Clinical Performance of a Powered Surgical Stapler for Left Atrial Appendage Resection in a Video-Assisted Thoracoscopic Ablation for Patients with Nonvalvular Atrial Fibrillation

Tao Yan,1 MD, Shijie Zhu,1 MD, Miao Zhu,1 MD, Kai Zhu,1 MD, Lili Dong,2 MD, Chunsheng Wang,1 MD and Changfa Guo,1 MD

Summary
Left atrial appendage (LAA) has been found to be associated with the occurrence of thromboembolism in patients with nonvalvular atrial fibrillation (NVAF). Stapling exclusion of LAA during surgical ablation could be an alternative to oral anticoagulation for NVAF patients. However, its safety and efficacy have rarely been examined. Thus, in this study, we aimed to evaluate the safety and efficacy of a powered surgical stapler for LAA resection during ablation for patients with NVAF.

Adult patients with NVAF undergoing stapler surgery were included in this study. LAAs of patients were cut off using a powered surgical stapler. Intraoperative transesophageal echocardiogram (TEE) was applied before and after the operation. Each patient received anticoagulant therapy for 2 months after surgery and was regularly followed up by appointment or via telephone call. Patients would undergo physical examinations, echocardiography, and 24-hour dynamic electrocardiogram in a local or in our hospital to determine whether there was a recurrence of atrial fibrillation (AF) or thromboembolism caused by AF.

In total, 124 patients were included in this study (male: 88 (71.0%); mean age: 62.3 years). Blood loss was less than 100 mL in all patients with no operative complications or hospital deaths. Moreover, 119 (96.0%) follow-up data were collected, with a mean period of 27.4 months. All patients discontinued oral anticoagulants 2 months after their operation. As per our findings, AF recurred in 23 patients (18.5%), with an average of 9.1 months after surgery. No patients were diagnosed with thromboembolism related to AF.

Stapling exclusion of LAA during surgical ablation could safely and completely resect the LAA. The effect of thrombus prevention was deemed satisfactory.

Key words: Thromboembolism, Stapler surgery, Surgical ablation

Atrial fibrillation (AF) has been identified as one of the most common arrhythmias in clinical setting. The prevalence of AF in adults is estimated to be between 2% and 4% currently, which is expected to increase by two- to threefold due to extended life expectancy. Thromboembolism is the primary hazard of AF, with its most common manifestation being ischemic stroke. Approximate 15% of ischemic stroke is caused by AF. The overall risk of ischemic stroke in patients with AF is about 20-30%, which is five times higher than that of the general population. Warfarin is the first-line anticoagulant drug in the clinic. However, the individual dose difference was significant. Repeatedly monitoring the international normalized ratio (INR) is necessary for patients taking warfarin, which seriously affected the compliance of patients and limited the clinical benefit. Although new oral anticoagulants such as dabigatran and rivaroxaban have been proved to be effective in the prevention of thrombosis in nonvalvular atrial fibrillation (NVAF) patients, high price, the risk of bleeding, and other factors restrict their clinical application.

Left atrial appendage (LAA) is the residual accessory structure of the embryonic left atrium. The LAA of a healthy person has a normal contractile function with a low probability of thrombosis. However, in patients with NVAF, the left atrium can be observed to be enlarged, with a significantly decreased filling and emptying velocity of the LAA. Moreover, the uneven inner wall of LAA is easy to cause eddy current in blood, which often leads to blood stasis, resulting in thrombosis. The previous study has shown that 90% of the thrombus in patients with NVAF originated from the LAA. A recent study

From the 1Department of Cardiovascular Surgery, Zhongshan Hospital, Fudan University, Shanghai, China and 2Department of Echocardiography, Zhongshan Hospital, Fudan University, Shanghai, China.
*These authors contributed equally to this work.
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Address for correspondence: Chunsheng Wang, MD or Changfa Guo, MD, Department of Cardiovascular Surgery, Zhongshan Hospital, Fudan University, 180 Fenglin Road, Shanghai, 200032, China. E-mail: wangchunsheng@fudan.edu.cn or guo.changfa@zs-hospital.sh.cn
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has demonstrated that as long as NVAF patients have cardioembolic thrombosis, it will definitely exist in the LAA. Therefore, it is of considerable significance to occlude or cut off the left atrial appendage as an alternative to anticoagulation during surgical ablation in order to reduce the risk of potential thrombus.

