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Cognitive behavioral intervention improves quality of life and perceived illness acceptance in patients after cardiac electrotherapy devices implantation

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Summary

Aim. This study is an attempt to provide an analysis of the influence of implementation of cognitive behavioral intervention (CBI) in patients after cardiovascular implantable electronic device (CIED) implantation on the quality of life following the procedure as well as the level of illness acceptance.

Method. The study group consisted of patients who underwent standard medical care related to CIED implantation and who additionally received CBI. Patients who received only standard medical care related to CIED implantation constituted a control group. CBI consisted of four sessions conducted over 30 (±3) days after the implantation. Demographic, clinical and psychological factors were assessed. *The Acceptance of Illness Scale* (AIS) and EuroQol-5D (EQ-5D) were applied.

Results. In total, 128 patients (women: 36.7%, mean age 64.5 ± 8.9) were included in the study. The proposed cycle of four structured CBI meetings was well accepted by the patients, which is confirmed by their high turnout for these meetings. After six months, quality of life indices were significantly improved in cardiac electrotherapy recipients assigned to CBI, including: *Visual Analogue Scale* EQ-5D (80.2 ± 11.8 vs. 64.9 ± 14.3; $p < 0.0001$) and better acceptance of illness (AIS: 35.6 ± 4.3 vs. 28.7 ± 6.1; $p < 0.0001$).

Conclusions. Implementation of CBI in patients after CIED implantation significantly improved indices of quality of life as well as illness acceptance, when compared to the control group of patients in standard care following electrotherapy. CBI showed multiple benefits in this population, as well as ensures the fulfillment of its expected therapeutic effect, while short duration of the intervention did not prolong the hospitalization itself.

Key words: cognitive behavioral intervention, quality of life, acceptance of illness

Introduction

The development of medical technology has contributed to progress in cardiac arrhythmia and conduction disorders treatment, including a higher number of patients with cardiac implantable electronic devices worldwide, starting from the simplest pacemakers to implantable cardioverter-defibrillators. According to the latest available data of 2017, provided by the National Health Fund, in Poland almost 29,789 pacemakers (PCMs), 8,332 implantable cardioverter-defibrillators (ICDs) and 3,749 cardiac resynchronization therapy (CRT) devices with ICD were implanted [1]. Studies show that when it comes to a general evaluation, implantation of a device improves health-related quality of life, however, as many as approximately 35% of patients with PCM or ICD showed symptoms of general psychological distress [2, 3]. Simultaneously, studies comparing the incidence of anxiety and depressive symptoms in patients with PCM and ICD show that anxiety disorders occur in 13.1%, 9.7% and 13.3% of patients with PCM, ICD without shocks and ICD with shocks respectively. Depressive disorders were observed in 5.2% of patients with PCM and 6.5% of patients with ICD [4]. The ambivalent feelings these patients experience as a result of perceived dependency on the device may lead to relative satisfaction and returning to full professional and social activity following the implantation procedure. Conversely, these same feelings can become a source of an extremely unfavorable situation, i.e., of developing anxiety or depressive disorders, post-traumatic stress disorder or poor quality of life [5, 6]. This study is an attempt to provide an analysis of the influence of implementation of cognitive behavioral intervention (CBI) in patients after cardiovascular implantable electronic device (CIED) implantation on the quality of life (QoL) following the procedure as well as the level of illness acceptance.

Material

The approval of the Bioethical Commission (RNN/103/10/KE) has been granted. The sample group included patients of both sexes, hospitalized in the clinical cardiology center for the implantation of a cardiovascular implantable electronic device (CIED). 154 patients were initially qualified for the trial. In the case of these patients, insertion of CIEDs (PCM, ICD, CRT, CRT-D) was considered necessary due to heartbeat disorders. 14 patients were excluded from randomization as they did not meet eligibility criteria ($n = 8$), refused to take part in the trial ($n = 4$) or due to other reasons ($n = 2$). 128 patients completed the full study protocol. 12 patients failed to appear at follow-ups during the program (3 from the CBI group and 9 from the control group). Two patients died during the 6-month observation. The group with inserted CBIs included 67 patients (52.3%) and the control group included 61 patients (47.7%). Women represented 36.7% ($n = 47$) of the entire group, whereas men – 63.3% ($n = 81$). Comparing the sample group and the control group from the point of view of sex, no substantial statistical discrepancies were found ($p = 0.13$). The mean age (at the moment of inclusion) was 64.5 ± 8.9 years in the case of the sample group and 67.8 ± 11.4 in the case of the control group ($p = 0.015$).

