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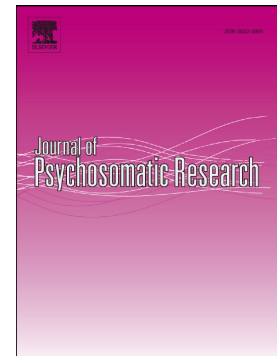
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**Illness Perceptions in Patients with Heart Failure and an Implantable Cardioverter
Defibrillator: Dimensional Structure, Validity, and Correlates of the Brief Illness
Perception Questionnaire in Dutch, French and German patients**

Short title:

Illness perceptions in Patients with Heart Failure

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Abstract

Background: Patients' illness perceptions are associated with psychological wellbeing and can be measured with the Brief Illness Perception Questionnaire (B-IPQ). However, little is known about illness perceptions in patients with heart failure. We examined the dimensional structure, validity and clinical and psychological correlates of the B-IPQ in Dutch, French and German patients with heart failure and an implantable cardioverter defibrillator (ICD).

Method: European heart failure patients (n=585) participating in the REMOTE-CIED study completed a set of questionnaires 1-2 weeks post ICD-implantation, including the B-IPQ. Information on clinical data was captured from patients' medical records.

Results: A two-factor structure (I='Consequences'; II='Control') represented 7 out of 8 B-IPQ items in the total sample and Dutch, German and French subgroups. The total B-IPQ had a Cronbach's α of .69, with the 'Consequences' subscale being more internally consistent ($\alpha=.80$). Both the B-IPQ and its 'Consequences' subscale were significantly correlated with a number of psychological characteristics, but not with clinical characteristics. Multivariable logistic regression analysis indicated that threatening illness perceptions as measured with the total B-IPQ were associated with poor health status (OR=2.66, 95%CI=1.72-4.11), anxiety (OR=1.79, 95%CI=1.001-3.19), depression (OR=2.81, 95%CI=1.65-4.77), negative affectivity (OR=1.93, 95%CI=1.21-3.09) and poor ICD acceptance (OR=2.68, 95%CI=1.70-4.22).

Conclusion: The B-IPQ demonstrated good psychometric properties in Dutch, French and German patients with heart failure. Psychological factors were the most important correlates of patients' perceptions of heart failure, emphasizing the importance of targeting maladaptive illness perceptions in this population, due to their impact on patients' wellbeing and quality of life.

Key words: illness perceptions, heart failure, implantable cardioverter defibrillator, dimensional structure, psychometric properties

Introduction

According to Leventhal's common sense model of self-regulation, illness perceptions are cognitive and emotional representations of illness or health threats (e.g., heart failure) as a reaction to situational stimuli (e.g., palpitations, chest pain or dyspnea). These representations lead to the adoption of coping behaviors. Subsequently, the efficacy of the illness representations and coping behaviors is evaluated and adjusted if necessary (1). Patients' cognitive illness perceptions are generally covered by five dimensions, and include beliefs about identity (ideas about name and symptoms), causes (ideas about origin), consequences (impact on life domains), timeline (ideas about duration), and cure or control (ideas about treatment and recovery) of their illness. Emotional perceptions consist of negative reactions, such as fear, anger or distress (1-3).

Illness perceptions play an important role in patient behavior and patient wellbeing. For example, Morgan et al. showed that illness perceptions were associated with psychological wellbeing and that they contribute more to psychological distress (i.e., anxiety and/or depression) than traditional covariates such as socio-demographic characteristics and functional status (4). A meta-analytic review of 45 studies measuring illness perceptions in a wide variety of medical conditions indicated that the perception of more severe consequences and more physical limitations was associated with worse physical, role and social functioning, higher distress levels, and lower wellbeing and vitality. Longer timeline perceptions were associated with higher distress levels, lower role and social functioning and lower vitality as well. By contrast, higher perceived control was associated with better social functioning, more wellbeing, lower distress levels, higher vitality and better disease state (5). Another systematic review showed an association between illness perceptions and survival in patients with end-stage renal disease (6), which further emphasizes the importance of patients' illness perceptions for managing chronic clinical conditions.

Heart failure is a common clinical syndrome, affecting 1-2% of the general population in developed countries, and due to an aging population and increased survival after acute cardiac events, the number of patients is growing (7, 8). Despite improved treatment options, heart failure is associated with a high risk for morbidity and mortality, impaired health status and frequent hospital admissions (7, 8). Heart failure patients who are at high risk for life threatening ventricular arrhythmias are preferably treated with implantable cardioverter defibrillator (ICD) therapy (9). Both heart failure and living with an ICD may negatively impact psychological wellbeing, with significant prevalences of depression (10-60% for patients with heart failure and 5-41% for patients with an ICD) and anxiety (11-45% for patients with heart failure and 13-63% for patients with an ICD) (10, 11). Although illness perceptions may also play an important role in this context, little is known about these perceptions in patients with heart failure.

