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Original Article

Pioneering Efforts: Cardiac Device Implantation Trends and Variable Patient Outcomes – A Community Benefit Tool

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Abstract

Objectives: To analyze trends in cardiac device implantation and interventions, along with patient outcomes, at the National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan.

Methodology: This retrospective study was conducted from January 2017 to December 2020 at NICVD, Karachi. Patients presenting to outpatient or emergency departments with diagnoses of bradycardia (sinus node dysfunction or atrioventricular blocks), heart failure, survival of sudden cardiac death (SCD), or cardiomyopathy, and meeting the American College of Cardiology (ACC)/American Heart Association criteria for device-based therapies, were included. Data on demographic characteristics, comorbid conditions, device types, indications, and post-procedural outcomes, including complications and mortality, were collected and analyzed.

Results: A total of 5,166 cases were analyzed over the four-year study period, with 2,991 (57.9%) males and a mean age of 58.2 ± 22.4 years. Hypertension was the most prevalent comorbidity, affecting 1,872 (36.2%) patients. Dual-chamber, rate-modulated pacemakers (DDDR) were the most frequently implanted devices, accounting for 1,943 (37.6%) cases, while single-chamber implantable cardiac defibrillators (ICDs) were predominantly used for secondary prevention in ischemic heart disease. Complete heart block was the most common indication, observed in 1,794 (34.7%) patients. Post-procedural complications were infrequent, with hematoma and wound infections being the most common. Mortality was reported in 23 (0.4%) patients.

Conclusion: Dual-chamber, rate-modulated pacemakers (DDDR) emerged as the most frequently implanted pacemakers, while single-chamber ICDs were the preferred defibrillators for secondary prevention. Complete heart block was the leading indication for device implantation. Post-procedural complications, including hematoma and wound infection, were rare, and overall mortality associated with cardiac device implantation was remarkably low.

Keywords: Cardiac devices, hypertension, ischemic heart disease, mortality, pacemaker, Pakistan

INTRODUCTION

The first cardiac pacemaker was implanted in a human approximately six decades ago. Advances in battery technology and innovations, such as leadless pacing, have significantly enhanced the longevity and functionality of these devices [1]. Over recent decades, the global incidence of pacemaker implantations has steadily increased, leading to significant reductions in mortality, particularly among individuals with atrioventricular (AV) block [2]. For instance, data from Australia indicates a pacemaker implantation rate of 653 per million population [3].

In 1985, the first implantable cardioverter-defibrillator (ICD) was introduced in the United States [4]. Initially designed for patients who survived sudden cardiac death (SCD) and exhibited malignant ventricular arrhythmias during electrophysiological studies despite antiarrhythmic therapy, ICD implantation was once considered technically challenging, with high associated mortality rates [5,6]. However, advancements over the past few decades have transformed ICDs into vital tools for reducing mortality among patients with heart disease and heightened SCD risk after comprehensive evaluation [7]. ICDs are now well-documented for their efficacy in both primary and secondary prevention of SCD [8].

Cardiac resynchronization therapy (CRT), with or without an integrated defibrillator, is a key treatment for symptomatic heart failure (HF) patients who exhibit severe left ventricular dysfunction and left bundle branch block, even after optimal medical therapy [9]. For those who do not respond to medical management, CRT has been shown to provide significant clinical benefits, including reduced morbidity, mortality, and hospitalizations [10].

In a developing country like Pakistan, access to medical care remains a significant challenge, particularly for financially disadvantaged patients. Pacemakers, which cost between PKR 150,000 to 300,000, are often unaffordable for the majority of the population. In this context, the National Institute of Cardiovascular Diseases (NICVD) in Karachi stands out as the largest cardiac institution in Pakistan, offering free-of-cost comprehensive cardiac services. These include treatments for bradyarrhythmias with pacemakers, malignant arrhythmias with ICDs, and heart failure with CRT, providing hope to patients who otherwise could not afford such care.

