

Research Article

Comparison of Functional Expansion Pharyngoplasty with Radiofrequency Volume Reduction of the Soft Palate in Surgery for Sleep-related Breathing Disorders

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Keywords

- Obstructive sleep apnea; Multilevel surgery; Uvulopalatopharyngoplasty; Tonsillectomy

Abstract

Objective: Many different surgical approaches at the level of the palate for obstructive sleep apnea (OSA) exist. The functional expansion pharyngoplasty (FEP) was first described 2013. The objective of this study is to evaluate the efficiency of FEP in comparison with radiofrequency-tissue volume reduction of the soft palate (radiofrequency uvulopalatopharyngoplasty, RF-UPPP).

Methods: 40 patients (group A) underwent surgery at the Cantonal Hospital of Basel-Land Liestal for OSA receiving FEP, tonsillectomy (TE) and nasal surgery if indicated. This cohort was retrospectively matched with 40 previously operated patients undergoing RF-UPPP, TE and nasal surgery if clinically indicated (group B). Respiratory polygraphy was obtained preoperatively and at 3 months postoperatively. Apnea hypopnea index (AHI) was defined as the primary outcome measure.

Results: Postoperative AHI significantly improved for groups A and B. However, improvement for Group B was significantly better.

Conclusion: FEP showed no significant advantage over RF-UPPP in an operative concept for treatment of OSA.

ABBREVIATIONS

AHI: Apnea Hypopnea Index; BMI: Body Mass Index; CPAP: Continuous Positive Airway Pressure Therapy; DISE: Drug Induced Sleep Endoscopy; ESP: Expansion Sphincter Pharyngoplasty; ESS: Epworth Sleepiness Scale; FEP: Functional Expansion Pharyngoplasty; OSA: Obstructive Sleep Apnea; PPM: Palatopharyngeus Muscle; PTS: Percentage Time in Supine Position; RF-UPPP: Radiofrequency Uvulopalatopharyngoplasty; sAHI: supine Apnea Hypopnea Index; SD: Standard Deviation; SI: Snoring Index; tAHI: total Apnea Hypopnea Index; TE: Tonsillectomy, UPPP: Uvulopalatopharyngoplasty; VAS: Visual Analog Scale

INTRODUCTION

Obstructive sleep apnea (OSA) is caused by an upper airway collapse during sleep producing hypoxaemia and sleep fragmentation. The consequence of which is daytime sleepiness with an increased risk of accidents as well as cardiovascular incidents. [1,2]. OSA affects at least 2 to 4% of the population [3]. The gold standard of therapy is still continuous positive airway pressure therapy (CPAP) [4]. But its effectiveness is limited by poor tolerance, low acceptance and suboptimal compliance [5,6]. The velopharyngeal sphincter is the narrowest part of the upper airway [7] and drug induced sleep endoscopy (DISE)

showed that most patients with OSA have obstruction caused by upper pharyngeal wall collapse [8]. In 1981 Fujita first described uvulopalatopharyngoplasty (UPPP) as both a surgical treatment of OSA and an alternative therapy for patients not tolerating CPAP [9]. Due to its diverse outcomes and side effects UPPP has been widely modified since then. In recent years, modifications using a less destructive approach and techniques that preserve more tissue have been adopted such as radiofrequency-tissue volume reduction UPPP (RF-UPPP) [10]. Still, the success rate of RF-UPPP and its modifications is part of a controversial discussion. RF-UPPP in combination with tonsillectomy has been suggested for surgical treatment of OSA [11]. However, computed tomography studies showed that the collapse of the lateral pharyngeal wall plays a major role in obstruction at the velopharyngeal sphincter [12]. Insufficient stabilization of the lateral pharyngeal wall may be the cause of failures after RF-UPPP. Several techniques to overcome these shortcomings of previous modifications of UPPP have been introduced such as expansion sphincter pharyngoplasty procedure (ESP) in 2007 by Pang and Woodson [13]. A modification of the ESP, the functional expansion pharyngoplasty (FEP) has been described by Sorrenti [14]. The stabilization of the lateral pharyngeal wall is achieved by a superolateral repositioning of the palatopharyngeus muscle and the fixation of it to the hamulus pterygoideus after tonsillectomy (TE). A success rate of 89.2% according to the criteria defined

by Sher [10] which imply a reduction of initial AHI by >50% and a postoperative AHI <20/h was reported. However, there was no comparison with other surgical approaches. The objective of this study is to compare the outcome of FEP with RF-UPPP. A group of patients who underwent TE with FEP was compared to a retrospectively matched group of patients who had TE and RF-UPPP.

