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National linguistic validation of the Tinnitus Handicap Inventory (THI). Assessment of disability caused by tinnitus in chilean spanish-speaking population

Carolina Der[1]
Eugenio Alzérreca[2]
José Tomás San Martín[3]
Liliana Román[4]
Isabel Zamorano[4]
Jorge Malhue[4]
Paola Aliaga[4]
Linda Coronelli[4]
Soledad Sarda[4]

Abstract

Introduction: The psycho-emotional assessment is of utmost importance for evaluation of patients with tinnitus. The Tinnitus Handicap Inventory (THI), is the most known and validated test for this purpose. **Objectives:** We propose a linguistic validation of the THI, in order to obtain reliable answers in our country. **Materials and Methods:** We performed a translation of the original English questionnaire and assessed its feasibility by applying it in a group of patients with tinnitus. Statistical analysis included internal validity (Cronbach's alpha) and linear correlation tests (Pearson coefficient). **Results:** We evaluated 60 patients with a mean age of 59 years. We obtained a Cronbach's alpha index of 0.97 for the whole questionnaire. **Conclusions:** The adapted version of the THI shows satisfactory levels of internal consistency for the assessment of disability caused by tinnitus.

Keywords: chile, quality of life, tinnitus, validation studies.

[1] Departamento de Cirugía, Servicio de Otorrinolaringología Clínica Alemana de Santiago. Hospital Luis Calvo Mackenna. - Clínica Alemana de Santiago, Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. - Santiago - AC - Chile. E-mail: cdercder@gmail.com
[2] Departamento de Cirugía, Servicio de Otorrinolaringología. - Universidad de Concepción - Concepción - AC - Chile. E-mail: josealzerreca@gmail.com
[3] Medicina General - Universidad del Desarrollo - Santiago - Chile. E-mail: josetomas.sanmartin@gmail.com
[4] Departamento de Cirugía, Servicio de Otorrinolaringología Clínica Alemana de Santiago. - Clínica Alemana de Santiago, Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. - Santiago - Chile. E-mail: lroman@alemana.cl. E-mail: izamorano@alemana.cl. E-mail: jmalhue@alemana.cl. E-mail: paliaga@alemana.cl. E-mail: lcoronelli@alemana.cl. E-mail: ssarda@alemana.cl
Institution: Surgery Department, ENT Unit, Clínica Alemana de Santiago, Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile.
Send correspondence to:
Carolina Der.
Clínica Alemana de Santiago, Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. Fono: 2101111. E-mail: cdercder@gmail.com
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INTRODUCTION

The term tinnitus comes from the latin *tinnire*[1] and means to tinkle. In medicine is defined as the conscious perception of sound that is not attributable to an external source.[2] It manifests as buzz, but can be perceived in other ways: whistling, hissing, clicking, or with complex tonal characteristics[3].

Its intensity is variable, from almost imperceptible to intolerable and intrusive, significantly compromising patient's quality of life (QOL) and even leading to suicidal ideation[4].

Tinnitus affects 10-15% of the population[5]. It is a frequent reason for consultation and patients come to a wide range of professionals: otolaryngologists, neurologists, psychiatrists, psychologists, and others. In the UK up to 5% of the adult population is at least moderately annoying by tinnitus and in 1% severely affects its QOL[2,5]. Its prevalence increases with age, focusing on over 45 year-old males[6]. In children has been described in 6.5% of patients, although up to 34% refers tinnitus when directly questioning[7].

The clinical characterization of tinnitus allows defining groups which try to orientate different etiologies and helps to establish conduct. It is then classified as subjectively or objective tinnitus. The subjective tinnitus cannot be perceived by another person, whereas the other can be identified by the examiner by means of auscultation or another method[8]. Likewise, we can distinguish the pulsatile tinnitus and the not-pulsatile; the first one is usually vascular, especially in unilateral tinnitus concordant with the patients' pulsations[6]. Also it can be classified as unilateral and bilateral[3]. These three axes: pulsatility, laterality and if it is objective or subjective can make a diagnostic approximation and orientate the clinician to a certain etiology.

