



Use of Wideband Acoustic Immittance in Neonates and Infants

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ABSTRACT

With widespread agreement on the importance of early identification of hearing loss, universal newborn hearing screening (UNHS) has become the standard of care in several countries. Despite advancements in screening technology, UNHS and early hearing detection and intervention programs continue to be burdened by high referral rates of false-positive cases due to temporary obstruction of sound in the outer/middle ear at birth. A sensitive adjunct test of middle ear at the time of screening would aid in the interpretation of screening outcomes, minimize unnecessary rescreens, and prioritize referral to diagnostic assessment for infants with permanent congenital hearing loss. Determination of middle ear status is also an important aspect of diagnostic assessment in infants. Standard single-frequency tympanometry used to determine middle ear status in infants is neither efficient nor accurate in newborns and young infants. A growing body of research has demonstrated the utility of wideband acoustic immittance (WAI) testing in both screening and diagnostic settings. Wideband power absorbance (WBA), a WAI measure, has been shown to be more sensitive than tympanometry in the assessment of outer/middle ear function in newborns. Furthermore, age-graded norms also support successful application of WBA in young

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Assessment of Middle Ear Function Using Wideband Acoustic Immittance: Current Practices and Future Prospects; Guest Editor, Hammam AlMakadma, Ph.D., Au.D. *Semin Hear* 2023;44:29–45. © 2023. The Author(s).

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Thieme Medical Publishers, Inc., 333 Seventh Avenue, 18th Floor, New York, NY 10001, USA
DOI: <https://doi.org/10.1055/s-0043-1764200>.
ISSN 0734-0451.

infants. Despite its merits, uptake of this technology is low among pediatric audiologists and hearing screening health workers. This report describes normative data, methods for assessment and interpretation of WBA, test–retest variations, and other factors pertinent to clinical use of WAI in newborns and infants. Clinical cases illustrate the use of WAI testing in newborn and infant hearing assessment.

KEYWORDS: Universal Newborn Hearing Screening, wideband acoustic immittance, conductive hearing loss, wideband power absorbance

THE IMPACT OF TEMPORARY CONDUCTIVE DYSFUNCTION AT BIRTH ON EARLY HEARING DETECTION AND INTERVENTION

Universal newborn hearing screening (UNHS) is adopted internationally as the standard-of-care for early detection of permanent congenital hearing loss.¹ In the United States, approximately 95 to 98% of all newborns nationwide receive UNHS in hospital inpatient settings as part of early hearing detection and intervention (EHDI) programs.^{2–4} In accordance with the Joint Committee on Infant Hearing (JCIH) 1–3–6 guidelines, timely diagnosis and intervention of permanent congenital hearing loss is achieved when hearing loss is identified by 1 month of age, fully diagnosed by 3 months of age, and infants are enrolled in intervention services by 6 months of age.³ Evidence shows that infants with congenital hearing loss who are identified by UNHS programs, and who receive timely intervention have better language development outcomes than their counterparts who are not identified by UNHS programs, or are late-to-diagnose (later than 6 months of age).^{5,6} Unfortunately, loss-to-follow-up, loss-to-documentation, and other sources of inefficiency result in late diagnosis/intervention for many infants. Nation-wide reports show that among infants who were identified to have a hearing loss, only 67.3% were documented to receive intervention by 6 months of age.⁴

Temporary conductive hearing loss at birth is a common occurrence among newborns who fail their hospital-based screening tests,^{7–9} and a compounding factor that contributes to the inefficiencies in UNHS outcomes and EHDI

programs in general. Conductive hearing loss in newborns is predominantly a result of non-pathological, naturally occurring events (e.g., ear canal vernix) and residual tissue in the middle ear cavity (e.g., embryonic/mesenchyme tissue) that obstruct the sound conduction at birth. Although these obstructions are transient in nature, they persist in newborn ears by considerable proportions up to 3 days after birth.^{10,11} This duration is long enough to impact the outcomes of hearing screening tests, which are performed prior to hospital discharge, typically within the first 48 hours of age.

The fail rate on hospital-based screening tests has been reported as high as 6.5%.¹² However, a high proportion of infants who fail (nearly 78–96%) reportedly pass their outpatient follow-up screening at 2 weeks to 1 month of age.^{12–15} Since EHDI programs target permanent congenital hearing loss, failure on hospital-based screenings due to temporary conductive hearing loss is considered a false-positive outcome. Because of the high proportions of false-positive outcomes, UNHS and EHDI programs are burdened with the task of indiscriminately rescreening and tracking all newborns that fail their screening, either on a second day prior to hospital discharge and/or 2 weeks to 1 month later in outpatient settings. A quick assessment of sound conduction at the time of the initial screening (e.g., using immittance tests) can guide informed decision-making to either rescreen (when conductive hearing loss is present) or to prioritize a direct referral to diagnostic evaluation (when sound conduction is normal). This will result in a reduction of unnecessary

hospital-based and outpatient rescreens, and consequently a mitigation of other associated inefficiencies (e.g., loss-to-follow-up).

IMMITTANCE TESTING IN NEWBORNS AND INFANTS

Traditional tympanometry with a probe tone of 226 Hz has been found to be inaccurate in identifying middle ear dysfunction in young infants below 7 months of age.^{16–18} For this reason, both ASHA (2004) and JCIH (2017) recommend use of high-frequency tympanometry (HFT) with a probe tone of 1,000 Hz in infants from birth up to 6 months of age. There are several methods for classification of HFT such as (1) simple visual classification system based on the tympanogram shapes in which presence of a peak or notching is indicative of normal middle ear function, and a flat or sloping tympanogram is suggestive of middle ear dysfunction^{19,20}; (2) shape classification system based on identifying positive or negative peaks relative to a baseline between +200 and –400 daPa^{21,22}; and (3) Vanhuysse model with four patterns of tympanograms.^{23,24} Although there is no universal agreement on normative HFT measurements, several studies have reported a combination of qualitative (trace description) and quantitative measures (e.g., peak compensated static admittance and tympanic width) to be used for middle ear assessment in infants.^{19,25,26}

