Comparative Effectiveness Review
Number 101

Effective Health Care Program

Otitis Media With Effusion: Comparative Effectiveness of Treatments

Executive Summary

Background

Definition of Otitis Media With Effusion

Otitis media with effusion (OME) is defined as a collection of fluid in the middle ear without signs or symptoms of acute ear infection.[1] OME has several potential causes. The leading causes include viral upper respiratory infection, acute otitis media (AOM), and chronic dysfunction of the eustachian tube.[2,3] However, other potential explanations include ciliary dysfunction, proliferation of fluid-producing goblet cells, allergy and residual bacterial antigens, and biofilm.[4] More recent research suggests that mucoglycoproteins cause the hearing loss and much of the fluid presence that is the hallmark of OME.[5,6] The presence of fluid in the middle ear decreases tympanic membrane and middle ear function, leading to decreased hearing, a "fullness" sensation in the ear, and occasionally pain from the pressure changes.

Prevalence of Otitis Media With Effusion

OME occurs commonly during childhood, with as many as 90 percent of children (80% of individual ears) having at least one episode of OME by age 10.[7] OME disproportionately affects some subpopulations of children. Those with cleft palate, Down syndrome, and other craniofacial anomalies are at high risk for anatomic causes of OME and

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at **www.effectivehealthcare.ahrq.gov/reports/final.cfm**.

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compromised function of the eustachian tube.[8] Individuals of American Indian, Alaskan, and Asian backgrounds are believed to be at greater risk,[9] as are children with adenoid hyperplasia. In addition, children with sensorineural hearing loss will likely be more affected by the secondary conductive hearing loss that occurs with OME.

Although rare, OME also occurs in adults. This usually happens after patients develop a severe upper respiratory infection such as sinusitis, severe allergies, or rapid change in air pressure after an airplane flight or a scuba dive. The incidence of prolonged OME in adults is not known, but it is much less common than in children.[10]

Many episodes of OME resolve spontaneously within 3 months, but 30 to 40 percent of children have recurrent episodes, and 5 to 10 percent of cases last more than 1 year.[1,11,12]

Despite the high prevalence of OME, its long-term impact on child developmental outcomes such as speech, language, intelligence, and hearing remains unclear.[7] The near universality of this condition in children and the high expenditures for treating OME (about $4 billion per year in the United States) make this an important topic for a comparative effectiveness review.

Diagnosis of Otitis Media With Effusion

Diagnostically, the core feature of OME is middle ear effusion (MEE), that is, fluid behind the eardrum in the middle ear. Tympanocentesis, which is the removal of fluid from behind the eardrum by using a needle to puncture the tympanic membrane, remains the gold standard for diagnosing MEE and OME. However, because tympanocentesis is an invasive procedure, it is rarely used for diagnosis. Tympanocentesis is not the same as myringotomy, in which the tympanic membrane is punctured to relieve pressure. A variety of supplemental examination techniques assist with identification. The most studied additional diagnostic method is pneumatic otoscopy, which is considered an accurate way to diagnose MEE by trained examiners.[7] To use this procedure, clinicians blow air through an otoscope, causing movement of the tympanic membrane that they can compare with normal movement of the membrane. Tympanometry is a supplemental diagnostic tool that indirectly measures middle ear pressure and tympanic membrane mobility. A "flat" tympanogram (Type B tympanogram) is consistent with OME. Additionally, children with OME often have a corresponding conductive hearing loss on pure-tone audiometry that measures 25 decibels (dB) or 10 dB above the IW hearing level of children with normal hearing.

Natural History and Treatment

Despite recent practice guidelines and systematic reviews,[8,13-20] the comparative benefits and harms of treatments and treatment strategies for OME are uncertain. The uncertainty stems from a lack of consensus regarding clinical and long-term functional outcomes of OME. Specifically, the authors of the most recent systematic review of the natural history of OME[8] found mixed evidence regarding the impact of OME in early childhood on later developmental outcomes. Although they concluded that children with early OME were at greater risk for temporary conductive hearing loss, they were unable to draw strong conclusions about the effect of early OME on later speech and language development. This lack of strong conclusions means it is not clear whether OME needs to be treated. Second, difficulty predicting the course of recurrence for individual patients, especially those with comorbid conditions, makes clinical decisions difficult. During topic refinement, the RTI-UNC Evidence-based Practice Center (RTI-UNC EPC) considered each of the known treatments in terms of uncertainty within the published literature (including gaps in the evidence), importance to clinicians, outcomes important to patients, and relevance to the U.S. population. Treatments examined in this review are indicated under Key Question 1.

Scope and Key Questions

The RTI-UNC EPC was charged with conducting this review because of the continuing uncertainty about efficacy, effectiveness, and particularly comparative effectiveness, as well as harms, for the included therapies. Providing more up-to-date and comprehensive comparative information will help many stakeholder groups make decisions about when and how to treat patients with this condition. This comparative review includes all interventions currently in use for treating OME—surgical, pharmacological, and nonpharmacological; we excluded antihistamines and decongestants, which have been extensively reviewed previously and demonstrated to have no benefit in this population. Antibiotics are the subject of a recent Cochrane review, and in cooperation with our Technical Expert Panel (TEP), we decided to not duplicate their work. We did not include this review as evidence because it was published in September 2012 after the deadline for including new reports in our

review.[21] For the most part, the treatments examined in the review are limited to those therapies that clinical guidelines recommended for managing OME.[20] However, we included several additional comparisons because more recent literature was available. Most notably, we included the findings of a recently published trial that examined adenoidectomy as an initial treatment with concurrent tympanostomy tubes (TT) placement in comparison with TT alone or watchful waiting because of the prominence of this large, carefully designed trial.[22]

The intent of our review was to cover the entire range of individuals who have OME; in particular, we sought evidence specific to populations who have not been examined in past reviews such as adults and children with comorbid conditions such as Down syndrome, cleft palate, or existing hearing loss. We did not limit the timeframe for outcomes, nor did we exclude any settings.

The EPC addressed five Key Questions (KQs) in this comparative effectiveness review.

KQ 1. What is the comparative effectiveness of the following treatment options (active treatments and watchful waiting) in affecting clinical outcomes or health care utilization in patients with OME? Treatment options include: tympanostomy tubes, myringotomy, oral or topical nasal steroids, autoinflation, complementary and alternative medical procedures, watchful waiting, and variations in surgical technique or procedures.

KQ 2. What is the comparative effectiveness of the different treatment options listed in KQ 1 (active treatments, watchful waiting, and variations in surgical procedures) in improving functional and health-related quality of life outcomes in patients with OME?

KQ 3. What are the harms or tolerability among the different treatment options?

KQ 4. What are the comparative benefits and harms of treatment options in subgroups of patients with OME?

KQ 5. Is the comparative effectiveness of treatment options related to factors affecting health care delivery or the receipt of pneumococcal vaccine inoculation?

We developed an analytic framework (Figure A) to guide our analysis. The populations of interest are in the box to the far left in the figure; the interventions appear in the middle; and the two sets of outcomes (for KQ 1 and KQ 2 on benefits, and also KQ 4 on important subgroups) appear on the far right. KQ 3 concerns harm (various types of adverse events). Finally, KQ 5 relates to a set of health care delivery or clinical factors (pneumococcal vaccination) that may influence choices of treatments or their clinical and quality-of-life outcomes.

