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Long-term effects of a single psycho-educational session in chronic tinnitus patients

Short title: Effects of single-session tinnitus education

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ABSTRACT

PURPOSE: To evaluate the effects of a single psycho-educational session on tinnitus burden in chronic tinnitus patients. The session is organised at a tertiary referral centre for otologic disorders at the University Hospital Antwerp as a group session (maximum of 10-15 patients a time) lasting for approximately 3-4 hours. The session focusses on different aspects of tinnitus.

METHODS: The current manuscript reports on 96 patients who completed the Tinnitus Functional Index (TFI), Visual Analogue Scale for mean loudness (VAS), Hyperacusis Questionnaire (HQ) and the Hospital Anxiety and Depression Scale (HADS) prior to treatment and at six-month follow-up. The TFI was chosen as the primary outcome. Paired samples-T tests were performed to evaluate therapy effect at 6-month follow-up. In addition, a logistic regression model revealed baseline TFI/VAS scores and duration of tinnitus as contributing factors to a significant decrease of the TFI.

RESULTS: The TFI total score showed a significant decrease ($p < 0.001$) at the 6-month follow-up time point. At follow-up 75% of patients reported their tinnitus to be under control not requiring any additional treatment. The logistic regression model showed that patients with higher baseline TFI scores, lower baseline mean VAS loudness ratings and shorter tinnitus duration were more likely to show clinically significant improvement on the TFI scale.

CONCLUSIONS: Regular Tinnitus Retraining Therapy or Cognitive Behavioural Therapy are effective though very time consuming and expensive treatments. A single psycho-educational group session was shown to be highly effective in decreasing the tinnitus burden, which increases feasibility and cost-effectiveness.

KEYWORDS: Tinnitus, education, Tinnitus Functional Index, Tinnitus therapy, psycho-education

Trial registration: Not applicable as this is a retrospective reporting of tinnitus outcome in the daily clinical practice, not a clinical trial.

INTRODUCTION

Tinnitus, the perception of a sound in the absence of an external sound source, affects 15% of the adult population [1, 2]. While tinnitus is a common symptom it may severely affect the quality of life as many patients suffer from sleep deprivation, concentration deficits and increased stress, anxiety and depression symptoms due to the tinnitus [3]. As such, the mental health of many patients is undeniably undermined. In order to guide patients towards appropriate therapy, thorough diagnosis is of paramount importance. Yearly approximately 1500 patients consult the TINTRA (centre for Tinnitus Treatment and Research Antwerp) clinic at the ENT department of the Antwerp University Hospital (UZA) with tinnitus being the primary complaint. Through a multidisciplinary approach consisting of thorough anamnesis and hearing investigations a ‘tinnitus profile’ is constructed for each patient individually leading to the most optimal therapy and/or combination of therapeutic actions. At first consultation, tinnitus characteristics (type, side and duration) are assessed and co-existing symptoms such as hearing loss, decreased speech understanding, otalgia, hyperacusis and vertigo are questioned. Potential triggers experienced by the patient are discussed and factors that may modulate/generate the tinnitus such as cochlear deficits and somatic components (temporomandibular joint deficits and/or cervicgia) [4, 5] are explored. Our group previously published guidelines on subjective tinnitus assessment in the clinical practice [6]. Finally, the impact of tinnitus on the quality of life is assessed using questionnaires. While the identification of underlying tinnitus causes should be determined and – if possible – treated, often the accompanying symptoms such as sleep and concentration deficits and tinnitus-associated anxiety and stress are most troublesome for the patient. As a consequence, many therapeutic interventions rely on psychological counselling such as Tinnitus Retraining Therapy (TRT) [7] and Cognitive Behavioural Therapy (CBT) [8] which both have proven to be effective in tinnitus treatment when it comes to the development of coping mechanisms by the patients. Full TRT and CBT therapies are usually intensive programs and therefore time-consuming. In many health care centres this expensive and time-consuming interventions are not reimbursed for the patient. Moreover, a certain amount of patients require such thorough therapy while for others, shortened forms of psycho-education may be sufficient [9]. Therefore, the current paper reports on the effects of a one-time informative psycho-education session tailored to tinnitus patients. When patients consider the tinnitus as bothersome or negatively affecting the quality of life, they are first guided towards attending the informative psycho-educational session in order to gain insights into the symptom and the cascade of accompanying confounders. The current study evaluates the effect of providing information to the patient on tinnitus burden over time by reporting outcome at 6-month follow-up. The present paper reports on the long-term follow-up of the first 101 consecutive patients attending the group session in the period of august 2017 until February 2019.

