

Recommendations for the use of pacifiers



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Pacifiers, also known as soothers, dummies and artificial teats are as rooted in history as they are in controversy. Pacifiers made of clay, silver, pearl or coral, and sugar teats have been described, some dating back to over thousands of years (1,2). Pacifier use is still widespread in today's culture, and a recent Canadian trial reports up to 84% of infants use one at least some of the time (3).

Pacifiers have been implicated in early weaning (4-11), increased frequency of otitis media (12-16) and dental problems (17-19). Other commonly held beliefs criticize pacifiers for interfering with speech development and normal sleep habits. However, there is a growing body of research on pacifiers and their possible protective effect against sudden infant death syndrome (SIDS) (20-24). Clear benefits are seen with pacifier use during painful procedures, self-soothing and non-nutritive sucking in the term and preterm infant (25-27).

This statement reviews the available evidence to provide recommendations about the use of pacifiers in healthy term infants and children. A special section is included for the preterm infant. Systematic review of the literature was performed using Medline and Cochrane Library databases, limited only to English language articles. A manual search of the citations from these references was also used.

PACIFIERS AND BREASTFEEDING

Step nine of the United Nations Children's Fund/World Health Organization "Baby Friendly Hospital Initiative: Ten Steps to Successful Breastfeeding" states "give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants"(28). This advice is widely disseminated by health care professionals and laypersons alike. It is supported by several observational studies showing a strong association between pacifier use and early weaning (4-11). Many breastfeeding experts warn that pacifier use may contribute to 'nipple confusion' or nipple preference, especially if introduced before breastfeeding has been fully established.

A recent randomized controlled trial done by Kramer et al (3) in Montreal, Quebec, compared two groups of mother-infant pairs and followed them for three months postpartum.

Both groups received a counselling intervention that promoted breastfeeding and discussed ways to calm a fussy baby. In addition, the experimental group was counselled to avoid pacifiers. They found a significant difference in pacifier avoidance (38.6% versus 16.0%) but no difference in rates of weaning before three months of age (18.9% versus 18.3%). In the observational analyses, however, pacifier use was strongly associated with early weaning. They concluded that pacifier use may be a marker of breastfeeding difficulties or reduced motivation to breastfeed, rather than a true cause of early weaning.

Another study randomly assigned healthy newborns to strict adherence to the United Nations Children's Fund/World Health Organization guidelines and another group to conventional care (29). Both groups were actively encouraged to breastfeed. They found no significant differences in breastfeeding frequency or duration in the first six months of life, despite high rates of pacifier use in both groups (69% to 76%).

La Leche League International recommends that pacifiers never be used as a substitute for the mother's breast or comforting. However, they also state that pacifiers can be of help to a breastfeeding mother when used judiciously, for short periods of time and in limited circumstances (30).

Pacifier use may be an identifiable factor in early weaning. However, because of the many possible confounders and biases in studying human behaviour, the exact cause and effect nature of this factor remains elusive.

PACIFIERS AND OTITIS MEDIA

Because of the high burden of illness of otitis media, it would be convenient to at least partially blame pacifier use, a controllable yet controversial risk factor. If pacifiers are a cause of early weaning (see above) and if breastfeeding is protective against otitis media (12,31,32) then it could be argued that pacifiers also contribute to the cause of otitis media. It has been suggested that pacifiers are fomites with high infectivity, although a study that cultured 40 recently used pacifiers found microorganisms on only 52.5% of paci-

fiers, meaning the other half of the pacifiers were surprisingly uncontaminated. The most common organism was alpha-hemolytic streptococci. The pacifiers were negative for the major pathogens that cause otitis media (33).

Pacifier sucking may impair the functioning of the eustachian tube by changing its patency, and the pressure balance between the nasopharynx and the middle ear. In one study, pacifier sucking was found in 40% of 601 children with chronic otitis media who required tympanostomy tubes in Toronto, Ontario (34).

