

Adaptation and Validation for European Portuguese of the Auditory Performance Categories-II and Infant-Toddler Meaningful Auditory Integration Scale for Children with Cochlear Implant

Adaptação e Validação para Português Europeu das Escalas Categories Auditory Performance-II e Infant-Toddler Meaningful Auditory Integration Scale em Crianças com Implante Coclear

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ABSTRACT

Introduction: The Categories of Auditory Performance II (CAP-II) scale and the Infant-Toddler Meaningful Audit Integration Scale (IT-MAIS) are simple and quick questionnaires that allow assessment of the auditory performance of children with cochlear implant (CI). The aim of this study was to translate, adapt and validate the European Portuguese version of the CAP-II and IT-MAIS scales.

Methods: A total of 85 participants completed the European Portuguese version of the CAP-II and IT-MAIS questionnaires, of which 45 were parents of children with pediatric cochlear implants (9.84 ± 4.22 years) and another 40 were parents of children with normal hearing (8.35 ± 3.56 years). Inter-rater reproducibility, test-retest reproducibility, comparison of study group *versus* control group results, internal consistency and correlation of the new scales were evaluated.

Results: The CAP-II and IT-MAIS scales showed high reliability and reproducibility, respectively, with an intraclass correlation coefficient (ICC) of 0.979 ($p < 0.001$) and a Spearman's correlation of 0.924 for the CAP-II scale, and an ICC of 0.932 ($p < 0.001$) and Spearman's correlation coefficient of 0.732 for the IT-MAIS scale. The IT-MAIS and CAP-II versions showed strong internal consistency (Cronbach's α coefficient value of 0.887 for the CAP-II scale and Spearman's positive correlation of 0.677 for the IT-MAIS scale, respectively) and allowed for the differentiation between children with normal hearing and post-implantation children ($p = 0.001$ and $p < 0.001$ respectively for each of the scales). There was no association between parental education and the results on the scales ($p > 0.05$).

Conclusion: The findings demonstrated that the European Portuguese version of these scales is a valid and reliable tool for assessing auditory performance in European Portuguese-speaking children with hearing loss.

Keywords: Child; Cochlear Implantation; Cochlear Implants; Quality of Life; Reproducibility of Results; Surveys and Questionnaires; Translations

RESUMO

Introdução: As escalas *Categories of Auditory Performance II* (CAP-II) e *Infant-Toddler Meaningful Auditory Integration Scale* (IT-MAIS) são questionários simples e de rápida aplicação que permitem avaliar o desempenho auditivo de crianças com implante coclear (IC). O objetivo deste estudo foi a tradução, adaptação e validação da versão em português europeu das escalas CAP-II e IT-MAIS.

Métodos: Um total de 85 participantes completaram a versão em português europeu dos questionários CAP-II e IT-MAIS, dos quais 45 eram pais de crianças com IC pediátrico ($9,84 \pm 4,22$ anos) e outros 40 eram pais de crianças com audição normal ($8,35 \pm 3,56$ anos). Foi avaliada a reprodutibilidade entre avaliadores, a reprodutibilidade teste-reteste, a comparação dos resultados do grupo de estudo *versus* grupo de controlo, a consistência interna e a correlação das novas escalas.

Resultados: As escalas CAP-II e IT-MAIS apresentaram uma elevada confiabilidade e reprodutibilidade, respetivamente com coeficiente de correlação intraclass (ICC) de 0,979 ($p < 0,001$) e correlação de Spearman de 0,924 para a escala CAP-II, e ICC de 0,932 ($p < 0,001$) e coeficiente de correlação de Spearman de 0,732 para a escala IT-MAIS. As versões do IT-MAIS e do CAP-II apresentaram uma forte consistência interna (valor do coeficiente α de Cronbach de 0,887 para a escala CAP-II e correlação positiva de Spearman de 0,677 para a escala IT-MAIS, respetivamente) e permitem diferenciar entre crianças com audição normal e crianças pós-implantação ($p = 0,001$ e $p < 0,001$ respetivamente para cada uma das escalas). Não se verificou existir associação estatisticamente significativa entre a escolaridade e o resultado nas escalas ($p > 0,05$).

Conclusão: A versão em português europeu destas escalas demonstrou ser uma ferramenta válida e confiável na avaliação do desempenho auditivo em crianças falantes de português europeu com deficiência auditiva.

