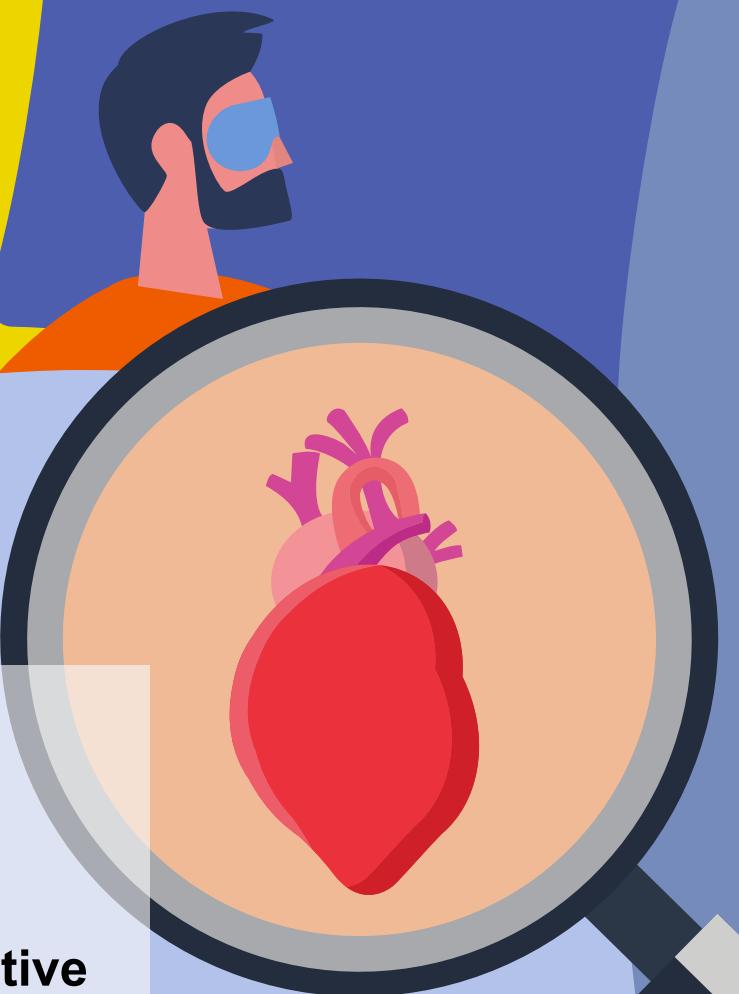


Cardio Sleep Review



Featured Articles:

Heart Failure and Sleep Apnea in a COVID World: A Cardiologist's Perspective

How WatchPAT® ONE is Adjusted for Success in the COVID-19 Area

Dedicated to the nexus of Cardiology and Sleep Apnea Management

Welcome Back!

Welcome to the new issue of Cardio Sleep Review!

The past twelve months have certainly been challenging. I hope his message finds each of you healthy and happy. I assumed my new role as President, U.S. of Itamar Medical in October. From the start, I have been so impressed with our physician partners as they have pivoted quickly and seamlessly to take care of patients using new COVID-era protocols. The shift was nothing short of amazing for all involved.

I was also humbled to witness our WatchPAT® technology and committed support teams assist so many patients and clinicians with at-home testing.

The declining COVID infection rates offer hope for getting back to business, getting back to living! We are excited to offer this issue of Cardio Sleep Review. You will find an interesting interview with cardiologist Dr. Dan Bensimhon and other COVID-related articles. Along with those are several in-depth looks at some of the specific challenges sleep apnea imposes on cardiac care.

We are also excited about the launch of the PAT® Academy website—a great new distance learning tool for clinicians interested in knowing more about WatchPAT® technology. The Academy site offers live webinars, interactive workshops, on-line courses and case studies.

I have firsthand knowledge of many of the challenges cardiologists are facing. I look forward to leveraging my cardiology and AFib background as the company explores new ways to diagnose and treat the large and undiagnosed U.S. patient population suffering from sleep apnea.

Incredibly the statistic for the number of patients who are still undiagnosed is up to 80% and this continues to be an area of focus for us as we navigate the sleep health space. For your patients, for your practice and for us, better health is a win-win-win situation.

