

# Left Atrial Appendage Remodeling After Lariat Left Atrial Appendage Ligation

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**Background**—Left atrial appendage (LAA) ligation with the Lariat device is being used for stroke prevention in atrial fibrillation. Residual leaks into the LAA are commonly reported after the procedure. Little is known about the anatomic LAA remodeling after Lariat ligation.

**Methods and Results**—In an exploratory study, we evaluated LAA 3-dimensional geometry via computed tomographic scan in 31 consecutive patients before Lariat closure and after a minimum of 30 days post procedure. Thirteen patients were classified as unfavorable cases based on anatomic criteria. Our population had an average age of  $70 \pm 12$  years, a mean CHADS2 (congestive heart failure, hypertension, age >75, diabetes mellitus, history of stroke) score of  $3.2 \pm 1.2$ , a mean CHADS2VASC (CHADS2 in addition to female sex, ages 65–75, as well as double impact of age >75, vascular disease) of  $4.2 \pm 1.5$ , and a mean HASBLED (hypertension, abnormal renal/liver function, stroke, bleeding predisposition/history, labile international normalized ratio, elderly, drugs/alcohol) bleeding score of  $4.0 \pm 1.1$ . Successful suture deployment was achieved in all cases, but 3 patients had intraprocedural residual flow into the LAA (leak). On follow-up, 10 patients (32%) had recanalized residual LAA cavities, which were morphologically similar to the original LAA, albeit significantly smaller in volume ( $22.5 \pm 13.3\%$  of the original volume). Recanalization was not associated with age, sex, comorbid conditions, stroke or bleeding risk scores, follow-up interval, baseline LAA volume, or morphology. Unfavorable cases had anatomic outcomes comparable with those of the anatomically favorable population. No patients have exhibited thromboembolism after  $842 \pm 338$  days post ligation.

**Conclusions**—Incomplete LAA ligation after Lariat is common. However, the remodeled LAA cavity is dramatically reduced. Diminished cavity size and tightening of the LAA orifice may play a role in the reduction of thrombus formation. (*Circ Arrhythm Electrophysiol.* 2015;8:1351-1358. DOI: 10.1161/CIRCEP.115.003188.)

**Key Words:** atrial appendage ■ remodeling ■ Lariat ■ left atrial appendage exclusion ■ remnant LAA ■ compassionate ■ stump

Atrial fibrillation (AF) is the most common sustained arrhythmia in adults.<sup>1</sup> AF increases the risk of stroke  $\leq 5$ -fold.<sup>2,3</sup> A considerable proportion of the mortality in AF patients is attributable to ischemic strokes, which account for 10% of early deaths and 7% of late deaths after AF diagnosis.<sup>4</sup> Oral anticoagulation is indicated for the prevention of thromboembolic strokes in patients with AF at risk, but is limited by underutilization, bleeding risks, and dependence on long-term compliance.<sup>5–7</sup>

The overwhelming majority of thrombi form within the left atrial appendage (LAA).<sup>8–10</sup> LAA-targeted therapies are emerging as a theoretically definitive solution to prevent AF-related thromboembolic phenomena. These therapies include transcatheter LAA ligation and occlusion techniques.<sup>7</sup> The Lariat LAA ligation procedure has been gaining increasing utilization. It consists of a percutaneously delivered suture of the LAA neck via a hybrid endocardial–epicardial approach.<sup>11</sup> Its initially reported<sup>11</sup> high early procedural success rate has been

reproduced.<sup>12–15</sup> However, questions remain as to its safety in unselected patient populations.<sup>14,15</sup>

Incomplete ligation of the LAA has been reported to occur with variable incidences ranging from 0<sup>12</sup> to 24%.<sup>15</sup> In all reported cases, flow leaks into the LAA have been detected as an incidental finding demonstrated by Doppler flow into the LAA on postprocedure transthoracic echo (TEE), without investigations of the residual LAA cavity. The impact of an incomplete Lariat LAA ligation on the LAA morphology remains uncertain. Here, we present an exploratory serial evaluation of LAA 3-dimensional (3D) geometry via computed tomographic (CT) scan of a small, diverse, consecutive sample of patients undergoing Lariat closure.

## Methods

### Data Collection

All patients gave informed consent to the procedures. Clinical data collection was performed under an Institutional Review Board–approved

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### WHAT IS KNOWN

- Lariat left atrial appendage (LAA) ligation is utilized as an alternative to oral anticoagulation for stroke prevention in atrial fibrillation patients at risk.
- Residual leaks into the LAA are common following Lariat LAA ligation, but little is known about the anatomic remodeling of the partially ligated LAA.

