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What is This?
Frequency of Otitis Media Based on Otoendoscopic Evaluation in Preterm Infants

James Coticchia, MD¹, Priyanka Shah, MD¹, Livjot Sachdeva¹, Kelvin Kwong, MD², Josef M. Cortez, MD³, Javan Nation, MD⁴, Tracy Rudd, AuD¹, Marwan Zidan, PhD³, Eugene Cepeda, MD³, and Bernard Gonik, MD⁵

Abstract

Objective. This study was conducted to determine the frequency of otitis media in preterm neonates using otoendoscopy and tympanometry.

Study Design. Prospective study.

Setting. Wayne State University, Hutzel Women’s Hospital Neonatal Intensive Care Unit.

Subjects and Methods. Eighty-six preterm infants were included (gestational age <36 weeks). Otoendoscopy and tympanometry were performed to detect the presence of otitis media. Kappa statistic and logistic regression were used for statistical analysis.

Results. Otoendoscopy was performed in 85 patients. The frequency of otoendoscopy-diagnosed otitis media was 72.9% (62/85). Tympanometry could be performed on 69.76% of the ears. There was 73.5% agreement between the findings of tympanometry and those of otoendoscopy. The association between the presence of otitis media and gestational age at birth was statistically significant. The lower the gestational age, the higher the frequency of otoendoscopy-diagnosed otitis media (P = .001).

Conclusion. Otoendoscopically diagnosed otitis media is frequent in preterm neonates. There was agreement between the results of tympanometry and those of otoendoscopy. The frequency of otitis media increased with lower gestational age.

Keywords
middle ear infection, preterm birth, VLBW infants, otoendoscopy, tympanometry

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Introduction

Acute otitis media (AOM) and otitis media with effusion (OME) are common clinical problems in infants and children in the US and the leading causes of hearing loss.¹ Although substantial epidemiologic data are available about the prevalence of ear infections in children, little is known about the prevalence of such infections in preterm neonates.

The reported frequency of otitis media (OM) in preterm neonates ranges between 13% and 97%. Several diagnostic modalities have been used including standard otoscopy,² pneumatic otoscopy,³ microbial cultures,⁴,⁵ and histology of the temporal bone.³,⁶ Most of these studies have not specified the average gestational age of neonates nor have they specified the age at the time of diagnosis.

Intra-amniotic infections are largely subclinical in nature. Mothers rarely have a fever or any other evidence of infection. Yet, preterm neonates are at a greater risk of congenital sepsis than those born at term. Moreover, a fetal inflammatory response syndrome (FIRS) is a risk factor for short- and long-term complications of preterm birth. These include pneumonia, bacteremia, necrotizing enterocolitis, bronchopulmonary dysplasia, periventricular leukomalacia, and cerebral palsy.⁷-¹¹
The wide variability in previous studies makes it difficult to draw conclusions regarding the frequency of OM in preterm infants (Table 1).2-6 For example, histopathologic studies on the middle ear cavities of deceased neonates have been used to address the relationship between ear infections and intra-amniotic infection.3,6 Vargha et al identified OM in 17% (44/253) of preterm neonates by performing tympanal suction drainage and performing microbial cultures.4 Eavey3 reported abnormal otoscopic findings in 97.7% of neonatal ears in 44 newborns admitted to a neonatal intensive care unit (NICU). Using a handheld otoscope or binocular microscope to assess the tympanic membrane (TM) and middle ear status could be challenging, given the inherent difference in TM orientation between neonates and adults. The TM in preterm infants, unlike adults, is not perpendicular to the posterior external auditory canal (EAC) but almost parallel.12 This orientation can make the consistent and accurate assessment of the TM and the middle ear status challenging, especially in preterm neonates.

Intra-amniotic infections are also associated with middle ear infections in the neonate. Previous studies have shown that neonates in a NICU have a higher risk of developing hearing loss with a reported incidence that is 10 to 20 times higher than that of full-term infants, and investigators have suggested a relationship between congenital infections and hearing loss.13-16 This study was conducted to determine the prevalence of OM in preterm neonates using multiple modalities for the assessment of AOM and OME.