Regards,
Shane Brown
President, U.S. Itamar Medical



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A New Year's Resolution: Better Sleep for Better Cardiovascular Health

This is the time of year for new year's resolutions. People take this time to improve their health by joining a gym, cutting out processed foods, or just plainly visiting their physician more often. One new year's resolution that could lead to better sleep and better health for your cardiac patients is sleep apnea evaluation. This sleep disorder is common among patients with cardiovascular disease and contributes to increased morbidity and mortality. Cardiac patients often suffer from sleep apnea, but unfortunately too commonly it remains undiagnosed.

PATHOPHYSIOLOGY OF SLEEP APNEA

There are two types of sleep apnea:

- **Obstructive sleep apnea:** airflow obstruction due to nocturnal relaxation of pharyngeal muscles.

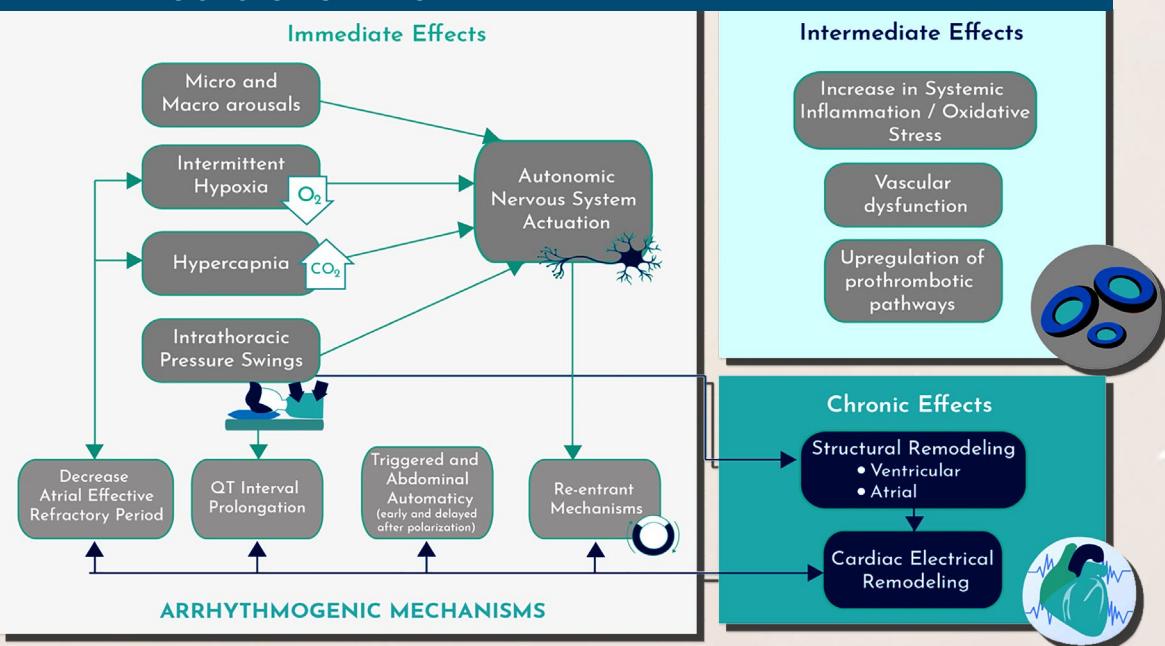
- **Central sleep apnea:** nocturnal neurologic cessation of all breathing effort.

OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA), caused by physiologic aspects of patients, is more common among obese and patients with coronary disease. Despite the disorder's prevalence, it is often missed during exams, and often goes undiagnosed.

OSA episodes have many detrimental consequences, including lower oxygen levels, due to obstructed airways. Obstructed airways also cause exerted abdominal effort, which causes changes in intrathoracic pressure and leads to oxidative stress. OSA also leads to constriction as well as increased pressure of pulmonary veins.

THE EFFECTS OF OBSTRUCTIVE SLEEP APNEA



SOURCE: <https://consultqd.clevelandclinic.org/exploring-the-connection-between-sleep-apnea-and-cardiovascular-disease/>

This causes the cardiac load to increase, which is very damaging to patients with a coronary disease whose hearts are already working overtime dramatically. OSA episodes cause a swing in intrathoracic pressure, which results in a decrease in cardiac output and is worse during REM sleep. Decreased cardiac output can ultimately lead to cardiogenic shock.

