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REVIEW ARTICLE

Do Pacifiers Reduce the Risk of Sudden Infant Death Syndrome? A Meta-analysis

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ABSTRACT. *Objective.* **Pacifier use has been reported to be associated with a reduced risk of sudden infant death syndrome (SIDS), but most countries around the world, including the United States, have been reluctant to recommend the use of pacifiers because of concerns about possible adverse effects. This meta-analysis was undertaken to quantify and evaluate the protective effect of pacifiers against SIDS and to make a recommendation on the use of pacifiers to prevent SIDS.**

Methods. **We searched the Medline database (January 1966 to May 2004) to collect data on pacifier use and its association with SIDS, morbidity, or other adverse effects. The search strategy included published articles in English with the Medical Subject Headings terms "sudden infant death syndrome" and "pacifier" and the keywords "dummy" and "soother." Combining searches resulted in 384 abstracts, which were all read and evaluated for inclusion. For the meta-analysis, articles with data on the relationship between pacifier use and SIDS risk were limited to published original case-control studies, because no prospective observational reports were found; 9 articles met these criteria. Two independent reviewers evaluated each study on the basis of the 6 criteria developed by the American Academy of Pediatrics Task Force on Infant Positioning and SIDS; in cases of disagreement, a third reviewer evaluated the study, and a consensus opinion was reached. We developed a script to calculate the summary odds ratio (SOR) by using the reported ORs and respective confidence intervals (CI) to weight the ORs. We then pooled them together to compute the SOR. We performed the Breslow-Day test for homogeneity of ORs, Cochran-Mantel-Haenszel test for the null hypothesis of no effect (OR = 1), and the Mantel-Haenszel common OR estimate. The consistency of findings was evaluated and the overall potential benefits of pacifier use were weighed against the potential risks. Our recommendation is based on the taxonomy of the 5-point (A–E) scale adopted by the US Preventive Services Task Force.**

Results. **Seven studies were included in the meta-analysis. The SOR calculated for usual pacifier use (with univariate ORs) is 0.90 (95% confidence interval [CI]: 0.79–1.03) and 0.71 (95% CI: 0.59–0.85) with multivariate ORs. For pacifier use during last sleep, the SORs calculated using univariate and multivariate ORs are 0.47 (95% CI: 0.40–0.55) and 0.39 (95% CI: 0.31–0.50), respectively.**

Conclusions. **Published case-control studies demonstrate a significant reduced risk of SIDS with pacifier use, particularly when placed for sleep. Encouraging pacifier use is likely to be beneficial on a population-wide basis: 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 US SIDS rate and the last-sleep multivariate SOR resulting from this analysis. Therefore, we recommend that pacifiers be offered to infants as a potential method to reduce the risk of SIDS. The pacifier should be offered to the infant when being placed for all sleep episodes, including daytime naps and nighttime sleeps. This is a US Preventive Services Task Force level B strength of recommendation based on the consistency of findings and the likelihood that the beneficial effects will outweigh any potential negative effects. In consideration of potential adverse effects, we recommend pacifier use for infants up to 1 year of age, which includes the peak ages for SIDS risk and the period in which the infant's need for sucking is highest. For breastfed infants, pacifiers should be introduced after breastfeeding has been well established.** *Pediatrics* **2005; 116:e716–e723. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2004-2631;** ***pacifiers, SIDS, risk factors, risk reduction, meta-analytic methods.***

ABBREVIATIONS. SIDS, sudden infant death syndrome; AAP, American Academy of Pediatrics; OR, odds ratio; CI, confidence interval; SOR, summary odds ratio; USPSTF, US Preventive Services Task Force.

