Original Investigation

Adenoidectomy as an Adjuvant to Primary Tympanostomy Tube Placement
A Systematic Review and Meta-analysis

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IMPORTANCE Adenoidectomy at initial tympanostomy tube placement (TT) may reduce the rate of repeated surgery for otitis media.

OBJECTIVE To assess the effectiveness of primary adenoidectomy as an adjuvant to TT (Ad + TT) compared with TT alone.

DATA SOURCES PubMed and EMBASE electronic databases were searched with no publication year restrictions beyond those of the individual databases.

STUDY SELECTION Articles that compared outcomes of children having undergone primary Ad + TT with children having undergone TT alone for middle ear disease.

DATA EXTRACTION Medical literature addressing Ad + TT was systematically reviewed. Data extracted included study design, age of children, and follow-up time frame. Level of evidence was assessed, and data were pooled where possible.

MAIN OUTCOMES AND MEASURES Proportion of children requiring repeated TT (r-TT). Secondary outcomes included proportion of children with recurrent acute otitis media (RAOM), otitis media with effusion (OME), otorrhea, or any combination of the 3.

RESULTS Fifteen articles met inclusion criteria. Ten studies (n = 71 353) reported that primary Ad + TT decreased the risk of r-TT or risk of RAOM, OME, or otorrhea compared with TT alone. Four studies (n = 538) reported no difference between Ad + TT groups compared with TT-only groups in the prevention of r-TT or of RAOM, OME, or otorrhea. Despite significant heterogeneity, limited meta-analysis and pooling of data revealed that the estimated rate of r-TT for children undergoing primary adenoidectomy was 17.2% (95% CI, 12.2%-22.2%) vs 31.8% (95% CI, 23.9%-39.8%) for children undergoing primary TT only. When stratified by age younger than 4 years, the protective effects of adenoidectomy were diminished.

CONCLUSIONS AND RELEVANCE The current evidence suggests that primary Ad + TT may be superior to TT only in decreasing the risk of r-TT and the risk of RAOM, OME, or otorrhea. Limitations include heterogeneity of the source data, with the predominance of retrospective data as well as studies with older children supporting the superiority of adjuvant adenoidectomy. The practice of Ad + TT may decrease the risk of repeated surgery in children older than 4 years.

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By the age of 3 years, approximately 1 in every 15 children in the United States has undergone tympanostomy tube placement (TT) for recurrent acute otitis media (RAOM), otitis media with effusion (OME), and conductive hearing loss.[1] Tympanostomy tube placement is the second most common pediatric surgery in the United States, following circumcision.[2] The annual cost of TT is more than $1.1 billion.[3,4] A range of 20% to 50% of children require additional sets of tympanostomy tubes owing to recurrent OME after the extrusion of their initial set of tympanotomy tubes.[5]

The current clinical practice guidelines for OME recommend surgical management for children with 4 or more months of OME with persistent hearing loss or other social and environmental risk; for recurrent or persistent OME in children with developmental risks such as craniofacial abnormalities regardless of hearing status; or for OME with structural damage to the middle ear or tympanic membrane.[5] Other common indications for surgical management include RAOM, defined as at least 3 episodes of acute otitis media in 6 months or at least 4 episodes of acute otitis media in 1 year.[6] Tympanostomy tube placement is the most common initial surgery, though TT with adenoidectomy has been suggested to have similar or superior efficacy in children 4 years or older.[7]

Adenoidectomy brings additional surgical and anesthetic risks. As a result, the procedure is generally not recommended as initial surgery without distinct indications such as adenitis, postnasal obstruction, or chronic sinusitis.[5] However, the current clinical practice guidelines recommend adenoidectomy to be performed during repeated TT (r-TT) in children, excluding children with overt or submucous cleft palate.[5] Studies have shown that adenoidectomy performed at r-TT decreases the need for further repeated surgery by up to 50%, regardless of adenoid size.[7-9]

