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What is This?
Temperature-controlled radiofrequency tongue base reduction for sleep-disordered breathing: Long-term outcomes

KASEY K. LI, MD, DDS, NELSON B. POWELL, MD, ROBERT W. RILEY, MD, DDS, and CHRISTIAN GUILLEMINAULT, MD, Stanford and Palo Alto, California

OBJECTIVE: Our goal was to evaluate the long-term outcomes of temperature-controlled radiofrequency reduction of the tongue base in sleep-disordered breathing.

METHODS: The 18 patients from our initial pilot study were reevaluated. Clinical examinations, polysomnography (PSG), questionnaires, visual analog scales, and a comparative SF-36 were used to assess long-term outcomes.

RESULTS: Sixteen of the original 18 patients completed this study; 2 patients were lost to follow-up. The mean follow-up was 28 months. There was a mean weight increase of 3.1 ± 7.9 kg. The original pretreatment Respiratory Disturbance Index (RDI) was a mean of 39.5 with a mean LSAT of 81.9%, and the posttreatment RDI was a mean of 17.8 with a mean LSAT of 88.3%. Follow-up PSG data showed a persistent improvement of the mean Apnea Index compared with pretreatment (5.4 vs 22.1) without significant changes compared with posttreatment (4.1). However, there were changes in the follow-up Hypopnea Index (HI) of 22.9 compared with the pretreatment and posttreatment HI values of 17.4 and 13.6, respectively. This resulted in a relapse of the RDI from a posttreatment value of 17.8 to 28.7. The LSAT also worsened from 88.3% to 85.8%. However, there was no significant deterioration in the quality-of-life measurements by SF-36 or in daytime sleepiness by Epworth Sleepiness Scale.

CONCLUSION: The success of temperature-controlled radiofrequency tongue base reduction for sleep-disordered breathing may reduce with time. PSG demonstrated that long-term relapse is primarily reflected in the HI without significant detrimental effects on the patient’s quality of life (SF-36) and sleepiness (Epworth Sleepiness Scale). Continual evaluation of this treatment modality is warranted.

The use of temperature-controlled radiofrequency (TCRF) to reduce soft tissue volume in the upper airway was first investigated in the animal tongue model.1 After TCRF treatment, tissue volume reduction results through a predictable pattern of wound healing that consists of coagulation necrosis leading to fibrosis and tissue contraction. The relationship of lesion size to total RF energy delivery and the resultant volume reduction have been shown to be closely correlated.1 Based on the findings from the animal tongue model, 3 investigations (soft palate, turbinate, and tongue) of TCRF for the treatment of sleep-disordered breathing (SDB) were subsequently completed in the human model.2-4

The application of TCRF to the human tongue in a serial fashion was shown to be the most effective use of this technology in improving SDB.4 The initial investigation of this novel treatment approach demonstrated objective improvement based on polysomnographic (PSG) parameters as well as subjective measurements based on the Epworth Sleepiness Scale (ESS). A reduction in tongue volume was also demonstrated on volumetric magnetic resonance imaging assessment. More importantly, the safety parameters for TCRF in the human tongue were established in that speech and swallowing were not affected based on barium swallow, speech evaluation, or subjective questionnaires. However, despite these encouraging initial results, the long-term treatment outcomes as well as the long-term effects of this new technology on the upper aerodigestive tract are entirely unknown.

The primary study objectives of this investigation were to evaluate the long-term effects of...
TCRF tongue base reduction on sleep, speech, swallowing, and quality-of-life issues.

MATERIALS AND METHODS

Study Design

This was a follow-up study of the first 18 patients treated with TCRF tongue base reduction for SDB. The study was conducted prospectively. Patient evaluation included clinical examination and questionnaires with visual analog scales (VASs) and Short Form-36 to subjectively assess speech, swallowing, sleep, and quality-of-life issues. PSG recordings and cephalometric radiographs were also obtained.