### Methods

A pilot study was conducted that included 30 preterm infants (born at less than 36 weeks of gestation), at 0 to 2 months of age, who were admitted to the NICU of Hutzel Women’s Hospital, Detroit, Michigan. The infants enrolled in this study underwent clinical examination of their middle ear by otoendoscopy and tympanometric evaluation. An attempt was made to perform the clinical examination as close to the day of birth as possible. Subsequently, additional 56 preterm neonates were included and the timeframe to the first middle ear examination after birth was narrowed. Otoendoscopy and tympanometric evaluations were performed within the first 3 days of birth for the second group.

Otoendoscopic evaluation was performed to study the signs and extent of middle ear disease based on changes in

| Table 1. Studies on the Frequency of Otitis Media in Preterm Neonates. |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Author                     | Study Group                | Diagnostic Technique(s)     | Frequency                  | Reference |
| de Sa, 1973                 | 130 infants, including preterm | Middle ear cavities examined histologically for amniotic aspirations | 56 (~43%): normal, no amniotic debris | 6         |
| Vargha, 1975               | 87 infants with respiratory tract infections: preterm | Tympanal suction drainage examined using microbial cultures | 55 (~43%): amniotic debris present | 4         |
| Berman, 1978               | 125 premature infants in neonatal intensive care unit | Otoscopy on 125 infants, tympanocentesis on 13 infants with tympanic membrane abnormality | 17 (~13%): otitis media, presence of purulent exudate | 24        |
| Balkany, 1978              | 125 infants: aged 1 day to 4 months; gestational age range: 25 weeks to full term | Binocular microscopy, tympanometry, tympanocentesis, microbial cultures to study middle ear effusions | 38 of 125 (30.4%) infants had otitis media | 5         |
| Pestalozza, 1988           | 970 newborns: aged 1-25 days; admitted to neonatal intensive care unit | Standard otoscopy | 205 (21.1%) of 970 newborns | 2         |
| Eavey, 1993                | 44 infants: admitted to neonatal intensive care unit; average gestational age was 34.2 weeks (range, 26 to 42 weeks) | Clinical otoscopy: using 3.5V halogen pneumatic otoscope | 97.7% of neonatal ears had some abnormal characteristics | 3         |
the TM. The following features were used for assessment: color, transparency, TM position, and TM thickness. The diagnosis of an apparently normal middle ear, OME, and AOM was based on the otoscopy grading scheme and diagnostic criteria described in Table 2. Due to the fact that unlike older infants and toddlers preterm neonates do not exhibit systemic signs of infection such as irritability and fever, it was anticipated that the diagnostic criteria for AOM would not be met. Therefore, we refer to otoendoscopically diagnosed OM.

High frequency tympanometry was performed after otoendoscopy using the Madsen Otoflex 100 (GN Otometrics North America, Schaumburg, Illinois) within 24 hours of the otoendoscopy to compare the visual findings with an objective assessment of middle ear pressure and TM compliance. High frequency tympanometry was performed by a team member who was masked to the otoendoscopy findings and clinical information. A probe with an appropriately sized tip was placed inside the EAC to obtain a good seal for the measurement of middle ear pressure and TM compliance. The 3 types of tympanograms and interpretations are displayed in Table 3.

Table 2. Otoscopy Grading Scheme Based on Tympanic Membrane Morphologic Characteristics.a

