Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. 59, No. 2, 2012
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.08.068

Procedural Complications, Rehospitalizations, and Repeat Procedures After Catheter Ablation for Atrial Fibrillation

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Objectives The purpose of this study was to estimate rates and identify predictors of inpatient complications and 30-day readmissions, as well as repeat hospitalization rates for arrhythmia recurrence following atrial fibrillation (AF) ablation.

Background AF is the most common clinically significant arrhythmia and is associated with increased morbidity and mortality. Radiofrequency or cryotherapy ablation of AF is a relatively new treatment option, and data on post-procedural outcomes in large general populations are limited.

Methods Using data from the California State Inpatient Database, we identified all adult patients who underwent their first AF ablation from 2005 to 2008. We used multivariable logistic regression to identify predictors of complications and/or 30-day readmissions and Kaplan-Meier analyses to estimate rates of all-cause and arrhythmia readmissions.

Results Among 4,156 patients who underwent an initial AF ablation, 5% had periprocedural complications, most commonly vascular, and 9% were readmitted within 30 days. Older age, female, prior AF hospitalizations, and less hospital experience with AF ablation were associated with higher adjusted risk of complications and/or 30-day readmissions. The rate of all-cause hospitalization was 38.5% by 1 year. The rate of readmission for recurrent AF, atrial flutter, and/or repeat ablation was 21.7% by 1 year and 29.6% by 2 years.

Conclusions Periprocedural complications occurred in 1 of 20 patients undergoing AF ablation, and all-cause and arrhythmia-related rehospitalizations were common. Older age, female sex, prior AF hospitalizations, and recent hospital procedure experience were associated with a higher risk of complications and/or 30-day readmission after AF ablation. (J Am Coll Cardiol 2012;59:143–9) © 2012 by the American College of Cardiology Foundation

The prevalence of atrial fibrillation (AF) among U.S. adults is expected to rise from 2.3 million to at least 5.6 million by 2050, with an increasing burden of medical costs (1,2). Catheter ablation, a newer treatment option for AF that uses radiofrequency or cryotherapy to electrically isolate the pulmonary veins and ablate arrhythmia foci, is increasing in use. Randomized studies have suggested that AF ablation may decrease arrhythmia burden and improve quality of life, and observational studies have suggested that ablation may be associated with lower ischemic stroke and death rates (3).

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Procedural complications have been reported to affect between 1% and 8% of patients undergoing AF ablation at experienced academic hospitals (4,5) and 7% to 10% among Medicare beneficiaries treated in centers of varying types (6). However, relatively little is known about use of AF ablation and complication rates in contemporary patient cohorts across the age spectrum treated in community settings. Furthermore, the frequency of rehospitalizations and repeat ablation procedures among unselected patients is not well understood.

Using data from the Healthcare Utilization Project California State Inpatient Database (7), we characterized trends in AF

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Manuscript received April 25, 2011; revised manuscript received August 22, 2011, accepted August 29, 2011.

Abbreviations and Acronyms

AF = atrial fibrillation

ICD-9 = International Classification of Diseases-9th Edition

ablation use, procedural complications, and repeat hospitalizations in a large, diverse contemporary population. We also sought to evaluate predictors of poor outcomes, including procedural complications and 30-day rehospitalizations.

Methods

Catheter ablation and arrhythmia. The California State Inpatient Database, from Healthcare Utilization Project (Agency for Healthcare Research and Quality), contains administrative data for all discharges from nonfederal hospitals in the state plus an encrypted linking variable to track hospitalizations of the same patient over time (7). We identified patients who received an initial AF ablation procedure between January 1, 2005, and November 31, 2008, by searching for discharges with a principal diagnosis of AF (International Classification of Diseases-9th Edition [ICD-9] 427.31) and a concurrent catheter ablation procedure code (ICD-9 37.34). We excluded patients with secondary diagnosis codes for atrial flutter, Wolff-Parkinson-White syndrome, nonparoxysmal atrioventricular nodal tachycardia, paroxysmal supraventricular tachycardia, paroxysmal ventricular tachycardia, and ventricular premature beats. We also excluded patients with diagnostic or procedural codes indicating implantation of a pacemaker or implantable cardioverter-defibrillator during the index admission (to exclude those undergoing atrioventricular node ablation) and patients undergoing open surgical ablation (Online Table A1). Patients were excluded from this analysis if they had received an AF ablation in 2004 to include only patients who presumably had their first AF ablation during the study period.

