Hearing Aid Fitting in Tinnitus: A Scoping Review of Methodological Aspects and Effect on Tinnitus Distress and Perception

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Abstract: Current evidence on efficacy of hearing aids (HAs) on tinnitus perception and annoyance is considered insufficient due to the heterogeneity of tinnitus characteristics and of methods used in the relevant clinical studies. This is a scoping review focused on the methodological aspects of clinical studies evaluating the value of HA fitting as part of tinnitus management over the past 10 years. Thirty-four studies were included in the review, showing important heterogeneity in almost all aspects of inclusion criteria, comparators, outcome measures, follow-up time and HA fitting procedures. Although all studies show that HA fitting has a positive impact on tinnitus perception in patients with hearing loss, the methodological heterogeneity does not allow robust conclusions. Future studies taking into account the different nature and goals of each tinnitus therapeutic modality and adapting their methods, endpoints and timelines according to them could lay the groundwork for obtaining high-quality evidence on whether and how HA fitting shall be implemented in tinnitus management strategies.

Keywords: tinnitus; hearing aid fitting; tinnitus perception

1. Introduction

Tinnitus is traditionally defined as the perception of a sound in the absence of external stimuli; however, this definition has recently been updated in order to include patient’s reaction and related annoyance as a determining factor [1]. Universally effective and accepted tinnitus treatment is currently pending, although a long list of substances and interventions, including but not limited to medicinal agents, sound treatment (ST), Transcranial Magnetic Stimulation (TMS), acupuncture and hearing amplification, has been tested for their efficacy in multiple studies [2].

Hearing loss and tinnitus are highly correlated, since it is estimated that up to 90% of patients experiencing tinnitus suffer from various degrees of hearing loss as well [3]. However, degree of hearing loss is not established as a prognostic factor for tinnitus existence and annoyance [4,5]. On top of this, approximately 10% of individuals with tinnitus have normal thresholds in Pure Tone Audiometry (PTA) [6]. This fact has triggered a wide interest in the literature with regards to cochlear synaptopathy which corresponds to a possible pathophysiological feature causing loss of the low spontaneous rate (low-SR) synapses without elevation of the PTA thresholds, as initially proposed by Schaette et al. (2011). Nevertheless, this concept has been recently questioned [7–9].

According to recent European guidelines, there is a weak recommendation for the hearing aids (HAs) in tinnitus treatment [1]. It is also stated that tinnitus presence should be taken into account during the hearing aid fitting procedure. However, supporting literature...
has been characterized as inadequate to draw certain conclusions, due to lack of relevant high-quality studies [1]. Hence, it should be highlighted that, although Randomized Clinical Trials (RCTs) are being considered as the best source of high-quality data, this study design is probably not applicable in the context of hearing aid fitting, since participants of control groups would immediately understand that they are provided with some kind of sham device. HAs mainly target hearing loss, their main effect cannot thus remain unnoticed. This is an intrinsic drawback that is very difficult to overcome [10]. Apart from these study design aspects, the primary and secondary endpoints that are chosen to assess the success or not of the intervention (hearing aid fitting) should be evaluated, since they may interfere with the quality of the results [11]. In the case of hearing aid fitting, commonly used outcome measures cannot reliably reflect the elimination of tinnitus that happens in a robust subgroup of patients.

A review and critical appraisal of published evidence on methodological aspects and results of clinical studies focusing on the effect of HA fitting on tinnitus perception could provide valuable insight for future studies and clinical practice.

2. Materials and Methods

This paper is a scoping review of the literature, aiming at pointing out the effect of hearing aid fitting on tinnitus perception and the methodological aspects of the relevant clinical studies. It is following the PRISMA Extension for Scoping Reviews (PRISMA-ScR) guidelines [12].

The main goals of this paper were to identify studies that describe hearing aid fitting in the case of people with tinnitus and evaluate their methodology as well as the effect of hearing aid fitting in tinnitus perception and related handicap, distress, annoyance and loudness.

Review questions were set as following: What are the methodological aspects of studies evaluating the effect of HAs fitting on tinnitus perception? Is there an effect of the various HA fitting devices and methods on the perception of tinnitus characteristics in adults with hearing loss? More specifically, the question was formulated according to the PICO template as following:

People: adults with tinnitus (bothersome or not) and hearing thresholds requiring amplification or not.

Intervention: hearing aid fitting, (no limitation on particular methodology, fitting technique).

Comparator: not applicable.

Outcomes: methodological aspects such as range of included hearing loss or outcome measures used and effect of HA fitting on tinnitus handicap, distress, annoyance and loudness as reported in questionnaires and scales used as outcome measures before and after hearing aid fitting.

2.1. Eligibility Criteria

Studies were selected according to the following criteria:

Study Samples: Target population consists of adults with tinnitus, with hearing thresholds requiring amplification or not. Particulars: There was no restriction in tinnitus type. Studies that had a primary goal other than evaluating tinnitus were not excluded, as long as the results of hearing aid fitting on tinnitus perception were reported. There was no restriction in types of hearing loss. Sudden hearing loss, age-related hearing loss, trauma, hereditary hearing loss, otosclerosis etc, were all included to the review.

Intervention: hearing aid fitting, (no limitation on particular methodology, fitting technique, laterality, manufacturer or equipment).

Clinical experimental studies, case reports, case series, observational studies (longitudinal and cross-sectional), methodological papers, randomized clinical trials were included. Studies conducted during the past 10 years have been chosen for inclusion; studies conducted with focus on hearing aid technology older than that has been consid-
ered as out of the scope of this review. On-going studies, pediatric population studies, cochlear implantation and Tinnitus Retraining Therapy (TRT)-related studies, reviews and meta-analyses, experts’ opinions and letters to the editor were all excluded. Articles in a language other than English were also considered non-eligible for this review.

2.2. Information Sources

Four major databases (Medline, Central, Web of Science, ClinicalTrials.gov (accessed on 19 May 2021) and Scopus) have been searched for eligible studies by two reviewers independently. The results were then hand-searched [13].

