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RESEARCH ARTICLE

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Can trained nurses exclude acute otitis media with tympanometry or acoustic reflectometry in symptomatic children?

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ABSTRACT

Objective Since acute otitis media (AOM) is the most prevalent bacterial infection in young children, the reliable exclusion of AOM by nurses might save physicians' time for other duties. The study aim was to determine whether nurses without otoscopic experience can reliably use tympanometry or spectral gradient acoustic reflectometry (SG-AR) to exclude AOM.

Design Three nurses were trained, who performed examinations with tympanometry and SG-AR. Pneumatic otoscopy by the study physician served as the diagnostic standard.

Setting Study clinic at primary health care level.

Patients. 281 children 6–35 months of age.

Main outcome measures Predictive values (with 95% confidence interval) for tympanometry and SG-AR, and the clinical usefulness, i.e. the proportion of visits where nurses obtained the exclusive test result from both ears of the child.

Results At 459 visits, the negative predictive value of type A and C1 tympanograms (tympanometric peak pressure >–200 daPa) was 94% (91–97%). Based on type A and C1 tympanograms, the nurse could exclude AOM at 94/459 (20%) of visits. The negative predictive value of SG-AR level 1 result (>95°) was 94% (89–97%). Based on the SG-AR level 1 result, the nurse could exclude AOM at 36/459 (8%) of visits.

Conclusion Type A and C1 tympanograms and SG-AR level 1 results obtained by nurses are reliable test results in excluding AOM. However, the clinical usefulness of these test results is limited by their rarity. Type A and C1 tympanograms were obtained by nurses from both ears of the child only at one-fifth of the symptomatic visits.

KEY POINTS

- Acute otitis media (AOM) is the most prevalent bacterial infection in young children. Nurses' role in excluding AOM is unknown.
- Type A and C1 tympanograms (tympanometric peak pressure >–200 daPa) obtained by nurses are reliable test results in excluding AOM.
- With type A and C1 tympanograms, nurses could exclude AOM only at one-fifth of the symptomatic visits.
- The clinical usefulness of the exclusion of AOM performed by nurses seems to be limited.

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Acute otitis media; children; exclusion; Finland; general practice; spectral gradient acoustic reflectometry; tympanometry

Introduction

Acute otitis media (AOM) is the most prevalent bacterial infection in young children [1]. Since parental suspicion of AOM causes an extensive number of visits to primary health care, reliable ear examination performed by nurses might save physicians' time for other duties. Furthermore, a lack of physicians is not an unknown problem in primary health care [2]. Thus, the access of children to reliable ear evaluation might be enhanced by training nurses to reliably exclude AOM. We chose our perspective of excluding AOM at symptomatic visits because healthy middle ears and ears with otitis media with effusion (OME) require no treatment. Our perspective is supported by the recent AOM guideline from the American Academy of Pediatrics emphasizing that AOM should be diagnosed and treated only when the otoscopic diagnosis is certain (i.e. the tympanic membrane is bulging, indicating acute infection) [3].

Tympanometry and spectral gradient acoustic reflectometry (SG-AR) are adjunctive diagnostic tools for pneumatic otoscopy [4–11]. Tympanometry has been

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found to be a useful tool for general practitioners [12,13]. Tympanometry is slightly more accurate than SG-AR in detecting middle-ear effusion (MEE) [8]. However, tympanometry has the disadvantage of requiring an airtight seal to the external auditory canal and the cooperation of the child. These requirements are not needed to perform SG-AR. Thus, SG-AR succeeds more often than tympanometry [9,10]. We have recently shown that nurses could reliably exclude MEE in asymptomatic children with type A and C1 tympanograms, which were obtained from both ears of the child at less than half of the asymptomatic visits [14]. Concerning symptomatic visits, none of the previous studies have investigated the clinical usefulness of tympanometry and SG-AR in primary health care, i.e. the proportion of visits where reliable test results are obtained from both ears of the child [4,7–11,15–17]. If tympanometric and/or SG-AR examinations performed by nurses were reliable in excluding AOM, a proportion of the symptomatic children might potentially go home without visiting a physician in the case where the child's overall condition is normal.

