Folia Cardiologica 2019
tom 14, nr 1, strony 1–12
DOI: 10.5603/FC.2019.0005

ISSN 2353–7752

Factors determining the quality of life after pacemaker implantation

Czynniki warunkujące jakość życia po implantacji kardiostymulatora

Marcin Kostkiewicz[1], Agnieszka Kostkiewicz[2], Barbara Ostafińska-Molik[3], Magdalena Kostkiewicz[4]

[1]Department of Cardiology, District Multispecialty Hospital No. 2, Rzeszow, Poland
[2]Department of Radiology and Diagnostic Imaging, District Multispecialty Hospital No. 2, Rzeszow, Poland
[3]Jagiellonian University, Institute of Education, Krakow, Poland
[4]Department of Cardiac and Vascular Diseases, Jagiellonian University, Collegium Medicum, Hospital John Paul II, Krakow, Poland

Abstract

Introduction. Health-related quality of life (HRQoL) after pacemaker (PM) implantation has been studied according to stimulation mode and indications, however these do not fully explain HRQoL changes. Aim of the study is to evaluate other factors.

Materials and methods. Single-center, prospective, observational study on 101 adult PM-recipients, with no periprocedural complications was performed. The study group was surveyed twice: periprocedural and 18 month follow-up (FU). Nottingham Health Profile to evaluate general HRQoL was performed. 83 participants completed full study protocol. Comparative analysis (periprocedural vs. end-of-FU) was performed to measure relationship between HRQoL-change and gender, place of residence, disability level, physical activity, level of care and support, BMI, diet, percentage of atrial and ventricular pacing (Ap&Vp), symptoms associated with rhythm and conduction disorders, severity of coronary heart disease and heart failure.

Results. Total HRQoL improvement occurred for the rural residents, obese and Vp > 79%. The study group improved significantly in two HRQoL domains: emotional reactions (E.R.) and sleep disorders (S.D.). Analyzing specific HRQoL domains (energy, pain, E.R.S.D. social alienation, movement limitations) improved patients are: female, self-mobile, high level of care and support, eating habits — changers, without syncope and angina symptoms. Age and body mass index (BMI) were identified as factors changing HRQoL-improving domain.

Conclusions. The improvement of HRQoL after PM implantation seems to be mainly related to S.D. and E.R. Important factors influencing HRQoL change are: place of residence, BMI and Vp. This impact of PM implantation on HRQoL requires further study

Key words: health-related quality of life, HRQoL, pacemaker, QoL, NHP

Folia Cardiologica 2019; 14, 1: 1–12

Address for correspondence: dr n. med. Marcin Kostkiewicz Klinika Kardiologii z Pododdziałem Ostrych Zespołów Wieńcowych, Kliniczny Szpital Wojewódzki nr 2 im. św. Jadwigi Królowej w Rzeszowie, ul Lwowska 60, 35–330 Rzeszów, Poland, e-mail: mkostkiewicz@o2.pl

Introduction

Increasingly more often we depart from purely biological approach to human health and assume a multifaceted point of view, where particular attention is focused on patient's emotions, wellbeing and everyday functioning. Health defined in these terms may be considered a fundamental determinant of the health-related quality of life (HRQoL) [1–3].

While numerous studies have been performed in patients with implanted pacemakers with regard to the stimulation mode and indications for pacing, little is known about other aspects influencing the HRQoL of patients who require constant cardiac pacing [1–9]. This study focuses on search for those factors.

Material and methods

The study included 101 consecutive adult patients (46 men, 55 women) aged 42 to 93 years (mean age 74.3 years) who had been admitted to the Cardiology Department of the 2nd Provincial Hospital in Rzeszow. Patients underwent implantation of a cardiac pacemaker according to the current ESC guidelines. Procedures were free of complications and involved placement of an endocavitary electrode in the right ventricular apex and/or left atrial auricle.

Exclusion criteria were as follows:

— mental disorders leading to non-compliance;
— difficulties communicating (significant hearing impairment, severe psychosomatic disorder);

Table 1. A compilation of the number of cardiac pacemaker types together with indications for implantation in study group A

Indications for implantation	Pacemaker type			
	AAI	VVI	VDD	DDD
Predominant heart rhythm: sinus rhythm				
SSS	6	–	–	33
AVB	–	5*	15	13
SSS + AVB	–	–	–	6
Trifascicular block accompanied by MAS	–	–	–	1
Predominant heart rhythm: atrial fibrillation or flutter				
Bradyarrhythmia	–	22	–	–
Total	6	27	15	53

Table 2. Study group characteristics depending on age, sex, place of residence and education*

	Women	Men	Total
		N (%)	
Study group	55 (54.5%)	46 (45.5%)	101 (100.0%)
Place of residence:			
• rural	36 (35.6%)	21(20.8%)	57 (56.4%)
• municipal	19 (18.8%)	25 (24.8%)	44 (43.6%)
Education:			
• incomplete primary	9 (8.9%)	1 (1.0%)	10 (9.9%)
• primary	31 (30.7%)	15 (14.9%)	46 (45.5%)
• vocational	7 (6.9%)	11 (10.9%)	18 (17.8%)
• secondary	6 (5.9%)	10 (9.9%)	16 (15.8%)
• tertiary	1 (1.0%)	7 (6.9%)	8 (7.9%)
• **no data**	**1 (1.0%)**	**2 (2.0%)**	**3 (3.0%)**
Age		M (SD), (min–max)	
	76.0 (8.04), (53–93)	72.3 (10.81), (42–89)	74.3 (9.53), (4–93)