METHODS

Audiological testing

Full ENT investigation is performed according to published standards [6] in each patient comprising of thorough anamnesis (including tinnitus aetiology and tinnitus characteristics) and micro-otoscopy followed by audiological testing. Pure tone audiometry is performed according to current clinical standards (ISO 8253-1, 1989) using a two-channel Interacoustics AC-40 audiometer (Interacoustics, Middelfart, Denmark) in a silent room. Air conduction thresholds are measured by use of headphones at 125Hz, 250Hz, 500Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz and 8 kHz. In cases where air conduction thresholds exceed the normality level of 20dB HL at one frequency between 250Hz and 4 kHz, bone conduction thresholds are measured. Tinnitus questionnaires are used in order to assess the tinnitus loudness, burden and the effects on the quality of life in general. Questionnaires are filled out at the first consultation and at 6-month follow-up.

Counselling

Regular group counselling sessions are organized at the tertiary referral tinnitus clinic TINTRA (Tinnitus Treatment and Research centre Antwerp) of the University Hospital Antwerp. For these sessions a small number of patients (N=10-15) who consulted our clinic with tinnitus as the primary complaint and who underwent all necessary diagnostic testing, are invited to participate in the session. The 3-hour session is built up as an informational and educational encountering with patients in which most part is dedicated to providing more insights into the symptom of tinnitus. We elaborate extensively on the differences in sounds that can be heard, the possible causes of tinnitus – with emphasis on hearing loss/damage – the perception of tinnitus and the interference in life, the triggers and the effects on - and influence by - the mental status and how all these factors interact with each other. An outline of the session can be found in the supplementary material. For patients requiring further

therapy, continued individual counselling or guidance towards other therapy forms is provided afterwards. All therapy was provided by certified audiologists.

Tinnitus Functional Index

The Tinnitus Functional Index (TFI) was chosen as the primary outcome. The TFI [10, 11] is a self-reporting questionnaire consisting of 25 items assessing the severity and the impact of the tinnitus in daily life through items targeting different aspects: intrusiveness, sense of control, cognition, sleep, auditory difficulties, relaxation, quality of life and emotional aspects. The TFI is often used for assessing treatment-related changes in tinnitus. A reduction of 13 points or more on the TFI can be considered as a meaningful, clinically relevant reduction to the patient [10].

Visual Analogue Scale

The mean tinnitus loudness throughout the day was assessed by use of a Visual Analogue Scale (VAS). In this case the patient had to indicate the mean tinnitus loudness over the last week on a scale from 0 (no tinnitus at all) to 100 (the most extreme loudness one can imagine) by use of a ruler [12].

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) [13, 14] is a self-assessment screening tool for symptoms of anxiety and depression. The questionnaire consists of 14 items in total of which half of them assessing signs of anxiety and depression respectively. A score of 8 or more on one or both subscales is considered as an increased risk for anxiety or depression symptoms.

Hyperacusis Questionnaire

The presence of hyperacusis was evaluated by a Dutch validated version of Khalfa's Hyperacusis Questionnaire (HQ) [15, 16]. According to Khalfa's HQ one can speak of the presence of hyperacusis when the score on the HQ is 28 or more. While validating the Dutch version of the HQ, Meeus also compared the HQ scores with other hyperacusis measurements and found that one can already speak of clinically relevant hyperacusis with a score of 22 on the Dutch HQ [15]. Therefore, a cut-off score for the presence of hyperacusis of 22 points was used in the present study.

Ethical Approval

The long-term follow-up of tinnitus patients was approved by the ethical committee of the University Hospital Antwerp (date: 6/11/2017; file number: 17/43/481). All patients signed an informed consent for the scientific use of their data.

