Hypopharyngeal Surgery in Obstructive Sleep Apnea

An Evidence-Based Medicine Review

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Objective: To perform an evidence-based medicine review of the literature describing outcomes of hypopharyngeal surgery in obstructive sleep apnea.

Design: We performed a MEDLINE search of English-language articles or abstracts using the keywords *sleep* and *surgery* in combination with any of the following terms: *hypopharynx*, *tongue*, *tongue base*, *epiglottis*, *genioglossus*, *advancement*, *mortised*, *genioplasty*, *glossectomy*, *tongue radiofrequency*, *hyoepiglottoplasty*, *hyoid*, *suspension*, and *stabilization*. Additional studies were identified from their reference lists. We reviewed abstracts to select publications reporting outcomes of hypopharyngeal surgery in obstructive sleep apnea. Articles were included only if patients underwent treatment of the palate for suspected retropalatal obstruction.

Data Extraction: Evidence-based medicine review for level of evidence, preoperative patient characteristics, surgical outcomes, and patient-specific factors associated with outcomes.

Results: We identified 36 articles. These were primarily case series studies (level 4 evidence), although some studies provided levels 1 and 2 evidence. Hypopharyngeal surgery demonstrates improvements in respiratory physiology during sleep, daytime somnolence, and quality of life. Several factors such as the body mass index, apnea-hypopnea index, Friedman stage, and SNB angle on lateral cephalogram have been associated with surgical outcomes. Considering the improvement in respiratory physiology alone, successful outcomes are achieved in 35% to 62% of patients; certain subgroups achieve higher success rates.

Conclusions: Hypopharyngeal surgery in obstructive sleep apnea is associated with improved outcomes, although this benefit is supported largely by level 4 evidence. Future research should include larger, higher-level studies that consider the variety of treatment effects, compare surgical treatments, and identify factors associated with outcomes.

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PLANNING FOR SURGICAL treatment of obstructive sleep apnea (OSA) begins with evaluation to determine the most likely site(s) of airway narrowing or collapse. By functionally dividing the pharynx into the retropalatal (corresponding to the portion of the oropharynx at the level of the soft palate and tonsils) and the so-called hypopharyngeal (actually corresponding to both the portion of the oropharynx at the level of the tongue base and the hypopharynx) regions, Fujita and Simmons[1] described the following 3 patterns of obstruction: type I, retropalatal obstruction alone; type II, both retropalatal and hypopharyngeal obstruction; and type III, hypopharyngeal obstruction alone.

In 1981, Fujita et al[2] described uvulopalatopharyngoplasty as a treatment for patients with retropalatal airway obstruction. Although highly effective for simple snoring, with a control rate ranging from 75% to 87%,[3] a literature review by Sher et al[4] showed an overall response rate of 40.7% (with response defined as a 50% decrease in the respiratory disturbance index and a postoperative respiratory disturbance index of <20, or as a 50% decrease in the apnea index and a postoperative apnea index of <10) in patients with OSA treated with uvulopalatopharyngoplasty alone, regardless of site of obstruction. In patients with suspected retropalatal narrowing alone (type I obstruction), the response rate increased to 52.3%, but for those with a component of hypopharyngeal obstruction (types II and III), the response rate was only 5.3%.[4]

In the years since the publication of that literature review,[4] several procedures have been developed to achieve higher response rates in patients with hypopharyngeal obstruction, and multiple studies have reported the results of the new and older procedures. The procedures available to treat hypopharyngeal obstruction in OSA include genioglossus advancement, mortised genioplasty, tongue radiofrequency treatment, surgical reduction of the tongue base (midline glossectomy), hyoepiglottoplasty, hyoid suspension, and tongue base

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stabilization. These procedures can be performed alone or in combination under the same anesthetic. The specific description of the technical aspects of these procedures is beyond the scope of this report, but multiple studies[5-41] have shown that these procedures improve outcomes in patients with suspected types II and III obstruction.

