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Sleep Apnea is a Public Health Problem

Given its prevalence and effect on health, quality of life and safety, obstructive sleep apnea (OSA) is emerging as a significant public health issue that demands a population level response. Millions of people suffer from all degrees of sleep disordered breathing from simple snoring without pathology to severe obstructive sleep apnea. Unfortunately, obstructive sleep apnea is not typically recognized as a chronic disease that is a primary cause of morbidity and mortality in the United States. Obesity, heart disease, stroke, and diabetes have more readily been accepted as major epidemics and threat to good health. Nevertheless, sleep disordered breathing affects as many as 9 percent of middle-aged women and 24 percent of middle aged men.¹ The National Sleep Foundation reports that as many as 18 million people suffer from obstructive sleep apnea.² Despite the large risk pool, population studies from the United States, Europe, Asia, and Australia have shown a high prevalence of undiagnosed sleep apnea in adults.³ As many as 90 percent of individuals with sleep apnea have never been diagnosed.⁴

The “Gold Standard”?

For the last 25 years, diagnosis by polysomnogram (PSG) and treatment with continuous positive airway pressure (CPAP) have been considered the “gold standard” of care for OSA. Recent developments in healthcare policy and Medicare reimbursement parameters have opened the eyes of clinicians and practitioners throughout the sleep industry that this current standard of care of diagnosis and treatment is failing to meet the population’s need for an intervention.

There is a growing recognition and understanding that patient acceptance and adherence to treatment with CPAP is very low. In November 2008, the Centers for Medicare & Medicaid Services (CMS) implemented a new

policy on OSA treatment with Continuous Positive Airway Pressure. This medical policy requires the patient to use their CPAP for 4 hours a night, 70 percent of nights, for one 30 day stretch during the first 90 days of therapy.⁵ When patients do not meet this metric, CMS will no longer pay for the patient’s CPAP and the equipment must be returned to the home care company.

Many patients are not meeting these very basic criteria. Questions are now being raised about this 25-year-old treatment paradigm.

This treatment protocol has been:

1. All patients that are positively diagnosed with OSA must try CPAP first.
2. If CPAP fails based on equipment download or patient self report, try an alternative therapy.
3. Oral Appliances and Surgery have been viewed as alternatives.

The “gold standard” has been called into question as early as 1993. In terms of diagnosis, Pack challenged the status quo in his discussion on the value of a home test for identifying patients with a high-probability of OSA and for excluding patients with little chance of having OSA.⁶ In 2006, the Institute of Medicine published a seminal report labeling sleep disorders and sleep deprivation, including sleep disordered breathing, “a public health crisis” and called for new therapies and treatment algorithms to reduce the burden of disease in the United States.⁷

Today, we should ask ourselves:

- Are we doing the right thing for patients if they cannot comply with our “gold standard” treatment?
- Is CPAP the gold standard OSA treatment for

the entire spectrum of disease or are different treatments more appropriate for different levels of disease severity?

- How effective is any treatment when it is not used?
- Do we know where all of the failed CPAP patients are? Have they given up and been lost in the system or are they being given other treatment options?
- Are therapies that were previously viewed as a second line or alternative treatment really first line therapy options?
- If we are truly looking out for the patient, wouldn't it make sense to try the least invasive treatment first?
- If a therapy has shown high patient adherence and effective treatment outcomes, would it not be a treatment of choice?

Barriers to Successful Treatment

There are several readily identifiable barriers that prevent large numbers of patients from getting treatment that they need to restore their health and quality of life.

The first barrier to care is ACCESS. Historically, the diagnosis and treatment for OSA has been dependent on sleep specialists and sleep lab facilities for diagnostic testing which are primarily concentrated in urban centers. Today, there are approximately 5200 boarded sleep physicians in the United States.^{8,9} That means that there is approximately one sleep physician for every 8000 people at risk for obstructive sleep apnea. Although there is not one central registry of sleep testing facilities, data suggest that there are not enough facilities to meet the need. Waiting lists for a PSG sleep test may be as long as 10 weeks¹⁰, with even longer waiting times in certain systems such as Veteran's Affairs Medical Centers.¹¹ This workforce and



BARRIERS TO SUCCESSFUL DIAGNOSIS AND TREATMENT



ACCESS TO CARE

- Limited numbers of sleep specialists
- Limited number of diagnostic facilities

TESTING

- Patient is unwilling or unable to complete PSG test

TREATMENT

- Patient not presented with treatment options
- Patient is unwilling to try treatment
- Patient is unwilling to use treatment

COMPLIANCE AND LONG-TERM MANAGEMENT

- Patient is unwilling to continue treatment
- Patient does not follow treatment regimen
- Patient does not return for regular follow-up
- Patient discontinues use of treatment

COST

- Cost of testing
- Cost of treatment (equipment, disposables)

infrastructure is inadequate in terms of meeting the diagnosis and treatment needs of the population at risk.

