Radiofrequency Tissue Volume Reduction of the Soft Palate in Simple Snoring

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**Background:** Snoring is common and often associated with social morbidity. Current therapies are generally unsatisfactory, but radiofrequency tissue volume reduction (RFTVR) palatoplasty offers a new approach.

**Objective:** To assess the outcomes and morbidity associated with RFTVR palatoplasty.

**Design:** Open, prospective trial.

**Setting:** Tertiary referral center.

**Patients:** 20 adults with loud habitual snoring without clinically significant obstructive sleep apnea.

**Interventions:** Three treatments with RFTVR to the middle, distal, and proximal thirds of the midline of the soft palate.

**Main Outcome Measures:** Clinical assessment (visual analog scores) before and after each treatment, polysomnography (with sound intensity measurements), and lateral cephalometry performed prior to the first treatment and 2 months following the final treatments.

**Results:** After treatment, there was a significant overall improvement in the snoring visual analog score (7.5 ± 1.5 to 4.6 ± 2.5; P < .001), a small reduction in the proportion of sleep spent snoring at 50 to 60 dB (P = .03), and mild pain that was controlled with simple analgesia. There were no long-term adverse effects. Individual response could not be predicted by demographic, polysomnographic, or cephalometric data. Treatment of the proximal third of the soft palate was associated with fewer adverse effects but also seemed less effective than at the other sites.

**Conclusions:** (1) The RFTVR palatoplasty is well tolerated with very low morbidity. (2) It is associated with subjective improvement in snoring in most patients. (3) Placement of lesions seems to influence outcome. (4) The improvement is accompanied by a marginal change in objective measurements, suggesting either an acoustic change independent of sound intensity or a placebo effect. (5) A randomized controlled trial is needed to further evaluate this therapy.


Snoring is a common problem, with 81% of men aged 40 to 65 years snoring for more than 10% of the night, and 22% for more than 50% of the night on home monitoring. Current therapies for simple snoring are unsatisfactory. Surgical modalities such as laser-assisted uvulopalatoplasty or uvulopalatopharyngoplasty are associated with significant morbidity. Other treatments require ongoing use rather than offering the prospect of a cure. Dental devices are often effective but are associated with substantial adverse effects. Continuous positive airway pressure is a very effective therapy, but patient compliance and acceptance is poor, particularly when snoring is not accompanied by obstructive sleep apnea of at least moderate severity.

Recently it has been suggested that radiofrequency tissue volume reduction (RFTVR) applied to the soft palate might offer a safe, effective alternative. This procedure involves thermocoagulation of tissue by low-intensity radiofrequency signal. The low temperature involved (60°C–90°C) results in a localized thermal lesion with minimum injury to surrounding tissue. It has been used in other fields for many years, including ablation of accessory cardiac conduction pathways, treatment for benign prostatic hyperplasia, and trigeminal gangliolotomy for neuralgia. The rationale for use of the therapy to treat snoring is that resorption of the thermocoagulated tissue and subsequent scarring stiffens and shortens the soft palate, reducing its tendency to vibrate.
PATIENTS AND METHODS

Twenty adult patients with socially problematic snoring were selected from among those presenting to a sleep disorders clinic. Subjects needed to meet the following criteria: age 18 years or older, bothersome snoring, maximum snore intensity of 30 dB or greater, and only simple snoring or mild obstructive sleep apnea (apnea-hypopnea index of ≤15). Subjects were excluded if there was a history of neurological, swallowing, or unstable psychiatric disorders, obesity (body mass index [BMI or Quetelet index, calculated as weight in kilograms divided by the square of the height in meters], >32), or if there was a history of previous pharyngeal surgery (excluding tonsillectomy or adenoidectomy). Informed consent was provided by all subjects.

