

Evaluation of Clinical Characteristics and Outcomes of Patients Undergoing Pacemaker Implantation in Western Indian State of Maharashtra

Dr. P. P. Deshmukh, Dr. Swapnil Bhedodkar, Dr. Atulsingh Rajput, Dr Mohit Singh, Dr Tanu Namdeo, Dr Suresh Sarwale, Dr Anish

Abstract: *At present, permanent pacemaker implantation is one of the most common therapeutic or prophylactic strategies in the management of patients with cardiac problems. The present study was undertaken to evaluate the clinical profile and outcomes of patients undergoing pacemaker implantation. Total 30 patients, who received permanent pacemaker for bradyarrhythmias from 1st August 2018 to 30th May 2019, were included in the study. A detailed analysis inclusive of history taking and clinical examination followed by biochemical work up (renal function test, thyroid function test, random blood sugar) and cardiac work up were done for each patient. The mean age of patients at implant was 60 years with male predominant. The most common presenting symptoms were syncope (in 66% of patients) followed by lightheadedness (63%), Fatigue (56%), palpitation (56%), and dyspnea (53%). Hypertension (63%) was the most common associated co-morbidity. Complete heart block (70%) was commonest indication of pacing followed by sick sinus syndrome (SSS) (23%) and trifascicular block (7%). The complications observed were pneumothorax and pacemaker implant site wound exudation in one patient each. Complete heart block (CHB) was the major indications of pacemaker implantation in present study and advanced age and male gender were associated with higher implantation rate with minimal complications. The pacemaker implantation is a lifesaving procedure and improves quality of life dramatically.*

Keywords: Pacemaker, Implantation, Bradyarrhythmias, Electrocardiography, Syncope, Sick sinus syndrome

1. Introduction

Pacemakers or artificial pacemakers (PMs) are small electronic medical devices which use the electric impulses delivered by the electrodes that sense intrinsic heart rhythm and provide electric stimulation when indicated [1]. Since the first implantation of a pacemaker (PM) in human by Senning and Elmqvist in 1958, implantable electronic devices have evolved into the mainstay of the treatment of cardiac rhythm disturbances [2] and have become a routine treatment for cardiac conductive disorders [3]. Today, more than 40 years after the first pacemaker implantation, world-wide implantation rate exceeds 400 000 every year [4]. According to 11th world survey of cardiac pacemaker and implantable devices, conducted in 2009, around 20,000 PMs were implanted annually in India [5]. However, at present the numbers must have grown several folds. Despite these growing numbers, there is no national registry in India who collects or tracks data of implanted devices [6].

Third degree heart block is the complete block or dissociation between the atria and the ventricles and a condition when none of the atrial impulses reach the ventricle. The causes of the third degree heart block in children could be congenital [7] or familial [8] and in adults is related to ischemia (of atrioventricular node) or could be non-ischemic [9]. However the worldwide, prevalence of third-degree heart block and sick sinus syndrome (SSS) is 0.04% [10] and 0.296% [11] respectively, whereas the prevalence of trifascicular block is 0.1% in the younger population and increases to 1% in the older population [12].

The clinical presentation depends on the level of the block and the escape rhythm that develops as a result [13]. "Symptomatic bradycardia" is defined as a documented

bradyarrhythmia that is directly responsible for the development of frank syncope or nearsyncope, transient dizziness or lightheadedness, and confusional states resulting from cerebral hypoperfusion attributable to slow heart rate. Patients who experience tachyarrhythmias usually present with a sensation of palpitation, chest pain, or pressure, rather than an abrupt loss of consciousness [14]. Studies discussing the clinical profile of the patients undergoing pacemaker implantation are available in Western literature but there are few studies from the India. Therefore present study was conducted to assess clinical profile and outcomes of patients with cardiac conduction defect undergoing pacemaker implantation in western Indian state of Maharashtra.

2. Materials and Methods

The present study was conducted in the Department of Medicine, Government Medical College, Ambejogai, Maharashtra, India, over a period of 10 months from 1st August 2018 to 30th May 2019. Total 30 patients with symptomatic bradyarrhythmias or asymptomatic cases with heart rate <40 beats/min were registered for the study after written informed consent was obtained. Patients with reversible bradyarrhythmias, drug induced bradycardia, electrolyte imbalance-induced bradyarrhythmias; patients not willing to participate in the study; and patients undergoing revision implantation; and patients aged <18 years were excluded from the study.

