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Efficacy of 1000 Hz tympanometry in infants birth to 4 months of age: A follow up study

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EFFICACY OF 1000 Hz TYMPANOMETRY IN INFANTS BIRTH TO 4 MONTHS OF AGE: A FOLLOW UP STUDY

by

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Abstract:* *Interpretation of 1000 Hz tympanometry is not standardized. Several compensated and uncompensated measures were analyzed and compared to otologic findings. Results of auditory brainstem testing and otoacoustic emissions were considered to better obtain middle ear status. Findings were inconclusive due to small sample size.

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Literature Review

Universal newborn hearing screening (UNHS) is now standard of care in the United States. The current challenge of UNHS is to achieve appropriate follow-up care. The Joint Committee on Infant Hearing (JCIH) recommends that medical and audiologic diagnosis occur by three months of age. With respect to treatment, the JCIH recommends that "for families who elect amplification in infants whom permanent hearing loss is diagnosed should be fitted with an amplification device within 1 month of diagnosis (JCIH 2007)." If hearing loss is present in young infants, determining the type and severity of the loss to guide treatment is a significant challenge for both medical practitioners and audiologists. Knowing the type of loss is important because it can mean the difference between pursuing medical/surgical treatment (as in the case of otitis media) versus audiologic management with hearing aids and/or cochlear implants (as in the case of sensorineural loss).

With respect to otologic diagnosis, the instruments available for the medical specialist (e.g., nurse practitioner, otolaryngologist, otologist) to determine middle ear status are the pneumatic otoscope and the otomicroscope. The diagnostic worth of pneumatic otoscopy has been questioned, but it has a higher sensitivity than visual or static otoscopy, which does not allow a measurement of the mobility of the tympanic membrane (Bluestone & Cantekin, 1979; Bluestone & Klein, 1988). Melker (1993) evaluated the diagnostic value of pneumatic otoscopy using 226 Hz tympanometry as the reference standard in 111 children from one to 16 years of age. Based on pneumatic otoscopy, a trained ear nose and throat nurse marked each ear as "highly probable effusion", "probable effusion" or "no effusion". Tympanograms were classified as normal if maximum compliance was equal to or greater than 0.2 ml and the estimate of middle ear pressure was between -199 to +200 daPa. If highly probable effusion was the criterion, sensitivity of pneumatic otoscopy was 45% and specificity was 99%. If both highly probable and probable effusion was the criterion, sensitivity rose to 88%; however, specificity fell to 88%. Pertinent to the current study, the youngest age group (one to five years) had abnormal pneumatic otoscopy in 56% of the children for one or both ears.

The best method for validating either tympanometry or otologic examination is myringotomy, to surgically determine the presence of effusion. Silva and Hotaling (1997) created a formal training program for four otolaryngology residents using pneumatic otoscopy and otomicroscopy. The residents were given didactic and clinical training. On the day of surgery the resident performed pneumatic otoscopy in the holding area, and otomicroscopy and myringotomy in the operating room. Following each procedure the resident was required to state whether or not middle ear effusion was present. Criteria for validation were set as follows: pneumatic otoscopy with 80% sensitivity and 70% specificity and otomicroscopy with 90% sensitivity and 80% specificity. A total of 275 ears from patients between birth and 18 years of age were examined. None of the four residents met criterion for sensitivity with pneumatic otoscopy after two months. Two residents met the criterion for specificity after two months. All four met the criterion for both sensitivity (80%) and specificity (70%) by the end of four months. With respect to otomicroscopy, only one resident met criteria for sensitivity and specificity after two months. After four months three of the four residents met the criteria for validation with the otomicroscope. This study illustrates that even with extensive training and practice, pneumatic otoscopy and otomicroscopy are not perfect. Although the authors do not report results by age groups, it is highly likely that the accuracy with the young infants was poorer than with the older children and teenagers. (Marchant, McMillan, Shurin, Johnson, Turczyk, et al., 1986; Paradise, Smith, & Bluestone, 1976)

Published studies in the diagnosis of otitis media in children have shown sensitivity of pneumatic otoscopy to be from 84.5% (Harris, Hutchinson & Moravec, 2005) to 97.2% (Lee & Yeo, 2004). Studies in specificity of pneumatic otoscopy have ranged from 33.3% (KC, Guragain, & Sinha, 2007) and 100% as illustrated in Tables 1 and 2 (Harris, Hutchinson & Moravec, 2005). In a study done by Marchant et al. in 1986, infants under the age of 5 months were examined using pneumatic otoscopy; the results of this examination were in agreement with high frequency tympanometry 93% of time.

Steinbach, Sectish, Benjamin, Chang and Messner (2002) note that the correlation of clinical finding between pediatric residents and pediatric otolaryngologists was in fair agreement overall. Pertinent to the current study, 25.6% of the children were under one year of age. Comparing otoscopic and tympanometric results, Steinbach et al. (2002) found a slight correlation with residents and a fair correlation with pediatric otolaryngologists. This correlation was done using K statistic analysis, a measure of correlation from 0 to 1, with 0 being random and 1 being perfect correlation. The authors assert that trainee physicians develop their own ideas of which clinical signs and symptoms indicate the presence of otitis media and these ideas persist throughout their training. In a similar vein, Thibodeau (1980) found that rotations which emphasize skill instruction lead to learning with short-term effect, “but often do not lead to long term habits, thus showing that even if the physician or nurse practitioner were taught using a validated otoscopy program, personal habit often wins out over formal instruction."

In addition to accuracy issues with otologic examination, definitive diagnosis is difficult because the middle ear system is dynamic and the health status of the ear can change in a matter of days or hours. Therefore, it is optimal when the otologic examination and audiologic examination are completed on the same day (Karzon & Lieu, 2006.)

The JCIH (2007) recommends high-frequency tympanometry to assess middle ear status in neonates and infants under the age of 6 months. Tympanometry with a 226 Hz probe is not valid for young infants because it produces both false negative and false positive results (Baldwin, 2006; Lantz, Petrak & Prigge, 2004; Mazlan et al., 2007; Meyer et al., 1997; and Purdy & Williams, 2000). The physiologic issues that preclude the use of the 226 Hz probe tone in young infants include the lack of fusion of the tympanic membrane to the tympanic ring, the overall decrease in the mass of the middle ear system, and the formation of the bony ear canal wall (Lantz, Petrak & Prigge, 2004).