Methodology

Eligibility criteria were as follows: the patient was qualified for implantation of CIED during hospitalization, the patient's age > 18, the patient's written consent to take part in the trial. Exclusion criteria were as follows: acute coronary syndrome, class IV heart failure according to NYHA classification guidelines, cardiogenic shock, cancer, addiction to alcohol, taking antidepressants or anxiolytics, no written consent from the patient to take part in the trial. The trial was a simple randomized controlled trial – patients were randomly allocated to one of two groups. The sample group included patients provided with usual medical care associated with the implantation of CIEDs who additionally received cognitive behavioral intervention. Patients receiving usual medical care associated with the insertion of CIEDs were the control group. Assignment of patients to one of the groups was carried out by asking each patient to select one of 140 envelopes with such an assignment (the assignments were distributed equally). Patients undergoing cognitive behavioral intervention participated in a structured series of four meetings: 1st – before implantation (during hospitalization), 2nd – after implantation (before the end of hospitalization), 3rd – 7–10 days after implantation, 4th – one month after implantation and, just like the patients from the control group, they underwent standard medical care before and after implantation. The structure of this program was similar to most CBI-based programs [7–10]. The intervention comprised four therapeutic meetings each lasting approx. 30–45 minutes and one follow-up meeting six months after implantation. The intervention has been conducted by two psychologists who have earlier completed courses in CBT.

Four key elements of the program with specific objectives were distinguished:

1. Education. The objective was to provide basic knowledge about the anatomy and physiology of the cardiovascular system, symptoms of heartbeat disorders and relevant treatments (including the implantation procedure), recommendations after the implantation of a cardiac electrotherapy device. The most common psychological consequences of implantation were also discussed.
2. Self-control. The objective was to teach patients how to be more aware of different signals coming from the body (e.g., muscular tension, pain) and how to cope with them. Another goal was to increase the ability to recognize and cope with emotional hardships in the periprocedural period – the method of small steps in completing tasks and increasing the sense of competence and feeling pleasure.
3. Cognitive restructuring. The goal was to recognize and work on dysfunctional beliefs concerning the cardiac electrotherapy devices implantation. The concept of positive and negative bias was presented and it was explained that our way of thinking may have influence on interpreting different events and, as a consequence, on our actions. Working with the patient on creating a relevant image of the disease and its treatment, which will make it easier for the patient to pursue independent activities after leaving the hospital.
4. Skills development and training. Teaching of relaxation techniques – breathing exercises (a simple method of breath control where emphasis is placed on teaching

the patient how to breathe diaphragmatically) and Jacobson's relaxation technique (it focuses on tightening and relaxing specific muscle groups in sequence). An additional goal was the acknowledgement of changes in the broader context of the future post-CIED-implantation life, i.e., everyday life with the device (everyday activities, professional life, physical activity).

The Table 1 below includes a brief description of each session.

Table 1. **Outline of cognitive behavioral intervention intervention**

Session no.	Description
1.	Discussion of particular cognitive behavioral therapy principles. The principle of confidentiality. Informative and emotional support before implantation procedure. Relaxation session.
2.	Enhancing the ability to recognize one's emotional problems. Developing, together with the patient, a relevant image of the disease and its treatment, which shall make it easier for the patient to live independently after leaving the hospital. Relaxation session.
3.	Developing a plan of how the patient will function with a cardiovascular implantable electronic device after leaving the hospital, which requires a change of lifestyle (physical activity, driving a car, quitting smoking). Relaxation session.
4.	Overcoming dysfunctional ideas about the cardiac electrotherapy devices implantation. Positive and negative bias in the way of thinking. Informational and emotional support offered to the patient. Relaxation session.

