Chronic Otitis Media With Effusion Sequelae in Children Treated With Tubes

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Objective: To determine incidence and prevalence of middle ear sequelae and abnormal tympanometry results among children with chronic otitis media with effusion (OME) who received standard treatment with tympanostomy tubes.

Design: Prospective cohort study.

Setting: Community clinic and academic medical center.

Patients: A total of 140 children followed up for 8 years after tube treatment.

Main Outcome Measures: Tympanic membrane perforation, atrophy, retraction, hearing loss, myringosclerosis, low static admittance (SA) and broad-peaked tympanogram, high SA and narrow-peaked tympanogram, and negative tympanometric peak pressure.

Results: Annual incidence of sequelae was typically greater during 3 to 5 years than 6 to 8 years of follow-up. Greatest increases in incidence during the 5-year follow-up were for atrophy (67%), high SA and narrow-peaked tympanogram (70%), and retraction pocket (47%). Prevalence of these sequelae also increased over time, whereas low SA and broad-peaked tympanogram and negative tympanometric peak pressure decreased during follow-up. Sequela tended to become bilateral over time, and concordance of different sequelae in the same ear was low ($\kappa$, 0.05-0.42).

Conclusions: Annual incidence of sequelae decreased during follow-up. This finding parallels decreasing incidence of OME and tube placement as children mature and demonstrates that sequelae are more likely to develop during active acute and chronic OME. The cumulative effect of incidence resulted in few ears free of sequelae by 8 years of follow-up. Based on this cohort of healthy children with OME, although the risk of sequelae decreased over time, functional and morphologic sequelae were prevalent and may put children at risk for continuing middle ear problems as they grow into adolescence and adulthood.


Tympanic membrane (TM) and middle ear sequelae have been reported in children who experience chronic otitis media with effusion (OME). This condition is often treated with tympanostomy tubes, making it difficult to separate effects of disease from effects of treatment. However, well-designed randomized studies have demonstrated that among children with chronic OME, some sequelae (e.g., myringosclerosis) are more common after tube treatment, whereas others occur at the same rate in tubed and untubed ears.1,4 The proportion of children or ears with a sequela at a given point in time (prevalence) can be estimated in a cross-sectional study, providing information about its current impact on the population. However, measuring development of new sequelae over time (incidence) requires a prospective study with regular follow-up. In contrast to prevalence, incidence data provide estimates of the risk of developing the sequela during a specified period in those who are free of it at the outset. There are only a few prospective studies with long-term follow-up and regular examination that are useful for determining the timing and concurrence of sequelae development.2,5 Sequelae incidence and prevalence rates among children with chronic OME treated with tympanostomy tubes who participated in the Long-term Sequelae of Otitis Media Study are presented herein.6

METHODS

PARTICIPANTS

Between February 26, 1987, and January 22, 1990, 6-month-old to 8-year-old children from
a suburban multispecialty clinic were enrolled in the study at the time of tympanostomy tube treatment for chronic OME (≥8 of the past 12 weeks). Children were excluded if they had pre-existing OM complications, sequelae, anatomic conditions predisposing to OM (eg, Down syndrome, craniofacial anomalies), sensorineural hearing loss of greater than 15 dB, or serious health problems. Inclusion and exclusion criteria are described in more detail in a previous publication. Written parental consent was obtained at the outset of the study, and at the time video-otoscopy and multifrequency tympanometry testing were initiated. The study was originally and annually approved by the University of Minnesota and Park Nicollet Medical Center Institutional Review Boards. Participants were examined quarterly for 3 years by otolaryngologists, semiannually during the fourth and fifth years, and annually after April 1995, when participants had been in the study at least 5 years. Examinations included pneumatic otoscopy, tympanometry, and air and bone conduction pure-tone audiometry. Video-otoscopy and multifrequency tympanometry (500-2000 Hz) were added beginning with the third annual visit. Agreement about retraction between 3 and 8 years for 3 examiners (L.L.H., R.M., G.S.G.) who reviewed videotaped otomicroscopy about retraction between 3 and 8 years for 3 examiners (L.L.H., R.M., G.S.G.) who reviewed videotaped otoscopy and multifrequency tympanometry testing was initiated. The study was originally and annually approved by the University of Minnesota and Park Nicollet Medical Center Institutional Review Boards. Participants were examined quarterly for 3 years by otolaryngologists, semiannually during the fourth and fifth years, and annually after April 1995, when participants had been in the study at least 5 years. Examinations included pneumatic otoscopy, tympanometry, and air and bone conduction pure-tone audiometry. Video-otoscopy and multifrequency tympanometry (500-2000 Hz) were added beginning with the third annual visit. Agreement about retraction between 3 and 8 years for 3 examiners (L.L.H., R.M., G.S.G.) who reviewed videotaped otomicroscopy was substantial (κ > 0.75).6,7 Criteria for additional tube surgery during the study were OME for 8 weeks, 2 symptomatic OM episodes in the previous 3 months, or OM with average hearing loss of 20 dB or greater from 500 to 4000 kHz.

