Effect of the Nursing Protocol of Care on Health-Related Outcomes for Patients Undergoing Permanent Pacemaker Implant

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Abstract:

Background: Patients undergoing permanent implantable pacemakers, challenge with multiple physical, psychological, and social complications. The patients may perceive the pacemaker device as electronic security or as a source of physical, psychosocial, and emotional discomfort. So self-care management for those patients and patients' practices will lead to improving their life and overcoming physical, social, and psychological problems, and improving their outcomes. **Aims:** to determine the effect of the nursing protocol of care on health-related outcomes for patients undergoing permanent pacemaker implant. Design: A quasi-experimental design was used. **Setting:** The study was conducted at the Cardio- Electrophysiology Unit at the new Main Alexandria University Hospital and follow-up on outpatients clinics **Sample:** data was conducted on 100 cardiac patients undergoing permanent pacemaker implants that were divided into two equal groups as study and control. **Tools:** Three tools were used in this study. **The tool I:** Structured Interview Schedule, **Tool II:** patients' Knowledge Assessment Questionnaire regarding pacemaker implant, **Tool III:** Patients' Health Outcomes Sheet. Results: Overall total scores of self-care practice and patient knowledge improved significantly in the study group immediately post and post three months from program implementation in comparison with the control group indicating a significant difference between the two groups after implementing a teaching program (P>0.001). **Conclusion:** Medication management, Postoperative pacemaker implant care, precautions followed postoperatively, diet modification, ADL and follow-up were improved significantly in the study group immediately post and post three months from the nursing protocol of care. **Recommendation:** a training program for nurses about the protocol of care for patients with a permanent pacemaker. Future studies are needed about artificial pacemaker issues to develop evidence-based nursing management guidelines from different health centers in Egypt.

Keywords- Health-related outcome, the nursing protocol of care, permanent pacemaker implant.

Introduction:

Cardiac pacemakers (PM) are an operative treatment for, atrioventricular block, sick sinus syndrome, and other severe cardiac dysrhythmias. The number of patients getting pacemaker implantation is steadily increasing as the population ages and cardiovascular disease becomes more common **(Vardas,2015).** A pacemaker is a small device that's placed under the skin in a patient's chest to help in contrsregular heartbeat (arrhythmia) **(Tarun & Bashar, 2019).** Although the implantation of PM is a minimally invasive procedure, there is the potential for complications during or after implantation **(Schmitto, 2016).**

In light of this, the risk of complications exists with any invasive procedure. Overall, complications occur in 1% to 6% of all pacemaker implantation procedures.3 Complications can range from superficial bleeding to fatal infections or cardiac arrest. Generator pocket hematoma is the most common, accounting for over 3% of pacemaker

complications. Also, according to the REPLACE Registry, Lead dislodgement typically occurs within the first 3 months after implantation. Patients over age 75 were twice as likely to develop lead dislodgement as their younger counterparts. It is a common cause of failure to capture and failure to sense. So, it requires the replacement of one or more lead wires **(Chao and Firstenberg 2017).**

Implanting a device is a life-changing experience for the person, both physically and psychologically **(Ghojazadeh 2015).** The patient may be affected and concerned not just by the diagnosis and implantation of the device, but also by its function. Important considerations about how to live with the device and what to do with it in the event of the severe or end-stage disease may also arise. Patients' coping reactions to their sickness and treatment are influenced by their beliefs and knowledge about their illness **(Haugaa et al 2018)** and **(Lane, et al. 2015).** Implantation of the pacemaker is a vital event in one's life. Pacemaker Implants save the patient from life-threatening arrhythmias. Cardiac pacemakers are life-saving for patients but pacemaker implantation does 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 pacemakers that can be prevented by performing pacemaker care practices. Patients needing pacemakers can often be depressed as a result of feeling dependent on an artificial device, fear of device malfunction, fear of death, and the high cost of pacemakers. The complications associated with the permanent implantation of a pacemaker can be minimized with adequate care practices **(Sharma and Singh 2018).**

So, Patient education and support are essential for enhancing self-care abilities, improving outcomes, and decreasing unnecessary hospitalizations. In nursing education, teaching and providing information to patients and relatives are of central importance **(Olshansky & Hayes, 2016).** Moreover, nurses can provide care to patients in all phases of pacemaker implantation. They have a role in preparing a helpful environment and assisting in the implantation of the permanent pacemaker intra-operatively; in the post-implantation unit, they keep their eyes on patients to prevent complications and provide individualistic holistic nursing care. They have an important role in helping patients and their families with rehabilitation care and adaptation to the new life **(Sharma and Singh 2018).**

Significance of the study

Implantation of pacemakers saves many lives and allows patients improved health and a fully productive life. It implies physical, psychological, social, and spiritual issues, even though the pacing is a complete success **(Sharma and Singh 2018).** Each year 1.25 million permanent pacemakers are implanted worldwide **(Raatikainen and Arnar 2017)**. The documented medical records of the statistical data of the cardio electrophysiology unit at the Main University Hospital revealed that the number of patients who were admitted for pacemaker insertion was about 200 patients in **2018 (Teleb 2021).**

Care for such a rapidly increasing population of patients is a challenge for all health care providers working in cardiology wards, operating rooms, or primary care practices., Caring for patients with permanent pacemakers needs knowledge about the device and its risks and guidelines for homecare and long-term to follow up., Patients' knowledge and self-care practices are crucial and constructive in achieving appropriate post-pacemaker implantation outcomes. Thus there's a serious need for patients' intervention protocol to provide and improve basic patients knowledge and practice for the care of patients with permanent pacemakers and improve their health outcomes **(Mohammed et al 2020).**

The operational definition of health-related outcomes:

A change in the health status of an individual, group, or population as a result of a planned intervention or a series of interventions, in this study refers to the patient's health problems, self-care practice,and complications after implantation of a permanent pacemaker.

