

Patients Characteristic, Indications, and Complications of Permanent Pacemaker Implantation: A Prospective Single-center Study

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Abstract

Background: Permanent pacemaker implantation is a relatively safe procedure that significantly improves morbidity and mortality among patients with bradyarrhythmias. This study was conducted to determine the patients' characteristics, indications, and complications of pacemaker implantation. **Materials and Methods:** This was a single-center, prospective study conducted in Azadi Heart Center, Duhok, Iraq between March 2013 and March 2020. All patients who had indications for permanent pacemaker implantation according to the current guidelines (AHA/ACC) were included and followed up for at least 1 year. **Results:** The study included 396 patients (242 males [61%] and 154 females [39%]) with a mean age of 65 ± 16 years. The most common presenting symptom was dizziness (63%). Atrioventricular block was the most common indication for pacing in 249 cases (63%), followed by sick sinus syndrome (SSS) in 138 patients (34.8%). The most common mode of pacing was DDD in 234 patients (59%). Among all patients undergoing permanent pacemaker implantation, 17 patients (4.25%) developed early and late complications. The most common early complication was pocket hematoma seen in four patients (1%), followed by pneumothorax in three patients (0.75%). Among late complications, painful shoulder was the most common affecting four patients (1%). **Conclusions:** Pacemaker implantation is a relatively safe procedure with a low complication rate. Elderly males were the most common group receiving permanent pacemaker. Dual-chamber (DDD) pacing mode was the most commonly used mode.

Keywords: Atrioventricular block, permanent pacemaker, sick sinus syndrome

INTRODUCTION

Artificial pacemakers are small electronic devices, which use the electric impulses delivered by the electrodes that sense the intrinsic heart rhythm and provide electric stimulation when indicated. The first definitive electronic pacemaker was implanted by Dr. Senning and Elmqvist in Sweden on October 8, 1958 using a thoracotomy to suture two epicardial leads; it lasted only few hours. Since then, for more than 50 years, pace makers have been the treatment for choice for bradyarrhythmia and heart block.^[1]

Permanent pacemaker implantation is a minimally invasive and relatively safe procedure that significantly improves morbidity and mortality in patients with symptomatic bradyarrhythmias.^[1-3]

Implantation of permanent pacemaker has been steadily increasing worldwide over the last years due to the increasing aging of population.^[1,4-7] The incidence of permanent pacemaker implantation increases with age.^[4] The median age of implantation as reported in various studies conducted globally ranges from 64 to 77 years with a male predominance, and the percentage of male patients ranging from 53.5% to 60%.^[5-8]

There are three main types of permanent pacemakers. (1) Single-chamber pacemakers (AAI and VVI): only one lead is implanted in the right atrium or right ventricle.

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(2) Dual-chamber pacemakers (DDD): two leads are implanted, one in the right atrium and another in the right ventricle; this is the most common type of pacing. (3) Biventricular pacemakers; it is also called cardiac resynchronization therapy (CRT-P); here a third lead is advanced to the coronary sinus for left ventricular pacing. CRT-P is mainly implanted to patients with heart failure, improving symptoms, and quality of life.^[9,10]

Indications for implantation of permanent pacing as defined by the ACC/AHA/HRS guidelines for device-based therapy of cardiac rhythm abnormalities are atrioventricular block (AVB), sick sinus syndrome (SSS), symptomatic bifascicular, and trifascicular block, symptomatic bradycardia, and chronotropic incompetence.^[9,10]

Aim of the study

The aim of this study was to determine the patients' characteristics, indications, and complications of permanent pacemaker implantation.

MATERIALS AND METHODS

A prospective study was conducted in Azadi Heart Center, Duhok/Iraq between March 2013 and March 2020. During this period, all patients who had indications for permanent pacemaker implantation according to the current guidelines (AHA/ACC) were included and followed up for at least 1 year.

Exclusion criteria

Patients requiring generator (box) replacement only and patients not coming for regular follow-up were excluded from this study.

