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Comparison of catheter ablation and surgical ablation in patients with long-standing persistent atrial fibrillation and rheumatic heart disease: A four-year follow-up study



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ABSTRACT

Background: In our previous prospective and randomized study, we have demonstrated that the concomitant surgical ablation using saline-irrigated cooled tip radiofrequency ablation (SICTRA) system is more effective than subsequent circumferential pulmonary vein isolation (CPVI) combined with substrate modification in treating patients with long-standing persistent atrial fibrillation (LS-AF) and rheumatic heart disease (RHD) undergoing cardiac surgery during middle-term follow-up. Whether this strategy also decreases longer-term arrhythmia recurrence is unknown. This study describes the 4-year efficacy of SICTRA for these patients. Furthermore, we seek to compare the electrophysiological characteristics for recurrent atrial tachyarrhythmia (ATa) at the session of catheter ablation between two groups.

Methods: Long-term follow-up was performed in 95 patients who underwent the catheter ablation strategy $(n=47,Group\,A)$ or SICTRA $(n=48,Group\,B)$ combined with valvular surgery for symptomatic LS-AF patients with RHD.

Results: After one procedure, Group B had a significantly higher freedom from ATa compared with Group A (29/48 vs 15/47, P = 0.005) after a mean follow-up of 54 months (range 48 to 63 months). Catheter-based mapping and ablation of recurrent ATa showed larger amounts of macro-reentrant atrial tachycardias (ATs) in Group B and higher incidence of pulmonary vein (PV) recovery in Group A. After multiple catheter ablations for recurrent ATa, sinus rhythm (SR) could be maintained equally between two groups.

Conclusions: Single procedure success seems to be higher with SICTRA but repeated catheter ablation potentially results in comparable outcomes in treating patients with LS-AF and RHD during long-term follow-up. More macro-reentrant ATs and more PV recoveries are identified to be responsible for ATa in SICTRA and catheter ablation group, respectively.

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1. Introduction

Rheumatic heart disease (RHD) is the prototype of structural heart disease that not only affects the heart valves, but also causes chronic inflammation in the atrium. Structural and electrical remodeling of the atrium has been described in these patients, leading to higher propensity for development and persistence of atrial fibrillation (AF) [1]. Since long-standing persistent AF (LS-AF) rarely returns to sinus rhythm (SR) if left untreated and several studies indicate that untreated AF has detrimental effects on heart rate, hemodynamics, and atrioventricular synchronicity and increases the thromboembolism risk, it may be advisable to treat AF at the time of other surgery [2,3]. A meta-analysis has

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concluded that when performed in addition to cardiac surgery, the Cox Maze procedure is associated with a significant increase in the odds of freedom from AF at 12 months of follow-up [4]. However, the complexity of the procedure and the length of time required to perform it are the deficiencies inherent to Cox Maze procedure [5–7]. Therefore, new techniques are needed to make the procedure safer and easier to perform.

Our previous prospective and randomized trial has demonstrated that concomitant AF surgical ablation using saline-irrigated cooled tip radiofrequency ablation (SICTRA) is more effective than subsequent catheter ablation in patients with LS-AF and RHD undergoing cardiac surgery during middle-term follow-up post-procedure (18 \pm 6 months) [8]. However, whether this strategy decreases longer-term atrial tachyarrhythmia (ATa) recurrence is unknown. Furthermore, we seek to identify and compare the electrophysiological characteristics for recurrent ATa at the session of catheter ablation between the two groups in the present study.

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2. Methods

2.1. Study design and study populations

The methodology for this clinical trial was previously described in detail [8]. The study was a prospective, randomized, controlled study that involved patients with RHD and LS-AF. We consecutively selected 106 patients with persistent AF pre-existing for more than 1 year and RHD who underwent valvular heart operation. The patients were then randomly divided into two groups: catheter ablation group (Group A) and surgical ablation group (Group B), with 53 patients in each arm. The inclusion criteria were as follows: inpatients of either sex, aged 18 or greater, with RHD and LS-AF, AF must be symptomatic and refractory to at least one anti-arrhythmic medication, and the patients are willing to provide written informed consent. Patients with paroxysmal AF, non-RHD, left atrial (LA) thrombus on transesophageal echo prior to the procedure, previously undergoing AF ablation and valve commissurotomy were excluded. The study protocol was approved by the Ethics Committee of our institution.

