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Phoenix Children's Hospital



NIX CHILDREN'S Hospital

Disclosures

- No financial conflicts to disclose
- Discussion of name brand product (Hummingbird) that is FDA approved for in-office ear tube placement age 6 months and up





Brief Outline

- Otitis media are we overdoing it?
 - Diagnosis, treatment, guidelines
- Tympanostomy tubes
 - History and guidelines
 - Office-based tubes in children
- Complications of otitis media





Audience Response Question:

In Arizona, acute otitis media in children is diagnosed:

- A. Too frequently
- B. Not frequently enough
- C. Exactly the right amount

Audience Response Question:

Otolaryngologists in Arizona place tympanostomy tubes:

- A. Too frequently
- B. Not frequently enough
- C. Exactly the right amount

Case presentation

• TS is a 2 yr 6 month old boy with a history of 5 ear infections in 6 months. Mom reports presenting symptoms of runny nose, irritability, poor sleep. These symptoms started again last night.

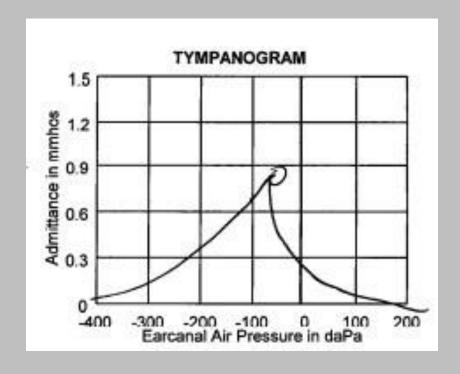
• PMHx/PSHx: None

Social history: in daycare daily, taken to urgent care for each episode

• Examination:



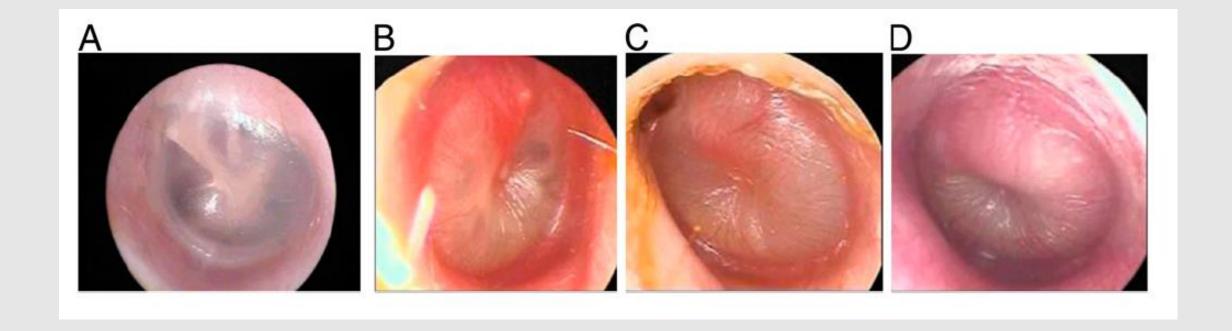
• Tympanogram:



What is your treatment recommendation?

- A. Reassurance
- B. Oral antibiotics
- C. Referral to ENT
- D. More than one of the above

Acute Otitis Media



Clinical Practice Guidelines

- The Diagnosis and Management of Acute Otitis Media (AAP 2013)
- Otitis Media with Effusion (AAO-HNS 2016)
- Tympanostomy Tubes in Children (AAO-HNS 2022)

Clinical Practice Guidelines are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." - Institute of Medicine









CLINICAL PRACTICE GUIDELINE

The Diagnosis and Management of Acute Otitis Media

The diagnosis of acute otitis media (AOM) should be made in children who present with

- moderate to severe bulging of the tympanic membrane (TM) or
- new onset of otorhea not due to acute otitis externa or
- mild bulging of the TM and recent (less than 48 hours) onset of ear pain or intense erythema of the TM.

AOM should not be diagnosed in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry).





