



ARTICLE

Pulmonary artery pressure sensor device performance in patients with atrial fibrillation/flutter

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Abstract

Background: Previous studies have demonstrated that hemodynamic-guided management using implantable pulmonary artery (PA) pressure sensor device reduces heart failure (HF) hospitalizations in patients with HF. It is unclear if atrial fibrillation/flutter (AF) affects the performance of the PA pressure sensor.

Methods: Using the National Readmission Database (NRD) we examined 90-day HF-specific and all-cause readmission in patients with and without AF after PA pressure sensor implantation in the US from 2016 to 2020 in a propensity score matched analysis. Our cohort comprised of adult patients (≥ 18 years) with an ICD-10 procedural code for PA pressure sensor implantation.

Results: We included 1515 hospitalizations with PA sensor implantation for 90-day readmission analysis. Among patients implanted with the PA pressure sensor, 17.2% of patients without AF and 16.3% of patients with AF were readmitted primarily for HF within 90-days of discharge (adjusted OR: 1.07, 95% CI 0.61-1.87, $p=0.800$). Whereas, 36.3% of patients without AF and 33.9% of patients with AF were readmitted for any cause within 90-days of discharge (adjusted OR: 0.85, 95% CI 0.53-1.37, $p=0.505$). In subgroup analysis, there was no difference in HF-specific or all-cause readmission in AF patients with HF with reduced ejection fraction or HF with preserved ejection fraction when compared to those without AF.

Conclusions: Analysis of a large, real-world cohort of HF patients with implantable PA pressure sensor showed that HF-specific and all-cause readmissions at 90 days after PA pressure sensor implantation were comparable between patients with and without AF.

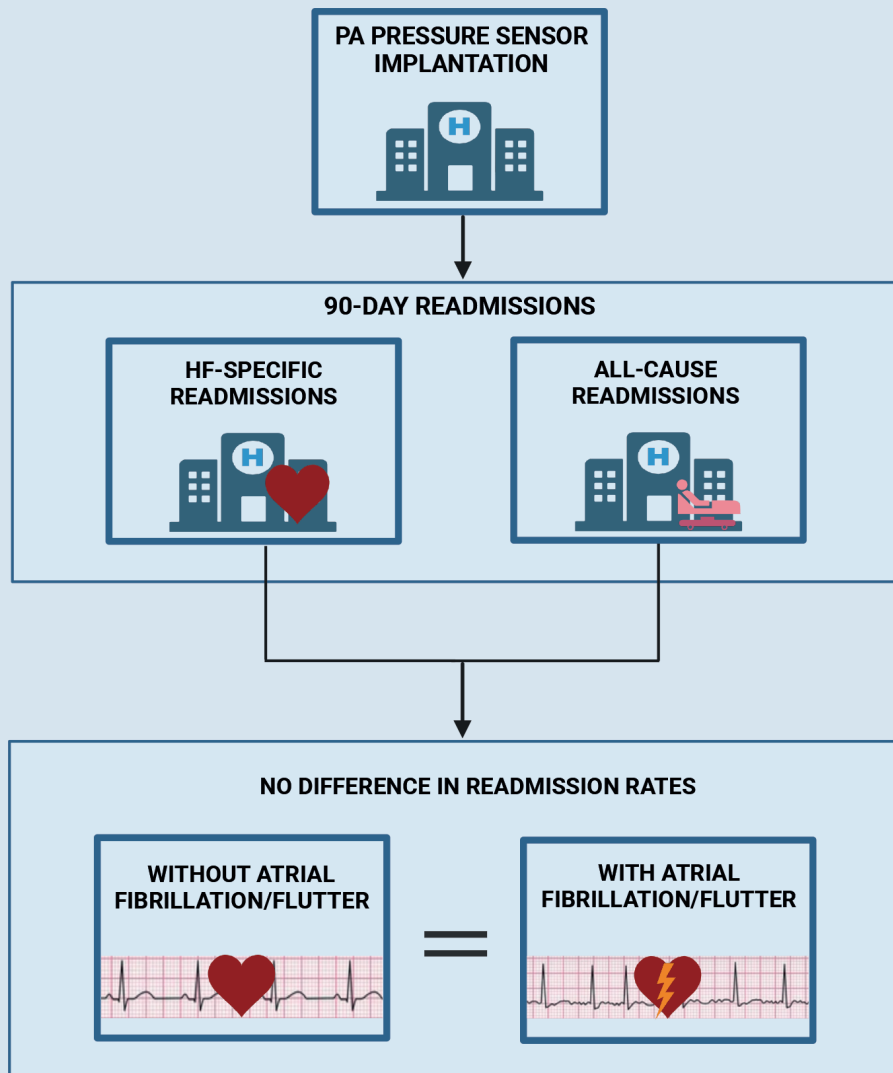
Key words: pulmonary artery pressure sensor; heart failure; atrial fibrillation; atrial flutter.

