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ORIGINAL

Cultural adaptation of a questionnaire on patient perceptions of artificial heart devices: methodological study

Adaptação cultural de questionário de percepções de pacientes sobre dispositivo cardíaco artificial: estudo metodológico

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ABSTRACT

Objective: To culturally adapt a questionnaire that evaluates patients' perceptions of the artificial heart device, technical concerns, and individual needs after a pacemaker implant or implantable cardioverter defibrillator. **Method:** Observational, cross-sectional study that covered the stages of translation of the questionnaire into spoken and written Brazilian Portuguese, evaluated by a committee of judges to obtain the first consensual version in spoken and written Portuguese in Brazil and evaluated with the target population. The questionnaire consists of 23 questions that assess different aspects of the patient's life regarding the implanted device. **Results:** Data were collected between February and June 2022, and 30 patients with pacemakers and 32 with implantable cardioverter defibrillators participated in the study. In the semantic validation, 60 (96.8%) patients answered that they "would not like to change anything in the questionnaire". **Conclusion:** The questionnaire on patient perceptions of artificial heart devices has been culturally adapted for use in Brazil.
Descriptors: Heart-Assist Devices; Perioperative Nursing; Perception.

RESUMO

Objetivo: Realizar a adaptação cultural de um questionário que avalia as percepções dos pacientes sobre o dispositivo cardíaco artificial, as preocupações técnicas e as necessidades individuais após o implante de marca-passo ou cardioversor desfibrilador implantável. **Método:** Estudo observacional, transversal, que percorreu as etapas de tradução do questionário para a língua portuguesa falada no Brasil, avaliado pelo comitê de juízes, para obtenção da primeira versão consensual em português falado e escrito no Brasil e avaliação com a população-alvo. O questionário é composto por 23 questões que avaliam diferentes aspectos na vida do paciente sobre o dispositivo implantado. **Resultados:** Os dados foram coletados entre os meses de fevereiro e junho de 2022 e participaram 30 pacientes com marca-passo e 32 com cardioversor desfibrilador implantável. Na avaliação semântica, 60 (96,8%) pacientes responderam que "não gostaria de mudar alguma coisa no questionário". **Conclusão:** O Questionário de percepções de pacientes sobre dispositivo cardíaco artificial se encontra adaptado culturalmente para o uso no Brasil.
Descritores: Coração Auxiliar; Enfermagem Perioperatória; Percepção.

INTRODUCTION

Chronic non-communicable diseases are a set of diseases that affect thousands of people. In 2019, overall mortality reached 74% of total deaths in Brazil, and in 2017, more than 41% were premature (under 60 years of age). Cardiovascular diseases (CVD) are among the most prevalent[1].

The World Health Organization reported classifying deaths and disabilities between 2000 and 2019. It showed that there was a fourfold increase in CVD, leading the NCD group and representing 16% of total deaths from all causes worldwide[2].

In Brazil, in 2019, NCDs ranked first in the number of deaths per chapter of the International Statistical Classification of Diseases and Related

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Health Problems (ICD)-10. In the age groups over 50, the leading causes of death in 2019 were circulatory system diseases[3].

As for cardiac arrhythmias, according to the Brazilian Society of Cardiac Arrhythmias, Brazil has more than 20 million people with these conditions, culminating in more than 320,000 sudden deaths/year[4].

Surgeries for pacemaker implantation (PM) and implantable cardioverter defibrillator (ICD) have increased in recent years, as well as the incidence of the number of complications, both physical and emotional[5].

After PM implantation, the individual may start living with the inherent interferences of the device itself. These environmental interferences are divided into home, social, professional, and hospital environments. In addition, they can be observed more frequently in older devices. Currently, the devices tend to be very reliable; however, some situations may interfere with their performance, such as, for example, inappropriate triggering, loss of stimulus triggering, reversion of the generator to asynchronous mode, inadequate acceleration, and inadequate setting change. Such interferences can trigger reversible and permanent dysfunctions, cardiac arrhythmias, and alteration of the electrode-heart junction[6].

Even in the presence of these complications, it is expected that the use of peacemakers does not entail restrictions on individuals' physical and social aspects. However, the lack of familiarity with these aspects and knowledge about the underlying heart disease and the artificial heart device itself may cause restrictions that are not necessary to these people's daily lives, which may affect their quality of life[5].

Individuals with ICD may experience negative situations, from the diagnosis of the cardiac condition with the indication for device implantation to stressful situations, such as the recovered cardiorespiratory arrest, the shocks emitted by the ICD, extended hospital stays, recurrence of cardiac arrhythmias that can lead to death, and uncertainty about the future[7].

