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A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry

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A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry

ABSTRACT

Introduction

Hearing loss (HL) is a global health issue affecting 20% of the world's population. A shortage of audiologists and audiometric sound booths are unable to meet demand for hearing care services. Boothless screening using tablet-based audiometry (TA) could address the challenges of limited resources. We aimed to assess the accuracy of TA to screen for HL at standard (0·25-8KHz) and extended high frequencies (>8KHz).

Methods

This was a prospective multicentre, cross-sectional diagnostic accuracy study. We enrolled adults (age ≥16 years) from audiology and ENT outpatient clinics in the UK between April 2022-September 2023. Patients underwent sound booth audiometry (SBA), TA, completed validated hearing-related questionnaires and the User Experience Questionnaire (UEQ) to assess patient usability.

Results

129 patients were enrolled with 127 patients (254 ears) included in the final analysis. Median age was 43 years (IQR 33-56), 55% (70/127) were female. 76% (96/127) and 68% (86/127) of patients had HL defined by British Society of Audiology (BSA) and American Speech-Language-Hearing Association (ASHA) criteria. Age was significantly associated with hearing loss (p<·0001). There was no significant difference in detecting HL between TA and SBA using either BSA or ASHA criteria at each frequency. 92% (1612/1751) of TA results were within 10dB agreement with SBA results. Sensitivity and specificity of TA for detecting HL was 77-100% and >85% respectively between 0·25-12·5KHz. In terms of patient usability TA showed significantly higher scores in attractiveness (p<·0001), novelty (p<·0001), efficiency (p=·0003), stimulation (p=·003) and perspicuity (p=.02).

Conclusion

TA demonstrated good sensitivity with high specificity for detecting HL at frequencies 0.25-12.5KHz and would be an acceptable accurate alternative to SBA. This would increase accessibility of HL screening and has the potential to be used as a diagnostic test in those without tinnitus where resources are limited.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Tablet-based audiometry has shown similar agreement to SBA alongside sensitivity, specificity, positive and negative predictive values for hearing loss detection at standard frequency ranges.

WHAT THIS STUDY ADDS

We have demonstrated good accuracy of tablet-based audiometry for hearing loss detection at both standard and extended high frequency ranges, strongly supporting tablet-based audiometry as both a screening and diagnostic test to identify hearing loss without audiometric sound booths.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

Implementing tablet-based audiometry allows non-audiologists to improve patient accessibility to hearing loss screening, thereby increasing ear hearing care capacity and facilitate integration of WHO strategy into global and national public health policy. This can reduce current health inequalities globally and assist in early hearing loss detection particularly where access to audiometry resource is limited.

INTRODUCTION

Hearing loss (HL) is a reduced perception of sound, defined by the WHO as hearing thresholds ≥20dB, which in 2019, affected 1·57 billion people or, 20·3% of the global population.[1,2] The incidence of HL increases with advancing age with 42% of those over 60 years having hearing impairment caused by natural degenerative changes in the ear, lifetime ototoxic injuries, genetic susceptibility and/or modifiable lifestyle behaviours. More than 50% of HL is preventable (ear infections, vaccine preventable illness, exposure to noise, chemicals and medications).[1] Intravenous aminoglycoside (IVAG) antibiotics remain a cornerstone of infection treatment and are used globally especially in patients with chronic respiratory infections such as those with multidrug-resistant tuberculosis (MDRTB) and other mycobacterial infections.[3] Irreversible ototoxicity is a known side-effect of IVAG; the global prevalence of HL associated with exposure to short courses of IVAG (<16 days) is 16·6% and for MDRTB is 40·6%.[4] Despite their widespread use, systems for identifying early HL in low- or middle-income countries (LMICs) are scarce.[5]

The Impact of unaddressed HL in children can cause delayed speech and language development continuing into adulthood, with children less likely to go onto higher education, more likely to be unemployed, have poorer mental health, lower quality of life, and social isolation affecting cognition. HL is the second highest modifiable risk factor (after depression) for enhancing dementia-related problems.[1,6] HL is associated with increased healthcare expenditure, loss of productivity and reduced quality of life with an estimated global cost exceeding $981 billion in 2019.[7]

The gold standard in high-income countries (HICs) for monitoring hearing is testing by audiologists within audiometric sound booths which reduce ambient noise and assess HL typically within speech range frequencies (0·25-8KHz).[8] However, the increased demand on audiology services, along with a shortage of audiologists has led to HICs unable to meet existing demand.[9,10] LMICs in particular have a scarcity of audiologists (78% of countries in Africa have less than one audiologist per one million population) compared to HICs (52% of countries in Europe have ten audiologists per one million population).[1] The expense of installing audiometric booths also limits

availability.[11] Age-related, noise- and drug-induced HL initially occurs at extended high frequencies (EHF, >8KHz) before affecting speech range frequencies and hence, EHF monitoring is recommended for early detection in high-risk populations allowing for alternative drug treatment regimens, reductions in noise exposure and aural rehabilitation. [12–16] A 5% reduction in the prevalence of HL has been estimated to reduce global costs by $49billion.[7] However, at present, EHFs are not routinely monitored during standard sound booth audiometry (SBA) with HL detection occurring only after progression to speech range frequencies.

Boothless audiometry using mobile technology could provide a solution to overcome the challenges of availability, cost and accessibility to the limited numbers of sound booths in LMICs and HICs.[1,17] Tablet-based audiometry (TA) using automated technology also reduces operator training requirement and allows trained staff other than audiologists to provide surveillance screening services.[17] Circumaural transducers used without booths for monitoring EHFs have good noise attenuation and could improve accessibility to hearing screening and achieve earlier diagnosis of HL.[18] Our previous work has demonstrated the use of TA as an accurate screening tool in individuals with cystic fibrosis (CF).[19] In this multicentre study, we analyse TA accuracy and acceptability compared to SBA in a general audiology and ear, nose and throat (ENT) outpatient clinic setting and assess patients' experience of using both audiometric techniques.

METHODS

Study design and procedures

Audiometry and data collection was performed prospectively in this diagnostic accuracy study of the Shoebox Standard Limited portable audiometer compared to SBA as the gold standard. Patients were enrolled across two sites in the UK from audiology and ENT outpatient clinics at Guy's & St Thomas' NHS Foundation Trust and University Hospitals Dorset NHS Foundation Trust.

Study participants ≥16 years old selected from either audiology or ENT clinic lists were approached for enrolment. Those who were able to provide informed consent were recruited between April 2022 and September 2023. Those who were aged <16 years or unable to provide informed consent were excluded. SBA was carried out by an audiologist in a sound attenuated booth/room. TA was self-administered by the patient with supervision by another staff member not carrying out SBA (pharmacist, ENT doctor, audiologist) in a quiet clinic room. Patients also completed validated hearing-related questionnaires (Hearing Handicap Inventory for Adults (HHIA), and if experiencing tinnitus of dizziness, Tinnitus Handicap Inventory (THI), and Dizziness Handicap Inventory (DHI)).[20–22] They were also asked to fill in the User Experience Questionnaire (UEQ) about their experience of TA and SBA, which is a quick validated tool to measure the user's experience.[23] Audiologists carrying out SBA were blinded to the TA results.

The clinical audiometer used in SBA was the Natus Aurical calibrated according to BSA standards.[24] TA was carried out using Shoebox Standard edition software application on Apple iPads with circumaural Radioear DD450 transducers measuring frequencies 0·25-16KHz, calibrated by Shoebox Limited to comply with American National Standards Institute standards

(ANSI S3·6-1996-2010). Adult pure tone automated test mode was selected on the Shoebox Standard application which uses a Modified Hughson Westlake algorithm. Hearing thresholds for 0·25KHz, 0·5KHz, 1KHz, 2KHz, 4KHz, 6KHz, 8KHz 10KHz, 12·5KHz, 16KHz were compared between TA and SBA.

Demographic information, medical and drug history, referral, reason for audiometry if known were recorded. Data were entered onto a RedCap database (14·1·4). Definition of HL was defined by the British Society of Audiology (BSA) as >20dB and American Speech-Language-Hearing Association (ASHA) standards as >25dB.[15,24] Scores for hearing-related questionnaires were assigned: no (0 points), sometimes (2 points) and yes (4 points) with total scores categorised into different severities.[25–27] Ethical approval was granted by the Health Research Authority (HRA) and Health and Care Research Wales (HCRW) West Midlands – Edgbaston Research Ethics Committee on 4/2/22 (IRAS project ID 298372) and registered on clinicaltrials.gov (NCT05847556).

Statistical analysis

Statistical analyses were performed using GraphPad Prism Version 10·1·1 (270). Right and left ear thresholds were combined for each frequency. Mean/median were calculated for parametric/non-parametric data. Chi-squared or Fisher's exact tests were used for categorical data. TA measurements were compared with SBA results using Bland Altman plots to visually assess agreement, correlation, paired t-tests to observe the differences between the two types of measurements, and simple linear regression was used to determine presence of proportional bias. Cronbach's alpha test was used to assess reliability. Sensitivity, specificity, positive and negative predictive values with 95% confidence intervals were calculated. Statistical significance was defined as $p<0·05$. Usability was analysed using the User Experience Questionnaire (UEQ) with data analysis performed through the online tools on www.ueq-online.org.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of this research.

RESULTS

Between 16/3/2022 and 15/9/2023, 129 patients were enrolled with 127 patients (254 ears) included in the final analysis (two patients were excluded-one was pregnant, the SBA and TA were more than one week apart for another participant). The numbers of possible tests and results available for data analysis are shown in Table S1.

Table 1 shows the demographic data and the incidence of HL based on BSA (76%) and ASHA (68%) thresholds: median age was 43 years (IQR 33-56), 70 (55%) were female, 79 (62%) were white British. 91 patients (72%) were referred by ENT and primary reasons for SBA were related to middle ear symptoms (24%) or dizziness/vertigo/balance issues (17%) (Table S2 and S3). Most common concurrent medication with ear related side effects were antidepressants (12%) and 42% of participants had received aspirin or NSAIDs in the previous three months (Table S4). Age

was significantly associated with HL regardless of the criteria used, all other characteristics were not (sex, ethnicity, hearing-related questionnaire scores) with no significant difference in HL between BSA and ASHA thresholds (Table 1).

Table 1 – Demographic patient data for frequencies 0·25-8KHz

Characteristic	N (%) or median (IQR)	Individuals with HL as per BSA threshold (%)	No HL (%)	P value	Individuals with HL as per ASHA threshold (%)	No HL (%)	P value
No. Patients	127 (100)	96 (76)	31 (24)	..	86 (68)	41 (32)	·21
Median age of patients, years	43 (33-56)	47 (36-60)	35 (26-43)	**<·0001**	48 (37-60)	35 (27-43)	**<·0001**
Female	70 (55)	54 (56)	16 (52)	·68	48 (56)	22 (54)	·85
HHIA				·10			·09
-0-16 (No handicap)	58 (46)	39 (41)	19 (61)		34 (40)	24 (59)	
-18-42 (mild-moderate handicap)	43 (34)	37 (39)	6 (19)		34 (40)	9 (22)	
-44-100 (significant handicap)	26 (20)	20 (21)	6 (19)		18 (21)	8 (20)	
THI				·51			·23
No symptoms	38 (30)	27 (28)	11 (35)		23 (27)	15 (37)	
-0-16 (slight/no handicap)	36 (28)	28 (29)	8 (26)		26 (30)	10 (24)	
-18-36 (mild handicap)	16 (13)	11 (11)	5 (16)		10 (12)	6 (15)	
-38-56 (moderate handicap)	17 (13)	12 (13)	5 (16)		10 (12)	7 (17)	
-58-76 (severe handicap)	11 (9)	9 (9)	2 (6)		8 (9)	3 (7)	
78-100 (catastrophic handicap)	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	
Missing data	9 (7)	9 (9)	0 (0)		9 (10)	0 (0)	
DHI				·23			·66
No symptoms	69 (54)	57 (59)	12 (39)		50 (58)	19 (46)	
-0-30 (mild)	35 (28)	24 (25)	11 (35)		22 (26)	13 (32)	
-31-60 (moderate)	15 (12)	9 (9)	6 (19)		9 (10)	6 (15)	
-61-100 (severe)	4 (3)	3 (3)	1 (3)		2 (2)	2 (5)	
Missing data	4 (3)	3 (3)	1 (3)		3 (3)	1 (2)	
Ethnicity (patients)				·23			·26
-African	5 (4)	2 (2)	3 (10)		2 (2)	3 (7)	
-Bangladeshi	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-Black other	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-Caribbean	5 (4)	4 (4)	1 (3)		3 (3)	2 (5)	
-Chinese	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-Indian	4 (3)	2 (2)	2 (6)		1 (1)	3 (7)	
-Other	4 (3)	2 (2)	2 (6)		1 (1)	3 (7)	
-Other mixed background	4 (3)	2 (2)	2 (6)		2 (2)	2 (5)	
-Unspecified	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-White & Asian	1 (1)	0 (0)	1 (3)		0 (0)	1 (2)	
-White & Black African	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-White & Black Caribbean	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-White British	79 (62)	66 (69)	13 (42)		60 (70)	19 (46)	
-White Irish	2 (2)	2 (2)	0 (0)		2 (2)	0 (0)	
-White Other	14 (11)	10 (10)	4 (13)		9 (10)	5 (12)	

IQR= interquartile range, HL= hearing loss, BSA= British Society of Audiology >20dB, ASHA=American Speech-Language-Hearing Association >25dB, HHIA=Hearing Handicap Inventory for Adults, THI=Tinnitus Handicap Inventory, DHI=Dizziness Inventory Handicap

There was no significant difference in detecting HL between TA and SBA using either BSA or ASHA criteria (Table 2). Mean pure tone thresholds for each frequency for TA and SBA are shown in Table 3. TA results were highly correlated for most frequencies (0·25-12·5KHz) but not directly

comparable to SBA results (except at 6KHz, 10KHz and 16KHz). 92% of TA results however were within 10dB agreement with SBA results highlighting agreement for most frequencies (Table S5).

