AAO Guidelines on Tympanostomy Tubes in Pediatric Practice

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DISCLOSURES
Objectives

- Discuss the purpose and process of the guideline development.
- Define the Guideline action statements.
- Identify several areas where there are research needs.
- Participate in an interactive discussion/Q&A
Tympanostomy Tubes in Children

• The *most common outpatient surgery* performed on children in the US
  – 667,000 annual procedures (*children <15*)
  – 1 in 15 children have tubes by age 3
• Indications include
  – Persistent middle ear effusion
  – frequent ear infections
  – ear infections that persist despite therapy
• Purpose is to ventilate the middle ear and improve eustachian tube dysfunction
Evidenced Based Guidelines

- Intended to produce optimal health outcomes for patients
- Intended to minimize harms
- Intended to reduce inappropriate variations in clinical practice
- Evidenced based statements reflect the quality of evidence and the balance of benefit and harm
Purpose of TT Guideline

• Provide clinicians with evidence-based recommendations on:
  – patient selection for TT
  – surgical indications for TT
  – management of TT in children

• To optimize the care of children with TT
• Children 6 months to 12 years
• To improve counseling and education of families considering tubes for their child
Guideline Development
American Academy of Otolaryngology Initiative

• Multidisciplinary panel
  – Pediatric otolaryngologist
  – Adult otolaryngologist
  – Otologist
  – Neurotologist
  – Anesthesiologist
  – Audiologist
  – Family physician
  – Behavioral pediatrician
  – Pediatrician
  – Speech/language pathologist
  – Pediatric nurse practitioner
  – Physician assistant
  – Otolaryngology resident physician
  – Consumer advocates
Literature Search

• 2 literature searches using a validated filter strategy in multiple data bases
  Information specialty with the Cochrane ENT Disorders Group
  – Initial search between 2005 and Feb 2012 yielded 4 guidelines and 15 systemic reviews
  – Second search between 1980 and March 2012 yielded 113 randomized clinical trials
• Distributed to panel members
Guideline Development

- September 2011-September 2012
- Series of conference calls
  - Defined scope and objectives
- 2 in-person meetings (Electronic decision support- Bridge-Wiz)
  - Creation of actionable recommendations and action statement profiles
- AAO Implementability Appraisal and Extractor software
  - Appraises adherence of the draft guideline to methodological standards
  - Ensure clarity of recommendations
  - Predict potential obstacles to implementation
  - September 2012- revisions made
- Extensive External peer review
- Scheduled review process will occur in 5 years
The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF)
Clinical Practice Guideline: Tympanostomy Tubes in Children

- Focused article to assist in implementing the guideline recommendations
  Summarizes the rationale, purpose, and 12 key action statements
  Full text version (free) [http://www.entnet.org](http://www.entnet.org) and AAO app
Guideline Key Action Statements

- Evidenced based action statement in **BOLD**
- **Strength of recommendation**
  - **Strong recommendation** (1)
  - **Recommendation** (9)
    - For (6) and Against (3)
  - **Option** (2)
- Action Statement Profile
Action Statement Profile

• Aggregate evidence quality
• Level of confidence in evidence
• Benefits
• Risks, harms, costs
• Role of patient preferences
• Benefit-harm assessment
• Value judgments: listed
• Intentional vagueness: describe
• Exceptions: listed
• Differences of opinion
STATEMENT 1
OME OF SHORT DURATION

• Clinicians should **not perform** TT insertion in children with a single episode of OME of less than 3 months’ duration, from the date of onset (if known) or from the date of diagnosis (if onset is unknown).
  • **Recommendation against**
  • **Grade C** based on observational studies (no RCTs in children with tubes <3m)

• Purpose of this statement to avoid surgery in children with short term OME that will resolve

• Prevalence rate OME following AOM
  – 70% at 2w
  – 40% at 1m
  – 20% at 2m
  – 10% at 3m

• Children with OME who are at risk for developmental delays or disorders are excluded from this recommendation (Statement 8)
STATEMENT 2
HEARING TESTING
STATEMENT 2
HEARING TESTING

- Clinicians should obtain an age appropriate hearing test if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for TT insertion.

