

Assessment of Trend, Indication, Complications, and Outcomes of Pacemaker Implantation in Adult Patients at Tertiary Hospital of Ethiopia: Retrospective Follow Up Study

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Background: A pacemaker is a device implanted in the chest to help people with symptomatic bradycardia and life-threatening irregular rhythm. However, it is also associated with many complications. Therefore, this study evaluated pacemaker-related complications and factors associated with them, as there is little data on pacemaker-related complications in sub-Saharan Africa and Ethiopia.

Methods: The study was conducted on 118 patients over 18 years old who had pacemakers implanted between 2017 and 2022 at Tikur Anbessa Comprehensive Specialized Hospital in Addis Ababa, Ethiopia who were reviewed by the authors from September 2022 to December 2022. Sociodemographic factors, clinical characteristics, and complications data were extracted using a structured questionnaire by retrospective review of patient records. The chi-square test or Fisher's exact test was performed to evaluate factors associated with complications.

Results: The median age of patients was 60.5 years (IQR = 15 years), with men accounting for 50.8% of patients. Hypertension was the most common comorbidity (64.2%). Symptomatic grade 3 AV block was the most common indication (78.8%) for pacemaker implantation. With a mean follow-up of 3.92 ± 1.94 years, 15.3% of patients had complications. Pneumothorax, pocket site infection, and lead dislodgement were the most common complications occurring in 2.54% of patients each. Patient age during surgery (p-value = 0.02), patient gender (p-value = 0.04), pacemaker implanting team (p-value = 0.01), and adherence to follow-up (p-value = 0.04) are related to pacemakers-related complications.

Conclusion: Pacemaker implantation is associated with many complications. Pneumothorax, pacemaker pocket infection, and lead dislodgement were the most common complications. Patient age at pacemaker implantation, patient gender, pacemaker implanting team, and follow-up compliance were factors associated with pacemaker-related complications. Skill development through specialized training and compliance counseling may improve outcomes for patients who have complications related to pacemaker implanting team and poor adherence to follow.

Keywords: pacemaker, pacemaker-related complications, associated factors

Introduction

A pacemaker is a device that is implanted in the chest to assist people with symptomatic bradycardia and life-threatening irregular rhythm.¹ Due to the population's increased life expectancy, its implantation rate has substantially increased globally.² It not only contributes to certain people's survival but also improves the quality of life for the majority of people, which explains its dramatic implantation increment.² The most common indications for permanent pacemaker therapy worldwide include high-grade atrioventricular block (AVB) and sinus node dysfunction.^{1,2}

Even though pacemakers are increasingly used globally to improve the quality of life and lengthen the lives of patients with life-threatening arrhythmia and symptomatic bradycardia, they are associated with several complications.² Some examples of complications include lead failure, lead dislodgement, thoracic trauma, vascular injury, pocket hematoma, infection, pneumothorax, infection, thrombophlebitis, and death.^{3–7}

Although understanding the magnitude of pacemaker-related complications is essential for initiatives to raise the standard of care, there are surprisingly few studies that assess their frequency in sub-Saharan nations, including none in Ethiopia. Therefore, the objective of this study is to evaluate complications related to pacemaker implantation and its associated factors in patients who underwent the procedure at Tikur Anbessa Comprehensive Hospital in Ethiopia from January 2017 to January 2022.

Methods

This study was conducted at Tikur Anbessa Comprehensive Specialized Hospital in Addis Ababa, Ethiopia who were reviewed by author between September 2022 and December 2022. All patients who met the criteria for inclusion were included. A follow-up study was employed with a retrospective chart review study design applied.

Eligibility Criteria

Inclusion criteria was all adult cardiac patients with permanent pacemakers older than 18 years old were treated at Tikur Anbessa Specialized Hospital is inclusion criteria. Patients with incomplete medical records or charts, those under the age of 18, those with ICDs, and those who had CRT were excluded.

Study Variables

Dependent variables were indication and complication of pace maker insertion, outcome, experience of the implanting team and adherence to follow up.