Incidence and prevalence of each sequela, including abnormal tympanometric measures, were calculated using ears as the unit of analysis. Some sequelae were assessed as present or absent. These included myringosclerosis, a white plaque with distinct margins on the TM surface; perforation, presence of a visible hole with absent TM mobility in an ear without a tube; and retraction pocket, atrophic area that moved principally to negative canal pressure. Other sequelae were graded, including generalized atrophy, hypermobility of thinned areas affecting 50% or more of the TM; and segmental atrophy, thinned areas affecting less than 50% of the TM. Pars tensa and flaccida severity definitions (mild, moderate, severe) appear in Table 1. The combined measure of retraction included pars tensa, pars flaccida, and/or retraction pocket. Since less than 3% of ears developed generalized atrophy between 3 and 8 years of follow-up, segmental and generalized atrophy were combined for the analyses. Collection of pars tensa and pars flaccida retraction data was initiated after the third year of follow-up; therefore, the prevalence of these 2 types of retraction and combined retraction were reported beginning with the sixth year. Hearing loss was defined as an average hearing level (500-4000 Hz) of 20 dB or higher or any of the thresholds at 30 dB or higher. For abnormal tympanometric measures, criteria for low static admittance (SA)/broad-peaked tympanogram were defined as an SA of 0.3 millimho or less or a tympanometric width of 160 daPa or higher. Criteria for high SA and narrow-peaked tympanogram were an SA of greater than 1.1 millimho or a tympanometric width of less than 80 daPa. Negative tympanometric peak pressure (TPP) was defined as −150 to −400 mm.

### Table 1. Proportion of Ears With Pars Tensa and Pars Flaccida Retraction by Severity

<table>
<thead>
<tr>
<th>Retraction</th>
<th>Description</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pars tensa</td>
<td>Mild Drumhead retraction without atrophy</td>
<td>0.12</td>
<td>0.08</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Moderate Retraction limits visible with or without touching bone</td>
<td>0.15</td>
<td>0.25</td>
<td>0.24</td>
</tr>
<tr>
<td></td>
<td>Severe Limits visible or not and adhered to bone</td>
<td>0.01</td>
<td>0.07</td>
<td>0.06</td>
</tr>
<tr>
<td>Pars flaccida</td>
<td>Mild Retraction barely noticeable</td>
<td>0.15</td>
<td>0.17</td>
<td>0.21</td>
</tr>
<tr>
<td></td>
<td>Moderate Neck of malleus visible</td>
<td>0.06</td>
<td>0.12</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>Severe Depth of retraction out of view, onto the malleus</td>
<td>0.01</td>
<td>0.02</td>
<td>0.02</td>
</tr>
</tbody>
</table>

### RESULTS

Mean age at the 3-year follow-up was 5.5 years (SD, 1.8 years; range, 3.5 -11.1 years), and 61% of participants were male. By the third year of follow-up, 44% of ears had undergone 1 tube surgical procedure, 32% had undergone 2 tube surgical procedures, and 24% had undergone more than 2 tube surgical procedures; 84% of additional tubes underwent 1 tube surgical procedure, 32% had undergone 2 tube surgical procedures, and 24% had undergone more than 2 tube surgical procedures; 84% of additional tubes

