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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Non-rigid stabilisation procedures for the treatment of low back pain

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 non-rigid stabilisation can be used in the NHS to treat people with low back pain. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 low back pain 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 for low back pain that is difficult to manage, 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.

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

Non-rigid stabilisation procedures for the treatment of low back pain

The medical name for this procedure is 'non-rigid stabilisation', but it is also known as 'flexible stabilisation' or 'dynamic stabilisation'. The procedure is not described in detail here – please talk to your specialist for a full description.

As a person gets older, the discs between the bones (vertebrae) in the spine start to shrink and joints between the bones can start to deteriorate. These changes can result in chronic (long-lasting) low back pain. Treatments include lifestyle advice, posture training, exercises, manual therapies, painkillers, non-steroidal anti-inflammatory medications and acupuncture. Surgery may sometimes be performed to reduce pain in a number of ways, including rigidly joining together the problem bones to stop them moving (called fusion surgery) or surgery to replace the worn discs. Non-rigid stabilisation procedures involve

joining the problem bones together using a non-rigid implant between two or more vertebrae. The procedure is done using either a general or epidural anaesthetic. An incision is made in the patient's back and the support device is implanted into the spine and secured to the vertebrae above and below the affected area. The aim is to stop the type of movement that causes chronic back pain but without rigidly fusing the spine, in the hope of limiting longer-term problems at other spinal joints as is sometimes seen following fusion surgery. However, additional procedures may be needed in some patients.

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 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 10 studies on this procedure.

How well does the procedure work?

In 2 studies, 2 out of 83 patients who had this procedure needed further surgery because of damage in the adjacent segment of the spine at up to 71 months after the procedure. In another study of 101 patients who had the procedure, 15 patients had 18 further procedures within the first year. In a study of 45 patients, 18 had the non-rigid stabilisation procedure and 27 had spinal fusion. X-rays at up to 75 months after the procedure showed deterioration in nearby sections of the spine in 7% of patients who had non-rigid stabilisation and in 36% of patients who had fusion.

A study of 103 patients (of whom 46 had the non-rigid procedure) measured back pain on a scale from 0 to 10 (with 10 being worst pain), and showed that average back pain improved from 7.3 before the procedure to 1.4 afterwards. The result was similar in the 57 patients who had fusion surgery, with an average score of 7.4 before the procedure reducing to 2.1 after it. The study of 101 patients measured leg pain on a scale from 0 to 100 and showed that average leg pain improved from 80.3 before the procedure to 25.6 afterwards. The study of 103 patients also looked at how patients' back or leg pain affected their ability to manage in everyday life, and showed that the 46 patients who had the non-rigid stabilisation procedure and the 57 patients who had fusion surgery reported a similar improvement. The study of 101 patients also showed that quality of life was significantly better after the procedure when patients' progress was checked after 1 year.

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 pain, improved functioning, return to work, patient satisfaction and quality of life, as well as low rates of deterioration and low rates of further surgery are key aims of this procedure.

Risks and possible problems

Tears in the covering of the spinal cord happened in 12 out of 101 patients in 1 study. Eleven were repaired during the procedure and 1 needed further surgery to repair it.

Three studies involving a total of 230 patients who had the procedure reported 11 problems with the screws used to fix the implant into position. The problems reported included the screws fracturing (1), loosening (7) or not being in the right position (2). There was also 1 report of part of the device fracturing when the screws were inserted.

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 in theory problems could include paralysis, blood vessel or internal organ damage, deterioration of nearby discs, increased forward curvature of the spine (‘sway back’), trapped nerves, sciatica or nerve damage from screws not being in the correct position, weakness and numbness or failure of the implant or infection resulting from screws breaking.

More information about low back pain

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 low back pain 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 'Non-rigid stabilisation techniques for the treatment of low back pain'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG239

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2358). 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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