

Do patient characteristics predict outcome in the outpatient treatment of chronic tinnitus?

Beeinflussen Patientenmerkmale den Erfolg einer ambulanten Behandlung des chronischen Tinnitus?

Abstract

Various patient characteristics were assessed before offering a treatment to reduce tinnitus related distress to 57 individuals suffering from chronic idiopathic tinnitus. Patients were randomly assigned to a cognitive-behavioral tinnitus coping training (TCT) and a habituation-based training (HT) modelled after Tinnitus Retraining Therapy (TRT) as conceived by Jastreboff. Both trainings were conducted in groups. It was hypothesized that comorbidity regarding mental disorders or psychopathological symptoms (DSM-IV diagnoses, SCL-90R score) and a high level of dysfunctional cognitions relating to tinnitus would have a negative effect on therapy outcome while both trainings proved to be highly efficacious for the average patient. Also further patient features (assessed at baseline) were explored as potential predictors of outcome. None of the hypotheses was corroborated by the data. On the contrary, a higher number of diagnoses was associated with better outcome (statistical trend) and a higher extent of annoyance and interference led to a larger positive change in patients if treated by TCT. No predictor could be identified for long-term success (follow-up ≥ 18 months) except regarding education. The higher the educational level, the larger was the improvement in HT patients. It is concluded that therapy outcome of TCT and HT can not reliably be predicted by patient characteristics and that early variables of the therapeutic process should be analysed as potentially predicting subsequent therapeutic outcome.

Keywords: tinnitus, cognitive-behavioural treatment, habituation based treatment, prediction, outcome, patient variables

Zusammenfassung

Es ist bisher noch nicht untersucht worden, ob der Erfolg einer ambulanten Behandlung von idiopathischem Tinnitus durch das Vorliegen einer psychopathologischen Belastung beeinträchtigt wird oder andere Tinnitus-relevante Patientenvariablen die Wirksamkeit moderieren.

In einem randomisierten Kontrollgruppendesign wurde die Wirksamkeit eines kognitiv-behavioralen Tinnitusbewältigungs-Trainings (TBT) und eines habituationsbasierten Trainings (HT), angelehnt an die Konzeption der Tinnitus Retraining Therapie nach Jastreboff, verglichen (N=57). Als Outcomekriterium fungierte der Beeinträchtigungsscore aus dem Tinnitusfragebogen von Goebel u. Hiller [1]. Mittels des MiniDIPS-Interviews wurden wesentliche psychopathologische Diagnosen abgeklärt. Aus der SCL-90R wurde der Globale Belastungsscore (GSI) als eine weitere unabhängige Variable genutzt. Ein Fragebogen zu dysfunktionalen Kognitionen zu Tinnitus lieferte die dritte Prädiktorvariable, zu der die Hypothese eines negativen Zusammenhangs zum Therapieerfolg formuliert wurde. Als potentielle Prädiktorvariablen wurden zusätzlich Dauer und Lautstärke des Tinnitus sowie andere Tinnitus-relevante Parameter ausgewählt.

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Die Hypothesen konnten nicht bestätigt werden. Es ergaben sich keine signifikanten Korrelationen weder in der Gesamtgruppe noch innerhalb der einzelnen Trainingsgruppen. Tendenziell zeigten sich bei der TBT Gruppe einige positive Zusammenhänge zwischen Ausgangsbelastung und Ausmaß des Erfolgs. Der Erfolg des HT (im follow-up) hing mit der Schulbildung der Patienten zusammen.

Beide Verfahren, die bezogen auf die Reduzierung der Tinnitusbelastung nahezu gleich wirksam sind, zeigen keine differentielle Effektivität in Abhängigkeit von der Psychopathologie des Patienten. Diese stellt also keine Kontraindikation für ambulante Therapien der verwendeten Art dar. Einige Daten sprechen dafür, dass bei mit TBT behandelten Patienten eine höhere psychopathologische Ausgangsbelastung und ein höheres Level an Tinnitus-bezogener Beeinträchtigung sogar eine größere Verbesserung erwarten lässt.

