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Adenoidectomy for Otitis Media with Effusion in 2 to 3 Year Old Children

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Abstract

Objective—To compare the efficacy of three surgical treatment combinations - myringotomy and tympanostomy tube insertion (M&T), adenoidectomy with M&T (A-M&T), and adenoidectomy with myringotomy (A-M) - in reducing middle ear disease in young children with chronic OME.

Methods—Children 24–47 months of age, with a history of bilateral middle-ear effusion (MEE) for at least 3 months, unilateral for 6 months or longer or unilateral for 3 months after extrusion of a tympanostomy tube, unresponsive to recent antibiotic, were randomly assigned to either M&T, A-M&T, or A-M. Treatment assignment was stratified by age (24–35 months, 36–47 months), nasal obstruction (no, yes) and previous history of M&T (no, yes). Subjects were followed monthly and with any signs or symptoms of ear disease for up to 36 months.

Results—Ninety-eight subjects were randomly assigned to the 3 treatment groups. Fifty-six subjects (57%) were 24–35 months of age; 63% had nasal obstruction, and 36% had previously undergone M&T. During the 36 months after entry, subjects were noted to have MEE for the following percentages of time: 18.6% in the M&T group, 20.6% in the A-M&T group, and 31.1% in the A-M group (M&T vs A-M&T, $p=.87$; M&T vs A-M, $p=.01$). By 36 months, there were no differences in the number of further surgical procedures for ear disease needed among the groups.

Conclusions—Adenoidectomy with or without tube insertion provided no advantage to young children with chronic OME in regard to time with effusion compared to tube insertion alone. Fewer tympanostomy tubes were placed in children undergoing A-M as their initial procedure, but this should be balanced by the performance of the more invasive surgical procedure and their increased time with effusion.

Keywords

Otitis media; Otitis media with effusion; Adenoidectomy; Myringotomy; Myringotomy and tubes

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INTRODUCTION

In 1994 the Agency for Health Care Policy and Research published guidelines for the treatment of otitis media with effusion (OME) [1]. For children ages 1–3 years, the guidelines stated that the lack of evidence and not the existence of data showing no efficacy was the reason the Panel did not recommend adenoidectomy (A) as a primary treatment for uncomplicated middle-ear effusion (MEE) in children younger than 4 years of age. The more recent 2004 Guidelines [2] recommendations were similar to the 1994 recommendations. This lack of evidence for or against efficacy, coupled with “the risk of postoperative bleeding” led the Panel to decide that adenoidectomy is not an appropriate primary treatment for uncomplicated MEE in children younger than 4 years of age. Based on the results from their study Gates et al [3] recommended adenoidectomy and myringotomy as first-line therapy in children 4 years and older with chronic OME. Therefore, it is important to determine whether adenoidectomy in young children is equally as effective as in older children in reducing middle-ear disease.

The specific aim of this study was to compare, by means of a randomized clinical trial, the efficacy of three surgical treatment combinations -- myringotomy and tympanostomy tube insertion (M&T), adenoidectomy with M&T (A-M&T), adenoidectomy with myringotomy alone (A-M) -- in reducing subsequent middle-ear disease in children aged 24–47 months with chronic OME unresponsive to recent antimicrobial treatment.

METHODS

Population, Enrollment and Assignment

Children 24 to 47 months of age with a documented history of bilateral MEE for at least 3 months, unilateral for 6 months or longer or unilateral for 3 months after extrusion of one tympanostomy tube with the other tube still in place and patent were eligible for the study. The study was approved by the Children's Hospital of Pittsburgh (CHP) Human Rights Committee (and later by the University of Pittsburgh Institutional Review Board). A standardized history was obtained for each child and the findings of a standardized ear, nose, and throat examination, including a detailed description of pneumatic otoscopy by a validated observer [4], were recorded. The history of ear disease, including the duration of MEE at entry, was obtained from medical records; in cases in which no or incomplete records were available, parental histories were used. Children were excluded from entry if they had any of the following conditions: previous tonsillectomy and/or adenoidectomy; previous ear surgery other than tympanocentesis or myringotomy with or without tube insertion; history of seizure disorder, diabetes mellitus, asthma requiring daily medication, or any health condition that could make entry potentially disadvantageous to the child; medical conditions with a predisposition for MEE, such as cleft palate, Down syndrome, congenital malformations of the ear; cholesteatoma or chronic mastoiditis; severe retraction pockets; acute or chronic diffuse external otitis; perforation of the tympanic membrane; intracranial or intratemporal complications of MEE; upper respiratory obstruction attributable to tonsil or adenoid enlargement or both with cor pulmonale, sleep apnea or severe dysphagia; conductive hearing loss attributable to destructive changes in the middle ear; sensorineural hearing loss; distance from CHP that would make follow-up difficult.