Our aim was to investigate whether nurses without otoscopic experience can reliably use tympanometry or SG-AR as a diagnostic tool to exclude AOM in young symptomatic children. Our second aim was to estimate the proportion of visits where nurses could exclude AOM from symptomatic children on the basis of tympanometry or SG-AR.

Material and methods

Study population and visits

This study was part of a project examining the optimal diagnosis and treatment of AOM in children between six and 35 months of age at a primary health care level (http://www.clinicaltrials.gov, identifier NCT00299455) in Turku, Finland [18]. The selection criteria of visits for this study were: between the years 2006 and 2009, visits where the children had acute symptoms (i.e. were symptomatic); visits at least three days apart; a maximum of six visits per child; and visits with successful SG-AR, tympanometry, and pneumatic otoscopy by a physician. Since most of the children were at preverbal age and could not describe their symptoms, parental evaluation was used to assess the symptoms of the child. According to the parents, these children suffered from acute symptoms and/or signs of respiratory tract infection (such as rhinitis, cough, or fever) or non-specific symptoms (such as irritability, night restlessness, or reduced appetite) during the preceding 48 hours before the visit.

Written informed consent was obtained from the parents of each child. The study protocol was approved by the Ethical Committee of the Hospital District of Southwest Finland.

Diagnostic procedures

We trained three nurses to perform tympanometry (MicroTymp2, Welch Allyn, Skaneateles Falls, NY) and SG-AR (EarCheck PRO Otitis Media Detector, Innovia Medical LLC, Omaha, NE). The nurses had no experience with pneumatic otoscopy, tympanometry, or SG-AR. In one training session lasting approximately two hours, we taught the nurses the principles of tympanometry and SG-AR and how to perform examinations with these devices. After the training, we checked how the nurses used the devices. During the study visits, one of the three nurses performed examinations. The examinations were independently performed without any guidance from the study physician [14].

Children were examined in an upright position. First, the nurse performed SG-AR and then tympanometry. After this, the study physician performed SG-AR, tympanometry, pneumatic otoscopy (Macroview otoscope Model 23810, Welch Allyn, Skaneateles Falls, NY), and video otoscopy (Jedmed, St. Louis, MO). Cerumen was carefully removed before pneumatic otoscopy. The order of diagnostic procedures was chosen to optimize the cooperation of the children during SG-AR and tympanometry.

Pneumatic otoscopy performed by the study physician was used as the diagnostic standard. The diagnosis of AOM required three criteria. First, middle-ear effusion had to be detected (at least two of the following tympanic membrane findings: bulging position, decreased or absent mobility, abnormal colour, or opacity not due to scarring). Second, acute inflammatory signs had to be present in the tympanic membrane (at least one of the following: distinct erythematous patches or streaks or increased vascularity over full, bulging, or yellow tympanic membrane). Third, children had to suffer from signs and symptoms of acute infection. Of the five study physicians, three made over 90% of the otoscopic examinations and had excellent inter-observer agreement (kappa values ranging from 0.80 to 0.92) [9].

Classification of diagnostic test results

All the tympanograms were evaluated by two study physicians (ML and AR) who were blinded to the results of the otoscopic examination. When disagreeing, AR made the final decision. The nurses did not interpret tympanograms. We classified the tympanograms

according to the classifications of Jerger [4] and Fiellau-Nikolajsen and Lous [19]. We separated markedly wide (>300 daPa) or low peaked (static acoustic admittance <0.2 mmho) tympanograms into the class Cs because these tympanograms have been shown to be associated with increased likelihood of MEE [7]. The five types of tympanograms were as follows: Type A (tympanometric peak pressure greater than −100 daPa); type C1 (pressure between −100 and −199 daPa); type C2 (pressure −200 daPa or less); type Cs (width >300 daPa or static acoustic admittance <0.2 mmho); and type B (flat). Flat tympanograms were repeated three times whenever possible. We divided the results of SG-AR into five manufacturer determined levels: <49° (level 5); 49–59° (level 4); 60–69° (level 3); 70–95° (level 2); and >95° (level 1). We recorded SG-AR examination as failed if the device repeatedly showed an error symbol, or the angle value was seen only for a moment.

