

Radiofrequency Surgery of the Soft Palate in the Treatment of Mild Obstructive Sleep Apnea is Not Effective as a Single-Stage Procedure: A Randomized Single-Blinded Placebo-Controlled Trial

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Objectives/Hypothesis: Radiofrequency (RF) surgery of the soft palate (SP) is an established treatment option for the treatment of snoring. Due to its minimally invasive character, it has received attention in the management of mild obstructive sleep apnea syndrome (OSAS).

Study Design: The aim of this study was to assess the efficacy and the occurrence of adverse events after single-stage SP RF surgery in patients with mild OSAS in a randomized single-blinded placebo-controlled trial in an outpatient department at a tertiary care center, academic teaching hospital.

Methods: Thirty-two patients with mild OSAS (apnea-hypopnea index [AHI] 5–15, body mass index <35) were randomized to receive a single session of RF surgery or placebo (insertion of applicator without energy delivery) with local anesthesia. The primary outcome measures were (AHI), Epworth Sleepiness Scale, and a 36-item short-form health survey quality-of-life questionnaire. The secondary measures were the soft tissue airway parameters in cephalo-

metric radiographs, snoring scores, and rates of adverse events.

Results: Neither objectively measured significances (active AHI 11.0 [5.0–9.0] to 13.0 [2.0–26.0] and placebo AHI 12.0 [5.0–8.0] to 11.0 [1.0–29.0], $P = .628$), nor were trends of a diminishing effect on symptoms of mild OSAS found in the treatment arms. No significant changes in the soft tissue airway parameters occurred. One patient (5.9%) in the active treatment group was cured.

Conclusions: RF surgery of SP is not recommended as a single-stage approach in mild OSAS.

Key Words: Radiofrequency, radiofrequency ablation, radiofrequency thermal ablation, soft palate, obstructive sleep apnea syndrome.

Laryngoscope, 119:1621–1627, 2009

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Editor's Note: This Manuscript was accepted for publication May 4, 2009.

This work was supported by the Helsinki University Central Hospital Research Fund, Helsinki, Finland, and Celon AG Medical Instruments, Teltow/Berlin, Germany (local representative Olympus Finland OY, Vantaa, Finland) for the free-of-charge use of the radiofrequency generator and the applicators.

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DOI: 10.1002/lary.20562

INTRODUCTION

The gold standard for treatment of obstructive sleep apnea syndrome (OSAS) is continuous positive airway pressure (CPAP). The problem with CPAP treatment is its low compliance, especially in mild OSAS patients.¹ Nevertheless, mild OSAS treatment is warranted due to the natural tendency of the disease to worsen in time² and the association of health disorders.³

Mandibular advancement appliance (MAA) is a recognized treatment alternative in mild OSAS. However, compliance is also an issue with MAA. It is estimated that 50% to 90% of the patients use the device on regular basis, but that the number of days/week or hours/night of use is highly variable.^{4,5}

Radiofrequency (RF) surgery of the soft palate (SP) has been established as a good treatment option in treatment of habitual snoring.^{6,7} Decreased snoring is probably based on the scarring-induced increased stability of the SP after RF surgery. Stabilizing the SP might also be helpful in preventing its collapse during

TABLE I.

Definition of the Compound Endpoint Score (CES) Used in the Assessment of the Treatment Outcome in Mild Obstructive Sleep Apnea Patients (N = 32) Treated With Radiofrequency Surgery or Placebo Treatment of the Soft Palate.

Points	3 p	2 p	1 p	0 p
AHI (events/hour)	<5	5–8	9–12	≥13
ESS (0–24 p)	<8	8–13	14–19	20–24
SF-36—PCS (0–100)	>60	50–60	40–49	<40
SF-36—MCS (0–100)	>60	50–60	40–49	<40

p = points; AHI = apnea-hypopnea index; ESS = Epworth sleepiness scale; SF-36 = 36-item short-form questionnaire; PCS = physical component score; MCS = mental component score.

inspiration occurring in OSAS. Therefore, and due to its minimally invasive character, RF surgery of the SP has received increased attention also in the treatment of mild OSAS. The published reports so far, however, have a major limitation of lacking control groups, and the results are controversial.

Our aim was to investigate the efficacy and the occurrence of adverse events after a single-stage SP RF procedure on patients with mild OSAS in a randomized placebo-controlled trial.

MATERIALS AND METHODS

Ethical Issues

The protocol of this prospective, placebo-controlled, single-blinded, randomized trial was reviewed and approved by the Research Ethical Board of Helsinki University Central Hospital. Written informed consent was obtained from all patients.

