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Original article

Improved Outcomes and Complications of Atrial Fibrillation Catheter Ablation Over Time: Learning Curve, Techniques, and Methodology

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ABSTRACT

Introduction and objectives: The outcomes of atrial fibrillation ablation procedures vary widely between different centers. Our objective was to analyze the results and complications of this procedure in our center and identify factors predicting the efficacy and safety of atrial fibrillation ablation.
Methods: In total, 726 atrial fibrillation ablation procedures were performed in our center between 2002 and 2009. Beginning in January 2008, a protocol for anticoagulation and conscious sedation was systematically applied. Outcomes and complications could therefore be compared in 2 well-differentiated groups: group A included 419 procedures performed prior to 2008 and group B included 307 procedures completed after 2008 using the new protocol.
Results: During an average follow-up of 8.7 months, 60.9% of patients were arrhythmia-free after one or repeat procedures. After only 1 procedure, the success rate was 41% and significantly higher in group B (51.6% vs 35.2% in group A; *P*=.001). There were 31 major complications (4.2%), 26 in group A (6.2%) and 5 in group B (1.6%) (*P*=.002). The implementation of the new protocol was an independent predictor of the absence of complications (odds ratio=0.406; 95% confidence interval, 0.214-0.769; *P*<.006).
Conclusions: Systematic application of an anticoagulation and conscious sedation protocol is associated with improved results and fewer complications of atrial fibrillation ablation. Factors not evaluated in the present study, such as operator experience and ongoing improvements in atrial fibrillation ablation technology, could have influenced these findings.

Evolución de la mejora en los resultados y las complicaciones de la ablación por catéter de la fibrilación auricular: aprendizaje, técnicas y metodología

Palabras clave:
Ablación por catéter de la fibrilación auricular
Protocolo
Complicaciones
Curva de aprendizaje

RESUMEN

Introducción y objetivos: Los resultados y las complicaciones del procedimiento de ablación de fibrilación auricular varían ampliamente entre los diferentes centros. Nuestro objetivo es analizar los resultados y las complicaciones derivadas de este procedimiento en nuestro centro e identificar los factores predictores de éxito y de seguridad.
Métodos: Entre 2002 y 2009 se realizó un total de 726 procedimientos de ablación de fibrilación auricular. Basándonos en la aplicación sistemática de un protocolo de anticoagulación y sedación consciente desde enero 2008, podemos establecer dos estrategias de ablación que constituyen dos grupos bien diferenciados: grupo A, constituido por 419 procedimientos realizados antes de enero 2008, y grupo B, formado por 307 procedimientos realizados después.
Resultados: El 60,9% de los pacientes no presentaron recurrencia arrítmica tras varios procedimientos durante un seguimiento medio de 8,7 meses. Con un único procedimiento, la tasa total de éxito fue del 41%, significativamente mayor entre los pacientes del grupo B (el 51,6 frente al 35,2% de éxito en el grupo A; p = 0,001). Hubo un total de 31 complicaciones mayores (4,2%); 26 en el grupo A (6,2%) y 5 en el grupo B (1,6%) (p = 0,002). La protocolización del procedimiento fue un factor predictor de la ausencia de complicaciones (odds ratio = 0,406; intervalo de confianza del 95%, 0,214-0,769; p < 0,006).
Conclusiones: La aplicación sistemática de un protocolo de anticoagulación y sedación consciente se asocia a la mejora de los resultados y la reducción de las complicaciones en el procedimiento de ablación

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de fibrilación auricular. Otros factores no evaluados en este estudio, como la curva de aprendizaje de los operadores y la progresiva mejora tecnológica, pueden haber influido en los cambios observados.

Abbreviations

AF: atrial fibrillation
LA: left atrium
OSAS: obstructive sleep apnea syndrome
PV: pulmonary veins
RF: radiofrequency
UFH: unfractionated heparin sodium

INTRODUCTION

Over the past decade, catheter ablation of atrial fibrillation (AF) has become a routine procedure in clinical practice. Operator learning curves have been paralleled by a considerable improvement in technology and systematization of the technique.[1–3] There is, however, little published data on how modifications to the technique, the acquisition of experience by operators, or the evolution of technology affects outcomes.

