

Clinical Profile and Early Complications after Single and Dual Chamber Permanent Pacemaker Implantation at Manmohan Cardiothoracic Vascular and Transplant Centre, Kathmandu, Nepal

Khanal J,¹ Poudyal RR,¹ Devkota S,¹ Thapa S,¹ Dhungana RR³

¹Department of Cardiology, Manmohan Cardiothoracic Vascular and Transplant Centre,

²Nepal Family Development Foundation, Kathmandu, Nepal.

ABSTRACT

Background: Permanent pacemaker implantation is a minimally invasive surgical procedure in the management of patients with cardiac problems. However, complications during and after implantation are not uncommon. There is lack of evidences in rate of complications with the selection of pacemakers in Nepal. Therefore, this study was performed to compare the frequency of implantation and complication rate between single chamber and dual chamber pacemaker.

Methods: The present study is based on all consecutive pacemaker implantations in a single centre between April 2014 and May 2015. A total of 116 patients were categorized into two cohorts according to the type of pacemaker implanted-single chamber or dual chamber. All patients had regular 2-weeks follow-up intervals with standardized documentation of all relevant patient data till 6-week after implantation. Data were presented as means \pm standard deviation (SD) for continuous variables and as proportions for categorical variables. Comparison of continuous variables between the groups was made with independent Student's t-test. For discrete variables distribution between groups were compared with Chi-square test.

Results: The mean age (\pm SD) of total population at implant was 64.08 (\pm 15.09) years. Dual chamber units were implanted in 44 (37.93%) of patients, single chamber in 72 (62.06%). Only 14 women (31.81%) received dual chamber compared with 42 women (58.33%) who received single chamber (Chi-square=18, DF=1, P = 0.0084). Complete atrioventricular block was the commonest (56.03%) indication for permanent pacemaker insertion followed by sick sinus syndrome (33.62%), symptomatic high-grade AV block (11.20%). Hypertension (dual chamber 21.55%, single chamber 40.51%) was the most common comorbidity in both cohorts. Complications occurred in 11 (9.48%) patients. More proportion of complication occurred in single chamber group (9 patients, 12.50%) than in dual chamber (2 patients, 4.54%). Complications occurring in dual chamber group include pocket hematoma 1 patient (2.27%) and arrhythmia in 1 patient (2.27%). Similarly, complications occurring in single chamber include RV perforation in two patients (2.77%) and one each (1.38%) had pocket hematoma, pneumothorax, infection, swelling at pocket site, arrhythmia in the form of NSVT, leads displacement, DVT and mortality.

Conclusions: Women were more likely to receive single chamber systems than men. More proportion of complication occurred in single chamber group than in dual chamber. Future prospective studies on larger number of patients are needed to confirm and support our findings.

Keywords: Complication; permanent pacemaker implantation; Nepal.

Correspondence: Dr Jeevan Khanal, Department of Cardiology, Manmohan Cardiothoracic Vascular and Transplant Centre, Kathmandu, Nepal. Email: kxanaljmed@gmail.com, Phone: +9779851105798.

INTRODUCTION

Permanent pacemaker implantation is one of the most common therapeutic or prophylactic strategies in the management of patients with cardiac problems at present.¹ The basic function of the pacemaker is to pace the heart in the absence of intrinsic impulses, and to recognize intrinsic cardiac electrical activity if present and restrain pacing consequently.

Optimal selection of the single or dual chamber pacemaker devices depend in terms of arrhythmia, their cost effectiveness and longevity.² However, considerable differences have been reported in the frequency of implantation of pacemakers and in the system selected.^{3,4} Some authors argued against dual chamber pacing on the basis of cost, a more complex implantation procedure, and an apparently higher complication rate than single chamber systems.⁵

Despite the relative ease of device implantation, the complication risk is still present and sometimes underestimated.⁶ Therefore, this study was performed to compare complication rate between single chamber and dual chamber pacemakers.

METHODS

This was hospital based, prospective study conducted at Manmohan Cardiothoracic Vascular and Transplant Centre (MCVTC), Department of cardiology, Maharajgunj, Kathmandu between April 2014 and May 2015. A total of 116 patients were categorized into two cohorts according to the type of pacemaker implanted- single chamber or dual chamber. The study site, one of the tertiary level cardiac centres in Nepal, provides advanced cardiac care to the patients from all over the country.

