

Effect of Sacubitril/Valsartan on the Early Recurrence of Atrial Fibrillation after Radiofrequency Ablation

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The research aimed to assess how sacubitril/valsartan altered the early recurrence of paroxysmal atrial fibrillation after radiofrequency catheter ablation. A total of 100 patients with paroxysmal atrial fibrillation and cardiac insufficiency admitted to the cardiology department, Jingzhou Central Hospital, between September 2019 and October 2021, were randomized to experimental (n=54) and control (n=46) groups. Following treatment with radiofrequency catheter ablation, postoperatively, the control group was given perindopril tert-butylamine and the experimental group were provided with sacubitril/valsartan. Clinical characteristics such as age, gender, body mass index, blood lipids, hypertension, diabetes, coronary heart disease history, stroke, smoking and drinking status, were preoperatively gathered. Each patient's N-terminal pro B-type natriuretic peptide test, dynamic electrocardiogram and transthoracic echocardiogram were examined before the surgical procedure, 1 mo after surgery, and 3 mo after surgery. Echocardiogram was used to assess the left ventricular end-diastolic diameter, the left ventricular ejection fraction, as well as the left atrium anteroposterior diameter. Dynamic electrocardiogram mainly assessed the presence or absence of recurrence of atrial fibrillation. The two groups were compared for preoperative and postoperative states of N-terminal pro B-type natriuretic peptide, left ventricular end-diastolic diameter, left ventricular ejection percent, left atrial anteroposterior diameter, adverse events, and drug withdrawal. Both groups received treatment for 3 mo. The experimental group seemed to have a 9.26 % early recurrence rate, while the control group had a 23.91 % early recurrence rate, with significant difference between the groups ($p<0.05$). The values of N-terminal pro B-type natriuretic peptide, left ventricular end-diastolic diameter, left atrium anteroposterior diameter, and left ventricular ejection fraction of the two groups showed a downward trend in both groups, with the difference between the test group was significant ($p<0.05$). There was no significant difference in adverse reactions and drug withdrawal between the two groups of patients after radiofrequency ablation ($p>0.05$). The combination of sacubitril/valsartan can reduce the early recurrence rate after radiofrequency catheter ablation of paroxysmal atrial fibrillation, improve the structure/function of the heart, thus leading to effective treatment and reduced recurrence rate.

Key words: Paroxysmal atrial fibrillation, heart failure, sacubitril/valsartan, radiofrequency, catheter, ablation, early recurrence

Atrial Fibrillation (AF) is the loss of regular and orderly electrical activity in the atrium, subsequent replacement with rapid and disorderly fibrillation waves, which usually lead to loss of effective systolic and diastolic function of the atrium; the left atrium and pulmonary veins are easily affected. As the left atrial appendage becomes structurally remodeled and the atrial pumping function is reduced or lost, it ultimately results in blood stasis and thrombosis in the left atrium, and the thrombosis may fall off and potentially trigger cerebral embolism. AF

can also lead to irregular ventricle contractions, mostly through decremental conduction within the atrioventricular node, resulting in reduced ventricular ejection function and even Heart Failure (HF). It is key to note that the main pathophysiological characteristics of patients with AF are arrhythmia, decreased heart function, and atrial mural thrombosis^[1-3]. In the early stage of AF, tachycardia causes calcium overload in atrial myocytes, thereby reducing L-type calcium ion current and shortening the effective refractory period of atrial myocytes.

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In view of the different shortening times of the effective refractory period of cardiomyocytes in the different regions of the atrium, the changes of increased dispersion of the effective refractory period, decreased frequency adaptation, or inverse changes in cardiomyocytes, is collectively termed as, atrial electrical remodeling^[4]. The continuous existence of AF leads to increased dispersion of the effective refractory period of cardiomyocytes. While the excitable and non-excitable myocardium coexists, a reentrant loop is formed in the atrium, and as the formed reentrant persists, it leads to AF. As the AF continues to exist for 6 or more months, the microstructure of myocardial cells becomes prone to irreversible damage, resulting in the appearance of myocardial fibrosis in the atrium and destroying the normal myocardial tissue structure. This change is called structure remodeling^[5]. Transcatheter Radiofrequency Ablation (RFA) has achieved remarkable results in the treatment of AF in recent years, and it is considered as the most promising technological breakthrough for the treatment of AF. Yet, recurrence of AF after RFA is still very common, and arguments on the drug treatment for patients with early recurrence after RFA are prevalent.

