

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of radiofrequency ablation of the soft palate for snoring

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2004

Procedure name

Radiofrequency ablation of the soft palate

Specialty societies

British Association of Otorhinolaryngologists & Head and Neck Surgery (ENT UK)

Description

Indications:

Snoring is a noisy inspiratory sound produced by vibrations and partial obstruction in the oropharynx(1). Habitual snoring is not of frivolous importance and can cause domestic disruption. It is a form of sleep disordered breathing, and can lead to disrupted sleep and subsequent daytime tiredness and poor concentration. Snoring can be associated with sleep apnoea, however for the purpose of this overview the studies reviewed have included patients who have a measured oxygen saturation no lower than 85% of normal.

Current treatment and alternatives

Conservative treatment methods for snoring include weight loss, avoidance of alcohol or sedatives, smoking cessation, and sleep positioning training. Some studies have investigated the use of physical appliances to maintain normal airflow dynamics during sleep. Alternative interventions include several procedures to address pharyngeal obstruction that can cause snoring, including laser assisted uvulopalatoplasty (LAUP) and uvulopalatopharyngoplasty (UPPP).

What the procedure involves:

Radiofrequency ablation (RFA) of the soft palate aims to reduce the volume of the palate tissue and to improve the texture of the remaining palate so that it becomes more dynamically stable. It is usually an outpatient procedure which involves the use

of a topical local anaesthetic. Radiofrequency energy (at a variety of frequencies and energy levels) is directed to the palate using an electrode delivery device, commonly to the mid portion of the palate from the uvular base to the posterior nasal spine. In addition two lateral applications are often given at a reduced energy level. The procedure is repeated a number of times if snoring symptoms persist.

Efficacy:

A small controlled study comparing RFA with the use of an oral appliance found that RFA improved snoring as assessed by patient's spouse's on a visual analogue scale from 7.50 (± 2.50) at baseline to 2.75 (± 2.50) at 8 weeks ($p < 0.001$). There was no significant difference in the snoring levels between the two groups as assessed by laboratory sleep assessment, also to 8 weeks(2). A randomised controlled study found visual analogue scale measured snoring loudness to be significantly improved following RFA. The score fell from 7.5(± 2.1) at baseline to 3.1(± 2.6) at week 16 ($P < 0.0006$). However objective evaluation of snoring using digital audio monitoring found no significant improvement at the same time point, and no inter-group comparisons were undertaken(3)

A case series of 60 patients undergoing RFA found that snoring score was reduced from 9.0 at baseline to 3.5 at 12.3 months following therapy(4). In a small case series symptoms were improved (as defined by a 3 point fall on snoring score) in 58% (11/19) of patients at 3 months and in 63% (12/19) at 9.5 months. This study demonstrated a significant decrease in the distance from the tip of the uvula to the bottom of the sella following RFA therapy but no changes in other palate dimensions, including the length of the soft palate were statistically significant(1). Another case series of 22 patients with a maximum follow up of 12 weeks found a significant decrease in snoring disturbance from 8.3(± 1.8) to 1.9(± 1.2) and a decrease in daytime tiredness as determined by the Epworth sleepiness scale(5).

Safety:

A comparative study in 41 patients undergoing either RFA, LAUP, or UPPP found mean pain duration to be significantly shorter following RFA 2.55 days compared to 13.90 and 14.33 days for the other methods respectively. Also pain assessment following RFA rated 0 on a visual analogue scale 10 days postoperatively(6). A similar reduction in pain duration with RFA compared to LAUP was reported in a small randomised controlled trial where pain persisted for 7.0 days following RFA whereas for LAUP it was 15.1 days(3)

In a case series of 60 patients undergoing RFA, reported adverse events included longer pain than expected in 10% (6/60) of patients and bleeding requiring an A and E visit in 2% (1/60)(4). A further case series of 20 patients noted some mucosal blanching in 30% (6/20) of patients, and 10% (2/20) had blanching of between 5 and 10 mm diameter. Throat swelling was reported by 20% (4/20) of patients and the same number received antibiotics(1). Following 117 treatments in the RFA arm of a comparative study sub-mucosal erosion was reported by 8% (11/117) of patients(6).

