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.
B y 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 tympanostomy 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 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 al10 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 al10 examined 6 randomized clinical studies comparing the aforementioned intervention groups. Van den Aardweg et al10 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. Key word 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
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 (9 studies), having previous TT in the intervention groups (3 studies), or did not report significant findings (10 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

### 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 (3 studies), or did not report significant findings (10 studies). The remaining 15 articles represent the final set (Table).

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Fig. 1. Search Strategy Flow

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

Qualitative Analysis
Qualitatively, 10 studies suggested that Ad + TT was superior to TT only, with a total of 71 353 patients. 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. Of the 8 studies, 5 were retrospective, with a total of 70 590 patients. The other 2 studies were randomized clinical prospective studies, with a total of 625 patients. One study was a prospective cohort study (75 patients); the other was a randomized clinical prospective study (63 patients).

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.

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. These 4 studies were all randomized clinical studies, with a total 538 patients.

Quantitative Analysis
The limited meta-analysis focused on the rate of repeated surgery for middle ear disease; the data was extracted from 10 studies. The remaining 5 studies were excluded for not containing data regarding the rate of repeated surgery. Of note, there was significant heterogeneity across the studies (I² = 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 (Fig. 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) (Fig. 2C).

Given that most of the patients (67 126 of the 71 425 patients) who underwent surgery for children requiring surgery for ear disease who were older than 4 years, the pooled 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 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. 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, 0.3% to 38%) for children undergoing primary TT only. However, only 2 studies met this criteria, resulting in the wide confidence intervals.
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
Adenoidectomy at Tympanostomy Tube Placement

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.
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REFERENCES