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NHS
National Institute for Health and Clinical Excellence

Soft-palate implants for simple snoring

1 Guidance

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.

2 The procedure

2.1 Indications

2.1.1 This guidance relates to patients who snore, but who do not experience episodes of apnoea (temporary suspension of breathing) or hypopnoea (abnormally slow or shallow respiration).

2.1.2 Snoring is caused by the vibration of soft pharyngeal structures during sleep which, in some patients, include the soft palate. Snoring may disturb the sleep of patients and their bed partners, and affect relationships.

2.1.3 Snoring may be improved by lifestyle changes such as weight loss, smoking cessation, changes in sleeping position and avoidance of alcohol or sleeping tablets. A variety of surgical interventions have been used for snoring, including injection snoreplasty (injection of sclerosant into the soft palate), radiofrequency ablation of the soft palate, laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, cautery-assisted palatal stiffening and soft-palate implants.

2.2 Outline of the procedure

2.2.1 Under local anaesthesia, a hollow introducer needle containing the implant is used to pierce the soft palate close to the junction with the hard palate, into its muscle layer. The needle is then withdrawn, leaving the implant in position. Mirror examination or nasal endoscopy may be used to check that the implant has not penetrated the nasal surface of the soft palate. Typically, two or three implants are inserted in a single procedure, at the midline of the soft palate or parallel to it. The aim of the procedure is to stiffen the soft palate over subsequent weeks as a result of fibrosis. The implants may be removed with forceps if necessary.

2.3 Efficacy

2.3.1 Snoring intensity was used as an outcome measure in some of the studies. This involved assessment by the patient's bed partner using a scale (usually 0–10) ranging from no snoring to snoring that caused the partner to leave the room. A randomised controlled trial (RCT) reported that mean scores decreased from 7.7 at baseline to 4.7 at 90-day follow-up ($p < 0.01$) in 10 patients with standard implants, compared with a decrease from 8.1 to 6.1 (not significant) in 10 patients with more rigid implants. In two case series, mean snoring intensity scores decreased from 7.6 and 8.5 at baseline to 3.7 and 5.0 at 90-day follow-up and 4.0 and 4.4 at 1-year follow-up, respectively ($n = 99$, values estimated from a diagram, p value not reported; $n = 25$, $p < 0.001$ vs baseline).

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2.3.2 Three case series combined patients with simple snoring and those with obstructive sleep apnoea (OSA) in their analyses. Mean snoring intensity scores at baseline, 90-day and 1-year follow-up were 7.1, 4.2 and 4.8, respectively ($p < 0.05$ vs baseline) in the first case series of 40 patients. In the second case series of 34 patients, the scores were 7.1, 3.4 and 4.8, respectively ($p < 0.001$ vs baseline). Mean snoring loudness scores in the third case series of 12 patients, measured on a scale from 0 to 100, were 79 at baseline and 48 at 90-day follow-up ($n = 9$, $p = 0.008$).

2.3.3 Reported baseline daytime tiredness (measured using the Epworth sleepiness scale [ESS]) based on patient-reported scores ranging from 0 [best] to 24 [worst]) were 8.0 and 8.3 at baseline in two case series. The scores decreased to 7.3 at 90-day follow-up ($n = 21$, not significant) and 5.2 at 1-year follow-up ($n = 99$, values estimated from a diagram, $p < 0.0001$), respectively. Three case series including patients with OSA and simple snoring reported decreases in mean ESS scores from 8.9 at baseline to 5.7 at 3-month follow-up ($n = 9$, $p = 0.007$), 6.1 to 4.9 at 1-year follow-up ($n = 40$, $p < 0.05$ vs baseline) and 9.3 to 5.6 at 1-year follow-up ($n = 34$, $p < 0.001$). For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers identified key efficacy outcomes as snoring intensity, daytime sleepiness, satisfaction and quality of life both in patients and in bed partners. One noted that it is difficult to document long-term benefits. Another observed that outcome measures are rarely validated, and range from sound level estimates to patients' and partners' satisfaction scores.

2.4 Safety

2.4.1 Four case series of 99, 25, 40 and 12 patients reported no postoperative infections.

2.4.2 Partial extrusion rates of 4% to 25% in patients were reported in five case series with follow-ups ranging from 71 days to 1 year (number not stated, $n = 25$, $n = 40$, $n = 34$, $n = 12$). An RCT of 20 patients reported extrusion of 40% (4/10) of rigid implants but 0% (0/10) of standard rigid implants at 6-month follow-up.

2.4.3 Studies reported pain scores, using a scale from 0 (no pain) to 10 (extreme pain), which ranged from 4.9 at 2-day follow-up to 0.2 at 90-day follow-up.

2.4.4 The RCT of 20 patients and the two case series of 99 and 40 patients did not report any severe adverse events following the procedure. For more details, refer to the 'Sources of evidence' section.

2.4.5 The Specialist Advisers considered that potential adverse events include sepsis, local infection, migration/extrusion of implants, 'foreign body' sensation, bleeding, pain, minor scarring and a compromise of continuous positive airway pressure.

2.5 Other comments

2.5.1 The Committee did not see any evidence on the use of this procedure for children.

3 Further information

3.1 The Institute has issued interventional procedures guidance on radiofrequency ablation of the soft palate for snoring (www.nice.org.uk/IPG124) and on soft-palate implants for obstructive sleep apnoea (www.nice.org.uk/IPG241).

Andrew Dillon
Chief Executive
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Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG240publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of soft-palate implants for simple snoring', March 2007.

Available from: www.nice.org.uk/ip388overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1414. 'Understanding NICE guidance' can be obtained by quoting reference number N1415.

The distribution list for this guidance is available at www.nice.org.uk/IPG240distributionlist

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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