Nevertheless, routine adoption of HFT in infants has been hindered by several issues such as lack of unanimous agreement on either the tympanometric shape classification or the optimal test parameter for assessing middle ear function in infants and limited data on correlation of HFT results with medically diagnosed middle ear pathology.²⁷ Furthermore, the significance of using peak compensated admittance, tympanometric peak pressure (TPP), and tympanometric width to assess middle ear function in infants has not been clearly demonstrated. Hence, there is a need for an alternative tool that permits accurate determination of outer and middle ear status. In recent years, wideband absorbance (WBA) test has been shown to be sensitive to middle ear dysfunction in neonates.^{28–31}

ANALYSIS AND INTERPRETATION OF WBA

Wideband Power Absorbance in Normal Ears

Normal measurements in newborns are well understood and have been described in several studies both in terms of power absorbance and reflectance.^{28,29,31–36} The normal newborn WBA is characterized by a large and broad absorbance peak roughly in the 1,100- to 2,200-Hz range with an absorbance value > 0.6 ³⁷; a secondary absorbance peak is also observed at frequencies $> 4,000$ Hz; and in newborns and infants younger than 3 months of age, a smaller absorbance peak at frequencies < 500 Hz is associated with resonant vibrations of the immature cartilaginous ear canal wall (described in Keefe et al).³³

To aid in the assessment of normal WBA measurements, multiple studies reported normative reflectance/absorbance range as a function of frequency in newborn ears that pass automated auditory brainstem response (AABR) and/or otoacoustic emission (OAE) tests. The normative ranges are typically constructed by determining the 10th percentile (lower bound of normal), and 90th percentile (higher bound of normal) values from a group of healthy newborns/infants with an assumed absence of outer/middle ear pathologies. The 10th and 90th percentile values are then plotted across frequencies producing a normative area on the plot. When a WBA measurement falls predominantly within the bounds of the normative area, one may infer a normal sound conduction in the outer/middle ear.

To illustrate the use of normative WBA area, a subset of the data that were previously described by AlMakadma and Prieve³⁸ were used for the construction of normative WBA area plots. The 10th and 90th percentile values were computed using 532 WBA repeated measurements from 84 newborn ears with normal hearing, indicated by transient-evoked OAE (TEOAE) hearing screening tests. Fig. 1A illustrates the resulting 10th to 90th percentile area of normal WBA, indicated by the grey shading across frequencies in the left panel. An example of a normal WBA measurement is shown by the dark blue solid line inside the

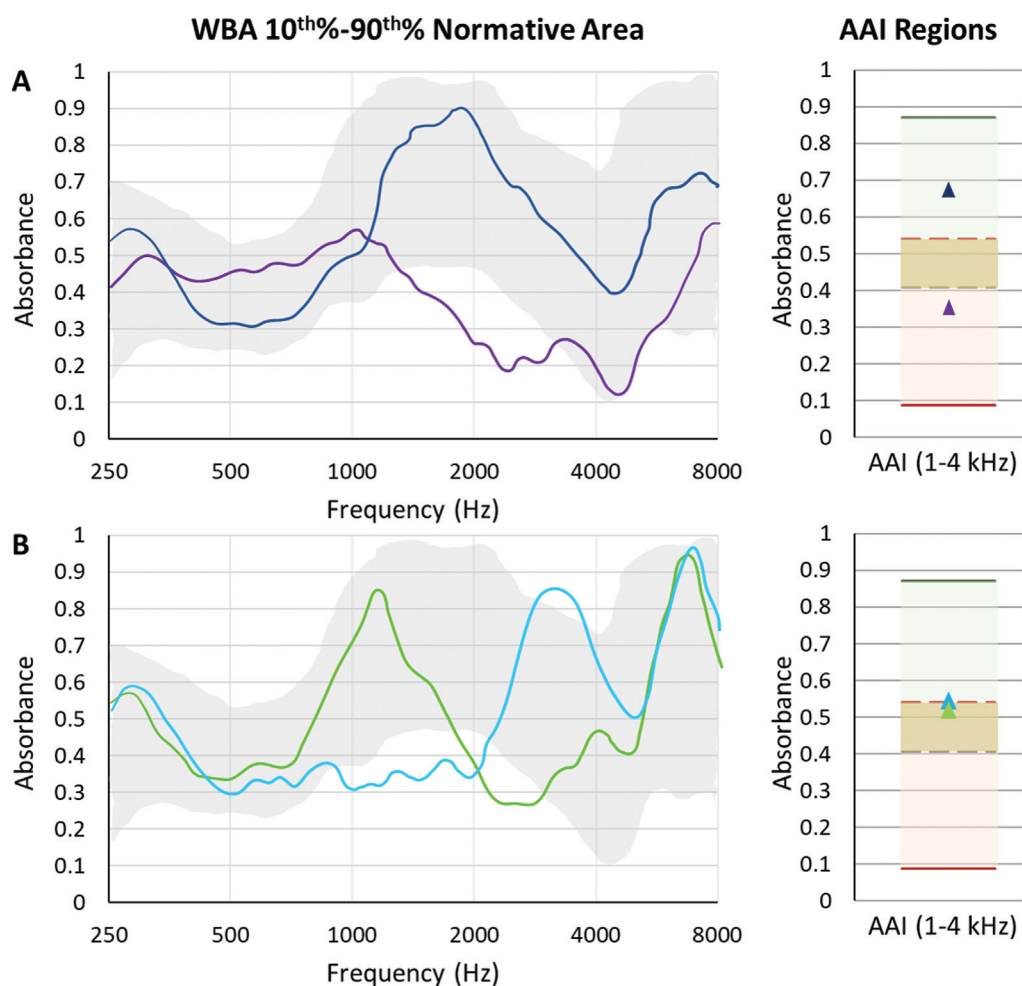


Figure 1 Assessment of wideband absorbance (WBA) using the 10th to 90th percentile normative ranges across frequencies, shown by the grey-shaded area in left column, and using the absorbance area index (AAI) regions shown in the right column. The AAI has a region for normal (top green-shaded area), a region of ambiguous classification (middle region delineated by the two horizontal dashed lines), and a region of abnormal (bottom pink-shaded area). (A) A normal WBA measurement (dark blue line) is shown in the left panel, and its corresponding AAI (dark blue-filled triangle) in the right panel. As well, an abnormal WBA (solid purple line) and its corresponding AAI (purple-filled triangle). The two measurements illustrate cases of clearly normal and clearly abnormal WBA and corresponding AAIs. (B) Two abnormal WBA measurements (light blue and green solid lines) and their corresponding AAI (light-blue-filled and green-filled triangles). Both AAIs fall within the region of ambiguity. Qualitative assessment of WBA patterns across frequency is necessary to make inferences about the nature of abnormality: a low-frequency shift of the major absorbance peak with abnormally reduced absorbance at higher frequencies indicates abnormal increase in mass (e.g., WBA in the green line), and a high-frequency peak shift with abnormally reduced absorbance at lower frequencies indicates abnormal increase in stiffness (e.g., WBA in the light blue line).

