Reliability and Performance of the Acoustic Reflectometer

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Test-retest reliability and performance of an acoustic reflectometer were evaluated for 78 patients in two clinical settings. For a majority of the cases, the repeat measurements did not vary by more than one or two units from the first measurement. The accuracy of the instrument, when compared with standard clinical instruments, indicated that the acoustic reflectometer performed adequately with cases of middle ear effusion and could be used most effectively as a supplement to pneumatic otoscopy.

Assessment of otitis media with middle ear effusion (OME) in children is a frequent health concern of pediatricians and family physicians. Recently a handheld device that measures acoustic sound reflected from the tympanic membrane was designed to enable a quick, safe, and accurate method for identifying OME.[1] The device, similar to an otoscope, is inserted into the opening of the ear canal. A variable probe signal of 80 dB sound pressure level is presented and directed toward the tympanic membrane. The reflected sound from the tympanic membrane is recorded at the microphone within the reflectometer. The greater the reflected sound recorded by the microphone, the greater the number indicated on the horizontal reflectivity scale, which ranges from 0 to 9. In general, reflectivity numbers greater than 6 indicate probable middle ear effusion.[2] A second, vertical scale on the reflectometer simultaneously gives length readings. Length readings, however, apparently do not increase the sensitivity of the reflectometer for identifying middle ear effusion.[1,2-4] The reflectometer's advantage over conventional pure tone audiometry is that it requires no behavioral response; its advantage over acoustic immittance measurements (tympanometry and acoustic reflexes) is that it requires no air-tight seal within the ear canal.[1] Consequently, the test can be performed on most patients with OME.

Acoustic reflectometry norms have been developed for children aged 7 months to 13 years. Analysis of data obtained on infants under 7 months indicates that this instrument performs as well as on this difficult to test population as it does with older persons.[1] Norms have not been established for persons older than 13 years; it has been suggested that greater reflectivity from the tympanic membrane may occur for older persons because of scarring of the tympanic membrane.[1] Buhrer et al,[4] however, reported no significant differences in results between persons aged under 13 and over 13 years.

When children below the age of 13 years have been evaluated clinically with the acoustic reflectometer, high sensitivity rates[5] (positive findings for patients who had the disease) have been found.[1,3] Poor sensitivity rates have been reported[4] when assessing the device for use as a screening tool to detect various ear diseases. Procedural and subject population differences between the studies make it difficult to further compare the results. When the reflectometer was used as a general screening tool, the reported sensitivity result was 62.3 percent and specificity result was 74.6 percent[4]; when the reflectometer was used as a supplement to pneumatic otoscopy examination for identifying middle ear effusion, the reported sensitivity rate was 94.4 percent and specificity rate was 72.9 percent.[3]

Not only should testing devices have high sensitivity rates and high specificity rates[5] (negative findings for patients who do not have the disease), but they should also be repeatable. In other words, the screening device should be precise.[6] It should yield the same information with repeated use with very little variation.

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No information is currently available concerning the test-retest reliability of the acoustic reflectometer. Consequently, the current study was undertaken to assess the reliability of the acoustic reflectometer with repeated measurements.

A secondary purpose was to further evaluate the relative accuracy of the acoustic reflectometer by comparing it with standard clinical procedures used to assess middle ear effusion.

METHODS

Patients evaluated in this study were seen in two separate clinics, a pediatric otologic diagnostic clinic and a family practice clinic. Thirty-two children aged between 2 and 18 years were seen in the pediatric otologic diagnostic clinic; 46 adults and children aged between 16 months and 76 years were seen in the family practice clinic.

Middle ear evaluations using pure tone air- and bone-conduction audiometry, acoustic immittance measurements (tympanometry and acoustic reflexes), and acoustic reflectometry measurements were performed by three certified audiologists and a graduate student under an audiologist's supervision.

