ARTICLE

Spectral Gradient Acoustic Reflectometry Compared With Tympanometry in Diagnosing Middle Ear Effusion in Children Aged 6 to 24 Months

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Objectives: To evaluate the accuracy of spectral gradient acoustic reflectometry (SGAR) in children aged 6 to 24 months, and to compare SGAR with tympanometry.

Design: Comparison of diagnostic tests.

Setting: Inner-city primary care center in Pittsburgh, Pennsylvania.

Participants: A total of 786 healthy children aged 6 to 24 months.

Main Outcome Measures: Test characteristics of SGAR (sensitivity, specificity, and positive and negative predictive values) and receiver operating characteristic curves from the SGAR and tympanometric data.

Results: The SGAR results were available for 3096 otoscopic examinations in 647 children. Tympanometric results were available for 2854 otoscopic examinations in 597 children. Using the recommended SGAR pass or fail cutoff, 53% of the ears in which effusion was present would have been considered effusion free (sensitivity, 47%). Only 10% of the ears without effusion would have been considered to have effusion (specificity, 90%). The area under the receiver operating characteristic curve was 0.78 for SGAR and 0.83 for tympanometry.

Conclusion: Spectral gradient acoustic reflectometry is slightly less discerning than tympanometry in predicting the presence or absence of middle ear effusion in children younger than 2 years.

Arch Pediatr Adolesc Med. 2007;161(9):884-888

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ACCURATE DETERMINATION of the presence or absence of otitis media is essential in determining both the nature of childhood illness and the advisability of treatment with antibiotics. Guidelines recently advanced both by the American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media[1] and by the American Academy of Family Physicians, American Academy of Otolaryngology–Head and Neck Surgery, and American Academy of Pediatrics Subcommittee on Otitis Media With Effusion[2] recommend pneumatic otoscopy as the primary diagnostic method. However, a child's resistance to examination or the presence of cerumen that obscures the tympanic membrane may make accurate diagnosis a considerable challenge, especially in a busy office setting, in children younger than 2 years. Even when the tympanic membrane is readily visualized, findings that distinguish the diseased from the effusion-free middle ear can often be subtle. Spectral gradient acoustic reflectometry (SGAR) and tympanometry, both tools that detect the presence of middle ear effusion (MEE), are attractive as adjuncts to pneumatic otoscopy because they are easy to use, require minimal patient cooperation, and may help objectify the diagnosis.

Since the introduction of SGAR in 1997, 3 studies[3-5] have evaluated its diagnostic capability, but each of the studies has had certain limitations. The results of the studies cannot be generalized to healthy children aged 6 to 24 months, the age group at highest risk for otitis media.

Tympanometry has been clinically available for more than 30 years and a number of systems for classifying tympanometric results have been developed, with varying degrees of accuracy.[6] Classification schemes for infants and young children have been based on only a few reported studies[7,8] that were limited by small sample sizes, lack of sociodemographic diversity, and a preponderance of enrolled children with histories of chronic or recurrent otitis media. Recently, Smith et al[9] compared the tympanometric and otoscopic findings of 3686 healthy children during their first 3 years of life and derived an algorithm for children aged 6 to 35 months that predicts the probability of MEE based on any combination of individual values for tympanometric height, pressure, and width.

In our study of healthy children aged 6 to 24 months, we evaluated the accu-

racy of SGAR in predicting the likelihood of MEE and compared its accuracy with that of tympanometry using this recently developed algorithm.

METHODS

GENERAL PROCEDURES

We analyzed data from a recent randomized, double-blind, placebo-controlled trial of the efficacy of influenza vaccine in preventing acute otitis media (AOM).[10] Presumably healthy children aged 6 to 24 months were eligible for the study. We excluded children who were born prematurely, had a craniofacial abnormality, or had tympanostomy tubes inserted.[10] We enrolled 786 children during the respiratory seasons of 2 successive years and followed them up prospectively for middle ear disease at routine and sick visits until at least the ensuing March 31. According to the vaccine trial protocol, all of the children who developed AOM were evaluated at that time using pneumatic otoscopy, tympanometry, and SGAR. At visits when children were diagnosed otoscopically as having either normal middle ear status or otitis media with effusion (OME), SGAR and tympanometry were performed as convenient for study personnel. The procedures were undertaken without regard to whether the diagnosis was OME or normal middle ear status because the focus of the study was the occurrence of AOM only.

