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Studying Life Effects & Effectiveness of Palatopharyngoplasty (SLEEP) Study: Subjective Outcomes of Isolated Uvulopalatopharyngoplasty

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Abstract

Objective. To test the hypothesis that uvulopalatopharyngoplasty (UPPP) improves sleep apnea–related quality of life (measured on the Functional Outcomes of Sleep Questionnaire [FOSQ]) at 3-month follow-up. Secondary objectives were to test (1) the stability of the outcomes at 6 months, (2) the effect on global sleep apnea quality-of-life change, and (3) the effect on sleep apnea symptoms.

Study Design. Multicenter, prospective, longitudinal case series.

Setting. Diverse university- and community-based otolaryngology practices.

Subjects and Methods. The cohort included 68 patients from 17 practices, with a mean ± standard deviation age of 44 ± 12 years and mean apnea-hypopnea index of 35 ± 32 events/hour. All patients underwent UPPP, defined as an open procedure modifying the shape and size of the palate, pharynx, and uvula, with or without tonsillectomy. Baseline data were collected on site before surgery, and outcome data were collected by mail 3 and 6 months after surgery, with follow-up rates of 51% and 50%, respectively.

Results. FOSQ scores improved from 14.3 ± 3.4 (scale 5-20, normal ≥17.9) at baseline to 17.2 ± 2.7 at 3 months (mean improvement 2.9; 95% confidence interval, 1.8-4.0; $P < .001$) and 17.5 ± 2.5 at 6 months (mean improvement 3.1; 95% confidence interval, 2.0-4.2; $P < .001$). All quality-of-life and symptom measures improved significantly at 3 and 6 months (all $P < .05$).

Conclusion. This prospective, multicenter, university- and community-based study provides evidence that UPPP significantly improves disease-specific quality of life and sleep apnea symptoms in patients with sleep apnea. Validity may be limited by significant loss to follow-up and absence of an unoperated control group.

Keywords

obstructive sleep apnea, sleep apnea, sleep-disordered breathing, uvulopalatopharyngoplasty, palatopharyngoplasty, tonsillectomy, quality of life

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Uvulopalatopharyngoplasty (UPPP) is the most common surgical treatment for obstructive sleep apnea. UPPP often physiologically improves but does not eliminate sleep apnea.[1,2] Consequently, the value of UPPP has

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been questioned in the sleep medicine literature.[3] However, basing the value of a treatment modality solely on physiological surrogate outcome measures such as polysomnography parameters may not reflect true treatment effects accurately.[4] Studies do support that UPPP provides benefit for clinically important outcomes such as motor vehicle accidents,[5] incidence of cardiovascular disease,[6,7] and mortality.[8,9]

Health-related quality of life may be the most important outcome to patients.[10] However, quality-of-life outcomes have rarely been evaluated for UPPP patients. In their comprehensive review of the literature in 1995, Schechtman et al[11] found that quality-of-life outcomes were sorely lacking yet were necessary for evaluating surgical treatment for sleep apnea. In a follow-up review in 2008, Megwalu et al[12] again found a relative infrequent use of validated quality-of-life measures. A literature search of UPPP and quality of life revealed a few articles that specifically assessed sleep-related quality of life in UPPP patients, but each article has important limitations.[13-15]

Our study focuses on patient-based outcomes related to palatal surgery for sleep apnea as a part of a larger, surgical cohort. To this end, our primary objective was to test the hypothesis that UPPP improves sleep-related quality of life measured on the Functional Outcomes of Sleep Questionnaire (FOSQ) at 3-month follow-up. Secondary objectives were to test (1) the stability of the outcomes at 6 months, (2) the effect on global sleep apnea quality-of-life change, and (3) the effect on sleep apnea symptoms, including daytime sleepiness measured on the Epworth Sleepiness Scale (ESS), snoring measured on a 100-mm visual analog scale (VAS), and others.

