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REVIEW

Types of Complications and Associated Factors in Patients Undergoing Permanent Cardiac Pacemaker Implantation: A Systematic Review

Firman Sugiharto[1], A Danang Asmara[1], Wulan Puspita Sari[1], Lurdes Acorta Freitas[1], Dadan Ramdani[1], Anastasia Anna[2], Aan Nuraeni[2], Yanny Trisyani[2], Yudi Purnomo[3]

[1]Master Study Program, Faculty of Nursing, Universitas Padjadjaran, Sumedang, West Java, Indonesia; [2]Department of Critical Care and Emergency Nursing, Faculty of Nursing, Universitas Padjadjaran, Sumedang, West Java, Indonesia; [3]Nursing Department, Hasan Sadikin General Hospital, Bandung, West Jawa, Indonesia

Correspondence: Anastasia Anna, Faculty of Nursing, Universitas Padjadjaran, Jl. Raya Ir. Soekarno KM. 21 hegarmanah, Jatinangor, Sumedang, West Java, Indonesia, Tel +6282130109989, Fax +62 02287793411, Email anastasia.anna@unpad.ac.id

Background: Permanent Pacemaker (PPM) implantation is essential in treating cardiac arrhythmias and conduction disorders, especially in patients with heart failure. Although PPM has been proven to improve quality of life and prolong life expectancy in patients with cardiac conduction disorders, post implantation complications still often occur.

Purpose: This study aimed to identify types of complications and associated predictors in patients undergoing PPM implantation.

Methods: This review used a systematic review design and follows the guidelines of the Cochrane Handbook for Systematic Reviews and the Preferred Reporting Item for Systematic Reviews and Meta-analysis (PRISMA). The database used was PubMed, CINAHL: Medline Ultimate, ScienceDirect, Scopus, and search engines: Google Scholar. Articles with observational designs and RCTs in English were included without limitation of publication year.

Results: This review analyzed 15 articles. The analysis showed that there are five categories of factors which influences the incidence of complications in patients after PPM implantation: demographic, pre-existing clinical, comorbid disease, procedural, operator experience, and activity factors. The complications that are most frequently reported are generator erosion, pacemaker infection, pneumothorax, atrial lead displacement, battery depletion, and even death after PPM implantation.

Conclusion: There are many incidents of complications and factors that influence complications in patients after PPM placement. The reported complications underscore the importance of careful patient selection and procedure execution to minimize risks. Healthcare providers should emphasize patients with risk factors to provide targeted monitoring and management. Integrating a multidisciplinary approach involving cardiologists, nephrologists, surgeons, and the nursing team is essential to optimizing patient care and improving clinical outcomes.

Keywords: complication, heart failure, permanent pacemaker, predictors

Introduction

A permanent Pacemaker (PPM) is a medical device implanted under the patient's skin to help regulate abnormal heart rhythms (arrhythmias).[1] There are three types of pacemakers, namely single-chamber pacemakers (stimulation of the right ventricle), dual-chamber pacemakers (stimulation of the ventricles and atria), and biventricular pacemakers also known as cardiac resynchronization therapy, or CRT (stimulation of both ventricles simultaneously).[2] PPM implantation is an essential procedure in the treatment of patients with cardiac arrhythmias and conduction disorders, especially in patients with heart failure.[3] This device can help regulate abnormal heart rhythms by sending electrical impulses to the heart muscle, ensuring a proper or regular pulse and rhythm.[4] This intervention is significant for patients experiencing symptomatic bradycardia, heart block, or other conditions in which the heart's electrical conduction is inappropriate or irregular.[5.]

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Some medical conditions that often require PPM implantation include sick sinus syndrome, atrioventricular (AV) block, and heart failure.[6] Sick sinus syndrome is a disorder where the sinus node, which functions as the heart's natural pacemaker, does not work properly, causing bradycardia, tachycardia, or an irregular rhythm.[3] Meanwhile, AV block occurs when the electrical signal between the atrium and ventricle is blocked or interrupted, which can cause bradycardia and fainting. Various conditions, both physical and psychological, experienced by patients after PPM implantation carry a significant risk of decreasing quality of life (QoL).[7] Therefore, the main aim of using PPM is to improve the quality of life of patients with these conditions, reduce symptoms such as dizziness, fainting, and fatigue, and prevent serious complications associated with arrhythmias, such as heart failure and stroke.[8.]

PPM implantation has significantly improved the quality of life and prolonged life expectancy in patients with cardiac conduction disorders.[9] In addition, PPM implantation can ensure the heart is regulated consistently, eliminating physical symptoms and allowing patients to carry out daily activities better.[8] Then, PPM helps prevent serious complications associated with arrhythmias, such as stroke and heart failure, which can be life-threatening.[10] Previous clinical studies reported that patients with cardiac pacing had significant improvements in physical and emotional parameters, including better exercise capacity and reduced levels of anxiety and depression.[11.]

Although PPM implantation is a generally safe procedure, there are some complications for patients. One of the complications that often occurs is bleeding, especially around the incision area or where the lead enters the vein.[12] In addition, infection is also a substantial risk related to the implantation procedure and to the device itself after insertion.[13] Then, a shift in the electrodes that are part of the pacemaker can occur, resulting in a change in position or failure to transmit electrical impulses.[8.]

Several predictors can influence complications after PPM implantation. Previous studies reported that age and health conditions were factors influencing complications in patients undergoing PPM implantation.[3] In addition, history of illness and use of medications can be factors that can cause complications.[9] Then, poor self-efficacy and self-care also have an impact on the emergence of complications in patients, so education to improve self-care is important.[14–16] Although studies describe complication factors in patients undergoing PPM implantation, knowledge gaps still need to be addressed in understanding the factors that influence clinical outcomes and complications in patients undergoing this intervention.