2.3. Search

Typically, literature search includes three sets of terms: terms concerning the health condition of interest (in our case, tinnitus), terms describing the intervention/exposure (Hearing aid fitting) and terms for the type of eligible studies (not applicable in our case since we have no particular limitation in study type) [14]. In this context, the search syntax for this scoping review for Medline was:

(amplification OR “hearing aid” OR (“hearing aids”[MeSH]) OR “hearing aid fitting”) AND (tinnitus OR tinnitus[MeSH])

The rest of the databases have been searched in a similar manner, using the same keywords. Filters of “10 years” and “English” language have been applied in all databases. Filters excluding non-clinical studies and pediatric studies have been applied whenever available. The whole search procedure and results have been evaluated by means of PRESS Evidence-Based Checklist [15].

2.4. Selection of Sources of Evidence

Studies obtained from the aforementioned search were reviewed independently by two authors. In that stage of analysis, the authors identified duplicates or multiple reports of the same study. Then, they screened the relevance of yielded studies to the set research questions by first examining the titles and abstracts of the yielded studies and then their full text. No disagreements between the two authors occurred at this stage.

2.5. Data Charting Process

Two reviewers screened full-text articles and produced a matrix of relevant data independently [16]. Ambiguities on data charting have been discussed and resolved by the senior authors.

2.6. Data Items

Extracted data items concerning methodological aspects and results of the included tinnitus studies:

- Main author, year of publication
- Sample size
- Whether specific age range was stated as inclusion criterion (Yes/No) and if yes, the actual range
- Whether tinnitus was identified as primary complaint of the participants in the inclusion criteria (Yes/No)
- Range of hearing loss as inclusion criterion (Yes/No)
- Research hypothesis
- Software used for HA fitting
- Whether it was stated that counseling on hearing aid and specific counseling on tinnitus was provided
- Fitting procedure on hearing aid fitting
- Fitting formula
- Number of visits needed for the HA fitting
- Use of masking sound or not
• Treatment of the control arm if existent
• Number of follow-up visits targeting evaluation of the intervention and their time course
• Outcome measures used and whether there was a defined primary outcome measure
• Evidence of improvement (according to corresponding outcome measure)

2.7. Synthesis of Results and Critical Appraisal of Individual Resources of Evidence

Results of this scoping review are presented in the form of comprehensive tables. Detailed qualitative analysis and critical appraisal of included studies can be found in the Discussion section.

3. Results

3.1. Selection of Sources of Evidence

Thirty-four studies were included in this scoping review. The process of their selection is provided in detail in Figure 1.

Figure 1. Study selection PRISMA flow diagram.

3.2. Characteristics of Sources of Evidence and Synthesis of Results

Characteristics of each study, such as authors’ names or year of publication, along with extracted data with regards to the methods used, are presented in Tables 1–3. Inclusion criteria (hearing loss range, tinnitus duration, tinnitus as primary complaint) and types of participants’ groups are presented in Table 1. Fitting methods and whether tinnitus-specific counseling has been provided can be found in Table 2, while results of each study with regards to their effect on tinnitus perception in Table 3. A comprehensive list of the methodological limitations of the clinical studies included in this scoping review may be found in Table 4.
| ID          | Study Design                        | Participants No | Age        | Hearing Loss (HL) Range                                      | Tinnitus Duration | Tinnitus Being Primary Complaint | Groups                                           |
|-------------|-------------------------------------|-----------------|------------|-------------------------------------------------------------|-------------------|----------------------------------|--------------------------------------------------|
| Acar, 2014  | Case Series                         | 24              | >65 years  | Sufficient HL to warrant the use of Hearing Aids (HAs)      | Not determined    | Yes                              | HA fitting                                      |
| Araujo, 2016| Case Series                         | 24              | 60–70 years| 41–60 dB HL at 500, 1000, 2000, and 4000 Hz                 | 4–30 years        | No                               | HA fitting Tinnitus Group vs. HA fitting without Tinnitus Group |
| Berberian, 2016 | Case Series               | 25              | No         | Mild to moderately severe HL                                | Not determined    | No                               | HL and bilateral tinnitus                       |
| Cabral, 2016 | Case Series                         | 17              | No         | Mild to severe sensorineural HL (SNHL) or mixed HL          | Not determined    | Yes                              | HA fitting                                      |
| Cribari, 2016 | Descriptive cross-sectional study   | 53              | >60 years  | SNHL or mixed HL, moderate, moderately severe, severe       | Not determined    | No                               | HA fitting                                      |
| dos Santos, 2014 | Randomized Control Trial (RCT)     | 49              | No         | Mild to moderate bilateral symmetrical SNHL                 | >6 months         | No                               | Combined fitting group vs. amplification alone group |
| Forti, 2010  | Case control study                  | 100             | No         | Ski slope or mild conductive HL                             | >6 months         | No                               | Open ear canal HAs vs. classical HAs            |
| Haab, 2019   | Case control study                  | 34              | No         | Mild to moderate hearing loss                               | >6 months         | No                               | spectrally notched HAs group-unmodified HAs of the same type group |
| Henry, 2015  | Case control study                  | 30              | >18 years  | Symmetrical [difference between left and right ear (0.5, 1, 2, 4 kHz) pure-tone averages ≤ 15 dB HL] SNHL within the mild to moderately severe range (four-frequency pure-tone average 25–70 dB HL) | Not determined    | No                               | HAs plus-noise (experimental) group-HAs only (control) group |
| Henry, 2017  | RCT                                 | 55              | No         | PTA average (0.5, 1, 2, and 4 kHz) 35–40 dB (mild to moderately severe hearing loss) | Not determined    | No                               | HAs vs. HAs + Sound Generator                  |
Table 1. Cont.

