Left Atrial Appendage Closure Reduces the Incidence of Postoperative Cerebrovascular Accident in Patients Undergoing Cardiac Surgery

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Background: Cerebrovascular accidents (CVA) are a major adverse event following cardiac surgery, for which atrial fibrillation (AF) is considered as a risk factor. We have recently performed left atrial appendage (LAA) surgical closure or amputation (LAAC/A), which is the main source of emboli, during open-heart surgery.

Methods and Results: A prospective observational study of 1,831 consecutive patients (69.2% male, aged 66.8±12.2 years) undergoing cardiac surgery between 2009 and 2013 was performed. The incidence of postoperative CVA within 6 months in patients with and without LAAC/A was compared. We further stratified patients according to their risk of CVA using CHA2DS2-VASc score: dichotomizing low-risk (score <2) and high-risk groups (≥2). A total of 369 patients (20.2%) underwent LAAC/A. Although these patients had larger left atrial diameter preoperatively and developed postoperative AF more frequently than those without LAAC/A (45.4 vs. 41.1 mm, 49.3 vs. 39.1%, respectively, both P<0.001), the CVA incidence was not different between the groups (3.5 vs. 3.0%, P=0.612). Multivariate analysis revealed no association between LAAC/A and CVA in patients with CHA2DS2-VASc score ≥2, whereas in patients with CHA2DS2-VASc score <2, LAAC/A was the only and independent factor negatively associated with CVA development (odds ratio <10⁻⁶; P=0.021).

Conclusions: Additional LAA procedure at the time of cardiac surgery reduces the incidence of early postoperative CVA in patients with low CHA2DS2-VASc score. (Circ J 2015; 79: 2591–2597)

Key Words: Atrial fibrillation; Cardiac surgery; Cerebrovascular accident; Left atrial appendage; Risk assessment

Atrial fibrillation (AF) is the most common significant cardiac arrhythmia. It affects more than 2.3 million individuals in the USA and 4.5 million in the European Union, and its prevalence has increased substantially in recent years. AF is associated with higher severity of ischemic cerebrovascular accidents (CVA) with worse outcome than emboli from carotid diseases, presumably due to embolization of larger particles associated with AF. In addition, AF is also associated with silent cerebral infarction and transient ischemic attack (TIA). The left atrial appendage (LAA) is the main source of emboli in patients with AF. AF is the most prevalent arrhythmia encountered after cardiac surgery, and previous studies have indicated that 20–50% of patients develop postoperative AF. Indeed, patients undergoing cardiac surgery are at high risk for CVA in the early postoperative period, which is associated with increased mortality and morbidity. Therefore, surgical closure or amputation of the LAA has been performed in patients with AF at the time of cardiac surgery. More recently, percutaneous LAA closure has been suggested in patients with high risk for stroke and contraindication for long-term oral anticoagulation.

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Such percutaneous LAA closure devices have not yet become available, and surgical device use is very limited in Japan. In addition, there have been several reports showing that residual peri-device flow into the LAA after closure device placement is common. Hence, we currently perform prophylactic simultaneous LAA closure or amputation (LAAC/A) in patients with enlarged LA except for those with contraindications. Some studies have assessed LAAC/A during cardiac surgery.
Diseased carotid was defined as >75% stenosis of the carotid artery. Intracranial vessel stenosis was defined as any possible stenosis detected on preoperative brain imaging that was not a contraindication for cardiac surgery. Mild calcification of the ascending aorta was defined as calcification associated with <50% of the entire circumference. Diseased aorta was defined as severe aortic calcification and/or intimal thickening >3 mm.

Duration of stay in the intensive care unit (ICU) and total hospital stay, mortality and re-exploration for bleeding were also compared between the groups to assess operative safety.

