Prognostic Significance of Post-Procedural Left Ventricular Ejection Fraction Following Atrial Fibrillation Ablation in Patients With Systolic Dysfunction

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Background: Atrial fibrillation (AF) ablation is associated with a good prognosis; nevertheless, the effect of post-procedural systolic function on a patient’s prognosis remains uncertain.

Methods and Results: Of 1,077 consecutive patients undergoing AF ablation, the prognosis of 150 patients with abnormal left ventricular ejection fraction (LVEF; <50%) was evaluated. Patients were categorized as having reduced LVEF (rEF; LVEF <40%), mid-range ejection fraction (mrEF; 40%≤LVEF<50%), or preserved LVEF (pEF; LVEF ≥50%). Post-procedural LVEF, evaluated 3 months after the procedure, was post-rEF in 28 patients (19%), post-mrEF in 49 (33%), and post-pEF in 73 (49%). During the median follow-up of 31 months, the cumulative ratios of the composite outcome (heart failure hospitalization or death) in the post-rEF, post-mrEF, and post-pEF groups were 18%, 5%, and 2%, respectively, at 1 year and 50%, 13%, and 4%, respectively, at 3 years (P<0.0001). The post-rEF group had a 4.5- to 5.0-fold higher risk of the outcome compared with the post-pEF group, whereas the post-mrEF group showed no risk after adjusting for confounders, including age ≥65 years, preprocedural LVEF category, and recurrence of atrial tachyarrhythmia.

Conclusions: Patients with post-mrEF had a comparable prognosis to those with post-pEF over a relatively long follow-up, whereas those with post-rEF had the poorest outcome of the 3 groups, regardless of preprocedural LVEF status.

Key Words: Atrial fibrillation; Catheter ablation; Death; Heart failure hospitalization; Left ventricular ejection fraction

Atrial fibrillation (AF) is often associated with impaired left ventricular ejection fraction (LVEF) and poor prognosis due to the absence of atrioventricular synchrony, a deficiency of atrial kick, irregularity, or tachycardia. Several randomized control studies have reported that AF ablation is associated with a good prognosis and significant LVEF improvement. In addition, several studies have reported predictors of LVEF improvement after AF ablation in heart failure patients. Nevertheless, the definition of LVEF improvement varies among studies, meaning that the relationship between LVEF improvement and prognosis is not clear. Therefore, the aim of the present study was to investigate the relationship between post-procedural LVEF (3 months after the procedure) and prognosis in patients who underwent AF ablation.

Methods

Study Population
This retrospective observational study screened 1,077 consecutive patients undergoing radiofrequency catheter ablation for AF (Figure 1). Of patients undergoing circumferential pulmonary vein isolation (PVI) between August 2009 and May 2019, 195 who had impaired LVEF (<50%) were enrolled in the present study. Patients who underwent cardiac resynchronized therapy after the procedure, those who were followed up for <6 months after the procedure, and those who did not receive echocardiographic evaluations 3 months after the index procedure were excluded. AF ablation was indicated based on previous expert consensus statements. Within the 1 month prior to each session, patients underwent 3-dimensional cardiac computed...
tomography and transthoracic echocardiography. Transesophageal echocardiography was performed in patients with persistent AF and those with paroxysmal AF with a high CHADS2 score (>2 points).

This study was conducted in accordance with institutional guidelines and the principles outlined in the Declaration of Helsinki. The study was approved by the Institutional Review Board of Tokyo Women’s Medical University (ID: 4190-R). All patients provided written informed consent prior to study participation.

Catheter Ablation Protocol
A detailed description of the catheter ablation protocol has been published previously.10 Wide circumferential PVI consisted of a point-by-point radiofrequency application using an image of the 3-dimensional mapping system (CARTO 3; Biosense Webster, Diamond Bar, CA, USA) with 2 long sheaths, 1 circular multielectrode catheter, and a 3.5-mm open-irrigated tip catheter (ThermoCool, ThermoCool SF, or ThermoCool STSF; Biosense Webster) as the ablation catheter. From February 2013, empirical superior vena cava isolation was routinely performed. The main goal of ablation was complete isolation of the thoracic vein (pulmonary vein and superior vena cava). Atrial overdrive pacing was induced by infusion of isoproterenol and the absence of dormant conduction was confirmed by infusion of ATP; these procedures were conducted for a minimum of 20 min after isolation of the ipsilateral pulmonary vein pair. If other atrial tachyarrhythmias (ATA) or non-pulmonary vein foci were triggered, they were targeted for elimination as much as possible.