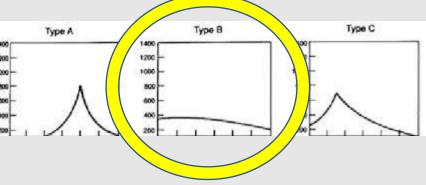








TABLE 4 Recommendations for Initial Management for Uncomplicated AOM^a

Age	Otorrhea With AOM ^a	Unilateral or Bilateral AOM ^a With Severe Symptoms ^b	Bilateral AOM ^a Without Otorrhea	Unilateral AOM ^a Without Otorrhea
6 mo to 2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation
≥2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation	Antibiotic therapy or additional observation ^c



2015 Meta-analysis of Abx vs. Placebo

- Searched 1966 to 2015
- High quality prospective studies of Abx vs. placebo
- High income countries
- Low risk of bias
- 13 RCT
- 3401 children/3938 AOM episodes



Cochrane Database of Systematic Reviews

Antibiotics for acute otitis media in children (Review)

Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM

2015 Meta-analysis of Abx vs. Placebo

- By 24 hours, 60% of children had recovered regardless of treatment arm
- Benefits from pain reduction:
 - 24 hours—no difference
 - 2-3 days—NNTB = 20
 - 4-7 days—NNTB = 16
 - 10-12 days—NNTB = 7
- Improved tympanometry NNTB = 11
- Reduced perforations NNTB = 33
- Adverse events from meds NNTH = 14



Cochrane Database of Systematic Reviews

Antibiotics for acute otitis media in children (Review)

Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM

2015 Meta-analysis of Abx vs. Placebo

Conclusions:

- 1. "In high income countries, most cases of AOM spontaneously remit without complications." p.2
- 2. "We found that antibiotics were not very useful for most children with AOM" p.3
- 3. "Severe complications were rare and did not differ between children treated with antibiotics and those treated with placebo." p.2
- 4. Quality = high; further research unlikely to change



Cochrane Database of Systematic Reviews

Antibiotics for acute otitis media in children (Review)

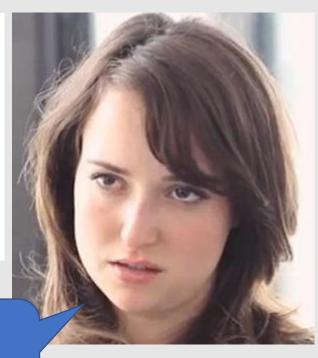
Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM



There's a 1 in 16 chance that this antibiotic will work better than placebo in reducing your daughter's ear pain in the next 7 days.







You must be kidding???



• 746 children, 6-35 m/o-enrollment visit

Prognostic Factors for Treatment Failure in Acute Otitis Media
Paula A. Tähtinen, Miia K. Laine and Aino Ruohola

Pediatrics 2017;140;

DOI: 10.1542/peds.2017-0072 originally published online August 8, 2017;

Pneumatic Otoscopy and Tympanometry on all

Middle Ear Fluid (2 of 3)	Sign of Acute Inflammation	Acute Symptoms (1)
Bulging position	Distinct erythema	Ear pain
Decreased/absent mobility	Increased vascularity	Fever
Abnormal color or opacity	-over bulging/full TM	Respiratory Symptoms
Air-fluid interfaces	-over yellow TM	

- 319 children; 6-35 m/o Dx with AOM
- 161 randomized to Amox-Clav; 158 to placebo, x7d
- Endpoint: time to "treatment failure"
 - Parents think worsening—any time
 - Parents perceive no improvement by day #3
 - Perforation
 - Severe infection
 - TM not improved by day #8 (Abx completed)



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- Rescue treatment was needed before day #8:
 - Amox-Clav = 6.8%
 - Placebo = 33.5%
- 31.7% reached treatment failure on/before day #8
 - Abx group = 19% treatment failure
 - Placebo = 45% treatment failure
- -NNT = 3.8

Table 2. Adverse Events.

Event	Amoxicillin– Clavulanate Group (N=161)	Placebo Group (N=158)	P Value
	no. (%	6)	
Any adverse event	85 (52.8)	57 (36.1)	0.003
Hospitalization	0	0	
Severe infection	0	2 (1.3)	0.15
Meningitis	0	0	
Pneumococcal bacteremia	0	1 (0.6)	
Radiographically confirmed pneumonia	0	1 (0.6)	
Complications of otitis media	1 (0.6)	5 (3.2)	0.10
Mastoiditis	0	0	
Perforation	1 (0.6)	5 (3.2)	
Diarrhea	77 (47.8)	42 (26.6)	<0.001
A little	57 (35.4)	36 (22.8)	
A lot*	20 (12.4)	6 (3.8)	