No serious side effects either swallowing or speech difficulties, bleeding, infection or pain were reported in a small randomised controlled trial(2), or a case series of 22 patients followed up for 12 weeks(5).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to radiofrequency ablation of the soft palate. Searches were conducted via the following databases, covering the period from their commencement to 16/09/2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with sleep disturbance due to snoring, but without obstructive sleep apnoea
Intervention/test	Radiofrequency ablation of the soft palate (not tongue base) and comparison to oral appliances and laser assisted uvulopalatoplasty
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 6 studies, 1 randomised controlled study, 2 comparative studies and 3 case series.

Existing reviews on this procedure

No existing systematic reviews or guidelines on this topic were identified during the literature search.

Table 1 Summary of key efficacy and safety findings on selective internal radiation therapy

Abbreviations used: RFA – radiofrequency ablation, LAUP – Laser-assisted uvulopalatoplasty, UPPP – Uvulopalatopharyngoplasty, RDI – respiratory disturbance index			
Study Details	Key efficacy findings	Key safety findings	Comments
<p>Cartwright R et al (2000)(2)</p> <p>Comparative study, Treatment options explained to patients and self selected. n=20 USA</p> <p>RFA of soft palate =10 Snore-X oral appliance =10</p> <p>Patients screened in sleep laboratory using standard 12-channel recording to rule out sleep apnoea.</p> <p>Mean age=53yrs, BMI=24, Respiratory Disturbance index=5.4, lowest O₂ saturation=88%. No significant differences between groups</p> <p>Most outcomes measured at 3days, 4weeks and 8 weeks. Questionnaire recording degree of pain, need for medication, difficulty of speech or swallowing. Spouse rating of snoring loudness.</p> <p>At 8 weeks patients whose spouses reported loudness less than 3 completed an Epworth Sleepiness Scale Survey . Laboratory sleep testing with a device to count minutes of sleep with soft, loud or no snoring, as a comparison to spouse reported events. Long term procedure efficacy spouse-reported questionnaire was completed at 6 months</p>	<p>Symptom improvement – spouse assessment of snoring There was a significant improvement on the 10 point snoring loudness scale with RFA therapy from a mean 7.50 points (SD ±2.50) at baseline to 2.75 points (SD ± 2.15) at week 8 (p<0.001).</p> <p>There was no significant agreement between the objective laboratory snoring assessment and spouse’s home report (p<0.07). possibly due to small number of cases</p> <p>Long term effectiveness of RFA A self-reported questionnaire by patients spouses at 6 months post procedure found that positive change in snoring reported by 7 responders was maintained to this time point. 2 other reported that the was a positive change for a short period only.</p> <p>Efficacy vs oral device Comparing the 8 week sleep assessment following RFA as compared to patients sleeping with the Snore X device, the mean percentage of sleep time which loud snoring was recorded after Somnoplasty was 8.03% (SD ±10.16%) Vs 3.28% (SD ±1.46) (p>0.24).</p>	<p>Procedure dynamics The entire procedure took approximately 20 minutes to complete.</p> <p>Adverse events No side effects were reported in swallowing difficulty, changes in speech, or pain reported 2 days post treatment with RFA.</p>	<p>Five of ten patients underwent a second RFA treatment, these are not separated in analysis.</p> <p>Not a true control as treatment choice given to patients, Snore X group is more of a comparison group.</p> <p>8 week lab assessment outcomes for Snore X were derived from a composite of 2 half night assessments with the device in or out.</p> <p>One-off assessment of snoring may not be sensitive to capture different snoring patterns on different nights.</p> <p>The method of snoring control in the patient without apnoea should be based on patient choice rather than the degree of efficacy.</p> <p>Somnoplasty carried out using a topical anesthesia, and an injection of 0.25% bupivacaine HCl at three sites. Low power radiofrequency energy was applied by a needle electrode to the soft tissue at the midline, and two lateral injections at half energy.</p>

