Surgical vs. Medical Treatment of Otitis Media in Children: Show Me the Evidence

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Objective

- Review the guidelines for diagnosis and treatment of otitis media in children
- Understand when to refer children for surgical intervention

- I have no financial disclosures

3 Otitis Media
Clinical Practice Guidelines

- American Academy of Pediatrics (2013):
  - The Diagnosis and Management of Acute Otitis Media
- American Academy of Otolaryngology – Head & Neck Surgery (2013):
  - Tympanostomy Tube Placement in Children
- American Academy of Otolaryngology – Head & Neck Surgery (2016):
  - Otitis Media with Effusion

2013 AAP Guideline for AOM

- Revision of 2004 AAP guidelines
- Scope:
  - Children 6 months to 12 years old
- Exclusions:
  - Cleft palate, craniofacial anomalies, Down syndrome, immune deficiency, cochlear implants
- 6 Key Action Statements

Key Action Statement #1

- Statement 1A:
  - Clinicians should diagnose AOM in children who present with ***moderate to severe bulging of the TM*** or ***new onset otorrhea*** not due to AOE
- Statement 1B:
  - Clinicians should diagnose AOM in children who present with ***mild bulging of TM*** and ***recent (<48h) onset of ear pain*** or ***intense erythema of TM***
- Statement 1C:
  - Clinicians should ***not*** diagnose AOM in children who do ***not*** have MEE (based on pneumatic otoscopy or tympanometry)
- Recommendation
- Purpose: provide clinicians with working definition of AOM and to differentiate AOM from OME

Key Action Statement #2

- The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain.

- Strong recommendation
- Purpose: pain is the major symptom of AOM
- Mainstays: oral ibuprofen and acetaminophen

Key Action Statement #3: Antibiotics

- Statement 3A:
  - Bilateral or Unilateral AOM, ***severe*** signs/symptoms: should prescribe Abx (strong recommendation)
- Statement 3B:
  - ***Bilateral*** AOM, children 6-23 months, ***without severe*** signs/symptoms: should prescribe Abx (recommendation)
- Statement 3C:
  - ***Unilateral*** AOM, children 6-23 months, ***without severe*** signs/symptoms: observation or Abx (recommendation)
- Statement 3D:
  - ***Unilateral or bilateral*** AOM, ***> 24 months***, ***without severe*** signs/symptoms: observation or Abx (recommendation)

Severe: moderate to severe otalgia, otlagia ≥ 48 hours, or temperature ≥ 39°C [102.2°F]

Key Action Statement #4: Choice of Antibiotic

- Statement 4A (recommendation):
  - Initial treatment for AOM in most patients: amoxicillin (high-dose)
- Statement 4B (recommendation):
  - Abx with additional ß-lactamase coverage (Augmentin or 3rd gen. cephalosporin) for AOM:
    - The child has received amoxicillin in the past 30 days, or
    - Has concurrent purulent conjunctivitis, or
    - Has a history of recurrent AOM unresponsive to amoxicillin
- Statement 4C (recommendation):
  - Reassess the patient if caregiver reports that symptoms have worsened or failed within 48-72 hours

Key Action Statement #5: Recurrent AOM

- Key Action Statement 5A:
  - Clinicians should ***NOT*** prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM
  - Recommendation
- Key Action Statement 5B:
  - Clinicians ***may*** offer tympanostomy tubes for recurrent AOM
  - (3 episodes in 6 months or 4 episodes in 1 year, with 1 episode in the preceding 6 months)
  - Option

Key Action Statement #6: Prevention of AOM

- Statement 6A:
  - Pneumococcal Vaccine recommended for all children (as per AAP schedule); strong recommendation
    - Meta-analysis: 29% reduction in AOM caused by all pneumococcal serotypes with PCV7 < 24 months
    - Overall benefit for all cases of AOM: 6%–7%
- Statement 6B:
  - Annual influenza Vaccine recommended for all children (recommendation)
    - Most cases of AOM follow viral URI
- Statement 6C:
  - Exclusive breastfeeding encouraged for at least 6 months (recommendation)
- Statement 6D:
  - Encourage avoidance of tobacco smoke exposure (recommendation)

