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December 3, 2020

Kannan Ramar, MD
President
American Academy of Sleep Medicine
2510 N. Frontage Rd.
Darien, IL 60561

AAO-HNS Comments on AASM CPG: “Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation”

Dear Dr. Ramar:

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) is pleased to submit comments to the American Academy of Sleep Medicine (AASM) regarding their Clinical Practice Guideline (CPG) “Referral of Adult with Obstructive Sleep Apnea for Surgical Consultation”. The proposed CPG was reviewed by our Sleep Medicine Committee, Guidelines Task Force, our Payment Policy Committee and sleep medicine specialists within our specialty. The following comments represent their collective thoughts and the opinion of our organization. We thank you for the opportunity to review this very important document.

Review by the Guideline Task Force

The American Academy of Otolaryngology-Head and Neck Surgery and its Foundation (AAO-HNS/F) recognizes that a number of organizations are producing clinical practice guidelines (CPGs), consensus statements, and other quality knowledge products that may benefit AAO-HNS/F members and their patients. The AAO-HNS/F has published its own rigorous methodology for developing such quality knowledge products which can be used by other organizations in assessing the standards against which their work product will be evaluated when requesting our endorsement. In these instances, the AAO-HNS/F is committed to evaluating these publications and determining whether an official endorsement is appropriate and/or would benefit Academy members and their patients.

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The AAO-HNS/F uses certain criteria to determine eligibility for consideration, and to evaluate its position on endorsing external publications. Meeting eligibility criteria for consideration of endorsement does not guarantee endorsement; neither does endorsement guarantee publication in *Otolaryngology-Head and Neck Surgery* or feature in other AAO-HNS/F web or print materials.

Recommendations are based on peer-reviewed evidence

An AASM commissioned taskforce (TF) developed this guideline and a corresponding systematic review. The recommendations provided in this Clinical Practice Guideline were developed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process. The TF assessed the following four components to determine the direction and strength of a recommendation: quality of evidence, balance of beneficial and harmful effects, patient values and preferences, and resource use. Recommendations are based on peer-reviewed evidence.

The publication is based on a comprehensive, systematic review of the literature.

The TF conducted a systematic review of the published scientific literature, focusing on patient-oriented, clinically relevant outcomes to answer 4 PICO (Patient, Intervention, Comparison, and Outcomes) questions regarding the surgical treatment of adults with OSA. A total of 272 observational studies and 8 RCTs were utilized in developing this guideline. Meta-analyses were performed on outcomes of interest, when possible, for each PICO question.

Cited evidence has been graded or classified according to quality and study design

The TF performed an extensive review of the scientific literature to retrieve articles that addressed the PICO questions. Separate literature searches were performed by the TF for each PICO question using the PubMed database. All studies were reviewed based on inclusion/exclusion criteria by two TF members. Any discrepancies between the reviewers were discussed and resolved by the two

reviewers or a third TF member. A total of 254 studies were determined to be suitable for meta-analysis and/or grading.

Recommendations directly correspond to evidence

The TF developed 2 strong and 2 conditional recommendations based on low-moderate quality evidence:

1. The TF made a strong recommendation in favor of discussing surgical referral based on a large body of low quality evidence from 220 observational studies and 3 randomized controlled trials (RCTs) showing clinically meaningful and beneficial differences in nearly all critical outcomes, and the benefits of discussing referral over the harms of no treatment.
2. The TF made a strong recommendation in favor of bariatric surgery referral based on moderate quality evidence from 28 observational studies and 3 RCTs that showed clinically meaningful improvements in several critical outcomes, and the benefits of discussing referral over the harms of no treatment.
3. The TF made a conditional recommendation in favor of surgical referral based on very low-quality evidence from 7 observational studies showing clinically meaningful improvements in several critical outcomes and the benefits of discussing referral over the harms of persistent PAP-related side effects or suboptimal use that likely vary depending on the patient's degree of use.
4. The TF made a conditional recommendation against surgical referral as initial treatment for OSA based on low quality evidence from 17 observational studies and 2 RCTs, the balance of benefits to harms favoring PAP as an initial treatment over surgery, and the benefits of discussing referral over the harms of PAP as an initial OSA therapy trial.