Statistics

The TFI score (pre-therapy versus follow-up) was chosen as the primary outcome. SPSS version 23 (SPSS 23.0, Inc., Chicago, IL, USA) was used in order to perform statistical analysis. Paired sample T tests were used in order to compare the TFI score pre-therapy and after approximately 6 months after the group session. In addition, a logistic regression model was used in order to explain a relevant TFI decrease after treatment. The level of statistical significance was defined as $p < 0.05$.

RESULTS

Patient demographics

The mean long-term follow-up was 5.82 months (SD = 1.4). In total 219 patients attended the informational group session of which 101 patients filled out the follow-up questionnaires that were sent to the home address (response rate = 46%). Five patients were excluded from further analysis due to incomplete answers. As a result, the long-term effects of the session were evaluated for 96 patients. The group consisted of 66 male and 30 female patients. Demographic data and baseline tinnitus characteristics are shown in table 1. No significant differences in baseline measures were present between male and female patients ($p > .05$).

Table 1 about here

Primary outcome

A decrease of 13 points on the total TFI score is generally considered as a clinically relevant difference noticeable by the patient [10]. In the current group 48 patients – corresponding to 50% of the population - showed a decrease of 13 points or more on the TFI. The distribution of change in TFI score is illustrated in figure 1. When looking at the TFI subscale scores there was a significant decrease ($p < 0.001$) for all subcategories with exception of the auditory category ($p = 0.07$) as depicted in figure 2. A gender difference ($p = 0.035$) was found for the effect of treatment as males and females showed a mean TFI decrease of 9.01 (± 15.86) and 16.71 (± 17.53) respectively. In total, 6 patients showed a 13-point increase at follow-up, which could be seen as a subjectively perceivable increase of the tinnitus.

Figure 1 about here

Figure 2: about here

Shortly after the group session nineteen patients indicated to be in need for further treatment. As a result, these patients received individual counselling focussing on the aspects particularly mentioned by the patient such as sleep, attention, concentration and anxiety. The total amount of extra counselling sessions depended on the needs of the patient. The average amount of additional sessions was 3.11 (± 2.74). In addition, five patients were enrolled into a neuromodulation protocol (see [17] for the currently applied neuromodulation protocol). As such, 25% of the patients pursued further treatment. The patients who attended further treatment did not have a significantly higher baseline TFI before therapy, nor did they show significantly other changes in TFI at follow-up compared to the patients who did not continue any therapy.

Secondary outcomes

As secondary outcome measures the VAS for mean tinnitus loudness, the HADS and the HQ were compared at follow-up versus baseline by use of a paired-samples T-test (table 2). A significant decrease of VAS was measured at follow-up as well as a decrease in the HADS fear subscale score. No changes were measured in the total HADS score nor in the HQ score.

Table 2 about here

Logistic regression model

A logistic regression model was used to determine which factors are determinative for a clinically relevant TFI decrease (i.e. 13 points decrease). The following variables were put into the equation: age, gender, TFI at baseline, HADS at baseline, VAS at baseline, HQ at baseline, hearing loss (Fletcher Index), tinnitus type, tinnitus side and tinnitus duration. Three variables showed significant influence on the clinically relevant decrease in TFI score: baseline TFI score, baseline VAS mean loudness score and the duration of tinnitus. The results of the logistic regression model are shown in table 3. The model shows that patients with a higher baseline TFI score are more likely to benefit from the therapy. Mean VAS score at baseline showed a negative influence meaning that higher VAS scores are less likely to show a clinically relevant TFI decrease. Finally, also patients with a longer tinnitus duration are less likely to improve to a greater extent.

