Surgical Treatments for Otitis Media With Effusion: A Systematic Review

abstract

BACKGROUND AND OBJECTIVE: The near universality of otitis media with effusion (OME) in children makes a comparative review of treatment modalities important. This study’s objective was to compare the effectiveness of surgical strategies currently used for managing OME.

METHODS: We identified 3 recent systematic reviews and searched 4 major electronic databases. Eligible studies included randomized controlled trials, nonrandomized trials, and cohort studies that compared myringotomy, adenoidectomy, tympanostomy tubes (tubes), and watchful waiting. Using established criteria, pairs of reviewers independently selected, extracted data, rated risk of bias, and graded strength of evidence of relevant studies. We incorporated meta-analyses from the earlier reviews and synthesized additional evidence qualitatively.

RESULTS: We identified 41 unique studies through the earlier reviews and our independent searches. In comparison with watchful waiting or myringotomy (or both), tubes decreased time with OME and improved hearing; no specific tube type was superior. Adenoidectomy alone, as an adjunct to myringotomy, or combined with tubes, reduced OME and improved hearing in comparison with either myringotomy or watchful waiting. Tubes and watchful waiting did not differ in language, cognitive, or academic outcomes. Otorrhea and tympanosclerosis were more common in ears with tubes. Adenoidectomy increased the risk of postsurgical hemorrhage.

CONCLUSIONS: Tubes and adenoidectomy reduce time with OME and improve hearing in the short-term. Both treatments have associated harms. Large, well-controlled studies could help resolve the risk-benefit ratio by measuring acute otitis media recurrence, functional outcomes, quality of life, and long-term outcomes. Research is needed to support treatment decisions in subpopulations, particularly in patients with comorbidities. Pediatrics 2014;133:296–311

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KEY WORDS
adenoidectomy, comparative effectiveness, myringotomy, otitis media with effusion, surgical treatments, systematic review, tympanostomy tubes

ABBREVIATIONS
AOM—acute otitis media
CI—confidence interval
CINAHL—Cumulative Index to Nursing and Allied Health Literature
EPC—Evidence-based Practice Center
KQ—key question
OME—otitis media with effusion
PICOTS—populations, interventions, comparators, outcomes, time frames, and settings
RCT—randomized controlled trial
SOE—strength of evidence

Dr Wallace selected articles for inclusion, extracted data, graded the strength of evidence, and drafted and revised the manuscript; Dr Berkman selected articles for inclusion, extracted data, graded the strength of evidence, and reviewed and revised the manuscript; Dr Lohr selected articles for inclusion and reviewed and revised the manuscript; Drs Harrison, Kimple, and Steiner selected articles for inclusion, extracted data, and reviewed the manuscript; and all authors approved the final manuscript as submitted.

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Otitis media with effusion (OME) is defined as a collection of fluid in the middle ear without signs or symptoms of acute ear infection. Fluid in the middle ear decreases tympanic membrane and middle ear function, leading to conductive hearing loss, “fullness” in the ear, and occasional pain from the pressure changes. Children with OME often have a conductive hearing loss on pure-tone audiometry that measures at 25 dB, a level that is 10 dB worse than the level for children with normal hearing. OME occurs commonly during childhood; as many as 90% of children (80% of individual ears) have at least 1 episode of OME by age 10. Many episodes of OME resolve spontaneously within 3 months, but 5% to 10% of episodes last more than 1 year; 30% to 40% of children have recurrent episodes. Despite the high prevalence of OME, its long-term impact on child developmental outcomes, such as speech, language, intelligence, and hearing remain disputed. A recent systematic review of the natural history of OME found mixed evidence regarding the impact of OME in early childhood on later developmental outcomes. Lacking clear evidence that OME influences children’s development, clinicians struggle with decision-making for this common condition. Many children with OME are actively treated; the annual total cost of treating OME in the United States in 1995 was estimated at $4 billion and may well be higher today.

The near universality of OME in children and the high cost of its treatment make it an important topic for a comparative review of treatment modalities. Accordingly, the Agency for Healthcare Research and Quality commissioned the RTI-University of North Carolina Evidence-based Practice Center (EPC) to conduct a systematic review of the comparative effectiveness and harms of treatments for OME. Our review was not designed to examine whether OME should be treated. Rather, we examined the relative effectiveness of a range of treatment options (tympanostomy tubes [tubes], myringotomy, adenoidectomy, oral or topical nasal steroids, auto-inflation, complementary and alternative medicine procedures, variations in surgical technique or procedures, and watchful waiting) in patients with OME of any age.

This article focuses solely on surgical interventions (ie, myringotomy, adenoidectomy, and tubes) and their comparators. In the United States, surgical treatments are common interventions for persistent or recurrent OME. In contrast, steroids are not recommended in current guidelines, and a recent review did not find them to be effective; auto-inflation is uncommon; and no randomized controlled trials (RCTs) provided evidence concerning complementary and alternative medicine procedures. A recent systematic review of antibiotics did not support routinely treating children diagnosed with OME with antibiotics.

We attempted to answer 5 key questions (KQs) concerning treatment comparisons for patients with OME: What is the comparative effectiveness of surgical treatments and watchful waiting in (1) affecting clinical outcomes or health care use and (2) improving functional and health-related quality of life outcomes? (3) What are the harms or tolerability of the different treatment options? (4) What are the comparative benefits and harms of treatment options in subgroups of patients? (5) Is the comparative effectiveness of treatment options related to factors affecting health care delivery or the receipt of pneumococcal vaccine inoculation? In reviewing the evidence to answer these questions, we were particularly interested in (1) determining whether we could find evidence to examine treatments in patient groups not included in earlier reviews, such as children with additional diagnoses, (2) examining a range of functional outcomes, in addition to short-term clinical outcomes and harms, and (3) providing 1 crosscutting review covering all surgical strategies that clinicians use for treating OME.