Patients

The patients were consecutively recruited and followed up at a tertiary care center, the Department of Otorhinolaryngology–Head and Neck Surgery, Helsinki University Central Hospital, Helsinki, Finland, which covers a population of 1.4 million. The eligibility criteria were: age between 30 and 65 years, habitual snoring (≥4 nights/week) for at least 1 year for which conservative treatment failed (weight reduction, sleep position therapy, avoidance of alcohol and sedatives), presence of excessive daytime sleepiness (EDS) according to subjective patient history, body mass index (BMI) <35 kg/m², and apnea-hypopnea index (AHI) between 5 and 15 events/hour. Based on the clinical examination of the upper airway obstruction site, the patients with only velopharyngeal obstruction were considered suitable. Patients with a retrolingual obstruction, skeletal deformities (retro- and/or micrognathia), subjective or objective nose breathing problems, or obstructive tonsil hypertrophy were not included in the study. Additional exclusion criteria were previous velopharyngeal or lingual surgery, exaggerated pharyngeal reflex, and cardiac pacemaker.

Sample Size

The study was designed to evaluate the efficacy of a single session of SP RF surgery in mild OSAS. The null hypothesis was that there is no difference between the treatment arms in management of mild OSAS, and the alternative hypothesis was that the RF surgery is superior to placebo. The sample size of this study was calculated using the mean change of 2 (standard deviation = 1.5) in the compound endpoint score (CES, Table I),

and no change was expected in the placebo group. With a desirable clinical effect of 1.3 in CES, tested with the 2-way Mann-Whitney *U* test (significance level of 0.05 and a power of 80%), 13 patients per group were considered sufficient for the statistical analysis. In total, 34 patients were eventually planned to be included in the trial in order to accommodate for possible dropouts.

Randomization and Procedure

The patients gave written informed consent, and after the baseline measurements were obtained they were randomly assigned to either the active treatment (AT) or the placebo treatment group (PT) by the surgeon (T.L.) picking up a sealed opaque envelope from a pack of 34 envelopes. The nursing staff taking care of the patient were blinded to the group assignment. The procedure and follow-up visits were performed by the same surgeon (T.L.). Follow-up visits were scheduled at a minimum of 4 and a maximum of 6 months after the treatment session, and the patients were then informed of which treatment group they belonged. The use of nonstudy interventions was discouraged throughout the trial.

Patients received a session of either SP RF surgery or placebo on an outpatient basis under local anesthesia. The oropharynx was sprayed with lidocaine, 10 mg/dose (Xylocain; AstraZeneca, Södertälje, Sweden) as a topical anesthetic. Additionally, a 24-gauge needle was used to inject lidocaine hydrochloride, 10 mg/mL cum epinephrine (Lidocain; Orion, Espoo, Finland) into the SP.

The commercially available bipolar RF surgery device (Celon AG Medical Instruments, Teltow/Berlin, Germany) generated the RF energy. The bipolar power control unit (CelonLab ENT) was used with an applicator (CelonProSleep) specifically designed for the use in the SP. The applicator's needle diameter is 1.3 mm, and the length of the free electrode is 14 mm. The RF surgery was applied by inserting the electrodes submucosally into five sites of the SP. The power settings were 10 W in the active treatment group. With these power settings the expected extent of coagulation in the SP would be 3.5 mm in diameter and 8.5 mm in length as provided by the manufacturer. In the placebo group, the applicator was inserted in the SP, but no energy was delivered.

Sleep Recordings

An ambulatory sleep registration (SOMNOcheck Effort; Weinmann Medical Technology, Hamburg, Germany) was carried out at a maximum of 3 months preoperatively and at a minimum of 4 and a maximum of 6 months after treatment in order to evaluate the possible changes in the severity of OSAS. Airflow with nasal and oral thermistor, snoring with a microphone, heart rate, oxygen saturation, body position with a sensor, and movements of the thorax and abdomen with detector belts were measured. The scores were automatically analyzed together with a manual edition of artifacts.

Questionnaires

The baseline measurement was done at a maximum of 3 months preoperatively, and the actual recording 1 week postoperatively. The last estimation was done at the follow-up visit at the minimum of 4 months and a maximum of 6 months after the treatment, and the patients completed the questionnaires as had been done initially.

The patients were asked to grade their symptoms associated with the treatment with a visual analogue scale (VAS).

