Original Research

Validation of Portable Screening Audiometry (PSA) test for screening of hearing impairment among elders in an urban setting, Sri Lanka

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Abstract

Introduction: Hearing impairment is the fourth leading cause of disability among the elderly worldwide. It is defined as the inability to perceive sounds below 25 dB in one or both ears. Often, individuals do not recognize the condition until it affects daily activities. In Sri Lanka, early identification through national programs is limited due to the lack of resources, specially screening tools at the community level.

Objectives: To validate the Portable Screening Audiometry (PSA) test for screening hearing impairment in elderly individuals aged 65 years and above in Sri Lanka

Methods: A clinic-based, descriptive cross-sectional study was conducted at the National Hospital of Sri Lanka. The study included 103 elderly participants. The PSA test was administered by a trained data collector, and its results were compared with Pure Tone Audiometry (PTA) performed by an audiology technician, which served as the gold standard. Reliability was assessed using the test-retest method.

Results: The mean age of participants was 75.0 years (SD=6.28). At 60 dB, the PSA test showed the highest validity, with a sensitivity of 88.3% (95% CI: 82.2, 93.0) and specificity of 64.7% (95% CI: 50.1, 77.6) against PTA. Test-retest reliability showed a Cohen's kappa of 0.81.

Conclusions & Recommendations: The PSA is a valid and reliable test for detecting hearing impairment in the elderly. Integrating PSA testing into primary healthcare settings (Health and Lifestyle Clinics) could enhance early detection and referral.

***Keywords**: validation, hearing impairment, Portable Screening Audiometry, screen for hearing, elders*

Introduction

The World Health Organization (WHO) has recognized hearing impairment as the fourth leading cause of disability globally (1). As individuals age, there is a decline in structural integrity as well as functional capacity of the ears leading to hearing impairment in a variable degree which in turn manifests as hearing impairment in one ear or both ears (2). The global estimates of hearing impairment range from 63.1% in the USA (3), 57.5% in India (4) to 39.4% in Brazil (5). Prevalence of hearing impairment, among elders 65 years and above ascertained through self-report or non-audiometric methods has been found to be 41% (6) and 30.5% (7) in Sri Lanka.

The Pure Tone Audiometry (PTA) is the 'gold' standard test to diagnose hearing impairment (8). It is a costly, non-portable equipment, which has to be operated by a qualified audiology technician in a soundproof booth. Thus, PTA is available only in secondary and tertiary care hospital settings and is relatively inaccessible for routine screening for hearing impairment in low resource settings at community level.

There are many screening methods adapted for assessing hearing impairment, which include simple audiometry-based tests, questionnaires to assess hearing using self-reports and mobile applications. Simple audiometry-based tests that are used for screening the hearing include the watch and click test, Renner's test (9), free field voice test and Whispered Voice Test (WVT) (10-11). Modern mobile applications that have been developed to assess hearing impairment are the uHear app (12) and the hear WHO app (13). The Portable Screening Audiometry (PSA) test is a screening test based on mobile audiometry.

The PSA test is performed using a portable audiometry apparatus which is a small device designed to emit sounds. These sounds are presented individually to each ear and results are manually recorded by the administering person. It offers a convenient method to assess hearing status in both clinical and research settings. It does not require a sound-proof booth and could be performed in an environment with minimal disturbance. Further, it does not cause any discomfort to the patient (2). PSA test is a simple test that does not require a specially trained technician (2). The PSA test has not been validated for assessing hearing impairment in any age group in the region or in Sri Lanka. The present study aimed to validate the PSA test to screen the elders 65 years and above in the Colombo district, Sri Lanka, for hearing impairment.

Methods

A clinic-based cross-sectional validation study was conducted from June to August 2022 at the ENT clinic of the NHSL, Colombo. Elderly people aged 65 years and above were the study population. Those who reported as they cannot hear were also included in the study. Those who are cognitively impaired were excluded using validated Mini Mental State Examination (MMSE) guide as cognition and attention was required to respond to the test. elders with upper respiratory tract infection and cerumen impaction which can result in temporary hearing impairment were also excluded through auroscopic examination from the study.