Sudden infant death syndrome (SIDS) is defined as the sudden death of an infant that was unexpected by history and unexplained by a postmortem examination that includes a case investigation, complete autopsy, and examination of the death scene.[1] Public-education initiatives such as the Back to Sleep campaign, which began in 1994, have been instrumental in the decrease of SIDS rates from 1.37 per 1000 live births in 1987 to 0.57 in 2002.[2] Similar reductions have been accomplished in other countries, including a 75% drop in England and an 81% decrease in the Netherlands.[3]

Although the incidence of SIDS in the United States has declined over the past decade, there was a reversal of trend with a 2.9% increase in the SIDS rate from 2001 to 2002.[2] Other measures may be needed to further reduce infants' risk of SIDS. Pacifiers have been recommended in the Netherlands[4] (for bottle-fed infants) and Germany[5] to decrease SIDS risk. However, the literature pertaining to pacifiers and SIDS show that this is a complex and often controversial topic of research. To date, no official recommendations have been made in the United States

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regarding pacifier use and SIDS.[6] This meta-analysis was undertaken to quantify and evaluate the protective effect of pacifiers against SIDS to make a recommendation on the potential use of pacifiers to prevent SIDS.

METHODS

Data Sources and Study Selection

We searched the Medline database (January 1966 to May 2004) to collect data on pacifier use and its association with SIDS, morbidity, or other adverse effects. The search strategy included published articles in English with the Medical Subject Headings terms "sudden infant death syndrome" (cot death is automatically coded as SIDS) and "pacifier" and the keywords "dummy" and "soother." Both human and animal studies were included, the latter for articles examining physiologic mechanisms associated with pacifier use. Combining searches resulted in 384 abstracts, which were all read and evaluated for inclusion. For the meta-analysis, articles with data on the relationship between pacifier use and SIDS risk were limited to published original case-control studies in English, because no prospective observational reports were found; 9 articles met these criteria. The bibliographies of these studies were checked also to identify other articles that may have been missed in the Medline search; no additional relevant studies were identified. Two independent reviewers evaluated each study according to preset criteria (see below); in cases of disagreement, a third reviewer evaluated the study, and a consensus opinion was reached.

Data Extraction

Nine articles were identified that include data about the association between pacifiers and SIDS.[4,7–14] One was eliminated from additional analysis, because a later publication from that study included the same subjects as reported in the earlier results.[9,10] The 8 remaining studies were evaluated on the basis of the 6 criteria developed by the American Academy of Pediatrics (AAP) Task Force on Infant Positioning and SIDS for its literature review of the relationship between sleeping position and SIDS[15] (Table 1). Criteria included (1) an appropriate definition for SIDS, (2) autopsies performed in >98% of cases, (3) an adequate description of SIDS ascertainment in the study population, (4) matched control subjects, (5) an adequate description of the process of control selection, and (6) inclusion of sufficient data to calculate odds ratios (ORs) and 95% confidence intervals (CIs) or the actual ORs and CIs. Based on this methodology, the AAP recommended against prone sleep positioning for infants.[15] In the current review, all of the SIDS studies met either 5 or 6 of the 6 criteria; failed criteria are listed in Table 1.

Calculation of Summary ORs

The 2-by-2 tables for the OR could not be recovered from every article included in this meta-analysis. In addition, for multivariate ORs reported in an article, reconstructing the 2-by-2 table was virtually impossible. Hence, we developed a script to calculate the summary OR (SOR) by using the reported ORs and respective CIs to weight the ORs. We then pooled them together to compute the SOR (the script and mathematical justifications are available on request from the corresponding author and at www.people.virginia.edu/~mss4x/pacifiers.html). These computations were implemented in R.[16] We performed the Breslow-Day test for homogeneity of ORs,[17] Cochran-Mantel-Haenszel test for the null hypothesis of no effect (OR = 1), and the Mantel-Haenszel common OR estimate. We performed a sensitivity analysis for the multivariate last-sleep data, because 1 study (Carpenter et al[7]) included some subjects from 2 of the other studies (L'Hoir et al[4] and Fleming et al[10]). For this analysis, the SORs were calculated in 3 ways: (1) with all studies included; (2) with the Carpenter et al[7] results excluded; and (3) with the L'Hoir et al[4] and Fleming et al[10] results excluded.

