

Evaluating the Reliability of 'AudiClick': A Click-Based Mobile App for Hearing Loss

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Abstract

Introduction:

To develop and validate a click-based mobile “AudiClick” app employing click noises for hearing assessments.

Materials and Methods:

This prospective comparative study compares the “AudiClick” app as a hearing screening tool to pure tone audiometry. Participants listened to sounds through wired earbud headphones that were connected to an Android or iOS device.

Results:

The study involved 110 participants aged between 18 to 80 years old. All degrees of hearing loss severity corresponds to pure tone average ($p < 0.01$) results. The app was also found to be effective at identifying hearing loss (80-99% sensitivity, specificity, positive predictive value, and accuracy). Test-retest reliability had also shown excellent ICC scores of 0.93.

Conclusions:

This study demonstrates that a mobile app using click sounds can be as efficient as pure tone audiometry for field screenings, while being more cost-effective and easier to develop

Keywords: Audiogram, Hearing Tests, Mobile Applications, Screening, Ear

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Introduction

One of the most common chronic disabilities worldwide is hearing loss. A global estimate in 2018 showed that 466 million people experienced incapacitating hearing loss, 93% of whom were adults and 7% were children. Among adults with debilitating hearing loss, 56% are males and 44% are females." 34 million of these enormous numbers are children. By 2050, the population is expected to reach over 900 million, with one in ten individuals suffering from a hearing loss that is incapacitating (1).

Hearing loss is one of the main causes of illness worldwide (2). Moreover, hearing loss has a significant negative economic impact on the world, with the productivity loss in the United States alone estimated to cost 100 billion international dollars (3). Hearing-impaired individuals may engage in less social interactions and fewer activities, which can result in psychosocial distress (4). As a result, undiagnosed and untreated hearing loss can significantly affect a patient's health.

The methods available to primary care physicians to test individuals for hearing loss are limited (5). If hearing loss is found, there may be more opportunity for counselling and therapeutic interventions (6).

Regrettably, there are few or no hearing care services available, especially in suburban or rural regions. This is more noticeable in developing countries where there are less qualified hearing care professionals and less-than-ideal facilities. The main causes of unrecognised hearing loss include geographic constraints, a lack of professional and public awareness, and scarce resources (2).

For individuals who are at risk for hearing loss, a thorough audiology work-up is required. This is often done in a soundproof environment using specialised, calibrated equipment. Clinical settings use a variety of tests to identify hearing loss. Tuning fork testing, free field voice tests, and pure tone audiometry will be the most prevalent (PTA). A specialist setting is required for further examination of significant hearing loss utilising objective tests.

The use of portable devices in health technology that enable screening testing is becoming more widely accepted (7). The use of mobile application-based audiograms offers a chance to assist with patient screening for

hearing loss in the senior population and hearing loss assessment in patients with recent otologic issues. These smartphone apps wouldn't take the place of traditional audiometric testing or the audiologist's job, but using them for screening could aid in identifying individuals with hearing impairment and offer a chance for early referral and education. Recently, several teams have looked at the reliability of mobile iOS and Android hearing test apps as well as automated audiograms. The relative accuracy of these automated audiograms has been supported by these studies (8-10).

Except for Saliba et al., previous studies have concentrated on the utilisation of different mobile-apps-based applications in a calm environment. They tested the audiometric application with noise exposure while evaluating noise cancellation techniques (11).

Our creation includes a user-friendly, interactive app that uses broadband clicks to identify hearing loss.

We hypothesize that, when employed on a smartphone, click-based mobile apps can be just as useful as pure tone audiometry for diagnosing hearing loss in patients. The majority of apps on the market employ pure tone to identify hearing loss, hence the authors are unaware of any hearing applications that use broadband clicks or other broadband noise as their principal mode of sound threshold detection (12). In order to screen for hearing loss, we aim to assess the validity and dependability of portable software audiogram apps employing broadband click noises.

Materials and Methods

Study Design

This is a prospective cross-sectional study aimed at comparing the effectiveness of a mobile app hearing screening with traditional pure tone audiometry in detecting individuals with hearing loss.

The study was conducted at the Otorhinolaryngology (ORL) clinic of the xxx in Kuala Lumpur, Malaysia, from February to December 2020. Reference for design study was done according to the STARD guideline for reporting diagnostic accuracy studies (Figure 1).

