

Summary of findings:





14 Adenoidectomy +/- tympanostomy tubes compared to tympanostomy tubes alone or no surgery for otitis media with effusion

Patient or population: Children aged 3 months to 18 years with otitis media with effusion

Setting: Hospital

Intervention: Adenoidectomy +/- tympanostomy tubes

Comparison: Tympanostomy tubes alone or no surgery

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		Without Adenoidectomy +/- tympanostomy tubes	With Adenoidectomy +/- tympanostomy tubes	Difference		
Hearing outcome assessed with: mean binaural hearing level measured over 4 frequency average follow up: range 12 to 24 months № of participants: 254 (1 RCT) ^{1,a}	-	The mean hearing outcome was 20.1 dB	-	MD 4.2 dB lower (2.6 lower to 5.7 lower) ^b	 MODERATE ^c	In children with OME treated with adenoidectomy plus TTs compared to TT s alone there is probably better hearing at 12-24 months. NNT Not quantifiable
Treatment Failure in children ≥4 years of age follow up: median 12 months № of participants: 737 (8 RCTs) ^{2,d,e}	RR 0.77 (0.68 to 0.86)	69.6%	53.6% (47.4 to 59.9)	16.0% fewer (22.3 fewer to 9.7 fewer)	 LOW ^{f,g}	In children >4 years with OME treated with adenoidectomy +/- TTs compared with non-surgical treatment or TTs only there is possibly less treatment failure at 12 months follow-up. NNT~6
Treatment Failure in children < 4 years of age follow up: median 12 months № of participants: 239 (8 RCTs) ^{2,d,e}	RR 0.98 (0.69 to 1.38)	29.7%	29.1% (20.5 to 41.0)	0.6% fewer (NS) (9.2 fewer to 11.3 more)	 LOW ^{f,g}	In children <4 years treated with adenoidectomy +/- TTs compared with non-surgical treatment or TTs only there is possibly no fewer treatment failures at 12 months follow-up. NNT Not Applicable
Resolution of OME (randomised by ear) assessed with: tympanometry follow up: median 6 months № of participants: 297 (3 RCTs) ^{3,h}	RR 2.29 (1.52 to 3.43)	17.0%	38.9% (25.8 to 58.3)	21.9% more (8.8 more to 41.3 more)	 LOW ⁱ	In children with OME treated with adenoidectomy plus TTs compared to TTs alone there is possibly more resolution of OME at 6 months follow-up. NNT ~5

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		Without Adenoidectomy +/- tympanostomy tubes	With Adenoidectomy +/- tympanostomy tubes	Difference		
Resolution of OME assessed with: tympanometry follow up: median 12 months № of participants: 298 (3 RCTs) ^{3,h}	RR 2.33 (1.36 to 4.01)	20.0%	46.6% (27.2 to 80.2)	26.6% more (7.2 more to 60.2 more)	 LOW ^a	In children with OME treated with adenoidectomy plus TTs compared to TTs alone there is probably more resolution of OME at 12 months. NNT ~4.
Complications of surgery (post- operative bleeding) № of participants: 508 (2 RCTs) ^{1,3,i}	RR 3.02 (0.32 to 28.87)	0.0%	0.0% (0.0 to 0.0)	0.0% fewer (NS) (0 fewer to 0 fewer)	 LOW ^{c,j}	In children with OME treated with adenoidectomy plus TTs compared to TTs alone there is possibly on complications post surgery.
Repeat tympanostomy tube surgery follow up: range 2 to 5 years № of participants: 879 (4 RCTs) ^{1,k}	RR 0.44 (0.35 to 0.54)	38.3%	16.9% (13.4 to 20.7)	21.5% fewer (24.9 fewer to 17.6 fewer)	 MODERATE ^l	In children with OME treated with adenoidectomy plus TTs compared to TTs alone there is possibly less repeat TTs surgery. NNT ~5
Repeat tympanostomy tube surgery follow up: range 1 to 5 years № of participants: 200 (10 observational studies) ^{5,m,n}	RR 0.54 (0.52 to 0.57)	32.0% ^o	17.3% (16.6 to 18.2) ^o	14.7% fewer (15.4 fewer to 13.8 fewer)	 VERY LOW ^p	In children with OME treated with adenoidectomy plus TT compared to TT alone there is possibly less repeat tympanostomy tube surgery. NNT ~7

*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 data taken from: MRC Multicentre Otitis Media Study Group 2012

- b. Lower mean difference corresponds to better hearing outcome.
- c. Imprecision: Small numbers. Optimal information size not reached.
- d. Treatment failure defined as: ≥ 4 AOM episodes (including episodes of otorrhoea) per year, presence of effusion for $\geq 50\%$ of the time (i.e. effusion for > 6 months), need for additional surgery, hearing improved by < 10 dB.
- e. Studies taken from: Boonacker Individual Patient Data Meta-analysis 2014 (Black 1990, Casselbrant 2009, Dempster 1993, Hamneren-Malmi 2005, Maw and Bawden 1993, Maw and Herod 1986, MRC Multicentre Otitis Media Study 2012, Nguyen 2004)
- f. Risk of Bias: Attrition bias and Re-call bias (Nguyen 2004)
- g. Publication Bias: 5 studies not included as individual patient data not supplied or unavailable, however there is no change in estimate of effect.
- h. Studies taken from: Cochrane Review, van den Aardweg 2010 (Black 1990, Dempster 1993, Maw 1986)
- i. Studies taken from: Cochrane Review, van den Aardweg 2010 (Gates 1987) and MRC 2012
- j. Imprecision: low event rate / rare event
- k. Studies taken from: (1) Mikals, 2014 (Meta-analysis with raw data provided for RCT's; Gates 1987, Black 1990, Maw & Bawden 1994), (2) Multicentre Otitis Media Study Group 2012
- l. Imprecision: Optimal information size not reached.
- m. Meta-analysis (Mikals 2014) combined RCT and observational studies looking at children undergoing adenoidectomy & tympanostomy tubes vs tympanostomy tubes for recurrent acute otitis media, otitis media with effusion and hearing loss.
- n. Studies taken from: Mikals, 2014 (includes observational retrospective studies and RCT's)
- o. No raw data available. Percentages extracted from published data (represented as rate %).
- p. Inconsistency: High heterogeneity with lumping of data from a variety of studies which broad outcomes.

References

1. MRC. Multicentre O, Media, Study, Group. Adjuvant adenoidectomy in persistent bilateral otitis media with effusion: hearing and revision surgery outcomes through 2 years in the TARGET randomised trial. *Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery*. 2012;37(2):107-16. Epub 2012/03/27. doi: 10.1111/j.1749-4486.2012.02469.x. PubMed PMID: 22443163.
2. Boonacker CW, Rovers MM, Browning GG, Hoes AW, Schilder AG, Burton MJ. Adenoidectomy with or without grommets for children with otitis media: an individual patient data meta-analysis. *Health technology assessment (Winchester, England)*. 2014;18(5):1-118. Epub 2014/01/21. doi: 10.3310/hta18050. PubMed PMID: 24438691; PubMed Central PMCID: PMC4780935.
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4. Mikals SJ, Brigger MT. Adenoidectomy as an adjuvant to primary tympanostomy tube placement: a systematic review and meta-analysis. *JAMA otolaryngology--head & neck surgery*. 2014;140(2):95-101. Epub 2013/11/30. doi: 10.1001/jamaoto.2013.5842. PubMed PMID: 24287958.