Radiofrequency Treatment for Obstructive Tonsillar Hypertrophy

Lionel M. Nelson, MD

Objective: To evaluate the safety and efficacy of in-office, temperature-controlled radiofrequency submucosal tissue volume reduction using the Somnoplasty procedure for the treatment of symptomatic chronic obstructive tonsillar hypertrophy.

Design: A prospective, nonrandomized, 3-phase protocol using in vitro and in vivo studies associated with operative tonsillectomy and clinical procedures performed in-office.

Setting: Hospital operating room and private practice otolaryngology office.

Study Population: In vitro studies of 14 tonsil specimens following tonsillectomy; in vivo studies of 11 tonsils before tonsillectomy; and clinical procedures performed on 9 adults, ages 24 to 47 years, with symptomatic chronic tonsillar hypertrophy.

Outcome Measures: For phase 1, histologic tissue sections; for phase 2, histologic tissue sections and clinician and patient questionnaires regarding procedure morbidity; and for phase 3, measurements of oropharyngeal airway size and clinician and patient questionnaires regarding procedure morbidity and symptom improvement.

Results: A 2-needle radiofrequency probe ablated tonsil stromal tissue while leaving overlying mucosa and underlying structures intact. On average, oropharyngeal airway was enlarged 12 mm, with a 70.8% calculated reduction in tonsil size. Procedures were well tolerated and had only minimal pain and dysphagia. There were no episodes of hemorrhage, and patients resumed normal activity within 1 to 2 days. Substantial improvement was reported in daytime sleepiness, snoring, voice clarity, swallowing, and throat irritation.

Conclusions: Temperature-controlled radiofrequency submucosal tissue volume reduction is a safe and effective method of treating symptomatic obstructive tonsillar hypertrophy. It is well tolerated by the patient under local anesthesia in the physician's office and has minimal postprocedure pain and dysphagia, with rapid return to normal activity. The procedure reduces tonsil size and increases airway size, leading to a reduction in symptoms.


Dr Nelson is in private practice of otolaryngology–head and neck surgery in San Jose, Calif. Dr Nelson is a paid consultant of and shareholder in Somnus Medical Technologies, Inc, Sunnyvale, Calif.
PATIENTS, MATERIALS, AND METHODS

Before initiating this study, a prototype radiofrequency electrode probe was designed by the author in conjunction with Somnus Medical Technologies, Inc (Sunnyvale, Calif), and it was extensively bench tested in their laboratories. This probe incorporated a penetrator template to breach the overlying tonsil mucosa through which a blunt, insulated tip, multiple-electrode pod would deploy into the tonsil stroma submucosally. This design (Figure 1) placed radiofrequency energy submucosally, and the blunted insulated tips avoided the risk of penetrating the underlying tonsil capsule, vessels, and muscle tissue in the tonsillar fossa. Three prototypes, with 1-, 2-, or 4-needle electrodes, were tested. All probes were designed to be compatible with a radiofrequency control unit that delivers specified power and energy levels at specified target temperatures (Somnus Medical Technologies, Inc).

One otolaryngologist (L.M.N.) performed the procedures either in the operating rooms at Good Samaritan Hospital, San Jose, Calif (phases 1 and 2), or in his general otolaryngology practice office (phase 3). All phases adhered to institutional review board guidelines approved by the Good Samaritan Hospital Institutional Review Committee and Quorum Review.