Transparency and appropriate management of conflicts of interest are satisfactorily addressed

The TF was required to disclose all potential conflicts of interest (COI), per the AASM's COI policy, prior to being appointed to the TF and throughout the research and writing of the guideline, systematic review, and supplemental materials. TF members with a Level 1 conflict were not allowed to participate. TF members with a Level 2 conflict were required to recuse themselves from any related discussion or writing responsibilities. The guideline states that all relevant conflicts of interest are listed in the "Disclosures section"; however, we were unable to locate this section within the guideline.

Multi-disciplinary panels are utilized

The AASM commissioned a task force (TF) comprised of experts in sleep medicine, otolaryngology, and bariatric surgery to develop this systematic review. We did find it somewhat curious that there were no primary care physicians involved in the study considering the focus on referral of adults with OSA for surgical consideration. This type of referral does occur through primary care offices on many occasions.

Methodology is documented

Methodology is well documented with details about the Expert Taskforce, literature search, evidence review, data extraction, meta-analysis, and the GRADE process. The document contains clear figures and supplemental material that includes the Guideline Meta-Analyses and Summary of Findings Tables.

Summary:

The American Academy of Sleep Medicine Clinical Practice Guideline: Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation meets most of the criteria for endorsement by the AAO-HNSF. The only criteria not fully met at this time is the full disclosure of conflicts of interest. The guideline states that all relevant conflicts of interest are listed in the "Disclosures section"; however, we were unable to locate this section within the guideline. Once the final document is completed, if the AASM

is able to provide the full disclosures list, our Executive Committee of the Board of Directors will be able to consider endorsement in full.

This clinical practice guideline (CPG) provides great value as it is intended to replace a previously published 2010 American Academy of Sleep Medicine (AASM) guideline on the use of surgery to treat adults with obstructive sleep apnea (OSA), providing updated recommendations based on current evidence. Although PAP therapy is recognized as the most efficacious treatment for OSA, it may not be the best option for some patients. There are several scenarios where effectiveness of PAP therapy can be compromised. The AASM Expert Taskforce (TF) conducted a comprehensive systematic review and developed recommendations, that are based on recognizing the importance of patient-specific values and preferences, regarding discussion around the referral process in terms of treatment for OSA in three different scenarios:

- (1) Patients who are intolerant or unaccepting of PAP therapy
- (2) Patients who have persistent suboptimal PAP adherence due to pressure-related side effects
- (3) Patients with obvious anatomical variations potentially amenable to surgery as initial OSA treatment

Furthermore, the process used to develop the document is transparent and methodology is well documented.

Review by clinical sleep medicine experts in otolaryngology

This section represents a collation of the comments we receive from our clinical experts, the majority of which are sub-certified in sleep medicine. First, we will report general comments submitted by our reviewers and follow that with comments specific to each recommendation.

General Comments

Systematic Review

Page 2 “ Positive airway pressure (PAP) has remained first-line therapy for all severities of symptomatic OSA since its initial

*description as a treatment for OSA in 1981.⁸ **Extensive evidence** from randomized clinical trials has demonstrated a beneficial effect of PAP therapy on sleepiness, QOL, and blood pressure (BP)^{9, 10}; however, adherence to PAP therapy is difficult for many patients, with an overall reported non-adherence rate ranging from 20-40%.¹¹⁻¹⁴*

Extensive evidence for PAP is flawed by sham PAP blinding issue. There is mixed data for QOL and BP decrease is usually small with PAP.

“The AASM updated the original systematic review² and original practice parameters¹ in 2010. The review focused on individual surgical interventions and their available data such as UPPP, modified UPPP, other pharyngeal procedures, laser assisted uvulopalatoplasty, upper airway radiofrequency treatment, soft palatal implants, multi-level simultaneous surgeries, and multi-level phased surgeries “

It is important to note that the 2010 AASM review specifically **did not** analyze modern lateral wall and other advanced pharyngoplasty approaches but rather focused on “classic” UPPP and multilevel surgery. This limited generalizability of conclusions with respect to effectiveness of palato-pharyngoplasty on the AHI. This is important to note as SR/PP 2010 paper is still used to adversely affect insurance approval for sleep surgery today.

