ORIGINAL ARTICLE

Crosscultural adaptation and reliability testing of the Implantable Cardioverter-Defibrillator Concerns questionnaire to optimize the care of Polish patients with implantable cardioverter-defibrillators

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ABSTRACT

BACKGROUND   Implantable cardioverter-defibrillator (ICD) placement has now become a standard procedure in patients with ventricular arrhythmias. The primary task of an ICD is to recognize and immediately interrupt life-threatening ventricular arrhythmia via an intracardiac electrical discharge, known as a shock.

AIMS   The aim of this study was to adapt and test the reliability of the Polish version of the Implantable Cardioverter-Defibrillator Concerns (ICDC) questionnaire, an instrument used to determine the concerns of patients with ICDs.

METHODS   Standard guidelines were applied with regard to the translation and cultural adaptation of the English version of the ICDC questionnaire in Poland. The study included 129 Polish patients with ICDs, including 28 women, at a mean (SD) age of 66.24 (12.94) years. The Cronbach α was calculated to analyze the internal consistency of the ICDC questionnaire.

RESULTS   The mean ICDC score for overall concerns was 36.63 (18.56); 9.19 (5.93) for factor 1 assessing the perceived limitations, and 9.72 (5.61) for factor 2 assessing device-specific concerns. The Cronbach α reliability coefficients ranged from 0.9619 to 0.9647, after each questionnaire item was deleted. The Cronbach α that characterized the internal consistency of the entire questionnaire was 0.96.

CONCLUSIONS   The Polish adaptation of the ICDC questionnaire proved to be a useful and quick tool to assess patients' concerns after ICD placement. Its use is recommended in the evaluation of all patients after device implantation in order to optimize therapy.

INTRODUCTION   The automatic implantable cardioverter-defibrillator (ICD) was implanted for the first time on February 4, 1980 at Johns Hopkins Hospital in Baltimore, Maryland, United States. One of the pioneers of ICD therapy was Mieczysław Mirowski, born in Warsaw, Poland, in 1924.[1,2] The number of patients with ICDs increases each year. Ventricular arrhythmias, the main cause of implantation, are frequent disorders and their incidence increases with age and the degree of cardiac damage. According to epidemiological data, sudden cardiac death occurs in 0.36 to 1.26 cases per 1000 people per year in the world, with a mean frequency of about 1 case per 1000 people per year. It can be assumed that sudden cardiac death affects at least 36 000 to 40 000 people

WHAT'S NEW?

In this study, we present the crosscultural adaptation and test the reliability of the Implantable Cardioverter-Defibrillator Concerns questionnaire to optimize the care of Polish patients with implantable cardioverter-defibrillators.

in Poland annually, with approximately 25 000 to 28 000 being expected to suffer from sudden cardiac arrest due to ventricular fibrillation. Implantable cardioverter-defibrillator placement has now become a standard procedure in patients with ventricular arrhythmias.[3,4] The basic and most important task of an ICD is to recognize and immediately interrupt life-threatening ventricular arrhythmia with an intracardiac electrical discharge, known as a shock. Modern cardioverter-defibrillators, apart from defibrillation and intracardiac cardioversion, have a number of additional functions, which have significantly improved patients' ability to tolerate the devices by limiting the number of high--energy discharges. Still, the experience of unpleasant shocks remains one of the basic problems for this patient population. Irritation, anxiety, bewilderment, and panic are common reactions to a defibrillator discharge, especially to the so-called electrical storm, which consists of a minimum of 3 ICD shocks per day. It is estimated that between 50% and 70% of patients sense ICD discharges within the first 2 years after implantation, and between 10% to 30% experience electrical storms.[5,6] Despite the effectiveness of these devices, patients can suffer from serious psychological difficulties, mainly anxiety and depression, which contribute to the deterioration of their quality of life (QoL) and reduce the potential benefits of the therapy.[7,8] Kohn et al[9] reported that offering psychological support prior to ICD placement, before discharge from the hospital, and during routine follow-up visits significantly reduced the levels of anxiety and depression in this population. Therefore, it is of importance to assess the severity of patients' concerns about the implanted device in the hospital and after discharge, during follow-up visits.[9] The Implantable Cardioverter-Defibrillator Concerns (ICDC) questionnaire is a standardized instrument, which can be used to assess patients' concerns related to an ICD and to identify patients with ICDs who are at risk of adverse clinical outcomes. The aim of this study was to adapt and test the reliability of the Polish version of the ICDC questionnaire.

