

Nathan Page, MD, FAAP

**Division of Otolaryngology** 

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 office ear tube placement age 6 months and up





## Audience Response Question:

In Arizona, acute otitis media in children is diagnosed:

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

## Audience Response Question:

Otolaryngologists in Arizona place tympanostomy tubes:

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



http://me.hawkelibrary.com/albums/acute-otitis-media/Severe AOM BB Right.jpg

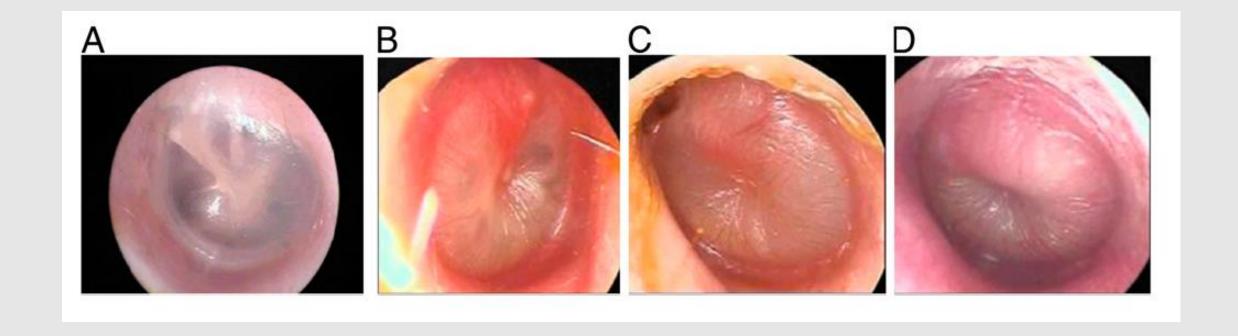




http://otitismedia.hawkelibrary.com/albums/mastoiditis/3 1.jpg



## Acute Otitis Media



## 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.

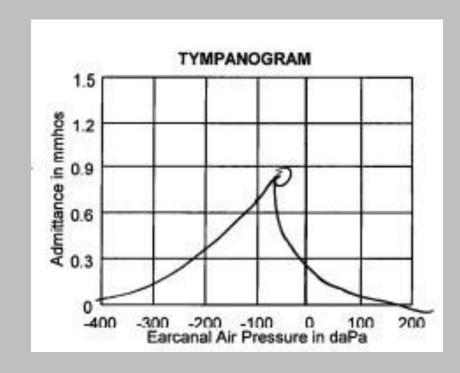
• PMHx/PSHx: None

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



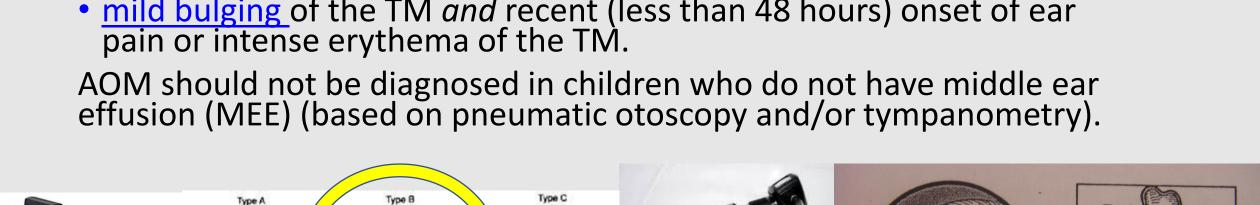
#### 2013 AAP Guideline:

CLINICAL PRACTICE GUIDELINE

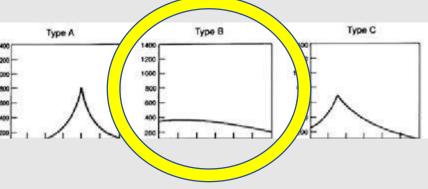
The Diagnosis and Management of Acute Otitis Media

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















- 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)

- Primary Outcomes:
  - 1. Ear pain at various time points
  - 2. Adverse events related to Abx
- Secondary Outcomes:
  - 1. Abnormal tympanometry
  - 2. TM perforations
  - 3. Contralateral AOM
  - 4. AOM recurrences
  - 5. Serious complications
  - 6. Long-term effects



**Cochrane** Database of Systematic Reviews

Antibiotics for acute otitis media in children (Review)

- 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)

#### **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

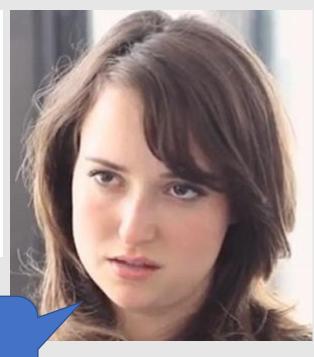
Antibiotics for acute otitis media in children (Review)



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.