The minimally acceptable size of the sample to evaluate criterion validity of PSA was calculated using the standard formula (14). Expected sensitivity and specificity (2) for an ear to be classified as hearing impaired using PSA was taken as 94.7% and 65.9% based on study conducted by Cardoso et al 2014 using PSA test. The estimated prevalence of hearing impairment was taken as 57%, considering evidence from India (4), as prevalence estimates for Sri Lanka using objective assessment methods was not available. A margin of error of 0.05 was considered for the calculation. Each ear was

considered as one study unit. The required number of ears was estimated as 206, with the inclusion of 103 eligible elders aged 65 years and above.

A convenient sample of elderly above 65 years who visited the medical, surgical, and ENT clinics of the NHSL, and their caregivers above 65 years of age, were recruited for the study. Although this study was conducted as hospital-based study for the feasibility of administering the PTA test, elders of both sexes and all age categories were included and the elders also represented the full spectrum of normal and impaired hearing.

Three pre-intern medical officers were trained to recruit eligible study participants and to conduct the PSA testing. Each study participant underwent PSA test with three readings for each ear at 40 dB, 60 dB, and 80 dB threshold levels in a the pre identified location of the ENT clinic where environment noise was ensured to be 55 dB or below level. The environmental sound level was monitored in four corners of the room before each test to ensure it was within the specified limits (0-55 dB) for the PSA testing using the 'NIOSH Meter app' (15). 'NIOSH Meter app' is a mobile application which is developed and validated by National Institute of Occupational Safety and Health in USA (16) for the measuring of sound level in locations.

Study units were seated comfortably in a relaxed position on a chair. Prior to administration of the PSA test, study units were instructed to remove hats, headbands, hearing aids, or any other articles that may interfere with proper positioning of the earphone cushions on the ears. They were provided with an explanation regarding how the hearing was tested by creating a sound that he will hear in one ear through the earphone and the need to indicate if he heard the sound by ringing the bell. They were also informed that a practice test will be conducted by giving two sounds per ear, before the testing proper. The study units were emphasized the importance of maintaining focus on the test, minimizing any unnecessary movements or distractions that could impact their ability to hear sounds during the test. The pre-prepared checklist was used to verify the arrangement and procedures before conducting each test.

Prior to conducting the formal test, the practice test was conducted for each ear using the following procedure. The two sounds used were levels of 10dB and 80dB. The sound level 10 dB, which is known to be lower than the human hearing threshold was used as no one would expect to hear it. Sound of 80 dB was used as it was expected to be heard by even a person who has a profound hearing impairment as per the ASHA and WHO classification (17-18), In testing 10 dB sound was not expected to be heard by anyone and 80dB sound was expected to be heard by all people with normal hearing. This method was specifically used to detect whether the study unit will erroneously ring the bell. Only the study units who exhibited accurate responses for both sounds in each ear were proceeded to the test proper. In this testing the sound levels used were 40 dB, 60 dB and 80 dB. These levels were used in alignment with the WHO recommended classification of hearing impairment as mild, moderate, and severe, which had also been endorsed by American Speech and Hearing Association (ASHA) guidelines, in administering PTA test (19).

The study units utilized the ringing of a bell as a responsive indicator to signify the presence of sound that they heard. Findings of the test were recorded by the data collector in the designated form as 'Yes' or 'No' for each ear, separately at each threshold level. In each form was designed to have separate places to write serial number for both PSA and PTA tests. The PSA equipment (AS608) was calibrated within the preceding one-year period according to guidelines issued by the manufacturer (20). Once completed the PSA test, the study participant was accompanied to the location in the ENT clinic for PTA testing. The test results of the PSA were not shared with the technician performing the PTA or with the study participant.

The gold standard PTA test was conducted by a single, qualified audiology technician using Interacoustic-AD27, pure tone audiometer. The test was conducted in a sound-controlled booth of the ENT clinic. The study units were comfortably seated in a relaxed posture on chair with in the acoustically controlled booth in the separate room of the ENT clinic. The study participant was instructed on maintaining alertness during the test, minimizing unnecessary movements or distractions that could affect their ability to hear sounds during the testing process. The checklist was used to ensure the proper adoption of procedures by the data collector prior to conducting the test.

In this testing with PTA, the sound level used was 25 dB. The results of PTA for each ear generated by the machine were recorded in the data reading sheet. A unique serial number assigned to each study participant at the commencement of their interview. This serial number was recorded in separate sections of the questionnaire, the PSA test recording sheet, and the PTA recording sheet. An ear was considered as having normal hearing at a 25 dB level, which is the threshold level in the gold standard test to consider the ear as "normal hearing," and if greater than 25 dB, it was considered as "hearing impaired".