CENTRAL SLEEP APNEA

Central sleep apnea (CSA) as opposed to obstructive sleep apnea, does not include thoracoabdominal effort. While physiologic in some cases, CSA is more often caused by sensitive chemo responses due to alterations in carbon dioxide levels. These alterations can be a result of arousal from sleep. In CSA episodes, Hunter-Cheyne-Stokes respiration can occur, which is a cyclical crescendo-decrescendo respiratory effort. This type of respiration is worse during NREM sleep.

Sleep apnea is more prevalent than one might think, affecting 30-60% of patients with underlying coronary disease and cardiovascular risk conditions such as diabetes, hypertension, and heart failure. Patients with underlying conditions such as coronary disease are more likely to develop sleep apnea, but may not be aware of it, which is why it is crucial to suggest that patients get tested.

SLEEP APNEA AND CARDIAC HEALTH

Both forms of sleep apnea are common in patients with underlying cardiovascular conditions.

Patients with heart failure have been shown to have fluid in the neck and alveoli of the lungs. This shift of fluid causes pharyngeal edema, nearly causing OSA. Episodes of OSA impair diastolic function and cause atrial and aortic enlargement. REM-related OSA, in particular, is associated with an increased risk for cardiovascular complications.

Patients with heart failure may also develop pulmonary congestion, which could cause CSA. Sleep apnea causes overworking of the heart and could potentially cause cardiovascular problems, if not worsen those already present. Sleep apnea tests should be suggested to patients with underlying conditions to reduce the risk of further heart damage.

EFFECTS OF SLEEP APNEA

Sleep apnea effects include, but are not limited to, lower oxygen levels, increased cardiac output, and increased blood pressure. All of these symptoms are harmful, especially to patients with coronary

disease. The effects of obstructive sleep apnea in cardiac patients can be ranked as immediate, intermediate, and chronic. Direct effects include lower oxygen and carbon dioxide levels, intrathoracic pressure swings, and fluctuations in the autonomic nervous system.

Intermediate effects include systemic inflammation, oxidative stress, vascular dysfunction, and upregulation of prothrombotic pathways. Chronic effects of sleep apnea include cardiac electrical and structural remodeling. Patients with sleep apnea typically have fatigue, headaches, memory impairment, and tend to snore at night.

A simple questionnaire for cardiac patients can determine if sleep apnea tests are needed and can serve as a future reference if these symptoms develop later on. Educating patients on the causes, symptoms, and effects of sleep apnea can help decrease this disorder's prevalence.

"Sleep apnea causes overworking of the heart and could potentially cause cardiovascular problems..."

GETTING TESTED

Although sleep apnea is associated with many cardiovascular complications, it can often go undiagnosed.

That's where WatchPAT® ONE can help. Patients can use this test in the comfort of their own beds (especially important in light of the COVID-19 pandemic) and in just a few simple steps, complete their sleep study. Once the test is complete, physicians can review the automatic results and discuss them with the patient.

With no wait time for the test or the results, no risk of exposure, and no need to mail in any part of the device, WatchPAT® ONE provides a simple solution for your cardiac patients.

As cardiac patients are vulnerable to sleep apnea, among other conditions, take the opportunity to recommend sleep apnea tests. Diagnosing sleep apnea is the first step to keeping a patient's health under control and reducing the risk of further complications. A proper diagnosis and taking the time to educate patients is what will get them on the right path toward appropriate treatment and better health. ■

Looking Back at Life's Simple 7



In 2010 the American Heart Association coined the term Life's Simple 7, referring to the seven most important predictors of heart health. The Simple 7 included four behaviors that patients could modify (smoking, weight, diet and exercise) as well as three biometric measures (blood pressure, cholesterol and blood glucose).¹

Along with identifying these seven factors and establishing metrics to track what 'good' looked like, the AHA also set a 10-year goal for improvement. The goal? A 20% reduction in cardiovascular disease and stroke mortality and a 20% improvement in cardiovascular health in all Americans by 2020.¹ While data isn't available through the end of 2020 at this time, the death rates from cardiovascular disease have decreased since the Simple 7's introduction,³ highlighting the potential effectiveness of the initiative.

But, we're not finished yet. In fact, a recent study suggests that adding sleep to the Simple 7 could improve the accuracy of cardiovascular disease risk prediction. We will be diving into the facts on why sleep is missing from this important list of risk factors in our next article.

