

Changes in the mental and physical components of the quality of life for patients six months after pacemaker implantation

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Abstract

Background: *The additional purpose for pacemaker implantation, beyond treating arrhythmias and conduction disturbances, is to improve the quality of life (QoL) of the patient. Most previous research has shown this purpose to have been achieved. However, the question as to whether all mental and physical components improve QoL to the same degree is still valid. The purpose of this study is to evaluate changes in the primary mental and physical areas of QoL in patients six months after they have had a pacemaker implanted.*

Methods: *Ninety eight patients with atrioventricular blocks (AVB) and 100 patients with sinus node dysfunction (SND) who were qualified for pacemaker implantation were included in this study. Every patient had a DDD(R)-type pacemaker with bipolar screw-in leads implanted. The ventricular lead was positioned in the right ventricular outflow tract. QoL was evaluated twice: three to five days before implantation and six months afterwards — the MLWHF questionnaire was used.*

Results: *A very high statistical improvement in QoL ($p \sim 0,0000$) — reduced number of points was found in all five areas of QoL in patients with SND and in four areas in patients with AVB. In the ‘anxiety/depression area’ in patients with AVB, the average number of points was higher ($p = 0.3871$), so QoL was worse.*

Conclusions: *Implanting a pacemaker improves QoL in patients with AVB and SND. In patients with AVB, anxiety/depression is made more intense. (Cardiol J 2009; 16, 3: 250–253)*

Key words: quality of life, pacing, atrioventricular blocks, sinus node dysfunction

Introduction

Since the implantation of the first cardiac pacemaker in 1958 by Ake Sening and Rune Elmquist, there has been significant progress in this field of medicine, including both the range of equipment and the techniques of implantation [1, 2]. Most research has shown these technologies can improve a patient’s health [3, 4]. Unfortunately, a huge number of factors can interfere with the final results of

implantation (for instance, support of family and friends, level of education, knowledge about procedure). Doctors can too often see patients only as clinical problems. But the psychological component of recovery is also very important. Emotional disorders, as a reaction of a patient to a somatic illness, can be an independent factor of the disease [5]. There has been some research that has evaluated the emotions of patients with implants, most looking at what is known as quality of life (QoL) [6, 7]. Most

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Table 1. Characteristics of patients included in the study.

	SND	AVB
Number of patients	98	100
Men	43 (44%)	59 (59%)
Women	55 (56%)	41 (41%)
Etiology		
Ischemic	28 (28.6%)	42 (42%)
Post infarction	26 (26.5%)	10 (10%)
Hypertension	15 (15.3%)	23 (23%)
Congenital	8 (8.2%)	2 (2%)
Idiopathic	15 (15.3%)	1 (1%)
Unspecified	6 (6.1%)	22 (22%)
Treatment		
Beta-blockers	58 (59.2%)	55 (55%)
ACE inhibitors	79 (80.6%)	67 (67%)
Diuretic drugs	40 (40.8%)	33 (33%)
Glycosides	16 (16.3%)	17 (17%)
Follow-up		
After-implantation complications	–	1 (1%)
Cardiological hospitalization	3 (3.1%)	9 (9%)
General hospitalization	13 (13.3%)	11 (11%)
Stroke	–	–
Death	–	–

SND — sinus node dysfunction; AVB — atrioventricular blocks

previous research has shown that this goal was attained, but the question ‘Do all mental and physical components improve QoL to a similar degree?’ is still valid. The purpose of this study was to evaluate changes in five main mental and physical areas of QoL in patients six months after they had a pacemaker implanted.

Methods

Ninety eight patients with atrioventricular blocks (AVB) and 100 patients with sinus node dysfunction (SND) who were qualified for pacemaker implantation (aged 71.3 ± 8.7) were included in this study (bioethical agreement no. NN-6501-23/05 was obtained). The basic characteristics of the patients are presented in Table 1. Optimal pharmacological treatment of existing heart disease was confirmed in all patients. We excluded patients with:

- a previously implanted pacemaker;
- chronotropic incompetence;
- both AVB and SND;
- persistent atrial fibrillation;
- severe heart failure (NYHA III or IV);

— other serious illnesses (such as cancer) that could interfere with the results of QoL.