Aims of the study:

- The current study aimed to determine the Effect of the nursing protocol of care on health-related outcomes for patients undergoing permanent pacemaker implant.
- The current study aimed to determine the effect of a nursing protocol of care on decreasing complications following a permanent pacemaker implant

Subjects and Methods

Research hypothesis:

- patients undergoing permanent pacemaker implants who receive nursing protocol of care will exhibit better health outcomes than those who do not receive.
- patients undergoing permanent pacemaker implants who receive nursing protocol of care will exhibit fewer complications than those who do not receive.

Research Design: A quasi-experimental research design was utilized to conduct this study.

Setting: The study was conducted at the Cardio- Electrophysiology Unit at the new Main Alexandria University Hospital and follow-up on outpatients clinics Alexandria.

Subjects:

A purposive sample of 100 adult patients with permanent cardiac pacemaker implantation aged from 20 up to 60 years old, of both sexes (male & female), able to communicate verbally, not scheduled for other surgeries, and agree to participate in the current study were recruited in the study. They were randomly assigned into two equal study and control groups (50 patients in each group).

The **Epi- the info-7** program was used to estimate the minimum sample size using the following parameters, the population size of patients on permanent pacemakers over the year 2020 =200, expected frequency =50%, acceptable error = 10%, confidence coefficient= 95%, minimum simple size= 55 patients.

Tools:

Three tools were used for data collection:

Tool I: **Structured Interview Schedule**. It was developed by the researchers based on reviewing relevant scientific literature **(Al-Ahmad, et al 2018 ; Sharma et al 2018; Carrion-Camacho et al 2019, and Timperley et al 2019)**.

It comprised of two parts:

Part 1: Patients' socio-demographic data; it included patients' age, sex, residence area, marital status, level of education, and occupation.

Part 2: Patients' history and clinical data; it included patients' diagnosis, diagnostic tests such as, ECG and echocardiogram, medication history, date of pacemaker implantation and previous family history of cardiac diseases such as complete heart block and heart failure.

Tool II: Patients' Knowledge assessment questionnaire regarding pacemaker implant. The researchers developed it after reviewing the related literature **(Johansen et al 2014; Ebada et al 2017 and Bayomi 2020)**. It is used to assess patients' knowledge regarding post-operative care of pacemaker implants. It consisted of 50 close-ended questions covering 4 main areas: **1.** Anatomy and physiology of the heart such as heart layers, chamber, valve, blood vessel, etc. **2.** heart disease as causes, risk factors, types, signs and symptoms, diagnosis, in addition to pacemaker implant indications, most common techniques, and complications. **3**. Postoperative care after pacemaker implants such as proper position after surgery and wound care. **4.** Patient and family pre-discharge instructions regarding the administration of medication, wound care, monitoring pulse rate, precautions to prevent infection, food regimen to reduce straining and constipation, exercise and avoiding heavy lifting, unusual symptoms, follow–up and finally postoperative complications.

The Scoring system of patients' knowledge was done as follows, each correct and complete answer received two scores, correct and incomplete received one score while no answer and do not know had zero scores. The total score ranged from 0 to 100. Total knowledge score is categorized as follows:

Poor knowledge < 50%, Average knowledge 50 <75 %, and good knowledge 75% and more.

Tool III: Patients' Health Outcomes Sheet: The researchers developed it after reviewing the related literature **(Johansen 2014; Ebada et al 2017 and Bayomi 2020)** to assess patients' health problems and self-care practice after permanent pacemaker implant. This sheet consisted of two parts include:

Part 1: Post permanent pacemaker implant complications: It was developed by researchers after reviewing the related literature **(Pakarinen et, al. 2010, Van Rees et, al. and 2011Greenspon et, al.2012)** and used to assess the presence or absence of signs and symptoms of **post permanent pacemaker implant**. Complications such as complications related to Failure to output, Failure to capture, Pacemaker syndrome, operative failure, over sensing and under sense. The scoring system (one score) was given for the presence of postoperative complications and (zero) for the absence of postoperative complications.

Part 2: Patients' self-care practices

It was developed by the researcher based on relevant literature **(Ali et al 2015, Feroze et al 2017and Sharma et al 2018)** to evaluate patient postoperative self-care practice. It comprised (6) main items; **medication management** included administration of medication, following prescribed medication and precautions of the drug side effects, **postoperative care** involving change wound dressing, **diet modification** contained time for eating and drinking, following appropriate food regimen, provision of adequate nutrition, and meals from outside, activities of daily living: included assessing **daily activities for patients** with permanent pacemaker including shopping, dressing, toileting, bathing, mode of transportation, feeding, **self-care practices after pacemaker**; involved monitoring pulse rate daily, avoiding pressure over pacemaker site, keeping cell phone opposite side of a pacemaker, not performing exertional physical activities and finally **follow-up visits.**

Scoring system of patients' practice: The respondent was given two scores for each correct complete answer, one score for correct and incomplete answers, and zero scores for incorrect answers. For each area, the scores of the items were summed-up and the total was divided by the number of the items, giving a mean score for the part. These scores were converted into a percent score and categorized as the following:

60% or more indicated good self-care practices. Less than 60% indicated poor self-care practices.

Method:

•Approval of the Ethical Committee was obtained.

•An official letter from the Faculty of Nursing, Alexandria University was submitted to the head of the cardiology department and the head of the cardio electrophysiology unit at the new Main University Hospital.

•An official permission to carry out the study was obtained from the head of the cardiology department and cardio electrophysiology unit and the hospital directors at the selected settings, after an explanation of the aim of the study.

•Data were collected over a period of 6 months from the beginning of January 2022 to the end of June 2022.

•Patients meeting the inclusion criteria were selected using a random sampling technique and divided into two equal groups (control group and study group).

- Group one (control group): received routine hospital care as "wound dressing, medications administration, and assessment of vital signs and hygienic care". They didn't receive the health education nursing intervention by the researcher.

-Group two (study group): received the nursing protocol of care.

Tools Validity:

Tool I, and III was developed by the researchers and translated into the Arabic language, and tool II was adopted. Tools were submitted to five experts in the field of Cardiology, and Medical Surgical Nursing for content and construct validity, and the necessary modifications were introduced accordingly.

Reliability testing for the study tools:

Tool II and tool III were estimated using Cronbach's Alpha test and were equal (0.784 and 0.865 consequently) to measure their internal consistency to evaluate how well the tools consistently measure what they were designed to measure.