STATISTICAL ANALYSIS

To determine if incidence and prevalence rates could have been affected by study withdrawal, the continuity-adjusted χ2 test was used to compare prevalence of sequelae at 3 years for withdrawals between 3 and 8 years (n=96 ears) and those who completed the 8-year visit (n=176 ears). Time to first occurrence of each sequela was calculated as the time interval between the visit date at year 3 and the visit date when the sequela was first observed. An ear was followed up until the sequela developed, the annual visit was missed, or the year 8 visit occurred. The actuarial method was used to estimate the percentage of ears without the sequelae between 3 and 8 years of follow-up. Ears of children who missed an annual visit were censored in the analysis because we assumed that ears free of sequelae and abnormal tympanometric measures at visits 2 years apart were not necessarily free of them for the entire interval. Incidence was defined as 100 minus the percentage not developing the sequela each year and was calculated only for those ears that were free of a specific sequela at 3 years of follow-up. Incidence of combined retraction was not calculated because of sparse data on pars tensa and flaccida retraction before 6 years of follow-up.

Prevalence was calculated by dividing the number of ears with a specific sequela by the total number of ears examined at that study visit. Prevalence at 3 and 8 years of follow-up was stratified by total number of tube surgical procedures by the third year of follow-up and compared with Mantel-Haenszel χ2 test for trend. The κ statistic was used to examine concordance between specific findings in the same ear (low SA and broad-peaked tympanogram and hearing loss, high SA and narrow-peaked tympanogram and atrophy, negative TPP and combined retraction) at 3 and/or 8 years. The κ statistic compared agreement between 2 variables (sequelae) in the same ear (both present or both absent) corrected for agreement observed by chance. We also evaluated prevalence of unilateral and bilateral sequelae (myringosclerosis, atrophy, combined retraction, hearing loss).
were placed during the first 3 years of the study. Two hundred seventy-five ears of 138 children were examined and/or tested at 3 years, and 167 ears of 84 children were examined and/or tested at 8 years. Rates of sequelae (myringosclerosis, atrophy, TM perforation, and hearing loss) at 3 years of follow-up did not differ significantly, *P*=.19, ‡P> .99, §P> .99, and ‡P > .61, respectively) for those who withdrew from the study and those who completed the 8-year follow-up.

Patterns of incidence varied by sequelae (Table 2). In general, annual incidence was greater in the 4- to 5-year follow-up than in the 6- to 8-year follow-up, with the range of annual incidence between 0% and 18%. Incidence of specific sequelae varied substantially. Sixty-seven percent of ears developed atrophy, 40% developed myringosclerosis, and 3% developed perforation between 3 and 8 years of follow-up (Table 2). One child had a cholesteatoma diagnosed 7 years after enrollment. At surgery, the cholesteatoma was found in a 3-mm-deep retraction pocket in the right ear that extended to the medial wall of the middle ear cleft. This child had been treated with only one set of tympanostomy tubes before cholesteatoma diagnosis.

Unlike incidence data that provide information about the risk of new sequelae in a 1-year period among ears without the sequela at the beginning of the period, prevalence describes the proportion of all ears with a given sequela at a specific point in time. Prevalence of sequelae and abnormal tympanometric measures between 3 and 8 years of follow-up are shown in the Figure, and prevalence of mild, moderate, and severe pars tensa and flaccida between 6 and 8 years of follow-up are given in Table 1. Perforation of the TM was the least prevalent at both times, affecting only 2% of ears. At year 8, the most prevalent sequelae were atrophy and pars tensa/flaccida retraction, each present in 55% of ears (Figure). Tympanometric measures of middle ear function changed considerably over time, although most children had normal hearing throughout the follow-up period. Prevalence of low SA and broad-peaked tympanograms declined from 38% to 8%, whereas high SA and narrow-peaked tympanograms increased from 23% to 64% (Figure). Related middle ear and TM changes (atrophy, retraction pockets) also increased throughout the same period. Of the 165 ears examined at 8 years of follow-up, 22 had no TM sequelae, 35 had no tympanometric

Table 2. Proportion of Sequela-Free Ears at 3 to 8 Years of Follow-up and Annual Incidence of Sequelae

