Accuracy and Reliability of Smartphone Self-Test Audiometry in Community Clinics in Low Income Settings: A Comparative Study

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Abstract

Background: There is a lack of hearing health care globally, and tele-audiology and mobile technologies have been proposed as important strategies to reduce the shortfall.

Objectives: To investigate the accuracy and reliability of smartphone self-test audiometry in adults, in community clinics in low-income settings.

Methods: A prospective, intra-individual, repeated measurements design was used. Sixty-three adult participants (mean age 52 years, range 20-88 years) were recruited from ENT and primary health care clinics in a low-income community in Tshwane, South Africa. Air conduction hearing thresholds for octave frequencies 0.5 to 8 kHz collected with the smartphone self-test in non-sound treated environments were compared to those obtained by reference audiometry.

Results: The overall mean difference between threshold seeking methods (ie, smartphone thresholds subtracted from reference) was −2.2 dB HL (n = 467 thresholds, $P = 0.00$). Agreement was within 10 dB HL for 80.1% (n = 467 thresholds) of all threshold comparisons. Sensitivity for detection hearing loss >40 dB HL in one ear was 90.6% (n = 84 ears), and specificity 94.2% (n = 84 ears).

Conclusion: Smartphone self-test audiometry can provide accurate and reliable air conduction hearing thresholds for adults in community clinics in low-income settings.

Keywords: audiometry, global health, hearing loss, mHealth, smartphone, telemedicine

Introduction

Hearing loss of a disabling degree affects almost half a billion people around the world[1] of whom the majority live in low- and middle-income countries[2]. Disabling hearing loss means a hearing threshold >40 dB HL in the better hearing ear for adults and >30 dB HL for children.[2] In many cases hearing loss is a treatable and even preventable condition[2], but to

enable treatment, detection must be available. Undiagnosed hearing loss can persist or progress and may result in a permanent disability. However, individuals with permanent hearing loss diagnosed and treated early, present with very favorable outcomes.[2]

Hearing assessments have traditionally been performed in a soundproof booth in hearing clinics where audiologists or specially trained nurses conduct testing. These facilities are only accessible for a limited part of the world's population. The cost of equipment is high and there is also a severe shortage of hearing health care professionals in most parts of the world.[3-5] The poor availability and long distances exclude people from basic hearing services. As a result, there is growing interest in solutions that leverage smartphone technologies to facilitate ear and hearing assessment and care.[6,7] Earlier studies[8-12] describe hearing tests utilizing iOS devices (iPhones, iPods and iPads) with various accuracy and performance. However, there have been limitations including use of non-calibrated headphones, high costs and poor availability in low-income countries. One of the newer alternatives is a pure tone hearing test using Android smartphones with calibrated headphones (hearTest, hearX Group, Pretoria). HearTest is based on the validated hearScreen technology.[13] An early version was designed as an investigator-operated test and demonstrated accurate testing in- and outside a soundproof booth.[14] More recently the software has been adapted for automated self-testing. After instructions and headphone placement provided by a facilitator, the patients can test themselves using the phone simply as a response button. The new version has been compared to standard manual audiometry in a soundproof booth with clinically accepted agreement between methods.[15] However, it has not been investigated in low-income communities under unfavorable ambient noise conditions.

The aim of the current study was to investigate the accuracy and reliability of smartphone self-test audiometry in adults, in community clinics in low-income settings.

Materials and Methods

Before study commencement, ethical clearance was provided by the Ethics Committee of the University of Pretoria, South Africa for the full study (approval number 102/2011) and from the Ethics Committee at Umeå University, Sweden for analyzing the data in Sweden (approval number 2016/257-31).

Study Design and Study Population

A prospective, intra-individual, repeated measurements design was used. The study was conducted following the Standards for Reporting Diagnostic accuracy studies (STARD) guidelines. Sixty-three participants were recruited between March and May 2016 from four different township community clinics in low-income areas of Tshwane (Pretoria), Gauteng, South Africa. These consisted of one district hospital ENT clinic (43 participants) and three primary healthcare clinics (20 participants). All participants except two were recruited in the community of Mamelodi, a township with about 110 000 households, of which only 61% are formal dwellings.[16] The remaining two participants were recruited from a primary health care clinic with similar socioeconomic standard as in Mamelodi. The enrolment was done consecutively from patients and volunteers in the waiting room. Written informed consent was collected from all participants.

