, and structured program (N = 4,383) can achieve higher levels of adherence than that seen in the general 'control group' population (N = 54,455) over a 90-day period. The size of both groups, even though unbalanced, support the generalizability of these findings. The control group population is large enough to represent a spectrum of standard care practices and serves as a good benchmark for comparison against the structured adherence management program.

Because the PAMS program was tailored based on patient reported problems and therapy use, a high level of patient satisfaction should have been seen since patients should have been receiving the right amount of information and support.

There was approximately a 16% higher rate of patients meeting CMS adherence requirements at each interval in the PAMS group compared to the control group. This is slightly lower than what was seen in a retrospective analysis evaluating of the impact of the DreamMapper (Philips Respironics, USA) mobile application on adherence. In that analysis, the percentage of patients meeting CMS adherence requirements was approximately 22% higher for those with DreamMapper. The difference may be due to the higher self-motivation displayed by CPAP patients who choose to download and utilize a mobile application versus patients who

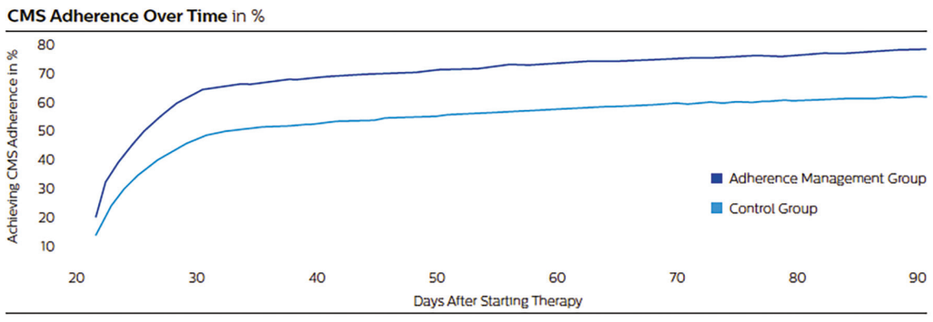

Figure 1: Proportion Meeting CMS Adherence Criteria Days 21 – 90 of Treatment

were placed in the PAMS program by their care provider.

In a recent review of the use of patient technology solutions, patients using the DreamMapper application while participating in the PAMS program were more likely to be adherent than patients not using DreamMapper, participating in the PAMS Program or both. In the conservative analysis, 89% of the patients placed in PAMS program who used the DreamMapper application (5,958 patients) met CMS compliance requirements compared to those not using it and with more hours

SUMMARY

In this large set of data, adherence seen in patients using a structured patient adherence management program was greater than that seen in a randomly selected sample representing a standard care model over a 90 day period. We believe the PAMS program helps engage patients proactively and provides the motivation, coaching and support to improve the speed and rate at which they accept their use of CPAP therapy for OSA. ■

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OSA and AFib Association – A New Review

Atrial Fibrillation (AFib) is the most common source for abnormal heart rhythm, affecting 33.5 million people worldwide. AFib is caused by disorganized electrical signals, which make the heart's two upper chambers—called the atria—quiver, instead of contracting properly. There are numerous risk factors for developing AFib. A relatively new defined risk factor is Obstructive Sleep Apnea (OSA), and the understanding of its exact relationship of it to AFib is still evolving. It is estimated that 21-74% of AFib patients have OSA (exact percentile differs depending on the OSA definition and the applied measuring technique). Conversely, patients with sleep apnea have around four times higher risk of developing AFib than control patients or the general population. A recently published review (https://jamanetwork.com/journals/jamacardiology/fullarticle/2674722) summarizes the current understanding of how OSA pathophysiology is associated with development of arrhythmogenic substrates, and on the ways in which OSA treatment helps AFib risk management. We present here some of the main reviewed findings.

MECHANISMS BY WHICH OSA CONTRIBUTES TO THE PATHOGENESIS OF AFIB

The repetitive obstructive respiratory events characterizing OSA cause negative intrathoracic pressure swings which mostly affect the thin-walled atria, causing it to over-stretch. Such acute atrial dilation shortens atrial refractoriness, slows conduction, and increases the occurrence of intra-atrial conduction block. Moreover, the cyclical deoxygenation and reoxygenation associated with sleep apnea increases oxidative stress, contributing to the atrial myocardial damage. In addition to the atrial remodeling factors, the pronounced sympathovagal activation that occurs toward the end of an obstructive episode induces acute electrophysiological arrhythmogenic changes and an increased frequency of premature atrial contractions with the potential to initiate AFib. The progressive atrial structural remodeling, along with transient apnea-associated electrophysiological changes, contributes to the reentry substrate for AFib and creates a complex and dynamic arrhythmogenic substrate in the atrium. Importantly, other chronic comorbidities such as obesity and hypertension further increase AFib risk in OSA patients.

CHALLENGES IN OSA DIAGNOSIS IN AFIB PATIENTS

Not all AFib patients show symptoms of OSA (e.g., daytime sleepiness). So, the general recommendation is to screen all AFib patients with a sleep study evaluation. However, it's important to note that the Apnea Hypopnea Index (AHI) should not be the only derived index by which OSA is determined. In a cohort study of 3542 adults, the magnitude of nocturnal oxygen desaturation (but not the AHI) was shown to be an independent predictor of new-onset AFib. Thus, evaluating the hypoxemic burden, as well as the AHI, is crucial for successful AFib evaluation.