With the significant reduction in incidence of repeated surgery following adjuvant adenoidectomy to r-TT, the question stands of whether adenoidectomy at the initial TT could have a similar reduction in repeated surgery. Many publications in the past 25 years have compared the efficacy of adjuvant adenoidectomy with the initial TT vs TT only in children with OME, RAOM, or hearing impairment. In 2010, van den Aardweg et al[10] published a Cochrane Review titled "Adenoidectomy for otitis media in children." The systematic review included a portion analyzing data comparing adenoidectomy with bilateral TT vs bilateral TT only. Van den Aardweg et al[10] examined 6 randomized clinical studies comparing the aforementioned intervention groups. Van den Aardweg et al[10] concluded that the data were too heterogeneous to pool into a meta-analysis and that the effect of adenoidectomy appeared "to be small and non-significant." The data included outcomes of times with middle ear effusion (2 studies) and numbers of episodes of RAOM (3 studies) during the follow-up period, as well as failures of tympanostomy tubes (1 study).[10]

We determined that a systematic review focusing on the outcomes of r-TT and failure of treatment would better answer the question of the efficacy of adjuvant adenoidectomy to primary TT compared with primary TT only. This systematic review was performed to objectively evaluate the existing literature with a focus on comparing the risk of repeated surgery between the intervention groups.

Methods

We conducted a systematic review of the medical literature for all prospective and retrospective studies regarding the effectiveness of primary adenoidectomy in conjunction with TT (Ad + TT) compared with TT only for the initial surgical treatment of middle ear disease. Inclusion criteria sought to identify all articles that presented prospective or retrospective data comparing the outcomes of children having undergone primary Ad + TT with children having undergone TT only for middle ear disease. Specific inclusion criteria required that each article presented (1) extractable data regarding indications, procedures, and outcomes for each group; (2) an adequately described study design, and (3) documented follow-up. Exclusion criteria were defined as (1) articles that did not involve children 18 years or younger, (2) single case reports, or (3) articles not available in the English language.

An a priori protocol was developed to search the PubMed and EMBASE databases as well as the Cochrane Library. Keyword and Medical Subject Heading (MeSH) searches were based on the combination of the term *adenoidectomy* with any of the following terms: *tympanostomy*, *ventilation tube*, *otitis media*, *glue ear*, or *ear effusion*. There were no publication year restrictions beyond those of the individual databases. We included both randomized and nonrandomized data. The date of the last search was August 16, 2012. Article titles and abstracts were then reviewed to determine their relevance based on the stated inclusion criteria. Full-text articles were retrieved from those deemed eligible by abstract review and were screened by each author independently. Manual cross-checks of the references were performed to further locate pertinent studies. Each selected article was assigned a level of evidence by each author using guidelines published by the Centre for Evidence-Based Medicine (CEBM) (http://www.cebm.net). An evidence table (**Table**) was constructed to display and analyze results. Conflict resolution was achieved collectively by both authors after discussion and mutual agreement.

To evaluate the effects of primary Ad + TT, we compared the following intervention groups in children undergoing their initial surgery for middle ear disease: (1) Ad + TT and (2) TT only.

The primary outcome measure was defined as the proportion of children requiring r-TT. Secondary outcomes included the proportion of children with RAOM, OME, otorrhea, or any combination RAOM, OME, and otorrhea. In addition to the outcomes, data extracted included study design, indication for surgery, age of children included in study, and follow-up time frame.

