NHS
National Institute for Health and Clinical Excellence

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Endovascular stent–graft placement in thoracic aortic aneurysms and dissections

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

Information about NICE Interventional Procedure Guidance 127

Ordering information

You can download the following documents from www.nice.org.uk/IPG127

- 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:

- N0876 (full guidance)
- N0877 (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 within the NHS. This guidance covers England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called endovascular stent–graft placement in thoracic aortic aneurysms and dissections. 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 endovascular stent–graft placement is safe enough and works well enough for it to be used routinely in thoracic aortic aneurysms and dissections.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endovascular stent–graft placement in thoracic aortic aneurysms and dissections 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 endovascular stent–graft placement in thoracic aortic aneurysms and dissections

The aorta is the large blood vessel that carries blood away from the heart. The section that runs down behind the heart in the chest is called the thoracic aorta. If a section of the thoracic aorta becomes weak, it starts to bulge outwards. This is called a thoracic aortic aneurysm. If blood starts to leak between the layers that make up the aorta wall, it's known as an aortic dissection. Aneurysms and dissections may rupture (burst), causing severe internal bleeding. There is a high risk of death if this happens, even with treatment.

The standard operation for an aneurysm of the thoracic aorta involves replacing the affected part of the aorta with a synthetic vessel or graft. A person with an aortic dissection might be treated with medicines or surgery, depending on the position of the leakage and the person's condition.

Stent–graft placement, which is the procedure NICE has issued guidance on, involves placing what's called a stent inside the place in the aorta where it's bulging or leaking. A stent is a tube designed to provide strength and support to a blood vessel. In this procedure, the stent is covered with synthetic graft material that should help it 'knit' together with the natural aorta. The stent–graft is usually guided into place through the blood vessels from a starting point at the top of the leg. X-ray images are used to get the stent–graft into the correct position.

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

Twenty-nine studies on stent–graft placement in thoracic aortic aneurysms and dissections were looked at.

When the results from 18 studies were looked at together, the stent–grafts were successfully put into place 93% of the time (93% is the same as saying 93 times out of 100). In one study, the stent–grafts were successfully put into place in all 67 patients.

When there were problems with the stent–graft procedure, doctors switched to an open procedure (open heart surgery). This means that they opened the patient's chest to get to the heart to repair the aorta. The number of patients in whom this happened went from none out of 26 patients in one study to 1 out of 14 patients (7%) in another.

In one study, the aneurysm got larger after surgery in 2 out of 29 patients (7%). This also happened in 4 out of 84 patients (5%) in another study. But this didn't happen to any of the 18 patients who had the procedure in a third study. Looking at the results for the aneurysm getting smaller after the stent–graft was put in place, this happened in all 18 patients in one study, but in only 5 out of 29 patients (17%) in another.

Risks and possible problems with the procedure

What the studies said

The numbers of patients who died in the studies went from 1 out of 37 (3%) in one study to 11 out of 46 (11%) in another. On average, these results cover a period of 14 months after the procedure. Looking at the figures for deaths within 30 days of the procedure, several studies had no deaths in this period, while the highest number of deaths was 2 out of 14 patients (14%).

The most common problem after the stent–graft was put in place was what's called an endoleak, when the aneurysm isn't sealed off fully when the stent–graft is in place. There was at least 1 patient with an endoleak in each of 19 studies NICE looked at. On average in these 19 studies, which had a total of 752 patients, 13 patients in every 100 who had the procedure had an endoleak within 12 months. In another five studies, with a total of 83 patients, there were no cases of endoleak.

In nine studies there were reports of damage to the blood vessel where the stent–grafts were inserted into the body. These affected 1 out of 26 patients (4%) in one study, 1 out of 27 patients (4%) in another, and 2 out of 34 patients (6%) in a third study. In one study, the stent cracked in 11 out of 84 patients (13%). In 6 patients from a total of 15 studies, the stent moved from its position in the aorta.

Other problems in individual studies included:

- problems affecting the site where the stent–grafts were put into the body – these happened in 8 out of 32 patients (25%)
- stroke, where the supply of blood to the brain is interrupted – this happened in 8 out of 43 patients (19%)
- kidney failure that meant the patient needed dialysis – this happened in 2 out of 19 patients (11%)
- paraplegia (where the lower part of the body becomes paralysed) – this happened in 3 out of 43 patients (7%).

What has NICE decided?

NICE has considered the evidence on endovascular stent–graft placement in thoracic aortic aneurysms and dissections. It has recommended that when doctors use it for people with thoracic aortic aneurysms and dissections, they should be sure that:

- it's a suitable option for the patient
- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

There should also be special arrangements for monitoring what happens when a person has endovascular stent–graft placement for a thoracic aortic aneurysm or dissection. NICE is asking doctors to send information about every patient who has the procedure and what happens to them afterwards to a central store of information called the thoracic stent–graft registry, so that the safety of the procedure and how well it works can be checked over time. The registry is supported by the Vascular Society of Great Britain and Ireland and the British Society of Interventional Radiology (www.bsir.org).

Endovascular stent–graft placement should be performed by a team of healthcare professionals who have access to facilities to be able to switch the patient to open surgery if this becomes necessary.

Other comments from NICE

There is not much information available on how long a stent–graft lasts once it's in place in the aorta.

What the decision means for you

Your doctor may have offered you endovascular stent–graft placement for a thoracic aortic aneurysm or dissection. 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 some patients in the NHS, depending on their individual condition. Nonetheless, you should understand the benefits and risks of endovascular stent–graft placement before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has also decided that more information is needed about endovascular stent–graft placement in thoracic aortic aneurysms and dissections. So NICE has 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 procedure, you will be asked to agree to your details being entered into an electronic database for this purpose. A clinician 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 endovascular stent–graft placement in thoracic aortic aneurysms and dissections 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 heart problems on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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