

RESEARCH ARTICLE

ASSESSMENT OF EFFECTIVENESS OF PERMANENT PACEMAKER CARE GUIDELINES ON PATIENT ACTIVITY AND ADHERENCE.

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Manuscript Info

Manuscript History

Received: 19 July 2018 Final Accepted: 25 August 2018 Published: September 2018

Keywords:-

Pacemaker Care Guidelines, Pacemaker, Adherence with Permanent care

Abstract

Objectives:The objectives of present study was to evaluate the effectiveness of Pacemaker Care Guidelines on pacemaker care practices adherence and performance in activities of daily living in patients with permanent pacemaker implantation.

Material and methods: A quasi experimental design was considered for the present study. Total 100 samples were taken (50 in each control and experimental group) from cardiology units of Advance Cardiac Centre, PGIMER, Chandigarh by total enumeration sampling. Pacemaker Care Guidelines were developed and taught to experimental group with routine care and only routine care was given to control group. Tools used were sociodemographic profile, personal profile, clinical profile, Barthel Index for ADL and pacemaker care practices adherence checklist. Interview schedule and observation method was used for assessment of outcome variables at pre pacemaker implantation, 1st, 5th, 10th post implantation day and after 1month and 2 month of pacemaker implantation.

Results: The present study revealed that 94% patients in experimental group exhibited good adherence with pacemaker care practices as in control group average adherence was seen in 90% patients with statistically significant difference (p value <0.01). whereas ,in term of performance of activities of daily living, the Barthel score was 19.80 \pm 0.40 (range 18-20) in experimental group and in control group the Mean Barthel score was 16.43 \pm 1.92 (range 11-18) at 2 month of post Pacemaker implantation was seen with statistically significant improvement in ADL in experimental group (p value <0.05)

Conclusion: In the present study, Pacemaker Care Guidelines were found effective in term of increasing adherence with pacemaker care practices and increasing independence in activities of daily living. Therefore such nursing guidelines should be taught to patients to improve pacemaker care and reduce the pacemaker related complications due to non-adherence.

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Introduction:-

Technological advancement is the blessing of 20th century to the mankind. Technology has helped humans in each and every aspect of life including healthcare. One of the technological health inventions in field of cardiology is artificial pacemaker.

Electrical activity of heart was first discovered during the 1800s. However, devices for controlling artificially the heart's rate were discovered in 20th century.¹In 1932, first artificial pacemaker was built by American physiologist Albert Hyman. Hyman tested this device on animals. First external pacemaker was developed by Canadian electrical engineer John Hopps (1950).²However,first clinical implantation of a fully implantable pacemaker into a human (Mr Arne Larsson) was done in 1958by Rune Elmqvist (inventor) and Ake Senning (surgeon), by attaching electrodes to myocardium layer by open thoracotomy. But this device worked for three hours only. The second implanted device lasted for two days. R. Larsson received 26 pacemakers during lifetime. He was of 86 years, when he died, in 2001, outliving the surgeon as well as the inventor.³

Focusing on Indian history of artificial pacemakers, According to Nair M et al cardiac pacemakers was introduced in India in 1966. First pacemaker was implanted at the "Institute of Post Graduate Medical Education and ResearchKolkataWest Bengal"in April 1967. After that, In 1968, cardiac pacing started at AIIMS, New Delhi.⁴

Pacemakers electrically stimulates myocardium layer of heart to depolarize or/and to initiate a contraction, when heart's sinoatrial node does not workadequately.⁵Pacemakers are of two types i.e. temporary and permanent, who are implanted according to the type of conduction system abnormality.⁶

Permanent pacemaker is a small size device like a matchbox. It weights approximately 20-50 g.⁷Pacemaker contains generator and leads with electrodes over it. Pacemaker generator contains a circuit and batteries to generate the rate and electric current to the heart through leads. Average Life of pacemaker batteries is 5-15years. The pacemaker electrodes send electrical activity to the generator; the generator's electrical response is then transmitted to heart by the leads.⁶

Gregoratos(2005) stated that pacemakers are implanted to approximately 9,00,000patientsglobally each year. Pacemakers treat bradyarrhythmiasas well as tachyarrhythmias and can also be combined with implantable defibrillators. Pacemakers are usedmainly for the treatment of sinus node dysfunction, atrioventricular blocks (second degree and third degree), fascicular blocks,neurocardiogenic syncope and for prevention and treatment of certain tachyarrhythmias. Biventricular pacing (cardiac resynchronization therapy) is the treatment of choice for advanced heart failure in bundle branch blocks. Many studies have reported that pacemakers can reduce symptoms of dysfunction and improve quality of life of patient.⁷

A survey was carried out by Indian Heart Rhythm Society (IHRS) andIndian 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 cardiac devices use has been remarkably increased globally. In Europe and North America, cardiac devices implants/million peopleare an average of 300 implants/million which is very high. In Indian scenario, it is at a mean of 25 implants /million population.⁸ Strickland(2013) stated that, currently more than 3 million patients worldwide are with implanted permanent pacemaker.⁹

