Original Investigation

Risk Factors Associated With Postoperative Tympanostomy Tube Obstruction

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IMPORTANCE Myringotomy and tympanostomy tube placement for chronic otitis media with effusion is the most common reason for a child to undergo anesthesia in the United States. Postoperative tube obstruction occurs in 1.4% to 36.0% of cases and remains a challenge in achieving middle ear ventilation.

OBJECTIVE To identify risk factors associated with tube obstruction.

DESIGN, SETTING, AND PARTICIPANTS Retrospective medical record review of 248 patients, mean age 2.54 years, seen between March 2007 and June 2011 in a tertiary care pediatric hospital.

INTERVENTIONS Tympanostomy tube placement and postoperative otic drop therapy.

MAIN OUTCOMES AND MEASURES Tube patency at postoperative visit, number of tube removals and revisions, age, sex, body mass index (BMI), middle ear fluid type at time of surgery, and time between surgery and first postoperative visit were examined. Type of surgery (tympanostomy tube placement alone, adenoidectomy + tympanostomy tube placement, tympanostomy tube placement + adenoidectomy + tonsillectomy) and its effect on tube patency were also reviewed.

RESULTS At first follow-up, 10.6% of patients had occlusion of one or both tubes. No significant association was found between tube patency and a patient's BMI percentile, sex, or procedure type. Patients with no middle ear fluid were more likely to have patent tubes than those who had serous fluid (odds ratio [OR], 3.5; 95% CI, 1.2-10.6; $P = .02$). A significant inverse correlation was found between patency and time between surgery and follow-up in that patients who had longer follow-up after surgery were less likely to have patent tubes (OR per day of follow-up delay, 0.990; 95% CI, 0.981-0.999; $P = .01$).

CONCLUSIONS AND RELEVANCE Tympanostomy tube obstruction was seen in 10.6% of patients. Serous fluid and increased time to postoperative visit were statistically significant indicators for tube occlusion.

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Myringotomy and tympanostomy tube (TT) placement for treatment of chronic serous otitis media, chronic otitis media with effusion, and recurrent acute otitis media is the most common reason a child receives general anesthesia in the United States.[1] The function of the TT is to maintain middle ear ventilation while providing an egress for fluid that may accumulate as sequelae from infection or negative barometric pressure. While TTs are largely well tolerated, tube clogging is a troublesome complication that may require office procedures, medication trials, and possibly tube replacement under another general anesthetic.

Postoperative blockage of TTs has been estimated to affect a mean of 6.9% of ears (range, 0%-37.3%).[2] Once the TT is blocked, patients may reaccumulate middle ear fluid, resulting in decreased hearing and discomfort. Causes of tube obstruction include epithelial casts, cerumen, inspissated secretions, and clotted or dried blood.

A variety of therapies to both prevent and treat tube obstruction have been described by several authors. A survey of 122 pediatric otolaryngologists found that 56% of surgeons administer antibiotic-only drops, while 35% administer a combination steroid/antibiotic ototopically with the aim of limiting postoperative otorrhea and blockage.[3] Phenylephrine has been shown to greatly reduce TT obstruction, especially when used in the presence of significant blood in the middle ear at the time of surgery.[4] Coating tubes with antibiotic ointment

Table 1. Incidence of Tympanostomy Tube Obstruction by Fluid Type

Fluid Type	Obstructed Tubes, No./Patients, No. (%)	*P* Value[a]
No fluid	6/105 (6)	Reference
Serous	5/25 (20)	**.02**
Mucoid	13/95 (14)	.06
Mucopurulent	1/10 (10)	.48
Purulent	2/13 (15)	.75
All fluid types	21/143 (15)	**.03**
Total	**27/248[b]** (11)	NA

Abbreviation: NA, not applicable

[a] Compared with no fluid; $P < .05$ are bolded.

[b] Total number of patients includes those with no fluid plus those with all fluid types.

has not been shown to significantly prevent obstruction from hemorrhage.[5] Microscopic debridement in the office may also be used to reinstate tube patency.

