NICE guidance

Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG181.

1 Guidance

1.1 Current evidence suggests that percutaneous occlusion of the left atrial appendage (LAA) is efficacious in reducing the risk of thromboembolic complications associated with non-valvular atrial fibrillation (AF). With regard to safety, there is a risk of life-threatening complications from the procedure, but the incidence of these is low. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out by a multidisciplinary team including a cardiologist and other appropriate clinicians experienced in the management of patients with AF at risk of stroke. Patients should be considered for alternative treatments to reduce the risk of thromboembolism associated with AF, and should be informed about these alternatives.

1.3 Percutaneous occlusion of the LAA is a technically challenging procedure which should only be carried out by clinicians with specific training and appropriate experience in the procedure.

1.4 This procedure should be carried out only in units with on-site cardiac surgery.

1.5 Any device-related adverse events resulting from the procedure should be

reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

2 The procedure

2.1 Indications and current treatments

2.1.1 Atrial fibrillation (AF) is the irregular and rapid beating of the atria. Patients with AF may be asymptomatic or may have symptoms such as fatigue, palpitations, chest pain, shortness of breath and fainting. They also have an increased risk of thromboembolic stroke. In non-rheumatic AF, thrombi largely develop in the left atrial appendage (LAA).

2.1.2 Patients with AF who are considered to be at high risk of thromboembolic stroke are often treated with warfarin anticoagulation therapy. Surgical intervention may involve obliteration of the LAA through an open or thoracoscopic approach.

2.2 Outline of the procedure

2.2.1 Percutaneous occlusion of the LAA is usually carried out with the patient under general anaesthesia. Using fluoroscopic guidance, a catheter is advanced through the femoral vein into the right atrium and then into the left atrium via a transseptal puncture. The location of the LAA is confirmed and the size of the LAA orifice is established by transoesophageal echocardiography (TOE). An appropriately sized device is selected and deployed in the mouth of the LAA where it is expanded to fit the space.

2.2.2 The position and patency of the occlusion device may be confirmed postoperatively using echocardiographic imaging.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more

detailed information on the evidence, see the overview.

2.3.1 A randomised controlled trial (RCT) of 707 patients treated by percutaneous closure of the LAA (n=463) or warfarin (n=244) reported 2.3 and 3.2 all-cause strokes respectively per 100 patient-years (rate ratio 0.71, credible interval [CrI] 0.35 to 1.64).

2.3.2 A case series of 111 patients reported stroke in 2 patients at 173- and 215-day follow-up. TOE at 1 and 6 months revealed a stable device in both patients and no thrombogenic layer on the surface of the device.

2.3.3 Transient ischaemic attack was reported in 2 patients in the case series of 111 patients (not otherwise described).

2.3.4 The RCT of 707 patients treated by the procedure or warfarin reported successful closure in 88% (408 out of 463) of patients randomised to the procedure.

2.3.5 The Specialist Advisers listed key efficacy outcomes as freedom from stroke, and other neurological and cardiac events.

2.4 Safety

2.4.1 Cardiac tamponade requiring median sternotomy, pericardiocentesis and ligation of the LAA occurred 4 hours after the procedure in 1 patient in the case series of 111 patients. The patient later developed deep vein thrombosis and died 27 days after the procedure (attributed to cerebral haemorrhage associated with anticoagulation therapy).

2.4.2 Cardiac arrest 30 minutes after the procedure because of device embolisation was reported in 1 patient, who subsequently died, in a case series of 73 patients.

2.4.3 Device embolisation was reported in less than 1% (3 out of 463) of patients in the RCT of 707 patients: 1 detected during the procedure, and 2 detected on TOE at 45-day follow-up (1 was removed percutaneously and 2 underwent surgery; not otherwise described).

2.4.4 The case series of 73 patients reported that 1 implant required open heart surgery because the device was unstable.

2.4.5 Delivery wire fracture requiring surgical removal was reported in 1 patient in the case series of 75 patients.

2.4.6 The RCT of 707 patients reported pericardial effusion successfully treated surgically or with pericardiocentesis in 5% (22 out of 463), pericardial effusion not requiring drainage in 2% (8 out of 463), oesophageal tear in less than 1% (1 out of 463) and procedure-related arrhythmia in less than 1% (1 out of 463) of patients treated by percutaneous occlusion.

2.4.7 Perforation of the right femoral artery when accessing the right femoral vein and left atrial thrombus at the time of the procedure preventing the implantation of the device was reported in 1 patient each in the case series of 111 patients.

2.4.8 The Specialist Advisers considered theoretical adverse events to include the inability to recover an incorrectly positioned device by endovascular means, so requiring emergency surgery; and persistent atrial septal defect.

2.5 Other comments

2.5.1 The Committee noted that the published evidence included different occlusion devices and were mindful that clinical outcomes may not necessarily be the same with all devices.

2.5.2 The Committee noted that new pharmacological products are in development for use in reducing the risk of thromboembolism associated with AF.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is

described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.