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Main Article

Sutter® bipolar radiofrequency volumetric tissue reduction of palate for snoring and mild obstructive sleep apnoea: is one treatment adequate?

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Abstract

Objective: To evaluate the efficacy of bipolar radiofrequency volumetric tissue reduction, using Sutter® technology, in the treatment of snoring and mild obstructive sleep apnoea.

Design: Prospective, non-randomised trial.

Methods: Fifty-two patients with simple snoring and mild obstructive sleep apnoea underwent bipolar radiofrequency palate reduction under local anaesthesia.

Results: All patients were Friedman stage II and III, with tonsil sizes graded as zero, one or two, a mean body mass index of 22.6, and a mean age of 36.2 years. Seventy-seven per cent of patients reported improvement in their snoring; patients' mean snoring level (assessed by visual analogue scale) improved from 8.9 to 3.4 ($p < 0.05$). Eighty-three per cent of patients reported an improvement in their Epworth sleepiness scale score, from a mean of 14.6 to 9.5. Seven out of the 17 patients (41.2 per cent) met the surgical success criteria (i.e. at least a 50 per cent reduction of the pre-procedure apnoea–hypopnoea index, and a post-procedure apnoea–hypopnoea index of below 15). Patients' mean apnoea–hypopnoea index improved from 13.6 to 9.8, and their mean lowest oxygen saturation improved from 88.3 to 92.5 per cent. Eighty-two per cent of patients reported an improvement in their quality of life as a result of the procedure.

Conclusion: One session of Sutter bipolar radiofrequency tissue volume reduction represents a viable method of treating snoring and mild obstructive sleep apnoea, with good results.

Key words: Radiofrequency; Palate; Obstructive Sleep Apnea; Snoring

Introduction

Sleep-disordered breathing is a spectrum of diseases which includes snoring, upper airway resistance syndrome and obstructive sleep apnoea (OSA). Snoring is caused by vibration of the soft palate, uvula, tonsils, tongue base, epiglottis and pharyngeal walls. Snoring is considered an objectionable social problem. In addition, most sleep authorities believe that it may represent an alarm warning of the possibility of OSA. Obstructive sleep apnoea is a common sleep disorder; Young *et al.* studied 602 state employees with attended overnight polysomnography and found that the incidence of sleep-disordered breathing was 24 per cent in men and 9 per cent in women.[1] Most cases of OSA go undetected; it is estimated that up to 93 per cent of females and 82 per cent of males with moderate to severe OSA remain undiagnosed.[2]

Many techniques have been used to treat snoring. The basis of all surgical methods is to create scar tissue in order to incite fibrosis and to stiffen the palate. This decreases the vibration of the palate and thus diminishes snoring; more importantly, the reduced collapsibility of the palate results in fewer apnoeic episodes.

Several of the newer surgical treatment methods for snoring involve the use of expensive implants or sophisticated equipment. Powell and Riley first described the use of radiofrequency volumetric tissue reduction in the upper airway.[3] The aim of this approach was to stiffen the soft palate in order to treat primary snoring. Temperature-controlled, radiofrequency volumetric tissue reduction is performed in order to stiffen and scar the soft palate. The advantages of this technique are that it is minimally invasive, causes little pain, has minimal complications and can be performed under local anaesthesia as a clinic procedure. The radiofrequency probe can also be applied to the inferior turbinates for relief of nasal obstruction and to the tongue base for treatment of OSA.

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Subjective results for radiofrequency volumetric tissue reduction of the palate have been encouraging, with studies reporting a 67 to 86.6 per cent improvement in snoring.[4,5] Stuck *et al.* have reported the largest series, with 322 snoring patients, and found an 84 per cent improvement rate.[6] Many authors have found that multiple sessions of radiofrequency volumetric tissue reduction may be required in order to achieve better subjective and objective results.[7–9]

We sought to investigate the use of Sutter® radiofrequency technology for the treatment of snoring and mild OSA, as a single treatment.