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- Symptoms improved with Amoxicillin—clavulanate > Placebo:
 - Resolution of fever—improvement noted 6 hours after the first dose
 - Poor appetite—seen by day #2
 - Decreased activity—seen by day #2
 - Irritability—seen by day #2
- No difference between Amoxicillin–clavulanate vs. Placebo:
 - Ear pain as reported by parents or by the children
 - Ear rubbing
 - Restless sleep or Excessive crying



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Secondary analysis—Tympanometry:

- 57/319 of "AOM" had "peaked tympanogram" Type A or C
- Of these, only 14% had treatment failure
 - 4 in Abx group failed (of 32)
 - 4 in Placebo group failed (of 25)
- NNT = 29

Peaked tympanogram ^b						
Yes	4/32 (12.5)	4/25 (16.0)			-3.5 (-21.7 to 14.7)	28.5
No	26/129 (20.2)	67/133 (50.4)	─	1	-30.2 (-41.8 to -18.6)	3.3

Secondary analysis:

• "Severe Bulging": Yes

Severe bulging of	the tympanic men	nbrane			
Yes	5/45 (11.1)	25/39 (64.1)	─	-53.0 (-73.5 to -32.4)	1.9
No	25/116 (21,6)	46/119 (38.7)		-17 ₋ 1 (-28 ₋ 8 to -5 ₋ 4)	5.8

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- 11% treatment failure with Abx
- 64% treatment failure with placebo
- $\bullet NNT = 1.9$

FINLAND 🏵 2



Alternative treatments

Chiropractic for Ear Infections

A natural solution to relieve and manage pain caused by ear infections.





J Chiropr Med. 2012 Sep; 11(3): 160-169.

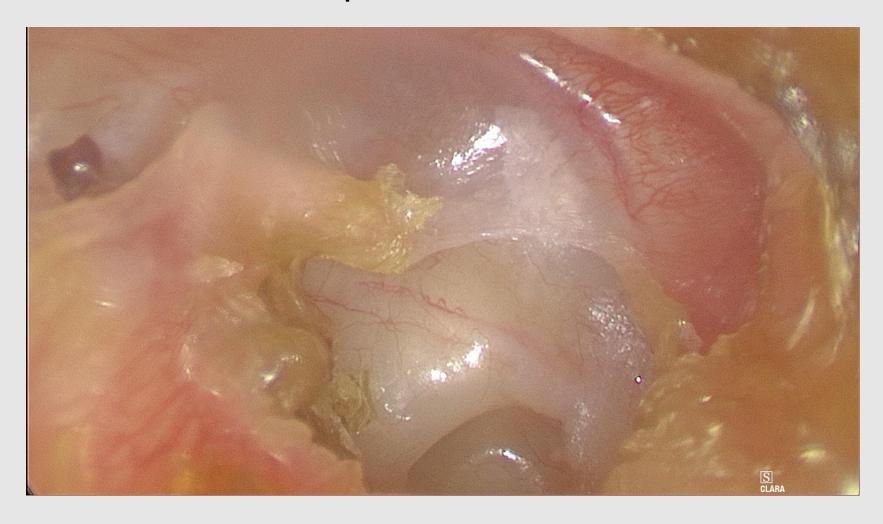
doi: 10.1016/j.jcm.2012.05.006

Otitis media and spinal manipulative therapy: a literature review

Katherine A. Pohlman, DC, MS, DICCP^{a,*} and Monisa S. Holton-Brown, DC, DICCP^b

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Pediatrician Pickups



Pediatrician Pickups







Tympanostomy





History

Myringotomy has been practiced since at least 1600s

• Tubes invented in mid-19th century

Became widespread in the mid-20th century

 Most common ambulatory surgery performed in the US – 667,000 (2006)





Prevalence of tubes

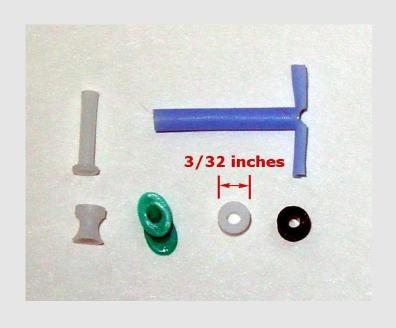
- By age 3, 1 in 15 children will have tubes (6.8%)
- Children in daycare are twice as likely to have tubes
- 10% need a second set of tubes (much higher in craniofacial, Down syndrome, etc)





