

Welcome Back! I am thrilled to introduce this issue of the Cardio Sleep Review, the third

in our series dedicated to expanding awareness of sleep apnea and providing insightful information on sleep apnea management.

This issue examines the importance of sleep screening in diagnosing OSA from the perspective of both physician and patient. Cardiologist Dr. Jeffrey Shanes discusses how screening is a priority in his practice, in response to the growing number of patients suffering with OSA and AFib. We also hear the moving story of a patient's decision to finally take a home sleep apnea test, and his subsequent diagnosis and treatment for both OSA and AFib that have led to a healthier life.

As a passionate advocate for interdisciplinary collaboration, pulmonologist Dr. Hitendra Patel describes the gains that can be made when cardiologists and sleep specialists work together to diagnose patients. He encourages cardiologists to use the STOP-BANG questionnaire as a systematic screening method to identify patients who may be at risk of OSA.

Reflecting on recent research, we investigate the relationship between OSA and increased risk of bradyarrhythmias. Additionally, we outline in detail the 2019 Reimbursement changes for HSAT, delineating the two components of service and billing requirements in the two primary

Our vision at Itamar Medical is to influence positive progress for sleep apnea management through our support of medical technology, practice tools and education. It is vital that cardiologists, electrophysiologists and sleep specialists work together to make sleep apnea management available and accessible to all patients who need it. Together, we can achieve infinitely more.

We hope you enjoy our third issue of Cardio Sleep Review.

If you have comments or topics you would like covered in future editions, please email us at info@itamar-medical.com.

Sincerely, Gilad Glick, CEO



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The Complex Interaction Between Heart Failure and Obstructive Sleep Apnea



Heart failure (HF) is a chronic, progressive condition in which the heart muscle is weakened and cannot pump enough blood to meet the body's needs for blood and oxygen. A better understanding of HF's pathogenesis and comorbidities is essential for improvement of risk stratification and prevention.

Among multiple comorbidities, sleep-disordered breathing (SDB), and obstructive sleep apnea (OSA), in particular, are the most common. Almost 50% of patients with HF have alterations of ventilation during sleep that can disrupt the positive effects of physiological sleep on the cardiovascular system. In two studies of patients

with HF undergoing polysomnography, OSA was detected in 37% and 11% of patients. The Sleep Heart Health Study, a prospective study of 6,424 men and women, indicated that the presence of OSA (defined as an apnea–hypopnea index [AHI] ≥10 per hour) favored the appearance of HF independently of other known risk factors, with a 2.20 relative risk.

The complex interaction between HF and OSA seems to be bi-directional. Some factors of HF can lead to the collapse of the upper airways, increasing the risk of OSA. For example, HF is characterized by fluid shifts from the legs to central structures (peripheral edema), especially in the supine position, which can lead to upper airways narrowing.

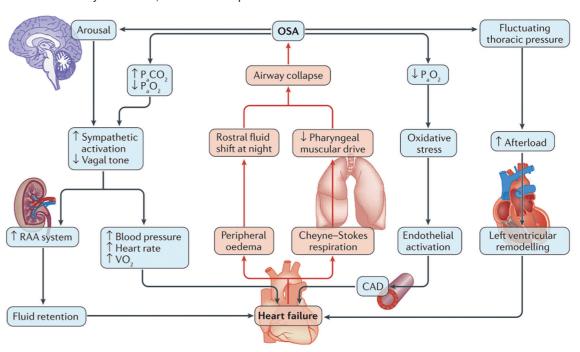
Conversely, OSA increases the risk of HF by multiple mechanisms. Obstructive apneas during sleep induce a series of systemic hemodynamic, autonomic, and humoral changes with adverse consequences on the cardiovascular system in individuals with normal ventricular function. The repeated occurrence of apneas and hypopneas has been associated with reduced endothelial function, an increase in the plasma concentration of inflammatory markers, increased platelet

aggregation, and increased variability in blood pressure and heart rate.

Moreover, the negative intrathoracic pressure during OSA results in increased venous return to the right ventricle and increased left ventricular (LV) transmural pressure, both damaging LV function. These recurrent events that accompany repeated obstructive apnea determine a further increase of the already elevated sympathetic activity in patients with HF, documented by increased plasma catecholamine. Obstructive events during sleep can also have long-term effects by the induction of genes involved in ventricular remodeling caused by the repetitive increases in wall stress, and by inducing myocyte slippage and contractile dysfunction. Accordingly, there's a growing understanding that the OSA-HF interaction has causal aspects and does not reflect mere co-morbidity.

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Schematic representation of the mutual interactions between OSA and HF. (CAD, coronary artery disease; PaCO₂, arterial partial pressure of CO₂; Pa O₂, arterial partial pressure of O₂; RAA, renin–angiotensin–aldosterone; VO₂, oxygen consumption rate.)

Parati, G. et al. Nature Reviews I Cardiology. 2016; 13(7):389

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How Obstructive Sleep Apnea **Increases the Risk of Bradyarrhythmias**

The American Heart Association defines bradycardia as a heart rate of less than 60 beats per minute (BPM), noting however that what should be considered "too slow" for an individual patient depends on various factors such as age. physical fitness and physiological condition. For example, during sleep the parasympathetic tone predominates (as NREM sleep occupies 80% of total sleep time), commonly resulting in bradyarrhythmias, sinus pauses greater than two seconds, and atrioventricular (AV) conduction delays. However, some cases of nocturnal bradyarrhythmias are not normal; these reflect acute bradycardia also prevalent in wakefulness and can lead to various complications. Obstructive Sleep Apnea (OSA) was found to be a promoting factor for these cases.

