

Emerging international evidence on prevention: Do pacifiers reduce the risk of SUDI?

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Why is there an issue about Pacifiers?

- First study – Mitchell et al. 1993
- Meta-analysis - Hauck et al. 2005
- Additional studies – one with sub-group analyses for high risk groups – Li et al. 2005
- The struggle to make further progress, especially for Maori and Pacific Island families
- The statement of the Task Force of the AAP, and the international response to that
- The issues of potential benefits and harms, decision-making in the face of imperfect info, and the complexity of messages

AAP Task Force statement 2005

AAP Policy Statement; Pediatrics 2005; 116(5):1245-55

- Some issues raised:
 - Coding shifts in diagnosis account for some of the SIDS decline in recent years
 - Risk of side-sleeping
 - Need to avoid excess soft bedding and objects
 - Hazard of adult bed-sharing
 - **Decreased risk associated with pacifier use at time of sleep**
 - Highlighting education of secondary caregivers and NICU caregivers about 'back to sleep'
 - Strategies to reduce head shape changes with supine placement

Agenda outline

- International literature on risk and protective factors
- Pacifiers and SIDS
 - Meta-analysis
 - Further study
 - Weighing it all up
- Where to from here
 - My view?
 - Your views
 - ... Our views...

International picture

- Rates of SIDS have decreased dramatically all over the world since about the early 1990s, largely due to prevention campaigns, and consistent with a steady decrease in prone sleeping
- SIDS remains a leading cause of infant death

Known risk factors - good evidence

- Sleeping prone (on front)
- Side sleeping has greater risk than exclusive supine sleeping
- Parental smoking (esp. mothers in pregnancy)
- Bed sharing (with parents who are smokers)
- Covering baby's head with bedding; redundant soft bedding/objects, esp if prone
- Overheating
- Late or no prenatal care
- Preterm birth and/or low birthweight
- Demographic factors – eg age, ethnicity, males, young and single mothers, low SES, higher parity,

Possible risk factors - emerging

- Bed sharing for non-smokers
 - At least in some situations
- ?Nicotine from NRT Rx

Possible protective factors - emerging or unclear

- ?Breastfeeding
- ?Adults sleeping in the same room as baby
 - UK Dept Health recommends babies sleep in a cot in parents' room for 1st 6/12
- Pacifiers (dummies), esp at time of last sleep

Pacifiers – the issues

- Studies have reported a lower risk of SIDS related to dummy use in the index sleep
- Is this real? – How good were the studies?
- Could it be causal?
- Can the findings of these studies be generalised – to NZ overall? - to Maori, Pacific children?
- Would there be more benefits than harms from recommending Pacifier use to prevent SIDS?
- What don't we know?



Pacifiers – the studies

1 st Author, yr	Location	Years	Cases: Controls
Mitchell, 93	NZ	87-90	485:1800
Arnestad, 97	Norway	84-92	121:307
Fleming, 99	UK	93-96	318:1299
L'Hoir, 99	Netherlands	95-96	73:146
Tappin, 02	Scotland	96-00	131:278
Hauck, 03	USA	93-96	260:260
McGarvey, 03	Ireland	94-98	203:622
Carpenter, 04	Europe	92-96	745:2411
Vennemann, 05	Germany	98-01	333:998
Li, 06	California	97-00	185:312

Systematic reviews and meta-analyses

– Greenhalgh, BMJ 1997

- A systematic review is an overview of primary studies that uses explicit and reproducible methods
- A meta-analysis is a mathematical synthesis of the results of two or more primary studies that addressed the same hypothesis in the same way
- Although meta-analysis can increase the precision of a result, it is important to ensure that the methods used for the review were valid and reliable

Meta-analysis

- Calculation of a single summary statistic for each study included
- Comparisons made between 'like' groups
- Common effect calculated by averaging the individual study effects

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Hauck F et al. Do Pacifiers reduce the risk of SIDS? A meta-analysis. *Pediatrics* 2005; 116: e716-e723.