“None of the studies identified in our literature review reported data for perioperative death.”

Death is a major complication that would be cited in any surgical paper where complications are noted. There are numerous papers that cite complications in the systematic review.

Clinical Practice Guideline

“I feel very strongly that ALL patients with sleep apnea should be told there are multiple treatment options and should have the opportunity to seek a surgical or dental appliance opinion if they wish.”

“The 2010 guideline made recommendations for specific surgical procedures, but it did not address the critical question of when to consider surgical treatment options.”

It is important to note that the 2010 AASM review specifically did not analyze modern lateral wall and other advanced pharyngoplasty approaches but rather focused on “classic” UPPP and multilevel surgery. This limited generalizability of conclusions with respect to effectiveness of palato-pharyngoplasty on the AHI. This is important to note as SR/PP 2010 paper is still used to adversely affect insurance approval for sleep surgery today.

“Suboptimal PAP adherence” is not an accurate term. A patient with an AHI of 60 and LSAT of 70% using PAP for 3-4 hours may still be at major CV risk due to time PAP is not used and may be poorly treated, not “sub-optimally” treated. Perhaps use “low PAP utilization”? Optimal use is for 100% of sleep and few patients achieve that. *“Positive airway pressure (PAP) is recognized as the most efficacious treatment for OSA”*. This is only true for normalizing the respiratory parameters of OSA (ie AHI, ODI, LSAT) but not for clinical sequelae of OSA where surgery and oral appliance therapy effectiveness is similar.

Upper airway surgery usually treats a population that has failed prior treatments such as PAP. This population is **different** than all comers who present with OSA and is more difficult to treat. Although, the concept of “rescue” treatment is mentioned in recommendation #1, I would recommend that CPG would note the particularly challenging population that surgery addresses in the abstract. This would help combat potential bias by non-surgical sleep specialists against sleep surgery.

Comments related to specific PICO recommendations

PICO 1:

While clinical outcomes were assessed, the benefit for survival, major cardiovascular disease, depression and dementia outcomes were not assessed. These are much more important than effect on blood

pressure. There very large population observational studies to support benefit. These include:

- a. Weaver EM, Maynard C, Yueh B. Survival of veterans with sleep apnea: continuous positive airway pressure versus surgery. *Otolaryngol Head Neck Surg.* 2004 Jun;130(6):659-65
- b. Lee HM, Kim HY, Suh JD, Han KD, Kim JK, Lim YC, Hong SC, Cho JH. Uvulopalatopharyngoplasty reduces the incidence of cardiovascular complications caused by obstructive sleep apnea: results from the national insurance service survey 2007-2014. *Sleep Med.* 2018 May;45:11-16
- c. Cho JH, Suh JD, Han KD, Jung JH, Lee HM. Uvulopalatopharyngoplasty May Reduce the Incidence of Dementia Caused by Obstructive Sleep Apnea: National Insurance Service Survey 2007-2014. *J Clin Sleep Med.* 2018 Oct 15;14(10):1749-1755
- d. Cho JH, Suh JD, Han KD, Lee HM. Uvulopalatopharyngoplasty reduces the incidence of depression caused by obstructive sleep apnea. *Laryngoscope.* 2019 Apr;129(4):1005-1009.

It is also important to note in the CPG, under PICO 1, that RCTs of surgery are most often unethical and extremely difficult to perform. This needs to be included to clarify why “*overall quality of data was low*”.

We commend the extensive evidence review, but for purpose of the referral question, the patients’ *preference and presentation of options* is just as important. There are many patients who do not adapt to PAP well, utterly refuse PAP, and even would not see a doctor due to dislike of the concept of using PAP. Referral to a sleep surgeon is vital for an informed presentation of the benefits, risks and alternatives to sleep surgery which are *often not well understood by patients nor by sleep medicine specialists*. Often, after a discussion of surgery, the patient is encouraged to return to PAP or oral appliance therapy. Without a referral, the patient cannot make an informed decision. Thus, the referral question is not really a question.

