

Assessment of effectiveness of Nurse led Pacemaker Care Guidelines on pacemaker implantation related complications among patients underwent permanent pacemaker implantation in Advanced Cardiac Centre, PGIMER, Chandigarh.

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Abstract

Background: Permanent pacemakers have emerged as the treatment of choice for bradyarrhythmias and selected tachyarrhythmias. However, pacemaker implantation is associated with considerable morbidity which can be significantly curtailed with active nursing care and education.

Objectives: The objective of the present research study was to develop Nurse led Pacemaker Care Guidelines and to evaluate its effectiveness on complications associated with permanent pacemaker implantation.

Material and methods: A quasi experimental design was considered for the study. Total 100 samples were taken (50 in each control and experimental group) from cardiology units of Advance Cardiac Centre, PGIMER, Chandigarh. Nurse led Pacemaker Care Guidelines was developed and taught to experimental group whereas routine care was provided to both groups. Tools used were patient profile, Southampton wound scoring system, QuickDASH questionnaire and pacemaker complication check list. Interview and observation method was used for assessment of complications till 2 month of post pacemaker implantation.

Results: The present study revealed that there was statistically significant difference ($p = <0.05$) in shoulder discomfort at 2 month of post PPI with control group mean \pm SD 72.67 \pm 5.14 and experimental group mean \pm SD = 64.54 \pm 6.69. Minor complications related to infection was found in 3 subjects in control group and in 2 patients in experimental group. Wound infection was found in 2 samples in control group, while lead dislodgement was found in 1 patient of control group in 2 month of post PPI. None of the sample developed other permanent pacemaker complications.

Conclusion: In the present study, Nurse Initiated Pacemaker Care Guidelines were found effective to eliminate pacemaker associated complications. Therefore nurse led pacemaker care clinics can be initiated to improve patient care and reduce the pacemaker complications.

Keywords: Nursing care, Nurse led pacemaker care, Pacemaker, Permanent pacemaker.

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I. Introduction of the study

Cardiovascular Diseases (CVD) are the top most cause of mortality globally.¹ In CVDs. Cardiac arrhythmias are the second major cause of death worldwide after coronary artery disease. Approximately 60% of all cardiac deaths occur due to arrhythmias proceeding sudden cardiac arrest. Cardiac pacemakers are the most reliable documented treatment for cardiac arrhythmias, especially for bradyarrhythmias.² Permanent Pacemaker is an artificial small size device like a matchbox, implanted commonly in infraclavicular region which electrically stimulates myocardium layer of heart.³

The implantation of the permanent pacemaker is the first step in the management of the patient with a pacemaker, and lifelong care is essential not only for the safety of the patient but is also for adequate utilization of the pacemaker devices.⁴

Reported incidences of complication rate of permanent pacemaker implantation ranges from 0.19% to 13.9%.² A study conducted by Stevenson et al on complications of Pacemaker Implantation, estimated that the rate of pacemaker infection ranges from 1 - 10%, perforation up to 1%, pocket hematoma about 4.9% which lead to prolonged hospitalization in 2.0%, reoperation in 1.0% of patients and sensing abnormalities occur in 3% of patients, Major and minor complications occur in approximately 4-7% of patients within 30 day of pacemaker implantation.⁵ According to Speedie et al (2012-2014) low complication rates and low mortality is seen in those pacemaker patients who have been on a regular follow up and are aware of complications.⁶ Mohamed et al reported that Nursing Teaching Protocol can help in reduction of complications in Permanent pacemaker patients.⁷

Nurses are expected to care for patients with pacemaker devices in all phases of permanent pacemaker implantation. More importantly, nurses perform best management of these patients with education of patients for routine device care and early identification of complications.⁸

Akyrou stated that nursing presence is fundamental in care of the patient with a permanent pacemaker. Nurses help the patient and his/her family with adaptation to daily living. In addition, the nurse teaches the patients how to observe the function of pacemaker and emphasizes the importance of regular follow-ups in pacemaker clinics.⁹ Similarly, Malm et al (2007) reveal that, Nurses should support the patient by providing clear, adequate and device focused information, and planning a self-care schedule based on the nurse's assessment of the patient's needs.¹⁰

Methods: Design, Setting, and Participants

This was a quasi-experimental study. Patients were enrolled from cardiology units of Advanced Cardiac Centre, PGIMER, Chandigarh by total enumeration technique. Control and experimental group contained 50 each sample. Nurse Initiated Pacemaker Care Guidelines was developed on the basis of extensive review of relevant literature, consultation with experts related to the field of cardiology, nursing education, nursing practice and nursing research.