Statement 6:

- Other factors that may reduce AOM:
  - Avoiding supine bottle feeding (“bottle propping”)
  - Reducing or eliminating pacifier use in the second 6 months of life
  - Altering child care-center attendance patterns

AAO-HNSF Clinical Practice Guideline:
Tympanostomy Tube Placement in Children

- Published July 2013
- Purpose:
  - To provide clinicians with evidence-based recommendations on patient selection, surgical indications, and management of tympanostomy tubes in children
- Scope: children 6 months to 12 years old with otitis media
- Children at risk for developmental delays or disorders ***are*** included:
  - Speech delay, autism, syndromes (Down, craniofacial), cleft palate, vision impairment, permanent hearing loss independent of OME
  - May derive enhanced benefit from tubes
- 12 key action statements

Key Action Statement #1: OME of Short Duration

- Clinicians should NOT perform tympanostomy tube insertion in children with a single episode of OME of less than three months duration
- Policy level: Recommendation
- Purpose:
  - Avoid unnecessary surgery and its risks, for condition that has reasonable likelihood of resolving

Key Action Statement #2: Hearing Testing

- Clinicians should obtain an age-appropriate hearing test:
  - If OME persists for three months or longer, ***or***
  - Prior to surgery when a child becomes a candidate for tympanostomy tube insertion
- Policy level: Recommendation
- Purpose:
  - Document hearing status
  - Improve decision-making regarding need for surgery
  - Establish baseline hearing prior to surgery
  - Detect co-existing SNHL

Key Action Statement #3: Chronic Bilateral OME with Hearing Difficulty

- Clinicians should offer bilateral tympanostomy tube insertion to children with:
  - *Bilatera*l OME for three months or longer ***and***
  - Documented hearing difficulties
- Policy level: Recommendation
  - Well-designed RCTs show reduced MEE prevalence and improved hearing after tube insertion
  - Observational studies document improved quality of life
  - Eliminates potential barrier to focusing and attention in learning environment (although evidence inconclusive)
  - Substantial role for shared decision-making with caregivers

Key Action Statement #4:
Chronic OME with Symptoms *Other* Than Hearing Loss

- Clinicians *may* perform tympanostomy tube insertion in children with:
  - *Unilateral or bilateral* OME for three months or longer, ***and***
  - Symptoms that are likely attributable to OME:
    - Balance problems
    - Poor school performance
    - Behavioral problem
    - Ear discomfort
    - Reduced quality of life
- Policy level: Option
  - Based on randomized controlled trials and before-and-after studies: equal benefit vs. harm

Key Action Statement #5: Surveillance of Chronic OME

- Clinicians should reevaluate, at three- to six-month intervals, children with chronic OME who do not receive tympanostomy tubes, until:
  - The effusion is no longer present
  - Significant hearing loss is detected
  - Structural abnormalities of the tympanic membrane or middle ear are suspected
- Policy level: Recommendation
- Opportunity for shared decision-making regarding surveillance interval

Key Action Statement #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
  - Recurrent AOM: ≥ 3 AOMs in 6 months, or ≥ 4 in last 12 months, with at least 1 in the last six months
- Policy level: Recommendation
- Purpose: Avoid unnecessary surgery for a condition that is likely to improve spontaneously
- Exceptions:
  - Severe AOM (with complications)
  - Multiple antibiotic allergies/intolerance

Statement #6: Recurrent AOM *without* MEE

- Where does this recommendation come from???
  - 15 RCTs of antibiotic prophylaxis for recurrent AOM
  - Excluded children with persistent MEE from participation
  - Highly favorable rates of improvement in the placebo groups
    - Baseline rate: 5.5 AOMs/year
    - Placebo: 2.8 AOMs/year (Rosenfeld and Kay, 2003)
- An RCT that specifically excluded children with baseline MEE found no benefit of tympanostomy tube insertion for reducing the subsequent incidence of AOM (Casselbrant et al. 1992)

