Acoustic Reflectometry in Discrimination of Otoscopic Diagnoses in Young Ambulatory Children

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Background: Studies concerning spectral gradient acoustic reflectometry (SG-AR) have analyzed middle ear effusion only as 1 entity. The usefulness of SG-AR to detect specific otoscopic diagnoses of otitis media in young children is unknown.

Methods: Among 515 children aged 6–35 months, we compared SG-AR with pneumatic otoscopy and evaluated the proportions of 5 manufacturer-recommended SG-AR levels in relation to specific otoscopic diagnoses in 2802 and 1240 examinations at symptomatic and asymptomatic visits, respectively.

Results: At asymptomatic visits, when the angle value was >95° (level 1), healthy middle ear was diagnosed in 76% of otoscopic examinations and acute otitis media in 5%. Levels 2 (70–95°) and 3 (60–69°) did not relate to any otoscopic diagnosis. Levels 4 and 5 associated with acute otitis media in 50% and 64%, and otitis media with effusion in 33% and 32% of examinations, respectively. At asymptomatic visits, levels 1, 2 and 3 were associated with healthy middle ear in 87%, 71% and 54% of examinations, respectively. With levels 4 and 5, otitis media with effusion was diagnosed in 62% and 79% of examinations, respectively.

Conclusions: SG-AR is not useful in making specific otoscopic diagnoses. Although the extremities of 5 SG-AR levels are able to differentiate ears with and without effusion, SG-AR is not able to differentiate acute otitis media from otitis media with effusion. Therefore, SG-AR can aid in diagnostics, but careful pneumatic otoscopy is needed to determine accurate diagnoses.

Key Words: diagnosis, otitis media, pneumatic otoscopy, spectral gradient acoustic reflectometry

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Otitis media affects almost every child before school age, and acute otitis media (AOM) is the most common indication to prescribe antimicrobial treatment at primary care level.1 Recently, the importance of accurate diagnostics for the optimal management of otitis media has been emphasized.2,3 Most diagnoses are made in primary care offices where physicians have limited time for cerumen removal and otoscopic examination. Therefore, adjunctive tools for diagnostics would be needed.

Spectral gradient acoustic reflectometry (SG-AR) measures the acoustic response of the tympanic membrane to a sound frequency sweep emitted by the instrument.4 SG-AR does not require an airtight fit in the ear canal, can be successfully performed also for a struggling child and emits a chirping sound that most children find pleasant. Previous studies with SG-AR have mostly included children undergoing tympanostomy tube placement and/or >3 years of age.4–10 Chianese et al11 compared SG-AR and tympanometric findings with pneumatic otoscopy in 545 outpatients <2 years of age and concluded SG-AR to be slightly less accurate than tympanometry but easily performed for an uncooperative child.

The aim of this study was to find out the usefulness of SG-AR to detect specific otoscopic diagnoses of otitis media. At primary care level, we examined young children with the whole range of otoscopic findings from healthy middle ear or minor middle ear effusion to AOM with bullae on the tympanic membrane.

MATERIALS AND METHODS

Study Population

We examined children aged 6–35 months who were initially brought for an outpatient visit due to parental suspicion of AOM. We followed these children in 2 cohorts at primary care level between 2006 and 2009. In the first cohort, children in whom we diagnosed AOM participated in our AOM treatment trial (www.clinicaltrials.gov identifier: NCT00299455) and thus we examined them regularly after enrollment visit on study days 3, 8, 15, 30 and 60.11 If AOM or otitis media with effusion (OME) was detected, we scheduled a follow-up visit every 2 weeks until the resolution of effusion or the referral for tympanostomy tube placement. In addition, we arranged sick visits whenever needed. In the second cohort, we followed the signs and symptoms of children who did not have AOM at the enrollment visit and examined them at 1 scheduled visit after approximately 12 days. 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 analyzed the results separately at symptomatic and asymptomatic visits because the symptomatic condition strongly affects the likelihood of middle ear effusion.12,13 At symptomatic visits, children had acute signs and symptoms of respiratory tract infection or nonspecific symptoms leading to parental suspicion of AOM. At asymptomatic visits, children did not have any symptoms. To minimize the repetition of the same result, we excluded visits <3 days apart. If a child had >6 visits, we included only the first 6 visits. Furthermore, visits on which all diagnostic procedures could not be performed were excluded.