Sackett et al[42] outlined many of the foundations of present-day evidence-based medicine, which they described as "the integration of [the] best research evidence with clinical expertise and patient values."[42(p1)] To describe the quality of research evidence, a hierarchy has been developed that assigns each study a level of evidence based on the study design and the quality of the study.[43] The following tabulation presents the study designs that correspond to the 5 levels of evidence.

Level of Evidence	Study Design
1	Randomized, controlled trial
2	Cohort study
3	Case-control study
4	Case series
5	Expert opinion

This tabulation is simplified because there is a great deal of overlap between study designs and levels of evidence as well as subgroups within the levels that reflect the quality of the study and data analysis.

Evidence-based medicine combines studies (based on their levels of evidence) to develop treatment recommendations. The strength of these recommendations is based on the quality of the available evidence.[43] The following tabulation presents the grades that correspond to the levels of evidence on which the recommendations are based.

Grade of Recommendation	Levels of Evidence Supporting Recommendation*
A	Consistent level 1
B	Consistent level 2 or 3 or extrapolation from level 1
C	Level 4 or extrapolation from level 2 or 3
D	Level 5 or troubling, inconsistent, or inconclusive studies of any level of evidence

*Levels of evidence are described in the preceding tabulation.

Evidence-based medicine is commonly misinterpreted as a technique that ignores all studies except the randomized controlled trial (level 1 evidence); although high-quality randomized controlled trials receive the most weight in an evidence-based medicine review, all available studies are explicitly included in the development of treatment recommendations. Again, clinical decisions will ultimately be based on clinical expertise and patient values as well as this evidence.

The objective of this study was to perform an evidence-based medicine review of hypopharyngeal surgery outcomes in OSA.

METHODS

We used multiple strategies to identify articles describing hypopharyngeal surgery outcomes. A MEDLINE search identified English-language articles or abstracts using the keywords *sleep* and *surgery* in combination with any of the following: *hypopharynx*, *tongue*, *tongue base*, *epiglottis*, *genioglossus*, *advancement*, *mortised*, *genioplasty*, *glossectomy*, *tongue radiofrequency*, *hyoepiglottoplasty*, *hyoid*, *suspension*, and *stabilization*. We reviewed abstracts to select publications reporting outcomes of hypopharyngeal surgery in patients with OSA. We identified additional publications from the lists of references in this subset of articles. Articles were reviewed only if patients underwent treatment of the palate when retropalatal obstruction was suspected.

All studies were reviewed for the following information:

- Preoperative characteristics of patient populations, such as body mass index (BMI) (calculated as weight in kilograms divided by the square of height in meters) and preoperative sleep study results such as the reported apnea-hypopnea index (AHI) and lowest oxygen saturation (LSAT) during sleep
- Postoperative sleep study results, such as AHI and LSAT
- Surgical success, defined by the most common criteria of sleep study results (ie, a reduction in AHI of 50% or more and an AHI of less than 20)
- Any factors (eg, preoperative BMI or AHI) that were associated with outcomes
- Improvement in daytime somnolence, measured by the Epworth Sleepiness Scale[44]
- Improvement in quality of life, measured as sleep-related quality of life (using the Functional Outcomes of Sleep Questionnaire[45] or the Symptoms of Nocturnal Obstruction and Related Events[46] questionnaire) or global health-related quality of life (based on the 36-Item Short-Form Health Survey[47])
- Level of evidence

We then compared the results for each procedure or combination of procedures according to the criteria for a successful surgical outcome as outlined. We used the χ^2 test to determine whether there was a difference in the share of patients with a successful outcome among treatments, and $P<.05$ was considered statistically significant.

RESULTS

We identified a total of 36 studies. Many studies did not report or did not consider some of the information we outlined in the "Methods" section. Thirty-four (94%) of the 36 studies were case series and therefore provided level 4 evidence.

