NHS
National Institute for Health and Clinical Excellence

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Direct C1 lateral mass screw for cervical spine stabilisation

Understanding NICE guidance – information for people considering the procedure, and for the public

Information about NICE Interventional Procedure Guidance 146

Ordering information

You can download the following documents from www.nice.org.uk/IPG146

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0945 (full guidance)
- N0946 (information for the public).

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Contents

About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called direct C1 lateral mass screw for cervical spine stabilisation. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether the new procedure is safe enough and works well enough for it to be used routinely for the treatment of a condition called atlantoaxial instability (see page 5).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of direct C1 lateral mass screw stabilisation and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Atlantoaxial instability is the medical name for having an excessive amount of movement between the first and second bones in the neck. It can happen as a result of damage or disease, or a person may be born with it. It can cause pain. And if there is pressure on the spinal cord (which is inside the spine), it can cause clumsiness and lack of coordination. Sometimes it can affect a person's walking and very rarely it can lead to paralysis or death.

Atlantoaxial instability is treated by fixing the first bone in the neck to the second. The standard way of doing this involves wires and bone grafts (using pieces of bone from other sites in the body). After this type of operation, the person needs to wear some form of neck support while the bones fix.

The new procedure NICE has looked at involves using screws to fix the bones together. The patient has a general anaesthetic and an opening is made in the back of the neck. Screws are inserted from the back into the first and second bones in the neck. The heads of the screws are then either connected together using metal rods (called a polyaxial screw and rod system), or connected to metal plates attached to the bones (called a screw and plate system). If part of the bone is pressing on the spinal cord, it can be removed during the surgery. A bone graft is placed between the two bones to 'weld' the bones together permanently. Usually, the person doesn't have to wear an external support after the procedure.

How well the procedure works

What the studies said

In studies, the new procedure was said to have been successful if the two bones welded together. This happened in all the patients who took part in three studies (196 people in total).

In a study that followed what happened in 157 patients, all the patients were said to have recovered clinically and neurologically (so their nervous system was working properly) after the procedure. But this study didn't describe how recovery was measured.

One study that looked at a screw and plate procedure found that it wasn't possible to get to the correct area of the neck to place the device in 9 out of 157 patients. The surgery had to be stopped in these patients.

What the experts said

The experts said that the new procedure was another way of carrying out a similar operation to weld the neck bones together.

Risks and possible problems with the procedure

What the studies said

In one study that looked at 157 patients and another that looked at 37, there were no reports of problems with the screws or connecting device used to fix the neck bones. In another study, six screws were found to be sticking out more than 4 mm from the first neck bone, but these were not causing any problems to the patients. One screw was found to be broken when it was checked 18 months after the procedure.

There were no reports of damage to the blood vessels in the area in the studies.

In one study, 18 out of 157 patients lost some sensation following a screw and plate procedure. In another study, 1 person out of 37 had an infection in the area of the surgery.

What the experts said

The experts said that bleeding (haemorrhage) was a possibility. And the screws could possibly break or loosen. Less likely but more seriously, the screws could be put in incorrectly, leading to damage to a major blood vessel or the spinal cord.

What has NICE decided?

NICE has considered the evidence on direct C1 lateral mass screw for cervical spine stabilisation. It has recommended that when doctors use this procedure for people with atlantoaxial instability, they should be sure that:

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

NICE has also said that the procedure should be done in specialist units where staff routinely carry out surgery on the bones in the neck.

Other comments from NICE

There haven't been many studies carried out on this procedure, and those that have been done do not provide a lot of information. The information is enough, though, to make recommendations because this procedure is used for a very specific purpose.

The studies used as evidence used two different methods, called the screw and plate system and the polyaxial screw and rod system. The differences between these methods make it difficult to compare the results of the studies.

What the decision means for you

Your doctor may have offered you direct C1 lateral mass screw for cervical spine stabilisation. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of direct C1 lateral mass screw before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

If you have the new procedure, it should be done in a specialist unit where the staff routinely carry out surgery on the bones in the neck.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on direct C1 lateral mass screw for cervical spine stabilisation that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more health information on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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