Inclusion criteria were age ≥18 years, no visually apparent actively draining or moist external auditory canals and a completed test with the reference method. Measurements with an

asymmetrical or unilateral loss >40 dB HL at any frequency with the index test were excluded to avoid registration of any contralateral hearing.

Reference Standard and Index Test

All participants performed one hearing test with the reference standard and one with the index test. The tests were air conduction pure tone threshold audiometry to compare thresholds.

The reference standard was, due to limited access to sound proofed facilities, a portable, Conformité Européenne (CE) certified, diagnostic audiometer (KUDUwave, eMoyoDotNet, Johannesburg, South Africa), validated for automated testing outside a soundproof booth.[17-19] It was already employed for audiometry at the involved primary health care clinics. The reference audiometer was operated via a PC laptop running Microsoft Windows 8. Insert earphones were used covered by circumaural noise reducing ear cups equipped with ambient noise monitoring microphones, which register when external noise is too loud. The reference audiometers underwent standard calibration using an 824 Type 1 sound level meter (Larson Davis, Provo, Utah, USA) with a G.R.A.S (Holte, Denmark) IEC 711 coupler for insert earphones. The testing procedure was according to ISO standard 8253-1:2010.

The index test was a smartphone self-test audiometry application called hearTest (hearX group, Pretoria, South Africa), preloaded onto a standardized Samsung Trend Neo smartphone connected to calibrated circumaural Sennheiser HD 280 pro headphones. The smartphone and the headphones were calibrated according to equivalent threshold sound pressure levels (ETSPL) described by Madsen and Margolis,[20] using a G.R.A.S RA0039 artificial ear using RION NL-52 sound level meter. The equipment was calibrated prior to commencement of the study, and no recalibration was performed during the study period. The smartphone audiometry testing was conducted automatically according to the ISO shortened ascending method (ISO 8253-1:2010) as described in a previous study.[15] Since it is automated, the examiner cannot influence the testing process. The smartphone application was in an investigational stage during the data collection for this project. It has subsequently received the CE certification indicating conformity with health and safety requirements set out in European directives.

The study protocol included octave frequencies between 0.5 and 8 kHz in the order 1, 0.5, 2, 4, and 8 kHz, for both methods. Hearing thresholds were measured between 10 dB HL and 85 dB HL except at 8 kHz where the maximum was 70 dB HL. Both the reference standard and the index test were in automated mode. In all cases, except one, the reference standard started with testing of the left ear. A standard clinical protocol was used and starting with the left ear was the default setting that could not be changed. To assess the reliability of the index test, a retest at 1 kHz was included at the end of the series for each ear. For the reference standard, there was only a retest at 1 kHz in the ear that was tested first. The thresholds from the retest at 1 kHz was used in all calculations to avoid using values when participants might not have been aligned to the testing situation.

Procedure

Prior to hearing assessment, a medical intern (JS), with previous training and experience in otoscopy, examined the ears with a hand-held video-otoscope to exclude actively draining or moist external auditory canals. Oral instructions about the test procedure were given, in

English in most cases, but in the participant's native language if needed and if an interpreter was available. The interpreters were informed and well acquainted about the test procedure. The testing was performed in ordinary examination rooms without soundproofing. Often many patients were present in the room at the same time and doors could be frequently opened and closed during testing. The hearing tests were conducted consecutively with less than ten minutes rest period in between. The reference standard was done first because it contains a conditioning function to ensure that the participant understands the procedure.

The instruction for the index test given to the participant was to touch a big response button in the center of the touchscreen every time a tone could be heard, even the faintest. Tones were presented automatically with duration of 1.2 seconds. The time interval between tones was randomized in length between 750 ms and 4000 ms to avoid anticipation and thus ensure true positive responses. To be regarded as a true positive response, the participant could touch the response button during the tone presentation or within 1.2 seconds after tone presentation.

The test time for the index test, the average response time and the number of false positive answers were automatically recorded. Results were transferred manually to an Excel sheet. After data collection was finished, explorative statistics was performed to get indications of problems with the data, including errors in the transformation to the Excel sheet.