Taxonomy for Pacifier Recommendation

Different taxonomies have been suggested when using the research literature to make recommendations that affect the health and well-being of the public.[18,19] The first step is to evaluate the

TABLE 1. Characteristics of Studies Reviewed for Meta-analysis

Study			No. of Infants		Controls Matched On	Time From Infant's Death or Identification of Controls to Interview With Parents	Failed Criteria*
Authors	Location	Years	SIDS	Controls			
Carpenter et al[7]	Europe	1992–1996	745	2411	Age, region	Median: 15 d (cases) and 18 d (controls)	None
Fleming et al[10]	United Kingdom	1993–1996	318	1299	Age	Two interviews, both within 2 wk	None
Hauck et al[11]	United States	1993–1996	260	260	Race/ethnicity, age, birth weight	2 wk	None
McGarvey et al[12]	Ireland	1994–1998	203	622	Age, region	<6 wk	None
Mitchell et al[13]	New Zealand	1987–1990	485	1800	Not matched	81% <7 wk	None
Tappin et al[14]	Scotland	1996–2000	131	278	Age, season, maternity unit	<28 d	None (1 was not stated explicitly but was implied)
Arnestad et al[8]	Norway	1984–1992	121	307	Gender, time of birth, region	Mean: 7 y	3, plus long lag time to interview and only included infants through 4 months
L'Hoir et al[4]	Netherlands	1995–1996	73	146	Age	Median: 34 d (cases) and 77 d (controls)	2

* AAP Criteria: 1, appropriate definition of SIDS; 2, autopsies performed in >98% of cases; 3, adequate description of SIDS ascertainment in the study population; 4, matched control subjects; 5, adequate description of process of control selection; and 6, inclusion of sufficient data to calculate ORs and 95% CIs or the actual ORs and CIs.[15]

quality of each relevant study, followed by determining the consistency of findings across studies. Based on these results, the "strength" or "grade" of recommendation is determined. The US Preventive Services Task Force (USPSTF) taxonomy uses a 5-point (A–E) scale. Its highest level recommends that "clinicians routinely provide the service to eligible patients" on the basis of sound evidence that the service improves important health outcomes and the benefits substantially outweigh the harms.[19] In this study, the consistency of findings was evaluated, and the overall potential benefits of pacifier use were weighed against the potential risks. We use the USPSTF taxonomy to identify the strength of the recommendation resulting from our analysis.

RESULTS

Eight published studies were reviewed (Table 1). One was eliminated from additional analysis because there had been a long lag time (on average, 7 years) between the infant's death and parental interview. Additionally, it included only infants who died through 4 months of age.[8] Five studies provided data for both usual‖ and last/reference-sleep pacifier use,[4,7,10,12,13] and 2 provided data for last/reference-sleep¶ pacifier use only (Tables 2 and 3).[11,14] In total, 9 ORs and 95% CIs were provided for usual pacifier use and 14 for last sleep use. When univariate ORs were analyzed, usual pacifier use was shown to be associated with a nonsignificant decreased risk of SIDS (SOR: 0.90 [95% CI: 0.79–1.03]) (Fig. 1).[4,7] However, based on 4 studies that provided multivariate ORs controlling for a variety of factors including sleeping position, usual pacifier use was associated with a significant reduced risk of SIDS (SOR: 0.71 [95% CI: 0.59–0.85]).

Pacifier use during last sleep had more consistent findings. All the ORs provided for last sleep use indicated a lower risk of SIDS on both univariate and multivariate analysis. All the 95% CIs spanned a range that was less than unity[4,7,10–13] except for those from the Scottish study.[14] The SORs calculated for both univariate and multivariate ORs, reported by 7 studies, were 0.47 (95% CI: 0.40–0.55) and 0.39 (95% CI: 0.31–0.50), respectively (Fig. 2). The multivariate ORs and CIs in the majority of last-sleep analyses, adjusting for several factors including infant sleep position, were further from unity than those on univariate analyses, indicating an even stronger inverse relationship. The multivariate last-sleep SOR was recalculated without the results from the European Concerted Action on SIDS Study (ECAS),[7] which included some of the subjects from the English and Dutch studies.[4,10] The resulting SOR was very similar (0.37 [95% CI: 0.27–0.50]). When this analysis was repeated with the ECAS results included and the 2 other studies removed, the resulting SOR again was similar (0.41 [95% CI: 0.31–0.54]).

The Breslow-Day test showed heterogeneity of the ORs used to calculate the usual pacifier univariate SOR, which was scattered among 2 of the 5 analysis data sources (1 very low and 1 well above unity). A

‖ "Usual" pacifier use refers to pacifier use during a specified time period before the infant died and a comparable time period for the control infant; the definition and time period varied from study to study.