The Brief Illness Perception Questionnaire (B-IPQ) originated from the Illness Perception Questionnaire (IPQ) and Illness Perception Questionnaire-Revised (IPQ-R), and was designed for quick and simple assessment of illness perceptions (12). The B-IPQ has been used in different populations, varying by age, illness type, country and language, with its psychometric evaluation indicating good concurrent and predictive validity, and sensitivity to change (13). However, the psychometric qualities of the B-IPQ have not been investigated in patients with heart failure, nor for German and French translations of the B-IPQ (13).

The objectives of the current study were 1) to examine the dimensional structure of illness perceptions as measured by the B-IPQ, 2) to assess the psychometric properties of the Dutch, French and German translations of the B-IPQ, and 3) to identify the clinical and psychological correlates of threatening illness perceptions in a sample of heart failure patients with an ICD.

Methods

Study Design and Participants

The sample consisted of 595 heart failure patients with a first-time implantable cardioverter defibrillator (ICD), who participated in the REMOTE-CIED study (14). The REMOTE-CIED study was a randomized trial primarily designed to examine the patient perspective on remote monitoring in heart failure patients with an ICD. Patients were recruited between April 2013 and January 2016 from 32 academic and general hospitals in France, Germany, the Netherlands, Spain and Switzerland. Consecutive patients receiving a de novo primary or secondary prophylactic ICD or cardiac resynchronization therapy defibrillator device (CRT-D) at one of the participating centers were screened for participation. Patients were aged between 18 and 85 years and suffering from symptomatic heart failure, defined as left ventricular ejection fraction (LVEF) $\leq 35\%$ and New York Heart Association (NYHA) functional class II or III at the time of implantation, with a higher NYHA functional class indicating more functional limitations. The Medical Ethics Committee of the participating hospitals approved the study protocol. The study was conducted in accordance with the Declaration of Helsinki, and all patients received written and oral information about the study and provided written informed consent.

Measures

For the participating patients, the first part of the REMOTE-CIED study consisted of the completion of a set of standardized and validated questionnaires at 1-2 weeks after ICD implantation (baseline, prior to randomization). The introductory page of the questionnaire informed the patients that the study was about their heart failure and ICD. Clinical data was collected from patients' medical records at time of implantation and entered in an electronic case report form by the local investigators at the participating centers.

Illness Perceptions were measured using official non-modified translations of the 9-item B-IPQ (12). The scale consists of eight items rated on an 11-point Likert scale from 0 and 10. Five items are designed to assess cognitive illness representations, i.e. consequences (“How much does your illness affect your life?” with 0 = no affect at all, and 10 = severely affects my life), timeline (“How long do you think your illness will continue?” with 0 = a very short time, and 10 = forever), personal control (“How much control do you feel you have over your illness?” with 0 = absolutely no control, and 10 = extreme amount of control), treatment control (“How much do you feel your treatment can help your illness?” with 0 = not at all, and 10 = extremely helpful) and identity (“How much do you experience symptoms from your illness?” with 0 = no symptoms at all, and 10 = many severe symptoms). Two items are designed to assess emotional representations, i.e. concerns (“How concerned are you about your illness?” with 0 = not at all concerned, and 10 = extremely concerned) and emotions (“How much does your illness affect you emotionally?” with 0 = not at all affected emotionally, and 10 = extremely affected emotionally) and one item to assess illness comprehensibility (“How well do you think you understand your illness?” with 0 = don’t understand at all, and 10 = understand very clearly). Item 3 (personal control), 4 (treatment control) and 7 (understanding) need recoding due to reversed scoring. For these eight items, the total score ranges from 0 to 80, with higher scores reflecting more threatening illness perceptions (12). Patients with total scores in the upper tertile of the B-IPQ were classified as having a threatening view of their illness. The ninth question is open-ended and asks patients to list the three most important causal factors of their illness; this question is not included in the current analyses.

Information on *socio demographic characteristics* included age, sex, marital status (single versus having a partner), educational level (secondary school or lower versus tertiary school or higher) and employment status (employed versus unemployed), and was collected by means of purpose-designed questions in the baseline questionnaire.

Clinical characteristics included cardiac resynchronization therapy, ICD indication (primary versus secondary prophylactic), NYHA functional class, heart failure etiology (ischemic versus non-ischemic), QRS duration, LVEF, atrial fibrillation, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, renal disease (glomerular filtration rate <60 ml/min/1.73m²), and anemia (hemoglobin value < 8.6 mmol/L for males and < 7.4 mmol/L for females). Information on *satisfaction with care* was obtained through a visual analogue scale (0-100). The higher the score, the more satisfied a patient is with the received care from the cardiology unit.

Health status was measured with the 23-item Kansas City Cardiomyopathy Questionnaire (KCCQ). This questionnaire assesses physical limitations, symptoms, social functioning, and health related quality of life (e.g. “Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?”). A summary score ranging from 0 to 100 can be computed, with higher scores indicating better patient-reported health status. The KCCQ is a valid and reliable tool to assess patient-perceived heart failure specific health status (15). The internal consistency of the KCCQ was good, with a Cronbach’s alpha of .98 in the current sample.

