Original Investigation

Pediatric Tympanostomy Tube Removal Technique and Effect on Rate of Persistent Tympanic Membrane Perforation

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IMPORTANCE Tympanostomy tube removal is a commonly performed pediatric procedure. Few studies have evaluated whether removal technique influences the likelihood of the tympanic membrane (TM) to heal.

OBJECTIVE To determine whether the technique used for tympanostomy tube removal affects the likelihood of persistent TM perforation healing in children.

DESIGN, SETTING, AND PARTICIPANTS Retrospective case series with medical chart review in a tertiary care pediatric health system of 247 children undergoing tympanostomy tube removal (341 ears) between 2010 and 2013 by 1 of 4 different techniques: (1) tube removal only; (2) freshening TM perforation edges; (3) performing patch myringoplasty; or (4) both freshening edges and performing patch myringoplasty.

MAIN OUTCOMES AND MEASURES Rate of persistent TM perforation after tympanostomy tube removal using the different removal techniques. Secondary outcomes included associations between persistent TM perforation and patient and tympanostomy tube characteristics.

RESULTS The overall persistent TM perforation rate was 10% (34 of 341 ears). Tube removal technique did not significantly influence likelihood for the TM to heal: perforations persisted in 11 of 97 ears (11%) with tube removal only, 6 of 68 ears (9%) with freshened TM perforation edges, 7 of 57 (12%) with patch myringoplasty, and 10 of 119 (8%) with both edges freshened and patch myringoplasty (P = .81). The mean (SD) age of patients with a persistent perforation at the time of tympanostomy tube removal was 8.5 (3.9) years vs 6.5 (3.2) years for those without a persistent perforation (P = .01). In patients with trisomy 21, there was a significantly higher rate of persistent TM perforation (OR, 8.65; 95% CI, 2.13-34.74; P = .002). Short-acting tubes were found to have a significantly lower rate of persistent TM perforation (13 of 194; 7%) than longer-acting tubes (9 of 41; 22%) (OR, 0.26; 95% CI, 0.09-0.71; P = .002).

CONCLUSIONS AND RELEVANCE No reduction in persistent TM perforation rate was found following tympanostomy tube removal if TM edges were freshened and/or a patch myringoplasty was performed. Increased pediatric age, longer-acting tympanostomy tubes, and history of trisomy 21 may negatively influence likelihood of closure.

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Tympanostomy tube placement for the treatment of otitis media is one of the most commonly performed procedures today in the pediatric population. In most cases, tympanostomy tubes spontaneously extrude 6 to 18 months after placement with complete repair of the tympanic membrane (TM) through migration of the squamous epithelial, fibrous, and mucosal layers.[1,2] In a subset of patients, these tubes require removal owing to prolonged retention or persistent otorrhea. Retained tubes that require removal have been associated with higher rates of persistent TM perforation than those that spontaneously extrude.[2] Tympanic membrane perforations can have significant implications for pediatric patients, including the need for mandatory water protection, possible conductive hearing loss, and an increased risk for recurrent otorrhea and cholesteatoma, thereby reinforcing the importance of promoting closure at the time of tube removal.[3-5] However, the optimal technique to promote closure of TM perforations at the time of tympanostomy tube removal remains unclear. The objective of this study was to examine the rates of persistent TM perforations after tympanostomy tube removal by 4 different techniques. Secondarily, several patient factors that may influence the likelihood for TM closure were analyzed.

Methods

Prior to initiation of this study, we obtained institutional board review approval from Nemours/Alfred I. duPont Hospital for Children; written informed consent was waived for this retrospective series. A retrospective case series with chart review of children who underwent tympanostomy tube removal at a tertiary care pediatric health system between January 2010 and November 2013 was conducted. Patients were identified by searching the electronic medical record for *Current Procedural Terminology* code 69424, tympanostomy tube removal. Patients who underwent removal of tympanostomy tubes owing to retained tube, persistent otorrhea, or both were included in the study. Patients underwent 1 of 4 operative removal techniques: (1) tube removal only; (2) tube removal with freshening the perforation edges; (3) performing patch myringoplasty; or (4) both freshening edges and performing patch myringoplasty. Patients who were not evaluated through follow-up appointments or did not have documented otologic examinations on follow-up were excluded from this study because there was no way to determine perforation status.