Predicting complications in patients undergoing PPM implantation is important in post-operative management and patient care planning. Understanding the factors of complications can enable health workers to take appropriate preventive steps and prepare appropriate treatment to reduce the possibility of complications.[6,17] Identifying high-risk patients for bleeding or infection may allow for antibiotic prophylaxis or specialized management during and after the procedure.[18] In addition, by knowing the risk factors associated with electrode implantation or allergic reactions, appropriate precautions can be taken to reduce the likelihood of such complications.

One of these gaps is the need for an in-depth understanding of individual risk factors that could more accurately predict post-operative outcomes, such as patient characteristics, underlying cardiac conditions, and environmental factors.[19] In addition, there is also a need for further research exploring the interactions between these factors and how they influence long-term patient outcomes.[7] To date, the main focus of research has often been on the technical effectiveness of pacemaker implantation procedures, while aspects such as post-operative management and factors affecting long-term prognosis have often received less attention. Therefore, this study aimed to identify types of complications and associated predictors in patients undergoing PPM implantation.

Materials and Methods

Design

This review uses a systematic review design and follows the guidelines of the Cochrane Handbook for Systematic Reviews and the Preferred Reporting Item for Systematic Reviews and Meta-analysis (PRISMA).[20,21] The study protocol was not published or registered.

Eligibility Criteria

Research questions and eligibility criteria for research articles using the PCC approach (Population, Concept, and Context). The research question of this review is what are the most common types of complications and associated factors experienced by patients after undergoing permanent cardiac pacemaker implantation?

P (*Population*): Patient with heart disease or heart failure

C (*Concept*): Predictor of complication

C (*Context*): Permanent pacemaker

The inclusion criteria in this review were original full-text articles in English with primary study. The studies analyzed had to discuss one of the outcomes of this review, such as the type of complications and factors associated with these complications. Types of studies such as RCT and observational (retrospective, prospective, and cross-sectional) with correlation methods were analyzed in this review.

Data Collection and Analysis

Search Strategy

The databases used for article searches were PubMed, CINAHL: Medline Ultimate, ScienceDirect, Scopus, and the search engine Google Scholar which was conducted on October 14, 2024. Keywords used a combination of boolean operators OR and AND. The keywords used were "heart disease OR heart failure OR coronary heart disease" AND "Pacemaker OR cardiac pacemaker" AND "complication OR side effects" AND "predictors OR factors OR determinants".

Study Selection and Quality Appraisal

Two authors (F.S., and A.D.A.) selected studies that met the eligibility criteria. Other authors (W.P.S., L.A.F., and D.R) checked duplication in the initial selection process using the Mendeley application. Then, four authors (F.S., A.D.A., W.P.S and Y.P) check the title, abstract, and full text for relevance to the research topic and establishes inclusion and exclusion criteria for the independent review of the screened records. Then, three authors (F.S, A.A, and A.N) checked each complete text with the Joanna Briggs Institute (JBI) critical assessment checklist in the final process.[22] After the assessment, the authors eliminated all studies with a JBI score of <70%. Next, the authors (A.A, A.N, Y.T and Y.P) decide if there are discrepancies in the review results. All authors had no differences of opinion regarding the appropriateness of the study.

Data Extraction and Analysis

All authors selected studies that fulfilled the eligibility criteria. In the initial stage, they checked for duplication using Mendeley's reference manager. Then, the authors checked the title, abstract, and full text to determine their relevance to the research topic and inclusion and exclusion criteria. Therefore, the articles analyzed in this review have been based on eligibility criteria.

In this review, data analysis was carried out thematically and qualitatively using an exploratory, descriptive approach. The data analysis process begins with identifying and presenting the data obtained in tabular form based on the articles reviewed. After obtaining the data, all authors analyzed and explained the results of each study, which focused on complication and its predictors in patients undergone pacemaker implantation.

The authors grouped the types of complications into seven themes: (1) pacemaker problems, (2) respiratory problems, (3) tissue injury brain, (4) vascular thrombosis, (5) undetected, (6) cardiac problems, and (7) other complications. In addition, predictors of complications are grouped into five predictor categories: (1) demographic, (2) pre-existing clinical, (3) comorbid diseases, (4) procedural factors, and (5) operator experience and activity.

Results

Study Selection

An initial literature search from several databases obtained 8.181 studies from PubMed (n=5.097), Scopus (n=232), ScienceDirect (n=2.286), CINAHL (n=266), and Google Scholar (n=300). Next, the author filtered the research based on

title, abstract, and inclusion criteria so that 29 articles were included. Of the 25 articles, the authors carried out full-text selection and excluded 14 articles because they did not meet the inclusion criteria in this review. Then, the authors assessed the quality of the 15 articles that would be included and appraised using the JBI critical appraisal tool. As a result, the authors included 15 studies in this review. Figure 1 depicts the number of studies analyzed using the PRISMA flowchart.

Study Characteristics

The authors identified cohort studies and RCTs that had passed the critical appraisal stage (n=15) (see Table 1). The focus population in this review is patients with heart disease who have had PPM implanted, either in a single or dual chamber. Most of the studies analyzed in this review were cohort studies (n=14). Most of the research on this topic was conducted in developed countries such as the United States (n=4), United Kingdom (n=2), Ethiopia (n=2), Netherlands, Iraq, Italy, Australia, Finlandia, Taiwan, and Saudi Arabia (n=1) (see Table 2). Participants (n=37,069) of the research analyzed were heart failure patients who had undergone PPM implantation with an average age in the range of 60–85 years.