The DIAGNOSTIC PROCESS itself can deter patients. Historically, patients have been required to undergo an overnight sleep test called a polysomnogram (PSG) in a sleep lab to be diagnosed with sleep apnea. The test requires the patient to sleep away from home and have a myriad of probes attached to their body to measure physiologic parameters while they sleep. Some patients will not go to a sleep lab for the test.¹² Others can not tolerate the test conditions or are unwilling to be away from home for a night and do not complete the test.¹²

The number of TREATMENT CHOICES for obstructive sleep apnea is limited. Continuous positive airway pressure (CPAP) has been considered the standard of care for OSA.¹³ Oral appliance therapy (OAT) and surgery to remove excess tissue in the throat or advance the lower

jaw have historically only been recommended as alternatives following the failure of CPAP therapy.¹⁴

In terms of CPAP therapy, problems with COMPLIANCE often result in under-treatment and suboptimal outcomes. In a recent study examining compliance rates from twelve clinical trials, researchers reported that between 46 and 83 percent of patients are non-adherent to CPAP treatment.¹⁵ In most cases, successful treatment of a chronic disease such as OSA requires a patient to continue treatment indefinitely. Since OSA tends to progress and get worse over time, it's important that patients return to their treating physician for regular follow-up. If they do not follow-up regularly, there is a high likelihood that the patient will not be adequately treated long-term.

Finally, COST is a barrier to care. Direct costs for a PSG test alone are high in order to cover the overhead, staff compensation and capital investments associated with the service. If CPAP therapy is prescribed, the patient must return for a second PSG to titrate the device. The cost of CPAP treatment includes not only the initial investment in the equipment but also ongoing costs for consumable components such as hoses and masks. Reimbursement for diagnosis and treatment depends on the patient's insurance coverage which may or may not include coverage for durable medical equipment. Often, the patient's out-of-pocket expense is relatively high. Cost can become an issue over a long period of time, so patients often do not follow-up with their sleep physician or have a follow-up PSG to monitor the efficacy of their CPAP treatment.

Need for a New Standard of Care

The sheer numbers of people who have sleep apnea and are at risk for developing the disease warrant thinking "outside the box." A population-based solution is needed so that more people get treated effectively. Recently, the Agency for Healthcare Research and Quality (AHRQ) announced that they will be funding clinical

research initiatives that focus on the comparative effectiveness of different treatment modalities for OSA. The only comparative studies to date have compared the efficacy (i.e. the effect in the laboratory under ideal conditions) of different interventions. It is only when compliance is taken into consideration that the effectiveness (i.e. the effect in everyday life) of a given therapy can be understood.¹⁶

In order to address the chronic nature of the disease, the optimum therapy will be the one that the patient is most compliant with over the longest period of time. The ideal therapy will also be able to accommodate changes in the disease since sleep apnea tends to become more severe over time. The importance of compliance with therapy cannot be over-emphasized. Except for surgery, all other treatments for sleep-disordered breathing involve patient behavior to administer the therapy. The treatment effect of the two noninvasive therapy choices - CPAP and oral appliances - is zero if a patient does not use the machine or appliance.

Successful treatment for sleep apnea will improve patient's health and quality of life. Patients who are successfully treated spend fewer dollars on healthcare than those that are untreated. They are less likely to have traffic accidents and are more likely to be more productive at work.

In most cases, sleep-disordered breathing is relatively easy to identify. Screening for sleep apnea at the primary care level can identify cases and help patients get timely treatment.¹⁷ Clinical screening programs can differentiate the likely OSA patient from the non-OSA patient and reduce the cost of diagnosis and treatment.¹⁸ These programs often include both objective tests, such as overnight pulse oximetry, and simple questionnaires that assess a patient's perception of the severity of symptoms, such as the Epworth Sleepiness Scale.

Overnight pulse oximetry is a simple home test that can be used to rule out OSA. This test

objectively measures oxygen saturation in the blood. Studies have shown that if oxyhemoglobin saturation (SpO₂) does not fall below 90 percent for greater than one percent of the night, then the likelihood of OSA is less than 4 percent.¹⁹ A recent study validating pulse oximetry for use in diagnosing apnea demonstrated that if the desaturation index (DEI) at 2 percent is below 12.2 per hour then there is 100 percent likelihood that the patient does not have OSA.²⁰

The goal of treatment in all cases of obstructive sleep apnea is to resolve the clinical signs and symptoms of the disease and normalize oxygen levels in the blood.^{13, 14} In the case of primary snoring without oxygen desaturations, the goal is to reduce symptoms to a subjectively acceptable level.¹⁴ Once the patient achieves a successful treatment outcome, the clinical management of sleep apnea involves continued patient education and monitoring to prevent progression of disease severity and mitigate risk of other diseases.

