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NEW RESEARCH PAPERS

Atrial Fibrillation in Patients With Left Ventricular Assist Devices

Incidence, Predictors, and Clinical Outcomes

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ABSTRACT

OBJECTIVES This study sought to determine the prevalence of atrial fibrillation (AF) and its association with cardiac outcomes in patients with left ventricular assist devices (LVADs).

BACKGROUND LVADs are pivotal treatments for end-stage heart failure and a critical bridge to heart transplantation.

METHODS Medical records of 249 consecutive patients who received an LVAD at Columbia University Medical Center were reviewed. Patient demographics, clinical variables, medications, and outcomes were recorded. Descriptive statistics were generated, and multivariable logistic regression was performed to assess the independent association of clinical variables with the presence of AF.

RESULTS Overall, AF was documented in 80 patients (32%) following LVAD placement. Before LVAD placement, 182 patients had no history of AF, whereas 67 patients had documented AF. Among these 67 patients, 56 (84%) continued to have AF following LVAD placement; 24 patients without a history of AF (13%) developed AF after LVAD placement. Patients manifesting AF after LVAD placement were more likely to have had AF before LVAD insertion ($p < 0.001$). There were no significant differences in risk of stroke or death for patients with AF before or following LVAD insertion.

CONCLUSIONS AF is common in patients with LVADs, with 32% manifesting AF after placement of their LVAD, including 13% without a prior documented history of AF. The presence of AF was not associated with increased risk of death or stroke. (J Am Coll Cardiol EP 2016;2:793–8) © 2016 by the American College of Cardiology Foundation.

Life-saving cardiac left ventricular (LV) assist devices (LVADs) are being implanted with increasing frequency in those with end-stage heart failure as destination or bridge to heart transplant therapy (1). Although the presence of ventricular arrhythmias has been well-documented in patients with LVADs (2), less is known of the presence, frequency, and duration of atrial arrhythmias, particularly atrial fibrillation (AF), in patients with LVADs. For example, prior studies have examined the frequency of preoperative ventricular arrhythmias in patients with implantable cardioverter-defibrillators (ICDs), demonstrating that those with pre-LVAD ventricular arrhythmias are at increased risk for post-LVAD ventricular arrhythmias, despite the impact of the LVAD on their LV failure (3). Other researchers have shown that ventricular arrhythmias occurring within 1 week of LVAD implantation may be associated with increased mortality and decreased transplantation rates (4). The purpose of this study was to determine the incidence of AF in those with LVADs and its role in cardiac outcomes.

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

CI = confidence interval

ECG = electrocardiogram

EMR = electronic medical record

HR = hazard ratio

ICD = implantable cardioverter-defibrillator

INR = international normalized ratio

LA = left atrial

LV = left ventricular

LVAD = left ventricular assist device

MI = myocardial infarction

OR = odds ratio

METHODS

We retrospectively reviewed the electronic medical records (EMRs) of all adults who underwent the placement of a LVAD between April 2008 and June 2014 at Columbia University Medical Center (Institutional Review Board #AAAE9657) to document AF. Patients were followed through October 2015 via EMRs to search for the incidence and treatment of AF post-LVAD. We reviewed all available progress notes, telemetry findings, electrocardiogram (ECG), and ICD findings for AF documentation. The chart review was conducted by a single reviewer (K.T.H.) and 2 independent electrophysiologists (H.G. and A.B.) read all 12-lead ECGs. All patients with documented AF had at least one 12-lead ECG documented in their medical record, which was available to be reviewed. Adjudication of ECGs was performed by a third cardiologist (A.G.) who was blinded to the initial 2 readers' ECG interpretations. We used the American Heart Association/American College of Cardiology AF guidelines and standard definitions to classify AF (5). AF duration following LVAD insertion was further characterized as short-term (<2 weeks), intermediate-term (2 weeks to 3 months), or long-term (>3 months). The use of antiarrhythmic agents for the treatment of arrhythmias was also documented.

STATISTICAL ANALYSIS. Demographic and clinical data are reported as mean ± SD for continuous variables and as frequencies for categorical variables. Univariate logistic regression was used to determine the relationship between measures of the occurrence of AF after LVAD insertion (presence of AF and development of new AF) and potential predictors of these measures (age, sex, clinical history, cardiovascular risk factors, medications, AF before LVAD insertion, and echocardiographic assessments). In addition, potential interactions between AF before LVAD insertion and other potential predictors (e.g., clinical history, cardiovascular risk factors, medications) were assessed with multivariable logistic regression. We used the following echocardiographic measurements of left atrial (LA) diameter for the classification of LA enlargement (6): 1) mild LA enlargement = 4.1 to 4.6 cm (men), 3.9 to 4.2 cm (women); 2) moderate LA enlargement = 4.7 to 5.2 cm (men), 4.3 to 4.6 cm (women); and 3) severe LA enlargement ≥5.2 cm for men and >4.7 cm for women, respectively (6). LV septal and posterior wall thickness >0.9 cm (women) and >1.0 cm (men) was classified as abnormal (6).