Information on *lifestyle characteristics* (i.e., body mass index, smoking status, use of alcoholic beverages and participation in cardiac rehabilitation) was obtained from purpose-designed questions in the questionnaire. Additionally, patients completed the 12-item European Heart Failure Self-care Behavior Scale (EHFScBS-12). The items on this scale are rated on a 5-point Likert scale from 1 ‘completely agree’ and 5 ‘completely disagree’ (e.g. “I weigh myself every day”). Total scores range between 12 and 60, with higher scores indicating worse self-care behavior. This scale is a valid and reliable tool to measure heart failure specific self-care behavior (16). Cronbach’s alpha was .72 in the current sample.

Information on use of *psychotropic medication* (i.e., antidepressants, anxiolytics and/or hypnotics) or *psychological treatment* was obtained from purpose-designed questions in the questionnaire. This information may serve as a proxy measure for prior or existing affective disorders, such as anxiety and depression.

Anxiety symptoms were measured using the 7-item Generalized Anxiety Disorder scale (GAD-7). Items on this scale are rated on a 4-point Likert scale from 0 'not at all' to 3 'almost daily' (e.g. "Over the last 2 weeks, how often have you felt nervous, anxious or on edge?"). The GAD-7 is a reliable and valid scale, with a cut-off value of ≥ 10 to classify patients with clinically relevant anxiety symptoms (17). Cronbach's alpha was .91 in this sample.

Depressive symptoms were measured with the 9-item Patient Health Questionnaire (PHQ-9). The items of this questionnaire mirror each of the 9 DSM-IV depression criteria, with items evaluated on a 4-point Likert scale from 0 'not at all' to 3 'nearly every day' (e.g. "Little interest or pleasure doing things"). A cut-off score ≥ 10 was used to classify patients with clinically relevant symptoms of depression. The PHQ-9 is a reliable and valid measure of depressive symptoms (18). Cronbach's alpha was .83 in the current sample.

Type D personality was measured using the 14-item Type D Scale (DS14). The items on this scale are rated on a 5-point Likert scale ranging from 0 'false' to 4 'true' and can be divided into a negative affectivity subscale (e.g. "I am often irritated") and a social inhibition subscale (e.g. "I find it hard to start a conversation"). Type D personality is defined as a score of ≥ 10 on both subscales (19). Cronbach's alpha was .88 for the negative affectivity subscale, and .85 for the social inhibition subscale in the current sample.

ICD-related concerns were measured with the 8-item ICD Patient Concerns questionnaire (ICDC), which is a brief version of the 20-item original questionnaire (20, 21). Items are scored on a 5-point Likert scale from 0 'not at all' to 4 'very much so' (e.g. "Getting too stressed in case my ICD

fires”), with higher scores indicating more concerns with higher severity. The psychometric properties of the brief ICDC are good (21). Cronbach’s alpha was .94 in the current sample.

ICD acceptance was measured using the 12-item Florida Patient Acceptation Scale (FPAS). Items are rated on a 5-point Likert scale from 1 ‘strongly disagree’ to 5 ‘strongly agree’ (e.g. “My device was my best treatment option”). The higher a patient’s total score, the higher the level of device acceptance. The FPAS is a valid and internally consistent measure of device acceptance (22). Cronbach’s alpha was .71 in this sample.

Statistical Analyses

Descriptive statistics were calculated for demographic, clinical and psychological characteristics for the total sample and stratified by threatening illness perceptions. Characteristics are reported as medians with interquartile ranges (IQR) for continuous variables and frequencies with percentages for categorical variables. To compare characteristics of patients with and without threatening illness perceptions, Fisher’s exact tests were used for categorical variables, and Mann Whitney-U tests for continuous variables. Principal component analysis (PCA) with Varimax rotation was used to determine the factor structure of the B-IPQ. To evaluate whether our data fulfilled the assumptions for carrying out a PCA, Bartlett’s test of sphericity and the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO-index) were evaluated. The number of factors to extract was based on eigenvalues and scree plot. To assess the internal consistency of the B-IPQ, Cronbach’s alpha and mean inter-item correlations (MIICs) were calculated. Correlations with clinical and psychological variables were calculated to examine convergent and divergent validity. For continuous variables, we calculated Pearson correlations and for dichotomous variables we calculated Point-biserial correlations. A correlation coefficient of .10 represents a small association, a correlation of .30 indicates a moderate association and a correlation coefficient of $\geq .50$ is considered as a large association, according to Cohen (23). Finally, a series of multivariable logistic

regression analyses were performed to examine correlates of threatening illness perceptions. In the first model, we examined socio demographic and clinical characteristics. Psychological characteristics were assessed in the second model and a third model combined significant socio demographic, clinical and psychological characteristics. All tests were two-tailed and a p-value of <0.05 was used to indicate statistical significance. All analyses were performed using SPSS 22.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Patient characteristics

The total analyzed sample comprised 585 patients, since 10 patients did not complete the B-IPQ and were therefore excluded from further analyses. These patients did not differ from the included patients on relevant demographic, clinical and psychological variables, except for their depression scores; i.e. patients who did not complete the B-IPQ were more likely to be depressed compared to patients who completed the B-IPQ ($p = .047$). Of all patients, 54% spoke Dutch ($N=318$), 25% German ($N=144$), 16% French ($N=92$) and 5% Spanish ($N=31$). Therefore, sub analyses for language were only performed on Dutch, German and French patients.