For the purpose of psychological assessment the following tools were used: the EuroQol-5D (EQ-5D) quality of life questionnaire and *the Acceptance of Illness Scale* (AIS). This study was registered on the EuroQol Group Foundation's website and a consent to use the EQ-5D-3L questionnaire was obtained.

The EQ-5D is a general, universal tool designed for studies of groups with diversified health conditions. Questions on QoL in the EQ-5D are grouped into five categories assessing the subjects with regard to: mobility, self-care, taking up usual everyday activities, defining occurrence and severity of pain, defining occurrence and severity of mood disorders. Three categories of answers were prepared for each of the studied parameters, based on which patients are classified into one of 243 possible conditions reflecting their present QoL as they themselves perceive it. The questionnaire is supplemented by *the Visual Analogue Scale* (VAS) on which the subject presents graphically an assessment of their health condition using the scale from 0 (the worst imaginable health condition) to 100 (the best possible health condition) [11]. In order to measure the level of illness acceptance *the Acceptance of Illness Scale* (AIS) was used. It includes eight statements describing consequences of poor health condition. They include acceptance of limitations imposed by the illness, lack of self-sufficiency, a feeling of dependence on others, and lower self-esteem. Acceptance of the illness is reflected by lower severity of negative reactions and emotions related to the present illness. The scale is designed to measure the level of illness acceptance. The higher illness acceptance, the better adaptation and lower mental discomfort [12]. By each statement the subject assesses their current condition on the scale from 1 – 'I fully

agree' up to 5 – 'I definitely don't agree'. All AIS statements express certain difficulties and limitations caused by the illness. Full agreement (grade 1) expresses poor adaptation to illness, whereas definite lack of agreement (grade 5) means acceptance of the illness. Therefore, the sum of all points is a general measurement of illness acceptance level, and it ranges between 8 and 40 points. A low result corresponds to a lack of acceptance or adaptation to illness as well as severe psychological distress. On the contrary, a high result shows acceptance of one's own illness, which is manifested by lower level of emotions related to it [12].

Statistical analysis of obtained data was carried out with the use of licensed statistical packages STATISTICA PL (version 10) and SPSS (version 21). The qualitative variables were characterized by providing a number of observations with particular feature options (*N*) and the respective percentage (%). Quantitative variables, on the other hand, were characterized by providing basic descriptions – the mean, standard deviation (*SD*), minimum and maximum value, median. The normality of quantitative variables was analyzed using the Saphiro-Wilk test. The Chi-squared test was applied to compare the distribution of qualitative variables in two independent groups. To analyze two independent groups from the point of view of quantitative variables either the Student's *t*-test was applied (in the case of normal distribution of a variable in both groups) or the Mann–Whitney *U* test (if distribution is not normal). When it comes to the analysis of changes over time in the case of quantitative variables – repeated measures two-factor analysis of variance was applied, and in the case of significant deviations from the assumed values – multivariate analysis of variance (MANOVA) and the non-parametric permutational analysis of variance (PERMANOVA). Duncan's new multiple range test was applied to pairwise comparisons. The McNemar or the McNemar–Bowker test was applied to analyze changes of qualitative variables over time. For the purpose of this study, results of $p < 0.05$ have been considered statistically significant. Higher values have been referred to as not statistically significant (marked in the tables as NS).

Results

The first EQ-5D questionnaire-based study was conducted in patients before implantation procedure. A comparative QoL analysis between the groups (CBI and non-CBI) initially revealed a lack of differences in five fields in which limitations of the subjects were assessed, i.e., mobility, self-care, taking up usual everyday activities, defining occurrence and severity of pain, defining occurrence and severity of mood disorders. When analyzing specific aspects of quality of life assessed based on the EQ-5D questionnaire, one may observe a very high rate of patients reporting, before implantation procedure, a moderate level of anxiety and depression as well as high level of anxiety and depression. In the study group as many as 89.6% ($n = 60$) of the patients experienced moderate and high level of anxiety, whereas in the control group it was 90.2% of the patients ($n = 55$) (p = NS). A lot of the patients also observed serious problems in their mobility and self-care (e.g., washing, getting dressed). Such a high percentage of patients reporting difficulties in these activities may, to a considerable

extent, result from restrictions imposed by medical staff already during hospitalization period but yet before implantation procedure. Table 2 presents a comparative summary of quality of life parameters based on the EQ-5D questionnaire for the study group and control group at the moment of being included in the study.