Echocardiographic Evaluation
In all patients, transthoracic echocardiography was performed in the left lateral decubitus position using an ultrasound system. All images were stored digitally, and relevant parameters were then measured according to the recommendations of the American Society of Echocardiography.11 Left atrial and left ventricular (LV) volumes were measured using the modified Simpson’s method. LV filling pressures were calculated by dividing the standard E-wave by the early diastolic mitral annular velocity (e’), resulting in a measurement of early diastolic mitral flow velocity (E/e’) at the septal wall, using color-coded tissue Doppler imaging with a 4-chamber view. In general, patients also underwent several other tests, including magnetic resonance imaging, myocardial scintigraphy, coronary angiography, myocardial biopsy, and, occasionally, genetic tests to identify structural heart diseases (SHDs) such as, coronary artery disease, idiopathic dilated cardiomyopathy, hypertrophic cardiomyopathy, valvular heart disease, congenital heart disease, or other cardiomyopathies, as the cause of cardiac dysfunction based on the current heart failure management guidelines.12

Follow-up
Patients were routinely followed up without the use of antiarrhythmic drugs (AADs) after the index procedure. Patients visited the outpatient clinic 1, 3, 6, 9, and 12 months after the index procedure and every 6 months thereafter. Echocardiography was routinely performed at 3, 6, and 12 months until LVEF was improved. The LVEF 3 months after the procedure was regarded as the post-procedural LVEF. In addition, ATA recurrence was evaluated prior to the echocardiographic evaluation to assess the effect of ATA recurrence on changes in LVEF. Medical records were reviewed for patient admissions or deaths during the follow-up period. The primary outcome was the composite of all-cause death and heart failure hospitalization (HFH). ATA recurrence was assessed using 24-h ambulatory electrocardiography monitoring every 3 months in the first year and every 6 months thereafter. In addition, a portable electrocardiograph (HCG-801R; Omron, Kyoto, Japan) was used for patients with frequent symptoms without a documented electrocardiogram and 2–3 daily pulse checks were made in asymptomatic patients. Recurrence was defined as symptomatic and/or documented ATA on 12-lead electrocardiography, 24-h ambulatory electrocardiography monitoring, or portable electrocardiography after a 2-month blanking period.

In accordance with the recent heart failure management guidelines,13 patients were categorized into 3 groups based on LVEF: reduced LVEF (rEF; LVEF <40%), mid-range EF (mEF; 40% ≤ LVEF <50%), and preserved LVEF (pEF;
LVEF ≥50%). In patients with pre- and post-procedural LVEF data, values are reported as pre- or post-rEF, pre- or post-mrEF, and pre- or post-pEF.

### Statistical Analysis
Continuous variables are expressed as mean±SD or as the median with interquartile range (IQR). Student’s t-test and the Wilcoxon test were used to compare continuous variables between the groups. Categorical variables were summarized as percentages. Fisher’s exact test was used to evaluate the significance of differences in categorical variables. The incidence of the primary outcome was assessed using the Kaplan-Meier method, and the significance of differences among groups were compared using the log-rank test with Bonferroni correction. Pre- and post-procedural LVEF were compared using the paired t-test. A Cox proportional hazards model was used to evaluate the predictors of the primary outcome in univariate and multivariate analyses, using 3 models that included relevant covariates: Model 1 included age ≥65 years, post-procedural LVEF category, and pre-rEF; Model 2 did. ATA recurrence, pre-rEF, and post-procedural LVEF category; and Model 3 did age ≥65 years, ATA recurrence, and post-procedural LVEF category.

All analyses were performed using JMP® 13 (SAS Institute, Cary, NC, USA), and 2-sided P<0.05 was considered significant.

### Results
#### Baseline Characteristics
Of the 176 patients with LVEF <50%, 20 did not have echocardiographic data at 3 months after the index procedure (although all received at least 1 echocardiographic evaluation within 1 year) and 6 underwent cardiac resynchronization therapy after the procedure. These 26 patients were excluded from the study and the remaining 150 patients (mean age 60±10 years, 87% men) were selected for evaluation. None of the patients experienced paroxysmal AF, and the mean preprocedural LVEF was 41%. In all, 93, 51, and 6 patients required 1, 2, and 3 sessions, respectively. At 1 and 5 years after the single procedure, sinus rhythm was maintained in 50% and 34% of patients, respectively, without AADs and in 75% and 65% of patients, respectively, with AADs. At 1 and 5 years after the final procedure, this proportion increased to 73% and 62%, respectively, of those without AADs and to 88% and 80%, respectively, of those using AADs. Six patients (5%) had persistent AF despite the use of AADs during the follow-up period (i.e., the combination of catheter ablation and medical therapy failed to maintain sinus rhythm). The ATA recurrence rate did not differ significantly between pre-mrEF and pre-rEF patients after the single and final procedures (P=0.84 and 0.05, log-rank test). Procedure-related complications were observed in 2 patients: 1 experienced transient ischemic attack immediately after the procedure, and the other had intra-abdominal hematoma due to wire perforation, which recovered without blood transfusion.