Socio demographic, clinical, lifestyle, psychological and treatment characteristics for the total sample and stratified by threatening illness perceptions (i.e., defined by B-IPQ total score in the upper tertile (≥ 46)) are shown in Table I. Patients with threatening illness perceptions had a lower median age, were more likely to be female and obese (i.e., body mass index >30). They also had lower patient-reported health status and were more often anxious, depressed, and treated by a psychologist. Additionally, they were more likely to have a Type D personality, and reported more ICD concerns and less acceptance of their device compared with patients without threatening illness perceptions. With regard to clinical characteristics, patients with threatening illness perceptions were more likely to have more severe heart failure symptoms (NYHA III).

Dimensional structure of the B-IPQ

We performed a factor analysis to examine the structural validity of the B-IPQ. The KMO-index (0.74) and Bartlett's test of sphericity ($p < .001$) indicated that the data fulfilled the assumptions for carrying out a factor analysis. The screeplot indicated a two-factor structure, showing a clear break after the second factor. These two factors had eigenvalues >1 , explaining 52% of total variance (factor I [consequences] = 33.88; factor II [control] = 17.80%; Table II). Factor I included questions 1 (consequences), 5 (identity), 6 (concern) and 8 (emotional response) and Factor II included questions 3 (personal control), 4 (treatment control) and 7 (understanding). Question 2 (timeline) did neither belong to factor I, nor to factor II. We repeated this analysis for the Dutch, German and French translations of the B-IPQ, all showing a comparable two-factor structure (Table II).

Internal consistency

Cronbach's alpha was used to measure the internal consistency of the consequences factor ($\alpha = 0.80$), the control factor ($\alpha = 0.52$), and the total B-IPQ scale ($\alpha = 0.69$). The internal consistency of the consequences factor and the total scale were sufficient, while the internal consistency of the control factor was low for both the total sample and stratified by language (Table III). Mean inter-item correlations (MIICs) were good for the consequence factor (0.51) and low for the control factor (0.27). The MIIC for the total scale was also on the lower end with 0.25. The internal consistency of the Dutch, French and German versions of the B-IPQ were comparable, which indicates that findings are robust across language and culture (Table III). Finally, all item-rest correlations were ≥ 0.20 , which indicates that every single item correlates sufficiently with the total scale (Table III). Based upon our analyses, only the consequences factor had good psychometric properties. Therefore we propose to use this factor as a distinct subscale to study perceived consequences of an illness in its own right. The control factor, however, could not be studied separately due to its low internal consistency.

Convergent and divergent validity of the B-IPQ

We calculated correlations between the B-IPQ total scores and B-IPQ consequence subscale scores with clinical and psychological characteristics to assess the convergent and divergent validity of the scale (Table IV). We found significant positive correlations between B-IPQ total scores and NYHA class > 1 ($r = 0.13$), negative affectivity ($r = .46$), social inhibition ($r = .14$), depressive symptoms ($r = .52$), anxiety symptoms ($r = 0.50$) and ICD concerns ($r = .36$). Significant negative correlations existed between B-IPQ total scores and health status ($r = -.51$) and device acceptance ($r = -.45$). Effect size was small for NYHA functional class and social inhibition, moderate to large for negative affectivity, ICD concerns and device acceptance, and large for depressive symptoms, anxiety symptoms and health status. We found no significant correlations between B-IPQ total scores and ICD indication, LVEF and heart failure self-care behavior. Correlations between B-IPQ consequences score, and clinical and psychological characteristics pointed in the same direction and were of comparable magnitude (Table IV).

Stratification of the total sample in language subgroups indicated a few differences in correlations between B-IPQ scores, and clinical and psychological characteristics. German and French B-IPQ scores correlated significantly with symptomatic heart failure but not with self-care behavior, in contrast to the total sample and the Dutch subsample. Furthermore, French B-IPQ scores correlated significantly with secondary ICD indication and not with social inhibition, in contrast to the total sample, and Dutch and German subsamples.

Independent correlates of illness perceptions and consequences

First, we performed a multivariable logistic regression analysis with socio demographic, clinical and comorbidity characteristics. Since all comorbidities were not significantly associated with threatening illness perceptions (with p 's ranging from .44 for chronic obstructive pulmonary disease to .68 for peripheral artery disease), we repeated the multivariable logistic regression without comorbidities.