In this study, patients with paroxysmal AF and HF who underwent radiofrequency catheter ablation were treated with sacubitril/valsartan or perindopril tert-Butylamine after surgery. The N-Terminal Pro B-Type Natriuretic Peptide (NT-proBNP) and dynamic Electrocardiogram (ECG) were measured before the procedure, as well as 1 mo and 3 mo later. Left Ventricular End-Diastolic Diameter (LVEDD), Left Ventricular Ejection Fraction (LVEF), left atrium anteroposterior diameter, adverse reactions and drug withdrawal were used to analyze the influence of sacubitril/valsartan on the early recurrence of paroxysmal AF after radiofrequency catheter ablation.

MATERIALS AND METHODS

General information:

A total of 100 patients with paroxysmal AF and cardiac insufficiency admitted to the Department of Cardiology at Jingzhou Central Hospital from December 2019 to October 2021 were divided into the experimental (n=54) and control (n=46) groups, with the postoperative control group obtaining perindopril tert-Butylamine and the experimental group receiving sacubitril/valsartan.

Inclusion criteria: Patients aged 50 y-75 y, with underlying cardiac diseases or signs of HF, accompanied by palpitations, chest tightness, dizziness, dyspnea, and other symptoms of AF; diagnosis of paroxysmal AF based on the AF diagnostic criteria (2017 edition), including patients with paroxysmal AF who had at least two episodes of AF in the past 12 mo (self-termination within 7 d or drug cardioversion within 48 h or electrical cardioversion) or patients taking class I, class II or class III antiarrhythmic drugs; diagnosis of HF as per the diagnostic criteria from the "Guidelines for the Diagnosis and Treatment of HF in China", validated by clinical symptoms and signs, ECG, chest radiograph, and echocardiography. The New York Heart Association (NYHA) deems cardiac function as II-III. All of the selected patients were informed about the study, signed an informed consent form, and the study was approved by the Jingzhou Central Hospital ethics committee.

Exclusion criteria: Severe liver and kidney dysfunction, or other organ dysfunction and systemic diseases, such as, bilateral renal artery stenosis, solitary kidney with renal vascular disease; the significant risk factors of chronic obstructive pulmonary disease, hyperthyroidism-related persistent ventricular tachycardia, rheumatic heart disease, idiopathic cardiomyopathy, acute myocardial infarction, electrolyte disturbance and valvular heart disease (such as severe aortic stenosis and mitral stenosis) and malignant tumors, acute inflammatory reactions, and mental illness.

Methods:

Prior to surgery, all patient received routine blood analysis, liver function, renal function, coagulation function, ECG, transthoracic echocardiography, chest radiograph, and other examinations, as well as a transesophageal echocardiogram to rule out left atrial thrombosis. We were able to successfully perform transcatheter RFA on both groups of patients.

Surgical procedure: Patients were in supine posture, and as standard disinfecting drape was placed, and 2 % lidocaine local anesthetic was administered.

Seldinger method: Puncture the right femoral vein three times, send the CS electrode to the coronary sinus vein through the 6 F short sheath, pierce the interatrial septum twice. As the large-head ablation electrode and the lasso electrode were injected into the left atrium with Johnson & Johnson ST cold saline

via the long sheath, the CARTO® 3 system is a three-dimensional mapping system, which was employed to facilitate point-by-point modeling. Perform circular vestibular ablation of both pulmonary veins using a power mode of 35W 43° until the pulmonary vein potential dissipates and the autonomous pulmonary vein potential appears. As repeated intravenous pulses of isoproterenol and rapid frequency stimulation failed to garner sustained atrial arrhythmia during the 15 min evaluation period, the procedure was deemed successful. The sheath was withdrawn, the wound was wrapped under pressure, and the patient was taken back to the ward for normal care such as stomach protection and ECG monitoring. All of the patients had RFA performed by the same surgeon, and no complications such as pericardial tamponade or atrial esophageal fistula occurred during or after the surgery. After surgical intervention, both groups of patients received conventional treatment for underlying diseases such as hypertension, diabetes, and hyperlipidemia. The experimental group was given sacubitril/valsartan (starting dose 50 mg/time, twice/day, according to patient tolerance; doubled once every 4 w, until it reaches 200 mg/time, twice/d, and maintaining the stipulated dose until the end of the treatment course. The control group was given perindopril tert-butylamine (starting dose of 4 mg, doubled every 4 w until reaching 8 mg/d); patients of either groups were provided with the recommended treatment of diuretics, receptor blockers, inotropic medications, and so on, based on their condition. The treatments were taken for 3 mo.