Statistical Analysis

Prior to data collection a power analysis was made with an accuracy set to 85% compared to the established method. Significance level was set to 99% and required power to 85% and the estimated minimal number of examinations was then 52 ears. The hearing thresholds from each ear were analyzed separately and the differences between the two methods were calculated for each frequency tested. From data of the hearing thresholds and the retest at 1 kHz, paired samples t-test was used for calculating the mean difference, the absolute mean difference and the reliability of index test. Significance was defined as $P < 0.05$ with the Wilcoxon signed rank test. The percentage of thresholds that agreed between methods within 5 and 10 dB HL respectively was determined. The sensitivity and specificity for the index test to detect disabling hearing were calculated. The definition of disabling hearing loss is a pure tone average (PTA) including 0.5, 1, 2 and 4 kHz >40 dB HL in the better hearing ear, but in this analysis the capability to detect a PTA >40 dB HL in one ear was calculated. Only ears with a measurable value at all the four frequencies were included in the PTA analyses.

Data analyses were conducted in MS Excel and in SPSS version 24.0.

Results and Analysis

Sixty-three participants were enrolled (71% females, 29% males) with a mean age of 52 years (range 20-88 years). The mean PTA of the tested ears in the study cohort was 38.1 dB HL (n = 85, SD 17.4). Sixteen ears (19%) had PTA ≤20 dB HL, 37 ears (44%) had PTA 21-40 dB HL, 30 ears (35%) had PTA 41-70 dB HL and 2 (2%) PTA >70 dB HL. Data from 5 of the 63 participants were excluded because of non-compliance to index test instructions, or responses were inconsistent (Figure 1). Of the remaining 580 hearing thresholds (5 frequencies × 2 ears × 58 subjects), 156 were recorded as missing values due to reasons including having reached maximum test levels (Figure 1). Example of technical issues included interruptions of the software with the ten instances in the index test coming from one participant (two ears) related to a software problem that could subsequently be solved. Of the 104 (57 for reference

standard + 47 for index test) non-responses at maximum intensity level, there was agreement between the methods in 64 (32 for reference standard + 32 for index test) measurements. In 11 of the non-responses the corresponding value was missing and in the remaining 29 a threshold was recorded with either the reference or index method.

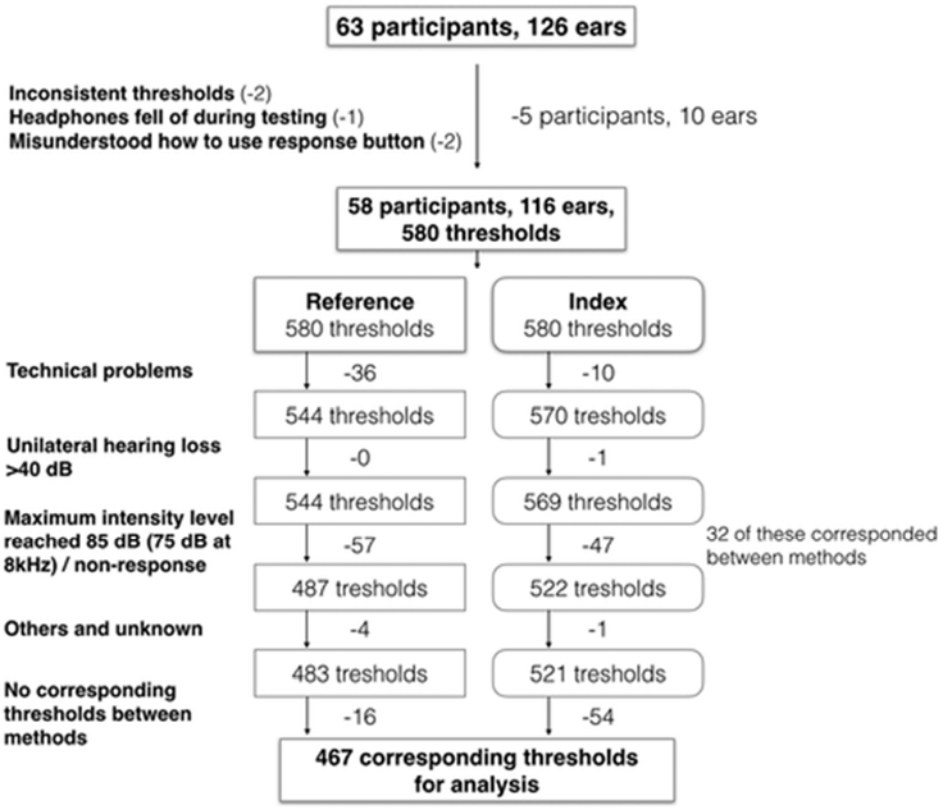

Figure 1. Flow diagram of excluded participants and missing values.