Table 2 – Hearing loss detected at pure tone thresholds according to BSA and ASHA criteria

Frequency	Paired results	BSA (>20dB)			ASHA (>25dB)		
		TA N (%)	SBA N (%)	P value	TA N (%)	SBA N (%)	P value
0·25KHz	231	54 (23)	56 (24)	·91	40 (17)	39 (17)	1·00
0·5KHz	231	53 (23)	62 (27)	·39	41 (18)	46 (20)	·63
1KHz	232	56 (24)	63 (27)	·52	40 (17)	42 (18)	·90
2KHz	233	61 (26)	70 (30)	·41	44 (19)	45 (19)	1·00
4KHz	230	107 (47)	104 (45)	·85	85 (37)	84 (37)	1·00
6KHz	228	95 (42)	111 (49)	·16	84 (37)	91 (40)	·56
8KHz	222	103 (46)	94 (42)	·44	91 (41)	83 (37)	·50
10KHz	72	36 (50)	39 (54)	·74	30 (42)	37 (51)	·32
12·5KHz	63	40 (63)	41 (65)	1·00	38 (60)	35 (56)	·72
16KHz	9	5 (56)	4 (44)	1·00	3 (33)	3 (33)	1·00

BSA= British Society of Audiology, ASHA=American Speech-Language-Hearing Association, Db=decibel, KHz=KiloHertz, TA = Tablet-based audiometry, SBA = sound booth audiometry, N=number, %=percentage

Table 3- Mean pure tone thresholds per frequency (paired)

Frequency	TA	SBA	P value	95% CI	r	95% CI	r^2	P value
	TV (±SD) dB	TV (±SD) dB						
0·25KHz	19·13±13·46	16·47±14·98	**<·0001**	1·85 to 3·47	0·91	0·88 to 0·93	0·83	**<·0001**
0·5KHz	18·79±13·69	17·53±16·12	**·003**	0·42 to 2·10	0·92	0·90 to 0·94	0·85	**<·0001**
1KHz	18·53±14·58	17·33±16·16	**·003**	0·43 to 1·99	0·93	0·91 to 0·94	0·86	**<·0001**
2KHz	19·18±14·45	18·18±16·83	**·02**	0·18 to 1·8	0·93	0·91 to 0·94	0·86	**<·0001**
4KHz	25·33±17·02	24·26±18·32	**·01**	0·24 to 1·88	0·94	0·92 to 0·95	0·88	**<·0001**
6KHz	26·45±19·18	26·12±20·83	·53	-0·70 to 1·36	0·93	0·90 to 0·94	0·86	**<·0001**
8KHz	29·95±22·38	24·95±22·37	**<·0001**	3·89 to 6·11	0·93	0·91 to 0·95	0·86	**<·0001**
10KHz	29·51±22·13	31·32±22·45	·10	-3·96 to 0·35	0·92	0·87 to 0·95	0·84	**<·0001**
12·5KHz	35·95±21·53	32·86±25·46	**·003**	1·04 to 5·15	0·95	0·92 to 0·97	0·91	**<·0001**
16KHz	22·78±8·70	22·22±11·21	·88	-7·92 to 9·03	0·41	-0·35 to 0·84	0·17	·27

TA = Tablet-based audiometry, SBA = sound booth audiometry, KHz=KiloHertz, TV=Threshold value, SD=standard deviation, dB=decibel, CI=confidence interval, r= Pearson Correlation coefficient, r^2= coefficient of determination, N=number, %=percentage

Within standard measured frequencies (0·25-8KHz) SBA had fewer unavailable results (UR) (1%, 14/1778) out of every test that could be performed, compared to TA (5%, 82/1778), where 38% (31/82) of unavailable results were associated with high THI scores (≥38) in which tinnitus symptoms were causing moderate to severe handicap (Table S6 and S7). At EHF (10-16KHz) 5% (36/762) of all possible tests, using TA, were unavailable (UR), with 42% (15/36) of unavailable results having accompanying significant tinnitus (Table S7). However, 70% (531/762) of all possible tests, using SBA, had no results available (UR) at EHF, with 85% (450/531) attributed to a lack of available EHF measuring facilities (Table S6). Non recordable (NR) results that were beyond maximum threshold limits were greater with TA (4%, 68/1778) than SBA (1%, 17/1778) out of every test that could be performed between 0·25-8KHz, which increased to 27% (202/762) and 8% (62/762) respectively at the EHF range (Table S1 and S8).

TA showed good sensitivity for detecting HL as defined by BSA criteria (range 77-100%) at all frequencies between 0·25-16KHz and ASHA criteria (range 78-100%) between 0·25-12·5KHz, with high specificity (>85%) for detecting HL using both BSA and ASHA criteria between 0·25KHz and 12·5KHz (Table 4). Accuracy of TA for detecting HL was ≥88% at frequencies 0·25-12·5KHz when assessed by both BSA and ASHA criteria. There was good positive predictive value (PPV) (≥80%) and negative predictive value (NPV) (≥81%) at all frequencies using both criteria except at 16KHz when using ASHA criteria. Overall sensitivity, specificity, PPV, NPV, accuracy for detecting HL based on BSA and ASHA criteria using TA are shown in Table 4.

Bland Altman analysis (Figure S1 and Table S9) show that the mean differences (bias) were within 5dB at all frequencies and above zero (except 10KHz), with 95% limits of agreement within 15dB of the bias between 0·25KHz – 6KHz but this increased at higher frequencies (8-16KHz). Simple linear regression was conducted to evaluate the presence of proportional bias, which identified a significant negative proportional bias for frequencies 0·25– 6KHz and 12·5KHz (Figure S1 and Table S10). Using the equations generated (Table S10), Table S11 predicts the threshold when TA measurements were the same as SBA i.e. no difference between the two readings where Y=0. This was found between 25-30dB for frequencies 0·5KHz, 1KHz, 2KHz and 6KHz. There was a fixed bias observed at 8KHz showing TA was consistently 5dB above SBA and <2dB lower than SBA at 10KHz.

Analysing usability, TA demonstrated good levels of attractiveness and novelty, excellent perspicuity and efficiency, and above average dependability and stimulation scales (Figure 1). Apart from dependability, all other scale means were significantly higher for TA compared to SBA with regards to attractiveness, perspicuity, efficiency, stimulation and novelty (Table S12). Cronbach's alpha coefficient showed acceptable reliability with all scales.

Table 4 Tablet-based audiometry sensitivity and specificity for hearing loss detection according to BSA and ASHA criteria

Frequency	N	BSA >20dB, % (95% CI)					ASHA >25dB, % (95% CI)				
		Sensitivity	Specificity	PPV	NPV	Accuracy	Sensitivity	Specificity	PPV	NPV	Accuracy
0·25KHz	231	79 (66-88)	94 (90-97)	81 (70-89)	93 (89-96)	90 (86-94)	82 (66-92)	96 (92-98)	87 (67-89)	96 (93-98)	94 (90-96)
0·5KHz	231	77 (65-87)	97 (93-99)	91 (80-96)	92 (88-95)	92 (87-95)	80 (66-91)	98 (95-99)	78-96)	95 (92-97)	94 (91-97)
1KHz	232	81 (69-90)	97 (93-99)	91 (81-96)	93 (89-96)	93 (89-96)	88 (74-96)	98 (95-100)	80-97)	97 (94-99)	97 (93-99)
2KHz	233	81 (70-90)	98 (94-99)	93 (84-97)	92 (88-95)	93 (89-96)	84 (71-94)	97 (93-99)	74-93)	96 (93-98)	94 (91-97)
4KHz	230	93 (87-97)	92 (86-96)	91 (84-95)	94 (89-97)	93 (88-96)	88 (79-94)	92 (87-96)	79-92)	93 (88-96)	91 (86-94)
6KHz	228	84 (76-90)	98 (94-100)	98 (92-99)	86 (81-91)	91 (87-95)	85 (76-91)	95 (90-98)	84-96)	90 (85-94)	91 (86-94)
8KHz	222	90 (83-96)	86 (79-91)	83 (75-88)	92 (87-96)	88 (83-92)	89 (80-95)	88 (81-93)	81 73-87)	93 (88-96)	88 (83-92)
10KHz	72	85 (69-94)	91 (76-98)	92 (79-97)	83 (70-91)	88 (78-94)	78 (62-90)	97 (85-100)	97 81-100)	81 (70-89)	88 (78-94)
12·5KHz	63	95 (83-99)	95 (77-100)	98 (85-100)	91 (73-98)	95 (87-99)	100 (90-100)	89 (72-98)	92 80-97)	100 (86-100)	95 (87-99)
16KHz	9	100 (40-100)	80 (28-99)	80 (41-96)	100 (40-100)	89 (52-100)	33 (1-91)	67 (22-96)	33 7-78)	67 (43-84)	56 (21-86)
Overall 0·25-16KHz	1751	86 (83-88)	95 (93-96)	90 (88-92)	92 (90-93)	91 (90-93)	86 (83-89)	95 (94-96)	88 85-90)	94 (93-95)	92 (91-94)
Overall 0·25-8KHz	1607	85 (82-88)	95 (93-96)	90 (87-92)	92 (91-93)	91 (90-93)	86 (82-89)	95 (94-96)	87 84-90)	95 (94-96)	93 (91-94)
Overall 10-16KHz	144	90 (82-96)	92 (82-97)	94 (87-97)	87 (78-93)	91 (85-95)	87 (77-93)	91 (82-97)	92 83-96)	86 (78-92)	89 (83-94)

N=paired results, BSA= British Society of Audiology, ASHA= American Speech-Language-Hearing Association, dB=decibel, KHz=KiloHertz, CI=confidence interval, PPV= Positive predictive value, NPV=Negative predictive value

DISCUSSION

In this study, we present results from the largest study to date measuring the accuracy of TA to detect and screen for HL including both standard frequencies (0·25-8KHz) and EHF (>8KHz) ranges using circumaural headphones. TA measurements were found to be identical to SBA between 25dB and 30dB at 0·5KHz,1KHz, 2KHz, 6KHz, which is the threshold used to define HL according to ASHA criteria (>25dB). TA was as effective as SBA in detecting HL for hearing thresholds between 0·25-12·5KHz, regardless of whether BSA or ASHA criteria were used, with good sensitivity, specificity and accuracy. Ultimately clinical decision making from either method would be identical. Patient user feedback analysing usability demonstrated that TA outperformed SBA indicating preference of TA over SBA (as shown in Vijayasingam et al).[19]

Previous studies using TA has shown similar agreement to SBA alongside sensitivity, specificity, positive and negative predictive values for HL detection to that seen within our study at standard frequency ranges.[19,28–31] In this study, we have analysed efficacy of TA in a cohort with a high incidence of HL (as expected in ENT/audiology outpatients) and demonstrated accuracy of HL detection according to both BSA and ASHA criteria at a wider range of frequencies. These results strongly support TA as a screening and diagnostic test to identify HL without audiometric sound booth requirement.

HL is expected to rise to 2·5 billion people (1 in every 4) by 2050, due to an increase in the aging population, with the largest increase expected in South-East Asia and Western Pacific Regions.[1] The current provision of audiology services is insufficient to meet existing global demands with SBA requiring audiologists, high-cost equipment and audiometric sound booths that are not always available especially in low-resource areas.[1] This is further compounded by the concentration of ear and hearing care (EHC) services in urban areas in many countries with limited availability in rural settings.[32,33]

Automated technology incorporated in TA allow use by non-audiologists enabling task-sharing and re-allocation with other healthcare professionals (HCPs) (following shorter training times) to reduce audiologist workload. This is the recommended WHO strategy to increase EHC capacity and facilitate integration of the WHO H.E.A.R.I.N.G. (Hearing screening and intervention; Ear disease prevention and management; Access to technologies; Rehabilitation services; Improved communication; Noise reduction; Greater community engagement) strategy into global and national public health policy.[1] Implementation of TA within clinical pathways has been shown to enable increased accessibility to EHC services, reducing travel barriers and waiting times in rural and urban areas and reducing current health inequalities in both LMIC and HICs.[17,34]

In this study, we identified limited facilities for EHF monitoring using SBA with only two out of six audiometric sound booths having this capability highlighting the limited ability for early HL detection in standard audiometric settings. TA has this provision when used with circumaural headphones which increases accessibility to EHF monitoring and enables the potential for TA to be used to detect early changes in hearing with ototoxic chemicals/medications and noise-induced HL as part of occupational screening in workplaces and ototoxicity monitoring programmes where aminoglycoside antibiotics are a core part of MDRTB, non-tuberculosis mycobacteria (NTM) and CF treatments. Detection of HL at early stages would help mitigate

significant HL by consideration of alternative therapies or dose adjustment through shared decision making. The portability of TA also enables use within stringent infection prevention control practices as often required in the presence of drug-resistant infections in CF, NTM or TB practices where currently routine ototoxicity monitoring is lacking.[35,36]

Although the use of digital technology such as TA can potentially improve societal HL detection and screening, considerable challenges still remain with a secondary increased demand for aural rehabilitation services and requirement for hearing aid use. Within LMICs the cost of hearing aids can limit uptake in individuals or services who lack the resources to purchase, fit, deliver, maintain and support hearing aid use. Hearing aid prices vary across different regions and although cheaper versions are available in LMICs, digital hearing aids remain costly and ongoing expenses, including batteries, can exceed the annual salary of an average African family.[37,38] Travel costs to EHC facilities, which are scarce in LMICs, may further present adoption barriers.[39] Devices that can be delivered by teleaudiology, together with rechargeable batteries/devices are potential solutions to help address ongoing costs and the lack of trained staff.[37,40] The WHO have proposed solutions to mitigate costs but the percentage of people needing hearing aids but not using them is 90% in the African WHO region compared to 77% in the European region.[1] HL is exacerbated by the time (usually 10 years) individuals accept that they have a hearing problem with the stigma of wearing hearing aids often associated with aging leading to delay.[41] Further education, communication and promotion of role models wearing hearing aids is required.[1,42] Health-economic modelling has suggested that increasing EHC services to cover 50% of the global population by 2030 would cost US$ 75 billion but would avert >110 million DALYs over 10 years, benefiting 1·25 billion people, producing US$1·2 trillion health gains resulting in US$2·1 trillion in productivity returning US$ 15·8 for every US$1 invested.[1]

Our study has nevertheless highlighted some limitations in use of TA for HL detection. Approximately a third of individuals with unavailable results had severe tinnitus symptoms suggesting that SBA would be more appropriate for HL screening/detection in tinnitus patients. Although, TA had a higher percentage of non-recordable results compared to SBA, this is likely due to the shorter threshold range available which is unlikely to affect clinical decision making regarding hearing aid requirement (which is based on patient's symptomatic need and their engagement and not whether the degree of HL is severe or profound).[43] We had fewer paired tests available at EHF in our cohort to analyse accuracy of TA compared to SBA given the high prevalence of HL. Furthermore, in our study we did not monitor ambient environmental noise levels to determine if they exceeded the maximum permissible which may explain the higher thresholds observed at low frequencies, consistently seen with other studies using mobile audiometry outside the sound booth environment.[44] Lastly, this study only tested adults who were able to consent, and hence we are unable to comment on accuracy and usability of TA in children (cognitive immaturity), and in individuals with cognitive impairment e.g. dementia.[44]

In summary, we have shown in this study that tablet-based audiometry is an acceptable, accurate alternative to audiometric sound booth testing to increase accessibility of HL screening at standard and extended high frequency ranges and can be used as a diagnostic test for HL in individuals without significant tinnitus. Further prospective research is required to evaluate efficacy and cost-effectiveness of TA within established clinical pathways and screening

programmes. Use of tablet-based audiometry within a global setting both in HICs and LMICs can likely assist in early HL detection particularly where access to audiometry resource is limited.