The AHA also classified these seven factors into three categories (ideal, intermediate and poor) to help create a common standard. ■

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LEVEL OF HEALTH FOR EACH METRIC			
	POOR	INTERMEDIATE	IDEAL
Current Smoking	yes	Former < 12 months	Never or quit >12 months Never tried; never smoked whole cigarette
BMI	30 kg/m ²	25-29.9 kg/m ²	18.5-25 kg/m ²
Pa	none	1-149 min/week moderate or 1-74 min/wk vigorous; 1-149 min/wk moderate+2X vigorous; ≥0 min,60 min of moderate or vigorous every day	≥150 min/week moderate or >75 min/wk vigorous; ≥150 min/wk moderate+2X vigorous; ≥60 min of moderate or vigorous every day
Healthy Diet Pattern, Number Of Components	0-1	2-3	4-5
Total Cholesterol	≥240 mg/dL	200-239 mg/dL or treated to goal	<200 mg/dL
Blood Pressure	SBP ≥140 mmHg or DBP ≥90 mmHg	SBP ≥120-139 mmHg or DBP 80-90 mmHg or treated to goal	<120 mmHg/<80 mmHg
Fasting Plasma Glucose	≥126 mg/dL	100-125 mg/dL	<100 mg/dL

Should sleep be included in the American Heart Association's "Life's Simple 7"?

Looking Forward: Life's Essential 8?...

10 years ago, the American Heart Association rolled out an initiative called Life's Simple 7, aimed at raising awareness of multiple factors that can contribute to cardiovascular disease.¹ These seven factors; blood pressure, cholesterol, blood sugar, smoking, weight, diet, and exercise can have a profound impact on cardiovascular health. In one study involving 7,622 participants, those who scored in the 'ideal' category for at least five of Life's Simple 7 reduced their risk of heart-related death by 78% compared to participants who did not meet those metrics.²

Life's Simple 7 has come a long way in raising risk factor awareness in the minds of clinicians and patients. However, as time has passed and additional research has been conducted, we've become aware of one additional cardiovascular risk factor that has been left out of heart health discussions for too long. Sleep.

"Sleep, like diet and physical activity, is a health behavior we engage in every day," says Nour Makarem, an associate research scientist at Columbia University Irving Medical Center in New York.³ "Increasingly, it is linked to not only the risk of heart disease but also to the risk factors that lead to cardiovascular disease".³

In 2020, Dr. Nour Makarem's team evaluated 1,920 patients who participated in the MESA Sleep study.³ The team investigated a variety of sleep characteristics and their impact on cardiovascular health.³ Dr. Makarem's research found that poor sleep quality was strongly associated with cardiovascular disease

- Patients with obstructed sleep apnea had a 200% greater chance of poor heart health.
- Variations in sleep duration were associated with a 24% greater risk of poor heart health
- Variations in sleep timing were associated with a 31% greater risk of poor heart health

The findings of this research highlight the important role that sleep can play in cardiovascular outcomes.³

"Despite this importance," says Dr. Makarem, "unlike diet and exercise, sleep has received less attention and is not currently included in guidelines for cardiovascular disease prevention or as a measure of cardiovascular health."³

With this in mind, we propose adding sleep to Life's Simple 7 and making it Life's Essential 8.

With 50 to 70 million Americans suffering from sleep disorders including sleep apnea,⁴ raising awareness of the link between sleep and cardiovascular health (and more importantly, screening for sleep disorders in the cardiology office) could significantly help improve cardiovascular outcomes.

American Heart Health month is the perfect month to begin stretching the Life's Simple 7 tool to fit the true realities of heart disease risk factors. Switch the conversation from "Life's Simple 7," to "Life's Essential 8," and be inclusive of all risk factors that could potentially impact your patients' cardiovascular well-being. ■

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Heart Failure and Sleep Apnea in a COVID World:

Cardiac Sleep Review (CSR) talks with Daniel Bensimhon, MD, Medical Director of The Advanced Heart and Mechanical Circulatory Support Program at Moses Cone Memorial Hospital in Greensboro, NC. Dr. Bensimhon is an Advanced Heart Failure cardiologist who treats patients with all levels of heart failure—from very mild (Class II) to patients who need full mechanical support and referral for cardiac transplantation (Class IV).

