

SPECIAL ARTICLES

## Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline

David Kent, MD<sup>1</sup>; Jeffrey Stanley, MD<sup>2</sup>; R. Nisha Aurora, MD, MHS<sup>3</sup>; Corinna Levine, MD, MPH<sup>4</sup>; Daniel J. Gottlieb, MD, MPH<sup>5</sup>; Matthew D. Spann, MD<sup>1</sup>; Carlos A. Torre, MD<sup>4</sup>; Katherine Green, MD, MS<sup>6</sup>; Christopher G. Harrod, MS<sup>7</sup>

<sup>1</sup>Vanderbilt University Medical Center, Nashville, Tennessee; <sup>2</sup>University of Michigan, Ann Arbor, Michigan; <sup>3</sup>Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey; <sup>4</sup>University of Miami, Miller School of Medicine, Miami, Florida; <sup>5</sup>VA Boston Healthcare System, Brigham and Women's Hospital, Boston, Massachusetts; <sup>6</sup>University of Colorado, Aurora, Colorado; <sup>7</sup>American Academy of Sleep Medicine, Darien, Illinois

**Introduction:** This guideline establishes clinical practice recommendations for referring adults with obstructive sleep apnea (OSA) for surgical consultation.

**Methods:** The American Academy of Sleep Medicine (AASM) commissioned a task force of experts in sleep medicine, otolaryngology, and bariatric surgery to develop recommendations and assign strengths based on a systematic review of the literature and an assessment of the evidence using the GRADE process. The task force evaluated the relevant literature and the quality of evidence, the balance of benefits and harms, patient values and preferences, and resource use considerations that support the recommendations. The AASM Board of Directors approved the final recommendations.

**Recommendations:** The following recommendations are intended as a guide for clinicians who treat adults with OSA. Each recommendation statement is assigned a strength ("Strong" or "Conditional"). A "Strong" recommendation (ie, "We recommend...") is one that clinicians should follow under most circumstances. A "Conditional" recommendation is one that requires that the clinician use clinical knowledge and experience and strongly consider the patient's values and preferences to determine the best course of action. (1) We recommend that clinicians discuss referral to a sleep surgeon with adults with OSA and BMI <40 kg/m<sup>2</sup> who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options (STRONG). (2) We recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class II/III, BMI ≥35 kg/m<sup>2</sup>) who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options (STRONG). (3) We suggest that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI <40 kg/m<sup>2</sup>, and persistent inadequate PAP adherence due to pressure-related side effects as part of a patient-oriented discussion of adjunctive or alternative treatment options (CONDITIONAL). (4) We suggest that clinicians recommend PAP as initial therapy for adults with OSA and a major upper airway anatomic abnormality prior to consideration of referral for upper airway surgery (CONDITIONAL).

**Keywords:** upper airway surgery, hypoglossal nerve stimulation, bariatric surgery, maxillomandibular advancement, obstructive sleep apnea

**Citation:** Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2021;17(12):2499–2505.

### INTRODUCTION

This clinical practice guideline is intended to replace the previously published 2010 American Academy of Sleep Medicine (AASM) guideline on the use of surgery to treat adults with obstructive sleep apnea (OSA)<sup>1</sup> and reflects the current recommendations of the AASM. Positive airway pressure (PAP) is well recognized as the most *efficacious* treatment for OSA, but therapy *effectiveness* may be compromised when patients are unable to sufficiently adhere to therapy or obtain adequate benefit. For some patients struggling with PAP, surgery may therefore be a less efficacious yet ultimately a more effective treatment option. The 2010 guideline made recommendations for specific surgical procedures, but it did not address the critical question of when to consider surgical treatment options.<sup>1</sup> The current guideline seeks to recognize clinical scenarios where such compromises should be discussed and to provide a framework for explicitly addressing the role of patient-specific values and preferences in the creation of a customized treatment plan evaluating the risks, benefits, costs, and side effects associated with various medical and surgical therapies.

