

Pacemaker implantation in the extreme elderly

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Abstract

Introduction There are scant data for pacemaker implant complications and readmission rates in the extreme elderly (age ≥ 80 years) despite their common use in this population. **Methods** This is a retrospective chart review of consecutive patients ($n=149$, age ≥ 80 years) who underwent pacemaker implantation at a community hospital electrophysiology program from July 2008 through June 2010. Single-, dual-, and biventricular-chamber pacemakers and generator changes were included for analysis; cardioverter-defibrillator devices, temporary pacemakers, and loop recorders were excluded. Standard procedures for implantation were used. Major complications were defined as death, cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemothorax, pneumothorax, transient ischemic attack, stroke, myocardial infarction, pericardial tamponade, and arteriovenous fistula. Minor complications were defined as drug reaction, conduction block, hematoma or lead dislodgement requiring reoperation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection. **Results** The overall mean age of implantation was 86 years. There were no intraprocedural complications. There was one major in-hospital complication (0.7%) and one minor in-hospital complication (0.7%). Within 30 days of implantation, there was an overall 5.4% rate of complications; four minor

(2.7%) and four major (2.7%). There was a 30-day cardiovascular-attributable mortality of 0.7% and an all-cause mortality of 2%. There was a 5.4% rate of readmission within 30 days of implantation.

Conclusions This report of pacemaker implantations in the extreme elderly reveals rates of implant complications comparable to data from younger patient populations while experiencing a higher 30-day all-cause mortality (that may be attributable to elevated all-cause mortality rates in this age group).

Keywords Device · Pacemaker · Implant · Complication · Elderly · Outcomes

Abbreviations

VVI Single-chamber ventricular pacemaker
DDD Dual-chamber pacemaker
BiV Biventricular

1 Introduction

The extreme elderly are the most rapidly growing segment of the US [1, 2] and pacemakers are commonly implanted in this population. There are few reports of pacemaker implant complications and outcomes in the extreme elderly and there is a persistent exclusion of elderly patients from ongoing clinical trials [3]; this paucity of data makes it difficult to estimate risks of device implantation for informed consent in this population. This is a retrospective chart review of extreme elderly patients (age ≥ 80 years) undergoing pacemaker implantations in the first 2 years of a newly established community hospital electrophysiology (EP) program.

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2 Methods

2.1 Patient population

Consecutive patients aged ≥ 80 years who underwent pacemaker implantation by two electrophysiologists (RTS and JLW) at The Good Samaritan Hospital Invasive Cardiac Electrophysiology Laboratory starting with its inception on July 2008 through June 2010 were included for retrospective analysis. This retrospective study was approved by The Good Samaritan Hospital Ethics Committee. Single-, dual-, and biventricular-chamber pacemakers and generator changes were included for analysis; cardioverter–defibrillator devices, temporary pacemakers, and loop recorders were excluded. The Good Samaritan Hospital is a 215-bed, not-for-profit, nonacademic, community hospital with open heart surgery.

2.2 Implant procedures

Standard procedures for implantation were used. Warfarin was held for any transvenous procedure (with few exceptions) but uninterrupted for generator changes. The majority of implantations were performed using subclavian venous approach but cephalic venous cutdown was utilized on occasion. Left subclavian puncture was guided by left subclavian venography unless contrast allergy or significant renal disease precluded its use. In addition, micropuncture kit was used for the first subclavian puncture and fluoroscopic-guided, first-rib approach was used for all subclavian punctures. Active fixation leads were used in the atrium and right ventricle (RV). Passive fixation leads were used in the RV and coronary sinus (CS).

Procedural sedation was provided by cardiac anesthesiology with few exceptions. Generally, procedures were performed under monitored anesthesia care though general anesthesia was used at the anesthesiologist's discretion. As a rule, all biventricular pacemaker implants were performed under general anesthesia using a laryngeal mask airway or endotracheal tube to minimize risk of patient movement during CS lead placement.