The joint effects of variables that were found to be significant by univariate analysis were assessed in multivariable logistic regression models that included age and sex. Cox proportional hazard models were used to compare the risk of death in those with and without AF, both before and after LVAD insertion, with observations censored at the end of follow-up or at the time of transplantation. Multivariable analyses were performed including age and sex along with variables significant by univariate analysis. Cox proportional hazard models were also used to assess the risk of stroke in those with and without AF; no multivariable analyses were performed because of the small number of strokes. The assumption of constant hazards in the Cox models was tested using Schoenfeld residuals. When hazard ratios (HRs) varied over time, a nonparametric Wilcoxon test was used to compare survival curves. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina). A p value of 0.05 was used for significance in all analyses.

TABLE 1 Characteristics of the Study Population (N = 249)

Age, yrs	58 ± 14
Men	201 (81)
Clinical history	
Ischemic etiology	92 (37)
Prior MI	90 (37)
Valve surgery	170 (69)
ICD	182 (73)
Cardiovascular risk factors	
Diabetes	91 (37)
Hypertension	191 (79)
Dyslipidemia	166 (68)
History of smoking	74 (38)
Medications	
Amiodarone	87 (35)
Beta-blockers	107 (43)
ACE/ARB	132 (53)
Clinical chemistry	
Na abnormal	108 (44)
BUN abnormal	189 (76)
Echocardiography	
Left atrial dimension abnormal	216 (93)
LV ejection fraction	16% ± 6%
Septal/posterior wall thickness abnormal	120 (52)
History of cardiac rhythm disturbances	
AF before LVAD insertion	67 (27)
Ventricular arrhythmias before LVAD insertion	59 (24)

Values are mean ± SD or n (%).

ACE = angiotensin-converting enzyme; AF = atrial fibrillation; ARB = angiotensin receptor blocker; BUN = blood urea nitrogen; ICD = implantable cardioverter-defibrillator; LV = left ventricular; LVAD = left ventricular assist device; MI = myocardial infarction; Na = sodium.

RESULTS

The characteristics of the 249 LVAD patients are presented in Table 1. The cohort was predominantly male (81%) with a mean age of 58 years. Among patients, 90 (37%) had suffered a prior myocardial infarction (MI), 170 (69%) had undergone valve surgery, and an ICD had been implanted in 182 (73%). Diabetes was present in 91 (37%), hypertension in 191 (79%), and dyslipidemia in 166 (68%), and 74 (38%) had a history of tobacco use. Medication usage included amiodarone in 87 (35%), beta-blockers in 107 (43%), and angiotensin-converting enzymes/angiotensin receptor blockers in 132 (53%). Serum sodium averaged 135 ± 5 mmol/l with 108 (44%) outside the normal range (135 to 145 mmol/l). Blood urea nitrogen averaged 34 ± 19 mg/dl and was elevated (>20 mg/dl) in 189 (76%). LVAD devices implanted included Heart Mate II (Thoratec Corporation, Pleasanton, California) in 218 (88%), DuraHeart (Thoratec Corporation) in 9 (4%), HeartWare Ventricular Assist Device (HeartWare, Framingham, Massachusetts) in 8 (3%), HeartMate Vented Electric (Thoratec Corporation) in 7 (3%), and a variety of other models in 7 (3%). LVADs were implanted as a bridge to transplantation in 111 (45%) and as a destination therapy in 138 (55%). Patients were followed for a mean of 20 months following LVAD placement (range 0 to 93 months).

Before LVAD insertion, 232 patients (93%) had echocardiographic assessments. LA diameter was normal in 16 (7%), mildly enlarged in 46 (20%), moderately enlarged in 63 (27%), and severely enlarged in 107 (46%). LV ejection fraction averaged 16 ± 6% (range 7% to 45%). LV posterior/septal wall thickness was abnormal in 120 (52%). AF before LVAD insertion was documented in 67 patients (27%), whereas 59 patients (24%) had a history of ventricular tachyarrhythmias, including ventricular fibrillation in 12 patients.