Patients undergoing genioglossus advancement as the sole treatment of hypopharyngeal airway obstruction (**Table 1**) demonstrated, on average, severe OSA before surgery.[5-8] After the procedure, there was significant improvement in the AHI in the 3 series that reported aggregate group data. Using the criteria for success based on AHI results, 3 studies[6-8] reported success rates of more than 60%; 1 series[5] had a lower rate. The 2 studies that considered the LSAT also showed an improvement in this metric.

One report[9] presented results for mortised genioplasty. In 33 patients with a mean preoperative BMI of 32.6, the procedure helped to achieve a successful AHI outcome in 16 patients (48%). The AHI improved from 60 to 29 ($P<.001$). Two factors were associated with AHI results. Patients with a preoperative BMI less than 30 before surgery had a successful outcome in 7 (64%) of 11 cases, compared with 9 (41%) of 22 patients with a BMI of 30 or more. Those with a preoperative AHI less than 50 had a successful outcome in 10 (71%) of 14 cases, while those with a preoperative AHI of 50 or more had similar results in only 6 (32%) of 19 cases. The LSAT for the group as a

Table 1. Genioglossus Advancement Results

Study	BMI, Mean	AHI, Mean		Success Rate, No./Total No. (%) of Cases*	LSAT†	Level of Evidence‡
		Preoperative	Postoperative			
Riley et al,[5] 1994	NR	NR	NR	9/23 (39)		4
Johnson and Chinn,[6] 1994	NR	59	14§	7/9 (78)	Yes	4
Lee et al,[7] 1999	NR	53	19§	24/35 (69)		4
Miller et al,[8] 2004‖	30	53	16§	16/24 (67)	Yes	4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); LSAT, lowest level of oxygen saturation; NR, not reported.

*Defined as 50% or more reduction in AHI and an AHI less than 20.

†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.

‡Described in the first tabulation.

§$P<.05$.

‖Describes use of the Genial Bone Advancement Trephine system.

Table 2. Tongue Radiofrequency Results

Study	BMI, Mean	AHI, Mean		Success, No./Total No. (%) of Cases*	LSAT†	EDS†	QOL‡	Level of Evidence§
		Preoperative	Postoperative					
Powell et al,[10] 1999	30	40	18‖	7/18 (39)	Yes	Yes	Yes	4
Stuck et al,[11] 2000	29	28	23	9/20 (45)		Yes		4
Woodson et al,[12] 2001	31	41	33‖	11/55 (20)	No	Yes	Yes	4
Stuck et al,[13] 2002	NR	25	17‖	6/18 (33)		Yes	No	4
Friedman et al,[14] 2003	32	44	28‖	N = 143 (approximately 40)¶	No	Yes		4
Fischer et al,[15] 2003#	27.5	32.6	22.0	5/15 (33)	Yes	Yes		4
Kao et al,[16] 2003		38.2	12.7	35/42 (83)	Yes			4
Riley et al,[17] 2003	30	35	15‖	NR	Yes	Yes		4
Woodson et al,[18] 2003	28	21	17	NR	No	Yes	Yes	1
Stuck et al,[19] 2004	27.4	25.3	16.7	6/18 (33)		Yes	Yes	4
Verse et al,[20] 2004	NR	27.8	22.9	5/15 (33)	No			4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence; LSAT, lowest level of oxygen saturation; NR, not reported; QOL, quality of life.

*Defined as 50% or more reduction in AHI and an AHI less than 20.

†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.

‡Refers to whether there was a statistically significant improvement (eg, increase) in the outcome. For studies that did not consider the outcome, the column is left blank.

§Described in the first tabulation.

‖$P<.05$.

¶The number was not specifically reported. The estimate was indirectly calculated from overall percentages of 2 separate groups of patients reported in the same article.

#Presents results and AHI.

whole improved from 72% to 80% ($P=.02$). No results were reported for daytime somnolence or quality of life.

