Incidence of Selected Pacemaker Related Outcomes among Patients with Permanent Pacemaker

Khina Sharma[1], Shruti[2], Neena Vir Singh[2], Yash Paul Sharma[3]

[1]M.Sc. Nursing (Critical Care Nursing), [2]Lecturer, NINE, [3]Professor and Head, Department of Cardiology,
[1,2,3]PGIMER, Chandigarh, India

ABSTRACT

Background: Permanent Pacemakers are one of the most reliable treatments for the 2nd most common cardiovascular disease i.e. cardiac arrhythmias, especially brady-arrhythmias.

Objectives: The objective of present study was to study the incidence of selected pacemaker related outcomes i.e anxiety, infection, Shoulder discomfort and performance of activities of daily living among patients.

Material and methods: A descriptive design was used for the study. Tools used were sociodemographic and clinical profile sheet, STAI anxiety scale, Barthel Index, Southampton wound scoring system and Quick DASH questionnaire. Interview schedule and observation method was used collection of data from 50 patients undergoing permanent pacemaker implantation in advanced cardiac centre, PGIMER Chandigarh by total enumeration sampling.

Results: In present study, majority of patients (80%) were in moderate anxiety in pre pacemaker implantation period. The shoulder discomfort mean ± SD score at one and two month of post pacemaker implantation was 74.54± 7.17 and 73.67± 6.72 respectively, with no statistically decrease in shoulder discomfort. The Barthel Index for Activites of daily living before pacemaker implantation and 2month of post implantation mean score ± SD was 14.86±2.60 and 16.43±1.92. Infection was found in 4% of patients at 1 month of post pacemaker implantation period.

Conclusion: In the present study, pacemaker patients do face moderate anxiety, infection, shoulder discomfort and they are not independent in performance of Activities of daily living. Focusing on these problems, health needs of such patients must be meet.

KEYWORDS: *Permanent pacemaker, Anxiety, pacemaker infection, shoulder discomfort in pacemaker patients*

INTRODUCTION:

Cardiovascular Diseases (CVD) are the top most cause of mortality globally. Health data obtained from approximately 190 countries by American Heart Association (2017) has shown that the cardiovascular disease is the number one cause of death worldwide with 17.3 million deaths annually. The number is expected to rise above 23.6 million by 2030.[1] In South-East Asia Region, Heart diseases cause approximately 1/4th of all deaths annually (2.0 million among males and 1.7 million among females). According to the studies, the Indian subcontinent has the highest rates of cardiovascular disease globally.[2]

In cardiovascular diseases, coronary artery disease is the most common disorder and cardiac arrhythmias are the second common cause of mortality in cardiovascular disease patients. Approximately 60% of all cardiac deaths occur due to arrhythmias leading to Sudden Cardiac Arrest. In India, annual incidence of Sudden Cardiac Arrest is 0.55 per 1,000 populations.[3] Cardiac pacemakers are the most reliable documented treatment for various cardiac arrhythmias, especially bradyarrhythmias since 1950.[4]Dr. Ake Senning was the first to implant a Pacemaker in a human being in 1958. Since then, pacemakers have been the treatment for choice for brady-arrhythmia and heart block.[5,6]

Pacemaker is an artificial device that electrically stimulates myocardium layer of heart to depolarize, to begin a contraction, when the heart's natural pacemaker does not function properly. This device may be temporary or permanent; depending on the patient's condition.[6] Artificial permanent pacemaker is a small size device like a matchbox. It weights approximately 20-50 g. It is usually implanted in infraclavicular region [8]

A survey carried out by the Indian Heart Rhythm Society (IHRS) and Indian Society of Electrocardiography (ISE) concluded approximately 37,000 artificial cardiac devices were sold in India from April 1, 2012 up to March 31, 2013. The implantation of cardiac devices has remarkably risen globally. In Europe and North America, cardiac devices implants per million people are at an average of 300 patients per million, which is very high. In the Indian setting, it is at

an average of 25 implants/million population.[9] Strickland (2013) stated that, currently more than 3 million patients worldwide are with implanted permanent pacemaker.[10]

