

HTA-Report | Summary

Therapy of unspecific tinnitus without organic cause

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Introduction

Ear noises (tinnitus) without a recognizable organic cause are a frequent symptom. It can lead to considerable impairments of the quality of life for the patients. A considerable need of the persons affected for an adequate and effective medical treatment arises from that. Until now neither causes of the symptomatic are cleared satisfactorily nor a standard therapy has been able is established for tinnitus.

There is a variety of medical and non-medical therapies in practice, which were not evaluated regarding its effectiveness by any systematic evidence oriented investigation.

The methodology of diagnosis and classification which should represent the base for a therapy is also just as unclear as the management of the tinnitus. There are used diagnosis and classification standards which should be checked. A multitude is done at clinical experiments to check emergence theories of tinnitus and derive therapies. The successes of these therapies as well as their patient safety vary widely.

The information that nothing can be done for these patients and these can at best adapt themselves to a life with tinnitus leads in the practice that various procedures which are far away from scientific thinking are used in practice.

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Question

The HTA report shall particularly treat the following questions:

- Which quality do the diagnostic methods to the recognition of tinnitus have?
- Which types of therapy show medical effectiveness at the acute or chronic tinnitus without an organic cause?
- Are psychological therapies effective with tinnitus without an organic cause?
- Which alternative methods of treatment show medical effectiveness?
- Which health economic effects have these therapeutic procedures?
- Are there ethical implications which must be discussed with these therapies?
- What is the legal basis of the treatment of tinnitus without an organic cause based?
- Which consequences (research need, future procedures) can be drawn?

Within the scope of the



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Medical assessment Methodology

According to the specifications of the evidence based medicine and specifications of DIMDI in all relevant medical literature databases, the relevant literature was retrieved, judged with regard to its methodical quality and included in the report. Qualitative synthesis procedures were used as method. All publications were excluded which is concerned at organically conditional tinnitus or were dedicated to primarily other hearing disorders like hearing losses etc.. Studies without controls as well as publications with methodologies these did not use statistical evaluations and clinical experiments were excluded for the most part unless the therapy should be mentioned as regards content because of their potential effectiveness.

Results

The analysis of publications of models for tinnitus shows that there is a variety of hypotheses and explanation models. The classifications are orientated on the one hand to the location of the tinnitus emergence (central peripheral) or to the type (acute, sub acute, chronic) and the degree of severity (compensatedly, decompensatedly). The classification systems have the purpose, the find a plausible course and to derive a suitable therapy. These systems developed by different authors become placed side by side in the literature without having ever been checked for consistence or agreement.

The diagnostic methods for the clarification of the non-specific tinnitus without an organic cause meet with the problem that this tinnitus cannot be measured objectively (it cannot be recognized by the physician). It remains the description of the symptomatic by the patients suffering. According to the current opinion the stepwise diagnostics is carried out also in the case of the subjective Tinnitus and enfolded a specific anamnesis together with otological and audio logical diagnostics, neurootological diagnostics as well as general and special medical audio logical procedures and imaging procedures. The diagnostic questionnaires which permit a subjective assessment of the heaviness and the annoyance degree of the tinnitus are used. Goebel and Hiller (2000) compared the construction features of eight different tinnitus scales. This one frequently used tinnitus questionnaire (TF) appeared at the best tested method.

The number of the therapies which treat tinnitus is exceptionally high and makes clear, that the search for "the" tinnitus therapy is still going on. The current knowledge for tinnitus shows that it is a multifactorial event and therefore there is not any standard therapy for tinnitus but an adopted therapy along the suspected cause.

Seven categories of the 69 therapy approaches given in the overview of Biesinger (1998):

1. Machine-aided acoustic therapies
2. Electrostimulation
3. Psychological therapy procedures
4. Tinnitus Retraining Therapy (TRT)
5. Pharmacological therapies
6. Surgical procedures
7. Other and alternative therapy procedures

The following results concerning medical effectiveness of the procedures could be gathered from the literature.

Ad 1: Machine-aided acoustic therapies

From the different studies to machine-aided acoustic therapy of tinnitus only two showed an evidence degree that allows scientifically correct statements about the effectiveness of these procedures.

