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;133:1–16
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
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 RCTs13; 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.10–12 We evaluated the risk of bias of each of the systematic reviews using AMSTAR (A Measurement Tool to Assess Systematic Reviews).14 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.15 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 5112 unduplicated citations in our literature searches (this included surgical and nonsurgical treatment options); 776 met criteria for full-text review (Fig 1). We excluded 636 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 report6). 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 report6). 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

| TABLE 1 Inclusion and Exclusion Criteria for Studies of OME |
|-----------------|----------------------------------------------------------|
| **Domain**      | **Description**                                          |
| Population      | 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. |
| Interventions   | • 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 |
| Comparator      | • 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). |
| Outcomes        | • Clinical outcomes: changes in middle ear fluid, episodes of AOM, hearing thresholds, vestibular function (ie, balance and coordination). |
| Timing          | Shorter studies looking at outcomes 0 to <3 mo postintervention. Longer studies looking at outcomes past 3 mo and into adolescence or adulthood. |
| Setting         | Studies conducted in the United States or internationally. Interventions provided in primary care offices where the patient is seen by a pediatrician, family physician, or nurse practitioner; subspecialist physician offices where the patient is seen by an otolaryngologist; surgical settings within a hospital or outpatient clinic; emergency departments; and craniofacial treatment centers. |

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more than 1 of the 6 main categories of comparisons. We assessed the 2 systematic reviews limited to RCTs as low risk of bias\(^{11,12}\). and the third as medium risk of bias.\(^{10}\)

**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.\(^{16–25}\) 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\(^{26–35}\) were included in previous systematic reviews,\(^{10,11}\) and 2 were new.\(^{36,37}\) 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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<td>Mean age: 5.8 y, Male: 58%</td>
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<td>Shah TT versus Mini Shah TT</td>
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<td>Mean age: unknown, (5–7 y), Male: unknown %</td>
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<td>Mean age: 72 mo, Male: 64%</td>
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<td>Heaton et al 1991</td>
<td>Shah TT place in anterosuperior quadrant versus Shah place interoinferior quadrant</td>
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<td>Mean age: unknown, (&lt;12 y), Male: unknown %</td>
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<td>Hern &amp; Jonathan, 1995</td>
<td>Shah Teflon TT + aspiration before placement versus Shah Teflon TT (no aspiration)</td>
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<td>Mean age: 68 mo, Male: 65.4%</td>
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<td>Pearson et al 1996</td>
<td>Shah Teflon TT + steroid otic drops preoperative versus Shah Teflon TT no drops</td>
<td>NRCT by ear, n = 163 (330 ears), Follow-up: 28 mo</td>
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<td>Kinsella et al 1994</td>
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<td>Mean age: 51 mo, Male: 43.3%</td>
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| Salam & Cable, 1993                       | Sheehy TT + otic drops versus Sheehy TT (no drops)                  | RCT by ear  
\(n = 162\) (324 ears)  
Follow-up: 2 wk  
Medium ROB | Mean age: 55.2 mo  
Male: 41.4% |
| Hampton & Adams, 1996                     | 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 2004                        | 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 1989                         | 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 2010            | 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 1999                           | Bilateral TT versus watchful waiting                                 | RCT  
\(n = 236\)  
Follow-up: 2 y  
Low ROB (Hellstrom) | Mean age: 62.7 y  
Male: 50.6% |
| Hall et al 2009                           | Bilateral TT versus watchful waiting                                 | RCT  
\(n = 241\)  
Follow-up: 2 y  
Low ROB (Hellstrom) | Mean age: unknown  
Male: unknown |
| Gates et al 1987                         | Bilateral TT versus myringotomy                                     | RCT  
\(n = 236\)  
Follow-up: 2 y  
Low ROB (Hellstrom) | Mean age: unknown  
Male: 59.3% |
| Gates et al 1989                         | Bilateral TT versus myringotomy                                     | RCT  
\(n = 236\)  
Follow-up: 2 y  
Low ROB (Hellstrom) | Mean age: unknown  
Male: 59.3% |
| Mandel et al 1992                        | Bilateral TT versus myringotomy versus watchful waiting              | RCT  
\(n = 111\)  
Follow-up: 3 y  
Low ROB (Hellstrom) | Mean age: 45.4 mo  
Male: 66.7% |
| Paradise et al 2001                       | Bilateral TT versus delayed treatment                               | RCT  
\(n = 429\)  
Follow-up: 3 y of age  
Medium ROB (Hellstrom) | Mean age: 15 mo  
Male: 56.9% |
| Johnston et al 2004                       | Bilateral TT versus delayed treatment                               | RCT  
\(n = 429\)  
Follow-up: 3 y of age  
Medium ROB (Hellstrom) | Mean age: 15 mo  
Male: 56.9% |
| Paradise et al 2005                       | Bilateral TT versus delayed treatment                               | RCT  
\(n = 74\) (148 ears)  
Follow-up: 24 mo  
Low ROB (Hellstrom) | Mean age: 72.8 mo  
Male: 64.9% |
| Black et al 1990                          | Unilateral TT versus myringotomy                                    | RCT  
\(n = 35\) (70 ears)  
Follow-up: 12 mo  
Low ROB (Hellstrom) | Mean age: 68.4 mo  
Male: 65.7% |
| Dempster et al 1993                       | Unilateral TT versus no surgery                                     | RCT (by person and ear)  
\(n = 35\) (70 ears)  
Follow-up: 12 mo  
Low ROB (Hellstrom) | Mean age: 68.4 mo  
Male: 65.7% |
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<td>Mean age: 69.8 mo Male: 55.6%</td>
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<tr>
<td></td>
<td>versus unilateral TT</td>
<td></td>
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<tr>
<td></td>
<td>Adenoidectomy versus no surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maw &amp; Herod, 198634,a</td>
<td>Adenoidectomy + unilateral TT (Shepard) versus unilateral TT (Shepard)</td>
<td>RCT by person and ear</td>
<td>Mean age: 63 mo Male: 66%</td>
</tr>
<tr>
<td></td>
<td>Adenoidectomy versus no surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filleau-Nikolajsen et al 198035</td>
<td>Adenoidectomy + myringotomy versus myringotomy</td>
<td>RCT</td>
<td>Mean age: unknown Male: 50%</td>
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</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 identified and 4 studies reported in the Hellstrom et al 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 Comparisons