<table>
<thead>
<tr>
<th>Grading Category</th>
<th>Color</th>
<th>Transparency</th>
<th>Tympanic Membrane Position/Landmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pearly grey</td>
<td>Transparent</td>
<td>Clearly defined lateral process of malleus and umbro</td>
</tr>
<tr>
<td>1</td>
<td>Increased vascularity especially along the annulus</td>
<td>Translucent or semi-transparent</td>
<td>Less defined lateral process of malleus or umbro or mild bulging of tympanic membrane</td>
</tr>
<tr>
<td>2</td>
<td>Generalized erythema of tympanic membrane</td>
<td>Opaque</td>
<td>Undefined lateral process of malleus or umbro, severe bulging of tympanic membrane</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prediction</th>
<th>Composite Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal middle ear</td>
<td>0</td>
</tr>
<tr>
<td>Otitis media with effusion</td>
<td>1-5</td>
</tr>
<tr>
<td>Acute otitis media</td>
<td>6</td>
</tr>
</tbody>
</table>

aThis table depicts numeric grading of the tympanic membrane. Normal tympanic membrane had a score of 0, tympanic membrane diagnosed with otitis media with effusion had a score of 1 to 5, and acute otitis media diagnosed tympanic membrane had a score of 6. Coticchia J, Kwong K, Sulek M. Prediction of otitis media using systematic tympanic membrane grading scheme prior to myringotomy. Oral Presentation at ASPO: April, 2013.

Table 3. Tympanogram Descriptions.a

<table>
<thead>
<tr>
<th>Types</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>Normal middle ear pressure</td>
</tr>
<tr>
<td>Type B</td>
<td>Indicative of certain effusion in the middle ear and could be representative of an infection</td>
</tr>
<tr>
<td>Type C</td>
<td>Negative middle ear pressure with or without effusion</td>
</tr>
</tbody>
</table>

aType A tympanogram represents a normal shaped curve with maximum compliance of the tympanic membrane occurring at or around atmospheric pressure. Type B tympanogram represents a flat curve whereas a type C tympanogram represents a flattened curve with peak compliance below 0 indicating negative middle ear pressure.

The observations from the otoendoscopy were recorded in digital format for subsequent evaluation.

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This observational study was reviewed and approved by the Human Investigations Committee (HIC) of Wayne State University. All parents provided written informed consent before any procedures were performed.

**Results**

Eighty-six preterm infants were evaluated from February 2010 to April 2013. The median age at diagnosis was 8.3 days (range, 2-73 days); this includes 30 infants who were a part of the pilot study with an average age of 17.3 days and 56 infants evaluated between 48 and 72 hours after birth. Of the 86 infants, 43% (37/86) were males. Gestational age ranged from 23 to 35 weeks (median: 30 weeks). Median birthweight was 1340 g (range, 526-3290 g). The demographic and clinical characteristics are described in [Table 4](#).

Eighty-five of 86 infants successfully underwent otoendoscopy in at least 1 ear. Of those patients, 62 (72.9%) had an abnormal TM finding, suggesting either AOM or OME. Tympanometry was successfully performed on 120 of the total 172 ears. Of those 120 ears, 117 were successfully studied using otoendoscopy. Of those 117 ears, otoendoscopic and tympanometric findings were in agreement in 86 cases (73.5% agreement; 50 abnormal and 36 normal). The kappa measure of agreement between tympanometric and otoendoscopic findings was significant with a value of 0.467 ($P < .001$). Otoendoscopy and tympanometry success rates and results are summarized in [Tables 5 and 6](#), respectively.

There was a significant association between gestational age and the otoendoscopic findings of the 85 patients ($P = .001$). For every 1 week increase in gestational age, the odds ratio of an abnormal otoendoscopic finding decreased to 0.70 ([Table 5](#)).

The association between birthweight and otoendoscopic findings was statistically significant ($P = .003$). With every 100 g increase in gestational weight, the odds ratio of an abnormal otoendoscopic finding decreased to 0.86 ([Table 5](#)).

Otoendoscopy was not associated with any adverse event such as bradycardia, temperature instability, or desaturation.

**Discussion**

This is the first study documenting the frequency of AOM and OME in preterm infants using otoendoscopy and tympanometry.

