Clinical Practice Guideline: Tympanostomy Tubes in Children

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Introduction

Insertion of Tympanostomy Tubes

- The most common ambulatory surgery performed on children in the United States.
- Each year, 667000 children younger than 15 years receive tympanostomy tubes insertion

Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report*. 2009;(11):1-25.

Tympanostomy Tubes

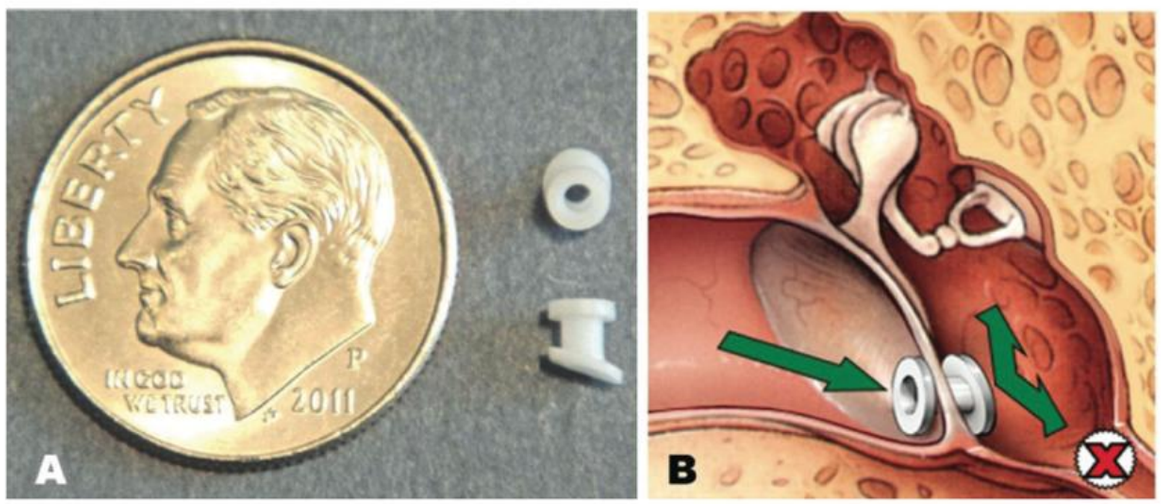


Figure 2. (A) Size of tympanostomy tube compared to a dime. (B) Tympanostomy tubes are also called "ventilation tubes" because the opening allows air to enter the middle ear directly from the ear canal (arrows), which bypasses the child's poorly functioning eustachian tube (X). Reproduced with permission.[3]

- Approximately 1/20th of an inch in width (1.27mm)
- Placed in the child's eardrum to ventilate the middle ear space

Rosenfeld RM. *A Parent's Guide to Ear Tubes.*, Ontario, C*Hamilton*anada: BC Decker; 2005.

Otitis Media in Children

- Children younger than 7 years are at increased risk of otitis media because of
  - Immature immune systems
  - Poor function of the eustachian tube

Bluestone CD, Swarts JD. Human evolutionary history: consequences for the pathogenesis of otitis media. *Otolaryngol Head Neck Surg*. 2010;143(6):739-744.

Placement of Tympanostomy Tube

- Improves hearing
- Reduces effusion prevalence
- May reduce the incidence of recurrent acute otitis media (AOM)
- Provides a mechanism for drainage and administration of topical antibiotic therapy for persistent AOM.

Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev*. 2010;(10):CD001801.

Placement of Tympanostomy Tube

- Improve disease-specific quality of life (QOL) for children with chronic OME, recurrent AOM, or both.

Rosenfeld RM, Bhaya MH, Bower CM, et al. Impact of tympa- nostomy tubes on child quality of life. *Arch Otolaryngol Head Neck Surg*. 2000;126(5):585-592.

Before This Clinical Practice Guideline

- Tympanostomy tubes are most often inserted
  - Persistent middle ear fluid
  - Frequent ear infections
  - Ear infections that persist after antibiotic therapy
- There are currently no clinical practice guidelines in the United States that address specific indications for surgery.

Purpose

- To provide clinicians with evidence-based recommendations on patient selection and surgical indications for and management of tympanostomy tubes in children.

Methods

PICO

- Population: Children (6 months to 12 years)
- Intervention: Tympanostomy tube insertion, including indications for tube placement, preoperative care, and postoperative care
- Comparison: Any techniques
- Outcome: Any
- Setting: Inpatient, outpatient

- 2005 ~ 2012/2 --> Clinical practice guidelines, systematic reviews, and meta-analyses
  - 10 guidelines and 19 systematic reviews or meta-analyses.
  - After removing duplicates, articles not obviously related to tympanostomy tubes, those not indicating or explicitly stating a systematic review methodology, and non–English language articles,
  - 4 guidelines and 15 systematic reviews or meta-analyses remained.
- 1980 ~ 2012/3 --> RCTs
  - 171 RCTs.
  - After removing duplicates, non–English language articles, and animal model studies,
  - 113 articles remained.

Table 4. Guideline definitions for evidence-based statements.