As a sub-analysis, all patients with and without a history of AF were dichotomized according to preoperative CHA2DS2-VASc score, although CHA2DS2-VASc score is a prediction model for estimating the risk of stroke in patients with non-rheumatic AF. Patients with CHA2DS2-VASc score <2 were categorized as low risk for stroke, and the rest were considered as high risk for stroke. The impact of LAAC/A on preventing postoperative CVA was investigated in both the low- and high-risk groups (Figure 1).

This study was approved by the institutional review board, and written informed consent was waived because of the observational data collection design.

**LAAC/A Surgical Procedure**

At Juntendo University Hospital, the LAA is (1) resected and closed using surgical suture from outside the LA; or (2) ligated using double purse string suture (Figure 2). Intraoperative transesophageal echocardiogram is performed to confirm complete closure of the LAA without any residual flow to the remaining structure. In addition, all patients except for those with renal insufficiency underwent chest CT using contrast agents postoperatively, to investigate the status of residual flow to the LAA. The procedure was done manually in the present surgery in patients with mitral disease and/or AF but, as far as we know, no studies have evaluated the efficacy of prophylactic surgical LAAC/A in the prevention of postoperative CVA for patients undergoing cardiac surgery, including coronary bypass surgery without valvular heart disease regardless of the presence or absence of preoperative AF. In the present study, we investigated the effect of concomitant LAAC/A with cardiac surgery on preventing CVA and assessed the safety of this procedure.

**Methods**

**Study Design**

The primary hypothesis was that LAAC/A reduces postoperative CVA in patients undergoing cardiac surgery. We enrolled 1,831 consecutive patients in a prospective observational manner. All patients underwent cardiac surgery at Juntendo University, Japan, between January 2009 and October 2013.

Patients were classified into those who received LAAC/A (LAAC/A group) and those who did not (non-LAAC/A group). Patients with a history of one or more cardiac surgeries who had already undergone a procedure on the LA or LAA were excluded from the study. The incidence of early postoperative CVA and AF up to 6 months after surgery in patients with and without LAAC/A was compared. We defined CVA as ischemic or hemorrhagic intracranial stroke and TIA associated with focal or global neurological deficit that resolved within 24 h. Patient characteristics including age, sex, LA diameter and left ventricular ejection fraction (LVEF) measured on preoperative echocardiogram, history of AF, diabetes mellitus, hypertension, prior stroke, peripheral vascular disease (PVD), and atherosclerotic changes in carotid and intracranial vessels as well as ascending aorta were compared between the groups.

Diseased carotid was defined as >75% stenosis of the carotid artery. Intracranial vessel stenosis was defined as any possible stenosis detected on preoperative brain imaging that was not a contraindication for cardiac surgery. Mild calcification of the ascending aorta was defined as calcification associated with <50% of the entire circumference. Diseased aorta was defined as severe aortic calcification and/or intimal thickening >3 mm.

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Results

LAAC/A Patient Characteristics

Table 1 lists the surgery type for all studied patients. During the investigation period, 369 out of 1,831 patients (20.2%) received LAAC/A. Because LAAC/A was performed initially only in patients who were in a stable condition or who required cardiopulmonary bypass, the LAAC/A group included fewer patients undergoing coronary bypass surgery alone and more patients undergoing valvular surgery.

Table 1 compares the preoperative clinical characteristics including echocardiographic findings of patients with and without LAAC/A. Patients who received LAAC/A were less likely to be male, had larger LA diameter and higher LVEF, more frequently had a history of AF, less frequently had diabetes mellitus, hypertension and PVD. Due to the nature of the observational study, we did not have a clear cut-off of LA diameter with which to decide which patients should receive this procedure. The mean LA diameter in patients receiving LAAC/A in the initial era (2009 and 2010) and the subsequent era were 48.9 mm and 44.0 mm, respectively. Age, incidence of previous stroke/TIA, and prevalence of atherosclerotic change in the carotid/intracranial vessels/aorta were not significantly different between the groups. This suggested that patients selected for LAAC/A, including those requiring coronary bypass surgery but without other atherosclerotic diseases, were in a stable condition and had better LVEF. In other words, patients, and no device was used to close the LAA. In the beginning, we limited this procedure to patients in stable preoperative condition and/or to those requiring cardiopulmonary bypass for surgery. The indication was later expanded to include patients undergoing off-pump coronary artery bypass surgery as well. The procedure is generally added for patients with large LA diameter regardless of preoperative AF history, but the final decision to perform this procedure was made in the operation room based on surgeon preference. This may be a limitation of the present prospective observational study.