Considering the emotional aspects inherent to the dependence on an artificial heart device, German researchers[8] conducted a study aimed at evaluating possible differences in psychosocial adaptation, quality of life, and incidence of mood disorders in people with PM and ICD. To carry out the study, the authors created a questionnaire to evaluate the patient's perception of using the device. Twenty-three questions were prepared by the medical team based on the clinical experiences of health providers in treating people with PM and ICD. The questions apply to users of both types of devices and assess the different aspects of the device's presence in their lives, such as: perception of the device, technical concerns about the device's operation, and the individual needs of its users.

Given the above, clinical practice needs to recognize the relevance of reports on the health of individuals with artificial heart devices since the evaluation of the person's perception of their health, quality of life, or functional status may reveal the impacts of surgical treatment and long-term treatment[9].

Thus, the study's purpose was to culturally adapt this questionnaire for use by Brazilians with PM and ICD.

METHOD

This is an observational, cross-sectional study of an instrument's cultural adaptation. The criteria established in *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) were used to prepare this article.

Professor Firat Duru, the lead author, emailed in October 2020 to authorize cultural adaptation and use of the questionnaire.

The research project was prepared by the ethical precepts of Resolution of the National Health Council No. 466 of December 12, 2012, and Resolution of the National Health Council No. 510 of April 7, 2016, and was approved by the Research Ethics Committee (CEP) of the School of Nursing of Ribeirão Preto (EERP) of the University of São Paulo (USP), Institutional Opinion number: 4,667,556 (CAAE: 45078720.3.0000.5393).

The stages of the cultural adaptation process were based on the international literature[10-12] and used in Brazil [13-15].

The stages covered were translating the questionnaire into Brazilian Portuguese, evaluating it by a committee of judges, providing the first consensual version in spoken and written Brazilian Portuguese, and validating it by the target population.

Two independent Brazilian translators who knew English were hired for the translation stage. They were called "Translator 1" and "Translator 2," and only one of them knew the purpose of the study. The first consensual version in spoken and written Brazilian Portuguese was obtained after a committee of judges evaluated "translated versions 1 and 2."

In this stage, the two versions were translated into spoken and written Brazilian Portuguese, and the original version in English was presented to a committee of judges. Five judges, all nurses with at least a doctorate, with expertise in the subject and the method, who mastered Portuguese and English, participated in the meeting. The evaluation was carried out via *Google Meet* in December 2021, with the participation of all experts and researchers. The meeting was organized by the main researcher. The judges established an 80% agreement to consider each question properly translated and adapted for use in Brazil[16].

At the beginning of the meeting, the lead researcher informed the study's objectives. Next, the main researcher read all the information on the questionnaire, the questions, and the answer options. The original version and the two translations into spoken and written Brazilian Portuguese were compared simultaneously. When one of the five judges disagreed, a better translation/adaptation of the question's wording was discussed until the final version was obtained. In the end, the first consensual version of the questionnaire was obtained in spoken and written Brazilian Portuguese.

Then, semantic validation of the translated material was performed to verify potential problems related to the target population's understanding of the questions and their answers.

This step was carried out following the DISABKIDS method adapted for Brazil by the Study Group on Health Measures (GPEMSA – CNPq) and followed the following steps: a) application of the first consensual spoken and written Brazilian Portuguese version to all participants, b) application of the "Semantic Validation Form - general impressions" to all patients, and c) application of the "Semantic Validation Form – specific", according to the designation of patient groups, as shown in Table 1[15, 17-18]. Data was collected through interviews with the participants.

Table 1 - Distribution of participants for evaluating the "Semantic Validation Form – specific", according to gender and questions of the Questionnaire on the perception of cardiac devices (n=62). Ribeirão Preto, SP, Brazil, 2022

Subset of questions about the Questionnaire on Heart Device Perception **Questions**	**Gender**			
	Female		**Male**	
	PM*	**ICD****	**PM***	**ICD****
1 – 5	3	4	3	4
6 – 10	3	3	3	3
11–15	3	3	3	3
16 – 20	3	3	3	3
21 – 23	3	3	3	3
Total	15	16	15	16

PM* - Pacemaker; ICD** - implantable cardioverter defibrillator.

According to the DISABKIDS manual, the researcher can list subsets to support the application of the "Semantic Validation Form – specific". In this study, we listed the gender of the participant since, in previous research, it was found that women with PM had worse evaluations of health-related quality of life when compared to men[19]. In addition, in another study, women with ICD had more symptoms of anxiety and depression when compared to men with the same device[20].