Cardiac patients in Pakistan face numerous challenges, from financial constraints to limited healthcare infrastructure. NICVD caters to patients from across the country, addressing a wide range of cardiac conditions. Given the rapid advancements in technology, evolving techniques, and enhanced clinical expertise, it is crucial to assess the trends, characteristics, and outcomes of ICD and CRT practices in such settings. This retrospective study aims to analyze the trends in cardiac device usage, interventions, and outcomes over a four-year period at NICVD, Karachi, Pakistan.

METHODOLOGY

Study Design: This was a single-center, retrospective study conducted over four years, from January 2017 to December 2020, at the National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan.

Ethics: The study was conducted following ethical guidelines and principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the NICVD Institutional Review Board, and patient confidentiality was maintained by anonymizing data.

Setting: The study was conducted in the electrophysiology laboratory of NICVD, which specializes in intracardiac device implantation procedures. This facility serves a diverse patient population, primarily from urban and peri-urban areas of Karachi and Sindh Province.

Participants: Patients presenting to the outpatient or emergency department with indications for device-based therapies were included in the study. These indications comprised bradycardia resulting from sinus node dysfunction or atrioventricular blocks, heart failure, survival of sudden cardiac death (SCD), and cardiomyopathy. Eligibility was determined according to the criteria established by the American College of Cardiology (ACC) and the American Heart Association (AHA) for device-based therapies. Patients with incomplete medical records or contraindications to device implantation were excluded from the study.

Variables: The primary variables in the study included demographic characteristics such as age and gender, along with clinical parameters like co-morbid conditions (e.g., diabetes and hypertension) and indications for device implantation. Device-related parameters were also assessed, including the types of devices implanted, such as implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy (CRT) devices, and pacemakers. Post-procedural outcomes were evaluated, focusing on complications such as pneumothorax, hematoma, and lead dislodgement, as well as mortality. Additionally, device performance metrics, including P wave and R wave sensing, pacing thresholds, and lead impedance, were recorded and analyzed.

Data Sources/Measurement: Data were collected from patient medical records, procedural logs, and follow-up reports. Procedural details recorded included the type of anesthesia used, the venous access method (subclavian or cephalic vein), and the type and length of leads utilized, such as 52 cm atrial leads (if indicated), 58 or 62 cm shock leads for ventricular placement, and 88 cm coronary sinus (CS) leads for left ventricular placement. Device performance metrics, including P wave and R wave sensing, pacing thresholds, and lead impedances, were measured during the first device interrogation on days 1, 10, and 30 following implantation. Additionally, adverse events such as hematomas necessitating wound reopening and infections were carefully documented.

Bias: Selection bias was minimized by including all eligible patients meeting the ACC/AHA criteria during the study period. Information bias was addressed through standardized data extraction forms and verification by independent researchers.

Study Size: The study included all patients undergoing device implantation during the study period. A total of 5166 patients were enrolled, ensuring sufficient statistical power for analysis of outcomes and complications.

Quantitative Variables: The quantitative data encompassed a range of key parameters, including demographic information such as age and gender, as well as technical metrics related to device performance, including impedance and pacing thresholds. Additionally, the analysis included the frequency of procedural complications, with specific focus on occurrences such as pneumothorax, pocket hematoma, and lead dislodgement, providing a comprehensive understanding of both patient characteristics and procedural outcomes.

Statistical Methods: Data were analyzed using SPSS version 26.0. Descriptive statistics, such as means and standard deviations for continuous variables and frequencies and percentages for categorical variables, were calculated. Chi-square tests were used to compare categorical variables, while independent sample t-tests were applied to compare continuous variables between groups. Post-procedural outcomes, including complications and mortality rates, were analyzed for potential associations with patient demographics, indications, and device types. A p-value < 0.05 was considered statistically significant.

RESULTS

Participants: Over the 4-year study period, a total of 5166 patients who underwent intracardiac device implantation were included in the analysis. Among the participants, 2991 (57.9%) were male, and 2175 (42.1%) were female, with a mean age of 58.2 ± 22.4 years. Patients under 20 years of age comprised 617 (11.9%), while 2245 (43.4%) were aged between 20–60 years, and 2304 (44.6%) were older than 60 years. A majority of the participants resided in rural areas (3256, 63%), while 1910 (37%) were from urban settings.