Average differences between the test methods (Table 1) across frequencies varied between 0.9 dB HL and −5.4 dB HL (index test subtracted from reference standard). Statistically significant differences were found at 0.5, 4 and 8 kHz. The percentage of threshold agreement (Table 2) within ≤10 dB HL was lowest (69.4%) at 0.5 kHz and highest (88.8%) at 2 kHz. The absolute difference varied between 6.5 and 8.8 dB HL, with the largest difference at 0.5 and 8 kHz. The sensitivity for the index test to detect a hearing loss >40 dB HL (Table 3) was 90.6% and specificity 94.2%. Test-retest reliability for index test evaluated from two measurements at 1 kHz (n = 102) showed no significant difference ($P = 0.11$, average difference 1.1 dB HL, SD 6.8).

Table 1. Mean and Median Thresholds of Reference and Index Methods and Mean and Median Differences (Index Test Subtracted From Reference Standard) Across Frequencies. Only Measurements That Had a Registered Threshold With Both Methods Were Included.

Frequency kHz	Threshold Comparisons N	Mean (Median) Reference Test dB HL	Mean (Median) Index Test dB HL	Mean (Median) Difference dB HL	Standard Deviation	*P* Value
0.5	98	38.7 (35)	41.8 (40)	−3.1 (0)	10.9	.006*
1	100	37.8 (35)	39.0 (35)	−1.2 (0)	8.8	.186
2	98	38.4 (35)	37.5 (30)	0.9 (0)	8.6	.418
4	101	36.7 (35)	40.0 (30)	−3.3 (−5)	10.8	.000*
8	70	33.9 (30)	39.4 (35)	−5.4 (−5)	9.8	.000*
All	467	37.3 (35)	39.5 (35)	−2.2 (−5)	10.0	.000*

*Paired samples t-test was used for calculating the mean difference, significance was defined as P < .05 with the Wilcoxon signed rank test.

Table 2. Absolute Difference between Reference and Index Methods across Frequencies and Agreement between Methods within ≤5 and ≤10 dB HL.

Frequency kHz	Threshold Comparisons n	Absolute Difference dB HL	Standard Deviation	Agreement ≤5 dB HL %	Agreement ≤10 dB HL %
0.5	98	8.8	7.0	49.0	69.4
1	100	6.8	5.6	65.0	85.0
2	98	6.5	5.6	65.3	88.8
4	101	8.1	7.8	57.4	81.2
8	70	8.7	7.0	48.6	74.3
All	467	7.7	6.7	57.6	80.1

Table 3. Sensitivity (%) and Specificity (%) of the Index Test to Detect Hearing Loss with Cut Off Limit PTA (0.5, 1, 2, 4 kHz) >40 dB HL.

	Sensitivity % (95% CI)	Specificity % (95% CI)	Ears (n)	Prevalence % (95% CI)
PTA > 40 dB HL	90.6 (75.0-98.0)	94.2 (84.1-98.8)	84	38.1 (27.7-49.3)

Average time for a hearing assessment with the index test, including the retest, was 512 seconds (SD 203, n = 56). The average response time after tone presentation was 1266 ms (SD 323, n = 56) and the mean false positive responses rate was 14% (SD 10, n = 56).

Discussion

Synopsis and Key Findings

Tele-audiology and mobile technologies have been proposed as important strategies to reduce the shortfall of hearing health care.[7,21] The smartphone self-test audiometry in this study demonstrates potential to provide reliable air conduction audiometry in low-income settings. It is the first study evaluating the self-test outside a soundproof booth in community clinics in low-income settings with substantial ambient noise and surrounding disturbances. The study showed a satisfactory mean difference between methods, but agreement could be improved by adding noise monitoring, a conditioning function and standardized instructions.

Comparison with Other Studies

The study showed an overall mean difference between methods of −2.2 dB HL. The mean difference was negative at most frequencies, indicating slightly poorer index test thresholds compared with the reference standard. The same pattern with higher index test thresholds has been found in two studies using the iOS application uHear.[9,22] Possible explanations for the

negative mean difference in this study include the different transducers that were used. The reference standard uses insert earphones covered by circumaural ear cups offering increased attenuation compared to only circumaural headphones of the index method.