The Promise of Dentistry

The first step in reducing the burden of sleep apnea in the United States is to create a primary care workforce that can reach the numbers of people who need treatment. As medical professionals, the dentist is perhaps positioned best to screen for sleep apnea, treat a significant portion of patients, and make referrals as necessary for more intervention. There are approximately 230,000 dentists in the United States.²¹ Demographically, dentists are located in most communities whereas sleep specialists are concentrated in urban areas. As primary care practitioners, dentists see many of their patients at least twice a year. In fact, on average 70 percent of the US population visits the dentist every year.²²

The link between dentistry and sleep apnea treatment may not be readily apparent to the average patient. The jaw, however, plays an important role in obstructive sleep apnea. Physiologically, the size of the airway directly depends on the position of the jaw. If the jaw

falls open and back while an individual is asleep, the size of the airway will decrease and the chances of total collapse will increase exponentially.²³ Oral appliances fitted to the teeth relationally position the jaw in a forward position, mimicking the jaw-thrust maneuver, a key principle of airway management in both cardiopulmonary resuscitation (CPR) and anesthesia. Dentists have extensive training in craniofacial anatomy and have specific skills necessary to treat a patient with oral appliance therapy for sleep apnea and prevent any potential problems related to the teeth, gums or jaw joint that might develop.

Legally, the treatment of any disease process or condition is based on state laws. Under most state laws the practice of dentistry is related to conditions and diseases which affect the teeth, jaws, temporomandibular joint, or related structures including their function and dysfunction. Since sleep apnea can be treated through dental therapies such as oral appliances and orthognathic (jaw) surgery, it falls within the scope of dentistry (unless otherwise defined by state law).

Dentists are well prepared to collaborate with physicians to treat OSA. The overlap of treatment modalities in medicine and dentistry for a particular diagnosis occurs frequently. The treatment given is based on patient complaints, symptoms, severity of the disease, efficacy and effectiveness of the treatment, referral patterns, the specialty and bias of the professional consulted, costs, and insurance coverage. Examples of this dental-medical overlap include diagnosis and treatment of nocturnal bruxism, temporomandibular disorders, myofacial pain and headaches.

Oral Appliance Therapy

The Practice Parameters published by the American Academy of Sleep Medicine in 2006 include oral appliances as a first line of therapy in the standard of care for the treatment of obstructive sleep apnea.

According to the guidelines, oral appliances (OAs) are indicated

“For patients with mild to moderate OSA who prefer OAs to Continuous Positive Airway Pressure (CPAP), and in all cases for those who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep position change.”¹⁴

Oral appliance therapy for sleep-disordered breathing has repeatedly been validated and shown to be efficacious.^{24, 25} Fortunately for the patient, oral appliance therapy has little morbidity and is reversible. Simple questionnaires and testing can quickly determine those patients who are oral appliance treatment failures or are being undertreated. Proper referral of the more severe patient or the patient who is not adequately treated with an oral appliance can be effected with little delay in treatment and no harm done to the patient. Studies have shown compliance rates as high as 95% with oral appliance therapy.^{26, 27} Because compliance rates are so high with oral appliance therapy, it can be a very effective treatment for patients over a long period of time.

Appliance Selection

Although dental appliances have been used for several decades to treat obstructive sleep apnea, the technology and sophistication of the products have significantly improved in recent years. Unfortunately, the oral appliances currently on the market are not standardized and vary greatly in quality, cost, and treatment effect. This leads to practical problems on many levels, namely for the provider prescribing an oral appliance, the patient when making a selection, and insurance companies when considering reimbursement.

A strong case may be made, however, that mandibular advancement devices of a certain caliber offer a population-based solution to sleep disordered breathing. They are relatively easy to

manufacture, convenient and portable, cost-effective, less obtrusive than CPAP, and have a primary care practitioner directly involved in the treatment.

Several criteria can be used to differentiate credible appliances that will achieve predictable results from those that will not. Independent clinical trials published in peer-reviewed medical journals are perhaps the most important validation of any device on the market. When interpreting the literature, it is extremely important to recognize which device is under investigation because device design can affect treatment outcomes.

