**Karolinska
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Hörselvård i Kenya; en regional fältstudie

Hearing health care in Kenya; a regional field study

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Abstract

The overall aims of this study were to describe and characterize patients' hearing health care and to evaluate a method for tele-audiology in a hearing clinic in Nyeri in Kenya. The study design was a field study with quantitative approach using consecutive sampling of patients visiting the hearing clinic. Questionnaires were used to identify the amount of visitors, the prevalence of hearing loss, tinnitus, ear diseases and malaria. In addition, hearing tests of patients were gathered during a four week period. The results of traditional hearing measurements with pure tone audiometry were compared to that of a new tele-audiology device, Kuduwave, to validate this tele-audiology method under field conditions. Also, the tele-audiology method was tested in a pilot study by doing a hearing test at a distance.

Eighty patients were included in this study. Thirty-five out of 54 adult patients had tinnitus. Forty patients received malaria medication and 37 patients had hearing aids. Comparative results between pure tone audiometry and Kuduwave in eleven patients showed significant differences on frequencies 250-2000 Hz on the right ear and 250 Hz and 1000 Hz on the left ear. Positive development of the hearing health care in the clinic was detected.

A field study is an opportunity to get close to the population to be studied. Tinnitus seemed to be a common symptom and about 50% of patients in this study had a history of malaria. Tele-audiology offers new opportunities in hearing health care.

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Sammanfattning

Det övergripande målet för denna studie var att beskriva en kännetecknande patientens hörselvård och utvärdera en tele-audiologi metod på en hörselklinik i Nyeri i Kenya. Designen för studien var en fältstudie med kvantitativ ansats som använde konsekutiv stickprov av patienter som besökte hörselkliniken. Frågeformulär användes för att identifiera mängden besökande, förekomsten av hörselnedsättning, tinnitus öronsjukdomar och malaria. Hörseltester av patienter samlades under en fyraveckors period. Resultaten av traditionella hörselmätningar med tonaudiometri jämfördes med en ny tele-audiology anordning, Kuduwave, för att validera denna tele-audiologiska metod under fältförhållanden.

Åttio patienter ingick i denna studie. Trettiofem av 54 vuxna patienter hade tinnitus. Fyrtio patienter hade fått läkemedel mot malaria och 37 patienter hade hörapparater. Jämförande resultat mellan tonaudiometri och Kuduwave med elva patienter visade signifikanta skillnader på frekvenserna 250-2000 Hz på höger öra och 250 Hz och 1000 Hz på vänster öra. Positiv utveckling av hörselvården i kliniken upptäcktes.

En fältstudie är en möjlighet att komma nära befolkningen som skall studeras. Tinnitus verkade vara ett vanligt symtom och cirka 50% av patienterna i denna studie hade haft malaria. Tele-audiologin erbjuder nya möjligheter för hörselvården.

What is known on this topic?

- Approximately 5 % of the world's population has disabling hearing loss of which 9 % are children. Around 10-15 % of adults in high-income countries are diagnosed with tinnitus.
- Hearing clinics are scarce in Kenya and there is a lack of skilled audiologist as in many other developing countries which make it difficult for patients with hearing problems to receive adequate care. Foreign aid project has been known to help the situation.
- Tele-health and tele-audiology use telecommunication in health care services. This is a new method, which needs more validation under field conditions.

What this paper adds?

- In this study, of 65 % of adult patients complaining of tinnitus, 94 % had hearing impairment of which 54 % had a history of medically treated malaria according to self-reported questionnaire. These findings acknowledge previous reports about common causes of tinnitus such as age, noise induced hearing loss and ototoxic drugs.
- Although the conditions by which qualified hearing health care in rural areas of a low income country in Africa is not always clear, the Kenyan hearing health care has been developed in recent years. A hearing clinic in Nyeri was started in 2003 by the Kenya Ear Foundation with help of a Swedish financed aid project and the clinic now manufactures its own hearing molds and has a well-functioning hearing screening program for both newborn and school children.
- Tele-audiology has started in Kenya and offers new opportunities in hearing health care services including diagnosis of hearing impairment to areas that otherwise are difficult to reach, especially in low income countries. This study offers a limited validation under field conditions of this new method as a pilot testing of tele-audiology method.

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1. Background

1.1. Hearing system's anatomy and physiology

The human auditory system can be divided into the peripheral auditory system (the outer, middle and inner ear), the central auditory system (auditory nerve, auditory pathways and different brain stem nuclei) and the auditory cortex (Møller, 2006; Pickles, 2005; Stach, 1998) (Figure 1 and 2).

Figure 1. The hearing system. (Permission from MED-EL Medical Electronics 30 /04/14).

Figure 2. The central auditory systems and the auditory cortex. Ascending auditory pathways in the auditory system (adapted from Kiernan, 1987, permission from Wolters Kluwer Health/Lippincott Williams & Wilkins Book Permissions Group 28/4/14).

The sound wave reaches the ear, and vibrates the tympanic membrane. The vibration is amplified by the special construction of the ossicles in the middle ear. The stapes transfer the mechanical vibration into the fluid filled inner ear through the oval window creating a travelling wave along the basilar membrane in the cochlea (Frolenkov, Belyantseva, Friedman & Griffith, 2004). The sensory cells of hearing, the inner and outer hair cells, are parts of the organ of Corti, which is placed on the basilar membrane in the Scala Media along the spiral of the cochlea (Figure 3). The travelling wave stimulates the hair cells and mechanically sensitive ion channels on top of the stereocilia (“the hairs”) are opened when the stereocilia are bent in shearing motion. The influx of ions depolarizes the inner hair cell, creating a release of transmitter substance. This release creates an electrical signal in the auditory nerve at the synapse connection with the inner hair cell. The role of the outer hair cells is mainly to amplify soft sounds. The nerve signal is transferred through the auditory pathways to the cortex. During the transfer several modalities of the sound such as frequency, loudness, temporal information and direction are relayed. In the auditory cortex the different aspects of the sound is compiled into meaningful information and compared to our memory of earlier detected sounds (Møller, 2006; Ohlemiller, 2008; Pickles, 2005).

Figure 3. Cross section of the cochlea (A) and the structure of the organ of Corti (B) (adapted from Emanuel & Letowski, 2009, Chapter 8, page 292, Figure 8-13). (Permission from Wolters Kluwer Health 05/13/13).

1.2. Hearing loss

There are two types of hearing impairment according to which part of the ear is affected, conductive and sensorineural hearing loss. Conductive hearing loss is caused by difficulties in the transmission of sound in the outer or middle ear. Sensorineural hearing loss is caused by damage in the inner ear, auditory nerve or the central auditory system. Sensorineural hearing loss can be divided into cochlear, retrocochlear (auditory nerve) and central (auditory system) hearing loss. Combined type of hearing loss is caused by both conductive and sensorineural damages (Møller, 2000; Stach, 1998).

A hearing loss or deafness can be hereditary (genetic cause or disease) or acquired (infectious diseases, head trauma, exposure to noise, ototoxic drugs or chemicals, or age). A common example of a conductive hearing loss is a chronic middle ear infection and a typical sensorineural hearing loss can be caused by aging, ototoxic substances or noise exposure (Clark, 2008; Møller, 2000; Rybak, 2008). Hereditary hearing loss is sensorineural and often bilateral. Approximately 70 % of the hereditary hearing loss is nonsyndromic, while 30 % is syndromic SNHL (Sivakumaran et al, 2013). Pfister and Rehm (2003) reported that nonsyndromic hearing impairment is a hereditary hearing loss without any other medical problems, while syndromic hearing impairment is associated with other medical problems. Wonkam et al (2013) examined 582 patients in Cameroon and identified 15 % genetic causes, of which 86 % were nonsyndromic and 14 % syndromic.

Prenatal infections caused by human cytomegalovirus (CMV), such as herpes or rubella, affects up to 5 % of children born in developing countries (Manicklal, Emery, Lazzarotto,

Boppana, & Gupta, 2013) and 0,2 % to 1,2 % of children born in developing countries (Karlton et al, 2012). CMV may cause congenital developmental delay, heart defects, eye abnormalities and auditory defects such as sensorineural deafness (Freeland, Jones & Mohammed, 2010). Sousa, França Barros and Sousa Neto (2012) found congenital rubella in 16 % of 43 children with severe bilateral sensorineural hearing impairment in a cross-sectional study in Brazil.