At this stage, the questionnaire questions were grouped as follows: questions 1 to 5; questions 6 to 10; questions 11 to 15; questions 16 to 20; and questions 21 to 23. Thirty patients with PM (15 women and 15 men) and 32 patients with ICD (16 women and 16 men) answered the specific questionnaire. Every three patients validated only the questionnaire questions on perceptions selected by the researchers[15, 17-18] (Table 1).

Data for the semantic validation were collected from patients treated at two arrhythmia outpatient clinics of a university hospital in the countryside of São Paulo.

The inclusion criteria for this stage were: 18 years old or older, having PM or ICD. Exclusion criteria were: symptoms and signs of clinical decompensation (dyspnea, arrhythmia with symptoms, presence of shock) on the day of the interview and the presence of disorientation regarding time, space, and person. For this second criterion, those who made a mistake or did not know how to answer three or more of the following questions were excluded: "What is the date today?", "How old are you?", "What day of the week is today?", "What is the name of the place where we are right now?", "What is your full name?", and "What is the name of the city where you were born?" [21].

The sociodemographic and clinical variables were collected to characterize the sample: date of interview, date of birth, date of device implantation, gender, partner presence, academic background, professional status, family monthly income, type of device, and medical diagnoses. To calculate their age, the date of birth was subtracted from the interview date. To calculate the time of the device implantation, the date of implantation was subtracted from the interview date.

To support the decision to change or not, the questions listed by the research participants, after the semantic evaluation stage, were changed when more than 90% of the patients requested/suggested the exact change.

German researchers developed the questionnaire to assess patients' perceptions of the artificial heart device[8]. The questionnaire consists of 23 questions applicable to both patients with PM and ICD and is aimed at evaluating different aspects of the implanted device, such as patients' perceptions of the device, techniques, concerns, and individual needs. The clinical team developed the questions based on their previous experiences working with patients with implanted devices.

Although the researchers are German, the questionnaire was developed in English. The answer options of the 23 questions differ from each other. The results are obtained through simple frequency and percentage of survey responses. No score is calculated[8].

The variables were entered into the Office Excel 2010 program to validate the database. Data entry was performed twice in different spreadsheets. After bank validation, data was entered in the IBM SPSS Program version 24.0 for Windows (SPSS, Inc., Chicago, IL, USA). Descriptive analyses of the study, simple frequency, and percentage were performed for qualitative variables. The analyses of central tendency (mean and median) and dispersion (standard deviation) were performed for the numerical variables.

RESULTS

Translation and two versions of the questionnaire, as well as the first consensual version in spoken and written Portuguese in Brazil

The questionnaire (8) was translated by two independent translators and differed regarding some questions. In the meeting, the judges compared the "translated versions 1 and 2" of the questionnaire with the original version in English. At this stage, the objective was to seek a consensus between the translations, maintaining the exact meaning of each item or word of the original version, or as close as possible, using terms from the context of Brazilian culture.

Figure 1 shows the questions of the original version of the questionnaire, the "translated versions 1 and 2" and the first consensual version in spoken and written Brazilian Portuguese. The different words in the translations are highlighted in bold. Some questions of versions 1 and 2 were chosen among those that presented the best meaning compared to the original version to achieve the final consensual version. The first final consensual version in spoken and written Brazilian Portuguese has questions merged from the two translated versions and some additions since the judges reviewed it through a joint discussion on the most appropriate translation of a given question to reach the goal.

Figure 1 – Presentation of the original version of the questionnaire, the translated versions 1 and 2, and the first consensual version in spoken and written Brazilian Portuguese. Ribeirão Preto, SP, Brazil, 2022

