Original Research Article

Epidemiology of pacemaker implantation among patients in Tanta university hospitals

Abstract

Background: This study describes cardiac pacing activity during 2021: demographic data of patients underwent permanent pacemaker implantation (PPM), risk factors, clinical presentations, indications, mode of pacing, and complications post PPM implantation. Cardiac pacemakers have become the common treatment of symptomatic bradycardia or high-grade atrioventricular block.

Methods: The study was carried out at the department of cardiology Tanta University Hospitals. 102 patients were included in this study. This study was done over a period of six months from October 2020 until April 2021 and follow up for 6 months. All the data about the patients underwent permanent pacemaker implantation were collected by the coordinator in the participating cardiac center.

Results: The most frequent risk factors of PPM implantation was hypertension (69%), followed by diabetes mellitus (29%), coronary artery disease (21%), chronic kidney disease (18%), hypothyroidism (6%), cardiomyopathy (3%), valvular heart disease (2%) and congenital heart disease (1%). The most common indication is complete heart block (69%), followed by second degree heart block "mobeitz type 2" (13%), slow atrial fibrillation (7%), symptomatic heart failure patients with LVEF ≤ 35% , QRS ≥ 150 ms (6%), trifascicular block (3%), sick sinus syndrome (2%). The most frequent mode of pacing used in our study was DDD mode (63%), followed by VVI mode (32%) with (78%) sinus rhythm and (22%) atrial fibrillation rhythm, then CRT-D (4%). Overall complication rate (9%) within 6 months. In our study the most common complication is infection (5%), followed by haematoma (1%), lead fracture (1%), pneumothorax (1%), and lead displacement (1%).

Conclusion: Approximately three-quarters of the patients related to atrioventricular block underwent permanent pacemaker implantaion. Approximately more than half of pacemakers related to patients underwent permanent pacemaker implantation were dual chamber pacemakers. Infection is the most common complication in our study and this is important for strict infection control measures.

Keywords: permanent pacemaker implantation, sinoatrial nodal dysfunction, atrioventricular block.

Introduction

Bradyarrhythmias generally require treatment when an intrinsic ventricular rate leads to clinical symptoms such as syncope, dizziness, or heart failure. Pacemaker implantation is the cornerstone therapy for symptomatic bradycardia. (**Lemke, Nowak, and Pfeiffer 2015) (1)**

Cardiac pacemakers have become the common treatment of symptomatic bradycardia or high-grade atrioventricular block. Pacemaker implant rates have increased exponentially in the last few years, especially in the elderly. The aging of the population, the technological advances of these devices, and the growing number of clinical indications are the main factors that contribute to the increase of this rate. **(Ector and Vardas 2007) (2)**

A pacemaker is a device that provides electrical stimuli to maintain or restore a normal heartbeat.it consists of two primary components: a pulse generator (battery and microcomputer) and one or more electrodes. The electrodes are attached directly to the inside of the heart. **(Erickson and Us 2012) (3)**

There are three basic types of permanent pacemakers, classified into: Single chamber pacemaker, dual chamber pacemaker, biventricular pacemaker**. (Occhetta et al. 2015) (4)**

Complications related to pacemaker insertion includes pneumothorax, hemothorax, subclavian artery laceration, nerve injury, thoracic duct injury, thromboembolic complications related to lead placement, tricuspid injury and tricuspid regurgitation, arrhythmias, perforation with or without tamponad, battery failure, circuit failure and lead failure due to insulation failure or coil fracture and Infection of implantable pacemaker. **(Verma and Knight 2019) (5)**

Patients and Methods

The study was carried out at the department of cardiology Tanta University Hospitals. 102 patients were included in this study underwent PPM implantation more than 18 years of age. This study was done over a period of 6 months from October 2020 until April 2021 and follow up for 6 months. A written informed consent was obtained from all participants. No risk for the subjects who share in this study. Any unexpected risks that appeared during this study were cleared to participants. Standard 12-lead ECG diagnose arrhythmias, conduction block (first, second- and third-degrees heart block, slow AFib, tri- fasicular block and LBBB) and sinus nodal block were also detected. Resting Transthoracic Echocardiography (TTE) is important imaging study for evaluating the underlying structural heart disease. LV dimensions and wall thickness, EF, left atrial diameter and volume were measured. It was done mainly to diagnose structural heart disease causing arrhythmias. Indications of pacemaker

implantations assessed which include Sino nodal dysfunction, complete atrioventricular block, mobeitz 1, mobeitz 2, trifascicular block, slow AFib.