Due to the rapid expansion of indications for ablation and the growing demand for AF ablation,[4–8] there is a need to identify and establish safe procedures, and to analyze the actual rate of complications occurring in different centers.

The aim of this study was to analyze outcomes and complications in patients who underwent percutaneous ablation of pulmonary veins (PV) in our center over the past 7 years. We also aimed to identify possible predictors of success in the treatment of AF and potential sources of complications.

METHODS

Between October 2002 and December 2009, a total of 726 percutaneous PV ablation procedures were performed in 542 patients using 3-dimensional non-fluoroscopic mapping (CARTO® or NAVX®).

All patients underwent transesophageal echocardiography in the 48 h prior to ablation to rule out the presence of thrombi. In 74.2% of the procedures performed, patients also underwent computed tomography (CT) or magnetic resonance imaging (MRI) of the left atrium (LA) and PVs. Images obtained were integrated with those from the electroanatomic mapping system to achieve better spatial resolution and anatomic definition during ablation.

Oral anticoagulation was discontinued 3 days before ablation, and administration of low molecular weight heparin was initiated the day before the procedure.

Beginning in January 2008, all procedures were performed using a protocol for anticoagulation and conscious sedation (Table 1). Patients following this anticoagulation and sedation protocol constituted group B, while patients in the group that underwent PV ablation before 2008 constituted group A.

All patients signed informed consent before the procedure and the study was approved by the center's ethics committee.

Ablation Procedure

Ablation was performed percutaneously via the femoral vein with monitoring of arterial oxygen saturation and invasive monitoring of blood pressure. After a double transseptal puncture, the LA was accessed and the ablation catheter positioned there. A circular catheter (Lasso®, Biosense-Webster Lasso, or Inquiry Optima®, St. Jude Medical) has been used since 2006 for recording and stimulation. Unfractionated heparin sodium (UFH) was then administered, based on established strategy. Three-dimensional mapping of the LA and adjacent structures was carried out using CARTO® (Biosense Webster) or NavX® (St. Jude Medical) and, whenever possible, MRI or CT scan was also used to optimize anatomical reconstruction. Radiofrequency (RF) was applied with an 8 mm ablation catheter or a 3.5 mm irrigated tip catheter to a target temperature of 55°C or 45°C and a maximum output of 60 or 40 W, respectively. Continuous RF lesions were used to encircle the ipsilateral PVs. Ablation lines were also created on the posterior wall, the LA roof, and the mitral isthmus. We ablated areas with high fragmentation of local electrograms in some subgroups of patients, based on AF type or atrium size. The fact that our center participated in randomized trials during the study period produced changes to the methodology for creating lines or ablating fragmented electrograms in certain patient groups.

The procedure aimed to reduce local PV electrogram voltage to <0.15 mV in patients in which a circular catheter was not used or to eliminate PV potentials when circular catheters were used. A further aim was to verify the bidirectional block between the LA and the PV. Blocking of the roof line was confirmed by the presence of double potentials and caudocraneal activation of the posterior wall. The isolation of the posterior wall was confirmed by the

Table 1
Anticoagulation and Conscious Sedation Protocol Applied Systematically in the Ablation of Atrial Fibrillation Since January 2008

Perioperative anticoagulation protocol
Starting dose, administered immediately after the transseptal puncture
a. <75 kg: 5000 UI UFH
b. >75 kg: 6000 UI UFH
Measure ACT every 10 min until ACT >200 s is reached
If ACT is:
a. 150-200 s, administer 3000 UI UFH and re-evaluate at 10 min
b. 201-250 s, administer 2000 UI UFH and re-evaluate at 30 min
c. 250 s, do not administer UFH and re-evaluate at 30 min
Postoperative anticoagulation protocol
In the 6 h immediately following the procedure, restart anticoagulation with LMWH at a dose of 1 mg/kg/12 h while also restarting warfarin until optimal anticoagulation dose is reached (INR >2). Maintain oral anticoagulation for at least 2 months. It can be discontinued in the absence of risk (>1 on the CHADS scale)
Conscious sedation
At start
Pethidine 25 mg + midazolam 1 mg in bolus±fentanyl 30 μg
Immediately prior to transseptal puncture
Fentanyl, <65 kg: 30 ml/h perfusion; ≥65 kg: 40 ml/h (300 μg/120 ml NSS = 2 bottles/120 ml NSS)
Immediately prior to application of radiofrequency
Fentanyl, 75 μg (5 ml) bolus±additional bolus of midazolam 1-2 mg as required

ACT, activated coagulation time; INR, international normalized ration; LMWH, low molecular weight heparin; NSS, normal saline solution; UFH, unfractionated heparin.

