Contemporary Guidelines for Tympanostomy Tube Placement

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Opinion statement

Tympanostomy tubes remain the most commonly performed operation globally. They facilitate drainage of middle ear fluid, direct delivery of ototopical antibiotics as well as other therapies, and reduce the risk of complications related to severe Eustachian tube dysfunction. They remain an invaluable tool especially in children at risk of speech and language delay. In this chapter, we will review the current indications for tube placement, risks, benefits, and controversies related to their use as well as innovations in the types of tympanostomy tubes currently in use.

Introduction

Otitis media (middle ear inflammation) is the second most common diagnosis made by healthcare professionals in children [1, 2••]. Otitis media is the umbrella term for all forms of middle ear inflammation including acute otitis media (AOM), otitis media with effusion (OME), acute suppurative otitis media (ASOM), chronic otitis media with effusion (COME), and chronic suppurative otitis media (CSOM).

There are a range of host and environmental factors that predispose children to middle ear inflammation and

infection. Some factors are modifiable such as breast-feeding, immunization and avoiding cigarette exposure and overcrowded daycares. Host factors such as genetic predisposition and craniofacial anomalies result in more persistent long-term disease that will often require intervention.

Tympanostomy tubes are most often inserted for persistent middle ear fluid, recurrent ear infections, or persistent ear infections despite appropriate systemic antibiotic therapy and tympanic membrane retraction at risk of cholesteatoma or ossicular erosion. Once placed, tympanostomy tubes significantly

improve hearing and reduce middle ear effusion prevalence [3••, 4]. Tubes have also been shown to improve disease-specific quality of life (QOL) in children with OME, reduce the incidence of recurrent AOM, and allow for topical administration of antibiotics at much higher concentrations than allowed by systemic delivery [5].

Risks of tympanostomy tubes are typically related to the risk of general anesthesia and potential for early tube extrusion, late tube extrusion, and perforation. Other possible sequelae include biofilm formation and chronic otorrhea, tympanosclerosis, shallow retraction pocket formation, acquired cholesteatoma, and the need for further tube placement.

Treatment

The natural history of otitis media begins with acute otitis media (AOM), defined as the rapid onset of signs and symptoms of middle ear inflammation, usually secondary to URI. Following AOM, otitis media with effusion (OME) may persist, defined as fluid in the middle ear space. OME persisting for 3 months or longer from the date of onset or the date of diagnosis is termed chronic OME. Recurrent AOM is defined as three or more well-documented and separate AOM episodes in the past 6 months or at least four documented separate AOM episodes in the past 12 months with at least one in the past 6 months [1].

Otitis media is important not only because it causes pain, malaise, and rare but important medical complications such as vestibular or balance problems, mastoiditis, and tympanic membrane rupture in some children, but also because it causes temporary conductive hearing loss in about half of affected children [6••]. OME is the most common cause of hearing impairment in infants and children worldwide, and permanent hearing loss related to otitis media has a prevalence of 2 to 35 per 10,000 [7]. As shown in Fig. 1, infants aged 9 to 35 months have significantly poorer hearing thresholds with unilateral OME, and especially if they have bilateral OME [8]. If undetected for long periods during the sensitive developmental period of birth to 3 years, hearing loss may lead to speech, language, behavioral, and academic problems [9]. Otitis media is much more common in children with certain risk factors, such as cleft palate [10], Down syndrome [11], and other cranial-facial anomalies; children with immune system suppression; children in poverty and from

Fig. 1. Mean hearing thresholds (± 1 SD) in infants and children aged 9–35 months who had no OME, unilateral OME, and bilateral OME, from a prospective study of 681 children in Pittsburgh [8].

indigenous native populations (Native American, Australian Aboriginal, and Alaskan Eskimos); and children who attend large day care centers or are in crowded conditions with other children [12, 13•]. Thus, treatments must address not only medical needs to reduce pain and prevent mastoiditis and tympanic membrane rupture, but also to improve hearing and balance function and prevent developmental complications such as speech, language, gross motor, and academic delays [6••, 7].

