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Validation of the Danish version of the Tinnitus Functional Index

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ABSTRACT

INTRODUCTION. Consensus about which questionnaire to use is necessary when it comes to evaluation of tinnitus. In Denmark, the Tinnitus Handicap Index is currently used. However, for evaluating treatment-related outcomes, the Tinnitus Functional Index (TFI) has been optimised for this and is being used in several countries. In this study, we aimed to provide validation of a professionally translated Danish version of the TFI to safely implement this questionnaire in clinical and scientific settings.

METHODS. At the Department of Audiology at Hospital West Jutland, Denmark, 133 adult patients suffering from tinnitus with or without hearing loss completed the Danish version of the TFI questionnaire (TFI-Da). Internal consistency was evaluated by Cronbach's alpha and test–retest reliability with Pearson's correlation.

RESULTS. Internal consistency was calculated for the total TFI score producing an excellent Crohnbach's alpha of 0.96. Crohnbach's alpha scores were also acceptable for all subgroups with values > 0.7. The test–retest reliability in terms of Pearson's correlation coefficient was 0.848 for the total TFI scores and was acceptable for all subgroups.

CONCLUSION. Our study showed a very high internal consistency and test-retest reliability when using the Danish version of the TFI questionnaire. Therefore, we recommend TFI-Da as the standard questionnaire for tinnitus patients in Denmark, especially for evaluation of treatment impact.

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Chronic subjective tinnitus is the perception of sound in the absence of an external acoustic stimulus. It is a highly prevalent condition, which is estimated to affect 10-15% of the adult population and known to be severely debilitating in approximately 1-2% of all people [1-3]. For many patients, tinnitus affects quality of life (QoL) by causing hearing difficulties and inducing negative emotions including depression and anxiety. Tinnitus has also been shown to interfere with sleep and concentration [1, 4, 5]. Risk factors for developing tinnitus are hearing loss, head injury, increasing age and male sex [1]. The prevalence is expected to increase, presumably due to increased exposure to damaging noise in the younger population [6].

To quantify the subjective severity of tinnitus and continuously evaluate treatment effects, clinicians and researchers must rely on disease-specific QoL questionnaires.

Numerous questionnaires have been developed to quantify subjective tinnitus of which nine different in English language have been utilised [7]. Consensus about which questionnaire to use, especially in the evaluation of treatment-related outcomes, is needed [8]. Even though the various tinnitus questionnaires have shown reproducibility and internal consistency, they have also been unable to measure responsiveness to treatment [7-9]. Until the Tinnitus Functional Index (TFI) was presented, the Tinnitus Research Initiative favoured the Tinnitus Handicap Inventory (THI), since it had been translated into several languages, which facilitated comparison between different studies [10]. Following these considerations, Meikle et al. in 2012 introduced the TFI to provide a comprehensive coverage of a broad range of symptoms and psychometric properties of tinnitus and, furthermore, allow for improved evaluation of responsiveness to treatment [3, 7].

The TFI has already been translated into several languages [3, 11, 12] and is promising to become the standard instrument in evaluation of tinnitus. Currently, the recommended questionnaire for evaluating tinnitus in Denmark is the THI. Due to the limitations of the THI with respect to responsiveness to treatment and the increased international use of the TFI, the aim of this study was to provide a professional translation and validation in order to facilitate the implementation of the TFI in Danish clinical and scientific settings.

METHODS

Population

This prospective study included 133 adult patients from the Audiology Department, Region Hospital West Jutland, Denmark. All patients referred to the department with tinnitus were asked to complete the Danish version of the questionnaire (TFI-Da) and had an audiogram performed. Both patients with and without simultaneous hearing loss were included.

The audiological patient charts and audiograms were reviewed by one of three doctors at the Audiology Department. Information concerning comorbidities, medication, neuro-trauma and noise exposure (work and spare time) was registered.

One patient was excluded due to an incomplete TFI-Da questionnaire.

Translation and validation

The original English version of the TFI questionnaire [7] was translated into Danish by a native Danish language professional. Subsequently, backward translation from Danish into English was performed by a native Danish non-health-related person. The final translation was validated by an English language professional.

Next, the TFI-Da was presented to 25 subjects, 12 health-related and 13 non-health-related subjects for modification before usage on the target population. Only minor changes were made. Finally, the internal validity was tested by ensuring that there were no redundant questions [7]. Similar to the English version, the TFI-Da questionnaire consists of 25 questions divided into eight subgroups: intrusive, sense of control, cognitive interference, sleep, auditory difficulties, QoL, relaxation and emotional distress (https://ugeskriftet.dk/files/a02220135_-_supplementary.pdf). Furthermore, each answer is graded on a five-point scale to reflect the severity of tinnitus: no problem (0-18), a small problem (18-31), a moderate problem (32-53), a big problem (54-72) and a very big problem (73-100) [13].

