Objective: To determine the efficacy of phenylephrine hydrochloride, a topical vasoconstrictor, in preventing tympanostomy tube obstruction.

Design: Prospective, randomized, double-blind, controlled trial of patients undergoing myringotomy with tympanostomy tube insertion.

Setting: Academic, tertiary referral medical center.

Patients: Two hundred eight patients were enrolled in the study; 157 patients (310 ears) returned for postoperative evaluation.

Interventions: Myringotomy with tympanostomy tube insertion was performed in all ears: 139 control ears received ototopical antibiotics and 171 treatment ears received ototopical antibiotics plus topical phenylephrine.

Main Outcome Measure: Postoperative tympanostomy tube obstruction.

Results: The overall incidence of tympanostomy tube obstruction was 5.2%; 8.6% in the control group and 2.3% in the treatment group. The treatment group demonstrated an odds ratio of 0.25 (95% confidence interval, 0.08-0.78; \( P = .02 \)).

Conclusion: The use of phenylephrine following tympanostomy tube insertion greatly reduces the incidence of tube obstruction.


The insertion of tympanostomy tubes (TTs) for otitis media with effusion (OME), acute otitis media and its complications, and recurrent OME has provoked considerable controversy. Nonetheless, myringotomy with the insertion of TTs is one of the most common operations performed on children in the United States. Otitis media with effusion is believed to occur due to anatomical or physiologic abnormalities of the eustachian tube or middle ear mucosa, infection, and/or allergy. The eustachian tube maintains equilibrium between middle ear pressure and atmospheric pressure and provides a pathway for the drainage of middle ear fluid. Tympanostomy tubes serve as artificial eustachian tubes, thereby equalizing middle ear pressure and allowing fluid to drain. Tympanostomy tubes were introduced in 1952 and are used frequently. The indications and the benefits of tube placement have been well documented. The indications include, but are not limited to, chronic OME despite antibiotic therapy, recurrent acute otitis media, complications of acute otitis media, and complications of OME. The benefits include the elimination of conductive hearing loss secondary to the presence of middle ear fluid, elimination of suppurative otitis media causing complications, a decrease in the number of episodes of acute otitis media, and reversal of middle ear mucosal hyperplasia. These benefits may lead to fewer physician visits, decrease in time lost from work and days missed from school, and less frequent need for antibiotics.

Myringotomy with the placement of TTs in children is generally an outpatient procedure, requiring a short time under general anesthesia in the operating room. Obstruction of the TT after surgery is a frustrating problem that has been esti-
PATIENTS AND METHODS

PATIENTS

From January 19, 1996, through March 31, 1996, all patients who underwent myringotomy with TT insertion at Children’s Hospital of Michigan, Detroit, were enrolled in the study. Myringotomy with TT insertion was performed by otolaryngology staff, fellows, and first- through third-year otolaryngology residents. Patients were randomized into 1 of 2 groups. Patients in group 1 (control) received ototopical antibiotics during the procedure and patients in group 2 received ototopical antibiotics plus topical 0.25% phenylephrine hydrochloride during the operation. All patients received postoperative ototopical antibiotics 3 times a day for 3 days following surgery. Informed consent was obtained prior to surgery.

SURGICAL TECHNIQUE

Surgery was performed using general anesthesia. The procedure was performed by removing cerumen and epithelial debris, then a myringotomy incision was created in the anteroinferior quadrant of the tympanic membrane and the effusion, if present, was gently suctioned from the middle ear space. The middle ear fluid status was classified as dry, serous, mucoid, or purulent. In addition, intraoperative bleeding was recorded. Minimal bleeding was defined as drops of blood not entering the TT, and moderate to severe included those with bleeding that either filled the TT or obstructed visualization during the operation. A fluoroplastic collar button ventilation tube (Smith & Nephew ENT, Bartlett, Tenn) was inserted. Control ears received approximately 6 drops of ototopical antibiotics and treatment ears received approximately 4 drops of ototopical antibiotic plus 4 drops of 0.025% phenylephrine hydrochloride. Drops were instilled into the external auditory canal. No effort was made to manipulate the drops in the external auditory canal after instillation.

Patients were excluded if there was granulation tissue in the middle ear, evidence of active chronic suppurrative otitis media with or without cholesteatoma, or they were not randomized prior to removal of external auditory canal debris. Likewise, if phenylephrine was used to control bleeding during the operation or if the intraoperative treatment differed from the group to which it was randomized, the ear was excluded from the study.

Parents were instructed to administer the ototopical antibiotic as 3 drops 3 times daily for 3 days. Assessment of patency was determined 2 to 6 weeks following surgery by otoscopy and pneumatic otoscopy. Examining physicians were blinded to which group the patient was randomized. In most cases, postoperative audiometry and tympanometry were performed as well.

STATISTICAL ANALYSIS

The main outcome of interest was TT obstruction, in particular, whether the phenylephrine prevented obstruction. In addition, we sought to determine if the covariates of effusion material and amount of bleeding contributed to blockage. General estimating equations were used. This method of analysis was chosen because a subject may have had tubes put into both ears. The outcomes from the 2 ears of the same subject are considered correlated or dependent. The generalized estimating equations account for this dependence within a subject while allowing one to model TT obstruction adjusted for other variables, such as effusion type and bleeding.

First, each of the covariates were individually tested for a relationship to TT obstruction. Reported results are the odds ratio (OR), 95% confidence interval (CI), and the P value testing the significance of the OR. The OR is defined as the estimated odds of blockage in the presence of 1 of the covariates.