Analyses of socio demographic and clinical factors showed that age <60 years, being female and symptomatic heart failure (i.e., NYHA class III) were significantly associated with threatening illness perceptions. Obesity was borderline significant (Table V, Model I). Next, we examined psychological correlates of threatening illness perceptions. Poor health status, anxiety, depression, negative affectivity and poor device acceptance were significantly associated with threatening illness perceptions (Table V, Model II). Finally, we performed a multivariable logistic regression combining socio demographic, clinical and psychological characteristics (Table V, Model III). In this model, only female sex and psychological characteristics were significantly associated with threatening illness perceptions (i.e., poor health status, anxiety, depression, negative affectivity and poor device acceptance).

Subsequently, we performed a series of multivariable logistic regression analyses to examine correlates of the consequences subscale. Again, all comorbidities were not significantly associated with consequences (with p's ranging from .20 for cancer to .89 for diabetes) and analyses were repeated without comorbidities. First, we examined socio demographic and clinical factors, showing that age <60 years and being female were significantly associated with a higher score on the consequences subscale, while NYHA class III symptoms and obesity were borderline significant (Table V, Model I). Next, we assessed psychological factors and found that poor health status, anxiety, negative affectivity, and poor device acceptance were significantly associated with a high score on the consequences subscale. Social inhibition was negatively associated with consequences (Table V, Model II). Finally, we combined socio demographic, clinical and psychological characteristics in one model (Table V, Model III). Socio demographic and psychological characteristics were significantly associated with illness consequences, but not with clinical characteristics. Age < 60, being female, poor health status, anxiety, negative affectivity and poor device acceptance were significantly associated with consequences and social inhibition was negatively associated with perceived consequences.

Discussion

Dimensional analysis of the B-IPQ indicated a two-factor structure, including a ‘consequences’ (i.e., consequences, identity, concern and emotional response) and a ‘control’ (i.e., personal control, treatment control and understanding) factor. Item 2, which measures the perceived longevity of heart failure, did not load on these components. The consequences factor had good psychometric quality and could therefore be used as a distinct subscale to measure perceptions of heart failure consequences. The control factor, however, cannot be used as a separate subscale due to its low internal consistency. This is not surprising, as treatment control and personal control appeared to be separate components in a previous principal component analysis of the revised illness perceptions questionnaire (IPQ-R) by Moss-Morris et al. (24). As suggested by this research group, beliefs about personal control over the disease may be more distinct from beliefs about the effectiveness of treatment in illnesses such as heart failure for which medical treatment is rather prescriptive, in comparison to illnesses where patients are required to make a personal choice between different treatment options.

The theoretical framework of illness perceptions suggests cognitive facets (i.e., consequences, timeline, personal control, treatment control, and identity) and emotional facets (i.e., concern and emotional response) of illness perceptions (1, 12, 25). According to our factor analysis in heart failure patients, the B-IPQ reflects two components consisting of both cognitive and emotional facets representing 1) perceived consequences or impact of heart failure and 2) perceived control of heart failure. This structure was robust for Dutch, German and French patient groups. To the best of our knowledge, only two other studies have examined the factor structure of the B-IPQ so far (26, 27). One study examined its dimensional structure in a sample of patients with cancer and found the same underlying factor structure with consequences, identity, concern and emotional response (emotional illness representations according to authors) loading high on the first factor, and personal control, treatment control and understanding belonging to the second factor (cognitive illness representations according to authors) (26). Another study, in patients with multimorbidity, confirmed the existence of a consequences

dimension (i.e., identity, consequences, understanding, concern, and emotional response) and a control dimension (i.e., personal control, treatment control), while timeline was a separate dimension (27). These and our results suggest that illness perceptions assessed with the B-IPQ might not be strictly divided into a cognitive and an emotional component, but rather represents how a patient thinks and feels about his current health status (consequences) versus about his ability to change it in the future (control). Future theoretical studies comparing the B-IPQ with other illness perceptions measures in different patient populations are needed to examine this alternative classification of illness perceptions.

Psychological factors (i.e., poor health status, anxiety, depression, negative affectivity and poor ICD acceptance), and not clinical factors, were independently and strongly associated with more threatening illness perceptions. This raises concerns about the value of illness perceptions above and beyond psychological distress. As discussed previously by Morgan et al. (4), feelings of anxiety and depression caused by the illness are integral aspects of illness perceptions on the one hand, but on the other hand psychological distress and poor quality of life may be outcomes of coping that largely depends on how the illness is perceived (5, 28). In addition, Zyrianova et al. showed that illness perceptions might act as a mediator in the relationship between anxiety, depression and pain in patients with arthritis (29). Longitudinal studies are needed to examine the complex interplay between illness, illness perceptions, coping, and clinical and psychological health outcomes. Yet, the fact that negative illness perceptions have been associated with worse outcomes in several patient groups underlines that changing these perceptions is an important treatment goal in its own right (5, 6). Over the past years, studies have assessed interventions targeted at changing illness perceptions to improve outcomes in patients with myocardial infarction (30, 31), diabetes (32) and chronic low back pain (33). These interventions achieved modest changes in illness perception and improvement in outcomes such as functional ability, diabetic control and return to work (30, 32, 33). Better insight into the B-IPQ could be of great help for further development of these interventions, also in patients with heart failure.