Independent variable were age and sex.

Operative Techniques and Procedures

The left Infraclavicular fossa with antepectoral plane was the default pocket for placing the generator with 1% Lidocaine local anesthetic, unless the patient had a history of pocket site infection in which case the right Infraclavicular fossa side would be chosen. The left subclavian vein was used for the insertion of the leads in 80 patients (67.8%), the left axillary vein in 35 patients (29.7%), the right subclavian vein in 2 patients, and the left cephalic vein in 1 patient. Prophylactic antibiotic with Ceftriaxone 1gm IV or Cefazolin 1gm IV was administered to all patients 1-hour before the procedure. In all cases active fixation was done. Anticoagulants were discontinued before the procedure without IV anticoagulant bridging. The pacemakers were checked as routine on the next day of implantation with cardiologist as part of postoperative follow up before discharge.

All patient had postoperative Chest X-ray before discharge. More than 85% of patients were discharged on the next day of implantation.

The Following Terms and Operational Definitions are Used

Early battery failure is the term used to describe a battery that fails before the manufacturer's specified lifespan. In our study, a drop in left ventricular ejection fraction below 40% in a patient whose initial ejection fraction was higher than 40% was referred to as pacemaker-induced cardiomyopathy. The patient was labeled as adherent if he/she did not miss any clinic follow-up sessions; otherwise, he/she was labeled as non-adherent.

Data Collection Tool and Procedure

Data was gathered using a structured questionnaire. After reviewing numerous works of literature, the instrument was developed. Information for this study was gathered by reviewing patient's medical records. Data collection and management were carried out by healthcare professionals who are knowledgeable and experienced. A two-day training was

given to both the supervisors and the data collectors. The training put a lot of emphasis on the objectives of the study, the content of the tool, the technique for gathering data, ethical issues, and the responsibilities of data collectors.

Data Quality Control

To ensure the quality of the data, the focus was placed on well-designed data collection tools. Supervisors and data gatherers both got training. To ensure validity and consistency, the instrument was pre-tested on 5% of the sample outside the study area. The lead researcher oversaw and guided the entire data-gathering procedure.

Data Processing and Analysis

To confirm the accuracy of the data, it was manually reviewed. The data was coded, and then after data cleaning in the Epi-data program version 4.4.2.1, it was exported to SPSS for Windows, version 25 (SPSS, Chicago, IL, USA) for analysis.

The normality of continuous variables was examined using the Shapiro–Wilk test. The choice was made based on the findings of the normality test, and then the pertinent descriptive statistics for continuous variables were carried out. To display categorical variables, which were described using absolute frequency and percentages, tables and graphs were employed. Based on appropriateness, the chi-square test or Fisher exact test was applied to evaluate the association of the dependent variable with the independent variables. To determine statistical significance, a p-value of less than 0.05 was used.

Results

Sociodemographic Characteristics of the Patients

Out of 128 patients 118 were included in this study, with 10 patients excluded because of an incomplete chart. More than three-quarters of the 118 patients who were included in this study fell within the age range of 23–70 years, with a median age of 60.5 years (IQR: 52 years to 67 years). More than half of the patients were from Addis Ababa (Table 1).

Table 1 Shows the Sociodemographic and Clinical Characteristics of Patients Who Underwent Pacemaker Implantation in Tikur Anbessa Hospital from 2017 to 2022

Sociodemographic Characteristics	Frequency	Percentage
Age of the patient		
23–70 years	93	78.8
71–90 years	25	21.2
Sex		
Male	60	50.8
Female	58	49.2
Residence		
Addis Ababa	66	56
Out of Addis Ababa	52	44
Clinical characteristics		
Symptoms before pacemaker implantation		
Syncope and dyspnoea on mild exertion	26	22
Presyncope, syncope, and dyspnoea on mild exertion	29	24.6

(Continued)

Table 1 (Continued).