METHODS The study included 129 patients with an implanted single- or dual-chamber cardioverter-defibrillator who had been hospitalized in the Department of Electrocardiology and Heart Failure, Katowice, Poland, to exchange their ICDs.

Study participants We included 129 consecutive patients (28 women; mean [SD] age, 66.24 [12.94] years). The minimum number of participants included in the study was estimated based on the literature, which shows that the minimum sample size should be at least 5-fold greater than the number of variables analyzed.[4] In this case, the number of variables was 20, so the minimum sample size should be 100.

The following inclusion criteria were defined: undergoing an ICD exchange procedure due to an elective replacement indicator[10] and providing consent to participate in the study. The exclusion criteria were as follows: cardiac resynchronization therapy with an ICD, diagnosed cancer in the active phase, previously diagnosed mental illness or stroke, and an incomplete questionnaire.

Participation in the study was anonymous and voluntary. The study was approved by a bioethical commission (KNW/0022/KB/36/18) and conducted in accordance with the Declaration of Helsinki and the principles of Good Clinical Practice.

Instruments Concerns about an ICD in the ICDC questionnaire are estimated using the Likert scale ranging between 0 (not at all) and 4 (very much so). This gives a possible overall score of 0 to 20 (for the number of concerns) and 0 to 80 (for increasing concerns). A higher result indicates a greater number of more serious concerns. The number of fears and increasing concerns can be used alone or in combination in order to achieve the overall number of concerns (maximum, 100). The ICDC questionnaire is divided into 2 subscales. The first subscale, factor 1, assesses perceived limitations (questions no. 4, 5, 6, 10, 11, 14, 18, 19, and 20), and the second subscale, factor 2, device-specific concerns (questions no. 1, 6, 9, 12, 13, 15, 16, and 17). The psychometric properties of the original ICDC questionnaire are good (Cronbach α of 0.94 for the entire questionnaire).[11]

Translation process A standard 2-way procedure was used to translate (from English into Polish and then from Polish into English) and culturally adapt the ICDC into Polish. After obtaining the consent of the author of the original instrument, the questionnaire was independently translated into Polish by 2 translators. A panel of specialists verified the phrasing and meaning of all questions, as well as the clarity and correctness of the instructions. The panel consisted of 2 cardiologists, 2 cardiovascular nurses, and a specialist in the field of health psychology. Each team member had experience in working with patients with ICDs. After specialists' evaluation, the questionnaire underwent the translation process once again. Then, the initial adaptation was used in a pilot study of 30 randomly selected patients. Eventually, the final Polish version of the ICDC was obtained and analyzed.

Statistical analysis Statistical analysis was conducted using the Polish version of the Statistica software (StatSoft, Tulsa, Oklahoma, United States). The internal consistency of the items included in the Polish version of the ICDC questionnaire was evaluated by calculating the Cronbach α coefficient. As recommended by Aron et al,[12] the values of Cronbach α were regarded as optimal at ≥90, good at ≥0.8, acceptable at ≥0.7, questionable at ≥0.6, poor at ≥0.5, and unacceptable at ≥0.5. The ceiling and floor effects were checked to detect outliers: more than 15% of the respondents obtained the lowest or highest scores. To evaluate the goodness of fit between the models and data, we used the χ^2 goodness of fit, weighted root mean square residual of less than 1, root mean square error of approximation

(RMSEA) of 0.05 or less, close fit for RMSEA, and the Tucker–Lewis index of 0.95 or greater.

RESULTS The mean (SD) ICDC score was 36.63 (18.56) (skewness, 0.2376; kurtosis, 0.3768) for overall concerns; 9.19 (5.93) for factor 1, ie, assessing the perceived limitations (skewness, 0.3786; kurtosis, 0.3932), and 9.72 (5.61) for factor 2, ie, device-specific concerns (skewness, 0.1941; kurtosis, 0.3893). The detailed characteristics of the total ICDC score are presented in TABLES 1 and 2.