Statistical analyses

Test characteristics for the diagnostic test results of the nurses were calculated by comparing the pneumatic otoscopic diagnosis of AOM by the study physician (the positive reference standard) with non-AOM situation, i.e. the middle ear was healthy or OME was detected (the negative reference standard). Sensitivity, specificity, positive predictive value, and negative predictive value were calculated with their respective 95% confidence intervals (CI).

The tympanometric diagnostic test result for AOM was the grouped result of type C2, Cs, and B tympanograms (the positive test result), which was contrasted with the grouped result of type A and C1 tympanograms (the negative test result). Correspondingly, the test characteristics for SG-AR were calculated for levels 2–5 (≤95°; the positive test result) vs. level 1 (>95°; the negative test result). For the reliable exclusion of AOM, we considered that the negative predictive value of the diagnostic test result should be at least 95%.

To estimate the clinical usefulness, we calculated the proportion of visits where the nurses obtained the exclusive test result for AOM (i.e. type A or C1 tympanogram, or SG-AR level 1) from both ears of the child with tympanometry or SG-AR. The statistical analyses were generated using SAS software (version 9.3 for Windows, SAS Institute Inc., Cary, NC).

Results

This study included 281 children, who had 459 symptomatic visits when a nurse performed tympanometry and/or SG-AR on one or both ears (Figure 1). The prevalence of AOM with pneumatic otoscopy by the study physician was 467/1782 (26%) of all tympanometric and/or SG-AR examinations performed by the nurse.

The median age of the children was 14 months (range 6–35), 64% of the children were male, the median number of previous AOM episodes was one (range 0–11), and the median age at first AOM episode was nine months (range 0–27).

Tympanometric examinations

The nurses performed 890 tympanometric examinations, 670 (75%) of which were successful, i.e. the children were cooperative during the examination. The three nurses succeeded in 96/138 (70%), 159/217 (73%), and 415/535 (78%) of performed tympanometric examinations, respectively. The proportions of AOM with different tympanogram types are presented in Table 1. The negative predictive value of type A and C1 tympanograms in excluding AOM was 94% (95% CI 91–97%) (Table 2).

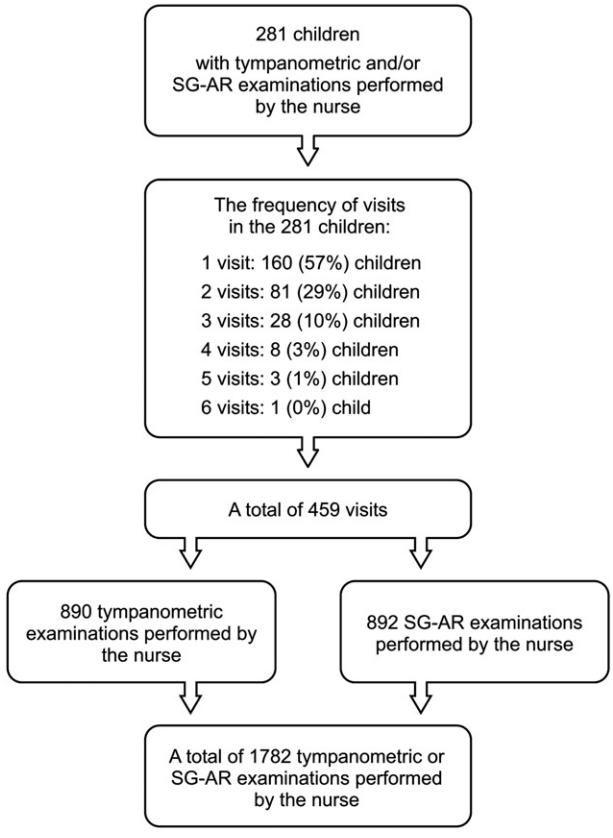

Figure 1. Flow chart of the included children, visits, and tympanometric and spectral gradient acoustic reflectometry (SG-AR) examinations.

