Effect of Patient Education on Anxiety and Depression in Patients with Intracardiac Device

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ABSTRACT

Aim: To learn about the effect of patient education on anxiety and depression in patients with intracardiac devices.

Background: Advances in the management of arrhythmias and heart failure have resulted in the increasing use of cardiac implantable electronic devices (CIEDs). Surprisingly even though these devices may save the recipient's life, these are life changing implying multiple challenges in the process of psychosocial adaptation. Studies suggest almost a quarter of patients experience anxiety and depression after pacemaker implantation which in turn negatively impacts their quality of life. Lack of information may result in self-imposed restrictions affecting ordinary daily life, further increasing psychosocial issues and turning into a vicious cycle. An intervention in the form of patient education is critical for improving self-care abilities, patient outcomes and reducing avoidable hospitalizations.

Methodology: In this experimental study, there were a total of 39 participants with intracardiac devices (post-operative patients who were hemodynamically stable and follow up patients to 1 to 2 months) aged between 18 to 80 years, the outcome measures used were Cardiac Anxiety Questionnaire and Cardiac Depression Scale.

Results: The difference between the pre- and post-values within the group was determined by the Wilcoxon-signed rank test. There was a statistically significant difference in both CAQ (Z value -4.801, p-value< 0.0005) and CDS scores (Z value -5.306, p-value< 0.0005). The sub-scales of CAQ showed significant differences with Fear (Z value -4.809, p-value< 0.0005), Avoidance (Z value -3.798, p-value< 0.0005) and HFA (Z value -3.640, p-value< 0.0005).

Conclusion: This study's findings concluded that patients with intracardiac devices had a significant decline in anxiety and depression post-patient education.

Keywords: CIEDs - Cardiac implantable electronic devices, PM - permanent pacemakers, ICD - implantable cardioverter defibrillators, AICD - Automatic implantable cardioverter defibrillator, CRT - Cardiac Re-synchronization Therapy, CVDs - cardiovascular diseases

INTRODUCTION

The cardiovascular system is made up of the heart and its associated blood vessels. Endocarditis, rheumatic heart disease, and conduction system anomalies are just a few of the disorders that can emerge in the cardiovascular system.[1] Cardiovascular disease, commonly known as heart disease,
encompasses four distinct conditions: coronary artery disease (CAD), also known as coronary heart disease (CHD), cerebrovascular disease (CVD), peripheral artery disease (PAD), and aortic atherosclerosis.[1] According to the World Health Organization, India accounts for one-fifth of cardiovascular deaths worldwide, particularly among the young. The Global Burden of Disease report’s findings show that India has a death rate from CVDs that is age-standardized at 272 per 100,000 people, far higher than the average death rate for the world, which is 235. It also indicated that more than a quarter (24.8%) of all deaths in India are related to CVDs.[2]

An increase in the use of cardiac implantable electronic devices (CIEDs) has been caused by advancements in the treatment of arrhythmias and heart failure, as well as limitations in conservative management and pharmacotherapy. These devices include implantable cardioverter defibrillators (ICDs), permanent pacemakers (PMs), and cardiac resynchronization therapy (CRT) pacemaker (CRT-P) or defibrillator (CRT-D).[3] A survey of cardiac implantable electronic device implantation in India conducted by the Indian Society of Electro-cardiology and Indian Heart Rhythm Society published in Indian Heart Journal Jan 2016 found out - Over the past ten years, CIED(cardiac implantable electronic device) use has dramatically expanded globally. With an average of 300 patients per million, CIED implants are common in North America and Europe. It hardly amounts to 25 implants per million persons in India.[3] The survey showed 80% of patients had pacemakers for bradycardia,10% were CRT-P/CRT-D implants and 10% were ICD implants thus making pacemakers the most commonly used CIED.[3]

Patients at risk of sudden death due to ventricular arrhythmias have had their lives spared by implantable cardioverter-defibrillators (ICD). Patients with bradyarrhythmia benefit from pacemakers, while patients with heart failure benefit from cardiac re-synchronization devices, which lower mortality and morbidity while enhancing the quality of life.[4]

A pacemaker is a small device used to treat certain arrhythmias. Arrhythmias cause the heart to beat too quickly, too slowly, or in an irregular rhythm. Pacemakers deliver electrical pulses to your heart to help it beat at a normal rate and rhythm. Pacemakers can also help your heart chambers beat in unison, allowing your heart to flow blood more efficiently to your body. If you have heart failure, this may be necessary.

