AN AUDIT OF THE COMPLICATIONS OF DUAL AND SINGLE CHAMBER PACEMAKER IN ADULT PATIENTS FOLLOWED OVER A PERIOD OF ONE YEAR

Zahoor Ahmad Khan[1], Shah Sawar[2], Kashif Ullah[3], Zahid Aslam Awan[4]

ABSTRACT

Objective: *To determine the frequency of dual and single chamber pacemaker complications in adults.*

Methodology: *This study was conducted in 151 pacemaker implanted patients and they were followed every month for 1 year, for evaluation / programming of pacemaker function and examining for device related complications.*

Results: *Out of 151 patients with pacemaker, 111(73.5%) patients received single chamber pacemaker and 40(26.5%) patients were implanted with dual chamber pacemakers. In one year follow up 21(13.9%) patients developed different complications while 130 patients had uneventful follow up. The different complications seen were infection 9(6%) patients, lead displacement 4(2.6%) patients, heart failure 3(2.0%) patients, Pacemaker syndrome, lead fracture, diaphragmatic twitching, pocket hematoma and keloid formation at scar site was noted in 1(0.7%) patient each. As a whole complications in single chamber was 73.5% compared to patient with dual chamber pacemaker which was 26.5%.*

Conclusion: *The rate of complications associated with PPM is not significant, but the rate of complications were more in single chamber pacemaker compared to dual chamber pacemaker. Infection was the major complication seen.*

Key Words: *Dual Chamber Pacemaker, Single Chamber Pacemaker, Pacemaker Programmer.*

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INTRODUCTION

Pacemaker is frequently implanted and yet accurate prospective data on implants complications is limited. It is reported that about 600,000 pacemakers are implanted each year worldwide and the total number of people with various types of pacemakers has already crossed 3 million[1].

Elderly patients aged 60 years or older are at increase risk of complications and these are the people referred for pacemaker implantation[2].

The increase in implantation rate also increases the complication rate[3]. The rate of acute complication of pacemaker is 4–5% and is mostly related to operator experience and the incidence of late complication of PPM has been reported 2.7%. Amongst the various complication, infection is relatively rare but devastating complication with incidence of 0.13% to 19.9% in PPM[4].

Although uncommon the majority of the venous access complications occur early after implantation. It includes bleeding hemothorax, pneumothorax and early embolism.

Venous thrombosis is another rare complication, a patient may present with upper extremity pain and swelling. Early device pocket site complications include bleeding with hematoma formation, wound dehiscence or infection. Early device pocket site infections are usually caused by staphylococcus aureus. Late complications (after 30 days) including pocket erosion, keloid formation, pacemaker migration and late infection usually caused by staphylococcus epidermidis. Approximately 6% of the pacemaker patients develop pocket infection[5,6]caused by rare organism like Bulkholderia pseudomallelei or Aspergillus[7,8].

Lead complications include lead

[1]Department Cardiology, Hayatabad Medical Complex, Peshawar - Pakistan

Address for Correspondence:
Dr. Zahoor Ahmad Khan
Department Cardiology,
Hayatabad Medical Complex, Peshawar - Pakistan
E-mail: drzahoorcd_79@yahoo.com

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dislodgement < 2% for ventricular lead and < 5% for atrial lead, lead fracture, insulation break, cardiac rupture caused by lead and pacemaker malfunction.The incidence of pacemaker syndrome ranges from 7% (which needs pacemaker revision) to 27% (mild to moderate symptoms)[9]. The incidence of lead fracture is almost 1% to 2.5 %[10]. Pocket hematoma is a frequent early complication of pacemaker or (ICD) and accounting for 14 – 17% of early re-operation. The rate of pocket hematoma is not increased in patient with coronary artery disease and who are taking aspirin[11].

