Summary of findings:

13. Tympanostomy tubes compared to no surgical intervention for otitis media with effusion

Patient or population: Children aged 6 months to 12 years with otitis media with effusion.

Setting: Hospital.

Intervention: Tympanostomy tubes (TTs) (Teflon biflanged, Donaldson and Bevel Bobbins ventilation tubes).

Comparison: No surgical intervention

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Tympanostomy tubes	**With Tympanostomy tubes**	**Difference**		
By child hearing level assessed with: Binaural mean hearing level on pure tone audiometry 500-4000Hz follow up: median 3 months № of participants: 215 (1 RCT) [1,a]	-	The mean by child hearing level was **26.3** dB HL	-	MD **11.9 dB HL lower** (9.6 lower to 14.2 lower) [b]	⨁⨁⨁◯ MODERATE [c,d]	In children with OME treated with TTs compared to no surgical intervention there is probably better hearing at 3 months follow-up. NNT not evaluable
By child hearing level assessed with: pure tone audiometry (500-4000Hz) or portable visual reinforcement audiometry follow up: range 6 to 9 months № of participants: 523 (3 RCTs) [2,e]	-	The mean by child hearing level was **30.1** dB HL	-	MD **4.2 dB HL lower** (6 lower to 2.4 lower) [b]	⨁⨁⨁◯ MODERATE [d,f,g]	In children with OME treated with TTs compared to no surgical intervention there is probably better hearing at 6-9 months follow-up. NNT not evaluable
By child hearing level assessed with: pure tone audiometry (500-4000Hz) or portable visual reinforcement audiometry follow up: median 12 months № of participants: 328 (2 RCTs) [2,h]	-	The mean by child hearing level was **27** dB HL	-	MD 0.41 dB HL (NS) lower (2.37 lower to 1.54 higher) [b]	⨁⨁⨁◯ MODERATE [d,f,g]	In children with OME treated with TTs compared to no surgical intervention there is possibly no difference in hearing outcomes at 12 months.

Summary of findings:

13. Tympanostomy tubes compared to no surgical intervention for otitis media with effusion

Patient or population: Children aged 6 months to 12 years with otitis media with effusion.

Setting: Hospital.

Intervention: Tympanostomy tubes (TTs) (Teflon biflanged, Donaldson and Bevel Bobbins ventilation tubes).

Comparison: No surgical intervention

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Tympanostomy tubes	**With Tympanostomy tubes**	**Difference**		
Comprehensive language development assessed with: Reynell test follow up: range 6 to 9 months № of participants: 394 (3 RCTs) [2,i]	-	-	-	SMD 0.09 higher (NS) (0.21 lower to 0.39 higher)	⨁⨁⨁◯ MODERATE [d]	In children with OME treated with TTs compared to no surgical intervention there is probably no difference in comprehensive language development at 6-9 months.
Expressive language development assessed with: Reynell, Schlichting follow up: range 6 to 9 months № of participants: 393 (3 RCTs) [2,i]	-		-	MD 0.03 SD higher (NS) (0.42 lower to 0.49 higher)	⨁⨁⨁◯ MODERATE [d]	In children with OME treated with TTs compared to no surgical intervention there is probably no difference in expressive language development at 6-9 months.
Time (proportion) with effusion in first year assessed with: otoscope and tympanometry № of participants: 574 (3 RCTs) [2,j]	-	The mean time (proportion) with effusion in first year was **0.6**	-	MD **0.32 lower** (0.48 lower to 0.17 lower)	⨁⨁◯◯ LOW [k,l]	In children with OME treated with TTs compared to no surgical intervention there is possibly less time spent with effusion at 12 months follow up.
Quality of life assessed with: TAIQOL survey follow up: median 2 years № of participants: 187 (1 RCT) [2,m]	Quality of life improved in six subdomains, whereas the number of complaints concerning appetite, anxiety, and aggression increased. Except for anxiety, children treated with tympanostomy tubes (TTs) showed greater improvement or less deterioration than the watchful waiting group. However, the differences were not statistically significant.				⨁◯◯◯ VERY LOW [d,n]	In children with OME treated with TTs compared to no surgical intervention there is insufficient evidence to report on quality of life scores.