Implantation of permanent pacemaker is only the first step in lifelong management of pacemakerpatients. Pacemaker care practices and long-term follow-ups are necessary not only for safety of pacemaker patient but also for the adequateuse of the pacing system. However in majority of places in India, pacemakerpatients are usually checked only once each yearor/and often only near the end of battery life.¹⁰

According to Timby and Smith (2010), Permanent pacemakers improve quality of life and prevent death. Maximum outcome after PPI (permanent pacemaker implantation) can only be attained if patients remain in lifelong compliance with pacemaker care practices.¹¹

Implantation of the pacemaker is a vital event of one's life. Pacemaker Implants saves the patient from life threatening arrhythmias. Cardiac pacemakers are life saving for patients but pacemaker implantation do change the normal activities of the patient. It changes the ADL (activity of daily living) performance of the patient along with

there are some serious problems associated with pacemaker that can be prevented by performing pacemaker care practices. The complications that may arise after PPI includes pacemaker site infection, bleeding, hematoma, pneumothorax, ventricular ectopy, hemothorax, tachycardia, stimulation of phrenic nerve, dislocation of the lead, frozen shoulder etc.¹² Along with physical complications, patients who require pacemaker may also be in stress due to the feelings of being dependent on an artificial device, fear of device malfunction, fear of death andhigh cost of pacemaker. The complications associated with permanent pacemaker implantation can be minimized with adequate practices about care of pacemaker. Studies have shown that in USA, non-compliance with pacemaker care and follow ups causes about 125,000 deaths/year which leads to about 10 to 25% of admissions in hospitals and nursing homes. Reported incidences of PPIcomplication rate ranges from 0.19% to 13.9%. ¹³The majority of pacemaker complications can be minimized by performing specific activities to the patients for early identification and continuous monitoring.

According to American Heart Association, permanent pacemaker patients must know the detailed restriction and precautions in ADL. Patients and family members must know about pacemaker's programmed lower and upper heart rate. Pulse rate should be checked daily. Patients should allow about eight weeks for pacemaker to settle firmly in place, during this period avoid sudden movements of the affected arm and for the first 4 weeks not raise the pacemaker side elbow higher than shoulder. Avoid causing pressure over pacemaker was implanted. However after surgery, patient will be able to perform all normal activities for a person of same age. Always carry pacemaker card with patient. Stay away from electromagnetic interference and patient must be aware of warning signs like dizziness, dyspnea, irregular pulse rate, edema etc. ¹⁴

According toa study done by Aqeel et al (2008) on 93 adult patients found that majority of pacemaker patients considersperforming many routine activities as unsafe like bending over (37%), automobiles driving (28%), sleeping on pacemaker side (30%), passing through metal detectors (31%), irons (55%),electrical wall switches (56%) and video cassette recorders/television (53%). Pacemaker patients'insufficient knowledge potentially leads to disabling life style modifications.¹⁵Therefore adherence to correct pacemaker care practices is needed for adequate adjustment with pacemaker device.

Findikoglu et al in 2015 studied Limitation of range of motion and shoulder disabilities in 49 pacemaker patients. Limitations of Range of Motion for abduction, flexion and internal rotation were significantly lower in pacemaker implanted arm sidecompared with other arm. Also, significant differences in the shoulder abduction, flexion and in external rotation were found as compared with the long-term pacemaker recipient (p<0.05). Low to moderate amount of shoulder disability was found in patients with cardiac devices (p value <0.05).

A study done by Akyrou concluded that nurses are essential in care of pacemaker patient. Nurses provide care to patients in all phases of pacemaker implantation. In the operation theatre nursesmakes the most conducive environment and assists in the implantation of the permanent pacemaker; in post PPI units, she keepsher eyes on patients for prevention of complications and provides individualistic holistic nursing care. She aids pacemaker patient and his/her family with rehabilitation care and adaptation to the new life. Also, nurse teaches the patient about observation of pacemaker function and battery and focuses on the importance of following the doctor's advice and regular follow-ups in OPDs or in pacemaker clinics.¹⁷

Malm et al (2007) did amulti-centre nursing study on effects of the self-care program on health-related quality of life among pacemaker patientsreveal that, it is necessary to include patients actively in self-care while in acute phase inthe hospital, nurses should support pacemaker patients in professional and kind way by providing accurate, relevant and clearinformation and planning self-care based on the nurse's assessment of pacemaker patient's needs.¹⁸

Stewartet al (1991) conducted a study on role of nurses in pacemaker patient education and follow-up care, concluded that suitable educational material given to pacemaker patientsduring inpatient and outpatient phases can lead independence and a positive attitude in pacemaker patients.¹⁹

Thus the present study was conducted to prepare pacemaker care guidelines and to evaluate the effectiveness of these nursing guidelines and protocols on ADL and adherence with pacemaker care practices among permanent pacemaker patients. So that patient can adopt with the changes made after pacemaker implantation.

Research Methodology:-

Research approach and design:

A Quantitative Approach with quasi experimental study design was used in the present study.

