Am J Cardiovasc Dis 2024;14(2):128-135
www.AJCD.us /ISSN:2160-200X/AJCD0155467

Original Article

Procedural and cardiovascular outcomes of geriatric vs non-geriatric patients undergoing permanent pacemaker implantation - a nationwide cohort analysis

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Received January 15, 2024; Accepted April 9, 2024; Epub April 15, 2024; Published April 30, 2024

Abstract: Background: Permanent pacemaker implantation is increasing exponentially to treat atrio-ventricular block and symptomatic bradyarrhythmia. Despite being a minor surgery, immediate complications such as pocket infection, pocket hematoma, pneumothorax, hemopericardium, and lead displacement do occur. Methods: The Nationwide Inpatient Sample was queried from 2016 to 2018 to identify patients with pacemakers using ICD-10 procedure code. The Chi-square test was used for statistical analysis. Results: The sample size consisted of 443,460 patients with a pacemaker, 26% were <70 years (male 57%, mean age of (60.6±9.7) yr, Caucasian 70%) and 74% were ≥70 years (male 50%, mean age of (81.4±5.9) yr, Caucasian 79%). Upon comparison of rates in the young vs elderly: mortality (1.6% vs 1.5%; P<0.01), obesity (26% vs 13%; P<0.001), coronary artery disease (40% vs 49%; P<0.001), HTN (74% vs 87%; P<0.01), anemia (4% vs 5%; P<0.01), atrial fibrillation (34% vs 49%; P<0.01), peripheral artery disease (1.7% vs 3%; P<0.01), CHF (31% vs 39%; P<0.001), diabetes (31% vs 27.4%; P<0.01), vascular complications (1.1% vs 1.2%; P<0.01), pocket hematoma (0.5% vs 0.8%; P<0.01), AKI (16% vs 21%; P<0.01), hemopericardium (0.1% vs 0.1%; P = 0.1), hemothorax (0.3% vs 0.2%; P<0.01), cardiac tamponade (0.4% vs 0.5%; P<0.01), pericardiocentesis (0.4% vs 0.4%; P<0.01), cardiogenic shock (4% vs 2.3%; P<0.01), respiratory complications (1.9% vs 0.9%; P<0.01), mechanical ventilation (5.1% vs 2.9%; P<0.01); post-op bleed (0.5% vs 0.3%; P<0.01), need for transfusion (4.8% vs 3.8%; P<0.01), severe sepsis (0.6% vs 0.5%; P<0.01), septic shock (2% vs 1%; P<0.01), bacteraemia (0.8% vs 0.4%; P<0.01), lead dislodgement (1.4% vs 1.1%; P<0.01). Conclusions: Our study revealed that the overall complication rates were lower in the elderly despite higher co-morbidities. This aligns with previous studies which showed lower rates in the elderly. Hence providers should not hesitate to provide guideline driven pacemaker placement in the elderly especially in patients with good life expectancy.

Keywords: Pacemaker, NIS, elderly, pacemaker complications, sinus node dysfunction

Introduction

As life expectancy has increased, individuals requiring pacemakers have increased accordingly. Indications for pacemaker implantation include treatment of symptomatic bradyarrhythmia, Mobitz type II and complete heart block. With advancements in technology, pacemaker insertion techniques and imaging guidance have helped increase procedure safety and decrease procedure time. The average age of pacemaker recipient has increased over time with about 70-80% of pacemakers implanted in patients over 65 years of age [1]. In other countries, rates of PPM insertion and prevalence has shown to correlate with increasing age. In a previous study, rates of implantation in patients over 75 years were double those of patients aged 65-74 years [2]. Cardiovascular comorbidities such as obesity, hypertension (HTN), type II diabetes mellitus (DMII), coronary artery disease (CAD), congestive heart failure (CHF),

arrhythmias syndromes are higher in older population. Overall complication rates with PPM insertion vary between 3.3-3.8%, but because of these comorbidities, complication rates with PPM insertion are often thought to be higher in the elderly [3, 4].

Postprocedural complications include hematomas, pocket infections, pneumothorax, and lead dysfunction/dislodgements. Despite physician beliefs that elderly patients have higher complication rates, literature has shown that rates are similar between elderly and young patient populations. In addition, despite these complications, several studies have shown that placement of permanent pacemakers can improve quality of life, physical activity and relieve symptoms [5-7]. In this study, we aim to better elucidate the risks and benefits of pacemaker implantation in the elderly by analyzing the effects of comorbidities and age on complication rates and in-hospital mortality in patients receiving their first permanent pacemaker.

