A2ZzZ

QUARTER THREE 2022 / VOLUME 31 / NUMBER 03

Treatment of RESIDUAL OSA IN CHILDREN

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By Regina Patrick, RPSGT, RST

Adenotonsillectomy is often a first-line treatment for obstructive sleep apnea (OSA) in children two years or older. However, research now indicates that an estimated 13%-29% of children have residual OSA after surgery. Therefore, treatments that could further reduce or eliminate residual OSA are needed.

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AAST THANKS ITS PRESTIGE PARTNERS

From the Editor

Autumn Is Around the Corner

By Rita Brooks, MEd, RPSGT, REEG/EPT, FAAST

As summer winds down and we move toward autumn, AAST is planning an in-person CCSH Designated Education Program in October. This program is designed for health professionals who work directly with sleep medicine patients, families and other health care practitioners to coordinate and manage patient care and improve outcomes. This AAST program, whether in person or online, is an approved pathway for those seeking the Certification in Clinical Sleep Health (CCSH) credential. Attaining the CCSH credential is an excellent way to expand your horizons in the sleep field and move into a broader patient-focused role.

There are many additional AAST educational offerings available online, including Advanced Pediatrics, Advanced Sleep Titration, Fundamentals of EKG and Fundamentals of Virtual Patient Monitoring learning modules. Most recently, the new Fundamentals of EKG workbook and E-book were released. Coming soon this fall will be the new Adult PSG Scoring learning module. Visit the Learning Center on the AAST website to review all of the educational programs and resources that are available.

In this issue of A_2Zzz, several new approaches for treatment of sleep disordered breathing are presented. One article discusses a new treatment, eXciteOSA by Signifier Medical Technologies, for snoring and mild obstructive sleep apnea (OSA) that entails daytime neurostimulation of the tongue. There are two new current procedural terminology (CPT) codes for use of this device that went into effect in April.

In an interview with Dr. David White, Brendan Duffy explores other alternative treatments that are being researched and developed for treatment of OSA. One is cold sculpting of the tongue; another is development of a sleep apnea "pill." Dr. White expects that at some time in the not-too-distant future there will be a pharmaceutical available that will be an option for many OSA patients.

The process of developing an inpatient screening program is outlined in T. "Massey" Arrington's article. He provides a compelling case for developing an inpatient screening program managed by a sleep navigator. This is a perfect role for a CCSH certified sleep professional. A successful program reduces hospital readmissions, improves patient outcomes and lives, and generates volume for the sleep center.

Enjoy the remaining days of summer and look forward to new and exciting learning opportunities as we move into autumn! Remember to take advantage of the free continuing education credits that accompany your membership and the member discounts on our many excellent educational offerings to attain, maintain and re-certify your credentials.

Sleep well!

Rita

President's Message

Education and Engagement and Events, Oh My!

By Laree J. Fordyce, RPSGT, RST, CCRP, CCSH, FAAST

As the seasons change from summer to fall and cooler days start becoming the norm, AAST is heating up with new education, engagement opportunities and events.

On the education front, I'm pleased to share that we will be launching adult PSG scoring modules later this year. Information on continuing education credits (CECs), module breakdowns and purchasing details will be shared throughout the fall ahead of the product's launch, so I encourage you all to keep your eyes on your emails and AAST's social media channels. In the meantime, members and non-members looking to advance their education are welcome to view our current offerings, including the Advanced Pediatrics, Advanced Sleep Titration, Virtual Patient Monitoring and CCSH modules on our website.

We've also started work on developing a home sleep apnea test (HSAT) learning module that will be launching in 2023. In an ever-changing health environment and digital world, this online course is designed for those looking to advance their knowledge and skills in working with patients who choose to do at-home sleep testing and treatment monitoring.

Additionally, AAST will be hosting its second, in-person CCSH Workshop Oct. 15-16 in Chicago. As part of AAST's initiative to offer safe, small-scale, in-person events for sleep professionals in 2022, this one-and-a-half day event is part of the AAST CCSH Designated Education Program and will foster an individualized, instructor-led learning experience that will allow for robust discussions with the instructors and attendees. I encourage you to learn more about the event on our website.

Shifting to engagement opportunities, I want to call to your attention the call for volunteers taking place right now. If you're new to AAST or are looking to get even more involved, please consider filling out the 2022-2024 volunteer interest form. Joining a committee is a great way to not only meet and work with fellow AAST members, but to also share your knowledge and expertise with fellow committee members, staff and the AAST membership at large. For those that may have questions about volunteering or a specific committee, please reach out to info@aastweb.org.

Also happening this fall is the announcement of the 2022-2023 Board of Directors slate. Nominations for new board members closed on July 1, and the Nominations Committee announced the slate on Sept. 9. For those that are AAST members, I encourage you to take part in the board of directors slate review process and review each candidate's summary here.

Lastly, I invite you all to join me in celebrating Sleep Technologists Appreciate Week (STAW). Taking place Oct. 23-29, this week highlights the many accomplishments made in sleep disorders centers, laboratories, educational facilities and within AAST this past year. Be sure to keep an eye on the AAST website for ways you and your team can celebrate #STAW2022.

I wish you all a safe and happy fall!

Instructions for Earning Credit

AAST members who read *A$_2$Zzz* and claim their credits online by the deadline can earn 2.00 AAST Continuing Education Credits (CECs) per issue, for up to 8.00 AAST CECs per year. AAST CECs are accepted by the Board of Registered Polysomnographic Technologists (BRPT) and the American Board of Sleep Medicine (ABSM).

To earn AAST CECs, carefully read the four designated CEC articles listed below and claim your credits online. You must go online to claim your credits by the deadline of **Dec. 31, 2022**. After the successful completion of this educational activity, your certificates will be available in the My CEC Portal acknowledging the credits earned.

COST

The *A$_2$Zzz* continuing education credit offering is an exclusive learning opportunity for AAST members only and is a free benefit of membership.

STATEMENT OF APPROVAL

This activity has been planned and implemented by the AAST Board of Directors to meet the educational needs of sleep technologists. AAST CECs are accepted by the Board of Registered Polysomnographic Technologists (BRPT) and the American Board of Sleep Medicine (ABSM). Individuals should only claim credit for the articles that they actually read and evaluate for this educational activity.

STATEMENT OF EDUCATIONAL PURPOSE & OVERALL EDUCATIONAL OBJECTIVES

A$_2$Zzz provides current sleep-related information that is relevant to sleep technologists. The magazine also informs readers about recent and upcoming activities of AAST. CEC articles should benefit readers in their practice of sleep technology or in their management and administration of a sleep disorders center.

READERS OF *A$_2$ZZZ* SHOULD BE ABLE TO DO THE FOLLOWING:

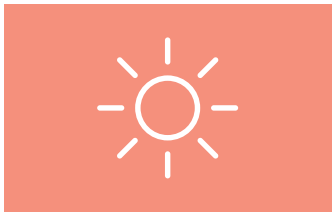
- Analyze articles for information that improves their understanding of sleep, sleep disorders, sleep studies and treatment options
- Interpret this information to determine how it relates to the practice of sleep technology
- Decide how this information can improve the techniques and procedures that are used to evaluate sleep disorders patients and treatments
- Apply this knowledge in the practice of sleep technology

You must go online to claim your CECs by the deadline of **Dec. 31, 2022**.