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Graphical abstract

Central Illustration: Post pulmonary artery (PA) sensor implantation, there was no difference in heart failure (HF) specific or all-cause readmission at 90-days in patients with or without atrial fibrillation/flutter.



Highlights

- Atrial fibrillation/flutter is a common pathology in patients undergoing pulmonary artery sensor implantation.
- Pulmonary artery sensor implantation has similar efficacy in preventing readmissions in patients with and without atrial fibrillation/flutter.
- Pulmonary artery pressure sensor is effective in patients with atrial fibrillation/flutter and HFrEF or HFpEF.

Introduction

Heart failure (HF) is a global health problem and a great burden to the healthcare system associated with high rates of hospitalizations and hospital readmissions. The incidence of HF is reported to be approximately 1 million new patients per year in the United States.¹ HF hospitalizations are a major financial burden to healthcare systems and the major contributors to inpatient costs are co-morbidities, invasive

procedures and hospital readmissions.² Hospital readmissions after HF hospitalization are frequent and negatively impact quality of life of patients with HF. Predictors of early readmission after HF hospitalization include low socioeconomic status,³ weekend admission,⁴ presence of mental health disorders,⁵ co-morbid medical conditions such as atrial fibrillation/flutter (AF).⁶

AF often co-exists with HF and contributes to the development and progression of HF.⁷⁻⁹ Similarly, HF can increase the risk of developing AF in several ways by elevating cardiac filling pressures, dysregulation of intracellular calcium, and autonomic and neuroendocrine dysfunction.¹⁰ Patients with concomitant HF and AF have significantly worse prognosis irrespective of left ventricular systolic function.¹¹ The presence AF also portends higher re-hospitalization risk among HF patients.⁶

Pulmonary artery (PA) pressure hemodynamic monitoring has been shown to reduce HF related hospitalizations and improve quality of life;¹² however, there is limited data on the efficacy of PA pressure hemodynamic monitoring and its impact on readmissions in HF patients with co-morbid AF. AF may potentially affect the accuracy of pressure tracings obtained by the PA pressure sensor device due to its irregular rhythm. This can potentially result in erroneous data interpretation and suboptimal management decisions impacting patient outcomes. Furthermore, AF has been shown to significantly alter the association between pulmonary artery wedge pressure (PCWP) and left ventricular end-diastolic pressure (LVEDP).¹³ Additionally, discrepancy between visually inspected and PA pressure sensor device averaged PA pressure waveforms has been reported in HF patients with co-morbid AF,¹⁴ which can potentially negatively impact the PA pressure sensor performance in patients with AF.

Since AF can potentially complicate the clinical performance of the PA pressure sensor device in patients with HF by affecting the accuracy and interpretation of pressure measurements, we aimed to determine the performance of PA pressure hemodynamic monitoring in HF patients with and without co-morbid AF by evaluating 90-day HF-specific and all-cause hospital readmission rates after PA pressure sensor implantation.

Methods

Design and data source

This was a retrospective analysis involving adult hospitalizations for PA pressure sensor implantation in the US from 2016 to 2020. We extracted our data from National Readmission Database (NRD). The NRD is part of the Healthcare Cost and Utilization Project (HCUP) that is sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NRD is drawn from HCUP State Inpatient Databases (SID) that contain reliable, verified patient linkage numbers that can be used to track a person across hospitals within a State, while adhering to strict privacy guidelines. In 2020, NRD was expanded to in-

clude 31 U.S states accounting for 62.2% of the total U.S resident population and 60.8% of all U.S hospitalizations. Hospitals in the NRD are stratified according to ownership control, number of beds, teaching status, and metropolitan/non-metropolitan location. The NRD contains a weighted sample of hospitalizations, and this can be used to derive national estimates. The study was exempt from institutional board review approval as the NRD database contains deidentified patient information.

