A Randomized Clinical Trial of the Efficacy of Radiofrequency Catheter Ablation and Amiodarone in the Treatment of Symptomatic Atrial Fibrillation

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Abstract

The limited efficacy and proarrhythmic risks of antiarrhythmia agents have resulted in alternative therapeutic approaches. Radiofrequency ablation has been reported to be an effective treatment of patients with atrial fibrillation. However, there is no randomized clinical trial comparing drug and radiofrequency ablation. The authors randomized 30 patients with chronic atrial fibrillation refractory to medication into amiodarone and radiofrequency ablation. The primary objective of this study was to compare the efficacy of amiodarone and radiofrequency ablation in the maintenance of sinus rhythm at 1 year after randomization. Pulmonary vein isolation and linear ablation of right atrium was the technique used for radiofrequency ablation. There were no significant differences in baseline patient characteristics between the 2 groups. The results of this study showed that the probability of free from atrial fibrillation was better in the radiofrequency ablation group compared to amiodarone (78.6% in the ablation group and 40% in the amiodarone group, p = 0.018). Radiofrequency ablation results in a significant reduction in symptoms relating to atrial fibrillation and a significant improvement in quality of life, whereas amiodarone had no significant effect on symptoms and quality of life. There was an ischemic stroke as a major complication related to radiofrequency ablation. Amiodarone was associated with adverse effects in 46.7 per cent of patients and needed discontinuation in 1 patient. In conclusion, radiofrequency ablation is an effective alternative treatment in patients with atrial fibrillation refractory to medication.

Key word : Atrial Fibrillation, Amiodarone, Radiofrequency Ablation

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. An estimated 2.2 million people in the United States suffer from AF with an overall prevalence of 0.89 per cent. The prevalence of AF begins to rise after the age of 40 and increases sharply after the age of 65[1]. AF is present in 6 per cent of people over the age of 65 and its prevalence was 7.3-13.7 per cent in people over the age of 80 [2,3]. AF can produce severe symptoms and complications including stroke[4] and congestive heart failure[5]. Symptoms and hemodynamic abnormalities associated with AF are related to the rapid and irregular ventricular rate and the loss of atrioventricular synchrony. Loss of atrial contraction is also responsible for the increased risk of thromboembolism[4,6,7]. The incidence of stroke in patients from previous studies with AF is approximately 4.5 per cent per year and the incidence is markedly increased in patients with diabetes, heart failure, hypertension or those with a history of thromboembolism[6]. Moreover, a poorly controlled ventricular response to AF may eventually lead to dilated cardiomyopathy[5].

The optimal management strategy of AF is still unclear. Numerous studies have suggested that AF can be treated with either rhythm control or rate control strategies to prevent complications such as stroke and cardiomyopathy and to reduce symptoms. Although it is logical that maintenance of the sinus rhythm would be the most beneficial treatment strategy for AF, this has not been proven. The recurrence rates of AF after cardioversion may be as high as 40-50 per cent, despite the use of effective antiarrhythmic drugs[8]. Pharmacological control of rapid ventricular response to AF may also be difficult requiring a combination of atrioventricular (AV) blocking drugs which can cause an adverse affect on cardiac function and produce intolerable side effects[8]. Alternative nonpharmacological treatments[9] have been developed including AV node ablation with pacemaker implantation, AV node modification for ventricular rate control and the surgical Maze operation [10]. Radiofrequency catheter ablation (RFCA) technique mimicking the surgical Maze operation has been developed to cure AF[11-15]. Preliminary reports in humans indicate an initial success rate of 60-70 per cent.

The Biosense system which is a novel mapping system can localize the position of the catheter tip with the use of fluoroscopy. This will enable the electrophysiologist to create the complete line of ablation[15].

The authors proposed to perform a randomized clinical trial comparing the RFCA using the Biosense system and amiodarone in patients with symptomatic AF refractory to antiarrhythmic medication. The primary objective was to compare the rate of normal sinus rhythm 1 year after RFCA or amiodarone. Secondary objectives were 1) to compare the quality of life 1 year after RFCA or amiodarone, and 2) to study the complications of RFCA and adverse effects of amiodarone in patients with AF.

