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ANXIETY IN PATIENTS WITH PERMANENT CARDIAC PACEMAKER AGED >60 YEARS OLD

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Abstract

Introduction: A cardiac pacemaker is a small implanted device to control abnormal heart rhythms. According to estimates, 3 million individuals worldwide live with an implanted permanent pacemaker (PPM) while about 600 thousand pacemakers are implanted, annually.

Purpose: to explore anxiety of pacemaker recipients as well as all the associated demographic and self-reported characteristics.

Material and Method: 100 outpatients with PPM were enrolled in the study. Collection of data was performed by the completion of the "Self-rating Anxiety Scale Zung (SAS)" which included patients' characteristics.

Results: From the 100 participants 65% were men, 66% were >70 years old, 60% married, 50,5% of primary education and 90% lived in Attica. In terms of anxiety, 50% of recipients scored less than 48 on SAS scale (wide of range: 20-80) indicating mild to low levels of anxiety. Regarding associated factors, anxiety was found to be statistically significantly associated with gender ($p=<0,001$), understanding of provided information ($p=<0,001$), understanding of precautions in electromagnetic fields ($p=0,021$), desire for more frequent and long term follow-up and devise assessment ($p=<0,001$ and $p=<0,001$, respectively).

Conclusions: Though pacemaker is an opportunity to prolong survival, however systematic assessment of anxiety and all the associated factors is considered to be of primary importance in clinical pacemaker settings.

Key words: : Pacemaker, arrhythmia, anxiety, Zung scale.

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INTRODUCTION

During recent decades, implantation of permanent pacemakers (PPM) has received a great deal of attention, mainly due to the ageing of population.[1,2] PPM recipients are over the age of 65 years old with 70–80% of all PPMs have being implanted at this age, worldwide.[1-3]

More in detail, rates for recipients over 75 years old double when compared to those aged 65–74 years and are highest in those aged ≥85 years while women consist approximately the 40% of cases.[1-3] Interestingly more, implantation rate in men was shown to be significantly greater than women during a period of 30-years.[2]

PPM implantation rate has increased due to several factors, including advances in device technology and an increasing number of indications for their use.[2] The Italian Pacemaker Registry (IPR) showed that the number of reported PMMs in Italy was 30,820 in 2003, 32,047 in 2004, 31,870 in 2005, 31,813 in 2006, and 31,146 in 2007.[4] Accordingly, from 1993 to 2009, 2.9 million patients received a primary PM in the USA.[5,6] Advances in device technology and better care of cardiovascular patients due to improved diagnosis and treatment may increase the implantation incidence.[2]

Though the first implantation of pacemaker to a human being was made in 1958 by Dr. Ake Senning, ever since these implanted devices are widely used for treatment for brady-arrhythmia and heart block.[5] The most common type of PPM is the dual-chamber where two leads are implanted, one in the right ventricle and one in the right atrium (PMMs-DDD).[5-7]

Implantation of PPM is associated with several benefits such as increased survival, improvement of bradycardia-related symptoms, better quality of life, and exercise tolerance. One of the main key-elements in pacemaker- related issues is co morbid illness which is shown to be strongly associated with long-term survival.[2]

However, this implanted device is not only associated with benefits but also with several complications.[5,7] Specifically more, complications can be divided into early including post-operative, during hospitalization and within 30 days and to late or short-term which occur in less than 3 months.[8] According-ing to estimates, complications are about 4-5% for the early ones and 2.7% for the late.[7]

In more recent years, that life expectancy of pacemaker recipients has significantly increased, the demand of exploring psychological issues such as anxiety has come to the forefront of clinical care. Interestingly, this medical device protect patients from a life-threatening arrhythmia but at the same time may trigger anxiety since it imposes several restrictions in patients' lives, such as physical, financial and social.[9,10]

Anxiety is an unpleasant emotion that affects about 24.9% of the population at some time in life while a high prevalence is documented in cardiac patients. Accordingly, there is noticed a growing demand for early screening of anxiety or identifying individuals at high risk with ultimate goal to implement such psychological intervention that enable them take responsibility for their health management.[11]

The aim of this study was to explore anxiety in permanent cardiac pacemaker recipients and the associated demographic and self reported characteristics.