CSR: Dr. Bensimhon, please tell our readers a little bit about your background and your practice.

Dr. Bensimhon: I'm Dan Bensimhon and I am an advanced heart failure cardiologist and Director of the Advanced Heart Failure and Mechanical Circulatory Support Program at Moses Cone Memorial Hospital in Greensboro, North Carolina. We're centered at a community hospital that manages six hospitals across central North Carolina under a program called Cone Health. We are a group of over 40 cardiologists in all different types of cardiology. Two of us are advanced heart failure cardiologists who specialize obviously in heart failure, cardiogenic shock and mechanical support.

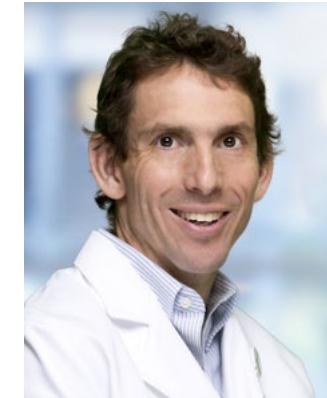
CSR: What is the relationship between cardiology and sleep apnea?

Dr. Bensimhon: I think we've always understood that sleep apnea and heart failure have a fairly tight link, but I think now that we're doing more and more testing, we're realizing that we probably underestimated how much sleep apnea is present in our population.

And in the studies of the relationship between sleep apnea and atrial fibrillation and hypertension, we've seen that it's very hard to get control of AFib, it's very hard to get control of high blood pressure, until you control the sleep apnea. So, they're two problems that overlap greatly and we are trying to figure out how to screen that patient population appropriately and treat them effectively.

A Cardiologist's Perspective

Dr. Daniel Bensimhon



CSR: Tell us how the COVID-19 pandemic has affected your practice and your patients.

Dr. Bensimhon: COVID-19 has posed challenges that we've never seen before. I think it's posed challenges for our patients and it's posed challenges for our physicians. Obviously as physicians who care for very sick patients, we want to keep in contact with them and, when something goes wrong, we want to bring them into the clinic and we want to be able to see them and provide care for them. Unfortunately, you know patients are rightly concerned. These are patients who have a lot of medical issues—not only heart disease but also a lot of other comorbidities, and if they were to come down with the virus they could be at very high risk for morbidity and mortality associated with COVID.

So, I had a lot of patients refusing sleep studies. In this instance we can say, "Hey, listen, you know I think you have sleep apnea. I'm not asking you to wear a CPAP mask today. What I'm asking you is let's just see how bad this is. Let's get an idea of what we're up against. Do you have obstructive sleep apnea? Do you have central sleep apnea? Is it mild, is it moderate, is it severe, and then let's get that data and let's sit down and have a talk about it."

CSR: How did you happen to start using the WatchPAT® ONE system?

Dr. Bensimhon: We went to WatchPAT®, the WatchPAT® ONE system, primarily for two reasons. The first reason is we liked the idea of having patients being able to test themselves at home. We also were impressed by the ability to detect central sleep apnea more effectively which the device seemed to detect more frequently than what we were seeing with our standard in-lab studies.

But what really pushed us over the edge was COVID. We really put our patients' health first and if just one patient were exposed to the virus—out of the hundreds we've tested—that would be too

much. So you know we liked the ease of use, we like the fact that patients could do it at home, but above all we felt we're getting a great test and we're keeping our patients as safe as possible during a very trying time.

CSR: The WatchPAT® ONE system is still relatively new. Did you have any other observations at your practice?

Dr. Bensimhon: The downstream benefits—something we didn't expect—is being able to get these patients up and into the WatchPAT® Cloud and now when patients come into our office, or we are on a televisit we can go into the cloud and look at the results of their test; we can also look at their compliance with therapy. So, like we do with our ICD/ICM reports or CardioMEMS data, we can now do the same to follow their sleep apnea during their visit or at any point when we are reviewing their care.

CSR: Explain how you work together with sleep physicians to affect patient outcomes.

Dr. Bensimhon: I am not trying to own the sleep medicine process but what I am trying to own are the outcomes that my patients experience. So, for me it's being part of the process of screening the patients when I see them, trying to develop an algorithm where I think "Boy, you might be at higher risk," and then being able to get them tested quickly. I then rely on our sleep doctors to go back and look at the data and help me understand the data that we have and who I need to be aggressive with and, if the baseline therapies aren't working, what therapy is next. I can't do that process, but I can at least drive the bus and I can at least say "Hey listen, I need your help for my patient who's riding along with me."