Patient comorbidities. Comorbid conditions were identified based on secondary diagnosis codes for coronary artery disease, heart failure, cerebrovascular disease, renal disease, hypertension, diabetes, valvular heart disease, and lung disease during the index AF ablation hospitalization and a concurrent "present on admission" indicator (Online Table A2). In addition, patients were classified as having coronary artery disease, heart failure, cerebrovascular disease, or lung disease if they had been hospitalized during the year before the index procedure with a primary diagnosis of these conditions. Patients were classified as having chronic renal disease, hypertension, diabetes, valvular heart disease, lung disease, or cancer if they had been hospitalized during the year before the index procedure with the relevant ICD-9 code as either the primary or a secondary diagnosis (Online Table A2).

The database does not provide detail to characterize the type or duration of AF. Therefore, we used the number of AF hospitalizations as a proxy to account for disease severity, defined as the number of hospitalizations with AF in the primary diagnostic position during the year before index ablation.

Outcomes. Acute procedural complications included cardiac perforation and/or tamponade, pneumothorax, hemothorax, procedure-related stroke, transient ischemic attack, vascular access complication (consisting of hemorrhage/hematoma, vascular complication requiring surgical repair, and accidental puncture), and in-hospital death (Online Table A2). Procedural complications were identified using secondary diagnoses coded during the index AF ablation admission.

We estimated rates of all-cause and cause-specific 30-day rehospitalizations. Cause-specific reasons for 30-day readmissions included procedural complications and primary diagnoses of AF or atrial flutter (Online Table A3). Long-term outcomes of interest included hospitalization for any cause and admission for arrhythmia recurrence at any time after ablation through the end of the study period. Arrhythmia recurrence was defined as a repeat hospitalization with a primary diagnosis of AF or atrial flutter or a repeat hospitalization with a procedure code for catheter ablation.

Statistical analysis. Categorical data are presented as frequencies and percentages; continuous data are presented as mean ± SD. Univariate comparisons were performed using *t* tests for continuous variables and chi-square tests for categorical and binary variables. Multivariable logistic regression with generalized estimating equations (to account for within-hospital clustering) were used to identify predictors of inpatient complication and/or 30-day all-cause rehospitalization. Patient demographics (age, sex, and race/ethnicity), primary payer, comorbid conditions, number of AF hospitalizations during the prior year, and recent hospital procedure experience were included in the multivariable model. Recent procedure experience was defined as the number of cases completed at a given center during the 12 months before each index AF ablation divided into quartiles for comparison.

We used Kaplan-Meier analyses to estimate all-cause readmission and arrhythmia rehospitalization rates. For the readmission analysis, patients were censored at the end of the study period (December 31, 2008). For the arrhythmia rehospitalization analysis, patients were censored if they died during a hospitalization or at the end of the study period. Ascertainment of death was limited to those that occurred within a California hospital because the database cannot be linked with the National Death Index.

A value of $p < 0.05$ was considered statistically significant. All analyses were performed using Stata version 11.0 (StataCorp LP, College Station, Texas).

Results

We identified 4,156 patients who received an initial AF ablation in California between January 1, 2005, and No-

Table 1 Baseline Characteristics for Patients With/Without Complications (Periprocedural and/or 30-Day Readmission) After AF Ablation