The primary design features that influence treatment outcomes are

retention (how well the device stays anchored on the teeth)²⁸

adjustability²⁹

degree of mandibular protrusion^{26, 28, 29}

complete coverage of all dentition²⁸

ability for the patient to self-titrate the device.²⁹

Non-custom (“boil and bite”) devices tend to be inferior to custom made devices. Typically, non-custom devices do not have the same retention as custom appliances and are more likely to fall out of the mouth. A recent study showed that non-custom oral appliances are not efficacious in treating obstructive sleep apnea.²⁸

The TAP® Oral Appliance

The TAP oral appliance is a custom, adjustable mandibular advancement device. It consists of upper and lower trays that are molded to a patient’s dentition and looks very similar to a sports mouth guard. The trays employ a hook and socket mechanism to engage and advance the mandible. Once engaged, the patient can advance their lower jaw using a small hex key. Patients are given a titration schedule by their

dentist, which will advance their lower jaw out to the optimal treatment position over time. The patient-adjustability feature eliminates frequent trips to the dentist for adjustment. Unique features of the TAP® make it the only device on the market that can be adjusted while in the patient's mouth. Thus, the TAP can be easily titrated during a PSG by a sleep technologist without requiring the patient to remove the appliance from their mouth.

The TAP oral appliance is supported by more than 20 independent clinical research papers. Several of the studies demonstrate that the TAP alone is clinically effective in treating severe sleep apnea.^{26, 29, 30} Selected research findings include:

TAP is the only oral appliance that is “not inferior to CPAP.”²⁹

TAP has compliance rates over 86% and as high as 95%.^{26, 30}

TAP treats all levels of sleep disordered breathing from mild to severe sleep apnea.^{27, 29, 31}

TAP therapy improves cardiac function³²

TAP therapy improves simulated driving performance³³

Airway Management, the company that manufactures the TAP, recently released a new, semi-custom version of the TAP device. The TAP Chairside (CS) employs the same advancement mechanism as earlier versions of the custom TAP device but can be fitted in the dentist's office. Although it is not quite as comfortable as a custom TAP, the semi-custom TAP CS allows the dentist to provide an immediate solution to the patient. This device serves as an intermediary or trial device while the patient waits for his or her custom TAP to be made. Because the advancement mechanisms and thermoplastic materials are the same and only the method of fabrication differs, the TAP CS can

be used to show that TAP Therapy is efficacious prior to the delivery of the custom TAP device.

The TAP is the only therapy on the market that has an attachment for a CPAP mask. The TAP-PAP® device combines CPAP with an oral appliance with a unique connector that eliminates the need for headgear. This combination therapy has two mechanical functions. The mandibular protrusion changes the relationships between the pharyngeal space, hyoid bone and tongue position while the positive air pressure acts as a pneumatic splint to further open the airway. TAP-PAP therapy addresses several of the primary problems that patients have with CPAP, namely claustrophobia, mask leakage and air pressure.

Compliance with TAP-PAP tends to be high. The TAP-PAP mask is held in place by a post attached to the TAP device. The post attachment mechanism eliminates the need for headgear thereby reducing the likelihood that patients feel claustrophobic. Unlike masks that are held in place by headgear, the TAP-PAP mask does not shift when the patient moves his or her head during sleep. Thus, there are fewer masks leaks with TAP-PAP. Finally, because the jaw is held in a fixed, protrusive position, the TAP-PAP reduces the amount of positive pressure needed to splint the airway.

By design, TAP-PAP Combination Therapy can achieve results that are greater than what either a TAP or a CPAP can achieve independently. Some may find that this new device achieves results that are greater than the sum of its parts. This treatment is appropriate for the patient with severe disease or complications. With its range of devices, the semi-custom TAP Chairside (CS), the custom TAP and the TAP-PAP, the TAP Therapy System offers a complete solution to sleep-disordered breathing.

The TAP® Standard of Care™

Treatment solutions alone will not mitigate the effects of a health epidemic. The TAP Standard of Care is a definitive treatment algorithm

designed to reduce the burden of all degrees of sleep disordered breathing. The care pathway calls upon dentists to become a primary care workforce. Our goal is for dentists to educate patients about sleep-related breathing disorders, help patients identify problems early and initiate treatment to prevent pathology from developing or disease from progressing. As such our treatment protocol at once serves as a primary, secondary and tertiary prevention strategy.

**TAP STANDARD
OF CARE GOALS**



1. Improve access to care
2. Increase the number of non-invasive treatment options
3. Reduce barriers that prevent patients from achieving a successful outcome
4. Increase the numbers of patients appropriately treated for sleep disordered breathing
5. Achieve predictable results
6. Improve therapy compliance
7. Maximize the lifetime of care

The TAP® Standard of Care™ simplifies the process for patients to reach a successful treatment outcome whether they suffer from primary snoring, a social problem, or from obstructive sleep apnea, a disease with clinical pathology.

The Standard of Care™ protocol is available to all dentists. Our mission is to educate and support the general dentist as well as the specialized dental sleep medicine practitioner. It is only when community-based dentists start treating patients for snoring and mild to moderate disease, monitoring patients for disease progression and referring the patient for more specialized care if necessary that the population-based approach will begin to work.