shaded area, falling entirely within the normal range across all frequencies. Features of normal WBA are observed in this example; that is, a major absorbance peak at 1,200 to 1,900 Hz, a secondary high-frequency peak at 7,000 to 8,000 Hz, and a small peak at approximately 300 Hz.

Assessment of Abnormal WBA Measurements

Dysfunction in the outer/middle ear due to temporary obstructions affects absorbance depending on the severity and type of dysfunction. Measurements exhibiting absorbance with reduced values below the 10th percentile of normal at most

frequencies are clear cases of abnormal sound conduction. Large reduction in the major absorbance peak in the mid-frequencies, below the 10th percentile of normal, is another clear indication of abnormal sound conduction. The solid purple line in the left panel of Fig. 1A illustrates this type of clearly abnormal absorbance.

However, because absorbance measurements can be sensitive to subtle changes in sound conduction, closer examination of the characteristics of absorbance pattern across frequency is often necessary during their evaluation. For example, the major (mid-frequency) absorbance peak may be shifted to higher or lower frequencies resulting in some absorbance values to be outside of the normal area at some frequencies but not others. The interpretive paradigm presented in the opening article of this edition (AlMakadma, Kei et al) is useful for making inferences about abnormal changes in mass- or stiffness-reactance. The left panel of Fig. 1B illustrates an absorbance measurement shown by the green solid line, where the principal absorbance peak is shifted to lower frequencies with reduction in absorbance values below the area of normal at higher frequencies. This pattern is consistent with increased mass loading, which can be associated with residual mesenchyme in the middle ear cavity.³⁹ A second example in this figure, as shown by the blue solid line, illustrates the opposite scenario where the absorbance peak is shifted to a higher frequency, and absorbance is reduced below normal at lower frequencies. This pattern is consistent with increased stiffness.

Absorbance Area Index

To simplify the assessment of WBA measurements, Hunter et al²⁹ proposed the use of *reflectance area index (RAI)*. Put simply, RAI is the average of power reflectance measurement across some frequency interval. Findings from Hunter et al show RAIs that were computed over the range of 1,000- to 2,000-Hz or 1,000- to 4,000-Hz intervals resulted in the most accurate test outcomes (determined by large areas under the receiver operating characteristic curve values of 0.9 for both RAIs). In this article, we have adapted the normative RAI region that were reported by Hunter et al and recomputed the equivalent *absorbance area index (AAI)* over

the 1,000- to 4,000-Hz interval. The right panels in Fig. 1 illustrate the normative region of AAI (1–4 kHz), showing the abnormal region in the transparent pink shade, between minimal AAI value (indicated by the solid red line) and the 90th percentile AAI value of abnormal (indicated by the dashed red line). As well, the region of normal is shown by the transparent green shade, bound between the 10th percentile AAI value of normal (indicated by the dashed green line) and the maximum AAI value (shown by the solid green line). An area of overlap between the normal and abnormal region (between the two dashed lines) indicates a region of ambiguity, where AAI values cannot be assessed conclusively as normal or abnormal.

To demonstrate the use of AAI, the two WBA measurements in the left panel of Fig. 1A were averaged between 1,000 and 4,000 Hz and the resulting AAI values were assessed using the AAI normative region in the right panel. The AAI value from the normal measurement is represented by the blue triangle symbol, and falls above the 90th percentile of abnormal, clearly within the normal region. By comparison, the AAI value from the abnormal measurement is represented by the purple triangle symbol, and falls below the 10th percentile of normal, clearly within the abnormal region. Additional examples from Fig. 1B illustrate AAI values (in the right panel) that correspond to the two WBA measurements (shown in left panel); blue- and green-triangle symbols represent AAI values that correspond to the WBA measurements that are shown by the solid lines in matching colors. Both AAI values fall within the region of ambiguity. Therefore, in such cases, assessment of AAI cannot determine whether alteration in sound conduction is sufficiently associated with passing or failing the newborn screening tests, respectively. Rather, a qualitative assessment in conjunction with the normative WBA area is recommended as described in the previous section.

USE OF ABSORBANCE OUTCOMES IN THE CONTEXT OF NEWBORN HEARING SCREENING

Temporary obstruction of newborn ear canals and reduced mobility of the tympanic

membrane are responsible for a large proportion of fail outcomes on OAE and AABR screening tests.^{7,8} Current practices in UNHS and EHDI programs are to rescreen all newborns who fail their screening tests. Rescreening is typically conducted on the following day or two prior to hospital discharge, and if newborns continue to fail the screening, at a follow-up outpatient visit 2 to 4 weeks later. Others refer to outpatient rescreening directly. The objective of repeated rescreen tests is to identify true positive cases, after a presumed temporary conductive hearing loss is expected to have resolved (e.g., typically 78–96% of infants pass when rescreened at outpatient visits).^{12,14} This approach is inefficient and costly, with valuable resources spent on supplies and labor, and considerable proportions of infants targeted for rescreening being lost to follow-up/documentation.

In this section, we present a model for use of wideband acoustic immittance (WAI) test outcomes in conjunction with screening outcomes to discern whether failure on OAE/AABR tests is associated with a conductive dysfunction or not. Rather than presuming temporary conductive dysfunction and rescreening all newborns indiscriminately, assessment of sound conduction in outer/middle ears will aid in making informed referrals for rescreening, or prioritization of newborns with true positive outcomes for diagnostic evaluation without the need for rescreening. Furthermore, supplementation of screening tests with WAI tests has the added benefit of mitigating parental anxiety through improved counseling when their newborns fail the screening.