Statement	Definition	Implication
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation) but the quality of evidence is not as strong (Grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and be sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (Grade D)[a] or that well-done studies (Grade A, B, or C)[a] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No recommendation	No recommendation means there is both a lack of pertinent evidence (Grade D)[a] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

[a]See **Table 5** for definition of evidence grades.

Classifying recommendations for clinical practice guidelines.
Pediatrics. 2004;114(3):874-877.

Table 5. Levels for grades of evidence.[a]

Grade	Treatment and Harm	Diagnosis
A	Well-designed randomized controlled trials performed on a population similar to the guideline's target population	Systematic review of cross-sectional studies with consistently applied reference standard and blinding
B	Randomized controlled trials; overwhelmingly consistent evidence from observational studies	Individual cross-sectional studies with consistently applied reference standard and blinding
C	Observational studies (case control and cohort design)	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards
D	Mechanism-based reasoning or case reports	
X	Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm	

[a]American Academy of Pediatrics classification scheme[37] updated for consistency with current level of evidence definitions.[38]

Classifying recommendations for clinical practice guidelines. *Pediatrics. 2004;114(3):874-877.*

Table 6. Summary of guideline action statements.

Statement	Action	Strength
1. OME of short duration	Clinicians should *not* perform tympanostomy tube insertion in children with a single episode of 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 AOM without MEE	Clinicians should *not* perform tympanostomy tube insertion in children with recurrent AOM who do not have middle ear effusion 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 middle ear effusion 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 (see **Table 2**).	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
11. Acute tympanostomy tube otorrhea	Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute TTO.	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)

1. OME of short duration

- Not perform tympanostomy tube insertion in children
  - single episode of OME
    - and
  - less than 3 months' duration

- Strength: Recommendation (against)
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High

- Benefits:
  - Avoidance of unnecessary surgery and its risks
  - Avoidance of surgery in children with a condition that has reasonable likelihood of spontaneous resolution
  - Cost savings
- Risks, harms, costs:
  - Delayed intervention in children who do not recover spontaneously and/or in children who develop recurrent episodes of MEE

2. Hearing Testing

- Age-appropriate hearing test
- OME persists for 3 months or longer
    - OR
- Prior to surgery when a child becomes a candidate for tympanostomy tube insertion.

- Strength: Recommendation
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High

- Benefits:
  - Documentation of hearing status
  - Improved decision making regarding the need for surgery in chronic OME
  - Establishment of baseline hearing prior to surgery
  - Detection of coexisting sensorineural hearing loss
- Risks, harms, costs:
  - Cost of the audiologic assessment

