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Predictors of complications and mortality among patients undergoing pacemaker implantation in resource-limited settings: a 10-year retrospective follow-up study

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Abstract

Introduction Pacemakers (PMs) are used to treat patients with severe bradycardia symptoms. They do, however, pose several complications. Even with these risks, there are only a few studies assessing PM implantation outcomes in resource-limited settings like Ethiopia and other sub-Saharan countries in general. Therefore, this study aims to assess the mid-term outcome of PM implantation in patients who have undergone PM implantation in the Cardiac Center of Ethiopia by identifying the rate and predictors of complications and death.

Methodology This retrospective study was conducted at the Cardiac Center of Ethiopia from October 2023 to January 2024 on patients who had PM implantation from September 2012 to August 2023 to assess the midterm outcome of the patients. Complication rate and all-cause mortality rate were the outcomes of our study. Multivariable logistic regression was used to identify factors associated with complications and death. To analyze survival times, a Kaplan–Meier analysis was performed.

Results This retrospective follow-up study included 182 patients who underwent PM implantation between September 2012 and August 2023 and were at least 18 years old. The patients' median follow-up duration was 72 months (Interquartile range (IQR): 36–96 months). At the end of the study, 26.4% of patients experienced complications. The three most frequent complications were lead dislodgement, which affected 6.6% of patients, PM-induced tachycardia, which affected 5.5% of patients, and early battery depletion, which affected 5.5% of patients. Older age (Adjusted Odds Ratio (AOR) 1.1, 95% CI 1.04–1.1, p value < 0.001), being female (AOR 4.5, 95% CI 2–9.9, p value < 0.001), having dual chamber PM (AOR 2.95, 95% CI 1.14–7.6, p value = 0.006) were predictors of complications. Thirty-one (17%) patients died during the follow-up period. The survival rates of our patients at 3, 5, and 10 years were 94.4%, 92.1%, and 65.5% respectively with a median survival time of 11 years. Patients with a higher Charlson comorbidity index before PM implantation (AOR 1.2, 95% CI 1.1–1.8, p = 0.04), presence of complications (AOR 3.5, 95% CI 1.2–10.6, p < 0.03), and New York Heart Association (NYHA) class III or IV (AOR 3.3, 95% CI 1.05–10.1, p = 0.04) were associated with mortality.

Conclusion Many complications were experienced by patients who had PMs implanted, and several factors affected their prognosis. Thus, it is essential to identify predictors of both complications and mortality to prioritize and address the manageable factors associated with both mortality and complications.

Keywords Pacemaker, Complication, Mortality, Predictors, Sub-Saharan, Resource-Limited

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Introduction

Pacemakers, which are small electronic devices implanted under the clavicle in the chest to sense and stimulate the heart's electrical activity, are used to treat patients with severe symptoms of bradycardia [1–3]. It has been available as a treatment option for patients with clinically significant bradyarrhythmia since its introduction in 1958 [4]. The most common indications for its implantation are Sinoatrial(SA) node dysfunction and high-grade Atrioventricular(AV) block [4, 5].

Even though regional differences in pacemaker implantation rates exist, the global pacemaker implantation rate is rising due to an aging population [6, 7]. The increased rate of implantation is because of its main benefits, which include improved quality of life and prolonged life expectancy [2, 7]. It has moreover proven a significant technological breakthrough, adding to its advantages [4].

But whether it is performed by an expert or inexperienced operator, there are complications associated with it, just like with any other invasive procedure [2, 8, 9]. Device malfunction and hardware implantation can lead to complications [6]. The estimated range of the complication rate is between 1 and 6%, with variations across studies [8]. Pneumothorax, hemorrhage/pocket bleeding, infection, pacemaker syndrome, superior vena cava syndrome, lead failure, and death are some of the complications that occur immediately after the procedure or later [8–13].

In sub-Saharan Africa, cardiac pacing is a relatively new concept with limited application [14]. Therefore, there is, however, a dearth of information regarding the mid-term outcomes (in terms of complication and mortality rate) of pacemaker implantation in adult patients in Ethiopia and throughout Africa. For example, there is only one study about complications related to pacemakers in Ethiopia [15]. The purpose of this study is to evaluate the mid-term outcomes for pacemaker implantations in adult patients treated at the Cardiac Center of Ethiopia by determining the rate of complications and mortality as well as the factors associated with them.

Methods

Study area and period

This study was conducted at the Cardiac Center of Ethiopia in Addis Ababa, Ethiopia, between October 2023 and January 2024, on patients who had undergone pacemaker implantation between September 2012 to August 2023. Pacemaker implantations were carried out by both local interventional cardiologists and a medical mission campaign from abroad. The center has three ECG machines and two Medtronic pacemaker programming machines available for use in patients to monitor their condition.

Study design

A retrospective, hospital-based follow-up study.

Eligibility criteria

This study included all patients over 18 years old who received a permanent pacemaker at the Cardiac Center of Ethiopia. Patients under the age of 18, those who underwent temporary pacemaker implantation, those with Cardiac Resynchronization Therapy (CRT), those with Intracardiac Cardioverter Defibrillator (ICD) devices, and those with incomplete charts or medical records were excluded.

Study variables

The dependent variables were the presence of complication/s or mortality of any cause.

