

# Translation, Cultural Adaptation and Contributions to the Validation of the Nijmegen Cochlear Implant Questionnaire (NCIQ) for European Portuguese



## Tradução, Adaptação Cultural e Contributos para a Validação da Escala Nijmegen Cochlear Implant Questionnaire (NCIQ) para o Português Europeu

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### ABSTRACT

**Introduction:** The Nijmegen Cochlear Implant Questionnaire (NCIQ) scale uses a simple and easily administered questionnaire to evaluate the adaptation of individuals to their cochlear implants. The aim of this study was to validate the NCIQ for European Portuguese, through its translation and cultural adaptation. It also presents the evaluation of reproducibility and the description of the results of this questionnaire in patients using IC.

**Material and Methods:** Fifty postlingually deaf adult multichannel cochlear implant users (uni- or bilateral) participated in the study. Participants used the cochlear implant for at least 12 months and were patients of the Department of Otolaryngology at the Egas Moniz Hospital in Lisbon. Permission, as well the guidelines for translation, were obtained from the authors of the scale. Translation and cultural adaptation were carried out, in addition to the evaluation of reproducibility and internal consistency.

**Results:** The participants were 44.0% male and 56.0% female, aged between 20 and 79 years (55.50 ± 15.69). The results of the study showed an overall level of satisfaction of 65.07 among cochlear implants users. The level of satisfaction of the subdomains was 64.40 in basic sound perception, 71.35 in advanced sound perception, 57.91 in speech production, 59.05 in self-esteem, 69.75 in activity and 68.50 in social functioning. Internal consistency (Cronbach  $\alpha$  score = 0.96) and test-retest reliability coefficients proved to be strong. Furthermore, the questionnaire's overall and subdomains average scores did not differ significantly from the results obtained with the original scale.

**Conclusion:** This adaptation of the NCIQ questionnaire for European Portuguese should be considered a good tool to evaluate the level of satisfaction of cochlear implant users and, so far, it is the only scale in this field validated for application in the Portuguese population.

**Keywords:** Cochlear Implantation; Cochlear Implants; Portugal; Quality of Life; Reproducibility of Results; Speech Perception; Surveys and Questionnaires; Translation

### RESUMO

**Introdução:** O questionário *Nijmegen Cochlear Implant Questionnaire* (NCIQ) consiste numa escala simples e de rápida aplicação para avaliar a satisfação dos indivíduos que utilizam implantes cocleares. O objetivo deste estudo foi a validação do NCIQ para o Português Europeu e avaliação da qualidade de vida em adultos utilizadores de implantes cocleares.

**Material e Métodos:** Participaram no estudo 50 adultos utilizadores de implante coclear multicanal (uni ou bilateral), com surdez pós-lingual, no mínimo com 12 meses de uso, implantados e seguidos no serviço de Otorrinolaringologia do Hospital Egas Moniz em Lisboa. Foram pedidas a autorização e as normas para a tradução do questionário aos autores da escala e realizada a tradução e retroversão do questionário, a adaptação cultural, e a avaliação da reprodutibilidade e da consistência interna.

**Resultados:** Os participantes eram 44,0% do género masculino e 56,0% do feminino, com idades compreendidas entre os 20 e os 79 anos (55,50 ± 15,69). Os resultados obtidos neste estudo demonstraram um nível de satisfação global de 65,07 nos utilizadores de implantes cocleares. O nível de satisfação dos subdomínios foi de 64,40 na perceção básica do som, 71,35 na perceção avançada do som, 57,91 na produção da fala, 59,05 na autoestima, 69,75 na atividade e 68,50 nas interações sociais. A versão traduzida do questionário NCIQ apresentou uma boa consistência interna para todos os domínios existentes no questionário ( $\alpha$  de Cronbach = 0,96). Verificou-se também uma boa reprodutibilidade inter-pesquisadores. Para a pontuação global e das subescalas do questionário, os resultados médios obtidos demonstraram não haver diferenças significativas com a escala original.