This guideline, in conjunction with the accompanying systematic review,<sup>2</sup> provides a comprehensive update of the available evidence and is designed to provide recommendations for when health care providers treating OSA should discuss referral for upper airway or bariatric surgery evaluation with adult patients with OSA. It intentionally does not provide recommendations for individual surgical procedures and instead focuses on the body of evidence surrounding surgery as a treatment option in the setting of residual or untreated OSA. It informs clinical care by considering specific, commonly encountered clinical scenarios in which consideration of surgery may provide patient benefit, acknowledging that the tools and knowledge base needed for comprehensive anatomic evaluation and patient counseling regarding the surgical experience are outside the practice boundaries of most health care providers. Procedural selection is a complex decision requiring an informed discussion of risks and benefits surrounding anatomically appropriate options that incorporates patient-specific values and preferences. Collaborative communication about patient care between a consulting surgeon and a

referring health care provider, leveraging each one's areas of expertise, is the management pathway most likely to yield satisfactory outcomes.

This guideline utilizes available evidence to support recommendations regarding discussion of referral in the following scenarios:

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

The treatment of adults with OSA should be based on a diagnosis of OSA established using objective testing performed in conjunction with a comprehensive sleep evaluation. For this guideline, the terminology “discuss referral” implies a discussion between the patient and health care provider regarding the option of surgical consultation as part of a comprehensive discussion of alternative treatment options to PAP. Under ideal circumstances, patients with inadequate PAP utilization will have had an opportunity to consult with a sleep medicine professional to address barriers to adherence, although access to such resources may be limited in some areas.<sup>3</sup> A threshold for adequate PAP adherence will vary between patients depending on their individual underlying medical history, symptomatology, disease severity, and response to PAP, and should be part of the discussion between the health care provider and patient. “Sleep surgeon” refers to an otolaryngologist or oral and maxillofacial surgeon with training and expertise in upper airway surgery who has an appropriate understanding of sleep medicine and modern surgical techniques for the treatment of OSA. If the patient elects for referral, the standard surgical consultation includes a detailed anatomic assessment for surgical treatment occasionally using tools unavailable to the average health care provider, such as flexible fiber-optic laryngoscopy. A discussion of the individual's expected risks and benefits of each appropriate treatment option is part of the standard informed consent process with the surgeon, including the risk of residual OSA. Following the principle of *primum non nocere* (“First, do no harm”), it is expected that surgery proceed only once the surgeon and patient have mutually agreed upon an acceptable risk profile. Inherent to this evaluation is the understanding that some referred patients will not be appropriate for surgical interventions and are expected to be counseled as such by surgical colleagues. It is additionally understood that many patients will ultimately elect against surgical therapy after an informed discussion with a surgeon. These individuals should be referred back to the health care provider for further OSA management. All patients should receive follow-up care to re-evaluate OSA symptoms; residual sleep-related symptoms, including residual sleep-disordered breathing, should be evaluated and addressed.

## METHODS

The AASM commissioned a task force (TF) of experts in sleep medicine, otolaryngology, and bariatric surgery to develop this

guideline and the supporting systematic review. Members of the TF were 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 these documents. In accordance with the AASM's conflicts of interest policy, 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. All relevant conflicts of interest are listed in the Disclosures section.

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. This review was designed to determine if surgical therapies for OSA are effective for improving outcomes of interest when analyzed collectively, which will inform recommendations for when health care providers treating OSA (subsequently referred to as “sleep clinicians” in this document) should discuss referral for upper airway or bariatric surgery evaluation with adults with OSA. Surgical procedures included pharyngeal soft tissue modifications, skeletal modification, and upper airway stimulation, as described further in the accompanying systematic review. Meta-analyses were performed on outcomes of interest, when possible, for each PICO question. Patients unaccepting of PAP were considered untreated for the purpose of these analyses. Therefore, comparisons of surgery to no treatment and/or assessment of efficacy before and after surgery to treat OSA in adult patients were performed. The clinical practice recommendations were then developed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process.<sup>4</sup> The TF assessed the following 4 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. Details of these assessments can be found in the accompanying systematic review.<sup>2</sup> Additional information is provided in the form of “Remarks” immediately following the recommendation statements, when deemed necessary by the TF. Remarks are based on the evidence evaluated during the systematic review and are intended to provide context for the recommendations and to guide clinicians in the implementation of the recommendations in daily practice.

A draft of the guideline and systematic review was made available for public comment for a 4-week period on the AASM website. The TF took into consideration all the comments received and made decisions about whether to revise the draft based on the comments. The revised guideline and systematic review were submitted to the AASM Board of Directors for subsequent approval.

