



## Parental role in the diagnostics of otitis media: Can parents be taught to use tympanometry reliably?



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### ARTICLE INFO

#### Article history:

Received 15 February 2014

Received in revised form 27 March 2014

Accepted 29 March 2014

Available online 12 April 2014

#### Keywords:

Diagnosis

Otitis media

Middle ear effusion

Pneumatic otoscopy

Parental tympanometry

Primary care

### ABSTRACT

**Objective:** Tympanometry can be used to detect middle ear effusion (MEE). As the need for rearrangement of clinical resources at the primary care level increases, it is important to determine whether layman parents could be taught to use the tympanometer reliably, aiming to reduce unnecessary physician visits during respiratory tract infections.

**Methods:** From our AOM treatment trial we enrolled 78 children (age 6–35 months) who had persistent MEE, parents were voluntary and willing to use a tympanometer at home, the child was sufficiently co-operative, and parents learned technically the use of the tympanometer. At home, parents were asked to perform daily bilateral tympanometry on their child. We included those parental tympanometric examinations, to which the corresponding tympanometric examination, within one day by a study physician was available. Parental tympanometric examinations were compared to the pneumatic otoscopy by a study physician which served as the diagnostic standard.

**Results:** This study involved 78 children and a total of 432 parental tympanometric examinations. From these 432 examinations, parents obtained an interpretable tympanogram in 83% (359/432) and physicians in 91% (393/432) (absolute rate difference 8%, 95% CI 3–12%). Both obtained an interpretable tympanogram from the same ear in 75% (326/432) of the tympanometric examinations. Of these 326 interpretable examinations, parents and physicians were in accordance with either a peaked or a flat tympanogram in 88% of examinations (288/326) (kappa-value 0.77). When the tympanogram was peaked, pneumatic otoscopy indicated healthy middle ear in 72% (122/169) of parental and in 69% (149/217) of study physicians' tympanometric examinations (absolute rate difference 4%, 95% CI –6% to 13%). When the tympanogram was flat, pneumatic otoscopy indicated any MEE in 92% of parental (174/190) and in 96% (169/176) of study physicians' tympanometric examinations (absolute rate difference 4%, 95% CI –9% to 1%).

**Conclusion:** This study showed that layman parents are able to use tympanometry technically successfully, and that the parental tympanometric examinations are as reliable as those obtained by study physicians.

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### 1. Introduction

Tympanometer is a non-invasive, handheld device providing objective, quantitative and graphic information of the potential presence of middle ear effusion (MEE). As a diagnostic tool, tympanometry can be performed on most of the cooperative

children in clinical setting. Tympanometric results are easy to interpret and the diagnostic reliability is good in excluding and/or detecting MEE [1,2].

As the need for rearrangement of clinical resources at the primary care level increases, it is a tempting possibility to give the parents a role in diagnostics by using tympanometry, aiming to reduce unnecessary visits during respiratory tract infections. Previous research concerning the parental use of tympanometer has focused on parental compliance [3,4] and success rates in performing tympanometry [5]. The aim of this study was to examine the reliability of tympanometric examinations performed by layman parents.

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## 2. Material and methods

### 2.1. Study population

We examined children aged 6–35 months who were initially brought for an outpatient visit due to parental suspicion of acute otitis media (AOM). Children in whom we diagnosed AOM ( $n = 322$ ) participated in our AOM treatment trial ([www.clinicaltrials.gov](http://www.clinicaltrials.gov) identifier NCT00299455). We examined them regularly on scheduled visits and additionally, whenever parents requested [6]. The study was conducted at primary care level between 2006 and 2009. Written informed consent was obtained from a parent of each child before any study procedure was done. All visits were free of charge, and no compensation for participation was given. The study protocol was approved by the Ethical Committee of the Hospital District of Southwest Finland.

In this study, we included children who had persistent MEE at a pre-scheduled study visit after the study drug period; the child was sufficiently co-operative during tympanometric examinations; parents were voluntary and willing to use the device at home; and parents learned technically the use of the tympanometer at the teaching visit. We included those parental tympanometric examinations, which were conducted at the teaching visit and at home at a study visit day or one day earlier and the tympanometric examination by a study physician was also available. To minimize the repetition of the same result, we excluded home examinations <3 days apart. If a child had >6 home examinations, we included only the first six examinations.

### 2.2. Diagnostic procedures by the study physician

Children were always examined in an upright position. The study physicians first performed acoustic reflectometry (EarCheck PRO Otitis Media Detector, Innovia Medical LLC, Omaha, NE, USA), then tympanometry (MicroTym2, Welch Allyn, Skaneateles Falls, NY, USA), and finally pneumatic otoscopy (Macroview otoscope model 23810, Welch Allyn, Skaneateles Falls, NY, USA). Cerumen was carefully removed before pneumatic otoscopy.