AF AFTER LVAD INSERTION. Following LVAD insertion, AF was documented in 80 patients (32%) (Figure 1). In 56 patients, AF had been documented before LVAD implantation, whereas in 24 patients AF occurred and was documented only after LVAD. AF was characterized as short-term (<2 weeks) in 39, intermediate-term (2 weeks to 3 months) in 6, and long-term (>3 months) in 35 patients. Twenty-four patients of the total group (10%) had no prior history of AF and developed AF following LVAD insertion, accounting for 13% of those patients without a history of AF.

By univariate logistic regression, variables associated with an increased likelihood of AF following LVAD insertion (n = 80) included: ischemic etiology, history of tobacco use, ICD placement, beta-blockers or amiodarone before LVAD insertion, and a history of previous AF (Table 2). There were no significant interactions between a history of previous AF and other variables associated with increased likelihood of AF following LVAD insertion. By multivariable logistic regression, the only variable associated with an increased likelihood of AF following LVAD insertion was a history of previous AF (18% vs. 85%; odds ratio [OR]: 18.54; 95% confidence interval [CI]: 6.63 to 51.84; p < 0.001) (Table 2). By univariate logistic regression, the likelihood of developing a de novo AF following LVAD insertion in those without a history of previous AF (24 patients) was increased in female patients (Table 3). By multivariable logistic regression, female sex was associated with an increased

FIGURE 1 Atrial Fibrillation Pre- and Post-LVAD Placement

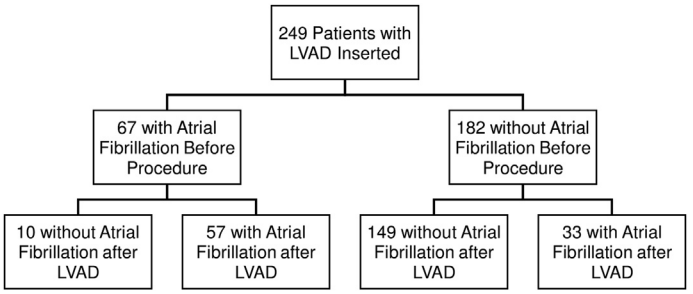

TABLE 2 Predictors of AF After LVAD Insertion

	Univariate Analyses			Multivariable Analysis		
	OR	95% CI	p Value	OR	95% CI	p Value
Age, per decade	1.16	0.95–1.42	0.15	0.93	0.62–1.40	0.72
Female	1.35	0.70–2.59	0.38	1.53	0.47–5.01	0.48
Ischemic etiology	**1.78**	**1.03–3.08**	**0.037**	1.92	0.66–5.53	0.23
Diabetes	1.55	0.90–2.68	0.12			
Hypertension	1.33	0.67–2.64	0.41			
Dyslipidemia	0.94	0.53–1.66	0.83			
History of smoking	**6.03**	**3.14–11.56**	**<0.001**	2.01	0.78–5.16	0.15
ICD	**3.11**	**1.53–6.34**	**0.002**	1.10	0.34–3.52	0.87
Prior MI	1.24	0.72–2.15	0.44			
Valve surgery	**0.35**	**0.20–0.62**	**<0.001**	0.45	0.18–1.17	0.10
Amiodarone	**2.05**	**1.18–3.55**	**0.011**	1.29	0.50–3.34	0.60
Beta-blockers	**8.58**	**4.63–15.90**	**<0.001**	2.37	0.89–6.32	0.09
ACE/ARB	0.85	0.50–1.45	0.54			
Na abnormal	1.18	0.69–2.01	0.55			
BUN abnormal	1.94	0.98–3.85	0.057			
LA dimension abnormal	1.60	0.50–5.12	0.43			
LV ejection fraction	0.99	0.95–1.04	0.73			
LV wall thickness abnormal	0.74	0.43–1.29	0.29			
AF before LVAD insertion	**33.51**	**15.42–72.81**	**<0.001**	**18.54**	**6.63–51.84**	**<0.001**

Bold values indicate statistical significance (p < 0.05).

CI = confidence interval; LA = left atrial; MI = myocardial infarction; OR = odds ratio; other abbreviations as in Table 1.