Methods

Literature Search Strategy

Search Strategy

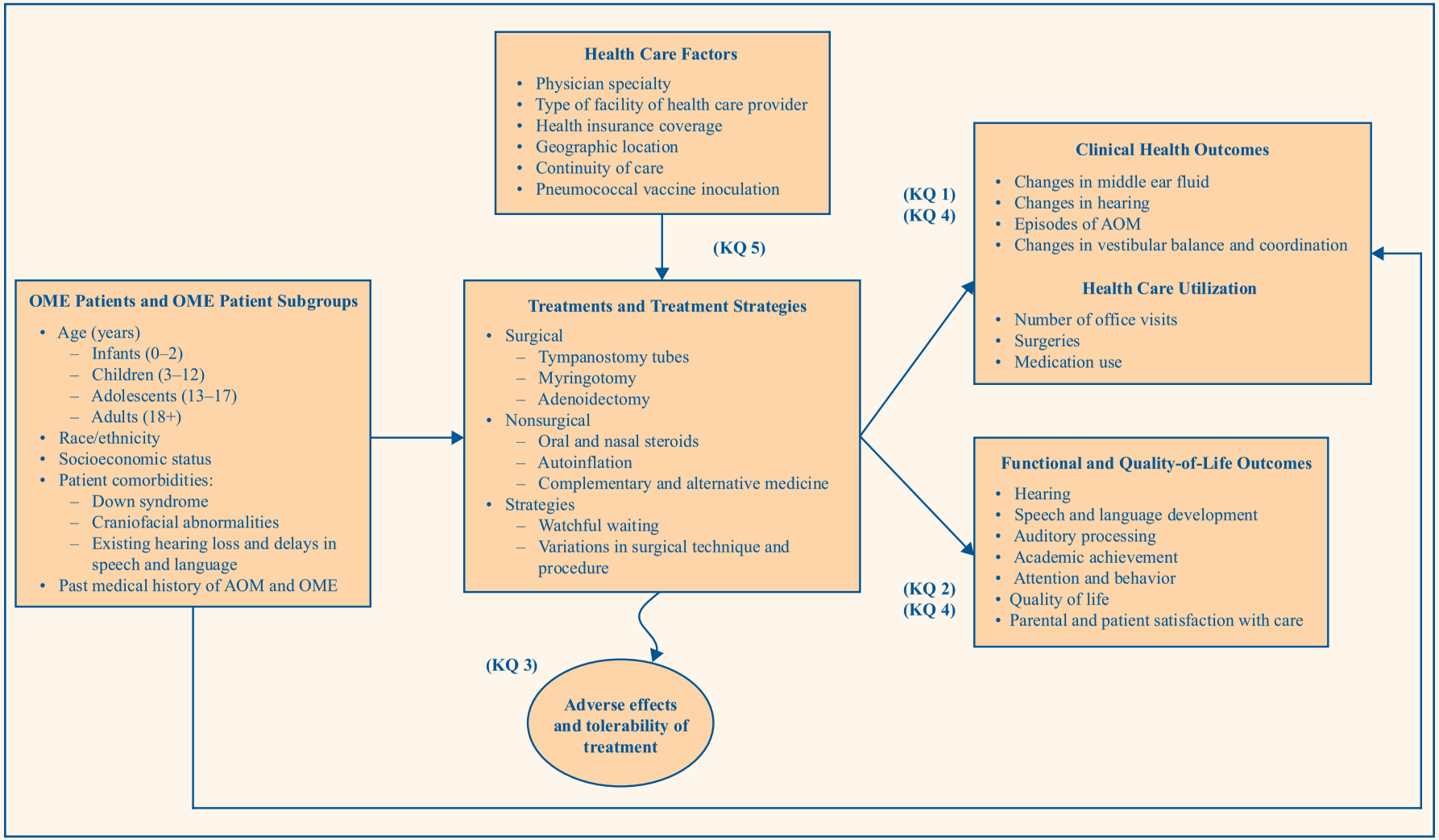
Five recently published systematic reviews on comparisons of interest (two on TT, one on adenoidectomy, one on steroids, and one on autoinflation)[13,15-18] were identified during the topic refinement stage of the review. An update of the steroid review[23] was added during peer review. As discussed in our review protocol, The Cochrane Collaboration conducted four of the reviews, and the Swedish Council of Technology in Health Care commissioned the fifth. The reviews covered the following treatment options for OME: TT, adenoidectomy, steroids, and autoinflation.

To avoid duplicating the work of these teams, we used these reviews as a starting point. We included evidence from these systematic reviews plus additional evidence that these reviews did not consider. The additional evidence included: additional outcomes data from studies that were included in the recent reviews but were not the focus of those reviews, observational studies done at any time, newer studies published since the last search dates in those reviews, and studies focusing on populations excluded from the reviews, such as adults with OME or children with Down syndrome or cleft palate, who may be differently affected by OME.

We searched MEDLINE® (via PubMed), Embase,® The Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®) to identify studies not included in the systematic reviews. An experienced research librarian used a predefined list of search terms and medical subject headings (MeSH). We reviewed our search strategy with our TEP and incorporated their input into our search strategy. We limited the electronic searches to English-language materials. We completed the initial search on 1/8/2012, and we completed an update during peer review on 8/13/2012.

We searched unpublished and grey literature relevant to the review topic. Methods for identifying grey literature included a review of trial registries. In addition, AHRQ requested Scientific Information Packets (SIPs) from the developers and distributors of the interventions identified

Figure A. Analytic framework for comparisons of interventions for otitis media with effusion



AOM = acute otitis media; KQ = Key Question; OME = otitis media with effusion

in the literature review. We included unpublished studies that met all inclusion criteria and contained enough information on their research methods to permit us to make a standard risk-of-bias assessment of individual studies. Finally, we manually searched reference lists of reviews, including trials and background articles, to look for relevant citations that our searches might have missed and that addressed our KQs. We imported all citations into an electronic database (EndNote® X4).

Inclusion and Exclusion Criteria

We developed inclusion and exclusion criteria with respect to the PICOTS (i.e., populations, interventions, comparators, outcomes, timeframes, and settings) framework. The review included only English-language studies of individuals with OME. We included five systematic reviews that had been determined a priori to fit our PICOTS criteria and the relevant studies included in those reviews; we also retained eligible studies that the earlier reviews had not used, and these included randomized controlled trials (RCTs), nonrandomized controlled trials, and cohort studies. We imposed no other restrictions so that we could consider studies with individuals of any age, racial or ethnic background, or coexisting condition.

The treatments of interest were TT, myringotomy, adenoidectomy, oral or intranasal steroids, autoinflation of the eustachian tube, complementary and alternative medicine (CAM) procedures, watchful waiting, and variations in surgical technique or procedures. With two exceptions, included studies had to compare at least two of these treatments. We considered inactive controls in comparison with steroid treatment and usual care in comparison with autoinflation, based on the Cochrane review inclusion criteria. Based on discussions with our TEP, because the effectiveness of CAM treatments was unknown and there were concerns about the quality of nonrandomized studies, we limited studies of CAM to RCTs.