Variable	All Patients (N = 4,156)	No Complications (n = 3,591)	Complications (n = 565)	p Value
Mean age, yrs	61.7 ± 12.0	61.2 ± 12.0	64.7 ± 11.8	<0.001
Age group, yrs*				<0.001
18–44	310 ± 7.5	286 ± 8.0	24 ± 4.3	
45–54	778 ± 18.7	693 ± 19.3	85 ± 15.0	
55–64	1,327 ± 31.9	1,157 ± 32.2	170 ± 30.1	
65–84	1,080 ± 26.0	912 ± 25.4	168 ± 29.7	
75–84	512 ± 12.3	415 ± 11.6	97 ± 17.2	
≥85	97 ± 238	77 ± 2.1	20 ± 3.5	
Age ≥65 yrs*†	1,689 ± 40.6	1,404 ± 39.1	285 ± 50.4	<0.001
Sex*†				<0.001
Male	2,819 (67.8)	2,484 (69.2)	335 (59.3)	
Female	1,219 (29.3)	997 (27.8)	222 (39.3)	
Primary payer†				<0.001
Medicare	1,513 (36.4)	1,251 (34.8)	262 (46.5)	
Private insurance	2,416 (58.3)	2,146 (59.8)	270 (47.8)	
Race/ethnicity				0.360
White	3,353 (80.7)	2,896 (80.7)	457 (80.9)	
Black	67 (1.6)	57 (1.6)	10 (1.8)	
Hispanic	243 (5.9)	203 (5.7)	40 (7.1)	
Other/missing	493 (11.9)	189 (5.3)	33 (5.8)	
Year				0.348
2005	684 (16.5)	577 (16.1)	107 (18.9)	
2006	944 (22.7)	815 (22.7)	129 (22.8)	
2007	1,206 (29.0)	1,046 (29.1)	160 (28.3)	
2008	1,322 (31.8)	1,153 (32.1)	169 (29.9)	
AF hospitalizations during year prior to ablation‡				<0.001
0	3,289 (79.1)	2,873 (80.0)	416 (73.6)	
1	671 (16.2)	563 (15.7)	108 (19.1)	
2	146 (3.5)	120 (3.3)	26 (4.6)	
≥3	50 (1.2)	35 (1.0)	15 (2.7)	
Coronary artery disease*	609 (14.7)	512 (14.3)	97 (17.2)	0.069
Heart failure*	388 (9.3)	306 (8.5)	82 (14.5)	<0.001
Renal disease*	139 (3.3)	106 (3.0)	33 (5.8)	<0.001
Cerebrovascular disease	57 (1.4)	45 (1.3)	12 (2.1)	0.098
Diabetes mellitus*	518 (12.5)	437 (12.2)	81 (14.3)	0.147
Valvular disease*	510 (12.3)	429 (12.0)	81 (14.3)	0.108
Hypertension*	2,090 (50.3)	1,776 (49.5)	314 (55.6)	0.007
Lung disease*	172 (4.1)	137 (3.8)	35 (6.2)	0.008
Mean no. of procedural experiences (SD)§	54.32 ± 53.2	55.8 ± 53.8	44.6 ± 48.0	<0.001
Quartile 1 (highest)	1,037 ± 25.0	933 ± 26.0	104 ± 18.4	
Quartile 2	1,015 ± 24.4	885 ± 24.6	130 ± 23.0	
Quartile 3	1,013 ± 24.4	858 ± 23.9	155 ± 27.4	
Quartile 4 (lowest)	1,091 ± 26.2	915 ± 25.5	176 ± 31.2	

Values are mean ± SD or n (%). *Significant predictors of 30-day readmission only. †Significant predictors of inpatient outcomes only. ‡Defined as the number of hospitalizations with atrial fibrillation (AF) in the primary diagnostic position; for full cohort, n = 31 for 3, n = 11 for 4, n = 5 for 5, and n = 3 for 6 AF hospitalizations. §Procedural experience is the number of AF ablations completed at a given hospital during the 12 months preceding each index case.

vember 31, 2008. The number of initial procedures almost doubled from 684 cases in 2005 to 1,332 cases in 2008; the mean annual volume of AF ablations per hospital was 15.4 throughout the study period. A total of 98 unique hospitals performed AF ablations during the study period; the number of hospitals increased from 60 in 2005 to 77 in 2008. In this sample, mean patient age was 61.7 years; hypertension (50.3%) and coronary artery disease (14.7%) were the most common comorbidities (Table 1). Most patients had not been hospitalized primarily for AF during the year before ablation (79.1%). Recent hospital procedural experience during the preceding 12 months varied from 7.0 ± 4.4 procedures in the lowest quartile to 136.9 ± 27.8 in the highest quartile. The observation time (from time of initial AF ablation through December 31, 2008) was a median (interquartile range) of 1.53 years (0.78 to 2.62).