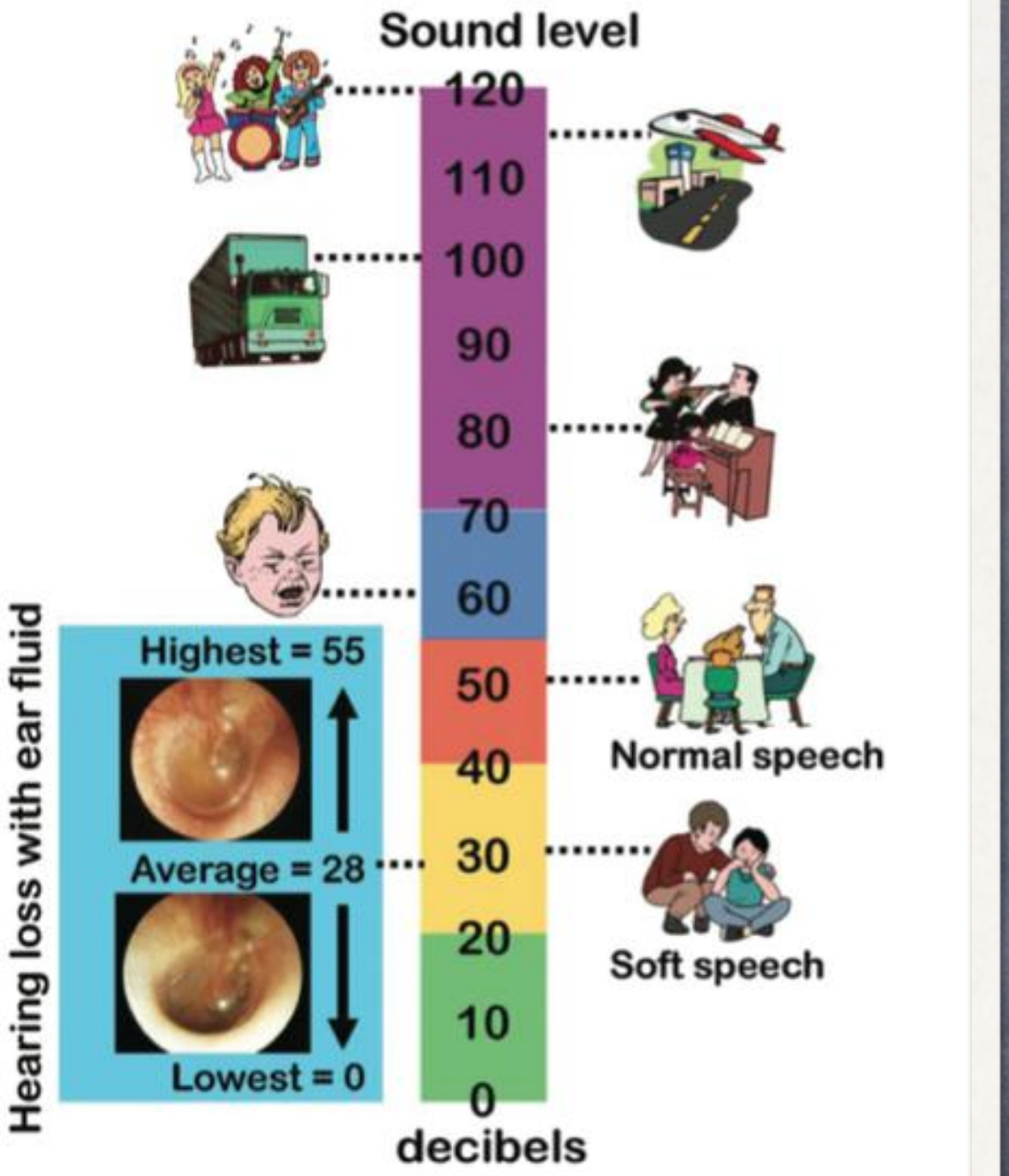


Figure 3. An average hearing level between 0 and 20 dB (hearing level) is normal (green), 21 to 40 dB is a mild hearing loss (yellow), 41 to 55 dB is a moderate loss (red), 56 to 70 dB is a moderately-severe loss, and 71 dB or higher is a severe or profound loss (purple). A child with average hearing loss from middle ear effusion in both ears (28 dB) would barely hear soft speech, with some children barely aware of normal speech or a baby crying. Reproduced with permission.[3]

- The impact of OME on hearing
  - 0 ~ 55 dB HL
- The average hearing loss associated with OME in children is 28 dB HL, while a lesser proportion (approximately 20%) exceed 35 dB HL.

Rosenfeld RM. *A Parent's Guide to Ear Tubes. Hamilton,* Ontario, Canada: BC Decker; 2005.

3. Chronic Bilateral OME with hearing difficulty

- Children with bilateral OME for 3 months or longer AND documented hearing difficulties.
  - Should offer bilateral tympanostomy tube insertion

- Strength: Recommendation
- Aggregate evidence quality: Grade B
- Level of confidence in the evidence: High

- Benefits:
  - Reduced prevalence of MEE
  - Improved hearing, improved child and caregiver QOL
  - Optimization of auditory access for speech and language acquisition
  - Elimination of a potential barrier to focusing and attention in a learning environment
- Risks, harms, costs:
  - Risk of anesthesia
  - Sequelae of the indwelling tympanostomy tubes (eg, otorrhea, granulation tissue, obstruction)
  - Complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation),

4. Chronic OME with Symtoms

- 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,
    - balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life.

- Strength: Option
- Aggregate evidence quality: Grade C

- Benefits:
  - Reduced prevalence of MEE
  - Possible relief of symptoms attributed to chronic OME
- Risks, harms, costs:
  - Risks from anesthesia
  - Sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction)
  - Complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation)

5. Surveillance of chronic OME

- Children with chronic OME who do not receive tympanostomy tubes
  - Reevaluate 3- to 6-months intervals, Until
    - The effusion is no longer present
    - Significant hearing loss
    - Structural abnormalities of the tympanic membrane or middle ear

- Strength: Recommendation
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High

- Benefits:
  - Detection of structural changes in the tympanic membrane that may require intervention
  - Detection of new hearing difficulties or symptoms that would lead to reassessing the need for tympanostomy tube insertion
  - Discussion of strategies for optimizing the listening-learning environment for children with OME, as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of examination(s)

6. Recurrent AOM without MEE

- Children with recurrent acute otitis media who do not have MEE in either ear at the time of assessment for tube candidacy
- Should not perform tympanostomy tube insertion

- Strength: Recommendation against
- Aggregate evidence quality: Grade A
- Level of confidence in evidence: High

- Benefits:
  - Avoid unnecessary surgery and its risks
  - Costsavings
- Risks, harms, costs:
  - Delay in intervention for children who eventually require tympanostomy tubes
  - Need for systemic antibiotics among children who continue to have episodes of recurrent AOM

7. Recurrent AOM with MEE

- Children with recurrent AOM who have unilateral or bilateral MEE
  - Should offer bilateral tympanostomy tube insertion

- Strength: Recommendation
- Aggregate evidence quality: Grade B
- Level of confidence in evidence: Medium

- Benefits:
  - Mean decrease of approximately 3 episodes of AOM per year
  - Ability to treat future episodes of AOM with topical antibiotics instead of systemic antibiotics
  - Reduced pain with future AOM episodes
  - Improved hearing during AOM episodes
- Risks, harms, costs:
  - Risks from anesthesia
  - Sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction)
  - Complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation)

Why bilateral insertion?