Study participants were the patients attending Out Patients Department (OPD) and emergency of MCVTC and subsequently admitting for permanent pacemaker implantation. Patients who had pre-existing permanent cardiac pacemaker (PM), defibrillator (ICD) or cardiac resynchronization therapy device (CRT) were excluded from the study. All eligible participants during 14 months period were enrolled in the study and followed up to 6-weeks after implantation. No one was lost to follow up.

Participants provided written informed consent after detailed explanation of research purpose and assurance of maintaining privacy and confidentiality. The institutional review board of institute of medicine assessed the ethical part and approved the study.

At initial visit, patients' detail history was recorded. The common co-morbidities included were left ventricular dysfunction (LVD), hypertension, diabetes mellitus (DM), chronic kidney diseases (CKD), coronary artery diseases (CAD), chronic obstructive pulmonary disease (COPD) and deep vein thrombosis (DVT). Likewise, information related to prominent symptoms such as syncope and palpitation, and major indications like complete heart block (CHB), sick sinus syndrome (SSS) and symptomatic high degree Atrioventricular (AV) block were also noted.

Permanent pacemaker implantations were performed in a fluoroscopic C arm equipped theatre. The implantation team consisted of a consultant who performed the implantation, Doctor of Medicine (DM) resident posted in cardiac catheterization laboratory, a cardiac physiologist who checked the pacemaker parameters, a pacemaker technician to operate the fluoroscope for imaging and a scrub nurse.

After implantation, patients were closely monitored on the ward for 48 hours followed by every two week intensive assessments for next 6 weeks to find if any complications occurred.

Data were compiled, edited and checked to maintain consistency prior to coding and entering in Epidata V.2.1 and exporting to SPSS V.16.0 for further analysis. For inferential statistics, chi-square and t tests were conducted to compare the proportions of categorical and mean of continuous variables respectively. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The baseline characteristics are presented in table 1. The mean (SD) age of total population at implant was 64.08 ± 15.09 years. Mean age of patients who received dual chamber pacemaker was 64.92 ± 13.20 years, not significantly different from those received single chamber pacemaker (65.80 ± 12.81 years, $P = 0.80$).

During the study period, a total of 54 women (48.27%) received pacemakers. Overall the mean age of women at pacemaker implantation was not significantly different from the age of men (63.2 ± 11.3 years vs. 65.0 ± 12.4 years, $P = 0.37$).

Dual chamber units were implanted in 44 (37.93%) of patients, single chamber in 72 (62.06%). Only 14 women (12.06%) received dual chamber compared with 42 women (36.20%) who received single chamber (Chi-square=18, DF=1, $P = 0.0084$).

Table 1. Baseline characteristics of patients with permanent pacemaker implantation.

Characteristics	Total number (N=116)	Dual chamber (n=44)	Single chamber (n=72)	P value
Female	56 (48.27%)	14 (31.81)	42 (58.33)	0.0084
Male	60 (51.72%)	30 (68.18)	30 (41.66)	0.56
Comorbidities				
LV Dysfunction	24 (20.69%)	9 (20.45)	15 (20.88)	0.20
Diabetes mellitus	13 (11.20%)	5 (11.36)	9 (12.50)	0.58
Hypertension	72 (62.06%)	25 (56.81)	47(65.27)	0.11
CAD	9 (7.75%)	4 (9.09)	5 (6.94)	0.87
CKD	28 (24.13%)	11 (25.00)	17 (23.61)	0.36
COPD	5 (4.31%)	2 (4.54)	3 (4.16)	0.09
DVT	2 (1.72%)	0 (0)	2 (2.77)	0.59
Indications				
CHB	65 (56.03%)	21 (47.72)	44 (37.93)	0.91
SSS	39 (33.62%)	19 (43.18)	20 (17.24)	0.44
Symptomatic high degree AV block	13 (11.20%)	6 (13.63)	7 (6.03)	0.51

Complete atrioventricular block was the commonest (65 patients; 56.03%) indication for permanent pacemaker insertion followed by sick sinus syndrome (39 patients; 33.62%), symptomatic high-grade AV block (13 patients; 11.20%).

Hypertension (62.06% of total population) was the most common comorbid condition underlying indications for pacemaker implantation.

CKD was the second most common disease prevalent among both cohorts. CKD was present in 24.13% of total implantation.

