

Left atrial appendage closure device complicated by late-onset pericardial effusion and tamponade: a case report

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Received 24 August 2020; first decision 15 October 2020; accepted 4 February 2021

Background

Late-onset complications of left atrial appendage occlusion (LAAO) device procedure are anecdotal and there are no such complications reported in literature using Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA).

Case summary

We report the case of a 74-year-old Caucasian man affected by paroxysmal atrial fibrillation with significant bleeding risk (familiar thrombocytopenia, macroscopic haematuria episodes during therapy with direct oral anticoagulants, HAS-BLED risk score: 4) and ischaemic risk as well (CHADSVASC score: 3). The patient was treated with LAAO device implantation for high bleeding risk. Subsequently, after 26 days from LAAO procedure, he was admitted to the emergency department for haematic cardiac tamponade. The patient was successfully treated with subxyphoidal pericardiocentesis in the acute phase, unfortunately cardiac arrest occurred during the transfer to the referral hospital for urgent cardiac surgery. Permanent neurological damage was reported and the patient died on day 28.

Discussion

LAAO late-onset complications are very rare and the case presented is the first case described of late-onset pericardial effusion and tamponade secondary to the Cardia Ultraseal LAAO device implantation. We present a revision of the literature regarding the occurrence of similar adverse events and discuss the hypothetical mechanism of this major complication.

Keywords

Left atrial appendage occluder • Atrial fibrillation • Pericardial effusion • Case report

Learning points

- To show a rare late-onset complication of the Ultraseal device characterized by cardiac tamponade.
- To highlight major differences of device geometry and implantation details that may be related to the occurrence of complications.
- To understand the importance of strict follow-up of patients treated with left atrial appendage occlusion device.

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Handling Editor: David Duncker

Peer-reviewers: Rami Riziq Yousef Abumualeq and Robert Schönbauer

Compliance Editor: Link Ngo

Supplementary Material Editor: Aiste Monika Jakstaite

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Introduction

Left atrial appendage occlusion (LAAO) is an interventional procedure that should be considered for stroke prevention in patients presenting non-valvular atrial fibrillation and high bleeding risk, with contraindications to chronic oral anticoagulant therapy. The early (≤ 7 days) complications rate reported in retrospective registries ranges between 1.8% and 5%, pericardial effusion represents the most frequent peri-procedural complication (1.9–2.6%).¹ However, there is anecdotal evidence on late complications, especially regarding late-onset pericardial effusion.

(Figure 1A–D). LAAO intervention was TOE guided and it was performed with moderate sedation (midazolam), 8000 UI of heparin were administered after trans-septal puncture. The procedure was carried out through right femoral access using a 11-Fr delivery sheath and a Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) 22 mm (disc diameter 28 mm) device was successfully implanted (Figure 2A). The early echocardiographic control did not report any device-related abnormality or any residual leak (Figure 2B). The hospital course was uneventful and the patient received a dual antiplatelet therapy (clopidogrel 75 mg o.d. and aspirin 100 mg o.d.) after discharge. We also scheduled the patient for a 1-month reassessment with platelet count and TOE.

Timeline

Day 1	The left atrial appendage occlusion intervention was carried out through right femoral access using a 11-Fr delivery sheath and Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) 22 mm (disc diameter 28 mm) device was successfully implanted.
Day 3	Absence of pericardial effusion at hospital discharge.
Day 26 11 a.m.	Access to the emergency department for acute interscapular pain: vital signs [blood pressure (BP) 113/70 mmHg, SO ₂ 97%, heart rate 104 b.p.m., Glasgow Coma Scale (GCS) 15, T 35.3°] evidence of pericardial effusion and sudden onset of haemodynamic impairment (BP 80/60 mmHg) with cardiac tamponade detection at transthoracic echocardiography scan. Chest computed tomography (CT) with contrast agent, performed before haemodynamic impairment, does not detect active bleeding. Platelet count was 107 000 units/mL.
Day 26 12 a.m.	An ultrasound-guided pericardiocentesis drained out 500 mL of haematic effusion and a drainage catheter was placed.
Day 26 4 p.m.	During the transfer to our referral hospital for urgent cardiac surgery, in the ambulance, an episode of ventricular tachycardia evolving suddenly in ventricular fibrillation alternating with pulseless electrical activity occurred and prolonged cardiac resuscitation was required. In specific 30 min of cardio-pulmonary resuscitation (CPR) was performed using a total of 8 mg of epinephrine, 300 mg of amiodarone with the occurrence of ventricular fibrillation treated firstly with 200 J shock, ineffective, subsequently 360 J shock was provided with the restoration of sinus rhythm at the second attempt, meanwhile 150 mL of haematic pericardial effusion were actively drained out.
Day 26 6 p.m.	At the surgery department admission, the patient was stable and presented only a small pericardial effusion without compression of the right heart chambers as assessed by a new CT scan.
Day 28	Despite the early treatment, neurological conditions were irreversibly compromised and the patient died with no more tamponade recurrences.

