International Journal of Pediatric Otorhinolaryngology 79 (2015) 1516–1521

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

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

Parental role in the diagnostics of otitis media: can layman parents use spectral gradient acoustic reflectometry reliably?

Nora Erkkola-Anttinen [a,b,*], Miia K. Laine [c], Paula A. Tähtinen [a], Aino Ruohola [a,d]

[a] Department of Paediatrics and Adolescent Medicine, Turku University Hospital, Turku, Finland
[b] City of Turku Welfare Division, Primary Healthcare Services, Turku, Finland
[c] Department of Medical Microbiology and Immunology, University of Turku, Turku, Finland
[d] University of Turku, Turku, Finland

ARTICLE INFO

Article history:
Received 5 May 2015
Received in revised form 25 June 2015
Accepted 27 June 2015
Available online 6 July 2015

Keywords:
Otitis media
Middle ear effusion
Otoscopic diagnosis
Parental
Spectral gradient acoustic reflectometry
Primary care

ABSTRACT

Objective: Spectral gradient acoustic reflectometry (SG-AR) can be used to detect middle ear effusion (MEE). Since both families and primary health care systems carry the burden of otitis media, our aim was to determine whether layman parents could be taught to use the SG-AR reliably.

Methods: We enrolled 359 children (age 6–35 months) whose parents were willing to use SG-AR at home. The parents were asked to perform bilateral SG-AR daily on their child. In this study, we included children who had undergone successful parental home SG-AR examination performed on the same day that a physician had also performed successful SG-AR examination and pneumatic otoscopy at the study clinic. We compared the parental and study physician SG-AR examination results to the study physicians' pneumatic otoscopy, which served as the diagnostic standard.

Results: We analyzed 571 successful parental home SG-AR examinations performed on the same day that a study physician had performed a successful SG-AR examination and pneumatic otoscopy at the study clinic. None of the evaluated SG-AR level combinations resulted in both high sensitivity and specificity. For symptomatic visits, the negative predictive value of a parental SG-AR level 1 to detect MEE was 64%. For parental SG-AR levels 4–5, the positive predictive value to detect MEE was 88%. However, for asymptomatic visits, the negative predictive value of a parental SG-AR level 1 to detect MEE was 83%.

Conclusion: This study showed that layman parents are able to use the SG-AR technically successfully. In symptomatic children, parentally obtained SG-AR level 1 examination is not adequate to exclude MEE. However, parentally obtained SG-AR levels 4–5 do indicate the presence of MEE. At the same time, in asymptomatic children, parentally obtained SG-AR level 1 examination seems to indicate a healthy middle ear. From the perspective of primary care, the implementation of parental SG-AR examinations in the diagnostic chain of otitis media would be intriguing. This study showed that the possibilities lie in the follow up of the resolution of MEE after an episode of OM in asymptomatic children. However, it seems that currently, the SG-AR technique is an obstacle for wider clinical implementation.

1. Introduction

Otitis media in young children is one of the most frequent causes for families to seek medical care, which places a great burden on both families and primary health care systems worldwide [1–3]. At the same time, primary health care units need to develop new approaches to established diagnostic procedures and to redistribute the physicians' visit resources. Thus, the question was raised of, whether it would be possible to give parents a role in the diagnostic chain of otitis media, using spectral gradient acoustic reflectometry (SG-AR) to exclude or to detect middle ear effusion (MEE).

The diagnosis of otitis media requires that MEE is detected [4], traditionally this is done by pneumatic otoscopy. An SG-AR device is hand-held, and is designed to provide this information objectively without the need for an airtight seal with the external auditory canal [5]. Previously, we have shown that SG-AR is not able to differentiate between different otoscopic diagnoses, but

* Corresponding author at: Department of Paediatrics and Adolescent Medicine, Turku University Hospital, Turku, Finland Turku University Hospital Foundation (TYKS säätiön tutkimusyksikkö), Sirkkalankatu 4 LH 1, FIN-20520 Turku, Finland. Tel.: +358 41 469 0707.
E-mail address: nora.erkkola-anttinen@turku.fi (N. Erkkola-Anttinen).

http://dx.doi.org/10.1016/j.ijporl.2015.06.040
0165-5876/

that it might be helpful to detect or to exclude MEE especially with the extreme SG-AR levels [6]. However, the diagnostic accuracy of parental SG-AR examinations to detect MEE has only been reported in older children before surgical treatments, such as ventilation tube insertion [7].

The aim of this study was to examine the diagnostic reliability of parental SG-AR examinations in outpatient children under three years of age, who are at the highest risk for otitis media.

