JAFIB

Original Research

Journal of Atrial Fibrillation

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Atrial Fibrillation in Heart Failure Patients with Preserved or Reduced Ejection Fraction - Prognostic Significance of Rhythm Control Strategy with Catheter Ablation

Nicolás Vecchio[1], Leonardo Ripa[2], Agustín Orosco[1], Leandro Tomas[1], Ignacio Mondragón[1], Adriana Acosta[1], Lujan Talavera[1], Santiago Rivera[1], Gastón Albina[1], Mirta Diez[1], Fernando Scazzuso[1]

[1] *Electrophysiology Fellowship. Instituto Cardiovascular de Buenos Aires.*

[2] *General Cardiology Fellowship. Hospital Central. Mendoza, Argentina.*

Abstract

Introduction: Atrial fibrillation (AF) and heart failure (HF) often coexist with an increase in morbidity and mortality. AF catheter ablation (CA) has proved to be a safe and efficient option for HF patients, but long-term evolution and prognosis remain uncertain. The aim is to assess the efficacy and safety of CA in HF patients with AF, and analyze HF long-term evolution.

Methods: We prospectively analyzed consecutive patients with AF and congestive HF or left ventricular ejection fraction (EF) less than 45%, who underwent CA of AF between 2011 and 2016. We excluded patients who did not complete one year of follow-up.

Results: Seventy-nine patients were included. Mean age was 62.1 years, 72.4% were men, 67.2% had hypertension and 8.6% were diabetics. Mean EF was 49%, left atrial area was 26.5 cm2 and mean CHA_2DS_2-VASc score was 2. 70.6% were on NYHA FC II-III.

The recurrence rate of AF was 60%, and after a second CA the rate decreased to 27.8%. Only persistent AF prior to the procedure was identified as independent predictor of recurrence. There was a significant NYHA FC improvement in the sinus rhythm (SR) group vs those with recurrence (63.6% vs 36.4%; p=0.047). None of the patients in SR were hospitalized, whereas six with recurrence were hospitalized due to HF (0% vs. 18.2%; p = 0.07). The rate of complications was 9.1%.

Conclusions: Catheter ablation of atrial fibrillation in heart failure presents an adequate success rate, improving symptoms and reducing rehospitalizations due to heart failure.

Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia in patients with and without heart failure (HF), affecting 1-2% of the population and up to 50% of the patients with heart failure[1,2]. AF is associated with increased mortality, with a 5-fold increased risk of stroke and a 3-fold increase in the risk of HF and hospitalizations[3,4].

The association between both conditions is well-known. There is a direct correlation between left ventricular ejection fraction (LVEF), New York Heart Association functional class (NYHA) and the prevalence as well as the duration of AF,[1,3] generating a loop that perpetuates both conditions, increasing morbidity and mortality[5].

Several studies comparing rhythm control versus rate control failed to demonstrate significant differences favoring either strategy in terms of NYHA or mortality[6-8]. This could be due to the fact that sinus rhythm (SR) was difficult to maintain in the rhythm control group.Atrial fibrillation catheter ablation (CA) has proved to be a safe and efficient option for patients with HF[9-11]. Although the efficacy of this procedure is lower in HF patients compared with those without structural heart disease, recent studies have indicated that the rate of SR at the long-term is higher than that achieved with medical therapy[12,13]. Several studies have analyzed CA in HF patients with reduced LVEF (with different cut-off points), but few have included those with preserved LVEF (HFpEF). We believe that improving the SR rate with CA will improve NYHA, quality of life, morbidity and mortality by reducing hospitalizations in HF patients.

The aim of the study is to evaluate the success rate, freedom from AF and complications associated with AF CA in HF patients with preserved or reduced LVEF. The predictors of AF recurrence, the rate of HF hospitalizations and the NYHA functional class after one year of follow-up according to the presence or absence of SR will also be analyzed.

Key Words

Atrial Fibrillation, Heart Failure, Preserved Ejection Fraction, Catheter Ablation, Hospitalization, Prognostic

Corresponding Author
Nicolás Vecchio.
Cuba 2628 12 C. Capital Federal. Argentina.1428.