Pilot study:

was initially carried out prior to the actual data collection phase on six patients to check the clarity, feasibility, and applicability of the tools and determine obstacles that may be encountered during the period of data collection, accordingly, needed modifications were done. Pilot study subjects were excluded from the study.

Data collection: After securing the administrative approval, data were collected over a period of 6 months from the beginning of January 2022 to the end of June 2022.

The actual study was implemented through four phases; assessment phase, program development phase, implementation phase, and evaluation phase.

I-Assessment phase:

Every patient in both groups (study and control group) was interviewed individually before surgery, to assess their basic data, knowledge about permanent pacemaker implants, and their self-care practices using tools I, II, and tool III part 1.

II-Program development phase:

Based on the results of the interview assessment sheet and the review of related literature **Vardas et al 2013**, **Mohamed and Abd El-Lateef 2014, Adel Ebada et al 2017, and Ali et al., 2021)**, an illustrated colored health teaching booklet was developed in the Arabic language by the researcher to help the patient and his family. It consisted of two parts

Part I: consisted of theoretical knowledge related to; the anatomy and physiology of the heart as heart layers, chamber, valve, blood vessel, heart disease as causes, risk factors, types, signs and symptoms, diagnosis, in addition to pacemaker implant indications, most common techniques, and complications. Postoperative care after pacemaker implants such as proper position after surgery and wound care. Patient and family pre-discharge instructions regarding the administration of medication, wound care, monitoring pulse rate, precautions to prevent infection, food regimen to reduce straining and constipation, exercise and avoiding heavy lifting, unusual symptoms, follow–up and finally postoperative complications.

Part II: consisted of practical knowledge related to pre-discharge instruction and self-care practice including monitoring pulse rate daily, avoiding pressure over the pacemaker site, , and not performing exertional physical activities. Also, activities of daily living and follow–up care and warning signs that required medical care.

•After the development of the booklet, it was submitted to 5 experts in the field to assure its content validity, clarity, and completeness in rewarding some words and changing instruction under picture from English to Arabic based on the committee.

III - Program implementation phase:

• Patients in the control group (II) received routine Hospital care, while patients in the study group (I) were managed as follows:

• The individualized teaching session was carried out for each patient and his/her caregiver before the operation in the cardiology department and in the conference room.

• Various teaching methods were used in the form of lectures, discussions, brainstorming, demonstration, and re-demonstration. Various educational media have been used, such as PowerPoint, shapes, flip charts, pens, papers, and comic videos.

• The program consisted of theoretical and practical sessions. The program included the following items:

A. Patients' education sessions:

Two sessions, education for every patient was carried out to provide new knowledge and practice. The duration of each session lasted approximately from 30 minutes to one hour depending on the patient; ability and needs.

An illustrated booklet in the Arabic language was used as a teaching and learning aid during each session. The patients kept the booklet for remembering the instruction and being a motivator for following it.

The first session: It was included theoretical information about knowledge related to postoperative care, such as proper position after surgery and Pre-discharge instruction.

The second session: It was included information about pre-discharge instruction and self-care practices including monitoring pulse rate daily, avoiding pressure over the pacemaker site, keeping cell phone opposite side of a pacemaker, and not performing exertional physical activities. Also, activities of daily living and follow–up care and warning signs that required medical care.

Reinforcement of instructions was carried out on the first day postoperatively follow-up in the outpatient clinic.

IV-Evaluation phase:

Evaluation of the program was done two times after one week and after three months postoperatively in the outpatient clinic using tool, II to assess patient knowledge postoperative and tool III to assess patient's problems and self-care practice after the operation.

Also, in this visit patient is checked by the physician to assess the presence or absence of postoperative complications and notify the researcher of the result. The above-mentioned activities were done on the first day, the first week, and the first three months postoperatively.

Ethical considerations:

Ethical permission was accessed from the institutional review board of the Faculty of Nursing, Damanhour University. Before starting data collection and application of the intervention, informed written consent for voluntary participation in the study was obtained from each patient after explaining the aim of the study. For illiterate patients, verbal explanations of the study's purpose and patients' oral consent were secured. The subject's privacy and anonymity were assured.

All patients were informed that they could withdraw from the study at any time if they wish not to continue.Data confidentiality was considered and respected

Statistical Analysis:

- The collected data were organized, coded, tabulated, and statistically analyzed using SPSS version 23 (Statistical Package for Social Studies) created by(SPSS Inc., Chicago, USA). For numerical values, the range mean and standard deviations were calculated.
- Quantitative continuous data were compared using the parametric Student t-test& Repeated measure ANOVA test
- Qualitative categorical variables were compared using chi-square or Fisher exact tests as appropriate.
- Graphics were done by using the Excel program.
- Statistical significance was considered at a p-value <0.05.Results:

Table (1): Distribution of both groups according to their socio-demographic & clinical data.

This table shows that the highest percentage of both the study group and control group were between the ages of 41-60 years old 80.0% and 70.0% respectively. Males were more prevalent in the study and the control group 76.0% and 60.0% respectively. 56.0% of the study group and 66.0% of the control group were married. The secondary education level was 38.0% in the study group and 44.0% of the control group were read and write.76.7% of the study group and 66.7% of the control group were workers. Also, 60.0% of the study group and 78.0% of the control group came from urban areas. 90.0% - 92.0% of patients in both the study group and control groups had no previous heart surgery respectively. Furthermore, 42.0% - 48.0% of the study group and 36.0% - 40.0% of the control group had Chronic disease and were smoking as a risk factor for heart disease. There were no statistically significant differences in socio-demographic characteristics & clinical data between the two groups.

Table (2): Mean difference and partial Eta Squared of patients' knowledge in the study group and control group regarding pace maker implant care throughout the program intervention

This table displays that the mean difference for total and all items of knowledge of the study group were significantly increased immediately post program implementation and where p values were found to be (<0.001*). **Also, it can be noticed** that there was a highly significant difference (p<0.001) continued post three months of the program implementation with the effect size 98.9%. Moreover, the scores for total and all items of knowledge of the control group were slightly increased immediately after routine nursing care but the differences were not statistically significant.