METHOD

Study population

This study was approved by the ethical committee. Inclusion criteria were 1) male or female aged 15-75 years, 2) symptomatic paroxysmal or persistent AF for more than 6 months, and 3) refractory to at least 1 antiarrhythmic medication including class IA or class IC agents, digitalis, beta-blocker, or calcium channel blocker 4) never been given amiodarone. Exclusion criteria were 1) transient AF or treatable cause of AF, 2) bleeding disorders, 3) thyroid disorders, 4) previous stroke, 5) severe underlying illness that limited life expectancy to less than 1 year, 6) psychiatric disorder, 7) valvular heart diseases, 8) unwilling to participate in this research.

Study protocol

Patients with symptomatic AF refractory to medication who were referred to Siriraj Hospital and fitted the screening criteria were randomized into 2 groups: RFCA and amiodarone.

Radiofrequency catheter ablation

All patients were given warfarin keeping the INR 2-3 for at least 3 weeks prior to the procedure. Transesophageal echocardiogram was performed within 24 hours before RFCA in order to exclude the possibility of intracardiac thrombus. RFCA was performed in the fasting state and general anesthesia was administered. Venous access was obtained by the Seldinger technique *via* the femoral vein. Transseptal puncture was performed with the Brockenbrough needle and Mullin sheath was used to pass the quadripolar ablation catheter (or NAVI-STAR, Biosense Webster Inc., Diamond Bar, CA, USA) into the left atrium. Heparin was titrated to keep the PTT of 60-90 seconds. The CARTO electroanatomic mapping system (Biosense Ltd., Tirat-HaCarmel, Israel) was used to create the anatomical map of the left atrium. Openings of the pulmonary veins and mitral valve

rings were identified. Ablation lines were drawn as a series of contiguous dots. Lines included a circular line isolating the ostia of the pulmonary veins and a line connecting this circular line with the mitral annulus (Fig. 1).

Right atrium anatomical map was then created. Openings of superior vena cava, inferior vena cava, tricuspid valve ring and coronary sinus opening were then identified. Linear ablation was performed between the tricuspid valve ring and IVC or ischmus region, from SVC to IVC, and horizontal linear ablation line at the level of mid right atrium (Fig. 1). A maximal temperature setting of 55°C was used. Completion of the line was confirmed with the Biosense system. The result was considered satisfactory when there was no evidence of impulse propagation across the ablation line but reached the region beyond the line of block by a different route. If the line of block was incomplete, further RF pulses were given to complete the line of block. The endpoint of the procedure was the completion of the application of the scheduled lines whether or not sinus rhythm was observed. If the patients remained in AF after the linear ablation lines were completed, electrical cardioversion was performed. Amiodarone was given for approximately 3 months at the dose of 200 mg per day to allow time for the healing process of the atria and the electrophysiologic changes of prolonged AF returned to normal.

Amiodarone administration

Amiodarone was given at the dose of 1,200 mg per day for 1 week, 600 mg per day for another 2 weeks and the maintenance dose was 200 mg per day. For those with persistent AF, external cardioversion was performed.

Doppler echocardiogram, thyroid function test, liver function test, chest roentgenography, and eye exam were performed at baseline, 6 and 12 months during amiodarone. If serious side effects occurred amiodarone was discontinued and class IA or IC agents were given.

Outcome measurement

All patients were followed-up at 1, 3, 6, 12 months after randomization. Frequency of symptom, rhythm assessment by 12-lead ECG and 24-hour ambulatory ECG monitoring, quality of life assessment and complications or adverse effects were recorded.

Quality of life was assessed by using general health and physical functioning scores the standard self-administered SF-36 questionnaire which has already been validated[16]. The score of each aspect range from 0 (worst) to 100 (best).

Statistical analysis

Continuous data was described as mean ± SD and comparisons were made by the use of the

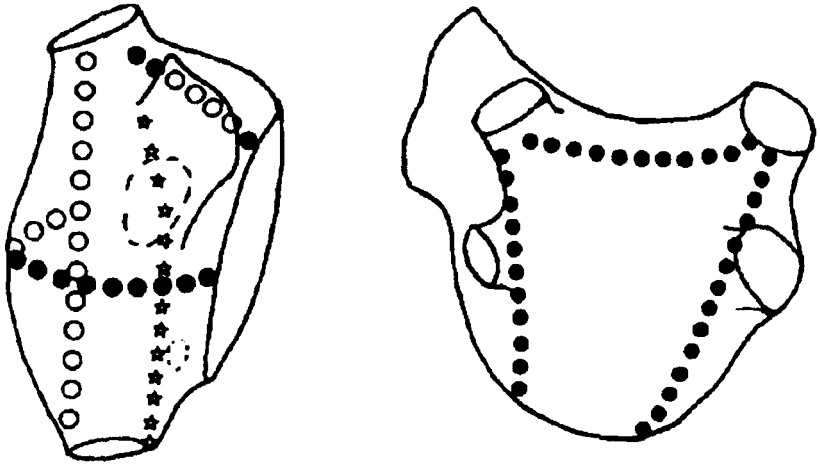

Fig. 1. Diagram of ablation line created in right atrium and left atrium. (IVC = inferior vena cava, LA = left atrium, PV = pulmonary vein, RA = right atrium, SVC = superior vena cava).

