International Journal of Cardiology 174 (2014) 497–502

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Efficiency of radiofrequency ablation for surgical treatment of chronic atrial fibrillation in rheumatic valvular disease

Xu Wang [1], Xin Wang [1], Yunhu Song, Shengshou Hu, Wei Wang *

Cardiovascular Surgery Department, Fuwai Hospital, Peking Union Medical College & Chinese Academy Of Medical Sciences, Beijing, 100037, China

ARTICLE INFO

Article history:
Received 12 November 2013
Received in revised form 12 February 2014
Accepted 22 March 2014
Available online 29 March 2014

Keywords:
Atrial fibrillation
Rheumatic heart valve disease
Ablation

ABSTRACT

Background: It remains unclear whether concomitant radiofrequency ablation procedure in valvular surgery could offer additional benefits to patients with rheumatic valvular disease. We designed a prospective and randomized control study to evaluate the efficacy of surgical radiofrequency ablation in patients with rheumatic heart disease.

Methods: From June 2008 to July 2011, 210 patients with chronic atrial fibrillation and rheumatic heart disease were randomized: (1) control group, patients underwent only valve replacement followed by amiodarone for rhythm control, (2) left atrial group (LA group), patients underwent valve replacement and left atrial mono-polar radiofrequency ablation, (3) bi-atrial group (BA group), patients underwent valve replacement and bi-atrial mono-polar radiofrequency ablation. The primary endpoints included: cardiac death, stroke, and recurrent AF after discharge.

Results: There was no perioperative death. One patient died 4 months after MVR in BA group. In univariate Cox analysis, the two ablation groups were associated with less AF (BA group vs control group: $P < 0.001$; LA group vs control group: $P < 0.001$) as well as atrial tachycardia arrhythmia (AF/AT/AFL) recurrent (BA group vs control group: $P < 0.001$; LA group vs control group: $P = 0.02$). The comparison between BA and LA groups revealed no differences in terms of AF ($P = 0.06$) or AF/AT/AFL ($P = 0.09$). Atrial transport function restoration rate 12 months after operation was 31.4% in LA group, 32.9% in BA group, and 8.6% in control group respectively ($P < 0.01$).

Conclusions: Radiofrequency ablation concurring with valvular surgery can bring a higher sinus rhythm restoration rate when compared with medical anti-arrhythmic drug therapy in low-medium risk rheumatic heart disease.

The trial was registered on Clinicaltrials.gov (registry number NCT01013688).

1. Introduction

Atrial fibrillation (AF) is the most common arrhythmia in clinical practice [1], especially for patients with valve heart diseases. Up to 30%–40% of patients about to receive mitral valve surgery are with preoperative chronic AF, and in most cases the arrhythmia still exists after the operation [2,3].

In recent decades, the clinical application of radiofrequency ablation for AF has achieved satisfactory results [4–6]. However, the reports were largely limited to non-rheumatic mitral valve diseases and little is known about surgical ablation outcomes for AF with rheumatic heart diseases. But in consideration of its distinctive pathogenesis and poorer clinical outcomes [7–9], we hypothesize that rheumatic AF might respond differently to surgical ablation therapy.

Although there were few studies focusing on AF ablation outcomes among patients receiving concomitant rheumatic mitral valve operations, those studies were generally small-sized or retrospectively-designed with controversy outcomes [10–15]. Up till now, there is no randomized controlled trial designed on this topic. The current RCT study aims to evaluate the clinical effectiveness of radiofrequency ablation for chronic AF combined with rheumatic mitral lesion.

2. Methods

2.1. Study design

Candidates were those diagnosed as rheumatic mitral valve diseases complicated with AF. The AF definition in the current study was consistent with that defined by ACC/AHA/ESC [16]. Inclusion criteria were as follows: AF duration > six months, age ≥ eighteen years, left atrial dimension ≤ 70 mm and without left atrial thrombus. Exclusion standards were as follows: AF duration ≤ six months, age < eighteen years old, emergency operation, left atrial dimension > 70 mm, left ventricular ejection fraction < 30%, left atrial thrombus, onset of acute myocardial infarction < six weeks, time of apoplexy < six months.