According to Timby and Smith (2010), pacemakers improve quality of life and prevent death. Optimal outcome after permanent pacemaker insertion can only be obtained if patients are supported in compliance to a lifelong with permanent pacemaker.[11]

The implantation of the permanent pacemaker is only the first step in the lifelong treatment of the patient with a pacemaker, and long-term follow-up is essential not only for the safety but is also the key to optimal utilization of the pacing system. However in most places in India, patients with implanted pacemakers are usually go for follow up only once in a year and often only toward the end of pacemaker battery life.[12]

According to Ackley & Ladwig (2007), In permanent pacemaker patients reporting anxiety, the attributed etiology is fear of dysfunction of the pacemaker and the feelings of helplessness due to dependence on artificial pacemaker and changes in lifestyle that the patient will have to do.[13]According to Duru et al. (2001); patients with a heart arrhythmia with a permanent pacemaker perceive it as an "extension of their life". However, anxiety of patients was associated with technical problems and pacemaker battery depletion.[13]

Vellone et al (2008) did a descriptive, correlational and comparative study on Anxiety and depression before and after a pacemaker implantation in Rome on 154 patients. They observed that Anxiety and depression in patients before and after a pacemaker implantation has been under studied despite an increased use of pacemaker therapy in the world. It was seen that, Anxiety and depression significantly decreased from the pre to the post implantation groups. People less old, less educated, with lower income and fewer children were more anxious and depressed before the implantation. [14]

Findikoglu et al in 2015 studied Limitation of movement and shoulder disabilities in 49 patients with permanent pacemaker. Limitations of motion for abduction, flexion, and internal rotation were reported to be significantly lower in the arm on the side of pacemaker compared with the opposite arm. Significant differences in shoulder abduction, flexion, and external rotation were reported compared with long-term recipient (P<0.05). However, the comparison in function of groups was found not significant. A low to moderate amount of shoulder disability was found in patients with cardiac devices (p value <0.05). [15]

A survey was carried out by Aqeel et al (2008) about Pacemaker patients' perception of unsafe activities in Karachi, Pakistan. A considerable proportion of pacemaker patients believed many routine activities unsafe including electrical wall switches (56%), irons (55%), television/video cassette recorders (53%), bending over (37%), passing through metal detectors (31%), driving automobiles (28%), and sleeping on the side of the pacemaker (30%). The researchers concluded that their patients perceived many safe routine activities as unsafe, eventually leading to disabling life style changes.[16]

Despite the known benefits of pacemaker devices and the greater ease in implantation, the incidence of infection is increasing. Baddour et al earlier reported that there was a 210% increase in artificial cardiac device related infection from 1993 to 2008[17]. Recent data show that the incidence of cardiac device-related infection ranged from 0.5%-4.8%. There has been a steady rise of infection at a rate of 2.5% per year in 2008 compared to 1.5% per year in 2004.[17] More importantly, about 3% of high risk patients who have cardiac device implanted can develop cardiac device-related infection. Infection is associated with morbidity, mortality and increased cost.[18] Additionally, it is estimated that the average cost to care for someone with cardiac device-related infection is $54,926.[19]

Implantation of the pacemaker is a vital event of one's life. Pacemaker Implants saves the patient from life threatening arrhythmias. But the complications of pacemaker implantation are not uncommon. The complications that may arise includes pacemaker site infection, bleeding, hematoma, pneumothorax, hemothorax, ventricular ectopy, tachycardia, dislocation of the lead, frozen shoulder, shoulder discomfort etc.[20] Along with physical complications, patients who require pacemaker may also be in fear, anxiety, stress and even depression due to the feelings of being dependent on an artificial device, fear of device malfunction, fear of death, expensive cost of pacemaker and lifelong follow up. Therefore the present study was conducted to study incidence of pacemaker related outcomes i.e. anxiety, infection, shoulder discomfort and performance of ADL among patients undergoing pacemaker implantation.

Material and Methods:
A Quantitative Research Approach with descriptive study design was used in the present study. This study was conducted in Cardiology wards of Advanced Cardiac Centre, PGIMER, Chandigarh from June –September, 2017. Sample population included patients undergoing permanent pacemaker implantation in PGIMER, Chandigarh. Patients was enrolled at time of admission and regular follow-up was done till 2month of post pacemaker implantation. The total sample size was 50. Inclusion Criteria included Patients undergoing permanent pacemaker implantation in ACC, PGIMER, Chandigarh and Patients willing to participate in the study. The variables in this study were anxiety of patient, pacemaker site infection, shoulder discomfort and Activities of Daily Living of the patient.

