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Totally endoscopic robotically assisted coronary artery bypass grafting

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/IPG128

- 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:

- N0878 (full guidance)
- N0879 (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 totally endoscopic robotically assisted coronary artery bypass grafting (TECAB grafting for short). 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 TECAB grafting is safe enough and works well enough for it to be used routinely for the treatment of coronary artery disease.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of TECAB grafting 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 TECAB grafting

The coronary arteries are the blood vessels that supply oxygen to the heart. In coronary artery disease, these blood vessels become 'furred up' with fatty deposits. They become narrower or blocked, especially if small blood clots become trapped in them. As a result, less blood and oxygen gets through to the heart. Angina and heart attack (also known as myocardial infarction) can happen. Angina is a pain and tightness across the chest and sometimes the neck, throat and arms that happen because not enough oxygen is getting to the heart. A heart attack is when the coronary artery becomes completely blocked so that there's no oxygen getting to part of the heart. The part of the heart that's affected will stop working completely unless the blockage is quickly removed.

Having a reduced oxygen supply to the heart can also lead to a long-term weakening of the heart muscle, which can put the person at risk of heart failure or arrhythmia. In heart failure, the heart isn't able to pump a healthy amount of blood around the body. An arrhythmia is the medical name for what happens when the normal heartbeat changes.

An operation called a coronary artery bypass graft (CABG for short) may be an option for someone with coronary artery disease. The standard operation involves opening up the person's chest to get to the heart. For this, the surgeon cuts lengthways through the breastbone (also called the sternum). Using a piece of blood vessel taken from another part of the body, the surgeon makes a bypass around the narrowed coronary artery so that blood carrying oxygen can get past it to the heart.

In the new procedure that NICE has looked at, which is called totally endoscopic robotically assisted coronary artery bypass (or TECAB) grafting, the surgeon uses small, remote-controlled robotic arms to carry out the procedure. This is done through much smaller openings in the chest, so it's not necessary to cut through the breastbone.

The patient's lungs are deflated and small openings are made between their ribs. The robotic arms, with surgical equipment attached, are placed in these small openings. The surgeon can see what is happening inside the person's chest because one of the robotic arms has a tiny camera attached to it. He or she carries out the operation by watching the pictures and controlling the robotic arms. The basic aim of the operation is the same as for the standard CABG operation – to make a bypass around the narrowed coronary artery.

Normally in a CABG operation the heart and lungs are made to stop working and blood is made to flow out of the body and into a heart and lung bypass machine that puts oxygen into the blood and pumps it around the body. TECAB grafting can sometimes be carried out on the heart while it's still beating, which means that this machine isn't needed.

Other ways of carrying out this type of operation have also been developed in an effort to avoid opening up the patient's breastbone, using a heart and lung bypass machine, and giving a general anaesthetic.

How well the procedure works

What the studies said

In a study that followed what happened in 22 patients who had a TECAB graft, 21 patients had a good, working bypass vessel when they were checked 3 months after the operation.

A lot of the studies that NICE looked at reported how long the operations took. In 45 patients who had the TECAB operation, the average time for an operation was 4 hours 12 minutes for people who had one bypass and 6 hours and 18 minutes for patients who had bypasses made for more than one of their arteries. Other averages for similar studies were 5 hours 47 minutes and 3 hours 6 minutes. In the studies, patients stayed in intensive care units for

14 to 74 hours, and stayed in hospital for 5 to 15¹/₂ days (patients who'd had more than one bypass tended to be the ones who stayed in for longer).

What the experts said

The experts said that bleeding in the area might make it difficult to see from the pictures which artery needs the bypass. They also said that there weren't many studies that had given useful information on how well the new bypass blood vessels worked after the operation.

Risks and possible problems with the procedure

What the studies said

The studies reported how many patients needed to be switched from the TECAB operation to another operation because of problems. Numbers for this went from 5 out of 27 patients (19%) in one study to 19 out of 37 patients (51%) in another study.

In a study that reported what happened in 45 patients who had the TECAB operation, there were problems gaining access through the surgical openings made between the ribs in three patients. In four patients, the heart and lungs were stopped for longer than normal. In one patient, the vessel became blocked so that blood didn't get to a section of the heart. In one patient, part of the brain became starved of oxygen during the operation and this led to brain damage. Arteries in the chest were damaged during the operation in one patient. And two patients needed to have more surgery because of bleeding around the connection between the bypass vessel and the existing vessel. None of the patients in this study had infection at the places where the openings into the chest were made.

There were no reports of patients dying during the TECAB operation in the studies NICE looked at.

What the experts said

The experts said that, in theory, a person having the TECAB operation could have a heart attack during the surgery, or an air pocket could build up around the lung (this is called a pneumothorax). A condition called cardiac tamponade was possible, where the heart becomes compressed and can't work properly. They also said that serious bleeding could happen, leading to death. Problems might also develop around the place where the bypass vessel joins onto the existing blood vessel.

What has NICE decided?

NICE has decided that if a doctor wants to carry out TECAB grafting, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

There should also be special arrangements for monitoring what happens when a person has the TECAB operation. NICE is asking doctors to send information about every patient who has the operation and what happens to them afterwards to a central store of information called the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor) so that the safety of the procedure and how well it works can be checked over time. NICE may look at TECAB grafting again when new information is published.

Other comments from NICE

NICE was not able to find any good studies that compared the TECAB operation with other surgical procedures developed to help treat coronary artery disease.

What the decision means for you

Your doctor may have offered you totally endoscopic robotically assisted coronary artery bypass (TECAB) grafting. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of TECAB grafting which you need to understand 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 the TECAB operation. 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 TECAB operation, 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 totally endoscopic robotically assisted coronary artery bypass grafting 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 coronary artery disease on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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