Temperature-Controlled Radiofrequency Tonsil Reduction in Children

Lionel M. Nelson, MD

**Objective:** To evaluate the safety and efficacy of temperature-controlled radiofrequency tonsil reduction in the treatment of children with a sleep-related breathing disorder associated with tonsillar obstructive hypertrophy.

**Design:** Prospective, nonrandomized, case series feasibility study of children meeting the criteria for tonsillectomy or adenotonsillectomy for the treatment of an obstructive sleep-related breathing disorder.

**Setting:** Community-based hospital.

**Patients:** Ten children, aged 4 to 13 years, presenting consecutively to a community-based otolaryngology practice with tonsillar or adenotonsillar obstructive hypertrophy implicated clinically in causing a sleep-related breathing disorder; their parents consenting to temperature-controlled radiofrequency tonsil reduction instead of surgical tonsillectomy.

**Intervention:** Temperature-controlled radiofrequency tonsil reduction, along with surgical adenoidectomy, if adenoids were present, under general anesthesia.

**Main Outcome Measures:** Tonsil size reduction, treatment morbidity, and symptom improvement with follow-up to 1 year. Baseline and 3-month posttreatment polysomnographic data were used.

**Results:** There was a reduction in tonsil size at 1 year of 75.0% on average, without evidence of regrowth during the 1-year follow-up. All children were drinking liquids in the recovery room, and most were eating soft diets within 6 hours; 8 of the 10 children were eating a normal diet by day 5. On average, the return to normal activity was 3.9 days, with 2.9 days of parental loss of work time. Quality-of-life variables all improved. Snore indexes decreased by 88.6%. Polysomnography at 3 months revealed an 84.2% reduction in the apnea index and a 52.3% reduction in the apnea/hypopnea index.

**Conclusion:** Temperature-controlled radiofrequency tonsil reduction seems to be a safe, effective, and minimally morbid treatment for tonsil hypertrophy in children with obstructive sleep-related breathing disorders.

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When adenotonsillar hypertrophy is implicated in pediatric sleep-related breathing disorders (SRBDs), surgical tonsillectomy and adenoidectomy (T&As) is usually the recommended treatment. Of the pediatric T&As performed in this country yearly, about 80% are performed for obstruction rather than infection.\(^1\) Although standard surgical T&As is certainly effective, the trade-off is usually significant postoperative morbidity. Those who take care of children are familiar with the associated postoperative pain, causing dehydration and weight loss; the risks of bleeding and infection; the adverse effects of prolonged narcotic use; and the loss of productive time for parents. For the most part, these problems are due to the tonsillectomy, rather than the adenoidectomy, portion of this procedure.

Temperature-controlled radiofrequency (TCRF), a technology known commercially as Somnoplasty (Gyrus ENT, LLC), has been shown to reduce enlarged obstructive tonsils in adults, without the significant pain and other morbidity of tonsillectomy or other types of tonsillotomy.\(^2\) Adult tonsil size was reduced, on average, by 70%, with results maintained during 1 year of follow-up.\(^3\)

Temperature-controlled radiofrequency works by heating target tissue through an electrode placed submucosally. By real-time temperature feedback, a computer algorithm within the radiofrequency generator regulates energy flow to form a controlled, precise, and predictable...
lesion. This lesion is then gradually resorbed by the body, thus shrinking tissue volume while leaving the overlying mucous membrane intact. Intact mucosa accounts for the minimal discomfort, the reduced risk of bleeding and infection, and the faster return to normal diet and activity.

The electrode for tonsil reduction is designed with a penetrator template and blunt insulated tips to avoid penetration of the underlying tonsil capsule and risk to the surrounding vasculature. By using this electrode, multiple lesions are then created submucosally in the tonsil stroma (Figure 1).

To see if TCRF technology could yield similar results safely and effectively in a pediatric population, as it has for adults, the following feasibility study was undertaken.

**METHODS**

The study (approved by the Institutional Review Committee of Good Samaritan Hospital, San Jose) was designed as a non-randomized prospective examination of the first 10 children older than 3 years presenting to my community-based otolaryngology practice with symptoms of an SRBD and clinically enlarged tonsils who met the protocol criteria. The criteria for selection were enlarged tonsils (at least 3+ on a 1+ to 4+ clinical scale), along with suggestive symptoms of an SRBD such as loud night snoring, daytime sleepiness, a fitful sleep pattern, witnessed gasping, or apnea events. Tonsil size was graded on clinical examination by the treating physician (L.M.N.), where 1+ indicates tonsils well within the fossa; 2+, extension to, and obscured visualization of, the posterior pillar; 3+, the tonsil is beyond the posterior pillar but not to the midline; and 4+, extension to the midline. Patients selected had similar histories and clinical findings as those who would ordinarily be candidates for surgical T&A in my practice, and their parents consented to TCRF tonsil reduction instead of surgical tonsillectomy. The 10 children selected (7 boys and 3 girls), aged 4 to 13 years, underwent baseline 12-lead polysomnography using one sleep center, confirming an SRBD.