Methods

Study Design

We performed a multicenter, prospective, university- and community-based, longitudinal case series of isolated UPPP as part of a larger prospective study of sleep apnea surgery. Results are presented only for the UPPP analysis. The multiple centers for this and the parent study included members of the BEST ENT (Building Evidence of Successful Treatments in Ear, Nose, and Throat) network of otolaryngologists who collaborate in prospective studies designed to evaluate the effectiveness and/or changes in disease-specific quality-of-life interventions on patients with ear, nose, and throat diseases.[16-19] The network is supported by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) and coordinated through the Duke Clinical Research Institute. Individual sites received no direct financial support for participation or enrollment of participants. This study was approved by the Duke Institutional Review Board (IRB) and each participating site IRB. IRB approval for community physicians who did not have their own IRB was provided by Duke University through an unaffiliated investigator agreement.

Patient Sample

Adults (18 years and older) with palatal obstruction believed to be consistent with the presenting symptoms of obstructive sleep apnea as assessed by the treating surgeon were eligible to participate in this study. Inclusion criteria included a sleep study demonstrating an apnea-hypopnea index ≥5 events per hour and symptoms of sleep apnea lasting more than 3 months. Qualifying symptoms included excessive daytime sleepiness or 2 of the following: choking or gasping during sleep, recurrent awakenings from sleep, unrefreshing sleep, daytime fatigue, or impaired concentration.[20] Individuals who had prior airway surgery were eligible, but patients who had other upper airway surgeries concomitant with UPPP or between UPPP and 3-month follow-up were excluded from this analysis. Other exclusion criteria included prior palate surgery (tonsillectomy without UPPP was allowed), history of radiation therapy to the head or neck, dysmorphic facies or craniofacial syndrome, American Society of Anesthesiologists class IV or V, major depression or unstable psychiatric disorder, pregnancy, illiteracy (unable to complete required forms), no phone or mailing address, or plan to change address during the follow-up period.

Research participants were recruited directly from the participating otolaryngology practices by the respective surgeons. The enrollment period was November 2004 to October 2006. Most sites enrolled consecutive patients during a part of this enrollment period until they reached their target sample. All enrolled patients gave informed consent.

Sleep Studies

Sleep studies were performed on all patients prior to enrollment and treatment. Sleep studies included types 1 to 3, full night or split night, and attended or unattended. Sleep study data were used to help define patient eligibility and baseline sleep apnea burden, but sleep study data were not included as an outcome measure. Posttreatment sleep study data were not collected for this study.

Treatment

The operational definition of UPPP was an open procedure modifying the shape and size of the palate, pharynx, and uvula, including resection of redundant or obstructive tissue and primary wound closure. UPPP includes tonsillectomy. The specific version of UPPP was left to the discretion of the treating surgeon. All patients underwent UPPP with or without tonsillectomy, and they had no other procedures.

Outcome Measures

The primary outcome variable is change in sleep-specific quality of life measured with the FOSQ at enrollment and at 3 months postoperatively. This instrument measures sleep-specific quality of life and has been validated in people with and without various sleep disorders.[21] It produces a score of 5 to 20; higher is better. Normal is 17.9 or higher. A 5-point change in the FOSQ score corresponds to an average change of 1 point or a change of 1 whole category of answer (ie, “extreme difficulty” to “moderate difficulty,” or “moderate difficulty” to “a little difficulty,” or “a little difficulty” to “no difficulty”) for every item in the 30-item instrument. Outcome

was also measured 6 months postoperatively to test for the stability of the sleep-specific quality-of-life change.

Secondary outcome measures included global sleep apnea quality of life and symptoms. Global sleep apnea quality-of-life change is a transition measure that asks, "In terms of sleep apnea and your health, has there been any change in your quality of life?" It is scored on a 15-point Likert scale ranging from −7 (*a great deal worse*) to +7 (*a great deal better*). It is modeled after a similar global quality-of-life instrument for asthma.[22] Daytime sleepiness was measured with the ESS. This 24-point scale has been validated in various sleep disorders and has been used extensively in the literature. A normal score is 10 or less, and scores >16 represent severely excessive daytime sleepiness.[23] The frequency of awakening with a headache per week was quantified as <1, 1 to 2, 3 to 4, 5 to 6, or 7. Patients quantified how much of a problem the sleep apnea and snoring is for them, each on a 100-mm VAS, with anchors *not a problem* (0) and *severe problem* (100). Presence or absence of symptoms of choking or gasping during sleep, recurrent awakenings from sleep, unrefreshing sleep, daytime fatigue, or problems concentrating was recorded. No other subjective outcomes were measured. All outcomes were measured 3 and 6 months postoperatively.

