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Literature review: Quality of life of patients with implanted devices for permanent cardiac pacing

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Abstract

The implantation of devices for permanent cardiac pacing is becoming more and more popular medical treatment for cardiac disorders. There are several types of devices that can be implanted into patients: pacemakers (PM), implantable cardioverter – defibrillators (ICD) and cardiac resynchronization therapy devices (CRT). All of the above-mentioned devices improve the quality of life and affect the survival. The quality of life is now considered as a significant purpose of treatment of patients with a cardiovascular disease. Surveys on the quality of life are especially useful to cardiac patients as they allow for conducting an overall assessment of their mental and physical state, the quality of life and the effectiveness of the treatment. In the available scientific literature, there are numerous analyses and data on the quality of life of patients with a cardiac pacemaker in different areas of its functionality. The presented review features research projects that measured the quality of life in various respects, e.g. limitations related to poor physical health, the impact of physical activity on everyday life, pain, general perception of health, emotional state and its impact on everyday life, limitations related to emotional problems or to physical health, mental health, vitality, and any issues related to the treatment of cardiac arrhythmias through the implantation of cardiac stimulation devices. In the earliest publications the numbers of participants were very low and thus the results may have been uncertain. However, more recent publications include sufficient number of participants to formulate general conclusions on the quality of life in the overall study population. The quality of life after implantation has improved significantly.

Keywords: quality of life, permanent cardiac pacing, literature review

Introduction

The implantation of devices for permanent cardiac pacing is becoming more and more popular medical treatment for cardiac disorders. There are several types of devices that can be implanted into patients depending on the patient's disease. There are pacemakers (PM), implantable cardioverter – defibrillators (ICD) and cardiac resynchronization therapy devices (CRT). In Poland between 2007 and 2014 the number of procedures with cardiac pacemakers increased from 18 900 to 28470, implantable cardioverter – defibrillators from 1595 to 8399 and cardiac resynchronization therapy devices from 580 to 3718 [1]. The first artificial cardiac pacemaker was implanted, in October 1958 by a Swedish cardiac surgeon Professor Åke Senning, to a patient with an atrioventricular block. In Poland, the first implantation took place in September 1963 in Gdansk. The surgery was performed by Professor Zdzisław Kieturakis and Doctor Wojciech Kozłowski. Cardiac pacemakers enable to overcome symptoms resulting from bradycardia, that is a low heart rate, and in many cases they can save the patient's life. The first implantable cardioverter–defibrillator was implanted in February 1980 at John Hopkins Hospital in Baltimore, United States of America [2]. The first ICD implantation with epicardial in Poland took place in 1989 at the Medical Academy of Silesia, and the first implantation with transvenous electrodes in 1995 at then Gdansk Medical Academy [3]. Implantable cardioverter–defibrillators stop life-threatening heart arrhythmias and prevent sudden cardiac death. The clinical application of cardiac resynchronization therapy, that improves the quality of life of patients with heart failures and reduces mortality, has only happened in 1994 [4].

The quality of life is now considered as a significant purpose of treatment of patients with a cardiovascular disease. Among the cardiac patients the subjective perception of well-being depends on the troublesome symptoms, their severity and frequency and level of satisfaction. The quality of life of these patients depends on many factors: the type of disease, the course of the disease, the overall physical state of health, as well as the psychological aspects. In Poland the issue of cardiac patients is still overlooked, patients are often left to their own device what in consequence leads to alienation, solitude, and deterioration in the quality of life. The surveys on the quality of life are especially useful to cardiac patients as they allow for conducting an overall assessment of their mental and physical state, the quality of life and the effectiveness of treatment. Comparative studies of the patients' quality of life from before and after the implantation of different types of stimulators are very rare in the literature. Prospective studies of patients before and after implantation of artificial cardiac

pacemakers are crucial in the context of a fair assessment of the reduction or reversal of ailments caused by arrhythmias. The lack of deterioration in the physical activity of patients with permanent cardiac pacing would be considered gratifying information.