All patients who fulfilled the entry criteria, who had completed a course of 10 days of a broad spectrum antimicrobial agent within the last month and whose parents gave informed consent were enrolled into the study. The children were randomly assigned within strata defined by age (24–35 months, 36–47 months), nasal obstruction (no, yes based on history provided by parent of snoring and/or mouth-breathing) and previous history of M&T (no, yes) into one of three treatment groups: 1) M&T, 2) A-M&T or 3) A-M. Children with one functioning tympanostomy tube were assigned to one of two treatment groups: 1) M&T or 2) A-M&T. The

children were scheduled for the assigned surgical procedure within 4 weeks after entry into the study.

Follow-up Observations and Subsequent Treatment

Subjects returned two weeks after surgery at which time an examination of the ears, nose and throat including pneumatic otoscopy, tympanometry and audiometry, was performed. After the first post-operative visit subjects were followed with monthly ear, nose and throat examinations which included pneumatic otoscopy and tympanometry for up to 36 months. Subjects were also evaluated at any time in the study clinic if otorrhea, OME, or signs and symptoms of acute otitis media (AOM), occurred and were treated according to a standardized treatment protocol.

Definition of Disease

The term MEE was used to designate middle-ear disease diagnosed as either OME or AOM. Otitis media (OM) was used to designate middle-ear disease diagnosed as OME, AOM, or otorrhea through a tube. OME was defined as asymptomatic MEE, ie, without the symptoms of inflammation characteristic of AOM. The determination of the presence or absence of effusion was based on a previously described decision-tree algorithm that combined admittance testing and pneumatic otoscopy by a validated otoscopist [5]. The following set of criteria using tympanometric width (TW) to categorize middle ear status was used: $TW \leq 150$ daPa = no OME; $TW \geq 350$ daPa = OME; TW between 150 daPa and 350 daPa = diagnose by otoscopy. The finding of fluid levels or bubbles on otoscopic examination superseded the above rules and automatically led to the diagnosis of OME.

The diagnosis of AOM required the finding of MEE on otoscopy with at least 1 symptom and 1 sign of inflammation. The symptoms of AOM included fever (a temperature $>37.2^{\circ}\text{C}$ [99.0°F] orally or $>37.8^{\circ}\text{C}$ [100.0°F] rectally, as taken by the parent or by measurement at the examination); earache or recent onset of ear tugging; and irritability, defined as a recent change in the child's behavior pattern with fussiness. Otoscopic criteria for the diagnosis of AOM included erythema and/or white opacification (other than from scarring) of the tympanic membrane, fullness or bulging of the tympanic membrane, white fluid level, and otorrhea from a perforation of a previously intact tympanic membrane.

Surgical Procedures

Myringotomy with tube insertion—M&T was performed using an operating microscope under general mask inhalation anesthesia on an outpatient basis. A radial myringotomy in the anterior-superior quadrant was performed and a Teflon Armstrong-type tympanostomy tube was inserted after the MEE had been aspirated. Antimicrobial drops were placed in the ear canal following the procedure.

Adenoidectomy and myringotomy with and without tubes—A-M and A-M&T were performed either on an inpatient or outpatient basis. Adenoidectomy was performed using electrocautery or curette or both, and St. Clair-Thomsen forceps and electrocautery with or without packing to obtain hemostasis. A myringotomy alone consisted of a wide incision in the inferior portion of the pars tensa followed by aspiration of the MEE and placement of ototopical antimicrobial drops.