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<p>Troell, R.J. et al (2000)(6)</p> <p>Comparative study, patients chose treatment option. USA n=41</p> <p>All patients required to have chronic disruptive snoring for more than 1 year leading to social disruption. Only those in whom the major site of obstruction was the palate were included.</p> <p>Chronic primary snoring determined by an RDI of less than 5 events per hour of sleep with no oxygen saturation less than 90% during sleep</p> <p>RFA of soft palate =22 LAUP or UPPP =19</p> <p>Age =40yrs, male =88%, BMI =27.4, Primary snoring =39%.</p> <p>Outcomes recorded were the Epworth Sleepiness Scale (ESS), sleep history. Fiberoptic nasopharyngoscopy, lateral cephalometric radiograph, and nocturnal polysomnography. Pain was measured on a visual analogue scale and the quantity of analgesic medication administered was recorded.</p> <p>The mean number of treatment was 3.6 (±1.2), the initial therapy is used for analysis. 8 patients had application at 1 site only , 4 patients at 2 sites, and 10 at 3.</p>	<p>No efficacy results reported</p>	<p>Procedure mechanics The mean RF energy delivered per treatment session was 688J (± 106J), and the duration of a single treatment visit was 141 secs. (± 30 secs.)</p> <p>Pain duration Mean pain duration (days)</p> <table border="1"> <thead> <tr> <th></th> <th>RFA</th> <th>UPPP</th> <th>LAUP</th> </tr> </thead> <tbody> <tr> <td>Total duration</td> <td>2.55</td> <td>14.33</td> <td>13.90</td> </tr> </tbody> </table> <p>(p=0.0001)</p> <p>Pain severity assessment</p> <table border="1"> <thead> <tr> <th></th> <th>RFA</th> <th>UPPP</th> <th>LAUP</th> </tr> </thead> <tbody> <tr> <td>Day1</td> <td>1.41</td> <td>7.88</td> <td>8.11</td> </tr> <tr> <td>Day10</td> <td>0.00</td> <td>3.80</td> <td>3.94</td> </tr> </tbody> </table> <p>(VAS)</p> <p>For intra group comparisons at both times (p=0.0001)</p> <p>Analgesic medication usage The mean number of days requiring narcotic pain medication for the RFA, LAUP, And UPPP groups were 0.2, 11.8 , and 12.4 days respectively</p> <p>Adverse events Among the 22 patients treated with FRA undergoing 117 treatments events were</p> <table border="1"> <tbody> <tr> <td>Submucosal erosion</td> <td>8% (11/117)</td> </tr> <tr> <td>Requiring oral analgesic</td> <td>5% (6/117)</td> </tr> <tr> <td>Requiring narcotic therapy</td> <td>1% (1/117)</td> </tr> </tbody> </table> <p>All resolved within 7 to 21 days without need for antibiotic or steroid therapy</p>		RFA	UPPP	LAUP	Total duration	2.55	14.33	13.90		RFA	UPPP	LAUP	Day1	1.41	7.88	8.11	Day10	0.00	3.80	3.94	Submucosal erosion	8% (11/117)	Requiring oral analgesic	5% (6/117)	Requiring narcotic therapy	1% (1/117)	<p>No follow up time was stated, but from results can be assumed to be a maximum of one month</p> <p>Efficacy results not stated despite outcome measures being defined</p> <p>Pain outcome scores recorded without correction for different analgesic regimens</p> <p>RFA ablates tissue at a lower temperature than laser therapy</p> <p>RF energy delivered at 465 kHz with an RF generator with custom made needle electrodes. 