Study population

Eligible patients for this study included US adults aged ≥ 18 years with and without AF who underwent inpatient PA pressure sensor implantation between 2016 and 2020. We used International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes for appropriate patient selection (*Supplementary Table 1*). Admissions were excluded as an index admission if the hospitalization had missing data for age, sex or in-hospital mortality, if the patient died during the hospital stay or was transferred to another acute care hospital. In the NRD, patient identifiers cannot be linked across the years, hence patients who had an index hospitalization on October 1 or later in any given year were excluded for the 90-day readmission analysis (Figure 1). Time to readmission was calculated by subtracting length of stay of index admission from time between index admission and the readmission. Planned/elective readmissions were excluded. Readmissions for nonspecific traumatic diagnoses were excluded using the NECODE. The NECODE provides a method of classifying injuries. The NECODE used for nonspecific traumatic readmission exclusion were ICD-10 codes which are "S, T, V, and Y"

Variables

Patient demographics included age, sex, primary insurance and median neighborhood household income (income quartiles were identified referred to patients as 1-low income, 2-middle income, 3-upper middle income and 4-high income) using the NRD variables. In 2020, quartile 1 reflected household income: $\leq \$49,999$; quartile 2: $\$50,000-\$64,999$; quartile 3: $\$65,000-\$85,999$; quartile 4: $\geq \$86,000$. We included hospital-specific variables including hospital bed size, hospital teaching status, and location. Comorbidities were identified using diagnoses codes from the ICD Tenth revision respective to years that were used in the NRD (*Supplementary Table 1*). We used the Charlson Comorbidity Index (CCI) to assess the severity of comorbid conditions.

Outcome measures

Unplanned (i.e., non-elective) readmissions after PA pressure sensor implant in patients with and without AF occurring within 90 days of discharge from the index hospitalization

were assessed. Readmissions were designated as either HF-specific readmissions, i.e., with HF being the primary reason for readmission or all-cause readmissions, i.e., with any reason for readmission. Agency for Healthcare Research and Quality discourages reporting tabulated data in a cell size less than or equal to 10 when using NRD database to protect patient privacy. Hence, in-order to have higher readmission proportion, we opted for 90-day readmission rather than 30-day readmission analysis. Subgroup analysis for HF patients with reduced ejection fraction (HF_rEF) and HF patients with preserved ejection fraction (HF_pEF) was performed. If an index hospitalization had more than one readmission within 90 days, we only included the first readmission for the 90-day readmission analysis.

Statistical analysis

As per specific Healthcare Cost and Utilization Project recommendations, we utilized the Healthcare Cost and Utilization Project STATA survey data analysis packages which incorporate the NRD-specific variables including hospital identifiers, stratum,

and discharge weights to account for clustering and large survey-weighted data analysis to obtain statistical and variance calculations independent of individual hospital discharge characteristics. The Student's *t*-test and the chi-squared test were used to compare continuous and categorical variables, respectively.

We used the propensity score to match patients with AF who had PA sensor device implantation to those who did not have co-morbid AF. A non-parsimonious multivariate logistic regression model was developed to estimate the propensity score for having 90-day readmission. The variables used to estimate the propensity score were age, gender, CCI, patients' household neighborhood income quartile, insurance status, hospital bed-size, hospital urban location and hospital teaching status. The family specified was binomial and link as logit during model building for propensity score. The double robust method was then used to generate treatment weights. Inverse probability of treatment weighting was used to match cases with controls using generalized linear models to estimate the odds of 90-day readmission. All analyses were performed using STATA version 16