METHODS AND MATERIAL

Design and period of the study

In the present study were enrolled 100 permanent cardiac pacemaker recipients living in community. It was a convenience sample. The research was conducted from October 2019 to January 2020.

Sample: inclusion and exclusion criteria

During the period which the research was conducted, from a total of 125 patients who were initially identified as eligible to participate in the study, only 100 were finally enrolled because 25 refused to participate.

Criteria for inclusion in the study were: a) diagnosis of cardiac disease and having an implanted permanent pacemaker, b) the ability to write and read the Greek language fluently, and c) living in community (not hospitalized patients). The exclusion criteria were patients with: a) a history of mental illness and b) a serious chronic disease.

Ethical considerations

The study was approved by the Ethical Committee of the hos-

pital where it was conducted. Patients who met the entry criteria were informed by the researchers for the purposes of this research. All patients participated only after they had given their written consent. Data collection guaranteed anonymity and confidentiality. All subjects had been informed of their rights to refuse or discontinue participation in the study, according to the ethical standards of the Declaration of Helsinki (1989) of the World Medical Association.

Data collection and procedure

Data collection was performed by the completion of "Self-rating Anxiety Scale (SAS) - Zung" which included socio-demographic and other self-reported characteristics. Data collected for each patient included: a) socio-demographic characteristics: gender, age, marital status, education level, residency and b) self-reported characteristics regarding implanted device. The method of interview was used for data collection.

Data were collected in the outpatient settings of a public hospital that patients were visiting for regular monitoring and follow-up. Completion of the each questionnaire lasted approximately 15 min and took place for each participant after the regular session of follow up. Specifically, the interview was conducted in a private room located beside the outpatient clinical setting.

Assessment of anxiety

The Self-rating Anxiety Scale (SAS) - Zung scale was used to assess anxiety in patients with PPM. The SAS scale consists of 20 items assessing how respondents felt during the previous week. Respondents are able to answer each question on a 4-point Likert scale. Each of the four-scale scoring is given a score of 1-4. Five questions are first to be reversed. The scores assigned to the questions are summed up, leading to a final score. Higher scores indicate higher levels of anxiety. [12]

Statistical analysis

Categorical data are presented as absolute and relative (%) frequencies, whereas continuous data are presented as the median (IQR, interquartile range).

The Kruskal-Wallis test was used to test the association be-

tween anxiety and a factor with more than two categories, while the Mann-Whitney test was performed to access the association between anxiety and a factor with two categories.

The level of statistical significance was set to α = 5%. All statistical analyses were performed using the SPSS version 20 package (SPSS Inc, Chicago, Il, USA).

RESULTS

Sample description

Men accounted for 65% of the sample, while 66% of the subjects were> 70 years of age, 60% were married, 50.5% of primary education, and 90% living in Attica. Regarding self reported characteristics, 33,3% reported to be well-informed about their health state, 62% reported to deeply understand all the provided by health professionals, 70% reported to be deeply aware of precautions relating to electromagnetic fields, 68% desired a more frequent and long term follow-up, 72% desired a more frequent device assessment.

Levels of anxiety

The 50% of the patients scored less than 48 on the scale of anxiety (range of values 20-80) indicating mild to low levels of anxiety.

Socio-demographic characteristics associated with anxiety

In terms, of socio-demographic characteristics, anxiety was found to be statistically significantly associated with gender (p=<0,001).

No other demographic characteristic was associated with anxiety.

Regarding self-reported characteristics, anxiety was found to be statistically significantly associated with the report that they deeply understood all provided information (p=<0,001), that were deeply aware of precautions relating to electromagnetic fields (p=0,021), the desire for a more frequent and long term-follow up (p=<0,001) and the desire for a more frequent device assessment (p=<0,001).

DISCUSSION

The present study showed mild to low levels of anxiety in

pacemaker-recipients. Although anxiety is common among cardiac patients or it may be a symptom of depression, nevertheless, it has not been extensively studied in terms of prevalence, nature and effects on patients' life.