	Original Version (English)	**Portuguese Version 1**	**Portuguese Version 2**	**First Consensual Version in Portuguese**
Title	Specially designed questionnaire used in the study	Adaptação de questionário de avaliação das percepções de pacientes sobre dispositivos cardíacos implantáveis.		Questionário de avaliação das percepções de pacientes sobre dispositivos cardíacos implantáveis
1	To what extent do you feel physically impaired by the implanted device (pacemaker, defibrillator)? • No impairment • Limited impairment • Considerable impairment • Disabling impairment	Até que ponto você se sente fisicamente **prejudicado** pelo **dispositivo** implantado (marca-passo, desfibrilador)? - Nenhuma **deficiência** - **Deficiência limitada** - **Deficiência** considerável - **Deficiência** incapacitante	Até que ponto você se sente fisicamente **debilitado** pelo **aparelho** implantado (marca-passo, desfibrilador)? - Nenhuma **debilitação** - **Pouca debilitação** - **Debilitação** considerável - **Debilitação** incapacitante	Até que ponto você se sente fisicamente prejudicado pelo aparelho implantado (marca-passo, desfibrilador)? ( ) Não me sinto prejudicado ( ) Um pouco prejudicado ( ) Muito prejudicado ( ) Totalmente prejudicado/ incapacitado
2	How often do you think about the implanted device? • Never • Sometimes • Several days a week • Every day	Com que frequência você **pensa sobre o dispositivo** implantado? - Nunca - **Algumas vezes** - Vários dias por semana - Todos os dias	Com que frequência você **pensa no aparelho** implantado? - Nunca - **Às vezes** - Vários dias por semana - Todos os dias	Com que frequência você pensa no seu aparelho implantado (marca-passo, desfibrilador)?* ( ) Nunca ( ) Às vezes ( ) Vários dias por semana ( ) Todos os dias
3	Did you feel depressed when you were informed about the necessity of a device implantation? • No • Yes, to some degree • Yes, considerably • Yes, very much	Você se sentiu deprimido quando foi informado sobre a **necessidade de implantar um dispositivo**? - Não - Sim, **em certa medida** - Sim, consideravelmente - Sim, muito	Você se sentiu deprimido quando foi informado sobre a **necessidade do implante do aparelho**? - Não - Sim, **até certo ponto** - Sim, consideravelmente - Sim, muito	Você se sentiu deprimido quando foi informado sobre a necessidade do implante do aparelho (marca-passo/ desfibrilador)?* ( ) Não ( ) Sim, um pouco ( ) Sim, mais do que pouco ( ) Sim, muito
4	Since implantation, to what extent are you preoccupied with your heart condition? • None • To some degree • Considerably • Very much	Desde **a implantação**, até que ponto **você está preocupado** com sua condição cardíaca? - **Nenhuma** - **Em certa medida** - Consideravelmente - Muito	Desde **o implante**, até que ponto **você se preocupa** com sua condição cardíaca? - **Nenhum pouco** - **Até certo ponto** - Consideravelmente - Muito	Desde o implante do aparelho (marca-passo/ desfibrilador), até que ponto você se preocupa com sua condição cardíaca? ( ) Não me preocupo ( ) Me preocupo um pouco ( ) Me preocupo mais do que um pouco ( ) Me preocupo muito
5	Did the implanted device change your image of your body? • Yes • No	O **dispositivo** implantado **arriscou** sua imagem de seu corpo? - Sim - Não	O **aparelho** implantado **mudou** sua imagem de seu corpo? - Sim - Não	O aparelho implantado (marca-passo/ desfibrilador) mudou a imagem que você tinha do seu corpo? ( ) Sim ( ) Não

6	To what extent do the visible changes at the implantation site disturb you? • Does not disturb • To some degree • Considerably • Very much	Até que ponto as mudanças visíveis no **local da implantação o perturbam**? - Não **perturba** - **Em certa medida** - Consideravelmente - Muito	Até que ponto as mudanças visíveis no **local do implante incomodam você**? - Não **incomodam** - **Até certo ponto** - Consideravelmente - Muito	Até que ponto as mudanças visíveis no local do implante do aparelho (marca-passo/ desfibrilador) incomodam você? ( ) Não me incomodam ( ) Me incomodam um pouco ( ) Me incomodam mais do que um pouco ( ) Me incomodam muito
7	Does the implanted device disturb you in daily life? • No • Yes, a little • Yes, considerably • Yes, very much	O **dispositivo** implantado **o perturba na vida diária**? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	O **aparelho** implantado **incomoda você em sua vida diária**? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	O aparelho implantado (marca-passo/ desfibrilador) incomoda você em sua vida diária? ( ) Não me incomoda ( ) Sim, me incomoda um pouco ( ) Sim, me incomoda mais do que um pouco ( ) Sim, me incomoda muito
8	Does the implanted device disturb you in your leisure activities? • No • Yes, a little • Yes, considerably • Yes, very much	**O dispositivo** implantado **o perturba** em suas atividades de lazer? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	**O aparelho** implantado **incomoda você** em suas atividades de lazer? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	O aparelho implantado (marca-passo/ desfibrilador) incomoda você em suas atividades de lazer? ( ) Não me incomoda ( ) Sim, me incomoda um pouco ( ) Sim, me incomoda mais do que um pouco ( ) Sim, me incomoda muito
9	Do you have anxiety about premature battery depletion? • No • Yes, a little • Yes, considerably • Yes, very much	**Você tem ansiedade sobre o esgotamento prematuro da bateria?** - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	**Você se sente ansioso(a) em relação a bateria acabar prematuramente**? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	Você se sente ansioso ao pensar que a bateria pode acabar antes do previsto? ( ) Não me sinto ansioso ( ) Sim, me sinto um pouco ( ) Sim, me sinto mais que um pouco ( ) Sim, me sinto muito
10	Do you have anxiety about malfunction of the implanted device? • No • Yes, a little • Yes, considerably • Yes, very much	**Você tem ansiedade sobre o mau funcionamento do dispositivo implantado**? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	**Você se sente ansioso(a) em relação ao mal funcionamento do aparelho implantado**? - Não - Sim, um pouco - Sim, consideravelmente - Sim, muito	Você se sente ansioso em relação ao mau funcionamento do aparelho implantado? ( ) Não me sinto ansioso ( ) Sim, me sinto um pouco ( ) Sim, me sinto mais do que um pouco ( ) Sim, me sinto muito
11	How well are you informed about the implanted device? • Badly • Moderately • Well • Very well	**Até que ponto você está bem informado sobre o aparelho implantado**? - Mal - Moderadamente - Bem - Muito bem	**Quão informado você está a respeito do aparelho implantado**? - Mal/**Pouco** - Moderadamente - Bem - Muito bem	Até que ponto você se sente informado sobre o aparelho implantado (marca-passo/ desfibrilador)? ( ) Mal-informado ( ) Pouco informado ( ) Muito informado ( ) Totalmente informado

