

# A randomized, prospective pilot comparison of 3 atrial appendage elimination techniques: Internal ligation, stapled excision, and surgical excision

Richard Lee, MD, MBA,<sup>a</sup> Patricia Vassallo, MD,<sup>b</sup> Jane Kruse, BS, RN,<sup>b</sup> S. Chris Malaisrie, MD,<sup>b</sup> Vera Rigolin, MD,<sup>b</sup> Adin-Cristian Andrei, PhD,<sup>b</sup> and Patrick McCarthy, MD<sup>b</sup>

## ABSTRACT

**Background:** Elimination of the left atrial appendage (LAA) attempts to reduce stroke in patients with atrial fibrillation (AF). A retrospective review suggests that various surgical techniques are often unsuccessful and may leave a stump or gap. In a pilot study, we prospectively evaluated 3 surgical techniques with long-term follow up to define effectiveness.

**Methods:** At a single institution, 28 patients undergoing concomitant AF surgery were randomized prospectively into 1 of 3 techniques of LAA elimination: internal suture ligation (IL), external stapled excision (StEx), and surgical excision (SxEx). The success of LAA elimination was assessed by transesophageal echocardiography (TEE) in all patients at the time of surgery. Failure of LAA closure consisted of either a stump (residual appendage tissue >1 cm in maximum length) or a gap (persistent flow between the left atrium [LA] and the LAA). Failure was treated intraoperatively when recognized. Late follow-up was obtained using a TEE at a mean of 0.4 years in 21/28 (75%) of patients.

**Results:** Early failure was recognized and treated in 1 patient in the IL group (13%), 6 patients in the StEx group (60%), and 2 patients in the SxEx group (20%) ( $P = .06$ ). On follow-up TEE, 4 of 7 patients in the IL group (57%) had developed gaps, 3 of whom (43%) with greater than mild flow. No patients in the StEx or SxEx groups had a gap ( $P = .03$ ). In late follow-up, 1 of 7 patients in the IL group (14%) had a stump, compared with 2 of 8 (25%) in the StEx group and 3 of 6 (50%) in the SxEx group ( $P = .35$ ). The overall failure rate was 57%: 5 of 8 (63%) in the IL group, 6 of 10 (60%) in the StEx group, and 5 of 10 (50%) in the SxEx group ( $P = .85$ ). No patient had a stroke at any time during follow-up.

**Conclusions:** LAA elimination is often incomplete and goes undetected. If the LAA is eliminated at the time of surgery, then TEE should be used intraoperatively to assess effectiveness and reintervention performed if warranted. Late assessment for completeness of closure should be considered before cessation of anticoagulation until more effective LAA techniques can be developed. (*J Thorac Cardiovasc Surg* 2016;152:1075-80)

Atrial fibrillation (AF) is the most common arrhythmia worldwide, and the incidence continues to increase in epidemic proportions. The left atrial appendage (LAA) is

emerging as an important target for stroke reduction in patients with AF. The LAA is the site of thrombus in 90% of nonrheumatic AF patients with stroke,<sup>1,2</sup> and LAA obliteration is an integral part of the maze operation.<sup>3</sup> In late follow-up, the combination of LAA elimination with an AF procedure has demonstrated a reduction

From the <sup>a</sup>Center for Comprehensive Cardiovascular Care, Saint Louis University, St Louis, Mo; and <sup>b</sup>Bluhm Cardiovascular Institute, Northwestern University, Chicago, Ill.

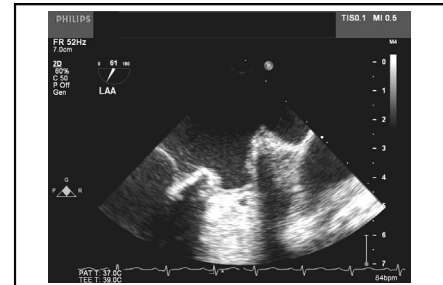
Received for publication Sept 18, 2015; revisions received March 25, 2016; accepted for publication June 9, 2016; available ahead of print July 12, 2016.

Address for reprints: Richard Lee, MD, MBA, Center for Comprehensive Cardiovascular Care, Saint Louis University, 3635 Vista Ave, DT 13th Floor, St Louis, MO 63110 (E-mail: rlee@slu.edu).

0022-5223/\$36.00

Copyright © 2016 by The American Association for Thoracic Surgery

<http://dx.doi.org/10.1016/j.jtcvs.2016.06.009>



Failed LAA excision.

### Central Message

Left atrial appendage elimination is frequently incomplete.

### Perspective

Patients with retrospective left atrial appendage (LAA) have demonstrated frequent failure, but only a small fraction of these patients are treated. This randomized prospective study verifies the shortcomings of current surgical LAA elimination techniques.

See Editorial Commentary page 1081.

Scanning this QR code will take you to the article title page.