A relevant study in a Geek sample of 250 patients with a PPM (mean age 71) showed high levels of anxiety in 27.2% of the sample. The same researchers also showed that women more frequently suffered high levels of anxiety (40%) than men (20%). Likewise, high levels of anxiety were observed in patients with primary school education (29.8%) and those who considered themselves anxious (37.9%) or were very anxious about their heart rate (56.2%) and the proper functioning of their device (57.4%). Furthermore, high levels of anxiety experienced patients who had someone helping them in their everyday activities (33.6%), those who believed that their life depends on health professionals (34%), those who did not believe that the pacemaker solved their cardiac problem (92.3%) and those who did not think that their quality of life was improved (66.7%).[9]

The finding of the present study that women experienced high levels of anxiety may be attributed to the different social and family roles of women, such as taking care of family members or elderly parents, etc. More in detail, when women perceive inability to care for their family, then in turn may experience higher levels of anxiety. Moreover, women have the tendency to underestimate symptoms of cardiac disease resulting in delay in seeking for medical care. However, after the establishment of cardiac disease, housework helps women to cope with the illness and maintain self-esteem, thus preventing mental-related problems. Furthermore, women respond to stress by developing tendentious and loving responses which maintain social well-being and facilitate stress relief. [13]

Cardiac pacemaker patients who declared not to fully understand the provided information about the implanted device had elevated levels of anxiety. Implantation is a safe method to treat severe chronic arrhythmia, however patients often experience anxiety and fear because they may not understand pacemaker related issues or show doubts regarding proper operation of the device. The need of information consists one of the basic principles concerning the rights of the pa-

tient. Interestingly, providing information has been considered as a key component of therapy that promotes health care decision-making, encourage patient's participation in treatment and enhances adherence to medical recommendations. Patients need information not only about the disease but also for more practical problems associated with everyday activities or medicines.[14,15]

Results also revealed elevated level of anxiety in participants who declared not to be deeply aware of precautions relating to electromagnetic fields. Patients may experience anxiety if they perceive as a threat either the device or the associated restrictions. Possibly, patients may feel unable to handle their "new state in life". Indeed, after implantation, the device needs to be checked periodically for normal functioning and battery energy. Also, there are observed differences in the ways of experiencing daily living after pacemaker implantation in regard to "perceived social participation" and "emotional state".[16]

Contrary to popular belief, new home appliances, do not interfere with pacemakers. However, other devices of older technology, need precautions such as cellular telephones (not kept in a breast pocket and keep kept six inches or more away from the pacemaker), magnets, airport security metal detectors or radiation therapy, medical procedures and others. Driving is generally restricted for about 2 weeks after implantation. Additionally more, patients need to have and carry with them an ID card with important information about the implanted device and the leads. Impressively, patients must carry this card at all times and everywhere.[17,18]

Additionally, pacemaker patients with high levels of anxiety, also feel more fatigue, thus indicating alleviation of the emotional burden as fundamental. interestingly, older patients felt more fatigue and the later the device is implanted the more fatigue the patients feel.[10] Therefore, health care professionals who are involved in the field of pacemaker is necessary to implement self-care programs based on patients' need.[19]

Patients who reported to need a more frequent long-term follow-up and a more frequent device assessment experienced elevated levels of anxiety. Clinical settings should encourage scheduled visits to emphasize patient responsibility in the ther-

apeutic regimen and support self-efficacy behaviors. Strengthening the emotional dimension of these patients may improve their quality of life and help them adapt to the device. Patient support groups involving frequent meetings where they exchange ideas, options and beliefs about the implanted device or therapy may be an alternative solution to combating anxiety.[10,17-19]

Prerequisite for an effective follow-up is the combination of trained personnel, a structured set of procedures and the creation of a reporting system. All these parameters may be incorporated into a national database regarding cardiac pacemakers. In regard to the frequency of follow up, this seems to vary from the early post-implant phase to the phase of maintenance. The main patient-related characteristics that determine the frequency of follow-up are co-morbidity, dependency on pacing, stability of rhythm and cardiovascular symptoms, patients' ability to recognize and respond to changes in clinical status and ability to reach clinic rapidly. On the other hand, the main pacemaker-related elements that determine the frequency of follow up are reliability of the pacing system, time since implantation, programmed parameters, type of pacemaker and complexity of pacing system. [20]