| ID     | Study Design                              | Participants No | Age       | Hearing Loss (HL) Range                          | Tinnitus Duration | Tinnitus Being Primary Complaint | Groups                                                                 |
|--------|-------------------------------------------|-----------------|-----------|------------------------------------------------|-------------------|----------------------------------|------------------------------------------------------------------------|
| Hodgson, 2017 [27] | Single-blind crossover clinical trial        | 16              | No        | High-frequency audible SNHL                      | >6 months         | No                               | RITE HAs with frequency compression group vs. RITE HAs without frequency compression |
| Jalilvand, 2015 [28] | Case control study                        | 974             | No        | Unilateral or bilateral HL                       | Not determined    | No                               | HAs vs. Noise Generator vs. both                                       |
| McNeil, 2012 [29] | Retrospective case series study            | 70              | No        | from mild to severe (no further explanation)    | Not determined    | Yes                              | Group of patients with HL and tinnitus                                |
| Newman, 2012 [30] | Retrospective between-subject clinical study | 56              | No        | Hearing levels not requiring amplification       | Not determined    | No                               | Neuromonics Tinnitus Treatment group-SG group                          |
| Ogut, 2012 [31]   | Case Series                                | 67              | No        | Any type of hearing loss                         | >3 months         | No                               | HAs Tinnitus Masking Therapy (TMT) group                               |
| Oz, 2013 [32]     | Double-Blinded RCT                         | 21              | No        | Not determined                                   | >6 months         | Yes                              | betahistine and HA and/or a noise device vs. betahistine alone         |
| Parazzini 2011 [33] | Case Control study                        | 91              | 18–75 years| HL < 25 dB at 2 kHz and HL > 25 dB at frequencies higher than 2 kHz, bilateral symmetrical HL | >6 months         | No                               | Tinnitus Retraining Therapy (TRT) with HA vs. TRT with sound generator |
| Peltier, 2012 [34] | Case Series                                | 38              | No        | Unclear (considerable hearing loss at high frequencies) | Not determined    | No                               | Linear octave frequency transposition (LOFT) hearing aid group         |
| Radunz, 2019 [35] | RCT                                       | 33              | >18 years | SNHL or mixed HL independent of degree and configuration | >3 months         | No                               | Gingko biloba extract EGb 761 group vs. Beltone® HA group vs. Gingko biloba plus HA group |
| Rocha, 2017 [36]  | Case series                                | 40              | >18 years | Symmetrical bilateral mild to moderate SNHL      | Not determined    | Yes                              | HL and tinnitus group                                                  |
Table 1. Cont.

| ID         | Study Design                  | Participants No | Age       | Hearing Loss (HL) Range               | Tinnitus Duration | Tinnitus Being Primary Complaint | Groups                                                                 |
|------------|-------------------------------|-----------------|-----------|---------------------------------------|-------------------|----------------------------------|------------------------------------------------------------------------|
| Schaette, 2010 [37] | Case control study          | 114             | No        | SNHL or mixed HL                      | >3 months         | Yes                              | HAs group vs. Noise device group                                      |
| Searchfield, 2010 [38] | Case control study          | 58              | No        | SNHL                                  | unclear           | No                               | Counseling group vs. Counseling plus HAs                              |
| Searchfield, 2016 [39] | Study 2: Prototype evaluation | 14              | <70 years | Symmetrical mild-moderate HL          | Not determined    | No                               | “3D” masking group vs. “2D” masking group                             |
|             | Study 3: Crossover pilot study | 9               | No        | Mild-moderate SNHL in the fitting range | >6 months         | No                               | TRT group vs. 3D masking group                                       |
| Shabana, 2018 [40] | Case Control study          | 40              | 20–80 years | No more than 70 dB HL threshold in each ear | >6 months         | No                               | HAs with Zen program activated vs. HAs without Zen program           |
| Shekhawat, 2013 [41] | Case Series                | 25              | No        | Mild to moderate high-frequency sloping SNHL in the audiometric range of 0.25 to 8 kHz | >2 years         | No                               | HA fitting group                                                     |
| Shekhawat, 2014 [42] | Double-blind, sham-controlled RCT | 40              | No        | Sloping mild to severe sensorineural hearing loss | >2 years         | No                               | real tDCS group vs. sham tDCS group                                  |
| Shetty, 2019 [43] | Case control study          | 20              | No        | Bilateral, symmetrical, mild to severe SNHL | unclear           | No                               | low pitch tinnitus group vs. high pitch tinnitus group               |
| Strauss, 2017 [44] | Case control study          | 20              | No        | No                                    | Not determined    | No                               | BTE HAs group vs. notched environmental sound technology (NEST) HAs group |
| Sweetow, 2010 [45] | Case Series                | 16              | No        | Mild to moderately severe HL          | >1 year           | Yes                              | HA fitting master, fractal + master, fractal + master + noise, fractal alone group conditions |
| Tyler, 2017 [46] | Pilot Study                | 20              | No        | No more than 70 dB hearing loss from 250 to 4000 Hz | >4 months         | No                               | HAs with zen program                                                 |
### Table 1. Cont.

| ID                  | Study Design       | Participants No | Age       | Hearing Loss (HL) Range                               | Tinnitus Duration | Tinnitus Being Primary Complaint | Groups                                                                 |
|---------------------|--------------------|-----------------|-----------|------------------------------------------------------|-------------------|----------------------------------|------------------------------------------------------------------------|
| Yakunina, 2019 [47] | Double-blinded RCT | 94              | >18 years | SNHL with PTA average of 250, 500, and 1000 Hz ≥ 25 dB HL, PTA of 2000, 4000, and 8000 Hz ≥ 40 dB, symmetric HL (difference between PTA of the right and left sides <15 dB HL) | Not determined    | No                               | HAs with wide dynamic range compression group vs. HAs with frequency translation group vs. HAs with linear frequency transposition group |
| Yokota, 2020 [48]   | Case Series        | 66              | No        | Not determined                                      | Not determined    | No                               | HAs group                                                              |
| Zarenoe, 2016 [49]  | RCT                | 50              | No        | Mild-to-moderate SNHL                                | Not determined    | No                               | Motivational Interviewing vs. HA fitting                              |
| Zarenoe, 2017 [50]  | Case control study | 92              | No        | Mild-to-moderate SNHL (PTA average) of 70 dB HL in both ears | Not determined    | Yes                              | HL (2 subgroups with and without HA counseling) + tinnitus-HL but no tinnitus group |

