

Understanding NICE guidance

Information for people who use NHS services

Using a balloon to temporarily stop blood flow during heart surgery

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how a balloon can be used to temporarily stop the blood flow through the heart for people who have heart surgery in the NHS. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 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 heart surgery 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 the back page.



What has NICE said?

This procedure can be offered routinely as a treatment option for people who need heart surgery 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.

The procedure should only be done by a team of very experienced doctors, and using continuous ultrasound of the heart from inside the oesophagus (transoesophageal echocardiography) to provide a clear image of the heart's movement.

Other comments from NICE

Advances in technology have meant that the balloons now work better and this improvement may result in fewer complications.

Your healthcare team should talk to you about whether this procedure is suitable for you and about any other treatment options available.

Using a balloon to temporarily stop blood flow during heart surgery

The medical name for this procedure is 'endoaortic balloon occlusion for cardiac surgery'.

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

During major heart surgery, the flow of blood through the heart needs to be stopped temporarily. This is usually achieved by using a surgical instrument to clamp the blood flow from the heart.

In endoaortic balloon occlusion, a flexible tube (catheter) with a balloon attached to its tip is inserted into an artery in the groin (femoral artery) and threaded up towards the heart. When the catheter is in the correct position in the aorta (the main artery from the heart) the balloon is filled with saline and blocks the aorta. This stops the blood flow from the heart. With the aorta blocked, the heart surgery can be performed. After heart surgery, the balloon and catheter are removed and the blood flow returns to normal.

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 this procedure is suitable for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

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?

Summary of possible benefits and risks

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

How well does the procedure work?

There was no information in any of the studies to say how well the procedure works by itself because it is only one part of the much larger heart operation.

As well as looking for information in 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 include how well the heart is protected from damage during the operation, whether the patient has a shorter hospital stay and how long the heart is stopped. This procedure could also reduce the risk of a stroke in patients who have a hardened aorta.

Risks and possible problems

In a study of 306 patients, 3 patients died within 30 days of the procedure, and a further 6 people died up to 20 months after the procedure. In four studies involving a total of 539 patients, 31 patients died in hospital after their operation.

In three studies involving 632 patients, a tear in the wall of the aorta was reported in 7 patients. However, in three other studies involving

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

305 patients there were no tears at all, and in a further study of 151 patients only one tear was reported, but it was not related to the procedure.

In a study of 449 patients, nervous system problems, such as stroke or paralysis down one side of the body, happened more frequently after this procedure compared with clamping the aorta, but numbers were not given in the study. In five other studies involving a total of 753 patients, 7 patients had a stroke or 'mini-stroke' (called a transient ischaemic attack).

In seven studies involving 993 patients, internal bleeding problems happened in 64 patients.

In two studies of 457 patients, 3 patients had a heart attack.

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 problems include damage to the aorta or the femoral artery, rupture or puncture of the balloon, movement of the balloon, difficulty placing the balloon in the right position, failure to stop the flow of blood (leading to problems completing the operation), or death. They said that other possible problems could be stroke, heart problems or a blood clot in an artery.

More information about heart surgery

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. Interventional procedures 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 'endoaortic balloon occlusion for cardiac surgery'.

This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG261

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1579).

We encourage voluntary sector organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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