

Summary of findings:



5. Relative effect for association: Parental counselling to restrict pacifier/dummy use compared to unrestricted pacifier/dummy use for prevention of acute otitis media

Patient or population: Children aged 0 to 7.24 years of age.

Setting: Primary health care / Day-care centres / Community.

Intervention: Parental counselling to restrict pacifier/dummy use (limit to moments of falling asleep after 6 months and discontinue use after 10 months of age). Single counselling session was provided.

Comparison: Unrestricted pacifier/dummy use.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Parental counselling to restrict pacifier/dummy use	With Parental counselling to restrict pacifier/dummy use	Difference		
AOM per person-months at risk assessed with: parental report follow up: median 4.6 months № of participants: 484 (1 RCT) ^{1,a}	Study in Finland found that with parental counselling against pacifier use there was a 29% lower occurrence of AOM/PMR in the intervention group. In the total series the occurrence of AOM/PMR was 33% higher in the group of children who used pacifier continuously than in those not using one or using it when falling asleep. ^b				 LOW ^{c,d,e}	In children who have restricted pacifier use compared to unrestricted pacifier use there is possibly less AOM per person months at risk. NNT Not able to be calculated (raw data not available)
Risk of rAOM (>3 episodes of AOM) assessed with: physician diagnosed AOM follow up: range 10 months to 5.6 years № of participants: 884 (2 observational studies) ^{2,3,f}	RR 0.49 (0.36 to 0.68)	21.6%	10.6% (7.8 to 14.7)	11.0% fewer (13.8 fewer to 6.9 fewer)	 VERY LOW ^{g,h,i}	In children who have restricted pacifier use compared to no pacifier use there are possibly fewer with rAOM at up to ~5 years follow-up. NNT 10

*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: Niemela 2000

b. Raw data not reported.

c. Risk of Bias: Nature of intervention makes blinding difficult.

d. Indirectness: Diagnosis of AOM was not made according predefined criteria or by trained staff but during routine visits to health care centres or private practices.

e. Imprecision: Single, small study

f. Studies: Rovers 2008 and Niemela 1995

g. Inconsistency: Pacifier use only measured at baseline in Rovers 2008. Diagnosis of AOM made by different physicians with differing pre-defined criteria. Short term follow-up in Niemela 1995 (median 10 months).

h. Imprecision: Optimal information size not reached.

i. Possible confounding: All children in Niemela 1995 attended daycare centres - not adjusted.

References

1. Niemela M, Pihakari O, Pokka T, Uhari M. Pacifier as a risk factor for acute otitis media: A randomized, controlled trial of parental counseling. *Pediatrics*. 2000;106(3):483-8. Epub 2000/09/02. PubMed PMID: 10969091.
2. Niemela M, Uhari M, Mottonen M. A pacifier increases the risk of recurrent acute otitis media in children in day care centers. *Pediatrics*. 1995;96(5 Pt 1):884-8. Epub 1995/11/01. PubMed PMID: 7478830.
3. Rovers MM, Numans ME, Langenbach E, Grobbee DE, Verheij TJ, Schilder AG. Is pacifier use a risk factor for acute otitis media? A dynamic cohort study. *Family practice*. 2008;25(4):233-6. Epub 2008/06/20. doi: 10.1093/fampra/cmn030. PubMed PMID: 18562333.