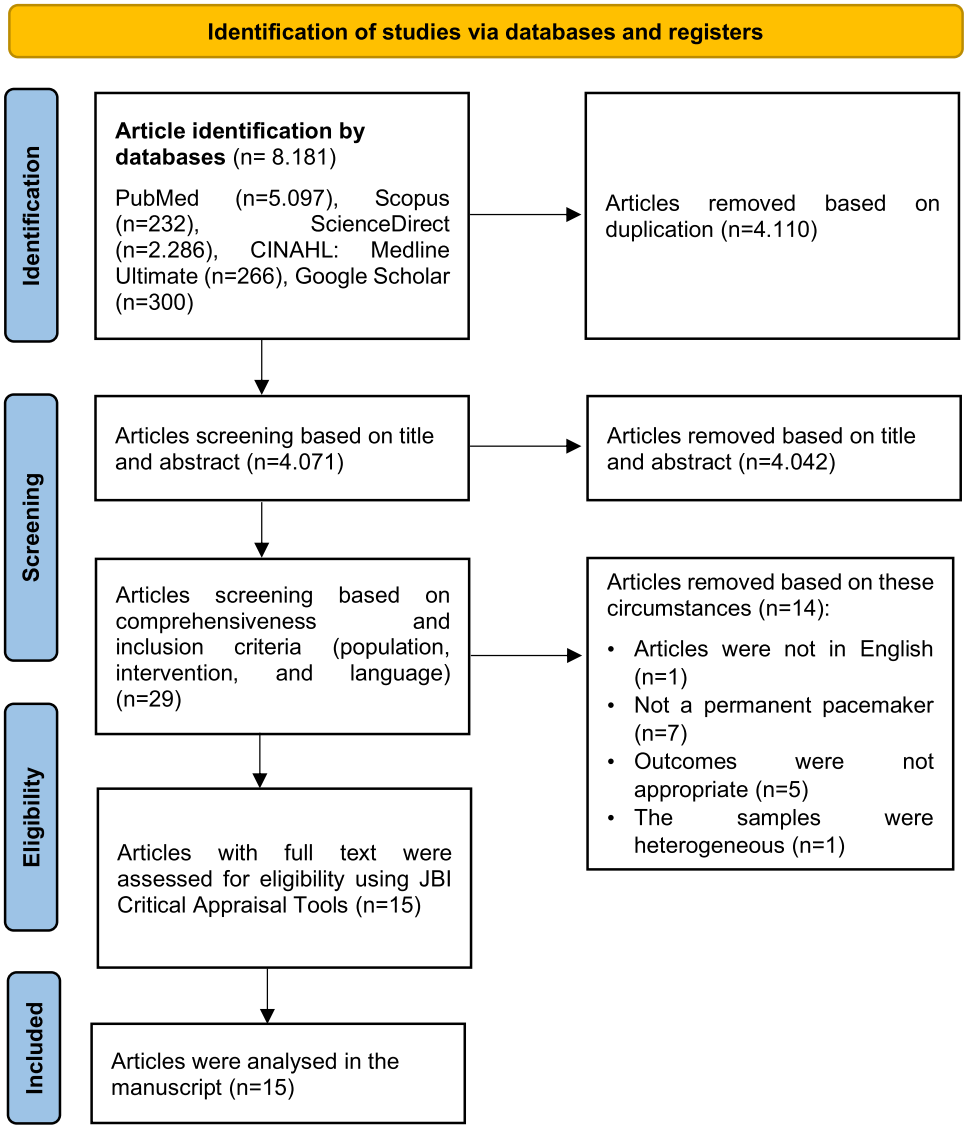

Figure 1 PRISMA Flow Diagram.
Notes: PRISMA figure adapted from Page MJ, McKenzie JE, Bossuyt PM et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021; 372: n71. Creative Commons.[20]

Table 1 JBI Critical Appraisal Results

Study	Design	JBI Critical Appraisal
[8]	Retrospective study	10/11 (90.9%)
[4]	Retrospective study	10/11 (90.9%)
[23]	Retrospective study	10/11 (90.9%)
[24]	Prospective study	8/11 (72.7%)
[25]	Prospective study	9/11 (81.8%)
[26]	Retrospective study	8/11 (72.7%)
[27]	Retrospective study	9/11 (81.8%)
[28]	RCT	11/13 (84%)
[29]	Retrospective study	10/11 (90.9%)
[30]	Retrospective study	10/11 (90.9%)
[31]	Retrospective study	11/11 (100%)
[32]	Retrospective study	11/11 (100%)
[33]	Retrospective study	11/11 (100%)
[34]	Prospective study	8/11 (72.7%)
[35]	Retrospective study	10/11 (90.9%)

Quality Assessment Results

Quality assessment was carried out by three authors (F.S, A.A, and A.N) on the 15 studies analyzed in this review. The results of the JBI analysis show that most of the studies analyzed used cohort studies. This method has the disadvantages of identifying the randomization process, blinding, and confounding factors, and strategies to address these often need to be included. All articles analyzed have a score >70% (see Table 1). In the cohort studies analyzed, some studies still need to include and explain follow-up treatment strategies. In addition, in RCT studies, the study still needs to be related to participant and outcome blinding. Table 1 shows the final results of the quality assessment.

Types of Complications in Patients with a Permanent Cardiac Pacemaker

This review identifies types of complications from PPM implantation for patients with cardiac electrical conduction disorders. Based on the analysis, there were eight categories of complications that can occur, such as pacemaker problems, respiratory problems, cardiac problems, brain problems, vascular thrombosis, tissue damage, undetected, and other complications.

These categories are grouped based on where the complication occurs. In the problems with pacemakers, the most common complications are infections, lead dislodgement, and battery depletion. Problems that occur in the respiratory system are pneumothorax, hemothorax, and in hospital respiratory insufficiency. In addition, implantation a pacemaker can also cause tissue injury such as generator erosion (the condition where the implantation area becomes swollen and pus appears), hematoma and superficial wound infection. Patients who have a pacemaker installed can also experience brain and vascular problems complication such as stroke or other cerebral vascular events (See in Table 3). Then, some complications cause lengthening of hospitalization time and death without the cause being known. On the cardiac side, the complications that often occur are heart failure, cardiac perforation, cardiac tamponade, blockade of the left bundle branch (LBBB), endocarditis and pericarditis. Other complication that can occur are sepsis, cancer and trauma. A complete explanation of complications due to permanent pacemaker implanted can be seen in Table 3.