Eleven studies[10-20] reporting tongue radiofrequency results are presented in **Table 2**. Overall, the patients were typically overweight or obese. The range of OSA severity included groups with moderate or severe OSA on the whole. Most of the studies reported a significant improvement in the AHI, and the proportion achieving a successful AHI outcome ranged from 20%[12] to 83%[16] in separate series. Most of the studies that reported results showed an improvement in the LSAT, daytime somnolence, and quality of life. In individual studies, amount of local anesthetic and electrolyte solution mixture injected before treatment[12] and the Friedman stage[14] were associated with outcomes. The evidence was mixed regarding the association between pretreatment AHI and successful outcomes.[14,16,17]

The case series for midline glossectomy are shown in **Table 3**.[21-25] These included groups that had a somewhat higher BMI and OSA severity (reflected by the AHI or the apnea index). Most had a statistically significant improvement in OSA severity. Again, the fraction of patients in whom a successful outcome by the sleep study criteria was achieved varied widely from 25%[23] to 83%.[25] Three of 4 series had improvement in the LSAT, but no results were reported for daytime somnolence or quality of life.

One study[26] presented results for hyoepiglottoplasty and reported that for 10 patients without craniofacial abnormalities (SNA angle [the angle measuring the anteroposterior relationship of the maxillary basal arch and anterior cranial base] ≥79° and SNB angle [anterior limit of the mandibular basal arch in relation to the anterior cranial base] ≥77° on lateral cephalography), the mean AHI

Table 3. Midline Glossectomy Results

Study	BMI, Mean	AHI, Mean		Success, No./Total No. (%) of Cases*	LSAT†	Level of Evidence‡
		Preoperative	Postoperative			
Fujita et al,[21] 1991	34.7	56	37	5/12 (42)	No	4
Woodson and Fujita,[22] 1992	32.8	59	16§	17/22 (77)	Yes	4
Mickelson and Rosenthal,[23] 1997	36.0	73	46§	3/12 (25)	Yes	4
Andsberg and Jessen,[24] 2000	NR	35‖	18§‖	7/22 (32)		4
Li et al,[25] 2004	NR	51	8§	5/6 (83)	Yes	4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence; LSAT, lowest level of oxygen saturation; NR, not reported; QOL, quality of life.
*Defined as 50% or more reduction in AHI and an AHI less than 20.
†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank. None of the studies considered EDS or QOL.
‡Described in the first tabulation.
§$P<.05$.
‖Determined using the apnea index.

Table 4. Hyoid Suspension Results

Study	BMI, Mean	AHI, Mean		Success, No./Total No. (%) of Cases*	EDS†	Level of Evidence‡
		Preoperative	Postoperative			
Vilaseca et al,[27] 2002	27.8	48.3	29.0§	5/9 (56)	Yes	4
Neruntarat,[28] 2003	29.3	44.5	15.2§	25/32 (78)	Yes	4
den Herder et al,[29] 2005	27.1	32.1	22.2	16/31 (52)	Yes	4
Bowden et al,[30] 2005	34.1	36.5	37.6	5/29 (17)	No	4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence.
*Defined as 50% or more reduction in AHI and an AHI less than 20.
†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.
‡Described in the first tabulation.
§$P<.05$.

decreased from 70 to 27 ($P<.01$) after surgery, and a successful outcome was achieved in 8 (80%) of 10 cases. The mean Epworth Sleepiness Scale score improved from 15 to 6 ($P<.05$), and mean±SD BMI improved from 32.0±5.0 to 30.5±5.0 ($P=.01$).[26]