## RECOMMENDATIONS

The recommendations in this guideline define principles of practice that should meet the needs of most patients in most situations. Each recommendation statement was assigned a strength

(“Strong” or “Conditional”). A “Strong” recommendation is one that clinicians should follow for almost all patients (ie, something that might qualify as a quality measure). A “Conditional” recommendation reflects a lower degree of certainty in the appropriateness of the patient care strategy for all patients. It requires that the clinician use clinical knowledge and expertise and strongly considers the individual patient’s values and preferences to determine the best course of action. The ultimate judgment regarding any specific care must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available treatment options, and resources. The AASM expects this guideline to have an impact on professional behavior, patient outcomes, and—possibly—health care costs. This clinical practice guideline reflects the state of knowledge at the time of publication and will be reviewed and updated as new information becomes available.

The following clinical practice recommendations are based on a systematic review and evaluation of evidence using the GRADE process. The implications of the strength of recommendations for guideline users are summarized in [Table 1](#). Remarks are provided to guide clinicians in the implementation of these recommendations.

### Surgical treatment of patients who are intolerant or unaccepting of PAP

**Recommendation 1: We recommend that clinicians discuss referral to a sleep surgeon with adults with OSA and BMI < 40 kg/m<sup>2</sup> who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options (STRONG).**

*Remarks: The recommendation to discuss referral is not required to result in referral and does not preclude patient consideration of other viable alternative treatment options (eg, mandibular advancement device, positional therapy, lifestyle changes). The strong recommendation to discuss surgical referral with patients with a BMI < 40 kg/m<sup>2</sup> is not a recommendation against (and does not preclude) discussion of surgical referral with patients with a BMI ≥ 40 kg/m<sup>2</sup> if the health care provider deems it an appropriate management discussion point. For patients within the BMI range of 35–40 kg/m<sup>2</sup>, discussion regarding a referral to both sleep and bariatric surgeons (as per Recommendation 2) to discuss management options is appropriate.*

The TF made a strong recommendation in favor of discussing surgical referral based on a large body of low-quality evidence from 4 randomized controlled trials (RCTs) and 239 observational

studies showing clinically meaningful and beneficial differences in nearly all critical outcomes, and the benefits of discussing referral over the harms of no treatment.

The TF investigated the use of upper airway surgery as rescue therapy for adults with OSA who were intolerant or unaccepting of positive airway pressure (PAP) to improve 1 or more of the following critical outcomes: excessive sleepiness, sleep quality, quality of life (QOL), snoring, blood pressure (BP), apnea-hypopnea index (AHI), and respiratory disturbance index (RDI). The TF also considered the risks of perioperative death and permanent dysphagia as critical outcomes for decision-making. Meta-analyses demonstrated a clinically significant reduction in excessive sleepiness, snoring, BP, and AHI/RDI, and a clinically significant improvement in sleep-related and general QOL. The results of the meta-analyses also demonstrated no clinically significant risk of permanent dysphagia. The incidence of perioperative death was not reported in the studies.

The overall quality of evidence was low due to imprecision and risk of bias associated with observational studies. The potential benefits of upper airway surgery as a rescue therapy include a reduction in excessive sleepiness, snoring, BP, and AHI/RDI, and an improvement in QOL in patients unaccepting of PAP therapy. Benefits demonstrated in the literature are limited to patients considered appropriate for surgery by the treating surgeon and may not be representative of all patients with OSA. The potential harms of upper airway surgery include short-term discomfort that is expected during postoperative recovery and is discussed during the preoperative informed consent process between the surgeon and patient. Additionally, potential persistent long-term side effects have been reported including dysphagia, taste alteration, mandibular paresthesia, perceived worsening of facial appearance, aspiration, hemorrhage, and globus pharyngeus, but the incidence of these is low. Surgery carries inherent risks, but based on their combined clinical expertise and the substantial effects of surgery on objective and subjective measures of disease, the TF judged that the potential benefits of a discussion regarding referral to a sleep surgeon with patients unaccepting of PAP therapy outweigh the potential harms of untreated OSA. The TF observed that the balance of risks vs benefits for upper airway surgery is highly dependent upon an individual patient’s OSA severity, symptoms, medical comorbidities, and selected surgical therapy but noted that a discussion of individualized risks and benefits is a standard component of the preoperative informed consent process. There are insufficient data to assess differences in resource requirements for surgical referral vs no treatment. Because acceptability of surgical interventions varies and there is little harm in discussing a referral, based on their combined