An AICD (Automatic implantable cardioverter defibrillator) is a cutting-edge device that treats ventricular arrhythmias such as ventricular tachycardia and fibrillation. It has become the first line of defense in patients at high risk of sudden cardiac death (SCD) and has shown consistent survival benefits in cardiac arrest survivors (SCA), patients with heart failure and severe systolic dysfunction (LVEF less than or equal to 35%), and patients with hypertrophic cardiomyopathy (HCM).[5] CRT (Cardiac re-synchronization therapy) aims to provide the failing heart a mechanical advantage that can significantly improve symptoms and mortality by targeting ventricular dyssynchrony, a condition that affects up to one-third of patients with highly symptomatic systolic HF.[5]

Although these technologies help patients live longer, they have a significant impact on their psychosocial lives. Anxiety and depression are found in 23 to 28 percent of implant patients, although they often go unnoticed and untreated.[6,7] In a comparative study of anxiety and depression among pacemakers and ICD, it revealed that the total prevalence of anxiety was 23.5% in the Pacemakers, and 28% in the ICD, respectively. In terms of depression, the findings revealed that the general prevalence of depression was 7.1 %, 23% in the Pacemakers and ICD, respectively. In terms of depression prevalence, there was a significant difference between Pacemaker and ICD recipients.[8,9]
Surprisingly, while these devices may save the recipient's life, they are also life-changing, posing various problems in the psychological transition process. After being sent home, recipients may have additional challenges and develop anxieties about living with devices.

Since the dawn of time, efforts have been undertaken continuously to assist those who suffer from depression and anxiety. Numerous studies have worked to assist patients by creating patient education modules, along with different pharmaceuticals and counseling. Thus, efforts are being made in unison to create a practical tool that would assist address some of the problems. Teaching patients the essentials of device management can help avoid issues. Patient education has become an essential component of the therapeutic approach to assisting cardiac patients with devices.

Patient education, which includes post-device implantation precautions and the importance of rehab, becomes a handy, easily accessible, and convenient tool that can aid in faster adaptation to daily life while also clearing misconceptions and promoting a better quality of life by attempting to reduce depression and anxiety.

MATERIALS & METHODS
This experimental study was carried out after the approval of the Institutional Ethics Committee. Participants with pacemakers, AICD, CRT-D or CRT-P aged between 18 – 80 years who were post-operative and following up to 1 to 2 months were included in the study. The purpose of the study was explained to each subject and written consent was taken. As soon as the consent was given, participants were explained how to rate the questionnaires (CDS, CAQ) in their language of preference (translated versions in Hindi and Marathi). Once the questionnaires were rated and filled, each participant was given the patient education verbally based on their language of preference (Hindi, English, Marathi). The information was repeated as needed by the participant. The questionnaires were again handed out to the participants and were asked to score post-education session to see if any difference was noted pre and post-patient education.

STATISTICAL ANALYSIS
Statistical analysis was done using the IBM SPSS software version 26. Median and interquartile ranges were calculated for continuous data. Continuous data was assessed for normality using the Shapiro-Wilk test. The difference between the pre and post-values within the group was determined by the Wilcoxon-signed rank test. The level of significance was considered to be \( p \leq 0.05 \).

RESULTS

<table>
<thead>
<tr>
<th>Gender</th>
<th>N</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>13</td>
<td>33.3 %</td>
</tr>
<tr>
<td>Male</td>
<td>26</td>
<td>66.7 %</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>100 %</td>
</tr>
</tbody>
</table>

Graph 1: Device distribution
Table 2: Shows the analysis of the anxiety and depression scores done using Wilcoxon-signed rank test

<table>
<thead>
<tr>
<th>Scales</th>
<th>Variables</th>
<th>Pre Median (IQR)</th>
<th>Post Median (IQR)</th>
<th>Z value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac anxiety (CAQ)</td>
<td>Fear</td>
<td>1.87 (1.50 - 2.37)</td>
<td>1.5 (1.12 - 1.87)</td>
<td>-4.809</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td></td>
<td>Avoidance</td>
<td>1.4 (1 - 2)</td>
<td>1 (0.80 - 1.20)</td>
<td>-3.798</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td></td>
<td>HFA</td>
<td>1.4 (1 - 2.2)</td>
<td>1.40 (0.80 - 1.60)</td>
<td>-3.640</td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>Cardiac depression (CDS)</td>
<td>CDS Score</td>
<td>1.61 (1.17 - 2.37)</td>
<td>1.33 (1.05 - 1.67)</td>
<td>-4.801</td>
<td>&lt;0.0005*</td>
</tr>
</tbody>
</table>

**Interpretation:**
The results revealed significant differences in the scores of CAQ and its subscales Fear, Avoidance, Heart Focused Attention (HFA) by p < 0.0005. There was a significant decrease in participants' pre and post-scores which showed statistical significance. The intervention also improved the depression thus reducing the CDS scores.