**Conclusão:** A adaptação do *Nijmegen Cochlear Implant Questionnaire* para Português Europeu deve ser considerada um bom instrumento para a avaliação da satisfação dos utilizadores de implantes cocleares e é, até ao momento, a única escala neste domínio validada para aplicação na população portuguesa.

**Palavras-chave:** Implante Coclear; Implantes Cocleares; Inquéritos e Questionários; Perceção da Fala; Portugal; Qualidade de Vida; Reprodutibilidade dos Testes; Tradução

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## INTRODUCTION

Cochlear implants (CI) are devices with the ability of transforming environmental sounds and noises into electrical energy and conducting these to the cochlear nerve, in order to generate a hearing sensation.<sup>1</sup> Cochlear implantation is currently a routine treatment for patients presenting with profound deafness or patients with severe deafness who do not benefit or have minimal benefit from hearing aids, provided that (i) the insertion of the electrodes into the cochlea is feasible, as confirmed by imaging, (ii) there is an auditory nerve and (iii) there are no risks of non-adherence to the treatment and rehabilitation plan.<sup>2-8</sup>

Most studies evaluating the efficacy of CIs are focused on the quantification of the audiological functional gain or speech recognition.<sup>9</sup> Few studies have been focused on measures to evaluate CI patients' satisfaction or quality of life of.<sup>10</sup> No significant correlations were found between these studies, aimed at assessing patients' satisfaction or quality of life, when compared to those evaluating audiological results,<sup>11-14</sup> suggesting that the assessment of functional gain or speech recognition is not enough for the assessment and quantification of the benefits of cochlear implantation.<sup>15</sup>

Different instruments have been used in the assessment of CI patients' level of satisfaction.<sup>16</sup> Scales are usually used for the assessment of different aspects related to its use, even though most scales are generic, not specifically designed to assess CI patients and without enough sensitivity or suitability to collect some of the aspects that are particularly relevant to patients.<sup>11,15,17,18</sup>

The Nijmegen Cochlear Implant Questionnaire (NCIQ)<sup>11</sup> is a specific scale for CI patients which has not yet been validated for European Portuguese and has been recognised as the most appropriate scale for assessing the patients' quality of life.<sup>19-22</sup> A scale designed specifically for the assessment of CI patients' satisfaction and quality of life and validated for the European Portuguese language would be extremely relevant, allowing the comparison of the results of Portuguese studies with international studies.

This study was aimed at the validity of the NCIQ for European Portuguese, throughout different phases: translation, cultural adaptation, assessment of reproducibility and description of the results of the application of this questionnaire to CI patients.

## MATERIAL AND METHODS

This study was approved by the Health Ethics Committee (*Comissão de Ética para a Saúde* - CES) of the *Centro Hospitalar de Lisboa Ocidental* (CHLO), in Lisbon, on 8 January 2020 – and was recorded with the no. 20170700050 in the National Register of Clinical Studies (*Registo Nacional de Estudos Clínicos* - RNEC). The study was conducted in accordance with the principles of the Declaration of Helsinki, updated in 2013. A signed informed consent was obtained from patients of legal age who agreed to take part in the study. A 50-patient convenience sample has been used, in-

cluding patients implanted and regularly attending the ENT (ear, nose and throat) department at the Egas Moniz Hospital of the CHLO, aged 20-79 and of both genders. The following inclusion criteria were met by the study participants: post-lingual hearing loss, bilateral deafness (not necessarily symmetrical), wearing a CI (single or bilateral), at least 12 months of implantation and use (the date the device was activated was taken into account when calculating the length CI use), sufficient ability to understand and read the Portuguese language in order to respond to all the NCIQ sub-domains. Patients with severe limitations in the ability to understand and express themselves were excluded from the study.

The approval obtained from the authors of the original NCIQ for its adaptation and validity into European Portuguese. This was granted on 12/09/2019 by the authors of the questionnaire from the University of Nijmegen<sup>11</sup> and the technique proposed by the Scientific Advisory Committee of Medical Outcomes Trust was followed.<sup>23</sup>

In the cultural adaptation and reproducibility test phase, the questionnaires were completed by 21 respondents. In the validation phase, 41 CI patients were contacted by telephone and invited to respond by post; 29 from these responded in full to the NCIQ European Portuguese questionnaire. A total of 50 patients were included in the study.