- Bilateral insertion of tympanostomy tubes is recommended even if only unilateral effusion is present because more than 70% of children have similar eustachian tube function on the right and left sides.

van Heerbeek N, Akkerman AE, Ingels KJAO, Entel JAM, Ziel- huis GA. Left-right differences in Eustachian tube function in children with ventilation tubes. *Int J Pediatr Otorhinolaryngol*. 2003;67:861-866.

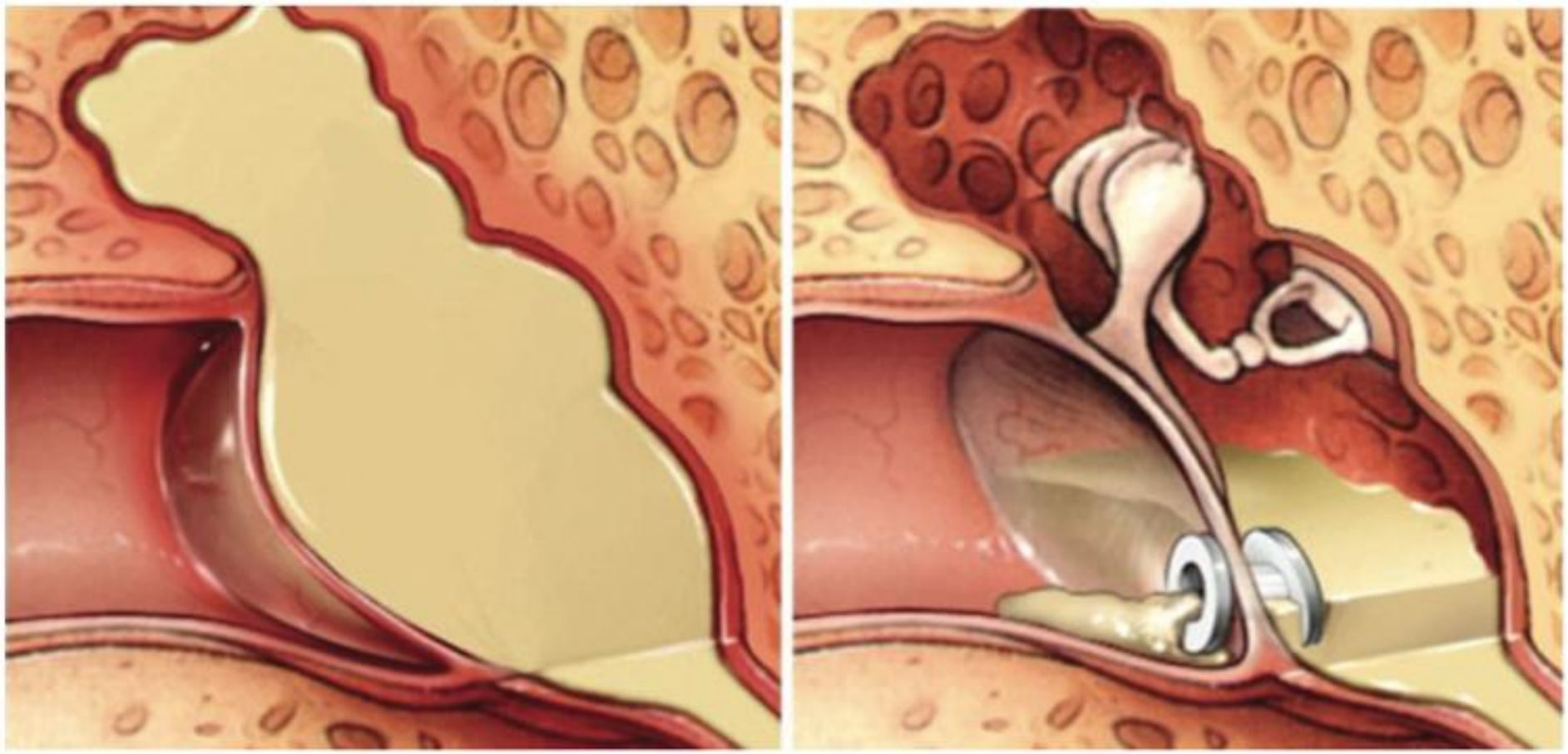


Figure 4. Acute otitis media without a tympanostomy tube (left) and with a tube (right). Without a tube, the tympanic membrane is bulging and inflamed, which causes pain and sometimes rupture. Reproduced with permission.[3]

Rosenfeld RM. *A Parent's Guide to Ear Tubes. Hamilton,* Ontario, Canada: BC Decker; 2005.

Table 8. Comparison of acute otitis media with and without a tympanostomy tube.[a]

Issue	AOM without a Tube	AOM with a Tube
Ear pain	Mild to severe	None, unless skin irritated or tube occluded
Drainage from the ear canal (otorrhea)	No, unless eardrum ruptures	Yes, unless tube obstructed
Duration of middle ear effusion after infection	Can last weeks or months	Usually resolves promptly
Needs oral antibiotics	Often	Rarely
Needs antibiotic eardrops	No benefit	Often
Risk of eardrum rupture	Yes	No, unless tube obstructed
Risk of suppurative complications	Rare	Exceedingly rare

Abbreviation: AOM, acute otitis media.
[a]Adapted.[3]

Rosenfeld RM. *A Parent's Guide to Ear Tubes. Hamilton,* Ontario, Canada: BC Decker; 2005.

