Radiofrequency Tissue Volume Reduction

Multilesion vs Single-Lesion Treatments for Snoring

Michael Ferguson, MD; Timothy L. Smith, MD, MPH; Adam M. Zanation; Wendell G. Yarbrough, MD

Objective: To compare the safety and efficacy of single-lesion and multilesion radiofrequency tissue reduction (RFTR) of the soft palate for the treatment of snoring.

Design: Prospective, nonrandomized clinical trial.

Setting: University hospital outpatient clinic.

Patients: Nonrandomized patients undergoing RFTR to treat socially unacceptable snoring. Of 47 patients, 16 received single-lesion treatments and 31 received multilesion treatments.

Intervention: Soft-palate RFTR was performed using a radiofrequency generator. Patients required 1 to 3 treatments based on improvement or withdrawal from the study, and each received 1, 3, or 4 lesions per treatment. Patients who received single-lesion therapy did not cross over into the multilesion group; however, 5 patients in the multilesion group received 4-lesion therapy after a treatment with 3 lesions.

Main Outcome Measures: Outcome measures were determined using visual analog scale questionnaires assessing level of snoring (snoring index) and level of pain (pain index) associated with the procedure. Adverse events and complications during treatment were cataloged. Data were collected before the procedure, 6 weeks after each treatment, and an average of 16 months after the last procedure.

Results: Single-lesion and multilesion groups showed significant improvement in snoring after RFTR treatments ($P<.01$ for both). However, compared with the single-lesion group, the multilesion group required fewer treatments (1.94 vs 2.38; $P=.05$) and was more than twice as likely to be cured after 2 treatments (61% vs 25%; $P=.02$). A trend toward improved clinical outcomes with increased number of lesions and total energy per treatment was observed when patients treated with 1, 3, or 4 lesions were compared. The 4-lesion group had the most pronounced improvement in snoring index score per treatment, the lowest number of treatments required for cure, and the greatest percentage of patients cured after 2 treatment sessions. Follow-up demonstrated minimal relapse of snoring in the multilesion group at a mean of 16 months. Although there was a statistically significant increase in pain in the multilesion group vs the single-lesion group, this increase did not increase narcotic use or time off work and was considered minimal by reporting patients.

Conclusion: Multilesion RFTR using higher energy levels per treatment is safe and has increased efficacy without increased complications relative to single-lesion therapy.


Snoring is a ubiquitous problem in American society. Results of epidemiological studies1-3 indicate that approximately 30% of all women and more than 40% of all men habitually snore. Furthermore, the percentage of the population that snores increases with increasing age.4 The actual number of snorers might be higher than reported because most snoring questionnaires depend on patient awareness of their own snoring, and subjective snoring is often grossly underreported.5 Snoring is classified as a parasomnia, or an undesirable physical phenomenon that occurs primarily during sleep6 and is commonly believed to be a precursor to more severe forms of sleep-disordered breathing, such as upper airway resistance syndrome, obstructive sleep hypopnea syndrome, and obstructive sleep apnea (OSA) syndrome.

The physiologic mechanism of snoring involves a change during sleep in the configuration of the collapsible regions of the upper airway. Because these regions are the known culprits of snoring, surgical techniques have traditionally focused on these anatomic areas for treatment. Uvulopalatopharyngoplasty (UPPP) was first introduced as a treatment for OSA but was also found to be effective for the treatment of snoring.7 The need for general anesthesia and the significant morbidity as-
MATERIALS AND METHODS

STUDY PROTOCOL

This prospective, nonrandomized clinical trial examined patients who had undergone RFTR of the palate at 2 institutions to determine the effect of single-lesion vs multilesion RFTR on snoring. Our hypothesis was that the creation of multiple lesions using higher total energy per treatment session would produce a more pronounced and earlier improvement in snoring, thus reducing the number of treatments required, the length of time before achieving the desired result, and, ultimately, the cost of the procedure. Specifically, this study compares patients treated with a single lesion, 3 lesions, or 4 lesions during each therapy session.