Table 2. **A comparative summary of quality of life parameters based on the EQ-5D questionnaire for the sample and control groups completed upon including the patients into the study**

EQ – 5D – study I	Value	Study group		Control group		p
		N	%	N	%	
Mobility	I have no problems in walking about	12	17.9	6	9.8	NS (p = 0.42)
	I have some problems in walking about	34	50.8	34	55.8	
	I am confined bed	21	31.3	21	34.4	
Self-care (e.g., washing, getting dressed)	I have no problems with self-care	15	22.4	19	31.1	NS (p = 0.40)
	I have some problems washing or dressing myself	44	65.7	33	54.1	
	I am unable to wash or dress myself	8	11.9	9	14.8	
Usual activities (e.g., work, household chores)	I have no problems with performing my usual activities	17	25.4	17	27.9	NS (p = 0.93)
	I have some problems with performing my usual activities	39	58.2	35	57.4	
	I am unable to perform my usual activities	11	16.4	9	14.7	
Pain/discomfort	I have no pain or discomfort	45	67.2	43	70.5	NS (p = 0.63)
	I have moderate pain or discomfort	13	19.4	13	21.3	
	I have extreme pain or discomfort	9	13.4	5	8.2	
Anxiety/ depression	I am not anxious or depressed	7	10.5	6	9.8	NS (p = 0.85)
	I am moderately anxious or depressed	39	58.2	33	54.1	
	I am extremely anxious or depressed	21	31.3	22	36.1	

The patients filled in the EQ-5D questionnaire once again in the first and sixth month following index hospitalization. The tables below present a summary of results recorded in the study group and in the control group – Table 3 for the first month and Table 4 for the sixth month, respectively.

Table 3. **A comparative summary of quality of life parameters in the study and control groups based on the EQ-5D questionnaire one month following index hospitalization**

EQ – 5D – study II	Value	Study group		Control group		p
		N	%	N	%	
Mobility	I have no problems in walking about	51	76.1	28	45.9	p = 0.0002
	I have some problems in walking about	15	22.4	23	37.70	
	I am confined bed	1	1.5	10	16.39	
Self-care (e.g., washing, getting dressed)	I have no problems with self-care	51	76.1	32	52.5	p = 0.009
	I have some problems washing or dressing myself	14	20.9	21	34.4	
	I am unable to wash or dress myself	2	3.0	8	13.1	
Usual activities (e.g., work, household chores)	I have no problems with performing my usual activities	50	74.6	32	52.5	p = 0.02
	I have some problems with performing my usual activities	15	22.4	23	37.7	
	I am unable to perform my usual activities	2	3.0	6	9.8	
Pain/discomfort	I have no pain or discomfort	43	64.2	37	60.7	p = 0.01
	I have moderate pain or discomfort	21	31.3	12	19.7	
	I have extreme pain or discomfort	3	4.5	12	19.7	
Anxiety/ depression	I am not anxious or depressed	43	64.2	24	39.3	p = 0.002
	I am moderately anxious or depressed	20	29.6	21	34.4	
	I am extremely anxious or depressed	4	6.0	16	26.2	

Comparing the study and control groups, we may observe statistically significant differences in each of the five QoL aspects between the two groups after the first month. A lower severity of problems may be observed in the group which underwent the intervention. An extreme pain/discomfort was experienced by 19.7% (n = 12) of individuals in the control group, whereas in the study group it was only 4.5% (n = 3). 26.2% (n = 16) of the control group patients were also moderately or extremely anxious, and as for the study group it was 6.0% (n = 4) of the patients.