Before implant, all selected patients were sent for complete diagnostic workup such as routine lab tests, electrocardiography (ECG), 24-h Holter monitoring, echocardiography, and electrophysiological study when necessary.

Implant procedure

All the procedures were performed by a single operator. In all the patients, the procedure was performed under local anesthesia. Pacemaker types were selected according to the patient age, physical activity, electrocardiogram, and ejection fraction by echocardiography. Puncture of left or right subclavian vein by Seldinger technique was performed under fluoroscopy guide, incision was made at the infraclavicular region, and a pocket was formed for the placement of the pacemaker generator. The leads were introduced through sheath into the cardiac chambers then tests for sensing and pacing as well as impedance were assessed at the time of implantation. Postoperatively all patients were examined for any complications such

as tamponade, pneumothorax, and hematoma. Also ECG and chest X-ray were taken for all patients both to evaluate lead positioning and to rule out pneumothorax. All patients were kept in hospital for at least 24 h after the procedure, before discharge pacemaker interrogation was performed for checking parameters.

Follow-up

Ten days after discharge all patients were re-examined at follow-up visits at the outpatient clinic for wound care and 4 weeks later for device interrogation, then routine interrogation was performed every 4–6 months thereafter.

Statistical analysis

Analysis of the data was done using SPSS software.

Ethical consideration

The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It was carried out with patients' verbal and analytical approval before sample was taken. The study protocol and the subject information and consent form were reviewed and approved by a local ethics committee according to the document number 212 dated 07/01/2013 to get this approval.

RESULTS

This study included 396 patients, 242 males (61%) and 154 females (49%), with a mean age of 65 ± 16 years. The youngest one was 2 years age and the oldest was 105 years age man. Patients' characteristics are shown in Table 1.

Clinical presentation

The most common presenting symptom was dizziness (63%), easy fatigability (26%), and syncope and presyncope (11%).

Table 1: Patient's characteristic

Patient's characteristics	No.	%
Mean age		
Sex		
Male	242	61
Female	154	39
Clinical presentation		
Dizziness	262	66
Easy fatigability	91	23
Syncope and presyncope	43	11
Smoking	146	36.8
Hypertension	134	33.8
Diabetes mellitus	47	11.86
Coronary artery disease	107	27
Heart block post cardiac surgery	5	1.25
Use of temporary pacing	53	13.4

Indications

AVB was the most common indication for pacemaker implantation in 249 cases (63%), mostly complete heart block in (78.8%) and second-degree Mobitz type II in (21.2%). In five cases (1.25%), the block was a complication of cardiac surgery (valve surgery and congenital heart disease). The second common cause for implanting pacemakers was SSS in 138 patients (34.8%). Third indication was symptomatic bifasicular and trifasicular block in seven patients (1.7%). Symptomatic bradycardia was an indication in only two patients (0.5%) as shown in Figure 1.

Modes of pacing

Dual-chamber pacemaker with DDD pacing mode was the most common mode used in 234 patients (59%) followed by single-chamber pacemaker with VVI mode 141 patients (35.6%). VDD mode was used in 21 patients (6.4%), as in Figure 2.

Complications

Complications were divided into early complications (it included peri-procedural and within the first 30 days after implantation), and late complications occurring after 30 days of implantation. Among the 396 patients undergoing permanent pacemaker implantation, 17 patients (4.25%) developed complications, of these 10 (2.5%) were early