Table 2
Baseline Patient Characteristics and Differences Between Subgroups According to Whether Ablation Was Completed Before or After January 2008

Patient baseline characteristics	Total (n=542)	Group A (<01/08) (n=270)	Group B (>01/08) (n=272)	*P*
Age	53.1±10.7	52.4±11	54±10	.086
Male	77%	76.6%	77.6%	.792
Arrhythmia type				
Paroxystic	51.3%	52.4%	49.8%	.547
Chronic	31.2%	27.4%	36.7%	.023
Long-standing chronic	13.4%	14.7%	11.6%	.317
Left flutter	4%	5.5%	1.9%	.035
Minimum duration, months	62.3±60.9	65.2±59.8	56.7±62.7	.173
Hypertension	42.2%	42.7%	41.6%	.791
Absence of heart disease	78.8%	77.2%	78.6%	.710
Tachymyopathy	7.3%	6.9%	7.9%	
Valvular heart disease	4.9%	5.9%	3.3%	
LA, mm	42±5.6 (25-59 mm)	41.6±5.4	42.7±5.8	.025
EF	58.3±9.7 (15%-84%)	58.4±10	58.1±9.3	.768
LVDD, mm	52.7±5.4	52.4±5.3	53.1±5.5	.170
LVSD, mm	34.1±6.2	33.7±5.8	34.7±6.6	.151
OSAS[a]	19.4%	18.1	21.5	.411
BMI	27.8±3.7	27.7±3.4	28.6±4.8	.284
Overweight/obesity	79.5%	79.7%	78.4%	.605
High performance athlete[b]	15.7%	13.9%	18.1%	.244

BMI, body mass index; EF, ejection fraction; LA, left atrium; LVDD, left ventricular diastolic diameter; LVSD, Left ventricular systolic diameter; OSAS, obstructive sleep apnea syndrome.
[a] Patients with an apnea-hypopnea index >10 on the Berlin questionnaire or patients who, at baseline, were using positive-pressure noninvasive ventilation apparatus, or continuous positive airway pressure at night[5].
[b] High performance athlete, patients regularly practicing vigorous prolonged sporting activity, at least 3 h/weekly for >2 years[7].

disappearance of potential and a lack of atrial capture with local capture. There was no systematic check of mitral isthmus block in patients without a history of left flutter.

In group A, midazolam and fentanyl were administered during the procedure based on the operator's judgement, while in group B a systematic sedation approach was taken, using dolantina, midazolam, and fentanyl (Table 2).

The anticoagulation strategy in group A was limited to initial bolus administration of UFH with variable monitoring of activated clotting time (ACT) and administration of variable amounts of heparin based on operator judgement. Anticoagulations of <250 ms were accepted. In group B, an initial bolus of 5000 or 6000 IU of UFH was given depending on the patient's weight, followed by regular and established monitoring of the ACT and administration of the established dose of heparin until values of between 250 ms and 300 ms were reached.

Follow-up

After ablation, and following the guidelines of the Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhtymia Society expert group,[4,5] anticoagulation was maintained in all patients for at least 3 months, and continued or discontinued based on the $CHADS_2$ risk score. The decision to continue or discontinue antiarrhythmic treatment during follow-up was made by the cardiologist. Patient follow-up included visits every 3 to 6 months for at least 1 year. At each visit a surface ECG and 48-hour Holter-ECG was carried out. Between 6 and 9 months, a transthoracic echocardiogram and a CT scan or MRI of the PVs was performed to rule out late complications.