We specified a broad range of outcomes (see Figure A). We included clinical outcomes such as changes in middle ear fluid, episodes of AOM, and hearing thresholds; use of health care; functional and quality-of-life outcomes such as speech and language development, behavior, and parental satisfaction with care; and harms.

We were interested primarily in treatment outcomes of 3 months or longer, but we included outcomes of less than 3 months. We focused on end-of-intervention results when they were the only endpoint data available, such as in the autoinflation treatment studies.

We did not exclude studies based on geography or the setting of the service provision.

Study Selection

A total of six trained members of the team reviewed article abstracts and full-text articles. First, two members of the team independently reviewed each abstract using the inclusion/exclusion criteria. One reviewer was always a senior member of the review team. If both reviewers agreed that the study did not meet eligibility criteria, we excluded it; otherwise, we included the abstract for full article review. Two members of the team independently reviewed each full-text article. One reviewer was always a senior member of the review team. If both reviewers agreed that a study did not meet eligibility criteria, we excluded it. Each reviewer recorded the primary reason for exclusion. If the reviewers disagreed about whether an article should be excluded or about the primary reason for exclusion, they resolved conflicts by discussion and consensus or by consulting a third member of the team. We screened unpublished studies identified through a grey literature search and review of SIPs using the same title/abstract and full-text review processes.

Data Abstraction

We developed a template for evidence tables for data synthesis using the PICOTS framework. For the five systematic reviews and additional studies that met our inclusion criteria, we abstracted relevant information into these evidence tables: characteristics of study populations, interventions, comparators, settings, study designs, methods, and results. We directly reviewed individual studies included in the systematic reviews to capture additional outcomes data that were not the focus of the earlier reviews and to determine the availability of subgroup analyses not included in the reviews.

Six trained members of the team participated in the data abstraction. One of the reviewers initially abstracted the relevant data from each included article using Microsoft Excel® software and a second more senior member of the team reviewed each data abstraction against the original article for completeness and accuracy.

Risk-of-Bias Assessment

The risk-of-bias assessment was conducted using two tools, one appropriate for trials based on the Cochrane

risk-of-bias tool[24] and modified by our EPC to be used to evaluate observational studies (including instructions to reviewers that some questions concerning trial study design would be considered not applicable) and AMSTAR (assessment of multiple systematic reviews),[25] appropriate for systematic reviews. We did not reevaluate the risk of bias of the studies included in the previous systematic reviews,[13,15-18,23] but the original review study authors had determined these studies to be of low or medium risk of bias.

Two independent reviewers rated the risk of bias for each study. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team. Results of this assessment were summarized in a rating of low, medium, or high risk of bias. High risk-of-bias studies were those that had at least one major issue that had the potential to cause significant bias and might invalidate the results.

Data Synthesis

Across all included studies, the populations, interventions, and outcome measures in the additional data were heterogeneous and did not lend themselves to a pooled analysis beyond what was currently available in the meta-analyses from the five earlier systematic reviews. Because we determined that additional quantitative analyses were not necessary or appropriate, we did all analyses qualitatively. Evidence used in the synthesis included the results from the earlier meta-analyses, additional data from individual studies contained in those systematic reviews, and data from the articles added from our own searches.

Strength of the Body of Evidence

We graded the strength of evidence based on the guidance established for the Agency for Healthcare Research and Quality Effective Health Care Program EPCs conducting comparative effectiveness reviews, as detailed in the paper by Owens and colleagues.[26] The EPC approach incorporates four key domains: risk of bias, consistency, directness, and precision of the evidence. The overall grade for strength of evidence is based on the scores for the four domains and reflects the strength of the body of evidence to answer the KQs on the comparative effectiveness, efficacy, and harms of the treatments and treatment strategies covered in this review.

A grade of high strength of evidence indicates that we have high confidence that the evidence reflects the true effect. Moderate strength of evidence implies that we have moderate confidence that the evidence reflects the true effect. Low strength or evidence suggests that we have low confidence that the evidence reflects the true effect. Insufficient strength of evidence signifies either that evidence is completely unavailable or that it does not permit estimation of an effect. Typically, evidence from just one study was considered insufficient to permit confidence in the estimation of an effect. Exceptions were single study bodies of evidence consisting of a relatively larger, low risk of bias trial, particularly if it showed a large magnitude of effect.

Two reviewers assessed each domain independently and assigned an overall grade for each treatment comparison for each key outcome listed in the framework. They resolved any conflicts through consensus discussion. If they did not reach consensus, the team brought in a third party to settle the conflict.

Applicability

We assessed the applicability of individual studies as well as the body of evidence. For individual studies, we examined factors that may limit applicability based on the PICOTS structure such as population characteristics, intervention characteristics, and comparators. We abstracted key characteristics of applicability into the evidence tables. During data synthesis, we assessed the applicability of the body of evidence using the abstracted characteristics. KQ 4 includes a detailed analysis of intervention effectiveness in population subgroups.