Reliability The Cronbach α reliability coefficients ranged from 0.9619 to 0.9647 after deleting each questionnaire item. The Cronbach α that

TABLE 1 Statistical characteristics of the total Implantable Cardioverter-Defibrillator Concerns score and the scores of the individual factors and items

Item	Concern ("I am worried about…")	Mean (SD)	Median (IQR)	Range
1	My ICD firing	1.17 (0.78)	1 (1–2)	0–4
2	My ICD not working when I need it to	1.08 (0.84)	1 (1–1)	0–4
3	What I should do if my ICD fires	1.12 (0.82)	1 (1–2)	0–4
4	Doing exercise in case it causes my ICD to fire	1.13 (0.84)	1 (0–2)	0–4
5	Doing activities / hobbies that may cause my ICD to fire	1.15 (0.86)	1 (1–2)	0–4
6	My heart condition getting worse if the ICD fires	1.24 (0.88)	1 (1–2)	0–4
7	The amount of time I spend thinking about my heart condition and having an ICD	1.1 (0.78)	1 (1–2)	0–4
8	The amount of time I spend thinking about my ICD firing	1.12 (0.88)	1 (0–2)	0–4
9	The ICD battery running out	1.23 (0.91)	1 (1–2)	0–4
10	Working too hard / overdoing things causing my ICD to fire	1.15 (0.84)	1 (1–2)	0–4
11	Making love in case my ICD fires	1.08 (0.89)	1 (0–2)	0–4
12	Having no warning my ICD will fire	1.3 (0.86)	1 (1–2)	0–4
13	The symptoms / pain associated with my ICD firing	1.22 (0.83)	1 (1–2)	0–4
14	Being a burden on my partner / family	0.86 (0.89)	1 (0–1)	0–4
15	Not being able to prevent my ICD from firing	1.17 (0.93)	1 (0–2)	0–4
16	The future now that I have an ICD	1.22 (0.79)	1 (1–2)	0–4
17	Problems occurring with my ICD, eg, battery failure	1.16 (0.85)	1 (1–2)	0–4
18	Getting too stressed in case my ICD fires	1.05 (0.79)	1 (1–1)	0–4
19	Not being able to work / take part in activities and hobbies because I have an ICD	0.88 (0.89)	1 (0–2)	0–4
20	Exercising too hard and causing my ICD to fire	0.66 (0.76)	0 (0–1)	0–4
Overall patients' scores				
Concerns, n		14.54 (6.17)	17 (12–19)	0–20
Increasing concerns		22.09 (13.13)	21 (13–31)	0–80
Overall concerns		36.63 (18.56)	37 (26–50)	0–100
Factor 1		9.19 (5.93)	8 (5–14)	0–36
Factor 2		9.72 (5.61)	9 (6–13)	0–32

Abbreviations: ICD, implantable cardioverter-defibrillator; IQR, interquartile range

Item	Concern ("I am worried about…")	Answer				
		Not at all	A little	Somewhat	Quite a lot	Very much so
1	My ICD firing	24 (18.6)	65 (50.4)	34 (26.3)	6 (4.65)	0
2	My ICD not working when I need it to	30 (23.2)	68 (52.7)	21 (16.3)	10 (7.7)	0
3	What I should do if my ICD fires	32 (24.8)	55 (42.6)	37 (28.7)	5 (3.7)	0
4	Doing exercise in case it causes my ICD to fire	34 (26.3)	48 (37.2)	43 (33.3)	4 (3.1)	0
5	Doing activities / hobbies that may cause my ICD to fire	31 (24)	56 (43.4)	34 (26.3)	8 (6.2)	0
6	My heart condition getting worse if the ICD fires	29 (22.5)	49 (37.9)	2 (1.6)	9 (6.9)	0
7	The amount of time I spend thinking about my heart condition and having an ICD	30 (23.3)	56 (43.4)	40 (31)	2 (1.6)	0
8	The amount of time I spend thinking about my ICD firing	36 (27.9)	49 (37.9)	37 (28.7)	7 (5.4)	0
9	The ICD battery running out	28 (21.7)	57 (44.2)	30 (23.3)	14 (10.8)	0
10	Working too hard / overdoing things causing my ICD to fire	31 (24)	54 (41.9)	38 (29.5)	6 (4.6)	0
11	Making love in case my ICD fires	37 (28.7)	54 (41.9)	29 (22.5)	9 (6.9)	0
12	Having no warning my ICD will fire	25 (19.4)	49 (37.9)	46 (35.7)	9 (6.9)	0
13	The symptoms / pain associated with my ICD firing	26 (20.2)	56 (43.4)	40 (31)	7 (5.4)	0
14	Being a burden on my partner / family	55 (42.6)	44 (34.1)	23 (17.8)	7 (5.4)	0
15	Not being able to prevent my ICD from firing	33 (25.6)	53 (41.1)	32 (24.8)	10 (7.7)	1 (0.77)
16	The future now that I have an ICD	24 (18.6)	57 (44.2)	43 (33.3)	5 (3.9)	0
17	Problems occurring with my ICD, eg, battery failure	30 (23.3)	56 (43.4)	35 (27.1)	8 (6.2)	0
18	Getting too stressed in case my ICD fires	31 (24)	67 (51.9)	25 (19.4)	6 (4.6)	0
19	Not being able to work / take part in activities and hobbies because I have an ICD	54 (41.9)	41 (31.8)	29 (22.5)	5 (3.9)	0
20	Exercising too hard and causing my ICD to fire	65 (50.4)	45 (34.9)	17 (13.2)	2 (1.5)	0