Case presentation

A 74-year-old Caucasian male patient (weight: 80 kg, height: 173 cm), with hypertension, moderate carotid vascular atherosclerosis, and familiar thrombocytopenia (mean platelets count: 55 000 units/mL), presented at our outpatient office for dyspnoea. The clinical evaluation detected a paroxysmal non-valvular atrial fibrillation (CHADSVASC score: 3). The patient firstly received Warfarin therapy and then a direct oral anticoagulant for labile international normalized ratio (INR) was started. However, based on a history of macro haematuria, thrombocytopenia and an estimated HAS-BLED risk score of four, we identified the patient as a potential candidate to LAAO, in order to prevent subsequent bleeding events, following European Society of Cardiology (ESC) 2020 guidelines of atrial fibrillation management.²

A transoesophageal echocardiography (TOE) study assessed the feasibility of LAAO procedure, documented a 'chicken wing' left atrial appendage (LAA) morphology, and excluded any luminal thrombosis

After hospital discharge, no physical accident occurred to the patient, however unexpectedly, 26 days after the percutaneous intervention, the patient acceded to our emergency department complaining of dorsal inter-scapular pain. A computed tomography (CT) scan and a transthoracic echocardiography study ruled out aortic dissection, but detected a circumferential pericardial effusion of maximum 22 mm (Figure 3). No active bleeding was demonstrated after contrast administration. Even though haemodynamically stable at presentation, the patient entered the intensive cardiac care unit. In the first hours after admission, morphological and Doppler signs of cardiac tamponade suddenly occurred. An ultrasound-guided subxyphoidal pericardiocentesis drained out 500 mL of haematic effusion and a drainage catheter was placed. During the transfer to our referral hospital for urgent cardiac surgery, an episode of ventricular tachycardia evolving suddenly into ventricular fibrillation occurred and prolonged cardiac resuscitation was required, meanwhile 150 mL of haematic pericardial effusion were actively drained out. The advanced cardiac life support protocol restored the sinus rhythm.

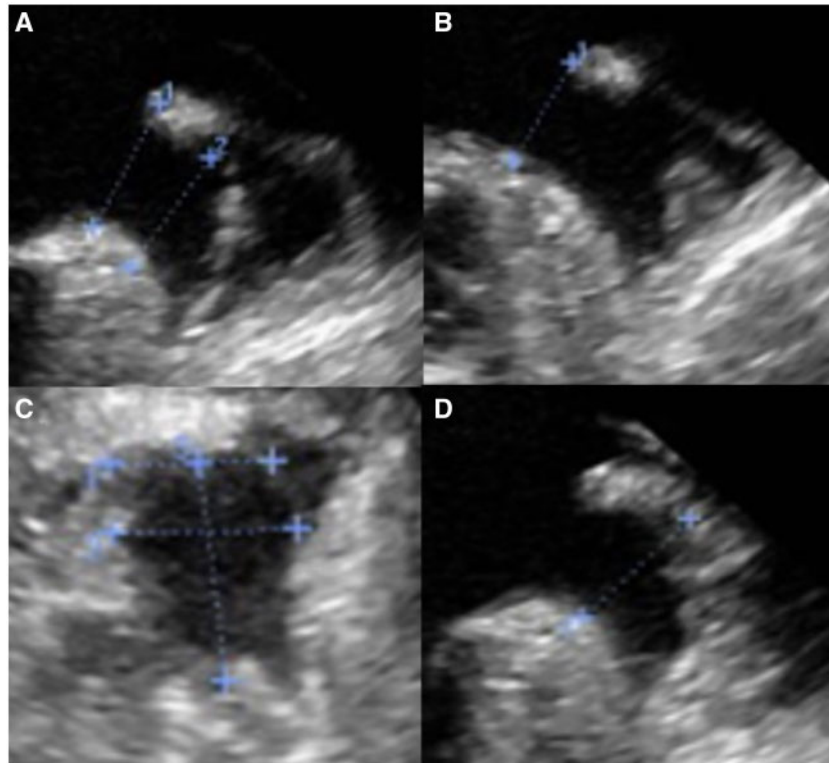


Figure 1 Transoesophageal echocardiography. (A) 70° mid-oesophageal view (1A: 19 mm; 2A: 18 mm); (B) 45° mid-oesophageal view (16 mm) (N° 2 = size measure); (C) 0° mid-oesophageal view; and (D) 95° mid-oesophageal view (18 mm).