**METHODS**

**Data Sources and Search Strategy**

We first considered systematic reviews recently completed by the Cochrane Collaboration or commissioned by a national government. Three systematic reviews investigated tubes and adenoidectomy and included data from randomized trials and nonrandomized studies. Comparison treatments included watchful waiting, myringotomy, and different tube types and insertion techniques. We then identified newer trials and observational studies through searches of Medline (via PubMed), Embase, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) for studies published in English and conducted in any geographic location or setting. Our initial search (January 8, 2012) was updated on August 13, 2012 and August 5, 2013. The Supplemental Information provides the initial set of search terms; Appendix A of the full report documents the complete set of search terms.

**Study Selection and Data Abstraction**

We developed inclusion and exclusion criteria with respect to a framework specifying populations, interventions, comparators, outcomes, time frames, and settings (PICOTS). Table 1 presents the PICOTS for the study. We included studies of individuals of any age or background with OME (and concurrent comorbidity); if other populations were included in a study, data had to have been analyzed separately for those with OME.

We used a dual review process to review each abstract and full-text article by using the inclusion/exclusion criteria. If the reviewers disagreed about an exclusion...
TABLE 1 Inclusion and Exclusion Criteria for Studies of OME

<table>
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<tr>
<th>Domain</th>
<th>Description</th>
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<tr>
<td>Population</td>
<td>All individuals with OME. Subpopulations include infants, adults, individuals from different racial/ethnic backgrounds, and special populations of any age, including individuals with craniofacial abnormalities (eg, cleft palate), Down syndrome, existing hearing loss, delays in speech and language, or a history of AOM or OME.</td>
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<tr>
<td>Interventions</td>
<td>Surgical interventions: tympanostomy tubes (also referred to as pressure-equalization tubes, grommets, and ventilation tubes), myringotomy (also referred to as paracentesis), and adenoidectomy with or without myringotomy.</td>
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<tr>
<td>Comparator</td>
<td>Different combinations of the above interventions and strategies. These include head-to-head comparisons of 1 or more treatments, treatment strategies (eg, watchful waiting/delayed treatment versus early treatment), or surgical procedures and techniques (eg, 1 type of tympanostomy tube or procedure versus another or different adjunct therapies to enhance the main intervention).</td>
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<tr>
<td>Outcomes</td>
<td>Clinical outcomes: changes in middle ear fluid, episodes of AOM, hearing thresholds, vestibular function (ie, balance and coordination).</td>
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<td>Timing</td>
<td>Shorter studies looking at outcomes 0 to &lt;3 mo postintervention.</td>
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<td>Setting</td>
<td>Studies conducted in the United States or internationally.</td>
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Decision or the primary criteria for exclusion, they resolved conflicts by consensus discussion. We abstracted detailed PICOTS data from newly included studies and summarized information from studies included in the earlier systematic reviews into evidence tables.

Risk-of-Bias Assessment

Two independent reviewers rated the risk of bias for each newly identified study by using the Cochrane Risk of Bias tool for RCTs. Our EPC developed additional or alternative questions for evaluating observational studies; for studies from the earlier systematic reviews, we relied on the original authors’ ratings. We evaluated the risk of bias of each of the systematic reviews using AMSTAR (A Measurement Tool to Assess Systematic Reviews). The 2 reviewers resolved disagreements by consensus discussion. We assigned risk-of-bias ratings of low, medium, or high; high risk-of-bias studies had at least 1 major issue with the potential to cause significant bias that might invalidate the results.

Data Synthesis

Evidence for this synthesis included results from meta-analyses conducted by the earlier Cochrane Review authors, additional data from individual studies in those systematic reviews, and the new studies from our searches. New studies did not lend themselves to either new pooled analyses or to modifying earlier meta-analyses. Therefore, we summarized the new evidence qualitatively.

Strength of the Body of Evidence

Two team members independently graded the strength of evidence (SOE) to answer each KQ, for each treatment comparison, following EPC guidance. The overall grade for SOE (high, moderate, low, or insufficient) is based on ratings for 4 domains: risk of bias, consistency, directness, and precision. It reflects reviewers’ confidence in the ability of a given body of evidence to answer KQs. We resolved disagreements through consensus discussions.

RESULTS

Literature Searches and Characteristics of Included Studies

We identified 5,112 unduplicated citations in our literature searches (this included surgical and nonsurgical treatment options); 776 met criteria for full-text review (Fig 1). We excluded 696 full-text articles based on our inclusion criteria (before the risk-of-bias assessment), leaving 80 included articles, of which 3 were systematic reviews. We recorded the reason that each excluded full-text publication failed to satisfy the eligibility criteria and compiled a comprehensive list of such studies (Appendix B of the full report). Of the 77 articles, 23 were omitted from our analyses for determining benefit because of high risk of bias in their study design (see Appendix E of the full report). One article determined to be at high risk of bias for determining benefit was included for harms only.

In this report, we discuss the subset of studies providing evidence on surgical interventions: 3 systematic reviews, 41 studies reported in 55 included articles. Of the 55 articles, 24 were included in an earlier systematic review, 13 were follow-up studies, and 18 were newly identified.

Table 2 summarizes the 41 unique studies that constitute the evidence base for this article; we specify study characteristics and risk of bias ratings. Of these, 5 studies were included in
more than 1 of the 6 main categories of comparisons. We assessed the 2 systematic reviews limited to RCTs as low risk of bias and the third as medium risk of bias.

Comparative Effectiveness for Clinical Outcomes

Most studies examined some clinical outcomes: most commonly, signs and symptoms of OME and hearing. A few studies examined subsequent acute otitis media (AOM). Table 3 documents findings on effectiveness in terms of clinical outcomes separately by treatment comparisons; we give results only when evidence was sufficient to draw a conclusion.

Tympanostomy Tube Comparisons

Eleven studies (8 RCTs) provided evidence concerning differences in clinical outcomes comparing tubes (by design, materials, size), insertion techniques, or topical prophylaxis therapies by comparing ears in the same child. Length of tube retention was longer in tubes that manufacturers identified as “long-term tubes.” Specifically, Goode T-tubes and Paparella tubes were retained longer than Shah and Shepard tubes. Because of sparse data, diversity of comparisons, and inconsistent findings, the evidence is insufficient for comparisons of other design features or for clinical outcomes.

