NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

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

Treating snoring by using radiofrequency energy to shrink and stiffen the roof of the mouth

Snoring is caused by vibration of the soft palate in the roof of the mouth. In this procedure, radiofrequency heat energy is used to produce scarring in the soft palate, which stiffens it and may reduce the vibrations that create the snoring sound.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make 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 IP overview was prepared in January 2013.

Procedure name

- Radiofrequency ablation of the soft palate for snoring

Specialist societies

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

Description

Indications and current treatment

Snoring is a noisy inspiratory sound produced by vibration and partial airway obstruction in the pharynx. It is a form of sleep-disordered breathing, and can lead to disrupted sleep, daytime tiredness and poor concentration – both for the person who snores and for anyone sleeping close by. Snoring can be associated with obstructive or central sleep apnoea. However, for the purpose of this overview, the reviewed studies included patients who had an oxygen saturation level no lower than 85%.

Conservative treatments involve lifestyle changes, including weight loss, avoiding alcohol and sedatives, stopping smoking and sleep position training. Physical appliances (such as dental or oral devices) have also been used to maintain normal airflow dynamics during sleep. Procedures available for pharyngeal airway obstruction include laser-assisted uvulopalatoplasty (LAUP) and uvulopalatopharyngoplasty (UPPP).

What the procedure involves

If clinical examination suggests that vibration of the soft palate is a major contributor to snoring, radiofrequency ablation aims to stiffen the soft palate. This may be combined with other techniques (such as removal of the uvula or tonsillectomy) to reduce airflow obstruction and vibration in the airway.

The procedure is usually done under local anaesthesia in outpatients. An electrode delivery device is introduced into the mouth and directed upwards towards the soft palate. A needle tip makes a series of very shallow punctures in the underlying muscle. Radiofrequency energy is delivered at each puncture site, commonly in the mid-portion of the palate from the uvular base to the posterior nasal spine. Alternatively, two lateral applications can be given at a lower energy setting and to several areas to either side. The intention is to scar and tighten the soft palate. If necessary the procedure can be repeated several weeks later: it is often carried out 2 or 3 times.

Outcome measures

The Epworth Sleepiness Scale (validated primarily in obstructive sleep apnoea) is an 8-item questionnaire that assesses to what degree a person is likely to doze off or fall asleep while engaged in certain activities of daily life. Responses to all 8 questions are rated on a 4-point scale, ranging from 0 (no chance of dozing) to 3 (high chance of dozing). A normal score is 0–9; 11–15 may indicate mild to moderate sleep apnoea or upper airway resistance syndrome, and 16 and above may indicate severe apnoea and narcolepsy.

The apnoea-hypopnoea index indicates the severity of sleep apnoea by combining the number of apnoeas with the degree of hypopneas. This combination gives an evaluation of the number of sleep disruptions and the potential for oxygen desaturation. The number of events is divided by the

number of hours of sleep. Scores of 5–14 episodes indicate mild sleep apnoea, 15–30 episodes indicate moderate sleep apnoea and more than 30 episodes indicate severe sleep apnoea.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to radiofrequency ablation of the soft palate for snoring. Searches were conducted of the following databases, covering the period from their commencement to 28 January 2013: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection 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 were 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, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with snoring.
Intervention/test	Radiofrequency ablation of the soft palate.
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 IP overview

This IP overview is based on 643 patients from 1 RCT[1], 2 non-randomised studies[2-3] and 5 case series[4-9].

Other studies that were considered to be relevant to the procedure, but were not included in the main extraction table (table 2), have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on radiofrequency ablation of the soft palate for snoring

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Stuck BA (2005)[1] **RCT** Germany Recruitment period: not reported Study population: patients with primary snoring n=**26 (RFA vs. sham therapy** – number of patients originally randomised unclear) Age: mean 43 years Sex: not reported Patient selection criteria: patients between 18–65 years, maximum BMI of 35 kg/m^2, with a maximum AHI or oxygen desaturation index of 15 were included. Patients with previous surgery to SP, uvular hypertrophy, OSA, other health conditions or professional voice users were excluded. Technique: 2 consecutive sessions of RFA (Somnoplasty RF generator Model S2, Gyrus ENT) delivered to patient under local anaesthesia with total energy delivered 3300 Joule, target temperature set at 85ºC. Second treatment session was performed 4–6 weeks after the initial session. Patients undergoing sham therapy (comparator group) underwent insertion of device needle without energy delivery. Follow-up: **6–8 weeks** (after the second treatment session) Conflict of interest/source of funding: one of the authors had received research support and equipment from the manufacturer but the paper reported that the study was not industry supported.	Number of patients analysed: **23 (12 RFA vs. 11 placebo)** Successful treatment (defined as postoperative snoring score <3) was reported in 2 patients in the RFA group. **Change in mean snoring scores** | | RFA | sham | | Before treatment | 8.1 (1.3) | 8.4 (1.6) | | After treatment | 5.2 (2.4) | 8.0 (2.3) | Data reported as mean (SD). Statistically significant difference between the two groups (p<0.05). **Daytime sleepiness (assessed with ESS)** | | RFA | sham | | Before treatment | 5.4 (4.6) | 5.2 (3.1) | | After treatment | 3.9 (3.3) | 4.3 (2.7) | Data reported as mean (SD). No significant difference (p=0.77) between the groups. **Functional parameters** Functional parameters (speech, taste, swallowing, pharyngeal irritation) remained unchanged in both groups.	Not reported.	**Follow-up issues:** • 3 patients lost to follow-up. **Study design issues:** • Computer-generated randomisation. Method of concealment of allocation not reported. Investigator blinded to randomisations. Sample size calculation (at 90% power) showed 12 patients needed in each group. • Snoring assessed by bed partner on 10 cm VAS, ranging from 'no snoring' (0) to 'excessive snoring (10), bed partner leaves the room'. Functional parameters assessed using 10 cm VAS, with scores ranging from 0 (no problem/not affected) to 10 (severe problem/severely affected).

