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# Diagnostic accuracy of a general practitioner with video-otoscopy collected by a health care facilitator compared to traditional otoscopy

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#### ABSTRACT

*Objective:* Video-otoscopy is rapidly developing as a new method to diagnose common ear disease and can be performed by trained health care facilitators as well as by clinicians. This study aimed to compare remote asynchronous assessments of video-otoscopy with otoscopy performed by a general practitioner. *Method:* Children, aged 2–16 years, attending a health center in Johannesburg, South Africa, were examined. An otologist performed otomicroscopy and a general practitioner performed otoscopy. Video-otoscopy was performed by a health care facilitator and video sequences were stored on a server for assessment by the same general practitioner 4 and 8 weeks later. At all examinations, a diagnosis was set and the tympanic membrane appearance was graded using the OMgrade-scale. The otologist's otomicroscopic diagnosis was set as reference standard to compare the accuracy of the two otoscopic methods. *Results:* Diagnostic agreement between otologist's otomicroscopic examination and the general practitioner's otoscopic examination was substantial (kappa 0.66). Agreement between onsite otomicroscopy and the general practitioners asynchronous video assessments were also substantial (kappa 0.70 and 0.80).

*Conclusion:* Video-otoscopy performed by a health care facilitator and assessed asynchronously by a general practitioner had similar or better accuracy compared to face-to-face otoscopy performed by a general practitioner.

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# 1. Introduction

Otitis media (OM) is a common disease and may lead to lifelong sequelae [1,2]. Approximately 740 million people world-wide will be affected annually by acute otitis media (AOM) or chronic suppurative otitis media (CSOM) and by the age of 10 at least 90% of children will have experienced otitis media with effusion (OME) [2,3].

Diagnosis of OM is based on a review of symptoms together with assessment of the tympanic membrane (TM) and middle ear status. However, diagnostic inaccuracy among pediatricians and general practitioners is a clinical challenge that may lead to over-diagnosis [4,5]. At the same time, access to health care differs around the world, with some areas lacking health personnel for accurate diagnosis [6]. Pediatricians and general practitioners usually use handheld otoscopes for diagnosis of middle ear disease, whereas otologists prefer otomicroscopes. However, rapid technological development has led to the introduction of cost-effective video-otoscopes to facilitate and improve the diagnostic outcome in otoscopy. Video-otoscopes allow capturing multiple images or video on computer or smartphone on the condition of the ear canal and TM with the possibility of interpretation either onsite or remotely [7–9]. Captured video-sequences allow for repeated back and forward examination of the recording [7].

1.1. Aim

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To evaluate the diagnostic accuracy of remote assessment of

video-otoscopy recordings captured by a health care facilitator and diagnosed by a general practitioner as compared with traditional otoscopy by a general practitioner.

### 2. Method

The Institutional Ethics Committee at the University of Pretoria, Pretoria, South Africa approved of the study.

Caregivers of children aged two to 16 years attending a primary health care clinic outside Johannesburg (Witkoppen Health and Welfare clinic), were offered a free ear examination. Over a two week period, 140 children were recruited [7,10,11] after informed consent.

#### 2.1. Reference standard

An experienced otologist (>35 years of practice) first examined the children's ears using a Leica M525 F40 surgical otomicroscope with a 6:1 zoom magnification  $(1.2-12.8\times)$  and a 300-W xenon fiber optic illumination. Cerumen was removed manually if needed, and when cerumen could not be removed sufficiently to visualize the TM, the diagnoses were considered as not possible to determine (NPD). The otologist examined both ears and gave one diagnosis for each ear (reference standard).

## 2.2. Index tests

The child was then examined by a general practitioner (GP) (>15 years of practice) who performed an otoscopic examination of both ears using a hand-held, Heine K100 Diagnostic otoscope, without knowledge of the otologists' diagnoses.

Video-otoscopy was finally performed by a trained health care facilitator who completed recordings of video-clips, >30 s in length that were stored on a laptop. The health care facilitator had a two-day training period on conducting video-otoscopy, provided by the otologist [7]. The video-otoscopic recordings were made with a Dino-Lite Pro Earscope with a LED light, a magnification of  $10-20\times$ , a frame rate of 30 frames/sec and a 1.3-megapixel resolution. The Dino-Lite video-otoscope was attached via a USB cable to a Lenovo ThinkPad 2.0 running Windows 7 via 2.0 interface or a Macbook pro running OSX v10.7.5. DinoCapture 2.0 software (AnMo Electronics Corporation) version 1.2.7 was used to record and view the video-otoscopic recordings. The recordings were saved onto a laptop as MOV- or WMV-files (Macbook Pro and PC) and ranged from 0.85 to 7.61 MB size (mean = 3.6 MB).

