Original Article

Comparing Upper Airway Stimulation to Expansion Sphincter Pharyngoplasty: A Single University Experience

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Abstract

Introduction: Expansion sphincter pharyngoplasty (ESP) is a surgical option for patients with obstructive sleep apnea (OSA). Upper airway stimulation (UAS) is an alternative that has shown success in initial outcomes studies. We compare outcomes of a cohort of patients undergoing UAS to ESP.

Methods: We compared demographic and polysomnographic data of the UAS to ESP cohorts. We also calculated the proportion of patients achieving surgical success.

Results: The ESP cohort consisted of 33 patients. The mean preoperative Apnea-Hypopnea Index (AHI), O_2 nadir, Epworth Sleepiness Scale (ESS), and BMI were 36.47 ± 20.01, 82.63 ± 5.37, 10.69 ± 4.42, and 29.6 ± 4.49, which improved to 13.47 ± 18.74, 84.84 ± 5.48, 7.00 ± 5.81, and 29.92 ± 4.59 postoperatively. There was a 63.64% success rate. The UAS cohort consisted of 75 patients. The mean preoperative AHI, O_2 nadir, ESS, and BMI were 36.76 ± 20.72, 80.24 ± 8.43, 11.18 ± 4.16, and 29.50 ± 3.96, which improved to 7.25 ± 11.19, 88.71 ± 3.25, 5.36 ± 3.35, and 29.36 ± 3.68 postoperatively. The success rate was 86.67%. We found a significant difference in gender, age, preoperative AHI, postoperative AHI, postoperative O_2 nadir, surgical success, and patients reaching an AHI less than 10 and 5.

Conclusion: Upper airway stimulation is a new surgical option for select patients with OSA showing comparable or improved outcomes to a cohort of patients undergoing ESP.

Keywords

obstructive sleep apnea, sleep apnea, sleep disordered breathing, sleep medicine, adult OSA surgical treatment

Introduction

Continuous positive airway pressure (CPAP) has long been considered the primary treatment modality for obstructive sleep apnea (OSA). Although highly effective, patient compliance has remained a significant challenge. Using a definition of adherence of greater than 4 hours of nightly use, rates of nonadherence have ranged from 46% to 83%.[1] Because such a large proportion of patients impacted by OSA are unable to tolerate CPAP, alternative treatment options including positional, dental, and surgical therapies are utilized.

Upper airway stimulation (UAS) (Inspire Medical Systems, Minneapolis, Minnesota, USA) therapy has emerged as a highly effective treatment alternative, providing improvement in both objective polysomnographic (PSG) variables, but also in subjective quality of life and daytime sleepiness measures. It acts through selectively stimulating the genioglossus muscle, alleviating obstruction in a multilevel fashion at the level of the velum and tongue base. Initial outcomes of UAS were evaluated through the STAR trial and have been followed through 48 months. These publications have shown endurance of improvement of all treatment outcome variables.[2-6]

To date, no study has compared the outcomes of UAS to any traditional surgical approach for OSA treatment. Uvulopalatopharyngoplasty (UPPP) is a surgical technique commonly used for the treatment of OSA in those patients unable to tolerate CPAP, first introduced by Fujita and colleagues[7-9] in the 1980s. At our institution, we perform expansion sphincter pharyngoplasty (ESP), a variation of UPPP first introduced by Pang and Woodson[10] in 2007. In

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Table 1. Comparison of Demographic and Preoperative Values of the Expansion Sphincter Pharyngoplasty (ESP) and Upper Airway Stimulation (UAS) Cohorts.

	ESP	UAS	*P*
Gender	28 male, 5 female	50 male, 25 female	.04
Age	43.48 ± 11.92	61.67 ± 11.92	<.001
Preoperative Apnea-Hypopnea Index	26.69 ± 20.32	36.76 ± 20.72	.003
Preoperative O_2 nadir	82.63 ± 5.46	80.24 ± 8.43	.285
Preoperative Epworth Sleepiness Scale	10.69 ± 4.51	11.18 ± 4.16	.565
Preoperative BMI	29.6 ± 4.56	29.5 ± 3.96	.989

this study, we compare subjective and objective treatment outcomes of a cohort of patients undergoing ESP to a cohort undergoing UAS. We hypothesize that those patients treated with UAS will have improved outcomes compared to the ESP population.