Polysomnography

Each patient underwent nocturnal PSG to document sleep parameters and the severity of SDB. Nocturnal monitoring included an electroencephalogram, electro-oculogram, chin and leg electromyograms, electrocardiogram (modified V 2 lead), airflow measurement by nasal cannula, thoracic and abdominal efforts, and pulse oximetry.

PSG recordings were scored using the international criteria of Rechtschaffen and Kales for sleep staging and the international definitions of sleep apnea, obstructive, mixed, and central apnea.

Questionnaires and Visual Analog Scales

Epworth sleepiness scale (ESS). The ESS reflected the chance of dozing in specific situations as well as daytime sleepiness.

Quality of life (SF-36 health survey, standard US version). The SF-36 questionnaire generates 8 subscores related to the general health of the respondent. Each subscore is based on a scale of 0 to 100, with 100 as the optimal health score. These subscores are called Physical Functioning (PF), Role-Physical (R-P), Bodily Pain (BP), General Health (GH), Vitality (VIT), Social Functioning (SF), Role-Emotional (R-E), and Mental Health (MH).

Physical Component scores (PCS) and Mental Component scores (MCS) were also obtained. These scores include each subscale weighted based on its relationship to the physical or mental components. These scores are on a 0-to-100 scale, with 50 as the optimum score.

Visual analog scales (VAS). Standard 10-cm VASs were used to evaluate the following variables: speech (containing anchors “no speech problems” and “extreme difficulty talking”) and swallowing (containing anchors “no swallowing problem” and “unable to swallow”).

Summary of Initial RF Treatment and Results

All 18 patients (17 men) enrolled in the initial study had the diagnosis of SDB and reported symptoms of daytime sleepiness. The mean age was 44.9 ± 8.7 years. The mean pretreatment body mass (BMI) was 30.2 ± 5.5 kg/m², and the mean posttreatment BMI was unchanged at 30.2 ± 5.8 kg/m².

The mean number of treatment session was 5.5 per patient. The mean overall total number of Joules administered per patient was 8490 ± 2687 J, with 1543 J per treatment session. The mean duration from the completion of treatment to the final PSG was 2.6 ± 0.7 months. The mean Respiratory Disturbance Index (RDI) improved from 39.5 ± 32.7 to 17.8 ± 15.6 (P = 0.003). The mean Apnea Index (AI) improved from 22.1 ± 33.0 to 4.1 ± 6.2 (P = 0.023), and the mean Hypopnea Index (HI) improved from 17.4 ± 11.9 to 13.6 ± 11.5 (P = 0.326). The mean oxygen saturation nadir (LSAT) improved from 81.9 ± 11.6 to 88.1 ± 5.3 (P = 0.03). The mean ESS improved from 10.4 ± 5.6 to 4.1 ± 3.2 (P = 0.0001), and the speech and swallowing VAS (VAS 0-10) did not change from baseline.

Statistical Analysis

Results are expressed as mean ± SD, and paired Student’s t tests were used to determine statistical significance. Statistical analyses were generated with an SAS computerized statistical package.

The SF-36 questionnaires were scored and compared with baseline and 2-month posttreatment scores. The primary analysis was paired t tests between the posttreatment and follow-up mean scores to determine whether statistically significant changes had occurred in the eight mean scores.

RESULTS

Sixteen of the original 18 patients completed this study. Two patients (both men) were lost to
follow-up. The mean follow-up period was 28 ± 4.0 months. There was a mean weight increase of 3.1 ± 7.9 kg. The follow-up PSG data showed a persistent improvement of the mean AI, but there was a trend of worsening HI, resulting in a trend of worsening RDI (Table 1). There was also a trend of worsening LSAT.

The quality-of-life measurements by SF-36 (Table 2) and excessive daytime sleepiness by ESS (Table 3) demonstrated persistent improvement compared with baseline, and no differences were found compared with posttreatment results. Although no changes in swallowing or speech were reported, the VAS measurement did increase significantly (Table 3).