The demographic data (age and sex distribution) and history of clinical symptoms were noted. Detailed clinical evaluation was done, followed by investigations including complete hemogram, blood glucose, blood urea and creatinine, lipid profile, thyroid profile, chest x-ray, ECG

and echocardiography. All the selected patients underwent permanent pacemaker implantation under the cover of transfemoral temporary pacemaker implantation. The permanent pacemaker was implanted using a subclavian vein approach on the right side of the chest. All the patients were administered with prophylactic intravenous antibiotic starting 1 h before intervention and continuing for 5 days. Teicoplanin, gentamicin, and ornidazole were given for Gram-positive, Gram-negative, and anaerobic coverage, respectively. After 5 days of intravenous antibiotics, oral amoxicillin clavulanate and levofloxacin were given for another 5 days. Patients were followed up closely for 6 weeks for the monitoring of early complications associated with pacemaker implantation.

Percentage analysis was used to describe distribution of demographic variables and baseline characteristics of study participants.

3. Observations and Results

Total 30 patients were enrolled in the study, among them 19 (63.33%) were males and 11 (36.66%) were females. The majority of patients (21; 70%) were in the age group of 50-70 years as shown in table 1. The mean age of study population was 60.96 years.

Table 1: Demographic data of the patients

Parameters		CHB (n=21)	SSS (n=7)	Trifascicular Block (n=2)	Total (n=30)
Age (years)	40-50	01 (4.76%)	03 (42.85%)	-	04 (13.33%)
	50-60	08 (38.09%)	01 (14.28%)	01 (50%)	10 (33.33%)
	60-70	08 (38.09%)	02 (28.57%)	01 (50%)	11 (36.66%)
	>70	04 (19.04%)	01 (14.28%)	-	05 (16.66%)
Sex	Male	14 (66.66%)	04 (57.14%)	01 (50%)	19 (63.33%)
	Female	07 (33.33%)	03 (42.85%)	01 (50%)	11 (36.66%)

The most common indication for pacemaker implantation were complete heart block (70%) followed by sick sinus syndrome (SSS) (23.33%), and trifascicular block (6.66%), (Figure 1).

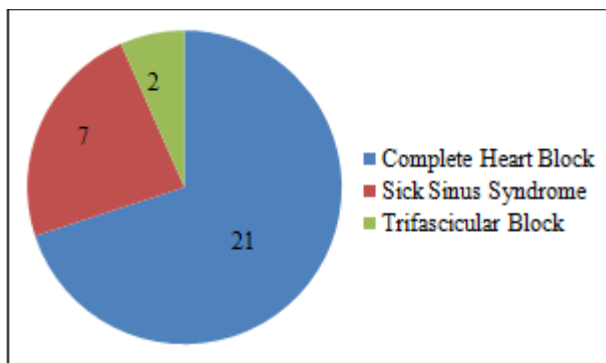


Figure 1: Indication for Pacemaker Implantation

Overall 28 (93.33%) patients were symptomatic at presentation, and these symptoms were attributed to bradycardia. The most commonly presenting symptoms were syncope, light headedness, Fatigue, palpitation, and dyspnea, in 66.66%, 63.33%, 56.66%, 56.66% and 53.33% of patients, respectively. Two patients did not have any symptoms but had heart rate <40 beats/min. Cardiac arrhythmias were associated with hypertension (19; 63.33%), diabetes mellitus (11; 36.66%), and coronary heart disease (CAD) (9; 30%). The symptoms and other comorbid condition in the various groups are shown in Table 2.

Table 2: Distribution of patients according to clinical symptoms and co-morbidities

Characteristic		CHB (n=21)	SSS (n=7)	Trifascicular Block (n=2)	Total (n=30)
Clinical symptoms	H/O Syncope	14 (66.66%)	04 (57.14%)	02 (100%)	20 (66.66%)
	Lightheadedness	11 (52.38%)	06 (85.71%)	02 (100%)	19 (63.33%)
	Fatigue	11 (52.38%)	04 (57.14%)	02 (100%)	17 (56.66%)
	Palpitation	10 (47.61%)	06 (85.71%)	01 (50%)	17 (56.66%)
	Dyspnea	10 (47.61%)	05 (71.42%)	01 (50%)	16 (53.33%)
	Angina	03 (14.28%)	02 (28.57%)	00 (0.0%)	05 (16.66%)
Comorbidities	Hypertension	13 (61.90%)	04 (57.14%)	02 (100%)	19 (63.33%)
	Diabetes Mellitus	07 (33.33%)	03 (42.85%)	01 (50%)	11 (36.66%)
	CAD	07 (33.33%)	02 (28.57%)	-	09 (30.00%)
	Smoking	05 (23.80%)	02 (28.57%)	-	07 (23.33%)
	Alcohol	04 (19.04%)	-	01 (50%)	05 (16.66%)
	Thyroid	02 (9.52%)	02 (28.57%)	01 (50%)	05 (16.66%)

83.33% of the patients underwent the single-chamber, rate-responsive pacing (VVIR) type of pacemaker implantation. The dual-chamber, rate responsive pacing (DDDR) type of pacemaker was implanted in 16.66% of patients who belonged to the complete heart block (CHB) group.