Research setting:

This study was conducted in Cardiology units of Advanced Cardiac Centre, PGIMER, Chandigarh from June – September, 2017.

Research sample:

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 100, out of which 1 patient from control group expired at 1month of post PPI due to associated morbidity.

Research Variables:

Independent variable:

The independent variable in this study was Permanent Pacemaker Care Guidelines for patients undergoing permanent pacemaker implantation.

Dependent Variable:

The dependent variables in this study were Adherence with pacemaker care practices and Activities of Daily Living (ADL) of the patient.

Research tool:

An interviewing questionnaire was developed after reviewing of related literature, which consisted of three parts:

Tool 1:

The following parts were there:- Sociodemographic profile sheet, Personal profile sheet and Clinical profile sheet. Sociodemographic profile sheet to assess socio - demographic characteristics of patients with permanent pacemaker insertion. It compromises items about age, sex, marital status, educational level, occupation and income. Personal data collected emphasised on dietary Habits, history of any addiction/ substance abuse, mobility and Body Mass Index of the patient.Clinical data sheet was used to assess clinical diagnosis and co-morbid diseases which included cardiac diseases, hypertension, diabetes etc.

Tool 2:

Barthel Index was used for ADL, which contains total 10 items i. e. feeding, grooming, bathing, toilet use, transfer, mobility, dressing, stairs, bowel and bladder. Each performance item is rated on this scale with a given number of points assigned to each level or ranking. A higher number is associated with a greater degree of independence. The amount of physical assistance and time needed to perform each item are used in determining the assigned value of each item. Total scores range from 0 - 20, with lower scores indicates increased disability.

Tool 3:

A checklist was prepared for assessment of adherence with pacemaker care practices. It included total 15 items like monitoring pulse rate daily, avoiding pressure over pacemaker site, keeping cell phone opposite side of pacemaker, wearing loose cotton clothes, performing light exercises like walking daily, performing follow up visits as advised, carring pacemaker card always, keeping pacemaker site dry and clean, eating high fibre food and vegetable diet, not lifting weights by pacemaker implanted side arm, staying away from electromagnetic interference, performing shoulder exercises, not performing right activity and 0 marks for not performing appropriate activity. No negative scoring was done. Scores was classified in poor (0-5), average (6-10) and good (11-15) adherence with pacemaker care practices.

Content validity:

The tools were reviewed for comprehensiveness, appropriateness, and legibility by experts in field of cardiology and nursing.

Ethical consideration:

Approval of research protocol was sought from the Institute's Ethics Review Committee of PGIMER Chandigarh and permission was taken from head of cardiology. This study was registered under CTRI (REF/2018/01/011389)

Pilot study:

A pilot study was carried out on 10 patients to assess the clarity, visibility, and time required to fulfil the tools before the actual data collection period i.e. in May-June, 2017.

Pacemaker care guidelines:

Guidelines were developed after extensive literature search and by consulting with experts in field of cardiology, nursing education, nursing practice and nursing research. Pacemaker care guidelines includes information about heart's basic structure, conduction system of the heart, ECG, cardiac arrhythmias, indications of permanent pacemaker implantation, pacemaker and its working, types of pacemaker, parts of permanent pacemaker, battery replacement, procedure of pacemaker implantation, expected complications, guidelines for patients with permanent pacemaker which included: self- monitoring of pulse rate, maintenance of self-vital chart , activity guidelines, physical exercises, exercise protocol for affected extremity, care of incision site, importance of pacemaker card, precautions while travelling, pacemaker and electronic devices/gadgets, heart healthy diet, sign of pacemaker malfunction and follow up. These guidelines were taught to patients by health education and return demonstration method at admission i.e. before PPI and return demonstration was taken from the patients. One supplemental booklet containing coloured pictures of these guidelines was also given to the patients. Recall of these guidelines was done till 3 days of post PPI.

Data collection:

Interview technique and Observation method were used for final data collection. Assessment of outcome variables was done before pacemaker implantation and on 1st, 5th, 10th day of post PPI and after 1st and 2nd month of Post PPI.

Statistical Package for Social Sciences (SPSS version 20) software was used for data analysis. Descriptive statistics and inferential statistics were used. Data was presented in form of tables and figures as suitable.

Data analysis and interpretation

Sociodemographic, Personal and Clinical profile of study subjects (table 1-3):

Table 1 shows the Sociodemographic distribution of study subjects in both groups. 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. More than the half of study subjects in both groups was male i. e. 60% in experimental and 64% in control group. Majority of study subjects were married (70% in control and 74% in experimental group), Hindu (82% in control and 68% in experimental group) and were unemployed(66% in control and 70% in experimental group). 58% of study subjects in control and 44% of study subjects in experimental group were living in villages and were having per capita income less than 1000 rupees. Both groups were homogenous and comparable as per age, gender, qualification, marital status, religion, type of family, per capita income, habitat, lifestyle pattern, occupation with p value >0.05.