## Procedures

### A – Translation from English to Portuguese and language adaptation

The questionnaire was distributed to two English translators, fluent in this language, who had not previously met each other and who were unaware of the questionnaire. The aim was to obtain two independent translations of the NCIQ.

### B - Review of the Portuguese translation by a review group

A review group including three bilingual professionals (Portuguese, fluent in English) in the field of Otorhinolaryngology and Audiology was set up, aimed at analysing both resulting documents. By consensus, any differences found in the translations were reduced, the best expressions and words for each question were selected and the text was adapted to Portuguese cultural knowledge. The result was a new and unique NCIQ questionnaire for European Portuguese

### C – Back translation

A copy of the NCIQ for European Portuguese was sent to two different English translators who were unaware of the original text and the study, as well as the initial translators, to avoid any influence on the translation. The back translation was obtained, and the same review group re-evaluated this version, comparing it with the original in English.

## D - Cultural adaptation

The cultural adaptation of the NCIQ for European Portuguese was aimed at obtaining a cultural equivalence between the English and Portuguese versions of the questionnaire. The questionnaires obtained from the first 21 patients were used to study the cultural adaptation and reproducibility. A first interviewer (interviewer 1) administered the questionnaire, orally reading each question that raised doubts, to identify any doubts that arose when interpreting the items on the questionnaire. According to Guillemin *et al.*,<sup>24</sup> the cultural equivalence is established when at least 80 per cent of individuals show no difficulty in understanding and answering each question. Whenever the value is lower than this threshold, then that question will be individually submitted to a new translation process. The European Portuguese version of the NCIQ was applied to the individuals at this stage and was answered in full; no constraints were found by the participants in understanding the questions.

## E- Reproducibility of the questionnaire

The questionnaire was applied to the same 21 patients interviewed in the cultural adaptation phase by a second interviewer (interviewer 2), to test inter-researcher reproducibility, with the test-retest application generally taking place between two consultations one month apart. The comparison of the results of the questionnaire was carried out by different interviewers and was used to assess inter-researcher reproducibility.

## Scoring

The NCIQ is a 60-item specific questionnaire for the assessment of the quality of life in adult CI patients, divided into three general domains, with different subdomains: physical (basic sound perception, advanced sound perception and speech production), psychological (self-esteem) and social (activity limitations and social interactions)<sup>11</sup> (Table 1).

The NCIQ includes 10 items for each subdomain. Five different responses were given for each of the first 55 items, including: 1 = “never”; 2 = “sometimes”; 3 = “often”; 4 = “mostly”; and 5 = “always”, while the five final items included 1 = “no”; 2 = “poorly”; 3 = “moderate”; 4 = “good”; and 5 = “excellent”. Responders were offered a “not applicable – N/A” response for each of the 60 items (whenever the item was not considered relevant). At least seven from ten items

must be responded to complete each specific subdomain. Responses are scored in such a way that a higher score (from 0 to 100) corresponded to greater satisfaction. The score for each subdomain was given as follows: 1 = 0, 2 = 25, 3 = 50, 4 = 75 and 5 = 100. There is an inverse recoding of the score of some items described in the code book of the final table of the questionnaire, i.e., a response as 1 corresponding to greater satisfaction (1 = 100, 2 = 75, 3 = 50, 4 = 25 and 5 = 0). Once the sum of all the items in a subdomain is obtained, the total score is divided by the number of complete responses. A score is also generated for each of the domains.

The questionnaire was initially designed so that the patients would write down each response themselves, using pen and paper, as suggested by the scale’s authors. However, during the cultural adaptation and inter-researcher reproducibility study phase, and to avoid any constraints in completing the questionnaire, an interview format has been considered, and responses were read aloud and noted down, allowing for better understanding of the items and response alternatives.

## Statistical analysis

Data were entered into a database and the Statistical Package for The Social Sciences (SPSS)<sup>®</sup> software version 20.0 for Windows was used for the statistical analysis.