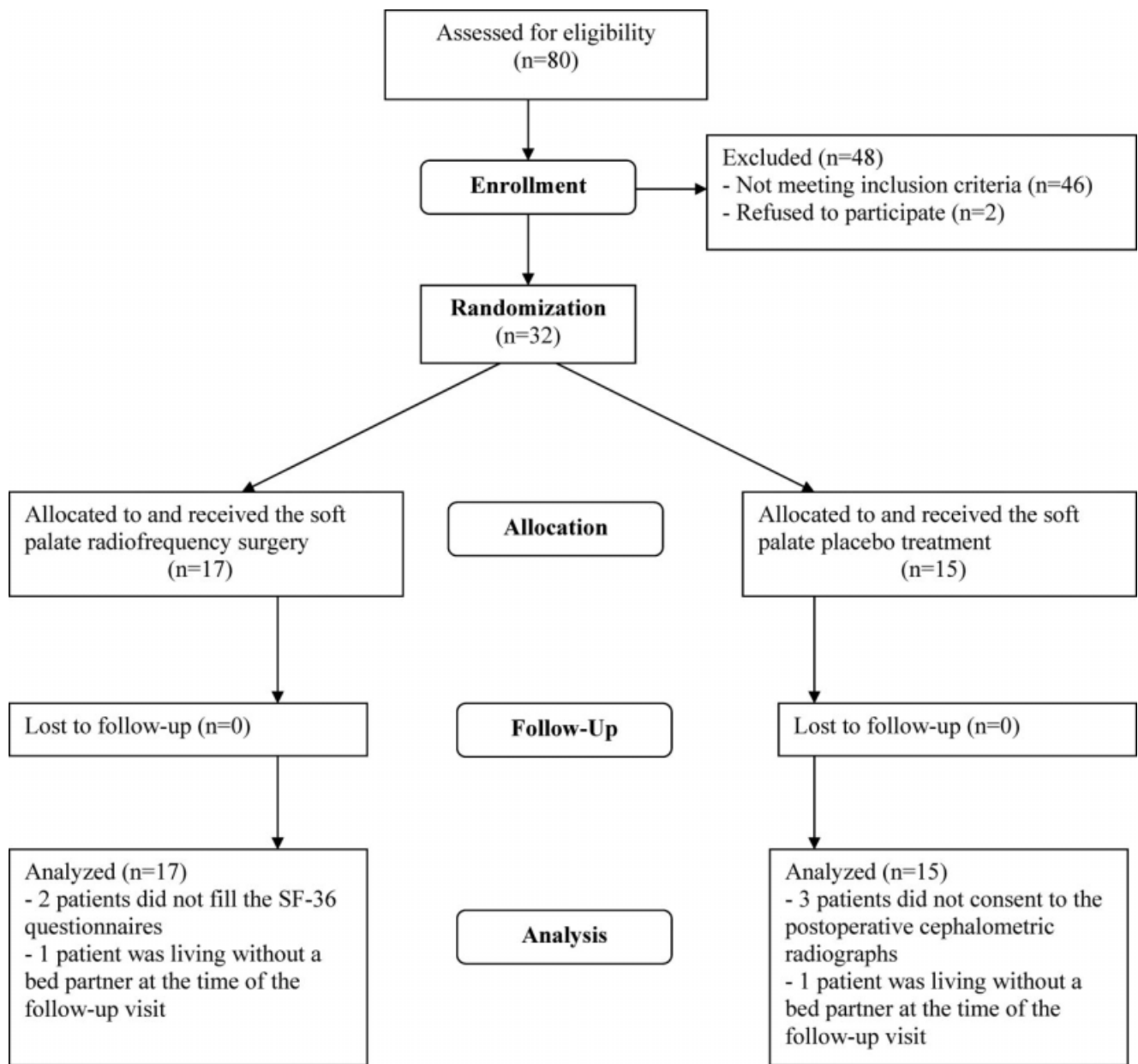


Fig. 1. Progress of participants in trial.

The symptoms were pain, swelling sensation of the SP, difficulty in drinking, breathing, speaking, and opening the mouth.

The patients assessed their snoring with a previously described grading scale, and an additional score was used for the bed partner.⁸ EDS was evaluated using the Epworth Sleepiness Scale (ESS). Additionally, a general quality-of-life (QOL) questionnaire validated in Finnish (36-item short-form health survey [SF-36]) was used. This analyzed eight different domains that were regrouped into physical and mental component scores.

Radiography

Cephalometric radiographic (CR) analysis was done at a maximum of 3 months preoperatively and a minimum of 4 and maximum of 6 months after treatment with patients in upright and supine body positions.⁹ The landmarks identified from lat-

eral cephalograms were digitized (twice with 2-week intervals in order to minimize the intraexaminer variation) and computer registered, and linear and angular variables were calculated (Viewbox 3.1 Cephalometric Software; dHal Software, Kifissia, Greece). The skeletal reference points and lines for measurement of head posture were defined accordingly.⁹ Cephalograms were analyzed in a single-blinded manner.

