Nine-year, single-centre experience of left atrial appendage occlusion: patient characteristics, procedural outcomes and long-term follow up

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Abstract

This is a review of 114 patients with atrial fibrillation who had left atrial appendage occlusion with an Amplatzer cardiac plug over a nine-year period done by a single operator. This shows that the procedure can be safely performed with a very low rate of major complications (< 1%) and a zero procedural mortality rate. Long-term follow up over an average of 38.5 months showed a 65% reduction in actual versus predicted stroke rate. This is similar to that seen with oral anti-coagulants and other published trials and registries involving left atrial appendage occlusion.

Keywords: atrial fibrillation, left atrial appendage occlusion, Amplatzer cardiac plug, Amulet

Methods

All patients were prospectively entered into a database after informed consent was obtained. Patient follow up to 31 March 2020 was done either at a recent out-patient examination or telephonically. Those patients who were lost to follow up by 31 March 2020 were excluded.

The first patient was enrolled in mid-November 2010. All patients, except two who had a Watchman device (Boston Scientific) implanted, had an Amplatzer (Abbott Vascular) device implanted. The first 40 patients received the Amplatzer cardiac plug (ACP I) and thereafter the Amulet device (ACP II).

All procedures were done under general anaesthetic with transoesophageal echocardiogram (TOE) guidance by one of only two TOE operators. Almost all patients had no pre-procedural TOE to look for left atrial appendage (LAA) thrombus and anatomical suitability for device-based occlusion. If patients were on OACT, this was stopped a few days earlier.

As soon as the patients were awake and able to swallow, aspirin 300 mg and clopidogrel 600 mg oral loading doses were given. Patients were observed in cardiac high care overnight and were discharged home the next day following trans-thoracic echocardiogram (TTE) confirming the LAA device was in situ and there was no pericardial effusion. All patients were discharged on aspirin 75–100 mg and clopidogrel 75 mg daily unless contra-indicated.

All patients were seen at 30 days follow up for TTE to confirm the device was in situ. Clopidogrel was stopped at one month and aspirin alone was continued indefinitely if there were no contra-indications. Thereafter, patients were either seen...
routinely on a six- or 12-month basis by the operator or referred back to the referring physician. No patients had a routine post-procedural TOE at follow up.

Results

A total of 131 patients were admitted to the cardiac catheterisation theatre for LAAO device implantation and 122 (93%) had a successful device implantation over the 112 months. In nine patients, the procedure was abandoned due to the presence of an LAA thrombus, inability to pass the TOE probe, the LAA was too large for the largest available device, or the anatomy was deemed unsuitable to safely release the device. In only three cases was a device actually opened and not deployed, giving an implant success rate of 97.6% (122/125).

Eight patients were lost to follow up between 30 days and three years post procedure. The remaining 114 patients were followed up to the end of March 2020 or had died, giving complete data on 93.4% of patients who had had a device implanted (Fig. 1).

The average age of patients was 74.2 years (range 51–87; SD 8.1; median 75) and the average length of follow up was 38.5 months (range 1.2–111.5 months; SD 26.8; median 35.7); 75% were male. The average CHADS2-VASc score was 3.9 (SD 1.2; median 4) and HAS-BLED score was 2.99 (SD 0.95; median 3) (Table 1).

There was one major complication (<1%). An Amulet device embolised to the descending aorta shortly after its release and was successfully removed percutaneously via the right femoral artery. However, the patient did sustain radiation burns due to the complexity of retrieving the device. There were no deaths, pericardial effusions requiring aspiration or strokes.

There were nine minor complications, including one pericardial effusion seen at seven days, which was treated conservatively as the patient was haemodynamically stable with no evidence clinically or on TTE of cardiac tamponade. Seven patients had a minor bleed from the femoral vein puncture site that required a superficial skin suture to be placed post procedure. One patient had a TIA during a difficult procedure due to very awkward anatomy of the LAA. The procedure was eventually abandoned as the anatomy was deemed unsuitable for LAA closure (Table 2).

In 71% (81) of patients, OACT was contra-indicated due to a previous life-threatening bleed, while 9% (10) had a high bleeding risk (HAS-BLED score > 3). In 20% (23) of patients, LAAO was indicated due to a combination of frailty not measured on HAS-BLED, repeated falls or lifestyle choice. Previous stroke or transient ischaemic attack (TIA) had occurred in 23% (26) of patients (Table 1).