A descriptive statistical analysis was used for the analysis of the different variables in the study, by obtaining the mean, minimum value, maximum value, and standard deviation for each item. Reproducibility was analysed using the interclass correlation coefficient (after confirming that data followed a normal distribution). The NCIQ’s internal consistency was also assessed using Cronbach’s  $\alpha$  for the NCIQ’s domains and subdomains. This coefficient is a statistical tool that quantifies the reliability of a questionnaire on a range of 0 to 1; 0.7 is the minimum acceptable value for a questionnaire to be considered as reliable.<sup>25</sup> Finally, the levels of satisfaction obtained were compared with those of the Dutch sample (Hinderink *et al.*).<sup>11</sup> A 0.05 level of significance was considered for the statistical tests.

## RESULTS

Fifty CI patients were included in the study (average age of 55.50 years; standard deviation 15.69; the youngest

Table 1 – Domains and subdomains of the NCIQ questionnaire

Domain	Subdomain	Items	Scoring
Physical	Basic sound perception	1, 7, 13, 19, 25, 31, 37, 42, 47, 52	1 = 0 2 = 25 3 = 50 4 = 75 5 = 100
	Advanced sound perception	5, 11, 17, 23, 29, 35, 40, 45, 50, 60	
	Speech production	3, 9, 15, 21, 27, 33, 56, 57, 58, 59	
Psychological	Self-esteem	4, 10, 16, 22, 28, 34, 39, 44, 49, 54	
Social	Activity limitations	6, 12, 18, 24, 30, 36, 41, 46, 51, 55	
	Social interactions	2, 8, 14, 20, 26, 32, 38, 43, 48, 53	

Recodification: 50, 27, 10, 16, 22, 34, 39, 49, 54, 6, 12, 18, 24, 30, 36, 41, 46, 51, 55, 2, 8, 14, 20, 26, 38, 43, 48, 53.

patient was aged 20 and the oldest 79) (Table 2); there was a slight female predominance (56%). The average length of CI use was 58.62 months, ranging from 14 to 216 months. The median was 40.00 with quartiles Q1 = 27.00 and Q3 = 75.00, with a minimum of 14.00 and a maximum of 216.00. The average daily duration of implant use was > 9h by 70% of the patients and > 13 by 40%. The hereditary origin was the most common identifiable cause of deafness leading to implantation.

A descriptive analysis of the results for each domain and subdomain of the questionnaire is shown in Table 3, based on the responses given by 50 participants. From the initial group of 21 patients, the responses of the main evaluator (interviewer 1) were considered, as no statistically significant differences were found in the comparison between the first and second application of the questionnaire for each item. The participants in this study showed greater satisfaction in the advanced sound perception domain (M = 71.35; SD = 20.22) and in the activity limitation subdomain (M = 69.75; SD = 21.26), while it was lower in the speech production domain (M = 57.91; SD = 22.10), as in the self-esteem subdomain (M = 59.05; SD = 15.23) (Fig. 1). The ranking of the domains in relation to the overall satisfaction (M = 65.07; SD = 16.21) of CI users was as follows: the advanced sound perception (M = 71.35; SD = 20.22), activity limitation (M = 69.75; SD = 21.26) and social interactions (M = 68.50; SD = 18.06) domains were above average while basic sound perception (M = 64.40; SD = 20.90), speech production (M = 57.91; SD = 22.10) and self-esteem (M = 59.05; SD = 15.23) domains were below average.

The reproducibility of the questionnaire was tested using the interclass correlation coefficient (Table 4), as data were numerical and followed a normal distribution. The results showed strong agreement between evaluators. Cronbach's  $\alpha$  coefficient was used to assess the scale's internal consistency. The results obtained for Cronbach's  $\alpha$ , the average inter-item correlation and the range of the item-total correlation are shown in Table 4. The total questionnaire

Table 2 – Patient characteristics

Characteristics	n = 50
Age (years)	55.50 ± 15.69
Male (no. and %)	22 (44%)
Length of CI use (months)	58.62 ± 48.56
CI use per day (no. and %)	
0 - 8 h	1 (2%)
9 - 12 h	15 (30%)
13 - 16h	20 (40%)
Undetermined	14 (28%)
Causes of hearing loss (no. and %)	
Hereditary	9 (18%)
Chronic otitis media	3 (6%)
Otosclerosis	2 (4%)
Autoimmune	2 (4%)
Meningitis	1 (2%)
Undetermined	33 (66%)

and all the subdomains showed adequate internal consistency values, with Cronbach's  $\alpha$  values ranging between 0.82 (self-esteem) and 0.96 (total scale).

