

Patient Demographics, Complications, and Hospital Utilization in 250 Consecutive Device Implants in a New Community Hospital Electrophysiology Program—Implications for ‘Niche’ Hospitals

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Background: Single-center reports on patient demographics and early (<6 weeks) device complication rates in academic hospitals are scant and non-existent for non-academic community hospital electrophysiology (EP) programs. **Objective:** The objective of our study was to examine the demographics, complications, re-admissions, and accessibility of care in a community EP program to add to the body of knowledge of ‘real-world’ defibrillator implant complications. **Methods:** Two hundred and fifty consecutive patients who underwent device implantation by a single electrophysiologist in a new non-academic community hospital EP program starting from its inception in July 2008 were included for analysis. Standard procedures for implantation were used. Pacemakers, defibrillators, and generator changes were included; temporary pacemakers were excluded. Major complications were defined as in-hospital 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 re-operation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection. **Results:** This community cohort had similar ejection fractions but was older with worse kidney function than those studied in prior reports. There was one major early complication (0.4%) and seven minor early complications (2.8%). Left ventricular lead placement was successful in 64 of 66 patients (97%). **Conclusions:** This is the first community-hospital-based EP program to examine device implant demographics and outcomes, and revealed an elderly, ill population with lower overall rates of complications than seen in national trials and available reports from single non-community centers. Contrary to current perceptions, these data suggest that community centers may subselect an elderly, ill patient population and can provide high-quality, cost-effective, and more accessible care.

There are reports that community hospitals have lower-risk, less ill patients compared with non-community centers.^{1,2} It is also suggested that non-community centers have better outcomes for a variety of conditions.^{3,4} Finally, Medicare provides non-community hospitals (e.g. academic teaching hospitals) more reimbursement than it costs to care for patients via indirect and direct medical education adjustments to account for treating ‘sicker’ patients.^{5,6}

Single-center reports on patient demographics and early (<6 weeks) device complication rates in non-community hospitals are scant and non-existent for non-academic community hospital electrophysiology (EP) programs. A newly established clinical cardiac EP program sought to be the first community hospital-based program to examine the demographics, complications, and re-admission rates associated with the initial 250 consecutive device implant patients.

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Methods

Patient Population. The first 250 consecutive patients who underwent device implantation by a single electrophysiologist (JLW) at The Good Samaritan Hospital Clinical Cardiac Electrophysiology Program, starting from its inception in July 2008, were included for analysis. Pacemakers, defibrillators, and generator changes were included; temporary pacemakers and implantable loop recorders were excluded. The Good Samaritan Hospital is a 215-bed not-for-profit, non-academic community hospital that performs open heart surgery.

Implant Procedures. Standard procedures for implantation were used. Generator changes, single-chamber, dual-chamber, and bi-ventricular pacemaker and defibrillator implantations were included. Warfarin was held for any transvenous procedure but uninterrupted for generator changes. The majority of implantations were performed using the subclavian venous approach, but cephalic venous cut-down 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, a micropuncture kit was used for the first subclavian puncture, and a fluoroscopic-guided, first-rib approach was used for all subclavian punctures. Active fixation leads were used in the atrium and for ventricular defibrillation leads, but passive leads were used in the vast majority of ventricular pacing (and coronary sinus [CS]) leads.

Procedural sedation was provided by cardiac anesthesiology with few exceptions. Generally, generator changes, pacemakers, and defibrillator implants were performed under monitored anesthesia care, although general anesthesia was used at the anesthesiologist's discretion. As a rule, all bi-ventricular defibrillator implants were performed under general anesthesia using a laryngeal mask airway or endotracheal tube to minimize the risk of patient movement during CS lead placement.

CS access was obtained using a 5F steerable octapolar EP catheter. Left ventricular (LV) leads were placed only if they were within the range from 2:30 to 5:30 o'clock in the left anterior oblique (LAO) view. CS venography was performed to assess anatomy and plan lead delivery unless contrast allergy or significant renal disease precluded its use. Defibrillation threshold testing was performed in the vast majority of patients to ensure a 10J safety margin. In the event of issues with defibrillation thresholds, single CS coils were placed using curved stylets. Routine stat portable chest radiographs were not performed post-implant; all patients had post-operative day one posterior

anterior (PA) and lateral chest radiographs (read by radiologists). Patients >80 years of age underwent early mobilization four hours post-operatively.

