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Uso de chupetes versus ningún uso de chupetes en lactantes nacidos a término que son amamantados para aumentar la duración de la lactancia materna

Cochrane Systematic Review - **Intervention** | Version published: 16 March 2011 **see what's new**

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Resumen *available in* English | Español

Antecedentes

Para iniciar con éxito y mantener la lactancia materna durante más tiempo, los Diez Pasos para la Lactancia Materna Exitosa de la Organización Mundial de la Salud recomiendan evitar completamente las mamas artificiales o los chupetes para los lactantes que son amamantados. Ofrecer el chupete en lugar de la mama para calmar al lactante puede dar lugar a episodios menos frecuentes de lactancia, lo que puede reducir la producción de leche materna y acortar la duración de la lactancia; sin embargo, lo anterior aún es incierto.

Objetivos

Evaluar el efecto del uso de chupetes versus ningún uso de chupetes en lactantes nacidos a término saludables cuyas madres han iniciado la lactancia materna y se proponen seguir con esta lactancia exclusivamente, sobre la duración de ésta, otros resultados de lactancia materna y la salud del lactante.

Métodos de búsqueda

Se realizaron búsquedas en el Registro Especializado de Ensayos Controlados del Grupo Cochrane de Embarazo y Parto (Cochrane Pregnancy and Childbirth Group's Trials Register) (31 de diciembre de 2010).

Criterios de selección

Ensayos controlados con asignación aleatoria y cuasialeatoria que compararan el uso de chupetes versus ningún uso de chupetes en lactantes nacidos a término saludables que han iniciado la lactancia materna independientemente de si nacieron en el domicilio o en el hospital.

Obtención y análisis de los datos

Dos autores evaluaron de forma independiente los estudios para su inclusión, evaluaron el riesgo de sesgo y extrajeron los datos.

Resultados principales

Se encontraron tres ensayos (con 1 915 lactantes) para su inclusión en la revisión pero sólo se incluyeron en el análisis dos ensayos (con 1 302 lactantes nacidos a término saludables que son amamantados). El metanálisis de los dos estudios combinados mostró que el uso de chupetes en los lactantes saludables que son amamantados no tuvo un efecto significativo sobre la proporción de lactantes con lactancia materna exclusiva a los tres meses (cociente de riesgos [CR] 1,00; intervalo de confianza [IC] del 95%: 0,95 a 1,06) ni a los cuatro meses de vida (CR 0,99; IC del 95%: 0,92 a 1,06); tampoco tuvo efecto sobre la proporción de lactantes con lactancia materna parcial a los tres meses (CR 1,00; IC del 95%: 0,97 a 1,02) ni a los cuatro meses de vida (CR 1,01; IC del 95%: 0,98 a 1,03).

Conclusiones de los autores

El uso de chupetes en los lactantes nacidos a término saludables que son amamantados, comenzado a partir del nacimiento o después de que se establezca la lactancia materna, no afectó significativamente la prevalencia ni la duración de la lactancia materna exclusiva y parcial hasta los cuatro meses de vida. Sin embargo, existe una falta de pruebas para evaluar las dificultades que enfrentan las madres en la lactancia materna a corto plazo y el efecto a largo plazo de los chupetes sobre la salud del lactante.

Resumen en términos sencillos *available in* English | Español

Efecto del uso de chupetes sobre la duración de la lactancia materna en los lactantes nacidos a término

La leche materna es superior a otros alimentos para los lactantes porque les proporciona nutrición balanceada y protección contra la alergia y la infección. La Organización Mundial de la Salud recomienda la lactancia materna exclusiva en los seis primeros meses y luego como un suplemento dietético. La

producción y el suministro de la leche materna se mantienen por la succión frecuente de la mama y la estimulación del pezón. Un chupete es un dispositivo de succión no nutritivo utilizado para calmar a un lactante, el cual se ha convertido en una norma social en muchas partes del mundo. Sin embargo, existe la creencia generalizada de que los chupetes pueden dificultar la producción de leche materna y dar lugar a la interrupción de la lactancia materna.