Criteria for Outcome

The primary outcome measures were change in AHI, ESS, and the SF-36 QOL questionnaires. The CES (Table I) was used as a measure for the primary outcome. We considered that a patient was cured if the post-treatment AHI was <5 and ESS <8. Additionally, an increase in both the mental and the physical component scores in SF-36, the other increase being >10%, was needed. The secondary outcome measures were change in

TABLE II.
Pre- and Post-treatment Clinical Parameters Values (Median and Range) in Mild Obstructive Sleep Apnea Patients Treated With Radiofrequency Surgery or Placebo Treatment of the Soft Palate.

Parameter	PreActive	PostActive	PrePlacebo	PostPlacebo	P Value
BMI, kg/m ²	29.0 (21.0–34.6)	30.0 (21.0–33.9)	25.6 (20.8–34.0)	25.7 (20.8–34.6)	.682
Neck circumference, cm	41.0 (35.0–46.0)	41.0 (35.0–46.0)	40.0 (36.5–44.0)	40.0 (36.5–64.0)	.882
Waist circumference, cm	102.0 (81.0–118.0)	103.0 (83.5–119.0)	96.5 (84.0–116.0)	98.0 (87.0–118.0)	.770
ESS (0–24 p)	10.0 (3.0–21.0)	7.0 (0.0–20.0)	8.0 (3.0–16.0)	5.0 (2.0–15.0)	.941
SNRSs (0–10 p)	6.0 (3.0–10.0)	5.0 (1.0–8.0)	6.0 (2.0–10.0)	5.0 (3.0–10.0)	.153
SNRSo (0–9 p)	6.0 (3.0–9.0)	5.0 (2.0–8.0)	7.0 (5.0–8.0)	6.0 (3.0–8.0)	.064
SF-36—PCS (0–100)	47.2 (22.7–64.1)	48.5 (33.0–67.4)	49.4 (37.6–60.4)	55.3 (19.1–63.7)	.713
SF-36—MCS (0–100)	53.7 (20.9–68.2)	55.3 (19.1–63.7)	51.6 (22.2–63.2)	45.0 (28.1–61.6)	.345
AHI (events/hour)	11.0 (5.0–15.0)	13.0 (2.0–26.0)	12.0 (5.0–8.0)	11.0 (1.0–29.0)	.628
ODI 4% (events/hour)	15.0 (2.0–32.0)	18.0 (1.0–41.0)	7.0 (4.0–37.0)	9.0 (2.0–45.0)	.313
Saturation, minimum (%)	82.0 (68.0–88.0)	82.0 (74.0–92.0)	83.0 (69.0–88.0)	83.0 (63.0–88.0)	.576
Saturation, average (%)	94.0 (89.0–97.0)	94.0 (90.0–96.0)	95.0 (94.0–96.0)	95.0 (92.0–96.0)	.970
CES (0–12 p)	6 (2–9)	6 (3–9)	6 (3–9)	7 (4–10)	.746

Pre = pretreatment value; Post = post-treatment value; Active = active treatment group; Placebo = placebo treatment group; P value = pre- and post-treatment statistical difference between values in the active and placebo treatment groups; BMI = body mass index; ESS = Epworth sleepiness scale; p = points; SNRSs = snoring scores assessed by the patient; SNRSo = snoring score assessed by the bed partner; SF-36 = 36-item short-form questionnaire; PCS = physical component score; AHI = apnea-hypopnea index; ODI 4% = oxygen desaturation index; MCS = mental component score; CES = Compound Endpoint Score.

the cephalometric radiographs, snoring questionnaires, and the occurrence of adverse events.

Statistics

The statistical analysis was conducted together with Professor Seppo Sarna from the Department of Public Health, Faculty of Medicine, University of Helsinki. The power calculations were done using nQuery Advisor 7.0 (Statistical Solutions Ltd., Boston, MA). The primary endpoint was the assessment of treatment effect at the follow-up visit. Comparisons between the groups were performed using a nonparametric approach (2-sample rank sum, Mann-Whitney *U* test). Results are expressed as medians and range, and they were generated using a computerized statistical package (SPSS 15.0; SPSS, Inc., Chicago, IL). The *P* value <.05 was considered statistically significant.

