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Original Article

Early outcome of permanent pacemaker implantation

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Abstract

Background

Permanent pacemaker implantation (PPI) is considered the most effective and safe procedure for treatment of symptomatic bradyarrhythmia. In this study we evaluated incidence of intraoperative and early postoperative (three month) outcome of PPI in our center.

Method

This is a cross sectional study carried out over a period twenty months between August 2015 to July 2018 (3 Years). All patients undergoing PPI at Nobel Medical College were enrolled in the study. Details of demographic data, medical history, hardware used and complications were recorded. Prospective follow up was done in outpatient department upto three months.

Result

A total of seventy-six patients were enrolled in the study. Fifty-one (67%) were male and twenty-five (33%) were female. Ninety percent of the patient was above the age of sixty-five years. Fifty-five (71%) received single chamber and twenty-one (28%) received dual chamber pacemaker. Majority of the patient (87%) had a diagnosis of complete heart block. There was no mortality upto 3 months. Majority (92%) of the patient had no complications at all. Two patients had pocket site infection. Lead dislodgment was noted in three patients. Lead perforation and acute tamponade occurred during intraoperative period in one case, which was successfully managed by pericardiocentesis.

Conclusion

In summary permanent pacemaker implantation was effective and relatively safe procedure in our center with no mortality.

Key words: *Bradyarrhythmia, outcome, permanent pacemaker*

Introduction

Cardiac pacemaker implantation is the treatment of choice in severe and/or symptomatic bradycardia. Implantation of PPI has increased significantly over the years. It is estimated that over 700,000 new pacemakers are implanted yearly, worldwide [1]. With widespread use, pacemaker technology has greatly evolved, and highly sophisticated devices have become available providing optimal support

for treating any type of bradyarrhythmias. Device miniaturization, advent of smart device, improvement and simplification of implantation technique, establishment of new cathlab centers and increase in the training of more physicians has led to the increase number of implantation every year. When the technology grows, safety concerns become more prominent. In this study we tried to evaluate the safety and

outcome of the permanent pacemaker implantation done in our newly established center.

Subjects and Methods

In this prospective observational study, we enrolled all patient undergoing permanent pacemaker implantation at Nobel Medical College, over a period of three years (Aug. 2015-July 2018). All patients were followed up to three months to record any complications of the procedure. Demographic, clinical, electrocardiographic and hardware profile were recorded and analyzed to find any association with complications.

Data are presented as mean values \pm SD or medians for continuous variables and as absolute and relative frequencies for categorical variables. Comparisons between groups were performed using Student's t-tests and chi-square tests, where appropriate.

Results

A total of seventy-six patients undergoing permanent pacemaker implantation were enrolled in the study. Sixty seven percent (n=51) were male and thirty three percent (n=25) were female. Mean age of the patients was 72 years. Ninety percent (n=68) of the patients were above the age of 65 years. Twenty eight percent (n=21) of the patient received dual chamber pacemaker and seventy two percent (n=55) received single chamber pacemaker. Eighty seven percent of the patients (n=66) received pacemaker for the diagnosis of complete AV block. Five patients had sick sinus syndrome and five had 2:1 AV block. Table1.

In this study, forty five percent (n=34) of the people were hypertensive, thirty-one(n=24) percent of the people were diabetic whereas twelve percent (n=9) of the people were smoker and lower number of people was suffering from hypothyroidism(n=9). Table2

Table 1. Demographic and disease characteristics

| Variables | Value |
|----------------|---------|
| Male | 51(67%) |
| Female | 25(33%) |
| Age > 65 years | 90%(68) |
| Age < 65 years | 10%(8) |
| Single Chamber | 55(72%) |
| Dual Chamber | 21(28%) |
| CHB | 66(87%) |
| SSS | 5(6.5%) |
| 2:1 AVB | 5(6.5%) |

Table 2. Comorbidities

| | |
|----------------|---------|
| Hypertension | 34(45%) |
| Diabetes | 24(31%) |
| Smoking | 9(12%) |
| Hypothyroidism | 9(12%) |

Only seven patient experienced complications associated with pacemaker implantation. Out of seven patients, two patients had pocket infection, three patients had lead dislodgement, and one patient had lead perforation and only one patient experienced with the complication of haemothorax. No death was direct result of pacemaker implantation. Table 3

