Clinical and procedural predictors of early complications of ablation for atrial fibrillation: Analysis of the national registry data

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BACKGROUND The risk assessment of the complication from atrial fibrillation (AF) ablation is important and needs to be updated.

OBJECTIVE The purpose of this study was to investigate the clinical and procedural factors associated with AF ablation-related early complications.

METHODS The Japanese Heart Rhythm Society invited electrophysiology centers in Japan to register data regarding all AF ablation procedures performed in September 2011, March 2012, and September 2012. Of the 46 putative predictors assessed in the univariate analysis, significant variables ($P < .1$) were entered into a stepwise logistic regression model for multivariate analysis.

RESULTS Data for 3373 cases were submitted by 165 centers, with 158 early complications reported in 151 patients (4.5%). We identified 13 significant variables in the univariate analysis. Multivariate analysis revealed that 8 (62%) of them were independent predictors of early complications. Female sex (odds ratio and 95% confidence interval 1.6; 1.13–2.27), hypertrophic cardiomyopathy (2.2; 1.08–4.5), valvular heart disease (2.53; 1.28–5.05), deep sedation during the procedure (1.53; 1.09–2.12), and complex fractionated atrial electrocardiogram ablation (1.88; 1.23–2.87) increased early complications. Preprocedural transesophageal echocardiography (0.63; 0.43–0.92), irrigated-tip catheter use (0.46; 0.3–0.69), and periprocedural novel oral anticoagulant use (0.55; 0.32–0.97) decreased them.

CONCLUSION The risk of early complications is increased by female sex, hypertrophic cardiomyopathy, valvular heart disease, deep sedation, and complex fractionated atrial electrocardiogram ablation. It is decreased by preprocedural transesophageal echocardiography, periprocedural novel oral anticoagulant, and irrigated-tip catheter use.

KEYWORDS Atrial fibrillation; Catheter ablation; Complication; Deep sedation; Novel oral anticoagulant

ABBREVIATIONS **AF** = atrial fibrillation; **CFAE** = complex fractionated atrial electrogram; **CM** = cardiomyopathy; **HCM** = hypertrophic cardiomyopathy; **J-CARAF** = Japanese Catheter Ablation Registry of Atrial Fibrillation; **JHRS** = Japanese Heart Rhythm Society; **NOAC** = novel oral anticoagulant; **PVI** = pulmonary vein isolation; **TEE** = transesophageal echocardiography

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Introduction

Atrial fibrillation (AF) is a common tachyarrhythmia, and catheter ablation is increasingly being used in its treatment. Catheter ablation is performed using a variety of strategies at a number of centers with differing levels of experience and skill. Moreover, the relatively high complication rates remain an unresolved problem.

Although there have been some reports about the incidence of complications after AF ablation and their clinical predictors, most of the previous reports had been based on

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data from high-volume and high-end hospitals and their incidents and complications may be different from those at centers performing fewer procedures or with less experience.[1,2] Furthermore, few reports have investigated the procedural variables associated with the ablation strategy and equipment used in the procedures, despite these potentially affecting the incidence of complication rates in AF ablation. Therefore, a report based on data that include the precise procedural variables from electrophysiology centers with varying experience and skill levels using a variety of ablation strategies is important.

The Japanese Heart Rhythm Society (JHRS) initiated 2 registries—the Japanese Catheter Ablation Registry[3,4] and the Japanese Catheter Ablation Registry of Atrial Fibrillation (J-CARAF)[5–7]—to collect regular objective data on indications, methods, performance, and safety of AF ablation. Most of the electrophysiological centers in Japan have participated in the J-CARAF. To assess the risk factors for complications related to AF ablation, we investigated the associated clinical and procedural variables reported in this registry.

Methods

Study population

Data from the J-CARAF were used in this study, and JHRS members were notified and requested to supply information voluntarily by mail. The study periods for the first, second, and third surveys were September 2011, March 2012, and September 2012, respectively. All relevant data were registered by JHRS members for AF ablation procedures performed within the respective periods. An online questionnaire was used to obtain the information retrospectively. The required variables included patient backgrounds, AF ablation procedures and strategies used, acute results, and early complications.

