Remote screening accuracy of first-time hearing aid users

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ABSTRACT

INTRODUCTION. Capacity constraints in Danish hearing healthcare may lead to diagnostic delays and repetitive pre-treatment audiological exams for hearing-impaired patients. This study investigated the effectiveness of remote ear-nose-throat (ENT) specialist assessments (RESA) for complicated hearing loss, comparing the accuracy of private ENT specialists and medical audiologists.

METHODS. RESA screening accuracy was determined for four ENT specialists, individually and as subspecialised groups. These assessments were benchmarked against “gold standard” in-person ENT assessments for 445 potential adult first-time hearing aid users.

RESULTS. Medical audiologists initially recorded lower RESA screening specificity and positive predictive values than private ENT specialists. However, after making two adjustments to the dataset, these differences were neutralised. Screening sensitivity was consistent across individual and grouped subspecialities.

CONCLUSIONS. RESA screening is a promising tool for timely diagnosis and treatment. The findings reveal that both private ENT specialists and medical audiologists may conduct RESA with high consistency and uniformity.

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TRIAL REGISTRATION. Not relevant.

Faced with capacity constraints and demographic shifts, Danish hearing healthcare is examining its initial screening process for potential first-time hearing aid (HA) users [1]. At present, private ENT specialists conduct detailed assessments before diagnosis and treatment; the latter is provided either in private or public audiology clinics for adults with mild to moderate hearing loss (HL) or in audiology hospital departments for adults with severe HL and children irrespective of HL severity [2]. This approach, however, introduces delays due to waitlists at ENT specialist clinics and repetitive pre-treatment audiological exams. The urgency of efficient assessments and timely treatment is highlighted by the potential adverse effects of untreated age-related HL on patients’ quality of life [3, 4].

To address these challenges, innovative diagnostic methods are being explored. A remote ENT specialist assessment (RESA) screening routine was trialled in a randomised controlled study (the InHEAR trial) with 751 adults, who were potential first-time HA users in 2021 and 2022 [5]. The purpose of RESA was to obviate the need
for in-person ENT consultations and to expedite treatment initiation. RESA facilitated remote assessment of adults with HL, identifying cases of severe or severely asymmetrical HL and serious ear disorders such as cholesteatoma, otosclerosis, tympanic membrane perforation or retraction, infections, etc. The trial affirmed the high screening accuracy of RESA compared with traditional physical ENT specialist assessments (PESA) [5].

The RESA screening routine involved a standardised examination conducted by certified audiology assistants in public or private audiology clinics. It incorporated three elements: 1) The patient-reported 15-item Consumer Ear Disease Risk Assessment (CEDRA) questionnaire [6, 7], known as “Risikovurdering af høreapparatbrugere” (RiHab) in Danish [8], which screens for 104 targeted ear diseases (TEDs) associated with HL, and the Tinnitus Handicap Inventory (THI) for patients with self-reported tinnitus [9], 2) an audiological examination and 3) digital images of the tympanic membranes captured by video-otoscopy. ENT specialists subsequently analysed the examination results remotely and referred participants for treatment as needed [5].

This new approach has garnered political interest for its potential to alleviate current organisational inefficiencies [1]. Audiologists may perform pre-HA assessments in other countries [10], and remote assessment may potentially serve to improve global hearing rehabilitation efficiency. In Denmark, where an in-person ENT specialist evaluation is required before HA fitting, RESA may potentially introduce variability in assessment accuracy among ENT specialist reviewers. In the InHEAR trial, two private ENT specialists and two medical audiologists (MAs) conducted RESA screening in 501 participants. Here, “medical audiologist” denotes ENT senior consultants with specialised skills and experience in diagnosing, treating and managing a wide range of hearing and balancing disorders in children and adults in the context of a hospital audiology department. This study analysed data from the InHEAR trial to ascertain if notable disparities in assessment accuracy existed among the four ENT specialists individually or between their subspecialist groups - private ENTs and MAs - in a RESA setting. Assessments were compared to an in-person “gold standard” conducted by ENT specialists with expertise in either audiology or otology.

**METHODS**

The InHEAR trial was previously described in detail [5]. In total, 751 adult potential first-time HA users were recruited and allocated to either RESA or PESA screening by an automated 2:1 allocation ratio. RESA screening was performed in 501 test group (TG) participants; PESA screening in 250 control group participants in accordance with current clinical guidelines [2]. The 501 TG participants are the focus of the present study.