Data Collection and Management

If a patient met eligibility criteria and agreed to participate, then he or she signed the consent form and completed the baseline questionnaire with demographic and medical information as well as the outcome measures. The treating physician completed a form with information about the baseline sleep study, past and planned procedures, American Society of Anesthesiologists class, and standardized examination findings.

Questionnaires and patient contact information were mailed to the Duke Clinical Research Center for data entry, and patients were contacted by the center staff to complete the follow-up questionnaires 3 and 6 months after UPPP. Patients were contacted by mail at least 3 times and called up to 5 times for follow-up. Data were entered into a secure database (Microsoft Access, Redmond, Washington) that met privacy requirements. Patient identifiers were removed from the database and sent to the principal investigator (EMW) for analysis.

Analysis

The database was cleaned and prepared for analysis by the principal investigator. This analysis was limited to patients who had UPPP alone. For continuous variables (including variables with a scale range of 15 or more), the paired *t* test was used to compare baseline and follow-up data. For ordinal data, the Wilcoxon sign rank test was used to compare baseline and follow-up data. Baseline variables were compared between the patients lost to follow-up and the followed patients using Student's *t* test (continuous variables), chi-squared test for linear trend (ordinal variables), and Fisher's exact test (dichotomous variables). All statistical tests were 2-sided. A *P* value less than .05 is considered statistically significant.

Results

The parent study of sleep apnea surgery enrolled 243 patients from 19 different states. For this analysis of UPPP alone, patients (N = 68) were enrolled from 17 practice locations from 15 different states with 9 practices (53%) university-based and 8 practices (47%) community-based. The patient sample consisted mainly of middle-aged men who were generally healthy but were obese, on average, with severe sleep apnea by apnea-hypopnea index criteria (**Table 1**). Overall, the patients were quite symptomatic with clinically important deficits in sleep-related quality of life. Most UPPP operations included tonsillectomy. A minority of patients had prior airway surgery. Follow-up data were obtained at 3 months and 6 months on 51% and 50%, respectively, of the patient sample.

The primary outcome was measured with the FOSQ, for which a normal score is ≥17.9. The patient sample had a clinically important baseline deficit in quality of life, which improved significantly and with large effect sizes at 3 and 6 months postoperatively (**Tables 2-4**). The observed 3-point change represents an average change of 0.6 points, or a change of just over half of a category, for every question in the 30-item FOSQ. Among patients who had an abnormal score at baseline and for whom follow-up data were available (mean baseline score 13.8 ± 3.2), 42% (13/31) normalized their score at 3 months.

All other symptom and quality-of-life outcomes were also improved 3 and 6 months after UPPP (all $P < .05$) with clinically important effects (**Tables 2-4**). Among patients who had an abnormal ESS at baseline (mean 15.9 ± 3.0) and for whom follow-up data were available, 75% (18/24) normalized their score at 3 months. Between 3 and 6 months, there was a minor but statistically significant setback in global sleep apnea–related quality of life ($P = .04$) and a statistical trend of a setback measured on the snoring VAS ($P = .07$), but each remained much improved compared to baseline (**Table 4**). Patients lost a mean 8 ± 15 pounds at 3 months ($P = .005$) and kept it off at 6 months. In this sample, this weight loss corresponds to a body mass index decrease of 1.1 ± 2.2 kg/m^2 at 3 months.

Almost half of the patient sample was lost to follow-up. There was no significant difference between the patients followed and the patients lost on most baseline variables, including demographics, general health, sleep apnea severity, symptoms, sleep-related quality of life, past surgical treatment, and current treatment (**Table 5**). The lost patients did have a significantly lower mean Friedman stage[2] ($P < .001$) and a trend toward significantly larger tonsils ($P = .054$).