Hyoid suspension was originally described by Riley et al[48] with suspension of the hyoid bone to the inferior border of the mandible. The technique was later revised to secure the hyoid arch anteriorly to the superior border of the thyroid cartilage.[5] Four studies[27-30] have considered the role of hyoid suspension as the sole procedure to treat hypopharyngeal airway obstruction (**Table 4**). The revised technique of hyoid suspension to the thyroid cartilage was used in all 4 series, and all patients had palate surgery performed previously or in the same setting. The patient populations are distinguished by their preoperative characteristics. Compared with the other 2 studies, the sample presented by Bowden et al[30] had a higher preoperative BMI and LSAT (82.1% vs 72.7% in the study by Neruntarat[28] and not reported in the other 2 studies). In turn, the postoperative results differ markedly in the raw improvements in AHI, as well as the proportion that achieved a successful outcome according to a sleep study; the population with the highest BMI and higher LSAT had the worst outcomes. The series by den Herder et al[29] also showed that hyoid suspension performed under the same anesthetic as palate surgery was associated with better outcomes (10 [71%] of 14 with successful AHI outcome) than for the procedure performed in isolation after previous, unsuccessful palate surgery (6 [35%] of 17 with successful AHI outcome). Finally, the series reported by Neruntarat,[28] Vilaseca et al,[27] and den Herder et al[29] showed an improvement in daytime somnolence, whereas the series reported by Bowden et al[30] did not.

Table 5 summarizes published results for the combination of genioglossus advancement with hyoid suspension.[5,27,31-35] The patient populations, on average, were overweight or obese, and they demonstrated severe OSA. Postoperatively, the improvements in AHI were statistically significant in some but not all of the studies. The share of patients achieving a successful AHI outcome ranged from 22%[34] to 77%,[35] and most studies that reported data for daytime somnolence showed an improvement after surgery. Lower AHI and BMI were associated with a higher likelihood of successful outcomes in the largest study; successful AHI outcomes were achieved in 93 (74%) of 125 patients with an AHI less than 60 and LSAT less than 70.[31] Evidence from the group of studies also suggested that an SNB angle of more than 78° on pre-

Table 5. Hyoid Suspension in Combination With Genioglossus Advancement or Mortised Genioplasty Results

Study	Technique	Other Procedures	BMI, Mean	AHI, Mean		Success, No./Total No. (%) of Cases*	EDS†	Level of Evidence‡
				Preoperative	Postoperative			
Riley et al,[31] 1994	Mandible	Palate, GA	29	27	9.5§	57 (133/233)		4
Riley et al,[5] 1994	Thyroid	Palate,‖ GA‖	30	45	13§	71 (17/24)§	Yes	4
Ramirez and Loube,[32] 1996	Mandible	Palate, GA	35	49	23	42 (5/12)		4
Utley et al,[33] 1997	Thyroid	Palate, GA	28.4	40.7	25	57 (8/14)	Yes	4
Bettega et al,[34] 2000	Thyroid	Palate, GA	27	47	47	24 (5/21)		4
Hsu and Brett,[35] 2001	Thyroid	Palate, GA	31.0	52.8	15.6	77 (10/13)	Yes	4
Vilaseca et al,[27] 2002	Thyroid	Palate,‖ GA	27.8	70.5	57.4	18 (2/11)	No	4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence; GA, genioglossus advancement; mandible, suspension of hyoid bone to mandible inferior border; palate, palate surgery; thyroid, suspension of hyoid bone to superior border of thyroid cartilage.

*Defined as 50% or more reduction in AHI and an AHI less than 20.

†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.

‡Described in the first tabulation.

§$P<.05$.

‖Indicates procedure(s) performed before hyoid suspension in a separate operative setting.

Table 6. Tongue Stabilization Results

Study	BMI, Mean	AHI, Mean		Success, No./Total No. (%) of Cases*	LSAT†	EDS†	QOL‡	Level of Evidence§
		Preoperative	Postoperative					
DeRowe et al,[36] 2000	<35	35	17‖	4/14 (29)				4
Woodson,[37] 2001	28.2	35	24‖	4/14 (29)	No	Yes	Yes	4
Terris et al,[38] 2002	31.5	33		6/12 (50 AHI)¶				4
Miller et al,[39] 2002	31.3	39	21‖	3/15 (20)	Yes			4
Thomas et al,[40] 2003				4/7 (57)		Yes		2
Sorrenti et al,[41] 2003	28.7	44.5	24.2‖	6/15 (40)		Yes		4

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence; LSAT, lowest level of oxygen saturation; QOL, quality of life.