| Variable | Control group | Experimental group | x^2 value (df) p value |
|----------------|----------------------|----------------------|----------------------------|
| | (n ₁ =50) | (n ₂ =50) | |
| | f (%) | f (%) | |
| Age(in years)* | | | |
| <40 | 05(10) | 04(08) | |
| 41-80 | 38(76) | 43(86) | 2.02 (2) 0.36 [#] |
| >80 | 07(14) | 03(06) | |
| Gender | | | |
| Male | 32(64) | 30(60) | 0.17 (1)0.83 |
| Female | 18(36) | 20(40) | |
| Qualification | | | |
| Non-literate | 21(42) | 24(48) | |
| Primary school | 07(14) | 03(06) | |
| Middle school | 06(12) | 05(10) | 4.22 (5) 0.67# |

Table 1:-Socio-demographic distribution of study subjects undergoing permanent pacemaker implantation N=100

| High school | 09(18) | 10(20) | |
|-----------------------------|--------|--------|----------------------------|
| Post high school | 02(04) | 02(04) | |
| Graduate and above | 05(10) | 06(12) | |
| Marital status | | | |
| Unmarried | 02(4) | 03(6) | |
| Married | 41(82) | 34(68) | 2.63 (2) 0.24 [#] |
| Widow/ Widower | 7(14) | 13(26) | |
| Religion | | | |
| Hindu | 35(70) | 37(74) | |
| Muslim | 01(02) | 03(06) | |
| Sikh | 13(26) | 9(18) | 1.78 (3)0.61 [#] |
| Christian | 01(02) | 01(02) | |
| Type of family | | | |
| Nuclear family | 26(52) | 32(64) | 1.47(1) 0.22 |
| Joint family | 24(48) | 18(36) | |
| Per capita income (in Rs)** | | | |
| <1000 | 21(42) | 19(38) | |
| 1001-2000 | 06(12) | 13(26) | |
| 2001-3000 | 10(20) | 05(10) | 2.25 (3)0.89 |
| >3000 | 13(26) | 15(30) | |
| Habitat | | | |
| City | 10(20) | 14(28) | |
| Town | 11(22) | 14(28) | 1.98 (2)0.37 |
| Village | 29(58) | 22(44) | |
| Life-style Pattern | | | |
| Sedentary | 26(52) | 17(34) | 3.34 (2) 0.18 |
| Mild worker | 18(36) | 24(48) | |
| Moderate worker | 06(12) | 09(18) | |
| Occupation | | | |
| Employed | 14(28) | 12(24) | |
| Unemployed | 33(66) | 35(70) | 1.52(02) 0.48 [#] |
| Student | 03(06) | 03(06) | |

*Age (mean ±SD, range) = 63.3 ±15.78, 14-93 # yate corrected chi-square

Table 2:-Distribution of Clinical variables of study subjects N=100

| Variable | Control group | Experimental group | ×2 value (df) p value |
|--------------------------------|----------------------|----------------------|----------------------------|
| | (n ₁ =50) | (n ₂ =50) | _ |
| | f (%) | f (%) | |
| Chief complaints of patient on | | | |
| admission | | | |
| Dyspnea | 39(78) | 35(70) | |
| • Yes | 11(22) | 15(30) | 0.83 (1) 0.36 |
| • No | | | |
| Dizziness | 03(06) | 04(08) | |
| • Yes | 47(94) | 46(92) | 0.15 (1) 0.69 [#] |
| • No | | | |
| Palpitations | 04(08) | 10(20) | |
| • Yes | 46(92) | 40(80) | 2.99(1) 0.08 |
| • No | 0.5 (50) | | |
| Syncope | 25(50) | 21(42) | |
| • Yes | 25(50) | 29(58) | 0.64 (1)0.42 |
| • No | 11(22) | 07(14) | |
| Presyncope | 11(22) | $\frac{0}{(14)}$ | 1.09 (1)0.20 |
| • Yes | 39(78) | 43(80) | 1.08 (1)0.29 |

| • No | | | |
|---------------------------------------------------------------------|--------|---------|----------------------------|
| Other(chest pain, Giddiness, ghabrahat, | | | |
| fatigue, weakness) | 20(40) | 20(40) | |
| • Yes | 30(60) | 30(60) | 0.40 (1) 0.52 |
| • No | | | |
| Clinical diagnosis of patient | | | |
| 2nd degree heart block | 06(12) | 14(28) | |
| Complete heart block | 30(60) | 23(46) | 5.32 (4) 0.24 [#] |
| 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 |
| Permanent Pacemaker Type | | | |
| Single chamber | 32(64) | 30(60) | |
| Double chamber | 16(32) | 16(32) | 0.73 (2) 0.84 [#] |
| Biventricular | 02(04) | 04(08) | |
| | 1 11 | LOT 1 1 | 1.1 detet OUTD |

yate corrected chi-square*DCMP-Dilated cardiomyopathy **CVA-cerebrovascular accident ***CHDcongenital heart diseas

Table 2 shows comparison of clinical variable of both groups. 78% of the study subjects control group and 70% of study subjects in experimental group presented with chief complaint of dyspnoea followed by syncope at admission. Clinical diagnosis of 60% patients in control and 46% patients in experimental group was complete heart block. Sick sinus syndrome and 2^{nd} degree heart block were the other main indications for permanent pacemaker implantation. Majority of study subjects in both group had Hypertension and Diabetes as comorbidity. Majority of the study subjects underwent single chamber pacemakers. Both group were comparable in terms of their clinical variables (p value >0.05).

