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ORIGINAL RESEARCH

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Comparison of four ventilation tubes commonly used in the pediatric population: A retrospective cohort study

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Abstract

Objective: To assess differences in otorrhea, tympanic membrane perforation, and time to extrusion in children receiving one of four commonly used, short-term ventilation tubes for the first time.

Methods: Retrospective chart review of 2 years of postoperative follow-up to analyze patient outcomes after insertion of either a Paparella type-I Activent, Armstrong Beveled, Modified Armstrong, or Armstrong Microgel ventilation tube. Incidence of complications was determined by reviewing provider notes. Adjusted multivariate logistic regression models were used to determine odds ratios of complications among the four tube types.

Results: A total of 387 patients were reviewed. The mean age was 2.4 years and 35.9% were female. Armstrong beveled tubes had the highest odds of otorrhea. Paparella type-I tube had the shortest time to extrusion of about 9 months, while Armstrong Beveled had the longest, at almost 19 months. When evaluating episodes of otorrhea each child experienced on average, per month, Armstrong beveled tubes had the highest monthly rate of otorrhea and Paparella type-I the least. No significant differences were found regarding tympanic membrane perforation.

Conclusions: This retrospective chart review showed that no tube was clinically superior across all complications. The findings from this study may give otolaryngologists an opportunity to consider choosing a specific type of tube according to the clinical situation. The large variations in extrusion times should be considered in terms of patient age, seasonality, and desired duration of tube placement.

Level of Evidence: 4.

KEYWORDS

acute otitis media, grommet, otitis media with effusion, tympanostomy tube complications, tympanostomy tube otorrhea, tympanostomy tubes

1 | INTRODUCTION

Tympanostomy tubes were first introduced in 1845, in Germany, but were not widely accepted into clinical practice until Beverly Armstrong introduced a small, plastic, grommet-shaped tube 100 years later.[1,2] Today, tympanostomy tube placement is one of the most frequently performed ambulatory procedures for pediatric patients in the United States.[3]

Various types of tympanostomy tubes have been developed since, classified into two broad categories: short-term, grommet-shaped tubes and long-term, "T-type" tubes. The main materials are fluoroplastic, silicone elastomer, and metal. Tubes may also be coated with various substances, such as silver-oxide, phosphorylcholine, albumin, and antibiotics.[4] The different materials and coatings have the goal of increasing biocompatibility with the middle ear and reducing biofilm formation. Although there are many types of tubes, there is little agreement about the ideal tube for various circumstances.

This study describes the experience of a tertiary academic institution with four common types of short-term tympanostomy tubes and reports differences in complication rates and time to extrusion through a retrospective chart review of first-time tympanostomy tube placement, with 2 years of follow-up.

2 | METHODS

The study was approved by the New York University Langone Medical Center Institutional Review Board. The electronic medical records were searched to review all cases of tympanostomy tube placement in the pediatric population up to 18 years of age at our tertiary care center. Patients were included if they had a first-time tympanostomy tube inserted in 2018 or 2019. Patients with craniofacial abnormalities, lacking follow-up, or concurrent or history of adenoidectomy were excluded from the analysis. Demographic information (sex, age), pre- and perioperative data (use of postoperative otic drops, laterality of the surgery), and postoperative data (complications, time to extrusion) were collected and analyzed. The tubes were inserted into the anterior inferior quadrant of the tympanic membrane. Tube type was determined by surgeon preference. Although there was some variability in the tube chosen, each surgeon had a preferred type. The four tube types used were Paparella type-I Activent, Armstrong Beveled, Modified Armstrong, and Armstrong Microgel, all manufactured by Medtronic Xomed, Inc., Florida, USA (Table 1 and Figure 1). Each chart was reviewed independently by two of the authors, for a minimum of 2 years, postoperative follow-up data.

