Long-term Mortality in Patients with Permanent Pacemaker Implantation

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Abstract
The development of implantable technology for cardiac rhythm management remains one of the seminal achievements of the second half of the 20th century. The development of artificial pacemakers for the electrical control of the cardiac rhythm has greatly enhanced the physician's ability to treat cardiac dysrhythmias. An ageing population and the extension of indications will in all probability result in an increasing number of cardiac device implantations.

Objective of the Study: To study mortality and morbidity in patients with permanent pacemaker implantation at a tertiary care hospital in North India.

Material and Methods: This was a two year prospective observational study conducted in the Department of Cardiology of Christian Medical College and Hospital, Ludhiana. This included a retrospective period of ten years from 1st July 2002 to 30th June 2012, and a prospective period of two years from 1st July 2012 to 31st July 2014. All patients admitted to Christian Medical College and Hospital, Ludhiana, who received a permanent pacemaker for bradyarrhythmias were included in the study. A detailed analysis of demographic profile, indications, complications and mortality data was performed.

Results: A total of 323 patients were included in the study of which more than 75% of the patients receiving the pacemaker were in the age group 56-85 yrs. Males received more pacemakers than females. The commonest presenting symptom was syncope. Complete heart block was the commonest ECG finding. Acquired A-V block was the most common indication of pacing. VVI was the commonest mode of pacemaker implantation. Complications were seen in 3.72% patients. During the entire study period death occurred in 7.1% patients.

Conclusion: Permanent pacemaker implantation is a relatively safe procedure with low complication rates and low mortality particularly in patients who have been on a regular follow up.

Introduction
The era of practical human cardiac pacemaker implantation began more than half a century ago in a laboratory at the University at Buffalo, New York, where Wilson Greatbatch’s mistake resulted in a circuitry that could control human hearts.¹ Since then the permanent pacemaker implantation has increased steadily across the globe over the past 4 decades.²

Editorial Viewpoint
- Ageing population with cardiac pacemakers have increasing morbidity due to different ailments.
- This study included 323 patients with pacemakers and noted morbidity and mortality.
- Acquired AV block was commonest indication of pacing with VVI being commonest mode.
- The study finds low complication rates and low mortality in patients who are on regular follow-up.

Studies have shown improvements in quality of life, exercise capacity, and disease progression in patients with pacemaker implantation.³ Advances in permanent pacemakers (PPM) have resulted in tremendous changes in the care of patients with a wide range of cardiac diseases, including atrioventricular block, sinus node dysfunction, and congestive heart failure.⁴ Permanent pacemaker use has increased because of several factors, including an aging population, advances in device technology, and an increasing number of indications for their use.⁴

Permanent pacemakers are implanted to prevent or treat
bradycardia caused by disorders of the cardiac conduction system. In addition, permanent pacemakers can also be performed to treat tachyarrhythmia and to treat heart failure (Cardiac resynchronization therapy - CRT). There have been two broad types of pacing systems: single chamber (ventricular) and dual chamber. The selection of either a single- or a dual-chamber pacemaker has clinical and economic implications. Specifically, the known physiological and suspected clinical benefits of dual-chamber pacing may be offset by the increased cost and decreased service life of these devices compared with single-chamber pacemakers.

The indications for pacemaker implantation have been changing over time. The indications of permanent pacemakers placed in broad categories are as per ACC/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. Long-term follow-up studies from this part of the world are limited. The present study is an observational study of the patients with permanent pacemakers over a 12-year period. An analysis of indication, complication, and survival data is presented here.

**Material and Methods**

The study was conducted in the Department of Cardiology at Christian Medical College and Hospital, Ludhiana. This was an observational study done over a period of 12 years which included a retrospective period of ten years from 1st July 2002 to 30th June 2012, and a prospective period of two years from 1st July 2012 to 31st July 2014.

All patients admitted during this time period who received a permanent pacemaker for bradycardias were included in the study. The indications of permanent pacemaker implantation were based on the ACC/AHA/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities.

The patient profile were assessed regarding age, sex, symptoms, angina or MI, presence or absence of syncope, cardiomyopathy, fatigue, JVP level, cannon waves, ECG findings, ECHO details before and after PPM insertion, diagnosis, indication for pacemaker implantation, mode of pacemaker, expected battery life, coronary angiograms prior or after implantation, CABG or PTCA prior or after the implantation, comorbidities, any rate lowering drugs consumed, requirement of temporary pacemaker insertion, requirement of generator change, complications post procedure, Pacemaker replaced or not, length of hospital stay, PPM replaced or not. Indication for replacement, survival, cause of death and telemetry data was studied.

In the retrospective period the details were determined from hospital case records, telephonically through letters and interview of the patients or close relatives if possible and telephonically. In the prospective period the patients were assessed personally and followed up at 1 week, 1 month, 6 months, 1 year and yearly thereafter.

