



Pacifiers and breastfeeding

Guest editor: Simona Di Mario¹

The place of pacifiers in the history of nursing dates back to ancient times: small clay objects given to infants to suck honey have been found in 3000-year-old babies' tombs. Pieces of fabric tied around food or soaked in sweet or alcoholic fluids were used from the 16th century onwards to calm newborn infants, as attested by the *Madonna with a Siskin*, a 1506 painting by Albrecht Dürer.² The use of pacifiers has been inversely linked to breastfeeding practice: at the end of the pre-industrial era, breastfeeding became less frequent while the use of pacifiers increased. Since 1970, with the resurgence of breastfeeding, pacifier use has become a hot topic of discussion among health professionals.

The main elements of the current debate on pacifiers

On the one hand, the use of pacifiers is thought to have negative effects:

- It may be an obstacle to adequate initiation and duration of breastfeeding. A recent Cochrane review, carried out to assess the effect of pacifiers on breastfeeding, has added more confusion than clarification to the topic.^{3,4}
- Prolonged use of pacifiers is associated with several child health problems such as a higher incidence of acute otitis media and dental malocclusion.

On the other hand, some researchers highlight the possible benefits associated with pacifiers:

- Pain control during small invasive procedures (venipuncture, vaccination).
- Some protection against Sudden Infant Death Syndrome (SIDS).

However, none of the studies supporting the protective effect of pacifiers on SIDS show as strong an effect as that observed for actual breastfeeding.^{5,6} As evidence accumulates on the protective effect of breastfeeding against SIDS,⁷ and as professional societies add breastfeeding as one of the six preventive interventions

¹ Paediatrician, MPH, SaPeRiDoc Servizio assistenza distrettuale, medicina generale, pianificazione e sviluppo dei servizi sanitari, Regional Health Authority of Emilia-Romagna, Bologna, Italy, e-mail: sdimario@regione.emilia-romagna.it

² Castilho SD, Rocha MA. Pacifier habit: history and multidisciplinary view. *J Pediatr (Rio J)* 2009;85:480-9

³ Jaafar SH, Jahanfar S, Angolkar M, Ho JJ. Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding. *Cochrane Database Syst Rev* 2011 Mar 16;3:CD007202

⁴ Jaafar SH, Jahanfar S, Angolkar M, Ho JJ. Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding. *Cochrane Database Syst Rev* 2012 Jul 11;7:CD007202

⁵ Hauck FR, Omojokun OO, Siadaty MS. Do pacifiers reduce the risk of sudden infant death syndrome? A meta-analysis. *Pediatrics* 2005;116:e716-23

⁶ Moon RY, Tanabe KO, Yang DC, Young HA, Hauck FR. Pacifier use and SIDS: evidence for a consistently reduced risk. *Matern Child Health J* 2012;16:609-14

⁷ Hauck FR, Thompson JM, Tanabe KO, Moon RY, Vennemann MM. Breastfeeding and reduced risk of sudden infant death syndrome: a meta-analysis. *Pediatrics* 2011;128:103-10.

See also *Breastfeeding Briefs*, issue 53, September 2012, www.ibfan.org

against SIDS,^{8,9} the risk that the promotion of pacifiers will reduce breastfeeding potentially places infants at higher risk not only for SIDS but also for all other conditions associated with inadequate breastfeeding. In this edition of *Breastfeeding Briefs* we discuss the evidence behind these issues.

Pacifiers and breastfeeding

In 2011, the Cochrane Library published a systematic review of randomized controlled trials (RCTs) titled *Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding*.³ Based upon two RCTs,^{10,11} the authors of the Cochrane review concluded that “Pacifier use in healthy term breastfeeding infants, started from birth or after lactation is established, did not significantly affect the prevalence or duration of exclusive and partial breastfeeding up to 4 months of age”. However, the Cochrane review did not take into consideration another RCT that reported a correlation between the use of pacifiers and breastfeeding discontinuation at 4 weeks.

The conclusions of the Cochrane review are not acceptable due to several severe flaws:

- High rate of contamination between intervention groups, i.e. the possibility that people allocated to one group learn and practice the intervention assigned to the other group. Mothers in the pacifier group used pacifiers in 71% of the cases, whereas mothers in the non-pacifier group used pacifiers in 44% of the cases (overall rates). Excess contamination between two treatment groups points to no difference or inconclusive results.
- The larger of the two studies included (1,021 infants out of a total of 1,302)¹⁰ had such strict exclusion and inclusion criteria that the population observed did not represent a “real” one. For example, the extremely high rate of exclusive breastfeeding at 3 months for both groups (> 85%) is much superior to the rate commonly seen in Europe (e.g. 48% in Italy, and in Sweden, between 68% at 4 months and 79% at 2 months).^{12,13} Inclusion criteria in the study under discussion were: participating hospitals had established breastfeeding programmes with early initiation of breastfeeding, lactation consultants and unrestricted rooming-in; mothers were encouraged to avoid pacifier use until breastfeeding was well established; at term healthy infants, exclusively breastfeeding, whose mothers had reported an intention to breastfeed for at least 3 months; non-use of pacifiers and lactation well established at the age of 2 weeks. Exclusion criteria were: breast problems that could interfere with breastfeeding (persistently sore nipples, mastitis, earlier breast surgery, and severely flat or inverted nipples); mothers who expressed a preference for or against the introduction of a pacifier were also excluded.
- The second, smaller, RCT (281 infants enrolled) included in the review, also suggests that the null effect of pacifiers on breastfeeding could be a false conclusion.¹¹ The authors presented the results based on actual exposure, in addition to the analysis based on exposure as assigned by randomization, to take into account the high contamination rate for pacifier use. The analysis by actual exposure showed a significant difference: in pacifier users the risk of early weaning (by 3 months) doubled compared to non-pacifier users.