Untreated human immunodeficiency virus (HIV) leads to acquired immunodeficiency syndrome (AIDS). According to UNAIDS (2012) 34 million people were infected with HIV in 2011. Van der Westhuizen, Swanepoel, Heinze and Hofmeyr (2013) found a significant increase of sensorineural hearing loss with HIV/AIDS progression.

Acute otitis media (AOM) is a common infection in children worldwide. In a study conducted by Alabi, Abdulkarim, Fatai and Abdulmajeed (2009) in a Nigerian hospital 64 of 200 (16 %) children had AOM as a result from fever episodes, and 40 % from malaria. AOM can be lead to a chronic otitis media (COM) that needs antibiotic treatment (Faddis, 2008). Untreated COM may cause damage of tissue and bone erosion and lead to conductive hearing loss (ibid.).

According to Nelson, Nelson, Concha-Barrientos and Fingerhut (2005), the noise-induced hearing loss (NIHL) from occupational noise is a global problem and estimated to constitute 16 % of the hearing problems in the world. NIHL affects the higher frequencies as 3000, 4000 and 6000 Hz showing characteristic 4000 Hz notch in the audiogram (ibid.), see section 1.5 Audiometry. According to the WHO (1991) the degree of hearing loss can be defined using the average of hearing level from four frequencies (500, 1000, 2000 and 4000 Hz) (Table 1.).

Table 1. Grades of hearing impairment. Audiometric ISO value = The average of hearing level at 500, 1000, 2000 and 4000 Hz.

Grade of impairment	Corresponding audiometric ISO value	Performance	Recommendations
0 - No impairment	25 dB or better (better ear)	No or very slight hearing problems. Able to hear whispers.	
1 - Slight impairment	26-40 dB (better ear)	Able to hear and repeat words spoken in normal voice at 1 meter.	Counselling. Hearing aids may be needed.
2 - Moderate impairment	41-60 dB (better ear)	Able to hear and repeat words spoken in raised voice at 1 meter.	Hearing aids usually recommended.
3 - Severe impairment	61-80 dB (better ear)	Able to hear some words when shouted into better ear.	Hearing aids needed. If no hearing aids available, lip-reading and signing should be taught.
4 - Profound impairment including deafness	81 dB or greater (better ear)	Unable to hear and understand even a shouted voice.	Hearing aids may help understanding words. Additional rehabilitation needed. Lip-reading and sometimes signing essential.

Ototoxicity is defined as hearing loss caused by drugs or chemicals through damaging the inner ear, both the hair cells by cellular damage, and also the vestibulo-cochlear nerve (Johnson & Morata, 2010; Rybak, 2008). The inner hair cells (IHC) can be damaged after the use of large doses of quinine (Ruedi, Furrer, Lüthy, Nager & Tschirren, 1952), which used to treat severe malaria in 58 countries (33 in Africa) as the first line of treatment (WHO, 2013, table 6.2). Gürkov et al (2008) found significant cochlear hearing loss with quinine treatment comparing to that of artemether/lumefantrine or otovaquone/proguanil treatment in a randomized clinical study in Ethiopia. Later drugs are used as a second treatment alternative.

Aminoglycosides, antibiotics such as neomycin and gentamycin, and cisplatin used for treatment of cancer can cause sensorineural hearing impairment by producing oxidative stress and damaging first row of OHC (Schacht, Talaska & Rybak, 2012). A retrospective study of Freeland et al (2010) conducted in Tanzania investigated 200 Tanzanian deaf children in the ages 5-12, of which 72 had had fever and 67 had been treated by ototoxic drugs such as quinine and/or gentamicin. According to Zhao and Mackenzie (2011) the ototoxicity from antimalarial drugs is well known, but the effects of the parasite *Plasmodium falciparum* on hearing loss needs more investigation. See further 1.3.1.

1.3. Hearing loss in a global perspective

Hearing loss can cause social and economic difficulties for individuals, families and countries. In 2005 it was estimated that 278 million people in the world had a moderate to profound (defined in table 1) hearing impairment (WHO, 2006). In 2012 it was estimated that 360 million persons had disabling (greater than 40 dB) hearing loss (WHO, 2012b). Nelson et al (2005) found occupational noise as a health problem worldwide, especially with the lack of hearing loss prevention programs in working environment in developing countries.

Untreated ear infections are common causes of hearing loss in low income countries (WHO, 2006). Diagnosed cases are often treated with cheap and effective antibiotics such as aminoglycoside leading to ototoxic effects causing permanent hearing impairment in patients of all ages (Lee et al, 2005).

Infectious diseases such as meningitis, measles and mumps can lead to hearing impairment. There is a meningitis-belt across sub-Saharan Africa including Kenya covering over 400 million inhabitants (WHO, 2012a). Bacterial meningitis is a serious public health problem in this belt-area (Agier et al, 2013). The main environmental causes for childhood deafness in Cameroon, sub-Saharan Africa, are reported to be meningitis (34 %) and rubella infection (0.5 %) (Wonkam et al, 2013).

1.3.1 Malaria

Malaria is transmitted to human by *Plasmodium* parasites through infected mosquitoes. Malaria is a common disease in sub-Saharan Africa, but also Asia, Latin America, and the Middle East and parts of Europe. In 2012 there were 207 million cases of malaria and about 627 000 deaths from malaria were reported worldwide (WHO, 2013). Africa accounted for 165 million cases and about 562 000 deaths.

Malaria diagnosis and treatment is very important but there are well-known side effects from the drugs used for treatment. Quinine, one of the most common antimalarial treatments, can cause ototoxic symptoms such as hearing loss and tinnitus (Shine & Coates, 2005). According to Lee et al (2005) also other antimalarial such as chloroquine and mefloquine are ototoxic. The national guidelines in Kenya recommend artemether-lumefantrine for elementary malaria and quinine for severe malaria and sulphadoxine-pyrimethamine in pregnancy (Ngure, Nyaoke & Minja, 2012) on the basis of efficacy (against resistance) and reasonable price.

1.4. Tinnitus

Tinnitus is the perception of sounds (e.g. ringing or buzzing) in the absence of any external auditory stimulation and chronic tinnitus is often related with hearing loss caused by aging or noise exposure (Eggermont & Roberts, 2004). Prevalence studies in high-income countries

indicate that tinnitus is a common phenomenon affecting an average of 10-15 % of the adult population (Andersson, Baguley, McKenna & McFerran, 2005; Pinto, Sanchez & Tomita, 2010). The prevalence of tinnitus in low income countries has hardly been studied. Sogebi (2012) found the prevalence of tinnitus in Nigerian middle aged and elderly patients to be 14.5 %.

According to Eggermont and Roberts (2004) chronic tinnitus is often connected to hearing impairment, caused by NIHL, or aging or ototoxic drugs. There are drugs such as antibiotics, anti-inflammatories (aspirin, ibuprofen), antimalarials (quinine, mefloquin) and cytotoxics (cisplatin, carboplatin) that may cause tinnitus as a side effect (Lee, Mistry, Uppal & Coatesworth, 2005). There are also other causes of tinnitus such as various diseases (e.g. Meniere's disease, vestibular schwannoma), cardiovascular diseases, neck and head injuries, infections (e.g. meningitis), dental problems, psychological factors (stress, depression). Even individuals with normal hearing can have tinnitus (Lockwood, Salvi and Burkard, 2002). Tinnitus severity has not been found to be related to hearing loss, age or gender (Pinto et al 2010).

1.5. Audiometry

Psychoacoustic measurements are used to determine hearing thresholds. One of the methods used is pure tone audiometry (PTA), which represents the weakest sound a person can hear at certain frequency. This is a detection test in which the listener must actively respond to the sound signal by pressing a button when the listener hears a beep. PTA is measured according to standardized measurement of the so-called ascending (upward) or modified Hughson-Westlake method (Almqvist et al, 2004; ASHA, 2005). The tones are presented either as air conducted signals through a standardized headphone in the ear, or bone conduction signals through a bone conducted phone located on the processus mastoid behind the ear. When the hearing threshold is recorded for a specific test frequency, it will be marked in an audiogram. In an audiogram the level of 0 dB hearing level (dB HL) at all test frequencies, is the average value for young normal hearing males (18-30 years of age). The PTA hearing test examines the hearing thresholds (in this order according to the Hughson-Westlake method) at 1000, 2000, 3000, 4000, 6000, 8000, 1000, 500, 250 and 125 Hz. The measurement is conducted in one ear at a time. The first signal is presented at a well audible level and then reduced in 20 dB steps until the tone is not perceived. Then the level is increased in 5 dB steps until the tone becomes audible again. The level where you first get three repeated responses is the level specified as the hearing threshold.