Table 1 provides a summary of recommendation-making matrix using hearing screening and WAI test outcomes. According to this model, newborns who fail their OAE or

AABR tests and have normal WBA outcomes should be prioritized for diagnostic evaluation. Fig. 2A illustrates a case example of failed TEOAE and normal WBA. For such cases, it is assumed that sound conduction is normal in the outer/middle ear, and failure on OAE/ABR is likely due to permanent congenital hearing loss, which is the prime target of EHDI programs. Therefore, speedy identification within the first 2 days of life and avoiding unnecessary referral for outpatient rescreening will minimize the probability of loss-to-follow-up, and improve the rate of early diagnosis. For newborns who fail OAE or AABR tests in association with abnormal WBA outcomes, rescreening according to existing protocols is warranted. Fig. 2B illustrates a case example for this combination of outcomes. Upon rescreening, WBA is expected to demonstrate signs of improved sound conduction which may result in a pass outcome on screening tests as AABR and/or OAE responses improve. Alternatively, if WBA improves upon rescreening, but newborns continue to fail their screening tests (e.g., similar to Fig. 1A), then a direct referral to diagnostic evaluation is recommended. If the rescreening was performed on a second day prior to discharge, a direct referral to diagnostic evaluation achieves the aforementioned benefits of avoiding unnecessary outpatient rescreens.

Table 1 also lists recommendations for ears that pass the hearing screening test. For newborns who pass their AABR or OAE screening and have no risk factors for hearing loss, they do not require further follow-up assessments as they are expected to have normal hearing. Fig. 2C illustrates a case example of a newborn with normal WBA and robust TEOAEs. However, it is important to note that for high-risk newborns who pass their hearing screening,

Table 1 Decision matrix showing recommendations contingent on screening and WAI test outcomes

Screening test outcomes	WAI test outcomes	Recommendations
AABR/OAE (fail)	Normal WBA	Prioritize for diagnostics
AABR/OAE (fail)	Abnormal WBA	Rescreen after a few days
AABR/OAE (pass)	Normal WBA	Discharge/targeted surveillance ^a
AABR/OAE (pass)	Abnormal WBA	Discharge/targeted surveillance ^a

Abbreviations: AABR, automated auditory brainstem response; OAE, otoacoustic emission; WAI, wideband acoustic immittance; WBA, wideband absorbance.

^aFor high-risk infants in accordance with existing guidelines.

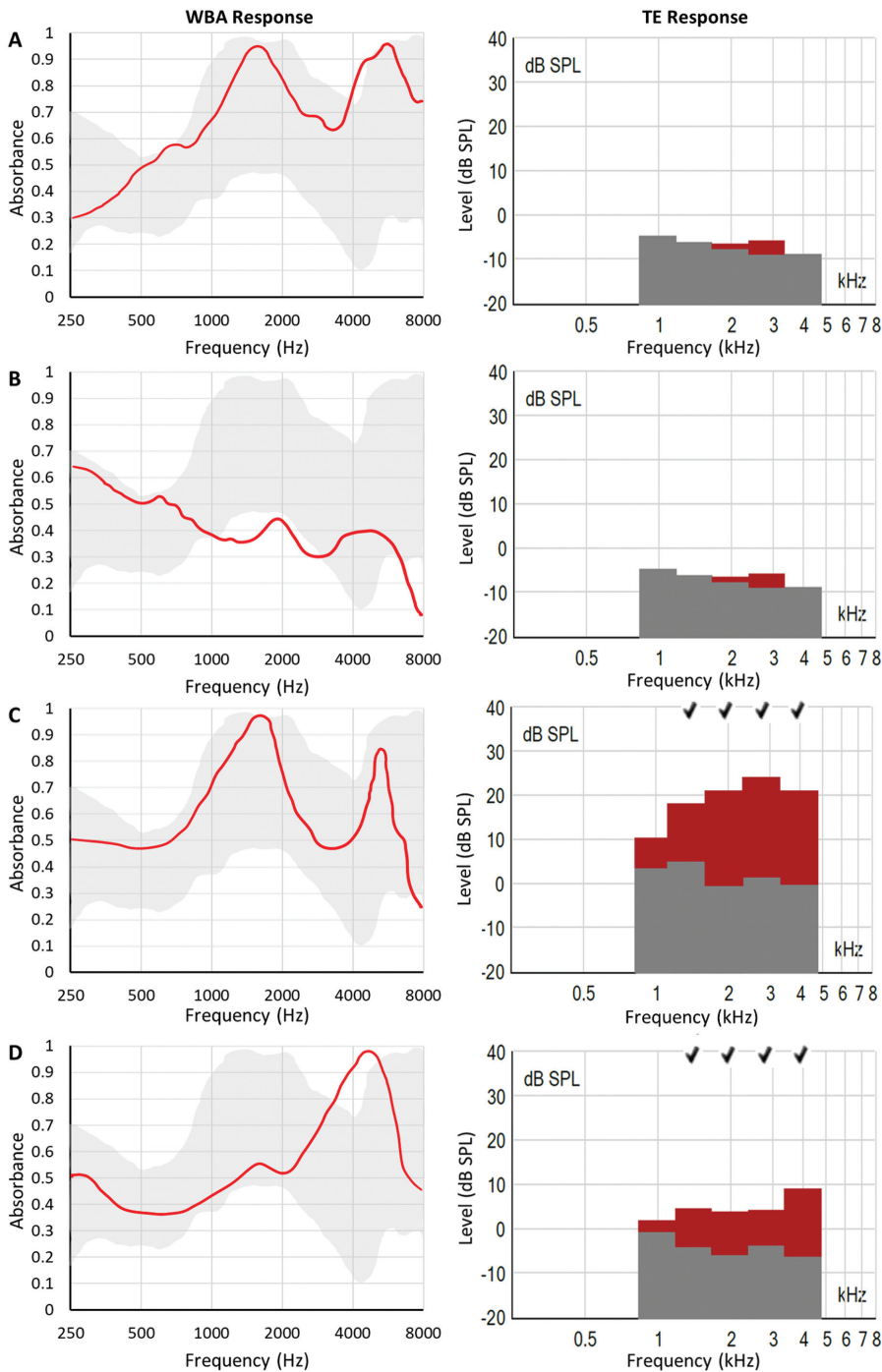


Figure 2 Interpretation of newborn hearing screening outcomes, based on TEOAE signal-to-noise ratio (shown in the right column) in conjunction with WBA measurements (shown in the left column) at birth. (A) Failed TEOAE screening along with normal WBA at birth is indicative of sensorineural hearing loss. (B) Failed TEOAE screening along with abnormal WBA is suggestive of obstruction of the sound conduction pathway. (C) Passed TEOAE screening and robust TE levels along with normal WBA indicative of normal hearing. (D) Passed TEOAE screening with slightly less robust levels and WBA pattern consistent with increased stiffness is indicative of residual obstructions in the sound conduction pathway.