Table (3): Mean self-care practice scores of both groups regarding pacemaker implant throughout the program phases

This table shows that there was a highly statistically significant difference between the study group and the control group immediate post and post-three months from program implementation in relation to overall self-care practice scores with a mean of 115.88 ± 6.81 which includes medication management, Postoperative pacemaker implant care, Precautions followed postoperatively, diet modification, ADL and follow-up. Overall total scores of self-care practice were improved significantly in the study group immediately post and post three months from program implementation in compared with the control group indicating a significant difference between the two groups after implementing a teaching program P>0.001.

Table (4): Comparison between the study group and control group in relation to the presence of post-operative pacemaker implant complications.

This table shows that the minority of both the control group and study group had problems with postoperative pacemaker implants. Low percentages of studied patients were complaining of Failure of the pacemaker to capture immediate post and 0.0% post 3 months in the study group while in the control group immediate post was 10.0% and post 3 months was 6.0%. Also, 10.0% of the study group had pacemaker syndrome immediately post and 0.0% after 3 months. While in the control group 12.0% had pacemaker syndrome immediately post and 34.0% after 3 months. Moreover, the study group had an operative failure of 2.0% immediately post and 0.0% after 3 months. In control group had 4.0% - 6.0% operative failure immediate and post 3 months respectively. There was a statistically significant difference between the two groups in relation to time immediate post and post 3 months from implementation program in presence of Pacemaker syndrome complication.

Table (5): Correlation between knowledge and self-care practices regarding pacemaker implant throughout the program phases.

This table illustrated that there is a statistically significant relation of 0.005 between the knowledge and self-care practices of the study groups in post-operation. While in the control group, there was a statistically

significant relation in pre, post, and follow-up assessments <0.001*, 0.025*, and 0.029* respectively. Also, there was no relation between knowledge and complication in the study group, while in the control group there was a negative correlation between knowledge and complication in post-operation 0.011*. As regards self, care practices, and complications there was a statistical correlation of 0.004* in post-operation while in the control group there was a negative correlation of <0.001*, 0.014* in the post and follow-up care.

Table (6): Relation between Overall Knowledge with Socio-demographic characteristics &Clinical data

This table shows that there was a statistically significant relation in pre-program in relation to marital status and level of education <0.001* in the control group, while in the study group there was a statistically significant relation in pre-program in relation to marital status, educational level, area of residence and previous surgery 0.033*, <0.001*, 0.003*, 0.030* respectively. As regards immediate post there was a statistically significant relationship between the control group and the study group found in patients' age, marital status, educational level, and risk factors 0.046*, *<0.5, *<0.001, and 0.04*. 0.006*, <0.001*, *<0.001*, 0.018* respectively. In post 3 months, there was a statistically significant relation of the control in age, sex, education, and area of residence 0.039*, 0.004, 0.003, 0.001, and 0.003. While in the study groups, sex, education, and previous surgery were 0.009, 0.003, and 0.005.

Table (7): Relation between Overall practice with Socio-demographic characteristics &Clinical data

This table clarified that there is a statistically significant relationship between the control and the study group. As regards pre-program, it was found that there was a statistical relationship between education and risk factors 0.02 and 0.08. While in the study group found marital status, education, area of residence, previous surgery, and risk factors 0.01, 0.01, 0.02, 0.012, and 0.019. Concerning immediate post in the control group in marital status, education, and risk factors 0.04, 0.01, 0.042 while in the study group found in sex, education and risk factors 0.032, .01 and 0.016. As regards, post 3 months found significant relation in the control group in marital status, education, and risk factors 0.01, 0.03, and 0.01. While in the study group in education and risk factors were 0.01 and 0.07.

Table (1): Frequency distribution of the study group and control group according to their Sociodemographic characteristics &Clinical data.

Sociodemographic characteristics&Clinical data		(N=100) Study Group No=50	%	Control Group No=50	%	Test of sig. (P-value)
Age	21-40	10	20.0	15	30.0	χ^2=1.333
	41-60	40	80.0	35	70.0	p=0.248
Mean±SD		48.30 ± 7.28		44.42 ± 5.38		t=3.031*
Min–Max		365.0 – 60.0		35.0 – 57.0		p=0.003*
Sex	Male	38	76.0	30	60.0	χ^2=2.941
	Female	12	24.0	20	40.0	p=0.086
Marital status	Single	3	6.0	2	4.0	
	Married	28	56.0	33	66.0	χ^2=1.348
	Divorced	15	30.0	11	22.0	^{MC}p= 0.762
	Widow	4	8.0	4	8.0	
Educational level	Illiterate	8	16.0	4	8.0	
	Read and Write	10	20.0	22	44.0	χ^2=7.125
	Secondary	19	38.0	13	26.0	p=0.068
	Higher Education	13	26.0	11	22.0	
Occupation	Worker	38	76.0	30	60.0	χ^2=2.941
	Not worker	12	24.0	20	40.0	p=0.086
Area of residence	Urban	30	60.0	39	78.0	χ^2=
	Rural	20	40.0	11	22.0	p=
Previous surgery	Yes	4	8.0	5	10.0	χ^2=0.122
	No	46	92.0	45	90.0	^{FE}p=1.000
Risk factors	Chronic disease	21	42.0	18	36.0	
	Smoking	24	48.0	20	40.0	χ^2=3.477
	Family history	5	10.0	12	24.0	p=0.176

χ2: Chi-square test *: Statistically significant at P ≤ 0.05

Table (2): Mean difference and partial Eta Squared of patients' knowledge in the study group and control group regarding pace maker implant care throughout the program intervention