Discussion

UPPP usually does not eliminate obstructive sleep apnea, but it appears to have beneficial physiological effect on the disorder.[1,2] UPPP may have an even greater effect on clinical outcomes, as has been suggested for mortality,[8,9] cardiovascular disease,[6,7] motor vehicle accidents,[5] symptoms, and satisfaction.[24] There are few studies examining sleep-related quality of life, which is another clinical outcome important to patients. Given the lack of patient-based data in the literature,

Table 1. Cohort Baseline Description (N = 68)

Variable	
Demographics	
Age, y, mean ± SD (range)	44 ± 12 (18-69)
Sex: male, %	78
Race: white, %	79
Marital status: married/partner, %	66
Employment status: full-time, %	76
General health	
American Society of Anesthesiologists class, mean ± SD (range)	1.7 ± 0.7 (1-3)
Current smoker, %	12
Alcohol use (drinks/wk), mean ± SD (range)	2.9 ± 4.5 (0-20)
Systolic blood pressure in clinic at enrollment, mm Hg, mean ± SD (range)	129 ± 10 (106-150)
Diastolic blood pressure in clinic at enrollment, mm Hg, mean ± SD (range)	82 ± 6 (69-100)
Anatomy	
Body mass index, kg/m^2, mean ± SD (range)	31 ± 5 (20-41)
Tonsil size (0-4), mean ± SD (range)	2 ± 1 (0-4)
Friedman stage (1-3), mean ± SD (range)	2.2 ± 0.6 (1-3)
Sleep apnea severity	
Apnea-hypopnea index, events/h, mean ± SD (range)	35 ± 32 (5-164)
Apnea index, events/h, mean ± SD (range)	19 ± 24 (0-96)
Lowest saturation, %, mean ± SD (range)	84 ± 7 (64-98)
Symptoms and quality of life	
Sleep apnea symptoms (0-5), mean ± SD (range)	4 ± 1 (0-5)
Awakening with headache, d/wk, mean ± SD (range)	2 ± 2 (0-7)
Sleep apnea problem visual analog scale (0-100), mean ± SD (range)	72 ± 27 (0-100)
Snoring visual analog scale (0-100), mean ± SD (range)	55 ± 34 (0-100)
Epworth Sleepiness Scale (0-24), mean ± SD (range)	13 ± 6 (0-22)
Functional Outcomes of Sleep Questionnaire (5-20), mean ± SD (range)	14 ± 3 (7-20)
Sleep apnea treatment	
Uvulopalatopharyngoplasty included tonsillectomy, %	63
Using continuous positive airway pressure therapy at baseline, %	44
Prior airway surgery: any, %	25
Prior airway surgery: nasal, %	18
Prior airway surgery: tonsillectomy or adenoidectomy, %	9
Prior airway surgery: tongue, %	6
Follow-up	
Total sample, No.	68
Follow-up data available: 3 months, No. (%)	35/68 (51)
3-month follow-up (median days), No. (range)	125 (77-170)
Follow-up data available: 6 months, No. (%)	34/68 (50)
6-month follow-up (median days), No. (range)	273 (167-849)

we designed this study to focus on important patient-reported outcomes rather than on polysomnography parameters.

This study supports the hypothesis that UPPP improves sleep-related quality of life measured with the validated FOSQ at 3 and 6 months after surgery. These data also support the hypotheses that UPPP improves daytime sleepiness, other defining sleep apnea symptoms, and global sleep apnea-related quality of life for at least 6 months after surgery. Almost half of the patients with abnormal quality-of-life scores at baseline and three-quarters of those with abnormal sleepiness scores at baseline were normalized after treatment.

Other studies have examined the effect of UPPP on quality of life, with each finding improvement with UPPP.[13-15] Each of these high-level studies had many important strengths, but none used a validated sleep-specific quality-of-life instrument, and each was limited to 1 or 2 sites of practice. One trial did not screen UPPP patients for the site of obstruction, so isolated UPPP may not have been appropriate for each patient.[14] In one of the studies, the majority of patients underwent tongue surgery in addition to UPPP, so the study reflects the effect of multilevel surgery rather than isolated UPPP.[15] Our study complements these studies by demonstrating a significant

