

Research Article

Accuracy of the Novel ENTraview Mobile Device to Increase Access to Screening and Provisional Diagnosis of Ear Disease in Underserved Communities Across India

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A B S T R A C T

Background: The WHO estimates that there are more than 360 million people (5% of the total population) currently living with disabling hearing loss. There is an enormous and often invisible, global burden of hearing loss and ear disease especially in low and middle-income countries, where environmental factors are significant and access to preventative and treatment health services is challenging. **Methods:** A retrospective sampling study was completed to compare the agreement in screening for and diagnosing ear disease/hearing issues between the CHWs using ENTraview and the ENT specialist diagnosis.

Results: Shruti ENTraview device otology functionality accuracy was examined over a total of 573 patients (34 ± 19 years old, 43% female). The most common diagnoses were CSOM in 50% of patients, wax in 35% and ASOM in 6%. The sensitivity rate of the community health worker diagnosis was 96.9% with corresponding 95% confidence interval of 95.1-98.1%.

Conclusion: The burden of ear disease and hearing loss, within communities across India, is high and barriers exist, for patients and providers, across the continuum of care, including access to early screening and diagnosis.

Keywords: Ear disease, Otitis media, India, Hearing Loss, ENTraview, Audiology, Otology, Innovation

Introduction

The WHO estimates that there are more than 360 million people (5% of the total population) currently living with disabling hearing loss.¹ There is an enormous and often invisible, global burden of hearing loss and ear disease especially in low- and middle-income countries, where environmental factors are significant and access to preventative and treatment health services is challenging.² The limited number of ENT specialists and audiologists, as well as the distribution of these resources within a low- and middle-income country, can amplify the barriers to care. Undiagnosed and untreated hearing loss and ear disease can put a strain on individuals, families and communities resulting in communication challenges, educational deficits, loss of work, depression and social isolation.

In order to directly address these challenges, in 2013, an innovative ear care program, called Shruti, was launched in rural and urban areas across India to increase awareness, screening, diagnosis and treatment for the underserved through a proprietary mobile otoscope named "ENTrview" and low-cost hearing aids, integrated with an intuitive mobile application with otology and audiology.

Shruti-trained Community Health Workers (CHWs) organize camps and go door-to-door with the ENTrview, a mobile device that allows CHWs to quickly screen and diagnose patients with chronic ear infections, other ear diseases and/or hearing loss. The screening devices are built on commonly available cell phone technology and designed for rugged settings making them portable and durable to heat and dust. An intuitive, user-friendly application interface allows the CHWs to collect and upload patient history and a photograph of the patient's ear drum, provide a preliminary diagnosis and then, when applicable, refer the patients to a local Shruti-partner ear, nose and throat specialist (ENT) for final diagnosis and affordable treatment. We sought to determine the accuracy of the in-field otology (assessment of the anatomy and diseases of the ear) performed by the Shruti CHWs with the ENTrview as compared to the diagnosis made by the ENT specialist.

Methods

To assess the otology accuracy assessment. The goal of the otology accuracy study was to conduct a sensitivity analysis of the diagnosis concluded by a community health worker for patient's hearing impairment utilizing ENTrview versus the one conducted on the same patient by an ENT specialist.

Study Participants

A retrospective sampling study was done to compare the accuracy of a Community Health Worker (CHW) preliminary diagnosis utilizing the ENTrview device versus the ENT specialist located at a Shruti partner site. At the time of study, the Shruti database had over 810,746 patients

screened, 265,613 had been referred (were detected with provisional issue) and 20,986 patients, who decided to seek treatment, had been registered at the partner site. From the 20,986 patients registered, a random sample of 573 patient records were selected for analysis from 115 centers. The sample was chosen from the patients who were enrolled and have had both a CHW provisional diagnosis and a final assessment available from the ENT specialist.

No incentives were offered to participants involved in the study and it was a free of charge screening for all the participants.

Devices Utilized for the Assessment

The Shruti CHW utilized the ENTrview device to carry out the field assessment and determine the provisional diagnosis. The Shruti site ENT specialist utilized the field assessment along with the uploaded image from the ENTrview as well as their own independent diagnosis tools/process, to carry out their assessment and make a final diagnosis.

