



Left atrial appendage occlusion (LAAO) for patients with atrial fibrillation who cannot take anticoagulant medications

What is atrial fibrillation and the left atrial appendage?

Atrial fibrillation is a common heart condition where people have an irregular and often abnormally fast heartbeat. The risk of having a stroke caused by a blood clot blocking a blood vessel in the brain is up to 5 times greater in people with atrial fibrillation.

The left atrial appendage is a small opening off a chamber of the heart called the left atrium. Many blood clots that cause a stroke in people with atrial fibrillation are thought to develop in this atrial appendage.

What is left atrial appendage occlusion (LAAO)?

LAAO is a minimally invasive procedure where a device is used to block the opening of the left atrial appendage (a bit like putting a cork in a bottle). The device is inserted through a large blood vessel in the groin while the patient is sedated or anaesthetised. By blocking the atrial appendage, it is hoped the number of blood clots that go on to cause a stroke will be reduced.

Why is this important?

To reduce the risk of stroke from blood clots in people with atrial fibrillation the normal treatment is with medications called anticoagulants. These drugs prevent the formation of blood clots. However some people with atrial fibrillation cannot take these medications and hence remain at high risk of having a stroke.

What we did

We assessed whether LAAO is safe and effective for reducing stroke risk in people with atrial fibrillation who cannot take anticoagulant medication. We also looked at whether LAAO was good value for money in this patient group.

What we found

None of the studies found compared patient outcomes in two or more groups observed over the same time period. In the studies we identified:

- A stroke caused by a blood clot, or death, occurred shortly after the procedure in 0% to 1% of patients treated with LAAO.
- The rate of strokes caused by a blood clot within 12 months of a LAAO procedure ranged from 0.6% to 6% of patients treated.

Seven studies, with a total of 3,119 patients, compared the number of strokes caused by blood clots in patients in their study with a predicted stroke rate based on published evidence. All seven studies reported reductions in stroke risk in patients treated with LAAO. The degree of reduction ranged from 57% to 84%. There are, however, some concerns about how trustworthy these results are due to the way the studies were conducted.

Adverse events (safety issues) relating to the LAAO procedure and devices include bleeding into the space surrounding the heart, major bleeding (any location), the device coming loose, and blood clots forming on the device. Six studies reported major adverse events, of any type, in 0% to 5.5% of patients treated with LAAO.

A higher volume of LAAO procedures performed at a hospital per year (18 or more) was associated with significant reductions in procedure complications and mortality compared with at hospitals that performed less than 3 procedures per year. Safety also improved with increasing cardiologist experience of performing the procedure.

A UK-based study found that LAAO offered reasonable value for money, with a small per patient cost saving of £70, if the costs were considered from the perspective of both the NHS and social care (where most stroke care occurs). Two studies from other countries found that LAAO was less expensive and more effective than treatment with aspirin.

What SHTG considered when developing advice for NHSScotland

- The LAAO procedure is a preventative procedure that has no immediate benefit for patients. This procedure does, however, present immediate risk to patients from complications which can be serious or even fatal.
- The range of possible complications that can occur during or following a LAAO procedure should be discussed with patients when making decisions about this intervention.
- Patients in Scotland are currently selected for LAAO based on rigorous criteria which should be maintained in future.
- There are currently very few LAAO procedures in Scotland (3 procedures in 2017-2018). These numbers may increase in the future if the procedure is commissioned nationally.
- The committee had reservations about the quality of the research available in the specific patient group of interest (patients with atrial fibrillation who are unable to take anticoagulant medications).

What is our advice to NHSScotland?

LAAO may be offered to patients with atrial fibrillation who are thought to be at high risk of having a stroke caused by a blood clot, and who cannot take anticoagulant medications. Prior to undergoing the LAAO procedure, a team of NHS specialists must carry out a risk assessment for

each individual patient. The potential future benefits of LAAO, the risks associated with the procedure and the need for long-term medication (antiplatelet therapy) should be discussed with each patient prior to making a treatment decision.

The number of LAAO procedures per hospital should be maximised to support optimal patient outcomes and ensure clinical experience of this procedure is achieved and retained.

Future work

Future research (some of which is already underway) should focus on studies comparing LAAO with standard medical therapy in patient groups, observed over the same time period, who cannot take oral anticoagulants.

This plain language summary has been produced based on SHTG Advice 06-19, August 2019