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Table 2 Outcomes During and After Hospitalization for AF Ablation

Inpatient Complication or Rehospitalization	Patients Undergoing AF Ablation (N = 4,156)
Any complication	211 (5.1)
Vascular complication	110 (52.1)
Hematoma/hemorrhage only	93 (44.1)
Perforation/tamponade	104 (49.3)
Stroke	10 (4.7)
Pneumothorax/hemothorax	4 (1.9)
Transient ischemic attack	3 (1.4)
Death	1 (0.5)
30-day rehospitalization	
All-cause	390 (9.4)
AF/atrial flutter	105 (26.9)
Any procedural complication	76 (19.5)
Pneumothorax/hemothorax	3 (0.8)
Vascular complication	45 (11.5)
Perforations/tamponade	12 (3.1)
Acute stroke*	19 (4.9)
Death	9 (2.3)

Values are n (% of complications or 30-day rehospitalizations). *Acute strokes include hemorrhagic and ischemic events plus transient ischemic attacks.
Abbreviation as in Table 1.

Inpatient complications occurred in 5.1% (n = 211) of AF ablations and did not vary according to study year. Vascular complications, primarily bleeding-related events, accounted for more than half of all complications (Table 2). One patient died during the index admission. Length of stay was 1.46 ± 1.96 days for those without complications and 3.42 ± 3.44 days for those with complications ($p < 0.001$). Within 30 days of index hospitalization, 9.4% (n = 390) of patients discharged alive were rehospitalized. AF or atrial flutter accounted for 26.9% of readmissions (n = 105), and procedural complications accounted for another 19.5% of readmissions (n = 76) (Table 2).

Age, sex, primary payer, heart failure, hypertension, chronic renal disease, lung disease, number of AF hospitalizations during the prior year, and procedure volume quartile were univariate predictors of inpatient complications and/or 30-day rehospitalization ($p < 0.05$ for each) (Table 1). In the multivariable analyses, female sex (odds ratio [OR]: 1.38 compared with males; 95% confidence intervals [CI]: 1.13 to 1.69) and number of AF hospitalizations during prior year (OR: 1.19 for each additional admission; 95% CI: 1.05 to 1.35) were significant predictors of the outcome (Table 3). The odds of inpatient complication and/or 30-day readmission increased in a stepwise fashion with increasing patient age, up to age 85 years (Table 3). Less hospital experience with AF ablation was also a significant predictor of the outcome, with a 57% increase in the odds of the outcome in the lowest compared with the highest quartile (Table 3). Every 5-U increase in the number of procedures completed during the prior 12 months decreased the odds of the outcome by 2% (OR: 0.98; 95% CI: 0.97 to 0.99).

In long-term follow up, 1,816 patients were readmitted after AF ablation for any reason. At 1 year, 61.5% of patients were free of hospital admission (95% CI: 59.9% to 63.1%) (Fig. 1). A total of 1,022 patients were rehospitalized for arrhythmia recurrence or repeat ablation. At 1 year, 78.3% (95% CI: 76.9% to 79.6%) of patients were free of readmission for recurrent arrhythmia or repeat ablation; at 2 years, 70.4% (9% CI: 68.7% to 72.0%) of patients were free of rehospitalization for recurrent arrhythmia or repeat ablation (Fig. 2). Among the 4,156 recipients of an initial AF ablation, 17.4% received additional ablation; 682 patients received 1 additional ablation, 36 received 2 additional ablations, 3 received 3 additional ablations, and 3 received 4 additional ablations during the study period.

Discussion

In a large contemporary cohort of patients who underwent AF ablation in California, 5% of patients experienced a periprocedural complication and almost 10% were rehospitalized with 30 days. By 1 year, 22% of patients were rehospitalized for arrhythmia recurrence or repeat ablation and almost 40% were rehospitalized for any reason.

Table 3 Multivariable Analysis for Predictors of Inpatient Complications Plus All-Cause 30-Day Rehospitalizations

Variable	Odds Ratio	95% Confidence Interval
Age group, yrs		
18–44	1.00 (reference)	N/A
45–54	1.52	0.94–2.45
55–64	1.77	1.13–2.79
65–74	1.86	1.09–3.15
75–84	1.95	1.10–3.46
>85	1.72	0.82–3.61
Female	1.38	1.13–1.69
Race/ethnicity*	1.10	0.86–1.40
Primary payer†	0.83	0.60–1.15
Procedural experience‡		
Quartile 1 (highest)	1.00 (reference)	N/A
Quartile 2	1.38	1.04–1.82
Quartile 3	1.64	1.25–2.15
Quartile 4 (lowest)	1.56	1.19–2.05
Year	0.94	0.86–1.03
AF hospitalizations§	1.19	1.05–1.35
Heart failure	1.33	0.99–1.80
Coronary artery disease	1.03	0.78–1.34
Hypertension	0.99	0.81–1.21
Diabetes mellitus	0.93	0.71–1.23
Cerebrovascular disease	1.35	0.70–2.60
Renal disease	1.43	0.92–2.22
Valvular disease	0.85	0.65–1.13
Lung disease	1.21	0.81–1.81