Methodology

Data source

We utilized the United States National Inpatient Sample (NIS) database for the years 2016 to 2018 to identify adult patients (≥18 years) who underwent permanent pacemaker implantation. Patients who underwent PPM were identified using ICD 10-codes. The NIS database is part of the Healthcare Cost and Utilization Project (HCUP) and is created by the agency for healthcare research and quality. All states that participate in the HCUP provide data and it covers >95% of the US population. NIS contains data pertaining to 5-8 million hospital stays from approximately 1,000 hospitals [8]. The dataset was designed to incorporate data from a 20% sample of discharges from all participating hospitals, which helps deliver stable, and precise estimations. The NIS database includes data from all short-term, non-federal, general, and other specialty hospitals in the US (rehabilitation and long-term acute care hospitals were excluded) in the form of de-identified patient information containing demographics, discharge diagnoses, comorbidities, procedures, outcomes, and hospitalization costs. The NIS database is publicly available and contains deidentified patient information, hence no Institutional Review Board approval was required.

Study population and patient characteristics

We performed a three-year population-based retrospective cross-sectional analysis from 2016-2018 in patients 18 years or older. We included all patients ≥18 years who underwent PPM implantation using the International Classification of Disease-10 (ICD-10) diagnosis codes and procedure codes. We excluded patients with missing data for age, sex, or mortality. We also excluded patients with indications for transfer to another acute-care facility to reduce the chance of data duplication. Additionally, we excluded patients who had generator changes or lead extractions. We identified study population, comorbidities, complications, and in-hospital outcomes using a combination of *ICD-10* codes. **Table 1** shows baseline patient characteristics which include age, sex, race, LOS (length of stay), total charges, ownership of hospital, region of hospital, bed size of hospital, indication of PPM, DNR (Do not resuscitate) status, co-morbidities, and complications among the two cohorts. Patients were also split into groups of <70 years (younger) and ≥70 years (elderly).

Study outcomes

The primary outcomes of this study were the rates of co-morbidities, indications of PPM, in-hospital mortality, and complication rate in patients <70 years (younger) and ≥70 years (elderly) with permanent pacemakers. Secondary outcomes evaluated in this study were mean total hospitalization charges, LOS, insurance type, geographic region, and bed size of hospital.

Statistical analysis

Statistical analyses were conducted using SPSS Statistics 25.0 (IBM Corp., Armonk, New York) software. Categorical variables were expressed as percentages and continuous variables as mean ± SD for normally distributed data or median with interquartile range for skewed data. Means and univariate linear regression were used for comparing total hospitalization charges, costs, and LOS. One-way ANOVA was used to compare means of two or more samples, Chi-square test of indepen-

Table 1. Baseline characteristics of study population

Variable (PPM)	Elderly (≥70 years) (n = 328615)	Younger (<70 years) (n = 114845)	*P*-value
Age (Years) (Mean)	81.4±5.9	60.6±9.7	<0.01
Male	50 (%)	57 (%)	<0.01
LOS (M ± SD)	5.64±5.9	7±9.9	<0.01
Total charges (USD)	118779±124760	153062±203216	<0.01
In-hospital mortality	1.5%	1.6%	<0.01
Race			<0.01
White	79 (%)	70 (%)	
Black	7 (%)	11 (%)	
Hispanic	7 (%)	10 (%)	
Others	6 (%)	9 (%)	
Insurance			<0.01
Medicare	93 (%)	46 (%)	
Medicaid	1 (%)	13 (%)	
Others (private/self-pay)	6 (%)	41 (%)	
Control/Ownership of hospital			<0.01
Government/Non-federal	7%	10%	
Private-non profit	78%	76%	
Private-invest-own	15%	14%	
Location/teaching status of hospital			<0.01
Rural	5.2%	4.7%	
Urban non-teaching	24.5%	21.4%	
Urban teaching	70.3%	74%	
Region of hospital			<0.01
Northeast	21%	17.2%	
Midwest	23%	23.4%	
South	37.2%	40%	
West	19%	20%	
Bed size of hospital			<0.01
Small	14.3%	13%	
Medium	30%	27.5%	
Large	56%	59.5%	
SSS/SND	45%	37%	<0.01
Second degree AV block	13.3%	11%	<0.01
Third degree AV block	35%	39%	<0.01
DNR status	8.8%	1.8%	<0.01
Comorbidities*			
Dyslipidemia	2.3 (%)	1.8 (%)	<0.01
DM11	27.4 (%)	31.2 (%)	<0.01
Tobacco use disorder	34 (%)	40.5 (%)	<0.01
Alcohol use disorder	1.3 (%)	4.2 (%)	<0.01
Cocaine	0.1 (%)	0.8 (%)	<0.01
Cannabis	0.1 (%)	1.2 (%)	<0.01
Opioids	0.3 (%)	1.9 (%)	<0.01
Obesity	13 (%)	26 (%)	<0.01
CAD	49.2 (%)	40.2 (%)	<0.01
HTN	87 (%)	74 (%)	<0.01