### WHAT THE STUDY ADDS

- In a substantial subset of patients, a partial LAA opening is associated with a residual, reduced LAA cavity.
- Retained LAA is morphologically similar to the original appendage, but significantly diminished in dimensions, volume and orifice diameter.

protocol. Initial data (n=8) were collected retrospectively from patient charts. The subsequent 23 patients were consecutive patients studied prospectively. This data included medical history, procedural reports, and major events, including thromboembolic and hemorrhagic incidences. CHADS2 (congestive heart failure, hypertension, age>75, diabetes mellitus, history of stroke), CHADS2VASC (CHADS2 in addition to female sex, ages 65–75, as well as double impact of age >75, vascular disease), and HASBLED (hypertension, abnormal renal/liver function, stroke, bleeding predisposition/history, labile international normalized ratio, elderly, drugs/alcohol) scores were then calculated (Table 1).

### Patient Selection

A total of 31 AF patients undergoing transcatheter LAA closure with the Lariat device were included in the study. Patients were assigned to the procedure based on clinical indication and anatomic eligibility. Clinical indication included individuals with a history or predisposition to thromboembolism concomitantly with a high risk of bleeding for whom long-term anticoagulation was contraindicated. Every patient's CHADS2, CHADS2VASC, and HASBLED scores, as well as anticoagulation history, were thoroughly examined, and those with elevated scores were considered. A clinical decision to recommend LAA isolation over oral anticoagulation (OAC) was then made by the treating physician. In 25 patients, a history of major bleed was the main reason for avoiding long-term maintenance on OAC. One patient had recurrent transient ischemic attacks while on OAC, whereas 2 others had recurrent strokes despite OAC. Two patients exhibited low appendage contractility secondary to electric isolation after catheter ablation of AF. One patient indicated unwillingness to receive life-long OAC. All candidates underwent cardiac CT to assess the LAA anatomy. Candidates with favorable anatomic findings were counseled on all available treatment options and those who chose the Lariat procedure were included. Candidates with so-called unfavorable LAA anatomy—a total of 13 patients—were included despite being considered compassionate cases by the Lariat manufacturer based on superiorly oriented LAA with the apex directed behind the pulmonary artery, multilobulated LAA, LAA width >40 mm, or posterior heart rotation.<sup>11</sup> These patients agreed to the Lariat under the terms that failure and possible surgical LAA occlusion could be necessary.

### Lariat LAA Ligation Procedure

The procedure combines subxyphoid epicardial and trans-septal access techniques to reach the LAA.<sup>7</sup> A 14F sheath is used to advance

a magnet-tipped guidewire into the pericardial space. In most cases (28/31), pericardial puncture was performed with the standard Touhy needle, as opposed to the long micropuncture needle approach (3/31). Femoral vein access was used to trans-septally pass a complementary magnet-tipped wire into the LAA. Once the magnetic tips were linked, a preloaded suture is advanced pericardially over the guidewire and tied at the base of the LAA, ligating its ostium.

### Anticoagulation

Anticoagulation was routinely kept for 1 month post procedure, but was discontinued in all patients afterward. This practice was used as a precautionary measure because thrombus formation has been repeatedly reported to occur after Lariat closure.<sup>16–21</sup> The choice of anticoagulating agent was left to the discretion of the performing physician.

### Imaging

Contrast-enhanced ECG-gated CT imaging was used. The Philips Brilliance CT 64-channel scanner was used, acquiring at 75% of the R–R interval. Imaging before the Lariat procedure included anatomic assessment of procedural suitability and stratification into favorable versus unfavorable candidates. A single follow-up repeat CT was subsequently performed for every patient. A minimum interval of 1 month post procedure was mandated in every case to allow sufficient time for LAA remodeling after closure. Secondary to the exploratory nature of the study, however, imaging for different patients was performed in a wide range of postprocedural intervals in efforts to identify any obvious anatomic anomaly that may have arisen secondary to the passage of time. The median follow-up interval was 257 (31–974) days. 3D reconstructions of the LAA were created using the Biosense Webster Carto 3 (Diamond Bar, CA) system and OsiriX (v.5.8.2, Pigeo, Vernex, Switzerland). Volume calculations were performed from CT images using the Phillips IntelliSpace Portal (software version V4.5.5.51035).

### Statistical Analysis

Gaussian continuous variables were reported as mean±SD, and non-Gaussian variables as median (minimum, maximum). Qualitative findings were described as numbers and percentages. Patients were stratified into 2 groups: those with a retained LAA remnant and those with complete obliteration of the LAA cavity at follow-up. Patient characteristics, including age, sex, comorbid conditions, stroke incidences, CHADS2, CHADS2VASC, HASBLED scores, morphological classifications, and LAA volumes, were compared. Univariate and multivariate analyses were performed using the Student *t* test, Fisher exact test, Mann–Whitney *U* test, and multiple logistic regression, where appropriate. Analyses were performed using Sigmapstat (version 3.11) and Stata software (version 13).