Esta revisión concluyó que para las madres que están motivadas a lactar a sus lactantes, el uso de chupetes antes o después de que se haya establecido la lactancia materna no afectó significativamente la prevalencia ni la duración de la lactancia materna exclusiva y parcial hasta los cuatro meses de vida. La revisión proporcionó pruebas moderadas de tres ensayos controlados con asignación aleatoria (que incluyeron 1 915 lactantes) que compararon el uso de chupetes y ningún uso de chupetes en lactantes saludables a término que son amamantados; dos de los ensayos (1 302 lactantes) se incluyeron en el análisis. Sin embargo, existe la creencia generalizada de que los chupetes pueden dificultar la producción de leche materna y dar lugar a la interrupción de la lactancia materna.

Conclusiones de los autores *available in* English | **Español**

Implicaciones para la práctica

En las madres motivadas hay pruebas moderadas de que el uso de chupetes antes y después de que la lactancia se haya establecido, en lactantes nacidos a término saludables que son amamantados, no reduce la duración de la lactancia materna hasta los cuatro meses de vida. Sin embargo, no hay información suficiente sobre los efectos perjudiciales potenciales de los chupetes en los lactantes ni en las madres. Según la presente revisión, se recomienda que hasta que haya más información disponible sobre los efectos de los chupetes sobre el lactante, las madres bien motivadas a lactar pueden tomar una decisión sobre el uso de un chupete según su preferencia personal.

Implicaciones para la investigación

Se recomienda investigación adicional para abordar el efecto del uso de chupetes sobre la duración de la lactancia materna que incluya mujeres menos motivadas. También se recomiendan ECAs bien diseñados para evaluar la tasa de dificultades con la lactancia materna que enfrentan las madres y que están asociadas al uso de chupetes y el efecto a largo plazo de dicho uso sobre la salud materna e infantil. Se recomienda investigación adicional para abordar el efecto del uso de chupetes sobre la duración de la lactancia materna que incluya mujeres menos motivadas. También se recomiendan ECAs bien diseñados para evaluar la tasa de dificultades con la lactancia materna que enfrentan las madres y que están asociadas al uso de chupetes y el efecto a largo plazo de dicho uso sobre la salud materna e infantil.

Antecedentes

available in English | **Español**

Se ha documentado bien la superioridad de la leche materna para la provisión de una nutrición equilibrada, así como la protección contra la alergia y la infección en los lactantes (Chandra 1979; Oddy 2001). Por lo tanto, la Consulta de Expertos de la Organización Mundial de la Salud (OMS) recomienda que los lactantes sean amamantados exclusivamente (sólo reciban leche materna sin otros líquidos, incluidos agua o sólidos) hasta los seis primeros meses de vida y como suplemento dietético posteriormente. Para iniciar con éxito y mantener la lactancia durante más tiempo y evitar la alimentación complementaria, los Diez Pasos para la Lactancia Materna Exitosa de la Organización Mundial de la Salud recomiendan no brindarles mamas artificiales ni chupetes a los lactantes que son amamantados. El uso de un chupete, un dispositivo de succión no nutritivo para calmar a un lactante, está relativamente generalizado y se ha convertido en una norma cultural en muchas partes del mundo (Barros 1995). A menudo se considera que los chupetes son inocuos e incluso necesarios y beneficiosos para el desarrollo del lactante (Victora 1997). Sin embargo, aún es motivo de controversia el uso de chupetes en los lactantes que son amamantados.