Methods

Study design and population

We conducted a prospective, observational and single-center study. Consecutive patients with a history of AF and signs and symptoms of HF or LVEF less than 45%, who underwent CA between July 2011 and March 2016, were included. The patients were refractory to or did not tolerate therapy, presenting inadequate ventricular response, recurrent AF or adverse events associated with the treatment.

The exclusion criteria were previous CA of AF, cardiogenic shock, contraindication to anticoagulation, left atrial appendage thrombus, pregnancy or severe comorbidities. Patients who did not complete one year follow-up were also excluded.

HFpEF was defined as LVEF equal to or greater than 50% and at least one of the following: -Signs and symptoms of HF (dyspnea, fatigue or fluid retention) -Echocardiographic evidence of diastolic dysfunction (left atrial enlargement, engorged inferior vena cava, pulmonary hypertension or elevated E/e´ filling velocity). -and elevated brain natriuretic peptide (BNP).

Strategy of anticoagulation

All the patients presented a CHA_2DS_2-VASc score ≥ 1 and received oral anticoagulation with new oral anticoagulants or vitamin K antagonists (VKAs) for at least 3 weeks. In patients receiving VKAs, therapeutic international normalized ratio (INR) was monitored and the anticoagulant was replaced by subcutaneous enoxaparin (1 mg/kg bid) before the procedure. In those cases receiving new oral anticoagulants, only the last dose was stopped.

During the procedure and before transseptal puncture, an intravenous bolus of unfractionated heparin was administered (200 UI/kg) and activated clotting time (ACT) was monitored every 30 minutes until it reached 350 seconds or greater. Intravenous protamine was administered after the procedure to revert anticoagulation before removing the intravascular introducers and sheaths. Two hours after the procedure ended, unfractionated intravenous heparin was administered by infusion pump. The following morning, subcutaneous low-molecular-weight-heparin (LMWH) and a VKA were administered. LMWH was not administered in patients taking new oral anticoagulants.

Catheter ablation procedure

All the procedures were performed under general anesthesia. All the patients underwent a 64-detector row computed tomography scan or cardiac magnetic resonance imaging if the patient had contraindications. Transesophageal echocardiography was performed during the procedure only if the levels of anticoagulation were inconsistent to exclude left atrial thrombi or to guide difficult transseptal punctures. 12-lead electrocardiogram (ECG) and intracardiac bipolar electrograms were recorded using electronic calibrators (EP-WorkMate 4.2 System, St. Jude Medical, Inc.) at a screen speed of 50 to 200 mm/s and were filtered at band-pass settings of 50 to 500 Hz.

A non-fluoroscopic mapping navigation system was used in all the cases (Ensite® Velocity® cardiac mapping system, St.Jude Medical Inc.). After both femoral veins were punctured, a decapolar catheter was placed in the coronary sinus. Under radioscopic guidance in the 40˚ left anterior oblique projection, two transseptal punctures were performed with Brockenbrough needles; then, two long preshaped introducers SL1 and SL2 (St. Jude Medical Inc.) were positioned. A circular duodecapolar Optima Plus® catheter and an irrigated-tip ablation catheter Therapy-Cool® (St. Jude Medical Inc.) were advanced through the introducers. The anatomical reconstruction was performed using the circular Optima Plus® mapping catheter which is capable of simultaneous recording from multiple points. The ablation catheter was used to identify the ostia and the antrum of the pulmonary vein (PV).

The electric activity of each PV was obtained using the circular catheter. Isolation started in the left superior PV and continued in the left inferior PV. The same sequence was used for the right PVs. Radiofrequency energy was delivered at the anterior and posterior aspect of each pulmonary vein with a power output of 40W and of 35 W, respectively. The lesions were applied to the antrum but not the ostia of the veins. The electrograms recorded by the ablation catheter before and after applying the ablation lesion were analyzed in each patient. The target was a reduction of the potential amplitude by 75% and the elimination or dissociation between atrial and PV activity. Once the isolation was completed, the presence of persistent block in each PV was evaluated.If necessary, ablation was repeated to consolidate the line of bidirectional block.