12	How well are you informed about your heart disease? • Badly • Moderately • Well • Very well	**Até que ponto você está bem-informado sobre** sua doença cardíaca? - Mal - Moderadamente - Bem - Muito bem	**Quão informado você está a respeito de** sua doença cardíaca? - Mal/**Pouco** - Moderadamente - Bem - Muito bem	Até que ponto você se sente informado sobre sua doença cardíaca? ( ) Mal-informado ( ) Pouco informado ( ) Muito informado ( ) Totalmente informado
13	Is the implanted device a source of security for you? • No • A little • Considerably • Very much	**O dispositivo** implantado **é uma** fonte de segurança para você? - Não - Um pouco - Consideravelmente - Muito	**O aparelho** implantado **é fonte** de segurança para você? - Não - Um pouco - Consideravelmente - Muito	Até que ponto o aparelho implantado (marca-passo/desfibrilador) traz segurança para você? ( ) Não traz segurança ( ) Um pouco ( ) Mais que um pouco ( ) Muita
14	Is the implanted device a life extender for you? • No • A little • Considerably • Very much	**O dispositivo** implantado é um extensor de vida para você? - Não - Um pouco - Consideravelmente - Muito	**O aparelho** implantado é um extensor de vida para você? - Não - Um pouco - Consideravelmente - Muito	Até que ponto você considera que o aparelho implantado (marca-passo/desfibrilador) pode prolongar sua vida? ( ) Não considero ( ) Um pouco ( ) Mais do que um pouco ( ) Muito
15	Is the implanted device a source of anxiety for you? • No • A little • Considerably • Very much	**O dispositivo** implantado é uma fonte de ansiedade para você? - Não - Um pouco - Consideravelmente - Muito	**O aparelho** implantado é fonte de ansiedade para você? - Não - Um pouco - Consideravelmente - Muito	Usar um aparelho implantado (marca-passo/ desfibrilador) causa ansiedade em você? ( ) Não ( ) Um pouco ( ) Mais do que um pouco ( ) Muita
16	Would you rather have more frequent appointments with your physician? • Yes • No	Você **gostaria de** ter consultas mais frequentes com seu médico? - Sim - Não	Você **preferiria** ter consultas mais frequentes com seu médico? - Sim - Não	Você gostaria de ter consultas mais frequentes com seu médico? ( ) Sim ( ) Não
17	Would you rather longer appointments with your physician? • Yes • No	Você **prefere consultas** mais longas com seu médico? - Sim - Não	Você **preferiria ter consultas** mais longas com seu médico? - Sim - Não	Você gostaria de ter consultas mais longas com seu médico? ( ) Sim ( ) Não
18	Would you also consider having psychological or psychotherapeutic support? • Yes • No	Você também consideraria ter apoio psicológico **ou** psicoterapêutico? - Sim - Não	Você também consideraria ter apoio psicológico **e** psicoterapêutico? - Sim - Não	Você gostaria de ter apoio psicológico ou psicoterapêutico? ( ) Sim ( ) Não
19	Would you also consider being involved in a support group? • Yes • No	Você também consideraria estar envolvido em um grupo de apoio? - Sim - Não	Você também consideraria estar envolvido em um grupo de apoio? - Sim - Não	Você gostaria de participar de um grupo de apoio? ( ) Sim ( ) Não

