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CASE REPORT
Electrophysiology

Case report: peri-device leakage after percutaneous left atrial appendage occlusion: plug, clip, or amputate?

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Background Although peri-device leakage is frequently observed after left atrial appendage occlusion (LAAO), there is no consensus on the optimal management strategy. It is unknown whether additional plugging should be preferred over surgical exclusion of the LAA, as experience with additional plugging is limited.

Case summary In this case report, we demonstrate the clinical implications of additional plugging and surgical exclusion in a 65-year-old male patient with peri-device leakage and recurrent thromboembolic events. After the recurrence of paroxysmal atrial fibrillation (AF) and a transient ischaemic attack despite adequate anticoagulation, the patient was opted for re-do pulmonary vein isolation and LAAO with a Watchman device. Due to multiple ischaemic strokes and recurrent AF in combination with significant peri-device leakage, additional plugging with a second device was performed. Post-procedurally, the patient had another ischaemic stroke and persisting peri-device leakage was observed during follow-up. Due to progressive symptoms of AF and patient's preference to discontinue DOAC, he underwent a Cox MAZE IV procedure, including amputation of the LAA with both devices. Within six months after surgery, the patient experienced two more ischaemic events. In the following two years, the patient remained free of any cerebrovascular accidents or recurrence of AF.

Discussion Additional plugging of peri-device leakage is not always successful in stroke prevention. In combination with recurrent AF, progressive symptoms, contraindication for oral anticoagulation, and patient's preference, surgical LAA exclusion could be preferred over additional plugging.

Keywords Peri-device leakage • Left atrial appendage occlusion • Atrial fibrillation • Stroke • Case report

ESC Curriculum 5.3 Atrial fibrillation • 7.5 Cardiac surgery

Learning points

- Additional plugging of peri-device leakage is not always successful in stroke prevention.
- In combination with recurrent atrial fibrillation, progressive symptoms, contraindication for oral anticoagulation and patient's preference, surgical left atrial appendage exclusion could be preferred over additional plugging.

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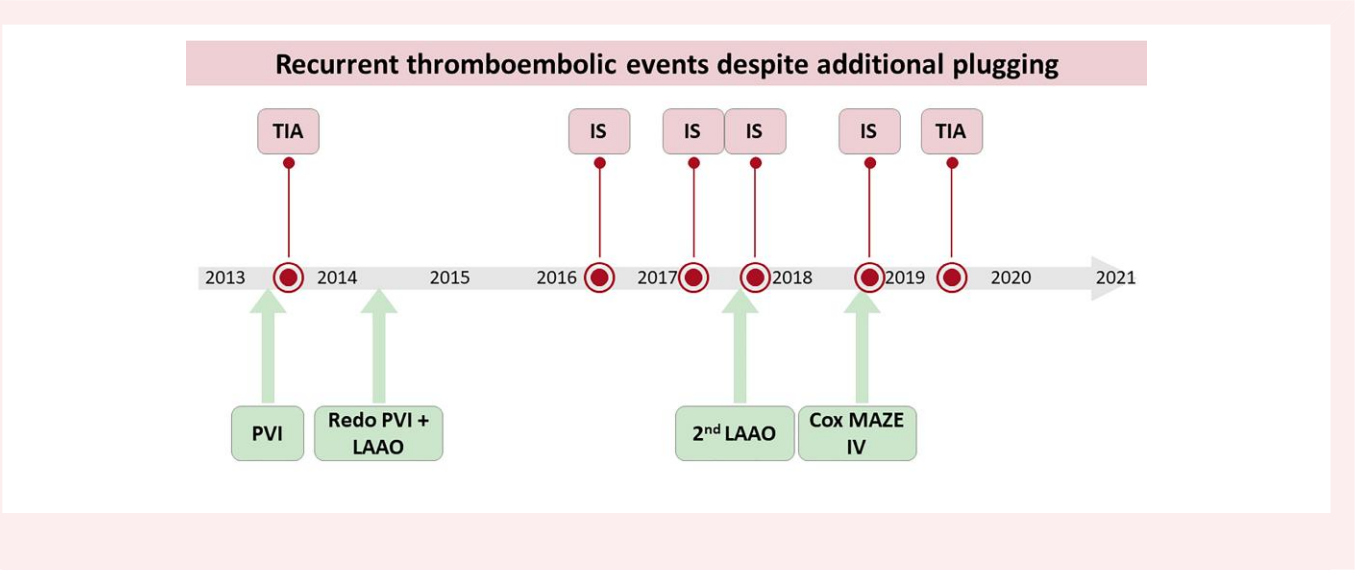
Introduction

Percutaneous left atrial appendage occlusion (LAAO) is indicated for stroke prevention in patients with atrial fibrillation (AF) and contraindications for long-term oral anticoagulation (OAC).[1] Although peri-device leakage is frequently observed after LAAO, there is no consensus on the optimal management strategy. Additional plugging is an option, but its clinical significance in stroke prevention has only been scarcely reported.[2,3] In addition, it is unknown whether additional plugging should be preferred over surgical exclusion of the left atrial appendage (LAA). In this case report, we demonstrate the clinical implications of additional plugging and surgical exclusion in a patient with peri-device leakage and recurrent thromboembolic events.