they should be monitored for hearing through targeted surveillance, according to existing guidelines.³ Although newborns who pass their screening tests are expected to have grossly normal auditory function, it is possible in some cases for WBA to exhibit signs of mild conductive dysfunction that does not significantly diminish AABR or OAE recordings. Such cases may be more prevalent in ears that pass AABR testing, as AABR was shown to be less sensitive than OAE in the detection of milder levels of hearing loss.⁴⁰ An example of such case is illustrated in Fig. 2D. Note that despite passing TEOAE screening criteria, the TEOAE levels are less robust compared to Fig. 2C where WBA was completely normal.

POWER ABSORBANCE IN OLDER INFANTS

Developmental Trajectory of WBA

The outer and middle ears are not completely mature at birth and undergo developmental changes during infancy. As newborns mature, the tympanic cavity increases in volume,^{31,41} the shape and orientation of tympanic membrane change and its thickness decreases,^{42–44} the ossicular chain ossifies and increases in weight and size, and the ear canal changes orientation, and the medial portion of its wall ossifies. With such changes, newborns' mass-dominated middle ear system becomes increasingly stiffness-dominated from the age of 6 months and beyond. In association with such changes, WAI recordings, including power absorbance/reflection measurements, have been shown to change systematically with the course of development. For a more detailed account of the developmental course of WAI measurements, the reader is referred to the previous review of Kei et al.⁴⁵ In general, WBA measurements in healthy ears demonstrate a decrease in absorbance values below 1 kHz and above 4 kHz with an increase between 2 and 4 kHz.^{33,45–47} The most dramatic changes occur between birth and 6 months of age, with gradual changes toward a more adult-like pattern by 18 months of age.

Fig. 3 illustrates developmental trajectory of WBA in a single infant who was tested at birth (short-dashed blue line), at 6 months (long-

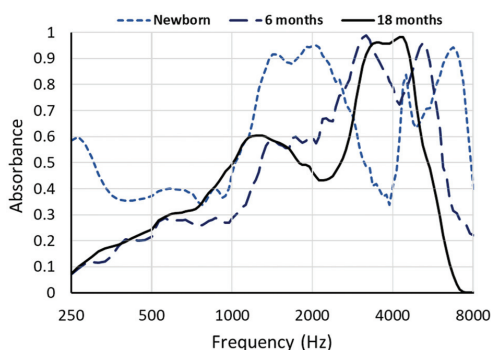


Figure 3 Longitudinal WBA measurement from an individual infant shown at birth (short-dashed line in light blue), at 6 months (long-dashed line in dark blue), and at 18 months of age (solid black line). A general trend of maturation-related increase in stiffness is indicated by a high-frequency shift of the major absorbance peak.

dashed blue line), and 18 months of age (solid black line). As the newborn matured, there was some decrease in absorbance in the low frequencies and the major absorbance peak shifted from 1,000 to 2,000 Hz region to higher frequencies at 6 months of age. The low-frequency peak at 250 Hz was present only at birth, indicating ossification of the ear canal wall was complete by 6 months of age.

A longitudinal study by Hunter et al⁴⁸ demonstrated that significant differences by age warranted the use of age-specific norms for newborns, 1 month, and 6 to 15 months. Use of age-appropriate norms allows clinicians to discern changes due to development and maturation from clinical changes (e.g., distinguishing increase in stiffness due to pathology vs. due to maturation). This is especially important whenever a clinician may follow the same pediatric patient over time. Therefore, when operating a WAI instrument, clinicians must be careful to select the age-appropriate norms to display on their screen.

Identification of Conductive Hearing Loss in Infants

Otitis media with effusion (OME), defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection,⁴⁹ is a common middle ear condition in infants and young children. OME in infants can lead to reduced hearing sensitivity and deficits in

speech and language development.^{50,51} Hence, it is important to regularly monitor young children with a history of middle ear dysfunction and hearing loss. Late detection of OME puts the affected infants at high risk for significant hearing loss that affects their language development and learning capability. Nevertheless, assessment of middle ear status can be challenging in this population as they are not always cooperative for otoscopy, tympanometry, and OAE testing. Hence, a fast and accurate test such as WBA would be very useful with these infants.

Studies have reported significantly reduced absorbance mainly between 800 and 4,000 Hz in ears with OME.^{32,52–54} As with newborns, infants who referred on OAE screening had significantly reduced WBA between 800 and 2,000 Hz than infants who passed OAE screening. Evaluation of WBA during diagnostic air- and bone-conduction ABR assessment of infants at approximately 3 months of age has also shown significantly reduced WBA between 800 and 2,500 Hz and at 6,300 Hz in the presence of significant air-bone gaps.⁵³ Thus, WBA has sufficient accuracy to be used in both hearing screening and diagnostic applications.

LOOSE PROBE-TIP FITTING AND ARTIFICIAL INCREASE IN ABSORBANCE

In order to ensure artifact-free measurements during WAI testing in newborns and infants, clinicians and/or hearing screening health workers must ensure proper fitting of the probe tips in the ear canals. This recommendation is especially important for testing in neonates and infants for the following reasons: First, achieving secure probe-tip fitting in narrow neonatal ear canals (diameters < 4 mm) can be challenging.³⁶ This is because the inserted portion of a small probe tip that is coupled to narrow ear canal openings must support the weight of the probe assembly and wiring. Second, because neonates and infants are not as compliant as adult patients, head movements will often result in slippage of the probe during testing.⁵⁵ In newborns, loose probe fitting has been associated with large artificial increase in absorbance at frequencies

< 1,000 Hz, and smaller but significant increases at frequencies between 1,000 and 6,000 Hz.³⁸ Such artificial increases may negatively impact clinical assessment of sound conduction; for example, a measurement with poor fitting maybe erroneously classified as normal due to artificially increased absorbance into the normal range, whereas in fact the sound conduction in the outer/middle ear may be abnormal.

