

Understanding NICE guidance

Information for people who use NHS services

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

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how **non-rigid stabilisation procedures** can be used to treat people with low back pain in the NHS in England, Wales and Scotland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 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.

What has NICE said?

NICE has decided that although there is some evidence that these procedures are beneficial for a group of patients, it's not clear how safe the procedures are. If a doctor wants to use this procedure, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens after the 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

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

As a person gets older, the discs between the small bones in the spine start to shrink and the flat surfaces of the bones can start to deteriorate. These changes can result in long-lasting back pain.

There are several treatment options. They range from painkillers and lower-back exercises to surgery that 'welds' the problem bones together and stops them from moving (called fusion surgery).

Non-rigid stabilisation procedures involve inserting a special support system into the back. Different systems are available and they are inserted using slightly different procedures. The aim is to stop the type of movement that causes pain but allow other normal movement.

Summary of possible risks and benefits

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?

In a study that followed what happened in 83 people who had a non-rigid stabilisation procedure, nearly half (35 out of 73 people) were unable to do anything before the surgery, compared with two people 3 years after surgery. Scores of people's inability to do everyday tasks went from 55% before surgery to 23% when they were checked 3 years later. In another study that involved 31 patients, two-thirds of patients said their back symptoms had gone or improved when they were asked 2 years later, but 1 person said their symptoms had got worse.

What does this mean for me?

If your doctor has offered you non-rigid stabilisation procedures for low back pain, he or she should tell you that NICE has decided that although there are benefits for some patients, the risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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?

In a study that compared a non-rigid stabilisation with fusion surgery, people who had the new procedure were able to move more in one area of the lower back than people who had fusion surgery. X-rays showed significantly less deterioration in the nearby sections of the spine in people who'd had non-rigid stabilisation compared with those who'd had fusion. There were no differences in other areas of the back.

In a study that asked 59 patients to assess their back pain, their pain score (on a scale of 1–100) went from 62 points before the procedure to 19 points about 3½ years later.

The expert advisers said that a non-rigid stabilisation procedure is sometimes carried out at the same time as other surgery on the back, so it's difficult to see the effects of the support system on its own.

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

Risks and possible problems

In one study, 7 out of 280 screws inserted as part of support systems became loose during the 3 years after surgery – 11 out of 83 people needed to have more surgery, and 8 of them had the support system removed. In another study, the screws were put in the wrong position in 3 out of 31 people and a screw became loose in one person. In this study, one person had a build-up of fluid around the lungs, one person developed heart problems, and one person had a tear in the covering of the spinal cord (called a dural tear).

In another study, 2 out of 51 people had dural tears, and 11 out of 51 people had to have more surgery.

In a study that compared a non-rigid stabilisation procedure with fusion surgery, more surgery was needed for 6% (1 person out of 18) who had the new procedure and for 19% of people who had fusion.

The expert advisers said that the possible side effects were wrongly positioned or broken screws, which could lead to nerve damage, infection, leakage of the fluid that bathes the spinal cord, and poor attachment of the support system to the bone. A person might still be in pain after the procedure, too.

They said the theoretical risks were: that the system would stop supporting the area (particularly in the long term); the spine would become more curved; and nerves might be damaged by loose or poorly positioned screws.

More information about back pain

NHS Direct online (www.nhsdirect.nhs.uk) 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. 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/about_guidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IIPG183

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1071).