Temperature-controlled radiofrequency tonsil reduction was performed under general anesthesia, with either endotracheal intubation or a laryngeal mask airway. All procedures were performed by the same otolaryngologist (L.M.N.) at Good Samaritan Hospital. Oropharyngeal exposure was obtained with a pediatric Crowe slotted ring retractor with the patient in a Rose T&A position. Tonsil pillar plane injections with medialization of the tonsil were then performed with 0.25% bupivacaine hydrochloride and 1:200,000 epinephrine (on average, 3.5 mL per tonsil). As illustrated in Figure 1, multiple TCRF lesions were then formed submucosally using dual blunt electrodes deployed through an insulated penetrator template device (TCRF tonsil model 2420 handpiece). Each set of lesions (average, 7.5 per tonsil) was placed approximately 1 cm apart over the medial face of the tonsil (electrodes were placed medial to lateral through the tonsil stroma) and was preceded by intratonsillar injection of isotonic sodium chloride solution (average, 6 mL per tonsil). Sets (4-9) of lesions (8-18 ablative lesions) were developed in each tonsil, depending on tonsil size.

Lesions were developed with a TCRF generator (Somnus S2; Gyrus ENT, LLC), set at 85°C, 1000 J (500 J per individual lesion on dual-electrode mode), and a maximum of 15 W of power. An adenoidectomy (in 8 of the 10 children, with 2 having undergone prior adenoidectomies) was performed concurrently with a surgical curette and electrocautery hemostasis. Patients were given perioperative and postoperative corticosteroids (intravenous dexamethasone, 0.5 mg/kg of body weight up to 6 mg, at surgery, and half that dose 6 hours later) and antibiotics (oral amoxicillin, 40 mg/kg per day, starting 3 days before surgery and continued for 7 days after surgery), and underwent short-stay oximetry-monitored observation (<23 hours) in the hospital.

The postoperative variables (for days 0-14) followed were pain levels (visual analog scale [VAS] score, scored by patients and their parents), oral intake, clinical assessment of tissue swelling and any complications, and loss of parental work time due to the child’s convalescence. Longer-term variables observed were tonsil size (1+ to 4+ clinical scale), SRBD and other obstructive symptoms (determined by the VAS and the Obstructive Sleep Apnea-18 questionnaire), and treatment mor-
RESULTS

On average, blood loss for the concomitant adenoidectomy was 12±4 mL (n=8). There was no measurable blood loss for the TCRF tonsil reductions (estimated as <1 mL by observation of sponges and micropediatric suction canister). As a consequence, anesthesia by laryngeal mask airway was considered safe, and was used on 3 patients without complication. The equipment charge per case included the cost of a “cold instrument” setup, identical to that needed for surgical T&A, plus a $350 disposable TCRF handpiece.

The operative time for TCRF tonsil reduction is a function of the number of lesions created. Typically, the number of lesions needed to cause adequate tissue reduction seems to be 12 to 18 (6-9 dual-electrode placements) per tonsil. The operative time (surgical exposure and treatment of both tonsils, excluding adenoidectomy) was 28.5±4.7 minutes (n=8). Surgical adenoidectomy added an additional 5.5±2.0 minutes (n=8).

All 10 children were drinking liquids in the recovery room and eating soft solids within the first day, most (7 of the 10 children) within 6 hours of surgery. Sustainable oral hydration was achieved by all within the first 24 hours. Of the 10 children, 8 were eating a normal diet by day 5 (range, 1-7 days), and the group returned to normal activity in 3.9±2.1 days. Initially, patients had moderate throat pain, diminishing during the first week. The average parent-rated VAS pain score was 4.5 on day 1, 2.9 on day 4, and 0.8 on day 7. The average child-rated VAS pain score was 5.1 on day 1, 3.1 on day 4, and 1.1 on day 7. Parents lost 2.9±1.8 working days.

Although all patients developed temporary peritonsillar edema and punctate mucosal slough at electrode placement sites, there were no postoperative treatment complications, including clinically significant airway obstruction or bleeding.