2.1 | Outcomes

The following physical examination findings were extracted from the electronic medical records: otorrhea, tympanic membrane perforation, cholesteatoma, months to extrusion, and removal under general anesthesia. At the time of data collections, all patients included in the analysis had tubes that were extruded or surgically removed. Otorrhea was further classified as complicated (requiring two or more types of otic antibiotic drops or escalation to oral antibiotics) or chronic (lasting more than 6 weeks, despite treatment). Complications reported at the immediate postoperative appointment and at any point after the first follow-up visit were recorded. Initial follow-up visits were scheduled for 2–6 weeks postoperatively, with additional follow-up at 3–6 months.

2.2 | Statistical analysis

Descriptive statistics, percentages, mean, medians, ranges, and standard deviations were computed to describe the characteristics of the study population. Multivariable logistic regression models, adjusted for age at surgery (continuous), sex (binary: female/male), and race (binary: White/Non-white), were used to assess the relationships between type of tubes and the outcomes. Odds ratios were computed

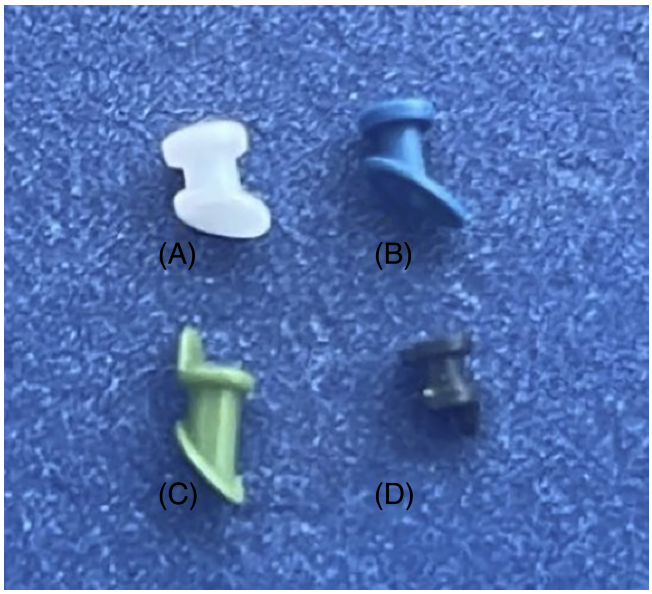

FIGURE 1 Ventilation tubes used in the study. A: Modified Armstrong; B: Armstrong Beveled; C: Armstrong Microgel; D: Paparella type I (5× magnification).

TABLE 1 Characteristics of tympanostomy tubes in this study.

Characteristic	Paparella type-I Activent	Armstrong Microgel	Armstrong Modified	Armstrong Beveled
Material	Silver oxide, silicone	Microgel (polyvinyl-pyrrolidone)	Fluoroplastic	Fluoroplastic
Inner flange diameter	2.4 mm	3.5 mm	3.5 mm	3.5 mm
Inner diameter	1.14 mm	1.14 mm	1.14 mm	1.14 mm
Mass[a]	4.9 mg	6.4 mg	12.7 mg	10.0 mg

[a]Material and diameters obtained from manufacturer. Mettler Toledo XS104 scale used to obtain masses.

and tested against the alternative hypothesis of being different than 1. Linear regression adjusted for age at surgery, sex, and race, was used to evaluate relationships between the types of tubes and mean time to extrusion. Ninety-five percent Wald-type confidence intervals were computed. The *p*-values were considered significant at a .05 level. R (R Core Team, Vienna, Austria) and RStudio (RStudio PBC, Boston, MA) were used to analyze the data.

3 | RESULTS

Electronic medical records of 962 patients were reviewed, of which 575 were excluded (243 previous or concurrent adenoidectomy, 332 lacking follow-up or documentation, and/or craniofacial abnormality). A total of 387 patients (35.9% female and average age 2.43 years) met the inclusion criteria (Table 2). Three main complications were recorded: otorrhea, perforation, and cholesteatoma (Table 3). These were further classified according to the onset of presentation of immediately after surgery or at any point after the first postoperative visit.