Palavras-chave: Criança; Implante Coclear; Implantes Cocleares; Inquéritos e Questionários; Qualidade de Vida; Reprodutibilidade dos Resultados; Traduções

INTRODUCTION

Cochlear implants (CI) represent a very effective treatment for children with severe to profound deafness. Early intervention seems to play an important role in post-implantation performance and the assessment of pre-lingual hearing development is crucial in the early identification and the

establishment of interventions to treat deafness.¹⁻⁴ Different scales have been developed for the assessment based on structured interviews with the parents, who are probably the best source for obtaining this information, as patients are usually infants or very young children.⁵⁻⁹

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As pre-lingual auditory development occurs before the onset of spoken language, usually around 18 - 24 months in children with normal hearing, scales that can be used in childhood until the onset of spoken language are required.¹⁰⁻¹⁴ This is the case of Categories of Auditory Performance II (CAP-II)⁵ and Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS),⁶ recommended up to the age of three, even though these could be used up to the age of 18. These are widely used, allowing a prospective assessment of the hearing performance in patients with cochlear implants (CI),^{8,15-22} mostly used when compared to other assessment tools because they are short, easy to perform and because they reflect children's progress in real life with high reproducibility and reliability.²³ In addition, they can be administered by physicians and other healthcare professionals, also by other professionals, including educators or teachers frequently dealing with children with CI.

The hearing performance of children with CI must be regularly assessed by close relationships, including parents or teachers. This requirement reflects the importance of validating a European Portuguese version of these questionnaires. This study was aimed at translating, adapting, and validating a European Portuguese version of the CAP-II and IT-MAIS to be used by physicians, speech therapists, audiologists, parents, special education teachers and other professionals dealing with children with CIs.

METHODS

The study was submitted and approved by the Health Ethics Committee (CES) of the Centro Hospitalar de Lisboa Ocidental (CHLO) on October 17, 2020, with reference number 20170700050 to the Registo Nacional de Estudos Clínicos (RNEC). The study was held in accordance with the principles of the Declaration of Helsinki (2013 revision) and written informed consent was signed by parents for their children's participation in the study.

Study sample

Our group of patients was recruited at the ENT (Ear, nose & throat) department of the Centro Hospitalar de Lisboa Ocidental during the period from January 2017 to January 2022. All the patients were implanted at the department, which is a national reference centre of cochlear implants approved by the Ministry of Health. Paediatric patients (aged 18 months to 18 years) with pre-lingual deafness and implanted with unilateral or bilateral CI were included. Patients older than 18, patients who developed language before implantation, and patients with neurological and psychological problems or other disorders that could affect their communication were excluded from the study. The control group (patients with no history of any hearing problem) was a convenience sample recruited at the pae-

diatrics outpatient clinic of the same institution, during the same period, with no history of hearing pathology and normal otoscopy. This cross-sectional study included a total of 85 participants, 45 post-CI patients and 40 participants in the control group. The European Portuguese versions of the CAP-II and the IT-MAIS were completed and evaluated by parents and speech therapists for the patient group, while these were only evaluated by parents as regards the control group.

Translation, back translation, and cultural adaptation

Both the CAP-II and IT-MAIS were validated to European Portuguese following the recommendations for cross-cultural adaptation²⁴ and following the authorisation by the authors was obtained, in addition to the rules for translation. The original English versions of the CAP-II and IT-MAIS were translated into European Portuguese by two bilingual professional translators fluent in English (whose native language was European Portuguese). These were revised by a committee including two ENT consultants, an audiologist, and a speech therapist. Any differences found in translations were reduced by consensus, selecting the best expressions and words for each question, adapted to the Portuguese cultural knowledge. A new and unique questionnaire was obtained for each scale. After the revision, the new European Portuguese versions of the CAP-II and IT-MAIS were then back-translated into English by two different translation professionals (whose native language was English) who were unfamiliar with the original text and the study, as well as the initial translators, avoiding any influence on the translation. The original CAP-II and IT-MAIS and the back-translated versions were compared to ensure that the original meaning was maintained. The similarity between the original English version and the back-translated English version were therefore assessed.