The cross-sectional nature of this study precludes any conclusions about the causality of the observed relationships. Furthermore, the majority of our sample was male and all patients were diagnosed with heart failure and implanted with an ICD. Therefore, our results may not be generalizable to women with heart failure or to other (cardiac) populations. Another limitation is the absence of information about events, shocks, health care use and cardiac medication. Strengths of our study are the large international sample of European patients with heart failure and an ICD and the availability of an elaborate set of socio-demographic, clinical and psychological characteristics. This enabled us to describe the population and to evaluate the psychometric properties of the B-IPQ, its divergent and convergent validity, and its correlates in three different languages and cultural settings (i.e., Dutch, German and French).

To the best of our knowledge, this is the first study to examine the dimensional structure, validity and correlates of illness perceptions as measured with the B-IPQ in patients with heart failure and an ICD. The dimensional structure of the B-IPQ and its associations with other psychological factors were robust across the Dutch, French and German samples, which confirms the cultural validity of the B-IPQ to assess illness perceptions in patients with heart failure. Based upon our results, we recommend to analyze all eight B-IPQ items in their own right and to calculate only a total score for the 4 items that loaded on the consequences factor. However, caution is warranted with the use of this subscale, since clustering of items may vary among illnesses (13). Therefore, future research should assess the dimensional structure of the B-IPQ and its theoretical implications in other clinical populations.

Author contributions *Concept/design:* H. Versteeg, M. Meine, J. Denollet, S.S. Pedersen; *Data collection:* I. Timmermans, H. Versteeg, M. Meine; *Data analysis/interpretation:* I. Timmermans and J. Denollet; *Drafting article:* I. Timmermans and J. Denollet; *Critical revision of article:* all authors; *Approval of article:* all authors.

Disclosures none.

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Table I. Clinical and psychosocial characteristics of the total sample, and stratified by threatening illness perceptions

	Total sample N=585	Threatening illness perceptions ^a N=194	No threatening illness perceptions N=391	p-value
<i>Socio Demographic Characteristics</i>				
Age, years – Median (interquartile range)	65 (58-73)	64 (55-73)	66 (60-73)	.02
Female	123 (21%)	56 (29%)	67 (17%)	.002
Having a partner	430 (74%)	142 (73%)	288 (74%)	.92
High educational level (tertiary)	356 (61%)	110 (57%)	246 (63%)	.15
Employed	122 (21%)	47 (24%)	75 (19%)	.16
<i>Clinical Characteristics</i>				
Cardiac resynchronization therapy	224 (38%)	73 (38%)	151 (39%)	.86
Secondary prophylactic ICD indication	86 (15%)	26 (13%)	60 (15%)	.62
Ischemic heart failure etiology	332 (57%)	90 (46%)	163 (42%)	.29
QRS duration, ms – Median (interquartile range)	119 (102-154)	117 (100-155)	120 (102-154)	.29
LVEF – Median (interquartile range)	27 (22-31)	27 (22-31)	28 (21-30)	.85
Symptomatic heart failure (NYHA III)	194 (33%)	82 (42%)	112 (29%)	.002
<i>Comorbidities</i>				
Diabetes mellitus	189 (32%)	59 (30%)	130 (33%)	.51
Chronic obstructive pulmonary disease	84 (14%)	33 (17%)	51 (13%)	.21
Renal disease	159 (25%)	47 (24%)	98 (25%)	.84
Atrial fibrillation	164 (28%)	50 (26%)	114 (29%)	.43
Hypertension	340 (58%)	112 (58%)	228 (58%)	.93
Anemia	64 (11%)	18 (9%)	46 (12%)	.40
<i>Lifestyle Characteristics</i>				
Body mass index >30	132 (23%)	54 (28%)	78 (20%)	.04
Smoking	94 (16%)	33 (17%)	61 (16%)	.72
Use of alcohol	278 (48%)	86 (44%)	192 (49%)	.29
Self-care behavior ^c – Median (interquartile range)	25 (20-32)	25 (19-30)	25 (20-32)	.99

Psychological Characteristics

Poor health status ^d	207 (35%)	110 (57%)	97 (25%)	<.001
Type D personality ^e	117 (20%)	66 (34%)	51 (13%)	<.001
ICD concerns ^f – Median (interquartile range)	9 (3-16)	13 (6-21)	7 (2-14)	<.001
Device acceptance ^g – Median (interquartile range)	58 (52-65)	52 (50-58)	60 (54-67)	<.001
Anxiety ^h	91 (16%)	60 (31%)	30 (8%)	<.001
Depression ⁱ	107 (18%)	76 (40%)	31 (8%)	<.001

Treatment Characteristics

Psychotropic medication ^j	88 (15%)	34 (18%)	54 (14%)	.27
Psychological treatment	28 (5%)	19 (10%)	9 (2%)	<.001
Cardiac rehabilitation	122 (21%)	44 (23%)	78 (20%)	.52

Results presented as N(%) for categorical variables, and as median(interquartile range) for continuous variables. Significant results are presented in bold.