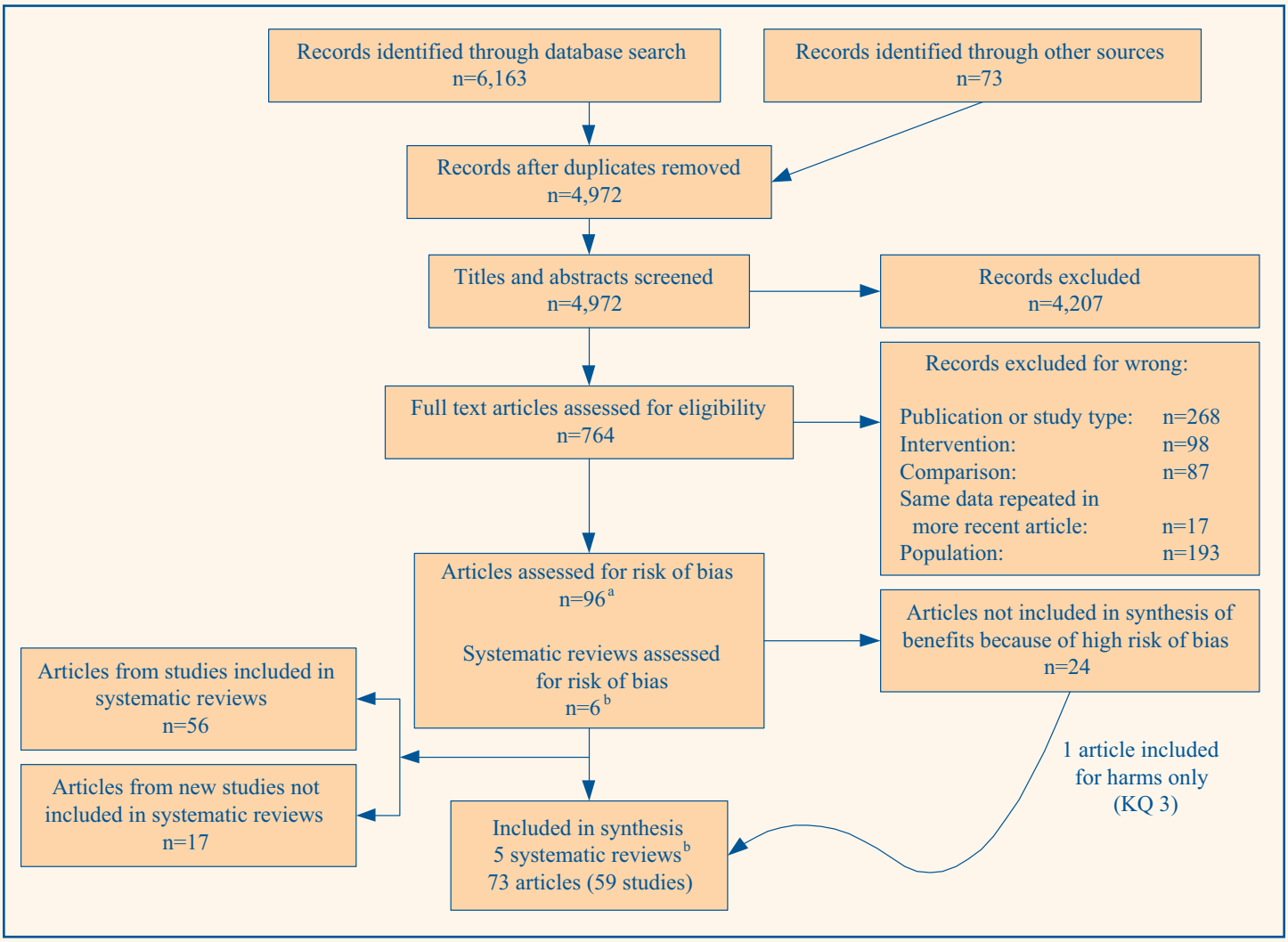
Results

This section is organized by KQ and then grouped by intervention comparison. The summaries of evidence findings are presented in Tables A–D by KQ. The full report contains summary tables. Appendix C contains evidence tables for included studies, and Appendix F has the strength of evidence grades for the main outcomes of each KQ. Except where otherwise noted, across KQs, the studies we included were limited to otherwise healthy children.

Literature Searches

We identified a total of 4,967 unduplicated citations and determined that 764 met criteria for full-text review (Figure B). We excluded 668 full-text articles based on our inclusion criteria and before risk-of-bias assessment. There were a total of 73 full-text articles, detailing 59 studies and five systematic reviews. Of the 59 studies, 42 studies were included in one of the five systematic reviews, and we included 17 additional studies. Of the 59 studies included in this review, 49 were RCTs (33 by person, 12 by ear, and 4 by person and ear), 6 were nonrandomized control trials

Figure B. Disposition of articles on otitis media with effusion



[a]We accepted the risk of bias assessment conducted by the review authors for the studies included in one of the 5 earlier systematic reviews (56 articles). We conducted our own risk of bias assessment for 17 new articles not included in one of those reviews.
[b]One of the 5 included systematic reviews was updated during our peer review period. We reviewed both the original report and the update.

(1 by person and 5 by ear), and 4 were cohort studies. Of the 17 articles not included in one of the five systematic reviews, we assessed 15 as medium risk of bias, 1 as low risk of bias and 1 as high risk of bias. Of the five included systematic reviews, four were limited to RCTs. We assessed four systematic reviews as low risk of bias and one as medium risk of bias.

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).

We did not include 23 high-risk-of-bias studies in our analyses (Appendix C of the full report). Virtually all lacked information on any baseline patient characteristics; of particular concern, unknown differences between groups based on age or time with OME could invalidate outcomes. Other serious concerns were a lack of control for selective concurrent treatment and lack of control for confounders in cohort studies.

Key Question 1. Comparative Effectiveness: Clinical Outcomes or Health Care Utilization

All but four of the 59 studies included in this review examined clinical outcomes. Thirty one studies and 12 meta-analyses examined signs and symptoms of OME. Thirty studies and six meta-analyses examined hearing as an outcome. Only three studies examined subsequent AOM as an outcome. No studies reported use of health services or balance outcomes. A description of the treatment comparisons and comparative effectiveness follows.

Tympanostomy Tube Comparisons

Six individually located studies[27-32] and eight studies[33-40] from one systematic review[13] addressed comparisons of TT. These studies compared different types of tubes (e.g., design, materials, size), approaches to insertion, or topical prophylaxis therapies. All comparisons were made between ears of the same individual.

Ten[27-31,33-37] of the 14 studies provided evidence for KQ 1; the other four provided evidence only for harms. Of these 10 studies, 7 were RCTs. Length of tube retention was higher in the longer term TT. Other TT comparisons and endpoints differed across studies. Because of sparse data, the diversity of comparisons, and inconsistent findings, the evidence is insufficient for comparisons of other design features or for hearing outcomes.

Tympanostomy Tubes Versus Watchful Waiting/Myringotomy

Two individual studies[41,42] and two systematic reviews[13,15] addressed comparisons between RCTs of TTs with either myringotomy or watchful waiting. The Browning et al.[15] systematic review reviewed 10 studies;[43-52] 7 were in comparison with watchful waiting or delayed treatment,[43-45,48,50-52] 2 were in comparison with myringotomy in the control ear,[46,49] and 1[47] included both myringotomy and watchful waiting arms. The Hellstrom et al.[13] systematic review included six of the studies that were in the Browning review; in addition, data on hearing outcomes from Gates et al. (1989)[53] were reported only in the Hellstrom review. We included as a companion study the Medical Research Council Trial of Alternative Regimens in Glue Ear Treatment (MRC TARGET)[22] that was a recently published version of the preliminary data included in the Browning review.[44] We also present additional reports of later followup of the cohorts of Maw and colleagues (1999),[43] Rovers and colleagues (2000),[45] and Paradise and colleagues (2001).[48]

TT placement decreased time with middle ear effusion by 32 percent compared with watchful waiting or delayed treatment (high strength of evidence) and up to 42 percent in comparison with myringotomy (moderate strength of evidence) at 1 year after surgery. Compared with watchful waiting or myringotomy (data combined), there was a 13 percent reduction through 2 years after surgery (moderate strength of evidence). Evidence was insufficient for longer followup. TT improved hearing through 9 months after surgery compared with watchful waiting (3–6 months: 8.8 dB; 6–9 months: 4.2 dB) (high strength of evidence); TT improved hearing by 10 dB at 4 to 6 months after surgery in comparison with watchful waiting or myringotomy (data combined) (high strength of evidence). Thereafter the differences in hearing became attenuated and were not significant at either 7 to 12 months compared with watchful waiting or myringotomy (low strength of evidence) or 12 to 18 months after surgery compared with watchful waiting (low strength of evidence). Evidence was insufficient for longer time periods and for other clinical outcomes or health utilization.

Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone

Seven individually located studies[54-60] and four studies[53,61-63] reported in the Hellstrom review examined outcomes in relation to TT plus adenoidectomy as compared with myringotomy plus adenoidectomy or adenoidectomy alone. We included another report[64] that was a followup study to the Bonding and Tos report (1985)[61] included in the Hellstrom review. Four of the studies compared TT in one ear with an ear that received no surgery, in children who all had had adenoidectomies. Three studies (four articles)[59,61,63,64] compared ear outcomes between ears with TT and ears with myringotomy, among children who all had had adenoidectomies. The other four studies[53,57,58,60] compared TT with myringotomy among children who all had had adenoidectomies.