The following tools were used to assess the various parameters:- Patient identification data sheet, Sociodemographic profile of patient., Personal profile of patient, Clinical profile of patient , STAI anxiety scale for assessment of patient's anxiety, QuickDASH questionnaire for assessment of shoulder discomfort, Southampton wound scoring system for pacemaker site assessment and Barthel Index for assessment of Activities of Daily Living.

STAI i.e. State Trait Anxiety Inventory is an introspective psychological inventory consisting of trait and state anxiety affect. State anxiety can be explained as nervousness, fear, discomfort leading to the arousal of the autonomic nervous system induced temporarily by current situations perceived as dangerous whereas Trait anxiety can be explained as a relatively enduring disposition to feel worry, stress, and discomfort. Only state scale was used in present study. It

comprises 20 items and was scored on 4-point forced-choice Likert-type response scales. Scores range from 20 to 80. Low scores suggest mild anxiety; median scores suggest moderate anxiety, while high scores suggest severe anxiety. Anxiety was assessed at pre pacemaker implantation period and at post pacemaker implantation period.

Southampton wound scoring system was used for assessment of the pacemaker incision site. It comprises total 6 grades, started from grade 0 to grade 6. According to grades given, Wounds scoring is as:- Normal healing (grade 0 or grade I), Minor complication (grade II or grade III) and Wound infection (grade IV or V) requires antibiotics or other treatment.

Barthel Index was used for ADL, which contains total 10 points i. e. feeding, grooming, bathing, toilet use, transfer, mobility, dressing, stairs, bowel and bladder. Each performance item was rated on this scale with a given number of points assigned to each level. A higher number was associated with a high likelihood of being able to live at home with a degree of independence. The amount of time and assistance required to perform each item were used in determining the assigned number of each item. Total scores range from 0 – 20, where lower scores depicting increased disability.

A standard questionnaire was used for assessment of shoulder discomfort among patients. This questionnaire depicts patient's symptoms as well as ability to do certain activities in the last week. There are total 11 items in the questionnaire like Open a tight or new jar, Do heavy household chores (e.g., wash walls, floors), Carry shopping bag/briefcase, Wash back, Use a knife to cut food, Limitation in work or other regular daily activities as a result of shoulder problem?, Shoulder pain, Tingling in shoulder and Difficulty in sleeping because of the pain in shoulder etc. Each item was scored on 5-point forced-choice Likert-type response scales. Scores are calculated by formula = [(sum of n responses/n) – 1] x 25, where n is equal to the number of completed responses.Thus the maximum score is 100. More the value means more shoulder discomfort.

Approval of research study was sought from the Institute's Ethics Review Committee of PGIMER Chandigarh and permission was taken from head of cardiology department. Tools were validated by a team of experts. In order to check the feasibility of the study, pilot study was done before the actual data collection period i.e. in May-June, 2017.

Interview technique and Observation method were used for final data collection. Assessment of outcome variables was done before pacemaker implantation and after pacemaker implantation till 2 month of implantation.

Data analysis was done with the help of Statistical Package for Social Sciences (SPSS version 20). Descriptive statistics i.e. mean. Percentage, frequency and standard deviation were used for describing the variables. In inferential statistics t-test was also used. Data was presented in form of tables and figures as suitable.

Results
Table 1: shows the Sociodemographic distribution of study subjects. The mean age± SD of the study subjects was 64.32±15.58 with range 16-88 years. Majority of study subjects were male (64%), non-literate (42%), married (70%), Hindu (82%) and were unemployed (66%). 58% of study subjects were living in villages.