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Competing interests

AS has received research grants from AstraZeneca & Pfizer, consulting fees from Mundipharma, AstraZeneca & Pfizer, participated on advisory board for Mundipharma & AstraZeneca. JC has received hospitality from Tillots. All other authors report no competing interests.

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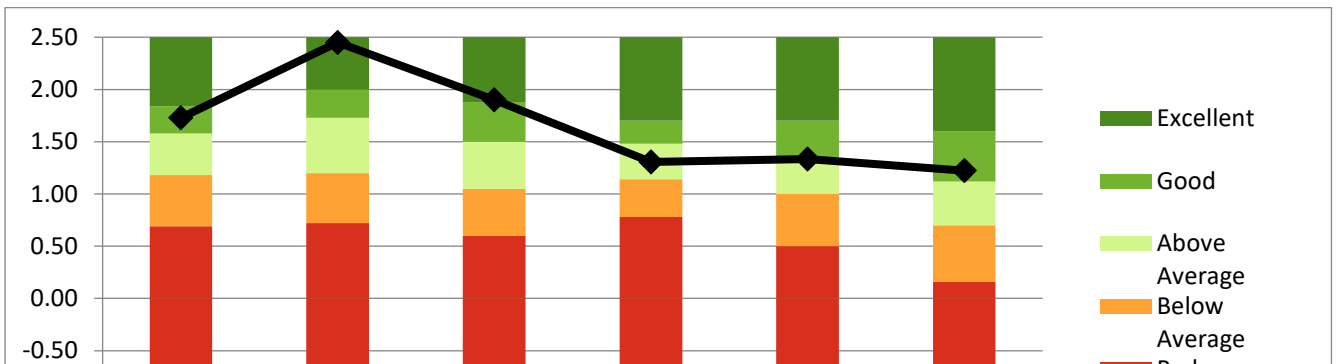
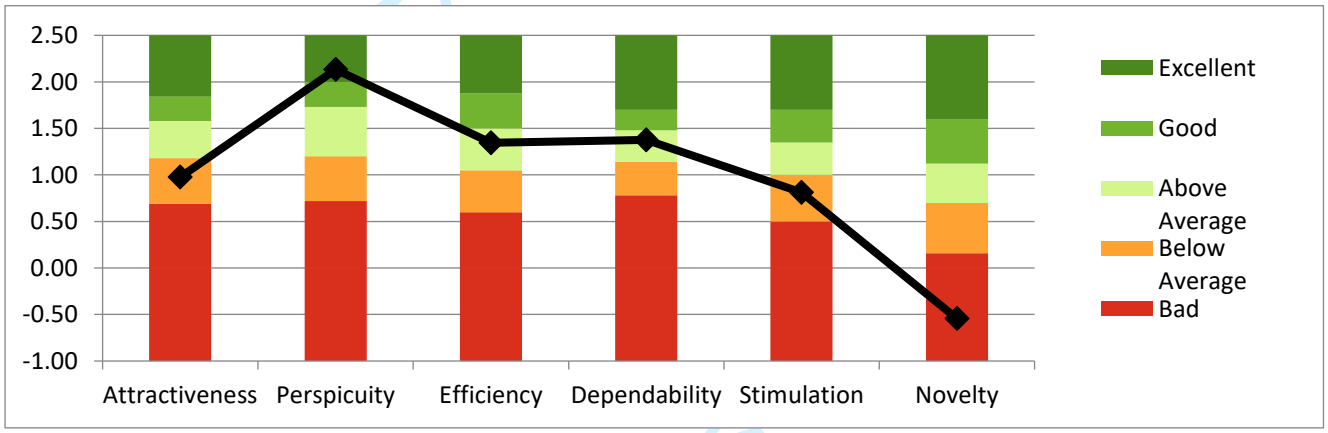
Figure 1 User Experience Questionnaire (UEQ) results

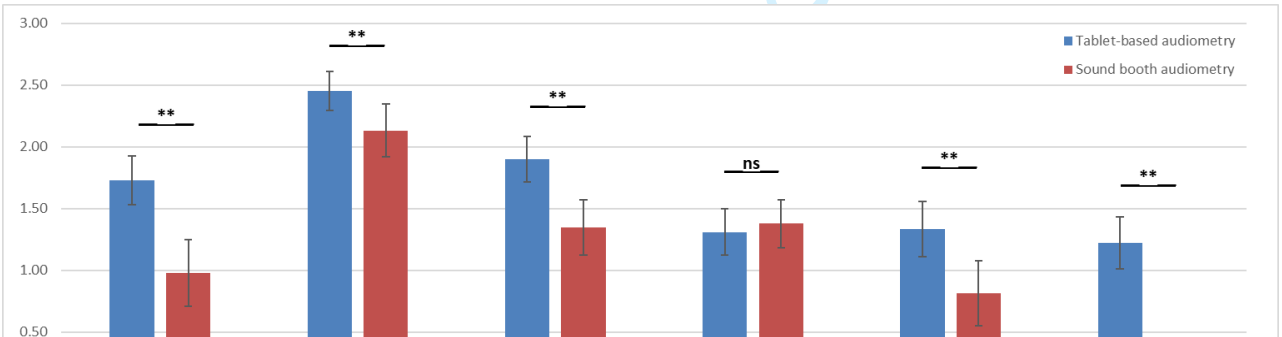
A) User Experience Questionnaire Benchmark graph of Tablet-based audiometry



B) User Experience Questionnaire Benchmark graph for Sound-booth audiometry



C) Comparison analysis of UEQ in tablet-based audiometry and sound booth audiometry



Comparison of scale means, ** = significant p<0.05, ns=not significant

A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry - Supplementary material

Table S1 - Numbers of possible tests and results

Frequency	Maximum possible tests	SBA			TA			Paired results
		Available results	UR	NR	Available results	UR	NR	
0.25 KHz	254	251	2	1	233	12	9	231
0.5 KHz	254	251	2	1	233	12	9	231
1 KHz	254	251	2	1	234	11	9	232
2 KHz	254	251	2	1	235	10	9	233
4 KHz	254	250	2	2	233	12	9	230
6 KHz	254	250	2	2	231	13	10	228
8 KHz	254	243	2	9	229	12	13	222
10 KHz	254	82	161	11	222	12	20	72
12.5 KHz	254	77	156	21	196	12	46	63
16 KHz	254	10	214	30	106	12	136	9

SBA = sound booth audiometry, TA = Tablet-based audiometry, KHz=Kilo Hertz, Available results (within threshold limits), UR unavailable results, NR = non recordable results as beyond maximum limits.

Table S2 - Referrals for sound booth audiometry

Referrals	**Number of patients (%)**
ENT	91 (72)
GP	19 (15)
Hospital -Acute medicine -Cystic fibrosis -Haematology -Nephrology -Neurology -Oncology	14 (11) 1 1 2 1 3 6
School nurse	1 (<1)
Self-referral	1 (<1)
(blank)	1 (<1)

Table S3 - Main reason for sound booth audiometry

Hearing loss	Number of patients (%)
ENT symptoms – including (congestion, parotid gland, nasal polyps, sinusitis	3 (2)
Middle ear symptoms – including cholesteatoma, otosclerosis otitis media, fungal infection, perforation, grommets, mastoiditis, retracted ear drum, eustachian tube dysfunction or congestion, conductive hearing loss	30 (24)
Drug-induced (chemo/radiotherapy, COVID-19 vaccine, Kaftrio, iron chelating agent, epidural)	5 (4)
Noise-induced	2 (2)
Unknown	18 (14)
Inner ear – including labyrinthitis, including sudden onset	6 (5)
Suspected/hereditary	2 (2)
Presbycusis	1 (<1)
Acoustic neuroma	1 (<1)
Other tumours causing hearing loss (oropharyngeal, paraglangliomas)	2 (2)
Syndrome (Postural Tachycardia Syndrome, Alport, Sebastian, Turners, Susacs)	5 (4)
Trauma (road traffic accident, diving)	2 (2)
Dizziness/vertigo/balance	22 (17)
Tinnitus	16 (13)
Meniere's disease	1 (<1)
Treatment/operation protocol (chemotherapy, radiotherapy, myringoplasty)	6 (5)
Auditory processing disorder	1 (<1)
Ear pain	1 (<1)
Impacted wax	1 (<1)
Fullness in ear	1 (<1)
Otitis externa	1 (<1)

Table S4- Medications with ototoxic side effects (dizziness, tinnitus, other ear related)

Concurrent Medications	N (%)	Medications in the previous 3 months	N (%)
Antidepressants	15 (12)	Loop diuretics	0 (0)
Aspirin or NSAIDs	11 (9)	Macrolides	4 (3)
Co-trimoxazole	1 (<1)	Intravenous aminoglycoside	1 (<1)
Quinolones	1 (<1)	Inhaled/nebulised aminoglycoside	0 (0)
Tetracyclines	1 (<1)	Ear drops containing aminoglycoside	4 (3)
CFTR modulators	1 (<1)	Vancomycin	0 (0)
Bisphosphonates	2 (2)	Cancer chemotherapy	2 (2)
ACEI & A2RA	13 (10)	Aspirin or NSAIDs	53 (42)
Antiepileptics	4 (3)	Quinine	0 (0)
Opioids	4 (3)	None	63 (50)
Calcium channel blockers	8 (6)		
Immunosuppressants	2 (2)		
Antipsychotics	2 (2)		
Lithium	1 (<1)		
Atorvastatin	7 (6)		
Cosopt eye drops	1 (<1)		
Chemotherapy	1 (<1)		
Iron chelating agent	1 (<1)		
Methylphenidate	1 (<1)		
Rutiximab	1 (<1)		
None	49 (39)		

N=number of patients, NSAIDs=non-steroidal anti-inflammatory drugs, CFTR=cystic fibrosis transmembrane conductance regulator, ACEI=angiotensin-converting enzyme inhibitors, A2RA=angiotensin 2 receptor antagonist

Table S5– Tablet audiometry threshold difference within 10dB of Sound Booth Audiometry

Frequency	Paired results	Paired results within 10dB of SBA (%)
0.25KHz	231	216 (94)
0.5KHz	231	220 (95)
1KHz	232	225 (97)
2KHz	233	221 (95)
4KHz	230	222 (97)
6KHz	228	207 (91)
8KHz	222	178 (80)
10KHz	72	63 (88)
12.5KHz	63	53 (84)
16KHz	9	7 (78)
Total	1751	1612 (92)

KHz=KiloHertz, SBA = sound booth audiometry, dB=decibel

Table S6- Sound booth audiometry unavailable results (UR)

	Sound booth audiometry Unavailable results, N (%)			
	0.25-8KHz	10KHz	12.5KHz	16KHz
Digital failure - Lost results	14 (100)	2 (1)	2 (1)	2 (1)
Digital failure - 10-16KHz not available		2 (1)	2 (1)	2 (1)
10-16KHz not requested		2 (1)	2 (1)	2 (1)
Not measured – unknown		5 (3)		58 (27)
10-16KHz Not available		150 (93)	150 (96)	150 (70)
Total	14	161	156	214

KHz=KiloHertz

Table S7–Tablet-based audiometry unavailable results (UR)

	Tablet-based audiometry unavailable results, N (%)									
	0.25KHz	0.5KHz	1KHz	2KHz	4KHz	6KHz	8KHz	10KHz	12.5KHz	16KHz
THI=0-16	0	0	0	0	0	1 (8)	0	0	0	0
THI=38-56	2 (17)	2 (17)	1 (9)	2 (20)	2 (17)	2 (15)	2 (17)	2 (17)	2 (17)	2 (17)
THI=58-76	3 (25)	3 (25)	1 (9)	2 (20)	3 (25)	3 (23)	3 (25)	3 (25)	3 (25)	3 (25)
Upload failure	4 (33)	4 (33)	4 (36)	4 (40)	4 (33)	4 (31)	4 (33)	4 (33)	4 (33)	4 (33)
Unknown	3 (25)	3 (25)	5 (45)	2 (20)	3 (25)	3 (23)	3 (25)	3 (25)	3 (25)	3 (25)
Total	12	12	11	10	12	13	12	12	12	12