*All others/missing compared with white. †Private insurance compared with Medicare. ‡Defined as the number of AF ablations completed at a given hospital during the 12 months preceding each index ablation. §Defined as the number of hospitalizations during the year before index ablation with AF in the primary diagnostic position; the odds ratio represents the increase per 1 U increase in AF hospitalizations.
N/A = not applicable; other abbreviation as in Table 1.

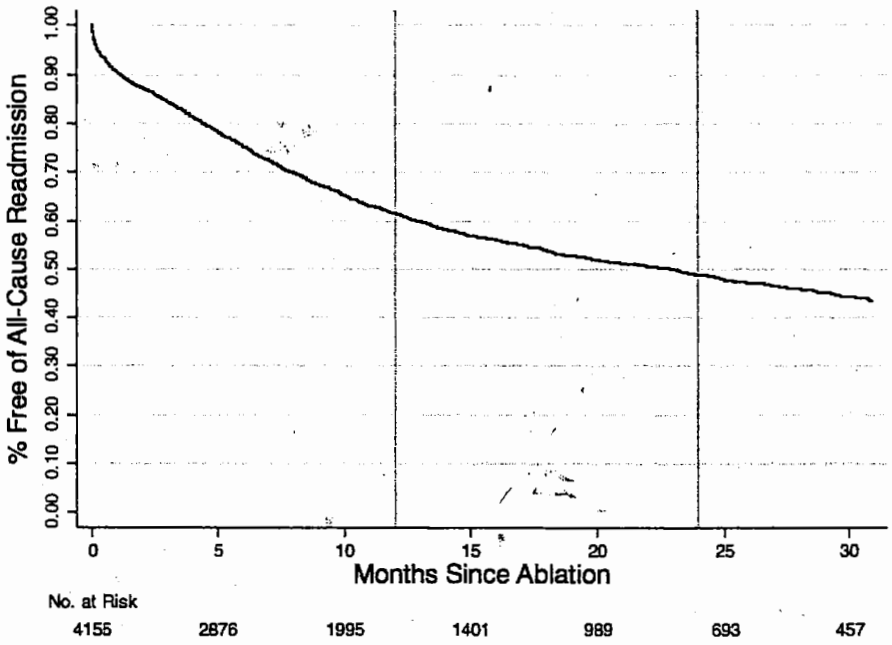

Figure 1 **Kaplan-Meier Curve for All-Cause Readmissions After Initial Atrial Fibrillation Ablation**

One year: 61.5% (95% confidence interval: 59.9% to 63.1%) of patients were free of all-cause hospital admission. **Reference lines** are at 12 and 24 months.