PTA machine was calibrated adhering to the standards set forth by the American Speech-Language-Hearing Association (ASHA) guidelines (21).

Appraising reliability of PSA test

Six study units who were identified as hearing impaired at 60dB and six study units with normal hearing were included. Participants for reliability were selected by principal investigator following completion of PTA test and directed them to the data collector to conduct PSA test. Data collector was unaware of PTA test results. Contact numbers of participants selected for reliability selected were recorded in the data collection sheets and were marked with a special color-coded indicator for easy identification, by the data collectors. They were invited to come for second assessment two weeks from the initial assessment. All of them were subjected to PSA test again and findings were recorded in the data collection sheet which were labelled with the corresponding serial number and securely stored separately to maintain accuracy and organization.

Diagnostic accuracy measures, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and likelihood ratio, were evaluated at 40dB, 60dB and 80dB threshold levels of the PSA test against the PTA test. The best suitable level was identified based on the values of sensitivity, specificity, PPV and NPV of each level. Sensitivity and specificity of the selected levels were disaggregated for age and sex of the participants. Cohen's Kappa coefficient was calculated to assess the reliability of PSA test.

Table 1: Distribution of the participants by socio-demographic characteristics (N=103)

Characteristics	Category	No.	%
Age categories (in completed years)	65-69 years	38	37.3
	70-74 years	32	30.6
	75 years and above	33	32.1
Sex	Female	58	56.3
	Male	45	43.7

Results

A total of 103 eligible elders (206 ears) were recruited for the study. The response rate was 100%. The mean age of the study sample was 75.04 (SD=6.28) years and majority were females (n=58; 56.3%) (Table 1). The distribution of the age and sex categories was compatible with population structure of Sri Lanka (22).

Table 2: Distribution of sensitivity and specificity of the PSA Test by 40dB ,60dB and 80 dB sound levels

Sound level	Sensitivity, % (95% CI)	Specificity, % (95% CI)
40 dB	95.6 (93.1, 98.2)	8.5 (0.05, 15.2)
60 dB*	88.3 (82.2, 93.0)	64.7 (50.1, 77.6)
80 dB	57.5 (49.3, 65 5)	92.4 (81.8, 98.0)

*Selected level

The sensitivity and specificity of the PSA test at three different sound levels (40 dB ,60 dB and 80 dB) are shown in Table 2. Sensitivity of the PSA test was best at 60 dB level, 88.3% (95% CI: 82.2, 93.0) while 40 and 80 dB showed sensitivity levels of 95.6% (93.1, 98.2) and 57.5% (95% CI: 49.3, 65 5), respectively. Specificity was of the PSA test was best at 60 dB level, 64.7% (95% CI: 50.1, 77.6), while 40 and 80 dB showed specificity levels of 8.5% (95% CI: 0.05, 15.2) and 92.4 (95% CI: 81.8, 98.0), respectively. Of the three sound levels considered, 60 dB was the sound level represented the best sensitivity and specificity. The diagnostic accuracy measures, PPV, NPV and accuracy of the PSA test at 60 dB level to detect hearing impairment were found to be high compared to 40 dB and 80 dB levels (Table 3).

Table 3: Distribution of diagnostic accuracy measures of PSA Test at 60 dB level to detect hearing impairment

Item	%	95% CI
Sensitivity	88.3	82.2, 93.0
Specificity	64.7	50.1, 77.6
Positive Predictive Value	88.3	82.2, 93.0
Negative Predictive Value	64.7	50.1, 77.6
Accuracy	76.6	70.1, 82.1
Positive Likelihood Ratio	2.5	1.7, 3.7
Negative Likelihood Ratio	0.2	0.1, 3.0

The specificity of the PSA test at 60 dB to detect hearing impairment further analysed by age category and sex. The sensitivity of PSA test at 60 dB to detect hearing impairment increased gradually across age groups, but this increment was not statistically significant. Specificity of the PSA test at 60 dB to detect hearing impairment across the age groups also deferred across age groups, similarly, this difference also was not significant. Sensitivity and specificity between male and female groups were also dissimilar but were not statistically significant (Table 4).