### Table 2. Hearing aid fitting related methodological aspects.

| ID                  | Software Used     | Fitting Procedure Using Real Ear Measurement (REM) | Fitting Formula (Such as NAL, DSL etc.) | Use of Masking Sound (Type) | Counseling Regarding Tinnitus |
|---------------------|-------------------|--------------------------------------------------|----------------------------------------|-----------------------------|------------------------------|
| Acar, 2014 [17]     | Not determined    | Not determined                                   | Not determined                         | No                          | No                           |
| Araujo, 2016 [18]   | Not determined    | Not determined                                   | Not determined                         | No                          | No                           |
| Berberian, 2017 [19]| Not determined    | Not determined                                   | Not determined                         | Individually calculated     | No                           |
| Cabral, 2016 [20]   | Not determined    | Not determined                                   | Not determined                         | No                          | No                           |
| Cribari, 2016 [21]  | Not determined    | Not determined                                   | Not determined                         | No                          | No                           |
| dos Santos, 2014 [22]| EasyFit          | Not determined                                   | NAL-NL1                                | White noise                 | Yes                          |
| Forti, 2010 [23]    | Not determined    | Not determined                                   | Not determined                         | No                          | Yes                          |
| ID | Software Used | Fitting Procedure Using Real Ear Measurement (REM) | Fitting Formula (Such as NAL, DSL etc.) | Use of Masking Sound (Type) | Counseling Regarding Tinnitus |
|----|---------------|-------------------------------------------------|----------------------------------------|----------------------------|----------------------------|
| Haab, 2019 [24] | Not determined | Not determined | Not determined | No | No |
| Henry, 2015 [25] | Not determined | Yes | NAL-NL2 | Masking noise | Yes |
| Henry, 2017 [26] | Not determined | Yes | Manufacturer’s fitting formula (only option) | White noise, pink noise, and a spectrally shaped sound based on the user’s hearing loss | Yes |
| Hodgson, 2017 [27] | Audioscan Verif | Yes | DSL(I/O) version 5.0 | No | No |
| Jalilvand, 2015 [28] | Not determined | Yes | NAL-NL1 | Noise generator | No |
| McNeil, 2012 [29] | Various | Yes | Various | Sound Generator (SG), Neuromonics tinnitus treatment (NTT) | Yes |
| Newman, 2012 [30] | Not determined | Not determined | Not determined | Band tailored masking sound | Yes |
| Ogut, 2012 [31] | NOAH-based custom programming | Not determined | Not determined | Wide-band noise | Yes |
| Parazzini, 2011 [33] | Not determined | Not determined | Not determined | SG | Yes |
| Peltier, 2012 [34] | Not determined | Not determined | Not determined | No | No |
| Radunz, 2020 [35] | Not determined | Not determined | Not determined | No | No |
| Rocha, 2018 [36] | OTO-Suite | Yes | NAL-NL1 | SG | Yes |
| Schaette, 2010 [37] | Siemens Connexx | Not determined | NAL-NL1 | Noise device | No |
| Searchfield, 2010 [38] | Not determined | Yes | Not determined | No | Yes |
| Searchfield, 2016 [39] | GN ReSound Aventa 2.0 | Not determined | NAL NL 2 | Rain sound | No |
| | GN ReSound Aventa 2.0 | Not determined | DSL(I/O) v.5.0 | Masking noise | Yes |
| Shabana, 2018 [40] | Compass version 5 on a NOAH 3 platform | Not determined | Not determined | Zen program | Yes |
| Shekawat, 2013 [41] | WolverineTM Hybrid Jig with Inspiria Extreme | Yes | DSL(I/O) v5.0 | No | No |
Table 2. Cont.

| ID               | Software Used                  | Fitting Procedure Using Real Ear Measurement (REM) | Fitting Formula (Such as NAL, DSL etc.) | Use of Masking Sound (Type) | Counseling Regarding Tinnitus |
|------------------|--------------------------------|--------------------------------------------------|----------------------------------------|-----------------------------|------------------------------|
| Shekhawat, 2014 [42] | Not determined                  | Not determined                                   | DSL(I/O) v5.0                          | No                          | No                           |
| Shetty, 2019 [43]   | NOAH or WINCHAP (v 3.00)        | Yes                                              | NAL-NL 2 or DSL (I/o) v5               | Speech-shaped noise          | No                           |
| Strauss, 2017 [44]  | Not determined                  | Not determined                                   | Not determined                         | Tailor made notch adjusted to the tinnitus frequency | No                           |
| Sweetow, 2010 [45]  | Compass v4.542 beta software with NOAH link | Not determined                                   | Not determined                         | Fractal tones, broadband noise | No                           |
| Tyler, 2017 [46]    | Not determined                  | Not determined                                   | Not determined                         | Zen program                 | Yes                          |
| Yakunina, 2019 [47] | Not determined                  | Not determined                                   | Not determined                         | No                          | No                           |
| Yokota, 2020 [48]   | Not determined                  | Not determined                                   | Not determined                         | No                          | No                           |
| Zarenoe, 2016 [49]  | Not determined                  | Not determined                                   | Not determined                         | No                          | No                           |
| Zarenoe, 2017 [50]  | Not determined                  | Not determined                                   | Not determined                         | No                          | No                           |

Table 3. Summary of research hypotheses, tinnitus assessment methods (tools, timeline) before and after HA fitting, overall study results.