A limited meta-analysis and pooling of the data was performed using a random effects model because of the heterogeneity of the source data. Standard error was estimated as the inverse of sample size. Potential publication bias was evaluated using funnel plot techniques in the Egger weighted-linear regression method. All analyses were performed using

Table. Evidence Table[a]

Source	Study Design	CEBM	No.	Age, Mean (SD) [Range], y	Follow-up Time, y	Significant Findings	Overall Conclusion
Kujala et al,[11] 2012	Prospective RCT	1b	200	1.40 (0.35) [0.83-2.00]	1	Of 100 Pts between 10 mo and 2 y with TT, 21 (21%) had RAOM and/or OME; 16 of 100 Pts (16%) with Ad + TT had RAOM and/or OME	No difference
Gleinser et al,[12] 2011	Retrospective	2b	870	3.49 (2.00)[b] [1.60-10.00]	...[c]	Of 780 Pts with TT alone, 178 (22.6%) needed r-TT; 6 of 90 Pts (6.7%) with Ad + TT needed r-TT	Ad + TT may decrease risk of r-TT
Casselbrant et al,[13] 2009	Prospective RCT	1b	62	2.87 (0.50)[b] [2.00-3.90]	3	By 36 mo, no difference in number of further surgical procedures for ear disease were needed among Ad + TT and TT groups	No difference
Kadhim et al,[14] 2007	Retrospective	2b	36 287	4.00 (NR)[b] [0.00-10.00]	...[c]	Of 6339 Pts with Ad + TT, 1291 (20.4%) required repeated surgery; 10 846 of 29 948 Pts (36.2%) with TT required repeated surgery	Ad + TT may decrease risk of r-TT
Ahn et al,[15] 2006	Retrospective	2b	423	4.87 (2.02) [0.00-18.00]	2.7	Of 135 Pts with Ad + TT, 36 (26.7%) had triple surgery; 135 of 288 Pts (46.9%) with TT had triple surgery	Higher proportion of Pts with TT alone had triple surgery compared with Pts with primary Ad + TT
Pereira et al,[16] 2005	Prospective cohort	2b	75	2.89 (1.54) [0.92-9.30]	3	Of 80 ears with Ad + TT, 8 (10%) had otorrhea; 15 of 66 ears (22.7%) with TT had otorrhea (*P* = .02)	Ad + TT may reduce risk of otorrhea
Hammarén-Malmi et al,[17] 2005	Prospective RCT	1b	217	1.9 (0.7) [1.0-4.0]	1	Of 102 Pts with Ad + TT, 10 (9.8%) required r-TT; 8 of 96 Pts (8.3%) with TT required r-TT	No difference
Nguyen et al,[18] 2004	Prospective RCT	1b	63	3.8 (NR) [1.5-9.5]	1	Of 23 Pts with Ad + TT, treatment failed in 5 (21 .7%); treatment failed in 17 of 40 Pts (42.5%) with TT, regardless of adenoid size	Ad + TT may reduce risk of RAOM and/or OME
Boston et al,[19] 2003	Retrospective	2b	2121	2.07 (NR)[d] [0.15-13.00]	...[c]	Of 527 Pts with Ad + TT, 42 (8%) required r-TT; 382 of 1594 Pts (14%) with TT required r-TT	Ad + TT may decrease risk of r-TT
Coyte et al,[8] 2001	Retrospective	2b	30 889	2.27 (NR)[d] [0.00-19.00]	2	Of 4125 Pts with Ad + TT, 375 (9.1%) required repeated surgery; 4855 of 26 714 Pts (18.2%) with TT required repeated surgery	Ad + TT may decrease risk of r-TT
Maw and Bawden,[20] 1994	Prospective RCT	1b	222	NR (NR) [2-9]	5	A lower proportion of Pts with Ad + TT required r-TT compared with Pts with TT at 1-5 y of f/u	Ad + TT may decrease risk of r- TT
Dempster et al,[21] 1993	Prospective RCT	1b	78	5.8 (1.3) [4.0-9.0]	1	There was no significant difference in otorrhea in Pts with Ad + TT vs TT at 6- and at 12-mo f/u	No difference
Honjo et al,[22] 1992	ProspectiveRCT	4	130	6.1 (NR) [4.0-8.0]	3	At 1-y f/u, 32 of 57 Pts (56%) with Ad + TT had OME and 61 of 73 Pts (84%) with TT had OME; at 2-y f/u, 19 of 57 Pts (33%) with Ad + TT had OME and 37 of 73 Pts (51%) with TT had OME; at 3-y f/u, 15 of 57 Pts (26%) with Ad + TT had OME and 18 of 73 Pts (25%) with TT had OME	Primary Ad + TT improved the cure rate from refractory OME during the first 2 y of f/u but made no difference by the 3-y f/u
Black et al,[23] 1990	Prospective RCT	1b	149	6.12 (0.22) [4.00-9.00]	2	Of 75 Pts with Ad + TT, 14 (19%) required repeated surgery; 33 of 74 Pts (45%) with TT required r-TT within the 24-mo f/u period	Ad + TT may decrease risk of r-TT
Gates et al,[24] 1988	Prospective RCT	1b	254	5.4 (NR) [4.0-8.0]	2	Of 125 Pts with Ad + TT, 17 (13.6) required r-TT; 36 of 129 Pts (27.9%) with TT required r-TT	Ad + TT may decrease risk of r-TT

