Complications of Otitis Media Before Placement of Tympanostomy Tubes in Children
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Objectives: To report the incidence of short-term complications from otitis media in children before placement of tympanostomy tubes (TTs) and to compare children treated according to the Agency for Health Care Policy and Research guidelines with those who were treated earlier or later than recommended.

Design: Retrospective outcomes review.

Patients: Subjects were children aged 10 or younger who had TTs inserted at a tertiary care county hospital from January 1, 1999, to December 31, 2000. Exclusion criteria included prior TT placement, any concurrent head and neck procedure, and craniofacial defects.

Intervention: Tympanostomy tube placement.

Main Outcome Measures: Any occurrences of otorrhea, tympanic membrane perforation, tinnitus, antibiotic reactions, speech or language delay, febrile seizures, or meningitis before placement of TTs documented in the county hospital records were recorded as complications. Hearing loss was considered separately.

Results: Of 147 children who met our criteria, 81 (55.1%) had 1 or more complications from otitis media before placement of TTs. Fifty-five (37.4%) had 2 to 6 complications documented. Adverse reactions to antibiotics were the most common complication, reported in 34 (23.1%).

Conclusions: Most children in this county hospital experienced short-term complications of otitis media before receiving TTs. Even the children treated “on time” according to the guidelines from the Agency for Health Care Policy and Research experienced complications; however, adherence to the guidelines had no significant effect on complications.

receiving a first set of TTs for OM at a tertiary teaching county infants within the first 4 months of age (Figure 1). The timing of TT placement is contingent on specific criteria. The AHCPR recommendations include initial testing by otoscopy with pneumatospopy and optional tympanometry. Follow-up appointments to evaluate clearing of OME are recommended at 6 and 12 weeks. At 12 weeks, audiological testing is recommended. If there is bilateral hearing loss of 20 dB or greater, referral to an otolaryngologist is optional for placement of TTs at 3 months or in children with no hearing loss (or no audiometry) and continuous OME before placement of TMs (Table 1). Strictly speaking, every child should have received audiological testing by the AHCPR protocol. However, many children did not receive the testing, and an approximation to the protocol was made to categorize this management as early, on time, or late. Management of OME, specifically placement of TTs, was considered on time in children who had hearing loss greater than 20 dB and continuous OME for 3 to 6 months or in children who had no hearing loss (or no audiometry) and continuous OME for 4 to 6 months. Tympanostomy tube placement was judged to be early in children with hearing loss greater than 20 dB and continuous OME for less than 3 months or in children with no hearing loss (or no audiometry) and continuous OME for less than 4 months. Children with no documented OME, including those children with mainly recurrent AOM, were also placed in the early management category. Management was deemed late in children with or without hearing loss with continuous OME for greater than 6 months.

Table 1. Categories of Management by Agency for Health Care Policy and Research Guidelines for Otitis Media With Effusion (OME)

<table>
<thead>
<tr>
<th>Duration of OME, mo</th>
<th>Early (n = 50)</th>
<th>On Time (n = 59)</th>
<th>Late (n = 38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>With hearing loss</td>
<td>&lt;3</td>
<td>3-6</td>
<td>&gt;6</td>
</tr>
<tr>
<td>Without hearing loss</td>
<td>&lt;4</td>
<td>4-6</td>
<td>&gt;6</td>
</tr>
</tbody>
</table>

The short-term complications and adverse effects of OM that were documented in these children before placement of TTs are summarized in Table 2. The most common short-term complication of OM (besides hearing loss) was adverse effects from antibiotic therapy; this occurred in 34 children (23.1%). The next most common complication was speech or language delay, noted in 31 children (21.1%). Otorrhea was the next most common adverse effect, recorded in 24 children (16.3%). Persistent perforation was noted in 12 children (8.2%). Febrile seizure was documented in 3 children (2.0%) before placement of TTs. Meningitis occurred in 2 children, one with viral meningitis with AOM and the second with Neisseria meningitides and concurrent AOM. Otitis externa occurred in 2 children, and tinnitus and balance problems occurred in 1 child each.

Table 2. Complications From Otitis Media in 147 Children Before Tympanostomy Tube Placement

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. (%) of Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing loss</td>
<td>67 (45.6)</td>
</tr>
<tr>
<td>Antibiotic sensitivity</td>
<td>34 (23.1)</td>
</tr>
<tr>
<td>Speech or language delay</td>
<td>31 (21.1)</td>
</tr>
<tr>
<td>Otorrhea</td>
<td>24 (16.3)</td>
</tr>
<tr>
<td>Perforation</td>
<td>12 (8.2)</td>
</tr>
<tr>
<td>Febrile seizure</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Otitis externa</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Meningitis</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Balance problems</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

Figure 1. Adverse effects of otitis media before tympanostomy tube placement.