All examinations, including micro-otoscopy, otoscopy and video-otoscopy, were performed consecutively the day the child attended the health center.

Video-otoscopic recordings were uploaded to a secure virtual database (Dropbox). The GP then accessed the server from Umeå University, Sweden, on two occasions 4 weeks and 8 weeks after onsite assessment (video-otoscopy 1 and 2), using a 24 inch Apple LED Cinema Display connected to a Macbook Pro. Recordings were anonymous and the order randomized. The GPs' assessments were recorded on an Excel spreadsheet and uploaded to the Dropbox server, which was managed by an independent investigator.

#### 2.3. Diagnosis

The diagnoses, made both synchronously and asynchronously were: Normal tympanic membrane (n-TM), otitis media with effusion (OME), acute otitis media (AOM) and chronic suppurative otitis media (CSOM) (Table 1) [12]. If the status of TM's could not be determined at otoscopy or at any of the two asynchronous video-otoscopic assessments (due to lack of co-operation, obstructing

cerumen or poor image quality) it was labeled as NPD.

We also used a validated image based grading scale, OMgrade [13], for grading of the TM appearance (Table 2). This grading scale is based on 6 grades with a subdivision of grade 5. The scale is based on assessing transparency and position of the TM.

#### 2.4. Exclusions

All cases with missing data or ears not possible to determine (NPD) at each diagnostic step were excluded. Not possible to diagnose (NPD) was due to ears with obstructing wax, a child not cooperating, or a video sequence with low quality.

#### 2.5. Data analysis

The diagnostic concordance for otoscopy and video-otoscopy was measured with percentage of agreement and Cohen's kappa using the otomicroscopy as reference standard. We used Landis and Koch characterizations of the kappa values: < 0 = no agreement, 0-0.20 = slight, 0.21-0.40 = fair, 0.41-0.60 = moderate, 0.61-0.80 = substantial, 0.81-1 = almost perfect agreement.

We used SPSS v24 for calculations of percentage of agreement, Cohen's kappa, frequencies and cross-tabulations. For the OMgrade calculations with a high number of ordinal variables the weighted kappa was calculated using StatsToDo online calculator: http:// www.statstodo.com/CohenKappa\_Pgm.php.

Sensitivity, specificity and Chi2-test were calculated using MedCalc online calculator: https://www.medcalc.org/calc/diagnostic\_test.php.

## 3. Results

One hundred and forty children were recruited during a twoweek period and 280 ears were examined. Seventy-four percent of all examined ears (280 ears) were diagnosed as normal TM's, 10% as OME, 0.7% AOM, 13% as CSOM and 10.4% as missing or NPD. The distribution of diagnoses in included ears can be seen in Table 3. The 105 ears (10.4%) that were not possible to determine (NPD) in at least one of the three examinations were excluded from the calculations of diagnostic accuracy, specificity and sensitivity, rendering 175 ears for inclusion in the study (Fig. 1).

#### 3.1. Agreement between reference standard and index tests

In 156 (89%) of the otoscopy assessments by the GP, the diagnosis was in concordance with the otologist's assessments compared to 159 (91%) and 165 (94%) of ears at video-otoscopy 1 and 2, respectively. Substantial agreement was found for both video-otoscopy and otoscopy (Table 4).

#### 3.2. Grading of TM

The agreement for OMgrade grading's (OMgrading) calculated with weighted kappa was 0.69 between initial otomicroscopy and otoscopy, versus 0.76 and 0.82, respectively for the two video-otoscopy assessments (Table 5). Findings were not significant except for the higher agreement of video-otoscopic OMgrading at assessment 2 (Table 5, p < 0.05) as compared with reference standard.

#### 3.3. Sensitivity and specificity

The calculations of sensitivity for otoscopy was 0.81 compared to 0.76 and 0.81, respectively, for video-otoscopy 1 and 2 (Table 6). We found specificity to be lower, for otoscopy (0.93) compared to

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