Comparison of two radiofrequency ablation devices for atrial fibrillation concomitant with a rheumatic valve procedure

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Abstract

Background: Perioperative and median-term follow-up outcomes have not been compared among procedures using radiofrequency ablation devices for permanent atrial fibrillation with concomitant rheumatic valve disease. We compared the sinus rhythm restoration efficacy of "non-irrigation" ablation forceps and an "irrigation" ablation device in patients with rheumatic valve disease undergoing a modified Cox maze radiofrequency ablation procedure due to permanent atrial fibrillation.

Methods: Data of 278 patients with rheumatic valve disease from the Cardiac Surgery Department of Sichuan Provincial People's Hospital who underwent the modified Cox maze radiofrequency ablation procedure between May 2013 and May 2017 were reviewed. The procedure was performed using "non-irrigation" ablation forceps (AtriCure, group A) in 149 patients and an "irrigation" ablation device (Medtronic, group M) in 129 patients. Data were collected prospectively, and follow-up was documented and compared between the groups.

Results: The radiofrequency procedure duration was 28.9 ± 3.8 min in group A and 29.5 ± 2.8 min in group M ($t = 1.623$, $P = 0.106$). The predicted radiofrequency time to the left atrium diameter was (Ya = 0.4964 X + 0.3762, $R^2 = 0.74$) in group A and (Ym = 0.4331 X + 4.3563, $R^2 = 0.8435$) in group M. The sinus rhythm (SR) conversion rate without use of anti-arrhythmic drugs was similarly good in groups A and M, with 75.2%, 72.5%, and 70.5% *vs.* 73.6%, 71.3%, and 69.8% at discharge, 6 and 12 months, respectively ($F = 0.084$, $F = 0.046$, $F = 0.046$, $P > 0.05$, respectively).

Conclusion: Two types of radiofrequency ablation devices characteristic of "non-irrigation" and "irrigation" bipolar ablation forceps were similarly efficient at SR restoration.

Keywords: Ablation device; Atrial fibrillation; Sinus rhythm; Rheumatic heart disease

Introduction

Atrial fibrillation (AF) is a rhythm disturbance that is defined by irregular, rapid, electrical, and mechanical activation of the atria, which causes unsynchronized atrial contraction and promotes thromboembolism.[1] If AF is not treated at the time of surgery, patients have less favorable early and late outcomes following their valve(s) surgery with or without tricuspid valve (TV) surgery.[2] All studies presented to date have demonstrated that the Cox maze III/IV procedure can be performed very safely and effectively in a broad group of patients, including those with a high risk (Euroscore >6), older age (>80 years), concomitant additional procedure, and a minimally invasive procedure.[3]

The efficacy of different ablative procedures for rheumatic heart valve disease has been analyzed.[4] Comparative studies have examined the efficacy of ablation performed using different energy sources.[5] Bipolar radiofrequency (RF) ablation has become the main choice as an adjunct to cardiac surgery due to its shorter procedure time and greater guarantee of transmurality.[6] Bipolar RF can be conducted easily and safely, and theoretically, a complete ablation with successful creation of transmural lines can be achieved.[7]

However, bipolar RF ablation devices in the clinical setting have been designed with different shapes and principles. Therefore, concerns exist regarding the choice of bipolar RF ablation devices during the maze procedure with major cardiac surgery, because these devices have specific characteristics, and their efficacies have not been compared. This study compared the efficacy between two types of RF ablation devices in permanent AF patients with concomitant rheumatic valve disease according to the

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"non-irrigation" and "irrigation" condition of the selected ablation forceps.

Methods

Ethical approval

This study was a single-center, retrospective, observational, cohort study of prospectively collected data from consecutively recruited patients at the Cardiac Surgery Department of Sichuan Provincial People's Hospital between May 2013 and May 2017. Institutional review board approval from the Ethics Committee was obtained with patient consent waived.