Test- retest reliability assessed using Cohen's Kappa coefficient indicated 0.81 for the PSA test. This value of 0.81 is substantial agreement as per Cohens J, 1960 (23).

Table 4: Distribution of sensitivity and specificity of the PSA Test at 60 dB disaggregated by age and sex of the study population

Characteristic	Category	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Age category	65-69 years	83.0 (69.2, 92.3)	65.5 (45.6, 82.1)
	70-74 years	88.2 (76.1, 95.6)	61.5 (31.6, 86.1)
	75 years and above	93.0 (83.0, 98.1)	66.7 (30.0, 92.5)
Sex	Male	86.6 (76.0, 93.7)	43.4 (23.2, 65.5)
	Female	89.7 (81.5, 95.2)	41.5 (35.3, 47.7)

Discussion

This study focused on validating the PSA test to screen the hearing status of elderly individuals aged 65 years and above in Sri Lanka. Currently, the implementation of hearing impairment screening programs is limited in Sri Lanka. There is national policy regarding elderly care, screening for hearing has not been included, although screenings for other conditions, for instance, visual impairment and NCDs are part of the policy. In the government sector, individuals with hearing impairment should refer from primary care to secondary or tertiary care, accounting further strain to an already overburdened healthcare system. In contrast, the introduction of PSA test would assist in alleviating this burden by identifying individuals with hearing impairment, ensuring that only those in need of specialized care are referred for further investigation. Additionally, there is no government-led hearing aid distribution program in place, in contrast, many private sector centres offer hearing screenings, provide hearing aids and cochlear implantations. Furthermore, there was no planned hearing screening programs for pre-school children or school-aged children or elders in the government sector or private sector. While routine hearing assessments are conducted in babies born at a few private hospitals, a comprehensive national screening program for hearing screening remains deficient.

The World Health Organization (WHO) has emphasized the importance of primary ear and hearing care (PEHC) as the strategy for prevention of deafness and hearing impairment. The WHO recommends that countries develop programmes and integrate PEHC programs into their primary healthcare systems to effectively address hearing impairment. Although diagnostic services are available in Sri Lanka, there is a requisite for the development and implementation of comprehensive national policies and programs targeting screening for hearing status across all age groups. At present, NCD screening conducted at HLCs at the primary care level thus integrating hearing screening into the same programme would be more effective and timelier requirement. Hence, the present study aims to assess the psychometric properties of the PSA test to ensure its reliability and validity in a clinic setting is noteworthy. For this study, participants were elders above 65 years of age, recruited from different clinics of the NHSL and their caregivers who met the eligibility criteria, encompassing a diverse population.

The study followed a stringent methodology, with participant recruitment based on eligibility criteria and sample size determined using the values for sensitivity, specificity, and prevalence from previous studies. This approach enhanced the power and precision of the study. The 60 dB sound level of the PSA test was found to be the most appropriate level to determine hearing impairment. The most suitable

sensitivity and specificity values were obtained at 60 dB level compared to these values at 40 and 80 dB. Furthermore, in the present study, the trained designated data collector was engaged for the PSA testing to mitigate the observer variability, while remaining data collectors were trained to gather socio-demographic and socio-economic information and to monitor the environmental sound level. The subjective variability was minimized through the uniform administration of the test, which was preceded by practice test and checklist was used to verify the preparation of subject for the test. The PSA machine (AS608) used for the data collection had been calibrated according to manual issued by the manufacturing company. The same PSA machine was utilized for testing for hearing status of all the participants. Hence, variability arises from the instrument could be eliminated. Elders with ear infections and cerumen impaction were excluded from the study, which may mask the true prevalence of hearing impairment. Additionally, the study did not include elders with cognitive impairment, who may have developed the condition due to hearing impairment.

The PSA test has demonstrated a sensitivity of 88.3% and specificity of. 64.7%. High sensitivity of PSA test is advantageous as it leads to fewer false negatives, most individuals with hearing impairment are correctly identified and allowing for early identification and referral for the further management. While with the low specificity, increases the likelihood of false positives, where individuals without hearing impairment may be misclassified as having impairment. Hence, elders who were incorrectly identified as having hearing impairment, were referred for unnecessary further diagnostic testing, such as PTA. It would cause an additional burden on healthcare facilities, increasing time for healthcare providers per one person. However, considering long term positive outcome of early diagnosis of hearing impairment for the elders, this cost implication could be considered as insignificant. Furthermore, sensitivity of other available methods is comparatively low while possessing nearly equivalent specificity to PSA test. Sensitivity and specificity of WVT is 69.23% and 90.41%, respectively (24). A single self-assessment question has a sensitivity of 78% (25) and a specificity of 67%, while the HHIE questionnaire has a sensitivity of 61.80% and a specificity of 85% (26). However, WVT, HHIE or PSA tests were not validated to Sri Lanka for any age group.

