Feasibility of closed-chest ligation of the left atrial appendage in humans

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BACKGROUND Atrial fibrillation is associated with an increased risk of embolic events. The left atrial appendage (LAA) is believed to be an incubator for thrombus formation. LAA exclusion has been advocated to potentially reduce embolic events arising from the LAA.

OBJECTIVE The aim of the study was to determine the feasibility of a closed-chest surgical suture ligation of the LAA in man.

METHODS Thirteen patients undergoing either mitral valve surgery (n = 2) or electrophysiological study and radiofrequency catheter ablation for atrial fibrillation (n = 11) underwent ligation of the LAA with the LARIAT snare device. In patients having an ablation procedure, pericardial access was obtained prior to the patients undergoing radiofrequency catheter ablation. After transseptal catheterization, endocardial and epicaridal magnet-tipped guide wires were positioned under fluoroscopic guidance to stabilize the LAA. Transesophageal echocardiography (TEE) was used as guidance for positioning a marker balloon at the ostium of the LAA. An over-the-wire approach was used to guide the LARIAT snare device over the LAA to allow closure and suture ligation of the LAA. TEE and contrast fluoroscopy were used to confirm acute closure of the LAA.

RESULTS Both mitral valve replacement (MVR) patients had complete closure of the LAA determined by visual inspection. Ten of 11 patients having ablation underwent a successful closed-chest LAA ligation procedure with TEE and contrast fluoroscopy verification of closure of the LAA. Only one of 11 procedures was terminated owing to the lack of echocardiography guidance of the snare over the marker balloon. One patient with pectus excavatum did have ligation of his LAA; however, a thorascopic procedure was required to remove the snare from the LAA owing to compression of the LARIAT by the concave sternum. There were no other significant complications.

CONCLUSIONS Catheter-based surgical suture ligation of the LAA is feasible in humans. This novel catheter approach may be appropriate for patients with atrial fibrillation who are ineligible for anticoagulation therapy. Further investigation is needed to demonstrate the long-term safety and efficacy of LAA closure.

KEYWORDS Atrial fibrillation; Thromboembolic stroke; Left atrial appendage; Suture ligation

ABBREVIATIONS **AF** = atrial fibrillation; **LAA** = left atrial appendage; **MVR** = mitral valve replacement; **TEE** = transesophageal echocardiography

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Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting over 6 million people worldwide.[1] Embolic stroke is the most severe consequence of AF. There is a five-fold increase in the likelihood of patients with AF having an embolic stroke compared with those without AF.[2] Since the risk of AF increases with age, the embolic stroke risk will dramatically increase with our aging population.

The risk of stroke is substantially reduced with the use of Coumadin; unfortunately, only 50%–60% of eligible patients take Coumadin and are in the therapeutic range.[3,4] Concerns with Coumadin include its narrow therapeutic window as well as the high risk of bleeding.[5] The risk of stroke is related to the occurrence of thrombus in the left atrium. At least 90% of thrombi that occur in nonvalvular AF originate in the left atrial appendage (LAA).[6] Neither catheter-based procedures nor antiarrhythmic drugs have proven sufficient on their own to prevent the concomitant use of oral anticoagulation. Surgical LAA exclusion has been advocated as a strategy for the prevention of embolic events. Although the surgical literature supporting closure of the LAA is limited, there are more recent data suggesting that closure with an implanted percutaneous device (Watch-

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man (Aritech Inc, Plymouth, Minnesota) is at least as good as long-term anticoagulation with Coumadin (Bristol-Myers Squibb Co, Princeton, NJ).[7]

This first-in-man study evaluates the feasibility of percutaneous closure of the LAA with a novel suture-based device using both transseptal and pericardial access. This approach may provide an alternative or adjunct to oral anticoagulation in patients with nonvalvular AF.

Methods

Patient population

Patients undergoing either mitral valve replacement (MVR) or catheter ablation for AF at John Paul II Hospital with a history of chronic or intermittent AF with at least one risk factor for stroke were identified for closure of the LAA. The protocol was conducted under the Ministry of Health with Ethics Committee approval at John Paul II Hospital, Krakow, Poland.