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Iseri M (2005)[2] **Non-randomised comparative study** Turkey Recruitment period: not reported Study population: simple snorers undergoing RF tissue reduction of SP IS. n=**70 (40 RFA vs. 30 IS)** Age: mean 49 years Sex: 73% male Patient selection criteria: patients with confirmed diagnosis of primary snoring with RDI <10 were included. Exclusion criteria were tonsillar hypertrophy, upper airway abnormality other than the SP that could be responsible for snoring or a known history of comorbid disease that could alter the healing process. Technique: with patients under local anaesthesia in an outpatient setting, RFA (Ellman, EMC Ellman International, Inc.) was delivered to 4 regions. Mean number of treatment sessions per patient: 1.5. IS (using polidocanol) was performed with topical anaesthesia only. Treatment was terminated if treatment failed to provide improvement after 2 injections. Follow-up: **6 weeks**. Conflict of interest/source of funding: not reported.	Number of patients analysed: 70 (40 vs. 30) **Reduction in snoring volume (assessed using VAS)** | | RFA | IS | |---|---|---| | Before treatment | 8.0 | 7.8 | | After treatment | 2.1 | 3.0 | When differences between pre- and post-treatment values in both groups were compared separately, RFA was found to be more effective than IS, (p=0.03). **Treatment success** – reduction in snoring as measured by satisfaction of bed partner | | RFA | IS | |---|---|---| | Satisfaction (evaluated by bed partner) | 87.5% | 76.7% |	| Complication | RF % (n) | IS % (n) | |---|---|---| | Superficial ulceration of mucosa 5 mm–1 cm | 30 (12) Resolved spontaneously after 4–6 weeks | 0 | | Oedema | 5 (2) exhibited oedema, which was treated by corticosteroids | 0 | | Mild sore throat | All | All | Mucosal breakdown reported in 2 patients (unclear which group); these healed without any sequelae. There were no reports of palatal fistula. **Mean discomfort and pain** (first 10 post-operative days) | | RFA | IS | |---|---|---| | Discomfort | 3.7 (1.2) | 2.4 (1.2) | | Pain | 2 (1.5) | 1 (0.5) | The differences between the groups were not statistically significant. 45% of patients treated by RFA needed non-narcotic analgesia and 30% needed narcotic analgesia. 37% of patients treated by IS needed non-narcotic analgesia.	**Study design issues:** • The methods used to recruit patients were not reported. • Snoring level assessed on 10 cm VAS by patient and satisfaction rates assessed by bed partner. • Discomfort rated on scale from 0 (no discomfort/no pain) to 10 (intolerable discomfort/pain). • The study reported patients were asked about satisfaction level with the procedure and would they have the procedure again. Results for this are not reported. **Study population issues:** • Patients were evaluated preoperatively with overnight sleep study to confirm the diagnosis of primary snoring and RDI<10. • Patients in the 2

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
			groups had similar mean values for RDI, lowest oxygen saturation levels and snoring index. **Other issues:** • The study reported patients were asked about satisfaction level with the procedure and would they have the procedure again. Results for this are not reported.

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details

Blumen MB (2002)[3]

Non-randomised comparative study

France

Recruitment period: 1998–1999

Study population: patients with habitual simple snoring or mild sleep apnoea (RDI<20/hr) and soft palate obstruction.

n=30 (15 RFA vs. 15 LAUP)

Age: mean 47 years

Sex: 70% male

Patient selection criteria: patients with simple snoring with or without daytime sleepiness, mild sleep apnoea, no or mild nasal obstruction, or no tonsil hypertrophy were included. Patients morbidly obese (BMI >30 kg/m^2), or those with active upper airway infection or coagulation abnormalities were excluded. Presence of a bed partner was necessary for subjective measurement of outcome.

Technique: under local anaesthesia a radiofrequency control unit (Somnus Medical Inc.) was used in the 15 patients having RF treatment. Maximum power was set at 10 W; maximum target temperature was 85ºC. After RFA treatment, patients were prescribed paracetamol, and if this was inadequate codeine prescription was added. Prednisolone 1 mg/kg was prescribed if swelling of the back of the throat occurred.

LAUP: under local anaesthesia using CO_2 laser

Mean number of treatments was 2.1 for RFA and 1.2 for LAUP (a maximum of 3 treatment

Key efficacy findings

Number of patients analysed: 30 (15 RFA vs.. 15 LAUP)

Snoring volume (assessed by bed partner using VAS)

	Before the procedure	6–8 weeks after procedure	% reduction
RFA	8.3	1.7	79.5%
LAUP	8	2.7	66.2%

Decrease in snoring volume was statistically significant (p<0.01) within each group.

Success (defined by final score of snoring volume on VAS of 3 or less and a bed partner who reported being satisfied).

	RFA	**LAUP**
Overall success rates	80%	46.6%
Satisfaction rates (partner)	86.6%	66.6%

Key safety findings

Mean duration and scores of pain and discomfort

	RFA	**LAUP**	**p**
Pain score after 7 days	0.5±0.5	5.4±2.9	<0.05
Pain score after 18 days	0.3±0.3	2.6±1.4	<0.01
Pain >5 days	0.4±1.1	3.7±2.9	NR
Pain duration (days)	2.2±2.6	9.5±3.8	NR
Discomfort score after 7 days	5.2±2.3	9.7±0.9	<0.01
Discomfort score after 18 days	3.2±2.6	8.0±1.8	<0.01
Discomfort >5 days	3.8±3.0	11.0±3.4	NR
Discomfort duration (days)	10.5±5.2	13.2±3.9	NR

Mean level 2 analgesic intake was statistically significantly (p<0.01) greater in the LAUP group but there was no difference for steroid intake.

Comments

Follow-up issues:

- There were no losses to follow-up.

Study design issues:

- The first 15 patients who underwent RFA or LAUP were included in the study.
- Treatment efficacy was evaluated by bed partner using VAS 0–10 for snoring volume (0 [no snoring] to 10 [loud enough to be heard from another room, or prompting partner to leave the room])
- Treatment tolerance was evaluated for 18 days on a daily basis on the following evaluation criteria: discomfort and/or pain; medication consumption; number of days on soft diet.
- Discomfort (defined as

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
sessions per patient was set to limit costs). A minimum 6-week interval occurred between treatments. Follow-up: 2 months Conflict of interest/source of funding: 'Generator was lent and 32 electrodes were given by Somnus Medical Technology Inc., Sunnyvale, CA. There was no financial support.'			abnormal sensation in the throat that did not modify patient's activities or modify their diet) and pain were evaluated on 2 separate analogue scales from 0–10; 0=no discomfort/pain, 10=intolerable discomfort/pain. • Baseline comparability in terms of age, sex, BMI, RDI or preoperative snoring volumes.

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Back LJ (2009)[4]
Case series
Finland
Recruitment period: retrospectively gathered in 2006
Study population: patients with sleep disordered breathing, having radiofrequency to the SP, inferior turbinate, and base of the tongue.
n=753 records reviewed, 413 included in analysis. 218 patients had RFA to the soft palate. Age: mean 45 years
Sex: 66% male

Patient selection criteria: patients with synchronous surgical treatment (e.g. septoplasty, tonsillectomy, uvulectomy, uvulopalatopharyngoplasty) were excluded.

