First-Choice Treatment in Mild to Moderate Obstructive Sleep Apnea

Single-Stage, Multilevel, Temperature-Controlled Radiofrequency Tissue Volume Reduction or Nasal Continuous Positive Airway Pressure

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Objective: To compare the efficacy of single-stage, multilevel, temperature-controlled radiofrequency tissue volume reduction (TCRFTVR) for the soft palate and base of the tongue with that of nasal continuous positive airway pressure (CPAP) in primary treatment of mild to moderate obstructive sleep apnea.

Design: A prospective nonrandomized clinical study.

Setting: Tertiary care referral center.

Patients: Data from 47 patients with mild to moderate obstructive sleep apnea treated between January 1, 2003, and October 31, 2006, were reviewed.

Interventions: Twenty-six patients underwent TCRFTVR and 21 underwent nasal CPAP as a primary treatment modality.

Main Outcome Measures: Baseline and 12-month posttreatment measurements using the Epworth Sleepiness Scale and polysomnography were compared.

Results: The baseline characteristics of the groups were not significantly different. Both methods showed meaningful results for the Epworth Sleepiness Scale and polysomnography variables 12 months after treatment compared with baseline measurements. The results were not significantly different in the posttreatment intergroup comparisons. Treatment success rates were 52.4% for nasal CPAP and 53.8% for TCRFTVR ($P = .92$).

Conclusion: Similar comparison results with nasal CPAP in objective and subjective variables make single-stage, multilevel TCRFTVR a good alternative in primary treatment of mild to moderate obstructive sleep apnea.


The relatively high incidence of obstructive sleep apnea (OSA) in the population has only recently been recognized.¹ Considering the documented associated risk of stroke, hypertension, and cardiac arrhythmias in OSA, the importance of developing an effective management strategy for patients with OSA has become clear. Although the use of nasal continuous positive airway pressure (CPAP) after pressure titration in the sleep laboratory offers effective reversal of the obstructive apneas, short- and long-term compliance becomes an issue in more than 50% of patients.²

The multiplicity of surgical modalities described for OSA suggests that no clear surgical approach has been widely accepted for the management of this disease. Most studies on various surgical approaches to OSA focus on a single surgical modality. Although this concept is helpful in reporting a procedure’s efficacy, most studies assume that patients with OSA are a homogeneous group with the same type of pathologic abnormality.² We believe that OSA is a multilevel, multifactorial disease process that creates a heterogeneous patient population. Observations since the early 1990s have shown that the pathophysiologic concept for a 2-level (retro-palatal and retrolingual) pharyngeal collapse is too simplified. Evidence indicates that many sites in the upper airway may contribute to pharyngeal obstruction.³ Therefore, the concept of 2-level pharyngeal collapse should be replaced by a dynamic “multilevel collapse concept,” reflecting the complex pattern of collapsibility of the entire pharyngeal tube during sleep.³ To improve the surgical cure rates for OSA, the entire upper airway must be brought under inspection, and each level of obstruction identified needs to be addressed. The treatment plan should potentially include nasal, oropharyngeal and palatal, and hypopharyngeal measures to improve the airway. Nasal, oropharyngeal, and hypopharyngeal surgical procedures have been used...
in 1, 2, or 3 steps. Traditionally, hypopharyngeal surgery has been reserved for patients with moderate to severe disease or for those who underwent unsuccessful primary uvulopalatopharyngoplasty (UPPP). Few studies have assessed multilevel treatment for patients with mild disease.

Multilevel obstruction is a common denominator for many patients with OSA, whether they have mild, moderate, or severe disease. Therefore, multilevel treatment may be appropriate for patients with mild to moderate disease. Because patients with mild to moderate disease are often unwilling to undergo multilevel invasive surgical correction, the options are limited to multilevel minimally invasive techniques that allow improvement in the airway at the 3 major levels of obstruction. Based on this hypothesis, selected patients with mild to moderate disease have been treated with multilevel minimally invasive techniques in the past several years. Procedures performed on these patients include corrective surgical procedures to improve the nasal airway, minimally invasive procedures to stiffen the palate, and radiofrequency tissue volume reduction of the tongue base. The objective of this study is to compare the efficacy of single-stage, multilevel, temperature-controlled radiofrequency tissue volume reduction (TCRFTVR) for the soft palate and base of the tongue with that of nasal CPAP in mild to moderate OSA.

METHODS

PATIENTS

This prospective clinical study was conducted in a tertiary care setting (Ministry of Health, Ankara Training and Research Hospital). Data from 47 patients treated between January 1, 2003, and October 31, 2006, were reviewed. Institutional review board approval was provided by the Ministry of Health, Ankara Training and Research Hospital, and informed consent was obtained from all the patients before participation in this study. As part of the treatment protocol for mild to moderate OSA, patients initially underwent polysomnography 12 months after surgery and 12 months after the beginning of nasal CPAP treatment in patients who tolerated the device.