Following permanent pacemaker implantation, there was dramatic improvement in the symptoms of the patients. The complications observed were pneumothorax and pacemaker implant site wound exudation in one patient each as shown in figure 2.

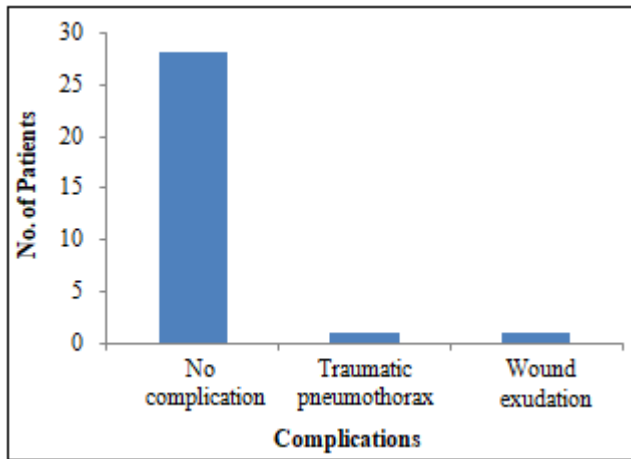


Figure 2: Complication in pacemaker implantation patients

4. Discussion

Out of total population (30 patients) who underwent pacemaker implantation, numbers of male patients were higher than the females (63.33% vs. 36.66%), which is comparable with the earlier studies [6, 15]. The mean age of population was 60.96 years, this outcome is identical to a study published in 2016 [16] and closely similar to the study done by Kumar et al [6]. Majority of patients (70%) were in 50-70 years of age group as similar to the previous studies [12,17] and this implies that pacemaker implantation is primarily required in the geriatric age group. The most common indication for permanent pacing in this study was complete heart block (70%) followed by sick sinus syndrome (SSS) (23.33%), and trifascicular block (6.66%) which is correlated with the other studies [1, 6, 18].

Permanent pacemaker implantation remains the only effective treatment for symptomatic bradycardia. In the present study, 93.33% of patients were symptomatic at presentation, and these symptoms were attributed to bradycardia. Syncope (66.66%) was the most common symptom; were comparable with previous studies [12, 17, 19, 20]. Palpitation was found to be more frequent in the SSS group, in 85.71% of those patients, whereas all 2 patients of the trifascicular group were suffering from syncopal attacks. Two patients were asymptomatic at presentation but had profound bradycardia with heart rates <40 beats/ min, and both of these patients were suffering from complete heart block; these observations are comparable with the earlier studies [12, 17, 20, 21].

Hypertension was the most common associated comorbidity with brady arrhythmias found in 63.33% of patients. The duration of hypertension ranged from 27 years to less than 1 year before the development of symptoms of bradyarrhythmia. None of our patients were on beta blockers, calcium channel blockers (CCBs or dihydropyridines), digoxin, or antiarrhythmics drugs at the time of presentation, which can lead to conduction block and present a similar clinical picture. Hypertension prevalence in the complete heart block and SSS groups was 61.90% and 57.14% respectively, whereas all 2 patients with trifascicular block were hypertensive. 36.66% of patients were diabetic, consistent with previous studies [19, 22]. None of our patients were suffering from type 1 diabetes mellitus. Seven

diabetes mellitus patients had CHB, whereas 3 had SSS and 1 had trifascicular block. Diabetes mellitus was found to be significantly associated with CHB in the present study, which was consistent with other studies [21,22]. Coronary artery disease (CAD) was noticed in 30% of patients. The diagnosis of CAD was on the basis of history, clinical examination, electrocardiography (ECG), and echocardiography, so this may be the reason for lower prevalence of CAD in the present study. Thyroid dysfunction was noticed in 5 (16.66%) patients; of these, 1 patient was suffering from hyperthyroidism and the rest from hypothyroidism. Complete heart block was noted in 2 patients, and SSS was also noted in 2 patients whereas trifascicular block was noted in 1 patient.