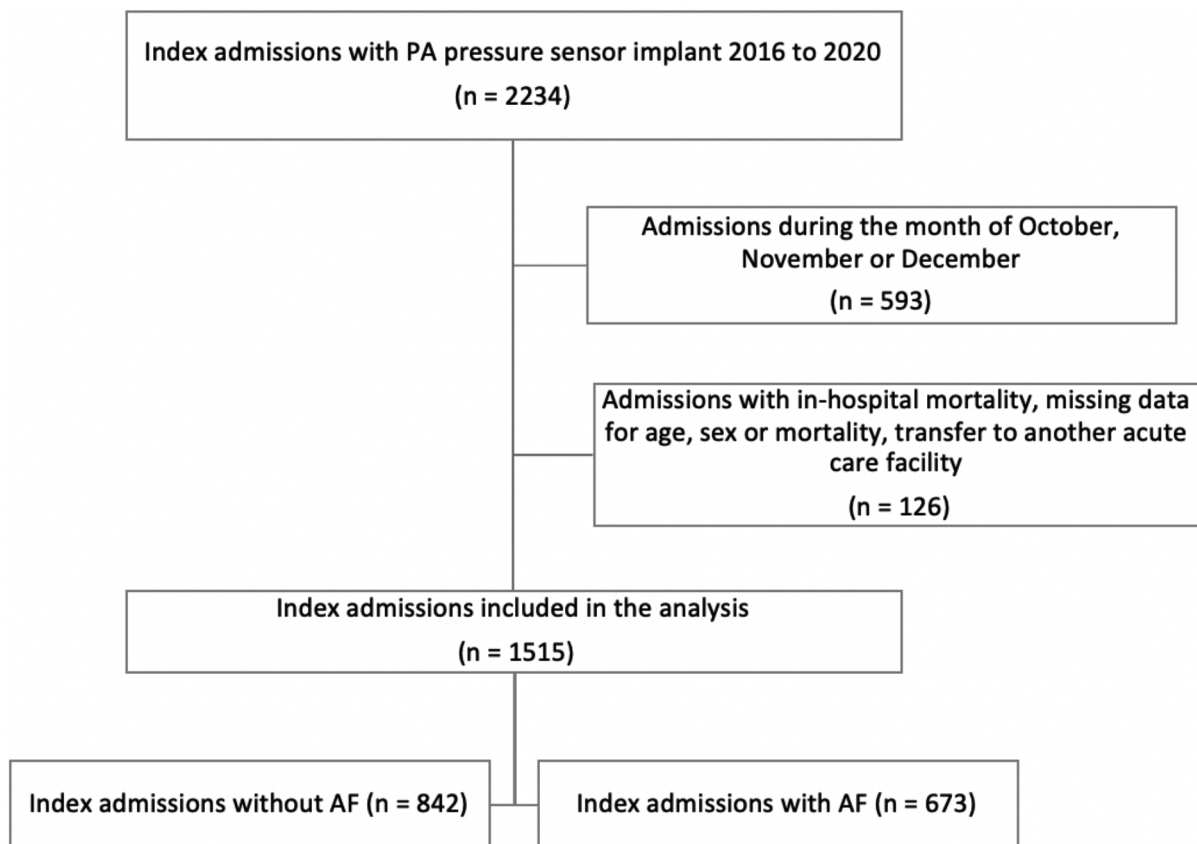


Figure 1. Inclusion criteria for 90-day readmission analysis. PA, pulmonary artery; AF, atrial fibrillation/flutter.

Results

Prevalence of AF among hospitalizations for PA pressure sensor implantation

Among 1515 hospitalizations for PA pressure sensor implantation assessed for the 90-day readmission analysis, 538 patients (35.5%) had co-morbid atrial fibrillation (16.5% paroxysmal, 1.2% persistent, 0.9% permanent, 16.9% unspecified) and 135 patients (8.9%) had co-morbid atrial flutter.

Baseline characteristics

The mean age of patients without AF was 65.7 years and mean CCI was 4.1, whereas the mean age of patients with AF was 68.9 years and the mean CCI was 4.5. Patients with AF were more likely to have complicated hypertension (77.4% vs 64.4%, $p<0.001$), COPD (33.2% vs 24.9%, $p=.014$), protein energy malnutrition (7.3% vs 4.0%, $p=0.039$), HFrEF (61.3% vs 54.1%, $p=0.046$) and liver disease (11.2% vs 7.1%, $p=0.043$) when compared to patients without AF as detailed in Table 1.

Table 1. Baseline patient characteristics for PA pressure sensor implant hospitalizations analyzed for 90-day readmission.