Currently, the surgical methods for LAA are mainly divided into the following types: (1) cut-and-sew technique; (2) LAA clip; (3) LAA occlusion; and (4) stapling exclusion of LAA. The stapler simplifies the surgical procedure and makes it more convenient for the surgeon to operate. Nevertheless, several previous studies have demonstrated unsatisfactory outcomes due to related complications, including leakage, bleeding, and tissue tears beneath the staple line. Those studies seemed to indicate that the stapler surgery was not a suitable option for LAA resection. However, with the redesigned staple geometry and the introduction of a power source, the safety and efficacy of the stapler surgery have been improved compared with the past. The first powered surgical stapler approved by the US Food and Drug Administration (FDA) was produced by Medtronic under the brand name “the iDrive Pierce system” in 2010. ECHELON FLEX Powered ENDOPATH Stapler produced by Ethicon was then approved for use by FDA in the next year.

In 2014, the launch of a new powered stapler and reload system, that is, ECHELON FLEX™ GST System, uniquely designed to provide a better grip on tissue, was announced by Ethicon. Although the previous study has shown that patients undergoing lobectomy can benefit from this new stapler system, its application for LAA resection in video-assisted thoracoscopic (VAT) ablation has not yet been reported. We retrospectively analyzed NVAF patients who underwent the stapler surgery utilizing ECHELON FLEX™ GST System during VAT ablation in Zhongshan Hospital in the past 4 years and evaluated its curative effect and prognosis in order to provide some clinical evidence for the safety and efficacy of stapler surgery during surgical ablation.

Methods

Patient selection: Adult patients with NVAF undergoing stapler surgery during VAT ablation at the Department of Cardiac Surgery in Zhongshan Hospital from January 2016 to September 2019 were included in the assessment. Excluded from the research were patients with valvular lesions or coronary artery heart disease, those who were unable to adhere to anticoagulation for at least 2 months, whose ejection fractions are less than 30%, and those who have some other contraindications to minimally invasive surgery. This study fully complies with the Declaration of Helsinki. Due to the particularity of this retrospective study, the informed consent was waived, but the study was approved by the ethics committee of Zhongshan Hospital, Fudan University.

Surgery procedure: The ablation and stapler surgery were performed on all patients in one single center (Zhongshan Hospital, Fudan University, Shanghai, China). Briefly, after the patient was placed in the right lateral decubitus position, a 4 cm incision was made in the left fourth intercostal space to enter the left hemithorax. LAA was then resected using a powered surgical stapler (ECHELON FLEX™ GST System, ETHICON, USA) (Figure 1) through VAT after the confirmation of the absence of mural thrombus by an intraoperative transesophageal echocardiogram (TEE) (Figure 2A). The length of the stump and the quality of the anastomosis were also evaluated via TEE after the operation (Figure 2B). Then, bilateral pulmonary vein isolation, ganglionic plexus evaluation and destruction, and resection of Marshall ligament were performed, with a linear lesion connecting the left atrial roof to the root of the aorta at the junction of the left coronary and the non-coronary cusp. After fixing the temporary pacing line, the same approach was applied to enter the right hemithorax. A bipolar radiofrequency clamp was used to make four ablation lesions to the superior vena cava, the inferior vena cava, the appendix of the right atrium, and the tricuspid valve annulus from a purse-string suture point on the right atrium.

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The incision was then closed after adequate hemostasis. The patient was sent to the Cardiac Surgery Intensive Care Unit with ECG monitoring for at least 24 hours after surgery. If there were no special circumstances such as adverse surgical complications, the patient would be discharged on the third day after the surgery.

Anticoagulant therapy: Each patient received anticoagulant therapy for 2 months after surgery. In the choice of anticoagulant drugs, we had a preference for warfarin or rivaroxaban. The dose of rivaroxaban was 15 mg/day. And the initial dose of warfarin was 3.0 mg/day. Patients taking warfarin would check the INR regularly to ensure that the INR was between 2 and 3 to prevent increased bleeding risk or poor anticoagulant effect.