Table 3. Complications

| | |
|-------------------|----|
| No complication | 69 |
| Pocket infection | 2 |
| Lead dislodgement | 3 |
| Lead perforation | 1 |
| Haemothorax | 1 |
| Death | 0 |

Table 4. Association of complications with different variables

| Characteristics | Value | P value |
|-----------------|----------------|---------|
| Age | < 65years | 0.85 |
| | > 65 years | |
| Sex | Male | 0.38 |
| | Female | |
| Type of PPI | Single Chamber | 0.54 |
| | Dual Chamber | |
| Diagnosis | CHB | 0.05 |
| | SSS | |
| | 2:1 AVB | |
| Comorbidities | Hypertension | 0.65 |
| | Diabetes | |
| | Smoking | |
| | Hypothyroidism | |

There is no significant association between age, sex, type of PPI and co-morbidities since p value is more than 0.05. There is significant association between diagnoses of the patient and complications (p value is 0.05). Table 4

Discussion

Pacemaker implantation is the only effective treatment for symptomatic bradycardia. Implantation of a pacemaker reduces symptoms caused by an insufficient blood supply to the vital organs such as the heart and brain, thereby improving patients' quality of life, sometimes even saving a life. Use of permanent pacemaker has been increasing in Nepal in the past few years owing to establishment of more cathlabs capable of performing the procedure. Similarly, it is reported in one study carried out in UK that the estimated average rate of new permanent pacemaker (PPM) insertion per annum is around 610 per million populations (pmp) [2]. However, only one center in Nepal has published the data regarding its safety and outcome [3]. In this present study we tried to evaluate the short-term (3 month) outcome of the patients undergoing permanent pacemaker implantation for various reasons. We don't have any pediatric age group patients. Mean age of the patients was 72 years (40-88). More than ninety percent of the patients were of age more than 65 years. These results are similar to those published by Khanal J et al [3]. A study carried out in Australia reported that the median age of pacemaker recipients was 86 years (interquartile range 83-89) [4].

Our study shows that less number of female patients is likely to receive the pacemaker therapy. Sixty seven percent of the patients were male. The report from Australia in one study is nearly similar to our result which revealed that 61% were male among pacemaker recipients [4]. A

study from Turkey shows that forty nine percent of the patients receiving pacemaker therapy were female [5]. Compared to this our number of female patients is less. The reason may be the less investment of society on female patients.

The effectiveness and cost-effectiveness of dual-chamber pacemakers over single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome has been demonstrated in various studies [6]. However in our study population single chamber pacemaker was the most frequently used one (72%). Main reason for it was financial constrain. The finding of the study done in Australia is different with our study, which revealed that 74% of the patients received a dual-chamber pacemaker [4].

In a study by Veerareddy S and et al sick sinus syndrome (55%) was the commonest cause of PPI [7]. In another study from Greece AV block (47%) was the commonest cause of permanent pacemaker implantation [8]. In our study complete heart block was the commonest (87%) cause of PPI. In our study most of the patients presented with syncope. It may be due to the reason that patient with SSS and pre-syncope didn't attend the clinic or were not properly diagnosed by the physicians on time.

In our study forty five percent of the patient population were having hypertension, thirty one percent had diabetes and twelve percent had hypothyroidism. Patients with heart block and hypothyroidism may or may not improve with treatment of hypothyroidism; it can be just an association. In our study twelve percent of the patients were having hypothyroidism. One study from China reported that 89.9% of the patients with hypertension, 24.1 % with diabetes, 15.2% with TIA and 15.2% with vascular disease were having Pacemaker implantation [9].

The majority of the cases had no complication in our study. Two patients had pocket site infection. Lead dislodgment was noted in three patients. Lead perforation and acute tamponade occurred during intraoperative period in one case. While comparing our findings with the reports from USA and Australia, we found similar results. According to the reports, the incidence of procedural complications is reported between 3% and 6% with around 50% of these complications being serious or requiring further treatment [10-12]. We also evaluated the correlation of different variables with the complications and outcome. Age, Sex, type of pacemaker, comorbidities were not significantly associated with the adverse outcome. However the patients presenting with complete heart block had more adverse outcome compared with other diagnosis like SSS, 2:1 AVB. (<0.05).

Conclusion

The patients with symptomatic bradycardia coming to our centre in emergency state were managed and made stable by Pacemaker Implantation with minimal complication and no mortality. Hence PPI proved as a safe, effective and life saving technique for this subset of patients.

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