THI=Tinnitus Handicap Inventory, KHz=KiloHertz,

Table S8 - Threshold Limits

Frequency	Tablet-based audiometry		Sound booth audiometry			
	Minimum dB	Maximum dB	Minimum dB		Maximum dB	
			GST	UHD	GST	UHD
0.25KHz	10	90	-10	-10	90	105
0.5KHz	10	90	-10	-10	110	110
1KHz	10	90	-10	-10	110	110
2KHz	10	90	-10	-10	110	110
4KHz	10	90	-10	-10	110	110
6KHz	10	90	-10	-10	100	110
8KHz	10	90	-10	-10	70	105
10KHz	10	85	-20	-	80	-
12.5KHz	10	80	-20	-	70	-
16KHz	10	55	-20	-	40	-

dB=decibel, KHz=KiloHertz, GST=Guy's & St Thomas', UHD=University Hospitals Dorset

Table S9 - Bland Altman results for each frequency

Frequency	N=	Bias	SD of Bias	95% limits of agreement	
				From	To
0.25KHz	231	2.662	6.251	-9.590	14.91
0.5KHz	231	1.255	6.439	-11.37	13.88
1KHz	232	1.207	6.035	-10.62	13.03
2KHz	233	1.009	6.395	-11.53	13.54
4KHz	230	1.065	6.291	-11.27	13.40
6KHz	228	0.3289	7.867	-15.09	15.75
8KHz	222	5.000	8.388	-11.44	21.44
10KHz	72	-1.806	9.166	-19.77	16.16
12.5KHz	63	3.095	8.153	-12.89	19.08
16KHz	9	0.5556	11.02	-21.05	22.16

N=paired results, KHz=KiloHertz, SD= standard deviation

Table S10 - Simple linear regression

Frequency	r^2	95% CI	P value	F statistic	DFn, DFd	Equation
0.25KHz	0.06170	-0.1685 to -0.05501	**0.0001**	15.06	1, 229	Y = -0.1118*X + 4.552
0.5KHz	0.1479	-0.2226 to -0.1166	**<0.0001**	39.74	1, 229	Y = -0.1696*X + 4.335
1KHz	0.07137	-0.1569 to -0.05676	**<0.0001**	17.68	1, 230	Y = -0.1068*X + 4.22
2KHz	0.1434	-0.2077 to -0.1078	**<0.0001**	38.68	1, 231	Y = -0.1577*X + 4.55
4KHz	0.04449	-0.1224 to -0.03014	**0.0013**	10.61	1, 228	Y = -0.07627*X + 3.956
6KHz	0.04556	-0.1369 to -0.03422	**0.0012**	10.79	1, 226	Y = -0.08553*X + 3.577
8KHz	1.506e-006	-0.05024 to 0.05118	0.9855	0.0003313	1, 220	Y = 0.0004683*X + 4.987
10KHz	0.001346	-0.1155 to 0.08468	0.7596	0.09434	1, 70	Y = -0.01541*X + 4.337
12.5KHz	0.2376	-0.2496 to -0.09264	**<0.0001**	19.01	1, 61	Y = -0.1711*X + 4.883
16KHz	0.07314	-1.487 to 0.7756	0.4815	0.5524	1, 7	Y = -0.3556*X + 4.656

r^2= coefficient of determination, CI= confidence interval, DFn= numerator degrees of freedom (regression df), DFd = denominator degrees of freedom (residual df), F statistic= explained variance Unexplained variance.

Table S11 Threshold at which Tablet-based Audiometry and Sound Booth Audiometry are equal

Frequency	Threshold (dB)
0.25KHz	41.6
0.5KHz	25.6
1KHz	29.2
2KHz	25.1
4KHz	38.8
6KHz	30.1
8KHz	N/A
10KHz	N/A
12.5KHz	-52.5
16KHz	N/A

dB=decibel, KHz=KiloHertz, N/A=not applicable

Table S12 - User Experience Questionnaire (UEQ) results of tablet-based audiometry & sound booth audiometry

A) Tablet-based audiometry

Scale	Mean	Std. Dev.	N	Confidence	Confidence interval		Cronbachs Alpha-coefficient	Confidence interval Cronbachs Alpha
Attractiveness	1.729	0.998	100	0.196	1.533	1.924	0.85	0.80-0.89
Perspicuity	2.450	0.808	100	0.158	2.292	2.608	0.75	0.65-0.62
Efficiency	1.900	0.951	100	0.186	1.714	2.086	0.69	0.56-0.77
Dependability	1.308	0.957	100	0.188	1.120	1.495	0.57	0.41-0.69
Stimulation	1.335	1.136	100	0.223	1.112	1.558	0.82	0.75-0.87
Novelty	1.223	1.073	100	0.210	1.012	1.433	0.63	0.49-0.73

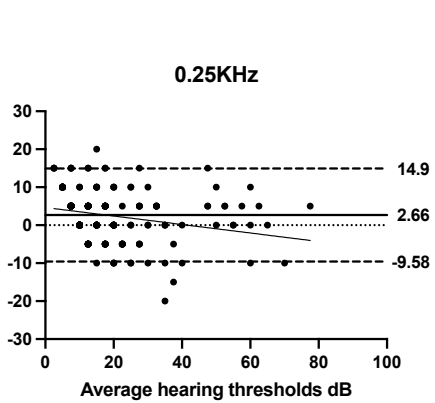
B) Sound booth audiometry

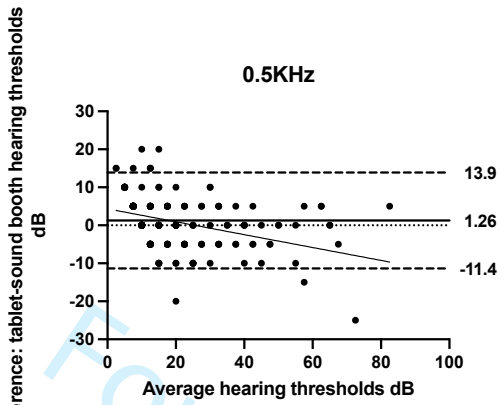
Scale	Mean	Std. Dev.	N	Confidence	Confidence interval		Cronbachs Alpha coefficient	Confidence interval Cronbachs Alpha
Attractiveness	0.977	1.324	93	0.269	0.708	1.247	0.91	0.88-0.94
Perspicuity	2.132	1.051	93	0.214	1.918	2.345	0.87	0.82-0.91
Efficiency	1.347	1.113	93	0.226	1.121	1.573	0.68	0.56-0.77
Dependability	1.376	0.945	93	0.192	1.184	1.568	0.56	0.39-0.69
Stimulation	0.812	1.296	93	0.263	0.548	1.075	0.86	0.81-0.90
Novelty	-0.543	1.188	93	0.241	-0.784	-0.302	0.69	0.57-0.78

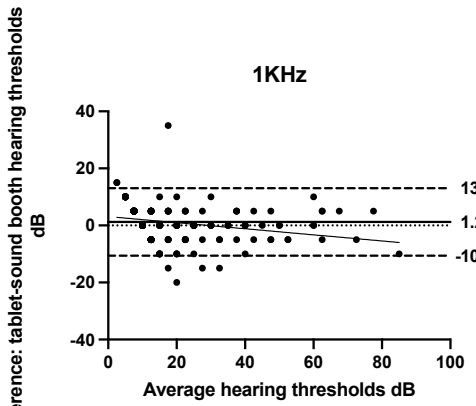
C) T-test of scale means tablet-based audiometry compared with sound booth audiometry

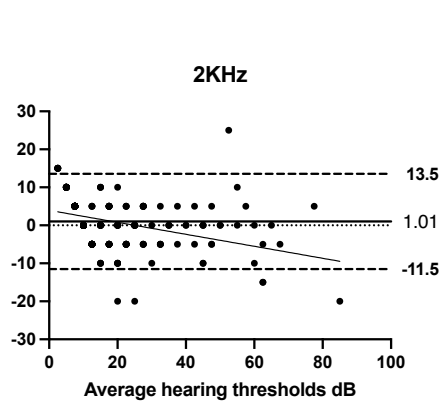
Scale	P value
Attractiveness	0.0000
Perspicuity	0.0201
Efficiency	0.0003
Dependability	0.6158
Stimulation	0.0033
Novelty	0.0000

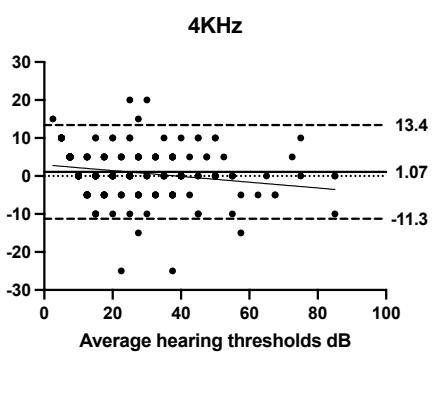
Figure S1 Bland Altman plot per frequency: difference between tablet-based and sound booth audiometry verses average hearing threshold

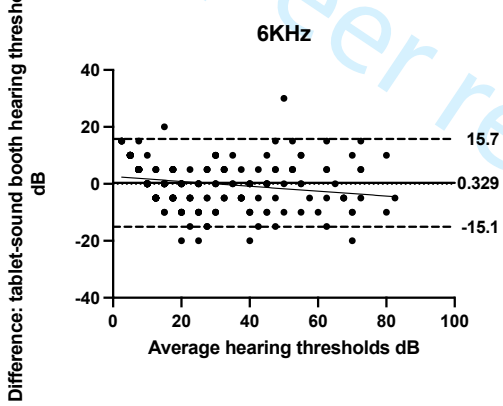


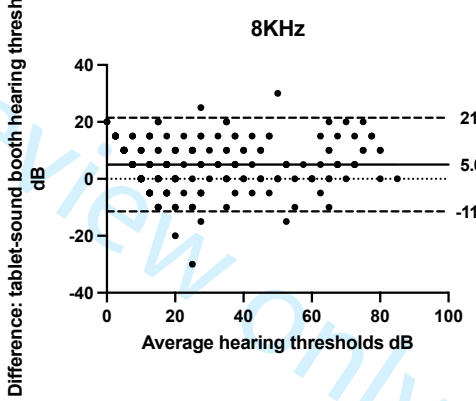


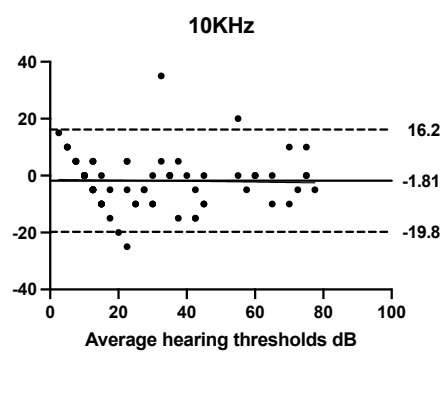


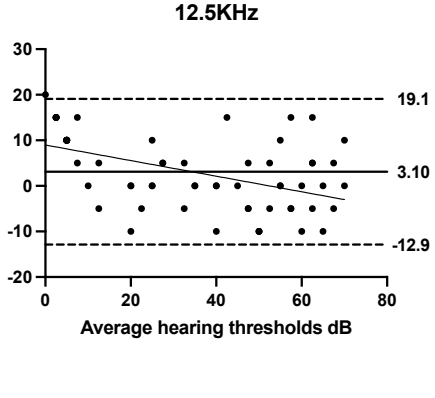


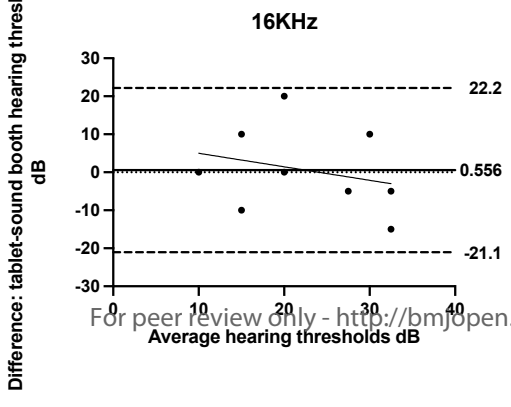












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A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry

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A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry

ABSTRACT

Objectives Hearing loss (HL) affects 20% of the world's population, with shortages of audiologists and audiometric sound booths unable to meet demand for hearing care services. We aimed to assess the accuracy of tablet-based audiometry (TA) to screen for HL at standard (0·25-8KHz) and extended high frequencies (>8KHz).

Design Diagnostic accuracy study.

Setting Two secondary care audiology and ENT outpatient clinics in the UK between April 2022-September 2023.

Participants Adults aged ≥16 years undergoing sound booth audiometry (SBA).

Interventions Tablet-based audiometry, hearing-related questionnaires, patient usability questionnaires.

Outcome measures Sensitivity, specificity and accuracy of TA compared to SBA for detecting HL. Patient usability assessment of TA and SBA.

Results 129 patients were enrolled with 127 patients (254 ears) included in the final analysis. Median age was 43 years (IQR 33-56), 55% (70/127) were female. 76% (96/127) and 68% (86/127) of patients had HL defined by British Society of Audiology (BSA) and American Speech-Language-Hearing Association (ASHA) criteria. Age was significantly associated with hearing loss (p<·0001), however hearing-related questionnaire scores were not significantly different between those with or without HL. There was no significant difference in detecting HL between TA and SBA using either BSA or ASHA criteria at each frequency. 92% (1612/1751) of TA results were within 10dB agreement with SBA results. Sensitivity and specificity of TA for detecting HL was 77-100% and >85% respectively between 0·25-12·5KHz. In terms of patient usability TA showed significantly higher scores in attractiveness (p<·0001), novelty (p<·0001), efficiency (p=·0003), stimulation (p=·003) and perspicuity (p=·02).

Conclusions TA demonstrated good sensitivity with high specificity for detecting HL at frequencies 0·25-12·5KHz and would be an acceptable accurate alternative to SBA. This would increase accessibility of HL screening and has the potential to be used as a diagnostic test in those without tinnitus where resources are limited.

Trial registration number NCT05847556)

Strengths and limitations of this study

- Prospective multicentre study measuring accuracy of tablet-based audiometry at both standard frequencies (0·25-8KHz) and extended high frequencies (>8KHz).
- Patient usability of a novel device is reported.
- Fewer paired test results at extended high frequencies were due to a lack of facilities measuring this frequency range.

- Ambient environmental noise was not measured.