20	Do you believe the public should be better informed about implantable devices for heart diseases? • Yes • No	Você acredita que o público **deve ser** mais bem informado sobre os **dispositivos** implantáveis para doenças cardíacas? - Sim - Não	Você acredita que o público **deveria ser** mais bem informado sobre **aparelhos** implantáveis para doenças cardíacas? - Sim - Não	Você acredita que as pessoas deveriam ser mais bem informadas sobre aparelhos implantáveis para doenças cardíacas? ( ) Sim ( ) Não
21	How do you feel now as compared to your status before the implantation? • Worse • Same • Better	Como você se sente **agora**, **em comparação com seu status antes da implantação**? - Pior - **O mesmo** - Melhor	Como você se sente **hoje**, **se comparado com seu estado antes do implante**? - Pior - **Igual** - Melhor	Como você se sente agora, em comparação com seu estado de saúde antes da implantação do aparelho (marca-passo/ desfibrilador)? ( ) Pior ( ) Igual ( ) Melhor
22	How long did it take you to adjust the implanted device? • Less than 1 month • Up to 6 months • Up to 1 year • Up to 2 years • Not yet	Quanto tempo **demorou para ajustar o dispositivo implantado**? - Menos de 1 mês - Até 6 meses - Até 1 ano - Até 2 anos - Ainda não	Quanto tempo **você levou para se adaptar ao aparelho implantado**? - Menos de um mês - Até seis meses - Até um ano - Até dois anos - Ainda não	Quanto tempo você levou para se adaptar ao aparelho implantado (marca-passo/ desfibrilador)? ( ) Menos de 1 mês ( ) Até 6 meses ( ) Até 1 ano ( ) Até 2 anos ( ) Ainda não me adaptei
23	Overall, was it worthwhile having the device implanted? • No • Probably • Yes	**Em geral**, valeu a pena ter o **dispositivo** implantado? - Não - Provavelmente - Sim	**De forma geral**, valeu a pena ter o **aparelho** implantado? - Não - Provavelmente - Sim	De forma geral, valeu a pena ter implantado o aparelho (marca-passo/ desfibrilador)? ( ) Não ( ) Provavelmente ( ) Sim

Semantic Validation

Data collection took place between February and June 2022. All patients who met the inclusion criteria agreed to participate in the research. Tables 2 and 3 show the sociodemographic and clinical characterization of the participants.

Table 2 – Sociodemographic characterization of the 62 participants, according to gender, partner presence, professional status, age, education, and time of device implantation (n=62). Ribeirão Preto, SP, Brazil, 2022

Variable	**Pacemaker** n= 30	**Implantable Cardioverter Defibrillator** n= 32
Gender, (n (%))		
Female	15 (50)	16 (50)
Partner (n (%))		
Yes	19 (63)	16 (50)
Professional status - (n (%))		
Inactive	18 (60)	23 (72)
Age - (Average (SD))*	50.7 (12.4)	45.8 (13.6)
Education in years (Average (SD))*	7.3 (4.1)	7.7 (5.3)
Device Implantation Time in years (Average (SD))*	6 (6.8)	4 (3.6)

*(Average (SD)) = Average (Standard Deviation)

PM patients - median age of 54.0 years, ranging from 20 to 72 years old. As for education, the median was eight years, ranging from lack of literacy to 15 full years of study. Finally, regarding time of implantation of the device, they presented a median of four years, ranging from less than one year of implantation to 24 years post-implantation.

The median age of ICD patients was 50.0, ranging from 18 to 67. As for education, the median was eight years, ranging from a lack of literacy to 19 full years of study. Finally, regarding the time of the device's implantation, they presented a median of four years, ranging from less than one year of implantation to 13 years post-implantation.

Table 3 shows the clinical characterization of the participants, highlighting the presence of associated diseases.

Table 3 – Clinical characterization of the 62 participants, according to the presence of associated diseases (n=62). Ribeirão Preto, SP, Brazil, 2022

Variable	**Pacemaker** n= 30 n (%)	**Implantable Cardioverter Defibrillator** n= 32 n (%)
Chagas Disease		
Yes	9 (30)	10 (31)
Sick Sinus Disease		
Yes	6 (20)	zero
Atrioventricular block		
Yes	16 (53)	2 (6)
Heart failure		
Yes	4 (13)	2 (6)
Hypertensive Cardiomyopathy		
Yes	1 (3)	13 (40)

The results of the "Semantic Validation Form - general impressions" of the semantic validation phase are shown in Table 4.