Graph 2. The boxplots showing median and inter-quartile range for fear subscale of the cardiac anxiety questionnaire

**Interpretation:**
Pre-intervention score of fear subscale of CAQ with median of 1.87 and IQR of 1.50-2.37 whereas Post-intervention score of fear subscale of CAQ with median of 1.5 and IQR of 1.12-1.87, thus indicates that Fear subscale of CAQ showed significant reduction in fear post-patient education.

Graph 3: The boxplots showing median and interquartile range for avoidance subscale of the cardiac anxiety questionnaire
Interpretation: Pre-intervention score of Avoidance subscale of CAQ with median of 1.4 and IQR of 1-2 whereas Post-intervention score of Avoidance subscale of CAQ with median of 1 and IQR of 0.80-1.2 thus indicates that Avoidance subscale of CAQ showed significant reduction in heart related Avoidance post-patient education.

Graph 4: The boxplots showing median and interquartile range for Heart Focused Attention subscale of the cardiac anxiety questionnaire

Interpretation: Pre-intervention score of HFA subscale of CAQ with median of 1.4 and IQR of 1-2.2 whereas Post-intervention score of HFA subscale of CAQ with median of 1.4 and IQR of 0.80-1.6, thus indicates that heart focused attention subscale of CAQ showed significant reduction in the heart focused attention post-patient education.

Graph 5: The boxplots showing median and interquartile range for total score of the cardiac anxiety questionnaire

Interpretation: Pre-intervention total score of CAQ with median of 1.61 and IQR of 1.17-2.37 whereas Post-intervention total score of CAQ with median of 1.33 and IQR of 1.05-1.67 indicates reduction in anxiety post-patient education.
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Graph 6: The boxplots showing median and interquartile range for total score of the cardiac depression scale (CDS)

Interpretation:
Pre-intervention total score of CDS with median of 73 and IQR of 64-85 whereas Post-intervention total score of CDS with median of 64 and IQR of 56-72 thus indicates reduction in depression post-patient education.

DISCUSSION
This study included 39 participants, out of which 33% of the participants were female and 66% were male. Out of all the participants, 12% were under the age of 30 and 87% were above 30 with a mean age of 52.05 years. Out of 39 participants 30 (76.9%) participants had a permanent pacemaker implanted (PPI), 7 (17.9%) had AICD (automated implantable cardioverter defibrillator) and 3 (5.1%) had CRT (cardiac resynchronisation therapy device). In the present study, the Cardiac Anxiety Questionnaire (CAQ) and Cardiac Depression Scale (CDS) were used to measure anxiety and depression which provided more disease-specific outcome measures. The CAQ is a self-report questionnaire with 18 items that are assessed on a five-point Likert-type scale with anchor values ranging from 0 (never) to 4 (always). It was created in 2000 by George Eifert, Thompson, and others. CAQ is made up of three components: fear of having heart sensations, avoidance of activities expected to trigger cardiac symptoms, and heart-focused monitoring and attentiveness.

This study revealed significant improvements in all three CAQ components, with the Fear component showing the greatest improvement with a z value of -4.809 and a median score of 1.87 reducing to 1.5 post-patient education. The questions focused on the fear component and covered concerns about patients' health, whether doctors believed their symptoms, how safe they felt around hospitals, and their inability to focus on tasks. The patient education they received helped them in a way that was not only merely educational but also provided them the confidence to embrace their circumstances, devices, and so the factor of worry and fear was less.