Independent variables include age, sex, nutritional status of the patient, comorbidity presence, Charlson comorbidity index, category of symptoms leading to implantation, New York Heart Association (NYHA) class of heart failure, pulmonary hypertension grade, presence of valve lesion, Tricuspid Annular Plane Systolic Excursion(TAPSE), Ejection Fraction(EF), Left Ventricular End Diastolic Diameter (LVEDd), index arrhythmia, type of pacemaker, venous access, mode of pacemaker lead fixation, pacemaker brand, and initial programmed values of the pacemaker.

Outcomes of the study

The presence of any of the complications (Lead dislodgement, Early battery failure, Pacemaker induced tachycardia, Pocket site infection and hematoma, Pleural Effusion, Sepsis, Pericardial Effusion, Infective Endocarditis, Subcutaneous Emphysema and Moderate Tricuspid regurgitation due to looped wire) and Mortality of any cause.

Operative techniques and procedures

In most cases, the left infraclavicular fossa in the antepectoral plane was the preferred pocket to implant the generator using a local anesthetic of 1% lidocaine. However, if there was a pocket site infection, the right side was utilized. The left subclavian vein, left axillary vein, right subclavian vein, or left cephalic vein were chosen for lead insertion. According to our protocol, all patients received prophylactic antibiotics, either IV ceftriaxone or IV cefazolin, one hour before surgery. Pacemaker lead fixation was performed either passively or actively. Anticoagulant medication was discontinued in our patients the night before the procedure. Most patients were discharged from the hospital the day after surgery.

The following terms and operational definitions are used

The Charlson Comorbidity Index was calculated by adding the patient's assigned weights for any comorbid conditions; if there are no comorbid conditions, a value of 0 is assigned. Underweight (<18.5 kg/m²), normal (18.5–24.9 kg/m²), overweight (>25 kg/m²), and obese (>30 kg/m²) were the BMI classifications used in this study. The tricuspid regurgitation jet velocity and the right atrial pressure, which is determined by the size and collapsibility of the inferior vena cava, were used to calculate the pulmonary artery systolic pressure using transthoracic echocardiography.

A battery that depletes before the lifespan recommended by the manufacturer is referred to as an early battery failure. Among the categories of symptoms, the patient is placed in the Cheyne Stoke attack group if one of their symptoms is syncope; if they have presyncope or dizziness but no syncope, they are placed in the Cheyne Stoke equivalent group; and if they do not have any of these symptoms, they are placed in the other symptoms group. If the patient has at least one complication, he/she is labeled as having a complication. Complications classified as early are those that happen within a month following the procedure and late complications are those after a month.

Data collection tool and procedure

A structured questionnaire was used for data collection. The tool was created after a careful review of the literature. From the body of research, a list of ICD-10-AM diagnosis codes representative of pacemaker implantation-related complications was created [16–18]. The data used in this study were obtained from a review of the patient's medical records and phone contact of family members of the patient for death confirmation. About death, the endpoint was established as the death of any cause because it was difficult to ascertain the exact cause of death for most patients based on the data obtained. Administration and data collection were supervised by experienced health professionals. A two-day training was organized for supervisors and data collectors. The training focused heavily on research objectives, instrument content, data collection method, ethical aspects, and data collection tasks.

Data quality control

The focus was on well-designed data collection tools to ensure data quality. To ensure validity and consistency, the instrument was pretested on 5% of the sample outside the study area. The principal investigator led and supervised the entire data collection process.

Data processing and analysis

The data was manually examined to ensure its accuracy. The data was coded and then exported to SPSS for Windows, version 25 (SPSS, Chicago, IL, USA) for analysis after being cleaned up with the Epi-data tool, version 4.4.2.1. Using the Shapiro–Wilk test, the normality of continuous variables was checked out. The normality test results were used to inform the decision, and the relevant descriptive statistics for continuous variables were then run. Categorical variables were described using absolute frequency and percentages. Tables and graphs were used to present the data. We computed crude and adjusted odds ratios to examine the relationship between predictors and the outcome variable (mortality or complications related to pacemakers). To control for confounders, variables with a statistically significant association with the outcome variable at P -value ≤ 0.20 in the univariable logistic regression analysis were considered candidates for the multivariable logistic regression. If a variable had a p -value of less than 0.05 at a 95% confidence interval, we identified it as a potential independent predictor of pacemaker-related complications or death. The 3-year, 5-year, 10-year, and median survival time of patients were estimated using the Kaplan–Meier estimator.

Results

Sociodemographic and clinical characteristics of the patients

The clinical and sociodemographic features of cardiac patients who had pacemaker implantation at the Cardiac Center of Ethiopia are illustrated in Table 1 and Figs. 1, 2, 3 and 4. The median age of the patients was 65 years old, with a M: F ratio of 1.1. 63.2% of the patients were underweight or of normal weight. More than 3/4th (75.8%) of the patients had comorbidities, of which 55 (30.2%) had one, 46 (25.3%) had two, 19 (10.4%) had three, and 4 (2.2%) had four, respectively. The most common comorbidity was hypertension (62.1%), which was followed by diabetes mellitus (47.8%). The median comorbidity index was 2, with 56% of patients experiencing only one symptom, 17.7% experiencing two symptoms, 5.5% experiencing three symptoms, and 16.5% experiencing four symptoms. At presentation, syncope was the most common symptom (67, or 36.8%), followed by easy fatigability (23.1%), and dyspnea (22%). Cheyne stoke equivalents (presyncope or dizziness) accounted for 39% of the primary symptoms reported by patients at the time of presentation. 75.3% of patients had symptoms classified as NYHA class 1 or 2. Moderate to severe pulmonary hypertension was present in just 24.7% of patients, or nearly 1/4th. 53.3% of the patients had valve lesions, more

