Clinical Commissioning Policy Statement: Left Atrial Appendage (LAA) Occlusion

December 2012

Reference: NHSCB/A10/b
NHS Commissioning Board
Clinical Commissioning Policy Statement: Left Atrial Appendage (LAA) Occlusion

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Prepared by the NHS Commissioning Board Clinical Reference Group for Specialised Cardiology

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**POLICY STATEMENT:**
Left Atrial Appendage (LAA) Occlusion

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| Treatment: | Left Atrial Appendage Occlusion device  
Watchman (Atritech Inc.)  
Amplatzer Cardiac Plug (St Jude Medical) |
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<tr>
<td>For:</td>
<td>The prevention of stroke in patients with atrial fibrillation</td>
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| Background: | Atrial fibrillation (AF) is the irregular and rapid beating of the atria, the upper two chambers of the heart, and is the commonest cardiac dysrhythmia in the UK. AF can lead to haemodynamic instability, to loss of atrial-ventricular synchrony which may produce congestive heart failure, and thromboembolism. Treatment includes drugs to control the heart's rate and rhythm, and cardioversion, which can restore sinus rhythm.  
AF increases the risk of stroke, but this risk can be mitigated with oral anticoagulants such as warfarin. However, usage of these drugs is reduced by contra-indications, dosing problems and difficulties with compliance. Other patients have thromboembolism despite apparently successful anti-coagulation. Aspirin is an alternative to warfarin.  
Occlusion of the left atrial appendage (LAA) is another possible means of reducing the risk of stroke in people with atrial fibrillation.  
AF carries an increased risk of stroke because of the possible embolism of thrombi caused by stasis of blood in the left atrium. In non-rheumatic AF, thrombi form most commonly in the left atrial appendage (LAA), a long tubular hooked structure which has a narrow junction with the main part of the atrium. The LAA appears to be a frequent source of thromboembolism in AF, probably because its structure promotes stagnation of blood in people with AF. There are a number of research reports that support the belief that the LAA is an incubator of thrombus in patients with AF, and |
therefore that its occlusion might reduce the risk of stroke. Percutaneous occlusion of the LAA is intended to close the appendage’s orifice so that thrombus is prevented from escaping into the circulation. It is usually carried out under general anaesthesia. The Watchman device is used most widely. An alternative device is the Amplatzer Cardiac Plug. This clinical commissioning statement covers any LAA occlusion device. NICE has concluded that percutaneous occlusion of the LAA is efficacious in reducing the risk of thromboembolic complications associated with non-valvular AF and that there is a low risk of life-threatening complications from the procedure.¹ The exact place in care pathways of LAA occlusion is not defined, but physicians are likely to consider it in patients at high risk of thromboembolism, especially those in whom anti-coagulation is either contra-indicated or ineffective. The overall aim of LAA occlusion is to prevent strokes so that treatment will improve survival and the quality of life. However, the evidence is not yet of the quality to make a long term judgment that the benefits of LAA occlusion outweigh the risks and / or that it is good value in the context of the provision of NHS services.

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<th>Commissioning position:</th>
<th>Left Atrial Appendage (LAA) occlusion devices for stroke prevention in people with atrial fibrillation will not be routinely commissioned and funded as the published data fails to show sufficient benefit for patients or good value for the NHS.</th>
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<td>Effective from:</td>
<td>1 April 2013</td>
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<td>Evidence Summary:</td>
<td>The prevalence of AF is about 8 per 1,000 and is somewhat higher in men. It is predominantly a disease of the elderly; its prevalence increases from about 0.5% at age 50 to 59 years to almost 9% at age 80 to 89 years. The annual incidence of stroke in people with AF is about 4%. Cardio-embolic strokes tend to be more serious than those with other causes: 64% of patients are dead or severely disabled twelve months after their event. There is evidence to support the idea that the LAA can be a source of thromboembolism in patients with AF: In 272 patients with non-rheumatic atrial fibrillation, nineteen (7%) had atrial thrombi detected by trans-oesophageal echocardiography, of whom sixteen had thrombus detected in the LAA and the remaining three had it detected at the</td>
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appendage’s orifice. A study of 24 people with atrial flutter reported that five (21%) had intra-atrial thrombus, all in the LAA. Patients with larger LAAs at surgery were more likely to have had an embolism. Low peak LAA filling and emptying velocities were reported as more common in those with a history of systemic embolism. Larger and more mobile thrombus has been associated with increased risk of thromboembolism.

Taken together, these reports support the belief that the LAA is an incubator of thrombus in patients with AF, and therefore that LAA occlusion might reduce the risk of stroke.

A randomised, controlled trial (PROTECT AF) reports that LAA occlusion with initial warfarin, followed by six months of clopidogrel and indefinite aspirin, is more hazardous than treatment with warfarin, and that there are no significant differences between these approaches in prophylaxis against thrombo-embolism and stroke. Procedure results improve with operator experience.

PROTECT AF indicates that there is little benefit from LAA occlusion followed by the drug regime used in that trial compared with warfarin, in people who are at moderate risk of stroke. It would be useful to compare the approach with other control treatments, such as aspirin and dabigatran, and in other risk categories. There are some concerns about the study design.

The available evidence does not greatly assist in the identification of patients for LAA occlusion. No studies were found comparing results of the treatment in different categories of patient, such as different risks of stroke or different reasons for unsuitability for warfarin. However, trials in progress may assist with this.

No health economic studies were found. It is difficult to estimate the cost-effectiveness of LAA occlusion because of the limited follow-up in the PROTECT AF trial and the uncertain costs associated with long-term warfarin in this group.

The main RCT in this area fails to demonstrate that the LAA occlusion device involved is better than the alternative therapies. The study design may mean that the device has worse outcomes than the usual therapy. Therefore the clinical effectiveness and the cost effectiveness are not established and there is the possibility of more harm than good to any patients receiving the device.

**Equality Impact:** The NHS Commissioning Board (NHS CB) is committed to ensuring equality of access and non-discrimination, irrespective of age, disability, gender reassignment, marriage
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In carrying out its functions, the NHS CB will have due regard to the different needs of different protected equality groups. This applies to all the activities for which they are responsible, including policy development, review and implementation.

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<th>Responsible CRG:</th>
<th>Specialised Cardiology CRG</th>
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<td>Date approved by NHS CB Clinical Assurance Group:</td>
<td>September 2012</td>
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<td>Date approved by NHSCB Board:</td>
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<td>Policy review date:</td>
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References


8. Solutions for Public Health (SPH), and Bazian. Occlusion of the left atrial appendage to prevent stroke in people with atrial fibrillation. Evidence review Commissioned by the National Specialised Services Transition Team (NSSTT) in England. September 2012.

Additional references