- Medline searched to find studies
- Studies reviewed, data extracted
- Studies pooled to give summary OR, CI
- Seven studies were included (Mitchell, Fleming, L'Hoir, Tappin, Hauck, McGarvey, Carpenter).

Results of Hauck et al. meta-analysis Summary odds ratios and 95% CI

	Univariate analyses	Multivariate analyses
Usual pacifier use and risk of SIDS	0.90 (0.79-1.03)	0.71 (0.59-0.85)
Last/reference sleep pacifier use and risk of SIDS	0.47 (0.40-0.55)	0.39 (0.31-0.50)

Additional study from California:

Li et al. *BMJ*, doi:10.1136/bmj.38671.640475.55 (pub 9 Dec 2005)

- Population-based case-control, 185 infants who died from SIDS and 312 control infants randomly selected from birth records (matched on age, county, maternal ethnicity)
- Participn rates: cases 50%, controls 41%
- Adjustment for relevant confounders
- Assessment of effect modification
 - Is risk of SIDS from dummy use different among subgroups based on categories of other risk factors? Eg, do dummies have a greater impact for babies of mothers who bedshare and smoke?

Li et al 2005 – results (i)

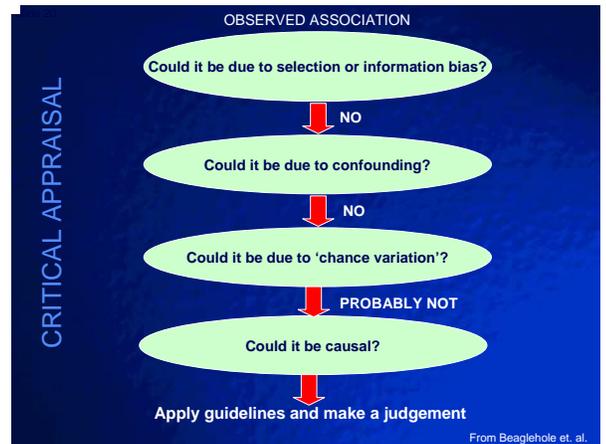
- Adjusted OR for SIDS in relation to dummy use in last sleep = 0.08 (0.03-0.21)
 - Strong and significant protective effect
- Dummies reduced SIDS risk in every category of other SIDS risk factors looked at
- Effect of dummies in reducing risk was stronger among those in an adverse sleep environment, eg prone or side sleeping, maternal smoking, soft bedding
- Thumb sucking was also associated with a reduced risk of SIDS (OR 0.43), but dummy use had an effect independently of this

Li et al 2005 – results (ii)

- Dummy use was associated with a strongly reduced risk of SIDS among those breastfeeding (current or ever) and those not breastfeeding
- Dummy use appeared to eliminate the otherwise negative effects of risk factors such as prone or side sleeping, bed sharing with smoking mothers and sleeping on soft bedding in the last sleep

Effect modification in Li study, adj ORs (95% CI)

Last sleep:	No dummy	Dummy	P for diff in OR
Supine	1.0	1.0	
Prone or side	2.6 (1.6-4.4)	0.7 (0.1-3.6)	0.38
Cosleeping: none or with nonsmoker	1.0	1.0	
With mother who smoked	4.5 (1.3-15.1)	1.1 (0.1-13.4)	0.26
Soft bedding: No	1.0	1.0	
Yes	1.4 (0.8-2.6)	0.3 (0.0-3.3)	0.15



Study quality

- 'Chance variation' – sample size
- Bias
- Confounding

- In my view, these issues don't offer an obvious explanation for the consistent, statistically significant finding of a strong protective effect of dummies, at the present time

Causal criteria

Is there evidence of a cause - effect relationship?

- Time sequence
- Strength of association
- Dose-response relationship
- Specificity of the association
- Consistency of the association
 - Within the study & with other studies
- Experimental evidence
- Biological plausibility

Plausibility:

By what mechanisms could dummies reduce the risk of SIDS?