Data Analysis. Major and minor complications were defined based on prior reports of device-related complications.⁷⁻⁹ Major complications were defined as in-hospital 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 re-operation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection. All complications that occurred within six weeks of implantation were included for analysis. Hospital admission data were used both prospectively and retrospectively to ensure inclusion of all re-admissions and complications; outpatient electronic medical records were analyzed to evaluate for possible admissions to a different medical center and complications not requiring hospitalization. Data were reported as mean \pm standard deviation (SD). Statistical comparisons were performed using a two-tailed, paired Student's t-test. A p-value \leq 0.05 was considered statistically significant.

Results

Patient Population. A total of 250 patients were included for analysis. Data were available for 99.6% of the patients except for ejection fraction on one of 55 generator changes. The mean age for pacemaker, implantable cardioverter-defibrillator (ICD), bi-ventricular ICD, and generator changes were 77 ± 10 , 67 ± 12 , 74 ± 9 , and 80 ± 10 years, respectively. Ninety of 250 implants (36%) were in females; females represented 47, 16, 22, and 56.6% of pacemaker, ICD, bi-ventricular ICD, and generator changes/implants, respectively. The mean creatinine (mg/dl) for pacemaker, ICD, bi-ventricular ICD, and generator changes was 1.2 ± 0.5 , 1.3 ± 0.8 , 1.4 ± 0.6 , and 1.2 ± 0.5 , respectively. Finally, the mean ejection fraction for pacemaker, ICD, bi-ventricular ICD, and generator changes was 0.57 ± 0.08 , 0.31 ± 0.11 , 0.24 ± 0.07 , and 0.48 ± 0.14 , respectively.

Implant Procedures. The majority (98%) of pacemaker implantations were performed via the subclavian venous approach with 2.0% via cephalic cut-down. Passive fixation (tined) leads were used in 90% (n=73) of the right ventricular (RV) pacing leads and 100% of the LV pacing leads; the remainder of the leads were active fixation. Atrial leads were placed in all bi-ventricular ICDs. Six of 81 pacemaker implants (7.4%) were placed urgently or emergently.

Fluoroscopy time (mean ± SD) was 8.7±4.6, 11.2±10.8, and 34.6±19.5 minutes for pacemakers, ICDs, and bi-ventricular ICDs, respectively. Contrast was used in 58 of 81 (71.6%), 41 of 50 (82%), and 60 of 64 (93.8%) of the pacemakers, ICDs, and bi-ventricular ICDs, respectively. Intravenous contrast totaled (mean ± SD) 16.6±7.2, 16.5±5, and 33.4±19.5cc for pacemakers, ICDs, and bi-ventricular ICDs, respectively. There were no contrast reactions.

An LV lead was unable to be placed in two patients. The first patient had only anterior CS branches that were unsuitable for LV lead placement. The second patient had persistent left superior vena cava (SVC) with no significant LV branches for lead placement; a dual-chamber ICD was successfully placed via the left persistent SVC.

Complications at Implant or within Six Weeks. Major complications occurred in one of 250 patients (0.4%) and minor complications occurred in seven of 250 patients (2.8%). The average age of the patients (mean ± SD) experiencing a major or minor complication was 78±9 years. *Table 1* lists the complications and treatment required. There was one major complication for pacemaker implantations (n=81, incidence 1.2%). This cerebrovascular accident occurred on post-implant day seven in a patient with atrial fibrillation whose warfarin was held for implant; subsequent venous thrombosis in the same patient outside the six-week time-frame revealed a factor V Leiden mutation. There were no major complications in ICD (n=50) or bi-ventricular ICD (n=64) implantations. The total major complication rate for all device implantations was one in 250 (0.4%). There were no deaths. Minor complications occurred in three of 81 (3.7%), two of 50 (4%), and two of 64 (3.1%) pacemaker, ICD, and bi-ventricular ICD implantations, respectively. The total minor complication rate for all device implantations was seven of 250 (2.8%). There were no major or minor complications in 55 generator changes.