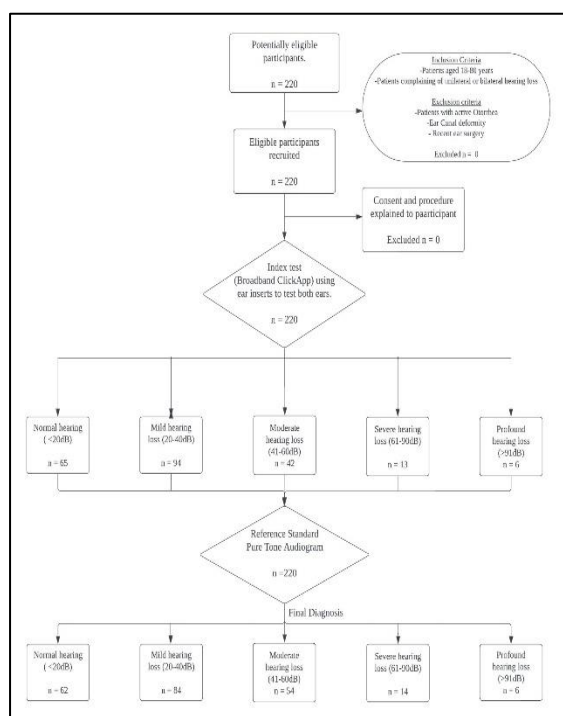


Fig 1: Flow Diagram of the study as guided by the STARD reporting guidelines for diagnostic studies

Participants

Participants included in this study were individuals aged 18 to 80 with a primary complaint of unilateral or bilateral hearing loss who underwent evaluation at the audiological department. Exclusion criteria consisted of participants with active otorrhea or bleeding, inherited or acquired external ear canal deformity, or recent ear surgery. In addition to that, participants with an underlying psychiatric or neurological disease were also excluded due to the subjective nature of the test.

Ethical Standards and Informed Consent

The study adhered to all applicable ethical standards, guidelines, and regulations set by the Universiti Malaya Research Ethics Committee (approval number: 2020114-8175). The research team ensured that the study design, data collection, analysis, and interpretation were conducted in accordance with the approved ethical guidelines.

Informed consent was obtained from all participants, and the manuscript provides a detailed description of the informed consent process, emphasizing the voluntary nature of participation, the study's purpose, the potential risks and benefits, and the measures taken to ensure confidentiality and privacy.

Intervention Technique

The study began with a thorough explanation of the procedure to each participant, followed by obtaining written consent. An otologic history and examination were conducted to ensure the absence of any current pathology and to ensure that the inclusion and exclusion criteria were met. A tuning fork test was performed to assess the hearing condition quickly. The Hughson-Westlake method was employed for pure tone audiometric testing, where responses to rising tones were recorded for both the audiometer group and the mobile app group (13,14). A tympanogram and clinical otoscopy was done in addition to the audiograms.

Click based mobile app

The index test involves Standardized mobile phones (iPhone 11 model and Galaxy S10 model) which were used in the study, along with commercially available wired earbuds provided with the mobile phones, which were calibrated before testing in every participant. The "AudiClick" app was developed by the main authors as listed in the manuscript. The index test used a mobile app which was programmed using the Flutter (v 1.13.7)-Dart programming language tool by the authors. As the app was programmed using Flutter, the results of the app is reproducible by another mobile phone with proper calibration.

A calibration process was implemented to ensure the accuracy of the AudiClick app used in this study. This involved comparing the app's sound intensity output to a known standard produced by an independent calibrated audiometer.

The app's settings, such as volume and intensity, were adjusted while playing a reference tone at a specific frequency. The goal was to align the app's output with the known sound level from our reference audiometer. The calibration procedure was repeated across multiple sound intensities and tested by two independent testers prior to ensure consistent results. Additionally, correction factors were introduced, if necessary, to fine-tune the app's calibration. Regular checks and updates were conducted to account for potential changes over time.

Hand-held Apple iPhone and Samsung Galaxy handsets were used to produce the noise, which

was delivered through commercially available earbuds. The Standard Click sound was calibrated and modified using an open-source audio editor (Audacity version 2.3.3). Click sounds were repeated 13 times at levels of 30 dB, 50 dB, 70 dB, and 90 dB in the better-hearing ear, within the broadband frequency range of 500 to 3000 Hz. Click noise was played for 2 seconds while waiting for response by the participant. The ambient noise was measured using a sound meter (Uni-T UT353 digital sound meter) was used to ensure ambient noise was constantly quiet throughout the test. Participants indicated their response to the sounds by nodding and saying "Yes" when they heard them. The participants sound threshold was reached when the participants were able to clearly respond to the lowest sound heard at the same level two out of three times.