> **"A recent meta-analysis revealed that patients with OSA not treated with CPAP have 57% greater risk of AFib compared to patients without OSA."**

Another factor that should be taken into account in the diagnosis process is screening not only for OSA, but also for Central Sleep Apnea (CSA). For example, in a study of 2911 participants, AFib was associated with CSA more than with OSA. Similarly, rhythm control by electrical cardioversion was not associated with changes in the absolute AHI scores but did have an association with reduced nocturnal central respiratory events and unmasked OSA. Nonetheless, the causal direction between AFib and CSA is not yet clear: the high proportion of central respiratory events may reflect the underlying cardiac disease, rather than representing a causal factor for AFib.

TREATMENT OF OSA IN AFIB PATIENTS

The presence of OSA substantially reduces the efficacy of catheter-based and pharmacological antiarrhythmic therapy, thus effectively treating OSA is crucial for AFib relief. CPAP, the gold-standard OSA treatment method, has been shown to be effective in AFib treatment. CPAP can help to maintain sinus rhythm in AFib-OSA patients and to reduce AFib recurrence after catheterbased AFib therapy. A recent meta-analysis revealed that patients with OSA not treated with CPAP have 57% greater risk of AFib compared to patients without OSA. However, since all the findings on CPAP efficiency in AFib are based on nonrandomized studies, and since CPAP use was only self-reported, the reviewers point to the incompleteness of the findings and suggest that more randomized prospective observations should be made before concluding on CPAP efficiency in AFib patients. Other OSA/CSA treatment interventions, such as ganglionated plexus ablation and renal sympathetic denervation, had been shown to attenuate AFib in a series of preclinical studies. Lifetime interventions that reduce OSA severity and risk such as weight control further contribute AFib ablation.

CONCLUDING RECOMMENDATIONS

Although, as indicated by the reviewers, there is a need for more studies before finalizing the conclusions on the association between OSA and AFib, the professional societies already incorporate some of the current findings in their recent recommendations. The 2016 European Society of Cardiology guidelines on AFib recommends that consideration be given to elicited clinical symptoms and signs of OSA and CPAP treatment to reduce AFib recurrence and improve AFib treatment results. Similarly, The "2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation" mentions OSA as a relevant modifiable risk factor for AFib and recommends screening for signs and symptoms of OSA when evaluating a patient for an AFib ablation procedure. It also states that treatment of OSA can be useful for patients with AFib, including those who are being evaluated to undergo an AFib ablation procedure. ■

What You Need to Know About

Coding, Billing and Reimbursement for Unattended Home Sleep Apnea Studies

By Rhonda Welch, CPC

Home Sleep Apnea Tests (HSAT) have increased in usage and based on recent estimates amount to about a third of all sleep apnea tests due to their cost effectiveness and accessibility in comparison to in-lab, HCP-monitored Polysomnography testing. An HSAT is a preference for many patients since they can take the test at home in a more natural, relaxing and private environment that is also more likely to reflect the actual disease manifestation.

Today, the vast majority of payers reimburse for HSAT and some recommend it as a first line diagnosis for sleep apnea. However, coding and billing requirements differ from payer to payer. This article will outline some of the basics, but it is always best to check with your payer for their specific requirements

With a few exceptions, licensed medical doctors, regardless of their specialty, can prescribe HSAT to patients who are suspected of having sleep apnea based on signs and symptoms and testing positive for high risk on validated instruments such as the STOPBANG, Epworth Sleepiness and DOISNORE 50 questionnaires. Physicians may also consider clinical symptoms such as atrial fibrillation and hypertension as signs for high pre-test probability, based on the most recent AASM guidelines.[1]

HST G CODES AND CPT CODES

In 2007 the AASM published the "Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients,"[2] which differentiated the HSATs by type (defined by the AASM). In the following year, Medicare introduced the HCPCS Level II codes G0398, G0399 and G0400 which followed the AASM types. G codes are "carrier determined," which means that payment is up to the discretion of the Medicare Administrative Contractors (MACs).

G CODES / SLEEP TYPE CLASSIFICATION

G0398 Home sleep study with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation.

G0399 Home sleep study with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation.

G0400 Home sleep study with type IV portable monitor, unattended; minimum of 3 channels.

In 2009, Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) which included the WatchPAT as a covered test. Today, most CMS MACs request the use of G codes to report HSATs and request the use of G0400 to report WatchPAT.[3]

In 2011, the AMA added the CPT codes 95800 and 95801 to describe HSAT using peripheral arterial tone (i.e. WatchPAT). Note that WatchPAT records sleep time so CPT 95800, not 95801, should be used to report HSAT using WatchPAT. Most commercial payers request the use of 95800 to report WatchPAT.

CPT CODES

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

95801 Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g. by airflow or peripheral arterial tone).

In 2017 AASM clarified their position in a guideline, noting that the types classification fails to consider new technologies such as peripheral arterial tonometry (PAT). They proposed another classification scheme but acknowledged that it has not been utilized by many. The AASM concluded that devices that measure PAT, actigraphy, and oximetry are technically adequate to diagnose OSA, and therefore recommended that physicians use such HSATs to diagnose OSA.[1]

"...the vast majority of payers reimburse for HSAT and some recommend it as a first line diagnosis for sleep apnea."

The bottom line is that there are multiple codes that can be used to report HSAT. Typically, CMS requests that WatchPAT be reported with G0400 and commercial payers request 95800. Since HSAT may be reported by more than one code, it is best to refer to the payer's medical policy to ensure you are reporting the correct code.