Benefits of tubes

- Improves hearing
- Reduces effusion prevalence
- Reduce incidence of RAOM (~3 episodes/year)
- Reduces pain with infection
- Provides a mechanism for drainage and pressure equalization
- Allows for administration of topical antibiotic therapy
- Improves QOL

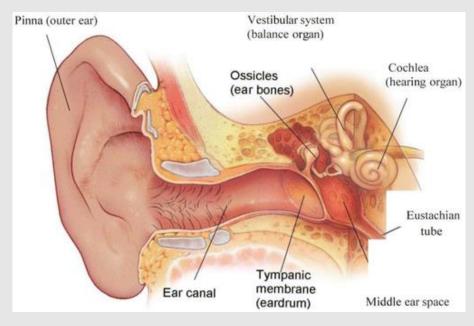




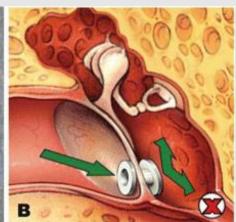
Complications of tubes

 Common: otorrhea, tympanosclerosis, focal atrophy, shallow retraction pocket

 TM perforations, which may require repair, are seen in about 2% of children









Cliffical Fractice Guideline FOUNDATION Statement

Clinical Practice Guideline: Otitis Media with Effusion (Update)

Richard M. Rosenfeld, MD, MPH¹, Jennifer J. Shin, MD, SM², Seth R. Schwartz, MD, MPH³, Robyn Coggins, MFA⁴, Lisa Gagnon, MSN, CPNP⁵, Jesse M. Hackell, MD⁶, David Hoelting, MD⁷, Lisa L. Hunter, PhD⁸, Ann W. Kummer, PhD, CCC-SLP⁹, Spencer C. Payne, MD⁹, Dennis S. Poe, MD, PhD¹⁰, Maria Veling, MD¹¹, Peter M. Vila, MD, MSPH¹², Sandra A. Walsh¹³, and Maureen D. Corrigan¹⁴

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DOI: 10.1177/0194599815623467
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Clinical Practice Guideline: Tympanostomy Tubes in Children

Richard M. Rosenfeld, MD, MPH¹, Seth R. Schwartz, MD, MPH², Melissa A. Pynnonen, MD, MSc³, David E.Tunkel, MD⁴, Heather M. Hussey, MPH⁵, Jeffrey S. Fichera, PA-C⁶, Alison M. Grimes, AuD⁷, Jesse M. Hackell, MD, FAAP⁸, Melody F. Harrison, PhD⁹, Helen Haskell, MA¹⁰, David S. Haynes, MD¹¹, Tae W. Kim, MD¹², Denis C. Lafreniere, MD¹³, Katie LeBlanc, MTS, MA¹⁴, Wendy L. Mackey, APRN¹⁵, James L. Netterville, MD¹⁶, Mary E. Pipan, MD¹⁷, Nikhila P. Raol, MD¹⁸, and Kenneth G. Schellhase, MD, MPH¹⁹

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- 1. Clinicians should not perform BMT in children with a single episode of OME of less than 3 month duration
- 2. Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR prior to surgery
- 3. Clinicians should offer BMT to children with bilateral COME AND documented hearing difficulties.
- 4. Clinicians may perform BMT in children with unilateral or bilateral COME AND symptoms (balance/vestibular problems, poor school performance, behavioral problems, ear discomfort, or reduced QOL)
- 5. If you DO NOT place tubes for COME, reevaluate effusions at 3- to 6- month intervals until effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the TM or middle ear are suspected



incul ridicitie Guideline

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- 6. Clinicians should not perform BMT for RAOM when children do not have a MEE in either ear at the time of assessment for candidacy.
- 7. Clinicians should offer BMT to children with RAOM with unilateral or bilateral MEE at time of assessment
- 8. Clinicians should determine if a child with RAOM or OME of ANY duration is at increased risk for speech, language, or learning problems from OM because of baseline sensory, physical, cognitive, or behavioral factors.
- 9. Clinicians may perform BMT in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly, as reflected by type B tympanogram or persistence of effusion