The largest differences between index test and reference standard were found in the lowest and highest test frequencies. The difference at 0.5 kHz (8.8 dB HL) was likely affected by the non-sound treated environments and poorer transducer attenuation for the index test compared to the reference standard. Screening protocols for school testing typically omit 0.5 kHz as a test frequency because of the effect of ambient noise levels.[23,24] The second largest difference was at 8 kHz (8.7 dB HL) and could partly be attributed to systematic differences due to transducer types and allowable differences in calibration of up to 6 dB SPL between methods. Differences between methods in the lower and higher frequencies have been reported in previous studies.[9,12,22,25]

The study showed threshold agreement between methods within ≤10 dB HL between 69.4% and 88.8% across frequencies. It could be compared to 89.5% to 98.1%, when the smartphone self-test audiometry was studied in a sound treated room.[15] The earlier, investigator-operated version of the smartphone audiometry, was studied in a similar environment as in the present study and with the same reference standard and had higher agreement, 88.6% to 97.7% across frequencies.[14] While the groups were comparable in terms of PTA, sample size and age, the investigator-operated version offered the tester the possibility to pause the testing if pretest instructions had been insufficient or ambient noise was excessive. Two iOS applications have demonstrated agreement within ≤10 dB HL between 94%[8] and 95%,[26] respectively. However, both these studies were performed in quiet rooms instead of busy community clinics.

Accuracy of the smartphone self-test audiometry could be enhanced by a noise monitoring function that automatically pause the test when noise levels surpass a critical limit. Another addition could be a conditioning function, to ensure comprehension of instructions. Both these changes have subsequently been included by the manufacturer. Another desirable addition could be a brief instruction video in the patient's native language. Language barriers contributes to unequal ear and hearing health care within countries[5] and South Africa is one of many countries where several languages are spoken.

The sensitivity of the index test for detection of disabling hearing loss was 90.6% and specificity 94.2%. Even though the application is not aimed specifically for screening, the results are comparable with earlier studies. Sensitivity ranges have been reported from 89% to 100% and specificity from 60% to 90%.[9,22,25,26]

Strengths

A strength of this study was its ecological validity with broad inclusion criteria representative of community clinics in low-income settings. Persons within the full range of PTA were included and also persons difficult to test (eg, non-English speakers). The overall results were still accurate, which means that the test can be used in heterogeneous populations. Furthermore, the STARD guidelines for reporting diagnostic accuracy were used.

Limitations

Information of the participant's earlier experience in handling smartphones and touch screens were not recorded. Uncertainty in handling the equipment could have influenced the accuracy. South Africa has eleven official languages, but we did not have an interpreter able to converse in all the languages in this community. It is possible that comprehension of instructions may have influenced hearing thresholds in a small minority of cases. The participants' PTA corresponds to mild hearing loss, which implies difficulties in telling whether the method is accurate for normal hearing persons. This could also partly explain some of the missing values in the category "reached maximum intensity level", a normal hearing population does not reach this hearing thresholds. The remaining missing values described in Figure 1 are not considered to affect the results since they should be randomly distributed.

The majority of participants began with the reference standard which could cause an order-effect with the risk of reduced concentration during the second test session. It may have contributed to the negative mean difference.

The lowest hearing threshold was 10 dB HL with both methods, and this could possibly lead to slightly overestimated accuracy due to a floor effect. However, testing <10 dB HL outside a soundproof booth is not a viable option considering ambient noise levels. Another limitation was that standard audiometry, testing in a soundproof booth, was not available. However, validated mobile audiometry was used, equivalent to standard air conduction audiometry and already employed in the clinics.[17-19]

Clinical Implication and Future Research Topics

The results in this study are encouraging and the clinical implications of the smartphone self-test audiometry can span from primary health care in a South African township to an occupational health setting as well as routine assessments in remote areas around the world. Future research could investigate the age at which self-tests become reliable for use in children and to evaluate the patient's experience of the self-test procedure.

Conclusion

Smartphone self-test audiometry with hearTest can provide accurate and reliable air conduction audiometry for adults in community clinics, in low-income settings. Smartphone solutions, like these, can make hearing testing more accessible, especially in low- and middle-income countries.

Declaration of Conflicting Interests
The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: JS, TL and GU declare no conflict of interest. The hearTest is property of the hearX group, where DS is lead inventor and co-founder. CL is scientific advisor for the hearX group.

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