OTOSCOPIC ASSESSMENTS

All of the otoscopic assessments were performed by validated otoscopists (A.H., D.H.K., Mary Ann Haralam, CRNP, Lisa Zoffel, CRNP, and Stephanie Konieczka, RN) who applied a specific diagnostic algorithm in differentiating AOM from OME. The diagnosis of MEE required the presence of at least 2 of 4 elements: decreased or absent tympanic membrane mobility, yellow or white discoloration of the tympanic membrane, opacification of the tympanic membrane not due to scarring, and visible bubbles or air-fluid levels. The diagnosis of AOM was based on the presence of either purulent otorrhea of recent onset not due to otitis externa or MEE accompanied by 1 or more of the following: ear pain or unaccustomed rubbing of the ear, marked redness of the tympanic membrane, and substantial bulging of the tympanic membrane.[11] For the present analysis, we did not distinguish between MEE associated with AOM and MEE associated with OME. The otoscopic diagnosis served as the gold standard for determining the presence or absence of MEE.

SPECTRAL GRADIENT ACOUSTIC REFLECTOMETRY

Physician investigators, pediatric nurse practitioners, a research nurse, and a research assistant (A.H., D.H.K., Mary Ann Haralam, CRNP, Lisa Zoffel, CRNP, and Stephanie Konieczka, RN) performed SGAR using an Ear Check PRO Otitis Media Detector (Innovia Medical, Lenexa, Kansas). The manufacturer recommends associating spectral gradient angles with the risk of MEE as follows: greater than 95°, low; 70° to 95°, low to moderate; 60° to 69°, moderate; 49° to 59°, moderate to high; and less than 49°, high (with any angle $<70°$ considered a positive test result for MEE).

TYMPANOMETRY

Tympanometry was performed by a member of the same study team (A.H., D.H.K., Mary Ann Haralam, CRNP, Lisa Zoffel, CRNP, and Stephanie Konieczka, RN) using a GSI 33 version 2 middle ear analyzer (Grason-Stadler, Inc, Milford, New Hampshire). To be included in the present analysis, a tympanogram had to be indicative of an intact tympanic membrane and had to be interpretable by virtue of showing good agreement between the printed numerical results and the graphic representation. Three values were derived from tympanograms: peak height (in milliliters), middle ear air pressure (in decapascals), and tympanometric width (in decapascals).

STATISTICAL ANALYSIS

We first assessed the accuracy of SGAR in predicting the presence of MEE by calculating sensitivity, specificity, positive predictive value, and negative predictive value using pass or fail cutoffs based on each of the 5 manufacturer-defined levels of probability of MEE as noted earlier, including the manufacturer's recommended pass or fail cutoff value of 70° or greater vs less than 70°. If a child had multiple visits, all of them were included in the analysis.

We next constructed receiver operating characteristic (ROC) curves using the SGAR data and the tympanometric data. The area under an ROC curve for a test summarizes its overall diagnostic accuracy. If the area under the curve approaches 1.0, the test has excellent diagnostic accuracy; if the area approaches 0.5, the test is unable to differentiate between those with and without the condition. One might consider the diagnostic accuracy of a test with an area under the curve of 0.60 to 0.70 to be poor; 0.71 to 0.80, fair; 0.81 to 0.90, good; and greater than 0.90, excellent.[12]

In constructing the ROC curve for the SGAR data, we treated the SGAR reading as a continuous variable and used estimates of the probability that an ear contains effusion from a logistic regression model. For the tympanometric data, we first estimated the probability of MEE as follows. When the tympanogram was flat, ie, showing no printed numerical results for peak height, middle ear air pressure, or tympanometric width, we based the probability of MEE on the proportion of ears with flat tympanograms that were found otoscopically to have MEE. For the remainder of the tympanograms, ie, those showing results for the 3 tympanometric values, we estimated the probability of MEE by entering the values into the following algorithm developed by Smith et al[9] as noted earlier. The algorithm entails use of the mathematical base e, whose value is approximately 2.71828: $A = -3.0538 - [4.8596 \times \text{height}] - [0.0028 \times \text{pressure}] + [0.0108 \times \text{width}]$, and probability of effusion $= e^A/(1 + e^A)$.