## Results

### Patient Characteristics

Overall, our population included 31 AF patients, 13 men and 18 women, with an average age of 70±12 years. The most common comorbidity was hypertension, followed by dyslipidemia, diabetes mellitus II, and congestive heart failure (Table 1). Mean CHADS2 score was 3.2±1.2, mean CHADS2VASC was 4.2±1.5, and the mean HASBLED bleeding score was 4.0±1.1 (Table 1).

### Preoperative Imaging

All patients selected for the study underwent CT anatomic evaluation before the procedure. They were classified according to the LAA morphological classifications described by

**Table 1. Patient Demographics and Clinical Events**

Patient Demographics and Clinical Events, n=31	
Age, y	70±12
Women	18 (58%)
Lariat to follow-up CT interval, d	257 (31–974)*
Post-Lariat thromboembolism-free interval, d	843±338
CHADS2	3.2±1.2
CHADS2VASC	4.2±1.5
HASBLED	4.0±1.1
Prior CVA/TIA	20 (65%)
Labile INR	13 (42%)
Bleeding history/predisposition	25 (81%)
Medication usage predisposing to bleeding	10 (32%)
Alcohol or drug use	4 (13%)
Hypertension	26 (84%)
Dyslipidemia	15 (48%)
Diabetes mellitus, congestive heart failure	11 (35%)
Coronary artery disease	7 (23%)
Chronic obstructive pulmonary disease, gastro-esophageal reflux disease	4 (13%)
Liver disease, inflammatory bowel disease, hypothyroidism	2 (6%)
Kidney disease, vascular disease, neoplasia, Sick sinus syndrome, obstructive sleep apnea, seizure disorder, benign prostatic hyperplasia	1 (3%)

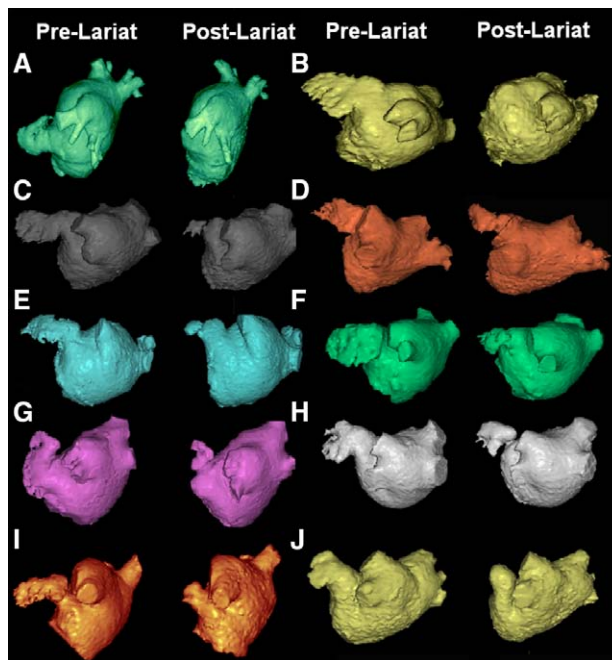
CHADS2 indicates congestive heart failure, hypertension, age>75, diabetes mellitus, history of stroke; CHADS2VASC, CHADS2 in addition to female sex, ages 65–75, as well as double impact of age >75, vascular disease; CT, computed tomography; CVA, cerebrovascular accident; HASBLED, hypertension, abnormal renal/liver function, stroke, bleeding predisposition/history, labile INR, elderly, drugs/alcohol; INR, international normalized ratio; and TIA, transient ischemic attack.

\*Non-Gaussian variables reported as median (minimum–maximum).

Di Biase et al.<sup>22</sup> The most common morphology was chicken wing (Figure 1A), encompassing 32% of the population. Of the remaining patients, 29% exhibited windsock morphology (Figure 1C), 26% exhibited cauliflower morphology (Figure 1D), and 13% showed cactus morphology (Figure 1B).

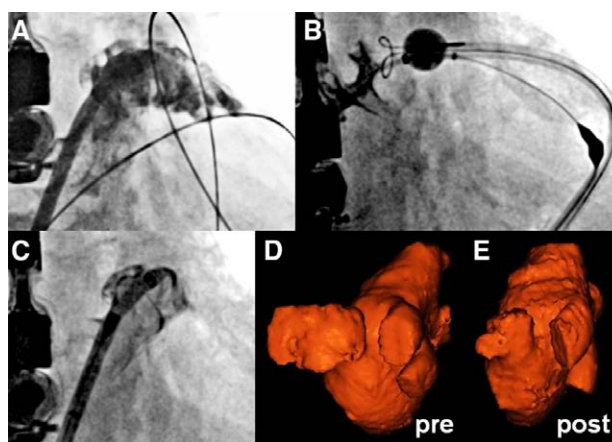
**Procedural Results and Complications**