In upcoming newsletter editions, we will explore additional topics including when to bill the global, technical and professional component of the code, credentialing and accreditation issues. ■

1. Kapur et al., *Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline*, 13 J. CLIN. SLEEP MED. 479 (Mar. 15, 2017). **2.** Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. *JCSM Journal of Clinical Sleep Medicine, Vol. 3, No. 7, 2007.* **3.** CMS Pub 100-03 Medicare National Coverage Determinations (NCD) - Sleep Testing for Obstructive Sleep Apnea (OSA). Transmittal R103NCD March 3, 2009.

Hospital Coding with WatchPAT™

The WatchPAT device has been given its own code, 98500, by the American Medical Association for reimbursement purposes. The following flowchart explains how physicians should report HSAT tests and associated procedures.

1. E&M NEW OR ESTABLISHED PATIENTVISIT (CPT® 99201-9925, 99211-99215)

- During patient visit, risk of obstructive sleep apnea (OSA) is suspected and documented (ICD-10-CM G47.33)
- Identify patients at risk of OSA with a STOPBANG, Epworth Sleepiness Test or DOISNORE50 Test
- Many commercial payers allow an E&M visit on the same date as 95800. Medicare will only allow an E&M code on the same date if it is for a separate and distinct reason

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2. CONDUCT PATIENT VERIFICATION OF ELIGIBILITY AND BENEFITS

- Medicare and most commercial payers cover 95800
- Many but not all payers require a prior authorization. Be sure to check the individual patient's plan since benefits can vary within a payer's plans. Include patient-specific diagnosis code(s), CPT code(s) and description of procedure and anticipated date of service

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3. CARDIOLOGIST PRESCRIBES HOME SLEEP TEST (CPT® 95800-TC)

- Cardiology office educates patient on Home Sleep Apnea Test (HSAT) and dispatches the test for patient to take home
- For the WatchPAT HSAT, the global code is 98500.
- If the Cardiologist provides the test and interprets the results, report the global 95800 (only if Cardiologist is sleep certified)
- If the Cardiologist only provides the test, report 95800-TC

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4. PATIENT CONDUCTS TEST AT HOME

- Patient takes test at home
- Patient returns or ship back the device to physician office

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5. PHYSICIAN INTERPRETS RESULTS (CPT® 95800-26)

- Sleep certified physician reads HSAT results and provides assessment
- If the physician provides the test and interprets the results, report the global 9500 (only physician is sleep certified)
- If the physician only interprets the results, report 95800-26

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6. CARDIOLOGIST REVIEWS RESULTS AND TREATMENT PLAN WITH PATIENT (CPT® 99201-9925, 99211-99215)

- Cardiologist reviews the results of the HSAT and treatment plan follow up with the patient
- May schedule a follow up visit in 3-6 months as needed

Note: Each payer has their own reimbursement requirements. Be sure to check for specific instructions. This flowchart is to be used as an example only.

REIMBURSEMENT INFORMATION

CPT® CODES

Report the following codes for commercial payers:

- 95800 if you provide HSAT AND interpret the results
- 95800-TC if you provide the test only
- 95800-26 if you interpret the results only

ICD-10-CM CODES

- G47.33 Obstructive Sleep Apnea
- G47.30 Sleep Apnea, Unspecified

PLACE OF SERVICE (POS)

- Place of Service is typically reported as POS 11 Office
- Some payers request POS 12 Home
- Always check with your local payer!

Itamar Medical provides this information only for your convenience. It is not intended as a recommendation of clinical practice or as legal advice. It is the responsibility of the provider to determine coverage and submit appropriate codes, modifiers, and charges for the services rendered. Contact your Medicare Administrative Contractor (MAC) or other commercial payer for interpretation of coverage, coding and payment policies.

2018 MEDICARE PAYMENT RATES

CPT® Code	National Average	Range of Payments (Low-Missouri, High - San Francisco)
Home Sleep Apnea Test		
95800	$181	$161-$228
95800-TC	$127	$110-$169
New Patient Office Visit		
99201	$45	$41-$54
99202	$76	$71-$90
99203	$110	$102-128
99204	$167	$157-193
99205	$211	$199-241
Established Patient Office Visit		
99211	$22	$20-$27
99212	$45	$41-$54
99213	$74	$69-87
99214	$109	$102-128
99215	$148	$138-$172

Obstructive Sleep Apnea (OSA)

WHO SUFFERS FROM OSA?
OSA affects over 100 million people worldwide.

THE COSTS OF OSA
Undiagnosed OSA patients incur $200,000 each in healthcare costs over a 2-year treatment period.

THE EFFECTS OF OSA

9 out of 10 people who suffer from OSA haven't been diagnosed or treated.

8.5 out of 10 people who suffer with congestive heart failure also suffer from OSA.

8 out of 10 obese people suffer from sleep disordered breathing.

People with OSA are more likely to die from sudden cardiac death. Sudden cardiac death is responsible for **450,000** deaths annually.