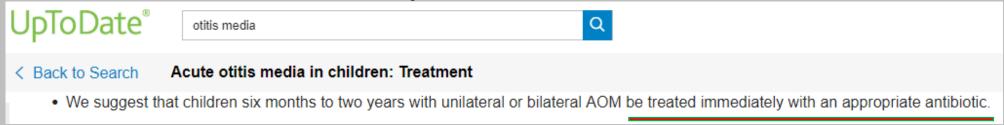






You must be kidding???

# What about *UpToDate*?



### Why? Because they work better than placebo ....



- Antibiotics reduced pain at two to three days (seven trials, 2320 patients): 11.6 versus 15.9 percent (relative risk [RR] 0.70, 95% CI 0.57-0.86)
- Antibiotics reduced tympanic membrane perforations (five trials, 1075 patients): 1.9 versus 4.8 percent (RR 0.37, 95% CI 0.18-0.76)
- Antibiotics reduced contralateral episodes of AOM (four trials, 906 patients): 10.6 versus 18.8 percent (RR 0.49, 95% CI 0.25-0.95)
- . Antibiotics did not affect the rate of late recurrence (six trials, 2200 patients): approximately 20 percent
- Antibiotics increased adverse events (vomiting, diarrhea, or rash): 27.1 versus 19.6 percent (RR 1.38, 95% CI 1.19-1.59)
- Serious complications (eq. mastoiditis, meningitis) were rare in both the treatment and placebo groups



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 Dx with AOM (38/ patients excluded—no AOM):

- 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
- $\cdot$  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)	

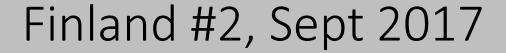
## PEDIATRICS<sup>®</sup>

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**Prognostic Factors for Treatment Failure in Acute Otitis Media** 

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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

#### Secondary analysis:

"Severe Bulging":

Severe bulging of the tympanic membrane
Yes 5/45 (11.1) 25/39 25/39 (64.1)

-53.0 (-73.5 to -32.4) 1.9 -17.1 (-28.8 to -5.4) 5.8

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

FINLAND 

2



25/116 (21.6) 46/119 (38.7)





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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

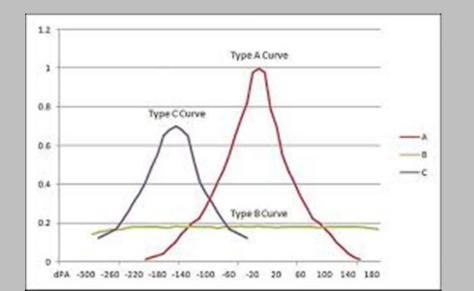
Peaked tympanogra	m <sup>b</sup>			
Yes	4/32 (12.5)	4/25 (16.0)	<del></del>	-3.5 (-21.7 to 14.7) 28.5
No	26/129 (20.2)	67/133 (50.4)	<b>─</b>	-30.2 (-41.8 to -18.6) 3.3
		1 /		1 '

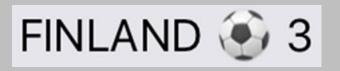
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 "These results are directly applicable in clinical practice; by withholding antimicrobial treatment from children with peaked tympanogram (A and C curves), the use of antimicrobial agents and the development of antimicrobial resistance could be reduced without increasing the risks for the child."







Prognostic Factors for Treatment Failure in Acute Otitis Media

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	A h	
res	4/32 (12.5)	4/25 (16.0)
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Peaked tympanograi

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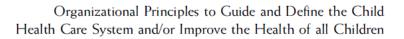
-30.2 (-41.8 to -18.6