Anemia	4.8 (%)	3.8 (%)	<0.01
Chronic lung disease	22 (%)	22 (%)	0.5
CHF	39 (%)	31 (%)	<0.01
Chronic liver disease	1.5 (%)	3.7 (%)	<0.01
PAD	3 (%)	1.7 (%)	<0.01
Prior prosthetic valve	4.9 (%)	4.7(%)	0.03
A. Fib	49 (%)	34 (%)	<0.01
CKD	29 (%)	15 (%)	<0.01
ESRD	2.5 (%)	5.5 (%)	<0.01
Coagulopathy	5.4 (%)	6.2 (%)	<0.01
Pulmonary Hypertension	10.6 (%)	8.1 (%)	<0.01
Cerebrovascular disease	0.9 (%)	0.8 (%)	0.2

PPM = Permanent pacemaker; LOS = length of stay; M = Mean; SD = Standard Deviation; USD = US dollar; SSS/SND = Sick sinus syndrome/Sinus node dysfunction; AV = Atrioventricular; DNR = Do not resuscitate; DMII = diabetes mellitus type II; CAD = coronary artery disease; HTN = Hypertension; CHF = congestive heart failure; PAD = peripheral artery disease; A. Fib = Atrial fibrillation; CKD = Chronic kidney disease; *ICD-10 codes were utilized to identify the comorbidities.

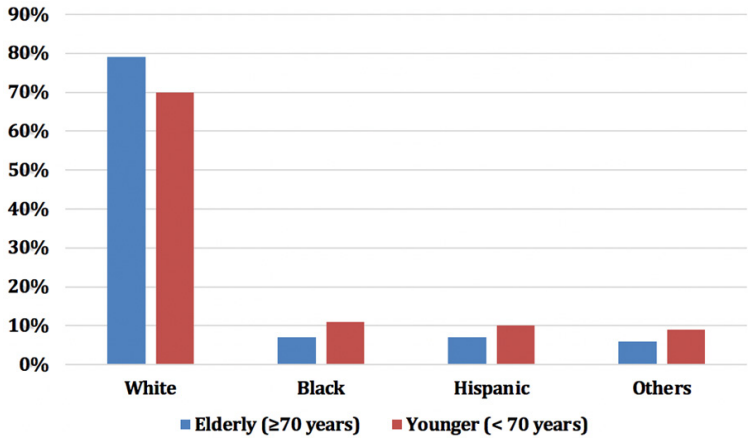

Figure 1. Race distribution amongst elderly and younger patient population.

dence, and Fisher's exact test for categorical variables as mentioned in **Table 1**. National estimates were calculated by applying discharge weights to the discharge data. All statistical analyses were performed with the Type I error rate set to 0.05.

Results

During the year 2016-2018, 443,460 patients underwent permanent pacemaker implantation in the US. Overall, the mean age for the study population was 61 years, majority of the patients were male (57%), and Caucasians (70%). We further divided the dataset into two cohorts: age ≥70 years (elderly/Geriatric cohort) and age <70 years (younger/non-geriatric cohort). Mean age in the two groups were 81 years and 61 years respectively. Caucasian patients were most likely to receive a PPM and the rates were higher among older Caucasians (**Figure 1**). Among the younger cohort, male patients were more likely to receive a PPM implantation, but the rates were similar among both sexes in the elderly group. Majority of the patients who underwent PPM placement had Medicare, but the rates of private insurance use was significantly higher in patients <70 years (39% vs 6%). Most of the PPMs implanted were in private, non-profit hospitals, urban teaching hospitals, large bed size hospitals, and hospitals in the southern region of the US (**Figure 2**). The rates of DNR status were 9% in the elderly and 2% in the younger patient population.