*Defined as 50% or more reduction in AHI and an AHI less than 20.

†Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.

‡Refers to whether there was a statistically significant improvement (eg, increase) in the outcome. For studies that did not consider the outcome, the column is left blank.

§Described in the first tabulation.

‖$P<.05$.

¶The authors report results for satisfying a criteria for successful outcome based on the AHI or apnea index. To compare results across case series, the results shown for this study (and for all studies in these tables) reflect the patients who achieved a successful outcome according to the AHI alone.

operative lateral cephalography was associated with better outcomes,[31] and an SNB angle of less than 73.5° was associated with poorer outcomes.[32]

One study[34] reported the combination of mortised genioplasty and hyoid suspension. Mean preoperative BMI was 25. The AHI did not change significantly (43 to 37; $P>.05$), and 5 (22%) of 23 patients had a successful AHI outcome.

A single series also described the combination of tongue radiofrequency and hyoid suspension.[20] The AHI improved from 39 to 21 ($P<.001$) after surgery, and there was also an improvement in LSAT. A successful outcome was achieved in 22 (49%) of 45 patients. The BMI was not reported.

Of the hypopharyngeal surgeries, the tongue stabilization procedure has been developed most recently and is marketed as the Repose System (InfluENT Medical LLC, Concord, NH). Published results for the procedure are presented in **Table 6**,[36-41] and these studies included patients who were, on average, overweight or obese. As a group, the patients had moderate or severe OSA based on their preoperative AHI. Each series demonstrated an improvement in AHI, and the proportion of patients with a successful outcome varied from 20% to 57%. The improvement in LSAT was mixed, but the 3 studies reporting data for daytime somnolence showed an improvement in the Epworth Sleepiness Scale score. There was an improvement in the Functional Outcomes of Sleep Questionnaire score in the 1 study that considered quality of life.

Published studies are summarized in **Table 7** according to individual procedures or combinations of procedures where multiple studies are available. Overall, the evidence supports primarily grade C recommendations for the benefits of hypopharyngeal surgery. The AHI results and the fraction of patients achieving a successful outcome based on the AHI criteria constitute the pri-

Table 7. Comparison of Procedures and Combinations of Procedures

Procedure	Grade*	Success, No./Total No. (%) of Cases†	Compared With GA + HS (*P* Value)	EDS‡	QOL§	Predictors
Genioglossus advancement	C−	56/91 (62)	No difference (.26)			
Mortised genioplasty	C	16/33 (48)	No difference (.48)			BMI, AHI
Tongue radiofrequency	B/C	95/269 (35)	Worse (<.001)	Yes	Yes	Technique, Friedman stage, AHI (mixed)‖
Midline glossectomy	C−	37/74 (50)	No difference (.45)			
Hyoid suspension	C−	51/101 (50)	No difference (.44)	Mixed¶		BMI?,# LSAT?, primary procedure
Genioglossus advancement and hyoid suspension	C−	180/328 (55)				BMI, AHI, SNB angle
Tongue stabilization	C−	27/77 (35)	Worse (<.01)	Yes	+/−	

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); EDS, excessive daytime somnolence; GA, genioglossus advancement; HS, hyloid suspension; LSAT, lowest level of oxygen saturation; QOL, quality of life; SNB angle, anterior limit of the mandibular basal arch in relation to the anterior cranial base.

*Described in the second tabulation. The minus sign indicates significant heterogeneity in results among studies.

†Defined as 50% or more reduction in AHI and an AHI less than 20.