Patients knowledge (I)Factor 1	Factor (J)1		(N=100) Study group No= (50) M-D(I-J)	Sig	p	Partial Eta Squared	Control group No= (50) MD(I-J)	Sig	P	Partial Eta Squared
Heart anatomy	**Pre**	**2**	6.080	<0.001*	F=411.946* (p<0.001*)	0.894	1.620	<0.001*	F=14.962* (p<0.001*)	0.234
		3	3.720	<0.001*			0.360	0.380		
	Immediate post	**3**	2.360	<0.001*			1.260	<0.001*		
Heart disease	**Pre**	**2**	7.360	<0.001*	F=550.465* (p<0.001*)	0.918	0.680	0.094	F=4.023* (p=0.021*)	0.076
		3	4.860	<0.001*			0.020	1.000		
	Immediate post	**3**	2.500	<0.001*			0.660	0.015*		
Postoperative care after pacemaker implant	**Pre**	**2**	33.420	<0.001*	F=1998.912* (p<0.001*)	0.976	2.920	<0.001*	F=12.142* (p<0.001*)	0.199
		3	26.500	<0.001*			1.600	0.029*		
	Immediate post	**3**	6.920	<0.001*			1.320	0.086		
Pre discharge instruction	**Pre**	**2**	20.080	<0.001*	F=1241.634* (p<0.001*)	0.962	0.600	0.402	F=1.902 (p=0.155)	0.037
		3	17.440	<0.001*			0.860	0.228		
	Immediate post	**3**	2.640	<0.001*			0.260	1.000		
Overall Knowledge	**Pre**	**2**	3.200	<0.001*	F=4391.086* (p<0.001*)	0.989	8.700	<0.001*	F=48.659* (p<0.001*)	0.498
		3	3.540	<0.001*			5.720	<0.001*		
	Immediate post	**3**	0.340	0.857			2.980	0.004*		

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using **Post Hoc Test (adjusted Bonferroni)**

P: P-value for comparing between before operation and each other period for every item in each group.

*: Statistically significant at $P \leq 0.05$

M/D : Mean Difference (i-j) between each other period for every items each group

Partial Eta Squared measuring the effect size of the program

Table (3): Overall mean score of the study group and control group, according to the patient's self-care practice related to pacemaker implant care throughout the program intervention

Patients self- care practice	N= (100) Study(N =50)			control(N =50)			P1		P2		P3	
	Pre	Immediate post	Post 3months	Pre	Immediate post	Post 3months	M/ D	P1	M/ D	P2	M/ D	P3
Medication management Mean ±SD	10.48 ± 4.45	17.40 3.18	±22.94 2.16	±11.72 18	±3. 8.52 4.11	± 8.18 ± 2.88	1.24	t=1.603 (p=0.113)	8.88	t=12.087* (p<0.001*)	14.71 6	t=29.01* (p<0.001*
Postoperative pacemaker implant care Mean ±SD	7.88 3.57	±13.64 2.04	±17.94 2.21	±7.36 2.82	±7.10 2.63	± 4.50 ± 2.75	0.52	t= 0.808 (p=0.421)	6.54	t=13.904* (p<0.001*	13.40 4	t=26.95* (p<0.001*
Precautions followed postoperatively Mean ±SD	0.0 0.0	±13.14 2.08	±18.06 1.41	± 0.0 ± 0.0	8.94 3.14	± 5.92 ± 3.44	–	–	4.20	t=7.887* (p<0.004*	12.13	t=23.10* (p <0.001*
Diet modification Mean ±SD	0.0 0.0	±20.86 2.19	±30.68 2.35	± 0.0 ± 0.0	10.80 3.48	± 9.62 ± 4.04	–	–	10.06	t=17.325* (p<0.006*	21.08 6	t=31.85* (p <0.001*
ADL Mean ±SD	0.0 0.0	±11.76 1.30	±16.34 0.85	± 0.0 ± 0.0	5.18 2.43	± 4.08 ± 2.34	–	–	6.58	t=16.875* (p<0.006*	12.28 6	t=34.86* (p <0.001*
Follow-up Mean ±SD	0.0 0.0	± 8.40 ± 1.34	9.92 0.27	± 0.0 ± 0.0	2.30 1.39	± 1.44 ± 3.10	–	–	6.10	t=22.350* (p<0.001*	8.48	t=19.239* (p <0.001*
Overall-Practice Mean ±SD	18.36 ± 7.06	85.20 6.96	±115.88 6.81	±19.08 4.03	±42.84 12.0	±33.74 12.72	± 0.72	t= 0.627 (p=0.533)	42.36	t=21.604* (p<0.001*	82.13 4	t=40.24* (p<0.001*

t:Student t-test

P1: P value for comparing between the two groups in Pre

P2: P value for comparing between the two groups in Immediate post

P3: P value for comparing between the two groups in post 3months

*: Statistically significant at P ≤ 0.05

M/D : mean difference

Table (4): Comparison between the study and control groups in relation to presence of post pacemaker implant complications or problems.

Post pacemaker implant complications or problems.		(N=100) control (No=50)				study (No=50)				significance test	
		Immediate post		Post 3months		Immediate post		Post 3months		P1	P2
		No	%	No	%	No	%	No	%		
Failure to output	Absent	50	100.0	50	100.0	50	100.0	50	100.0	–	–
Failure to capture	Absent	45	90.0	47	94.0	48	96.0	50	100.0	χ^2=1.382	χ^2=3.093
	Present	5	10.0	3	6.0	2	4.0	0	0.0	^{FE}p=0.436	^{FE}p=0.242
Pacemaker syndrome	Absent	44	88.0	33	66.0	45	90.0	50	100.0	χ^2=0.102	χ^2=20.482*
	Present	6	12.0	17	34.0	5	10.0	0	0.0	p=0.749	<0.001*
Operative failures	Absent	47	94.0	48	96.0	49	98.0	50	100.0	χ^2=1.042	χ^2=2.041
	Present	3	6.0	2	4.0	1	2.0	0	0.0	^{FE}p=0.617	^{FE}p=0.495
Over sensing	Absent	50	100.0	50	100.0	50	100.0	50	100.0	–	–
Under sensing	Absent	50	100.0	50	100.0	50	100.0	50	100.0	–	–

χ2: Chi-square test FE**: Fisher Exact**
*: Statistically significant at P ≤ 0.05

Table (5): Correlation between knowledge and self-care practices regarding pacemaker implant throughout the program phases.