The most common indication of PPM was sick sinus syndrome/sinus node dysfunction (SSS/SND, 43%), followed by third degree heart block (33%) and second-degree heart block (13%) (**Figure 3**). The most common comorbidities among all PPM recipients were HTN (84%), CAD (47%), tobacco use disorder (36%), DMII (28.4%), CKD (25%), CHF (37%), and chronic lung disease (22%). Overall, the rates of the following comorbidities were higher in the elderly: dyslipidemia (2.3% vs 1.8%), CAD (49% vs 41%), peripheral artery disease (3% vs 1.7%), CHF (39% vs 31%), anemia (4.8% vs 3.8%), pulmo-

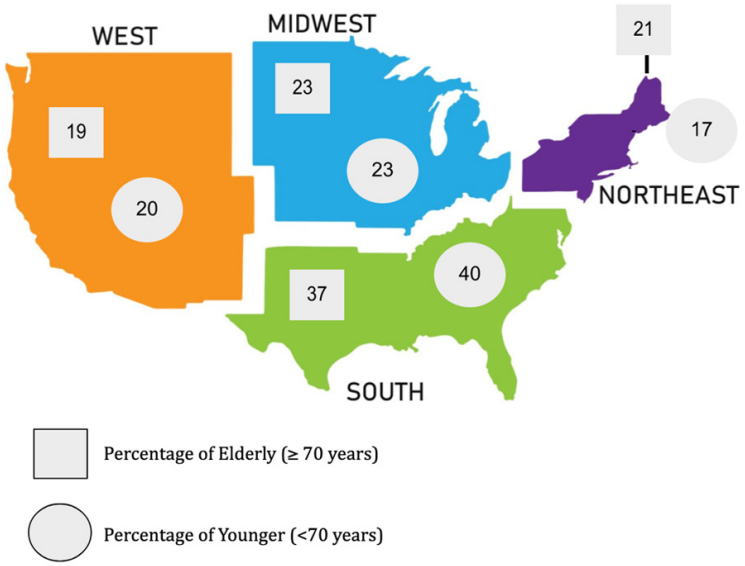

Figure 2. Percentage of patients with pacemakers amongst the elderly and younger populations.

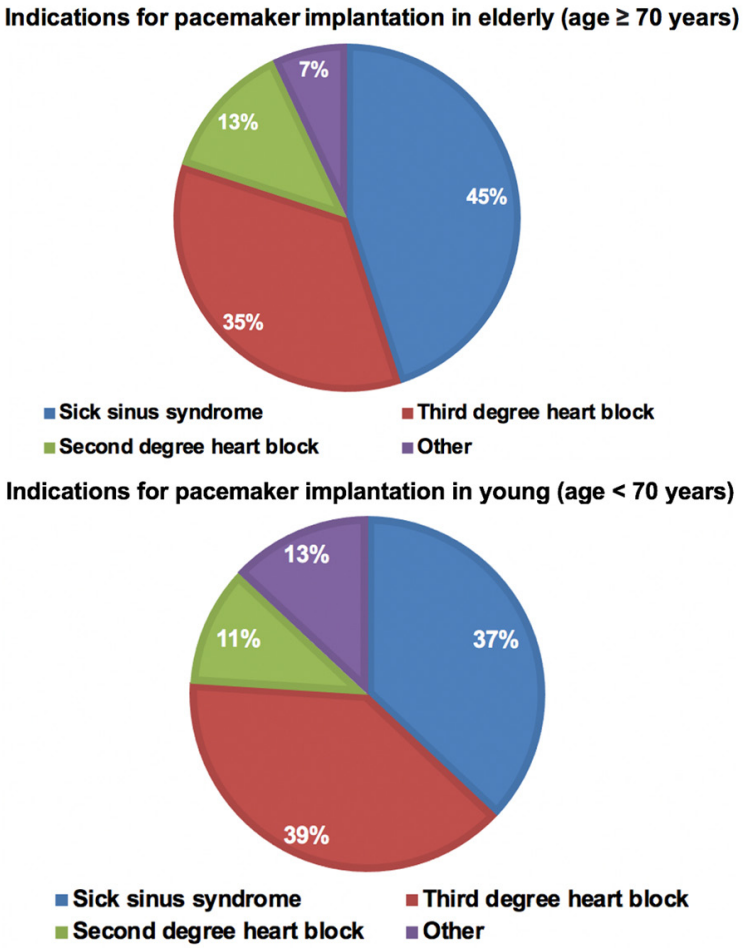

Figure 3. Indications of pacemaker implantation amongst elderly and younger patient populations.