We used all the methods available to discriminate local or remote electrical activity: After pulmonary veins isolation, all the patients with persistent AF underwent electrical cardioversion. In sinus rhythm , other AF ablation techniques were used at the discretion of the treating physician: ablation lines at the cavotricuspid isthmus in the case of atrial flutter history; superior venae cavae or coronary sinus were mapped using the circular duodecapolar catheter and ablated in case of electric activity; complex fractionated atrial electrograms (CFAEs) were mapped with the circular duodecapolar catheter; finally a voltage map was made and those areas with intermediate voltage values (between 0.1 and 0.5 mV) in the left atrium were homogenized.

Patients underwent neurological examination after recovery from anesthesia at the electrophysiology laboratory and before discharge. Upon discharge, the patient continued with the same antiarrhythmic and anticoagulant agent prior to the procedure.

Follow-up

Follow-up visits were scheduled with the electrophysiology service at 1, 3, 6, 9 and 12 months with ECG and 24-hour Holter. In all the cases, the patients underwent physical examination and were interrogated about symptoms suggestive of arrhythmia and HF. If necessary, medical treatment was adjusted and laboratory tests or cardiac imaging tests were ordered. All the visits to the emergency department and hospitalizations due to HF or arrhythmia were also recorded.

Blanking Period

Due to the inflammatory process after catheter ablation, episodes of AF, atrial flutter (AFL) or atrial tachycardia (AT) within the first three months are not considered arrhythmia recurrence.

Success

Success at follow up was defined as the absence of episodes of AF, AFL or AT lasting for more than 30 seconds and documented by Holter monitoring, ECG or centralized monitoring station after the 3-month blanking period. In case of AF recurrence, a second ablation procedure was suggested to the patient.

Clinical improvement

Clinical improvement was defined as improvement by at least one NYHA and a reduction of signs of venous congestion without need of drug adjustment.

Complications

The following events related to the procedure were included:

1.Vascular complications: groin hematoma with a 5-point fall in hematocrit, pseudoaneurysm or femoral arteriovenous fistula.

2.Cardiac tamponade.

3.Stroke or transient ischemic attack (TIA).

4.Worsening of heart failure during the procedure-related hospitalization.

5.Prolonged hospitalization not due to social issues.

Statistical analysis

Discrete variables are expressed as percentages and continuous variables as mean with its corresponding standard deviation. The chi square test was used to compare discrete variables and continuous variables were analyzed using the Student's t test or the Mann-Withney test depending on the distribution of the sample. A multivariate analysis was performed using the Cox proportional hazard regression model. The Kaplan-Meier method was used to compare the groups with and without success. A p value < 0.05 was considered statistically significant. All the statistical procedures were performed using the software package SPSS 21.0.

Ethical considerations

The study protocol was evaluated and approved by the Committee on Ethics of the Instituto Cardiovascular de Buenos Aires. The Argentine personal data protection law 25,326 ensures the confidentiality of all the information. The study was conducted following the recommendations of the Declaration of Helsinki. The principles of the Declaration of Helsinki are fulfilled as the study was approved by the Committee on Ethics, underwent risk benefit assessment and each individual involved in this study was qualified by training to perform the task.

Results

A total of 796 consecutive drug-refractory patients who underwent an AF CA were enrolled. Of these, 99 patients presented signs and symptoms of HF or LVEF less than 45%. We excluded 4 patients with cardiogenic shock, 7 with contraindication to anticoagulation, and 6 with left atrial appendage thrombus, leaving 82 patients in the final analysis.

Baseline characteristics of the population

The cohort was made up of 82 patients undergoing AF CA with signs and symptoms of HF or a LVEF < 45%. Three patients did not complete the 1-year follow-up period and were excluded from the recurrence analysis. Mean age was 62.1 ± 10.5 years and 72.4% were men; 67.2% had hypertension and 8.6% were diabetics. Left ventricular ejection fraction was 49 ± 13.1% and 48.3% had a LVEF < 45%. 25 patients had HFpEF (45%). Left atrial area was 26.5 ± 7 cm2, mean CHA_2DS_2-VASc score was 2, 44.8% presented paroxysmal AF, 38% persistent and 17.2% long-standing persistent AF (total persistent 55.2%). NYHA II-III was present in 70.6%. The antiarrhythmic treatment included amiodarone (63.8%), propafenone (15.5%) and sotalol (6.9%), and 13.8% were not receiving any antiarrhythmic drug due to intolerance[Table 1].