Study Design

The objective of this retrospective sampling study was to assess an acceptable diagnostic accuracy rate for a Community Health Worker to diagnosis hearing issue utilizing ENTrview. A sensitivity analysis was conducted to assess the accuracy of a community health worker at properly diagnosing a patient's hearing impairment utilizing ENTrview when compared versus an ENT specialist. The reference for comparison was a site ENT specialist assessment and diagnosis. Due to the availability of a large database of patients that have had otology assessments completed by a community health worker and reviewed by an ENT specialist and the same version of the Shruti ENTrview device is currently being used in the field, a retrospective sampling study was an efficient design for this study. For a patient to be reported into the otology database, a community health worker completes an otology assessment in the field utilizing ENTrview and if the community health worker screens the patient with a hearing issue, the patient is entered into the database. Due the patients being pre-screened by the community health worker prior to being entered in the database, only a sensitivity analysis could be conducted. A specificity analysis could not be conducted because patients with normal hearing were not entered in the database. The sensitivity rate of the community health worker properly diagnosing a patient using ENTrview was defined as the proportion of time the community health worker's diagnosis matched the ENT specialist final diagnosis.

Statistical Analysis

Predefined analysis plans and sample sizes were developed prior to the study. Details of the analysis plans are described

below. The primary objective of the study was to assess an acceptable diagnostic accuracy rate for a Community Health Worker to diagnosis ear disease or hearing loss-utilizing ENTraview. A sensitivity analysis was conducted. Performance criteria were defined for the study and included a primary objective with hypothesis of the sensitivity rate of the CHW diagnosis is greater than 80%. That is, the CHW diagnosis matched the ENT specialist in at least 80% or more patients. The analysis plan estimated an agreement rate of 85% or higher and therefore a sample size of 573 subjects affords over 85% power to test this objective using binomial exact methods. For each patient assessment, there were 10 diagnosis codes that could be used by the CHW and the ENT specialist in their diagnosis; Acute Otitis Media (AOM), Acute Suppurative Otitis Media (ASOM), Chronic Suppurative Otitis Media (CSOM), Otitis Media with Effusion (OME), hearing loss, tinnitus, Wax, otomycosis, foreign body, nose-throat and otitis externa. Agreement was defined if the CHW diagnosis matched the ENT specialist diagnosis. Sensitivity was calculated as the number of patients, which the CHW and ENT specialist agree on diagnosis divided by the total number of patients in the study. A corresponding 95% confidence interval was calculated using binomial exact methods. If the full 95% confidence interval was above 80%, the objective was considered met.

Table 1. Distribution of Hearing Loss Diagnoses Observed (per ENT Specialist)

Diagnosis by ENT Specialist	Number of patients (%)
CSOM	288 (50%)
Wax	199 (35%)
ASOM	33 (6%)
Foreign body	14 (2%)
Hearing loss Wax	12 (2%)
CSOM Hearing loss	11 (2%)
CSOM Tinnitus	3 (0.5%)
CSOM Wax	3 (0.5%)
Foreign body Wax	3 (0.5%)
CSOM ASOM	2 (0.3%)
ASOM OTO	1 (0.2%)
ASOM Wax	1 (0.2%)
OME	1 (0.2%)
Tinnitus Wax	1 (0.2%)
Wax Nose throat	1 (0.2%)

Results

A total of 573 patients had records sampled in the database with complete data. The average age was 34 ± 19 years

old and 43% were female. The most common diagnoses were CSOM in 50% of patients, wax in 35% and ASOM in 6% (Table 1).

The sensitivity rate of the community health worker diagnosis was 96.9% with corresponding 95% confidence interval of 95.1-98.1%. When a patient was diagnosis with a hearing issue by the ENT specialist, the community health worker had the same diagnosis 96.7% of the time. Because the whole 95% confidence interval was above 80% performance criteria, the primary objective of the study was considered met (Table 2).