The condition more frequently associated with the subjective tinnitus, is hypoacusia[9]. Other reasons include exposition to noises, traumas of head and neck, local inflammation and use of medicaments[10]. Nevertheless, in 40 % of the cases the reason of the tinnitus can't be identified[11].

The evaluation of tinnitus is important for the physician and for the investigator. In the first case, it will allow to measure the magnitude of the symptom, to know the effect of therapies, or to follow-up patients. In the second case, it will be useful in developing investigation protocols.

For this, two alternatives exist. Firstly tinnitometry, which involves the confrontation of frequency and intensity, the mask ability of tinnitus and the search for the residual inhibition and secondly and most important, psycho-emotional medicine[12].

For the measurement of the psychological impact and the disability of tinnitus, the test known as Tinnitus Handicap Inventory (THI, Newman & Jacobson, 1967). Has been accepted by the principal centers because of its reliability, safety and supported validity[13,14].

This test consists of 25 questions easily understood by the patients with three answers for every question: "yes", "sometimes", or "not". It gives 4 points to "yes", 2 points to "sometimes", and 0 point to "not", and the sum of the total score goes from 0 to 100[13,14]. This score determines degrees of disability for tinnitus from slightly to severely impaired (Table 1).

Table 1. Degrees of disability for tinnitus in relation to values obtained in the THI.

Degree of disability for tinnitus	Values of THI
Without disability	0 - 16
Slight	18 - 36
Moderate	38 - 56
Severe	58 - 100

The THI is subdivided in three subscales, first, Functional scale, named by Newman consisted of 11 items, including the area of mental function (for example. Due to the tinnitus, it is difficult to concentrate?), the area of social/occupational function (for Example. Due to the tinnitus, is it difficult to enjoy social activities as going out to eat or going to the cinema?), and the area of physical function (for Example. Due to the tinnitus is it difficult to him to sleep in the night?)[13,14].

The second subscale is the Emotional scale composed by 9 items that include affective answers provoked by the tinnitus, as anger, frustration, irritability and depression (for Example. Does he feel altered by the tinnitus?). The third scale is the Catastrophic scale composed by 5 items that reflect the desperation of the patient, disability to be able to escape of the problem, perception of having a critical illness, loss of the control and his disability to face the problem (for Example. Does he believe that it has an incurable disease?)[13,14].

The THI is translated into several languages and adapted or validated according to the language and the idiosyncrasy of every country in numerous publications. For Spanish-speaking population exists a Spanish version of Herráiz et al.[15], translated from the English and adapted to the daily language of Spain. This version differs from our language in vocabulary and does not correspond to the linguistic local culture, without exist up to the minute experiences published of his use in Chile. In 2006, Peña et al.[16] proposed a linguistic homologation of this scale publishing a translation to the Spanish local language.

Objective

The general aim of this work is to realize a national linguistic validation of the THI. As specific aims we will try (1) to generate a test of auto application and easy

correction in the clinical national services, (2) to obtain a reliable method for the measurement of results in the treatment of tinnitus in Chilean patients, (3) and to rely on an instrument that it should allow to measure the degree of psychological impact and disability generated by tinnitus.