A comparison of one complete with a partial suppression of the tinnitus using maskers the partial suppression was more successful, what the authors explain by the combination with the Tinnitus Retraining Therapy (TRT). The supply with a Tinnitus masker proved superior in another study in comparison with an apparatus switched off (placebo).

Ad 2: Electrostimulation

In an observation study of electro-stimulation the results were not evaluated statistically, it was described that a successful medical treatment can be expected in about 50 % of the cases. Later, obviously the same authors published a study the same patient collective (under exclusion of organic illnesses). A complete tinnitus reduction was seen in 7 % of the cases, an improvement in 53 % of the cases.

Ad 3: Psychological therapy procedures

Regarding hypnosis the results cannot be considered conclusive.

Biofeedback can be an effective method in individual cases; but for repeatability it is unreliable. A study to treatment with Neurobiofeedback cover that the steering of attention on the brain current activities away from the tinnitus had a positive therapeutic effect. The effect consists primarily that the patients get the feeling of self-control, away from the paralyzing faint feeling. From eight controlled studies to relaxation techniques and cognitive behaviour therapy four studies showed a therapy success (effectiveness) and four could not prove effectiveness. Composite therapies proved generally to be more effective than individual types.

The behaviour medical psychotherapy could demonstrate a positive therapy effect. However exclusively psychological questionnaires were consulted for the evaluation of the results (subjective view). The assessed tinnitus loudness, the acceptability of the tinnitus and the ability, tinnitus and the related stress reduced significantly. The medical treatment consisted of a complex psychotherapeutic medical treatment (counselling, relaxation techniques and cognitive techniques). The author sees the indication given for such a medical treatment only in 1 % to 8 %, namely at patients after acute hearing loss which a psychic event preceded.

In an experiment with a cognitive therapy and relaxation short-term successes could be stated (for one month), the values returned on the initial value after four months. Also only coincidental and short-term successes could be achieved with cognitive behaviour therapy training, autogenic training and structured group psychotherapy.

Ad 4: Tinnitus Retraining Therapy (TRT)

The results of the TRT, published until now, are methodically frequently bad and scientific of a little value. This also holds for studies from of USA and Great Britain, where particularly therapy improvements are only accepted in the extreme levels; gradual improvements are frequently included very inaccurately.

Many studies presented until now regarding Tinnitus Retraining Therapy are not informative in their scientific sense.

In a study with 95 patients with a chronic tinnitus TRT could show a significant, more than six months lasting stable success by comparison to a combination of TET with group behaviour therapy (improvement be achieved around at least ten points in the tinnitus questionnaire (TF)).

Ad 5: Pharmacological therapies

Pharmacological therapies often show incompatibilities with the substances or its side effects. Numerous studies to pharmacological methods show a high drop out rate.

Rheological drugs (medicines for hemodilution) could not show any statistically confirmed effect in the treatment of tinnitus. Some experiments with medicine combinations were made methodically meanly and did not show any significant results.

Studies to medical treatment with tocinides (lidocaine) showed repeatable positive effects on tinnitus in higher dosages (as of 1.2 mg / day). Aggravations were also watched sporadic. It is warned before the use of this medicine since it is used for the treatment of life-threatening cardiogenic dysrhythmia and therefore should not be given for other disorders.

From a study with Lamotrigine as a medicine, carried out methodically immaculate, the therapy had a positive effect only for a small amount of patients. The treatment success with Lamotrigine cannot be predicted since according to statement of the authors no criterion for a treatment success could be found.

Two studies with GABA receptor agonists could not achieve therapeutic effects at tinnitus. Undesired side-effects were observed. Injections with Caroverine (a glutamate antagonist) achieved significant successes for a special form of the tinnitus, the "Cochlear-Synaptic Tinnitus (CST)".

A tricyclic antidepressant (Amitriptiline) could prove superiority opposite placebo. This effect could be confirmed in another study. However Clonazepam (a benzodiazepine), could not reach any improvement. Short constant improvements were reached at other Benzodiazepins (Clonazepam, Diazepam, Flurazepam, Oxacepam and Alprazolam). If the medicine was cancelled the tinnitus reappeared.