Patients

The eligibility criteria included the following: (1) adult rheumatic heart valve disease with a left atrium (LA) ≤70 mm, (2) presenting with AF lasting at least 12 months without spontaneous conversion, and (3) having undergone a valvular replacement procedure concomitant with surgical radiofrequency ablation.[8] Patients were excluded from this study if they had active coronary artery disease requiring additional coronary artery bypass grafting or infective endocarditis. A total of 149 patients who received "non-irrigation" ablation forceps-based radiofrequency ablation (AtriCure, Inc., Cincinnati, OH, USA) were termed group A, and another 129 who received an "irrigation" ablation device-based radiofrequency ablation (Medtronic, Inc., Minneapolis, MN, USA) were termed group M.

Operative Approach

All procedures were performed by senior surgeons via a median sternotomy using cardiopulmonary bypass (CPB) with bicaval venous drainage during moderate hypothermia (28–32°C). Antegrade irrigation of crystalloid cardioplegia with a histidine-tryptophan-ketoglutarate solution was used to arrest the heart. LA size reduction was performed when the LA was more than 60 cm. The modified Cox maze radiofrequency ablation procedure of the two groups aimed to mimic most of the incisions and sutures of the classical Cox maze procedure. The AF ablation in group A was performed with the AtriCure biopolar radiofrequency ablation device (AtriCure Inc., West Chester, OH, USA). The AF ablation in group M was performed using an irrigated radiofrequency ablation device (Cardioblate; Medtronic) with the power generator set at 25 W. Energy was applied by oscillating the probe back and forth with a preselected catheter tip temperature of 60°C and a saline irrigation flow rate of 4 to 6 mL/min.[9] The choice to use either ablation device was at the discretion of the surgeon. An equal quota exists for the number of ablation devices that can be imported each year. Basically, both types of devices are alternately available. The ablation time was calculated from start to end. Both ablation devices were used to complete the whole ablation line.

The ablation protocol was previously described.[10] Briefly, the right-sided procedure was performed on the beating heart before aortic cross-clamping. Ablation lines were created between the superior and inferior caval cannulation sites. Additional lines were drawn from the medial aspect of the base of the excised right atrial appendage into the annulus of the TV and from the caudal end of the surgical incision at the atrioventricular groove to the posterior part of the annulus of the TV. Three ablation lines for the right atrium were preceded on the intercaval, inferior cavotricuspid isthmus through the coronary sinus and Waterston groove. The septal part of the procedure was performed in a later stage of the operation immediately before opening the LA to prevent tearing of the septum. In the LA, the LA appendage was amputated, oversewn from the epicardial surface with a double-layer suture using 4/0 polypropylene at its orifice after the ablation procedures, and reinforced with ablation around the orifice. The left and right pulmonary veins were encircled, and a connecting line between both islands of the pulmonary veins was drawn across the left atrial roof and floor. Ablation lines were also set up from the ablation line isolating the left pulmonary vein to the base of the left atrial appendage amputation site and to the posterior mitral valve annulus. In addition, the Marshall ligament was ablated. Induction of transmural lesions was estimated visually intra-operatively and was assumed when the endocardium turned whitish during ablation and warning of successful transmurality began. To ensure complete blockage of the ablation lines, each bipolar RF lesion is created by three ablations with the clamp to ensure lesion transmurality.

Post-operatively, the cardiac rhythm was continuously monitored. Amiodarone (600 mg) was intravenously administered for 24 h and then decreased by half the next day, followed by oral amiodarone administration for 3 months depending on the heart rate.

Inflammatory Reaction and Cardiac Injury Index

The neutrophil-lymphocyte ratio (NLR), which is defined as the ratio of absolute counts of neutrophils to that of lymphocytes, was calculated through regular blood test results pre-operatively and post-operatively at 12 h. Samples for determination of the troponin I (TnI) protein level usually were collected 12 h after the procedure.

Follow-up

Patients were discharged from the hospital, and continuous oral anti-coagulation with warfarin sodium was continued for at least 6 months. The patients' international normalized ratios were measured three times per week for the first week following ablation for potential dose-adjustments due to drug interactions and thereafter as necessary.