World Health Organizations, Global surveillance, prevention and control of Chronic Respiratory Diseases: A comprehensive approach. 2007. Harvard Health Publications "Average Life Expectancy: Measuring Yours" July 2006 I Finkel, KJ. Sleep Med. 2009 Aug;10(7):753-8 I U.S. Census Bureau, Population, 2010 I Institute of Medicine. Sleep disorders and sleep deprivation: an unmet public health problem. Washington, DC: The National Academies Press; 2006. I Jiang –Journal of Cardiac Failure 2007 I Connor, J. BMJ. 2002 May 11; 324(7346): 1125. I O'Keeffe & Patterson. Obesity Surg 2004 I "Obstructive Sleep Apnea and the Risk of Sudden Cardiac Death: A Longitudinal Study of 10,701 Adults" Journal of the American College of Cardiology. 2013 I Kryger et al. Sleep 1996 I The Center of Medicare and Medicaid Services (CMS) CPT codes published rates June 2012 I Collop, N. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. Journal of Clinical Sleep Medicine, Vol. 3, No. 7, 2007

Home Testing Provides Cardiologists Quick Answers to Sleep Issues and Why That's Critical

Omar Burschtin, MD

The Mount Sinai Integrative Sleep Center in New York City has established a unique program to provide cardiologists with a quick and efficient way of diagnosing sleep apnea for their patients especially those with arrhythmias. In this Q&A, Dr. Omar Burschtin, sleep specialist and Medical Director of the Sleep Program, speaks with Cardio Sleep Review about the need for such a program and how it has become highly successful in a short time.

CSR: Your sleep clinic devotes Wednesday mornings to cardiac patients with suspected sleep disorders. When did you start this program and why?

Dr. Burschtin: While the degree of consequences of mild sleep apnea on health outcomes is still debatable, we know that moderate to severe sleep apnea has a significant impact on certain medical conditions and many of them are in the cardiovascular spectrum of diseases. As a sleep doctor, I have a special interest in taking care of those patients with cardiac arrhythmias, including atrial fibrillation, TIA, and strokes. We are here to help prevent those conditions from occurring or recurring by making sure these patients are treated adequately, quickly and efficiently.

Sleep apnea is a common comorbidity to AFib, which affects about 2.7 to 6.1 million patients in the U.S. alone. The treatment for their atrial fibrillation is often cardioversion (electrical or chemical) or ablation. As a cardiologist, you might suspect your patient has sleep apnea, but you don't have two or three months to wait for your patient to undergo sleep testing and another few weeks for you to get the results. We wanted to be able to get answers for cardiologists sooner, before they performed the cardioversion or ablation. So, a little more than a year ago, we set up a program where we devote Wednesday mornings to cardiology patients who need sleep testing. We know that managing AFib patients with obstructive sleep apnea greatly improves outcomes and patient care. If they have sleep apnea and are treated, it reduces the chance of their having recurring arrhythmias after their treatment.

We see as many patients as we can schedule into the Wednesday morning program. If they're appropriate candidates and we can get the insurance approvals, we send them home with the WatchPAT for sleep testing that night. Patients then return the device themselves the next day or have someone bring it in for them. We review the results and send a report to their cardiologists that day. We started the Wednesday mornings with a vision to provide an immediate point-of-care and try to resolve a vacuum of the presence of sleep medicine in cardiac care.

CSR: Why has there traditionally been a delay in testing cardiac patients for sleep apnea?

Dr. Burschtin: Often the patients and their doctors don't see getting to the bottom of their sleep disorder as urgent. There are multiple reasons for this related to family, distance, nursing homes, that make coming to a sleep center difficult for them, if not impossible. Or maybe they can physically, but they are elderly and they refuse. If they meet the criteria, we can do home sleep testing and that allows us to get the answers we need right away. Home sleep testing with WatchPAT is easy for the patients and the results are reliable.

CSR: Are cardiologists aware of the need for sleep testing in their patients?

Dr. Burschtin: I think that cardiologists are pretty aware. The problem is not so much awareness. The problem is as a cardiologist you don't think it's fair to delay your patient's treatment five months until he can get a consultation, testing, scoring and therapy for his sleep issues. That's why we started our Wednesday morning program and our team approach.

There are things that need to be done in a few days if you want to be efficient and responsible. That's why I think the development of a team that makes sure there is no vacuum in any elements of that multidisciplinary approach to the study of patients is critical. There are some 90 sleep disorders and our sleep program takes care of all of them. We see some with more frequency than others, but sleep apnea is the majority of them – the bread and butter we take care of on a daily basis.

CSR. Which patients are candidates for home sleep testing?

Dr. Burschtin: Essentially, we follow the recommendations of the American Academy of Sleep Medicine for home testing versus attended polysomnography (PSG). If the patient is a candidate for home testing, then we do home testing. If we're looking for someone who is a hypoventilator, CO_2 retainer, has a polysomnia or behavior disorder, moderate to severe COPD, or someone with congestive heart failure with very diminished ejection fraction, we do attended polysomnography instead.

CSR: Are home test studies as valuable as sleep center studies?

Dr. Burschtin: The home test studies are clinically validated against PSG. If you're looking for something else, like brain activity or polysomnia, then a home study is not the right way to go. We use two types of devices for home sleep testing, and it depends what we're looking for. The WatchPAT allows us to be very efficient.

CSR: How many patients do you see at your center on a Wednesday morning?

Dr. Burschtin: It's variable but as many as come. We allow 20 minutes for a follow-up patient and 40 minutes for a new one. So, it's whatever we can fit in the morning. If the patient from cardiology isn't available on Wednesday morning, they can come any other day. And once I see them on a Wednesday and we make a diagnosis and start with therapy, they can come for follow-up any other day. I'm trying to preserve the Wednesday morning for new patients where they need this immediate approach. If I do follow-up on a Wednesday, I don't have space for a new one.

> **"As a cardiologist, you might suspect your patient has sleep apnea, but you don't have two or three months to wait for your patient to undergo sleep testing."**

CSR: What makes your sleep center and your Wednesday morning program so successful?