PATIENTS

Patients enrolled in this study were nonrandomized individuals who elected to undergo RFTR to treat their socially unacceptable snoring. Inclusion criteria included bothersome snoring that disturbed the patient’s bed partner. No patients with symptoms suggestive of OSA (excessive daytime somnolence, witnessed apnea, excessive sleep requirements, or morning headaches) were enrolled. All patients were extensively screened for lack of risk factors suggestive of OSA in the history or physical examination (body mass index [BMI, calculated as weight in kilograms divided by the square of height in meters] >31; neck circumference ≥43 cm in men and ≥41 cm in women; maxillary or mandibular deficiency; cervical scoliosis; telescoping of the uvular mucosa; lateral wall hypertrophy; rugae of the posterior pharyngeal wall; and enlarged tonsils, adenoids, or both). Patients who had any of these risk factors or a positive polysomnography (PSG) study result indicative of OSA were excluded from the study. Tongue size was assessed using the classification of Mallampati et al, with all patients determined to be either class 1 or class 2. Careful and thorough informed consent was obtained from all patients regarding diagnostic workup and treatment of snoring. Institutional review board–approved informed consent was obtained from all participants who enrolled before Food and Drug Administration approval of RFTR.

Patients undergoing single-lesion RFTR were treated with a single lesion to the midline of the palate (see the “Procedure” subsection). Patients in the multilesion group received either 3 or 4 lesions per treatment session. Five patients in the multilesion group received 3-lesion therapy for their first treatment and then received 4 lesions for additional treatment sessions.

POLYSOMNOGRAPHY

For our patient population in general, PSG is a covered health care benefit only for patients who have overt signs and symptoms of OSA. By design, this study population did not have signs and symptoms of OSA other than snoring, and despite extensive counseling regarding the risks of OSA, many patients made an informed decision not to undergo PSG. Reasons given by patients regarding their decision to forego PSG related primarily to the expense, inconvenience, and waiting time associated with the test. Twelve patients agreed to undergo standard monitored overnight PSG before treatment. From these data, the apnea index (apnea episodes per hour), hypopnea index (hypopnea episodes per hour), respiratory disturbance index (apnea index + hypopnea index), and lowest arterial oxygen saturation were determined.

VISUAL ANALOG SCALES

Snoring Index

Visual analog scale (VAS) questionnaires were used to evaluate the level of snoring symptoms in each patient. Based on a 10-point scale, the questionnaires were completed by each patient’s bed partner before the first treatment and 6 weeks after treatment. In addition, patients and their bed partners were seen in follow-up or contacted by

RESULTS

Forty-seven patients who underwent soft-palate RFTR were evaluated for this study. Of these patients, 12 agreed to undergo overnight PSG before initiation of RFTR treatments. The mean respiratory disturbance index score for patients evaluated using PSG was 6.0±4.3, and the low-

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telephone, and longer-term snoring index (SI) scores were determined at periods ranging from 2 months to 26 months after the procedure. The snoring scale ranged from a level 0 (no snoring) to a level 10 (a partner leaving the room because of intolerable snoring). A score less than 3 indicated that snoring was present but was not bothersome to the bed partner, and, in general, this level of snoring correlated with patients’ desire for no further treatments.

**Pain Index**

A 10-point VAS was used to assess postprocedure pain, with 0 indicating no pain and 10 indicating the worst pain ever experienced by the patient. Patients assessed postprocedural pain at their first clinic visit after the procedure.

**Statistical Analyses**

GraphPad InStat (GraphPad Software Inc, San Diego, Calif) or Statview (SAS Institute, Cary, NC) software and the unpaired t test were used to compare single-lesion and 3- or 4-lesion groups for pain or success rate after 2 treatment sessions. For analyses of patients receiving multiple lesions, data for the 3- and 4-lesion groups were combined (including 5 patients who received both 3 and 4 lesions). As opposed to the multilesion group, all analyses of the 3- and 4-lesion groups excluded the 5 patients who received both 3 and 4 lesions. Two-tailed P ≤ .05 was considered statistically significant.

**Procedure**

Soft-palate RFTR was performed on each patient using a radiofrequency generator (Somnus Medical Technologies Inc, Sunnyvale, Calif). Probes designed to deliver submucosal radiofrequency energy were used to treat the midline and paramedian of the soft palate. Each electrode was supplied with an insulating cover (Somnus Medical Technologies Inc) that allowed exposure of only 1 cm of active electrode to avoid mucosal injury during treatment. After informed consent was obtained, the soft palate was anesthetized with 14% benzocaine topical spray, followed by submucosal injection of 1% lidocaine with 1:100000 epinephrine in the proposed treatment area. No patients required use of sedatives or additional pain medications to tolerate the procedure. Single-lesion treatments were aimed at the midline region of the soft palate, midway between the hard and soft palatal junction and the base of the uvula. Patients in the 3-lesion group received treatments at the midline and lateral regions of the soft palate, just above the superior pole of the tonsillar pillars. Patients in the 4-lesion group received 2 paramedian lesions and 2 lateral lesions. Target levels for tissue temperature and energy delivered were determined before initiation of the procedure and were recorded immediately after the procedure. Tissue temperature was regulated via feedback thermocouples in the tip of the electrode and was maintained at 85°C by alterations in power determined automatically by programs within the radiofrequency generator. After the procedure, patients were observed in the outpatient clinic for approximately 10 minutes before discharge.