READ AND EVALUATE THE FOLLOWING FOUR ARTICLES TO EARN 2.0 AAST CECS:

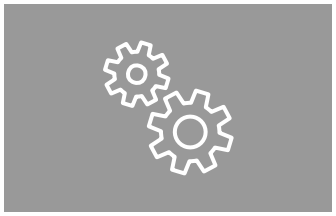
Treatment of Residual OSA in Children

Objective: *Readers will review multiple treatment options for residual OSA for pediatric patients and gain a working knowledge of current research into which treatment options can best relieve residual OSA.*



Daytime Neuromuscular Electrical Stimulation for Treatment of Mild OSA

Objective: *Readers will review the concepts of upper airway musculature and neuromuscular electrical stimulation to the tongue and understand how the eXciteOSA device is treating mild OSA during the day.*



Developing an Inpatient Sleep Navigator Program

Objective: *Readers will review how one sleep system developed an inpatient sleep navigator program and gain a working knowledge of how a sleep navigator program could benefit their own community's sleep system.*

Health Literacy and the Sleep Patient

Objective: *Readers will review how health literacy impacts the sleep patient's self-efficacy and self-management and gain a working knowledge of how health literacy is important in achieving long-term outcomes, as well as what to consider in creating patient education materials.*

Treatment of RESIDUAL OSA IN CHILDREN

By Regina Patrick, RPSGT, RST

Read more

Adenotonsillectomy (i.e., total removal of the adenoids and tonsils) is often a first-line treatment for obstructive sleep apnea (OSA) in children two years or older with enlarged adenoids and tonsils and cures OSA in most of these children. However, research now indicates that an estimated 13%-29% of children have residual OSA after adenotonsillectomy, but among children who are overweight/obese, up to 75% have residual OSA after adenotonsillectomy.[1-4] Residual OSA can be problematic because continued OSA-related arousals can contribute to poor school performance, difficulty concentrating, irritability and behavioral problems and other symptoms. Therefore, treatments that could further reduce or eliminate residual OSA are needed. Various treatments are increasingly being researched to relieve residual OSA, such as positive airway pressure (PAP), myofunctional therapy, orthodontic devices, weight loss and drug therapy, and some findings have been promising.

In OSA, upper airway muscles relax excessively during sleep, which allows structures supported by the muscles to collapse into and block (i.e., obstruct) the upper airway, which restricts airflow. The blood oxygen level consequently decreases. To compensate for the reduced oxygenation, a person makes increasingly strong efforts to breathe. Despite this effort, the airway obstruction remains. When the oxygen level falls to a certain point, the respiratory center in the brain triggers a brief arousal, during which the upper airway muscle tone is restored, opening the airway. At this point, the person is able to take some deep, quick breaths to restore the blood oxygen level.

The most common treatment for OSA in children is PAP therapy. In this treatment, slightly pressurized air is blown through a mask that fits over the nose or nose and mouth. The pressure of the air pushes against upper airway tissues to prevent their collapse into the airway, thereby preventing OSA and sleep disruption.

For children with OSA and enlarged adenoids and tonsils, removing these tissues totally or partially is often curative. However, adenoidectomy alone (i.e., without tonsillectomy) is not recommended for treating OSA in children because residual OSA is more likely after the procedure and many children who undergo adenoidectomy ultimately have to undergo a total tonsillectomy.[5]

In adenotonsillectomy, the adenoids and the tonsils are fully removed. In adenotonsillotomy, most of the adenoids and tonsils are removed. Total adenoidectomy has the risks of post-surgery bleeding, pain, eustachian tube injury and velopharyngeal incompetence (i.e., abnormal movement of the lateral and posterior pharyngeal walls and soft palate caused by injury to the cranial nerves that innervate the adenoids and tonsils), whereas these complications are less frequent with adenotonsillotomy. Various studies have indicated that adenotonsillotomy is effective and safe for children with obstructive sleep apnea syndrome (OSAS).[6,7] However, a drawback of adenotonsillotomy, particularly in younger children,[1] is regrowth of the adenoids and tonsils and the consequent recurrence of OSA. When adenoid or tonsil regrowth occurs, a total tonsillectomy may be needed to resolve OSA.[1,7]

For children with OSA and enlarged adenoids and tonsils, removing these tissues totally or partially is often curative.

The success rate of adenotonsillectomy in obese children with OSA is less than that of nonobese children with OSA (24%-46% versus 80%).[3,8] However, the characteristics that increase the risk of residual OSA after adenotonsillectomy are unknown and have been a recent research focus.

Some research indicates that the maxilla of children with OSA is often narrower than normal.[4,9] In addition, a small mandible (i.e., jawbone) similarly has been noted in children and adults with OSA.[4] However, whether an abnormal facial structure is a predisposing factor for the residual OSA after adenotonsillectomy is unclear. To investigate whether a link exists, Maeda and colleagues[4] examined the oropharyngeal structure of Japanese children diagnosed with OSA. All children underwent a polysomnographic study before and after adenotonsillectomy. The average apnea-hypopnea index (AHI) dropped by 75% after adenotonsillectomy, but 85% of the children had residual OSA (i.e., AHI >1 event/hour). Maeda noted that children with residual OSA had smaller than normal mandibles and suggested that this factor may need to be taken into consideration before adenotonsillectomy or adenotonsillotomy.

If a child continues to have residual OSA after adenotonsillectomy, adenotonsillotomy or PAP treatment, the child may benefit from other treatments such as myofunctional therapy, orthodontic devices, weight loss and drug therapy.

Myofunctional Therapy

Myofunctional therapy involves the use of various oropharyngeal exercises with the goal of improving lip closure and tone, promoting nasal breathing, and improving the tone and position of the tongue and orofacial muscles. Examples of exercises are as follows:

1. With lips closed, press the right index finger on the right nostril and inhale gently through the left nostril. At the end of inhalation, remove the right index finger from the right nostril, press the left index finger on the left nostril, and exhale through the right nostril. Alternate these actions five times. This

exercise encourages nasal breathing, which can help stabilize the airway during sleep.

2. Stick out the tongue as far possible. While looking at the ceiling, try to touch the chin with the tongue, hold this position for 10-15 seconds and then relax. Repeat five times. This exercise increases tongue tone and strength.
3. Press the tip of the tongue on the top of the front teeth (i.e., incisors). Slowly slide the tongue tip backward across the hard palate, and then relax. This exercise strengthens the tongue and throat muscles.

Oropharyngeal exercises have few complications and are easily learned. However, performing the exercises consistently may be more problematic for children.

Rapid Maxillary Expansion

For some children, an orthodontic device such as the rapid maxillary expander (also called rapid palatal expander) may help relieve OSA events. A rapid maxillary expander fits into the roof of a patient's mouth. Two arms of the expander are glued to the inside of the upper molars. The center of the expander contains a screw that is turned once daily for a few weeks. Each turn gradually pushes the arms away from each other, thereby widening the maxilla. A wider maxilla creates more room in the upper airway, which may improve airflow during sleep and reduce OSA events.

Pirelli and colleagues[10] demonstrated that rapid maxillary expansion in children at a normal weight without enlarged adenoids reduced the AHI to normal (from approximately 12 events/hour to <1 event/hour) at four months after beginning the treatment. They suggested that rapid maxillary expansion may be useful for treating abnormal breathing during sleep. However, literature reviews[11,12] note that, although the use of orthodontic devices to expand the upper airway has been shown to reduce OSA in children, insufficient studies exist to definitively support using oral appliances to treat OSA in children.