We then plotted an ROC curve from the various probabilities of MEE generated by the data set, using pneumatic otoscopy as the gold standard, and estimated the area under the curve. Finally, we compared the areas under the respective ROC curves for SGAR and tympanometry using data only from the 504 children who underwent both tests, with a method that adjusts for correlations occurring owing to repeated measures on the same individual over time.[13]

Analysis was performed separately for the right and left ears and we used 2-tailed tests for all of the analyses, setting statistical significance at $P < .05$.

RESULTS

STUDY SAMPLE

Selected demographic and clinical characteristics of the 545 children who underwent both SGAR and tympanometry are shown in **Table 1**. The characteristics of these children did not differ significantly from those of the 242 children who underwent SGAR only, tympa-

Table 1. Demographic and Clinical Characteristics of Children With at Least 1 Ear for Which Spectral Gradient Acoustic Reflectometry, Tympanometry, and Otoscopy Were Performed

Characteristic	Children, No. (%) (n = 545)
Age at entry, mo	
6-12	259 (48)
13-18	156 (29)
19-24	130 (24)
Sex	
Male	297 (54)
Female	248 (46)
Race	
Black	223 (41)
White	282 (52)
Asian	3 (0.6)
Hispanic	6 (1)
Other	31 (6)
Daycare (> 3 children and > 10 h/wk)	164 (30)
Otitis prone (> 3 diagnoses of AOM in 6 mo or > 4 diagnoses of AOM in 12 mo)	123 (23)
Other household children	347 (64)
Exposure to household cigarette smoke	184 (34)

Abbreviation: AOM, acute otitis media.

nometry only, or neither. Certain clinical characteristics (day care attendance, otitis prone, other household children, and exposure to household cigarette smoke) were included to demonstrate the sample's exposure to risk factors for otitis media.

SPECTRAL GRADIENT ACOUSTIC REFLECTOMETRY

The SGAR results were available for 3096 otoscopic examinations in 647 of the 786 eligible children. Middle ear effusion was diagnosed otoscopically in 1790 (58%) of these examinations (AOM in 1170 examinations [38%] and OME in 620 examinations [20%]). **Table 2** shows SGAR test characteristics at pass or fail cutoffs based on the 5 manufacturer-defined categories of probability of MEE. Using the manufacturer's recommended pass or fail cutoff for diagnosing MEE (≥70° vs<70°), 53% of the ears in which effusion was present would have been considered effusion free (sensitivity, 47%), whereas only 10% of the ears without effusion would have been considered to have effusion (specificity, 90%). Using a more stringent criterion of greater than 95° vs 95° or less would have increased sensitivity to 78% but reduced specificity to 64%. The estimated area under the ROC curve generated by all of the SGAR data was 0.78 (**Figure**).

TYMPANOMETRY

A total of 2854 tympanograms were obtained from 597 children. Of these, 2104 tympanograms were interpretable; 1706 included values for height, width, and pressure and 398 were flat. Middle ear effusion was diagnosed otoscopically in 711 tympanograms (42%) (AOM in 1170 tympanograms [38%] and OME in 620 tympanograms [20%]). Among the 398 ears with flat tympanograms, 375 (94%) were diagnosed otoscopically with effusion. Entering the data from the remaining (ie, other than flat) tympanograms into the algorithm described earlier gave an estimated area under the ROC curve of 0.83.

SGAR VS TYMPANOMETRY

Among children undergoing both SGAR and tympanometry, comparison of the ROC curves generated by the 2 tests shows the estimated area under the tympanometry-generated curve to be significantly greater than that under the SGAR-generated curve. The consistency of our findings is demonstrated by the similarity between the results obtained from the right ear and those obtained from the left ear. For the right ear, the area under the curve was 0.82 for tympanometry compared with 0.77 for SGAR ($P=.02$). For the left ear, the results were 0.85 and 0.77, respectively ($P<.001$).

COMMENT

The 2004 clinical practice guidelines on diagnosis and management of AOM and otitis media with effusion recommended tympanometry as an adjunctive method useful to confirm otoscopic diagnoses.[2] Spectral gradient acoustic reflectometry was not recommended until such time as its accuracy was to be validated in further studies. In our study, using the gradient angle pass or fail cutoff of 70° or greater vs less than 70° (levels 1 and 2 vs levels 3-5) recommended by the SGAR instrument's manufacturer, we found sensitivity in detecting MEE to be relatively low (47%) and specificity to be relatively high (90%) (Table 2). Predictably, using the more stringent criterion of greater than 95° vs 95° or less gave increased sensitivity at the expense of specificity, whereas using less stringent criteria gave increased specificity at the expense of sensitivity. Because the prevalence of MEE in the children we studied (58% of the ears tested) was somewhat higher than that expected in an unselected population of children in the same age group,[14] the positive and negative predictive values for SGAR that we found cannot be generalized to other seemingly healthy children.