Student *t*-test for paired and unpaired data wherever appropriate. Categorical data were described as frequencies and percentages and comparisons were performed by the chi-square test. Repeated-measure ANOVA was used to test the changes over multiple time points with the use of LSD post hoc analysis. Grouping effect was also tested to compare the differences between the patients with RFCA and amiodarone. Probability of free from AF in each group was estimated by the Kaplan-Meier method and compared by the log-rank test. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Thirty patients with chronic paroxysmal or persistent AF were randomized to amiodarone and RFCA. Baseline characteristics, presenting symptoms, underlying diseases, types of AF, echocardiographic findings are described in Table 1. There were no significant differences in these parameters between the amiodarone and RFCA groups. Failed drugs included beta-blocker in 19 (63.3%), calcium channel blocker in 8 (26.7%), digitalis in 9 (30%), antiarrhythmic agent class IA in 1 (3.3%), class IC in 17 (56.7%). There were no significant differences in the proportion of drug failure in both groups. The average number of failed drugs were 1.9 ± 0.7 in the amiodarone group and 1.7 ± 0.6 in the RFCA group. Two patients had a history of failed electrical cardioversion.

Results of RFCA

Among 15 patients randomized to RFCA, RFCA could not be performed in 1 patient due to failure of transseptal puncture. RFCA procedure was completed in the remaining 14 patients. Among 7 patients who were in AF rhythm at the start of the procedure, 2 required electrical cardioversion to convert AF to sinus rhythm at the end of the procedure. AF turned to sinus rhythm during ablation in 5 patients. The sites of ablation that changed AF to sinus rhythm were left upper pulmonary vein in 2 patients, left lower pulmonary vein in 1 patient, right upper pulmonary vein in 1 patient and orifice of superior vena cava in 1 patient. Table 2 shows the procedure time, mapping time, ablation time fluoroscopic time and number of radiofrequency applications during the RFCA procedure in the left atrium and right atrium. Left atrial procedure required longer mapping time, longer

Table 1. Baseline characteristics of patients randomized to amiodarone and RFCA.

	Amiodarone (n=15)	%	RFCA (n = 15)	%	P-value
Age (years)	48.6 ± 15.4		55.3 ± 10.5		0.173
Male	8	53.3	11	73.3	0.256
Symptom duration (months)	48.2 ± 63.7		62.9 ± 58.3		0.514
Symptom frequency (per month)	34.0 ± 20.2		40.7 ± 22.6		0.397
Presenting symptom					
Palpitation	13	86.7	15	100	0.464
Dizziness	1	6.7	2	13.3	1.000
Presyncope	2	13.3	4	26.7	0.648
Syncope	2	13.3	1	6.7	1.000
Chest pain	3	20	3	20	1.000
Dyspnea on exertion	6	40	1	6.7	0.080
Underlying disease					
Diabetes mellitus	3	20	1	6.7	0.591
Hypertension	7	46.7	4	26.7	0.256
Ischemic heart disease	1	6.7	1	6.7	1.000
Dilated cardiomyopathy	1	6.7	0	0	1.000
Prolapse mitral valve	0	0	1	6.7	1.000
Pulmonary hypertension	1	6.7	0	0	1.000
No	4	26.7	9	60	0.065
AF type					
Paroxysmal	10	60	11	73.3	0.704
Persistent	6	40	4	26.7	
Echocardiogram					
Left atrial diameter (mm)	39.2 ± 7.1		39.6 ± 7.7		0.989
Left ventricular ejection fraction	61.8 ± 8.8		63.7 ± 9.5		0.581

Table 2. Descriptions of RFCA procedure at left atrium and right atrium.