Baseline characteristics	PA pressure sensor implant hospitalizations without AF (n=842)	PA pressure sensor implant hospitalizations with AF (n=673)	p-value
Mean age, years	65.7	68.9	<0.001
Mean length of stay, days	11.1	13.3	0.053
Female, n (%)	354 (42.1)	244 (36.2)	0.149
Index hospitalization on a weekend	124 (14.7)	81 (12.0)	
Insurance, n (%)			0.049
Medicare	599 (71.2)	509 (75.7)	
Medicaid	85 (10.1)	36 (5.3)	
Private insurance	135 (16.0)	120 (17.9)	
Neighborhood household income quartile, n (%)			0.423
First	154 (18.3)	116 (17.2)	
Second	179 (21.3)	125 (18.6)	
Third	232 (27.5)	172 (25.6)	
Fourth	277 (32.9)	260 (38.6)	
Past medical history			
Mean CCI	4.1	4.5	0.031
Uncomplicated hypertension, n (%)	178 (21.2)	91 (13.6)	0.005
Complicated hypertension, n (%)	542 (64.4)	521 (77.4)	<0.001
Diabetes mellitus, n (%)	470 (55.8)	333 (49.5)	0.085
Obesity, n (%)	285 (33.9)	186 (27.6)	0.107
Dyslipidemia, n (%)	522 (62.0)	451 (67.0)	0.191
Peripheral arterial disease, n (%)	64 (7.6)	46 (6.8)	0.733
Smoking, n (%)	76 (9.0)	48 (7.2)	0.401
COPD, n (%)	210 (24.9)	223 (33.2)	0.014
Major depressive disorder (%)	117 (13.9)	96 (14.3)	0.891
Alcoholism, n (%)	30 (3.6)	13 (2.0)	0.103
Protein energy malnutrition, n (%)	34 (4.0)	49 (7.3)	0.039
Non-rheumatic valvular heart disease, n (%)	134 (15.9)	135 (20.1)	0.170
Rheumatic valvular heart disease, n (%)	105 (12.5)	102 (15.1)	0.386
Heart failure with reduced ejection fraction, n (%)	456 (54.1)	413 (61.3)	0.046
Heart failure with preserved ejection fraction, n (%)	197 (23.4)	174 (25.8)	0.461
Right ventricular failure, n (%)	18 (2.2)	41 (6.1)	0.002
Tricuspid regurgitation, n (%)	36 (4.3)	42 (6.2)	0.191
Anemia	386 (45.8)	340 (50.5)	0.209
Presence of pacemaker, n (%)	63 (7.5)	65 (9.6)	0.401
Presence of ICD, n (%)	186 (22.1)	170 (25.3)	0.296
Prior CABG, n (%)	140 (16.6)	108 (16.1)	0.818
Prior PCI, n (%)	159 (18.9)	92 (13.7)	0.029
Prior MI, n (%)	168 (20.0)	116 (17.3)	0.290
Presence of prosthetic valve, n (%)	76 (9.0)	73 (10.9)	0.369
Malignant cancer, n (%)	41 (4.9)	44 (6.5)	0.395
Liver disease, n (%)	60 (7.1)	75 (11.2)	0.043

PA, pulmonary artery; AF, atrial fibrillation/flutter; CCI, Charlson comorbidity index; COPD, chronic obstructive pulmonary disease; ICD, implantable cardioverter defibrillator; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; MI, myocardial infarction.

90-day HF-specific readmission

Among patients implanted with the PA pressure sensor, 17.2% of patients without AF and 16.3% of patients with AF were readmitted primarily for HF within 90-days of discharge (adjusted OR: 1.07, 95% CI 0.61-1.87, $p=0.800$). In subgroup analysis, there was no difference in HF-specific readmission in AF patients with HFrEF (adjusted OR: 0.98, 95% CI 0.53-1.83, $p=0.962$) or HFpEF (adjusted OR: 1.01, 95% CI 0.34-3.02, $p=0.978$) when compared to the patients without AF as shown in Figure 2.