Components of guidelines: Nurse Led Pacemaker Care Guidelines is a comprehensive package of care of patient with pacemaker implantation. It includes information about

- anatomy and physiology of heart including conduction system,
 - ECG and cardiac arrhythmias
 - pacemaker, its purpose, parts and working
 - procedure of pacemaker implantation and expected complications
 - guidelines for patients with permanent pacemaker which included: self- monitoring of pulse rate and temperature, maintenance of self-vital chart, activity guidelines, physical exercises, exercise protocol for affected extremity, care of incision site, pacemaker card importance, travelling precautions, precautions during operating electromagnetic devices, diet education, sign of pacemaker malfunction and follow up.
- Routine care consisted of wound care, education about complications, affected shoulder movement restriction, precautions during operating electromagnetic devices and routine follow up.

Data collection:

The researcher enrolled the patients at hospital admission and collected their baseline data during May-October, 2017. Nurse Initiated Pacemaker Care Guidelines were administered to the study subjects in experimental group by demonstration and health education method before pacemaker implantation and recall of guidelines was done at 1st, 2nd and 3rd post PPI days along with routine care. Supplemental Booklet was given for better understanding. In control group only routine care was provided. Researcher developed and implemented a checklist of pacemaker complications and also used QuickDASH questionnaire for assessment of shoulder discomfort and Southampton wound scoring system for infection assessment. The validity and reliability of the research tools was assessed. Data was collected before PPI, 5th day, 10th day, 1 month and 2 month of post PPI by interview, direct and indirect observation. One patient was expired in control group because of comorbidities after 1 month of post pacemaker implantation.

Data Analysis

Effectiveness of Nurse Led Pacemaker Care Guidelines was assessed by doing descriptive as well as inferential statistical analysis of data by SPSS version 20. Analysed data was presented in form of tables, graphs and figures.

II. Results

In the present study, both groups were homogenous and comparable as per sociodemographic, clinical and personal profile with p value >0.05 . The mean age \pm SD of the experimental study subjects were 62.28 ± 16.07 (range: 14-93 years) and in control group age \pm SD was 64.32 ± 15.58 with range 16-88 years. Majority of the study subjects in both groups were male, married and unemployed. 78% of the study subjects in control group and 70% of study subjects in experimental group presented with chief complaint of dyspnoea. Clinical diagnosis of majority of subjects was complete heart block followed by Sick sinus syndrome and 2nd degree heart block. . Majority of study subjects in both group had Hypertension and Diabetes mellitus as comorbidity. Majority of the study subjects underwent single chamber, MRI compatible, VVIR mode pacemakers.

Table 1: sample characteristics of study subjects n=100

Variable	Control group (n ₁ =50) f (%)	Experimental group (n ₂ =50) f (%)	χ ² value (df) p value
Age(in years)*			
<40	05(10)	04(08)	2.02 (2) 0.36 [#]
41-80	38(76)	43(86)	
>80	07(14)	03(06)	
Gender			
Male	32(64)	30(60)	0.17 (1) 0.83
Female	18(36)	20(40)	
Chief complaints of patient on admission			
Dyspnea			0.83 (1) 0.36
• Yes	39(78)	35(70)	
• No	11(22)	15(30)	
Palpitations			2.99(1) 0.08
• Yes	04(08)	10(20)	
• No	46(92)	40(80)	
Syncope			0.64 (1)0.42
• Yes	25(50)	21(42)	
• No	25(50)	29(58)	
Other(chest pain, Giddiness, ghabrahat, fatigue, weakness)			0.40 (1) 0.52
• Yes	20(40)	20(40)	
• No	30(60)	30(60)	
Clinical diagnosis of patient			
2nd degree heart block	06(12)	14(28)	5.32 (4) 0.24 [#]
Complete heart block	30(60)	23(46)	
Sick Sinus Syndrome	10(20)	07(14)	
Bundle branch block	02(04)	04(08)	
Sinus bradycardia	02(04)	02(04)	
Co-morbidities			
Diabetes mellitus	14(28)	12(24)	0.21 (1) 0.64
Hypertension	27(54)	22(44)	1.00 (1) 0.31
Coronary Artery Disease	05(10)	01(02)	2.83 (1) 0.20 [#]
Other (DCMP, CHD, CVA)	12(24)	08(16)	1.00 (1) 0.31
Dietary Habits			
Vegetarian	28(56)	34(68)	1.52 (1) 0.30
Non- vegetarian	22(44)	16(32)	
Alcoholic			
Yes	04(08)	03(06)	1.95 (3) 0.59 [#]
Occasional	01(02)	03(06)	
Left	06(12)	09(18)	
No	39(78)	35(70)	
Smoker			
Yes	03(06)	06(12)	1.11 (2) 0.66
Left	06(12)	06(12)	
No	41(82)	38(76)	