MATERIAL AND METHODS

We realized a prospective study and analysis for statistical validation of a quality test of life and its psychological impact. We divided the investigation in 4 stages:

1. Translation of the original document in English "Tinnitus Handicap Inventory" of Newman and cols. After possessing authorization of the author for the accomplishment of the project, we made a translation of the original questionnaire to the Spanish in independent form, for doctors of bilingual and Spanish native language. On the basis of these translations a questionnaire was made in Spanish who was checked and retro translated into the English for a professional certified translator. Finally the coherence was compared between the version retro translated to English and the original version in English to obtain a definitive questionnaire.
2. Viability of the questionnaire: in the second phase, a group of ENT residents, of Spanish native language evaluated the questionnaire. In a group activity, every article was read while the participants were following the reading in a printed material. They should have answered to 2 questions for every article: what does deal you with this question? And is another way of asking the same thing and that turns out to be clearer? The answers were taken in account by a group reviser composed by medical specialists in otolaryngology for final alterations to the questionnaire. In this manner we finished the confection of the questionnaire THI in his national version in Spanish. (THI-CL).
3. Application of the questionnaire: a group of 60 patients with tinnitus was submitted to the questionnaire THI-CL in his final version, for evaluation of disability produced by the tinnitus. This phase was realized in the Service of Otolaryngology of German Clinic of Santiago. It was considered to be a criterion of incorporation, 18 year-old patients, with tinnitus subjectively diagnosed, unilateral or bilateral of more than 6 months of duration and refractory to treatment. Was considered a criterion of exclusion the presence of neurological disease or have psico-organic damage. We didn't realize segregation on the basis of audiometric results or demographic variables. There was delivered an informed consent to every patient who should have been well-read and signed before the participation in the study and possess the approval of the Scientific Educational Department and Committee of Ethics of German Clinic of Santiago for the development of the investigation.
4. Statistical Analysis: We calculated the frequency of distribution, medians and standard diversion of every item of the questionnaire THI-CL. For the analysis of internal consistency of the test or reliability, we applied the test of Cronbach's Alpha Coefficient to the total score of the THI-CL questionnaire and every subscale. Besides, calculation of the Cronbach's alpha coefficient was realized eliminating an item to the time of the questionnaire simultaneously, for determine the dependent variation of each item. It was considered a value of Cronbach's Alpha bigger than 0.8 as satisfactory. Additional to this, we realized a *Student's t*-test for independent samples, to define if the total score of the THI-CL and each of his sub scales were presenting statistically significant differences between men and women.

Finally we realized a Pearson›s coefficient of correlation between the result of the total score of THI-CL and each of his subscales by the age of the patient and we used the statistical program JMP 9 Version.

RESULTS

We evaluate 60 patients who answered all questionnaires in all the cases. The average of age was 59 years with a median of 61 years (range: 20-81 years; ED: 12 years). 51.6% of the patients was men.

With regard to the answers of each one of 25 items in the questionnaire THI-CL, the percentage of answers "yes" changed between a range of 4-70%; for the response "sometimes" this percentage changed between 5-45 % and for the response "not", this variation was between 20-84 % (Table 2).

Gender differences

Student's t-test did not observe statistically significant differences for independent samples between the results of total average of the THI-CL questionnaire among men and women (Men: average = 26.4/ED = 18; Women: average = 29.2/ED = 18.4). For the functional

Table 2. Distribution frequency in percentage of the answers obtained in the questionnaire THI - E. (F) represents the questions included in the functional scale. (E) represents the questions of the emotional scale. (C) represents the questions of the catastrophic scale.