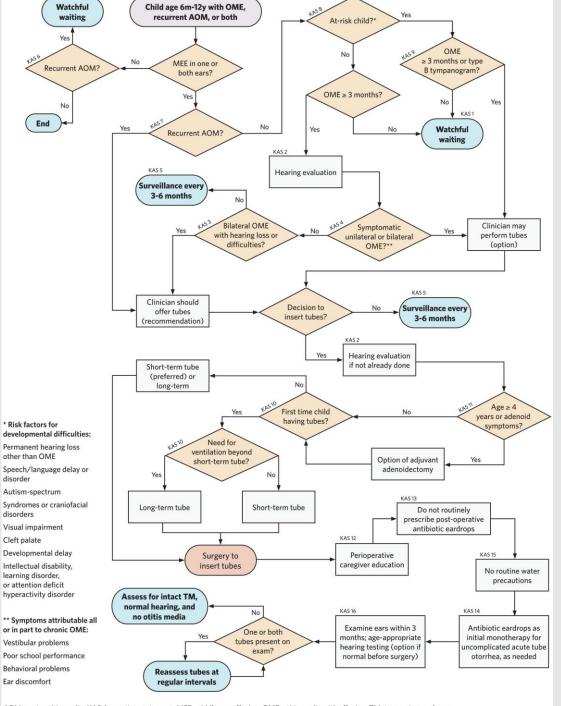


Tympanostomy Tube Otorrhea Guidelines:

- 11. Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea
- 12. Clinicians should NOT encourage routine, prophylactic water precautions (use of earplugs, headbands, avoidance of water sports or swimming) for children with tympanostomy tubes

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





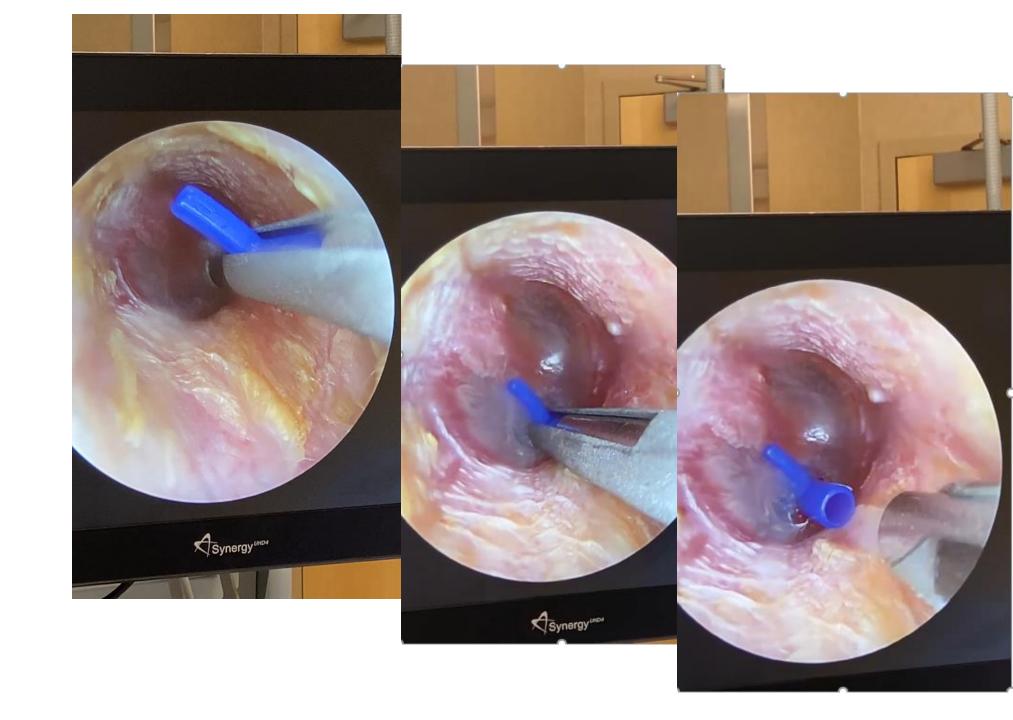
AAO Position Statement

In-Office Placement of Tubes in Pediatric Patients While Awake

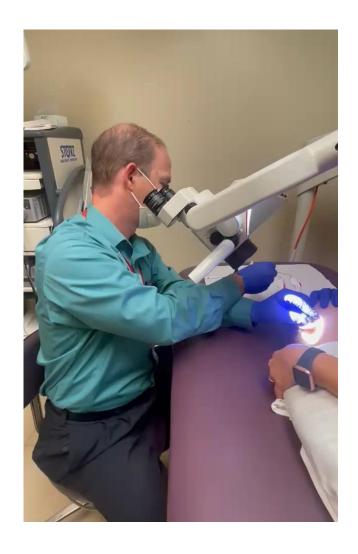
The position of the AAO-HNS is that tympanostomy tubes are safe and effective for managing otitis media in children who meet current guidelines for tube insertion [Rosenfeld 2013]. Although insertion of tympanostomy tubes in children is generally accomplished in the operating room under general anesthesia, insertion in the clinic in appropriately selected patients using shared decision making between clinicians and families can be appropriate.²

