

# Left atrial appendage elimination techniques: stapled excision versus internal suture obliteration

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**Background:** This study was conducted to compare the efficacy and safety of left atrium appendage (LAA) elimination using stapled excision with those using internal suture obliteration.

**Methods:** In all, 158 patients with atrial fibrillation who underwent surgical elimination of the LAA during cardiac surgery and later underwent postoperative computed tomography (CT) were enrolled. Of these, 102 patients underwent stapled excision (SE group), and 56 underwent internal suture obliteration (IO group). The efficacy endpoint was LAA excision failure, including a remnant LAA (>1 cm) or communication between the left atrium (LA) and LAA. The safety endpoint was bleeding from the elimination site. The CT was performed at a median of 12.8 months (interquartile range, 0.3–39.9) after surgery.

**Results:** The efficacy endpoint was observed in 5 (4.9%) and 9 patients (16.1%) in the SE and IO groups, respectively (P=0.036). In the SE group, a remnant LAA was found in 5 patients and extravasation of the dye was not observed. In the IO group, a remnant LAA, a communication between the LA and LAA, and both findings were observed in 1, 6, and 2 patients, respectively. The safety endpoint occurred in 12 (11.8%) and 0 patients (0%) in the SE and IO groups, respectively (P=0.009).

**Conclusions:** Stapled excision of the LAA was associated with a lower rate of LAA elimination failure compared to internal suture obliteration. However, care should be taken to prevent staple-related bleeding.

Keywords: Cardiac; arrhythmia therapy; surgical equipment

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#### Introduction

Atrial fibrillation (AF) is the most prevalent arrhythmia and an independent risk factor for stroke and systemic thromboembolism (1). In AF patients, the overall risk of stroke per year is reported to be 5% (2,3). The risk of stroke is age-dependent, being about 16-fold higher in AF patients in their 50s than those in their 80s (3). The left atrium appendage (LAA) is an important source of thrombi in AF patients (4). Therefore, elimination of the LAA may be a key procedure in AF patients who undergo cardiac surgery to reduce further thromboembolic events (5-7).

Surgical LAA elimination techniques include surgical excision, stapled excision, internal suture obliteration and epicardial clip occlusion (8,9). Previous studies have demonstrated controversial results regarding the safety

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Table 1 Preoperative data of the study patients

Variables	SE group (n=102)	IO group (n=56)	P value
Age (years)	66.9±9.4	62.1±8.7	0.002
Female, n (%)	55 (53.9)	38 (67.9)	0.089
Body surface area (m <sup>2</sup> )	1.6±0.2	1.6±0.2	0.626
Risk factors, n (%)			
Smoking	24 (23.4)	9 (16.1)	0.270
Hypertension	41 (40.2)	14 (25.0)	0.055
Diabetes mellitus	20 (19.6)	9 (16.1)	0.583
History of stroke	19 (18.6)	9 (16.1)	0.687
Chronic kidney disease	24 (23.5)	12 (21.4)	0.763
Dyslipidemia	22 (21.6)	8 (14.3)	0.264
Chronic lung disease	8 (7.8)	4 (7.1)	0.874
Peripheral vascular disease	3 (2.9)	1(1.8)	>0.999
NYHA class ≥3	43 (42.2)	17 (30.4)	0.144
Diameter of the LA	61±12	63±14	0.371
LV ejection fraction (%)	57±8	57±6	0.810

Values are n (%) or mean ± SD. NYHA, New York Heart Association; LA, left atrium; LV, left ventricle.

and efficacy of various LAA elimination techniques (9-12). Therefore, this study compared the safety and efficacy of stapled excision and internal suture obliteration of the LAA.

We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi. org/10.21037/jtd-21-1138).

#### Methods

#### Patient characteristics

The study protocol was reviewed by the Institutional Review Board of our institution and approved as a minimalrisk retrospective study and individual consent was waived (approval no. H-2101-025-1185). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Between January 2013 and February 2020, a total of 234 AF patients underwent LAA elimination during concomitant cardiac surgery. Of these patients, 10 patients who underwent previous cardiac surgery were excluded. A total of 158 patients (male:female, 65:93) who later underwent postoperative computed tomography (CT) were enrolled in the this study. Of these, 102 patients underwent LAA elimination using stapled excision (SE group) and 56 patients with internal suture obliteration (IO group). A total of 49 patients of the stapled excision group in the previous study (12) were included in this study. All enrolled patients were included in the analyses. The mean age at the surgery was  $65.2\pm9.4$  years. The median duration of AF was 3.4 years (interquartile range, 0.3-9.0 years). Hypertension (34.8%) and chronic kidney disease (22.8%) were the most common comorbidities. The SE group patients were older than the IO group (P=0.002) (*Table 1*).