The aim and rationale of this study,which was conducted in Cardiology department Hayatabad Medical Complex, was to enable us to know the complications associated with single or dual chamber pacemaker implantation in our setup and helped us in taking steps to prevent these complications in timely manner to prevent morbidity associated with these complications and timely follow up. Still significant numbers of patients develop device related complications.

METHODOLOGY

After Hospital Ethical committee permission, this descriptive study was conducted at Cardiology Outdoor Patient Department from 26th Nov 2008 to 31st Jan 2010.

A total of 151 patients implanted with permanent pacemaker were followed up every month for one year in the cardiology OPD. Informed consent was taken for history taking, clinical examination, ECG, x-ray chest (x-ray chest penetrated view) and pacemaker programmer. Patients were asked for unusual symptoms such as dizziness, vertigo, syncope, shortness of breath, pulsation in the neck and abdomen, fatigue, cough, palpitations, ECG of each patients was recorded for any arrhythmia. Echocardiography was done for patients giving history of heart failure. Wound site was examined and then the patients were subjected to programmer interrogation for battery life, lead impedance, and lead displacement, threshold for pacing, sensitivity and arrhythmias by a trained programmer technician of the hospital. Patients with post myocardial infarction and post cardiac surgery patients who are on temporary pacemaker and do not need permanent pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy as these are the confounders and will make the study results biased were therefore excluded from the study.Patients aged 18 years and above both male and female implanted with single or dual chamber permanent pacemaker were included in the study.

RESULTS

This was a hospital based follow up study of 151 patients with permanent pacemaker. Single chamber pacemaker was implanted in 111(73.5%) patients and dual chamber pacemaker in 40(28.5%) patients.

Mean age was 56.34 years± 16.73 SD with range of 18-85 years. 88(58.3%) patients were male and 63(41.7%) were female. Out of 88 male patients, 57(64.77%) were implanted with single chamber pacemaker and 31(35.23%) patients received dual chamber pace makers. Similarly out of 63 female, 54(85.71%) female patients were implanted with single chamber pacemakers and 9(14.29%) patients with dual chamber pacemaker (Table 1).

Out of 151 patients, complications were seen in 21(13.9%) patients and 130(86.1%)

Table 1: Age wise distribution of gender

Age	Gender		Total
	Male	Female	
18-30	13 8.6%	7 4.6%	20 13.2%
31-50	15 9.9%	11 7.3%	26 17.2%
51-70	47 31.1%	40 26.5%	87 57.6%
>70	13 8.6%	5 3.3%	18 11.9%
Total	88 58.3%	63 41.7%	151 100.0%

Table 2: Complications in Single and Dual Chamber Pacemaker

Complications	Type of Pacemaker Implanted		Total
	Single Chamber	Dual Chamber	
Pacemaker Infection	8 5.3%	1 .7%	9 6.0%
Lead Fracture	1 .7%	- -	1 .7%
Lead displacement	4 2.6%	- -	4 2.6%
Pacemaker Syndrome	1 .7%	- -	1 .7%
Heart Failure	3 2.0%	- -	3 2.0%
Others	3 2.0%	- -	3 2.0%
Normal	91 60.3%	39 25.8%	130 86.1%
Total	111 73.5%	40 26.5%	151 100.0%

patients had uneventful follow up for 1 year. Infection was the commonest complication and it was noted in 9(6%) patients. Eight (5.3%) patients with PPM infection were with single chamber and 1(0.7%) patient with dual chamber. The next major complication was lead displacement which was noted in 4(2.6%) patients. Heart failure was seen in 3(2.0%) patients with single chamber pacemaker. Pacemaker syndrome and lead fracture was seen in 1(0.7%) patient each and three(2.1%) other complications consisting of diaphragmatic twitching, pocket hematoma and keloid formation at scar site was noted in 1(0.7%) patient each. As a whole complications in single chamber was found more than dual chamber pacemaker although statistically insignificant. Chi-square test was used to compare the complications in single and dual chamber pacemaker and p-value was 0.367 (Table 2).