The treatment protocol calls for dentists and physicians to work together. This Standard of Care allows dentists and physicians to collaborate in a variety of ways.

Some patients will have already been diagnosed with OSA and some will have tried and failed CPAP. Dentists who care for these patients may collaborate with the patient's primary care physician and/or sleep physician about the status of the patient's treatment. Some patients will seek treatment for snoring and in the process will be screened for OSA. For those patients with a high likelihood of OSA, dentists may refer patients to a physician for a diagnosis and/or an evaluation of their comorbidities prior to initiating treatment. Alternatively, they may order a home sleep test or PSG and collaborate with a physician for confirmation of a diagnosis prior to initiating treatment. Once the patient's device is properly titrated according to the overnight pulse oximetry results, the dentist may refer the patient to a physician to confirm that there is no further pathology or presence of comorbidities.

TAP-PAP Therapy necessarily involves interdisciplinary collaboration between the dentist and physician. Never before has there been a written protocol outlining how the dentist and physician can collaborate to treat the sleep apnea patient with a device that requires the dentist to manage the oral appliance therapy and the physician to manage the positive airway pressure therapy.

Principles of the TAP® Standard of Care

Consultation and Patient Education

The dentist must administer an informed consent. The dentist has a duty to have enough knowledge and understanding of sleep disordered breathing to educate the patient on treatment options, morbidity of the treatment, and outcomes.

Patient Identification and Selection

Any patient complaining of sleep-disordered breathing can be treated by the dentist. It is imperative that the dentist screen all patients who complain of snoring for obstructive sleep

apnea. Dentists can use simple home sleep testing devices to objectively identify cases that have a high likelihood of OSA. These cases must be managed and objective and subjective outcomes documented to show that the intervention has improved the patient's condition.

Dentists may see a variety of sleep patients in their practices, including patients who

- Have a chief complaint of snoring,
- Refuse to undergo a polysomnogram (PSG) test

Have been diagnosed by PSG test

- Prefer to try an oral appliance as a first line of therapy
- Are unwilling or unable to wear CPAP
- Are compliant with CPAP but desire an alternative or a substitute while traveling,
- Are a candidates for surgery but would prefer trying a non-invasive option first, and
- Have experienced a surgical failure

When a patient is not a good candidate for oral appliance therapy, it is incumbent upon the dentist to help the patient find another treatment option and refer the patient to the appropriate provider.

Screening and Treatment

The dentist should follow a standard of care for the sleep disordered breathing patient that will assure appropriate treatment. The routine evaluation should include sleep questionnaires, medical history, physical examination of the head, neck and pharynx, and overnight pulse oximetry. Should the dentist choose, overnight pulse oximetry may be substituted by more involved home sleep tests (Level II or III home sleep test) or a PSG test overseen by a sleep

physician.

The TAP Standard of Care includes the following screening and treatment algorithm:

If pathology of the upper airway is ruled out and the chief complaint is snoring with no symptoms of sleepiness and no oxygen desaturations, then the definitive treatment is an oral appliance.

If the patient snores and is sleepy but has no desaturations, there is little evidence that the patient has obstructive sleep apnea. The dentist may choose to initiate treatment for snoring and may choose to refer the patient to a physician for further evaluation. The patient's treatment of choice in this case is typically an oral appliance. Follow-up questionnaires for sleepiness must be completed after oral appliance therapy and failures should be referred to a physician for evaluation.

If the patient desaturates greater than one percent of the night below ninety percent, then OSA is a possibility. The dentist may refer a patient to a physician for evaluation and a home sleep test or PSG for confirmation of disease. After oral appliance therapy, if the desaturation is less than one percent of the night below ninety percent then OSA is practically ruled out, particularly if there are no remaining symptoms.

At any time if the patient continues to desaturate or have symptoms after treatment, with the patient's understanding and permission, the dentist may refer the patient to his or her primary care physician for further analysis and/or refer the patient to a sleep physician. The dentist may offer the patient TAP-PAP therapy and must collaborate with a physician to initiate therapy.

At any time if the patient continues to desaturate or have symptoms after treatment with TAP-PAP, with the patient's understanding and permission, the dentist should refer the

patient to his or her primary care physician for further analysis and/or refer the patient to a sleep physician.

Do No Harm

The greatest potential harm that a dentist can cause is not maximizing the benefit of oral appliance therapy for the patient if he or she attempts to treat the patient's sleep disordered breathing with little knowledge, training and skill. The highly inconsistent results and numerous failures of both dentists and many oral appliances in the past have given oral appliance therapy a poor reputation among many sleep physicians. The TAP Standard of Care is designed to help the dentist achieve predictable results when treating patients for sleep-disordered breathing. It was created to facilitate collaborating with physicians to care for patients with a variety of levels of disease.