One RCT compared 2 different procedures for myringotomy (radiofrequency myringotomy with and without mitomycin C) on both middle ear and hearing outcomes. Most individuals in each arm received adenoidectomy (73% and 67%, respectively). Evidence was insufficient for concluding superiority of either procedure concerning OME effusion or hearing outcomes.

Myringotomy Plus Adenoidectomy Comparisons

One retrospective cohort study compared laser myringotomy with cold knife myringotomy in children also receiving an adenoidectomy. 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 trials were from the van den Aardweg et al systematic review; the eighth was the newly published Trial of Alternative Regimens in Glue Ear Treatment study.

<table>
<thead>
<tr>
<th>Study Design, Sample Size, Duration, Quality Rating</th>
<th>Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gates et al 1987</td>
<td>Adenoidectomy + Myringotomy versus Adenoidectomy + TT (Shepard) versus Myringotomy versus TT (Shepard)</td>
</tr>
<tr>
<td>Roydhouse, 1980</td>
<td>Adenoidectomy + TT versus TT versus medical treatment</td>
</tr>
<tr>
<td>Casselbrant et al 2009</td>
<td>Adenoidectomy + TT (Armstrong) versus Adenoidectomy + myringotomy versus + TT (Armstrong)</td>
</tr>
</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.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.

* Included only the arm randomized to no adenoidectomy.

* In Browning et al 2010.11
* In Browning et al 2010 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 and for improving hearing at 24 months (better ear standard mean difference of −0.66, 95% CI −0.93 to −0.40) (low SOE). The evidence was insufficient for determining the effectiveness of adenoidectomy plus tubes in relation to effusion or hearing because outcome results were mixed. Hearing outcomes were superior with adenoidectomy and tubes in comparison with watchful waiting at 24 months (low SOE). Evidence was insufficient to determine the effectiveness of adenoidectomy compared with other 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 language26,28,31,35,55–57; 2 trials (5 articles) reported on cognitive development,
academic achievement, or both26,31,55–57, and 3 trials (7 articles)26,31,36,37,55–59 reported on behavioral competence.