Although a number of high-frequency probe tones have been explored over the past 30 years (Baldwin, 2006; Kei et al., 2007), a 1000 Hz probe tone seems to be the most commonly used frequency at this time (JCIH 2007; Karzon & Lieu, 2006; ASHA, 2004; Kei et al., 2004; Margolis et al., 2003; and Bass-Ringdahl, Hanks, Holte & Zapala, 2003.) Limited normative data are available for 1000 Hz tympanometry, especially when considering infants between birth to 6 months of age (Calandruccio, Fitzgerald & Prieve, 2006; Kei et al., 2004; and Margolis et al., 2003). Measures included in recent normative data studies by Kei et al. 2004 and Margolis et al. 2003, include the following:

- Y+200 mmho, which is static admittance when the pressure is +200 daPa.
- Y-400 (-tail) mmho, which is the static admittance when the pressure is -400 daPa or at the most negative pressure measurable.
- Y peak, which is the static admittance when the pressure is at the peak.
- Ypc+200 mmho is the static admittance of the peak minus the static admittance at +200 daPa.
- Ypc-400 (-tail) mmho is the static admittance of the peak minus the static admittance at -400 daPa or the most negative pressure measurable.

Consensus is lacking for a standardized approach to categorizing and interpreting 1000 Hz tympanograms. Instrumentation factors such as pump rate and direction of the pressure sweep affect tympanometric results, with increased pump rate resulting in increased admittance (Katz 2002). For example, Margolis (2003) used a positive to negative direction at a rate that varied from 600 daPa/sec at the tails to 200 daPa/sec near the peak; whereas, Kei et al. (2004) and Kei et al. (2007) used a pressure sweep rate of 400 daPa/sec.

Otoacoustic emissions (OAEs) are a standard component of the diagnostic audiology protocol for infants and children (Prieve, Calandruccio, Fitzgerald, Mazevski & Georgantas, 2008; Sininger 2007). The absence or diminution of either transient-evoked otoacoustic emissions (TEOAEs) or distortion-product otoacoustic emissions (DPOAEs) is a diagnostic sign of middle ear pathology (Prieve et al., 2008). OAEs will be absent or reduced in an ear with a conductive pathology because the eliciting stimulus is diminished traveling to the cochlea through the middle ear with pathology and the emission (if any is elicited) is diminished traveling in reverse through the middle ear with pathology (Prieve et al., 2008). If there are other indicators of middle ear pathology (otologic examination, bone conduction auditory brainstem response testing (BC ABR), tympanometry), the absence or reduction of OAEs adds to the diagnosis of middle ear pathology in cases of normal hearing, slight hearing loss and mild hearing loss. Although OAEs can corroborate middle ear pathology when used in conjunction with other audiologic measures, they are not a stand-alone technique for diagnosing conductive hearing loss or middle ear pathology.

In addition to 1000 Hz tympanometry and DPOAEs, the audiologist has bone conduction ABR available as an indicator of conductive pathology. However, it is often difficult to obtain these measures on young infants during an ABR obtained with natural, rather than sedated, sleep. In studies by Karzon and Lieu (2006) and Andrews et al. (2004), bone conduction ABR measures were obtained for 47 % of 51 young infants with hearing loss, and 43% of 30 young infants with hearing loss respectively. Although the air-bone gap for ABR has high diagnostic value, the uncertainty that it can be obtained within the test session makes it a problematic indicator of middle ear pathology.

Although clinicians can compare their results to the limited normative data for 1000 Hz tympanometry, what clinicians need to know is whether results correlate with middle ear pathology. It is the aim of this study to determine to what extent 1000 Hz tympanometry agrees with otologic findings by experienced otolaryngologists or nurse practitioners in young infants (1 to 4 months of age). In particular, the following questions/issues will be examined.

1) Does 1000 Hz tympanometry predict the middle ear status as determined by an otologic examination?

2) If 1000 Hz tympanometry does predict middle ear status which of the tympanometric measures is the best predictor?

3) Does the use of additional tests in the audiologic battery, such as bone conduction ABR and DPOAEs, improve the correlation between audiologic findings and otologic findings?

4) Do the normative data collected in the current subject sample agree with those published in the literature?

Methods

Authorization to perform research on human subjects was received from the Human Research Protection Office of Washington University School of Medicine.

Participants

Babies from birth to 4 months corrected age who were scheduled for a non-sedated auditory brainstem response (ABR) test were recruited from the audiology department of St. Louis Children's Hospital. Parents of infants were contacted by phone prior to the appointment to determine if they were interested in participating in the study. Informed consent was obtained on the day of the test prior to the appointment.

Of 84 subjects contacted, 27 expressed interest in the study and information was mailed to their home for consideration. Due to failure to keep appointments (n= 2) or a decision to not participate (n= 1), informed consent was obtained for 24 subjects (9 male; 15 female). No subjects were withdrawn after consent had been obtained. Participants ranged in post gestational age from 37-116 days with a mean age of 69 days, and a standard deviation of 22 days, at the time of the appointment. Nineteen of the subjects were born full- term, and five were premature.

Procedure

Prior to audiologic assessment, a board certified otolaryngologist with at least 2 years of experience as an attending physician or pediatric nurse practitioner with more than 6 years of experience with pediatric otolaryngology performed an otologic examination. Otologic findings were reported as “clear”, “fluid”, “fluid and air” or “not determinable". The otologic report form also had a section for comments and recommendations. Upon completion of the otologic examination, the physician or nurse practitioner sealed the form in an envelope to be opened at the conclusion of audiologic assessment.

ABR, bone conduction ABR, high frequency tympanometry, and DPOAEs were performed by or supervised by one of four licensed audiologists each with at least 10 years of pediatric experience.

Equipment

Otoscopy was administered using the Welch Allyn pneumatic otoscope, the Storz E.N.T. microscope or the Wild Heerbrugg E.N.T. microscope. The GSI TympStar Version 2 was used for high-frequency tympanometry. DPOAEs were obtained from three different pieces of equipment, the Audera, the GSI-70 and the Otoread, that self-calibrate upon the start of each run. ABR was obtained with a two-channel Nicolet Spirit.

All audiologic equipment used to assess tympanometry, ABR and DPOAEs is calibrated yearly by trained technicians who adhere to the national association of special equipment distributors, according to applicable manufacturer and ANSI specifications (S3.6 – 1996).

With respect to ABR, calibration measures for air-conduction stimuli were obtained with a type 1 sound level meter (SLM), (Larson-Davis 824) with a 1-inch microphone (Larson-Davis 2575) in a 2 cc coupler. The SLM was set to fast with a linear frequency response using peak hold. For the air conduction click stimulus 0 dBnHL was 38.4 dB

SPL peak for the left insert and 38.6 dB SPL peak for the right insert. For air conduction tone burst stimuli 0 dBnHL was 34.3 dB SPL peak (right insert) and 33.9 dB SPL peak (left insert) at 500 Hz, 19.5 dB SPL peak (right insert) and 19.7 (left insert) at 1000 Hz, 26.2 SPL peak (right insert) and 26.7 dB SPL peak left insert, at 2000 Hz and 24.8 dB SPL peak (right insert) and 24.7 dB SPL peak (left insert) at 4000 Hz. Bone conduction stimuli were measured in an artificial mastoid (Larson-Davis AMC 493) with the same sound level meter. For the bone conduction click stimulus 0 dBnHL was 49.6 dB SPL peak. For bone conduction tone burst stimuli, 0 dBnHL was 59.4 dB SPL peak at 500 Hz, 43.6 dB SPL peak at 1000 Hz, 41.9 dB SPL peak at 2000 Hz, and 39.8 dB SPL peak at 4000 Hz.