Following hypertension and CKD, LV dysfunction was present in 20.69% of total population.

Diabetes mellitus was present in 11.20%. Similarly, CAD was present in 7.75%.

COPD was present in 5 patients (4.31%). DVT was present in two patients (1.72%).

Complications occurred in 11 (9.48%) patients. More proportion of complication occurred in single chamber group (9 patients, 12.50%) than in dual chamber (2 patients, 4.54%). Complications occurring in dual chamber group include pocket hematoma 1 patient (2.27%) and arrhythmia in 1 patient (2.27%). Similarly, complications occurring in single chamber include pocket hematoma (1 patient, %), RV perforation in two patients (2.77%), pneumothorax in 1 patient (1.38%), infection in 1 patient (1.38%), swelling at pocket site in 1 patient(1.38%),

arrhythmias in form of NSVT in 1 patient (1.38%), leads displacement in 1 patient in single chamber (1.38%) , DVT in 1 patient(1.38%), and death in 1 patient(1.38%),

DVT in 1 patient (1.38%)and death (1.38%).

DISCUSSION

We performed the prospective study of indications, comorbidities and complications related to permanent pacemaker implantation. Our goal was to collect complications within the 6-weeks period from the time of implantation.

The present study had some limitations. First, study population was not evenly distributed to each type of pacemaker cohort. The sample size of the total study population was too small to allow for a generalization of the results. Second, the study was non-randomized, with regard to implanted pacemaker type. Third, we did not take other complications, such as pacemaker syndrome, quality of life, and events related to venous access into consideration. Large prospective randomized studies that include clinical endpoints such as survival or quality of life are needed to investigate this difference in more detail and reveal its potential implications.

Analysis of data from 116 patients suggests a sex bias in choice of a pacemaker system. Women were more likely to receive single chamber systems and less likely to receive dual chamber than men. These findings cannot be explained by differences in the underlying cardiac disorders or demographic data. Doctors generally implant single chamber pacemakers in elderly patients rather than dual chamber systems. Several studies of factors influencing cardiovascular interventions showed that sex was no longer a determinant once clinical variables had been adjusted for.⁷ Our results agree with two retrospective studies in the United States in which women were found to receive a dual chamber system less frequently than men.⁸

Dual chamber pacemakers have been shown to offer haemodynamic advantages over single chamber pacemaker.⁹ Although there is evidence that patients treated by advanced pacing have a better quality of life, it is not known whether this improvement is equal in men and women.

What other reasons could there be for doctors deciding in favour of a single chamber pacemaker in women? Firstly, there are some "soft" indications for implanting pacemakers (class II indications in the American College of Cardiology/American Heart Association guidelines). Doctors are known to behave differently towards men

and women as far as both diagnostic and therapeutic strategies are concerned.¹⁰

Doctors seeing women with “soft” indications may tend to implant single chamber pacemakers whereas they choose dual chamber for men. Some of the “hard” indications may also be being neglected in women. Women often present their symptoms differently from men.¹¹

They are more likely to receive the same treatment as men if they present their symptoms as men do.¹²

Finally, we found some published evidence that women sometimes reject sophisticated care in favour of more simple treatments. They may therefore choose not to have dual chamber systems.¹³

Since the implantation of the first artificial pacemaker in 1958 these devices have become the treatment of choice in bradycardias.¹⁴

There are two often related reasons for implanting a cardiac pacemaker: to relieve symptoms and to improve survival. Most patients treated with pacemaker implantation are elderly persons with either chronic atrioventricular-block (AVB) or sick sinus syndrome (SSS).¹⁵

Permanent pacing for complete heart block was the commonest indication in this study (56.03%) and it was comparable (42%) to that reported from a similar population. Untreated complete heart block has a one year and five year mortality of 50% and 75%-90% respectively; while survival is 70%-85% at five years in those paced.¹⁶

Sick sinus syndrome was responsible for 33.62% of patients paced in this report and it was identical to that reported from a similar district general population in UK.