3.1 | Otorrhea

Among the patients, 110 (28.4%) experienced one or more episodes of otorrhea (Table 4). Adjusted odds ratios (aOR) for age, sex, and race among the four tube types are given in Table 5. Patients with the Armstrong Beveled tube had significantly higher odds of any form of otorrhea, referred to as generalized otorrhea, compared with those with the Armstrong Microgel (aOR: 4.69, 95% CI: 1.83–12.04, $p < .01$) and the Paparella type-I (aOR 4.50, 95% CI: 1.80–11.27 $p < .01$). The difference between the Armstrong Beveled and the Modified Armstrong was not statistically significant. Children with Armstrong Beveled tubes had the highest rate of episodes of otorrhea per month (0.920), followed by Modified Armstrong (0.552), Armstrong Microgel (0.482), and Paparella type-I (0.372; Table 4). The only statistically significant difference was found between the Paparella type-I and the Modified Armstrong ($p < .05$).

While 110 patients (28.4%) experienced generalized otorrhea, only 27 (7.0%) had complicated otorrhea (requiring two or more types of otic antibiotic drops or escalation to oral antibiotics) and 8 (2.1%) had chronic otorrhea (lasting more than 6 weeks despite treatment). There were no significant differences in the odds ratios of having complicated or chronic otorrhea among the four tube types analyzed (Table 5). Two patients with intractable otorrhea required surgical removal of their tubes (Modified Armstrong and Beveled Armstrong).

3.2 | Perforation

Tympanic membrane perforation occurred in three patients (Table 3). There were no significant differences in odd ratios between the tube types in relation to the likelihood of tympanic membrane perforation (Table 5). Two patients (Beveled Armstrong and Armstrong Microgel) required myringoplasty to repair the perforation, while the third one did not have surgery at the time of data collection.

3.3 | Other complications

One case of cholesteatoma was reported in a patient who received a modified Armstrong tube (Table 3). This patient had bilateral cholesteatomas that required middle ear exploration.

TABLE 2 Demographic characteristics (age and sex) of the study group by tympanostomy tube type.

Variable	Modified Armstrong ($N = 67$)	Armstrong Microgel ($N = 112$)	Paparella type-I tube ($N = 183$)	Armstrong Beveled ($N = 25$)	Overall ($N = 387$)
Age at surgery					
Mean (SD)	2.54 (1.55)	2.08 (1.07)	2.62 (1.63)	2.31 (1.71)	2.43 (1.49)
Median [min, max]	2.10 [0.800, 6.80]	1.75 [0.600, 5.5]	2.20 [0.100, 9.00]	1.60 [0.800, 6.90]	2.00 [0.100, 9.0]
Sex					
Female	33 (49.3%)	35 (31.3%)	61 (33.3%)	10 (40.0%)	139 (35.9%)
Male	34 (50.7%)	77 (68.8%)	122 (67.7%)	15 (60.0%)	248 (64.1%)

TABLE 3 Complications associated with each type of tube immediately postoperatively and after the most recent follow-up.

Complication	Patients	Modified Armstrong $n = 67$	Armstrong Microgel $n = 112$	Paparella type-I $n = 183$	Armstrong Beveled $n = 25$	Total $n = 387$
Otorrhea	Postoperative	6 (9.0%)	9 (8.0%)	12 (6.6%)	7 (28%)	34 (8.7%)
	Last follow-up	22 (32.8%)	26 (23.2%)	39 (21.3%)	12 (48%)	99 (25.6%)
Perforation	Postoperative	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.03%)
	Last follow-up	3 (4.5%)	3 (2.6%)	3 (1.6%)	1 (4.0%)	3 (0.8%)
Cholesteatoma	Postoperative	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Last follow-up	1 (1.5%)	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)

TABLE 4 The number of episodes and rate of otorrhea (episodes of otorrhea each child experienced in 1 month, on average) for each tube type.