**Follow-Up**

Patients returned for a follow-up appointment 6 to 8 weeks after the initial procedure and at that time completed questionnaires regarding pain and snoring results. Further treatments were offered based on results from the previous treatment. Patients who did not come to their follow-up appointment and patients for whom longer follow-up data were needed were contacted by telephone. Bed partners completed the SI and patients completed the pain index and relayed information on any complications. Patients in this study received a maximum of 3 treatment sessions at which 1, 3, or 4 lesions were created. The treatment end point was either patient satisfaction (a score of ≤ 5 on the VAS) or patient withdrawal from the treatment protocol at their request. Reasons for withdrawal and complications were documented.

Of single-lesion patients, 25% obtained a cure (SI score ≤ 5) after 2 treatment sessions (Table 2). Short-term follow-up demonstrated no decrease in efficacy of the procedure at an average of 4 months after the last procedure. The multilesion group, including all patients receiving either 3- or 4-lesion treatment (including 3 who received both 3- and 4-lesion treatments at different treatment sessions), comprised 26 men and 5 women (Table 1). The average age of these patients was 53 years, and their average BMI was 28.7. Nineteen patients received 3 lesions, 7 received 4 lesions, and 5 received a combination of both. For 3-lesion treatments, lesions were created at the midline and the lateral regions of the soft palate, just above the superior pole of the tonsillar pillars. Patients in the 4-lesion group received 2 paramedian lesions and 2 lateral lesions (see the “Materials and Methods” section) (Figure 2). For the multilesion group, an average of 1546 J was delivered per treatment (vs 1546 J per treatment in the single-lesion group), with an average of 537 J per lesion. In actual practice, more energy was delivered to the midline lesion compared with the lateral lesions. The preprocedure SI score in the mul-
tile lesion group was higher than that in the single-lesion group (9.10 vs 8.94) and was roughly equivalent to a bed partner’s perception of intolerable snoring. Compared with patients treated with single-lesion therapy, more improvement in snoring per treatment session was noted (1.46 vs 2.14; P = .20). The average number of treatment sessions was decreased in the multilesion group compared with the single-lesion group (1.94 vs 2.38; P = .05). Likewise, the percentage of patients achieving an SI score ≤5 (indicating a clinical cure) after 2 treatments increased significantly compared with the single-lesion group (61% vs 25%; P = .02).

Further analyses of the multilesion group revealed that 15 men and 4 women (mean age, 53 years; BMI, 28.5) comprised the 3-lesion group (Table 1). The 3-lesion data from the 5 patients receiving both 3 and 4 lesions are excluded from these analyses. This group received, on average, 1580 J per treatment, with a mean of 527 J delivered to each lesion (Table 2). After 2 treatment sessions, the percentage of patients obtaining a clinical cure trended toward improvement relative to the single-lesion group (47% vs 25%; P = .18). In the 3-lesion group, 6 patients (32%) withdrew from the study before 3 treatments without achieving a clinical cure. These patients were considered failures in analyses of treatment efficacy. Most commonly, patients who withdrew early did so because of a failure of the first procedure to meet personal expectations of improved snoring.

The 4-lesion group included 6 men and 1 woman (Table 1). Their mean age was 52 years, and their mean BMI, 29.2, was the highest of the 3 groups. Again, the 4-lesion data from the 5 patients receiving both 3 and 4 lesions are excluded from analyses of this group. The 4-lesion group had the highest average total joules per treatment at 2420 (Table 2). Before intervention, the 4-lesion group had the most bothersome snoring of any study group (SI score, 9.25). The 4-lesion group also had the most pronounced improvement in SI score per treatment session at 2.30. Increasing the number of palatal lesions to 4 further reduced the average number of treatments necessary for satisfactory snoring reduction (SI score ≤5) to 1.92. Despite the relatively small number of patients in the 4-lesion treatment group (n=7), the marked increase in the percentage of patients cured after 2 treatment sessions remained statistically significant compared with single-lesion patients (71% vs 25%; P = .04). No patients in the 4-lesion group withdrew before completion of the study.