Tympanometric calibration data were obtained on October 17, 2008. The probe tone measure was 991 Hz at 85.1 dBSPL. Immittance scale linearity was within tolerances from .5-5 ml. Pressure readings were: +200 daPa = +205 daPa, +100 daPa = +100 daPa, 0 daPa = 0 daPa, -100 daPa = -102 daPa, -200 daPa = -206 daPa, -300 daPa = -305 daPa, -400 daPa = -408 daPa. All measures were within tolerances per relevant ANSI standards.

The Audera and GSI 70 were calibrated on October 17, 2008. The Otoread, was calibrated upon purchase after the October calibration date. Each piece of equipment was within acceptable tolerances. The areas measured on the GSI-70 were frequency, output, microphone compensation, microphone floor noise, distortion channel 1, distortion channel 2, probe tone condition, probe seal check, microphone sensitivity and source reference. The exact levels of calibration were not indicated for the Audera otoacoustic emission software, but it is noted on the calibration certificate that is the machine was calibrated for otoacoustic emissions and was within tolerances.

Procedure

Infants in the study received an otologic examination, ABR, high-frequency tympanometry and DPOAEs. The otolaryngologist or nurse practitioner performed pneumatic otoscopy or a microscopic ear exam. Excess cerumen and/or debris was removed from the patient's ear canal as necessary for examination. The otolaryngologist or nurse practitioner determined middle ear status prior to the initial audiologic assessment. Results were placed in a sealed envelope for review by an audiologist at the conclusion of the audiologic assessment. In addition to ABR, the audiologist administered high-frequency tympanometry and DPOAEs to complete the experimental protocol.

Tympanometry was performed by presenting a 1000 Hz probe tone at 85 dB SPL with the pressure range set to +200 to -400 daPa. The rate of pressure change was 600 daPa/sec on the tympanogram's positive and negative tails. Rate of pressure change decreased to 200 daPa/sec near peak admittance. A check of the tympanometer's pump was done before each research subject. The check consisted of running a tympanogram with the probe placed in a 2cc cavity. The tympanometer was judged to be in good working order if a volume of 2.0 cc was obtained.

DPOAE instruments were set to obtain emissions at 1000, 2000, 3000 and 4000 Hz. F1 was set at 55 dB and F2 was set at 65 dBSPL. ABR thresholds were obtained for click stimuli, and tonebursts at 500 Hz, 1000 Hz, 2000, Hz and 4000 Hz. Bone conduction click and tone burst stimuli were also part of the ABR protocol.

Biologic listening checks were performed prior to the arrival of the subject.

Results

Otologic and 1 kHz tympanometry results were obtained for all 48 ears of the 24 participants. Of the 48 infant ears 20 (42%) had DPOAE's measured and 47 (98%) had ABR. No measures of BC ABR were obtained for the 10 infants with hearing loss, defined as > 20 dBnHL for a click stimulus, 2000 Hz and 4000 Hz tonebursts or > 30 dBnHL for 500 and 1000 Hz tonebursts.

Data analyses included descriptive statistics mean, standard error, standard deviation, minimums, maximums, sensitivity and specificity, and point biserial correlation. Data were analyzed using all ears (48), all ears minus the ears with indeterminate otologic results (44), counter balanced selection of right versus left ear (24), and all ears minus the ears with flat tympanograms and indeterminate otologic examination (33).

A point biserial correlation is a Pearson correlation used to determine the relationship between two variables when one is scalar. In the current study, static admittance was scalar and otologic results were nominal. No significant correlation was found between otologic results and tympanometric measures (Y+200, Ypc+200, Y-tail, Ypc-tail and Ypeak). The specific correlations may be seen in Tables 3-6.

The mean values for Y+200, Ypc+200, Y-tail, Ypc-tail and YPeak were not significantly different for all ears, right or left ears (randomized) and exclusion of indeterminate otologic results as shown in Figure 1 and Tables 7-10.

Six ears were otologically and audiologically normal (Table 11). Results of the 1000 Hz tympanometry from these ears were compared to the normative data from Margolis et al. (2003), Kei et al. (2004), Kei et al. (2007) and Mazlan et al. (2007). Normative data comparisons can be found in Tables 12-16 and Figure 2.

Sensitivity and specificity for the measures obtained with 1000 Hz tympanometry are shown in Table 17. The best measures when considering both sensitivity and sensitivity were Ypc^{+200} (22% sensitivity and 70% specificity) and Y^{peak}, (22% sensitivity and 70% specificity). Sensitivity and specificity were also measured based on visual inspection by three audiologists with more than 10 years of experience each. Sensitivity for visual inspection was 29% and sensitivity was 42% (Table 18).

Results of each ear for audiologic and 1000 Hz results can be seen in Table 19. A (–) indicates a normal finding and a (+) indicates an abnormal finding, a (?) indicates a measure that could not be determined. Blank cells indicate the test was not attempted or completed. Table 19 depicts all of the ears in the data set. It should be noted that bone conduction ABR is not depicted in the table as it was not utilized in the current sample.

Discussion

This study illustrates the clinical importance of using all tools available to make a correct diagnosis. The importance of an interdisciplinary approach seems to be especially vital for this infant population. Data from the literature and the current study illustrate repeatedly that no measure shows 100% sensitivity and specificity. Discrepancies between audiologic and otologic findings were observed in a number of ears. Inconsistencies appeared in both directions, as illustrated in Table 18, i.e., findings of otologically normal in light of numerous abnormal audiologic indicators (ears: 1L, 9R, 9L, 15R, and 15L), as well as findings of otologically abnormal in light of numerous normal audiologic indicators (ears: 2L, 19R, 19L, 22R, 23R and 23L).

Discrepant otologic examinations are also very clearly demonstrated when looking at sensitivity and specificity (Table 18). In general the current data resulted in specificity being better than sensitivity. Sensitivity is as low as 11% suggesting that the tympanogram does not predict the otologic findings for ears with middle ear pathology. Examination of the data indicated a number of ears for which the other audiologic tests (ABR and DPOAEs) agreed with the 1000 Hz tympanograms (i.e., were abnormal). This suggests that the otologic examination was in error. Because the sample size was small, these discrepant examinations had a large effect on the data.