⁸ American Academy of Pediatrics, Task Force on Sudden Infant Death Syndrome, Moon RY. SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics* 2011;128:e1341-67

⁹ Young J, Watson K, Ellis L, Raven L. Responding to evidence: breastfeed baby if you can--the sixth public health recommendation to reduce the risk of sudden and unexpected death in infancy. *Breastfeed Rev* 2012;20:7-15

¹⁰ Jenik AG, Vain NE, Gorestein AN, Jacobi NE; Pacifier and Breastfeeding Trial Group. Does the recommendation to use a pacifier influence the prevalence of breastfeeding? *J Pediatr* 2009;155:350-4.e1

¹¹ Kramer MS, Barr RG, Dagenais S, Yang H, Jones P, Ciofani L, Jané F. Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. *JAMA* 2001;286:322-6

¹² Cuoghi C, Di Mario S, Borgini B, Bragliani M, Castelli E, Tramonti D. Prevalence of breastfeeding and other preventive intervention in Emilia-Romagna Region in 2011. [Prevalenza dell'allattamento al seno e altri interventi preventivi in Emilia-Romagna. Ricerca triennale Anno 2011] Sixth Edition. Bologna: Regione Emilia-Romagna; Oct. 2012

¹³ Statistics Health and Diseases. Breastfeeding, children born in 2002. The National Board of Health and Welfare. Centre for epidemiology. Stockholm 2004 [Swedish, summary in English].

- The larger of the trials included had a significant conflict of interest. As the authors of the Cochrane review admitted later on, the study had been funded by an association established in Switzerland by a company that produces pacifiers.¹⁰

Based on the methodological flaws and relevant conflict of interest detected in this systematic review, I and other colleagues sent a comment to the Cochrane Library editorial team and to the review authors.¹⁴ It took months before our comment was published and even more before the authors of the review published an answer and modified the text of the review. The title was modified, some amendments were added, the conflict of interest was revealed, but the conclusions remained substantially the same.⁴ Thus, the original message to health professionals, misleading as it is, remains: do not discourage pacifiers, as they do not interfere with breastfeeding. Based on the critical appraisal of the systematic review, and on the positive results of an association derived from one excluded RCT¹⁵ and from several other observational studies,^{16,17} it is the contrary that seems more probable.

Pacifier use and other negative effects

Possible interference with breastfeeding is only one of the undesirable consequences associated with pacifier use. Descriptions of risks and benefits of prolonged and intensive use of a pacifier are available.^{2,18} Here we give only two examples choosing the ones with more robust evidence of an association: dental malocclusion and acute otitis media.

- **Anterior open bites, posterior crossbites and other dental malocclusions** have been detected in several studies.² Usually the severity of the harmful effects of pacifiers depends on the duration, frequency, and intensity of their use. A longitudinal prospective study provides robust evidence to this effect:¹⁹ 867 children were assessed at 15, 24 and 36 months of age for the non-nutritive sucking habit (digit or pacifier) and at 43 and 61 months of age for dental malocclusions. The study demonstrated that the risk of dental malocclusion was higher in persistent suckers (reporting a sucking habit in two of the follow-up interviews) than in occasional suckers. At 43 months of age, 51.6% of persistent suckers and 4.5% of occasional suckers showed an anterior open bite; at 61 months of age the proportion was 16.9% versus 5.6%. Posterior cross bite was present in 23% of persistent suckers and 6% of occasional suckers both at 43 and at 61 months of age. The study further concludes that pacifier use causes malocclusion even more so than digit sucking.
- **Acute otitis media incidence and relapses** have been associated with pacifier use.¹⁸ Two meta-analyses investigating risk factors for acute otitis media have now confirmed that pacifier use increases the risk of developing otitis media. The first reviewed 22 studies published between 1966 and 1994 from various countries and concluded that there is a 24% increase in risk of otitis media in children using a pacifier.²⁰ The second reviewed studies published between 1966 and 2005 and, though it did not quantify the association, it concluded that avoidance of pacifier use is one of the modifiable risk factors for the prevention of acute and recurrent acute otitis media.²¹ Among subsequent intervention studies providing evidence of an association between pacifier use and otitis media, the most cited and debated was conducted in Finland in 2000. 272 children were enrolled in intervention clinics where parents were

¹⁴ Di Mario S, Cattaneo A, Basevi V, Magrini N. Feedback to: Jaafar SH, Jahanfar S, Angolkar M, Ho JJ. Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding. *Cochrane Database Syst Rev.* 2012 Jul 11;7:CD007202

¹⁵ Howard CR, et al. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. *Pediatrics* 2003;111:511-8.