Numerous studies have demonstrated increased prevalence of bradyarrhythmias in OSA patients. The classic study by Guilleminault et al looked at 400 patients with OSA.1 Of these, 48% had significant nocturnal arrhythmia with 18% bradyarrhythmia, 11% sinus arrest, and 8% AV blocks, compared to a 3% prevalence of nocturnal bradyarrhythmias in the general population.^{1,2} There were no important differences in age, body weight, apnea-hypopnea index (AHI), or minimum oxygen saturation between patients with and without arrhythmias. In a more recent Japanese study by Abe et al, 1,350 OSA patients and 44 control subjects were screened, and significant differences were noted in the increase in incidence of sinus bradycardias (12.5% with OSA vs. 2.3% control, p=0.036) and sinus pause (8.7% with OSA vs. 2.3% control, p<0.001).3 Importantly, long-term monitoring with implanted pacemakers reveals an even higher incidence of bradyarrhythmias (up to 34%), suggesting that OSA can increase the risk for bradycardia dramatically.4

In addition to increasing the prevalence of bradyarrhythmias, some studies have found that OSA severity is correlated to the severity of bradyarrhythmias, with up to 3 times higher incidence of bradycardic arrhythmias in patients with severe OSA, compared to milder OSA.5 This correlation could suggest a causal relation between the two. with OSA promoting bradycardia.

The mechanism by which OSA can reduce the heart rate is demonstrated in Figure A. During OSA, structural changes occur in the airway to obstruct airflow (Resp), and the resulting apnea activates hypoxic reflexes (SaO₂%). These in turn lead to profound elevation in sympathetic nerve activity (SNA) and subsequent elevation of atrial blood pressure (ABP) as well as a decrease of the heart rhythm (ECG). Various studies confirmed that the elevation in vagal tone is the key contributor to the bradyarrhythmias, while other factors such as sinus node anatomy or atrioventricular conduction remain largely intact in OSA patients.6 The finding that intravenous atropine administration eliminates the marked sinus arrhythmia and bradyarrhythmias observed in such patients supports this hypothesis.6 Moreover, mimicking OSA in wakefulness with Muller's maneuver results in induced bradycardia, further confirming that the combination of prolonged negative intrathoracic pressures and the resulting hypoxemia provide the necessary underlying "mix" for this unique pathophysiology.7

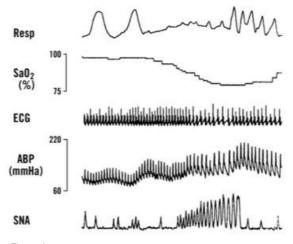


Figure A.

The crossover between bradyarrhythmias and OSA is also made apparent by the beneficial treatment of OSA on bradycardia severity. Specifically, positive airway pressure (PAP) therapy has been shown to be highly effective in abolition and reduction of bradyarrhythmias. In the Abe study, CPAP therapy dramatically reduced sinus bradycardia (p<0.001) and sinus pauses (p=0.004).3 Thus, the current recommendation for patients with bradyarrhythmias at risk for OSA is to perform overnight polysomnography prior to pacemaker implantation, especially in younger

individuals without underlying cardiac disease. Permanent pacemakers should be considered if significant bradyarrhythmia or pauses persist after an adequate treatment trial with PAP therapy.

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OSA AND HEART DISEASE: CONNECTING THE DOTS

+25MM ADULT

IN THE US AFFLICTED WITH OSA1 30 TO 70 YEARS OLD2

THAT'S 26% OF ADULTS



ATRIAL FIBRILLATION Ш

OF AFIB PATIENTS HAVE OSA4



4

RISK OF DEVELOPING AFIB AMONG THOSE WITH OSA4

INCREASE IN AFIB RISK FOR OSA PATIENTS WITH **HEART FAILURE**

~5MM AMERICANS ARE LIVING WITH CONGESTIVE HEART FAILURE⁵

ARE DIAGNOSED IN THE US EACH YEAR5

11-37% OF HF

RELATIONSHIP BETWEEN OSA AND HF9 FUNCTIONAL RECOVERY AFTER STROKE14

STROKE

72% OF STROKE/TIA



INCREASED RISK

OF OSA IN STROKE PATIENTS

TREATMENT OF OSA

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2019 Reimbursement **Update for Home Sleep Apnea Testing**

MODIFIERS USED FOR UNATTENDED HOME **SLEEP APNEA TESTING**

Home sleep apnea testing (HSAT) has two components of service which can be billed separately or together if the same physician is conducting both components.

The technical component (TC) captures the administration of the test including patient instruction, the cost of the equipment, supplies and personnel to perform the procedure. The modifier -TC should be appended to the CPT® code, for example, 95800-TC. The place of service (POS) code reflects the location where the test was conducted. Medicare often requests POS 12 for home, while commercial payers often request POS 11 for office. Check with your payer to ensure the correct billing code. The date of service should be the date the test was performed.

The professional component (26) captures the interpretation of the home sleep test results by a qualified healthcare professional. The modifier -26 should be appended to the CPT® code, for example, 95800-26. The POS should reflect the location where the physician interpreted the test results, which is typically POS 11 for office for both Medicare and commercial payers. The date of service should be the date the physician interpreted the results.

The global service may also be billed if the technical and professional components of the service are performed by the same provider. No modifier is necessary. As an example, the provider would bill 95800. The location would be either POS 12 for home or POS 11 for office following the direction of the payer. The dates of service may be either the date the study was performed or the date the study results were reviewed and interpreted.

The practice should choose which date to use and remain consistent in reporting.