The four ENT specialists individually and remotely evaluated all three components of the standardised examination for each of the 501 TG participants. These components included the RiHab and THI test outcomes and total scores, the audiological examination and still images of the tympanic membranes. The RiHab score (range 0-28) indicated the risk of having one or more TEDs requiring medical intervention before HA prescription [5, 6]. The THI score provided insights into the perceived tinnitus handicap severity in patients who reported tinnitus [6, 7]. While the authors of the original tool, CEDRA, recommend a cut-off score of four or more as a heightened risk indicator for TEDs associated with HL, based on a prior study involving 246 participants (of whom 75.2% displayed one or more TEDs), the present study applied the threshold value of eight to enhance the tool’s specificity from 72% to an estimated 95% [7]. The change, though reducing the screening sensitivity to around 53%, was anticipated to be counterbalanced by the additional audiological measurements and visual imaging [7].

The audiological examination included a standardised tone and speech audiometry with determination of bone conduction thresholds at five frequencies (250 Hz, 500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz) and air conduction (AC) thresholds at seven frequencies (125 Hz, 250 Hz, 500 Hz, 1,000 Hz, 2,000 Hz, 4,000 Hz and 8,000 Hz), a
speech recognition score test using Dantale I, a monosyllabic speech identification test in quiet presented at the most comfortable level, acoustic reflex thresholds at four frequencies (500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz) and a 226 Hz tympanometry. Correct masking was applied as needed. The pure-tone average (PTA) was defined as the mean of AC thresholds at 500, 1,000, 2,000 and 4,000 Hz (AC-PTA-4) and utilised to delineate normal hearing (AC-PTA-4 ≤ 20 dB), mild HL (AC-PTA-4 of 21-40 dB), moderate HL (AC-PTA-4 of 41-60 dB) and severe HL (AC-PTA-4 ≥ 61 dB). Severely asymmetrical HL was defined as AC-PTA-4 asymmetry above 30 dB between ears or a minimum of 20% disparity in interaural speech recognition score. The diagnostic criteria for severe HL followed current Danish HA management guidelines [2, 5].

Based on the data, the four ENT specialists classified participants into three diagnostic groups, considering the presence, type and severity of HL, along with any suspected or confirmed ear disorders: the first group exhibited audiometric thresholds within the normal range without any additional ear symptoms (CEDRA scores < 8). The second group comprised individuals with mild or moderate HL who had no ear symptoms (CEDRA scores < 8). The third group consisted of patients with severe or severely asymmetrical HL and patients with suspected/diagnosed ear disorders (CEDRA scores ≥ 8) [2]. In accordance with existing clinical guidelines and irrespective of group allocation, all patients with an asymmetrical sensorineural HL of 15 dB or more at two adjacent octave frequencies were offered a supplementary magnetic resonance imaging (MRI) of the internal auditory canal to exclude tumours in the cerebellopontine angle, such as a vestibular schwannoma [11].

Group-one participants had a physical follow-up by an ENT specialist to exclude TEDs, without repeating the audiometric or tympanometric measures. Group two received HAs from public or private audiology clinics, and group three was referred to the Audiology Department of Aalborg University Hospital, Denmark for further ENT specialist evaluation before HA fitting. Participant data were stored in REDCap [12, 13] hosted by Aalborg University Hospital, in which an automatic algorithm randomly allocated participants to one of the four ENT specialist assessors, expecting assessment variations among them.

Participants were reassessed by ENT specialists in medical audiology or otology at the Department of Audiology Aalborg University Hospital, 2-4 months after HA fitting. This 30-minute “gold standard” evaluation included audiological assessments and an objective ENT examination with bilateral oto-microscopy, after which participants were classified into one of the three diagnostic categories.

**Ethical approval**

The North Denmark Region Committee on Health Research Ethics was notified about the trial prior to patient recruitment. The Committee waived the need for a formal application before patient recruitment could be initiated (case no. 2020-000992).

**Statistical methods**

All data analyses were performed using R statistical software v4.1.2 [14]. The sensitivity, specificity, positive predictive value and negative predictive value of RESA screening, for the ENT specialists individually and for the two subspecialists groups, were calculated by comparing RESA assessments with “gold standard” ENT specialist assessments employing Fisher’s exact test on two-by-two tables. Pearson’s χ² test was used to assess potential associations between the two assessments. The same statistical measures were calculated for the comparison of the screening accuracy between the private ENT specialists and MAs. All measures were reported with 95% confidence intervals (CI), and a p value < 0.05 was deemed statistically significant.

The RESA screening accuracy was determined for each of the four ENT specialists and within each subspecialist group against the “gold standard” ENT specialist assessment performed 2-4 months after treatment. Adjustments were made to the dataset before and after analysis. Initially, a RiHab cut-off score of eight suggested false
positive TEDs in first-time HA users when all other data indicated normalcy of ears and hearing. Consequently, eight participants were recategorised from the third group to the first group of normal hearing for the adjusted analyses. Furthermore, 15 participants initially misclassified to the third group due to cases of minor asymmetrical HL requiring an MRI to rule out vestibular schwannoma were recategorised to the second group in the adjusted analysis in accordance with the project protocol and clinical guidelines [2, 5]. Any confusion regarding patient processing was resolved early in the study, leading to a refinement in the assessment instructions for the digital ENT specialist reviewers.