Phase 1 of the study examined the feasibility of the different probe designs. The histologic effects of radiofrequency on human tonsil tissue and penetration of the underlying tonsil capsule were evaluated (Table 1). Fourteen tonsils (7 pairs from 7 patients who had undergone tonsillectomy) were each treated with a prototype RFTVR tonsil probe. Various amounts of radiofrequency energy and probe placements were used in this phase to refine treatment procedures. The control unit was set with the parameters of 85°C and 8 W for 3 to 6 minutes, with an average energy of 1240 J, ranging from 392 to 2060 J. The tonsils were sectioned, photographed, and prepared for histologic examination by the Department of Pathology, Good Samaritan Hospital. The patients in this phase met the following criteria for inclusion: scheduled for surgery before participating in the study, provided informed consent, no upper respiratory tract cancer or radiation therapy, and no participation in another drug or device study for the past 6 months. Antibiotics were given 1 week before treatment. The treatment protocol was as follows. Patients were treated with 2 to 4 ablations per tonsil using the 2-needle probe. The control unit was set at 15 W and 85°C. The average dose given to each tonsil was 2301 J, with a range of 1012 to 4015 J. The total treatment time per tonsil for all ablations averaged 4.5 minutes, with a range of 1.9 to 9.4 minutes. Postoperatively, patients were hospitalized for observation overnight and then followed up in the office at 1 day, 1 week, 4 weeks, and 12 weeks after treatment. Evaluation consisted of photographs, measurements of the oropharyngeal airway between the tonsils (Table 4), and patient questionnaires on treatment morbidity (Table 5 and Table 6) and symptom improvement (Table 7). The latter included the standard Epworth Sleepiness Scale (0-24) and visual analog scales (0-10) for daytime sleepiness, snoring, speech difficulties, swallowing difficulties, and throat irritation. Tonsil size reductions were calculated from the oropharyngeal airway measurements by subtracting the baseline measurement between the tonsil and the uvula from the posttreatment measurement between the tonsil and the uvula.

Applied to reducing tonsil size, RFTVR has several significant advantages over current tonsillectomy procedures. With the present ability to accurately deliver specific amounts of radiofrequency energy at relatively low temperatures (50°C-95°C) to submucosal target tissue using the Somnoplasty system, heat dissipation and damage to adjacent tissue structures are minimized. Limiting tissue desiccation and protein denaturation primarily to tonsil stroma spares overlying mucosa and underlying muscle and blood vessels, thus reducing edema, pain, and risk of hemorrhage. Laser and electrocautery techniques, by contrast, deliver temperatures around 750°C to 900°C, which are far in excess of therapeutic needs, since tissue protein denaturation at 47°C, thus extending collateral damage to surrounding structures. In addition, since tonsil RFTVR...
can be performed under local anesthesia, it is suitable for in-office outpatient application in adults and most teenagers.

This study was undertaken to demonstrate that tonsil RFTVR can be a safe, effective, and less invasive method for the treatment of symptomatic chronic tonsil enlargement with similar efficacy to the higher-morbidity techniques currently available.

### Results

#### Phase 1

From the various probes tested, the 2-needle and 4-needle probes produced substantial lesions, ranging from 30% to 60% of the total tonsil tissue, depending on the energy settings of the control unit (Table 1). The 2-needle probe with a penetrator template (Figure 1) could easily penetrate through the overlying mucosa of a human tonsil in vitro and deliver a radiofrequency target ablation while sparing the underlying tonsil fibrous capsule. This probe was more manageable and more flexible for ablation placement than the 4-needle...
probe. Both the 2-needle probe and the 4-needle probe were tested in phase 2.

PHASE 2

In vivo studies confirmed the ease of placement of the 2-needle prototype probe vs the 4-needle prototype probe (Tables 2 and 3). The 2-needle probe was able to penetrate the tonsil mucosa and achieve radiofrequency tonsil stroma ablation without visible damage to the underlying muscular or vascular structures in the tonsil fossa bed or tonsil pillars. The tonsil underlying fibrous capsule was penetrated in 1 of 11 tonsils tested when evaluated following tonsil removal. However, no underlying muscle or vascular changes were apparent. Postoperative evaluation revealed no greater pain or edema, delayed healing, or scarring on the radiofrequency-treated side. No postoperative bleeding or infections were reported on either side. Tissue ablation of the tonsil with the 2-needle probe ranged from 30% to 50%, depending on the energy settings of the control unit, and this probe was used for phase 3.