The neurohormone melatonin showed inconsistent results, for the authors difficult to be explained. The study was made immaculate, however improvements could shown only in subjective questionnaires, could not be achieved in audiometric measures.

A German retrospective study suggests a graded pharmacological therapy by means of rheological infusion therapy, applications of neurotransmitters, and injections of lidocaine. This method achieved a disappearance or a recovery of the complaints at 95.3 % of the acute and 26.7 % of the chronic cases.

Ad 6: Surgical procedures

The effects of the operative excision of the stapes (stapedectomy) showed significant effects concerning tinnitus. This method is a routine operation to recover hearing, effects on tinnitus were observed only coincidentally. In 73 % of the cases the tinnitus disappeared completely, in 17 % an improvement occurred and 10 % did not show any change. Two persons suffered from an aggravation. Another study could confirm these results.

Regarding the medical treatment of hearing losses with cochlea implantations five studies of a review could be classified as the criterions according to high quality. The authors classify the danger of a reinforcement of the tinnitus as low.

According to another study with cochlea implantations an improvement could be reached with nine of 22 patients. Three patients, who did not suffer from tinnitus before the operation, got tinnitus afterwards. There are generally high chances for improvements of tinnitus after cochlea implantations; however the risk of deterioration is also given with this method.

Ad 7: Other and alternative therapy procedures

The hyperbaric oxygen therapy assumes that tinnitus is caused by a lack of oxygen. After acute events with tinnitus consequence the hyperbaric oxygen

therapy can be considered successful. The therapy should be started in the first month after appearance of tinnitus.

The methods of transcranial, electromagnetic and transcutaneous nerve stimulations did not show any significant effects on tinnitus. Also the effect of low laser treatment where disappointing. A combination from low laser application and ginkgo preparation showed both improvements and aggravations. Although the “pneumatic external contra-pulsation” is described as an unproblematic usable procedure and as a hopeful and practicable therapeutic agent by the authors, although 10 % of the patients had to be withdrawn because of complications associated with the treatment. There was no placebo group. This method should be investigated by an ethical check in the light of the authors of the presenting HTA report.

The acupuncture treatment showed significant improvements in a study in comparison with a control group. The complete improvement rate was 51.4 %. In another study the effectiveness of this therapy could not be confirmed. Another five studies between 1993 and 1999 could not demonstrate any therapeutic effect of acupuncture on tinnitus.

Ginko-Biloba preparations did not show any positive effects in large-scale studies on tinnitus. Several positive side-effects could be recorded (general well-being, increased desire for sex, reduction of headache and malaise etc.). In another study Ginkgo-Biloba showed a higher effect compared with placebo.

A homeopathic medical treatment experiment with the D 60 thinning of a tinnitogenic substance did not show any significant differences compared with a placebo group. The authors explained that with the difficulty to measure tinnitus adequately.

Discussion

Within the last decades thousands of articles were published concerning directly or indirectly with the phenomenon tinnitus. Despite decades of research the therapies seem to be at the beginning. Numerous models for explaining tinnitus exist and led to a variety of therapeutic approaches. The diagnostic methods of Tinnitus are carried out according to a established procedure. Concerning the quality of these procedures no statement can be made since the current literature is missing. A study could be found about the tinnitus questionnaires, which shows the tinnitus questionnaires (TF) as the instrument of the best quality.

Normally neither the diagnostic procedures nor the therapeutic method classes or the individual therapies reach scientifically usual levels in medicine. Psychological therapy procedures reached sporadic significant successes which can't be hold over time. At the alternative methods of treatment no single one could prove medical effectiveness.

Unsolved consequences for insurance, economics as well as legal problems have resulted for the patients and give an unsatisfactory situation.

Numerous competitive tinnitus models lead to an unbelievable creativity in trying out different therapy approaches. No convergence of the therapy procedures can be seen within the last decades of the tinnitus research, contrariwise always more and more creativity for new approaches. On the other hand there is almost no therapy approaches witch has been developed definitely. These have apparently led to a search for further models of tinnitus which lead to further therapeutic approaches. No single method has such an approach that measured with conventional assessment scales (randomized clinical studies, independent confirmation examinations with a corresponding case number, superiority opposite placebo etc.) that it can be considered as

a promising form of therapy. All types of therapy are therefore unsuitably to be regarded as therapy of the choice.