Descriptive Data: Hypertension was the most prevalent comorbid condition, affecting 1872 (36.2%) patients, followed by diabetes mellitus in 1380 (26.7%). Cardiomyopathy and left ventricular dysfunction were noted in 1142 (22.1%) and 910 (17.6%) cases, respectively. Additionally, 544 (10.5%) patients were smokers, and chronic kidney disease was identified in 68 (1.3%) cases.

Indications for Procedures: Primary prevention was the predominant purpose for device implantation, performed in 4002 (77.5%) cases, whereas secondary prevention accounted for 1164 (22.5%). Among the participants, 846 (16.4%) had an ejection fraction of less than 40%, 198 (3.8%) had an ejection fraction of

40–60%, and 838 (80.1%) had greater than 60%, requiring either single or dual pacemakers.

Table 1: Baseline Characteristics of Patients (n=5166)

Characteristics	Number (%)
Gender	
Male	2991 (57.9%)
Female	2175 (42.1%)
Age (Years)	
<20	617 (11.9%)
20-60	2245 (43.4%)
>60	2304 (44.6%)
Area of Residence	
Rural	3256 (63.0%)
Urban	1910 (37.0%)
Co-morbid Conditions	
Diabetes Mellitus	1380 (26.7%)
Hypertension	1872 (36.2%)
Smokers	544 (10.5%)
Chronic Kidney Disease	68 (1.3%)
Left Ventricular Dysfunction	910 (17.6%)
Cardiomyopathy	1142 (22.1%)
Indications	
Primary	4002 (77.5%)
Secondary	1164 (22.5%)
Ejection Fraction	
< 40%	846 (16.4%)
40 to 60%	198 (3.8%)
>60% single and dual pacemaker	838 (80.1%)

Yearly Trends: Illustrates a consistent upward trend in intracardiac device implantations over the 4-year period (Figure 1).

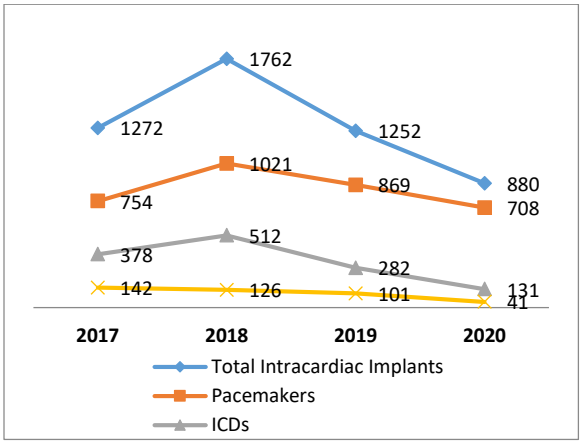

Figure 1: Yearly Trends in Number of Intracardiac Implants during 4 year Study Period (2017-2019)

Outcome Data: Dual-chamber, rate-modulated pacing (DDDR) devices were the most commonly implanted pacemakers, accounting for 1,943 (37.6%) cases, followed by dual-sensor ventricular demand rate-responsive (VVIR) pacemakers in 1,119 (21.7%) cases. Cardiac resynchronization therapy pacemakers (CRTP) were used in 124 (2.4%) cases, while ventricular demand pacing (VVI) and single-lead atrial-triggered ventricular (VDD) pacemakers were less frequently employed, each in 4 cases. In terms of cardiac defibrillators, single ICDs were the most frequently used, with 787 (15.2%) cases, while dual ICDs accounted for 486 (9.4%) cases. Cardiac resynchronization therapy devices (CRTD) were used in 386 (7.5%) cases, primarily for ischemic cardiomyopathy, and generator changes were performed in 313 (6.1%) cases.