| ID               | Research Hypothesis                                                                 | Outcome Measures               | Follow Up (Time) | Results                                                                 |
|------------------|-------------------------------------------------------------------------------------|--------------------------------|------------------|-------------------------------------------------------------------------|
| Acar, 2014 [17]  | Hearing Aid (HA) fitting improves tinnitus perception                             | Tinnitus Handicap index (THI)  | 3 months         | Significant improvement, even controlled by degree of hearing loss (HL) |
| Araujo, 2016 [18] | Improvement of tinnitus with HA usage and effect of tinnitus presence in HA satisfaction | THI, visual analog scale (VAS) | 1 month after HA fitting, 3 months of effective use of HAs | Significant decrease of the THI at the end of the follow-up period |
| Berberian, 2017 [19] | HAs and maskers decrease tinnitus annoyance                                      | THI,VAS                        | at least 6 months | Significant decrease of THI based on categorization (no actual scores provided) |
| Cabral, 2016 [20] | To assess the remission of emotional and auditory tinnitus impacts on users of hearing aids. | Tinnitus Acceptance Questionnaire (TAQ), Tinnitus Handicap Questionnaire (THQ) | 3 months         | Statistically significant improvement in both tinnitus domains after 3 months of HA usage |
| ID                | Research Hypothesis                                                                 | Outcome Measures | Follow Up (Time)          | Results                                                                                                                                                                                                                                                                                                                                 |
|------------------|-------------------------------------------------------------------------------------|------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cribari, 2016 [21] | Evaluate and qualify tinnitus in a group of elderly hearing aid wearers and determine the impact of symptoms on their quality of life. No baseline measurements were done | THI              | Not determined            | Recording was made only after HA fitting so no comparisons were feasible                                                                                                                                                                                                                                                        |
| dos Santos, 2014 [22] | Combined use of amplification and sound generator is more effective than amplification alone in reducing the discomfort of tinnitus | THI, VAS         | 3 months after fitting    | No superiority of the combined use of amplification and sound generator over conventional amplification alone in reducing the discomfort of tinnitus.                                                                                                                                                                               |
| Forti, 2010 [23]   | Use of open ear canal HAs in tinnitus treatment                                      | THI, VAS         | 9 months after fitting    | Both groups showed improvement with regards to tinnitus (almost 50% according to THI). No significant differences between the two groups (open HAs and HAs). Control patients reported a lower comfort of use than OHA patients. No statistically significant correlations were found between THI or VAS among the different type of OHAs. |
| Haab, 2019 [24]    | A tailor-made notch, individually adjusted to the tinnitus-frequency, in a hearing-aids amplification range | Tinnitus Questionnaire (TQ52) | 3, 6 months               | Differences between initial and final measurements differ in a statistically significant level between groups, in favor of the group using spectral masking.                                                                                                                                                                               |
| Henry, 2015 [25]   | Compare the use of combination instruments for tinnitus management with and without the use of broadband noise produced from the instruments. | Tinnitus Functional Index (TFI) | 1–3 weeks HA adjustments, 3–4 months final evaluation | Both groups (control and experimental) revealed significant improvement based on reductions in mean TFI index scores. 26 of the 30 participants (86.7%) reported meaningful reduction in their tinnitus.                                                                                                                                                                      |
| Henry, 2017 [26]   | Relative efficacy of conventional receiver-in-the-canal hearing aids (HA), the same hearing aids with a sound generator (HAI1SG), and extended-wear, deep fit hearing aids (EWAR) | TFI              | 1–3 weeks after fitting, 2 months after fitting, 4–5 months after fitting | All devices appear to offer clinically significant improvement in the functional effects of tinnitus but no statistical significance before-after, among devices or among groups was found.                                                                                                                                                      |
| ID | Research Hypothesis | Outcome Measures | Follow Up (Time) | Results |
|----|---------------------|------------------|-----------------|---------|
| Hodgson, 2017 [27] | A crossover trial comparing FC to conventional wide dynamic range compression (WDRC) amplification in tinnitus patients. | TFI | 6–8 weeks after fitting | Following the WDRC trial 44% of participants had tinnitus reduced by a clinically significant degree, only 19% achieved this in the FC trial. Wide dynamic range compression (WDRC) resulted in larger improvements in TFI and rating scale scores than when combined with FC across a group of tinnitus sufferers with high-frequency hearing loss and tinnitus. |
| Jalilvand, 2015 [28] | Comparison of hearing aid fitting and sound generator | patients’ satisfaction scale | 1, 6, 12, 24 months after fitting | Amplification of sounds is effective in reducing or eliminating tinnitus loudness compared to noise generator. |
| McNeil, 2012 [29] | Hearing aids would be most effective when their frequency range encompassed an individual’s tinnitus pitch. | TRQ | 3 months after fitting | Clinically significant improvement in 51%. Total masking during HA use in Masking more common in low pitch tinnitus |
| Newman, 2012 [30] | To evaluate changes in perceived tinnitus handicap, following 6 months of sound therapy treatment using either Sound Generators (SGs) or Neuromonics Tinnitus Treatment | THI | 1–6 months post fitting | No statistically significant differences were found between SGs and Neuromonics tinnitus treatment (NTT) at baseline or at the 6 months interval. |
| Ogut, 2012 [31] | Effect of tinnitus masking therapy (TMT) in our patient group in tinnitus | THQ, TRQ | 4, 6, 8, 10, 12 weeks, 4, 5, 6 months, 8, 10, 12 months | Relief from annoyance was 55.9% and decrease of tinnitus effect on life was 67.2% at three months. Total rate for any degree of relief was 79.3% in normal hearing group, where in hearing-loss group it remained at 61.2% |
| Oz, 2013 [32] | Wide band differs from narrow band masker in terms of tinnitus | VAS, Mini-Tinnitus Questionnaire | 3 months | No statistically significant differences between groups-however both showed significant improvements |
| Parazzini, 2011 [33] | TRT with HA vs. TRT with sound generator | THI, VAS | 3, 6, 12 months | No significant differences between HA and sound masker |
Table 3. Cont.

