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Stent-graft placement in abdominal aortic aneurysm

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

Ordering information

You can download the following documents from www.nice.org.uk/IPG163

- 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:

- N1006 (full guidance)
- N1007 (information for the public).

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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 stent-graft placement in abdominal aortic aneurysms. 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 stent-graft placement in abdominal aortic aneurysms is safe enough and works well enough for it to be used routinely.

This guidance replaces the previous guidance on stent-graft placement in abdominal aortic aneurysms (which was interventional procedure guidance number 10).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of stent-graft placement in abdominal aortic aneurysms 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

The aorta is the main blood vessel that carries blood away from the heart. An abdominal aortic aneurysm is the medical name for a 'bulge' somewhere in the section of the aorta that travels down through the abdomen. The bulge (aneurysm) happens because of a weakness in the wall of the aorta. If the aneurysm bursts (ruptures), it causes internal bleeding, which is serious.

The standard operation for an abdominal aortic aneurysm involves making an opening in the area, opening up the weakened section of the aorta and patching it with a tube-shaped graft made from a synthetic material. The aorta is sewn back together so that blood can flow through it again. This operation is known as open surgical repair.

The new procedure NICE has looked at avoids making a large opening in the abdomen. Instead, the graft is put over an artificial piece of rigid tubing called a stent. This is threaded up to the aneurysm through the blood vessels, starting from a blood vessel in the leg. It's put in place across the aneurysm and the graft works in the same way as the graft in the standard procedure. The stent keeps the blood vessel open and gives it extra support. The surgeon uses X-rays to guide him or her during the procedure. There may be more stages than this in a person's surgery, but this will depend on the individual needs of the patient.

How well the procedure works

For this procedure, NICE undertook what is known as a 'systematic review'. This means that evidence from all available sources was looked at, whether it had been published or not. Experts' opinions may also be included in a systematic review.

What the studies said

One study which compared stent-graft placement and open surgical repair checked on people around 3 years after their surgery. It found that the aneurysm had gone on to burst in 5 out of 543 people who had had the new procedure compared with 1 out of 539 people who had had the open surgical repair. In another study, the aneurysm had burst in 1 out of 534 people who'd had the new procedure. Seven similar types of study involved a total of 3859 people who had the new procedure. Out of these, 13 had had a burst aneurysm following surgery.

Some of the studies also looked at the number of people who needed further surgery after the first operation. In one study, 85 out of 529 people (16%) who had had the new procedure needed further surgery, compared with 36 out of 519 people (7%) who'd had the standard operation. In other studies, about 1 in 5 people needed further surgery after the stent-graft placement compared with just over 1 in 20 people after the standard operation.

Another study looked at stent-graft placement in people considered unfit for open surgical repair. This study checked on people 4 years after the stent-graft placement and found that just over 1 in 4 people who'd had stent-graft placement had needed further treatment at least once compared with 1 in 25 of the group who'd had standard medical care. This result is not straightforward, though, because some of the people who had standard care went on to have stent-graft

placement. If this is taken into account, then the results for the two groups become similar, with just under 1 in 3 people in both groups going on to have further treatment.

Risks and possible problems with the procedure

What the studies said

Information from three studies showed that 12 out of 759 people (2%) died within 30 days of having the stent-graft procedure. As a comparison, 33 out of 709 people (5%) who had the standard operation died in this time period. The stent-graft procedure was also carried out in a group of people who weren't fit enough to have the standard operation – 13 out of 150 people (9%) in this group died within 30 days of having the procedure.

One study followed what happened in people for 4 years after the surgery. It found that around the same number of people died (from all causes) regardless of whether they'd had the stent-graft procedure or the standard operation.

The most common problem that affected people who had the stent-graft procedure was what's called an endoleak. In an endoleak, blood leaks into the area between the stent and the aneurysm. From the studies, it seems that about 1 in 5 people had an endoleak in the year following the stent-graft procedure. Problems affecting the lungs and involving bleeding were less common after the stent-graft procedure than after the standard operation.

In studies that reported on the problems that happened in the year after the procedure, the stent moved in about 1 person in 100, and the stent broke in around 3 in 100 people.

There have been recent improvements in the way the stent-graft procedure is carried out, and these have meant that there are now fewer problems during and after the procedure.

What has NICE decided?

NICE has considered the evidence on stent-graft placement. It has recommended that when doctors use this procedure for people with abdominal aortic aneurysms, they should be sure that the patient understands:

- what is involved
- that the long-term effects of having a stent-graft aren't clear
- that there's a risk of serious problems that may mean they need further surgery
- that they'll need to have check ups for the rest of their life.

After this discussion, if the procedure is to go ahead, the doctor should ensure that:

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

NICE has also said that it's important that the stent-graft procedure isn't used for patients who might be put at particular risk by having it. This is especially important for people who would normally be thought unfit for surgery.

Finally, NICE has recommended that doctors send information about every patient who has the stent-graft procedure and what happens to them afterwards to a central store of information called a registry so that the safety of the procedure and how well it works can be checked over time.