8. At Risk Children

- 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

- Strength: Recommendation
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: High for Down syndrome, cleft palate, and permanent hearing loss; medium for other risk factors

- Benefits:
  - Facilitation of future decisions about tube candidacy
  - Identification of children who might benefit from early intervention (including tympanostomy tubes)
- Risks, harms, costs: None

9. Tympanostomy tubes and At-Risk Children

- 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
- May perform tympanostomy tube insertion

- Strength: Option
- Aggregate evidence quality: Grade C

- Benefits:
  - Improved hearing
  - Resolution of MEE in at-risk children who would otherwise have a low probability of spontaneous resolution
  - Mitigates a potential obstacle to child development
- Risks, harms, costs:
  - Risk of anesthesia,
  - Sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction),
  - complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation),

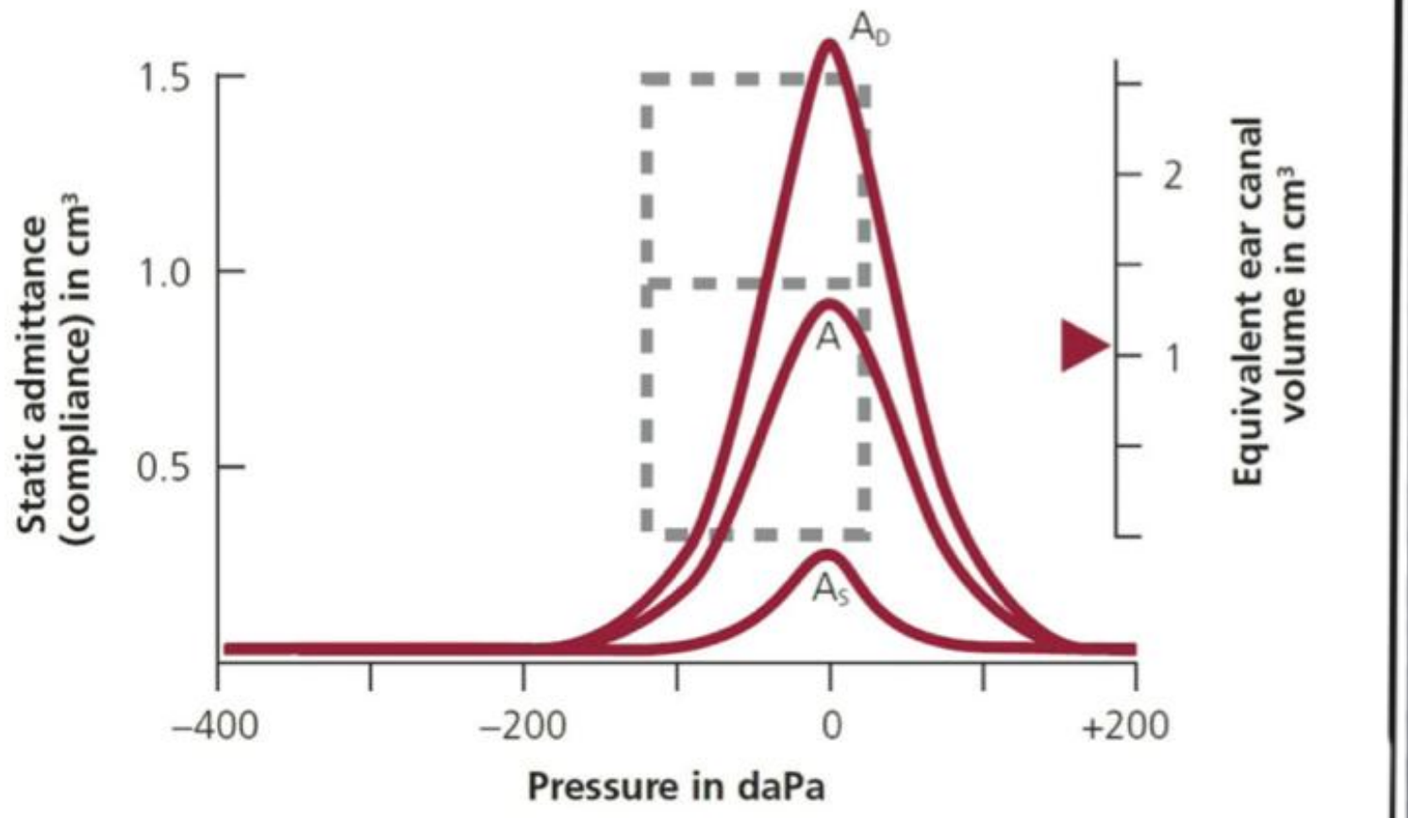
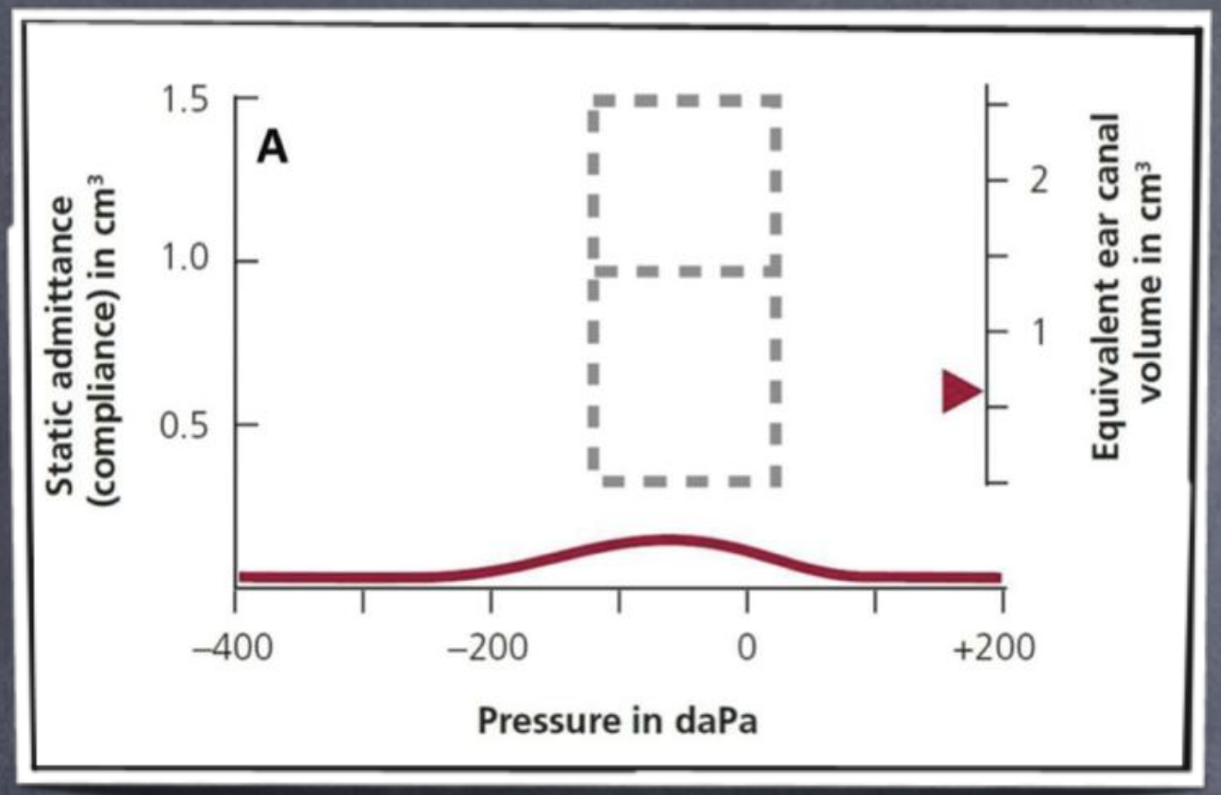
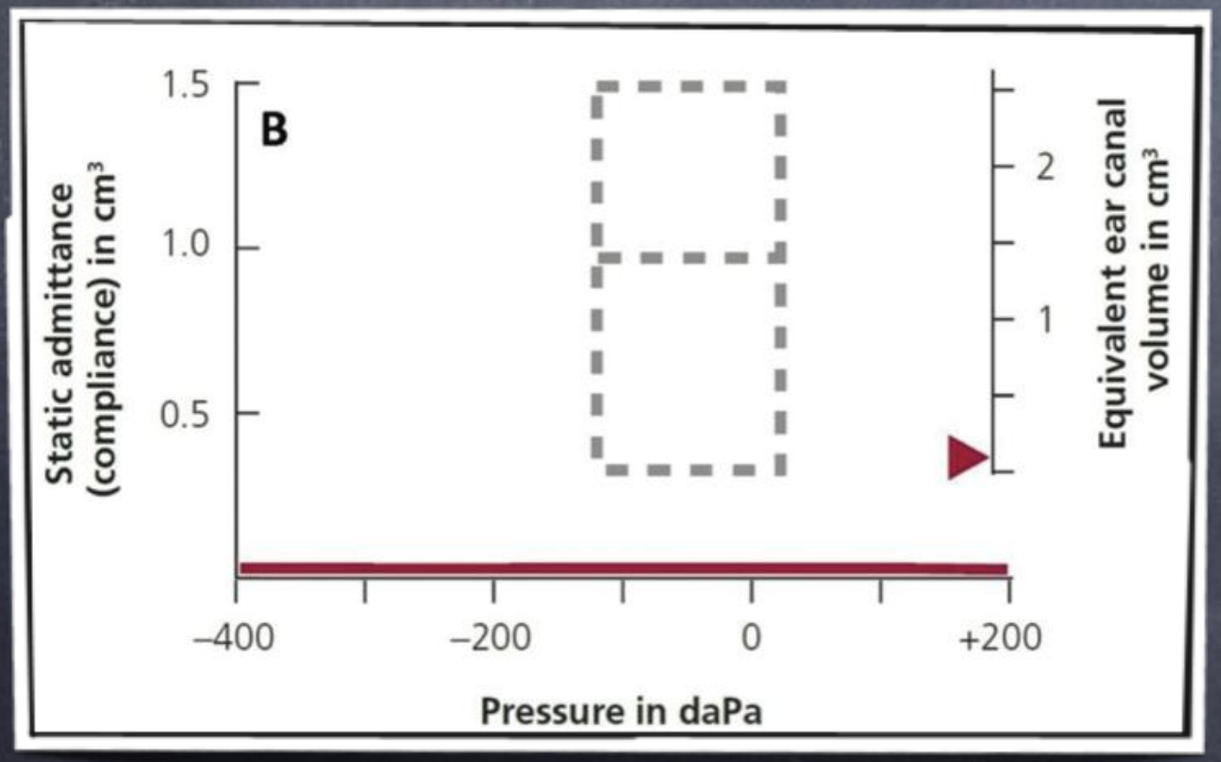