RESULTS

Thirty-two male patients fulfilled the initial inclusion criteria for enrollment in this study from January 2005 to June 2007. To accelerate the evaluation of the results, it was decided to close the project at 32 enrolled patients, 17 patients in AT and 15 in PT. Three patients from the PT group did not consent the postoperative CR, and two patients from the AT group did not complete the SF-36 questionnaire. Additionally, two patients (one from each group) were living without bed partners at the time of the follow-up visit. However, they all completed other parts of the study protocol (Fig. 1). As evidence of a successful randomization process, the groups were well matched at the baseline in terms of demographic data and pretreatment clinical parameters (*P* = .078–0.852, Table II). The median time for the follow-up visit was 4 months (range, 4–6 months). There were no significant changes in the BMI, waist, and neck circumferences during the follow-up (Table II).

The RF surgery was well tolerated. Also, the PT group experienced symptoms during the first postoperative day (POP). However, a statistically significant difference in VAS scores of pain (POP 1), swelling sensation (POP 1, 2, 3, 4, and 6), and speaking (POP 1) were encountered between the treatment groups (Fig. 2). After 1 week a few patients still reported elevated VAS scores in the AT group in swelling sensation and were not fully recovered from the treatment. Four months after the treatment, none of the patients reported any treatment related symptoms or complications (Fig. 2).

There were no statistically significant changes in the CES, clinical parameters, or in the results of the sleep registrations, e.g., AT AHI 11.0 (range, 5.0–9.0) to 13.0 (range, 2.0–26.0) and PT AHI 12.0 (range, 5.0–8.0) to 11.0 (1.0–29.0), *P* = .628 (Table II). There was no statistical trend to be found in the snoring questionnaires and ESS (Table II).

Initially, the SF-36 QOL indexes of both treatment groups were comparable to normal Swedish data (Finnish data not available, *P* = .721–.959). However, despite some improvement in three out of eight domains in the AT group, the analysis of physical and mental scores did not show significant improvement between the groups in the initial and final evaluations.

In the assessment of treatment success based on different parameters, only one patient (1/17, 5.9%) in the AT group had a successful treatment response (post-treatment AHI <5, ESS <8, and substantial improvement of the symptoms).

CR measurements of craniofacial and airway parameters are presented in Tables III and IV. There were no intergroup differences in the initial evaluations (*P* = .058–1.000). Of particular interest in this setting were the possible changes in the soft palate dimensions measured in upright and supine positions, which showed