Abbreviations: AF, Atrial Fibrillation; LA, Left Atrial; BA, Bi-Atrial; AF/AT/AFL, Atrial Tachycardia.

* Corresponding author at: 167A, Bei Li Shi Road, Xi Cheng District, Beijing 100037, China.
E-mail address: drweiwang0728@hotmail.com (W. Wang).

[1] The first two authors contributed equally to this paper.

http://dx.doi.org/10.1016/j.ijcard.2014.03.153
0167-5273/

From June 2008 to July 2011, 432 consecutive patients with rheumatic mitral valve disease and AF required surgical intervention. As is shown in Fig. 1, there were 432 consecutive patients that require surgical intervention, among which 186 patients were not eligible. Among the remaining 246 patients, 36 candidates declined to enter the study. Finally, we got 210 subjects with written consents. Patients were randomly assigned, in 1:1:1 ratio, into three groups: (1) control group, patients underwent only valve replacement followed by amiodarone, (2) left atrial group (LA), patients underwent valve replacement and left atrial mono-polar radiofrequency ablation, and (3) bi-atrial group (BA), patients underwent valve replacement and bi-atrial mono-polar radiofrequency ablation. The random table was generated by the SAS software. After randomization, the study processes were blinded to the patients, coordinators and the investigators who were responsible for the patient assessment but were not blinded to participant surgeons. The study was approved by the ethics committee of Fuwai Hospital, Peking Union Medical College (ID: 875).

2.2. Endpoints

Primary endpoints relate to one-year outcomes that included cardiac death, stroke, and recurrent AF after discharge; secondary endpoints include recurrent atrial tachycardia (a combination of atrial fibrillation, atrial flutter, and other types of atrial tachycardia), prosthetic dysfunction, and pacemaker implantation. Cardiac death was defined as deaths from cardiovascular causes or unknown causes; stroke was defined as newly occurred stroke after discharge; recurrent AF after discharge was defined as AF recurrence among converted individuals; and prosthetic dysfunction was defined as a prosthetic valve failure requiring surgical interventions.

Blinded adjudication board includes two senior cardiologists involved in assessment and classification of endpoints. If difference in opinions occurred in the assessment, a third cardiologist will be invited to help solve the disagreement.

2.3. Surgical procedures

A median sternotomy approach and conventional ascending aorta and bicaval cannulation were used for all patients. A standard right atrial free wall incision was made and atrial septum approach was used to expose left atrial cavity. The left-sided MAZE procedure was performed with the same technique in both experimental groups. Left auricle was removed with Marshall ligament disconnection. In general, the ablation procedure included encirclement of the pulmonary veins with extension to the mitral valve annulus as well as extension to the appendage amputation site (Supplemental Fig. 1). An additional ablation line between the pulmonary vein encirclements was made at the left atrial dome. After ablation, patients received mitral valve replacement or other procedures.

In BA group, the patients received additional ablation procedures on right atrium: a free wall incision, a line from coronary sinus to orifice of the inferior vena cava, and a line from coronary sinus to tricuspid annulus (Supplemental Fig. 1).

2.4. Peri-operative care

The baseline characteristics were evaluated and all patients routinely received echocardiography, 12-lead electrocardiography and Holter monitoring preoperatively.

For all but those with heart rate <60 bpm postoperatively, amiodarone was intravenously infused in a loading dose of 150 mg over 10–15 min right after the procedures, then at a maintenance dose of 1 mg/min for 6 h, and then 0.5 mg/min. All the patients were submitted to the examination of chest X-ray, a 12-lead surface electrocardiogram (ECG), echocardiogram, and Holter monitoring before discharge.

For those still in AF after surgery, cardioversion was attempted during hospital stay. Those still in AF at discharge were planned to have electrical cardioversion one month later. For patients remaining in AF three months postoperatively, further conversion attempts were at physicians' judgment.