	Total	Left Atrium	Right Atrium	P-value
Mapping time (min)	77.0 ± 28.7	54.4 ± 22.2	19.1 ± 9.8	0.006
Ablation time (min)	211.6 ± 27.5	124.1 ± 29.1	85.0 ± 17.9	0.043
Fluoroscopic time (min)	118.1 ± 30.3	80.0 ± 41.8	33.9 ± 19.1	0.080
Number of attempts	102.3 ± 17.1	47.4 ± 14.9	53.4 ± 7.6	0.409
Procedure time (min)	357.4 ± 47.6			

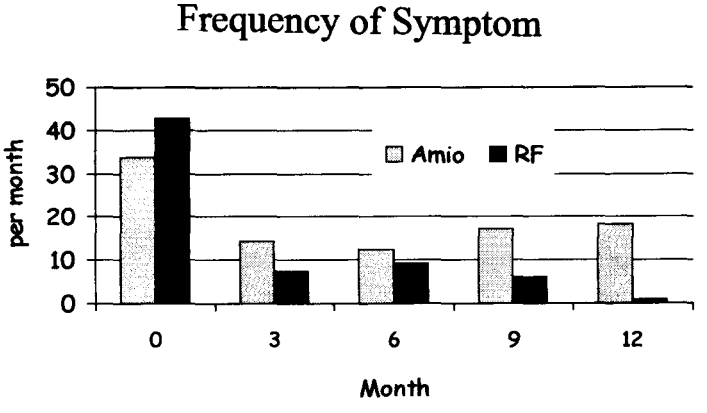

Fig. 2. Frequency of symptoms of patients in the amiodarone and RFCA groups during the 1-year follow-up.

ablation time and tended toward longer fluoroscopic time. RFCA caused 1 stroke from cerebral infarction which occurred immediately after finishing the procedure. There was also 1 minor complication of groin hematoma.

Effects of treatment on symptoms and quality of life

The effect of amiodarone and RFCA on the frequency of symptoms at 3, 6, 9, and 12 months after the procedure is shown in Fig. 2. There was a non-significant reduction in the frequency of symptoms in the amiodarone group ($p = 0.388$), whereas in the RFCA group the frequency of symptoms was significantly decreased ($p < 0.001$) from an average of 42.8 ± 22.6 attacks per month at baseline to 0.9 ± 2.8 attacks per month at 1 year after procedure. The frequency of symptoms in the RFCA group was significantly decreased at every visit after the procedure. However, between group analysis showed no significant differences ($p = 0.335$).

Fig. 3 shows the effect of amiodarone and RFCA on the general health score and physical functioning score. There were no significant changes in the general health score at 6 and 12 months in the amiodarone group compared to baseline ($p = 0.860$). In contrast, the score was significantly higher in the RFCA group ($p = 0.007$) during the follow-up visits at 6 and 12 months. The between group analysis showed significant differences ($p = 0.048$). Amiodarone also had no effect on the physical functioning score ($p = 0.351$), whereas RFCA significantly improved the physical functioning score ($p < 0.001$). However, between group analysis showed no significant differences ($p = 0.691$).

Effects of treatment on cardiac rhythm

Fig. 4 shows the Kaplan-Meier curve of probability of AF free in the amiodarone and RFCA groups. Nine patients (60%) in the amiodarone group and 3 patients (21.4%) in the RFCA group had recurrence of AF at 1 year after randomization. Log-rank