INTRODUCTION

Hearing loss (HL) is a reduced perception of sound, defined by the WHO as hearing thresholds ≥20dB, which in 2019, affected 1·57 billion people or, 20·3% of the global population.[1,2] The incidence of HL increases with advancing age with 42% of those over 60 years having hearing impairment caused by natural degenerative changes in the ear, lifetime ototoxic injuries, genetic susceptibility and/or modifiable lifestyle behaviours. More than 50% of HL is preventable (ear infections, vaccine preventable illness, exposure to noise, chemicals and medications).[1] Intravenous aminoglycoside (IVAG) antibiotics remain a cornerstone of infection treatment and are used globally especially in patients with chronic respiratory infections such as those with multidrug-resistant tuberculosis (MDRTB) and other mycobacterial infections.[3] Irreversible ototoxicity is a known side-effect of IVAG; the global prevalence of HL associated with exposure to short courses of IVAG (<16 days) is 16·6% and for MDRTB is 40·6%.[4] Despite their widespread use, systems for identifying early HL in low- or middle-income countries (LMICs) are scarce.[5]

Delayed diagnosis of HL in children can cause speech and language development issues continuing into adulthood, with children less likely to go onto higher education, more likely to be unemployed, have poorer mental health, lower quality of life, and social isolation affecting cognition. HL is the second highest modifiable risk factor (after depression) for enhancing dementia-related problems.[1,6] HL is associated with increased healthcare expenditure, loss of productivity and reduced quality of life with an estimated global cost exceeding $981 billion in 2019.[7]

The gold standard in high-income countries (HICs) for monitoring hearing is testing by audiologists within audiometric sound booths which reduce ambient noise and assess HL typically within speech range frequencies (0·25-8KHz).[8] However, the increased demand on audiology services, along with a shortage of audiologists has led to HICs unable to meet existing demand.[9,10] LMICs in particular have a scarcity of audiologists (78% of countries in Africa have less than one audiologist per one million population) compared to HICs (52% of countries in Europe have ten audiologists per one million population).[1] The expense of installing audiometric booths also limits availability.[11] Age-related, noise- and drug-induced HL initially occurs at extended high frequencies (EHF, >8KHz) before affecting speech range frequencies and hence, EHF monitoring is recommended for early detection in high-risk populations allowing for alternative drug treatment regimens, reductions in noise exposure and aural rehabilitation. [12–16] A 5% reduction in the prevalence of HL has been estimated to reduce global costs by $49billion.[7] However, at present, EHFs are not routinely monitored during standard sound booth audiometry (SBA) with HL detection occurring only after progression to speech range frequencies.

Boothless audiometry using mobile technology could provide a solution to overcome the challenges of availability, cost and accessibility to the limited numbers of sound booths in LMICs and HICs.[1,17] Tablet-based audiometry (TA) using automated technology also reduces operator training requirement and allows trained staff other than audiologists to provide surveillance

screening services.[17] Circumaural transducers used without booths for monitoring EHFs have good noise attenuation and could improve accessibility to hearing screening and achieve earlier diagnosis of HL.[18] Boothless audiometry measuring EHF is therefore required to detect HL in ototoxic drug and noise exposure or where SBA is unavailable. TA using Shoebox has been validated in other studies in children and adults attending audiology outpatients, emergency departments, or patients with cognitive impairment, at frequencies up to 8KHz.[19–26] Our previous work has demonstrated the use of TA as an accurate screening tool in individuals with cystic fibrosis (CF) up to frequencies of 12·5KHz.[27] Unlike most other published studies, we have conducted a multicentre study, analysing TA accuracy compared to SBA at both standard frequencies (0·25-8KHz) and EHF up to 16KHz, in a general audiology and ear, nose and throat (ENT) outpatient clinic setting. Additionally, we have also focused on assessing the TA and SBA approaches from the patients' perspective, including the usability of both audiometric processes.

METHODS

Study design and procedures

Audiometry and data collection were performed prospectively in this diagnostic accuracy study conforming to STARD guidelines of the Shoebox Standard Limited portable audiometer compared to SBA as the gold standard.[28] Patients were recruited from audiology and ENT outpatient clinics at Guy's & St Thomas' NHS Foundation Trust and University Hospitals Dorset NHS Foundation Trust across two locations in the UK. Ethical approval was obtained from the Health Research Authority (HRA) and Health and Care Research Wales (HCRW) West Midlands – Edgbaston Research Ethics Committee on February 4, 2022 (IRAS project ID 298372) and registered on clinicaltrials.gov (NCT05847556) where the full protocol can be accessed.

Demographic information, medical and drug history, referral, reason for audiometry if known were recorded. Data were entered onto a RedCap database (14·1·4). Definition of HL was defined by the British Society of Audiology (BSA) as thresholds >20dB and American Speech-Language-Hearing Association (ASHA) standards as thresholds >25dB.[15,29] Scores for hearing-related questionnaires were assigned: no (0 points), sometimes (2 points) and yes (4 points) with total scores categorised into different severities.[30–32]

Any patient aged 16 years or over attending the ENT and audiology clinics, between April 2022 and September 2023, who consented were eligible to participate. Those exposed to ototoxic medicines or noise and who agreed to take part in the study were also included and listed in the Supplementary material. Those who were aged <16 years or unable to provide informed consent were excluded. SBA was carried out by an audiologist in a sound attenuated booth/room. TA was self-administered by the patient with supervision by another staff member not carrying out SBA (pharmacist, ENT doctor, audiologist) in a quiet clinic room. Objective measures do not always correlate with subjective symptoms and disability experienced varies among individuals with the same disease.[33] Use of questionnaires to assess disease burden can help address symptoms that are not identified by standard hearing tests. We wanted to observe if the presence of tinnitus affects TA performance, and how TA compares to hearing-related questionnaires for HL

screening. Validated hearing-related questionnaires were completed by patients in between SBA and TA sessions: Hearing Handicap Inventory for Adults (HHIA, 25-item assessment of hearing impairment on emotional, social adjustments in adults), and if experiencing symptoms of tinnitus or dizziness, Tinnitus Handicap Inventory (THI, 25-item reviewing functional, emotional and catastrophic disability scales) and Dizziness Handicap Inventory (DHI, 25-item evaluating functional, emotional and physical domains).[34–36] They were also asked to fill in the User Experience Questionnaire (UEQ) about their experience of TA and SBA, which is a quick validated tool to measure the user's experience.[37] The UEQ assesses hedonic and pragmatic quality aspects involving 26 polarised statements graded on a 7-point Likert scale to gauge patient opinions on six scales: attractiveness, perspicuity, dependability, efficiency, novelty, stimulation. This was created on a Qualtrics survey to produce an electronic form. Patients completed two UEQs (one for each type of audiometry) after finishing both audiometry sessions. As SBA was part of the patient's standard of care, 30-45 minutes was allowed for TA, ototoxicity questionnaires and UEQs. Audiologists carrying out SBA were blinded to the TA results.

The clinical audiometer used in SBA was the Natus Aurical calibrated according to BSA standards.[29] TA was carried out using Shoebox Standard edition software application on Apple iPads with circumaural Radioear DD450 transducers measuring frequencies 0·25-16KHz, calibrated by Shoebox Limited to comply with American National Standards Institute standards (ANSI S3·6-1996-2010). Adult pure tone automated test mode was selected on the Shoebox Standard application which uses a Modified Hughson Westlake algorithm. Hearing thresholds for 0·25KHz, 0·5KHz, 1KHz, 2KHz, 4KHz, 6KHz, 8KHz 10KHz, 12·5KHz, 16KHz were compared between TA and SBA.

Statistical analysis

Sample size calculation was performed to measure sensitivity and specificity of TA compared to SBA with an expected sensitivity at 90% and specificity of 85%, with 95% confidence interval, using an estimated prevalence of hearing loss higher than the normal population of 50% given the cohort being referred for ENT review, and an expected 10% drop out rate. This revealed a minimum of 109 patients was required to achieve statistical power. Statistical analyses were performed using GraphPad Prism Version 10·1·1 (270). Right and left ear thresholds were combined for each frequency. Mean/median were calculated for parametric/non-parametric data. Chi-squared or Fisher's exact tests were used for categorical data. TA measurements were compared with SBA results using Bland Altman plots to visually assess agreement, correlation, paired t-tests to observe the differences between the two types of measurements, and simple linear regression was used to determine presence of proportional bias. Cronbach's alpha test was used to assess reliability. Sensitivity, specificity, positive and negative predictive values with 95% confidence intervals were calculated. Statistical significance was defined as $p<0·05$. Usability was analysed using the User Experience Questionnaire (UEQ) with data analysis performed through the online tools on www.ueq-online.org.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of this research.

RESULTS

Between 16/3/2022 and 15/9/2023, 129 patients were enrolled with 127 patients (254 ears) included in the final analysis (two patients were excluded-one was pregnant, the SBA and TA were more than one week apart for another patient) (Figure S1). The numbers of possible tests and results available for data analysis are shown in Table S1. 98% (124/127) of patients carried out TA on the same day as SBA, with 2% (3/127) of TA performed within five days of SBA.

Table 1 shows the demographic data and the incidence of HL based on BSA (76%) and ASHA (68%) thresholds: median age was 43 years (IQR 33-56), 70 (55%) were female, 79 (62%) were white British. 91 patients (72%) were referred by ENT and primary reasons for SBA were related to middle ear symptoms (24%) or dizziness/vertigo/balance issues (17%) (Table S2 and S3). Most common concurrent medication with ear related side effects were antidepressants (12%) and 42% of patients had received aspirin or NSAIDs in the previous three months (Table S4). Age was significantly associated with HL regardless of the criteria used, all other characteristics were not (sex, ethnicity, hearing-related questionnaire scores) with no significant difference in HL between BSA and ASHA thresholds (Table 1). Based on BSA criteria in patients without apparent HL, 39% (12/31), 39% (12/31) and 58% (18/31) had HL, tinnitus and dizziness symptoms respectively, causing at least mild handicap or above based on questionnaire scores of HHIA>16, THI>16 and DHI>0. A similar trend was observed with ASHA criteria at 41% (17/41), 39% (16/41) and 51% (21/41) respectively in patients with no HL.

Table 1 – Demographic patient data for frequencies 0·25-8KHz

Characteristic	N (%) or median (IQR)	Individuals with HL as per BSA threshold (%)	No HL (%)	P value	Individuals with HL as per ASHA threshold (%)	No HL (%)	P value
No. Patients	127 (100)	96 (76)	31 (24)	..	86 (68)	41 (32)	·21
Median age of patients, years	43 (33-56)	47 (36-60)	35 (26-43)	**<·0001**	48 (37-60)	35 (27-43)	**<·0001**
Female	70 (55)	54 (56)	16 (52)	·68	48 (56)	22 (54)	·85
HHIA				·10			·09
-0-16 (No handicap)	58 (46)	39 (41)	19 (61)		34 (40)	24 (59)	
-18-42 (mild-moderate handicap)	43 (34)	37 (39)	6 (19)		34 (40)	9 (22)	
-44-100 (significant handicap)	26 (20)	20 (21)	6 (19)		18 (21)	8 (20)	
THI				·51			·23
No symptoms	38 (30)	27 (28)	11 (35)		23 (27)	15 (37)	
-0-16 (slight/no handicap)	36 (28)	28 (29)	8 (26)		26 (30)	10 (24)	
-18-36 (mild handicap)	16 (13)	11 (11)	5 (16)		10 (12)	6 (15)	
-38-56 (moderate handicap)	17 (13)	12 (13)	5 (16)		10 (12)	7 (17)	
-58-76 (severe handicap)	11 (9)	9 (9)	2 (6)		8 (9)	3 (7)	
78-100 (catastrophic handicap)	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	
Missing data	9 (7)	9 (9)	0 (0)		9 (10)	0 (0)	
DHI				·23			·66
No symptoms	69 (54)	57 (59)	12 (39)		50 (58)	19 (46)	
-0-30 (mild)	35 (28)	24 (25)	11 (35)		22 (26)	13 (32)	
-31-60 (moderate)	15 (12)	9 (9)	6 (19)		9 (10)	6 (15)	
-61-100 (severe)	4 (3)	3 (3)	1 (3)		2 (2)	2 (5)	
Missing data	4 (3)	3 (3)	1 (3)		3 (3)	1 (2)	
Ethnicity (patients)				·23			·26
-African	5 (4)	2 (2)	3 (10)		2 (2)	3 (7)	
-Bangladeshi	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-Black other	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-Caribbean	5 (4)	4 (4)	1 (3)		3 (3)	2 (5)	
-Chinese	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-Indian	4 (3)	2 (2)	2 (6)		1 (1)	3 (7)	
-Other	4 (3)	2 (2)	2 (6)		1 (1)	3 (7)	
-Other mixed background	4 (3)	2 (2)	2 (6)		2 (2)	2 (5)	
-Unspecified	1 (1)	1 (1)	0 (0)		1 (1)	0 (0)	
-White & Asian	1 (1)	0 (0)	1 (3)		0 (0)	1 (2)	
-White & Black African	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-White & Black Caribbean	2 (2)	1 (1)	1 (3)		1 (1)	1 (2)	
-White British	79 (62)	66 (69)	13 (42)		60 (70)	19 (46)	
-White Irish	2 (2)	2 (2)	0 (0)		2 (2)	0 (0)	
-White Other	14 (11)	10 (10)	4 (13)		9 (10)	5 (12)	

IQR= interquartile range, HL= hearing loss, BSA= British Society of Audiology >20dB, ASHA=American Speech-Language-Hearing Association >25dB, HHIA=Hearing Handicap Inventory for Adults, THI=Tinnitus Handicap Inventory, DHI=Dizziness Inventory Handicap

There was no significant difference in detecting HL between TA and SBA using either BSA or ASHA criteria (Table 2). Mean pure tone thresholds for each frequency for TA and SBA are shown in Table 3. Sub-analysis of mean pure tone paired thresholds (Tables S5 and S6) comparing only where SBA thresholds were abnormal according to BSA (>20dB) and ASHA (>25dB) criteria for hearing loss revealed that six (0·5KHz, 1KHz, 2KHz, 6KHz, 8KHz, 10KHz) and five (0·5KHz, 2KHz, 6KHz, 8KHz, 10KHz) thresholds respectively remain significantly different compared to

seven thresholds (0·25-4KHz, 8KHz, 12·5KHz) of all paired thresholds (Table 3). TA results were highly correlated for most frequencies (0·25-12·5KHz) but not directly comparable to SBA results (except at 6KHz, 10KHz and 16KHz) (Table 3). 92% of TA results however were within 10dB agreement with SBA results highlighting agreement for most frequencies (Table S7).