The study was approved by the local hospital board. No ethical approval of the study was necessary.

Validation

Subjects were presented to the TFI-Da at their first visit at the Department of Audiology and were invited to

submit a second version within five months after their initial visit, thus allowing for test-retest comparability.

Audiological assessment

Pure tone audiometry was performed for air conduction at 0.25, 0.5, 1, 2, 4, 6 and 8 kHz and for bone conduction (BC) at 0.5, 1, 2 and 4 kHz. Hearing loss was defined as thresholds of 25 dB or poorer at two or more frequencies. Hearing losses were categorised as conductive in case of air bone gaps (ABG) beyond 10 dB at two or more neighbouring frequencies and BC values superior to 25 dB in at least three out of four frequencies. Hearing losses were categorised as mixed in case of ABG values of 10 dB or more in at least two neighbouring frequencies and BC thresholds of 25 dB or poorer in at least two frequencies. Hearing losses were categorised as sensorineural (SNHL) if ABG was below 10 dB in at least three frequencies and BC thresholds of 25 dB or poorer in at least two frequencies. Speech recognition threshold values of 20 dB or lower were categorised as normal, and discrimination scores of 75% or higher were categorised as normal. Threshold Carhart was calculated as the average of thresholds at 0.5, 1, 2 and 4 kHz. Thresholds of 25 dB or poorer at 4 or 6 kHz with superior thresholds at neighbouring frequencies were classified as noise-related hearing losses.

Statistical analysis

All data including demographics, diagnoses, medication use, clinical examination and psychometric properties were analysed using Stata 14.2.

To evaluate the reliability of the Danish version of the TFI, internal consistency in total and in-between the subgroups was calculated with Crohnbach's alpha coefficients. Coefficients > 0.7 were considered acceptable [2]. Test-retest reliability was calculated by Pearson's coefficient. Coefficients > 0.7 were considered strong correlations [14]. $p < 0.05$ was considered significant.

Trial registration: not relevant.

RESULTS

Demographics of the included 133 patients are listed in **Table 1**.

TABLE 1 Patient characteristics.

Patients, n	133
Gender, male, n (%)	82 (61.2)
Age, median (range), yrs	55.8 (22.6-80.3)
Comorbidities, n/N (%)[a]	
Otological	9/113 (8.0)
Neurological	13/113 (11.5)
Psychiatric	25/113 (22.1)
Cardiovascular[b]	36/113 (31.9)
Endocrinological	6/113 (5.3)
Traumatic brain injury, n/N (%)[c, d]	24/122 (19.7)
Noise exposure, n/N (%)	44/122 (36.0)
Ototoxic medication, n/N (%)[e, f]	1/101 (1)

a) Due to non-available data, missing data were registered for 20 subjects regarding comorbidities.
b) Hypertension was included.
c) Due to non-available data, missing data were registered at 11 subjects regarding traumatic brain injury.
d) Includes head trauma and neurosurgical injury.
e) Due to non-available data, missing data were registered at 32 subjects regarding medication use.
f) Includes platinum-based drugs, gentamicine, quinine, aminoglycosides and some cytostatics [17].

The two most commonly reported comorbidities were cardiovascular (32%) and psychiatric diseases (23%), and 29% of patients had involvement of more than one organ system.

Work-related noise exposure was stated by 24%, whereas 8% of the patients reported noise exposure in their spare time. Only three patients reported noise exposure both at work and in their spare time.

Use of the most common ototoxic medication was only reported in a single patient who received cisplatin.

Psychometric properties

Total TFI-Da scores and sub scores were calculated for 133 patients (see **Table 2**). For retesting, 23 patients

completed the TFI-Da questionnaire a second time. The mean time to retest was 37 days (11-130 days) after the primary test. For internal consistency, we calculated a total Crohnbach's alpha value of 0.96. The test-retest reliability was calculated with Pearson's correlation coefficient and was estimated to 0.848 for the total TFI-Da score. For sub-score values, see Table 2.

TABLE 2 Patients' psychometric data (N = 133).