Table 4 – Results of applying the "Semantic Evaluation Form - general impressions" of the semantic validation phase of the 62 participants (n=62). Ribeirão Preto, SP, Brazil, 2022

Variable	Pacemaker (n=30) n (%)	Implantable Cardioverter Defibrillator (n=32) n (%)
What did you think of our questionnaire in general?		
Very good	4 (13)	13 (41)
Good	26 (87)	19 (59)
Are the questions understandable? If not, what questions?		
Easy to understand	28 (93)	31 (97)
Sometimes difficult	2 (7)	1 (3)
Regarding the response categories: did you have any difficulty using them? Please explain.		
None/no difficulty	28 (93)	29 (91)
There are some difficulties	2 (7)	3 (9)
Are the questions relevant to your health condition?		
Extremely relevant	27 (90)	30 (94)
Sometimes relevant	2 (7)	2 (6)
No/no relevance	1 (3)	zero
Would you like to change anything in the questionnaire?		
No	30 (100)	30 (94)
Would you like to add anything to the questionnaire?		
No	23 (77)	23 (72)
Were there any questions that you did not want to answer? If so, why?		
No	25 (83)	31 (97)

Of the participants, 96.8% (n=60) answered they "would not like to change anything in the questionnaire".

Regarding the specific validation of the questions on the questionnaire, the responses of the 62 participants were analyzed.

In general, the participants had no difficulty in understanding the questions and considered the writing adequate.

Regarding question 3 - "Did you feel depressed when you were informed about the necessity of a device implantation (pacemaker/ defibrilla-

tor)?", five patients (8.1%) suggested adding the word "sad" immediately after the word "depressed". Considering the criteria established to change the questions, the request was not accepted since more than 90% believed the wording of the item was appropriate.

Regarding question 4 - Since implantation, to what extent are you preoccupied with your heart condition?", seven patients (11.3%) suggested replacing the words "heart condition" with "heart problem". Considering the criteria established to change the questions, the request was not accepted, since more than 90% believed the wording of the item to be appropriate.

In question 12 - "How well are you informed about your heart disease?", four patients (6.4%) suggested replacing the words "heart disease" with "heart problem", a request not accepted by the researchers.

In addition to these suggestions, one patient raised the importance of a question related to postoperative pain. Another patient suggested knowing about the interference of household appliances in the proper device operation and the possibility of shock in patients who implanted the ICD. Considering the criteria established to change the questions, the requests were not accepted.

Thus, the first consensual version in spoken and written Brazilian Portuguese obtained after evaluation by the Committee of Judges was considered the "final consensual version in spoken and written Portuguese in Brazil".

DISCUSSION

According to the Brazilian Registry of Pacemakers, Defibrillators, and Cardiac Resynchronizers (RBM), since the first implant surgery of an artificial cardiac device, performed on January 5, 1990, until December 31, 2014, 306,886 implant surgeries have already been registered. For the first implant, 216,537 surgeries were performed, of which 190,747 were for pacemaker implants, 13,725 were for ICD, 6,683 were for resynchronizers, and 4,052 were for cardio defibrillators with resynchronizers. There is no information for 1,330 surgeries. 90,349 surgeries were also performed for device replacement[22].

In 2019, in total, there were 18,665 pacemaker implants, with the Southeast region having the most implants, 8,076, followed by the South region, with 4,401; the Northeast region, with 3,985; the Central-west region, with 1,525 and, finally, the North region with 678 implants procedures. Regarding ICD implants, there is a different regional panorama to pacemaker implants, with the southern region, with 9,512, the most significant number of ICD implants, followed by the Southeastern region, with 3,837; the Northeast region, with 3,067; the Central-West region, with 1,458, and the North region, with 247 implants in that year[3].

Patients with PM already have severe underlying heart diseases, which can often be life-threatening. For these patients, the indication of a pacemaker implant may be one of the last treatment alternatives, in addition to the implantation of the device and, ultimately, a heart transplant. If, on the one hand, patients depend on the pacemaker implant for their survival, they also begin to live with the inherent uncertainties of depending on a device. These patients, in addition to experiencing the signs and symptoms of the underlying heart disease itself, may also have intrinsic experiences of inadequate device performance[23].

According to the literature, most patients using ICDs tend not to have difficulties in using the device, but some may experience psychological problems during the process[24]. We have found reports of pain and discomfort at the implant site, especially in the immediate postoperative period, sleeping difficulty, concerns about sexual life, loss of libido, body image distortion, decreased performance of social activities and physical activities, worry about the possible presence of shocks, as well as concern about the malfunction of the ICD[7].