Other normative studies did not discuss the success rate of high-frequency tympanometry (Margolis et al., 2003; Mazlan et al., 2007; and Swanepoel et al., 2007). Since these studies were retrospective in nature, only completed tests were used for data analysis. Table 7 indicates the normative data from the current study; these data fall well into the norms set by Margolis et al. (2003), Mazlan et al. (2007) and Swanepoel et al. (2007).

No significant correlation between 1000 Hz tympanograms and otologic findings was observed. This can most likely be attributed to small sample size and a larger correlation would be seen between otologic findings and tympanometric measure with a larger sample size. Kei et al., (2003) also noted a non significant correlation with otologic examinations in his study. The negative association noted in the point bi-serial correlation suggests that the 1000 Hz tympanograms did not correspond well with the otologic findings. It should be noted that with such a small sample size the correlation could have been shifted with just a few outlying pieces of data.

In the current study the physician or nurse practitioner was blind to the audiologic results, and the audiologist was blind to the otologic examination until the end of the test session. Although this is necessary for research, in clinical practice the physician would have all of the available evidence to guide the final otologic diagnosis.

The data were analyzed the data using a counterbalanced selection of right versus left ear, randomly picking the ear to start the counterbalance. This was done because it could be argued that the ears are not independent of each other. By randomly picking the ear to include in the analysis the authors are taking this variability of dependence out. In subjects who had 2 affected ears, the ear used in the analysis was picked; the same was done for subjects with 2 unaffected ears. For subjects who had one affected ear that ear was chosen for analysis. As was seen in the Results section the correlation using this analysis did not significantly change.

Originally the data were analyzed with the indeterminate otologic examinations being considered abnormal, as was the case in ears 5R, 5L, and 18R. It was decided upon data analysis of all of the ears that this might not be a fair distinction and it was then decided to run the analyses on all ears minus the indeterminate otologic call, providing a better indication of sensitivity. This was determined because the inability to make an otologic assessment did not automatically mean pathology at the ear. The means of the data did not change significantly, but this condition was still used for sensitivity and specificity to give the most accurate portrayal.

One of the challenges in the current study was trying to figure out the best way to classify flat tympanograms. Since an un-baselined measurement was used for the current study a flat tympanogram would not necessarily have an abnormally low static admittance for Y^{-tail}, Y^{+200} and Y^{peak}. The compensated measures, Ypc^{+200} and Ypc^{-tail}, do yield abnormal values for flat tympanograms. It is for this reason that the data were analyzed using all ears, and all ears minus the ears with flat tympanograms. When determining sensitivity and specificity, all ears minus the ears with indeterminate otologic examinations were used and all of the measurements were considered abnormal for flat tympanograms. Figure 3 illustrates a flat tympanogram and each of the corresponding values. The uncompensated values fall within the normative values used in the current study and those found by Margolis et al., (2003). The compensated values and peak do not; however, it is obvious that the values are meaningless and should not be counted as normal. The value for Y+200 is indicated by C1 in the figure, Ypc+200 is the value in mmhos indicated by tymp 1, Y-tail is the value corresponding to -400 on the X axis of the printout, Ypc-tail is calculated by taking the peak (which there is none) minus the –tail value of 1.2, Ypeak is obviously not calculated in this case.

The current study used the same pump speed for the peak; however, the pump speed for the tails differed. This difference in pump speed would affect the normative data for the peak to tail difference (Ypc+200 and Ypc-tail, resulting in a difference in norms from Swanepoel et al. (2007) in comparison to this study's normative values).

When conducting an experiment such as this, it is important to remember the challenges faced by clinicians every day. This study was carried out with real patients in a real clinical environment as opposed to a research environment, where time and most importantly the state of the infant were a factor. Since the infants were scheduled for a natural sleep ABR, when they saw the otolaryngologist or nurse practitioner they were sleep-deprived and hungry. This meant that most babies were very easily agitated during the otologic examination, and this compounded with the small ear canal could have caused some of the discrepant otologic examinations that were seen in the study. This same infant state had an effect upon the tests (and quality of these tests) the audiologist could provide. Only 20 of the 48 ears (42%) had otoacoustic emissions measured likely due to the wake state of the infant; however this test was attempted at the end of the testing session so the infant was naturally waking up from a sometimes 2 hour nap. This awake state may have also contributed to the reduced quality of some of the tracings for high-frequency tympanometry. Other factors could have contributed to the low numbers of DPOAE measures obtained, they are, time constraints and inability to get a seal in the ear.

The only true validation for otologic examination and for high-frequency tympanometry is myringotomy. It is unlikely that this validation standard can be studied in infants' birth to four months of age because so few infants meet the criteria for myringotomy or myringotomy with tympanostomy tube placement. As myringotomy is an invasive procedure, it would not be ethical to perform this unless an infant met clinical indications.

The current study did not control for otologic instrumentation. The clinician was free to use either pneumatic otoscopy and/or otomicroscopy. There is evidence to suggest that accuracy is greater with otomicroscopy (Lee & Yeo, 2004.) It is possible that insistence on otomicroscopy in the age range would be prudent. In addition, none of the medical personnel in this study were validated otoscopists. It would be beneficial to have validated otoscopists based on the youngest age range possible, e.g., birth to 9 months of age.

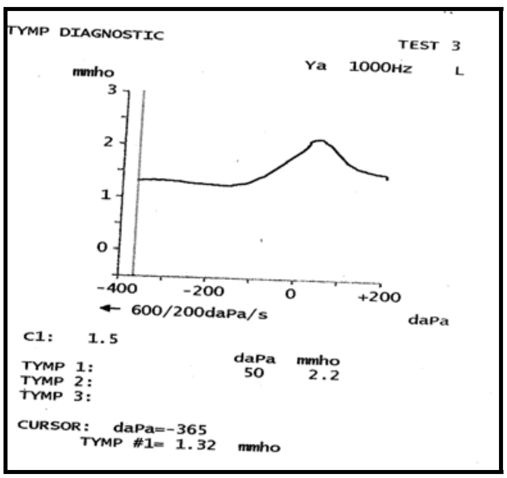
Measures of BC ABR would have been extremely useful for several ears (9L, 10R, 10L (attempted but could not be completed because of wake state), 12R, 12L, 13L 15R, 15L (patient awake for all tone specific information) 16R, 16L, 19L, 21R, 21L, 24L.) In one instance it was noted that bone conduction ABR was attempted but could not be completed due to patient wake state. Reliance on flat 1000 Hz tympanograms; may have to audiologists to not attempt bone conduction ABR, in addition time constraints may have made it impossible for the audiologist to obtain bone conduction ABR thresholds.