SOURCES:

- "Polysomnography and Other Sleep Studies" Noridian Healthcare Solutions, Medicare Part B and Durable Medical Equipment (DME) Provider Outreach and Education (POF) March 2016
- CGS Contract Administrators LLC Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Appea (L33718).
- "Guidance on Coding and Billing the Date of Service" MLN Matters SF17023 CMS Medical Learning Network

2019 CHANGES TO NATIONAL PAYMENT **RATES FOR HSAT**

CMS published significant changes to payments for HSATs in their 2019 Final Medical Physician Fee Schedule (MPFS). CPT® code 95806 (Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort, e.g., thoracoabdominal movement) received a 19% decrease in global service payment from the prior year while 95800 (Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis, e.g., by airflow or peripheral arterial tone and sleep time) remained largely the same with a 4% decrease (see Table 1).

The payment rate for each service is based on a formula which takes into account clinician work, practice expenses, and the cost of professional liability insurance. The relative cost of these inputs is represented by relative value units (RVUs) which are adjusted for variation in different markets and multiplied by an annually updated standard called the "conversion factor."

In 2017, the RUC recommended new RVUs to CMS for home sleep tests. However, in the 2019 final MPFS, CMS made two significant changes

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CPT® Code	2019 Medicare National Payment	2018 Medicare National Payment	2019 Total RVUs	2018 Total RVUs
95800	\$172.63	\$180.72	4.79	5.02
95806	\$140.55	\$173.52	3.90	4.82

Table 1: 2018 & 2019 Medicare Payment Comparison

which affected the relative payments of 95800 and 95806. The first change affected the work RVU (wRVU) for both 95800 and 95806 and the second change was to the practice expense (PE) inputs for 95806.

CMS reduced the wRVU from the RUC recommendations, noting that the reductions were based on comparing home sleep tests to similar procedures (pacemaker programming device evaluation; 93281, 93260). CMS noted that these procedures had similar wRVUs and intraservice times. In addition, CMS noted that with procedure volumes increasing and service time decreasing, physicians were becoming more efficient at performing the procedure which under the resource-based format of the RVU system supported a reduction in the wRVU. CMS reduced the wRVUs for both 95800 and 95806 (see Table 1).

The practice expense (PE) RVU represents supplies and equipment used in a medical procedure. The pricing for the WatchPAT™ supplies and equipment (CPT® code 95800) was not identified for adjustment under the 2019 Final Rule and the PE RVU was relatively level year over year. However, CMS reviewed the pricing

for supplies and equipment utilized for 95806 and reduced the PE RVU from 3.47 in 2018 to 2.92 in 2019.

The combined changes to the wRVUs and PE RVUs resulted in a 19% decrease in the global service fee for 95806 while the global service fee for 95800 had a 4% decline. This represents an approximately 23% difference in global service reimbursement between these two codes for calendar year 2019.

SOURCES:

- Physician and Other Health Professional Payment System, Payment Basics, Medpac, October 2017
- MLN Fact Sheet, Medicare Fee Schedule, ICN 006814
- RVS Update Committee (RUC), AMA website, www.ama-
- Calendar Year 2019 Medicare Physician Fee Schedule, Final Rule [CMS-1693-F]. Federal Register, November 23,

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 paver for interpretation of coverage, coding and payment policies.

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Closing the Loop on Sleep **Apnea Management**

Speaking with cardiologists across the country about the care pathway for sleep apnea management of their patients, we are often asked:

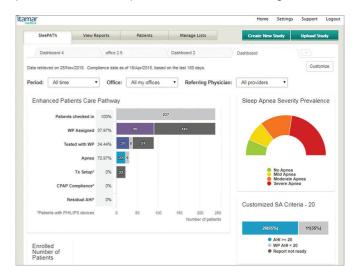
> "How do I know what happens to the patient after we diagnose them?"

A significant physician concern is the breakdown of communication regarding a patient's care among different disciplines. This concern is being addressed by sharing vital data through hospital-networked electronic medical records (EMR) and/or proprietary software provided by outside sources. As Medicare and private insurers move toward a more value-based reimbursement, physicians need information to more accurately monitor complex patients across multiple providers. Physicians often struggle to get the information they need. Hospitals and private practices have concerns around who will fund and conduct this additional data collection and monitor the quality of the reporting. These costs further stretch medium-to-small practices to their limits. Once physicians acquire the needed information, they are often frustrated with the inability to pare down the data to make educated decisions on the patient's care continuum.

Many industry partners have focused their attention and resources on solving these problems. Itamar Medical's mission is to improve cardiac patient care through the integration into the care continuum of innovative and clinically efficient sleep apnea management solutions that reduce overall healthcare

> So, how did we answer the question, "How do I know what happens to the patient after we diagnose them?"

We have created **SleePATh™**, an IT solution to manage the data of an individual patient's journey through the care pathway of sleep apnea management. This program is integrated into our cloud-based data solution called CloudPAT™. The interface allows the user to visualize the practice at a macro level down to micro level patient-specific results. Using data provided by CPAP makers like Philips Respironics, we can provide a Cardio Sleep Dashboard to the cardiologist.

