NICE guidance

Soft-palate implants for obstructive sleep apnoea

Interventional procedures guidance
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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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on soft-palate implants for obstructive sleep apnoea (OSA) raises no major safety concerns, but there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Therefore, soft-palate implants should not be used in the treatment of this condition.

2 The procedure

2.1 Indications

2.1.1 Obstructive sleep apnoea (OSA) is characterised by repeated, reversible episodes of apnoea (temporary suspension of breathing) and hypopnoea (abnormally slow or shallow respiration) during sleep, loud snoring and excessive daytime sleepiness.

2.1.2 The soft pharyngeal structures of patients with OSA collapse when the patient is asleep, causing apnoea or hypopnoea (reduction of airflow by at least 50% over 10 seconds or more). In response to an episode of apnoea or hypopnoea the patient will spontaneously move or waken, often subconsciously, to reopen the airway. The episodes of apnoea or hypopnoea can recur throughout the night. This disturbs both the patients and their sleeping partners. OSA is associated with extreme daytime sleepiness, although the patients themselves may be unaware of the condition. OSA is more common in obese individuals and can be exacerbated by alcohol consumption and sedative medication.

2.1.3 The diagnosis and severity of OSA can be confirmed by sleep studies, which may involve inspiratory airflow measurement, pulse oximetry, recording of snoring, recording of sleep patterns using electroencephalography, or video recording. The apnoea–hypopnoea index (AHI) is the combined number of apnoea and hypopnoea episodes experienced on average per hour of sleep. An AHI score of 5 to 14 events per hour is defined as mild, 15 to 30 as moderate and a score above 30 as severe OSA.

2.1.4 OSA may be improved by lifestyle changes such as weight loss, smoking cessation, changes in sleeping position and avoidance of alcohol or sleeping tablets. Continuous positive airway pressure (CPAP) is most commonly used for severe OSA. Mandibular advancement devices, injection snoreplasty (injection of sclerosant into the soft palate), radiofrequency ablation of the soft palate, laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty and cautery-assisted palatal stiffening have also been used.

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 In five case series of patients treated with soft-palate implants and with follow-ups of between 3 months and 6 months, mean AHI score decreased from 25.0 to 22.0 (n=63, p against baseline = 0.05), from 12.7 to 11.5 (n=29 patients, not significant), from 16.2 to 12.1 (n=25, p=0.033), from 33 to 25 (n=23, $p<0.05$) and from 16.5 to 11.2 (n=16, $p<0.05$).

2.3.2 Three case series of 63, 25 and 23 patients reported baseline daytime tiredness (measured using the Epworth sleepiness scale [ESS] from 0 [best] to 24 [worst]). At follow-up intervals of between 3 months and 6 months, there were significant reductions from baseline in mean ESS scores, from 11.0 to 6.9, 9.7 to 5.5 and 13.2 to 8.7, respectively ($p<0.001$ for all). A case series of 29 patients reported a reduction in ESS score in 52% (15 out of 29) of patients (4- to 6-month follow-up).

2.3.3 In the two case series of 63 and 23 patients, the mean lowest oxygen saturation during sleep was reported as 82% and 87% at baseline, and 83% and 89% at 90-day and 6-month follow-up, respectively (n=53, not significant at 90 days and $p<0.05$ at 6 months). For more details, see the overview.

2.3.4 The Specialist Advisers considered key efficacy outcomes to be reduction in snoring, change in AHI, sleep quality, oximetry, snoring intensity and quality of life.

2.4 Safety

2.4.1 In four case series, extrusion of the implant was reported in 8% (2 out of 25) of patients (74- to 100-day follow-up), 0% (0 out of 23) of patients (6-month follow-up), 3% (10 out of 372) of implants (n=125 patients, 4-6-month follow-up) and 10% (20 out of 202) of implants (n=63 patients, 90-day follow-up). Most studies reported that extruded implants were easily removed; however, the study of 29 patients reported that 'considerable force' under local anaesthesia was required to remove one extruded implant.

2.4.2 The two case series that combined patients with mild OSA with those who had simple snoring only reported partial extrusion of implants in 18% (6 out of 34) and 17% (2 out of 12) of patients or 9% (9 out of 102) and 9% (3 out of 34) of implants, respectively.

2.4.3 Mucosal irritation or ulceration at the site of implantation occurred in 6% (4 out of 63) of patients in one case series and resolved within 2 weeks. Three case series of 23, 34 and 12 patients reported that no patients experienced infection or inflammation at the implantation site. No other adverse effects were reported in

any of the studies. For more details, see the overview.

2.4.4 The Specialist Advisers considered potential adverse events to include sepsis, local infection, migration or extrusion of the implant, failure of the implant, 'foreign-body' sensation, minor scarring of the soft palate and compromise of CPAP.

2.5 Other comments

2.5.1 The Committee noted specialist advice that the soft-palate implants might exceptionally be appropriate for the treatment of snoring associated with sleep apnoea.

3 Further information

3.1 NICE has issued interventional procedures guidance on radiofrequency ablation of the soft palate for snoring. NICE has also issued technology appraisal guidance on continuous positive airway pressure (CPAP) for the treatment of sleep apnoea/hypopnea syndrome.

Sources of evidence

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

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.