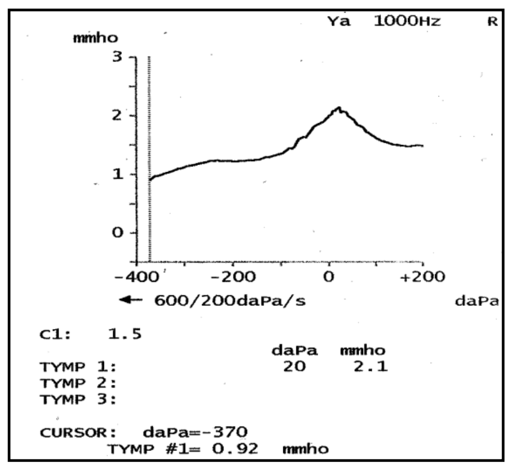
The accurate diagnosis of hearing loss in infants is not yet an exact science. It is clear from this study that clinicians should use all of the tools available to them to make the most accurate diagnosis. Some tests may need to be repeated to ensure the most accurate reading. Working in a multi-disciplinary team helps the diagnosis of hearing loss and otitis media be as accurate as possible, especially since there is evidence that infants who develop otitis media with effusion within the first 3 months of life may be predisposed to chronic middle ear issues through early childhood (Blake, 1991; Marchant et al., 1984 and Williams, Purdy & Barber, 1995).

Case Study: Subject 2 L Erroneous Otologic examination

This case illustrates a possible erroneous otologic finding in the left ear by the physician or nurse practitioner. The right ear was considered otologically normal, in agreement with audiologic findings. However, the left ear was considered “fluid and air” or abnormal. All audiologic indicators for both ears were within normal limits, i.e., 1 kHz tympanograms, ABR for clicks and tone bursts at 1000, 2000, and 4000 Hz, as well as distortion product otoacoustic emissions 2000-4000

Below you will see the tympanograms for ear:





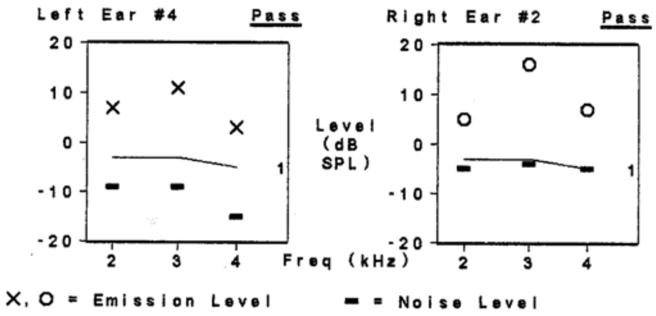
All measures for this tympanogram meet the normative values used in the current study (Margolis et al., 2003).

The ABR is displayed below:

	Click	1000 Hz	2000 Hz	4000 Hz
Right Ear	15	30	20	20
Left Ear	15	30	20	20

As illustrated the responses all fell within normal limits.

Finally, the DPOAE's indicate normal outer hair cell function. It is unlikely that on ears with "fluid and air" would produce such robust and symmetric robust emissions.

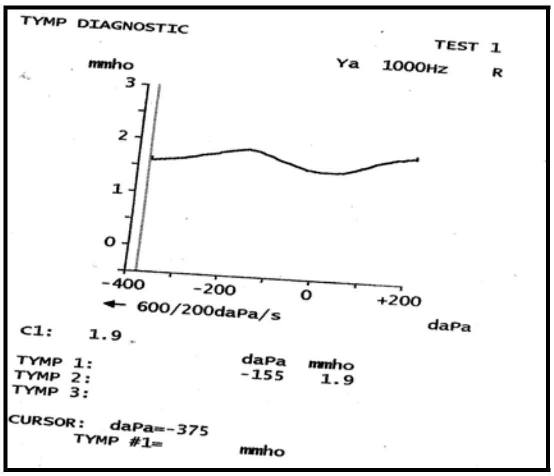


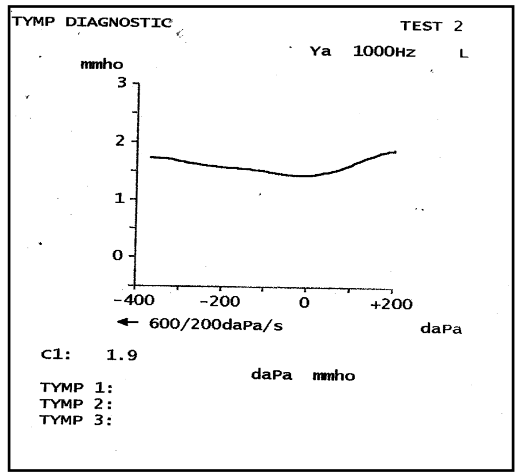
Freq (kHz)	2	3	4	2	3	4
DP	7	11	3	5	16	7
NF	-9	-9	-15	-5	-4	-5
DP-NF	16	20	18	10	20	12

As it was mentioned above otologic examinations are difficult to make in infant ears. This is just example of one of 12 otologic examinations that were felt to be discrepant.

Case study 2: Erroneous tympanogram subject 11 L

This case illustrates when high-frequency tympanometry does not equate with the otologic examination or the other objective measures. The otologic examination determined both ears to be clear.





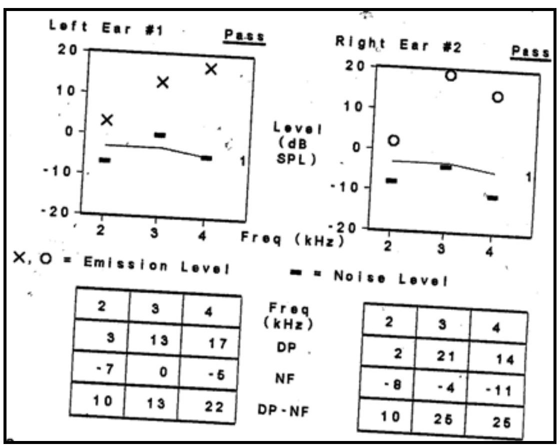
The ABR was within normal limits for the click and for frequencies 1000-4000 Hz.

	Click	1000 Hz	2000 Hz	4000 Hz
Right Ear	15 dBnHL	30 dBnHL	15 dBnHL	15 dBnHL
Left Ear	15 dBnHL	30 dBnHL	15 dBnHL	15 dBnHL

The DPOAE's in this case were also robust. An emission of greater than 5 dB signal to

Instrument	Sensitivity	N (ears)	Source

noise ratio was considered to be a present otoacoustic emission in this study.



As it has been reported throughout this study none of the tests or measures are 100% accurate, in this case since hearing is not being affected the flat tympanograms do not add any clinical value.