Clinical follow-up: Patients with NVAF were followed up by appointment or via telephone on the 3, 6, 12 months and then yearly after discharge from the hospital. Patients would undergo a series of examinations, including echocardiography, dynamic electrocardiogram, INR, and some other related inspections in a local hospital or in our hospital to determine whether there was a recurrence of AF (after the first 3 months of surgery, the recurrence of AF, atrial flutter (AFL), or atrial tachycardia would be considered as recurrence of AF) or anatomic leakage. If the patient showed signs of stroke, a brain magnetic resonance imaging examination would be performed immediately. When the patient had a stroke with no evidence showing it was caused by other underlying diseases, we believed it was due to AF.

Statistic analysis: All statistical analyses were performed using SPSS 22.0 statistical software for Windows. For quantitative variables, mean ± standard deviation or median and interquartile range (IQR) were calculated as descriptive statistics, and data were presented as frequencies and percentages for categorical variables.

Results

Baseline characteristics: In total, 124 patients, including 34 (27.4%) paroxysmal NVAF and 90 (72.6%) persistent NVAF, in Zhongshan Hospital from January 2016 to September 2019 undergoing stapler surgery during VAT abla-
tion were included in this study, of whom 88 (71.0%) were male, with a mean age of 62.3 ± 8.1 years (range 23 to 77 years). The mean left ventricular ejection fraction (LVEF) and left atrial size were 64.0 ± 5.4% (range 39% to 77%) and 44.1 ± 5.5 mm (range 30 to 60 mm), respectively. Further, 65 (52.4%) patients were determined to have hypertension, of whom 4 (3.2%) had a history of stroke and 8 (6.5%) had diabetes. Detailed baseline characteristics are shown in Table I.

**Surgical outcomes:** All patients had successful stapler surgery through VAT in Zhongshan Hospital with no pulmonary vein injury. No patients were converted to thoracotomy or cardiopulmonary bypass. Intraoperative TEE indicated the absence of LAA mural thrombus in all patients before the use of stapler equipment. Under the confirmation of intraoperative TEE, LAAs were resected in all patients with stumps less than 5 mm, and no leakage was found of anastomoses. Moreover, 81 (65.3%) patients turned to sinus rhythm during the operation. The rest of the patients (34.7%) recovered their sinus rhythm through electric defibrillation after the surgery. The intraoperative blood loss of each patient was less than 100 mL. No surgical complications or hospital deaths occurred. Electrocardiographic monitoring within 3 days after the operation demonstrated a significant reduction in atrial tachyarrhythmias. Upon discharge, all patients converted to sinus rhythm except five (4.0%). Detailed surgical outcomes are shown in Table II.

**Clinical follow-up:** Because of the loss of 5 (4.0%) patients, follow-up data of 119 patients (96.0%) were collected, with a mean period of 27.4 months (range 12 to 55 months). No mortality occurred during the follow-up. All patients discontinued taking oral anticoagulants 2 months after the operation. TEE showed that the LAA was flat without mural thrombosis 3 months after the operation. AF recurred in a total of 23 patients (18.5%), with an average of 9.1 months (range 3 to 40 months) after surgery, of whom 19 (82.6%) were male, with a mean age of 61.3 ± 8.2 years (range 42 to 74 years). There were 19 (82.6%) persistent AF and 4 (17.4%) paroxysmal AF. The mean LVEF and left atrial size were 64.0 ± 3.8% (range 57% to 70%) and 45.1 ± 5.3 mm (range 33 to 58 mm), respectively. Eleven patients had hypertension; five patients had both hypertension and diabetes; and two patients had a history of stroke. In particular, three patients had both hypertension and diabetes, and one patient had diabetes and a history of stroke. The success rate of freedom from AF at 3, 6, 12, 24, 36, and 48 were 92.4% (110/119), 87.4% (104/119), 84.0% (100/119), 81.7% (89/109), 74.6% (47/63), and 73.9% (17/23), respectively. No patients developed thromboembolism due to AF after discharge.