Methods

After approval from the Thomas Jefferson University Institutional Review Board, we performed a retrospective review of the senior author's surgical database. We included all patients undergoing ESP in isolation, without additional sleep surgery, between 2011 and 2016 or UAS between 2014 and 2016, a preoperative sleep study, and completion of a postoperative sleep study after ESP or postoperative titration PSG after UAS. We excluded all patients who did not have follow-up with a postoperative sleep study.

Our surgical criteria for UAS implantation include diagnosis of moderate to severe OSA with an Apnea-Hypopnea Index (AHI) greater than 15, inability to tolerate CPAP therapy, a central apnea index less than 25% of the overall AHI, and favorable anatomy on drug-induced sleep endoscopy (DISE). We do not use BMI greater than 32 as an absolute contraindication to implantation. In 2013, we started to routinely perform DISE at our institution. Prior to that time, we performed ESP on all patients who appeared to have obstruction at the level of the velum on office exam. Since performing DISE as part of our preoperative workup, we now perform ESP on patients with complete concentric collapse at the level of the velum (who don't have evidence of significant maxillary or mandibular deficiency) in isolation or as part of a staged approach to treating multilevel collapse. However, at many institutions, where DISE is not part of the operative planning process, palate surgery, such as ESP, is the primary treatment modality for treatment of OSA in those unable to tolerate CPAP.

Data for this study were gathered in a retrospective manner and included demographic variables, preoperative sleep study, surgical, and postoperative sleep study data. We compared demographic data including age, gender, BMI, and pre- and postoperative Epworth Sleepiness Scale (ESS) scores of the ESP to UAS cohorts. We then compared preoperative PSG outcomes, postoperative PSG outcomes, proportion of patients reaching surgical success, and proportion of patients reaching a postoperative AHI less than 15, 10, and 5 of the ESP to UAS cohorts. We defined surgical success as a decrease in postoperative AHI by at least 50% and to a value of less than 20.

Statistical analysis was performed using SPSS version 24 software. Continuous variables, including age, ESS, BMI, AHI, and O_2 nadir, were analyzed in a nonparametric manner using a Mann-Whitney U Test. Categorical variables, including gender, rate of surgical success, and rate of postoperative AHI less than 15, 10, and 5, were analyzed using a Fisher's exact test.

Results

At the time of this analysis, we had performed 96 UAS implantations at our institution, 75 of which had completed postoperative titration PSG and were included. This cohort consisted of 50 men and 25 women with a mean age of 61.67 ± 11.92 years. During the study period, 97 patients underwent ESP, with 33 patients meeting inclusion criteria and included in the analysis. This consisted of 28 men and 5 women with a mean age of 43.48 ± 11.92 years. The preoperative mean ± standard deviation values of BMI, ESS, AHI, and O_2 saturation nadir of both cohorts are presented in Table 1. The postoperative values are presented in Table 2.

Of the UAS cohort, 86.67% reached surgical success; 89.33%, 77.33%, and 58.67% reached a treatment AHI of less than 15, 10, and 5, respectively. Of the ESP cohort, 63.64% reached surgical success; 75.76%, 54.55%, and 36.36% reached a postoperative AHI of less than 15, 10, and 5, respectively (Table 3) (Figure 3).

In comparing the 2 cohorts, we found significant differences in gender breakdown ($P = .04$), mean age ($P < .001$), mean preoperative AHI ($P = .003$), postoperative AHI ($P = .003$), postoperative O_2 saturation nadir ($P = .001$), rate of surgical success ($P = .008$), and rate of postoperative AHI less than 10 and 5 ($P = .017$, $P = .027$). The increased number of patients reaching a treatment AHI less than 15 approached significance ($P = .065$) (Figures 1 and 2).

Table 2. Comparison of Postoperative Values of the Expansion Sphincter Pharyngoplasty (ESP) and Upper Airway Stimulation (UAS) Cohorts.

	ESP	UAS	*P*
Postoperative Apnea-Hypopnea Index	13.47 ± 19.03	7.25 ± 11.19	.003
Postoperative O_2 nadir	84.84 ± 5.57	88.71 ± 3.25	.001
Postoperative Epworth Sleepiness Scale	7.00 ± 5.96	5.36 ± 3.35	.516
Postoperative BMI	29.91 ± 4.66	29.36 ± 3.68	.675

Table 3. Comparison of Rates of Surgical Success and Treatment AHI Less Than 15, 10, and 5 Between the Expansion Sphincter Pharyngoplasty (ESP) and Upper Airway Stimulation (UAS) Cohorts. Values represent percentages.