Table 2 Study Characteristics

Author and Years	Methods	Country	Participants				Findings	
			Sample size	Diagnosis	Mean Age	Type of Chamber	Complication after PPM Implantation	Predictor of Complication
Fadahunsi et al (2016)[8]	Correlational analysis with a retrospective approach	United States	651	TAVR	84 (80–88)	Single and Dual chamber	**30 Days Clinical Outcome** 1. Mortality (n=39, 6.0%) 2. Heart Failure (n=32, 4.9%) 3. Composite of mortality and heart failure (n=69, 10.6%) 4. Stroke (n=14, 2.2%) 5. MI (n=2, 0.3%) **1-Year Clinical Outcome** 1. Mortality (n=114, 24.1%) 2. Heart failure (n= 78, 16.5%) 3. Composite of mortality and heart failure (n=176, 37.3%) 4. Stroke (n= 18, 3.1%) 5. MI (n=8, 1.7%)	Not Reported
Rajah et al (2022)[4]	Correlational analysis with a retrospective approach	Saudi Arabia	170	TAVI	77 (74–81)	Single and dual chamber	**30 days outcome** 1. Heart failure (n=3, 6.2%) 2. Composite of mortality or heart failure (n=3, 6.2%) **1 year outcome** 1. Mortality (n=3, 6.2%) 2. Heart failure (n=5, 10.4%) 3. Composite of mortality or heart failure (n=7, 14.6%)	Not Reported
Ravaux et al (2021)[23]	Correlational analysis with a retrospective approach	Netherlands	222	SAVR	68.6 (±10.5)	N/I	In-hospital respiratory insufficiency (n=4, 2.1%) In-hospital cardiac conduction abnormalities (n=143, 64.4%) In-hospital mortality (n=2, 0.9%)	Previous cardiac surgery (OR 3.23; 95% CI 1.34–7.77) (p=0.01) Previous mitral valve surgery (OR 3.25; 95% CI 1.28–8.32) (p=0.01) In-hospital cardiac conduction abnormalities (OR 4.48; 95% CI 3.36–5.98) (p<0.001) Vasopressor use (OR 2.52; 95% CI 1.68–3.79) (p<0.001)

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Aggarwal et al (1995)[24]	Correlational analysis with a prospective approach	United Kingdom	1.088	N/I (First permanent pacemaker implanted)	74.8 ± 12.2	Single and Dual chamber (Sub-clavian vein route)	**Complication** **Requiring re-operation** 1. Pacemaker pocket infection (n = 10, 0.9%) 2. Generator erosion (n = 5, 0.5%) 3. Haematoma or serous fluid collection (n = 5, 0.5%) 4. Electrode displacement (n = 15, 1.4%) **Doesn't require reoperation** 1. Superficial wound infection (n=9,0.8%) 2. Undersensing (n = 10, 0.9%)	Operator experience (p=0.039)
Tobin et al (2000)[25]	Correlational analysis with a prospective approach	United States	1.332	N/I	>65 years old	Dual chamber (70%) (Sub-clavian vein route)	**Incidence of complication** 1. Atrial lead displacement (n=16, 1.2%) 2. Heart Failure (n=32, 4.9%) 3. Pneumothorax with chest tube (n=20, 1.5%) 4. Hemothorax (n=1, 0.08%) 5. Pericardial tamponade (n=3, 0.2%) 6. Death (n=1, 0.08%)	Operator activity (r=0.90, p=0.002) Experience (years implanting) (r =0.81, p =0.016)
Kiviniemi et al (1999)[26]	Descriptive analysis with a retrospective approach	Finlandia	571	N/I Patient with sick sinus syndrome, atrioventricular block, and atrial fibrillation combined with atrioventricular block	72 ± 13	Single and Dual chamber (Cephalic vein, 70%)	**Early complication (<2 weeks after the implantation)** 1. Myocardial Perforation (n=3, 0.7%) 2. Pneumothorax with chest tube (n=20, 1.5%) 3. Lead Dislodgement (n=7, 2.5%) 4. Wound Hematoma Requiring Evacuation (n=5, 1.1%) 5. Deep Vein Thrombosis (n=1, 0.2%) 6. Pacemaker Infection (n=5, 1.1%) 7. Failure to Sense or Capture (n=4, 0.9%) **Late complication (>2 weeks after the implantation)** 1. Failure Due to Dislodgement of atrial lead (n=6, 3.3%) and ventricular lead (n=5, 0.6%) 2. Failure to Capture Due to failure at lead-myocardial interface (n=3, 0.7%) 3. Fracture of lead generator failure due to radiation therapy (n=2, 0.4%) 4. Pacemaker Infection (n=3, 0.7%) 5. Erosion (n=4, 0.9%) 6. Pacemaker Infection (n=5, 1.1%) 7. Atrioventricular Block in Patients with AAI/AAIR-Pacemaker (n= 3, 0.7%)	Not Reported

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Table 2 (Continued).

Author and Years	Methods	Country	Participants				Findings	
			Sample size	Diagnosis	Mean Age	Type of Chamber	Complication after PPM Implantation	Predictor of Complication
Harcombe et al (1998)[27]	Correlational analysis with a retrospective approach	United Kingdom	2.621	N/I	Male (73 years) Female (76 years).	Single and Dual chamber	**Late complication (>6 weeks after the implantation)** 1. Infection (n=18, 0.7%) 2. Erosion (n=20, 0.8%) 3. Electrode problem (n=5, 0.2%) 4. Miscellaneous (n=7, 0.7%)	Elective Unit Replacement (p<0.001). The rate of complications was significantly higher in patients having EURs compared with those receiving their first implant, at 6.5% (3.3% to 9.7%) v 1.4% (0.9% to 1.9%), p< 0.001.
Link et al (1998)[28]	Correlational analysis with single-blind, multicenter, randomized controlled trial	United States	407	N/I	76 ± 8 years	N/I	**Complication** 1. Ventricular lead dislodgement (n=7 1.7%) 2. Atrial lead dislodgement (n=2, 0.5%) 3. Pneumothorax (n=8,2%) 4. Cardiac perforation (n=4, 1%) 5. Subclavian vein thrombosis (n=1, 0.25%) 6. Erosion (n=1, 0.25%) 7. Infection (n=1, 0.25%) 8. Death (n=1, 0.25%)	Age >75 years (p=0.01) Lower weight (p=0.04)
Mazza et al, (2013)[29]	Correlational analysis with a retrospective approach	Italy	490	HF	77±8 years	Single or dual chamber	1. Left bundle-branch block (LBBB) was reported in 30 (8%) patients, and an LVEF,50% in 64 (13%) patients. 2. During a follow-up of 27+21 months, 32 (7%) patients reached the combined endpoint of HF death or hospitalization. On.	**Multivariate analysis** Left bundle-branch block (HR 5.1; 95% CI 1.9–14.2) (p=0.002) LV ejection fraction (<50%) (HR 3.5; 95% CI 1.1–11.1) (p=0.033) **Univariate analysis** Age (>75 years) (HR 3.76; 95% CI 1.3–11.2) (p=0.033) COPD (HR 2.94; 95% CI 1.2–7.1) (p=0.033) CKD (HR 5.43; 95% CI 2.3–13.1) (p<0.001)