OME resolves spontaneously in 75 % of children within 3 months when it follows an episode of AOM. If the date of OME onset is unknown, 56 % of cases resolve spontaneously, while those with a clearly documented date of onset resolve without intervention 90 % of the time. Thus, a “watchful waiting” approach for OME is recommended for 3 months before considering surgical intervention with myringotomy and tympanostomy tubes (M&T) [3••, 4, 6••]. While antibiotic treatment is commonly used for AOM, antibiotics are not effective for OME and thus are not recommended. Tympanostomy tubes are most often inserted because of persistent OME or recurrent AOM that persists after antibiotic therapy. Newly published guidelines from the American Academy of Otolaryngology-Head and Neck Surgery [14••] cover the natural history, sequelae, prevention, and treatment recommendations for OME in children aged 2 months to 12 years. These guidelines, developed by an interdisciplinary panel, provide a major contemporary source for evidence-based recommendations that clinicians can use in planning care for children affected by OME.

Diet and lifestyle

There are a number of modifiable risk factors that caregivers should be educated about for their potential in helping to prevent AOM and OME in young children [15]. The risk for recurrent AOM and chronic OME requiring ventilation tubes (VT) is higher in infants and children who were not breastfed, whose caregivers smoke, who use pacifiers, and who are at increased risk for early URI (cared for in large day care centers, living in crowded conditions, certain indigenous populations, or having genetic risk factors).

Recommend exclusive breastfeeding for at least the first 6 months

A systematic review [16••] found that exclusive breastfeeding during the first 6 months was associated with a 43 % reduction in ever having AOM in the first 2 years of life. After 2 years of age, there is no evidence that breastfeeding protects against AOM; however, there were few studies and the evidence quality is low.

Recommend smoking cessation programs for caregivers of infants and young children

A systematic review [17] found that exposure to secondhand tobacco smoke, particularly smoking by the mother, significantly increases the risk of OME in childhood; this risk is particularly strong for OME requiring surgery. The review showed that 130,200 annual cases of child OME episodes in the UK and 292,950 of frequent AOM cases in the USA are directly attributable to secondhand smoke exposure in the home.

Recommend limiting pacifier use in older infants not at risk for sudden infant death syndrome

A comprehensive review [18] found benefits of pacifier use in reported ability to soothe/comfort, decreased risk of sudden infant death syndrome, and a probable synergistic role in adjunctive pain relief. The greatest risks of pacifier use are an increased incidence of acute otitis media, possible negative impact on breastfeeding, and dental malocclusion particularly if usage is greater than 2–3 years.

Recommend influenza vaccination

A Cochrane systematic review [19••] of ten trials (six trials in high-income countries and four multicenter trials in high-, middle-, and low-income countries) involving 16,707 children aged 6 months to 6 years found a 20 % reduction in at least one episode of AOM over at least 6 months of follow-up. There was a 30 % reduction in the use of antibiotics in vaccinated children. The pneumococcal vaccine demonstrated early promising results, and following the introduction of the vaccine, AOM complications like mastoiditis initially decreased; however, they returned to pre-vaccination levels after a few years. Concerns now relate to serotype replacement and a rise in non-pneumococcal pathogens. Research is currently underway evaluating different vaccine regimens for both the timing and the number of serotypes targeted.

Pharmacologic treatment

The natural history of otitis media with effusion (OME) has been outlined above. The most recent clinical practice guideline for OME advises strongly against the use of steroids (intra-nasal and systemic), systemic antibiotics as well as antihistamines and nasal decongestants [14••]. Once tympanostomy tubes have been placed, however, there is a role for topical therapy.

Topical antibiotics have a number of advantages over systemic delivery including significantly higher concentrations of antibiotics delivered to the site of infection, no systemic side effects, typically less expense incurred than a systemic treatment course, and the potential to alter the local microenvironment.

The high concentration available through topical delivery is important in relation to the avoidance of drug resistance. The high concentrations also improve the efficacy of concentration-dependent drugs like aminoglycosides or quinolones. A 0.3 % solution of ciprofloxacin contains 3000 mcg/mL. In contrast, amoxicillin at 90 mg/kg delivers 6–10 mcg/mL. The bacteriocidal lethality of these medications is enhanced by how much they exceed the minimal inhibitory concentration (MIC). The concentration of topical antibiotics is always well above the MIC making the emergence of bacterial resistance extremely unlikely.