# Surgical procedures, operative data and postoperative anticoagulation

All procedures were performed through a median sternotomy, with aorto-bicaval cannulation under moderate hypothermia and cold cardioplegic arrest. Neither the morphology of the LAA nor positional relationship of LA and LAA was criteria to avoid stapled excision. The choice of LAA elimination technique was according to each surgeon's preference; stapled excision was performed by two surgeons having hundreds of experiences in valvular heart surgery, and internal suture obliteration was performed by one senior surgeon having thousands of experience in valvular heart surgery.

Variables	SE group (n=102)	IO group (n=56)	P value
CPB time (minutes)	171±56	240±65	<0.001
ACC time (minutes)	117±38	174±54	<0.001
Concomitant procedure, n (%)			
Aortic valve surgery	26 (25.5)	21 (37.5)	0.114
Mitral valve surgery	67 (65.7)	49 (87.5)	0.003
Tricuspid valve surgery	45 (44.1)	29 (51.8)	0.356
Arrhythmia surgery	91 (89.2)	47 (83.9)	0.339
Coronary artery bypass grafting	7 (6.9)	0 (0.0)	0.052

Table 2 Operative data of the study patients

Values are n (%) or mean  $\pm$  SD. CPB, cardiopulmonary bypass; ACC, aortic cross clamp.

All of the patients in the SE group underwent LAA excision with an Endo GIA Vascular Stapler (Medtronic, Minneapolis, MN, USA) using a single 60 mm cartridge (n=84) or both 60 mm and additional 45 mm cartridges (n=18). Purple-colored cartridges were used in the most of patients (n=48, 30.4%). In the middle of study periods, Tan-colored cartridge was used in xxx following thoracic surgeons' advice (n=53, 33.5%). Since LAA excision technique using staplers were adopted, details about bleeding and reinforcement sutures have been recorded in our institutional database. In the IO group, internal suture obliteration was performed with a double-layer continuous suture or multiple mattress interrupted sutures reinforced with pledgets. The LAA was not excised in any patients. LAA excision or internal suture obliteration was performed after the completion of all other procedures, before closing the left atriotomy.

Mean cardiopulmonary bypass (CPB) and aortic cross clamp (ACC) times were 196 $\pm$ 67 and 137 $\pm$ 52 minutes, respectively. All patients underwent either mitral valve surgery (n=116) or maze procedure (n=138). Other cardiac procedures included tricuspid valve surgery (n=74), aortic valve operation (n=48) and coronary artery bypass grafting (n=7). The CPB and ACC times were significantly longer and concomitant mitral valve related procedures were more frequently performed in the IO than SE group (*Table 2*).

Low-molecular-weight heparin was initiated postoperatively in all patients, usually on postoperative day 1 and overlapped with warfarin anticoagulation. The target international normalized ratio ranged from 2.0 to 3.0 based on the types of concomitant procedures. Aspirin (100 mg/day) was added in 7 patients who underwent concomitant coronary artery bypass grafting.

#### Evaluation of early clinical outcomes

Operative mortality was defined as death within 30 days of the operation or during the same hospitalization. Postoperative low cardiac output syndrome was defined as the need for mechanical supports or inotropic support to maintain systolic blood pressure >90 mmHg even after correction of reversible factors. Respiratory complications included postoperative pneumonia or >48 hours of prolonged ventilator support. Acute kidney injury was defined as an increase of >50% in serum creatinine from the base level according to the Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease criteria (13). Postoperative stroke, either hemorrhagic or embolic, was defined as any new neurological deficit presenting in hospital with accompanying neuroimaging confirmation (CT or brain magnetic resonance imaging), and diagnostic confirmation by a neurologist. Other thromboembolic events were defined as systemic thromboembolic events other than a stroke or transient ischemic attack.