Table 3:-Distribution of Personal variables of study subjects N=100

| Variables | Control group | Experimental group | \star^2 value (df) p |
|--------------------------|---------------|--------------------|---------------------------|
| | $H_1 = 50$ | $\Pi_2 = 50$ | value |
| | 1 (70) | 1 (70) | |
| Dietary Habits | | | |
| Vegetarian | 28(56) | 34(68) | 1.52 (1) 0.30 |
| Non- vegetarian | 22(44) | 16(32) | |
| Alcoholic | | | |
| Yes | 04(08) | 03(06) | |
| Occasional | 01(02) | 03(06) | 1.95 (3) 0.59# |
| Left | 06(12) | 09(18) | |
| No | 39(78) | 35(70) | |
| Smoker | | | |
| Yes | 03(06) | 06(12) | |
| Left | 06(12) | 06(12) | 1.11 (2) 0.66 |
| No | 41(82) | 38(76) | |
| Altered Mobility | | | |
| Prior to hospitalization | | | |
| • Present | 02(04) | 01(02) | 0.34 (2)1.00 [#] |
| • Absent | 48(96) | 49(98) | |
| During hospitalization | | | |
| • Present | 03(06) | 01(02) | 1.37 (2) 0.61# |
| • Absent | 47(94) | 49(98) | |

| After hospitalization | | | |
|-----------------------------------------|----------------|---------------------|----------------------------|
| • Present | 01(02) | 01(02) | 1.01 (2) 0.31 |
| • Absent | 49(98) | 49(98) | |
| Body Mass Index (kg/m ²)* | | | 6.18 (3) 0.10 [#] |
| <18.5 | 04(08) | 6(12) | |
| 18.5-24.9 | 34(68) | 28(56) | |
| 30-34.9 | 06(12) | 14(28) | |
| 35-39.9 | 06(12) | 02(4) | |
| EMI** equipment use | | | 1.10 (2) 0.80 |
| cellphone | 39(78) | 41(82) | |
| welding equipment | 01(02) | 02(04) | |
| No | 10(20) | 07(14) | |
| # yate corrected chi-square | | \$fisher exact test | |
| *PMI - body mass index (mass SD range | -22.82 + 02.02 | 15 25 **EMI | alactromagnatic |

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

Table 3 representing that majority of study subjects in both groups were vegetarian, non-alcoholic, non-smoker. Both group were homogenous in terms of dietary habits, addictions like alcohol and smoking, mobility, BMI and Electromagnetic Interference equipment's use (p value >0.05).

Assessment of effectiveness of pacemaker care guidelines on Adherence with pacemaker care practices (Table 4-5):

| Question | Control | group | | | | Experin | nental gro | oup | | |
|-------------------|-----------------|-----------------|------------------|--------------------|--------------------|-----------------|-----------------|------------------|--------------------|---------------------------|
| | 1 st | 5 th | 10 th | 1 | 2 | 1 st | 5 th | 10 th | 1 | 2 |
| | P/PPI | P/PPI | P/PPI | month | month | P/PPI | P/PPI | P/PPI | month | month |
| | day | day | day | P/PPI | P/PPI | day | day | day | P/PPI | P/PPI |
| | $n_1 = 50$ | $n_1 = 50$ | $n_1 = 50$ | n ₁ =50 | n ₁ =49 | $n_2 = 50$ | $n_2 = 50$ | $n_2 = 50$ | n ₂ =50 | n ₂ =50 |
| | f(%) | f(%) | f(%) | f(%) | f(%) | f(%) | f(%) | f(%) | f(%) | f(%) |
| Monitors pulse | 01(02) | 02(04) | 02(04) | 01(02) | 01(02) | 38(76) | 41(82) | 45(90) | 45(90) | 44(88) |
| rate daily | | | | | | | | | | |
| Keep pacemaker | 50(100) | 50(100) | 48(96) | 30(60) | 34(69.4) | 50(100) | 50(100) | 50(100) | 45(90) | 47(94) |
| site dry and | | | | | | | | | | |
| clean | | | | | | | | | | |
| Avoids pressure | 50(100) | 50(100) | 50(100) | 42(84) | 39(79.5) | 50(100) | 50(100) | 50(100) | 50(100) | 48(96) |
| on pacemaker | | | | | | | | | | |
| implantation site | | | | | | | | | | |
| Kept cellphone | 50(100) | 50(100) | 50(100) | 44(88) | 44(89.7) | 50(100) | 50(100) | 50(100) | 50(100) | 50(100) |
| opposite side of | | | | | | | | | | |
| pacemaker | | | | | | | | | | |
| Wear loose | 50(100) | 48(96) | 46(92) | 37(74) | 29(59.2) | 50(100) | 50(100) | 48(96) | 50(100) | 50(100) |
| fitting cotton | | | | | | | | | | |
| clothes. | | | | | | | | | | |
| Performs light | 05(10) | 14(28) | 20(40) | 22(44) | 22(44.9) | 36(72) | 41(82) | 42(84) | 46(92) | 48(96) |
| exercises like | | | | | | | | | | |
| walking daily | | | | | | | | | | |
| Carries | 13(26) | 11(22) | 11(22) | 10(20) | 17(34.7) | 28(56) | 48(96) | 48(96) | 48(96) | 49(98) |
| pacemaker card | | | | | | | | | | |
| always | | | | | | | | | | |
| Not lifts weights | 50(100) | 50(100) | 50(100) | 46(82) | 38(77.6) | 50(100) | 50(100) | 50(100) | 50(100) | 40(80) |
| more than 4kg | | | | | | | | | | |
| by pacemaker | | | | | | | | | | |
| implanted side | | | | | | | | | | |