WHO (2010) has a recommendation for hearing screening of newborns for early detection of hearing impairment and Olusanya (2011) insists the development of this program worldwide. The methods used in newborn hearing screening are different automated tests such as otoacoustic emissions (AOAE) testing and automated auditory brainstem response (AABR). This screening test give a pass or fail result and further diagnostics are needed to establish and confirm hearing loss or deafness (Neumann & Indermark, 2012). School screening is used for early identification of hearing impairment in school children often based on screening guidelines from the American-Speech-Language-Hearing Association (ASHA, 1990). Screening procedure checks frequencies 1000, 2000 and 4000 Hz and are tested at a screening level 20 dB HL, each ear separately at the same way as a normal hearing test. A screening level of 20 dB HL means that only hearing thresholds higher than 20 dB HL are recorded.

1.6. Tele-audiology. The Kuduwave audiometer

In Africa, only South Africa and Egypt have educated audiologists to diagnose and treat hearing loss. This means that in the major parts of Africa there are very few professionals that can diagnose and treat persons with hearing impairments (Fagan & Jacobs, 2009). In Kenya as a whole there are only 14 audiologists and most of them work in private clinics. One way to solve this problem is to enable the few existing professionals to use new, internet-based methods, like tele-audiology, including video otoscopy, hearing aid fitting and hearing tests by computer links.

The future of tele-audiology offers opportunities to reach out to the distance places with hearing health care (Swanepoel, Olusanya & Mars, 2010). Swanepoel (2012) emphasizes the importance of hearing health care and suggest tele-audiology, as well as other health care systems using tele methods, as the future for providing hearing health services worldwide.

Audiology telemedicine, for example interactive video, teleconsultation, testing patients at distant sites, is developing according to Krumm and Syms (2011) and includes many diagnostic tools such as video otoscopy, tympanometry, hearing aid fittings, TEOAE, distortion product otoacoustic emissions (DPOAE), AABR, videonystagmography (VNG) as well as hearing testing and counseling.

Tele-audiology diagnostic is a new method that enables hearing to be assessed at a distance with a portable tele-audiology device. An example is a robust and suitable equipment including an audiometer (KUDUwave-5000, Figure 4.), appropriate software and soundproof headphones, uses broadband, webcam and Skype connection, for distance hearing tests. The test can be performed both automatically and manually (Swanepoel et al, 2010). Complete audiometry can be implemented for both air and bone conducted sound stimulation with plug phones and bone conductor placed in the fore-head. The audiometer has two microphones on the circumaural earcup that monitor the environmental noise in octave bands during testing and this is visually represented in real-time on the software together with the test results. The monitoring of the environmental noise secure the quality of the measurements especially since no sound proof booths are used.

Figure 4. KUDUwave audiometer showing insert earphones, circumaural earcups housing audiometer, and forehead bone conductor mounted centrally on headband. Source: GeoAxon, Pretoria, South Africa

In a pilot study conducted in South Africa using tele-audiology to compare face-to-face and remote testing (Swanepoel, Koekemoer & Clark, 2010), no clinically significant differences between the results from these two audiometric tests were found. The use of tele-audiology has now started in Kenya and this might have great significance for the development of hearing healthcare in Kenya and other African countries as well as in countries outside Africa.

1.7. Facts about Kenya, development and hearing health care in Kenya

Figure 5. Map of Kenya.

Kenya is a republic with a population of over 43 million in 2012 (World Bank Group, 2014). Life expectancy was 57 years in 2011 (Sida, 2013). Area of Kenya is 582 646 km² and there are many different ethnic groups such as kikuyu about 17 %, luhya 13.5 %, kalenjin 13 %, lu0 10 %, kamba 10 %, other 37 % (census of population 2009) covering 42 tribes and 42 languages. Official languages are Swahili (Kiswahili) and English. The majority religions are Christianity (82 %), Islam 11 % and others 7 % (Sida, 2013). Mean years of school education in Kenya is 7 (Sweden 12) and Gross National Income (GNI) is 1.5 per capita (Sweden 36) (UNDP, 2013).

Various infections such as meningitis are common causes of hearing loss in Kenya. Otitis-media is one of the ear, nose and throat (ENT) diseases in Kenya that can cause hearing impairment (Njoroge & Bussmann, 2006). One of the common causes of hearing loss in Kenya is otological trauma. Oburra (1998) examined ear trauma, hearing loss and tinnitus in Kenyan patients and found that road traffic accidents and trauma caused by violent law enforcers were the most common causes of otologic trauma. The most common complaints were pain, hearing loss and tinnitus.

1.7.1. The hearing clinic in Nyeri

In collaboration between Umeå University, Falun Hospital and Kenya Ear Foundation (KEF) was initiated in 2002 and a hearing clinic was officially inaugurated in Nyeri, Kenya in 2003. There were four personnel working at this clinic. The clinic offered hearing tests with PTA and KW. The use of the KW device was found as a valuable complement and the use was growing and especially the automated version of the testing were used as a complementary test which enabled the testing of more patients in a shorter time. However, some problems

were noticed when using the KW device. Some patients (especially women with traditional hair-styles) found the device uncomfortable. In some older patients there were problems with understanding the more complicated instructions for the test. But on the other hand young patients had no problems with the KW testing.

At the clinic hearing aid fitting was offered with different kinds of behind-the-ear and body worn hearing aids, but not in-the-ear hearing aids because this was a low-cost hearing clinic. They offered both analog and some digital hearing aids. They had learned how to manufacture molds for hearing aid fitting and had gotten the equipment from Sweden to be able to manufacture these.

There has been a development of the installment of more health care clinics also offering hearing health care in Kenya the last 5 years which is an improvement and recognition of the silent disability of a hearing loss. The personnel at the Nyeri clinic had also noticed a rising awareness among people of the need to take care of their hearing and seek help in time is also a result of the increased number of clinics.

The clinic offered AOA screening for newborn at the delivery ward and hearing screening at schools around Nyeri. During the years 2005 to 2011 18 259 hearing tests were conducted at schools in Nyeri. These tests revealed that 2.4 % (n=428) of the school children had a possible hearing loss above 20 dB HL. These children were recommended for further testing and diagnosis to their family physicians or hospital.

Problems with acceptance of hearing loss especially in children were raised by the personnel who also offered counseling for families to help both them and the children. Now 64 schools for the deaf are available in Kenya.

Problem formulation

The problem to provide the audiological diagnosis, intervention of hearing impairment and to develop the hearing health care services is important to investigate in developing countries such as Kenya. New technologies like tele-audiology will help quicken the development and make audiological diagnoses more available in remote parts of the country, but the devices and services needs to be evaluated. There is a need for validation of new methods under field conditions to make the diagnoses of more patients secure.

The knowledge of causes and status of the hearing health in the patients visiting the clinics may also differ from patients in developed countries and this need to be investigated.

1.8. The aims and research questions

The overall aims of this field study were to describe the patients visiting a hearing clinic by investigate the hearing and the possible causes for hearing loss in these patients. Another aim was to evaluate a new method for tele-health within audiology in Kenya by validation the diagnostic method used and to pilot test the distance use of the method.

1.8.1. Specific research questions

1. What characterizes the hearing and what are the possible causes of hearing loss in patients visiting a hearing clinic?

2. Do diagnostic results from automated testing with the Kuduwave audiometer, under field conditions, differ from results from traditional pure tone audiometry, performed in sound proof boxes?
3. Can the Kuduwave method be used on distance using tele-audiology?

2. Materials and methods

2.1. Design and approach

During a four week period, a field study was conducted in a Kenyan central province.

The study used a quantitative research approach, in which the goal is to measure and explain (Nyberg, 2000). The design was to investigate a consecutive sampling of patients visiting a hearing clinic during a set period of time. To identify the amount of visitors, the prevalence of hearing loss, tinnitus, ear diseases and malaria a questionnaire was used and hearing tests were performed. The questionnaire was used to ascertain the underlying known causes of hearing loss, which may vary in different countries.

A study-specific, self-reported questionnaire was used to characterize the patients and to investigate the possible causes of hearing loss (Appendix I). The questionnaire was assembled by using part of the questions from a validated questionnaire: Questionnaire on Hearing and Noise – NoiseScan, which was constructed as an analysis program (Pyykkö, Toppila, Starck, Juhola & Auramo, 2000).