Abbreviations: Ad, adenoidectomy; Ad + TT, adenoidectomy with tympanostomy tube placement; CEBM, Centre for Evidence-Based Medicine; f/u, follow-up; NR, not reported; OME, otitis media with effusion; Pts, patients; RAOM, recurrent acute otitis media; RCT, randomized clinical trial; TT, tympanostomy tube placement.

[a] A summary of reviewed studies to include author, publication year, study design, level of evidence according to CEBM (http://www.cebm.net), total number of subjects, age range and mean, length of follow-up time, significant findings, and overall conclusion of each study.

[b] Mean (SD) age was calculated based on age categories reported in the article.

[c] Studies documented follow-up but did not specify length of follow-up time.

[d] Mean age estimation was based on median age reported in the article.

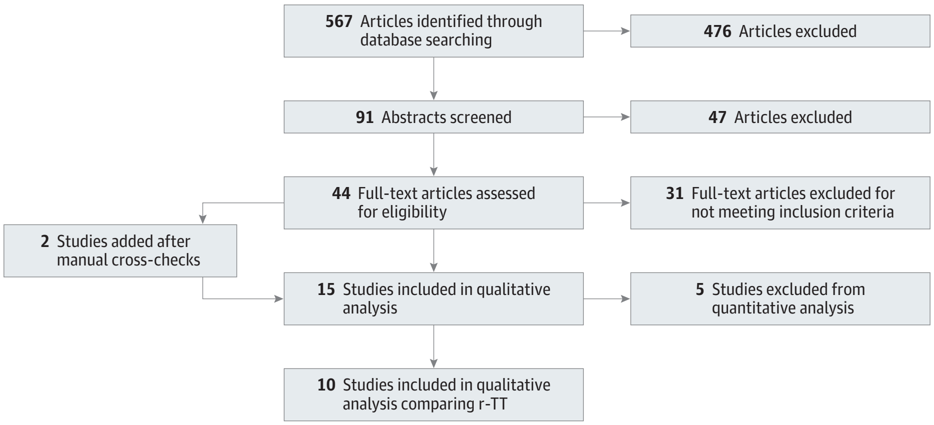
STATA IC version 11.2 (StataCorp). For all analyses, the null hypothesis was rejected when the *P* value was less than .05. Given the degree of heterogeneity, only data regarding repeated surgery for ear disease was subject to pooling.