**Table 1**—Implications of strong and conditional recommendations for users of AASM clinical practice guidelines.

<b>Strong recommendation</b> “We recommend ...”	Almost all patients should receive the recommended course of action. Adherence to this recommendation could be used as a quality criterion or performance indicator.
<b>Conditional recommendation</b> “We suggest ...”	Most patients should receive the suggested course of action; however, different choices may be appropriate for different patients. The clinician must help each patient determine if the suggested course of action is clinically appropriate and consistent with his or her values and preferences.

The ultimate judgment regarding the suitability of any specific recommendation must be made by the clinician and patient.

clinical expertise the TF judged that most patients would generally be accepting of a discussion regarding referral. The choice to pursue referral is expected to vary between patients based on personal values, beliefs, and expectations for recovery time or pain with surgery.

## Surgical treatment of patients with obesity with bariatric surgery

**Recommendation 2: We recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class II/III, BMI  $\geq$  35) who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options (STRONG).**

*Remarks: The recommendation to discuss referral is not required to result in referral and does not preclude patient consideration of medical weight loss strategies or other viable alternative treatment options for OSA. For patients within the BMI range of 35–40 kg/m<sup>2</sup>, discussion regarding a referral to both sleep and bariatric surgeons (as per Recommendations 1 and 3) to discuss management options is appropriate. The strong recommendation to discuss surgical referral with patients with OSA, obesity, and PAP intolerance or unacceptance is not a recommendation against (and does not preclude) discussion of surgical referral with patients with OSA, obesity, and adequate PAP use if the health care provider deems it an appropriate management discussion point. Other organizations, such as the National Heart, Lung, and Blood Institute, recommend consideration of bariatric surgery for individuals suffering from obesity (class II/III, BMI  $\geq$  35 kg/m<sup>2</sup>) and OSA, regardless of PAP adherence status.<sup>5</sup>*

The TF made a strong recommendation in favor of bariatric surgery referral based on moderate-quality evidence from 2 RCTs and 28 observational studies that showed clinically meaningful improvements in several critical outcomes, and the benefits of discussing referral over the harms of no treatment.

The TF investigated the use of bariatric surgery to improve 1 or more of the following critical outcomes: BP, QOL, sleep quality, OSA severity, and excessive sleepiness. The TF also considered the risk of perioperative death as a critical outcome for decision-making, although the risk of other serious persistent adverse events and motor vehicle accidents was also reviewed. The TF identified 2 RCTs and 28 pre- vs postsurgical treatment observational studies comparing the use of bariatric surgery vs no treatment that reported on 1 or more of the critical outcomes. Meta-analyses demonstrated a clinically significant improvement in all critical outcomes. None of the studies reported on the risk of perioperative death and motor vehicle accidents.

The overall quality of evidence was moderate due to large effect sizes in the observational studies and due to imprecision in the RCTs. The benefits of bariatric surgery in patients with obesity and OSA include a reduction in AHI/RDI, BP, oxygen desaturation index (ODI), excessive sleepiness, BMI, snoring, and optimal PAP level, and an increase in the minimum oxygen saturation during sleep (LSAT). Benefits demonstrated in literature are limited to patients considered appropriate for bariatric surgery by the treating surgeon and may not be representative of all