Other comments from NICE

The procedure to insert a stent-graft is improving rapidly as doctors gain more experience in doing this type of surgery.

Two of the important studies looking at procedures to repair aneurysms are carrying on and long-term results are expected from these in 2010.

What the decision means for you

Your doctor may have offered you stent-graft placement for an abdominal aortic aneurysm. 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 stent-graft placement in abdominal aortic aneurysms before you agree to it. In particular, you need to understand that there are uncertainties about the long-term effects of the procedure, and the possible problems that can happen, such as endoleaks. Also, your doctor should explain that you may need to have further surgery after the stent-graft procedure if there's a problem, and you'll need to have regular check ups for the rest of your life.

NICE has also recommended that some details should be collected about every patient who has this procedure. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have the stent-graft placement, you will be asked to agree to your details being entered into an electronic database for this purpose. A doctor looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be allowed to have the procedure.

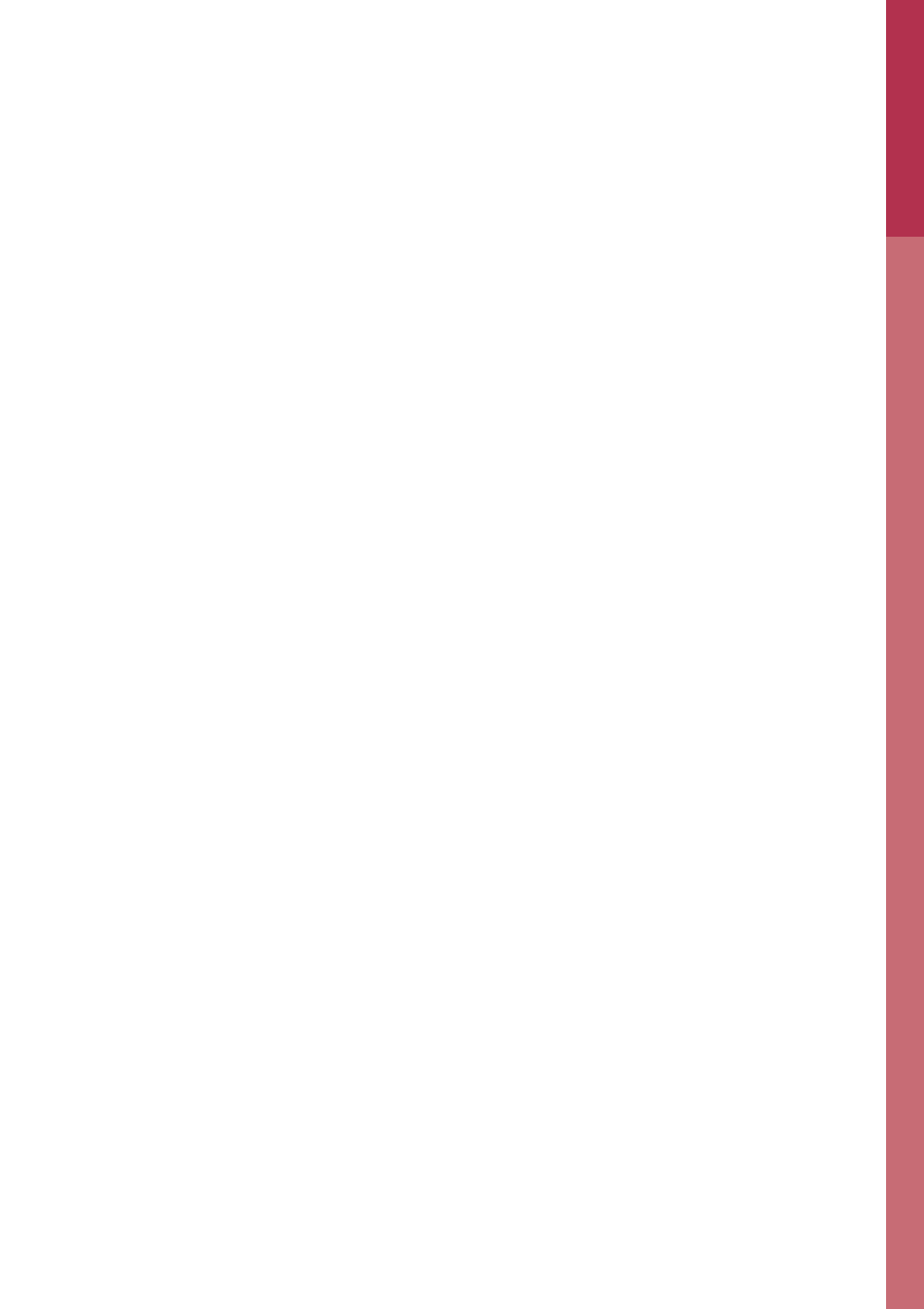
Further information

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 stent-graft placement in abdominal aortic aneurysms 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 information on aneurysms on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.



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