93.33% of patients had presented with bradycardia, i.e., heart rate <50 beats/min, and among these, 43.33% of patients had heart rate <40 beats/min. The minimum heart rate of 30 beats/min was noticed. All the 2 patients with heart rate >60 beats/min belonged to the brady-tachy syndrome group and we had reviewed their previous records and found that they had paroxysmal atrial fibrillation or supraventricular tachycardia. The mean heart rate in CHB group was much lower (40.31 ± 5.21) compared to the heart rate in the SSS group (55.39 ± 23.07) and in the trifascicular block group (48.33 ± 15.06). Overall, 46.66% of the study population had cardiomegaly on x-ray chest. Considering subgroups, 50% of patients in the CHB group had cardiomegaly, whereas 43.33% patients in the SSS group and 33.33% in the trifascicular group had cardiomegaly. These findings are similar to study done by Kanse et al [21]. Three-fourths of our patients had normal left ventricular systolic function, whereas only around 13.33% of patients had moderate to severe left ventricular systolic dysfunction.

In the current study, single chamber VVIR was the more common pacing mode (83.33%) as compared to dual chamber DDDR pacing mode (16.66%), which is similar to the data obtained from earlier reports from developing countries [1, 6, 21, 23]. This is in contrast to the trend observed in developed nations and reflects the underlying economic issues in healthcare and lack of health insurance in developing countries. This further implies that permanent pacemakers are implanted mainly when they are essential for survival rather than for an improved quality of life as is prevalent in the general population in India.

The permanent pacemaker implantation is considered to be minor surgery; this does not mean that it is exempt from complications and technical failures in the short and long term [24]. It is with a generally low complication rate mostly between 4-6.1% [25, 26]. In this study subclavian route was used in most of the patients which remains the most widely employed route for pacemaker implantation [1, 27]. Permanent pacemaker implantation is a relatively safe procedure as indicated by the low complication rate of 6.66% (only 2 patients) in this study and this rate is similar to the rates reported worldwide [1, 25, 28]. Among them, one patient had pneumothorax, which was undergoing dual-chamber pacemaker insertion. This patient did not have any symptoms, and x-ray chest was suggestive of minimal pneumothorax (<10% of the pulmonary field in the chest x-ray film). The patient was treated conservatively. This

outcome is comparable with the study done by Kanse et al [21] and Aggarwal et al [29]. Wound infection was suspected in 1 patient of VVIR pacemaker implant, the pus culture was sterile. There were no deaths observed as a complication of pacemaker implantation in the present study which is correlated with the previous studies [21, 30]. The mean duration of the hospital stay was 5.7 days, implying that permanent pacemaker implantation has a low peri-operative and post-operative morbidity.

5. Conclusion

From the results of present study, it was evident that geriatric population constitutes the major bulk of permanent pacemaker implantation with male predominance. Most of the patients were symptomatic due to bradyarrhythmias and syncope was the most common clinical symptom. Complete heart block (CHB) was the major indications of pacemaker implantation and single chamber (VVIR) was the most common mode of implanted pacemaker. After pacemaker implantation, there was significant improvement in symptoms and quality of life.

Thus, pacemaker implantation is a relatively safe procedure with a low complication rate for patients with symptomatic bradyarrhythmia.