There were no complications associated with pericardial or trans-septal access. Four of the patients (13%) had bloody drainage from the pericardium at the end of the procedure and were admitted for Cardiac Care Unit intensive monitoring. Total drainage was 45 to 82 mL overnight, and there was no ongoing bleeding in any of the cases when the drain was removed the next day. The remainder of subjects experienced an uncomplicated clinical course. Three subjects exhibited a leak on TEE evaluation during the procedure (10%, Figure 2). All 3 leaks were measured as 2-mm flow jets (Figure 2B). No thrombi were ever evident on intraoperative TEE evaluation. Procedure success was defined as effective positioning of the Lariat snare in the LAA ostium and suture deployment at the base of the LAA (Figure 2A). Procedure success was achieved in all 31 patients. In 4 cases (13%), a residual LAA stump remained unoccluded because of difficulties reaching the LAA base all the way to the ostium with the Lariat snare

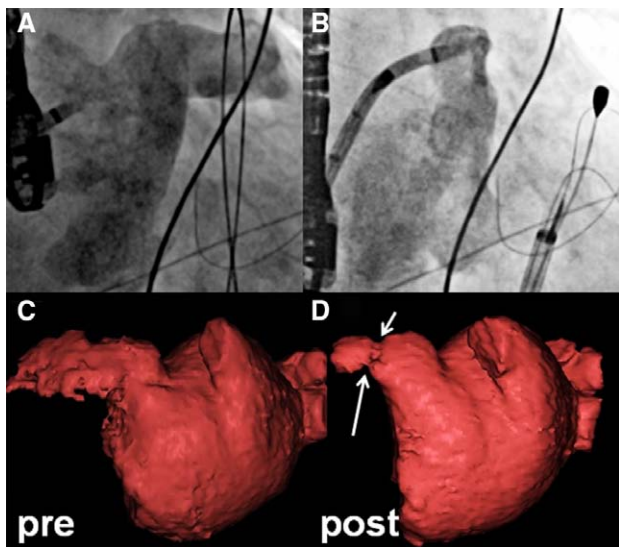


**Figure 1.** Three-dimensional reconstructions from computed tomographic scans of left atrial (LA) anatomy depicting LAA remodeling subsequent to Lariat LAA ligation. **A and B,** Complete obliteration of the LAA after ligation. **C–H,** Partial opening at the LAA neck and retention of a small remnant cavity morphologically similar to the original LAA but significantly reduced in volume. **I and J,** Residual LAA stumps of variable sizes with complete occlusion at the Lariat site.

(Figure 3). In 1 case, there was a large secondary lobe of the LAA directed upward and posteriorly. The Lariat snare was advanced up to the LAA base, but could not be advanced to capture this posterior lobe in its entirety, and instead was deployed bunching the anterior and superior lobes together (Figure 4A) still resulting in complete closure.



**Figure 2.** Residual left atrial appendage (LAA) stump after failure to advance the Lariat snare into the LAA base. **A,** Initial procedural LAA angiogram. **B,** Best Lariat snare position achieved during the procedure. The most posterior aspect of the LAA could not be captured. The suture was delivered in the most advanced snare position achieved. **C,** Final LAA angiogram showing a retained stump, which appears larger than the retained stump in **B,** likely to its compression with the snare during suture delivery. **D and E,** Three-dimensional reconstructions of the LAA before and after procedure, showing the residual LAA stump.



**Figure 3.** Leak and retained left atrial appendage (LAA) cavity in a windsock LAA. **A**, Baseline LAA angiogram. **B**, Final, post-Lariat angiogram showing a stump, but complete LAA ligation without leak. **C** and **D**, Three-dimensional reconstructions of the LAA before and after procedure, showing the residual LAA stump followed by a narrow waist (arrows) and a reduced residual LAA cavity.

### Post Lariat LAA Remodeling

Patients were followed up with CT scans a minimum of 1 month post procedure (Figure 1). Mean interval before follow-up CT was  $209 \pm 272$  days, with a median of 257, ranging from 31 to 974 days. Overall, LAA morphologies post Lariat could be divided into 3 categories:

1. Complete elimination of the LAA cavity in 12 of 31 patients (38.7%). In these cases, the left atrium had a

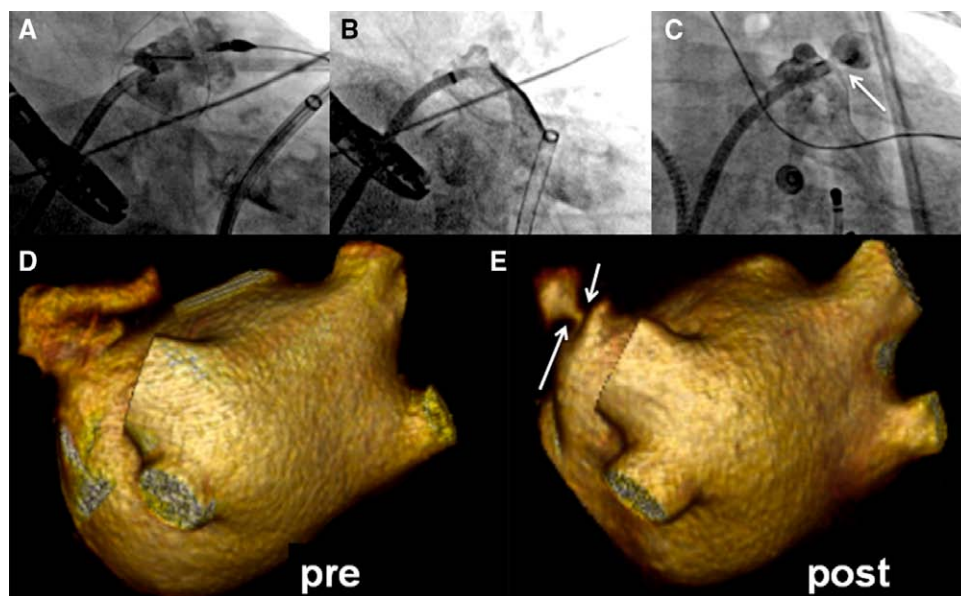
smooth contour at the LAA origin with no visible stump. Figure 1A and 1B shows examples.

2. Residual LAA stump with complete occlusion at the Lariat site in 9 of 31 patients (29%). Figure 1I and 1J show examples of retained LAA stump of variable sizes. Although the Lariat deployment site showed complete occlusion, a stump was present representing a residual LAA cavity. The presence of a stump could be predicted from the acute procedural results if the Lariat snare did not reach the base of the LAA. Figure 2 shows an example.
3. Partial Lariat opening (leak) with retention of a residual LAA cavity (remnant) in 10 of 31 patients (32.3%). The retained small remnant LAA cavity was present beyond the ligation site, which was obvious as a narrow waist between the LAA and the retained LAA cavity. The width of the waist was measured as  $5.2 \pm 2.7$  mm. All remnant LAA cavities showed a significant reduction in volume to  $22.5 \pm 13.3\%$  ( $P < 0.001$ ) of the original LAA volume (Figure 1C–1H, from  $9.9 \pm 1.9$  to  $2.1 \pm 1.2$  mL after ligation).

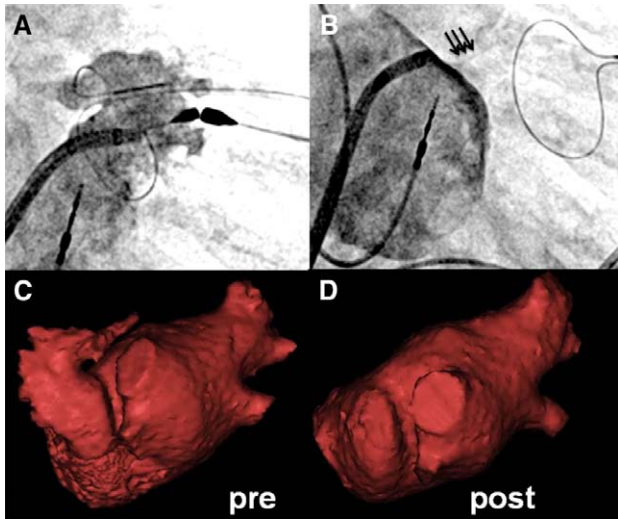
### Unpredictability of LAA Remodeling

Acute procedural results did not consistently correlate with LAA retention on follow-up. Residual leak during the procedure occurred in 3 of 31 patients. Of these, in 2 of 3, the acute post-procedural leak was completely closed on follow-up imaging.

Figures 3 and 4 show acute procedural results in patients that later developed leaks in different LAA sizes and morphologies. Both had complete LAA ligation with absent flow after suture delivery. Conversely, incomplete LAA occlusion with flow leak into the LAA at the end of the Lariat procedure could seal completely on follow-up imaging. Figure 5 shows an example.



**Figure 4.** Leak and retained left atrial appendage (LAA) cavity in a chicken-wing LAA. **A**, Baseline LAA angiogram. **B**, Final, post-Lariat angiogram showing complete LAA ligation without leak. **C**, Follow-up LAA angiogram performed on a repeat procedure (for atrial fibrillation [AF] ablation) 8 weeks later, showing a narrow neck and a small sac-like LAA cavity. **D** and **E**, Three-dimensional reconstructions of the LAA before and after procedure, showing the residual LAA stump followed by a narrow waist (arrows) and a reduced residual LAA cavity.