2.2. Surgical procedure

All operations were performed by means of a median sternotomy using standard cardiopulmonary bypass. The heart was arrested by infusing a cold blood cardioplegic solution through the aortic root. The diseased valve was either repaired or replaced and the left atrial appendage (LAA) was sewed at its base in both groups of patients. An additional modified Maze III procedure using SICTRA system (Cardioblate, Medtronic Inc.) was performed in patients of Group B as described previously [3]. For catheter ablation of AF mainly performed in LA, we did not perform right atrial (RA) SICTRA, and left-side SICTRA was performed as described by Abreu Filho et al. [3]. The ablation pattern in LA included radiofrequency (RF) isolation of the left and right pulmonary veins (PVs), an interconnecting line between them, a left PV to atrial appendage line, and a mitral annulus to PV line. Patients in Group A only underwent valvular operation.

2.3. Post-operative care and follow-up in Group B

Post-operative care and follow-up in Group B was performed as described previously [8]. Early post-operative care was similar to that for the routine open-heart surgery. The cardiac rhythm was continuously monitored until a stable rhythm returned. Anti-arrhythmic drug (AAD) was administrated on a routine basis, and amiodarone was the first choice anti-arrhythmic drug. The anticoagulation management protocol was the same as that applied for routine open-heart surgery. Heparin was administered after resolution of post-operative bleeding. After removal of chest tubes, oral anticoagulant therapy with warfarin was started as a long-lasting treatment, targeting international normalized ratio range 2.5–3.0.

All data were obtained for each patient during the post-operative period, before hospital discharge, and after the first, third, sixth, and every 6 months thereafter. Surface electrocardiogram (ECG) was performed and repeated 1 day, 1 week, 1, 3, 6 months and every 6 months thereafter. Monthly telephone inquiry was applied to evaluate the severity of symptoms, and cases were always asked to record their ECG when having symptoms indicating atrial arrhythmia onset. Twenty-four hour Holter recording was performed at 3-month intervals post-procedure to document any form of atrial arrhythmias. Spiral computed tomography was performed at 3 months after the procedure in all cases to assess PV stenosis. We set the blanking period of the first 1 month after operation. After the blanking period, any episode of symptomatic or asymptomatic ATa lasting over 30 s with ECG/Holter documentation was considered a recurrence, which comprised AF, atrial tachycardia (AT, including atrial flutter [AFL]). Patients with recurrent ATa were first treated with AADs, and electrophysiological study with RF ablation was performed at least 6 months after the operation if recurrent ATa was drug-refractory.

$2.4.\ Post-operative\ care\ and\ catheter\ ablation\ for\ atrial\ fibrillation\ in\ Group\ A$

2.4.1. Post-operative care

Patients in Group A received only rate control therapy after open heart surgery. Betablockers and digoxin were used and cardiac rhythm was continuously monitored until a stable rhythm returned. Other AADs were not used to avoid the effect of SR restoration of those drugs. Surface ECG was performed and repeated 1 day, 1 week, 1, 3, and 6 months post-operation. Twenty four hour Holter monitoring was performed at 3 and 6 months after the operation. Patients with post-operative AF were subjected to catheter ablation. Warfarin was used as a long-lasting anticoagulation treatment, targeting INR range 2.5–3.

2.4.2. Electrophysiological study and catheter ablation

Patients with post-operative AF received an electrophysiological study and subsequent catheter ablation of AF 6 months after the heart surgery. Before ablation, all patients underwent transesophageal echocardiography to exclude intracardiac thrombi. Warfarin was discontinued and low-molecular heparin was used 3 days pre-ablation. All AADs including amiodarone were discontinued five half-lives before electrophysiological study and ablation. Electrophysiological study was performed under post-absorptive state with conscious sedation. Patients received heparin before the transseptal puncture and throughout the electrophysiological study and ablation procedure to maintain an active clotting time (ACT) of 300–350 s and usually ACT was measured at 30 min interval during the procedure. A circular mapping catheter (Lasso, Biosense Webster) and a

3.5-mm open-irrigation tip catheter (Thermocool, Biosense Webster) were used for ablation. Under the guidance of an electroanatomical mapping system (CARTO, Biosense Webster), we reconstructed the LA anatomy, taking care to avoid metal valve impairment or catheter entrapment when manipulating the catheter at the mitral annulus.