Key Action Statement #7: Recurrent AOM *with* MEE

- Clinicians *should* offer bilateral tympanostomy tube insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy
- Policy level: recommendation
- Benefits:
  - Mean decrease of approx. 3 episodes AOM per year
  - Ability to treat future AOMs with topical vs. oral Abx
  - Reduced pain and improved hearing during future AOMs
- Presence of effusion at time of assessment serves as marker of diagnostic accuracy for AOM
- Substantial role for shared decision-making with caregiver

Key Action 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
- Policy level: Recommendation
- Purpose: to identify children who might benefit from early intervention
- Nearly all RCTs exclude “high-risk/special needs” children:
  - Lack of quality evidence of impact of tubes in this population
  - Panel considered risk status as important factor in tube decision
    - Less tolerant of OME or AOM

Key Action Statement #9: Tympanostomy Tubes and 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 three months or longer
- Policy level: Option
  - Based on observational studies, with balance between benefit and harm
- Benefits: improved hearing mitigates potential obstacle to child development, speech/language development
  - Lack of high-quality evidence in this population
  - Significant role for caregiver shared decision-making

Key Action Statement #10: Perioperative Education

- In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding:
  - Expected duration of tube function
  - Recommended follow up schedule
  - Detection of complications
- Policy level: Recommendation
- Purpose:
  - To define caregiver expectations, recognize complications, stress importance of follow-up
  - Importance of caregiver education in promoting good outcomes

Key Action Statement #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
  - Based on RCTs with preponderance of benefit over harm
  - Stress importance of pumping the tragus
- Benefits:
  - Increased efficacy covering otorrhea pathogens (Pseudomonas, MRSA)
  - Avoiding unnecessary systemic Abx
- Exceptions:
  - Complicated otorrhea, cellulitis, concurrent bacterial sinusitis or pharyngitis, children who are immunocompromised

Key Action Statement #12: Water Precautions

- Clinicians should ***not*** encourage routine, prophylactic water precautions for children with tympanostomy tubes:
  - Earplugs or headbands not recommended
  - Do not need to avoid swimming or water sports
- Policy level: Recommendation
  - Based on RCTs, observational studies
- Ear plugs:
  - Trivial reduction of any otorrhea episode, from 56% to 47%
  - Mean otorrhea incidence decreased from 0.10 to 0.07 per month
- Exceptions:
  - Active/prolonged otorrhea
  - Lake swimming (possibly)
  - Otalgia with water (possibly)

AAO-HNSF Clinical Practice Guideline:
Otitis Media with Effusion

- Published February 2016
- Revision of 2004 guidelines
- Purpose:
  - Identify quality improvement opportunities in managing OME and to create explicit and actionable recommendations to implement these opportunities in clinical practice
- Scope: children 6 months to 12 years old with otitis media
- 13 key action statements

Key Action Statement #1: Pneumatic Otoscopy

- **STATEMENT 1a: The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing OME in a child**

- **STATEMENT 1b : The clinician should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing loss, or both**

- Benefit: Improve diagnostic certainty; reduce false-negative diagnoses caused by effusions that do not have obvious air bubbles or an air-fluid level; reduce false-positive diagnoses that lead to unnecessary tests and costs; readily available equipment; document mobility of the tympanic membrane; efficient; cost-effective

- Policy level: Strong recommendation

Key Action Statement #2: Tympanometry

- **STATEMENT 2: Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy**

- Policy level: Strong recommendation

- Particularly useful settings: intolerance of pneumatic otoscopy, inability to perform pneumatic otoscopy, partially obstructing cerumen, narrow EAC, equivocal findings on pneumatic otoscopy, rule out OME in an at-risk child, objective confirmation of OME before surgery

Key Action Statement #3: Failed Newborn Hearing Screening

- **STATEMENT 3: Clinicians should document in the medical record counseling of parents of infants with OME who fail a newborn hearing screen regarding the importance of follow-up to ensure that hearing is normal when OME resolves and to exclude an underlying sensorineural hearing loss (SNHL)**

