Prevention and Management of Complications of Left Atrial Appendage Closure Devices

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KEYWORDS

• Left atrial appendage • Atrial fibrillation • WATCHMAN device • Amplatzer cardiac plug • LARIAT • Pericardial effusion

KEY POINTS

- The most common complication of left atrial appendage (LAA) occlusion or ligation is pericardial effusion, which may be caused during transseptal puncture, manipulation of equipment within the LAA, device deployment and retrieval, and, particular to the LARIAT procedure, dry pericardial access and manipulation of the endocardial and epicardial magnet-tipped wires.
- The incidence of periprocedural complications seems to decrease with increasing operator experience.
- Strategies to reduce the incidence of procedural complications include multiplanar imaging by 3-dimensional (3D) transesophageal echocardiography during transseptal puncture, use of a pigtail catheter to advance device delivery sheaths into the LAA, careful flushing of all left atrial sheaths, and avoidance of substantial tension on the epicardial wire during the LARIAT procedure.
- Awareness of, and preparation for, the management of procedural complications can increase patient safety and improve the risk-benefit ratio for LAA closure.

INTRODUCTION

Atrial fibrillation (AF) is associated with an ongoing risk of thromboembolic stroke and systemic embolism due to stasis and thrombus formation within the LAA. The risk of thromboembolic stroke and systemic embolism is estimated for a particular individual by incorporating comorbidities into risk scores such as the $CHADS_2$ and the CHA_2DS_2VASC models.[1–3] Warfarin, the oral direct factor Xa inhibitors rivoraxaban and apixaban, and the oral direct thrombin inhibitor dabigatran have been shown in large, randomized, clinical trials to reduce the risk of stroke but at the cost of major bleeding.[4–6] The decision to treat a patient with AF with anticoagulation is based on balancing these well-quantified thromboembolic and bleeding risks. Transcatheter LAA occlusion or ligation, by eliminating the nidus for thrombus formation, may reduce the thromboembolic risk in AF while abrogating the need for long-term anticoagulation and thereby eliminating the long-term bleeding risk observed with medical therapy. Device therapy, however, exposes the patient to a new hazard, that of procedural risk. The overall success of any effective device therapy depends critically on procedural safety, particularly when the goal of the device is to reduce the risk of a low-frequency event in an asymptomatic patient, such as LAA appendage closure for stroke prevention in AF. The issue of procedural safety is also of particular importance in the setting of LAA closure,

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as there exist minimal robust randomized clinical trial data to support its use compared with that supporting the use of oral anticoagulant therapy. Herein, the author reviews the available data pertaining to procedural risk during LAA closure, identifies common procedural complications, and discusses strategies for their prevention and management.

INCIDENCE OF COMPLICATIONS DURING TRANSCATHETER LAA CLOSURE

WATCHMAN LAA Occluder

The WATCHMAN LAA occluder (Boston Scientific, Natwick, MA, USA) consists of a nitinol frame and polyethylene terephthalate cap. Tines along the circumference of the midbody secure the device within the LAA after implantation. The device is introduced into the LAA through a 14F sheath delivered from the right femoral vein via a transseptal puncture. The appropriate-sized device is chosen through a combination of transesophageal echocardiography and fluoroscopy. Key procedural aspects that influence complication rates include transseptal technique, flushing of the large delivery sheath, manipulation of the delivery sheath and implantation of the device within the fragile and thin-walled LAA, and recognition of inappropriate device size or position (**Table 1**).

Procedural outcomes of WATCHMAN LAA occluder implantation have been examined in 2 randomized clinical trials performed in the United States,[7,8] a continuing access registry in the United States,[9] and 1 observational, European multicenter registry.[10] In the PROTECT-AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) trial, 463 patients were randomly allocated to device implantation; implantation was attempted in 449 patients. Serious pericardial effusion (requiring drainage or surgical intervention) occurred in 22 patients (4.8%) and nonserious pericardial effusions (requiring no intervention) occurred in an additional 8 patients (1.7%); procedure-related ischemic stroke occurred in 5 patients (1.1%), predominantly due to air embolism; cardiac perforation requiring surgical repair occurred in 7 patients (1.6%); and device embolization occurred in 3 patients (0.6%). Procedural outcomes seem to have improved since this initial experience: among the 460 patients enrolled within the Continuing Access to PROTECT-AF (CAP) registry, serious pericardial effusion within 7 days occurred in only 2.2% ($P = .019$ compared with PROTECT-AF), and there was only a single cardiac perforation requiring repair. With respect to the timing of complications, 89% of the serious pericardial effusions within PROTECT-AF and CAP were detected within 24 hours of the procedure. In PROTECT-AF, the cause of pericardial effusion was the transseptal puncture in 9% of cases; from manipulation within the LAA of sheaths, wires, catheters, or the delivery system in 41%; from the device deployment process in 18%; and from an unclear cause in 32%.[9] The subsequent PREVAIL (Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device In Patients with Atrial Fibrillation Versus Long-Term Warfarin Therapy) randomized clinical trial further confirmed improved procedural safety, with rates of serious pericardial effusion similar to that of the CAP registry (1.5%); only 1 patient required surgical repair of a cardiac perforation.[8] Newer operators had similar procedural safety outcomes than experienced operators, suggesting that a substantial learning curve may not be required to achieve a safe result. Safety event rates in the smaller European ASAP (ASA Plavix Feasibility Study with WATCHMAN Left Atrial Appendage Closure Technology) registry were generally similar to that observed in CAP registry and PREVAIL. The improvement in procedural safety is likely due to changes in delivery sheath management, as detailed later.

Amplatzer Cardiac Plug

The Amplatzer cardiac plug (ACP) (St Jude Medical, Minneapolis, MN, USA), like the WATCHMAN LAA occluder, is a nitinol-based device that is implanted through a delivery sheath that is manipulated into the LAA via a transseptal puncture. Not surprisingly, similar types of procedural complications can occur, and, like the WATCHMAN experience, procedural safety has improved with time. In the original observational, European experience of 143 cases, the rate of tamponade was 4%, procedural stroke 2%, and device embolization 1%.[11] In a subsequent prospective, observational, adjudicated European multicenter registry of 204 patients undergoing ACP implantation, serious pericardial effusion occurred in 3 patients (1.5%), all of which occurred early; there were no procedure-related strokes; and there were 3 cases of device embolization (1.5%), all of which occurred within the first 7 days of implantation. A newer-generation ACP device incorporates design changes that may reduce the risk of embolization.[12] In summary, the procedural complications rates observed with the ACP are qualitatively similar to that seen with the WATCHMAN LAA occlude. The results of the ongoing Amplatzer Cardiac Plug randomized, clinical trial (NCT01118299) will provide further insights regarding device and procedural safety.