	Primary test	Retest	Pearson's r (p-value)	Cronbach's alpha
Total TFI-Da scores, mean ± SD[a]	48.3 ± 21.1	50.6 ± 21.0	0.85 (< 0.005)	0.96
TFI-Da sub-scores, mean ± SD				
Intrusive	61.8 ± 23.1	64.1 ± 20.5	0.80 (< 0.005)	0.84
Sense of control	66.2 ± 24.5	68.0 ± 22.9	0.68 (< 0.005)	0.75
Cognitive	45.8 ± 25.9	52.3 ± 24.0	0.89 (< 0.005)	0.94
Sleep	40.9 ± 34.3	47.6 ± 36.2	0.85 (< 0.005)	0.95
Auditory	48.7 ± 26.0	49.6 ± 22.6	0.66 (< 0.005)	0.71
Relaxation	50.3 ± 26.9	51.2 ± 27.3	0.74 (< 0.005)	0.80
Quality of life	35.7 ± 28.0	40.2 ± 27.5	0.78 (< 0.005)	0.85
Emotional	39.4 ± 29. 2	38.9 ± 27.3	0.68 (< 0.005)	0.78

SD = standard deviation; TFI-Da = Tinnitus Functional Index (0-100 scale), Danish version..
a) Total TFI-Da scores in the primary test showed normal distribution.

Audiological assessment

Hearing loss was registered in 85% of the patients. Of all patients suffering from hearing loss, 92.6% suffered from SNHL in the right ear, 91.5% in the left ear and 86.2% suffered from bilateral SNHL. Compared with BC, minor and insignificant ABG were observed.

Right-sided tinnitus was reported in 15.2% of the patients, 15.2% had left-sided tinnitus and 69.9% had bilateral tinnitus.

For 55.6% of the patients, hearing impairment and tinnitus were located to the same ear. For the full distribution of audiological data, see **Figure 1** and **Table 3**.

FIGURE 1 Distribution of audiological data. **A.** Air conduction. **B.** Bone conduction.

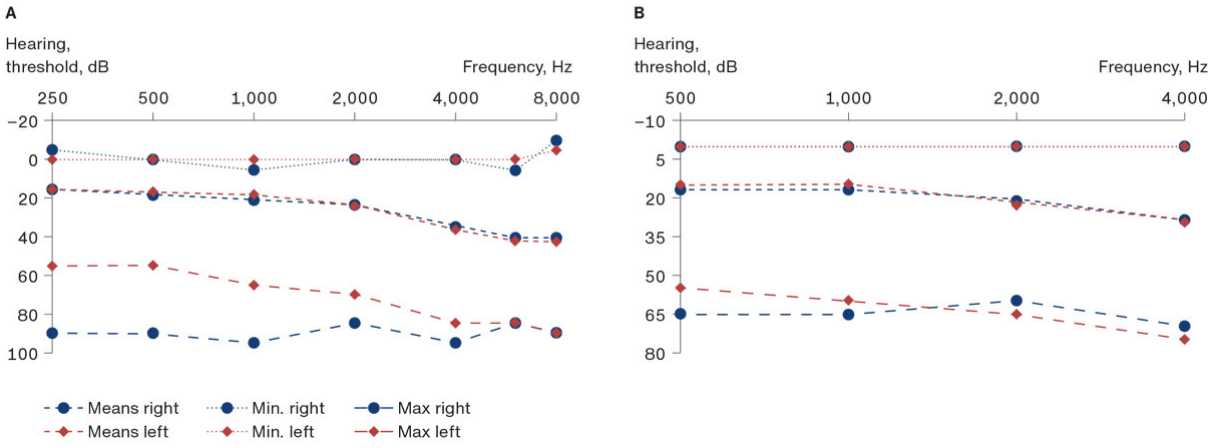

TABLE 3 Patients' audiological evaluation (N = 133).

	Right ear	Left ear	Bilateral
Type of hearing loss, n (%)[a, b]			
Sensorineural hearing loss	91 (68.4)	99 (74.4)	81 (60.9)
Conductive hearing loss	1 (0.8)	1 (0.8)	0
Mixed hearing loss	8 (6.0)	7 (5.3)	2 (1.5)
No hearing loss	33 (24.8)	26 (19.6)	20 (15.0)
Noise-induced hearing loss	45 (33.8)	47 (35.3)	28 (21.1)
SRT, mean ± SD (n = 129)	13.9 ± 11.0	13.8 ± 9.4	-
DS for left ear, mean ± SD (n = 131)	95.1 ± 11.5)	95.8 ± 10.0	-
TC, mean ± SD (n = 127)	23.8 ± 13.2	23.6 ± 11.7	-

DS = discrimination score; SD = standard deviation; SRT = speed reception threshold; TC = Threshold Carhart
a) Defined as thresholds of ≥ 25 dB at ≥ 2 frequencies, for definition of type of hearing loss, see the Methods section.
b) For 20 patients the audiogram did not include ≥ 1 frequencies for uncertain reasons.