Patient preparation

A total of 16 patients were screened for the feasibility study. Three patients were excluded from attempted suture ligation of the LAA. One patient was eliminated during the prescreening computed tomography owing to a superiorly oriented LAA. Two patients were disqualified at the initiation of the procedure. One patient had a mobile LAA thrombus identified by transesophageal echocardiography (TEE), while the other patient had pericardial adhesions noted during pericardial access. Prescreening exclusion criteria included (1) prior cardiac surgery, (2) a superior oriented LAA, (3) an LAA larger than 40 mm, (4) recent myocardial infarction within 3 months, (5) prior embolic event within the last 30 days, (6) New York Heart Association class IV heart failure symptoms, and (7) thoracic radiation.

A total of 13 patients underwent attempted suture ligation of the LAA. The initial two ligations in patients undergoing ligation of the LAA were performed during MVR surgery. The remaining 11 patients underwent concomitant radiofrequency catheter ablation for AF. Informed consent was obtained before the procedure. The patients were prepped and draped in the usual sterile fashion for an electrophysiological study and catheter ablation with the addition of a surgical preparation of the subxyphoid and chest region. Before the electrophysiology study and catheter ablation, pericardial access via a subxyphoid approach was performed, and a 0.35“ wire was left in the pericardial space.

Open-chest ligation of the LAA

After sternotomy and placement of the patient on cardiopulmonary bypass, a magnet-tipped guide wire was placed into the apex of the LAA directly from the atriotomy, and a 20-mm occlusion balloon was advanced to the ostium of the LAA. A second magnet-tipped guide wire was positioned on the epicardial surface of the LAA and attached to the wire inside. This eliminated grasping or retraction of the friable LAA when the LARIAT (SentreHeart, Inc, Palo Alto, CA) snare device was positioned at the base of the LAA. The occlusion balloon was inflated at the LAA ostium to prevent movement of the snare when closed on the LAA. The suture was tightened, and the snare was removed from the LAA.

Closed-chest ligation of the LAA

The products used (SentreHEART, Palo Alto, CA) for ligation of the LAA were described in initial preclinical studies.[8,9] Briefly, the procedure uses three components: (1) a 20-mm compliant occlusion balloon, (2) 0.025” and 0.035“ magnet-tipped guide wires, and (3) a 12-Fr suture delivery device.

The initial two patients undergoing closed-chest LAA ligation had a minimally invasive surgical pericardial window created to access the pericardial space. In the remaining nine patients, percutaneous pericardial access was obtained as described by Sosa et al.[10] The desired pericardial access approach is from the anterior surface of the heart, with the needle directed in the anterior-lateral direction. A 14-Fr soft-tipped epicardial guide cannula (SentreHEART, Inc.) was placed into the pericardial space. After preparation to evacuate all the air from the 20-mm occlusion balloon (EndoCATH, SentreHEART, Inc, Palo Alto, CA), the catheter was back loaded with a magnet-tipped 0.025” endocardial guide wire (FindrWIRZ, SentreHEART, Inc, Palo Alto, CA) and positioned in the LAA through the 8.5-Fr SL1 transseptal catheter (St. Jude Medical) under fluoroscopic guidance. A left atriogram was performed to delineate the LAA (Figure 1A). Advancement of the magnet-tipped endocardial guide wire into the LAA was performed. An LAA angiogram (appendagram) was performed through the lumen of the EndoCATH to assure placement of the magnet-tipped guide wire in the distal tip of the LAA. This was typically performed in the right anterior oblique view to optimize visualization of the magnet-tipped guide wire at the distal tip of the LAA. The 0.035“ magnet-tipped epicardial guide wire was inserted through a 14-Fr soft-tipped epicardial guide cannula (SentreHEART, Inc.) into the pericardial space and attached to the endocardial magnet-tipped guide wire (Figure 1B). The snare was advanced over the epicardial magnet-tipped wire and positioned over the LAA. Snare positioning at the ostium of the LAA was guided by the EndoCATH balloon location at the opening of the LAA. Confirmation of the position of the EndoCATH balloon was performed with TEE (Figure 2B). After verification of the placement of the snare, the snare was closed. A left atriogram was performed to assure that a diverticulum was not present. Once verification of the absence of an LAA diverticulum, the surgical suture was tightened to ligate and exclude the LAA. The LARIAT snare was removed from the pericardial space. A suture cutter was advanced over the suture to cut the suture near the LAA. TEE was performed 60 days postligation of the LAA.