patients with obesity and OSA. While the benefits of bariatric surgery are clinically significant, the surgeon needs to consider factors that would make a patient at higher risk for surgical intervention, which are not captured by this analysis. Selection bias may be present in the observed outcomes as adherence with lifestyle changes is required of patients undergoing bariatric surgery. It is difficult to determine whether the effects of bariatric surgery on BP and the Epworth Sleepiness Scale (ESS) are directly attributed to weight loss from surgery or the lowering of AHI. Potential harms of bariatric surgery include short-term discomfort that is expected during postoperative recovery and is discussed during the preoperative informed consent process between the surgeon and patient. Additionally, iron malabsorption, gastric ulcer, vitamin deficiency, bowel obstruction or leak, gastrointestinal reflux disorder, and gastric band slippage have been reported but the incidence of these is low. Bariatric surgery carries inherent risks but based on their combined clinical expertise and the substantial effects of bariatric surgery on objective and subjective measures of disease, the TF judged that the potential benefits of a discussion regarding referral to a bariatric surgeon with patients who are intolerant or unaccepting of PAP therapy outweigh the potential harms of untreated OSA. The TF observed that the balance of risks vs benefits for bariatric surgery is highly dependent upon an individual patient's OSA severity, symptoms, medical comorbidities, and selected surgical therapy but noted that a discussion of individualized risks and benefits is a standard component of the preoperative informed consent process. There is insufficient evidence in the literature to compare the costs of bariatric surgery to nutritional care or untreated OSA. Because acceptability of surgical interventions varies and there is little harm in discussing referral, based on their combined clinical expertise the TF judged that most patients would generally be accepting of a discussion regarding referral. The choice to pursue referral is expected to vary between patients based on personal values, beliefs, and expectations for recovery time or pain with surgery.

## Surgical treatment of patients to facilitate PAP use

**Recommendation 3: We suggest that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI < 40 kg/m<sup>2</sup>, and persistent inadequate PAP adherence due to pressure-related side effects as part of a patient-oriented discussion of adjunctive or alternative treatment options (CONDITIONAL).**

*Remarks: Available data suggest that upper airway surgery has a moderate effect in reducing minimum therapeutic PAP level and increasing PAP adherence. The decision to offer referral should be based on the clinician's judgment of a patient's current PAP adherence and tolerance as well as the patient's treatment preferences. Low degrees of nonadherence or minimal side effects may preclude consideration of a referral. Referral may be informed by the presence of other surgically treatable conditions that contribute to upper airway obstruction (eg, persistent nasal obstruction, chronic tonsillitis, malocclusion). For patients within the BMI range of 35–40 kg/m<sup>2</sup>, discussion regarding a referral to both sleep and bariatric surgeons (as per Recommendation 2) to discuss management options may be appropriate. The conditional recommendation to*

*discuss surgical referral with patients with a BMI < 40 kg/m<sup>2</sup> is not a recommendation against (and does not preclude) discussion of surgical referral with patients with a BMI ≥ 40 kg/m<sup>2</sup> if the health care provider deems it an appropriate management discussion point, especially as some surgical therapies that reduce minimum therapeutic PAP level (eg, nasal surgery) are not anticipated to be impacted by BMI.*

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 inadequate use that likely vary depending on the patient's degree of use.

The TF investigated the use of surgery as an adjunctive procedure to facilitate the use of PAP by improving 1 or more of the following critical outcomes: optimal PAP level, excessive sleepiness, sleep quality, PAP adherence, snoring, and sleep-related QOL. The TF also considered the risks of perioperative death and permanent dysphagia as critical outcomes for decision-making. The TF identified 7 observational studies comparing pre- vs postsurgical treatment comparing 1 or more of the critical outcomes. Meta-analyses of data extracted from these studies were used to determine whether changes in these outcomes were clinically significant. The results of the meta-analyses demonstrated a clinically significant, moderate reduction in optimal PAP level and a clinically significant, moderate improvement in PAP adherence with surgery. The incidence of perioperative death and permanent dysphagia was not reported in these studies. None of these studies reported on either QOL or snoring.

The overall quality of evidence was very low due to imprecision and risk of bias associated with observational studies. The potential benefits of upper airway surgery as an adjunctive procedure to facilitate effective PAP therapy include a reduction in optimal PAP level, excessive sleepiness, and AHI/RDI, as well as an increase in PAP adherence and lowest oxygen saturation (LSAT). Benefits demonstrated in the literature are limited to patients considered appropriate for surgery by the treating surgeon and may not be representative of all patients with PAP-related side effects or inadequate use. The potential harms of upper airway surgery as an adjunctive procedure include short-term discomfort that is expected during postoperative recovery and is discussed during the preoperative informed consent process between the surgeon and patient. Surgery carries inherent risks but based on their combined clinical experience and the moderate effects of surgery on PAP pressure requirements and adherence, the TF judged that the potential benefits of a discussion regarding referral to a sleep surgeon for consideration of surgery as an adjunctive procedure to facilitate PAP use may, in some patients, outweigh the potential harms of inadequate PAP-related side effects and adherence depending on their severity. If referral is discussed, the TF observed that the balance of risks vs benefits for upper airway surgery is highly dependent upon an individual patient's OSA severity, symptoms, medical comorbidities, and selected surgical therapy but noted that a discussion of individualized risks and benefits is a standard component of the preoperative informed consent process. There are insufficient data to