Results

The initial literature search revealed 567 potential articles. Both authors (S.M. and M.B.) independently selected articles for abstract review, resulting in 91 abstracts of interest. The other 476 articles were excluded for not comparing primary Ad + TT with TT only in the treatment of otitis media. The 2 authors independently reviewed the abstracts and selected a total of 44 full-text articles for review. The other 47 abstracts were excluded for not containing the intervention groups of interest. The 44 articles were manually cross-checked, and 2 articles were added to the set. The predetermined inclusion criteria were applied, and 15 articles were identified to meet inclusion parameters, which included the 2 additional articles (**Figure 1**). The remaining 31 articles were excluded for a variety of reasons including tonsillectomy in their intervention groups without isolated Ad + TT groups (9 studies), having previous TT in the intervention groups (1 study), lack of data about the primary outcome measures of interest for this systematic review (15 studies), or duplicate data with studies included in this review (6 studies). The remaining 15 articles represent the final set (Table).

The overall level of the evidence is grade B, given that most studies included were assigned a CEBM level 2b or 1b. Of the articles, 9 were prospective randomized clinical

Figure 1. Search Strategy Flow



Flow diagram displaying the results of the systematic search strategy. r-TT indicates repeated tympanostomy tube placement.

studies.[11,13,17,18,20-24] Five articles were retrospective studies.[8,12,14,15,19] One article was a prospective cohort study.[16] Sample sizes ranged from 62 to 36 287 patients (total number of patients in all 15 studies, 72 021). Sample sizes for prospective randomized clinical studies ranged from 62 to 254 patients. Samples sizes for retrospective studies ranged from 423 to 36 287 patients. The prospective cohort study had a sample size of 75 patients. Age ranges overall were from 1.8 months to 19 years. The prospective randomized clinical studies had age ranges from 10 months to 9 years. The retrospective studies had age ranges from 1.8 months to 19 years.

Qualitative Analysis

Qualitatively, 10 studies suggested that Ad + TT was superior to TT only, with a total of 71 353 patients.[8,12,14-16,18-20,23,24] Eight studies showed a reduction in the rate of r-TT in the Ad + TT group compared with the TT-only group, with a total of 71 215 patients.[8,12,14,15,19,20,23,24] Of the 8 studies, 5 were retrospective, with a total of 70 590 patients.[8,12,14,15,19] Of the 8 studies, 3 were randomized clinical prospective studies, with a total of 625 patients.[20,23,24] The other 2 studies showed a reduction in RAOM, OME, or otorrhea or a combination of the 3 outcomes, with a total of 138 patients.[16,18] One study was a prospective cohort study (75 patients)[16]; the other was a randomized clinical prospective study (63 patients).[18]

One study showed that Ad + TT helped improve cure rate from refractory OME during the first 2 years of follow-up but made no difference by year 3 of follow-up, with a total 130 patients.[22]

Four studies from the set showed that there was no difference between Ad + TT compared with TT only in repeated surgery, OME, RAOM, or otorrhea.[11,13,17,21] These 4 studies were all randomized clinical studies, with a total 538 patients.[11,13,17,21]

Quantitative Analysis

The limited meta-analysis focused on the rate of repeated surgery for middle ear disease; the data was extracted from 10 studies.[8,12-15,17,19,20,23,24] The remaining 5 studies were excluded for not containing data regarding the rate of repeated surgery.[11,16,18,21,22] Of note, there was significant heterogeneity across the studies (I^2 = 60.0%; P = .007). However, each study presented clear outcome data regarding the need for repeated surgery. The pooled data demonstrate that undergoing a primary Ad + TT results in a lower rate of repeated surgery. The pooled estimate of the rate of r-TT for children undergoing a primary adenoidectomy was 17.2% (95% CI, 12.2% to 22.2%) vs 31.8% (95% CI, 23.9% to 39.8%) for children undergoing primary TT only (**Figure 2A-B**). The pooled odds ratio of undergoing r-TT if a child undergoes primary Ad + TT was 0.44 (95% CI, 0.42 to 0.47) (Figure 2C).