Ensuring Secure Probe-Tip Fitting

The key to proper probe fitting is to ensure a snug probe-tip fitting and a stable probe assembly. The best way to get a hermetic seal from a quiet or sleeping neonate is firstly to turn the neonate's head sideways with the test ear facing up. The clinician may gently pull the neonate's pinna backward with one hand and insert the probe assembly with an appropriate tip downward into the entrance of the ear canal with the other hand. During the insertion, the clinician may extend a finger against the neonate's head to brace the probe which is then positioned to aim in the direction of the eardrum without obstruction. During the test, the clinician must hold the probe assembly steady without any movements. Alternatively, a hands-free method to stabilize the probe assembly is to secure it against the walls of the bassinet when the baby is not moving. If the placement of the probe is not correct, the absorbance results may show signs of loose probe fitting or in some cases the probe tip is blocked by the ear canal wall. When this happens, the clinician should refit the probe with careful attention to the placement and orientation to achieve optimal absorbance results.

Identifying Signs of Acoustic Leaks in WBA

There are several approaches that clinicians may take to assess the presence of leak-related artifacts in their measurements. One manufacturer-recommended approach for the HearID system (Mimosa Acoustics Inc.) is to monitor signal-to-noise ratio (SNR) during data collection.⁵⁶ The HearID's Middle Ear Analyzer (MEPA) module displays live measurements of sound pressure and noise floor spectra, as several responses are recorded and averaged. A refitting of the probe tip is recommended

if SNR levels do not improve in the low frequencies on suspicion of acoustic leaks. One limitation of this approach is that SNR levels at the low frequencies maybe compounded by other factors such as environmental noise or myogenic noise; both factors are commonly encountered in newborns and infants.⁵⁵ As a result, recordings with high levels of low-frequency noise may not exhibit the expected leak-related patterns of absorbance (i.e., inflated absorbance that decreases gradually from low to low-mid frequencies).⁵⁷ Rather, high levels of noise that are recorded in the ear canal are associated with rapid fluctuations in absorbance measurement across the low-frequency range, irrespective of whether high noise is related to loose-probe fitting and acoustic leaks or not.³² Another limitation of the SNR assessment approach is that other manufacturers do not display SNR recordings.

Another approach is to use criteria based on absorbance, and other WAI measures, in the low frequencies where leak-related changes are most obvious. Recent work by AlMakadma and Prieve³⁸ showed that changes in absorbance in association with loose probe fitting were best predicted by low-frequency absorbance and low-frequency impedance phase. They recommended that leak-related inflation in absorbance can be determined whenever absorbance average in the 250- to 1,000-Hz frequency interval is greater than 0.58 and impedance phase average in the 500- to 1,000-Hz interval is greater than -0.11 cycles. Fig. 4 illustrates the use of these criteria in the form of a template on the absorbance-frequency graph (panel A), and impedance phase-frequency graph (panel B). The boxes outlined in the solid red color show the values of absorbance and impedance phase that meet the criteria for poor/leaky probe fits, and the boxes outlined in solid green lines show the values that are typical of good probe-tip fitting. The figure illustrates five measurements that were obtained in the same newborn ear with repeated reinsertion of the probe tip. Two absorbance and corresponding impedance phase measurements (brown-colored solid lines) fall within the green-outlined boxes are examples of well-fitted probe tips, and the three measurements (shown in different degrees of blue-colored solid lines)

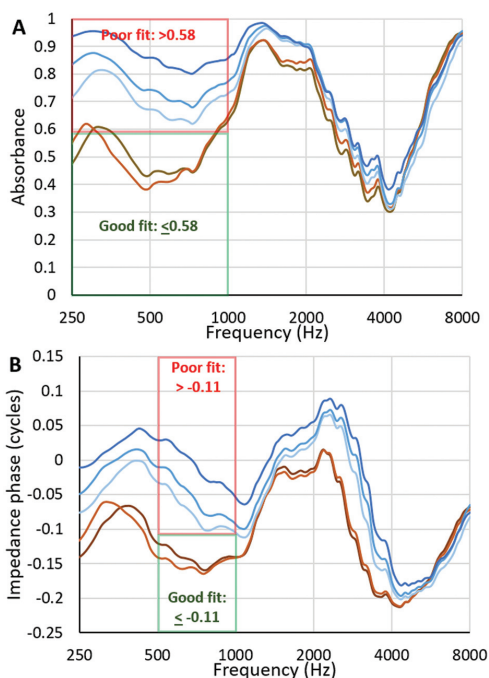


Figure 4 Graphical template for use of probe-fit criteria recommended by AlMakadma and Prieve⁵⁵ to determine whether a refitting of a loose probe fit is necessary based on low-frequency absorbance and low-frequency impedance phase. Five repeated WBA measurements from the same newborn ear with probe reinsertion are shown with three examples of a poor probe fit (shown by the solid lines in three shades of blue), and two examples of a good fit (shown by the solid lines in two shades of orange-brown). (A) The red-outlined box delineates values of low-frequency absorbance >0.58 that are due to suspected leaks, whereas the green-outlined box delineates values ≤ 0.58 to indicate good fits. (B) The red-outlined box delineates values of low-frequency impedance phase > -0.11 cycles that are due to suspected leaks, whereas the green-outlined box delineates values ≤ 0.11 cycles to indicate good fits.

that fall within the red-outlined boxes are examples of affected measurements due to poor/leaky probe fits. It should be noted that the criteria suggested by AlMakadma and Prieve³⁸ have been tested for ears with normal outer- and middle-ear sound conduction, and that efforts to validate the use of these criteria in ears with abnormal sound conduction are underway.