¹⁶ Callaghan A, Kendall G, Lock C, Mahony A, Payne J, Verrier L. Association between pacifier use and breast-feeding, sudden infant death syndrome, infection and dental malocclusion. *Int J Evid Based Healthc* 2005;3:147-67

¹⁷ Karabulut E, Yalçın SS, Ozdemir-Geyik P, Karaağaoğlu E. Effect of pacifier use on exclusive and any breastfeeding: a meta-analysis. *Turk J Pediatr* 2009;51:35-43

¹⁸ Sexton S, Natale R. Risks and benefits of pacifiers. *Am Fam Physician* 2009;79:681-5

¹⁹ Duncan K, McNamara C, Ireland AJ, Sandy JR. Sucking habits in childhood and the effects on the primary dentition: findings of the Avon Longitudinal Study of Pregnancy and Childhood. *Int J Paediatr Dent* 2008;18:178-88

²⁰ Uhari M, Mäntysaari K, Niemelä M. A meta-analytic review of the risk factors for acute otitis media. *Clin Infect Dis* 1996;22:1079-83

²¹ Lubianca Neto JF, Hemb L, Silva DB. Systematic literature review of modifiable risk factors for recurrent acute otitis media in childhood. *J Pediatr (Rio J)* 2006;82:87-96

taught not to use pacifiers, and 212 children were enrolled in control clinics where no advice about pacifier use was given. In the intervention group, pacifier use was reduced by 21% and led to 29% fewer episodes of otitis media compared to the control group.²² The main limitations of the study were that as it was retrospective (based on memory), it was amenable to distortion (recall bias) and likely to overestimate the association between pacifier use and otitis. Nevertheless, the conclusions of this study are coherent with those of another study.²³

The main limitations of the Finnish study were overcome by a large prospective cohort study conducted in the Netherlands in 2008.²⁴ 476 children, aged between 1 and 2 years, participating in the Utrecht Health Project, were investigated for use of pacifiers (at baseline, 216 used them and 260 did not); prospectively they were followed up for an average of 2.9 years to detect acute and recurrent acute otitis media episodes. The study found that the rate of *acute* otitis media was similar between pacifier users and non-users (35% versus 32%), whereas the risk of *recurrent* otitis media was significantly higher among pacifier users (90% increase). Possible explanations for such an association are: increased reflux of nasopharyngeal secretions into the middle ear thus facilitating the entrance of pathogens, and changes in dental structure causing dysfunction of the Eustachian tube.^{22,24} Based on the accumulating body of evidence, the AAFP/AAP joint guidelines on otitis media recommend that, in order to prevent otitis media, physicians advocate for little or no use of pacifiers in the second 6 months of life.²⁵ The Institute for Clinical Systems Improvement makes a similar recommendation, but suggests avoiding the use of a pacifier by 10 months of age.²⁶

Pacifiers and SIDS

Despite the risks associated with pacifier use, there was a resurgence of interest in pacifiers in the 1990s, due to the association observed in some case-control studies between pacifier use and SIDS. In particular, a meta-analysis of seven case-control studies published between 1966 and 2004⁵ concluded that pacifier use protected against SIDS, halving the risk. Encouraging pacifier use, concluded the meta-analysis authors, would result in one case of SIDS averted for every 2,733 infants using a pacifier when going to sleep. Interestingly, there were no studies in the meta-analysis able to disentangle the effects of pacifier use and of breastfeeding on SIDS. In 2005, at the time of publication of this systematic review, the protective effect of breastfeeding on SIDS was still not widely accepted: even if the American Academy of Pediatrics, for example, acknowledged that several benefits were associated with exclusive and prolonged breastfeeding, it clearly stated that SIDS prevention was not one of them.²⁷

It is more difficult to understand the reason why the most recent population-based case-control study (260 SIDS cases and 260 controls) did not correct the association between pacifier use and SIDS occurrence for “actual breastfeeding”, but only for “ever breastfeeding”.⁶ The study was published in 2012, when the protective effect of breastfeeding against SIDS had become clear, and was co-authored by the first author of the 2005 systematic review. As admitted by the authors, the sample size was not large enough to allow adjustment for actual breastfeeding. Yet the conclusions were strong: “We found that pacifier use may offer additional protection for infants with older, married, non-smoking, breastfeeding mothers who have received adequate prenatal care”.