90-day all-cause readmission

Among patients implanted with the PA pressure sensor, 36.3% of patients without AF and 33.9% of patients with AF were readmitted for any cause within 90-days of discharge (adjusted OR: 0.85, 95% CI 0.53-1.37, $p=0.505$). In subgroup analysis, there was no difference in all-cause readmission in AF patients with HFrEF (41.1% vs. 35.5% with adjusted OR: 0.75, 95% CI 0.44-1.27, $p=0.289$) or HFpEF (42.5% vs 40.6% with adjusted OR: 0.89, 95% CI 0.34-2.31, $p=0.812$) when compared to the patients without AF in Figure 3. The five most common etiologies of 90-day readmission post hospitalization for PA sensor implantation are listed in Table 2.

Discussion

In this large, nationwide, observational analysis of hospitalizations of HF patients for PA pressure sensor implantation, we observed comparable rates of HF-specific and all-cause readmissions in patients with and without co-morbid AF. These data are consistent with prior studies demonstrating reduction in HF hospitalizations in patients managed with the PA pressure sensor device.¹⁵ The results of our investigation extend the findings of a previously published study evaluating 117 patients that showed a similar performance of remote PA pressure sensor between HF patients with and without co-morbid AF in reducing HF readmission rates.¹⁶ The diagnosis AF is associated with an adverse prognosis in HF patients with a greater risk of hospitalization and mortality.^{17,18} AF imposes deleterious hemodynamics changes in patients with HF secondary to the beat-to-beat variations in atrial and ventricular preload, myocardial contractility, as well as the rapid ventricular response.^{19,20}

Furthermore, elevated PA pressure or left atrial pressure is associated with increased risk of mortality in HF patients, and even small decreases in PA pressure correlate with decreased mortality.²¹ Implantable PA pressure sensors provide an opportunity to carefully monitor changes in PA pressures remotely in HF patients and allow for early intervention to prevent worsening HF and hospitalizations. While adjusting diuretic therapy and decongestion is central to managing HF patients with the PA pressure sensor, this strategy might not