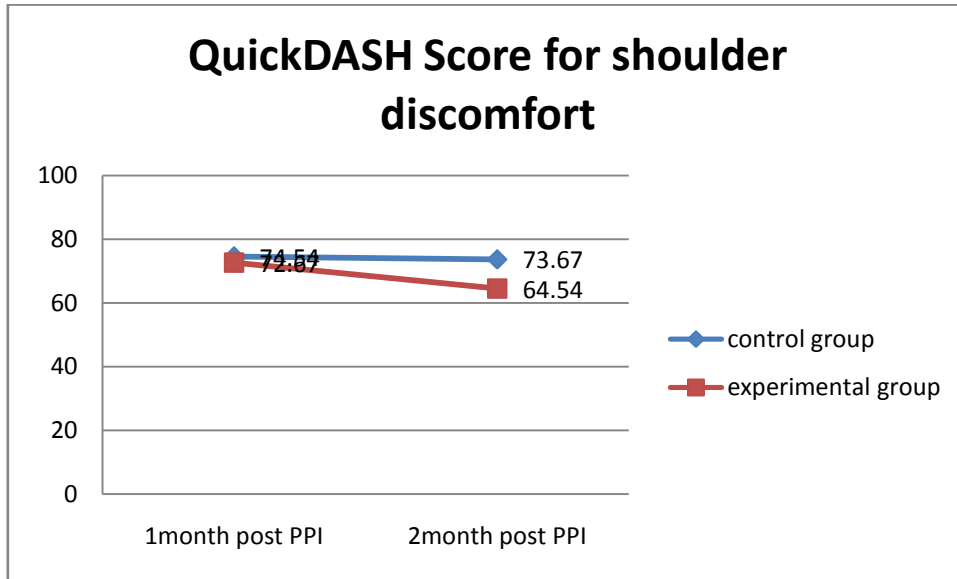
yate corrected chi-square

Shoulder discomfort was measured by QuickDASH questionnaire. Mean score±SDdecreased from 1month post PPI to 2month post PPI from 74.54± 7.17 to 72.67±5.14 in control and from 73.67±6.72 to 64.54±6.69 in experimental group. Exercises were performed by experimental group after 1 month of post PPI and follow up was done at 2 month post pacemaker implantation with 3days weekly telephonic follow up by researcher. There was no statistically significant difference in shoulder discomfort scores at 1 month follow up. However at 2 month follow up there was statistically significant difference in both groups with p value <0.001 with shoulder exercises (chest stretch, punches, band pull and arm raise). But none of the patient reported frozen shoulder in 2 month follow up other that shoulder difficulty.

Table 3: Comparison of shoulder discomfort before and after shoulder exercises between subjects in control and experimental group (assessed by quickDASH Score): n=99

quickDASH score (total highest score = 100)	Control group (n ₁ =49) Mean± SD, range	Experimental group (n ₂ =50) Mean± SD, Range	t test (df) p value
At 1month (before initiation of	74.54± 7.17,	73.67±6.72,	1.49 (97) 0.13

shoulder exercises)	55-90	62.50-87.50	
At 2month (after 1month of initiation of shoulder exercises)	72.67±5.14, 55-87.50	64.54±6.69, 52.25-77.50	6.77 (97) <0.001



Present study revealed that minor complications related to infection was found in 3 subjects in control group and in 2 patients in experimental group. Wound infection was found in 2 samples in control group, while lead dislodgement was found in 1 patient of control group in 2 month of post PPI. None of the study sample developed other major primary complication like pacemaker failure, frozen shoulder, cardiac tamponade, congestive heart failure, pacemaker syndrome, haematoma, haemorrhage, pneumothorax and hemothorax in 2 month post PPI period.