The patients were followed up at 3, 6, 12, 24, and 36 months post-operatively or whenever they developed symptoms consistent with recurrent AF.[11] Each visit consisted of a detailed history and routine clinical, electrocardiographic, and echocardiographic evaluations and laboratory testing. A 24 h Holter-ECG recording was performed at discharge and at the 6-month and 12-month follow-ups. All ECG and Holter monitoring results were reviewed by a study investigator. Anyone of the following three rhythms was considered post-operative AF: any

documented AF, atrial flutter or atrial tachycardia lasting more than 30 s. Heart rate-controlling drugs instead of rhythm-conversion drugs were prescribed if arrhythmia recurrence occurred at 3 months.

Statistical Analysis

All statistical analyses were performed with SPSS software (version 17.0; SPSS Inc., Chicago, IL, USA). Continuous variables are expressed as the mean ± standard deviation and were compared using Student independent samples *t* test for means of normally distributed continuous variables and the Mann-Whitney *U* non-parametric test for variables with skewed distributions as appropriate based on the parametric test assumptions. Categorical variables are expressed as frequencies and percentages. The outcomes were compared using the χ^2 or Fisher exact test. SR restoration was compared between the groups using analysis of variance. The correlation equation between the radiofrequency time and the left atrial diameter was analyzed with a scatter diagram. A *P* value <0.05 was considered a statistically significant difference between the groups.

Results

Patient demographics

No significant differences were found among the baseline data between groups A and M [Table 1]. Of the patients undergoing mitral valve replacement, almost half of them received aortic valve replacement, and approximately 80% received tricuspid annuloplasty for functional tricuspid regurgitation with either suture or ring annuloplasty.

Operative outcomes and survival

The operative and follow-up outcomes are summarized in Table 2. No significant differences were found in the aortic cross-clamp and CPB times between groups A and M. The AF frequency ablation time was 28.9 ± 3.8 min in group A and 29.5 ± 2.8 min in group M ($t = 1.623$, $P = 0.106$) [Table 2]. A linear relationship existed between the surgical ablation procedure duration and the LA diameter size ($Y = 0.4714\ X + 1.9597$, $R^2 = 0.7699$). The predicted radiofrequency time to the LA diameter was ($Ya = 0.4964\ X + 0.3762$, $R^2 = 0.74$) in group A and ($Ym = 0.4331\ X + 4.3563$, $R^2 = 0.8435$) in group M.

Post-operative outcome

None of the parameters, including the NLR and TnI, at 12 h post-operatively were significantly different between the groups [Table 2]. Seven patients in group A and five in group M suffered a transient severe atrial ventricular block during their hospital stay, which was supported with a temporary pacemaker and delayed medication. Two

Table 1: Baseline characteristics of patients with rheumatic valve disease undergoing the modified Cox maze radiofrequency ablation procedure.

Variable	Group A (*n* = 149)	Group M (*n* = 129)	Statistical value	*P* value
Age (years)	53 ± 11	52 ± 10	0.388*	0.615
Female gender	87	76	0.008†	0.929
Body mass index (kg/m^2)	23.1 ± 2.4	23.0 ± 2.3	0.313*	0.755
AF duration (months)	26.3 ± 12.3	27.4 ± 12.0	0.779*	0.437
Cardiothoracic ratio	0.62 ± 0.08	0.62 ± 0.07	0.334*	0.739
Neutrophil-lymphocyte ratio	3.16 ± 1.30	3.19 ± 1.28	0.150*	0.881
Tricuspid regurgitation classification	3.0 ± 0.8	2.9 ± 0.8	0.992*	0.322
Left ventricular diameter (mm)	54.5 ± 7.7	54.3 ± 7.2	0.184*	0.854
Left ventricular ejection fraction (%)	52.6 ± 8.1	53.2 ± 7.7	0.565*	0.573
NYHA class			1.076†	0.783
I	2	3		
II	40	39		
III	69	59		
IV	38	28		
Motor dysfunction	7	5	0.113†	0.737
6-min walking distance (m)	210 ± 66 (*n* = 142)	211 ± 74 (*n* = 124)	0.079*	0.937
Median Euroscore	3.6 ± 1.9	3.7 ± 2.0	0.203*	0.839
NLR (before operation)	3.2 ± 1.3	3.2 ± 1.3	0.150*	0.881
Left atrium diameter (mm)	57.4 ± 6.6	58.1 ± 6.0	0.906*	0.366
Left atrium reduction	55	49	0.034†	0.854
Implantation prosthesis type			0.186†	0.666
Biological	32	25		
Mechanical	117	104		