Weight Loss

Weight loss can improve OSA, even before adenotonsillectomy, and may be a treatment option for children with obesity with residual OSA after adenotonsillectomy.[13,14] In a recent study, Andersen and colleagues[14] studied the effects of weight loss management on the resolution of sleep-related respiratory events in children who are obese with OSA. They found that, with weight loss, breathing was normalized by the end of the study (12 months) in 44% of the children. They further found that children with enlarged tonsils achieved the same effect with weight loss as did children without enlarged tonsils. Andersen proposes that obesity treatment should be considered among the first-line treatments for OSA in children and adolescents who are overweight/obese.

Drug Therapy

People with OSA tend to have a low-grade chronic inflammatory state,[15] which may contribute to increased adenotonsillar size in children with OSA. Therefore, some research has focused on treating OSA by using drug therapy to reduce inflammation.

Nasal Corticosteroid Therapy

In people with OSA, adenoids and tonsils have an increased number of glucocorticoid receptors.[16,17] Glucocorticoids are corticosteroids that reduce the number of leukocytes and macrophages and indirectly block the production of leukotrienes, thereby reducing inflammation. Glucocorticoid treatment has had encouraging results.

Brouillette and colleagues[18] treated children with OSA with a six-week course of intranasal fluticasone (a glucocorticoid receptor agonist) or a placebo. Fluticasone significantly reduced the number of respiratory events by approximately 46%, whereas the number of respiratory events increased by approximately 16% in the placebo group; the AHI decreased in 92% of the treated group but in only 50% of the placebo group; and arousals decreased to a greater extent in the treated group. An interesting finding was that changes in tonsillar size and adenoidal size from the baseline size were not significantly different between the two groups. Brouillette suggests that corticosteroids may help ameliorate OSA in children.

In another study, Kheirandish-Gozal et al.[17] demonstrated that corticosteroid drugs reduced cellular proliferation and proinflammatory cytokine production in tonsil and adenoid tissues (retrieved during adenotonsillectomy) that were placed in a medium that contained fluticasone, budesonide (a glucocorticoid receptor agonist) or dexamethasone (a glucocorticoid). All children had been diagnosed with OSA before the surgery. Corticosteroid drugs increased cellular death and substantially reduced the concentrations of inflammatory substances (e.g., tumor necrosis factor-alpha). Kheirandish-Gozal suggests that anti-inflammatory treatment with corticosteroid drugs could potentially be used to reduce adenotonsillar size in children with OSA.[16,17]

Leukotriene Receptor Antagonist Drug Therapy

Leukotrienes are produced by white blood cells and are released in response to an allergen. Leukotriene receptors are increased in the tonsillar tissues of children with OSA.[19] Blocking the actions of leukotrienes reduces the inflammatory response.

For now, scientists remain uncertain regarding which factors could be used to predict residual OSA in children.

Monteklast, a leukotriene receptor antagonist, has successfully reduced OSA events in children. Goldbart and colleagues[20] treated children with sleep-disordered breathing with monteklast daily for 16 weeks. Before and after treatment, the size of the adenoids were measured. Adenoid size and respiratory-related sleep disturbances were significantly reduced after treatment. These effects did not occur in a group of children with sleep-disordered breathing who did not receive this treatment.

For now, scientists remain uncertain regarding which factors could be used to predict residual OSA in children. Some risk factors appear to be overweight/obesity and certain features of the craniofacial structure (e.g., small oropharynx, narrow maxilla, small mandible),[8,21] but more research is needed to clarify this. More research is also needed to determine which treatment approach (e.g., myofunctional exercises, orthodontic devices, drug therapy) would be best for a child with residual OSA. With greater clarity on these issues, physicians could tailor OSA treatment in children to reduce the likelihood of residual OSA.

REGINA PATRICK, RPSGT, RST, *has been in the sleep field for more than 20 years and works as a sleep technologist at the Wolverine Sleep Disorders Center in Tecumseh, Michigan.*

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BRPT Announces Its A-STEP/STAR Educational Grant Winners

The Board of Registered Polysomnographic Technologists (BRPT) recently announced the winners of its inaugural A-STEP/STAR Educational Grant Program. Learn more about the program and the winners here: **www.brpt.org/brpt-announces-its-a-step-star-educational-grant-winners**.

A Technologist's Guide to Performing Sleep Studies

Designed as an introductory resource, the *Technologist's Guide to Performing Sleep Studies* provides step-by-step instructions for collecting sleep study data from patients. It includes sections that cover suggestions for putting the patient at ease, reviewing the patient's symptoms and medications, attaching the sensors, preparing to record, biological calibrations, artifact detection and correction, and documentation.

Purchase *A Technologist's Guide to Performing Sleep Studies* eBook in the AAST Learning Center

AAST

Daytime Neuromuscular Electrical Stimulation for Treatment of Mild OSA

By Jessie P. Bakker, PhD, MS

Since the early 1980s when the first patients with severe obstructive sleep apnea (OSA) were successfully treated by a prototype continuous positive airway pressure (CPAP) device made from a vacuum cleaner motor, the field of sleep medicine has been dominated by device-based therapies that aim to open the airway mechanically during sleep. Whether they work by using pressurized air as a splint, pulling the lower jaw forward, stimulating the tongue to move and stiffen with each breath or prevent sleep in the supine position, existing OSA treatment devices have one thing in common: they only work while they are used during sleep. While countless users have experienced the life-changing benefits of treating their OSA, many have wondered whether they could train their body to breathe normally without the use of a nighttime device. Now, for the first time, a device designed to do just that is commercially-available for people suffering from primary snoring and mild OSA.

In 2015, the co-founders of a London-based start-up — Signifier Medical Technologies — came together with one goal in mind: to develop a treatment that targets an underlying cause of OSA, thereby freeing patients from their overnight devices. Akhil Tripathi, co-founder and CEO, had an established track record of successful medical device development, while Anshul Sama, co-founder and otolaryngologist, brought his extensive understanding of upper airway anatomy, physiology and the landscape of existing OSA treatments. Together, they and their team studied the history of upper airway neuromuscular electrical stimulation (NMES) — what worked, what didn't work — and designed and tested what would eventually become eXciteOSA.

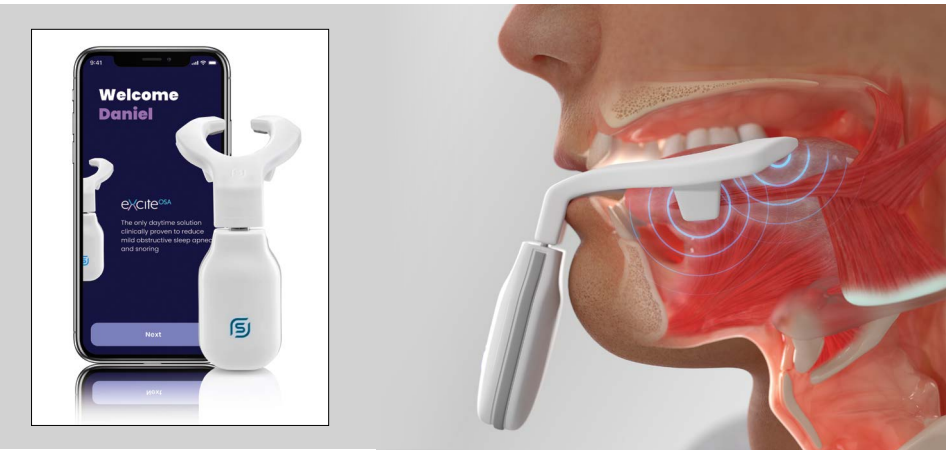
An Overview on Upper Airway Strength and Endurance in OSA