²² Niemelä 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;106:483-8

²³ Warren JJ, Levy SM, Kirchner HL, Nowak AJ, Bergus GR. Pacifier use and the occurrence of otitis media in the first year of life. *Pediatr Dent* 2001;23:103-7

²⁴ 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. *Fam Pract* 2008;25:233-6

²⁵ American Academy of Pediatrics. Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. *Pediatrics* 2004;113:1451-65

²⁶ ICSI - Institute for Clinical Systems Improvement. Health Care Guideline: Diagnosis and Treatment of Otitis Media in Children. Ninth Edition. Bloomington, January 2008. Available at: www.icsi.org (accessed November 22, 2012)

²⁷ American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome. The changing concept of sudden infant death syndrome: diagnostic coding shifts, controversies regarding the sleeping environment, and new variables to consider in reducing risk. *Pediatrics* 2005;116:1245-55

As SIDS is a rare but tragic and devastating event, understanding risk factors to provide reliable advice and guidance to parents and health professionals is of utmost importance; however, it is not easy. Difficulties are linked to:

- Lack of definite quantification of SIDS cases. Since SIDS is “not a cause from which babies die, but a category to which they are assigned if no cause can be found for their death” [see *Breastfeeding Briefs*, N° 53], the incidence is difficult to ascertain. Not all cases of SIDS undergo a complete autopsy, an examination of the death scene and a full review of the clinical history.²⁸
- Small numbers of events. In recent years, as more attention has been paid to its definition, many of the cases that were previously classified as SIDS are now classified as SUID (Sudden Unexpected Infant Deaths) or as ASSB (Accidental Suffocation and Strangulation in Bed), resulting from suffocation, asphyxia and other ill-defined or unspecified causes of death. In addition, the positive effect of the “Back to Sleep Campaign”, launched in many countries at the beginning of the 1990s, has decreased the incidence of SIDS cases. Thus, fewer cases are available to examine and understand the causes.
- Inherent limits of the studies on SIDS due to their case-control design (no other study design is possible for such a condition). Such studies cannot help understand the temporal sequence of events leading to the baby’s death. For example, does the baby die because s/he does not breathe due to a central nervous system problem? Or does s/he stop breathing because of being entrapped in the bed sheets which causes an alteration to the brain and leads to the baby dying? Likewise, the specific contribution of different factors is difficult to assess. For example, does the pacifier reduce the risk of SIDS? Or is pacifier use at night a marker of a baby prone to crying, and who therefore has a better arousal capacity than a baby not using a pacifier?
- Possible misleading information gathered from studies that make comparisons based on “last” sleep. Researchers refer to “last” sleep when information is gathered exclusively in relation to the night during which the baby died. By definition there is only one “last” sleep, and it probably differs from the baby’s “usual” sleep – one after which the baby awakes normally in the morning, i.e. alive. It is possible that conditions occurring during the “last” sleep in the case group (i.e. babies who die with SIDS) are not the “usual conditions at sleep” and cannot be compared with a “reference” sleep in the control group (i.e. babies who are alive). Comparing the usual sleep condition of the cases with the usual sleep condition of the control subjects seems to be more appropriate. When studies assessing the impact of pacifier use on SIDS occurrence were analysed for “usual” sleep instead of “last” sleep the association measured was smaller, thus reducing the strength of the recommendation based on these studies.²⁹

In relation to SIDS prevention it is worth considering that, after years of accumulating evidence of an association between breastfeeding and reduced risk of SIDS^{30, 31, 32, 33}, recently the American Academy of Pediatrics and other international agencies have added breastfeeding among the recommendations to reduce the risk of SIDS and SUDI.^{8,9}

Pacifiers and pain control

Pacifiers, alone or in conjunction with other non-pharmacological interventions, are used to reduce procedural pain. Since 2004, the American Academy of Pediatrics has listed pacifier use among the key methods for pain relief, along with oral sucrose, skin-to-skin contact and breastfeeding, in newborns and

²⁸ Willinger M, James LS, Catz C. Defining the sudden infant death syndrome (SIDS): deliberations of an expert panel convened by the National Institute of Child Health and Human Development. *Pediatr Pathol* 1991;11:677-84

²⁹ Buzzetti R, D'Amico R. The pacifier debate. *Pediatrics* 2006;117:1850

³⁰ McVea KL, Turner PD, Pepler DK. The role of breastfeeding in sudden infant death syndrome. *J Hum Lact* 2000;16:13-20

³¹ Ip S, Chung M, Raman G, Chew P, Magula N, DeVine D, Trikalinos T, Lau J. Breastfeeding and maternal and infant health outcomes in developed countries. *Evid Rep Technol Assess (Full Rep)* 2007;1-186

³² Vennemann MM, Bajanowski T, Brinkmann B, Jorch G, Yücesan K, Sauerland C, Mitchell EA; GeSID Study Group. Does breastfeeding reduce the risk of sudden infant death syndrome? *Pediatrics* 2009;123:e406-10

