

Summary of findings:

### 30. Tympanostomy tubes compared to no surgery for recurrent acute otitis media

**Patient or population:** Children aged 0 to 3 years with recurrent acute otitis media (rAOM).

**Setting:** Hospital.

**Intervention:** Tympanostomy tubes (TTs)

**Comparison:** No surgery.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Tympanostomy tubes	With Tympanostomy tubes	Difference		
Hearing loss - Difference in mean decibel hearing. Ears with TTs compared to contralateral ears used as controls assessed with: Pure tone audiometry follow up: median 2 years № of participants: 44 (1 RCT) <sup>1,a</sup>	At 6 months post TT insertion a small but significant difference is found between TT and non-TT ears; better hearing in TT ears (-3.7dB [-7 to 0 dB]).  At 12 months post insertion there is no significant difference (-0.8dB [-4.0 to +2.0 dB]).  At 24 months, a small but significant difference is found; better hearing in non-TT ears (1.7dB [0 to +4.0dB]).				⊕⊕○○ LOW <sup>b,c</sup>	In children with rAOM receiving TTs compared to no surgery there is possibly an improvement in hearing at 6 months, which is not sustained at 12 months follow-up.  NNT not evaluable
Incident rate of AOM episodes/child/year assessed with: parental report + pneumatic otoscopy +/- tympanometry +/- otomicroscopy +/- otorrhea. follow up: range 6 to 12 months № of participants: 385 (3 RCTs) <sup>2,3,4,d</sup>	-	The mean incident rate of AOM episodes/child/year was <b>1.29</b> episodes/patient/yea <sub>r<sup>e</sup></sub>	-	rate ratio <b>0.8</b> <b>episodes/patient/yea r fewer</b> (0.45 more to 1.43 more)	⊕○○○ VERY LOW <sub>b,f,g</sub>	In children with rAOM receiving TTs compared to no surgery there are possibly fewer AOM episodes/child/year.
Proportion of children otitis free follow up: range 6 months to 2 years № of participants: 511 (5 RCTs) <sup>2,3,4,5,h</sup>	<b>RR 1.81</b> (1.44 to 2.27)	28.6%	<b>51.8%</b> (41.2 to 65.0)	<b>23.2% more</b> (12.6 more to 36.4 more)	⊕⊕○○ LOW <sup>b,g</sup>	Children with rAOM receiving TTs compared to no surgery are possibly more likely to remain free of otitis media at 6-24 months follow-up.  NNT ~4

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Change in Quality of Life from baseline assessed with: QOL-OM-6 tool follow up: range 4 to 12 months № of participants: 77 (1 RCT) <sup>6,i</sup>	OM-6 QOL questionnaire at base line, 4 months and 12 months post-surgery showed increase in QOL for both TTs (n=42) and no surgery (n=35) groups, with no difference between groups in mean improvement.				⊕⊕○○ LOW <sup>g,i</sup>	In children with rAOM treated with TTs compared to no surgery there is possibly no difference in QOL scores at 4-12 months follow-up.

\*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; NS: Not significant; NNT: Number needed to treat; NNH: Number needed to harm; MD: Mean difference

**GRADE Working Group grades of evidence**

**High quality:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Explanations**

- a. Study: Le 1991
- b. Risk of Bias: Selection and performance bias
- c. Imprecision: Estimate of effect covers harm and benefit at different time points
- d. Studies taken from: (1) Cochrane Review: McDonald 2008 updated 2011(Gebhart 1981), (2) Kujala 2012, (3) Gonzales 1986
- e. Mean incident rate calculated with an unweighted mean.
- f. Inconsistency: High heterogeneity
- g. Imprecision: Optimal information size not reached / small study
- h. Studies taken from: (1) Cochrane Review: McDonald 2008 updated 2011(Gebhart 1981 El Sayed 1996), (2) Kujala 2012, (3) Casselbrant 1992, (4) Gonzales 1986
- i. Study: Kujala 2014
- j. Risk of Bias: Attrition bias, raw QOL data not available

**References**

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