Table 1: Socio-demographic profile of study subjects undergoing permanent pacemaker implantation
N=50

Variable	Study subjects (n$_1$=50) f (%)
Age(in years)*	
<40	05(10)
41-80	**38(76)**
>80	07(14)
Gender	
Male	**32(64)**
Female	18(36)
Qualification	
Non-literate	**21(42)**
Primary school	07(14)
Middle school	06(12)
High school	09(18)
Post high school	02(04)
Graduate and above	05(10)
Marital status	
Unmarried	02(4)
Married	**41(82)**
Widow/ Widower	7(14)
Religion	
Hindu	**35(70)**
Muslim	01(02)
Sikh	13(26)
Christian	01(02)

Type of family	
Nuclear family	**26(52)**
Joint family	24(48)
Per capita income (in Rs)**	
<1000	**21(42)**
1001-2000	06(12)
2001-3000	10(20)
>3000	13(26)
Habitat	
City	10(20)
Town	11(22)
Village	**29(58)**
Life-style Pattern	
Sedentary	**26(52)**
Mild worker	18(36)
Moderate worker	06(12)
Occupation	
Employed	14(28)
Unemployed	**33(66)**
Student	03(06)
Occupation type	
Require mental effort	05(10)
Require muscular effort	11(22)
None	**34(78)**

Table 2: shows 78% of the study subjects presented with chief complaint of dyspnoea. Clinical diagnosis of 60 % patients was complete heart block. Sick sinus syndrome and 2nd degree heart block were the other main indications for permanent pacemaker implantation. Majority of study subjects had Hypertension and Diabetes as comorbidity. Majority of the study subjects underwent single chamber, MRI compatible, VVIR mode pacemakers.

Table 2: Clinical profile characteristics of study subjects

N=50

Variable	Study subjects (n_1=50) f (%)
Chief complaints of patient on admission	
Dyspnea	
➢ Yes	**39(78)**
➢ No	11(22)
Dizziness	
➢ Yes	03(06)
➢ No	47(94)
Palpitations	
➢ Yes	04(08)
➢ No	46(92)
Syncope	
➢ Yes	25(50)
➢ No	25(50)
Presyncope	
➢ Yes	11(22)
➢ No	39(78)
Other(chest pain, Giddiness, ghabrahat, fatigue, weakness)	
➢ Yes	20(40)
➢ No	30(60)
Clinical diagnosis of patient	
2nd degree heart block	06(12)
Complete heart block	**30(60)**
Sick Sinus Syndrome	10(20)
Bundle branch block	02(04)
Sinus bradycardia	02(04)
Co-morbidities	
Diabetes mellitus	14(28)
Hypertension	**27(54)**
Coronary Artery Disease	05(10)
Other (DCMP*, CHD**, CVA***)	12(24)

Temporary pacemaker insertion done before PPI	
Done	07(14)
Not done	**43(86)**
Pulse generator replacement	
Yes	05(10)
No	**45(90)**
Permanent Pacemaker Type	
Single chamber	**32(64)**
Double chamber	16(32)
Biventricular	02(04)
MRI**** compatibility	
MRI compatible	**34(68)**
MRI non-compatible	16(32)
Pacemaker Code:	
➢ VVIR*****	**26(52)**
➢ DDDR******	13(26)
➢ VVI******	06(12)
➢ DDD********	05(10)

#yate corrected chi-square *DCMP-Dilated cardiomyopathy **CVA-cerebrovascular accident ***CHD-congenital heart diseas
****MRI- Magnetic resonance imaging   *****VVIR: ventricles ventricles inhibitory rate modulation
******DDDR: dual dual dual rate modulation *******VVI: ventricles ventricles inhibitory ********DDD: dual dual dual

Table 3: representing that majority of study subjects were vegetarian, non-alcoholic, non-smoker. 20% participants suffered from altered sleep pattern during hospitalization. More than half of study subjects were having normal Body Mass Index i.e. 18.5-24.9. The main EMI Equipment used was cell phone (78%).