Arrhythmia recurrence was defined as any episode of atrial tachyarrhythmia lasting >30 s recorded beyond the first 3 months after ablation. The first 3 months after ablation were considered the wash-out or window period and any arrhythmic events occurring during that time were not counted as recurrences.[4]

Clinically relevant complications associated with the ablation procedure were recorded. Major complications were defined as those which were life-threatening, caused permanent damage, or required therapeutic intervention and a prolonged stay in hospital.[9]

Statistical Analysis

Continuous variables are expressed as means ± standard deviations and categorical variables as percentages. Differences in the baseline characteristics of patients who received ablation before and after implementation of the anticoagulation and sedation protocol were analyzed using the Student t test and χ^2 statistics. The same methods were used to test for differences between patients in which the procedure was successful and those in which it was not, and in patients with and without clinically relevant complications. To determine the success of the technique, we assessed arrhythmia-free survival using the Kaplan-Meier method and a Cox regression model for the multivariate analysis of all significant factors. Finally, to determine which factors independently predicted complications, all those which were significant in univariate analysis were included in a binary logistic regression model and their odds ratio (OR) estimated. Statistical significance was set at $P<.05$ in all analyses.

RESULTS

From October 2002 until December 2009, a total of 726 PV ablation procedures was performed in 542 patients using

nonfluoroscopic mapping. The baseline characteristics of the population are shown in Table 2. Overall, 77% of patients were male, mean age was 53 years, 21.2% had structural heart disease, and 42.2% had hypertension. Mean PV diameter in the LA was 42 mm and left ventricle ejection fraction was preserved in most patients. Paroxysmal AF was present in 51.3% of patients, 31.3% had persistent AF, 13.4% had long-standing persistent AF, and 4% had left atrial flutter. At least a second procedure was required in 153 patients (28.2%), giving a total of 184 reablations.

Ablation Outcomes

After 24 months of follow-up, the overall probability of success after only 1 ablation procedure was 41.1% (51.6% of patients in group B compared to 35.2% in group A, *P*=.001). That percentage rose to 60.9% after a repeat procedure. Among patients with a recurrence, 75.3% had predominantly AF and 24.7% had atypical atrial flutter. Table 3 shows the characteristics of patients with and without recurrence of arrhythmia after the first ablation. As shown by the survival curves after the first procedure, arrhythmia recurred more frequently in patients with paroxysmal AF (Fig. 1A), hypertension (Fig. 1B), dilated LA (Fig. 1C), and obstructive sleep apnea syndrome (OSAS) (Fig. 1D). Table 4 shows the predictors of recurrence: hypertension and OSAS were found to independently predict recurrence after a first ablation procedure. Patients with a dilated LA (>44 mm) and paroxysmal AF showed a tendency toward recurrence but the trend was not statistically significant in multivariate analysis. The presence of structural heart disease or a mitral line did not independently predict recurrence.

Ablation Complications

In total, 61 clinically relevant complications (8.4%) were recorded, 48 in group A (11.5%) and 13 in group B (4.2%). The difference between the groups was statistically significant (*P*=.002) (Table 5). Overall, 31 complications (4.2%) were classified as serious; this type of complication was also significantly more common in group A (26, 6.2%) than in group B (5, 1.6%; *P*=.002). Thirty complications (4.1%) were classified as minor and there were no statistically significant differences between groups for this type of complication (22 in group A, 5.2%, and 8 in group B, 2.6%; *P*=.129). The observed differences between subgroups were mainly due to a reduction in embolic complications (coronary and cerebrovascular) in Group B, as shown in Table 5. We recorded a total of 9 coronary air embolisms (1.2%), all of which were transient; in all cases, complete resolution of clinical angina and ST segment elevation in the ECG was achieved with intravenous nitroglycerin. Of these 9 recorded cases of coronary air embolism, 8 (1.9%) occurred prior to the implementation of the protocol (group A) and 1 (0.3%) afterwards (group B). We also recorded 9 cerebral transient ischemic attacks (TIAs). Other major complications were infrequent, with the exception of cardiac tamponade (7, 1%). There were 4 (0.6%) femoral pseudoaneurysms requiring surgical repair of the artery. Of particular note was a rupture of the mitral subvalvular apparatus due to entrapment of the circular catheter during electroanatomical mapping of the LA; in this case, urgent surgical repair of the mitral valve was required. Of further note was a cardiac perforation due to tearing of the venoatrial union of the left superior PV during mapping; this required urgent pericardiocentesis and surgical suture of the tear. With regard to minor complications, there were no differences in the need to interrupt the procedure due to transseptal puncture or aortic pericardial puncture (without cap) (3.8% in group A and 2.3% in group B; *P*=.29). We recorded 3 cases of pericarditis with nonsevere associated pericardial effusion (0.4%), 2 (0.3%) cases of esophagitis (transient dysphagia with retrosternal burning pain without evidence of atrial-esophageal fistula), and 2 patients (0.3%) had significant stenosis of the PV (defined as a reduction to less than 50% of the vascular diameter of at least one PV) without clinical consequences. The only factors showing a statistically significant association with higher prevalence of any type of complication were protocolization of the procedure, the use of a circular catheter (both protective), and being female (Table 6). Protocolization of the procedure (OR=0.406, 95% confidence interval [95%CI], 0.214 to 0.769; *P*<.006) and being male (OR=0.503, 95%CI, 0.275 to 0.919; *P*<.026) were independent predictors of the absence of complications. Although procedures in group B took slightly longer (162±48 min in group B compared to 131±45 min in group A,