Given that most of the patients (67 126 of the 71 425 patients where meta-analytic techniques were applied) were presented in 2 large retrospective studies,[8,14] analysis without these studies was performed to identify if an appreciable difference in rates existed. In this analysis,[12,13,15,17,19,20,24] the pooled estimate of the rate of r-TT for children undergoing a primary adenoidectomy was 17.9% (95% CI, 9.9% to 25.9%) vs 33.4% (95% CI, 28.0% to 38.1%) for children undergoing primary TT only, demonstrating that the large studies' effect sizes were in line with the smaller studies.

When stratifying based on age, prior data and clinical experience suggest that children younger than 4 years may have a different set of expectations compared with children requiring surgery for ear disease who were older than 4 years. As such, studies were assessed and divided between those that exclusively focused on children younger than 4 years and those that included older children. When articles that only included children younger than 4 years were excluded, the pooled estimate of the rate of r-TT for children undergoing a primary adenoidectomy was 16.8% (95% CI, 11.3% to 22.3%) vs 35.5% (95% CI, 26.6% to 44.3%) for children undergoing primary TT only.[8,12,14,15,19,20,23,24] When studies clearly included only children younger than 4 years, the pooled estimate of the rate of r-TT for children undergoing a primary adenoidectomy was 19.2% (95% CI, 0.3% to 38%) vs 16.8% (95%CI, −0.39% to 33.9%) for children undergoing primary TT only.[13,17] However, only 2 studies met this criteria, resulting in the wide confidence intervals.[13,17]

Figure 2. Forest Plots of the Random Effects Models

A

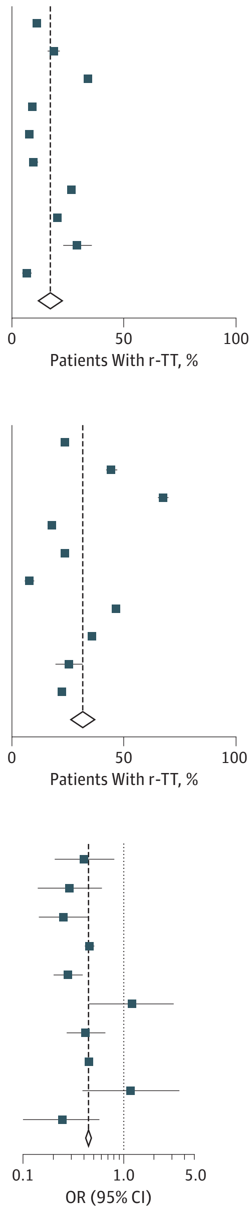
Source	Rate of r-TT (95% CI), %
Gates et al,[7] 1987	11 (10-13)
Black et al,[23] 1990	19 (16-21)
Maw and Bawden,[20] 1994	34 (32-35)
Coyte et al,[8] 2001	9 (9-9)
Boston et al,[19] 2003	8 (8-8)
Hammaren-Malmi et al,[17] 2005	10 (8-12)
Ahn et al,[15] 2006	27 (25-28)
Kadhim et al,[14] 2007	20 (20-20)
Casselbrant et al,[13] 2009	29 (23-35)
Gleinser et al,[12] 2011	7 (4-9)
Overall (I^2 = 100%, P < .001)	17 (12-22)

B

Source	Rate of r-TT (95% CI), %
Gates et al,[7] 1987	24 (23-26)
Black et al,[23] 1990	45 (42-47)
Maw and Bawden,[20] 1994	67 (65-70)
Coyte et al,[8] 2001	18 (18-18)
Boston et al,[19] 2003	24 (24-24)
Hammaren-Malmi et al,[17] 2005	8 (6-10)
Ahn et al,[15] 2006	47 (46-48)
Kadhim et al,[14] 2007	36 (36-36)
Casselbrant et al,[13] 2009	26 (19-32)
Gleinser et al,[12] 2011	23 (23-23)
Overall (I^2 = 100%, P < .001)	32 (24-40)