**DISCUSSION**

This study was aimed at translating, culturally adapting, and validating the Nijmegen Cochlear Implantation Questionnaire (NCIQ) into European Portuguese. The validity of this scale provides the Portuguese clinical community with a useful tool for the assessment of quality of life in adult CI users. As the ENT department of the Centro Hospitalar de Lisboa Ocidental is a national reference centre in cochlear implants approved by the Ministry of Health, there was a need for a tool as this one, allowing the multidimensional assessment of the patients' satisfaction, the identification of issues and improvement of patients' follow-up.

Table 3 – Descriptive analysis of the results in the domains and subdomains of the questionnaire (n = 50)

Domain	Subdomain	M	SD	min	máx
<b>Physical</b>		64.82	18.11	19.17	97.5
	Basic sound perception	64.40	20.90	20	97.5
	Advanced sound perception	71.35	20.22	17.5	100
	Speech production	57.91	22.10	10	97.5
<b>Psychological</b>					
	Self-esteem	59.05	15.23	20	87.5
<b>Social</b>		69.13	18.82	21.25	95.0
	Activity limitations	69.75	21.26	12.5	97.5
	Social interactions	68.50	18.06	20	100
<b>Global</b>		65.07	16.21	18.33	95.42

M: mean; SD: standard deviation; min: minimum; max: maximum

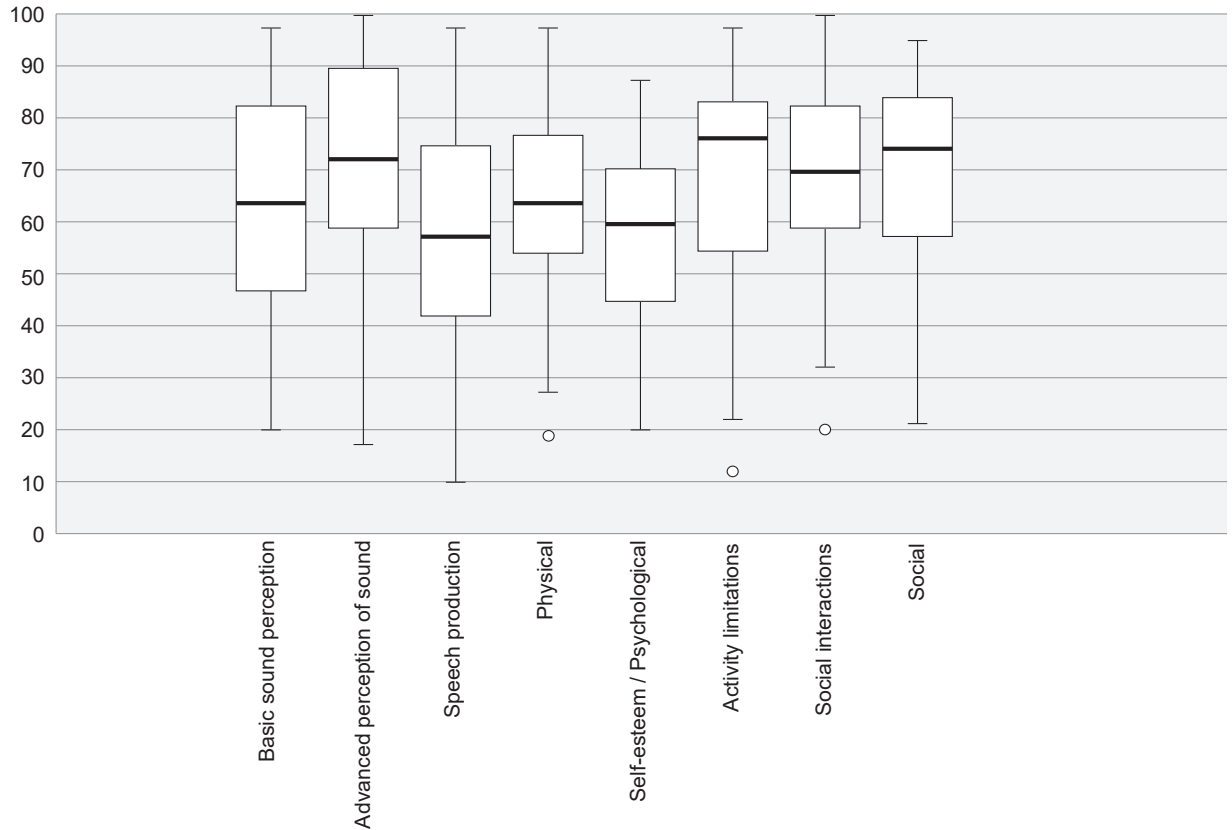


Figure 1 – Scores obtained for the domains and subdomains of the NCIQ questionnaire for European Portuguese

The Nijmegen Cochlear Implant Questionnaire is used clinically to assess the quality of life after cochlear implantation.<sup>26,27</sup> This scale is already widely used in international clinical settings, with translations and validations available in several languages, including Spanish, Italian and Mandarin.<sup>28-30</sup>

Our version of the NCIQ for European Portuguese (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/16632/15010.pdf>) showed strong internal consistency (Cronbach's  $\alpha$  coefficient value of 0.96), in line and even stronger than those described in literature.<sup>11,28-30</sup> The NCIQ provides an