Observation index: Andrade *et al.*^[6] defined the early recurrence of AF after RFA within 3 mo of the operation in their Substrate and Trigger Ablation for Reduction of AF (STAR-AF) study. We therefore primarily relied on whether there was AF within 3 mo of RFA and the duration was >30 s, to determine whether to term it an early recurrence^[7]. A 24 h Holter ECG was examined to check recurrence of AF (despite symptoms during the study period, the ECG shows AF or large reentrant atrial tachycardia) (lasts for >30 s). We checked NT-proBNP, Holter ECG, and echocardiogram before surgery, as well as 1 mo and 3 mo later. The echocardiogram primarily assessed the heart's structure, such as the LVEDD, LVEF, and the left atrium's anteroposterior diameter.

Statistical analysis:

The percentage composition of the count data was performed in Statistical Package for the Social

Sciences (SPSS) 26.0 statistical analysis software (IBM, Armonk, New York, United States of America (USA)). For continuous variables, mean and standard deviation were used, while for categorical variables, frequencies and percentages were used. For continuous variables, the unpaired Student's t-test was used, and for categorical variables, the Chi-square (χ^2) test or Fisher's test was used. Statistical significance was defined as a $p < 0.05$. Measurement data (not satisfying normal distribution) were represented as median (third quartile-first quartile). The comparison of differences between groups was done using the rank sum test; comparison of grade data between groups was performed using rank sum test. The test level is Alpha ($\alpha = 0.05$) (two-sided test), and a $p = 0.05$ indicates that the difference is statistically significant.

RESULTS AND DISCUSSION

There were no significant differences in age, gender, Body Mass Index (BMI), smoking, drinking, Coronary Heart Disease (CHD), cerebral infarction, low-density lipoprotein, urea nitrogen, creatinine value, Uric Acid (UA), AF stroke anticoagulation score (CHA2DS2-VASc), or statin use. Table 1 illustrates the baseline characteristics.

Prior to the radiofrequency catheter ablation, there was no statistically significant difference in NT-proBNP levels between the experimental and control groups. However, NT-proBNP decreased in both groups 1 mo and 3 mo since surgery, with a statistically significant difference between the two groups. Table 2 depicts the changes in NT-proBNP of the two patient groups.

Before surgery, there were no significant differences between both the experimental and control groups in definitions of LVEDD, LVEF, and left atrium anterior and posterior diameter indicators. The experimental group, on the other hand, had their LVEDD measured 1 mo and 3 mo after the operation. The left atrium's anteroposterior diameter was significantly smaller than that of the control group, while the left ventricle's ejection fraction was significantly higher, with a statistically significant difference between the two groups. The changes in the heart-related indicators of the two groups of patients are shown in Table 3-Table 6.

During treatment, patients in both groups experienced mild symptoms of hypotension, cough/dyspnea, fatigue, gastrointestinal symptoms, angioedema,

dizziness, or paresthesia, but they rebounded on their own. In the case of drug withdrawal, there was no significant difference between the two groups of adverse reactions. Table 7 depicts adverse reactions and discontinuation of the two groups.

The experimental group had a significantly lower rate of early recurrence of AF than in the control group, with a statistically significant difference between the groups. Table 8 depicts a comparison of the early recurrence rate of AF between the two groups.

TABLE 1: COMPARISON OF CLINICAL CHARACTERISTICS OF THE CONTROL AND EXPERIMENTAL GROUPS

Group	Control group (n=46)	Experimental group (n=54)	χ^2	P
Age (year)	63±9	61±10		0.183
Sex			0.429	0.512
Male (%)	26 (57)	34 (63)		
Female (%)	20 (43)	20 (37)		
BMI (kg/m ²)	23.40±2.98	59±3.11		0.76
Smoking (%)	9 (20)	14 (26)	0.567	0.451
Drinking (%)	10 (22)	15 (28)	0.483	0.487
Hypertension (%)	32 (70)	30 (56)	2.069	0.15
Diabetes (%)	4 (9)	4 (7)	0.056	0.813
Stroke (%)	5 (11)	9 (17)	0.693	0.405
CHD (%)	9 (20)	8 (15)	0.397	0.529
LDL-C (mmol/l)	2.19±0.71	2.14±0.69		0.74
Creatinine (mmol/l)	75.3±17.4	75.7±16.8		0.907
BUN (mmol/l)	6.0±1.6	6.0±1.5		0.838
UA (mmol/l)	350.2±105.7	350.4±95.6		0.992
CHA2DS2-VASc	1.50±0.81	1.61±0.96		0.537
Statins (%)	14 (30)	19 (35)	0.254	0.615
NYH (%)			0.351	0.554
II	34 (74)	37 (69)		
III	12 (26)	17 (31)		