C

Source	OR of r-TT (95% CI)
Gates et al,[7] 1987	0.40 (0.20-0.79)
Black et al,[23] 1990	0.29 (0.14-0.60)
Maw and Bawden,[20] 1994	0.25 (0.14-0.44)
Coyte et al,[8] 2001	0.45 (0.40-0.50)
Boston et al,[19] 2003	0.27 (0.20-0.38)
Hammaren-Malmi et al,[17] 2005	1.20 (0.45-3.17)
Ahn et al,[15] 2006	0.41 (0.26-0.64)
Kadhim et al,[14] 2007	0.45 (0.42-0.48)
Casselbrant et al,[13] 2009	1.18 (0.38-3.60)
Gleinser et al,[12] 2011	0.24 (0.10-0.56)
Overall (I^2 = 60.0%, P = .007)	0.44 (0.42-0.47)



A, Forest plot of the random effects model of the rate of repeated tympanostomy tube placement (r-TT) in children undergoing primary adenoidectomy in addition to tympanostomy tube placement (TT) for middle ear disease demonstrating a pooled success rate of 17.2% (95% CI,12.2%-22.2%). Weights are from random effects analysis. B, Forest plot of the random effects model of the rate of r-TT placement in children undergoing TT without primary adenoidectomy for middle ear disease demonstrating a pooled success rate of 31.8% (95% CI, 23.9%-39.8%). Weights are from random effects analysis. C, Forest plot of the random effects model of the odds ratio (OR) of r-TT in children undergoing primary adenoidectomy in addition to TT compared with children undergoing TT only for middle ear disease demonstrating a pooled odds ratio of 0.44 (95% CI, 0.42-0.47). Weights are from random effects analysis.

When studies were limited to level 1b quality data, only 5 studies met inclusion criteria. In these studies, the pooled estimate of the rate of r-TT for children undergoing a primary adenoidectomy was 20.4% (95% CI, 9.2% to 31.6%) vs 34.1% (95% CI, 13.2% to 54.9%) for children undergoing primary TT only.[13,17,20,23,24]

Unfortunately, insufficient data were available regarding surgical indication to allow further subgroup analysis. Funnel plots for the rate of r-TT for each group were constructed to quantitatively assess for publication bias. While the rates were variable, which is consistent with the marked heterogeneity of the data, the plots were relatively symmetric and demonstrated no preponderance of small study effects or publication bias in a specific direction.

Discussion

The goal of this review was to gain insight into the role that primary adenoidectomy plays in children undergoing initial TT for middle ear disease. On the basis of previous literature and experience, many otolaryngologists proceed with an adenoidectomy at the placement of a second set of tympanostomy tubes regardless of the presence of symptomatic adenoid disease. The primary stimulus for this investigation was to determine the evidence regarding adenoidectomy at the primary surgery as a means to decrease the rate of further surgical procedures.

The presented evidence demonstrates that although there have been many excellent studies investigating the surgical management of RAOM and OME, there is a significant amount of heterogeneity. However, qualitatively, there is a preponderance of studies that suggest benefits both in a decreased rate of r-TT as well as complications such as otorrhea as well as RAOM and OME when an adenoidectomy is performed at the time of initial TT. The limited quantitative analysis supports the notion of the protective effect of adenoidectomy against further surgery because the estimated rate of r-TT in children who underwent adenoidectomy was roughly half the rate of children who underwent primary TT alone. These rates were robust and consistent when the pooled data were limited to only level 1b studies as well as when the pooled data excluded the 2 large retrospective studies.