PHASE 3

Significant tonsil tissue reduction was achieved gradually during 12 weeks following a single treatment of submucosal radiofrequency tonsil stroma ablation (Figure 2) in all patients. Intraoral space between tonsils enlarged an average of 12 mm (54.5%), which calculates to a reduction in tonsil size of 70.8% (Table 4). Procedures were well tolerated under local anesthesia without premedication, and postoperative pain and dysphagia were mild. No respiratory obstructive symptoms, infections, or bleeding complications related to the procedure were encountered (Tables 5 and 6). All patients had noticeable but tolerable tonsillar swelling and localized mucosal slough at electrode placement sites, which generally subsided after 1 week. Patients returned to pretreatment activity within 1 to 2 days of treatment. In addition to the increase in intraoral space, patients also reported a substantial improvement in daytime sleepiness, snoring, speech difficulties, swallowing difficulties, and throat irritation at 12 weeks after final treatment (Table 7).

Figure 2. Tonsillar reduction by temperature-controlled radiofrequency submucosal tissue volume reduction. Tonsils of patient 7 are shown before treatment (top) and 12 weeks after treatment (single treatment) (bottom).

Table 7. Summary of Symptom Improvement After Radiofrequency Submucosal Tissue Volume Reduction Treatment in 9 Patients

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<th>Epworth Scale (0-24)</th>
<th>Daytime Sleepiness (0-10)</th>
<th>Snoring (0-10)</th>
<th>Speech Difficulties (0-10)</th>
<th>Swallowing Difficulties (0-10)</th>
<th>Throat Irritation (0-10)</th>
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<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
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<td>Post</td>
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<tr>
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<td>4.4</td>
<td>3.9</td>
<td>1.3</td>
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<td>Range</td>
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<td>0-7.8</td>
<td>0-8.4</td>
<td>0-7.5</td>
<td>0-1.4</td>
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<tr>
<td>SD</td>
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<td>5.7</td>
<td>3.0</td>
<td>2.7</td>
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*Pre indicates pretreatment; Post, 12 weeks after final treatment.

COMMENT

Tonsillectomy is one of the most frequently performed procedures in the western world. All of us who perform these procedures are well aware of the associated postoperative consequences, which typically include considerable pain, weight loss, and dehydration due to difficulty swallowing, sometimes necessitating hospitalization. Other negative consequences include adverse effects associated with frequent and/or prolonged use of narcotic analgesics, occasional hemorrhage requiring reoperative intervention, and loss of productive time for patients, their families, and their employers. Tonsillectomy by laser or electrocautery dissections as an alternative to traditional dissection techniques has not decreased postoperative pain or hemorrhage rates. Laser surgery of mucosal tissues causes
Radiofrequency energy is an alternative technology capable of producing thermal ablation of tonsillar tissue that causes gradual tonsil reduction while leaving the mucosa intact. The gradual continuation of tissue volume reduction for about 8 to 12 weeks following radiofrequency treatment explains why the patient trials (phase 3) produced considerably more tissue reduction (70.8%) than was apparent during phases 1 and 2 (30%-50%) in this study. Although the present study shows that tonsil RFTVR can be safe and efficacious in humans, further work on probe design is needed to minimize the temporary tissue edema and eliminate the localized mucosal slough at the site of probe entry that was encountered in these trials. It is unclear at this point whether tonsil RFTVR results in a permanent reduction in tonsil size or whether future treatments will be necessary. A protocol to treat obstructive tonsillar and adenoidal hypertrophy in children under general anesthesia is planned. The patients chosen for this study had obstructive tonsillar hypertrophy and not infectious tonsillitis, and procedural modifications may be necessary to treat infected tonsils. More extensive studies will need to be performed to address these issues.

In conclusion, mucosal-sparing, temperature-controlled RFTVR is a safe and effective method for treating obstructive tonsillar hypertrophy in adults. It is well tolerated as an in-office procedure with the patient under local anesthesia and avoids the postprocedure morbidities and discomfort of more invasive treatments currently practiced for this condition. A substantial improvement was seen in the oropharyngeal airspace size and in patient symptoms, including daytime sleepiness, snoring, speech difficulties, swallowing difficulties, and throat irritation. Further work is needed to examine whether this procedure would be equally as effective in a pediatric population and whether it could also be used to treat infectious tonsillar disorders.

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Reprints: Lionel M. Nelson, MD, Suite 510, 2505 Samaritan Dr, San Jose, CA 95124.

REFERENCES