Diagnostic Procedures

Children were always examined in an upright position. The order of diagnostic procedures was designed to optimize the cooperation of children during SG-AR because cerumen removal
and/or otoscopic examination often cause fussiness and struggling, leading to failure of SG-AR examination. The study physicians first performed SG-AR (EarCheck PRO Otitis Media Detector, Innovia Medical LLC, Omaha, NE), then tympanometry (MicroTymp2, Welch Allyn, Skaneateles Falls, NY) and finally pneumatic otoscopy (Macroview Otoscope Model 23810, Welch Allyn). Cerumen was carefully removed before pneumatic otoscopy. Digital pneumatic video otoscopy was used to document the findings (Jedmed, St. Louis, MO). All study physicians were validated to assess otoscopic findings. Of the 5 study physicians, 3 (M.K.L, P.A.T., A.R.) made over 90% of the diagnoses and had an excellent agreement (kappa values from 0.80 to 0.92).

Pneumatic otoscopy served as the diagnostic standard, and we classified the otoscopic findings into 5 otoscopic diagnoses. OME was categorized as air-interface OME (a-OME) when visible air-effusion interface and/or air bubble(s) were seen or as complete OME (c-OME) when otoscopic examination showed that the middle ear was completely filled with effusion. Similarly, AOM was categorized as air-interface AOM (a-AOM) with visible air-effusion interface and/or air bubble(s) or complete AOM (c-AOM) when the middle ear was completely filled with effusion. If there were no pathologic otoscopic findings, the middle ear was categorized as healthy.

The diagnosis of AOM required the following 3 criteria. First, middle ear effusion had to be detected by means of pneumatic otoscopic examination that showed at least 2 of the following tympanic membrane findings: bulging position, decreased or absent mobility, abnormal color or opacity not due to scarring, or air-effusion interface. Second, at least 1 of the following acute inflammatory signs in the tympanic membrane had to be present: distinct erythematous patches or streaks or increased vascularity over full, bulging or yellow tympanic membrane. Third, signs and symptoms of acute infection had to be present.

Spectral Gradient Acoustic Reflectometry

We classified the SG-AR angle value according to the manufacturer’s recommendations into 5 levels corresponding to the risk of middle ear effusion: <49°, high risk of middle ear effusion (level 5); 49–59°, moderate-high risk (level 4); 60–69°, moderate risk (level 3); 70–95°, low-moderate risk (level 2) and >95°, low risk (level 1). SG-AR was performed only once if successful angle value because higher angles values were obtained when air-fluid interfaces were seen in otoscopy. When a-OME and c-OME were diagnosed, values ≥70° (ie, levels 1–2) were obtained in 404/589 (69%) and 203/593 (34%) examinations, respectively (levels 1–2 versus levels 3–5; P < 0.001). Corresponding figures for the diagnoses of a-AOM and c-AOM were 66/178 (37%) and 77/586 (13%), respectively (P < 0.001).

The above figures reveal that a-OME was related significantly more often to higher angles values ≥70° (ie, levels 1–2) than to lower levels, a result that indicates the potential diagnostic value of the SG-AR angle value. The lower values were obtained significantly more often to lower angles values, a result that indicates the potential diagnostic value of the SG-AR angle value.

The diagnoses of AOM and OME are presented concurrently in this issue of Pediatric Infectious Disease Journal.

SG-AR gave a wide range of angle values for all 5 otoscopic diagnoses (Fig. 1). When the angle value was 120 (ie, the upper end of angle range), healthy middle ear was diagnosed in 452 of the 513 examinations (88%). On the other hand, when the otoscopic diagnosis was healthy middle ear, the angle value 120 was obtained in only 452 (22%) of 2096 examinations. Of the 524 examinations with level 5 (<49°) result, any OME or any AOM was diagnosed in 493 (94%) examinations.

The amount of effusion in the middle ear affected the SG-AR angle value because higher angles values were obtained when air-fluid interfaces were seen in otoscopy. When a-OME and c-OME were diagnosed, values ≥70° (ie, levels 1–2) were obtained in 404/589 (69%) and 203/593 (34%) examinations, respectively (levels 1–2 versus levels 3–5; P < 0.001). Corresponding figures for the diagnoses of a-AOM and c-AOM were 66/178 (37%) and 77/586 (13%), respectively (P < 0.001).

RESULTS

We enrolled 515 patients. Their mean age was 16 months (range 6–35 months), mean number of previous AOM episodes 2 (range 0–12) and mean age at first AOM episode 10 months (range 0–29 months). Of the total of 2856 visits, 2123 were included in the analyses based on our criteria to minimize the repetition of the same result. At the included visits, the 3 diagnostic examinations were performed in both ears. This led to 4246 SG-AR examinations, 4042 (95%) of which succeeded. The results of tympanometry are presented concurrently in this issue of Pediatric Infectious Disease Journal.

FIGURE 1. Cumulative proportions of the spectral gradient acoustic reflectometry (SG-AR) angle values in relation to the five otoscopic diagnoses in all 4042 successful examinations.
than a-AOM, and the same applied to c-OME when compared with c-AOM.