Before reviewing how eXciteOSA works, it's worth revisiting the role of the upper airway musculature in OSA. As is the case with all skeletal muscles, the genioglossus (tongue) muscle contains a mix of slow-twitch and fast-twitch fibers. Slow-twitch fibers contain more mitochondria, which produce energy aerobically; they contract slowly, and are suited to sustained, long-duration activity as they are resistant to fatigue. In contrast, fast-twitch fibers produce energy anaerobically, and are involved with short-burst power activities. Put simply, the skeletal muscles of marathon runners tend to have more slow-twitch (high endurance) fibers, while sprinters tend to have more fast-twitch (high strength) fibers. Studies have shown that patients with OSA have a greater proportion of fast-twitch muscle fibers in their tongue, and therefore a lower proportion of slow-twitch fibers compared to controls.[1,2] When stimulated with a platinum electrode, biopsies taken from the tongues of patients with OSA demonstrate greater fatiguability compared with biopsies taken from controls,[1] particularly amongst those who are not obese.[2]

Consistent with this in vitro evidence, multiple studies have found that patients with OSA are able to generate significantly greater force with their tongue, but also exhibit significantly less tongue muscle endurance, compared with controls.[3,4] Given that each apnea/hypopnea is typically terminated by a rapid activation of upper airway muscles in order to re-open the occluded airway, it has been hypothesized that untreated OSA is a form of strength training resulting in a shift from slow-twitch to fast-twitch muscle fiber composition in the genioglossus and surrounding muscles.[5] Thus, although in lay terms we often hear OSA referred to as being associated with muscle weakness, evidence suggests that muscle endurance is the most likely contributor to the development of OSA.

Applying the Known Concept of Neuromuscular Electrical Stimulation to the Tongue

The proportion of slow-twitch versus fast-twitch muscle fiber proportions varies from person to person, and is largely determined by genetics, although modifiable through training. NMES has been used in sports medicine, rehabilitation and physiotherapy



for decades, with different stimulation patterns targeting endurance versus strength training.[6] For example, eight to 10 weeks of low-frequency NMES is associated with a fast-to-slow twitch muscle fiber transition in the knee extensor, hamstring and quadricep muscles.[7,8] Given that the genioglossus is the same muscle type as the limbs, it is logical to assume that the same shift would result from NMES applied to the tongue. Indeed, a 2007 study applied electrical stimulation to the genioglossus of New Zealand white rabbits and found that the proportion of slow-twitch fibers almost doubled over a period of seven days.[9] The evidence indicates that OSA is associated with reduced slow-twitch muscle fibers, combined with the knowledge that low-frequency NMES is associated with a phenotype shift from fast-twitch to slow-twitch fibers in other skeletal muscles, therefore presents a promising alternative therapy option.

The first assessment of NMES applied to the genioglossus took place in the 1990s, resulting in a published case study demonstrating that stimulation applied both externally (beneath the chin) and internally (beneath the tongue) was associated with an apnea-hypopnea index (AHI) reduction from 13.2 to 3.9 events/hour.[10] In the first clinical trial of low-frequency (6.5 pulses per second) NMES for OSA, a modest but statistically-significant reduction in the AHI of 8 events/hour was observed, alongside significantly improved daytime sleepiness.[11] Finally, a 2004 clinical trial of high-frequency (50 pulses per second) NMES found a reduction in objectively-measured snoring but no change in the AHI.[12]

The evidence indicates that OSA is associated with reduced slow-twitch muscle fibers.

Designing eXciteOSA

These early trials indicated that electrical stimulation of the genioglossus may result in an improved upper airway muscle response amongst patients with OSA. In order to design a viable treatment device however, the co-founders at Signifier Medical Technologies faced many important decisions. For example, given the evidence that skeletal muscles respond differently to high- versus low-frequency stimulation,[6] what is the appropriate frequency (pulses per second) to apply to the tongue? How often should therapy be applied, and over what duration? Which patients with OSA are most likely to respond to NMES? What is the best way of directing stimulation to the genioglossus?

In all three trials described above, stimulation was applied submentally using at least one electrode placed externally underneath the chin. While testing various eXciteOSA prototypes, investigators at Signifier found that applying stimulation from beneath the chin resulted in inadequate recruitment of the extrinsic rather than intrinsic musculature. As a result, they developed a mouthpiece that relies entirely on intraoral stimulation by placing electrodes directly on the conductive wet surface of the tongue, ensuring both vertical and diagonal patterns of stimulation of the intrinsic muscles.

eXciteOSA was developed by taking what is known about the role of the genioglossus in OSA pathophysiology and developing a version of NMES that can be delivered directly to the tongue muscles intraorally. The product was launched commercially in 2021 as the first daytime device designed to deliver NMES to the genioglossus, with the aim of increasing muscle endurance to promote airway patency.

How eXciteOSA Works

The product consists of four components:

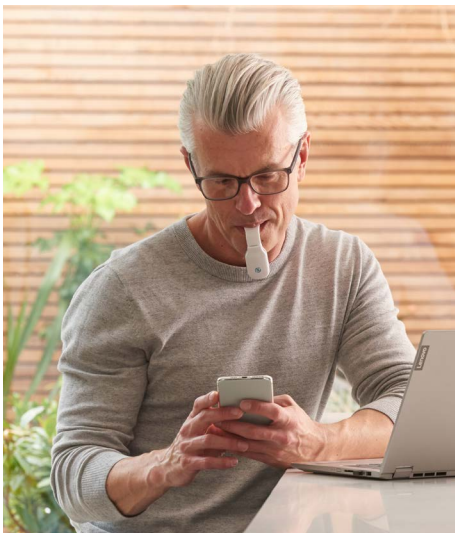
1. A rechargeable control unit that attaches to the mouthpiece via a USB-C connection;
2. A washable, flexible mouthpiece with an electrode array that fits onto the tongue;
3. A smartphone app that pairs with the control unit to control therapy via Bluetooth, which allows the user to initiate therapy sessions and adjust the intensity; and
4. A physician portal for remote monitoring and long-term patient management.

To initiate a session, the user connects the mouthpiece to the control unit, then places the mouthpiece onto their tongue. When placed correctly, two electrode pads make contact with the anterior surface of the tongue and two additional electrodes contact the lateral surfaces of the tongue near the molars.

Once the user begins a session within the app, electrical impulses are delivered for periods of six seconds interspersed by four-second rest periods. Over the course of each 20-minute therapy session, electrical impulses are delivered at 3 Hz, 10 Hz and 20 Hz frequencies (pulses per second) in five-minute sequences. The intensity (electrical current) of the stimulation is adjustable within the app on a scale of 1-15; users are instructed to apply stimulation at their maximum tolerated level, which for most people increases over time as they become accustomed to the sensation. The app will prevent a second therapy session from being initiated within a single day. Further, if a therapy session is aborted before completion or paused for >3 minutes, the app will prevent initiation of a new session for a period of 30 minutes.