Table 2. Otolaryngology Accuracy Sensitivity Results

Number of Patients	Number of assessments CHW and ENT specialist agree ¹	Sensitivity rate (95% CI)
573	555	96.9% (95.1-98.1%)

Table 3. Otolaryngology Accuracy Study Results, by Diagnosis Code(s)

Diagnosis code by ENT specialist	Number of Patients Diagnosed by ENT specialist (%) (N=573)	Number of Patients which CHW Matched the ENT Diagnosis (% matching)
CSOM	288 (50%)	277 (96.2%)
Wax	199 (35%)	195 (98.0%)
ASOM	33 (6%)	31 (93.9%)
Foreign body	14 (2%)	14 (100%)
Hearing loss Wax	12 (2%)	12 (100%)
CSOM Hearing loss	11 (2%)	11 (100%)
CSOM Tinnitus	3 (0.5%)	3 (100%)
CSOM Wax	3 (0.5%)	3 (100%)
Foreign body Wax	3 (0.5%)	3 (100%)
CSOM ASOM	2 (0.3%)	2 (100%)
ASOM OTO	1 (0.2%)	1 (100%)
ASOM Wax	1 (0.2%)	0 (0%)
OME	1 (0.2%)	1 (100%)
Tinnitus Wax	1 (0.2%)	1 (100%)
Wax Nose throat	1 (0.2%)	1 (100%)

Discussion

In many developing countries, hearing loss is measure problem due to lack of skilled professional, unavailability of audiological test and high cost of audiological equipment. It is necessary to notice hearing loss as early as possible and to ensure this hearing should be check from time to time

especially in individuals with higher risk factors for hearing loss. In many recent publications have reported successful use of smart phone application in audiology.³ Increase utility of internet based hearing test have suggested by some studies.^{4,5} Some studies have demonstrated testing environment had a significant impact on the accuracy of results.⁶ In 2015 study by Paglialongaa, Tognola and Pincirolino showed that, in hearing health care, there is a distribution of available apps in five major categories; (i) education & information (23%) (ii) Hearing testing (18%) (iii) Rehabilitation (24%) (iv) SOUND enhancement (28%) and (v) assistive tools (7%).⁷ In July 2013 Medtronic launched “Shruti” to create sustainable program of low-cost otology care including awareness, screening, diagnosis and treatment to the underserved, particularly in densely populated, low-income urban settlements and rural areas by leveraging medical technology, telecommunication and frugal innovation. In our study, we were performed Otology accuracy assessment. In our study Shruti ENTview device otology functionality accuracy was examined over a total of 573 patients. The most common diagnoses were CSOM in 50% of patients, wax in 35% and ASOM in 6%. When a patient was diagnosed with a hearing issue by the ENT specialist, the community health worker had the same diagnosis 96.9% of the time. This, in addition, to the ease of use and minimal cost makes it viable to be used on a large volume of subjects with ease in a short period. With a high accuracy of otology on-field assessment Shruti program will created an accurate way to increase access to screening/awareness, early diagnosis and affordable treatment, for individuals with diagnosed ear disease as well as hearing loss, through their technology innovation and WHO guideline-based trained CHW workforce.

Conclusion

The burden of ear disease and hearing loss, within communities across India, is high and barriers exist, for patients and providers, across the continuum of care, including access to early screening and diagnosis. In order to address these issues, in 2013, an innovative ear care program, called Shruti, was launched in rural and urban areas across India to increase awareness, screening, diagnosis and treatment for the underserved. Determining the accuracy of the in-field otology assessments performed by the Shruti trained community-health workers (CHWs) using it tele-otology screening device named “ENTview” as compared to the diagnosis made by the ENT specialist.

The first goal was to conduct a sensitivity analysis of the diagnosis concluded by a community health worker for a patient’s hearing impairment utilizing ENTview versus the one conducted on the same patient by an ENT specialist. It was found that when a patient was diagnosed with a hearing issue by the ENT specialist, the community

health worker had the same diagnosis 96.9% of the time, when screened using ENTview. Because the whole 95% confidence interval was above 80% performance criteria, the primary objective of the study was considered met.

With a high accuracy of otology on-field assessment, it can be concluded that the Shruti program created an accurate way to increase access to screening/awareness, early diagnosis and affordable treatment, for individuals with diagnosed ear disease as well as hearing loss, through their technology innovation and WHO guideline-based trained CHW workforce.

Conflicts of Interest: None

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