Table 2. Outcomes Between Baseline, 3 Months, and 6 Months

Outcome	Baseline, Mean ± SD	3 Months, Mean ± SD	6 Months, Mean ± SD	*P* Value[a] (0-3 mo)	*P* Value[a] (0-6 mo)	*P* Value[a] (3-6 mo)
Primary						
Functional Outcomes of Sleep Questionnaire (5-20)	14.3 ± 3.4	17.2 ± 2.7	17.5 ± 2.5	**<.001**	**<.001**	.77
Secondary						
Epworth Sleepiness Scale (0-24)	12.9 ± 5.5	7.0 ± 4.7	6.9 ± 4.2	**<.001**	**<.001**	.54
Sleep apnea symptoms (0-5)	3.7 ± 1.1	1.1 ± 1.5	1.5 ± 1.7	**<.001**	**<.001**	.32
Awakening with headache, d/wk	1.7 ± 2.3	1.0 ± 2.1	1.0 ± 1.9	**.048**	**.008**	.66
Sleep apnea problem VAS (0-100)	68 ± 30	24 ± 28	24 ± 27	**<.001**	**<.001**	.88
Snoring VAS (0-100)	53 ± 32	8 ± 12	18 ± 22	**<.001**	**<.001**	.07
Global sleep apnea QOL change, −7 to +7[b]	—	3.5 ± 2.6	2.5 ± 2.7	**<.001**	**<.001**	**.04**
Body mass index self-report, kg/m^2	30 ± 4	29 ± 4	29 ± 5	**.006**	**<.001**	.41

Abbreviations: QOL, quality of life; VAS, visual analog scale.
[a]*P* value based on the 1-sample paired *t* test (2-sided) for comparison of means for continuous variables or Wilcoxon signed rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance ($P < .05$).
[b]Global sleep apnea QOL change is a transition measure, which is measured only at outcome.

Table 3. Three-Month Outcomes

Outcome	No.	Difference, Mean ± SD[a]	95% CL	*P* Value[b]	Effect Size[c]
Primary					
Functional Outcomes of Sleep Questionnaire (5-20)	35	2.9 ± 3.3	1.8, 4.0	**<.001**	0.85
Secondary					
Epworth Sleepiness Scale (0-24)	35	−5.9 ± 6.0	−8.0, −3.8	**<.001**	1.07
Sleep apnea symptoms (0-5)	35	−2.7 ± 1.5	−3.2, −2.1	**<.001**	2.45
Awakening with headache, d/wk	31	−0.7 ± 2.0	−1.4, 0.0	**.048**	0.30
Sleep apnea problem VAS (0-100)	34	−44 ± 36	−57, −31	**<.001**	1.47
Snoring VAS (0-100)	33	−45 ± 32	−57, −34	**<.001**	1.41
Global sleep apnea QOL change, −7 to +7[d]	35	3.5 ± 2.6	2.6, 4.4	**<.001**	1.35

Abbreviations: CL, confidence limits; QOL, quality of life; VAS, visual analog scale.
[a]Difference = 3-month score − baseline score.
[b]*P* value based on paired *t* test (2-sided) for comparison of means for continuous variables or Wilcoxon signed rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance ($P < .05$).
[c]Effect size = (3-month score − baseline score)/(baseline standard deviation). Positive indicates uvulopalatopharyngoplasty (UPPP) improved the outcome; negative indicates UPPP worsened the outcome. Effect size ≥ 0.20 is clinically important; ≥ 0.80 indicates large effect size.[25]
[d]Global sleep apnea QOL change is a transition measure, which is measured only at outcome.

Table 4. Six-Month Outcomes

Outcome	No.	Difference, Mean ± SD[a]	95% CL	*P* Value[b]	Effect Size[c]
Primary					
Functional Outcomes of Sleep Questionnaire (5-20)	32	3.1 ± 3.1	2.0, 4.2	**<.001**	0.91
Secondary					
Epworth Sleepiness Scale (0-24)	34	−5.8 ± 5.6	−7.7, −3.8	**<.001**	0.98
Sleep apnea symptoms (0-5)	34	−2.1 ± 1.6	−2.7, −1.6	**<.001**	1.75
Awakening with headache, d/wk	30	−0.9 ± 1.8	−1.6, −0.2	**.008**	0.39
Sleep apnea problem VAS (0-100)	32	−46 ± 31	−57, −35	**<.001**	1.64
Snoring VAS (0-100)	31	−37 ± 33	−49, −25	**<.001**	1.12
Global sleep apnea QOL change, −7 to +7[d]	33	2.5 ± 2.7	1.5, 3.4	**<.001**	0.93