Despite an array of therapies to decrease rates of TT blockage, predictors of tube obstruction have yet to be fully elucidated. Studying factors associated with postoperative obstruction, such as the character of middle ear fluid and the type of ototopical agent administered, would yield important information to optimize postoperative tympanostomy care. Identifying patients at risk for tube obstruction may facilitate earlier intervention with microscopic debridement and topical therapies. In this study, we aimed to (1) identify types of effusions associated with increased rates of tube obstruction; (2) assess whether blockage rates were associated with adjunctive procedures (eg, adenoidectomy + adenotonsillectomy), patient age, body mass index (BMI), and sex; and (3) provide suggestions to optimize postoperative tympanostomy care and limit tube obstruction and replacement. Preventing tube occlusion may have significant value in limiting the need for tube reinsertion and further anesthetic risk to the child.

Methods

After approval by the Nemours/Alfred I. duPont Hospital for Children institutional review board, we conducted a retrospective medical record review on consecutive patients who underwent myringotomy and TT placement from March 2007 to June 2011. Only patients who had identical fluid types in both ears at the time of surgery were included in this study; patients with differing fluid types were excluded for ease of analysis. Two hundred forty-eight patients met the inclusion criteria. Preoperative, intraoperative, and postoperative findings were reviewed. The following variables were considered: middle ear fluid type at the time of surgery, tube patency at first postoperative follow-up, subsequent need for tube reinsertion after initial TT placement, patient age, sex, BMI, and time between surgery and follow-up visits.

Middle ear irrigation using saline was performed when needed to evacuate middle ear effusions prior to TT insertion. In all cases, phenylephrine was administered into the external auditory canal immediately following tube placement regardless of the presence or absence of middle ear fluid. A postoperative prescription for otic drops was given according to presence and type of effusion. Patients with mucoid, purulent, or mucopurulent effusions were treated with ciprofloxacin, 0.3%/dexamethasone, 0.1%, combination otic solution (5 drops twice daily for 7 days), and patients whose middle ears contained serous effusion or no fluid were administered sulfacetamide sodium, 10%, ophthalmic solution (3 drops, 3 times daily for 3 days). Tube obstruction was confirmed by otoscopy at the first office visit 3 weeks postoperatively. Tympanometry was used to confirm blockage when physical examination could not establish tube patency.

Fluid type, TT patency, and need for tube reinsertion were analyzed by χ^2 analysis. *P* values were obtained comparing middle ear fluid type and tube patency using *t* testing to evaluate for statistical significance. Multivariate logistic regression analysis was performed to estimate the relationship of demographic, clinical, and intraoperative findings with the occurrences of postoperative clogged tubes.

Results

Our patient cohort (N = 248) comprised 151 boys (61%) and 97 girls (39%). The mean patient age was 2.54 years (age range, 139 days to 14 years), with 138 patients (56%) younger than 2 years and 110 (44%) 2 years or older. Two hundred seven patients underwent bilateral myringotomy with tube insertion (BMT) alone, while 28 patients received BMT + adenoidectomy, and 13 patients had BMT + adenotonsillectomy. The mean number of days between surgery and first follow-up visit was 25.9 days. Two hundred seventeen patients had a recorded BMI at the time of surgery. The mean BMI percentile for age in children younger than 2 years was 68.4, and in children 2 years or older, it was 57.7. The distribution of fluid types found in both ears at the time of surgery is as follows:

43%, None

38%, Mucoid

10%, Serous

5%, Purulent

4%, Mucopurulent

Overall, 36 patients (10.6%) experienced tube obstruction of one or both ears diagnosed during follow-up. Comparison of tube blockage and absence of fluid (43% of patients) vs all fluid types revealed statistical significance for occlusion with any type of ear fluid ($P = .03$). A patient with any type of fluid in the middle ear at the time of surgery was more likely to experience tube occlusion a patient without any ear fluid (odds ratio [OR], 2.6; 95% CI, 1.1-6.1). Patients with serous fluid (10% of study participants) had the highest rate of tube blockage (20% rate of obstruction per child; $P < .03$) (**Table 1**). Children were more than 3 times as likely to have patent tubes if they had no middle ear fluid than if they had serous fluid (OR, 3.5; 95% CI, 1.2-10.6; $P = .02$) (**Table 2**). No other similar relationship was found between other fluid types. Mucoid fluid was the most common effusion encountered (38% of patients); however, clogging rates were not statistically significant com-