Tonsil size reduction was progressive following TCRF treatment, with discernible reduction noted clinically by 2 weeks and continued reduction to 6 to 8 weeks posttreatment. One child (patient 008) was lost to follow-up after 1 month. For the remaining 9 children, a comparison at 3 months demonstrates a statistically significant reduction in tonsil size from a baseline of 3.2±0.6 to 1.1±0.7 (unit of measure is the clinical 1+ to 4+ size scale as described in the “Methods” section) (P<.001). Figure 2 illustrates this typical early progression in one of the children. The eventual size reduction of 75% on average is noted at the 1-year follow-up, a statistically significant change from 3.2±0.6 to 0.8±0.4 (unit of measure is the clinical 1+ to 4+ size scale as described in the “Methods” section) (P<.001). There was no evident regrowth of tonsil tissue in any of the 9 subjects on repeated examination during the 1-year follow-up (Table).

Symptoms and signs of upper airway obstruction and SRBD quality-of-life issues showed a similar pattern of initial improvement remaining stable during the follow-up year. Statistically significant reductions in snore indexes and Obstructive Sleep Apnea-18 scores (P<.001 for both) were noted. Improvements in daytime sleepiness, speech, and swallowing dysfunction scores were also significant at 3 months (P<.001 for all). The improve-

Table: Summary of Baseline and Posttreatment Clinical Findings for 9 Patients*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Time After Treatment, mo</th>
<th>3</th>
<th>6</th>
<th>12</th>
</tr>
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<tbody>
<tr>
<td>Tonsil grade</td>
<td>3.2±0.6</td>
<td>1.1±0.7</td>
<td>1.0±0.6</td>
<td>0.8±0.4</td>
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<td>Snore index</td>
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<td>0.7±0.9</td>
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<td>Daytime sleepiness score</td>
<td>3.0±2.3</td>
<td>1.1±1.3</td>
<td>0.6±0.8</td>
<td>0.7±1.4</td>
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<tr>
<td>Speech score</td>
<td>2.6±2.1</td>
<td>0.9±0.9</td>
<td>0.5±0.6</td>
<td>0.6±0.6</td>
<td></td>
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<tr>
<td>Swallowing dysfunction score</td>
<td>1.4±1.7</td>
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<td>0.3±0.2</td>
<td>0.3±0.3</td>
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<tr>
<td>Obstructive Sleep Apnea-18 questionnaire score</td>
<td>44.2±16.0</td>
<td>26.3±6.6</td>
<td>25.6±5.0</td>
<td>26.8±5.1</td>
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*Data are given as mean ± SD. The 10th patient was lost to follow-up after 1 month posttreatment.
ment in all of these variables remained relatively stable during the 1-year follow-up (Table).

Polysomnography at 3 months posttreatment demonstrates, on average, a reduction in the apnea index of 84.2% (1.9±2.6 to 0.3±0.3 episodes per hour) and in the apnea/hypopnea index of 52.3% (8.8±7.6 to 4.2±4.9 episodes per hour). However, on analysis, this did not prove to be statistically significant (P = .10 and P = .16, respectively). The incremental improvement in oxygen desaturation nadir (89.9%±2.8% to 90.4%±2.9%) was also not considered significant (P = .77).

This pilot study was undertaken to test the feasibility of using TCRF tonsil reduction as an alternative to other tonsillar procedures in the treatment of pediatric obstructive SRBDs associated with adenotonsillar hypertrophy. The study demonstrates definite advantages and disadvantages vs existing tonsillectomy procedures and capsule-sparing excisional tonsillotomies. The minimally invasive mucosa-sparing aspects of TCRF seem to reduce postoperative pain. The VAS pain levels in this study, as reported by the study subjects, were 5.1 and 1.1 on posttreatment days 1 and 7, respectively. Using a similar method, Warnock and Lander reported pain levels of 6.5 and 2.7 on days 1 and 7, respectively, following pediatric surgical tonsillectomy or T&A. The prevalence of dehydration and weight loss following surgical tonsillectomy has been correlated with the level of pain intensity.6,7 There also seems to be a direct relationship between pain intensity toward the end of postoperative week 1 following pediatric surgical tonsillectomy or T&A and the number of unscheduled physician's office and emergency department visits.5 A more rapid return to a normal diet and activity for the child seems to equate with less work time loss for parents, 3 days in this study instead of the 7 days reported in the literature.8

The operative blood loss for TCRF tonsil reduction is estimated as less than 1 mL. Blood loss for monopolar electrosurgical tonsil resection and plasma-mediated tonsil ablation in children has been reported as 83.8 and 90.9 mL, respectively.9 Given the minimal blood loss with TCRF tonsil reduction, less stringent precautions for airway protection seem reasonable and the less invasive larypeal mask airway seems to be a safe alternative to endotracheal intubation.