The quantitative measurements of the hearing ability of the patients were performed using, in some cases, two different methods, which were compared.

A tele-audiology method was tested in a pilot study by doing a hearing test at a distance between two clinics.

2.2. Samples

All patients, adults and children, who sought treatment in the hearing clinic at Mathari Consolata Mission Hospital in Nyeri during 31st July to 30th August 2011 were included in the study. All patients who came to clinic were asked to participate. Patients, who did not understand English, were helped with translation by one of the staff at the clinic. Participation was voluntary. Of the eligible 82 patients 80 were included in the study and two patients declined participation.

Eleven patients were included in the validation of a new tele-audiology method with Kuduwave.

The hearing clinic consisted of four personnel. All four employees were included in the study and participated by answering a questionnaire.

2.3. Data collection

The study-specific questionnaire used, contained socio-demographic information (gender, age), reasons for seeking care, history of ear diseases, ear surgeries, tinnitus, exposure to noise and solvents and questions about malaria and medication.

Traditional hearing test with pure tone audiometry (PTA) was performed on all patients if possible. PTA was performed in a sound-isolated booth using a clinical audiometer (Madsen OB 822).

The telecommunications audiology method (Kuduwave, KW) was validated. Kuduwave 5000 (GeoAxon, South Africa), a portable audiometer and was used with insert earphones. Measurements were performed in a silent office room. Measurements with tele-audiology were performed on a number of patients and then compared with traditional hearing measurement methods as pure tone audiometry (PTA) in the same patients. The validation was done by comparing the differences in the audiograms made by the two methods in a sample of patients (n=11). These patients were selected during the first week of the study.

To evaluate the tele-audiology function, a pilot hearing measurement was done at a distance between two clinics.

The questionnaire aimed for staff members (Appendix II) contained background information as gender, age, education, degree, working length, and duty and the results were used for background information.

2.4. Data analysis

All statistical analyses were performed using IBM® SPSS® version 22. The data from questionnaire regarding experience of hearing loss, tinnitus, malaria, exposure to noise are presented descriptively with frequencies, means, medians and percentages. Paired Students t-tests were performed to compare the left and the right ear in patients.

The validation of the tele-audiology method in comparison to PTA, was conducted, using dependent Student's test, to statistically compare deviation from zero of the audiometric results for each person at each frequency between 125-8000 Hz. The Bonferroni correction was used as a post hoc adjustment of p-values on this t-test to control false-positive results. Student's test p-value (0.05) was divided with 18, which is the number of tests (two ears and 9 frequencies=18) giving the new significance level (0.0027). Both results from original t-tests and post-hoc adjustments will be presented.

3. Ethical considerations

This study has been evaluated by Kenya Ear Foundation in Nairobi by Executive Director of Medical Services, Dr. Manuel J. D'Crus and anchored in the Consolata Hospital management – Nyeri and St. Claire's Hospital Kaplong-Sotik, Kenya.

Helgesson (2006) emphasizes the importance of informed consent, where preserving the autonomy, privacy, and that the subjects are not exposed to unacceptable risks. Participants were informed of the confidentiality and voluntariness of their participation and the right to withdraw any time without any influence on their future treatment. All of the processing and archiving of material takes place in confidentiality (WMA Declaration of Helsinki, 2008). Participants (patients and staff) were informed verbally and by signing the consent form

(Appendix III and IV). The potential risks to the subject to be injured during a hearing test are minimal. It is more time consuming to do double audiometric testing, which was done in the validation section with 11 patients, but none of the patients expressed any concern of difficulties.

4. Results

Full results are reported in the article manuscript (Appendix I) and are only summarized here. Eighty patients and four employees were included in the study. The personnel had been working 4-9 years at this clinic, their median age was 37.5 years (range 32-46). Three of them worked as a patient attendants and one of them as a manager and acoustician. Characteristics of patients are presented in Figure 1 and Table 1, 2 and 3. Thirty-five adult patients and one child complained of tinnitus; 40 patients (about 50%) had a history of malaria and received malaria medication; 37 patients had hearing aids. Median hearing thresholds are demonstrated in Figure 2-4. Figure 2 shows the median hearing thresholds for 11 children and 29 adults with malaria. Children had more hearing loss in the low frequency range compared to adults. Paired t-test showed a significant better hearing in the right ear for children's median hearing thresholds, see Figure 3. Comparative results between PTA and KW, calculated with dependent Student's t-test of the differences' deviation from 0 in measured hearing levels separately for right and left ear, showed significant differences on frequencies 250-2000 Hz on the right ear and 250 Hz and 1000 Hz the left ear, while the differences on the left ear did not reach significance after Bonferroni correction, see box plot in figure 5 and 6. In all cases the KW method resulted in higher thresholds compared to PTA.

5. Discussion

This study shows that among adult patients seeking care, tinnitus seemed to be a common symptom. Thirty-five out of 54 patients presented at Nyeri clinic had tinnitus. About 50 % of all patients had a history of malaria. A comparison between two methods of hearing testing, PTA and KW in 11 patients resulted in significant differences between the methods on frequencies 250-2000 Hz on the right ear and 250 and 1000 Hz on the left ear.

Low-income countries such as Kenya, often have lack of resources in audiology. There are few specialists e.g. ENT-doctors, audiologists and speech therapists. There is often also lack of equipment such as measuring devices, ear mold manufacturing and hearing aids (McPherson, 2014). This lack of expertise is a big problem and cause major complications for patients with impaired hearing, from newborn to the elderly for diagnoses and hearing rehabilitation. National and international aid projects try to solve the problem and the establishment of the hearing clinic in Nyeri 2003, was a collaboration project between hearing clinics in Sweden and the Kenya Ear Foundation. This field study had the aim to characterize patients seeking care in this clinic and it also wanted to investigate the possibilities and validity of a new tele-audiology method that could be a future development for such clinics in developing countries (Swanepoel, Olusanya & Mars, 2010).

This field study used a quantitative approach by using questionnaires, hearing tests and a comparison between PTA and KW under field conditions.

As a special part a pilot test was performed to evaluate the use of tele-audiology in practice by doing a hearing test at a distance. The advantage of doing distance testing is that skilled personnel situated in one clinic can be used to test more patients in several locations also the patients do not need to travel long distances to visit the clinic (Swanepoel, Koekemoer &

Clark, 2010). Potential difficulties with such a test could be the Internet connection required for implementation. In this study the connection worked successfully. Some of the challenges in tele-audiology are test environments, equipment with both hardware and software and Internet connection (Swanepoel, Olusanya & Mars, 2010). Lancaster, Krumm, Ribera and Klich (2008) emphasize the importance of adequate bandwidth speed for Internet and the interactive video needed a webcam to provide tele-audiology services. Our conclusion from the pilot testing was that tele-audiology in hearing health care has a potential by providing services to distant locations.

The testing of 11 patients by comparing these two diagnostic methods was a small validation of the new tele-audiology method. The comparison of PTA and KW was made using a dependent Student's t-test to compare the individual values of the measured variable (dB HL) for each frequency (125-8000 Hz) to examine if there was a significant difference between the methods. Since many comparisons were made (9 frequencies on 2 ears) a Bonferroni correction was performed as a post hoc test to avoid a type I error (Armstrong, 2014). This is a correct statistical method for multiple comparisons for partly dependent variables. However, in this case the use of a stricter significance level ($p < 0.0027$ versus $p < 0.05$) might make the results of the comparison better and thus underestimate the found differences. The differences found between the two methods showed higher thresholds with KW on the lower frequencies in both ears. Swanepoel, Koekemoer and Clark (2010) used the same analysis method in their study including 30 normal hearing persons in clinical sound treated rooms and in 4% of cases the results differed by 10 dB. MacLennan-Smith, Swanepoel and Hall (2013) had a bigger sample ($n=147$) in validation of PTA and KW and they also analyzed their results using Student's t-test and in 5% of cases the results differed by more than 5 dB. None of the studies did find any significant differences between KW and PTA. Storey, Muñoz, Nelson, Larsen and White (2014) found significant different results for the noise conditions (non-sound-treated room) between KW and PTA and they also found 5% of cases the results differed on thresholds with KW compared to PTA as much as 60 dB at 250 Hz and 8000 Hz, with higher thresholds from KW.