- 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





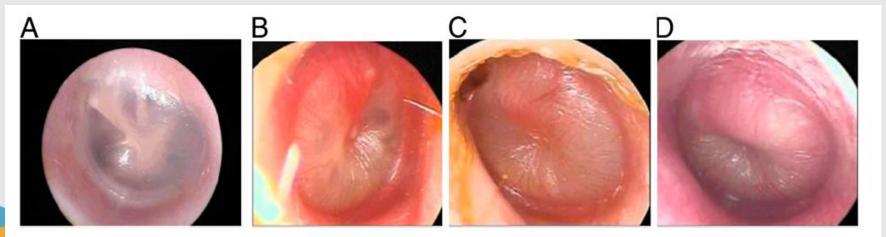




#### CLINICAL PRACTICE GUIDELINE

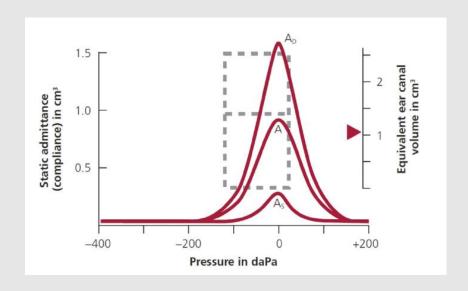
#### The Diagnosis and Management of Acute Otitis Media

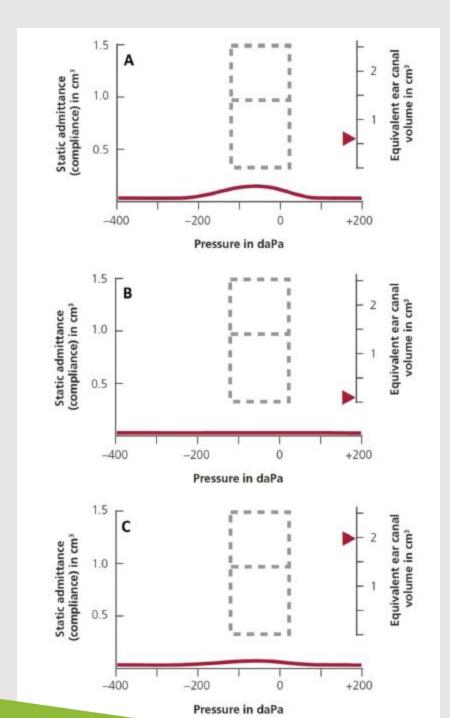
- Diagnose AOM in children with:
  - moderate to severe bulging of the TM OR new onset otorrhea not due to acute otitis externa
  - Mild bulging of TM AND recent (less than 48 hrs) onset of ear pain (holding, tugging, rubbing), or intense erythema of TM





## Tympanometry

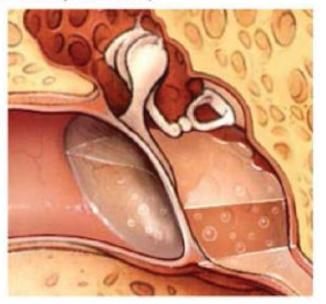






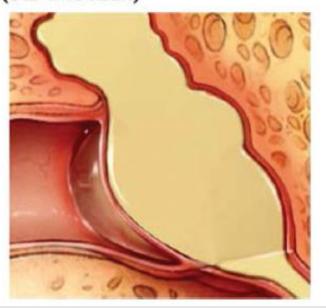
Otitis Media with Effusion (ear fluid)





Acute Otitis Media (ear infection)







# Pediatrician Pickups







# Tympanostomy





## History

Myringotomy has been practiced since at least 1600s

• Tubes invented in mid-19<sup>th</sup> century

Became widespread in the mid-20<sup>th</sup> century

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





### Prevalence of tubes

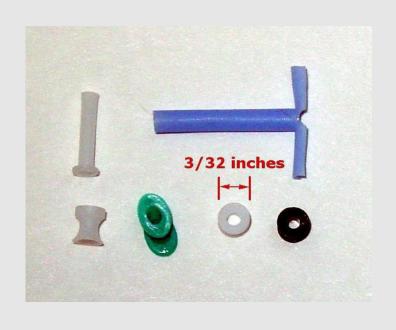
- By age 3, 1 in 15 children will have tubes (6.8%)
- Children in daycare are twice as likely to have tubes
- 10% need a second set of tubes (much higher in craniofacial, Down syndrome, etc)