In total, 165 centers registered AF ablation cases at rates of 1–79 cases/mo (median 5 cases/mo; Figure 1). We included 3373 patients (mean age 62 ± 11 years; 2567 men and 806 women) who received catheter ablation for AF (2173 paroxysmal AF, 733 persistent AF, and 467 long-standing persistent AF).[5,7] This study conformed to the guiding principles of the Declaration of Helsinki.

Clinical and procedural variables

We included the following 46 variables in the analysis as putative predictors of early complications: age, female sex, left atrial dimension, paroxysmal AF, long-standing persistent AF, lone AF, severe valvular heart disease, congestive heart failure, hypertension, diabetes, stroke, coronary artery disease, $CHADS_2$ score, CHA_2DS_2-VASc score, dilated cardiomyopathy (CM), hypertrophic cardiomyopathy (HCM), CM other than dilated CM and HCM (other CM), congenital heart disease, sick sinus syndrome, thyroid disease, chronic kidney disease on hemodialysis, chronic obstructive pulmonary disease, no antiarrhythmic drug history, cases of the first AF ablation session, cases performed in high-volume centers (defined as centers with ≥10 AF ablation cases/mo), preprocedural transesophageal echocardiography (TEE), preprocedural computed tomography or magnetic resonance imaging, CARTO (Biosense Webster, CA, USA) use, EnSite (St. Jude Medical, MN, USA) use, periprocedural oral anticoagulant therapy, periprocedural vitamin K antagonist intake, periprocedural novel oral anticoagulant (NOAC) intake, irrigated-tip catheter, no sedation during the procedure, deep sedation (no purposeful response to single verbal stimulation), conscious sedation, electrical cardioversion during the procedure, arterial pressure monitor during the procedure, ablation other than pulmonary vein isolation (PVI), complex fractionated atrial electrogram (CFAE) ablation, focal ablation, linear ablation, ganglion plexus ablation, coronary sinus ablation, cavotricuspid isthmus ablation, and superior vena cava ablation. We included neither fluoroscopic time nor procedure time as potential predictors because the prolongation of these times would result from, rather than cause, complications.

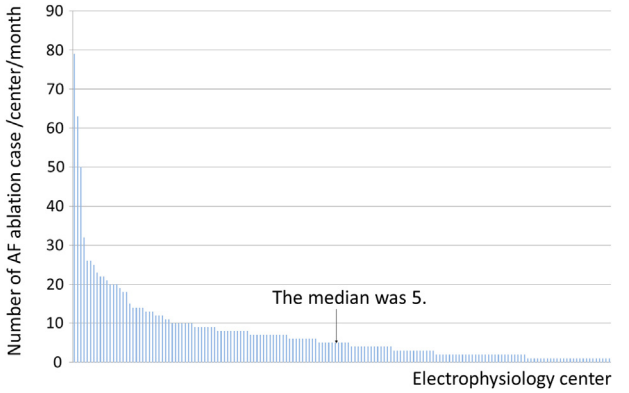

Figure 1 The distribution of the number of AF ablation cases per center per month in the third survey. In September 2012, we ranked 165 electrophysiology centers that participated in this survey according to the number of AF ablation procedures. AF = atrial fibrillation.

Complications

All documented complications before the patient's discharge from the hospital were reviewed by the physicians of each center. We recorded 158 incidents among the 3373 included patients, of whom 7 experienced multiple complications. In total, 151 patients (4.5%) experienced complications. Precise information about the complications had previously been reported.[5] In this study, we categorized the complications into 3 categories: hemorrhagic, thromboembolic, and other complications. The hemorrhagic complications were divided into vascular and nonvascular. We sorted 6 of the 7 patients who experienced 2 complications into the same category. Nonvascular complications (76 patients) included cardiac tamponade or hemopericardium, and hemothorax. The vascular complications in 36 patients included puncture site hematoma, retroperitoneal hemorrhage, pseudoaneurysm, and arteriovenous fistula. Thromboembolic complications (in 10 patients) included transient ischemic attack, symptomatic cerebral infarction, and asymptomatic cerebral