	(N=100) Study group (No=50)						Control group (No=50)					
	Pre		Post		Follow up		Pre		Post		Follow up	
	r	P	r	P	R	p	r	p	R	p	r	P
Knowledge vs. Self-care practice	0.147	0.307	0.391*	0.005*	-0.044	0.762	-0.503*	<0.001*	0.317*	0.025*	0.308*	0.029*
Knowledge vs. Complication			0.053	0.713	-0.064	0.658			-0.356*	0.011*	0.145	0.315
Self-care practice vs. Complication			0.397*	0.004*	0.068	0.641			-0.530*	<0.001*	-0.346*	0.014*

r: Pearson coefficient
*: Statistically significant at p ≤ 0.05

Table (6): Relation between Overall Knowledge with Socio demographic characteristics &Clinical data

Socio demographic characteristics & Clinical data	Overall Knowledge					
	Control(N =50)			Study (N =50)		
	Pre	Immediate post	Post 3months	Pre	Immediate post	Post 3months
	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.
Age						
21-40	16.93 ± 3.92	23.87 ± 4.88	20.67 ± 4.95	16.20 ± 2.90	91.80 ± 2.49	76.0 ± 2.75
41-60	18.09 ± 5.09	27.54 ± 7.46	24.66 ± 8.12	19.18 ± 4.71	88.60 ± 4.69	74.53 ± 3.94
t (p)	**0.782 (0.438)**	**2.062* (0.046*)**	**2.127* (0.039*)**	**1.902 (0.063)**	**2.960* (0.006*)**	**1.115 (0.270)**
Sex						
Male	17.80 ± 5.50	27.83 ± 7.54	25.90 ± 7.42	19.42 ± 3.80	89.32 ± 4.81	75.58 ± 3.35
Female	17.65 ± 3.50	24.35 ± 5.49	19.80 ± 6.11	15.92 ± 5.76	89.0 ± 3.57	72.42 ± 4.08
t (p)	**0.118 (0.907)**	**1.888 (0.065)**	**3.049* (0.004*)**	**1.976 (0.068)**	**0.244 (0.809)**	**2.705* (0.009*)**
Marital status						
Single	13.50 ± 0.71	26.0 ± 8.49	14.50 ± 0.71	16.33 ± 4.51	92.33 ± 1.15	76.67 ± 2.08
Married	18.15 ± 4.62	24.70 ± 4.97	22.79 ± 7.11	17.79 ± 4.52	91.11 ± 4.48	75.54 ± 4.39
Divorced	20.18 ± 0.60	34.91 ± 4.91	29.36 ± 5.90	21.27 ± 1.91	85.73 ± 2.76	73.93 ± 2.43
Widow	9.75 ± 4.50	17.75 ± 4.99	17.25 ± 4.92	15.75 ± 8.06	87.0 ± 2.16	71.75 ± 0.96
F (p)	**7.439* (<0.001*)**	**15.530*(<0.s*)**	**5.362* (0.003*)**	**3.171* (0.033*)**	**7.614 * (<0.001*)**	**1.846 (0.152)**
Educational level						
Illiterate	19.75 ± 9.0	19.75 ± 3.30	17.75 ± 6.95	17.50 ± 4.47	86.63 ± 4.24	72.38 ± 5.53
Read and Write	19.64 ± 3.17	31.73 ± 5.52	29.41 ± 5.34	15.30 ± 5.83	90.10 ± 4.01	72.70 ± 4.55
Secondary	13.23 ± 4.69	20.77 ± 6.06	16.15 ± 5.0	18.42 ± 3.31	92.95 ± 2.53	76.95 ± 1.03
Higher Education	18.55 ± 1.57	25.0 ± 1.41	22.27 ± 3.0	22.0 ± 2.86	84.77 ± 1.54	74.85 ± 2.76
F (p)	**7.570*(<0.001*)**	**16.706*(<0.001*)**	**21.885*(<0.001*)**	**5.578* (0.002*)**	**21.594*(<0.001*)**	**5.368* (0.003*)**
Occupation						
Worker	17.55 ± 4.89	26.15 ± 6.43	22.60 ± 7.04	17.71 ± 4.34	88.36 ± 4.24	73.79 ± 4.76
Not worker	17.87 ± 4.75	26.63 ± 7.38	24.03 ± 7.85	18.92 ± 4.63	89.58 ± 4.63	75.22 ± 3.27
t (p)	**0.228 (0.820)**	**0.239 (0.813)**	**0.659 (0.513)**	**0.838 (0.406)**	**0.861 (0.394)**	**1.222 (0.228)**
Area of residence						
Urban	18.10 ± 4.75	26.82 ± 7.54	25.10 ± 7.17	17.33 ± 4.0	90.63 ± 4.79	74.60 ± 4.31
Rural	16.45 ± 4.78	25.09 ± 4.25	17.64 ± 5.66	20.45 ± 4.75	87.15 ± 3.13	75.15 ± 2.78
t (p)	**1.015 (0.315)**	**0.982 (0.334)**	**3.177* (0.003*)**	**2.502* (0.016*)**	**2.865* (0.006*)**	**0.504 (0.617)**
Previous surgery						
Yes	19.0 ± 9.70	23.60 ± 3.05	17.60 ± 6.35	23.25 ± 3.86	91.0 ± 2.94	79.75 ± 2.99
No	17.60 ± 4.06	26.76 ± 7.21	24.11 ± 7.39	18.17 ± 4.40	89.09 ± 4.61	74.39 ± 3.52
t (p)	**0.320 (0.765)**	**0.962 (0.341)**	**1.891 (0.065)**	**2.230* (0.030*)**	**0.811 (0.422)**	**2.948* (0.005*)**
Risk factors						
Chronic disease	19.24 ± 4.68	29.71 ± 7.80	25.57 ± 7.31	18.78 ± 4.78	87.89 ± 4.25	74.22 ± 5.17
Smoking	17.13 ± 4.33	24.92 ± 4.88	22.83 ± 7.68	19.05 ± 4.82	88.60 ± 4.92	74.40 ± 3.0
Family history	14.40 ± 5.68	20.0 ± 5.34	17.60 ± 3.58	17.50 ± 3.83	92.33 ± 2.57	76.42 ± 1.44
F (p)	**2.638 (0.082)**	**6.102* (0.04*)**	**2.606 (0.084)**	**0.453 (0.638)**	**4.354* (0.018*)**	**1.469 (0.241)**

t: Student t-test **F: F for One way ANOVA test** *: Statistically significant at $p \leq 0.05$