20% topical benzocaine anaesthetic and 2ml of 0.5% bupivacaine injected along the treatment site. The mid-portion of the palate was selected for treatment.</p> <p>In patients undergoing LAUP 90% of the uvula was amputated and bilateral trenches of the soft palate about 2 cm from the uvular and 1cm from the tonsillar pillars were removed up to the muscular crease. UPPP patients had tonsils removed if present with electrocautery, and the soft palate was conservatively removed after the location of the muscular crease was noted</p>
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<p>Terris, D.J. et al (2002)(3)</p> <p>USA</p> <p>Randomised controlled trial n=17</p> <p>RFA =10 LAUP =7</p> <p>Mild sleep disordered breathing documented by polysomnography, and failed on conservative treatment</p> <p>Computer Randomised to group (no details of blinding) and patients crossed over if therapy failed (after outcomes measured)</p> <p>Age=50.3yrs, BMI=27.5, Preoperative Epworth sleepiness scale score =7.06</p> <p>No significant differences between groups in terms of demographic or disease severity at baseline</p> <p>Severity of sleep disordered breathing measured by polysomnography, objective assessment of snoring loudness by digital audio recording, and subjective partner assessed snoring loudness on visual analogue scale at 16 weeks. Office visit for clinical assessment at 1day, 1, 3, and 16 weeks.</p>	<p>Subjective evaluation of snoring 60% (6/10) of the RFA patients achieved a satisfactory reduction in snoring as reported by their sleep partner, and among the LAUP group this figure was 86% (6/7).</p> <p>Snoring loudness at week 16- Visual analogue scale</p> <table border="1"> <thead> <tr> <th></th> <th>Pre-op (SD)</th> <th>Post-op (SD)</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>RFA</td> <td>7.5 (±2.1)</td> <td>3.1 (±2.6)</td> <td>0.0006</td> </tr> <tr> <td>LAUP</td> <td>8.6 (±1.5)</td> <td>2.9 (±2.0)</td> <td>0.0013</td> </tr> </tbody> </table> <p>Objective evaluation of snoring Digital audio monitoring at week 16 (dB) RFA n=5 (50%) LAUP n=3 (43%)</p> <table border="1"> <thead> <tr> <th></th> <th>Pre-op (SD)</th> <th>Post-op (SD)</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>RFA</td> <td>19.4 (±8.1)</td> <td>16.6 (±9.0)</td> <td>0.46</td> </tr> <tr> <td>LAUP</td> <td>22.3 (±3.2)</td> <td>16.3 (±4.2)</td> <td>0.24</td> </tr> </tbody> </table> <p>Primary snoring frequency. There was no significant change in snoring frequency (Hz) from baseline to 16 weeks in either the RFA or LAUP groups</p> <p>Daytime fatigue There was no significant change in Epworth sleepiness score from baseline to 16 weeks in either the RFA or LAUP groups</p>		Pre-op (SD)	Post-op (SD)	p	RFA	7.5 (±2.1)	3.1 (±2.6)	0.0006	LAUP	8.6 (±1.5)	2.9 (±2.0)	0.0013		Pre-op (SD)	Post-op (SD)	p	RFA	19.4 (±8.1)	16.6 (±9.0)	0.46	LAUP	22.3 (±3.2)	16.3 (±4.2)	0.24	<p>Post operative pain Duration of pain RFA 7.0 ± 4.4 Days LAUP 15.1±4.5 Days</p> <p>Pain index (sum of visual analogue pain score for all days of pain) was significantly lower in the RFA group. RFA 18.3 ± 13.7 Days LAUP 62.5 ± 23.9 Days* (p=0.002)</p> <p>* figure in text does not reconcile with that presented in table (67.5 days)</p> <p>Swallowing discomfort Patients in the LAUP group experienced more difficulty in swallowing than those undergoing RFA to 3 weeks (p=0.0004)</p>	<p>No inter-group analysis, only comparison to baseline in each group.