- Increased arousal/responsiveness
- Increased ability to breathe through mouth & nose if obstructed
- Making it harder for child to turn to a prone position
- Improving relevant muscle tone and helping airway to be open
- Helping to stop the face getting buried in soft bedding that obstructs airway

Alm et al. Acta Paediatrica 2006; 95: 260-262.

Number needed to treat (from meta-analysis)

- If causality is assumed, then NNT is 2733 (95% CI 2416-3334), for 1 SIDS death prevented, based on US national SIDS rate and the last-sleep multivariate summary OR from Hauck et al. 2005.

Generalisability

- To what extent can the results be applied to other populations or groups?
- Eligible population, source population, other relevant populations
- Consider non-participation, whether results are likely to be applicable to other groups, consistency with other evidence and studies, plausibility

Generalisability

- ?? High versus low risk infants
- ??What is the Li et al. paper telling us?

What this study (Li et al) adds

- Use of a dummy during sleep was associated with a reduced risk of SIDS consistently across a wide range of socioeconomic characteristics and risk factor profiles
- Use also reduced the adverse effects of a prone sleep position, sleeping with a mother who smoked, and soft bedding'

Li, et al. BMJ 2006;332:18-22 (7 January)

But, concerning the second point above, remember this is one study and there are issues with participation, study size and power to detect effect modification. We need information on the effects of dummies in high vs low risk groups from other, larger studies as well.

- To recap, there is an effect of pacifier use at time of last sleep that is fairly strong, consistent and statistically significant
- What is the downside?

Pacifiers - potential risks

- Increase in otitis media related to pacifier use
- ? Impact on breastfeeding – initiation, continuation
 - Studies of this: Does pacifier use diminish breastfeeding? Observational studies have related pacifier use to early weaning.
- But ? chicken and egg (Scott et al. Pediatrics 2006)
 - Do dummies cause breastfeeding difficulties?
 - Or have mothers with lower breastfeeding used them because they were already having difficulties
 - Need RCTs as best study design
- RCTs – Canada, USA and Australia

RCTs of pacifier use and breastfeeding

- Kramer et al, JAMA 2001 – total of 281 infants
 - Intention to treat analysis showed no effect of discouraging pacifiers on weaning at 3/12
 - 'As treated' observational analysis showed some effect; in combination this suggests that pacifier use is a marker of BF difficulties rather than causing early weaning
- Howard et al, Pediatrics 2003, 700 infants
 - Bottles/cups for supplemental feeding, pacifiers early vs late. Pacifier use in 1st 4/52 lessened exclusive BF at 1 mth.
- Collins et al, BMJ 2004 – total of 319 infants
 - Preterm infants
 - Dummy use did not affect breast feeding (defined in various ways, up to 6/12 post discharge)
- Need more and bigger studies before we can really say we know the total answer about the impact of pacifiers on breastfeeding

Breastfeeding and health

- Breastfeeding is the best source of nutrition for most new babies
- Lower breastfeeding increases the risks of
 - Bacterial meningitis
 - Glue ear
 - GI & respiratory infections
 - Teeth – malocclusion
 - Breast cancer in mothers
- Breastfeeding reduces the risk of post-neonatal death

Chen and Rogan, Pediatrics 2004:

- Odds ratio for all cause mortality in 'ever BF' vs 'never BF' was 0.79, 95% CI 0.67-0.93

Effects of dummies on health

- Effects other than through breastfeeding, eg increase in otitis media, GI infections, ?malocclusion
 - North et al. Pediatrics 1999, cohort study
- Asphyxia due to pacifiers – very rare; 25 cases, not all fatal, reported in literature in 40 years (Wehner et al. 2003).
- Quantification of total effects – unknown impact of dummies on all-cause mortality and morbidity
- Guidance?
 - AAP recommendations on BF
 - AAP & dummies
 - Messages for bottle vs breast –fed babies

Synthesis of information

- Task Force statement: Evidence of a decrease in SIDS with pacifiers is “compelling”; evidence of potential harm to breastfeeding and teeth is not.