Data are presented as number (percentage).

Abbreviations: see TABLE 1

characterized the internal consistency of the entire questionnaire was 0.96. The coefficients for the total and item–total correlation, as well as those determined after deleting each item, are shown in TABLE 3. For factor 1, the Cronbach α reliability coefficients ranged from 0.89 to 0.91 after deleting each item. The Cronbach α that characterized the internal consistency of factor 1 was 0.91. In the analysis of factor 2, the Cronbach α reliability coefficients ranged from 0.92 to 0.92 after deleting each item. The Cronbach α that characterized the internal consistency of factor 2 was 0.93.

Confirmatory factor analysis   To test the model, confirmatory factor analysis was conducted on the 20-item scale. All goodness-of-fit tests including χ^2 goodness of fit, weighted root mean square residual, RMSEA, close fit for RMSEA, and the Tucker–Lewis index were satisfactory (TABLE 4).

Feasibility   The ceiling effect was not observed in this study, ie, none of the participants obtained the highest score (100 points), but 7.7% of the participants obtained the lowest score (0 points) representing the floor effect.

The final version of the ICDC questionnaire translated into Polish is presented in Supplementary material.

DISCUSSION   The 20-item ICDC questionnaire by Frizelle[11] is a tool for assessing the number and severity of patient concerns about an implanted ICD by obtaining information about life concerns. The questionnaire is recognized as a reliable scale and it can be used by healthcare workers to provide comprehensive care, identify specific problems, and perform purposeful interventions.[13] Until now, there has been no psychometric tool in Poland to specifically assess

TABLE 3 Psychometric characteristics of the Polish adaptation of the Implantable Cardioverter-Defibrillator Concerns questionnaire

Item	Concern ("I am worried about…")	Corrected item–total correlation	Cronbach α if item deleted
1	My ICD firing	0.74	0.96
2	My ICD not working when I need it to	0.73	0.96
3	What I should do if my ICD fires	0.82	0.96
4	Doing exercise in case it causes my ICD to fire	0.81	0.96
5	Doing activities / hobbies that may cause my ICD to fire	0.76	0.96
6	My heart condition getting worse if the ICD fires	0.81	0.96
7	The amount of time I spend thinking about my heart condition and having an ICD	0.72	0.96
8	The amount of time I spend thinking about my ICD firing	0.76	0.96
9	The ICD battery running out	0.75	0.96
10	Working too hard/overdoing things causing my ICD to fire	0.83	0.96
11	Making love in case my ICD fires	0.75	0.96
12	Having no warning my ICD will fire	0.78	0.96
13	The symptoms / pain associated with my ICD firing	0.8	0.96
14	Being a burden on my partner / family	0.61	0.96
15	Not being able to prevent my ICD from firing	0.8	0.96
16	The future now that I have an ICD	0.73	0.96
17	Problems occurring with my ICD, eg, battery failure	0.73	0.96
18	Getting too stressed in case my ICD fires	0.76	0.96
19	Not being able to work / take part in activities and hobbies because I have an ICD	0.64	0.96
20	Exercising too hard and causing my ICD to fire	0.58	0.96