Abbreviations: CL, confidence limits; QOL, quality of life; VAS, visual analog scale.
[a]Difference = 6-month score − baseline score.
[b]*P* value based on paired *t* test (2-sided) for comparison of means for continuous variables or Wilcoxon signed rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance ($P < .05$).
[c]Effect size = (6-month score − baseline score)/(baseline standard deviation). Positive indicates uvulopalatopharyngoplasty (UPPP) improved the outcome; negative indicates UPPP worsened the outcome. Effect size ≥ 0.20 is clinically important; ≥ 0.80 indicates large effect size.[25]
[d]Global sleep apnea QOL change is a transition measure, which is measured only at outcome.

Table 5. Baseline Comparison of Patients Followed and Lost at 3 Months

Variable	Followed	Lost	*P* Value[a]
Demographics			
No. (%)	35/68 (51)	33/68 (49)	
Age, y, mean ± SD	46 ± 12	44 ± 11	.46
Sex: male, %	77	79	1.00
Race: white, %	83	76	.70
Marital status: married/partner, %	63	70	.61
Employment status: full-time, %	77	84	.19
General health			
American Society of Anesthesiologists class, mean ± SD	1.7 ± 0.7	1.8 ± 0.8	.83
Current smoker, %	11	12	1.00
Alcohol use, drinks/wk, mean ± SD	3.1 ± 5.3	2.6 ± 3.5	.64
SBP in clinic at enrollment, mm Hg, mean ± SD	127 ± 10	131 ± 10	.24
DBP in clinic at enrollment, mm Hg, mean ± SD	81 ± 7	84 ± 5	.13
Anatomy			
Body mass index, kg/m^2, mean ± SD	30 ± 5	31 ± 6	.49
Tonsil size (0-4), mean ± SD	1.5 ± 0.9	2.0 ± 1.0	.054
Friedman stage (1-3), mean ± SD	2.4 ± 0.5	1.9 ± 0.6	**<.001**
Sleep apnea severity			
Apnea-hypopnea index, events/h, mean ± SD	31 ± 32	39 ± 32	.31
Apnea index, events/h, mean ± SD	16 ± 19	25 ± 30	.26
Lowest saturation, %, mean ± SD	85 ± 7	82 ± 7	.23
Symptoms and quality of life			
Sleep apnea symptoms (0-5), mean ± SD	3.7 ± 1.1	3.4 ± 1.3	.20
Awakening with headache, d/wk, mean ± SD	1.6 ± 2.2	2.0 ± 2.1	.46
Sleep apnea problem VAS (0-100), mean ± SD	68 ± 30	75 ± 22	.28
Snoring VAS (0-100), mean ± SD	53 ± 31	58 ± 37	.58
Epworth Sleepiness Scale (0-24), mean ± SD	12.9 ± 5.5	12.2 ± 5.8	.59
Functional Outcomes of Sleep Questionnaire (5-20), mean ± SD	14.3 ± 3.4	14.4 ± 3.1	.90
Sleep apnea treatment			
UPPP included tonsillectomy, %	60	67	.62
Current CPAP therapy at baseline, %	35	55	.13
Prior airway surgery: any, %	29	21	.58
Prior airway surgery: nasal, %	20	15	.75
Prior airway surgery: tonsillectomy or adenoidectomy, %	9	9	1.00
Prior airway surgery: tongue, %	3	9	.35

Abbreviations: CPAP, continuous positive airway pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure; UPPP, uvulopalatopharyngoplasty; VAS, visual analog scale.

[a]*P* value based on Student's *t* test (2-sided) for comparison of means for continuous variables, chi-square test for linear trend for ordinal variables, and Fisher's exact test for dichotomous variables. Bold indicates statistical significance ($P < .05$).

improvement in quality of life using a validated sleep-specific quality-of-life instrument in a multisite study.

The major strength of this study is the enrollment from multiple practices, both university-based and community-based, with many different surgeons from a wide geographic distribution across the United States. The heterogeneity of site types and locations minimizes selection bias, and the heterogeneity of surgical techniques maximizes generalizability (external validity). This degree of heterogeneity and generalizability has not been achieved in an UPPP quality-of-life study before.