  Recommendation - grade C based on observational and cross sectional studies

- Purpose of this statement is to promote an important factor in decision making when OME becomes chronic or when a child becomes a candidate for tubes (Statements 3, 4, 6, 9)

- Benefit - Allows documentation of hearing status, improved decision making regarding the need for TT

Hearing Loss with Ear Fluid
Lowest=0  Average=28  Highest=55
STATEMENT 3
CHRONIC BOME WITH HEARING DIFFICULTY
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CHRONIC BOME WITH HEARING DIFFICULTY

- Clinicians should offer bilateral TT insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties.

  Recommendation - Grade B based on well designed RCTs showing resolution of MEE and improved hearing with tubes, observational studies with improved QOL.

- Purpose of this statement
- Children with OME for 3m will have spontaneous resolution in 3m(20%), 6m(25%) and 1yr(30%) additional observation.
- Recent guideline have advised that children by considered for surgical intervention.
- RCTs suggest healthy children with COME can be safely observed for 6-12m without developmental sequelae or reduced QOL.
- Shared decision making between clinician and child’s caregiver considering risks and benefits to the child.
STATEMENT 4
CHRONIC OME WITH SYMPTOMS

- Clinicians may perform TT insertion in children with unilateral or bilateral OME for 3 months or longer AND symptoms that are likely attributable to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life.
  
  *Option - Grade C*

- Purpose - to facilitate intervention for children with chronic OME and associated symptoms likely the result of OME who do not meet criteria for tube placement

- MEE is associated with other problems other than hearing loss
MEE may have a direct and reversible impact on vestibular function/gross motor proficiency.
Certain behavioral problems occur disproportionately with OME including distraction, attention disorders, frustration and aggressiveness.
STATEMENT 5
SURVEILLANCE OF CHRONIC OME
STATEMENT 5
SURVEILLANCE OF CHRONIC OME

- Clinicians should reevaluate, at 3-6 month intervals, children with chronic OME who do not receive TT, 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
  - Grade C based on observational studies

- Purpose- to avoid the sequelae of chronic OME and to identify children who develop symptoms

- Benefits
  - to detect structural changes that may require intervention
  - To detect new hearing difficulties or other symptoms requiring tubes
  - Ongoing education to parents

- Recall
STATEMENT 6
RECURRENT AOM WITHOUT MEE
STATEMENT 6
RECURRENT AOM WITHOUT MEE

- Clinicians should *not* perform TT insertion in children with recurrent acute otitis media who do not have MEE in either ear at the time of assessment for tube candidacy.

*Recommendation against*
- Grade A based on a meta-analysis of RCTs

- Purpose- to help children avoid surgical intervention when not necessary
- Absence of MEE at time of assessment suggests favorable prognosis
- Difficulty is accurately diagnosing AOM is well documented
- RCTs on antibiotic prophylaxis for recurrent AOM without MEE
  - Favorable rates of improvement in the placebo groups,
  - 5.5+ AOM/yr baseline
  - 2.8 AOM on prophylaxis
  - 41% no AOM for 6 months
  - 83% <2 AOM
- Risk- delay in intervention for children who need tubes and need for additional antibiotics
- Excludes complications of AOM, immunosuppression, ‘at risk children’
STATEMENT 7
RECURRENT AOM WITH MEE

• Clinicians should offer bilateral TT insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy.
  
  Recommendation
  – Grade B, based on RCT with minor limitations

• Effusion serves as marker for diagnostic certainty and indicator of underlying ETD

• Bilateral insertion as 70% of children have similar ETD on both sides

• Benefits of tube placement
  – Reduce incidence of AOM
  – Decrease pain with AOM
  – Treatment with ototopicals
STATEMENT 8
AT RISK CHILDREN
STATEMENT 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*
- **Grade C** based on observational studies

- Purpose- to highlight the importance of identifying children with co-morbid conditions that
  - alter their susceptibility to AOM/OME
  - potential developmental sequelae from MEE

- Benefits- this helps to identify children who might benefit from early intervention

- The panel assumes that at risk children would be less likely to tolerate OME or AOM than an otherwise healthy child
Table 2. Risk factors for developmental difficulties.