Cheng et al, (2019)[30]	Correlational analysis with a retrospective approach	Taiwan	100	N/I	84.5	N/I	Most of the patients (74.1%) died of non-cardiac causes **Non-Cardiac causes (n=40)** 1. Pneumonia (n=14, 35%) 2. Sepsis (n=12, 30%) 3. Cancer (n=8, 20%) 4. Cerebral vascular accident (n=5, 12.5%) 5. Trauma (n=1, 2.5%)	**Univariate Analysis** Major presenting symptom, dyspnea (OR 2.18; 95% CI 1.07–4.47) (p=0.013) eGFR <30 (OR 2.56; 95% CI 1.31–5.00) (p=0.006) BMI <21 (OR 2.41; 95% CI 1.19–4.90) (p=0.01) Atrial fibrillation with slow ventricular response (OR 3.42; 95% CI 1.39–8.40) (p=0.007) **Multivariate Analysis** Age at implantation (OR 1.06; 95% CI 0.99–1.14) (p=0.09) eGFR <30 (OR 4.07; 95% CI 1.95–8.52) (p<0.001) BMI <21 (OR 2.50; 95% CI1.16–5.39) (p=0.02) Atrial fibrillation with slow ventricular response (OR 2.31; 95% CI0.90–5.90) (p=0.08)
Vijayarajan et al (2022)[31]	Correlational analysis with a retrospective approach	Australia	28.714	Sick sinus syndrome, completed heart block, AV block and bradycardia	80 (73–86)	Single or dual chamber	1. Venous thromboembolism (n: 44, 0.15%) 2. Infection post-implantation (n= 177, 0.62%) 3. Pocket complications (n= 7, 0.02%) 4. Cardiac injuries (n = 37, 0.13%) 5. Pericardial effusion (n=173, 0.60%) 6. Cardiac tamponade (n=54, 0.19%) 7. Pneumothorax (n=322, 1.12%) 8. Mechanical complications (n=462, 1.61%) 9. Lead manipulation (n=368, 1.68%) 10. Generator manipulation (n=21, 0.07%) 11. Embolisms, fibrosis, haemorrhage, pain, stenosis or thrombosis (n=642, 2.23%)	Male (OR 0.79; 95% CI 0.72–0.87) (p<0.001) Age–per 1-year increase (OR 0.989; 95% CI 0.985–0.993) (p<0.001) All cardiac valve surgery (OR 2.88; 95% CI 2.37–3.50) (p<0.001) Complete heart block (OR 1.22; 95% CI 1.08–1.36) (p<0.001) Hypertension (OR 1.16; 95% CI 1.04–1.30) (p=0.01) Acute coronary syndrome (OR 1.36; 95% CI 1.06–1.75) (p=0.02)
Nasir et al (2022)[32]	Correlational analysis with a retrospective approach	Ethiopia	182	N/I	65 (58.8–72.3)	Single or dual chamber	1. Lead dislodgement (6.6%) 2. PM-induced tachycardia (5.5%) 3. Early battery depletion (5.5%).	Age (OR 1.1; 95% CI 1.04–1.1) (p<0.001)
Markos et al (2024)[33]	Correlational analysis with a retrospective approach	Ethiopia	118	N/I	60.5	N/I	1. Pneumothorax (n=3) 2. Pocket site infection (n=3) 3. Lead dislodgement (n=3) 4. Cardiac arrest, survive (n=2) 5. Pocket hematoma (n=1) 6. Early battery depletion (n=1). 7. Death (n=1)	Age during surgery (p = 0.02), Gender (p = 0.04) Pacemaker implanting team (p= 0.01),

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Table 2 (Continued).

Author and Years	Methods	Country	Participants				Findings	
			Sample size	Diagnosis	Mean Age	Type of Chamber	Complication after PPM Implantation	Predictor of Complication
Ahmed (2022)[34]	Descriptive analysis with a prospective approach	Iraq	396	N/I	65 ± 16	N/I	**Early complication** 1. Pocket hematoma (n=4; 1%) 2. Pneumothorax (n=3; 0.75%) 3. Pocket infection (n=1; 0.25) 4. Lead dislodgement (n=1; 0.25) 5. Acute pericarditis (n=1; 0.25) **Late complication** 1. Painful shoulder (n=4; 1%) 2. Late pocket infection (n=2; 0.5) 3. Lead malfunction (n=1; 0.25)	Not Reported
Sohail et al (2007)[35]	Correlational analysis with a retrospective approach	United States	87	N/I	63±17	N/I	1. Pocket infection (n=17; 59%) 2. Pocket infection with bacteremia 3. (n=7; 24%) 4. PPM-related endocarditis (n=3; 10%) 5. Bacteremia without signs of pocket infection (n=2; 7%)	>2 leads vs 2 leads (OR 5.41 95% CI 1.44–20.29) (p=0.01) Corticosteroid use (OR 13.90 95% CI 1.27–151.7) (p=0.03) Received antibiotic pro- phylaxis prior to implantation procedure (OR 0.087 95% CI 0.016–0.048) (p=0.005)

Abbreviations: ACS, Acute Coronary Syndrome; AF, Atrial Fibrillation; BMI, Body Mass Index; CAVB, Congenital Atrioventricular Blocks; CKD, Chronic kidney disease; COPD, Chronic obstructive pulmonary disease; ECC, extracorporeal circulation; LBBB, GFR, Glomerular filtration rate; Left Bundle Branch Block; LVEF, LVEF, Left ventricular ejection fraction, RBBB, Right Bundle Branch Block; SAVR: Surgical Aortic Valve Replacement; TAVR: Transcatheter Aortic Valve Replavement, TAVI: Transcatheter Aortic Valve Implantation.