Electrophysiological study and catheter ablation procedure were performed as we previously described [8]. Circumferential pulmonary vein isolation (CPVI) was performed at the posterior wall 1 cm and at the anterior wall 5 mm away from the angiographically defined PV ostia. The endpoint of circumferential PV ablation was PV isolation, which was defined as disappearance of all PV potentials or LA-PV potential dissociation. After CPVI, AF was either persistent or converted to AT or SR. For those with AF persistent, complex fractionated atrial electrograms (CFAEs) in the LA were mapped and ablated. The endpoint of CFAEs ablation was either elimination of CFAE areas or AF conversion to regular AT or SR. If AF persisted following CPVI and CFAE ablation, linear ablation was carried out. The mitral line was performed first followed by roof line if AF persisted. Complete block of mitral and roof lines was confirmed by observing the reversal of the expected activation sequence at one side of the line, whereas pacing from the other side. Last, AT after CPVI, CFAEs and linear ablation was mapped and ablated. To ensure that all patients received the same treatment, linear ablation along mitral line and roof line was also performed in patients with SR after CPVI and CFAE ablation. After CPVI, CFAE ablation, linear ablation, and AT ablation, if AF or AT was not terminated, 300-360 J direct current cardioversion was applied to restore SR.

2.4.3. Post-ablation management and follow-up

All cases received low-molecular-weight heparin injection for 3–5 days and warfarin anticoagulation, keeping INR between 2.5 and 3. Amiodarone was given intravenously at a dose of 600 mg/day for 3 days. Then the drug was given orally, starting at 600 mg/day for 1 week and then tapered to 200–400 mg/day for 3 months after the ablation, and was withdrawn 3 months later in cases without ATa recurrence, but was continued in cases with ATa recurrence. Patients were routinely followed up using the aforementioned method as used in Group B. We set the blanking period of the first 1 month after ablation. After the blanking period, any episode of symptomatic or asymptomatic ATa lasting over 30 s with ECG/Holter documentation was considered a recurrence. Re-ablation was performed at least 1 month after the initial procedure if recurrent ATa was drug-refractory. Spiral computed tomography was performed at 3 months after the procedure in all cases to assess PV stenosis.

2.5. Electrophysiological study and catheter ablation protocol for ATa recurrence

Repeated electrophysiology procedures were undertaken for drug-refractory recurrent ATa. The initial strategy was an assessment of PV recovery, followed by closure of all PV conduction gaps and electrical reisolation. For AF recurrence, ablation of CFAEs was only performed in those with AF persistence. For AT or AFL, the suspected macroreentrant ATa was initially mapped in the right atrium using CARTO three dimensional mapping, and in the majority of instances, entrainment was performed from the RA isthmus as well as through the distal coronary sinus. If entrainment or RA mapping indicated a LA origin of the tachycardia, transseptal catheterization was performed for LA mapping and ablation. If a focal AT was suspected, it was mapped using the CARTO three-dimensional mapping and ablated at the site of earliest activation.

2.6. Study endpoints

The primary endpoint of the study was freedom of any recurrence of ATa lasting 30 s 48 months post-procedure after adjunctive SICTRA or catheter ablation in addition to valvular surgery. The second endpoint included the need for re-ablation and incidence of peri-procedural complications.

2.7. Statistical analysis

Statistical analysis was performed using the Statistical Program for Social Sciences (version 16.0 SPSS Inc., Chicago, IL, USA). Continuous data were analyzed with a Student's t-test. Chi-square test was used for categorical variables. ATa-free survival at 48 months was analyzed with Kaplan–Meier statistics, with difference between groups assessed using the log-rank test. Two-tailed test of significance is reported and a P < 0.05 was considered statistically significant.

3. Results

3.1. Patient characteristics

Three patients in Group A showed no AF after valvular operation and did not perform electrophysiological examination. Three patients in Group A and four patients in Group B were lost to follow up over the study period. The death of one Group B patient was not related to the surgical procedure. There were 47 patients in Group A and 48 patients in Group B that completed the entire study (Fig. 1). Characteristics of the 95 randomized patients were distributed similarly between the 2 groups and are summarized in Table 1.

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