| ID | Research Hypothesis | Outcome Measures | Follow Up (Time) | Results |
|----|---------------------|------------------|------------------|---------|
| Peltier, 2012 [34] | Effect of linear octave frequency transposition (LOFT) hearing aid in tinnitus | VAS | Not determined | 81% report long term tinnitus suppression |
| Radunz, 2020 [35] | Comparison between the effect of the use of the individual hearing aid, the use of Gingko biloba preparation and their combination | THI, VAS | 90 days following treatment | Hearing aids were more effective in patients with shorter time to onset of tinnitus. G. biloba extract alone or in combination with the hearing aids was effective regardless of tinnitus duration. |
| Rocha, 2018 [36] | Real ear measurement (REM) is assistive to tinnitus treatment | THI, VAS | 3, 6 months after initial evaluation | Significant decrease of THI in this group of patients |
| Schaette, 2010 [37] | Comparison of tinnitus suppression effects of conventional type HAs and frequency-lowering HAs in patients with HFHL | VAS, Tinnitus Questionnaire | 1, 2, 3, 6 months after initial examination | There were no significant differences in primary or additional variables between hearing aid types at either 3 or 6 months. |
| Searchfield, 2010 [38] | Effect of HAs combined with counseling compared to counseling only | THQ | 12 months post management | THQ scores were reduced following intervention but only the HA group scores were found to differ significantly. The percentage improvement in total THQ score for the HA group (37%) was approximately twice that of counseling alone (13%). |
| Searchfield, 2016 [39] | Study 2: Determine masking preferences amongst participants. | THI | 2–2, 4 weeks | There was a significant difference in THI change between the 3D and center masking |
| | Study 3: Provide preliminary evidence of the effectiveness of spatial masking with counseling relative to a therapy using TRT principles. | TFI, Tinnitus Severity Numeric Scale (TSNS) | 2–4 weeks, 2 months | The 3D scores reduced slightly more (11.78) than TRT (6.89) but the treatment by time interaction was not statistically significant |
| Shabana, 2018 [40] | Effectiveness of counseling and using amplification and sound stimulation (Zen tones of fractal music) technology | THI, TFI | After counseling, 4 months after HAs fitting | Statistically significant difference of THI scores between the post-counseling and following hearing aids fitting with or without Zen program, amount of improvement in the study group than in the control group except in THI emotional subscale score |
| ID                          | Research Hypothesis                                                                                                                                                                                                                                                                                                                                 | Outcome Measures                                                                 | Follow Up (Time)                                | Results                                                                                                                                                                                                 |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Shekhawat, 2013 [41]       | To examine the effects of high frequency modification of the DSL(I/O) v5.0 prescriptive procedure on short-term tinnitus perception.                                                                                                                                                                                                                     | TFI                                                                             | Not determined                               | The higher the tinnitus pitch, the more the preferred real-ear output tended to match DSL(I/O) v5.0. For low- pitched tinnitus (<4 kHz) the preferred output tended to be lower than that of DSL(I/O) v5.0 across the entire frequency range. |
| Shekhawat, 2014 [42]       | To assess if combination of tDCS and hearing aids may facilitate priming of the brain for sound therapy resulting in greater hearing aid benefit in a shorter period of time.                                                                                                                                                                           | Tinnitus Case History Questionnaire (TCHQ), TFI, TSNS, THQ, VAS                  | 3 and 6 months following hearing aid fitting | The use of hearing aids led to a significant reduction in tinnitus handicap as measured with the TFI.                                                                                                                                                              |
| Shetty, 2019 [43]           | (1) to determine the effect of gain adjustment on tinnitus perception in low and high pitch tinnitus groups (2) to compare SNR 50 using NAL NL 2 and DSL (I/o) v 5.0 fitting formulae in high and low pitch tinnitus groups and (3) to compare tinnitus relief data and SNR-50 scores pre- and post- hearing aid use.                                                                                                         | THI                                                                             | 30 days after fitting                          | In the low pitch tinnitus group, the significantly lesser gain adjustment was noted in DSL (I/o) v5 (0.5) than NAL-NL 2 (1.83). Similarly, for the high pitch tinnitus group, gain adjustment required was significantly less using DSL (I/o) v5 (1.16 dB) compared to NAL-NL 2 (5.6 dB). Additionally, speech perception in noise was unaffected by the adjusted gain at tinnitus pitch using either NAL NL 2 or DSL (I/o) v5 prescriptive formulae. |
| Strauss, 2017 [44]          | Proof-of-concept that tinnitus distress can be reduced by the notch-induced lateral inhibition in NEST                                                                                                                                                                                                                                           | Tinnitus Questionnaire 12 (TQ12)                                                | 3 weeks post therapy                          | Both TQ12 and τ factor improvement more prominent in notched environmental sound technology (NEST) group (both groups improved though)                                                              |
| Sweetow, 2010 [45]          | To determine if the presence of various acoustic stimuli delivered through a hearing aid would reduce short-term tinnitus annoyance, and lower the subjective tinnitus handicap.                                                                                                                                                                           | THI, Tinnitus Reaction Questionnaire (TRQ), Tinnitus Annoyance Scale (TAS)       | 1, 3 and 6 months after fitting               | The four fractal settings had similar median annoyance ratings, significantly better than the unaided (control) group TRQ: initial improvement, not consistent to 6 months. THI significant improvement at 6 months. |
| ID                  | Research Hypothesis                                                                 | Outcome Measures                | Follow Up (Time) | Results                                                                                                                                                                                                 |
|---------------------|------------------------------------------------------------------------------------|---------------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tyler, 2017 [46]    | Zen tones in the context of the Zen therapy are beneficial for tinnitus.          | Tinnitus Primary Function       | 3, 6 months posttreatment | Statistically significant improvement in after 6 months (not right after HA fitting) in terms of TFI, VAS, TPFQ in a group of 20 patients fitted with Zen HAs                                              |
|                     | 1. to isolate and evaluate the effects on tinnitus of HA alone without accompanying counseling or any other therapy | Questionnaire (TPFQ), TFI, THQ, VAS |                  |                                                                                                                                                                                                     |
|                     | 2. to investigate whether HAs provide long-term tinnitus suppression that lasts after cessation of their use | THI, VAS awareness, VAS annoyance | 3 months after fitting, 6 months after initial evaluation | HAs, with or without FL, seem to be effective for longer-term relief of tinnitus among patients with HFHL, and not only for the period of their use (3 months after) |
|                     | 3. to explore how Frequency Lowering (FL) techniques (LFT and FT) performed compared with conventional WDRC in the same open-fit HA device in terms of tinnitus suppression for patients with high frequency hearing loss (HFHL) |                                |                  |                                                                                                                                                                                                     |
| Yokota, 2020 [48]   | Effect of HA fitting in tinnitus                                                   | THI, VAS                        | 1–12 months      | Statistically significant improvement in all patients either with unilateral or bilateral tinnitus                                                                                                       |
| Zarenoe, 2016 [49]  | Effects of Motivational Interviewing (MI) as an adjunct to regular hearing aid fitting for patients with tinnitus and hearing loss. | THI                             | 3 months after fitting | Both groups significantly decreased THI levels, hence the MI group showed statistically significant larger improvement                                                                                      |
|                     | Effect of hearing aids on memory tinnitus annoyance, capacity, sleep quality, hearing problems, speech recognition. | THI                             | 3 months after fitting | Pre/post changes were significant for both groups on the Reading Span, PQSI and HHIE. The results of the THI revealed a significant improvement ($p < 0.001$) at follow-up for patients in the hearing loss and tinnitus matched group. |
Table 4. Methodological limitations of the clinical studies included in this scoping review that may have a significant impact on the quality of results and their generalizability.

| Limitations                                                                 |
|----------------------------------------------------------------------------|
| Small or inadequate sample size                                             |
| Inadequate demographic inclusion/exclusion criteria (e.g., wide age range)  |
| Inadequate hearing-related inclusion/exclusion criteria (hearing thresholds range, tinnitus as primary complaint or not) |
| Inadequate randomization or blinding                                        |
| Inadequate (short or non-clarified) follow-up timeline                      |
| Inadequate selection of tinnitus assessment tools                          |
| Unclarified tinnitus characteristics (e.g., vague tinnitus onset or tinnitus duration) |
| Inadequate selection of primary and secondary endpoints for effect size assessment |
| Inadequate study design (e.g., non-controlled)                              |

4. Discussion

This scoping review aimed to summarize current evidence on efficacy of HA fitting on tinnitus characteristics and patients’ annoyance, along with the methodologies the relevant studies have used.