Table 1 Presents the sociodemographic and clinical characteristics of patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023

Patients characteristics	Frequency(percentage)
Age in years, median (IQR)	65(58.8–72.3)
Sex	
Male	95(52.2)
Female	87(47.8)
Nutritional status based on BMI measured in kg/m ^{2a} , n (%)	
Underweight or normal	115(63.2)
Overweight or obese	67(36.8)
Comorbidity/ies yes, n (%)	138(75.8)
Charlson comorbidity index, median (IQR)	2(1–3)
Category of symptoms leading to implantation, n (%)	
Cheyne stokes attack(syncope)	67(36.8)
Cheyne stokes equivalents (presyncope or dizziness)	71(39)
Other symptoms	44(24.2)
NYHA class of HF, n (%)	
1 or 2	137(75.3)
3 or 4	45(24.7)
Pulmonary hypertension grade, n (%)	
No or mild	142(78)
Moderate or severe	40(22)
Presence of valve lesion yes, n (%)	97(53.3)
TAPSE in mm, median (IQR)	21(20–24)
EF, median (IQR)	63(60–68)
LVEDd, median (IQR)	39(35–41)
Diastolic dysfunction yes, n (%)	79(43.4)
Grade of diastolic dysfunction	
One	145(79.7)
Two or three	37(20.3)
Index arrhythmia	
Complete heart block	138(75.8)
2nd degree AV block	20(11.1)
Atrial fibrillation with slow ventricular response	10(5.5)
Sinus node dysfunction	7(3.8)
Symptomatic sinus bradycardia	7(3.8)
Types of pacemaker, n (%)	
Single chamber (VVI/VVIR)	56(30.8)
Dual chamber (DDD/DDDR)	126(69.2)
Venous access, n (%)	
Subclavian	167(91.8)
Cephalic or axillary	15(8.2)
Mode of fixation, n (%)	
Passive	20(11)
Active	162(89)
Brand of a pacemaker, n (%)	
Medtronic	159(87.4)
St Jude	23(12.6)
Initial atrial threshold in volts, median (IQR)	0.63(0.5–0.8)

Table 1 (continued)

Patients characteristics	Frequency(percentage)
Initial ventricular threshold in volts, median (IQR)	0.65(0.5–0.9)
Initial atrial resistance in holms, median (IQR)	516(450–597)
Initial ventricular resistance in holms, median (IQR)	655(554–798)
Initial P wave in millivolts, median (IQR)	2.5(1.5–3.2)
Initial R wave in millivolts, median (IQR)	4.1(2–9)
Initial atrial sensitivity in millivolts, median (IQR)	0.5(0.5–2)
Initial ventricular sensitivity in millivolts, median (IQR)	2.8(2–2.8)
Pulse width in milliseconds, n (%)	
0.4	115(57.2)
0.5	86(42.8)
On medications yes, n (%)	136(74.7)
Follow-up duration in months, median (IQR)	72(36–96)
Complications yes, n (%)	48(26.4)
Death yes, n (%)	31(17)

Other symptoms include symptoms of heart failure (easy fatigability, dyspnea, and body swelling) and symptoms like chest pain and palpitation

Abbreviations: NYHA New York Heart Association, HF Heart Failure, IQR Interquartile range, TAPSE Tricuspid Annular Plane Systolic Excursion, EF Ejection Fraction, LVEDd Left Ventricular End Diastolic diameter, AV Atrioventricular

Terms: VVIR mode stands for Ventricular pacing, Ventricular sensing, Inhibitory response to a sensed event, and Rate modulation, DDDR mode stands for Dual chamber pacing with Dual Sensing and Dual Response

^a BMI Categories (kg/m²): Underweight: < 18.5; Normal: 18.5–24.9; Overweight: 29–29.9; Obese ≥ 30

than half. 21 mm, 39 mm, and 63%, respectively, were the median TAPSE, LVEDd, and EF. 43.4% had diastolic dysfunction. For over three-quarters of the patients (75.8%), a complete heart block was the reason for pacemaker implantation. 69.2% of patients had a dual chamber pacemaker (DDD/DDDR) implanted. 91.8 percent of patients had their pacemakers implanted via the subclavian vein. Approximately 87.4% of patients used a Medtronic brand, and 89% of patients underwent active fixation during implantation. Initially, the ventricular and atrial thresholds were set at 0.65 and 0.63 V, respectively. 74.7% of the patients were on medication. One medication was taken by 47.2% of the patients, two by 16.5%, three by 5.5%, and four by 5.5% of the patients. The most often prescribed medication for the patients (22%), was an ACE inhibitor. The median duration of follow-up was 72 months (IQR, 36–96), (Range 2–144). Forty-Eight (26.4%) patients developed complications; 34 patients (18.7%) had one complication; 10 patients (5.5%) had two complications; 2 patients (1.6%) had three complications; and 4 patients (1.6%) had 4 complications. 6.6% of patients