Medical Treatment Protocols

New episodes of AOM—The treatment for an episode of AOM consisted of a 10-day course of amoxicillin (40 mg/kg/day in 2 divided doses), and for those who failed this treatment amoxicillin-clavulanate (40 mg/kg/day of the amoxicillin component in 2 divided doses) for

10 days. If the child was allergic to amoxicillin, alternative medication including one of the newer cephalosporins or macrolides was given.

Persistent MEE—If after the initial surgical procedure(s) OME developed and persisted for 3 months, amoxicillin (40 mg/kg/day in 2 divided doses) was prescribed for 10 days. If MEE persisted bilaterally for 4 consecutive months or cumulatively for 6 of the 12 previous months, or unilateral MEE for either 6 consecutive months or cumulatively for 8 of the 12 previous months, M&T was performed in all children regardless of initial random assignment and the subject continued to be followed in the study. At this time adenoidectomy was also recommended in children randomized to M&T.

Otorrhea—For each episode of otorrhea a culture was obtained and the subject was started on amoxicillin-clavulanate (40 mg/kg/day of the amoxicillin component in 2 divided doses), or an alternative medication if the child was allergic, and neomycin, polymixin B, and hydrocortisone otic suspension (Cortisporin®, 3 drops TID). Later in the study ciprofloxacin and ofloxacin otic drops became available and were used to treat otorrhea. Treatment was adjusted according to the culture result.

Blocked tympanostomy tubes—If a tympanostomy tube became blocked, ototopical antibiotic drops were used for 7–10 days to try to unplug the tube.

Acoustic Immittance and Audiometric Testing

Acoustic immittance testing was performed at all scheduled visits using a GSI-33 Middle Ear Analyzer (Grason-Stadler, Inc, Milford, NH). The test included an estimate of the acoustic equivalent volume of the external ear canal and a tympanogram from which estimates of peak compensated static acoustic admittance, tympanometric width, and tympanometric peak pressure were determined.

Audiometry was performed at entry. Audiometric procedures varied as a function of the age of the child. For children 30 to 47 months of age, play audiometry was used to obtain pure tone thresholds at audiometric test frequencies between 0.5 and 8 kHz and a speech recognition threshold (SRT) in each ear using an adaptive (down 10dB, up 5 dB) procedure. Threshold was considered the lowest level to which the child responded three times out of a maximum of six presentations. Bone-conduction testing was done when air-conduction thresholds exceeded 15 dB HL. For children 24 to 29 months visual reinforcement audiometry with a unilateral head turn was used to obtain soundfield minimum response levels [6]. Stimuli used were speech and warble tones at audiometric test frequencies of 500 to 4000Hz.

Statistical Considerations

Data were analyzed by the “intent-to-treat” principle. Results are presented for the first 18 months, which would represent the effect of the first randomly assigned surgical procedure, as well as the entire 36-month follow-up. The primary outcome was the proportion of time with MEE. An estimate of the proportion of time with MEE was obtained by constructing intervals whose endpoints were the midpoints between the dates of 2 successive visits. The MEE status for the entire interval was then assumed to be the same as the status at the visit within the interval. In cases in which there were more than 91 days between 2 successive visits, interpolation was applied for a maximum of 45.5 days. Middle ear status was considered to be unknown for the remaining days in the interval. For an individual, the proportion of time with effusion was defined as the sum of the length of time of all visits with effusion divided by the length of time observed in the study. The average proportion of time with effusion in the treatment groups was compared by applying the arc sine transformation to the proportion of time with effusion for each individual, then using a weighted regression analysis where the

weights were equal to the length of time observed in the study. Adjustment was made in the regression model for the stratification variables. The differences between the rates of episodes of AOM and otorrhea, respectively, for the 0–18 month interval and the 0–36 month interval, respectively, were assessed using a Poisson regression model in which the stratification variables were included as independent variables.

Comparisons of selected subject characteristics between the treatment groups at entry were performed using a chi square test for categorical variables. SAT data were compared using analysis of variance. SRT and PTA data were analyzed by assuming a normal distribution and using the method of generalized estimating equations.