Technique: RFA of the soft palate was carried out under local anaesthesia (Coblator II, Arthrocare Corp.) and ORL Set Marinescu (Sutter Medizintechnik Freiburg, Germany) with bipolar generators and applicators. The average number of ablations per treatment sessions was 5 in the SP group.

Follow-up: unclear
Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 218

Efficacy findings not reported.</td>
<td>Complications: 3.7% (8/218) treatment sessions
<table>
<tr><th>Complication</th><th>n; timing</th></tr>
<tr><td>Submucosal swelling of the lateral oropharyngeal walls and moderate dyspnoea (treated by corticosteroid therapy)</td><td>1 (immediately after procedure)</td></tr>
<tr><td>Submucosal haematoma of the SP and a post-operative haemorrhage (needing haemostasis)</td><td>1</td></tr>
<tr><td>Swelling of the uvula (needing hospital admission)</td><td>1 (1 day after the procedure)</td></tr>
<tr><td>Bleeding (after 3rd RFA session; treated with bipolar coagulation)</td><td>1 (19 days after a third session; further bleeding 4 days later ‘managed conservatively’)</td></tr>
<tr><td>Infection (treated by oral antibiotics)</td><td>6 (‘post-operative’; 3/6 had moderate infectious complication and 1 patient developed peri-tonsillar abscess following infection (timing unclear; needed surgical drainage)</td></tr>
</table>
</td>
<td>Study design issues:
• The primary outcome measure was the type and frequency of complications.
• 753 records of all patients treated with RFA of the upper airways at a single academic teaching hospital were initially reviewed. 413 were included in the analysis, the results of which for the 218 patients who had RFA to the SP are reported here.</td>
</tr>
</table>

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Hultcrantz E (2010)[5]

Case series (multi-centre)
Sweden
Recruitment period: not reported
Study population: patients with habitual, socially disruptive snoring
n=29
Age: mean 48 years
Sex: 89% male

Patient selection criteria: patients with habitual socially disruptive snoring, AHI <10 in a full night sleep respiratory recording, BMI <28 kg/m^2, and no other known medical disease.

Technique: with patient under local anaesthesia, RF energy (Ellman Surgitone, Ellman International) was delivered to 4 locations of the soft palate in the first treatment session. During 2nd through to 4th sessions, 2 regions were usually treated. Most patients were treated 4 times (mean 3.6). Treatment was at 4–6 week intervals.

Follow-up: mean 40 months

Conflict of interest/source of funding: not reported.</td>
<td>Number of patients analysed: 28
Median snoring severity (as assessed by patient using VAS)
<table>
<tr><th>Before treatment (1 week)</th><th>6 months after treatment[a]</th><th>After 3 years</th></tr>
<tr><td>8.6</td><td>3.6</td><td>5.0</td></tr>
</table>
[a]The difference from baseline was statistically significant (p<0.0001).
Long-term follow-up
<table>
<tr><th>Outcome</th><th>3–4 years after treatment</th></tr>
<tr><td>VAS score ≤ 5</td><td>11 patients</td></tr>
<tr><td>Daytime sleepiness (assessed using ESS)</td><td>9.8 (5.2)</td></tr>
<tr><td>Satisfied with outcome</td><td>25% of the patients were satisfied with outcome</td></tr>
<tr><td>Decrease in snoring (to half or less compared with their own baseline).</td><td>28% (8/29). These patients had less daytime sleepiness and were more satisfied.</td></tr>
<tr><td>Diary evaluation (n=10)</td><td>Number of awakenings each night (for both patient and partner) were reduced during treatment period.</td></tr>
<tr><td>Received additional treatment (because of no significant improvement)</td><td>28%[b] (8/29); mandibular advancement devices (n=4); RF uvulopalatoplasty (n=3); continuous positive airway pressure (n=1)</td></tr>
</table>
[b]2 patients reported worse AHI scores resulting in further therapy.</td>
<td>A purulent infection in the palate after the first treatment was reported in 1 patient with type 2 diabetes.

There was ulceration at the treatment sites in 5 patients. All ulceration healed within a couple of weeks.</td>
<td>Follow-up issues:
1 patient with infection after the first treatment was excluded from the analyses.
Patients were seen after 6 months and followed up with a questionnaire at 3–4 years.
Study design issues:
Patients and partners evaluated snoring, sleep quality and daytime sleepiness. Pre-operative questionnaire was not validated.
Pain graded on a 3-point scale, with 0 indicating no pain to 3 indicating severe pain.</td>
</tr>
</table>

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details

Johnson, JT (2002)[6]

Case series

USA

n=**75**

Recruitment period: 1998 to 2000

Study population: patients with SP diagnosed as site of snoring and had respiratory disturbance index of <15 or non-apnoeic snoring.

Age: mean 55 years

Sex: 73% male

Patient selection criteria: patients >18 years old having received treatment with RFA to the palate were included.

Technique: RFA procedure (Somnus Technology) conducted in outpatient setting under local anaesthesia; 2 or 3 palate sites were treated at each appointment. Treatment was repeated at 6-weekly intervals at the patient's request until snoring was controlled or the patient decided to end treatment. The mean number of treatments was 1.8, and the energy delivered was 1940 J.

Follow up: mean 12 months.

Conflict of interest/funding: not reported.

Key efficacy findings

Number of patients analysed: **60**

Subjective rating of snoring severity (VAS) (after a mean of 12 months)

	Pre-treatment	Post-treatment
Snoring severity (overall)	9.0	3.5
Responders 85% (51/60)	9.2 (range 6 to 10)	3.2
Non-responders 15% (9/60)	7.5 (range 6 to 10)	6.6

Patients were considered responders if the post-operative snoring score was <5 and had been reduced by 50% from baseline.

Key safety findings

Patient reported adverse events

	% (n)
Bleeding (needing attention at emergency department)	2 (1); no bleeding was noted on evaluation, no further treatment needed.
Pain lasting longer than expected	10 (6)

Patients also noted extra drainage with head colds, snoring with excess alcohol, inability to roll Rs and/or slight change in volume and pitch (actual numbers not reported).

Comments

This study was included in the overview for the original guidance (IPG124).

Follow-up issues:

- Complete data were available for 80% (60/75) of patients treated.

Study design issues:

- Retrospective review.
- Patients were contacted by telephone to determine response to therapy.
- Snoring was rated on the VAS, with 0=no snoring, 5=very loud snoring, 10='horrific' snoring (the worst imaginable).
- Snoring rated by bed partner.