Methods

Fifty-two patients who attended our snoring and sleep subspecialty clinics were offered radiofrequency tissue volume reduction using Sutter technology (Sutter, Freiburg, Germany). Patients were recruited over a five-month period. Inclusion criteria were: age > 18 years, body mass index (BMI) < 28, tonsil size grade one or two, Mallampati grades I and II, minimal tongue base collapse (<25 per cent, as seen on Muller's manoeuvre), and either simple snoring (apnoea–hypopnoea index less than five) or mild OSA (apnoea–hypopnoea index < 15).

The study protocol and methodology was reviewed and approved by our institutional review board and ethics committee. All procedures were performed by one surgeon (KPP). There were no conflicts of interest. All equipment and devices were purchased and were not sponsored by the company.

Patients underwent comprehensive clinical assessment, including a thorough physical examination, nasoendoscopy and level one, overnight, attended polysomnography. Patients completed the Epworth sleepiness scale (ESS) and a visual analogue scale (VAS) for snoring before and 7, 14, 30, 60, 90, 120 and 180 days after surgery. The patient's sleep partner completed a similar scale for snoring. The patient also completed a VAS for pain on post-operative days 1, 3, 7 and 14. Examination included height, weight, neck circumference, BMI and blood pressure, together with assessment of the nasal cavity, posterior nasal space, oropharyngeal area, soft palatal redundancy, uvula size and thickness, tonsillar size, and Mallampati grade. Flexible nasoendoscopy was performed for all patients, and collapse during a Muller's manoeuvre was graded for the soft palate, lateral pharyngeal walls and base of tongue on a five point scale.[5] We excluded patients who were less than 18 years old or who had a BMI > 28, tonsillar hypertrophy grades three or four, macroglossia, or an apnoea–hypopnoea index > 15.

Polysomnography

Monitoring during polysomnography included electroencephalography, electro-oculography, electromyography of the chin, electrocardiography, body position, nasal and oral airflow, thoracic and abdominal effort, limb movement, pulse oximetry, and snoring sound level. Complete sleep staging was performed and polysomnographic variables evaluated, including sleep parameters, sleep time, sleep latency, sleep efficiency, rapid eye movement (REM) and non-REM events, arousals, respiratory events (apnoea–hypopnoea index), oxygen desaturation, snoring level, body position, and limb movements. All polysomnograms were scored by a sleep technologist and reviewed by a sleep physician.

Outcome measures included subjective improvement in snoring, reported using a VAS, and improvement in sleepiness, indicated by the Epworth scale. Quality of life (QOL) measurements were based on questionnaires given to patients, with fixed responses of either 'no improvement', 'mild improvement', 'moderate improvement' or 'great improvement'. All patients were made to gauge their sleep quality improvement based on a VAS.

Objective changes were determined from polysomnographic findings. Surgical success was judged by the following criteria: a reduction of at least 50 per cent of the pre-procedure apnoea–hypopnoea index; and a post-procedure apnoea–hypopnoea index of below 15.

Procedural technique

The procedure was performed under local anaesthesia in the out-patient clinic. The patient was seated in an examination chair with their mouth open. Topical lidocaine (10 per cent) was used to anaesthetise the palatal region. A total of 3 ml of 1:100 000 adrenaline and 2 per cent xylocaine was injected into three sites within the soft palate. Bipolar radiofrequency tissue volume reduction was performed, using Sutter equipment with a dual probe hand piece, at four to six sites within the soft palate depending on its size. The probe was inserted into both sides of the soft palate, with a minimum of two insertion points on both sides, and a total of at least four sites (see Figure 1). Insertion points were tailored to the patient's soft palate length and size. The power was set at 16 watts and the duration at about 9 seconds.

Post-operatively, all patients were prescribed anaesthetic gargles and lozenges, non-steroidal anti-inflammatory agents (naproxen sodium), narcotics (such as codeine), and cyclo-oxygenase-2 inhibitors. All patients with mild OSA post-operative underwent polysomnography three months after the procedure. All complications were recorded and reported in this paper.