TABLE 3 Predictors of New AF After LVAD Insertion

	Univariate Analyses			Multivariable Analysis		
	OR	95% CI	p Value	OR	95% CI	p Value
Age, per decade	0.90	0.67–1.20	0.46	0.98	0.73–1.33	0.92
Female	**4.11**	**1.66–10.13**	**0.002**	**4.06**	**1.61–10.27**	**0.003**
Ischemic etiology	1.46	0.61–3.50	0.40			
Diabetes	1.55	0.64–3.78	0.33			
Hypertension	1.05	0.36–3.03	0.93			
Dyslipidemia	0.93	0.37–2.33	0.87			
History of smoking	2.77	0.88–8.69	0.08			
ICD	2.09	0.74–5.89	0.16			
Prior MI	1.06	0.44–2.58	0.90			
Valve surgery	0.51	0.21–1.26	0.14			
Amiodarone	0.81	0.30–2.18	0.68			
Beta-blockers	1.53	0.61–3.84	0.37			
ACE/ARB	0.61	0.25–1.44	0.26			
Na abnormal	0.99	0.41–2.35	0.97			
BUN abnormal	1.17	0.44–3.14	0.76			
LA dimension abnormal	0.64	0.17–2.45	0.51			
LV ejection fraction	0.97	0.90–1.05	0.46			

Bold values indicate statistical significance ($p < 0.05$).
Abbreviations as in Tables 1 and 2.

likelihood of newly developed AF (29% vs. 9%, OR: 4.06; 95% CI: 1.61 to 10.27; p = 0.003) (Table 3).

FOLLOW-UP. During follow-up, 73 patients died (29%) and 11 (4%) experienced a stroke. Neither a history of previous AF before LVAD insertion (HR: 1.17; 95% CI: 0.64 to 2.12; p = 0.61) nor the presence of AF following LVAD insertion (HR: 1.38; 95% CI: 0.79 to 2.40; p = 0.26) was related to mortality (Table 4). Plots of Schoenfeld residuals indicated that hazard ratios for a history of previous AF and for AF following LVAD insertion tended to decrease with time. However, neither was associated with significant differences in survival by the Wilcoxon test (p = 0.26 and p = 0.12, respectively). By univariate analysis, only prior MI was significantly related to risk of death (HR: 1.85; 95% CI: 1.09 to 3.15; p = 0.024). The use of antiarrhythmic agents for the treatment of arrhythmias was not related to mortality (Table 4). By multivariable analysis, female sex was associated with increased risk of death (HR: 2.14; 95% CI: 1.14 to 4.03; p = 0.018), and there was a nonsignificant trend for prior MI (HR: 1.68; 95% CI: 0.97 to 2.90; p = 0.06). The risk of stroke following LVAD insertion was not related to a history of previous AF before LVAD insertion (HR: 0.59; 95% CI: 0.13 to 2.72; p = 0.50) or to the presence of AF following LVAD insertion (HR: 1.23; 95% CI: 0.36 to 4.20; p = 0.74). Only 11 patients were diagnosed with a stroke during their follow-up (7 ischemic and 4 hemorrhagic). Anticoagulation was not therapeutic (international normalized ratio [INR] <2.0) in 7 of the 11 patients who experienced a stroke. Four patients with AF were among the group that experienced a stroke.

TABLE 4 Predictors of Death After LVAD Insertion

	Univariate Analyses			Multivariable Analysis		
	HR	95% CI	p Value	HR	95% CI	p Value
Age, per decade	1.21	0.97–1.50	0.09	1.21	0.96–1.54	0.11
Female	1.84	0.997–3.40	0.051	**2.14**	**1.14–4.03**	**0.018**
Ischemic etiology	1.27	0.74–2.17	0.38			
Diabetes	0.70	0.40–1.23	0.22			
Hypertension	1.51	0.65–3.55	0.34			
Dyslipidemia	1.24	0.67–2.27	0.49			
History of smoking	0.87	0.47–1.62	0.65			
ICD	1.29	0.66–2.49	0.46			
Prior MI	**1.85**	**1.09–3.15**	**0.024**	1.68	0.97–2.90	0.06
Valve surgery	1.00	0.56–1.79	0.99			
Amiodarone	1.11	0.64–1.92	0.72			
Beta-blockers	1.03	0.60–1.76	0.93			
ACE/ARB	1.09	0.64–1.87	0.74			
Na abnormal	0.94	0.54–1.63	0.82			
BUN abnormal	1.57	0.77–3.20	0.22			
LA dimension abnormal	1.11	0.34–3.58	0.87			
LV ejection fraction	1.00	0.96–1.05	0.91			
LV wall thickness abnormal	1.64	0.93–2.87	0.09			
AF before LVAD insertion	1.17	0.64–2.12	0.61			
AF after LVAD insertion	1.38	0.79–2.40	0.26			
LV wall thickness abnormal	0.59	0.24–1.46	0.25			

Bold values indicate statistical significance ($p < 0.05$).
Abbreviations as in Tables 1 to 3.