</p> <p>RFA of palate carried out using a customised palate handpiece delivering 600J to the midline and 300J to either side of the palate. Patients were treated with postoperative corticosteroids.</p> <p>LAUP was performed encompassing uvular and palatal reduction, including bilateral vertical trenches through the palate and ablation of the tonsils if present.. Patients received postoperative corticosteroids.</p> <p>Patients in each group underwent 3 procedures or fewer if symptoms resolved. Not clear if analysis is based on 1st treatment.</p> <p>Authors acknowledge that the 16 week period used for assessment of procedure pain may not prove sufficient for efficacy outcomes given known long term failure rates.</p> <p>Treatment efficacy needs to be balanced against operative pain.</p>
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Study Details	Key efficacy findings	Key safety findings	Comments
<p>Johnson, J.T. et al (2002)(4)</p> <p>Case series USA n=60 (80% of 75 patients undergoing this procedure agreed to participate)</p> <p>Patients treated at one site from Feb 1998 to May 2000</p> <p>Patients had a respiratory disturbance index of <15 or nonapnoeic snoring. The soft palate was the diagnosed site of snoring.</p> <p>Patients snoring at baseline and follow up (mean 12.3 months) was assessed by family member or significant other person on a 10 point visual analogue scale from 0 no snoring 5 very loud snoring 10 horrific snoring.</p> <p>Age=55.4yrs, Male =63%, Baseline snoring index 9.0 (range 6 to 10).</p> <p>RFA procedure conducted in outpatient setting under local anaesthesia. Two or three palate sites were treated at each appointment. Treatment was repeated at 6 weekly intervals at the patients request, mean number of treatments was 1.8, and energy delivered was 1940J.</p>	<p>Subjective assessment of snoring At 12.3 months the mean visual analogue scale snoring score was 3.5 from a baseline of 9.0.</p> <p>Efficacious therapy Patients were considered responders if the postoperative snoring score was <5 and had been reduced by 50% from baseline.</p> <p>85% (51/60) patients were responders. With a mean snoring score falling from 9.2 (range 6 to 10) to 3.2 after therapy.</p> <p>15% (9/60) patients were classified as non responders</p>	<p>Patient reported adverse events Longer pain than expected 10% (6/60) Bleeding (A&E visit) 2% (1/60)</p> <p>Other reported findings Patients also noted extra drainage with head colds, snoring with excess alcohol, inability to roll Rs, slight change in volume and pitch.</p>	<p>Relatively high loss to follow up for 12 month study.</p> <p>Night to night variability in both the snorer and the listener.</p> <p>Potentially skewed scale if mid point (5 out of 10) is 'loud snoring'</p> <p>The amount of energy delivered did not correlate with response to therapy or not.</p>