Thus it was seen that the frequency of complications in single chamber pacemaker patients were more i.e.73.5% compared to patients with dual chamber pacemaker which was 26.5%.

DISCUSSION

In our study infection was also the commonest complication and it was noted in 9 (6%) patients. The PASE (Pacemaker Selection in the Elderly) study was a prospective study designated to evaluate quality of life in the dual chamber pace maker recipients aged 60 years or older randomized to DDDR versus VVIR programming. Quality of life improved significantly after pacemaker implantation (P< 0.001), but there was no difference between the two pacing modes in the quality of life, cardiovascular events or death. During the course of trial, 53 patients (26%) were reprogrammed to dual chamber pacing due to pacemaker syndrome[12].

After PPM implantation, the device related pacemaker infection has been reported to vary from 0.13 – 19.9% and infective endocarditis accounts for approximately 10% of all cases of device infection, it is lethal infection and mortality rate of 30 – 35% have been reported. Ulsan DZ, Sohail MR and their colleagues found 189 patients with cardiac device infection in follow up of pacemaker patients in Mayo Clinic from 1991 – 2003 and device explantations was done in 182 patients (96%) due to cardiac device infection[13].

Cajoto IV and his colleagues have reported pacemaker infection from 1 – 7% and the pulse generator pocket infection was most common[14].

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Pacemaker Registry study, wound infection was noted in 6 patients (0.5%). Hematoma was noted in 23 patients, (1.9%) lead dislocation in 25 patients (2.1%) lead disconnection in 2 patients (0.2%) and insulation break in 2 patients (0.2%)[15] while pocket hematoma was seen in our study in 1 patient (0.7%).The reported incidence of pacemaker syndrome varies from 1.7% to 83% as reported in PASE trial (Pacemaker Selection in Elderly). In our study pacemaker syndrome and lead fracture was seen in 1 patient (0.7%) each. Ausubel and Furman estimated the incidence of pacemaker syndrome to range from 7% to 20%[16].

The overall incidence of pacemaker syndrome, as prospectively defined in the Mode Selection Trial (MOST) was 18%[17].

The incidence of early lead dislodgment has been reported to 1% in VVI pacemakers and 5.2% in the DDD pacemakers as reported by Catanzaro JN and his colleagues[18]. The next major complication in our study was lead dislodgment after pacemaker infection ,which was 4(2.6%) patients. The incidence of heart failure has been reported to be 3.2% in single chamber pacemakers and 3.3% in dual chamber pacemakers in the United Kingdom Pacing And Cardiovascular Events (UKPACE) study in 2021 patients aged 70 and above[19].

If we compare our tertiary care centre study with other developed countries studies in pacemaker related complications, the rate of complications is less except pacemaker pocket infection. No explanations for device related infection was done in our study and all patients responded to proper antibiotics therapy.

In PASE trial (Pacemaker Selection in Elderly) 25 patients (6.1%) developed complication. In our study, 21 patients developed pacemaker related complication. Similarly lead dislodgment was noted in 4 patients (2.6%) in our study as compared to 1% in VVI and 5.2% in DDD pacemaker patients in Catanzaro JN and his colleagues study[18].

The incidence of heart failure was reported to be 3.2% in single chamber pace maker and 3.3% in dual chamber pacemaker in UK PACE trial. Heart failure was noted in 3 patients (2%) in our study. The observations and rate of complications in PPM in this study goes hand in hand with the other mentioned studies in the literature[19].

CONCLUSION

Pacemaker therapy is well known and established therapy for sick sinus syndrome, higher degree atrioventricular block, electrical, mechanical and other cardiac rhythm disorders. The rate of complications associated with PPM is not significant in this high burden and experienced operators centre.

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None Declared

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CONTRIBUTORS

ZAK conceived the idea and planned the study. SS, KU & ZAA did the data collection and analyzed the study. All the authors contributed significantly to the research that resulted in the submitted manuscript.