# Evaluation of the left atrial appendage using computed tomography

For the evaluation of the LAA, electrocardiogram-gated cardiac CT scans were performed with dual-source CT (Somatom Force; Siemens Medical Solutions, Forchheim, Germany). Image acquisition was gated to 40% of the RR interval. The contrast injection protocol consisted of 70 mL of iopromide (Iomeron 400; Bracco Diagnostics, Milan, Italy) followed by 50 mL of an 8:2 mixture of normal saline and contrast medium at a flow rate of 4 mL/sec.

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Variables	SE group (n=102)	IO group (n=56)	P value
Operative mortality, n (%)	2 (2.0)	0 (0.0)	0.539
Complications, n (%)			
Acute kidney injury	32 (31.4)	11 (19.6)	0.113
LCOS	11 (10.8)	11 (19.6)	0.124
Respiratory complication	12 (11.8)	6 (10.7)	0.842
Bleeding reoperation	8 (7.8)	1 (1.8)	0.160
Hemorrhagic stroke	0 (0.0)	0 (0.0)	>0.999
Embolic stroke	2 (2.0)	2 (3.6)	0.615
Mediastinitis	0 (0.0)	0 (0.0)	>0.999

 Table 3 Early clinical outcomes

LCOS, low cardiac output syndrome.

Gated cardiac CT scans were performed at first pass and 2 minutes after contrast administration. One radiologist, who was specialized for cardiovascular imaging, reviewed all the CT scans. The median interval between the operation and CT scan was 12.8 months (interquartile range 0.3–39.9 months). All enrolled patients underwent CT scanning.

Patients with decreased renal function underwent contrast enhanced CT scans with pre- and post-scan managements to prevent aggravation of renal dysfunction with a consultation to a nephrologist.

# Efficacy and safety endpoints of left atrial appendage elimination

The primary efficacy endpoint was LAA elimination failure. In the SE group, this was defined as the presence of a remnant LAA (an LAA pouch with a maximum length >1 cm on three dimensional CT scan) or extravasation of radiocontrast dye outside the LA. In the IO group, it was defined as the presence of a remnant LAA (an LAA pouch with a maximum length >1 cm on three dimensional CT scan) or residual communication between the LA and obliterated LAA. In addition, the presence of a LA thrombus was evaluated as the secondary efficacy endpoint.

The safety endpoint was defined as bleeding from the elimination site requiring reinforcement sutures during surgery or reoperation.

#### Statistical analysis

Statistical analyses were performed using the SPSS software

package (version 23.0; IBM Corp., Armonk, NY, USA). Data are expressed as the mean  $\pm$  standard deviation, median with interquartile range, or a proportion. Comparisons between the two groups were performed using the chi-square test or Fisher's exact test and Student's *t*-test for categorical and continuous variables, respectively. The data were assumed to follow normal distribution as the sample size was greater than 30 based on central limit theorem. Fisher's test was adopted when 25% of expected frequencies is less than or equal to 5 in 2×2 contingency table. A P value <0.05 was considered as statistically significant.

#### **Results**

#### Early clinical outcomes

Early mortality occurred in 2 and 0 patients in the SE and IO groups, respectively. One patient died of aggravation of ischemic colitis which was present preoperatively on the 23rd postoperative day. The other patient expired due to septic shock on the 13th postoperative day. Postoperative complications included acute kidney injury (n=43, 27.2%), low cardiac output syndrome (n=22, 13.9%), respiratory complications (n=18, 11.4%), postoperative bleeding requiring reoperation (n=9, 5.7%) and stroke (n=4, 2.5%). There were no statistically significant differences in operative mortality or postoperative complications between the two groups (*Table 3*).

#### Evaluation of efficacy endpoint

The CT scans of the patients with successful LAA

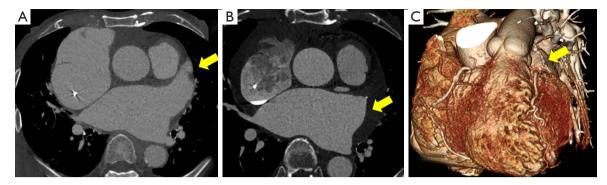


Figure 1 A case of successful left atrial appendage (LAA) elimination in the stapled excision group. (A) Preoperative electrocardiogramgated computed tomography (CT) scan showing LAA. (B) A two-dimensional and (C) three-dimensional postoperative CT scan showing a completely excised LAA. The arrow indicates well excised LAA.