MATERIALS AND METHODS

All patients who were enrolled in the study suffered from either OSA and CPAP intolerance or malcompliance. OSA was defined as a combination of the total apnea-hypopnea index (tAHI) ≥ 5 /h with at least one symptom of disturbed sleep (e.g. elevated Epworth Sleepiness Scale, ESS) or tAHI ≥ 15 /h without symptoms [15]. The patients received a detailed upper airway evaluation to assess the site of obstruction using either nocturnal manometry of the upper airways with the ApneaGraph® system (MRA Medical Ltd, Gloucestershire, UK) or a drug induced sleep endoscopy (DISE) using 2,6-Diisopropylphenol (Propofol®) target-controlled infusion and BIS™ monitoring [16]. Patients with obstruction at the retrolingual level were excluded from the study. Only patients who still had tonsils and a primary upper airway obstruction at the level of the tonsils and soft palate were included. A primary palatal collapse was defined by a >50% obstruction at the velopharyngeal level in the upper airway manometry and/or if the velopharyngeal airway was narrowed by >50% during DISE. AHI was measured using respiratory polygraphy with the Nox T3 Sleep Monitor™ system (Nox Medical, Reykjavik, Iceland) preoperatively. All patients answered a standardized questionnaire regarding snoring (visual analog scale, VAS, 1-10) and daytime sleepiness using the ESS.

Between May 2015 and February 2016, 40 patients who met the inclusion criteria underwent a treatment with FEP and TE (group A). TE was performed regardless of the size of the tonsils. In case of impaired nasal breathing patients additionally underwent both a septoplasty and inferior turbinate reduction. Three months post surgery patients had a respiratory polygraphy and answered the same standardized questionnaires regarding snoring and daytime sleepiness using ESS. Additionally, patients were asked specifically if they had experienced postoperative side effects.

Data from the patients of group A was compared to a cohort of 40 patients from our database of patients who had received surgery for OSA who had TE and RF-UPPP and nasal surgery if clinically indicated (group B). All patients in group B received the same preoperative work-up and had the same indication for surgery as group A. The patients of group B had a radiofrequency-tissue volume reduction uvulopalatopharyngoplasty (RF-UPPP) at the level of the palate according to the technique described by Marinescu [17]. The patients were chosen from our database which includes all patients who are operated at the Cantonal Hospital of Basel-Land for OSA since 2005. Data as total AHI (tAHI), AHI in supine position (sAHI), Body Mass Index (BMI), snoring index (SI), ESS and postoperative side effects were gathered using a standardized questionnaire in a prospective manner preoperatively and three months postoperatively. Up to

October of 2016 the database included 339 subjects. The control group (group B) was matched retrospectively, primarily for total AHI and secondarily for BMI.

All patients received a thorough ENT examination and tonsil size was assessed using the Friedman grading system [18]. The demographic data of groups A and B is shown in Table (1).

For FEP we used the technique described by Sorrenti [14]. After removal of the tonsils, the palatopharyngeus muscle (PPM) was dissected in the midpoint of the tonsillar fossa. The muscular fasciculus was mobilized and separated from the superior pharyngeus constrictor muscle. Then the PPM was transected up and the so formed superior flap was elevated with a superolateral rotation and affixed to the palatine musculature near the pterygoid hamulus using a 2.0 Vicryl™ suture. As a result of this procedure the soft palate moved forward and an immediate widening of the antero-posterior and lateral oropharynx occurs. Suturing the tonsillar pillars using a 2.0 Vicryl™ suture completed the operation.