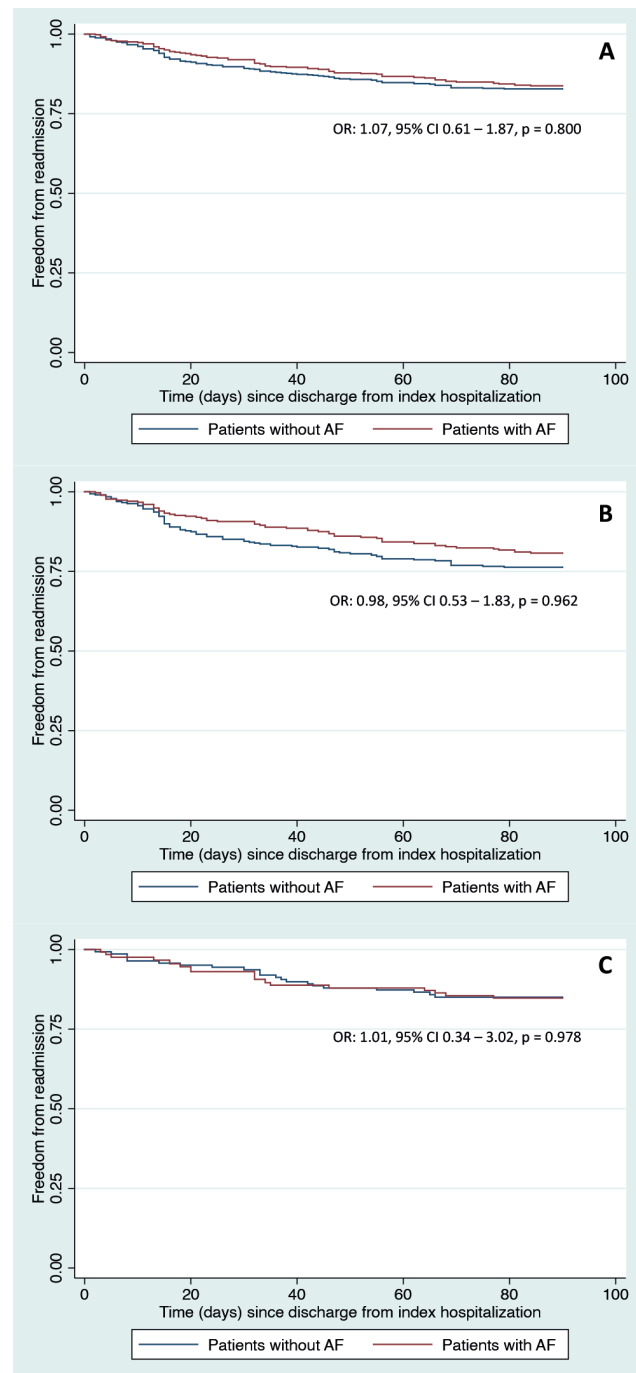


Figure 2. Risk for 90-day HF-specific readmission after PA pressure sensor implant hospitalization (reference group: patients without AF). A) Comparable risk of 90-day HF-specific readmission in all HF patients. B) Comparable risk of 90-day HF-specific readmission in patients with HFrEF. C) Comparable risk of 90-day HF-specific readmission in patients with HFpEF. OR, odds ratio; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; PA, pulmonary artery; AF, atrial fibrillation/flutter.

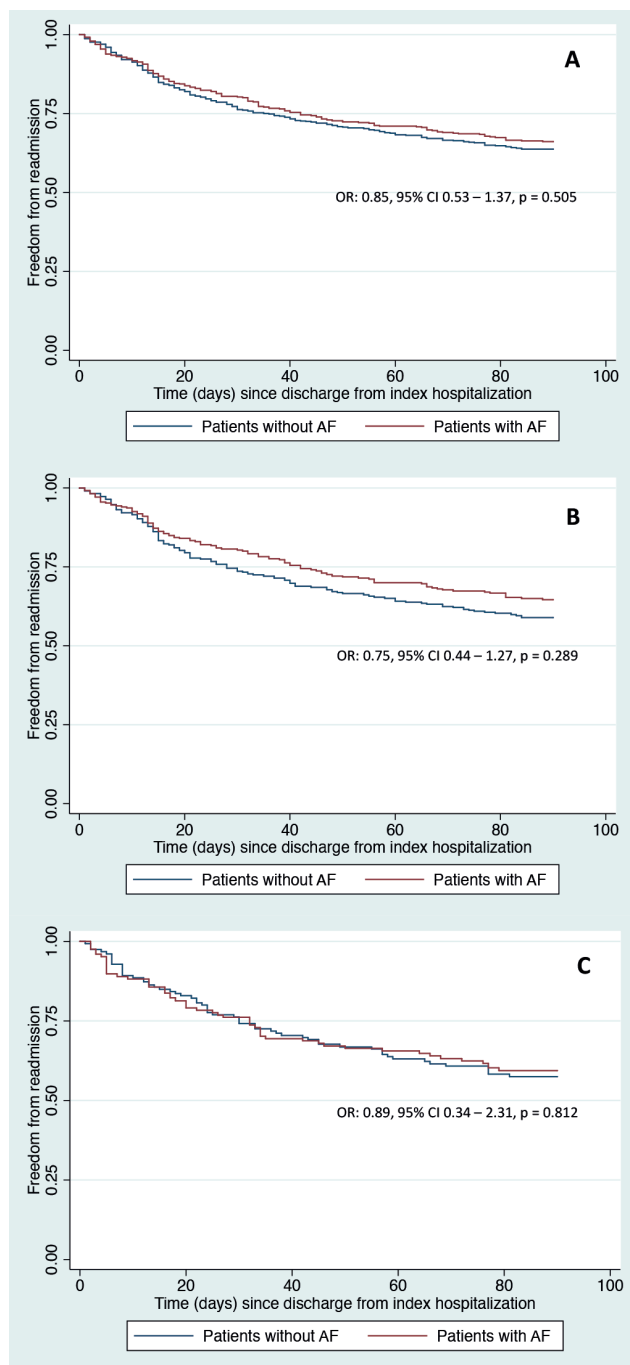


Figure 3. Risk for 90-day all-cause readmission after PA pressure sensor implant hospitalization (reference group: patients without AF). A) Comparable risk of 90-day all-cause readmission in all HF patients. B) Comparable risk of 90-day all-cause readmission in patients with HF rEF. C) Comparable risk of 90-day all-cause readmission in patients with HF pEF. OR, odds ratio; HF, heart failure; HF rEF, heart failure with reduced ejection fraction; HF pEF, heart failure with preserved ejection fraction; PA, pulmonary artery; AF, atrial fibrillation/flutter.