Figure 5. Normal type A tympanogram result. The height of the tracing may vary but is normal when the peak falls within the 2 stacked rectangles. The A_D tracing (upper) indicates an abnormally flexible tympanic membrane, and the A_S tracing (lower) indicates stiffness; the presence of a well-defined peak, however, makes the presence of effusion low. Reproduced with Permission.[106]

- A normal type A tympanogram, with peak pressure greater than -100 mm water, is associated with effusion in only 3% of ears at myringotomy.

Onusko E. Tympanometry. *Am Fam Physician. 2004;70(9):* 1713-1720.





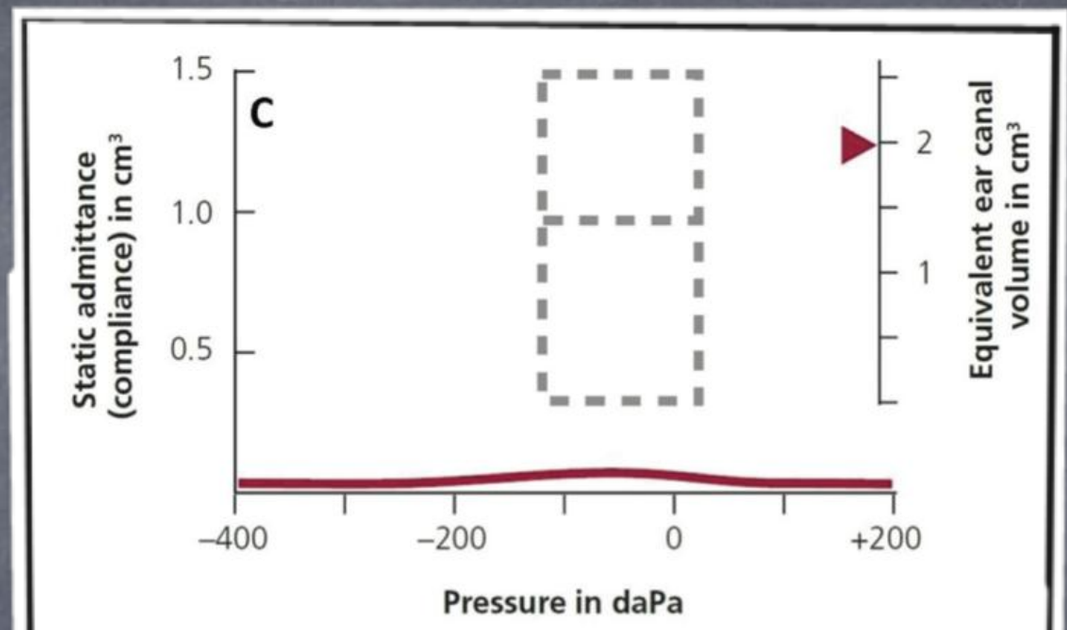


Figure 6. Abnormal type B tympanogram results. (A) A normal equivalent ear canal volume usually indicates middle ear effusion. (B) A low volume indicates probe obstruction by cerumen or contact with the ear canal. (C) A high volume indicates a patent tympanostomy tube or a tympanic membrane perforation. Reproduced with permission.[106]

- A type B, or flat curve, tympanogram is associated with MEE in 85% to 100% of ears.
- Normal ear canal volume for children
  - 0.3~0.9 cm

Onusko E. Tympanometry. *Am Fam Physician. 2004;70(9):* 1713-1720.

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.

- Strength: Recommendation
- Aggregate evidence quality: Grade C

- Benefits:
  - Define appropriate caregiver expectations after surgery
  - Enable caregivers to recognize complications early
  - Improve caregiver understanding of the importance of follow-up
- Risks, harms, costs: None

11. Acute Tympanostomy Tube Otorrhea

- Children with uncomplicated acute tympanostomy tube otorrhea
  - Prescribe topical antibiotic eardrops only, without oral antibiotics

Definition

- Acute: otorrhea of less than 4 weeks' duration
- Uncomplicated: TTO that is not accompanied by high fever (38.5°C, 101.3°F),
- Concurrent illness requiring systematic antibiotics (eg, streptococcal pharyngitis, bacterial sinusitis), or cellulitis extending beyond the external ear canal to involve the pinna or adjacent skin.