*Due to group characteristics, percentage values are presented for the whole group; N — number; M — mean; SD — standard deviation

Table 3. Study group characteristics depending on subjective perception of disability, physical activity, as well as level of care and support in everyday life

Patient characteristics	N	Percentage (%)
Level of disability		
Bedbound	1	1.0
Sitting up	3	3.1
Walking with aid	16	16.3
Walking independently	78	79.6
Total	98	100.0
Level of physical activity		
Normal	70	71.4
Slightly limited	17	17.3
Significantly limited	11	11.2
Total	98	100.0
Level of care and support		
High	76	80.0
Moderate	12	12.6
Low	7	7.4
Total	95	100.0

N — number of patients

Table 4. Study group characteristics depending on body mass index (BMI)

BMI [kg/m^2]	N	Percentage (%)
≤ 18 — underweight	0	0.0
18–25 — normal body mass	24	24.5
25–30 — overweight	33	33.7
≥ 30 — obesity	41	41.8

N — number of patients

— recently diagnosed illness that is not directly associated with arrhythmia or conduction disturbances, but might impact HRQoL:
  - unstable angina,
  - acute myocardial infarction,
  - coronary revascularization during the last 3 months;
— acute stroke
— predicted survival < 1.5 years
— active cancer;
— advanced heart failure (New York Heart Association [NYHA] III or IV);
— lack of patient's consent to participation in the study

Table 1 presents the types of implanted cardiac pacemakers and indications for their implantation. Table 2–4 present the characteristics of the study group.

After implantation, the pacemaker was programmed depending on clinical characteristics of a patient, *i.a.* by activating algorithms that reduce ventricular stimulation, and the patient was followed up for 1.5 years with regular outpatient visits (Figure 1).

Follow-up schedule could be modified as needed. Patients were free to choose a physician in general practice and specialist outpatient clinic. The attending physician was not informed of the follow-up and was free to make decisions regarding optimal pharmacotherapy and pacemaker settings.

Patients filled out two surveys at the beginning and at the end of follow-up: our own questionnaire and Nottingham Health Profile (NHP) assessing HRQoL.

All comparative analyses (evaluation at the time of the procedure vs. at the end of follow-up) were performed on a group of 83 patients who completed the necessary questionnaires twice (Figures 1, 2).

Acquired data were used to analyze the change in HRQoL after pacemaker implantation and to evaluate the relationship between observed changes and sex, age, place of residence, level of disability, level of care and

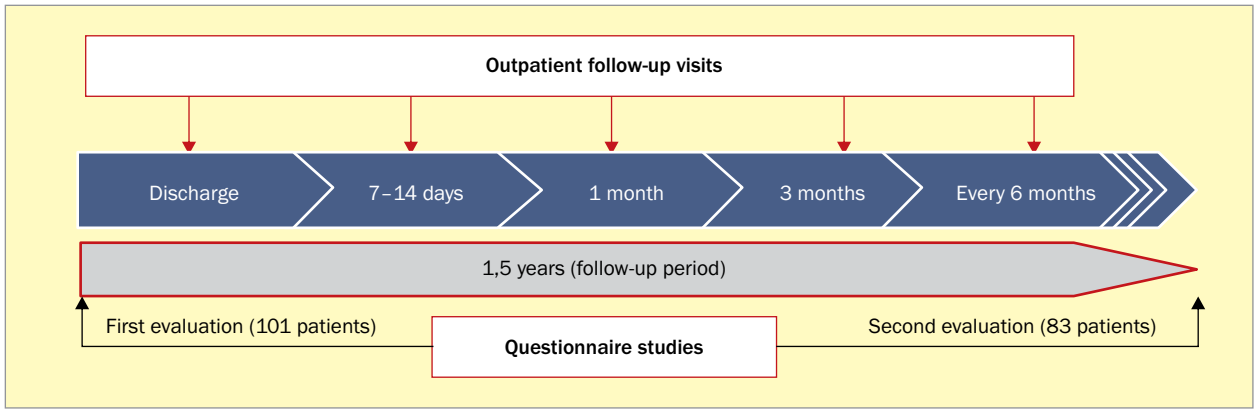

Figure 1. Timetable of follow-up visits and questionnaire studies

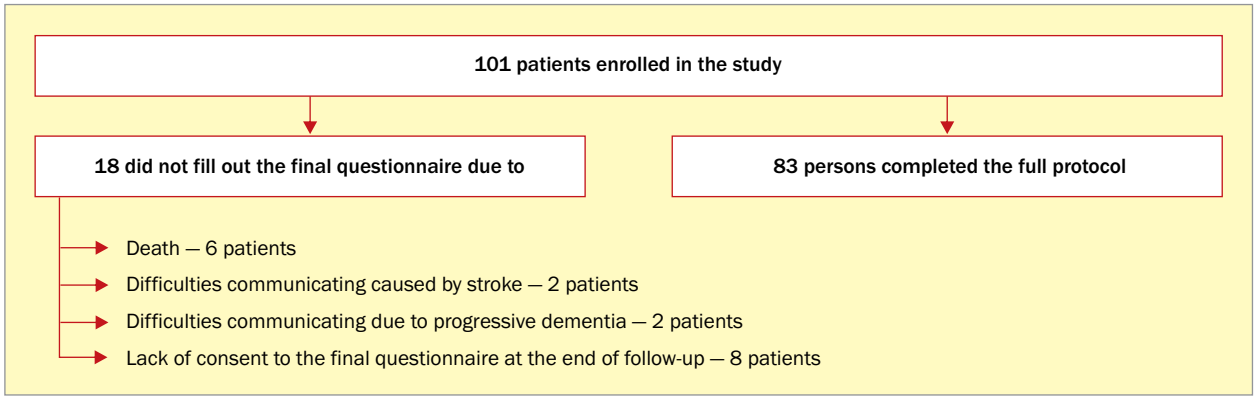

Figure 2. Flowchart of questionnaire studies

social support, BMI, physical activity, diet, percentage of ventricular and atrial stimulation, symptoms associated with arrhythmia and conduction disturbances, as well as the severity of ischemic heart disease and heart failure.