Two small studies found that TT conferred no additional benefit to adenoidectomy alone for reducing the recurrence of OME (insufficient strength of evidence); three studies comparing TT and adenoidectomy with myringotomy and adenoidectomy produced mixed results (insufficient strength of evidence). Five of six studies failed to find a difference in hearing at various endpoints between TT and myringotomy among children who had also received adenoidectomies (low strength of evidence). We found mixed results for hearing when comparing TT with watchful waiting in children who also received adenoidectomies (insufficient strength of evidence).

Myringotomy Comparisons

Only one RCT compared two different procedures for myringotomy on both middle ear and hearing outcomes.[65] The two procedures were radio frequency myringotomy with mitomycin C, a topical chemotherapeutic agent and radio frequency myringotomy alone. A majority of individuals in each arm received adenoidectomy (73% and 67%, respectively). There was insufficient evidence for concluding superiority of either myringotomy procedure for OME signs and symptoms or hearing outcomes.

Myringotomy Plus Adenoidectomy Comparisons

One retrospective cohort study compared two different procedures for myringotomy.[66] The comparison was between laser myringotomy and cold knife myringotomy. In both groups all individuals received an adenoidectomy. The evidence is insufficient for determining superiority for either myringotomy approach for OME signs and symptoms. No study examined hearing or any other clinical outcome.

Adenoidectomy Versus Other Interventions

Eight RCTs provided all the evidence for adenoidectomy in comparison to TT, myringotomy, watchful waiting, or no surgery among patients with OME. Seven of the RCTs were included in the Cochrane review by van den Aadweg et al.[16,46,49-51,67-69] and the eighth was the newly published MRC TARGET trial.[22] The trials examined adenoidectomy with and without myringotomy versus nonsurgical treatment or myringotomy only; adenoidectomy with unilateral TT versus a unilateral TT only (comparison by ears); adenoidectomy with bilateral TT versus bilateral TT only; and adenoidectomy plus TT versus watchful waiting.

Adenoidectomy was superior to no treatment for resolution of OME at both 6 months (risk difference of 0.27 [95% CI, 0.13 to 0.42] measured through otoscopy and 0.22 [95% CI, 0.12 to 0.32] as measured through tympanometry; high strength of evidence) and 12 months postsurgery (risk difference of 0.29 [95% CI, 0.19 to 0.39] through tympanometry; high strength of evidence). Adenoidectomy was superior to no treatment for hearing in one study at 6 months but not at 12 months; in a second study, no differences were detected between adenoidectomy and no treatment (insufficient strength of evidence for mixed findings). One single study found that adenoidectomy and myringotomy were superior to myringotomy alone for reducing time with effusion ($p<0.001$).and improving hearing at 24 months (better ear standard mean difference of -0.66 [95% CI, -0.93 to -0.40]; low strength of evidence). Because results were mixed, the evidence was insufficient for determining the effectiveness of adenoidectomy when added to TT in relation to effusion or hearing (insufficient strength of evidence). Hearing outcomes were superior with adenoidectomy and TT compared with watchful waiting at 24 months (low strength of evidence). There was insufficient evidence to determine the effectiveness of adenoidectomy compared with other treatments for recurrence of AOM.

Oral or Topical Nasal Steroids

The included evidence consisted of one systematic review conducted by The Cochrane Collaboration,[18] that was updated while we were conducting our review,[23] that examined oral steroids and topical intranasal steroids. The update review includes the studies included in the earlier review, nine RCTs of oral steroids[70-78] and three RCTs of topical intranasal steroids,[79,80] and adds one recent RCT conducted by Williamson et al.[80,81] All studies were in comparison with placebo controls; some of the oral steroid studies included antibiotics in both arms. All studies examined signs and symptoms of OME and hearing.

Results of a meta-analysis[18] comparing oral steroids with controls did not show differences in middle ear effusion at 1–2 months post treatment (low strength of evidence); nor did a meta-analysis comparing oral steroids with control along with adjunct antibiotics (moderate strength of evidence). Due to limited data, evidence was insufficient for determining the effectiveness of oral steroids with and without antibiotics for OME signs and symptoms at followup beyond 3 or more months. Topical intranasal steroids did not show differences in cure rate at various followup points with antibiotics (insufficient strength of evidence) or without antibiotics (low strength of evidence). The evidence was insufficient for determining the effectiveness of oral steroids with and without antibiotics for hearing at any time point. The RCT by Williamson et al.[80,81] comparing intranasal steroids with controls did not find differences in OME cure rate or in hearing at one or more months post treatment (low strength of evidence). There was insufficient evidence for comparing either oral or topical intranasal steroids with controls for any other clinical outcomes.

Autoinflation

One Cochrane review conducted by Perera et al.[17] summarized evidence from six RCTs of any form of autoinflation, a technique designed to increase pressure in the oropharynx forcing open the eustachian tube though a nasal balloon or other process. The review included five studies with children[82-86] and one study with adults, 16–75 years of age.[87] All studies were in comparison with no autoinflation, and other treatments (e.g., antibiotics, analgesics) were permitted as long as they were given equally to both arms. Meta-analyses comparing autoinflation with controls found an improvement in OME at 1 month or less, post treatment (low strength of evidence). Evidence was insufficient for drawing

conclusions regarding improvements in OME at longer time periods or for other clinical outcomes, including hearing.

Key Question 2. Comparative Effectiveness: Functional Outcomes or Quality of Life

Only a subset of the treatment comparisons reported functional or quality of life outcomes. These include TT versus watchful waiting, TT plus adenoidectomy versus myringotomy plus adenoidectomy, and steroids versus control. In general, there were no differences between the treatments. The studies included to address KQ 2 are described under KQ 1.

Tympanostomy Tubes Versus Watchful Waiting/Myringotomy

Meta-analyses reported by Browning et al.[15] did not find any differences in language development at 6 and 9 months post treatment between TT and watchful waiting (moderate strength of evidence for no differences). With one exception, studies examining children during preschool and elementary school years failed to find a difference in language skills. In the one exception where a difference favoring TT was reported, the investigators used a teacher rating of children's language; this difference disappeared at 8 years of age when they used a direct assessment of language (low strength of evidence for no difference). We did not find differences between TT and watchful waiting in any RCTs reporting cognitive development, academic achievement or quality of life at any time point (all low strength of evidence for no difference). Studies reported mixed findings for behavior outcomes at less than 1 year (insufficient strength of evidence); three studies reporting behavior at more than 1 year reported no difference (low strength of evidence). No studies comparing TT with myringotomy reported on functional or quality of life outcomes (insufficient strength of evidence).

Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy

One study comparing TTs plus adenoidectomy with myringotomy plus adenoidectomy reported quality of life outcomes.[60] The two groups did not differ at any time point (insufficient strength of evidence). Strength of evidence was insufficient for all speech/language, cognitive, and behavioral outcomes because there were no studies including these outcomes.

Oral or Topical Nasal Steroids

Two studies comparing steroids to control (three reports)[79-81] examined functional outcomes. In one small study, patients receiving intranasal steroids plus oral antibiotics did not differ in parents' assessment of their children's symptoms from patients receiving placebo plus antibiotics (insufficient strength of evidence); nor did patients receiving intranasal steroids differ from controls in parent reported hearing outcomes (low strength of evidence). No studies comparing topical or oral steroids to control examined any other functional outcomes (insufficient strength of evidence).