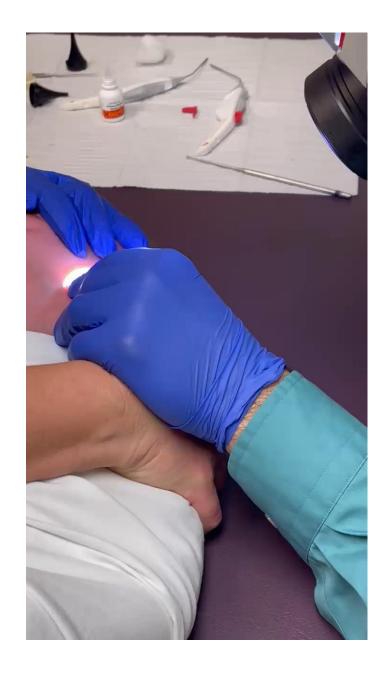
Adopted 7/9/19

The AAO position statement supports in-office ear tube surgery in awake pediatric patients. This statement is not an endorsement for the use of the Hummingbird Tympanostomy Tube System but does cite the clinical data.









My experience

- About 100 kids
- Age 6 months-4 years 8 months (and a few >12yo)
- Parents overall very happy
- Two kids overly anxious/irritable at follow up exam
- Currently tracking longevity of tubes
- Some tubes performed at initial office visit

Tympanic Membrane Perforations

- Spontaneous
- Traumatic
- Chronic



Tympanic Membrane Perforations

- "Spontaneous" secondary to acute otitis media
- Treatment typical for AOM +/- ototopical drops
- Should close without additional treatment
- Needs follow up to ensure healing

- When should I refer?
 - If the perforation does not close after
 ~1 month
 - Recurrent perforations



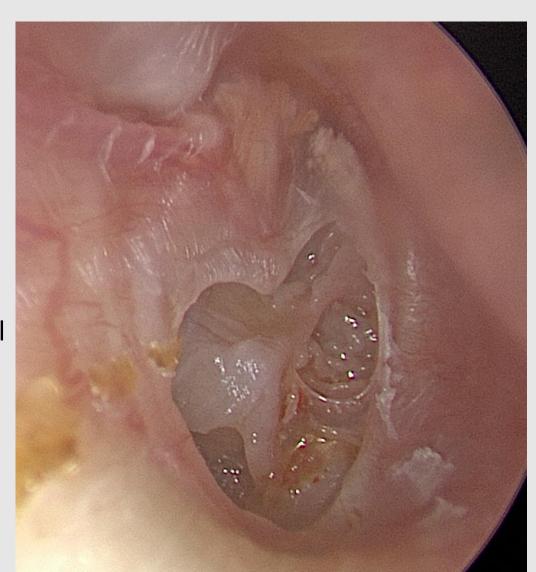
Tympanic Membrane Perforations

Traumatic perforations

- Most small to moderate perforations heal without intervention
- No prophylactic antibiotics required
- Ototopical drops are indicated if there is potential contamination of the middle ear, or when otorrhea is present

• When to refer

- If there is concern for contamination or residual foreign body
- Large perforation
- Associated dizziness or hearing loss
- Family or provider concern
- Not emergent best seen after 7-10 days to allow for inflammation to resolve and debris to clear.