Economic assessment Methodology

For the economic assessments of non-specific tinnitus costs two studies were available, these two studies are generally speaking, don't show the principle of the representativeness and don't permit any conclusion on economics of therapy, nor direct, indirect or intangible costs.

Results

Rosanowski et al. (2001) refer about social insurance legal aspects of the tinnitus treatment in a general intended article. The Tinnitus Retraining Therapy (TRT) is explained that the TRT consists of recognized methods of treatment – each one - be able to be covered with the social health insurance. With the TRT a putatively new therapy is implemented now, which has to prove its value. It is referred that this therapy is nothing new.

Medicine costs for patients with chronically complex Tinnitus

In a retrospective study pharmaceuticals were examined with patients with a chronic tinnitus, to investigate the costs.

The application of the pharmaceuticals which shall lead to an improvement in the blood flow or an optimization of the metabolism and were ordered consciously for the treatment of tinnitus was exclusively investigated. This was medicines with the following trade names: Aequamene, Dusodril, Natil, Pentoxe, Ribraine, Rökane, Tebonine, Trental, Vasomotal as well as vertigo Heel.

The total costs amounted to DM 354706, (€ 181358) - this is DM 836.60 (€ 428) per head.

Considerable costs arise only with the chronically complex tinnitus for the cardiovascular substances.

These numbers based only for oral vascular medications costs of more than € 51129188.10 only for these patients. The values are probably much higher nowadays.

Discussion

Methods which are covered by the social insurance are used at the tinnitus therapy frequently. The problem arises now that the refunds of the social insurance are applied to a disorder for which this therapy is normally not checked or no evidence of effectiveness exists. The entitlement has consequently to be analysed firstly. On the other hand the patient covered social insurance legally has claim to an adequate medical treatment according to the § 135 ff SGB V. This leads to an area of conflict since only procedures may be brought to this legislation whose effectiveness was checked adequately.

The role of the claiming of benefits on therapy procedures which deal with the side effects is also unclear. This field also seems particularly problematic, if single therapy methods established for other areas are used combined and this combination is reported to the social insurance as adequate tinnitus therapy, describing analogously from Rosanowski et al. (2001).

Ethical assessment Methodology

Ethical problems in combination with therapy for non-specific chronically tinnitus wasn't investigated separately. All articles in combination with tinnitus diagnostics and therapy were checked regarding the existence of usable ethical interests. No publications which explicitly dealt with ethical problems were found. One article with ethical contents in the broadest sense was found, it is described in the results.

Results

Various therapeutic experiments regarding treatment of non-specific tinnitus without an organic cause experiments reach ethically problematic limits are described. This is primarily the case if treatments have considerable side effects. The information that nothing can be done for these patients and they had to adapt to a life with tinnitus leads to usage on various procedures which are outside science since the symptom reduction is in the main goal for these patients.

It requires an ethical analysis of some tinnitus therapies, primarily with heavy, chronic types of tinnitus which primarily show a considerable psychic comorbidity with depressions and/or anxiety disturbances. Medical types of treatment are important for acute tinnitus, the reduction of the ear noises on weekdays and dealing with the treatment objectives in case of chronic tinnitus.

In more severe cases patients with comorbidities like depressions and anxiety disturbances, mostly the principles of retraining therapy are not sufficient, psychological treatments begin here.

Possibilities for the cooperation were offered in the ambulatory area with psychologists and psychotherapists so that patients not are "sent away" by the ear-nose-throat (E-N-T) physician to the psychological diagnostics and therapy.

It had to be warned of therapeutic experiments with medicines which are used for other serious illnesses, like epilepsy or cardiac dysrhythmia since their side effects can be assessed difficultly. That also applies for drugs which affect the neurotransmitters. A clinical therapy attempt is the pneumatic counter-pulsation, in this experiment shall be increased the inner ear circulation by a reversed pulse wave. This may influence the circulation and had to be considered carefully.