SG-AR examinations

The nurses performed 892 SG-AR examinations, of which 782 (88%) were successful. The three nurses succeeded in 112/140 (80%), 472/537 (88%), and 198/215 (92%) of performed SG-AR examinations. The proportions of AOM with SG-AR levels 1–5 are presented in Table 3. The negative predictive value of SG-AR level 1 result in excluding AOM was 94% (95% CI 89–97%) (see Table 2).

Clinical usefulness

Of the 459 visits, tympanometry was successfully performed on both ears of the child at 302 (66%) visits. The nurses obtained type A or C1 tympanogram (peak pressure >-200 daPa) from both ears of the child at 94 visits. Thus, the exclusive test result was obtained at 20% (94/459) of all visits (Figure 2). Of these 94 visits, AOM was diagnosed with pneumatic otoscopy at six (6%) of the visits.

SG-AR was successfully performed on both ears of the child at 373/459 (81%) visits. The nurses obtained the exclusive test result (i.e. level 1) from both ears of the child at 36/459 (8%) of all visits. Of these 36 visits, AOM was diagnosed with pneumatic otoscopy at two (6%) visits.

Discussion

Table 1. Successful tympanometric examinations ($n = 670$) performed by the nurses.

	Pneumatic otoscopic diagnosis by the physician			
Tympanometric result[1] of the nurse (n, %)	Healthy middle ear ($n = 291$)	Otitis media with effusion ($n = 213$)	Acute otitis media ($n = 166$)	Total ($n = 670$)
A	159 (89%)	11 (6%)	9 (5%)	179
C1	71 (65%)	32 (29%)	7 (6%)	110
C2	46 (46%)	42 (42%)	12 (12%)	100
Cs	0 (0%)	5 (83%)	1 (17%)	6
B	15 (5%)	123 (45%)	137 (50%)	275

Notes: Classification of tympanograms. Type A (tympanometric peak pressure greater than −100 daPa); type C1 (pressure between −100 and −199 daPa); type C2 (pressure −200 daPa or less); type Cs (width >300 daPa or static acoustic admittance <0.2 mmho); and type B (flat).

Statement of principal findings

We showed that type A and C1 tympanograms (peak pressure >-200 daPa) and SG-AR level 1 results ($>95°$) obtained by the nurses were reliable test results in excluding AOM. However, these test results were obtained only at one-fifth of the symptomatic visits, which limits their clinical usefulness. Uncooperative young children, inexperienced nurses, and the rarity of exclusive test results at symptomatic visits seem to be the major factors reducing the clinical usefulness of excluding AOM by nurses.

Strengths and weaknesses of the study

The strengths of our study include the quality of reference diagnostics by trained otoscopists using video otoscopy and the large study population at the primary health care level, where most of the episodes of AOM are diagnosed and treated. Furthermore, the participating children represented the age group with the highest incidence of AOM. Thus, this study setting reflects the reality in which symptomatic children with suspected AOM are actually examined. The use of pneumatic otoscopy as a diagnostic standard instead of myringotomy can be considered a limitation of this study. However, pneumatic otoscopy is the only diagnostic standard that can be used in uncomplicated AOM episodes in primary health care. Since myringotomy was not performed, the otoscopists' agreement to myringotomy could not be analysed. Furthermore, the relatively high prevalence of AOM may underestimate the usefulness of tympanometry and SG-AR in the exclusion of AOM. It is of importance that the study physicians interpreted the tympanograms, and the skills of nurses in interpreting tympanograms were not studied. Finally, only a few nurses performed examinations. On the other hand, specific nurses could be trained to perform tympanometric and SG-AR examinations in primary health care to achieve optimal success rates with these devices.

