Long-term outcomes of pharyngoplasty for Obstructive Sleep Apnea Syndrome

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ABSTRACT:
Introduction: Pharyngoplasty techniques for the treatment of obstructive sleep apnea syndrome (OSAS) have evolved, which improved the understanding of the anatomy, patient selection, and adoption of functional approaches.

Aim: To analyze long-term results of pharyngoplasty in OSAS patients.

Material and methods: Between 2007 and 2021, a total of 234 adult patients with OSAS who had previously failed positive airway pressure (PAP) therapy underwent sleep surgery. Of this group, 75 patients met the criteria of a minimum 5-year follow-up. To date, 25 patients completed the follow-up study protocol, including the medical history, visual analog scale (VAS) for snoring loudness, body mass index (BMI), endoscopy of the upper airways, type III sleep study, and standardized questionnaires including Epworth Sleepiness Scale (ESS) and EQ-5D-5L Euro – Quality of Life Questionnaire.

Results: The average period of follow-up was 96.80 ± 30.20 months. The mean age of participants was 54.6 ± 14.02 and the mean BMI 30.28 ± 2.74. Patients underwent uvulopalatopharyngoplasty (n = 21) and expansion sphincter pharyngoplasty (n = 4) between 2008–2015. A long-term improvement in sleep parameters was observed for the mean AHI (29.84 ± 20.06 before and 19.45 ± 18.53 after surgery, p = 0.0294), and the median VAS (8.13 before and 3.78 after surgery), mean oxygen saturation during sleep 94.5% (IQR 93.0–95.25), and the median ESS score was 6.17 ± 4.57. The majority of patients reported subjective long-term improvement in sleep quality and a reduction of snoring.

Conclusions: In OSAS patients who failed PAP therapy, pharyngoplasty may provide a long-term improvement in upper airway obstruction during sleep.

KEYWORDS: long-term postoperative results, obstructive sleep apnea, pharyngoplasty, sleep surgery

ABBREVIATIONS
AHI – Apnea/Hypopnea Index
BMI – Body Mass Index
BRP – barbed reposition pharyngoplasty
CI – confidence interval
COVID-19 – coronavirus disease 2019
EO – economic operator
EQ-5D-5L – Euro – Quality of Life Questionnaire the EQ-5D-5L version
ESP – expansion sphincter pharyngoplasty
ESS – Epworth Sleepiness Scale
GERD – gastrointestinal reflux disease
IQR – interquartile range
LOS – lowest oxygen saturation
MOS – mean oxygen saturation
OSAS – obstructive sleep apnea syndrome
PAP – positive airway pressure
PDPFEx – pharyngoplasty with dorsal palatal flap expansion
PG – polygraphy
SARS-CoV-2 – severe acute respiratory syndrome coronavirus 2
SD – standard deviation
U3P – uvulopalatopharyngoplasty
VAS – visual analogue scale

INTRODUCTION
Sleep apnea is the most common sleep-related breathing disorder and remains one of the most complex and socially relevant problems in modern medicine [1]. Obstructive sleep apnea syndrome (OSAS) is defined as repeated episodes of upper airway closure during sleep based on an apnea-hypopnea index of at least 5 per hour of sleep and excessive daytime sleepiness [2]. Obstructive sleep apnea occurs with the collapse of upper airway tissues during sleep that intermittently reduces or obstructs the airflow from the nose and mouth into the lungs. The prevalence of OSAS is as high as 5% in women and 14% in men [3].

Sleep apnea is responsible for significant morbidity and mortality due to its impact on many organ systems. There is an increased...
risk of lung and cardiovascular diseases, stroke, neurocognitive disorders including learning disabilities, attention deficit, proneness to the work and traffic accidents [4–9]. Despite increased public awareness, the disease is still often underdiagnosed [10]. Undiagnosed and untreated OSAS is associated with decreased quality of life for the patient and family members, leading to shortened life expectancy and costs to the patient, family, and society [10].