assess differences in resource requirements for surgical referral vs inadequate PAP use. Because acceptability of surgical interventions varies and there is little harm in offering referral, based on their combined clinical expertise the TF judged that most patients would generally be accepting of a discussion regarding referral but that its clinical utility may be more limited in patients who are partially PAP adherent as opposed to those who are completely untreated. The choice to pursue referral is expected to vary between patients based on personal values, beliefs, and expectations for recovery time or pain with surgery.

### **Surgical treatment as *initial* therapy in patients with a major upper airway anatomical abnormality**

**Recommendation 4: We suggest that clinicians recommend PAP as initial therapy for adults with OSA and a major upper airway anatomic abnormality prior to consideration of referral for upper airway surgery (CONDITIONAL).**

*Remarks: Major upper airway anatomic abnormalities considered by the task force included tonsillar hypertrophy and maxillo-mandibular abnormalities. While data suggest a clinically significant benefit from surgical intervention in these populations, PAP should be recommended as initial treatment as it carries minimal risk relative to surgery. The decision to discuss referral for initial surgical therapy should be based on the clinician's judgment of the patient's medical history as consideration of initial surgical intervention may be justified in the setting of other surgical indications affecting upper airway patency (eg, chronic tonsillitis, malocclusion, abnormal lesion, or growth). The conditional recommendation does not preclude discussion of surgical referral prior to the initial PAP trial if the health care provider deems it an appropriate management discussion point. Furthermore, this recommendation is for the initial treatment of OSA and does not address management of patients who have previously trialed PAP, as detailed in Recommendations 1–3.*

The TF made a conditional recommendation against surgical referral as initial treatment for OSA based on low-quality evidence from 2 RCTs and 15 observational studies, 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.

The TF investigated the use of surgery to improve 1 or more of the following critical outcomes: AHI/RDI, excessive sleepiness, sleep quality, LSAT, sleep-related QOL, snoring, and oxygen desaturation. The TF also considered the risks of perioperative death and permanent dysphagia as critical outcomes for decision-making, although the risk of other serious persistent adverse events and motor vehicle accidents was also reviewed. The TF identified 2 RCTs and 15 pre- vs postsurgical treatment observational studies comparing the use of surgery vs no treatment that reported on 1 or more of the critical outcomes. Studies including patients with prior PAP treatment were not excluded from analysis as prior PAP exposure was not anticipated to reasonably affect response to anatomy-altering surgery. Meta-analyses demonstrated a clinically significant reduction in AHI/RDI, excessive sleepiness, snoring, and oxygen desaturation

index (ODI) and a clinically significant improvement in the LSAT with surgery. There was no evidence to assess improvement in sleep-related QOL. The results of the meta-analyses also demonstrated no clinically significant risk of permanent dysphagia. The incidence of perioperative death was not reported in the studies. None of the studies reported on the risk of motor vehicle accidents.