The effects of other variables on TM perforation closure were also assessed: patient age, sex, and comorbidities including trisomy 21, seasonal allergic rhinitis (SAR), gastroesophageal reflux disease (GERD), cleft lip and/or palate, number of tympanostomy tubes placed, length of tube retention, indication for tympanostomy tube removal, and presence of adenoids.

Operative notes were reviewed, and patients were categorized by removal procedure: (1) removal of tympanostomy tube without any further intervention; (2) removal followed by freshening TM edges with a Rosen needle; (3) removal of tube followed by patch myringoplasty with Gelfilm (Pfizer), Gelfoam (Pfizer), EpiDisc (Medtronic), or paper patch; and (4) removal followed by edges freshened with a Rosen needle and then patch myringoplasty. In addition to the category of TM removal technique, the type of tympanostomy tube removed was also noted. Armstrong, Paparella type I, collar button, Reuter bobbin, and Tiny Titans were grouped as short-acting tympanostomy tubes. Long-acting tubes included Paparella type II, butterfly, and T tubes. Rates of TM healing were determined by documented otologic examination at postoperative office visits. Persistent TM perforation was documented when a perforation was still apparent at the last documented follow-up.

The associations between the variables assessed for distributional characteristics are described using mean (SD) and proportions when appropriate. Unadjusted and adjusted associations between the covariates and perforation status were estimated using single-variable and multivariable logistic regressions. Since some patients underwent bilateral operations, while others only had 1 ear undergoing tube removal, potential clustering of the data by subject was examined using both mixed-effects logistic regressions with patient identification as the random-effects component as well as their fixed-effects counterparts. Since the estimated regression coefficients obtained using the mixed-effects model were almost identical to the fixed-effects logistic regression model, and the patient-level covariates such as trisomy 21 equally affect both ears, we report only the main effects logistic regression model results for procedure-specific results.

The relationship between perforation status and its potentially associated characteristics were quantified in terms of unadjusted odds ratios (ORs) or adjusted ORs with the associated 95% CIs. We quantified the logistic regression analysis using area under the receiver-operating curve (AUC), which is an accuracy measure ranging from 0 to 1: an AUC value of 0.5 means that the model has no discriminatory power between the presence or absence of perforation; an AUC value close to either 0 or 1 is highly accurate at discriminating between the 2 perforation statuses.

Results

Association of Persistent TM Perforation With Characteristics of Patients and Tympanostomy Tubes by Number of Ears

A total of 341 ears were examined in 247 children. The overall persistent TM perforation rate was 10% (34 of 341 ears). The mean (SD) age of patients with a persistent perforation at the time of tympanostomy tube removal was 8.5 (3.9) years vs 6.5 (3.2) years for those without a persistent perforation ($P = .01$). The effect of several additional factors, by ear, on persistent TM perforation after tube removal was evaluated (**Table 1**). There was no significant difference in persistent perforation rates by sex (OR, 1.17; 95% CI, 0.54-2.58; $P = .81$), indication for tympanostomy tube removal (OR, 0.58; 95% CI, 0.24-1.44; $P = .28$), total sets of tympanostomy tubes placed (OR, 1.05; 95% CI, 0.24-3.92; $P > .99$), or presence of adenoid (OR, 0.82; 95% CI, 0.38-1.77; $P = .72$). In addition, there was no significant difference in persistent TM perforation rate in patients who later

Table 1. Association by Number of Ears of Patient and Tympanostomy Tube Characteristics With Persistent TM Perforation