**Discussion**

There is still controversy as regards the treatment of the LAA in clinical practice. In this study, we conducted a retrospective analysis to evaluate the clinical performance of a novel powered surgical stapler during VAT ablation, which indicated that LAA resection with this stapler sys-
Figure 2. Transesophageal echocardiogram (TEE) images. A: Intraoperative TEE before LAA resection with the absence of mural thrombus. B: Intraoperative TEE after LAA resection with straight cut line and complete anastomosis. C: The three-dimensional TEE image 3 months after discharge, showing no stumps and leakage.

| Parameters                             | Values                     |
|----------------------------------------|----------------------------|
| Gender, n (%)                          | 88 (71.0)                  |
| Male                                   | 88 (71.0)                  |
| Female                                 | 36 (29.0)                  |
| Age, years, mean ± SD, (range)         | 62.3 ± 8.1 (23 to 77)      |
| CHADS2, mean ± SD, (range)             | 1.6 ± 1.0 (0 to 5)         |
| Type of NVAF, n (%)                    |                            |
| Persistent                             | 90 (72.6)                  |
| Paroxysmal                             | 34 (27.4)                  |
| LA diameter, mm, mean ± SD, (range)    | 44.1 ± 5.5 (30 to 60)      |
| LVEF, %, mean ± SD, (range)            | 64.0 ± 5.4 (39 to 77)      |
| Medical history, n (%)                 |                            |
| Hypertension                           | 53 (42.7)                  |
| Diabetic mellitus                      | 1 (0.8)                    |
| History of preoperative stroke         | 3 (2.4)                    |
| Hypertension and diabetic mellitus     | 8 (6.5)                    |
| Hypertension and stroke history        | 4 (3.2)                    |
| Diabetic mellitus and stroke history   | 1 (0.8)                    |
| History of catheter ablation           | 5 (4.0)                    |

NVAF indicates nonvalvular atrial fibrillation; LA, left atrium; and LVEF, left ventricular ejection fraction.

tem was a safe procedure for patients with NVAF. Intraoperative blood loss was less than 100 mL for each patient. There were no adverse surgical complications and mortality during hospitalization. A previous study using a
manual stapler to remove 222 cases of LAA that showed that 10% of patients required additional sutures to repair tissue tears beneath the staple line. Seven (3%) cases required reoperation due to bleeding. A randomized controlled trial performing manual stapler resection of the LAA concomitantly with coronary artery bypass grafting (CABG) demonstrated four (8%) patients had intraoperative tears related to the stapler. In another randomized controlled trial, authors applied a powered stapler to resect the LAA for patients with AF. Six (60%) patients required additional intraoperative sutures. The stapler we used for LAA resection, ECHELON FLEX™ GST System, has optimal compression integrated with better grasping during the surgery, which reduced the effect of tissue slippage, as well as leakage and bleeding. Compared with those studies, intraoperative blood loss of each patient was fewer than 100 mL in our study. There were no reoperations, no hospital deaths, and no tissue tears. Unlike the cut-and-sew procedure, which requires cardiopulmonary bypass, stapler surgery is performed with the assistance of thoracoscopy. The small incision reduces the burden of patients, leading to a reduction in complications.

More importantly, using the stapler system to eliminate the LAA was effective for thromboembolism prevention. Healey et al. reported that stumps of the LAA larger than 1 cm were found in nine (27%) patients undergoing stapler surgery concomitantly with CABG. In another previous study, a powered stapler was applied in 10 patients, and 2 (20%) had residual stumps larger than 1 cm in the follow-up. The formation of stump often affects the outcome of surgery and may even increase the risk of embolism. The ECHELON FLEX™ GST System can deliver four times less tissue slippage for more targeted tissue transections through its Gripping Surface Technology (GST), which helps reduce stump formation. In our study, none of the patients showed stumps during follow-up (Figure 2C). The results of a similar retrospective study utilizing ECHELON FLEX™ Powered ENDOPATH Stapler demonstrated that only two patients (1%) developed cardiogenic thromboembolisms, which seemed to be a satisfactory result. However, during our average follow-up of 27.4 months, no patients developed AF-related embolic events. These results proved our surgical method to be an effective treatment which can become an alternative for patients with NVAF.

Currently, other surgical methods, including suture ligation, LAA clip, and LAA occlusion, are also applied to LAA elimination. Suture ligation procedure is a commonly used surgical method, which has the advantages of simple operation and low cost. However, it may have a weak effect on preventing postoperative thrombus in patients with NVAF due to the high incidence of incomplete suture. A previous study showed that 33% of patients have intraoperative incomplete ligated LAAs and 40% of patients were found leakage after surgery. Compared with the suture ligation technique, no patients in our study were found to have leakage, which was beneficial for patients with NVAF to prevent thrombosis.