Table 3 Types of Complications Categories

Categories	Sub Categories	References
Pacemaker problems	Pacemaker pocket infection	[24,33–35]
	Electrode displacement	[24]
	Atrial lead displacement	[25,28]
	Ventricular lead displacement	[25,28]
	Lead Dislodgement	[26,31–34]
	Pacemaker Infection	[26–28,31]
	Failure Due to Dislodgement of atrial lead and ventricular lead	[26]
	Failure to Capture Due to failure at lead-myocardial interface	[26]
	Inappropriate fixation of the lead into connector block	[26]
	Electrode problem and lead malfunction	[27,34]
	Mechanical complications	[31]
	Generator manipulation	[31]
	Battery Depletion	[32,33]
	Pocket hematoma	[34]
Respiratory problems	Pneumothorax	[25,26,28,31,33,34]
	Hemothorax	[25]
	In-hospital respiratory insufficiency	[23]
Tissues injury	Haematoma or serous fluid collection	[24]
	Superficial wound infection	[24]
	Generator erosion	[24,26–28]
	Wound Hematoma Requiring Evacuation	[26]
Brain problems	Stroke	[8,36]
	Cerebral vascular accident	[30]
Vascular thrombosis	Deep Vein Thrombosis	[26]
	Subclavian vein thrombosis	[28]
	Venous thromboembolism	[31]
	Embolisms, fibrosis, haemorrhage, pain, stenosis or thrombosis	[31]
Undetected	Miscellaneous	[27]
	Mortality	[4,8,23,28,33]
	Under sensing	[24]

(*Continued*)

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Table 3 (Continued).

Categories	Sub Categories	References
Cardiac problems	MI	[8]
	In-hospital cardiac conduction abnormalities	[23]
	Heart Failure	[4,8,29]
	Cardiac perforation	[26,28]
	LBBB	[29]
	Cardiac injuries	[31]
	Pericardial effusion	[31]
	Cardiac tamponade	[25,31]
	AV Block	[26]
	Cardiac arrest	[33]
	Pacemaker induce tachycardia	[32]
	Endocarditis and Pericarditis	[34,35]
Others complications	Sepsis	[30]
	Cancer	[30]
	Trauma	[30]

Abbreviations: AF, Atrial Fibrillation; LBBB, Left Bundle Branch Block; MI, Myocardial infarction.

Predictors of Complication in Patients with a Permanent Cardiac Pacemaker

This review identifies factors and predictors associated with complications in patients after undergoing the PPM implantation. Based on the results, five categories of factors and predictors are analyzed, such as (a) demographics, (b) pre-existing clinical, (c) comorbid disease, (d) procedural factors, and (e) operator experience and activity factors.

Factors included in demographic factors were age (older age or >75 years), age at implantation, BMI, and Gender (Male). In addition, LBBB, AF with slow ventricular response, LVEF (<50%), eGFR (<30%), major presenting dyspnea, complete heart block, and in-hospital cardiac conduction abnormalities were included in the pre-existing clinical category. Another category of factors was comorbid disease, where there were four diseases reported to be associated with post-PPM procedure complications, namely COPD, CKD, hypertension, and ACS. Then, eight factors are included in the procedural factors category, including ECC time (minutes), vasopressor use, elective unit replacement, previous cardiac surgery, previous mitral valve surgery, >2 leads vs 2 leads, corticosteroid use, and antibiotic prophylaxis prior to the implantation procedure. The last factor category is operator experience and activity, including operator activity, experience (years implanting), and pacemaker implanting team.

Discussion

This systematic review aimed to identify types of complication and associated factors associated in patients with a history of single or dual-chamber PPM implantation. The study found 15 articles related to this topic that were successfully analyzed. Based on the research results, five categories of factors were analyzed, such as demographic factors, pre-existing clinical factors, comorbid disease factors, procedural factors, and operator experience and activity factors. In addition, there were eight clinical outcome categories grouped based on the location of the complication, such as in pacemaker, respiratory, cardiac, brain, vascular thrombosis, tissues, undetected, and other areas (see Table 3).

Each category has different characteristics of complications based on its location. Common complications in the pacemaker category include infection, generator erosion, and lead dislodgement.[26,31–34] On the respiratory side, pneumothorax and hemothorax often occur as complications.[25,26,28,31] PPM implantation can also cause hematoma and infection in the tissue around the implantation area. Patients can also experience neurological disorders such as strokes or other cerebral vascular events.[8,36] Cardiac complications can include heart failure, cardiac perforation, cardiac tamponade, and LBBB.[4,8,29] In the context of the "Tissue problems" category, frequent complications include hematoma formation, accumulation of serous fluid, and superficial wound infections.[24,26–28] Wound hematomas that require evacuation are a serious concern. Understanding the various factors that can influence the possibility of this complication is very important to ensure optimal treatment for patients after pacemaker implantation. In this context, a thorough understanding of these factors is essential in treating patients after pacemaker implantation to minimize the risk of complications that may arise.

Demographics Factors

In the demographic characteristics category, age (over 75 years) was the most frequently reported predictor of post-PPM implantation complications.[28,31–33] Elderly patients are more likely to have varying degrees of hypercoagulability and be bedridden after surgery, which will cause poor blood circulation and result in post-operative complications, such as venous thrombosis.[38] In addition, previous studies reported that male gender was an independent predictor of all-cause mortality.[37] Recent guidelines on cardiac pacing and resynchronization therapy identify an association between the male gender and a higher risk of post-invasive PM.[39] Male patients have a larger aortic annulus.[39] Thus, it can be speculated that oversized measurements are less common in men, which may positively impact atrioventricular conduction.[40.]