Traditional pure tone audiometry was performed in a sound-isolated booth whereas the KW measurements were done in an office room. The rooms were not well isolated, and one could hear patients' conversation and crying children from the waiting room. This may have affected the results in the low frequency range. Thresholds on low frequencies are usually more affected by higher background noise (Bromwich, Parsa, Lanthier, Yoo and Parnes, 2008). However, the aim of the validation was to test the KW under field conditions and sound proof boxes are seldom available in distant clinical. MacLennan-Smith et al (2013) used continual monitoring of noise when testing the KW audiometer without audiometric booth in comparison with audiometric booth. Another reason for the differences between the methods may have been the location of the insert earphones near the eardrum with KW, which can be difficult to manage in a clinical situation.

The response rate of this study was high. All 80 patients filled the questionnaire, and parents filled instead of their children. Newton, Macharia, Mugwe, Ototo and Kan (2001) studied the use of questionnaire and PTA in ENT clinics in six districts in Kenya and they found a response rate of 88% of parents for children aged 2-7.5 years and they concluded that the use of questionnaire is useful in developing countries to detect hearing loss.

Approximately 32 million children (9%) have a moderate to profound hearing loss worldwide (WHO, 2012B). Early detection of hearing loss in children is important and in this study there were 26 children. This hearing clinic had done 18 259 hearing screening tests at schools in

Nyeri during the last six years and they found that the overall % of children with hearing loss was 2.4. This may be an explanation for the large number of children in this study because those children who failed the hearing screening were recommended for further testing. Omondi, Ogol, Otieno and Macharia (2006) found hearing impairment in 2.5% of school children in Kisumu district, Kenya. It is the availability of audiological health care that is the problem in most developing countries because there are an insignificant number of otolaryngologists (Njoroge & Bussmann, 2006). Same problem applies to ENT surgeons and audiologists, and Fagan and Jacobs (2009) found a number of 40 ENT surgeons, four audiologists and three speech therapists in Kenya. Parental consciousness of hearing impairment was investigated by Omondi et al (2006) and the authors found that most of the parents (67%) were aware of this.

The small sample, 80 patients, should be discussed. More patients over a longer period of time would have been given more information and dissemination of the causes of hearing loss than this study did. The selection will be a bias in this study when the patients visiting the clinic usually know they have hearing problems and this means that the proportion of tinnitus and hearing loss is much larger than in general prevalence studies. This affected the results in this study e.g. by showing a tinnitus prevalence (45%) which is higher than in other studies. One of the quantitative research criteria applicable to a study is generalizability (Polit & Beck, 2010). One may question whether the selection bias in this study is an obstacle for the generalizability of our study since participants actually sought hearing health care due to high probability of having hearing problems. The prevalence of hearing problems thus cannot be generalized to the population, but only to the population that actually seek care. The survey questions may give some information about possible causes of hearing loss.

According to Patel and Davidson (2003) it is important to know what we intend to measure in a quantitative study, where both validity and reliability have an important role. Validity means the extent to which a concept, conclusion or measurement is well-founded and corresponds accurately to the real world and the researcher is attempting to measure, and reliability implies accuracy in measurements (Holme & Krohn Solvang, 1997). Using standard questionnaires with relevant questions for patients, the study has endeavored validity. The number of patients in comparisons between PTA and KW was small, and this affects validity. Audiometric testing was performed in a reliable manner according to standard clinical national standard method, and in this way has reliability achieved. The audiologist's competency leads to the correct decisions about the reliability of the measurement methods, and this confirm the validity and reliability.

One difficulty with a field study is the unpredictable and unexpected events that may influence the planned procedures e.g. weather conditions, power failure, and lack of hearing aids. Heavy rain resulted in indoor water damage and prevented us from patient examination in two days. Another obstacle was a power failure which prevented us from performing hearing tests on 10 patients who were present at the clinic. Another day we had no electricity and no patients. Hearing aids are an important part of rehabilitation and this kind of clinic depends on assistance and economic support in order to provide aids for patients. The strength of this study was the interest among the population for participation, only few declined participation. All patients were motivated to participate in the study.

The characteristic of Nyeri clinic was patients' endurance to wait for their turn, sitting on the waiting room's hard benches, not complaining that they had to wait for hours for their turn. They had many patients from the whole Kenya but even from neighboring countries such as Rwanda and Sudan.

The author had also done interviews with the staff, but the qualitative approach was not included in this study. The decision to use one approach was made to make the study report manageable. Recommended further research can use alternative approaches, e.g. qualitative, for studying the hearing health care development in a region in Kenya. A more extensive quantitative study can be achieved by extending the time period for data collection from one to several months to reach more participants in the study. Another option might be to use both quantitative and qualitative approach rather than use only one in a study.

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Manuscript

(According to the assignment for the review. Focus in results.)

Appendix

I. Questionnaire to patients

II. Questionnaire to staff

III. Information about this study and consent form to patients

IV. Information about this study and consent form to staff

Appendix I

Institution for Clinical Sciences,
Intervention and Technology
Section for Audiology
Karolinska Institution
SE-141 83 Huddinge
Sweden

and

Institution for Neurobiology
Health Sciences and Society
Section for Nursing Care
Karolinska Institution
SE-141 83 Huddinge
Sweden

Questionnaire

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from you, as covered in the following questions.

Are you:

Male

Female

☐☐

What is your age?

.....

Which of the following describes best
your main activity?

employment or self employment

☐

retired	☐
housework	☐
student	☐
seeking work, unemployed	☐
other (please specify)	☐

Do you have any hearing problems? Yes No

☐ ☐

Do you have somebody in your family who has hearing problems?

 Yes No

☐ ☐

If yes, who, and how is he/she related to you?

.....

.....

Do you have tinnitus (buzzing, ringing or whistling sounds in your ears)?

 Yes No

☐ ☐

If you have tinnitus – how long time did you have it?

.....

If you have tinnitus, how often does it occur?

☐ Sometimes

☐ Often

☐ All the time

Have you had any ear diseases?

☐ **Yes** Acute ear inflammation **in childhood**
 (>3 times) with pain, discharge from the ear

- ☐ **Yes** Acute ear inflammation **as an adult**
(>3 times) with pain, discharge from the ear
- ☐ **Yes** Chronic ear inflammation with tympanic membrane perforation and
a feeling of deafened ear, discharge from the ear
(lasting >3 months)
- ☐ No
- ☐ Do not know

Have you had any operations done in the ear?

Yes	No	Do not know
☐	☐	☐

If you have had an ear operation, do you know what was done?

.....

Have you been exposed to noise from shooting or hunting?

Yes	No
☐	☐

At my present job, I am being **exposed to noise** as follows:

Noise means surrounding sound that are so loud that you cannot
communicate at a normal voice level.

Yes	No
☐	☐

If Yes; Fill in below as carefully as you can.

Noise exposure hours/day.....

Noise exposure days/week.....

Do you use some kind of hearing protectors at work?

Use of hearing protectors:

☐ Always

☐ Often

☐ Seldom

☐ Never

At my present job, I am being **exposed to solvents, paints or glues**

☐ Yes

☐ No

If yes, do you know what kind of substances?

.....

Have you been in an accident?

Yes

☐

No

☐

If you have been in an accident, what kind of accident was it? Did you hurt yourself in the head?

.....

Have you had malaria?

Yes

☐

No

☐

If you have had malaria, did you get some medication?

Yes

☐

No

☐

Which kind of medication did you get?

.....

Do you use some kind of hearing aid?

Yes

☐

No

☐

Appendix II

Institution for Clinical Sciences,
Intervention and Technology
Section for Audiology
Karolinska Institution
SE-141 83 Huddinge
Sweden

and

Institution for Neurobiology
Health Sciences and Society
Section for Nursing Care
Karolinska Institution
SE-141 83 Huddinge
Sweden

Questionnaire (to staff members)

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from you, as covered in the following questions.

- 1. Are you:** Male Female
☐ ☐

2. What is your age?

- 3. Did your education** continue after leaving school? Yes No
☐ ☐

- 4. Do you have a Degree or professional qualification?**
Yes	No
☐	☐

5. If you have a Degree, what kind of Degree do you have?

6. For how long time have you worked here?

7. What kind of job do you have?

8. How many patients do you see in one day?

Appendix III

Institution for Clinical Sciences,
Intervention and Technology
Section for Audiology
Karolinska Institution
SE-141 83 Huddinge
Sweden

and

Institution for Neurobiology
Health Sciences and Society
Section for Nursing Care
Karolinska Institution
SE-141 83 Huddinge
Sweden

Information about this study and patient consent form

A study will be performed to examine the prevalence of hearing loss, tinnitus, noise exposure, exposure to chemical substances such as solvents, ear infection, malaria and medication. The study is going to take place here at the KEF Swedish Hearing Aid Center in Nyeri and Kaplong, Kenya during the period of August-September in 2011.