CS access was obtained using a 5-F steerable octapolar EP catheter or a 0.035-in. J-tip guidewire, depending on operator preference. Left ventricular (LV) leads were placed only if they were within the range from 2:30 to 5:30 o'clock in left anterior oblique view. CS venography was performed to assess anatomy and plan lead delivery unless contrast allergy or significant renal disease precluded its use. Routine portable chest radiographs were performed post-implant (RTS); all patients had postoperative day 1 posterior–anterior and lateral chest radiographs (read by radiologists).

2.3 Data analysis

Major and minor complications were defined based upon prior reports of device-related complications [4–7]. Major complications were defined as death, cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemothorax, pneumothorax, transient ischemic attack (TIA), stroke, myocardial infarction, pericardial tamponade, and arteriovenous fistula. Minor complications were defined as drug reaction, conduction block, hematoma or lead dislodgement requiring reoperation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection. All complications that occurred within 30 days of implantation were included for analysis (http://www.medicare.gov/Hospital/Static/InformationforProfessionals_tabset.asp?activeTab=2&Language=English&version=&subTab=5#POC3) [6, 8]. Hospital admission data were used retrospectively to ensure inclusion of all readmissions and complications; outpatient electronic medical records were analyzed to evaluate for possible admissions to a different medical center and complications not requiring hospitalization. Data are reported as the mean \pm standard deviation. Statistical comparisons were performed using a binary logistic regression model (SPSS V. 16, IBM Corp., Somers, NY, USA) using backward condition (stepwise) multivariate analysis and Hosmer–Lemeshow test of goodness-of-fit for the model. Model estimation was terminated at the iteration when model parameter estimates ($-2 \log$ likelihood) change by <0.001 . Gender (M/F), complications (yes/no), readmissions (yes/no), urgent/emergent placement (yes/no), and device type (VVI, DDD, BiV pacemaker, and generator change) were defined as categorical variables and all other parameters were defined as continuous variables. A p value ≤ 0.05 was considered statistically significant.

3 Results

3.1 Patient population

A total of 149 patients were included for analysis. Data were available for 96.7% of patients except ejection fraction (EF) on 3 of 92 pacemaker implantations. Table 1 depicts the demographics and type of device implanted for patients in this study. The overall mean age of implantation was 86.2 ± 4.5 years, with a mean creatinine of 1.3 ± 0.5 and mean EF of 0.53 ± 0.12 . Ninety-one of 149 patients (61.1%) were female.

3.2 Implant procedures

The majority (95.7%) of pacemaker implantations were performed via subclavian venous approach, with 4.3% via

Table 1 Demographics and device type of patients

	Overall (n=149)	VVI (n=16)	DDD (n=71)	BiV pacemaker (n=5)	Generator change (n=57)
Age (years)	86.2±4.5	89.3±4.8	84.8±3.8	84.6±2.1	87.2±4.7
Female	61.1%	81.3%	60.6%	40%	57.9%
Weight (kg)	73.9±18	62.9±11.3	76.9±16.5	82.0±23.7	72.5±19.6
Creatinine (mg/dL)	1.3±0.5	1.2±0.4	1.3±0.5	1.8±1.1	1.3±0.5
EF	0.53±0.12	0.54±0.11	0.57±0.08	0.28±0.08	0.5±0.13

VVI single-chamber ventricular pacemaker, DDD dual-chamber pacemaker, BiV biventricular

cephalic cutdown. Passive fixation (tined) leads were used in 68.5% (n=63) of RV pacing leads and 100% of LV pacing leads; the remainder of leads were active fixation. LV pacing leads (n=5) were successfully placed in 83.3% of patients in whom LV lead placement was attempted (n=6). Of 92 pacemaker implants, 17 (18.5%) were single-chamber systems. Of 92 pacemaker implants, 10 (10.9%) were placed urgently or emergently.

