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Comparison of Traditional Upper Airway Surgery and Upper Airway Stimulation for Obstructive Sleep Apnea

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Abstract

Objective: To compare patients with moderate-severe obstructive sleep apnea (OSA) undergoing traditional single and multilevel sleep surgery to those undergoing upper airway stimulation (UAS).

Study Design: Case control study comparing retrospective cohort of patients undergoing traditional sleep surgery to patients undergoing UAS enrolled in the ADHERE registry.

Setting: 8 multinational academic medical centers.

Subjects and Methods: 233 patients undergoing prior single or multilevel traditional sleep surgery and meeting study inclusion criteria were compared to 465 patients from the ADHERE registry who underwent UAS. We compared preoperative and postoperative demographic, quality of life, and polysomnographic data. We also evaluated treatment response rates.

Results: The pre and postoperative apnea hypopnea index (AHI) was 33.5 and 15 in the traditional sleep surgery group and 32 and 10 in the UAS group. The postoperative AHI in the UAS group was significantly lower. The pre and postoperative Epworth sleepiness scores (ESS) were 12 and 6 in both the traditional sleep surgery and UAS groups. Subgroup analysis evaluated those patients undergoing single level palate and multilevel palate and tongue base traditional sleep surgeries. The UAS group had a significantly lower postoperive AHI than both traditional sleep surgery subgroups. The UAS group had a higher percentage of patients reaching surgical success, defined as a postoperative AHI $<$20 with a 50% reduction from preoperative severity.

Conclusion: UAS offers significantly better control of AHI severity than traditional sleep surgery. Quality life improvements were similar between groups.

Keywords

obstructive sleep apnea, sleep apnea, Rhinology, Otolaryngology, sleep surgery, sleep disordered breathing, sleep medicine

Introduction

Obstructive sleep apnea (OSA) is a disease characterized by recurrent episodes of nocturnal upper airway obstruction leading to ventilatory disruption and sleep disturbance. In June of 1980, Dr. Colin Sullivan successfully showed positive pressure delivered to the airway could eliminate the upper airway obstruction, effectively treating OSA.[1] Continuous positive airway pressure (CPAP) was born. However, despite the ability to customize the delivery of positive pressure and increase the comfort of therapy, many patients struggle to tolerate this intervention. Weaver et al showed 46%-83% of patients were unable to adhere to therapy greater than 4 hours per night.[2]

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Table 1. Airway Surgery Categorization.

Airway Level	Specific Type of Surgery
Palate (n = 158)	• Traditional UPPP +/- tonsillectomy (n = 129) • Expansion sphincter pharyngoplasty (n = 61) • Z-plasty (n = 21) • Radiofrequency ablation of the palate (n = 59) • no specified (n = 20)
Tongue-base (n = 74)	• Genioglossus advancement (n = 3) • Radiofrequency tongue base ablation (n = 0) • Hyoid Suspension (n = 29) • Tongue-base glossectomy (TORS, lingual tonsillectomy, etc) (n = 44) • Partial Pharyngectomy (n = 10)
Epiglottis (n = 2)	• Epiglottectomy (n = 2)

Because CPAP is an unacceptable treatment option for many patients with OSA, alternative therapies have been developed. In 1981 Fujita published the use of uvulopalatopharyngoplasty (UPPP) for the treatment of OSA.[3] This involved removing residual palantine tonsillar tissue and redundant mucosa along the tonsillar pillars and soft palate in an effort to increase the size of the oropharyngeal airway. This procedure offered meaningful benefit for many patients and significantly improved the apnea burden.[4] A meta analysis by Caples et al showed a 33% reduction in the AHI with this intervention.[5] Since the introduction of the UPPP, further refinements of the procedure have been developed to remove redundant tissue and reconstruct and support normal anatomy, thus limiting upper airway obstruction at the level of the velum and oropharynx.[6-12] These interventions are commonly combined with procedures designed to eliminate obstruction at the tongue base, allowing for alleviation of multilevel upper airway obstruction.[13]