METHODS

The population studied included all children aged 10 or younger receiving a first set of TTs for OM at a tertiary teaching county hospital from January 1, 1999, to December 31, 2000. Data were gathered by retrospective medical chart review from birth or earliest record until placement of TTs. Exclusions included any concurrent head and neck surgery performed at the time of first TT placement, any craniofacial deformity, and any prior TT placement or any other prior ear surgery. Hearing was assessed using visual reinforcement audiometry or pure-tone audiometry. In some cases, school or clinic auditory screening test results were used in the absence of other testing. A 2-sided unpaired t test was used to compare rates of complications in the groups of children according to adherence to the AHCPR guidelines. The management of OM in these children was compared with the model taken from the AHCPR guidelines. Children were categorized as “early,” “on time,” or “late” based on the continuous duration of OME and the results of audiometric testing if done before placement of TTs (Table 1). Strictly speaking, every child should have received audiological testing by the AHCPR protocol. However, many children did not receive the testing, and an approximation to the protocol was made to categorize this management as early, on time, or late. Management of OME, specifically placement of TTs, was considered on time in children who had hearing loss greater than 20 dB and continuous OME for 3 to 6 months or in children who had no hearing loss (or no audiometry) and continuous OME for 4 to 6 months. Tympanostomy tube placement was judged to be early in children with hearing loss greater than 20 dB and continuous OME for less than 3 months or in children with no hearing loss (or no audiometry) and continuous OME for less than 4 months. Children with no documented OME, including those children with mainly recurrent AOM, were also placed in the early management category. Management was deemed late in children with or without hearing loss with continuous OME for greater than 6 months.

RESULTS

The short-term complications and adverse effects of OM that were documented in these children before placement of TTs are summarized in Table 2. The most common short-term complication of OM (besides hearing loss) was adverse effects from antibiotic therapy; this occurred in 34 children (23.1%). The next most common complication was speech or language delay, noted in 31 children (21.1%). Otorrhea was the next most common adverse effect, recorded in 24 children (16.3%). Persistent perforation was noted in 12 children (8.2%). Febrile seizure was documented in 3 children (2.0%) before placement of TTs. Meningitis occurred in 2 children, one with viral meningitis with AOM and the second with Neisseria meningitides and concurrent AOM. Otitis externa occurred in 2 children, and tinnitus and balance problems occurred in 1 child each.

Of 147 children who met the inclusion criteria, 81 (55.1%) had 1 or more short-term complications from OM before placement of TTs. This number increased to 105 (71.4%) when hearing loss greater than 20 dB was included. Fifty-three children (36.1%) had between 2 and 10 complications documented (Figure 1). Hearing loss of 20 dB or greater was found in 67 children (45.6%) of the 147 total children and 78.8% of the 85 children with documented hearing tests. Sixty-two (42.2%) of the children had no documented hearing test.

The mean number of short-term complications before surgery in the entire group of children was 1.2. Children in the early management group had a mean of 1.0 complication. Children in the on-time group had a mean of 1.1 complications.
of 1.3 complications. Children in the late management group had a mean of 1.3 complications. There were no statistically significant differences between these means using a 2-tailed nonpaired t test among subgroups compared individually or compared with the remainder of the population.

Complications increase with age by 0.1 complication per year, from 1.0 complication at age 1 year (Figure 2). This trend of increased number of complications with increasing age in the total group of children was not statistically significant. The mean age of children increased in the management groups from 2.2 years in the early group to 2.7 years in the on-time group to 3.4 years in the late group. The variable of age is thus confounded with the management of OME in predicting increasing complications.

The variables of ethnicity and sex were compared with complication rates and had no significant associations. The population included 87 boys and 60 girls. The children included 38 African American patients (including 16 with African immigrant parents), 35 Hispanic patients, 12 Native American patients, 2 Southeast Asian patients, and 40 white patients.

The analysis of complications considered hearing loss separately, as it has a significant adverse effect on children. However, the selection of those who underwent a first placement of TTs is confounded by selection of children with hearing loss, because hearing loss is a factor in the recommended protocol to determine the need for TT placement.