4.1. Primary Methodological Aspects of Included Studies

Half of the studies included in this review had less than 40 participants, only three had over 100, whereas there was only one large scale retrospective audit with 974 participants, comparing HAs and sound generators (Table 1). No sample size calculation is described in any of the studies. In addition, no power calculation was provided, neither ad hoc or post hoc.

A vast majority of studies (25 out of 34) did not set strict age criteria (Table 1). This fact might have an effect on the results since groups might not be adequately heterogeneous. Although HL is far more common in older adults, three of the studies with certain age range as inclusion criterion set an upper limit (two of them 70 and one 80 years). Acceptance rates of HA are lower in younger adults and this could lead to lower representation of younger individuals compared to their actual proportion among tinnitus patients. On top of this, older adults might not be familiar with modern technologies recently implemented in HAs, like mobile applications and this could lead to selection bias and higher rates of drop outs, or sub-optimal use in terms of duration. None of the studies, even those who set a certain age range, took these potentially determining factors into consideration.

Only eight out of 34 studies (20.5%) have clearly set tinnitus as a primary complaint as a certain inclusion criterion (Table 1). Hence identified as a drawback in tinnitus studies, a strict prerequisite of tinnitus as a primary complaint might not be absolutely relevant in studies targeting HA effectiveness in tinnitus. In patients with HL as a primary complaint, hearing aid fitting is indicated anyway. At the same time, a subgroup of patients with tinnitus as a primary complaint, also suffers from HL adequate to set a HA. In real conditions, there is a wide range of importance perception and level of annoyance correlated, between the two poles of HL and tinnitus. This means that patients belong to a wide spectrum between hearing loss and tinnitus as primary complaints—and all the shades in between.
This of course cannot eliminate the possibility of patients with HL as a primary complaint hence with a considerably bothersome tinnitus, even catastrophic, or vice versa: patients could mention tinnitus as a primary complaint and at the same time have important communication barriers due to severe hearing loss [51,52]. In conclusion, tinnitus as a primary complaint is of limited value in studies evaluating HA effectiveness in tinnitus, compared to studies targeting other interventions.

Related with this issue is the range of HL suitable for study inclusion. Although all but one studies reported that they targeted patients with HL requiring amplification, only six clearly determined specific thresholds per frequency as inclusion criteria (Table 1). Eighteen of the studies provided some generic HL degrees (mild, moderate, severe), with a large heterogeneity, especially in regards to sever HL. Eleven studies did not have neither a broad determination of HL range, either with absence of any relevant information or with statements like “any type of HL” or “significant loss to warrant HA fitting”. One study included only adults with hearing thresholds not requiring amplification [30]. Potential issues of this broad definitions are twofold. Different types of HAs are optimal for different types of HL. In most of the studies without specific HL inclusion criteria it can only be assumed that the relevant rules are applied, since a relevant statement is not made. Moreover, even if this was valid, it could lead to methodological discrepancies.

Less than half of the studies (14 out of 34) set clear inclusion criteria for tinnitus duration at the time of fitting (Table 1). This could potentially cause a difficulty to estimate effectiveness and clearly sets a potential selection bias. Absence of strict range of tinnitus onset is a draw of tinnitus literature in general, however in the evaluation of the HA effect, this might be even more influential, since there is a considerable proportion of patients who present total or intermittent elimination of tinnitus, which is not usually the case in other types of interventions. It is unknown though, whether a longer tinnitus duration might make more difficult tinnitus elimination or vice versa. In addition, none of the studies used tinnitus onset as a prognostic factor.

4.2. Hearing Aid Fitting Procedure

Only 12 out 34 studies gave a clear reference of the fitting formula used (Table 2). The vast majority used NAL (5 used NAL-NL1 and 3 used NAL-NL2), whereas 3 used DSL. This parameter could be potentially important in regards to tinnitus suppression, on top hearing loss amplification, given that different formulas provide different gain patterns. Hence, it is interesting that no study presents a justification about the selected formula nor a predefined hypothesis that one might be more effective on tinnitus compared to another.

With regards to counseling, it is considered the cornerstone of most tinnitus treatments [53]. Majority of the studies included in this review do not describe what type of counseling was included in participants’ workflow or whether they provided any counseling at all. Taking into account the confusion existing among counseling solely for HA fitting, counseling as part of TRT, long-term counseling through Cognitive Behavioral Therapy approaches and actual structured counseling targeting tinnitus, it is evident that the absence of this particular information in the included studies create a significant methodological limitation. Indeed, this is reflected in our results, as well. Only two studies present a clear description of the structured counseling they have conducted; Rocha et al. (2018) reported structured counseling using materials with videos and illustrations proposed by Siemens Audiology Solutions through counseling “Counseling Suite3.3”. Newman and Sandridge (2012) also presented a detailed list of topics addressed during participants’ education sessions. The rest of the studies reported some kind of counseling, mostly use components of TRT [23,26,33], while three of them do not provide any information [31,32,35]. Commercially available material which is integrated to specific hearing assistive devices (such as Widex Zen therapy) was also used in two studies, however it should be taken into account that this type of counseling deviates from the standard tinnitus counseling conducted by clinicians and its reproducibility is by default limited [40,46].
4.3. Tinnitus Assessment Methods

According to recent recommendations, outcome measures should be carefully chosen in tinnitus-related clinical studies, depending on the type of intervention. As for HAs, intrusiveness, sense of control, concentration and quality of sleep were among the dimensions that should be targeted by the outcome measures [52].