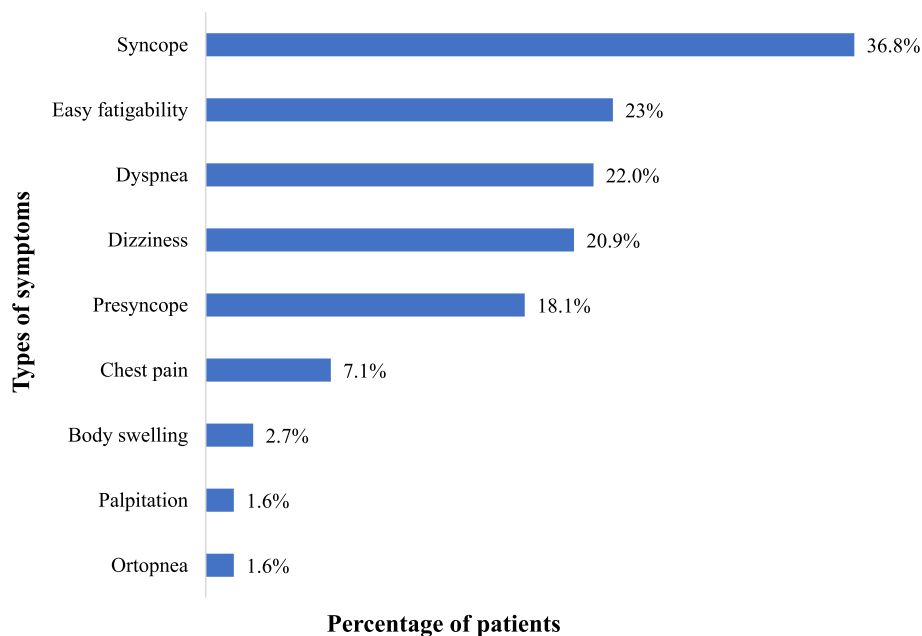


Fig. 1 Depicts the type of symptoms experienced by patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023. Note: A single patient may have more than one symptom

experienced lead dislodgement, which was the most common complication. Early battery failure (5.5%) and pacemaker-induced tachycardia (each occurred in 5.5% of patients) were the second most common pacemaker-related complications. The early pacemaker-related complications occurred in 18.9% of patients and included pacemaker-induced tachycardia, pocket site hematoma, pocket site infection, pericardial effusion, pleural effusion, subcutaneous emphysema, and pneumothorax; all other complications occurred later. Thirty-one (17%) patients died during the follow-up period. Nine patients (5%) died from COVID-19-associated complications (that was ARDS), three patients (1.6%) from complications related to diabetes (that was renal failure), and 19 patients (10.4%) had an unknown cause of death.

Predictors of complications

Multivariable logistic regression analysis revealed that age, sex, pacemaker type, and NYHA class of heart failure were associated with pacemaker-related complications, as shown in Table 2. Furthermore, Table 2 demonstrated that age, sex, and pacemaker type were the variables associated with pacemaker-related complications in multivariate analysis. When a person becomes one year older, his odds of developing pacemaker-related complications increase by 10%. Compared to males, females had a 4.5 times higher likelihood of developing pacemaker-related

complications. Patients with Dual-chamber pacemakers were three times more likely to develop pacemaker-related complications than patients with single-chamber pacemakers.

Survival rate and predictors of mortality

The survival rate and predictors of complications are displayed in Fig. 5 and Table 3, respectively. Median survival time was 11 years (132 months). Overall survival rates at 3, 5, and 10 years were 94.4%, 92.1%, and 65.5% respectively. In bivariate analysis, variables associated with mortality were ejection fraction, age, Charlson comorbidity index, presence of complications, and NYHA class. In multivariable logistic regression analysis, the only variables associated with mortality were gender, Charlson comorbidity index, presence of complications, and NYHA class. Females were 21% less likely to die than males. For each unit of increase in the Charlson comorbidity index, the likelihood of death increases by 1.2-fold. When complications occur, the odds of death increase by 3.5 times. Compared to patients in NYHA classes 1 or 2, those in classes 3 or 4 have 3.3-fold increased odds of dying.

Discussion

This study assessed the mid-term outcome of patients with implanted pacemakers by determining the rate of complication and death as well as the contributing factors for them. When compared to the majority of similar

