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## International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl



## Validity of automated threshold audiometry in school aged children

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#### ARTICLE INFO

Keywords: Agreement Automation Conventional Validity

#### ABSTRACT

Background: Automated hearing tests have the potential to reduce the burden of disease amongst learners by introducing such services within the school context.

*Methods*: The aim of the study was to conduct a validation study on normal and hearing impaired learners, comparing air and bone conduction automated test results to conventional test results in 50 school aged learners (n = 100 ears) within a noise controlled school environment using a cross sectional comparative study design. The KuduWave 5000 (Emoyo.net) was used in this study.

Data analysis: The spearman's correlation coefficient was calculated to determine test-retest reliability. The mean and standard deviation (SD) was measured for each frequency. The absolute mean difference (AMD) and SD was calculated for both air and bone conduction testing at each frequency for automated testing. A paired sampled t-test and a one way ANOVA was used to identify any significant differences. Alpha was set as 0.05. Results: There was significant correlation between thresholds obtained for automated test one and test two for normal hearing and hearing impaired group. The spearmans correlation coefficient was high (close to  $\pm$ 1) for majority of the results for both groups across the frequency range. Both air and bone conduction testing across the frequency range of 250 Hz–2000 Hz and at 8000 Hz were not statistically significant (p < .005) for both groups, however at 4000 Hz for bone conduction testing in the hearing impaired group, there was a statistically significant difference (p = .003). This was attirubted to the variaibilty in bone conduction test results often due to force and placement of the bone vibrator.

Conclusion: The findings indicate that automated audiometry can yield relaible results that are comparable to conventional test results. Key clinical considerations include extending the response time, regular rest periods, improving instructions and comfort levels.

#### 1. Introduction

Automated audiometry uses algorithms and software that can be used to conduct a hearing test based on programmed test protocols. The benefits of automated audiometry include standardization of test procedures and protocols, improvement in diagnostic accuracy by reducing clinician variability and efficient electronic record keeping [1,3–7,34,35]. To realise these benefits, automated audiometry must produce results that are reliable and comparable to conventional methods of audiometric testing.

Pure tone audiometry testing is regarded as the gold standard [9]. Therefore audiologists compare other audiology tests to this gold standard. Several studies have been conducted demonstrating the reliability and validity of automated audiometry when compared to standard conventional measures [1,5,10–15]. These studies found that automated audiometry provided air and bone conduction results that were in agreement with conventional measures.

However, these studies were primarily based on the adult population and most authors motivated for similar studies to be conducted on children due to possible child related factors that may influence reliability. A systematic review of automated audiometry concluded that future studies should focus on determining the validity of automated audiometry in children and in patients with different types and degrees of hearing loss [3]. An international study by Ref. [16] found that the results of automated and conventional testing differed in children. They recommended that further research was required to identify factors leading to such responses. Ref. [12] found that automated methods in testing provided accurate air conduction results with children aged four to eight years, although this was only obtained after several inconsistent audiograms were identified and removed. They suggested that future studies need to identify factors that may influence the reliability of automated tests results in children. Ref. [3] conducted diagnostic pure tone audiometry in schools without a sound treated environment and found no significant difference between manual and automated air-

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and bone-conduction across frequencies for these thresholds.

Whilst all of the above studies suggest that automated audiometry is comparable to conventional test results in both adults and children, there is an evidence based gap regarding validation studies of automated audiometry on children presenting with different types and degrees of hearing loss. The aims of this study were to determine i) the test-retest reliability of the automated method ii) the level of agreement between the automated and conventional test results obtained in children with varying degrees of hearing loss and iii) to identify key clinical considerations that need to be taken into account when assessing children using automated methods.

#### 2. Methods

Ethics approval was obtained from the Biomedical Research Ethics Committee at KwaZulu-Natal University (BE288/15). Approval was also granted from a special needs school to recruit participants. Participants were recruited after parental consent and learner assent was obtained.

Learners at the school were either hearing impaired or presented with physical challenges. All children at the school (n=200) were given information letters as well as consent and assent letters, inviting them to participate in the study. A total of 50 learners (100 ears) consented to participate in the study. This was based on their availability and willingness to participate. Ref. [17] recommends that 15 to 20 subjects would be required for estimating the reliability of a quantitative variable Learners were from grades one to seven and their ages ranged from 6 to 13 years with the mean age of 11.2 years (SD=2.18).