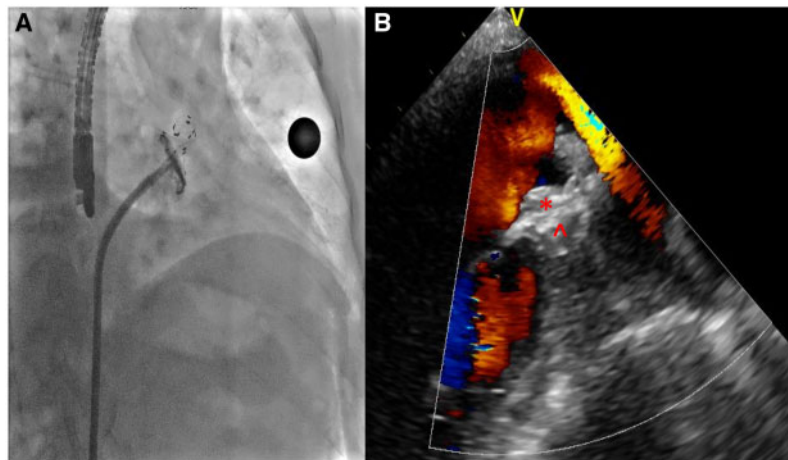


Figure 2 (A) Angiographic right anterior oblique 25° view: contrast media injection shows absence of peri-device leaks. (B) Intraprocedural transoesophageal echocardiography: 95° mid-oesophageal view, colour-Doppler shows optimal device delivery (asterisk: atrial disc part; arrow: bulb part).

At the surgery department admission, the patient was stable and presented only a small pericardial effusion without compression of the right heart chambers as assessed by a new CT scan. Unfortunately,

despite the early treatment, his neurological conditions were irreversibly damaged and he died few days later, with no more tamponade recurrences.

Discussion

Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) is a new generation LAAO device, consisting of two different sections (bulb and atrial disc), articulated for maximizing the anatomic compatibility with



Figure 3 Computed tomography scan shows severe circumferential pericardial effusion (asterisk).

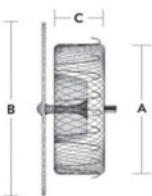
different morphologies. The pacifier principle is the mechanism of action: the bulb is the anchoring part deeply positioned in the LAA structure, whereas the atrial disc provides the sealing of the LAA ostium. Preliminary data hypothesized some advantage of this system, related to the lower rate of peri-device leaks occurrence, due to its improved stability.³

Compared to other devices studied in randomized trial or registries with a high number of patients, such as WATCHMAN⁴ (Boston Scientific, Marlborough, MA, USA) and AMPLATZER⁵ (Abbott Vascular, Santa Clara, CA, USA), the Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) system was tested in only small retrospective cohorts. In these series, the device appeared to be safe, without any excess rate of adverse events.⁶

In our case, both the clinical course and the imaging studies, suggested a possible role of the implanted device with the occurrence of haematic pericardial effusion. The hypothesized underlying mechanism could be a chronic traumatic damage caused by the device itself, which ended with acute LAA micro-perforation symptomatic for dorsal pain and subsequent occurrence of haematic pericardial effusion and tamponade.

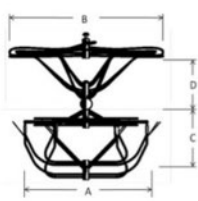
Unfortunately, autopsy was not performed in our case. However, there are several clinical and radiological aspects that may suggest a cause-effect relationship with the occurrence of haematic pericardial effusion and LAAO device implantation. Firstly, the pericardial effusion was haematic and its occurrence was preceded by acute interscapular pain suggesting an acute pericardial irritation caused by the

1 AMPLATZER™ Amulet™



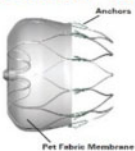
Lobe Length (mm) (C)
7.5
7.5
7.5
7.5
10
10
10
10

ULTRASEAL II®



C	D
8 mm	7 mm
8 mm	7 mm
8 mm	7 mm
8.5 mm	7.5 mm
9 mm	8 mm
9.5 mm	8.5 mm
10 mm	9 mm
10.5 mm	9.5 mm
11 mm	10 mm