³³ Hauck FR, Thompson JM, Tanabe KO, Moon RY, Vennemann MM. Breastfeeding and reduced risk of sudden infant death syndrome: a meta-analysis. *Pediatrics* 2011;128:103-10

infants younger than 6 months of age.^{34,35} Several systematic reviews have been conducted with the aim to assess non pharmacological methods to reduce pain in term and pre-term infants undergoing painful procedures such as venepuncture, immunization, and heel lance. One systematic review focused on the effectiveness of sucrose administration;³⁶ one on breastfeeding or breastmilk administration;³⁷ and one on other methods such as non-nutritive sucking, kangaroo care, waddling/tucking, touch/massage, swallowing water, and toy distraction.³⁸

With respect to sucrose administration during painful procedures, a systematic review of forty-four studies (3,496 infants enrolled) published between 1966 and April 2009 revealed that oral sucrose (\pm pacifier) compared to water alone (\pm pacifier) reduced pain after heel lance or eye examination, as measured with various behavioural scales.³⁶ A systematic review aimed at assessing the analgesic effect of breastfeeding for procedural pain included 11 studies published up to February 2006.³⁷ High heterogeneity among studies, differences in the control groups and variations of outcomes prevented pooling of the data, and therefore only individual studies could be compared to one another. Nonetheless, the authors of the systematic review concluded that breastfeeding reduced procedural pain more effectively than placebo (sterile water), pacifier use, swaddling, being placed in the mother's arms, and it was as effective as glucose administration, whereas supplemental breastmilk was no better than placebo. Finally, the systematic review on other interventions to reduce procedural pain included 51 trials (total infants enrolled 3,396) published up to April 2011.³⁸ Heterogeneity among trials was once again a problem, and few trial results could be pooled. In addition, studies often had small sample sizes, and there was no discussion on the clinical significance of the measured results. For example, non-nutritive sucking was reported to significantly reduce pain-related distress in pre-term infants by 0.38 points. This estimate was based on four studies which included 132 intervention infants and 70 control infants. Scales used to measure pain differed in the four included trials, with scales ranging from 0 to 3 (PIPP scale) and 54 to 837 (stress level scale). It is not easy to understand the clinical significance of the reported reduction of 0.38 points in relation to the different scales used.

Other RCTs published afterwards have confirmed the analgesic effect of breastfeeding in comparison to pacifier use. Procedural pain due to heel lance was measured in 228 healthy newborns randomized to four groups: breastfeeding, pacifier alone, pacifier plus sucrose, or nothing.³⁹ Newborns in the breastfeeding group had significantly shorter crying periods than all other groups (0.19 seconds versus 10.7 in both pacifier groups and 51.7 in the control group), and lower points in a behavioural pain scale (modified Neonatal Facial Coding System, NFCS) ranging from 0 (no pain) to 5 (severe pain) points (0.6 points versus 1.5 in the pacifier plus sucrose group, 2.1 in the pacifier alone group, and 3.9 in the control group). The analgesic effect of pacifier sucking and sucrose was tested in a RCT enrolling 165 newborns receiving Hepatitis B immunization via intramuscular injection.⁴⁰ Pain was measured by NFCS ranging from 0 (no pain) to 48 points (severe pain), by crying time, and by physiological parameters (heart and respiratory rate) monitored via electrocardiogram (ECG). Pain was significantly lower among infants in the pacifier and sucrose groups (-11.3 and -11.7 points, respectively, in the NFCS, and lower respiratory and heart rates), whereas crying time was significantly shorter in the sucrose group than in the pacifier and control groups. Even if data

³⁴ Zempsky WT, Cravero JP; American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Anesthesiology and Pain Medicine. Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics* 2004;114:1348-56

³⁵ Fein JA, Zempsky WT, Cravero JP; the committee on pediatric emergency medicine and section on anesthesiology and pain medicine. Relief of Pain and Anxiety in Pediatric Patients in Emergency Medical Systems. *Pediatrics* 2012;130:e1391-e1405

³⁶ Stevens B, Yamada J, Ohlsson A. Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database Syst Rev* 2010;(1):CD001069

³⁷ Shah PS, Aliwalas LI, Shah V. Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database Syst Rev*. 2006;(3):CD004950

³⁸ Pillai Riddell RR, Racine NM, Turcotte K, Uman LS, Horton RE, Din Osmun L, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Gerwitz-Stern A. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database Syst Rev* 2011;(10):CD006275

³⁹ Iturriaga GS, Unceta-Barrenechea AA, Zárata KS, Olaechea IZ, Núñez AR, Rivero MM. Analgesic effect of breastfeeding when taking blood by heel-prick in newborns. *An Pediatr (Barc)* 2009;71:310-3

⁴⁰ Liaw JJ, Zeng WP, Yang L, Yuh YS, Yin T, Yang MH. Nonnutritive sucking and oral sucrose relieve neonatal pain during intramuscular injection of hepatitis vaccine. *J Pain Symptom Manage* 2011;42:918-30

supporting the evidence of an analgesic activity of non-pharmacological methods for procedural pain control such as non-nutritive sucking, oral sucrose, breastfeeding, and skin-to-skin contact are difficult to compare and are often of low quality, consistency of results and lack of major side effects call for adopting one or more of them whenever a newborn is at risk of experiencing procedural pain. Common sense would suggest that whenever possible, the best option would be to encourage breastfeeding shortly before, during and after the procedure: breastfeeding per se is associated with less pain; in addition there is the calming effect of sucking and of ingesting something sweet (lactose). In the case of non-breastfed babies, non-nutritive sucking with or without sucrose is an alternative. Skin-to-skin contact, holding in the mother's arms, rocking and swaddling are also advisable.