Tympanostomy Tubes Versus Myringotomy or Watchful Waiting

Twelve RCTs compared tubes with either myringotomy or no surgery (ie, watchful waiting, delayed treatment); of these, 10 studies were included in previous systematic reviews, and 2 were new. Tube placement decreased the time with middle ear effusion by 32% in comparison with watchful waiting or delayed treatment at 1 year after surgery (high SOE). Relative to a combined comparison group of watchful waiting or myringotomy, tubes reduced effusion by 13% through 2 years after surgery (moderate SOE). Evidence was insufficient for longer follow-up.
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<tr>
<td>Tympanostomy tube comparisons</td>
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<tr>
<td>14 studies (6 in 1 previous systematic review)</td>
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<tr>
<td>Wielinga et al 199016</td>
<td>Silicone Goode TT versus Teflon Armstrong TT</td>
<td>RCT by ear, n = 15 (30 ears) Follow-up: average 6.8 y</td>
<td>Mean age: 79.2 mo Male: 60%</td>
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<tr>
<td>Abdullah et al 199417</td>
<td>Silicone Shah permavent TT versus Polyethylene Shah TT</td>
<td>NRCT by ear, n = 25 (50 ears) Follow-up: 29 mo</td>
<td>Mean age: 72 mo Male: 64%</td>
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<td>Licameli et al 200818</td>
<td>Phophoryl-choline coated fluroplastic Armstrong TT versus uncoated fluroplastic Armstrong TT</td>
<td>RCT by ear, n = 70 (140 ears) Follow-up: 24 mo</td>
<td>Mean age: 19 mo Male: 64.3%</td>
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<tr>
<td>Iwaki et al 199819</td>
<td>Teflon Shepard TT versus Silicone Goode T-tube versus Silicone Paraparella II TT</td>
<td>RCS by ear, n = 137 (220 ears) Follow-up: 24 mo</td>
<td>Mean age: 72.1 mo Male: 62%</td>
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<tr>
<td>Ovensen et al 200020</td>
<td>TT + acetyl cysteine versus TT + placebo</td>
<td>RCT by person and ear, n = 75 (150 ears) Follow-up: 39 mo</td>
<td>Mean age: 38 mo Male: 64%</td>
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<tr>
<td>Slack et al 198720</td>
<td>Shepard TT versus Shah TT versus Paparella TT</td>
<td>RCS by ear, n = 559 ears Follow-up: Until extrusion or end of study period</td>
<td>Mean age: unknown (%) Male: unknown %</td>
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<tr>
<td>Hesham et al 201223</td>
<td>TT + mitomycin C versus TT (adenoidectomy in 55% and adenotonsillectomy in 20% when warranted)</td>
<td>RCT by ear, n = 55 (110 ears) Follow-up: &gt;6 mo</td>
<td>Mean age: 5.8 y Male: 58%</td>
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<tr>
<td>Studies in Hellstrom et al 201110</td>
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<tr>
<td>Hampal et al 199121</td>
<td>Shah TT versus Mini Shah TT</td>
<td>RCT by ear, n = 116 Follow-up: 1 y</td>
<td>Mean age: unknown (5–7 y) Male: unknown %</td>
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<tr>
<td>Dingle et al 199323</td>
<td>Shepard TT versus Sheehy TT</td>
<td>RCT by ear, n = 146 (292 ears) Follow-up: 21–36 mo</td>
<td>Mean age: 72 mo Male: 64%</td>
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<tr>
<td>Heaton et al 199122</td>
<td>Shah TT place in anterosuperior quadrant versus Shah place interoinferior quadrant</td>
<td>RCT by ear, n = 54 (108 ears) Follow-up: 26 mo</td>
<td>Mean age: unknown (&lt;12 y) Male: unknown %</td>
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<td>Hern &amp; Jonathan, 198925</td>
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<td>Youngs &amp; Gatland, 198824</td>
<td>Shah Teflon TT + aspiration before placement versus Shah Teflon TT (no aspiration)</td>
<td>RCT by ear, n = 55 (110 ears) Follow-up: 18 mo</td>
<td>Mean age: 88 mo Male: 65.4%</td>
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<td>McRae et al 198923</td>
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<td>Pearson et al 199625</td>
<td>Shah Teflon TT + steroid otic drops preoperative versus Shah Teflon TT no drops</td>
<td>NRCT by ear, n = 165 (330 ears) Follow-up: 29 mo</td>
<td>Mean age: 75.8 mo Male: 66%</td>
</tr>
<tr>
<td>Kinsella et al 199441</td>
<td>Shepard TT no-touch technique versus Shepard TT touch technique</td>
<td>NRCT by ear, n = 60 (120 ears) Follow-up: 7–10 d</td>
<td>Mean age: 51 mo Male: 43.3%</td>
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<tr>
<td>Treatment Comparison</td>
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</table>
| Salam & Cable, 199362                                | Sheehy TT + otic drops versus Sheehy TT (no drops)                   | RCT by ear  
\( n = 152 \) (324 ears)  
Follow-up: 2 wk  
Medium ROB | Mean age: 55.2 mo  
Male: 41.4% |
| Hampton & Adams, 199675                              | Armstrong TT anterior placement versus Armstrong TT posterior placement | RCT by ear  
\( n = 109 \) (218 ears)  
Follow-up: 6 wk to 29 mo  
Medium ROB | Mean age: 66 mo  
Male: 59.6% |
| Tubes versus watchful waiting or myringotomy         | 12 studies (10 in 1 previous systematic review, 6 of which were in another previous systematic review) | | |
