# Radiofrequency ablation of the soft palate for snoring

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# Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG124.

#### **1** Recommendations

This document replaces previous guidance on radiofrequency ablation of the soft palate for snoring (NICE interventional procedure guidance 124).

- 1.1 Current evidence suggests that there are no major safety concerns associated with radiofrequency ablation of the soft palate for snoring. The evidence on the short-term efficacy of the procedure is adequate, although uncertainties remain about its efficacy in the longer term. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.
- 1.2 During the consent process clinicians should, in particular, inform patients of the uncertainty about the procedure's long-term efficacy and of the possible need for further procedures if symptoms recur.
- 1.3 Patient selection is important: the sound of snoring can arise from several different levels in the upper airway and this procedure should only be used for patients whose snoring has been shown to be caused by abnormal movement of the soft palate and in whom sleep apnoea has been excluded.
- 1.4 NICE encourages further research into radiofrequency ablation of the soft palate for snoring. This could take the form of data collection, with the specific aim of documenting long-term outcomes and the need for further treatment.

#### 2 Indications and current treatments

- 2.1 Snoring is a noisy inspiratory sound produced by vibration and partial airway obstruction in the pharynx. One cause is vibration of the soft palate. It can lead to disrupted sleep, daytime tiredness and poor concentration both for the person who snores and anyone sleeping close by.
- 2.2 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).

# 3 The procedure

- 3.1 Radiofrequency ablation aims to stiffen the soft palate. It may be combined with other techniques (such as removal of the uvula or tonsillectomy) to reduce airflow obstruction and vibration in the airway.
- 3.2 The procedure is usually done using 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, 2 lateral applications can be given at a lower energy setting and to several areas on 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.

# 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- 4.1 A randomised controlled trial of 23 patients comparing radiofrequency ablation (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; 0: no snoring, 10: excessive snoring prompting bed partner to leave the room) for the radiofrequency ablation group at 6 to 8-week follow-up, compared against the sham group. The mean score decreased from 8 to 5 in the radiofrequency ablation group and from 8.4 to 8.0 in the sham group (p<0.05 for difference between groups). However, only 2 out of 12 patients in the radiofrequency ablation group had a score below 3 (defined as the criterion for success).
- 4.2 In the randomised controlled trial of 23 patients, daytime sleepiness (assessed using the Epworth Sleepiness Scale; lower scores indicating a better outcome) at 6 to 8-week follow-up decreased from 5 before the procedure to 4 after the procedure in the radiofrequency ablation group, and from 5 to 4 in the sham group. The difference between the 2 groups was not statistically significant (p=0.77).
- 4.3 A case series of 52 patients measured quality of life using a questionnaire. Thirtynine per cent (20 of 52) of patients reported a 'great' improvement, 19% (10 of 52) reported a 'moderate' improvement, 25% (13 of 52) reported a 'mild' improvement and 17% (9 of 52) reported 'no improvement'. The mean quality-oflife score improved from 4 to 9 (p<0.05) at a mean follow-up of 7 months (details on the scale not reported).
- 4.4 In a case series of 29 patients, 25% of patients (number not reported) reported satisfaction with the outcome 3 to 4 years after the procedure. Further treatment was carried out in 28% (8 of 29) of patients (4 had mandibular advancement devices, 1 had continuous positive airway pressure and 3 had radiofrequency-assisted uvulopalatoplasty).
- 4.5 The specialist advisers listed the following key efficacy outcomes: improvement in snoring and upper airway obstruction leading to resolution of daytime sleepiness and improved quality of life for patient and partner.

# 5 Safety

This section describes safety outcomes from the published literature that the Committee

considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- Bleeding was reported in 2 patients in a case series of 218 patients. One patient developed a submucosal haematoma of the soft palate (timing unclear) associated with haemorrhage that needed haemostasis (no further details). Another patient had bleeding after their third radiofrequency ablation treatment (19 days after the procedure), which was treated by bipolar coagulation.
- 5.2 Airway oedema (timing unclear) needing treatment with corticosteroids was reported in 5% (2 of 40) of patients after radiofrequency ablation in a nonrandomised comparative study of 70 patients comparing radiofrequency ablation against injection snoreplasty.
- 5.3 Swelling of the uvula (1 day after the procedure) needing hospital admission (no further details) was reported in 1 patient in the case series of 218 patients.
- 5.4 Mild to moderate mucosal erosion (timing unclear) was reported in 48% (10/23) of patients in a case series of 23 patients.
- 5.5 Infection of the soft palate was reported in 6 patients after the procedure in the case series of 218 patients (timing unclear; treated by oral antibiotics). One patient went on to develop a peritonsillar abscess that needed surgical drainage.
- 5.6 Ulceration at the site of radiofrequency ablation probe insertion was reported in 5 patients in the case series of 29 patients. All ulcers healed within 'a couple of weeks'.
- 5.7 The specialist advisers listed perforation of palate and palatal fistula as anecdotal adverse events. They also said that a theoretical adverse event was regurgitation due to palatal insufficiency.

#### 6 Further information

#### Information for patients

NICE has produced <u>information on this procedure for patients and carers</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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# **Endorsing organisation**

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

#### Accreditation