#### Follow-up
During the median follow-up of 31 months, the primary
outcomes occurred in 18 (12%) patients: 11 HFHs (7%) and 7 all-cause deaths (5%; n=3 cardiac issues, n=2 any malignancies, and n=2 other issues). No significant differences were found in the type of AF, history of AF, or prevalence of known SHD, including ischemic or non-ischemic cardiomyopathy, hypertrophic cardiomyopathy, or congenital heart disease, between patients who experienced the outcome and those who did not.

Differences in Clinical Characteristics Among the 3 LVEF Categories

Table 1 shows the differences in characteristics among the 3 categories of post-procedural LVEF. No differences were noted in the type of AF, history of AF, or history of HFH for AF; however, SHD was more frequently observed in patients in the post-rEF group. Standard drugs for heart failure, including angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, mineralocorticoid receptor antagonists, or AADs, were more frequently used in the post-rEF group. ATA tended to recur more frequently after the single procedure in the post-rEF group. The distribution of recurrence type, including paroxysmal and persistent AF and paroxysmal and persistent atrial tachycardia, did not differ significantly among the 3 groups (P=0.31). The left atrial volume index (LAVI) and E/e' did not differ significantly among the 3 groups.

In the Kaplan-Meier curve analysis using Bonferroni correction, a significant difference was found in the incidence of the outcome between the post-rEF and post-mrEF (P=0.0003) and post-rEF and post-pEF (P<0.0001) groups, but not between the post-mrEF and post-pEF groups. The cumulative ratios of the outcomes in the post-rEF, post-mrEF, and post-pEF groups were 18%, 5%, and 2%, respectively, 1 year after the procedure and 50%, 13%, and 4%, respectively, 3 years after the procedure (Figure 3A). Similar findings were noted among the 3 groups with regard to the incidence of HFH (Figure 3B). Nevertheless, there was no significant difference in mortality rate among the 3 groups (Figure 3).

Predictors of Outcome

Table 2 shows hazard ratios of the outcomes based on univariate analysis. Age ≥65 years, preprocedural LVEF category, LAVI, ATA recurrence before LVEF evaluation,
and post-procedural LVEF were significantly associated with the outcome. Multivariate analyses were performed using 3 models that included variables considered to be related to the primary outcome: Model 1 included age ≥65 years, post-procedural LVEF category (post-pEF, post-mrEF, and post-rEF), and pre-rEF; Model 2 included ATA recurrence, pre-rEF, and post-procedural LVEF category; and Model 3 did age ≥65 years, ATA recurrence, and post-procedural LVEF category. In every assessment, post-rEF emerged as an independent predictor of outcomes.

In the multivariate analysis, the post-rEF group had a 4.5- to 5.0-fold higher risk of the outcome than the post-pEF group. In contrast, there was no significant difference in the risk of outcomes between the post-mrEF and post-pEF groups in either the univariate or multivariate analyses (Table 3).

**Discussion**

**Main Finding**

In the present study we explored the association between post-procedural LVEF at 3 months and prognosis in patients who underwent AF ablation. First, 43% of patients who experienced ATA recurrence had an attenuated LVEF increase 3 months after the index procedure. Second, patients in the post-rEF subgroups developed the primary outcomes (HFH or death) more commonly than those in the post-mrEF and post-pEF subgroups (who had almost comparable outcomes). Third, the multivariate analysis adjusting for confounders, including pre-LVEF categorization and ATA recurrence, found that post-mrEF patients had comparable outcomes to post-pEF patients, whereas those in the post-rEF subgroup had a 4.5- to 5.0-fold greater risk of the outcomes than those in the post-pEF subgroup.

