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Clinical Implications of Leaks Following Left Atrial Appendage Ligation With the LARIAT Device

Carola Gianni, MD,[a,b] Luigi Di Biase, MD, PhD,[a,c,d,e] Chintan Trivedi, MD, MPH,[a] Sanghamitra Mohanty, MD, MS,[a] Yalçın Gökoğlan, MD,[a] Mahmut F. Güneş, MD,[a] Rong Bai, MD,[a] Amin Al-Ahmad, MD, CCDS,[a] J. David Burkhardt, MD,[a] Rodney P. Horton, MD,[a,d] Andrew K. Krumerman, MD,[c] Eugen C. Palma, MD, CCDS,[c] Miguel Valderrábano, MD,[f] Douglas Gibson, MD,[g] Matthew J. Price, MD,[g] Andrea Natale, MD[a,c,d,g,h,i,j,k]

ABSTRACT

OBJECTIVES The aim of this study was to evaluate the incidence and clinical implications of leaks (acute incomplete occlusion, early and late reopenings) following LAA ligation with the LARIAT device.

BACKGROUND Percutaneous LAA ligation with the LARIAT device may represent an alternative for stroke prevention in high-risk patients with atrial fibrillation with contraindications to oral anticoagulation.

METHODS This was a retrospective, multicenter study of 98 consecutive patients undergoing successful LAA ligation with the LARIAT device. Leaks were defined as the presence of flow as evaluated by transesophageal echocardiography (TEE). TEE was performed during the procedure, at 6 and 12 months, and after thromboembolic events.

RESULTS Leaks were detected in 5 (5%), 14 (15%), and 19 (20%) patients at the 3 time points. During follow-up, 5 patients developed neurological events (4 strokes and 1 transient ischemic attack). Two occurred early (1 fatal stroke and 1 stroke with multiple recurrences in the following months), and TEE was not repeated after the events. The remaining 3 occurred late (after 6 months) and were associated with small leaks (<5 mm). In 2 of 3 cases, such a small leak was missed by the standard evaluation on 2-dimensional TEE, being evident only with the aid of 3-dimensional imaging.

CONCLUSIONS Incomplete occlusion of the LAA after LARIAT ligation is relatively common and may be associated with thromboembolic events. Proper long-term surveillance with careful TEE should be considered to detect leaks, which can be managed with either resumption of oral anticoagulation or percutaneous transcatheter closure.
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From the [a]Texas Cardiac Arrhythmia Institute, St. David's Medical Center, Austin, Texas; [b]Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy; [c]Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, New York; [d]Department of Biomedical Engineering, University of Texas, Austin, Texas; [e]Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy; [f]Division of Cardiac Electrophysiology, The Methodist Hospital, Houston, Texas; [g]Division of Cardiovascular Diseases, Scripps Clinic, La Jolla, California; [h]MetroHealth Medical Center, Case Western Reserve University School of Medicine, Cleveland, Ohio; [i]Division of Cardiology, Stanford University, Stanford, California; [j]Electrophysiology and Arrhythmia Services, California Pacific Medical Center, San Francisco, California; and the [k]Dell Medical School, University of Texas, Austin, Texas. Dr. Di Biase has received honoraria from Biosense Webster, Boston Scientific, Biotronik, Medtronic, Stereotaxis, and St. Jude Medical. Dr. Al-Ahmad has a received honoraria from Medtronic. Dr. Burkhardt has received honoraria from Biosense Webster, Stereotaxis, and St. Jude Medical. Dr. Horton has received honoraria from Boston Scientific and St. Jude Medical. Dr. Valderrábano has received honoraria and research funding from Boston Scientific, Hansen Medical, Medtronic, St. Jude Medical; honoraria from Biosense Webster, SentreHeart. Dr. Gibson has received honoraria from Boston Scientific and SentreHeart. Dr. Price has received honoraria from Boston Scientific, St. Jude Medical, and W.L. Gore & Associates. Dr. Natale has received honoraria from Biosense Webster, Medtronic, and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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ABBREVIATIONS AND ACRONYMS

2D = 2-dimensional

3D = 3-dimensional

AF = atrial fibrillation

LAA = left atrial appendage

OAC = oral anticoagulation

TEE = transesophageal echocardiography

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and a major cause of morbidity and mortality, mainly because it is an independent risk factor for stroke (1–4). Left atrial appendage (LAA) thromboembolism is the dominant cause of stroke in patients with AF (5,6). Oral anticoagulation (OAC) reduces thromboembolic events in selected patients, but it is associated with a significant risk for bleeding in high-risk patients (7,8). Therefore, several techniques to exclude the LAA have been developed over the years, from surgical ligation to excision through out transcatheter closure devices (5,9–14).