¶ The case infant's "last sleep" refers to the period of sleep during which the infant died, and the "referent sleep period" refers to a defined time period on which the control infant sleep questions are based. The latter varied from study to study.

TABLE 2. Relationship Between "Usual" Pacifier Use and SIDS

Study	No. of Infants With Usual Pacifier Use, n/N (%)		Univariate OR (95% CI)	Multivariate OR (95% CI)	Confounders Adjusted for in Multivariate Analysis*	Comments
	SIDS	Controls				
Carpenter et al[7]	394/630 (63)	1492/2230 (67)	0.88 (0.72–1.06)	0.74 (0.58–0.95)	1–5, 7, 8, 10, 14, 16, 26, 27, 29, 32	Multivariate OR and CI found in appendix to article
Fleming et al[10]	194/318 (61)	786/1299 (61)	1.03 (0.78–1.36)	Not provided		These data are for "usual nighttime use"; similar data were given for daytime use
L'Hoir et al[4]	15/73 (21)	86/146 (59)	0.19 (0.09–0.36)	0.24 (0.11–0.51)	2–5, 9, 10, 13, 15, 32	
McGarvey et al[12]	119/155 (77)	411/620 (66)	1.95 (1.25–3.06)	1.47 (0.62–3.50)	1, 3, 5, 7, 8, 11, 12, 19, 21, 24, 25, 27, 30	
Mitchell et al[13]	74/392 (19)	372/1591 (23)	0.76 (0.57–1.02)	0.71 (0.50–1.01)	1–4, 7–14, 16–20, 26, 32	ORs significant at $P = .06$; postneonatal only; "usual" was defined as any use during the past 2 wk

* Multivariate adjustments: 1, maternal age; 2, parity; 3, birth weight; 4, infant exposure to tobacco smoke (prenatal or postpartum); 5, factors related to socioeconomic status; 6, found with head/face covered; 7, infant sleep position; 8, bed sharing; 9, infant age; 10, infant gender; 11, ever breastfed; 12, gestation; 13, maternal age at first live birth; 14, region; 15, breastfeeding duration; 16, marital status; 17, ethnic group; 18, occupation; 19, education; 20, factors relating to prenatal care; 21, blanket used; 22, factors relating to surface on which infant was placed; 23, sleep location; 24, pillow used; 25, factors related to overheating; 26, admitted to NICU; 27, postneonatal infant health problems; 28, room sharing; 29, singleton birth; 30, infant exposure to alcohol; 31, infant exposure to illegal drugs; and 32, other(s).

TABLE 3. Relationship Between "Last-Sleep" Pacifier Use and SIDS

Author	No. of Infants With Last Sleep Pacifier Use, *n*/*N* (%)		Univariate OR (95% CI)	Multivariate OR (95% CI)	Confounders Adjusted for in Multivariate Analysis*
	SIDS	Controls			
Carpenter et al[7]	130/359 (36)	653/1185 (55)	0.47 (0.34–0.64)	0.44 (0.29–0.68)	1–8, 10, 14, 16, 21, 25–32
Fleming et al[10]	124/313 (40)	664/1296 (51)	0.62 (0.46–0.83)	0.41 (0.22–0.77)	1–7, 9, 11, 12, 23–25, 27, 29–32
Hauck et al[11]	39/260 (15)	83/260 (32)	0.33 (0.21–0.54)	0.34 (0.17–0.71)	1, 4, 7, 8, 16, 19, 20, 22, 24 (univariate OR and CI second decimal places provided by author [F.R.H.], which were not in the published article)
L'Hoir et al[4]	8/73 (11)	69/146 (47)	0.16 (0.07–0.36)	0.05 (0.01–0.29)	2–7, 9, 10, 13, 21, 32
McGarvey et al[12]	45/151 (30)	355/635 (55)	0.34 (0.22–0.50)	0.10 (0.03–0.31)	1, 3, 5, 7–9, 11, 12, 19, 21, 24, 25, 27, 30
Mitchell et al[13]	19/391 (5)	165/1586 (10)	0.44 (0.26–0.73)	0.43 (0.24–0.78)	1–4,7–14,16–20,26,32
Tappin et al[14]: "a little" use	27/116 (2)	94/265 (35)	0.55 (0.32–0.95)	0.59 (0.30–1.17)	1–2, 4, 5, 7, 8, 22, 26
Tappin et al[14]: "a lot" use	20/116 (17)	39/265 (15)	0.91 (0.47–1.76)	Not provided	Not applicable