Static Otoscopy	78.7%	121	(KC, Guragain, & Sinha 2007)
Pneumatic Otoscopy	87.7%	81	(Mills 1986)
	93%	163	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	87%	222	(Toner & Mains, 1988)
	90.5%	201	(Shiao & Guo, 2004)
	97.2%	85	(Lee & Yeo, 2004)
	84.5%	35	(Harris, Hutchinson, & Moravec, 2005)
	94.4%	121	(KC, Guragain, & Sinha, 2007)
Video Telescopy	97.8%	201	(Shiao & Guo, 2004)
Otomicroscopy	100%	85	(Lee & Yeo, 2004)

Table 1 shows sensitivity of otoscopy in the literature

Table 2 shows specificity of otoscopy in the literature

Instrument	Specificity	N (ears)	Source
Static Otoscopy	22.2%	121	(KC, Guragain, & Sinha, 2007)
Pneumatic Otoscopy	91.4%	81	(Mains, 1986)
	89%	222	(Toner & Mains, 1988)
	58%	163	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	38.5%	85	(Lee & Yeo, 2004)
	77.3%	201	(Shiao & Guo, 2004)
	100%	35	(Harris, Hutchinson, & Moravec, 2005)
	33.3%	121	(KC, Guragain, & Sinha, 2007)
Video Telescopy	100%	201	(Shiao & Guo, 2004)
Otomicroscopy	61.5%	85	(Lee & Yeo, 2004)

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Table 3 shows the point biserial correlation for all ears across the top. The highlighted portions are the correlations, which are not significant.

Point biserial correlation all ears

		Otologic	Y+200	Ypc+200	Y-tail	Ypc-tail	Ypeak
Otologic examination	Pearson Correlation	1.000	-.099	-.101	-.248	.015	-.081
	Sig. (2-tailed)		.503	.497	.089	.918	.583
	N	48.000	48	48	48	48	48

Table 4 shows the point biserial correlation for all ears minus the ears with indeterminate otologic examination across the top. The highlighted portions are the correlations, which are not significant.

Point biserial correlation all ears minus the ears with indeterminate otologic examination

		Otologic	Y+200	Ypc+200	Y-tail	Ypc-tail	Ypeak
Otologic Examination	Pearson Correlation	1.000	-.063	-.018	-.172	.053	-.013
	Sig. (2-tailed)		.683	.906	.265	.731	.933
	N	44.000	44	44	44	44	44

Table 5 shows the point biserial correlation for randomly picked right or left ears for all ears across the top. The highlighted portions are the correlations, which are not significant.

Point biserial correlation randomly picked right or left ear

		Otologic	Y+200	Ypc+200	Y-tail	Ypc-tail	Ypeak
Otologic examination	Pearson Correlation	1.000	-.114	-.141	-.263	.065	-.100
	Sig. (2-tailed)		.594	.510	.215	.764	.642
	N	24.000	24	24	24	24	24

Table 6 shows the point biserial correlation for all ears minus the indeterminate otologic examination and flat tympanograms. The highlighted portions are the correlations, which are not significant.

Point biserial correlation all ears minus flat tympanograms

		Otologic	Y+200	Ypc+200	Y-tail	Ypc-tail	Ypeak
Otologic Examination	Pearson Correlation	1.000	-.259	-.132	-.227	-.050	-.152
	Sig. (2-tailed)		.152	.472	.211	.784	.406
	N	32.000	32	32	32	32	32

Table 7

Descriptive statistics for all ears

		N	Minimum	Maximum	Mean		Std. Deviation
Otologic examination		Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
Clear otologic call	Y+200	36	.80	2.60	1.5667	.07325	.43948
	Ypc+200	36	.00	4.30	.8194	.16944	1.01667
	Y-tail	36	.00	2.82	1.1456	.09075	.54449
	Ypc-tail	36	.00	5.28	1.1803	.22784	1.36706
	Ypeak	36	.00	6.70	2.3186	.23385	1.40312
	Valid N (listwise)	36					
Abnormal otologic call	Y+200	12	1.00	1.90	1.4750	.08083	.28002
	Ypc+200	12	.00	1.60	.6083	.15397	.53336
	Y-tail	12	.52	1.32	.8600	.07698	.26666
	Ypc-tail	12	.00	2.36	1.2233	.22974	.79583
	Ypeak	12	1.00	3.10	2.0833	.21136	.73216
	Valid N (listwise)	12					

Table 8

Descriptive statistics for all ears minus the ears with indeterminate otologic examination

Otologic Examination		N	Minimum	Maximum	Mean		Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
Clear otologic call	Y+200	36	.80	2.60	1.5667	.07325	.43948
	Ypc+200	36	.00	4.30	.8194	.16944	1.01667
	Y-tail	36	.00	2.82	1.1456	.09075	.54449
	Ypc-tail	36	.00	5.28	1.1803	.22784	1.36706
	Ypeak	36	.00	6.70	2.3186	.23385	1.40312
	Valid N (listwise)	36					
Abnormal otologic call	Y+200	8	1.00	1.80	1.5000	.09063	.25635
	Ypc+200	8	.00	1.60	.7750	.18589	.52576
	Y-tail	8	.52	1.32	.9200	.10172	.28770
	Ypc-tail	8	.00	2.36	1.3550	.29039	.82136
	Ypeak	8	1.00	3.10	2.2750	.24257	.68609
	Valid N (listwise)	8					

Table 9

Descriptive statistics randomly picked right or left ears

Otologic Examination		N	Minimum	Maximum	Mean		Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
Clear otologic call	Y+200	15	.80	2.10	1.5267	.09733	.37696
	Ypc+200	15	.00	3.20	.8933	.26012	1.00745
	Y-tail	15	.00	2.82	1.1820	.18614	.72093
	Ypc-tail	15	.00	3.67	1.0933	.32467	1.25743
	Ypeak	15	.00	5.10	2.3180	.34897	1.35156
	Valid N (listwise)	15					
Abnormal otologic call	Y+200	9	.40	1.90	1.4333	.15366	.46098
	Ypc+200	9	.10	1.20	.6556	.14055	.42164
	Y-tail	9	.50	1.32	.8556	.10540	.31619
	Ypc-tail	9	.53	2.21	1.2333	.23769	.71306
	Ypeak	9	1.20	2.90	2.0889	.22635	.67905
	Valid N (listwise)	9					

Table 10

Descriptive statistics for all ears minus indeterminable and flat tympanograms

Otologic Examination		N	Minimum	Maximum	Mean		Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
0	Y+200	26	1.20	2.60	1.7577	.06231	.31771
	Ypc+200	26	.00	4.30	1.1346	.20335	1.03690
	Y-tail	26	.50	2.82	1.2169	.11132	.56765
	Ypc-tail	26	.08	5.28	1.6342	.26638	1.35826
	Ypeak	26	1.000	6.700	2.84115	.252693	1.288485
	Valid N (listwise)	26					
1	Y+200	7	1.30	1.80	1.5714	.06442	.17043
	Ypc+200	7	.20	1.60	.8857	.17242	.45617
	Y-tail	7	.52	1.32	.9086	.11671	.30878
	Ypc-tail	7	.60	2.36	1.5486	.24996	.66132
	Ypeak	7	1.900	3.100	2.45714	.184980	.489412
	Valid N (listwise)	7					