PICO 3:

The question is somewhat problematic as it is focused on facilitating **PAP** adherence or lowering pressure level. The relevant question is

whether the patient's OSA is better treated after surgery, using PAP, oral appliance, positional therapy, or other means. Asking for better PAP outcome is problematic as it is very difficult psychologically to resume and succeed in a failed treatment once again. We think the question would be more relevant if it isn't limited to PAP.

PICO 4:

Statement 4 requires revision. First, using a negative makes the statement confusing. Negative statements are best avoided for the adult learner. Second, there is data to support referral for tonsillectomy as initial treatment in select groups of patients such as those that are non-obese and have significant tonsil hypertrophy. Research demonstrates that removal of tonsils in adults with tonsil hypertrophy results in significant improvement in OSA. In Senchak et al the AHI before surgery ranged from 5.4 to 56.4 events per hour. The mean AHI decreased from 18.0 to 3.2 events per hour after surgery, a reduction of 82%. The responder rate--with subjects achieving at least a 50% reduction of AHI to a value <15--was 94.7%. Following tonsillectomy, there were statistically significant reductions in median lowest saturation of oxygen level and Epworth Sleepiness Scale and Berlin scores. Other studies that have examined tonsillectomy outcomes in select adult patients with tonsillar hypertrophy have shown similar excellent outcomes. This is in stark contrast to tonsillectomy in patients with small tonsils in whom PAP should be recommended as the initial therapy.

*Otolaryngol Head Neck Surg. 2015 May;152(5):969-73. doi: 10.1177/0194599815575721. Epub 2015 Mar 27. The effect of tonsillectomy alone in adult obstructive sleep apnea. Senchak AJ1, McKinlay AJ2, Acevedo J3, Swain B3, Tiu MC4, Chen BS4, Robitschek J5, Ruhl DS6, Williams LL7, Camacho M6, Frey WC8, O'Connor PD

*Laryngoscope. 2016 Dec;126(12):2859-2862. doi: 10.1002/lary.26038. Epub 2016 Apr 23. Tonsillectomy in adults with obstructive sleep apnea. Holmlund T1, Franklin KA2, Levring Jäghagen E3, Lindkvist M4,5, Larsson T1, Sahlin C6, Berggren D1.

* Camacho M, Li D, Kawai M, Zet al. Tonsillectomy for adult obstructive sleep apnea: A systematic review and meta-analysis. *Laryngoscope*. 2016 Sep;126(9):2176-86. doi: 10.1002/lary.25931. Epub 2016 Mar 22. PMID: 27005314.

In the corresponding systematic review the authors note that “surgery as a first-line treatment results in a clinically significant reduction in AHI/RDI, sleepiness, snoring, BP, and ODI, and increase in LSAT in adults with OSA and major anatomical obstruction.” Furthermore, the conclude that “analyses of very limited evidence suggest that upper airway surgery does not result in a clinically significant increase in risk of serious persistent adverse events.” Despite this evidence reported during their own literature review, the CPG still failed to recommend tonsillectomy as initial therapy.

It appears that the main reason that the authors recommend PAP over tonsillectomy is due to surgical risk. The following statement that appears in the discussion regarding the fourth statement is concerning. “The TF judged that the potential benefits of surgical referral discussion in patients with major anatomical obstruction do not exceed the potential benefits of an initial PAP trial for OSA in the absence of other medical conditions affecting upper airway patency.” The majority of panel members were not surgeons and thus there is inherent bias in this decision/statement. If a group of sleep surgeons were asked to discuss this statement, there would be a much different consensus. Thus, as this statement is NOT evidence based it should be removed. Surgical risk for tonsillectomy is low. There are no head to head studies comparing these two interventions on which to base this risk assessment. **In children with OSA, tonsillectomy is the primary therapy as opposed to PAP therapy. Why is tonsillectomy okay for children but too risky for adults?**

It is not appropriate to lump craniofacial abnormalities into the same statement as tonsillar hypertrophy. The grouping of tonsillar hypertrophy with craniofacial anomalies display a distinct lack of appreciation for the various phenotypes of OSA and how they may ultimately affect sleep outcomes. Surgical outcomes between craniofacial surgery and tonsillectomy may not be the same and surgery to correct craniofacial abnormalities have a much higher

morbidity than tonsillectomy. For these reasons, the grouping itself is not valid. The surgery should be separated into two separate PICO questions.