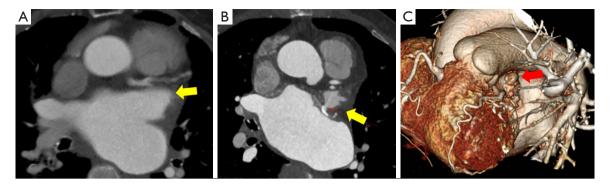
**Figure 2** A case of successful left atrial appendage (LAA) elimination in the internal suture obliteration group. (A) preoperative electrocardiogram-gated computed tomography (CT) scan showing LAA. (B) A two-dimensional and (C) three-dimensional postoperative CT scan showing a completely obliterated LAA. The arrow indicates well obliterated LAA.



Figure 3 A case of left atrial appendage (LAA) elimination failure in the stapled excision group. (A) Preoperative electrocardiogram-gated computed tomography (CT) scan showing LAA. (B) A two-dimensional and (C) three-dimensional postoperative CT scan showing LAA remnant after stapled excision. The arrow indicates remnant LAA.

elimination in the SE and IO groups are presented in *Figures 1,2*, respectively. A remnant LAA was seen in 5 (4.9%) patients in the SE group (*Figure 3*). Extravasation of radiocontrast dye was not found in any patients. In the IO

group, a LAA remnant, residual communication between the LA and LAA, and both findings were seen in 1, 6, and 2 patients, respectively (*Figure 4*). The occurrence rate of the efficacy endpoint was significantly lower in the SE than in



**Figure 4** A case of left atrial appendage (LAA) elimination failure in the internal suture obliteration (IO) group. (A) Preoperative electrocardiogram-gated computed tomography (CT) scan showing LAA. (B) A two-dimensional and (C) three-dimensional postoperative CT scans showing incompletely obliterated LAA. Residual communication between the left atrium and LAA are shown. The arrow indicates incompletely obliterated LAA.

Table 4 Occurrence rates of efficacy and safety endpoints

Variables	SE group (n=102)	IO group (n=56)	P value
Efficacy endpoint (= LAA elimination failure), n (%)	5 (4.9)	9 (16.1)	0.036
LAA remnant	5 (4.9)	1 (1.8)	
Residual communication (or extravasation of dye)	0 (0)	6 (10.7)	
Both findings	0 (0)	2 (3.6)	
LA thrombus, n (%)	1 (1.0)	0 (0.0)	>0.999
Safety endpoint (= elimination site bleeding), n (%)	12 (11.8)	0 (0)	0.009
Control during index operation	12 (11.8)	0 (0)	
Staple line bleeding	8 (7.8)	-	
Bleeding from surrounding tissues	4 (3.9)	-	
Reoperation for LAA elimination site bleeding	0 (0)	0 (0)	

LAA, left atrium appendage; LA, left atrium.

the IO groups (4.9% vs. 16.1%, P=0.036) (Table 4).

In addition, LA thrombus was found in one patient in the LAAE group and target international normalized ratio was increased in this patient.

#### Occurrence of safety endpoint

In the SE group, bleeding from the LAA elimination site was controlled intraoperatively in 12 patients (11.8%). There were 8 (7.8%) cases of bleeding from the staple line and 4 (3.9%) cases of bleeding from surrounding tissues requiring reinforcement sutures (*Table 4*). Occurrence of bleeding events were not associated with the types of cartridge (P=0.734). No patient in the IO group had bleeding from the LAA elimination site. No patient in either group required reoperation due to LAA elimination site bleeding. The occurrence rate of the safety endpoint was significantly higher in the SE than in the IO group (11.8% *vs.* 0%, P=0.009).

#### Discussion

The present study demonstrates two main findings. First, stapled excision of the LAA resulted in better results in terms of complete elimination of the LAA than internal suture obliteration. Second, stapled excision of the LAA was associated with a fairly high rate of excision site bleeding due to staple line disruption or tears in the surrounding epicardial tissues.

The elimination of the LAA has been considered as a key procedure in AF patients who undergo cardiac surgery to reduce thromboembolic events (5,6). Recently, a randomized controlled clinical trial called 'LAAOS III trial' (7) confirmed this advantage once again; in this trial, 2,379 AF patients with CHA2DS2-VASc score equal or over 2 were randomly assigned to undergo or not undergo LAA elimination during cardiac surgery. The study results showed that the risk of ischemic stroke or systemic embolism was lower in LAA elimination group than the other group. Various surgical techniques have been proposed for the elimination of the LAA during cardiac surgery to prevent thromboembolic events associated with AF. These include an external approach such as suture ligation, stapled or surgical excision, and an internal approach such as suture obliteration (8,9,14). Previous studies have demonstrated the advantages and disadvantages of each technique. When considering effectiveness, complete exclusion of the LAA from bloodstream may be important to prevent a late stroke or systemic embolization (6,9).

