Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Off-pump coronary artery bypass grafting

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 off-pump coronary artery bypass grafting (CABG) can be used in the NHS to treat people with coronary artery disease (also known as coronary heart disease). 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 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 coronary artery disease 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 page 7.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with coronary artery disease 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.

If a doctor wants to use off-pump CABG for coronary artery disease, they should make sure that patients are told that they will be offered off-pump CABG rather than on-pump surgery, but that conversion to on-pump may be a possibility. Patients should also be told about the possible disadvantages of the procedure (for example, recurrence of symptoms), as well as the advantages, including the lower incidence of stroke. This should happen before the patient agrees (or doesn't agree) to the procedure.

Cardiac surgical teams who are skilled in both off-pump and onpump surgery should decide which patients should have this procedure, and the procedure should be done only by these teams.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor) so that the safety of the procedure and/or how well it works can be checked over time.

This procedure may not be the only possible treatment for coronary artery disease.

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

Off-pump coronary artery bypass grafting

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

Coronary artery disease occurs when vessels carrying blood to the heart (coronary arteries) become narrowed or blocked by the build-up of fatty deposits. This can cause problems such as angina (chest pain), heart attack and heart failure.

One of the treatment options for coronary artery disease is coronary artery bypass grafting, often referred to as CABG. This is usually performed 'on pump' with the heart temporarily stopped. A healthy blood vessel (usually from the leg or chest) is attached to selected coronary arteries so that the blood flow bypasses the section of blocked artery. A special bypass machine is used to maintain the circulation and deliver oxygen to the blood while the heart isn't beating.

The aim of the off-pump procedure is to reduce the risk of stroke associated with on-pump CABG. The procedure is performed with the patient under general anaesthesia. The chest is cut open. An immobilising device is used to minimise movement of the beating heart and the selected arteries are held still while the healthy blood vessel grafts are stitched to them.

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 off-pump CABG is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

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?

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

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 9 studies on this procedure.

How well does the procedure work?

A large study of several smaller studies (5537 patients in total) reported no significant difference in long-term death rate between off-pump and on-pump CABG.

In another study the proportion of patients with serious long-term problems (death, stroke or heart attack) was higher in the on-pump group than in the off-pump group (367 out of 2377 and 72 out of 637 patients) after 1 year. In a study of 2203 patients, the proportion of patients with serious side effects (death, heart attack or further procedures) was higher in the off-pump group than in the on-pump group (105 out of 1104 patients and 78 out of 1099 patients) between 1 month and 1 year after the operation.

In a report of 86,047 UK patients, 1-year survival was around 96% and 5-year survival was 89% for both on-pump and off-pump CABG.

Two large studies of smaller studies (involving a total of 302,537 patients) found there was no significant difference in the risk of patients needing further procedures in patients who had off-pump CABG compared with those who had on-pump CABG.

One study of 3014 patients reported that there was no significant difference in graft failure in patients who had off-pump CABG (181 out of 402) compared with patients who had on-pump CABG (697 out of 1518), 12 to 18 months after the procedure. A study of 2203 patients treated by off-pump or on-pump CABG reported that significantly fewer

grafts were inserted than were planned in 18% of patients in the offpump group and 11% in the on-pump group.

In 1 study, off-pump CABG was converted to on-pump CABG during the procedure in 12 out of 312 patients.

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 key success factors are the need for further procedures to improve blood supply, relief of symptoms and length of stay in hospital.

Risks and possible problems

A large study of 297,000 patients that looked at the results of several different studies reported that death within 30 days of the procedure was lower in patients who had off-pump CABG than in those who had on-pump CABG. Another study, of 2203 patients, found no significant difference: 18 out of 1104 patients who had off-pump CABG and 13 out of 1099 patients who had on-pump CABG died within 30 days.

The study of 297,000 patients showed that stroke occurred less frequently in the off-pump group than in the on-pump group.

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 that in theory, possible problems could include infection, bleeding and problems with the kidneys. Inaccurate stitching of the blood vessels may cause the graft to fail.

More information about coronary heart disease

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on coronary heart disease, visit our website at www.nice.org.uk

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 'off-pump coronary artery bypass grafting'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG377

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email <u>publications@nice.org.uk</u> and quote reference N2416). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

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

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