Table 2: Types of Pacemakers and Procedures Done with regards to Indications (n=5166)

Indications	Number (%)
Dual sensor ventricular demand rate responsive (VVIR) pacing (n=1119)	
Complete Heart Block	1066 (54.8%)
2:1 AV Block / High Degree AV Block	681 (35.0%)
Sinus Node Dysfunction	196 (10.1%)
Cardiac resynchronization therapy pacemaker (CRTP) (n=124)	
Transient Complete Heart Block	601 (53.7%)
Complete Heart Block	476 (42.5%)
Atrial Fibrillation with Slow Ventricular Rate	45 (4.0%)
Ventricular demand pacing (VVI) (n=4)	
Complete Heart Block	68 (55.3%)
High Degree AV Block	42 (34.7%)
Ischemic Cardiomyopathy	14 (11.3%)
Primary Prevention	9
Secondary Prevention	5
Ventricular demand pacing (VVI) (n=4)	
High Degree AV Block	3 (75.0%)
Complete Heart Block	4 (25.0%)
Single-lead atrial triggered ventricular (VDD) pacemaker (n=4)	
Complete Heart Block	3 (75.0%)
2:1 AV Block / High Degree AV Block	1 (25.0%)

Indications for Device Implantation: Complete heart block was the most common indication for device implantation, observed in 1794 (34.7%) patients. High-degree atrioventricular (AV) block and sinus node dysfunction were among other frequent indications.

Post-Procedural Complications: The most common post-procedural complication was hematoma, observed in 175 (3.4%) patients, followed by wound infections in 158 (3.1%). Pneumothorax occurred in 53 (1.0%) patients, while other complications included LV lead readjustment (30, 0.6%), RV lead readjustment (41, 0.8%), and RA lead readjustment (93, 1.8%). Pocket evacuations were required in 73 (1.4%) cases. Mortality was documented in 20 (0.4%) patients.

Main Results: The study demonstrates that dual-chamber pacemakers (DDDR) were the most commonly used devices, especially in patients with complete heart block, while single ICDs dominated among defibrillators. Most procedures were performed for primary prevention, reflecting a proactive approach in managing cardiovascular risks. Despite the high number of procedures, post-procedural complications were infrequent, with hematoma and wound infections being the most common, and a low mortality rate of 0.4% was observed.

Table 3: Types of Cardiac Defibrillators, Cardiac Resynchronization Devices and Procedures Done with regards to Indications

Indications	Number (%)
Single implantable cardiac defibrillator (ICD) (n=787)	
Ischemic Cardiomyopathy	531 (67.5%)
Primary Prevention	217
Secondary Prevention	314
Non-Ischemic Cardiomyopathy	212 (26.9%)
Primary Prevention	75
Secondary Prevention	137
Hypertrophic Cardiomyopathy	36 (4.6%)
Arrhythmogenic Right Ventricular Dystrophy	5 (0.6%)
Others	3 (0.4%)
Dual ICD (n=486)	
Ischemic Cardiomyopathy	329 (67.7%)
Primary Prevention	150
Secondary Prevention	179
Non-Ischemic Cardiomyopathy	139 (28.6%)
Hypertrophic Cardiomyopathy	11 (2.3%)
Arrhythmogenic Right Ventricular Dystrophy	4 (0.8%)
Others	3 (0.6%)
Cardiac resynchronization therapy devices (CRTD) (n=386)	
Ischemic Cardiomyopathy	196 (50.8%)
Primary Prevention	51
Secondary Prevention	145
Non-Ischemic Cardiomyopathy	106 (27.5%)
Primary Prevention	62
Secondary Prevention	44
Complete Heart Block	53 (13.7%)
High Degree AV Block	31 (8.0%)
Generator Change (n=313)	
Complete Heart Block	124 (39.6%)
2:1 AV Block / High Degree AV Block	84 (26.8%)
Sinus Node Dysfunction	98 (31.3%)
Atrial Fibrillation with Slow Ventricular Rate / Complete Heart Block	7 (2.2%)

DISCUSSION

This study presents the largest dataset spanning four years on trends in the use of cardiac devices and interventions performed at the National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan. Our findings indicate that dual-chamber, rate-modulated pacemakers (DDDR) were the most commonly implanted devices (37.6%), followed by single-chamber pacemakers (VVIR) at 21.7%. These results align with trends observed in developed countries, where DDD/DDDR pacemakers are the most frequently utilized pacing modalities. Notably, the global use of DDDR pacemakers has increased over time, rising from 82% in 2008 to 91% in 2012 [11].