Dr. Burschtin: I think the success of a program is a formula I have: experience plus knowledge multiplied by attitude. That's my formula for success. Lots of people have good experience and knowledge. It's the attitude that differentiates us. You need to have the right attitude to modify the way you do things to become excellent. The cardiologists we work with—and they are from across the Mount Sinai network and elsewhere—appreciate that we have a comprehensive program that will deliver the answers they need in a timely fashion. They know they can count on us. I think this service is the right approach. We take care of our patients from A-to-Z. Their home testing results come directly to us and we provide the interpretation. We recommend the patient begin auto CPAP when it's indicated and send them for a sleep center study if it's needed. The severity of the sleep apnea is not a contra indication for using auto-CPAP. There is some difference of opinion but there is nothing in the American Academy of Sleep Medicine that says for sleep apnea you cannot use CPAP.

CSR: How have you grown the sleep center program and why?

Dr. Burschtin: Before I arrived from NYU, there was one full time sleep doctor plus a half—so 1.5 FTE. Now this fall a new junior doctor is coming. She was our fellow last year. With her, we will have eight sleep doctors plus one physician's assistant. That tells you we're putting a lot of resources into supporting the needs of the community and that we also have a very strong research program and education program. We do about 13 sleep studies a day at our center Monday to Friday and most (about 10) are at-home. Our research is ongoing. The areas of research here are very wide. Right now, we're doing more research in terms of central sleep apnea and its consequences. The need for sleep studies is on the rise because of many factors including obesity, hypertension, diabetes, and kidney disease. Cardiologists are becoming more aware of sleep apnea's role in treating cardiac conditions. And as we grow the sleep program, we will have an opportunity to interact with other departments in the hospital and take it to the next level. ■

Patients Appreciate the Value of Home Testing—From a Cardiologist with Sleep Apnea

Dr Rick Pumill, MD

A practicing cardiologist, Rick Pumill, MD, has "pretty severe" obstructive sleep apnea. That may be why he has a great interest in the condition that affects one in five adults than other cardiologists.

Science has proven a direct correlation between sleep apnea and some of the heart conditions that Dr. Pumill sees every day in his busy practice including hypertension, atrial fibrillation and congestive heart failure. It's virtually impossible to treat cardiac disease without treating their underlying sleep apnea. "That's why, if we don't diagnose sleep apnea and treat it if it's found, we are doing a great disservice to our patients," he said during a recent interview.

Dr. Pumill's practice is a referral practice. "Patients who come to see me are sent by someone else either because they are not getting better or their current treating physician needs subspecialty input to better manage their heart care," Dr. Pumill explained. He finds that patients generally listen "to me because by the time they get to me, they are scared they are going to die or had a family member die of heart disease. Still, getting them to go for that sleep test overnight in a sleep lab has always been a challenge."

Not only are patients reluctant, he said, but it's also time-consuming to get the necessary insurance approvals and difficult to get the test scheduled. Adding to the scheduling problem is the fact that the lab may only be open evenings. "By the time you get everything you need, it can easily take two months or more,".

Compliance for sleep testing is extremely low. The patients just don't follow up as often as they should. Pumill adds that it's not unusual for patients to come back to his office for follow-up visits months later only to learn they never went for their sleep lab test. Or if they did go, they never got the results. "Again, because the sleep lab isn't open during the day, even if they went for the study, tracking down the results, is not easy either," he said.

Cost is also a factor, Dr. Pumill notes. Sleep studies performed in a lab are extremely expensive, sometimes in the thousands of dollars, with large components generally an out of pocket expense.

HOME SLEEP TESTING CHANGING THE LANDSCAPE

Being able to send patients he suspects may have sleep apnea home the same day as the office consultation with sleep-testing devices like the WatchPAT™ has changed his practice considerably and definitely for the better, he said.

Dr. Pumill decides whether patients should be tested for sleep apnea by talking with them and their bed partners. "I don't use questionnaires," he said. He also looks for physical signs including an abnormal EKG showing enlargement of the right side of the heart. "That's a tipoff," he said. Also, he said, if he sees someone who has atrial fibrillation, "it's something to think about. If I see someone with refractory hypertension, it's something to think about. And if I see someone who is obese, it's something to think about." Another hint: The patient has a round face, a small mouth and a 17-inch or greater neck like he does. That anatomy is an obvious sign, said Dr. Pumill, who blames these anatomical features for his sleep apnea. At 5'10" and 180 pounds, obesity isn't his issue, he said with a laugh.

> **"If we don't diagnose sleep apnea and treat it if it's found, we are doing a great disservice to our patients."**

Unless Dr. Pumill suspects the patient has a serious heart condition that requires testing in a sleep lab, he sends the patient home with a WatchPAT. What he likes about home sleep testing is the ease of doing it, the immediacy of the results, and high patient compliance.

When he sends patients home with the sleep test, patients use it that evening. The patients or their surrogates bring their devices back to the office

the next day. Reaction time is quick, Dr. Pumill said. “We get the results and, if they do have sleep apnea, we contact the durable medical supply company near them and set them up with a CPAP machine all within 72 hours.”

Dr. Pumill explains to his patients how easy home testing is with the WatchPAT. “I tell patients that the home-testing device is very user-friendly and comfortable. I find they are able to use it properly with no trouble at all. And they don’t have to leave their house.”