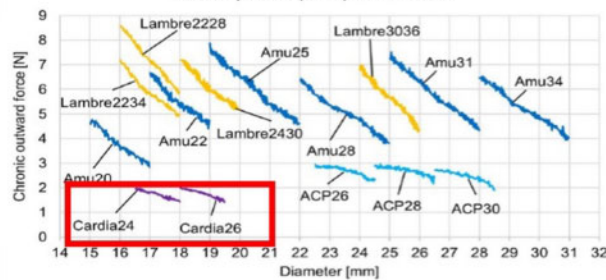
WATCHMAN™ LAAC Device



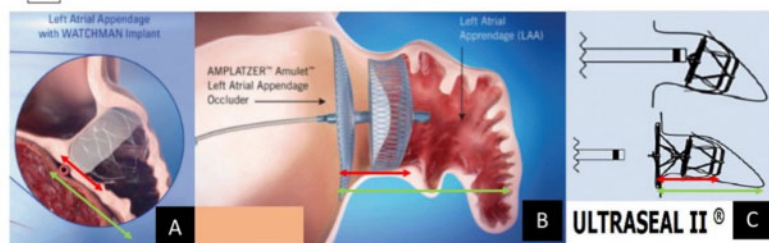
Intra-appendage length is related to the compression provided by the operator during the device delivery

2

COF of pacifier principle occluders



3



Ultraseal device is characterize by:

- 1: the longest intra-appendage part;
- 2: the lowest chronic outward force (COF);
- 3: implantation with the largest compression.

Figure 4 Comparison between AMPLAZER AMULET, WATCHMAN, and ULTRASEAL II. Panel 1 shows higher intra-appendage length of the ULTRASEAL II at baseline device conformation; Panel 2 shows chronic outward forces of all the main devices. ULTRASEAL II has the lower forces, therefore it needs higher compression in the implantation phase (Panel 3) as a result a larger intra-appendage length is observed compared with other devices (red and green arrows) after the implantation (adapted from Menne et al.⁷ and Sabiniewicz et al.³)

haematic effusion. Secondly, the CT scan played an 'indirect key role' excluding several causes of haematic pericardial effusion (such as aortic dissection and solid tumours that could infiltrate the pericardial membrane). Thirdly, there are no other anamnestic events that may be associated with this clinical manifestation (such as trauma).

The low flexibility of the Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) nitinol mesh structure, as previously reported in others settings, may be associated to increased torque of the device by the beating heart. Furthermore, a bench test showed that the Ultraseal, a large-meshed device for interatrial defect closure, very similar to Ultraseal, needs a high compression force during implantation as a result of its low radial strength.⁷ In addition, compared to other devices, the bulb part is much larger. Consequently, when the device is deeply inserted in LAA, a higher surface area within the appendage wall is directly overlapped, having more chance of causing friction (Figure 4).

All these aspects could be responsible for major complications such as the left atrium or left appendage wall erosion⁸ and the detachment of the luminal part of the device, as signalled in a recent case series.⁹

The described case was not the only case of late-onset pericardial effusion.

Previous cases of LAA erosion or circumflex coronary artery laceration occurred after an Amulet (Abbott Vascular, Santa Clara, CA, USA) device implantation.¹⁰ A case of acute onset pericardial irritation and subsequent late-onset haemorrhagic pericarditis complicated by cardiac tamponade occurred after a WATCHMAN (Boston Scientific, Marlborough, MA, USA) device implantation.¹¹ The main hypothesized mechanism was a micro-perforation occurring immediately after the implantation procedure.

Conclusion

LAAO late-onset complications are anecdotal, however not negligible. To our knowledge, this is the first case described of late-onset pericardial effusion and cardiac tamponade caused by Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA) device. Our clinical case may suggest the importance of a strict follow-up evaluation of patients treated with this device, in order to identify and prevent late-onset complications. Further prospective multicentre registry regarding Ultraseal safety and efficiency should be provided.

Lead author biography



Dr Stefano Albani graduated in medicine at the University of Turin and specialized in Cardiology at the University of Trieste. A fellow of the Italian Society of Cardiology, he is involved in many research projects,

with important Italian institutions, in many fields of the cardiovascular medicine. In specific, he does research in interventional cardiology, heart failure and cardiovascular imaging. Currently, Covid-19 pandemic stopped his training in interventional cardiology, he hopes to be able to continue his training as soon as possible.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

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 guidance.

Conflict of interest: None declared.

Funding: None declared.

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