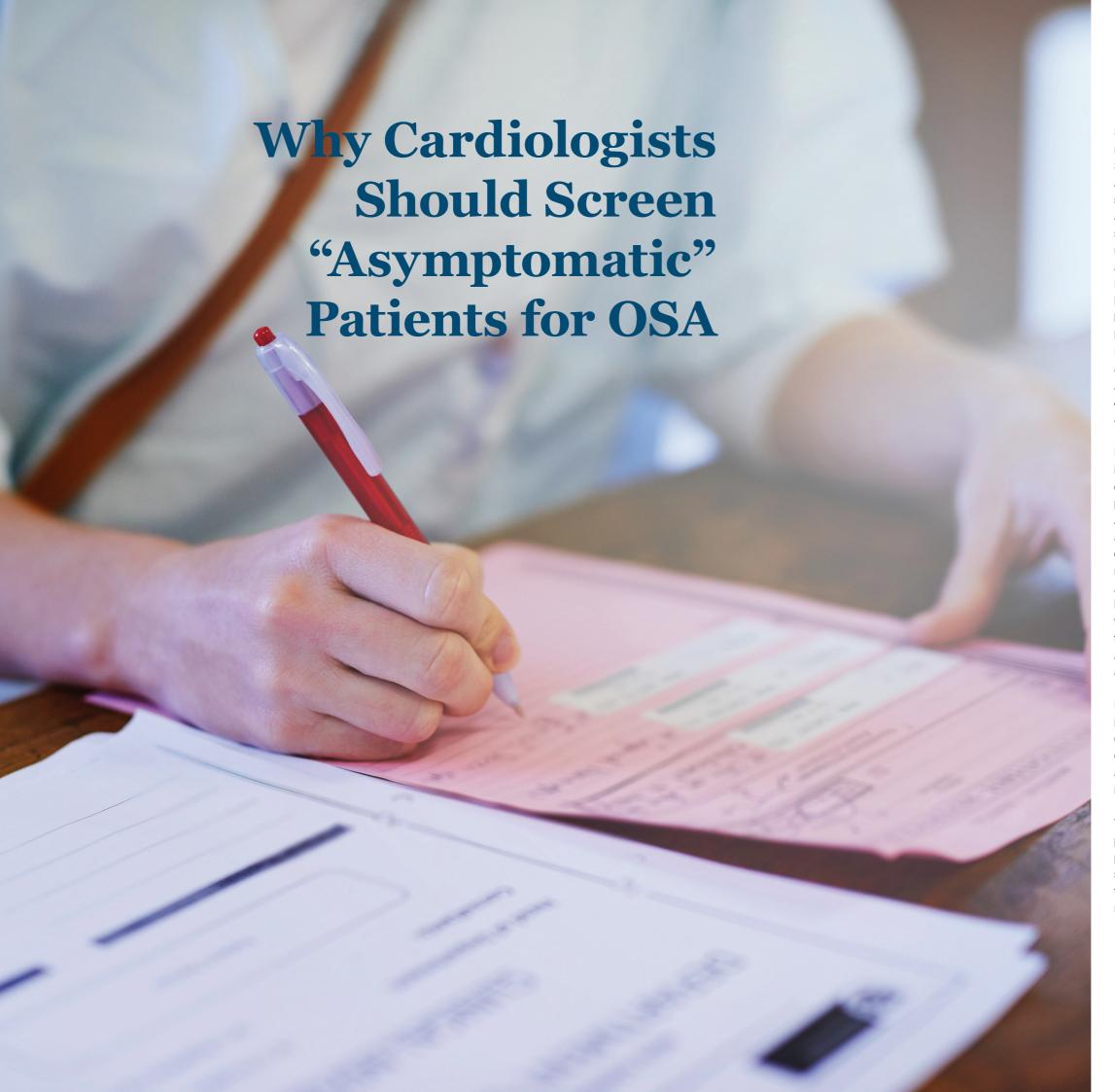


This dashboard allows the cardiologist to track multiple aspects of a patient's sleep apnea status, as well as office program statistics, anytime from anywhere. The key components are:

- Simple interface showing the care pathway progress—where the patient is in the continuum of care
- · Diagnosis status and results-did the patient receive a WatchPAT Home Sleep Apnea Test and was it returned with a validated test result
- CPAP compliance—has the patient met Medicare guidelines for CPAP compliance
- The number of days and hours on CPAP
- Residual sleep apnea—what is the severity of sleep apnea, as identified by the Apnea Hypopnea Index (AHI) while wearing

The SleePATh product is available, at no charge, as part of the turnkey program for Cardiology called the Total Sleep Solutions (TSS). TSS is a one-of-a-kind sleep apnea management service for the cardiology practice, providing diagnosis and treatment planning to millions of cardiac patients with undiagnosed sleep apnea.

For more information please contact your local Itamar sales representative or email us at infousa@itamar-medical.com.



Sleep disorders, including sleep apnea, are on the rise, posing a significant health issue in the United States. According to the American Sleep Apnea Association, as many as 22 million Americans suffer from sleep apnea - and of those, as many as 80 percent have cases that are moderate to severe but may not know it. Sleep apnea is widely underdiagnosed and severely underreported, according to an analysis of the Sleep Heart Health Study.1 Untreated, sleep apnea also can lead to a host of cardiac issues including high blood pressure, chronic heart failure, pulmonary hypertension, stroke and atrial fibrillation.2 Research has even confirmed links between sleep apnea and both type 2 diabetes and depression.^{3,4} A new study published in the European Respiratory Journal found a possible link between sleep apnea and dementia.5

Dr. Jeffrey Shanes, who has practiced as an interventional cardiologist in Elmhurst, Illinois, said cardiologists are seeing a significant increase in patients with atrial fibrillation. "We are seeing more AFib every day in our routine practices - probably a quarter to a third of patients will have had a diagnosis of AFib and an equal, if not greater, number of new consults will be diagnosed with AFib. It's truly an epidemic. It's unbelievable," he said. In addition, many patients come to the hospital ER having had a stroke and only then learn that they have AFib, Dr. Shanes said. According to the American College of Cardiology, about 20% to 30% of all strokes are due to AFib.

Dr. Shanes believes a part of this increase in AFib is due to a parallel rise in the number of adults with OSA. Research has shown a strong link between OSA and AFib. Both conditions also are linked to aging and the average age of the U.S. population is increasing, Dr. Shanes noted.

The good news is that identifying OSA in cardiac patients can help lead to better, more tailored and preventive treatment, Dr. Shanes said. Indeed, he said, more data is coming out in scientific journals that shows treating OSA in patients with AFib can reduce their AFib burden.