Sociodemographic Characteristics	Frequency	Percentage
Syncope, light-headedness, and dyspnoea on mild exertion	63	53.4
Comorbidities		
Hypertension	64	54.2
Hypertension and diabetes mellitus	14	11.9
Others (diabetes mellitus, HIV, thyrotoxicosis, COPD, CVA)	7	5.9
Structural heart diseases (chronic rheumatic heart disease, ischemic heart disease)	11	9.3
None	22	18.6
History of heart failure		
Yes	18	15.3
No	100	84.7
Echocardiographic finding		
LVH	34	27.1
Pulmonary hypertension	17	14.4
Degenerative heart diseases	21	17.8
Others ((HCM, ischemic heart diseases, rheumatic heart diseases, prosthetic valve, Epstein anomaly of tricuspid valve)	14	11.9
Normal	34	28.8
Anticoagulants		
Warfarin or rivaroxaban	8	6.8
No anticoagulants	110	93.2
Other medications		
Aspirin	8	6.8
Aspirin, amlodipine and enalapril	27	22.9
Amlodipine	21	17.8
Enalapril	15	12.7
Diuretics (furosemide and hydrochlorothiazide)	8	6.8
Others (insulin, oral hypoglycaemic agents, beta-blockers, propylthiouracil)	13	11
No medications	26	22
Indications for pacemaker implantation		
Symptomatic 3rd-degree AV block	93	78.8
Atrial fibrillation with fixed block	8	6.8
Initially for 3 rd degree block later for generator depletion	7	5.9
2:1 2nd-degree AV block and sinus node dysfunction	10	8.5

(Continued)

Table 1 (Continued).

Sociodemographic Characteristics	Frequency	Percentage
Implanted by		
Local team	64	54.2
During the campaign/mission	54	45.8
Implantation procedure		
1 st time	107	90.7
For generator change	7	5.9
Lead removal and reimplantation	4	3.4
Generator type		
Medtronic	73	61.9
St Jude	45	38.1
Mode of pacemaker		
Single chamber (VVIR)	24	20.3
Double chamber (DDIR, DDDR)	94	79.7
Adherence		
Adherent	54	45.8
Not adherent	64	54.2
Complications		
At least one complication	18	15.3
No complication	100	84.7

The mean follow-up period of the study participants was 3.92±1.94 years. The majority of patients (53.4%) experienced light-headedness, syncope, and mild dyspnoea before pacemaker implantation, with hypertension being the most common comorbid condition (64.2%). Less than half of patients (28.8%) showed normal echocardiographic findings, and a significant percentage of patients (84.7%) had no history of heart failure. Only 6.8% of patients were using oral anticoagulants (warfarin or rivaroxaban), while 22.9% of patients were also taking enalapril, amlodipine, and aspirin. Symptomatic third-degree AV block was the most frequent indication (78.8%) for pacemaker implantation. A local team implanted more than half of the pacemakers, and more than three-quarters of them were done so for the first time. The majority (79.7% of cases) used dual chamber mode pacing, with more than half of the cases using a generator under the Medtronic brand. With a complication rate of 15.3%, more than half of the patients do not adhere to follow-up (Figure 1 and Table 1).

Age of the patient, sex, symptoms before pacemaker implantation, type of operating team, and adherence to follow-up were the factors associated with pacemaker implantation complications (Table 2).

Discussion

This study evaluated the rate of pacemaker-related complications and its associated factors. Comparable complication rate to other studies were found, and multiple associated factors like patient age, patient sex, pacemaker implanting team, and follow-up adherence were also identified. We identified also the most common pacemaker-related complications as