‡Refers to whether there was a statistically significant improvement (eg, decline) in the outcome. For studies that did not consider the outcome, the column is left blank.

§Refers to whether there was a statistically significant improvement (eg, increase) in the outcome. For studies that did not consider the outcome, the column is left blank.

‖Some studies have shown that AHI is a predictor of outcomes and others have not.

¶Some studies have shown a benefit and others have not.

#Question marks indicate that these factors may or may not be predictors because different studies with populations that varied according to AHI and LSAT showed very different benefits from these procedures.

mary method of comparing surgical results, because other outcomes have not been as widely reported. Successful AHI outcomes vary from 35% to 62% for the treatments. Individual studies report substantial heterogeneity for various procedures and combinations of procedures (reflected in the grade column of Table 7). Results of a χ^2 test showed that when aggregated data are used to compare procedures with the most widely reported treatment, the combination of genioglossus advancement and hyoid suspension, tongue radiofrequency treatment and tongue stabilization are associated with lower rates of successful AHI outcomes.

COMMENT

A wide variety of procedures are available to treat hypopharyngeal airway obstruction in OSA. Most of the surgical literature reporting their results consists of case series with few direct comparisons of surgical treatments. These patient populations are preselected by surgeons (who presumably identify patients who would be expected to obtain the most benefit from surgery and, more specifically, the procedure or combination of procedures); this preselection biases the comparison among distinct series of patients. However, although results for the various procedures or combinations of procedures vary widely, it is clear that these procedures developed to treat hypopharyngeal airway obstruction in OSA offer substantial improvement in surgical outcomes compared with palate surgery alone (which achieves a successful outcome by respiratory physiology criteria in only 5% of patients with types II and III obstruction).

The combination of genioglossus advancement and hyoid suspension to treat hypopharyngeal obstruction has been considered by some to be a barometer to measure other surgical treatment outcomes after the publication of a large series using this combination to treat hypopharyngeal obstruction.[31] Comparing results across isolated case series can be difficult; however, preoperative patient characteristics such as BMI and AHI were largely similar in the studies reviewed herein. These similarities facilitate a comparison of the most commonly performed procedures with the combination of genioglossus advancement and hyoid suspension. The available evidence suggests that tongue radiofrequency treatment and the tongue stabilization procedure do not achieve the same rate of successful outcomes according to the AHI criteria.

There are certain caveats to this statement. This statement describes the results of an evidence review and does not incorporate clinical expertise and patient values that must be considered in making treatment decisions.

All patients included in this review had surgical palate treatment performed in conjunction with hypopharyngeal procedures or in a previous setting. However, outcomes of hypopharyngeal procedures can be limited by residual palatal obstruction, even after palate surgery. Because residual palatal obstruction should not vary among these studies, it should not affect a comparison of different hypopharyngeal surgical treatments.

In recent years, greater attention has been devoted to the multiple outcomes of surgical and nonsurgical treatment extending beyond an exclusive focus on sleep study results. Daytime somnolence and quality of life are often the primary motivation for patients seeking treatment for sleep disorders, and clinicians should not focus exclusively on sleep study results because these have not been shown to relate to health outcomes and have shown relatively little correlation to daytime somnolence or quality of life.[49] Historically, however, sleep study results are the major outcome that has been reported in the literature, and this is the basis for their use in our review. As investigators explore and report assessments of other end points, future reviews of surgical and nonsurgical OSA treatments will undoubtedly consider a wider array of outcomes.

The choice among procedures includes the consideration of risks as well as outcomes. Operative risks can vary widely between procedures and patients. A discussion of surgical risks is outside the scope of this review, but a consideration of procedural risks is a central issue in surgical decision making.

Finally, this review includes only the published literature, and there may be a bias against the publication of results that do not compare favorably with historical data. This review, however, includes series with wide variations in results that attest to the breadth of the literature in this area.