Treatment is aimed to eliminate the risk factors and prevent upper airway collapse. The treatment method is selected on an individual basis and based on the pathogenesis of the airway collapse and the severity of OSAS. The most effective method of keeping the upper airway open is the administration of positive air pressure (PAP). However, this has limited effectiveness mainly due to low patient compliance. Therefore, several other therapeutic methods have been introduced to eliminate the mechanism of upper airway collapse including weight loss, decreased alcohol intake, use of oral appliances, positional therapy, and a variety of surgical techniques [11–15].

Indications for surgery include diagnosis of OSAS and not being suitable or having failed other non-invasive treatment methods. The presence of severe excessive daytime sleepiness and the presence of comorbid conditions (e.g., cardiovascular diseases) are also considered surgical indications.

Moreover, identification of the anatomic airway abnormalities that are causing the disorder (e.g., deviated septum, hypertrophic turbinates, adenoids, hypertrophic palatine tonsils, elongated uvula, low hanging palate, large tongue base, etc.) is useful in selecting the surgical target [16]. The most important objectives in OSAS surgery are to select the patients who could benefit from surgery and to identify the specific surgical method that is suitable for a particular patient.

As it is for all treatment methods for OSAS, surgery does not always resolve OSAS or even adequately decrease its severity. In part due to the continued risk factors and surgical complications, OSAS may partially improve or worsen again in time. Therefore, it is important to investigate the long-term outcomes of the OSAS surgery, to be able to enhance the criterion for the selection of surgical candidates and optimize the selection of surgical methods. Thus, a study was conducted to analyze the long-term results of the pharyngoplasty procedures for the treatment of OSAS.

**MATERIAL AND METHODS**

**Consent of the Bioethics Committee and Informed Consent Form**

The study was approved by the Bioethics Committee at the Medical University of Białystok (R-I-002/535/2017). All participants were informed of the study and signed an informed consent form. Participation in the study was voluntary. Participants had the right to withdraw their consent at any time during the study.

**Study design**

This is a novel single-center retrospective study evaluating the long-term (minimum 5 years) results of the surgical treatment of patients with OSAS who failed previous non-surgical treatment methods (PAP).

**Study protocol**

The study was conducted in the Department of Otolaryngology between January 2020 and August 2021. Patients with OSAS were enrolled in the study based on the inclusion and exclusion criteria. The inclusion criteria were: a) adult participants who failed positive airway pressure therapy (PAP), b) participants who underwent pharyngoplasty for OSAS, c) at least 5 years of postoperative follow-up. All patients underwent the following procedures before and after surgery: physical and otolaryngological examination, body mass index (BMI) measurement, the visual analogue scale of snoring loudness (VAS), Epworth Sleepiness Scale (ESS), EQ-5D–5L (Quality of Life Questionnaire, EQ-5D-5L version), and a type III sleep study (PG).

All surgeries were performed by a single surgeon who is the first author (E.O.). Of 234 adult patients who failed PAP therapy, 75 had their surgery performed at least 5 years prior. However, to date, only 25 patients were able to complete long-term follow-up. Due to restrictions (SARS-CoV-2 pandemic, difficult contact with patients), the follow-up study protocols of the remaining 50 of them could not be completed yet. Continuing the efforts to expand the study sample, the preliminary outcomes are analyzed and presented here.

The follow-up visit consisted of a medical history, a sleep apnea questionnaire created by the authors, and a physical and otolaryngological examination. The authors’ sleep apnea questionnaire included nocturnal and daytime symptoms associated with breathing disorders during sleep. A history of comorbid disorders and chronically taken medications was collected. The sleep apnea questionnaire also included the history of smoking, alcohol use, weight gain over the past 10 years, other treatment of breathing disorders during sleep used before surgery and their effects, postoperative complications (pain in the first days, postoperative bleeding from the throat [early and late], difficulty in swallowing, impaired taste, solid food intake restriction, dry throat, foreign body sensation in the throat). Each patient evaluated the effectiveness of surgical treatment on a three-point scale: no improvement, temporary improvement or permanent improvement.