Unfortunately, the data were not robust enough to allow an extensive stratification of subgroups of children undergoing surgery. In particular, the available data precluded stratification by surgical indication of RAOM vs OME despite the known variation in clinical course. However, it does appear that in children younger than 4 years, adenoidectomy may not provide the same protective effect as in older children. One plausible explanation may be that children who have persistent ear disease at an older age may have a more complex process of eustachian tube dysfunction that leads to recalcitrant disease, possibly leading to more benefit gained by the addition of adenoidectomy to TT. Another plausible explanation may be that adenoid tissue is most active in children between age 4 and 10 years before their involution during puberty, possibly attributing more to the pathophysiology of eustachian tube dysfunction in children of that age.[25] However, the inability to stratify the data by surgical indication, the limited number of studies focusing on young children exclusively as well as unknown confounders in the retrospective data may also have produced the age-based finding. Of note, the 4 prospective randomized clinical trials showing no difference between adjuvant adenoidectomy with primary TT and primary TT alone include the study with age range below age 2 years,[11] both studies with age ranges below age 4 years,[13,17] as well as 1 of the 7 studies with age ranges below 9 years.[21] The randomized clinical trials containing younger subjects disproportionately support the hypothesis that there is no difference.

As in all systematic reviews, the outcomes are only as strong as the source data. While most of the studies demonstrated superior results with adenoidectomy with primary TT, the majority of the patients (n = 70 590) were from retrospective studies.[8,12,14,15,19] Only 763 patients favoring Ad + TT were from prospective studies.[16,18,20,23,24] Of this prospective data, 75 patients were from a cohort study.[16] The predominance of retrospective data in supporting adjuvant adenoidectomy is a significant limitation. For one, the patients included in the retrospective studies include children within a much wider age range than the majority of the randomized clinical studies. This could skew the results because younger children are more likely to have repeated surgery due to the natural course of otitis media and anatomic development, lending the appearance of increased risk of repeated surgery in the tube placement alone group. In addition, there may have been selection bias in that children younger than 4 years may have had less adenoidectomies owing to the desire to avoid potentially increased morbidity in younger children, which would also affect the appearance of increased risk of repeated surgery in the tube placement only group. In the retrospective studies, which include children up to age 18 years, there may be a selection bias toward older children. This contrasts with all of the prospective randomized clinical trials, which have age ranges below age 2 years (1 study),[11] below age 4 years (2 studies),[13,17] or below age 9 years (7 studies).[16,18,20-24] Unfortunately, the available retrospective studies do not provide raw data to effectively stratify across age ranges, limiting a comparison with the prospective studies where stratification is possible. As such, conclusions regarding children younger than 4 years are limited. However, the subanalyses excluding the large retrospective studies and limiting to level 1b data demonstrate similar findings to the overall analysis, suggesting that the preponderance of retrospective data does not significantly change the overall findings of the quantitative analysis.

Publication bias is always a primary concern in systematic reviews, and the heterogeneity of the data may be due to some degree of such bias. Although methodologically limited in this review, funnel plots demonstrated reasonable symmetry. An extensive attempt to discover all positive and negative studies was made. Furthermore, the high degree of variability may have been due to a heterogenous set of indications to replace tympanostomy tubes beyond those of the clinical practice guidelines that were published after many of the studies were performed.

Conclusions

On the basis of the best available data, primary adjuvant adenoidectomy at the time of TT appears to provide a protective effect against repeated surgery or complications in children older than 4 years with RAOM or OME. However, the additional morbidity of an adenoidectomy needs to be carefully weighed against the modest improvement in outcomes. Furthermore, given the high volume of surgically managed ear disease, an a priori cost-effectiveness analysis is appropriate to determine the public health implications of such a strategy. Should the cost savings and quality-of-life effects of primary Ad + TT outweigh the major complication risks of adenoidectomy, perhaps a large-scale clinical trial designed to determine at what age adenoidectomy becomes advantageous may be performed, since these data are limited. Currently, otolaryngologists may consider offering primary adenoidectomy as a means to prevent further surgical procedures in children older than 4 years undergoing initial surgery for otitis media.

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Acquisition of data: Mikals.
Analysis and interpretation of data: Mikals and Brigger.
Drafting of the manuscript: Mikals.
Critical revision of the manuscript for important intellectual content: Mikals and Brigger.
Statistical analysis: Brigger.
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Study supervision: Brigger.

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