SPSSv.21.0 software for Windows was used to conduct the statistical analysis of the acquired material. After checking for normality of distribution we employed statistical significance (mainly parametric) tests: Student's *t*-test for dependent variables, ANOVA analysis of variance for more than two groups, Student's *t*-test for independent variables, Wilcoxon's test, Kruskal-Wallis test, Pearson's R correlation coefficient, and Spearman's Rho.

Beside significance analysis, we also determined (only for statistically significant tests) the effect size — so-called Cohen's d for independent variables and Hedges g for dependent variables. Value below 0.2 may be considered statistically insignificant, effect size between 0.2 and 0.49 corresponds to a small change, 0.5–0.79 — intermediate, and above 0.8 — large (strong effect).

Changes in HRQoL are presented as differences of mean measurements performed with an NHP questionnaire for consecutive HRQoL domains, according to the following equation:

difference in means (X) = (mean value measured in perioperative period) – (mean value measured at the end of follow-up)

where: X > 0 signifies improvement in HRQoL, and X < 0 — worsening of HRQoL.

We checked whether and how selected factors influence change in HRQoL.

Results

The following results were obtained (Table 5). It was shown in the study group that improvement in HRQoL after pacemaker implantation involves mainly sleep disorders (S.D.) and emotional reactions (E.R.).

We demonstrated a relationship between change in HRQoL and place of residence, BMI, and percentage of ventricular stimulation.

Also, significant changes in specific HRQoL domains were shown depending on sex, level of disability, physical activity, social care and support, change of nutritional habits after the procedure, and symptoms associated with arrhythmia and conduction disorders, as well as with symptoms of angina.

Moreover, age, BMI, level of physical activity and NYHA class were identified as parameters influencing the HRQoL domain that changed after the procedure.

Discussion

Numerous clinical studies analyzed the HRQoL of patients subject to constant cardiac pacing [4–9, 10–16].

Improvement in HRQoL after pacemaker implantation was demonstrated, *i.a.* in PASE [4], CTOPP [5], and FOLLOWPACE [17] trials and its relationship with the stimulation mode was disproven in those studies [4, 5, 18] even when indications for pacing (atrioventricular block vs. SSS) were taken into consideration [6]. However, opposite results were also reported [4, 19, 20]. In the face of such a large number of studies examining the above-mentioned associations, our study focused on search for factors other than stimulation mode and indications for pacing that might influence HRQoL after pacemaker implantation.

Such studies are rare. FOLLOWPACE was the largest study of this kind, showing that improvement in HRQoL depends mainly on periprocedural HRQoL, patient age, cardiological comorbidities, and atrial fibrillation with bradycardia as an indication for cardiac pacing.

In the above study, factors that might potentially modulate HRQoL were selected and their true impact on HRQoL was examined after pacemaker implantation. We assumed similar approach in our own study [21], demonstrating an association between change in HRQoL after pacemaker

Table 5. Results

Study group		Category	Total	Sex		Place of residence		Age			
HRQoL		Study group	Entire study group	Women	Men	Municipal	Rural	< 70	70 –75	76–80	> 80
		N	83	44	39	37	46	20	18	24	21
	Energy	X	−0.012	0.182	−0.230	−0.243	0.174	−0.200	0.055	0.083	0.000
		P	0.919 (NS)	0.281 (NS)	0.163 (NS)	0.173 (NS)	0.272 (NS)	0.428	0.805	0.732	1.000
		Effect size	–	–	–	–	–				
	Pain	x	0.205	0.386	0.000	−0.784	1.000	0.900	0.111	−0.458	0.380
		p	0.439 (NS)	0.345 (NS)	1.000 (NS)	**0.057**	**0.002**	0.074	0.819	0.347	0.555
		Effect size	–	–	–	–	**0.48**				
	Emotional reaction	x	0.493	0.954	−0.025	−0.243	1.087	0.050	−0.388	0.916	1.19
		p	**0.054**	**0.012**	0.939 (NS)	0.456 (NS)	**0.004**	0.908	0.510	0.084	**0.018**
		Effect size	g = 0.21	g = 0.39	–	–	**0.45**				g = 0.56
	Sleep disorders	x	0.663	0.568	0.769	0.027	1.174	0.850	1.000	0.375	0.523
		p	**0.001**	0.026	**0.010**	0.917 (NS)	**0.000**	0.070	**0.015**	0.334	0.077
		Effect size	**g = 0.4**	**0.35**	**0.43**	–	**0.72**		**g = 0.64**		
	Social alienation	x	0.072	0.204	−0.076	−0.189	0.283	0.050	−0.222	0.041	0.380
		p	0.636 (NS)	0.408 (NS)	0.653 (NS)	0.314 (NS)	0.221 (NS)	0.815	0.298	0.903	0.329
		Effect size	–	–	–	–	–				
	Limitation of mobility	x	−0.241	−0.136	−0.359	−0.648	0.087	0.050	−0.277	−0.416	−0.285
		p	0.249 (NS)	0.668 (NS)	0.181 (NS)	**0.045**	0.749 (NS)	0.883	0.544	0.399	0.444
		Effect size	–	–	–	**0.34**	–				
	Total HRQoL	x	1.180	2.159	0.077	−2.081	3.804	1.700	0.277	0.541	2.190
		p	0.122 (NS)	**0.069**	0.934 (NS)	**0.028**	**0.000**	0.165	0.860	0.732	0.215
		Effect size	–	–	–	**0.37**	**0.56**				