Indications for ototopical therapy include an acute infection with otorrhea through a patent tympanostomy tube. Otorrhea is the most common sequela of tympanostomy tubes with a mean incidence of 26 % (range 4–68 %) in one observational study [20]. As outlined in the clinical practice guideline on tympanostomy tubes in children [5] (see Table 1), clinicians should prescribe topical antibiotics, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea.

Acute otorrhea typically improves with administration of topical antibiotic therapy, provided the drops actually reach the middle ear space. In most cases,

Table 1. Adapted from: Summary of guideline action statements from the Clinical Practice Guideline: Tympanostomy Tubes in Children—Executive Summary. [6]**Statements and Action Strength:**

1. OME of short duration:
 - Clinicians should not perform tympanostomy tube insertion in children with a single episode of otitis media with effusion (OME) of less than 3 months' duration.
 - Recommendation against
2. Hearing testing
 - Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer (chronic OME) OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion
 - Recommendation
3. Chronic bilateral OME with hearing difficulty
 - Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer (chronic OME) AND documented hearing difficulties
 - Recommendation
4. Chronic OME with symptoms
 - Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, vestibular problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life
 - Option
5. Surveillance of chronic OME
 - Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who did not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected
 - Recommendation
6. Recurrent acute otitis media (AOM) without middle ear effusion (MEE)
 - Clinicians should not perform tympanostomy tube insertion in children with recurrent AOM who do not have MEE in either ear at the time of assessment for tube candidacy
 - Recommendation (against)
7. Recurrent AOM with MEE
 - Clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy
 - Recommendation
8. At-risk children
 - Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors
 - Recommendation
9. Tympanostomy tubes in at-risk children
 - Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly, as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer (chronic OME)
 - Option
10. Perioperative education
 - In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications
 - Recommendation

Table 1. (Continued)**Statements and Action Strength:**

11. Acute tympanostomy tube otorrhea

- Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea
- Strong recommendation

12. Water precautions Clinicians should not encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes

- Recommendation (against)

this will occur if the ear canal is cleaned of debris by dry mopping if necessary. Crusting can be cleared with hydrogen peroxide topically (which can be safely used with a tympanostomy tube in place). Persistent debris despite these measures may require suctioning either with a head light or under a microscope. Finally, having the caregiver “pump” the drops in by pushing on the tragus results in improved middle ear delivery.

The family/caregiver should be educated on those ototopical medications that are suitable in the context of tympanostomy tube placement, as non-approved drops may cause pain or potentially even damage the hearing.

Class of drugs (if applicable)**Ciprofloxacin 0.2 % (Ciloxin)**

Standard dosage:

Contraindications: Known allergic reaction

Main drug interactions:

Main side effects:

Special points: Commonest reason for failure is inadequate topical delivery due to excessive debris in the external auditory canal. Can be overcome by ear mopping or direct suction

Cost/costeffectiveness: Approximately \$8 (solution—generic product); inexpensive

Ciprofloxacin 0.3 % + Dexamethasone 0.1 % (Ciprodex)

Standard dosage: (6 months and older) Four drops of ciprofloxacin 0.3%/dexamethasone 0.1 % into the affected ear(s) twice a day for 7 days

Contraindications: Known allergic reaction

Main drug interactions: None

Main side effects: Discomfort, of ear (3 %); otalgia (0.4 to 2.3 %); pruritus of skin, ear (1.5 %)

Special points: Patient should avoid swimming or submerging ear in water during therapy. For otic use only. Do not use in the eyes. Have patient warm the bottle in the hand for 1 or 2 min before instillation. Instruct patient on proper instillation technique.

