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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating neurogenic claudication caused by lumbar spinal stenosis using a spacer device between the vertebrae

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

This leaflet is about when and how using a spacer device can be used in the NHS to treat people with neurogenic claudication caused by lumbar spinal stenosis. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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 neurogenic claudication due to lumbar spinal stenosis 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 7.

What has NICE said?

This procedure can be offered routinely as a treatment option provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

Specialist spinal surgeons who are able to offer patients a range of surgical treatment options should decide which patients should be offered this procedure.

Other comments from NICE

The procedure may not provide a long-term cure and patients should be warned that further surgery may be necessary.

This procedure may not be the only possible treatment for neurogenic claudication. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Treating neurogenic claudication caused by lumbar spinal stenosis using a spacer device between the vertebrae

The medical name for this procedure is 'Interspinous distraction for lumbar spinal stenosis causing neurogenic claudication'. The procedure is not described in detail here – please talk to your specialist for a full description.

Nerves run through the spine down a 'tunnel' called the spinal canal. In the condition called lumbar spinal stenosis, the tunnel narrows due to wear and tear of the spinal discs and joints. The nerves that go through this narrowed canal may be squeezed when the person stands or walks any distance, causing nerve tingling, pain, numbness or weakness in the legs (this is called neurogenic claudication). Symptoms are relieved

when the spine is flexed (when sitting or leaning forwards). Non-steroidal anti-inflammatory medications and rest may relieve the symptoms, or surgery may be used to remove tissue pressing on the nerves.

This procedure involves implanting a spacer device into the space between two vertebrae to relieve pressure on the nerves and, therefore, pain in the legs when standing or walking. Under a local anaesthetic and a sedative (or sometimes a general anaesthetic), the patient lies so their spine is positioned as it would be when they were sitting or leaning forward (when the nerves are not being squeezed). X-rays are used to pinpoint the place where the implant needs to be put in. A cut is made, and the spacer device is put into position so that the spine cannot move back (extend) and squeeze the nerves. Different types of implant are available and slightly different procedures are used for putting them in place. More than one spacer may be inserted if there is narrowing of the spinal canal at more than one level.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks it is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it. You should also be informed that the procedure may not provide a long-term cure and that further surgery may be necessary.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

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 13 studies on this procedure.

How well does the procedure work?

In a study of 191 patients, symptoms improved in 45% of patients who had the procedure and in 7% of patients who had anti-inflammatory medication and rest. In another study, 61 patients had either this procedure or fusion surgery. Before and after the procedure patients scored their pain out of 10 and answered a questionnaire about how their back or leg pain affected their ability to manage in everyday life. Back and leg pain improved significantly after both procedures, but there were no significant differences between the 2 groups.

The study of 191 patients showed that 6 of the 100 patients who had the procedure needed further surgery. Of the 91 patients treated with medication and rest, 24 had surgery later. This study also showed that quality of life was significantly better in the patients who had the procedure when their progress was checked after 2 years.

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 relief of leg pain and improved functioning are key aims of this procedure.

Risks and possible problems

In 4 studies involving a total of 396 patients (241 procedures), there were 9 problems with the placement of the implant, reported in the studies as ‘malpositioning’, ‘migration’, ‘fracture’ or dislocation’. A study of 69 patients reported a fracture of the spinous process (part of the vertebra), which happened to 1 patient during the procedure and

3 patients after the procedure (1 was the result of trauma, which was not explained further).

In 2 studies involving a total of 244 patients, 26 patients asked for the device to be removed, but the average timing of the request was not included.

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 infection and movement of the device are possible problems that could occur.

More information about lumbar spinal stenosis

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on lumbar spinal stenosis and other back problems, visit our website at www.nice.org.uk

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. This 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 www.nice.org.uk/aboutguidance

This leaflet is about 'Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG238

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2356). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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