### 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

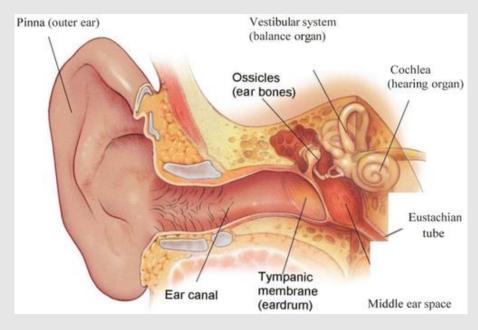




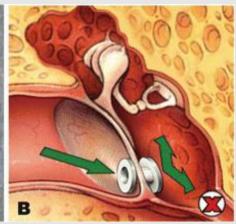
## Complications of tubes

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

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









Normal TM, clear middle ear





Serous effusion

Tube in healthy ear

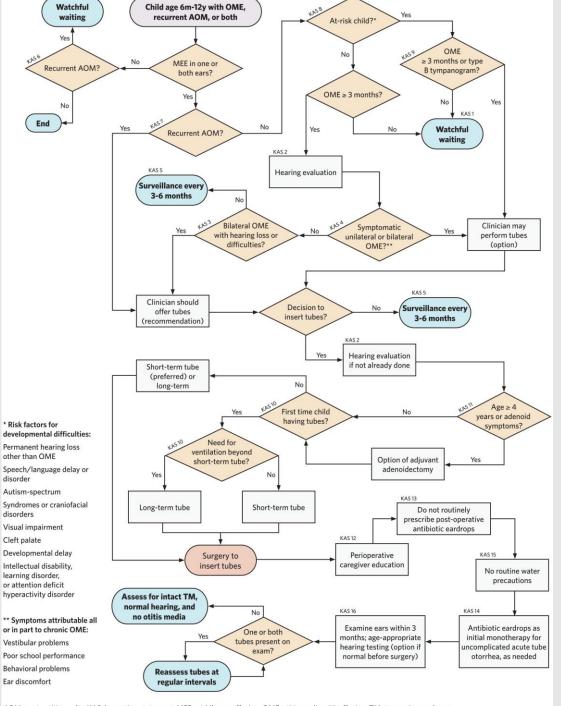


## Tympanostomy Tube Otorrhea Guidelines:

- 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

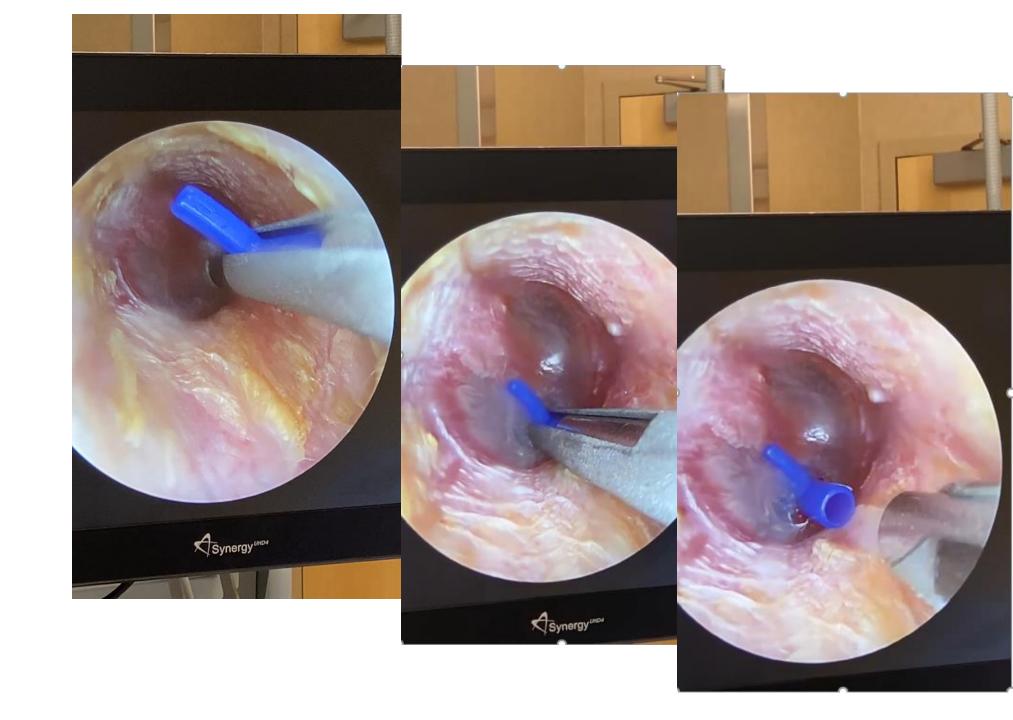
The position of the AAO-HNS is that tympanostomy tubes are safe and effective for managing otitis media in children who meet current guidelines for tube insertion [Rosenfeld 2013]. Although insertion of tympanostomy tubes in children is generally accomplished in the operating room under general anesthesia,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