* Multivariate adjustments: 1, maternal age; 2, parity; 3, birth weight; 4, infant exposure to tobacco smoke (prenatal or postpartum); 5, factors related to socioeconomic status; 6, found with head/face covered; 7, infant sleep position; 8, bed sharing; 9, infant age; 10, infant gender; 11, ever breastfed; 12, gestation; 13, maternal age at first live birth; 14, region; 15, breastfeeding duration; 16, marital status; 17, ethnic group; 18, occupation; 19, education; 20, factors relating to prenatal care; 21, blanket used; 22, factors relating to surface on which infant was placed; 23, sleep location; 24, pillow used; 25, factors related to overheating; 26, admitted to NICU; 27, postneonatal infant health problems; 28, room sharing; 29, singleton birth; 30, infant exposure to alcohol; 31, infant exposure to illegal drugs; and 32, other(s).

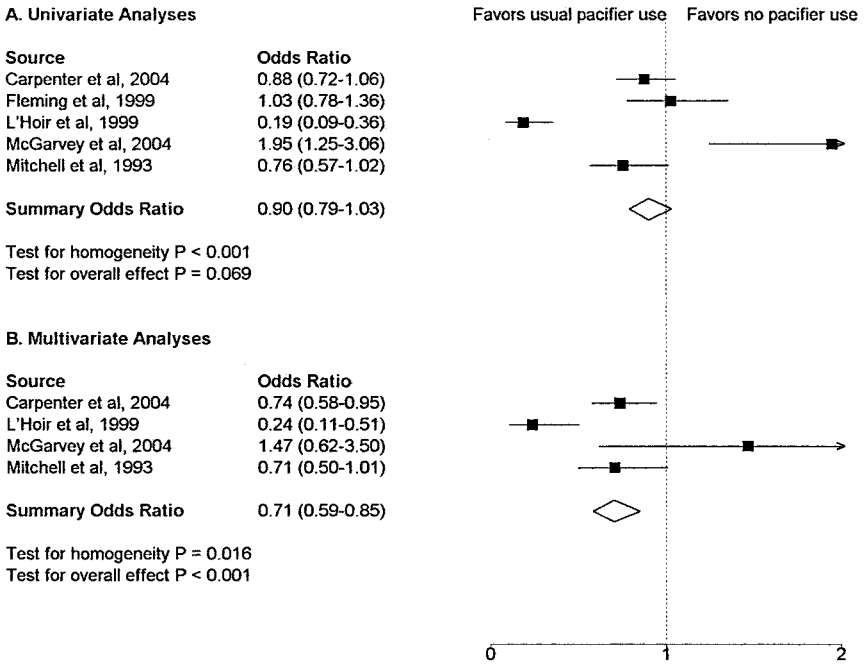

Fig 1. Usual pacifier use and risk of SIDS: univariate and multivariate analyses.

similar pattern of heterogeneity was found for the usual-use multivariate SOR.

For the last-sleep univariate SOR, 1 OR (of 8) caused the majority of the heterogeneity. However, the study primarily responsible for the heterogeneity had the lowest OR,[4] indicating an even more favorable outcome than the average. Finally, the ORs for the last-sleep multivariate SOR also were heterogeneous, but similarly, this was caused primarily by 2 very low ORs (ie, favoring pacifier use).