Table 2. Odds Ratios of Tympanostomy Tube Obstruction by Fluid Type

Fluid Type	Odds Ratio (95% CI) of Obstruction	P Value[a]
No fluid		
All fluid types	2.6 (1.1-6.1)	**.03**
Purulent	2.7 (0.6-12.0)	.75
Serous	3.5 (1.2-10.6)	**.02**
Mucoid	2.2 (0.9-6.1)	.06
Mucopurulent	1.8 (0.2-13.1)	.48
Mucopurulent		
Mucoid	1.3 (0.2-9.4)	.08
Purulent	1.5 (0.2-14.7)	.70
Serous	2.0 (0.3-15.0)	.08
Mucoid		
Purulent	1.2 (0.3-4.4)	.11
Serous	1.6 (0.6-3.7)	.85
Purulent		
Serous	1.3 (0.3-5.8)	.12

[a] *P* < .05 are bolded.

Table 3. Obstruction Rates, Additional Tympanostomy Tube Insertions, and Fluid Types Between Age Groups[a]

Characteristic	Age <2 Years (n=138)	Age ≥2 Years (n=110)	P Value[b]
Tube obstruction	19 (13.7)	8 (7.3)	.10
1 Extra set of tubes required	44 (31.9)	25 (22.7)	.11
≥2 Extra sets of tubes required	25 (18.1)	5 (4.5)	**.001**
No fluid	58 (42)	47 (42.7)	.91
Mucoid fluid	49 (35.5)	46 (41.8)	.31
Serous fluid	11 (8)	14 (127)	.22
Mucopurulent fluid	9 (6.5)	1 (0.9)	**.03**
Purulent	11 (8)	2 (1.8)	**.03**

[a] Unless otherwise noted, data are number (percentage) of patients.

[b] *P* < .05 are bolded.

pared with children without any ear fluid. A patient was more likely to subsequently require exactly 1 extra set of tubes if he or she presented with either mucoid (*P* = .003) or serous (*P* = .03) middle ear fluid compared with patients with no fluid.

No statistically significant relationship was found between patency and a patient's BMI, sex, or procedure type (adenoidectomy + myringotomy and TT placement, adenotonsillectomy + myringotomy and TT placement, myringotomy and TT insertion alone) at first follow-up (mean time to follow-up, 25.9 days). Those patients who underwent adenotonsillectomy in addition to the BMT procedure were significantly less likely to require 1 tube reinsertion (*P* = .049) or more than 2 BMTs (*P* = .04). Two of the patients with mucopurulent effusions were treated with oral antibiotics for a course of 7 days following their surgery: one patient received amoxicillin for severity of inflammation in the middle ear and presence of acute otitis at the time of surgery, and the other patient was treated with sulfamethoxazole/trimethoprim for concurrent suppurative adenoiditis at the time of surgery.

Children younger than 2 years had clogged tubes 13.7% of the time at first follow-up, while 7.3% of patients 2 years or older had obstructed tubes (*P* = .10). Children younger than 2 years required an extra set of tubes more often than patients 2 years or older (31.9% vs 22.7%); however, this did not show statistical significance. Patients younger than 2 years, however, were far more likely to require 2 or more sets of tubes compared with children 2 years or older (18.1% vs 4.5%; *P* = .001). Comparison of middle ear fluid types between age groups (<2 years vs ≥2 years) did reveal changes in prevalence of fluid types seen: mucopurulent fluid was seen in 6.5% of younger patients vs 0.9% older ones (*P* < .03), and purulent effusion was seen in 8.0% of younger patients vs 1.8% of older ones (*P* < .03) (**Table 3**).

The mean number of days until first follow-up visit was 25.9 days. There was a significant relationship showing that the more time that passed between surgery and the first follow-up, the more likely the patient had a clogged tube. For every day increase in time between surgery and follow-up, the odds of patency changed by a factor of 0.990 (95% CI, 0.981-0.999) (*P* = .02). In other words, someone whose first follow-up is 5 days after surgery is only 0.990 as likely to show patency as someone whose first follow-up is 4 days after surgery (a 1% decrease in likelihood).