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<p>Bäck, L.J.J. et al (2002)(1)</p> <p>Case series Finland n=20</p> <p>Patients had nocturnal polysomnography to document severity of snoring, and were required to have a maximum oxygen saturation decrease of less than 15%</p> <p>Age=43yrs, Male=95%, BMI=25.7Kg/m²</p> <p>Visual analogue scales were used to assess postoperative pain, swelling and speech out to 2 weeks. Snoring score on a 10 point scale (0= no snoring 10=heavy snoring and partner leaves the room) were recorded both by the snorer and partner, at 3 months and a median 9.5 months. Palate dimensions were recorded at baseline and at 3 months by 1 radiologist, blinded to the purpose of the study</p> <p>Outpatient treatment of patients using a wand to deliver 216-234 volts) for 15 seconds in the midline of the soft palate 1cm below the junction of the hard and soft palate and laterally on both sides. Treatment was repeated in all patients after 1 week.</p>	<p>Evaluation of snoring by snorer and partner</p> <p>Using the definition of improvement of a decrease of 3 points on the snoring scale, 58% (11/19) of the snorers reported improvement at 3 months, and 63% (12/19) at 9.5 months. 39% (7/18) of partners noted improvement at 3 months and 33% (6/18) at 9.5 months.</p> <p>MRI evaluation of palate dimensions 3 months postoperatively, Median (95% CI)</p> <table border="1"> <thead> <tr> <th></th> <th>baseline</th> <th>3mnths</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Length of soft palate</td> <td>42 (39-44)</td> <td>42 (38-44)</td> <td>0.849</td> </tr> <tr> <td>Tip of uvula to bottom of sella</td> <td>57.5 (54-59)</td> <td>55.5 (51-57)</td> <td>0.005</td> </tr> </tbody> </table> <p style="text-align: center;">Distance in mm</p> <p>All other dimensions were not significantly changed from baseline to 3 months.</p>		baseline	3mnths	p	Length of soft palate	42 (39-44)	42 (38-44)	0.849	Tip of uvula to bottom of sella	57.5 (54-59)	55.5 (51-57)	0.005	<p>Patient reported adverse events Events reported to 3 months</p> <table border="1"> <tbody> <tr> <td>Mucosal blanching less than 5mm</td> <td>30%(6/20)</td> </tr> <tr> <td>Mucosal blanching less than 10mm</td> <td>10%(2/20)</td> </tr> <tr> <td>Throat swelling</td> <td>20%(4/20)</td> </tr> <tr> <td>Received antibiotics</td> <td>20%(4/20)</td> </tr> <tr> <td>Received corticosteroids</td> <td>5%(1/20)</td> </tr> </tbody> </table> <p>Minor transient changes in speech, and swallowing difficulties were encountered.</p>	Mucosal blanching less than 5mm	30%(6/20)	Mucosal blanching less than 10mm	10%(2/20)	Throat swelling	20%(4/20)	Received antibiotics	20%(4/20)	Received corticosteroids	5%(1/20)	<p>Self reported findings with potential placebo affect.</p> <p>Snorer and partner snoring scores correlated significantly at 3 months r=0.792 (p<0.001)</p> <p>MRI provides indirect information regarding changes in the stability of the soft palate.</p> <p>The overall agreement between self-and partner reported symptoms was generally high, however both measurements are subjective.</p>
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Study Details	Key efficacy findings	Key safety findings	Comments
<p>Powell, N.B. et al (1998)(5)</p> <p>Case series USA n=22</p> <p>One investigator undertook all procedures, using a customised needle electrode delivery device. Following a 20% benzocaine topical anaesthetic a mean energy of 688J was delivered to the mid-portion of the palate from the uvular base to the posterior nasal spine. Energy was delivered for 60 to 170 seconds. Sedative premedication was not given and antibiotics and corticosteroids were not used.</p> <p>Age=45yrs, Male=81%, BMI=27.4 Kg/m²</p> <p>All patients seeking treatment for symptomatic chronic snoring and daytime sleepiness, with symptoms present for >1yr. Only those in whom the major site of obstruction was located at the palate were included. Maximal saturated oxygen drop permitted was to 85% during sleep.</p> <p>At baseline, post treatment, at 2 or 3 days, and at 3 to 4 weeks the following outcomes were evaluated. Epworth sleepiness scale (ESS), VAS scores for pain, speech, swallowing, and snoring (0= no snoring 10=heavy snoring and partner leaves the room).A clinical interview and examination was undertaken at each time point. At baseline, 2 or 3 days, and at 8 to 12 weeks polysomnography was performed in the sleep laboratory.</p>	<p>Treatment effects on palate dimensions There was a significant reduction in the distance from the nasal spine to the soft palate from a mean 46.5(±3.8mm) to 41.0(±3.6mm) (p<0.0001)</p> <p>Daytime tiredness Self reported daytime tiredness as assessed by the validated Epworth Sleepiness scale showed a significant decrease from a mean 8.5(±4.5) at baseline to 5.2(±3.3) post-treatment (p<0.0001)</p> <p>Effect on snoring A visual analogue scale reported measure of pain as self assessed by patient and partner showed a significant decrease in disturbance. Scores fell from a mean 8.3(±1.8 points) at baseline to 1.9(±1.2) (time point not stated).</p>	<p>Recovery from procedure 9% (2/22) of the patients used a narcotic oral analgesic at some time after the first round of treatment</p> <p>Adverse events There were no major complications of bleeding, infection, tissue slough speech problems or swallowing difficulties during the investigation.</p> <p>There were temporary statistically significant deterioration in respiratory disturbance index, and nadir oxygen saturation at 2 to 3 days following the procedure, but these resolved by 3 to 4 weeks.</p> <p>50% (11/22) of patients experienced some erosion of the surface mucosa at 2 to 4 days postoperatively. Oral analgesics were used in 6 of these cases, and all lesions healed without further treatment.</p>	<p>Only palate site of snoring patients are included</p> <p>Many outcomes are analysed at a range of time points rather than at one discrete point, thus many comparisons may not be equal.</p> <p>Study describes the first use of this equipment in vivo at this site, so may be some degree of learning curve. Early and late results were not compared.</p> <p>Patients returned for up to 6 treatment sessions.</p>