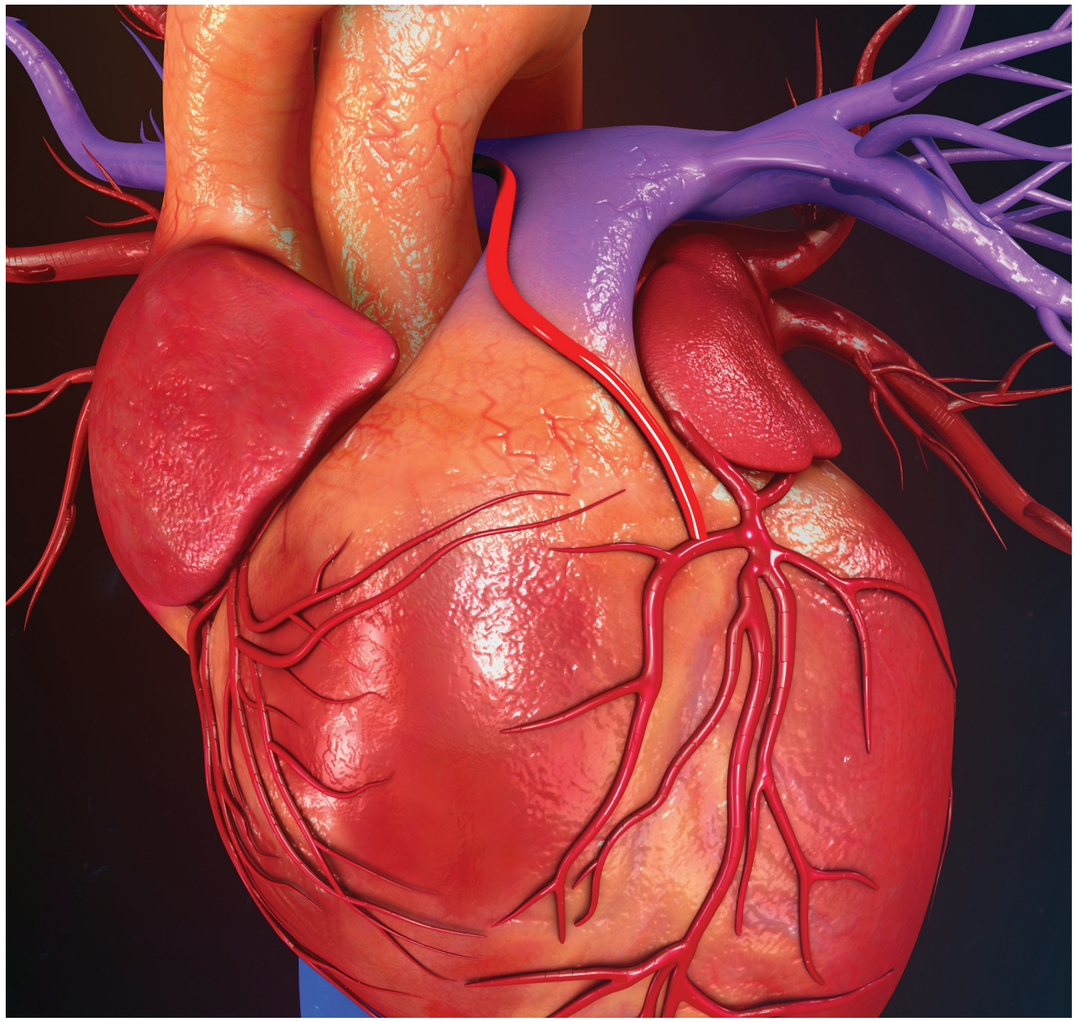
When he gets the results, Dr. Pumill consults with the physician who treats his own sleep apnea to determine the best course of treatment.

The cost of home testing, at around $200, is a wonderful bonus, especially when compared to a sleep lab test, Dr. Pumill noted. Many patients today have high-deductible insurance plans and may have to pay as much as $6,000 out-of-pocket, so they’re grateful that they can do sleep testing at home for far less. Insurance companies also are more likely to approve a home sleep test than a lab study test for that reason.

> **“If they go for sleep testing and need a CPAP and get it before their surgery, it’s a much safer recovery when they come home after their operation.”**

Dr. Pumill can point to at least two patients he has seen recently where home sleep testing was invaluable. “One patient came to see me for chest pain that started after he was in a car accident,” he said. The patient was driving with his son and stopped at a red light. He fell asleep and accidently stepped on the gas, striking a parked car. His chest went into the steering wheel when it happened. “When he told me he fell asleep at the wheel, I suspected sleep apnea and sent him home with a sleep testing device,” Dr. Pumill recalled. The WatchPAT data indicated that the patient did have severe sleep apnea. Because the patient had an abnormal EKG, Dr. Pumill ordered a stress test and saw he had coexisting coronary artery disease, which he also treated. “But we wouldn’t have found that he had sleep apnea unless we did the testing. It was critical to his overall care and getting a good outcome, as well as a safety factor since the patient had been falling asleep at the wheel for years,” Dr. Pumill said.

Another patient Dr. Pumill had was on CPAP for years and thought he was doing quite well, Dr. Pumill said. However, the patient was still tired all the time and his blood pressure was poorly controlled. “I convinced him to use the WatchPAT, which he could attach even if he was sleeping with his CPAP mask,” Dr. Pumill said. “The beauty of the WatchPAT is you can do it while you’re wearing your CPAP.” The study showed the patient had an AHI of 17 despite using his nasal mask, but he wasn’t using the chin strap from his machine and so the CPAP wasn’t effective. “We wouldn’t have learned the source of the problem without the WatchPAT,” Dr. Pumill said.