Characteristic	Persistent TM Perforations/Total Ears, No. (Perforation Rate, %)	OR (95% CI)	*P* Value
Sex			
Female	13/142 (9)	1 [Reference]	.81
Male	21/199 (11)	1.17 (0.54-2.58)	
Comorbidities[a]			
Trisomy 21	5/11 (45)	8.65 (2.13-34.74)	.002
Cleft lip/palate	0/6	NA	NA
SAR	3/64 (5)	0.40 (0.09-1.40)	.16
GERD	7/55 (13)	1.40 (0.52-3.60)	.46
Indication for tympanostomy tube removal			
Prolonged retention	25/264 (9)	0.58 (0.24-1.44)	.28
Otorrhea	5/36 (14)	1 [Reference]	
Prolonged retention and otorrhea	0/18	NA	
Total sets of tympanostomy tubes placed			
≤3	31/312 (10)	1 [Reference]	>.99
≥3	3/29 (10)	1.05 (0.24-3.92)	
Category of tube			
Short acting	13/194 (7)	0.26 (0.09-0.71)	.002
Long acting	9/41 (22)	1 [Reference]	
Adenoid			
Present	15/165 (9)	0.82 (0.38-1.77)	.72
Absent	19/175 (11)	1 [Reference]	

Abbreviations: GERD, gastroesophageal reflux disease; NA, not applicable; OR, odds ratio; SAR, seasonal allergic rhinitis; TM, tympanic membrane.

[a] Absence of the comorbidity is the reference category for each.

required a replacement tympanostomy tube (OR, 0.83; 95% CI, 0.15-2.9; $P > .99$) nor in relation to length of tube retention: patients with a persistent TM perforation had an average tube placement duration of 3.1 years vs 3.4 years in those without a persistent TM perforation ($P = .53$). There was a significant difference in average length of follow-up time. Patients with persistent TM perforations had an average follow-up of 13.2 months vs 2.9 months in patients without persistent perforation ($P < .001$).

In patients with trisomy 21, there was a significantly higher rate of persistent TM perforation (OR, 8.65; 95% CI, 2.13-34.74; $P = .002$). In contrast, for other medical conditions including cleft lip and/or palate ($P = .89$), SAR (OR, 0.4; 95% CI, 0.091.40; $P = .89$), and GERD (OR, 1.40; 95% CI, 0.52-3.62; $P = .46$), no significant difference was found (Table 1).

Short-acting tubes were found to have a significantly lower rate of persistent TM perforation (13 of 194; 7%) than longer-acting tubes (9 of 41; 22%) (OR, 0.26; 95% CI, 0.09-0.71; $P = .002$). Of 341 ears examined, 107 did not have a type of tube mentioned in the operative notes, so these were listed as unknown. Patient characteristics of sex ($P = .98$), trisomy 21 ($P = .10$), SAR ($P = .09$), GERD ($P = .07$), and indication for tympanostomy tube removal ($P = .57$) did not differ significantly between ears with short-acting tubes and those with long-acting tubes. However, ears receiving long-acting tubes were in children of significantly older mean (SD) age (9.46 [3.8] vs 5.59 [2.32] years; $P < .001$), had a greater median (range) number of previous tympanostomy tube sets placed (3 [1-7] vs 1 [0-9]; $P = .02$), had a longer mean (SD) tube retention time (3.25 [1.46] vs 2.53 [1.15] years; $P = .004$), and were more likely to be in children who had a previous adenoidectomy ($P < .001$) (Table 1).

Association of Persistent TM Perforation With Characteristics of Patients and Tympanostomy Tubes by Number of Patients

After determining the perforation rate by number of ears (n = 341) for each variable, additional analysis was performed by number of patients (n = 247) (**Table 2**). The same trends were observed in both analyses. In particular, analysis by number of patients revealed no significant difference in perforation rates based on sex (OR, 1.24; 95% CI, 0.54-2.98; $P = .60$), indication for tube removal (OR, 0.74; 95% CI, 0.24-2.43; $P = .57$), total sets of tympanostomy tubes placed (OR, 0.96; 95% CI, 0.32-5.13; $P > .99$), or presence of adenoid (OR, 0.65; 95% CI, 0.28-1.48; $P = .29$). As in the analysis by number of ears, a significantly increased rate of persistent perforation was found for patients with trisomy 21 (OR, 5.43; 95% CI, 1.67-31.00; $P = .03$) and for long-acting tubes vs short-acting tubes (OR for short-acting tubes, 0.19; 95% CI, 0.08-0.63; $P = .01$) (Table 2).