**AF Ablation and LVEF Improvement**

It is often difficult to discriminate patients with arrhythmia-induced cardiomyopathy (AIC) from those with organic heart disease due to a reversible condition in the absence of atrial or ventricular arrhythmia. AF is the atrial arrhythmia that most commonly induces AIC, and its treatment by...
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Impact of LVEF on Prognosis Following AF Ablation

LVEF has a substantial effect on prognosis in chronic heart failure patients.\(^6\) It also has a key role in the prognosis of heart failure patients undergoing AF ablation. Some large trials have reported the association of AF ablation with LVEF increase and better prognosis than medical treatment.\(^1\) Addion et al reported that LVEF normalization after AF ablation was associated with reduced death or HFH rates.\(^2\) Studies have also reported a relationship between poor prognosis and known heart disease,\(^1\) as well as preprocedural late gadolinium enhancement in the left atrium.\(^3\) In contrast to these observations, poor outcomes, even in the presence of LVEF improvement after AF ablation, have been reported. In a previous study, a median increase in LVEF of 8% was observed in patients after AF ablation and a higher post-ablation LVEF was found in 68% of patients; however, approximately 30% of patients either died or, among those with severely reduced LVEF, experienced HFH.\(^2\) In the present study, we recorded a mean increase in LVEF of 9%, and the primary outcome (death or HFH) was observed in 12% of patients, partially consistent with findings of the previous study with a similar follow-up period (31 in the present study vs. 38 months in the previous study). This difference in the rate of the primary endpoint may not be explained by the ATA recurrence rate with or without AADs (33% vs. 35% at 5 years), but rather the difference in preprocedural LVEF severity (31% vs. 41%). Thus, although there is a close relationship between LVEF improvement and good prognosis, the prognostic impact of post-procedural LVEF remains uncertain.

In the present study, we evaluated the prognosis of patients undergoing AF ablation based on the 3 categories of post-procedural LVEF, in accordance with recent guidelines.\(^1\) Considering the LVEF transition from before

\| Variables | HR  | 95% CI       | P value |
|-----------|-----|--------------|---------|
| Age ≥65 years | 2.78 | 0.99–8.31   | 0.05    |
| Pre-rEF    | 2.12 | 0.70–6.74   | 0.18    |
| Post-pEF   | 1.00 |              |         |
| Post-mrEF  | 0.97 | 0.19–4.08   | 0.96    |
| Post-rEF   | 4.53 | 1.33–16.87  | 0.02    |

**Model 2**

| Variables | HR  | 95% CI       | P value |
|-----------|-----|--------------|---------|
| ATA recurrence | 2.29 | 0.80–7.50   | 0.12    |
| Pre-rEF    | 1.52 | 0.52–4.59   | 0.44    |
| Post-pEF   | 1.00 |              |         |
| Post-mrEF  | 0.88 | 0.18–3.71   | 0.87    |
| Post-rEF   | 4.60 | 1.30–17.52  | 0.02    |

**Model 3**

| Variables | HR  | 95% CI       | P value |
|-----------|-----|--------------|---------|
| Age ≥65 years | 2.35 | 0.80–6.57   | 0.09    |
| ATA recurrence | 2.35 | 0.84–7.65   | 0.11    |
| Pre-pEF    | 1.00 |              |         |
| Post-mrEF  | 0.99 | 0.20–4.14   | 0.99    |
| Post-rEF   | 4.97 | 1.63–17.06  | <0.0001 |

Abbreviations as in Tables 1, 2.
to after AF ablation, poor outcomes predominantly occurred in those subgroups transitioning from pre-rEF to post-rEF and from pre-mrEF to post-rEF (Figure 2B). This suggests an association of rEF with the poorest outcome, which may be due, in part, to the underlying SHDs or difficulty in maintaining sinus rhythm. A previous study reported that the increase in LVEF was limited following AF ablation in the presence of organic heart disease.\textsuperscript{18} However, in the present study, SHDs did not affect the outcome rate in univariate analysis. This could underscore the fact that the type of SHD or disease severity may have an important effect on the outcome rate, rather than the mere presence of SHD itself (although this was difficult to assess statistically because of the small number of patients). Most recently, a study suggested that AF had no significant effect on the outcome in heart failure patients with severely impaired LVEF;\textsuperscript{19} nevertheless, this did not encourage us to defer AF ablation in this population because a substantial number of patients (26/50) in the pre-rEF group transitioned to the post-mrEF and post-pEF groups after AF ablation. Although an implantable cardiac defibrillator is recommended for primary prevention in patients with an LVEF <35% and heart failure symptoms of New York Heart Association functional class >II, regardless of the kind of underlying heart disease,\textsuperscript{20} our data suggest that it is preferable to make this decision after AF ablation because of the high possibility of LVEF improvement.

