Issue date November 2007

Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating obstructive sleep apnoea by inserting implants into the roof of the mouth

NICE 'HealthTech guidance' advises the NHS on when and how new surgical procedures can be used in clinical practice.

This leaflet is about when and how inserting implants into the roof of the mouth can be used in the NHS to treat people with obstructive sleep apnoea. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

HealthTech guidance makes recommendations on the safety of a procedure and how well it works. The word 'procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe obstructive sleep apnoea or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 5.

What has NICE said?

There is evidence to say that this procedure is safe. However, there is not enough evidence to say whether it works in the treatment of obstructive sleep apnoea, a potentially serious condition for which other treatments exist. For this reason, NICE has said that this procedure should not be used.

Other comments from NICE

NICE has said that in exceptional cases, soft-palate implants may be appropriate to treat snoring associated with sleep apnoea.

This procedure may not be the only possible treatment for obstructive sleep apnoea. Your healthcare team should talk to you about any other treatment options available.

Treating obstructive sleep apnoea by inserting implants into the roof of the mouth

The procedure is not described in detail here – please talk to your doctor for a full description.

Obstructive sleep apnoea is a breathing disorder in which the airway is blocked repeatedly during sleep as the muscles of the mouth and throat relax. The blockage causes breathing to stop for a few seconds. In some people, the soft palate (the back part of the roof of the mouth) is also involved.

People with obstructive sleep apnoea usually snore and experience severe sleep disturbance and serious daytime sleepiness. They may not realise that they have obstructive sleep apnoea.

Obstructive sleep apnoea is more common in people who are obese and it can be worsened by drinking alcohol and taking sedatives.

Obstructive sleep apnoea may be improved by lifestyle changes (for example, losing weight, stopping smoking, changing sleeping position, and avoiding alcohol and sleeping tablets).

NICE has looked at a procedure called soft-palate implants for obstructive sleep apnoea. In this procedure, thin implants are inserted into the soft palate under a local anaesthetic. The aim of the procedure is to make the soft palate stiffer and less likely to vibrate.

What does this mean for me?

Your doctor should not offer you this procedure, because there is not enough evidence to say whether it works.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at six studies on this procedure.

How well does the procedure work?

Five studies involving a total of 156 patients checked progress after 3 months and 6 months. The studies looked at how many breathing disturbances (due to obstructive sleep apnoea) the patients had every hour and whether this number had improved (that is, lessened) after the procedure. The average improvement was small, ranging from 8 fewer breathing disturbances per hour to only 1.2 fewer breathing disturbances per hour.

Three studies involving a total of 111 patients looked at daytime tiredness between 3 months and 6 months after the procedure. These

studies used a scale ranging from 0 (best) to 24 (worst). The three studies showed that daytime sleepiness got better after the procedure, by approximately 4 points on the scale.

Two studies, involving 86 patients, looked at the amount of oxygen in the blood during sleep before and after the procedure, and found that it was very slightly higher 90 days after the procedure, although this was not significantly different.

There was little long-term information to say whether even these minor benefits lasted in the long term.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the goals of treatment are reducing snoring, reducing snoring intensity, reducing the number of breathing disturbances, improving sleep quality, increasing the amount of oxygen in the blood and improving quality of life.

Risks and possible problems

In four studies involving a total of 236 patients, there were some problems with the implants becoming dislodged. In two studies this was reported as the number of patients who experienced problems (2 out of 48 patients). In two studies this was reported as the number of implants that had to be removed (30 out of 574). In most cases the implants were removed easily but one study stated that one implant had to be removed using ‘considerable force’.

Two further studies involved a total of 46 patients who had both mild obstructive sleep apnoea and snoring problems. Of these 46 patients, 8 had problems with implants becoming dislodged (this affected 12 out of 136 implants).

There were not many problems reported. Three studies involving a total of 69 patients did not report any infection or inflammation. One study of 63 patients reported that 4 patients experienced irritation or ulcers where the implants had been inserted, but these healed within 2 weeks.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include infection, the implants moving or becoming dislodged, the sensation of a foreign body, bleeding, minor scarring and possible airway problems.

More information about obstructive sleep apnoea

NHS Direct online may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see NICE's about our guidance page.

NICE's guidance on soft-palate implants for simple snoring is available. NICE has also issued guidance on radiofrequency ablation of the soft palate for snoring.

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1417).

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ISBN: 978-1-4731-7791-8
N1417 1P Nov 07