Fluoroscopy time in minutes was 10.4±8.5 for pacemaker implantations. Contrast was used in 55 of 92 (59.8%) of the pacemaker implantations; mean intravenous

contrast usage was 9.5 cm³. No contrast was used for generator changes. There were no contrast reactions.

3.3 Complications in-hospital or within 30 days

There were no intraprocedural complications. In-hospital major complications occurred in 1 of 149 patients (0.7%) and minor complications occurred in 1 of 149 patients (0.7%). Within 30 days of implantation, there was an overall 5.4% rate of complications; four minor (2.7%) and four major (2.7%) complications. There was a 30-day

Table 2 Device type and presentation for patients with complications and/or readmissions within 30 days of implant

	Implant type	Presentation	Postoperative day number	Treatment
Complication				
1	DDD	Atrial lead dislodgement (noncapture)	0	Patient opted for no revision
2	VVI	Death (GI bleed)	2	N/A
3	VVI	Drug reaction (rash)	3	Antibiotics discontinued
4	DDD	Superficial thrombophlebitis (left upper extremity swelling)	4	Supportive (no anticoagulation)
5	VVI	CVA (left arm weakness)	7	Heparin/coumadin
6	DDD	Death (unknown cause)	23	N/A
7	DDD	TIA (mental status changes)	27	Heparin/coumadin
8	Generator change	Acute cholecystitis	29	N/A
Readmission				
1	Upgrade DDD to BiV pacemaker	Diaphragmatic stimulation	2	Device reprogramming
2	VVI	CHF (shortness of breath)	2	Diuresis
3	DDD	Superficial thrombophlebitis (left upper extremity swelling)	4	Supportive (no anticoagulation)
4	Generator change	Clostridium difficile colitis (abdominal discomfort and diarrhea)	5	Supportive with antibiotics
5	VVI	CVA (left arm weakness)	7	Heparin/coumadin
6	VVI	COPD exacerbation (shortness of breath)	13	Supportive with antibiotics
7	Generator change	Pneumonia (shortness of breath, cough, fever)	19	Supportive with antibiotics
8	DDD	TIA (mental status changes)	27	Heparin/coumadin

DDD dual-chamber pacemaker, VVI single-chamber ventricular pacemaker, GI gastrointestinal, N/A not available, CVA cerebrovascular event, TIA transient ischemic attack, CHF congestive heart failure, COPD chronic obstructive pulmonary disease, BiV biventricular

cardiovascular-attributable mortality of 0.7% and an all-cause mortality of 2%. Seven of eight (87.5%) complications occurred in females. The average age of patients experiencing major or minor complication was 88.5 ± 4.5 years. Table 2 lists the device type and presentation for complications occurring within 30 days of implantation. Major and minor complications within 30 days of implantation were seen in 3 of 16 (18.8%), 4 of 71 (5.6%), 0 of 5 (0%), and 1 of 57 (1.8%) VVI, DDD, BiV pacemaker, and generator changes, respectively.

3.4 Hospital utilization within 30 days

The mean hospital stay (from implant to discharge) for pacemakers was 2.1 days (range=1–22 days) Fifty-two of 57 (91.2%) generator changes were same-day procedures; 5 of 57 (8.8%) generator changes stayed overnight after their procedure. Eight of 149 patients (5.4%) were readmitted within 30 days of implantation. Six of eight readmissions (75%) occurred in females. The average age of patients experiencing readmission was 85.3 ± 4.8 years. Table 2 lists the device type and presentation for patients readmitted within 30 days of implantation. Readmissions were seen in 3 of 16 (18.8%), 2 of 71 (2.8%), 1 of 5 (20%), and 2 of 57 (3.5%) VVI, DDD, BiV pacemaker, and generator changes, respectively.