Barnett et al[3] examined 155 children aged 6 months to 14 years (mean age, 4 years; 35% aged<2 years) who were undergoing myringotomy and tube insertion and compared SGAR results with the presence or absence of middle ear fluid at surgery. As the children were not a representative group (58% of the total of 299 ears examined contained effusion, as did 50% of the 105 ears examined in children aged<2 years), results from this study—and particularly the predictive values—are not widely generalizable. The study also may not have involved enough children aged 6 to 24 months—the age group at highest risk for otitis media—to justify drawing conclusions about the performance of the test in children in the younger age group. Additionally, in an unstated proportion of the sample, SGAR and surgery were not performed on the same day, allowing for the possibility of change in middle ear status between assessments.

Table 2. Spectral Gradient Acoustic Reflectometry Test Characteristics for Detecting Middle Ear Effusion in Individual Ear Assessments

Angle (Ears, No.)	Manufacturer-Stated Probability of MEE	Ears With MEE, No. (%)	Pass or Fail Cutoff	Sensitivity, %	Specificity, %	PPV, %	NPV, %
> 95° (1225)	Low (level 1)	393 (32)	Level 1 (pass) vs levels 2-5 (fail)	78	64	75	68
70°-95° (892)	Low to moderate (level 2)	549 (62)	Levels 1-2 (pass) vs levels 3-5 (fail)	47	90	87	55
60°-69° (324)	Moderate (level 3)	246 (76)	Levels 1-3 (pass) vs levels 4-5 (fail)	34	96	92	51
49°-59° (417)	Moderate to high (level 4)	376 (90)	Levels 1-4 (pass) vs level 5 (fail)	13	99	95	45
< 49° (238)	High (level 5)	226 (95)	NA	NA	NA	NA	NA
Total (3096)		1790 (58)					

Abbreviations: MEE, middle ear effusion; NA, not applicable; NPV, negative predictive value; PPM, positive predictive value.

Block et al[4] studied 528 healthy children (870 ears), but the number of children aged 6 to 24 months may have been limited; only 27 of the children were aged 6 to 11 months, and the number of the 261 children aged 1 to 5 years who were younger than 24 months was not indicated. In a second study, Block et al[5] focused mainly on children aged 6 to 24 months but included only children with AOM, thus not permitting calculation of the specificity of SGAR.

Somewhat in contrast to our results using the recommended cutoff values of 70° or greater vs less than 70°, Barnett et al[3] found sensitivity of 72% and specificity of 73% (calculated from their Table 2). Differences in results between their study and ours may stem from differences in the age distributions of the populations studied (37% of the children aged < 2 years in their study vs 100% in ours) and in the acuity of illnesses (mainly chronic in their study vs mainly acute in ours). Similarly, using the same cutoff value, the sensitivity found by Block et al[4] was higher (67%) and the specificity slightly lower (87%) than the values we found in our study. Differences in results between their study and ours may stem not only from a difference in the age distributions of the populations studied (in their study, 5% of the children were aged 6-11 months and 45% of the children were aged 6-18 years), but also from a difference in the prevalence of MEE (20% of the ears had MEE in their study [calculated from their Table 1] vs 58% in ours).

In comparing the test characteristics (sensitivity, specificity, and positive and negative predictive values) of SGAR and tympanometry, both Barnett et al[3] and Block et al[4] necessarily used discrete pass or fail cutoff values for both tests. This method, however, limits the comparison to the respective cutoff values chosen and allows for the possibility that different pairs of cutoff values would give different results. A fuller understanding of the relative capabilities of the 2 tests, taking into account all of the data, is obtained by comparing the ROC curves that the 2 tests generate. In our study, we found the area under the tympanometry-generated curve (0.83) using the algorithm developed by Smith et al[9] to be significantly greater than the area under the ROC curve generated by the SGAR data (0.77). Of further interest, the area under our tympanometry-generated curve was virtually identical to the area under the tympanometry-generated curve (0.84) found by Smith and colleagues in their study sample of children aged 6 through 35 months, notwithstanding that