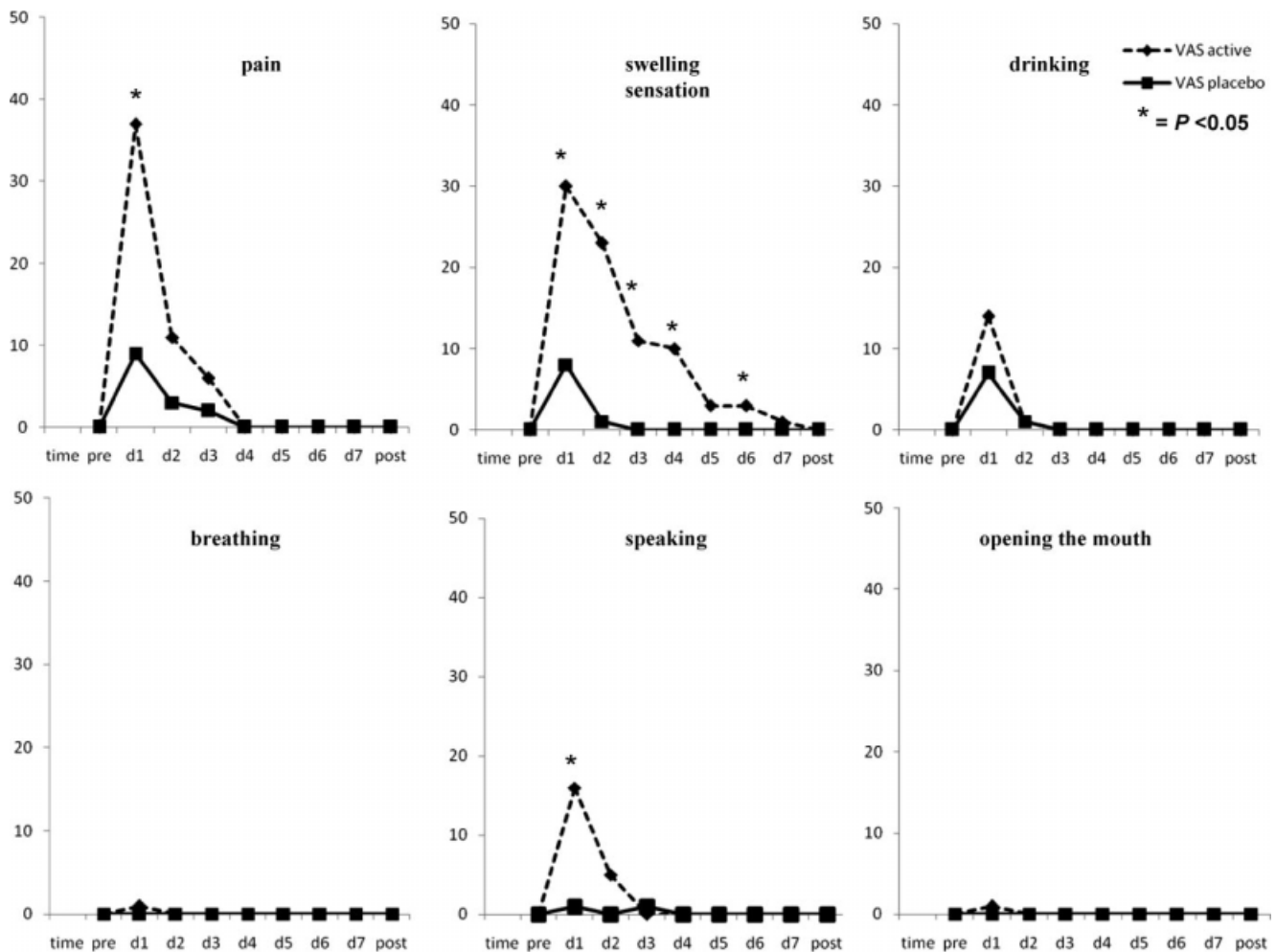


Fig. 2. Visual analogue scale scores (median) of symptoms related to radiofrequency surgery or placebo treatment of the soft palate in 32 mild obstructive sleep apnea patients. VAS = visual analogue scale; pre = preoperative value; d1 = the first postoperative day; d2/ 3/ 4/ 5/ 6/ 7 = the days following the treatment day; post = the assessment of the symptoms 4 months after the treatment; VAS active = VAS scores of the active treatment group; VAS placebo = VAS scores of the placebo treatment group; * = a statistically significant difference ($P < .05$) between the treatment arms.

no significant differences between the groups ($P = .140-.948$).

DISCUSSION

To our knowledge, this is the first randomized placebo-controlled study on the effects of SP RF surgery in treatment of mild OSAS. In this treatment setting only one patient (5.9%) in the AT group was cured in a short-term follow-up. Neither objectively measured statistical significances nor trends of a diminishing effect on symptoms of mild OSAS were encountered. As the reduction of AHI and the symptoms clearly pose a treatment target in mild OSAS patients, CPAP and MAA use show limited compliance, and SP RF surgery results are insufficient and new treatment modalities need to be developed.

Previously, Brown et al. found that RF surgery of the SP lacked clinical efficacy in patients with moderate OSAS.¹⁰ Blumen et al. concluded that SP RF surgery is effective in treating mild to moderate OSAS patients,

and up to 65.5% were cured (i.e., respiratory disturbance index < 10 events/hour); however, 21.0% of the patients remained sleepy according to their ESS.¹¹ Hoffman et al. compared the efficacy of uvulopalatopharyngoplasty and SP RF surgery in treating mild OSAS, and the latter had no effect on OSAS severity.¹²

It is reasonable to assume that the patients in this study were not able to distinguish between placebo and RF surgery due to the minimally invasive character of the procedure and the minimal postoperative treatment related symptoms. In fact, the PT group also experienced some degree of symptoms of the treatment emphasizing the assumption that the patients did not know to which treatment arm they belonged. Of additional interest is that only male patients fulfilled the inclusion criteria during the recruitment time, possibly reflecting the gender difference of the occurrence of mild OSAS.

A weakness of this trial is that the results are based on a short-term follow-up of up to 6 months. In general, potential effects need to be reconfirmed after a longer follow-up period. As the effects achieved in this trial were

TABLE III.

Upright Pretreatment Values (Median and Range) in Cephalometric Radiographs of Different Craniofacial Parameters⁹ in Mild Obstructive Sleep Apnea Patients (N = 32) Treated With Radiofrequency Surgery or Placebo Treatment of the Soft Palate.