Procedure and complications

The acute procedural success rate was 90%. In one year of follow-up, 47 presented AF after the blanking period (success rate of 40% after one procedure).

The AF freedom rate in HFpEF was lower than in the general population and there was no significant difference compared with reduced LVEF (48% vs 32% respectively; p= 0.28). Median time to recurrence was 4 ± 3.2 months in patients with reduced ejection fraction and 6 ± 2.8 months in HFpEF (p= 0.67). Twenty eight patients underwent a second ablation procedure. The recurrence rate after the second procedure was 44.4% at one year. Therefore, the success rate of SR maintenance after two procedures increased to 72.2%. In addition to pulmonary veins isolation, ablation of extrapulmonary foci was performed in 25 patients (43%). There were no significant differences between patients with recurrence or AF freedom (48% vs. 40%; p= 0.12).

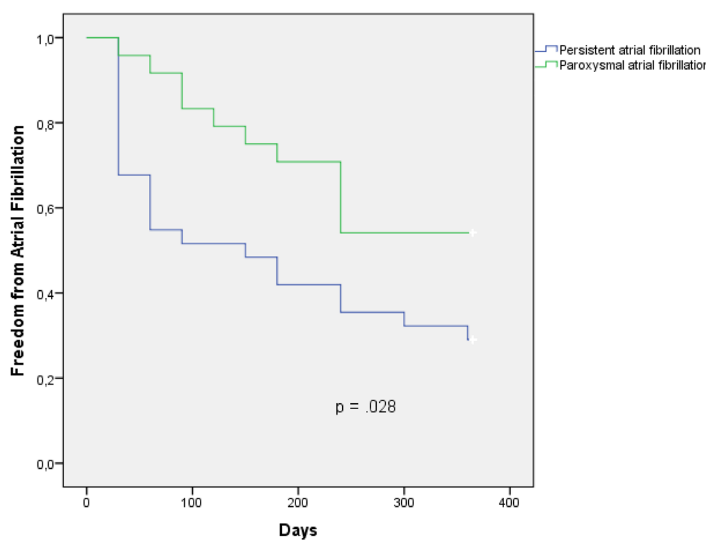


Figure 1: **Freedom from atrial fibrillation compared by the Kaplan-Meier curves with the log-rank test for overall survival. Persistent atrial fibrillation showed a higher recurrence rate compared to paroxysmal atrial fibrillation.**

Of the 110 ablations (82 in the first and 28 in a second procedure), 10 complications occurred (five in reduced and five in HFpEF; total 9.1%): 8 after the first procedure and 2 after the second ablation, and included: 4 HF worsening, 3 vascular complications, 2 cardiac tamponade requiring pericardiocentesis and 1 extreme bradycardia. None of the patients presented stroke, atrioesophageal fistula, symptomatic pulmonary vein stenosis or procedure-related mortality [Table 2].

The rate of complications was 9.1%. There were no significant differences between cardiac tamponade (1.81% vs. 1.9%; p= 0.36) or vascular complications (2.72% vs. 2.3%; p = 0.62%) compared with the trials published for the general population in our country[14].

Predictors of recurrence and follow-up

Patients with recurrence of AF were compared with those who remained free from AF to identify predictors of recurrence and to evaluate the clinical outcome during follow-up. Baseline characteristics such as NYHA functional class, persistent AF, left atrial area or LVEF were analyzed by multivariate analysis using Cox regression. Only persistent AF prior to the procedure was identified as an independent predictor of AF recurrence at 1-year follow-up. [Table 3] A Kapplan-Meier survival curve was performed with the Log-Rank test to compare the free survival from AF according to paroxysmal or persistent AF. [Figure 1] Finally, 79 patients who completed 12 months of follow-up after the first procedure were analyzed. Fourteen patients who remained free from AF presented significant improvement of their functional class, while only twelve patients with recurrent AF had improvement (63.6% vs. 36.4%; p = 0.047). Also, none of the patients in SR were hospitalized, whereas 6 patients with recurrent AF were hospitalized due to HF (0% vs. 18.2%; p = 0.07) [Figure 2]. Thus, 95.5% of the patients in SR and