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Pang KP (2009)[7] **Case series** Singapore Recruitment period: over a 5-month period Study population: patients with simple snoring or mild OSA. Mean BMI was 22.6 kg/m^2. All patients classified as Friedman stage II and III, with tonsil sizes graded as 0, 1 or 2. n=**52** (35 simple snorers; 17 mild OSA) Age: mean 36 years Sex: 96% male Patient selection criteria: patients >18 years of age, BMI <28 kg/m^2 with either simple snoring (AHI<5) or mild OSA (AHI <15), tonsil size grade 1 or 2, Mallampati grades (to predict ease of ventilation) I and II, minimal tongue base collapse (<25% as seen on Muller's manoeuvre). Patients with tonsillar hypertrophy grades 3 or 4 or macroglossia were excluded. Technique: procedure was performed under local anaesthesia in an outpatient clinic. Bipolar RF tissue volume reduction was done (Sutter) with a dual probe hand piece, at 4 to 6 sites within the soft palate depending on its size. Power was set at 16 watts and duration at about 9 seconds. Mean operation time was 13.6 minutes. Follow-up: **mean 7 months**	Number of patients analysed: **52** **Improvement in snoring** 77% (40/52) of the patients reported some improvement in their snoring. Patients' mean snoring level (assessed by VAS) improved from 8.9 to 3.4 (p<0.05) at 90 days after procedure. **Improvement in snoring intensity and QoL** | Degree of improvement	Snoring intensity (patient and partner reported)[a] % (n)	QOL (self-reported) % (n)
---	---	---
Great	40 (21/52)	38.5 (20)
Moderate	28	19.2 (10)
Mild	-	25 (13)
No benefit	23	17.3 (9) | [a]Data for remaining patients not specifically described. **Improvement in sleepiness** – 90 days (assessed using ESS); mean (range) | Pre-procedure	Post-procedure	p value
---	---	---
14.6 (10 to 16)	9.5 (5 to 12)	NR | 9 patients (17%) reported feeling no less tired post-operatively than they were pre-operatively. 'Many' patients reported they felt more alert during the day, and slept better at night, with fewer episodes of choking sensation and gasping for air. **Improvement in mean QOL, sleep quality and**	**Complications** Patients reported 'minimal' post-operative pain | VAS pain score; mean (range)	2.6 (1.3 to 4.9)
---	---	 Pain (measured by VAS on post-operative days 1, 3, 7 and 14) peaked on the second post-operative day. No significant analgesia was needed. All patients had minimal odynophagia. There were no complaints of post-operative haemorrhage, dysphagia or velopharyngeal incompetence.	**Follow-up issues:** • All patients were followed up. **Study design issues:** • Patients attending snoring and sleep subspecialty clinics were offered the procedure. • Primary outcome was to investigate the use of RF technology for the treatment of snoring and mild OSA as a single treatment. • All procedures performed by one surgeon. • Improvements in snoring intensity were reported using a VAS. • QOL measurements were based on questionnaires with 4 possible responses (no, mild, moderate or great improvement). • Patients completed the

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Conflict of interest/source of funding: authors reported that there were no conflicts of interest – all equipment and devices were purchased and were not sponsored by the company.	**Snoring intensity at 90 days** The differences in scores were statistically significant ($p<0.05$) for all 3 outcomes. [a] in patients who benefited from the procedure. **Repeat treatment** Repeat treatment was needed in 6 patients (none were satisfied with outcome after first procedure); all 6 indicated improvement after the second treatment.		ESS and VAS for snoring before and 7, 14, 30, 60, 90,120 and 180 days after the procedure.

	Before the procedure	After the procedure
QOL (assessed using question-naire)	4.3	8.6
Sleep quality (assessed using VAS)	2.4	7.1
Snoring intensity[a] (assessed using VAS)	8.9	3.4

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Blumen M B (2008)[8] **Multi-centre case series** (this study was designed as a randomised single-blind study to compare the safety and efficacy of 4 different RF devices; for IPAC evaluation overall data have been reported) France Recruitment period: 2002–2004 Study population: patients with simple snoring. Mean BMI 24.8 kg/m^2. n=**120** Age: mean 47 years Sex: 78% male Patient selection criteria: inclusion criteria were >18 years, AHI <10/h sleep, with SP apparently responsible for vibration, and presence of a stable partner. Exclusion criteria included ESS >10 with level 3 nocturnal recording; chronic nasal obstruction, obesity (BMI >30 kg/m^2) and tonsillar hypertrophy. Technique: procedures were carried out using local anaesthesia on an outpatient basis. 3 punctures were performed. Patients were treated with Ellman, Select Sutter, Coblator or Somnus generators. Parameters used were those recommended by the manufacturer with exception for 1 device where a higher dose was delivered. Patients were prescribed paracetamol (level 1 analgesia) for post-operative pain; if this was inadequate, codeine (level 2 analgesia) was added. Prednisolone was also prescribed on the	Number of patients analysed: **104** **Mean snoring sound intensity (VAS)** Before the procedure: 7.9 (1.7) After the procedure: 4.4 (2.7) p value: <0.0001 Data reported: mean (SD) Patients with >50% improvement in snoring: 46% Partner's satisfaction[a]: 62.5% considered 'satisfied'. [a]Partners' responses were classified as satisfied if they reported being very satisfied, moderately satisfied or satisfied.	Soft palate lesions (on day 8) Soft palate lesions after first session: 37 lesions (11.6% of punctures) Soft palate lesions after second session: 49 lesions (16.8% of punctures) Mean discomfort and pain (days) • Discomfort: 2.7 (2.8) • Pain: 1.3 (1.6) The results are mean over 18 days.	**Follow-up issues:** • 16 patients were excluded from final analysis – 14 failed to attend follow-up visit, 1 was excluded because a different generator was used over 2 treatments, 1 patient refused treatment (reason not provided). **Study design issues:** • Endpoints were efficacy on snoring (scored by partner) and safety of treatment. • Snoring sound intensity was evaluated before and 8 weeks after each treatment session on a 10 cm VAS – 0=no snoring; 10=one member of the couple having to leave the room or snoring heard in another room. • Partner's global satisfaction was measured according to 5

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
first day and continued if the patient experienced a sore throat. Follow-up: 8 weeks after each treatment session (efficacy); 18 days (safety). Conflict of interest/source of funding: none			possible options (very satisfied, satisfied, moderately satisfied, slightly satisfied or dissatisfied. • Discomfort or pain assessed daily on a 10 cm VAS (0-absent to 10-very severe)

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Johnson TJ (2008)[9]

Case series
USA
Recruitment period: not reported
Study population: patients with socially unacceptable snoring and minimal OSA (defined as RDI of 20 or fewer events per hour as measured by monitored multichannel polysomnography). Mean BMI 28 kg/m^2.
n=23
Age: mean 43 years
Sex: 74% male

Patient selection criteria: all patients had flexible transnasal laryngoscopy with Muller manoeuvre to confirm that the uvula and soft palate were the most likely sources of snoring.