**Tymanostomy Tubes Versus Watchful Waiting or Myringotomy**

Meta-analyses reported by Browning et al.11 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).

**Tymanostomy Tubes Plus Adenoectomy Versus Myringotomy Plus Adenoectomy**

One trial comparing adenoectomy 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.

**Tymanostomy Tube Comparisons**

Eleven studies that compared tube length or insertion techniques reported on otorrhea.16–20,22,25,60–63 Longer-term tubes related to a higher probability of otorrhea in 3 studies16,19,60 (low SOE). Evidence about otorrhea 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).

**Tymanostomy Tubes Versus Watchful Waiting or Myringotomy**

Nine trials compared side effects for tubes with side effects for watchful waiting or myringotomy.28,30,33,36,37,46,54,56,65 Otorrhea 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 Adenoectomy Versus Myringotomy Plus Adenoectomy or Adenoectomy Alone**

We reviewed 9 trials (11 articles) that examined harms of these procedures, including repeat tubes, otorrhea, perforation, and tympanosclerosis.38,40–47,66,67 In 3 trials (4 articles) (all participants with adenoectomy),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).

**Adenoectomy Versus Other Interventions**

Three RCTs (4 articles)28,46,53,54 reported harms related to adenoectomy. Two of the trials28,46,54 reported 1 case each (among 416 subjects) of a postoperative hemorrhage after adenoectomy (low SOE). Evidence was insufficient for other harms.

<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>ITTs 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 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; TT, 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, 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, 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.

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 colleagues 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, 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 AOM 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; we could not determine the severity of these complications, however. Otorrhea occurred more frequently in ears with longer-term tubes than with

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 = 1129)</td>
<td>Typanosclerosis 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)</td>
<td>Otorrhea occurred more frequently in ears with tubes.</td>
<td>Low for harms of tubes</td>
</tr>
<tr>
<td>TTs plus adenoidectomy versus adenoidectomy only</td>
<td>3 studies (2 RCTs, 1 NRCT) (n = 485)</td>
<td>Typanosclerosis occurred more frequently in ears with tubes than ears with only adenoidectomy or with myringotomy.</td>
<td>Moderate 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 inconsistent 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 for whether tubes confer a clinical benefit when added to adenoidectomy is also limited. Adding tubes to adenoidectomy and myringotomy did not improve hearing but was more likely to result in tympanosclerosis. Children who received both tubes and adenoidectomy had better hearing outcomes than children who were actively monitored.

No studies meeting our inclusion criteria addressed subpopulations with coexisting conditions, so this article pertains mainly to otherwise healthy, typically developing children. Only 2 studies were designed to examine treatments in children 2 years or younger;30,31 in other studies, investigators did not provide sufficient information on age of the target population or included a wide age range of children. Thus, we could not ascertain the applicability of the tested intervention to specific age groups. We identified no studies of surgical treatments in adults.

Future Research Needs

The evidence base is clearly limited for infants and adults. It is virtually nonexistent for children with major coexisting or congenital conditions, such as those with cleft palate, Down syndrome, and sensorineural hearing loss, who may be disproportionately affected by OME. Future research needs to fill these gaps by examining treatments for children with such craniofacial anomalies or developmental disorders and for adults.

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;60 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.70,71

Many cases of OME start after episodes of AOM. Vaccines to prevent pneumococcal disease can decrease the frequency of AOM.72 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 MRC54 and Paradise et al31 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

The authors thank Amy Greenblatt, Loraine G. Monroe, Karen Crotty, Andrea Yuen, and Christiane E. Voisin for their assistance in conducting the systematic review. They also thank Meera Viswanathan for her input on standard Agency for Healthcare Research and Quality EPC protocols. Finally, we thank Loraine G. Monroe for her assistance in preparing the manuscript.
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Surgical Treatments for Otitis Media With Effusion: A Systematic Review
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