| Koopman et al 200446                                | Unilateral TT + cold knife myringotomy versus laser myringotomy       | RCT by ear  
\( n = 208 \) (416 ears)  
Follow-up: 6 mo  
Medium ROB | Mean age: 50.4 mo  
Male: 51.9% |
| Mandel et al 198937                                 | TT + myringotomy versus myringotomy versus watchful waiting           | RCT  
\( n = 109 \)  
Follow-up: 3 y  
Medium ROB | Age: 45.7 mo  
Male: 66.9% |
| Studies in Browning et al 201017                     | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 182 \)  
Follow-up: 18 mo  
Low ROB (Hellstrom) | Mean age: 35.4 mo  
Male: 48.4% |
| Maw et al 199959,a                                   | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 241 \)  
Follow-up: 2 y  
\(< \) High ROB8 | Mean age: 62.7 y  
Male: 50.6% |
| Hall et al 200916                                   | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 187 \)  
Follow-up: 12 mo  
Medium ROB (Hellstrom) | Mean Age: unknown  
Male: 58.8% |
| MRC Multicentre Otitis Media Group, 200357          | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 236 \)  
Follow-up: 2 y  
Low ROB (Hellstrom) | Mean Age: unknown  
Male: 59.3% |
| MRC Multicentre Otitis Media Group, 201224          | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 111 \)  
Follow-up: 3 y  
\(< \) High ROB8 | Mean age: 45.4 mo  
Male: 66.7% |
| Rovers et al 200039,a                               | Bilateral TT versus watchful waiting                                  | RCT  
\( n = 429 \)  
Follow-up: 3 y of age  
Medium ROB (Hellstrom) | Mean age: 15 mo  
Male: 56.9% |
| Rovers et al 200119                                 | Bilateral TT versus myringotomy                                       | RCT  
\( n = 111 \)  
Follow-up: 3 y  
\(< \) High ROB8 | Mean age: 45.4 mo  
Male: 66.7% |
| Gates et al 198729,a                                | Bilateral TT versus myringotomy                                       | RCT  
\( n = 111 \)  
Follow-up: 3 y  
\(< \) High ROB8 | Mean age: 45.4 mo  
Male: 66.7% |
| Gates et al 198946                                 | Bilateral TT versus myringotomy                                       | RCT  
\( n = 111 \)  
Follow-up: 3 y  
\(< \) High ROB8 | Mean age: 45.4 mo  
Male: 66.7% |
| Mandel et al 199249                                 | Bilateral TT versus myringotomy versus watchful waiting               | RCT  
\( n = 111 \)  
Follow-up: 3 y  
\(< \) High ROB8 | Mean age: 45.4 mo  
Male: 66.7% |
| Paradise et al 200131,a                             | Bilateral TT versus delayed treatment                                 | RCT  
\( n = 111 \)  
Follow-up: 3 y of age  
Medium ROB (Hellstrom) | Mean age: 15 mo  
Male: 56.9% |
| Johnston et al 200444                               | Bilateral TT versus delayed treatment                                 | RCT  
\( n = 111 \)  
Follow-up: 3 y of age  
Medium ROB (Hellstrom) | Mean age: 15 mo  
Male: 56.9% |
| Paradise et al 200560                               | Unilateral TT versus myringotomy                                      | RCT (by person and ears)  
\( n = 74 \) (148 ears)  
Follow-up: 24 mo  
\(< \) High ROB8 | Mean age: 72.6 mo  
Male: 64.9% |
| Black et al 199052                                  | Unilateral TT versus myringotomy                                      | RCT (by person and ear)  
\( n = 35 \) (70 ears)  
Follow-up: 12 mo  
\(< \) High ROB8 | Mean age: 68.4 mo  
Male: 65.7% |
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<tr>
<td>Maw &amp; Herod, 1986 (^3^4) a; Maw &amp; Bawden, 1994 (^3^5)</td>
<td>Unilateral TT versus no surgery (^d)</td>
<td>RCT (by person and ear) 56 (112 ears) Follow-up: 12 mo Medium ROB (Hellstrom)</td>
<td>Mean age: 63.7 mo Male: 57.1%</td>
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<tr>
<td>Rach et al 1991 (^3^3)</td>
<td>Bilateral TT versus watchful waiting</td>
<td>RCT (n = 43) Follow-up: 6 mo &lt; : High ROB (^b)</td>
<td>Mean age: unknown (all preschoolers) Male: unknown %</td>
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<td>TT plus adenoidectomy versus myringotomy plus adenoidectomy or adenoidectomy alone</td>
<td>11 studies (4 in 1 previous systematic review)</td>
<td>Brown et al 1978 (^3^8) TT (Shepard) + adenoidectomy versus adenoidectomy</td>
<td>RCT by ear (n = 55) (110 ears) Follow-up: 5 y Medium ROB</td>
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<td>Austin, 1994 (^3^9) TT + adenoidectomy versus adenoidectomy</td>
<td>RCT by ear (n = 31) (62 ears) Follow-up: 3 mo Medium ROB</td>
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<td>Lildholdt, 1979 (^4^0) TT (Donaldson) + adenoidectomy versus adenoidectomy</td>
<td>NRCT by ear (n = 91) (182 ears) Follow-up: until extrusion or 8 mo Medium ROB</td>
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<td>D’Eredita &amp; Shah, 2006 (^4^1) TT (Shah mini) + adenoidectomy versus CDLM + adenoidectomy</td>
<td>RCT (n = 30) Follow-up: 12 mo Medium ROB</td>
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<td>Popova et al 2010 (^4^2) TT (Donaldson) + adenoidectomy versus myringotomy + adenoidectomy</td>
<td>RCT (n = 30) Follow-up: 12 mo Medium ROB</td>