Although internal suture obliteration of the LAA may be a simple and inexpensive choice for LAA exclusion, it is associated with incomplete obliteration in 10-30% of patients (11), predisposing them to thromboembolic events (15). Another study (10) showed that stapled excision resulted in 90% complete LAA elimination. However, comparative analyses between those two elimination techniques are limited. Despite surgeons' common sense that the LAA excision using staple might be a good option for LAA elimination, previous studies have demonstrated unsatisfactory results of the LAA excision. A previous randomized controlled study compared the effectiveness of internal ligation, stapled excision and surgical excision in 28 patients (9). The overall failure of LAA elimination was around 57% without any significant differences among the three groups. However, the study was limited due to the sample size being too small to detect a possible difference.

Thus, as a continuum of our previous study (12), this study compared the efficacy of stapled excision and internal suture obliteration in 168 patients, which was relatively large patient population compared to previous studies (9,11). A total of 50 patients of the stapled excision group in the previous study were included in this study. We found that stapled excision of the LAA during cardiac surgery resulted in complete elimination in more than 95% of patients. This is consistent with findings of a previous study showing a 90% success rate after stapled excision (10). However, in contrast to the favorable efficacy results, this study also showed an association with a high rate of stapled excisionrelated bleeding directly from the staple line or from surrounding tissues, as reported previously (12), whereas no safety events occurred after internal suture obliteration. Because the LAA is not a linear structure, has variable morphology, and has a thin wall at the base, there may a risk of vascular staple line disruption. In addition, manipulation of the bulky vascular stapler in a narrow pericardial space might result in soft tissue tears around the LAA.

The epicardial clip is recently introduced device for LAA elimination, and the safety and efficacy of this technique has been reported (16,17). However, low flexibility and relatively bulky size of the device makes it difficult to use in a specific angulation or configuration (18). In addition, it is not popularized yet in many countries including ours. In our country, the use of the epicardial clip is very limited and it is insurance-covered only in cases of minimally invasive cardiac surgery.

Previous studies used transesophageal echocardiography (TEE) to evaluate the results of surgical LAA elimination. Although TEE is an effective tool for visualization of the LA and LAA, it is an invasive and costly procedure. Recently, non-invasive cardiac CT scans have been used to evaluate LAA elimination sites or intracardiac thrombi, and cardiac CT is a reasonable alternative to TEE (19,20). Cardiac CT became a routine follow-up protocol after surgical elimination of the LAA at our institution during the later study period. Therefore, patients in the early study period underwent CT scans at a longer time period after surgery than those in the later study period.

The present study has several limitations. First, this was a retrospective study performed at a single institution. Second, not all patients who underwent surgical LAA elimination underwent a subsequent CT scan. Third, the baseline characteristics between the two groups were not identical. Although, selection of the elimination technique was based on the surgeon's preference rather than patient characteristics, these differences might have affected our study results. The results were compared using univariate analyses because the effect of baseline characteristics on the study results, particularly the efficacy endpoint, may be minimal. Moreover, our analysis did not include other elimination techniques including epicardial clip.

In addition, follow-up clinical outcomes related to AF such as thromboembolism and bleeding were not evaluated because the study only included patients who underwent

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CT scans after surgery. The number of events (data not shown) was too small to draw any relevant longitudinal outcome data. Finally, the different intervals between the index operation to CT scan, which is inevitable as a retrospective study, are one of the limitations of the present study.

#### Conclusions

Stapled excision of the LAA was associated with a lower rate of LAA elimination failure compared to internal suture obliteration. However, cautious handling of the vascular stapler is recommended to prevent LAA excisionrelated bleeding from staple line disruption or injury to surrounding soft tissues.

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#### Footnote

*Reporting Checklist:* The authors have completed the STROBE reporting checklist. Available at https://dx.doi. org/10.21037/jtd-21-1138

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was reviewed by the Institutional Review Board of our institution and approved as a minimal-risk retrospective study and individual consent was waived (approval No.: H-2101-025-1185).

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