^aThreatening illness perceptions: B-IPQ total score in upper tertile (>45); ^bLVEF: left ventricular ejection fraction (104 missing); ^cSelf-care behavior: total score European Heart Failure Self Care Behavior Scale (EHFSCBS-12); ^dHealth status: total score Kansas City Cardiomyopathy Questionnaire (KCCQ); ^eType D personality: score of >10 on both negative affectivity and social inhibition subscales of Type D scale (DS14); ^fICD concerns: total score on ICD concerns scale (ICDC); ^gDevice acceptance: total score on Florida Patient Acceptance Scale (FPAS); ^hAnxiety: total score of >10 on General Anxiety Disorder questionnaire (GAD-7); ⁱDepression: total score of >10 on Patient Health Questionnaire (PHQ-9); ^jPsychotropic medication: antidepressants, anxiolytics and/or hypnotics

Table II. Construct validity of the B-IPQ

		<u>Total Sample</u> (N=585)		<u>Dutch B-IPQ</u> (N=318)		<u>German B-IPQ</u> (N=144)		<u>French B-IPQ</u> (N=94)	
		Factor I	Factor II	Factor I	Factor II	Factor I	Factor II	Factor I	Factor II
IPQ 1	Consequences	0.83	-0.10	0.78	-0.24	0.84	-0.11	0.85	-0.15
IPQ 6	Concern	0.80	-0.02	0.86	-0.15	0.83	-0.15	0.71	0.27
IPQ 5	Identity	0.78	-0.08	0.74	-0.27	0.84	-0.03	0.73	0.19
IPQ 8	Emotional response	0.75	-0.08	0.79	-0.03	0.83	-0.09	0.72	-0.25
IPQ 3	Personal control	-0.11	0.73	-0.48	0.79	-0.10	0.70	0.12	0.58
IPQ 4	Treatment control	-0.19	0.69	-0.12	0.76	-0.20	0.65	-0.03	0.74
IPQ 7	Understanding	-0.03	0.68	-0.06	0.57	0.02	0.73	0.04	0.65
IPQ 2	Timeline	0.22	0.27	0.23	0.06	0.07	0.08	-0.06	0.45
Eigenvalues		2.71	1.42	2.97	1.32	3.04	1.34	2.31	1.68
% of Variance		33.88	17.80	37.16	16.53	37.99	16.80	28.81	21.05

Loadings of scales that are assigned to a factor are presented in bold.

Table III. Internal validity of the B-IPQ

Item		<u>Total Sample</u>	<u>Dutch</u>	<u>German</u>	<u>French</u>
		Item-Rest r	Item-Rest r	Item-Rest r	Item-Rest r
<i>Consequences</i>					
IPQ 1	How much does your illness affect your life? (Consequences)	0.66	0.66	0.70	0.67
IPQ 6	How concerned are you about your illness? (Concern)	0.64	0.76	0.70	0.50
IPQ 5	How much do you experience symptoms from your illness? (Identity)	0.59	0.63	0.69	0.52
IPQ 8	How much does your illness affect you emotionally? (Emotional Response)	0.59	0.62	0.68	0.48
		$\alpha = 0.80$	$\alpha = 0.83$	$\alpha = 0.85$	$\alpha = 0.74$
		MIIC = 0.51	MIIC = 0.56	MIIC = 0.59	MIIC = 0.43
<i>Control</i>					
IPQ 3	How much control do you feel you have over your illness? (Personal control)	0.38	0.40	0.31	0.29
IPQ 4	How much do you think your treatment can help your illness? (Treatment control)	0.34	0.39	0.29	0.29
IPQ 7	How well do you feel you understand your illness? (Understanding)	0.29	0.26	0.28	0.25
		$\alpha = 0.52$	$\alpha = 0.53$	$\alpha = 0.47$	$\alpha = 0.44$
		MIIC = 0.27	MIIC = 0.28	MIIC = 0.23	MIIC = 0.22
<i>Not included in analysis</i>					
IPQ 2	How long do you think your illness will continue? (Timeline)				

Item-Rest r = item-rest correlation; α = Cronbach's alpha; MIIC = mean interitem correlation.