The acoustic reflectometer (Endeco Acoustic Otoscope*) emits an 80-dB sound pressure level probe signal that varies rapidly in frequency from 2 kHz to 4.5 kHz. The reflectometer is placed in the ear canal with the tip completely covering the canal opening and directed toward the tympanic membrane. Concurrently, the ear canal is straightened and the reflectometer adjusted. The largest number illuminated during this manipulation is taken as the reflectivity value from the horizontal interval scale. This procedure was performed on each subject by two different testers. The time between repeated measurements varied between 15 and 30 minutes.

For the purposes of this study, fail criteria involved only the reflectivity measurements. Previously, the breakpoint of 0 to 4 pass and 5 to 9 fail had been found[4] to yield the best sensitivity and specificity values. This breakpoint and three other breakpoints were evaluated, 0 to 3 pass and 4 to 9 fail; 0 to 3 pass, 4 to 5 retest, 6 to 9 fail; 0 to 5 pass and 6 to 9 fail.

Acoustic immittance measurements were made with an immittance meter (Teledyne TA-4D) and included tympanometry and acoustic reflex. Criteria for pass or fail were negative pressure values greater than 150 mm H_2O and no reflex at 100-dB hearing level at 1,000 Hz.[7]

Portable audiometers (Beltone 10-D and Beltone 110) were used to obtain pure tone audiometric results using the Carhart-Jerger procedure.[8,9] An air-bone gap of 10 dB or greater was defined as a conductive loss. Air- and bone-conduction results greater than 20 dB with no apparent gap between thresholds were defined as a sensorineural hearing loss.

Examination procedures for the pediatric otologic diagnostic clinic included case history, pneumatic otoscopy (observation of the tympanic membrane movement), and when indicated, cerumen removal for visualization of the tympanic membrane. Diagnoses of otitis media with middle ear effusion, perforation, or retraction were considered fail. Diagnoses of tympanosclerosis, partial occlusion, or patent ventilation tube in the tympanic membrane were considered pass. In all cases audiologic testing preceded the examination by the board-certified otolaryngologist.

Examination procedures for the family practice clinic followed the same protocol as above with the following three exceptions: (1) Subjects were seen by the physician prior to seeing the audiologists; therefore, cerumen removal occurred prior to testing. (2) The physicians employed were residents whose assessments were each confirmed by a board-certified family practice preceptor. (3) The physicians utilized a form for describing the condition of the tympanic membrane: normal, retracted, inflamed, fluid filled, compliant (normal, slight, none), and tubes.

RESULTS

RELIABILITY

Test-retest reliability (Pearson-product moment correlation coefficient) for reflectivity was $r = .67$ and length was $r = .64$. A t test for related measures[10] indicated no significant differences ($t = 1.35$) between reflectivity readings made by two testers. Mean difference between the two readings was 0.158 with a standard error of 0.117. Reliability for individual cases was examined to evaluate the agreement between the first screening and rescreening with the acoustic reflectometer using both length and reflectivity units (Table 1). Reflectivity unit agreement +/− 1 unit was 73 percent, +/− 2 units was 89 percent. Length unit agreement +/− 1 unit was 79 percent; +/− 2 units was 83 percent. In most cases (89 percent) a change of one or two reflectivity units would not have changed the diagnostic category. Categorical changes would have occurred only 20 percent of the time when reflectivity readings were at the breakpoint, for example, between 4 and 5.

Further data analysis was confined to cases of otitis media with middle ear effusion, and only reflectivity readings were used.

SENSITIVITY AND SPECIFICITY

An analysis of variance was performed to determine whether differences existed between the two clinical

*The Acoustic Otoscope is manufactured by Endeco Medical, Inc, 13 Atlantis Drive, Marion, MA 02738.