- Policy level: recommendation

- Can have transient OME as newborn
- Early identification of SNHL important

Key Action Statement #4: Identifying At-risk Children

- **STATEMENT 4a: Clinicians should determine if a child with OME is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors**
- **STATEMENT 4b. : Clinicians should evaluate at-risk children for OME at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at risk prior to this time)**

- Examples: SNHL, speech/developmental delay, autism, Down syndrome, visual impairment
- Policy level: recommendation
  - observational studies regarding the high prevalence of OME in at-risk children, expert opinion on the ability of prompt diagnosis to alter outcomes

Key Action Statement #5: Screening Healthy Children

- **STATEMENT 5: Clinicians should not routinely screen children for OME who are not at risk and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort**

- Policy level: recommendation against
  - Systematic review of RCTs showed no language benefit for children screened for OME who received early intervention
- Assessing the child for OME is appropriate during routine well child visits and whenever ear-specific symptoms exist

Key Action Statement #6: Patient Education

- **STATEMENT 6: Clinicians should educate families of children with OME regarding the natural history of OME, need for follow-up, and the possible sequelae**
- Policy level: recommendation
- Topics to discuss: risk factors for OME (tobacco smoke, pacifier use), likelihood of spontaneous resolution

Key Action Statement #7: Watchful Waiting

- **STATEMENT 7: Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or 3 months from the date of diagnosis (if onset is unknown)**

- Policy level: strong recommendation
  - OME following AOM: 75%-90% resolution by 3 months
  - Newly diagnosed OME : 56% resolution by 3 months
  - Chronic OME: 19% resolution by 3 months

- Exceptions: At-risk children (SNHL, speech delay, autism, Down syndrome, visual impairment) may be offered tympanostomy tubes earlier than 3 months if there is a type B tympanogram in one or both ears

Key Action Statement #8: Medical Therapy

- **STATEMENT 8a. STEROIDS: Clinicians should recommend against using intranasal steroids or systemic steroids for treating OME**

- **STATEMENT 8b. ANTIBIOTICS: Clinicians should recommend against using systemic antibiotics for treating OME**
  - **2016 Cochrane review – resolution of effusion at 2-3 months more likely with abx (NNT 5), side-effects, no impact on QOL/development/need for tympanostomy tube placement**

- **STATEMENT 8c. ANTIHISTAMINES OR DECONGESTANTS: Clinicians should recommend against using antihistamines, decongestants, or both for treating OME**

- *Policy level: strong recommendation against*
  - *Systematic reviews of RCTs*

Key Action Statement #9: Hearing Test

- **STATEMENT 9: Clinicians should obtain an age-appropriate hearing test if OME persists for ≥3 months OR for OME of any duration in an at-risk child**
- Policy level: recommendation
- Effects of hearing loss: speech delay, poor school performance, behavioral problems

Key Action Statement #10: Speech and Language

- **STATEMENT 10: Clinicians should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development**

- Policy level: recommendation

Key Action Statement #11: Surveillance

- **STATEMENT 11: Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.**

- Policy level: recommendation

- Healthy children with no risk factors can usually be observed 6-12 months with low risk of sequelae or impact on QOL
- Favorable natural history

Key Action Statement #12: Surgical Intervention

- **STATEMENT 12a. SURGERY FOR CHILDREN <4 YEARS OLD: Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a child <4 years old; adenoidectomy should not be performed unless a distinct indication (eg, nasal obstruction, chronic adenoiditis) exists other than OME.**

- **STATEMENT 12b. SURGERY FOR CHILDREN ≥4 YEARS OLD: Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a child 4 years old or older.**

- Policy level: recommendation
  - Systematic review of RCTs (tubes/adenoidectomy) and observational studies (adenoidectomy)

Key Action Statement #13: Outcome Assessment

- **STATEMENT 13: When managing a child with OME, clinicians should document in the medical record resolution of OME, improved hearing, or improved QOL.**

- Policy level: recommendation

References

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