Hospital Utilization within Six Weeks. The mean hospital stay for pacemakers, ICDs, and bi-ventricular ICDs was 4.1 days (range one to 22), 2.4 days (range one to 23), and 2.7 days (range one to 16), respectively. Eleven of 250 patients (4.4%) were re-admitted within six weeks of the implant. Four of these 11 readmissions (36.4%) were not device-related. The average age of patients (mean ± SD) requiring re-admission was 82±4 years. *Table 2* lists the patient characteristics for those re-admitted.

Discussion

To our knowledge, we are the first US community-hospital-based EP program to examine the demographics, complications, and re-admission rates associated with 250

Table 1: Patient Complications

COMPLICATION	AGE	PRESENTATION	DAYS POST-OP	TREATMENT
Atrial lead dislodgement (BiV ICD)	65	CXR, loss of capture	1	Revision
Coronary sinus lead dislodgement (BiV ICD)	85	CHF, loss of capture	3	Revision
Cerebrovascular accident (PPM)	81	Left arm weakness	7	Heparin/warfarin
Antibiotic reaction (D-ICD)	66	Rash	3	Observation
Antibiotic reaction (BiV ICD)	81	Urosepsis/rash/VT/ICD firing	8	Antibiotics/steroids, CHF treatment
Superficial thrombophlebitis (D-ICD)	84	Left upper extremity swelling	4	Supportive measures (no anticoagulation)
Internal jugular venous thrombosis (D-ICD)	75	Left neck pain	15	Heparin/coumadin
Device infection (DDD)	88	Wound dehiscence	31	Antibiotics/explant

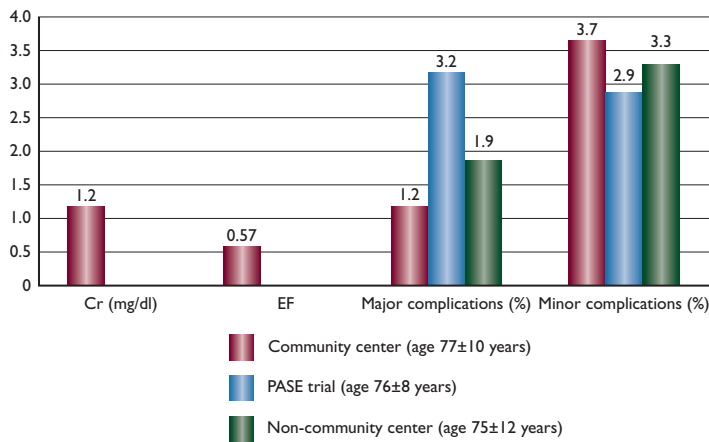
AF = atrial fibrillation; BiV = bi-ventricular; CHF = chronic heart failure; CXR = chest X-ray; DDD = dual-chamber pacemaker; D-ICD = dual-chamber implantable cardioverter-defibrillator; ICD = implantable cardioverter-defibrillator; PPM = permanent pacemaker; VT = ventricular tachycardia.

Table 2: Patient Admissions

AGE	PROCEDURE	INDICATION	POST-OP DAY PRESENTATION	REASON FOR RE-ADMISSION
88	VVI	AF/SSS	31	Device infection
75	AVN/DDD	AF/SSS	3	Polymyalgia rheumatica
81	BiV ICD	ICMP (30%)	5	Presyncope unrelated to arrhythmia
81	BiV ICD	ICMP (15%)	8	Antibiotic reactions (rash), urosepsis VT requiring device therapy, CHF
85	BiV ICD	NICMP (15%)	2	CHF from atrial lead dislodgement and resultant AV dyssynchrony
79	BiV ICD	ICMP (30%)	6	Hematoma from polycythemia vera autophlebotomizing into pocket
82	VVI	AF/SSS	13	COPD exacerbation
84	DDD	SSS, symp brady	4	Superficial thrombophlebitis, no anticoagulation
85	DDD generator change	ERI	19	Pneumonia
76	D-ICD	ICMP (32%)	15	Left internal jugular thrombus
81	VVI	AF/SSS	7	Cerebrovascular accident