A research group from Finland stated that pacifier use is a significant risk factor for acute otitis media in a prospective study of children in day care centres (13), and in a meta-analysis of risk factors for otitis media (12). Their most recent study looked at the effect of parental counselling about pacifier use and the subsequent occurrence of otitis media in these children (14). The intervention group received counselling on the negative aspects of pacifiers. Interestingly, at the end of the study, there were more children still using a pacifier in the intervention group than the control group (68% versus 66.5%). However, fewer children in the intervention group used it continuously and the occurrence of acute otitis media was decreased by 29% in this group. Their results suggested that restricting pacifier use to the moments of falling asleep would reduce the occurrence of acute otitis media. Based on their earlier work, they have also suggested that pacifier use be restricted to the first 10 months of life when the need to suck is strongest and the risk of acute otitis media is low.

A recent survey of parents of children aged 12 months or younger also found the risk of developing otitis media to be twice as high in pacifier users (15). This study was limited by a random definition of pacifier use being greater than 5 h per day, and the reliability of parental reporting. A similar study based on questionnaire reporting by parents of infants in their first year of life, found the occurrence of otitis media higher in pacifier users (OR 1.20) (16).

Pacifier use appears to be a risk factor in the development of otitis media; however, it is only one of the many factors involved in the pathogenesis. The pacifier's culpability seems to increase with prolonged and more frequent use.

PACIFIERS AND DENTITION

Dental caries, malocclusion and gingival recession are commonly cited problems associated with pacifiers. Most studies have found that these problems exist only with prolonged (after age five) or inappropriate use (sweetened pacifier) (17).

A recent study showed significant differences in dental arch and occlusion characteristics in users at 24 months and 36 months of age compared with those that had stopped sucking by 12 months of age (18). Another study looked at children aged two to five years and also found significant increases in overjet (greater than 4 mm), openbite and posterior crossbite in pacifier users. The longer the use was, in months, the stronger the association with openbite and crossbite (19).

Both the Canadian Dental Association (CDA) and the American Dental Association (ADA) have similar publications on the appropriate use of pacifiers (35,36). The CDA recommends pacifiers over thumb sucking because it is easier for a parent to control the sucking habit. They advise against putting sugar, honey or corn syrup on a soother because of the risk of promoting caries. They state that a sucking habit should stop before the permanent teeth erupt. The ADA also advises parents who choose to use a pacifier to use a clean, unsweetened one. They state that although prolonged use can harm the teeth, it is easier to wean a child's sucking habit from a pacifier than from a thumb.

PACIFIERS AND SUDDEN INFANT DEATH SYNDROME

Currently, four research teams have published studies showing an association between pacifier use and a reduced risk of SIDS. The best available evidence comes from case control studies that examined the sleep positions and sleep environments of infants, including the use of pacifiers, with parental interviews or questionnaires. There are no studies showing an increased risk.

Mitchell et al (20) from New Zealand compared 485 deaths due to SIDS with 1800 control infants. They report that pacifier use was significantly less in cases than in controls (OR 0.44, 95% CI 0.26-0.73). This observation was made even before their National Cot Death Prevention Campaign began in 1992.

Arnestad et al (21) from Norway reviewed 121 SIDS deaths and found only 10% 'always used' a pacifier, compared with 24% of controls. They conclude that the use of a pacifier could be a favourable factor in preventing SIDS.

In 1998, L'Hoir et al (22) in the Netherlands reported 12% of cases versus 48% of controls used a pacifier (OR 0.19). Their conclusions state that pacifiers should be recommended, at least for bottle-fed babies.

Fleming et al (23) from the United Kingdom undertook a three-year case control study as part of the large population based Confidential Enquiry into Stillbirths and Deaths in Infancy study. They found no difference between cases and controls in routine use of a pacifier. However, fewer SIDS infants used a pacifier for their last sleep than did controls for their reference sleep (OR 0.62, 95% CI 0.46-0.83). This led to the suggestion that only those babies who routinely use a pacifier but who do not do so for their last sleep are at higher risk for SIDS.

The Chicago Infant Mortality Study (24) examined the sleep environment in 260 SIDS deaths within a primarily black, urban population to help reduce the incidence in this high-risk group. They found the use of a pacifier substantially lowered the risk of SIDS in their sample population (OR 0.3).

There are many theories on how pacifiers might be protective in the sleep environment. This is also of interest to those speculating on the exact mechanism of SIDS (37), since its incidence dropped dramatically after the Back-to-Sleep campaign in Canada and similar campaigns abroad.