Postoperative Management

All patients who developed postoperative AF were treated with anticoagulant therapy unless they had active bleeding. In such cases, heparin was given i.v. or warfarin per os. Beta-blockers were also given either i.v. or orally for patients with postoperative AF unless contraindicated.

Statistical Analysis

Data are given as mean±SD. Normality was evaluated for each variable on the basis of normal distribution plots and histograms, and with Kolmogorov-Smirnov test. Clinical characteristics and postoperative data were compared between the groups using Student’s unpaired two-tailed t-test for continuous variables or chi-squared test for categorical variables. Multivariate logistic regression analysis was used to select factors associated with CVA. Given that the aim of this study was to investigate the effect of LAAC/A as well as preoperative cardiac function on preventing CVA with or without accompanying postoperative AF, we selected LAAC/A (yes=1, no=0), postoperative AF (yes=1, no=0) and preoperative LVEF as covariables to be included in the multivariate analysis. All statistical analysis was performed using JMP 7.0 (SAS Institute, Cary, NC, USA).
patients were considered at high risk for stroke. **Table 3** summarizes the comparison of clinical characteristics between patients with and without LAAC/A who were further subdivided into low and high risk for stroke. Similar to the comparison of the total cohort, patients receiving LAAC/A had larger LA diameter, higher LVEF, more frequently had previous AF, and less frequently had atherosclerotic comorbidities such as diabetes and hypertension in both the low- and high-risk groups for stroke.

The impact of LAAC/A on postoperative course including CVA incidence in patients with low and high risk for stroke is given in **Table 4**. Postoperative AF was observed in 130 out of 377 patients (34.4%) with low risk of stroke, whereas it was observed in 628 out of 1,454 patients (43.2%) with high risk for stroke. The AF incidence was higher in patients receiving LAAC/A than in those who did not, regardless of stroke risk group (both P<0.05). CVA occurred in 7 patients (1.9%) with low risk for stroke and in 50 patients (3.4%) with high risk for stroke, but this was not statistically significantly different between those who did and did not undergo LAAC/A procedure. Of note, however, none of the patients with LAAC/A and low risk for stroke developed CVA postoperatively. The length of ICU stay was relatively shorter in patients with LAAC/A and low risk for stroke, but the total hospital stay was longer in patients with LAAC/A and high risk for stroke.

**Table 1. Clinical Characteristics in Patients With and Without LAAC/A**

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>LAAC/A (n=369)</th>
<th>Non-LAAC/A (n=1,462)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65.4±13.8</td>
<td>67.1±11.7</td>
<td>0.166</td>
</tr>
<tr>
<td>Male</td>
<td>213 (57.7)</td>
<td>1,054 (72.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LA diameter (mm)</td>
<td>45.4±10.1</td>
<td>41.1±7.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>60.9±14.6</td>
<td>57.6±14.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>History of AF</td>
<td>94 (25.5)</td>
<td>133 (9.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>67 (18.2)</td>
<td>571 (39.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>227 (61.5)</td>
<td>1,068 (73.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous stroke/TIA</td>
<td>30 (8.1)</td>
<td>155 (10.6)</td>
<td>0.159</td>
</tr>
<tr>
<td>PVD</td>
<td>25 (6.8)</td>
<td>281 (19.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Atherosclerotic changes in carotid and/or intracranial vessel</td>
<td>6 (1.6)</td>
<td>37 (2.5)</td>
<td>0.305</td>
</tr>
<tr>
<td>Mild calcification of the ascending aorta</td>
<td>35 (9.5)</td>
<td>178 (12.2)</td>
<td>0.150</td>
</tr>
<tr>
<td>Diseased aorta</td>
<td>5 (1.36)</td>
<td>20 (1.37)</td>
<td>0.985</td>
</tr>
</tbody>
</table>