Validity and generalisability of the studies

- There is some variation in the energy delivered and delivery device used between studies.
- Few controlled trials are available comparing RFA to other interventional or conservative treatments, and only one used randomisation to determine treatment option, the others may be subject to selection bias
- Most studies use a carefully selected patient population, whose snoring has been determined to be attributable to the soft palate.
- Many studies use repeat therapy and not clear if analysis is based on initial treatment session.
- Partner evaluated VAS scales not assessed for replicability, and often do not correlate with objective assessment of snoring

Specialist advisors' opinions

- There is need to repeat the procedure (at least once) before snoring symptoms improve.
- Benefit may only be temporary, and those with mild symptoms may benefit most.
- Radiofrequency ablation much less painful than other invasive alternatives
- Can be used in the outpatient or office setting with local anaesthetic only
- Adverse events included some ulceration, and rarely, haemorrhage or secondary infection
- This procedure is likely to be undertaken at a few specialist centres
- ENT surgeons often will not provide this procedure and Health Authorities prevent the treatment of snorers.

Issues for consideration by IPAC

- Common recidivism of symptoms may not be addressed with short term follow-up
- Alternative invasive treatments are often painful
- Difficult to consider acceptable treatment morbidity for the indication of snoring
- The intervention is also used to treat sleep apnoea, but snoring is the only indication considered here.

References

- (1) Back LJJ, Tervahartiala PO, Piilonen AK, Partinen MM, Ylikoski JS. Bipolar radiofrequency thermal ablation of the soft palate in habitual snorers without significant desaturations assessed by magnetic resonance imaging. *American Journal of Respiratory & Critical Care Medicine* 2001; Vol. 166(6):15.
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- (3) Terris DJ, Coker JF, Thomas AJ, Chavoya M. Preliminary findings from a prospective, randomized trial of two palatal operations for sleep-disordered breathing. *Otolaryngology - Head & Neck Surgery* 2002; 127(4):315-323.
- (4) Johnson JT, Pollack GL, Wagner RL. Transoral radiofrequency treatment of snoring. *Otolaryngology - Head & Neck Surgery* 2002; 127(3):235-237.
- (5) Powell NB, Riley RW, Troell RJ, Li K, Blumen MB, Guilleminault C. Radiofrequency volumetric tissue reduction of the palate in subjects with sleep-disordered breathing. *Chest* 1998; Vol. 113(5):-1174.
- (6) Troell RJ, Powell NB, Riley RW, Li KK, Guilleminault C. Comparison of postoperative pain between laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, and radiofrequency volumetric tissue reduction of the palate. *Otolaryngology - Head & Neck Surgery* 2000; Vol. 122(3):-409.