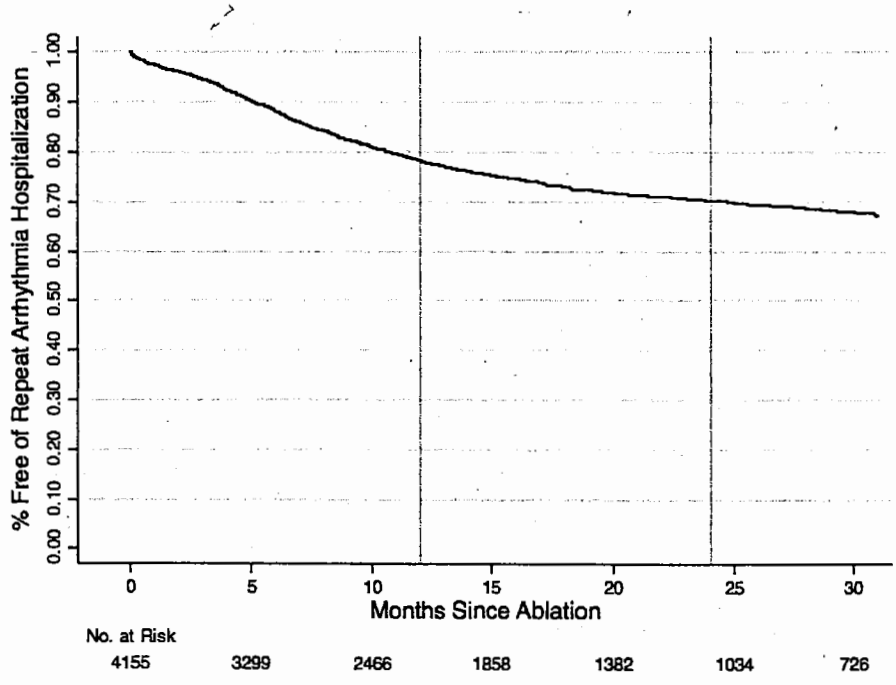

Figure 2 **Kaplan-Meier Curve for Hospitalization for Arrhythmia Recurrence* or Repeat Ablation After Initial Atrial Fibrillation Ablation**

One year: 78.3% (95% confidence interval: 76.9% to 79.6%) of patients were free of hospitalization for recurrent arrhythmia or repeat ablation. Two years: 70.4% (95% confidence interval: 68.7% to 72.0%) of patients were free of hospital admission for recurrent arrhythmia or repeat ablation. *Recurrent arrhythmia is defined as hospitalization for atrial fibrillation or atrial flutter. **Reference lines** are at 12 and 24 months.

Periprocedural complication rates following AF ablation have ranged from 1% to 8% in smaller studies of high-volume centers (4,9), and the complication rate was 9.1% in a study of Medicare beneficiaries (6). The periprocedural complication rate of 5.1% in this study is derived from a large contemporary cohort that is more representative of the general AF population than prior estimates from selected patient cohorts (6,10).

Policymakers have begun to focus on 30-day readmission rates as a potential marker of quality of care. Prior studies of AF ablation have not reported 30-day readmission rates, which we found to be 10% overall (most commonly for AF and atrial flutter) and 12.1% among patients age 65 years and older. This readmission rate after AF ablation is lower than the 14.6% 30-day readmission rate of Medicare beneficiaries after percutaneous coronary intervention (8) and lower than the 20.1% readmission rate of Medicare beneficiaries after heart failure hospitalization (11), although still high for an elective procedure.

Hospitalization for recurrent arrhythmia or repeat ablation occurred frequently, affecting 22% of patients at 1 year and 30% of patients at 2 years (Fig. 2). Randomized controlled trials have reported AF recurrence in 13% to 44% of AF ablation recipients (12,13), and a worldwide survey of centers offering AF ablation reported recurrence in 48% to 57% of recipients at a median of 12 months' follow-up (4). The estimate in our study was at the lower end of the reported range because the database does not capture outpatient or asymptomatic recurrence. Our findings were therefore consistent with previous studies that observed that AF ablation has limited success in preventing arrhythmia recurrence over longer-term follow-up (4). We further demonstrated that these recurrences were often severe enough to result in costly hospitalizations.

Slightly <20% of patients in this cohort of unselected AF ablation recipients received multiple ablations, which is lower than the rates reported from specialized centers. The worldwide survey mentioned previously reported that more than 25% of patients received repeat ablations within a median follow-up time of 12 months (4). The difference between our findings and those from specialized centers may be due to a more aggressive approach of specialty centers in treating recurrent arrhythmias. Alternatively, specialized centers may select patients who are healthier or who have disease that is more amenable to ablation, making repeat ablation more attractive.

The increased procedural risk for women undergoing AF ablation was consistent with patterns seen in other cardiovascular procedures. Women undergoing percutaneous coronary intervention have more than a 2-fold higher risk of vascular complications than men (14–16), perhaps because of smaller body size or higher levels of anticoagulation among women (17). However, a report on risk factors for bleeding with unfractionated heparin found that female sex remained a risk factor after controlling for weight, heparin dose, and activated partial thromboplastin time, suggesting that mechanisms other than medication dosing could account for increased bleeding risk in women (18).