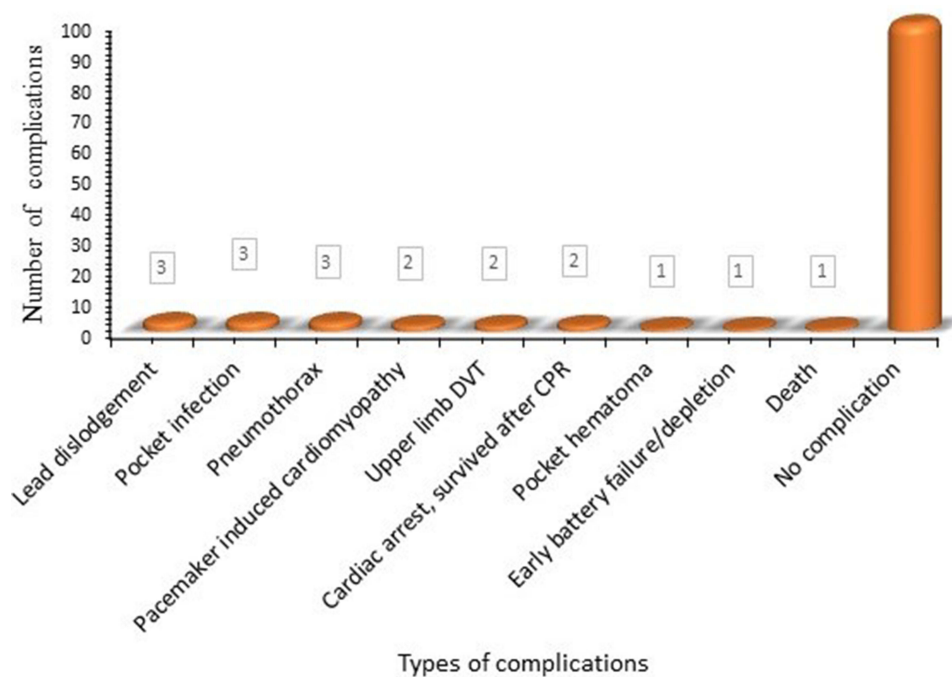


Figure 1 Number and type of complications of patients who underwent pacemaker implantation in Tikur Anbessa Hospital from 2017 to 2022.

pneumothorax, lead dislodgement, and pocket infection, followed by pacemaker-induced cardiomyopathy, cardiac arrest that requires resuscitation, and upper limb DVT.

Studies that looked at the magnitude of complications related to pacemaker implantation found that the rate of complications ranged from 3.6% to 21.6%.⁸⁻¹⁷ Variations in patient sociodemographic factors among studies, patient

Table 2 Shows Factors Associated with Complication of Patients Who Underwent Pacemaker Implantation in Tikur Anbessa Hospital from 2017 to 2022

Sociodemographic Characteristics	No Complication N (%)	At Least One Complication N (%)	P value
Age of the patient at procedure			0.02
<=70 years	83(83)	10(55.6)	
>70 years	17(17)	8(44.4)	
Sex			0.04
Male	55(55)	5(27.8)	
Female	45(45)	13(72.2)	
Residence			0.61
Addis Ababa	57(57)	9(55.6)	
Out of Addis Ababa	43(43)	9(44.4)	
Clinical characteristics			
Symptoms			0.12

(Continued)

Table 2 (Continued).

Sociodemographic Characteristics	No Complication N (%)	At Least One Complication N (%)	P value
Syncope and dyspnoea on mild exertion	23(23)	3(16.7)	
Presyncope, syncope, and dyspnoea on mild exertion	21(21)	8(44.4)	
Light-headedness, syncope, and dyspnoea	56(56)	7(38.9)	
Comorbidities			0.32
Hypertension	56(56)	8(44.4)	
Hypertension and diabetes mellitus	10(10)	4(22.2)	
Others (diabetes mellitus, HIV, thyrotoxicosis, COPD, CVA)	6(6)	1(5.6)	
Structural heart diseases (chronic rheumatic heart disease, ischemic heart disease)	8(8)	3(16.7)	
None	20(20)	2(11.1)	
History of heart failure			0.47
Yes	14(14)	4(22.2)	
No	86(86)	14(77.8)	
Echocardiographic finding			0.95
LVH	27(27)	5(27.8)	
Pulmonary hypertension	15(15)	2(11.1)	
Degenerative heart diseases	17(14.4%)	4(3.4%)	
Others ((HCM, ischemic heart diseases, rheumatic heart diseases, prosthetic valve, Epstein anomaly of tricuspid valve)	13(13)	1(5.6)	
Normal	28(28)	6(33.3)	
Anticoagulants			0.61
Warfarin or rivaroxaban	8(8)	0(0)	
No anticoagulants	92(92)	18(100)	
Other medications			0.16
Aspirin	7(7)	1(5.6)	
Aspirin, amlodipine and enalapril	22(22)	5(27.8)	
Amlodipine	20(20)	1(5.6)	
Enalapril	13(13)	2(11.1)	
Diuretics (furosemide and hydrochlorothiazide)	6(6)	2(11.1)	
Others (insulin, oral hypoglycaemic agents, beta-blockers, propylthiouracil)	8(8)	5(27.8)	
No medications	24(24)	2(11.1)	
Indications for pacemaker implantation			0.21
Symptomatic 3rd-degree AV block	81(81)	12(66.7)	