Upper airway stimulation (UAS) is an alternative option for the treatment of OSA in select patients who have been unable to tolerate CPAP. UAS received FDA approval in 2014 (Inspire Medical Minneapolis MN), the same year the Stimulation Therapy for Apnea Reduction (STAR) trial was published.[14] This technology takes advantage of the anatomic branching pattern of the hypoglossal nerve and selectively stimulates the genioglossus muscle in conjunction with respiration. This allows for stiffening and contraction of the tongue, alleviating the upper airway obstruction leading to OSA. It has shown improvement in both symptoms and objective polysomnographic variables. The ADHERE registry is an ongoing international, multi-center registry of patients undergoing UAS therapy from 2010-2019.[15] Its goal is to measure safety, objective and subjective OSA outcomes efficacy, and therapy adherence in a real-world postmarket setting.

With this study we compare objective polysomnographic and subjective symptom outcome variables from the the ADHERE registry to an international multi-center cohort of similar CPAP intolerant OSA patients undergoing traditional OSA surgical interventions for the treatment of OSA. We also perform a subanalysis of those patients undergoing traditional multilevel OSA surgery. We hypothesize that UAS will show superior outcomes to both single and multilevel traditional OSA surgical interventions.

Methods

A retrospective, international, multi-center chart review was designed. The authors' surgical databases of patients undergoing surgical intervention for OSA between 2003-2019 were queried. The traditional airway surgery dataset included patients with a history of OSA, who were intolerant to CPAP, and underwent surgical intervention. We compared this dataset to the ongoing ADHERE registry study. Each center evaluated their surgical database and collected the study datapoints on a common Excel template. The datapoints from each center were then combined and analyzed.

We documented demographic data including gender, body mass index (BMI), and age. We also collected the preoperative AHI, Epworth Sleepiness Score (ESS), drug-induced sleep endoscopy (DISE) findings if available, and tonsil size. A variety of airway surgeries were utilized and were categorized based on airway level. (Table 1). Multilevel procedures were defined as a surgery on at least 2 or more airway levels. Post-operative outcomes included BMI, AHI, and ESS.

The Upper Airway Stimulation dataset from the ADHERE registry is tracking AHI and ESS in a standard of care setting at pre-operative baseline and at 12-months following UAS implantation. The follow-up sleep study performed at 12-months is a full night polysomnogram (PSG) or home sleep test (HST) with therapy active. The design and results of this registry have been previously described.[16]

To ensure similar comparisons between the two groups, we first selected patients from the traditional airway surgery cohort that would have met UAS criteria: specifically, AHI between 15-65 events/hour, BMI $\leq$35, and the absence of

Table 2. Baseline Demographics between Groups.

	Airway Surgery (n = 233)	Upper Airway Stimulation (n = 465)	*P*-value
Age (years)	46.1 ± 11.8 46 [38, 55]	59.5 ± 10.8 60 [52, 68]	<.001
Gender (% Male)	88%	83%	.10
Baseline BMI (kg/m^2)	28.3 ± 3.4 28.5 [25.9, 31.0]	29.5 ± 3.9 29.4 [26.6, 32.0]	<.001
Baseline AHI (events/hour)	35.0 ± 13.1 33.5 [25.0, 44.0]	35.5 ± 15.0 32.0 [23.9, 43.5]	.88
Baseline ESS	11.3 ± 5.1 12.0 [8.0, 15.0]	11.9 ± 5.5 12.0 [8.0, 16.0]	.22

complete concentric collapse at the velum during drug induced sleep endoscopy. We then compared the post-operative AHI and ESS between the traditional airway surgery cohort and ADHERE registry. We also performed a subgroup analysis of single-level palate and multi-level surgery compared to the ADHERE registry. Single-level tongue-base surgery was excluded from the subgroup analysis as there were only two patients. The responder rate to surgery was measured using two definitions: the Sher Criteria (50% reduction in AHI, and final AHI ≤20), and final AHI ≤15.

