Left Atrial Appendage Occlusion: British Cardiovascular Intervention Society and British Heart Rhythm Society Position Statement

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Abstract

Percutaneous left atrial appendage occlusion aims to reduce the risk of stroke in patients with AF, particularly those who are not good candidates for systemic anticoagulation. The procedure has been studied in large international randomised trials and registries and was approved by the National Institute for Health and Care Excellence in 2014 and by NHS England in 2018. This position statement summarises the evidence for left atrial appendage occlusion and presents the current indications. The options and consensus on best practice for pre-procedure planning, undertaking a safe and effective implant and appropriate post-procedure management and follow-up are described. Standards regarding procedure volume for implant centres and physicians, the role of multidisciplinary teams and audits are highlighted.

Keywords

Left atrial appendage, stroke, AF, anticoagulation, NICE guidance

Received: 20 November 2023 **Accepted:** 13 January 2023 **Citation:** *Interventional Cardiology* 2024;19:e02. **DOI:** https://doi.org/10.15420/icr.2023.42

Disclosure: TRB has received honoraria from Boston Scientific, and is a member of the Clinic Events Committee for Boston Scientific Clinical Trials. PAC has received honoraria from Abbott, and is Chair of the British Cardiovascular Intervention Society Structural Heart Disease Research Group. BC has received honoraria from Abbott Medical and support from Boston Scientific to attend meetings. GJC has received payment for expert reports for coroners' inquests in the UK, is a Data Safety Monitoring Board member for the ORBITA CTO trial, and is honorary secretary of British Cardiovascular Intervention Society. DG has received honoraria from Abbott Medical. DH has received honoraria from Abbott, Boston and Eclipse. JK has received grants and honoraria from Boston Scientific and Abbott Vascular, and is Immediate Past Chair of the ESC Council for Stroke. JDN has received honoraria from Abbott Medical UK. All other authors have no conflicts of interest to declare.

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This joint British Cardiovascular Intervention Society and British Heart Rhythm Society position statement is accompanied by a secondary publication in *Arrhythmia & Electrophysiology Review*, the official journal of the British Heart Rhythm Society (https://doi.org/10.15420/aer.2024.08).

AF is the most common abnormal heart rhythm. It increases the risk of stroke by five times. Percutaneous left atrial appendage occlusion (LAAO) was developed as an alternative to oral anticoagulation. The procedure has been studied in large international randomised trials and registries and was approved by the National Institute for Health and Care Excellence (NICE) in 2014 and NHS England in 2018. There is an underutilisation of LAAO in the UK compared to similar European countries and the USA, with only a few specialist centres, a handful of trained operators and limited referral networks. This British Cardiovascular Intervention Society and British Heart Rhythm Society Position Statement has been drawn up by 10 cardiologists with extensive experience in patient selection and the technicalities of the procedure to help increase therapy awareness and establish standards for best practice. Surgical approaches are not considered in this position statement.

Oral anticoagulants (OACs) are recommended for stroke prevention therapy in patients with AF and a CHA_2DS_2-VASc score of ≥2. Anticoagulation lowers the risk of stroke by two-thirds. Most people can take anticoagulants without complication. However, in a minority, there is a risk of major bleeding with associated morbidity and mortality. Embolic strokes caused by non-rheumatic AF are almost invariably due to left atrial appendage (LAA) thrombus. Therefore, in patients who have relative or absolute contraindications to anticoagulation, an alternative stroke prevention therapy is to occlude the LAA, sealing it off from the circulation.

Evidence

Initial trials randomised patients with AF who were eligible for anticoagulants to either LAAO or OACs. These trials demonstrated non-inferiority of the percutaneous procedure. They also highlighted the need

for experienced operators and good procedural technique. Subsequent prospective registries have focused on patients with contraindications to OACs and have compared observed stroke rates with predicted rates based on the CHA2DS2-VASc score. LAAO was associated with significantly lower stroke rates than predicted.

NHS England's commissioning through evaluation exercise followed 525 patients with contraindications to OACs who underwent LAAO in 10 UK centres and showed a two-thirds reduction in stroke compared to the expected rate, following which NHS England approved the procedure. In 2021 the number of LAAO implants per million population in Germany was >70; in France, Italy and Spain it was 20–30 and in the UK it was <5, with considerable geographic variation.

Indications

Percutaneous LAAO is indicated in individuals with paroxysmal, persistent or permanent AF (unrelated to mitral stenosis), a high risk of stroke (CHA_2DS_2-VASc score ≥2) and a life expectancy of >3 years, who have a relative contraindication to long-term oral anticoagulation, intolerance of OAC or embolic stroke despite OAC.

Pre-procedure

The patient should ideally be seen in clinic by the implanting physician. If distance makes this impractical, the alternative is a phone or video assessment, although this may risk frail patients being inappropriately accepted for the intervention. Patients should be aware that they will need to take a minimum of a single antiplatelet agent for 6 months post-procedure to cover the period of endothelialisation of the device.

The need for pre-procedural imaging of the LAA is debated. Omitting pre-procedural imaging simplifies the process for the patient and limits exposure to radiation, contrast, discomfort and inconvenience. For the operator, knowing the anatomy of the appendage in advance from a CT-scan or transoesophageal echocardiogram (TOE) can be helpful.