CPAP IS STANDARD OF CARE FOR OSA

Dr. Pumill believes that CPAP is the best treatment for obstructive sleep apnea in most cases. (Mandibular devices are effective in a small group of people, as is positional therapy he noted. And a new pacemaker-like device has recently become available for people unable to tolerate CPAP therapy.) However, Dr. Pumill knows many patients are reluctant to use a CPAP machine, fearing it’s cumbersome and makes sleeping difficult. Here’s another example where his personal experience comes into play. Dr. Pumill uses a CPAP for his own sleep apnea. “I don’t hesitate to tell them about my experience with CPAP and I find sometimes that can help, too,” Dr. Pumill said. Key to compliance is having the respiratory therapist from the durable medical goods company spend time with the patient learning their sleep habits and finding the most comfortable mask for them.

People who have OSA and however reluctantly go on CPAP often come back and tell me “it changed their life,” Dr. Pumill said. “And often it’s the same people who were fighting it and didn’t want to do it.”

If Dr. Pumill has a cardiology patient he suspects has sleep apnea and who requires surgery, he encourages them to have their sleep test before their surgery if at all possible. Communicating this information to the surgeon and anesthesiologist is also imperative. “If you have a patient who has surgery that’s going to cause more shallow breathing while they’re recovering, and if they’re on pain medication, it’s a setup for disaster,” Dr. Pumill said. “If they go for sleep testing and need a CPAP and get it before their surgery, it’s a much safer recovery when they come home after their operation.”

Dr. Pumill has been sending patients for sleep testing for years. “I sent my first patient about 25 years ago for a sleep study,” he said. Sleep studies are really not anything new, he adds. But as more is studied and written in the literature about the association between congestive heart failure, atrial fibrillation and other heart conditions and sleep apnea, “people are paying more attention to it,” he said. Thanks to home sleep testing devices sleep testing no longer has to be a big production nor take the patient away from his or her bed, Dr. Pumill said. Not only is this good news for patients but also for the doctors treating them. ■

WatchPAT Direct - Advanced In-Home Sleep Testing Delivered to Your Patient's Door

Male, slightly overweight, family history of heart disease, suffering from atrial fibrillation. There are around 6 million of those patients in the US alone and growing. There is a 50% chance that these patients also suffer from sleep apnea, which is described in the latest studies as a prominent risk factor and potential underlaying cause for the manifestation of the irregular heart rhythm. Despite this common knowledge, it is estimated that 80% of this group remain undiagnosed and untreated, mostly because they place their sleep apnea symptoms as secondary to their heart illness. These patients are typically referred to a cardiologist to try and manage their irregular heart rhythm and the risk of stroke that it carries. It is common sense that cardiologists will step in and educate the patients about the fact that their sleep apnea issues are related to their heart illness, and offer an easy diagnosis. Once formally educated and diagnosed, it is much more likely that an AFIB patient will be interested in managing this aspect of the disease. What is not obvious is the availability of resources and focus of the cardiologist to engage in sleep apnea diagnosis.

THE SOLUTION

The WatchPAT Direct program streamlines the home sleep apnea testing process for both prescribing physicians and their patients by providing a mail-order-like home delivery service model for the WatchPAT® sleep apnea testing device to the patient. The WatchPAT device is easy to use and is applied just like wearing a wrist watch, with a simple finger sensor. For physicians, the WatchPAT direct program provides a scalable, cost effective, and almost resource free solution to ensure their patients are being diagnosed for this emerging cardiac risk factor, sleep apnea, especially for high volume practices. For patients, the WatchPAT direct program is convenient and comfortable, and eliminates the need to drive back and forth to the cardiology practice, which in turn promotes better patient compliance with the program. WatchPAT direct shipment can be scheduled immediately or when needed upon insurance pre-authorization—so doctors and patients quickly receive the information they need.

THE WATCHPAT DIRECT PROGRAM

The WatchPAT Direct Home Sleep Testing program is as simple for cardiologists as clicking a button. After suspecting clinical signs and symptoms of sleep apnea by reviewing a STOP-BANG questionnaire results, and after receiving insurance pre-authorization for the test, the participating practice can log into the Itamar CloudPAT HIPAA-compliant physician portal, enter details about the patient's information and click "order".

Itamar then manages the entire logistical process and immediately prepares a testing kit to ship to its destination. The company handles all patient contact to ensure the test is efficiently and appropriately completed. As part of the program, a dedicated WatchPAT Direct representative personally calls every patient to confirm a delivery date and to provide instructions for the testing. Itamar also operates a patient call-in helpdesk until 2am EST where operators are available to assist and answer questions, to complement the step-by-step illustrated test instructions shipped with the device.

During the testing, the WatchPAT device stores all patient data as it is acquired. When testing is complete, the patient repacks the device in the original container for shipping back to Itamar using a pre-addressed and pre-paid label. An Itamar representative also calls the patient to ensure that they've completed the test and returned the device.

Immediately after receiving the device, Itamar staff upload the patient's data to CloudPAT, the same HIPAA-compliant web-based cloud application platform the cardiologist used to order the test. An automated scoring and raw report are then created automatically by the system in few minutes and emailed to the sleep expert for review and, if needed, a prescription for appropriate therapy.

On average, 3 days after the device is returned to the WatchPAT direct operational center in Atlanta, the cardiologists receive an email that the sleep report is available through the CloudPAT portal. By contrast, the same testing process can take weeks or even months through traditional referral to a sleep practice. The easy-to-read report includes a mapping of patient sleep stages, the main indices of critical respiratory events, such as AHI, oxygen saturation statistics and much more. The report is downloadable through the CloudPAT portal and can also be sent directly to sleep specialists so they can follow up on the patient.