Conclusions

Based on the above-cited evidence, and in accordance with other researchers,² use of pacifiers produces more harm than benefit, since pacifiers prevent the establishment of breastfeeding and lead to early breastfeeding cessation. Parents should be fully informed of the advantages and disadvantages associated with the use of pacifiers in order to make well-informed decisions as to using them or not.

Abstracts

Castilho SD, Rocha MA. Pacifier habit: history and multidisciplinary view. J Pediatr (Rio J) 2009;85:480-9 [Article in English, Portuguese]

The objectives of this study were to review the history of pacifiers using a multidisciplinary literature review, searching for pros and cons of pacifier use, with the purpose of providing health professionals with arguments for parents requesting guidance. History and art books, as well as non-medical literature and museums were used for the historical survey. Multidisciplinary data were collected from MEDLINE, LILACS, SciELO, and The Cochrane Library. Studies published in the last 5 years, with an abstract in Portuguese, English and Spanish, were assessed for inclusion if the keyword "pacifiers" was present. Based on the studies collected, the authors stated that there is evidence that pacifier precursors have been used since neolithic times to calm children. Small balls made of fabric containing food are portrayed in paintings. Other balls made of non-perishable material have persisted over time. Pacifiers have been used to stimulate sucking or to coordinate the sucking reflex in order to assist early breastfeeding initiation in newborns. Some authors suggest that pacifiers reduce the incidence of Sudden Infant Death Syndrome (SIDS), but this is controversial. Others suggest that pacifiers prevent the establishment of breastfeeding and lead to weaning. Their use may cause suffocation, poisoning, or allergies and increases the risk of

caries, infections, and parasitic intestinal diseases. Harmful effects are related to the frequency, duration, and intensity of the habit. The authors recommend that pacifier use be discontinued by the age of 3 or 4 years in order not to affect the child's speech and dentition development. They conclude that there are more harmful effects than benefits in using pacifiers and that health professionals should inform parents of the pros and cons so as to be able to make an informed decision regarding their use.

Jaafar SH, Jahanfar S, Angolkar M, Ho JJ. Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding. Cochrane Database Syst Rev 2012 Jul 11;(7):CD007202 Update of Cochrane Database Syst Rev. 2011;(3):CD007202.

The World Health Organization's *Ten Steps to Successful Breastfeeding* recommends total avoidance of artificial teats or pacifiers for breastfeeding infants as pacifier use is believed to lead to less frequent episodes of breastfeeding and, consequently, may reduce breastmilk production and shorten breastfeeding duration. However, the association between pacifier use and breastfeeding remains unclear. This systematic review aimed to assess the effect of unrestricted versus restricted pacifier use on the duration of breastfeeding, other breastfeeding outcomes and infant health amongst healthy, full-term newborns whose mothers had initiated breastfeeding and

intended to exclusively breastfeed their infant. The authors searched the Cochrane Pregnancy and Childbirth Group's Trials Register (14 March 2012). Randomised and quasi-randomised controlled trials comparing unrestricted versus restricted pacifier use in healthy, full-term newborns who had initiated breastfeeding regardless of whether they were born at home or in the hospital were selected. The review authors found three trials (1,915 babies) for inclusion in the review, but included only two of them (1,302 healthy full-term breastfeeding infants) in the analysis. The meta-analysis of the two combined studies showed that pacifier use in healthy breastfeeding infants had no significant effect on the proportion of infants *exclusively breastfed* at 3 and at 4 months of age, and had no effect on the proportion of infants *partially breastfed* at 3 and at 4 months of age. Based on these results, the authors conclude that pacifier use in healthy term breastfeeding infants, started from birth or after lactation is established, does not significantly affect the prevalence or duration of exclusive and partial breastfeeding up to 4 months of age. However, the study lacks evidence assessing the short-term breastfeeding difficulties faced by mothers, and the long-term effect of pacifiers on breastfeeding and on the infants' health.