Introduction

Chronic tinnitus leads to considerable distress in about 15%-24% of the afflicted individuals [2], [3], [4]. It is now generally acknowledged that psychological processes modulate the negative impact of tinnitus on the individual. Consequently psychologically based treatments have been developed to help the tinnitus sufferer to better cope with the disorder and regain her/his former quality of life. Therapies addressing psychological mechanisms like dysfunctional appraisal, selective attention and avoidance behaviour in their intervention strategies are able to reduce tinnitus induced disability, whereas medical interventions so far are not able to eliminate tinnitus nor do they modify its psychologically harmful consequences [5].

Cognitive-behavioral treatment (CBT) with a directive to improve coping with tinnitus have proved to be efficacious judged by criteria set by evidenced based medicine [6]. Habituation based treatment like Tinnitus Retraining Therapy [7] also focus on the modification of psychological processes by what the authors call "directive counselling". This seems to be the most influential component of the treatment compared to the application of noise generators applied to foster habituation [2], [8], [9]. Habituation based treatment was rarely examined in randomized controlled designs [10], thus its base of evidence is weaker. A recent study by Zachriat & Kröner-Herwig [2] analyzed the efficacy of a cognitive-behavioral tinnitus coping training (TCT) and HT (closely resembling TRT as conceived by Jastreboff & Hazell [7]) in a comparative randomized controlled trial using disability due to tinnitus as the main outcome criterion. It could be shown that both treatments are efficacious with effect sizes in the high range ($0.94 \leq d \leq 1.0$). Stability of improvement was documented as well (for over 18 months).

The current study aims to explore whether patient variables can predict the outcome of these two outpatient treatments with a very similar efficacy and whether they do it differentially. To our knowledge there is only one study that examined patient variables as predictors of therapy outcome in tinnitus treatment. A physiological

variable, i.e. muscle reactivity of head muscles, was predictive of outcome after a psycho-physiological treatment (biofeedback combined with CBT; [11]).

A few prospective studies have examined the course of symptoms after a first consultation in a tinnitus treatment centre and related it to baseline features of the patients. Holgers et al. [12] found depression and physical immobility to be predictors of absence of work as an indicator of a negative course of illness. Erlandson & Hallberg [13] described impaired concentration, depressed mood, negative attitudes, hypersensitivity to sound and an average hearing level to be predictive of quality of life in tinnitus sufferers. Andersson et al. [14] report on a study on tinnitus sufferers consulting a treatment institution for help of which only 59% received cognitive-behavioural treatment. Tinnitus related distress 4.9 years after the clinical contact was predicted by the maskability of tinnitus at first assessment.

The potential predictors considered in this prospective study are patient variables assessed by self-report, some of which have been discussed as potential negative predictors like psychopathological comorbidity or a high level of psychopathological symptoms at baseline [15]. Also a higher level of dysfunctional cognitions could be an obstacle to change in therapy. Especially if we can identify differential predictors first assumptions regarding treatment of first choice for specific patient groups may be deduced.

The following hypotheses will be tested:

1. Mental disorders (DSM-IV diagnoses) at baseline predict a less favourable outcome regarding tinnitus related disability at different assessment points after therapy (post therapy, follow-up).
2. A high level of psychopathological symptoms at baseline (SCL-90R) predicts a less favourable outcome.
3. A high level of dysfunctional cognitions relating to tinnitus (TDCQ, see Method) predicts a less positive outcome.
4. The predicted negative correlations are larger in HT than TCT.

This differential effect is expected because TCT also focuses on cognitive restructuring and on general deficits in stress coping and problem-solving, which

should alleviate the predicted negative impact, whereas HT does not.

Furthermore, sociodemographic, tinnitus related and general well-being related variables will be analysed in an exploratory way regarding their predictive capacity.

Method

Patients seeking help for their tinnitus were recruited by newspaper announcements. Main inclusion criteria for participation in the study were tinnitus for a period of more than 3 months, absence of a treatable somatic disease underlying tinnitus, and a minimum level of tinnitus distress defined by the score of the Tinnitus Questionnaire (≥ 25) (TQ, [1]; for further criteria see Zachriat & Kröner-Herwig [2]).