**Table 2. Postoperative Outcome in Patients With and Without LAAC/A**

<table>
<thead>
<tr>
<th></th>
<th>LAAC/A (n=369)</th>
<th>Non-LAAC/A (n=1,462)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative AF</td>
<td>182 (49.3)</td>
<td>571 (39.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CVA</td>
<td>13 (3.5)</td>
<td>44 (3.0)</td>
<td>0.612</td>
</tr>
<tr>
<td>Re-exploration</td>
<td>5 (1.4)</td>
<td>10 (0.7)</td>
<td>0.201</td>
</tr>
<tr>
<td>Mortality</td>
<td>7 (1.9)</td>
<td>29 (2.0)</td>
<td>0.915</td>
</tr>
<tr>
<td>ICU stay (days)</td>
<td>2.7±4.7</td>
<td>2.9±6.3</td>
<td>0.778</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>16.8±15.6</td>
<td>15.4±16.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data given as n (%) or mean±SD. AF, atrial fibrillation; CABG, coronary artery bypass grafting; LA, left atrial; LAAC/A, LA appendage closure or amputation; LVEF, left ventricular ejection fraction; TIA, transient ischemic attack; PVD, peripheral vascular disease.

LAAC/A was more frequently performed in patients with valvular heart disease associated with large LA diameter and a history of AF with no atherosclerotic risk factors.

**Effect of LAAC/A on CVA Development and Postoperative Course**

**Total Cohort.** **Table 2** compares postoperative outcome between patients with and without LAAC/A. Among a total of 1,831 patients, 753 patients (41.1%) developed postoperative AF, and AF episodes were observed more frequently in patients receiving LAAC/A than those without the procedure. In contrast, a total of 57 of 1,831 patients (3.1%) developed postoperative CVA, and the CVA incidence was not significantly different between those with and without LAAC/A. There were 3 cases of CVA which possibly developed during the peri-operative period and were diagnosed while patients were still in the ICU. There were no significant differences in re-exploration for bleeding, in-hospital mortality, or length of ICU stay between the groups, but patients receiving LAAC/A had longer total hospital stay compared with the non-LAAC/A group.

**Stroke Risk Groups.** As a sub-analysis, we stratified patients according to CHA2DS2-VASc score. Among 1,831 patients, 377 (20.6%) were considered to be at low risk for stroke, defined as CHA2DS2-VASc score <2, and the remaining 1,454 patients were considered at high risk for stroke. **Table 3** summarizes the comparison of clinical characteristics between patients with and without LAAC/A who were further subdivided into low and high risk for stroke. Similar to the comparison of the total cohort, patients receiving LAAC/A had larger LA diameter, higher LVEF, more frequently had previous AF, and less frequently had atherosclerotic comorbidities such as diabetes and hypertension in both the low- and high-risk groups for stroke.

The impact of LAAC/A on postoperative course including CVA incidence in patients with low and high risk for stroke is given in **Table 4**. Postoperative AF was observed in 130 out of 377 patients (34.4%) with low risk of stroke, whereas it was observed in 628 out of 1,454 patients (43.2%) with high risk for stroke. The AF incidence was higher in patients receiving LAAC/A than in those who did not, regardless of stroke risk group (both P<0.05). CVA occurred in 7 patients (1.9%) with low risk for stroke and in 50 patients (3.4%) with high risk for stroke, but this was not statistically significantly different between those who did and did not undergo LAAC/A procedure. Of note, however, none of the patients with LAAC/A and low risk for stroke developed CVA postoperatively. The length of ICU stay was relatively shorter in patients with LAAC/A and low risk for stroke, but the total hospital stay was longer in patients with LAAC/A and high risk for stroke.
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regardless of the presence or absence of preoperative AF, on postoperative CVA development. Admittedly, this is a preliminary analysis, and further investigation is needed to elucidate the effect of the procedure on preventing CVA and on long-term outcome. The results included some selection bias, which could not be avoided due to the prospective nature of the present observational study. We initially chose patients in stable condition requiring cardiopulmonary bypass for the primary surgery, and added LAAC/A to ensure the safety of the procedure, but we felt that the present results are still worth reporting.