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<td>Shishegar &amp; Hobboghi, 2007 (^4^3) TT (Shepard) + adenoidectomy versus myringotomy + adenoidectomy</td>
<td>RCT by ear (n = 30) (60 ears) Follow-up: 6 mo Medium ROB</td>
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<td>Vlastos et al 2011 (^4^4) TT (Shepard) + adenoidectomy versus myringotomy + adenoidectomy</td>
<td>RCT (n = 52) Follow-up: 12 mo Medium ROB</td>
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<td>Studies in Hellstrom et al 2011 (^1^0)</td>
<td>RCT (n = 255) Follow-up: 2 y Low ROB (Hellstrom)</td>
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<td>Gates et al 1989 (^4^6) TT + adenoidectomy versus myringotomy + adenoidectomy</td>
<td>RCT by person and ear (n = 139) (270 ears) Follow-up: 10 y Medium ROB (Hellstrom)</td>
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<td>Maw &amp; Bawden, 1994 (^4^8) TT (Shepard) + adenoidectomy/ adenotonsillectomy versus adenoidectomy/adenotonsillectomy</td>
<td>RCT by person and ear (n = 139) (270 ears) Follow-up: 10 y Medium ROB (Hellstrom)</td>
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<tr>
<td>Liidholdt, 1983&lt;sup&gt;47&lt;/sup&gt;</td>
<td>TT (Donaldson) + adenoidectomy versus adenoidectomy</td>
<td>RCT by ear, n = 150 (300 ears), Follow-up: 5 y, Medium ROB (Hellstrom)</td>
<td>Mean age: 46.8 mo, Male: 56.7%</td>
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<td>Bonding &amp; Tos, 1985&lt;sup&gt;46&lt;/sup&gt; Tos &amp; Stangerup, 1989&lt;sup&gt;46&lt;/sup&gt; Caye-Thomasen et al 2008&lt;sup&gt;57&lt;/sup&gt;</td>
<td>TT (Donaldson) + adenoidectomy versus myringotomy + adenoidectomy</td>
<td>NRCT by ear, n = 224 (448 ears), Follow-up: 6–7 y, Medium ROB (Hellstrom)</td>
<td>Mean age: unknown, Male: unknown %</td>
</tr>
<tr>
<td>Myringotomy comparison 1 study</td>
<td>Bonding &amp; Tos, 1985&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Intervention: Radiofrequency myringotomy + mitomycin C, Comparison: Radiofrequency myringotomy</td>
<td>RCT by ear, n = 60, Follow-up: 3 mo, Medium ROB</td>
</tr>
<tr>
<td>Myringotomy with adenoidectomy comparison 1 study</td>
<td>Rajab, 2005&lt;sup&gt;49&lt;/sup&gt;</td>
<td>Intervention: Laser myringotomy + adenoidectomy, Comparison: Cold knife myringotomy + adenoidectomy</td>
<td>RCT by ear, n = 49 (87 ears), Follow-up: 6–48 mo, Medium ROB</td>
</tr>
<tr>
<td>Adenoidectomy comparisons 8 studies (7 in 1 previous systematic review)</td>
<td>MRC Multicentre Otitis Media Group 2012&lt;sup&gt;54&lt;/sup&gt;</td>
<td>Adenoidectomy + bilateral TT (Shepard) versus bilateral TT (Shepard) versus WW</td>
<td>RCT, n = 376, Follow-up: 24 mo, Medium ROB</td>
</tr>
<tr>
<td>In van Aardweg et al 2010&lt;sup&gt;11&lt;/sup&gt; Black et al 1990&lt;sup&gt;32,b&lt;/sup&gt;</td>
<td>Adenoidectomy versus no surgery</td>
<td>RCT by person and ear, n = 149 (149 ears), Follow-up: 2 y &lt; High ROB&lt;sup&gt;35&lt;/sup&gt;</td>
<td>Mean age: 75 mo, Male: 58.4%</td>
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<tr>
<td></td>
<td>Adenoidectomy versus Adenoidectomy + unilateral TT</td>
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<td>Adenoidectomy versus unilateral TT</td>
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<td>Adenoidectomy + unilateral TT versus no surgery</td>
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<td>Adenoidectomy + unilateral TT versus unilateral TT</td>
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<td>Adenoidectomy + unilateral TT versus no surgery</td>
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<td>Adenoidectomy versus unilateral TT</td>
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<td></td>
<td>Adenoidectomy versus no surgery</td>
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<tr>
<td>Dempster et al 1993&lt;sup&gt;51,e&lt;/sup&gt;</td>
<td>Adenoidectomy + unilateral TT versus unilateral TT</td>
<td>RCT by person and ear, n = 72 (72 ears), Follow-up: 12 mo, Medium ROB (Hellstrom)</td>
<td>Mean age: 69.6 mo, Male: 55.6%</td>
</tr>
<tr>
<td>Maw &amp; Herod, 1986&lt;sup&gt;54,b&lt;/sup&gt;</td>
<td>Adenoidectomy + unilateral TT (Shepard) versus unilateral TT (Shepard)</td>
<td>RCT by person and ear, n = 103 (103 ears), Follow-up: 12 mo, Medium ROB (Hellstrom)</td>
<td>Mean age: 63 mo, Male: 66%</td>
</tr>
<tr>
<td>Filleau-Nikolajsen et al 1980&lt;sup&gt;31&lt;/sup&gt;</td>
<td>Adenoidectomy + myringotomy versus myringotomy</td>
<td>RCT, n = 42, Follow-up: 6 mo &lt; High ROB&lt;sup&gt;35&lt;/sup&gt;</td>
<td>Mean age: unknown (5 y old cohort), Male: 50%</td>
</tr>
</tbody>
</table>
Tubes improved hearing in the short-term: up to 9 months after surgery in comparison with watchful waiting (3–6 months: 8.8 dB; 6–9 months: 4.2 dB) (high SOE); up to 6 months after surgery in comparison with either watchful waiting or myringotomy (4–6 months: 10 dB) (high SOE). Thereafter, the differences in hearing became attenuated and were not statistically significant at 7 to 12 months compared with watchful waiting or myringotomy (low SOE) or at 12 to 18 months compared with just watchful waiting (low SOE). Evidence was insufficient for longer time periods and for other clinical outcomes.

Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone

Seven studies that we newly identified38–44 and 4 studies45–48 reported in the Hellstrom et al10 review examined outcomes for adenoidectomy plus different adjunctive therapies. Specifically, we compared the effectiveness of tubes when added to adenoidectomy with myringotomy or no surgery. Two small studies failed to find a difference between tubes plus adenoidectomy and adenoidectomy alone in reducing OME recurrence (insufficient evidence). Results of 3 studies comparing tubes and adenoidectomy with myringotomy plus adenoidectomy on OME recurrence were mixed (insufficient evidence). For hearing measured at various times, ranging from 1 month to 6 years, 5 studies failed to find a difference in hearing between the addition of tubes versus myringotomy (low SOE for no difference). We found mixed results for hearing in studies that compared the additive impact of tubes with adenoidectomy alone (insufficient evidence).

Myringotomy Plus Adenoidectomy Comparisons

One retrospective cohort study compared laser myringotomy with cold knife myringotomy in children also receiving an adenoidectomy.50 Because evidence was limited to 1 observational study, we concluded that it was insufficient for determining the superiority of either myringotomy approach in relation to OME signs and symptoms.

Adenoidectomy Versus Other Interventions

Eight RCTs (11 articles) provided evidence for adenoidectomy compared with tubes, myringotomy, watchful waiting, or no adenoidectomy (unilateral ear surgery with nonoperated ear as comparison) (Table 2). Seven trials49,32–34,51–53 were from the van den Aardweg et al systematic review12; the eighth was the newly published Trial of Alternative Regimens in Glue Ear Treatment study.54

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**TABLE 2**

<table>
<thead>
<tr>
<th>Treatment Comparison</th>
<th>Types of Treatments/Comparisons</th>
<th>Study Designs, Sample Size, Duration, Quality Rating</th>
<th>Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gates et al 198729a</td>
<td>Adenoidectomy + Myringotomy versus Adenoidectomy + TT (Shepard) versus Myringotomy versus TT (Shepard)</td>
<td>RCT</td>
<td>Mean age: unknown (4–6 y) Male: 59.9%</td>
</tr>
<tr>
<td>Roydhouse, 198012</td>
<td>Adenoidectomy + TT versus TT versus TT (Shepard) medical treatment</td>
<td>RCT</td>
<td>Mean age: 85 mo Male: 55.9%</td>
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<tr>
<td>Casselbrant et al 200953</td>
<td>Adenoidectomy + TT (Armstrong) versus Adenoidectomy + myringotomy versus TT (Armstrong)</td>
<td>RCT</td>
<td>Mean age: 34.6 mo Male: 66.4%</td>
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</tbody>
</table>

For studies with more than 1 publication, the first listed is the primary source and the others are supplementary or follow-up articles. CDLM, contact diode laser myringotomy; NRCT, nonrandomized controlled trial; RCS, retrospective cohort study; ROB, risk of bias; TT, tympanostomy tubes; WW, watchful waiting.

a In Hellstrom et al 2011.10
b Risk of bias analyses performed by authors of systematic review; the authors only included studies that were low or medium, but they did not indicate what the risk of bias was for individual studies.
c Included only the arm randomized to no adenoidectomy.
d In Browning et al 2010.11
e In Browning et al 201011 and Hellstrom et al 2011.10
Adenoidectomy was superior to no adenoidectomy for resolution of OME at 6 months postsurgery measured through otoscopy (risk difference of 0.27, 95% confidence interval [CI] 0.13–0.42) and through tympanometry (0.22, 95% CI 0.12–0.32) (high SOE for both). It was also superior at 12 months postsurgery measured through tympanometry (risk difference of 0.29, 95% CI 0.19–0.39) (high SOE). Hearing outcomes were superior with adenoidectomy compared with no adenoidectomy in 1 RCT at 6 months but not at 12 months. In a second RCT, investigators detected no differences (insufficient evidence for mixed findings).

One RCT found that adenoidectomy and myringotomy were superior to myringotomy alone for reducing time with effusion (0.76 standard mean difference (95% CI 0.26 to 1.26)) and 18 months (0.69 standard mean difference (95% CI 0.27 to 1.11)). Evidence was insufficient for mixed treatments for recurrence of AOM.

**Comparative Effectiveness for Functional Outcomes or Quality of Life**

Two treatment comparisons (tubes versus watchful waiting and tubes plus adenoidectomy versus myringotomy plus adenoidectomy) included functional or quality-of-life outcomes (Table 4). Four trials (7 articles) reported on language,

<table>
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<tr>
<th>Table 3: SOE for Interventions to Improve Clinical Outcome</th>
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<tbody>
<tr>
<td><strong>Intervention and Comparator</strong></td>
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<tr>
<td>TT versus watchful waiting, delayed treatment, or myringotomy</td>
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<tr>
<td>TT + adenoidectomy versus myringotomy + adenoidectomy or adenoidectomy alone</td>
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<tr>
<td>Adenoidectomy + myringotomy versus myringotomy</td>
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<tr>
<td>TT + adenoidectomy versus watchful waiting</td>
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academic achievement, or both26,31,55–57, and 3 trials (7 articles)26,31,36,37,55–59 reported on behavioral competence.

**Tympanostomy Tubes Versus Watchful Waiting or Myringotomy**

Meta-analyses reported by Browning et al11 included trials conducted by Maw and colleagues,26,55 Rovers and colleagues,28 Paradise and colleagues,31,56,57 and Rach and colleagues.55 The meta-analyses comparing tubes with watchful waiting did not find any differences in language at 6 and 9 months after treatment (moderate SOE for no differences). With 1 exception, trials examining children during preschool and elementary school years failed to find a difference in language skills (low SOE for no difference).55–57 In the 1 exception, the difference disappeared at 8 years of age. We did not find differences between tubes and watchful waiting in any trials reporting cognitive development, academic achievement, or quality of life at any time point (all low SOE for no difference). Studies reported mixed findings for behavior outcomes at <1 year (insufficient evidence); 3 trials reporting behavior at 1 year or more after treatment reported no difference (low SOE). No studies comparing tubes with myringotomy reported on functional or quality-of-life outcomes (insufficient evidence).

**Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy**

One trial comparing adenoidectomy plus the addition of tubes versus myringotomy did not find differences in quality of life at any time point (insufficient evidence); no other functional outcomes were reported.44

**Harms of Treatments for OME**

Most studies examining surgical comparisons reported on harms. Table 5 provides the findings and SOE for harms by treatment comparisons.