Table 1: Baseline characteristics before ablation

	Total(82)	Recurrence(47)	Freedom from AF (32)	p
Age	62.1 +/- 10.2	61.0 +/- 11.5	63.8 +/- 9.1	0.41
Male sex	72.4%	72.7%	81.8%	0.43
Hypertension	67.2%	63.6%	77.3%	0.28
Diabetes	8.6%	6.1%	13.6%	0.33
Smoking habit	58.6%	63.6%	54.5%	0.50
Coronary artery disease	20.7%	24.2%	13.6%	0.33
Idiopathic cardiomyopathy	43.3%	41.2%	36.4%	0.79
Myocarditis.	13.3%	11.8%	18.2%	0.77
Tachycardiomyopathy	13.3%	17.6%	9.1%	0.52
Stroke	5.2%	6.1%	4.5%	0.80
CHA_2DS_2-VASc score	2	2	2	0.48
Preserved ejection fraction	43%	40%	54%	0.59
Previous HF hospitalization	41.4%	33.3%	54.5%	0.11
Type of atrial fibrillation				
Paroxysmal	44.8%	33.3%	59.1%	0.59
Persistent	55.2%	66.7%	40.9%	0.6
NYHA				
I	25.9%	24.2%	31.8%	0.53
II	67.2%	69.7%	68.2%	0.63
III	3.4%	6.1%	0.0%	0.23
Medication				
Amiodarone	63.8%	78.8%	40.9%	0.004
Beta blockers	55.2%	57.6%	54.5%	0.82
Propafenone	15.5%	9.1%	22.7%	0.15
Oral anticoagulant	91.4%	93.9%	90.9%	0.67
Echocardiography				
LVEF (%)	49 +/- 13	48 +/- 14	50 +/- 11	0.61
LA (cm2)	26.5 +/- 6	29 +/- 6	26 +/- 6	0.11
LVEF <= 45%	48.3%	48.5%	45.5%	0.82

AF: Atrial fibrillation. HF: Heart failure. NYHA: New York Heart Association. LVEF: Left ventricular ejection fraction. LA: Left atrium.

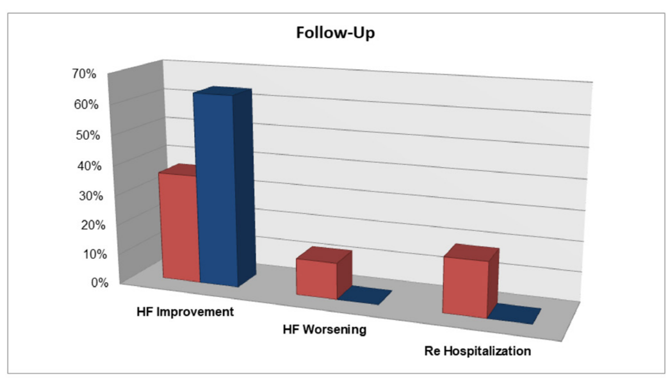
Table 2: Major complications.A higher rate of complications is observed due to the inclusion of worsening of heart failure. The same is not a reported complication in the general population.

Complications: 10 in 110 procedures (9.1%)	
Worsening of Heart Failure	4 (3.63%)
Cardiac tamponade	2 (1.81%)
Groin hematoma	3 (2.72%)
Extreme bradicardia	1 (0.91%)

Table 3: Multivariate Cox regression analysis of predictive factors in recurrence for overall survival. Persistent atrial fibrillation was the only independent predictor (p = 0.042).