nary hypertension (11% vs 8%), HTN (87% vs 74%), AF (49% vs 34%), and CKD (29% vs 15%). However, the rates of alcohol use disorder (1.3% vs 4.2%), DMII (27% vs 31%), tobacco use disorder (34% vs 41%), cocaine (0.1% vs 0.8%), cannabis (0.1% vs 1.2%), opioids (0.3% vs 1.9%), obesity (13% vs 26%), chronic liver disease (1.5% vs 3.7%), ESRD (2.5% vs 3.5%), and coagulopathy (5.4% vs 6.2%) were lower in the elderly. Upon comparison of complication rates, the following were higher in the elderly: AKI (21% vs 17%), vascular complications (1.2% vs 1.1%), pocket hematoma (0.8% vs 0.5%), cardiac tamponade (0.5% vs 0.4%), and pericardiocentesis (0.5% vs 0.4%). The in-hospital mortality rates were almost similar in both groups (1.5% vs 1.6%). The following complications rates were lower in the elderly: hemothorax (0.2% vs 0.3%), cardiac complications (2.8% vs 4.4%), cardiogenic shock (2.3% vs 4%), respiratory complications (0.9% vs 1.9%), post-op bleed (0.3% vs 0.5%), need for transfusion (3.8% vs 4.8%), mechanical ventilation (2.9% vs 5.1%), bacteremia (0.4% vs 0.8%), severe sepsis (0.5% vs 0.6%), septic shock (1% vs 2%), and lead dislodgement (1.1% vs 1.4%). There were no differences in the rates of AV fistula (0.1% vs 0.1%), pseudoaneurysm, hemoperitoneum (0.1% vs 0.1%), and hemopericardium (0.1% vs 0.1%) (**Tables 1**, **2**).

Discussion

Permanent pacemakers are routinely used to treat bradyarrhythmias, such as heart block and sick sinus syndrome. With current advancements, the incidence of PPM placement has

Table 2. Complications of permanent pacemaker placement

	Complications		
Variable (PPM)	Elderly (≥70 years) (n = 328615)	Younger (<70 years) (n = 114845)	*P*-value
AKI	21 (%)	16.3 (%)	<0.01
Vascular complications	1.2 (%)	1.1 (%)	<0.01
Arteriovenous Fistula	0.1 (%)	0.1 (%)	<0.01
Pseudoaneurysm	0.1 (%)	0.1 (%)	0.1
Local site hematoma	0.8 (%)	0.5 (%)	<0.01
Hemoperitoneum	0.1 (%)	0.1 (%)	0.8
Hemopericardium	0.1 (%)	0.1 (%)	0.1
Hemothorax	0.2 (%)	0.3 (%)	<0.01
Cardiac complications	2.8 (%)	4.4 (%)	<0.01
Tamponade	0.5 (%)	0.4 (%)	<0.01
Pericardiocentesis	0.5 (%)	0.4 (%)	<0.01
Cardiogenic shock	2.3 (%)	4 (%)	<0.01
Respiratory complications	0.9 (%)	1.9 (%)	<0.01
Post-operative bleed	0.3 (%)	0.5 (%)	<0.01
Need for blood transfusions	3.8 (%)	4.8 (%)	<0.01
Mechanical ventilation	2.9 (%)	5.1 (%)	<0.01
Infection			
Bacteremia	0.4 (%)	0.8 (%)	<0.01
Severe sepsis	0.5 (%)	0.6 (%)	<0.01
Septic shock	1 (%)	2 (%)	<0.01
Lead dislodgement	1.1 (%)	1.4 (%)	<0.01

ESRD = End stage renal disease; AKI = acute kidney injury.