Table 3 about here

DISCUSSION

The current manuscript reports on the effects of a single, 3-hour duration, informational group counselling session for chronic tinnitus patients. Significant improvement by means of the TFI score were obtained at 6-month follow-up. Tinnitus education sessions were also found to be highly effective by previous studies measured at a 3 to 6-month follow-up time point where 1 or 2 sessions were sufficient in the support of the patient. Moreover, no effect differences were found between limited tinnitus education versus full TRT/CBT programs [18-21] while other studies showed an superior effect of TRT and CBT intervention over educational care [8]. Nevertheless, huge heterogeneity exists in the outcomes of educational counselling alone versus other approaches [20] mainly due to the lack of an international standard measure of tinnitus therapy effectiveness. Often the rate of tinnitus recovery or the decrease of tinnitus severance is considered as the primary outcome but numerous validated scales are currently used as a measurement of tinnitus decrease and/or improvement of quality of life e.g. the Tinnitus Questionnaire (TQ)[22], the Tinnitus Functional Index (TFI)[10], the Tinnitus Handicap Inventory (THI)[23], Visual Analogue Scales for tinnitus loudness and/or annoyance, etc. The scattered use of questionnaires challenges the comparison of treatment outcomes in various therapy protocols. Depending on the desired topic to assess, one measure of tinnitus burden may be more suitable than the other. For example, the TQ can be chosen over the THI when tinnitus-related sleep disturbance needs to be assessed [24]. In addition, recently it was shown that the TFI showed a high sensitivity to change after intervention [25, 26]. Another important issue that can be raised in this context is the interpretation of a decrease in score on any kind of tinnitus questionnaire. In the current manuscript a rather strict cut-off of 13 points decrement on the TFI was used as this is the point where patients actually notice change in the perceived tinnitus burden [10] in contrast to most other studies where a significant decrease in the primary outcome is usually considered as successful treatment [8, 27]. This point was chosen as there is, inevitably, some variation in scores in a test-retest condition in the absence of any subjective tinnitus change. The decrease with 13 points should represent a true, subjectively perceived difference in tinnitus burden and therefore holds a stronger argument for research purposes than solely the use of significance levels. Such cut-off scores were also used in a recent retrospective study where it was also shown that tinnitus tends to improve over time with most patients undergoing a form of therapy [28]. Subsequently, a 13 point increase of the TFI represents a perceivable increase of the tinnitus. In the current study half of the patients showed a clinically relevant decrease pointing out the strength and the utility of short educational programs [29].

A significant gender difference was found as women showed a higher TFI decrease (mean decrease of 16.71 ± 17.53) compared to men (9.01 ± 15.86). This phenomenon was also seen in several other tinnitus treatments [30] and tinnitus researchers are currently investigating possible underlying reasons for this difference. One hypothesis is that women more often express specific personality traits such as “openness” (= more extravert) and “open-mindedness” which makes them more susceptible for psychological interventions [31] but further research is currently ongoing.

A limitation of the current report is that there was no inclusion of a control group in order to account for placebo effects/bias from attending the educational group session. In a clinical setting it is not ethically justifiable to abstain help-seeking patients from treatment for a long period of 6 months. Drop-out during the follow-up period would be very high as patients would quest for therapy elsewhere. As a result, many studies assess the comparison of distinct treatments so no patients are restrained from therapy and the compliance remains high [18, 32]. In addition, the response rate at follow-up was below 50% which raises questions concerning possible bias of responders. It might be the case that either patients were more likely to respond when they were in need for further treatment or vice versa, were reluctant to respond when they considered the provided therapy as non-useful. At baseline there were no significant differences between the primary and secondary outcomes scores. Moreover, all patients were personally contacted approximately two weeks after the session where it was questioned whether they would require further treatment, as described in the methods section. No negative reactions towards the session were reported at that time and all patients who had further treatment of any kind completed the follow-up questionnaires. As such, despite this limitations, the current study holds sufficient evidence that a single psycho-education session is an efficacious intervention to lower the tinnitus burden in a large group of patients as roughly 3/4th of the patients did not require any additional treatment after the session and stated to have their tinnitus under control. Nevertheless, currently, more effort is made to increase the response rate in the future. As such, patients are informed about the follow-up questionnaires and are motivated to respond. However, patients' response might still be biased and one may consider an at random approach in future studies or apply statistical testing to assess whether missing data is completely at random or not [33, 34].

The logistic regression model learned that patients with higher TFI baseline scores and with shorter duration of tinnitus existence were more likely to show a 13-point decrease on the TFI. A bit more surprising was the fact that TFI was more likely to decrease in patients with a lower baseline VAS loudness scoring. A link between tinnitus severity and the accompanying annoyance, tinnitus loudness and duration was previously described by Hiller and Goebel who found that tinnitus lasting less than 12 months had a stronger influence on annoyance than on loudness whereas for patients with longer tinnitus duration the tinnitus affected the grading of the loudness (VAS) to a greater extent than the annoyance grading [35]. Nevertheless there are also a sufficient amount of authors reporting a change of tinnitus disturbance over time but not in tinnitus loudness [28, 36]. The outcome variation in studies concerning tinnitus loudness shows that this parameter is not sufficient reliable to use as a sole outcome measure and that the use of broader questionnaires is more correlated to the tinnitus burden.