cont. →

	Diet — 29		Level of physical activity (study group: 80, no data: 3)		BMI			Level of care and social support (study group: 78. no data: 5)			Level of disability (study group: 81. no data: 2)	
Yes. After implantation only	Yes. Before implantation only	Yes. Before and after implantation	Lack of physical activity	Physical activity	Normal BMI	Overweight	Obesity	High	Intermediate	Low	Walks independently	Does not walk independently
10	11	33	10	70	18	27	38	62	10	6	67	14
–0.069	–0.113	–0.090	–0.134	0.193	–0.416	–0.031	0.128	0.000	–0.100	0.000	0.000	0.000
0.680	0.430	0.598	0.375	0.311	0.269	0.876	0.418	1.000	0.678	1.000	1.000	1.000
0.046	0.363	0.212	0.326	0.000	–0.166	–0.625	1.000	0.225	–0.100	1.166	0.298	–0.181
0.891	0.292	0.594	0.371	1.000	0.795	0.108	0.015	0.431	0.915	0.504	0.316	0.837
							g = 0.40					
0.279	0.295	0.121	0.903	–0.193	–0.083	0.187	0.923	0.516	0.200	1.666	0.597	0.000
0.385	0.285	0.714	**0.010**	0.576	0.918	0.672	0.006	0.063	0.828	0.215	0.055	1.000
			g = 0.37				g = 0.47					
0.544	0.568	0.363	0.596	0.774	1.166	0.562	0.589	0.822	0.100	0.666	0.820	–0.272
0.050	**0.049**	0.254	0.018	**0.011**	**0.001**	**0.037**	0.076	**0.001**	0.853	0.102	**0.000**	0.192
g = 0.3	g = 0.3		g = 0.33	g = 0.49	g = 1.2	g = 0.38		g = 0.46			g = 0.47	
0.116	–0.045	0.000	0.057	0.096	0.083	–0.437	0.487	–0.032	0.600	0.333	0.104	–0.363
0.535	0.793	1.000	0.769	0.698	0.674	**0.046**	0.060	0.837	0.329	0.750	0.514	0.531
						g = 0.36						
–0.488	0.045	–0.424	–0.038	–0.580	–1.083	–0.562	0.282	–0.354	0.300	0.000	–0.238	–0.818
0.098	0.887	0.232	0.889	0.068	0.071	0.071	0.368	0.134	0.671	1.000	0.288	0.203
0.418	1.204	0.181	1.711	0.290	–0.500	–1.031	3.512	1.112	1.000	3.833	1.582	–1.636
0.672	0.193	0.862	0.108	0.775	0.815	0.336	0.003	0.189	0.684	0.427	0.072	0.408
							g = 0.51					

cont. →

Severity of heart failure symptoms (study group: 76, no data: 6, dysfunction of the motor system that prevents assessment: 1)				Severity of ischaemic heart disease symptoms (study group: 77, no data: 6)				Symptoms associated with arrhythmia and conduction disorders			Percentage of ventricular stimulation (study group: 78, no data: 5)		
No symptoms	NYHA I	NYHA II	NYHA II/III	No symptoms	CCS 1	CCS 2	CCS 3	Syncope	Fainting	Other	0–35 >	< 35–79 >	< 79
33	14	14	15	55	9	9	4	26	29	28	46	9	23
0.090	0.090	–0.250	0.125	0.089	–0.666	–0.428	0.000	–0.038	0.034	–0.035	–0.051	0.100	0.071
0.628	0.839	0.495	0.802	0.501	0.184	0.289	1.000	0.852	0.873	0.861	0.793	0.591	0.702
0.636	–0.545	0.344	2.500	–0.074	0.333	1.000	3.250	0.423	0.310	–0.107	0.358	–0.500	0.285
0.139	0.380	0.127	**0.019**	0.774	0.667	0.559	0.061	0.378	0.498	0.816	0.335	0.596	0.438
			g = 0.9										
0.409	1.454	1.250	–0.125	0.552	1.333	–1.000	1.750	0.153	0.758	0.535	0.179	–0.100	1.464
0.465	0.091	**0.060**	0.815	**0.046**	0.057	0.420	0.340	0.748	0.082	0.225	0.578	0.832	**0.002**
				g = 0.25									g = 0.66
1.272	1.545	–1.50	0.000	0.701	1..333	0.000	1.250	0.153	0.862	0.928	0.615	0.000	1.178
0.001	**0.013**	**0.080**	1.000	**0.000**	0.057	1.000	0.342	0.678	**0.008**	**0.004**	0.076	1.000	**0.000**
g = 0.81	g = 0.91			g = 0.45					g = 0.52	g = 0.61			g = 0.75
–0.090	0.363	–0.750	–0.625	0.029	1.000	–0.285	1.000	0.307	–0.103	0.035	0.410	–0.700	0.000
0.680	0.307	1.000	0.095	0.862	0.225	0.457	0.391	0.266	0.712	0.885	0.061	0.111	1.000
–0.045	0.454	0.000	–0.125	–0.313	–2.000	0.000	1.250	–0.615	0.172	–0.321	–0.256	–0.800	0.142
0.896	0.424	0.391	0.815	0.173	0.225	1.000	0.141	0.069	0.672	0.344	0.409	0.196	0.684
2.272	3.363	–0.250	1.750	0.985	1.333	–0.714	8.500	0.384	1.896	1.178	1.358	–2.000	3.000
0.062	0.205	0.091	0.259	0.209	0.667	0.865	0.160	0.781	0.137	0.394	0.247	0.268	**0.017**
													g = 0.48