3.5 Possible factors influencing rates of complication and readmissions

Multivariate analysis was used to assess the influence of various factors on complication and readmission rates. The binary logistic regression model using backward condition (stepwise) analysis starts with the possible covariates (age, sex, weight, creatinine, EF, device type, urgent/emergent placement) and at each step (iteration) removes the least significant covariate until the model estimates demonstrate no improvement. None of the covariates demonstrated a statistically significant influence on complication or readmission rates. Table 3 examines possible factors influencing complication rates. The order of decreasing significance of covariates for complications was urgent/emergent>sex>device>EF>age>weight>creatinine. Overall, female sex, device type, and urgent/emergent placement demonstrated a nonsignificant trend toward increased rates of complication. Table 4 examines possible factors influencing readmission rates. The order of decreasing significance of covariates for readmissions was device type>age>creatinine>urgent/emergent>EF>sex>weight. Overall, increased age and device type demonstrated a nonsignificant trend toward increased readmission rate.

Table 3 Backward conditional (stepwise), binary logistic regression modeling of complication covariates

Observed	Predicted	Variables (covariates) included in each iteration				
		Major/minor complication			Percentage correct	
		No	Yes			
Step 1	Major/minor complication	No	140	1	99.3	Age, sex, weight, creatinine, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.0		
Step 2	Major/minor complication	No	140	1	99.3	Age, sex, weight, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.0		
Step 3	Major/minor complication	No	140	1	99.3	Age, sex, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.0		
Step 4	Major/minor complication	No	140	1	99.3	Sex, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.0		
Step 5	Major/minor complication	No	140	1	99.3	Sex, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.0		
Step 6	Major/minor complication	No	141	0	100.0	Sex, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage		94.6		

No *p* values reached significance ($p < 0.05$)

Table 4 Backward conditional (stepwise), binary logistic regression modeling of readmission covariates

Observed	Predicted	Variables (covariates) included in each iteration				
		Readmission			Percentage correct	Variables (covariates) included in each iteration
		No	Yes			
Step 1	Readmission	No	141	0	100.0	Age, sex, weight, creatinine, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 2	Readmission	No	141	0	100.0	Age, sex, creatinine, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 3	Readmission	No	141	0	100.0	Age, creatinine, EF, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 4	Readmission	No	141	0	100.0	Age, creatinine, device type, urgent/emergent
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 5	Readmission	No	141	0	100.0	Age, creatinine, device type
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 6	Readmission	No	141	0	100.0	Age, device type
		Yes	8	0	0.0	
		Overall percentage			94.6	
Step 7	Readmission	No	141	0	100.0	Device type
		Yes	8	0	0.0	
		Overall percentage			94.6	

No *p* values reached significance (*p*<0.05)

4 Discussion

These data suggest that overall rates of implant complications are comparable to data from younger patient populations though a higher 30-day all-cause mortality. Table 5 depicts the device implant complications of prior reports compared to this extremely elderly cohort. Of note, these prior studies included patients of all ages (not exclusively elderly) and are depicted in reverse chronological order (to highlight complication rates as techniques and results have evolved). The majority of prior studies did not report post-implant length of stays or hospital readmission rates. In addition, there were only two prior studies that described complication rates in patients with a mean age >80 years [9, 10]. A retrospective chart review of 17,826 patients undergoing pacemaker implantation during a 3-year period in Germany was performed by Nowak et al. [9]. They only included data from implantation until hospital discharge. Noseworthy et al. [10] specifically looked at defibrillator implant complications (and had average EF of 0.36) but was included for comparison because they specifically looked at patients aged >80 years. The rates of implant complications, readmissions, and lengths of stays from our report compare

favorably to those in prior reports despite the advanced age of this population.