Table 3
Differences in Baseline Characteristics Between Patients With and Without Recurrence After a First Procedure

Ablation outcomes (procedure) after a maximum of 24 months of follow-up	Recurrence of arrhythmia (58.9%)	No recurrence of arrhythmia (41.1%)	*P*
Group A/B	64.8% in group A vs 48.4% in group B	35.2% in group A vs 51.6% in group B	.001
Age, years	53.6±10.8	52.4±10.8	.267
Sex	59% males vs 58.4% females	41% males vs 41.6% females	.917
Hypertension	66.7% with hypertension vs 52.5% normotensives	33.3% with hypertension vs 47.5% normotensives	.003
Dilated LA (>44 mm)	69% with dilated LA vs 52.9% with undilated LA	31% dilated LA vs 47.1% undilated LA	.003
EF, %	58.1±9.6	58.7±9.3	.584
Structural heart disease	68.1% with vs 56.3% without heart diseae	31.9% with vs 43.7% without heart disease	.042
PAF	54.8% PAF vs 65% no PAF	45.2% PAF vs 35% no PAF	.031
Duration of arrhythmia, months	64.2±50.7	59.9±61.4	.463
OSAS	77.1% OSAS vs 55.3% no OSAS	22.9% OSAS vs 44.7% no OSAS	.001
BMI	28.1±3.4	27.3±4	.166
EPS time, min	144±51.7	147.6±49.3	.542
RF time, s	2689±1195	2686±1184	.984
RL	61.1% RL vs 47.8% no RL	38.9% RL vs 52.2% no RL	.066
ML	65.2 ML vs 47% no ML	34.8% ML vs 53% no ML	.003

BMI, body mass index; EF, ejection fraction; EPS, electrophysiological study; LA, left atrium; PAF, paroxystic atrial fibrillation; ML, mitral line; OSAS, obstructive sleep apnea syndrome; RF, radiofrequency; RL, roof line.
Group A, prior to January 2008; Group B, after January 2008.