HYHA — New York Heart Association; CCS — Canadian Cardiovascular Society; BMI — body mass index; HRQoL — health-related quality of life; NS — not significant

implantation with place of residence, patient BMI and percentage of ventricular pacing.

Moreover, a detailed analysis of the study group showed that patients characterized by: female sex, residence in rural areas, ability to move independently, high level of care and social support, obesity, change in nutritional habits after the procedure, high percentage of cardiac pacing, symptoms of arrhythmia and conduction disorders other than syncope, and absence of angina symptoms, gain greater benefit with regard to specific HRQoL domains (energy, pain, E.R., S.D., social alienation, limitation of mobility).

Moreover, age and BMI were identified as factors influencing the HRQoL domain that changes after implantation.

Below, we discuss all of the above-mentioned factors and their association with change in HRQoL after pacemaker implantation.

High percentage of ventricular stimulation, obesity, and living in rural areas as main factors determining improvement in HRQoL after cardiac pacemaker implantation.

Percentage of ventricular stimulation. Percentage of stimulated atrial (Ap) and ventricular (Vp) QRS complexes derives from the condition of pacemaker and conduction system and cardiac pacemaker mode.

Few authors report the percentage of atrial and ventricular stimulation while discussing the results of their studies in patients after cardiac pacemaker implantation. There is no benefit in providing this information in the absence of data on pacemaker settings, as it cannot be determined whether the observed stimulation rate results from pacemaker's settings or the disease itself. Authors of the CTOPP [5] indicate that pacemaker dependency (defined as HR < 50/min), which might potentially result in higher percentage of stimulated QRS complexes, does not in fact lead to statistically significant differences in HRQoL between patients with different stimulation modes. In the analysis performed by Gribbin et al. [6] mean percentage of stimulated QRS complexes amounted to 64%. Authors reported also that 25% of patients presented with 100% Vp and 5% did not require pacing at all. In this study there was no association between Vp and HRQoL after pacemaker implantation. Hemel et al. [22] came to similar conclusions in their study, which demonstrated no association between percentage of QRS complexes generated at the preset stimulation rate (DDDR mode) and HRQoL. Interpretation of the results of above clinical trials regarding lack of impact of percentage of Vp on HRQoL is only seemingly straight-forward. It is generally known that manufacturers of cardiac pacemakers make their best effort to introduce more modern and increasingly effective algorithms to avoid unnecessary Vp. In short, there is little data on the influence of implantable pacemaker mode and the condition of physiological pacemaker and conduction system on the percentage of Vp.

It seems that the results of this study should be interpreted in this context. It showed positive correlation between percentage of Vp and improvement in HRQoL as well as a statistically significant change in HRQoL in the group of patients with percentage of Vp exceeding 79%. The improvement involved the following domains: E.R. and S.D. ($P < 0.01$), and was not observed among patients with lower stimulation rates.

Only statistically insignificant results were obtained for Ap (not included in the results table).

Obesity. The analyses of studies unrelated to pacemaker implantation showed that obesity negatively affects HRQoL by influencing physical capacity, sleep quality, mood, sexual life, ability to perform social roles and interactions [23].

No analyses on the change in HRQoL depending on the value of BMI have been performed to date.

In our study group we analyzed change in HRQoL among patients with normal BMI, overweight and obese. BMI influenced the HRQoL domain affected by the greatest change. Among patients with normal BMI the highest improvement was noted with regard to S.D. ($g = 1.2$). This change was less pronounced ($g = 0.36$), yet statistically significant ($p < 0.05$) among overweight patients. No statistically significant improvement in this domain was seen in the obese patients, although the observed change approached borderline statistical significance. There was, however, a statistically significant improvement with regard to pain and emotional reactions. It might be related to obstructive sleep apnea, the severity of which depends on BMI and significantly impairs the quality of sleep.

Living in rural areas. Different HRQoL change profiles were demonstrated for residents of rural vs. municipal areas. Patients living in rural regions gained clear benefit with regard to HRQoL following pacemaker implantation. Significantly better results were obtained for pain, E.R. and S.D. Residents of municipal areas experienced negative changes to their HRQoL after pacemaker implantation that included significant worsening of mobility and a trend toward greater perception of pain.

How should we interpret changes in HRQoL depending on the place of residence?