PROTOCOL

The study was an open, prospective design and was approved by a hospital ethics and research committee. Prior to first treatment, clinical assessment (visual analog scores [VASs] of snoring [partner assessment] and of sleepiness and the Epworth sleepiness score7), polysomnography (sleep staging, oronasal flow [thermistor], chest and abdominal motion [inductance plethysmography; Respitrace, Ardsley, NY], sound intensity monitoring [Model NA-24; Rion, Tokyo, Japan]), and lateral cephalometry were performed. The VAS of snoring (range, 0-10) was derived from a rating made on a continuous scale from none to very intense (patient leaves bedroom). The VAS of sleepiness was derived from a scale ranging from no tendency to sleep to constantly falling asleep during the day. Polysomnography was performed in a small room (4 × 4 × 2.7 m) that was relatively nonabsorbent for sound. Using an extension cable, the omnidirectional microphone of the sound intensity meter was set in a fixed position relative to the sound source, being 1 m above the subject’s head, in accordance with our previously published methods.8 The polysomnogram was analyzed according to the standards of the American Thoracic Society.9

Following this initial evaluation, subjects received 3 RFTVR treatments to the soft palate at intervals of at least 2 weeks. The procedures were performed in a surgical recovery room. Topical lidocaine (4%) followed by submucosal infiltration of 2% lidocaine with epinephrine were used as local anesthetics. A radiofrequency generator (Somnus Medical Technologies, Sunnyvale, Calif) and a hand-held electrode were used to deliver 650 J (constant electrode temperature of 85°C) to the midline of the soft palate. Treatments were provided to the middle, distal, and proximal thirds of the soft palate successively. Clinical assessment was performed at days 3 and 7 after each treatment. A VAS was used to evaluate pain, speech, and swallowing after therapy. The subjects were asked to rate the following characteristics: pain, on a continuous scale from none to severe (pain that does not resolve even after analgesic medication); the effect on speech, on a continuous scale from none to severe (difficulty talking); and difficulty swallowing, on a continuous scale from none to severe (unable to swallow without pain even after analgesic medication).

Subjects were reevaluated 8 weeks after the final treatment. Clinical assessment was again made using the VAS of snoring intensity (partner assessment) and of sleepiness and the Epworth sleepiness score.7 Polysomnographic and lateral cephalometry were repeated.

ANALYSIS

Data are presented as mean ± SD. Analysis was performed using a statistical software package (SigmaStat; Jandel Corporation, Oxon, England). Clinical and cephalometric data were compared before and after treatment by a paired t test. Polysomnographic outcomes were compared by a Mann-Whitney rank sum test. The relationships of baseline demographic, polysomnographic, and cephalometric data to improvements in subjective snoring were examined by forward stepwise linear regression. P<.05 was considered significant.

Thus far, there has been limited evaluation of this new therapy. The purpose of this study is to use subjective (patient and partner reports) and objective (sound intensity monitoring) means to evaluate the potential efficacy of RFTVR of the soft palate to treat simple snoring and to examine its adverse effects and complications. Because we are interested in the effect of placement of the lesions, we designed the study so that the lesions were made in a fixed order to 3 fixed locations, and assessed efficacy after each treatment.

RESULTS

SUBJECTS

Sixteen of 20 patients were men (mean ± SD age, 43.2 ± 11.1 years). A mean ± SD of 650 ± 7.18 J was delivered at each treatment, with an average duration of 2.43 ± 0.52 minutes. The mean interval between treatments was 26.9 ± 12.1 days. There was no significant change in Epworth sleepiness score (baseline, 8.1 ± 4.0; posttreatment, 6.7 ± 4.0) or sleepiness VAS (baseline, 3.0 ± 2.0; posttreatment, 2.6 ± 2.2). Polysomnographic data and BMI before and after treatment are given in Table 1.

SUBJECTIVE SNORING

There was a significant improvement in subjective snoring for the group (from 7.5 ± 1.5 to 4.6 ± 2.5; P<.001). While 18 of 20 patients reported some improvement in subjective snoring (Figure 1), only 8 patients reported an improvement of at least 50%. Improvements in subjective snoring for the group were noted after the first (middle third of the soft palate) and second (distal third) treatments but not after the third (proximal third) treatment (Figure 2).