Other factors included in the demographic characteristics are BMI and age at implantation of PPM. Patients with a BMI <21 had significantly lower cumulative survival than patients with a BMI of 21–27.[30] In the elderly population, underweight may indicate loss of appetite, poor nutrition, and poor emotional well-being.[37] This can lead to limited daily activities, sarcopenia, weakness, and an increased risk of death.[41,42] Previous studies reported that the older a person is when PPM is installed, the risk of experiencing more significant complications can be more significant.[30]

Pre-Existing Clinical Factors

Abnormalities in the electrical conduction of the heart experienced by patients during hospital treatment are also a determining factor in the incidence of complications from PPM implantation in the future.[23] This condition may increase the risk of complications such as arrhythmia, pacemaker dysfunction, or failure of cardiac synchronization.[23] AF can cause post-implantation hemodynamic instability due to ongoing changes in heart rhythm.[30] In addition, pre-existing LBBB is a risk factor for developing heart failure. In the long term, LBBB has been associated with increased cardiac mortality,[43] and progression of heart failure.[44] Then, complete heart block (CHB) may increase the risk of postoperative complications such as lead dislocation or hemodynamic imbalance, and patients are at risk of serious arrhythmic events or hypotension during and after the procedure.

Other factors included in the pre-existing clinical category are LFEV <50%, eGFR (<30%), and major presenting dyspnea.[29,30] Patients with LVEF <50% have a dramatically increased risk of heart failure events that can be caused by ventricular and atrioventricular desynchrony.[29] Meanwhile, patients with low eGFR values indicate a significant decline in kidney function.[29] This condition is at a higher risk of infection, bleeding, and impaired wound healing. In addition, Cheng et al concluded that patients with dyspnea as the main initial symptom were associated with worse long-term survival compared with those presenting with symptoms of dizziness, presyncope, or syncope.[30] Patients who experience severe shortness of breath prior to pacemaker implantation are at higher risk of cardiac decompensation post-procedure.[45,46]

Comorbid Disease Factors

CKD is one of the comorbid diseases that has the highest OR value (OR= 5.43) (See Table 4).[29] CKD, expressed by high serum creatinine levels and a decrease in eGFR, is one of another the high category predictors that influence the incidence of complications in patients who have undergone PPM implantation.[29] Higher pre-procedure serum creatinine

Table 4 Categorization of Predictor of Complication in PPM Implantation

Categories	Highest Ratio OR/HR (95% CI)	Lowest Ratio OR/HR (95% CI)	r Correlation	Ref
Demographic Factors				
Age (older age or >75 years)	1.1 (1.04–1.1)	0.989 (0.98–0.99)	–	[28,31–33]
Age at implantation	1.06 (0.99–1.14)	1.06 (0.99–1.14)	–	[30]
BMI	2.41 (1.19–4.90)	2.41 (1.19–4.90)	–	[28,30]
Gender (Male)	0.79 (0.72–0.87)	0.79 (0.72–0.87)	–	[31]
Pre-Existing Clinical Factors				
LBBB	5.1 (1.9–14.2)	5.1 (1.9–14.2)	–	[29]
AF with slow ventricular response	3.42 (1.39–8.40)	3.42 (1.39–8.40)	–	[30]
LVEF (<50%)	3.5 (1.1–11.1)	3.5 (1.1–11.1)	–	[29]
eGFR (<30%)	2.56 (1.31–5.00)	2.56 (1.31–5.00)	–	[30]
Major presenting dyspnea	2.18 (1.07–4.47)	2.18 (1.07–4.47)	–	[30]
Complete heart block	1.22 (1.08–1.36)	1.22 (1.08–1.36)	–	[31]
In-hospital cardiac conduction abnormalities	4.48 (3.36–5.98)	4.48 (3.36–5.98)	–	[23]
Comorbid Diseases Factors				
COPD	2.94 (1.2–7.1)	2.94 (1.2–7.1)	–	[29]
CKD	5.43 (2.3–13.1)	5.43 (2.3–13.1)	–	[29]
Hypertension	1.16 (1.04–1.30)	1.16 (1.04–1.30)	–	[31]
ACS	1.36 (1.06–1.75)	1.36 (1.06–1.75)	–	[31]
Procedural Factors				
ECC time (minute)	1.01 (1.00–1.01)	1.01 (1.00–1.01)	–	[23]
Vasopressor	2.52 (1.68–3.79)	2.52 (1.68–3.79)	–	[23]
Elective Unit Replacement	–	–	$p<0.001$	[27]
Previous cardiac surgery	3.23 (1.34–7.77)	3.23 (1.34–7.77)	–	[23]
Previous mitral valve surgery	3.25 (1.28–8.32)	3.25 (1.28–8.32)	–	[23]
>2 leads vs 2 leads	5.41 (1.44–20.29)	5.41 (1.44–20.29)	–	[35]
Corticosteroid use	13.9 (1.27–151.7)	13.9 (1.27–151.7)		[35]
Received antibiotic pro- phylaxis prior to implantation procedure	0.087 (0.016–0.048)	0.087 (0.016–0.048)	–	[35]
Operator Experience and Activity Factors				
Operator activity	–	–	r=0.90	[25]
Experience (years implanting)	–	–	r=0.81	[25]
Pacemaker implanting team	–	–	$p=0.01$	[33]

Abbreviations: ACS, Acute Coronary Syndrome; AF, Atrial Fibrillation; BMI, Body Mass Index; CKD, Chronic kidney disease; COPD, Chronic obstructive pulmonary disease; ECC, extracorporeal circulation, GFR, Glomerular filtration rate; LBBB, Left Bundle Branch Block; LVEF, Left ventricular ejection fraction.