Otoscopic findings were categorized as follows. When MEE was not detected, the middle ear was categorized as healthy. When visible air-effusion interface and/or air-bubble(s) were detected, MEE was categorized as air-interface MEE (a-MEE). When the middle ear was completely filled with effusion, MEE was categorized as complete MEE (c-MEE). We categorized both otitis media with effusion and AOM as MEE, because our study group has previously showed that tympanometry is not able to distinguish between different diagnostic categories [1].

### 2.3. Classification of tympanograms

Tympanometry was performed using a MicroTym2 tympanometer with a printer. The device uses a probe tone of 266 Hz and a sweep range of +200 to –400 daPa, from positive to negative pressure with a speed of  $400 \pm 40$  daPa/s. Tympanograms were classified to the original classification by Jerger, as modified by Orchik et al. and Zielhuis et al. [7–9]. Peaked tympanograms were classified to be type A when tympanometric peak pressure was over –100 daPa, type C1 when pressure was between –100 and –200 daPa, C2 when pressure was lower than –200 daPa, and Cs when the tympanogram was low-peaked or wide (peak compliance less than 0.2 mmho, width over 300 daPa). A flat tympanogram was classified to be type B. If a flat tympanogram was obtained, tympanometry was repeated three times whenever possible. In other cases, tympanometry was repeated twice. Only clearly interpretable tympanograms without artifacts were classified. In this study, three study physicians independently interpreted the tympanograms blinded to the otoscopic diagnoses

(N.E.-A, M.K.L., A.R.), and when disagreeing, A.R. made the final decision.

### 2.4. Parental tympanometry

At the teaching visit, the study physician taught the parents verbally and graphically the principles of tympanometry. After that, the study physician taught parents to use the tympanometric device independently. At the end of the study visit, parents performed tympanometric examination on their child. The time used at this teaching visit varied between 20 and 30 min.

At home, parents were asked to perform daily bilateral tympanometry on their child, at approximately the same time each day, and to print out the tympanograms. In case of a flat tympanogram, the examination was asked to be repeated three times whenever possible. Parents brought the printed tympanograms to the next scheduled study visit.

### 2.5. Statistical analyses

We compared the results of parental and physician tympanometric examinations to each other and to the pneumatic otoscopy by a study physician which served as the diagnostic standard. We analyzed the agreement of parental and physician tympanometric examinations by calculating the kappa-value. We calculated the absolute rate difference between the parental success rate of tympanometric examinations at home and at the study visit; between the success rate of parental and physician tympanometric examinations; and between parental and physician tympanometric examinations and the pneumatic otoscopy done by a study physician. Statistical analyses were done with SPSS<sup>®</sup> Statistics 21 (IBM Software).

## 3. Results

We enrolled 78 children whose parents were willing to conduct tympanometric examinations at home. Home examinations were not conducted in 4/78 (5%) of children because parents were unable to perform tympanometry independently. Five families conducted home examinations, but none of them on set days. Thus, home examination results of 69 children were at our disposal. The median age of these children was 18 months (range 6–35 months). From these children, 71% were boys, median of previous AOM episodes was 2 (range 0–10) and median age at first AOM episode was 9 months (range 2–27 months).

From these 69 children, we included 94 parental tympanometric examinations performed first at the teaching visit at the study clinic, and 338 tympanometric examinations performed later independently at home. Parents obtained an interpretable tympanogram (i.e. type A, C1, C2, Cs or B) in 91% (86/94) of the tympanometric examinations at the teaching visit, and in 81% (273/338) of the tympanometric examinations at home (absolute rate difference 11%, 95% CI 2–19%). All of the 432 parental tympanometric examinations were analyzed together, because the home and teaching visit examinations were equally reliable in predicting a healthy middle ear when the tympanogram was peaked, and MEE when the tympanogram was flat (data not shown).

From these 432 examinations, parents succeeded to obtain an interpretable tympanogram in 83% (359/432) and physicians in 91% (393/432) (absolute rate difference 8%, 95% CI 3–12%). Parents and physicians both obtained an interpretable tympanogram from the same ear in 75% (326/432) of the tympanometric examinations. Of these 326 interpretable examinations, parents and physicians agreed on the same type tympanogram (i.e. A, C1, C2, Cs or B) in 71% (233/326) as shown by the bolded figures in Table 1.

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