Table 6: Comparison of Post PPI complications among subjects in control and experimental group at 2 month of post PPI n=99

Complications	Control group (n ₁ =49) f (%)	Experimental group (n ₂ =50) f (%)	x ² (df) p-value
Pacemaker site infection (assessed by Southampton wound scoring system)			2.41 (2) 0.07*
Minor complications	03 (06.1)	02(04)	
Wound infection	02(04)		
Total	05 (10.2)	02(04)	
Lead dislodgement	01(02)	
Absent	43 (87.8)	48(96)	

*Fisher exact test

III. Discussion

In present study, the mean age of study subjects was 63.3±15.78. Similarly, Nagwa (2014) reported that prevalence of PPI is more between 61-80 years⁷. Similar results were found by Hanaa (2017) with mean age ±SD= 65.7±5.7 of pacemaker study subjects¹¹. In relation to gender, 64% from control group and 60% from experimental group were male. This finding is in agreement with that of Panda (2011) and Elsayed (2013) who found that, prevalence of permanent pacemaker implantation was 1.5 times more in males in respect of females.¹²

Present study revealed that more than 50% of sample studied had chronic diseases i.e. diabetes and hypertension, this result goes with Nagwa Mohamed (2014) who reported that approx. half of the patients were having hypertension and/or diabetes⁷. In relation to clinical diagnosis of patient more than half of the patients were diagnosed with complete heart block. This finding matches with study done by Nagwa Mohamed (2014) study in which 75% patients who underwent PPI were diagnosed with complete heart block⁷.

Focusing on complications, Infection in pacemaker patients is a rare but serious complication. Pacemaker site infection is one of the major reasons of readmission into cardiac centres and patient morbidity after pacemaker implantation.

Past studies has shown that the pacemaker site infection ranges from 1% to >10%.²⁰ Baddour et al reported that there is 210% increase in pacemaker device infection from 1993 to 2004.⁴⁷ A study done by Johansen1 et al concluded that infection may occur either as a surgical wound infection, within 1 year after PPI(permanent pacemaker implantation) or as late-onset lead endocarditis.

In current study 3 patients of control group developed minor wound complications and 2 developed wound infection, while only 1 patient in experimental group developed infection in 2 month of post PPI. On comparing the results with study done by Nagwa(2014), showed that, after implementation of Nursing Teaching Protocol, 3.3% patients of control group developed wound infection as compare to experimental group, none of the subject developed infection¹⁵.

In the present study, shoulder discomfort was decreased statistically significantly in experimental group after shoulder exercises with p value <0.001. Findikoglu et al (2015) revealed that a low to moderate amount of shoulder disability is found in patients with cardiac devices (P<0.05).⁴⁵ Another study done by James et al (2011), patients of experimental group were instructed on a series of exercises to be completed 3 days per week for 6 weeks after 1 week of PPI. Study results showed a statistically significant improvement in shoulder discomfort with p value <0.03 among study subjects after shoulder excercises¹⁴.

In present study primary complications found were infection (minor 6% and serious wound infection in 4%), lead dislodgement (2%) in control group. However, there was no statistically significant difference in occurrence of complication in both groups was found with p value < 0.05. Whereas, In that study done by Mohamed (2014),found that only one patient (3.3%) of the experimental group developed complications after application of nursing intervention protocol in comparison to nine subjects (30%) of the control group with p value 0.01⁷.

Thus the previous studies and the current studies focuses that a systematic nursing teaching and practices based guidelines about permanent pacemaker care can reduce the chances of occurrence of the complications and allow the patients to adapt more easily to the pacemaker devices. These guidelines provide autonomy to nurses for implementation on patients scheduled for pacemaker implantation. "Nurse Led pacemaker care guidelines" must be practiced in clinical settings to improve pacemaker device care and to reduce the associated complications.Nurse led clinics can be started with similar guidelines for pacemaker patients.Informational booklets of these guidelines must be available in cardiac department and pacemaker clinics.Special pacemaker nurses can be trained and appointed with the objective of teaching the patient about pacemaker and to improve patient's skills of pacemaker care.