Table 4. **A comparative summary of quality of life parameters in the study group vs. the control group based on the EQ – 5D questionnaire in the sixth month following index hospitalization**

EQ – 5D – study III	Value	Study group		Control group		p
		N	%	N	%	
Mobility	I have no problems in walking about	59	88.1	44	72.1	NS (p = 0.07)
	I have some problems in walking about	7	10.5	15	24.6	
	I am confined bed	1	1.5	2	3.3	
Self-care (e.g., washing, getting dressed)	I have no problems with self-care	58	86.6	42	68.9	p = 0.04
	I have some problems washing or dressing myself	8	11.9	18	29.5	
	I am unable to wash or dress myself	1	1.5	1	1.6	
Usual activities (e.g., work, household chores)	I have no problems with performing my usual activities	61	91.1	40	65.6	p = 0.002
	I have some problems with performing my usual activities	5	7.5	18	29.5	
	I am unable to perform my usual activities	1	1.5	3	4.9	
Pain/discomfort	I have no pain or discomfort	56	83.6	41	67.2	NS (p = 0.09)
	I have moderate pain or discomfort	8	11.9	14	22.9	
	I have extreme pain or discomfort	3	4.5	6	9.8	
Anxiety/ depression	I am not anxious or depressed	54	80.6	30	49.2	p = 0.0004
	I am moderately anxious or depressed	11	16.4	21	34.4	
	I am extremely anxious or depressed	2	3.0	10	16.4	

In the 6-month observation period, the group of patients undergoing CBI showed a greater improvement in QoL in terms of: 'self-care', 'usual activities' and 'anxiety', whereas in 'pain' and 'mobility' the difference in favor of the CBI group was not significant (however, a positive trend was observed $p > 0.05$, but < 0.10). It seems that pain and discomfort in walking about plays a less important role six months following the procedure in the patients who underwent the procedure with no complications, thus, the intervention in such a long observation period seems not to affect these measurements.

Table 5. **Comparison of changes over time (p level, McNemar-Bowker test) in quality of life parameters based on the EQ-5D questionnaire in the control and study groups throughout the 6-month observation period**

Mobility	Changes over time:	0 vs. 1	0 vs. 6	1 vs. 6
	Study group	< 0.0001	< 0.0001	NS (0.09)
	Control group	0.0002	< 0.0001	0.004
Self-care (e.g., washing, getting dressed)	Changes over time:	0 vs. 1	0 vs. 6	1 vs. 6
	Study group	< 0.0001	< 0.0001	NS (0.31)
	Control group	NS (0.051)	0.0002	NS (0.052)
Usual activities (e.g., work, household chores)	Changes over time:	0 vs. 1	0 vs. 6	1 vs. 6
	Study group	< 0.0001	< 0.0001	0.04
	Control group	0.02	0.0003	NS (0.37)
Pain/discomfort	Changes over time:	0 vs. 1	0 vs. 6	1 vs. 6
	Study group	NS (0.14)	NS (0.12)	0.003
	Control group	NS (0.13)	NS (0.91)	NS (0.32)
Anxiety/ depression	Changes over time:	0 vs. 1	0 vs. 6	1 vs. 6
	Study group	< 0.0001	< 0.0001	NS (0.10)
	Control group	0.0004	< 0.0001	NS (0.51)

0 – the study conducted during the index hospitalization; 1 – the study conducted in the first month following the index hospitalization; 6 – the study conducted in the sixth month following the index hospitalization

Majority of significant differences between the groups in subsequent studies involve mobility. In the intervention group, we observe statistically significant differences in symptoms severity distribution in the period of one month as compared to the period preceding implantation, and in the period of six months as compared to the pre-implantation period – in the subsequent studies the percentage of patients having no mobility problems increases. The difference between the study conducted after six

months and one month is not statistically significant, however, an increase in the percentage of patients having no mobility problems may still be observed. Analogically, in the non-CBI group in the subsequent periods of the study, we may observe a statistically significant increase in the percentage of patients with no mobility problems. Here it is worth mentioning that a significant increase may be also observed after six months as compared to one month. On the other hand, as it was already proved before, the values are lower than in the group with psychological intervention.

The least statistically significant changes in time are related to pain. In the second study, in the intervention group the percentage of patients experiencing no pain as compared to pre-implantation period decreased slightly, while in the others the symptoms became less severe (a transition from 'extreme' to 'moderate' category). In the sixth month, there occurred a significant difference as compared to the first month – it may be observed that the percentage of patients experiencing no pain increases (a transition from 'moderate' to 'no pain' category). In the group that was not subject to psychological intervention there were no significant changes over time.