Discussion

Tinnitus patients are in an area of conflict with their symptom, the medical and non medical treatment options and the necessity to trust a physician. After a medical clarification the physicians prescribed frequently blood flow drugs firstly, when these don't work, the patients received a statement often that they must live with the symptom since there is no effective therapy available. The level of suffering of the patients frequently is the reason that they find alternative types of treatment which are often not evaluated whether they work.

Independently of the described unsatisfactory therapy options, experimental methods are used, showing behind an adopted effectiveness's often negative side effects, e.g. this has happened at the pneumatic contra-pulsation. About 10% of the tinnitus patients had to break off the medical treatment because of therapy associated complaints at this method. A number of medicines are found at the pharmacological methods, which have an effect on the neuro-

transmitter system and therefore arouse a number of side effects like are nausea, dizziness and stomach intestine disturbances, as the most frequent ones. Medicines which are used for severity clinical disturbances like epilepsy, psychoses and cardiac dysrhythmia also would be used to treat tinnitus. It seems unclear, whether the used experimental methods had a medically comprehensible basis and are component of the considerations of ethics commissions.

All types of treatment point to an ethical problem which was not discussed in the literature. The expected lack of success of numerous therapy approaches coupled with the often strong level of suffering of the patients will induce attending physicians to venturing forward on medical scientifically unsecured land, in the hope to help the patients.

The following questions would have to be discussed primarily:

- Does the patient know the lack of success of the method applied?
- What is promised to the patient? Alleviation, healing which is based on in general unsecured evidence?
- Are established therapy procedures used which apply to related illnesses?
- How is the lacking validity of prognosis dealt with?
- Which legal questions come up concerning incident side effects?

The role of ethics commissions has to be rendered more precisely about the creativity of new therapy approaches in the coming years. It seems unreasonable that no restriction of the inventiveness is imposed on single attending physician on the search for adequate methods. A stronger networking of institutions or attending physicians for tinnitus seems adequate to be able to carry out studies with better quality or higher case numbers.

Furthermore is in the case of the establishment of competence centres or similar the attempt made to bring more methodical quality into the studies and to start with a standardization of the diagnostics or success parameters for therapies. Research results could be compared in a broader consequence.

Legal considerations

Methodology

No separate literature research was carried out to the legal interests since a comprehensive primary selection of the literature was carried out. An article which outlines the social insurance legal aspects could essentially be found. Furthermore the guideline topic also is mentioned since they are basically an instrument to achieve scientific levels.

Results

Guidelines regarding tinnitus

Guideline of the German society for ears-nose-throat (ENT), head-neck surgery, tinnitus (AWMF guideline register no. 017/06437)
The guidelines of the "German society for ears-nose-thread, head-neck surgery (DG ENT KHC) contain a classification and indicate the useful diagnostic and therapeutic corridor within the attending physician can carry out an individual care to its patients. Deviations require documented reasons. In principle, the guidelines are evidence-based though their single segments in a different extent (www.tinnitusportal.de). In addition to this guideline an algorithm already passed "ear noises" of the German Society for Otolaryngology, head and neck surgery. This algorithm was taken into account in this guideline.

Guidelines of the TCC-Disease management program: A Disease management program (DMP) of the tinnitus (the tinnitus Care-Concept, TCC) is used in Germany since 2000. The guidelines are according with national guidelines, though the corridor is narrower: The requirements of the TCC guidelines on the evidence for medical care are higher, the choice of the possible medical care procedures is thus smaller. Furthermore the supply is presented in particular and is available in the internet within a frame of the DMP (www.tinnitusportal.de).

Social insurance legal aspects

Methods which are contained in the catalogue of benefits of the social insurance as refundable are used at the tinnitus therapy often. The problem arises now that refundable achievements are applied to a disturbance for which this therapy normally is not checked or does not show any evidence. The benefit entitlement has consequently to be analysed at first. On the other hand the patient covered social insurance legally has claim to an adequate medical treatment according to the § 135ff SGB V. This leads to an automatic area of conflict since by this legislation only procedures may be used whose evidence was checked adequately.