 Table 4:-Frequency distribution of Adherence with Pacemaker Care Practices of the study subjects
 N=100

| arm. | | | | | | | | | | |
|--------------------|---------|---------|---------|--------|----------|---------|---------|---------|---------|---------|
| Stays away from | 50(100) | 29(58) | 30(60) | 30(60) | 30(60) | 50(100) | 50(100) | 50(100) | 50(100) | 50(100) |
| Electromagnetic | | | | | | | | | | |
| Interference | | | | | | | | | | |
| Performs | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 45(90) |
| exercises for | | | | | | | | | | |
| prevention of | | | | | | | | | | |
| shoulder | | | | | | | | | | |
| stiffness. | | | | | | | | | | |
| Don't Continues | 50(100) | 50(100) | 50(100) | 48(96) | 48(98) | 50(100) | 50(100) | 50(100) | 50(100) | 50(100) |
| to perform | | | | | | | | | | |
| physical | | | | | | | | | | |
| activities when | | | | | | | | | | |
| get tired | | | | | | | | | | |
| Don't Lift | 50(100) | 49(98) | 48(96) | 34(68) | 33(67.4) | 50(100) | 50(100) | 50(100) | 50(100) | 25(50) |
| affected arm | | | | | | | | | | |
| above shoulder | | | | | | | | | | |
| level till 1 month | | | | | | | | | | |
| Eat high fiber | 13(26) | 30(60) | 30(60) | 26(52) | 30(61.2) | 14(28) | 40(80) | 42(84) | 42(84) | 45(90) |
| food and | | | | | | | | | | |
| vegetable diet | | | | | | | | | | |
| Activity | 50(100) | 50(100) | 50(100) | 48(96) | 48(98) | 50(100) | 50(100) | 50(100) | 50(100) | 50(100) |
| restriction till | | | | | | | | | | |
| 2month of post | | | | | | | | | | |
| PPI | | | | | | | | | | |
| Performs | 50(100) | 50(100) | 42(84) | 44(88) | 42(85.7) | 50(100) | 50(100) | 50(100) | 50(100) | 48(96) |
| treatment/ | | | | | | | | | | |
| follow up visits | | | | | | | | | | |
| as advised | | | | | | | | | | |

Table 4represents the adherence of pacemaker care practices like monitoring pulse, not lifting weight, avoiding pressure on affected side, diet, shoulder exercises, electromagnetic interference, carrying pacemaker card, regular follow ups etc.in both groups on 1st, 5th, 10th post implantation day and at 1 and 2 month postoperative follow ups. The adherence was seen more in experimental group in compare to control group in each parameters in different observations.

Table 5:-Comparison of Adherence with pacemaker care practices among study subjects N=100

| | Adherence score | Poor | Average | Good | Chi- |
|-----------------------|----------------------|-------------|--------------|---------------|----------|
| | | adherence | adherence | adherence | square |
| | | (score 0-5) | (Score 6-10) | (Score 11-15) | (df) p- |
| | | f(%) | f(%) | f(%) | value |
| 1 nd Post | Control group | 10(20) | 39(78) | 01(02) | |
| PPI day | $(n_1 = 50)$ | | | | |
| | Experimental group | 04(08) | 20(40) | 26(52) | 31.8(2) |
| | $(n_2=50)$ | | | | <0.001 |
| 5 th Post | Control group | 04(08) | 43(86) | 03(06) | |
| PPI day | $(n_1 = 50)$ | | | | 50.6 (2) |
| | Experimental group | 01(02) | 11(22) | 38(76) | <0.001 |
| | (n ₂ =50) | | | | |
| 10 th Post | Control group | 03(06) | 41(82) | 06(12) | |
| PPI day | $(n_1=50)$ | | | | 52.2 (2) |
| | Experimental group | 00 | 08(16) | 42(84) | <0.001 |
| | (n ₂ =50) | | | | |
| 1 Post | Control group | 01(02) | 45(90) | 04(08) | |
| PPI | $(n_1 = 50)$ | | | | 67.3(2) |

| month | Experimental group | 00 | 05(10) | 45(90) | <0.001 |
|--------|--------------------|----|----------|----------|------------|
| | $(n_2=50)$ | | | | |
| 2 Post | Control group | 00 | 44(89.8) | 05(10.2) | <i>A</i> . |
| PPI | $(n_1 = 49)^*$ | | | | 69.6(1) |
| month | Experimental group | 00 | 03(06) | 47(94) | <0.001 |
| | $(n_2 = 50)$ | | | | |

1 subject expired due to existing comorbidity.