Table 2 – Hearing loss detected at pure tone thresholds according to BSA and ASHA criteria

Frequency	Paired results	BSA (>20dB)			ASHA (>25dB)		
		TA N (%)	SBA N (%)	P value	TA N (%)	SBA N (%)	P value
0·25KHz	231	54 (23)	56 (24)	·91	40 (17)	39 (17)	1·00
0·5KHz	231	53 (23)	62 (27)	·39	41 (18)	46 (20)	·63
1KHz	232	56 (24)	63 (27)	·52	40 (17)	42 (18)	·90
2KHz	233	61 (26)	70 (30)	·41	44 (19)	45 (19)	1·00
4KHz	230	107 (47)	104 (45)	·85	85 (37)	84 (37)	1·00
6KHz	228	95 (42)	111 (49)	·16	84 (37)	91 (40)	·56
8KHz	222	103 (46)	94 (42)	·44	91 (41)	83 (37)	·50
10KHz	72	36 (50)	39 (54)	·74	30 (42)	37 (51)	·32
12·5KHz	63	40 (63)	41 (65)	1·00	38 (60)	35 (56)	·72
16KHz	9	5 (56)	4 (44)	1·00	3 (33)	3 (33)	1·00

BSA= British Society of Audiology, ASHA=American Speech-Language-Hearing Association, Db=decibel, KHz=KiloHertz, TA = Tablet-based audiometry, SBA = sound booth audiometry, N=number, %=percentage

Table 3- Mean pure tone thresholds per frequency (paired)

Frequency	TA	SBA	P value	95% CI	r	95% CI	r^2	P value
	TV (±SD) dB	TV (±SD) dB						
0·25KHz	19·13±13·46	16·47±14·98	**<·0001**	1·85 to 3·47	0·91	0·88 to 0·93	0·83	**<·0001**
0·5KHz	18·79±13·69	17·53±16·12	**·003**	0·42 to 2·10	0·92	0·90 to 0·94	0·85	**<·0001**
1KHz	18·53±14·58	17·33±16·16	**·003**	0·43 to 1·99	0·93	0·91 to 0·94	0·86	**<·0001**
2KHz	19·18±14·45	18·18±16·83	**·02**	0·18 to 1·8	0·93	0·91 to 0·94	0·86	**<·0001**
4KHz	25·33±17·02	24·26±18·32	**·01**	0·24 to 1·88	0·94	0·92 to 0·95	0·88	**<·0001**
6KHz	26·45±19·18	26·12±20·83	·53	-0·70 to 1·36	0·93	0·90 to 0·94	0·86	**<·0001**
8KHz	29·95±22·38	24·95±22·37	**<·0001**	3·89 to 6·11	0·93	0·91 to 0·95	0·86	**<·0001**
10KHz	29·51±22·13	31·32±22·45	·10	-3·96 to 0·35	0·92	0·87 to 0·95	0·84	**<·0001**
12·5KHz	35·95±21·53	32·86±25·46	**·003**	1·04 to 5·15	0·95	0·92 to 0·97	0·91	**<·0001**
16KHz	22·78±8·70	22·22±11·21	·88	-7·92 to 9·03	0·41	-0·35 to 0·84	0·17	·27

TA = Tablet-based audiometry, SBA = sound booth audiometry, KHz=KiloHertz, TV=Threshold value, SD=standard deviation, dB=decibel, CI=confidence interval, r= Pearson Correlation coefficient, r^2= coefficient of determination, N=number, %=percentage

Within standard measured frequencies (0·25-8KHz) SBA had fewer unavailable results (UR) (1%, 14/1778) out of every test that could be performed, compared to TA (5%, 82/1778), where 38% (31/82) of unavailable results were associated with high THI scores (≥38) in which tinnitus symptoms were causing moderate to severe handicap (Table S8 and S9). At EHF (10-16KHz) 5% (36/762) of all possible tests, using TA, were unavailable (UR), with 42% (15/36) of unavailable results having accompanying significant tinnitus (Table S9). However, 70% (531/762) of all possible tests, using SBA, had no results available (UR) at EHF, with 85% (450/531) attributed to a lack of available EHF measuring facilities (Table S8). Non recordable (NR) results that were beyond maximum threshold limits were greater with TA (4%, 68/1778) than SBA (1%, 17/1778) out of every test that could be performed between 0·25-8KHz, which increased to 27% (202/762) and 8% (62/762) respectively at the EHF range (Tables S1 and S10).

TA showed good sensitivity for detecting HL as defined by BSA criteria (range 77-100%) at all frequencies between 0·25-16KHz and ASHA criteria (range 78-100%) between 0·25-12·5KHz, with high specificity (>85%) for detecting HL using both BSA and ASHA criteria between 0·25KHz and 12·5KHz (Table S11). Accuracy of TA for detecting HL was ≥88% at frequencies 0·25-12·5KHz when assessed by both BSA and ASHA criteria. There was good positive predictive value (PPV) (≥80%) and negative predictive value (NPV) (≥81%) at all frequencies using both criteria except at 16KHz when using ASHA criteria. Overall sensitivity, specificity, PPV, NPV, accuracy for detecting HL based on BSA and ASHA criteria using TA are shown in Table S11. There is higher sensitivity using the TA approach at EHF (8-12·5KHz) ranging from 85-95% (BSA) or 78-100% (ASHA) compared to low frequencies (0·5-2KHz) of 77-81% (BSA) or 80-88% (ASHA). Conversely specificity is lower at EHF (8-12·5KHz) between 86-95% (BSA) or 88-97% (ASHA) compared to low frequencies (0·5-2KHz) of 97-98% (BSA) or vs 97-98% (ASHA).

Bland Altman analysis (Figure S2 and Table S12) show that the mean differences (bias) were within 5dB at all frequencies and above zero (except 10KHz), with 95% limits of agreement within 15dB of the bias between 0·25KHz – 6KHz but this increased at higher frequencies (8-16KHz). Simple linear regression was conducted to evaluate the presence of proportional bias, which identified a significant negative proportional bias for frequencies 0·25– 6KHz and 12·5KHz (Figure S2 and Table S13). Using the equations generated (Table S13), Table S14 predicts the threshold when TA measurements were the same as SBA i.e. no difference between the two readings where Y=0. This was found between 25-30dB for frequencies 0·5KHz, 1KHz, 2KHz and 6KHz. There was a fixed bias observed at 8KHz showing TA was consistently 5dB above SBA and <2dB lower than SBA at 10KHz.

Different user processes are involved with TA (minimal human interaction with button on tablet) and SBA (audiologist and button), with the usability analysis showing that TA demonstrated good levels of attractiveness and novelty, excellent perspicuity and efficiency, and above average dependability and stimulation scales (Figure 1). SBA displayed excellent perspicuity, above average efficiency and dependability, below average attractiveness and stimulation with poor novelty scales. The scale means are reported in Table S15, with Cronbach's alpha coefficient showing acceptable reliability with all scales.

DISCUSSION

In this study, we present results from the largest study to date measuring the accuracy of TA to detect and screen for HL including both standard frequencies (0·25-8KHz) and EHF (>8KHz) ranges using circumaural headphones. TA measurements were found to be identical to SBA between 25dB and 30dB at 0·5KHz,1KHz, 2KHz, 6KHz, which is the threshold used to define HL according to ASHA criteria (>25dB). TA was as effective as SBA in detecting HL for hearing thresholds between 0·25-12·5KHz, regardless of whether BSA or ASHA criteria were used, with good sensitivity, specificity and accuracy. Ultimately clinical decision making from either method would be identical. Patient user feedback analysing usability demonstrated that TA outperformed SBA indicating preference of TA over SBA (as shown in Vijayasingam et al).[27]

Previous studies using Shoebox have shown similar agreement to SBA alongside sensitivity, specificity, positive and negative predictive values for HL detection to that seen within our study at standard frequency ranges.[20,21,23,24,27] In this study, we have analysed efficacy of TA in a cohort with a high incidence of HL (as expected in ENT/audiology outpatients) and demonstrated accuracy of HL detection according to both BSA and ASHA criteria at a wider range of frequencies. These results strongly support TA as a screening and diagnostic test to identify HL without audiometric sound booth requirement. Other mobile technologies with EHF monitoring have been used as part of ototoxicity monitoring programmes to detect chemotherapy-induced ototoxicity (OtoID, touch screen portable audiometer, HearTest using Android systems), and noise-induced HL Creare (wireless audiometer) in boothless environments such as hospital clinics and the military.[38,39]

HL is expected to rise to 2·5 billion people (1 in every 4) by 2050, due to an increase in the aging population, with the largest increase expected in South-East Asia and Western Pacific Regions.[1] The current provision of audiology services is insufficient to meet existing global demands with SBA requiring audiologists, high-cost equipment and audiometric sound booths that are not always available especially in low-resource areas.[1] This is further compounded by the concentration of ear and hearing care (EHC) services in urban areas in many countries with limited availability in rural settings.[40,41]

Automated technology incorporated in TA allow use by non-audiologists enabling task-sharing and re-allocation with other healthcare professionals (HCPs) (following shorter training times) to reduce audiologist workload. This is the recommended WHO strategy to increase EHC capacity and facilitate integration of the WHO H.E.A.R.I.N.G. (Hearing screening and intervention; Ear disease prevention and management; Access to technologies; Rehabilitation services; Improved communication; Noise reduction; Greater community engagement) strategy into global and national public health policy.[1] Implementation of TA within clinical pathways has been shown to enable increased accessibility to EHC services, reducing travel barriers and waiting times in rural and urban areas and reducing current health inequalities in both LMIC and HICs.[17,42]

In this study, we identified limited facilities for EHF monitoring using SBA with only two out of six audiometric sound booths having this capability highlighting the limited ability for early HL detection in standard audiometric settings. TA has this provision when used with circumaural headphones which increases accessibility to EHF monitoring and enables the potential for TA to

be used to detect early changes in hearing with ototoxic chemicals/medications and noise-induced HL as part of occupational screening in workplaces and ototoxicity monitoring programmes where aminoglycoside antibiotics are a core part of MDRTB, non-tuberculosis mycobacteria (NTM) and CF treatments. As demonstrated by the UEQ scores, patients found TA easier to use, more efficient, more interesting, more innovative and highlights the usability of TA to facilitate with EHF monitoring into these hearing screening programmes. Detection of HL at early stages would help mitigate significant HL by consideration of alternative therapies or dose adjustment through shared decision making. The portability of TA also enables use within stringent infection prevention control practices as often required in the presence of drug-resistant infections in CF, NTM or TB practices where currently routine ototoxicity monitoring is lacking.[43,44]

Digital technology such as TA could potentially improve societal HL detection if implemented in future routine hearing screening programs increasing accessibility especially in resource limited areas. HL is exacerbated by the time (usually 10 years) individuals accept that they have a hearing problem with the stigma of wearing hearing aids often associated with aging leading to delay.[45] Additional interventions such as guidance and internet-based hearing healthcare training should accompany those recommended hearing assist devices to encourage help-seeking health behaviour.[46,47] However, considerable challenges still remain with a secondary increased demand for aural rehabilitation services and requirement for hearing aid use. Within LMICs the cost of hearing aids can limit uptake in individuals or services who lack the resources to purchase, fit, deliver, maintain and support hearing aid use, as well as costs of batteries and travel to EHF facilities.[48–50] Health-economic modelling has suggested that increasing EHC services to cover 50% of the global population by 2030 would cost US$ 75 billion but would avert >110 million DALYs over 10 years.[1]

Our study has nevertheless highlighted some limitations in use of TA for HL detection. Approximately a third of individuals with unavailable results had severe tinnitus symptoms suggesting that SBA would be more appropriate for HL screening/detection in tinnitus patients. Although, TA had a higher percentage of non-recordable results compared to SBA, this is likely due to the shorter threshold range available which is unlikely to affect clinical decision making regarding hearing aid requirement (which is based on patient's symptomatic need and their engagement and not whether the degree of HL is severe or profound).[51] We had fewer paired tests available at EHF in our cohort to analyse accuracy of TA compared to SBA given the high prevalence of HL. Furthermore, in our study we did not monitor ambient environmental noise levels to determine if they exceeded the maximum permissible which may explain the higher thresholds observed at low frequencies, consistently seen with other studies using mobile audiometry outside the sound booth environment.[52] Lastly, this study only tested adults who were able to consent, and hence we are unable to comment on accuracy and usability of TA in children (cognitive immaturity), and in individuals with cognitive impairment e.g. dementia.[52]

In summary, we have shown in this study that tablet-based audiometry is an acceptable, accurate alternative to audiometric sound booth testing to increase accessibility of HL screening at standard and extended high frequency ranges and can be used as a diagnostic test for HL in individuals without significant tinnitus. Further prospective research is required to evaluate efficacy and cost-effectiveness of TA within established clinical pathways and screening

programmes. Use of tablet-based audiometry within a global setting both in HICs and LMICs can likely assist in early HL detection particularly where access to audiometry resource is limited.

Figure legends

IQR = interquartile range, HL= hearing loss, BSA = British Society of Audiology >20dB, ASHA = American Speech-Language-Hearing Association >25dB, HHIA=Hearing Handicap Inventory for Adults, THI=Tinnitus Handicap Inventory, DHI=Dizziness Inventory Handicap, dB = decibel, KHz = KiloHertz, TA = Tablet-based audiometry, SBA = sound booth audiometry, N=number, % = percentage, TV = Threshold value, SD=standard deviation, CI=confidence interval, r= Pearson Correlation coefficient, r^2= coefficient of determination.