Note: Data are expressed as number (%), median (range) or mean±standard error of the mean, LDL-C: Low Density Lipoprotein-Cholesterol and BUN: Blood Urea Nitrogen

TABLE 2: COMPARISON OF NT-proBNP BETWEEN TWO GROUPS OF PATIENTS

Group	A (pg/ml)	B (pg/ml)	C (pg/ml)
Control (46)	861.50 (1540.50-681.00)	614.5 (1037.50-478.75)	473.00 (656.75-398.75)
Experimental (54)	781.00 (1147.00-570.00)	431.00 (579.25-286.50)	211.00 (300.50-124.75)
χ^2	1.632	4.319	7.037
p	0.103	0.001	0.001

Note: Data are expressed as (A): Before operation; (B): 1 mo after operation and (C): 3 mo after operation

TABLE 3: COMPARISON OF LVEF BETWEEN THE TWO GROUPS

Group	A	B	C
Control (46)	62.00 (63.25-56.75)	61.00 (63.00-56.75)	63.00 (65.00-58.50)
Experimental (54)	60.50 (65.00-58.00)	62.00 (66.00-60.00)	65.00 (67.00-61.75)
χ^2	0.108	1.379	2.608
p	0.914	0.168	0.009

Note: (A): Before operation; (B): 1 mo after operation and (C): 3 mo after operation

TABLE 4: COMPARISON OF THE DIFFERENCE BETWEEN THE TWO GROUPS WITH LVEF 3 MO AFTER OPERATION AND BEFORE OPERATION

Group	C-A
Control (46)	1.50 (2.00-1.00)
Experimental (54)	3.50 (5.00-2.00)
χ^2	4.550
p	0.001

Note: (C-A): The LVEF difference between 3 mo after operation and before operation

TABLE 5: COMPARISON OF LVEDD BETWEEN THE TWO GROUPS OF PATIENTS

Group	A	B	C
Control (46)	48.00 (50.00-46.00)	47.00 (49.00-45.00)	45.00 (47.25-43.00)
Experimental (54)	47.50 (50.00-44.00)	45.50 (48.25-43.75)	43.50 (45.25-41.00)
χ^2	0.844	1.39	3.118
p	0.399	0.165	0.002

Note: (A): Before operation; (B): 1 mo after operation and (C): 3 mo after operation

TABLE 6: COMPARISON OF ANTERIOR AND POSTERIOR LAD OF THE TWO GROUPS OF PATIENTS

Group	A	B	C
Control (46)	38.76±3.91	38.13±3.69	37.15±3.62
Experimental (54)	39.06±5.50	37.54±5.24	34.98±4.72
t	0.304	0.644	2.546
p	0.762	0.521	0.012

Note: (A): Before operation; (B): 1 mo after operation and (C): 3 mo after operation

TABLE 7: ADVERSE REACTIONS AND DISCONTINUATION OF THE TWO GROUPS OF PATIENTS AFTER DRUG TREATMENT

Group	Control (46)	Experimental (54)	p
Adverse reactions	Low blood pressure	2 (4)	3 (6)
	Cough or dyspnea	1 (2)	0 (0)
	Fatigue	1 (2)	1 (2)
	Gastrointestinal symptom	2 (4)	1 (2)
	Angioedema	2 (4)	1 (2)
	Dizziness or paresthesias	2 (4)	2 (2)
	Total	10 (22)	8 (15)
Discontinuation	0 (0)	0 (0)	

Note: Data are expressed as number (%)

TABLE 8: COMPARISON OF THE EARLY RECURRENCE RATE BETWEEN THE TWO GROUPS OF PATIENTS

Group	n	Early recurrence rate
Control	46	11 (23.91)
Experimental	54	5 (9.26)
χ^2		3.969
p		0.046

Note: Data are expressed as number (%)