(Continued)

Table 2 (Continued).

Sociodemographic Characteristics	No Complication N (%)	At Least One Complication N (%)	P value
Atrial fibrillation with fixed block	7(7)	1(5.6)	
Initially for 3 rd degree block later for generator depletion	5(5)	2(11.1)	
2:1 2nd-degree AV block and sinus node dysfunction	7(7)	3(16.7)	
Implanting team			0.01
Local team	49(49)	15(83.3)	
During the campaign/mission	51(51)	3(16.7)	
Implantation procedure			0.26
1 st time	92(92)	15(83.3)	
For generator change	5(5)	2(11.1)	
Lead removal and reimplantation	3(3)	1(5.6)	
Generator type			0.2
Medtronic	59(59)	14(77.8)	
Sent Jude	41(41)	4(22.2)	
Mode of pacemaker			1
Single chamber (VVIR)	21(21)	3(16.7)	
Double chamber (DDIR, DDDR)	79(79)	15(83.3)	
Adherence			0.04
Adherent	50(50)	4(22.2)	
Not adherent	50(50)	14(78.8)	

volumes, and Centre-to-Centre differences in experience levels may all account for this heterogeneity in the rate of complications.

In comparison to studies conducted in Norway, Australia, Germany, the United States, Iraq, Senegal, Cameroon, and Ghana, which showed complication rates of 12%, 7.2%, 3%, 4.2%, 4.25%, 3.9%, 9.7%, and 7%, respectively, this study's complication rate of 15.3% is greater.^{8–10,12,13,15,16} But compared to research from the Netherlands and Nigeria, where complication rates were reported to be 21.6% and 17.6%, respectively, our study's complication rate was lower.^{11,14}

Pneumothorax is a pacemaker-related event in 0.6–3.9% of patients, according to studies. Pneumothorax occurred in 2.54% of study participants in our study, which is about in line with other studies' findings.^{8,15,16,18–22} When compared to individual studies, it is greater than those conducted in Taiwan (0.6%), the United States (1.3%), the United States (1.5%), Denmark (0.9%), the Netherlands (2.24%), Norway (2.8%), Cameroon (1.6%), and Senegal (0.6%), but lower than those made in Spain (3.9%).^{8,15,16,18–22} This variation in pneumothorax magnitude between studies may be explained by variations in professional experience among centres, variations of venous access for implantation, and the inclusion of patients with CRT and ICD in quantifying the pneumothorax rate in some of these researches.

Pacemaker pocket Infection rate was 2.54% in our study, which is greater than those in Spain (1.61%), Iraq (0.25%), India (1.5%), Kenya (1.4%), but lower than Cameroon (3.1%).^{9,16,20,23,24} The variability in pocket infection rates between centres may be explained by the existence of a chronic illness, the patient's immune system, and the use of different aseptic procedures.

In this study, lead dislodgment occurred in 2.5% of patients; this rate was higher than that of the United States (2.4%), Poland (2.4%), the Netherlands (4.9%), Iraq (0.25%), and Senegal (0.6%), but lower than that of Kenya.^{9,11,13,15,23,25} The use of various fixation types and differences in follow-up duration in the studies can account for this disparity in lead dislodgement rate.