Table 11

Descriptive statistics normative data from current study

	N	Minimum	Maximum	Mean		Std. Deviation
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic
Y+200	6	1.50	2.00	1.8000	.07303	.17889
Ypc+200	6	.50	1.30	.8167	.13017	.31885
Y-tail	6	.55	.92	.6900	.06894	.16888
Ypc-tail	6	.80	2.70	1.7233	.27009	.66159
Ypeak	6	2.10	3.30	2.6167	.16617	.40702
Valid N (listwise)	6					

Table 12, normative values in the literature for Y+200

I kHz	N	Infant Age	Mean	Standard Deviation	Min	Max
Kei et al. (2003)	212 ears	Neonate	3.2 left ear 2.06 right ear	1.11 left ear 1.07 right ear	n/a	n/a
Margolis et al. (2003)	43 ears	14-28 days	1.4	0.4	0.7	2.3
Mazlan et al. (2007)	40 ears	42-49 days	1.4	0.41	0.62	2.78
Wilson (2008)	11 ears	28-84 days	1.58	0.37	1.10	2.30
Current Study	6 ears	40-92 days	1.8	0.18	1.5	2.00

Table 13, normative values in the literature for Ypc+200

1 kHz	N	Age	Mean	Standard Deviation	Min	Max
Kei et al. (2003)	212 ears	Neonate	1.04 Left ears 1.16 Right ears	0.51 Left ear 0.58 Right ear	n/a	n/a
Margolis et al. (2003)	43 ears	14-28 days	1.3	1.0	0	5.0
Mazlan et al. (2007)	40 ears	42-49 days	1.01	0.52	0.35	2.58
Wilson (2008)	34 ears	28-84 days	1.20	0.99	0.19	4.48
Current Study	6 ears	40-92 days	0.82	0.32	0.5	1.30

Table 14, normative values in the literature for Y-tail

1 kHz	N	Infant Age	Mean	Standard Deviation	Min	Max
Margolis et al. 2003	43 ears	14-28 days	0.8	0.4	0	1.7
Wilson 2008	11 ears	28-84 days	1.01	0.42	0.65	2.16
Current Study	6 ears	40-92 days	0.8	0.17	0.55	.92

Table 15, normative values in the literature for Ypc-tail

1 kHz	N	Infant Age	Mean	Standard Deviation	Min	Max
Margolis et al. 2003	43 ears	14-28 days	1..9	1.3	0.1	6.0
Wilson 2008	23 ears	28-84 days	1.65	0.93	0.65	4.98
Current Study	6 ears	40-92 days	1.71	0.66	0.80	2.7

Table 16, normative values in the literature for Ypeak

1 kHz	N	Infant Age	Mean	Standard Deviation	Min	Max
Margolis et al. (2003)	43 ears	14-28 days	2.7	1.2	0.8	7.0
Mazlan et al. (2007)	40 ears	42-49 days	2.35	0.71	1.16	4.5
Swanepoel et al. (2007)	177 ears	7-28 days	2.4	0.7	1.2	5.1
Wilson (2008)	11 ears	28-84 days	2.56	0.79	1.70	4.45

Table 17, shows the sensitivity and specificity of the otologic examination in the current study

Measure	Sensitivity	Specificity
Y+200	13%	74%
Ypc+200	22%	67%
Y –tail	11%	46%
Ypc-tail	22%	61%
Ypeak	22%	70%
DPOAE	0%	86%

Table 18, shows the sensitivity and specificity of the otologic examination to the audiologic call

Otologic call and Audiologic call	Sensitivity	Specificity
	29%	42%

Table 19 Results of otologic examination, Y+200, Ypc+200, Y-tail, Ypc-tail, Ypeak, DPOAE and ABR results for each ear. A "-" indicates results were within normal limits, A "+" indicates results were outside the normal limits, A "?" indicates results were interminable, and a blank cell means data were not obtained for that measure.

Subject	Otologic examination	Y^{+200}	Ypc^{+200}	Y^{-tail}	Ypc^{-tail}	Y^{peak}	DPOAE	ABR AC
1 R	-	-	+	+	+	-		-
*1 L	-	-	+	+	+	+		+
2 R	-	-	-	-	-	-	-	-
*2 L	+	-	-	-	-	-	-	-
3 R	-	-	-	-	-	-		-
3 L	-	-	-	-	-	-		-
4 R	-	-	-	-	-	-		-
4 L	-	-	-	-	-	-		-
5 R	?	-	+	-	+	+		-
5 L	?	-	-	-	-	-		-
6 R	-	-	-	-	-	-	-	-
6 L	-	-	-	-	-	-	-	-
7 R	-	-	-	+	-	-		-
7 L	-	-	-	+	+	-		-
8 R	-	-	+	-	+	+		-
8 L	-	-	+	-	+	+		-
*9 R	-	-	+	+	+	+		?
*9 L	-	-	+	+	+	+		+
10 R	-	-	-	-	-	-	+	+
10 L	-	-	-	-	-	-	+	+
11 R	-	-	+	+	+	+	-	-
11 L	-	-	+	+	+	+	-	-
12 R	+	-	+	-	+	+		+
12 L	-	-	-	-	-	-		-
13 R	-	-	-	-	-	-		-
13 L	-	-	-	-	-	-		-

14 R	-	-	-	-	-	-	-	-
14 L	-	-	-	-	-	-	-	-
*15 R	-	+	+	-	+	-		+
*15 L	-	-	+	-	+	+		+
16 R	-	-	-	+	-	-		-
16 L	-	-	-	+	-	-		-
17 R	-	+	-	+	+	-	-	-
17 L	-	-	-	-	-	-	-	-
18 R	-	-	-	+	-	-	-	-
18 L	?	-	+	+	+	+	-	-
*19 R	+	-	-	-	-	-	-	-
*19 L	+	-	-	-	-	-	-	-
20 R	+	-	-	-	-	-		-
20 L	-	-	-	-	-	-		-
21 R	-	-	-	+	-	-		+
21 L	-	-	-	+	-	-		+
*22 R	+	-	-	-	-	-	-	-
22 L	-	-	-	-	-	-	-	-
*23 R	+	-	-	-	-	-	-	-
*23 L	+	-	-	-	-	-	-	-
24 R	-	-	+	+	+	+		-
24 L	+	-	+	+	+	+		+