Percutaneous LAAO should only rarely be undertaken in patients with LAA thrombus identified on pre-procedural imaging, usually only after a targeted period of anticoagulation has failed to resolve the thrombus.

Procedure

Use of vascular ultrasound to guide access to the right femoral vein is strongly recommended. The procedure is usually performed under general anaesthesia so that TOE can be performed to exclude LAA thrombus, guide transseptal puncture, size the LAA device landing zone and assess device seal and stability. TOE should be undertaken by a dedicated interventional echocardiographer. LAAO can also be performed safely and effectively by experienced operators under light sedation using intracardiac echo (ICE), which may aid procedural scheduling. ICE-guided LAAO is not advised during an operator's first 50 cases. Fluoroscopy-only guided LAAO is inadvisable.

The optimal septal puncture location is usually inferior and posterior. Heparin should be given before transseptal puncture, but otherwise be given immediately after puncture, aiming for an activated clotting time of 250–350 seconds. Particular attention needs to be paid to de-airing of equipment while working in the left atrium, as left atrial pressure may be low in patients who have been nil by mouth in preparation for surgery. IV saline should be given if necessary to ensure a mean left atrial pressure ≥10 mmHg.

Ball-and-engage techniques avoid deep instrumentation of the LAA and may be preferred for some device types. Device sizing varies according to the manufacturer. The device should be opened in the device slowly and deliberately to allow minor adjustments, rather than abruptly. Once the device is deployed, its position, orientation, compression, overhang and seal should all be assessed by echocardiography and fluoroscopy. Stability testing is of uncertain value but forms a part of the instructions for use for some devices.

Post-procedure

Post implant, the patient should be monitored for a minimum of 2 hours with periodic routine observations. Most procedures are now scheduled as day cases. Before discharge, the patient should be assessed for vascular haemostasis and signs of a pericardial effusion. An echocardiogram can be helpful in case of doubt.

Antiplatelet treatment post-procedure ranges from a usual minimum of a single antiplatelet agent for 6 months to a maximum of dual antiplatelet treatment for 3 months followed by a long-term single antiplatelet. In the absence of a secondary reason to continue antiplatelets, these should be stopped after 6 months. Anticoagulant agents should preferably be avoided, as these undermine the rationale for the procedure.

Imaging practice in follow-up varies considerably. No regimen has proven superiority. Many operators arrange a TOE or CT a couple of months after the procedure. However, the value of these tests, other than to comfort the implanter, is not clear. Failure to seal the LAA is rare with good procedural technique. Outside a clinical trial, routine follow-up using CT or TOE is not necessarily recommended.

Stroke during follow-up should prompt urgent imaging of the LAAO device by TOE or CT to assess for possible device-related thrombus. Optimal management of device-related thrombus is uncertain, but most operators offer low-dose anticoagulation for 3 months followed by repeat imaging.

Standards

For best results, implanting centres and individual operators need to concentrate procedural volumes in order to maximise experience. Complication rates should be as low as possible because this is a preventive rather than a therapeutic procedure. Procedures should take place in a cardiothoracic centre to facilitate good immediate access to a range of potential expertise in the event of a serious complication.

Centres need to be commissioned by NHS England in order to be reimbursed for the procedure. All cardiothoracic centres in the UK should provide LAAO as part of a comprehensive regional approach to stroke prevention.

It is not mandatory for a multidisciplinary team (MDT) to discuss patients for possible LAAO. Referrer and operator are rarely, if ever, the same; therefore, the procedure benefits from an inherent multidisciplinary approach in almost all cases. Written advice from an expert in another discipline regarding inadvisability of anticoagulation can act in lieu of the MDT.

An implanting team needs to be proficient with LAA imaging, transseptal access, catheter manipulation in the left atrium and device deployment. LAAO should not be undertaken at the same time as AF ablation outside clinical trials. Familiarity with wide-bore arterial and venous access, snares and vascular closure devices is also required.

Implanting centres should establish a comprehensive referral network to raise awareness of the therapy, educating potential referrers to encourage equity of access. A centre should do a minimum of 25 procedures per year, rising to a minimum of 50 procedures per year after 3 years. An operator should do a minimum of 25 procedures per year, rising to a minimum of 50 procedures per year after 5 years. An operator who is undertaking ≥50 procedures per year can be a trainer to consultant colleagues or fellows. Each centre should have a minimum of one operator and a maximum of four operators.

Operators should be experienced in managing complications, in particular pericardial effusion, device embolisation and femoral vascular problems. Device manufacturers have established training courses which usually include theory, procedural simulation, observation of live cases and proctored implants. Operators should attend established training courses before starting a programme and have on-site proctoring for an initial 5–10 cases. They should maintain exposure to ongoing education at dedicated meetings. Training usually occurs in the setting of a dedicated post-certificate of completion of training fellowship or at consultant level.

Implant data should be recorded locally and submitted nationally for audit. A minimum dataset has been established by the British Cardiovascular Intervention Society, hosted by the National Cardiac Audit Programme. Local activity should be presented at audit meetings at least twice a year.

Conclusion

Percutaneous LAAO is a good treatment option in patients with AF who are unable to take OACs. Provision in the UK is currently very limited and there is significant geographical variation. All cardiothoracic centres in the UK should provide LAAO as part of a comprehensive regional stroke prevention strategy. ❑