Findings in relation to other studies

Table 2. Predictive values (with respective 95% confidence intervals [CI]) for the diagnostic test results with tympanometry ($n = 670$) and spectral gradient acoustic reflectometry (SG-AR) ($n = 782$) obtained by the nurses[1].

	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
Type C2, Cs, and B vs. type A and C1 tympanograms[2]	90% (85–94%)	54% (50–58%)	39% (35–44%)	94% (91–97%)
SG-AR level 2–5 ($\leq 95°$) vs. level 1 ($>95°$) results	95% (91–98%)	26% (22–30%)	32% (28–36%)	94% (89–97%)

Notes: Pneumatic otoscopy by the study physician served as the diagnostic standard; acute otitis media (AOM) was contrasted with non-AOM (i.e. healthy middle ear or otitis media with effusion).

[2]Classification of tympanograms. Type A (tympanometric peak pressure greater than −100 daPa); type C1 (pressure between −100 and −199 daPa); type C2 (pressure −200 daPa or less); type Cs (width >300 daPa or static acoustic admittance <0.2 mmho); and type B (flat).

Table 3. Successful spectral gradient acoustic reflectometry (SG-AR) examinations ($n = 782$) performed by the nurses.

	Pneumatic otoscopic diagnosis by the physician			
SG-AR result of the nurse (*n*, %)	Healthy middle ear ($n = 329$)	Otitis media with effusion ($n = 244$)	Acute otitis media ($n = 209$)	Total ($n = 782$)
Level 1 (>95°)	117 (74%)	32 (20%)	10 (6%)	159
Level 2 (70–95°)	129 (53%)	83 (34%)	33 (13%)	245
Level 3 (60–69°)	43 (40%)	34 (31%)	32 (29%)	109
Level 4 (49–59°)	34 (31%)	36 (33%)	40 (36%)	110
Level 5 (<49°)	6 (4%)	59 (37%)	94 (59%)	159

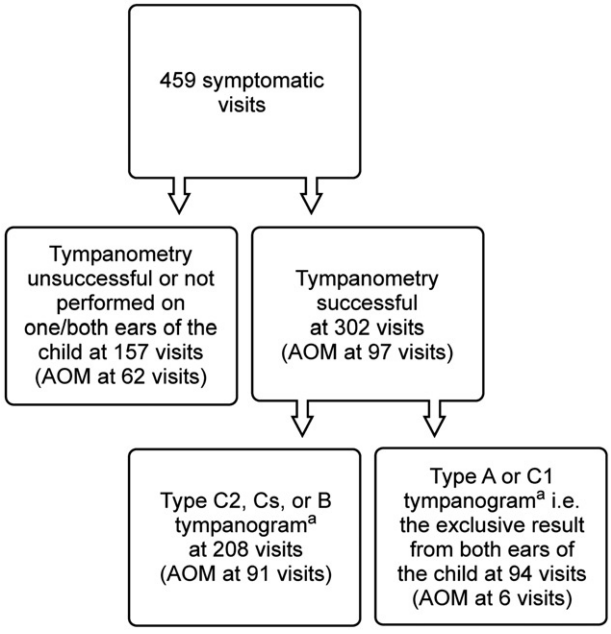

Figure 2. Exclusion of acute otitis media (AOM) based on tympanometry performed by the nurses at symptomatic visits ($n = 459$). Type A and C1 tympanograms from both ears of the child were regarded as the exclusive test result for AOM.
Notes: [a]Classification of tympanograms. Type A (tympanometric peak pressure greater than −100 daPa); type C1 (the pressure between −100 and −199 daPa); type C2 (pressure −200 daPa or less); type Cs (width >300 daPa or static acoustic admittance <0.2 mmho); and type B (flat).