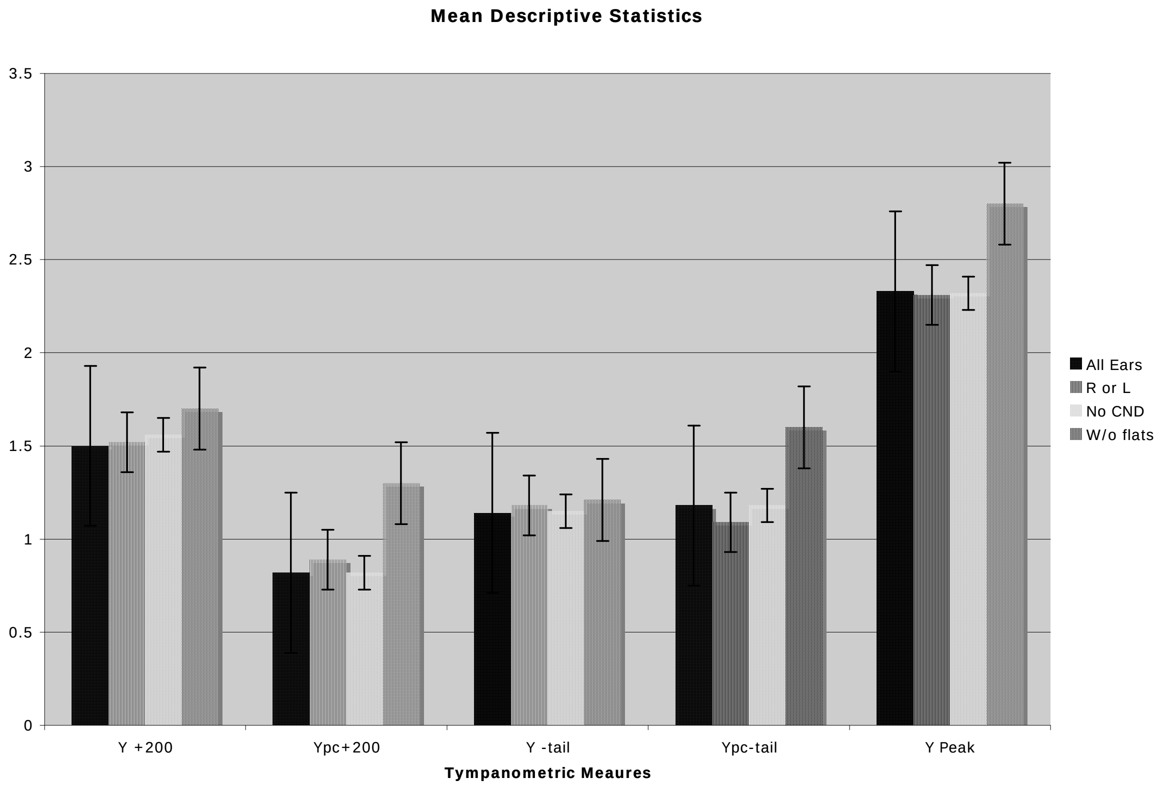


Figure 1 shows the mean values for all ways the data were analyzed

Legend

All Ears- All ears included in current study
R or L- Counterbalanced right versus left ears
No CND- All ears minus indeterminate otologic examinations
W/O Flats- All ears minus indeterminate otologic examination and ears with flat tympanograms.

Figure 2 shows the normative values for each measure in the literature and in the current study

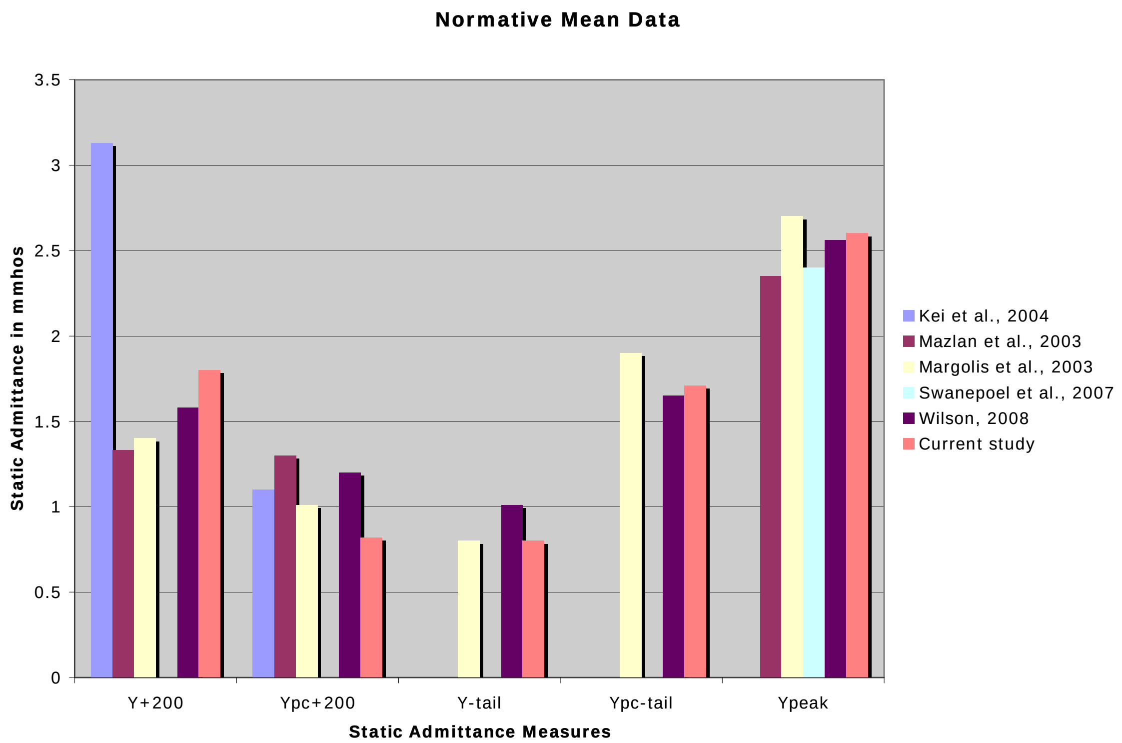
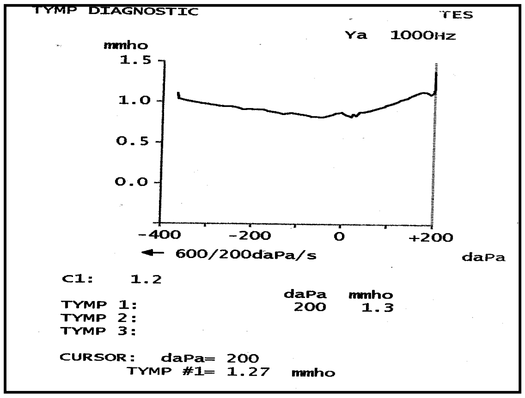


Figure 3 Example of a flat tympanogram and corresponding values derived



Y^{+200} = 1.2 mmhos
Ypc^{+200} = 0.1 mmhos
Y^{-tail} = 1.2 mmhos
Ypc^{-tail} = 0.0 mmhos
Y^{peak} = no peak

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