- Strength: Strong recommendation
- Aggregate evidence quality: Grade B
- Level of confidence in evidence: High

- Benefits:
  - Increased efficacy by providing appropriate coverage of otorrhea pathogens, including *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA)
  - Avoidance of unnecessary overuse and adverse effects of systemic antibiotics, including bacterial resistance
- Risks, harms, costs:
  - Additional expense of topical otic antibiotics compared with oral antibiotics
  - Potential difficulties in drug delivery to the middle ear if presence of obstructing debris or purulence in the ear canal

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 tympanostomy tubes.

- Strength: Recommendation against
- Aggregate evidence quality: Grade B
- Level of confidence in evidence: High

- Benefits:
  - Allows for normal activity and swimming
  - Reduced anxiety
  - Cost savings
- Risk, harm, cost:
  - Potential for slight increase in otorrhea rates in some children

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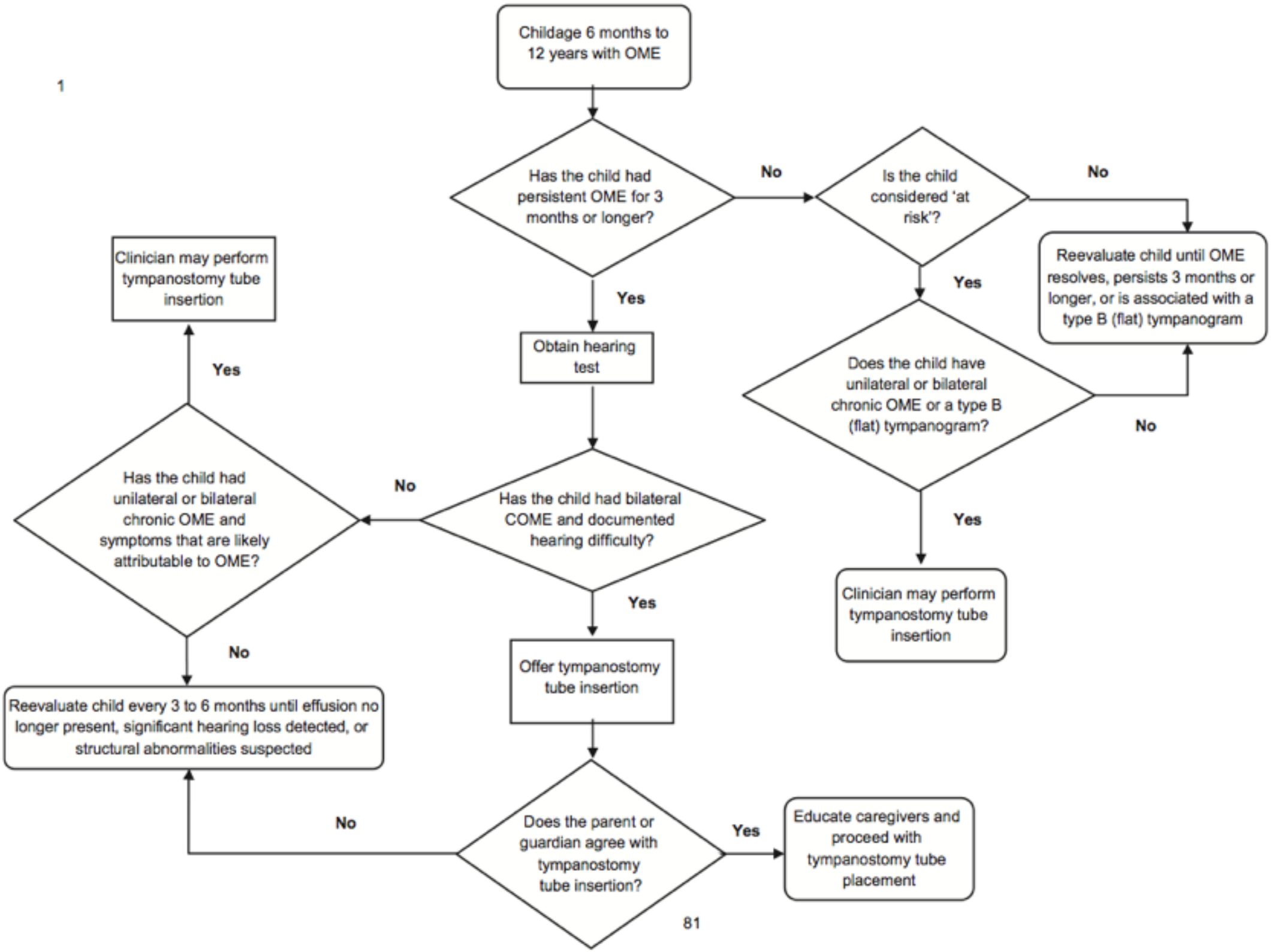

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Figure 9. Algorithm of guideline's key action statements for children with otitis media with effusion.

Table 6. Summary of guideline action statements.

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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
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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
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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)

Thank you