Can recommendations be made yet?

- Recommendations have been made by the Task Force on SIDS of the AAP.
- Others have been taking this up, eg the Swedish group.

Task Force on SIDS (AAP) recommendations – summary (a)

- Promote 'back to sleep' & discourage side sleeping
- Firm sleep surface, avoid soft materials under infant. Firm mattress & sheet
- Keep soft objects & loose bedding out of cot
- No smoking in pregnancy or in infants environment after birth
- Encourage separate sleeping in own cot, in same room as parents; don't bed share during sleep, or when parent v. tired / under the influence. Don't sleep with baby on chair or sofa.
- Consider offering pacifier at nap & bed time
 - Use when putting baby down, don't reintroduce once asleep. Don't force baby to have it.
 - Regular cleaning & replacement, and no sweet coatings
 - For BF infants, delay pacifier till 1/12 to ensure BF establishment

Task Force on SIDS (AAP) recommendations – summary (b)

- Avoid overheating & overbundling
- Avoid commercial devices marketed to reduce SIDS
- Don't use home monitors purely as a SIDS-reducing strategy
- Protect baby's head shape
- Continue 'back to sleep' campaign and intensify educn of secondary caregivers; have a special focus on ethnic groups at particular risk. Ensure professionals in NICUs and well-infant nurseries implement the recommendations well before discharge

Opportunity costs / dilution of other messages known to be impt

- We need to be careful to ensure that existing successful messages are not diluted by new ones or by complexity. Need effective uptake of all important information.

Recommendations of Swedish group (Alm et al. 2006)

- Discourage side sleeping; go for exclusive supine
- When breastfeeding established, 'can very well' use a pacifier at nap and bed time
- Encourage sleeping in same room but different bed (can be increased risk of SIDS with bed sharing if infant <2-3 mths, esp if mother smokes. If mother is over-tired, or taking drugs/alcohol then all bed sharing should be discouraged.
- No nicotine use (and that includes NRT gum and patches too).

Editor's note in J. Hum. Lact. 2006; 22(1):7-10

- On the new AAP recommendations:

"...it is important that lactation consultants recognise the constraints under which medical providers must work. ...[They] carry the risk if adverse outcomes occur...particularly if they ...[deviate] from "best practice" as established by published policy statements....Lactation consultants can play an impt role in providing support for both providers and mothers as they determine how best to protect the infants in their care."

What else do we need to know (i)?

- Risk factor prevalences now, and trends in these over time, for total popn and high risk groups
 - How well is the 'back to sleep' message still impacting?
 - What is the prevalence of side sleeping, and has it gone up as prone has gone down?
 - What do we know about smoking trends now?
- What are the risk factor prevalences and trends among Maori; how do they differ from non-Maori?

What else do we need to know (ii)?

- Impact of pacifiers on breastfeeding from larger RCTs. Impact of breastfeeding on SIDS
- Impact of pacifiers on all-cause mortality and morbidity, from RCTs
- Do pacifiers mitigate the effects of other SIDS risk factors? – need info from other studies to supplement that from the Li study
- Are pacifier findings generalisable to all ethnic groups?

Possible alternative options for NZ concerning pacifiers

- Embrace the Task Force recommendations on pacifiers (and other interventions) in a renewed public health campaign – or similar
 - Take care not to dilute existing messages
- ?Wait for further information about possible harms on pacifiers
 - Are there studies underway? Can they be done?
 - Need large numbers; issue of contamination
- Have informed one-to-one conversations with mothers about benefits and potential harms – difficult
- Promote existing messages harder / better
- Other options?
- Universal vs targeted vs combination
- Enablement vs suggesting
 - With pacifiers, move from 'You shouldn't' to 'you can' or 'you should'?