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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Replacing worn discs in the lower spine with artificial discs

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 artificial discs can be used in the NHS to treat people with worn discs in their lower spine. 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.

NICE has produced this guidance because 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 worn discs in the lower spine 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 people with worn discs in their lower spine 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.

A team of specialist doctors who are experienced in the management of worn discs in the lower spine should decide which patients should have this procedure. It should only be carried out in patients who have not improved after standard treatments or for whom standard treatments are unsuitable.

The studies that NICE looked at mostly assessed patients for only a short time. NICE has encouraged further research into artificial disc replacement and encourages doctors to collect and publish longer-term results and include information about which patients were treated and whether further surgery was needed.

Artificial disc replacement in the lower spine

The medical name for this procedure is 'Prosthetic intervertebral disc replacement in the lumbar spine'. The procedure is not described in detail here – please talk to your doctor for a full description.

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

The spine is made up of small bones called vertebrae that are separated by tough discs that sit between the bones and act like cushions. If the discs at the base of the spine become worn, it is known as degenerative disc disease. This often happens as a person ages and can cause lower back pain. In most patients, the symptoms improve over time, although they may need treatment with drugs, injections or physiotherapy. Those with severe symptoms that do not improve sometimes need surgery. Spinal fusion involves joining two or more of the bones in the backbone together using a bone graft to try and stop them moving and causing pain.

Prosthetic intervertebral disc replacement in the lumbar spine involves removing the damaged disc and inserting an artificial disc in its place. The patient is given a general anaesthetic and the procedure is carried out through a cut in the patient's abdomen. The damaged disc is partially or fully removed and an artificial disc inserted. The artificial disc is designed to act like a natural disc, allowing painless movement between the bones. Depending on the number of discs affected, a person may have one or more discs replaced at different places in the spine during the same operation.

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 artificial disc replacement 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.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

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?

Summary of possible benefits and risks

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 8 studies on this procedure.

How well does the procedure work?

A study compared 205 patients treated with artificial discs with 99 patients who had spinal fusion. Patients who had artificial disc replacement reported significantly more improvement compared with those who had spinal fusion up to 6 months after their operations. However, by 12 months the difference between the groups was no longer significant.

In a study of 236 patients, 161 were treated with artificial discs and 75 with spinal fusion. Three months after surgery, the patients who had disc replacement reported an improvement in their quality of life (measured using a questionnaire) of 87%, whereas those who had spinal fusion experienced an improvement of 70%. However, at 24 months the difference between the groups was no longer significant.

A study of 106 patients treated with artificial discs found that 82% had 'excellent' (no pain) or 'good' results and 18% had 'fair' or 'poor' (no improvement or worse) results an average of 13 years after surgery. In the same study, 86 out of 96 patients eligible for work had returned, including 28 out of 36 doing manual work.

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 main success factors are pain relief, reduced disability, return to work, quality of life and reduced need for further treatment.

Risks and possible problems

In one study, 1 out of 44 patients treated with an artificial disc had a vertebral fracture that needed further surgery. A study of 304 patients found that major complications affecting the nerves in the back were more common after fusion surgery (5%) than after artificial disc replacement (2%). Further surgery was needed within 2 years in 9% of patients who had disc replacement and in 10% of patients who had spinal fusion in a study of 688 patients. In a study of 2490 patients, 14% of those treated with spinal fusion developed degenerative disc disease in neighbouring discs compared with 1% of patients treated with artificial discs. In the study of 236 patients, signs of infection were found in 2 out of 75 patients treated by spinal fusion and none of the patients treated with artificial discs 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 possible complications include injury to blood vessels, vertebral fracture, retrograde ejaculation in men (in which semen is passed back into the body during sex), continuing symptoms and wear to and movement in the disc. In theory, they may also include nerve and bowel injury, bleeding, infection, bladder problems and disc failure needing an operation.

More information about degenerative disc disease

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.

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 'Prosthetic intervertebral disc replacement in the lumbar spine'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG197

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1905). 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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