If a dentist is going to diagnose and treat SDB, he must be able to place the jaw in the most effective treatment position. This necessarily requires home or sleep lab titration of the device utilizing objective measurements of results such as pulse oximetry, home sleep study, or PSG. This also requires the use of adjustable oral appliances as treatment appliances. Just as CPAP pressures are adjustable and titrated, so must oral appliances be adjustable and titrated.¹⁹

Long Term Management

Long term management of TAP® Therapy requires dental intervention to prevent teeth from moving and prevent damage to the oral cavity. This is best accomplished by the dental professional who focuses on periodic check-ups, prevention, early intervention, accessibility, affordability and appropriate referral when warranted. The oral cavity, dentition, and temporomandibular joint must be healthy for the patient to benefit from long term oral appliance therapy.

TAP® STANDARD OF CARE TREATMENT ALGORITHM



ABBREVIATIONS

AHI	Apnea Hypopnea Index
CT ₉₀	Cumulative Time that oxygen saturation is less than 90%
T ₉₀	Percent of Time with SpO ₂ Below 90%
DEI ₂	Desaturation Event Index at 2%
ESS	Epworth Sleepiness Scale
OA	Oral Appliance
OAT	Oral Appliance Therapy
OSA	Obstructive Sleep Apnea
SDB	Sleep-disordered breathing
SpO ₂	Oxyhemoglobin Saturation
TAP®	Thornton Adjustable Positioner®
	Clinical Decision

INITIAL EVALUATION

PATIENT WITH SUSPECTED SLEEP DISORDERED BREATHING (SDB)

Interview

- Symptoms: Snoring, Witnessed Apneas, Sleepiness, etc.
- Comorbidities: Hypertension, Diabetes, Stroke, Depression, etc.
- Previous diagnosis and/or treatment (including treatment non-adherence)

Screen and Assess

- Clinical assessment: History and physical
- Patient questionnaires: ESS, Thornton Snoring Scale (TSS)
- *Optional:* Sleep Observer Scale (SOS), Functional Outcomes of Sleep Questionnaire (FOSQ)
- Determine pre-test probability of OSA (e.g. Adjusted Neck Circumference)

CLINICAL DECISION MAKING

Test

- Overnight home pulse oximetry (>4 hours of sleep) to determine baseline (Min. Standard)
- Level III home monitor (>4 hours of sleep)

Evaluation

- Determine if T₉₀ < 1% of night
- Determine if DEI₂ < 12.2

T₉₀ < 1% of night
and DEI₂ , 12.2

T₉₀ < 1% of night
and DEI₂ , 12.2

How severe is the
patient's sleepiness?

ESS ≤ 7

ESS ≥ 8

Obtain Diagnosis
Refer to physician for
evaluation of comorbidities
and/or diagnosis
or
Order a home sleep test or
PSG and consult/collaborate
with physician to confirm
diagnosis

Any observed apneas?
Comorbidities?

No

Yes

TAP THERAPY (SNORING ONLY, NO OSA)

SEE: TAP THERAPY (NO OSA) ALGORITHM

PATIENT WITH PREVIOUS DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA (OSA)

Mild or moderate OSA
Patient chooses oral appliance
therapy (OAT) as primary
treatment option

Severe OSA
Patient is unsuccessful with or
non-adherent to CPAP

Initiate TAP Therapy Protocol

Severe OSA
Patient is interested in TAP-
PAP Combination Therapy

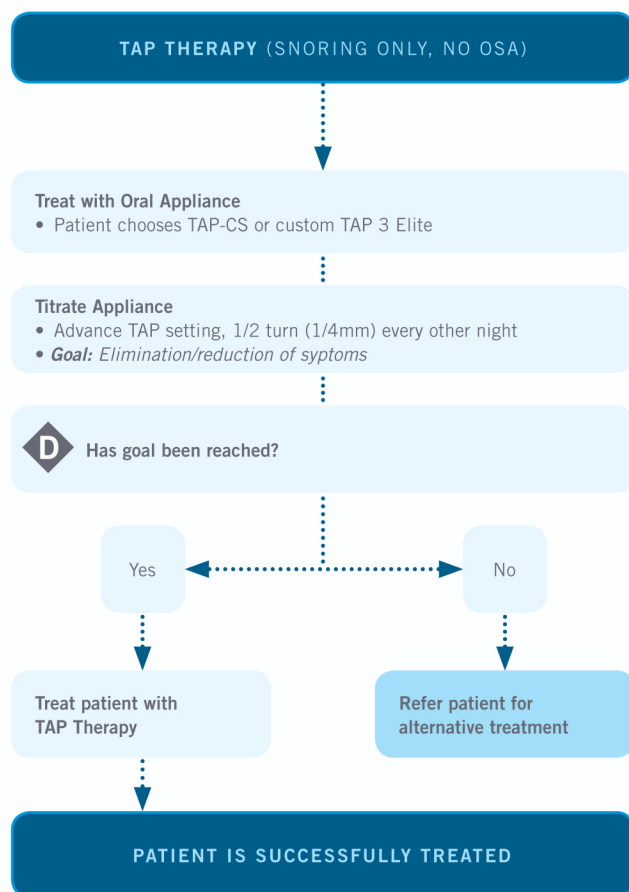
Contact patient's physician
before initiating TAP Therapy
Protocol