N	Pregunta	Frecuencia Distribución %		
		Si	A veces	No
1F	¿Le cuesta concentrarse por culpa del ruido o zumbido de oído?	9	36	55
2F	¿Le cuesta escuchar a los demás debido a que el zumbido o ruido del oído es muy fuerte?	9	39	52
3F	¿Lo pone mal genio el zumbido o ruido del oído?	27	27	46
4F	¿Se siente confundido por culpa del zumbido o ruido del oído?	20	21	59
5C	¿Se desespera con el ruido o zumbido del oído?	21	25	54
6E	¿Se queja mucho por tener el zumbido o ruido en el oído?	14	34	52
7F	¿Le cuesta quedarse dormido en la noche por culpa del zumbido o ruido del oído?	17	45	38
8C	¿Cree que el problema de su zumbido o ruido del oído es algo sin solución?	70	5	25
9F	¿El zumbido o ruido del oído es un problema que le impide disfrutar de la vida, como por ejemplo, salir a comer con amigos o ir al cine?	13	11	76
10E	¿Se siente desilusionado por culpa del zumbido o ruido del oído?	18	16	66
11C	¿Cree que tiene un enfermedad incurable?	48	7	45
12F	¿El zumbido o ruido de oído le impide pasarlo bien?	13	12	75
13F	¿Le estorba el zumbido o ruido del oído en su trabajo o en las labores de la casa?	21	25	54
14F	¿Se siente a menudo de mal genio por culpa del zumbido o ruido del oído?	14	29	57
15F	¿Le cuenta comprender lo que lee por culpa del zumbido o ruido del oído?	4	13	83
16E	¿Se siente alterado por el zumbido o ruido de oído?	20	30	50
17E	¿Siente que el zumbido o ruido del oído ha echado a perder las relaciones con sus familiares y amigos?	5	11	84
18F	¿Le cuesta sacarse de la cabeza el zumbido o ruido y concentrarse en otra cosa?	14	36	50
19C	¿Siente que no puede controlar el zumbido o ruido del oído?	62	18	20
20F	¿Se siente a menudo cansado por culpa del zumbido o ruido del oído?	14	21	65
21E	¿Se siente deprimido por causa del zumbido o ruido del oído?	14	21	65
22E	¿Lo pone nervioso el zumbido o ruido de oído?	20	41	39
23C	¿Siente que no puede hacerle frente al zumbido o ruido del oído?	45	18	37
24F	¿Empeora el zumbido o ruido del oído cuando está estresado?	38	32	30
25E	¿Se siente inseguro por culpa del zumbido o ruido del oído?	16	18	66

scale Men did not observe differences between the answers (either: mean score = 15.4/ED = 9.2; Women: average = 15.6/ED = 8.6). Neither difference was observed in the emotional scale (mean score = 7.9/ ED = 6.3; Women: average = 7.8/ED = 6.8). The catastrophic scale did not show significant differences (Men: average = 11.5/ED = 5.2; Women: average = 11,1/ED = 7.3) (Table 3).

Correlation with age

Statistically significant correlation was not observed between the age and the total score obtained of THI by means of the Pearson's coefficient of correlation ($r = 0.27/P = 0.5$). Significant correlation was not also obtained between the functional age and the scales ($r = 0.04/P = 0.85$), emotional ($r = 0.32/P = 0.87$) and catastrophic ($r = 0.18/P = 0.45$).

Table 3. Average scores (± ED) and range of scores of the questionnaire THI-E and his subscales, more THI's scores and subscales in his original version in English (THI-US).

	Total THI	Functional	Emotional	Catastrophic
THI-CL (average)	34,4 ± 22	15,4 ± 8,8	7,7 ± 6,6	11,3 ± 6,2
THI-US (average)	25,4 ± 20,5	11,0 ± 9,7	8,2 ± 8,4	6,1 ± 4,5
THI-CL (range)	2 - 82	0 - 44	0 - 24	0 - 20
THI-US (range)	2 - 94	0 - 44	0 - 32	0 - 18

Intern Consistency

The Cronbach's Alpha coefficient was 0.97 for the complete questionnaire, 0.95 for the functional scale, 0.98 for the emotional scale and 0.95 for the catastrophic scale.

By removing every item of the questionnaire, and calculating the Cronbach's Alpha coefficient again, a variation between 0.972 and 0.963 was observed. (Table 4).

Table 4. Results of the index of Cronbach's Alpha coefficient for internal consistency of the test THI-E and for the Cronbach's Alpha coefficient of the original test THI in English.