Key Question 3. Harms or Tolerability

Six of the treatment comparisons included in the review reported on harms. These included comparisons between different types of TT, TT versus watchful waiting/myringotomy, TT plus adenoidectomy versus myringotomy plus adenoidectomy/adenoidectomy alone, steroids, and autoinflation. Only a limited range of harms was included for any comparison. Few significant differences in harms were reported.

Tympanostomy Tube Comparisons

We reviewed nine studies that reported on otorrhea.[27-32,37-39] Otorrhea rates differed by TT type, with placement of longer term TT related to a higher probability of otorrhea (low strength of evidence). 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 strength of evidence).

Tympanostomy Tubes Versus Watchful Waiting/Myringotomy

We reviewed nine studies that compared side effects for TT with side effects for watchful waiting or myringotomy.[57,64,88-94] Otorrhea and tympanosclerosis occurred more frequently in ears that had TT than watchful waiting or myringotomy (low strength of evidence). Evidence was insufficient for other harms due to either conflicting results or data reported in only a single study.

Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy/Adenoidectomy Alone

We reviewed nine studies that examined harms.[33-35,48,53,95-98] These included repeat TTs, otorrhea, perforation, and tympanosclerosis or myringosclerosis. The risk of tympanosclerosis was higher with TT than myringotomy or no surgery in addition to adenoidectomy (moderate strength of evidence). Results for other harms were either mixed, were reported in single studies, or were lacking precision (insufficient strength of evidence).

Adenoidectomy

Only two studies (three articles)[22,46,53] reported harms. In both studies, there was one report of a postoperative hemorrhage following adenoidectomy (low strength of evidence). Evidence was insufficient for other harms.

Oral or Topical Nasal Steroids

Evidence for harms of steroids comes from the systematic review and its update.[28,29] A meta-analysis of two RCTs in the updated review[29] comparing oral steroids plus antibiotics with control plus antibiotics reported no difference in mild to moderate adverse events at 2 weeks to 6 months. A second RCT[31,99] found no significant differences in mild adverse harms such as stinging nose, nose bleed, dry throat, or cough between those receiving nasal steroids and those receiving placebo control (low strength of evidence). Evidence concerning serious harms was sparse for either nasal or oral steroids (insufficient strength of evidence).

Autoinflation

None of the studies that compared autoinflation to control[17] provided quantitative information on rates of serious or mild harms, only verbal statements indicating there were few harms noted (insufficient strength of evidence).

Key Question 4. Comparative Effectiveness of Interventions for Subgroups of Patients

One of the explicit goals of this review was to examine treatment options for subgroups of patients including individuals defined by age groups and subpopulations at greater risk for OME such as individuals of American Indian, Alaskan, and Asian backgrounds and individuals with cleft palate, Down syndrome, and other craniofacial anomalies. Our search found very few studies of any subgroups that met our inclusion criteria. Two treatment comparisons examined comparative effectiveness of interventions for subgroups of patients—TT plus adenoidectomy versus myringotomy plus adenoidectomy/adenoidectomy alone and autoinflation.

Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone

One study[60] included children with sleep apnea and OME. The study did not find differences in hearing thresholds between children who received TT plus adenoidectomy and children who received myringotomy plus adenoidectomy (insufficient strength of evidence). Quality of life scores were measured in only one study (insufficient strength of evidence).

Autoinflation

One study[87] included in the systematic review of autoinflation[17] included adults 16 to 75 years of age. The autoinflation group was significantly more likely to experience a complete recovery than those in the control group at the end of treatment and 50 days later (low strength of evidence).

Key Question 5. Comparative Effectiveness by Health Care Factors

No included studies or systematic reviews examined effectiveness of intervention comparisons by any health care factors.

Discussion

Key Findings and Strength of Evidence

Key Question 1. Comparative Effectiveness: Clinical Outcomes or Health Care Utilization

Table A summarizes the strength of evidence for comparative effectiveness of treatments on clinical outcomes. We are able to draw some conclusions regarding surgical treatments.

We examined several design, placement, and material features of TTs. Longer acting TT such as Goode T-tubes and Paparella tubes were retained longer than shorter acting Shah and Shepard TTs; No other TT features were associated with clinical outcomes.

Compared with watchful waiting, TT decreased the number of children with MEE at 1 year after surgery (high strength of evidence); compared with myringotomy, TT decreased time with effusion at 1-year followup (moderate strength of evidence). TTs continued to improve MEE at 2-year followup (moderate strength of evidence), but the effect washed out thereafter. TT also improved hearing relative to watchful waiting or myringotomy, but the effect was shorter in duration, not lasting beyond 9 months after treatment (high strength of evidence). We found only limited evidence for drawing conclusions about the relative benefits of TT for other clinical outcomes such as OME recurrence or episodes of AOM.

We examined the evidence for whether TT or myringotomy differentially improved clinical outcomes when they were added to adenoidectomy. Based on finding no differences in hearing at any time point in five studies, we concluded that hearing outcomes do not differ (low strength of evidence); evidence was insufficient for all other clinical outcomes. However, TT plus adenoidectomy

Table A. Strength of evidence for interventions to improve clinical outcomes			
Intervention and Comparator	**Number of Studies (Sample Sizes)**	**Outcome and Results**	**Strength of Evidence**
TT vs. watchful waiting, delayed treatment, or myringotomy	MA of 3 RCTs (N=574)	TT had less persistent middle ear effusion at 1 year compared with watchful waiting or delayed treatment: 32% less time (95% CI, 17% to 48%).	High for benefit
	2 studies (N=294)	TT had less time with effusion through 1 year compared with myringotomy.	Moderate for benefit
	MA of 3 RCTs (N=426)	TT had less persistent middle ear effusion at 2 years compared with watchful waiting or myringotomy: 13% less time (95% CI, 8% to 17%).	Moderate for benefit
	MA of 3 RCTs (N=523) + 1 RCT (N=248)	TT had better measured hearing for up to 9 months than watchful waiting. MA results: -4.20dB (95% CI, -4.00 to -2.39).	High for benefit
	MA of 3 RCTs (by ears) (N=230)	TT had better measured hearing for up to 6 months than watchful waiting or myringotomy: -10.08 (95% CI, -19.12 to -1.05).	High for benefit
	MA of 3 RCTs (by ears) (N=234)	No difference between TT and watchful waiting or myringotomy in measured hearing at 7-12 months: -5.18dB (95% CI, -10.43 to 0.07).	Low for no difference
	MA of 2 RCTs (N=328); MA of 2 RCTs (N=283)	No difference between TT and watchful waiting in measured hearing at 12 months: -0.41dB (95% CI, -2.37 to 1.54) and 18 months -0.02 dB (95% CI, -3.22 to 3.18).	Low for no difference
TT + adenoidectomy vs. myringotomy + adenoidectomy	6 studies: 3 RCTs by person (N=431); 2 RCTs (by ears) (N=338); 1 NRCT (by ears) (N=193)	No difference in measured hearing between groups at 6 and 12 months and at more than 3 years.	Low for no difference
Adenoidectomy vs. no treatment	MA of 2 RCTs (by ears) (N=153); MA of 3 RCTs (by ears) (N=297)	Adenoidectomy had better OME resolution than no treatment at 6 months. The risk difference was 0.27 (95% CI, 0.13 to 0.42) measured through otoscopy and 0.22 (95% CI, 0.12 to 0.32) measured through tympanometry.	High for benefit
	MA of 3 RCTs (by ears) (N=298)	Adenoidectomy had better OME resolution than no treatment at 12 months. The risk difference was 0.29 (95% CI, 0.19 to 0.39).	High for benefit
Adenoidectomy + myringotomy vs. myringotomy	1 RCT (N=237)	Adenoidectomy and myringotomy had less mean time with effusion than myringotomy alone at 24 months: -0.76 standard mean difference (95% CI, -1.02 to -0.49).	Low for benefit
	1 RCT (N=237)	Adenoidectomy and myringotomy had better hearing than with myringotomy alone at 24 months measured as standard mean difference time with hearing level ≥ 20: worse ear: -0.65 (95% CI, -0.91 to -0.39); better ear: -0.66 (95% CI, -0.93 to -0.40).	Low for benefit
TT + adenoidectomy vs. WW	1 study (n = 250)	TT plus adenoidectomy improved hearing at 3 to 24 months.	Low for benefit
Oral steroids vs. controls	MA of 3 RCTs (N=106);	No difference in persisting OME at 1-2 months (no antibiotics provided in either group): OR=0.55 (95% CI, 0.21 to 1.48).	Low for no difference

