Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

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

Treating ventricular tachycardia using heat energy delivered to the outside of the heart by a thin tube

This leaflet is about when and how heat energy delivered to the outside of the heart by a thin, flexible tube (called a catheter) can be used in the NHS to treat people with ventricular tachycardia. 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 ventricular tachycardia 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 8.

What has NICE said?

The evidence on this procedure is only from a small number of patients, but it shows that the procedure works in carefully selected patients and that there are no major safety issues. This procedure can be offered routinely as a treatment option for people with ventricular tachycardia 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 this procedure, they should take extra steps to ensure that patients understand the risks of potentially serious complications, including damage to the heart muscle. This should happen before the patient agrees (or doesn't agree) to the procedure. A team of specialist doctors experienced in treating heart rhythm disorders should decide who has this procedure. It should include experts in the heart's electrical activity and in removing abnormal tissue. The procedure should only be carried out by cardiologists with training in the heart's electrical activity, operating on the heart and removing abnormal tissue, and in units with emergency cardiac surgery support.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at 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 has encouraged further research into the procedure.

This procedure may not be the only possible treatment for ventricular tachycardia. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Treating ventricular tachycardia using heat energy delivered to the outside of the heart by a thin tube

The medical name for this procedure is 'percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia'. 'Epicardial' refers to the outermost membrane of the heart and 'radiofrequency ablation' means using heat energy to remove tissue. The procedure is not described in detail here – please talk to your specialist for a full description.

Ventricular tachycardia is a life-threatening heart condition. It occurs when the electrical impulses controlling the heartbeat become erratic so the hearts beat too quickly. The heart cannot then efficiently pump blood around the body. Ventricular tachycardia, if left untreated, may cause sudden cardiac death. Treatments include medicine to control the heart's rhythm and rate. Surgical procedures, such as inserting an implantable cardiac defibrillator (ICD) (a small device like a pacemaker that's implanted into the patient) and ablation carried out from inside the heart, can be offered to people who have persistent ventricular tachycardia.

The procedure is carried out with the patient sedated or under general anaesthetic. A special thin tube is inserted through the skin and positioned next to the epicardium (the outer layer of the heart wall). X-rays are used to make sure it is positioned properly. Heat is passed to the tip of the tube to break down the parts of the heart muscle where the abnormal electrical impulses are. The patient is given steroids to reduce the risk of inflammation around the heart. Ablation from the inside and outside of the heart may be combined.

What does this mean for me?

The evidence on this procedure is from a small number of patients, but NICE has said that it is safe enough and works well enough for use in the NHS. If your doctor thinks the 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. Your doctor should fully explain what is involved and the risks of potentially serious complications, including damage to the heart muscle. You should only be asked if you want to agree to this procedure after this discussion. You should be given written information, including this leaflet, and be able to discuss it with your doctor before you decide.

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 seven studies on this procedure.

How well does the procedure work?

In three studies involving 35 patients who had the procedure, the abnormal electrical circuits had disappeared in 32 patients within an average of between 14 and 25 months. 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 the main success factors were stopping the ventricular tachycardia, and a reduction in the need for an ICD.

Risks and possible problems

None of the patients died as a direct result of having the procedure. Three died because their heart failure got worse; 1 patient out of 48 died several weeks after the procedure and 2 (out of 20) died within an average of 12 months. In a study of 20 patients, 1 patient developed abnormal connections between an artery and a vein, which needed surgery. Another developed problems with the electrical currents in the heart. In a study of 10 patients, 1 developed a collection of blood in the sac around the heart, and 3 developed inflammation of the sac. In another study, 2 out of 10 patients needed pain relief because of short-lasting pain in the chest.

In the study of 48 patients, the membranes around the heart became inflamed in 3 patients but this was resolved within a week.

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 theoretical problems were puncturing

the heart muscle and stomach; inflammation of the membranes around the heart; perforation of the heart; damage to the coronary artery, throat, lungs and the nerve to the diaphragm, and to vessels and organs in the abdomen.

More information about ventricular tachycardia

NHS Choices (<u>www.nhs.uk</u>) 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.

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 'percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG295

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 N1838).

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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