#### 2.1. Equipment

Each participant underwent testing via conventional and automated audiometric methods. A calibrated AC33 two channel clinical audiometer, TDH39 headphones and a B-71 bone oscillator was used for air and bone conduction testing. The KUDUwave 5000 (Emyoy.net), a computer-based audiometer was used for automated testing, using an HP ultrabook laptop with Windows version 10 installed. The audiometer was calibrated by a qualified technician before use. The device was new and used for the first time for this study. Deeply inserted insert foam tips were used for air conduction testing and the Radioear B-71 bone oscillator with an adjustable headband was used for automated bone conduction testing. Both the conventional and automated audiometers had patient response buttons.

#### 2.2. Data collection procedure

All participants underwent an otoscopic examination and tympanometry testing to confirm that the outer and middle ear status was normal. They were tested using both conventional and automated methods. Both ears were tested across the frequency range of 250 Hz-8000 Hz for air conduction testing and 250 Hz-4000 Hz for bone conduction testing. Conventional testing was conducted in a sound treated booth, whilst automated testing was conducted in the classroom environment. The classroom was situated in a relatively quiet area of the school. The room had several windows and two entrances, potentially posing a threat of noise exposure. Noise measurements were taken at regular intervals to ensure that noise levels remained below 50dBA. Automated air conduction testing required deep insertion of the foam tip and then placing the circum-aural earphones over the ears to provide additional noise reduction. Automated bone conduction testing was performed by placing the bone oscillator on the forehead of the patient whilst the headphones and insert earphones covered both ears. The modified Hughson-Westlake method was used to establish thresholds [18]. Masking for both air and bone conduction followed [19] considerations for applying masking. For bone conduction masking in the automated method, a sustained and continuous masking level was presented at 20dBs above the air conduction threshold as used in previous studies [14,20]. Participants were also re-tested via the automated method to check for test-retest reliability.

All participants were tested by a qualified audiologist. To eliminate bias, participants were tested in a counterbalanced manner. The participant tested first for conventional methods was tested last for automated audiometry. This was done to reduce the memory effect. There was a rest period of more than an hour between test methods as well as between testing and retesting. Ref. [19] standardized protocol was used for conventional testing in terms of ear selection, frequency and intensity selection, and instruction. For automated testing, the following additional measures were put into place in accordance with the KuduWave operating manual (2015): The patient was placed approximately 1.5 m away from the laptop computer. The response time was set at 1500 ms and two measurements for automated audiometry were taken on every participant. According to the default protocol, the left ear was assessed first.

Due to the age of participants and to ensure that the academic programme was not affected, each participant was only tested once for conventional audiometry therefore test-retest reliability for conventional testing could not be ascertained. However, the school regulations require that every learner be assessed annually. Therefore, all conventional audiograms were compared to the audiograms recorded in the year and only in cases with large discrepancies, was the learner retested. Only three learners required a re-test. A total of 100 ears were analysed. Participants were appropriately referred based on any new pathologies identified.

#### 2.3. Data analysis

Statistical analysis was conducted using the SPSS version 24. The mean hearing thresholds obtained via both methods as well as the standard deviation (SD) was calculated for each frequency. Spearman's correlation coefficient was calculated to determine the correlation between both automated tests one and two for both air and bone conduction. A similar analytical framework as that used by Ref. [2] was used to compare the hearing thresholds obtained by the automated and conventional methods. The absolute mean difference (AMD) and SD was calculated for both air and bone conduction testing at each frequency for both automated as well as for the conventional testing. Absolute mean difference measures can account for positive and negative variation in the data and was therefore used [2]. A paired sampled t-test and a one way ANOVA was conducted. A paired t-test was used to compare the mean hearing threshold differences between both methods for both air and bone conduction testing across the frequency range and the ANOVA compared the means between the two tests to determine if they were statistically significantly different from one another. Alpha was set at 5%.

#### 3. Results

A total to 50 children participated in the study (n = 100 ears), twenty with normal hearing and 30 with varying degrees of sensory-neural hearing loss. Six participants presented with mild hearing loss (12%), eight with moderate hearing loss (16%), six participants with moderate to severe hearing loss (12%), four with severe to profound hearing loss (8%) and six participants with profound hearing loss (12%). For ease of interpretation, results are presented for the normal hearing group and then the hearing impaired group and is not meant to imply that any differences should be seen for automated audiometry in the normal hearing group when compared to the hearing impaired group.

For both the normal hearing group as well as the hearing impaired group, the test-retest reliability between test 1 (T2) and test 2 (T1) was significant, indicating good correlation (Tables 1 and 2). The correlation coefficient was high (close to +1) in most cases except for bone

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