TAP THERAPY (OSA)

SEE: TAP THERAPY (OSA) ALGORITHM



TAP® THERAPY ALGORITHM (SNORING ONLY, NO OSA)

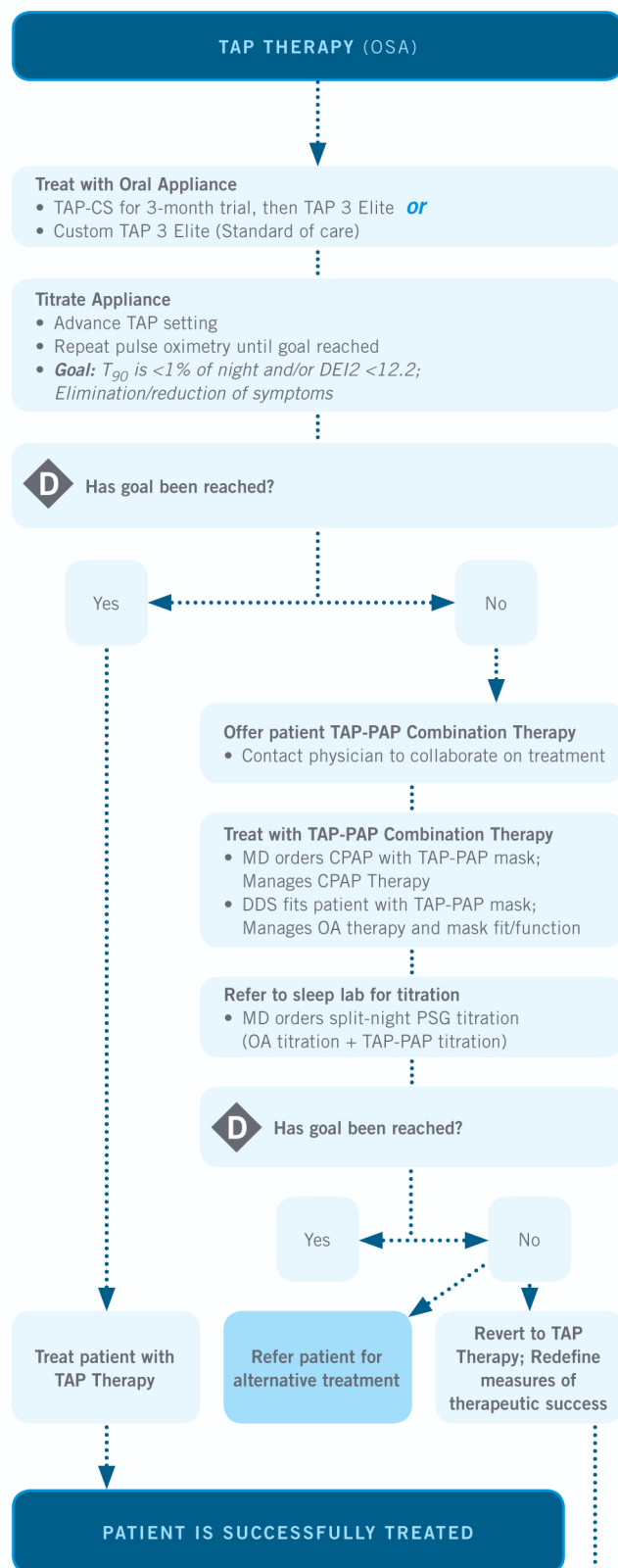


LONG-TERM MANAGEMENT

Annual check-up and evaluation

- Check appliance for damage
- Reevaluate objective and subjective measures of disease (pulse oximetry and questionnaires)

TAP® THERAPY ALGORITHM (OSA)



LONG-TERM MANAGEMENT

Annual check-up and evaluation

- Check appliance for damage
- Reevaluate objective and subjective measures of disease (pulse oximetry and questionnaires)