Table A. Strength of evidence for interventions to improve clinical outcomes (continued)			
Intervention and Comparator	**Number of Studies (Sample Sizes)**	**Outcome and Results**	**Strength of Evidence**
Oral steroids + antibiotics vs. controls + antibiotics	MA of 3 RCTs (N=243)	No difference in persisting OME at 1-2 months (antibiotics provided to both groups): OR=0.75 (95% CI, 0.45 to 1.27).	Moderate for no difference
Topical intranasal steroids vs. controls	1 RCT (N=217)	No difference in OME cure rates at 1, 3, and 9 months.	Low for no difference
	1 RCT (N=217)	No difference in hearing loss at 3 and 9 months.	Low for no difference
Autoinflation vs. controls	MA of 2 RCTs (N=185)	Improvement in OME at <1month: RR=3.84 (tympanometry change C2 to C1 or A) and RR=2.72 (tympanometry change B to C1 or A).	Low for benefit

CI = confidence intervals; dB = decibels; MA = meta-analysis; NRCT = non-randomized controlled trial; N = number; OME= otitis media with effusion; OR = odds ratio; RCT = randomized controlled trial; RR = risk ratio; TT = tympanostomy tubes; vs. = versus

improved hearing at 3 to 24 months compared with watchful waiting (low strength of evidence). Adenoidectomy is superior to no treatment for improving the likelihood of OME resolution at 6 and 12 months after surgery (high strength of evidence). Adenoidectomy plus myringotomy was superior to myringotomy alone at 2 years after surgery for improving OME resolution and hearing (low strength of evidence). Evidence was insufficient for other outcomes. Evidence was also insufficient for comparisons between different approaches to myringotomy with and without adenoidectomy because of the limited number of studies.

We have reached some conclusions for nonsurgical interventions. Oral steroids do not offer any improvements in OME at 1 to 2 months after treatment (low strength of evidence). Similarly, oral steroids with antibiotics do not provide improvements in OME at 1 to 2 months (moderate strength of evidence). A recent study (low risk of bias) provided additional evidence that OME and hearing outcomes were not improved through the use of topical intranasal steroids through 9 months after treatment. These findings support the current clinical practice guidelines that recommend against the use of oral and intranasal steroids in treating OME in children. Although autoinflation improved MEE at less than 1 month after treatment (low strength of evidence), evidence was insufficient for reaching conclusions for other outcomes, largely because outcomes across studies testing autoinflation were not measured at consistent lengths of followup or through consistent measures.

Key Question 2. Health-Related Quality of Life and Functional Outcomes

Table B summarizes the strength of evidence for health-related quality of life and functional outcomes. We found only limited evidence regarding these outcomes. Language comprehension and language expression outcomes at 6 to 9 months were not significantly better among children with OME who received TT than among those who were limited to watchful waiting or delayed treatment (moderate strength of evidence). Results for cognitive development, behavioral competence, and academic achievement were similar; outcomes from TT versus watchful waiting or delayed treatment at various followup times did not differ (low strength of evidence). Evidence was insufficient to reach conclusions related to differences in either behavioral outcomes or quality of life for this treatment comparison.

Quality of life outcomes were measured in one small study comparing TT and adenoidectomy versus myringotomy and adenoidectomy, but we considered the evidence to be insufficient to reach conclusions. Topical steroids do not improve parent-reported hearing difficulties of their children at up to 9 months (low strength of evidence). However, evidence was insufficient to reach conclusions about other quality of life outcomes for oral steroids.

Key Question 3. Harms Associated With Interventions To Treat Otitis Media With Effusion

Table C summarizes the OME interventions on which we had low, moderate, or high strength of evidence about

Table B. Health-related quality of life and functional status			
Intervention and Comparator	**Number of Studies (Sample Sizes)**	**Outcome and Results**	**Strength of Evidence**
TT vs. watchful waiting or delayed treatment	MA of 3 RCTs (N=394) and 2 RCTs (N=503)	No difference in language comprehension at 6 to 9 months post-intervention (mean difference, 0.09; 95% CI, -0.21 to 0.39) or at preschool and elementary school age.	Moderate for no difference
	MA of 3 RCTs (N=393) and 2 RCTs (N=503)	No difference in language expression at 6 to 9 months post-intervention (mean difference, 0.03; 95% CI, -0.41 to 0.49) or at preschool and elementary school age.	
	2 RCTs (N=503)	No difference in cognitive development at 9 months post-intervention or at preschool and elementary school age.	Low for no difference
	3 RCTs (N=710)	No difference in behavior at 1 year or more.	Low for no difference
	2 RCTs (N=503)	No difference in academic achievement at elementary school age.	Low for no difference
Intranasal steroids vs. controls	1 study (N=144)	No difference in parent-reported hearing difficulties at 3 and 9 months or in median days with hearing loss at 3 months.	Low for no difference

N = number; NR = not reported; SR = systematic review; TT = tympanostomy tubes; vs. = versus

Table C. Strength of evidence for harms of interventions			
Intervention and Comparator	**Number of Studies (Sample Sizes)**	**Outcome and Results**	**Strength of Evidence**
TT vs. TT	1 RCT (N=30 ears); 2 observational studies (N=779 ears)	Otorrhea occurred more frequently in ears with longer-term TT than in ears with shorter-term TT after 1 year or more.	Moderate for harms of longer-term TT
TT vs. watchful waiting or myringotomy	5 studies (N=1,129)	Tympanosclerosis occurred more frequently in ears that had TT, based on examinations after the TT had been extruded.	Moderate for harms of TT
	4 studies (N=960)	Otorrhea occurred more frequently in ears with TT.	Low for harms of TT
TT plus adenoidectomy vs. adenoidectomy alone or with myringotomy	3 studies (N=485)	Tympanosclerosis occurred more frequently in ears with TT than ears with only adenoidectomy or myringotomy.	Moderate for harms of TT
Adenoidectomy vs. other treatments	2 studies (N=739)	Although rare, adenoidectomy increased the risk of postsurgical hemorrhage.	Low for harms of adenoidectomy
Oral nasal steroids vs. control	5 studies (N=637)	No difference in mild adverse events such as vomiting and diarrhea.	Low for no difference
Topical nasal steroids vs. control	2 studies (N=215)	No difference in mild adverse events such as nasal stinging, dry throat, and cough.	Low for no difference

N = number; NR = not reported; SR = systematic review; TT = tympanostomy tubes; vs. = versus

safety and harms. In relation to TT, we considered concerns such as otorrhea, tympanosclerosis, cholesteatoma, or surgical complications. In relation to steroid treatment, we considered problems such as diarrhea and nasal stinging.