Use of artificial intelligence

The OpenAI language model, GPT-4, CHatGPT (2023, May 24), was employed for text correction and revision.

Trial registration: not relevant.

RESULTS

Among the 501 participants who underwent RESA screening, 445 (89%) successfully completed the trial; 31 withdrew; and 24 participants were lost to follow-up. One participant died during the study. Baseline characteristics are shown in Table 1.

TABLE 1 Baseline characteristics (analysed population).

<table>
<thead>
<tr>
<th></th>
<th>Test group 1 (n₁ = 231)</th>
<th>Test group 2 (n₂ = 214)</th>
<th>Total (N = 445)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (± standard deviation), yrs</td>
<td>62 (± 11.3)</td>
<td>63 (± 11.2)</td>
<td>63 (± 11.3)</td>
</tr>
<tr>
<td>Female participants, n (%)</td>
<td>123 (53)</td>
<td>118 (56)</td>
<td>241 (54)</td>
</tr>
<tr>
<td>Diagnostic subgroups, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal hearing</td>
<td>67 (29)</td>
<td>60 (28)</td>
<td>127 (29)</td>
</tr>
<tr>
<td>Simple hearing loss</td>
<td>140 (61)</td>
<td>137 (64)</td>
<td>277 (62)</td>
</tr>
<tr>
<td>Complicated hearing loss</td>
<td>24  (10)</td>
<td>17  (8)</td>
<td>41  (9)</td>
</tr>
</tbody>
</table>

As suggested by overlapping 95% CIs within each column of Table 2 across the four ENT specialists, no significant individual differences were discerned in screening accuracy between the four before and after adjustments made to the dataset.
As presented in Table 3, the 86% (95% CI: 83%-88%) screening specificity of the MA subgroup was significantly lower than the specificity of the private ENT specialist subgroup of 92% (90-94%) in the pre-adjustment analysis, as indicated by non-overlapping 95% CIs. However, after adjustments had been made to the dataset, no statistically significant differences in screening accuracy were observed between the two groups as indicated by the overlapping 95% CIs within each column of Table 2.

**DISCUSSION**

In the present study, we evaluated the remote screening accuracy of two private ENT specialists and two MAs [5]. Screening sensitivity among the four ENT specialists was consistent, without significant individual differences or...
when grouped by subspeciality. However, the MAs demonstrated a tendency to recommend further physical assessments more frequently than private ENT specialists for participants with milder HL or ear conditions as indicated by the lower pre-adjusted RESA screening specificity in the MA group. This may reflect the private ENT specialists’ proficiency in guiding first-time HA users to suitable treatments, whereas MAs may focus on complex audiological conditions after referral. Notably, a lower specificity in an online screening tool may be advantageous, leading to more referrals for advanced evaluation and treatment and reducing the risk of missed complex cases. Conversely, a very high screening specificity may potentially lead to omission of serious cases since only confirmed cases would be referred. The observed discrepancy in specificity may also arise from limitations in the RiHab tool, exaggerated participant responses for cost-free HAs or procedural misunderstandings during assessment of minor asymmetric HL.

Similar studies on diagnostic concordance in otolaryngology telemedicine corroborate these findings [15, 16]. In a study, 58 adults with HL or tinnitus received remote ENT reviews before HA fitting [15]. A 94.8% diagnostic and treatment plan concordance was recorded between remote and blinded otologist reviews. For 12 participants who underwent an in-person review, the concordance was 83.3%. Overall, 75.7% reduced their hospital visits by one, and 65.6% avoided any clinic attendances for reviews.

CONCLUSIONS

Although the generalisability of this study is constrained by its small sample, with only two ENT representatives per subspecialist group, our findings suggest that ENT specialists, both private ENTs and MAs, may execute RESA screenings accurately, streamlining patient care without compromising patient safety. Remote screening has the potential to refine diagnostic efficiency and speed up HA fitting in Denmark and other developed countries where initial assessments are performed before treatment by a hearing professional [5, 10]. However, the study underscores the need to refine the interpretation of RiHab scores, particularly in instances where other audiological and visual data suggest normal hearing and ear conditions, but RiHab scores are high. Future research may focus on creating a new screening instrument to better identify risk factors and symptoms of serious ear disorders related to HL in prospective first-time HA users in a RESA screening setting.

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