We are grateful if you would like to participate in this study. It is voluntary to participate and you can always cancel your participation.

As a participant we will ask you to answer a questionnaire. We will also do hearing tests.

The questionnaire and the participation will be processed in confidence.
The results of the study will be presented in an essay in which you are treated confidentially.

Thank you for your cooperation.

.....

Consent and signature of participant

Appendix IV

Institution for Clinical Sciences,
Intervention and Technology
Section for Audiology
Karolinska Institution
SE-141 83 Huddinge
Sweden

and

Institution for Neurobiology
Health Sciences and Society
Section for Nursing Care
Karolinska Institution
SE-141 83 Huddinge
Sweden

Information about this study and consent form

A study will be performed to examine how the tele-audiology does work in Kenya. The study is going to take place here at the KEF Swedish Hearing Aid Centers in Nyeri and Kaplong, Kenya during the period of August-September in 2011.

As a participant we would like you to answer a questionnaire and in connection with the submission to participate in a short interview. The interview will be recorded and after transcription the tape will be destroyed.

We are grateful if you would like to participate in this study. It is voluntary to participate and you can always cancel your participation.

The questionnaire, the interview and the participation will be processed in confidence. The results of the study will be presented in an essay in which you are treated confidentially.

Thank you for your cooperation.

.....

Consent and signature of participant

Hearing health care in Kenya; a regional field study

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Abstract

Objectives: To describe and characterize patients' hearing health and to evaluate a method for tele-audiology in a hearing clinic in Nyeri in Kenya.

Study design: Field study with quantitative approach using consecutive sampling of patients visiting the hearing clinic.

Methods: Questionnaires were answered by patients to identify the amount of visitors, the prevalence of hearing loss, tinnitus, ear diseases and malaria. In addition, hearing tests of patients were gathered during a four week. The results of hearing measurements with pure tone audiometry was compared to that of a new tele-audiology device, Kuduwave, as a validation testing of the tele method under field conditions. Also the tele-audiology method was tested in a pilot study by doing a hearing test at a distance.

Results: Eighty patients were included in this study. Thirty-five out of 54 adult patients had tinnitus. Forty patients received malaria medication and 37 patients had hearing aids.

Comparative results with eleven patients between pure tone audiometry and Kuduwave showed significant differences on frequencies 250-2000 Hz on the right ear and 250 Hz and 1000 Hz on the left ear.

Conclusions: A field study is an opportunity to get close to the population to be studied. Tele-audiology offers new opportunities in hearing health care.

Keywords: audiometry, hearing aid, hearing clinic, hearing loss, malaria, noise exposure, screening, tele-audiology

Introduction

Approximately 360 million people worldwide have a moderate to profound hearing loss (>40 dB), of which around 32 million are children (1). Hearing impairment may worsen the development of spoken language, communication, school education and the individuals' chances to obtain employment.

Tinnitus is the perception of sound in one or both ears in the absence of any external auditory stimulation. Its prevalence, reported by most epidemiological studies, is around 10-15 % in average (2, 3). Hearing impairment, aging or ototoxic drugs are some of causes to connected with chronic tinnitus (4).

Hearing loss and deafness can be congenital (genetic or complications during pregnancy and childbirth) or acquired (infectious diseases, chronic ear infection, trauma, exposure to noise, ototoxic drugs/solvents, age). For example a chronic middle ear infection can cause a conductive hearing loss, while aging, ototoxic substances or noise can cause sensorineural hearing loss (SNHL) (5, 6). Ear infections such as otitis media, are common bacterial infections that may result in hearing impairment and affect language development (7). Noise-induced hearing loss (NIHL) afflicts 16 % of the adult population in the world (8). Bacterial meningitis is a severe epidemic public health problem in the African meningitis belt that may result in severe hearing impairment or deafness (9). Over 400 million people lives in this belt area of sub-Saharan Africa including northern Kenya (10).

Although malaria is a very common disease in Africa, it can also be found in South America, Eastern Mediterranean, South-East Asia, Western Pacific and East part of Europe.

Worldwide, approximately 207 million cases of malaria and nearly 627 000 deaths due to

malaria were reported in 2012. In Africa the estimated number of malaria cases and number of deaths were 165 million and 562 000 people, respectively (11). One of the main causes for malaria epidemics is climate, especially after high rainfall (12). Diagnostic testing, malaria treatment and prevention are important factors in combatting the disease. Unfortunately, malaria medication such as quinine and chloroquine have ototoxic side effects that damage the inner ear and cause hearing impairment (13), (14). There is, however, no better alternative than quinine to treat severe malaria (15).

The Republic of Kenya has a population of 43.18 million people (2012) (16). According to the World Malaria Report (11) there were 5.8 million reported malaria cases and 785 malaria-attributed deaths in Kenya in 2012. Recommended medications, according to the national guidelines in Kenya, are quinine for severe malaria, artemether-lumefantrine for uncomplicated malaria and sulphadoxine-pyrimethamine during pregnancy (17).

WHO classifies the degree of hearing impairment base on clinical audiometry and by using an average for the most relevant frequencies for human speech (500, 1000, 2000, 4000 Hz) (18). Accordingly a moderate hearing loss is equivalent to an average hearing level between 40-60 dB HL. WHO (19) emphasizes the importance of early detection of hearing impairment in newborn, infants, and in school-age children. Recommended screening methods such as otoacoustic emissions (OAE) are one of the different approaches to early identification of hearing impairment. School-age screening guidelines (20) will ensure that children with hearing impairment will be identified in time and minimized the risk for delays in speech and language development and poor school education. Thus, hearing screening is cost-effective for public health and hearing health care.

In adults the standard procedure for diagnosing a hearing impairment is pure-tone audiometry that according to international guidelines (21) determines hearing thresholds at the frequencies 125-8000 Hz using an ascending method.

Tele-audiology is a new method that enables assessment of hearing at a distance with a portable tele-audiology device (22). It can improve chances for an early diagnosis of hearing impairment and enable intervention in a geographically isolated population (23).

The aims of this field study were to describe various aspects of hearing health care in Kenya by 1) describing characteristics of patients treated at the Nyeri hearing clinic, 2) investigating the validity of tele-audiology in the measurement of hearing ability, 3) pilot test if the tele-audiology method can be used on distance.

Methods

The study used a quantitative research approach, in which the goal is to measure and explain (24). The design was to investigate a consecutive sampling of patients visiting a hearing clinic during a set period of time.

A study-specific, self-reported questionnaire was used to characterize the patients and to investigate the possible causes of hearing loss (Appendix I). The questionnaire was assembled by using part of the questions from a validated questionnaire: Questionnaire on Hearing and Noise – NoiseScan, which was constructed as an analysis program (25).

The quantitative measurements of the hearing ability of the patients were performed using, in some cases, two different methods, which were compared.

A tele-audiology method was tested in a pilot study by doing a hearing test at a distance between two clinics.

This field study analyzed several outcomes including patient's hearing tests and results from questionnaires to identify the amount of visitors, the prevalence of hearing loss, tinnitus, ear diseases and malaria in the clinic.

The audiologist in this study followed the hearing screening guidelines by ASHA (26) and every patient were screened with otoscopy before hearing test.

Setting

This field study was performed at the Kenya Ear Foundation (KEF) - Swedish Hearing Aid Center, Mathari Consolata Mission Hospital in Nyeri, Kenya during four weeks in 2011.

Participants

The study used a consecutive sample approaching all patients who sought hearing health care at the clinic during 31st July to 30th August 2011 regarding possibly participation. Of the 82 approached patients 80 participated (response rate 98%). All the four employees at the clinic answered a questionnaire regarding their background.

Measures

Questionnaires

Patients' questionnaire included questions from the validated questionnaire Questionnaire on Hearing and Noise – NoiseScan (25). The questionnaire contained socio-demographic information (gender, age), medical history and possible exposures to noise and medications.

Hearing measurements

Traditional hearing tests with pure tone audiometry (PTA) were performed in a sound-isolated booth. For traditional hearing measurements a clinical audiometer (Madsen OB 822) was used and for tele-audiology a portable audiometer with insert earphones Kuduwave 5000 (KW) from GeoAzon, South Africa was used (27). The KW measurements were made under field conditions in a quiet office room. The two methods, PTA and KW, were compared regarding the measured hearing thresholds.