	ESP	UAS	*P*
Surgical success	63.64	86.67	.008
Postoperative Apnea-Hypopnea Index <15	75.76	89.33	.065
Postoperative Apnea-Hypopnea Index <10	54.55	77.33	.017
Postoperative Apnea-Hypopnea Index <5	36.36	58.67	.027

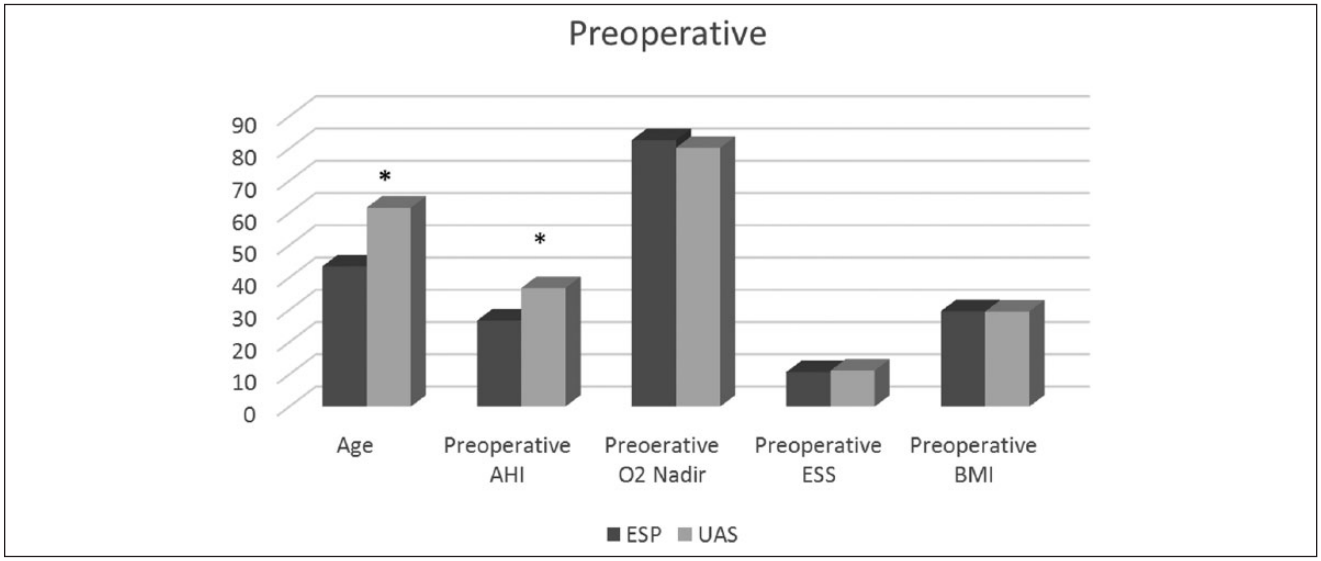

Figure 1. Comparison of demographic and preoperative values of the expansion sphincter pharyngoplasty (ESP) and upper airway stimulation (UAS) cohorts. Significant differences denoted by *.

Discussion

Uvulopalatopharyngoplasty was first introduced over 30 years ago. It was designed to relieve obstruction at the level of the palate by removing redundant tissue and provide a surgical option for treatment of OSA.[7-9] In 2007, Pang and Woodson[10] developed expansion sphincter pharyngoplasty in an effort to treat obstruction from the palate and lateral pharyngeal walls. During this procedure, any palatine tonsillar tissue is removed and the palatopharyngeus muscle is pexied in a vector toward the hamulus in an effort to expand the size of the velum. In their initial publication, they evaluated 22 patients undergoing ESP and 23 undergoing UPPP. They found a significant improvement in AHI and oxygen desaturation nadir in both groups. When comparing the ESP and UPPP cohorts, they found a larger proportion of ESP patients reaching treatment success. They defined success via 2 methods, a 50% decline in postoperative AHI and AHI less than 20 and a 50% decline in postoperative AHI and AHI less than 15. The ESP was significantly more successful than UPPP using both criteria.[10]