**Sleep Study**

Polygraphy was performed on each patient using a type III sleep study device (SOMNOtouch, SOMNOmed). The assessment included the following parameters: mean oxygen saturation (MOS), lowest oxygen saturation (LOS) and Apnea/Hypopnea Index (AHI). AHI is an indicator of apnea (obstructive, central, mixed) and hypopnea episodes and measures the number of apneas and hypopneas per hour of sleep. Apnea is defined as a decrease in the airflow of at least 90% of the initial value
between 27–84 years of age (mean 54.6 ± 14.02) and the majority were men (88%). The follow-up period ranged from 60 to 121 months (mean 96.80 ± 30.20, median 88 months).

Biometric data of patients were obtained, BMI was calculated. Seventeen patients had comorbidities such as diabetes, gastroesophageal reflux disease, and hypertension. The characteristics of the group are presented in Tab. I.

for at least 10 seconds, and hypopnea as a decrease in the airflow by at least 30%, lasting at least 10 seconds, accompanied by a decrease in arterial blood oxygenation of at least 3% or excitation [17]. MOS estimated as normal varies between 94% and 98% during sleep [13]. The final follow-up visits were conducted between July 2020 and July 2021 and included the same procedures as in the pre-operative period.

**Statistical analysis**

Statistical analysis was performed using GraphPad Prism 9. The results were presented as the mean ± standard deviation or the number of patients and the percentage of the entire study group. Categorical variables are presented as a percentage. For comparison of the results, the Wilcoxon signed-rank test was used. P-values < 0.05 were statistically significant.

**RESULTS**

Between the years 2007–2015, a total of 234 patients had undergone sleep surgery within the oropharynx performed by the first author. The distribution of types of pharyngoplasty procedures is shown in Fig. 1. The 25 patients included in the current study had undergone the following procedures: uvulopalatopharyngoplasty n = 21, expansion sphincter pharyngoplasty n = 4. Patients were between 27–84 years of age (mean 54.6 ± 14.02) and the majority were men (88%). The follow-up period ranged from 60 to 121 months (mean 96.80 ± 30.20, median 88 months).

Biometric data of patients were obtained, BMI was calculated. Seventeen patients had comorbidities such as diabetes, gastroesophageal reflux disease, and hypertension. The characteristics of the group are presented in Tab. I.
These complications were temporary (lasting from 3 days to a year after surgery) and persistent (present during the final postoperative visit). Eleven patients reported postoperative complications, of which 4 reported the occurrence of one of them, and 7 – more than one. No life-threatening conditions such as airway restriction, sudden decrease in blood saturation, massive hemorrhage were observed.

**Quality of life**

Based on the EQ-5D-5L questionnaire, most patients reported no problems with movement, self-care, daily activities, and anxiety/depression. Slight pain or discomfort was felt by 48% of the respondents. The median Visual Analog Scale of subjective quality of life (scale from 0–100) was 75.

**DISCUSSION**

Surgical treatment of sleep-related breathing disorders is relatively new and is constantly evolving. None of the current techniques provides ideal results and each is associated with complications or a chance of immediate or late failure. Therefore, it is important to ensure not only short-term but also long-term results of the operation.
The gold standard of treatment for OSAS is still the PAP therapy, but its effectiveness depends on many factors, e.g. the duration of its use [13, 18]. The therapy compliance is generally low here. The experience of the first author shows that about 50% of patients who qualify for PAP do not tolerate this method, and based on the literature, 46% of patients stop the treatment within the first 5 years [19]. Therefore, failure or non-compliance of the PAP therapy leads to the consideration of surgical intervention in these patients.