Patients were randomly assigned to treatment conditions: 1. cognitive-behavioral tinnitus coping training (TCT), 2. habituation based training (HT). It was conceived after Jastreboff [16] but conducted as group training as was TCT (for a more detailed description of treatment see Zachriat & Kröner-Herwig [2]). A third treatment condition consisted of a one-session intervention (education), which will not be considered further.

Differences in the TQ total scores between baseline and post-therapy assessment periods are used as outcome measures. TQ was assessed at baseline (T0), at week 15 (T1) and at week 92 respectively 79 (T2). Week 15 marks the end of the 11-session TCT. Because of the very different time course of HT it coincided with the 4th group session in TRT (one was to follow). The difference in time schedule of the follow-up assessments for TCT and HT was dictated by organisational reasons, but is not assumed to be relevant considering the rather long time period between the beginning of therapy and the follow-up. The change score (T0-T1) serves as the first outcome measure (post) and (T0-T2) as the second (follow-up).

A DSM-IV diagnosis [17] was given on the basis of a structured interview (MiniDips; [18]). Psychopathological symptoms were assessed by the SCL-90R in its German version [19]. Dysfunctional cognitions were measured by the Tinnitus-Dysfunctional-Cognitions Questionnaire (TDCQ, [20]). Tinnitus related variables were either registered by a questionnaire answered before entering the study or by a diary (given for 1 week) before treatment began (Table 1).

Correlational analysis was done by rank correlation (Spearman's Rho) and in case of nominal data by consistency analysis (K). The significance level was set at $\alpha=5\%$.

Results

Of the 83 patients fulfilling the criteria of inclusion, 29 were assigned to TCT and 31 to HT. After assignment 2 patients dropped out of TCT and 1 out of HT (plus one dropout at follow-up). Mean age of patients in the treat-

ment groups was approximately 53 yrs, gender was predominantly male and more than 30% had a higher education (Table 1). Regarding these characteristics no significant differences were found between TCT and HT. Based on the total sample of patients ($n=57/56$) the hypotheses that comorbid psychopathology either defined by the assignment of one or more diagnoses (sensu DSM-IV) or assessed by the symptom questionnaire (SCL 90R) correlates negatively with outcome could not be corroborated (Table 1), neither regarding the post treatment change in TQ nor regarding follow-up. Furthermore we did not find support for a negative association between outcome and dysfunctional cognitions at post treatment. At follow-up a small negative correlation ($r=-0.21$) was found, but did not reach the preset significance level ($\alpha=5\%$). All correlations and hence R^2 were not significant. These findings are corroborated by the results obtained in separate analyses of each treatment group. Against our hypothesis, however, a statistical trend ($\alpha\leq 10\%$) is documented: TCT patients tend to exhibit greater improvement when assigned comorbid diagnoses ($Rho=0.34$). The 4th hypothesis assuming a difference in the size of the predicted negative correlation coefficients between groups finds no empirical support.

Except in two cases no further significant correlations of improvement with the examined variables from the domain of sociodemographic factors, tinnitus related variables and well-being related variables were found. Since the two significant correlations are relatively small ($Rho\ max.=0.30$) they only explain a modest amount of variance in the outcome measure. The correlations indicate that a high level of tinnitus related annoyance and interference with activities, reported at baseline, is predictive of a more favourable outcome. Loudness, though not significant, reveals a similar kind of association to improvement.

These effects found in the total sample at post therapy are mainly determined by TCT participants. Analyzed separately 4 significant or nearly significant correlations with the criterion similar to the ones just described are found here: annoyance by tinnitus ($Rho=0.36$; $\alpha\leq 10\%$), interference with concentration ($Rho=0.43$; $\alpha\leq 5\%$), disturbance in a calm environment ($Rho=0.34$; $\alpha\leq 10\%$). In the group of HT treated patients we do not find any significant association of the examined variables with outcome. Only education tends to positively correlate with treatment success ($Rho=0.33$; $\alpha\leq 10\%$).

At follow-up no substantial correlation is found in the total sample, only a trend towards a significant effect related to education ($Rho=0.25$, $\alpha\leq 10\%$), which becomes significant when HT is analyzed separately ($Rho=0.38$, $\alpha\leq 5\%$).