Follow up patients for 6 months after pacemaker implantation and observation of complications which include infection, haematoma, lead fracture, pneumothorax and lead displacement.

Statistical analysis

Continuous variables were summarized using means or medians based on the normality; normally distributed variables were summarized using the mean and standard deviation (SD), while the normally distributed variables were summarized using the median. Categorical data were summarized as the frequency and percentage. All analyses were made by using SPSS 11.0

Results

Demographic data showed mean age for study population of 62.43 ± 9.9 years old, with 44% males and 56% females (table 1).

Table (1): Demographic data in studied population

Data		Mean ±SD	
Age (33 – 89 Ys)		62.43 ±9.9	
Gender	Male	N (102)	Ratio (100%)
		45	44%
	Female	57	56%

The most frequent risk factors in patients with PPM implantation related to this study was hypertension (69%), followed by diabetes mellitus (29%), smoking (24%), coronary artery disease (21%), chronic kidney disease (18%), hypothyroidism (6%), cardiomyopathy (3%), valvular heart disease (2%) and congenital heart disease (1%) (table2).

Table (2): Risk factors & Past History in studied population

	N (102)	Ratio (100%)
HTN	70	69%
Smoking	24	23%
DM	30	29%

Valvular Heart Disease	3	2%
Congenital Heart Disease	1	1%
Coronary artery disease	22	21%
Cardiomyopathy	4	3%
Thyroid Disease	7	6%
Chronic Kidney Disease	19	18%

The most frequent symptoms of patients underwent pacemaker implantation was dizziness (70%), followed by palpitation (36%), shortness of breath (36%), syncope (24%), easy fatigability (20%), and chest pain (10%) (table 3).

Table (3): Symptoms in studied population

	N (102)	Ratio (100%)
Palpitation	37	36%
Dizziness	71	70%
Easy Fatigability	21	20%
Syncope	25	24%
SOB	37	36%
Chest Pain	11	10%

The most common indication for PPM implantation is complete heart block (69%), followed by second degree heart block "mobeitz type 2" (13%), slow atrial fibrillation (7%), symptomatic heart failure patients with LVEF ≤ 35% , QRS ≥ 150 ms (6%), trifascicularblock (3%), sick sinus syndrome (2%) (table 4).

Table (4): Indications of PM in studied population

	N (/ 102)	Ratio (100%)
Sick Sinus Syndrome	2	2%
Complete Heart Block	71	69%
Slow AF	7	7%

Mobeitz Type 1	0	0
Mobeitz Type 2	13	13%
Trifascicular Block	3	3%
LVEF ≤ 35% , QRS ≥ 150 MS , NYHA Class II : IV	6	6%

The most frequent mode of pacing used in our study was DDD mode (63%), followed by VVI mode (32%) with (78%) sinus rhythm and (22%) AFib rhythm, CRT-D (4%) and CRT (1%) (table5).

Table (5): Different Modes of PM in studied population

Modes of PM			
		N (102)	Ratio (100%)
VVI		32	32%
	Sinus rhythm	25	78%
	AFib rhythm	7	22%
DDD		64	63%
CRT-D		5	4%
CRT		1	1%

Table (6): Echocardiographic data in studied population

Data	Mean ±SD
LV EF (26 – 77 %)	62.0 ± 12

Echocardiographic data in studied population

	N (102)	Ratio (100%)
Normal	46	45%
LVH	17	16%
IHD	14	14%
Degenerative MR	11	11%
DCM	8	8%
Dilated aortic root with moderate AR	2	2%
Prothetic aortic valve	2	2%
Prothetic mitral valve	1	1%
Post tertralogy of fallot repair with severe MR	1	1%

Table (7): Laboratory investigations in studied population

Data	Mean ±SD
Urea	49.1 ±43.3
S.cr	1.36 ±1.26
K+	4.2 ±0.6
TSH	2.5±1.4

Follow up patients post PPM implantation for 6 months. The overall complication rate (9%) within 6 months. In our study the most common complication is infection (5%)

with 4 cases required device removal and only one case with superficial surgical site infection (SSI) for follow up with conservatively managemed, followed by haematoma (1%) at surgical site which was conservatively managed, lead fracture (1%) with impedance more than 2000 ohm which managed by lead placement with extraction of fractured lead, pneumothorax (1%) noticed post operative patient was tachyapneic and desaturated and diagnosis confirmed after chest X-RAY and managed with chest tube insertion, and lead displacement (1%) with non-captured beats which managed by lead reposition.