## DISCUSSION

This investigation demonstrated that 2 years after the completion of TCRF treatment on the tongue base in subjects with SDB, there was no statistically significant worsening of SDB based on PSG results. However, there was a trend of declining success. Indeed, previous reports have documented relapse of SDB in patients after sur-

### Table 1. Polysomnography results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Posttreatment</th>
<th>Follow-up</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDI</td>
<td>39.5 ± 22.7</td>
<td>17.8 ± 15.6</td>
<td>28.7 ± 29.4</td>
<td>0.29</td>
</tr>
<tr>
<td>Apnea Index</td>
<td>22.1 ± 33.0</td>
<td>4.1 ± 6.2</td>
<td>5.4 ± 10.3</td>
<td>0.88</td>
</tr>
<tr>
<td>Hypopnea Index</td>
<td>17.4 ± 11.9</td>
<td>13.6 ± 11.5</td>
<td>22.9 ± 23.1</td>
<td>0.20</td>
</tr>
<tr>
<td>Total sleep time</td>
<td>337 ± 89</td>
<td>346 ± 75</td>
<td>337 ± 97</td>
<td>0.66</td>
</tr>
<tr>
<td>Sleep Efficiency Index (%)</td>
<td>80 ± 10</td>
<td>80 ± 10</td>
<td>80 ± 10</td>
<td>0.80</td>
</tr>
<tr>
<td>Oxygen saturation nadir (%)</td>
<td>81.9 ± 11.6</td>
<td>88.1 ± 5.3</td>
<td>85.8 ± 6.6</td>
<td>0.18</td>
</tr>
<tr>
<td>REM sleep (%)</td>
<td>11.4 ± 7.5</td>
<td>17.4 ± 8.9</td>
<td>14.5 ± 7.8</td>
<td>0.16</td>
</tr>
</tbody>
</table>

*Paired Student’s t tests were performed on the change scores between posttreatment and follow-up.

### Table 2. SF-36 scores

<table>
<thead>
<tr>
<th>Domain</th>
<th>Posttreatment</th>
<th>Follow-up</th>
<th>Mean change</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>91.00 ± 13.08</td>
<td>92.00 ± 15.67</td>
<td>1.00 ± 20.79</td>
<td>0.44</td>
</tr>
<tr>
<td>Role-Physical</td>
<td>95.00 ± 10.54</td>
<td>92.50 ± 23.72</td>
<td>-2.50 ± 27.51</td>
<td>0.61</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>87.30 ± 18.37</td>
<td>80.70 ± 19.31</td>
<td>-6.60 ± 27.58</td>
<td>0.77</td>
</tr>
<tr>
<td>General Health</td>
<td>74.60 ± 16.53</td>
<td>79.10 ± 11.59</td>
<td>4.5 ± 13.01</td>
<td>0.15</td>
</tr>
<tr>
<td>Vitality</td>
<td>60.00 ± 23.57</td>
<td>71.00 ± 13.50</td>
<td>11.00 ± 17.76</td>
<td>0.05</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>81.30 ± 20.58</td>
<td>92.50 ± 16.87</td>
<td>11.20 ± 15.91</td>
<td>0.03</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>86.60 ± 28.25</td>
<td>96.70 ± 10.44</td>
<td>10.10 ± 31.71</td>
<td>0.17</td>
</tr>
<tr>
<td>Mental Health</td>
<td>76.00 ± 13.73</td>
<td>82.00 ± 7.83</td>
<td>6.00 ± 15.00</td>
<td>0.12</td>
</tr>
<tr>
<td>Physical Component</td>
<td>54.00 ± 4.08</td>
<td>52.39 ± 7.89</td>
<td>-1.61 ± 9.50</td>
<td>0.69</td>
</tr>
<tr>
<td>Mental Component</td>
<td>48.99 ± 8.34</td>
<td>54.73 ± 4.06</td>
<td>5.74 ± 8.14</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*Paired Student’s t tests were performed on the change scores.