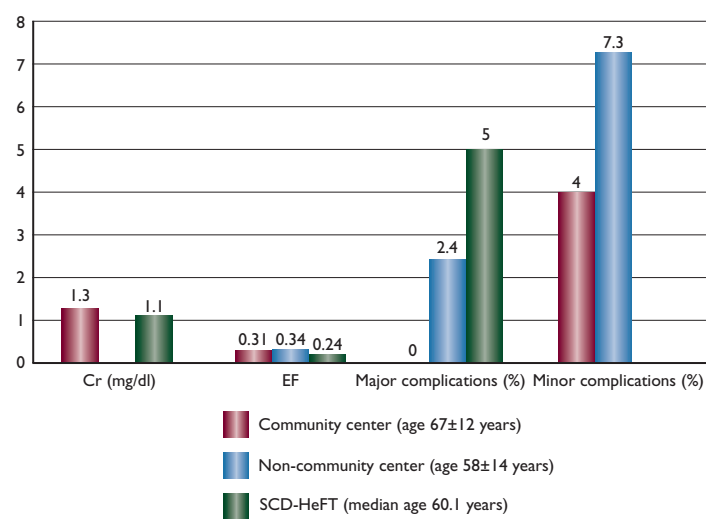
AF = atrial fibrillation; AV = atrioventricular; AVN = atrioventricular node; BiV ICD = bi-ventricular implantable cardioverter-defibrillator; CHF = chronic heart failure; COPD = chronic obstructive pulmonary disease; DDD = dual-chamber pacemaker; D-ICD = dual-chamber implantable cardioverter-defibrillator; ERI = elective replacement indicator; ICD = implantable cardioverter-defibrillator; ICMP = ischemic cardiomyopathy; NICMP = non-ischemic cardiomyopathy; SSS = sick sinus syndrome; symp brady = symptomatic bradycardia; VT = ventricular tachycardia; VVI = single-chamber pacemaker.

Figure 1: Baseline Characteristics and Complications of Patients Undergoing Pacemaker Implantation



A total of 81 patients underwent pacemaker implantation. Complications at our center (a community center) were compared with those from a national trial (PASE Trial⁹) and a single non-community center.¹⁰ Neither ejection fraction (EF) nor creatinine (Cr) was reported for the compared trials.

Figure 2: Baseline Characteristics and Complications of Patients Undergoing Defibrillator Implantation



A total of 50 patients underwent defibrillator implantation. Complications at our center (a community center) were compared with those from a national trial (SCD-HeFT¹¹) and a single non-community center.⁸ Creatinine (Cr) was not reported for the single center's series. Percent minor complications were not reported for SCD-HeFT. EF = ejection fraction.

consecutive device implant patients in this setting. Our data add to the body of knowledge concerning 'real-world' rates and types of device implantation complication as well as re-admission rates after device implantation. In particular, our data provide an objective glimpse into the level of care quality and accessibility that can be offered in a community hospital. This report revealed an elderly, ill population with lower overall rates of complications than seen in national trials and available reports from single non-community

centers. *Figures 1–3* depict the demographics and complication rates seen in this report versus those reported from non-community centers and national trials.^{8–13} Of note, attempts were made to extrapolate the complication rates from these studies using literature-established definitions^{7–9} of major and minor complications when details were available to allow a more accurate comparison. We examined possible predictors of complications and re-admissions to our center based on patient demographics. Age was a significant predictor of re-admissions ($p=0.00017$) and showed a non-significant trend as a predictor of complications ($p=0.32$). Neither creatinine nor ejection fraction was a significant predictor of complications or re-admissions ($p>0.5$).

A recent study of the national ICD registry examined complication rates based on physician certification.⁷ For ICDs, electrophysiologists had overall and major complication rates of 2.7 and 1.1%, respectively. For bi-ventricular ICDs, electrophysiologists had overall and major complication rates of 4.8 and 1.8%, respectively. Eighty-six percent of these procedures were performed at private/community hospitals, with 12.7% performed at non-community hospitals. Of note, this national database includes only implant and pre-hospital discharge complication rates. Our data (including complications out to six weeks) compare favorably with data with lower rates of major complications.