SCREENING WITH QUESTIONNAIRE ROUTINE

Dr. Shanes is so adamant about the benefits of identifying sleep disorders that when he had his own practice, he made screening for OSA a priority. He instituted a practice where he had his medical assistants administer the STOP-BANG questionnaire for every patient. The questionnaire asks patients about their sleeping and snoring habits and looks for known risk-factors for sleep apnea: a neck circumference of 17 inches or more for men and 16 inches or more for women; and a body mass index of greater than 35, which is obese.6 The questionnaire takes less than two minutes to administer, so it doesn't negatively impact office workflow, he noted. Having such a screening algorithm in place helps identify many more patients with OSA than leaving it to clinical judgment alone, Dr. Shanes said.

Before seeing the patient, Dr. Shanes would review the results of the questionnaire and, if the patients had three or more risk factors, he would strongly suggest they undergo an at-home sleep study. "I would tell the patients, this is why I am concerned about possible OSA, what the implications are, and why I recommend a sleep study." If the study showed they had sleep apnea, Dr. Shanes also would explain what it could mean for their cardiovascular disease. "Colleagues may vary a little on how many risk factors before they recommend a sleep study, but for me it's three or more and I would offer them the study," he noted. "That makes it consistent for every patient." Dr. Shanes convinced many of his colleagues in his practice to do the same. "We found that the benefit of putting such a screening algorithm in place is that it helped us to identify many more patients with OSA early on," he said.

Another group of patients who need sleep studies are those who, while in the hospital for another reason whether hip replacement or pneumonia or something else, are placed on monitors that show their heart rate dropping to the 20s and 30s at night, Dr. Shanes said. "In the past, we wouldn't say too much about that drop," he said. "But now that we're so tuned into OSA, those are another type of patient we say must get a sleep study as an outpatient because we don't do sleep studies in the hospital. We find that a lot of those patients who have heart rates in the 20s and 30s that we



discovered by accident, when we screen them for sleep apnea, turn out to have it indeed."

Since he began routinely screening, Dr. Shanes has found that of the patients he recommends for a sleep study, about 60 percent turn out to have moderate to severe sleep apnea. "You wouldn't have guessed it," he said. It's a significant number, and much higher than he could have anticipated, he said. It has made him aware of how widespread a problem sleep apnea is among cardiology patients, motivating him to become an advocate for aggressively identifying patients who have this powerful and independent risk factor for cardiovascular disease.

SHOULDN'T BE LEFT TO CLINICAL JUDGMENT ALONE

Many cardiologists believe that they can identify patients with OSA simply by taking their medical history, doing a physical exam and using good clinical judgment, Dr. Shanes said. It is possible, he noted, to "eyeball" patients for risk of OSA. He adds, however, that leaving it up to clinical judgment alone clearly misses many who may

be at risk. For whatever reason, patients tend to be reluctant to bring up the fact that they are not sleeping well at night and may be unaware that they are not breathing, he said. Too often, it is only by chance that their spouse or bed partner mentions it during an exam, he said. "People may claim that they don't feel tired during the day, because they don't realize it until after they are treated and are sleeping better," he said.

Some cardiologists will order sleep tests only for patients with hypersomnia, snoring and obesity. However, asymptomatic patients need to be screened as well, Dr. Shanes said. Patients can have OSA and not have overt symptoms or the typical body habitus associated with OSA.

Using diagnostics like calcium scoring and hs-CRP, cardiologists are able to identify patients who are at higher risk for myocardial infarction, stroke or sudden death. "Diagnosing 'asymptomatic' patients who have sleep apnea would add a new dimension in terms of stratifying patients who are at increased cardiovascular risk and may be candidates for more aggressive cardiovascular

"Identifying patients with OSA is no less important than screening for other cardiovascular risk factors including high cholesterol, hypertension and diabetes..."

protective therapies. In addition, the time and cost for screening and testing appropriate patients with a home sleep study is minimal."

AT-HOME SLEEP STUDIES MEAN MORE COMPLIANCE

Understandably, Dr, Shanes said, patients are reluctant to go to a sleep center to sleep hooked up to wires, leads and monitors and under constant observation. Not only do they find the inlab test uncomfortable, many also have issues even getting to the lab, especially if they are elderly and don't drive or have transportation, he said.

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However, since sleep testing now can be done at home, the vast majority of his patients whom he recommends be tested agree to it, Dr. Shanes said. "And I have not had any patients who have been unable to perform the test with their at-home devices." Not only is the at-home sleep study easy to do, Dr. Shanes said, "but also we get the results right away. We get a report within 24 to 48 hours. So, we know the results and can send the patient to a sleep specialist if indicated." The results from the at-home test are reported in a way as to be clear and actionable for the cardiologist who initially ordered the exam, he said. Fortunately, OSA is relatively inexpensive to treat. Basically, patients are given continuous positive airway pressure (CPAP) machines, which prevent the airway from closing during sleep, Dr. Shanes said. A study published in the Journal of the American College of Cardiology Clinical Electrophysiology in 2015 found that the use of CPAP is associated with significant reduction in recurrence of AFib in patients with OSA.7

In any field, it takes a long time for researchers to come out with the data to support screening and for screening to become part of a medical society guidelines, Dr. Shanes said. Screening for sleep apnea is just now getting on cardiologists' radar, he said. What's needed to move it along, he



Dr. Jeffrey Shanes, interventional cardiologist

said, is "education, education," Much research has been devoted to identifying new risk factors for cardiovascular conditions including stroke, heart attack and congestive heart failure, Shanes said. "Most clinicians have incorporated screenings for metabolic syndrome, hs-CRP, and coronary calcification into their practices in order to identify patients earlier for more aggressive preventive therapies." he said. It's time, he added. that cardiologists do the same for OSA because of its link to atrial fibrillation and other cardiovascular diseases. Clearly, patients with OSA need to be identified and treated.