	Modified Armstrong ($N = 67$)	Armstrong Microgel ($N = 112$)	Paparella type-I tube ($N = 183$)	Armstrong Beveled ($N = 25$)	Overall ($N = 387$)
Episodes of otorrhea					
0	43 (64.2%)	84 (75.0%)	139 (76.0%)	11 (44.0%)	277 (71.6%)
1	14 (20.9%)	15 (13.4%)	27 (14.8%)	6 (24.0%)	62 (16.0%)
2	7 (10.4%)	8 (7.1%)	10 (5.5%)	7 (28.0%)	32 (8.3%)
3	3 (4.5%)	1 (0.9%)	7 (3.8%)	1 (4.0%)	12 (3.1%)
4	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	1 (0.3%)
5	0 (0%)	2 (1.8%)	0 (0%)	0 (0%)	2 (0.5%)
6	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	1 (0.3%)
Episodes of otorrhea per child per month	0.552	0.482	0.372	0.920	0.470

TABLE 5 Odds ratios with confidence intervals of having complications, adjusted for age, race, and sex among the four tube types.

		Modified Armstrong	Armstrong Microgel	Paparella type-I	Armstrong Beveled
A	Generalized otorrhea				
	Modified Armstrong				
	Armstrong Microgel	0.48 (0.24, 0.95)**			
	Paparella type-I	0.50 (0.26, 0.95)**	1.04 (0.59, 1.83)		
	Armstrong Beveled	2.25 (0.85, 5.97)	4.69 (1.83, 12.04)***	4.50 (1.80, 11.27)***	
B	Complicated/*chronic otorrhea*				
	Modified Armstrong				
	Armstrong Microgel	0.70 (0.21, 2.34)/*1.67* (*0.17, 16.75*)			
	Paparella type-I	0.84 (0.28, 2.54)/*0.73* (*0.06, 8.46*)	1.21 (0.46, 3.17)/*0.44* (*0.07, 2.70*)		
	Armstrong Beveled	1.07 (0.19, 6.11)/*5.77* (*0.48, 69.18*)	1.53 (0.29, 8.10)/*3.45* (*0.52, 22.83*)	1.27 (0.26, 6.31)/*7.92** (*0.97, 64.74*)	
C	Perforation				
	Modified Armstrong				
	Armstrong Microgel	0.91 (0.14, 5.73)			
	Paparella type-I	0.85 (0.15, 4.91)	0.94 (0.20, 4.33)		
	Armstrong Beveled	1.37 (0.12, 16.17)	1.51 (0.15, 15.28)	1.61 (0.17, 15.24)	

Note: A: aOR of generalized otorrhea. B: aOR of complicated/*chronic otorrhea*. C: aOR for tympanic membrane perforation.
Abbreviation: aOR, adjusted odds ratios.
*$p < .1$; **$p < .05$; ***$p < .01$.

3.4 | Extrusion

Patients were followed for a minimum of 2 years through chart review to determine the mean time to extrusion (Table 6). The Paparella type-I tube had the shortest mean time to extrusion of 8.8 and 9.3 months in the left and right ears, respectively, while the Armstrong Beveled had the longest time to extrusion of 18.4 and 20.6 months, respectively. The mean time to extrusion between left and right ears for the same tube type was not significantly different. When adjusted for age, sex, and race for all the ears, the differences in time to extrusion between the tubes were statistically significant, except for the Modified Armstrong and Armstrong Beveled tubes ($p > .1$; Table 7). Among the tube insertions, 34 (8.8%) required removal in the operating room under general anesthesia. Two were removed because of persistent otorrhea and the rest because of delayed extrusion.

TABLE 6 Mean time (in months) to extrusion of all tube types.

Type of tube	Side	Mean	SD	Min	Max	Median
Paparella type-I tube	Left	8.80	6.77	0	25	6.5
	Right	9.25	5.93	0	27	7.0
Armstrong Beveled	Left	18.4	11.28	3	34	19.5
	Right	20.55	10.52	3	34	18.0
Armstrong Microgel	Left	13.8	7.49	0	40	13.0
	Right	13.88	8.48	0	40	12.0
Modified Armstrong	Left	19.07	8.97	0	32	19.0
	Right	17.24	8.21	5	33	16.0
Overall	Left	12.67	8.63	0	40	12.0
	Right	12.94	8.36	0	40	11.0

Note: There were no significant differences between left versus right ear for same tube type.
Abbreviation: SD, standard deviation.

