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The pacifier debate ☆

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ABSTRACT

A variety of studies have indicated that pacifier use lowers the risk of SIDS. Many observational studies have demonstrated a negative association between pacifier use and breastfeeding duration. However, observational studies cannot be used to determine whether the pacifier is the real cause of breastfeeding cessation. Evidence for causation can be better supplied by randomised controlled trials (RCTs). Three RCTs have been conducted on the relationship between pacifiers and breastfeeding, but each study has limitations, implying that the evidence of not causal effect can be questioned. We have recently presented the results of a large RCT which demonstrated that in mothers who are successfully breastfeeding at 2 weeks, the recommendation to offer a pacifier does not modify the prevalence of exclusive and any breastfeeding at different ages or the duration of lactation.

It is therefore important that lactation consultants and international agencies reexamine their staunch position to discourage the use of pacifiers on the basis of a supposed adverse effect on the success and duration of breastfeeding.

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1. Introduction

Pacifiers are a nearly universal symbol of babyhood. The use of pacifiers is quite common in many countries around the world. 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]. Excavations in Italy, Cyprus and Greece suggest that pacifiers are at least 3000 years old [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].

Pacifier use has always been a controversial topic since the recommendations for or against its use have been grounded on either its benefits or drawbacks. Pacifiers have been implicated in early weaning [4–11], increased frequency of otitis media [12–16], and malocclusion [17]. Clear benefits are seen with pacifier use during painful procedures, self-soothing and non-nutritive sucking in the term and preterm infant [18–20]. Pacifiers provided to premature infants reduce the length of hospital stay [21]. In addition, more recently, several studies have shown that the use of a pacifier protects against Sudden Infant Death Syndrome (SIDS) [22–26].

2. Non-nutritive sucking

Non-nutritive sucking (NNS), defined as sucking without the delivery of fluid, is a naturally occurring phenomenon recognised as a pacifying mechanism for preterm and term infants, also present among domesticated animals. Thumb sucking and other sucking movements have been seen by prenatal ultrasound in human foetuses as early as the 12th week of gestation [27]. A significant number of children are born with blisters on their fingers caused by sucking in the womb.

NNS is a natural function that should be viewed as a component of the total sucking experience and plays an important role in the clinical well being of the infant [28]. It is clear that sucking alters or modulates the behavioural state of the infant [29]. One has to say that the main obvious function of a pacifier is to replace the tendency of an infant to suck on thumbs, fingers or even toes. Indeed, what is also clear is that, perhaps less than 5% of children suck on both a pacifier and a finger [30,31].

Why is the replacement of thumb sucking important?

1. Pacifiers can be sterilised, thumbs cannot.
2. Secondly, there is a great deal of both observational and research evidence that a pacifier sucker gives up the habit before a thumb sucker. Larsson's data demonstrate that at the age of 3 years, over twice as many children are still sucking a thumb as compared to pacifiers, although at the beginning there were significantly more pacifier suckers than thumb suckers.
3. Most important, there is evidence today that pacifier use significantly reduces the risk of SIDS.

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2.1. Sudden infant death syndrome and pacifier use

In 1979, Cozzi et al. postulated that pacifiers might protect against SIDS [32]. In 1993 Mitchell et al. published a landmark study on research they had carried out in New Zealand. It was concluded that pacifiers used routinely or in the reference sleep, reduced the risk of SIDS by 24% and 56% respectively [22]. To date, several case–control studies and two meta-analyses have confirmed this finding [33,34].

Two meta-analyses of 7 case–control studies have shown a protective effect for pacifier use, particularly when used at bedtime. Hauck's meta-analysis has shown that the risk of SIDS is reduced in as much as 61% [32]. The summary odds ratio calculated for usual pacifier use was 0.71 (95% CI: 0.59–0.85). For pacifier use during last sleep, summary odds ratio was 0.39 (95%CI: 0.31–0.50). The study by Mitchell et al. reports the pooled odds ratios (ORs) from case–control studies that examined the association between pacifiers and SIDS. On the basis of routine pacifier use, the pooled OR was 0.83 (95% CI: 0.75–0.93) and for the last sleep, the pooled OR was 0.48 (95% CI: 0.43–0.54) [34]. The results of both meta-analyses, including studies performed in various countries and including infants of different social levels, are remarkably consistent, showing that the use of pacifiers is associated with an approximate halving of the risk of SIDS. Even more, a recent study from California has strengthened these conclusions by reporting a 90% reduced risk of SIDS among pacifier users during last sleep compared with control infants (adjusted OR: 0.09; 95CI:0.04–0.25). This strong association was present among breastfed and bottle-fed infants [35].

Several mechanisms have been postulated to explain the protective effect of pacifiers, but none has been universally accepted. It has been suggested that the use of a pacifier, similarly to the supine sleeping position, decreases the threshold for infant arousal [36], meaning that a child who is placed to sleep with a pacifier requires less stimulation to wake up. Decreased arousal responsiveness to a life-threatening challenge such as obstructive apnoeas, cardiac arrhythmia, or external conditions leading to hypoxia and asphyxia has been implicated in SIDS.