been rising steadily with over 600,000 devices placed annually [9]. The main indications remain sick sinus syndrome, third degree hart block, Mobitz type II second degree heart block, tachycardia-bradycardia syndrome, symptomatic bradycardia, and cardiomyopathies [10]. Aging of the conduction system is commonly seen in the elderly. Infiltrative cardiac disease, myocardial infarction, heart block after valve replacement, alcohol septal ablation are some of the etiologies for PPM implantation especially in the younger population [10]. As the incidence of sinus node dysfunction and AV block increases with age, need for PPM implantation in the elderly is increasing. Most of the trials exclude elderly patients, thus limiting outcomes data in this age group. The average age of pacemaker recipient is now 75 years ±10 years [4]. Previous studies have investigated the effects of age on pacemaker safety and complication rates after PPM placement [11-13]. Over the years, one study has shown an increase in pacemaker implantation with an increase in age at implantation despite patients having higher comorbidities [14]. In previous studies, although periprocedural complications such as pneumothorax was higher in older patients, the total rate of periprocedural complications were comparable to historical values [6]. Our study showed that the rate of pacemaker hematoma and cardiac tamponade was higher in the elderly which is similar to previously published data in the elderly population [3, 13]. Despite this the overall complication rate was lower in patients over 70 years of age. In another study, all complications, except for pneumothorax, were higher in patients less than 70 years, including lead dislodgement and infections. This current study demonstrates similar findings, with complication rates of hemothorax, cardiogenic shock, respiratory complications, post-op bleed, need for transfusion, mechanical ventilation, bacteremia, severe sepsis, septic shock, lead dislodgement being higher in patients less than 70 years. Even among patients >80 years, the rates of complications were similar to those of younger patients [7]. Furthermore, the rates of complication beyond the periprocedural period were found to be independent of age [6, 11-13, 15].

In addition to age, comorbidities are also used to risk-stratify pacemaker implantation. Previous studies have shown that comorbidities independently influence mortality in patients undergoing PPM [16]. Five-year survival rates following PPM placement have been found to be lower in patients with Charlson Comorbidity Index (CCI) >7, when compared to patients with lower CCI in a retrospective study from 20 years ago [17]. Previously, prolonging life expectancy was one of the major indications for PPM however with expansion of indications to symptom control, improving exercise tolerance, pacemakers are being implanted in patients with higher comorbidities. With improved medical management patients with multiple co-morbidities are overall living longer. More recent studies have shown improved survival in elderly with PPM, one study showed nonagenarians with PPM implantation had 30% higher survival compared to nonagenarians without PPM with similar comorbidities [1, 18]. This current study demonstrated that even though patients over 70 had higher comorbidities of CAD, PAD, CHF, Anemia, Pulmonary Hypertension, HTN, AF, and CKD, they had similar in-hospital mortality rates to younger patients receiving pacemakers. Although this study did not assess long term outcomes following PPM placement, these results indicate that post-procedurally PPMs are safe even in older patients. Age and comorbidities should not specifically be a hinderance to pacemaker implantation especially with newer and modern device implantation techniques. Cephalic vein access and imaging guidance for access and lead fixation which have shown to decrease complication rates [19]. Use of cephalic cut down, screw in lead, creation of sub pectoral pocket can be techniques used to decrease pneumothorax, lead dislodgement and pocket hematoma/infection in the elderly [20]. In addition, quality of life should be considered as an indication for PPM implantation despite higher comorbidities. Symptom relief remains an indication for pacemaker implantation in the elderly, especially those with good life expectancy. PPMs are therefore effective therapies for patients aged 80 and older with life expectancies of at least 8 years and have been shown to improve quality of life [21].

Despite having the advantage of being the largest inpatient database in the United States, the NIS database has some limitations. The database may underestimate the total PPM implantation rates as it does not capture outpatient procedures and may have inappropriate coding. The accuracy of data depends highly on training and expertise of the coders. The available data is cross-sectional and does not provide long term outcomes. In addition, the NIS suffers from the absence of clinical data such as medications and laboratory values which could play an important role in determining outcomes.

Conclusions

In summary, this study represents real-world experience in a large population of patients undergoing PPM implantation. Our study found that overall complication rate was lower in the elderly despite higher co-morbidities. This is similar to previous studies where the rates were lower in the elderly. Hence guideline driven pacemaker placement in elderly should be performed especially in patients with good life expectancy.

Disclosure of conflict of interest

None.

Abbreviations

AF, atrial fibrillation; AKI, acute kidney injury; CAD, coronary artery disease; CHF, congestive heart failure; CKD, chronic kidney disease; DMII, diabetes mellitus type II; DNR, Do not resuscitate; ESRD, end-stage renal disease; HTN, Hypertension; HCUP, Healthcare Cost and Utilization Project; ICD-10, International Classification of Disease-10; NIS, National Inpatient Sample; PPM, permanent pacemaker; PAD, peripheral arterial disease.

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