Statistics

The paired *t*-test (Proc Means' procedure in SAS software) was used to determine the statistical significance of differences in patients' mean pre- and post-operative results.

Results

Fifty-two patients underwent bipolar radiofrequency tissue volume reduction for management of their snoring or mild OSA. Patients comprised 50 men and two women, with a mean age of 35.7 years (range 21 to 47 years). Patients' mean BMI was 22.6 (range 20.6 to 27.2). All patients were classified as

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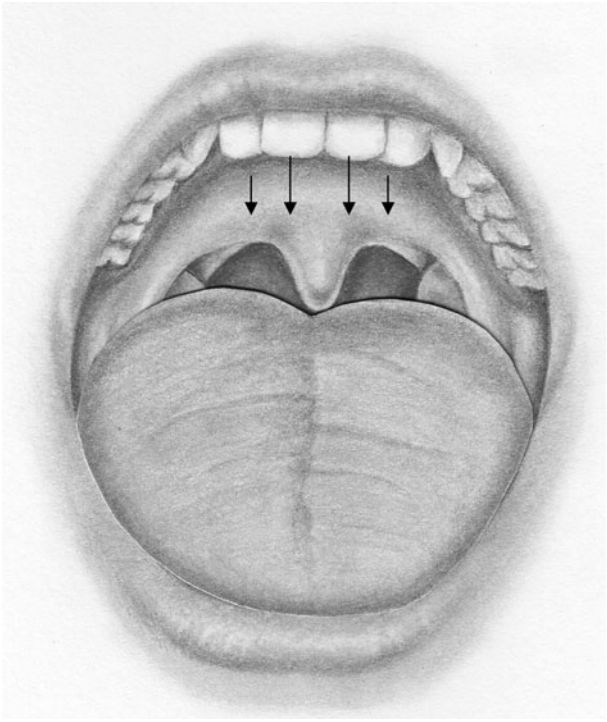

FIG. 1
Regions of the palate to which bipolar radiofrequency were applied.

Friedman stage II and III,[6] with tonsil sizes graded as zero, one or two. The mean pre-operative apnoea–hypopnoea index was 13.6 (range 3.1 to 13.8), with a mean pre-operative AI (apnoea index) of 5.6 (range 0.9 to 11.1). The mean pre-operative lowest oxygen saturation was 89.1 per cent (range 86 to 98 per cent). Patients with mild OSA underwent polysomnography three months post-operatively. Seventeen patients had mild OSA (with a mean apnoea–hypopnoea index of 13.6) and 35 were simple snorers (with a mean apnoea–hypopnoea index of 4.8). The mean follow-up time for all 52 patients was 6.8 months. The mean operative time was 13.6 minutes (range 9 to 21 minutes).

Forty out of the 52 patients (76.9 per cent) reported some improvement in their snoring, while 21 out of the 52 (40.4 per cent), together with their bed partners, reported great improvement in their snoring. Twenty-eight per cent of the 52 patients and their bed partners reported a moderate improvement in their snoring. However, 23.1 per cent of patients reported no benefit from the procedure. Based on their reported VAS scores, patients who benefited from the procedure appeared to experience a gradual reduction in snoring intensity over time, from a pre-operative level of 8.9 (range 7.3 to 9.0) to a low of 3.4 (range 2.5 to 4.6) at 90 days post-operatively ($p < 0.05$).

Similar improvements were seen in patients' Epworth scale results, which decreased from 14.6 pre-operatively (range 10 to 16) to 9.5 (range five to 12) at 90 days post-operatively. However, nine patients (17.3 per cent) reported feeling no less tired post-operatively than they were pre-operatively. Many patients reported that they felt more alert during the day and slept better at night, with less episodes of choking sensation and gasping for air.