Having cardiologists test for sleep disorders is still very new and evolving, Dr. Shanes said. "It is going to take a little while to figure out exactly what the best role is." At this time, Dr. Shanes said, "We don't have large, randomized trials that say if you screen asymptomatic patients for OSA, you're going to prevent a stroke, you're going to prevent sudden death, you're going to prevent AFib. There's a lot of data out there that sure makes it suspicious for all those types of things." However, he said, "All the data points in this direction. Sometimes you just have to connect the dots." Identifying patients with OSA is no less important than screening for other cardiovascular risk factors including high cholesterol, hypertension and diabetes, Dr. Shanes said.

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OSA, AFib Patient: "Get Tested, It May Save Your Life. It Saved Mine!"

When the sleep specialist looked at the results of Floyd Rowland's second sleep test, he asked, "How are you even alive?" The at-home sleep test confirmed what the former Marine from Oceanside, California, already suspected: he had severe obstructive sleep apnea (OSA). His Apnea-Hypopnea Index (AHI) was 64, which meant he woke up at least 64 times in an hour and stopped breathing for at least 10 seconds each time.

Floyd, 58, had known he had OSA since his first inlab sleep test in 2007. But because of his military background, his inclination was to put everyone else first and he did not seek treatment.

Soon after Floyd was first diagnosed with OSA, he had other issues that seemed to him more pressing to deal with: aging and ill parents and inlaws, his wife's two bouts of cancer, and his best friend dying. And if all that wasn't enough, he just wasn't aware of how serious sleep apnea can be. "I just kept putting my own health on the backburner," he said.

TWO DIAGNOSES: FIRST OSA, THEN AFIB

It all began in 2007, after he returned from a tour of duty that included Desert Storm. Floyd's wife, Sylvia, noticed him snoring and not breathing while he slept, and alerted his doctors. At his doctor's urging, Floyd agreed to the in-lab sleep study. Sleeping hooked up to monitors and under the scrutiny of technicians was a difficult and unpleasant experience for him. "You have to sleep in a strange bed with someone watching you on camera. You're hooked up to multiple leads and with goo in your hair." With pressing family issues to manage, Floyd ignored the diagnosis of OSA.



Research has shown that OSA can cause atrial fibrillation. About six years after the first sleep test, Floyd was diagnosed with AFib. Floyd and Sylvia had come home from a party when he felt his heart racing. Sylvia took one look at him and urged him to go the ER, but he said no. About six hours into the evening, with no change, he relented. His symptoms were successfully treated medically with metoprolol and atenolol.

Exactly one year later to the day, while on a family vacation cruise, Floyd had another AFib episode. Once back at home, he went to see his doctor, who again was able to address the problem with medication though he continued to have periodic episodes. Whenever he found his heart racing, his solution was to take a baby aspirin and rest.

FAMILY MEMBERS SPUR HIM TO ACTION

Both conditions seemed to get worse with time. Sylvia became increasingly alarmed when Floyd would fall asleep during the day-in the middle of conversations and even while driving. Sylvia discussed her concerns with Floyd's younger brother, Bill, who lived in Georgia.

About three years ago, at another family gathering, Sylvia and Bill "ganged up" on Floyd. "Apparently, Billy caught me not breathing," Floyd said. Sylvia and Bill told Floyd he could no longer sit back. He had to do something about both his medical issues or, they feared, he would have a stroke and die.

Floyd finally agreed to see a doctor about it. His provider recommended another sleep test. Floyd agreed but only because this time he could do it at home in his own bed using the WatchPATTM. "I wasn't going through the nightmare of having someone watch over me again," he said. "The WatchPAT was very easy to use."

This time, when the test results came back, Floyd realized: "How can I be that sick? But there it was in black and white." He was diagnosed with severe OSA. His physician convinced him of the need to control both his AFib and OSA to help prevent a stroke. This motivated him to treat his OSA with a continuous positive airway pressure (CPAP) machine.

CPAP WAS VALENTINE'S DAY PRESENT

Floyd came home with his CPAP on Valentine's Day, February 2017. "My wife was crying for happiness because I had finally done something about my sleep apnea."

The CPAP has made his life so much better, he said. "I don't fall asleep during the day anymore," he said. "I feel like a whole different person. I'm not waking up multiple times each night. I haven't slept like that in 10 years."

Admittedly, Floyd was somewhat reluctant to get a CPAP because he didn't want the discomfort of wearing a mask every night. Fortunately, the CPAP he was given fits just over his nose and is not at all uncomfortable or bulky, he said.

About eight months later, in October that year, Floyd underwent a cryoablation for his AFib. The cryoablation and CPAP have changed his life, he said. "I have not to this day had another AFib attack," Floyd said. "And I have more energy to do the things I enjoy."

GRATEFUL FOR 'PUSH' FROM FAMILY,

Floyd never sleeps without his CPAP and is grateful to his wife and brother for pushing him to take action. "Between my doctors, my persistent stubborn little brother and my lovely wife, I owe them my life," he said. "If I had not gotten my sleep apnea taken care of, I would not have been able to fix my heart."

Although Floyd doesn't like being in the spotlight, he has become an advocate for taking care of one's health issues sooner rather than later and especially with addressing sleep apnea. Says Floyd: "Now I tell people whenever the subject comes up: You have to be more aware of your health and don't be afraid to ask for help and discuss your symptoms with your doctors. If they tell you to take a sleep test, take it, don't wait. There's an easy and comfortable way now to get the results at home, in your own bed. Sleep apnea is a serious health hazard."