Procedures

Patients were interviewed and assessed by a speech therapist, with a parent. The questionnaires were applied by the speech therapist, by orally reading each question that raised doubts, aimed at identifying any doubts that arose in the interpretation of the questions. Cultural equivalence was established when at least 80% of the individuals showed no difficulties in understanding and answering each question.²⁵ The European Portuguese version of the questionnaires was fully responded, and no understanding constraints were found. The questionnaires were repeated 14 days later with the same parent to assess reproducibility (test-retest). This measure was assessed by determining intraclass correlation coefficient (ICC). Concurrent convergent validity was also used by measuring the strength of the correlation between both scales in European Portuguese.

On the other hand, validity was assessed through the ability of the CAP-II and IT-MAIS to differentiate between post-implantation patients and the control group.

Scoring

The CAP-II scale allows a linear and hierarchical ranking of 10 categories for the assessment of the results of paediatric CI in daily life [Appendix 1, Table 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/20169/15355>)]. It differs from more technical measures in that it is readily applied and easily understood by non-specialist professionals and parents. It is organised into a hierarchy of performance categories, associated with auditory perception, which increasing difficulty. The score ranges from the lowest level of not being aware of environmental sounds to the highest level of being able to talk on the phone to a familiar person. Two additional categories and scores were included with the original CAP scale by Gilmour *et al.*,¹⁷ representing the ability to talk in a group and on the phone with a stranger. This CAP-II scale consists of 10 categories and allows the ability to fully assess the maximum benefit of CI, particularly in bilateral implantation. The score ranges from the lowest level of not being aware of environmental sounds (0) to the highest level of having the ability to talk on the phone with a familiar person (9).

The IT-MAIS is a 10-item scale designed to assess the patient's listening behaviour [Appendix 1, Table 2 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/20169/15355>)]. The first two items are aimed at assessing the patient's vocal behaviour, as well as the compliance and trust in the device. The following four items assess the spontaneous detection and response to their own name and to environmental sounds and signals. The final four items assess the ability to acknowledge and discriminate sounds such as the differences between male and female voices, speech sounds and others, or the differences in vocal tone that convey emotions. There are five possible answers for each of the questions, and each question is scored by the frequency of each behaviour, ranging from 0 ("never showed this behaviour") to 4 ("always showed this behaviour"). A 40-point total score is possible on the IT-MAIS scale, with a higher score on the scale corresponding to better performance. For the first item on the IT-MAIS scale ("Is the patient's vocal behaviour affected while wearing the device?"), we adjusted the score for this question in the control population and assigned the maximum value (4) to all individuals. The IT-MAIS scale is derived from an earlier scale, the Meaningful Auditory Integration Scale (MAIS).²⁶ These two versions differ in the first two items of the questionnaire, assessing the child's vocal behaviour and confidence in the device and, due to

the way they were developed, the MAIS items can only be applied to older children with CI.

Statistical methods

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 28.0 (SPSS Inc, IBM, Armonk, NY). Categorical data were presented as numbers and percentages and continuous data as mean, standard deviation, and variation. The chi-square test was used for the comparison between two categorical ratios. Fisher's exact test and t-test were used for the comparison between two means. Kappa statistics was used for the identification of discrepancies between different questionnaires. The evaluation of reproducibility (test-retest) using Spearman's test, interclass correlation and Cronbach's α test were obtained for the assessment of the levels of agreement between questionnaires. The Cronbach's α test was also used to assess the internal consistency of the IT-MAIS. As data did not follow a normal distribution (Kolmogorov-Smirnov test), non-parametric Mann-Whitney test was used for the comparison of the two independent samples in terms of age and total scores. The consistency of the CAP-II was analysed, considering that Cronbach's α could not be used since this scale has only one item, while concurrent validity was calculated using Spearman's correlation with the IT-MAIS scale. Discriminant validity was carried out by comparing the results of both groups. A p -value < 0.05 was considered statistically significant.

RESULTS

A total of 85 participants have completed the European Portuguese versions of the CAP-II and IT-MAIS questionnaires, including 45 parents of patients with CI and 40 parents of patients included in the control group. The average age of the implanted patients was 5.46 ± 4.48 years (range 1 - 16 years), while the average age of the patients in the control group was 8.35 ± 3.56 years (range 3 - 17 years). There were no statistically significant differences in the average age between both groups ($p = 0.078$). Twenty male patients (44.4%) were included in the implanted group, while 19 male patients (47.5%) were included in the control group. Most patients underwent bilateral cochlear implantation (29 patients, 64.4%). The average time after cochlear implantation was 49.09 ± 31.74 months (range 3 - 110 months) (Table 1). Most parents had basic education or less (29, 64.4%), 10 parents had higher education (22.3%) and this information was unavailable regarding six parents (13.3%).