Technique: tissue reduction was performed via a channelling technique using a coblation device (ReFlex Ultra 55 Wand), using local anaesthesia on an outpatient basis. The palate was treated at 3 separate sites, and each channel was completed in approximately 11 seconds. If snoring persisted at 1-month follow-up, a repeat procedure was offered, and if this failed patients were offered a third procedure.
1 patient received a fourth procedure.

Follow-up: 1 month</td>
<td>Number of patients analysed: 21
Subjective and objective assessment of snoring outcomes
<table>
<tr><th></th><th>Before the procedure</th><th>Change in score after the proc-edure</th><th>% (n) of patients improve d ≥50% (n=21)</th></tr>
<tr><td>snoring intensity score[a]</td><td>7 (2)</td><td>-4 (3)</td><td>48 (10)</td></tr>
<tr><td>loudness of snoring[a] (SNAP) in dB</td><td>12 (6)</td><td>-4 (7)</td><td>24 (5)</td></tr>
<tr><td>snoring index[b;c]</td><td>290 (182)</td><td>-48 (185)</td><td>24 (5)</td></tr>
<tr><td>RDI[b;c] (events per hour)</td><td>11 (9)</td><td>-1 (13)</td><td>38 (5)</td></tr>
</table>
[a] statistically significant (p<0.05) change compared with pre-operative value ; [b]NS; [c]number of snores per hour
Data reported as mean (SD)
Rate of concordance between subjective and objective assessment ranged between 42 and 63%.
QOL
74% (17/23) reported improvement but degree of improvement was only statistically significant (p<0.05) in the vitality category.</td>
<td>Surgical complications (outcomes following complications not reported)
<table>
<tr><th>Complication</th><th>n</th></tr>
<tr><td>Mild to moderate mucosal erosion</td><td>10</td></tr>
<tr><td>Sloughing</td><td>7</td></tr>
<tr><td>Mild scarring</td><td>6</td></tr>
<tr><td>Detectable needle scarring</td><td>3</td></tr>
<tr><td>Mild weight loss</td><td>3</td></tr>
<tr><td>Mild oedema</td><td>2</td></tr>
<tr><td>Mild ulcer</td><td>1</td></tr>
<tr><td>Dysphagia</td><td>1</td></tr>
</table>
Post-operative pain
<table>
<tr><td>Mean score over 7 days</td><td>3±2</td></tr>
</table>
33% (7/21) patients reported an average pain score of less than 1.
No patient needed opioid analgesia; pain was managed with aspirin or NSAIDs.</td>
<td>There may be some overlap with patients included in Johnson (2002)
Follow-up issues:
Reduction in snoring intensity (reported by bed partner) not assessed in 2 patients who did not have bed partners.
Subjective ratings of snoring loudness were provided by patients' bed partners using a VAS from 0 (no snoring) to 10 (terrible snoring).
Objective snoring analysis made using SNAP recording system, a take-home polysomnograph device that generates an RDI and analyses acoustic measurements of oronasal respirations.
Intensity of post-operative pain was</td>
</tr>
</table>

Abbreviations used: AHI, apnoea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; IS, injection snoreplasty; LAUP, laser-assisted uvuloplasty; NSAIDs, non-steroidal anti-inflammatory drugs; MAD, mandibular advancement devices; NR, not reported; OSA, obstructive sleep apnoea; QOL, quality of life; RFA, radiofrequency ablation; RF, radiofrequency; RDI, respiratory disturbance index; SD, standard deviation; SP, soft palate; UPPP, uvulopalatopharyngoplasty; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Conflict of interest/source of funding: study was partially supported by a research grant from Arthro-Care Corp and the Stout Family Fund for head and neck cancer research.	**Treatment failure** 4 patients in whom treatment failed underwent further investigation that suggested the source of snoring was soft palate. Patients were treated by LAUP and all 4 reported good subjective results.		measured on a 0 (no pain)–10 (severe pain) scale and reported in patient-held diary for first 7 days. • Post-operative QOL measured using SF-36 health survey.

Efficacy

Reduction in snoring

A randomised controlled trial (RCT) of 23 patients comparing radiofrequency ablation (RFA) (n=12) against a sham procedure (n=11) showed a significant improvement in snoring scores (assessed by bed partner using a 10-point visual analogue scale [VAS]; 0=no snoring, 10=excessive snoring prompting bed partner to leave the room) for the RFA group at 6–8 week follow–up, compared against the sham group. The mean score decreased from 8.1 to 5.2 in the RFA group and from 8.4 to 8.0 in the group treated by the sham procedure; the difference was significant ($p<0.05$ for difference between groups). However, only 2 out of 12 patients in the RFA group had a score below 3 (defined as the criterion for success)[1].

A case series of 23 patients measured snoring reduction (using a commercial monitoring system). Mean loudness of snoring (measured in decibels) was significantly lower, reducing by 4 points from 12 on a VAS ($p<0.05$) 1 month after the procedure. The mean snoring index decreased by 48 points from 290 and mean respiratory disturbance index decreased by 1 point from 11, but both of these reductions were non-significant[9].

In a case series of 120 patients, mean snoring sound intensity measured on a 10-point VAS (with 0 indicating no scoring and 10 indicating snoring heard in another room or the partner having to leave the room; assessed by partner) decreased from 7.9 to 4.4 ($p<0.0001$) at 8-week follow-up[8].

In a case series of 52 patients, patients and their partners reported improvements in snoring intensity, with 40% of patients reporting great improvement, 28% of patients moderate improvement and 23% of patients no improvement. The level of improvement in the remaining patients was not reported[7].

In a case series of 29 patients, median snoring on a VAS before treatment was 8.6, and 6 months after treatment it had decreased to 3.6 ($p<0.0001$), increasing to 5.0 after 3–4 years[5].

Daytime sleepiness (Epworth Sleepiness Scale)

In the RCT of 23 patients, there was no significant improvement in daytime sleepiness in the treatment group compared with the sham group. In the treatment group, the score on the Epworth Sleepiness Scale (ESS) at 6 to 8-week follow-up decreased from 5.4 before the procedure to 3.9 after the procedure in the RFA group, and it decreased from 5.2 to 4.3 in the sham group; the difference between the 2 groups was not statistically significant ($p=0.77$)[1].

The case series of 52 patients, 35 patients with simple snoring and 17 patients with mild obstructive sleep apnoea, reported a reduction in ESS from 14.6 to 9.5

(p value not reported). Nine patients in the same study reported no difference in pre- and post-treatment tiredness[7].

Patient and partner satisfaction

In the case series of 120 patients, 63% of partners reported being very satisfied, moderately satisfied or satisfied with the treatment outcome 8 weeks after treatment[8].