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Permanent hearing loss independent of otitis media with effusion</td>
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<tr>
<td>Suspected or confirmed speech and language delay or disorder</td>
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<td>Autism-spectrum disorder and other pervasive developmental disorders</td>
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<td>Syndromes (eg, Down) or craniofacial disorders that include</td>
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<td>cognitive, speech, or language delays</td>
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<td>Blindness or uncorrectable visual impairment</td>
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<td>Cleft palate, with or without associated syndrome</td>
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<td>Developmental delay</td>
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*Sensory, physical, cognitive, or behavioral factors that place children who have otitis media with effusion at increased risk for developmental difficulties (delay or disorder).*
STATEMENT 9
TUBES AND AT-RISK CHILDREN

• Clinicians may perform TT insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly as reflected by a flat tympanogram or persistence of effusion for 3 months or longer. Option

• Purpose- to facilitate prompt management of children with OME with sensory, physical, cognitive or behavioral factors that place them at increased risk for developmental delays or disorders

• Shared decision making
STATEMENT 10
CAREGIVER EDUCATION

• Clinicians should educate caregivers of children with TT regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications.

  Recommendation
  – Grade C based on observational studies with limitations

• Benefits
  – Define appropriate caregiver expectations after surgery
  – Enable caregivers to recognize complications early
  – Improve caregiver understanding of the importance of follow-up
How to Care for Your Child’s Ear Tubes

Ear tubes help protect your child from ear infections, middle-ear fluid (liquid behind the eardrum), and the hearing problems that go along with them. Most tubes last about 6 to 18 months, allowing many children time to outgrow their ear problems. Most tubes fall out by themselves. The chance of a tube falling in, instead of out, is very rare. Tubes that do not come out after 3 or more years may need to be removed by your doctor.

Possible Complications of Ear Tubes

Complications of ear tubes are usually minor. Some children develop a white mark or patch on the eardrum which is called sclerosis. It does not affect your child’s hearing or future chance of ear infections. Some children develop a small depression or pocket in the eardrum at the tube site after it falls out. Again, this does not affect hearing and rarely requires treatment. About 1-2 out of every 100 children will develop a small hole (perforation) of the eardrum after the tube falls out. The hole will often close on its own over time, but if it does not, it can be patched in the operating room.

Ear Tubes and Water Precautions

Some children with ear tubes wear ear plugs when swimming. The ear plugs keep water out of the ear canal and out of the ear tube. However, water does not usually go through the tube during swimming. As a result, ear plugs are not necessary for most children. Although most children with tubes do not need ear plugs, they may be necessary in the following situations:
- Pain or discomfort when water enters the ear canal
- Discharge or drainage is observed coming out of the ear canal
- Frequent or prolonged episodes of ear discharge

Other times when ear plugs may be needed on an individual basis are:
- Swimming more than 6 feet under water
- Swimming in lakes or non-chlorinated pools
- Dunking head in the bathtub (soapy water has a lower surface tension than plain water)

A variety of soft, fitted ear plugs are available, if needed, as are special neoprene headbands to cover the ears. Never use Playdoh or silly putty as an earplug, because it can become trapped in the ear canal and require surgical removal. Once the tube becomes blocked or comes out, ear plugs are not needed if there is no hole in the eardrum.

Ear Tube Follow-Up and Aftercare

Routine follow-up with your doctor every 4 to 6 months is important to make sure that your child’s tubes are in place and to check for any possible problems. All children need follow-up no matter how well they are doing. Children often feel well even when there is a problem with the tube. Once the tubes fall out, your child should return for a final re-check after 6-12 months so your doctor can check the ears and be sure that fluid has not built up again.

Ear Tubes and Ear Infections

Your child may still get an ear infection (acute otitis media) with a tube. If an infection occurs, you will usually notice drainage or a bad smell from the ear canal.