Timeline

Timeline describing interventions and thromboembolic events. IS, ischaemic stroke; LAAO, left atrial appendage occlusion; PVI, pulmonary vein isolation; TIA, transient ischaemic attack.



Case report

A 65-year-old Caucasian male, with a history of paroxysmal AF (pAF), hypertension, hyperlipidaemia, and chronic obstructive lung disease (CHA_2DS_2-VAS_c score 2), was referred for percutaneous pulmonary vein isolation (PVI) in 2013. Timeline illustrates the interventions and thromboembolic events in this patient. Upon admission, there were no other significant findings during cardiovascular physical examination except for aforementioned cardiovascular history. After the initially successful PVI, the patient was treated with acenocoumarol (target INR: 2.0–2.5) for anticoagulation. Due to the recurrence of pAF and a transient ischaemic attack (TIA) despite adequate anticoagulation therapy (INR = 2.1), the patient was opted for re-do PVI and LAAO with a Watchman device (21 mm). Three months after the initial PVI, patient was admitted again for this procedure. One day prior to the procedure, acenocoumarol was stopped and low-molecular-weight heparin (100 mg/day) was started (INR = 1.4). Pre-procedurally, we assessed whether LAA anatomy was suitable for LAAO by taking a CT scan of the heart and performing TEE (made during the previous PVI) (*Figure 1*). Peri-procedurally, we ensured optimal occlusion of the LAA with TEE and angiography. Post-procedurally, the patient was maintained on (initially) heparin (target range APTT: 50–70 s) (until INR > 2.0), aspirin (80 mg/day), and acenocoumarol (target INR: 2.0–3.0). At three months of follow-up, transoesophageal echocardiography (TEE) showed less than 3 mm peri-device leakage (*Figure 1*), which was considered as successful LAAO. Subsequently, the patient was maintained on clopidogrel (75 mg/day) and aspirin (80 mg/day). According to the guideline recommendations, the patient used after three months only aspirin (80 mg/day).[1]

In the following years, the patient had two more ischaemic strokes and multiple AF recurrences. The first stroke occurred two years after LAAO. Consequently, the patient switched from aspirin to clopidogrel (75 mg/day). One year later, the patient experienced a second stroke, and was maintained on dabigatran (300 mg/day) afterwards. We performed a TEE one week after this stroke and it showed a significant increase in peri-device leakage of more than 7 mm (*Figure 1*). In addition, other reasons for stroke, such as significant atherosclerosis in intra and/or extra cranial artery, were ruled out on CT. We also investigated if the patient had any coagulation defects, which he did not have. Consequently, there were three options for management of the leakage: 1) lifetime direct OAC (DOAC), 2) additional percutaneous closure with a second device, or 3) surgical clipping or amputation of LAA. Because the patient experienced many side-effects, including nausea, vomiting, and diarrhoea, from DOAC use (dabigatran, apixaban, and rivaroxaban), he underwent percutaneous closure with a second device (Amplatzer vascular plug 2) (12 mm). One day prior to the procedure, DOAC (rivaroxaban) was stopped and aspirin (80 mg/day) was started. Peri-procedurally, the peri-device leakage seemed to be successfully treated with additional plugging.

On the first post-procedural day, the patient had another ischaemic stroke, while using clopidogrel (75 mg/day) and rivaroxaban (20 mg/day). At one month follow-up, persisting peri-device leakage (4 mm) was observed on TEE (*Figure 1*). In addition, the patient developed an amiodarone-induced hyperthyroidism. The patient also experienced persisting side-effects from DOAC use and preferred to discontinue it. Due to progressive symptoms of AF after discontinuation of amiodarone and