The results with the CAP-II questionnaire are shown in Table 2. Item 7 of the questionnaire ("comprehension of conversation with a familiar interlocutor without lip-reading") received the most responses, while item 2 of the

Table 1 – Characteristics of the patients (n = 45)

Characteristics	
Age in years, mean (SD)	5.46 (4.48)
Age in years, range	1 - 16
Gender	
Male, n (%)	20 (44.4%)
Female, n (%)	25 (55.6%)
Time following cochlear implantation in years, mean (SD)	5.96 (4.48)
Cochlear implant	
Unilateral, n (%)	16 (35.6%)
Bilateral, n (%)	29 (64.4%)
Parent education	
Data unavailable, n (%)	6 (13.3%)
4 th year, n (%)	1 (2.2%)
6 th year, n (%)	2 (4.4%)
9 th year, n (%)	2 (4.4%)
Basic education, n (%)	24 (53.3%)
Higher education, n (%)	10 (22.3%)

SD: standard deviation

questionnaire (“perception of sounds in the surrounding environment”) received the fewest responses. The mean score for the CAP-II questionnaire was 6.58 ± 2.37 out of a total possible score of 10.

The results with the IT-MAIS questionnaire are shown in Table 3. Items 1, 4, 6 and 7 of the questionnaire received more responses for the “often” option, while items 2, 3, 5, 8, 9 and 10 of the questionnaire received more responses for the “always” option. The mean score for the IT-MAIS questionnaire was 27.62 ± 8.84 out of a total possible score of 40.

The European Portuguese versions of the CAP-II and IT-MAIS questionnaires showed excellent performance in test-retest (> 0.9). Reliability was assessed with the two-way mixed model because it considered that the examiners were fixed, and the subjects randomised. The CAP-II scale showed an ICC reliability = 0.979 (95% CI = 0.949 - 0.991, $p < 0.001$) and a Spearman correlation coefficient of 0.924 ($p < 0.01$). The IT-MAIS scale showed a reliability of ICC = 0.932 (95% CI = 0.838 - 0.971, $p < 0.001$) and a Spearman correlation coefficient of 0.732 ($p < 0.001$).

The IT-MAIS scale showed good internal consistency, with a Cronbach’s α coefficient of 0.887. The correlation with the IT-MAIS scale was obtained for the assessment of the consistency of the CAP-II, since this was a single-item scale, not allowing the use of Cronbach’s α . For concurrent validity, the CAP-II scores showed a positive correlation with the IT-MAIS scores, with a Spearman correlation value of 0.677 and $p < 0.001$ (Fig. 1).

Discriminant validity was assessed by comparing the parents between both groups and showed that the Portuguese version of the CAP-II and IT-MAIS scales allowed the differentiation between children with normal hearing and post-implantation (Table 4).

Only 22.3% of the parents had higher education and any potential relationship between parental education and the patient’s level of hearing performance was analysed. There was no statistically significant association between education and the results on the CAP-II and IT-MAIS scales ($p > 0.05$).

Table 2 – CAP-II scale in children with cochlear implant

Item	n	%
1	2	4.4
2	1	2.2
3	1	2.2
4	4	8.9
5	5	11.1
6	8	17.8
7	9	20.0
8	4	8.9
9	5	11.1
10	6	13.3

The most frequent response is shown in dark grey

Table 3 – Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) in children with cochlear implant

Item	Never		Rarely		Sometimes		Frequently		Always	
	n	%	n	%	n	%	n	%	n	%
1	8	17.8	8	17.8	10	22.2	12	26.7	7	15.6
2	5	11.1	4	8.9	4	8.9	6	13.3	26	57.8
3	2	4.4	1	2.2	6	13.3	5	11.1	31	68.9
4	3	6.7	6	13.3	7	15.6	18	40.0	11	24.4
5	3	6.7	2	4.4	8	17.8	13	28.9	19	42.2
6	3	6.7	5	11.1	8	17.8	15	33.3	14	31.1
7	3	6.7	2	4.4	11	24.4	16	35.6	13	28.9
8	3	6.7	2	4.4	8	17.8	15	33.3	17	37.8
9	3	6.7	3	6.7	12	26.7	10	22.2	17	37.8
10	9	20.0	1	2.2	10	22.2	9	20.0	16	35.6

The most frequent responses for each item are shown in dark grey

DISCUSSION

This study was aimed at developing a European Portuguese version of the CAP-II and IT-MAIS scales. These are useful tools for training parents, teachers, and healthcare professionals in assessing children’s daily hearing performance following CI, improvement after implantation and for follow-up. In addition, the CAP-II and IT-MAIS scales are a popular and widely used tool for the assessment of the quality of life after CI, since both can be easily administered and allow for reliable results in implanted children.