If your child gets an ear infection with visible drainage or discharge from the ear canal:
1. Do not worry: the drainage indicates that the tube is working to drain infection from the middle ear space. Most children do not have pain or fever with an infection when the tube is in place and working.
2. Ear drainage can be clear, cloudy, or even bloody. There is no danger to hearing.
3. The best treatment is antibiotic ear drops (ofloxacin or ciprofloxacin-dexamethasone). Place the drops in the ear canal two times a day for up to 10 days. “Pump” the flap of skin in front of the ear canal (tragus) a few times after placing the drops. This will help the drops enter the ear tube.
4. Ear drainage may build up or dry at the opening of the ear canal. Remove the drainage with a cotton-tipped swab dipped in hydrogen peroxide or warm water, a cotton ball to absorb drainage, or gently suction with an infant nasal aspirator.
5. Prevent water entry into the ear canal during bathing or hair washing by using a piece of cotton saturated with Vaseline to cover the opening; do not allow swimming until the drainage stops.
6. To avoid yeast infections of the ear canal, do not use antibiotic eardrops frequently or more than 10 days at a time.
7. Oral antibiotics are unnecessary for most ear infections with tubes unless your child is very ill, has another reason to be on an antibiotic, or the infection does not go away after using ear drops.

If your child gets an ear infection without visible drainage from the ear canal:
1. Ask your primary doctor if the tube is open (functioning); if it is, the infection should resolve without a need for oral antibiotics or antibiotic ear drops.
2. If your doctor gives you an antibiotic or ear drop prescription anyway, ask if you can wait a few days before filling it; chances are high you will not need the medication. Use acetaminophen or ibuprofen to relieve pain, if necessary, during the first few days.
3. If the tube is not open, the ear infection is treated as if the tube was not there; the blocked tube does not do any harm (and will not cause a problem), but it also does not do any good.

When to Call the Ear Doctor (Otolaryngologist)

Call the ear doctor if any of the following occur:
1. your child’s regular doctor can’t see the tube in the ear
2. your child has hearing loss, continued ear infections or continued ear pain/discomfort
3. ear drainage continues for more than 7 days
4. drainage from the ears occurs frequently
5. there is excessive wax build-up in the ear canal
STATEMENT 11
ACUTE TUBE OTORRHEA
STATEMENT 11
ACUTE TUBE OTORRHEA

- Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute TT otorrhea.

- Strong Recommendation
  - Grade B, based on RCTs

- Purpose- promote topical antibiotic therapy and discourage systemic antibiotics in managing uncomplicated acute TTO

- Rates of clinical cure with abx
  - Topical therapy- 77%-96%
  - Systemic- 30%- 67%
  - No improvement with both

- Benefits of ototopicals
  - Ensure clear canal, pump tragus

- Choice of drops
- Otomycosis
- Granulation tissue (4%)
STATEMENT 12
WATER PRECAUTIONS
STATEMENT 12
WATER PRECAUTIONS

- Clinicians should *not* encourage routine, prophylactic water precautions (use of earplugs or headbands; avoidance of swimming or water sports) for children with TT.

- *Recommendation against* (Grade B)

- Purpose- to avoid unnecessary restrictions on child activity including swimming, diving, lakes/streams, ototopicals for prophylactic measures after swimming, use of earplugs/headbands

- No statistically significant benefits to routine earplug use

- Clinical practice is lagging behind for routine water precautions (NW US)
  - Otolaryngologists 47% and PCP 73% still recommend precautions
Most scientists regarded the new streamlined peer-review process as ‘quite an improvement.’
Review

- Emphasis is placed on shared-decisions with caregivers
- Children likely to benefit from tubes:
  - bilateral OME more than 3 months with hearing difficulties,
  - chronic OME with symptoms (e.g., vestibular problems, poor school performance, behavioral problems, ear discomfort, reduced QOL)
  - recurrent AOM with persistent MEE
  - at-risk children (for developmental delays or disorders) who have OME that is likely to persist (flat tympanogram or present at least 3 months)
- Tubes are not recommended when
  - OME persists less than 3 months
  - recurrent AOM without persistent effusion
- Management strategies are discussed including
  - caregiver education
  - treating tube otorrhea with topical antibiotic drops (not systemic)
  - not recommending routine water precautions with bathing or swimming
THANK YOU