In the case series of 29 patients, 25% of patients (numbers not reported) reported satisfaction with the outcome 3 to 4 years after the procedure. Two patients reported worse apnoea-hypopnea index scores. Further treatment was carried out in 28% (8/29) of patients (4 had mandibular advancement devices, 1 had continuous positive airway pressure and 3 had radiofrequency-assisted uvulopalatoplasty)[5].

Quality of life

The case series of 52 patients measured quality of life using a questionnaire with fixed responses. Thirty-nine per cent (20/52) of patients reported a 'great improvement', 19% (10/52) reported 'moderate improvement', 25% (13/52) reported 'mild improvement' and 17% (9/52) reported 'no improvement'. Mean quality-of-life score improved from 4.3 to 8.6 ($p<0.05$) at mean follow-up of 7 months (details on the scale not reported)[7].

In the case series of 23 patients, 74% reported improvement in quality of life (assessed using the SF-36 health survey), but improvement was only statistically significant ($p<0.05$) in the vitality category[9].

Functional parameters

In the RCT of 26 patients, functional parameters (speech, taste, swallowing and pharyngeal irritation) assessed using a 10-point VAS were unchanged in both the treatment and sham groups[1].

Repeat treatment

In the case series of 23 patients, 4 patients in whom treatment with RFA failed went on to have treatment with laser-assisted uvuloplasty, which was successful[9].

Safety

Bleeding

Bleeding was reported in 2 patients in a case series of 218 patients. One patient developed a submucosal haematoma of the soft palate, associated with haemorrhage that needed haemostasis (no further details reported) under

general anaesthesia. Another patient had bleeding after their third RFA session. This was treated by bipolar coagulation, and further minor bleeding reported 4 days later was 'managed conservatively' (no further details reported)[4].

Bleeding needing attention at the emergency department was reported by 1 patient in a case series of 75 patients, but the authors reported that no bleeding was noted on evaluation by the investigators and the patient did not need further therapy[6].

Oedema/swelling

Airway oedema needing treatment with corticosteroids was reported in 2 patients following RFA in a non-randomised comparative study of 70 patients (40 treated by RFA and 30 treated by injection snoreplasty)[2]. Mild oedema was reported in 2 patients in the case series of 23 patients[9].

Swelling of the uvula (1 day after the procedure) needing hospital admission (no further details reported) was reported in 1 patient in the case series of 218 patients. The same case series described a patient who developed submucosal swelling of the lateral oropharyngeal walls (immediately after the procedure) causing moderate dyspnoea , which was treated by corticosteroids[4].

Infection/abscess

Infection of the soft palate occurred in 6 patients after the procedure in the case series of 218 patients. These were treated by oral antibiotics, and 1 patient went on to develop a peritonsillar abscess that needed surgical drainage[4].

A purulent infection of the palate in a patient with diabetes was reported in the case series of 29 patients[5].

Mucosal erosion/ulcers

Mild to moderate mucosal erosion was reported in 48% (10/23) of patients in the case series of 23 patients[9]. Ulcers were reported in 1 patient in the same case series.

Ulceration at the site of RFA probe insertion was reported in 5 patients in the case series of 29 patients (all ulcers healed within a couple of weeks)[5].

Sloughing

Sloughing was reported in 7 patients in the case series of 23 patients (no further details reported)[9].

Dysphagia and weight loss

Dysphagia and mild weight loss were reported in 1 and 3 patients respectively in the case series of 23 patients 1 month after the procedure[8].

Validity and generalisability of the studies

- The evidence in table 2 includes retrospective evaluations.
- Only 1 case series of 23 patients reported objectively measured post-operative outcomes in snorers alone after 1 month using a commercial sound recording device monitor. Other studies reported that efficacy outcomes were assessed subjectively by bed partners and patients.
- The longest follow-up period reported was 3–4 years in 1 study of 29 patients.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Soft-palate implants for simple snoring. NICE interventional procedures guidance 240 (2007). Available from http://guidance.nice.org.uk/IPG240

Technology appraisals

- Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. NICE technology appraisal 139 (2008). Available from http://guidance.nice.org.uk/TA139

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Bhik Kotecha, Professor Nirmal Kumar, British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK).

- One specialist adviser performs the procedure regularly and the other specialist adviser has performed it at least once.

- One specialist adviser considered this an established practice and no longer new and the other specialist adviser considered it to be a novel procedure with uncertain efficacy and safety.
- One specialist adviser noted that 10–50% of specialists are performing this procedure and the other specialist adviser noted that fewer than 10% of specialists are performing this procedure.
- Key efficacy outcomes: improvement in snoring and upper airway obstruction leading to resolution of daytime sleepiness; improved quality-of-life parameters for patient and partner.
- The specialist advisers listed the following anecdotal adverse events: bleeding, oedema and ulcers of palate, perforation of palate and palatal fistula. Theoretical adverse events: mild ulceration, and infection and regurgitation due to palatal insufficiency. Both specialist advisers stated that if safe and efficacious the procedure is likely to be carried out in most or all district general hospitals.
- The potential impact of the procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, was considered to be major by one specialist adviser and moderate by the other specialist adviser.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- There were no ongoing trials identified.

References

1. Stuck BA, Sauter A, Hörmann K et al. (2005) Radiofrequency surgery of the soft palate in the treatment of snoring. A placebo-controlled trial. SLEEP 28 (7): 847–50
2. Iseri M, Balcioglu O (2005) Radiofrequency versus injection snoreplasty in simple snoring. Oncology-Head and Neck Surgery 133: 224–8
3. Blumen MB, Dahan S, Wagner I (2002) Radiofrequency versus LAUP for the treatment of snoring. Otolaryngology–Head and Neck Surgery 26 (1) 67–73
4. Back LJ, Liukko T, Sinkkonen ST et al. (2009) Complication rates of radiofrequency surgery in the upper airways: a single institution experience. Acta Otolaryngologica 1469-73
5. Hultcrantz E, Harder L, Loord H et al. (2010) Long-term effects of radiofrequency ablation of the soft palate on snoring. European archives of otorhinolaryngology 267: 137–42
6. Johnson JT, Pollack GL, Wagner RL (2002) Transoral radiofrequency treatment of snoring. Otolaryngology–Head and Neck Surgery 127: 235–7.
7. Pang KP, Siow JK (2009) Sutter bipolar radiofrequency volumetric tissue reduction of palate for snoring and mild obstructive sleep apnoea: is one treatment adequate? The Journal of Laryngology & Otology 123: 750–4
8. Blumen MB, Chalumeau F, Gauthier A et al. (2008) Comparative study of four radiofrequency generators for the treatment of snoring. Otolaryngology-Head and Neck Surgery 138: 294–9
9. Johnson JT, Vates J, Robin et al. (2008) reduction of snoring with a plasma-mediated radiofrequency-based ablation (Coblation) device. Ear, Nose & Throat Journal 87 (1): 40–3