It's not about owning the whole sleep apnea process. It's not about owning the testing process. It's about owning the patient outcomes and making sure that we walk with them through the steps of this from diagnosis to adequate therapy. ■

How WatchPAT® ONE is Adjusted for Success in the COVID-19 Area



There is little doubt that 2020 and the advent of COVID-19 will forever reshape the face of health-care. From the meteoric rise in telemedicine to increasing stringency in infection prevention protocols, hospitals, clinics, and testing facilities must now adapt in order to succeed in the coming years. And one prime example of adaptation is that of sleep apnea testing.

By its very nature, traditional sleep apnea testing is not only high-touch (thanks to the devices used and staff required) but also high exposure, due to the length of time patients are expected to spend within a clinic's walls and the nature of aerosols spread during irregular breathing and snoring. While the area within these walls provides safety for patients during testing, the truth is that some studies show that the longer a person spends in a public setting—which a sleep clinic has to be—the more likely their chances of contracting the virus.

This is why doctors and clinics across the world are turning to home-based sleep apnea testing.

In order to get the clinical data necessary to treat their patients without compromising their safety, cardiologists and sleep physicians now see home testing as the preferred way to diagnose sleep apnea conditions, all in an environment that's both safe and familiar to their patients.

However, while moving the location of the test from the clinic or hospital to the patients home is definitely a step in the right direction for patient safety, there are other areas of potential infection risk requiring more necessary actions to ensure the highest level of mitigation.

COVID, AND THE RISE OF DISPOSABLE HOME SLEEP APNEA TESTS

A second area of infection risk embedded with the home sleep testing devices that are typically dispatched from one patient home to the next.

Traditionally, all home sleep apnea testing devices on the market are designed to be re-used with some elements being disposable or washable, but this now serves as a potential risk of infection from previous patients or even staff to the next patients, as well as back again when the staff receives the device.

This creates vulnerability where there should be only a sense of safety, and is the driving force behind the recently issued American Association of Sleep Medicine "COVID-19 Mitigation Strategies" guidelines and rise in demand for fully disposable home sleep apnea tests (HSATs).

WATCHPAT® ONE—THE FIRST AND ONLY FULLY DISPOSABLE HSAT

This need is exactly why Itamar Medical created WatchPAT® ONE, the first fully disposable HSAT. This one-time use device provides patients the comfort of sleep apnea testing in their own home and in their own bed, while ensuring they are never exposed to potential infection from reused devices and contamination transmitted from previous patients.

Patients simply:

1. Attach the chest sensor
2. Strap on the WatchPAT bracelet to their non-dominate hand
3. Slip on the finger probe
4. WatchPAT® ONE is connected with blue tooth to a simple smartphone app which in turn transmits the WatchPAT® ONE's 7 channels of data to the cloud.

As soon as the study is complete, the prescribing clinician or the assigned board-certified sleep physician can review the automatically scored study results and provide interpretation and the patient can safely throw the WatchPAT® ONE away. There is no need to mail the device or any part of it back, eliminating the chance that someone could be exposed to possible infection. Imagine, no delays in data transfer, which results in faster diagnosis, as well as protecting staff and patient alike.

And, since WatchPAT® has been clinically validated against polysomnography (PSG), with a documented correlation of up to 89%¹, it provides not only outstanding patient compliance but also clinical reliability.

In the COVID era, WatchPAT® is the answer sleep physicians and patients are searching for to provide the testing they need without compromising safety. ■

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Screening Questionnaires Fail to Predict Sleep Apnea in Patient with Atrial Fibrillation

While it has long been understood that sleep apnea often underlies heart issues, the rate of the condition is still under-diagnosed in these patients, leaving their condition and its possible complications to worsen unchecked. Yet, the reason for the difficulty in reaching a sleep apnea diagnosis, especially in patients living with atrial fibrillation, has been a matter of debate. Now however, two separate peer-reviewed studies have revealed a common issue behind the diagnostic failure—the fact that the questionnaires currently in use are not identifying the sleep apnea patient in proper way.

Here we will take an in-depth look at each study in order to highlight the conclusions reached by the research teams.