La producción y el suministro de la leche materna se mantienen por la succión frecuente de la mama y la estimulación del pezón (Aarts 1999; Neville 1988). Para lograr una lactancia exitosa los lactantes deben aprender a acoplarse a la mama y succionar adecuadamente durante los primeros días de vida. La técnica efectiva de succión de la mama requiere que el lactante tenga la boca bien abierta, con la lengua bajo la areola. La expresión de la leche de la mama se realiza mediante succiones lentas y profundas, mientras que la succión de un chupete es básicamente una succión superficial (Righard 1992) donde el lactante realiza succiones cortas y rápidas con un esfuerzo mínimo. Las diferencias mecánicas entre la succión de la mama y de un chupete pueden dar lugar a "confusión del pezón" (Gomes 2006; Neifert 1995), acoplamiento incorrecto a las mamas y succión superficial de los pezones de la madre (Righard 1998). Una técnica indebida al succionar las mamas puede dar lugar a pezones agrietados y mastitis, lo que puede impedir de forma adicional la lactancia materna. Las pruebas de un estudio de cohortes informaron que las dificultades para la lactancia materna durante la primera semana posparto se asociaron significativamente con la interrupción de la lactancia materna en la décima semana de vida (Scott 2005). Existe la creencia basada en pruebas observacionales de que la exposición temprana de los lactantes al chupete se asocia con interrupción de la lactancia materna exclusiva a los tres a seis meses (Mascarenhas 2006; Scott 2005), y de la lactancia materna en general a los 12 meses (Scott 2005). Ofrecer el chupete en lugar de la mama para calmar al lactante puede dar lugar a episodios menos frecuentes de lactancia materna. Lo anterior a su vez puede reducir la producción de leche materna y acortar la duración de la lactancia materna a largo plazo (Howard 1999). Además, los lactantes pueden acostumbrarse al chupete y desarrollar una preferencia por una mama artificial en lugar del pezón de la madre.

Por otro lado, aún está poco claro si la interrupción de la lactancia materna y la intención materna de

retirarle al lactante la lactancia materna exclusiva precede al uso de un chupete o viceversa. Es posible que una madre pueda haber tenido dificultades para la lactancia materna temprana e intente interrumpirla al introducirle el chupete al lactante antes de adoptar la alimentación con biberón. Es interesante señalar que las pruebas también muestran que los chupetes pueden tener un efecto positivo sobre la lactancia materna porque pueden ayudar a retirar al lactante de la mama y, por lo tanto, aumentar el intervalo entre las tomas y posiblemente la ingesta de leche materna por parte del lactante (Victora 1997). Las pruebas observacionales también indican que el uso ocasional del chupete no tiene efecto sobre la duración de la lactancia materna en comparación con el uso diario del chupete (Ullah 2003; Vogel 2001) y por lo tanto aún está poco claro si los chupetes son un factor causal independiente para reducir la duración de la lactancia materna. Además, el uso de chupetes podría ser un factor protector contra el síndrome de muerte súbita del lactante (Mitchell 2006; Saririan 2006), aunque su mecanismo se desconoce. Sin embargo, la succión prolongada y no nutritiva del chupete se asocia con un mayor riesgo de otitis media aguda recurrente (Jackson 1999), candidiasis oral (Darwazeh 1995) y maloclusión dental (Caglar 2005).

Por lo tanto, el objetivo de esta revisión es estudiar el efecto de la exposición al chupete versus ninguna exposición al chupete en lactantes saludables cuyas madres han iniciado la lactancia materna y se proponen amamantar exclusivamente, sobre la duración de la lactancia materna y la salud infantil.

Objetivos *available in* English | **Español**

Evaluar el efecto del uso de chupetes versus ningún uso de chupetes en lactantes nacidos a término saludables cuyas madres han iniciado la lactancia materna y se proponen seguir exclusivamente con la lactancia materna, sobre la duración de ésta, otros resultados de lactancia materna y la salud del lactante.

Métodos *available in* English | **Español**

Criterios de inclusión de estudios para esta revisión

Tipos de estudios

Todos los ensayos controlados con asignación aleatoria, incluidos los ensayos con asignación cuasialeatoria.

Tipos de participantes

Lactantes nacidos a término saludables que han iniciado la lactancia materna, independientemente de si nacieron en el domicilio o en el hospital. Se excluirán los estudios donde participen lactantes expuestos a alimentación con biberón antes de su inclusión.

Tipos de intervenciones

Uso sin restricción o activamente promovido de un chupete comparado con asesoramiento contra el uso de un chupete. Se excluyeron los estudios que evalúan el uso ocasional de chupetes para proporcionar alivio del dolor de un procedimiento.