Descriptive statistics were calculated for all variables. *P*-values comparing baseline demographics were calculated with the Wilcoxon rank sum test and Fishers exact test, due to non-normal distribution. Similarly, due to non-normal distributed AHI, data is shown as median. Wilcoxon rank sum was used for *P*-values when comparing AHI and responder rates between UAS and traditional airway surgery. Non-parametric ANOVA using the Kruskal–Wallis test was used to calculate differences in Sher Responder rate between UAS and the traditional airway surgery subgroups. Dunn's test for multiple comparisons was used to calculate *P*-value when comparing AHI and responder rates between UAS and the surgery subgroups.

Data from the authors' surgical databases and the ADHERE registry was approved by the respective sites' Institutional Review Board (IRB) or Ethics Committee.

Results

There were 284 patients from 8 centers in the traditional airway surgery database. Of these, 51 were excluded from analysis due to failure to meet UAS indications (44 had complete concentric collapse at the velum, six had an AHI outside 15-65 events/hour, and one had a BMI >35). Thus, there were 233 patients that received airway surgery and would have met UAS criteria. There were 465 patients in the ADHERE registry that were implanted with UAS and had follow-up data through 12-months. We only included those enrolled in the ADHERE registry who had undergone implantation, had postoperative sleep study assessment, and follow-up data through 12 months. 66% of the traditional airway surgery group had surgical intervention after 2014 overlapping with the UAS timeframe. 59% of the traditional airway surgery group underwent DISE. 100% of the UAS group underwent DISE. Both groups were predominantly male, overweight, with severe OSA and excessive daytime sleepiness. The traditional surgery group was younger and tended to have a slightly lower BMI; both were statistically significant. (Table 2). The most common traditional airway surgery was single-level palatal surgery (68%), followed by multi-level surgery (31%). Isolated tongue-base surgery was not common (<1%).

The airway surgery group had a follow-up sleep study 173 ± 162 days after surgery (Median: 121 [95,188]). The type of sleep study was not available though our analysis. The UAS group had their sleep follow-up 383 ± 169 days after surgery (Median: 366, [306-422]), and was 70% diagnostic PSG, 28% home sleep test, and 2% unknown type. The shorter airway surgery follow-up duration compared to UAS was statistically significant.

Looking at OSA outcomes, both groups had similar baseline AHI of 35 events/hour and both groups had a significantly lower post-operative AHI compared to baseline. However, the cohort treated with UAS had a significantly larger reduction of AHI (−21.4 ± 17.8 vs −15.9 ± 17.3 events/hour, $P < .001$) than those treated with airway surgery. Regarding patient-reported symptoms, baseline ESS was similar in both groups, and both had a post-operative decrease. The ESS decrease between airway surgery and UAS was similar, with a non-significant trend towards larger decrease in sleep surgery (−5.8 + −5.2 vs −4.7 + −5.2, $P = .06$). (Table 3).

A subset anaylais was then performed. The airway surgery group was further evaluated by type of surgery (eg, single-level palate vs multi-level) and compared to UAS. While there was no significant difference in baseline AHI between the 3 groups ($P = 0.15$), the post-operative AHI was consistently lower in the UAS group than single-level surgery ($P = 0.002$) and multi-level surgery ($P = 0.013$). (Figure 1).

Table 3. Post-operative Outcomes between Airway Surgery and UAS groups.