Multivariate analysis enables testing of adjusted effects. That is, whether phenylephrine is still important in preventing blockage after controlling for other influential effects, such as bleeding and effusion type. Again, general estimating equation modeling was used. Testing was used to look for differences in the proportion of patients who returned for postoperative evaluation and those who did not with respect to randomization group.

Finally, an intent-to-treat analysis was performed. Intention-to-treat is an analytical principle, the purpose of which is to include all subjects, whether they dropped out of the study or not, in an attempt to eliminate possible bias that may occur when subjects drop out. We assigned all subjects unavailable for follow-up to either obstructed or unobstructed outcomes and compared incidence of obstruction for these 412 cases between treatment and control groups. Thus, we performed a sensitivity analysis to determine the influence of individuals unavailable for follow-up on the results.

RESULTS

Two hundred eight patients were enrolled in the study, and 157 patients returned for postoperative examination, enabling evaluation of 310 ears. Of these, 139 received ototopical antibiotics alone and 171 received ototopical antibiotics plus topical phenylephrine. Patients ranged in age from 3 months to 26 years (mean ± SD age, 42.4 ± 38.4 months). A likelihood ratio χ2 test was used to look for differences in rate of phenylephrine use between the returning and nonreturning groups. No difference was found, with both groups having approximately 55% of the patients in the treatment group.
Obstruction of TTs in the postoperative period is frustrating, and the ineffectiveness of a blocked tube itself is the most important aspect. What clinicians tend to forget, though, are the direct health care expenditures and indirect nonmedical costs that are encountered as a result of a blocked TT. Direct health care expenditures include an increase in the number of office visits to treat the obstruction and the cost of the drops that are used in an attempt to unblock the tube. More important is the cost of reoperation if the TT fails to unblock. Indirect, nonmedical costs are what the family experiences. These include transportation to and from the office, lost wages from missing work to take the child to the office, and the child's missed school hours for his/her appointments. Thus, an intervention that has the potential to decrease these costs may be useful.

If phenylephrine is used to decrease the incidence of postoperative TT obstruction, then can phenylephrine affect hearing? None of the patients in this study who underwent postoperative audiography experienced worsening of their hearing: all were either the same or improved. (Of course, only the better-hearing ear was able to be evaluated in the younger children.) One study has looked at the effect of topical epinephrine applied to the round window membrane. A 60% decrease in cochlear blood flow was seen, which recovered after removal of the epinephrine from the round window membrane. No patient experienced a worsening of his/her hearing after surgery. Likewise, the application of topical phenylephrine to the round window membrane of gerbils caused an approximately 25% decrease in cochlear blood flow. However, there are no data in the literature regarding the effect of topical phenylephrine on cochlear blood flow or hearing in humans.

Previous studies have evaluated methods to prevent TT obstruction. Antibiotic ointment applied to the TT prior to insertion has been shown to have no statistically significant effect (P > .20) on the incidence of TT obstruction. Similarly, ototopical antibiotics used in the postoperative period have not been shown to decrease the incidence of TT obstruction. In contrast to these studies, one reports the use of xylometazoline hydrochloride to prevent TT obstruction. Although no obstruction of the TT was found in the ears that received the treatment, increased time was spent “push-

### Table 1. Tympanostomy Tube Obstruction

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Obstructed</th>
<th>Unobstructed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine hydrochloride</td>
<td>4 (2.3)</td>
<td>167 (97.7)</td>
</tr>
<tr>
<td>ATB</td>
<td>12 (8.6)</td>
<td>127 (91.4)</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (2.7)</td>
<td>182 (97.3)</td>
</tr>
<tr>
<td>Minimal</td>
<td>8 (5.3)</td>
<td>88 (91.7)</td>
</tr>
<tr>
<td>Moderate to severe</td>
<td>3 (11.5)</td>
<td>23 (88.5)</td>
</tr>
<tr>
<td>Effusion type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry</td>
<td>4 (2.8)</td>
<td>141 (97.2)</td>
</tr>
<tr>
<td>Serous</td>
<td>2 (6.5)</td>
<td>32 (93.5)</td>
</tr>
<tr>
<td>Mucoid</td>
<td>8 (7.2)</td>
<td>103 (92.8)</td>
</tr>
<tr>
<td>Purulent</td>
<td>2 (6.4)</td>
<td>29 (93.6)</td>
</tr>
</tbody>
</table>

*ATB indicates ototopical antibiotic. All data are presented as number (percentage).

### Table 2. Amount of Bleeding by Effusion Type

<table>
<thead>
<tr>
<th>Effusion Type</th>
<th>Dry</th>
<th>Serous</th>
<th>Mucoid</th>
<th>Purulent</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>114 (98.3)</td>
<td>4 (3.6)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Minimal</td>
<td>26 (3.3)</td>
<td>77 (96.7)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Moderate to severe</td>
<td>8 (9.1)</td>
<td>63 (90.9)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*All data are presented as number (percentage).
ing the solution into the middle ear” and repeatedly suctioning blood and secretions. Most importantly, no statistical analysis was performed on the data. 3

In summary, in our study there was an overall incidence of TT obstruction of 5.2%. The use of phenylephrine following TT insertion considerably reduces the incidence of TT obstruction. Increased bleeding increases the likelihood of obstruction, and there was no diminution in hearing following the use of topical phenylephrine.

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REFERENCES