**Figure 5.** Complete left atrial appendage (LAA) ligation despite acute procedural residual flow into the LAA. **A**, Baseline LAA anatomy showing a posterior, elongated LAA lobe. The Lariat snare could not be advanced over the lobe, which was bunched up with the LAA neck. **B**, A small residual leak (arrows) is present after suture delivery. **C** and **D**, Three-dimensional reconstructions of the LAA before and after procedure, showing a complete occlusion on follow-up.

LAA leaks occurred in patients with all baseline LAA morphologies—windsock, chicken wing, cactus, or cauliflower. The maximum width of the LAA—commonly used to qualify a case as anatomically unfavorable could not predict the occurrence of leaks ( $30.2\pm 8.8$  mm in leak cases versus  $32.8\pm 7.5$  mm in complete ligations;  $P=0.4$ ).

The study sample was too small to yield sufficient power capable of establishing statistical associations. However, as derived from the limited population, no correlation could be found between LAA retention and age, sex, morphological classification, pre-Lariat LAA volume, stroke prevalence, CHADS<sub>2</sub>, CHADSVASC, HASBLED scores, or any specific comorbidity (Table 2). Furthermore, the interval between Lariat procedure and follow-up CT had no evident bearing on LAA retention, thus ruling out a temporal factor contributing to this finding.

Postprocedure course was uncomplicated. All patients were treated with colchicine for prevention of pericardial inflammation. Three patients had pleuritic chest pain that subsided after 5 to 12 days but was not associated with pericardial fluid. Patients tolerated temporary anticoagulation well, with no evidence of hemorrhagic complications. Overall, patients received rivaroxaban (13, 42%), dabigatran (9, 29%), apixaban (6, 19%), and warfarin (3, 9%) for 1 month only, after which anticoagulation was discontinued in all cases. At a mean of  $859\pm 344$  days following Lariat procedure in retained LAA patients and  $835\pm 343$  days in nonretained LAA patients, all of our population remains thromboembolism free to date (Table 2).

### Anatomically Unfavorable Cases

Thirteen patients were identified as having unfavorable anatomic characteristics. The majority of this population had chicken wing morphologies (69%;  $P<0.001$ ). These patients

had comparable baseline demographics and clinical predictors to the remainder of the population (Table 2). Two patients from the anatomically unfavorable group had an evident leak on intraoperative TEE, as opposed to 1 case in the anatomically favorable population. However, on follow-up, patients were equally likely to retain an LAA remnant (30.8% in unfavorable versus 33.3% in anatomically favorable cases;  $P=1.00$ ) and exhibited similar remodeling volume reductions of  $83.0\pm 12.3\%$  in unfavorable versus  $73.9\pm 13.38\%$  in more favorable cases ( $P=0.33$ ; Table 2). Complex remodeling of the LAA stump could occur after ligation of a large LAA. Figure 6 shows an example of an LAA with a large secondary lobe directed superiorly and posteriorly. The snare was deployed grabbing both the main LAA neck and the posterior–superior lobe at once (similar to the approach shown in Figure 5), achieving complete ligation, but leading to a complex stump morphology on follow-up CT. Patients with unfavorable anatomic criteria were followed  $854\pm 304$  days, whereas those with favorable criteria were followed  $834\pm 369$  days post procedure ( $P=0.65$ ). All patients regardless of initial anatomic favorability status remain thromboembolism-free after Lariat ligation.

### Discussion

This study primarily serves an observational purpose in a yet unexplored intervention-induced premise. Its main finding is that although the vast majority of patients undergoing Lariat LAA closure achieve complete ligation at the procedure, on follow-up imaging, a substantial fraction of the patients show variable portions of retained LAA cavity with residual blood flow into either an LAA stump or a residual but significantly reduced LAA cavity. The anatomic remodeling of the residual LAA cavity is unexpected and reflects a potential pathophysiological mechanism that may have implications for stroke prevention.

### Assessment of LAA Remodeling

The Lariat device is Food and Drug Administration approved for soft tissue approximation, but has been widely used in percutaneous LAA ligation.<sup>7,23</sup> To date, information on the anatomic outcomes of Lariat LAA ligation has been limited.<sup>24</sup> Animal studies have yielded safe and reliable ligation of the LAA with a completely endothelialized orifice of the structure up to 3 months post procedure.<sup>25</sup> Our data confirm that this end point is indeed clinically achievable in the majority of cases. However, a significant subset of patients has retained a portion of the structure (Figure 1). A priori, the desired therapeutic effect is exclusion of the LAA cavity from the circulation by occluding blood flow from the LA body. Our data support that a second pathophysiological mechanism is at play, which is atrophy of the LAA myocardium and reduction of the LAA size. Regardless of the efficacy of LAA neck ligation, strangulation of the epicardial blood vessels that supply blood flow to the LAA myocardium occurs to variable degrees. The 2 effects are inextricably linked but may be antagonistic to one another. Although effective flow occlusion requires tissue in the LAA neck to bunch up as it is circumferentially compressed by the suture, ischemia and