The 0.7% in-hospital all-cause mortality is comparable to other reports of elderly patients [6, 9, 11]. The 2% 30-day all-cause mortality in this study is higher than that seen in prior reports of substantially younger pacemaker implant populations [6, 8, 12–14]; however, there are no other reports that provide an accurate 30-day mortality rate for pacemaker implantation in the extreme elderly. Nowak et al. [9] provided data for implant and in-hospital complications only. Furthermore, death was not listed explicitly as a complication but they reported a 0.6% rate for ventricular fibrillation in patients aged >90 years. When US death rates are examined for ages >80 years, there is a 6.4–13.0% annual mortality rate [15]; this crudely translates to a 0.5–1.1% 30-day mortality rate for this age group independent of concomitant surgery. This US population-based 30-day mortality rate for patients aged >80 years may help explain our 30-day all-cause mortality when compared to outcomes in pacemaker trials of substantially younger patients (especially given our 0.7% cardiovascular-attributable 30-day mortality rate).

Over 10% of patients (10 of 92) in this series had their pacemaker placed urgently or emergently, which has been

Table 5 Device implant complications of prior reports compared to this extremely elderly cohort listed in reverse chronological order

Study	Year	No. of patients	Mean age	Patients aged >80 years (%)	Lead dislodgements (%)	PTX (%)	Perforation (%)	Infection (%)	In-hospital death (%)	Early all-cause mortality (%)	Length of stay post-implant (days)	Hospital readmission rate (%)
Present ^a	2011	149	86	100	1.1	0	0	0	0.7	2.0 (30 days)	2.1	5.4
[7] ^b	2010	125	79	56	0	0	0	0.7	0	0 (6 weeks)	2.1	4.4
[9] ^c	2009	17,826	75.5	38.7	3.0	0.5	0.2	0.1	0.1	N/A	N/A	N/A
[11] ^d	2007	1,198	73.7	N/A	2.1	1.9	0.2	0.5	0.9	N/A	3	N/A
[27] ^e	2005	1,884	72.1	N/A	2.6	0.6	0.1	0.5	N/A	N/A	N/A	N/A
[10] ^f	2004	29	83.3	100	0	3.4	3.4	3.4	0	20.6 (1 year)	N/A	N/A
[8]	2003	2,010	74	N/A	2.6	1.5	0.3	0.2	0	0.7 (30 d)	N/A	N/A
[28]	2003	1,214	71	N/A	0.9	0.6	0.08	0.33	N/A	N/A	N/A	N/A
[12] ^g	1999	446	72	N/A	6.4	1.1	0.7	1.1	0	0 (2 weeks)	N/A	4.9–6.3
[6]	1998	407	76	N/A	2.2	2	1.0	0.25	0.25	0.25	3.1	N/A
[13] ^h	1995	1,088	74.8	N/A	1.4	1.7	0	0.9	0	0 (2 months)	N/A	3.3
[14] ⁱ	1995	598	69.7	N/A	4.6	3	0.2	0.5	0	0 (6 weeks)	N/A	5.6
[23] ^j	1995	519	70	29	N/A	1.5	0.2	0.4	N/A	N/A	N/A	N/A
[29]	1994	2,019	N/A	N/A	1.6	0.6	0	0.8	N/A	0.1	N/A	N/A
[26] ^k	1989	632	N/A	N/A	1.9	1.7	0.6	0.6	N/A	N/A	N/A	N/A

^a No patient died within 24 h of pacemaker implant. In-hospital death at 48 h due to gastrointestinal bleed^b Data are for 6 weeks follow-up. Manuscript reported length of stay from initial hospitalization; data presented here represents post-implant length of stay. There was one wound dehiscence in patients that underwent pacemaker implant ($n=81$) or pacemaker generator changes ($n=55$)^c Data available for implant and in-hospital complications only. There were 6,904 patients aged >80 years. Hemothorax was defined as a perforation for this table. Death was not listed but rates of ventricular fibrillation was 0.1% for all patients and 0.6% for patients aged >90 years^d Only in-hospital events were reported^e Complications are for the first 3 months; 12.4% death rate over the mean 5-year follow-up (early death rate not provided); 13.8% of patients lost to follow-up^f Study of implantable defibrillators in age >70 years. Average EF of patients age >80 years was 0.36^g Readmission rate was 4.9% at 2 weeks and 6.3% at 3 months^h 3.2% rate of reoperation; readmission rate not providedⁱ Data available for 586 of 598 patients. Readmission rate not provided; there was 5.6% rate of reoperation^j Perforation rate not reported; results are for tamponade only. Follow-up was not available for 13% of patients^k Hemothorax ($n=4$) counted as perforation; 14.7% of complications not listed in Fig. 5 of their paper