The duration of the procedure for each group was measured using the timer function on smartphones. Both groups participated in a familiarization session, which involved step-by-step instructions and test sounds to elicit a reaction from the participants to the tested noise. In the case of unilateral hearing loss, the normal ear was stimulated first.

To ensure a distraction-free environment, the evaluations took place in a soundproof room with sufficient airflow and minimal human intervention. The examination time of each participant was recorded at the conclusion of the study.

Audiometer

The designated audiometer model used in the audiometric group underwent uniform calibration according to DIN EN 60645-1:2018-0814. The Itera II Madsen audiometer equipment was employed to test each subject, and earbuds were used to determine the hearing threshold. The hearing threshold was reached when the individual responded by pressing on a response button twice out of three times to the lowest sound level. Sound levels were reduced by 10 dB when the test noise was heard and increased by 5 dB when it was not.

Participants responded to noise stimuli by clicking a reaction button. Pure tones at a fixed duration of 2 seconds were delivered. The response was recorded at frequencies ranging from 125 Hz to 8 kHz, with seven distinct frequencies tested (125 Hz, 250 Hz, 500 Hz, 1

kHz, 2 kHz, 4 kHz, and 8 kHz). Hearing threshold at the Pure Tone Average was obtained at 500Hz, 1000Hz, and 2000Hz frequencies which was then used to compare to values obtained from the mobile app.

Statistical Analysis and Sample Size Calculation

Statistical analysis was performed using IBM SPSS Statistics, version 23. Categorical variables of the mobile app group and pure tone audiometry group were compared using the chi-squared test. A p-value less than 0.05 was considered statistically significant. A sample size calculation was conducted to determine the required sample size. An online sample size calculator (<https://clincalc.com/stats/samplesize.aspx>) was utilized for the power analysis. With a power of 90% and a marginal error (type one error for alpha value = 0.05) of 5%, a minimum sample size of 50 patients (50 ears, 95% confidence interval) was determined for each group.

Results

Demographics and Otologic Findings

A total of 110 participants, corresponding to 220 ears, were included in this study. Among the participants, 66 (60%) were female and 44 (40%) were male. Among the participants, 44 (40%) participants were young adults (18-39 years old), 47 participants (42.7%) were middle aged adults (40-65 years) and 19 participants (17.3%) are old aged (65 years and above) age groups. Otoscopic findings revealed that 80% of the cases had normal ear findings, 3 (14%) had retracted tympanic membranes, and 12 (5.5%) had perforated tympanic membranes at the time of presentation.

Tympanometry results indicated that the majority of participants had normal tympanic membranes, with 70% of the ears showing Type A tympanometry, followed by 11% Type C, 9% Type B, 8% Type Ad, and 2% Type As. No adverse effects were noticed throughout the course of this study.

Comparison of Click-Based Mobile App to a standardized audiometer

Statistically significant relationship ($p < 0.01$) was observed between the use of click-based mobile apps and pure tone average obtained through pure tone audiometry for diagnosing hearing loss (Table.1).

Table 1: Statistical significant correlation between mobile app and pure tone audiometry results. The Chi-squared test was used to determine statistical significant correlation due to its categorical nature. The Phi's correlation coefficient indicates strength of correlation.

Degree of hearing loss	Mobile app	Pure Tone Audiometry	Phi's Coefficient	Significance (p-value)
Normal hearing	65 (29.5%)	62 (28.2%)	0.83	<0.01
Mild hearing loss	94 (42.7%)	85 (38.6%)	0.69	<0.01
Moderate hearing loss	42 (19.1%)	53 (24.1%)	0.73	<0.01
Severe hearing loss	13 (5.9%)	14 (6.4%)	0.72	<0.01
Profound hearing loss	6 (2.7%)	6 (2.7%)	0.66	<0.01
Total (ear)	220	220		

The mobile app demonstrated higher sensitivity for most levels of hearing loss, except for moderate and severe cases (Table 2), (Figure 2). Limitations may arise when higher frequency loss cannot be discerned due to the app's ability to test hearing loss only within the frequency range of 1000 to 4000 Hz, which are known to be important for speech thresholds as seen in sloping hearing loss. However, the click-specificity app exhibited relatively good accuracy in identifying hearing loss. The test also demonstrated a strong positive and negative predictive value across the board for hearing loss (Table 2).