L'Hoir et al. suggested that the presence of a pacifier in the mouth might prevent the infant from turning his face straight down and thus preventing obstruction of mouth and nose [37]. Mitchell et al suggested that continuous sucking would also increase the tension of the muscles of the upper airway, keeping the tongue in a more forward position and so protecting the airway [22].

3. Relationship between sudden infant death syndrome and breastfeeding

One meta-analysis of 23 studies reported an overall risk of SIDS twice as high for formula-fed infants compared with breastfed infants (crude odds ratio of 2.11; 95%CI 1.66 to 2.68) [38]. The studies differed in their definition of breastfeeding exposure. Also, the studies varied in their description of SIDS. Three studies were specifically designed to examine the relationship of breastfeeding and SIDS. Recently, the USA Agency for Healthcare Research and Quality (AHRQ) has performed a more stringent meta-analysis incorporating 6 studies in which SIDS was rigorously defined and the duration of breastfeeding specified [39]. They found that ever breastfeeding reduced the risk of SIDS compared with never breastfeeding, with an adjusted odds ratio of 0.64 (95% CI 0.51–0.81).

Therefore, breastfeeding should be recommended not only for the well known benefits associated to its practice but also for this protective effect against SIDS.

4. Pacifiers and breastfeeding

The association between pacifier use and duration of breastfeeding remains highly controversial. In the late 1980s, the World Health Organization and UNICEF adopted avoidance of pacifiers as one of the Ten

Steps of Successful Breastfeeding. Step 9 of the programme states: "Give no artificial teats or pacifiers to breastfeeding infants" [40].

The potential impact of pacifiers on breastfeeding should be clearly understood especially now that the American Academy of Pediatrics guidelines recommend the use of the pacifier in infants at bedtime to reduce the risk of SIDS [41]. The recommendations have caused a broad discussion among lactation consultants [42].

Many observational studies have been published indicating a strong negative association between pacifier use and breastfeeding duration [6,8,10,11,43]. However, observational studies cannot determine if pacifier use causes breastfeeding cessation or if it was decreased breastfeeding which led to increased pacifier use. Does pacifier use have an adverse effect on breastfeeding? Or is it simply a marker of breastfeeding difficulties or of an attempt to wean the baby? Evidence for causation can be better supplied by randomised controlled trials (RCTs) where pacifiers are introduced at a set time.

RCTs have not shown that providing pacifiers results in shortened breastfeeding duration, except when pacifiers are given in the first 5 days. In multivariate analyses, Howard found that pacifier use in the first 5 days versus pacifier use after 4 weeks postpartum was associated with shorter breastfeeding duration [44].

A Swiss trial of healthy breastfeeding newborns evaluated the effect of the avoidance of pacifier, bottle, and supplemental feeding for the first 5 days versus no restrictions on pacifiers and fluid supplementation [45]. They found no differences in breastfeeding duration. This study was not designed to evaluate separately effects of pacifiers and bottle–nipple exposure. The intervention was limited to the peripartum hospitalisation period.

A more recent trial by Kramer et al., looking at a longer period of pacifier avoidance, randomised mothers of healthy full-term breastfeeding infants during the postpartum stay to groups that were either counselled in pacifier avoidance or given no specific counselling in pacifier use [3]. Although an association between pacifier use and early weaning from the breast was found, no such association was seen when the data were analyzed by group allocation. Because of the wide confidence intervals reported in the trial, a larger sample would have been required to exclude small changes in the risk of early weaning in relationship to counselling.

Given the scarcity of studies with sufficient power and rigorous design to address the impact of recommending pacifiers on breastfeeding, we conducted a multicentre, randomised, single blind, non-inferiority trial to assess the effects of such a recommendation on breastfeeding prevalence and duration [46]. The population included 1023 mothers highly motivated to breastfeed whose newborns regained birth weight by 15 days who were assigned to offer vs. not to offer pacifiers. Our RCT found no differences in the primary outcome (exclusive breastfeeding at 3 months), in the prevalence of exclusive and any breastfeeding at any monthly time points or in the total duration of breastfeeding [46].

5. Conclusions

There is no doubt that breastfeeding is clearly beneficial in many aspects for infants and their families. Health care workers should therefore promote this practice by appropriate counselling. Pacifiers are commonly used to prevent infant crying and their need is more frequent when breastfeeding is being abandoned. Although prevalence and duration of breastfeeding are lower in infants who use pacifiers, several RCTs demonstrate there is no link between the advice to use a pacifier and the success and duration of breastfeeding. Our large RCT has demonstrated that when mothers are determined to breastfeed for more than 3 months, and they are successfully breastfeeding at 2 weeks, the advice to use or not to use a pacifier does not affect breastfeeding. On the grounds of current knowledge on the association of pacifier use and decreased incidence of SIDS, we suggest that physicians, nurses and associations for the promotion of lactation

modify their advice: once breastfeeding is well established, appropriate use of pacifiers should be recommended to assure safer sleep for our infants.

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