Symptomatic Visits

At symptomatic visits, when the angle value was >95° (level 1), otoscopic diagnosis was almost exclusively healthy middle ear or a-OME (Table 1; Fig. 2A). In contrast, level 4 (50–59°) and level 5 (<49°) results were related to any OME or any AOM. Levels 2 (70–95°) and 3 (60–69°) did not relate to any particular otoscopic diagnosis.

Looking the results from the other point of view, when the middle ear was diagnosed as healthy, only 540 (44%) of 1220 examinations showed SG-AR level 1 result but 1011 (83%) showed levels 1–2. When the otoscopic diagnosis was a-OME, 285 (67%) of 423 examinations showed levels 1–2 result. C-OME and a-AOM were not related to any particular SG-AR level results. When c-AOM was diagnosed, 440 (75%) showed levels 4–5.

At symptomatic visits, the ROC analysis gave the area under the curve value of 0.81 (95% confidence interval: 0.79–0.83), corresponding to good diagnostic accuracy in detecting any OME or any AOM.

Asymptomatic Visits

At asymptomatic visits, levels 1, 2 and 3 were associated with healthy middle ear in 461 (87%), 303 (71%) and 67 (54%) examinations, respectively (Table 2; Fig. 2B). Levels 2 and 3 were less often associated with healthy middle ear. Level 4–5 results were obtained only in 161 (13%) of all 1240 successful SG-AR examinations at asymptomatic visits.

From the other perspective, when the middle ear was diagnosed as healthy, 461 (53%) of 876 examinations showed SG-AR level 1 result and 764 (87%) of examinations showed levels 1–2. With the otoscopic diagnosis of a-OME, level 1–2 result was obtained in 119 (72%) of 166 examinations. C-OME was not related to any particular SG-AR level.

At asymptomatic visits, the area under the curve value from the ROC analysis was 0.76 (95% confidence interval: 0.73–0.79), corresponding to fair diagnostic accuracy in finding any OME or any AOM.

DISCUSSION

Our study shows that SG-AR is not useful in detecting specific otoscopic diagnoses of otitis media because all otoscopic diagnoses are related to both low and high SG-AR angle values. However, the extremities of the SG-AR angle range, namely levels 1 and 5, are related to healthy middle ear and any effusion, respectively. Taken these together with the high success rate of the examinations, SG-AR is useful in differentiating between healthy middle ears from those with effusion in roughly half of all examinations.

### TABLE 1. Spectral Gradient Acoustic Reflectometry (SG-AR) Results in Relation to the 5 Otoscopic Diagnoses in 2802 Successful Examinations at Symptomatic Visits

<table>
<thead>
<tr>
<th>Otoscopic Diagnosis, N</th>
<th>Healthy Middle Ear (N = 1220)</th>
<th>Air-interface OME (N = 423)</th>
<th>Complete OME (N = 399)</th>
<th>Air-interface AOM (N = 177)</th>
<th>Complete AOM (N = 583)</th>
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<tbody>
<tr>
<td>SG-AR level, N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Level 1 (&gt;95°) (N = 708)</td>
<td>540</td>
<td>94</td>
<td>39</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Level 2 (70–95°) (N = 862)</td>
<td>471</td>
<td>191</td>
<td>92</td>
<td>51</td>
<td>57</td>
</tr>
<tr>
<td>Level 3 (60–69°) (N = 339)</td>
<td>117</td>
<td>70</td>
<td>46</td>
<td>40</td>
<td>66</td>
</tr>
<tr>
<td>Level 4 (50–59°) (N = 441)</td>
<td>73</td>
<td>51</td>
<td>96</td>
<td>39</td>
<td>182</td>
</tr>
<tr>
<td>Level 5 (&lt;49°) (N = 452)</td>
<td>19</td>
<td>17</td>
<td>126</td>
<td>32</td>
<td>258</td>
</tr>
</tbody>
</table>
As a new aspect, we compared SG-AR results with 5 otoscopic diagnoses instead of including only children with AOM or grouping various effusion findings together.6,7,9,11 This allowed us to observe that the 5 otoscopic diagnoses were related to overlapping SG-AR levels, which points out the difficulty of associating SG-AR results with any otoscopic diagnosis. Interestingly, the SG-AR angle values were higher (ie, levels 1 and 2) in association with a-OME when compared with a-AOM, and likewise higher with c-OME than c-AOM. This leaves open the possibility that the SG-AR angle values might be affected by the position of tympanic membrane or even by middle ear pressure. Based on our results, the SG-AR angle values are affected by the amount of middle ear effusion as OME and AOM with air-effusion interfaces showed significantly higher angle values than OME and AOM with complete effusion. However, the clinical significance of especially a-OME could be questioned. If this diagnosis was grouped together with healthy ears, the diagnostic accuracy of SG-AR would be somewhat improved. In any case, level 2 cannot be considered to indicate healthy middle ear, in contrast to the manufacturer’s recommendation. Therefore, our results suggest that “the gray diagnostic area” comprises of levels 2 and 3 and is even wider than previously recommended.6,11