**Tympanostomy Tube Comparisons**

Eleven studies that compared tube length or insertion techniques reported on otitis media.20,22,25,60–65 Longer-term tubes related to a higher probability of otitis media in 3 studies16,19,60 (low SOE). Evidence about otitis media was insufficient for other tube comparisons. For other harms, such as perforation, cholesteatoma, occlusion, tympanosclerosis, and the presence of granulation tissue, the evidence was too limited to determine a direction of effect (insufficient evidence).

**Tympanostomy Tubes Versus Watchful Waiting or Myringotomy**

Nine trials compared side effects for tubes with side effects for watchful waiting or myringotomy.28,30,33,36,37,46,54,64,65 Otitis media and tympanosclerosis occurred more frequently in ears with tube placement than in ears with watchful waiting or myringotomy (low SOE). Evidence was insufficient for other harms because of either conflicting results or data reported in only a single study.

**Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone**

We reviewed 9 trials (11 articles) that examined harms of these procedures, including repeat tubes, otitis media, perforation, and tympanosclerosis.38,40–47,66,67 In 3 trials (4 articles) (all participants with adenoidectomy),38,45,47,66 the risk of tympanosclerosis was higher with tubes than with myringotomy or no ear surgery (moderate SOE). Results for other harms were mixed, reported in single studies, or lacked precision (insufficient evidence).

**Adenoidectomy Versus Other Interventions**

Three RCTs (4 articles)29,46,53,54 reported harms related to adenoidectomy. Two of the trials29,46,54 reported 1 case each (among 416 subjects) of a postoperative hemorrhage after adenoidectomy (low SOE). Evidence was insufficient for other harms.

### Table 4: SOE for Interventions to Improve Functional Outcomes and Health-Related Quality-of-Life Outcomes

<table>
<thead>
<tr>
<th>Intervention and Comparator</th>
<th>No. of Studies (Sample Sizes)</th>
<th>Outcome and Results</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIs versus watchful waiting or delayed treatment</td>
<td>MA of 3 RCTs (n = 394) and 2 RCTs (n = 503)</td>
<td>No difference was observed in language comprehension at 6 to 9 mo postintervention (mean difference, 0.09; 95% CI −0.21 to 0.39) or at preschool and elementary school age.</td>
<td>Moderate for no difference</td>
</tr>
<tr>
<td></td>
<td>MA of 3 RCTs (n = 393) and 2 RCTs (n = 503)</td>
<td>No difference was observed in language expression at 6 to 9 mo postintervention (mean difference, 0.03; 95% CI −0.41 to 0.49) or at preschool and elementary school age.</td>
<td>Low for no difference</td>
</tr>
<tr>
<td></td>
<td>2 RCTs (n = 503)</td>
<td>No difference was observed in cognitive development at 9 mo postintervention or at preschool and elementary school age.</td>
<td>Low for no difference</td>
</tr>
<tr>
<td></td>
<td>3 RCTs (n = 710)</td>
<td>No difference was observed in behavior at 1 y or more</td>
<td>Low for no difference</td>
</tr>
<tr>
<td></td>
<td>2 RCTs (n = 503)</td>
<td>No difference was observed in academic achievement at elementary school age.</td>
<td>Low for no difference</td>
</tr>
</tbody>
</table>

MA, meta analysis; TIs, tympanostomy tubes.
Comparative Benefits and Harms for Patient Subgroups

Although we attempted to examine treatment effectiveness or harms for key subgroups characterized by clinical conditions (eg, cleft palate, Down syndrome, or sensorineural hearing loss) or sociodemographic factors (eg, age), we could not identify studies that covered most of our subgroups of interest. In a single study of children with sleep apnea and OME,44 all of whom had adenoidectomy to treat that condition, tubes and myringotomy did not differ significantly in terms of any measured outcomes (insufficient evidence).

Factors Affecting Health Care Delivery or the Receipt of Pneumococcal Vaccine Inoculation

No study examined issues related to health insurance coverage, physician specialty, type of facility of the provider, geographic location of patients, presence or absence of continuity of care, or previous use of pneumococcal virus inoculation. Thus, evidence is insufficient for all such factors.

DISCUSSION

Clinical Findings

In an extensive systematic review commissioned by the Agency for Healthcare Research and Quality,6 we examined the comparative effectiveness and harms of various surgical and nonsurgical treatments for OME. This article focuses on surgical procedures (tubes, myringotomy, and adenoidectomy and their comparators, including watchful waiting and delayed treatment); these are the most common modalities for managing OME. Tubes yield short-term benefits in comparison with either watchful waiting or myringotomy. The lack of differences between tubes and either myringotomy or watchful waiting beyond 1 or 2 years after surgery is not surprising given the natural history of untreated OME and the duration of tubes. In an analysis of resolution rates of OME across prospective studies, the average resolution rate by ear was 88% at 10 to 12 months and 97% at 16 to 24 months; the average resolution rate by child was 95% at 7 to 12 months.68

Tubes did not show benefits for language, cognitive, or academic skills at any point; skills of those who received or did not receive tubes were generally within normal limits. Thus, the conductive hearing losses that children may have experienced did not appear to translate to difficulties in language-based skills. These studies support the findings of Roberts and colleagues5 whose meta-analyses indicated that OME and its associated hearing loss had no or very small negative associations with children’s later language development. Very recent recommendations, however,7 are that clinicians should offer bilateral tubes to children with bilateral OME for 3 months or longer and documented hearing difficulties.

OME may lead to the development of AOM; the most recent guidelines for managing AOM69 offer tubes as a treatment of recurrent AOM if effusion is present. Our evidence, however, was insufficient to conclude that tubes reduced episodes of AOM in children with OME.

Evidence was also insufficient to conclude that tubes varying in length of retention differed in OME recurrence or in hearing outcomes; no studies comparing design features of tubes examined functional or quality-of-life outcomes. Although most studies comparing tubes with watchful waiting or myringotomy used short-term tubes, we could not determine whether short-term tubes reduced time with OME, produced fewer episodes of AOM, or improved hearing.