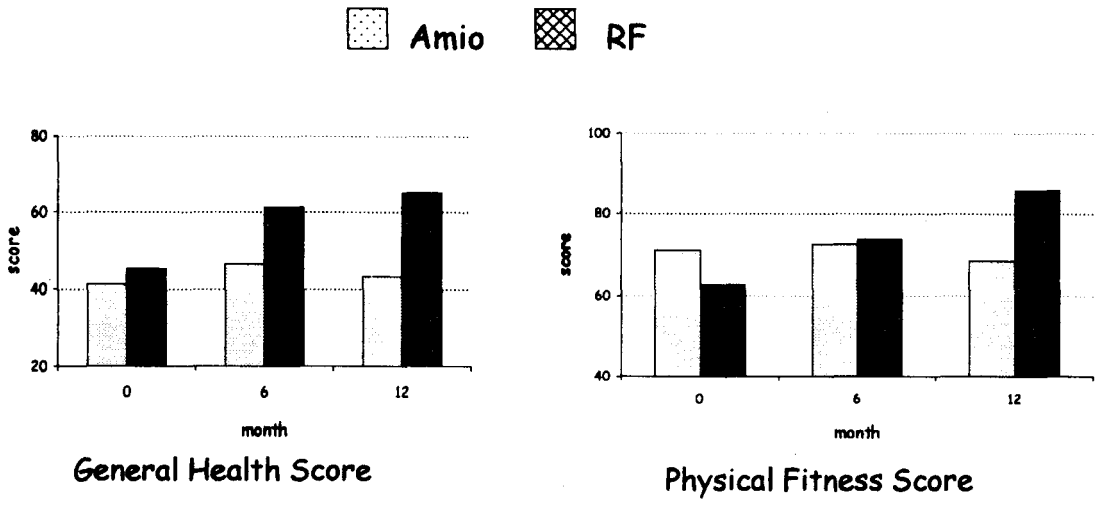

Fig. 3. Quality of life score at baseline, 6 and 12 months in the amiodarone and RFCA groups.

test showed significant differences between the 2 groups for the probability of AF free at 1 year ($p = 0.018$).

Adverse effects of amiodarone

The average maintenance dose of amiodarone at the end of the study was 183.3 ± 9.0 mg per day. A total of 7 patients (46.7%) in the amiodarone group experienced at least 1 adverse effect from amiodarone: 6 had GI side effects mainly nausea, 2 of each had corneal microdeposit, hypothyroidism and abnormal liver function test, one of each had hyperthyroidism and sinus node dysfunction. Three patients (21.4%) in the RFCA group had amiodarone side effects during the 3-month period of amiodarone after RFCA: 2 had GI side effects and 1 had sinus node dysfunction. One patient with sinus node dysfunction had dizziness and another had presyncope. Sinus node dysfunction recovered in 1 patient after amiodarone dose reduction and required drug discontinuation in another. Patients with hypothyroidism required short-term hormone replacement. One patient with hyperthyroidism required a short-term antithyroid drug. All patients with abnormal liver function test are asymptomatic and returned to baseline after amiodarone dose reduction.

DISCUSSION

In the present study the authors have shown that the rate of AF free at 1 year after randomization was significantly higher in the RFCA group compared to amiodarone (78.6% *vs* 40%). Besides, RFCA significantly improved symptoms and quality of life. However, RFCA can cause serious complications related to the procedure, i.e. stroke. A total of 46.7 per cent of patients in the amiodarone group experienced at least 1 adverse effect from amiodarone.

RFCA was first reported to be an effective treatment of AF in humans by Schwartz et al[11] and Haissaquerre et al[12]. Linear ablation of the right atrium can eliminate AF in approximately 40 per cent. Linear ablation of the left atrium is more efficacious with a success rate of approximately 60 per cent[12]. However, it is more difficult to create a complete ablation line and has an increased risk of complications such as thromboembolic events. Biatrial ablation was more effective than right atrial or left atrial ablation[12,14]. The problems of linear ablation were the prolonged procedure time and incomplete ablation line which caused the recurrence of AF after ablation. Most patients with paroxysmal AF had at least one focal trigger mainly in the pulmonary veins [17]. The procedure time for pulmonary vein ablation for focal triggers was shorter than linear ablation. The success rate of RFCA of focal triggers of AF has been reported to be up to 70 per cent[18]. However, Garstenfeld et al[19] reported that the recurrence rate was as high as 68 per cent with the rate of pulmonary vein stenosis of 8 per cent. The high recurrence rate is probably due to the high proportion of multiple

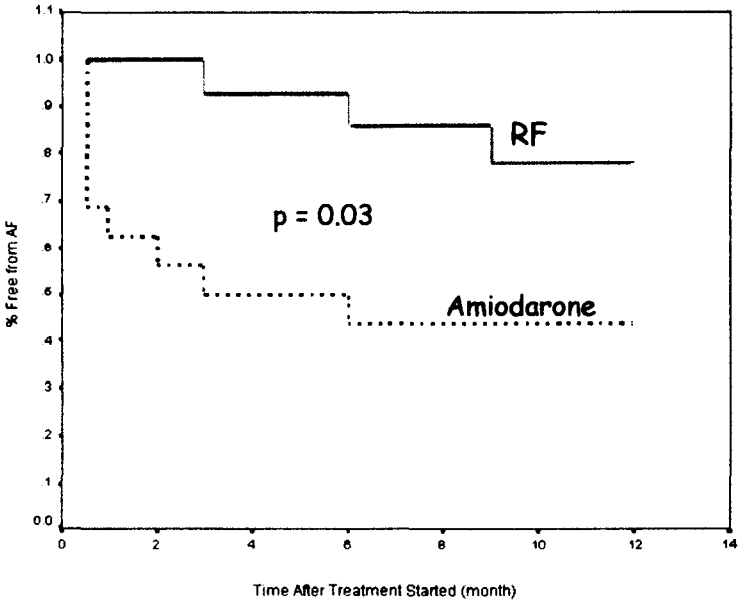

Fig. 4. Kaplan-Meier analysis of probability of AF free at 1 year in the amiodarone and RFCA groups.