Tele-audiology measurement

In a pilot test one patient in Nyeri was evaluated with KW by a clinician and the author in Kaplong (317 km away) to investigate how tele-audiology worked in practice by doing a hearing test at a distance. The results from this hearing test were compared with PTA after return to Nyeri.

Analyses

Statistical calculations were performed with the IBM® SPSS® version 22. All the variables from questionnaires were summarized with standard descriptive statistics such as frequencies, means, medians, percent and standard deviations.

Hearing thresholds were analyzed by calculating and comparing medians for different groups for each frequency (125-8000 Hz) measured.

Comparison of PTA and the new tele-audiology method with KW was performed using the audiometric results for each frequency in both measurements between 125-8000 Hz for 11 patients. Possible differences between the two methods were tested with dependent Student's test. A significant level of $*p < 0.05$ was applied in all analyses. The Bonferroni correction was used as a post hoc adjustment of p-values on this t-test to control false-positive results. P-value 0.05 was divided with 18 (number of tests with two ears and 9 frequencies) giving the

new significance level of 0.0027. Both results from original t-tests and post hoc adjustments will be presented.

Results

Participant characteristics

A total of 80 patients, 54 adults and 26 children were included in this study. Two patients declined to participate. Age distribution is seen in figure 1 and participant characteristics presented in table 1. Eleven patients were included in the validation of the KW device.

Distribution of adults with tinnitus by sex is presented in Table 2. There were 35 adults with tinnitus, with a median age of 53 (23-81) years, making a prevalence of 64.8%, of which 35% had tinnitus continuously. Thirty-three participants with tinnitus had a hearing loss and two had normal hearing. Table 3 presents the possible etiology to hearing impairment among patients. Twenty had history of malaria, six had ear inflammation in childhood, five were exposed to noise from shooting or hunting, three were exposed to noise at work, one patient was exposed to solvents (and noise) and one was involved in an explosive accident.

A total of 40 patients had had malaria (11 children and 29 adults). All 40 had received malaria medication. Quinine was given to 17 patients (8 children), four of them got pyrimethamine, two patients got halofantrine (one child), one sulphamethopyrazine-pyrimethamine and one chloroquine, 16 received unknown medication (two children). Figure 2 shows the results of median hearing thresholds for all patients that had history of malaria. All had a hearing impairment. Children's hearing loss was more affected in low frequency range compared with adults with malaria.

Twelve children out of 26 and 25 adults out of 54 had hearing aids. Four patients started a hearing aid fitting when they visited the clinic during this study. Seven of the children and 22 of the adults with hearing aid had a history of malaria.

Hearing thresholds

Hearing thresholds for children, women and men are shown in figure 3 and 4. Seventy-five patients had hearing loss and the remaining five patients who did not have hearing loss due to this visit, included two patients with tinnitus and three children who controlled their ears after ear infections. All 75 patients had a hearing loss as expected. In children the hearing tests showed significantly better hearing in the right ear (Figure 3) at 1000-4000 Hz. The children had less hearing loss in the high frequencies compared to adults, which was an expected result. The causes of hearing loss in children were ear infection (n=5), bacterial meningitis (n=2), mumps (n=1), human immunodeficiency virus (HIV positive) and human cytomegalovirus (CMV) (n=1) and other unknown syndrome (n=1).

OAE was performed on seven children. None of them passed the test and four of these children had not been using hearing aid, thus a hearing aid fitting was started during the visit. The hearing thresholds did not differ significantly between women and men (Figure 4). Three patients were HIV positive and two of them had severe hearing loss. One patient had a hearing loss in the low and high frequencies, but normal hearing at middle frequencies, and this patient had a history of malaria too.

Comparison between traditional hearing test with pure tone audiometry (PTA) and Kuduwave (KW) – a pilot study

Three patients were pre-tested with KW to enable the best possible performance with the new method and they were not included in the final comparison.

In this study 11 adult patients were included in the comparison of PTA and KW. A twelfth patient were tested using both methods but had to be excluded, since he was completely deaf in one ear and had severe hearing impairment in the other ear, which contributed to a negative outcome when using KW.

Student's test tested if the differences in the measured thresholds with respective method (PTA and KW) differed from zero. A significant difference between the methods was found ($p < 0.05$) on the frequencies 250 Hz, 500 Hz, 1000 Hz and 2000 Hz on the right ear, and on the frequencies 250 Hz and 1000 Hz on the left ear. This significant difference remained only in the right ear (250-2000 Hz) after the Bonferroni correction ($p < 0.0027$), whereas no significant difference was found in the left ear. In all these frequencies the KW measurements gave significantly higher thresholds compared to the PTA measurements. The results of differences for all frequencies are shown, separately for right and left ear, in box plots (Figure 5 and 6).

The evaluation of tele-audiology in practice - a pilot test

Tele-audiology with Kuduwave was performed in Kaplong, Western province of Kenya, and did the diagnostic application of tele-audiology with KW. The connection was through Skype with the patient presented at Nyeri hearing clinic (317 km away). The connection worked successfully. The results were compared to that of the traditional hearing test conducted on the same patient later at our return to the clinic. The results are included in the comparison between PTA and KW.

The staff perceptions when using the KW device in practice was that they found the KW to be a valuable complement and they used it as a complementary test which enabled the testing of more patients in a shorter time. However, some problems were noticed when using the KW device. Some patients (especially women with traditional hair-styles) found the device

uncomfortable, some older patients had problems with understanding the more complicated instructions for the test. But on the other hand, young patients had no problems with the KW testing.

Discussion

The purpose of the present field study was to examine self-reported reasons for visiting hearing clinic and to describe the audiological services. We also wanted to validate the tele-audiology function under field conditions.

The study used quantitative method to describe the characteristic of visiting patients by using self-reported questionnaires and performing audiometric testing, and validation of KW by comparing it to PTA measurements. This study used standardized questionnaires and the audiometric testing was performed using the national standard method, and thus the study has endeavored both validity and reliability (28). The sample of patients in this study was low (n=80) and can't be generalized to the general population in Kenya, but only to the population who sought hearing health care during the four week period (29).

Most children, who sought treatment at the clinic, were from the age group 0-9 years. There were some indications that hearing loss was noticed earlier in boys (62% boys from 1.5-14 years old vs. 38% girls from 3-17) and parents sought help earlier for their sons than daughters.

KEF – Swedish hearing aid center has a hearing screening program for newborn. They use OAE measurements every day at the Mathari Consolata Mission hospital in Nyeri. Omondi et al (30) found the average age of first diagnoses of hearing impairment to be 5.5 years in

Kisumu, Kenya, where chronic otitis media was the main reason for hearing impairment. In Sweden universal neonatal screening with OAE are performed in almost all 100 000 babies born annually since 2005 (31). At the Child Welfare Center children's hearing are examined again at the age of four. According to the National Board of Health and Welfare's (Socialstyrelsen) (32) recommendation and mapping all newborns are offered a hearing screening with OAE and hearing screening in connection to school start in Denmark, England, Finland, Norway and Sweden.

They also have a hearing screening program for school children in Nyeri. The purpose of school screening project is to identify those who may be at risk of falling into hearing loss group of handicap among a large population of children. 18 259 screening tests were performed between 2005 and 2011 resulting in an overall possible hearing loss of 2.4 %.

According to Statistics Sweden (Statistiska Centralbyrån, SCB) there were 888658 pupils in compulsory comprehensive schools vs. 402 pupils, i.e. 0.05% with impaired hearing in 2011/12 in Sweden (33).

Our results indicate that tinnitus was a common symptom among these patients. The prevalence of tinnitus was 64.8 % in adult patients with a diverse history of hearing loss, noise exposure, malaria and malaria medication. Our results are in accordance results from Eggermont and Roberts (4) which also indicate age, noise induced hearing loss and ototoxic drugs, such as quinine as a common cause of tinnitus. The large prevalence of tinnitus found in this study is greater compared to other studies from developing countries (45%) and much greater compared to the tinnitus prevalence in the general population in developed countries (14.5%) (3). This could be due to the selection, bias in our study (low number of participants and specialized clinic). Savastano (34) found that children seldom complain of tinnitus and Bae et al (35) found otic tinnitus (acoustic source in the ear vs. vascular) as the most common

tinnitus in childhood. In this study we identified one adolescent patient with a 4 year history of tinnitus.

Age-related hearing loss, NIHL, ear diseases and ototoxic medication seemed to be common causes of hearing loss in this group of patients (see Table 3). About 50 % of patients in this study had a history of malaria, which is a common disease in sub-Saharan Africa. Gürkov et al (36) found significant cochlear hearing impairment in patients with history of malaria treated with quinine.