Table 5 predicts that there was increase in adherence in both groups on subsequent reading till 2 month of post pacemaker implantation. At 1 day of post PPI 78% of patients in control group were having average adherence as in experimental group 40% were having average and 52% were having good adherence with pacemaker care practices. At 2 month of post PPI, only 10% patient from control group were having good adherence as in experimental group 94% patients were having good adherence with pacemaker care practices. High statistically significant difference in pacemaker care practices adherence among study subjects in control and experimental group with p value <0.001 in each observation was noted. Average (score between 6-10) adherence was seen in control group as in experimental group good adherence (score 11-15) was there.

Assessment of effectiveness of pacemaker care guidelines on ADL (Table 6-7):-

 Table 6:-Comparison of independence of activities of daily living <u>between study subjects</u>(Assessed by Barthel index for ADL):

 N=100

| Barthel score | Control group | Experimental group | t value(df) p value |
|----------------------|--------------------|--------------------|----------------------------|
| (max score | n ₁ =50 | n ₂ =50 | |
| = 20) | Mean ±SD, | Mean ±SD, | |
| | Range | Range | |
| Pre Pacemaker | 14.86±2.60, | 15.34±1.78, | 1.07 (98) 0.28 |
| implantation score | 9-18 | 11-19 | |
| Post pacemaker | | | |
| implantation day 1 | 3.56±1.43, | 4.88±1.54, | 4.42 (98) <0.001 |
| | 1-8 | 2-9 | |
| Post pacemaker | | | |
| implantation day 2 | 5.80±2.47, | 10.04±2.24, | 8.96(98) < 0.001 |
| | 1-12 | 4-15 | |
| Post pacemaker | | | |
| implantation day 3 | 7.92±2.57, | 12.84±2.42, | 9.82(98) < 0.001 |
| | 1-12 | 6-17 | |
| Post pacemaker | | | |
| implantation day 5 | 10.08±2.65, | 15.18±1.93, | 10.9(98) < 0.001 |
| | 2-16 | 8-18 | |
| Post pacemaker | | | |
| implantation day 10 | 12.44±1.79, | 17.26±1.30, | 15.33(98) < 0.001 |
| | 7-16 | 12-19 | |
| Post pacemaker | | | |
| implantation month 1 | 14.96±2.44, | 18.98 ± 0.86 , | 10.93(98) < 0.001 |
| | 5-18 | 16-20 | |
| Post pacemaker | n ₁ =49 | | |
| implantation month 2 | 16.43±1.92, | 19.80±0.40, | 11.95(97) < 0.001 |
| | 11-18 | 18-20 | |

Table 6 represents the independence in ADL in both groups. It was seen that there was no statistically significant difference in pre PPI Barthel Index score of both groups. This shows that both groups were comparable in terms of activities of daily living (p value >0.05). Baseline Barthel Index value of control group was 14.86 ± 2.60 and in experimental group was 15.34 ± 1.78 at pre PPI Phase. The values can be less because of the brady-arrhythmias and associated features like decreased pulse rate, syncope, presyncope, dyspnea, dizziness etc. There was statistically significant difference in post PPI ADL score of both groups in subsequent observations with p value <0.001. Table 7 shows, comparison of Barthel score within the study subjects. Scores varied in both groups. In experimental group

the Barthel Index score increased from 15.34 ± 1.78 (before PPI) to 15.51 ± 1.74 (post 2 month of PPI) in control group and in experimental group, the score was increased from 15.34 ± 1.78 to 19.38 ± 0.83 . There was statistically significant difference in both study subjects before and after giving Nurse Initiated Pacemaker Care Guidelines at 2month follow up (p value <0.05).

Table 7:-Comparison of independence in activities of daily living <u>within subjects</u> in control and experimental groupbefore and after giving Nurse Initiated Pacemaker Care Guidelines at 2month follow up.N=100

| Group | Barthel score | Mean± SD | Mean Difference | t test (df) p value |
|------------------------------|--------------------|------------|------------------|--------------------------|
| | | | ±SD | |
| Control group | Pre assessment | 15.10±1.98 | | |
| (n ₁ =49) | Barthel Score | | -0.40 ± 1.11 | 2.55(48) 0.01 |
| | Barthel Score at 2 | 15.51±1.74 | | |
| | month | | | |
| Experimental | Pre assessment | 15.34±1.78 | | |
| group | Barthel Score | | -4.04±1.93 | 14.74(49) < 0.001 |
| $(n_2=50)$ | Barthel Score at 2 | 19.38±0.83 | | |
| | month | | | |

Discussion:-

The survival rate of patients with brady-arrhythmias is improved a lot after the discovery of pacemaker technology. Although pacemaker implantation is becoming very common in twenty first century but in absence of poor care the chances of complications associated with these devices are also not uncommon. Nurses are present during all stages of pacemaker implantation and are an important member of the multidisciplinary team involved pacemaker implantation and long term care. A complete nursing intervention initiated since admission of patient for pacemaker implantation till the regular follow ups of patient can successfully reduce pacemaker related complications.