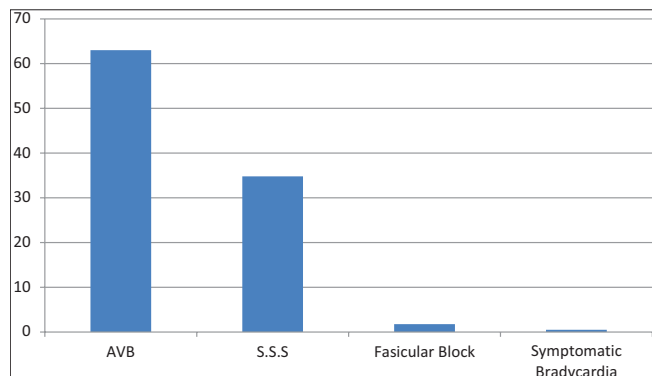


Figure 1: Indications of pacing

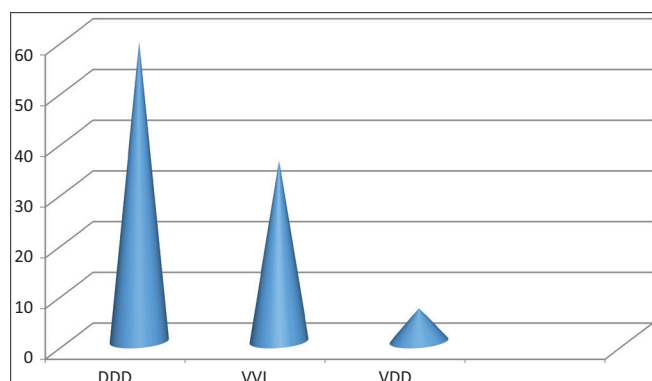


Figure 2: Mode of pacing

and 7 patients (1.75%) had late complications as shown in the table. The most common early complication was pocket hematoma, which was seen in four patients (1%), three patients (0.75%) developed pneumothorax, acute pericarditis was diagnosed in one patient (0.25%), one patient had lead dislodgement (0.25%), and one patient (0.25%) developed superficial pocket infection. Among late complications, painful shoulder was the most common affecting four patients (1%) followed by late pocket infection in two patients (0.5%) and one patient had lead malfunction (0.25%), as shown in Table 2.

DISCUSSION

Since the first implantation of permanent pacemaker in 1958, it remains the only effective therapy for symptomatic bradyarrhythmias. With increase aging of the population, the risk of developing degenerative conduction defects and bradyarrhythmias increases. Also advances of diagnostic facilities lead to more detection of cases requiring permanent pacemaker implantation.

This study was conducted to review patient's characteristics details, indications, modes of pacing and complications of procedures. In this report, the mean age in the study population was 65 years, which is the same as in the national survey of cardiac pacemakers in Iran by Oraii *et al.*^[11] (65.4 years). In a study performed in Turkey by Erdogan *et al.*^[12] the mean age of patients was 66.8 years. Also in a study by Bhat *et al.*^[13] in India, the mean age of patients was 67 years. This was also comparable to age distribution reported worldwide.^[1-5] This indicates that pacemaker implantation is primarily required in the geriatric age group due to the higher prevalence of degenerative conduction diseases and sinus node dysfunction in this specific age group. This study also explored male predominance in 242 patients (61%) as compared with 154 (31%) in females. This was comparable

Table 2: Complications of pacemaker implantation

Complications	No.	%
Early	10	2.5
Pocket hematoma	4	1
Pneumothorax	3	0.75
Pocket infection	1	0.25
Lead dislodgement	1	0.25
Acute pericarditis	1	0.25
Air embolism	0	0
Cardiac perforation	0	0
Pericardial effusion and tamponade	0	0
Death	0	0
Late	7	1.75
Painful shoulder	4	1
Late pocket infection	2	0.5
Lead malfunction	1	0.25
Total	17	4.25

to sex distribution reported by Bhat *et al.*^[13] (60% males), by Oraii *et al.*^[11] (56.2% males), and by Carrión-Camacho *et al.*^[14] (56.13%).

In this study, the main indication for permanent pacemaker implantation was AVB in pacing in 249 cases (63%), followed by SSS in 138 patients (34.8%). In a study by Oraii *et al.*,^[11] the most common indication of pacing in Iran was AVB (56.1%), whereas SSS was the second most common one (20.8%). In the USA, SSS was the primary indication for pacemaker implantation in over 50% of patients,^[15] as reported by Bhat *et al.*^[13] (SSS in 52.5% vs. 47.5% AVB). This difference can be explained by the difference in the availability of more advanced diagnostic facilities that can detect more cases of SSS.