The main findings are as follows: (1) LAAC/A can be safely performed without increasing mortality, length of ICU stay or re-exploration rate; (2) although patients with LAAC/A had a higher rate of postoperative AF with underlying preoperative status indicative of tendency to develop AF, the incidence of CVA was lowered to a rate similar to that in patients without LAAC/A and lower incidence of AF after surgery; and (3)
when patients were classified according to stroke risk using CHA2DS2-VASc score, LAAC/A was the only factor associated with prevention of postoperative CVA in patients with low risk for stroke, regardless of postoperative AF status.

It is crucial to prevent stroke in patients undergoing cardiac surgery regardless of the risk for postoperative AF. Echahidi et al reported that the incidence of perioperative stroke was 3.2% after coronary bypass surgery, 2.8% after valve surgery, and 6.7% after coronary artery bypass grafting plus valvular surgery. The incidence of CVA in the present cohort was similar or slightly better than in that study; in the present study it was approximately 3%, although we included more patients undergoing both coronary artery bypass grafting and valvular surgery. Postoperative AF development is multifactorial, and it is difficult to completely prevent or predict its occurrence following cardiac surgery. Indeed, in the present cohort, >40% of patients developed AF, and its occurrence was not dependent on the procedure. Therefore, we need to explore ways to prevent stroke regardless of preoperative risk for developing AF.

To date, a variety of methods to close the LAA have been developed and the efficacy of these methods has been investigated. Healey et al published the results of the Left Atrial Appendage Occlusion Study (LAOAS), which was the first prospective, randomized trial to evaluate the effect of LAA closure on the subsequent incidence of stroke following coronary artery bypass surgery in 2005. They closed the LAA by either epicardial suture or epicardial stapling, which resulted in approximately 30% of patients having residual flow between the LA and the LAA, and there was no significant reduction in the incidence of stroke. The guidelines, however, still recommend amputation of the LAA at the time of mitral valve surgery and surgical LAA closure in patients at risk of postoperative AF to reduce the incidence of subsequent thromboembolic events. The PROTECT-AF trial investigated the safety and efficacy of the Watchman device for LAA occlusion, and the latest follow-up data showed non-inferiority and superiority of the device to prevent stroke as compared with warfarin. The safety and efficacy of the Amplatzer plug (St Jude Medical, St. Paul, MN, USA) for LA closure appear to be similar to those of the Watchman. Bartus et al used transesophageal echocardiography to evaluate LAA-LA residual flow in a serial manner after the procedure to ensure “successful closure”, but the long-term efficacy in preventing CVA has not yet been elucidated.

Therefore, the present finding that complete LAAC/A at the time of open heart surgery, regardless of the risk for stroke even in patients without cardiopulmonary bypass, may reduce the risk of early perioperative stroke or eliminate the risk of stroke without increasing the risk of perioperative bleeding or other complications following surgery, is important. The time required to add LAAC/A was approximately 15 min in studied cases including off-pump surgery (data not shown). Due to the nature of the present prospective observational study, we initially selected patients in stable condition and with less comorbidity to ensure the safety of the procedure. Despite this limitation, we found that addition of LAAC/A did not increase the mortality rate or re-exploration rate due to bleeding and did not affect the length of ICU stay. Total hospital stay was longer in patients with LAAC/A than those without, but this was because LAAC/A patients were more prone to develop postoperative AF, therefore anticoagulation adjustment was required.

