

FROM THE FAMILY PRACTICE INQUIRIES NETWORK

# Are tympanostomy tubes indicated for recurrent acute otitis media?

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## ■ EVIDENCE-BASED ANSWER

For children with recurrent acute otitis media (here defined as 3 or more episodes in 6 months, or 4 or more in a year), tympanostomy tubes are indicated if middle-ear effusion is present. Tubes reduce the frequency of recurrent acute otitis media by 2 to 3 episodes per year in these patients (strength of recommendation [SOR]: **A**; based on randomized controlled trials).

Further benefits include improved quality of life for both child and caregiver and greater parental satisfaction (SOR: **B**; based on trials that included patients with recurrent acute otitis media or otitis media with effusion).

Tympanostomy tubes do not decrease the number of recurrent acute otitis media episodes in children without middle-ear effusion (SOR: **A**, based on randomized controlled trials). These children run the risk of adverse outcomes of tube placement, including transient or recurrent otorrhea, tympanosclerosis, focal atrophy, perforation, and cholesteatoma (SOR: **A**; based on meta-analysis).

## ■ EVIDENCE SUMMARY

Several randomized controlled trials and a meta-analysis demonstrated that the children most likely to benefit from tympanostomy tubes are those more than 6 months old with middle-ear effusion who have had 3 or more episodes of acute otitis media in 6 months, or 4 or more episodes in 12 months.<sup>1-4</sup> Data are inadequate to determine the lowest rate of recurrence that would suggest a benefit from tube placement.

A meta-analysis of 5 randomized trials comparing no surgery with placement of tubes for recurrent acute otitis media with or without middle-ear effusion showed that the placement of tubes resulted in a mean absolute decrease in acute otitis media incidence of 1.0 per year (95% confidence interval [CI], 0.4–1.6), and a decrease in the prevalence of middle-ear effusion by 115 days per year (95% CI, 11–220).<sup>4</sup> The benefit of tubes for recurrent acute otitis media was demonstrated only in studies in which middle-ear effusion was

present.<sup>2,3</sup> one found 3.01 (95% CI, 2.18–3.84) fewer acute episodes per year;<sup>1,4</sup> the other found 2.27 (95% CI, 1.03–3.51) fewer.<sup>2,4</sup>

One randomized controlled trial of 264 children, aged 7 to 35 months, with a history of recurrent acute otitis media but free of middle-ear effusion, compared tubes with medical therapy and found no difference in recurrence over 2 years.<sup>3</sup> The medical therapy arm received prophylaxis with either amoxicillin or placebo. The amoxicillin arm had 0.6 fewer episodes of acute otitis media per year compared with the other 2, a statistically significant 40% decrease (relative risk reduction=0.4).<sup>3</sup>

The average time with otitis media of any type (acute otitis media, otitis media with effusion, or otorrhea) also decreased—15.0% in the placebo group, 10.0% in the amoxicillin group, and 6.6% in the tympanostomy tube group (amoxicillin vs. placebo,  $P=.03$ ; tubes vs. placebo,  $P<.001$ ).<sup>3</sup> Higher dropout rates occurred in the amoxicillin and medical treatment groups.<sup>3</sup>

In prospective studies of patients receiving tubes for recurrent acute otitis media and otitis media with effusion, measures of quality of life—physical suffering, emotional distress, activity limitation, hearing loss, speech development, caregiver concern/worry, parental post-tube satisfaction,<sup>4,5,6</sup> and an ear symptom score<sup>6</sup>—improved after tube placement. Within several weeks of tube placement, 79% of children had improved quality of life, 17% had trivial change, and 4% were worse.<sup>4</sup>

A meta-analysis reporting sequelae of tympanostomy tubes found an absolute complication rate of 26% for transient otorrhea and 4% for chronic otorrhea.<sup>4</sup>

Compared with nonsurgical treatment, complication rates for tube placement were reported in 0.7% of surgically treated ears.<sup>7</sup> Complications included:

- tympanosclerosis (relative risk [RR]=3.5 [95% CI, 2.6–4.9])
- focal atrophy (RR=1.7 [95% CI, 1.1–2.7])
- perforation (RR=3.5 [95% CI, 1.5–7.1])
  - 2% with short-term tubes
  - 16% with long-term tubes
- cholesteatoma (RR=2.6 [95% CI, 1.5–4.4]).

## ■ RECOMMENDATIONS FROM OTHERS

The Institute for Clinical Systems Improvement 2001 guidelines for recurrent acute otitis media treatment in children recommends initial antibiotic prophylaxis with amoxicillin (20 mg/kg/day) for 2 to 6 months (based on randomized controlled trial data). If there are 2 recurrences of acute otitis media during that time, then referral to an otorhinolaryngologist for possible tympanostomy tube placement is recommended.<sup>8</sup>

**CLINICAL COMMENTARY**

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Of the remaining challenges to the care of children with recurrent acute otitis media, 2 major issues are accurate diagnosis and the lack of information about long-term results. Diagnosis is difficult and requires pneumotoscopy and/or tympanometry. Without those techniques, a red drum (unless it is bulging) has a <40% positive predictive value for recurrent acute otitis media with effusion. On the other hand, with pneumotoscopy or tympanometry, the positive predictive value is 78% to 85%.

We don't want to refer children unnecessarily for tubes. Delaying referral up to 9 months in children aged 6 to 36 months with middle-ear effusion does not seem to hurt language acquisition at 3 years of age. At this point, I know of no long-term follow-up studies of randomized controlled trials of >4 years to assess differences in language acquisition and hearing.

## REFERENCES

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