Dual-chamber pacemaker (DDD) was the most common type implanted in this study and form 59% of all cases as compared with 35.6% single-chamber pacemaker with VVI mode and VDD mode in 6.4%. Selection of pacing types is very important and dual-chamber pacemaker is the recommended type in most cases as single-chamber pacing is associated with a higher incidence of atrial fibrillation, congestive heart failure, and pacemaker syndrome. This was reported in several large trials.^[20-22]

In appropriately selected cases single-chamber, VDD pacemaker may be a suitable, less costly alternative to DDD devices, but with time there may be loss of adequate atrial sensing which will end up in a pacemaker working practically in VVI mode with its known adverse consequences.^[16] In many developing countries, the most commonly used pacemaker type is single-chamber pacing; this was observed in a study by Bhat *et al.*^[13] who reported single-chamber VVI as the most common mode of pacing in 62.5% of total cases as compared with dual-chamber DDD pacing (28.5%). Also Oraii *et al.*^[11] reported single-chamber pacemaker (VVI) in 68.9%, whereas only 13.8% of patients received dual-chamber pacemakers. This is in contrast to the trend observed in developed nations such as USA^[15] and Europe^[17] and reflects the underlying economic issues in healthcare and lack of health insurance in developing countries, which further implies that permanent pacemakers are implanted mainly for survival issue rather than for improving quality of life. Also the experience of operator affects the selection of device type as implantation of atrial lead is more complex, time-consuming, and carries the risk of dislodgement more than that of ventricular lead.

Despite being minimally invasive procedure, implantation of permanent pacemaker is not free from complications during or after implantation. Complications of pacemaker implantation are usually divided into early which occurs postoperatively, during hospitalization, and within 30 days and late complications which occur after that. Also complications in general are either related to venous access (e.g., pneumothorax), or to leads (e.g., lead

dislodgement) and the generator pocket (e.g., hematoma and infection) and can be defined as major (e.g., death, cardiac perforation, and tamponade) and minor (e.g., drug reaction, hematoma). In this study, complications were detected in a total of 17 patients (4.25%), of these 10 (2.5%) were early and 7 patients (1.75%) had late complications; this rate is similar to the rates reported worldwide.^[2,18]

The most common early complication was pocket hematoma, which was seen in four patients (1%) which detected early postoperatively and managed conservatively in three patients, whereas in one patient it requires reexploration of wound and hemostasis. In two of these patients, they were on dual antiplatelets shortly after primary percutaneous coronary intervention; another patient was a case of chronic atrial fibrillation with high CHADS-VASC score on direct oral anticoagulant.

The second most common early complication was iatrogenic pneumothorax which was detected in three patients (0.75%): two patients were males and one patient was female; all were old age and the two males were smoker with features of chronic obstructive disease. These cases were recorded in the early part of study which later dramatically reduced. This may be due to increasing learning curve of the operator and the use of fluoroscopy guide for vein puncture. In all three cases, it requires chest tube insertion and the period of admission extended to average of 4 days postoperatively. This percentage of pneumothorax is much more lower rate reported in many other studies.^[2,3,19,20] In this study, one patient had lead dislodgement (0.25%) that required reimplantation of lead and one patient (0.25%) developed superficial pocket infection which treated conservatively by parenteral broad-spectrum antibiotic.

Among late complications, painful shoulder was the most common affecting four patients (1%) which may be explained by the period of immobility at the implanted site. The percentage of painful shoulder after cardiac devices implantation was reported to be as high as 60% of patients 3 months after the procedure.^[21,22]

Late pocket infection occurred in two patients (0.5%), one of them treated conservatively but in the other patient it required complete extraction of the whole system and implantation of new system.^[23,24]

CONCLUSIONS

Pacemaker implantation is a relatively safe procedure with a low complication rate. Elderly males were the most common group receiving permanent pacemaker. Dual-chamber (DDD) pacing mode was the most commonly used mode.

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Conflicts of interest

There are no conflicts of interest.

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