focal triggers which have been reported to be up to 69 per cent of cases[20]. Another reason for the high recurrence rate may be related to the non-pulmonary vein initiating focal triggers such as posterior left atrium, surrounding pulmonary vein ostia, within coronary sinus, or within superior vena cava which have been reported to be up to 30 per cent of patients[21]. Besides, the rate of the pulmonary vein stenosis after RFCA of pulmonary vein may be as high as 40 per cent when assessed by the transesophageal Doppler flow study of the pulmonary vein velocity[22].

In the present study, the outcome of RFCA in maintenance of the sinus rhythm was 79 per cent which is comparable to previous reports. Swartz et al [11] reported a success rate of linear ablation for the treatment of AF to be 23 of 29 patients at an average of 2 years follow-up. Mean procedure time was 12 hours which is much longer than in the present study. Two of 29 patients had a stroke which is the same rate as the present study. It is recommended that anticoagulation during the procedure should be strictly monitored to avoid this complication. Pulmonary vein ablation had very few embolic complications probable due to its shorter procedure time.

To date there is no previous randomized control trial between drug and RFCA for the treatment of AF. The efficacy of antiarrhythmic drugs in the rhythm control of AF is approximately 50 per cent during the 1-2 year follow-up[23,24]. Although antiarrhythmic drugs are the preferred method of treating patients with AF, there could be potential dangers from their proarrhythmic properties. Overall, the incidence of torsade de pointes appears to be lowest with amiodarone which has been reported to be less than 1 per cent[25]. However, amiodarone is associated with many adverse effects including cardiovascular, pulmonary, thyroid, gastrointestinal, dermatologic, neurologic, ophthalmologic toxicity. Overall incidence of adverse effects ranged between 17-44 per cent during the 1-2 year follow-up and needed withdrawal in 1-16 per cent[26]. Besides, amiodarone also had interaction with digoxin, warfarin, quinidine, procainamide, flecainide and interaction with pacemaker and internal defibrillator. Adverse effects of amiodarone occurred in 46.7 per cent of patients in the present study and needed discontinuation in 1 patient due to sinus node dysfunction.

In conclusion, from the result of the present study, RFCA could be an alternative treatment for AF refractory to medication. Elimination of AF frees the patients from both antiarrhythmic medications and oral anticoagulation.

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การศึกษาเปรียบเทียบผลการรักษา Atrial Fibrillation โดยวิธี Radiofrequency Ablation และยา Amiodarone

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เนื่องจากยาที่ใช้รักษา atrial fibrillation (AF) มีประสิทธิภาพไม่ดีนักและโอกาสเกิดผลข้างเคียงสูง คณะผู้วิจัยจึงทำการศึกษาวิธีการรักษา AF ด้วย radiofrequency catheter ablation (RFCA) เทียบกับยา amiodarone ศึกษาอัตราการเป็น sinus rhythm ที่ 1 ปี RFCA ทำโดยใช้วิธี pulmonary vein isolation และ linear ablation ของ right atrium ได้ศึกษาผู้ป่วย 30 ราย ผลการศึกษาพบว่า RFCA ทำให้ผู้ป่วยอยู่ใน sinus rhythm ที่ 1 ปีได้ดีกว่า amiodarone (78.6% เทียบกับ 40%, p = 0.018) RFCA ทำให้อาการดีขึ้นชัดเจนและทำให้คุณภาพชีวิตดีขึ้น ภาวะแทรกซ้อนของ RFCA เกิด ischemic stroke 1 ราย ผู้ป่วยที่ได้ amiodarone เกิดผลข้างเคียง 46.7% และต้องหยุดยา 1 ราย ดังนั้น RFCA จึงเป็นทางเลือกหนึ่งในการรักษาผู้ป่วย AF ที่ไม่ตอบสนองต่อยา

คำสำคัญ : หัวใจห้องบนเต้นเร็วไม่สม่ำเสมอ, การจี้หัวใจด้วยคลื่นไฟฟ้าความถี่สูง

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