SNORING INTENSITY

There was a statistically significant but clinically irrelevant increase in the maximum measured snoring intensity monitoring (inductance plethysmography; Respitrace, Ardsley, NY), sound intensity monitoring [Model NA-24; Rion, Tokyo, Japan]), and lateral cephalometry were performed. The VAS of snoring (range, 0-10) was derived from a rating made on a continuous scale from none to very intense (patient leaves bedroom). The VAS of sleepiness was derived from a scale ranging from no tendency to sleep to constantly falling asleep during the day. Polysomnography was performed in a small room (4 × 4 × 2.7 m) that was relatively nonabsorbent for sound. Using an extension cable, the omnidirectional microphone of the sound intensity meter was set in a fixed position relative to the sound source, being 1 m above the subject’s head, in accordance with our previously published methods.8 The polysomnogram was analyzed according to the standards of the American Thoracic Society.9

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sity following treatment (baseline, 60.2 ± 3.9 dB; post-
treatment, 64.9 ± 5.3 dB; \( P = .03 \)). There was a slight
redistribution of snoring intensity, with a reduction in
the proportion of sleep time spent snoring in the range
of 50 to 60 dB (\( P = .03 \)) and a marginal increase (not sig-
nificant) in snoring at 40 to 50 dB (Figure 3).

ADVERSE EFFECTS OF TREATMENT

There was minimal morbidity associated with the treat-
ment. Visual analog scores for pain, swallowing, and
speech are shown in Figure 4. There was a trend for
more prolonged symptoms after the second treatment (to
the distal third of the soft palate), but these differences
were not significant. Patients used the combination drug
paracetamol/codeine (500 mg/30 mg) for up to 4 days
after each treatment.

Mucosal ulcers developed in 3 patients after the treat-
ment to the distal third of the soft palate. In 1 of these
patients, the lesion occurred following movement dur-
ing treatment, which resulted in exposure of the mu-
sa to the active electrode. The ulcers healed sponta-
neously by 3 to 5 weeks.

CEPHALOMETRY

The cephalometric parameters used are shown in
Figure 5 and the data given in Table 2. There were
trends toward a reduction in palatal width and length,
but these did not reach statistical significance.

CORRELATES WITH IMPROVEMENT
IN SUBJECTIVE SNORING

The percentage change in subjective snoring intensity was
significantly correlated with both total energy delivered
(\( r = 0.29; P = .03 \)) and time since first treatment (\( r = 0.25;\)
\( P = .05 \)). However, each of these variables explains less

Table 1. Body Mass Index* and Polysomnographic Data
Before and After Treatment†

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline</th>
<th>Posttreatment</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body mass index†</td>
<td>27.1 ± 2.8</td>
<td>27.5 ± 3.2</td>
<td>NS</td>
</tr>
<tr>
<td>Apnea-hypopnea index, per sleep hour</td>
<td>3.3 ± 3.1</td>
<td>6.6 ± 8.1</td>
<td>NS</td>
</tr>
<tr>
<td>Arousal index, per sleep hour</td>
<td>19.4 ± 7.9</td>
<td>19.2 ± 9.6</td>
<td>NS</td>
</tr>
<tr>
<td>Sleep efficiency</td>
<td>82.6 ± 9.6%</td>
<td>82.5 ± 11.8%</td>
<td>NS</td>
</tr>
<tr>
<td>Mean sleep arterial saturation</td>
<td>95.7% ± 1.4%</td>
<td>95.6% ± 1.3%</td>
<td>NS</td>
</tr>
<tr>
<td>Nadir sleep saturation</td>
<td>88.3% ± 3.5%</td>
<td>86.7% ± 5.5%</td>
<td>NS</td>
</tr>
</tbody>
</table>

* Calculated as weight in kilograms divided by the square of the height in meters.
† Unless otherwise indicated, data are mean ± SD. NS indicates not significant.
than 10% of the total variation in improvement in subjective snoring. This measure did not correlate with baseline demographic, polysomnographic, or cephalometric data.

**COMMENT**

Despite widespread interest in and promotion of RFTVR, there is a relative paucity of published information on its efficacy and adverse effects when used on the soft palate to treat snoring, and none on the effects of site of placement of the lesions. Our study was aimed at addressing these issues in a cohort of simple snorers.