levels may also be associated with persistent inflammatory status,[47] which can interact negatively with lesions caused by valve implantation at the annular level, causing atrioventricular conduction defects.[23] In addition, ACS and coronary pathology are independent predictors of all-cause mortality in patients after PPM implantation.[30,37] Patients with COPD were associated with a two-fold increase in the likelihood of shock.[48] Previous meta-analyses reported that patients with COPD were significantly associated with the risk of atrial fibrillation (AF), ventricular arrhythmias, and sudden cardiac death.[49] Then, patients who have uncontrolled blood pressure may have an increased risk of bleeding during the procedure, and chronic hypertension can also worsen left ventricular function (systolic dysfunction), which in turn can complicate patient management after PPM implantation.[33,50]

Procedural Factors

Long-term use of corticosteroids can also increase the high risk of infection, which has the highest OR value compared to other variables (OR=13.9).[35] Corticosteroids can cause blood vessel fragility, delayed wound healing, and increased risk of infection.[51] Chronically used corticosteroids suppress the immune response and can interfere with wound healing by reducing collagen production and tissue regeneration, prolonging the healing time, and increasing the risk of complications.[52,53] Therefore, administering antibiotic prophylaxis before PPM implantation is essential to prevent infection, a common complication after implantation, especially in elderly patients.[35] In addition, the use of vasopressors during the PPM placement procedure may increase the risk of complications.[23] Vasopressors, used to maintain blood pressure during hypotensive conditions, can cause extreme vasoconstriction, reducing blood flow to the area around the pacemaker. Vasopressor use has also been associated with impaired perfusion of other organs, which can worsen kidney failure.[54]

Another factor influencing complications is ECC time.[23] Longer ECC time may contribute to an increased risk of complications because it is related to the duration the patient is on cardiopulmonary bypass, which can lead to systemic inflammation, tissue damage, and a higher risk of infection.[23] In addition, placement of more than two pacemaker leads has been identified as a high risk factor for infection.[35] An increase in the number of leads can mean a more complex procedure and longer surgery time. This inherently increases the duration of exposure to potential pathogens in the surgical environment thereby increasing the risk of infection.[35] So, with the presence of more leads, there is increased tissue manipulation and dissection required, which can result in greater tissue trauma.[35,54]

The rate of complications after pacemaker implantation in patients undergoing Elective Unit Replacement (EUR) is much higher than in patients undergoing pacemaker implantation for the first time.[27] The complication rate after EUR is approximately 6.5%, while the complication rate after first-time insertion is approximately 1.4%.[27] The majority of cases of post-EUR complications involve erosion, which appears to be more common in these patients than in those undergoing first-time implantation. Incidents of complications also occur frequently in patients who have previously undergone heart surgery.[23] Previous heart surgery can affect the anatomical structure of the heart, such as scar tissue or changes to other valves.[55] This can make the PPM implantation procedure more complicated and increase the risk of complications such as bleeding, valve perforation, or cardiac arrhythmias.[55]

Operator Experience and Activity Factors

Factors included in the operator experience and activity category are operator activity, experience, and pacemaker implanting team.[25,33] Previous studies reported that there was a significant relationship between complications after PPM implantation, such as pneumothorax (0.2%), pericardial tamponade (0.08%), hemothorax and death (0.16%) with operator activity and experience.[25] The fewest complications occurred in operators who had handled >40 cases/year and had experience >10 years.[25] The lowest complication rate occurs in operators experienced in the cephalic vein cutting technique. Previous study concluded that low operator experience is an independent predictor of complications after PPM implantation.[56] In addition, the team performing pacemaker implantation also plays an important role in the clinical outcome. The experience and skills of the surgical team greatly affect the risk of complications. Teams with more experience and expertise are more likely to be able to reduce the risk of complications such as infection, lead dislocation, or technical errors during implantation.[33]

Implication for Practice

In this review, the predictors that influence the incidence of complications in patients after PPM implantation are multifactorial. The author observed that almost every sample in every article reviewed had more than one factor, accompanied by other risk factors such as age, gender, comorbid diseases, and other coexisting factors. Therefore, various steps can be taken based on the findings in this review to reduce the risk of complications after PPM implantation.

First, the examination and selection of patients must be carried out very strictly. A comprehensive assessment of the patient before PPM implantation is essential, including evaluation of risk factors such as advanced age, male gender, and the presence of comorbidities. Identifying patients at high risk of complications, considering appropriate additional preventive measures, and managing comorbidities also play an essential role. In addition, standardized surgical protocols can reduce procedure variations and improve patient safety. Ensuring that the cardiologist team performing PPM implantation is well-trained and experienced is very important.

After the procedure, close monitoring during the postoperative period is critical to detecting and treating complications as early as possible. Patients must also be given clear guidance regarding the signs of complications to look out for and when to contact medical personnel immediately. So, educating patients and families about the importance of following post-operative medical instructions is essential. Information regarding a healthy lifestyle and necessary routine controls must be communicated clearly to reduce the risk of long-term complications.

Strength and Limitation Study

There are several limitations to this review. Studies discussing this in participants with permanent pacemakers still need to be improved, so the cumulative number of participants tends to be small. The author did not limit the year of publication in order to make the literature search more comprehensive. In addition, the results of this review show that most of the articles analyzed in this review were conducted in developed countries, so it is necessary to carry out similar research in developing countries so that the results of this review can be better generalized.

Conclusion

This study succeeded in identifying the types of complications and associated factors in patients after PPM implantation. The analysis showed five categories of factors: demographic, pre-existing clinical, comorbid disease, procedural, and operator experience and activity factors. In addition, there are eight categories of complications, which are grouped based on the location of the complication, namely pacemaker problems, respiratory problems, tissue injury, brain problems, vascular thrombosis, undetected, cardiac problems, and other complications. The complications most frequently reported are generator erosion, pacemaker infection, pneumothorax, atrial lead displacement, and even death after PPM implantation. Therefore, health workers, including nurses, must be more disciplined in screening and risk assessments to help the medical team prepare better complication mitigation strategies.

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