This study found 1.7% pacemaker-induced cardiomyopathies, which is less than studies from Korea (16.1%), Norway (9%), and the United States (12.3%).^{26–28} The lower rate of pacemaker-related cardiomyopathy in our study can be attributed to the shorter follow-up time.

We reported an upper limb DVT rate of 1.7%, which was lower than studies conducted in Brazil (6%) and Iran (21%), but was greater than the one from Australia (0.15%).^{10,29,30} Prior reports used different imaging modality approaches, and types of cardiac rhythm management devices, which could be the cause of this significant variation in studies results.

Our studies' 1.7% pacemaker-related cardiac arrest necessitating resuscitation rate is significantly lower than studies conducted in 14 sub-Saharan countries, which found that 20% pacemaker-related cardiac arrest required resuscitation.³¹ In the sub-Saharan study done in 14 countries, there were more pacemaker-rated cardiac arrests during the skill transfer to cardiologists by the trainers.

In our study, 0.8% of patients developed a pocket hematoma, which is higher than studies conducted in Germany (0.2%) and Spain (0.32%), but lower than studies conducted in Cameroon (1.5%), Iraq (1%), and the Netherlands (2.9%).^{9,11,12,16,21} This discrepancy in pocket hematoma rate can be explained by differences in age distribution and comorbidities like coagulopathy.

Our study's early battery failure rate of 0.8% is greater than the global rate of 0.24%.³² The advancement in pacemaker batteries can be attributed to the generally lower rate of early battery depletion.

The rate of mortality following pacemaker implantation primarily depends on the length of follow-up and may or may not be related to the pacemaker. Our study found a death rate that was higher than studies conducted in Australia (0.73%), Iraq (0%), the USA (0.08%), and Kenya (0.0%), but lower than those conducted in Senegal (1.2%), Spain (5.2%), and France (3.9%).^{9,10,13,15,20,23,33}

Studies conducted in the USA and Australia that were similar to ours showed an association between sex and complications related to pacemakers.^{10,22} Because they have 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.

Similar to our research results, studies from the USA, and Netherlands, have shown that complications related to pacemakers are associated with aging. This is because older people have more comorbidities than younger people.^{11,34} In contrast, a study conducted in Turkey revealed that younger patients have a greater rate of complications associated with pacemakers.³⁵

As with any procedure, operator experience is essential to reducing pacemaker-related complications, as was found in our study. This also received backing from research from the United States and Norway.^{8,13}

In our facility, one of the follow-up procedures is evaluating pacemaker abnormalities to identify them early and manage them to avoid complications. However, just 45.8% of our patients were adherent to follow-up, which is the biggest problem with our patients. An issue with adherence was found by various other centres as well. For example, two studies from the USA revealed that only 42.4% and 41.3% of patients adhered to the initial 2–12 weeks of follow-up.³⁶

Conclusion

Pacemaker implantation is associated with many complications. Pneumothorax, pacemaker pocket infection, and lead dislodgement were the most common complications. Patient age at pacemaker implantation, patient gender, implant group type, and follow-up compliance were factors associated with pacemaker-related complications. Skill development through specialized training and compliance counseling may improve outcomes for patients who have complications related to implant group type and poor adherence to follow.

Limitations of the Study

This study had limitations. First, because this was a single-center study with a small sample size, it is difficult to generalize. Second, the retrospective nature of the study may have introduced classification bias into this study. However, it provides valuable information for quality improvement by providing baseline complication data and data for comparing pacemaker complications from other centers and pointing out areas of concern and areas that need improvement to reduce complications.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent and Ethical Clearance

The study complied with the Declaration of Helsinki. A letter of ethical clearance was obtained from Addis Ababa University, College of Health Sciences, Institutional Review Board (protocol number =013/22SNM). Written informed consent was obtained from each patient to participate in the interview and to extract data from their medical charts. Privacy and confidentiality were ensured during patient interview and medical chart review.

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