Clinical Evidence Supporting eXciteOSA

eXciteOSA was first tested in a proof-of-concept trial of n=13 participants with primary snoring or mild OSA, which resulted in a significant reduction in bed-partner reported snoring intensity over six weeks.[13] Subsequently, a multi-center, single-arm trial was undertaken amongst participants with primary snoring (n=50) or mild OSA (n=65).[14,15] Across the full study sample, the average percentage of total sleep time spent snoring above 40 decibels — the threshold commonly used to define nighttime noise pollution —



dropped by 41% (p<0.01) over the six-week treatment period. In the subset of patients with mild OSA, the AHI reduced from 10.2 to 6.8 events/hour on average (p<0.01), alongside significant improvements in the 4% oxygen desaturation index (ODI), Epworth Sleepiness Scale and Pittsburgh Sleep Quality Index.[16] Adherence to therapy was 85%, meaning participants completed an eXciteOSA therapy session on average 85% of days. In a subset of 51 participants identified as responders (representing 78% of the sample), the AHI dropped from 10.4 to 5.0 events/hour. A post-hoc analysis found that 46% (n=30 of 65) experienced a complete treatment response over six weeks, defined as a follow-up AHI of <5 events/hour.

As a new-to-world therapy, Signifier Medical supported a 2022 investigator-initiated study conducted at University of California San Diego (UCSD) in order to learn more about the eXciteOSA mechanism of action.[17] A sample of n=20 patients with primary snoring or mild OSA underwent measurements of tongue strength and endurance using the IOPI device (IOPI Medical; Woodinville WA USA), followed by an in-lab polysomnography (PSG) at baseline, which included wires placed in the tongue to measure genioglossus electromyography (EMG). These procedures were repeated after one month of eXciteOSA. No change in genioglossus EMG was observed, indicating that the impact of eXciteOSA is mediated through an alternative pathway. Importantly, and consistent with prior studies,[3,4] the investigators observed a significant improvement in genioglossus endurance (time to task failure increased from 22 to 37 seconds on average; p=0.03). The investigators also observed a significant improvement in PSG-determined sleep efficiency (75% to 84%; p<0.01), and in the subset of patients with mild OSA at baseline, the AHI reduced from 17.4 to 7.4 events/hour (n=11; p>0.05 but not statistically powered; post-hoc analysis).

Accessing eXciteOSA

eXciteOSA was granted marketing authorization by the Food and Drug Administration (FDA) as a Class II medical device through the de novo pathway in early 2021, and is indicated for the treatment of adults (aged >=18 years) suffering from primary snoring or mild OSA (AHI <15 events/hour). In a prior clinical trial,[14] adverse events were limited to 15% of patients, and included excessive salivation, tingling sensation on the tongue and tooth sensitivity. No serious adverse events were reported.

As of mid-2022, eXciteOSA is commercially available in the United States, Canada, the United Kingdom and Germany, with more regions coming soon. To date, over 6,000 patients have begun therapy worldwide. CMS established two new Level II Healthcare Common Procedures Coding System (HCPCS) codes to describe eXciteOSA that went into effect April 1, 2022. Signifier Medical Technologies is committed to broad patient access for this new therapy and has educated health insurance payors on the value of eXciteOSA, and will continue to share the evidence required to achieve widespread coverage.

Future Directions

As a new-to-world therapy, there remains much to learn about how best to integrate eXciteOSA intraoral NMES into the OSA care pathway. Signifier Medical Technologies is dedicated to engaging with the sleep research community to produce high-quality evidence from rigorous clinical trials. Four clinical trials are currently underway, with further studies and real-world evidence protocols under development.

The team at Signifier is eager to learn from the experiences of patients and clinicians as they begin and continue their journey with eXciteOSA. Sleep professionals and patients can learn more at exciteosa.com *or contact the team using the form at* https://signifiermedical.com/contact/.

JESSIE P. BAKKER, PHD, MS, *is the executive vice president of medical affairs at Signifier Medical Technologies. In this role, she is responsible for developing and overseeing the clinical development strategy for eXciteOSA, the first FDA-granted daytime treatment for obstructive sleep apnea. Dr. Bakker has extensive experience in sleep research, including the development and validation of digital measurement, diagnostic and therapy tools.*

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Developing an Inpatient Sleep Navigator Program

By T. "Massey" Arrington, MBA, RPSGT, RST, CCSH

I will go ahead and admit it right now — I'm old. An "original gangster" sleep technologist. Paper polygraphs, ink squirting all over my scrubs and I can "hear" when a patient goes into rapid eye movement (REM) sleep old. Thus, you will understand that when I write about developing an inpatient sleep navigator program, the history goes back a long time. In 1996, after selling a sleep center I founded to a large, multi-national hospital company, I was afforded the opportunity to meet with the chief executive officer. He was a very well respected hospital leader and to be honest, I was lucky he had agreed to spend five minutes with me, much less the entire hour we ended up discussing sleep and all of its possibilities on improving patient outcomes.

At that time, this health system owned and operated well over 100 locations across the United States, and we were experiencing the golden age of attended sleep study growth. As we looked ahead to the next five to 10 years, we discussed the fact that there were striking similarities between our patients suffering with untreated sleep apnea and many of the patients being seen in the intensive care unit (ICU). Multiple comorbidities, obesity, type II diabetes, multiple hypertension medications and of course, significant witnessed hypoxemia. Re-admission penalties were still on the horizon and were not yet a significant cost to most hospitals. I recall commenting during our discussion, "Wouldn't it be nice if we could screen everyone who comes in our hospital doors for untreated apnea, imagine the lives (and marriages) we would save!"

It only took me another 25 years to pull it off, and we certainly weren't alone. Across the country there were numerous, brilliant sleep physicians, technologists and leaders all struggling with the same thoughts and ideas. The turning point for me and my organization, with respect to getting appropriate inpatient screening in place, occurred on Jan. 24, 2017, when the U.S. Preventive Services Task Force released its recommendations about the effectiveness of screening for obstructive sleep apnea (OSA).[1] While they concluded that there was insufficient evidence for screening asymptomatic patients,

Wouldn't it be nice if we could screen everyone who comes in our hospital doors for untreated apnea, imagine the lives (and marriages) we would save!

they did find evidence that treating symptomatic patients did improve outcomes. Just one year earlier, the American Association of Sleep Medicine (AASM) had commissioned Frost and Sullivan to investigate the dynamics of sleep apnea diagnosis and treatment and its impact on health care and workplace economics in the U.S. The result was a 25-page report titled "Hidden Health Crisis Costing America Billions: Underdiagnosing and Undertreating Obstructive Sleep Apnea Draining Healthcare System."[2] This report was a gold mine in terms of actual financial data. Together, these two articles highlighted two key facts: 1) sleep apnea was (and continues to be) grossly underdiagnosed and 2) this was and still is costing health care providers and insurers billions of dollars each year.

What screening tool should we use? How would testing be ordered? Who would educate the patient? What would the flow even look like? How would success be tracked?

Armed with this information, my team and I made our pitch: screen every inpatient for OSA and subsequently have sleep testing scheduled as part of the discharge plan for anyone identified at a high risk of untreated sleep apnea. Of course, this sounds simple, but the reality was not. There were so many factors to consider. What screening tool should we use? How would testing be ordered? Who would educate the patient? What would the flow even look like? How would success be tracked?

In the end, we opted to utilize the STOP-Bang, a tool originally developed and validated as a screening tool to identify surgical patients who are at high risk of OSA.[3] Given the sensitivity results from the initial research on the STOP-Bang, we opted to use a positive score of 5 or higher, which has a 96% likelihood of detecting any OSA.[4]

While some centers across the globe screen specific inpatient populations, such as those status post myocardial infarction (heart attack), chronic obstructive pulmonary disease (COPD) or stroke, we decided to go with everyone. Literally everyone that gets admitted. Why? The prerequisite for suffering from untreated sleep apnea (or any sleep disorder, for that matter) comes down to two essential factors: 1) Are you human? and 2) Do you sleep? Believe it or not, all the patients admitted fell within these constraints.