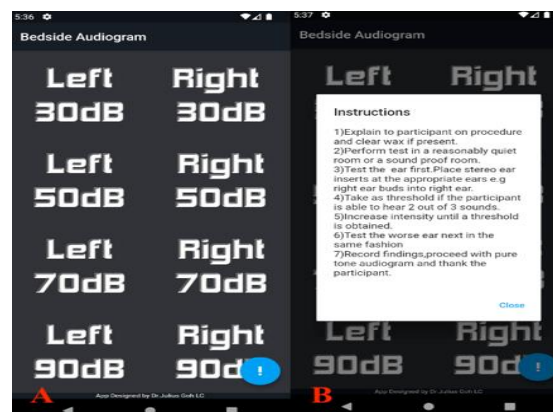


Fig 2: The Click based "AudiClick" mobile app used for hearing screening.

Table 2: various statistical measures to assess the usability of the app as a diagnostic tool.

Degree of hearing loss	Sensitivity (%)	Specificity (%)	Accuracy (%)	Positive predictive value (%)	Negative predictive value (%)
Normal	90.3	94.3	93.2	86.2	96.1
Mild	85.9	84.4	85.0	77.7	90.5
Moderate	69.8	97.0	90.5	88.1	91.0
Severe	71.4	98.5	96.8	76.9	98.1
Profound	66.7	99.1	98.2	66.7	99.1

In addition to that, the "AudiClick" app had also performed reliably in all age groups. As for the strength of correlation using Phi's coefficient, Normal, moderate and severe hearing loss was associated with a high degree of correlation of above 0.70 whereby other degrees of hearing loss demonstrated weak correlation of below 0.70.

Test Duration

The majority (95.5%) of users of the "AudiClick" mobile app for hearing screening reported that the task could be completed in less than a minute. In contrast, 54.1% of users of pure tone audiometry tests reported that it took longer than five minutes to complete the task,

indicating a significantly longer duration compared to the click-based mobile app.

Test-Retest Reliability

To assess the test-retest reliability of the audiometer and click-based mobile app, a subgroup of 15 participants (30 ears) was randomly selected from the original sample. These participants underwent the same hearing screening procedure using both the audiometer and the mobile app on two separate occasions, with an interval of 4 weeks between tests. The order of administration was counterbalanced across participants to minimize any potential order effects.

The data obtained from the two test sessions were analysed to determine the test-retest

reliability of the measures provided by the audiometer and mobile app. The test-retest reliability was assessed using intraclass correlation coefficient (ICC) analysis. Single measure ICC=0.871 and average measure ICC=0.931, values greater than 0.75 were considered indicative of excellent reliability, values between 0.60 and 0.74 indicated good reliability, values between 0.40 and 0.59 indicated fair reliability, and values less than 0.40 indicated poor reliability. The test-retest reliability results for both the audiometer and mobile app are summarized in Table 3.

The ICC values for the measures obtained from the ranged from 0.86 to 0.97, with an average ICC value of 0.93 indicating excellent test-retest reliability across different hearing loss levels. These findings suggest that both the Click-based mobile app consistently provided reliable results when used for repeated hearing screenings. The ICC values indicate that the measures obtained from both devices were stable over time and were not significantly influenced by factors such as participant variability or measurement error.

Table 3: The IntraClass Correlation Coefficient (ICC) demonstrate excellent test-retest reliability

	Intraclass Correlation Coefficient		
	Intraclass Correlation	95% Confidence Interval	
		Lower Bound	Upper Bound
Single Measures	0.871	0.747	0.937
Average Measures	0.931	0.855	0.967