Extended follow-up of the multilesion patients at an average of 16 months after the procedure revealed that the SI score had worsened by an average of 0.2 points. This is equivalent to only a 2.9% worsening of snoring from maximal improvement and was not statistically significant. Only 1 patient reported a return to his preprocedure snoring baseline at extended follow-up, with the remaining patients demonstrating little or no tendency toward relapse.

Because of the increased energy delivered with each treatment session in the multilesion group, the possibility that postprocedure pain or complications might be increased was evaluated. Although there was a statistically significant increase in the average pain index score between the single-lesion and multilesion groups (1.22 ± 1.29 vs 2.69 ± 1.52; P = .04), the average pain index score for all patients regardless of the number of lesions correlated with minimal pain.

![Figure 1. Single-lesion radiofrequency tissue reduction. Submucosal delivery of a midline palatal lesion between the junction of the hard and soft palates and the head of the uvula.](image)

**Table 1. Patient Characteristics**

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Single-Lesion (n = 16)</th>
<th>Multilesion* (n = 31)</th>
<th>3-Lesion† (n = 19)</th>
<th>4-Lesion† (n = 7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men, No.</td>
<td>11</td>
<td>26</td>
<td>15</td>
<td>6</td>
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<tr>
<td>Women, No.</td>
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<td>5</td>
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<td>1.76</td>
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<td>Body mass index, mean, kg/m²</td>
<td>27.4</td>
<td>28.7</td>
<td>28.5</td>
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</tbody>
</table>

*The multilesion group includes the 3-lesion (n = 19) and 4-lesion (n = 7) groups and 5 patients who received a combination of 3- and 4-lesion treatments.
†The 3- and 4-lesion groups comprised patients who received 3-lesion treatment only or 4-lesion treatment only.
No patients in either the single-lesion or multileison group required use of narcotic pain medication. Complications of RFTR were uncommon in all treatment groups examined. Nearly all patients reported some degree of palatal edema and an associated globus sensation that made sleep uncomfortable. This sensation was worse on the day of the treatment and normalized during the next 2 to 4 days. No palatal ulcerations or uvular slough were seen. No patients reported dysphagia or odynophagia, and no patient refused second or third treatments as a result of pain or complications. In addition, no patient missed any days of work beyond the day of the procedure.

<table>
<thead>
<tr>
<th>Table 2. Treatment Parameters and Results*</th>
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<tr>
<td><strong>Patient Group</strong></td>
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<tr>
<td></td>
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<tr>
<td>Joules/treatment, mean</td>
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<tr>
<td>Joules/lesion, mean</td>
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<td>Preoperative SI score, mean</td>
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<tr>
<td>Postoperative SI score, mean</td>
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<td>SI score improvement per treatment, mean</td>
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<td>Treatments, mean, No.</td>
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<td>Pain index score after treatment, mean</td>
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<tr>
<td>Cured after 2 treatments, %</td>
</tr>
</tbody>
</table>

*SI indicates snoring index.
†The multileison group includes the 3-lesion (n = 19) and 4-lesion (n = 7) groups and 5 patients who received a combination of 3- and 4-lesion treatments.
‡The 3- and 4-lesion groups comprise patients who received 3-lesion treatment only or 4-lesion treatment only.
§P values are calculated compared with the single-lesion group.
||Cure is defined as an SI score ≤ 5.

Initial management of obstructive snoring frequently incorporates conservative measures including diet modifications, weight loss, avoidance of alcohol and sedatives, various dental appliances, external nasal dilator strips, and alterations in sleep habits. Because behavioral modifications and nonprocedural remedies are frequently unsuccessful, snorers often resort to surgical therapy. The first surgical treatment commonly made available to the public was UPPP, introduced by Fujita et al in 1981. Although designed for treatment of OSA, UPPP is also effective in the treatment of snoring, with most series reporting initial success rates of greater than 90%. The drawbacks of UPPP include the requirement for general anesthesia and the association with significant postoperative pain and complications. To avoid the requirement for general anesthesia and hospital admission associated with UPPP, LAUP was introduced by Kamami in 1990. However, after the procedure, LAUP can be equally as painful as UPPP. In addition, LAUP can require multiple procedures for successful diminution of snoring, and the cost might be equivalent to UPPP.