Major and minor complications are defined based upon prior reports of device-related complications. Major complications have been defined as death, cardiac arrest, cardiac perforation, cardiac valve injury, hemothorax, pneumothorax, transient ischemic attack, stroke, myocardial infarction, pericardial tamponade, and arterial-venous fistula. Minor complications have been defined as drug reaction, conduction block, hematoma or lead dislodgement requiring reoperation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection.

**Results**

The study comprised of an analysis of patients who underwent permanent pacemaker implantation over 12 year period. The retrospective group included 257 patients and the prospective group included 66 patients. Total number of patients included in the study were 323 out of which two hundred and forty seven patients (76.5%) who received the permanent pacemaker were in the age group between 56 – 85 yrs. There were more male patients (204, 63.16%) who received more pacemaker implantations than female patients (119, 36.84%). The commonest presenting symptom was syncope (116, 35.9%). The commonest associated symptom was fatigue (279, 86.3%). Hypertension was present in 97 (30%) and Diabetes Mellitus in 52 (16.1%) patients.

The most common indication of pacing was acquired A-V block (259, 80.18%) followed by Sinus node dysfunction (56, 17.34%) (Table 1). VVI (230, 71.21%) was the commonest mode of pacemaker implantation followed by VDD (48, 14.86%) and DDD (45, 13.93%).

Coronary angiography was performed in 55 patients (17.0%) during the entire follow-up period. Three hundred and eleven (96.2%) underwent temporary pacemaker implantation prior to permanent pacemaker implantation.

Ninety one (28.17%) patients required generator change following a permanent pacemaker implantation during the study period. Complications were seen in 12 (3.72%) patients during the entire study period following pacemaker implantation (Tables 2 and 4). Twenty three (7.1%) patients

**Table 1: Distribution of subjects according to indications**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total (N=323)</th>
<th>No.</th>
<th>%nage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired A-V block</td>
<td>259</td>
<td>80.18</td>
<td></td>
</tr>
<tr>
<td>Sinus node dysfunction</td>
<td>56</td>
<td>17.34</td>
<td></td>
</tr>
<tr>
<td>Permanent pacing in children</td>
<td>7</td>
<td>2.17</td>
<td></td>
</tr>
<tr>
<td>HOCM</td>
<td>1</td>
<td>0.31</td>
<td></td>
</tr>
</tbody>
</table>

**The study comprised of an analysis of patients who underwent permanent pacemaker implantation over 12 year period.**
common indication of pacing (5.57%) patients had the mode died during the study period (Table 3).

Pacing mode change was performed in 35 (10.83%) patients. During the follow up period 18 (5.57%) patients had the mode changed from VDD to VVI, 17 (5.26%) patients had made changed from DDDR to VVI, one (0.31%) patient had their pacemaker upgraded to DDDR, one (0.31%) patient had epicardial leads placed.

Discussion

Our study has shown that VVI is still the most commonly implanted pacemaker mode at our centre. Although the number of physiological pacemaker implantation is steadily increasing. We found syncope to be the commonest presenting symptom seen in 35.9%. This was followed by presyncope (33.1%) and dyspnea (25.7%). Our study is in accordance with Pyatt JR et al who in a study of 833 patients also found syncope to be the commonest presenting symptom (44%) followed by presyncope (25.3%).

In the present study the most common indication of pacing was acquired A-V block (79.57%) followed by Sinus node dysfunction (17.34%). The other indications were permanent pacing in children and those with congenital heart disease (Table 1). Mayosi et al in a retrospective study showed that ECG indications for pacing were atrio-ventricular block (62%), sick sinus syndrome (25%)

and miscellaneous group (13%). Brady et al in a retrospective study survival data from 546 elderly patients found the indications for pacing were A-V block (52%) and sick sinus syndrome (48%). Uslan et al showed that overall 55.2% of permanent pacemaker implantation recipients had an indication of atrio-ventricular block, 22.8% sinus node dysfunction, 10% biventricular conduction disturbance (both atrioventricular block and sinus node dysfunction), 9.3% carotid sinus hypersensitivity and 2.6% cardiomyopathies.

In the present study majority of pacemaker implantation were of VVI (71.21%) followed by VDD (14.86%) and DDD (13.93%). The frequency of VVI pacemakers gradually decreased as noted in the follow up from 75.88% (retrospective) to 53.03% (prospective). Same time frequency of VDD increased from 8.95% to 37.88%. The frequency of DDD mode also decreased from 15.18% to 9.09%.