Table (8): Outcomes of PM in studied population

Outcomes of PM		
	N (/ 102)	Ratio (100%)
Normal	93	91%
Hematoma	1	1%
Lead Fracture	1	1%
Infection	5	5%
Pneumothorax	1	1%
Lead displacement	1	1%

Table (9): Management of PM complications in studied cases

Complication	Management
Hematoma	conservative
Lead fracture	Lead removal and replacement another lead

Infection	4 cases required device removal and one case was SSI required conservative management and follow up. No infective endocarditis
Pneumothorax	Chest tube insertion
Lead displacement	Lead reposition

Discussion

Over the last decade there has been a significant increase in the number of cardiac device implantation as permenant pacemaker (PPM) worldwide. Many studies and meta- analysis proved the effectiveness of implanted cardiac rhythm devices in treatment of conduction abnormalities, so the number of implanted devices has been increased all over the world. **(Korantzopoulos et al. 2009) (6)**

In this study, the incidence of PPM in females was more than males and these results concordant with **(Ann et al., 2015) (7)** studied 1307 patients mainly females (50.4%) more than males (49.6%), and discordant with **(Nowak et al., 2010) (8)** studied 17 826 patients mainly 8421 patients were female (47.2%) and 9405 patients were male (52.8%), **(Johansen et al., 2011) (9)** studied 44630 patients mainly 24 023 patients were male (53.8%) and 20 607 patients were female (46.2%), **(Humphries & Hawkins, 2020) (10)** studied 570,000 patients mainly males (58.1%) more than females (41.9%).

The mean age in this study is concordant with **(Khalifa et al., 2021) (11)** studied 100 patients with mean age of 58.1 ± 9.4 and **(Sohail et al., 2007) (12)** studied 29 case patients with mean age of 62 ± 18 and this is could be explained by this study and Khalifa et al., 2021 were carried out in the same country and these results discordant with **(Nichols & Vose, 2017) (13)** studied 15266 patients with mean age of 73.26 ± 12.24 and **(Kataoka et al., 2020) (14)** studied 797 patients with mean age of 79.5 ± 10.7 and this could be explained by a younger population structure in developing countries as compared with developed countries.

Hypertension was the most prevalent risk factor in this study with incidence 69%, this is concordant with these studies **(Eck et al., 2008) (15)** studied 1526 patients with main risk factors of hypertension was the most common co-morbidity (69.1%), followed by diabetes (34.8%), hypercholesterolemia (28.1%), and coronary artery disease (25.8%), **(Khalifa et al., 2021) (11)** studied 100 patients with main risk factors of hypertension was the most common co-morbidity (58%), followed by coronary artery disease (32%), diabetes mellitus (31%) ,and chronic kidney disease (3%), **(Kataoka et al., 2020) (14)** studied 797 patients with main risk factors of

hypertension was the most common co-morbidity (61.9%), followed by diabetes mellitus (22.8%) ,dyslipidaemia (21.6%), myocardial infarction (4.6%), and haemodialysis (2.7%).

Complete heart block was the most prevalent indication of pacemaker implantation in this study with incidence 70%, this is concordant with **(Eck et al., 2008) (15)** studied 1526 patients with the most common indication of pacemaker implantation was complete heart block (40%), then sick sinus syndrome (35%), and slow afib (17%), **(Johansen et al., 2011) (9)** studied 44630 patients with the most common indication of pacemaker implantation was complete heart block (43.5%), followed by sick sinus syndrome (32.7%), then slow atrial fibrillation (14%), **(Pombo Jiménez et al., 2020) (16)** studied 15 833 patients with the most common indication of pacemaker implantation was complete heart block (39.6%), followed by sick sinus syndrome (SSS) (28.4%) of implantations, then second- degree AVB (15.6%), and slow AFib (12.4%), and these results discordant with **(Haug et al., 2011) (17)** studied 535 patients with the most common indication of pacemaker implantation is sinus nodal dysfunction (42.6%), then complete heart block (38.5%), and slow atrial fibrillation (14,4%). In **(Haug et al., 2011) (17)** SSS was the most prevalent indication of pacemaker implantation and this could be explained by sick sinus syndrome is more common in old age and life expectancy is more in developed countries more than developing countries. In developing countries sick sinus syndrome is under estimated because of limitation of screening facilities.