overall score and a score for each of three domains and six subdomains (Fig. 2). The results obtained in this study showed a 65.07 overall satisfaction level in CI users. The social domain was the one with the highest score, reflecting an improvement in hearing abilities and social interactions of CI patients.<sup>31,32</sup> The high score obtained in the advanced sound perception subdomain reflects the improvement in speech perception and, subsequently, in communication. This subdomain, together with the basic sound perception subdomain are the ones that best reflect the benefit of CI users in accessing sounds and speech.<sup>15,26,27,31,33</sup> When compared to Hinderink's original work, similar scores of the

Table 4 – Global assessment and assessment of each of the six subdomains for internal consistency (Cronbach's alpha) and test-retest reproducibility (intraclass correlation coefficient) of the NCIQ

Subdomain	Cronbach's alpha	Mean inter-item correlation	Range of item-total correlation	Interclass correlation
Basic sound perception	0.88	0.42	0.309 - 0.726	0.97
Advanced sound perception	0.87	0.41	0.369 - 0.759	0.98
Speech production	0.88	0.42	0.344 - 0.749	0.97
Self-esteem	0.82	0.31	0.286 - 0.700	0.94
Activity limitations	0.88	0.43	0.332 - 0.782	0.96
Social interactions	0.83	0.34	0.039 - 0.760	0.95
Total	0.96	0.27	0.042 - 0.757	0.99



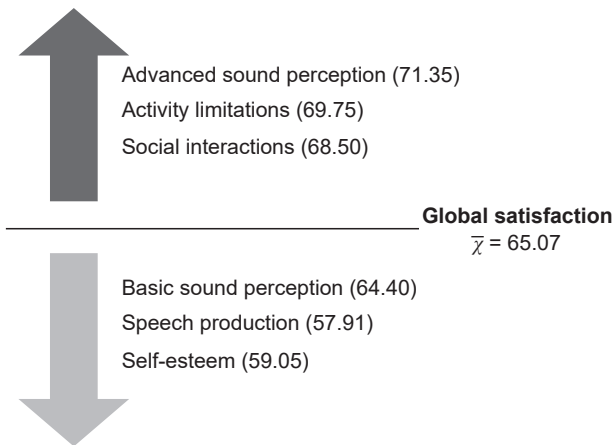


Figure 2 – Ranking of subdomains in relation to global satisfaction of the scale

subdomains were obtained, except regarding advanced sound perception and speech production. All respondents have fully completed the questionnaires, suggesting that they understood all the items and were comfortable answering them. Good internal consistency was found, with Cronbach's  $\alpha$  coefficient values  $> 0.80$  in all six subdomains of the questionnaire. All the items in the scale were kept, as internal consistency was not affected by any of the items. Therefore, the removal of any items would affect the construct validity of the measure and would not contribute to significantly improve the already adequate internal consistency.