**Abbreviations and Acronyms**

AF	= atrial fibrillation
IL	= internal suture ligation
LA	= left atrium
LAA	= left atrial appendage
StEx	= external stapled excision
SxEx	= surgical excision
TEE	= transesophageal echocardiography

in expected stroke after surgical treatment of AF.<sup>4,5</sup> More recently, interest in the LAA has increased because percutaneous implantation of a device that excludes the LAA has proven to be as effective as warfarin,<sup>6</sup> and is now approved by the US Food and Drug Administration.

Unfortunately, recent retrospective reviews of patients undergoing transesophageal echocardiography (TEE) for various indications have shown that surgery for LAA elimination often fails, with rates exceeding 50%.<sup>7-9</sup> These studies have been limited by an unknown denominator, however, because the overwhelming majority of patients receiving intervention had no postoperative assessment. A prospective assessment of surgical LAA ligation is unavailable. We performed a pilot trial of 3 surgical techniques—internal ligation (IL), stapled excision (StEx), and surgical excision (SxEx)—to provide necessary and sufficient data for the design of a definitive trial.

**MATERIALS AND METHODS**

The study was approved by Northwestern University's Institutional Review Board (no. STU00031186) and funded by a private donor. The patients consented to the study, which included randomization into surgical technique and late follow-up TEE. At a single institution, 28 patients undergoing combined surgery for mitral repair or replacement and AF were randomized into 1 of the 3 surgical LAA elimination techniques by 1 of 4 surgeons. Patients age >70 years and those with renal failure or previous sternotomy were excluded. Eight patients underwent IL using a double-layer running Prolene suture (Ethicon, Somerville, NJ) to eliminate the orifice. Ten patients underwent StEx using an Endo GIA stapler (Covidien, Sunnyvale, Calif), and 10 patients underwent SxEx with edge reapproximation using a running Prolene suture. Subsequently, 1 patient in the SxEx group was deemed too fragile for excision and so underwent IL.

The success of closure was assessed in real time in multiple views after cessation of cardiopulmonary bypass by an experienced echocardiographer. Success was determined based on previously reported criteria,<sup>7</sup> including no remnant pouch >1 cm in maximum length after closure (stump) and the absence of a color flow jet between the left atrium (LA) and the LAA (gap). Persistent flow was further divided into none, trace, mild, and greater than mild. Images were saved and blindly assessed after deidentification. Surgeons were allowed to modify the appendage at the time of surgery with additional sutures or free tie ligation (IL); however, this was counted as an early failure in technique. The AF procedure was predominately a left or biatrial Cox maze IV with bipolar radiofrequency and cryothermia at the isthmus. Late TEEs were performed after 3 months,

with the same criteria were used to determine success or failure. Overall failure was defined as presence of a gap or a stump on either TEE. In addition, length, base width, and widest width of the LAA were recorded.

Comparisons of continuous variables were performed using 1-way analysis of variance or the Kruskal-Wallis test. For categorical variables, proportions are presented, and group comparisons are based on the  $\chi^2$  test or Fisher's exact test. Statistical significance was declared at the 2-sided 5%  $\alpha$  level, and there were no multiplicity adjustments. Exact methods for binomial proportions were used to create 95% confidence intervals.

**RESULTS**

Baseline, intraoperative, and postoperative demographic data were comparable (Table 1). The patient designations and flow are provided in a CONSORT diagram in Figure 1.

**Safety**

There were no operative or 30-day deaths, no reexplorations for bleeding, and no early strokes or transient ischemic attacks. There were no significant differences among the groups in length of hospital stay (7 days) or readmission (10%). During follow-up, there were 2 late deaths, both in the StEx group ( $P = .14$ ). There were no late strokes.

**Efficacy**

Early results are presented in Table 2. There was a trend toward a greater need for intraoperative intervention in the StEx group ( $P = .06$ ), in which 3 patients had a large stump and 3 patients had bleeding, compared with 1 large stump and 1 case of bleeding in the SxEx group and none of either in the IL group. Although there was no statistical difference among the 3 groups, none of the IL patients had a stump, and only 1 patient with excision of any kind had residual flow.

Late follow-up TEE was performed in 75% of all patients, at a mean of  $0.4 \pm 0.1$  years (Table 3). The IL group had a higher rate of gaps and significantly greater flow ( $P = .03$ ). More than one-half of all interventions failed. On late follow-up, there were no strokes and no reoperations for any valve.

Overall failure of LAA elimination (early plus late) was 57%, including 5 of 8 (63%) in the IL group, 6 of 10 (60%) in the StEx group, and 5 of 10 (50%) in the SxEx group ( $P = .85$ ).

**DISCUSSION**

Although this was only a feasibility study, our data suggest that complete elimination of the LAA should not be assumed with any of the current surgical techniques. This finding is consistent with the results of previous retrospective studies.<sup>2,7,8</sup> Initially, internal ligation usually provides a stump-free elimination, but often tears through the tissue, likely because of tension, causing a

Download English Version:

<https://daneshyari.com/en/article/2978605>

Download Persian Version:

<https://daneshyari.com/article/2978605>

[Daneshyari.com](https://daneshyari.com)