We have seen car accident patients admitted with broken bones who scored a seven, for example. The cause of admission does not correlate directly to whether a person will yield a positive or negative STOP-Bang. Some admission types have a higher probability, yes, but everyone can suffer from an untreated sleep disorder. Screening takes about 27 seconds, faster if the patient knows their neck size, so why not screen everyone?

We also spent almost a year discussing by whom and how screening would take place and subsequently who would perform the necessary patient education and documentation. Initially, we utilized a nurse navigator. However, nursing is an incredibly busy field and even prior to the COVID-19 pandemic, nurses were in extremely short supply. After lengthy discussions with our medical director and talent acquisition teams, the decision was made to utilize technologists certified in clinical sleep health (CCSH) — a relatively new, and in my opinion, far underutilized credential awarded by the Board of Registered Polysomnographic Technologists (BRPT).

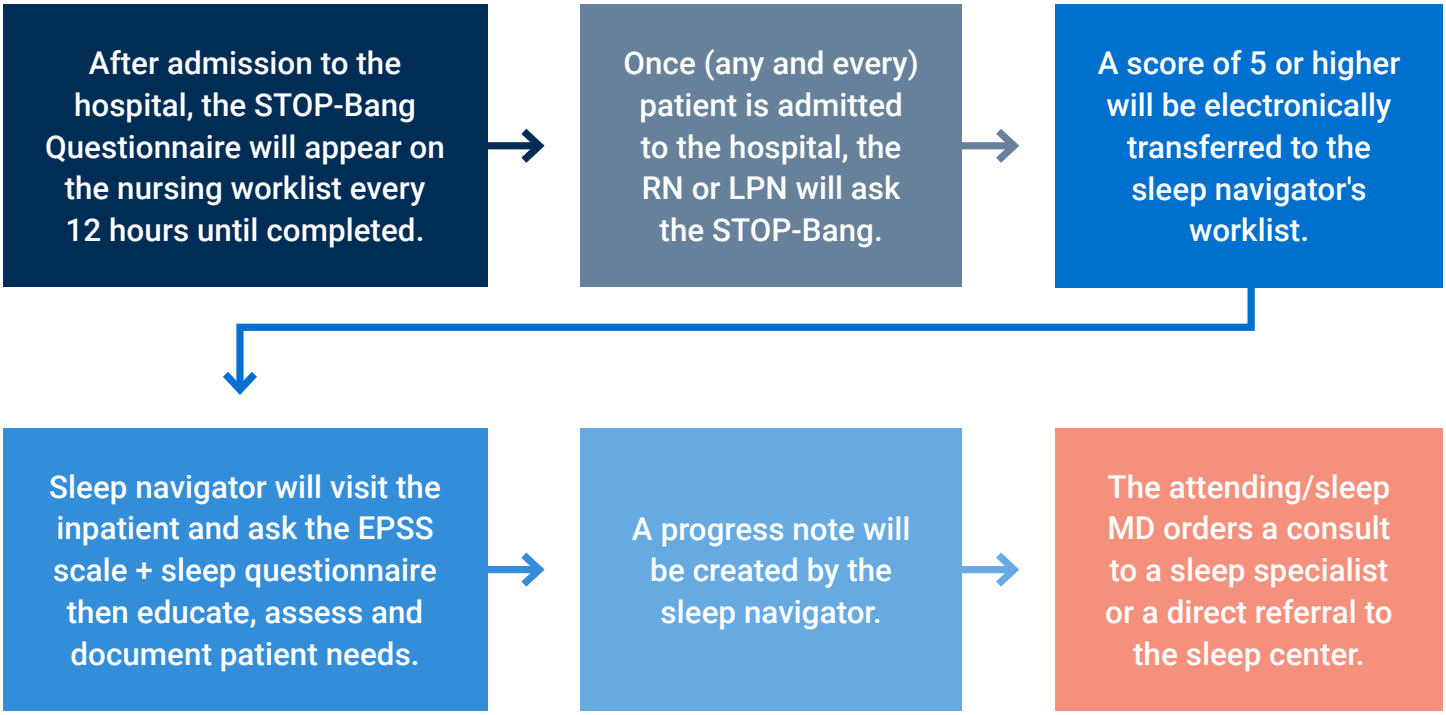
The process, although it took a lot of interaction and engagement from multiple departments, ended up being relatively smooth and effective. A high-level overview of the process can be viewed in the chart below.

Once we turned the process on, the results were immediate and to be honest, quite dramatic. I was expecting perhaps 5%-10% of admissions would end up with a positive STOP-Bang and of that subset perhaps 1% would be persuaded to undergo diagnostic sleep testing as part of their discharge plan. The actual results in the first 12 months ended up being much more remarkable.

Roughly 6,000 patients were screened at one hospital in the first year. A whopping 16% of those admissions screened positive with a STOP-Bang score of 5 or higher. Of that subset, nearly 50% decided to schedule a consult and/or sleep testing. Essentially, after factoring in all the math, 5% of all admissions were ending up having a sleep study and had never before been evaluated or treated for sleep apnea.

I've had a few people tell me that this number seems low. Five percent of 6,000 patients equates to roughly an incremental increase in testing of 300. That is above and beyond standard referrals. To a center struggling to keep attended sleep study volume up, that is a dramatic amount of new business volume. Finances aside however, that is also a lot of lives saved and we also experienced a marked drop in readmissions. In that first year, only six patients were readmitted and two passed away. This was less than 1% of our total positive screens. Considering that the mean and median hospital admission rate can range between 2.6% and 19% for all causes, our 1% was a notable improvement and statistically relevant.[5]

In July 2021, Dr. Bill Mayfield, a thoracic surgeon at Wellstar Health System stated "the navigator is the glue to facilitate



synchronous care" while speaking at a national conference. For our program, screening inpatients and utilizing a sleep navigator has been a source of extreme growth in positive patient outcomes, reductions in readmissions and an increase in lives saved. If you find your program is in need of reducing readmissions and you want to improve the lives of your patients in your community, investigate how you can implement inpatient screening to yield nothing but positive results.

T. "MASSEY" ARRINGTON, MBA, RPSGT, RST, CCSH, *is the assistant vice president of respiratory and sleep services at the Wellstar Health System in Marietta, Georgia, and a proud board member of AAST.*

...utilizing a sleep navigator has been a source of extreme growth in positive patient outcomes...

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Health Literacy and the Sleep Patient: Are We Missing an Opportunity for Improved Health and Well-being?

By Robyn Woidtke MSN, RN, RPSGT, CCSH, FAAST

Low health literacy is a pivotal concern for the provision of adequate medical care across the spectrum of chronic conditions, and obstructive sleep apnea (OSA) falls under this umbrella. In view of the fact that most OSA patients also have a comorbid disorder, this issue is even more compelling to ensure patients understand their conditions and the importance of treatment.[1]

As noted by Jamil,[2] compared to 23 industrialized countries, "the United States scored below the international average for literacy, numeracy and problem solving." According to the Centers for Healthcare Strategies,[3] in the U.S., poor health literacy is estimated at 36% and costs the country $236 billion a year. A 2020 report by United Healthcare[4] found that in the Medicare population, better health literacy improves safety, the patient experience, medical outcomes and overall quality of life.