RESULTS

The study was conducted from 1997 through 2005. Ninety-nine children were enrolled, which is 45% of the calculated sample size of 220; termination was based on the low accrual rate and ending of the funding period. Subject characteristics at entry for the three surgical groups are shown in TABLE 1. The stratification variables (age, nasal obstruction and previous tubes) were balanced by design. The mean age of subjects in each group was 34.7, 34.3, and 35.4 months in the M&T, A-M&T, and A-M groups, respectively. Approximately 60% of all children had nasal obstruction and one-third had undergone previous tympanostomy tube insertion. The distributions of the remaining variables were similar in the three treatment groups and none was statistically significantly different. Hearing measures obtained at entry are shown in TABLE 2.

Distribution of the length of follow-up according to treatment assignment is also shown in TABLE 1. One child who was randomized was found to be ineligible and was excluded from the analyses. Of the 98 remaining children, 3 (3.1%) children did not return for a follow-up visit after entry. Twenty-one (21.4%) children were followed for less than 12 months, while 74 (75.5%), 66 (67.3%), 61 (62.2%) and 58 (59.2%) children were followed for 12, 18, 24 and 36 months, respectively. There was no significant difference between the groups with respect to length of follow-up. Of those subjects with follow-up, 6 children did not receive the assigned surgical procedure: 4 in the A-M&T group (1-M&T, 1-A-M, 2-no surgery) and 2 in the A-M group (1-M&T, 1-no surgery).

Tube life

“Tube life”, the length of time after insertion until a tympanostomy tube became permanently nonfunctional (tube extruded or became blocked), was calculated for the first set of tubes in the M&T and A-M&T groups. Right and left ears behaved similarly. The median “tube life” was 16.34 months in the M&T group and 13.78 months in the A-M&T group. Eighteen children in each group were observed until both the right and left tubes of a set became non-functional. The median time until the 1st tube became non-functional was 13.68 and 10.77 months in the M&T and A-M&T groups, respectively. The median time until the 2nd tube became non-functional was 16.90 and 18.08 months, respectively.

Percent time with middle ear effusion

TABLE 3 shows the mean percentages of time with MEE and OM according to treatment group during the first 18 months and the entire 36-month follow-up. There were no significant differences in percentage of time with MEE or with OM between the M&T and A-M&T groups during the first 18 months (95% CI on the difference in mean percentage of time: (–15.34%, 2.92%), and (–15.28%, 3.12%), respectively) or during the 36 months of follow-up (95% CI on the difference in mean percentage of time: (–9.58%, 5.68%) and (–9.68%, 5.66%), respectively). However, both of these groups spent significantly less time with MEE than the

children in the A-M group ($p < .01$ and $p < .05$ during the first 18 months and 36 months of follow up, respectively). Children in the M&T and A-M&T groups spent approximately 2.1 and 3.3 months, respectively, with MEE while children in the A-M group spent approximately 6.4 months with MEE during the 18 month follow-up. During the 36-month follow-up, children in the M&T and A-M&T groups spent approximately 6.7 and 7.4 months with MEE, respectively, while children in the A-M group spent approximately 11.2 months with MEE.

Distribution of surgical procedures

The mean number of days from randomization to first surgery for the M&T, A-M&T and A-M groups was 20.1, 27.4, and 26.3 days, respectively. During the first 18 months, 14 children underwent two surgical procedures because of ear disease: 3 (9.7%) children each in the M&T and A-M&T groups and 8 (24.2%) children in the A-M group. During the 36 month follow-up, a total of 26 children needed an additional surgical procedure because of ear disease. In the M&T group 8 children underwent repeat M&T and 1 child underwent M without tube insertion (total of 9 children, 29%) and 9 (29.0%) children in the A-M&T group needed a repeat M&T, while 8 (24.2%) children in the A-M group underwent M&T following their initial scheduled ear procedure; one child in the M&T group and 2 children in the A-M&T group required a third set of tubes. In addition, 4 subjects in the M&T group underwent adenoidectomy with the second M&T; 4 subjects in the A-M&T group and 2 subjects in the A-M group underwent tonsillectomy.