A sole outcome measure was used in 16 of the studies, whereas the rest used from two up to four outcome measures, with a moderate variance, since nine evaluation tools including validated questionnaires and scales were used in total. Most of the studies (19/34 or 55.9%) used Tinnitus Handicap Index (THI) as a primary outcome measure (Table 3), five Tinnitus Functional Index (TFI) [39–42,46], one Tinnitus Reaction Questionnaire (TRQ) [29] and two Tinnitus Handicap Questionnaire (THQ) [31,38]. Four studies used more than 2 scales [42,45–47]. Scales were used as secondary outcome measures in nine studies and THQ, TQ and THI in two studies each (Table 3).

Although the selected outcome measures could be evaluated as satisfactory, given that they are both in line with the rest of the literature and with the recent recommendations, the main point in regards to evaluation is that these well-established tools are not designed for an intervention that has a far more binary nature compared to the rest. There is a considerable proportion of patients that experience total or close to total tinnitus elimination, at least during HA usage during the day. Questionnaires might globally reflect the change in quality of life, daily function or emotion due to these changes. The opposite could be valid for non-responders.

An additional limitation of currently used methods is that metrics targeting correlation between HA usage and tinnitus suppression in the time domain, usage duration and effect on tinnitus, comparison of HA usage individuals with and without tinnitus as well as some more trivial aspects like tinnitus relapse after HA removal and its effect are still missing. Ecological momentary assessment with use of mobile devices could be a very interesting research field towards this direction. Finally, the effect of total elimination is not well weighted though it might be the case that some patients respond very well and some not at all (binary response).

4.4. Follow-Up Period

Table 3 clearly shows that participants’ follow up timeline ranged a lot across included studies. The majority of studies had a follow up time commonly used in the literature (13 of them had 3 months and 5 had 6 months). Only 1 study had a follow up period more than 12 months [28], whereas 3 had a follow up time less than 3 months (ranging from 3 weeks to 2 months) [39,43,44]. These latter are not considered adequate to draw conclusions in the context of tinnitus studies in general, however the effect of hearing aids is not as latent as in other interventions like sound therapy and CBT. On top of this, HA effect on tinnitus has two contradictory characteristics in the time domain: it is intermittent during the day, depending on whether the hearing aid is used or not and on the other hand, it is continuous in the largest time scale, since typically the effect, if present is not expected to substantially change during the period of HA usage. However, it is impressive that none of the studies report any evaluation of these parameters (effect during the day and stability of long-term effect). This latter could be an interesting research question for future studies.

4.5. Results

Before being able to interpret the results of clinical studies comparing two different tinnitus therapeutic modalities, one should take into account that different outcome measures may be more suitable for specific types of tinnitus treatment than others. In the context of COMiT’ID study, Hall et al. (2018) identified and reported the widest approved outcome measures for clinical trials of Sound-, Psychology-, and Pharmacology Based interventions for chronic subjective tinnitus. In the case of HA related clinical studies, COMiT’ID suggests that the minimum set of outcome measures should contain the following: “ability to ignore”, “concentration”, “quality of sleep” and “sense of control”, while
psychology-based ones should include endpoints such as “mood”. Although, “what” each clinical study should include as endpoint is clearly stated, to date, no consensus on “how” this endpoint should be obtained and compared between treatment groups exists [11]. In clinical studies comparing a HA fitting with CBT-based therapy, a valid approach would be the inclusion of endpoints relevant to both treatments and the estimation of the effect of each treatment separately. This approach may enable comparisons between treatments in a more binary way, where each treatment has failed or succeeded at creating a significant tinnitus benefit with regards to its corresponding outcomes.

Studies included in this review seem to have adequately covered all the aforementioned core outcome domains through validated tools such as THI or through VAS. However, the same tools are used for all different types of treatment under evaluation, so the interpretation and generalization of their results should be done with caution.

The first important question that has direct research and clinical implications is whether there is evidence that HA fitting may have positive impact in tinnitus perception, distress or annoyance and if yes, what the possibility of improvement that should be expected after HA fitting is. Previous systematic review on HA fitting effect in terms of tinnitus benefit in adults with hearing loss and tinnitus concluded that only one clinical study was of adequate quality and thus no safe conclusion could be reached [54].

According to the outcome measures used, HA fitting-related improvement was up to 50%, while the proportion of participants showing at least some improvement ranged from 40% to 85% (Table 3).

As for the effectiveness, a clear trend can be identified among the case series included. All studies claimed a persistent significant improvement, regardless of the type of HA provided and the outcome measures used. Consistency of this finding among eleven studies is important, however it should be evaluated taking into account, on top of low methodological level and heterogeneity, that two of them did not conduct statistical analysis [21,31]. Moreover, one study shows that this improvement may elapse if patients abandon their HA.

In regards to superiority, only two case control studies compared hearing aid fitting with other types of interventions, namely TRT [33] and counseling [38]. In the latter study, HA fitting was claimed to be superior; however this obviously cannot be considered adequate evidence to draw conclusions. The rest of the case control studies compared either different types of devices and fitting techniques or HA fitting alone versus some kind of maskers or sound generators.

Whether HA fitting alone is inferior to HA fitting and sound therapy combined still remains unclear. Some studies have shown no statistically or clinically significant difference between HA and combined therapy [22,26], whereas others concluded that the overall benefit was significantly higher in those patients having undergone HA fitting and sound masking [24,25,40,44]. Finally, Jalilvand et al. (2015) showed that amplification alone was superior to sound therapy by means of a noise generator, while Newman and Sandridge (2012) compared sound therapy with broad band noise (BBN) and with Neuromonics Tinnitus Treatment (NTT) observing no statistically significant difference.

This review has identified seven RCTs, out of which three evaluated the additional effect of sound generator, maskers and fitting techniques (frequency transposition) [22,26]. In none of these trials an additional effect of these interventions was concluded. Other RCTs compared HA fitting against gingko biloba and motivational interviewing [35,49], hence their findings were contradictory and the superiority could not be established.

To conclude, hearing aid fitting, itself, should be considered a valid tinnitus management approach for patients with HL. Current evidence implies that the size of its effect is clinically non-negligible. However, whether it should be combined with sound therapy or not needs further investigation through large scale longitudinal controlled studies. Future studies should overcome the heterogeneity of tinnitus assessment tools and outcome measures used, the different follow-up timelines and the conflicts of interest in those studies using commercially available tools so that they can lead safely to robust conclusions. Future
studies with adequate study design and sample sizes, clearly set demographic inclusion criteria, clear ranges of hearing loss and tinnitus characteristics of the included subjects are warranted.

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