As for the VAS EQ-5D, if a comparison is made between the two groups, there are no statistically significant differences observed in the zero-phase study, i.e., before implantation. The mean result of the VAS EQ-5D before implantation in the study group was 50.8 ± 18.9 and in the control group it was 52.1 ± 15.4 ($p = 0.64$), whereas the obtained results in the two groups differ significantly both after one month and six months. In the intervention group, we observe a higher quality of life – the mean VAS result in the study group 30 days after implantation was 68.3 ± 13.9, whereas in the control group it was 58.4 ± 14.4 ($p = 0.003$). The mean VAS result six months after implantation in the study group was 80.3 ± 11.8, and in the control group it was 64.9 ± 14.3 ($p < 0.001$). Table 6 presents a comparative summary of VAS EQ-5D results of the study and control groups before implantation as well as in the first and sixth month following implantation.

Table 6. **A comparative summary of VAS EQ-5D results in the study and control groups before implantation and in the first and sixth month following index hospitalization**

VAS EQ – 5D	Study group Mean ± standard deviation	Control group Mean ± standard deviation	p
VAS EQ-5D – study I	50.8 ± 18.9	52.1 ± 15.4	NS (p = 0.64)
VAS EQ-5D – study II	68.3 ± 13,9	58.4 ± 14.4	p < 0.0003
VAS EQ-5D – study III	80.3 ± 11.8	64.9 ± 14.3	p < 0.0001

Study I – before device implantation; study II – 1 month (± 3 days) following implantation; study III – 6 months (± 1 week) following implantation

For measuring the level of illness acceptance among the patients following implantation of cardiac pacemaker implantation, the AIS was used three times in the 6-month observation period. When analyzing the level of illness acceptance before implantation (study I), no statistically significant differences between the two groups were identified. The mean AIS result in the study group was 24.5 ± 6.6, while in the

control group it was 24.4 ± 6.6 (p = 0.93). However, both after the first and sixth month the results obtained in the study group and the control group differ significantly. In the CBI group, we may observe that statistically significant AIS values are higher. The mean AIS result in the study group 30 days following implantation was 31.4 ± 5.4, and in the control group it was 26.0 ± 6.4 ($p < 0.0001$), whereas the mean AIS result six months following implantation was 35.6 ± 4.3 in the study group and 28.8 ± 6.1 ($p < 0.0001$) in the control group. Table 7 presents a comparative summary of AIS results in the study and control groups before implantation and in the first and sixth month following implantation.

Table 7. **A comparative summary of AIS results in the study group and control group before implantation and in the first and sixth month following index hospitalization**

AIS	Study group Mean ± standard deviation Median (quartile 1–3)	Control group Mean ± standard deviation) Median (quartile 1–3)	p
AIS – study I	24.4 ± 6.6 24 (19–30)	24.4 ± 6.6 25 (20–28)	NS (p = 0.93)
AIS – study II	31.4 ± 5.4 32 (28–36)	26.0 ± 6.3 27 (23–30)	p < 0.0001
AIS – study III	34.6 ± 4.3 35 (32–37)	28.8 ± 6.1 28 (26–32)	p < 0.0001

Study I – before device implantation; study II – 1 month (± 3 days) following implantation; study III – six months (± 1 week) following implantation

Discussion

Owing to proper functioning of the heart, well-being of a patient following implantation of a cardiac electrotherapy device should improve [13]. Thus, an important element of this study was to assess the quality of life in the group of subjects, both at the beginning as well as in the first and sixth month following the procedure. Numerous studies indicate that the quality of life of patients after implantation of a cardiac electrotherapy device is better than before the implantation. In their study, Gribbin et al. [14] observed an improvement in some quality of life aspects considered in the study already one month following the surgery, regardless of the type of inserted cardiac electrotherapy device (VVI, DDD, AAI). The results presented in this study generally correspond to those obtained in majority of others, including the MOST and CTOPP studies [15, 16]. However, not all studies enable us to draw such uniform conclusions. At this point it is worth referring to the WHERE study [17]. It reported a decrease in the quality of life six months after implantation. There is a certain discrepancy between the results presented by the Italian team and those of studies discussed earlier. Attempting to find a reliable justification of the aforementioned discrepancy, it should be assumed that there are differences between the two studies. What may be