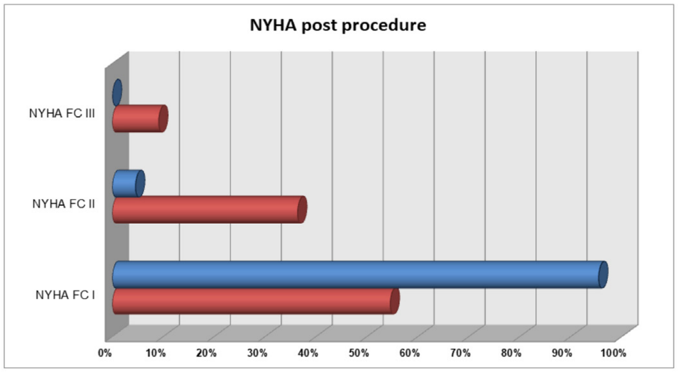
	log HR	(95% IC)	p
Age	0.98	(0.95 – 1.01)	.33
Persistent AF	2.41	(1.38 – 5.47)	.042
LVEF	0.99	(0.96 – 1.02)	.5
LA size	0.99	(0.94 – 1.06)	.97
NYHA	1.24	(0.66 – 2.55)	.54

AF: Atrial fibrillation. NYHA: New York Heart Association. LVEF: Left ventricular ejection fraction. LA: Left atrium.



	Recurrence (47)	Freedom from AF (32)	p
HF Improvement	36.4%	63.6%	0.047
HF Worsening	12.1%	0.0%	0.09
Re Hospitalization	18.2%	0%	0.07

Figure 2: Differences at one year follow-up between patients with recurrence or freedom from atrial fibrillation. Heart failure functional class improvement was statistically significant using Chi-Square Test



	Recurrence (47)	Freedom from AF (32)	p
NYHA post			0.004
NYHA FC I	54.5%	95.5%	0.001
NYHA FC II	36.4%	4.5%	0.008
NYHA FC III	9.1%	0.0%	0.14

Figure 3: **NYHA Functional Class at one year follow-up. Patients free from atrial fibrillation have better functional class than those with recurrence using Chi-Square Test.**

54.5% of those with recurrence of AF were free from HF or in functional class I (p = 0.001)[Figure 3].

Discussion

Main findings

The results reported in this study indicate that AF ablation in HF patients with reduced or preserved LVEF is a safe and acceptable therapeutic option. The acute success rate was high, 90% after the procedure, and although 47 patients had arrhythmia recurrence, a second procedure was successful in maintaining SR at one year in 72.2% of the cases, without increasing the incidence of complications. The improvement of symptoms and the hospitalization rate showed that SR maintenance had significant benefits in these patients. Of the variables analyzed, persistent AF before the procedure had a significant association with AF recurrence at one year. Probably, early intervention of AF in HF patients will improve SR rate during follow-up.

Our study also analyzed the population with preserved LVEF. The recurrence rate of AF at one year of follow-up was higher than in the general population, however, they also benefited clinically with catheter ablation[14].

The rate of complications was higher in our study due to HF worsening, a complication that was not included in publications evaluating the general population (9.1% vs. 4.6%; p = 0.03)[14]. We did not register major events such as death or stroke. Also, no patient required inotropic agents, vasopressors or mechanical ventilation.

Pathophysiology and previous studies

Atrial fibrillation and HF are two conditions that impair quality of life and reduce longevity. The prevalence of AF in patients with HF enrolled in clinical trials ranges between 15 and 45%[15-19]. Atrial fibrillation increases the risk of embolic stroke and tachycardiomyopathy, and is associated with reduced survival. The association between HF and AF worsens the prognosis, with a survival rate between 25 and 40% at 5 years according to the previous NYHA. Each condition increases the severity and worsens the outcome of the other.

There are several pathophysiological mechanisms that perpetuate both pathologies. Heart failure produces diastolic insufficiency, electromechanical remodeling of the left atrium, increased sympathetic tone and hydrosaline retention. This increases the rate of episodes of AF. Atrial fibrillation begins as an isolated ectopic activity mainly from the pulmonary veins. Subsequently, with the chronicity of both pathologies, the electrical and mechanical remodeling of the left atrium worsens, causing the perpetuity of the arrhythmia from multiple wave fronts. The electrical and anatomical changes associated with AF worsen heart failure, a situation that also worsens the evolution of atrial fibrillation, generating a vicious loop[20].

Several studies have compared the efficacy of rate control versus rhythm control in HF patients, but did not show better outcomes with one strategy over the other. However, these studies only used medical treatment for rhythm control with suboptimal efficacy to maintain patients in SR[6]. In addition, 21% of the patients in the rhythm control group crossed over to the rate control group due to impossibility to maintain SR, and 10% of those in the rate control group crossed over to the rhythm control group, mostly due to HF worsening[21]. The adverse events of the medications and the presence of contraindications in patients with structural heart disease were other factors that failed to maintain SR.