Discussion

There is great variability in the methods otolaryngologists use to prevent and manage postoperative TT obstruction. Most authors recommend otic drops to maintain tube patency.[6] Office debridement may be used to reestablish a patent lumen when occlusion is identified. In this study, 10.6% of patients experienced tube blockage. Our finding of a statistically significant relationship between serous effusions and TT obstruction leads to several theories. Children with serous effusions were over 3 times as likely to develop tube blockage (*P* = .02). Drop duration and composition may explain this finding: given that we administered sulfacetamide otic solution for serous effusions for 3 days only, it is possible that this shorter course with fewer total drops (3 days vs 7 days, 27 total drops vs 70 total drops) of irrigant resulted in greater rates of tube obstruction. The composition of sulfacetamide and the absence of a steroid in suspension may also make it less efficacious in preventing occlusion. A 7-day course of drops (in patients with mucoid, mucopurulent, and purulent effusions) may prevent TT obstruction regardless of the type of drop administered. This caveat does not apply, however, to children treated for serous vs clear middle ears because they would have usually received the same drop regimen. Without controlling for drop content and duration, we cannot be certain whether the increased rate of tube occlusion when children had serous effusions was due to a shorter, or different, drop regimen than that used for children with mucoid effusions. This remains an area for further study.

Several authors have studied TT clogging and the type of topical agent given postoperatively. Oxymetazoline and ciprofloxacin have been shown to be equally efficacious in preventing both postoperative otorrhea and TT obstruction.[7] All

topical antimicrobial agents or antimicrobial-steroid mixtures have been shown to be superior to saline drops alone.[8] It is reasonable to postulate that any type of ear irrigant, other than saline, will prevent tube blockage if given for an adequate period. To our knowledge, the effect of drop type on tube obstruction has not been examined with a larger study. Information obtained from such a study may alter clinical practice guidelines that could have major implications for health care costs and efficacy.

The type of tube used in patients with middle ear effusions also warrants further discussion. Most of our patients received beveled Armstrong grommet tubes (Anthony Products) (inner diameter, 1.14 mm). There may be a role for larger-caliber tubes in patients who require an additional set of tubes because of TT blockage or in whom serous, or all, effusions are found at surgery. Further study is needed regarding tube length and prevalence of tube obstruction as well. Elongated TTs have a theoretical increased incidence of clogging due to larger luminal surface area and opportunity for intraluminal plugging. Although patient need and surgeon preference will most often prevail in deciding which TT is appropriate, greater knowledge of tube behavior would be very useful to the otolaryngologist.

Our study examined factors associated with TT obstruction. An unexpected, yet important, result of our analysis suggests that a longer course of topical otic drops should be administered when *any* type of fluid is encountered in the ear at the time of surgery. One must consider the added cost and risk to the patient and the need to remove a nonfunctioning TT because of clogging. The benefit of a longer course of ototopicals may far exceed the risk of organism resistance and expense when considering the potential for additional surgery. In addition, patients at risk for tube plugging would likely benefit from shorter postoperative follow-up time and heightened vigilance of TT inspection in the office setting.

Comparisons between age groups (<2 years vs ≥2 years) yielded some statistical significance. There was a higher prevalence of mucopurulent and purulent fluid types in children younger than 2 years compared with older patients. This likely reflects a higher baseline frequency of acute otitis in the younger age group. In addition, children younger than 2 years were far more likely to require more than 1 set of ear tubes compared with older children (P = .001) (Table 3). This finding, matched with an increase in tube clogging in patients who did not follow up sooner, suggests that patients younger than 2 years may benefit from more timely and judicious postoperative follow-up to prevent TT obstruction.

Duration of follow-up influenced the finding of patency. We theorize that this is due to a higher likelihood of debris building up or, for example, intercurrent middle ear fluid from upper respiratory infections occluding the lumen. Further study is required to better understand this finding.

Conclusions

Post-TT obstruction remains a frequent and challenging aspect of surgical treatment of otitis media in children. We found that children with serous effusions and those with longer follow-up durations have occluded tubes more often. Further study is warranted to determine if changes in postoperative drop duration and composition improve patency rates.

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Study concept and design: Conrad, Levi, Inverso, Shah.
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