2.5. Follow-up

All patients were followed up in outpatient clinic at three months, six months and one year after discharge. The follow-up information were obtained mainly from regular outpatient clinic visits. If the patients didn't come back as scheduled, phone calls were made to obtain required information. If unscheduled visits occurred, hospital cards were used to retrieve the information. If necessary, the attending physicians were contacted for those patients not going to the outpatient clinic of our institute. In this study, the follow-up completion rate was 100%.

During follow-up period, all patients took warfarin and adjusted the dose according to standard anticoagulation protocols. Oral amiodarone, in a dose of 200 mg/day, was maintained for 3 months and then withdrawn when the AF recurrence was absent. In case of recurrent AF, β-blockers would be administered.

The patients of control group needed to take oral amiodarone for one year. Patients in control group required to monitor their heart rates at home (to count heart rate three times per day). If the heart rate was lower than 50 bpm, the patients should report to our researching staff. The chest X ray, liver function, and thyroid function were also routinely monitored (at three months, six months, and one year postoperatively).

There were three patients who withdrew from amiodarone for reported low heart rate (<50 bpm), two patients for abnormal liver functions (three months postoperatively), and one patient for abnormal thyroid functions. Patients with abnormal liver or thyroid function would be switched from amiodarone to β-blockers while for withdrawal for heart rate reasons, amiodarone protocol was discontinued and resumed when the heart rate was over 50 bpm.

While reexamined, the patients had to undergo Holter and echocardiography. In the current study, we adhered to a pre-defined three-month blanking protocol. We didn't document tachyarrhythmia events during this period. Three months after ablation, discontinuation of amiodarone was recommended. ECG, 24-hour Holter recording and transthoracic echocardiogram were obtained at our outpatient clinic in three, six, and twelve months following surgery. Any documented episode of AF or atrial tachyarrhythmia (AF/AT/AFL) lasting more than 30 s (by ECG or Holter) was considered a recurrent arrhythmic event. In the event of symptoms suggestive of ATs, patients were required to undergo additional ECG and Holter in the referring hospital.

2.6. Echocardiography assessment

The echocardiography was evaluated by experienced cardiologist. During the follow-up visit, we focused on evaluating the size and function of the left atrium. The changes of left atrium diameter (δLAD) were obtained by the following formula:

$$\delta LAD_{6m} = LAD_{6m} - LAD_0$$

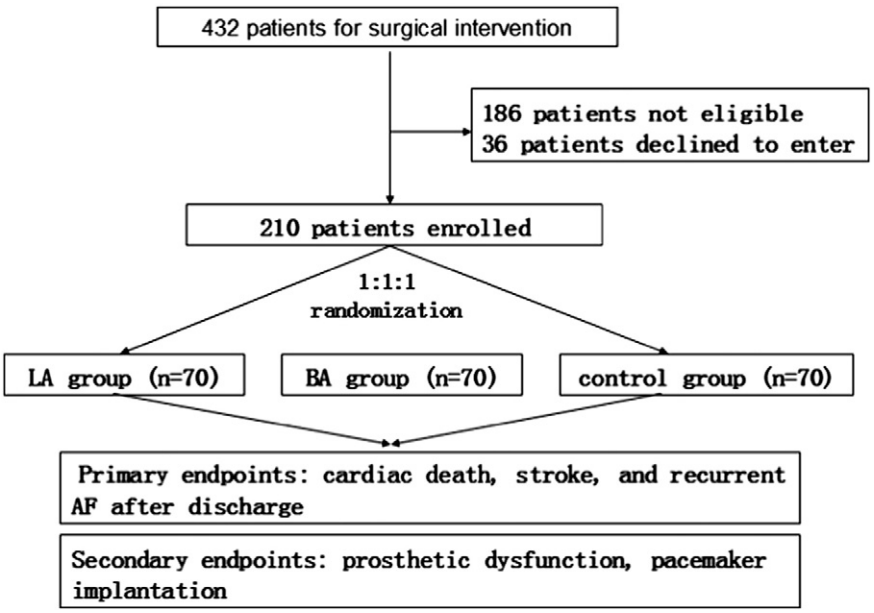

Fig. 1. The flow chart of the current trial. LA: left atrial group. BA: Bi-atrial group.