LV lead placement success in 64 of 66 patients (97%) in this report exceeded the success seen in prior reports. The MIRACLE study program¹⁴ reported a 91.6% success rate for LV lead placement, while COMPANION¹³ revealed an 89% success rate for LV lead placement. Another report indicated a similar 92% success rate with LV lead placement.¹⁵

Implications of These Findings. There is debate as to whether cardiology procedures are best performed at non-community hospitals.³ It is postulated that non-community hospitals (i.e. large academic teaching hospitals) are the 'safety nets' of the US healthcare system.¹⁶ However, non-community hospitals account for only 3.1–12.0% of the hospitals providing care for Medicaid patients. Hospitals with minor or no teaching status accounted for 76.6–86.2% of the hospitals providing care for Medicaid patients. Community hospitals represent more than 85% of all US registered hospitals and are responsible for more than 95% of total hospital admissions.¹⁷ More interesting is the fact that the Medicare Payment Advisory Commission believes that Medicare's payments should "recognize the value of enhanced patient care provided in teaching hospitals and other settings

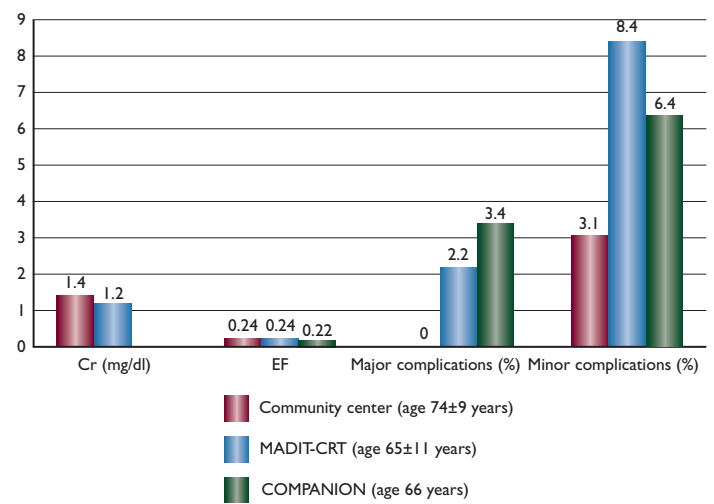
where residents and other health professionals train when the added value of patient care justifies its higher costs."⁶

The outcomes data we present here support the quality and improved access to care that a clinical cardiac EP program provides this community hospital. Current reimbursement schemes favor academic over community centers without regard to outcomes; a nationally recognized academic center in Pennsylvania receives ~39% higher ($p=0.019$) Medicare reimbursement for an acute myocardial infarction despite 95% of our patients receiving percutaneous coronary intervention (PCI) within 90 minutes of arrival (compared with the academic center's rate of 81%), with no difference in 30-day mortality.¹⁸ Non-community centers have higher care delivery costs than community hospitals due to differences in the intensity with which similar patients are treated rather than the quality of care or graduate medical education *per se*.^{19,20} Interestingly, there is prior evidence that not only do community physicians see a similar case mix to non-community academic physicians,²¹ but they also treat an older patient population and request 50% fewer consultations than non-community physicians.²² Our data presented here reveal an older patient population (with higher creatinines and similar ejection fractions) and lower rates of complications compared with non-community hospitals. It is duly noted that many facets of chronic care reimbursement are suboptimal and beyond the scope of this report. That said, in an era of increasing cost containment and 'pay-for-performance,' more attention needs to be paid to center-dependent outcomes rather than generalization based on historical assumptions.

In addition, recent data suggest that ICDs continue to be underutilized (despite their class I indication after cardiac arrest) with a large discrepancy in utilization by the size of the discharge hospital, which may suggest regional influences and gaps in resource allocations to community hospitals.²³ Our data indicate that a small, non-academic community hospital can provide high-quality and more accessible healthcare to an elderly, ill population.