Table IV. Correlations of total and consequence scores of the B-IPQ with clinical and psychological characteristics

	Total sample		Dutch patients		German patients		French patients	
	Total score	Consequences score	Total score	Consequences score	Total score	Consequences score	Total score	Consequences score
<i>Clinical characteristics</i>								
Secondary indication for ICD	.02	.06	-.002	.04	-.009	.04	.21*	.22*
NYHA class III	.13**	.12**	.19**	.17**	.05	.02	.12	.15
LVEF in %	.008	<.001	.006	.003	.02	.07	-.14	-.19
<i>Psychological characteristics</i>								
KCCQ total score	-.51**	-.51**	-.50**	-.51**	-.60**	-.58**	-.52**	-.53**
DS14 – NA total score	.46**	.46**	.44**	.45**	.56**	.55**	.41**	.46**
DS14 – SI total score	.14**	.10*	.15**	.10	.28**	.21*	-.12	-.04
PHQ-9 total score	.52**	.50**	.51**	.50**	.65**	.59**	.51**	.55**
GAD-7 total score	.50**	.54**	.52**	.56**	.63**	.63**	.48**	.54**
ICDC total score	.36**	.36**	.39**	.40**	.34**	.33**	.36**	.33**
FPAS total score	-.45**	-.43**	-.48**	-.49**	-.40**	-.40**	-.41**	-.38**
EHFScBS-12 total score	-.06	-.09*	-.15**	-.18**	.07	.03	.20	.14

** = p<.001, * = p<.05

Table V. Correlates of threatening illness perceptions and high perceived consequences ^a

	<u>Threatening illness perceptions</u>			<u>High perceived consequences</u>		
	OR	95% CI	P	OR	95% CI	P
Model I						
<i>Socio Demographic and Clinical Characteristics</i>						
Age < 60	2.00	1.18 – 3.39	.01	1.88	1.13 – 3.16	.02
Female sex	2.12	1.31 – 3.42	.002	2.58	1.59 – 4.18	<.001
Having a partner	1.20	0.76 – 1.92	.44	1.03	0.66– 1.63	.89
Higher educated	0.79	0.52 – 1.20	.27	0.70	0.46 – 1.05	.09
Employed	0.80	0.43 – 1.47	.47	1.03	0.57 – 1.85	.92
CRT-D	0.92	0.59 – 1.42	.70	0.95	0.62 – 1.45	.81
Primary prophylactic indication	1.09	0.62 – 1.93	.77	1.33	0.76 – 2.30	.32
NYHA Class III	1.82	1.19 – 2.80	.006	1.51	0.99 – 2.31	.06
LVEF (in %)	0.99	0.97 – 1.03	.76	1.01	0.98 – 1.04	.66
Obesity	1.53	0.95 – 2.50	.08	1.60	1.00 – 2.57	.05
Smoking	0.98	0.55 – 1.74	.95	1.44	0.83 – 2.49	.19
Use of alcohol	1.09	0.72 – 1.66	.69	1.00	0.66 – 1.50	.99
Model II						
<i>Psychological Characteristics</i>						
Poor health status	2.66	1.73 – 4.09	<.001	3.09	2.01 – 4.73	<.001
Anxiety	2.01	1.07 – 3.78	.03	3.12	1.61 – 6.05	.001
Depression	2.92	1.61 – 5.29	<.001	1.69	0.91 – 3.12	.10
Negative affectivity	1.76	1.08 – 2.86	.02	2.21	1.37 – 3.56	.001
Social inhibition	0.81	0.51 – 1.28	.36	0.57	0.36 - 0.91	.02
Poor ICD acceptance	2.74	1.75 – 4.30	<.001	2.48	1.57 – 3.90	<.001
High levels of ICD concerns	1.19	0.75 – 1.89	.46	1.43	0.91 – 2.24	.12
Poor self-care behavior	0.87	0.55 – 1.38	.56	0.81	0.51 – 1.27	.35
Model III						
<i>Combined</i>						
Age < 60	1.50	0.95 – 2.34	.08	1.75	1.12 – 2.73	.01
Female sex	1.81	1.10 – 2.99	.02	2.06	1.24 – 3.43	.005
NYHA Class III	1.01	0.64 – 1.60	.96	1.03	0.66 – 1.62	.90
Obesity	1.46	0.90 – 2.35	.12	0.94	0.58 – 1.52	.80
Poor health status	2.54	1.63– 3.97	<.001	3.07	1.97 – 4.81	<.001

Anxiety	2.01	1.08 – 3.76	.03	3.06	1.60 – 5.91	.001
Depression	2.64	1.46 – 4.77	.001	1.50	0.81 – 2.77	.20
Negative affectivity	1.82	1.13 – 2.93	.01	2.36	1.48 – 3.73	<.001
Social inhibition	0.75	0.47 – 1.19	.22	0.53	0.33 – 0.84	.007
Poor ICD acceptance	3.01	1.93 – 4.71	<.001	2.55	1.62 – 4.01	<.001

^a Multivariate logistic regression analyses; all factors except for LVEF were entered as dichotomous variables.

CRT-D = cardiac resynchronization therapy – defibrillator; NYHA = New York Heart Association functional class; LVEF = left ventricular ejection fraction.

* $P \leq 0.05$; ** $P \leq 0.01$; *** $P \leq 0.001$.

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Highlights

- Little is known about illness perceptions in patients with heart failure
- Analysis of the B-IPQ indicated two factors: consequences and control perceptions
- The consequences factor is internally consistent and can be used as a separate subscale
- Not medical but psychological factors are important correlates of heart failure perceptions
- These findings were robust across Dutch, French and German patient subgroups

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