Pang et al[11] performed a meta-analysis in 2016 in which they included 4 studies evaluating ESP outcomes. They found an overall success rate of 86.3%, defining success as a 50% decline in postoperative AHI and AHI less than 20. When comparing outcomes to a control group undergoing UPPP, there was a significant improvement in postoperative AHI in the ESP group.[11]

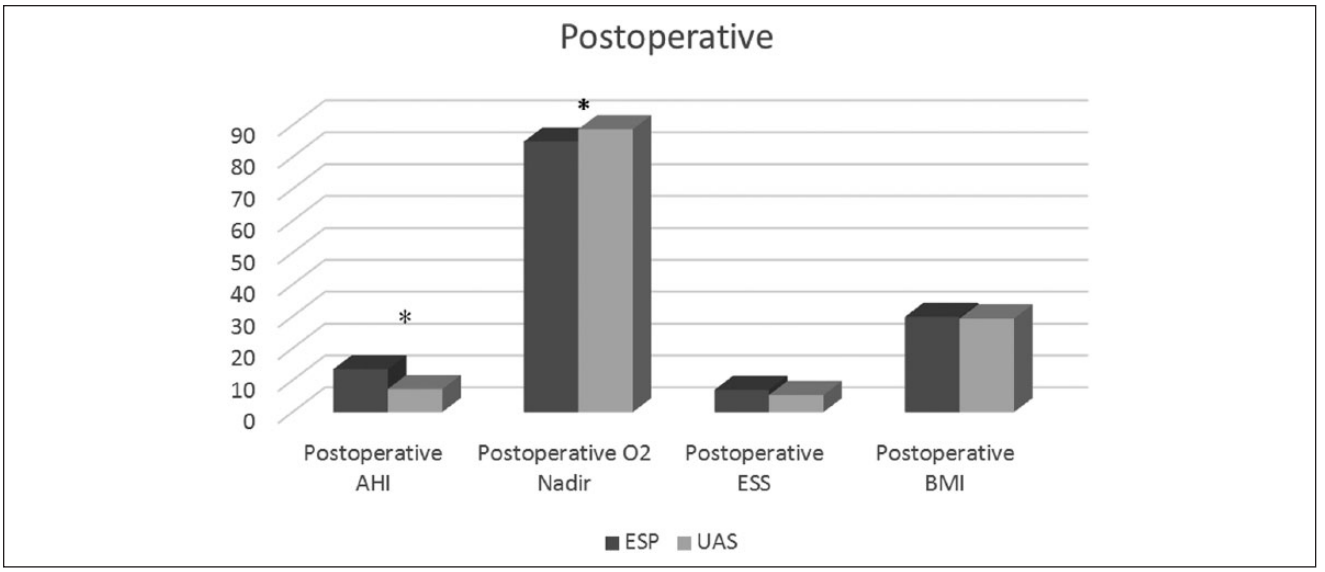

Figure 2. Comparison of postoperative values of the expansion sphincter pharyngoplasty (ESP) and upper airway stimulation (UAS) cohorts. Significant differences denoted by *.