	THI Total	Functional	Emotional	Catastrophic
Alfa Cronbach THI-E	0.97	0.95	0.98	0.95
Alfa Cronbach THI-US	0.93	0.86	0.87	0.68

DISCUSSION

The great individual variability for the degree of interference in the daily life and the disability that the tinnitus provokes, determines an imperious need to use questionnaires that value the impact produced by this one. For it, the acufenometrics measurements do not contribute sufficient information to establish a category or degree of psycho-emotional severity that allows to certify the condition of a patient in a certain minute of his disease or treatment.

Of alternative or complementary form, multiple instruments of measurement have been in use, as the visual analogous scale (VAS) who, in response to a precise question, codes in a scale from 0 to 10 the magnitude of a criterion as the intensity of perception of the tinnitus or the level of induced inconvenience[17]. Other authors have published experiences with questionnaires as the Beck's scale of depression, of frequent use in psychology, to estimate in an objective way the disability produced for tinnitus[18]. These measurements allow to quantify of a reproducible form, although subjective, the severity and the tolerance of a tinnitus.

From the publication of the THI, numerous translations and validations to different languages have arisen as response to the need of make an objective evaluation in these patients of the level of psychological affectation that they show. As is demonstrated in the original version and in the Danish and Italian validation, Chilean version of the THI does not seem to be affected by age and sex so much for the total score and for each of his sub scales, which contributes furthermore to his cultural validity[19,20].

One of the characteristics that do the THI one of the most worldwide applied questionnaires in the patients' evaluation with tinnitus is his easy accomplishment correction and interpretation, demonstrating in different international studies a great facility of reproduction for the evaluation of tinnitus after a treatment[14,15]. Our experience was similar, achieving that the patients were answering entirely the questionnaire in all the cases, without difficult reports before the exposition of a question.

As for the results of internal validity of the test, we obtained a Cronbach's alpha index of 0.97 for the full THI-CL questionnaire, satisfactory considering an index of 0.8.

In the Spanish adjustment for Herraíz et al.[15], an index of 0.9 is described, whereas in his original version in English this index was of 0.93 for the complete questionnaire[13].

The consistence of the different subscales was similar in comparison to the questionnaire in his original English version, for the functionally and emotionally scales (0.95 in THI-CL compared to 0,86 in the original one and 0.98 in THI-CL compared to 0.87 in the original)[13]. On the other hand, in the catastrophic scale, our results in the Cronbach's Alpha index were better than those of the original study (0.95 in THI-CL compared to 0.68 in the original one). In the article of *Newman*, the authors justify the low value obtained by the limited number of questions that compose this scale (5 items). In our experience, a satisfactory result was obtained, without difference between the sub scales.

We observed a variation between 0.972 and 0.963 on the Cronbach's Alpha coefficient, when each question of the questionnaire was removed one at a time, for what it is possible to assume that none of the items of the questionnaire affects the validity of the scale.

The easy reproduction and reliability in the evaluation of the psychological impact of the tinnitus, has done of the THI an important questionnaire in the patients' study with tinnitus submitted to a therapeutic intervention. Is considered to be significant, a difference bigger than 20 points between the initial pre-treatment questionnaire and the result post therapy in the follow-up[14]. One of the limitations of the questionnaire happens when the initial score is minor to 20 points, situation in which statistically there has not corroborated a difference between both measurements[14]. With regard to this limitation, Newman et al.[14], postulate that only the change of category of disability degree (Table 1), would allow to demonstrate an improvement later to the establishment of a treatment.

The application of the THI questionnaire has spread to other areas of the audiology, as the evaluation of the adjustment to auditory prostheses in patients with hypoacusia and tinnitus, where it is possible to quantify the degree of satisfaction and response of the patient to his treatment[21].

CONCLUSIONS

The adapted version of the THI to our population presents a suitable equivalence with the original version in English, with satisfactory levels of internal consistency and easy reproduction, so that it is possible to use it in

the Chilean population for the evaluation of the disability generated by tinnitus.

This validation supposes an important help on having generated a tool to know the impact of this symptom in the quality of life of our patients, and providing criteria to measure the evolutionary control of the therapeutic interventions.

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