Knowledge of typical absorbance measurements in ears with or without conductive hearing loss, together with an understanding of the effect of acoustic leaks, will enable clinicians to assess their measurements of leak-related artifacts. In addition to the use of the earlier-

suggested approaches/guidelines, a replication of measurement with removal and refitting of the probe tip may provide assurance when in doubt. A “replicable” measurement should not vary more than the expected test–retest magnitude. High test–retest variation in low-frequency absorbance when acoustic leaks are present has been reported.^{32,38}

Effect of Collapsed Ear Canals on WBA Measurements

Because of immaturities in the ear canals of newborns, cartilaginous ear canals are prone to being collapsed in the first few hours after birth. Collapsed canals maybe spontaneous, or in association with tension from hunched shoulders. Partially or completely collapsed canals affect WBA measurements by increasing reflections from the lateral portion of the ear canal. Previous reports described the effect of collapsed canals on WAI measures in the presence of tympanometric pressure sweeps (i.e., wideband tympanometry).^{58,59} However, to the knowledge of the authors, no previous reports have described spontaneous collapsed in ambient measurement conditions. Fig. 5 shows examples of WBA when ear canals are collapsed and when they are not. Panel A shows an example of a collapsed canal that was induced

by introducing a negative pressure sweep in the ear canal. Using a research system (Titan MATLAB-operated research module) and a custom research software, first a measurement was obtained under an ambient condition resulting in normal WBA pattern (shown in the blue solid line). Next, without removing the probe, static pressure was swept from 0 to -400 daPa and the pump was released allowing pressure to go back to 0 daPa. Immediately following the pressure sweep, WBA was measured once more resulting in an abnormal measurement (shown in the orange solid line). The principal absorbance peak around 1,700 Hz and the low-frequency peak around 250 Hz diminished as a result, and instead a single broad peak appears with significantly decreased absorbance over the low-mid frequency range followed by negative absorbance values around 4,000 Hz. Negative absorbance values are often associated with errors in measurement related to acoustic termination⁶⁰ (e.g., collapsed canals or when probe tips are occluded). A third WBA measurement was obtained in the same ear canal following removal and reinsertion of the probe to allow recovery of the ear canal. This resulted in restoration of the normal WBA pattern, albeit with some reduction in the mid and low frequencies (shown by the black

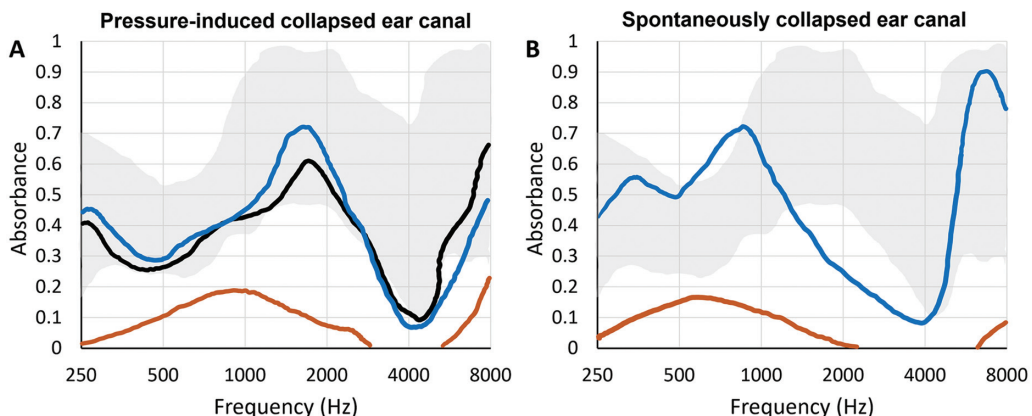


Figure 5 (A) Illustration of WBA measurement in a pressure-induced collapsed ear canal: WBA was measured first under an ambient pressure condition (shown in blue solid line) followed by a negative pressure sweep from 0 to -400 daPa that was released back to 0 daPa. Without probe removal, WBA was measured again showing a significantly different pattern (shown in the orange solid line), likely a result of sound reflections from the collapsed portion of the ear canal. Following probe removal and reinsertion, WBA was measured a third time showing a near-complete restoration of WBA (shown in the black solid line) indicating the ear canal was uncollapsed. (B) Example of WBA measurement in the presence of a spontaneously collapsed canal (shown by the orange solid line), and a second WBA measurement that was obtained with gentle pulling of the pinna to uncollapse the canal (shown by the solid blue line).

solid line). The change in WBA pattern observed with these procedures suggests that the WBA pattern obtained following the negative pressure sweep is due to collapsed ear canal walls. This pattern could also be observed spontaneously in some newborns without pressurization of the ear canal. An example of this is shown in Fig. 5B in the orange solid line. In this ear, it was difficult to obtain a normal WBA measurement with multiple probe reinsertions, until the pinna was gently pulled to open the ear canal resulting in the WBA pattern shown by the blue solid line.

The prevalence of spontaneously collapsed canals in newborns is not an irrelevant one, as indicated by preliminary findings from ongoing research efforts. Although this remains to be an active area of investigation, clinicians are advised to use the case examples provided here to identify WBA measurements that are affected by collapsed canals. The issue of collapsed canals in association with immaturities of the ear canal wall may result in temporary conductive hearing loss, leading to failure on OAE and AABR hearing screening tests.

TEST-RETEST IN NEWBORNS AND INFANTS

Absorbance/reflectance measurements with test-retest have been shown to have good reliability.^{32,61} Nevertheless, knowledge of the expected test-retest changes in WBA measurements is an important consideration for clinical tests. Without this knowledge, it is difficult to ascertain whether changes in repeat measurements are clinically remarkable, or simply due to variations that are inherent to test techniques or subject-related factors.^{38,52,55}

It is widely recognized that subject-related noise in the newborn and infant population is a major contributor to test-retest variability. Measurements in restless or crying babies are easily contaminated by high levels of noise or in association with acoustic leaks due to slippage of the probe.^{38,52,55} Therefore, it is important for clinicians to optimize test conditions to reduce contaminations and improve test-retest variability. This may be achieved by testing in quiet rooms (e.g., in screening settings), calming down the babies or testing them after they

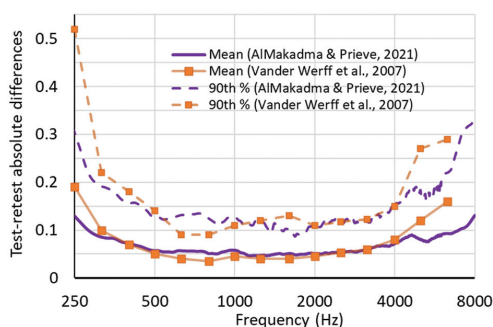


Figure 6 Mean and 90th percentile of test-retest difference magnitudes for newborns, shown by the solid and dashed purple line, respectively, and for infants, shown by the solid and dashed orange lines with interconnected squares symbols, respectively.

are fed and sleepy. This is in addition to ensuring proper probe-tip fitting using the methods suggested in the previous sections.