PREOPERATIVE EVALUATION

Physical examination of the upper airway was supplemented with nasopharyngoscopy using the Muller maneuver and with lateral cephalometric radiographs. Patients were classified as having oropharyngeal obstruction if elongation of the soft palate was present and if soft-palate collapse against the pharyngeal wall was observed using the Muller maneuver. Hypopharyngeal obstruction was defined as collapse of the base of the tongue against the postero-lateral pharyngeal wall or a narrow posterior airway space based on cephalometric analysis. All candidates demonstrated greater than 50% collapse at the levels of the base of the tongue and the soft palate.

SURGICAL TECHNIQUES

All surgical procedures were performed by the same surgeon (K.C.) at the outpatient facility of the Ministry of Health, Ankara Training and Research Hospital. Patients underwent conscious sedation (midazolam hydrochloride) and monitored local anesthesia (lidocaine, 1%). Antibiotic therapy with amoxicillin potassium clavulanate potassium and analgesia with acetaminophen were given for 5 days postoperatively. Surgical techniques performed in the nose included turbinate reduction by means of radiofrequency and septoplasty with or without nasal valve suspension procedures when septal deviation was present. The TCRFTVR was performed using a radiofrequency generator (Gyrus-ENT, Memphis, Tennessee). Inferior turbinate treatments delivered 330 J successively to 3 different sites of the turbinate (to the upper and lower areas of the anterior portion and to the middle portion). Palate treatments consisted of 650 J delivered to the midline and 325 J to each side to create 3 nonoverlapping lesions. Tongue base treatments consisted of delivering 3000 J to 10 locations equally dispersed to the right and left sides of the midline between the circumvallate papillae and the vallecula.

POSTOPERATIVE EVALUATION AND FOLLOW-UP

All of the patients were evaluated at the clinic using ESS and polysomnography 12 months after surgery and 12 months after the beginning of nasal CPAP treatment in patients who tolerated the device.

CLINICAL EVALUATION

All of the patients had a comprehensive clinical history that included answering a specific questionnaire as described by Marin et al. Daytime sleepiness was estimated using the Epworth Sleepiness Scale (ESS) (8-item questionnaire, ranging from 0 [no chance of dozing] to 3 [high chance of dozing]) to rate hypsomnia on a total score point from 0 (getting enough sleep) to 24 (seek the advice of a sleep specialist). Physical examination included measurement of body mass index and neck circumference. Sleep evaluation was performed by means of full polysomnography. All-night polysomnography studies monitored electroencephalograms, electro-oculograms, chin and leg electromyograms, electrocardiograms, nasal and oral airflow measures, thoracic and abdominal efforts, and pulse oximetry. The variables analyzed were the AHI, the lowest arterial oxygen saturation, and the percentage of sleep time with oxygen-hemoglobin saturation less than 90%.
STATISTICAL ANALYSIS

All statistical analyses were performed using a commercially available software program (SPSS version 11.5; SPSS Inc., Chicago, Illinois). Continuous variables are expressed as mean (SD). Means were compared using the t test. Differences between preoperative and postoperative measurements within groups were tested using the paired samples t test. Nominal variables were tested using the Pearson χ² test or the Fisher exact test. P < .05 was considered statistically significant.

RESULTS

Of the 47 consecutive patients enrolled in the study, 26 were treated with TCRFTVR and 21 were treated with nasal CPAP; TCRFTVR and nasal CPAP were proposed as treatment alternatives to all of the patients. The patients' baseline characteristics are listed in Table 1. No differences in baseline clinical and sleep data were noted in the TCRFTVR and nasal CPAP groups. Mean (SD) baseline polysomnography data were consistent with mild to moderate OSA syndrome (AHI, 29.1 [7.6]; sleep time with oxyhemoglobin saturation less than 90%, 14.7% [4.3%]). In patients who underwent TCRFTVR, no significant perioperative complications, such as postoperative bleeding, a need for tracheotomy, or uncontrollable pain were noted. All of the patients received routine antibiotic and analgesic therapy. In Table 2, the radiofrequency group shows similar results for objective and subjective variables and treatment success rates compared with the nasal CPAP group.