We found that that recent procedural experience with AF ablation was inversely related to complication rates, which was consistent with the general observation that higher hospital volume has been associated with better outcomes for various procedures (19–21) and medical conditions (22). Our measure of procedural experience differed from the methods used to estimate hospital volume in prior publications in that we assessed the number of procedures performed in the prior 12 months as the metric, rather than the average procedure volume over several years. This measure of recent experience captured the effect of the "learning curve" for new procedures such as AF ablation. Our finding of better outcomes among patients treated at centers with more procedural experience in the prior 12 months suggested that higher procedure volumes are needed to gain proficiency, maintain proficiency, or both.

Study limitations. The administrative data used in this analysis lack the detail that is available in trials and registries. Physician characteristics and full assessment of comorbidities (i.e., including outpatient diagnoses) were unavailable for the analyses. This limitation is counterbalanced by the larger sample size and the absence of reporting bias introduced by selective publication of results from specialized centers. Data about procedural technique, medication use, and type of AF (e.g., paroxysmal or persistent) were unavailable. We did, however, use the number of AF hospitalizations during the year before index ablation as a proxy for disease severity.

The patients in this study were representative of the general AF ablation population, but certain limitations in our cohort assembly should be noted. We identified patients who had their "first" procedure between 2005 and 2008, looking back through 2004. Some patients may have had procedures before 2004. Given the smaller number of AF ablations completed in earlier years, however, the number of misclassified patients should be small. Patients who had pacemakers placed before the index hospitalization and who may have had an atrioventricular junction ablation were not excluded.

Our study did not include a comparison of patients with AF treated with antiarrhythmic drugs. We found high rehospitalization rates following ablation, but patients with AF treated with other methods may have similar or higher rates. Also, 18% of patients without reported complications were hospitalized for 2 or more days, some of whom may have had a complication that was not coded in the hospital discharge abstract. Finally, the database could not be linked with the National Death Index; therefore, we could not accurately assess mortality late after the procedure, although we could detect all deaths during the index admission.

Conclusions

AF ablation is a newer treatment option that is being used with increasing frequency. In this large, unselected cohort of AF ablation recipients, 1 in 20 patients experienced a periprocedural complication and almost 1 in 10 were rehos-

pitalized within 30 days of the procedure. Older age, female sex, prior AF hospitalizations, and recent hospital procedure experience were factors associated with a high risk of complications and/or 30-day rehospitalization after AF ablation. Future investigations should be directed at identifying ways to decrease procedural complication rates, arrhythmia recurrence, and readmissions.

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Key Words: atrial fibrillation ▪ complication ▪ outcomes ▪ pulmonary vein isolation.

APPENDIX

For supplementary tables, please see the online version of this article.

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Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST) A 2-Center Randomized Clinical Trial

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January 03, 2012

Editor's Note: This article is based on Boersma LV, Castella M, van Boven W, Berruezo A, Yilmaz A, Nadal M, et al. Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST): A 2-Center Randomized Clinical Trial. Circulation 2012;125: 23-30.

Introduction

This two-center prospective randomized study was designed to compare the efficacy and safety of radiofrequency catheter ablation (CA) versus minimally-invasive surgical ablation (SA) in specific subgroups of patients with symptomatic atrial fibrillation (AF) refractory to at least 1 antiarrhythmic drug. The inclusion criteria were left atrial (LA) diameter of 40-44 mm in association with hypertension, LA diameter ≥45 mm, or a prior unsuccessful CA procedure. Exclusion criteria included long-standing persistent AF, LA diameter >65 mm, and left ventricular ejection fraction <45%.

Methods

Neither the CA nor the SA strategy was uniform between the 2 centers. At 1 of the centers, the CA strategy consisted only of circumferential antral ablation to isolate the pulmonary veins using a standard 4-mm-tip radiofrequency ablation catheter and the SA strategy consisted of a video-assisted thoroscopic approach, epicardial pulmonary vein isolation using a bipolar radiofrequency ablation clamp, bilateral epicardial ganglia ablation, and additional LA ablation lines at the operator's discretion. At the other center, antral pulmonary vein isolation was performed using a 3.5-mm irrigated-tip ablation catheter, along with additional LA ablation lines at the discretion of the operator, and the SA strategy consisted of pulmonary vein isolation with the bipolar radiofrequency ablation clamp, isolation of right atrial ganglionated plexi, and surgical division of the ligament of Marshall. The LA appendage was excised in all SA patients. Antiarrhythmic drug therapy was discontinued after a 3-month blanking period. Cardioversion was permitted during the blanking period.