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There were no significant leaks (> 5 mm) past the device. If a significant leak was seen on either TOE or left atrium angiogram immediately after device deployment, the device was either redeployed in a different position or the device size was changed.

One hundred and twenty patients (96%) were discharged on dual antiplatelet therapy (DAPT) for one month, and thereafter reduced to low-dose aspirin only. Five patients were discharged on aspirin only. The average length of hospital stay was 1.1 days (one to six days).

A total of 35 (30.7%) patients died during the follow-up study period (average of 2.5 years post procedure), ranging from 96 days post procedure (primary amyloidosis not previously diagnosed)
to 2,700 days (seven years five months at the age of 86 years). There were six strokes (5.3% of total or 1.7% per year). The average CHADS2-V AS score was 4, and four patients died due to the stroke or consequences thereof. The majority of patients died from cardiovascular causes (heart failure, myocardial infarction, sudden cardiac death), cancer, renal failure and complications arising from a fall. Three patients had a TIA.

There were 10 major bleeding events (8% or 2.8% per year). Two occurred while on DAPT soon after the procedure, resulting in the withdrawal of clopidogrel, while eight occurred while on aspirin only, resulting in cessation of all antiplatelet therapy. In total, 17 patients (14.9%) were on no antiplatelet therapy at long-term follow up. None of these patients had an embolic event. At the last follow up, 97.4% of the patients were on single (82.5%) or no antiplatelet therapy (14.9%) (Table 3).

Discussion

This single-centre registry of LAAO using almost exclusively the Amulet device is in line with previously published registries of LAAO but has a longer period of follow up than most registries and trials.14-17

The indications for LAAO, age of the patients, and CHADS2-V AS and HAS-BLED scores are very similar to other registries. Currently, almost all patients receiving LAAO have a relative or absolute contra-indication for OACT, with very few patients either refusing OACT or not having it because of a lifestyle choice due to high-risk activities. The current 2016 ESC guidelines list LAAO as a class 2b indication procedure.1

There were six strokes (stroke incidence 5.3%; 1.7% per year) documented during follow up, with four fatalities (Fig. 2). These occurred between six months and four years after LAAO implantation (average 2.6 years). All these patients were on low-dose aspirin only at the time of the stroke. The predicted stroke rate per year according to a CHADS2-V AS score of 3.9 is 4.8%. This represents a 65% stroke risk reduction. This is in keeping with other published registries and trials on LAAO showing equivalence with warfarin2,3 and the newer direct OACT.16-17 There were three TIAs and no other documented thrombo-embolic (TE) events. (TE incidence was 7.9%; 2.5% per year). The predicted TE risk was 6.7%, equating to a 63% risk reduction.

There was no routine use of TOE at six to 12 weeks post device implant as there is currently no clear evidence linking the presence of device-related thrombus (DRT) and systemic embolic events.4-5 Furthermore, starting patients on OACT to manage DRT carries significant risk in this particular group of patients in whom OACT was contra-indicated in over 80% of patients.

Only two of the six stroke patients were managed at our hospital. Both had a TOE post stroke. No DRT was seen in either patient. One patient who presented with a small stroke at three months post LAAO implantation was subsequently found to have a severe ipsilateral internal carotid artery stenosis, which was successfully stented. A year later, he suffered a further small stroke and TOE showed the Amulet device had shifted slightly and was partially protruding from the LAA orifice. Although no DRT was seen, the patient was started on lifelong OACT and remained well three years later.

A further patient who had a TIA a year post LAAO was found to have a significant patent foramen ovale (PFO) on TOE. There was no device-related thrombus, and the device was well seated and fully endothelialised. The PFO was subsequently closed percutaneously.

The overall mortality rate was 30.7%, however, this is not unexpected for this population of patients with AF who were elderly (average age 74 years; SD 8.1), had multiple co-morbidities (CHADS2-V AS 3.9), and were followed up for a prolonged period of time (3.2 years; SD 2.17). The expected mortality rate in patients with AF is two to four times higher than the average population and worsens as the CHADS2-V AS score increases.6-13 The majority of patients died from cardiovascular causes or malignancy, which is in keeping with reported literature.

Limitations of this study include a single-centre, single-operator registry with a limited number of patients enrolled. Eight patients were lost to follow up and were not included in this registry. Not all patients were followed up by the operator and it is possible some embolic events were not reported.

Conclusion

This single-centre registry showing follow up over a prolonged period of time confirms the efficacy of LAAO as an acceptable alternative to OACT.

References