Association of Persistent TM Perforation With Tympanostomy Tube Removal Technique

Tympanostomy tube removal technique was examined to determine the persistent TM perforation rate by number of ears using the with 4 differing techniques of removal (**Table 3**). Perforations persisted in 11 of 97 ears (11%) with tube removal only, 6 of 68 ears (9%) with freshened TM perforation edges, 7 of 57

Table 2. Association by Number of Patients of Patient and Tympanostomy Tube Characteristics With Persistent TM Perforation

Characteristic	Persistent TM Perforations/Total Patients, No. (Perforation Rate, %)	OR (95% CI)	*P* Value
Sex			
Female	12/107 (11)	1 [Reference]	.60
Male	18/140 (14)	1.24 (0.54-2.98)	
Comorbidities[a]			
Trisomy 21	3/7 (43)	5.43 (1.67-31.00)	.03
Cleft lip/palate	0/4	NA	NA
SAR	2/43 (5)	0.34 (0.12-1.70)	.27
GERD	6/38 (16)	1.64 (0.71-4.82)	.25
Indication for tympanostomy tube removal			
Prolonged retention	21/197 (11)	0.74 (0.24-2.43)	.57
Otorrhea	5/36 (14)	1 [Reference]	
Prolonged retention and otorrhea	0/14	NA	
Total sets of tympanostomy tubes placed			
≤3	24/229 (10)	1 [Reference]	>.99
≥3	2/18 (11)	0.96 (0.32-5.13)	
Category of tube			
Short acting	11/144 (8)	0.19 (0.08-0.63)	.01
Long acting	7/26 (27)	1 [Reference]	
Adenoid			
Present	11/128 (9)	0.65 (0.28-1.48)	.29
Absent	15/118 (13)	1 [Reference]	

Abbreviations: GERD, gastroesophageal reflux disease; NA, not applicable; OR, odds ratio; SAR, seasonal allergic rhinitis; TM, tympanic membrane.

[a] Absence of the comorbidity is the reference category for each.

(12%) with patch myringoplasty, and 10 of 119 (8%) with both edges freshened and patch myringoplasty (*P* = .81). (Table 3). The TM removal technique also failed to show a difference in perforation rate when analyzed by number of patients (n = 247) (*P* = .83) (Table 3).

Further Analysis of Patient and Tympanostomy Tube Characteristics

For each of the patient and tympanostomy tube variables found to have statistically significant association with higher rates of perforation (increased age, trisomy 21, and long-acting tube), single-variable logistic regression analyses were performed to assess for any influence of surgical technique on these variables. A significant interaction was found between age at the time of surgery and technique (**Table 4**). Tube removal alone was associated with the youngest mean age (6.20 years), followed by freshened edges (6.42 years), both freshened edges and myringoplasty patch placed (6.70 years), and only myringoplasty patched placed (7.96 years) (*P* = .01). By χ^2 analysis, not the presence or absence of trisomy 21 (*P* = .31) nor long- vs short-acting tympanostomy tubes (*P* = .50) significantly interacted with removal technique for difference in persistent TM perforation rate (**Table 5**).

A multivariable logistic regression analysis of trisomy 21 and age revealed an AUC of 0.677. When the technique at time of tube removal was included with trisomy 21 and age, multivariable logistic regression analysis revealed an AUC of 0.687.

Discussion

While many studies to date have looked at surgical treatment for chronic TM perforations in the pediatric population, few studies have examined the optimal approach to promote TM membrane closure at the time of tympanostomy tube removal in pediatric patients. Of these studies, most have small sample sizes owing to the high rates of spontaneous tympanostomy tube extrusion in the pediatric population. To our knowledge, the present study represents the second largest case series on this topic to date.