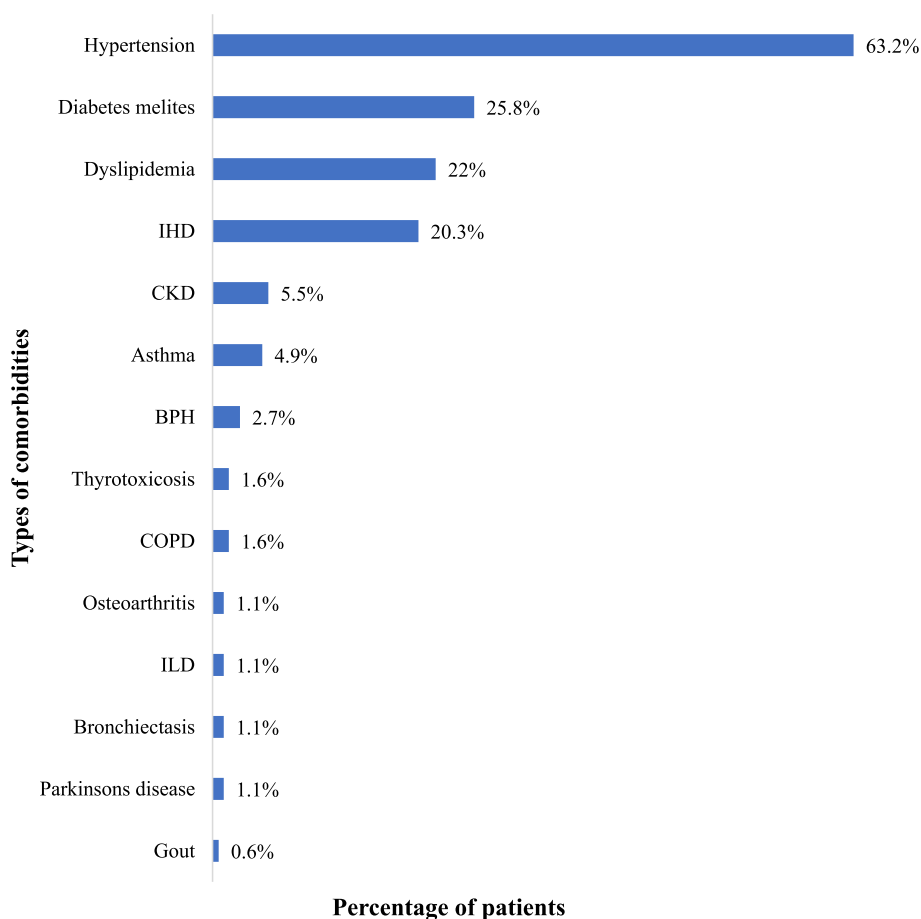


Fig. 2 Demonstrates the type of comorbidities associated with patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023. Note: a single patient may have more than one comorbidity. Abbreviations: ILD-Interstitial lung disease, COPD-Chronic Obstructive Lung disease, BPH-Benign Prostatic hyperplasia, CKD-Chronic Kidney Disease, IHD-Ischemic Heart Disease

studies conducted in different settings, our study found a higher rate of complications but a lower rate of death; however, a direct comparison is difficult because studies vary in terms of follow-up periods and patients’ age groups [14,19–24]. Additionally, it identified multiple independent predictors of pacemaker-related complications (age, sex, and pacemaker type) in addition to various independent predictors of death (gender, Charlson comorbidity index, presence of complications, and history of heart failure).

In comparison, our study’s 26.4% complication rate is higher than that of similar studies conducted in Poland (1.1%), the United Kingdom (3%), the United States (4.2%, 7.5%), India (5.4%), Iraq (4.25%), Australia and New Zealand (4.7%), Germany (6.1%), Spain (3.6%), China (8.1%, 17.1%), Columbia (8.9%), Kenya (8.9%), Finland (13.9%), Ethiopia (15.3%), and Turkey (22.7%), but it is lower than that of other studies conducted in the USA (29.1%) and Spain (55.1%) [5, 15, 19, 23, 25–38]. This disparity could be explained by variations in the follow-up

duration, operator experience, age group, and pacemaker type among studies.

Studies from Columbia and the USA revealed that most complications occurred early—73.5% in Columbia and 97% in the USA—which is consistent with our study, which found that 70.8% of complications occurred early [27, 33]. Nonetheless, research from Finland (6.7% early complications versus 7.2% late complications) and Spain (17.42% early complications versus 37.74% late complications) revealed that late complications were frequent [29, 32]. This variation could be accounted for by differences in the types of complications observed in different research.

In line with our findings, which show that lead dislodgement occurred in 6.6% of patients, lead dislodgement was most common in the United Kingdom (11.4%), the United States (2.4%), Nigeria (5.9%), Kenya (3.3%), South Africa (3.15%), and Ethiopia (2.54%) [15, 19, 21, 39, 40]. However, data from China, Turkey, and Spain indicate that pocket-site hematomas and infections are

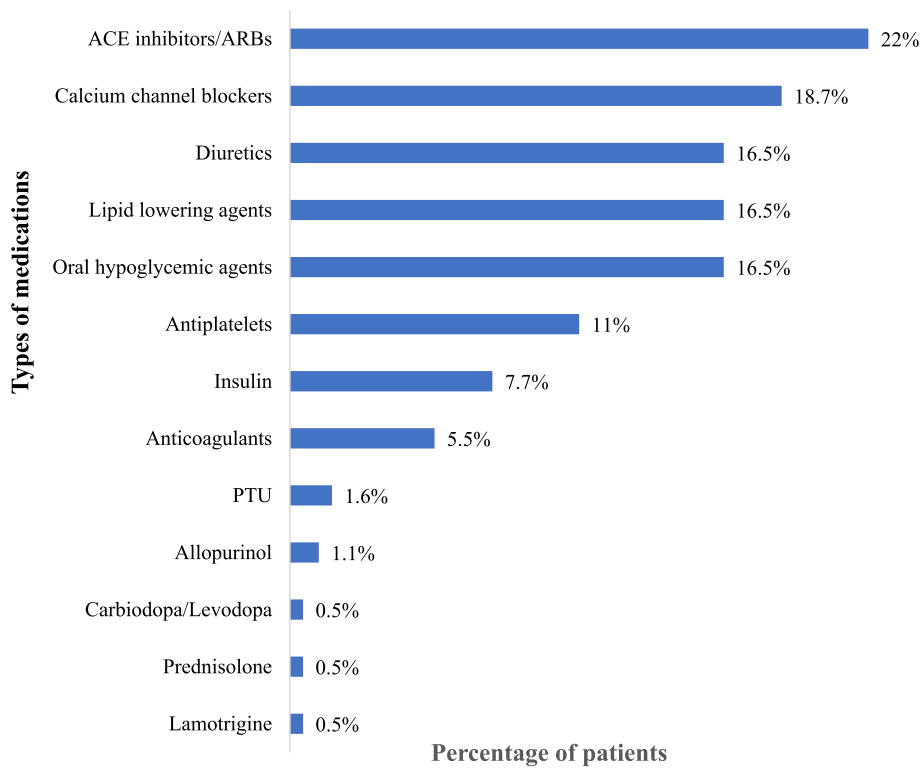


Fig. 3 Shows the type of drugs that have been taken by patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023. Note: A single patient may have taken more than one medication. Abbreviations: PTU-Propylthiouracil, ACE-Angiotensin converting Enzyme, ARB-Angiotensin Receptor Blocker