Table 1: Criteria of outcome, list of potential predictors, descriptive data and correlation coefficients

Criterion: TQ total score	Diff post # 13.35 ± 11.51	Diff f-up# 14.97 ± 12.39	Total sample (n=56/57)	
Variables	Scale description	m/sd; %	Correlation coef.	
Sociodemographic:			post	f-up
age	in years	52.65 ± 11.36	-0.09	-0.14
gender	m/f	m: 63.2%	k=0.59	k=0.55
education	no graduation – university grade (1-5)	3.12 ± 1.34	0.03	0.25(*)
Predictors (hypoth.)				
SCL-90 R	t-scores	57.5 ± 15.71	0.11	-0.01
comorbidity	no. of diagnoses	0.86 ± 1.17	0.14	0.05
dysfunctional cognitions (i**=15)	not true – completely true (0-3)	1.22 ± 0.68	-0.05	-.21(*) one sided
Questionnaire at admission				
duration of tinnitus problem	no. of months	66.86 ± 62.65	0.05	0.13
occurrence of tinnitus	rare – continuous (1-5)	2.74 ± 0.55	-0.03	0.11
annoyance	not at all – extremely (1-100)	58.81 ± 16.74	0.30*	0.01
interference with daily life activities	not at all – extremely (1-100)	46.93 ± 19.61	0.29*	0.14
loudness	very low – extremely (1-100)	57.98 ± 16.92	0.22(*)	0.10
impairment of concentration	rare – always (1-5)	3.12 ± 0.93	0.12	0.12
sleep disturbance	rare – always (1-5)	3.02 ± 1.39	-0.03	0.05
suppression of tinnitus	easy – impossible (1-5)	2.86 ± 0.81	0.25 ^(†)	0.08
hearing problems	yes / no	yes: 42.1% no: 54.4 %	k=0.72	k=0.62
hearing device	yes / no	yes: 8.8% no: 91.2%	k= 0.65	k=0.61
visits to physician	no. of visits	2.37 ± 3.72 (n=48)	0.04	0.11
disturbance in calm environment	not at all – very much (1-5)	2.68 ± 0.87	0.24 ^(†)	0.06
worry/hopeless regarding tinnitus	rare – always (1-5)	2.32 ± 0.89	0.04	0.08
tension/irritation	rare – always (1-5)	2.54 ± 0.91	0.14	0.16
Tinnitus diary data				
time of conscious perception	hrs/per day	10.43 ± 4.7	-0.16	0.04
loudness	not at all – extremely (0-10)	5.02 ± 1.9	0.05	-0.07
disturbed sleep	not at all – extremely	3.27 ± 2.55	-0.01	0.04
annoyance	not at all – extremely (0-10)	3.84 ± 1.98	0.03	0.06
wellbeing	not at all – extremely (0-10)	5 ± 1.67	0.10	0.01
stress	not at all – extremely (0-10)	3.62 ± 2.08	0.22	0.19

(*) p ≤ 0.10

* p ≤ 0.05

** no. of items

difference score: pre-post/pre-follow-up

Discussion

The results of our analysis lend no support to the notion that if chronic disabling tinnitus is accompanied by psychopathological symptoms or even by a diagnosis of a mental disorder a less positive outcome has to be expected from outpatient treatment. Interestingly there is an even contrary trend in patients treated by TCT, they tend to improve more, at least at the post-assessment period (but not at follow-up). In Germany, psychosomatic clinics deliver treatment to tinnitus sufferers if their psychosocial functioning is severely impaired and if they are diagnosed with a mental disorder (e.g. somatoform disorder, anxiety disorder, depression). Out-patient treatment is supposed to be less efficacious under these conditions. Bearing the high general efficacy of the treatment in mind (e.g. [2]), it can be concluded that irrespective of patients' psychopathology, tinnitus focussed counselling and cognitive-behavioural interventions in an outpatient setting work very well regarding the main goal of treatment: the reduction of tinnitus related disability. Patients with a higher psychopathological burden do not seem to run a greater risk for treatment failure. On the basis of our data, however, no conclusions can be drawn regarding the influence of comorbidity on other possible treatment goals (e.g. improvement of general well-being, reduction of psychopathological symptoms). Although the assumption of a negative impact of comorbidity on therapy outcome is often made, also in other areas of psychological therapy, various other studies did not find any influence on the outcome [21], [22], [23]. Data on the general outcome achieved in a psychotherapeutic outpatient treatment centre (including tinnitus treatment) recently presented, even demonstrated a positive correlation between patient improvement and comorbidity, similar to the one found in the TCT patient group (Hiller, personal communication).