The current findings also emphasize that short-term intervention in tinnitus patients is desirable. As full psychological programs are time consuming and expensive, shorter educational sessions are more practically feasible and cost-effective in a clinical setting [18, 20].

In conclusion, it can be stated that short psycho-education counselling for tinnitus patients is a valid alternative for TRT or CBT programs and fairly feasible to implement in daily practice. Sessions provided in small groups of patients render a higher cost-effectiveness than individual counselling and should be the first step in caregiving to tinnitus patients, preferably in an early stage. Patients requiring further, more thorough therapy can be guided towards more extensive TRT or CBT afterwards.

FUNDING

Not applicable

CONFLICT OF INTEREST

No conflict of interest for any of the authors is applicable.

AVAILABILITY OF DATA AND MATERIAL

Data can be made available upon request.

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FIGURE LEGEND

Figure 1: Distribution of the change in TFI score (follow-up TFI score minus baseline TFI score). Positive changes reflect a decrease of TFI score over time. The zero-line is indicated. In addition a line is drawn at the 13-point difference which indicates a clinically, relevant change.

Figure 2: TFI total score and subscale scores pre-therapy and at follow-up.

TABLE LEGEND

Table 1: Demographic data and tinnitus characteristics at baseline for males and females. No significant differences in baseline characteristics between and females was apparent.

Table 2: Paired-samples t-test results for the secondary outcomes with inclusion of Bonferroni correction for multiple testing.

Table 3: Logistic regression model explaining the presence of a clinically relevant TFI decrease. Originally ten items were put into the equation. The current table shows the variables that yielded statistical significance. Nagelkerke R² was 0.3 meaning 30% of the variance was explained by the current model.

	Male	Female	p-level
Mean age (years)	53.2 (± 14.5)	52.2 (± 13.5)	0.75
Mean Fletcher Index (dB HL)	13.3 (± 16.1)	15.7 (± 15.5)	0.54
Mean tinnitus duration (years)	4.8 (± 8.0)	3.5 (± 4.9)	0.41
Tinnitus type			
<i>Pure tone</i>	46	20	
<i>Noise</i>	15	5	
<i>Polyphonic</i>	5	5	
Tinnitus side			
<i>Unilateral</i>	20	14	
<i>Bilateral</i>	43	13	
<i>Central</i>	3	3	
Mean TFI baseline	53.2 (± 17.6)	57.4 (± 22.2)	0.3
Mean VAS baseline	56.2 (± 21.4)	58.8 (±20.4)	0.6
Mean HQ baseline	20.2 (± 8.5)	21.0 (± 7.6)	0.6
Mean HADS baseline	14.2 (+7.9)	14.2 (± 6.6)	0.3

Table 1: Demographic data and tinnitus characteristics at baseline for males and females. No significant differences in baseline characteristics between and females was apparent.

	p-value	p-value (Bonferroni)
Change in VAS mean loudness	0.02	> 0.05
Change in HQ	0.13	> 0.05
Change in HADS		
<i>Total HADS</i>	0.058	> 0.05
<i>HADS-fear</i>	0.024	> 0.05
<i>HADS-depression</i>	0.048	> 0.05

Table 2: Paired-samples t-test results for the secondary outcomes with inclusion of Bonferroni correction for multiple testing.

	B	Wald	Odds ratio (OR)	95% C.I. for OR lower	95% C.I. for OR upper	p-value
TFI baseline	0.49	5.12	1.05	1.01	1.09	0.024
VAS baseline	-0.41	6.83	0.96	0.93	0.99	0.009
Tinnitus duration	-0.92	4.24	0.91	0.83	0.99	0.039

Table 3: Logistic regression model explaining the presence of a clinically relevant TFI decrease. Originally ten items were put into the equation. The current table shows the variables that yielded statistical significance. Nagelkerke R^2 was 0.3 meaning 30% of the variance was explained by the current model.