TABLE 7 Linear regression adjusted for age, race, and sex to evaluate relationship between types of tubes and mean time to extrusion.

	Modified Armstrong	Armstrong Microgel	Paparella type-I	Armstrong Beveled
Modified Armstrong				
Armstrong Microgel	−5.456 (−8.979, −1.932)***/*−3.599 (−7.045, −0.152)***			
Paparella type-I	−9.961 (−13.309, −6.613)***/*−7.422 (−10.805, −4.038)***	−4.505 (−7.220, −1.790)*** /*−3.823 (−6.527, −1.119)***		
Armstrong Beveled	−0.786 (−6.281, 4.710)/*3.255 (−1.979, 8.490)*	4.670 (−0.576, 9.915)*/*6.854 (1.901, 11.806)***	9.175 (4.049, 14.301***/*10.677 (5.767, 15.587)***	

Note: Adjusted linear regression showing the relationship between type of tube and mean time to extrusion, with left ear (confidence interval)/*right ear* (*confidence interval*). Positive/negative values represent an increase/decrease in mean time to extrusion.
*$p < .1$; **$p < .05$; ***$p < .01$.

4 | DISCUSSION

This study analyzed differences in four frequently used tympanostomy tubes in pediatric patients receiving tubes for the first time. The study population was comparable to that reported in previous literature in terms of age average and gender distribution.[5–8] To avoid collection bias while analyzing complication rates, patients with a history of or concurrent adenoidectomy were excluded from the study sample.

4.1 | Otorrhea

Otorrhea emerged as the most common complication, affecting over 25% of patients at least once during the lifetime of the ventilation tube.[9] Previous reports have indicated an incidence ranging from 25% to 75%.[10–12] The low incidence documented in the current study could have been influenced by the lockdowns and social isolation associated with the COVID-19 pandemic, as many patients in the cohort were followed after March 2020. It is worth noting that all patients in our study were treated before the Clinical Practice Guidelines for Tympanostomy Tubes in Children were updated; therefore, they were instructed to instill antibiotic ear drops for up to 7 days postoperatively.[13] The Armstrong Beveled tube exhibited the highest rate of otorrhea, but it was also the smallest sample size. After the Armstrong Beveled, the Modified Armstrong had the highest rate of otorrhea. When analyzing the rate of otorrhea per month to account for the varying times to extrusion, the Armstrong Beveled and Modified Armstrong still had the highest rates of otorrhea. Both these tube types are made of fluoroplastic, compared with the Armstrong Microgel and Paparella type-I which were made of softer materials, including silver oxide, silicone, polyvinylpyrrolidone, and fluoroplastic (Table 1). We further classified the type of otorrhea experienced by the patients into complicated or chronic as these are more serious and difficult to treat.

When analyzing the prevalence of these types of otorrhea among the different ventilation tubes, there was no significant difference in their prevalence among the four tube types. Studies have shown that Microgel and Activent-coated tubes reduce biofilm formation and otorrhea.[14,15] However, they did not differentiate between the severity of otorrhea, as in this study. A possible explanation for our findings is that intractable otorrhea requires more aggressive management and may be due to patient-specific characteristics rather than to tube-specific qualities. Simple otorrhea, on the other hand, may be more dependent on tube characteristics.

Our results also show that for most cases, simple otic antibiotic drops will resolve the otorrhea and that escalation to oral antibiotics is usually unnecessary. While some data suggested that the rates of acute otitis media after tube insertion are no different than those of patients who did not undergo the procedure, ear tubes provide a major advantage, in that they allow direct targeting of the infection without the need for systemic antibiotics and their associated complications.[16]

4.2 | Perforation

In this study, permanent tympanic membrane perforation was determined via otoscopy in the follow-up visit following tube extrusion. It was found less often than otorrhea was. While long-term tubes have perforation incidences of over 16%, short-term tubes, such as those evaluated here, have an incidence of 2.2%.[12] This study did not find a significant difference in perforation rates between the four tube types. This is likely because the tubes analyzed were intended for short-term use and the main factor contributing to a tube's likelihood of causing a perforation is the time in the tympanic membrane and the larger mass and inner diameter of the long-term tubes.[12] However, it is also possible that we did not see a difference because this was a rare outcome, as one would expect a higher prevalence of tympanic membrane perforations with heavier tubes (Table 1).

