Otorrhea in Infants With Tympanostomy Tubes Before and After Surgical Repair of a Cleft Palate

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Objective: To compare the incidence of otorrhea in a group of infants with cleft palate (CP) and tympanostomy tubes before and after surgical repair of the CP.

Design: Prospective observational study.

Setting: Otolaryngology clinic at a tertiary care children's hospital.

Patients: Thirty-three infants with CP and middle ear effusions who underwent tympanostomy tube placement. Subjects were observed from the time of tube placement until 6 months after CP repair.

Main Outcome Measure: Incidence of otorrhea before and after CP repair.

Results: Subjects were observed a mean of 6.3 months before CP repair and 6 months after CP repair. Before CP repair, 11 of 33 infants (33%) had no episodes of otorrhea, compared with 22 of 33 (67%) after CP repair (P = .007). Fourteen infants (43%) had 2 or more episodes of otorrhea before CP repair compared with 2 (6%) after CP repair (P = .001). Before CP repair, significantly fewer tubes were patent at the time of the audiologic evaluation compared with after CP repair (39 of 62 [63%] vs 52 of 66 [79%]; P = .048). Average speech reception threshold for the infants with tympanostomy tubes before CP repair was 18.1 dB compared with 12.6 dB after CP repair (P = .01).

Conclusion: The incidence of otorrhea after tympanostomy tube placement before CP repair is higher than the incidence after CP repair, although more than half of all infants (19 [58%]) had either 1 or no episodes of otorrhea before CP repair.


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The presence of otitis media with effusion (OME) in children with a cleft palate (CP) is nearly universal because of poor tensor veli palatini function leading to severe eustachian tube dysfunction.1-4 The middle ear fluid results in a conductive hearing loss in many patients. Audiologists are vigilant regarding infant hearing, particularly since the advent of universal newborn hearing screening in the United States. In a population already at risk for speech and language problems, conductive hearing loss is an unwanted comorbidity. As a result, it is common practice for children with a CP to undergo placement of middle ear ventilation tubes to eliminate the middle ear effusions.

Fear of postoperative otorrhea has been a deterrent to placement of tympanostomy tubes in infants with middle ear effusions and an unrepaired CP.5-6 Otorrhea is a common complication after tympanostomy tube placement (TTP) in children with or without a CP, and the incidence has varied from 3.4% to 83% according to published reports.7-9 Anecdotal reports of unremitting otorrhea in the CP population before palate repair have cautioned practitioners to delay treatment of chronic middle ear fluid until after the palate is closed.6,8 This study examines the incidence of post-TTP otorrhea both before and after CP repair.

METHODS

This study was approved by the Institutional Review Board for Human Subjects at Stanford University. We conducted a prospective observational study of infants with middle ear effusions and CP with or without cleft lip at the Pediatric Otolaryngology–Head & Neck Surgery Clinic at Lucile Packard Children's Hospital at Stanford. Study subjects were fol-
lowed up with bimonthly examinations (by an otolaryngology pediatric nurse practitioner [G.C.], a pediatric otolaryngologist [including A.H.M. and K.W.C.], or a pediatric audiologist with behavioral audiometry and tympanograms), and their families were contacted by telephone during the nonvisit months by the pediatric nurse practitioner from the time of tube placement until 6 months after CP repair.

Medical records were reviewed for documentation of infant hearing test results. All infants were scheduled for postoperative audiology testing; however, behavioral testing could not be completed for most infants younger than 7 months because of their developmental inability to respond to the testing situation with good reliability.

Statistical analysis was performed by means of unpaired t tests, with P < .05 used as the threshold for statistical significance.

## RESULTS

Forty-one patients were enrolled from November 19, 2003, until March 31, 2006. Eight patients did not complete the study: 1 had no CP repair because of multiple comorbidities, 2 families initially provided informed consent and then elected to defer placement of middle ear ventilation tubes, 3 had appointment-schedule adherence problems, 1 had the tympanostomy tubes removed at the time of the CP repair, and 1 had normal middle ears at the time of CP repair (after early tube placement and subsequent extrusion). Thirty-three patients composed the final study population: 16 female and 17 male. Eight patients had an isolated CP, 12 patients had an isolated cleft lip and palate, and 13 patients had other anomalies that may or may not have been related to the clefting condition, such as Pierre Robin sequence, Stickler syndrome, oculoauricular vertebral spectrum, Beckwith-Wiedemann syndrome, and amniotic band sequence, as well as unrelated congenital heart disease and urinary and orthopedic disorders. All but 3 of the infants were formally examined by a pediatric medical geneticist.