A DDD(R)-type pacemaker with bipolar screw-in leads was implanted in each patient. The ventricular lead was positioned in the right ventricular outflow tract (87.4%). Due to technical problems or unacceptable electric parameters, the right ventricular lead was implanted into the interventricular septum (10.1%) or apex (5.2%) in the rest of the patients. The atrial lead was implanted in all patients into the auricle of the right atrium. None of the special functions for the pacemaker model was activated. AV delay was optimized four days after implantation. QoL was evaluated twice: three to five days before implantation and six months later. The Minnesota Living With Heart Failure (MLWHF) questionnaire was used to evaluate QoL. This questionnaire in essence measures the patient’s perceptions of the effects of congestive heart failure on their lives. But due to the similarity of the symptoms of heart failure to those associated with heart rhythm disorders, we decided to use it in the research presented here. So, this 21-question questionnaire featured a further five questions about five basic areas of life. Some of the 21 questions proved too difficult for our patients (average ages 71.3). Complete answers were obtained only to the five questions evaluating how they felt in the following areas: mobility, self-service, every day activity, pain and anxiety/depression.

Statistical analysis

The Shapiro-Wilk test was used to check for normality. For the statistical comparison of the results before and after pacemaker implantation, the Wilcoxon test was used. Differences between the group with AVB and the group with SND was tested using the Mann-Whitney test. $P < 0.05$ was recognized as statistically significant

Results

Summarized results in the five main areas of QoL in patients with AVB and SND (independently) are presented in Table 2. Values are presented as median \pm standard deviation (SD). The higher the number of points, the lower the quality of life. It can be seen that patients with AVB analyzed in this study presented a more pronounced distortion in all five areas of QoL when compared to the SND group. Statistical improvement in QoL was found in all areas of life, except one — the ‘anxiety and depression’ area in patients with AVB. In those patients, we found average worsening of the level

Table 2. Average results in quality of life before/after implantation in five main areas of quality of life in patients with atrioventricular blocks and sinus node dysfunction.

	Sinus node dysfunction		p Wilcoxon	Atrioventricular blocks		p Wilcoxon
	Before (X ¹ ± SD)	After (X ¹ ± SD)		Before (X ¹ ± SD)	After (X ¹ ± SD)	
Mobility	0.70 ± 0.62	0.25 ± 0.25	↓0.0000	0.91 ± 0.59	0.57 ± 0.63	↓0.0002
Self-service	0.54 ± 0.62	0.23 ± 0.30	↓0.0000	0.98 ± 0.67	0.56 ± 0.67	↓0.0000
Every day activity	0.96 ± 0.74	0.46 ± 0.50	↓0.0000	1.06 ± 0.78	0.59 ± 0.62	↓0.0000
Pain	1.30 ± 0.71	0.61 ± 0.81	↓0.0000	1.30 ± 0.77	0.80 ± 0.59	↓0.0000
Anxiety/depression	1.03 ± 0.83	0.51 ± 0.50	↓0.0000	1.02 ± 0.76	1.04 ± 0.74	↑ 0.3871

¹arithmetical mean in points (range 0–2), a lower value in points means higher physical/emotional state of the patient

Table 3. Comparison of the quality of life between the groups with atrioventricular blocks (AVB) and sinus node dysfunction (SND).