Tympanic Membrane Perforations - Chronic

- Please refer
- Hearing testing
- Otorrhea management
- Discussion of repair



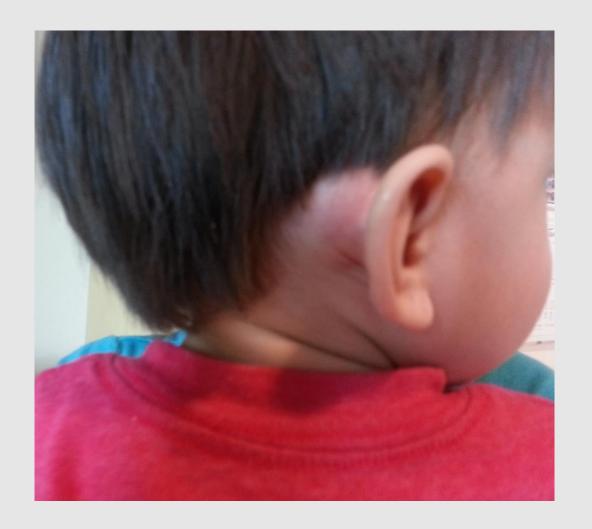
Acute Mastoiditis

- The most common complication of AOM
- Typically develops less than 10 days after onset of AOM
- 50% of patients <2yo
- 50-75% without antecedent AOM
- Higher rate in countries where abx are not prescribed for AOM

Acute Mastoiditis

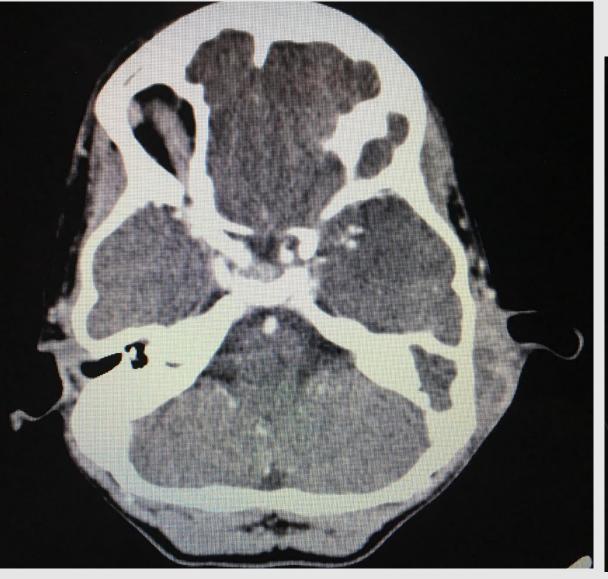
- Clinical Criteria
 - Acute otitis media plus:
 - Protrusion of the pinna "down and out"
 - Postauricular edema/erythema
 - Tenderness to palpation
- Treatment
 - IV abx +/- surgery





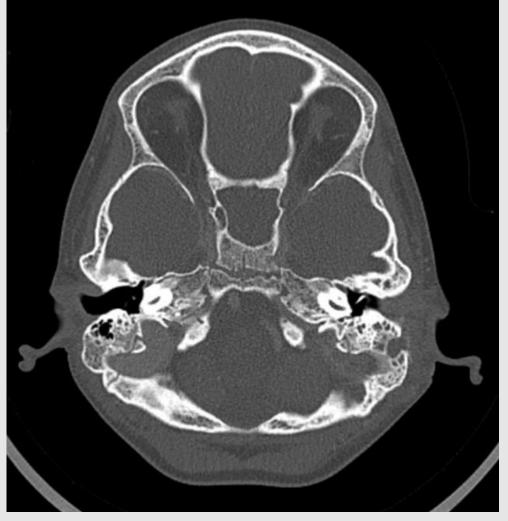


Coalescent mastoiditis



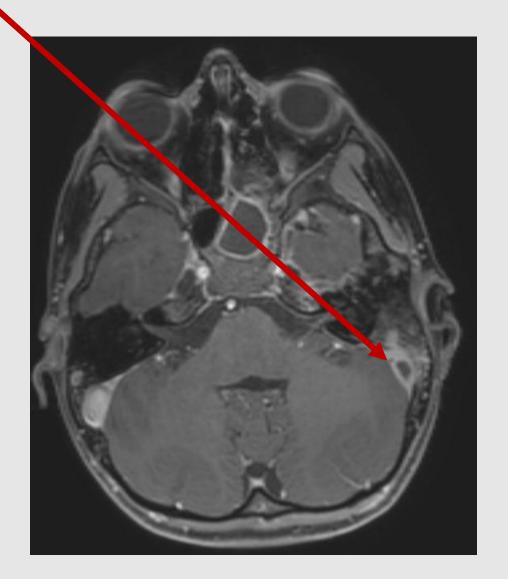






Sigmoid Sinus Thrombosis





Questions?