Surgical techniques have evolved in conjunction with expanding knowledge of the anatomy of the upper airways, the pathomechanisms of their obstruction, and OSAS phenotypes and endotypes [20, 21]. Surgery in OSAS has evolved from ablative methods such as radical uvulopalatopharyngoplasty (U3P) to more functional soft tissue interventions such as expansion sphincter pharyngoplasty (ESP), barbed stitch reposition pharyngoplasty (BRP), and the latest – pharyngoplasty with dorsal palatal flap expansion (PDPFEx) [11, 22, 23].

There is no consensus on the optimal duration of the long-term outcomes of OSAS surgery. A 2019 systematic review concluded that the duration of follow-up after intervention should be above 34 months [24]. In our study, we chose a minimum period of 60 months. In addition, the longest follow-up period exceeded 10 years, the median being 88 months, which is one of the longest follow-up periods in the available literature. Commonly used criteria for success in sleep surgery are the reduction of AHI after treatment to less than 20 events per hour or the reduction of this index by more than 50% of the baseline value [25]. Such a decrease in AHI depends on many factors, e.g. the choice of the appropriate technique of surgery [26]. In patients with Friedman score of III and IV, the effectiveness of oropharyngeal procedures is high [27].

One method of evaluation of outcomes after surgical intervention in the case of OSAS is to repeat the sleep study with a focus
on LOS, MOS, and AHI [18]. In our long-term study, all three parameters improved, although only the reduction in AHI was statistically significant.

The results of our study are consistent with those presented by other authors. De Apodaca et al. observed a decrease in AHI from 34.84 to 14.54, which was maintained for a 4-year follow-up period after surgery [28]. Similarly, He et al. showed a 15.4-year reduction in AHI in the 5-year postoperative follow-up. Yin et al. in 2020, adopting Shea’s surgical success criteria, achieved success in 60% of patients after surgery for modified uvulopalatopharyngoplasty with uvular preservation [29].

A reduction in AHI was achieved in the majority (68%) of the study group patients. This observation corresponds to systematic reviews indicating the effectiveness of surgery, especially in severe forms of OSAS [30, 31]. Most of the patients in the study group reported comorbidities and one in five declared themselves to be a tobacco smoker. The literature has shown a positive correlation with the occurrence of concomitant diseases such as type II diabetes, hypertension, gastroesophageal reflux disease, and increased AHI [16]. According to Kim et al., factors such as smoking can affect AHI through the development of local inflammation and a predisposition to obstruction in the upper respiratory tract [3, 32].

The incidence of surgical complications after U3P varies depending on the results of studies conducted by different authors. For example, Haavisto et al. reported an early complication rate in a group of 101 patients of up to 25%, including postoperative hemorrhage in about 14% of operated patients, without specifying the bleeding site [33]. Esclamado et al. showed a lower rate of complications—about 13%, in a study group of 135 patients [34]. Other studies have described the development of inflammation in the postoperative period, such as pneumonia or wound infections in 2% to 14% of patients [35, 36]. Kezirian et al. observed 0.2% of fatal complications within 30 days after surgery [37].

Surgery often does not lead to a cure for OSAS. Most patients report a significant reduction in symptoms after surgery, however, some of them require complementary treatment.

Limitations

The limitations of this study include:

1. No control group – the pre-post study model evaluates one group after the follow-up period without comparing it to a healthy control group observed during a similar period;
2. Shortly after the start of the study, restrictions related to the COVID-19 pandemic prevented a full assessment of all patients who underwent pharyngoplasty during the study period;
3. A small study group limited further analysis of factors including gender, BMI, and age;
4. Due to the evolution of OSAS diagnostic standards, the patient’s assessment after the follow-up period was more detailed than before surgery, so the possibilities of comparing baseline values of parameters such as SF-36 and EQ-5D-5L to post-follow-up values were limited.

CONCLUSION

In patients with OSAS who failed positive airway pressure therapy, surgical treatment may provide long-term improvement in upper airway patency. This treatment reduces the number of apnea and hypopnea episodes during the night, decreases the volume of snoring, reduces the feeling of drowsiness during the day in most patients, and increases their quality of life.

REFERENCES