	Before (X ¹ ± SD)		p Mann-Whitney	After (X ¹ ± SD)		p Mann-Whitney
	SND	AVB		SND	AVB	
Mobility	0.70 ± 0.62	0.91 ± 0.59	↑ 0.0161	0.25 ± 0.25	0.57 ± 0.63	↑ 0.0001
Self-service	0.54 ± 0.62	0.98 ± 0.67	↑ 0.0000	0.23 ± 0.30	0.56 ± 0.67	↑ 0.0000
Every day activity	0.96 ± 0.74	1.06 ± 0.78	↑0.1620	0.46 ± 0.50	0.59 ± 0.62	↑ 0.0448
Pain	1.30 ± 0.71	1.30 ± 0.77	~0.4989	0.61 ± 0.81	0.80 ± 0.59	↑ 0.0129
Anxiety/depression	1.03 ± 0.83	1.02 ± 0.76	↓0.4567	0.51 ± 0.50	1.04 ± 0.74	↑ 0.0000

¹arithmetical mean in points (range 0–2), a lower value in points means higher physical/emotional state of the patient

of anxiety and/or depression. Additional comparison between groups with AVB and SND was also performed. The results are presented in Table 3. The values relating to anxiety and depression before implantation were similar in both analyzed groups. A significant difference was observed in the values after implantation.

Discussion

Over the last 20 years, the results of several, international, multi-center clinical trials in which one of the purposes was quality of life evaluation after implantation of a pacemaker, have been published. In most, QoL as experienced by patients with different types of pacing was evaluated. The Canadian Trial of Physiologic Pacing (CTOPP) trial was one of the larger investigations of this type. This was a randomized investigation that compared atrial-based pacing (AAIR or DDDR) to ventricular pacing (VVIR). During three years of follow-up, a significant reduction for DDDR was obtained in the quantity of atrial fibrillation exclusively, but this was connected with a higher number of complications [8]. The quality of life was estimated

using SF-36 and SF-6 questionnaires; in all areas no significant improvement was noted [6]. Mode Selection Trial in Sinus Node Dysfunction (MOST) was the second largest trial in which improvements in the quality of life in patients with DDD pacemakers were proven. The results of the MOST trial, as well as international guidelines, were the theoretical basis for the research presented here. For this reason, DDD pacemakers were implanted in all patients included in this study [9].

The main aim of this research was to answer the question: ‘Has QoL changed after six months of follow-up, and if so, in which areas?’ in two separate groups of patients, when the process of implantation, the programming of the devices and the cardiological treatment have been similar. In line with our hypothesis, QoL statistically improved in both groups, with one exception: anxiety and depression in the group with atrioventricular blocks. In our opinion, the results obtained can be explained by the fact that symptoms before implantation are usually more intense in this group and patients usually know about total ‘dependence’ on the pacemaker after implantation. Therefore, we think that implantation of a pacemaker does not remove anxiety but

may sometimes intensify it. This is proven by the results presented, which permit a practical conclusion to be drawn, in addition to one hypothesis:

- patients with AVB should be educated more carefully about life with a pacemaker;
- psychotherapy may be a useful method of support of these patients [10].

The results we present are generally consistent with the results of major trials such as MOST and CTOPP [9, 10]. A few studies, such as Stofmeel et al., have used a modified SF-36 questionnaire for patients with implanted pacemakers. This questionnaire is known as 'Aquarel'. All these studies have confirmed an improved quality of life in the groups studied [6, 7, 11–13]. Unfortunately, not all studies show such uniform conclusions: an example is the results of the trial WHERE [14]. However, it is difficult to compare these studies, mostly due to the fact that different QoL questionnaires were used.

Anxiety and depression are very common in patients who have been in hospital and this is connected with their somatic diseases. They can be seen especially strongly in patients whose disease might have very serious, unforeseeable problems. Our research proves that this phenomenon is also associated with patients with implanted pacemakers.

Limitations of the study

In the research presented here, we used the MLWHF questionnaire, which is not officially designed for patients after pacemaker implantation. Only one questionnaire (Aquarel) is designed for this group, but there are no validated national versions of it available. The large number of QoL tools makes it difficult to compare results with other studies. Another limitation to our study was the brief period of follow-up (six months). We aim to continue the presented research.

Conclusions

Implanting a DDD pacemaker improves the quality of life in patients with AV blocks and in patients with Sinus Node Dysfunction. Patients qualified for implantation due to AVB showed more

pronounced (not statistically significant) emotional problems, presenting as higher levels of anxiety and depression.

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