For RF-UPPP, the technique described by Marinescu was performed using the RaVoR™ -system (Sutter Medizintechnik GmbH, Freiburg, Germany), including a CRURIS® radiofrequency generator and a bipolar needle electrode. The bipolar probe was inserted 5-6 times in different locations at each side of the soft palate. Thermo-controlled radiofrequency-energy was applied for 3-5 seconds at approximately 32 joules for thermal tissue volume reduction of the soft palate. Septoplasty and/or inferior turbinoplasty was performed if indicated by the findings of the ENT examination and if subjective nasal breathing was impaired.

tAHI was defined as the primary outcome and was assessed using Nox T3 Sleep Monitor™ system preoperatively and at three months postoperative. Additionally, sAHI and percentage time in supine position (PTS) were recorded. The success of surgical treatment was defined according to the Sher criteria [10]. Snoring index (SI) was assessed using a visual analog scale (VAS, 1-10) with 1 meaning no snoring and 10 meaning extremely disturbing snoring. Three months post surgery the patients answered a standardized questionnaire regarding SI, ESS and side effects. All patients were asked about side effects such as globus sensation, dysphagia, unbearable pain, dysgeusia, speech disorders and unintentional weight loss (the latter was defined as persistent weight loss, which was undesired by the patient). All patients had a respiratory polygraphy to determine the postoperative AHI. The study was approved by the Ethics Committee of the University of Basel. Mann-Whitney-Test, Wilcoxon matched-pairs signed-ranks Test and Fisher's exact Test were applied for statistics using the program Instat® and Prism® from GraphPad Software. Differences with p-value <0.05 were considered to be statistically significant.

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RESULTS

Preoperative tAHI and BMI were similar for both groups as expected since these were the criteria for the retrospective matching of group B. Both groups did not significantly differ regarding preoperative sAHI, PTS, age, ESS, SI and tonsil size.

There were significantly more accompanying nasal surgeries performed in group B, of which 70% of patients (28/40) had simultaneous septoplasty and turbino-plasty, compared to only 40% of patients (16/40) in group A (p-value 0.013). All baseline data are listed in (Table 1).

As for the primary outcome, the pre and postoperative tAHI are depicted in (Figure 1). Preoperative tAHI for group A was 18.2/h (SD +/- 10.7/h) and 18.1/h (SD +/- 11.4/h) for group B. Postoperative tAHI for group A was 10.8/h (SD +/- 9.5/h) and 7.5/h (SD +/- 8.3/h) for group B. Comparison of pre- and postoperative tAHI showed a significant reduction for both groups (p-value 0.0001). However, the reduction of tAHI was significantly higher for group B compared to group A (p-value 0.013).

Table 1: Baseline characteristics of patient groups.

	Group A (n=40)	Group B (n=40)	p-value
tAHI (/hours)	18.2 ± 10.7	18.1 ± 11.4	0.870
sAHI (/hours)	38.2 ± 27.3	36.9 ± 26.2	0.932
PTS (%)	31.1 ± 24.0	30.5 ± 22.2	0.991
BMI (kg/m ²)	27.9 ± 3.2	28.1 ± 3.6	0.706
Age (years)	44.0 ± 10.1	40.4 ± 10.1	0.111
ESS (points)	7.6 ± 4.8	7.2 ± 4.1	0.646
SI (points)	7.4 ± 2.1	8.1 ± 2.0	0.122
Nasal surgery (% , n)	40 (16/40)	70 (28/40)	0.013
Size of tonsils (Friedman classification)	1.8 ± 0.6	1.7 ± 0.7	0.771

Group A: functional expansion pharyngoplasty (FEP) & tonsillectomy (TE). Group B: radiofrequency-tissue volume reduction of the soft palate (RF-UPPP = radiofrequency uvulopalatopharyngoplasty) & TE. Tahi: Total Apnea-Hypopnea Index; Sahi: Supine Apnea-Hypopnea Index; PTS: Percentage Time in Supine Position; ESS: Epworth Sleepiness Scale; SI: Snoring Index; N: Number Of Patients

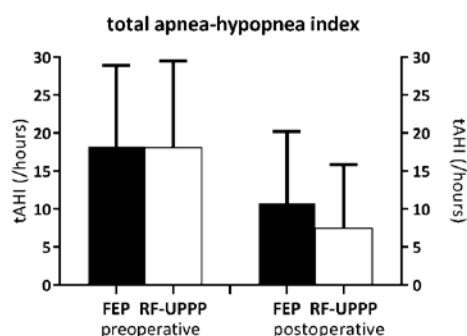


Figure 1 Total apnea-hypopnea index (tAHI). Pre- and postoperative total apnea-hypopnea-index (tAHI) for group A (with functional expansion pharyngoplasty, FEP, and tonsillectomy, TE) and group B (with radiofrequency-tissue volume reduction, RF-UPPP, and TE). Significant reduction of pre to postoperative tAHI in group A and B (p-value 0.0001 twice). Also a significant intergroup difference of postoperative tAHI was found (p-value 0.013). The vertical bars mark the standard deviation.