The nurses' success rates with tympanometry were lower than most of the previously reported success rates [11,16,20]. On the other hand, corresponding success rates have been reported in children of less than two years of age [8], who are the most difficult to examine [20]. The nurses' success rates seem to have been affected by the children' young age, the nurses' experience, the tympanometer model used, and whether the examinations (ears) or visits were analysed. The nurses were inexperienced at the beginning, and they gradually became more experienced during the study. Thus, in clinical practice, nurses might perform better if they were already experienced with the devices when starting to perform tympanometric examinations. Furthermore, the tympanometer model, MicroTymp2, used in this study has been found difficult to handle, and the tympanograms obtained from MicroTymp2 can be difficult to interpret [21]. It is of importance that better success rates may be obtained with a more easily handled tympanometer (e.g. GSI tympanometers, Grason-Stadler, Eden Prairie, MN).

Analysing the clinical usefulness, i.e. the success of tympanometry and SG-AR from both ears of the child at a symptomatic visit, was a new practical perspective which none of the previous studies have investigated. Previously, Teppo et al. [15] found that nurses could not reliably exclude MEE with SG-AR in young symptomatic children. Blomgren et al. [16] concluded that, on the basis of a brief teaching session, nurses could not be taught to detect MEE with tympanometry in children undergoing tympanostomy tube placement. On the other hand, we have recently shown that nurses could reliably exclude MEE with type A and C1 tympanograms in asymptomatic children of 6–35 months of age [14]. Correspondingly, in our current study, type A and C1 tympanograms by the nurses were reliable in excluding AOM. However, since type A and C1 tympanograms are relatively rare at symptomatic visits, these test results were obtained from both ears of the child only at one-fifth of the visits. Even though type C2 and Cs tympanograms would increase the proportion of visits where AOM could be excluded, these test results are associated with increased likelihood of AOM and, thus, are not reliable in excluding AOM. Finally, since SG-AR level 1 result was rarely obtained from both ears of the child, it seems that SG-AR will have to remain as a supplementary device when tympanometry is unsuccessful or unavailable. However, since tympanometry and SG-AR often succeed in the same ears, performing SG-AR after tympanometry adds only a little benefit.

The exclusion of AOM by trained nurses might be applied in a case where the parental primary concern is the suspicion of AOM, and the child's overall condition has been evaluated to be normal. Notably, since the aim of this study was to evaluate the accuracy and clinical usefulness of tympanometric and SG-AR devices, a structured questionnaire would have to be designed and validated to exclude any serious signs and conditions in the child. When symptomatic children with respiratory tract infection attend a health care centre and the primary concern is suspected AOM, trained nurses might first complete a structured questionnaire, perform tympanometry, and give instructions concerning pain medication. If the child's overall condition was not normal, or AOM could not be excluded with tympanometry or SG-AR, a physician would examine the child. Of great importance, since these examinations

at one particular time point are a snapshot of a dynamic disease, new examination of the child would have to be performed by a physician at any time if the symptoms of the child worsened.

Meaning of the study

This study has practical significance for both Scandinavian guideline makers and health care centres. Nurses might be involved in excluding AOM because they can be trained to reliably use tympanometry, and type A and C1 tympanograms can be used to exclude AOM. The exclusion of AOM might be applied in a case where the parental primary concern is the suspicion of AOM, and the child's overall condition has been evaluated to be normal. However, since AOM could be excluded only at one-fifth of the visits, the clinical usefulness of nurses excluding AOM seems to be limited. In fact, the exclusion of AOM by nurses might be most useful in settings where there is a lack of physicians.

If individual health care centres consider implementing the exclusion of AOM by nurses, they should perform the following actions: survey their lack of physicians, investigate the prevalence of AOM, choose an appropriate tympanometer, train the nurses, and evaluate the nurses' tympanometric success rates and their skills in interpreting tympanograms. Of great importance, since the aim of this study was to evaluate the accuracy and usefulness of tympanometric and SG-AR devices, a structured questionnaire would have to be designed and validated to exclude any serious signs and conditions in the child.

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The study protocol (http://www.clinicaltrials.gov, identifier NCT00299455) was approved by the Ethical Committee of the Hospital District of Southwest Finland.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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