Material and methods

Criteria for inclusion/exclusion from the research

The following research included published studies that measured any aspect of quality of life, such as limitations related to poor physical health, the impact of physical activity on everyday life, pain, general perception of health, emotional state and its impact on everyday life, limitations related to emotional problems or to physical health, mental health, vitality, and any issues related to the treatment of cardiac arrhythmias through the implantation cardiac stimulation devices.

Criteria for inclusion included studies of patients who had stimulation devices implanted, irrespective of gender but with regard to age – patients over 18.

Statistical analysis

In order to find the articles related to the quality of life after implantation of artificial cardiac pacemakers published before June 2017 several search engines were used: PubMed-Medline, Embase, The Cochrane Library**,** PsychINFO, and Google Scholar. Websites connected to the researched topic, magazines, direct links and the pages Web of Science with regard to citations and quoted articles were also searched. The databases were researched with the use of the title of this work: „Literature review:"Quality of life of patients with implanted devices for permanent cardiac pacing", and terms such as: „quality of life", „patients' satisfaction", „emotional problems of cardiac patients", „implantation of artificial cardiac pacemakers", „cardiac disorders". The terms were searched individually and in combinations. To identify all the relevant studies, the synonyms of the above-mentioned terms were also researched, e.g. „implantation", „arrhythmia", „pacemaker", „implantable cardioverter – defibrillator", „cardiac resynchronization device", „depression".

The articles were initially identified through the analysis of the content included in the titles and summaries. After a thorough analysis of the full text, articles that fulfilled all the criteria were used in the research.

There were no language restrictions.

Results

During the initial research phase reports were found, out of which 87 were selected on the basis of the information included in the titles and summaries. From among thirty-seven unabridged articles sixteen met the criteria for further analysis. The selection process is presented in Figure 1. The details of the selected works are presented in table 1.

Articles selected during initial search	→	138
Articles selected on the basis of the title and the summary	→	87
Articles downloaded in unabridged version	→	37
Articles meeting the criteria	→	16

Figure 1.The flowchart presenting the selection process

Table 1. The summary of the research project

Publication	Researcher	Study design	The number of participants
1978	Fukatani et al.	Cross-sectional study	59
1989	Lau et al.	Randomized cross-over trial – double-blind trial	16
1992	Linde-Edelstam et al.	Randomized cross-over trial – double-blind trial	17
1994	Lukl et al.	Randomized controlled clinical trial– double-blind trial	21
1995	May et al.	Prospective study	21
1996	Deharo et al.	Randomized cross-over trial – single-blind trial	18
1997	Aydemir et al.	Cross-sectional study	84
1998	Lamas et al.	Randomized controlled clinical trial	400
2001	Duru et al.	Cross-sectional study	210
2003	Young et al.	Randomized controlled clinical trial – double-blind trial	369
2003	Kamphuis et al.	Prospective study	167
2005	Whang et al.	Prospective cohort study	645
2006	Leosdottir et al.	Cross-sectional study	125
2007	Newall et al.	Cross-sectional study	95
2009	Młynarski et al.	Cross-sectional study	198
2013	Uchmanowicz et al.	Clinical control group	100

Discussion

In the available scientific literature, there are numerous analyses and data on the quality of life of patients with a permanent cardiac pacing in the different areas of its functionality. However, the results of these studies are often inconsistent, ambiguous and not without errors. The presented review features research projects by publication date.

Cross-sectional study carried out by Fukatani et al. [5] in the years between 1967 and 1976 evaluated the quality of life of 59 patients with a pacemaker aged between 39 and 80. The improvement in symptoms after the implantation was observed in the majority of patients, out of which 32 patients (54%) were physically active.

Lau et al. conducted randomized cross-over double-blind trial [6]. They have tested 16 patients with bradycardia, who were implanted randomly with VVI or VVIR, with the average patient age 56. The researchers used the Nottingham Health Profile (NHP) questionnaire. A more significant improvement in the quality of life was observed in the patients with VVIR in terms of pain, sleep, emotional reactions, social isolation, and physical activity.

A randomized cross-over double-blind trial by Linde-Edelstam et al. [7] focused on the quality of life of 17 patients with atrioventricular block and retained sinoatrial node functions after the implantation of DDD and VVIR devices. The researchers observed that patients with DDD experienced a decrease in the cardiovascular symptoms such as dyspnoea, vertigo and palpitation. This lessening of symptoms improved the well-being and the cognitive functioning of the studied patients.