But what is health literacy? The Centers for Disease Control and Prevention (CDC) define it as "the degree to which individuals have the ability to find, understand and use information and services to inform health-related decisions and actions for themselves and others."[5] In addition, it is important to keep in mind numeracy, which also can impact one's ability to comprehend information. Again, looking to the CDC, "numeracy is the ability to access, use, interpret and communicate mathematical information and ideas to engage in and manage mathematical demands of a range of situations in adult life."[6] In sleep medicine, we use terms in our conversations with patients, which require an understanding of numeracy. For instance, apnea-hypopnea index (AHI), oxygen desaturation index (ODI) and total sleep time (TST). We also use terms such as compliance or adherence with respect to a percentage of continuous positive airway pressure (CPAP) usage, but many people do not understand these concepts and it can be confusing. It is a lot for people to think about.

Adding to health literacy issues, it is also important to consider the notion of treatment burden. Treatment burden is defined as "the work that patients must do to implement management of care."[7] This includes making time for appointments, obtaining medication or other treatment and making lifestyle changes (exercise, grocery shopping, etc.). When one has low health literacy, therefore difficulty understanding what to do, the treatment burden can be extremely high.

Many individuals are embarrassed by their inability to read and/or write, to understand forms or directions and have difficulty asking for help. There are many reasons for low health literacy, which include older age, culture, English as a second language, social economic situation, level of education and other social determinants of health. Social determinants of health can have dramatic impacts on health literacy.[8] With regard to sleep, if one lives in an environment that does not promote or provide the ability for optimal sleep, sleep deprivation may contribute to one's inability to comprehend and be actionable on their health. Similar to food deserts, I call these "sleep deserts," where there is not adequate opportunity to sleep or access to conditions which promote good sleep. Difficult sleep conditions (e.g., bed sharing, sleeping on couches, violent neighborhoods) are not uncommon. These circumstances can and do have a harmful impact on a person's ability to sleep and therefore may impact one's ability to optimally function. There may also be sleep illiteracy, in other words, people do not understand the importance of sleep and the impacts on the lack thereof.[9]

When one has low health literacy, therefore difficulty understanding what to do, the treatment burden can be extremely high.

How does low health literacy impact the community of OSA patients and how can we help?

In 1998, Dr. Andrew Chesson[10] conducted a study regarding reading levels of brochures for OSA patients. He assessed patient facing materials from the then American Sleep Disorders Association (ASDA) and the National Sleep Foundation (NSF). His research found that few met any of the readability criteria, which is needed for patients to comprehend their diagnosis and treatment. What his team found was that the reading level of the language in the brochures was too high for most people and these materials were difficult to comprehend.

In a 2021 article by Robbins et al,[11] 20 web-based patient education materials (PEMs) from a variety of sources including medical device manufacturers (ResMed), the American Academy of Dental Sleep Medicine (AADSM), American Academy of Sleep Medicine (AASM) and American Thoracic Society (ATS) among others

were researched. They used a variety of evaluation resources including the CDC's Clear Communication Index (CCI), the Patient Education Materials Assessment Tool (PEMAT), Simple Measure of Gobbledygook (SMOG) and Flesch-Kincaid readability. What they found is that little has changed over the past 25 years. While there were some bright spots, very few PEMs met the requirements for ease of use, readability or other score measures. Though Chesson's group reviewed available brochures and Robbins' group, internet-based materials, the outcome was similar. A likely one-third of patients cannot understand the PEMs provided to them or accessed via the internet. How patients read materials from the internet differs from written materials, thus if your organization is using both options to provide information, different approaches may need to be used.

This is important research. It is known that suitably written and thoughtful materials can enhance self-efficacy, self-agency and therefore promote better health outcomes. The sleep health field has work to do!

More and more individuals are now using the internet to seek health information. A recent publication by the U.S. Department of Commerce National Telecommunication and Information Administration[12] found that more than 50% of households use the internet for any type of health care related information. They also found that individuals who use telehealth have higher incomes, are more likely to be educated and live in metropolitan areas. These findings are in alignment with lower health literacy facts as well.

If we think about the impact of sleep disorders on sleep itself, we know that sleep deprivation negatively affects executive function, memory and decision-making.[13] Combine sleep deprivation with low health literacy, and it is no wonder that sleep patients have difficulty in self-management and care in the home. We also know that the current health care payor environment does not seem to value the importance of this aspect of sleep health care. Little reimbursement is available for patient education, training and follow-up care in sleep health, in particular for patients with OSA. In other medical specialties such as endocrine (diabetes) and cardiology, patients are provided with adequate resources to be successful, including payment for diabetic educators and cardiac rehabilitation services.

Data supports that better health literacy improves OSA outcomes.[14,15] More advocacy by our field and patients is needed to move the payment needle forward. The cost burden of OSA alone to the U.S. is estimated at over $90 billion[16] and thus it deserves payors' attention.

As frontline sleep health care providers, what can be done?

First, we can look to ourselves, particularly our behavior when speaking to patients.

Organizations have a duty to provide patients the information in understandable form to enable them to be proactive in their care.

Do we value their opinion and that they are capable of making the decision that is right for them? Are we humble? Do we listen to what they have to say? These are just a few questions to ask ourselves. (A good overview on communication techniques can be found on a blog from Tulane School of Public Health.[17])

It is also important to look to your organization. Do they have a health literacy team? How are patient education materials reviewed? According to Healthy People 2030,[18] "organizational health literacy is the degree to which organizations equitably enable individuals to find, understand and use information and services to inform health-related decisions and actions for themselves and others." Thus, organizations have a duty to provide patients the information in understandable form to enable them to be proactive in their care. Having patients review materials produced by organizations is an effective way to elicit feedback and engage the community.

Clinicians can take the time to learn techniques such as the "Teach Back" method (see link to the right), understand the importance of asking open-ended questions and maintain a seated and open posture. This technique allows for patients and practitioners to be on the same physical level. We can also review and revise PEMs to meet a sixth-grade reading level. Look for signs of low health literacy such as inability to complete forms or statements such as "I forgot my glasses; I will take it home to read." Also, lack of adherence to recommendations such as missing appointments and recommended follow up are cues that can indicate a patient with low health literacy. It is not always just about a mask.

In conclusion, as sleep health professionals, we can do our part by critically reviewing patient education materials we provide to our patients, whether written or on the internet, and locate the most understandable information for patients across the spectrum of health literacy levels. We can educate ourselves on communication skills and obtain training. Communication and health literacy go hand in hand, and we can make a difference! It takes courage to change the status quo, but little by little, it can be done.

While writing this piece and doing the research, I came across a several valuable resources which are quick to review, interact with and to learn from. Arming ourselves with knowledge and obtaining training, is crucial to helping patients close the gap with regards to their understanding about sleep and associated disorders. I hope you find them helpful.

- Centers for Disease Control and Prevention
  - www.train.org/main/search?type =course&query= health%20literacy
  - www.train.org/main/search?type=course &query=health%20communication
- Health Literacy Online: A Guide for Simplifying the User Experience
  - health.gov/healthliteracyonline/
- Institute for Healthcare Advancement (IHA): Always Use Teach Back
  - www.teachbacktraining.org/home
- Agency for Healthcare Research and Quality Health Literacy
  - psnet.ahrq.gov/primer/health-literacy#
- National Academy of Medicine: Identifying Credible Sources of Health Information in Social Media: Principles and Attributes
  - nam.edu/identifying-credible-sources-of-health-information-in-social-media-principles-and-attributes/?utm_source= National+Academy+of+Medicine &utm_campaign=b6e1a8b193-Top+10 +Perps_COPY_01&utm_medium=email&utm_term=0_b8ba6f1aa1-b6e1a8b193-150924561

Take Action!