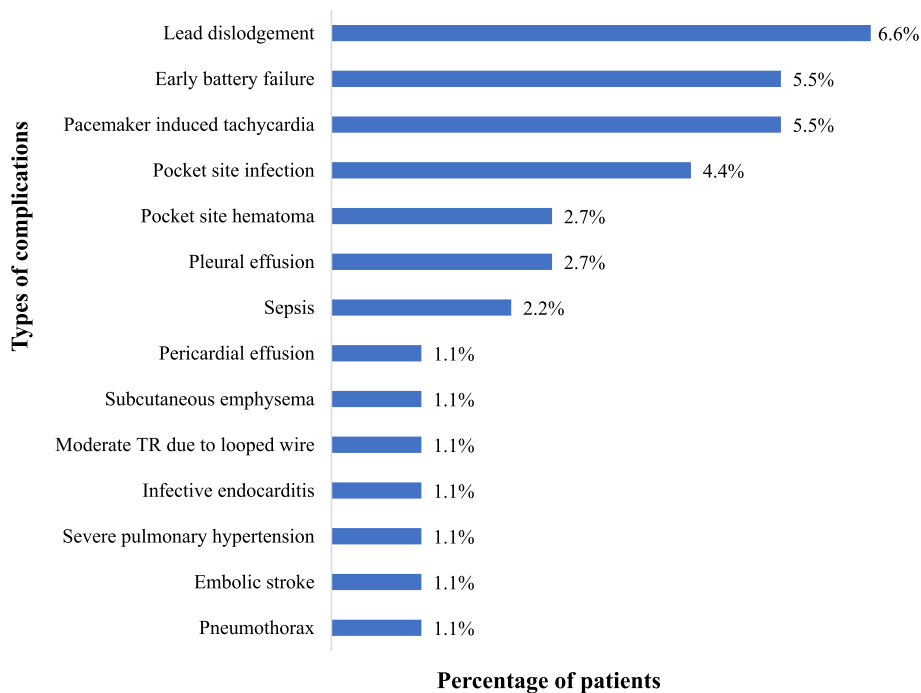


Fig. 4 Demonstrates the types and number of complications in patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023. Note: A single patient may have more than one complication

Table 2 Presents predictors of complications in patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023

Patients characteristics	no complication	at least one complication	COR (95%CI)	P value	AOR (95%CI)	P value
Age	63.5(56–73)	75.5(60.8–80)	1.1(1.02–1.2)	<0.001	1.1(1.04–1.1)	<0.001
Sex						
Female	55(41)	32(66.7)	2.9(1.4–5.7)	<0.001	4.5(2–9.9)	<0.001
Male	79(59)	16(33.3)	1		1	
NYHA Class of HF						
Class 1 or 2	107(79.9)	30(62.5)	1		1	
Class 3 or 4	27(20.1)	18(37.5)	2.3(1.2–4.9)	0.02	1.63(0.71–3.7)	0.23
Initial ventricular sensitivity	2.8(2–2.8)	2.8(2–2.8)	1.2(0.94–1.4)	0.18	1.6(0.47–3.1)	0.7
Presence of diastolic dysfunction						
No	81(60.4)	22(45.8)	1		1	
Yes	53(39.6)	26(54.2)	1.8(0.93–3.5)	0.0	2(0.95–4.4)	0.07
EF	63(60–65)	60(55.5–65)	0.98(0.94–1)		0.98(0.94–1.01)	0.23
Type of pacemaker						
Single chamber (VVI/VVIR)	49(36.6)	7(14.6)	1		1	
Double chamber (DDD/DDDR)	85(63.4)	41(85.4)	3.4(1.4–8)		2.95(1.14–7.6)	0.006

* Abbreviations: AOR Adjusted Odds Ratio, COR Crude Odds Ratio, VVI/VVIR mode stands for Ventricular pacing, Ventricular sensing, Inhibitory response to a sensed event, and Rate modulation; DDD/DDDR mode stands for Dual chamber pacing with Dual Sensing and Dual Response, EF Ejection Fraction, HF Heart Failure, NYHA New York Heart Association