Regarding care guidelines after the implant procedure, patients should not raise the arm on the side of the implant for a few weeks and should wait for medical clearance to make movements of greater amplitude. Physical and sexual activities may be resumed after a joint decision with the medical team and the postoperative evolution of individuals. The use of household appliances is generally allowed since artificial heart devices are airtight. Special care should be taken in environments with magnetic fields, such as places with metal detectors, because, in these situations, the operation of the devices is interrupted momentarily and can resume as people move away from the place[25].

Currently, the number of measurement instruments that assess individuals' characteristics and health outcomes is increasing and is available for use in clinical research and the health assessment of the general population. Cultural adaptation is necessary for a country that in-

tends to use an instrument built and validated in another culture through methodological procedures[26].

As for the study, to culturally adapt a questionnaire that assesses patients' perceptions of the artificial heart device, when we compare the sociodemographic and clinical characteristics of patients who originally answered the questionnaire[8], we can observe both differences and similarities with patients who participated in the semantic validation stage in Brazil.

The original study had 76 patients with PM and 76 patients with ICD, and ICD patients were divided into ICD patients with post-implantation shock (n=45) and ICD patients with no post--implantation shock (n=31). It is noteworthy that the perception assessment questionnaire was built based on the clinical experience of the surgeons who followed these patients and that the questionnaire was used concomitantly with a scale to assess symptoms of anxiety and depression and a generic instrument to assess health-related quality of life validated psychometrically for the language of origin[8].

In the original study, patients with pacemakers had a mean age of 59.4 years (Standard Deviation (SD) =9.9), while Brazilian patients were, on average, 50.7 years (SD=12.4). Brazilian patients had a lower mean age when compared to the patients of the original study; however, the median age of Brazilians was 54 years, ranging from 20 to 72 years old.

As for ICD patients, in the original study, patients with shock had a mean age of 59.7 years (SD=13.0), and for those with no shock, the mean age was 56.2 years (SD=12.8). Like the patients with pacemakers, Brazilian patients' mean age was lower than the age of the original study participants, 45.8 years (SD=13.6). The median found was 50 years old; the youngest participant was 18 years old, and the oldest was 67 years old. The variation in age can favor the process of cultural adaptation to another language, making it possible to understand it in different strata.

The time of implantation of the artificial cardiac devices of the participants of the original study was shorter when compared to that of Brazilian patients, namely: meantime of implantation of PM of 3.1 years and ICD of 2.3 years, while in the study, it was 6 years and 4 years, respectively. However, it is worth mentioning the variance of time of implantation of the two groups investigated in Brazil, patients with PM had implantation ranging from less than one year to 24 years of implantation, as well as patients with an interval of less than one year of implantation to 13 years after implantation. This variation can also favor the cultural adaptation process of a questionnaire since a patient with little implant time will understand the nature of the issues, and a patient with more implant time will have greater experience with the device.

The academic background of the participants was not found in the original study. We think this variable is important in the process of cultural validation of an instrument since literacy is directly related to the ability to understand the questions, thus favoring more reliable answers. In the present study, patients with PM had, on average, 7.3 years of schooling (SD=4.1), ranging from illiterate patients to people with 15 years of study. As for ICD patients, the mean number of years of study was 7.7 years (SD=5.3), ranging from illiterate people to patients with 19 years of study. Given the results, we can infer that the questions of the questionnaire and the response scales were understandable at different levels of education.

Regarding the semantic validation results, in the questionnaire's general assessment, 60 participants (96.8%) answered that they "would not like to change anything in the questionnaire". The requests for changes throughout the questionnaire were isolated and made by a few participants. This reinforced the decision to maintain the first consensual version in spoken and written Brazilian Portuguese, obtained after evaluation by a committee of judges.

As a study limitation, we identified that the data collection was carried out in a single Health Unit; however, even in the face of this limitation, we found satisfactory results in the questionnaire adaptation process.

Nonetheless, it is essential to emphasize the importance of future studies to evaluate the applicability of the questionnaire, as well as to consider the aspects that a few patients raised but that can influence the daily lives of people who depend on an artificial cardiac device to live, such as the presence of postoperative pain, the knowledge of the interference of household appliances in the device's operation and the possibility of the presence of shock in patients who have implanted the ICD.

CONCLUSION

After translating the questionnaire into spoken and written Brazilian Portuguese, evaluating it by the committee of judges, creating the first

consensual version in spoken and written Brazilian Portuguese, and validating its semantics by the target population, we conclude that the "Questionnaire on patient perceptions of artificial heart devices" is culturally adapted for use in Brazil.

Given the above, we present a valid questionnaire for evaluating aspects of the daily lives of people with artificial heart devices, which may improve the instrumentalization of research in this area of interest.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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