



## Editorial

### What should pediatricians recommend regarding the use of pacifier in infants? Reflections and comments on its role in the reduction of sudden infant death syndrome (SIDS)

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## What should pediatricians recommend regarding the use of pacifier in infants? Reflections and comments on its role in the reduction of sudden infant death syndrome (SIDS)

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Sudden infant death syndrome (SIDS) is the sudden death of an infant under 1 year of age, which remains unexplained after a thorough case investigation, including a complete autopsy, examination of the death scene, and review of the clinical history<sup>1,2</sup>. It remains the most frequent cause of death during the first months of life. It is rare during the neonatal period, increases to a peak between 2 and 3 months of age, and then decreases until the first year of life. The impact of SIDS on the family and society, implies an important sensitivity in medicine, and specially in pediatrics, that points towards studies to identify the risk factors and their prevention, with the goal of decreasing the incidence

A number of independent risk factors for SIDS have been consistently identified across studies: prone sleep position, sleeping on a soft surface, overheating, maternal smoking during pregnancy, young maternal age, preterm birth and/or low birth weight, and male gender. In 1992, in response to epidemiological reports from Europe and Australia, the American Academy of Pediatrics (AAP) recommended that infants be laid down (first it advised that the nonprone position, and then the supine position)<sup>3</sup>, what led to the "Back to Sleep" campaign, that has been implemented around the world, and that has been associated with the decrease in the incidence of SIDS. However new variables have been associated with SIDS, and AAP (Task Force on Sudden Infant Death Syndrome)<sup>4,5</sup> has updated the new recommendations that have been published in November 2005. The AAP<sup>5</sup> includes, among its 11 recommendations, offering a pacifier at nap time and bedtime in infants up to 1 year of age.

The protective effect of pacifiers against SIDS has been known for some time. In 1979, Cozzi et al<sup>6</sup> postulated that pacifiers might protect against sudden infant death syndrome (SIDS). Support for this hypothesis was first reported in New Zealand in 1993<sup>7</sup>. Since then there have been other studies that have supported this observation. There have been 7 case-control studies published in the meta-analysis in Pediatrics of November 2005<sup>8</sup> (5 studies come from European countries, 1 from United States, and 1 from New Zealand) and a prospective study in Scandinavia whose unpublished data are in the report published in Pediatrics in May, 2006<sup>9</sup>. All but one of the studies observed an increased prevalence of use among the control subjects compared with case subjects. The studies have occurred both before and after the reduction in SIDS that followed the recommendation to place infants supine to sleep in those countries, so the results can be applied to other

countries.

When univariate Odds Ratios (OR) were analyzed, usual pacifier use was shown to be associated with a non significant decreased risk of SIDS, (OR: 0.90 [95% CI: 0.79-1.03]). However, based on studies of multivariate OR, usual pacifier use was associated with a significant reduced risk of SIDS (OR: 0.71 [95% CI: 0.59-0.85])

For the pacifier use during last sleep, The OR calculated for univariate OR, were 0.47 (95% CI: 0.40-0.55) and for multivariate OR were 0.39 (95% CI: 0.31-0.50). From the results of this meta-analysis 1 SIDS death could be prevented for every 2733 (95% CI: 2416-3334) infants who use a pacifier when placed for sleep (number needed to treat), based on the number of SIDS rate in United States, and the last-sleep multivariate OR resulting from this analysis. The review by Mitchell et al<sup>9</sup> reports consistent results (including 2 unpublished studies) All of them showed a reduced risk of SIDS (OR: 0.83 [95% CI: 0.75-0.93]) for routine pacifier use and OR: 0.48 [95% CI: 0.43-0.54]) for pacifier use for the last sleep.

According to these results using the pacifier could be included as a level B strength of recommendation (according to the U.S. Preventive Service Task Force) based on the consistence of findings among the available studies (case-control studies which are of weaker design than controlled trials or cohort studies), and the likelihood that the beneficial effects will outweigh any potential negative effects. Even so the relation between pacifier and SIDS decrease fulfils the conditions that determine the causality: consistent findings, strong association, dose-response effect, biological plausibility and causal factor preceding the outcome<sup>8</sup>. After the last studies, new publications have come out that confirm the findings, one in Germany<sup>11</sup> and another one in the United States<sup>12</sup>. The last one is critically appraised in this issue of "Evidencias en Pediatría". In this study the adjusted odds ratio was 0.08 (95% CI: 0.03-0.21), which translates to a 92% reduction of risk in infants who used a dummy during the last sleep compared with infants who did not use it. There was a consistent trend towards use of a dummy during sleep being associated with a greater reduction of risk when an infant was in an adverse sleep environment (sleeping prone or on the side, sleeping with a mother who was a current smoker, or sleeping on soft bedding).

The discussion is open: what pediatricians should advise

in relation to pacifier, as in other recent editorials is discussed<sup>13</sup>. Two last commentaries on the use of pacifier: the mechanism of reduction of SIDS, and the potential detrimental effects.

The mechanism by which pacifiers might reduce the risk of SIDS (or its absence increase the risk) is unknown, but several mechanisms have been postulated: avoidance of the prone sleeping position<sup>14</sup>, protection of the oropharyngeal airway<sup>6</sup>, reduction of gastroesophageal reflux through nonnutritive sucking<sup>7</sup> and lowering the arousal threshold<sup>15</sup>. The potential disadvantages must be considered. (reduction in breastfeeding, higher risk of infections, dental malocclusion, accidents, etc). The main concerns are related to the reduction of breastfeeding<sup>16,17</sup>, although the well-designed randomized clinical trials have produced conflicting results<sup>18-20</sup>. The same concerns came across with the potential association of pacifier use and higher risk of otitis media which could be the result of confounding factors<sup>21</sup>. Dental malocclusions are usually associated with a long term use, and are unlikely to develop if stopped by 6-12 months of life.

The "Back to Sleep" campaign has been shown to be efficacious and efficient, in decreasing the SIDS in many countries. Why is different, according to what has been stated above, to promote the use of pacifier in infants throughout the first year of life?. The three reasons that might be argued against this recommendation are: 1) the design, based in case-control studies rather than controlled trials or cohort studies with no evident cause-effect; 2) the mechanism for this protective effect is unknown; 3) detrimental effects associated. These arguments could also apply in any case to the back to sleep recommendation, with the further difficulty that the detrimental effects associated with this position (the dramatic increase in the incidence of positional plagiocephaly) have been demonstrated and have implied specific recommendations of AAP<sup>22</sup>.

Scientific societies should include an active policy in promoting the use of pacifier (for all sleep episodes, including daytime naps and nighttime sleeps) as the recent publications recommend<sup>5,9,13</sup>:

- 1.- For breastfeed infants, delay pacifier introduction until 1 month of age to ensure that breastfeeding is firmly established.
- 2.- In children feed with bottle offer the pacifier in the first days of life, because their mothers have other characteristics that may place their infants at greater risk for SIDS.
- 3.- The pacifier should not be reinserted once the infant falls asleep.
- 4.- Pacifiers should not be coated in any sweet solution
- 5.- Pacifier should be phased out at the end of the first year of life

Pediatricians must (and can) have a position about the

data published on the relation between the use of pacifier and SIDS. The aim of this editorial is to open once again, a controversy, that is no new, as one of the authors explained six years ago when he named the pacifier as the "seat belt" in the prevention of SIDS<sup>2</sup>.

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