Evidence for harms of tubes was limited. In comparison with either watchful waiting or myringotomy, tympanosclerosis and otorrhea occurred more frequently in ears with tubes than ears with only adenoidectomy or with myringotomy. Although rare, adenoidectomy increased the risk of postsurgical hemorrhage.

Table 5: SOE for Harms of Interventions

<table>
<thead>
<tr>
<th>Intervention and Comparator</th>
<th>No. of Studies (Sample Sizes)</th>
<th>Outcome and Results</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TT comparisons</td>
<td>1 RCT (n = 30 ears), 2 observational studies (n = 779 ears)</td>
<td>Otorrhea occurred more frequently in ears with longer-term tubes than in ears with shorter-term tubes after 1 y or more</td>
<td>Low for harms of longer-term tubes</td>
</tr>
<tr>
<td>TTs versus watchful waiting or myringotomy</td>
<td>5 RCTs (n = 1128)</td>
<td>Tympanosclerosis occurred more frequently in ears that had tubes, based on examinations after the tubes had been extruded.</td>
<td>Moderate for harms of tubes</td>
</tr>
<tr>
<td>TTs plus adenoidectomy versus adenoidectomy plus myringotomy versus adenoidectomy alone</td>
<td>4 RCTs (n = 960); 3 studies (2 RCTs, 1 NRCT (n = 485))</td>
<td>Otorrhea occurred more frequently in ears with tubes.</td>
<td>Low for harms of tubes</td>
</tr>
<tr>
<td>Adenoidectomy versus other treatments</td>
<td>2 trials (n = 739)</td>
<td>Although rare, adenoidectomy increased the risk of postsurgical hemorrhage.</td>
<td>Low for harms of adenoidectomy</td>
</tr>
</tbody>
</table>

NRCT, nonrandomized controlled trial; TT, tympanostomy tubes.
shorter-term tubes. Other harms such as perforations, cholesteatoma, and atrophy were inconsistently investigated or reported.

Adenoidectomy results in less time with effusion or better hearing (or both) when compared with no treatment or as an adjunct to myringotomy. Evidence was insufficient to determine the comparative effectiveness of adenoidectomy for reducing the recurrence of AOM or improving functional outcomes. Evidence for harms of adenoidectomy was limited (1 case of hemorrhage reported in each of 2 trials). Evidence was limited (1 case of hemorrhage reported in each of 2 trials). Evidence for harms of adenoidectomy was limited (1 case of hemorrhage reported in each of 2 trials). Evidence was limited (1 case of hemorrhage reported in each of 2 trials).

Several interventions have not been subjected to rigorous research methods. Inserting tubes remains a common procedure, yet little evidence is available about different types of tubes or insertion techniques. An ongoing Swedish trial plans to enroll a large cohort of children in an RCT comparing different tubes; the results from this trial may provide the needed evidence regarding which tubes are more (or less) beneficial. Other researchers are designing treatments to counteract the otological effects of gastroesophageal reflux disease.

Many cases of OME start after episodes of AOM. Vaccines to prevent pneumococcal disease can decrease the frequency of AOM. As rates of vaccination increase, the character of OME may change because bacterial infections will be less likely to play a role in the disease process. The use of vaccines to prevent OME was outside the scope of this review, but research documenting whether they decrease the rate of OME in young children would contribute to understanding prevention of this condition.

Few studies included in this article were rated as low risk of bias, and improving methods in future research is critical. Study design heterogeneity is a considerable barrier to synthesizing evidence: baseline measures were not always provided; outcome measures and time points for collecting outcomes differed. Moreover, investigators did not routinely report on reoccurrence of AOM or on functional outcomes; no study measured discomfort from OME. Studies did not routinely provide (or document) effect sizes; many researchers fail to report their statistical power (the RCTs of the MRC being notable exceptions). Missing data were often not addressed, and even if attrition was acknowledged, statistical procedures were rarely used to correct for this problem.

CONCLUSIONS

Overall, we found a small and uneven body of evidence across treatment comparisons and outcomes. Compared with watchful waiting or myringotomy, we found strong and consistent evidence that tubes decreased effusion and improved hearing over a short period but did not affect speech, language, or other functional outcomes. Weaker evidence suggested that tube placement also increased the rate of side effects, such as otorrhea and tympanosclerosis. Although adenoidectomy decreases the number of children with OME in the short-term relative to watchful waiting, less is known about its long-term outcomes, particularly with respect to functional outcomes. Additional research and better methods are needed to develop a comprehensive evidence base to support decision-making among the various treatment options, particularly in subpopulations defined by age and coexisting conditions.

ACKNOWLEDGMENTS

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READING TO SEE HOW OTHERS FEEL: I thoroughly enjoy transporting myself into another world while reading a good book. However, although books have made for interesting conversation starters with friends, I had never thought what I read would influence my interactions with peers. While I have not seen a connection between my reading selection and socialization, new research hints at the potential association between social psychology and literary genre choice. As reported by National Public Radio (Shots: October 4, 2013), a recent study indicates that the type of literature one recently read can influence the ability to understand others’ emotions. Researchers had study participants read either literary fiction (defined as introspective and character driven), popular fiction (defined as plot driven), or nothing, and then complete emotion identification standardized testing. Surprisingly, individuals who read the literary fiction excerpts had stronger performance on the testing than those who read popular fiction or nothing at all. One possible explanation is that readers of literary fiction gain greater perspective on society when using their imaginations to envision a written world. Perhaps the next time I am struggling to understand what a family member or friend is thinking, I should reach for the nearest classic.

Noted by Leah H. Carr, BS, MS-IV
Surgical Treatments for Otitis Media With Effusion: A Systematic Review
Ina F. Wallace, Nancy D. Berkman, Kathleen N. Lohr, Melody F. Harrison, Adam J. Kimple and Michael J. Steiner

Pediatrics 2014;133;296; originally published online January 6, 2014;
DOI: 10.1542/peds.2013-3228

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Supplementary material can be found at:
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