DISCUSSION

This study demonstrated that AF is a common arrhythmia in LVAD patients, but the presence of AF was not associated with an increased mortality risk. Our findings extend the previous results by Stulak et al. (7), who examined a similar size heart failure population (n = 389) with LVADs and concluded that preoperative AF was not associated with increased mortality. These findings also support those of Enriquez et al. (8), who recently reported that, although paroxysmal or persistent AF was present in 51.9% of LVAD patients, only persistent AF was independently associated with the composite endpoints of death or heart failure hospitalization, but not death alone (HR: 3.54; 95% CI: 1.52 to 8.25; p < 0.01). A difference between our findings and those of Enriquez et al. is that more of our patients were taking amiodarone (35%) or beta-blockers (43%), mainly for the treatment of documented ventricular arrhythmias. These medications may have further suppressed the development of AF because long-term use of beta-blockers is common in those with hypertension and heart failure.

Clinical implications include the fact that aggressive treatment of AF with maintenance of sinus

rhythm as the therapeutic goal may not be warranted in this setting and may have higher than usual incidence of adverse effects. Because mortality and stroke incidence are not associated with AF, further prospective studies exploring the risks and benefits of rate versus rhythm control and the impact of AF on repeat hospitalizations and quality of life (including potential symptomatic relief) in LVAD patients with AF are warranted.

Because AF is the most common arrhythmia encountered in clinical practice (9), it is not surprising that 22% of our LVAD patients had AF (present both before and after the placement of their LVADs). Our findings of AF are similar to those reported in other heart failure registries such as the OPTIMIZE-HF registry (Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with heart Failure) and the ADHERE (Acute Decompensated Heart Failure National Registry) registry, which reported an appropriately 23% to 31% rate of AF (10,11). These findings may be explained by severe cardiovascular and hemodynamic abnormalities resulting from advanced heart failure requiring LVAD placement. Enlargement of the left atrium is an independent risk factor for incident AF in the general population (12–14). The Cardiovascular Health Study demonstrated a 10-mm increase in the LA diameter was associated with a 74% increased risk (95% CI: 44 to 111) of new-onset AF after multivariable adjustment (15).

Our findings also did not demonstrate an increase in mortality or strokes in those patients manifesting AF pre-LVAD or post-LVAD. However, the majority of individuals who suffered a stroke in our cohort did so in the setting of a subtherapeutic INR level. These findings reinforce not only the need for continued surveillance of AF in LVAD patients, who are a high-risk group for developing AF, but also for their requirement to remain in therapeutic range of anticoagulation. These findings are especially important in light of the difficulties inherent in management of anticoagulation of LVAD patients, including bleeding complications resulting from acquired von Willebrand disease (16).

STUDY LIMITATIONS. First, this was a retrospective study, and definitive assessment of whether AF affects outcomes can only be ascertained by a prospective study. Because this retrospective study was conducted at a single-center institution, patient demographics and clinical practice may be different from those at other centers. Second, AF was documented in the EMRs and did not capture events at outside facilities (such as ICD interrogations) or asymptomatic AF that patients may have experienced in the absence of cardiac monitoring. Because of the large referral nature of our LVAD center population, many ICD follow-ups were not performed at our center. In addition, general surveillance of LVAD patients for whom follow-up data were available may have increased ICD-detected AF episodes. Thus, the true burden of AF before as well as after LVAD placement may be underestimated. Finally, the management of AF, when recognized, was left to the discretion of the treating physicians; therefore, treatment was not standardized.

CONCLUSIONS

In patients with LVADs, AF is common, with 32% manifesting AF after LVAD placement. This number includes 13% of the patients without a history of AF before LVAD. The presence of AF was not associated with the development of stroke or mortality. INR values were subtherapeutic in the majority of patients who suffered a stroke.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: The presence of AF is common in heart failure patients before and after the placement of a LVAD. However, neither a history of previous AF before LVAD insertion nor the presence of AF following LVAD insertion was related to mortality. Similarly, the development of new AF following LVAD insertion in those without a history of previous AF did not relate to overall mortality.

TRANSLATIONAL OUTLOOK: The presence of AF in an LVAD population is not associated with increased mortality. In clinical practice, the aggressive treatment of AF with adequate ventricular rate control using a rhythm-control strategy (e.g., amiodarone) may not be justified because potential risks of treatment may not outweigh potential benefits. Prospective studies that further examine the frequency, type, treatment, and impact of AF before and after LVAD placement using long-term internal cardiac monitoring are warranted.

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KEY WORDS **atrial fibrillation, cardiac outcomes, left ventricular assist devices, stroke**