Table 4: Post-Procedural Complications (n=5166

Characteristics	Number (%)
Post procedure Complications	
Wound Infection	158 (3.1%)
Hematoma	175 (3.4%)
Pneumothorax	53 (1.0%)
LV Lead Readjust	30 (0.6%)
RV Lead Readjust	41 (0.8%)
RA Lead Readjust	93 (1.8%)
Pocket Evacuation	73 (1.4%)
Mortality	20 (0.4%)

In this study, 77.5% of interventions were performed for primary prevention, reflecting a proactive approach in patient selection for cardiac interventions. International data demonstrates variability in primary prevention rates for implantable cardioverter defibrillators (ICDs), with Denmark reporting a 46% rate, Sweden 62%, Germany 55%, the United Kingdom 57%, Spain 62%, Canada 73%, and the United States 75% [12-15]. The emphasis on primary prevention in our cohort underscores an aggressive yet evidence-based strategy in addressing cardiac device implantation needs. Ischemic cardiomyopathy was the most common indication for single ICDs, dual ICDs, and CRTDs, consistent with global registry data. However, recent findings from Denmark suggest no significant reduction in mortality rates among patients receiving primary prevention ICDs for non-ischemic cardiomyopathy [16].

The study also revealed that cardiac resynchronization therapy pacemakers (CRTP) accounted for 2.4% of cases, while cardiac resynchronization therapy defibrillators (CRTD) were used in 7.5% of cases. In contrast, developed countries such as Sweden and France report significantly higher CRTP and CRTD implantation rates [13-15]. The disparity is largely attributable to resource constraints, as the cost of CRTP and CRTD devices remains prohibitive for many patients in resource-limited settings like ours. Additionally, most patients receiving CRT devices in this study had ischemic cardiomyopathy, mirroring trends reported in national cardiac device registries globally [4,7].

Demographic analysis showed a male predominance (57.9%), aligning with regional and international data. A study by Shenthar et al. in India found that 64% of cardiac device recipients were male, while data from the United States also indicates a male majority among recipients [18]. In terms of age, 44.6% of patients in our study were older than 60 years, with a mean age of 58.2 ± 22.4 years. Similar findings were reported in India, where the majority of cardiac device recipients were above 60 years. However, the PANORAMA study, which analyzed data from 8,586 patients across four continents, demonstrated variations in median age, ranging from 65 years in India and the Middle East to 76 years in Western Europe. These differences may reflect regional disparities in socioeconomic conditions, disease patterns, and practice guidelines [19-21].

The NICVD's provision of free cardiac device implantation has significant implications for healthcare delivery in Pakistan. By enhancing cardiac function, reducing hospitalizations, and extending life expectancy, this initiative improves patient quality of life in a setting where many cannot afford such treatments. Additionally, it alleviates the burden on the healthcare system by reducing emergency admissions and complications, while easing financial strain on families and allowing patients to remain productive. This equitable approach serves as a model for similar programs in Pakistan and other resource-constrained countries.

Limitations: This study has several limitations. As a single-center, retrospective analysis, the findings may not be fully generalizable to the national population. The absence of a national registry for cardiac implants further limits the scope of available data. Additionally, clinical, functional, and echocardiographic outcomes during follow-ups were not recorded. Future multicenter studies with longitudinal follow-up are necessary to provide more comprehensive insights into device efficacy, patient quality of life, and current practices in Pakistan. Comparative studies involving similar populations in other low- and middle-income countries (LMICs) could help contextualize these findings and inform strategies for improvement. Establishing a national registry for cardiac implants should be prioritized to support research and enhance clinical practice.

CONCLUSION

Dual-chamber, rate-modulated pacemakers (DDDR) were the most commonly used pacing devices, while single ICDs were the most frequently implanted cardiac defibrillators. Complete heart block emerged as the most prevalent indication for device placement. Post-procedural complications, including hematoma and wound infections, were observed but remained infrequent. Overall, the mortality rate among patients undergoing cardiac device implantation was low, highlighting the effectiveness of these interventions in improving patient outcomes.

AUTHORS' CONTRIBUTION

GK, DN, FS, RQ, MSA, and GI: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work.
GK, DN, FS, RQ, MSA, and GI: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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