A 7-day Holter monitor was performed pre-ablation and at 3, 6, and 12 months of follow-up. The 1° efficacy end point was freedom from any LA tachyarrhythmia lasting >30 seconds during 3-12 months of follow-up in the absence of antiarrhythmic drug therapy. The 1° safety end point was the rate of significant adverse events (SAEs) during 12 months of follow-up.

Results

One-hundred twenty-four patients (mean age 56 years, mean LA diameter 43 mm) with AF (paroxysmal in 67%) were randomly assigned to CA (n=63) or SA (n=61). A prior unsuccessful CA procedure had been performed in 67% of patients. The baseline Holter monitor demonstrated no AF in 48% of patients, paroxysmal AF in 20%, and continuous AF in 32%. In the CA group, a LA ablation line was made at the roof in 48% of patients, at the mitral isthmus in 27%, and at both sites in 23%. In the SA group, additional lines were created in 31% of patients.

The 1° efficacy point at 12 months of follow-up was achieved significantly more often in the SA group (65.6%) than in the CA group (36.5%). Efficacy was not significantly different between the 2 study sites and was not affected by the use of an irrigated-tip catheter or the creation of supplementary ablation lines.

The primary safety end point of SAEs was significantly higher in the SA group (34.4%) than in the CA group (15.9%). The rate of procedural SAEs was significantly higher in the SA group (23%) than in the CA group (3.2%). The most common procedural SAEs in the SA group were pneumothorax (10%) and the need for pacemaker implantation (3.3%). The only procedural complications in the CA group were 1 case each of cardiac tamponade and stroke. During the 12 months of follow-up, the rates of SAEs were similar in the SA and CA groups (11.5% versus 12.6%, respectively). The most common SAEs during follow-up were pneumonia (3.2%) and AF-induced heart failure (3.2%) in the CA group and pneumonia (3.3%) and delayed hydrothorax (3.3%) in the SA group.

Conclusions

Surgical ablation of AF in patients who have had an unsuccessful prior CA procedure or who have an enlarged LA is more effective than radiofrequency CA but is associated with a higher risk of procedural SAEs.

Perspective

This study is important because it is the first randomized comparison of surgical versus catheter ablation of AF. It is noteworthy that the study was performed in selected patients with AF, most commonly patients who already had already failed a CA procedure. Therefore the results should not be generalized to all patients with drug-refractory AF.

The results of AF ablation, whether performed with a catheter or surgically, are highly dependent on the ablation strategy that is employed. One of the probable reasons that SA had greater efficacy than CA in this study is that the surgical approach was more comprehensive than the catheter approach and consisted not only of pulmonary vein isolation and linear ablation, but also ablation of ganglionated plexi and excision of the left atrial appendage. On the other hand, the CA strategy was relatively minimalistic, consisting only of antral pulmonary vein isolation in approximately 50% of patients. Because the majority of patients in this study had failed a prior CA procedure, extra-pulmonary venous triggers may have been responsible for recurrent AF in some patients. Yet the CA strategy did not include any attempts to identify extra-pulmonary venous AF triggers, even among the patients with paroxysmal AF, who made up two-thirds of the study population. Furthermore, in the patients with persistent AF, complex atrial fractionated electrograms were not targeted. While antral pulmonary vein isolation with or without 1-2 ablation lines is a reasonable initial strategy for persistent AF, in patients who have failed a prior CA procedure, success is unlikely to be achieved without more extensive ablation outside the antral regions.

A limitation of the study is that the ablation strategy that was used at the 2 centers that participated in the study was different in the CA and SA arms. Because there was not a significant difference in efficacy between the 2 centers, this limitation probably did not affect the results of the study.

Another limitation has to do with the objective documentation of recurrent AF during follow-up. It is difficult to argue that the absence of AF on 7-day Holter monitor recordings during follow-up was a reliable indicator of freedom from AF when approximately one-half of the subjects had no AF on the baseline 7-day monitor.

Despite its limitations, this randomized study provides new data that could be helpful to clinicians for making evidence-based recommendations to patients with AF who have not responded adequately to antiarrhythmic drug therapy. The study highlights the possible advantage (greater efficacy) and disadvantage (greater risk) of SA compared to CA.

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Edward F. Lundy M.D. Ph.D. F.A.C.C.

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