It appears that these changes might be related to a specific demographic status of the Sub-Carpathian region, which is dominated by small, agricultural settlements remote from large municipal agglomerations. Consequently, their inhabitants have limited access to specialist healthcare. Possibly, the effects of pacemaker implantation observed in residents of rural areas might be augmented due to compulsory visits to cardiology outpatient clinics required for pacemaker control resulting in better care for other healthcare issues, as well as due to improved level of family support. The results of

this analysis were somewhat surprising and will require further investigation.

Sex, age, NYHA class, level of disability, physical activity, social care and support, change in nutritional habits after implantation and symptoms associated with arrhythmia and conduction disorders, as well as the absence of symptoms of angina as factors influencing improvement in HRQoL with regard to S.D. and E.R.

Sex. Some studies [6, 18, 24] report an association between female sex and poorer HRQoL after pacemaker implantation; however, other study [19] did not report this relationship. There were no analyses showing worse HRQoL in men.

However, current analysis pertained to change in HRQoL after the procedure, not to its absolute levels. For the first time statistically significant results were demonstrated with regard to: significant improvement in the E.R. domain of HRQoL for females only, improvement in sleep quality in both sexes (greater effect in men).

Age. Literature data is equivocal: some researchers demonstrate less improvement in HRQoL after pacemaker implantation with age, while others show no differences in HRQoL levels among older and younger patients [6, 19, 20, 24].

The analysis of HRQoL results in our study group demonstrated improvement in sleep quality among patients aged 70 to 75 years and in emotional reactions among patients over 80 years of age. On that basis, age may be considered a modifying factor for HRQoL domain that will change after the procedure.

NYHA and Canadian Cardiovascular Society (CCS) class. There is no data on the influence of those factors on HRQoL change after pacemaker implantation. Obtained results show that NYHA class influences improvement in HRQoL domains, while the presence of symptoms of angina before implantation is associated with the lack of HRQoL improvement after pacemaker implantation.

Level of disability. The analysis of HRQoL change depending on the level of disability showed statistically significant reduction of S.D. among independently walking patients. This is the first publication to report such an association.

Level of care and social support. Caregivers play a great role in providing proper HRQoL. Some studies [25] indicate that patients who had been cared for by their spouses experience statistically significant improvement in HRQoL after cardiac pacemaker implantation compared to other patients.

It was shown that patients declaring high level of care and social support (defined as family care on a level that is expected by the patient) reported significant improvement in the domain of HRQoL related to S.D. after pacemaker implantation.

Physical activity. There are no analyses in the available literature regarding an association between physical activity and HRQoL among patients subject to constant cardiac pacing.

In our study, the analysis of HRQoL changes depending on declared physical activity showed improvement in the E.R. domain only among patients who had not previously declared physical activity. On the other hand, we noted greater improvement in sleep quality domain among patients declaring physical activity.

There were no significant changes in the assessment of global HRQoL. We observed, however, modification of HRQoL domains associated with physical activity.

One should keep in mind certain limitations of the above analysis — it was based on self-proclaimed intensity and regularity of physical activity reported by predominantly elderly patients. It was not always possible to verify this data through the family or caregivers. It may be the source of error due to underestimation or overestimation of the level of physical activity by the patient. Verification of those parameters is difficult, if not impossible. In fact, the very awareness that the analysis of physical activity is being performed may motivate change (*e.g.* increase in activity) followed by restoration of old habits after the end of the study.

Diet. No analyses have been found to date regarding HRQoL change depending on diet. The obtained results indicate improvement in the study group with regard to S.D. among patients declaring change in diet following pacemaker implantation.

This analysis may be prone to error due to a small number of patients declaring change in nutritional habits.

Symptoms associated with arrhythmia and conduction disorders. There were previous reports [19, 25] that perception of arrhythmia might be the main determinant of HRQoL both before and after pacemaker implantation.

In our study we analyzed the relationship between HRQoL and symptoms related to arrhythmia and conduction disorders. It was shown that sleep quality domain of HRQoL is significantly improved only among patients without Adams-Stokes syndrome.

Similar analyses were conducted by Benzer [19], although they involved a much smaller group of patients. Moreover, the data concerning symptoms were obtained indirectly from the European Pacemaker Patient Identification Card (in our study this data was collected from medical records and during detailed physical examination). Most importantly, patients identified by Benzer's as having "syncope and dizziness", constituted two separate groups in our study.

The lack of precise definition of a term "sensation of arrhythmia" (MAS, pre-MAS, other?) in the studies by Chen

and Chao [25] also made it difficult to compare between their results and that from our own study, where such a distinction — MAS, pre-MAS, other — was associated with great clinical value.

An unexpected result, such as lack of HRQoL improvement in patients after syncope, may be explained by the fact that syncopal episodes are treated more seriously by both patients and doctors, usually resulting in fast-track diagnostics and immediate pacemaker implantation in case of syncope of arrhythmic origin with indications for cardiac stimulation. It may be expected that in such cases HRQoL is not significantly affected due to a short time between syncope and pacemaker implantation; thus, the lower increase in the HRQoL after implantation. Patients suffering from other symptoms, which recur and lead to significant drop in HRQoL, take more time before undergoing diagnostics.

Also, it should be considered whether presyncope episodes or other unpleasant symptoms experienced with consciousness might affect HRQoL to a much greater extent than short-lasting episodes of loss of consciousness accompanied by retrograde amnesia, especially if they are not associated with a serious trauma.

Summary and limitation of the study

It is worth emphasizing that the study included consecutive patients undergoing pacemaker implantation regardless of age or indications for pacing, and general NHP questionnaire — the shortest, most transparent and intelligible for the patient — was used for HRQoL assessment [2]. It seemed to be the reason for such a high percentage of patients (82%) who completed the study.