	Airway Surgery	Upper Airway Stimulation	*P*-value
Final AHI			
Mean ± SD (n)	19.3 + −16.3 (196)	14.1 + −14.4 (465)	<.001
Median [IQR]	15.0 [6.9, 27.7]	10.0 [4.1, 18.0]	
AHI change			
Mean ± SD (n)	−15.9 + −17.3 (196)	−21.4 + − 17.8 (465)	<.001
Median [IQR]	−15.7 [−27.9, −6.7]	−19.6 [−30.7, −13.0]	
Final ESS			
Mean ± SD (n)	5.9 + − 4.0 (129)	7.3 + −4.7 (415)	.01
Median [IQR]	6.0 [3.0, 9.0]	6.0 [3.5, 10.0]	
ESS change			
Mean ± SD (n)	−5.8 + − 5.2 (124)	−4.7 + −5.2 (388)	.06
Median [IQR]	−5.0 [−9.0, −2.0]	−4.0 [−8.0, −1.0]	

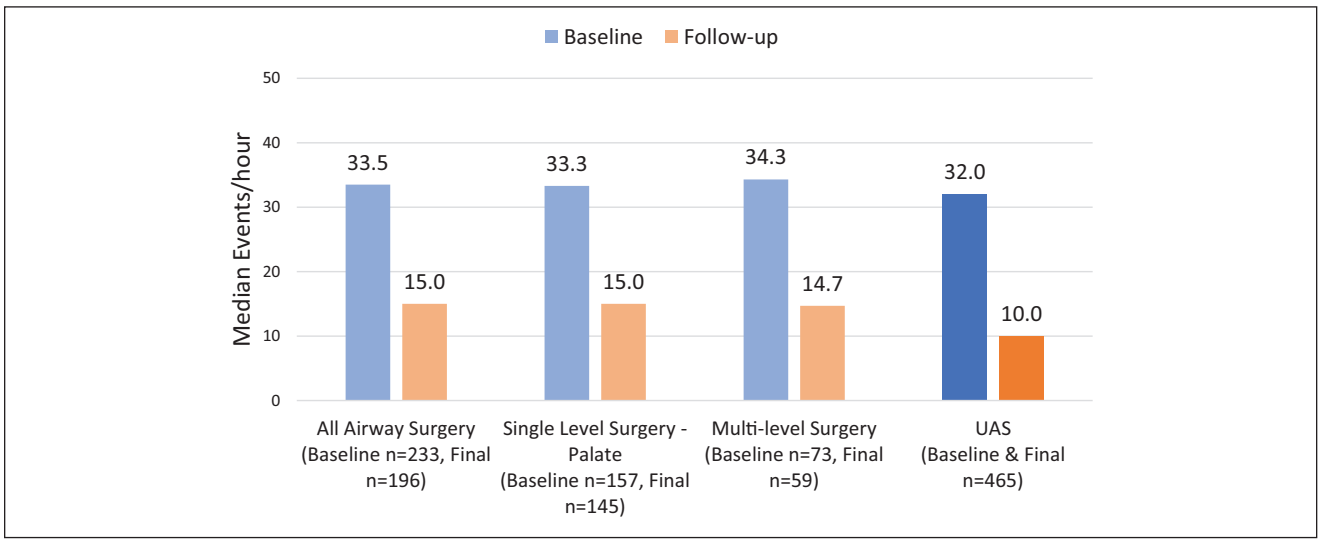

Figure 1. Pre and postoperative Apnea Hypopnea Index.

The surgical response rate was also calculated for each of the four groups using two response definitions: the Sher criteria (50% decrease in AHI AND final AHI ≤20) and postoperative AHI ≤15. The Sher surgical response rate of all traditional airway surgery, single level intervention, or multi-level intervention, was 48-49%. By comparison, the UAS surgical response rate was 70%. Non-parametric ANOVA demonstrated a difference in Sher response rate between the four groups ($P < .001$) and the pairwise comparison, adjusted for multiple comparisons, between UAS and the three surgical groups (all traditional surgery, single-level, multi-level) showed UAS had a statistically significant higher Sher responder rate than each of the three surgical groups.

When using the AHI ≤15 criteria, the UAS responder rate was also consistently higher than all airway surgeries ($P < .001$). The non-parametric ANOVA also revealed a difference in the AHI ≤15 responder rate between UAS and the three surgical groups ($P = .003$). Pairwise comparison of AHI ≤15 responder rate between UAS and single-level surgery was statistically significant, but was not significant between UAS and multi-level surgery. (Table 4).