TABLE 1. SCREENING AND RESCREENING PERCENTAGE OF AGREEMENT FOR REFLECTIVITY AND LENGTH UNITS FOR ACOUSTIC REFLECTOMETER

Unit Difference	Reflectivity No. (%)	Length No. (%)
0	36 (27)	83 (63)
1	61 (46)	21 (16)
2	21 (16)	05(04)
3	11 (08)	06(05)
4	03 (02)	08 (06)
5		05 (04)
6		03 (02)
7		03 (02)
8		00 (00)
9		01 (01)

TABLE 3. SENSITIVITY AND SPECIFICITY RATES FOR ACOUSTIC REFLECTOMETER, USING FOUR DIFFERENT BREAKPOINTS, RELATIVE TO STANDARD ACOUSTIC IMMITTANCE

Breakpoint	Sensitivity (%)	Specificity (%)	No.
0-3 pass; 4-9 fail	66.0	51.9	148
0-3 pass; 6-9 fail*	60.6	87.1	64
0-4 pass; 5-9 fail	48.9	79.6	148
0-5 pass; 6-9 fail	33.0	92.6	148

**4 and 5 were omitted and counted as retest*

groups (family practice clinic and pediatric otologic clinic) for reflectometry. The analysis of variance indicated that there were no significant differences between the pediatric otologic clinic and the family practice clinic on the basis of reflectometry ($F/154 = .21$, $P = .64$). As no significant differences existed between the groups, data were combined for further analysis.

As the middle ear condition cannot be ascertained clinically with absolute certainty, the relative accuracy of the acoustic reflectometer was determined by comparing it with accepted standard clinical procedures (visualization of the tympanic membrane and visible middle ear structures as well as tympanic membrane mobility) and instruments (pure tone audiometry and acoustic immittance).

Acoustic reflectometry measurements were first compared with the standard pure tone audiometry measurements. The various reflectometer breakpoint comparisons are shown in Table 2. The breakpoint of 0 to 4 pass and 5 to 9 fail yielded the best sensitivity and specificity combination. Agreement rates were further improved with the omission of the 4 to 5 numbers, which lie on the boundary between the pass or fail categories.

Comparisons for sensitivity and specificity were

TABLE 2. SENSITIVITY AND SPECIFICITY FOR ACOUSTIC REFLECTOMETER, USING FOUR DIFFERENT BREAKPOINTS, RELATIVE TO STANDARD PURE TONE AUDIOMETRY

Breakpoint	Sensitivity (%)	Specificity (%)	No.
0-3 pass; 4-9 fail	75.0	52.3	140
0-3 pass; 6-9 fail*	68.3	86.8	94
0-4 pass; 5-9 fail	69.2	78.4	140
0-5 pass; 6-9 fail	58.8	92.0	140

**4 and 5 counted as retest and were omitted from analysis*

made between acoustic immittance measurements and the acoustic reflectometer. Acoustic immittance measurements were taken as the standard for comparison of the sensitivity and specificity values for four different breakpoints (Table 3). For the breakpoint of 0 to 3 pass and 4 to 9 fail, immittance and reflectometry agreed 51.9 percent of the time with nondiseased ears; they agreed 66.0 percent of the time on the diseased ears. If, however, a separate categorization of retest was used for the borderline results (4 and 5), the sensitivity and specificity rates improved. For this case the 0 to 3 pass and 6 to 9 fail breakpoint was most efficient.

Finally the acoustic reflectometer was compared with the standard physician assessment. The best sensitivity and specificity agreement was seen (Table 4) between the breakpoints of 0 to 4 pass and 5 to 9 fail. Specificity agreement was 71.2 percent and sensitivity agreement was 60.7 percent. Again, if the borderline values are omitted, or considered as retest, the sensitivity and specificity rates improved to 63.1 percent and 77.3 percent.

Using immittance and pure tone instruments as standards, results were next compared with the physician assessment. The agreement was 73.3 percent specificity, 50.6 percent sensitivity for immittance, 73.3 percent specificity, and 69.2 percent sensitivity for pure tone (Table 5).