Recently, the use of radiofrequency energy for tissue volume reduction has been developed for snoring treatment. Heat generated by temperature-controlled radiofrequency energy denatures critical cellular proteins within a controlled volume, causing cell loss resulting in scarring and contraction of the soft tissue and subsequent improvement of upper airway obstruction. Submucosal delivery and temperature control of radiofrequency energy are thought to be important in diminishing complications and postprocedure pain.

The goal of RFTR for the treatment of snoring has been to provide a minimally invasive office-based therapy with results comparable to other available procedures but with decreased morbidity and disruption of patients’ normal activities in the periprocedure period. On introduction of RFTR palatal therapy for snoring, recommendations were to perform single palatal lesions at each treatment session. Because the number of sessions necessary to obtain adequate snoring reduction was excessive using the single palatal lesion technique, we began treating with increased en-

![Figure 2. Four-lesion radiofrequency tissue reduction. The typical paramedian and lateral location of 4-lesion radiofrequency tissue reduction.](http://archotol.jamanetwork.com/pdfaccess.ashx?url=/data/journals/otol/11851/ on 09/30/2017)
ergies and multiple lesions in an attempt to decrease the number of visits necessary for snoring reduction.

Previous studies have demonstrated the effectiveness of radiofrequency energy for the treatment of snoring; however, no study to date, to our knowledge, has detailed the ability to improve the treatment outcome by alterations in the RFTR procedure.12,13 Our results show a statistically significant improvement in the percentage of multileesion patients cured after 2 procedures (61%) compared with the single-lesion group (25%). In addition, although there was no significant difference between the 3- and 4-lesion patients, the improvement seen in the 4-lesion group relative to the 3-lesion group and the significant difference between the single- and 4-lesion patients point to a clear trend toward increased efficacy with lesion number and total energy delivered. Likewise, the improvement in the SI score per procedure showed a clear trend correlating with increased number of lesions and increased energy delivered per treatment. The 4-lesion group had the highest total energy delivered and demonstrated the largest improvement in SI score per treatment session. In addition, the 4-lesion group had the lowest number of treatments performed per patient. Pain after the procedure was significantly greater in patients treated with multiple lesions but was still considered minimal by patients and was controlled with use of nonprescription analgesics. The increased pain observed with increased number of lesions and total energy delivered did not result in unplanned time away from work.

These data suggest that multileesion RFTR will result in a successful outcome after 2 treatment sessions for most patients. In addition, delivery of increased numbers of lesions was safe and was not associated with increased complications. Although not directly evaluated in this study, decreased numbers of treatment sessions until cure likely translate directly into less time away from work, less visits to the physician, and a less costly health care experience compared with single-lesion RFTR treatments.

Patient selection might directly impact the effectiveness of RFTR treatment of snoring. It is likely that RFTR therapy for snoring might be less successful in patients with concomitant OSA, but because of our attempt to exclude patients with OSA and the inability to attain PSG on all patients, we could not evaluate this variable. Although it would have been preferable to obtain sleep studies on all patients interested in snoring therapy, we found that certification and payment through third-party payers for PSG in this selected group of snorers with no other indicators of OSA was constraining.

Evaluation of long-term snoring results after UPPP17 or LAUP18 has revealed that snoring can recur over time after these procedures. Similarly, with single-lesion RFTR of the palate for snoring, an extended follow-up study19 revealed a significant relapse rate. With mean follow-up of 14 months, the authors found that 41% of their patients treated with single-lesion RFTR had relapse in snoring. For the entire cohort of 22 patients, the authors found that SI score increased 98% during follow-up.19 These authors suggested that the effectiveness in snoring reduction provided by RFTR diminishes over time and therefore patients might need to expect to undergo further “tune-up” treatments.10 Although our study was not designed to examine extended-term efficacy, we found that patients in the multileesion group followed up for a mean of 16 months had only a 2.9% increase in their SI score. These data contrast with the 98% increase in SI score seen by Li and colleagues and suggests that multileesion RFTR snoring therapy might provide longer-lasting results than single-lesion therapy. Longer-term evaluation of our patients treated with single lesions is needed for direct comparison. In addition, further studies examining patients who received multiple lesions will be needed to determine the long-term effectiveness of multileesion vs single-lesion therapy.

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Corresponding author and reprints: Wendell G. Yarbrough, MD, Department of Otolaryngology/Head and Neck Surgery and Department of Biochemistry and Biophysics, University of North Carolina School of Medicine, Neurosciences Hospital, CB 7600, UNC Hospitals, Chapel Hill, NC 27599-7600 (e-mail: wgy@med.unc.edu).

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