Episodes with acute otitis media/otorrhea during follow-up

TABLE 4 shows the distributions of episodes of AOM and otorrhea through a tube for subjects completing 18 and 36 months follow-up in each of the treatment groups. The addition of adenoidectomy to M&T did not prove any advantage in the average monthly rate of AOM. As expected, children who were randomized to A-M had fewer episodes of otorrhea.

Complications/sequelae of treatment

One child in the A-M&T group had persistent bilateral TM perforations which eventually required bilateral tympanoplasties. One child in the A-M&T group had difficulty during anesthesia which led to performance of M&T only.

DISCUSSION

The results show that children who were randomized to A-M had a significantly higher average percent time with MEE. A greater percentage of these children required an additional surgical procedure compared to children who had undergone M&T with or without A during the 18-month follow-up but by 36 months there were no differences in the percentages of subjects undergoing further ear procedures. Also there were no significant differences in percentage of time with MEE, additional surgical procedures, average rates of AOM or otorrhea episodes between children in the M&T and A-M&T groups, indicating that in children ages 24 through 47 months adenoidectomy does not add any further benefit to M&T for the treatment of MEE.

Like the 1994 Guidelines [1] the more recent guidelines published for treatment of otitis media did not recommend adenoidectomy as first-line surgical treatment of OME in children unless a distinct indication exists (e.g., adenoiditis, postnasal obstruction, chronic sinusitis) [2]. For those without another indication for adenoidectomy, the recommendation for initial surgery remains myringotomy with tube insertion, because of limited short-term benefits in children 3 years old or older and lack of data showing efficacy of adenoidectomy in younger children.

Three large retrospective studies assessed the efficacy of adenoidectomy for MEE in young children. Boston et al [7] evaluated the need for additional tube insertion in 2121 patients

undergoing bilateral M&T at a pediatric hospital between 1995 and 2000. The median age of patients undergoing adenoidectomy at the time of M&T was 3.67 years compared to 1.54 years in those not undergoing adenoidectomy. Adenoidectomy reduced the probability of needing a second set of tubes (0.08 vs 0.24, $p<.001$). In 686 of these children for whom risk factor information was evaluated, patients younger than 18 months at the initial procedure were significantly more likely to have a second procedure (26.3% vs 15.9%, $p<.001$) as were those with the presence of craniofacial abnormalities and a family history of adenoidectomy, tonsillectomy or tube insertion.

Coyte et al [8] evaluated the effect of adenoidectomy or adenotonsillectomy at time of tympanostomy tube insertion on the rate of reinsertion of tubes and re-hospitalization for OM-related conditions in 37,316 Canadian children (≤ 19 years) who received tubes as their first surgical procedure for otitis media. Compared to tube insertion alone, adenoidectomy was associated with a reduction in the likelihood of reinsertion of tubes (RR 0.5, 95% CI 0.5–0.6; $p<.001$); compared to adenoidectomy, adenotonsillectomy reduced the risk even further (RR 0.8, 95% CI 0.7–1.0; $p=0.02$). They concluded that performing adenoidectomy or adenotonsillectomy at the time of the initial tympanostomy tube insertion substantially reduces the likelihood of additional hospitalization and operations related to OM among children 2 years or older. However, patients undergoing adjuvant procedures were older than those who only underwent tympanostomy tube insertion (median age 4 years vs 2 years, respectively) and other conditions affecting the choice of procedure such as airway obstruction were not discussed.

The third large retrospective study assessed the benefits of adjuvant pharyngeal surgery (adenoidectomy, adenotonsillectomy and tonsillectomy) at the time of tympanostomy tube insertion in 51,373 children less than 10 years of age in Western Australia [9]. Twenty-nine percent of the children had pharyngeal surgery at the time of the first tube insertion; children 4–9 years of age were 2.5 times more likely to undergo such surgery at their first tympanostomy tube insertion than were younger children. The proportion of children having a second tube insertion was 16% lower in children who had adenoidectomy and 17% lower with adenotonsillectomy compared to children who had tube insertion alone as their first procedure. Although these studies seem to indicate adenoidectomy may be beneficial even in young children, these results should be interpreted with caution as they are retrospective and subject to the inherent problems of such studies.