Parameter	Upright Value		P Value
	Active (n=17)	Placebo (n=15)	
Cranial base			
Anterior cranial base, S-N (mm)	78.3 (64.8–83.4)	78.6 (67.1–81.6)	.682
Posterior cranial base, S-Ba (mm)	50.8 (45.0–58.1)	49.9 (40.8–56.6)	1.000
Cranial base angle, NSBa (°)	124.9 (114.8–131.4)	124.3 (118.7–135.6)	.911
The position of maxilla, SNA (°)	86.4 (78.7–92.7)	84.7(78.9–88.8)	.350
The position of mandible, SNB (°)	82.8 (62.7–86.8)	83.7 (77.2–88.3)	.911
Facial divergence, SN/MP (°)	28.6 (19.6–39.9)	30.9 (22.3–37.6)	.655
Maxilla/mandible			
Mandibular length, PNS-ANS (mm)	58.2 (49.5–63.0)	57.8 (51.0–65.5)	.941
Maxillary length, CD-Gn (mm)	128.3 (117.6–143.8)	131.4 (108.5–147.3)	.058
Gonian angle, Me-GOinf-Art (°)	130.9 (116.3–145.3)	127.2 (118.2–144.6)	.710
Lower anterior facial height, ANS-Me (mm)	77.9 (64.7–87.6)	80.6 (62.2–85.2)	.176

Active = radiofrequency surgery treatment group; Placebo = placebo treatment group; P value = the intergroup statistical difference between the values in the active and placebo treatment groups; S = sella, center of sella turcica; N = nasion, the most anterior point of the nasofrontal structure; Ba = basion, the lowest point on the anterior border of the foramen magnum; A = subspinale, the most posterior point of anterior contour of upper alveolar process; B = supramentale, the most posterior point of anterior contour of lower alveolar process; MP = mandibular plane, tangent to the lower border of the mandible through menton; PNS = posterior nasal spine, the tip of the posterior nasal spine; ANS = anterior nasal spine, the tip of the anterior nasal spine; CD = condy-lion, the most superior point on the condyle of the mandible; Gn = gnathion, the most anterior and inferior point on the mandibular symphysis; Me = the most inferior point of the mandibular symphysis; GOinf = the most inferior point at the angle of mandible; Art = articulare, the point of intersection between the posterior border of the mandibular condyle and the lower border of the cranial base.

minimal and RF surgery results usually deteriorate over time, a longer follow-up with this treatment setting most probably would not have changed the outcome. An additional weakness is the low median ESS scores in both the treatment groups, although the complaint of the patients was excessive daytime sleepiness according to the subjective patient history. Consequently, there is no knowledge whether the possible change from this pre-treatment ESS score is also of clinical significance.

No significant changes between the treatment groups were detected in CR analysis. The method measures the length and thickness of the SP by four reference

points. In some patients, the form of the SP could be described as the letter “s” after the treatment. Thus, the values were not always comparable between before and after the treatment and between treatment groups.

In the treatment of snoring with the present results, a comparison of the reduction of snoring after RF surgery of the SP in mild OSAS seems to indicate that the pathophysiology of primary snoring and snoring in OSAS may be different. One presented hypothesis is that the progression from snoring to the clinical disease of mild OSAS could be attributed to peripheral neuro-genic changes, and the effects of SP RF surgery might

TABLE IV.

Pre- and Post-Treatment Values (Median and Range) in Cephalometric Radiographs of Different Soft Tissue Airway Parameters⁹ in Mild Obstructive Sleep Apnea Patients (N = 32) Treated With Radiofrequency Surgery or Placebo Treatment of the Soft Palate.

Parameter (mm)	PreUpright	PostUpright	P Value	PreSupine	PostSupine	P Value
PNSu1						
Active	40.7 (35.1–52.9)	42.9 (29.7–50.5)	.879	45.5 (34.5–52.8)	43.5 (33.0–54.9)	.227
Placebo	42.4 (32.6–55.7)	42.8 (33.8–51.5)		43.7 (37.1–56.7)	43.2 (36.5–57.0)	
u1-u2						
Active	9.1 (5.0–17.1)	8.9 (5.1–18.8)	.586	5.8 (2.4–10.7)	6.3 (3.2–12.7)	.616
Placebo	9.2 (4.2–14.5)	11.0 (6.3–14.0)		5.0 (1.7–7.2)	4.8 (2.7–8.6)	
ve-ve2						
Active	9.3 (5.1–14.3)	9.5 (4.9–13.7)	.948	3.7 (1.2–12.2)	3.5 (1.3–8.6)	.140
Placebo	7.9 (4.9–12.1)	8.6 (4.5–11.2)		2.5 (0.7–6.6)	3.5 (2.0–8.5)	
sp1-sp2						
Active	14.1 (11.0–20.7)	13.3 (10.0–18.0)	.879	14.5 (13.4–18.8)	15.1 (11.8–21.5)	.948
Placebo	14.3 (11.2–20.2)	13.9 (11.4–21.9)		14.8 (10.5–18.4)	15.2 (12.1–23.8)	