Abbreviations: see TABLE 1

TABLE 4 Goodness-of-fit indices of the model for the Implantable Cardioverter-Defibrillator Concerns questionnaire

Model	χ^2 goodness of fit				RMSEA		TLI
	χ^2	df	P value	RMSEA	95% CI	CFit	
ICDC	40.05	20	0.0049	0.0477	0–0.095	0.405	0.903

Abbreviations: CFit, close fit using RMSEA; df, degrees of freedom; ICDC, Implantable Cardioverter-Defibrillator Concerns; RMSEA, root mean square error of approximation; TLI, Tucker–Lewis index

the level of patient functioning after ICD placement, after ICD discharges, and even after electrical storms. The significance of using questionnaires in particular patient groups is indicated by numerous publications presenting language adaptations of the scales to the Polish conditions, including the Arrhythmia-Specific Questionnaire in Tachycardia and Arrhythmia.[14]

The purpose of our study was to adapt the ICDC questionnaire to the conditions of the Polish population and to assess the reliability of this questionnaire in patients with ICDs. Testing the reliability of the questionnaire was based on establishing the standard psychometric features of the scale, while the Cronbach α coefficient was considered to be a measure of its internal consistency. The internal consistency of the Polish ICDC adaptation was 0.96, which was similar to that of the original instrument (0.94). The values of the internal consistency in validation studies of other language versions are not available in any of the worldwide references. Actually, the most frequent validated tool is a shortened version of the questionnaire—developed by Susanne Pedersen[15,16] and consisting of 8 items selected from the original 20-item questionnaire.

Educating patients with ICDs is a crucial element of the therapeutic plan. The patient should receive information about the way of ICD functioning, care of the postoperative wound, guidelines for dealing with household appliances, and

returning to work and physical activity. The analysis of patients' fears at this stage will enable healthcare professionals to adjust education to patients' needs and plan targeted education to address the problems of an individual. This will help to eliminate problems at a later stage of the ICD patient's functioning. Not dealing with the problems of patients with ICDs or limitations on their activities, eg, hobbies, physical activity, or sexual activity, is not a solution, as it only causes frustration associated with these limitations and deterioration of QoL and disease acceptance.[17-19]

Psychiatric anxiety is not a rare problem in patients undergoing long-term ICD therapy. The prevalence of anxiety and concerns in ICD patients is increasing, and the implantation guidelines are being expanded to include prevention of sudden cardiac death in high-risk patients.[20] Although numerous studies have confirmed that ICD placement improves patients' QoL, the problems associated with implantation, frequent shocks, and a poor understanding of the therapy by a patient may exacerbate their anxiety and depression. Implantable cardioverter-defibrillator placement and therapy can also cause strong anger, stress, and fear in patients receiving treatment.[21] In secondary prevention of cardiovascular diseases, patients presenting risk factors for depression are more frequently monitored and they are less often willing to change their lifestyles and comply with therapeutic recommendations and requirements.[22]

Numerous ICD discharges are a relevant negative factor contributing to mental disorders and lowered QoL. Decline in psychosocial functioning and QoL is a common observation after the occurrence of an ICD shock.[23] Even patients who have not experienced an ICD discharge may have difficulties with adjusting to the new situation owing to fear of shock, which can cause increased anxiety, withdrawal behavior, and negative perception of self-efficacy.[24]

Markers of psychosocial needs in patients with ICDs include: younger age (below 50 years), insufficient knowledge of the condition of the heart and/or an ICD, a significant history of psychological problems, poor social support, and comorbidities. Previous studies have reported that the incidence of depression is generally higher in women than in men. Rahmawati et al[26] demonstrated this finding in a cohort study of patients with ICDs in Japan. In that study, women showed a higher incidence of depression and were more worried about ICDs than men.[25,26]

Conclusions   Our study showed that the tested questionnaire is valid and reproducible and can be used to assess the concerns of patients with ICDs in Poland. The Polish adaptation of the ICDC questionnaire has proven to be a useful and quick tool to assess patient concerns after ICD placement. It is recommended to be used in the assessment of all patients after device implantation in order to optimize their therapy.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

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