Furthermore, there has been a paucity of studies on pediatric tympanostomy tube removal technique and its influence on perforation rate, with the most recent publication over 5 years ago.[6] The present study evaluated the persistent TM perforation rate of 341 ears in 247 children and found it to be 10% (34 of 341). Overall, we found no statistical difference in the rate of persistent TM perforation following tube removal alone vs tube removal with freshening of TM edges and/or undertaking a patch myringoplasty. This finding was consistent with a previous study by Adkins and Friedman,[6] where no difference in persistent perforation was seen in 111 ears of 82 pediatric patients regardless of treatment at the time of removal. The overall 10% rate of persistent TM perforation following tympanostomy tube removal was also consistent with rates observed by others. Studies that included removal of both long- and short-acting tubes, as ours did, showed per-

Table 3. Tympanostomy Tube Removal Technique and Likelihood of Persistent TM Perforation

Tympanostomy Tube Removal Technique	TM Perforations/Total Ears or Patients, No. (Perforation Rate, %)	*P* Value
By number of ears		
None	11/97 (11)	.81
Edges freshened	6/68 (9)	
Patch placed	7/57 (12)	
Edges freshened and patch placed	10/119 (8)	
By number of patients		
None	7/69 (10)	.83
Edges freshened	4/48 (8)	
Patch placed	6/42 (14)	
Edges freshened and patch placed	9/88 (10)	

Abbreviation: TM, tympanic membrane.

Table 4. Patient Ages at Time of Tympanostomy Tube Removal

Tympanostomy Tube Removal Technique	Patient Age at Tube Removal, Mean (SD), y	*P* Value
Tube removal alone	6.20 (3.62)	.01
TM edges freshened	6.42 (3.09)	
Patch placed	7.96 (3.87)	
TM edges freshened and patch placed	6.70 (2.81)	

Abbreviation: TM, tympanic membrane.

foration rates ranging from 7% to 15%, with even higher rates commonly reported in studies of long-term tubes only.[4-9]

We also examined the influence of other factors on persistent TM perforation, as have other researchers. Pribitkin et al[7] reported TM perforation closure rates to be independent of technique at time of tube removal unless more than 3 sets of tympanostomy tubes had been placed, in which case paper patching was associated with a significantly lower persistent perforation rate. Additional studies have discussed the higher likelihood of persistent perforation with longer duration of tube retention, particularly after 3 years.[2,8,9]

We found no significant difference in persistent TM perforation rates by patient sex, indication for tympanostomy tube removal, number of sets of tympanostomy tubes, or duration of tube retention. Eustachian tube dysfunction was expected to significantly affect the likelihood of persistent perforation. While we found this to be true in patients with trisomy 21, we did not find a significant difference in patients with cleft lip and/or palate or in those having adenoid tissue.

Patients with trisomy 21 were found to have a markedly increased risk of persistent TM perforation (OR, 8.65). However, we did not find any significant interaction between trisomy 21 and the 4 techniques used for tympanostomy tube removal. These findings suggest that the technique of closure and presence of trisomy 21 are independent variables as related to the likelihood for a perforation to heal.

Higher rates of persistent TM perforation were identified in patients who underwent removal of long-acting tympanostomy tubes compared with short-acting tubes. Saito et al[10] reported that the rate of persistent perforations in patients with long-acting tubes was improved with the use of patch myringoplasty following tube removal. Specifically, when Paparella type II and T tubes were removed and a Steri-Strip (3M) tape patch was not applied, perforation rates of 16.7% and 18.0%, respectively, were observed.[10] This rate of perforation was reduced to 3.33% for Paparella type II tubes and 0% for T tubes when a tape patch was used.[10] Tape patches were not used in any of the patients in the current study. However, other types of patches were used and did not yield a significantly reduced perforation rate in ears with either long- or short-term tubes. Furthermore, the surgical technique was not found to significantly interact with the type of tympanostomy tube removed, as related to the likelihood of persistent perforation.

In the present study, several patient factors differed between children with short-acting vs long-acting tubes. In particular, those with long-acting tubes were older, had a greater number of previously placed tympanostomy tubes, and had an increased tube retention time. Such findings suggest that it may be the underlying patient disease, the eustachian tube dysfunction, that contributes to the increased rate of persistent TM perforation.