DISCUSSION

This analysis found that pacifier use when an infant is placed for sleep has a significant protective effect against SIDS. This conclusion is supported even further by a recent report from a California study that found a 90% reduced risk of SIDS among pacifier users during last sleep compared with control infants (adjusted OR: 0.09; 95% CI: 0.04–0.25).[20] Even with these compelling statistics, an unidentified parental care practice or infant behavioral factor may be the cause of the reduced SIDS risk in infants who use a pacifier at sleep, and adjusting for these factors may result in a lack of association between pacifier use and SIDS. Although this possibility exists, it is unlikely because of the large number of factors that were controlled for in the multivariate analyses, including maternal and infant ages, parity, birth weight, socioeconomic status, smoking, and sleep position. Some studies adjusted for more subtle potential confounders including index of prenatal care and season, and a significant association between pacifier use and reduced risk of SIDS was reported consistently. Studies that report significant

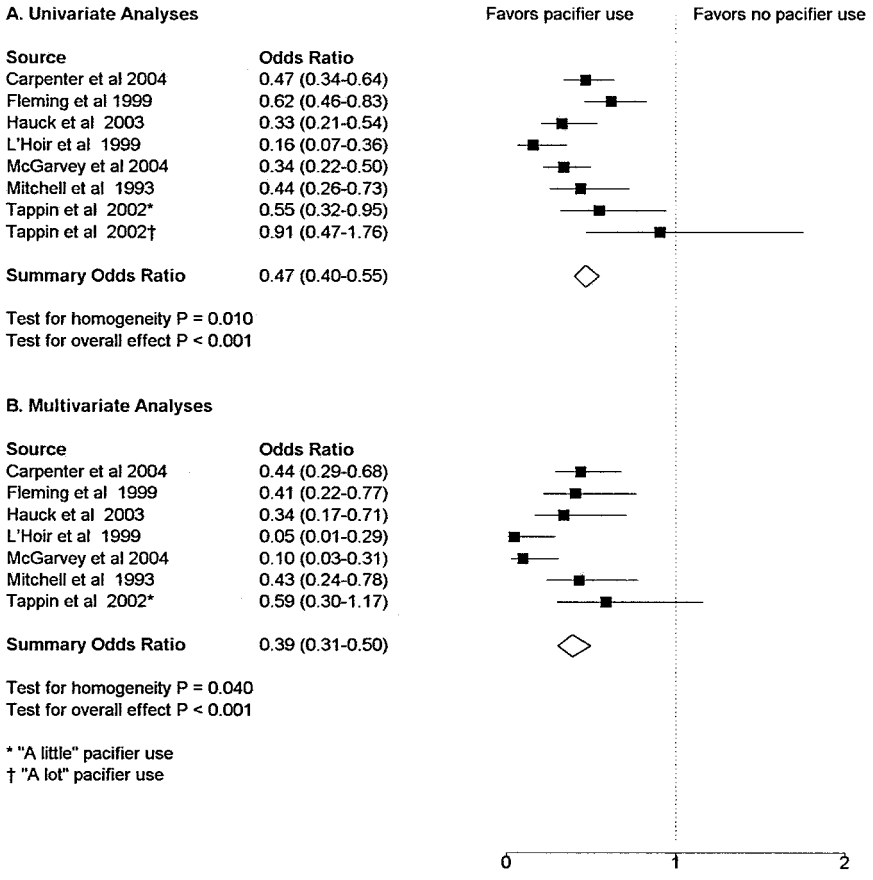

Fig 2. Last/reference-sleep pacifier use and risk of SIDS: univariate and multivariate analyses.

associations may be preferentially published, resulting in an overestimate of true effect and potentially biasing the results of the meta-analysis.[21] It is unlikely in this case for a number of reasons. The pacifier results were all part of larger studies examining potential risk and protective factors for SIDS; thus, results were published along with other findings. There was some heterogeneity of results, particularly for usual use of pacifiers, again indicating that results were not selectively reported. Finally, 1 of the authors (F.R.H.) attends the international SIDS meetings regularly and has frequent contact with SIDS researchers in both the United States and around the world and is not aware of other unpublished studies or studies published in other languages that would contradict these findings.