COMMENT

Treatment of OSA is aimed at reducing the number of episodes of apnea-hypopnea, decreasing the number of arousals, and normalizing oxyhemoglobin saturation levels. These changes have been correlated with improvements in daytime alertness and quality of life.4 The mainstay of therapy for OSA syndrome is nasal CPAP, which maintains a patent airway during sleep, thereby avoiding apnea. However, although nasal CPAP is highly effective, compliance with and acceptance of treatment is a problem.6

Because most patients with OSA have multilevel disease, the need for multilevel repair is evident. The concept of single-stage multilevel treatment is not new. Multilevel treatment generally includes the palate, the tonsil area, and the hypopharynx. Often, a nasal corrective procedure is included as well. Few studies have looked at multilevel minimally invasive treatment.3-6,8 Steward9 studied 22 patients who underwent combined radiofrequency reduction of the palate and base of the tongue, and he reported a success rate of 59%. None of his patients had concomitant nasal surgery.9 Fischer et al10 reported a similar study of 16 patients undergoing radiofrequency reduction of the palate and tongue base with a success rate of only 33%.10 Whereas all of the patients in the study by Fischer et al10 had moderate disease, those in the study by Steward9 had mild to moderate disease. Although many surgeons include nasal surgery with UPPP, this is the second study to include a combined 3-level treatment with minimally invasive techniques, at the level of the soft palate and the base of the tongue, in addition to nasal surgery. The present study differs from the study by Friedman et al11 in comparing nasal CPAP results and multilevel radiofrequency treatments in patients with mild to moderate disease. Friedman et al11 reported their multilevel surgery results without comparing them with any other surgical or nonsurgical treatment.

The limitations of the present study include the small study population. With uniform staging criteria, perhaps multicenter surgical trials will be more easily conducted, and perhaps there will be higher-level evidence for surgical efficacy in the treatment of OSA syndrome. Another limitation is that multiple intranasal procedures were used in various combinations. The different types of nasal procedures in such a small population make it hard to determine how or which procedures affected the overall outcome. An advantage of this study is that all the procedures, especially TCRFTVR, were performed by a single surgeon.

Numerous studies5,7,9,11,12 have demonstrated that correction of an obstructed nasal airway using both surgical and nonsurgical means leads to a significant improvement in patient symptoms, such as snoring, nighttime arousals, and daytime energy levels. However, nasal surgery alone in the treatment of moderate to severe OSA has been shown to be of limited benefit, with success rates of less than 20%. The effect of a narrow nasal airway is significant by causing an increase in the velocity of airflow through the nose, thus increasing the collapse of the airway through Bernoulli forces, or by causing mouth breathing, which is accompanied by posterior displacement of the base of the tongue.2,13,14

On the other hand, opening the nasal airway may cause worsening of snoring due to increased airflow that makes the palatal collapse more readily.13

The small sample size leaves little statistical power to detect important differences in stratified analyses. Thus, we are limited in our ability to identify important treatment or covariate features that affect short- and long-term outcomes. The nonrandomized study design fur-
ther compromises our ability to test the independent treatment effects of these covariates because confounding variables may distort the observed effects of these covariates. Because the pathogenesis of sleep apnea is multifactorial, undefined studies may introduce confusing factors that need to be clarified. We are planning various stratified analyses to begin to examine the effects of other variables on outcome. Friedman et al15 showed that OSA-hypopnea syndrome severity based on polysomnography data (AHI) is a significant factor in predicting successful treatment. Patients with mild disease based on polysomnography data do not have a better chance of successful treatment than do patients with severe disease. Severity of disease should not be incorporated into the staging system.15 Despite these facts, this study is unique, being the first, to our knowledge, to compare the efficacy of nasal CPAP with that of single-stage, multilevel TCRFTVR in mild to moderate OSA with relatively long-term follow-up.

In patients with single-stage, multilevel TCRFTVR of the tonsils and soft palate, pharyngeal scar formation in the centripetal direction may lead to medial traction of the posterior tonsillar pillars or even of the lateral pharyngeal walls, and a dominating obstruction at the base of the tongue would persist. The base of the tongue might be exposed to a higher pressure gradient, according to the law of Bernoulli, to increased collapse, and to subsequent aggravation of OSA. Surgical therapy is effective because it enlarges the upper airway and decreases collapsibility.3,16

Surgical success has been defined as an AHI of 20 or less and a 50% or greater reduction in the AHI. Both criteria must be present for the outcome to be defined as successful.17 Nasal CPAP dramatically improves daytime symptoms in patients with OSA, which is considered a good response to therapy. In the same way, to consider a surgical technique successful, the patient must report a significant improvement in daytime sleepiness (eg, reducing the ESS score to <10).6 The present surgical success included improvement in both variables (AHI and ESS). In the success group, patients remain free of daytime symptoms and show improvements in polysomnography data. This makes these findings even more significant because we are not limited by the changes in the AHI, which, by the way, would have resulted in a more significant rate of success had they been looked at alone and without considering clinical improvement. As noted in a recent article by Megwalu and Piccirillo,18 however, the lack of consensus in the definitions for research for OSA has generated a lot of confusion and a lack of solid literature to support surgical intervention for OSA.