In our study, the cultural adaptation and assessment of the scale's reproducibility were carried out with a group of 21 patients from the study group, in line with the number suggested in literature (20 to 40).<sup>24,34</sup> A sample size ( $n = 50$ ) that would allow the study of internal consistency was used for its validity and, although not high, was even higher than that of the original study ( $n = 45$ ).<sup>11</sup> Despite the good results obtained, it is worth mentioning that satisfaction with CI can vary depending on different factors including the cause of hearing loss, the length of sensory deprivation, the patient's age at diagnosis and intervention, education, motivation and family support.<sup>27,31,35</sup> In addition, the subjectivity associated with the term 'quality of life' should also be considered, as it is related to each patient's perception of the health situation.

There are different questionnaires for the assessment of quality of life in CI patients, even though these are usually time-consuming, difficult to complete and with poor sensitivity to small improvements or deterioration.<sup>18</sup> The Glasgow Benefit Inventory (GBI), even though not a specific questionnaire, could be adapted to patients undergoing cochlear implantation and<sup>36</sup> is aimed at the assessment of changes in quality of life in relation to a non-specific previous situation, without reference, for example, to the pre-implantation period. The Satisfaction with Amplification in Daily Life (SADL)

uses a simple and easy-to-apply questionnaire to assess adaptation to hearing aids, which can also be adapted to CI, and has also been translated and validated into European Portuguese by the authors of this study.<sup>37,38</sup> The Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire is aimed at the quantification of issues in communication in daily life situations, and consists of 24 multiple-choice questions, positively or negatively formulated. The APHAB's negative aspects are the way the questions are designed (some refer to situations with which patients may not be familiar [theatre, conferences, religious services]), the complexity of the scoring system and depending on a fully completed questionnaire.<sup>39</sup> Finally, it does not clarify the impact of hearing loss on the patient's quality of life.

Sample size could represent one of the limitations of this study, even though we consider that it is adequate for the Portuguese population. Another limitation was the lack of comparison between the data obtained and the results of speech perception tests, which could significantly contribute to a more detailed understanding of the impact and effectiveness of this scale. The length of this 60-item questionnaire can also be considered another limitation to its full implementation in clinical practice. The original work described some lack of reliability in the self-esteem and speech production subdomains,<sup>11</sup> although this negative aspect was not confirmed in our study. Finally, a positive aspect of this study is the timing of the collection of NCIQ scores, which was not carried out retrospectively.

## CONCLUSION

The validity of the NCIQ scale for European Portuguese shows strong internal consistency, reproducibility and is in line with other studies. This adaptation is a good tool for assessing the satisfaction of cochlear implant patients in Portugal, as it is the only scale that has been translated, culturally adapted into European Portuguese, and validated for this purpose. The fact that it is a simple questionnaire, with practical scoring and numerical indices, allows its clinical use for a multidimensional assessment of satisfaction in cochlear implant patients, as well as the comparison between studies and research.

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## AUTHOR CONTRIBUTION

LRR: Project development and planning, data collection, writing of the manuscript, statistical analysis, revision of the final manuscript.

LC, KG, FC, GN: Project planning; data collection; writing of the initial manuscript.

RS, AO: Data collection, writing of the initial manuscript.

PE: Project planning, writing of the initial manuscript, revision of the final manuscript.

## HUMAN AND ANIMAL PROTECTION

The authors declare that this project complied with the regulations that were established by the Ethics and Clinical Research Committee, according to the 2013 update of the Helsinki Declaration of the World Medical Association.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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