**Table 2. Patient Demographics, Clinical Events, and Lariat Outcomes in Retained Versus Nonretained and Favorable Versus Unfavorable LAA Populations**

	Remnant LAA, n=10	Nonretained LAA, n=21	Anatomically Unfavorable, n=13	Anatomically Favorable, n=18
Demographic				
Age, y	69±10	71±13	75±8	67±14
Women	6 (60%)	12 (57%)	7 (54%)	11 (61%)
Clinical measures				
CHADS2	3.1±1.2	3.3±1.3	3.5±1.1	3.0±1.3
CHADS2VASC	4.0±1.6	4.3±1.5	4.6±1.5	3.9±1.5
HASBLED	3.6±1.0	4.2±1.1	4.5±1.1	3.6±1.0
Prior CVA/TIA	6 (60%)	14 (67%)	10 (77%)	10 (56%)
Labile INR	4 (40%)	9 (43%)	6 (46%)	7 (39%)
Bleeding history/predisposition	6 (60%)	19 (90%)	12 (92%)	13 (72%)
Medication usage predisposing to bleeding	2 (20%)	8 (38%)	6 (46%)	4 (22%)
Alcohol or drug use	1 (10%)	3 (14%)	2 (15%)	2 (11%)
Outcomes				
Lariat to follow-up CT interval, d*	93 (31–974)	90 (31–961)	66 (34–961)	102 (31–974)
Post-Lariat thromboembolism-free interval, d	859±344	835±343	854±304	835±369
Leak in procedural TEE	1 (10%)	2 (10%)	2 (15%)	1 (6%)
Stump left unoccluded intraoperatively	2 (20%)	2 (10%)	2 (15%)	2 (11%)
Hemopericardium	1 (10%)	3 (14%)	1 (8%)	3 (17%)
Maximum LAA width, mm	30.2±8.8	32.8±7.5		
Pre-Lariat LAA volume, mL	9.9±1.9	8.1±3.7	9.5±3.9	8.0±2.7
LAA remnant on follow-up CT (3D)	All	None	4 (30.8%)	6 (33.3%)
Volume reduction post Lariat	77.5% ±13%		83.0±12.3%	73.9±13.38%
LAA stump on follow-up CT (3D)	NA	NA	3 (23.1%)	6 (33.3%)
Remnant laa waist diameter, mm	5.2±2.7			
Chicken wing morphology	2 (20%)	8 (38%)	9 (69%)	1 (6%)
Windsock morphology	3 (30%)	6 (29%)	2 (15%)	7 (39%)
Cauliflower morphology	4 (40%)	4 (19%)	1 (8%)	7 (39%)
Cactus morphology	1 (10%)	3 (14%)	1 (8%)	3 (17%)

CHADS2 indicates congestive heart failure, hypertension, age>75, diabetes mellitus, history of stroke; CHADS2VASC, CHADS2 in addition to female sex, ages 65–75, as well as double impact of age >75, vascular disease; CT, computed tomography; CVA, cerebrovascular accident; HASBLED, hypertension, abnormal renal/liver function, stroke, bleeding predisposition/history, labile INR, elderly, drugs/alcohol; and LAA, left atrial appendage; INR, international normalized ratio; TEE, transthoracic echo; and TIA, transient ischemic attack.

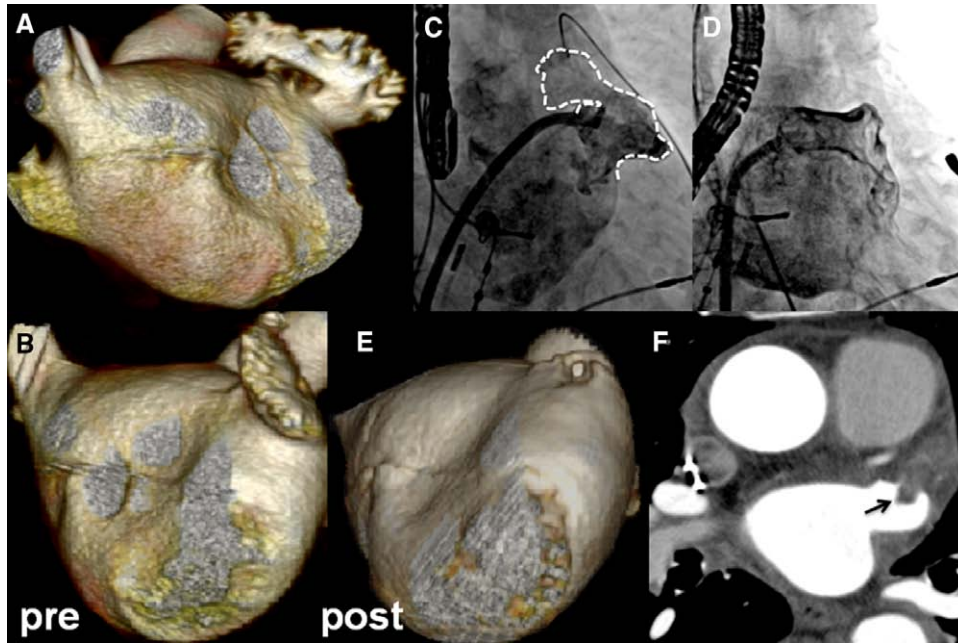
\*Non-Gaussian variables reported as median (minimum–maximum).