This is the only analysis to include such a broad range of factors potentially influencing the HRQoL. Previous reports on the topic were very disappointing with regard to methodology, due to analyses limited to data contained in the European Pacemaker Patient Identification Card [19], or failure to include comorbidities other than cardiovascular [18].

One should keep in mind local sociodemographic and cultural factors while analyzing HRQoL. The strong correlation between HRQoL and place of residence or BMI may be related to the aforementioned factors and may not be observed in other regions of the country, while the relationship between HRQoL and percentage of ventricular pacing may result from methodology of the study.

Further analyses are necessary to elucidate these uncertainties.

Conclusions

Association between change in HRQoL after pacemaker implantation with place of residence, patient BMI and percentage of ventricular pacing has been demonstrated. It was shown in the study group that improvement in HRQoL after pacemaker implantation involves mainly sleep disorders and emotional reactions.

Conflict(s) of interest

The authors declare no conflict of interest.

Streszczenie

Wstęp. Jakość życia zależna od stanu zdrowia (HRQoL) po implantacji kardiostymulatora (PM) była przedmiotem wielu analiz, w których dominowała ocena zależności HRQoL od trybu stymulacji i wskazań do zabiegu. Czynniki te nie wyjaśniają jednak w pełni zmian HRQoL, co motywuje do poszukiwania innych uwarunkowań zmiany HRQoL po implantacji PM.

Materiał i metody. Przeprowadzono jednoośrodkowe, prospektywne badanie obserwacyjne u 101 dorosłych pacjentów, którym bez powikłań implantowano PM. Pacjentów ankietowano 2-krotnie — w okresie okołozabiegowym i na zakończenie 18-miesięcznej obserwacji (FU). Jakość życia zależną od stanu zdrowia oceniano za pomocą kwestionariusza *Nottingham Health Profile*. Pełen protokół badania ukończyło 83 pacjentów. W tej grupie przeprowadzono analizę porównawczą (okres okołozabiegowy *v.* FU) w celu pomiaru związku między zmianą HRQoL a: płcią, miejscem zamieszkania, poziomem niepełnosprawności, aktywnością fizyczną, poziomem opieki i wsparcia, wskaźnikiem masy ciała (BMI), dietą, odsetkiem stymulacji przedsionkowej i komorowej (Ap i Vp), objawami związanymi z zaburzeniami rytmu i przewodzenia, zaawansowaniem choroby wieńcowej i niewydolności serca.

Wyniki. Poprawa HRQoL po implantacji PM nastąpiła u mieszkańców wsi, osób otyłych i tych z Vp ponad 79%. W całej badanej grupie znaczną poprawę obserwowano w zakresie dwóch domen HRQoL — reakcji emocjonalnych (E.R.) i zaburzeń snu (S.D.). Analizując poszczególne domeny HRQoL (energia, ból, wyobcowanie społeczne, E.R.S.D. ograniczenia ruchowe), poprawę obserwowano u kobiet, osób zdolnych do samodzielnego poruszania się, osób z wysokim poziomem opieki i wsparcia, oraz tych, którzy po implantacji PM zmienili nawyki żywieniowe, a także tych, którzy nie doświadczyli omdlenia i dławicy piersiowej. Wiek i BMI zidentyfikowano jako czynniki zmieniające domenę HRQoL ulegającą poprawie po implantacji.

Wnioski. Poprawa HRQoL po implantacji PM wydaje się związana głównie z S.D. i E.R. Ważnymi czynnikami wpływającymi na zmianę HRQoL są miejsce zamieszkania, BMI i odsetek Vp. Wpływ implantacji PM na HRQoL wymaga dalszych badań.