The average age of patients at the initial TTP surgery was 4.2 months, and the average age at the CP repair was 10.5 months. Nineteen of the 33 patients had a cleft lip and palate and had the initial tube surgery coordinated with the cleft lip repair. The remaining 14 patients had their initial tube surgery as a stand-alone procedure. Grommet-style tympanostomy tubes were used for all infants.

Thirty-three subjects were observed for a total of 207 months before CP repair (time from tube insertion until CP repair: average, 6.3 months) and 198 months after CP repair (6 months after CP repair for each child). The observations are summarized in Table 1. Overall, more patients had ongoing trouble with otorrhea before the CP was repaired than after the repair.

The results of newborn infant hearing screening were available for 31 of the 33 infants, and 25 of the 31 (81%) passed bilaterally. Four infants failed the hearing screen in 1 ear and 2 failed in both ears. All infants who had “refer” results proceeded to have normal audiology test results in the presence of functional tympanostomy tubes with the exception of 1 infant who demonstrated a unilateral hearing loss that required amplification.

After TTP, the infants were scheduled for behavioral audiology testing. The results are summarized in Table 2.

### Table 1. Recorded Episodes of Otorrhea Before and After Cleft Palate (CP) Repair

<table>
<thead>
<tr>
<th>Observed Episodes of Otorrhea, No.</th>
<th>Before CP Repair</th>
<th>After CP Repair</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>11 (33)</td>
<td>22 (67)</td>
<td>.007</td>
</tr>
<tr>
<td>1</td>
<td>8 (24)</td>
<td>9 (27)</td>
<td>.78</td>
</tr>
<tr>
<td>≥2</td>
<td>14a (43)</td>
<td>2 (6)</td>
<td>.001</td>
</tr>
</tbody>
</table>

aThree patients had 2 episodes, 4 had 3 episodes, 3 had 4 episodes, 3 had 5 episodes, and 1 had 7 episodes.

### Table 2. Audiology Testing Results

<table>
<thead>
<tr>
<th>No. of patients tested</th>
<th>Before CP Repair</th>
<th>After CP Repair</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age at audiology evaluation, mo</td>
<td>7.0</td>
<td>12.7</td>
<td>NA</td>
</tr>
<tr>
<td>Average interval after tube surgery, mo</td>
<td>2.7</td>
<td>3.2a</td>
<td>NA</td>
</tr>
<tr>
<td>Tympanostomy tube patency, No.</td>
<td>39/62 (63)</td>
<td>52/66 (79)</td>
<td>.048</td>
</tr>
<tr>
<td>Average speech reception threshold in sound field, dB HL</td>
<td>18.1c</td>
<td>12.6</td>
<td>.01</td>
</tr>
</tbody>
</table>

Abbreviations: CP, cleft palate; HL, hearing level; NA, not applicable.

Five of 33 infants did not require a replacement set of tubes at the CP repair surgery. As a result, the post-CP repair audiogram is following the initial set of tubes accounting for the longer interval after tube surgery. The average interval after tube surgery without these 5 patients was 2.1 months.

Likely tube patency was assessed by tympanometry at the time of audiologic evaluation. Sixty-three percent of tubes were patent in the pre-CP repair group compared with 79% of tubes in the post-CP repair group (P = .048). The average speech reception threshold was somewhat worse in the children with tympanostomy tubes before CP repair (18.1 dB) compared with 12.6 dB after CP repair (P = .01).

### COMMENT

Postoperative tympanostomy tube otorrhea is a known complication of tympanostomy tubes in children who are otherwise healthy. In a long-term prospective study by Ah-Tye et al\(^8\) 230 tubes in healthy children that extruded during the observation period (range, 19 days to 38.5 months) were observed. Seventy-five percent of children developed 1 or more episodes of otorrhea within 12 months after TTP, and 83% developed otorrhea within 18 months. In that study, the mean number of episodes of otorrhea per child was 0.79 in the first 6 months after TTP, 1.50 in the first 12 months, 2.17 in the first 18 months, and 2.82 in the first 24 months. The median estimated duration of drainage was 10 days. In 2001, a meta-analysis by Kay et al\(^7\) evaluated 134 articles for tympanostomy tube sequelae and found that transient otorrhea occurred in 16% of patients in the immediate postoperative period, and 26%
developed otorrhea later in the course of tube placement. Seven percent of patients demonstrated recurrent otorrhea and 3.8% had chronic otorrhea. Conclusions from the comprehensive literature review and analysis characterized the sequelae after tube placement as short-term inconvenience rather than long-term morbidity. To our knowledge, otorrhea in the population of infants with a CP has not been systematically studied.