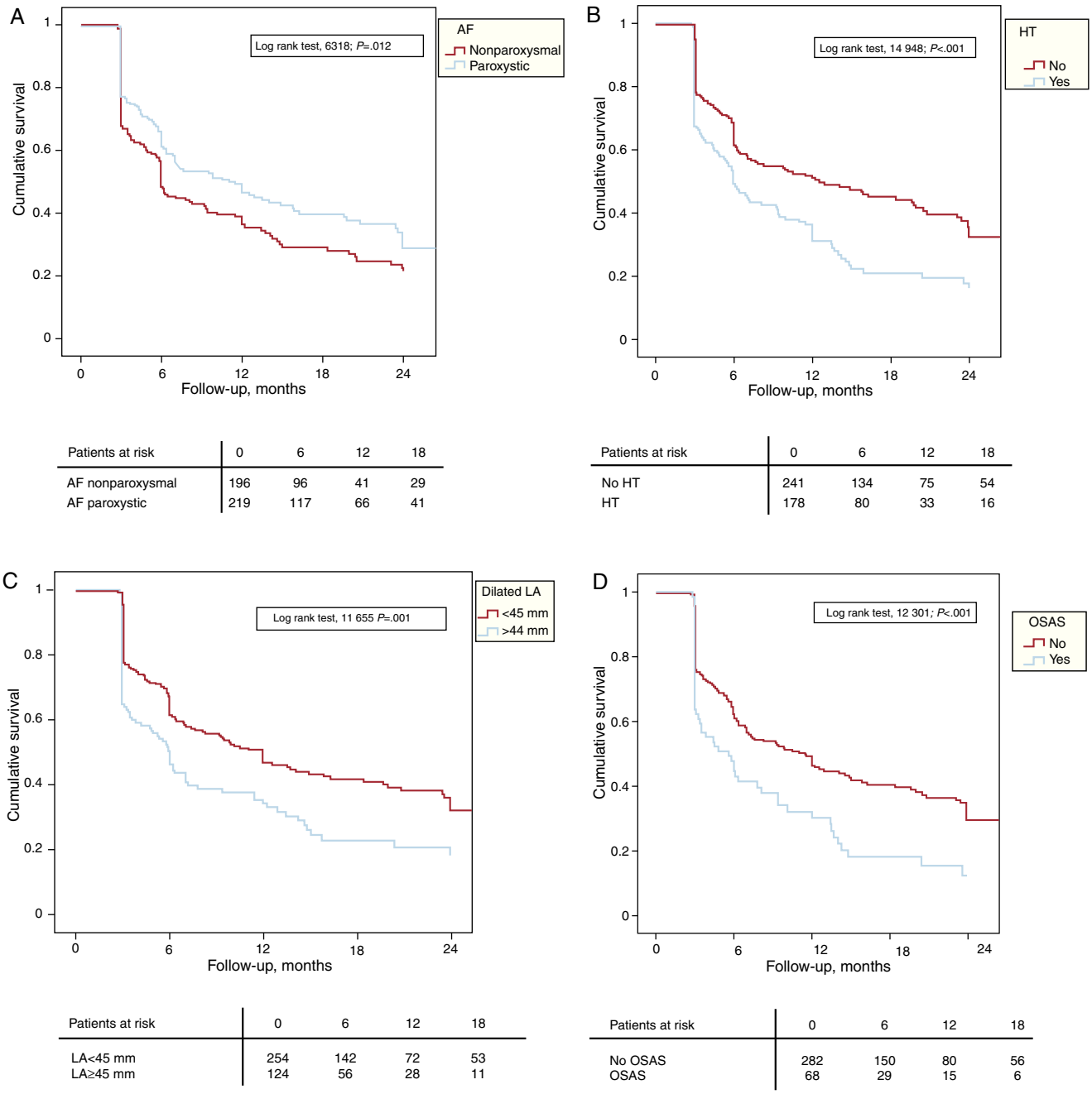

Figure 1. A: survival analysis (Kaplan-Meier) arrhythmia-free follow-up after an initial ablation procedure, according to the type of atrial fibrillation. B: survival analysis (Kaplan-Meier) arrhythmia-free follow-up after an initial ablation procedure in hypertensive and normotensive patients. C: survival analysis (Kaplan-Meier) arrhythmia-free follow-up after an initial ablation procedure in patients with left atrial diameter >44 or <45 mm. D: survival analysis (Kaplan-Meier) arrhythmia-free follow-up after an initial ablation procedure in patients with and without obstructive sleep apnea syndrome. AF, atrial fibrillation; HT, hypertension; LA, left atrium; OSAS, obstructive sleep apnea syndrome.

Table 4
Multivariate Analysis: Independent Predictors of Arrhythmia Recurrence

Variables	HR	95%CI	*P*
Hypertension	1.502	1.102-2.046	.010
OSAS	1.420	1.008-2.001	.045
Dilated LA	1.293	0.945-1.769	.108
Paroxystic AF	0.841	0.624-1.133	.256

95%CI, 95% confidence interval; AF, atrial fibrillation; HR, hazard ratio; LA, left atrium; OSAS, obstructive sleep apnea syndrome.