SEE PAGE 1058

The LARIAT device (SentreHeart, Redwood, California) allows the percutaneous ligation of the LAA through the delivery of a suture via a combined endocardial and epicardial approach (15). As with surgical ligation, there may be residual or de novo leaks that potentially reduce the long-term efficacy of this procedure (16–19). We report our experience of the incidence and clinical implications of leaks following LAA ligation with the LARIAT device.

METHODS

STUDY DESIGN. This was a retrospective, multicenter, observational cohort study of consecutive patients with AF who underwent successful transcatheter LAA ligation with the LARIAT device for stroke prevention at 4 centers across the United States. LAA ligation was indicated in patients at risk for stroke (high $CHADS_2$ [cardiac failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack] or CHA_2DS_2-VASc [cardiac failure, hypertension, age ≥75 years, diabetes mellitus, stroke or transient ischemic attack or thromboembolism, vascular disease, age 65 to 74 years, female sex] score, previous LAA isolation) in whom OAC was contraindicated (history of significant bleeding), poorly tolerated, or failed (thromboembolic event despite anticoagulation). Patients were excluded if they had symptomatic carotid artery disease, aortic arch or descending aorta complex atheroma, prior open heart surgery, or unsuitable LAA anatomy (LAA ostial diameter >40 mm or LAA posterior to the pulmonary artery) (20). Moreover, patients were not included in the study if LARIAT deployment was attempted but the procedure was unsuccessful because of LAA thrombus (n = 2), pericardial adhesions (n = 5), or a residual leak ≥5 mm (n = 1).

Data were collected from patient records using structured case reports forms. Clinical events were site reported and not independently adjudicated. The study was approved by the hospitals' institutional review boards.

PROCEDURE. The LARIAT procedure has previously been described in detail (20). In brief, patients undergo LARIAT ligation under general anesthesia. Pericardial and transseptal access are obtained with fluoroscopy and transesophageal echocardiographic or intracardiac echocardiographic guidance. Unfractionated heparin is administered to achieve a goal activated clotting time of 250 to 300 s. A magnet-tipped endocardial guidewire is advanced into the LAA, and a magnet-tipped epicardial guidewire is advanced into the pericardium and connected to the endocardial guidewire. The epicardial snare and suture are advanced over the wire and closed at the mouth of the LAA. Intraprocedural transesophageal echocardiography (TEE) and contrast-enhanced fluoroscopy are used to assess for incomplete closure.

FOLLOW-UP. Post-procedural medical therapy (including antithrombotic therapy) was prescribed according to the operator's preference. All patients underwent clinical follow-up visits at 6 and 12 months. Transesophageal echocardiographic complete follow-up to assess for residual or new leaks was available in 96 of 98 patients (98%); adjunctive 3-dimensional (3D) TEE was available in 47 of 96 patients (49%) across all 3 time points and in 96 of 98 (98%) at the end of follow-up. An incomplete occlusion, or leak, was defined as evidence of flow into the LAA as assessed by TEE. It was considered small if <5 mm and large if ≥5 mm. A leak was defined as acute when it was detected at the time of the procedure, early when it was evident before or at 6-month follow-up *(early reopening)*, and late when it was first evident after 6-month follow-up *(late reopening)*.

STATISTICAL ANALYSIS. Continuous variables are presented as mean ± SD and categorical variables as counts and percentages. Analyses were performed using Excel 2010 (Microsoft, Redmond, Washington) and GraphPad 6 (GraphPad Software, La Jolla, California).

RESULTS

PATIENT POPULATION. A total of 98 consecutive patients undergoing successful LAA ligation with the LARIAT device were included. The mean age was 73 ± 8 years, and 35% of patients were women. The mean $CHADS_2$ score was 2.7 ± 1.2, the mean CHA_2DS_2-VASc

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