The aim of the present study was to assess the effectiveness of Pacemaker Care Guidelines on ADL and adherence with pacemaker among patients undergoing pacemaker implantation till 2 month of post PPI. The Pacemaker Care Guidelines were basically the nurse initiated pacemaker care guidelines taught to patients in experimental group by health education method and demonstration method. It was ensured that patients learnt these guidelines by redemonstration. Supplementary booklets were given to patients of these guidelines. Regular follow-up of patients in control and experimental group was done till 2 months and the 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 age²⁰. In the study done by Nagwa (2014)majority of study group patients were between 61-80 years, this study also supports the current finding¹³. Similar results was found by Hanaa (2017) with mean age \pm SD= 65.7 \pm 5.7 of pacemaker study subjects²¹.

In relation to gender, the present results revealed that, majority of study subjects were male i.e. 64% from control group and 60% from experimental group were male. This finding is in agreement with that of Panda (2011) andElsayed (2013) who found that, the prevalence of the permanent pacemaker implantation in males was 1.5 times that in females²⁰.

Regarding habitat, this study revealed that majority of subjects was residing in rural area. This may be due to less availability of specialized hospitals providing pacemaker implantation in rural areas. Similar results were found by Hussein (2005) and Elsayed (2013) i.e. approximately two thirds of the studied subjects were residing in rural areas²².

Focusing on co-existing diseases the present study revealed that more than half of subjects studied have chronic diseases i.e. diabetes and hypertension, this result agree with Nagwa Mohamed (2014) who reported that approx. half of the patients were having hypertension and/or diabetes¹³.

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 block¹³.

Regarding adherence with pacemaker care activities like pulse checking, avoiding contact with electro-magnetic interference, avoiding strenuous activities, wearing loose clothes, avoiding pressure on pacemaker implantation site, carrying pacemaker card, avoid lifting arm above shoulder level etc., there was statistically significant difference between present study subjects (p value<0.05). At 1 day of post PPI 78% of patients in control group were having average adherence as in experimental group 40% were having average and 52% were having good adherence with pacemaker care practices. At 2 month of post PPI, only 10% patient from control group were having good adherence as in experimental group 94% patients were having good adherence with pacemaker care practices. Average (score between 6-10) adherence was seen in control group as in experimental group good adherence (score 11-15) was there.

In present study, 88% patients were monitoring their pulse daily in experimental group in comparison with control group. Study done by Hanna (2017) on effectiveness of home pacemaker care program found that 95% study subjects check their pulse daily²¹.

In present study 98% patients of experimental group were carrying pacemaker card daily as compare to 36% patients of control group. Study done by Hanna (2017) revealed that 100% patients carry pacemaker card routinely after pacemaker care program²¹.

100% study subjects in experimental group of present study stays away from electro-magnetic interference in present study. Hanna (2017) revealed that 82.5% patients stay away from electro-magnetic interference with highly significant p value $(<0.001)^{21}$.

In the current study it was seen that the independence in performance of activities of daily living like feeding, bathing, grooming, mobility, transfer, toilet use, stair use etc. were improved in experimental as well as in control group with p value< 0.05 in pre-pacemaker implantation to 2 month of pacemaker implantation. But the mean difference between both groups was more in experimental group with highly statistically significant p value i.e. <0.001.

A study conducted in Sweden on 13 pacemaker patients showed that pacemaker patients used to restrict their ADL due to insufficient pacemaker care knowledge, were avoiding electromagnetic fields and were hesitant of using the microwave ovens and mobile phones. However, it was a quantitative study, therefore cannot be used for comparison purpose.²³

A study done in South Africa on 94 pacemaker patients, to study patient's perceptions of living with pacremaker. However, the study did not focused on specific daily activities, but the study revealed that up to 50% of the pacemaker patients felt handicapped after the pacemaker implantation and 53% of the pacemaker patients felt they become less active after the pacemaker implantation than before. Although, this study did not find specific reasons from the patients for these negative assumptions.²⁴

Doctors and nurses usually believe that patients resume normal activities almost immediately after PPI. However, pacemaker patients themselves may perceive interference to the pacemaker device function by various routine activities and equipments, and hence continue to lead restricted and disabled lives. Patients used to self-impose unnecessary restrictions on routine activities that patients perceived to be dangerous to the working of pacemaker. Thus ADL of patients used to impair. Thus the previous studies and the current studies focuses that a systematic teaching and practices based information about permanent pacemaker care can improve the activities of daily living of patients and increases adherence with pacemaker care practices which allow the patients to adapt more easily to the pacemaker devices.

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