2. Material and methods

2.1. Study population

We enrolled children aged 6 –35 months who were initially brought for an outpatient visit due to parental suspicion of acute otitis media (AOM). The children were followed in two cohorts. In the first cohort, children in whom we diagnosed AOM participated in our AOM treatment trial (www.clinicaltrials.gov identifier NCT00299455), and they were examined regularly in scheduled visits [8]. In the second cohort were children in whom we did not diagnose AOM at the enrollment visit, who were then followed for signs and symptoms and were re-examined at one prescheduled visit after approximately 12 days. For both cohorts, we arranged acute visits whenever needed. In these cohorts, we provided families with an SG-AR device if: (1) the child was sufficiently co-operative, (2) the parents were voluntarily willing to use SG-AR at home, and (3) the parents learned how to use the SG-AR device technically at the teaching visit.

In this study, we included children with successful a parental home SG-AR examination performed on the same day that a study physician had performed an SG-AR examination and pneumatic otoscopy at the study clinic. To minimize the repetition of results, we excluded parental SG-AR examinations conducted at home on the teaching visit day and on study visit days less than 3 days apart from the previous visit, and also study visits exceeding six per child.

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.

We categorized study visits into two different visit types: symptomatic and asymptomatic. Symptomatic visits were those where the child suffered from acute symptoms and signs of respiratory tract infection, or nonspecific symptoms causing parental suspicion of AOM. Visits were categorized as asymptomatic when the child had no symptoms. Since the child younger than 3 years of age could not describe their symptoms, parental evaluation was used to define the symptoms of the child.

2.2. Diagnostic procedures by the study physician

The children were always examined in an upright position. The study physician first performed SG-AR (EarCheck PRO Otitis Media Detector, Innovia Medical LLC, Omaha, NE, USA), then tympanometry (MicroTymp2, 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.

Pneumatic otoscopy was the diagnostic standard, and otoscopic findings were categorized as follows. The diagnosis of acute otitis media (AOM) required three criteria. First, middle ear effusion had to be detected (with at least two of the following tympanic membrane findings: bulging position, decreased or absent mobility, abnormal color, or opacity not due to scarring). Second, acute inflammatory signs had to be present in the tympanic membrane (with at least one of the following: distinct erythematous patches or streaks or increased vascularity over full, bulging or yellow tympanic membrane). Third, the child had to present the signs and symptoms of acute inflammation. The diagnosis of otitis media with effusion (OME) was based on the following three criteria: first, middle ear effusion shown by reduced mobility of the tympanic membrane; or by visible air-fluid interface; second, a retracted or normal (i.e., slightly concave) position of the tympanic membrane; and third, the absence of acute inflammatory signs in the tympanic membrane (i.e., distinct erythematous patches or streaks). The middle ear was diagnosed as healthy when pathologic otoscopic findings and/or MEE were not detected. Based on the knowledge that SG-AR is not able to differentiate between different otoscopic diagnoses [6], in this study MEE was categorized as any OME and/-or any AOM.

We classified the SG-AR angle values obtained by the EarCheck PRO device according to the manufacturer's recommendations into five numerical levels and five angle value ranges corresponding to the risk of MEE. Level 5 (angle value less than 49°) indicated a high risk of MEE; level 4 (angle value range 49–59°) indicated a moderately high risk of MEE; level 3 (angle value range 60–69°) indicated a moderate risk of MEE; level 2 (angle value range 70–95°) indicated a moderately low risk of MEE; and level 1 (angle value greater than 95°) indicated a low risk of MEE. SG-AR was considered to be successful if an angle value (49–120°) was seen on the screen of the device. SG-AR was performed only once if a successful angle value was immediately obtained, otherwise it was repeated, depending on the co-operation of the child. The examination was considered to have failed if the SG-AR instrument displayed an error symbol or if the angle value was seen only momentarily [6].

2.3. Parental SG-AR examination

At the teaching visit, the study physician first explained the principles of SG-AR for parents. After that, the study physician taught the parents how to perform examinations with the consumer model (EarCheck™ Middle Ear Monitor; Innovia Medical LLC, Lenexa, KS, USA). Then, the parents independently performed SG-AR on their child and the study physician helped when needed. The time used for this teaching session varied between 10 and 20 min.

The SG-AR results of the consumer model were classified according to the manufacturer's recommendations into five levels (1–5) and three colors corresponding to the probability of MEE. Level 5 (red color) indicated a high risk of MEE; level 4 (red color) indicated a moderately high risk of MEE; level 3 (red color) indicated a moderate risk of MEE; level 2 (yellow color) indicated a moderately low risk of MEE; and level 1 (green color,) indicated a low risk of MEE.

At home, the parents aimed to perform daily bilateral SG-AR on their child, at approximately the same time each day. Parents performed SG-AR at home also at the study visit days. SG-AR was considered to be successful if the black signal light indicated a SG-AR level. In the case of an error result, the parents were asked to repeat the examination three times, whenever possible. The parents recorded the SG-AR results in a symptom diary. If the SG-AR value changed by two levels over two consecutive days, we instructed the families to contact the study physician. The parents returned the SG-AR devices and completed symptom diaries at the end of the study follow-up. The parents who performed the SG-AR examinations in this study were layman, who represented vast range of educational and professional backgrounds.