Additionally, patients with a major anatomical abnormality (tonsillar hypertrophy; craniofacial abnormality; nasal obstruction) require a surgical consultation. The sleep physician would be guilty of withholding information from a patient if a major anatomic abnormality is observed and not discussed with the patient. Surgical consultation does not preclude the initiation of therapy with PAP, however it should be considered in conjunction with PAP. This is especially true with maxillofacial surgery due to potential delays in therapy due to surgeon availability, dental billing, orthodontia, etc. Therefore, a patient is best served by a multidisciplinary, team-based approach by receiving information up front which improves patient knowledge of their disorder and allows for treatment and financial planning.

Major anatomic abnormality may be a sign of a more severe underlying disease process that presents with sleep-disordered breathing. For instance, 3 to 4+ tonsils, can be commonly seen with HPV-associated tonsil cancer or lymphoma, not to mention chronic tonsillitis, allergy, and laryngopharyngeal reflux disorder. Craniofacial anomaly may be associated with syndromic disorders; nasal blockage; malocclusion; TMJ disorder; and cosmetic retrognathia. Surgical consultation is recommended unless the sleep physician is prepared to fully assess for these underlying disorders. Likewise, a sleep surgeon would be expected to refer an OSA patient to pulmonary sleep physician if there was a history consistent with narcolepsy, restless leg, COPD, etc.

Major anatomic abnormality may increase the rate of PAP failure or unacceptance due to high pressures; poor mask fit; or nasal blockage.

The Recommendation does not seem to address the potential benefit of Tonsillectomy alone, especially in patients with 3 to 4+ tonsils. This is especially true of young adults (age < 30 years) with tonsillar hypertrophy and milder forms of OSA where the long-term effectiveness of PAP is unclear. Tonsillectomy should be considered

as first-line therapy in patients with 4+ tonsils. Please see the following paper:

Camacho M, et al. Tonsillectomy for Adult Obstructive Sleep Apnea: A Systematic Review and Meta-analysis. *Laryngoscope* 2016; 126: 2176-2186.

This paper reviews a number of studies not included in your analysis. This paper found that tonsillectomy alone resulted in cure (mean AHI 2.4) in 84% of patients with AHI<30. Therefore, a risk of your recommendation is that patients with potentially curable OSA will instead be treated with a chronic therapy with high rates of long-term non-adherence. If these patients are not aware that tonsillectomy would be of benefit, they may stop PAP and stop seeing their sleep physician which is commonly the case. The main risk of tonsillectomy short-term is bleeding in 1-2% of cases which is less worrisome in adults than children. Long-term risks of dysphagia, globus, or scarring are very low compared to more comprehensive forms of palatal surgery.

Studies analyzed for this question should not be of only treatment naïve patients, as it does not affect the recommendation rationale. Thus, include any studies performed in patients who tried PAP with tonsil hypertrophy such as:

- a. Rotenberg BW, Theriault J, Gottesman S. Redefining the timing of surgery for obstructive sleep apnea in anatomically favorable patients. *Laryngoscope*. 2014 Sep;124 Suppl 4: S1-9

Patient preference has not been given sufficient consideration. Patient preference may override the risks mentioned. If there is a large effect size or high probability of success, many if patients would opt for a single surgical procedure, especially tonsillectomy, rather than the prospect of life-long PAP therapy.

The group should consider revising the 4th statement as follows, **“In healthy adults with OSA and tonsil hypertrophy, clinicians should discuss both PAP therapy and referral to a sleep surgeon for consideration of surgery as initial treatment options with the ultimate management strategy based on patient preference.”**

This would be similar to current guideline recommendations for the

use of PAP therapy OR mandibular advancement devices for adults with non-severe OSA. One could argue that the risks of oral appliance which can include malocclusion and jaw pain are similar to those of tonsillectomy in the appropriately selected patient.

Thank you very much for considering our comments related to your proposed guideline “Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation”. If there are any questions, please contact us directly.

Sincerely,



James C. Denneny III, MD
Executive Director and CEO