Discussion

The initial STAR trial data, which supported the FDA approval of UAS, showed markedly improved objective measures of OSA with significant reductions in the apnea hypopnea index (AHI) and improvement in the oxygen desaturation index (ODI). In addition, subjective symptom assessments also improved. There was a significant reduction in the Epworth sleepiness score (ESS) and improvement in the Functional Outcomes of Sleep Questionaire (FOSQ).[14] The cohort of patients in the STAR trial was

Table 4. Response Rate, by Surgery Type.

Responder Definition	Airway Surgery (n = 196)	Single level - Palate (n = 140)	Multi-level (n = 54)	UAS (n = 465)	*P*-value (UAS vs airway surgery)[1]	*P*-value (UAS vs single level – Palate)[2]	*P*-value (UAS vs Multi-level)[2]
AHI ≤15	51%	51%	52%	66%	<.001	.004	.11
AHI ≤20 and 50% reduction (Sher Criterion)	48%	49%	48%	70%	<.001	<.001	<.001

Note. 1. Wilcoxon rank sum test.
2. Dunn's test, adjusted for multiple comparisons.

followed and reassessed at 18, 24, 36, 48, and 60 months after initiation of the study. At each of these time points, the improvements seen in AHI, ODI, ESS, and FOSQ remained stable.[17-21] Following publication of the original STAR data, clinical data from single and multicenter cohorts became available. Kent et al reported on 20 patients, showing significant reductions in AHI and ESS.[22] Heiser et al reported a cohort of 31 patients with a treatment AHI of 7.1 compared to baseline of 32.9.[23] Huntley et al compared cohorts of patients at two separate academic centers. The authors showed similar results between insitutions with significant improvements in both symptom and polysomnogram variables. Usage was more than 6 hours per night almost one year after implantation.[24]

The ADHERE registry is a multi-institutional, international, registry of patients undergoing UAS for management of OSA. This study is ongoing and collects data on UAS patients to evaluate demographic information, preoperative disease severity, surgical outcomes, surgical and device related complications, and device usage and compliance. The initial study was published in 2018 and included 301 patients. This study showed significant improvement in both AHI and ESS variables with an excellent safety profile. In addition, the average usage was 6.5 hours per night with 96% of patients utilizing therapy greater than 20 hours per week.[15] A follow-up study included 508 patients and showed good control of apnea burden. It also showed that increasing age and a lower BMI were predictive of treatment success.[16]

This is the first study to retrospectively compare the emerging UAS therapy outcomes to multiple surgical approaches for OSA. Traditional airway surgery remains the most common surgical approach for treating OSA, with approximately 35 000 cases done annually.[25] The traditional approach to the management of OSA has involved the identification of the single or multilevel source of upper airway obstruction and subsequently addressing it. These approaches involve removal of redundant tissue at the palate, oropharynx, and tongue base. In recent years, this has been combined with reconstruction of the palatine and pharyngeal musculature. Historically, the uvulopalatopharyngoplasty has been the most commonly performed procedure to address obstruction at the palate and oropharynx. Tongue base obstruction has been managed through removal of lingual tonsillar tissue and/or some of the tongue musculature. While these surgical approaches have worked for some, on average, there have been challenges with the ability to achieve consistent AHI reduction with durable results, particularly in patients with moderate to severe OSA.[26] In light of the high efficacy and durability results from UAS, we wanted to understand how these compared against traditional airway approaches to help inform our therapy choices.