In a randomized controlled clinical trial, Lukl et al. [8] examined 21 patients with average age 68 $^{+}/_{-}$ 8 years. The patients' pacemakers were set in DDD and VVIR modes due to sick sinus syndrome (8 patients) or complete heart block (13 patients). The quality of life was measured by the means of a questionnaire on cardiovascular symptoms, physical activity, and self-reported health. Also, in this case, the researchers observed a significant improvement in the average of quality of life. There has been a decrease or a total clearance of such symptoms as dyspnoea exertional, episodes of vertigo, palpitation, and general tiredness. The results of the above research implied that the stimulation with the DDD stimulation provided the patients with a better quality of life than the VVIR stimulation.

May et al. [9] assessed the quality of life of 23 patients before and after the ICD implantation. During the course of research 4 patients have died. The Sickness Impact Profile (SIP) score was used to measure the quality of life. The overall result of the SIP test ($11{,}2 \pm 9{,}3$, $P < 0{,}05$) after 6 months of research was worse but returned to its original score from before the implantation and after 12 months. This was caused mostly by temporary emotional problems.

The randomized cross-over trial – single-blind trial carried out by Deharo et al. [10] compared the quality of life of 18 patients (14 men and 4 women) after the implantation of DDD and

VVIR pacemakers. The questionnaire on the quality of life and the stress tests were made one month after the implantation. The researchers observed that the permanent pacemakers improved the quality of life involving the health. No relevant differences in the modes of stimulations were seen, although the DDD mode recorded a better mood among the patients.

In a cross-sectional study by Aydemir et al. [11] examined the psychological aspect of the quality of life of 84 patients with a pacemaker. The symptoms of depression were determined by the Modified Hamilton Depression Rating Scale (mHDRS). Nine patients were diagnosed with a clinical depression (mHDRS $\geq$ 17) with an average score 7,57 $\pm$ 7,46. The worsening of depressive symptoms was higher among women. Other symptoms included: work problems (53,6%), mental unrest (48,8%), loss of energy (42,9%) and hypochondria and insomnia (39,3%).

Lamas et al. [12] compared the DDDR stimulation (atrial and ventricular pacing, atrial and ventricular sensing, dual response, rate-adaptive) for dual-chamber pacemakers and VVIR (ventricular pacing, ventricular sensing, inhibition response, rate-adaptive) for ventricular pacemakers. The study involved 407 patients over 65 who required constant pacemaker to prevent or treat bradycardia. Patients who had congestive heart failure at the time of implantation or atrial fibrillation without documented sinusitis for more than six months were excluded from the study. The quality of life was assessed via Short-Form General Health (SF-36). General evaluation of the patients' health was made before the implantation and 3, 9 and 18 months after the procedure. After 3 months a significant improvement in the quality of life was observed. .There were no relevant differences in the results between DDDR and VVIR after 3 and 18 months. After 9 months of observations, a better state of mental health was observed among the patients stimulated with DDDR. There have been visible benefits from DDDR stimulation among the patients with a sinus node dysfunction.

Duru et al. [13] conducted a cross-sectional study in the psychosocial adaptation, quality of life and the frequency of schizo-affective occurrences in a group of patients with pacemakers and implantable defibrillators. They have examined 210 patients aged from 40 to 70, who have undergone an implantation of a pacemaker (n = 124) or ICD (n = 86) between 1993 and 1999. Time that passed from the implantation was 3,1 years in the subgroup with pacemakers and 2,3 years for the ICD subgroup. The researchers used the Short-Form General Health (SF-36) as a research tool. There has been no difference between the three groups (with a pacemaker, ICD with and without shocks) in relation to the results in all aspects of SF-36.

Major depressive disorders (HAD> 10) were observed in 5,2%, 6,5% i 6,6% of patients respectively. A slightly lower frequency applied for anxiety-based disorders (HAD> 10) - 13,1%, 9,7%, 13,3% respectively. The results of physical and psychological components were comparable in all three groups.