Most ears in this study (264 of 341) underwent tympanostomy tube removal for the indication of prolonged retention. Other indications included persistent otorrhea (59 of 341) or both otorrhea and prolonged retention (18 of 341). While the upregulation of inflammatory factors in a patient with chronic otorrhea may aid in healing a perforation when a tympanostomy tube is removed, as opposed to the patient having a tube removed for chronic retention, the present study did not show a significant difference in persistent perforation rate among the various indications for removal.

Researchers have reported that the success of TM patching was significantly higher in patients younger than 7 years (91.3%) vs those 7 or older (67.5%).[2,11] In our study, the average age of patients with a persistent TM perforation was significantly older (8.5 years) than those without (6.5 years). Further assessment with single-variable regression resulted in significantly differing mean ages among the 4 treatment groups, indicating that an interaction may exist. Interestingly, the youngest patients on average underwent tube removal alone while the oldest underwent myringotomy patch placement.

While assessing TM perforation status following tympanostomy tube removal, one must consider the cumulative interactions between those factors associated with higher perforation rates and the technique used at the time of tube removal. The AUC for trisomy 21 and age together was very similar to the AUC for trisomy 21, age, and technique at tube removal. This provides further evidence that despite other factors being associated with increased risk of perforations, the technique of tube removal did not significantly affect these results.

Limitations of this study include the retrospective design and the inherent variations in technique that are introduced with procedures performed by multiple physicians. In addition, the duration of follow-up postoperatively was not the same for all patients. The average follow-up for patients without TM perforation was 2.9 months vs 13.2 months for patients with a perforation. This can be explained by the tendency to discharge pa-

Table 5. Interaction Analysis of Tympanostomy Tube Removal Technique and Variables Associated With Persistent TM Perforation[a]

Variable	Tympanostomy Tube Removal Technique				*P* Value[b]
	Freshen Edges	Edge and Patch	Patch	Remove Tube Only	
Trisomy 21					
No	66 (97)	117 (98)	53 (93)	94 (97)	.31
Yes	2 (3)	2 (2)	4 (7)	3 (3)	
Category of tube					
Short acting	10 (16)	14 (18)	6 (29)	11 (15)	.50
Long acting	54 (84)	62 (82)	15 (71)	63 (85)	

Abbreviation: TM, tympanic membrane.

[a] Unless otherwise noted, data are number (percentage) of ears in the noted category.

[b] *P* values calculated by χ^2 analysis.

tients with full TM closure earlier and to schedule follow-up visits for those with perforations for a longer period.

Most operative notes in the present study did not include information regarding size or location of the perforation. While the technique used seemed consistent for each surgeon regardless of the particular patient, the retrospective nature of the study precludes us from knowing whether patient factors, including perforation size or location, affected decision making regarding technique. This potential limitation is mitigated by the apparent predilection by institutional site for one technique or another. This further reinforces the notion that patient factors may have had less influence on technique than did surgeon preference.

Finally, though the sample size in the present study is robust compared with those of previous studies, it remains small. This small sample size may have decreased the likelihood of detecting some significant statistical differences. For example, while there were wide ranges in persistent TM perforation rates between the various tube types within each of the 2 categories of short-acting and long-acting tubes, the sample size was not large enough to assess for statistical differences in length of intubation or perforation rate between each of the types of tubes used.

A prospective study is needed to determine which patients will most likely benefit from adjunctive procedures at the time of tympanostomy tube removal. Furthermore, a large prospective study of persistent TM perforation rate for each type of tube within the short- and long-acting categories could potentially guide tympanostomy tube selection at the time of placement, thereby reducing the likelihood of subsequent perforations.

Conclusions

Following tympanostomy tube removal for persistent otorrhea and/or retained tube, there is a high likelihood of complete closure of the TM. The rate of persistent TM perforation appears to be independent tympanostomy tube removal technique (tube removal alone vs tube removal along with freshened edges and/or patch placement). Older children, those with retained long-term types of tubes, and those with trisomy 21 are likely to have increased risk for persistent TM perforations, regardless of surgical technique. Further prospective study is needed to delineate which patient populations receive the most benefit from adjunctive procedures at the time of tympanostomy tube removal.

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