Pre = pretreatment value; Post = post-treatment value; P value = the statistical evaluation of the pre- and post-treatment differences between the treatment groups; Active = radiofrequency thermal ablation treatment group; Placebo = placebo treatment group; PNSu1 = soft palate length; u1-u2 = minimal distance from tip of uvula to posterior pharyngeal wall; ve-ve2 = minimal distance from velum to posterior pharyngeal wall; sp1-sp2 = thickness of soft palate.

then be different.¹³ The discrepancy of snoring treatment results can also be explained due to differences in the treatment protocol, because we used a single-stage treatment setting. The total amount of energy applied and number of lesions created, however, are in concordance with current literature, and a second SP placebo treatment might be difficult to justify ethically. Additional treatment sessions may diminish the symptoms in mild OSAS patients, but this cannot be assessed in the present study.

CONCLUSION

In this treatment setting, RF surgery of the SP for mild OSAS was not superior to placebo in reducing symptoms and parameters in sleep registrations. Accordingly, RF surgery of the SP is not recommended as a single-stage approach in mild OSAS. The results of this trial emphasize the need of controlled clinical trials to evaluate treatment alternatives for mild OSAS.

Acknowledgments

The authors acknowledge Professor Seppo Sarna, Department of Public Health, Medical Faculty, University of Helsinki, Finland for the assistance in the statistical evaluations, and the Helsinki University Central Hospital Research Fund, Helsinki, Finland for financial support. The authors also acknowledge Celon AG Medical Instruments, Teltow/Berlin, Germany (local representative Olympus Finland OY, Vantaa, Finland) for the free-of-charge usage of the radiofrequency generator and the applicators.

BIBLIOGRAPHY

1. Yetkin O, Kunter E, Gunen H. CPAP compliance in patients with obstructive sleep apnea syndrome. *Sleep Breath* 2008;12:365–367.
2. Sahlman J, Pukkila M, Seppa J, Tuomilehto H. Evolution of mild obstructive sleep apnea after different treatments. *Laryngoscope* 2007;117:1107–1111.
3. Buchner NJ, Sanner BM, Borgel J, Rump LC. Continuous positive airway pressure treatment of mild to moderate obstructive sleep apnea reduces cardiovascular risks. *Am J Respir Crit Care Med* 2007;176:274–280.
4. Hoekema A, Stegenga B, De Bont LG. Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea: a systematic review. *Crit Rev Oral Biol Med* 2004;15:137–155.
5. Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep* 2006;29:244–262.
6. Stuck B, Maurer J, Hein G, Hormann K. Radiofrequency surgery of the soft palate in the treatment of snoring: a review of the literature. *Sleep* 2004;27:551–555.
7. Stuck B, Sauter A, Hormann K, Verse T, Maurer J. Radiofrequency surgery of the soft palate in the treatment of snoring. A placebo-controlled trial. *Sleep* 2005;28:847–850.
8. Back LJ, Tervahartiala PO, Piilonen AK, Partinen MM, Ylikoski JS. Bipolar radiofrequency thermal ablation of the soft palate in habitual snorers without significant desaturations assessed by magnetic resonance imaging. *Am J Respir Crit Care Med* 2002;166:865–871.
9. Back L, Liuikko T, Rantanen I, et al. Hypertonic saline injections to enhance the radiofrequency thermal ablation effect in the treatment of base of tongue in obstructive sleep apnea patients: a pilot study. *Acta Otolaryngol* 2008;10:1–9.
10. Brown FJ, Kerr P, Kryger M. Radiofrequency tissue reduction of the palate in patients with moderate sleep-disordered breathing. *J Laryngol Otol* 2001;30:193–198.
11. Blumen MB, Dahan S, Fleury B, Hausser-Hauw C, Chabolle F. Radiofrequency ablation for the treatment of mild to moderate obstructive sleep apnea. *Laryngoscope* 2002;112:2086–2092.
12. Hoffman T, Schwantzer G, Reckenzaun E, Koch H, Wolf G. Radiofrequency tissue volume reduction of the soft palate and UPPP in the treatment of snoring. *Eur Arch Otorhinolaryngol* 2006;263:164–170.
13. Svanborg E. Impact of obstructive apnea syndrome on upper airway respiratory muscles. *Respir Physiol Neurobiol* 2005;147:263–272.