The data are shown as *n* or mean ± standard deviation. Groups A and M indicated using the AtriCure and Medtronic biopolar radiofrequency ablation device, respectively. * *t* value. † χ^2 value. AF: Atrial fibrillation; EuroSCORE: European System for Cardiac Operative Risk Evaluation; NLR: Neutrophil-lymphocyte ratio; NYHA: New York Heart Association.

Table 2: Operative outcomes of patients with rheumatic valve disease undergoing the modified Cox maze radiofrequency ablation procedure.

Variables	Group A ($n = 149$)	Group M ($n = 129$)	Statistical value	*P* value
Mitral + aortic valve replacement	69	64	0.302†	0.582
Tricuspid valvuloplasty			1.063†	0.588
No	23	26		
De Vega	42	34		
Artificial rings	84	69		
Radiofrequency time (min)	28.9 ± 3.8	29.5 ± 2.8	1.621*	0.106
Aortic cross clamping (min)	97 ± 21	99 ± 20	0.706*	0.481
Cardiopulmonary bypass (min)	139 ± 22	141 ± 22	0.850*	0.396
Procedural time (min)	219 ± 32	225 ± 34	1.498*	0.135
NLR (12 h after procedure)	4.68 ± 1.49	4.88 ± 1.60	1.104*	0.271
TnI (12 h after procedure, ng/mL)	6.75 ± 2.90	7.05 ± 3.51	0.768*	0.443
Post-operative ventilation time (h)	27 ± 14	27 ± 12	0.131*	0.896
Drainage volume from chest tubes (mL)	786 ± 158	771 ± 181	0.738*	0.461
Duration of intensive care unit stay (h)	41 ± 17	40 ± 15	0.488*	0.626
Post-operative length of stay (days)	11 ± 3	10 ± 2	0.905*	0.366
Permanent pacemaker implantation	2	2	0.021†	0.884
At discharge survival	148	128	0.010†	0.918
30-day survival	147	128	0.208†	0.648
1-year survival	147	127	0.021†	0.884

The data are shown as *n* or mean ± standard deviation. Groups A and M indicated using the AtriCure and Medtronic biopolar radiofrequency ablation device, respectively. * *t* value. † χ^2 value. NLR: Neutrophil-lymphocyte ratio; TnI: Cardiac troponin I.

Table 3: Sinus rhythm conversion rate and excision performance.

Variables	Group A ($n = 149$)	Group M ($n = 129$)	Statistical value	*P* value
Follow-up (months)	19 ± 7 ($n = 148$)	19 ± 7 ($n = 128$)	0.110*	0.912
Sinus rhythm conversion at discharge	112 (75.2)	95 (73.6)	0.084‡	0.772
Sinus rhythm conversion at 6 months	108 (72.5)	92 (71.3)	0.046‡	0.830
Sinus rhythm conversion at 12 months	105 (70.5)	90 (69.8)	0.046‡	0.831
Stroke	5	3	0.263†	0.608
Left atrium diameter (mm, 1 year)	38.5 ± 4.8 ($n = 146$)	39.1 ± 4.9 ($n = 125$)	0.990*	0.323
6-min walking distance (m, 1 year)	374 ± 100 ($n = 137$)	370 ± 104 ($n = 121$)	0.350*	0.726

The data are shown as *n*, *n* (%) or mean ± standard deviation. Groups A and M indicated using the AtriCure and Medtronic biopolar radiofrequency ablation device, respectively. * *t* value. † χ^2 value. ‡ *F* value.

patients in each group did not recover before discharge from the hospital and thereafter received permanent pacemaker implantation.