Two well-designed randomized clinical trials have shown that adenoidectomy is efficacious for the treatment of OME in children. However neither of the studies specifically evaluated children younger than 4 years of age. Maw [10,11] enrolled 103 children 2–11 years of age with bilateral chronic OME and followed them for one year. Subjects were randomly assigned to adenoidectomy, adenotonsillectomy or no surgery; all underwent unilateral tympanostomy tube placement. Adenoidectomy (A) was significantly more effective compared to the control group in regard to resolution of fluid and there was a “better resolution rate” in older (6 years and up) children. Looking at older children Gates and coworkers [3] randomly assigned 578 children 4 to 8 years old with chronic OME to four different groups and followed them for 2 years. The myringotomy (M) group had the greatest amount of time with fluid (51 weeks). The A-M and A-M&T (myringotomy and tube) groups both had a lower percentage of time with effusion (31 and 27 weeks), respectively than M&T alone (36 weeks). Thus, based on these results and the lower incidence of otorrhea in subjects without tubes, Gates et al recommended A-M as the “first line” procedure.

In 1990 Paradise and colleagues [12] studied 213 children 1–15 years old with recurrent AOM or OME (the percentage with each indication is not specified) who had previously had M&T. Children were randomly assigned to adenoidectomy or no adenoidectomy; M&T was also

performed at the same time for specific indications. Of the 99 subjects who were randomized, 36 children were between 1–4 years of age. Results indicated there was a significant reduction in OM during the first 2 years in the children who underwent adenoidectomy compared to those who did not. For the children followed but whose parents chose not to allow random assignment, the results also favored adenoidectomy compared to no adenoidectomy.

Two more recent randomized clinical trials have evaluated the efficacy of adenoidectomy in young children with recurrent AOM. Both studies concluded that adenoidectomy cannot be recommended as the primary treatment in very young children. [13,14]

The rationale for the use of adenoidectomy in the treatment of OME includes possible improvement of Eustachian tube function, as a large adenoid could cause Eustachian tube dysfunction by blocking the nasopharyngeal orifice of the tube [15]. Maw [10] reported that the resolution rate of MEE was better after adenoidectomy in children with larger adenoids compared to children with smaller adenoids. However, others have shown that there is no association between the size of the adenoid and the outcome of the surgical procedure [12, 16]. Other factors such as colonization of the nasopharynx are thought to contribute to the development and persistence of OME. Brook et al [17] showed that the quantitative bacterial load in the adenoids of children with OME was higher than in control children. Recent studies have demonstrated that the adenoids in children with OM contain mucosal biofilms [18,19]; the mechanical debridement of the nasopharynx may reduce the bacterial load.

In this study, Armstrong tympanostomy tubes were used, which have been shown in previous studies [20] as well as in the present study to have a “tube life” of approximately 12 months. If tubes with a shorter tube life had been used, the number of surgical procedures would probably have been higher. Therefore, in young children who are likely to continue to have middle-ear pathology, tubes with longer tube life are recommended to avoid repeat surgery.

In spite of the less than expected recruitment the results of the study demonstrate that adenoidectomy did not increase the efficacy of M&T for the treatment of chronic OME in these young children. The poor recruitment was caused by many factors. Probably the most important factor was the emergence of resistant *S. pneumoniae* which resulted in prophylactic antimicrobial agents no longer being recommended for recurrent AOM and tympanostomy tube insertion becoming the treatment of choice. Consequently children with OM were having tympanostomy tubes inserted at an earlier age and there were fewer eligible children for this study.

The results from the present study suggest that in young children adenoidectomy provided no additional benefit to insertion of tympanostomy tubes as an initial procedure for OME and should be reserved for those with nasal indications for adenoidectomy, such as nasal obstruction, recurrent rhinorrhea and/or chronic adenoiditis. If a second surgical procedure is needed after initial M&T, adenoidectomy with M&T is recommended as there is evidence that future need for surgical treatment may decrease, at least in older children [3,7–9].

Adenoidectomy with myringotomy only (no tube insertion) allowed some children to avoid tube insertion but have middle-ear effusion for a longer period of time; however, all underwent adenoidectomy, a surgical procedure with greater risks and cost compared to tympanostomy tube insertion alone. In children 4 years or older adenoidectomy with myringotomy alone may be effective, but tube insertion is advised for younger children. Tonsillectomy is not recommended for chronic OME due to lack of evidence of efficacy and the risks of the procedure outweigh the benefits [2].