<table>
<thead>
<tr>
<th>Sequela</th>
<th>Cumulative Proportion Without Sequela by Year of Follow-up (±2 SEs)</th>
<th>(Annual Incidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 Years</td>
<td>4 Years</td>
</tr>
<tr>
<td>Retraction pocket (n = 188)</td>
<td>1.00</td>
<td>0.92 (±0.04) [0.08]</td>
</tr>
<tr>
<td>Atrophy (n = 182)</td>
<td>1.00</td>
<td>0.83 (±0.06) [0.17]</td>
</tr>
<tr>
<td>Myringosclerosis (n = 137)</td>
<td>1.00</td>
<td>0.83 (±0.07) [0.17]</td>
</tr>
<tr>
<td>Hearing loss (n = 251)</td>
<td>1.00</td>
<td>0.94 (±0.03) [0.06]</td>
</tr>
<tr>
<td>Perforation (no tube) (n = 186)</td>
<td>1.00</td>
<td>0.99 (±0.02) [0.01]</td>
</tr>
<tr>
<td>Negative peak pressure (n = 201)</td>
<td>1.00</td>
<td>0.85 (±0.05) [0.15]</td>
</tr>
<tr>
<td>High static admittance/narrow peaked tympanogram†‡ (n = 213)</td>
<td>1.00</td>
<td>0.83 (±0.05) [0.17]</td>
</tr>
<tr>
<td>Low static admittance/broad peaked tympanogram§ (n = 172)</td>
<td>1.00</td>
<td>0.91 (±0.04) [0.09]</td>
</tr>
</tbody>
</table>

*One hundred percent of ears included in the analysis were free of the specific sequela at year 3.
†High static admittance was defined as 1.1 millimho or higher or a tympanometric width of less than 80.
‡Tympanometric peak pressure was −150 to −400 mm.
§Low static admittance was defined as 0.3 millimho or lower or a tympanometric width of 160 or higher.

A, Percentage of ears with the sequela at 3 to 8 years of follow-up. B, Percentage of ears with tympanometric abnormality or hearing loss at 3 to 8 years of follow-up.
abnormalities, but only 9 were normal (no sequelae or abnormal tympanometric measures). Five children had no sequelae in either ear, 7 had normal tympanometry in both ears, but only 2 had normal ears bilaterally.

Prevalence of myringosclerosis, retraction pocket, and negative TPP increased significantly \( (P = .002, P = .01, \) and \( P = .008, \) respectively) with the number of tympanostomy tube treatments at 8 but not at 3 years of follow-up. The proportion of ears with low SA and broad-peaked tympanograms showed a significant increase with number of tubes at 3 but not 8 years of follow-up, whereas hearing loss increased at both time points as the number of tubes increased. None of the other sequelae were related to number of tube surgical procedures (data not shown).

Occurrence of similar morphologic sequelae and abnormal tympanometric measures in the same ear at 3 and 8 years of follow-up were evaluated. At 3 years of follow-up, 30% of ears had low SA and broad-peaked tympanograms alone, none had hearing loss alone, and 7% had both. Most ears were free of both sequelae at 3 and 8 years (63% and 90%, respectively). Fifteen percent of ears had high SA and narrow-peaked tympanograms alone, 19% had atrophy alone, and 6% had both at 3 years of follow-up. In contrast, at 8 years of follow-up, 27% of ears had high SA and narrow-peaked tympanograms alone, 15% had atrophy alone, and 39% had both. Also at year 8, 42% of ears had combined retraction alone, less than 1% had negative TPP alone, and 13% had both combined retraction and negative TPP \( (\kappa = 0.20). \) The only paired sequelae to achieve moderate concordance \( (\kappa = 0.42) \) were hearing loss and low SA and broad-peaked tympanogram at 8 years of follow-up. However, the 2 sequelae most likely to occur in the same ear were high SA and narrow-peaked tympanogram and atrophy \( (39\%) \) at 8 years of follow-up.

Whether a sequela was primarily unilateral or bilateral varied by sequela type and years of follow-up. With the exception of hearing loss, children were more likely to have bilateral than unilateral sequelae by 8 years of follow-up. Comparing hearing loss over time, 2% of children had hearing loss at both 3 and 8 years, 5% had hearing loss at 3 but not at 8 years, and 3% had hearing loss at 8 but not at 3 years.