However, it is noteworthy that pacemaker recipients may not follow medical advice. A recent study showed that among 250 patients, after implantation, 17.6% of them continued smoking, 85.3% consumed alcohol occasionally and 44.4% did not exercise at all. Additionally, 49.8% had not reduced the usage of a mobile phone, 88.4% knew they had to carry a device identification card (ID card) but only 74.8% "always" carried this special card, 52.4% had someone else to help them with their daily activities. More intriguing, almost all the participants believed that the pacemaker solves the problem of arrhythmia (94.8%). [10]

Study limitations

The results should be interpreted with caution as they are limited by the method of convenience sampling. This method is not reprehensive of all patients in Greece, thus limiting the generalizability of results. Also, the study was cross sectional and collected data at one point in time, thus not allowing determination of the causal relation between anxiety and device implantation or exploration of changes over time.

CONCLUSIONS

The results of the study will help health professionals to understand the multidimensional nature of the problems these patients are facing. Therefore, it is essential to integrate systematic anxiety assessment into clinical care in order to take the necessary measures to alleviate emotional burden. Nowadays, the demand for pacing services will continue to grow as population is growing older.

Future research will be meaningful if they involve a group of patients in pre-implantation and post-implantation phases with a follow-up of one or more years afterwards.

In future, research efforts may shed more light on this sensitive population and the burden of their physical emotions.

Conflict of interest. The authors declare that they have no conflict of interest.

Ethical approval

The study was approved by the Medical Research Ethics Committee of the hospital.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Research involving human participants

All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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ANNEX

TABLE 1. Distribution of the sample according to socio-demographic characteristics.

Characteristics	N (%)
Gender	
Male	65 (65,0%)
Female	35 (35,0%)
Age	
61-70	34 (34,0%)
>70	66 (66,0%)
Family Status	
Married	60 (60,0%)
Divorced or widowed	40 (40,0%)
Education Level	
Primary School	53 (50,5%)
Secondary School	27 (27,3%)
University	19 (19,2%)
Residency	
Attica	80 (90%)
Rural area	20 (20%)

TABLE 2: Distribution of the sample according to concerns regarding hemodialysis.

	N (%)
Are you informed about the state of health?	
Very	33 (33,3%)
Enough	35 (35,4%)
Little	31 (31,3%)
Do you deeply understand all the provided information?	
Yes	62 (62%)
No	38 (38%)
Are you deeply aware of precautions relating to electromagnetic fields?	
Yes	70 (70%)
No	30 (30%)
Do you desire a more frequent long-term follow-up? (Yes)	68 (68,0%)
Do you desire a more frequent device assessment? (Yes)	72 (72%)

TABLE 3: Effect of permanent cardiac pacemaker on patients' anxiety

	Median (IQR, 25º-75º)
Anxiety Zung (Range of values : 20-80)	48 (40-55)

TABLE 4: Effect of permanent cardiac pacemaker on patients' anxiety

	Anxiety- Zung Median (IQR 25º-75º)	p-value
Gender		<0,001
Male	43 (34-52)	
Female	50 (47-54)	
Age		0,174
61-70	45 (36-50)	
>70	48 (41-54)	
Marital status		0,241
Divorced or widowed	48 (43-54)	
Married	45 (36-52)	
Education Level		0,127
Primary	48,5 (43,5-54,5)	
High Scholl	45 (34-53)	
University	43,5 (39-51)	
Occupation		0,149
Employee	40 (31-54)	
Pensioner	47 (39-54)	
Residency		0,396
Attica	45 (38-54)	
Rural area	47 (40-52)	

TABLE 5: Effect of permanent cardiac pacemaker on patients' anxiety

	Anxiety-Zung Median (IQR 25º-75º)	p-value
Level of information about state of health		0,931
Very	46 (38-53)	
Enough	45 (40-52)	
Little/ Not at all	46 (38-53)	
Do you deeply understand all the provided information?		**<0,001**
Yes	43 (36-50)	
No	52 (45-56)	
Are you deeply aware of precautions relating to electromagnetic fields?		**0,021**
Yes	45 (38-52)	
No	50 (44-57)	
Do you desire a more frequent long-term follow-up?		**<0,001**
Yes	39 (32-45)	
No	50 (44-55)	
Do you desire a more frequent device assessment?		**<0,001**
Yes	35 (31-47)	
No	50 (43-55)	