4.3 | Extrusion

An ideal ventilation tube should have several functions. Primarily, by ventilating the middle ear, it should control the otitis media which prompted the tube insertion. Ideally, the tube should remain in the tympanic membrane long enough for the underlying pathology to resolve, but not so long as to cause long-term problems, need for removal under general anesthesia or to create perforations that need repair. While overall complications showed minimal variances, noteworthy distinctions emerged in the extrusion time among the four tube types.

Time to extrusion depends on the tube type, but typically occurs 6–24 months after insertion.[17] The ideal time to extrusion is strongly dependent on the patient's clinical condition. Tubes inserted in a child with recurrent acute otitis media who need to minimize infection for the upcoming winter will be in place less time than those of the child with a cleft palate who needs ventilation to resolve otitis media with effusion. The better choice for ventilating younger children is with a tube that lasts a mean of 20 months, whereas, for an older child, a tube that lasts only throughout the winter and extrudes before summertime may provide more patient and family satisfaction. Water precautions in older children are an additional consideration. It has also been shown that there are increased rates of complications, especially among older children when ventilation tubes are in place for longer than 2 years.[18] Therefore, appropriate tube selection for patients is critical. In addition to medical considerations, parental preferences should be considered in the decision regarding the duration of tube placement. While significant differences in time to extrusion were seen between the tube types, it is reassuring that there was no difference in time to extrusion between the left and right tubes of the same model.

Previous studies have evaluated mean time to extrusion of certain tube types. The Armstrong beveled grommet was reported to last 10.9 months[5,6] in one study and 15.5 months in another,[5,6] which aligns with the 12-month average found in this study. While the Armstrong beveled grommet had the longest time to extrusion, the Paparella type-I tube had the shortest, at about 9 months. Interestingly, the time to extrusion correlated with the mass of the tubes, with the two heaviest tubes (Beveled Armstrong and Modified Armstrong) having the longest times to extrusion. The two tubes with the shortest time to extrusion (Paparella type-I and Armstrong Microgel) also had the lowest rates of operative removal. Additionally, future studies can assess whether the type of tube inserted and the time to extrusion has any relation to the odds of requiring a second set of tubes.

When examining the monthly incidence of otorrhea per child, the outcomes were consistent with earlier observations, indicating that the two fluoroplastic tubes (Armstrong Beveled and Modified Armstrong) continued to exhibit the highest rates of otorrhea. This implies that the duration the tube stayed in position did not impact the overall otorrhea rate.

4.4 | Other considerations

A major limitation of this study was the non-randomized, retrospective design. Each surgeon usually used the same type of tube. Additionally, each tube type had a different sample size given the retrospective nature of this study. While it is unlikely that this played a major role in explaining the differences found, it may have had a confounding effect. Future, prospective studies may address these issues.

5 | CONCLUSION

Tympanostomy tubes are a proven, effective treatment for otitis media. Currently, consensus regarding the ideal tube is lacking, and instead, otolaryngologists may be overwhelmed with the variety of choices. While the ideal tube has not been found and given the variety of conditions that tympanostomy tube insertions are used to treat, it is unlikely that there will be a panacea. Rather, tubes should be selected based on the needs of the individual patient. This study showed that among children receiving ear tubes for the first time, the major difference between tube types was the time to extrusion. No significant differences were found in the rates of complications. In our practice, after the conclusion of this study, we had significant supply chain difficulties with limited selection of tube types available. Based on this data, each physician was able to make a more informed decision as to which type of tube to use. Additionally, we now include time to extrusion as part of our standard preoperative discussion with

parents. These findings may also help other otolaryngologists choose the appropriate tube type for specific clinical situations.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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