implicated in elevated complication rates due to cardiac perforation [16]. Of these 10 urgent/emergent cases, there was one minor (atrial lead dislodgement) and one major complication (TIA) though no perforations or deaths. We found that emergent/urgent placement demonstrated a nonsignificant trend toward readmission rates but not complication rates.

4.1 Limitations

This report has a limited sample size though, in fact, may be biased toward higher complication rates because it included the first 149 consecutive implants of patients aged ≥ 80 years undergoing pacemaker implantation since the inception of the program. Extreme elderly was defined by age ≥ 80 years based upon prior reports [10, 17–21]. One could argue that the patient population was biased to favor uncomplicated patients. Our prior report of device implants suggested that the patient population in our center is generally a more elderly, ill patient population than in prior reports [7]. We included generator changes in this report as this procedure is performed routinely in the extreme elderly and prior reports have suggested “disappointingly high” rates of complications (6.5%) in patients undergoing pacemaker generator changes [22]. We chose a 30-day window for complications as this is consistent with prior reports [6, 8] and mortality/complications over longer time frames may reflect other complicating illness (especially in an extremely elderly cohort), patient behavior, or post-discharge care received (<http://www.hospitalcompare.hhs.gov/staticpages/for-professionals/ooc/data-collection-methods.aspx>). Though the Good Samaritan Hospital is the only hospital in the county and the authors (RTS and JLW) are the only providers of EP services at this hospital, this is not a “closed system” and underestimation of complications/readmissions is possible.

There was a low rate of VVI implants in this study; 81.5% of patients had DDD or BiV pacing systems. This is comparable to a prior report of 76% of patients receiving DDD systems [23]. In addition, the Pacemaker Selection in the Elderly Investigators [24] found that 26% of patients with single-chamber pacing developed pacemaker syndrome and had to be crossed over to dual-chamber pacing. In MOST, clinical pacemaker syndrome was demonstrated in 48.9% of crossover patients [25]. Our report is of two, larger-volume operators (> 12 cases per year) [26] and consistent with data suggesting that DDD pacemakers do not have higher rates of implant complication when compared with VVI pacemakers [13, 23] as well as data that frequent implanters are more prone than infrequent implanters to utilize DDD pacemakers [26]. Indeed, our series reveals a bias toward DDD devices, possibly to avoid subjecting patients to the added risk of a repeat procedure.

Of note, there are reports that describe higher rates of complications with DDD versus VVI systems [9, 11, 12, 27–29]. Interestingly, we found that device type (specifically VVI) had nonsignificant trend towards higher complication rates; the VVI group had the highest age of 89.3 years when compared to patients receiving DDD, BiV pacemakers, or generator changes.

5 Conclusion

Our data contribute to the body of knowledge concerning pacemaker implantation in the extreme elderly and suggest that pacemaker implantation in the extreme elderly can be performed safely. We found overall rates of implant complications comparable to data from younger patient populations while experiencing a higher 30-day all-cause mortality (that may be attributable to elevated all-cause mortality rates in this age group). Multivariate analysis revealed that none of the covariates analyzed demonstrated a statistically significant influence on complication or readmission rates. Female sex, device type, and urgent/emergent placement demonstrated a nonsignificant trend toward increased rates of complication; increased age and device type demonstrated a nonsignificant trend toward increased readmission rate. These data provide a “real-world” examination of short-term complication rates in the extreme elderly and can serve as the basis of a more informed consent process for device implantation in this age group that is increasing in prevalence.

Disclosure The authors report no conflicts of interest.

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