Table 3: Personal profile of study subjects
N=50

Variables	Study subjects $n_1=50$ f (%)
Dietary Habits	
Vegetarian	**28(56)**
Non- vegetarian	22(44)
Alcoholic	
Yes	04(08)
Occasional	01(02)
Left	06(12)
No	**39(78)**
Smoker	
Yes	03(06)
Left	06(12)
No	**41(82)**
Altered bowel function	
Prior to hospitalization	
➢ Present	02(04)
➢ Absent	48(96)
During hospitalization	
➢ Present	**19(38)**
➢ Absent	31(62)
After hospitalization	
➢ Present	15(30)
➢ Absent	35(70)
Body Mass Index (kg/m²)*	
<18.5	04(08)
18.5-24.9	**34(68)**
30- 34.9	06(12)
35- 39.9	06(12)
EMI** equipment use	
cellphone	**39(78)**
welding equipment	01(02)
No	10(20)

 *BMI = body mass index (mean±SD, range)= 23.82± 03.92, 15-35   **EMI: electromagnetic interference

Table 4: this table represents the Anxiety score by STAI Scale. 80% of patients in pre pacemaker implantation period were moderate anxious (score 41-60), 18% were mild and 2% were in severe anxiety. While in post pacemaker implantation period 72% were in mild, 28% in moderate and none of the patients were in severe anxiety. The results show that patients posted for pacemaker implantation exhibits anxiety due to change in health condition and need of artificial device for survival.

Table 4: Assessment of Anxiety of study subjects

N=50

Anxiety levels (score range: 20-80)	State anxiety before pacemaker implantation f(%)	State anxiety after pacemaker implantation f(%)
Mild Anxiety (score 20-40)	9(18)	36(72)
Moderate Anxiety (score 41-60)	40(80)	14(28)
Severe Anxiety (score 61-80)	1(2)	00

Table 5: represents the Barthel Index score of activities of daily living. Baseline Barthel Index value was 14.86±2.60, as maximum attainable score was 20. The values can be less because of the brady-arrhythmias and associated features like decrease pulse rate, syncope, fatigue, weakness etc. At 5th post PPI day the score (Mean±SD) was 10.08±2.65 with range 2-16. With increase in post PPI days, there was increase in Barthel Index score and patient started to perform Daily activities.

Table 5: Assessment of independence in performance of activities of daily living *of subjects* under study

N=50

Barthel score (max score= 20)	Mean ±SD, Range
Pre Pacemaker implantation score	14.86±2.60, 9-18
Post pacemaker implantation day 5	10.08±2.65, 2-16
Post pacemaker implantation day 10	12.44±1.79, 7-16
Post pacemaker implantation month 1	14.96±2.44, 5-18
Post pacemaker implantation month 2	n_1=49 16.43±1.92, 11-18

Table 6: is frequency and percentage distribution of pacemaker implantation site assessment of study subjects on 5th, 10th post implant days and at 1 and 2 month follow ups, which shows that deep and severe wound was not found in any study subject but pus at one point of <2cm area was found in 2 patients of at 1 month assessment.

Table 6: Assessment of permanent pacemaker site among study subjects by Southampton Wound Scoring System

N=50

Score (by Southampton Wound Scoring System)		Post PPI day 5 n_1=50 f(%)	Post PPI day 10 n_1=50 f(%)	Post PPI month 1 n_1=50 f(%)	Post PPI month 2 n_1=49 f(%)
0: Normal Healing		42(84)	44(88)	46(92)	49(100)
I: Normal healing with mild bruising or erythema	A: Some bruising	02(04)	03(06)	....	....
	B:-Considerable bruising	01(02)	....	....	....
	C:- Mild erythema	....	....	....	....
II: Erythema and other signs of inflammation	A:-At one point	01(02)	....	01(02)	....
	B:-Around sutures	01(02)	01(02)	01(02)	....
	C:-Along wound	....	....	....	....
	D:-Around wound	....	....	....	....
III: Clear or haemoserous discharge	A:- At one point only (< 2 cm)	01(02)	01(02)	01(02)	....
	B:-Along wound (> 2 cm)	....	....	....	....
	C:- Large volume	....	....	....	....
	D:-Prolonged (> 3 days)	....	....	....	....
IV: Pus	A:-At one point only (< 2 cm)	....	....	02(04)	....
	B:-Along wound (> 2 cm)	....	....	....	....
V: Deep or severe wound infection with/without tissue breakdown; haematoma requiring aspiration		....	....	....	....