P<.001) and RF application times were longer (3221±984 ms in group B compared to 2307±1062 ms in group A, *P*<.001), these factors were not predictors of complications.

DISCUSSION

The increasing prevalence of AF and growing demand for AF ablation means that increasing numbers of centers are performing

Table 5
Differences in Complications Associated With Pulmonary Vein Ablation According to Whether the Procedure Was Performed According to a Protocol or Not (Group A: Procedures Performed Before January 2008, Without a Protocol; Group B: Procedures Performed After January 2008, Using a Protocol)

Complications	Total (n=726)	Group A (n=419)	Group B (n=307)	*P*
Major	31 (4.3)	26 (6.2)	5 (1.6)	.002
TIA	9 (1.2)	8 (1.9)	1 (0.3)	.087
Coronary embolism	9 (1.2)	8 (1.9)	1 (0.3)	.087
Cardiac tamponade	7 (1)	6 (1.4)	1 (0.3)	.248
Subvalvular mitral rupture	1 (0.1)	0	1 (0.3)	.423
PE	1 (0.1)	1 (0.2)	0	.392
Femoral pseudoaneurysm	4 (0.5)	3 (0.7)	1 (0.3)	.642
Minor	30 (4.1)	22 (5.2)	8 (2.6)	.129
Complicated transseptal puncture	23 (3.2)	16 (3.8)	7 (2.3)	.290
Pericarditis	3 (0.4)	3 (0.7)	0	.267
Esophagitis	2 (0.3)	1 (0.2)	1 (0.3)	.825
Asymptomatic stenosis of PV	2 (0.3)	2 (0.5)	0	.511
Total	61 (8.4)	48 (11.4)	13 (4.2)	.002

PE, pulmonary embolism; PV, pulmonary veins; TIA, transient ischemic accident.
Data are expressed in no. (%).

the treatment. AF ablation is a complex procedure and its complications, although infrequent, can be serious. The outcomes presented in several series vary widely and depend critically on the center's experience and the type of AF. The high published rates of success in treating paroxysmal AF (over 80% in the series first published by pioneering groups) have decreased to under 70% in more recent series.[10–12] The results also vary widely if we compare success rates for the same group over time, from 6 month success rates of <60% to 1 year recurrence-free rates of >90%.[10,13] Such differences can be attributed to the learning curve and accompanying technological advancement. The same occurs in persistent AF where success rates range from 50% to 75%, depending on the center, technique, and methodology for the detection of recurrences.[12,14] In our series, the overall success rate for ablation was 60.9%, which is somewhat lower than those published by some of these groups. This higher percentage of recurrences in our group may have been due to the use of a very strict definition of recurrence. We considered that any registered arrhythmic episode of over 30 s duration from the third month of follow-up onwards should be recorded as a recurrence, regardless of whether it was symptomatic or not or whether the patient was taking anti-arrhythmic drugs. We also performed 48-h (occasionally 7-day) Holter monitoring at 3, 6, and 12 months and insistently recommended that patients obtain ECG recordings if they suffered any symptoms suggestive of arrhythmia. In our center, all procedures included in the series were performed using non-fluoroscopic mapping of the LA together with 3-dimensional CT or MRI images obtained prior to the procedure. The latter were especially useful in dealing with complex anatomies. We also used an irrigated ablation catheter in over 80% of cases. The main objective was to electrically isolate the PVs by applying RF at the venoatrial junction. Previously published studies have shown that PV ablation is less effective in hypertensive patients with dilated LA, nonparoxysmal AF, and OSAS[15–22]; in our series, we found that hypertension and OSAS were the most powerful independent predictors of recurrence. We also observed that patients with linear mitral isthmus ablation had a higher number of recurrences. Incomplete realization, without verification of the blockade, could have led to a proarrhythmic outcome. For that reason, over the last 2 years the vast majority of procedures have been performed without the mitral line. On the other hand, we found that using a circular catheter to map the LA was associated with a lower rate of total complications. Nevertheless, as this approach was infrequently used in group A and systematically introduced in group B there could be a time effect; whether or not it actually reduces complications is therefore not so clear-cut.