Other strengths of this study are its prospective design, use of validated instruments, patient-oriented outcomes assessment, the consistency of the outcomes, and physicians not involved in collecting outcomes data (which would risk reporting bias by patients or physicians). All of these features strengthen the validity of the findings by reducing biases that might exaggerate the treatment effects.

This study has important limitations. The follow-up rate was relatively low. Follow-up is a particular challenge for multisite studies where the follow-up is obtained by mail from research staff not familiar to the research participants. These methods were necessary for this AAO-HNSF-sponsored BEST ENT study. Furthermore, community-based studies include patients who may not be familiar with the importance for the research follow-up. These challenges for follow-up

may be a trade-off for the major strength of generalizability described above. It is worth noting that the follow-up rate was similar to other published multicenter, community-based studies in the otolaryngology literature.[19,26]

One of the main concerns with a low follow-up rate is that the followed patients may have experienced better outcomes that are captured in the outcomes analysis, which would exaggerate the reported treatment effectiveness. It is reassuring that the only baseline differences between patients followed and lost from this cohort were that the followed patients had smaller tonsils and a higher Friedman stage, both of which predict that the *followed patients* would have a *worse* outcome,[2] opposite to the feared bias. That is, to the best of our ability to compare the followed to the lost patients, the followed patients appear more likely to have experienced worse outcomes, which would blunt the reported treatment effectiveness (a conservative bias toward the null hypothesis of no treatment effect). Nevertheless, it is impossible to know how the lost patients actually did, so the low follow-up rate still poses an important risk of bias.

This study was a case series with no control group, which risks regression to the mean, placebo effect, or other natural variation being ascribed to a treatment effect. The risk of a placebo effect is possible because the outcomes are self-reported. Placebo control is not feasible for UPPP because of the visible anatomic effects and the significant postoperative pain. However, the consistency of the benefits across outcome measures suggests there is a real beneficial effect. Furthermore, some of the outcome variables reflect specific events (eg, choking or gasping during sleep, recurrent awakenings from sleep, the number of awakenings with headache per week, and the FOSQ), which are less prone to a placebo effect. Also, the rating of the snoring problem often reflects the concern of a bed partner, which may also be less prone to a placebo effect.

The lack of polysomnography outcomes is a study limitation. However, the purpose of this study was to quantify the effect of UPPP on quality of life and symptoms in a heterogeneous surgical and clinical population. Polysomnography parameters do not correlate well with these outcome measures either at baseline or at outcome.[4] The polysomnographic variability between laboratories and scoring technologists[27] would make it difficult or impossible to compare polysomnography results across multiple different centers in a valid way without a standardized central polysomnography core.[28] The study burden and prohibitive expense of polysomnography would have made the current study and its primary outcome impossible. This study highlights the need for a more accessible and accurate objective surrogate measure of sleep apnea disease burden and outcome.

Surgical complication is another important clinical outcome, and it was not included in this study. Some have suggested that UPPP complications are frequent enough to justify not ever doing UPPP, even in clinical trials.[3] However, it is important to note that the studies that show frequent UPPP complications also found that the complications were usually minor, they often decreased with time, and few patients regretted UPPP.[24,29] Surgical complications produce an adverse effect on quality of life, so the improvement we observed in quality of life suggests the patients experienced a net benefit.

Some of the directions for future research include assessment of cardiovascular outcomes of UPPP, assessment of subjective and objective patient-oriented outcomes of multilevel surgery, prognostication of beneficial outcomes, and the effects of surgery in subgroups. The Studying Life Effects and Effectiveness of Palatopharyngoplasty parent study has data to begin to address these directions and will be analyzed separately.

Conclusions

This prospective, multicenter, university- and community-based study provides evidence that UPPP significantly improves disease-specific quality of life and sleep apnea symptoms in patients with sleep apnea. Validity may be limited by significant loss to follow-up and absence of an unoperated control group.

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Disclosures

Competing interests: B. Tucker Woodson is a consultant for Medtronic, Johnson & Johnson, Resmed, and Inspire Medical and has a device patent with Philips Respironics. Timothy Smith is a consultant for Intersect ENT and Entrigue and received a grant from the National Institutes of Health. Michael G. Stewart is on the medical advisory board of Merck.

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