<table>
<thead>
<tr>
<th>Variable</th>
<th>N = 86</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at diagnosis (days)</td>
<td>8.3</td>
</tr>
<tr>
<td>Male (43%)</td>
<td>37</td>
</tr>
<tr>
<td>Female (57%)</td>
<td>49</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>30</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>1340</td>
</tr>
<tr>
<td>Birth head circumference (cm)</td>
<td>27</td>
</tr>
</tbody>
</table>

**Table 4. Clinical and Demographic Characteristics of Neonates.**

The use of the 1.9 mm 0 degree endoscope allows a range of movement to obtain good visualization of the TM, despite of its horizontal orientation ([Figures 1-3](#)). Moreover, the digital capture of the otoendoscopic view of the TM allows evaluation by independent examiners. Otoendoscopy is a safe and fast technique that causes minimum discomfort to the neonates.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Predictors</th>
<th>Odds Ratio</th>
<th>95% CI for the Odds Ratio</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Univariate logistic</td>
<td>Gestational age</td>
<td>0.70</td>
<td>0.57-0.87</td>
<td>.001</td>
</tr>
<tr>
<td>Univariate logistic</td>
<td>Birthweight</td>
<td>0.86</td>
<td>0.77-0.95</td>
<td>.003</td>
</tr>
<tr>
<td>Univariate logistic</td>
<td>Birth head circumference</td>
<td>0.83</td>
<td>0.69-0.98</td>
<td>.030</td>
</tr>
</tbody>
</table>

**Table 5. Statistical Analyses.**

*This table depicts the univariate odds ratios, along with 95% confidence intervals and $P$ values, for each of the predictors (changes in gestational age by 1 day, birthweight by 100 g, and birth head circumference by 1 cm) with respect to abnormal otoendoscopic findings.
TM abnormalities were assessed with a graded otoendoscopic score (Table 2). This grading system had been validated in another study by comparing otoendoscopic grade to tympanocentesis results in children undergoing bilateral myringotomy and tubes for recurrent acute otitis media or...

**Table 6. Otoendoscopy Results.**

<table>
<thead>
<tr>
<th>Category</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who underwent successful otoendoscopy in at least 1 ear</td>
<td>98.8% (85/86)</td>
</tr>
<tr>
<td>Patients who underwent successful otoendoscopy in both ears</td>
<td>91.9% (79/86)</td>
</tr>
<tr>
<td>Patients who underwent successful otoendoscopy in only one ear</td>
<td>6.9% (6/86)</td>
</tr>
<tr>
<td>Total number of ears examined with otoendoscopy</td>
<td>95.3% (164/172)</td>
</tr>
</tbody>
</table>

Diagnoses according to the grading scale:
- No demonstrable pathology 37.8% (62/164)
- Otitis media with effusion 31.7% (52/164)
- Acute otitis media 30.5% (50/164)

**Table 7. Tympanometry Results.**

<table>
<thead>
<tr>
<th>Category</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who underwent successful tympanometry in at least 1 ear</td>
<td>75.6% (65/86)</td>
</tr>
<tr>
<td>Patients who underwent successful tympanometry in both ears</td>
<td>63.9% (55/86)</td>
</tr>
<tr>
<td>Patients who underwent successful tympanometry in only one ear</td>
<td>11.6% (10/86)</td>
</tr>
<tr>
<td>Total number of ears diagnosed with tympanometry</td>
<td>69.8% (120/172)</td>
</tr>
</tbody>
</table>

Type A tympanograms 48.3% (58/120)
Type B tympanograms 36.7% (44/120)
Type C tympanograms 15.0% (18/120)

**Figure 1.** Otoendoscopy image of a tympanic membrane of a preterm infant with no demonstrable pathology. Score evaluated using the grading scale. The membrane is unremarkable, transparent with clearly defined landmarks.

**Figure 2.** Otoendoscopy image of tympanic membrane of a preterm infant with otitis media with effusion. Score evaluated using grading scale. The membrane is translucent showing increased vascularity and less defined landmarks.

**Figure 3.** Otoendoscopy image of tympanic membrane of a preterm infant with acute otitis media. Score evaluated using the grading scale. The membrane is hypervascular, opaque, and shows undefined landmarks with bulging.