SR restoration outcomes

One sudden death occurred, and five and three strokes occurred in groups A and M during the follow-up period, respectively. The SR restoration rate was similarly good, with 75.2%, 72.5%, and 70.5% (112, 108, and 105) *vs.* 73.6%, 71.3%, and 69.8% (95, 92, and 90) at discharge, 6 and 12 months after the RF ablation procedure in groups A and M, respectively [Table 3].

Discussion

In this comparative cohort study, we documented the median-term results for SR restoration in patients with AF concomitant with rheumatic valve disease through application of two different types of RF ablation forceps. The "non-irrigation" and "irrigation" conditions of the ablation devices used here were represented by the Atricure and Medtronic products, respectively. We observed that use of "non-irrigation" ablation forceps was similar to that of "irrigation" ablation devices in terms of the cardiac injury index and RF efficacy.

The potential benefits, as well as the safety and efficacy of a surgical maze procedure for AF during valve operations, are well documented. The rationale for restoring SR in patients undergoing cardiac surgery with concomitant AF includes (1) improved survival, (2) reduction in the risk of thromboembolism, (3) elimination of the need for oral anti-coagulation, (4) reduction of symptoms associated with a high heart rate, and (5) restoration of atrial contraction and thus improvement of cardiac output.[12] In our center, the average age of the recruited patients is relatively young, and approximately 60% of patients undergoing mitral valve replacement surgery experiencing AF receive a concomitant Cox Maze ablation, which is

greater than the average of 39% of patients reported worldwide.[13]

Various ablation devices using different energy sources have been developed to perform the ablation, including radiofrequency (unipolar and bipolar), cryoablation, microwave, laser, and high-frequency ultrasound.[14] RF bipolar ablation devices have become popular due to their ease and speed of use and high rate of transmural completeness.[15] The critical condition for successful ablation seems to be transmural scar formation, which causes a complete conduction block. In healthy subjects, the mean thickness in the posterior LA between the pulmonary veins ranges from 2.3 ± 1.0 mm between the superior veins to 2.9 ± 1.3 mm between the inferior veins.[16] LA dilatation and thickening are especially pronounced during the course of mitral valve disease, and the LA wall thickness may reach 5 to 6 mm.

Experimental data demonstrated that heating tissue with radiofrequency energy for approximately 1 min at 70 to 80°C produced lesions that were 3 to 6 mm deep, which usually was sufficient to create a transmural line for the conduction block. Our results showed that an average of 29 min was required for RF ablation in both groups. The RF time was positively associated with the LA size in both groups; thus, a more enlarged LA wall needed more RF time.

In terms of the transmural completeness of RF ablation, there is no definitive evidence that the ablated lesion completely blocks electrical conduction. The surgeon can be sure that the conduction will be blocked as the whole atrial wall is cut off only during the maze operation. We are only capable of indirectly judging the results according to appropriate parameters when setting up an ablating device. Currently, "non-irrigation" ablation forceps and "irrigation" ablation device are the two main radiofrequency ablation equipment types. Among the modalities of radiofrequency ablation, each device has particular shape characteristics and safety profiles. In our retrospective study, neither device was preferable to the other based on the surgeons' choice. Moreover, the senior surgeons were skilled at using both devices. Conversely, neither of the devices was more appropriate for certain clinical conditions. Theoretically, the "non-irrigation" ablation device was characteristic of a straight forceps and direct heating without saline irrigation, whereas the "irrigation" ablation device was characteristic of curved forceps and heating with saline irrigation. Although the "non-irrigation" and "irrigation" ablation devices have different shapes, both devices share a parallel clamp with similar contact force and can be performed bidirectionally to produce similar connection lines.[17] Our observations showed that the ablation time and SR restoration efficacy were comparable between the two types of ablation forceps.