The TAP® Standard of Care™

Step 1. Initial Evaluation

- Educate patient about sleep disordered breathing and treatment options
- Administer an informed consent
- Conduct history and physical - review risk factors, symptoms, comorbidities
- Assess subjective questionnaires (e.g. Epworth Sleepiness Scale, Thornton Snoring Scale, Sleep Observer Scale, etc.)
- Determine pre-test probability of having obstructive sleep apnea
- Dispense overnight pulse oximetry test to obtain to screen for OSA and establish a pre-treatment baseline of the patient's condition

Step 2. Screening

- Patient self-administers overnight pulse oximetry test at home

Step 3. Evaluation of Test Results, Clinical Recommendations and Shared Decision Making

- Review test results
- Recommend treatment options (Oral Appliance Therapy, CPAP therapy, Surgery)

Option 1: Treatment for Primary Snoring

- If oxygen saturation (SpO₂) is not lower than 90% for more than 1% of the night and the desaturation event index at 2% (DEI₂) is less than 12.2 – rule out obstructive sleep apnea
- If no other symptoms and/or comorbidities

Option 2: Therapy for Sleep Disordered Breathing

- This therapy is appropriate for snoring accompanied by significant symptoms/comorbidities and for obstructive sleep apnea
- If oxygen saturation (SpO₂) is lower than 90% for more than 1% of the night and the desaturation event index at 2% (DEI₂) is more than 12.2 – assume pathology related to obstructive sleep apnea
- If conditions above not met but snoring and other significant symptoms and/or comorbidities are present
- If previous diagnosis of obstructive sleep apnea
- If previous attempt of CPAP therapy
- *Note: If patient has not been previously evaluated and/or diagnosed by a physician for OSA*
 - Educate patients that have a high likelihood of OSA that the disease often has significant comorbidities that should be monitored by a physician
 - Educate patients that they will need a home sleep test or an overnight PSG test interpreted by a sleep physician to be diagnosed
 - Educate patients that therapy will only be reimbursed if they have been diagnosed with OSA
 - Refer patient to their primary care or a sleep physician for evaluation and diagnosis

Step 4. Treatment with TAP®

- Select TAP™ device
 - TAP-CS™ (a semi-custom device suitable for 3 month trial)
 - Custom TAP-3™ (Standard of Care due to durability)
- Repeat informed consent, educate patient about pros and cons of treatment
- Fit patient with device, adjust for comfort
- Goal of treatment
 - Primary snoring: Elimination or reduction of subjective symptoms
 - Sleep-Disordered Breathing (Snoring accompanied by significant symptoms/comorbidities and for obstructive sleep apnea): oxygen saturation (SpO2) is not lower than 90% for more than 1% of the night and the desaturation event index at 2% (DEI2) is less than 12.2; Elimination and/or reduction of symptoms; Elimination and/or reduction comorbidities

Step 5. Titration

- Instruct patient to advance the TAP™ ½ turn (¼ mm) every other night until snoring (as reported by bed partner) goes away or patient begins to feel better (approximately 3 weeks)
 - Note: titration over time prevents adverse side effects, should side effects (e.g. jaw pain) occur, slow the advancement protocol
- After patient completes first titration period
 - Primary Snoring: evaluate patient for subjective symptoms and side effects
 - Sleep Disordered Breathing: repeat overnight pulse oximetry
- If treatment achieves goal (see Step 4): skip to Step 8
- If treatment *does not* achieve goal
 - Primary Snoring: refer for alternative treatment
 - Sleep Disordered Breathing: offer patient TAP-PAP Combination Therapy™ or refer for alternative treatment
- Dentist may choose to refer patient to physician for a home sleep test or PSG to confirm proper titration has been achieved

Step 6. Treatment with TAP-PAP Combination Therapy™

- Collaborate with physician to administer therapy
- Physician orders CPAP with TAP-PAP mask, manages CPAP therapy
- Repeat informed consent, educate patient about pros and cons of treatment
- Dentist fits patient with TAP-PAP mask, manages OA therapy and mask fit/function
- Goal of treatment: normalized PSG test; Elimination and/or reduction of symptoms; Elimination and/or reduction comorbidities

Step 7. Titration in a Sleep Lab

- Physician orders split-night PSG titration
- ½ night TAP® titration, ½ night TAP-PAP titration
- If treatment achieves goal (see Step 6): skip to Step 8
- If treatment does not achieve goal: revert to TAP® Therapy and redefine measures of therapeutic success, or refer for alternative treatment (surgery)

Step 8. Establish Long-Term Management Protocol for Patient

- Create a six-month or annual check-up schedule to assess condition of the medical equipment and reevaluate patient
- Administer subjective questionnaires to evaluate patient's condition and overnight pulse oximetry test (if sleep disordered breathing)

Note: The dentist must practice according to state laws. It is the dentist's responsibility to abide by his/her state's dental practice act when implementing this Standard of Care.

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