Despite the availability of audiology services at all clinics, 42% of the children had no prior audiogram. All of the procedures were performed by an otolaryngologist on a teaching service at the county hospital. No patient was operated on without a staff otolaryngologist examining the patient in the clinic, reviewing the history, and agreeing to perform the procedure. All of the staff were familiar with the AHCPR recommendations. Because this was a retrospective study, there was no protocol to determine the exact indications for TT placement. Each otolaryngologist in the clinic used his or her best judgment in decision making for patient management. Variations from the AHCPR recommendations occurred because of many factors, including decisions made by otolaryngologists, primary care physicians, parents, and children. Not all of the staff believed each child would be best served by the AHCPR recommendations. Private discussions following this study indicated that some otolaryngologists believed that the audiogram was unnecessary because the decision to place TTs was made based on the history and physical examination; therefore, the audiogram would not alter the management decision.

Adverse events from antibiotics used to treat AOM and OME were common problems in this pediatric population. These effects included vomiting, diarrhea, yeast infections, rashes, hives, and anaphylactic reactions. The most common antibiotic used was amoxicillin, which was also the most common cause of adverse effects. Specific antibiotic adverse effects were not always well-documented and thus are not reported.

Speech and language delay was recorded when the parent or the medical record documented the delay. There were many children with these delays mentioned, but the benefit of TTs in preventing speech and language delay is not clear. Some investigations have shown an association between OME and language delay, with improvement in TT placement in preschool children. Others have shown no benefit, such as a recent controlled trial that studied the effect of TT placement on language development in 1- to 2-year-old children with OME.

Perforation and otorrhea are common complications after placement of TTs. However, in this study, these problems occurred before placement of TTs in significant numbers: otorrhea in 1 in 6 children and perforations in 1 in 16 children. Otitis externa occurred in 2 children, 1 with a candidal infection and 1 subsequent to otorrhea. Febrile seizures occur in 2% to 5% of children and were documented in 2% of our population, thus representing a normal prevalence in this population. These complications are more typically due to AOM than OME. Tinnitus and balance problems are less common complications of OME in children and were seen in only 1 child each.

Meningitis associated with AOM occurred in 2 children. However, the causative organisms were viral meningitis and N meningitides. There was no identification made of the organism causing the concurrent AOM. An otogenic source cannot be considered for these cases of meningitis. The usual route of invasion for meningitis from AOM is from bacteremia; however, direct extension by preformed pathways or thrombophlebitis can occur rarely. It is unclear how the OM and meningitis are associated, in these cases.

Serious complications can also occur from AOM and chronic OME. These complications would not have been seen in this study if they did occur in the population because of the exclusion criteria of previous or concurrent operations on the ears, the lack of postoperative data, and the absence of a control group that did not receive TTs. A complete list of complications of OM is available in an otology textbook. These more serious complications are not seen as frequently in developed countries as in the past, presumably because of the use of antibiotic therapy. Courville showed that death from serious com-

Figure 2. Complications vs age at surgery.
plications of OM was more common before the introduction of penicillin. The potential still exists for these complications to occur in untreated OM. In a 1986 study from South Africa reviewing untreated middle ear disease in black patients, 335 cases of serious otogenic complications were treated during 6 years. One hundred sixty-seven of these complications occurred in patients aged 10 or younger: 50 meningitis cases, 28 brain abscesses, 26 extradural abscesses, and 23 cases of lateral sinus thrombosis (other uncommon complications are not listed here).

The AHCPR criteria were introduced more than 9 years ago, but they have not achieved universal adherence. The criteria represented the best practice at the time. It was thought that introduction and use of the criteria would reduce the reliance on TTs to treat difficult cases of OME. The present study shows that, whether the timing of TT placement is early, on time, or late, the incidence of short-term complications of OME is nearly the same. No statistical differences were found between the groups we defined. Although this study is limited because of the retrospective nature of the data, it does not support the use of the AHCPR guidelines to avoid these complications of OM. A larger long-term controlled prospective study should be undertaken to assess the efficacy of the guidelines. A control group of children who did not undergo TT placement would provide useful information. If adherence to the guidelines fails to show decreased rates of complications, their continued use could be questioned.

CONCLUSIONS

Tympanostomy tubes have been recommended for OME to decrease many adverse effects and complications of this common childhood disease. These include common irritating effects such as pain and hearing loss, potentially long-term negative effects such as delayed speech and language development, and more serious complications such as cholesteatoma, intratemporal and intracranial infections, and thrombosis. This study evaluated 147 children with TTs placed, in whom many adverse effects of OM were documented before surgery. The timing of TT placement did not significantly affect the rate of short-term complications in this study.

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REFERENCES