One recent study suggests that pacifiers lower the auditory arousal threshold (38). They may provide a mechanical barrier to rolling over into the prone position. Sucking on a pacifier keeps the tongue forward maintaining upper airway patency. An infant who is soothed by a pacifier may not move as often during sleep, thus limiting the chance of becoming covered by blankets. Others postulate that pacifiers might reduce gastroesophageal reflux and subsequent apnea. It has also been suggested that pacifier use could lead to slight carbon dioxide retention and increase the respiratory drive.

Based on the above evidence, there appears to be an association between the use of a pacifier and a reduced risk of SIDS. The pathophysiology of SIDS, upon which pacifiers may exert a positive effect, remains unclear. No recommendation to use pacifiers to reduce the risk of SIDS can be made at this time. However, the evidence is sufficient that paediatricians and other health care professionals should be cautious before routinely advising against their use.

PACIFIERS AND INFECTION

Pacifiers are frequently colonized with microorganisms. The question is whether or not this colonization leads to clinically significant infection. One study cultured and followed 95 healthy children aged one to 24 months, for yeast (39). None developed oral candidiasis, but those who used a pacifier were almost twice as likely as controls to be colonized with any candida species (52% versus 28%, $P < 0.02$). The pacifiers also cultured positive for *Candida albicans* in 22% of silicone pacifiers and 75% of latex pacifiers. The authors suggested that the smoother surface of the silicone contributed to this difference.

As mentioned above, Brook et al (33) cultured recently used pacifiers and found only 21 out of 40 positive. These were mostly gram-positive organisms. Five were positive for *C. albicans* and none were positive for *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*. They speculate on the inhibitory activity of the pacifier material and the survival of oral flora on wet pacifiers.

The Avon Longitudinal Study of Pregnancy and Childhood is a population-based study from the United Kingdom following over 10,000 infants (40). This study group looked at infections associated with pacifier and digit sucking behaviour in 15-month-old children. Mothers were asked to report on the general health of their children up to 18 months of age. They found that children who sucked their digit were more likely to have had any reported infection (undefined) compared with those that sucked a pacifier, but those that sucked both were at highest risk (pacifier OR 1.07, digit OR 1.18, both OR 1.46). The clinical significance and causality of these results are unknown. Further study is ongoing with this cohort.

Based on the above evidence, pacifiers can be considered a fomite, but their ability to cause clinically significant infections is questionable. The appropriate care and cleaning of pacifiers will limit contamination and should still be stressed to parents.

PACIFIERS AND ANALGESIC EFFECT

In its position statement, "Prevention and management of pain and stress in the neonate", the Canadian Paediatric Society refers to the use of pacifiers as a simple comfort measure to be used whenever possible for minor painful procedures (25). This nonpharmacological intervention has also been reviewed as an analgesic along with the effects of oral sucrose (26). Most studies have shown a synergistic analgesic effect with the use of oral sucrose or glucose plus non-nutritive sucking on a pacifier. However, in a randomized trial of the analgesic effects of sucrose, glucose and pacifiers in term infants, pacifiers were superior to either of the sweet solutions (27). The use of a pacifier during painful procedures in both term and preterm neonates is a simple, noninvasive and effective adjunct in pain management.

PRODUCT SAFETY

There are case reports in the literature of accidental hangings, aspirations and facial trauma due to makeshift pacifiers. The Hazardous Products (Pacifiers) Regulations of the Health Protection Branch of Health Canada came into effect in 1974 (41). The policy outlines the appropriate design and construction of pacifier products. It was amended in 1996, after several deaths occurred with the use of rigid products, to specify that pacifiers must have a collapsible or hinged handle and it states, "any loop of cord or other material attached to the product is not more than 14 inches in circumference" (41). Health Canada is continuing to monitor pacifier products, including levels of di-isononyl phthalate (DINP), a polyvinyl chloride (PVC) used to soften plastic products (42). To date, pacifiers are not considered a risk for DINP since a comprehensive review of the Canadian marketplace did not identify its presence in any pacifier. Pacifiers currently available in Canada are made of latex or silicone. In 1985 Health Canada also issued a policy for determining levels of N-nitrosamines, carcinogens leached from rubber, in the rubber used for bottle nipples and pacifiers. This policy was revised in 2002 (43) to regulate N-nitrosamine levels at less than 10 ppb. Health Canada's booklet "Is your Child Safe?" provides information to parents about pacifier safety (44).