One can speculate about the causes of children's hearing loss in low-frequency range such as ear infections and medication. However, due to the low number of patients in this study, no conclusions can be made. There were three patients with known HIV and all of them had hearing problem. Significant increase in hearing loss during HIV disease progression has been reported (37).

Age-related hearing loss and NIHL (38), (39) and ear infections (40) are some of the most common causes for hearing impairment. Freeland et al (41) found that a third of children with profound hearing loss or deafness in Tanzania had received ototoxic drugs such as quinine and/or gentamicin against fever without weight control, which can mean an overdosed medication. Our findings confirm these earlier findings.

As presented in this study less than 50 % of participants (12 children out of 26 and 25 adults out of 54) had hearing aid. The main reason for the low number of hearing aids is the cost of these devices. Compared to other clinics, hearing aids was cheaper in this clinic; for children, a body worn 5000 Kenya shillings (KES), an analog 6000 KES and a digital 14000 KES, and for adults, a body worn 20000 KES, an analog 25000 KES and a digital hearing aid 45000

KES. Children are given priority and those not able to buy one get a free hearing aid, financed by the Kenya Ear Foundation.

Low-income countries, e.g. Kenya, often have lack of resources in audiology. There are few specialists such as ENT-doctors, audiologists and speech therapists. There is often also lack of equipment such as measuring devices, ear mold manufacturing and hearing aids (42). This lack of expertise is a problem and cause major complications for patients with impaired hearing, from newborn to the elderly for diagnoses and hearing rehabilitation. National and international aid projects try to solve the problem and the establishment of the hearing clinic in Nyeri 2003, was a collaboration project between hearing clinics in Sweden and the Kenya Ear Foundation.

The staff at the Nyeri clinic could describe a positive development of hearing health care in Nyeri in recent years. The clinic supported from the Swedish Rotary organization by visits from voluntary teams including ENT specialists, technical engineer and audiologist. New hearing clinics have been opened in the last few years in Kenya, however, the clinic in Nyeri had many patients from different places in Kenya and also from other countries such as Rwanda and Sudan. They offer counselling for parents who denied their child's hearing loss.

Our findings indicated significant differences in the low frequency range in the comparison between PTA and KW. The differences between the hearing thresholds measured with PTA and KW in the frequencies 250-2000 Hz on the right ear, and 250 and 1000 Hz on the left ear may presumably be caused from disturbing sounds from adjacent rooms. Traditional pure tone audiometry was performed in a sound-isolated booth whereas the KW measurements were done in an office room. The rooms were not well isolated, and one could hear patients'

conversation and crying children from the waiting room. This may have affected the results in the low frequency range (43). MacIennan-Smith et al (44) controlled the environmental noise by using a monitoring of noise in their study. Their study was conducted in two different environments with KW; first in a natural environment in a room provided by the retirement home facility in a quiet furnished room and second in a certified audiometric booth at an audiology clinic. They found no significant differences. Storey et al (45) found that 5% of the hearing threshold results with KW compared to PTA differed as much as 60 dB at frequencies 250 Hz and 8000 Hz with higher thresholds from KW and they found a significant difference for the noise conditions (non-sound-treated room) between KW and PTA. Swanepoel et al (27) found no clinically significant difference with comparing KW and PTA in the same sound treated room. Another possible reason for the detected differences may be the placement of the insert earphones with KW, in an ideal situation the earphones should be placed very near the eardrum (44) which can be difficult to manage in a clinical field situation. One patient was excluded from the comparative analysis between PTA and KW, since the patient was almost deaf in the right ear and had severe hearing loss in left ear. Thus it was difficult to perform the KW test since despite similar stimulus levels in traditional PTA and the KW (100-110 dB HL), differences on low frequencies makes it difficult to receive responses from the worst ear comparing to PTA.

One disadvantage with KW is the fact that some women did not want to take on KW headphones because they used the wig. KW headphones are larger and heavier than typical PTA headphones. Pure tone audiometry with one of patients was very difficult to perform because she couldn't understand the instructions so well, but she could manage the automatic KW better which could be used in such situations.

Our limited pilot test of long-distance tele-audiology between Kaplong and Nyeri demonstrated that the technology works and this development is promising. Similar comparative study has been conducted (27) between Pretoria, South Africa and Dallas, North America with no significant differences between PTA and KW measurements and remote testing through Skype. In order to reach and provide hearing health care to e.g. rural and other unavailable areas or wherever there is a lack of qualified personnel to perform hearing tests and hearing screening of infants, tele-audiology can be a good solution (46).

The study identified tele-audiology as a promising future audiological method to be used as long distance testing in distant and isolated areas. The use of tele-audiology has now started in Kenya and this might have a great significance also for the development of hearing health care in other African counties as well as in countries outside Africa. The method can also be applicable to the northern part of Sweden, where long distance can be an obstacle to the children and adults hearing health care.

Field studies are of great importance in analyzing the results in a situation-based research. However, some issues may have great influence on the performance of the study. Power failure and electricity cut-off, weather (heavy rain, humid and cold indoors) and lack of material as hearing aids are some issues, that can influence the number of possible participants and consequently the quantitative results.

Conclusion

Our findings regarding tinnitus prevalence indicates that tinnitus is a common symptom at this clinic. Hearing loss in connection with a history of malaria was also common. A field study is an excellent way to do a research study. The sample size of 80 patients is perceived as a limitation and further research will be needed.

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Ethical approval

This study has been evaluated by Kenya Ear Foundation in Nairobi by Executive Director of Medical Services, Dr. Manuel J. D'Crus and anchored in the Consolata Hospital management in Nyeri.

Conflict of interest

There are no conflicts of interest to declare

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Figure 1. Age distribution classified in 9 years period for all the patients in this study divided in female and male participants.

Table 1. Characteristics of the participants

Gender	Participant n=80	Age range	Median age
Women	31 (39%)	21-78	42
Men	23 (29%)	24-83	60.5
Girls	10 (12%)	3-17	9.5
Boys	16 (20%)	1.5-14	5
Employees	4	32-46	37.5
	Main activity, adults		
Employment	26		
Retired	10		
Housework	12		
Unemployed	3		
Other (specify)	2	Missionary	Religious sister

Table 2. Prevalence and characteristics for tinnitus in adults.

<i>Tinnitus (adults)</i>	
Adults (female:male)	35 (23:12)
<i>Tinnitus duration</i>	
≤1 year	6 (19%)
1≤5 years	19 (61%)
5<10 years	2 (7%)
≥10 years	4 (13%)
<i>Tinnitus, how often?</i>	
Sometimes	20 (59%)
Often	2 (6%)
All the time	12 (35%)

Table 3. Characteristics of participants, possible causes for hearing impairment

	Children n=26	Adult n=54
Family hearing impairment history	5	10
Ear diseases in childhood	5	7
Ear diseases as an adult		5
Chronic ear inflammation	0	4
Ear operation	1	5
Exposure to noise (shooting, hunting)		5
Exposure to noise (work)		3
Exposure to solvents, paint or glues		1
Accident (head trauma)		3
Malaria	11 (4:7)	29 (16:13)
Malaria medication	11	29
HIV+	1	2

Figure 2. The median hearing thresholds for 11 children and for 29 adults, who had had malaria.

Figure 3. The median hearing thresholds for 11 of 26 children who were hearing tested of the respective frequency left and right ear with traditional pure tone audiometry

Figure 4. Women and men, the median hearing thresholds for 48 of 54 adults of the respective frequency left and right ear with traditional pure tone audiometry

Figure 5. Box plot of the difference between PTA and KW right ear (R125-R8000). Difference was calculated by subtracting the individual hearing threshold for each of the 11 patients measured with PTA from the threshold measured with KW for each frequency between 125-8000 Hz, when $p < 0.05$ ie 1 * for frequencies 250-2000 Hz for the right ear with Student's t-test. Same results with the Bonferroni correction when $p < 0.0027$.

Figure 6. Box plot of the difference between PTA and KW left ear L125-L8000). Difference was calculated by subtracting the individual hearing threshold for each of the 11 patients measured with PTA from the threshold measured with KW for each frequency between 125-8000 Hz, when $p < 0.05$ ie 1 * for frequencies 250 and 1000 Hz for the left ear with Student's t-test. The Bonferroni correction did not reach significance on the left ear when $p < 0.0027$.