The European Portuguese versions of the IT-MAIS and CAP-II showed strong internal consistency (Cronbach’s α coefficient value of 0.887 and Spearman’s positive correlation of 0.677, respectively). All questionnaires were fully completed, showing that the participants understood all the questions and were comfortable answering these. There were significantly lower CAP-II and IT-MAIS scores in patients with CI compared to those in the control group ($p < 0.001$). These results showed the ability of the European Portuguese version of the scales to discriminate between patients with normal hearing and those with CI, as well as their potential ability in follow-up. There were no statistically significant associations between parent’s education and the scores with both scales ($p > 0.05$).

A cycle has been completed by the authors with this study, starting with the adaptation and validation into European Portuguese of a scale for hearing aid users (SADL),²⁷ followed by a scale for adult CI users (Nijmegen)²⁸ and finally two scales for paediatric CI patients (CAP-II and IT-MAIS). The decision to validate these two scales for paediatric CI patients was explained by the fact that they are easy-to-use, complementary scales, and although both assess the hearing performance, the auditory component (IT-MAIS) and speech component (CAP-II) are mainly assessed.

The IT-MAIS scale showed similar internal consistency and reliability in several languages such as Persian, Italian, Mandarin, German and Polish. These similarities were found in populations with different cultural and linguistic characteristics, suggesting that the onset of pre-lingual hearing development has a similar evolution in all children.^{29,30} The Persian version of the IT-MAIS showed an intraclass correlation in line with the Portuguese version (ICC = 0.96, 95% CI = 0.93 - 0.98), with acceptable reliability (Cronbach’s α = 0.74) and good internal consistency of the items.³¹ The psychometric properties of the IT-MAIS in Mandarin were assessed by Zhong *et al.*, and ICC and Cronbach’s α values of 0.92 and 0.83 have been obtained, respectively.⁸ The psychometric properties of the IT-MAIS in Italian also showed good intraclass reliability (ICC = 0.93), and the total Cronbach’s α was 0.91.¹⁹ There are also several validated versions of the CAP-II test in different languages. The Arabic version of the CAP-II showed strong test-retest reliability, shown by a high ICC (0.9), as well as a high Spearman correlation of 0.9 when correlating test-retest scores.¹⁵ These results were in line with those of the Mandarin version of the CAP-II, with similar findings in terms of ICC values (0.924), Spearman correlation index (0.842) and Kappa (0.688).³²

Despite the good results, it is worth mentioning that the satisfaction obtained with the CI can vary depending on different factors including the cause of deafness, the length of time of sensory deprivation, the patient’s age at diagnosis and intervention, parental education, motivation, and family support.³³⁻³⁵ One of the limitations of the study is the variable implantation time, as well as the sample size. Another limitation was the fact that audiological screening tests were not carried out in the control group, as these were recruited from the same hospital and only a subjective hearing assessment was carried out. However, these patients had no history of hearing problems or delayed language