The magnitude of test-retest differences has been reported in a number of carefully conducted studies for newborns testing in hospital settings,³⁸ and in outpatient screening and diagnostic settings for older infants.⁵² Fig. 6 illustrates the magnitude of test-retest differences: For newborns younger than 48 hours of age, test-retest difference means and 90th percentile values are shown across frequency in solid and dashed purple lines, respectively. For infants who were tested at an average of 7.6 weeks of age in outpatient screening settings, test-retest difference means and 90th percentile values are shown across frequency by the orange square symbols which are interconnected by solid and dashed orange lines, respectively.

Clinicians or screening health workers often need to rescreen babies who fail their initial test. If the initial fail was due to abnormal WBA measurement, subsequent screenings may demonstrate an improvement in WBA measurement along with passing on OAE or AABR tests. However, more subtle changes in sound conduction may be measured instead (e.g., when testing on a second day). Such changes can be assessed as significant if they exceed the 90th percentile values of test-retest difference. Clinicians may conclude that sound conduction has improved. Otherwise, if changes in WBA are less than the 90th percentile values, they can be attributed to test-retest variability.

FUTURE DEVELOPMENTS AND RESEARCH

Wideband Tympanometry in Infants

WBA measured under pressurized conditions (wideband tympanometry [WBT]) provides information on acoustic properties of the middle ear across a broad range of frequencies and ear canal pressures. In some applications, WBT provides two-dimensional graphs comparing WBA at 0 daPa and at TPP. The advantage of testing WBA in the TPP is that it compensates for any differences in pressure between the ear canal and the middle ear. Thus, WBT is reported to be good indicator of middle ear function and effects of maturation.⁶³⁻⁶⁵ Research has shown WBT to be equally or more sensitive to middle ear dysfunction compared to WBA measured under ambient pressure conditions in children and adults.^{28,66-68} However, because tympanometric pressurization of immature ear canals is known to cause a volume change due to compliance of the ear canal walls, a factor that is known to influence acoustic measurements,^{33,69} the utility of WBT testing in newborns continues to be a subject of continued investigation.⁵⁸ WBT yields a large amount of data across frequency and pressure continuum. However, currently only qualitative profiles or pattern recognition strategies are used to interpret WBT data. Nevertheless, quantitative analysis techniques to classify middle ear as either normal or abnormal can augment visual classification approach.^{28,58,70} There is a need for identification of univariate key indicators that are sensitive for middle ear function. Studies have shown that WBA at ambient pressure is similar to WBA at TPP in infants from birth to 24 months.^{47,61,71} However, there are limited data on WBT in infants with middle ear dysfunction. Further research examining WBA and WBT in infants with middle ear disorders would provide useful information for the diagnosis of conductive conditions in infants.

WAI SCREENING INSTRUMENTS

Currently, there are two devices that offer WBA measurements to assess middle ear function in neonates and infants, in combination

with an OAE and/or AABR hearing screening tests: (1) The Titan system from Interacoustics (Denmark) and (2) the Otostat and the HearID systems from Mimosa Acoustics (Champaign, IL). There are several similarities between the two systems: (1) both are suitable for all populations including neonates and young infants; (2) both use broadband stimuli, and analyze responses over fairly similar frequency ranges. This is despite some differences in stimulus type, proprietary signal processing, and probe calibration techniques. (3) Both systems have age-appropriate normative data that the user may select to aid in the assessment and interpretation of normal middle ear function. (4) The user may conduct a combination of tests into one protocol; for example, the user may perform WBA testing and OAE hearing screening with a single probe insertion.³⁸

Main differences between the two WBA systems are (1) the Titan system requires a PC connection to perform WBA while Otostat system is PC independent and (2) both ambient WBA and wideband tympanometry can be performed with Titan, while only ambient WBA can be performed with the Mimosa system.

The question on whether using different systems yields consistent measurements has been the subject of attention by researchers.⁷² A comparison of WBA measurements within the same newborn ears using the Titan and HearID system revealed no significant systematic differences between the two systems; except for a 0.08 difference around 2,000 Hz, where Titan recorded systematically greater measurements than the HearID system.^{73,74} Although this difference is smaller in magnitude than test-retest differences, and hence is unlikely to impact clinical assessment, this nonetheless points to the need for standardization of calibration methods,⁷⁵ especially that systems from other manufacturers are likely to emerge in the future.

CONCLUSION

Routine assessment of sound conduction in the outer/middle ears of newborns and infants is expected to positively impact EHDI programs by mitigating inefficiencies in the standard

operation of the program. Interpreted alongside screening tests, clinicians will be able to discern whether newborns fail their screening due to a conductive or a sensorineural hearing loss. Although not yet adapted at a large scale, there are sufficient data and research to permit use of WAI in a clinical context. WAI testing is increasingly considered in authoritative guiding documents for EHDI programs (e.g. JCIH, 2019),⁷⁶ and is projected to be recommended as a standard-of-care test in the future pending further development and refinement. Therefore, clinicians are encouraged to adapt this technology, taking advantage of commercially available systems, to practice and apply concepts in WAI testing, assessment, and interpretation that have been presented in this resource.

CONFLICT OF INTEREST

None declared.

ACKNOWLEDGMENTS

Some of the data presented in this work were a part of a research project supported by the William Demant Foundation (Project Grant 20-0292) awarded to Hammam AlMakadma (PI). Some of the data presented in this article were a part of a research project supported by the Australian National Health and Medical Research Council (Project Grant APP1046477) awarded to Joseph Kei (PI), Sreedevi Aithal (AI), and Venkatesh Aithal (AI).

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