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Original article

Safety and efficacy of contemporary catheter ablation for atrial fibrillation patients with a history of cardioembolic stroke in the era of direct oral anticoagulants

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ABSTRACT

Background: The safety and efficacy of the contemporary atrial fibrillation (AF) ablation in patients with a recent or previous history of cardioembolic stroke (CS) or transient ischemic attack (TIA) remain to be established.
Methods: A total of 447 patients who underwent first-ever contact force (CF)-guided AF ablation with circumferential pulmonary vein isolation were included. Of these, 17 had CS or TIA within 6 months before ablation (Group 1), 30 more than 6 months before ablation (Group 2), and the other 400 without CS or TIA (Group 3). Procedural complications and recurrence of AF and atrial tachyarrhythmias were compared among the 3 groups.
Results: The mean age was 71 ± 7, 66 ± 9, and 61 ± 11 years in Groups 1, 2, and 3, respectively ($p < 0.05$, Group 1 versus Group 3). The oral anticoagulants were warfarin ($n = 108$, 24.1%), dabigatran ($n = 101$, 22.6%), rivaroxaban ($n = 147$, 32.9%), apixaban ($n = 87$, 19.5%), and edoxaban ($n = 4$, 0.9%), and did not differ among the 3 groups. Median follow-up period was 14 [IQR 12–22], 13 [12–14], and 12 [10–16] months, respectively. One episode of cardiac tamponade, 2 episodes of arteriovenous fistula, and some minor complications occurred in Group 3, but no complications occurred in Groups 1 and 2 in the periprocedural period. Although one episode of CS occurred 11 days after the procedure in Group 3, there were no periprocedural CS, TIA, or major bleedings in Groups 1 and 2. AF recurrence-free rate after the procedure was 76.5%, 86.7%, and 79.1% in Groups 1, 2, and 3, respectively, and there was no difference in Kaplan–Meier curves among the 3 groups.
Conclusion: The safety and efficacy of CF-guided AF ablation in the era of direct oral anticoagulants in patients with a recent or previous history of CS or TIA are similar to those in patients without it.

Introduction

Atrial fibrillation (AF) is a common arrhythmia in clinical practice and plays a key role as a cause of cardioembolic stroke (CS) [1]. A recent pooled study in Japanese non-valvular atrial fibrillation (NVAF) patients ($n = 3588$) without anticoagulation showed that age ≥75 years, hypertension, and prior cerebral infarction or transient ischemic attack (TIA) among $CHADS_2$ score components are a significant risk factor for incidence of ischemic stroke components [2]. Notably, prior cerebral infarction or TIA shows the highest hazard ratio (HR) = 3.25 among them, suggesting that it is of significant importance to manage adequately NVAF patients with prior cerebral infarction or TIA in order to prevent recurrence of CS [2]. Although anticoagulation therapy significantly reduces the incidence of thromboembolic events including CS [3,4], prior cerebral infarction or TIA remains being a significant risk after adjusting for anticoagulation therapy [5,6].

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Catheter ablation is an effective treatment for the patients with drug-refractory symptomatic AF [7], since successful AF ablation may reduce the risk of cardiovascular events including CS and death [8,9]. We and others demonstrated that recently developed contact force (CF)-guided AF ablation is more effective and safe than the conventional AF ablation without use of CF systems [10–12]. Furthermore, direct oral anticoagulants (DOACs) are shown to be comparable to warfarin in patients undergoing AF ablation [13–15]. Although a recent report showed that AF patients with a prior history of cerebral infarction can safely undergo AF ablation, mostly non-CF-guided ablation with warfarin, without periprocedural thromboembolic complications [16], little is known about safety and efficacy of AF ablation with use of CF systems and DOACs for those patients at high risk of thromboembolic events. The purpose of this study was to investigate the safety and efficacy of CF-guided AF ablation in patients with a recent or prior history of CS or TIA in the era of DOACs.

Methods

Study population

A total of 466 patients undergoing their first-ever CF-guided AF ablation from October 2012 to December 2015 were included. Patients with left ventricular ejection fraction (LVEF) < 30% (n = 7) or left atrial diameter > 55 mm (n = 12) were excluded. The remaining 447 patients were divided into 3 groups according to the history of CS or TIA: 17 with CS or TIA within 6 months before AF ablation (Group 1), 30 more than 6 months before the ablation (Group 2), and the other 400 without CS or TIA (Group 3). Flow chart of the study patients is shown in Fig. 1. Clinical characteristics, anticoagulant use, ablation protocol, procedural complications, and follow-up data were retrospectively obtained from the medical records. The study protocol was approved by the Ethics Committee of our institution (2016-1035).