The overall quality of evidence was low due to imprecision and risk of bias associated with the observational studies. The potential benefits of upper airway surgery as an initial therapy include a reduction in excessive sleepiness, snoring, systolic blood pressure, AHI/RDI, and ODI and an increase in LSAT. Benefits demonstrated in the literature are limited to patients with a major anatomical obstruction considered appropriate for surgery by the treating surgeon and may not be representative of all patients with OSA with similar anatomic findings. The potential harms of surgery include short-term discomfort that is expected during postoperative recovery and is discussed during the preoperative informed consent process. Additionally, potential persistent long-term side effects have been reported including dysphagia, taste alteration, mandibular paresthesia, aspiration, hemorrhage, and globus pharyngeus, but the incidence of these is low. Given that even low surgical risks are elevated as compared to the minimal risk of initial PAP therapy, the balance of benefits to harms favors PAP therapy as initial treatment over discussion of referral for surgical evaluation. Nevertheless, the presence of major anatomical obstruction may tip the balance in favor of surgical referral depending on a patient's upper airway medical history. Despite the low risk of surgical referral discussion, there is no harm in an initial trial of PAP therapy if other surgical indications are not present. Given that the intent of discussion of sleep surgery referral in this clinical scenario is consideration of upper airway surgery prior to any PAP trial, based on their combined clinical expertise, 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. Based on their combined clinical expertise, the TF judged that most patients would generally be accepting of a discussion regarding referral for surgical evaluation as there is little harm in the act of offering. Patient acceptance of surgical interventions will vary, and the clinical utility of referral may be more limited in patients who are partially PAP adherent. The choice to pursue referral is expected to vary between patients based on personal values, beliefs, and expectations for recovery time or pain with surgery.

## DISCUSSION

Positive airway pressure (PAP) is recognized as the most efficacious treatment for the majority of OSA outcomes if worn consistently, but a growing body of literature confirms that a substantial portion of patients do not accept or tolerate it as a treatment option.<sup>6-9</sup> Poor adherence to PAP therapy likely compromises patients' ability to derive all potential subjective and objective benefits. A variety of alternatives to PAP for OSA treatment exist, including surgical interventions. New diagnostic tools and improved surgical

techniques have proliferated over the last 10–15 years as surgeons have developed more effective and less morbid procedures better tailored to the individual patient's anatomy.

Surgical treatments for OSA demonstrate large reductions in objective disease burden and patient-centered outcomes as compared to no treatment. Patients who are intolerant or unaccepting of PAP therapy should be informed that surgical management is one of several viable alternative treatment options. The recommendation to discuss referral does not preclude a patient-oriented discussion of other viable alternative treatment options (eg, mandibular advancement device, positional therapy, behavioral changes) that may yield favorable benefit over no further treatment. The decision to undergo surgical treatment for OSA is a personal one, and the risk-benefit ratio will vary given an individual's own values, personal preferences, anatomy, and medical history. Health care providers are encouraged to consider these factors during a discussion regarding referral, understanding that as the field of surgery continues to rapidly evolve, the surgeon may ultimately have the most current and comprehensive understanding of the evidence surrounding a patient's individualized surgical indications, risks, and potential outcomes. A patient-tailored discussion of appropriate surgical risks and benefits is a standard component of the informed consent process conducted by the surgeon so that a patient may make an informed decision. A discussion of the short-term and long-term side effects of surgery are part of that conversation. A potential limitation regarding this management option is access to a surgeon familiar with the variety of modern surgical techniques for OSA. Sleep surgeons have a responsibility to remain current on new discoveries underlying the pathophysiologic mechanisms of OSA, as these findings will likely inform an individual patient's surgical candidacy in the future. Close collaboration with referring sleep medicine colleagues will help foster multidisciplinary educational opportunities. Surgeons interested in treating this patient population should have an appropriate understanding of sleep medicine and modern surgical techniques.

Upper airway surgery may have a moderate effect on decreasing therapeutic PAP requirements (ie, optimal PAP level) and increasing PAP adherence although this estimate is based on a small number of uncontrolled observational studies. Considering the very low risk of surgical referral discussion and the informed consent process, clinicians should consider discussing referral to a surgeon with patients struggling with PAP tolerance and adherence who have not responded adequately to previously attempted nonsurgical treatments.

Some patients are noted to have major anatomic obstruction on initial evaluation, such as tonsillar hypertrophy or significant maxillomandibular deficiencies. Despite the large effect size seen with the appropriately indicated surgery, the high efficacy, low cost, and minimal harm of PAP therapy justify an initial trial prior to consideration of surgical referral. It is important to remember that additional patient history (eg, chronic tonsillitis, malocclusion) may justify discussion of a surgical referral prior to an initial medical therapy trial. Patients with major anatomic obstruction who refuse PAP therapy should discuss referral for surgical evaluation with their health care provider.

Weight loss can have a substantial impact on OSA disease burden in obese patients. Bariatric surgery is the most effective therapy for weight loss in patients with class II or III obesity.