Young et al. [14] qualified to their randomized controlled clinical trial 369 patients with implanted CRT and ICD devices. The quality of life was measured in a Minnesota Living with Heart Failure (MLHFQ) questionnaire. The measurements were made after 1, 3 and 6 months. The improvement was observed in both groups.

Kamphuis et al. [15] examined 167 patients after cardiac arrest (patients with ICD are n=132). The patients filled four questionnaires: RAND-36, Heart Patient Psychological Questionnaire (HPPQ), State–Trait Anxiety Inventory (STAI) and Centre for Epidemiologic Studies Depression Scale (CES-D) shortly after the admission and 1, 6 and 12 months after the implantation. The research subjects were divided into four groups on the basis of the number of electric shocks. HPPQ didn't disclose any differences between the groups. However, with time there has been a decrease in the well-being of all groups (P <0,001) and an improvement in the disability-related responses. (P <0,001). The mental health, anxiety and depressive disorders didn't significantly change in either group.

A prospective study TOVA (Triggers of Ventricular Arrhythmias) carried out by Whang et al. [16] examined 645 patients with ICD. The data was gathered in 31 facilities in the United States. The patients completed the Centres for Epidemiologic Studies Depression (CES-D) scale. The overall quality of life and the mental well-being of patients with an implantable cardioverter–defibrillator have not changed no matter if they experienced electric shocks. However, the patients with ICD who were defibrillated do not adapt well to life with this device and they are more anxious than patients with ICD who weren't.

A cross-sectional study by Leosdottir et al. [17] focused on the comparison of the quality of life of Islanders after the ICD implantation (n=44) with randomly selected patients with a pacemaker (n=81). Mental disorders and anxiety and depressive symptoms were measured by Icelandic Quality of Life Questionnaire (IQL), the General Health Questionnaire (GHQ), the Beck Anxiety Inventory (BAI), and the Beck Depression Inventory (BDI). The examined groups did not differ in terms of the quality of life, anxiety level, depression and overall mental health. Patients with ICD were more in fear of death and were more concerned about malfunctions of the device, return to work and driving a car.

Newall et al. [18] examined the New Zealand population in terms of the quality of life. The group consisted of 46 patients with an implantable cardioverter – defibrillator and 49 with a pacemaker. The Hospital Anxiety and Depression Scale (HADS) and the SF-36 questionnaire were the main research tools. The researchers observe a high level of satisfaction and low level of clinical depression and anxiety in the group with ICD. Patients with ICD thoughts about their devices more often than patients with a pacemaker.

Młynarski et al. [19] examined the changes that occur in the quality of life of patients six months after the DDDR implantation. 198 patients were included in the study, 98 with atrioventricular blocks and 100 with sinus node dysfunction. The average age of the patients was 71,3. For the QOL assessment the Minnesota Living with Heart Failure (MLWHF) questionnaire was used. The researchers noticed a statistical improvement in the quality of life in all its aspects apart from one - "the anxiety and depression among the patients with atrioventricular blocks.

In a controlled study Uchmanowicz et al. [20] examined 100 patients (women n = 47, men n = 53) after the implantation of a pacemaker. The average age of the women taking part in the study was 61.8, men - 63.8. The control group consisted of 58 patients qualified for the procedure of pacemaker implantation. The quality of life was measured with the use of a standard MacNew Heart Disease Heath Related Quality of Life Questionnaire (MacNew). In terms of mental aspects the average quality of life (n = 100) was 5,348 ± 0,92. The result of the control group (n = 50) was 4,196 ± 0,85, with p = 0,000000. In the psychical domain the patients after implantation received the quality of life of 5,379 ± 1,01, and those from the control group - 3,516 ± 1,05, with p = 0,000000. In the social domain, the patients after the implantation reached the level of quality of life of 5,550 ± 0,99, and the patients the procedure of pacemaker implantation – 3,692 ± 1,08, with p = 0,000000. The researchers have observed a higher quality of life in people who have undergone pacemaker implantation.

Conclusions

In the article the literature dedicated to the quality of life of patients with implanted devices for permanent cardiac pacing. In the earliest publications the numbers of participants were very low and thus the results may have been uncertain. However, more recent publications have a sufficient number of participants to formulate general conclusions on the quality of life in the overall study population. The quality of life after implantation has improved significantly.

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