References

- [1] Bhat S, Kumar D, Parimoo A. Characteristics, indications and complications in patients undergoing permanent pacemaker implantation: a single centre study. *Int J Res Med Sci* 2018;6:4053-7.
- [2] Larsson B, Elmquist H, Ryden L, Schuller H. Lessons from the first patient with an implanted pacemaker: 1958–2001. *Pacing Clin Electrophysiol* 2003;26:114–24.
- [3] Morgan JM. Basics of cardiac pacing: selection and mode choice. *Heart*. 2006;92(6):850-54.
- [4] Brunnera M, Olschewskib M, Geibela A, Bodea C, Zehendera M. Long-term survival after pacemaker implantation Prognostic importance of gender and baseline patient characteristics. *European Heart Journal* 2004;25:88–95.
- [5] Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009—a world society of Arrhythmia's project. *Pacing and Clinical Electrophysiology*. 2011;34(8):1013-27.
- [6] Kumar B, Prakash J, Kumari S, Manjunath CN. Trends in Permanent Pacemaker Implantation in Indian Population: A Single Centre Experience. *Journal of Clinical and Diagnostic Research*. 2018;12(12):OC10-OC12.
- [7] Griffiths SP: Congenital complete heart block. *Circulation*. 1971, 43:615.
- [8] Baruteau AE, Behaghel A, Fouchard S, et al.: Parental electrocardiographic screening identifies a high degree of inheritance for congenital and childhood nonimmune isolated atrioventricular block. *Circulation* 2012, 126:1469-1477.
- [9] Lev M: Anatomic basis for atrioventricular block . *Am J Med*. 1964, 37:742–748.
- [10] Smyth NP. Cardiac pacing. *Ann Thorac Surg* 1979;27:270-83.
- [11] Shul'man VA, NikulinaStu, Puzyrev VP, et al. The etiological aspects of the sick sinus syndrome. *Ter Arkh* 1993;65:38-42.
- [12] Lone NA, Khan KA, Jalal S, Jan VM, Rather HA, Nazir S, et al. Clinical profile and outcome in patients with bifascicular block: The role of invasive electrophysiological study in planning treatment. *Journal of Chinese Clinical Medicine* 2010;5:19-25.
- [13] Penton GB, Miller H, Levine S: Some clinical features of complete heart block . *Circulation*. 1956, 13:801-824.
- [14] Tyagi LK, Singh V, Gaur K, et al. Epidemiology, pathophysiology and treatment of different types of syncope: A review. *Global J Pharmacol* 2009;3:166-70.
- [15] StyliadisIH, Mantziari AP, Gouzoumas NI et al. Indications for permanent pacing and pacing mode prescription from 1989 to 2006. Experience of a single academic centre in Northern Greece. *Hellenic J Cardiol*. 2008;49:155-62.
- [16] Dêbski M, Ulman M, ZŹ Bek A, et al. Gender differences in dual-chamber pacemaker implantation indications and long-term outcomes. *Acta Cardiologica*. 2016;71(1):41-45.
- [17] Rubenstein JJ, Schulman CL, Yurchak PM, DeSanctis RW. Clinical spectrum of the sick sinus syndrome. *Circulation* 1972;46:5-13.
- [18] Larsen P, Kerr A, Hood M et al. Pacemaker use in New Zealand—data from the New Zealand implanted cardiac device registry (ANZACS-QI 15). *Heart, Lung and Circulation*. 2017;26(3):235-39.
- [19] Jain M, Kiyawat P, Kiyawat S. Clinical profiles of patients undergoing pacemaker implantation in India. *JMSCR* 2018;6(6):44-47.
- [20] Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA 3rd, Freedman RA, Gettes LS, et al. American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines; Heart Rhythm Society. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation* 2013;127:e283-352.
- [21] Kanse VY, Chongtham DS, Salam KS et al. Clinical profiles and outcomes of patients undergoing pacemaker implantation. *J Med Soc* 2015;29:40-4.
- [22] Movahed MR, Hashemzadeh M, Jamal MM. Increased prevalence of third-degree atrioventricular block in patients with type II diabetes mellitus. *Chest* 2005;128:2611-4.
- [23] Shenthari J, Bohra S, Jetley V et al. A survey of cardiac implantable electronic device implantation in India: By Indian Society of Electrocardiology and Indian Heart Rhythm Society. *Indian Heart J*. 2016;68:68-71.
- [24] Parsonnet, V.; Bernstein, A.D.; Lindsay, B. Pacemaker-implantation complication rates: An analysis of some contributing factors. *J. Am. Coll. Cardiol*. 1989;13:917–921.

- [25] Stevenson RT, Lugg D, Gray R et al. Pacemaker implantation in the extreme elderly. *J Interventional Cardiac Electrophysiology*. 2012;33:51-58.
- [26] Kotsakou M, Kioumis I, Lazaridis G et al. Pacemaker insertion. *Ann Transl Med* 2015;3(3):42.
- [27] Bernstein AD, Parsonnet V. Survey of cardiac pacing in the United States in 1989. *Ame J Cardiol*. 1992;69:331-38.
- [28] Uslan DZ, Tleyjeh IM, Baddour LM et al. Temporal trends in permanent pacemaker implantation: a population-based study. *American Heart J*. 2008;155:896-903.
- [29] Aggarwal RK, Connelly DT, Ray SG et al. Early complications of permanent pacemaker implantation: No difference between dual and single chamber systems. *Br Heart J* 1995;73:571-5.
- [30] Chauhan A, Grace AA, Newell SA et al. Early complications after dual chamber versus single chamber pacemaker implantation. *Pacing Clin Electrophysiol* 1994;17:2012-5.