TM abnormalities were assessed with a graded otoendoscopic score (Table 2). This grading system had been validated in another study by comparing otoendoscopic grade to tympanocentesis results in children undergoing bilateral myringotomy and tubes for recurrent acute otitis media or...
chronic otitis media with effusion. The sensitivity and specificity of detecting OME were 94.7% (95% CI, 73.5-100.0) and 91.2% (95% CI, 76.3-97.7), respectively. For AOM, the sensitivity and specificity of detection were 85.7% (95% CI, 46.6-99.5) and 100% (95% CI, 90.8-100.0), respectively.\(^{22}\)

The evaluation of middle ear disease sometimes includes tympanocentesis for microbial assessment. However, this procedure was not performed because of the observational nature of the study and the need for preliminary data before the study would consider this procedure in preterm neonates. This is a limitation of the study, and this is why we refer to otoendoscopy-diagnosed disease.

That previous studies of infants evaluated in the NICU showed little agreement between otoendoscopy and tympanometry may be related to the inability of the technique to distinguish a pliable ear canal from TM mobility.\(^{23,24}\) The agreement in findings between otoendoscopy and tympanometry herein could be explained by the optimal visualization and assessment of the TM using the otoendoscopy technique. This technique may become a useful diagnostic tool for middle ear diseases in preterm neonates.

Several investigators have described AOM or purulence in the middle ear of term and preterm infants.\(^{4-6,24-26}\) Some of these conclusions were based on clinical examinations while others were based on histological examination of the temporal bone.\(^{6,27,28}\) The anatomical constraints of clinical exam of the middle ear in preterm infants may account for some of the variability in the literature. The validated otoendoscopic examination within the first 72 hours of birth combined with blinded high frequency tympanometry provides high resolution images of the TM in preterm infants. This advanced imaging technique enabled us to overcome the difficult anatomical challenges previously described.

Among previous studies on ear infections in neonates, some specifically focused on the presence of amniotic fluid in the middle ear, suggesting its role in this pathology.\(^{3,6,27,29-31}\) The study designs ranged from examining the middle ear cavity histologically for the presence of amniotic aspirations to determining the association of meconium stained amniotic fluid with the incidence of OM in neonates—preterm, full-term newborns, as well as deceased. This concept has been discussed by Eavey\(^{3}\) in a study that involved (1) clinical examination of neonates for TM abnormalities, (2) retrospective histological analysis of temporal bones of deceased neonates for the presence of amniotic fluid cellular content, and (3) a demonstration of the concept using an animal model. This investigation found abnormality in approximately 97% of TMs in a cohort of full-term and preterm infants. Histological examination of temporal bones from term infants demonstrated the presence of mesenchyme, fluid, and squamous debris in the middle ear. The animal study demonstrated that amniotic fluid cellular contents elicit a pathological inflammatory response in the middle ear.\(^{3}\)

Both AOM and OME are clinical diagnoses that require specific findings. For AOM, there should be presence of middle ear effusion and otoscopic signs of middle ear inflammation and rapid onset of signs and symptoms such as irritability, fever, and otalgia. For OME, there should be a presence of middle ear effusion without otoscopic evidence of substantial inflammation of the middle ear.\(^{32}\)

However, these evidence-based clinical practice guidelines for AOM are recommended for patients “from 2 months through 12 years of age with uncomplicated acute otitis media.” Unfortunately, preterm neonates in the NICU do not demonstrate systemic signs of infection such as “fever, irritability, and otalgia.” The first sign of AOM in preterm neonates is often spontaneous drainage without any preceding systemic symptomatology. It is obvious from these definitions that accurate in vivo imaging is a prerequisite to arrive at clinical diagnoses.

Since the underlying organisms causing infection, if any, were not known, it was difficult to feel confident that the right problem was being addressed. In order to adequately address the infectious entity, some mechanism to identify underlying pathogens needs to be incorporated with these diagnostic tests. Optical coherence tomography (OCT) or any other noninvasive modality for detection and identification of pathogens would present a feasible approach toward this end.