Sleep Specialist to Cardiologists: "Working Together Will Serve Our Patients Well"

Dr. Hitendra Patel, board certified in internal medicine, pulmonary disease, critical care and sleep medicine, and Medical Director of the WellStar Sleep Program in Georgia, would like to see his specialty partner more closely with cardiologists. Dr. Patel believes that when sleep specialists like himself work in tandem with cardiologists, they can help identify and prevent cardiovascular risks that can lead to stroke, sudden death and other cardiovascular threats to their patients' lives.

Links between heart disease and sleep disorders have been clearly established, Dr. Patel said. And more links continue to be identified, he said. "We are learning more recently about the relationship between atrial fibrillation (AFib) and central sleep apnea. We all know that congestive heart failure and cardiomyopathy are related to central sleep apnea, but now we know AFib as well," he said.

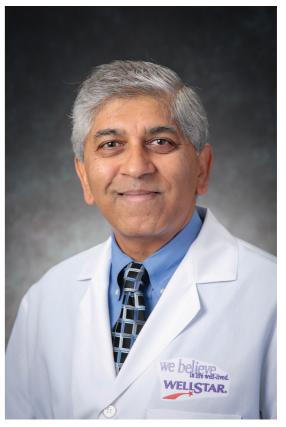
Dr. Patel has no doubt that the vast majority of cardiologists are aware of the links between the heart diseases they treat and sleep disorders, especially between obstructive sleep apnea (OSA) and atrial fibrillation (AFib), both of which are on the rise across the country. Because time is at such a premium in today's medical practices and increasingly patients are presenting with comorbidities, logistics may prevent them from taking time to routinely add screening for OSA to their protocols.

The good news, Dr. Patel said, is such screening can be added with a reliable, concise, and easy-to-use questionnaire that takes no more than 2 minutes to administer to each patient. The questions are referred to as STOP-BANG

for Snoring, Tiredness, Observed apnea, high blood Pressure, Body mass index, Age, Neck circumference, and Gender.¹ Staff can ask the eight yes-no questions before cardiologists examine their patients and, if the results show a risk for moderate to severe OSA, cardiologists can know to order sleep testing at that visit.

SLEEP NAVIGATORS COULD BE THE SOLUTION FOR THE CARDIOLOGY PRACTICE

If cardiologists are afraid that they don't have the time or staff to administer the test, they may



Dr. Hitendra Patel, Medical Director of the WellStar Sleep Program

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be able to follow a model being considered at Wellstar, where appropriate sleep screening can be hard wired into the cardiologists' office. A sleep navigator can help facilitate this process. WellStar's sleep navigator is a respiratory therapist. It's a great start to a much-needed healthcare professional addition, Dr. Patel said.

Sleep specialists have seen a significant uptick in referrals from the sleep navigator taking on this role. "You clearly could see a direct correlation," Dr. Patel said. "And the administration backed the position because the pro forma was there," he added. The increase in referrals for sleep testing indicated that the cardiologists were flagging possible OSA in a good number of their patients that they might not have otherwise, he said.

Having someone from the sleep medicine department in the cardiologists' office doesn't interfere with the day-to-day workflow, Dr. Patel noted. "Cardiologists are aware of the sleep problem. They appreciate that someone is taking care of it for them."

After review of the STOP-BANG results, cardiologists have three options: 1) refer the patient for an in-lab sleep test, 2) refer the patient for an at-home sleep test, or 3) refer the patient to a sleep specialist. Cardiologists will meet much less resistance from their patients when they refer them for an at-home sleep test, Dr. Patel said. Patients prefer the at-home test because it means they can sleep in their own bed and they find the

home device very easy to use, Dr. Patel said. Also, the cost (co-pay) is likely lower for the home test than it is for the sleep lab test, Dr. Patel said. The quality of the at-home test results is comparable to in-lab tests, he noted.

COLLABORATION BETWEEN CARDIOLOGIST AND SLEEP SPECIALIST MAKES IT EASY FOR ALL

The cardiologist should have the results of the at-home sleep test within 24 hours, 48 hours at the most, Dr. Patel said. If the results show moderate to severe sleep apnea or other sleep disorders, the cardiologist can refer the patient to a sleep specialist. "As sleep specialists, we work in partnership with cardiologists. We ensure that that their patients get appropriate follow-up care for their sleep disorders," Patel said. "We copy the cardiologist on the patient record and keep them informed as to how we are treating their patient. They are very happy with this type of collaboration. Cardiologists don't have time to deal with the sleep aspect of their patients' care. We try to make it as convenient as possible for the cardiologist."

Dr. Patel believes that not just cardiologists but all specialists are seeing the tip of the iceberg when it comes to patients with sleep disorders. "I firmly believe there's a huge undiagnosed population of patients with a variety of sleep disorders, and more and more comorbidities are identified every year as well as their relationships with other diseases. Heart issues are one of the longest established comorbidities for sleep disorders, and we are seeing more nuances on the relationship between

sleep and the heart. As we learn more about sleep and how it's affecting all parts of us, including the heart, we will see an increasing need to be vigilant about screening people for sleep disorders. Many patients walking around may be asymptomatic, but they could have sleep disorders that are affecting their heart and overall health."

Dr. Patel is working to convince cardiologists sleep testing is not just "an extra task to put on their plate." but rather a valuable step they should incorporate in their practices to treat "the whole patient." Sleep apnea may not be a cardiac condition per se, Dr. Patel said, but "it is a significant risk when cardiologists are treating patients for congestive heart failure, or atrial fibrillation, or really any other cardiac disease."

Sleep may be "the new kid on the block" when compared to other health conditions that have been studied for centuries, Dr. Patel said. "It's relatively a new field and we need to do ongoing research to discover more about sleep disorders because, you name it, sleep touches it. We do know that heart disease and sleep are closely related and that attention must be paid to this relationship. Sleep isn't as 'sexy' a topic for people as the heart, but we have to take the relationship very seriously."