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Contributors

The study was designed by JC, AS and FD. JC, EL, CWL and PP carried out data collection. JC performed the statistical analysis and created all figures and tables. JC, FD, AS interpreted the data. FD is guarantor of the manuscript. The manuscript was circulated to all authors for critical revisions and all authors approved the final version of the manuscript.

Data availability statement

Data are available upon reasonable request.

Competing interests

AS has received research grants from AstraZeneca & Pfizer, consulting fees from Mundipharma, AstraZeneca & Pfizer, participated on advisory board for Mundipharma & AstraZeneca. JC has received hospitality from Tillots. All other authors report no competing interests.

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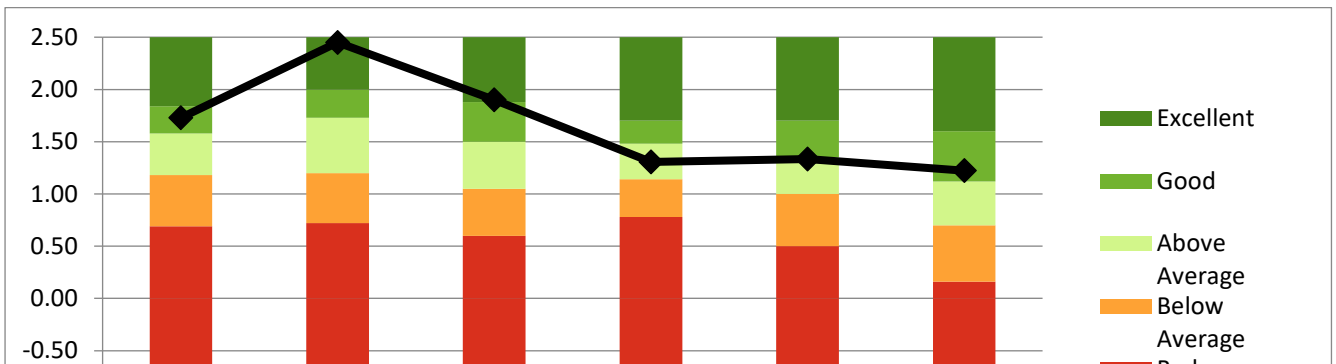
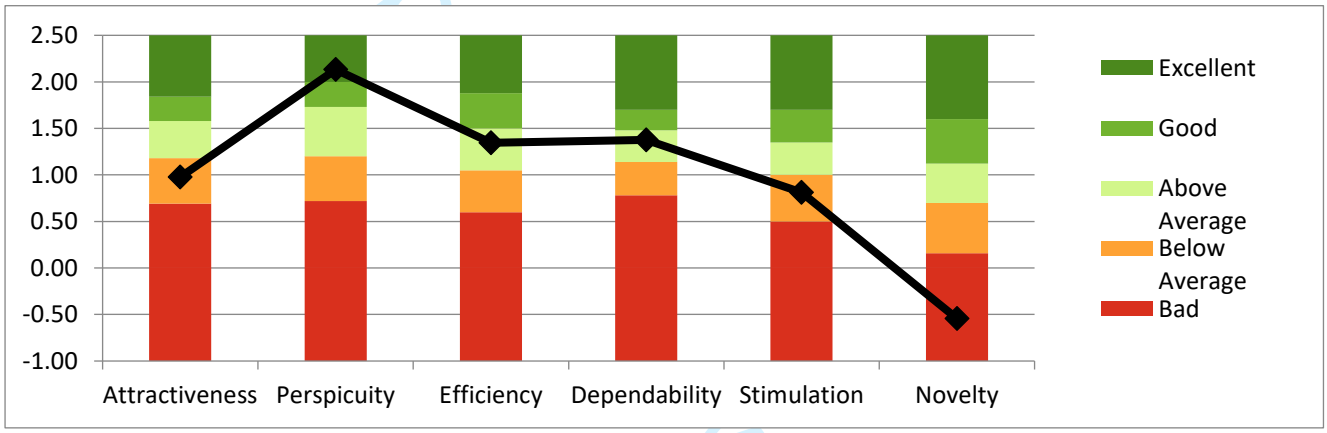
Figure 1 User Experience Questionnaire (UEQ) results

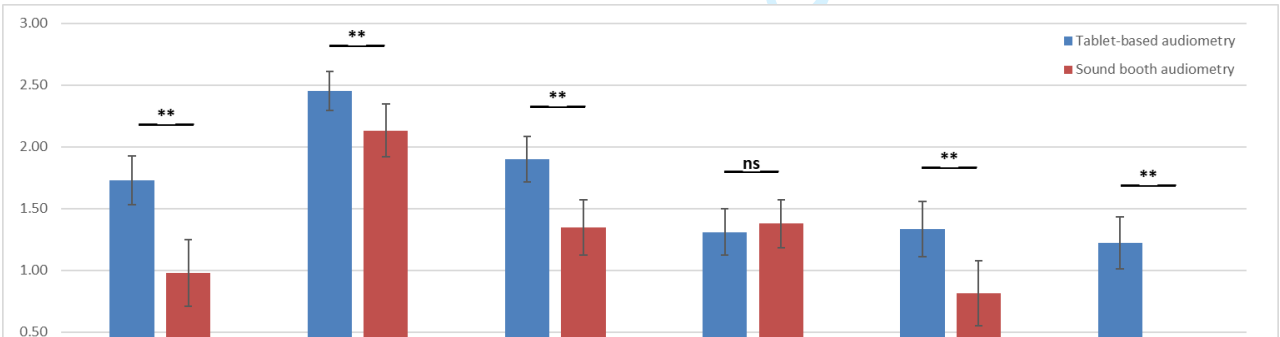
A) User Experience Questionnaire Benchmark graph of Tablet-based audiometry



B) User Experience Questionnaire Benchmark graph for Sound-booth audiometry



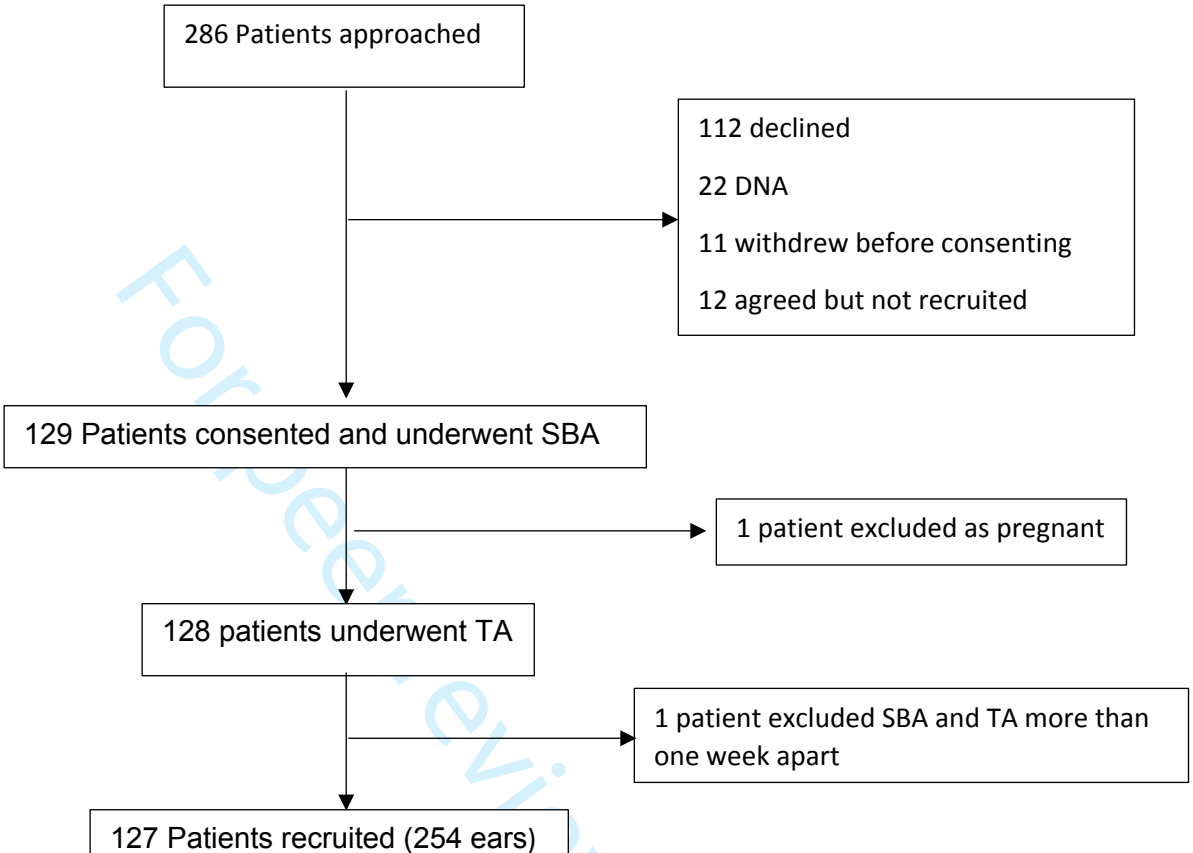
C) Comparison analysis of UEQ in tablet-based audiometry and sound booth audiometry



Comparison of scale means, ** = significant p<0.05, ns=not significant

A globally applicable solution to hearing loss screening: a diagnostic accuracy study of tablet-based audiometry - Supplementary material

Figure S1 Flowchart of participants



Patients were tested at ten frequencies with hearing loss detection percentages reported in Table 2. SBA = sound booth audiometry, TA = Tablet-based audiometry

Table S1 - Numbers of possible tests and results

Frequency	Maximum possible tests	SBA			TA			Paired results
		Available results	UR	NR	Available results	UR	NR	
0.25 KHz	254	251	2	1	233	12	9	231
0.5 KHz	254	251	2	1	233	12	9	231
1 KHz	254	251	2	1	234	11	9	232
2 KHz	254	251	2	1	235	10	9	233
4 KHz	254	250	2	2	233	12	9	230
6 KHz	254	250	2	2	231	13	10	228
8 KHz	254	243	2	9	229	12	13	222
10 KHz	254	82	161	11	222	12	20	72
12.5 KHz	254	77	156	21	196	12	46	63
16 KHz	254	10	214	30	106	12	136	9

SBA = sound booth audiometry, TA = Tablet-based audiometry, KHz=Kilo Hertz, Available results (within threshold limits), UR unavailable results, NR = non recordable results as beyond maximum limits.

Table S2 - Referrals for sound booth audiometry

Referrals	Number of patients (%)
ENT	91 (72)
GP	19 (15)
Hospital -Acute medicine -Cystic fibrosis -Haematology -Nephrology -Neurology -Oncology	14 (11) 1 1 2 1 3 6
School nurse	1 (<1)
Self-referral	1 (<1)
(blank)	1 (<1)

Table S3 - Main reason for sound booth audiometry

Hearing loss	Number of patients (%)
ENT symptoms – including (congestion, parotid gland, nasal polyps, sinusitis	3 (2)
Middle ear symptoms – including cholesteatoma, otosclerosis otitis media, fungal infection, perforation, grommets, mastoiditis, retracted ear drum, eustachian tube dysfunction or congestion, conductive hearing loss	30 (24)
Drug-induced (chemo/radiotherapy, COVID-19 vaccine, Kaftrio, iron chelating agent, epidural)	5 (4)
Noise-induced	2 (2)
Unknown	18 (14)
Inner ear – including labyrinthitis, including sudden onset	6 (5)
Suspected/hereditary	2 (2)
Presbycusis	1 (<1)
Acoustic neuroma	1 (<1)
Other tumours causing hearing loss (oropharyngeal, paraglangliomas)	2 (2)
Syndrome (Postural Tachycardia Syndrome, Alport, Sebastian, Turners, Susacs)	5 (4)
Trauma (road traffic accident, diving)	2 (2)
Dizziness/vertigo/balance	22 (17)
Tinnitus	16 (13)
Meniere's disease	1 (<1)
Treatment/operation protocol (chemotherapy, radiotherapy, myringoplasty)	6 (5)
Auditory processing disorder	1 (<1)
Ear pain	1 (<1)
Impacted wax	1 (<1)
Fullness in ear	1 (<1)
Otitis externa	1 (<1)

Table S4- Medications with ototoxic side effects (dizziness, tinnitus, other ear related)

Concurrent Medications	N (%)	Medications in the previous 3 months	N (%)
Antidepressants	15 (12)	Loop diuretics	0 (0)
Aspirin or NSAIDs	11 (9)	Macrolides	4 (3)
Co-trimoxazole	1 (<1)	Intravenous aminoglycoside	1 (<1)
Quinolones	1 (<1)	Inhaled/nebulised aminoglycoside	0 (0)
Tetracyclines	1 (<1)	Ear drops containing aminoglycoside	4 (3)
CFTR modulators	1 (<1)	Vancomycin	0 (0)
Bisphosphonates	2 (2)	Cancer chemotherapy	2 (2)
ACEI & A2RA	13 (10)	Aspirin or NSAIDs	53 (42)
Antiepileptics	4 (3)	Quinine	0 (0)
Opioids	4 (3)	None	63 (50)
Calcium channel blockers	8 (6)		
Immunosuppressants	2 (2)		
Antipsychotics	2 (2)		
Lithium	1 (<1)		
Atorvastatin	7 (6)		
Cosopt eye drops	1 (<1)		
Chemotherapy	1 (<1)		
Iron chelating agent	1 (<1)		
Methylphenidate	1 (<1)		
Rutiximab	1 (<1)		
None	49 (39)		

N=number of patients, NSAIDs=non-steroidal anti-inflammatory drugs, CFTR=cystic fibrosis transmembrane conductance regulator, ACEI=angiotensin-converting enzyme inhibitors, A2RA=angiotensin 2 receptor antagonist

Table S5 Mean pure tone thresholds per frequency with high hearing loss thresholds based according to BSA criteria (paired SBA >20dB)