The PSA test is an objective screening method, whereas other methods such as the HHIE, single self-assessment question and the Whispered Voice Test (WVT), are subjective and may introduce variability. The accuracy of the WVT depends on the experience of the investigator administering the test (27), while the HHIE and similar questionnaires rely on the understanding of elders, which can become challenging as cognitive abilities decline with age. In contrast, the PSA test remains independent of this subjective variability. Hence, it is more reliable screening method to assess hearing status.

Moreover, PSA test is a suitable as a community screening tool owing to user-friendliness, and non-invasiveness. It does not require a trained technician to administer the test. Unlike PTA test which requires qualified audiology technician the PSA test can be administered by any health care person with training at community setting. Additionally, the diagnostic indices of the PSA test are independent of the observer, it does not depend on the experience and competency of the observer. The PSA test does not require a soundproof booth or sound-treated room and could be administered in a sound-controlled environment which is economically crucial for low-income countries in planning and implementing screening test for hearing.

The validated PSA test should be carried in sound-controlled environment or quiet environment to ensure accurate results. The desirable sound level is below 55dB which is equivalent to the noise of general conversation between two people in a library.

Ideally the test could be conducted in a separate room to ensure quiet environment and to avoid any distractions. Furthermore, provision of proper training for healthcare personnel on recognizing and mitigating background noise can enhance the accuracy of PSA results in non-clinical community settings. The test only identifies the presence or absence of the hearing impairment, which makes it suitable screening test, as in the community setting, degree of the hearing impairment does not have a major impact on referrals.

The elders are the most vulnerable population group at risk of developing hearing impairment compared to other age groups. The present study demonstrates that the PSA test is an appropriate test for assessing the hearing status of the elderly. Hence, it is noteworthy to incorporate this test into the existing primary care system to screen for hearing, as it will further enhance quality of care provided for them. Since, existing NCD screening available in the HLC clinics it would be more appropriate hearing screening to be incorporated. It would not give arise to human resource constraint. The referral pathway and data flow will also not be limitation. Hence, this could be effectively managed without placing burden on the system. As result, comprehensive care can be provided for the elders.

Limitations

Validation was conducted as hospital-based study for the feasibility of administering the PTA test, though ideally it should be conducted in community setting. However, the fact that elders of both sexes and all age categories were included, and the elders also represented the full spectrum of normal and impaired hearing support the applicability of results to elders in other settings.

Conclusions & Recommendations

Advocate policymakers for the implementation of hearing screening programs for screen the elderly population using validated PSA test at primary health care institutes to assess hearing status of elders. Furthermore, routine screening programs using the validated PSA test could be implemented in primary healthcare settings to improve wellbeing of the elderly. Integrating PSA testing at HLCs, will facilitate early detection and referral when needed. Additionally, healthcare providers should receive proper training on administering and interpreting the PSA test to ensure smooth functioning of the programme. Campaigns raising public awareness on regular hearing screenings and early intervention while monitoring the functional status of the programme are in priori.

Public Health Implications

- Hearing is a vital sense that impacts overall well-being. Hearing impairment can decline QoL, reduced independence in Activities of Daily Living (ADLs) and increasing susceptibility to health challenges such as social isolation, and higher healthcare costs particularly among the growing elderly population. Implementing suitable screening test, PSA test to assess hearing status will become vital. Early detection and management not only enhance QoL but also assist in independency, enabling older adults to maintain a more active lifestyle.

Author Declarations

Competing interests: The authors declare that they have no competing interests.

Ethics approval and consent to participate: Ethics approval for this study was granted by the Ethics Review Committee of the Faculty of Medicine, University of Colombo (Reference number: EC-22-032). Prior to conduct the study, permission was obtained from the Deputy Director General of Health Services at the National Hospital of Sri Lanka. Informed written consent was obtained from all participants.

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