Discussion regarding bariatric surgery referral should be considered in this population, which may be considered in parallel with medical weight loss options as well as other OSA treatments. During the consultation, the surgeon will discuss lifestyle changes necessary to be successful with bariatric surgery. Ultimately, patients will have to agree to major lifestyle changes to be successful with bariatric surgery, and some are not ready for these changes. Although not specifically included in this review, available data suggest bariatric surgery can reduce positive airway pressure requirements and improve PAP adherence. Referral may be limited by proximity to a bariatric surgery center, and varying insurance coverages may impact patient access to this treatment option. A growing evidence base from patients outside the US with class I obesity and access to bariatric surgery suggests significant potential health benefits in this population as well. The potential for surgical weight loss benefits in patients with OSA and body mass index less than 35 kg/m<sup>2</sup> will require further evaluation in the coming years.

## REFERENCES

1. Aurora RN, Casey KR, Kristo D, et al. American Academy of Sleep Medicine. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep*. 2010;33(10):1408–1413.
2. Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. 2021;17(12):2507–2531.
3. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2019;15(2):335–343.
4. Morgenthaler TI, Deriy L, Heald JL, Thomas SM. The evolution of the AASM clinical practice guidelines: another step forward. *J Clin Sleep Med*. 2016;12(1):129–135.
5. National Institutes of Health; National Heart, Lung, and Blood Institute; North American Association for the Study of Obesity. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. NIH Publication No. 00-4084. [https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd\\_c.pdf](https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd_c.pdf). Accessed August 17, 2021.
6. Cistulli PA, Armitstead J, Pepin JL, et al. Short-term CPAP adherence in obstructive sleep apnea: a big data analysis using real world data. *Sleep Med*. 2019;59:114–116.

7. Jacobsen AR, Eriksen F, Hansen RW, et al. Determinants for adherence to continuous positive airway pressure therapy in obstructive sleep apnea. *PLoS One*. 2017;12(12):e0189614.
8. Kohler M, Smith D, Tippet V, Stradling JR. Predictors of long-term compliance with continuous positive airway pressure. *Thorax*. 2010;65(9):829–832.
9. Virk JS, Kotecha B. When continuous positive airway pressure (CPAP) fails. *J Thorac Dis*. 2016;8(10):E1112–E1121.

## ACKNOWLEDGMENTS

The task force acknowledges the early contributions of Edward Weaver, MD, MPH (University of Washington Medical Center, Seattle, WA), who assisted with the development of the PICO questions and project charter. The task force also thanks Ofer Jacobowitz, MD, PhD (Icahn School of Medicine at Mount Sinai, New York, NY); Eric J. Kezirian, MD, MPH (Keck School of Medicine of University of Southern California, Los Angeles, CA); Reena Mehra, MD, MS (Cleveland Clinic, Cleveland, OH); and Sanjay R. Patel, MD (University of Pittsburgh Medical Center, Pittsburgh, PA) for serving as external reviewers of the document and providing valuable feedback.

This guideline was endorsed by the American Society for Metabolic and Bariatric Surgery and the Alliance of Sleep Apnea Partners. The American Academy of Otolaryngology–Head and Neck Surgery affirmed the value of this guideline.

## SUBMISSION & CORRESPONDENCE INFORMATION

**Submitted for publication August 3, 2021**

**Submitted in final revised August 3, 2021**

**Accepted for publication August 3, 2021**

Address correspondence to: David Kent, MD, Department of Otolaryngology, Vanderbilt University, 3601 21st Avenue South, Nashville, TN 37232;

Email: davidkentmd@gmail.com

## DISCLOSURE STATEMENT

The development of this paper was funded by the American Academy of Sleep Medicine (AASM). Dr. David Kent is listed as an inventor on U.S. and international patent applications regarding surgical treatments for OSA owned and licensed by Vanderbilt University (VU) to Nyxoah SA. Dr. Kent receives a portion of any licensing revenues as per standard VU technology transfer policy. The licensed treatment methodologies do not currently exist in prototype or commercial form and are not represented in the surgical literature reviewed by the TF. The licensing agreement was completed in early 2021, after completion of the initial clinical practice guideline, supporting systematic review, and public comment period. Mr. Harrod is employed by the AASM. The other authors report no conflicts of interest.