Frequency		TA	SBA	r	95% CI	P value
	N=	TV (±SD) dB	TV (±SD) dB			
0·25KHz	56	36.79±16.14	37.95±13.97	0.90	-0.7328 to 3.054	.2245
0·5KHz	62	36.13±15.59	39.19±14.94	0.91	1.385 to 4.744	**.0005**
1KHz	63	36.67±17.04	38.81±15.31	0.94	0.6305 to 3.655	**.0062**
2KHz	70	36.07±15.95	38.64±15.67	0.90	0.8642 to 4.279	**.0037**
4KHz	104	39.47±15.20	40.34±14.70	0.91	-0.3723 to 2.103	.1685
6KHz	111	41.17±17.81	43.33±16.06	0.87	0.5008 to 3.824	**.0112**
8KHz	94	50.27±20.06	46.65±16.57	0.88	-5.606 to -1.628	**.0005**
10KHz	39	43.59±20.52	47.95±16.81	0.91	1.572 to 7.146	**.003**
12·5KHz	41	48.66±15.21	48.9±14.38	0.89	-1.987 to 2.474	.8262
16KHz	4	28.75±4.787	32.5±6.455	-0.67	-12.65 to 20.15	.5195

TA = Tablet-based audiometry, SBA = sound booth audiometry, KHz=KiloHertz, TV=Threshold value, SD=standard deviation, dB=decibel, CI=confidence interval, r= Pearson Correlation coefficient, %=percentage

Table S6 Mean pure tone thresholds per frequency with high hearing loss thresholds based according to ASHA criteria (paired SBA >25dB)

Frequency	N=	TA TV (±SD) dB	SBA TV (±SD) dB	R	95% CI	P value
0·25KHz	39	42.82±15.42	43.59±13.23	0.87	-1.656 to 3.194	.5247
0·5KHz	46	40.54±15.46	44.13±14.35	0.90	1.591 to 5.583	**.0007**
1KHz	42	43.81±16.34	45.71±14.42	0.93	-0.04048 to 3.85	.0547
2KHz	45	43.22±15.42	46.22±14.85	0.86	0.5736 to 5.426	**.0166**
4KHz	84	42.86±14.92	43.99±14.07	0.89	-0.3408 to 2.603	.1302
6KHz	91	44.89±17.27	47.36±14.97	0.85	0.5754 to 4.370	**.0112**
8KHz	83	52.95±19.49	49.52±15.49	0.87	-5.535 to -1.332	**.0017**
10KHz	37	45.14±19.88	49.19±16.35	0.90	1.171 to 6.937	**.0072**
12·5KHz	35	52.86±11.96	53±11.19	0.80	-2.373 to 2.659	.9088
16KHz	3	26.67±2.887	35±5.00	0.00	-6.009 to 22.68	.1296

TA = Tablet-based audiometry, SBA = sound booth audiometry, KHz=KiloHertz, TV=Threshold value, SD=standard deviation, dB=decibel, CI=confidence interval, r= Pearson Correlation coefficient, %=percentage

Table S7– Tablet audiometry threshold difference within 10dB of Sound Booth Audiometry

Frequency	Paired results	Paired results within 10dB of SBA (%)
0.25KHz	231	216 (94)
0.5KHz	231	220 (95)
1KHz	232	225 (97)
2KHz	233	221 (95)
4KHz	230	222 (97)
6KHz	228	207 (91)
8KHz	222	178 (80)
10KHz	72	63 (88)
12.5KHz	63	53 (84)
16KHz	9	7 (78)
Total	1751	1612 (92)

KHz=KiloHertz, SBA = sound booth audiometry, dB=decibel

Table S8- Sound booth audiometry unavailable results (UR)

	Sound booth audiometry Unavailable results, N (%)			
	0.25-8KHz	10KHz	12.5KHz	16KHz
Digital failure - Lost results	14 (100)	2 (1)	2 (1)	2 (1)
Digital failure - 10-16KHz not available		2 (1)	2 (1)	2 (1)
10-16KHz not requested		2 (1)	2 (1)	2 (1)
Not measured – unknown		5 (3)		58 (27)
10-16KHz Not available		150 (93)	150 (96)	150 (70)
Total	14	161	156	214

KHz=KiloHertz

Table S9–Tablet-based audiometry unavailable results (UR)

	Tablet-based audiometry unavailable results, N (%)									
	0.25KHz	0.5KHz	1KHz	2KHz	4KHz	6KHz	8KHz	10KHz	12.5KHz	16KHz
THI=0-16	0	0	0	0	0	1 (8)	0	0	0	0
THI=38-56	2 (17)	2 (17)	1 (9)	2 (20)	2 (17)	2 (15)	2 (17)	2 (17)	2 (17)	2 (17)
THI=58-76	3 (25)	3 (25)	1 (9)	2 (20)	3 (25)	3 (23)	3 (25)	3 (25)	3 (25)	3 (25)
Upload failure	4 (33)	4 (33)	4 (36)	4 (40)	4 (33)	4 (31)	4 (33)	4 (33)	4 (33)	4 (33)
Unknown	3 (25)	3 (25)	5 (45)	2 (20)	3 (25)	3 (23)	3 (25)	3 (25)	3 (25)	3 (25)
Total	12	12	11	10	12	13	12	12	12	12

THI=Tinnitus Handicap Inventory, KHz=KiloHertz,

Table S10 - Threshold Limits

Frequency	Tablet-based audiometry		Sound booth audiometry			
	Minimum dB	Maximum dB	Minimum dB		Maximum dB	
			GST	UHD	GST	UHD
0.25KHz	10	90	-10	-10	90	105
0.5KHz	10	90	-10	-10	110	110
1KHz	10	90	-10	-10	110	110
2KHz	10	90	-10	-10	110	110
4KHz	10	90	-10	-10	110	110
6KHz	10	90	-10	-10	100	110
8KHz	10	90	-10	-10	70	105
10KHz	10	85	-20	-	80	-
12.5KHz	10	80	-20	-	70	-
16KHz	10	55	-20	-	40	-

dB=decibel, KHz=KiloHertz, GST=Guy's & St Thomas', UHD=University Hospitals Dorset

Table S11 Tablet-based audiometry sensitivity and specificity for hearing loss detection according to BSA and ASHA criteria

Frequency	N	BSA >20dB, % (95% CI)					ASHA >25dB, % (95% CI)				
		Sensitivity	Specificity	PPV	NPV	Accuracy	Sensitivity	Specificity	PPV	NPV	Accuracy
0·25KHz	231	79 (66-88)	94 (90-97)	81 (70-89)	93 (89-96)	90 (86-94)	82 (66-92)	96 (92-98)	80 (67-89)	96 (93-98)	94 (90-96)
0·5KHz	231	77 (65-87)	97 (93-99)	91 (80-96)	92 (88-95)	92 (87-95)	80 (66-91)	98 (95-99)	90 (78-96)	95 (92-97)	94 (91-97)
1KHz	232	81 (69-90)	97 (93-99)	91 (81-96)	93 (89-96)	93 (89-96)	88 (74-96)	98 (95-100)	93 (80-97)	97 (94-99)	97 (93-99)
2KHz	233	81 (70-90)	98 (94-99)	93 (84-97)	92 (88-95)	93 (89-96)	84 (71-94)	97 (93-99)	86 (74-93)	96 (93-98)	94 (91-97)
4KHz	230	93 (87-97)	92 (86-96)	91 (84-95)	94 (89-97)	93 (88-96)	88 (79-94)	92 (87-96)	87 (79-92)	93 (88-96)	91 (86-94)
6KHz	228	84 (76-90)	98 (94-100)	98 (92-99)	86 (81-91)	91 (87-95)	85 (76-91)	95 (90-98)	92 (84-96)	90 (85-94)	91 (86-94)
8KHz	222	90 (83-96)	86 (79-91)	83 (75-88)	92 (87-96)	88 (83-92)	89 (80-95)	88 (81-93)	81 (73-87)	93 (88-96)	88 (83-92)
10KHz	72	85 (69-94)	91 (76-98)	92 (79-97)	83 (70-91)	88 (78-94)	78 (62-90)	97 (85-100)	97 (81-100)	81 (70-89)	88 (78-94)
12·5KHz	63	95 (83-99)	95 (77-100)	98 (85-100)	91 (73-98)	95 (87-99)	100 (90-100)	89 (72-98)	92 (80-97)	100 (86-100)	95 (87-99)
16KHz	9	100 (40-100)	80 (28-99)	80 (41-96)	100 (40-100)	89 (52-100)	33 (1-91)	67 (22-96)	33 (7-78)	67 (43-84)	56 (21-86)
Overall 0·25-16KHz	1751	86 (83-88)	95 (93-96)	90 (88-92)	92 (90-93)	91 (90-93)	86 (83-89)	95 (94-96)	88 (85-90)	94 (93-95)	92 (91-94)
Overall 0·25-8KHz	1607	85 (82-88)	95 (93-96)	90 (87-92)	92 (91-93)	91 (90-93)	86 (82-89)	95 (94-96)	87 (84-90)	95 (94-96)	93 (91-94)
Overall 10-16KHz	144	90 (82-96)	92 (82-97)	94 (87-97)	87 (78-93)	91 (85-95)	87 (77-93)	91 (82-97)	92 (83-96)	86 (78-92)	89 (83-94)

N=paired results, BSA= British Society of Audiology, ASHA= American Speech-Language-Hearing Association, dB=decibel, KHz=KiloHertz, CI=confidence interval, PPV= Positive predictive value, NPV=Negative predictive value

Table S12 - Bland Altman results for each frequency

Frequency	N=	Bias	SD of Bias	95% limits of agreement	
				From	To
0.25KHz	231	2.662	6.251	-9.590	14.91
0.5KHz	231	1.255	6.439	-11.37	13.88
1KHz	232	1.207	6.035	-10.62	13.03
2KHz	233	1.009	6.395	-11.53	13.54
4KHz	230	1.065	6.291	-11.27	13.40
6KHz	228	0.3289	7.867	-15.09	15.75
8KHz	222	5.000	8.388	-11.44	21.44
10KHz	72	-1.806	9.166	-19.77	16.16
12.5KHz	63	3.095	8.153	-12.89	19.08
16KHz	9	0.5556	11.02	-21.05	22.16

N=paired results, KHz=KiloHertz, SD= standard deviation

Table S13 - Simple linear regression

Frequency	r^2	95% CI	P value	F statistic	DFn, DFd	Equation
0.25KHz	0.06170	-0.1685 to -0.05501	**0.0001**	15.06	1, 229	Y = -0.1118*X + 4.552
0.5KHz	0.1479	-0.2226 to -0.1166	**<0.0001**	39.74	1, 229	Y = -0.1696*X + 4.335
1KHz	0.07137	-0.1569 to -0.05676	**<0.0001**	17.68	1, 230	Y = -0.1068*X + 4.22
2KHz	0.1434	-0.2077 to -0.1078	**<0.0001**	38.68	1, 231	Y = -0.1577*X + 4.55
4KHz	0.04449	-0.1224 to -0.03014	**0.0013**	10.61	1, 228	Y = -0.07627*X + 3.956
6KHz	0.04556	-0.1369 to -0.03422	**0.0012**	10.79	1, 226	Y = -0.08553*X + 3.577
8KHz	1.506e-006	-0.05024 to 0.05118	0.9855	0.0003313	1, 220	Y = 0.0004683*X + 4.987
10KHz	0.001346	-0.1155 to 0.08468	0.7596	0.09434	1, 70	Y = -0.01541*X + 4.337
12.5KHz	0.2376	-0.2496 to -0.09264	**<0.0001**	19.01	1, 61	Y = -0.1711*X + 4.883
16KHz	0.07314	-1.487 to 0.7756	0.4815	0.5524	1, 7	Y = -0.3556*X + 4.656

r^2= coefficient of determination, CI= confidence interval, DFn= numerator degrees of freedom (regression df), DFd = denominator degrees of freedom (residual df), F statistic= explained variance Unexplained variance.

Table S14 Threshold at which Tablet-based Audiometry and Sound Booth Audiometry are equal

Frequency	Threshold (dB)
0.25KHz	41.6
0.5KHz	25.6
1KHz	29.2
2KHz	25.1
4KHz	38.8
6KHz	30.1
8KHz	N/A
10KHz	N/A
12.5KHz	-52.5
16KHz	N/A

dB=decibel, KHz=KiloHertz, N/A=not applicable

Table S15 - User Experience Questionnaire (UEQ) results of tablet-based audiometry & sound booth audiometry

A) Tablet-based audiometry

Scale	Mean	Std. Dev.	N	Confidence	Confidence interval		Cronbachs Alpha-coefficient	Confidence interval Cronbachs Alpha
Attractiveness	1.729	0.998	100	0.196	1.533	1.924	0.85	0.80-0.89
Perspicuity	2.450	0.808	100	0.158	2.292	2.608	0.75	0.65-0.62
Efficiency	1.900	0.951	100	0.186	1.714	2.086	0.69	0.56-0.77
Dependability	1.308	0.957	100	0.188	1.120	1.495	0.57	0.41-0.69
Stimulation	1.335	1.136	100	0.223	1.112	1.558	0.82	0.75-0.87
Novelty	1.223	1.073	100	0.210	1.012	1.433	0.63	0.49-0.73

B) Sound booth audiometry

Scale	Mean	Std. Dev.	N	Confidence	Confidence interval		Cronbachs Alpha coefficient	Confidence interval Cronbachs Alpha
Attractiveness	0.977	1.324	93	0.269	0.708	1.247	0.91	0.88-0.94
Perspicuity	2.132	1.051	93	0.214	1.918	2.345	0.87	0.82-0.91
Efficiency	1.347	1.113	93	0.226	1.121	1.573	0.68	0.56-0.77
Dependability	1.376	0.945	93	0.192	1.184	1.568	0.56	0.39-0.69
Stimulation	0.812	1.296	93	0.263	0.548	1.075	0.86	0.81-0.90
Novelty	-0.543	1.188	93	0.241	-0.784	-0.302	0.69	0.57-0.78

C) T-test of scale means tablet-based audiometry compared with sound booth audiometry

Scale	P value
Attractiveness	<0.0001
Perspicuity	0.0201
Efficiency	0.0003
Dependability	0.6158
Stimulation	0.0033
Novelty	<0.0001

Figure S2 Bland Altman plot per frequency: difference between tablet-based and sound booth audiometry verses average hearing threshold