Duncan K, McNamara C, Ireland AJ, Sandy JR. Sucking habits in childhood and the effects on the primary dentition: findings of the Avon Longitudinal Study of Pregnancy and Childhood. Int J Paediatr Dent 2008;18:178-88

This is a longitudinal observational cohort aimed to determine the prevalence of non-nutritive sucking habits and the effects on the developing dentition of young children. The Children in Focus group (including 891 children) of the Avon Longitudinal Study of Pregnancy and Childhood Study was examined in detail. Questionnaire data on non-nutritive sucking habits were collected at 15 months, 24 months, and 36 months of age. Dental examinations were performed on the same children at 31 months, 43 months and 61 months. At 15 months, 63.2% of the children had a sucking habit, 37.6% using a dummy and 22.8% a digit. By 36 months, sucking had reduced to 40%, with a similar prevalence of dummy and digit sucking. Both habits had effects on the developing dentition, most notably in upper labial segment alignment and the development of anterior open bites and posterior cross-bites. Based on the data collected, the authors concluded that the majority

of children had non-nutritive sucking habits up to 24 months of age. Both digit and dummy sucking were associated with observed anomalies in the developing dentition, but dummy-sucking habits had the most profound influence on the anterior and posterior occlusions amongst these children.

Lubianca Neto JF, Hemb L, Silva DB. Systematic literature review of modifiable risk factors for recurrent acute otitis media in childhood. J Pediatr (Rio J) 2006;82:87-96

This systematic review aimed to collect evidence about modifiable risk factors for recurrent acute otitis media. MEDLINE databases with no language restriction were searched; the studies selected had been published between January 1966 and July 2005. Using the descriptors "acute otitis media"/"risk factors", 257 articles were found. These included randomized clinical trials, cohorts, case-control and cross-sectional studies that contained analyses of modifiable risk factors for the development of recurrent acute otitis media as their main objective and samples of individuals up to the age of 18 years. Except when relevant, the following were excluded: non-systematic reviews, reports of cases, series of cases, and medical society guidelines. Based on the collected evidence, the authors identified nine risk factors linked to the host and eight others linked to the environment. Of the first group, allergy, craniofacial abnormalities, gastro-oesophageal reflux and the presence of adenoids were classified as modifiable. In the second category, upper airway infections, day-care centre attendance, presence of siblings/family size, passive smoking, breastfeeding and the use of pacifiers were included. The modifiable risk factors established for recurrent acute otitis media were pacifier use and attendance in day-care centres.

Moon RY, Tanabe KO, Yang DC, Young HA, Hauck FR. Pacifier use and SIDS: evidence for a consistently reduced risk. Matern Child Health J 2012;16:609-14

Previous studies have suggested that pacifier use at sleep time decreases the risk of sudden infant death syndrome (SIDS). It is yet unclear whether pacifier use can modify the impact of other sleep-related factors upon SIDS risk. The objective of this study was to examine the association between pacifier use during sleep and SIDS in relation to

other risk factors, and to determine if pacifier use modified the impact of these risk factors. The data source was a population-based, case-control study of 260 SIDS deaths and 260 matched living controls. Pacifier use during “last” sleep decreased SIDS risk by 50% to 80%. Furthermore, pacifier use decreased SIDS risk more when mothers were ≥ 20 years of age, married, non-smokers, had had adequate prenatal care, and if the infant was ever breastfed (no correction was possible for actual breastfeeding due to small numbers). Also, when the infant was sleeping in the prone/side position, was bedsharing, and when soft bedding was present, pacifier use also decreased the risk of SIDS. The association between adverse environmental factors and risk of SIDS was modified favourably by pacifier use, but the interactions between pacifier use and these factors were not significant. The authors concluded that pacifier use may provide an additional strategy to reduce the risk of SIDS for infants at high risk or in adverse sleep environments.

Shah PS, Aliwalas LI, Shah V. Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database Syst Rev.* 2006;(3): CD004950

The primary objective of this review was to evaluate the effectiveness of breastfeeding or supplemental breastmilk in reducing procedural pain in neonates. The secondary objective was to conduct subgroup analyses based on the type of control intervention, the type of painful procedure, the gestational age and the amount of supplemental breastmilk given. The authors searched MEDLINE (1966-2006), EMBASE (1980-2006), CINAHL (1982-2006), the Cochrane Central Register of Controlled Trials (Issue 4, 2005 of Cochrane Library), abstracts from the annual meetings of the Society for Paediatric Research (1994 - 2006) and major paediatric pain conference proceedings. No language restrictions were applied. Randomized or quasi-randomized controlled trials of breastfeeding or supplemental breastmilk versus no treatment/other measures in neonates were eligible for inclusion in the review. The study must have reported on either physiologic markers of pain or validated pain scores. The methodological quality of the trials was assessed using the information provided in the studies and by personal communication with the authors. Eleven eligible studies were identified. Marked hetero-