In a follow up study in UK in 2002 DDD mode was the most commonly used in 55.1% patients followed by VVI (40%) and AAI (4.9%). Jelic V et al in a retrospective follow up study found a total of 1377 patients (96.23%) had VVI pacemakers, 32 (2.24%) had VVIR and 22 (1.54%) had DDDR or AAI pacemakers. In a study by Uslan DZ at al it was noted that the use of dual chamber pacing mode was increasing over time from 18.6% of device recipients in 1980 to 1984 to 71.2% of patients in 2000 to 2004 (p<0.0001) overall 56.4% of device recipients received dual chamber pacemakers. Greenkopf AJ et al found that overall use of pacemaker implantation increased by 55.6% between 1993 to 2009. By 2009 DDD use increased from 62% to 82% and single chamber ventricular pacemaker use fell from 36% to 14%. Use of DDD devices was higher in urban, non-teaching hospital (79%) compared with urban teaching hospitals (76%) and rural hospitals (7.2%). In FOLLOWPACE study it was found that the most common mode of pacemaker at the time of leaving hospital after implantation was DDD (68%), VVI (24%), AAI (5%), VDD (2%) and DDI (2%).

In our study 12 (3.72%) patients experienced complications during the entire study period. REPLACE study in 2010 looked at complication rates in permanent pacemakers and implantable cardioverter defibrillator patients. It was found that 5 out of 99 patients who received permanent pacemaker developed complications.

In our study there were 23 deaths which were observed during entire follow up. During the prospective period there was one death. There were 22 deaths noted during the retrospective period. There were 20 sudden deaths in the entire study period of which nineteen were in the retrospective period (Tables 3, 4, 5). All the 20 sudden deaths happened at home. Muller et al in a retrospective study on 2256 patients who were followed up after pacemaker implantation found that 1020 (45%) patients had died. 10% died of sudden death, 29% died of heart failure, 14% died of stroke, 10% died of cancer, 22%
Table 5: PPM implantation – long term follow up mortality data

<table>
<thead>
<tr>
<th>Study</th>
<th>Muller C et al14</th>
<th>Brant J et al15</th>
<th>Jahangir A et al16</th>
<th>Present study</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>2256</td>
<td>213</td>
<td>432</td>
<td>323</td>
</tr>
<tr>
<td>Country</td>
<td>Austria</td>
<td>Sweden</td>
<td>U.S.</td>
<td>India</td>
</tr>
<tr>
<td>Mortality</td>
<td>1016 (45%)</td>
<td>35 (16.4%)</td>
<td>238 (55%)</td>
<td>23 (7.1%)</td>
</tr>
<tr>
<td>Cause of death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 sudden death</td>
<td>104 (10%)</td>
<td>7 (3.3%)</td>
<td>14 (3.2%)</td>
<td>19 (5.8)</td>
</tr>
<tr>
<td>2 heart failure</td>
<td>298 (29%)</td>
<td>3 (1.4%)</td>
<td>56 (12.9%)</td>
<td></td>
</tr>
<tr>
<td>3 Stroke</td>
<td>145 (14%)</td>
<td>2 (0.9%)</td>
<td>23 (5.3%)</td>
<td></td>
</tr>
<tr>
<td>4 Cancer</td>
<td>102 (10%)</td>
<td>6 (2.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Misc</td>
<td>367 (36%)</td>
<td>17 (7.9%)</td>
<td>145 (33.5)</td>
<td>4 (1.23%)</td>
</tr>
</tbody>
</table>

Limitations

This study was conducted in two parts with a retrospective and prospective follow up period for pacemaker implantation and subsequent follow up. In the prospective period, the information regarding the indication and other aspects of pacemaker implantation was actively assessed while in the retrospective period, it was ascertained from the case records and the follow up was done telephonically or through letter writing. It is possible that in the retrospective group evaluation and assessment of the permanent pacemaker selection may be different from the real time decision making process that may not be reflected in the case records. The choice of pacemaker was also influenced by the affordability of the patient.

Also, pacemaker selection was not randomized, and unknown, undocumented confounding variables that could not be determined by a retrospective review of the medical records may have led to the selection of one device over the other.

Conclusion

The present study has shown that although VVI pacemakers are still the most commonly implanted mode, the physiological pacemakers are on the rise irrespective of the age group in which they are being implanted. In developing country like India, pacemaker type could partly be due to the patient preference but more so related to the affordability of the patients. The complications observed in the present study are low and are comparable to other studies. Close monitoring of the patient in the post-operative period and careful follow up on a long term basis required for patients with permanent pacemaker could be a determining factor. Permanent pacemaker implantation is a relatively safe procedure with low complication rate and low mortality on long term follow up. A meticulous follow up of these patients at regular intervals is of paramount importance.

References

11. van Eck JW, van Hemel NM, de Vooget WG, et al; FOLLOWPACE investigators. Routine follow-up after pacemaker implantation: frequency, pacemaker programming and