The responder rate defined by the Sher criteria was 55% (22/40 patients) in group A and 65% (26/40 patients) in group B. The difference was statistically insignificant (p-value 0.49).

Supine AHI is often worse than AHI in non-supine position in OSA. Therefore, sAHI was registered separately because differences in tAHI may be the simple result of different percent time in supine position. However, pre- and postoperative PTS was similar for both groups. Preoperative PTS was 31% for group A and 30% for group B and postoperative PTS was 37% for group A and 34% for group B.

There was a significant reduction of pre to postoperative sAHI for both groups (p-value < 0.0002 for group A, p-value < 0.0001 for group B). The preoperative sAHI of group A was 38.1/h (SD +/- 27.3/h) and for group B 36.9/h (SD +/- 26.2/h). sAHI postoperatively dropped to 21.1/h (SD +/- 19.6h) in group A and 12.5/h (SD +/- 14.3) in group B. The intergroup comparison showed a significantly greater reduction of sAHI for group B as compared to group A. The results for sAHI are shown in Figure (2).

ESS as a measure for daytime sleepiness is depicted in Figure (3). The preoperative ESS was 7.6 points (SD +/- 4.8 points) for group A and 7.2 points (SD +/- 4.1 points) for group B. Postoperative ESS for group A was 3.2 points (SD +/- 2.9 points) and group B 4.3 (SD +/- 3.6 points). Therefore ESS significantly improved for both groups (p-values for group A <0.0001 and for group B 0.0002) and there was no significant difference between both groups (p-value=0.206).

The postoperative SI improved significantly for both groups (p-value < 0.0001 for group A and B) as shown in Figure (4). The preoperative SI was 7.4 points (SD +/- 2.1 points) in group A and 8.1 points (SD +/- 2.0 points) in group B. The postoperative SI could be lowered to 3.0 points (SD +/- 2.0 points) in group A and 3.2 (SD +/- 2.0 points) in group B without a significant difference between both groups (p-value 0.697).

There was no significant intergroup difference of pre and postoperative BMI (p-values preoperative 0.706 and postoperative 0.764).

Globus sensation was the most frequent side effect mentioned after FEP and RF-UPPP. 35% of patients in group A reported globus sensation and 23% in group B. The difference between both groups was not significant (p-value 0.32). Postoperative hemorrhage occurred in 10% of group A and 8% of group B (p-value 1.0). Other side effects such as dysphagia, unintentional weight loss, unbearable pain, dysgeusia and speech disorders are enlisted in Table (2). There were no significant differences between both groups.

DISCUSSION

Our study showed similar results for FEP with TE and RF-UPPP with TE at 3 months postoperative. Both techniques proved to be effective in the treatment of OSA. No superiority of FEP over RF-UPPP could be demonstrated. On the contrary, the reduction of postoperative tAHI was significantly higher in group B than in group A. Our success rate of 65% for the group with TE and RF-UPPP is in accordance with a previous study by Lim et al. [11], who found a responder rate of 66% using the same technique.

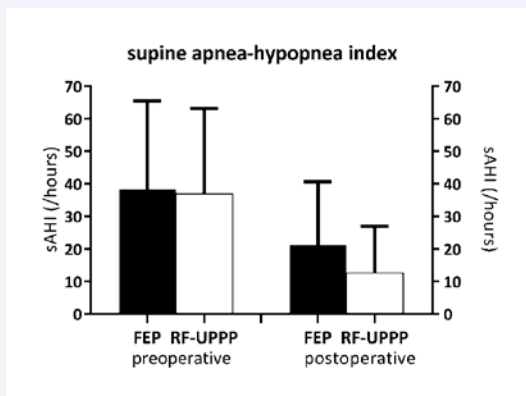


Figure 2 Supine apnea-hypopnea index (sAHI)- Pre- and postoperative supine apnea-hypopnea-index (sAHI) for group A (with functional expansion pharyngoplasty, FEP, and tonsillectomy, TE) and group B (with radiofrequency-tissue volume reduction, RF-UPPP, and TE). Significant improvement of postoperative sAHI in group A (p-value 0.0002) and B (p-value 0.0001). The intergroup difference of postoperative sAHI was significant too (p-value 0.021). The vertical bars mark the standard deviation.