IV. Recommendations

- Similar study can be conducted on larger population.
- True experimental design can be considered for the similar study.
- Other means of educational aids like mobile applications, audio assisted and video assisted methods can also be used.
- Longitudinal studies can be conducted for the long term follow up of pacemaker patients.

V. Conclusion

In the present study, "Nurse Initiated Pacemaker Care Guidelines" were found effective in term of reducing complications related to permanent pacemaker implantation among patients with permanent pacemaker. Therefore such nursing guidelines should be taught to patients to improve pacemaker care and reduce the pacemaker complications.

References

- [1]. Emelia J, Michael J, Stephanie E, Mary C, Sandeep R, Rajat D et al. Heart Disease and Stroke Statistics–2017 Update: A Report from the American Heart Association. *Circulation*. [Internet]. 2017 [Cited 2018 March 16]; 18(2): 209-209. Available from: [Modey-Davies A, Cohhe S. Cardiac pacing. The Lancet. 1997; 349\(9044\): 41-46.](http://news.heart.org/american-heart-association-statistical-report-tracks-global-figures-first-time/)
- [2]. Modey-Davies A, Cohhe S. Cardiac pacing. *The Lancet*. 1997; 349(9044): 41-46.
- [3]. Lewis S L, Heitkemper M M, Dirksen S R, Bucher L. *Medical Surgical Nursing; Assessment and management of client problems*. 9thed. Mosby Company; 2010.
- [4]. Rajgopal S, Kapoor A, Bajaj R, Vora A, Sethi K, Sinha N et al. CSI/IHRS practice guidelines on follow-up of patients with permanent pacemakers. *Indian Heart Journal*. 2012;64:S12-S17.
- [5]. Stevenson R, Lugg D, Gray R, Hollis D, Stoner M, Williams J. Pacemaker implantation in the extreme elderly. *Journal of Interventional Cardiac Electrophysiology*. 2011;33(1):51-58.
- [6]. Speedie A, Mathew C, Shahi RS and Calton R. Long-term Mortality in Patients with Permanent Pacemaker Implantation. *J Assoc Physicians India*. 2016; 64 (9):18-22.

- [7]. Mohamed N, Mohamed A and Mohamed Z. Effectiveness of Educational Program on Knowledge and Practice of Patients Undergoing Permanent Pacemaker. IOSR Journal of Nursing and Health Science. 2016; 72-83
- [8]. Stevens M, Jennas J, DiFusc P. An overview of the latest management of cardiac device infection. Journal for the Clinical Nursing Specialists. 2016; 4(2) ; 28.
- [9]. Akyrou D B. Nursing care of the patient with an artificial pacemaker. Neseleutike. 1992;31(139):43-54.
- [10]. Malm D, Karlsson J E, Fridlund B. Effects of a self-care program on the health-related quality of life of pacemaker patients: a nursing intervention study. Can J Cardiovasc Nurs. 2007;17(1):15-26.
- [11]. Hanaa, Yossif A, Ebtisam, Abd El-aal M. Home Care for Patients with Permanent Pacemaker Insertion. Journal of Nursing and Health Science. 2017;6(4); 49-57.
- [12]. Elsalam A, Shafy A, Rahim A. Effect of an educational program on the performance of nurses working with cardiac patients. [Internet]. 2010 [Cited 2017,Oct.06] available at: <http://drepository.asu.edu.eg/xmlui/bitstream/handle/1234567/143264/D8%B52399.pdf?sequence=1>
- [13]. Findikoglu G, Yildiz B S, Sanlialp M, Alihanoglu Y I, Kilic I D, Evregul H et al. Limitation of motion and shoulder disabilities in patients with cardiac implantable electronic devices. Int J Rehabil Res. 2015;38(4):287-93.
- [14]. James D, Daniels, Sun S, Zafereo J, Minhajuddin A, Nguyen C et al. Preventing Shoulder Pain After Cardiac Rhythm Management Device Implantation. Pacing Clin Electrophysiol. 2011;34(6):672-678.

Sharma K, et al. "Assessment of effectiveness of Nurse led Pacemaker Care Guidelines on pacemaker implantation related complications among patients underwent permanent pacemaker implantation in Advanced Cardiac Centre, PGIMER, Chandigarh." *IOSR Journal of Nursing and Health Science (IOSR-JNHS)*, 9(2), 2020, pp. 58-63.