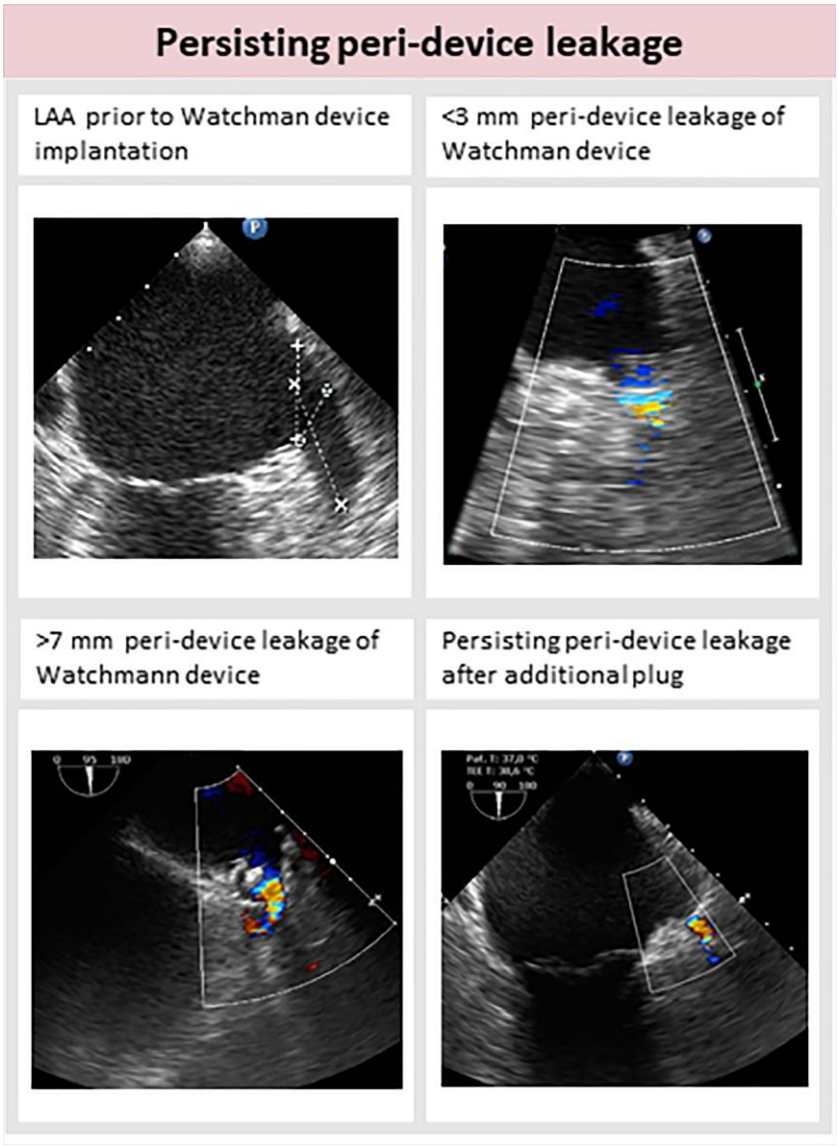


Figure 1 Peri-device leakage. Left panel: transoesophageal echocardiogram with colour Doppler showing <3 mm peri-device leakage of Watchmann device at 3 months follow-up. Middle panel: transoesophageal echocardiogram with colour Doppler showing >7 mm peri-device leakage of Watchmann device at 2-year follow-up. Right panel: transoesophageal echocardiogram with colour Doppler showing persisting peri-device leakage after additional implantation of a second device (AVP 2) at 1-month follow-up.

patient's preference to discontinue DOAC, the patient underwent a Cox MAZE IV procedure, including amputation of the LAA with both devices. Three days prior to surgery, the patient stopped with rivaroxaban and continued with aspirin (80 mg/day). Intraoperatively, examination of the LAA showed no signs of clots, complete endothelialization of the Watchman device and a device-LAA ostium mismatch of approximately 4 mm. Post-operatively, the patient was maintained on (initially) heparin (0.3 mL/day), acenocoumarol (target INR: 2.5–3.5), and aspirin (80 mg/day). On the first post-operative day, the patient developed right-sided paresis which was attributed to recurrent ischaemia of the left hemisphere, which recovered within the next month. In the following weeks, heparin was stopped, and the patient remained on clopidogrel (75 mg/day) and acenocoumarol (target INR: 2.5–3.5). After three months, only acenocoumarol was continued. Six months after the surgery, the patient had again a TIA. In the following two years, the patient remained free of any cerebrovascular accidents or recurrence of AF.

Discussion

Peri-device leakage is common because of discrepancy in size and shape between the LAA ostium and the Watchman device. The Watchman device is only available in a few sizes and has a round shape unlike the oval LAA ostium. Recognition of this inevitable mismatch, ≥ 3 mm width of peri-device flow was defined as significant peri-device leakage.[4] In a subanalysis of the PROTECT-AF study, percutaneous closure of

the LAA with the Watchman device was compared with warfarin therapy in patients with AF. At 12 months follow-up, TEE showed that 32% ($n = 125$) had peri-device leakage, of whom 36.8% ($n = 46$) had significant (≥3 mm) peri-device leakage.[5] Peri-device leakage was not associated with an increased risk of thromboembolism, but the low event rate limited the power of this outcome (18 events per 642 patient-years vs. 9 events per 450 patient-years). Interestingly, we observed that the peri-device leakage increased over time, from being non-significant at three months follow-up to more than 7 mm at two years follow-up after LAAO. The risk of thromboembolism from these increasing peri-device leakages are unknown and may be more important than stable peri-device leakages.