Possible Role of 'Niche' Hospitals. Specialty hospitals are under increasing scrutiny, but there may be a role for 'niche' hospitals that, while offering the full spectrum of general hospital care, can provide certain procedures at an exceptional level of quality and cost-effectiveness. Recent literature continues to document the paucity of data available on rates and predictors of ICD implantation in routine clinical practice.^{24,25} The Ontario ICD Database²⁴ revealed major complications related to *de novo* defibrillator implantations in 4.1% of procedures. Adjusting our data to

Figure 3: Baseline Characteristics and Complications of Patients Undergoing Bi-ventricular Defibrillator Implantation



A total of 64 patients underwent bi-ventricular defibrillator implantation. Complications at our center (a community center) were compared with those from national trials (MADIT-CRT,¹² COMPANION¹³). Creatinine (Cr) was not reported for the COMPANION Trial. EF = ejection fraction.

match their definition of major complications, our center had major complications in 1.0% of *de novo* defibrillator implantations (a 76% relative reduction in major complications). The cost of major complications among Medicare beneficiaries receiving implantable defibrillators was examined in 30,984 patients.²⁵ They found that 10.8% of patients experienced one or more complications resulting in an increase in length of stay by 3.4 days and costs by \$7,251. Superiorly performing 'niche' hospitals that reduce major complication rates from defibrillator implants by 76% in the US (conservative estimate of 100,000 yearly implants) could realize an estimated \$60 million in cost savings while improving patient safety.

Limitations. This report has a limited sample size, and it may be biased toward higher complication rates because it included the first 250 consecutive device implants from inception of the program. One could argue that the patient population was pre-selected to favor uncomplicated patients. No patients were referred to outside hospitals for device implantation and the demographics of patients in this report indicate older patients with similar ejection fractions and higher creatinines (when available for comparison) than patients included in PASE, MADIT-CRT, and COMPANION. Also, there is no generally accepted definition for an academic hospital, thus a non-community hospital was defined as one that has a medical school, at least one other health professions school or program, and an affiliated teaching hospital. In addition, many studies were not single-center, none was single-

operator, and many of the national trials may have included community hospital implants, thus 'apples-to-apples' comparison of this community center with other centers was difficult. A prior study did examine pacemaker-implantation complication rates of 632 consecutive implants at a single non-community institution.²⁶ They found a 2.4% rate of hemothorax/pneumothorax and an overall complication rate of 5.7% (number of deaths not reported). There was a substantially large incidence of complications experienced by low-volume (<12 implants per year) implanters. Our report here is that of a single, larger-volume operator.

Finally, one could argue that the results of this study were predictable: if an academic-trained electrophysiologist starts a practice in a community hospital and is the sole operator, one would not expect the outcomes of device implantation to be any different simply because the operator moved to a different lab. There are two potential flaws to this thought process. One, there is the implicit belief that the academic center has the 'best outcomes' and there is no way for outcomes to improve (or deteriorate). Second, just as medical errors are most often attributable to flaws in the 'system,' there is evidence that medical successes are due to inherent qualities in the 'system.' This is exemplified in several studies examining

outcomes in coronary artery bypass surgical programs^{27,28} that suggest that processes of care are pivotal in determining outcomes of coronary artery bypass grafting procedures, and that these system factors might be more important to outcomes than surgeon experience or volumes. This report is not an attempt to show that community hospitals should perform EP device implants. Rather, we have described our system and objectively analyzed our outcomes to demonstrate that a focused community hospital EP team can develop an EP program with exceptional outcomes.

Conclusion

This is the first report of the demographics and complication rates of the initial 250 consecutive patients in a non-academic community hospital EP program. There was one major early complication (0.4%) and seven minor early complications (2.8%). Eleven of 250 patients (4.4%) were re-admitted within six weeks of implantation. Four of these 11 re-admissions (36.4%) were not device-related. Contrary to current perceptions, these data suggest that community centers may subselect an elderly, ill patient population and can provide high-quality, cost-effective, and more accessible care. Highly performing 'niche' hospitals may offer improved quality care while reducing costs. ■

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