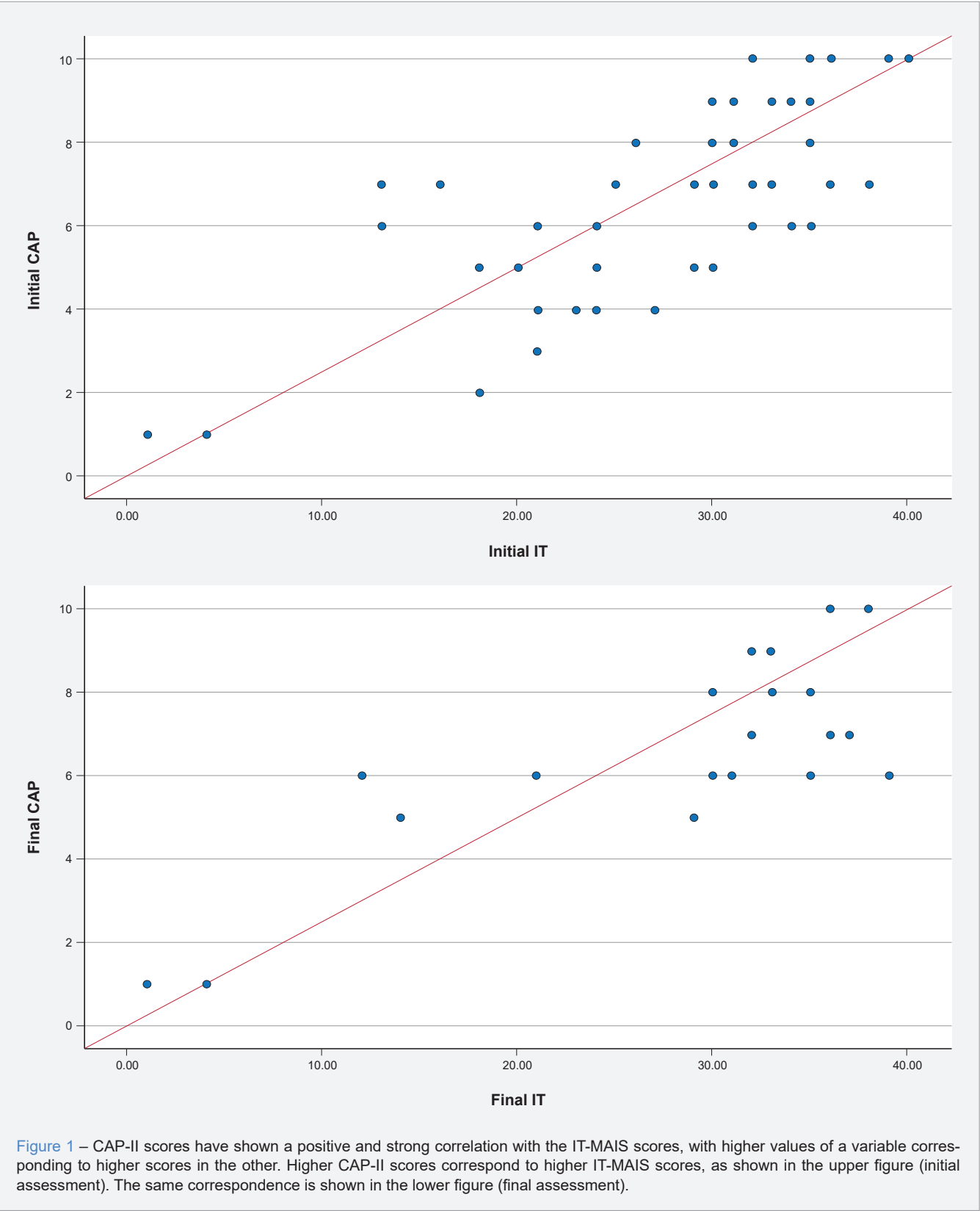


Figure 1 – CAP-II scores have shown a positive and strong correlation with the IT-MAIS scores, with higher values of a variable corresponding to higher scores in the other. Higher CAP-II scores correspond to higher IT-MAIS scores, as shown in the upper figure (initial assessment). The same correspondence is shown in the lower figure (final assessment).

development described by their parents. We will address these limitations in future studies. The IT-MAIS and CAP-II are the first scales validated for European Portuguese for the assessment of the hearing performance of children with CI, they can be applied to children of any age, easy-to-use by healthcare professionals or other professionals dealing with these patients, complementary to each other and they showed strong internal consistency and reliability.

CONCLUSION

The European Portuguese versions of the CAP-II and IT-MAIS questionnaires are valid and reliable tools for the assessment of auditory performance in Portuguese-speaking paediatric patients with hearing loss and who underwent cochlear implantation. These scales allowed the assessment of the patient's hearing performance in real life and in follow-up after implantation.

AUTHOR CONTRIBUTION

LRR: Study design, data collection, writing of the manuscript.

KG, ASP, CP, GN: Study design, data collection, writing of the manuscript.

RS: Data collection, writing of the manuscript.

AO, PE: Study design, writing and critical revision of the 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.

CONFLICTS OF INTEREST

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

DATA CONFIDENTIALITY

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

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