DISCUSSION

The acoustic reflectometer appears to be a reliable instrument. For the majority (89 percent) of the middle ear cases, including all types of pathology, the repeat measurements by a second tester did not vary by more than one or two units from the first measurement. For most of the assessments (85 percent), a change of one or two units would not shift an ear from a pass to a fail position upon retest. The precision of the instrument might be enhanced, however, by the addition of a retest or questionable category. Those measurements that fell on the borderline between pass and fail (4 to 5)

TABLE 4. SENSITIVITY AND SPECIFICITY RATES FOR STANDARD ACOUSTIC REFLECTOMETER, USING FOUR DIFFERENT BREAKPOINTS, RELATIVE TO MEDICAL DIAGNOSIS

Breakpoint	Sensitivity (%)	Specificity (%)	No.
0-3 pass; 4-9 fail	75.0	46.6	127
0-3 pass; 6-9 fail*	63.2	77.3	81
0-4 pass; 5-9 fail	60.7	71.2	127
0-5 pass; 6-9 fail	42.9	86.3	127

**4 and 5 were omitted and counted as retest*

TABLE 5. SENSITIVITY AND SPECIFICITY RATES FOR STANDARD PURE TONE AIR- AND BONE-CONDUCTION AUDIOMETRY AND STANDARD ACOUSTIC IMMITTANCE RELATIVE TO MEDICAL DIAGNOSIS

Standard	Sensitivity (%)	Specificity (%)	No.
Pure tone*	69.2	73.3	127
Immittance**	50.6	73.3	135

**Only conductive and mixed losses were evaluated*
***Pressure peak and acoustic reflex were evaluated*

could be considered questionable and retested within one week.

The accuracy of the instrument when used to identify only cases of middle ear effusion appears to be as good as that of standard clinical instruments when using the breakpoint of 0 to 4 pass, 5 to 9 fail. The acoustic reflectometer sensitivity and specificity rates of 60.7 percent and 71.2 percent compare favorably with pure tone (69.2 percent sensitivity and 73.3 percent specificity) and immittance (50.6 percent sensitivity and 73.3 percent specificity). The reflectometry sensitivity rates can be increased by the use of breakpoint 0 to 3 pass, 4 to 5 retest (omitted in analysis), and 6 to 9 fail.

Results were based on four indirect measures of middle ear function. Direct measures of the presence of middle ear fluid or bacteria involve an invasive activity that cannot ethically be performed except for treatment. Although using indirect measures may not be totally satisfactory, it is preferable to completely ignoring the issue.

Comparison of the medical assessment of the ear to any of the three instruments indicates some area of disagreement. This disagreement between otologic examination and immittance is not unusual.[11] When evaluating ears identified as having middle ear effusion, immittance audiometry has been found to be extremely sensitive,[12,13] but it also appears to generate high overreferral rates, sending to physicians those persons whose ear condition was deemed not to need treatment. ". . . Controversies exist in the medical community as to what constitutes treatable middle-ear disease and how medical management should be conducted . . .."[7] Additionally, some researchers[14] have found that immittance audiometry detects the presence of the middle ear disease before otologic or audiologic manifestations are apparent. Hence, it is not surprising that there is not better agreement between immittance and otoscopy.

Pure tone audiometry has been found not to be so sensitive to middle ear effusion as immittance audiometry, but it does provide other essential information about hearing sensitivity.

Even though difficulties exist concerning referral for abnormal results, it appears that the acoustic reflectometer does perform as well as other clinical instruments for cases of middle ear effusion. To achieve the best balance between the sensitivity and specificity rates, the acoustic reflectometer should be used in conjunction with pneumatic otoscopy. This combination would provide several advantages:

1. It would help the physician identify middle ear effusion that might not be visible otoscopically.
2. It could be used on very young, uncooperative patients as well as older patients. (Generalizability of the results from this study to children under 16 months of age cannot be made; others[1] have reported results for younger infants.)
3. It is a convenient and rapid means of evaluating the middle ear for effusion.
4. It does not require a behavioral response from the patient.

It should be cautioned that the reflectometer does not perform well as a general screening tool geared toward identifying middle ear disorders in children and adults,[4] nor is it effective in separating those disorders into categories. Its most effective use is as a supplemental tool to pneumatic otoscopy in the detection of middle ear effusion.

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