Cardiac catheterization and ablation protocol

Cardiac catheterization and CF-guided AF ablation procedure were performed as described previously [10,11,17,18]. A 6 Fr double decapolar steerable catheter (BeeAT, Japan Lifeline Co, Tokyo, Japan) was inserted into the coronary sinus via the internal jugular vein under local anesthesia. Two 8.5 Fr long sheaths (Daig SL1, St.Jude Medical, St Paul, MN, USA) were inserted into the left atrium (LA). A 10 Fr SoundStar ultrasound catheter (Biosense Webster, Diamond Bar, CA, USA) was inserted into the right atrium, and anatomic mapping of the LA by CartoSound module equipped in a CARTO3 system (Biosense Webster) was performed. Intracardiac echography (ICE) images were displayed through the CartoSound module using an Acuson X300PE echocardiography system (Siemens Medical Solutions USA, Mountain View, CA, USA). The ICE image of LA was integrated with computed tomography (CT) image as previously described [17].

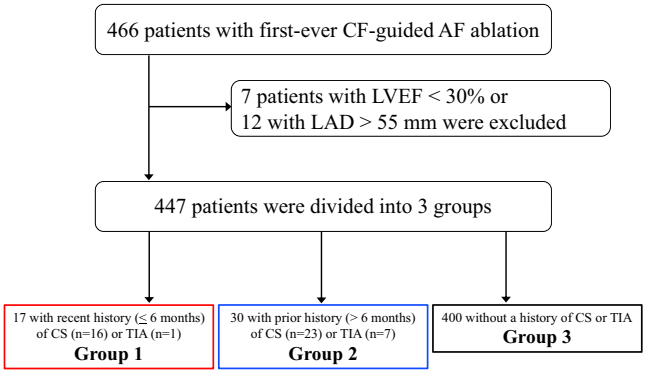

Fig. 1. Flow chart of the study patients. CF, contact force; AF, atrial fibrillation; LVEF, left ventricular ejection fraction; LAD, left atrial diameter; CS, cardioembolic stroke; TIA, transient ischemic attack.

AF ablation was performed by way of circumferential pulmonary vein isolation (CPVI) for all patients using a Thermocool SmartTouch catheter (Biosense Webster). Isolation of superior vena cava and left atrial linear ablation were performed for selected patients with persistent AF at operator discretion. Carvotricuspid isthmus (CTI) ablation was performed for all patients with a history of typical atrial flutter. 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 endpoint of CPVI was elimination of all PV potentials recorded by a circular catheter (Lasso Nav or PentaRay NAV, Biosense Webster) placed at the ostium of the PV, and LA-PV block during pacing from the circular catheter at 10-V output with 1-ms pulse width. When there was a conduction gap in the encircling linear ablation line, touch-up ablation targeting the earliest electrogram site was performed until complete elimination of the gap.

Periprocedural anticoagulation therapy

All patients took warfarin with therapeutic prothrombin time-international normalized ratio (PT-INR) or DOACs for at least 4 weeks before the procedure. Preprocedural transthoracic and transesophageal echocardiography were performed for all patients to assess cardiac function, LA diameter, and mitral regurgitation grade, and to confirm the absence of left atrial thrombi. Contrast enhanced CT was also performed. A bridge therapy using heparin after warfarin interruption was not performed before and after the procedure. When a PT-INR was <2.0 on admission, warfarin was continued. When a PT-INR was ≥2.0, warfarin was stopped on the day of the procedure. All DOACs were skipped only on the morning of the procedure day.

During ablation, we administered 5000 units of heparin after transseptal puncture, measured activated clotting time (ACT) every 10 min, and administered additional dose of heparin to maintain ACT between 300 and 350 s.

In patients with a PT-INR < 2.0 on the day of the procedure, 600 units per hour of intravenous heparin was infused every 3 h after the procedure until the next morning. In patients with a PT-INR ≥ 2.0 on the day of the procedure, or on rivaroxaban or edoxaban, oral anticoagulant was resumed after the procedure. In patients on dabigatran or apixaban, oral anticoagulant was restarted on the evening of the day of the procedure.

Follow-up and outcomes

All patients were seen in the clinic at 1 and 3 months after CPVI and every 3 months thereafter until 12 months to perform 12-lead electrocardiogram (ECG) and a 24-h Holter ECG. After 12 months follow-up, every 6 months follow-up was performed if the patients were seen in our clinic. The efficacy outcome was freedom from AF and any atrial tachyarrhythmias, which were defined as any asymptomatic or symptomatic AF and atrial tachyarrhythmias lasting more than 30 s detected by either a 12-lead ECG or a 24-h Holter ECG at every visit to the clinic, beyond a blanking period defined as 3 months after CPVI. The safety outcomes were the incidence of periprocedural complications and the recurrence of CS or TIA.

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