THE BENEFITS

For physicians, using the WatchPAT Direct program to carry out home sleep testing for their patients offers a major time-to-treatment advantage because the test can be administered quickly, and results are available within a few days. Itamar manages the entire process, from the moment they receive the order for a patient to delivery of the interpreted report. The WatchPAT Direct program also requires no upfront investment on the part of the physician or hospital—all equipment is rented per test, maintained, and managed by Itamar.

A patient survey shipped with the device indicates that patients appreciate the ease of testing at home, the simplicity of the WatchPAT device and the comfort of the WatchPAT direct operation.

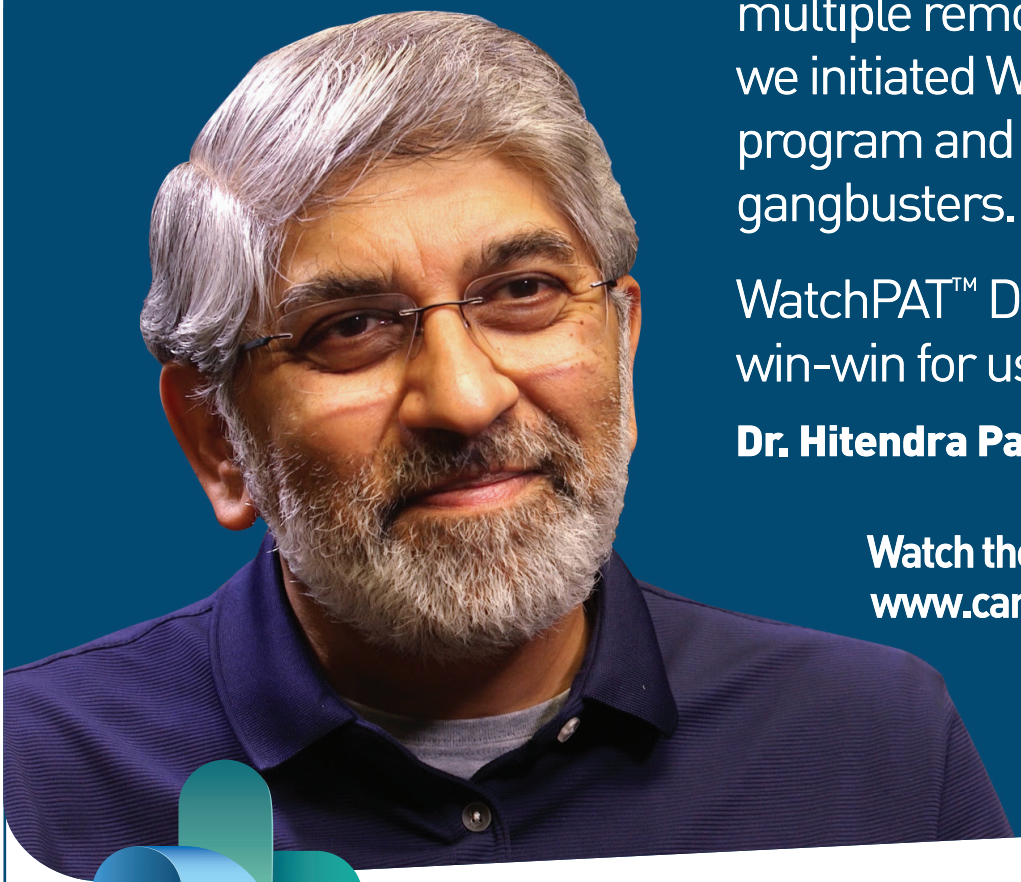
The WatchPAT Direct Program

- Patients reached by a representative to confirm their availability and to schedule the home sleep test.
- A purified kit is prepared for each patient, with a new sensor.
- Kits are shipped to the patients according to the scheduled test day.
- Patients receive a call from Patient Support Center on the test day with Instructions for Use. Patients can also call Patient Support Center 24/7 for any assistance with the test.
- Patients take the test in the comfort of their own bed. The next day, patients ship the device back with our prepaid shipping labels.
- Once the device is received, the study is uploaded to CloudPAT and sent to the referring physician.

"A WIN-WIN" FOR PHYSICIANS AND PATIENTS

Dr. Hitendra Patel, lead physician of WellStar pulmonary medicine in Georgia and medical director of their sleep program, calls WatchPat Direct "a win-win all around." When Wellstar first partnered with Itamar, they purchased WatchPAT devices and distributed them to patients through their offices. To better serve Wellstar's multiple remote locations, each with extended catchment areas, Patel and his staff worked with Itamar on the development of WatchPAT Direct, and, according to Patel, "the ship to patient direct took off like gangbusters."

With WatchPAT Direct, Itamar is making the entire home sleep apnea testing process fast and convenient, helping sleep specialists, cardiologists, and others to enhance patient care by integrating in-home sleep testing into their practices. ■



"To better serve our patients in multiple remote locations, we initiated WatchPAT™ Direct program and it took off like gangbusters.

WatchPAT™ Direct is a complete win-win for us."

Dr. Hitendra Patel

Watch the full video on www.cardiosleepsolutions.com

Sleep Apnea is a known contributor for all types of arrhythmias and diagnosing it can be as simple as ordering a holter or an event monitor

WatchPAT™ Direct offers a customizable workflow to best serve your clinic's needs with minimal effort from your staff.

Expand your HSAT program today with
WatchPAT™ Direct
Home Delivery Service

itamar medical

WatchPAT™
Home Sleep Testing Device