DISCUSSION

The primary aim of this study was to provide a professional translation and validation of the TFI-Da questionnaire. Overall, the Danish version of the TFI questionnaire showed excellent internal consistency with a total Crohnbach's alpha of 0.96. Test-retest reliability was acceptable with a total Pearson's r of 0.85.

Our results are comparable with those of previous studies demonstrating Crohnbach's alpha values in the range of 0.8-0.97 and Pearson's r falling in the 0.78-0.91 range [2, 7, 13, 15].

The mean interval from test to retest was 37 days. Fackrell et al. [15] performed retest 7-21 days after the primary test, whereas Müller et al. [2] retested 70 days after the primary test. An interval that is neither too short nor too long is important to ensure that patients do not remember their previous answers and that their symptoms do not change significantly. Unfortunately, it was not technically feasible to perform a retest for all patients at a fixed interval, which would have been optimal.

When evaluating the sub scores, test-retest reliability showed a strong correlation in all subgroups, except for the categories Sense of control, Auditory and Emotional, where we found moderate correlations. The TFI-Da scores in the retest were higher than the scores in the primary test, except for the Emotional sub-score. It is possible that patients tended to focus more on the problem after the primary test.

We found normally distributed TFI-Da scores with a mean total TFI-Da score of 48.3 and a standard deviation (SD) of ± 21.1. The variances were overall homogenic in both the tests and retests, implying that the variances were equally distributed. The mean total TFI-Da score and also the SDs are in line with those reported by other studies: Fackrell et al. (TFI = 40.6, SD: ± 20.1) [15], Meikle et al. (TFI-Da = 54.46, SD: ± 24.7) [7] and Peter et al. (TFI-Da = 40.7, SD: ± 23.2) [13]. The Swedish study by Müller et al. [2] had a lower mean value of 31.74. However, this study included participants from the general population reporting tinnitus rather than patients from outpatient clinics. Furthermore, our study population consisted of patients reporting tinnitus as their primary complaint, which may explain the relatively high mean TFI-Da score compared with the cited studies [2, 7, 13, 15].

The patients in our study reported a high TFI-Da score in the sub scores Intrusive and Sense of control, indicating how tinnitus distresses the patients the most. These findings are in line with results from Müller et al. [2] and Chandra et al. [16] who also reported their highest scores in these subcategories.

Our study population consisted of a higher proportion of men than women with a mean age of 55.8 years. This is comparable to other similar studies [2, 7]. Noise exposure was reported in 36% of the group and the majority of patients also suffered from hearing loss. This was expected as noise exposure may cause SNHL, which is associated with tinnitus [1, 2].

The prevalence of cardiovascular disease as a comorbidity within our study group is comparable to the worldwide prevalence [17]. Likewise for psychiatric diseases, the prevalence in our study group was in line with findings from a study by Bhatt et al. [18] who also found that a higher proportion of patients with tinnitus than subjects without tinnitus had psychiatric diseases. Direct comparison between our study and similar studies with respect to characterisation of the patients is in part hindered by the fact that only a few other studies have elaborated on comorbidities and other parameters.

In Denmark, the clinical guideline recommends THI to evaluate the amount of distress caused by tinnitus. This may be because THI is the only self-reported tinnitus questionnaire that has been translated and validated for use in Denmark. Additionally, the THI is the most translated and used tinnitus questionnaire worldwide [7]. However, the THI was never intended to evaluate responsiveness to treatment [8]. The THI consists of a three-point ordinal scale, whereas the TFI consists of a ten-point scale, which may facilitate stratification of subgroups and evaluation of responsiveness to treatment. Another important difference is that the THI questionnaire contains some catastrophic items. These items may provoke fears of worsening of the tinnitus among some patients [7]. This is not true for the TFI questionnaire, which makes it a useful tool in the clinical setting.

From this study, no conclusions may be drawn about the TFI questionnaire's ability to evaluate responsiveness to treatment. Accordingly, future studies evaluating responsiveness to treatment using the TFI are warranted.

CONCLUSION

Our study showed a very high internal consistency and validity when using the Danish version of the TFI questionnaire. We therefore find it reasonable to recommend the TFI-Da as the standard questionnaire for tinnitus patients in Denmark.

However, more studies are needed to evaluate the TFI as a tool to assess treatment effect.

https://ugeskriftet.dk/files/a02220135_-_supplementary.pdf

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