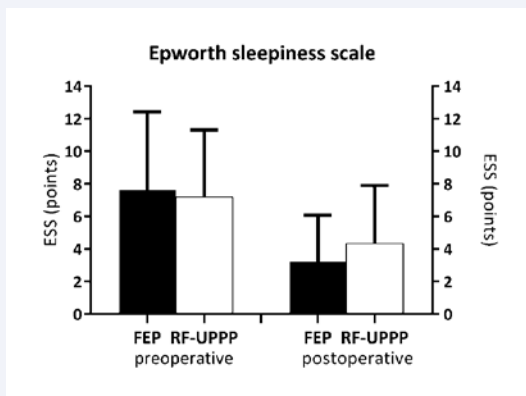


Figure 3 Epworth sleepiness scale (ESS)- Pre- and postoperative scores on the Epworth Sleepiness Scale (ESS) for group A (with functional expansion pharyngoplasty, FEP, and tonsillectomy, TE) and group B (with radiofrequency-tissue volume reduction, RF-UPPP, and TE). ESS was significant lower post- than preoperative in group A (p-value 0.0001) and B (p-value 0.0002). No significant intergroup difference of postoperative ESS was found (p-value 0.206). The vertical bars mark the standard deviation.

However, the study by Lim did not have a control group. Currently there are no other published studies about FEP except aforementioned by Sorrenti et al. [14], in particular there are no randomized trials with a control group. Postoperative sAHI was significantly lower in group B, while there was no change of PTS from pre to postoperative within both groups. So the hypothetical explanation that patients in group A were sleeping longer in supine position than in group B can be discarded. In the study published by Sorrenti [14] no information about sAHI and PTS is given. Additionally, it is not clearly stated if all patients underwent TE simultaneously with FEP or if some patients already had their tonsils removed at the time FEP was performed. These factors may explain the difference in the response rate as compared to

our results. In our study, both groups of patients had concurrent TE and sAHI as well as PTS were similar. In our opinion, this data should be given in order to assess postoperative outcome regarding tAHI correctly.

Pang and Woodson [13] found a responder rate of 82% for ESP compared to only 68% for classical UPPP described by Fujita [9]. However, the preoperative tAHI in their study was 43/h which is considerably higher than the tAHI in our study. In the study of Sorrenti [14], who described a modification of ESP as FEP, the responder rate was 89% and the preoperative tAHI was 33/h. The lower responder rate in our study populace may be partially explained by the considerably lower preoperative tAHI of 18/h because the goal to reduce initial AHI by >50% may be more difficult for AHI values which are elevated only moderately above normal. Therefore, these studies may not be compared.

Our patient groups were retrospectively matched from our database with patients who had undergone surgery for OSA. An advantage of our study is a very homogenous preoperative demographic data with no significant intergroup difference

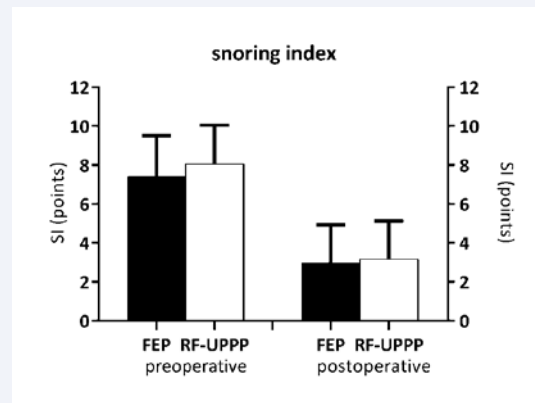


Figure 4 Snoring index (SI): Pre- and postoperative scores on the snoring index (SI) for group A (with functional expansion pharyngoplasty, FEP, and tonsillectomy, TE) and group B (with radiofrequency-tissue volume reduction, RF-UPPP, and TE). SI improved significantly in group A and B (both p-value 0.0001). There was no significant intergroup difference of postoperative SI (p-value 0.697). The vertical bars mark the standard deviation.

