

Summary of findings:





**15. Autoinflation devices compared to watchful waiting for otitis media with effusion**

**Patient or population:** Children aged 3 to 11 years with otitis media with effusion

**Setting:** Primary health care and Hospital

**Intervention:** Autoinflation devices (Otovent®, carnival blower + balloon and Politzer devices) for a duration of 1 week to 3 months (ranged across studies)

**Comparison:** Watchful waiting

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty	What happens
		Without Autoinflation	With Autoinflation	Difference		
Hearing - average improvement $\geq$ 10 dB assessed with: pure-tone audiogram (250 Hz to 2000 Hz) follow up: range 3 weeks to 3 months № of participants: 125 (2 RCTs) <sup>1,a</sup>	<b>Relative Risk 0.80</b> (0.22 to 2.88)	27.0% <sup>b</sup>	<b>21.6%</b> (5.9 to 77.8)	5.4% fewer (NS) (21.1 fewer to 50.8 more)	 LOW <sup>c,d</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is insufficient evidence to show a difference of $>10$ dB in hearing during 3 weeks to 3 months follow-up.  NNT Not Applicable
Pure-tone threshold - assessed with: pure-tone audiogram (250 Hz to 2000 Hz) follow up: median 7 weeks № of participants: 179 (2 RCTs) <sup>1,e</sup>	-	-	-	MD 7.02 higher (NS) (6.92 lower to 20.96 higher)	 LOW <sup>f,g,h</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is insufficient evidence to show a difference in hearing at 7 weeks follow-up.  NNT Not Applicable
Tympanogram improvement - B to C1/A assessed with: tympanometry follow up: median 1 months № of participants: 508 (4 RCTs) <sup>1,2,i</sup>	<b>Relative risk 1.72</b> (1.23 to 2.40)	35.6% <sup>j</sup>	<b>61.2%</b> (43.8 to 85.5)	<b>25.6% more</b> (8.2 more to 49.8 more)	 LOW <sup>c,k</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is possibly tympanogram improvement at up to 1 month follow-up.  NNT ~4
Tympanogram improvement - B/C2 to C1/A assessed with: tympanometry follow up: median 1 months № of participants: 588 (6 RCTs) <sup>1,2,i</sup>	<b>Relative risk 1.48</b> (0.88 to 2.48)	35.6% <sup>j</sup>	<b>52.7%</b> (31.3 to 88.3)	17.1% more (NS) (4.3 fewer to 52.7 more)	 LOW <sup>c,g,k</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is possibly no tympanogram improvement $<1$ month follow-up.  NNT Not Applicable

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Tympanogram improvement - B/C2 to C1/A follow up: range 1 to 3 months № of participants: 530 (5 RCTs) <sup>1,2,m</sup>	<b>Relative Risk 1.27</b> (1.07 to 1.49)	38.3%	<b>48.7%</b> (41.0 to 57.1)	<b>10.4% more</b> (2.7 more to 18.8 more)	 LOW <sup>c,k</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is possibly tympanogram improvement at 1-3 months follow-up.  NNT ~10
Adverse effects - Nosebleeds and Ear Pain assessed with: parental report follow up: median 3 months № of participants: 320 (1 RCT) <sup>2,n</sup>	<b>RR 0.90</b> (0.55 to 1.45)	16.3%	<b>14.6%</b> (8.9 to 23.6)	1.6% fewer (NS) (7.3 fewer to 7.3 more)	 LOW <sup>o,p</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there are possibly no more adverse events (nosebleeds or ear pain) at 3 months follow-up.  NNT Not Applicable
Disease specific quality of life assessed with: standardised change in OMQ-14 score follow up: mean 3 months № of participants: 247 (1 RCT) <sup>2,n</sup>	-	-	-	<b>SMD 0.42 SD lower</b> (0.63 lower to 0.22 lower) <sup>q</sup>	 LOW <sup>r</sup>	In children with OME who have autoinflation therapy compared to watchful waiting there is possibly lower OMQ-14 score indicating better QOL at 3 months follow-up.  NNT Not quantifiable

\*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; MD: Mean difference; RR: Risk ratio; SMD: Standardised mean difference; NS: Not significant; NNT: Number needed to treat; NNH: Number needed to harm

**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. Studies taken from: (1) Cochrane Review, Perera 2013 (Blanshard 1993, Brooker 1992)
- b. Raw data not available from Cochrane Review. Baseline risk taken from watchful waiting group in Brooker 1992
- c. Risk of Bias: Blinding not possible of participants. Unclear blinding of outcome assessors.
- d. Imprecision: Broad estimate of effect. Includes benefit and harm.
- e. Studies taken from: (1) Cochrane Review, Perera 2013 (Arick 2005, Fraser 1977)
- f. Risk of Bias: Lack of blinding of participants, however audiologists blinded to otologic findings (Arick 2005). Unclear blinding Fraser 1977. Not rated down.
- g. Inconsistency: High heterogeneity. Not rated down.
- h. Imprecision: Optimal information size not reached. Broad estimate of effect.

- i. Studies taken from: (1) Cochrane Review, Perera 2013 (Blanshard 1993, Ercan 2005, Stangerup 1992), (2) Williamson 2015
- j. Raw data not available from Cochrane Review. Baseline risk taken from watchful waiting group in Williamson 2015
- k. Indirectness: Tympanostomy is a surrogate for functional hearing. Not rated down.
- l. Studies taken from: (1) Cochrane Review, Perera 2013 (Blanshard 1993, Brooker 1992, DeNobili 2008, Ercan 2005, Stangerup 1992), (2) Williamson 2015
- m. Studies taken from: (1) Cochrane Review, Perera 2013 (Blanshard 1993, DeNobili 2008, Ercan 2005, Stangerup 1992), (2) Williamson 2015
- n. Study: Williamson 2015
- o. Risk of Bias: Lack of participant blinding. Otagia and nosebleed reported anecdotally.
- p. Imprecision: Single study with small numbers. Broad estimate of effect.
- q. Lower score denotes better QOL.
- r. Risk of Bias: Lack of participant blinding.

## References

1. Perera R, Glasziou PP, Heneghan CJ, McLellan J, Williamson I. Autoinflation for hearing loss associated with otitis media with effusion. The Cochrane database of systematic reviews. 2013(5):Cd006285. Epub 2013/06/04. doi: 10.1002/14651858.CD006285.pub2. PubMed PMID: 23728660.
2. Williamson I, Vennik J, Harnden A, Voysey M, Perera R, Breen M, et al. An open randomised study of autoinflation in 4- to 11-year-old school children with otitis media with effusion in primary care. Health technology assessment (Winchester, England). 2015;19(72):1-150. Epub 2015/09/18. doi: 10.3310/hta19720. PubMed PMID: 26377389; PubMed Central PMCID: PMC4781307.