The role of the claiming of benefits on therapy procedures which deal with the entered side effects is also unclear. The area also seems particularly problematic, if single therapy methods established for other areas are used combined and this Combination is reported to the social insurance as adequate tinnitus therapy, describing analogously at Rosanowski et al. (2001).

Discussion

In the literature no sources which explain therapy with the legal situation of tinnitus were found. Some seem questions arise which are possibly regarded as urgent. Among other things it is all about the following questions:

- Are the tinnitus therapies in such a "recognized state" to be able to be offered by selected attending physicians?
- Is the patient protected sufficient legally for such a therapeutic type?
- Is there a consequent strict line in the filed of the private health insurance?
- Who is liable for possible resultant damages?
- Where is the limit of the medical estimation in an area where there is a lack of administrative regulations?
- How directive is the algorithm "hearing noises" legally?
- Does the attending physician owe only the treatment or a particular success?

Summarizing discussion of all results

Within the last decades thousands articles deal directly or indirectly with the phenomenon tinnitus. Despite decades of research the therapies seem to stand at the beginning. Numerous explanation models provide explanations for the appearance of symptoms on a hypothetical character. The different explanation models lead to a variety of therapy approaches.

Numerous competitive tinnitus models led to an unbelievable creativity in trying out different therapy approaches. Experiments carried out in the 70-ties and 80-ties did not show clear studies design. The uncontrolled growth of therapy approaches can be seen as a fact of the field between scientific uncertainty about the pathogenesis of tinnitus and treatment desires of the patients.

Neither the diagnostic procedures nor the therapeutic method classes or the individual therapies reach usual scientific levels according to the evidence based medicine. The diagnostic procedure evaluated best is the tinnitus questionnaire (TF) which based on a subjective self-assessment of characteristics of tinnitus.

The psychological therapy procedures also could reach only occasionally significant results which were not constant over time. A combination of Tinnitus Retraining Therapy with a group therapy seemed to be best.

At the alternative methods of treatment no method could assure medical effectiveness.

From this for patients and the attending physicians most unsatisfactory situations arise unsolved problems at national- insurance legal, economic as well as law - at least gather from the literature.

There is on the one hand partly a very high level of suffering for the patients at the tinnitus which draws intuitively comprehensible claim to curative treatment on the other hand the therapies generally are not enough assured, that an improvement in the symptomatic can be expected.

Methods which are covered by the social insurance as refundable are used at the tinnitus therapy often. The problem arises now that refundable achievements are applied to a disturbance for which this therapy normally not checked or don't show any evidence. The benefit entitlement has consequently to be analysed at first. On the other hand the patient covered social insurance legally has claim to an adequate medical treatment according to the § 135ff SGB V. This leads to an automatic area of conflict since following this legislation being allowed to be used only methods which's evidence was checked adequately.

The role of the claiming of benefits on therapy procedures which deal with the entered side effects is also unclear. The area also seems particularly problematic, if single therapy methods established for other areas are used combined and this Combination is reported to the social insurance as adequate tinnitus therapy, describing analogously at Rosanowski et al. (2001). Some seem questions arise which are possibly regarded as urgent. Among other things it is all about the following questions:

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- Who is liable for possible resultant damages?
- Where is the limit of the medical estimation in an area where there is a lack of administrative regulations?
- How directive is the algorithm "hearing noises" legally?
- Does the attending physician owe only the treatment or a particular success?

Conclusion

The numerous therapeutic approaches, seeming completely incoherent to their effects should be coordinated concerning meaningfulness, on the success parameters and with patient safety in light of the most plausible explanation models for non-specific chronic tinnitus. Further facilities of competence centres or related science- directing facilities are recommendable. The variety of therapeutic approaches is at a time of fact finding basically desirable. However it must be stated, that also experimental methods interfere in the canon of the used methods with severe side effects. Ethic commissions should insist on success parameters and the medical therapeuti-

cally plausibility with published explanation models of the Tinnitus survey or demand.

Examinations which are carried out also at small case numbers show often methodical insufficiencies. It has to be demanded also here that the minimal requirements on a scientifically clinical experiment, such as design, case number calculation, analytic statistics, control group, are at least be fulfilled.

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