### Comment

This study demonstrates that annual risk of new OM sequelae (incidence) declined considerably throughout 3 to 8 years of follow-up for most sequelae studied. Declining incidence of OM (low SA and broad-peaked tympanogram) and its sequelae reported in this study parallels the pattern of decreasing OM incidence and prevalence in childhood reported by others.\(^{10,11}\) Nine percent to 18% of ears per year showed evidence of a new episode of OME or middle ear dysfunction (tympanograms with low SA and broad-peaked tympanogram or negative TPP) during the fourth and fifth years of follow-up, which decreased to 0% to 8% per year in the sixth through eighth years. With fewer episodes of acute and persistent OME during the later period, a decrease in both tympanostomy tube treatment and the inflammatory processes that result in permanent changes to the TM and middle ear (eg, myringosclerosis, perforation) were also less likely to occur, leading to a decreasing incidence of sequelae over time. In contrast, annual incidence rates for 3 sequelae (atrophy, high SA and narrow-peaked tympanogram, and retraction pocket) showed a lower rate of decrease throughout the entire follow-up period and remained at 9% to 15% at 8 years of follow-up. These sequelae are related in that they are either indicators of an overly compliant TM (high SA) or they are the consequence of TM thinning and damage (atrophy and retraction pocket). Repeated OM episodes (as evidenced by the 8% or greater prevalence of flat tympanograms throughout follow-up) initiate production and release of an inflammatory mediator cascade. One of these mediators (collagenase) breaks down collagen fibers, thereby thinning and weakening the TM, which becomes prone to hypermobility, generalized atrophy, and retraction and may not be able to return to its normal state.

Incidence of atrophy was higher than that of myringosclerosis between 3 and 8 years of follow-up. Myringosclerosis tends to occur earlier in the disease process and is associated with tube insertion.\(^{1-4,13}\) and new occurrences are less frequent over time. The proportion of ears free of myringosclerosis declined at the same rate as high SA and atrophy until about 5 years (Table 2). At that point, the percentage of ears free of myringosclerosis showed a lower rate of decline, whereas the percentage of ears free of atrophy and high SA declined at a higher rate. The Figure depicts the increasing prevalence of atrophy and high SA and the leveling off of myringosclerosis prevalence. Rising annual prevalence in permanent sequelae results from existing cases and incident cases occurring during the next year.

The high prevalence of sequelae and the finding that only 9 ears were free of sequelae and tympanometric abnormalities at 8 years reveal that few children in this study escaped sequelae associated with chronic OME and tube treatment. However, some of these effects are transient (negative TPP, flat tympanograms) or do not appear to confer any negative functional effects on the eardrum or middle ear (myringosclerosis). Only a few ears developed serious sequelae (cholesteatoma, perforation, severe retraction) during the 5 years of follow-up.

Hearing loss, an OM sequela of interest to both clinicians and researchers, was less common during follow-up than many other sequelae. Researchers have shown that conductive hearing loss associated with OM is typically in the mild-to-moderate range, with approximately 30% of children with OME having hearing levels greater than 20 dB.\(^{14,15}\) In an earlier report\(^{6}\) on this cohort, 5- to 6-dB poorer hearing levels were associated with TM retraction occurring between 4 and 6 years of follow-up. Maw and Bawden\(^6\) reported a similar finding of 3- to 4-dB poorer hearing associated with attic retraction at 7 and 10 years after tube treatment.\(^2\) Also in this cohort, numbers of study visits with OM and tympanostomy tube placements significantly predicted high-frequency (4000-kHz) hearing loss among effusion-free ears.\(^{16}\) The one child who developed cholesteatoma (0.7%) during follow-up after tube placement is consistent with the finding that 0.6% of ears developed cholesteatoma during an average follow-up of 4 years.\(^{17}\)
We know of no other reports of annual incidence of OM sequelae, although others have reported prevalence of sequelae in children with chronic OME or recurrent OM treated with tympanostomy tubes. Rates of myringosclerosis during 3 to 6 years of follow-up (44%-54%) in the current study were similar to previous reports of 29% to 48%. However, prevalence of atrophy was considerably more variable. Maw and Bawden reported that 24% and 21% of ears in their cohort had segmental atrophy at 4 and 7 years, respectively, of follow-up compared with 25% to 48% of ears in our cohort with generalized or segmental atrophy during the same follow-up period. In the study by Schilder et al, prevalence of atrophy was 75% at 3 to 6 years of follow-up, but these authors did not provide a definition of atrophy, and nearly half of the tube recipients were excluded from the study because they did not meet various criteria, which could account for higher reported rates. Retraction rates of 26% to 37% have been reported at 4 to 8 years of follow-up compared with pars tensa and pars flaccida retraction rates of 38% at 6 years in this study. We used the retraction definitions of these authors, so the rates should be directly comparable.