Characteristics of Patients With mrEF
In contrast with the results of the post-rEF groups, the frequency of the outcome did not differ significantly between the post-mrEF and post-pEF groups, which is partially consistent with our previous results.\textsuperscript{21} Using a Japanese registry, the Chronic Heart Failure Analysis and Registry in the Tohoku District 2 (CHART-2 Study) found that mrEF was associated with unplanned HFH but not with death and pEF, concluding that mrEF was an “overlap” transition zone rather than an independent entity.\textsuperscript{22} In an acute heart failure study, Cho et al found higher in-hospital mortality and lower long-term survival rates in the rEF than mrEF and pEF groups with non-ischemic etiology.\textsuperscript{23} Fonarow et al reported a higher prevalence of heart failure with pEF and similar mortality and rehospitalization rates regardless of LVEF category after discharge.\textsuperscript{23} Various conclusions were made regarding the prognosis in heart failure patients in terms of LVEF differences; nevertheless, there was no definite confirmation. In the present study, post-mrEF was not associated with the composite outcome compared with post-pEF in the univariate and multivariate analyses, even after adjusting for several relevant confounders. This suggests that patients in the post-mrEF group had relatively safe and low-risk profiles regardless of preprocedural LVEF.

Comparison With Other Studies With Regard to ATA Recurrence
Several previous studies have similarly investigated the clinical utility of AF ablation in patients with heart failure. The famous Catheter Ablation versus Standard Conventional Therapy in Patients with Left Ventricular Dysfunction and Atrial Fibrillation (CASTLE-AF) randomized control trial demonstrated the superiority of AF ablation to medical therapy in heart failure patients with severe systolic dysfunction.\textsuperscript{2} The CASTLE-AF investigators reported a 5-year ATA recurrence rate of 37% following AF ablation.\textsuperscript{2} Their strategy consisted of simple PVI with additional approaches being at the operator’s discretion (51.7%). Similarly, Black-Maier et al reported the clinical effectiveness of AF ablation in heart failure patients.\textsuperscript{24} In that report, the ATA recurrence rate was approximately 33%, regardless of preprocedural LVEF category, following AF ablation. The strategy reported by Black-Maier et al involved substrate modification in the left atria in a non-negligible number of patients.\textsuperscript{25} In addition, in both studies, more than 30% of patients used amiodarone to maintain sinus rhythm.\textsuperscript{24} In contrast, in the present study, ATA recurrence was observed in 65% and 75% of patients at 1 and 5 years after the index procedure, respectively, with or without AADs. Although our strategy, namely PVI and isolation of the superior vena cava without any substrate modifications regardless of the patient’s background, was different from that in the previous 2 studies, the freedom-from-ATA rate with or without AADs was not inferior. In addition, the follow-up period in the study of Black-Maier et al was approximately 10 months,\textsuperscript{24} significantly shorter than that in the present study, and their data were partially based on the outcomes of multiple procedures, which potentially affected their ATA recurrence rate.

Study Limitations
First, the present study defined post-procedural LVEF categories based on echocardiographic data 3 months after the procedure, and ATA recurrence was evaluated before the procedure, nearly equivalent to early recurrence, to clearly assess the effectiveness of recurrence on the absolute LVEF change; therefore, LVEF was considered to reflect the results of AF ablation (long-term follow-up reflects the effects of several interventions, such as strengthening drug treatment or disease progression). However, we could not assess longitudinal changes in LVEF, which may have resulted in our overlooking the LVEF trajectory during the late phase. Second, the retrospective observational design and non-negligible number of patients with no echocardiographic follow-up at 3 months could have resulted in selection bias. Third, the low incidence rate of the outcome could statistically undermine this study; nevertheless, we were able to create 3 multivariate models, including 3 variables, comprising the LVEF category and the other 2 confounders. The multivariate analysis of all models showed that post-rEF is an independent predictor of the outcome. This may improve the confidence in our statistical analysis.

Conclusions
In this study, over a relatively long follow-up, post-mrEF and post-pEF patients had comparable prognoses, whereas post-rEF patients had the poorest outcomes among the 3 categories, regardless of preprocedural LVEF. LVEF normalization was not strictly required to avoid poor outcomes. Post-mrEF may be an indicator of good prognosis in patients with systolic dysfunction undergoing AF ablation.

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IRB Information
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Data Availability
The deidentified participant data will not be shared.

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Supplementary Files
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