Table 7: represented that the mean QuickDASH score ± SD of shoulder discomfort was 74.54± 7.17 at 1 month of post PPI and 72.67±5.14 at 2month of post PPI. Maximum score was 100. There was no statistically significant difference in shoulder discomfort at 1 and 2 month follow-up. This shows that patients face shoulder discomfort at site of pacemaker implantation due to arm immobilization and restriction of shoulder movement.

Table 7: Assessment of shoulder discomfort at 1 month and 2 month of post pacemaker implantation

N=49

Quick DASH score (max attainable score 100)	mean± SD	Mean difference ±SD	t test (df) p value
QuickDASH score at 1 month QuickDASH score at 2month	74.54± 7.17 73.67±6.72	0.86± 3.06	1.97 (48) 0.06

Discussion

Pacemaker devices are the blessing of technology for patients with cardiac rhythm abnormality. The survival rate of patients with brady-arrhythmias is improved a lot after the arrival of pacemaker technology. It is a small battery powered device which is usually implanted in infraclavicular region. It saves life of the patient, but it is not a very comfortable artificial device for the patient. Patients need to make mange modifications to ensure safety and adequate pacemaker function. Although pacemaker implantation is becoming very common in twenty first century but in absence of knowledge and poor care the chances of psychological and physical complications associated with these devices are also not uncommon.

The purpose of the present study was to see the factors: anxiety, infection, Shoulder discomfort and performance of activities of daily living among the pacemaker implantation patients. Regular follow-up of patients was done till 2 months and the selected outcome variables were assessed time to time.

In present study, the mean age of study subjects was 63.3±15.78. Similar findings were obtained by Elsalam (2010), who said that pacemaker are implanted in individuals of all ages ,but the most in older adults, this is due to an increase in abnormalities of impulse generation and conduction with advancing age[21]. In the study done by Nagwa (2014) majority of study group patients were between 61-80 years, this study also supports the current finding[22]. Similar results was found by Hanaa (2017) with mean age ±SD= 65.7±5.7 of pacemaker study subjects[23].

In relation to gender, the present results showed that, majority of study sample were male i.e. 64% from control group and 60% from experimental group were male. This finding is in agreement with that of Elsayed (2013) and Panda (2011) who found that, prevalence of permanent pacemaker in males was 1.5 times that in female[21].

Regarding habitat, this study revealed that majority of subjects were residing in rural area. This may be due to non-availability of specialized hospitals affording pacemaker insertion in rural areas. Similar results were found by Hussein (2005) and Elsayed (2013) i.e. approximately two thirds of their studied subjects were residing in rural areas[24]. As regards having co-existing diseases the present study revealed that more than half of sample studied have chronic diseases i.e. diabetes and hypertension,this result agree with Nagwa Mohamed (2014) who reported that approx. half of the pacemaker patients were having hypertension and/or diabetes[22].

In relation to clinical diagnosis of patient more than half of the patients were diagnoses with complete heart block. This finding matches with study done by Nagwa Mohamed (2014) study in which 75% patients who underwent permanent pacemaker implantation were diagnosed with complete heart block.[22]

Present study found that the majority of patients were in moderate (score 41-80) state anxiety before pacemaker implantation period because of many factors like being diagnosed with heart disease, need of artificial device to live, expenditure of treatment etc. Mild to moderate anxiety in post pacemaker implantation period was seen and the major cause of anxiety were fear of pacemaker malfunctions, its interference with electronic devices, being dependent on artificial device, battery end etc. Similar results were found by the study done by Figueroa et al (2016), study showed that 81.8% of patients encounter anxiety in the pre-test and it reduced to 45.5% in the phase of post –evaluation after interventions.[25] Similarly, in a research study, performed at the Hospital General de Mexico (2011), 27.9% pacemaker patients experienced moderate to severe anxiety.[13]

Similar study done by Xin et al on Influence of Continuous Nursing on the Psychological State and Coping Style of elderly patients who were undergoing pacemaker implantation from Harbin City (China). In the study Routine nursing was applied to the control group; continuous nursing support was provided for the intervention group from January 2014 to January 2015. The anxiety level in pre and post periods of the two groups were compared by using Zung's Self - Rating Anxiety Scale. It was seen that in Intervention group (n = 54) anxiety was reduced from 44.5 ± 9.2 to 35.2 ± 7.8 with continuous nursing as in Control group (n = 49) it was reduced from 43.9 ± 8.9 to 41.6 ± 7.8 in pre and post periods with p value <0.001.[26]