geneity in terms of control intervention and pain assessment measures were noted among the studies. Neonates in the breastfeeding group had statistically significant lower increases in heart rate, reduced proportion of crying time, and reduced duration of crying compared to the swaddled group or the pacifier group. Neonates in the breastfeeding group had a significant reduction in duration of crying compared to the fasting (no intervention) group, but there was no significant difference when compared to the glucose group. Premature Infant Pain Profile scores were significantly different between the breastfeeding group when compared to the placebo (sterile water) group and the group positioned in the mother’s arms. However, these scores were not statistically significantly different in the breastfeeding group when compared to the no treatment group and the glucose group. “Douleur aigue nouveau-né” scores (another behavioural scale for pain assessment) were significantly different in the breastfeeding group when compared to the placebo group and the group positioned in the mother’s arms, but not when compared to the glucose group. Neonates in the supplemental breastmilk group had significantly less increase in heart rate and “Neonatal Facial Coding Score” (another behavioural scale for pain assessment) compared to the placebo group. The differences in the duration of crying time and oxygen saturation change between the supplemental breastmilk group and the placebo group were not statistically significant. Neonates in the supplemental breastmilk group had significantly higher increases in heart rate changes and duration of crying time compared to the glucose/sucrose group. No study was identified that has evaluated the safety/effectiveness of repeated administration of breastfeeding or supplemental breastmilk for pain relief. The authors conclude that whenever available, breastfeeding or breastmilk should be used to alleviate procedural pain in neonates undergoing a single painful procedure compared to placebo, positioning or no intervention. The administration of glucose/sucrose had similar pain reduction effectiveness as breastfeeding. The effectiveness of breastmilk for repeated painful procedures was not established and further research is needed. These studies should include various control interventions including glucose/sucrose and should target preterm neonates.

Pillai Riddell RR, Racine NM, Turcotte K, Uman LS, Horton RE, Din Osmun L, Ahola

Kohut S, Hillgrove Stuart J, Stevens B, Gerwitz-Stern A. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database Syst Rev* 2011; (10):CD006275

This systematic review aimed to assess the efficacy of non-pharmacological interventions – with the exception of breastmilk, sucrose, and music – for acute pain in infants and children up to 3 years of age. Included interventions were (as described in the Cochrane review): 1. Kangaroo care (also known as skin-to-skin contact): an infant is placed on the care-giver's bare chest during a painful procedure or for soothing after a painful procedure. 2. Swaddling/facilitated tucking: the infant is securely wrapped in a blanket to prevent his/her limbs from moving around excessively. Facilitated tucking involves firmly containing the infant using the care-giver's hands on both head and lower limbs to maintain a "folded-in" position. The infant may or may not be wearing clothes. 3. Non-nutritive sucking-related strategies: an object (e.g. pacifier, non-lactating nipple) is placed into the infant's mouth to stimulate oro-tactile or sucking behaviours during a painful event. Pacifier plus water was included; pacifier plus sucrose was not included. 4. Swallowing water: water is administered for ingestion without an instrument that would incite extensive sucking (e.g. water administered by a dropper). 5. Rocking, holding or both: the infant is held or gently moved up and down or side to side (or both) by the care-giver. 6. Simulated rocking and water: as opposed to being held by an adult, the infant is placed in a bassinet-type machine that provides a swaying motion. In addition, water is administered in a manner that does not incite extensive sucking. 7. Touch/massage: the infant's body is "stroked" to provide some type of counter-stimulation to the nociceptive input. 8. Structured parental involvement: parents are instructed or informed of strategies that are

accepted as pain-reducing but are not given any materials to aid them. A variety of strategies may or may not be enacted such as rocking, holding, shushing, talking, rubbing, tickling, and distracting attention without toy or video. 9. Maternal voice: an infant is exposed to a reproduction of his/her mother's voice, designed to help simulate the fetal environment. 10. Parental presence: simply allowing the parent to be present during a painful procedure but not interacting extensively with the child in a manner thought to be pain reducing. In this systematic review, analyses accounted for infant age (preterm, neonate, older) and pain response (pain reactivity, pain-related regulation). The authors searched several biomedical databases, reference lists, and they contacted researchers via electronic list-servers. Participants included infants from birth to 3 years. Only randomized controlled trials (RCTs) or RCT cross-overs that had a no-treatment control comparison were eligible for inclusion. Fifty-one studies, with 3'396 participants, were analyzed. The most commonly studied acute procedures were heel-sticks (29 studies) and needles (n = 10 studies). The most effective interventions for reducing pain reactivity were non-nutritive sucking-related interventions (preterm: -0.42; neonate: -1.45), kangaroo care (preterm: -1.12), and swaddling/facilitated tucking (preterm: -0.97). The study showed that the most effective interventions for immediate pain-related regulation were: non-nutritive sucking-related interventions (preterm: -0.38; neonate: -0.90), kangaroo care (-0.77), swaddling/facilitated tucking (preterm: -0.75), and rocking/holding (neonate: -0.75). Because of the significant methodological heterogeneity noted in several of the studies, the authors question the lack of findings in certain analyses. However, there is evidence that different non-pharmacological interventions can be used with pre-terms, neonates, and older infants to significantly manage pain behaviours associated with acutely painful procedures.

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Guest editor: Simona Di Mario. **Editorial team:** Adriano Cattaneo, Lida Lhotska, Robert Peck, Elaine Petitot-Côté and Marina Rea. **Lay-out:** Lena Nyffenegger.

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