October is Health Literacy Month. Learn how you and your lab/hospital/center can collaboratively work together to create awareness around health literacy by visiting the Institute for Healthcare Advancement's webpage **here**.

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became enamored by the field of sleep in 1985. She began her career in sleep in the neonatal field before transitioning into sleep clinic administration roles and eventually the medical sleep device industry. Woidtke holds a master's degree in nursing science and a bachelor's in clinical research administration. She has authored numerous publications and lectured on a variety of sleep related topics and is currently the principal at Sleep for Nurses, a sleep-focused educational endeavor specifically developed for practicing nurses.

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PAP Versus Pill: A Conversation With Dr. David White

By Brendan Duffy, RPSGT, RST, CCSH

Over 20 years ago in 1995, Dr. David White was asked at a sleep conference in Australia to gaze into the future and speculate on how we would be treating sleep apnea patients. Dr. White said, "If CPAP is still the way we are treating sleep apnea in 20 years, we will be a failed field!" In the audience was none other than Dr. Colin Sullivan, the first person to ever describe continuous positive airway pressure (CPAP) for humans.

Dr. Sullivan disagreed and speculated that CPAP would still be present but would become as comfortable and normalized as a pair of eyeglasses. As it turns out, it appears that neither of these legendary sleep stalwarts was quite accurate. CPAP is still the primary therapy for most sleep apnea patients. While great strides have been made to CPAP masks and headgear designs, they hardly can be considered as comfortable as eyeglasses.

So what exactly does the near future look like for sleep apnea treatment and diagnosis? We are living in a time where sleep testing devices are becoming more robust and dynamic in their race to become a lab-quality home sleep test (HST) option. This progress is not limited solely to how efficiently and conveniently we can test and diagnose patients, but also how best to treat their sleep apnea after diagnosis. Sleep medicine appears to be in an exciting and dynamic time; and according to Dr. White, a non-CPAP mask option, in the form of a pill, is not too far away.

I had the pleasure to discuss the future of sleep medicine with Dr. White and it was a fascinating and exciting discussion. Dr. White is a legend in the sleep medicine field and has played an important role in the exploration of sleep phenotyping. He has held many titles in his career in sleep medicine, including director of the sleep disorders program at Brigham and Young Hospital, medical officer and consultant for Philips Respironics and past president of the American Academy of Sleep Medicine (AASM).

His work revolves around the mindset that if we can understand the cause of apnea for each individual, then a customized solution can be offered that is specific to the unique needs of each patient. There are several different physiological variables that occur and cause patients to develop sleep apnea. The focus will be on identification of each patient's pathology and physiology. Therefore, treatment will vary from the options available today. Other than CPAP, oral appliances and surgical treatments, few other options are available right now. Of course, CPAP therapy dominates the therapeutic treatment arena.

While many patients are treated and do well with CPAP therapy, many others struggle with the mask and hose option, while others are not even diagnosed, in part because they "don't want to sleep with a mask." What follows is a debrief of my conversation with Dr. White on a new, oral, CPAP alternative.

Dr. White, you are currently involved with a few new alternatives for CPAP, one of which is with Apnimed. You're also involved in and/or knowledgeable about other fascinating therapy modes currently in human trials. One such non-mask option being the Inspire hypoglossal nerve stimulation.

Inspire is doing very well. It's interesting technology! The other one that is out there that you should look at is CRYOSA. CRY means cold. You know how some people do cold sculpting of the stomach to try and get rid of fat? They are doing something similar — cold sculpting the tongue. There is reasonable data that sleep apnea patients have an increased amount of fat in their tongues so researchers are applying cooling to patients' tongues to get rid of "tongue fat" to treat sleep apnea. They are in human trials now so that's evolving.

It appears there are interesting happenings around the corner! So what exactly is Apnimed working on with their pharmacological trials?

Apnimed's primary offering is AD109, which is a combination of two drugs — atomoxetine and aroxybutynin — that work together to mitigate the collapse of the airway muscles during sleep. Atomoxetine is a norepinephrine reuptake inhibitor. The reason we picked a drug like this is that animal (rat) data suggests that loss of muscle activation during sleep, particularly loss of pharyngeal dilator muscle activation during non-rapid eye movement (NREM) sleep, is primarily due

While many patients are treated and do well with CPAP therapy, many others struggle with the mask and hose option.

to decreased norepinephrine input to the motor neurons that control the muscle, i.e., the neurons in your brain that produce norepinephrine decrease their firing rate. They project directly to nerves that activate your upper airway muscles. When you go to sleep, these norepinephrine neurons reduce their firing and eventually quit firing primarily in rapid eye movement (REM) sleep. What you are doing is losing an excitatory neural input to these muscles and their activity goes down. The reuptake inhibitor increases the amount of norepinephrine that is in the synapse between these neurons and increases muscle activity. Increasing norepinephrine levels increased muscle activity in rats quite a bit. Thus, a norepinephrine reuptake inhibitor was one choice.

Aroxybutynin is an anticholinergic. When you go into REM sleep there is active inhibition of virtually all muscles. The skeletal muscles are paralyzed when you are in REM sleep. However, the mechanism of this reduced muscle activity during REM sleep in the upper airway muscles is different from other skeletal muscles. The pharyngeal muscles have active cholinergic inhibition during REM sleep. And so, we thought let's get an anticholinergic to work in REM sleep.

We thought a norepinephrine reuptake for NREM and an anticholinergic for REM sleep might work and did a study with this combination on approximately 20 human patients in Boston out of our lab.

How did the study turn out? Are there any insights you can share with readers?

There was a substantial and clinically important reduction in sleep apnea severity on this drug combination, which we found very exciting. We also demonstrated that muscle activity went up substantially during sleep on these medications.

After this and further work, we are quite comfortable that the norepinephrine is working by activating the muscles. Exactly how the aroxybutynin is working is still unclear. Is it working purely as an antimuscarinic agent as a means of blocking this inhibition or is it just sedating the patient and overcoming the alerting effects of the atomoxetine? We don't fully understand this at this time, but do know that the combination of the two drugs does work pretty well.

To wrap things up, what are three takeaways that we should know about this new type of "sleeping pill for apnea"?

One, there is a pretty high probability that in the next two to four years a pharmaceutical will come out to treat OSA. Two, it will treat a reasonable slice of sleep apnea patients but not everyone. And three, the side effects associated with each agent will be modest.

It was a great honor to speak with Dr. White and this is another fascinating look into the near future for sleep medicine. Each day we are introduced to new diagnostic and treatment research and development. This advancement would certainly be a major disruptor in the sleep medicine field and yet another solution out there for the millions that suffer from sleep apnea — especially those that will not or cannot tolerate CPAP masks!

Author's Note: Since my conversation with Dr. White, Apnimed has received U.S. Food and Drug Administration (FDA) fast track designation. This designation is intended to facilitate and expedite the review of new drugs to fill an unmet medical need. Per an Apnimed company news release (https://apnimed.com/news/) from June 28, 2022, they are completing Phase 2 clinical trials and hope to then meet with the FDA to discuss the Phase 3 development program.

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