Several mechanisms have been postulated to explain the protective effect of pacifiers, but none has been universally accepted. The literature has focused on arousal, mouth breathing/airway patency, and sleep position. Franco et al[22] found a lower arousal threshold (ie, increased arousal responsiveness) in infants who frequently used a pacifier, including during sleep. This is significant, because decreased arousal responsiveness to a life-threatening challenge such as obstructive apneas, cardiac arrhythmia, or external conditions leading to hypoxia and asphyxia has been implicated in SIDS. The effect that pacifier use has on increasing this responsiveness could benefit an infant who otherwise might not respond appropriately to such a challenge. Other authors theorize that pacifier use enhances an infant's ability to breathe through the mouth if the nasal airway becomes obstructed.[4,23,24] Similarly, it has been hypothesized that retroposition of the tongue can lead to obstructive apnea and asphyxiation.[22] Sucking on a pacifier requires forward positioning of the tongue, thus decreasing this risk of oropharyngeal obstruction.[23] The influence of pacifier use on sleep position may also contribute to its apparent protective effect against SIDS.[4,8,24]

A common debate in the proposed schemes is that of direct versus learned effects of pacifier use on arousal, breathing, and sleep position; that is, does having a pacifier in the mouth directly influence autonomic or mechanical function only during pacifier use, or do frequent pacifier users undergo adaptive changes that are beneficial even when the pacifier is not in the mouth? In the study by Franco et al,[22] pacifiers became dislodged from the mouths of >80% of infants within the first hour of sleep, and Weiss and Kerbl[25] found 78% of pacifier-usage episodes to be <15 minutes. If pacifiers rarely remain in the mouth of a sleeping infant for an extended period of time, then it is possible that habitual pacifier use during the day and the beginning of sleep has adaptive effects that continue after the pacifier falls out of the mouth. Some of the SIDS studies, however, point to a direct beneficial effect of pacifiers, evidenced by the findings that usual pacifier use was not protective whereas last sleep use was.[10,12,13] An Irish study reported that the infants who habitually used a pacifier but did not do so on the night of last sleep were at higher risk of SIDS than regular users who did use

one at last sleep.[12] Because pacifiers are dislodged easily, the displacement of the pacifier might contribute to more sleep disruption and easier arousability of the infant.[26] As increased arousal thresholds have been reported in infants with SIDS risk factors (eg, prenatal exposure to tobacco and preterm delivery), the direct arousal effect of pacifier use and dislodgment may account for the apparent protective effect of last/reference-sleep pacifier use and the lack of a protective effect when pacifiers are usually used but not at last sleep.

It is possible also that other factors associated with not using the pacifier at last sleep among habitual users may play a role in increasing the risk of SIDS, such as the infant being ill, resulting in the pacifier being refused or not offered. In the Irish study, the increased risk of not using a pacifier at last sleep remained significant after adjusting for illness and crying/colic, implying that illness was not a factor.[12] Additional research is needed to understand the factors that may influence the use and nonuse of pacifiers, including parenting behaviors and infant factors.

Concerns about recommending the use of pacifiers on a population-wide basis have focused primarily on breastfeeding, otitis media and other infections, and dental malocclusion. One randomized, controlled trial found that early pacifier users (2–5 days at introduction) were slightly less likely to be exclusively breastfed at 1 month compared with nonusers.[27] Pacifier introduction after 1 month of age was not detrimental to breastfeeding duration. Other trials did not show an effect of pacifiers on breastfeeding duration among term[28,29] or preterm[30] infants.

Although some dental malocclusions, notably posterior crossbite, have been found more commonly among pacifier users than nonusers; the differences generally disappear after cessation.[31] It has been shown that infants not offered pacifiers were more likely to suck their fingers, a habit that is more difficult to break[32] and more likely to cause malocclusion.[31] The American Academy of Pediatric Dentistry's policy on oral habits states: "nonnutritive sucking behaviors (ie, finger or pacifier sucking) are considered normal in infants and young children and usually are associated with their need to satisfy their urge for contact and security."[33] The policy indicates that pacifiers are unlikely to cause long-term problems if stopped by the age of 3 years. Others have suggested curtailment of pacifier use beginning at the age of 2 years and discontinuation by the age of 4 to minimize the development of malocclusion.[34]

An ~1.2- to 2-times increased risk of otitis media has been associated with pacifier use.[35–38] Because otitis media is less common among infants who are <6 months of age,[39,40] the risk for infection during the peak SIDS incidence period would be low. Other mild infant health symptoms based on subjective ratings of mothers were found to be associated with pacifier use in the first 6 months of life.[41] Additional research is needed to assess these and other potential illnesses and to determine if any associations that might be found are causal.