Pacing for sick sinus syndrome is based on the association of symptoms with specific dysrhythmias; it effectively relieves symptoms of bradycardia and can facilitate more aggressive drug treatment of tachyarrhythmias,¹⁷ but there is no evidence that pacing asymptomatic patients improves prognosis.¹⁸

Our study was undertaken to assess the complication rate in a tertiary cardiac centre in Kathmandu. Most procedures are performed by cardiologists. Studies comparing the complication rates of dual versus single chamber pacemaker implantation have previously reported either no difference¹⁹ or a higher complication rate for dual than single chamber pacing.²⁰

Implantation of permanent pacemakers (PM) represents an effective treatment option for several cardiac arrhythmias. The incidence of acute complications from device implantation, such as pneumothorax, cardiac effusion, and lead perforation ranges from 1% to 7%.²¹

The determination of procedural adverse events is complex, related to the specific type of procedure and patient comorbidities such hypertension.²²

Complications associated with the implantation procedure itself have occurred in nine patients. Two patients had RV perforation and treated urgently surgical intervention. In other one patient the catheter electrode dislodged and the procedure had to be repeated. The bipolar catheter electrode perforated the myocardium in RV apex, in the same area where the temporary catheter had perforated a few days earlier. The other cardiac perforations occurred during the procedure and treated by pigtail insertion.

In our study, pocket hematoma and RV perforation were two most frequent early complications of pacemaker. The incidence of perforation after permanent pacemaker is reportedly between 0.3% and 1.2%.²³

The complications rate (1.723%) was comparable to that reported (2.48%) from a district general hospital and similar to that reported (2.8%) from a tertiary centre.²⁴

Infection in a permanently implanted PM is a serious complication. It may occur either as a surgical site infection (SSI), occurring within 1 year after implantation, or as late-onset endocarditis. Rates of infection after system placement have varied considerably, from 0.13% to 19.9%, and antimicrobial therapy alone (without removal of the entire system) is complicated by mortality and frequent infection relapse. Pacemaker implantation rates are on the rise worldwide, and the population of patients living with a PM is growing.²⁵

Implantation of dual- and triple-chamber devices was associated with a two-fold higher risk of infection than implantation of single-chamber devices.²⁶ We observed no difference in the incidence of infections between the two patient groups.

The overall mortality rate in all patients was 0.86%, due to causes unrelated to the pacemaker implantation itself.

Our finding of lower rate of complication associated with infection might be due to preprocedural use of broad spectrum antibiotic.

In addition, a large (500 patients) prospective randomized study showed that, with meticulous preoperative skin preparation, use of a topical antibiotic spray into the pacemaker pocket, and close postoperative follow up, patients gained no advantage from routine prescription of prophylactic antibiotics.²⁷

CONCLUSIONS

Women were more likely to receive single chamber systems and less likely to receive dual chamber systems than men. More proportion of complication occurred in single chamber group than in dual chamber. None of the complications were found to be related significantly with types of pacemaker implanted. Future prospective studies on larger number of patients are needed to confirm and support our findings.