### Table 3. Questionnaire visual analog results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Posttreatment</th>
<th>Follow-up</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS</td>
<td>10.4 ± 5.7</td>
<td>4.1 ± 3.2</td>
<td>4.5 ± 3.4</td>
<td>1.00</td>
</tr>
<tr>
<td>Snoring</td>
<td>4.7 ± 3.5</td>
<td>2.0 ± 1.4</td>
<td>3.5 ± 2.7</td>
<td>0.01</td>
</tr>
<tr>
<td>Speech</td>
<td>1.2 ± 1.9</td>
<td>0.6 ± 1.1</td>
<td>2.5 ± 2.9</td>
<td>0.02</td>
</tr>
<tr>
<td>Swallowing</td>
<td>1.1 ± 1.9</td>
<td>0.3 ± 0.5</td>
<td>1.3 ± 2.2</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Paired Student’s t tests were performed on the change scores between posttreatment and follow-up.
gery of the soft palate. Snoring, a sign of relapse, have been reported after uvulopalatopharyngoplasty, laser-assisted uvulopalatoplasty, and TCRF on long-term follow-up.8–11 In a 4-year follow-up uvulopalatopharyngoplasty, Larsson et al12 found that preoperative obesity (BMI >30 kg/m²) and weight gain are 2 significant factors contributing to the relapse of SDB. Clearly, the same risk factors were found in our subjects, thus potentially contributing to the findings of this study.

The initial pilot investigation of TCRF tongue base reduction was designed as a feasibility study to assess the potential effect of TCRF on the tongue base. Consequently, although improvement of SDB was seen at the completion of the study, moderate SDB persisted. The persistent repetitive nocturnal airway collapse and the elevated negative pressure exerted on the airway could be significant factors contributing to the worsening trend of SDB on follow-up. It should be emphasized, however, that the trend of worsening RDI was primarily based on the HI. This finding can be partially contributed to by differences in the methods used to detect airflow limitation during PSG between the initial pilot study and this follow-up study. Traditionally, oronasal airflow is monitored with a thermistor that measures temperature as a surrogate of airflow. A thermistor is used in the initial PSG recordings. In recent years, a nasal cannula connected to a pressure transducer has been increasingly used to monitor flow because of its improved sensitivity in detecting respiratory events.13–15 Consequently, a higher RDI is scored with the use of a nasal cannula. This factor may explain why despite a worsening RDI trend, there were no changes in the symptomatology of the subjects.

Minimal adverse effects on speech and swallowing were detected with objective and subjective measures after the TCRF treatment.4 Although the subjective measurement on speech using VAS (0 to 10) was still minimally affected (2.5) on long-term follow-up, it was found to be significantly higher. Although none of the patients had reported problems with speech, continual evaluation is clearly warranted.

Volumetric tongue base reduction by surgical methods has long been advocated in the management of SDB.16–18 However, although improvement of PSG parameters has been achieved shortly after surgery, no long-term follow-up studies are available. TCRF tongue base reduction differs from traditional tongue base reduction surgery in that RF creates tissue coagulation necrosis, leading to fibrosis and contraction.1 Although volumetric reduction of the tongue is achieved, some portions of the tongue muscle have been replaced by scar tissue. It is unknown whether reconstitution of the scar tissue by tongue muscle occurs. However, it is quite possible that, as with any other surgical scars, the gradual maturation and softening of scar tissue develop over time, potentially contributing to laxity of the tongue and leading to relapse and worsening of SDB. Clearly, continual investigation and follow-up of the patients treated with this novel technique are warranted.

REFERENCES

12. Larsson LH, Carlsson-Nordlander B, Svanborg E. Four-year follow-up after uvulopalatopharyngoplasty in 50 un-