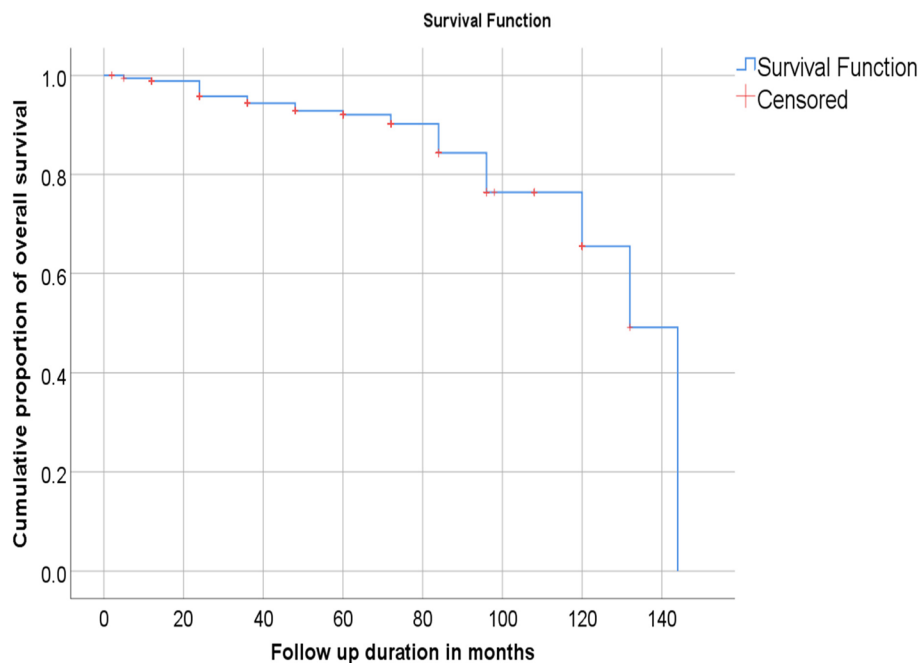


Fig. 5 A Kaplan–Meier survival curve depicts the overall survival over a follow-up period in patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023

the most common pacemaker-related complications [26, 30, 32]. This variability in the proportions of complications may be due to differences in risk factors among populations and follow-up duration in various studies

for different kinds of complications. Nowadays, remote cardiac implantable electronic devices have the potential to identify lead problems earlier than traditional care,

Table 3 Shows predictors of mortality in patients who underwent pacemaker implantation at the Cardiac Center of Ethiopia from 2012 to 2023

Patients characteristics	Not died	Died	COR(CI)	AOR(CI)	P value
Age	65(57–74)	75(62–80)	1.04(1–1.1)	1(0.96–1.1)	0.79
Sex					
Male	75(49.7)	20(64.5)	1	1	
Female	76(50.3)	11(35.5)	0.54(0.24–1.21)	0.79(0.34–1.8)	0.6
Charleston comorbidity index	2(1–3)	3(2–4)	1.3(1.1–1.3)	1.2(1.1–1.8)	0.04
EF	63(60–68.3)	60(50–65)	0.93(0.9–0.97)	1(0.92–1.01)	0.15
LVEDd	45(43–50)	51(43–65)	1.04(0.9–1.1)	0.98(0.94–1.04)	0.56
Symptom indication					
Cheyne stoke attack	51(33.8)	16(51.6)	2(0.7–5.6)	1.1(0.38–3.3)	0.85
Cheyne stoke equivalent	62(41)	9(29)	0.92(0.3–2.8)	0.7(0.22–2.1)	0.5
Heart failure	38(25.2)	6(19.4)	1	1	
Presence of complication					
No	117(77.5)	17(54.8)	1	1	
Yes	34(22.5)	14(45.2)	2.8(1.3–6.33)	3.5(1.2–10.6)	0.03
Initial ventricular threshold	0.63(0.5–0.8)	0.6(0.4–0.8)	0.42(0.12–1.4)	0.23(0.05–1.1)	0.07
Mode of pacemaker					
Single chamber	51(33.8)	5(16.1)	1	1	
Double chamber	100(62.2)	26(83.9)	2.7(0.96–7.3)	1.81(0.65–5.1)	0.3
Type of pacemaker					
Medtronic	136(90.1)	23(74.2)	5.12(0.67–13.5)	0.22(0.03–1.91)	0.17
St Jude	15(9.9)	8(25.8)	1	1	
NYHA-class of HF					
NYHA class 1 or 2	122(80.8)	15(48.4)	1	1	
NYHA class 3 or 4	29(19.2)	16(51.6)	4.5(2–10.1)	3.3(1.05–10.1)	0.04

* Abbreviations: AOR Adjusted Odds Ratio, COR Crude Odds Ratio, EF Ejection Fraction, HF Heart Failure, NYHA New York Heart Association, LVEDd Left Ventricular End Diastolic Diameter

which could improve outcomes by identifying lead dislodgement earlier [41, 42].

Pacemaker-induced tachycardia, which is uncommon these days, happened in 5.5% of patients in our study. This reentrant tachyarrhythmia, which usually affects dual chamber pacemakers, is mainly caused by an abnormality in the pacing device [2, 12, 43, 44]. Our study's high dual chamber pacemaker patient proportion may be the cause of the high percentage of patients with pacemaker-induced tachycardia.

According to all pacemaker registries, premature battery failure was the most frequent reason for device malfunction [45]. The intended lifespan of pacemaker batteries is six to fifteen years, however, various manufacturers have received reports of premature depletion [45–48]. In our study, we observed 5.5% of patients experiencing premature depletion of their pacemaker batteries.

In comparison with studies conducted in Denmark and Italy, which reported PM-related infections of 2.04 and 0.6%, respectively, we reported a higher pacemaker-related complication rate of 4.4% [49, 50]. The definitions of pacemaker-related infections, the use of antibiotic

prophylaxis, surgical techniques, patient characteristics, and the inclusion criteria of device types (including or excluding ICDs and CRTs) across the studies make direct comparison difficult.

Studies conducted in the UK, South Africa, and Ethiopia have found an association between female sex and complications related to pacemakers, which aligns with our findings [15, 21, 51]. Smaller veins, thin vessel walls, a smaller right ventricle, and less tissue between the subclavian vein and pleura, females are more likely to experience complications from pacemakers.

In line with our research, studies conducted in China and Ethiopia have found that pacemaker-related complications are associated with older age; however, a study conducted in Turkey found the opposite [15, 25, 30]. Dual chamber pacemaker implantation in Turkey was primarily performed on younger patients, which may have increased the risk of atrial lead dislodgement. A possible reason for the association between pacemaker-related complications and old age in our study is the higher prevalence of severe or numerous comorbidities in older people.