Appendix A: Additional papers on radiofrequency ablation of the soft palate from snoring not included in the summary tables

Article title	Number of patients/follow-up	Comments	Direction of conclusions
Boudewyns A, Van De HP. Temperature-controlled radiofrequency tissue volume reduction of the soft palate (somnoplasty) in the treatment of habitual snoring: results of a European multicenter trial. <i>Acta Oto-Laryngologica</i> 2000; 120(8):981-985.	n=45 8 weeks	Patients also had mild sleep apnoea	Snoring improved in snoring scale of a mean 3.5 points
Sher AE, Flexon PB, Hillman D, Emery B, Swieca J, Smith TL et al. Temperature-controlled radiofrequency tissue volume reduction in the human soft palate. <i>Otolaryngology - Head & Neck Surgery</i> 2001; 125(4):312-318.	n=113 8 weeks	Comparison of single versus multiple treatment sessions	Multiple session more successful reducing snoring by 4.9 points
Kania RE, Schmitt E, Petelle B, Meyer B. Radiofrequency soft palate procedure in snoring: influence of energy delivered. <i>Otolaryngology - Head & Neck Surgery</i> 2004; 130(1):67-72.	n=43 6 weeks	Comparison of energy levels used in RFA for snoring	Higher energy levels led to better snoring scores
Ferguson M, Smith TL, Zanation AM, Yarbrough WG. Radiofrequency tissue volume reduction; multilesion vs single-lesion treatments for snoring. <i>Archives of Otolaryngology -- Head & Neck Surgery</i> 2001; Vol. 127(9):-1118.	n=47 6 weeks and 16months	Comparison of single versus multiple treatment sessions	Multi-session RFA using higher energy is safe and more efficacious than single treatment
D'Souza A, Hassan S, Morgan D. Recent advances in surgery for snoring-somnoplasty (radiofrequency palatoplasty) a pilot study: effectiveness and acceptability. <i>Revue de Laryngologie Otologie Rhinologie</i> 2000; 121(2):111-115.	n=22 6 weeks	A case series with 6 weeks follow up where we have longer	Radio-frequency somnoplasty effective and safe, but results dependant on BMI
Hukins CA, Mitchell IC, Hillman DR. Radiofrequency tissue volume reduction of the soft palate in simple snoring. <i>Archives of Otolaryngology -- Head & Neck Surgery</i> 2000; Vol. 126(5):-606.	n=20 2 months	A case series with 2 months follow up where we have longer	RFA has low morbidity and reduces snoring on objective measurement, RCT's required to confirm effects
Li KK, Powell NB, Riley RW, Troell RJ, Guilleminault C. Radiofrequency volumetric reduction of the palate: An extended follow-up study. <i>Otolaryngology - Head & Neck Surgery</i> 2000; Vol. 122(3):-414.	n=22 14 months	31% of patients had sleep apnoea and not reported separately	Success diminishes over time
Stuck BA, Starzak K, Verse T, Hormann K, Maurer JT. Complications of temperature-controlled radiofrequency volumetric tissue reduction for sleep-disordered breathing. <i>Acta Oto-Laryngologica</i> 2003; 123(4):532-535.	n=322 122 days	Only 13% (34/322) patients were snorers, and only 30 procedures performed on soft palate	Complication rates with RFA are low and events are mild.

Appendix B: Literature search for 260 Radiofrequency ablation of the soft palate

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1. electrosurgery/
2. electrosurgery.tw.
3. 1 or 2
4. radiofrequency/
5. radiofrequency.tw.
6. radiofrequency ablation.tw.
7. or/4-6
8. palatal resection.tw.
9. palatal stiffening.tw.
10. somnoplasty.tw.
11. or/1-10
12. soft palate/
13. soft palate.tw.
14. Snoring/
15. snoring.tw.
16. or/12-15
17. 11 and 16