At present, clinical consequences of additional plugging for peri-device leakage has only been demonstrated in small case series, where none developed stroke after follow-up of only six months.[2,3] We report the first case in which stroke could not be prevented with additional plugging of the leakage. As additional plugging is not always successful in treating peri-device leakage, patients are faced with a life-long use of DOAC. This possible consequence is an important consideration in patients who experience severe side-effects of DOACs. In such scenarios, surgical LAA exclusion could be a desirable alternative for treating peri-device leakage.

Surgical LAA exclusion is proven to be a safe and successful strategy for stroke prevention.[6] Surgical LAA exclusion also introduces the possibility for concomitant AF surgery, which could be preferred to further reduce the risk of cerebrovascular accident and improve quality of life. In addition, surgical LAA exclusion itself is considered to have anti-arrhythmic properties as it creates electrical isolation and may also reduce susceptibility to AF. To date, no large study has been performed on the outcomes of surgical exclusion after peri-device leakage.

A novel treatment option for peri-device leakage is thoracoscopic LAA clipping (with AF surgery). Surgical LAA exclusion by thoracoscopic clipping has several advantages: 1) less invasive, 2) more successful closure rate than percutaneous LAAO and 3) electrical isolation of the LAA.[7] Recently, Kougioumtzoglou et al. showed in a case series that thoracoscopic clipping over a closure devise is feasible and safe.[8] We could have also chosen to perform this procedure, however this would have precluded complete electrical isolation of the LAA as the clip is placed distally from the device(s).

In this case report, recurrent thromboembolic events occurred after both additional plugging and surgical LAA exclusion. Peri-device leakage is likely to be the major underlying cause for this after additional plugging, as it was still present on TEE. The recurrence of thromboembolic events even after surgical LAA exclusion should remind us that there are also other reasons for recurrent embolism, located outside the LAA, and perhaps also unrelated to AF.

Conclusion

Additional plugging of peri-device leakage is not always successful in stroke prevention. In combination with recurrent AF, progressive symptoms, contraindication for OAC and patient's preference, surgical LAA exclusion could be preferred over additional plugging. Future randomized controlled trials are required to investigate the superiority of surgical exclusion (i.e. thoracoscopic clipping) in preventing thromboembolic events (and recurrence of AF) in patients with peri-device leakage.

Lead author biography

Ramdat Misier is a PhD candidate at Erasmus Medical Center in Rotterdam, the Netherlands. His research projects are aimed at unravelling the pathophysiology of complex cardiac tachyarrhythmias, particularly in patients with congenital heart disease. In addition, he has a keen interest in (paediatric) cardiac surgery and clinical electrophysiology.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The authors confirm that written consent for submission and publication of this case report, including images and associated text, has been obtained from the patient in line with COPE guidelines.

Conflict of interest: None declared.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

References

1. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC Jr, *et al.* 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American college of cardiology/American heart association task force on clinical practice guidelines and the heart rhythm society in collaboration with the society of thoracic surgeons. *Circulation* 2019;**140**:e125–ee51.
2. Hornung M, Gafoor S, Id D, Vaskelyte L, Hofmann I, Franke J, *et al.* Catheter-based closure of residual leaks after percutaneous occlusion of the left atrial appendage. *Catheter Cardiovasc Interv* 2016;**87**:1324–1330.
3. Suradi HS, Park J, Poulin M-F, Kavinsky CJ. Case report: percutaneous closure of residual leak following left atrial appendage occlusion. *Eur Heart J Case Rep* 2020;**4**:1–4.
4. Holmes DR, Reddy VY, Turi ZG, Doshi SK, Sievert H, Buchbinder M, *et al.* Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet* 2009;**374**:534–542.
5. Viles-Gonzalez JF, Kar S, Douglas P, Dukkipati S, Feldman T, Horton R, *et al.* The clinical impact of incomplete left atrial appendage closure with the watchman device in patients with atrial fibrillation: a PROTECT AF (percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation) substudy. *J Am Coll Cardiol* 2012;**59**:923–929.
6. Whitlock RP, Belley-Cote EP, Paparella D, Healey JS, Brady K, Sharma M, *et al.* Left atrial appendage occlusion during cardiac surgery to prevent stroke. *N Engl J Med* 2021;**384**:2081–2091.
7. van Laar C, Verberkmoes NJ, van Es HW, Lewalter T, Dunnington G, Stark S, *et al.* Thoracoscopic left atrial appendage clipping: A multicenter cohort analysis. *JACC Clin Electrophysiol* 2018;**4**:893–901.
8. Kougioumtzoglou AM, Smith T, Swaans MJ, Boersma LVA, van Putte BP. Thoracoscopic left atrial appendage clipping as novel treatment option for peri-device leakage. *EP Europace* 2018;**20**:955.