The extreme ends of the SG-AR angle range seem to provide useful diagnostic information. In agreement with previous studies,6,9,12,16 level 1 (>95°) was mainly associated with healthy middle ear although in symptomatic children minor effusion was also detected by pneumatic otoscopy. Importantly, the upper end of level 1 angle range (ie, 120°) virtually excludes any effusion and is thus a reliable indicator of healthy middle ear. The usefulness of this result is, however, somewhat modest because only a fraction of healthy middle ears was associated with SG-AR result 120°. The other end of the angle range (ie, level 5) has been associated with middle ear effusion in all studies, including ours. However, according to our results, only two-thirds of the level 5 results are related to AOM even at asymptomatic visits. Thus, our results emphasize the inability of SG-AR to differentiate AOM from OME.

Reliable adjunctive tools would be needed to support pneumatic otoscopy because, as recently emphasized, an accurate diagnosis is the cornerstone of the optimal management of otitis media.2,3,12,16 SG-AR examination is easy to learn and pleasant to a child. These aspects have promoted the marketing of consumer models of SG-AR to families.17 This is worrisome because the diagnostic accuracy of SG-AR is far from ideal even in the hands of trained physicians. The accuracy of SG-AR may even have been overestimated in study settings that typically have higher prevalence of middle ear effusion than unselected children in outpatient settings.18 This is reflected by our finding that ROC analysis gave better diagnostic accuracy at symptomatic visits with high prevalence of middle ear effusion when compared with asymptomatic visits. It seems to us that careful pneumatic otoscopy remains the only accurate method to determine the diagnosis.

The strengths of our study are based on the study population and quality of diagnostics. We examined the typical age group of otitis media at primary care level where most otoscopic examinations are performed. Our trained study physicians with an excellent interobserver agreement performed >4000 examinations and had prespecified diagnostic criteria. Our definition for AOM was even stricter than that recommended by the 2004 guideline of the American Academy of Pediatrics.19 The fact that the same study physician performed first SG-AR and then pneumatic otoscopy can be considered as a limitation of our study. However, the order of diagnostic procedures was designed to optimize the co-operation of young children during SG-AR examination. Moreover, using pneumatic otoscopy instead of tympanocentesis as the gold standard decreased the objectivity of our study. However, tympanocentesis is not justified without need of microbiologic diagnosis. All in all, our study responds to everyday practice at primary care level and thus our results are largely applicable.

To conclude, SG-AR is not useful in diagnosing specific otoscopic diagnoses of otitis media because it is not able to differentiate AOM from OME. SG-AR could be used as an additional diagnostic tool by taking advantage of the extreme ends of the SG-AR angle range to indicate healthy middle ears and middle ears with any effusion. However, accurate diagnosis can only be based on careful pneumatic otoscopy.

ACKNOWLEDGMENTS

We thank Elizabeth D. Barnett, MD, Professor of Pediatrics, Boston University School of Medicine, for lending us one EarCheck PRO device.

REFERENCES


TABLE 2. Spectral Gradient Acoustic Reflectometry (SG-AR) Results in Relation to the 5 Otoscopic Diagnoses in 1240 Successful Examinations at Asymptomatic Visits

<table>
<thead>
<tr>
<th>SG-AR level, N</th>
<th>Healthy Middle Ear (N = 876)</th>
<th>Air-interface OME (N = 166)</th>
<th>Complete OME (N = 194)</th>
<th>Air-interface AOM (N = 1)</th>
<th>Complete AOM (N = 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 (&gt;95°) (N = 527)</td>
<td>461</td>
<td>36</td>
<td>30</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Level 2 (70°–95°) (N = 426)</td>
<td>303</td>
<td>83</td>
<td>42</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Level 3 (60°–69°) (N = 124)</td>
<td>67</td>
<td>25</td>
<td>32</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Level 4 (50°–59°) (N = 89)</td>
<td>33</td>
<td>15</td>
<td>40</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>Level 5 (&lt;49°) (N = 72)</td>
<td>12</td>
<td>7</td>
<td>50</td>
<td>19</td>
<td>22</td>
</tr>
</tbody>
</table>

*The child developed respiratory symptoms and had fever the following day.
†The child was asymptomatic at the time of diagnosis, but had had respiratory infection recently and restless sleep 2 nights before.
‡The other child did not have any symptoms preceding or afterward. The middle ear had been completely healthy 15 days before this diagnosis.


