Comparison of lesion formation between contact force-guided and non-guided circumferential pulmonary vein isolation: A prospective, randomized study

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BACKGROUND Contact force (CF) monitoring could be useful in accomplishing circumferential pulmonary vein (PV) isolation (CPVI) for atrial fibrillation (AF).

OBJECTIVE The purpose of this study was to compare procedure parameters and outcomes between CF-guided and non-guided CPVI.

METHODS Thirty-eight consecutive AF patients (mean age 60 ± 11 years, 28 paroxysmal AF) undergoing CPVI were randomized to non–CF-guided (n = 19) and CF-guided (n = 19) groups. CPVI was performed with the ThermoCool SmartTouch catheter in both groups. The end-point was bidirectional block between the left atrium (LA) and PV. In the CF group, CF was kept between 10 and 20 g during CPVI, whereas in the non-CF group, all CF information was blanked. Radiofrequency energy at 30 W in the anterior and 25 W in the posterior LA wall was applied for 20–25 seconds at each point.

RESULTS CPVI was successfully accomplished without any major complications in both groups. Mean CF in the non-CF and CF groups were 5.9 ± 4.5 g and 11.1 ± 4.3 g, respectively, for left-side CPVI, and 9.8 ± 6.6 g and 12.1 ± 4.8 g, respectively, for right-side CPVI (both $P < .001$). The procedure and fluoroscopy times for CPVI in the non-CF and CF groups were 96 ± 39 minutes and 59 ± 16 minutes, respectively ($P < .001$), and 22 ± 63 seconds and 9 ± 20 seconds (P = NS), respectively. Total number of residual conduction gaps was 6.3 ± 3.0 in the non-CF group and 2.8 ± 1.9 in the CF group ($P < .001$). During 6-month follow-up, 84.2% of patients in the non-CF group and 94.7% in the CF group were free from any atrial tachyarrhythmias ($P = .34$).

CONCLUSION CF-guided CPVI is effective in reducing procedure time and additional touch-up ablation and may improve long-term outcome.

KEYWORDS Atrial fibrillation; Catheter ablation; Contact force; Computed tomography; Pulmonary vein isolation; Fluoroscopy time

ABBREVIATIONS 3D = three-dimensional; **AF** = atrial fibrillation; **CF** = contact force; **CPVI** = circumferential pulmonary vein isolation; **CT** = computed tomography; **FTI** = force-time integral; **ICE** = intracardiac echography; **LA** = left atrium; **PV** = pulmonary vein; **RF** = radiofrequency

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Introduction

The efficacy and safety of radiofrequency (RF) catheter ablation of atrial fibrillation (AF) has been established,[1] and the 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation recommended ablation as a Class I indication for drug-refractory, symptomatic paroxysmal AF when it is performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced center.[2] This statement indicated pulmonary vein (PV) isolation as an essential procedure for AF ablation irrespective of the type of AF. The most important and urgent issue in AF ablation is the relatively high recurrence rate after ablation. It has been demonstrated that recurrence of AF after ablation is associated with resumption of conduction between the left atrium (LA) and previously isolated PV.[3–5] Thus, incomplete PV isolation by ablation is responsible for AF recurrence, which indicates the necessity of achieving complete and permanent PV isolation with the use of different technologies other than conventional RF ablation strategies.

One such technology recently developed is a catheter system that can monitor the real-time contact force (CF) of the catheter tip to the endocardial wall during ablation. A recent experimental study revealed that CF is a major determinant of RF lesion size, and CF monitoring may optimize RF power and application time to maximize lesion

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formation and avoid steam pop and thrombus during ablation.[6] Excessive CF has been shown to increase the risk of cardiac perforation.[7] A recent clinical study showed that CF during AF ablation correlates with clinical outcome, and arrhythmia control is best achieved by applying an average CF >20 g, whereas clinical failure is universally noted with an average CF <10 g.[8] Thus, CF monitoring during ablation is expected to facilitate effectively and safely the procedure of circumferential pulmonary vein isolation (CPVI) for AF.[9] To evaluate its advantage prospectively and quantitatively, we randomly assigned AF patients to CF-guided and non-guided CPVI and compared the procedure parameters and outcomes between the 2 groups.

Methods

Study population

The study protocol was approved by the Ethics Committee of our institution, and written informed consent was obtained from all patients before the study.