The subscale of Avoidance also showed improvements post-patient education with a z value of -3.798 and inter-quartile range shifting from (1 - 2) to (0.80 – 1.20). The questions focused on the Avoidance subscale included patients frequently avoiding activities that are strenuous for them. Various dos and don'ts with specified timelines, such as shoulder restriction up to 3 months and not beyond, so that the patient can return to their normal previous lives without any shoulder disorders like
Glenohumeral joint adhesive capsulitis or painful arc syndrome. In addition to that, the clear information about the level of physical activity to follow post-procedure and the importance of follow-ups with the physiotherapist post-discharge, could be one explanation for the observed benefits. The component of HFA (heart focused attention) showed significant improvement post-patient education with a z value of -3.640 and inter-quartile range reduction from (1 - 2.2) to (0.80 – 1.60). The CAQ scale focused on the HFA subscale with the questions encompassing how frequently the patients were paying attention to their heartbeats, increased heart rate causing sleep issues and concentrated more on how the patient’s increased focus on heart rate affects their daily activities. The significance of the device, how they perform at a fixed heart rate, and the safe degree of physical activity following the treatment were all beneficial in lowering the patient’s heart-focused attention. The need to pay attention to safety, care, and self-awareness, rather than overzealousness, was undoubtedly the explanation for the huge change after education.

David L. Hare and Cynthia R. Davis developed the Cardiac Depression Scale in 1996 primarily to identify the less severe "reactive" depression in a cardiac population, as opposed to the other depression measures. Reactive depression, as opposed to the more severe and symptomatic major depression, is more characteristic of the sort of depression experienced after an Acute Coronary Syndrome. This study also found a highly significant improvement in depression scores on the CDS with a z score of -5.306. The median scores decreased from 73 before education to 64 after education, with interquartile ranges shifting from (64 - 85) before education to (56 -72) after education. In terms of scoring, the questions in this scale featured a mixed blend of positive and negative components, which implies that certain items were reverse-scored to avoid the response biases inherent with multi-item scales that are phrased in a single direction. This scale's questions covered sleep disruptions, confusion about their lives, mood disorders, cognition issues, hopelessness, inactivity, and anhedonia. The possible explanation for the reduction in scores can be in-depth detailed information right from the point of surgery, throughout the hospitalization phase till post discharge phase, also information about how and why devices are used, their basic working mechanism, various dos and don'ts with the specified timeline in terms of daily life activities as in case of shoulder restriction up-to 3 months and not beyond, so that the patient can back to their normal previous lives, care of device around other electromagnetic devices with specifications in terms of distance as well as complete avoidance of certain magnetic field devices, immediate post-op care about the wound and the safe mobilization information, the importance of medications and follow ups, staying vigilant about red flags and what to do in case of emergencies, information about approaching cardiologists, physiotherapists for getting back in their daily roles. Answering doubts and repeating material in case of misunderstandings all this contributed to the favorable significance for this study.

Evidence available regarding the effect of any form of patient education or any education modules on post device implantation population is scarce. In reviewing the literature, there was ample evidence suggesting the increased prevalence of anxiety and depression in post-cardiac device implantation in Western as well as Asian countries but there was scant research on how patient education affected anxiety and depression in these population. Moreover, a study by Massoma Aqeel et al., (2008) demonstrated that many ordinary activities are viewed as risky by pacemaker patients, potentially leading to incapacitating changes in lifestyle. Further research is necessary to ascertain the causes of these misunderstandings and to
identify whether similar issues also affect and hamper other patient populations. Hence this study aimed at educating patients with intracardiac devices to avoid misunderstandings amongst the cardiac population with intracardiac devices. Also, a new study regarding the prevalence of anxiety, depression and stress among various CVD’s done by Damodar G., Subhakar Raju R., et al [16] suggested Psychological factors are increasingly being recognized as important factors when examining how patients with heart issues or CVDs are managed. When left untreated, depression, anxiety, and stress are common in individuals with heart illnesses and are linked to a lower quality of life in terms of mental health. The prevalence of severe anxiety and depression accounted for nearly 28.4%.

A descriptive cross-sectional study was carried out in New Delhi AIMS [17], India with the primary goal of evaluating pacemaker patients' quality of life and knowledge both early and later on after pacemaker implantation to create an informational booklet. Patients in the later phase had a higher mean knowledge score than those in the early phase (p = 0.008). Patients in the early phase reported a decreased quality of life in the environment (p = 0.014) and social relationships (p = <0.0001) compared to those in the later period. During the early stages of pacemaker implantation, there was a weakly positive link between knowledge and quality of life in the domains of social interactions (r = 0.38, p = 0.0052) and physical health (r = 0.32, p = 0.0206). The study concluded that during the initial stages following pacemaker installation, knowledge and quality of life were subpar. Therefore, creating an informational brochure for these individuals would aid in enhancing their self-care practices and averting more issues.