Cost/costeffectiveness: \$182 (suspension—generic form not available); expensive

Polymyxin B-neomycin-hydrocortisone

Standard dosage: Four drops, three to four times daily

Contraindications:	Known allergic reaction
Main drug interactions:	None
Main side effects:	Discomfort, of ear (3 %); otalgia (0.4 to 2.3 %); pruritus of skin, ear (1.5 %)
Special points:	Patient should avoid swimming or submerging ear in water during therapy. For otic use only. Do not use in the eyes. Have patient warm the bottle in the hand for 1 or 2 min before instillation. Instruct patient on proper instillation technique.
Cost/costeffectiveness:	Brand: \$42.00 (solution or suspension)/10 mL

Ofloxacin

Standard dosage:	Ten drops into affected ear(s) twice daily for 14 days (chronic purulent otitis media-perforation of tympanic membrane)
Contraindications:	Patients with a history of hypersensitivity to ofloxacin, to other quinolones, or to any of the components in this medication
Main drug interactions:	Specific drug interaction studies have not been conducted with ofloxacin otic solution 0.3 %.
Main side effects:	Pruritus (4 %), earache (1 %)
Special points:	Warm by hand for 1 to 2 min
Cost/costeffectiveness:	\$34.00 ±/5 mL (generic available); inexpensive

Proper administration of antibiotic drops is also important for acute otitis externa—drops should be applied to the child lying down and the ear positioned upward. Drops can then be placed along the side of the ear canal until it is filled. A gentle massage of the pinna can help mobilize applied drops into the canal. The Clinical Practice Guideline: Acute Otitis Externa [21] can be referenced for more information on the use of aural toilet and wicks to further assist with administration of antibiotic drops.

Interventional procedures

Tympanostomy tube (TT) placement remains the most commonly performed operation in the USA. A large body of research has evaluated the benefits of this procedure, and much of it remains controversial.

Tympanostomy tube insertion has been shown to result in improvements of short-term quality of life (QOL) [22]. The efficacy of TT placement in the management of chronic OME has been examined in RCTs and systematic reviews. For children with COME, tube placement reduces the prevalence of MEE by 32 % in the first year and results in improved hearing thresholds [20, 22].

When deciding which tube to use when, there are a number of factors that go into the decision. Depending on the duration of patient needs, as well as whether prior tubes have been placed, will determine which tube is selected. While there is a large body of research evaluating different TTs, a recent analysis using a Markov cohort decision analysis concluded that intermediate TT may provide optimal balance in outcomes [23]. Historically, there were short-term and long-term tubes available. The emergence of new “intermediate-length” tubes may offer a trade-off between the short- and long-term tubes with lower perforation rates and high myringoplasty repair success rates (see Table 2).

Table 2. Long-term outcomes of differing tympanostomy tubes

Tympanostomy tube	Grommet (Pope etc.)	Intermediate tube (Triune)	Long term (T-tube)
Perforation rate ^a	2 %	2 %	12 %
Early extrusion rate ^a		5 %	5 %
Myringoplasty success ^a	90 %	90 %	75 %
Otorrhea, unspecified type ^b	14.8 %		32.5 %
Otorrhea needing tube removal ^b	0.9 %		13.5 %
Atrophy or retraction at tube site ^b	25 %		23.3 %
Tympanosclerosis ^b	25.1 %		21.0 %
Blockage of tube lumen ^b	7.4 %		9.1 %

^aAdapted from [23]^bAdapted from [33]

Surgery

Perioperative education

Key points that warrant discussion with the patient and family prior to the placement of TT include the importance of follow-up visits, management of common TT problems, the expected duration of the tube, and potential long-term complications.

Routine follow-up ensures that the TTs have remained in place and are functioning, the hearing has been maximized, and there are no signs of complications from the tube. Into the long term, the ears should be examined until the tubes have extruded (this can often be done by the primary care physician) and a final evaluation by the otolaryngologist to ensure the tympanic membrane has healed.

Early referral back to the otolaryngologist should be made if the tube can no longer be seen or is occluded, if there is a reported change in hearing status, or if another complication occurs (persistent/recurrent otorrhea, granuloma formation, perforation that persists, retraction pocket formation, or concern for cholesteatoma).

The parents should be advised re the expected duration of the tube. Short-term tubes typically last 10–18 months; long-term tubes can last for several years [24]. The tube is designed to be placed and remain long enough for the child to outgrow their middle ear disease. Despite this intention, up to 50 % of children will require reoperation within 3 years [25, 26].