the key issue here are different QoL questionnaires as well as methods of preparing patients for device implantation – particularly informing them on how it works and thus easing their concerns – this may significantly influence the quality of life level [18]. At the same time, it should be emphasized that the results of tests conducted immediately after implantation of a cardiac electrotherapy device may be influenced by many factors (e.g., support of family and friends, level of education, knowledge of the procedure, awareness of device dependence). We impose many restrictions on patients and inform them on and warn against numerous threats [19]. When analyzing specific quality of life aspects in this study, significant benefits from CBI were noticed only after one month, as well as after six months. Presented study results indicate a need to appreciate the significance of planned psychological support, both in hospital and outpatient care in this specific group of patients following implantation of a cardiac electrotherapy device. These activities may have a significant impact on patients' self-esteem concerning health condition and perception of their own future. Thus, they also affect the quality of the patients' functioning in a family and course of process of their adaptation to living a with a cardiac electrotherapy device. This issue is considerably important since at present indications for implantation of cardiac electrotherapy system are getting broader. They apply not only to the patients who develop dangerous symptoms of arrhythmia, but also to prevention groups [20]. The most important issue is developing an adequate attitude towards cardiac electrotherapy devices, explaining the device's mechanisms of action, prophylaxis of abnormal behavior [21].

This study also assessed the level of illness acceptance – a complex process which begins when the disease is suspected and continues throughout the whole treatment until the end of the patient's life. Some patients have serious difficulties when trying to accept cardiac electrotherapy device and adapt to the situation: they think that implantation was not necessary, they do not accept the device, have a negative attitude towards medical check-ups, do not follow doctor's recommendations, do not accept restrictions, deny the illness or rebel against it, they think of or even explicitly say that they want to remove the device [22, 23]. These are processes that not only deteriorate patient's mental condition but also pose a threat to their health or even life. A patient who suffers from psychological problems accepts treatment to a lower extent, reports more somatic complaints and their well-being is subjectively lower. The mean AIS result in subsequent studies increased reaching its highest values six months following implantation. The mean AIS result six months following implantation in the study group was 35.6 ± 4.3, whereas in the control group it was 28.7 ± 6.1. The obtained results indicate that the applied CBI significantly promoted improvement in acceptance of illness.

During the study, after qualifying patients for the study group (the CBI group), it was observed that the patients were eager to participate in subsequent meetings. Out of 70 patients qualified for the study group at the beginning, 67 patients underwent the whole cycle, whereas in the case of control group, only 61 patients completed the trial (the difference was not statistically significant). Observations made in this study correspond to the results presented in the literature, which indicate that, as compared to other forms of therapy, CBI is highly acceptable in the group of patients who underwent implantation of a cardiac electrotherapy device [18]. The proposed

cycle of four structured CBI meetings was well accepted by the patients, which was confirmed by high attendance to the sessions during the intervention, and at the same time it ensured the expected therapeutic effect with a short period of the intervention without prolonging hospitalization.

The results of studies over CBI program indicate its positive and long-term effects. Due to a low number of patients in the sample group, the obtained results need to be confirmed by a more representative group of patients. The results correspond to the existing findings on effectiveness of CBI techniques. Literature data confirm the efficacy of CBI intervention before and after implantation [24–28].

Efforts should be made to ensure that a team of specialists taking care of post-implantation patients includes a psychologist who knows and understands problems faced by them. It is important not to wait for intervention of a specialist for too long, since long-lasting difficulties may be a source of subsequent ones, and fixed disorders require a longer therapy [29]. The main limitations of this study include: one-center nature of the trial, limited size of both the study group and the control group as well as moderately long observation period (six months).

Conclusions

1. The applied cognitive behavioral intervention in patients after CIEDs implantation entailed a considerable improvement in the quality of life and a better acceptance of illness as compared to the group of patients provided with a standard care following electrotherapy procedure.
2. The proposed cycle of four structured CBI meetings was well accepted by the patients, which was proved by very frequent participation in sessions throughout the intervention, and it also ensured the expected therapeutic effect with a short intervention duration without prolonging hospitalization.
3. Effects of the intervention were satisfactory both in short – as well as long-term observation.

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