SLEEP APNEA IN ABLATION CANDIDATES WITH PAROXYSMAL ATRIAL FIBRILLATION

The first study, reported in IJC Heart & Vasculature, set out to determine the prevalence, characteristics, and risk factors as well as type of sleep apnea most common in ablation candidates with paroxysmal atrial fibrillation.

The researchers recruited 579 patients with paroxysmal AF and utilized polygraphy for two nights at home to diagnose sleep apnea. These results were also compared against questionnaire results including, the Epworth Sleepiness Scale (ESS), STOP-Bang Questionnaire, and Berlin Questionnaire (BQ), which assessed the degree of sleep apnea symptoms.

The team found that approximately 82.7 percent of patients had an apnea-hypopnea index (AHI) ≥ 5 , with 42.1 percent of those studied having an AHI ≥ 15 . The researchers also determined that the predominant type of sleep apnea affecting these patients was obstructive and that AHI increased with:

- Age
- BMI
- Waist and neck circumference
- Body and visceral fat

Importantly, the researchers also found no association between ESS and AHI and stated in their conclusions that “The high prevalence of SA detected in this study may indicate that SA is under-recognized in patients with AF.”

They also reported that none of the screening questionnaires predicted SA reliably.

THE PREVALENCE OF UNDIAGNOSED SLEEP APNEA IN PATIENTS WITH SYMPTOMATIC ATRIAL FIBRILLATION

The second study we will discuss, briefly titled, “Prevalence of OSA in patients with AF”, set out to examine the prevalence of sleep apnea in atrial fibrillation patients referred for ablation.

This stated goal is due to the fact that while sleep apnea is known to be common in atrial fibrillation patients and is also associated with atrial remodeling as well as a high recurrence post-ablation, the prevalence of atrial fibrillation patients with undiagnosed sleep apnea had not been well established.

The research team recruited 188 patients scheduled to undergo ablation and who had no prior diagnosis of sleep apnea. All participants were required to complete the STOP-Bang sleep apnea screening questionnaire and undergo home sleep apnea testing.

The results of the home sleep apnea testing were positive in 82.4 percent of participants without a prior diagnosis of sleep apnea as follows:

- Mild- 43.8 percent
- Moderate- 32.9 percent
- Severe- 23.2 percent

For all positive participants a predominantly obstructive component was observed.

The researchers also found that a positive STOP-Bang questionnaire was not predictive for sleep apnea and that symptoms of the condition, including snoring, daytime sleepiness, and observed apneic episode were reported at a similar frequency in patients positive and negative for sleep apnea.

The conclusion of the study was that while undiagnosed sleep apnea is exceedingly prevalent in patients with atrial fibrillation who are referred for ablation, the use of screening questionnaires or symptom evaluation for diagnosis has limited predictive value.

The authors also stated that, “A universal SA screening strategy may be considered in all patients with symptomatic AF.”

HOME SLEEP APNEA TESTING ENHANCES DIAGNOSIS AND CARE

The results of these studies mean that physicians treating atrial fibrillation patients can no longer afford to rely upon screening questionnaires for sleep apnea diagnosis, since these tools are failing to pinpoint the condition accurately, which ultimately translates to a failure to provide appropriate care.

Instead, home sleep apnea testing is necessary on a broad scale for patients with atrial fibrillation so that they can receive the necessary treatment with continuous positive airway pressure ventilators to improve atrial fibrillation control. ■

“Sleep apnea is known to be common in atrial fibrillation patients and is also associated with atrial remodeling as well as a high recurrence post-ablation”



Does it all

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An Easy And Remote Solution
Designed Exclusively For Cardiology Practices

As simple as a push of a button, check out how WatchPAT® TurnKey does it all for your practice

- Sleep apnea patient diagnosis and treatment in an average of less than 2 weeks
- Diagnostics that differentiate between obstructive and central sleep apnea
- An ecosystem that includes board-certified sleep physicians
- Continuous patient compliance monitoring and support for best-in-class outcomes
- Eliminates red tape, with no preauthorization, billing, reimbursement or extra cost to your clinic for the program

To learn more about WatchPAT® TurnKey,
visit <https://www.itamar-medical.com/cardiology/watchpat-turnkey/>

WatchPAT® TurnKey A simple, seamless solution