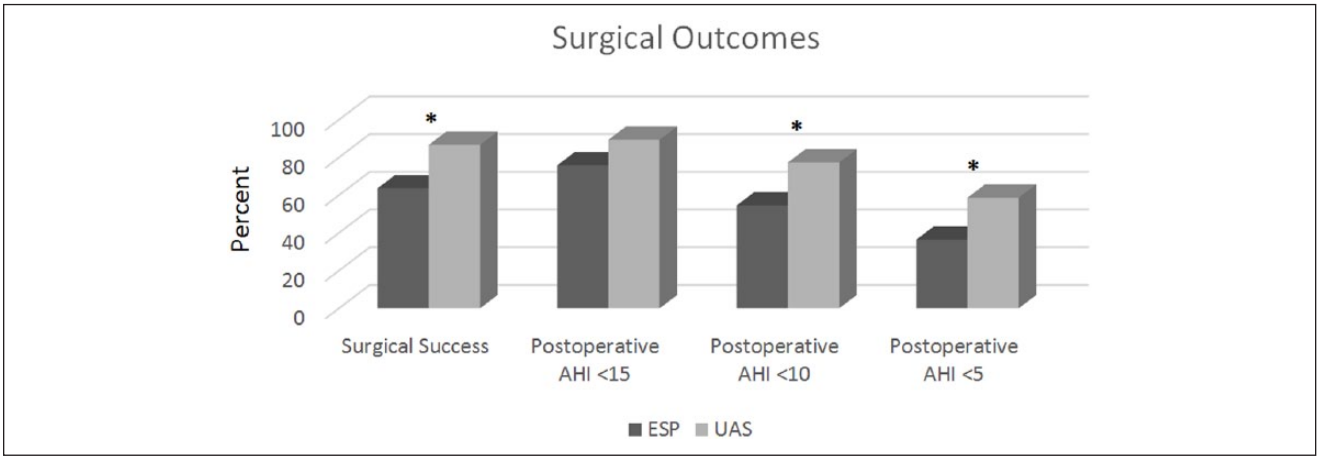

Figure 3. Comparison of rates of surgical success and treatment Apnea-Hypopnea Index (AHI) less than 15, 10, and 5 between the expansion sphincter pharyngoplasty (ESP) and upper airway stimulation (UAS) cohorts. Significant differences denoted by *.

Vicini et al[12] performed a study of patients undergoing multilevel surgery at the palate and tongue base. They compared 12 patients undergoing transoral robotic tongue base resection and UPPP to 12 patients undergoing transoral robotic tongue base resection and ESP. They found a lower postoperative AHI in the ESP group, which reached the limit of significance when compared to the UPPP group, $P = .05$.[12]

Upper airway stimulation therapy completed its clinical trial with the STAR trial and was available for clinical use in 2014. Since that time, the 18-, 24-, 36-, and 48-month STAR trial extension studies have been supplemented by single-institution outcome studies.[2-6] Kent at al[13] evaluated 20 patients undergoing UAS implantation and found a significant improvement in both AHI and ESS with treatment, in agreement with the STAR trial outcomes. Heiser et al[14] reviewed a cohort of 31 patients who underwent titration PSG at 2 months postoperatively and home sleep testing at 6 and 12 months. They found the mean AHI to decline from a baseline of 32.9 to 11.5 during the entire night of the 2-month titration PSG. During the 6- and 12-month follow-up home sleep studies, they found treatment AHIs of 7.6 and 7.1, respectively.[14]

This study represents the largest single-institution cohort of patients undergoing UAS implantation outside of a clinical trial setting. In the 75 patients undergoing postoperative titration PSG, we found a significant reduction in AHI, improvement in oxygen desaturation nadir, and fall in ESS. In addition, the majority of patients reached surgical success with over half

obtaining cure. When compared to a cohort of patients undergoing ESP, we found a larger proportion of women, older patients, and a higher preoperative AHI in the UAS cohort. This suggests that UAS may be appealing to a wider population of OSA patients. Postoperative outcomes also showed a significant improvement in the AHI and oxygen desaturation nadir of the UAS cohort when compared to those undergoing ESP. Lastly, we found significantly more patients reaching surgical success, an AHI less than 10, and an AHI less than 5 in the UAS cohort. More UAS patients reached an AHI less than 15, and this approached significance.

The primary limitation of this study is its retrospective design. Conclusions regarding ESP and UAS efficacy comparisons are limited by lack of randomization to the 2 treatments. The 2 populations were also divergent in baseline variables. A significant number of patients undergoing ESP did not have postoperative PSG, thus limiting the size of the included cohort. It is feasible that those patients obtaining posttreatment PSG in the ESP cohort do not represent the outcomes of all patients undergoing the procedure. In addition, ESP is performed on patients with complete concentric collapse of the palate and does not provide multilevel relief of obstruction. However, this study does provide an outcome summary and comparison to a widely used traditional surgical approach for OSA. Finally, our UAS PSG outcomes are determined through a titration PSG. Future studies with prospectively randomized patients would be needed to explore these preliminary conclusions.

Conclusion

Historically, surgical options for the treatment of OSA were limited to tracheostomy, oropharyngeal soft tissue procedures, such as uvulopalatopharyngoplasty, and orthognathic surgery. Upper airway stimulation is an alternative treatment option that has shown comparable or improved outcomes to a cohort of patients undergoing traditional soft tissue palate surgery. UAS should be considered in patients with OSA unable to tolerate CPAP who meet clinical indications.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Drs Doghramji and Boon are consultants for Inspire Medical. There are no other conflicts of interest.

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