Given the mounting evidence and the growing number of heart patients with sleep disorders, Dr. Patel said, it's time for cardiologists and sleep specialists to work together and make screening for sleep disorders the standard of care.

STOP-BANG QUESTIONNAIRE

SNORING

Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?

Yes No

TIRED

Do you often feel tired, fatigued, or sleepy during daytime?

Yes No

OBSERVED

Has anyone observed you stop breathing during your sleep?

Yes No

BLOOD PRESSURE

Do you have or are you being treated for high blood pressure?

Yes No

BMI

BMI more than 35?

Yes No

AGE

Age over 50 years old?

Yes No

NECK CIRCUMFERENCE*

Neck circumference greater than 17 inches (male) or 16 inches (female)?

Yes No

GENDER

Gender male?

Yes No

High to moderate-high risk of OSA: answering yes to three or more items

Low risk of OSA: answering yes to less than three items

* Neck circumference is measured by a healthcare professional

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Impact of OSA on Abdominal Aortic Aneurysms

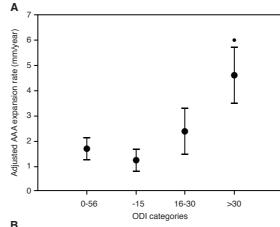
Abdominal aortic aneurysm (AAA) is a potentially life-threatening condition that may be exacerbated by Obstructive Sleep Apnea (OSA). OSA has been verified as an independent causal factor in the pathogenesis of hypertension and vascular dysfunction. More specifically, several pathomechanisms have been suggested to account for the potential adverse effect of OSA on AAA:

- 1. The intrathoracic pressure changes leading to shear stress on artery walls
- Intermittent hypoxia leading to oxidative stress, sympathetic stimulation, and possibly atherosclerosis
- Arousal-induced sympathetic activation inducing subsequent repetitive blood pressure surges and chronic hypertension.

The attempts to link OSA to AAA are based on early studies of patients with Marfan syndrome. In the early 1990s it was first suspected that OSA may have deleterious effects on the aorta in Marfan syndrome patients. Later researchers demonstrated higher prevalence of OSA in those patients and described a correlation between OSA severity (as measured by the apnea-hypopnea index [AHI]) and aortic root diameter (r=0.5, p<0.001). In a follow-up longitudinal study of 44 Marfan syndrome patients, only subjects with OSA developed an aortic event (after a median follow-up time of 29 months). Although the relative risk of OSA was not successfully assessed due to the small sample size, this remains the only longitudinal study which investigated the effect of OSA on the aorta by means of events, rather than disease parameters.¹

Several cross-sectional studies on the general population found a positive association between the aortic root diameter and OSA severity. Interestingly, simulating OSA in healthy volunteers with the use of Muller's maneuver induced considerable changes in both blood pressure and proximal aortic diameter and area, probably due to increased aortic dilatory pressures. Observational studies have consistently reported that OSA is highly prevalent among patients with AAA. In one such study by Mason and colleagues, 127 patients (11 women, mean age 67.9±6) with an abdominal aortic measurement greater than or equal to 30 mm were examined. Home sleep monitoring was used to assess OSA presence in terms of ODI (>4%) and AHI. Approximately 40% of the patients were found to have an ODI greater than 10 per hour, representing a 5-fold greater incidence than in a comparable normal population. Similarly, 29% of the patients had AHI greater than 15, almost two times higher than the normal prevalence values. These results correspond to other studies demonstrating up to 60% OSA presence in AAA patients, significantly higher than the estimated prevalence of 17% in the general population. Importantly, subjective reports did not reveal a correlative sleepiness, suggesting that daytime sleepiness is not suitable for detecting OSA in AAA patients.2

The researchers went on to examine whether OSA can explain occurrences of AAA expansion. They compared the AAA diameter of two duplex scans; one from the recruitment phase and another before the sleep study (median follow-up time was



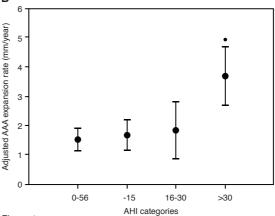


Figure 1.

18 months). Severe OSA, represented by ODI and AHI greater than 30, was found to be significantly associated with a high AAA expansion rate (Figure 1. ODI: 2.9 mm per year, p=0.009; AHI: 2.2 mm per year, p=0.043). These results were derived after adjustment to cardiovascular risk factors and medication use, and therefore represent OSA relative risk. The presence of correlation only at severe OSA suggests a threshold effect rather than a simple linear dose–response relationship between OSA severity and AAA expansion rate.²

Through these studies, it is becoming clear that successful diagnosis of OSA in AAA patients can be an important factor in managing the risk of lethal aortic complications. Future studies will hopefully examine the potential beneficial effects of OSA treatment on AAA.

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Are you Systematically Screening Your Patients?



92M patients have cardiovascular disease in the US¹



50% also suffer from sleep apnea²



80% remain undiagnosed²

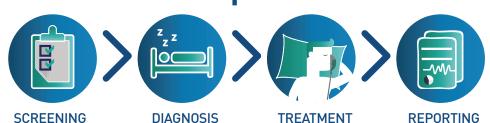
Undiagnosed sleep apnea is a major comorbidity and risk factor in CVD



Screening Sleep Apnea Can Improve

Patient Outcomes³

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- 1 Heart Disease and Stroke Statistics 2017 At-a-Glance
- 2 Sleep Apnea and Cardiovascular Disease, JACC Vol. 52, No. 8, 2008, August 19, 2008:686–717
- 3 Young et al, J Sleep 2008; Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort

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