Of the 52 patients, 82.7 per cent reported some improvement in their overall quality of life as a result of the procedure. Twenty out of the 52 (38.5 per cent) reported 'great improvement' in their QOL, while 19.2 per cent reported a 'moderate improvement' and 25 per cent reported a 'mild improvement'. Nine patients reported no QOL improvement post-procedure. Patients' mean QOL, reported using a questionnaire, improved from 4.3 to 8.6 ($p < 0.05$). Patients' mean sleep quality, reported using a VAS, increased from 2.4 pre-operatively to 7.1 90 days post-operatively ($p < 0.05$).

Post-operative polysomnographic data were documented in the 17 patients with mild OSA. Seven of these 17 patients (41.2 per cent) met the surgical success criteria (i.e. a reduction of at least 50 per cent of the pre-procedure apnoea–hypopnoea index, and a post-procedure apnoea–hypopnoea index below 15). These 17 patients' mean apnoea–hypopnoea index improved from 13.6 pre-operatively to 9.8 post-operatively (although this change was not statistically significant). Refering to the 17 patients the lowest oxygen saturation improved from 88.3 per cent pre-operatively to 92.5 per cent post-operatively (a statistically insignificant change). Notably, the seven 'successful' patients (of the 17 with mild OSA) showed an overall decrease in mean BMI, from 25.1 pre-operatively to 22.0 post-operatively; in contrast, the mean BMI of the 'failure' group (the remaining 10 patients) remained fairly stable (this difference was statistically insignificant). There were no great improvements in the proportion of slow wave or REM sleep. None of these 17 patients showed a deterioration of apnoea–hypopnoea index; this included the 10 patients who did not meet the surgical success criteria.

Six patients required a second session of radiofrequency volumetric tissue reduction. None of these patients had been satisfied with the outcome of their first procedure. All six improved after their second treatment, as indicated by improvements in their VAS scores for snoring, QOL responses, Epworth scale scores and sleep quality VAS scores.

Complications

Patients reported minimal post-operative pain. The procedure itself was painless, and the post-procedure pain was minimal (as reported using VAS scores), requiring no significant analgesia. Patients reported a mean VAS pain score of only 2.6 (range 1.3 to 4.9) which peaked on the second post-operative day. All patients had minimal odynophagia, and there were no complaints of post-operative haemorrhage, dysphagia or velopharyngeal incompetence.

Discussion

The high cost of laser, along with the pain caused by laser-assisted uvulopalatoplasty, prompted the development of bipolar radiofrequency volumetric tissue reduction, which delivers temperature-controlled, microwave energy to the soft palate. In this

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procedure, energy is delivered to the submucosal surface through an angled probe, which may be either single or dual, and may be either bipolar or monopolar. The resultant soft tissue protein coagulation causes scarring and stiffening of the tissue, with a decrease in palatal flutter and snoring and, hopefully, a reduction in apnoeic events. The major advantages of this procedure are its minimal pain and promising results. Its outcomes are very similar to those of all other similar office-based procedures, with a snoring reduction rate of about 80 per cent and improvements in daytime sleepiness, QOL and overall long term results of 60–70 per cent.[10–12] Multiple treatments are usually recommended for better results, and most data show that two to three treatment sessions may be optimal.[10–13]

Subjective parameters: snoring, tiredness and quality of life

Many authors have found that the subjective reduction in snoring after radiofrequency volumetric tissue reduction is in the range of 70 to 80 per cent.[10–16] Most patients also report a reduction in their daytime tiredness and improvements in their Epworth sleepiness scale results.[10,12,15,16] Our data showed that 76.9 per cent of patients (40 of the 52) had some form of improvement in their snoring, while 40.4 per cent (21 out of 52 patients) of the patients and their bed partners reported 'great improvement' in their snoring level. Twenty-eight per cent of the patients and their bed partners reported a 'moderate improvement' in their snoring intensity. Patients' Epworth sleepiness scale results also showed an impressive decrease, from a mean of 14.6 pre-operatively (range 10 to 16) to 9.5 (range 5 to 12) 90 days post-operatively.