Infection in a permanently implanted Pacemaker is a 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%. [27] Baddour et al reported that there is 210% increase in pacemaker device infection from 1993 to 2004.[17] A study done by Johansen1 et al concluded that infection may occur either as a surgical site infection (SSI), occurring within 1 year after pacemaker implantation or as late-onset pacemaker lead endocarditis.[28]

Present study revealed that 6% patients of control group developed minor wound complications and 4% developed wound infection at 1month of post pacemaker implantation. On comparing the results with study done by Nagwa (2014), showed that, 3.3% patients of developed wound infection in the study.[22]

In the current study it was seen that the independence in performance of activities of daily living (ADL) like feeding, bathing, grooming, mobility, transfer, toilet use, stair use etc. was affected due to cardiac rhythm disorder and limitation of shoulder movement due to pacemaker implantation and after artificial device implantation ADL were improved with increase in post Pacemaker implantation days. No previous study till date is done to see the performance of activities of daily living in patients with pacemaker implantation devices.

Previous studies have shown that due to restriction of affected shoulder movement (due to risk of lead displacement) chances of shoulder discomfort are there. In the present study, QuickDASH Questionnaire (maximum attainable score-100) was used to measure the shoulder discomfort. The shoulder discomfort score was (mean ±SD) 74.54±7.17 (at 1 month of P/PPI) and 73.67±6.72 (at 2 month of P/PPI). There was no statistically significant decrease in shoulder discomfort with p value <0.05 with one month time. This shows that specific interventions like

shoulder exercises are required to limit shoulder discomfort and improve ADL. Study done by James et al (2011) supports the results of present study. In the study done by James et al (2011), control group received routine instructions as in the exercise group, during the 1-week post implant visit, patients were instructed on a series of exercises to be completed 3 days per week for 6 weeks. Study results showed a statistically significant improvement in shoulder discomfort with p value <0.03 among study subjects after shoulder excercises.[29]

Findikoglu et al (2015) studied Limitation of movement and shoulder disabilities in 49 patients with permanent pacemaker. Shoulder Range of Motion was measured using a digital goniometer. The opposite arm was used as the control. Limitations of Range of Motion for abduction, flexion, and internal rotation were found to be significantly lower in the arm on the side of pacemaker compared with the opposite arm. Significant differences in shoulder abduction, flexion, and external rotation were found compared with long-term recipient (p value <0.05). However, the functional comparison of groups was not significant. A low to moderate shoulder disability was found in patients with permanent pacemaker (P value <0.05). [15]

Therefore present study reveals that permanent pacemaker implantation causes disturbance in life of patient as adjustment with artificial device need time, skill as well as knowledge. It may cause psychological as well as physiological problems like anxiety, infection, shoulder discomfort, dependence for ADL etc. Thus a systematic teaching and practices based information about permanent pacemaker care can be taught to patients and family to reduce the chances of occurrence of the complications and allow the patients to adapt more easily to the pacemaker devices.

Conclusion:
From the results of the present study, it can be conducted that:
➢ Patients with permanent pacemakers exhibits moderate anxiety before as well as after pacemaker implantation.
➢ Infection can occur at pacemaker implantation site. Therefore care must be taken to prevent pacemaker site infection.
➢ Patient experiences shoulder discomfort due to restriction of shoulder movement in post pacemaker implantation period.
➢ There is decrease in ADL by pacemaker patients. Performance of tasks of Activities of daily living increases with increase in post pacemaker implantation days.

Recommendations:
➢ Pacemaker care guidelines can be prepared and taught to patents by means of educational aids like simple booklets, mobile applications, audio assisted and video assisted methods for better understanding of the patients with permanent pacemaker.
➢ Longitudinal studies can be conducted for the long term follow up of pacemaker patients.
➢ Special pacemaker nurses can be trained and appointed in Cardiac Centres with the objective of teaching the patient about pacemaker and to improve their skills of pacemaker care.

➢ Informational booklets of pacemaker care can be make available in cardiac department and pacemaker clinics for pacemaker patients

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