Table 2: Postoperative complications.

	Group A (n=40)	Group B (n=40)	p-value
Globus sensation (n)	14	9	0.323
Tonsillar bleeding (n)	4	3	1.000
Unbearable pain (n)	0	2	0.494
Unintentional weight loss (n)	1	1	1.000
Dysgeusia (n)	5	2	0.432
Speech disorders (n)	5	2	0.432
Dysphagia (n)	5	8	0.546
Group A: functional expansion pharyngoplasty (FEP) & tonsillectomy (TE). Group B: radiofrequency-tissue volume reduction of the soft palate (RF-UPPP = radiofrequency uvulopalatopharyngoplasty) & TE. N: Number of Patients			

regarding tAHI, sAHI, BMI, age, tonsil size, SI and ESS. The only exceptions are accompanying nasal procedures, which were performed significantly more often in group B than in group A. The influence of nasal surgery on postoperative AHI is still controversial. A meta-analysis by Ishii et al. has shown that nasal surgery can improve snoring and daytime sleepiness but has no effect on tAHI [19]. However, another meta-analysis by Verse and Wenzel [20] showed a reduction of initial AHI of 33.3/h by 3.3/h corresponding to an improvement of 10%. Assuming a possible beneficial effect of 10% on tAHI by nasal surgery alone, the amount of improvement of tAHI would be 0.73/h for group A (initial tAHI 18.2/h, thereof 10% in 40% of patients adding up to $1.82/h \times 0.4 = 0.73/h$) and 1.27/h for group B (initial tAHI 18.1/h, thereof 10% in 70% of patients adding up to $1.81/h \times 0.7 = 1.27/h$). Thus the possible effect by nasal surgery alone would account for a difference of 0.5/h between both groups and postoperative tAHI would still be significantly lower for group B. Therefore, we think that the difference in nasal surgery between both groups does not impact the significance of our results because of the minimal and controversial effect of nasal surgery on postoperative AHI.

Based on the above mentioned results we have abandoned FEP and RF-UPPP has become our method of choice at the level of the soft palate.

One weakness of our study is our presentation of only short-term results. Another drawback is the fact that both groups were not equally balanced for nasal surgery which could have been overcome in a prospective randomized trial. The fact that DISE was not performed in all patients is another limitation. Factors such as concentric palatal collapse or collapse of the lateral pharyngeal wall may adversely affect the outcome. However, the significance of these findings in DISE on postoperative outcome is not yet well established [21]. A further weakness is that we cannot distinguish the contribution of TE and of the procedures at the level of the soft palate (FEP or RF-UPPP) to surgical success. Simple RF-UPPP was ineffective for the treatment of mild to moderate OSA in a placebo-controlled trial [22]. In a study with 144 patients after multilevel surgery for OSA the odds ratio to be a responder was 5.7 for patients who had simultaneous TE compared to those who had no TE because the tonsils were removed previously [23]. Therefore, the removal of the tonsils is a major decisive factor for a successful outcome within the concept of surgery for OSA. An overall success rate of 80% has been shown for tonsillectomy alone as a surgical treatment of OSA [24]. There is no evidence in the literature as to how tonsil size influences the outcome of surgery. In our study, size of the tonsils was registered preoperatively and there was no difference of tonsil size between both groups. In our opinion, preoperative tonsil size should be indicated in studies with surgery for OSA in order to enable later comparison.

In our study, patients with retrolingual obstruction were excluded from the study. This group of patient needs a multilevel approach for treatment of OSA. Depending on the individual anatomy trans-oral robotic surgery (TORS), coblation tongue surgery of the tongue base [25] or mandibular advancement splints may be proposed [26].

We strongly suggest randomized and prospective trials with

long-term follow-up to evaluate new operative methods such as FEP and recommend RF-UPPP as the treatment of choice in OSA patients until new evidence is shown.

CONCLUSION

The rate of success of different surgical approaches at the level of the palate for obstructive sleep apnea is controversial. 2013 a new modification of the expansion sphincter pharyngoplasty procedure was described, called the functional expansion pharyngoplasty (FEP). Three months post surgery AHI significantly improved for patients who had FEP or RF-UPPP. Improvement after RF-UPPP was significantly better compared to FEP. We recommend RF-UPPP as the treatment of choice in OSA patients.

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