However, one possible limitation regarding our interpretation has to be taken into account. The level of psychopathology may have been relatively low in our sample, with 52.6% of the patients having no diagnosis. Goebel [24] reports of 47% of tinnitus patients suffering from anxiety or somatoform disorders and up to 85% from depressive disorders in an inpatient setting. The average number of comorbid diagnoses assigned in our sample (lower than 1) is supportive of the view. The T-score of the SCL-90R, with the mean lying less than one standard deviation above population norms, also underlines this argument. It can be assumed that many tinnitus patients with severe psychological problems do not apply for outpatient therapy within a research context. However, the variance in the predictor variables (SCL-90R: $sd=15.71$; 23.3% of the patients having up to 5 diagnoses) is large enough that even a small trend should have been revealed in the correlation coefficients, if it was existent as hypothesized.

Also our hypothesis that a high level of tinnitus related dysfunctional cognitions should negatively affect treatment outcome was not corroborated, neither in the total

sample nor in the specific treatment groups. The small negative correlation in the follow-up data should not be overrated in the light of the many correlations calculated, but leaves this variable a candidate for further exploration. At the moment we have no reason to assume that beliefs and attitudes of patients regarding the "catastrophic" effects of tinnitus when entering treatment do make the interventions less efficacious, be it TCT or HT.

Some correlation coefficients of our exploratory analysis point to a contrary direction than expected in that they reveal a positive correlation between improvement and the level of subjective distress induced by tinnitus. This was demonstrated in items like <interference with activities of daily life> or <annoyance by tinnitus>. Thus a higher level of disability (at least as reflected in these items) should not lead to therapeutic pessimism but rather encourage a positive expectation when treatment is TCT. Our argument that TCT minimizes the expected negative impact of a high level of disturbance by tinnitus or general psychopathology by directly addressing general problem-solving competencies in patients has to be reformulated. Patients with larger disability at baseline seem to enjoy a special advancement (albeit small). This argument is supported by the finding that TCT treated patients improve markedly in general psychological well-being after therapy when compared to HT treated patients (see [2]).

Most of the examined tinnitus related symptoms or features of the patients when entering therapy do not moderate therapy success or restrict its efficacy. Neither duration of tinnitus nor the level of sleep disturbance, hearing problems or stress level experienced by the patient affects outcome of treatment. Also no significant correlations are found regarding the sociodemographic variables age and gender. Education interestingly has an influence regarding the maintenance of improvement, especially when HT is concerned. This is an unexpected finding, since it could be assumed that directive counselling as the main component of HT is less intellectually challenging as cognitive-behavioural therapy. But this correlation has an only modest clinical implication, since the variance explained is less than 16%.

The negative conclusions from this study therefore are, that we cannot predict short or long-term outcome by patients' characteristics. Thus we cannot select a treatment format, be it TCT or HT, which seems especially apt for a specific group of patients. The positive conclusion is that every patient has a reasonable chance to profit from trainings like TCT or HT which have an overall high efficacy. In the light of these findings it can be assumed that the interaction of patient characteristics, therapy format and features of the therapist influence subsequent outcome of treatment, rather than one single factor. A focus on the patient obviously does not promise much progress in the tailoring of an optimal treatment format. This conclusion is supported by general process research in psychotherapy proposed by Clarkin & Levy [25] who state *"Most reviews of client variables in relationship to the psychotherapy process and outcome are pessimistic*

because of the inconsistent and less than clear relationships described...". Lambert and Ogles [26] report, that a delayed improvement in symptoms in the very early period of psychotherapy is indicative of treatment failure regarding the individual patient. If this is fed back to the therapist as a "warning signal" it can be utilized by therapists to reduce failure rates. Further research in outpatient treatment of tinnitus should focus on processes in the early phase of therapy which might signal potential treatment failure and enable the therapist to counteract.

Notes

Conflicts of interest: none declared

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