Discussion

The most popular subjective hearing test is pure tone audiometry, which is the gold standard (15). Nevertheless, it can be expensive and difficult to find, especially in primary health care, which can cause delays in the referral and management processes (16,17). Given that the majority of healthcare professionals have smartphones at their disposal, a click-based mobile app hearing screening tool is easily accessible and may be a more affordable method of detecting hearing loss as it is easier to program than an individualized pure tone set-up (18). While cost was a crucial factor in the usage of our app, our research compared the viability of click-based screening to pure tone audiometry to find a quicker and easier method for identifying hearing loss in the general population. In this study, the click-based mobile app hearing tool was just as effective as a pure tone audiogram at detecting all levels of hearing loss, from normal to profound. When used in a soundproof space, it is as sensitive, focused, and precise as a pure tone audiometer in identifying the degree of hearing loss. However, using the mobile app, we were unable to recognize significant frequencies of hearing loss. Audio files are made up of broadband noises with predetermined sound intensities, so click-based mobile apps hearing aids are straightforward and only need little programming and

calibration (19). As apps are software-based, it is possible to make them widely accessible, particularly in rural areas. However, a pure tone audiogram requires comprehensive audiology gear, including a soundproof room, an audiometer, and headphones to complete the test. These services are typically only offered at secondary or tertiary hospitals and might not be appropriate for people who cannot move around. A click-based mobile app can also be helpful because it is user-friendly and doesn't require much training. According to the study, screening for hearing loss takes less than a minute compared to pure tone audiometry, which may take much longer. This shows that the test length is significantly lower. However, due to its technical requirements, a pure tone audiometer must be used by a technician or audiologist who has received professional training (20).

The lack of these specialists makes it challenging to make an urgent diagnosis of hearing loss after business hours as well as on weekends and holidays. Moreover, the COVID-19 pandemic severely influenced hearing screening testing, resulting in a backlog of cases that were either lost to follow-up or had their testing put off. The click-based mobile software will support post-pandemic hearing screening efforts (12).

While using audiometry requires professionals and expensive equipment,

developing such an app might be expensive, especially when done in-house for iOS or Android. Programmers may now create mobile apps with less chance of failure because to the introduction of open-source, cross-platform software frameworks from platforms like React Native, Ionic, and Flutter. Fortunately, neither iOS-based nor Android-based devices used by our researchers during our usage had ever had an app failure. Although the researchers independently developed the app, we estimate the cost to develop a mobile app similar to ours would be in the range of 1000-5000USD per app, including maintenance and upkeep. As a result, it would be significantly less expensive than a conventional audiogram because it is reproducible and easily adaptable. If the tests used are straightforward, the researchers would also advise designing from cross-platform software frameworks to ensure a low risk of failure in the long term.

It's important to note that the AudiClick app, when used for context of testing, can help detect mild hearing loss (greater than 25 dBHL in the better ear) but was unable to differentiate the degree of hearing loss accurately as severe to profound hearing loss. This is in contrast to other apps that are also able instead able to differentiate hearing loss of above 25dB (21,22).

In this context, it is believed that individuals that are trained in smartphone usage can conduct hearing assessments using self-operated AudiClick hearing screening. This broadens its potential application in large populations and in areas remote from major urban centers.

Thus, this tool can be easily employed within the realm of primary healthcare to identify significant hearing impairment. In addition to detection of hearing loss during screening, there is an opportunity to provide education to users about hearing loss and the need to direct users to a health professional for further assessment. One way to achieve this is to provide a summary of findings and list additional steps specialist level referrals (22). The study has its drawbacks. There is also a lack of masking in this study which may impact accuracy in certain hearing losses. The accuracy of this mobile app has not yet been evaluated in a non-specialty clinic setting without a soundproof room because the study was conducted in a single centre and an enclosed soundproof room. Further research will validate the application in a realistic setting to

assess the viability and precision of identifying hearing loss. The study should also be tested in two distinct clinical settings, with the potential use of noise-cancelling earphones to lessen background noise because only earbuds were used in the testing. Also, the mobile app was unable to distinguish between sensorineural, conductive, or mixed hearing loss.

Conclusion

Our investigation found that the click-based broadband mobile app 'AudiClick' was as accurate and sensitive in identifying hearing loss as pure tone audiometry. It is a quick, convenient, and useful screening tool, particularly in primary healthcare. Such an app can be used to screen individuals for suspected hearing loss, allowing for early identification and referral to a hearing center. It should be noted that the click-based broadband mobile app is only designed to be used as a screening tool and is not intended to take the place of pure tone audiometry as the industry-standard subjective hearing test.

Competing Interest

The authors of this manuscript declare that they have no conflicts of interest, either financial or personal, that could influence or bias the research or its interpretation. The study was conducted with complete impartiality and objectivity, free from any external influences that may compromise its integrity. The "AudiClick" app is a prototype app that has not been submitted to the general app store for public consumption.

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