Otorrhea was more common among ears with TT than those without (low strength of evidence), especially for those TT designed to stay in longer. Tympanosclerosis was more common in children who had TT than those who were actively monitored or who had myringotomy (low strength of evidence). Likewise, tympanosclerosis was more common when TT were added to adenoidectomy than for adenoidectomy alone or with myringotomy (moderate strength of evidence). Additionally, the risk of post-surgical hemorrhage, although rare, was associated with adenoidectomy, not any other comparison treatments.

We concluded that mild adverse events are not significantly higher with topical nasal steroids than with placebo (low strength of evidence). However, evidence was insufficient to reach conclusions related to oral steroids and serious adverse events from oral or topical steroids. Evidence was also insufficient concerning the surgical risks from the insertion of TT or those from myringotomy procedures with adenoidectomy.

KQ 4. Outcomes for Important Patient Subgroups

Table D provides the limited evidence we found for patient subgroups. Although we attempted to examine treatment effectiveness or harms for key subgroups characterized by clinical variables (e.g., cleft palate, Down syndrome, or sensorineural hearing loss) or sociodemographic factors (such as age), we could not identify studies that covered most of our subgroups of interest.

One study examined children with sleep apnea and OME, and one examined adults with OME. Among children with sleep apnea, all of whom had adenoidectomy to treat that condition, the addition of TT or myringotomy did not differ significantly in terms of any measured outcomes (insufficient strength of evidence). The study of autoinflation in one systematic review[17] found differences in rates of recovery between those receiving autoinflation and those who were in the control group. Individuals in the autoinflation group were significantly more likely to experience a complete recovery than those in the control group at both the end of treatment ($p<0.001$) and at 50 days after treatment ($p<0.001$). Similarly, the ears of the participants receiving autoinflation had better recovery rates than control ears at both time points ($p<0.001$). Strength of evidence was low for benefit.

Key Question 5. Health Care Factors

No studies 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 prior use of pneumococcal virus inoculation. Evidence is thus insufficient for all such factors.

Applicability

This review was intended to apply to individuals with OME of all ages. Findings about all interventions are likely to be applicable to otherwise healthy children other than infants. In some cases, study authors did not provide sufficient information on age of the target population (e.g., provided only the average age without providing the age range) or included a wide age range of children, rendering it difficult to ascertain applicability of the tested intervention to specific age groups. The evidence base is clearly limited for adults and for infant children, and 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.

We provided evidence on all the commonly used treatments for OME, including TT, myringotomy, adenoidectomy and watchful waiting; we also examined outcomes from use of steroids upon the advice of our TEP, even though they are not recommended in current U.S. guidelines. We also provided evidence for autoinflation, an alternative noninvasive treatment strategy. We note the limitation in the evidence that not all studies comparing TT to other surgical or non-surgical treatments provided information regarding the type of TT used, limiting

Table D. Strength of evidence for subgroups

Intervention and Comparator	Number of Studies (Sample Sizes)	Outcome and Results	Strength of Evidence
Autoinflation vs. control	1 RCT (N=396 ears)	Adults (16–75) with OME: differences between groups in composite measure of recovery (otoscopy, tympanometry, audiometry) at end of tx and 50 days after tx.	Low for benefit (one study)

OME = otitis media with effusion; tx = treatment; RCT = randomized control trial

conclusions that can be made at this level of specificity. We also sought to include CAM procedures, but no RCTs met our inclusion criteria.

We did not limit the outcomes of interest. However, the bulk of the literature concerned reductions in OME and measured hearing. Only a few studies included quality-of-life outcomes, and none included satisfaction with care. Included studies were limited to head-to-head comparisons that collected a variety of harms, but they were not uniformly collected in all studies. We recognize that other study designs may have expanded our identification of possible harms. We did not limit the time frame for followup but were most interested in outcomes 3 months or more following treatment. Studies were conducted in clinical settings. They generally included populations from the United States and Western Europe, but a few studies were conducted in other countries including Egypt, Iran, and Japan.

Research Gaps

Research gaps in treatments for OME exist in several areas. We recommend the following for improving the research base.

The first area is to expand research in subgroups that were targeted in this review but for whom no evidence could be amassed. These groups include infants and toddlers who are developmentally vulnerable for language acquisition and for whom a mild conductive hearing loss over a shorter period of time may be more detrimental than for older children. Children with craniofacial anomalies such as cleft palate and other developmental disorders including Down syndrome and sensorineural hearing loss have not been a part of most treatment studies. When we did find studies on children with comorbid conditions, we excluded them for reasons such as having no valid comparison group (e.g., case series with no comparator) or data combined with children with acute AOM. Additionally, only limited research is available on treatment effectiveness in adults; we could identify only one study about treatments for adults.

The second area is to examine treatments that have heretofore not been subjected to rigorous research methods. For instance, despite the interest in CAM treatments, the lack of carefully designed investigations of these treatments is clear. While insertion of TT remains a common procedure, we have little evidence regarding different types of TT or routines for insertion. An ongoing Swedish trial plans to enroll a large cohort of children in an RCT comparing different TT; results from this trial may be able to provide the needed evidence regarding which TT are more (or less) beneficial. Some researchers are designing treatments to counteract the otological effects of gastroesophageal reflux disease; further research of promising treatments is welcome.

Methods deficiencies constitute a third gap. Measures are not uniform; investigators do not report on reoccurrence of AOM and functional outcomes; time points for collecting outcomes differ; and baseline measures are not always provided. Pain or discomfort resulting from OME was not measured in any studies. Studies do not routinely document effect sizes and many researchers fail to report their statistical power calculations of the sample size needed to find an effect (the RCTs of Williamson et al., the MRC, and Paradise et al. being notable exceptions). Missing data are often not addressed, and even if attrition is acknowledged, statistical procedures are rarely used to correct for this problem. We encourage investigators to give far more attention to their methods in the service of greatly improving the literature base.

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 TT decreased effusion and improved hearing over a short period but did not affect longer-term speech, language, or other functional outcomes. However, we found weaker evidence that TT placement also increases 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 effects particularly with respect to functional outcomes. Steroids were not found to provide a benefit. Additional research and better methods are needed to develop a comprehensive evidence base to support decisionmaking among the various treatment options, particularly in subpopulations defined by age and coexisting conditions.

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Full Report

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