CONCLUSION

Based on the results from the present study universal adenoidectomy concurrent with tympanostomy tube insertion is not recommended as first line surgical treatment in children 2–4 years of age for chronic OME.

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TABLE 1

Distribution of Subject Characteristics at Entry and Length of Follow-Up

Characteristic	Treatment Assignment (N=98)		
	M&T (N=32)	A-M&T (N=32)	A-M (N=34)
No. of Subjects (%)	No. of Subjects (%)	No. of Subjects (%)	No. of Subjects (%)
Age			
24–35 months	19 (59.4)	18 (56.3)	19 (55.9)
36–47 months	13 (40.6)	14 (43.8)	15 (44.1)
Nasal obstruction present	19 (59.4)	21 (65.6)	22 (64.7)
Previous tubes	11 (34.4)	12 (37.5)	12 (35.3)
Male	19 (59.4)	24 (75.0)	22 (64.7)
Race			
White	28 (87.5)	21 (65.6)	26 (76.5)
African-American	2 (6.2)	11 (34.4)	6 (17.6)
Oriental	1 (3.1)	0	0
Biracial	1 (3.1)	0	1 (2.9)
Other	0	0	1 (2.9)
Maternal education			
<12 years	3 (9.4)	3 (9.4)	2 (5.9)
HS graduate	23 (71.9)	22 (68.8)	27 (79.4)
16+ years	5 (15.6)	6 (18.8)	5 (14.7)
Unknown	1 (3.1)	1 (3.1)	0
Number of AOM episodes in previous year			
0–1	8 (25.0)	8 (25.0)	11 (32.4)
2–3	10 (31.3)	9 (28.1)	7 (20.6)
>4	12 (37.5)	12 (37.5)	13 (38.2)
Unknown	2 (6.2)	3 (9.4)	3 (8.8)
Length of time followed			
No follow-up	1 (3.1)	1 (3.1)	1 (2.9)
<18 months	9 (28.1)	9 (28.1)	11 (32.4)
18–34 months	2 (6.3)	2 (6.3)	4 (11.8)
35–36 months	20 (62.5)	20 (62.5)	18 (52.9)

M&T - myringotomy and tube; A-M&T - adenoidectomy with myringotomy and tube; A-M - adenoidectomy with myringotomy

TABLE 2

Mean Hearing Measures at Entry

	Treatment Assignment		
Hearing	M&T	A-M&T	A-M
SAT[*]			
Mean	26.25	20.00	27.22
(SD)	(8.76)	(10.00)	(12.53)
N	8	4	9
SRT^{**}			
Right:			
Mean	26.96	20.42	19.55
(SD)	(9.14)	(8.59)	(8.72)
N	23	24	22
Left:			
Mean	26.11	18.81	21.50
(SD)	(10.79)	(7.57)	(11.37)
N	18	21	20
PTA^{***}			
Right:			
Mean	31.79	24.25	26.73
(SD)	(7.28)	(9.34)	(12.50)
N	7	10	13
Left:			
Mean	30.71	25.42	26.15
(SD)	(10.50)	(10.66)	(10.88)
N	7	9	13

M&T - myringotomy and tube; A-M&T - adenoidectomy with myringotomy and tube; A-M - adenoidectomy with myringotomy; SAT - speech awareness threshold; SRT - speech reception threshold; PTA - pure tone average

* M&T vs A-M&T vs A-M: $p=.53$

** M&T vs A-M&T vs A-M: $p=.01$

*** M&T vs A-M&T vs A-M: $p=.28$

TABLE 3

Percentage of Time with Middle Ear Effusion and Otitis Media During 18 and 36 Months of Follow-up*