Post-operative care

As outlined previously, tube otorrhea is the most common post-operative complication of TT placement. Management of tympanostomy tube otorrhea is outlined in detail above (“[Pharmacologic treatment](#)”).

Pain is rarely a problem post-op though in some children, loud noises may become startling and cause distress in a child who has had a significant hearing loss secondary to long-term middle ear effusions.

Water precautions are unnecessary for most children with TTs but should be implemented in children who develop otorrhea, pain, or discomfort on exposure

to water. Other occasions when ear plugs may be needed include swimming deeper than 6 ft of water, head immersion in lakes or non-chlorinated pools as well as soapy bathwater (soapy water has a lower surface tension than plain water).

Cost/cost-effectiveness

A number of studies have evaluated the cost-effectiveness of tympanostomy tubes [27, 28]. Faccione determined that a reduced number of office visits, antibiotic usage, and the fact that healthy children are less likely to need to visit a healthcare provider result in a net improvement in quality of life in the child with COME. Mui et al. suggest that TIs are cost-effective through their multiyear analysis and cost breakdown of healthcare costs with a net savings of \$398 million over 2 years when comparing tympanostomy tube placement to medical treatment.

Assistive devices

Hearing aids (HA) are a rarely used but promising alternative to VT for children at higher risk for long-term chronic OME, hearing loss, and speech-language problems. In a qualitative interview study [29] with parents regarding the risks and benefits of VT compared to hearing aids for children with cleft lip/palate, VTs may be seen as a simple fix, but some parents have concerns about adverse consequences. Other parents worry about anticipated social stigma associated with HAs. However, parents of children who wore a HA described them as easy to manage and well tolerated, at least until children got older and started to comment on their appearance. In another comparative study [30] of 47 children with HA and 50 with VT, significant between-group differences were noted with regard to perceptions related to bullying, feelings of inadequacy, and embarrassment. The overall negative perceptions of non-hearing aid users were not reported by hearing aid users. There is a need for studies comparing assistive devices to tympanostomy tube treatment, as these studies are not comparative and have not measured risk versus benefit of alternative treatments with hearing aids or other assistive devices.

Bone-anchored hearing aids (BAHA) have been studied in children with Down syndrome in 18 centers in the UK and Ireland [31]. Soft tissue complications were encountered in 21 patients (49 %). Osseointegration failures were encountered in four cases (9 %). There was a high level of satisfaction with the BAHA system among patients, parents, and caregivers.

Speech and language effects

Negative effects of chronic, ear-life OME on children's speech and language development and behavior secondary to prolonged periods of conductive hearing loss have long been hypothesized. A number of prospective studies have examined this question in the USA and internationally. The effect of hearing loss due to OME is presumed to depend upon severity, age at onset, duration, and presence in both ears (bilateral). Environmental factors such as quality of childcare and caregiver interaction have been shown to positively impact speech and language of all children, but especially those with hearing loss due to OME [32].

Systematic reviews have found little to no lasting impact of OME on otherwise normally developing children [1, 9]. However, most studies have measured OME rather than hearing loss so should be interpreted cautiously [14••]. Children at risk due to cleft palate, Down syndrome, and other craniofacial anomalies and children from native and indigenous communities are more likely to have early, severe, and

protracted OME and thus should receive regular hearing assessment and speech-language developmental screening [14●●].

Conclusions

Every year, approximately half a million Americans undergo tympanostomy tube placement. In most cases, tubes are placed in children for either chronic otitis media with effusion or recurrent acute otitis media. While the evidence continues to be debated particularly in relation to the long-term hearing outcomes in certain populations, sufficient high-level evidence exists to support their use.

When considering tympanostomy tube placement, the patient and family should be educated about the risks and benefits of tube placement. Tympanostomy tube otorrhea is the most common complication related to tube placement and is best managed through the use of topical antibiotics. Long-term tubes are associated with a higher perforation rate and the patient should be counseled accordingly.

Tympanostomy tube placement should be personalized in all cases to the patient's needs and clinical picture with long-term follow-up to ensure uncomplicated extrusion and resolution of the condition that prompted the initial placement.

Compliance with Ethical Standards

Conflict of Interest

Niall D. Jefferson and Lisa L. Hunter declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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