The study by Manal Houssien Nasr et al(2015) [18], aimed to assess the impact of a counseling program on patients with permanent pacemakers' knowledge and self-efficacy. It was discovered that there were statistically significant differences in all knowledge and self-efficacy items between the pre/post and follow-up exams after following the counseling program (p=0.001). There is a significant difference in anxiety and depression levels between the post and follow-up tests and the pretest. The counseling program had a positive effect in improving knowledge, anxiety and depression and in turn the self-efficacy of patients with permanent implanted pacemakers. There was also a positive correlation between levels of patients' knowledge as regards their self-efficacy and level of anxiety and depression. The current study findings were consistent with this study, which found a significant improvement (p<0.0005) in anxiety and depression following patient education in a population with all intracardiac devices. Helen Goodman [19], suggested the need to understand people's perception of their education needs before and after discharge and also helps further in the investigation and improve the restoration process. These included improvements to the literature and patient education sessions as well as changes to encourage a more seamless transition into the community. The findings also suggested that further research into the issue of psychological discharge planning following cardiac surgery is necessary. In accordance with all the previous studies, an effort to develop a patient education as an effective, inexpensive tool was made in the current study which proved to be of higher significance in lowering patient’s anxiety as well as depression.

Furthermore a study by Deborah Snegalatha, Jasmin Anand et al.[11], conducted a descriptive cross-sectional study with an aim to assess the knowledge and attitude of patients regarding permanent pacemakers (PMs) and their quality of life (QOL) after the permanent PM implantation. The majority of respondents (54.3%) had knowledge that was mostly adequate, 55.7% had mostly positive attitudes, and 46% had a moderate
quality of life. Between participants' knowledge and QOL, there was a statistically significant positive connection (r = 0.340; P = 0.004), and between participants' attitudes and QOL, there was a statistically significant positive correlation (r = 0.559; P = 0.001). The relationship between attitude and age was quite strong. A deliberate effort must be made to help patients cope better after PM implantation. This study gives us an idea about how patient’s existing knowledge and perception can have an impact on their QOL. The findings of this present study do support the use of patient education as a comprehensive tool to aid in lowering anxiety and depression among people with intracardiac devices.

A single-center prospective, single-blinded study was carried out by experts at the cardiology department of the University of Pamukkale Hospital in 2018 [20]. This study was designed to assess the effect of patient education on knowledge of safety and awareness regarding living with cardiac implantable electronic devices (CIEDs) throughout phase I cardiac rehabilitation. It was demonstrated that a carefully planned education interview is essential for significantly increasing patients' awareness about the safety of CIEDs and adjusting to life with these devices. Patients might adapt to daily life more rapidly as a result, encounter fewer misconceptions and inaccurate information, and eventually enjoy an enhanced standard of living after device implantation.

In this study Question and answer session was also held post-patient education, if the patient needed additional information or to clear any doubts, also information was repeated for some of the participants as required. The patient education developed in this study was a collaborative effort from cardiologists, physiotherapists and device related instruction manuals were also taken into consideration, thus developing a comprehensive, informative patient education.

This study does, however, emphasize the advantages of patient education as well as the necessity of more research in this field. To optimize patient education programs' efficacy, future research ought to investigate the best ways to deliver them, as well as their ideal contents and lengths of time. Research is also needed to determine whether the benefits have been sustainable over the long run.

**CONCLUSION**

In conclusion, this research offers convincing evidence of the beneficial effects of patient education on individuals with anxiety and depression post-cardiac device implantation. It is clear from an in-depth analysis of the data gathered that participant mental health outcomes have significantly improved as a result of the introduction of a patient education program. Given its comprehensive, educational, user-friendly, and simple design, patient education can help lower depression and anxiety in individuals using intracardiac devices. This study also proves that, following patient education, it is easier to gain patient compliance toward the acceptance of the intracardiac device required for the illness. Hence, the results of this study highlight how crucial it is to include patient education in healthcare practices.

Acknowledging the critical role that education plays in advancing mental health and overall well-being, medical professionals can work toward treating anxiety and depression with an increased holistic and patient-focused approach.

**Declaration by Authors**

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