Otolaryngologists have historically been hesitant to place tympanostomy tubes in infants with CP because of the risk of intractable otorrhea and the unknown efficacy of the procedure. An infant with a patent cleft is at risk not only for the usual infection-related otorrhea but also for developing otorrhea from nasopharyngeal reflux through poorly functioning, patulous eustachian tubes.

In this study, 57% of infants who underwent TTP before CP repair had 0 or 1 episode of otorrhea. The incidence of otorrhea declined after the palate was repaired, and 94% had 0 or 1 episode of otorrhea in the 6 months after CP repair. Although the incidence of otorrhea after TTP clearly declined after the CP was repaired, the evidence shows that a majority of infants did not have severe problems with otorrhea, and thus otorrhea may not be a strong deterrent to proceeding with "early" placement of ventilation tubes in this patient population. This study also showed, however, that, for tympanostomy tubes placed before CP repair, the tubes were more likely to become blocked or extruded, possibly owing to the narrowness of the infant middle ear space. The increased incidence of blocked or extruded tubes likely led to the poorer hearing outcomes in the pre-CP repair group at the time of audiologic follow-up. Although the time from surgery to postoperative audiologic evaluation varied slightly in the 2 groups (2.7 vs 3.2 months), the finding of an increased extrusion/blockage rate in the pre-CP repair group is likely real because the time to audiologic evaluation was longer in the post-CP group (giving the infant more time for the tube to become extruded or blocked).

Audiologic outcomes were examined in a controlled prospective study of 39 Finnish infants with CP who were followed up for 6 years after primary TTP at age 6 months. Age-matched children with OME without CP were used as the comparison group. Tubes were found to be equally effective in the patients with CP. No significant difference was found in the audiologic outcome for both groups, and no instances of sensorineural hearing loss were identified. A prospective study by Andrews et al of 40 children with CP undergoing auditory brainstem response testing at 3 months of developmental age resulted in a wide range of air conduction responses to click stimuli, from 25 to 102 dB normalized hearing level (nHL), and bone conduction results were from 0 to 55 dB nHL. At the time of testing, 83% of patients presented with middle ear abnormality as determined by high-frequency tympanometric testing. In the United Kingdom, where the Andrews et al study was conducted, the authors advocated placement of short-term middle ear ventilation tubes at the time of the surgical repair of the CP at age 6 months. Attempts were being made to determine criteria for placement of the tubes via auditory brainstem response testing, with a suggestion of 55 dB nHL conductive hearing loss or more.

In this study, the normalization of hearing in the presence of functional tubes was thought to be particularly valuable for the 6 infants (4 with unilateral and 2 with bilateral hearing loss) who did not pass the newborn infant hearing screen. Excepting 1 infant who was found to have a unilateral hearing loss that required amplification despite patent tubes, failure to pass the initial screening in the remainder of the infants was presumably due to middle ear effusions resulting in a conductive hearing loss.

Children with a CP are known to have speech delay, which is thought to be due, at least in part, to the constant OME. According to the 2005 Cochrane review of grommets (ventilation tubes) for hearing loss associated with OME in children without other medical problems (such as a CP), hearing levels improved by 9 dB at 6 months after surgery (95% confidence interval, 4-14 dB) and 6 dB at 12 months after surgery (95% confidence interval, 3-9 dB). The review also evaluated all studies regarding OME and speech development, cognition, behavior, or quality of life. The evidence suggested that, although tympanostomy tubes provide a short-term hearing improvement in children with simple OME, no effect on speech and language development has been proved. However, it is unknown whether, for this high-risk population with inherent speech concerns due to the CP, tympanostomy tubes may have a more significant positive impact than in a low-risk population of children with OME.

A limitation of this study is the lack of a control group who did not receive TTP. Unfortunately, the prevalence of middle ear effusions in this population is nearly universal. Surgical management with TTP around the time of CP repair is generally considered the standard of care and makes it difficult to obtain long-term control subjects.

Most of the children—19 of the 33 patients—had their TTP surgery coordinated with the cleft lip repair; however, for the remaining 14 infants, the risk to benefit ratio of stand-alone surgery must be carefully weighed given the outcomes with "early" tube placement.

In conclusion, tympanostomy tubes placed before CP repair in young infants are more likely to extrude or become blocked early in the postoperative course, leading to a lessened hearing benefit from the tubes. Postoperative tympanostomy tube otorrhea occurs with increased frequency in patients with CP who have not undergone repair of their CP compared with patients who have had their CP repaired, but more than half of the patients who undergo early TTP have little or no problem with otorrhea, in contrast to previous anecdotal reports of universal problems with otorrhea.
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REFERENCES