Summary of findings:

13. Tympanostomy tubes compared to no surgical intervention for otitis media with effusion

Patient or population: Children aged 6 months to 12 years with otitis media with effusion.

Setting: Hospital.

Intervention: Tympanostomy tubes (TTs) (Teflon biflanged, Donaldson and Bevel Bobbins ventilation tubes).

Comparison: No surgical intervention

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Tympanostomy tubes	**With Tympanostomy tubes**	**Difference**		
Adverse effects – otorrhoea follow up: range 12 to 24 months № of participants: 213 (1 observational study) [3,o]	Rates of TTs otorrhoea vary widely between RCTs; MRC TARGET trial found a rate of 2% over 24 months (mean age 60 months) whilst Rovers 2000 reported a rate of 83% over 12 months (mean age 19.5 months). Best data in Australian children is from Jassar 2009 (cohort study); 36% across 213 Indigenous and non-Indigenous children in the NT 1996-2004. [p]				⊕◯◯◯ VERY LOW [q,r]	In children with OME treated with TTs compared to no surgical intervention there is insufficient evidence to report on otorrhoea at 1 to 2 years.

***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; **SMD:** Standardised 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: MRC 2001
b. Lower mean difference corresponds to better hearing outcome.
c. Risk of Bias: Risk of selection bias however demographic, audiometric, tympanometric and otoscopic findings similar for randomised and non-randomised groups. Not rated down.
d. Imprecision: Small studies, optimal information size not met.
e. Studies taken from: Cochrane Review, Browning 2010 (Maw 1999, MRC: TARGET 2001, Rovers 2000)
f. Risk of Bias: attrition bias , selective reporting noted. Not rated down.
g. Indirectness: Only 1 frequency available for comparison in Maw 1999, whilst 4 frequency average measured in other studies. Not rated down.
h. Studies taken from: Cochrane Review, Browning 2010 (MRC: TARGET 2001, Rovers 2000)
i. Studies taken from: Cochrane Review, Browning 2010 (Maw 1999, Rach 1991, Rovers 2000)
j. Studies taken from: Cochrane review, Browning 2010 (Mandel 1992, Paradise 2001, Rovers 2000)
k. Risk of Bias: Ability to blind assessor as to the presence of a grommet or its sequelae is not possible.
l. Inconsistency: High heterogeneity
m. Study data: Rovers 2001
n. Indirectness: TAIQOL is a generic quality of life measure which has not been validated for otitis media, whereas other specific otitis media quality of life measurements are now available.
o. Study: Jassar 2009
p. Indirectness: Data from Jassar 2009 included children with TT insertion for OME and RAOM.

q. Risk of Bias: Only those attending follow-up appointments included in analysis
r. Imprecision: Small study

References

1. MRC. Surgery for persistent otitis media with effusion: generalizability of results from the UK trial (TARGET). Trial of Alternative Regimens in Glue Ear Treatment. Clinical otolaryngology and allied sciences. 2001;26(5):417-24. Epub 2001/10/27. PubMed PMID: 11678951.
2. Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. The Cochrane database of systematic reviews. 2010(10):Cd001801. Epub 2010/10/12. doi: 10.1002/14651858.CD001801.pub3. PubMed PMID: 20927726.
3. Jassar P, Sibtain A, Marco D, Jose J, Hunter G. Infection rates after tympanostomy tube insertion, comparing Aboriginal and non-Aboriginal children in the Northern Territory, Australia: a retrospective, comparative study. The Journal of laryngology and otology. 2009;123(5):497-501. Epub 2008/06/26. doi: 10.1017/s002221510800306x. PubMed PMID: 18577271.