There are approximately 33.5 million patients worldwide who might have AF, and the morbidity and mortality rate is high^[8]. As per most recent research, the prevalence of AF in Chinese citizens aged 35 y is 0.7 %, and the prevalence is as high as 2.4 % for 75 y old Chinese citizens, with nearly 34 % being newly discovered patients with AF^[9]. According to the China HF registry study, the fatality rate of HF patients in China is 4.1 %, and 24.4 % of HF patients receive AF^[10]. At present, the pathogenesis of AF includes the research topics of reentry theory, multiple wavelet theory, local trigger foci, anatomical structures such as superior vena cava and Marshall's ligament, genetics, ion channel abnormalities, inflammation, etc. However, AF is not triggered by a single mechanism. It occurs due to the combined action of multiple triggering mechanisms. Although transcatheter RFA has emerged as the most promising technology for treating AF, recurrence is common, and drug control to reduce recurrence after AF has emerged as a research hotspot.

AF and HF are major cardiovascular epidemics in these modern times, and they share common risk factors and pathogenesis; the morbidity and mortality are significantly higher in patients with HF^[2,11,12]. Although evidence-based treatment guidelines exist for both diseases, when AF and HF co-occur^[13,14], the treatment strategies in the guidelines are less clear. Given the risks of antiarrhythmic drugs and their incomplete success in maintaining sinus rhythm, catheter ablation has become the first-line treatment in symptomatic AF patients with normal cardiac function^[15]. Recently, catheter ablation has been shown to improve the prognosis of patients with AF and HF, thereby becoming the most radical and technologically advanced therapy of AF. However, the recurrence of AF after RFA is still very common, especially in patients with persistent AF, and the success rate of RFA is still worrying because of the electrical and structural remodeling of the left atrium. A comprehensive study of the process and mechanism of AF will discover more effective prevention strategies.

AF structural and electrical remodeling is a complex pathophysiological process, and a comprehensive study of its process and mechanism will aid in the development of a more effective new strategy for its prevention and treatment. Muller *et al.*^[16] discovered that the volume of the left atrium was significantly reduced after RFA in 91 % with AF. Several observational studies have shown that patients

with AF and HF had improved LVEF following successful RFA, with an average LVEF improvement of approximately 13 %^[17]. If it can successfully prevent atrial enlargement or intervene in myocardial fibrosis, it may effectively prevent the occurrence of AF. Studies have shown that inflammation, myocardial fibrosis, left atrial volume, hypertension, CHD, sleep-disordered breathing, and obesity are closely related to the recurrence of AF. Current evidence points towards obesity as significantly associated with the recurrence of AF. BMI, as an evaluation index of obesity, has a significant impact on the recurrence of AF^[17]. Recent studies have shown that the relationship between the increase of Left Atrial Diameter (LAD) and atrial fibrosis correlated positively; hence it is currently believed that the increase of LAD and then atrial fibrosis is the mechanism of AF occurrence and recurrence^[17]. Sacubitril/valsartan is currently the world's first Angiotensin Receptor-Neprilysin inhibitor (ARNi), which is produced by Novartis. As a new type of salt complex co-crystal composed of angiotensin II receptor antagonist valsartan, ARNI is a novel anti-HF drug, which also inhibiting Neutral Endopeptidase (NEP) and enhancing natriuresis. On the other hand, peptide systems can simultaneously inhibit the effect of renin-angiotensin-aldosterone system^[18,19], which has a beneficial effect on improving myocardial remodeling. In contrast, sacubitril/valsartan, which is safer, also helps improve myocardial damage and left atrial remodeling in patients with HF and AF. We find that sacubitril/valsartan inhibits Angiotensin II (ANG-II)-mediated atrial fibrosis, delays AF remodeling, spreads the effective refractory period of the atrium, and aids in the prevention of AF^[20]. Thus sacubitril/valsartan acts on myocardial L-type calcium channels, leads to the ultra-fast activation of potassium channels of atrial muscles, blocks atrial block to produce irregular reentry, inhibits repeated attacks of AF, and improves the maintenance rate of sinus rhythm. Furthermore, when AF occurs, myocardial cells significantly increase the activity and expression of Matrix Metalloproteinases (MMPs)^[21]. Sacubitril/valsartan can also inhibit the expression of MMPs, and thereby inhibits remodeling of the heart structure after AF, thus protects cardiac function.

In conclusion, sacubitril/valsartan can significantly reduce the early recurrence of AF after RFA. Its mechanism for reducing AF recurrence may inhibit structural and electrical remodeling of the heart. However, further research is essential to determine whether it affects late recurrence after the RFA of AF.

Conflict of interests:

The authors declared no conflict of interests.

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