The most common mode of pacemaker implantation was DDD mode (63%), this is concordant with **(Eck et al., 2008) (15)** studied 1526 with the most common mode of pacemaker implantation is DDD (68%) and followed by VVI (24%), **(Kirkfeldt et al., 2014) (18)** studied 5918 patients with the most common mode of pacemaker implantation is DDD mode (51%), then VVI mode (20%), and CRT-D (8%), **(Pombo Jiménez et al., 2020) (16)** studied 15 833 patients with the most common mode of pacemaker implantation is DDD mode (51.5%), then VVI mode (38.5%) while in **(Mode Prescription from 1989 to 2006 . Experience of a Single Academic Centre in Northern Greece, 2008) (19)** mode of PPM rates changed from 1989 to 2006. In 1990, VVI is the most common mode of PPM (97%) and DDD (3%) while in 2006, DDD mode (64.1%), and VVI mode (28.6%). mode of PPM rates changed from 1989 to 2006. This indicates that incidence of dual chamber pacemakers increased nowadays. In this study, the elevated number of cases of VVI mode with sinus rhythm (78%) more than AFib rhythm (22%) of total PPM with VVI mode. This could be explained by availability of single chamber pacemaker in hospital and increased number of patients with extreme of age.

The size of pacemaker generators has been reduced, the quality and durability of pacemaker electrodes have increased, active fixation electrodes have been introduced, and implantation techniques have been improved, which all should reduce the rate of complications.The incidence and PPM complications in convential pacing observed PPM complications within 6 months.

In this study, complications rate post PPM was more than complications rate in **(KiviComplications related to permanent pacemaker therapyniemi et al., 1999) (20)** , studied 571 patients with early complications rate post pacemaker implantation was (6.7%) where the most common complication was infection (1.1%), haematoma requiring evacuation (1.1%), atrial lead dislodgement (1.1%), myocardial perforation (0.7%) and deep vein thrombosis (0.2%) and **(Shakya et al., 2017) (21)** complications rate post pacemaker implantation was (2.4%) and the most common complication was pocket infection (0.9%), then pocket trouble (0.5%), sepsis (0.3%), pneumothorax (0.2%), and lead perforation (0.1%), this could be explained by good control of risk factors and good preparations of patients in developed countries. While complications rate was high in this study and **(Khalifa et al., 2021) (11)**, studied 100 patients with complications rate post pacemaker implantation was (13%) where the most common complication was infection (9%) and haematoma (3%).

In this study, infection rate (5%) was the most common complication. The infection rate post PPM implantation was more than the infection rate in **(Mittal et al., 2014) (22)**, studied 2880 patients in which Patients developed infection are 33 patients (1.1%), **(Ann et al., 2015) (7)**, studied 1307 patients and 12 patients from total developed infection with incidence rate 1.3/1000 device-years, **(Kirkfeldt et al., 2014) (18)**, studied 5918 patients and 49 patients (0.8%) developed infection, **(Haug et al., 2011) (17)**, studied 535 patients and 4 patients (0.7%) developed infection.. This could be explained by good and strict infection control in developed countries. Increasing the incidence rate of infection post CIED is due to long hospital stay of patients and they exposed to infection during this period. Older age and several co-morbidities also increase the risk of infection post PPM implantation. While the infection rate post PPM implantation was concordant with **(Khalifa et al., 2021) (11)**, studied 100 patients and 9 patients (9%) developed infection because both studies were conducted in the same region.

Limitations

1. Small sample size for the whole study and some co-morbidities like chronic kidney disease patients.

2. The results were obtained from a single medical center (cardiology department, Tanta university hospital).

3. The follow-up period was only 6 months; longer follow-up periods may show different results.

Recommendations

Based on our results of the current study we recommend:

• Our study had modest sample size, so we recommend for well-designed and larger PPM epidemiology recruiting more hospitals and more patients over Delta hospitals

and even nationwide for better representation of demographic and clinical characteristics of pacemaker implantion Egyptian patients.

• Adherence to infection control protocol measures.

Conclusion

This study provides an important results of PPM epidemiology at Tanta university hospitals after the publication of the recent cardiac pacing guidelines in 2021. Factors like age and comorbidities determined the likelihood of pacemaker implantations. Approximately three-quarters of the patients related to atrioventricular block underwent permanent pacemaker implantation. Approximately more than half of pacemakers related to patients underwent permanent pacemaker implantation were dual chamber pacemakers. Infection was the most common complication in our study and this is important for strict infection control measures. Having a better insight into these predictors would allow a better triage of patients who would benefit from its implantation.

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