The prevalence of specific sequelae (myringosclerosis, retraction pocket, TPP, hearing loss) increased with the number of tube treatments by 8 years of follow-up. However, since all children with chronic OME in this study were treated with tubes, it cannot be specifically determined whether sequelae are the consequence of disease persistence and severity or the result of number of tube treatments for refractory disease. Four studies that assigned ears to unilateral tympanostomy tube placement have reported TM sequelae 2 to 10 years later. Reported rates of tympanosclerosis (myringosclerosis) in the tubed ear have ranged widely: 20% at 10 years, 42% at 5 years, 48% at 1 to 3 years, and 57% at 2 years. In each study, the rate in the tubed ear was significantly higher than the rate in the nontubed or unoperated ear. The wide range of myringosclerosis rates associated with tubes could be due to tube type, cotreatment with adenoidectomy, age, OME severity, or other factors. Associations of retraction and atrophy with tympanostomy tubes are less strongly supported. In one study, atrophy or retraction occurred in 25% of tubed ears compared with 6% of ears not treated with tubes (P = .05). However, 3 other studies reported no relationship between tubes and retraction. Unspecified region of retraction was reported in 15% of tubed ears vs 11% of ears without tubes; pars tensa retraction occurred in 18% of tubed ears and 16% of ears without tubes; and attic retraction was present in 35% of tubed and 34% of nontubed ears, whereas rates of pars tensa retraction were the same for both ears (13%). Localized pars tensa atrophy was reported in 6% of tubed ears and 4% of ears not treated with tubes, whereas moderate-to-severe atrophy was present in 7% of tubed ears and 9% of nontubed ears. At 10 years of follow-up, Maw and Bawden found that 22% of tubed ears and 5% of nontubed ears had localized pars tensa atrophy.

Sequelae tended to be bilateral rather than unilateral at 8 years of follow-up. Previous studies have shown that bilateral acute OM and OME predict later chronic or recurrent OME. This suggests that bilaterality may represent a more serious disease process that in turn results in bilateral sequelae. Presence of different sequelae in the same ear probably results from the ongoing effects of chronic OME complicated by episodes of acute OM.

The strengths of this study are that it provides long-term, comprehensive follow-up of children treated with tubes for chronic OME. Examinations were performed quarterly for the first 3 years, twice a year for the fourth and fifth years, and annually thereafter. Families who moved out of the area often continued to participate in the study, but children did drop out over time. Differential withdrawal of those who had fewer middle ear problems during follow-up could skew the results, resulting in higher incidence and prevalence rates than one would obtain if the whole cohort was available. However, it is unlikely that study withdrawals biased these results. Prevalence of sequelae studied at 3 years did not differ significantly for withdrawals and those who participated through 8 years of follow-up. A weakness of the study is that all children in the cohort had chronic OME and were treated with tympanostomy tubes, making it difficult to separate effects of disease from effects of treatment. However, only myringosclerosis has been linked to tympanostomy tubes in all studies in which ears were randomized to unilateral tube treatment. Another study weakness is that participants were not a representative sample of children with chronic OME and tubes but were typically middle class, suburban, and white.

In conclusion, based on the experience of this cohort of healthy children treated with tubes for chronic OME, sequelae typically developed earlier rather than later in disease and treatment. However, several morphologic and tympanometric sequelae (atrophy, retraction pocket, pars tensa and flaccida retraction, high SA and narrow-peaked tympanogram) were present in more than 50% of ears by 8 years of follow-up. Sequelae also tended to become bilateral over time, but concordance of similar morphologic sequelae in the same ear was only fair. Although the risk of OM decreases with age, sequelae that result from disease and/or tube treatment remain prevalent. These conditions may put children at risk for continuing middle ear problems as they grow into adolescence and adulthood.

Accepted for publication September 18, 2002.

This study was supported by research grants P01 DC00133 and P50 DC03093 from the National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Bethesda, Md.

This study was presented at the Association for Research in Otolaryngology Midwinter Meeting, St Petersburg Beach, Fla, January 30, 2002.

We acknowledge Samuel C. Levine, MD, a neurotologist who provided expertise to define the sequelae categories and design the video data collection form used in the study. He also provided valuable second opinions in examining study children and video recordings of ear examinations.

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REFERENCES


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