Appendix A: Additional papers on radiofrequency ablation of the soft palate for snoring

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Back LJ, Koivunen P, Pyykko I et al. (2012) The impact of pretreatment assessment of oropharynx on interstitial soft palate radiofrequency surgery outcome-a multi-center study in patients with habitual snoring. Sleep and Breathing 16 (1): 199–204	N=74 Follow up=13 weeks	Systematic clinical pre-treatment oropharyngeal examination scores showed that the increasing grade of the uvula correlated significantly with short-term post-treatment change in snoring. Patients with habitual snoring and uvula grade lll should be initially treated with soft palate interstitial RF surgery and concomitant uvular surgery.	Focus was on assessing patients using oropharyngeal examination scores to assist patient selection and likelihood of successful outcome.
Back LJ, Hytonen ML, Roine RP et al. (2009) Radiofrequency Ablation Treatment of Soft Palate for Patients with Snoring: A Systematic Review of Effectiveness and Adverse Effects. The Laryngoscope 119 (6): 1241–50	N=842 Follow up=6 weeks	The review provides evidence that SP RFA causes less post-operative pain than other interventions, and the risk of adverse events to the patients seems to be small. It may reduce symptoms of snoring at least in the short-term.	Studies included in the review are included in table 2 or appendix A.
Birkent H, Soken H, Akcam T et al (2008) the effect of radiofrequency volumetric tissue reduction of soft palate on voice European Archives of otorhinolaryngology 265(2):195-8	N=26 Follow up= 6 weeks	Findings indicate that this procedure does not have a significant impact on the mean fundamental frequency and formant frequencies of vowels	Larger studies included in table 2.
Boudewyns A, Van De HP. (2000) Temperature-controlled radiofrequency tissue volume reduction of the soft palate (somnoplasty) in the treatment of habitual snoring: results of a	n=45 Follow up=8 weeks	Snoring improved in snoring scale of a mean 3.5 points	Larger studies included in table 2.

European multicenter trial. Acta Oto-Laryngologica 120(8):981-5.			
Cartwright R, Venkatesan TK, Caldarelli D et al. (2000) Treatments for snoring: a comparison of somnoplasty and an oral appliance. Laryngoscope (10 Pt 1):1680-1683.	n=20 Follow up=8 weeks	Comparing the 8 week sleep assessment following RFA as compared to patients sleeping with the oral appliance 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).	Larger studies included in table 2.
De Vito A, Frassineti S, Panatta ML et al. (2012) Mulitlevel radiofrequency ablation for snoring and OSAHS patients therapy: long-term outcomes. European archives of otorhinolaryngology 269 (1): 321–30	N=187 Follow up=5 years	Results suggested an important role of RF therapy in the improvement of snoring but not for significant apnoea-hypopnoea reduction.	Results are presented for RFA of soft palate and tongue together.
D'Souza A, Hassan S, Morgan D. Recent advances in surgery for snoring-somnoplasty (radiofrequency palatoplasty) a pilot study: effectiveness and acceptability. Revue de Laryngologie Otologie Rhinologie 2000; 121(2):111-115.	n=22 Follow up=6 weeks	Radiofrequency somnoplasty effective and safe, but results dependant on BMI.	Larger studies included in table 2.
Ferguson M, Smith TL, Zanation AM, Yarbrough WG. Radiofrequency tissue volume reduction; multilesion vs single-lesion treatments for snoring. Archives of Otolaryngology -- Head & Neck Surgery 2001; Vol. 127(9):-1118.	n=47 6 weeks and 16months	Multi-session RFA using higher energy is safe and more efficacious than single treatment	Comparison of single versus multiple treatment sessions
Franklin KA, Antilla H, Axelsson S et al. (2009) Effects and Side-Effects of Surgery for Snoring and Obstructive Sleep Apnea-A Systematic Review. SLEEP 32 (1): 27–35	N=15 studies	There was no significant effect on day-time sleepiness, apnoea reduction, snoring and quality of life after RFA. Subjective snoring was reduced in one trial after RFA.	Multiple interventions were assessed. Meta-analysis included one study evaluating RFA to soft palate. Stuck (2005)[1] is included in table 2.
Haraldsson PO, Karline J, Lysdahl M et al. (2002) voice quality after radiofrequency volumetric tissue reduction of the soft palate in habitual snorers	N=16 Follow up= 2 months	Snoring was somewhat successfully treated, as evaluated by spouses; snoring score was reduced from 8.2 ±2.9 to 4.1 ± 2.5 (p <0.01) on	Larger studies included in table 2.

Laryngoscope 112(7 Pt 1):1260-3		a 10-grade rating scale	
Hoffman T, Schwantzer G, Reckenzaun (2006) Radiofrequency tissue volume reduction of the soft palate and UPP in the treatment of snoring. European archives of otorhinolaryngology 263 (2): 164–70	N=79 (47 UPPP vs. 32 RFTVR) Follow-up=4 months	The success rate of radiofrequency tissue volume reduction (RFTVR) is lower compared to the more invasive technique of UPPP. Due to its minimally invasive character, RFTVR is suitable as a first step treatment for snoring, but patients should be counselled about possible success rates and different treatment options.	Larger studies included in table 2.
Kania RE, Schmitt E, Petelle B et al. (2004) Radiofrequency soft palate procedure in snoring: influence of energy delivered. Otolaryngology - Head & Neck Surgery 130(1):67-72.	n=43 Follow up=6 weeks	Higher energy levels led to better snoring scores	Comparison of energy levels used in RFA for snoring
Li KK, Powell NB, Riley RW et al (2000) Radiofrequency volumetric reduction of the palate: An extended follow-up study. Otolaryngology - Head & Neck Surgery 122(3):-414.	n=22 Follow up=14 months	No adverse effect was reported. Subjective snoring scores relapsed by 29% overall. Nine patients (41%) noted relapse of snoring from 2.1 ± 1. 1 to 5.7 ± 2.7 ($p< 0.001$). Eight of the patients underwent further RF treatment with a reduction of snoring from 5.8 ± 2.9 to 3.3 ± 3.1 ($p = 0.01$).	31% of patients had sleep apnoea. Results not reported separately.
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	N=22 Follow up= 4 weeks	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 ($p<0.00001$)	Larger studies included in table 2.
Sandhu GS, Vatts A, Whinney D et al (2003) somnoplasty for simple snoring- a pilot study Clinical Otolaryngoly Allied Science 28(5):425-9	N=10 Follow up= 3 months	60% of patients subjectively reported improvement in snoring. Objectively, only 30% showed improvement in duration of snoring (38-48% better) with no change in intensity.	Larger studies included in table 2.
Stuck BA, Starzak K, Verse T et al(2003) Complications of temperature-controlled	n=322 Follow up=122 days	9 (2.0%) postoperative complications were observed as follows: ulcerations of the	Only 13% (34/322) patients were snorers, and only 30 procedures performed on soft

