



Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation

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What has NICE said?

<u>Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation</u> works well enough for use in the NHS, but there are serious, well-known risks associated with this procedure. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

A healthcare team experienced in electrophysiology (diagnosing and treating electrical problems of the heart) and in doing complex <u>ablation procedures</u> should decide which patients should be offered percutaneous endoscopic laser balloon pulmonary vein isolation and should carry out treatment.

NICE is asking health professionals to send information about everyone who has the procedure and what happens to them afterwards to the <u>UK Central Cardiac Audit</u> Database so that the safety of the procedure can be checked over time.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure, and discuss the possible benefits and risks with you. In particular, they should explain the potential complications, the risk of atrial fibrillation returning and the uncertainty about how likely the procedure is to be successful in the short term. You should also be told how to find more information about the procedure. You should only be asked if you want this procedure after having this discussion. Your health professional should ask you if details of your procedure can be collected.

Other comments from NICE

NICE said that most of the evidence is on using this procedure in younger patients and in people with atrial fibrillation that comes and goes.

The condition

Atrial fibrillation happens when the electrical impulses that control your heartbeat become uncoordinated. It causes the heart to beat irregularly and usually too fast. Some people with atrial fibrillation may not have any symptoms, but others may have palpitations, chest pain, dizziness, shortness of breath and tiredness.

Atrial fibrillation can increase your risk of having a stroke. Lowering your risk may include taking drugs to prevent blood clots forming. Other drugs such as anti-arrhythmics or beta-blockers may be used to try and control your heartbeat. If these drugs do not work, or you cannot tolerate them, then ablation procedures may be suitable. Ablation destroys the tissue causing the heart to beat irregularly and stops it causing atrial fibrillation.

NICE has looked at using percutaneous endoscopic laser balloon pulmonary vein isolation as another treatment option.

NHS Choices may be a good place to find out more.

The procedure

Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation aims to maintain normal heart rhythm.

The procedure is done under general anaesthesia or sedation using a laser balloon catheter. The laser balloon catheter consists of a catheter (thin tube) with a small balloon attached, an endoscope (a thin tube with a camera on the end) and an optical fibre that delivers heat energy. The laser balloon catheter is inserted into a vein in the top of the leg (the femoral vein) and guided into the heart. When in place, the balloon is inflated to position the catheter at the opening to one of the pulmonary veins (the veins that carry blood from the lungs to the heart). Laser energy is then applied to each pulmonary vein to isolate the abnormal electrical triggers to the heart.

Benefits and risks

When NICE looked at the evidence, it decided that there was enough evidence to show that percutaneous endoscopic laser balloon pulmonary vein isolation works, although there are some serious, well-recognised complications associated with this procedure. The 9 studies that NICE looked at involved a total of 1,128 patients.

Generally, they showed the following benefits:

- About 60% of patients were drug-free and had no symptoms of atrial fibrillation at 12 months.
- In patients with persistent (permanent) atrial fibrillation, 75% had no atrial fibrillation at 12 months.
- In patients with atrial fibrillation that comes and goes, 75% had no atrial fibrillation at 4 years.

Atrial fibrillation came back within a year of the procedure in up to 28% of patients. Between 6% and 25% of patients needed to have the procedure repeated.

The studies showed that the risks of percutaneous endoscopic laser balloon pulmonary vein isolation included:

- lesions in the oesophagus (gullet) caused by heat damage, in 82% of patients
- moderate narrowing of the pulmonary vein, in 22% of patients
- ulcers in the oesophagus in 10% of patients
- diaphragm paralysis lasting more than 90 days, in 4% of patients

- phrenic nerve paralysis (the phrenic nerves run from the neck to the diaphragm) or injury in up to 4% of patients
- injury to veins or arteries in up to 4% of patients
- fluid collecting around the heart preventing it beating properly in up to 3% of patients
- stroke or transient ischaemic attack ('mini-stroke') in less than 1% of patients.

In 8% of patients a different procedure was needed to correct the abnormal heart rhythms. One patient died suddenly 6 days after the procedure, but this was not related to the procedure.

NICE was also told about some other possible risks: catheter failure needing a minor surgical procedure to remove it safely from the femoral vein.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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Accreditation