The success rate of any protocol has to be weighed against associated morbidity and risks. Although the success rate of the TCRFTVR group was only 53.8%, morbidity was low, and complications were all temporary and minor. On the other hand, approaching mild to moderate disease with more invasive surgery, such as UPPP, has had only limited success. Historically, classic thinking was that, if UPPP was not universally successful for unselected patients, it may be more likely to be successful for patients with mild disease. Many studies,6,10,11,15,18 however, have shown that the success rate for unselected patients with mild disease is no better than the overall success rate of UPPP for patients with moderate to severe disease in the general population. Nasal CPAP compliance, on the other hand, is much lower for patients with mild vs severe disease. An oral appliance is also an option, but many patients will seek further treatment after nasal CPAP and an oral appliance have been tried and found unacceptable.15,19 Few options are available to patients with mild to moderate disease except for the same aggressive multilevel surgery used for severe disease. Recent data, however, indicate significant cardiovascular risk secondary to even mild disease.20 Given the scarcity of better options, this approach seems logical and practical despite having a significant failure rate.

In conclusion, TCRFTVR, as a minimally invasive, single-stage, multilevel treatment, offers reasonable improvement in subjective symptoms and objective polysomnography findings in patients with mild to moderate OSA. Similar comparison results with nasal CPAP for objective and subjective variables make single-stage, multilevel TCRFTVR a good alternative in primary treatment of mild to moderate OSA.

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Table 2. Changes in Subjective and Polysomnographic Variables 12 Months After Treatment

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-nCPAP</th>
<th>Post-nCPAP</th>
<th>P Value (Pre-nCPAP vs Post-nCPAP)</th>
<th>Pre-TCRFTVR</th>
<th>Post-TCRFTVR</th>
<th>P Value (Pre-TCRFTVR vs Post-RF)</th>
<th>P Value (Post-TCRFTVR vs Post-nCPAP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS score, mean (SD)</td>
<td>11.1 (3.1)</td>
<td>8.4 (2.9)</td>
<td>.006</td>
<td>10.8 (3.2)</td>
<td>8.2 (2.7)</td>
<td>.003</td>
<td>.81</td>
</tr>
<tr>
<td>AHI, mean (SD), events per hour</td>
<td>28.5 (6.9)</td>
<td>15.7 (4.2)</td>
<td>&lt;.001</td>
<td>29.6 (7.8)</td>
<td>16.1 (3.9)</td>
<td>&lt;.001</td>
<td>.74</td>
</tr>
<tr>
<td>CT90, mean (SD), %</td>
<td>15.2 (3.8)</td>
<td>11.1 (1.9)</td>
<td>&lt;.001</td>
<td>14.3 (4.5)</td>
<td>10.7 (1.8)</td>
<td>&lt;.001</td>
<td>.46</td>
</tr>
<tr>
<td>Lowest oxygen saturation, mean (SD), %</td>
<td>98.4 (8.5)</td>
<td>93.5 (5.6)</td>
<td>.03</td>
<td>86.8 (9.9)</td>
<td>94.6 (4.9)</td>
<td>&lt;.001</td>
<td>.48</td>
</tr>
<tr>
<td>Treatment success, %a</td>
<td>52.4</td>
<td>53.8 (3.8)</td>
<td>.92</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CT90, sleep time with lowest oxygen saturation less than 90%; ESS, Epworth Sleepiness Scale; nCPAP, nasal continuous positive airway pressure; RF, radiofrequency; TCRFTVR, temperature-controlled radiofrequency tissue volume reduction.

aTreatment success is defined as a change in the AHI of 50% or greater and a posttreatment AHI of 20 or less and an ESS score less than 10.
Author Contributions: All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Ceylan. Acquisition of data: Ceylan, Emir, Kizilkaya, Tastan, Yavanoglu, Uzunkulaoglu, Samim, and Felek. Analysis and interpretation of data: Ceylan, Emir, and Yavanoglu. Drafting of the manuscript: Ceylan. Critical revision of the manuscript for important intellectual content: Ceylan, Emir, Kizilkaya, Tastan, Yavanoglu, Uzunkulaoglu, Samim, and Felek. Administrative, technical, and material support: Ceylan, Emir, Kizilkaya, Tastan, Uzunkulaoglu, Samim, and Felek. Study supervision: Ceylan, Emir, Kizilkaya, Tastan, Yavanoglu, Uzunkulaoglu, Samim, and Felek.

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