Table (7): Relation between Overall practice with Socio demographic characteristics &Clinical data

Socio demographic characteristics & Clinical data	Overall practice					
	Control(N =50)			Study (N =50)		
	Pre	Immediate post	Post 3months	Pre	Immediate post	Post 3months
	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.	Mean ± SD.
Age						
21-40	20.0 ± 2.07	42.67 ± 11.03	32.87 ± 9.36	21.80 ± 6.43	84.60 ± 6.35	119.60 ± 2.07
41-60	18.69 ± 4.59	42.91 ± 12.54	34.11 ± 14.02	17.50 ± 7.02	85.35 ± 7.16	114.95 ± 7.27
t (p)	**1.394 (0.170)**	**0.066 (0.947)**	**0.368 (0.715)**	**1.760 (0.085)**	**0.302 (0.764)**	**1.987 (0.053)**
Sex						
Male	18.53 ± 4.11	42.77 ± 12.32	33.60 ± 14.26	19.42 ± 6.88	84.03 ± 7.0	115.39 ± 7.39
Female	19.90 ± 3.86	42.95 ± 11.81	33.95 ± 10.33	15.0 ± 6.80	88.92 ± 5.52	117.42 ± 4.42
t (p)	**1.180 (0.244)**	**0.052 (0.958)**	**0.101 (0.920)**	**1.945 (0.058)**	**2.208* (0.032*)**	**0.894 (0.376)**
Marital status						
Single	19.0 ± 4.24	34.0 ± 1.41	23.50 ± 4.95	21.67 ± 4.04	85.67 ± 1.15	117.33 ± 3.51
Married	19.30 ± 4.50	41.48 ± 11.06	30.45 ± 10.09	21.68 ± 5.46	83.79 ± 8.43	115.54 ± 8.63
Divorced	17.64 ± 2.46	52.55 ± 9.51	48.73 ± 9.32	11.33 ± 4.37	85.60 ± 2.50	116.47 ± 2.85
Widow	21.25 ± 2.87	31.75 ± 12.71	24.75 ± 11.87	19.0 ± 9.13	93.25 ± 3.59	115.0 ± 6.06
F (p)	**0.885 (0.456)**	**5.041* (0.04*)**	**11.270*(<0.01*)**	**12.250*(<0.01*)**	**2.383 (0.082)**	**0.122 (0.947)**
Educational level						
Illiterate	19.75 ± 2.63	41.25 ± 5.74	30.75 ± 8.06	13.75 ± 6.14	90.75 ± 4.46	106.0 ± 11.46
Read and Write	16.73 ± 3.78	42.64 ± 10.24	35.59 ± 14.24	20.90 ± 6.23	89.50 ± 6.82	119.70 ± 3.59
Secondary	21.08 ± 3.99	34.23 ± 12.43	24.38 ± 8.06	24.0 ± 3.09	80.05 ± 6.93	118.74 ± 1.97
Higher Education	21.18 ± 2.44	54.0 ± 7.43	42.18 ± 8.15	11.0 ± 3.06	86.0 ± 0.0	114.85 ± 2.48
F (p)	**6.08* (0.02*)**	**7.636* (<0.01*)**	**5.284* (0.03*)**	**26.396*(<0.01*)**	**10.162*(<0.01*)**	**14.246* (<0.01***
Occupation						
Worker	20.0 ± 3.89	42.55 ± 11.55	33.65 ± 12.21	18.14 ± 6.71	88.14 ± 6.32	114.0 ± 9.43
Not worker	18.47 ± 4.07	43.03 ± 12.48	33.80 ± 13.26	18.44 ± 7.28	84.06 ± 6.92	116.61 ± 5.48
t (p)	**1.328 (0.190)**	**0.138 (0.891)**	**0.040 (0.968)**	**0.134 (0.894)**	**1.918 (0.061)**	**0.974 (0.344)**
Area of residence						
Urban	18.62 ± 3.57	42.38 ± 10.78	33.56 ± 12.71	20.80 ± 6.51	84.60 ± 8.60	116.50 ± 7.93
Rural	20.73 ± 5.24	44.45 ± 16.11	34.36 ± 13.38	14.70 ± 6.34	86.10 ± 3.18	114.95 ± 4.72
t (p)	**1.557 (0.126)**	**0.401 (0.695)**	**0.182 (0.856)**	**3.279* (0.02*)**	**0.870 (0.390)**	**0.785 (0.436)**
Previous surgery						
Yes	16.80 ± 4.32	36.40 ± 8.96	28.40 ± 8.02	25.0 ± 3.37	85.50 ± 5.32	117.0 ± 7.07
No	19.33 ± 3.97	43.56 ± 12.16	34.33 ± 13.07	17.78 ± 7.01	85.17 ± 7.12	115.78 ± 6.86
t (p)	**1.345 (0.185)**	**1.273 (0.209)**	**0.989 (0.328)**	**3.653* (0.012*)**	**0.089 (0.929)**	**0.340 (0.736)**
Risk factors						
Chronic disease	18.81 ± 3.88	47.57 ± 11.10	42.0 ± 12.24	15.61 ± 6.33	88.50 ± 5.0	112.0 ± 9.66
Smoking	18.25 ± 3.58	38.67 ± 10.50	27.79 ± 9.35	18.15 ± 7.74	84.55 ± 8.21	117.70 ± 2.96
Family history	24.20 ± 3.56	43.0 ± 17.04	27.60 ± 10.64	22.83 ± 4.71	81.33 ± 5.02	118.67 ± 2.90
F (p)	**5.421* (0.08*)**	**3.386* (0.042*)**	**10.631*(<0.01***	**4.296* (0.019*)**	**4.551* (0.016*)**	**5.483* (0.07*)**

t: Student t-test **F: F for One way ANOVA test** *: Statistically significant at p ≤ 0.05

Discussion:

Pacemakers electrically stimulate the myocardium layer of the heart to depolarize or/and initiate a contraction, when the heart's Sinoatrial node does not work adequately. (1) Pacemakers are of two types i.e. temporary and permanent and are implanted according to the type of conduction system abnormality **(Beny 2016).** Caring of these patients requires knowledge about the device and its complications and the related factors and also the patient's hemodynamic condition, nurses' information and knowledge can be crucial and constructive in patients' training and hence the reduction of complications during the life with a device **(Lane et al 2015).** Providing nursing care and proper nursing processes for these patients can prevent complications and defects in the device's performance **(Nasr et al 2015).**

This study illustrated that the highest percentage of both the study and control groups were between the ages of 40-60 years old. This study is in line with **Ali et al (2021),** who stated that more than half of the patients were aged from 50 years to less than 60 years. This study is not in line with **Mohamed& HadiAtiyah (2016)** who clarified that the majority of the age group was (23-27) years old. Also, this study is not in line with **Mohamed et al (2020)** who found that the study groups were within the age group 18-25 years.

This study revealed that males were more prevalent in the study and the control group, this study is in line with **Mohamed& HadiAtiyah (2016)** who added that most of the study sample 60% were male. Also, this study is in line with Ali et al (2021), who found that more than half of the patients in the study and control groups were male. This result is not in line with **Mohamed & Abd El-Lateef (2014)** who demonstrated that the majority of both study and control group patients were females 63.3%.

This research concluded that the study group had high statistically significant differences in mean scores found between pre, immediate post & post three months from program implementation in relation to heart anatomy, heart disease, Postoperative care after pacemaker implant, and Predischarge instruction among the study group as compared to the control group P <0.001*., This is in line with **Mohamed & Abd El-Lateef (2014)** who illustrated that all subjects of the study and control group were having an unsatisfactory knowledge level before protocol application, this percentage decreased after one and two months of protocol application. A high significant statistical difference was found between the three visits. Also, this result is in line with **Ebada et al (2017)** who concluded that there was no statistically significant difference between the number of patients who have a satisfactory level of knowledge pre-implementation of self-care guidelines about pacemaker implantation operation, following pacemaker work, medications, physical activities allowed, proper nutrition, wound care and stress management on both groups. Concerning the level of knowledge about these items posts the implementation of self-care guidelines, there was a highly statistically significant difference between the study and control groups regarding all items p<0.001.

This study found that overall total scores of self-care practice were improved significantly in the study group immediately post and post three months from program implementation as compared with the control group indicating a significant difference between the two groups after implementing a teaching program (P>0.001). This result is in line with **Ebada et al (2017)** who demonstrated that the satisfactory level of self-care practices regarding breathing exercise, pulse measurement, physical exercises, and relaxation techniques showed no statistically significant differences between both groups pre self- care guidelines implementation. While there was a highly significant difference between the study and control groups regarding self-care practices post implementation of the self-care guidelines p <0.001.

The present research revealed that the mean difference for each domain of the patient's self-care practice, including medication management, postoperative pacemaker implant care, precautions followed postoperatively, diet modification, ADL and

follow-up were improved significantly in the study group immediately post and post three months from program implementation compared with the control group indicating a significant difference between the two groups post-implementation program P>0.001., This is in line with **Ebada et al (2017)** who revealed that there were highly statistically significant differences between a number of patients in the study group regarding their total practice and total Nursing Sensitive patient Outcomes post implementation of self-care guidelines P<0.001.

This study found that the minority of both (control and study groups) had problems with postoperative pacemaker implants. This is in line with **Jing et al (2020)** who reported that the incidence of postoperative complications in patients with permanent pacemaker implantation was low, and the complications were mainly related to the capsular bag. Factors, such as older age, high BMI, smoking history, poor nutritional status, and decreased platelet counts, were independent risk factors resulting in postoperative complications in patients with Permanent Pacemaker Implantation.

This study revealed that there was a statistically significant relationship between the knowledge and self-care practices of the study group in post-operation. This is confirmed by **Yossif & Abd El-aal (2017)** who reported that there was a positive highly statistically significant correlation between the studied sample's total knowledge score and their total practices score. Also, this finding is supported by **Shahrbabaki, et al. (2016)** who reported that the improvement level of the study group in practice scores post implementation of the educational program as compared to the control group with highly statistically significant differences between the two groups during the post assessment.

Concerning the relation between total knowledge with socio-demographic characteristics & clinical data, the current research revealed that there was a statistically significant relationship among the study group in pre-program with marital status, educational level, area of residence, and previous surgery. As regards immediate post program, there was a statistically significant relationship between the control group and the patient's age, marital status, educational level, and risk factors. These interpretations are supported by **Rayamajhi, et al. (2021),** who reported that there was a significant association between level of knowledge with age, sex, ethnicity, education status, and regular exercise after permanent pacemaker implantation (PPI).

Regarding the relation between the overall practice with socio-demographic characteristics & clinical data, the current research illustrated a statistically significant relationship among the study group in pre-, post, and post-3 months program with the patients' educational level and risk factors. While regarding the Preprogram there was a statistically significant relationship between the study group with patient marital status and area of residence. This result war in agreement with **Rayamajhi, et al. (2021)** who sated that, Patient practice was significantly related to gender (p = < .001), education level (p = < .001) and regular exercise (p = < .001) after implantation of a permanent PPI stimulator.

Conclusion:

Based on the findings of the results of this study, it can be concluded that knowledge, medication management, postoperative pacemaker implant care, precautions followed postoperatively, diet modification, ADL and follow-up were improved significantly in the study group immediately post and post-three months from the nursing protocol of care as well as there was a minimal post-operative problem among the study group.

Recommendations:

Based on the findings of the present study, the following recommendations should be considered:

- Developed booklet should be available to all patients undergoing permanent pacemakers.
- Conducting periodic training programs for nurses about the protocol of care for patients with a permanent pacemakers.

- Future studies are needed about artificial pacemaker issues to develop evidence-based nursing management guidelines from different health centers in Egypt.
- Replication of the study on a larger probability sample from different geographical distributions for generalization of the results.

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Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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