PACIFIERS AND THE PRETERM INFANT

Sucking on hands and digits is an innate behaviour seen both in the fetus and the neonate. This non-nutritive sucking is now considered part of routine developmental care of the preterm infant facilitated by the use of pacifiers (45). Non-nutritive sucking provides comfort, state regulation and an opportunity to organize oromotor development. More rapid weight gain, lower incidence of necrotizing enterocolitis and earlier hospital discharge have also been attributed to non-nutritive sucking during nasogastric tube feedings (46).

A recent systematic review from Hamilton, Ontario analyzed 19 studies on non-nutritive sucking (47). This was done as part of the Neonatal Collaborative Review Group for the Cochrane Collaboration using standard review

protocol. They found that non-nutritive sucking significantly decreased the length of hospital stay (mean -7.1 days, 95% CI -12.6 to -1.7). Even though non-nutritive sucking showed no significant effect on other outcome measures such as weight gain, age to full oral feeds, behavioural state, heart rate or oxygen saturations, it was not found to have any negative outcomes. Longer-term follow-up is needed to establish the full impact of non-nutritive sucking on the preterm infant.

SUMMARY

The decision to use pacifiers in infants and children remains controversial and an individual choice for today's parents. Many experts agree that pacifiers may be associated

TABLE 1
New grades for recommendations from the Canadian Task Force on Preventive Health Care for specific clinical preventive actions

Level of evidence	Description
I	Evidence obtained from at least one properly randomized trial.
II-1	Evidence obtained from well-designed controlled trial without randomization.
II-2	Evidence obtained from well-designed cohort or case controlled analytic studies, preferably from more than one centre of research group.
II-3	Evidence obtained from comparisons between times and places, with or without the intervention. Dramatic results in uncontrolled experiments could also be included in this category.
III	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.
Grades	
A	There is good evidence to recommend the clinical preventive action.
B	There is fair evidence to recommend the clinical preventive action.
C	The existing evidence is conflicting and does not allow making a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.
D	There is fair evidence to recommend against the clinical preventive action.
E	There is good evidence to recommend against the clinical preventive action.
I	There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

The task force recognizes that, in many cases, patient-specific factors must be considered and discussed, such as the value the patient places on the clinical preventive action, its possible positive and negative outcomes, and the context or personal circumstances of the patient (medical and other). In certain circumstances where the evidence is complex, conflicting or insufficient, a more detailed discussion may be required. Data from reference 48

with otitis media, early weaning and dental problems, but the nature of this association along with the scope of this negative impact is still unclear. Pacifier use may be protective against SIDS, which is significantly consequential, and indeed further research is needed to validate this claim. Due to the lack of strong evidence, either for or against the use of pacifiers, selective use and safe use cannot be over-emphasized to those who choose them. Paediatricians and other child health care providers must be vigilant in advising parents on the appropriateness of pacifier use (see parent handout) and be aware of the available evidence to date to support this advice.

RECOMMENDATIONS

- Counsel about safe and appropriate use of pacifiers should be part of routine anticipatory guidance in the care of newborns, infants and children.
- Until further research leads to more conclusive evidence on adverse outcomes, health care professionals should recognize pacifier use as a parental choice determined by the needs of their newborn, infant or child.
- Early pacifier use should signify to health care professionals possible breastfeeding difficulties (evidence level I, grade A [Table 1]).
- Infants and children with chronic or recurrent otitis media should be restricted in their use of a pacifier (evidence level II-2, grade A).
- Pacifiers should not be routinely discouraged as the current evidence suggests a decreased risk of sudden infant death syndrome associated with their use (evidence level II-2, grade A).
- Pacifiers should continue to be used in neonatal intensive care units for non-nutritive sucking and comfort in the preterm or sick infant (evidence level I, grade A).

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Principal author: Dr Michelle Ponti, Sudbury, Ontario

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.