One of the major findings of the present study was that postoperative AF was independently associated with CVA development in the total cohort and in those with preoperative high risk for stroke on CHA2DS2-VASc score, but LAAC/A was not. We assumed that those patients already had multiple underlying atherosclerotic risk factors, and that postoperative AF itself would be a key trigger of CVA; therefore we could not prove the effect of LAAC/A on preventing CVA in this preliminary analysis. Cha et al reported on the mechanisms of stroke according to CHA2DS2-VASc score and showed that CHA2DS2-VASc score increased, the incidence of cardioembolism decreased and that of atherothrombosis increased. Further, nearly 80% of our patients were classified into the high stroke risk group, and therefore the results for the total cohort were highly influenced by the large proportion of high stroke risk patients. In contrast, in patients with low risk for stroke according to CHA2DS2-VASc score, additional LAAC/A was the only factor to reduce the incidence of CVA, even though they have more than 30% prevalence of developing of AF. This suggests that LAAC/A is an effective tool to prevent CVA even if patients develop AF, as long as they do not have multiple atherosclerotic risk factors. We speculate that stroke was more likely caused by clots from LAA in the low stroke risk patients. Hypercoagulability after cardiac surgery plays an important role in cardioembolism, even in patients without atherosclerotic risk factors. Hypercoagulability is caused by surgical trauma and associated tissue injury. Rafii et al noted increased coagulability in 43.5% of coronary artery bypass graft patients. Therefore, LAAC/A had a strong impact on preventing postoperative CVA in low stroke risk patients.

We also assume that the reason why we failed to show the effect of LAAC/A on preventing CVA in the total cohort and in the high stroke risk patients was simply because we did not perform LAAC/A in patients with multiple atherosclerotic factors. In this preliminary observation, this selection bias may have prevented statistical confirmation of the independent efficacy of the procedure, but the present results still suggest that complete LAAC/A may be a helpful technique to reduce the incidence of early perioperative stroke as well as of subsequent stroke during the chronic phase in a particular patient population.

Regarding safety, concomitant LAAC did not result in increased re-exploration rate for bleeding or mortality, and it was safely performed without additional complications. Whitlock et al reported that additional LAA excision at the time of cardiac surgery is a small procedure with a low intrinsic likelihood of adverse events. Furthermore, we performed routine intraoperative transesophageal echocardiogram for all patients to confirm complete closure without residual flow. In the case of ligation, a double purse string suture is used, which provides increased reliability compared with a simple ligation.

The strengths of the present study include the relatively large sample size. Limitations include the selection bias, which caused heterogeneity in patient characteristics and which possibly affected the results of analysis. Patient selection was dependent on surgeon preference and changed with time. In the present study, we did not perform independent analysis of patients undergoing cardiac surgery with and without cardiopulmonary bypass, although several previous studies discussed the relationship between hypercoagulability and off-pump bypass surgery. Nevertheless, this is the preliminary report on the possible beneficial effect of LAAC/A, which we believe is worth reporting. Postoperative AF as well as CVA can occur in various time frames. The present strategy of LAAC/A would prevent CVA caused by AF-associated cardiogenic thrombus; therefore, the perioperative procedure-related CVA episodes should have been excluded, but we failed to identify
the exact onset of CVA in several patients, and the total number of patients who had CVA was only 57 (3.1%); thus, we were unable to discriminate between perioperative and postoperative CVA in the present analysis. Furthermore, due to the short follow-up period, we were unable to classify postoperative rhythm status into paroxysmal AF, persistent AF, long-standing persistent AF or permanent AF. Another limitation of the study was that cardiogenic CVA may not always be related to thrombi located in the LAA. Onalal and Crystal, however, reported that more than half of intracardiac thrombi were found in the LAA of AF patients regardless of the type of AF. Therefore, we still believe that this procedure has the potential to prevent CVA associated with postoperative AF.

Conclusions
Additional LAA procedure at the time of cardiac surgery is safe, and significantly reduces the rate of CVA development, especially in patients with low CHA2DS2-VASc score.

Disclosures
None.

References