radiofrequency volumetric tissue reduction for sleep-disordered breathing. Acta Oto-Laryngologica 123(4):532-5.		tongue base or soft palate; dysphagia necessitating hospital admission; temporary palsy of the hypoglossal nerve; and an abscess of the base of the tongue.	palate
Uloza V, Balseviclus T, Sakalauskas R et al. (2009) Changes in emotional state of snoring and obstructive sleep apnea patients following radiofrequency tissue ablation. European archives of otorhinolaryngology 266 (9): 1469–73	N=37 Follow-up= 2-3 months	Reduction of sleepiness and depression was statistically significant after RFTA.	Patients had both simple snoring and obstructive sleep apnoea hypopnea syndrome. Only 9 patients were simple snorers.
Uloza V, Balseviclus T, Sakalauskas R et al. (2010) Changes in emotional state of bed partners of snoring and obstructive sleep apnoea patients following radiofrequency tissue ablation: a pilot study. Sleep and Breathing 14 (2): 125–30	N=36 Follow-up= 2-3 months	A statistically significant decrease of mean Beck Depression Inventory-Second edition scores for the entire group of patients' bed partners was observed. There was no statistically significant difference between pre and post treatment mean daytime sleepiness scores in both OSAHS and in simple snoring patients' bed partners when measures with ESS.	Larger studies included in table 2.
Terris DJ, Coker JF, Thomas AJ et al. (2002) Preliminary findings from a prospective, randomized trial of two palatal operations for sleep-disordered breathing. Otolaryngology - Head & Neck Surgery; 127(4):315-323	N=17 Follow up= 16 weeks	60% (6/10) of the RFA patients achieved a satisfactory reduction in snoring as reported by their sleep partner and 86% (6/7) in the patients treated by LAUP group this figure was	Larger studies included in table 2.
Toh ST, Hsu PP, Ng YH et al. (2008) Incidence of complications after temperature controlled radiofrequency treatment for sleep disordered breathing: a Singapore sleep centre experience. The Journal of Laryngology & Otology 22 (5): 490–4	N=76 Follow-up= N not reported	Incidence of minor complications following soft palate and uvula treatment, per treatment session was 10.95. The incidence of moderate complications in the soft palate and uvula group was 0. There were no major complications in the entire study population.	Combined outcomes reported for patients having RFA to uvula and soft palate.
Troell RJ, Powell NB, Riley RW et al (2000) Comparison of	N=41	Among the 22 patients treated with RFA,117	Larger studies included in table 2.

postoperative pain between laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, and radiofrequency volumetric tissue reduction of the palate. Otolaryngology - Head & Neck Surgery Vol. 122(3):-409.	Follow up= unclear	treatments events were Reported: submucosal erosion 8% (11/117); needing oral analgesic 5% (6/117) and needing narcotic therapy 1% (1/117)	

Appendix B: Related NICE guidance for radiofrequency ablation of the soft palate for snoring

Guidance	Recommendations
Interventional procedures	**Radiofrequency ablation of the soft palate for snoring NICE interventional procedure guidance 124 (2005)** 1.1 Current evidence suggests that there are no major safety concerns associated with radiofrequency ablation (RFA) of the soft palate for snoring. However, evidence on the short term efficacy is limited and long term outcomes are uncertain. Therefore this procedure should not be used without special arrangements for audit, consent and research. 1.2 Clinicians wishing to undertake radiofrequency ablation of the soft palate for snoring should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and that they are fully informed about alternative treatment options, including lifestyle changes. Patients should also be provided with clear written information, and use of the Institute's is recommended. • Audit and review clinical outcomes of all patients having radiofrequency ablation of the soft palate for snoring. 1.3 Publication of efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence. **Soft-palate implants for simple snoring. NICE interventional procedure guidance 240 (2007)** 1.1 Current evidence on soft-palate implants for simple snoring raises no major safety concerns. However, the evidence on

	efficacy is based on small case series only and there is a lack of well-controlled and comparative data. Therefore, this procedure should only be used in the context of research. 1.2 Further research should include explicit details of patient selection, and both clinical and quality-of-life outcomes.
Technology appraisals	**Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. NICE technology appraisal 139 (2008)** 1.1 Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS). 1.2 CPAP is only recommended as a treatment option for adults with mild OSAHS if: • they have symptoms that affect their quality of life and ability to go about their daily activities, and • lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate. 1.3 The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.

Appendix C: Literature search for radiofrequency ablation of the soft palate for snoring

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/01/2013	January 2013
Database of Abstracts of Reviews of Effects – DARE (CRD website)	28/01/2013	January 2013
HTA database (CRD website)	28/01/2013	January 2013
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/01/2013	January 2013
MEDLINE (Ovid)	28/01/2013	1946 to January Week 3 2013
MEDLINE In-Process (Ovid)	28/01/2013	January 25, 2013
EMBASE (Ovid)	28/01/2013	1974 to 2013 Week 04
CINAHL (NLH Search 2.0 or EBSCOhost)	28/01/2013	N/A
BLIC (Dialog DataStar)	28/01/2013	N/A

Trial sources searched on 28/01/2013

- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search

- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

# ▲	Searches
1	Electrosurgery/
2	Electrosurger*.tw.
3	radiofrequen*.tw.
4	radio-frequenc*.tw.
5	(RFTVR or RFVTR).tw.
6	somnoplast*.tw.
7	Pulsed Radiofrequency Treatment/
8	RFA.tw.
9	or/1-8
10	(velum* adj3 palatin*).tw.
11	(palat* adj3 resect*).tw.
12	(palat* adj3 stiffen*).tw.
13	Palate, Soft/
14	(soft* adj3 palat*).tw.
15	Snoring/
16	snor*.tw.
17	stertor*.tw.
18	(stertor* adj3 breath*).tw.
19	(nasal adj3 obstruct*).tw.
20	exp Nasal Obstruction/
21	exp Rhinitis/
22	rhinitis*.tw.

23	exp Turbinates/
24	turbinat*.tw.
25	(nasal adj3 (block* or congest* or decongest*)).tw.
26	or/10-25
27	9 and 26
28	**limit 27 to ed=20121001-20130128**