The NLR has emerged as a better indicator of inflammatory reactions and has been widely studied in several cardiovascular diseases. An elevated pre-ablation inflammatory environment indicated by the NLR was associated with increased development of AF recurrence after catheter ablation.[18] We documented similar changes in terms of inflammatory reactions and the cardiac injury index. In another comparative study, cryoablation showed less systemic inflammatory reactions but higher myocardial injury than radiofrequency ablation.[19] The inflammatory reaction has been shown to be important for the pathogenesis of AF and its outcomes after treatment. Compared with patients with conversion to SR after surgical ablation, those with AF recurrence expressed more intense oxidative stress and upregulation of collagen, transforming growth factor beta 1, and intra-nuclear nuclear factor of activated T-cells.[20] Thus, we could predict that similar inflammatory reactions after RF ablation might result in comparable effects on the SR restoration rate.

In accordance with the consensus, the ablation pattern must include the lesion toward the mitral valve annulus, which was always included in our patients. Regarding ablation of the isthmus, Castella *et al* demonstrated that bipolar clamps were not sufficient to achieve complete ablation of the atrioventricular junction in an anatomical study.[21] They concluded that an additional monopolar ablation device or the cut-and-sew technique was required to complete the isthmus ablation. In our center, we only use bipolar RF without monopolar RF for the sake of economic costs. The simplified method could also attain promising results because it ensured confluent ablation line formation between the left pulmonary veins and the mitral and TV annuli.[13] Our follow-up observation showed that the ablation lines were similarly safe and effective at converting AF to SR by each of the methods only if performed correctly.

The need for an early post-operative permanent pacemaker (PPM) after biatrial surgical procedures have been reported to range from 6% to 23%.[22] We documented rates of 4.7% and 3.9% for the patients in groups A and M, respectively, who presented with a low heart rate, some of whom recovered from a severe atria-ventricular block during the prolonged hospitalization observation, which was supported by medication and an external temporal pacemaker. The other two patients in each group received post-operative PPM implantation.

The most common explanation for the late failure is associated with the large size of the LA. The basic theory claims that if the LA is larger than 6 cm, then the ablation lines of the maze procedure do not interrupt the re-entry circuits because they are too far apart.[23] Early arrhythmia recurrence is regarded as a significant predictor of arrhythmia recurrence.[24] We also observed that the consistent SR restoration rate was very high at the three-time points. This finding suggested that early restoration could predict a successful conversion rate in the long term.

Despite the valuable information obtained from this study, the study was a non-randomized investigation conducted by retrospective review, which introduced inherent selection biases. The findings should prompt the initiation of prospective registries and trials to standardize these procedures and hence enable comparisons of procedural data and outcomes. However, all data were collected prospectively, and this study included a series of consecutive patients. In addition, all of the patients underwent 24 h of continuous cardiac monitoring at follow-up, and some patients only had AF recurrence around the other follow-

up time point, leading to a possible underestimation of the incidence of recurrent AF. Longer 72-h cardiac monitoring may be needed in the future for follow-up. Nevertheless, during the follow-up from discharge and at 6 and 12 months, more than 90% of the patients in both groups maintained a continuous consistent SR. Due to a lack of electrophysiological mapping systems for individual patients, we could not determine whether the failures were due to an inability to properly complete the lesion sets or because the underlying mechanism of AF in these patients could not be eliminated with the Cox maze radiofrequency procedure. Our impression was that the failures occurred on the condition of advanced atrial remodeling and subsequent substrate modifications, such as atrial fibrosis. Although much of the focus on surgical AF ablation has been on the energy sources, lesion sets, and modalities, patient-related factors can also greatly influence the outcomes, and all of these factors need to be considered together and not in isolation.

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Conflicts of interest

None.

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