Our study agrees with previous work of the procedure seems to be associated with minimal morbidity and is suitable for outpatient administration. Only simple analgesia is required postoperatively, and subjects are able to return to work within hours of therapy. This is a distinct advantage over other surgical modalities. Three patients developed mucosal ulceration, which was associated with minor discomfort and healed spontaneously within 3 to 5 weeks. Each occurred following treatment to the distal third of the soft palate, as might be expected because it is thinner, making placement of the lesion without breaching the mucosa more difficult. Postprocedural pain was also increased at this site. Previous investigators have reported sloughing of the uvula as a complication of this treatment, which is likely to reflect coagulation of its arterial supply. We did not observe this complication in our cohort. Our experience with this treatment indicates that it is safe and well tolerated.

Most patients reported improvement in subjective snoring following the treatment. However, only 8 patients (40%) described more than a 50% reduction in subjective snoring. We were not able to identify clinical, polysomnographic, or radiological characteristics useful in predicting a clinical response to treatment. The degree of improvement in objective snoring correlated only to the period since first treatment and total energy delivered to the soft palate. These parameters are interrelated because a standard energy was delivered for each treatment, and they explain less than 10% of the variability in the improvement in subjective snoring.

Problems with appropriate selection of patients are not unique to this therapy. Patient selection has been extensively investigated with respect to conventional palatal surgery. Selection of patients with snoring generated only by palatal flutter should improve outcome from these
procedures. While wakeful fiberoptic nasopharyngoscopy seems to be of limited use, sleep nasendoscopy shows promise as a technique to locate snoring and has found noise generation at a site other than the soft palate in 30% of adult snorers. This may explain the variability in clinical response to this therapy. Subjects with nonpalatal snoring would not be expected to improve with radiofrequency palatal reduction, and those with snoring arising from palatal flutter alone may improve more than if snoring is generated from multiple sites. The use of sleep nasendoscopy to determine the site of snoring has been shown to have predictive power in identifying success following uvulopalatopharyngoplasty. However, it is a difficult procedure and not suitable for generalized screening of patients being considered for palatal surgery.

There was a reduction in snoring overall following treatment to the middle and distal thirds of the soft palate but not after the treatment to the proximal third. It seems that lesions directed toward the thinner, free edge of the soft palate are more effective, but also seem to be associated with marginally more severe and prolonged adverse effects. The treatment resulted in a trend toward a reduction in the length and width of the soft palate, which is consistent with our understanding of its mechanism. The formation of fibrous scar tissue would result in shrinkage of the soft palate, in addition to decreasing the compliance and altering the shape of this membrane. It would be expected that a thermal lesion to the thinner part of the soft palate would have a more substantial effect on the stiffness and shape of the soft palate than a lesion in the thicker, proximal tissue. Further work on the optimal placement of thermal lesions needs to be performed.

We selected an 8-week period between final treatment and final evaluation because previous histologic examination of the inflammatory changes following radiofrequency lesions demonstrated that edema had completely resolved by this time. There was also considerable tissue retraction at the site of the lesion.

There was a discrepancy between the subjective changes in snoring and changes in snoring intensity. The redistribution of snoring intensity from the range of 50 to 60 dB to 40 to 50 dB is of uncertain significance, particularly as maximum snoring intensity increased marginally. This raises the possibility of a significant placebo effect. However, partners often reported that the character of the snoring had changed. Therefore, it is possible that radiofrequency palatal reduction has acoustic effects independent of snoring intensity. Sound frequency analysis may provide further information. The discrepancy between subjective and objective measures of snoring is not unique to this therapy and has also been reported following uvulopalatopharyngoplasty, with studies showing very poor correlation between subjective and objective assessments of snoring. In addition, perception of snoring is highly subjective, with significant disagreement between listeners, and therefore subjective snoring assessment also reflects this variability.

We are satisfied that this therapy conforms to the aphorism “first do no harm.” The procedure is relatively simple and well tolerated, and has minimal impact on the subjects’ capacity to work within hours post-surgery, unlike conventional palatal surgery. The principle of treatment seems sound, and our evaluation suggests that it may prove to be a useful therapy. Placement of the lesions toward the free edge of the soft palate seems more effective but associated with more adverse effects than placement near the hard palate. These findings justify a randomized controlled trial, which is now required to further evaluate the therapy. Number and placement of lesions will be of considerable importance in the design of such a study.