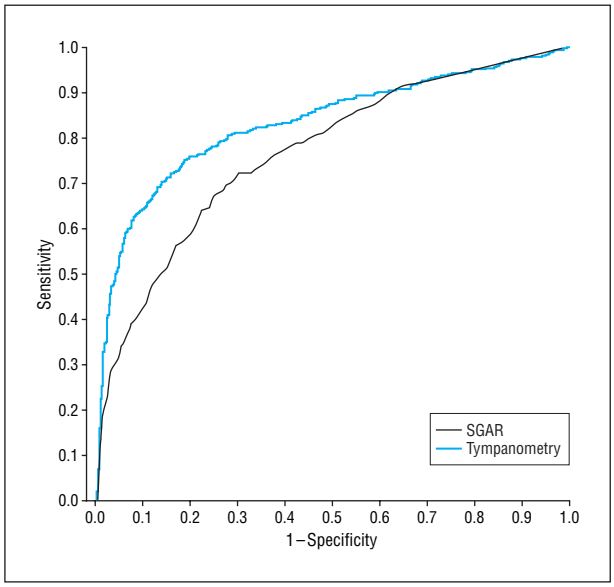

Figure. Comparison of receiver operating characteristic curves for spectral gradient acoustic reflectometry (SGAR) and tympanometry.

the prevalence of MEE in their sample was much lower than in ours (14% of ears vs 58% of ears, respectively). The similarity of results in the 2 studies affirms the validity of the algorithm by Smith and colleagues.

Certain limitations of our study require mention. First, the gold standard we used for determining the presence or absence of MEE was the clinical diagnosis based on findings at pneumatic otoscopy. Although the study otoscopists were validated, the results based on findings at tympanocentesis might have differed. However, as noted previously, reliance on otoscopic diagnosis is unavoidable in any ethical study involving a normative population because one would not subject children without apparent middle ear disease to tympanocentesis or myringotomy. A second limitation of our study lies in the fact that our results cannot be generalized to children older than 24 months. The performance of SGAR might be better in older children.

We conclude that SGAR is slightly less discerning than tympanometry in predicting the presence or absence of MEE in children younger than 2 years. Because of the relatively low sensitivity (47%) of SGAR that we found in such children at the pass or fail cutoff recommended by the instrument's manufacturer (≥ 70° vs < 70°), and

even given the higher sensitivity (78%) found using the more stringent cutoff of greater than 95° vs 95° or less, the test would not seem well suited for ruling out the presence of MEE in children in that age group. (By contrast, in children aged 6-35 months, a tympanometric cutoff consisting only of tympanometric height ≥ 0.6 mL vs < 0.6 mL—without regard to the other tympanometric parameters, namely, width and pressure—gives a sensitivity of 97%. A less stringent cutoff consisting of height ≥ 0.5 mL vs < 0.5 mL gives a sensitivity of 94%.[9]) On the other hand, the relatively high specificity (90%) found at the manufacturer-recommended cutoff suggests that in such children, given their expected prevalence of MEE, test failure using that cutoff is likely to indicate that MEE is indeed present. That likelihood would increase progressively with progressively narrowing spectral gradient angles.

What then is the place of SGAR in the clinician's armamentarium for children younger than 2 years? Both SGAR and tympanometry are simple, noninvasive, inexpensive tests. Comparing the 2 tests on the basis of both diagnostic accuracy and the breadth of information conveyed about middle ear status, tympanometry in our judgment is clearly the preferable of the two. However, unlike tympanometry, SGAR can be performed in relatively uncooperative children and its successful performance does not depend, as does that of tympanometry, on achieving an airtight seal between the instrument and the walls of the external auditory canal. Also, for the clinician with access to only a desktop model tympanometer (handheld models are available commercially), SGAR offers the additional advantage of easy portability at the bedside. Under such circumstances and also, of course, for the clinician with no access to tympanometry but with access to SGAR, the tests can certainly serve to provide a measure of assistance in either confirming or calling into question otoscopic diagnoses.

Accepted for Publication: March 20, 2007.
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Financial Disclosure: None reported.
Funding/Support: This work was supported by departmental funds from the School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania.

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