REFERENCES

1. Lopez-Jimenez F, Goldman L, Orav EJ, Ellenbogen K, Stambler B, Marinchak R, Wilkoff BL, Mangione CM, Yoon C, Vitale K, Lamas GA. Health values before and after pacemaker implantation. *American Heart Journal*. 2002;144(4):687-92.
2. Brunner M, Olschewski M, Geibel A, Bode C, Zehender M. Long-term survival after pacemaker implantation: Prognostic importance of gender and baseline patient Characteristics. *European Heart Journal*. 2004; 25, 88–95.
3. European Working Group on Cardiac Pacing. Cardiac pacing. *European Heart Journal*. 1987;8 (suppl F):212.
4. Ray SG, Griffith MJ, Jamieson S, Bexton RS, Gold RG. Impact of the recommendations of the British Pacing and Electrophysiology Group on pacemaker prescription and on the immediate costs of pacing in the Northern region. *British Heart Journal*. 1992;68:5314.
5. Aggarwal RK, Connelly DT, Ray SG, Ball J, Charles RG. Early complications of permanent pacemaker implantation: no difference between dual and single chamber systems. *British Heart-Journal* 1995;73:571-575.
6. Chua JD, Wilkoff BL, Lee I, Juratli N, Longworth DL. & Gordon SM. Diagnosis and management of infections involving implantable electrophysiologic cardiac devices. *Annals of Internal Medicine*. 2000; 133: 604-608.
7. Wenger NK, Speroff L, Packard B. Cardiovascular health and disease in women. *New England Journal of Medicine*. 1993;329:24756.
8. Lamas GA, Pashos CL, Normand SLT, McNeil B. Permanent pacemaker selections and subsequent survival in elderly Medicare pacemaker recipients. *Circulation* 1995;91:10639.
9. Proctor EE, Lemann RB, Mann DL. Single versus dual chamber sensor-driven pacing: comparison of cardiac outputs. *American Heart Journal*. 1991;122:72832.
10. Armitage KE, Schneiderman LJ, Bass RA. Response of physicians to medical complaints in men and women. *Journal of American Medical Association*. 1979;241:21867.
11. Shaw LJ, Miller DD, Romeis JC, Kargl D, Younis LT, Chaitman BR. Gender differences in the noninvasive evaluation and management of patients with suspected coronary artery disease. *Annals of Internal Medicine*. 1995;120:559-66.
12. Healy B. The Yentl syndrome. *New England Journal of Medicine*. 1991;325:274-6.
13. Horton HL, Marinchak RA, Rials SJ, Kowey PR. Gender differences in device therapy for malignant ventricular arrhythmias. *Archives of Internal Medicine*. 1995;155:234-5.
14. Muller C, Cernin J, Glogar D et al. Survival rate and causes of death in patients with pacemakers: dependence on symptoms leading to pacemaker implantation. *European Heart Journal*. 1988; 9(9):1003–9.
15. Tveskov C, Skytthe A, Arnsbo P, Vaupel JW, Møller M, Christensen K. Twins with implanted pacemakers: Is there an increased mortality risk for the co-twin? A follow-up study based on the Danish Twin Registry and the Danish Pacemaker Register. *Europace*. 2005; 7: 598e603.
16. Alpert MA, Curtis JJ, Sanfelippo JF, et al. Comparative survival after permanent ventricular and dual chamber pacing for patients with chronic high degree atrioventricular block with and without pre-existent congestive heart failure. *Journal of American College of Cardiology*. 1986;7:925–32.
17. Rasmussen K. Chronic sinus node disease: natural course and indications for pacing. *European Heart Journal*. 1981;2:455–9.
18. Shaw DB, Holmann RR, Gower JI. Survival in sinoatrial disease (sick sinus syndrome). *British Medical Journal*. 1980;280:139.
19. Mueller X, Sadeghi H, Kappenberger L. Complications after single versus dual chamber pacemaker implantation. *Pace*. 1990;13:711-4.
20. Chauhan A, Grace AA, Newell SA, et al. Early complications after dual chamber versus single chamber pacemaker implantation. *Pace*. 1994;17(Pt II):2012-5.
21. Kiviniemi MS, Pirnes MA, Eränen HJ, Kettunen RV, Hartikainen JE. Complications related to permanent pacemaker therapy. *Pacing Clinical Electrophysiology*. 1999;22:711–720.
22. Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, R, Gotipaty V, Shinn T, Dan D, Leon A, Feldman LA, Stuart A, Winston SA, John J, Gallagher DJ, Langberg JJ, Holcomb R. Complication Rates Associated With Pacemaker or Implantable Cardioverter-Defibrillator Generator Replacements and Upgrade Procedures.

Results From the REPLACE Registry. *Circulation*. 2010; 122: 1553-1561.

23. Ellenbogen KA, Hellkamp AS, Wilkoff BL, Camunás JL, Love JC, Hadjis TA, Lee KL, Lamas G. Complications arising after implantation of DDD pacemakers: the MOST experience. *American Journal of Cardiology*. 2003; 92: 740-741
24. Mugica J, Ritter P, Lazarus B, et al. Evaluation of early complications after ventricular single chamber pacemaker implants in a specialist centre: 9483 patients over 24 years. *European Journal of Cardiac Pacing and Electrophysiology*. 1993;3:21-6.
25. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. *Infection Control and Hospital Epidemiology*. 1999;20:250-278.
26. Klug D, Balde M, Pavin D, Hidden-Lucet F, Clementy J, Sadoul N, et al: PEOPLE Study Group. Risk factors related to infections of implanted pacemakers and cardioverter-defibrillators: results of a large prospective study. *Circulation*. 2007;116:1349-55.
27. Ramsdale DR, Charles RG, Rowlands DB, Singh SS, Gautam PC, Faragher EB. Antibiotic prophylaxis for pacemaker implantation: a prospective randomised trial. *Pace*. 1984;7:844-9.