A review of literature also demonstrated that there is an approximately 3-fold increase in the size of the oval window between 24 and 35 weeks in utero. In addition, there is incomplete mineralization of the otic capsule before 31 weeks.\(^{33}\) These histological observations suggest that the normal anatomical barriers between the middle ear and inner ear may not be fully developed, thus raising the specter that infectious or inflammatory products from the middle ear may more readily gain access into the inner ear.

Although postmortem histological examination of the temporal provides information regarding pathology of the middle ear, these studies cannot be extrapolated to provide clinical information regarding active infection or inflammation of the middle ear. Although this concept has been outlined in several studies, the high variability in the methods and results of these studies makes it impossible to draw any valid conclusion and warrants a more directed state-of-the-art approach.

The most important anatomical risk factor for OM in infants and toddlers is functional or anatomical variation of the eustachian tube (ET). The normal function of the ET is ventilation, drainage, and protection of the middle ear from infected nasopharyngeal secretions. Anatomically, the ET in younger children compared to adults is shorter, with a less acute angle. We hypothesize that a shorter and flatter ET allows more reflux of nasopharyngeal contents into the middle ear. It is quite probable that extremely preterm infants would have a very short ET, and this may predispose them to endoscopically diagnosed OM.

There are several limitations in this study. First, the small sample size may limit the possibility of performing meaningful subgroup analysis to investigate the differences in OM frequency in preterm neonates based on birth weight, gestational age, or other potential risk factors, such as history of nasotracheal intubation, perinatal infections, and so on.
Second, the inability to perform tympanometry on all the patients due to difficult EAC anatomy may have skewed the results in either direction. This problem could be addressed in future studies by using custom-made tympanometry probes sized appropriately for preterm infants. Third, the lack of pathogen identification is a limitation. Given that underdiagnosed OM could be a risk factor for hearing loss and serious central nervous system infection, consideration must be given to tympanocentesis so that a firm diagnosis can be established and a rational choice of antimicrobial agents be made. Lastly, the design of this study was cross-sectional in nature. Longitudinal studies are desirable.

The results of our study demonstrate that otoendoscopically diagnosed OM is a common entity in preterm infants, particularly during the first 72 hours of life. Underdiagnosis of OM has potentially serious consequences. For example, undiagnosed acute bacterial OM may be a source of microorganisms that could invade the bloodstream and predispose to labyrinthitis, leading to hearing loss, meningitis, and encephalitis. Also, since the temporal bone has not yet matured in these preterm infants, it is unclear if standard anatomic barriers of the round window and oval window would prevent the spread of infectious or inflammatory mediators from the middle to the inner ear.

Future studies include: (1) the use of a custom-made tympanometry probe to enhance the fit in the EAC, or even replacement of tympanometry with acoustic reflectometry, which is not dependent on the fit of an EAC probe; (2) longitudinal examinations; (3) incorporating a hearing assessment, such as an auditory brainstem response and otosaccular emission, to elucidate the relationship between congenital OM and hearing impairment in preterm infants; and (4) middle ear fluid aspiration via tympanocentesis for pathogen identification.

Author Contributions

James Coticchia, conception and design, acquisition of data, analysis of data, drafting the article, final approval of the manuscript; Priyanka Shah, design of study, acquisition of data, analysis of data, drafting the article, final approval of the manuscript; Livjot Sachdeva, conception and design, acquisition of data, analysis of data, drafting the article, final approval of the manuscript; Kelvin Kwong, acquisition of data, analysis of data, drafting the article, final approval of the manuscript; Jose M. Cortez, design of study, analysis of data, revising the article for important intellectual content, final approval of the manuscript; Tracy Rudd, acquisition of data, drafting the article, final approval of the manuscript; Javan Nation, acquisition of data, drafting the article, final approval of the manuscript; Marwan Zidan, design of study, analysis of data, revising the article for important intellectual content, final approval of the manuscript; Eugene Cepeda, design of study, analysis and interpretation of data, drafting the article, final approval of the manuscript; Bernard Gonik, conception and design, revising the article for important intellectual content, final approval of the manuscript.

Disclosures

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Sponsorships: None.

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References