#### Adopted 7/9/19

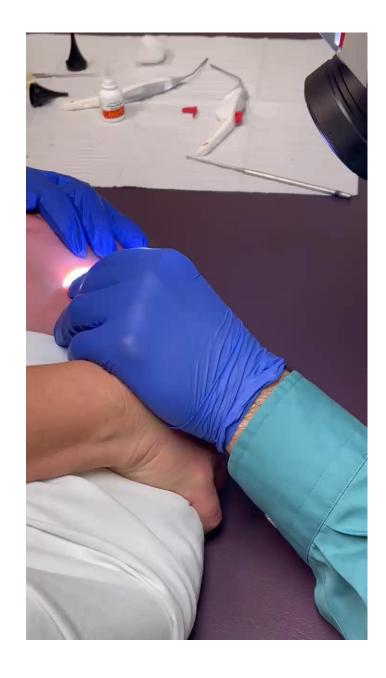
The AAO position statement supports in-office ear tube surgery in awake pediatric patients. This statement is not an endorsement for the use of the Hummingbird Tympanostomy Tube System but does cite the clinical data.











## 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



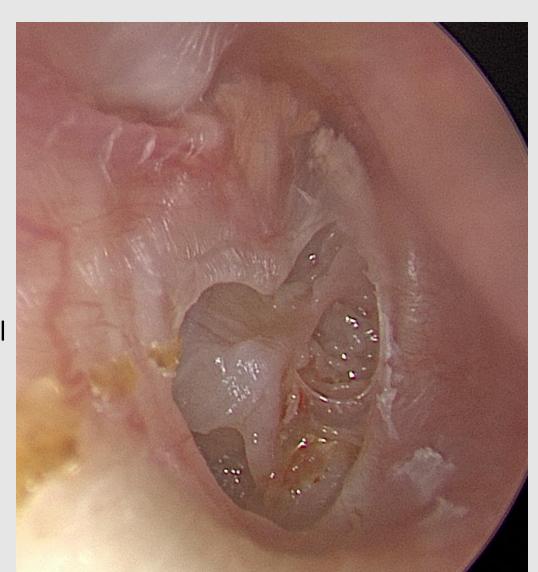
## Tympanic Membrane Perforations

#### 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







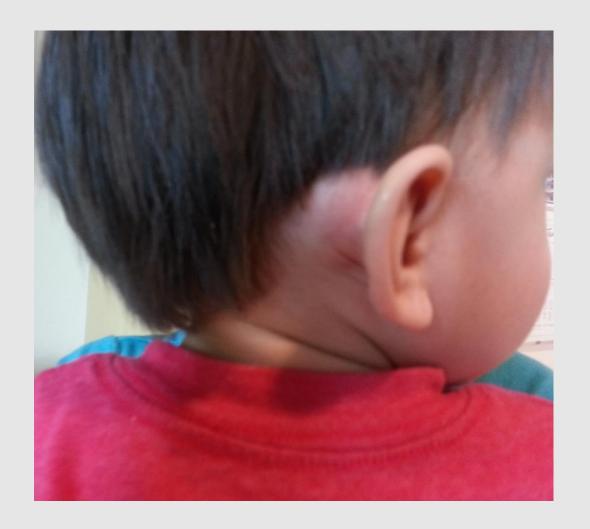
### Acute Mastoiditis

- The most common complication of AOM
- Typically develops less than 10 days after onset of AOM
- 50% of patients <2yo</li>
- 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





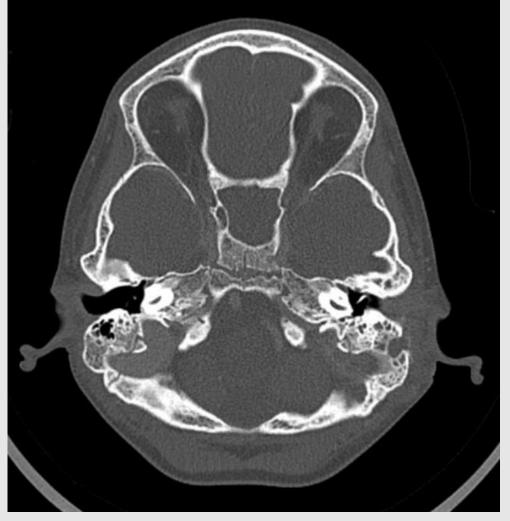


# Coalescent mastoiditis









# Sigmoid Sinus Thrombosis





# Questions?