Similar to our findings, research from the UK and Germany showed that dual-chamber pacemakers are more likely than single-chamber pacemakers to cause complications; but other research from the UK, China, and Switzerland showed that there is no difference in the incidence of complications between dual and single chamber pacemakers [26, 39, 52–55]. Atrial lead dislodgement is the primary cause of increased complications with dual-chamber pacemakers. Given its lower cost, faster implantation time, and reduced risk of complications, the VDD pacing system may be a viable option for some patients in place of the DDD mode [56].

In addition to helping patients recover from symptoms, pacemakers also reduce the mortality risk for patients with clinically significant bradycardia [57]. However, Short-term benefits like decreasing mortality from pacemaker implantation are evident, but long-term outcomes are markedly different [58]. Studies show that a variety of factors affect patient mortality in patients who already have pacemakers [58].

Incidence of mortality across studies was reported using mortality during the total follow-up period or the median follow-up period. A study done in Australia revealed a death rate of 8% after a 90-day follow-up, while a study done in the USA revealed a death rate of 0.08% after a 30-month follow-up [19, 59]. Moreover, studies carried out in Germany and Poland showed a 39.7% death rate and 48.6% death rate, respectively, after a 30-year follow-up and 4-year follow-up, respectively [60, 61]. We reported 17% mortality after 144 months of follow-up. With a median follow-up period of 29 months, 6.4 years, 50.9 months, 34 months, 26 months, and 3.67 years, respectively, studies done in Taiwan, Poland, Spain, Cameroon, Nigeria, and Cote d'Ivoire identified death rates of 15.5%, 36.5%, 3.6%, 13.5%, 11.8%, and 25.8% [23, 38, 40, 62–64]. The incidence of death is determined by the length of the median follow-up period and the overall duration of follow-up, as shown in the research mentioned above. Furthermore, because our study was conducted during the COVID-19 era and many of our patients died from COVID-19-related complications, the study period had a major impact on mortality.

Moreover, the median survival time and the five-year period indirectly assess the death rate. Studies differ in the 5-year and median survival times for similar reasons as the death rate. The 5-year survival rate of 90% in our study is higher than the 63%, 32%, 82%, 65.6% and 66%, 45%, and 60.6% reported from Sweden, Taiwan, Poland, Germany, Italy, and the Czech Republic, respectively [20, 23, 24, 65–69]. Our median survival time of 110 months is greater than the reported times from Kenya, Iran, and Germany, which are 36 months, 51 months, and 101.9 months, respectively [28, 65, 70].

The presence of cardiovascular disease, such as heart failure, is a predictive factor for pacemakers these days [17]. This is supported by our research, studies conducted in Taiwan, the Netherlands, and Australia that identified that heart failure is a predictor of mortality in patients with pacemakers [17, 62, 71]. The association between class 3 and class 4 heart failure in patients with pacemakers and mortality may be explained by the development of fatal ventricular arrhythmia in most patients with advanced heart failure.

The Charleston Comorbidity Index is claimed to be a very well predictor of long-term prognosis and survival chances [72]. Our research substantiated this claim. An Australian study reported that a high Charlson comorbidity score was a predictor of death in patients with pacemakers, which is consistent with our findings [71].

A report from the USA corroborated our study's findings, indicating that pacemaker-related complications are associated with an increased risk of death from all causes [73]. Pneumothorax, infections associated with pacemakers, and pocket hematoma are among the reported complications that are associated with mortality [73, 74].

Conclusion

Many complications were experienced by patients who had pacemakers implanted, and several factors affected their prognosis. Thus, it is essential to identify predictors of both complications and mortality to prioritize and address the manageable factors associated with both mortality and complications.

Limitations of the study

Because it is conducted in a single center, generalizations are difficult to make. Given that this study was retrospective in nature, classification bias might have been present. Nonetheless, it provides valuable information for quality improvement by providing mortality and complication data for comparing pacemaker complications from other centers and highlighting areas of concern and needed improvement. This quality improvement endeavor also benefits from the identification of predictors of complication and mortality.

Abbreviations

AV	Atrioventricular
COVID-19	Coronavirus disease 2019
CRT/ICD	Cardiac Resynchronization Therapy/Implantable Cardioverter-Defibrillator
DDDR	Dual-chamber rate-modulated
ECG	Electrocardiography
EF	Ejection Fraction
LVEDd	Left Ventricular End Diastolic diameter
NYHA	New York Heart Association
TAPSE	Tricuspid Annular Plane Systolic Excursion
VVIR	Ventricular Rate Modulated Pacing

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Authors' contributions

M.N and S.M. Developed the proposal, wrote the main manuscript text, Analysis of the Result and overall Supervision. K.D and M.B. Did the Procedures (pacemaker Implantation), reviewed and edited the manuscript. M.A. Prepared all Figures and Tables, Data Analysis. All authors Reviewed the Manuscript and discussed the results and contributed to the final manuscript.

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Availability of data and materials

All study data can be made available from the corresponding author upon a reasonable request.

Declarations**Ethics approval and consent to participate**

The Institutional Review Board (IRB) of Saint Paul's Hospital Millennium Medical College granted ethical clearance (Ethical Approval Number: PM23/288). The corresponding author can provide a scanned copy of the approval letter upon request. During contact with family members for death confirmation, informed consent was obtained through a phone call with responding family members.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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