There are few published reports of subjective QOL improvements after radiofrequency treatment of the palate. We demonstrated that, following bipolar radiofrequency volumetric tissue reduction using Sutter technology, 82.7 per cent of our 52 patients reported some improvement in their overall QOL. Of the 52 patients, 38.5 per cent reported a 'great improvement' in their QOL, 19.2 per cent reported a 'moderate improvement' and 25 per cent reported a 'mild improvement'. These promising results were achieved after only one session of bipolar radiofrequency volumetric tissue reduction.

Objective parameters: polysomnography

Most authors concur that the use of radiofrequency volumetric tissue reduction of the palate for the treatment of OSA can be unpredictable and that results are at best modest.[17,18] Reported rates of surgical success (defined as a reduction of at least 50 per cent of the pre-procedure apnoea–hypopnoea index, and a post-procedure apnoea–hypopnoea index of below 15) range from 30 to 50 per cent.[18,19] Fischer *et al.* reported a success rate of 30 per cent in patients with mild OSA after one session of radiofrequency volumetric tissue reduction.[19] However, Brown *et al.* studied 12 patients with OSA and demonstrated only a slight improvement in their mean apnoea–hypopnoea index, from 31.2 ± 5.1 to 25.3 ± 4.2 ($p < 0.05$), and no clinically significant differences in any other sleep parameters, comparing pre- and post-treatment results.[20] Steward *et al.* demonstrated that repeated radiofrequency volumetric palatal reduction treatments were associated with greatly improved OSA-specific QOL, and that additional radiofrequency volumetric tissue reduction of the tongue and palate led to further great improvement in QOL and reaction times.[21]

- **Many surgical techniques have been used to treat snoring. The basis of each method is to create scar tissue, in order to promote fibrosis and to stiffen the palate**
- **This study investigated the use of Sutter® bipolar radiofrequency technology for the treatment of snoring and mild obstructive sleep apnoea (OSA), in a single treatment session**
- **One treatment session of bipolar radiofrequency tissue volume reduction appears to represent a viable method of treating snoring and mild OSA**

There were 17 patients with mild OSA in our series. Seven of these 17 patients (41.2 per cent) met the surgical success criteria. The mean apnoea–hypopnoea index improved from 13.6 pre-operatively to 9.8 post-operatively. The lowest oxygen saturation of these 17 patients also improved from 88.3 to 92.5 per cent. We note that our patients were carefully selected and had a favourable mean BMI of 22.6. However, patients' BMI reduced slightly from 25.1 pre-operatively to 22.0 post-operatively (this change was statistically insignificant).

We attribute our encouraging results to use of a dual probe (available with the Sutter equipment), and to the fact that at least four to six areas of the palate were treated. We also acknowledge that this study had a short follow-up period of six months, and that our sample size of 52 patients may be viewed as small.

While most of our patients reported encouraging subjective improvements in their QOL and snoring, we note that these changes were not statistically significant. This observation is in keeping with the fact that scores for QOL, Epworth sleepiness scale and snoring were discordant with the objective parameters measured.

Complications

Our complication rates were low, at 2 per cent of all sessions performed, and this represented only odynophagia. Pain was also minimal, with a mean VAS pain score of only 2.6 (range 1.3 to 4.9) which peaked on the second day. We encountered no post-operative haemorrhage, dysphagia or velopharyngeal incompetence. As with other investigations of the same

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procedure, our complication rate was minimal. Stuck *et al.* reviewed 322 patients who received 497 treatment sessions, and found a complications rate of 2.0 per cent, including ulceration of the soft palate and dysphagia necessitating hospital admission.[6] Similarly, Kezirian *et al.* found a low complication rate of 1.6 per cent for 470 treatment sessions.[22]

Conclusion

Bipolar radiofrequency volumetric tissue reduction, using Sutter technology, appears to have promising results for patients with snoring and mild OSA. One treatment session resulted in significant reduction in snoring intensity, improvement in sleep quality and QOL, and reduction in daytime sleepiness. There was also a 41.2 per cent success rate for patients with mild OSA.

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