	Months 0-18**				Months 0-36***			
	M&T (N=31)	A-M&T (N=31)	A-M (N=33)	M&T (N=31)	A-M&T (N=31)	A-M (N=33)		
Condition	Mean % (SD)	Mean % (SD)	Mean % (SD)	Mean % (SD)	Mean % (SD)	Mean % (SD)	Mean % (SD)	
MEE	11.91 (16.22)	18.12 (20.22)	35.66 (24.93)	18.64 (14.17)	20.59 (16.39)	31.11 (20.76)		
OM	12.84 (16.38)	18.92 (20.36)	35.82 (24.99)	19.21 (14.15)	21.22 (16.58)	31.25 (20.79)		

**p-values: (MEE) M&T vs A-M&T vs A-M, p<.001. M&T vs A-M&T, p=.21 M&T vs A-M, p<.001 A-M&T vs A-M, p=.001

**p-values: (OM) M&T vs A-M&T vs A-M, p<.001 M&T vs A-M&T p=.24 M&T vs A-M, p<.001 A-M&T vs A-M, p=.002

***p-values: (MEE) M&T vs A-M&T vs A-M, p=.02 M&T vs A-M&T, p=.87 M&T vs A-M, p=.01 A-M&T vs A-M, p=.02

***p-values: (OM) M&T vs A-M&T vs A-M, p=.03 M&T vs A-M&T p=.88 M&T vs A-M, p=.02 A-M&T vs A-M, p=.03

M&T - myringotomy and tube; A-M&T - adenoidectomy with myringotomy and tube; A-M - adenoidectomy with myringotomy MEE - middle ear effusion: OME or AOM; OM - otitis media: OME, AOM, or otorrhea through a tube

* Restricted to subjects with follow-up; comparisons adjusted for stratification variables

TABLE 4

Distribution of Episodes of Acute Otitis Media and Otorrhea *

	Treatment Assignment					
	0-18 months**		0-36 months***		0-36 months***	
AOM episodes	M&T (N=22)	A-M&T (N=22)	M&T (N=22)	A-M&T (N=22)	M&T (N=22)	A-M&T (N=22)
0	17 (77.3)	16 (72.7)	16 (72.7)	9 (45.0)	8 (42.1)	8 (47.1)
1	4 (18.2)	5 (22.7)	2 (9.1)	4 (20.0)	7 (36.8)	5 (29.4)
2	1 (4.5)	1 (4.5)	2 (9.1)	6 (30.0)	1 (5.3)	3 (17.6)
3	0	0	1 (4.5)	1 (5.0)	2 (10.5)	0
4-6	0	0	1 (4.5)	0	1 (5.3)	1 (5.9)
Average Rate (per month)	0.016	0.021	0.042	0.028	0.030	0.032
Otorrhea episodes						
0	14 (63.6)	13 (59.1)	20 (90.9)	11 (55.0)	10 (52.6)	14 (82.4)
1	6 (27.3)	6 (27.3)	2 (9.1)	5 (25.0)	4 (21.1)	3 (17.6)
2	1 (4.5)	2 (9.1)	0	3 (15.0)	4 (21.1)	0
3-4	1 (4.5)	1 (4.5)	0	1 (5.0)	1 (5.3)	0
Average Rate (per month)	0.030	0.039	0.006	0.021	0.024	0.006

**p-values: (Rates of AOM) M&T vs A-M&T vs A-M, p=.07 M&T vs A-M&T, p=.58 M&T vs A-M, p=.03 A-M&T vs A-M, p=.07

***p-values: (Rates of Otorrhea) M&T vs A-M&T vs A-M, p=.007 M&T vs A-M&T, p=.59 M&T vs A-M, p=.02 A-M&T vs A-M, p=.003

***p-values: (Rates of AOM) M&T vs A-M&T vs A-M, p=.90 M&T vs A-M&T, p=.77 M&T vs A-M, p=.65 A-M&T vs A-M, p=.82

***p-values: (Rates of Otorrhea) M&T vs A-M&T vs A-M, p=.02 M&T vs A-M&T, p=.66 M&T vs A-M, p=.02 A-M&T vs A-M, p=.009

M&T - myringotomy and tube; A-M&T - adenoidectomy with myringotomy and tube; A-M - adenoidectomy with myringotomy; N - number of subjects

* Restricted to subjects completing follow-up for each interval; comparisons of rates adjusted for stratification variables