Previous literature has compared UAS to traditional surgical approaches, with results that favored UAS. When comparing UAS to UPPP, Shah et al found better control of apnea burden in the UAS group with a significantly larger proportion reaching surgical cure of AHI less than 5.[27] When comparing UAS to expansion sphincter pharyngoplasty, Huntley et al found the UAS group had a significantly lower postoperative AHI and significantly higher surgical success rate.[28] In a separate publication, when comparing UAS to transoral robotic (TORS) base of tongue reduction, outcome data showed a significantly higher success and surgical cure rate with a lower postoperative length of stay and readmission rate in the UAS group.[29]

With this study we compare a large cohort of patients, collected in a multi-institutional fashion, who have undergone traditional surgical intervention to the multi-institutional data from the ADHERE registry. We attempted to match cohorts by imposing the same demographic and disease severity selection criteria to both groups. In similarly selected patients we found the UAS group to be significantly older with an increased BMI, but with similar baseline polysomnographic and quality of life indices. UAS may have been a more acceptable intervention to an older demographic of patients given UAS's previously published outcome statistics and safety profile, especially favoring an older population, particulary when compared to more traditional surgical interventions.[15,16,30] More traditional airway surgery may expose older patients to a higher risk of post-operative complications and longer post-operative hospital stay.[31,32]

The outcome measures of this study assessed the polysomnographic and quality of life improvement in patients undergoing traditional sleep surgery to the ADHERE registry. The most common traditional intervention was single level palate surgery which included traditional UPPP, expansion

sphincter pharyngoplasty, Z-palatoplasty, and radiofrequency ablation of the palate. 31% of the cohort underwent a multilevel approach, addressing obstruction at the palate, oropharynx, and/or hypopharynx. We saw significantly lower AHI with significantly greater change in AHI in the ADHERE group compared to all patients undergoing traditional surgery. The AHI reduction the the ADHERE and traditional surgery groups were 21.4 and 15.9 respectively. Although these reach statistical significance, we are unable to assess clinical significance with these datapoints alone. However, the response rates (Table 4) are significantly greater in the UAS group which may suggest clinical benefits.

When we performed a subset analysis of those undergoing isolated palate surgery and those undergoing multilevel surgery for comparison to the ADHERE cohort, we found similar results. UAS offered a significantly improved AHI along with significantly better rates of surgical success than palate or multilevel surgery.

This study represents the first multi-institutional comparison of traditional sleep surgery to UAS and allows for assessment of large cohorts of patients. In many patients, UAS provides multilevel improvement of upper airway obstruction, at both the tongue base and palate, not addressed by UPPP, or its variants, alone. In this study, we are able to demonstrate that patients treated with UAS have superior efficacy in PSG outcomes compared to patients that underwent palatal or multilevel palate and tongue base surgery. While we did not collect post-operative safety data in this study, prior literature suggests UAS may be better tolerated. Traditional airway surgery has been shown to have an 11% rate of respiratory distress and 3-5% rates of postoperative bleeding and dehydration.[33] By comparison, these complications were not seen in UAS. The most common UAS post-operative complications were $<$1-2%, consisting of temporary tongue weakness and temporary dysphagia.[16]

Despite these strengths, there are some limitations inherent in this study. The study was designed as a retrospective analysis, there are baseline differences in demographics, and there is not contemporary accrual of the entirety of both cohorts, limiting definitive comparison of our study groups. This creates the possibility of selection bias between groups. Because of the retrospective design, our evaluation of patient reported quality of life was limited to the Epworth Sleepiness Score. In addition, there were differences in follow-up intervals in the traditional surgical and ADHERE groups. Lastly, we do not have consistency in the scoring rules used to score the sleep studies in the patients undergoing traditional soft tissue surgery. This limits our ability to directly compare AHI between the two groups. These weaknesses could be rectified by designing a prospective assessment with strict follow-up protocol. However, the evaluation presented here represents differing institutional treatment algorithms and allows for a "real world" comparison.

Conclusion

Patients treated with Upper airway stimulation have improved objective and comparable subjective outcomes when compared to similar patients treated with traditional airway surgery. This study represents the largest and first multicenter comparison of UAS to traditional surgical interventions for OSA and suggests that for selected patients, UAS is a viable treatment option.

Authors' Note

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Declaration of Conflicting Interests

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