Thirty-eight consecutive patients undergoing CPVI for AF were randomly assigned to non–CF-guided group (non-CF group, n = 19) or CF-guided ablation group (CF group, n = 19). There were 29 men and 9 women (mean age 60 ± 11 years). Twenty-eight patients had paroxysmal AF, and the other 10 had nonparoxysmal AF. The absence of thrombus in the LA was confirmed by transesophageal echocardiography before CPVI. All patients were administered an anticoagulant for at least >4 weeks before the study. Warfarin (n = 18) was not interrupted before and after the CPVI procedure. Dabigatran (n = 19) and rivaroxaban (n = 1) were skipped only on the morning of the procedure. These anticoagulants were continued for at least 6 months after ablation.

After finishing the randomized study, in another group of 20 patients (12 male, mean age 63 ± 10 years) with paroxysmal (n = 17) or persistent AF (n = 3), we validated the effectiveness of CF at 10–20 g in accomplishing CPVI. Furthermore, in another group of 5 patients (3 male, mean age 46 ± 13 years) with paroxysmal (n = 4) or persistent AF (n = 1), we examined the influence of accumulating experience of CF-guided ablation on accomplishing CPVI while CF information was blinded.

LA imaging by computed tomography

ECG-gated and contrast-enhanced computed tomographic (CT) imaging was performed by injecting 2.0 mL/kg of contrast medium at 2.0 mL/s within 1 to 13 days (mean 6 ± 4 days) before CPVI. Images were acquired at the end-tidal position during 1 breath-hold using a 64-row multidetector CT (Somatom Definition, Siemens Healthcare, Forchheim, Germany). Three-dimensional (3D) CT images were reconstructed at 50% of the R-R interval and recorded as DICOM data. The accuracy of CT acquisition at the end-tidal position and 3D reconstruction at 50% of the R-R interval in integrating the CT image with the intracardiac echography (ICE) image was validated in our previous study.[10]

Cardiac catheterization

The procedure was performed while patients were in the fasting state. With patients under local anesthesia, a 6Fr double decapolar steerable catheter (BeeAT, Japan Lifeline Co, Tokyo, Japan) was inserted into the coronary sinus via the internal jugular vein. A 10Fr SoundStar ultrasound catheter (Biosense Webster, Diamond Bar, CA) was inserted into the right atrium via the right femoral vein, and anatomic mapping of the LA by CartoSound module equipped in a CARTO3 system (Biosense Webster) was performed. After transseptal puncture was performed, 5000 units of heparin was injected into the LA, followed by repetitive injection of 1000 to 2000 units of heparin to maintain an activated clotting time ≥ 300 seconds during the procedure. Two 8.5Fr long sheaths (Daig SL1, St. Jude Medical, St. Paul, MN) were inserted into the LA. By asking the patient to swallow contrast medium, anatomic position of the esophagus was confirmed.

CartoSound image of the LA and integration with CT image

ICE images were displayed through the CartoSound module using an Acuson X300PE echocardiography system (Siemens Medical Solutions USA, Mountain View, CA). ICE plane LA images were obtained at the end-tidal position and 50% of the R-R interval as described previously.[10] The range of the contours sampled was 6 to 9 between the ostia of the right PV and left PV, and these contours were registered as the LA ICE image. After visual alignment, the 2 images were integrated with the installed surface registration program.

AF ablation

CPVI in this study was performed by 2 operators (MK, KO) having experience with >200 cases of AF ablation. Before initiation of the study, the operators performed CF-guided ablation in 5 patients in order to become familiar with CF monitoring during ablation and to decrease bias due to a learning curve for this new technology. CPVI was done in the integrated 3D image using an open-irrigated ThermoCool SmartTouch catheter (Biosense Webster) in all study patients. The ablation catheter was advanced into the LA via the long sheath, which was then pulled back to the right atrium in order to reduce systemic thromboembolic risk. The present catheter measures CF based on electromagnetic location technology. RF energy was delivered at 30 W in the anterior aspect of the CPVI line and 25 W in the posterior aspect using a Stockert 70 (Biosense Webster) RF generator. While RF energy was being delivered, the catheter tip was dragged by about 2 mm every 20–25 seconds. The end-point of CPVI was elimination of all PV potentials recorded by a circular catheter (Lasso Nav, Biosense Webster) placed at the ostium of the PV, and PV-to-LA block during pacing from 10 pairs of the circular catheter at 10-V output with 1-ms pulse width.

In the CF group, the operator attempted to keep CF between 10 and 20 g during CPVI (Figure 1A, light green to blue in the color bar). The operator could check the CF using the force and direction panel, force graph, and tip display on