The superiority of CA over antiarrhythmic treatment in patients with symptomatic AF has been already demonstrated[22-25]. several studies analyzed the role of CA in HF patient using functional endpoints with different results.

The study by McDonald et al., included patients with persistent AF and advanced HF and failed to demonstrate significant improvement in LVEF and in other secondary endpoints as six-minute walk distance, quality of life and NTproBNP, compared with a rate control strategy. After 14 months, only 50% of the patients in the CA group remained in SR The inclusion of patients with persistent AF and advanced HF could explain the high rate of recurrence without achieving the final endpoints.

In patients with AF refractory to antiarrhythmic treatment, left ventricular dysfunction and HF in NYHA class II-III, pulmonary veins isolation showed significantly better quality of life, longer six-minute walk distance and higher LVEF compared with ablation of the AV node and biventricular pacing after 6 months[11].

The CAMTAF trial analyzed CA in patients with persistent AF, HF and LVEF < 50% and showed significant improvement of LVEF, oxygen consumption and quality of life at 6 months compared with rate control. Freedom from AF was achieved in 81% of patients at 6 months of follow-up without antiarrhythmic drugs[12]. Despite the short follow-up period, the high rate of freedom from AF is associated with clinical improvement.

More recently, a study compared CA versus rate control in patients with persistent AF, HF and LVEF < 35%. The primary endpoint

-improvement in oxygen consumption at 12 months was significantly higher in patients undergoing CA. The Minnesota score and BNP also showed significant improvement[26]. None of the studies mentioned above analyzed rehospitalization due to HF, a significant prognostic indicator.

Finally, the CASTLE-AF study,[27] a randomized trial recently presented in the 2017 ESC congress, enrolled 363 patients with symptomatic paroxysmal or persistent AF, intolerance to take at least one antiarrhythmic drug, LVEF less than 35% and NYHA FC ≥2 with implantable cardioverter-defibrillator or cardiac resynchronization therapy-defibrillator with home monitoring capabilities. This study showed that catheter ablation was superior at preventing death or heart failure admissions (28.5% vs. 44.6%; p = 0.007). However, unlike our work, HF patients with preserved LVEF were not included. It is known that atrial fibrillation is a frequent cause of diastolic failure and that diastolic failure predisposes to AF recurrence after medical treatment or radiofrequency ablation[28,29]. Therefore, HFpEF patients would also benefit from catheter ablation.

Clinical Implications

The clinical impact found in our work is due to keeping patients with HF in SR. The success achieved with catheter ablation improves the functional class and reduces re-admissions for heart failure in HF patients with reduced or preserved LVEF.

This is achieved without increasing the rate of complications, as has occurred in pharmacological treatment trials to maintain SR. As we have previously seen, most of the studies evaluating CA in HF patients showed benefits in terms of quality of life, six-minute walk distance and LVEF. Our initial experience shows that the success rate at one year in patients with HF and AF treated with CA was acceptable, and that the patients who remained in SR had better NYHA functional class and fewer re-hospitalizations. Symptoms relief and reduction of hospitalizations are endpoints with a positive impact on the evolution of the disease and on the healthcare system. Likewise, patients with preserved LVEF, a poorly studied population, benefited as much as those with reduced ejection fraction.

Study Limitations

This study has several potential limitations. Firstly, it is a single-center and observational study. The rate of success and of complications could be different in each center. In addition, the ablation technique varies according to each case and to the discretion of the attending physician. Secondly, although we recorded the complications in our database, those occurring after discharge could have been lost. Thirdly, the information about patients living in other cities or neighboring countries followed-up by telephone calls could be underestimated.

Conclusions

Catheter ablation of atrial fibrillation in heart failure patients presents an adequate success rate in patients refractory or intolerant to antiarrhythmic treatment, improving symptoms and reducing re-hospitalizations due to heart failure. The benefit was observed both in preserved and reduced ejection fraction. Persistent atrial fibrillation is an independent predictor of recurrence.

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