Table 6
Differences in Patients and Procedure Characteristics of Cases With Complications. Univariate Analysis

	Complications, %		
Variable analyzed	Yes	No	*P*
Use of circular catheter	3.1	7.8	.019
Use of protocol for the procedure	4.2	10.5	.002
Male	6.8	11.8	.040
Hypertension	8.3	7.9	.850
OSAS	8.1	9	.771
History of stroke	12.9	8.4	.382
Heart disease	4.8	9.2	.067
Mitral line	5.9	6.3	.842
Roof line	5.3	9.2	.094
Paroxistic AF	7.6	8.3	.750
Dilated LA	7.1	9.9	.201

AF, atrial fibrillation; LA, left atrium; OSAS, obstructive sleep apnea syndrome.

Although operator learning curves and technological advances have led to lower complication rates, we still had a 4.2% rate of major complications in our series. That is similar to the rate observed in the last worldwide survey on the methods, efficacy, and safety of catheter ablation for human AF.[23]

The majority of complications occur during or immediately after the procedure. Cardiac tamponade is still the most common, potentially life-threatening complication and in most cases is related to the transseptal puncture procedure. In our series, this complication did not decrease significantly over time, although this was probably due to the incorporation of a new operator in the last 2 years of the series; learning curves are highly important with regard to this complication. In our study, of the 61 complications observed, 79% derived from the transseptal puncture (with or without tamponade) and cerebral or coronary embolic events. However, after the introduction of the protocol for periprocedural anticoagulation and conscious sedation, we observed a reduction

in thromboembolic complications, from 8 before the introduction of the protocol to 1 after. Before introduction of the protocol, the procedure was performed by applying an initial UFH bolus, variably monitoring the ACT, and administering variable doses of UFH based on operator judgement, all of which entailed accepting suboptimal levels of anticoagulation (<250 s). Under the new protocol, the goal is to maintain ACT levels of >250 ms throughout the procedure.

Of course, careful handling of the pods and continuous irrigation systems is particularly important to avoid thrombus formation and introduction of air into the system. In large part, these are responsible for many of the cardioembolic events that occur, particularly coronary events. In this sense, training nurses to monitor anticoagulation levels and irrigation systems, as well as to detect complications early, is essential.

The significant reduction in complications over the years is clearly due to various factors. On the one hand, systematization of anticoagulation during the procedure has helped to achieve optimal and stable levels of anticoagulation, which could explain the lower rate of embolic complications from 2008 onwards. Likewise, ongoing analysis of complications and the exhaustive search for potential causes has contributed to the education of both medical and nursing staff. The learning curve has led to considerable attention being paid to catheter manipulation and the identification of potential sources of complications which no doubt further helps to prevent their occurrence.

In 2008, in parallel with the anticoagulation protocol, we also introduced a conscious sedation protocol for all patients. This was developed using recommendations from colleagues in the anesthesiology service and may have also helped reduce complications by increasing patient comfort, thereby improving catheter stability and the safety of the procedure.

Study Limitations

As this was a prospective, nonrandomized study, it was not possible to determine how much of the improvement in outcomes and complications derived from the 3 factors involved: learning, technological improvements, and the implementation of protocols. On the other hand, as the correlation between patient-perceived symptoms and episodes of persistent arrhythmia is often poor, the way arrhythmic recurrences were monitored and recorded during follow-up was key to evaluating the success of the procedure. In this sense, it is important to point out that outcomes were monitored similarly in both study groups. Finally, the lack of standardization and data relating to technical aspects of the procedures, for example in regard to the use of mitral lines, roof lines, or circular catheters, especially in the earlier stages of the study, could also be considered a limitation. Randomized studies are needed to analyze the predictive value of such factors.

CONCLUSIONS

Outcomes and complication rates in PV ablation have improved significantly over the years.

The systematic application of anticoagulation and conscious sedation protocols was associated with improved outcomes and reduced complications in AF ablation. Other factors not measured in this study, such as the operator learning curve and ongoing improvements in technology, may have contributed to these changes.

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CONFLICTS OF INTEREST

None declared.

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