Pacifiers provide other beneficial effects including management of discomfort as determined by reductions in crying and other validated measures during painful procedures.[42,43] A systematic review of 19 studies on nonnutritive sucking among preterm infants found that it reduced the length of stay by an average of 7 days and was not found to have any adverse outcomes.[44]

CONCLUSIONS AND RECOMMENDATION

The results of our meta-analysis show a strong correlation between giving an infant a pacifier and reducing his or her risk of dying from SIDS. The results indicate that the effect is strongest when given at last/reference sleep. Encouraging pacifier use is likely to be beneficial on a population-wide basis: 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 national SIDS rate and the last-sleep multivariate SOR resulting from this analysis. Therefore, we recommend that pacifiers be offered to infants as a potential method to reduce the risk of SIDS. The pacifier should be offered to the infant when being placed for all sleep episodes including daytime naps and nighttime sleeps. This is a USPSTF level B strength of recommendation based on the consistency of findings among the available studies (which are of weaker design [ie, case-control studies rather than controlled trials or cohort studies]) and the likelihood that the beneficial effects will outweigh any potential negative effects.[19] Because these studies are observational in design, it is helpful to examine factors that have been proposed to help determine the "causality" of an observed factor on an outcome.[45] These factors include (1) consistent findings, (2) strong association, (3) dose-response effect, (4) biological plausibility, and (5) causal factor preceding the outcome. We demonstrated above that all of these criteria have been satisfied. There is a strong and consistent association between pacifier use when the infant is put down for sleep and reduced risk of SIDS; there is an apparent dose response in that use for all sleep periods is necessary; there are several biologically plausible mechanisms proposed currently, supported by research findings; and the pacifier nonuse precedes the SIDS outcome.

The potential detrimental effects suggest that pacifier use should be of limited duration. We support pacifier use for infants up to 1 year of age, which includes the peak ages for SIDS risk[3] and the 1- to 5-month-old range in which an infant's need for sucking is highest.[46,47] For breastfed infants, pacifiers should be introduced after breastfeeding has been well established, which is consistent with the AAP policy statement on breastfeeding.[48] Because SIDS is less common in the first month of life, it is reasonable to delay pacifier introduction during this lower risk period. The pacifier should not be used as a substitute for nursing or feeding, nor should it be coated with sugar, honey, or other sweet substances. Once the infant falls asleep, the pacifier should not be reintroduced if it falls out of the mouth, nor should infants who refuse a pacifier be forced to take one.

We recommend cessation of pacifier use by 12 months of age, because otitis media risk is higher, whereas SIDS risk declines considerably after this age. The risk of otitis media associated with pacifier use may be reduced by frequent cleaning and replacement of damaged pacifiers. Medical professionals should educate parents of infants about these practices. To ensure maximal breastfeeding success, mothers need regular support, encouragement, and assistance with developing proper breastfeeding techniques to build confidence in breastfeeding, because these qualities have been observed in mothers who give pacifiers to their infants and continue breastfeeding.[49]

Although the rates of SIDS have halved since recommendations have been made to place infants supine for sleeping, there are still close to 2300 deaths in the United States attributed to SIDS each year, and the declining trend has reversed recently, with the SIDS rate increasing by 2.9% from 2001 to 2002.[2] In addition to the consistent and large beneficial effect of pacifiers shown in well-designed case-control studies of SIDS, the intervention would be inexpensive and easy to implement, requiring minimal behavioral change on the part of parents and other caregivers. Pacifier use is already common and acceptable to many parents; in the United States, rates of use range from 36% to 74%[35,50–52] and are equally high or higher in other countries.[32,53–55] As for the criticism that we should not implement an intervention without understanding the mechanism of its action,[10] the same could be said for implementing the supine sleeping recommendation for SIDS prevention. Although the mechanism for its beneficial action is still not known, few would argue against this intervention now that we have experienced its dramatic beneficial results. Implementing this new intervention may help us come closer to reaching our goal of eliminating these tragic deaths. Ongoing monitoring of rates of SIDS and other sudden unexpected deaths using population-based infant mortality statistics, as well as pacifier usage in these infants and in the general population, will be needed to help evaluate the impact of this recommendation.

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