eventual scar and atrophy of compressed tissues may lead to thinning of the bunched up tissue and appearance of a luminal opening inside the suture. Interestingly, by the time this happens and the partial opening occurs, tissue atrophy in the LAA distal to the suture has also occurred, leading to a residual LAA cavity that is morphologically similar to the original LAA, but substantially smaller in volume and anatomic measurements. Morphological characteristics of the LAA, including volume, neck axes, and orifice size have been demonstrated to tie into thrombus formation and consequent thromboembolic risk.<sup>22,26–28</sup> In instances of failure to completely obliterate the LAA, these parameters were dramatically altered. Consequences of these changes are yet unclear, but our data to date suggest that no enhanced stroke risk is present in this population. Indeed, none of the patients with retained LAA had thromboembolic complications after 859±344 days of follow-up. It is noteworthy that neither the

presence of leak on postoperative TEE or angiogram nor the incomplete intraoperative occlusion of the LAA offered a reliable predictor of future LAA retention. Furthermore, the favorability of anatomic criteria had no bearing on the anatomic outcome after the Lariat procedure.

### Relevance of LAA Remodeling

Our study shows that LAA ligation and remodeling post Lariat is not an all-or-none phenomenon and that remodeling after a successful, angiographically, and echocardiographically complete LAA ligation can lead to: (1) partial opening of the LAA neck; and (2) a residual-reduced LAA cavity. Partial openings after Watchman LAA occlusion have been reported to occur<sup>29</sup> but seem to be devoid of clinical relevance as they are not associated with increased stroke risk. The applicability of Watchman data to the Lariat seems limited, given that partial openings with the Watchman device are eccentric and associated with



**Figure 6.** Complex left atrial appendage (LAA) stump morphology after successful Lariat ligation of a complex LAA. **A** and **B**, Three-dimensional reconstructions of the LAA before ligation. A large posterior–superior LAA lobe is seen. **C** and **D**, LAA angiograms before and after Lariat ligation, showing complete occlusion without leaks. **E** and **F**, Computed tomographic images post Lariat, showing protruding LAA tissue against the LAA neck (arrow, density consistent with tissue and not with thrombus), and a complex, ring-like geometry of the LAA stump.

typically high-flow velocities and communicate the LA with a nonremodeled LAA cavity distal to the Watchman device.

### Study Limitations

Our study had multiple limitations. The most important limitation of this series is that it was too small to allow conclusions about stroke risk. Although no patient had strokes or embolic phenomena on follow-up, a critical gap of knowledge remains, which relates to the clinical implications for stroke risk of partially occluded but remodeled LAA cavities. Our single-center study was limited to the work of 3 physicians, who are well experienced with the technique, which may account for the relatively low complication rates as opposed to an 8.1% incidence in the literature.<sup>30</sup> One particularly relevant complication is pericarditis, which has been repeatedly reported after Lariat ligation.<sup>11,12</sup> In our series, perhaps because of pre-emptive treatment with colchicine, no pericarditis was documented, but the presence of subclinical pericarditis and its contribution to the pathophysiologic mechanism underlying remodeling deserves further investigation in subsequent trials.

We did not perform follow-up TEE in all patients. However, the clinical need of surveillance of LAA ligation completeness was well served by CT, and our study was not designed to test the relative imaging merits of TEE versus CT in this population. As the study is exploratory in nature, CTs were conducted within a range of postprocedure intervals. Although they all satisfy the minimum requirement to allow sufficient remodeling (1 month), the temporal variability runs the risk of introducing bias to our results. Furthermore, selection bias may arise from the fact that patient preference played into inclusion in the study.

Moreover, the inclusion of both anatomically favorable and unfavorable patients into the sample may pose another source of bias.

### Conclusions

The LAA undergoes significant remodeling after Lariat ligation. In a significant proportion of patients undergoing Lariat LAA occlusion, a partial LAA opening with a residual, reduced LAA cavity develops. Further studies, including clinical (stroke) and anatomic end points, are required to determine the clinical relevance of residual LAA cavities. Moreover, establishment of reliable follow-up imaging strategies (and timings) may be crucial to better identify these outcomes.

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### Disclosures

None.

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