prove effective since changes in PA pressures may not consistently correspond to changes in volume status.²² However, management of HF patients with the PA pressure sensor also offers the opportunity to optimize guideline-directed medical therapy to improve quality of life and survival of HF patients.²³

Although previous clinical trials evaluating the clinical benefits of the PA pressure sensor in HF patients demonstrated reduction in HF hospitalizations, a PA pressure sensor guided approach did not significantly reduce mortality.²⁴⁻²⁶ However, a recent meta-analysis encompassing three pivotal trials evaluating the remote PA pressure sensor (CHAMPION, GUIDE-HF, and MONITOR-HF) reported a significant reduction in a total HF readmission and all-cause mortality.¹⁵ The low rates of HF hospitalization associated with PA pressure implantation found in our study are in line with previously published trials evaluating the clinical benefits of implantable PA pressure sensor for HF management, including CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association Functional Class III Heart Failure Patients) trial, the LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) trial and the GUIDE-HF (Hemodynamic-Guided Management of Heart Failure) trial.^{24,26,27} Those trials collectively included 500 patients (50.7%) with atrial arrhythmias; however, they did not specifically study the effect of arrhythmias on the performance of the PA pressure monitoring device.¹⁵

To the best of our knowledge, our study is the largest analysis comparing the performance of remote PA pressure sensor use in HF patients with and without AF. Our study provides supportive evidence that hemodynamic-guided management using the PA pressure sensor device is feasible, effective in HF patients with AF, and not adversely impacted by atrial arrhythmias.^{13,14}

Table 2. Five most common etiologies of 90-day readmission after hospitalization for PA sensor implantation.

ICD-10 CM code	Etiology of readmission	Percentage of total readmissions
I130	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	23.7%
I110	Hypertensive heart disease with heart failure	7.4%
N179	Acute renal failure	7.0%
A419	Sepsis caused by an unspecified organism	4.2%
I5023	Acute on chronic systolic heart failure	3.6%

Limitations

There are several limitations of this study that merit discussion. NRD database studies are subject to all the biases associated with retrospective analyses including selection, confounding, and measurement biases. We cannot exclude that patients may have been represented in multiple hospitalizations, as the database does not track the same patient across the years. Although patients who died during the PA pressure sensor implant index hospitalization were excluded, our analysis cannot account for competing risk of post-discharge death. We excluded the October to December admissions for the 90-day readmission analysis; hence, our analysis does not account for readmission outcomes of patients admitted for PA pressure sensor implantation during these months. The data regarding guideline directed medical therapy for heart failure and New York Heart Association classification is not available in the NRD, hence, the impact of these factors on readmission outcomes could not be assessed. Since data regarding medical therapy is not available in the NRD, we could not determine baseline diuretic therapy or change in diuretic therapy in response to abnormal PA pressure sensor readings. We could not determine if rate or rhythm control strategy was employed for the management of AF. Given significant proportion of patients with unspecified atrial fibrillation, we could not accurately stratify the readmission outcomes based on different AF phenotypes. The ECG tracings or echocardiography images were not available for illustration purposes. Lastly, the NRD lacks the data regarding circulatory inflammatory cytokines or electroanatomic mapping, hence, the influence of such factors on readmission outcomes could not be determined.

Conclusions

In this large, nationwide, observational analysis of hospitalizations of HF patients for PA pressure sensor implantation, the rates of 90-day HF-specific and all-cause readmissions were similar in HF patients with or without AF. While our results provide supportive evidence that use of the PA pressure sensor device is effective in reducing HF hospitalizations in patients with AF, additional prospective randomized trials are warranted to confirm these findings.

Contributions

MUA, JA, contributed to the analysis of data and drafting the manuscript; MY, RA, contributed to the interpretation of data and drafting the manuscript; NF, contributed to conception of the study and interpretation of data; MAM, RB, contributed to conception of the study and making substantial revisions to the manuscript. All authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest

The authors declare that they have no competing interests, and all authors confirm accuracy.

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Online supplementary material:

Table 1. Diagnosis codes utilized in study.