In addition to safety, this pilot study was undertaken to ascertain preliminary information as to how many energy would be needed with this technique to adequately reduce a child’s tonsil for SRBD control. Therefore, the first child to undergo this procedure in the study received a fairly conservative 4000 J per tonsil. This proved safe, with minimal postoperative morbidity, but resulted in a subsequent reduction in tonsil size of only 25% on the left side and 0% on the right side by 3 months, unchanged at the 6-month follow-up. At the request of his parents, this child was treated a second time (the only one in the study to be treated more than once), further reducing tonsil size by 75% on the left side and 66% on the right side in total. Impressed by the first patient’s minimal postoperative morbidity, the remaining children were given an average of 7510.5 J per tonsil, reducing their tonsils by 75% on average with a single treatment.

All the children in this limited case series showed a significant improvement in airway obstructive symptoms and signs. What proportion of this improvement was due to the adenoidectomy or tonsil reduction alone is not known, and the study was not designed to investigate this issue. However, the usual community practice for the treatment of pediatric SRBDs in the presence of adenoid and tonsil enlargement is to address both areas simultaneously. This study investigated whether TCRF tonsil reduction could be effectively substituted for more invasive excisional tonsil procedures in the treatment of pediatric SRBDs without compromising outcomes. The improvements in symptoms and clinical findings seem to indicate that it can. Despite the fact that some tonsilar tissue remains following TCRF, this limited series shows no regrowth during the 1-year follow-up.

This study highlights certain shortcomings of TCRF in its present design for tonsil reduction. Radiofrequency tissue ablation of any type produces a thermal injury with acute inflammatory tissue edema. Based on observations in this study, the acute peritonsillar tissue swelling in children seems to become clinically apparent about 4 to 6 hours postoperatively, peaking at about 12 to 18 hours and significantly diminishing during the next 12 to 24 hours. Although no child in this study showed evidence of acute airway obstructive signs or symptoms, such as stridor, dyspnea, or measured oxygen desaturation, for the child who starts with an already compromised oropharyngeal airway (tonsil size 3+ or 4+), short-stay hospital observation becomes warranted, at least for the first 18 hours. Alternatives, such as treating one tonsil at a time or giving less energy so that the procedure becomes “staged,” are not practical given the need for a general anesthetic in a pediatric population.

The operative time for TCRF tonsil reduction (28.5 minutes in this study) is generally greater compared, for example, with the 16.2 minutes reported for monopolar electrosurgical tonsillectomy and the 23.8 minutes reported for plasma-mediated ablation tonsillectomy.9 There is an additional charge for the disposable TCRF handpiece. How the additional initial expenses for added operative time and instrumentation compare with the overall expenses incurred for loss of parental work time and readmission for bleeding and dehydration that can be associated with surgical tonsillectomy have yet to be studied.

The volume of tonsil tissue reduction with TCRF does not seem to be uniform between patients despite similar energy inputs as adjusted by tonsil size. Because tonsil volume reduction is a gradual process for 6 to 8 weeks following TCRF, a decision at surgery as to how much tissue reduction will actually result cannot be made. In an adult population in whom TCRF tonsil reduction can be an in-office procedure under local anesthesia, repeated treatments, if needed, are not as significant an issue. However, for children, the need for a general anesthetic in an operating room makes this approach impractical. Although a more predictable esti-
mate of actual tissue volume reduction is obviously desirable, all children in this study (with the exception of the first one, who received less energy by design) attained enough ablation to resolve the tonsillar component of obstruction. Solutions for some of these issues may be forthcoming as we gain more experience with this procedure.

In conclusion, TCRF tonsil reduction seems to be a safe and effective way of treating enlarged tonsils in children, with results maintained during 1 year of follow-up. Despite the need for better outcome prediction and posttreatment edema control, the relatively minimal postoperative morbidity incurred with this technique could make it an attractive alternative to the surgical tonsillectomy portion when T&A is indicated in the treatment of an SRBD and airway obstruction. Validation of these preliminary findings awaits the results of a larger, independent, multicenter, controlled study that is under way.

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Corresponding author: Lionel M. Nelson, MD, 2505 Samaritan Dr, Suite 510, San Jose, CA 95124 (e-mail: L.Nelson580@aol.com).

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