Słowa kluczowe: jakość życia uwarunkowana stanem zdrowia, HRQoL, PM, QoL, NHP

Folia Cardiologica 2019; 14, 1: 1–12

References

1. Broda G. Jakość życia — ważny pomiar zdrowia. Kardiol Pol. 2009; 67(10): 1086–1087.
2. Wrześniewski K. Jak badać jakość życia pacjentów kardiologicznych? Kardiol Pol. 2009; 67(7): 790–794.
3. Kawecka-Jaszcz K, Klocek M, Tobiasz-Adamczyk B. Jakość życia w chorobach układu sercowo naczyniowego. Metody pomiaru i znaczenie kliniczne, Termedia Wydawnictwa Medyczne, Poznań 2006.
4. Lamas GA, Orav EJ, Stambler BS, et al. Quality of life and clinical outcomes in elderly patients treated with ventricular pacing as compared with dual-chamber pacing. Pacemaker Selection in the Elderly Investigators. N Engl J Med. 1998; 338(16): 1097–1104, doi: 10.1056/NEJM199804163381602, indexed in Pubmed: 9545357.
5. Newman D, Lau C, Tang ASL, et al. CTOPP Investigators. Effect of pacing mode on health-related quality of life in the Canadian Trial of Physiologic Pacing. Am Heart J. 2003; 145(3): 430–437, doi: 10.1067/mhj.2003.167, indexed in Pubmed: 12660665.
6. GRIBBIN G, KENNY R, MCCUE P, et al. Individualised quality of life after pacing. Does mode matter? Europace. 2004; 6(6): 552–560, doi: 10.1016/j.eupc.2004.07.011.
7. Linde-Edelstam C, Nordlander R, Unden AL, et al. Quality-of-life in patients treated with atrioventricular synchronous pacing compared to rate modulated ventricular pacing: a long-term, double-blind, crossover study. Pacing Clin Electrophysiol. 1992; 15(10): 1467–1476, doi: 10.1111/j.1540-8159.1992.tb02920.x.
8. Lau CP, Rushby J, Leigh-Jones M, et al. Symptomatology and quality of life in patients with rate-responsive pacemakers: a double-blind, randomized, crossover study. Clin Cardiol. 1989; 12(9): 505–512, indexed in Pubmed: 2791372.
9. Oto MA, Müderrisoglu H, Ozin MB, et al. Quality of life in patients with rate responsive pacemakers: a randomized, cross-over study. Pacing Clin Electrophysiol. 1991; 14(5 Pt 1): 800–806, indexed in Pubmed: 1712957.
10. Connolly SJ, Kerr CR, Gent M, et al. Effects of physiologic pacing versus ventricular pacing on the risk of stroke and death due to cardiovascular causes. Canadian Trial of Physiologic Pacing Investigators. N Engl J Med. 2000; 342(19): 1385–1391, doi: 10.1056/NEJM200005113421902, indexed in Pubmed: 10805823.
11. Lamas GA, Lee KL, Sweeney MO, et al. Mode Selection Trial in Sinus-Node Dysfunction. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction. N Engl J Med. 2002; 346(24): 1854–1862, doi: 10.1056/NEJMoa013040, indexed in Pubmed: 12063369.
12. Menozzi C, Brignole M, Moracchini PV, et al. Intrapatient comparison between chronic VVIR and DDD pacing in patients affected by high degree AV block without heart failure. Pacing Clin Electrophysiol. 1990; 13(12 Pt 2): 1816–1822, indexed in Pubmed: 1704547.
13. Hargreaves MR, Channon KM, Cripps TR, et al. Comparison of dual chamber and ventricular rate responsive pacing in patients over 75 with complete heart block. Heart. 1995; 74(4): 397–402, doi: 10.1136/hrt.74.4.397.
14. Linde-Edelstam C, Nordlander R, Pehrsson SK, et al. A double-blind study of submaximal exercise tolerance and variation in paced rate in atrial synchronous compared to activity sensor modulated ventricular pacing. Pacing Clin Electrophysiol . 1992; 15(6): 905–915, doi: 10.1111/j.1540-8159.1992.tb03081.x.
15. Oldroyd KG, Rae AP, Carter R, et al. Double blind crossover comparison of the effects of dual chamber pacing (DDD) and ventricular rate adaptive (VVIR) pacing on neuroendocrine variables, exercise performance, and symptoms in complete heart block. Heart. 1991; 65(4): 188–193, doi: 10.1136/hrt.65.4.188.
16. Deharo JC, Badier M, Thirion X, et al. A randomized, single-blind crossover comparison of the effects of chronic DDD and dual sensor VVIR pacing mode on quality-of-life and cardiopulmonary performance in complete heart block. Pacing Clin Electrophysiol. 1996; 19(9): 1320–1326, indexed in Pubmed: 8880795.
17. van Eck JW, van Hemel NM, van den Bos A, et al. Predictors of improved quality of life 1 year after pacemaker implantation. Am Heart J. 2008; 156(3): 491–497, doi: 10.1016/j.ahj.2008.04.029, indexed in Pubmed: 18760131.
18. Udo EO, van Hemel NM, Zuithoff NPA, et al. Long term quality-of-life in patients with bradycardia pacemaker implantation. Int J Cardiol. 2013; 168(3): 2159–2163, doi: 10.1016/j.ijcard.2013.01.253, indexed in Pubmed: 23453871.
19. Benzer W, Oldridge N, Anelli Monti M, et al. Clinical predictors of health-related quality of life after pacemaker implantation. Wien Klin

Wochenschr. 2006; 118(23-24): 739–743, doi: 10.1007/s00508-006-0714-y, indexed in Pubmed: 17186169.
20. Fleischmann KE, Orav EJ, Lamas GA, et al. Pacemaker implantation and quality of life in the Mode Selection Trial (MOST). Heart Rhythm. 2006; 3(6): 653–659, doi: 10.1016/j.hrthm.2006.02.1031, indexed in Pubmed: 16731465.
21. Kostkiewicz M. Odległa ocena kliniczna, elektrokardiograficzna oraz jakość życia pacjentów leczonych implantacją kardiostymulatora. Praca doktorska. Uniwersytet Jagielloński, Kraków 2013.
22. van Hemel NM, Holwerda K, Slegers P, et al. The contribution of rate adaptive pacing with single or dual sensors to health-related quality of life. EP Europace. 2007; 9(4): 233–238, doi: 10.1093/europace/eum021.
23. Kushner RF, Foster G. Obesity and quality of life. Nutrition. 2000; 16(10): 947–952, doi: 10.1016/s0899-9007(00)00404-4.
24. Oliveira BG, Velasquez-Melendez G, Rincón LG, et al. Health-related quality of life in Brazilian pacemaker patients. Pacing Clin Electrophysiol. 2008; 31(9): 1178–1183, doi: 10.1111/j.1540-8159.2008.01159.x, indexed in Pubmed: 18834470.
25. Chen HM, Chao YF. Change in quality of life in patients with permanent cardiac pacemakers: a six-month follow-up study. J Nurs Res. 2002; 10(2): 143–150, indexed in Pubmed: 12119599.