LAA clip is a new surgical device first reported by Ailawadi et al. in 2011. The device is placed at the base of the LAA to block blood flow into the LAA. Ellis et al. reported that this is an attractive surgical procedure because it can be used as an independent surgical method to prevent thrombosis. The average operation time is only 92 minutes, and 93.9% of patients achieve complete closure. Any postoperative systemic anticoagulant therapy is not needed for patients who receive LAA clip surgery. Compared with the stapler, the clip is more convenient for surgeons to operate, as it can be placed in the neck of the LAA due to the shape of the clip. However, the clip surgery often results in some smooth-walled stumps, and whether these stumps will increase the risk of stroke or systemic embolism is still unknown. Besides, it is possible to misjudge whether the closure is utterly effective due to unfamiliarity with the device even if there is the assistance of intraoperative TEE. In addition, the first LAA clip has just been approved for 1 year and has not been widely used in China. Moreover, compared with the stapler, the cost of this device is too expensive for some patients, which is also worthy of attention.

LAA occlusion (LAAO) has made rapid development since its clinical application in 2001. With the release of long-term follow-up results of some randomized controlled trials (PROTECT AF, ASAFLAP, and PREVAIL, et al.) in recent years, the American Heart Association (AHA) and European Society of Cardiology (ESC) have written it into guidelines as an alternative treatment (evidence level IIb) for NVAF patients with high stroke risk and long-term contraindications for anticoagulation. A registered US National Cardiovascular Data Registry (NCDR) study showed that only 1.9% of patients with occluder implantation developed peripheral leakage, and postoperative stroke (0.17%) and death (0.19%) were rare, which is slightly higher compared to our study. The effect of LAAO will be affected by the anatomical morphology of the LAA. The stapler operation is performed with the assistance of VAT, with LAA resection under direct vision during the operation, which will not be restricted by the anatomy of the LAA and can increase the success rate of the operation. Even after LAAO surgery, current guidelines point out that patients still need to receive oral anticoagulant therapy for at least 3 months.

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**Table II. Surgical Outcomes (n = 124)**

| Parameters                              | Values |
|-----------------------------------------|--------|
| Surgical approach, n (%)                | VAT 124 (100) |
|                                          | Thoracotomy 0 (0) |
| Cardiopulmonary bypass, n (%)           | 0 (0) |
| Stumps of LAAs, n (%)                   | < 5 mm 124 (100) |
|                                          | > 5 mm 0 (0) |
| Anastomotic leakage, n (%)              | 0 (0) |
| Operative bleeding, n (%)               | < 100 mL 124 (100) |
|                                          | > 100 mL 0 (0) |
| Surgical complications, n (%)           | 0 (0) |
| Perioperative mortality, n (%)          | 0 (0) |
| Intraoperative sinus rhythm, n (%)      | 81 (65.3) |
| Sinus rhythm at discharge, n (%)        | 119 (96) |

VAT indicates video-assisted thoracoscopic.
and long-term use of aspirin is also required. Whether aspirin can be stopped needs follow-up clinical trials like STOP Aspirin. In our study, all patients discontinued oral anticoagulant therapy 2 months after surgery, with no patients developing strokes. In addition, there are more than 10 kinds of devices in clinical applications, including Watchman, Amplatzer Amulet, and LAmbr.\textsuperscript{25,30,31} There are different understandings about the clinical pathway of LAAO surgery. Whether the efficacies of different types of devices and different clinical pathways are consistent has not been confirmed yet; thus, follow-up studies are needed to determine a more uniform and transparent standard.

Although stapler surgery was an alternative method for LAA resection based on our study, the availability of the closure or resection devices would depend on each regional situation. There are several limitations to our study. First, this research is a retrospective real-world study rather than a randomized controlled study. A control group should be established for further study. Second, the surgery was performed in one single center by one single surgeon. The small number of patients with NVAF limits the effectiveness of statistics and the reliability of conclusions. Multicenter research should be conducted to verify the result.

Conclusion

The 2-year outcomes of VAT stapling exclusion of LAA during surgical AF ablation in our study demonstrated no surgical complications and mortality and a low recurrence rate in patients with NVAF. No patients developed thromboembolism after surgery. This is a safe and effective surgical method for treating patients with NVAF and can be an alternative for clinical application.

Disclosure

Conflicts of interest: All authors have completed the IC-MJE uniform disclosure form. The authors have no conflicts of interest to declare.

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