Evidence-based medicine is often used to discard all studies except the randomized, controlled trials that represent level 1 studies. This is clearly not the purpose of evidence-based medicine or this review. The hypopharyngeal surgery literature provides primarily level 4 evidence, and this review can be used to compare procedures—albeit in an imperfect manner—and identify factors associated with outcomes. Two randomized studies[18,40] provide higher-level evidence, and they illustrate important points about study design.

One randomized, controlled trial[18] compared radiofrequency treatment of the tongue and palate with placebo radiofrequency treatment and continuous positive airway pressure. Sixty surgical candidates were randomized to receive active or placebo radiofrequency treatment; the comparison group of patients receiving continuous positive airway pressure was not randomized to receive tongue radiofrequency treatment or placebo treatment. This study is significant for 2 reasons. It represents one of a few randomized, controlled trials in otolaryngology–head and neck surgery or any other surgical field. Second, it reinforces the importance of considering the spectrum of treatment outcomes. As summarized in Table 2, tongue radiofrequency treatment did not lower the AHI, but it improved daytime somnolence, quality of life, and vigilance; the placebo group had no changes in any measured outcomes. Subsequent analysis of this study population demonstrated that polysomnography indices were not correlated with these other measures in this population.[49] The independence of polysomnography findings from self-reported measures was also shown in a previous study of a separate sample.[50] Obstructive sleep apnea is associated with substantial morbidity and increased mortality; to our knowledge, the magnitude of these effects has never been correlated with polysomnography results. Researchers should measure the effects of OSA treatment directly rather than blindly relying on polysomnography results to measure all treatment outcomes.

A second randomized trial[40] was a pilot study comparing the tongue stabilization procedure with genioglossus advancement. Seventeen patients underwent palate surgery in combination with either tongue stabilization or genioglossus advancement. Overall, there were no statistically significant differences in outcomes (specifically, AHI or daytime somnolence) between the 2 groups.

Statistical power is the ability to detect a difference between 2 groups if one truly exists. A power calculation determines the number of patients who must be enrolled in a study for the study to have valid conclusions (particularly if they show no difference in results among treatments), and statistical power provides the foundation to make conclusions once a study is completed.

In the study by Woodson et al[18] that compared a surgical intervention with placebo, a power calculation was performed at the outset and determined that 30 patients should be enrolled in each group. That level of enrollment was achieved in the study, and the study conclusions were thereby strengthened. In the study by Thomas et al,[40] however, no power calculation was presented, although the authors presumably performed the calculation because they presented their results as a pilot study. If it is assumed that a difference of 20% in the percentage of patients achieving a successful surgery outcome is clinically meaningful, a study would need to enroll 100 patients in each of 2 surgery treatment groups to have 80% statistical power (a common threshold) to detect such a difference. (The sample size for the study by Thomas et al was much higher than that for the study by Woodson et al because the former compared 2 surgical interventions while the latter compared an intervention with a placebo.) Our review raises the issue of comparing 2 surgical treatments in a randomized trial; this power calculation suggests that a well-designed study would need to be extremely large and would almost certainly require multi-institutional collaboration.

Studies that use level 1 evidence provide the most systematic evaluation of specific research questions. However, they present significant logistical difficulties. Fortunately, other study designs can address some of these same questions. The existing literature has identified several factors that may be associated with better or worse outcomes after surgery, and the development of larger studies—even level 2 (cohort studies) or level 3 (case-control studies) evidence—can advance our understanding of surgical results to improve clinical decision-making and patient counseling.

In conclusion, evidence-based medicine considers all available research evidence in the context of clinical judgment and patient values. Hypopharyngeal surgery in OSA—like most surgical treatments—is supported largely by case series studies (level 4 evidence). Hypopharyngeal procedures have demonstrated improvements in many outcomes, including respiratory physiology during sleep, daytime somnolence, and quality of life. Future research should include larger, higher level studies that compare surgical treatments and identify factors associated with outcomes.

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