Tipos de medida de resultado

La lactancia materna total o exclusiva se define como ningún alimento (sólido ni líquido, incluida agua) diferente de la leche materna. La lactancia materna casi exclusiva permite líquidos suplementarios poco frecuentes que no sean una fórmula de leche, y en la lactancia materna parcial se proporcionan regularmente otros suplementos lácteos junto con la lactancia materna (Labbok 1990).

Definición de lactancia materna y lactancia materna parcial

Resultados primarios

Duración de la lactancia materna medida por uno de los siguientes resultados:

- duración media de la lactancia materna exclusiva (meses) como la definió Labbok 1990;
- duración media de cualquier lactancia materna o parcial (meses);
- prevalencia o proporción de lactantes con lactancia materna exclusiva o parcial a los tres, cuatro y seis meses de vida.

Resultados secundarios

- Tasa de dificultades para lactancia materna (pezones agrietados, ingurgitación mamaria, mastitis).
- Satisfacción materna y nivel de confianza en la crianza.
- Media de episodios/frecuencia de llanto y agitación infantil por día.
- Salud de los lactantes: incidencia de síndrome de muerte súbita del lactante, candidiasis oral, otitis media y maloclusión dental.

Results

Description of studies

Results of the search

The search identified nine reports of five randomised controlled trials (RCTs). We have included three studies and excluded two.

Included studies

*See*Characteristics of included studies. We included three studies involving 1915 babies (Jenik 2009; Kramer 2001; Schubiger 1997). However, only two of these studies (involving 1302 babies: Jenik 2009; Kramer 2001) contribute data to the analyses.

Jenik 2009: a multicentre-trial evaluated pacifier use in breastfeeding infants once lactation was well established for whether it reduced the prevalence or duration of breastfeeding. A total of 1021 mothers highly motivated to breastfeed were recruited and randomly assigned to whether pacifier was offered (n = 528) or not offered (n = 493). The study was designed as a non-inferiority trial and only mothers who were already successfully breastfeeding at two weeks and who indicated their intention to continue to do so for at least three months were enrolled. Mothers with breast problems that could interfere with breastfeeding (sore nipples, mastitis, inverted nipples, breast surgery) were not included. Participating mothers were interviewed at one, two, three, four, five, six, eight, 10 and 12 months after births or until breastfeeding ended. Interviews were conducted by a research assistant using a structured questionnaire designed to assess exclusive or any breastfeeding prevalence, duration of breastfeeding and whether the baby had used a pacifier. The primary outcome was prevalence of exclusive breastfeeding at three months. The main secondary outcomes were the prevalence of exclusive and any breastfeeding and duration of any breastfeeding. Primary analysis was by intention to treat. Comparison between the two groups in the study did not show any difference in the baseline characteristics namely the infant birthweight, mode of delivery, maternal age and education, and onset of breastfeeding.

Kramer 2001: a double-blind RCT, examined whether or not regular pacifier use is related to weaning by three months of age. A total of 281 healthy breastfeeding women who intended to breastfeed their infant longer and their healthy term singleton infants were randomised to one of two counselling interventions provided by a trained research nurse. In the experimental group (n = 140) the mother was asked to avoid pacifier use when the infant cried or fussed and to first offer the breast and, failing that, to try carrying or rocking the infant. In the control group (n = 141) all options were discussed for calming the infant, including breastfeeding, carrying, rocking and pacifier use. To ascertain the outcome mothers were asked to complete a validated behaviour diary on three consecutive days, when their infants were four, six and nine weeks of age. Study mothers were interviewed at three months by a research assistant who was blinded to the intervention status of the mother. A total of 258 (91.8%) mother-infant pairs completed three months follow-up.

Schubiger 1997: a multicentre prospective randomised trial evaluated whether avoidance of bottles and pacifiers in the first five days of life affected long-term breastfeeding performance. However, as a result of high attrition bias (more than 20% loss of participants), we have not included data from this study in the analysis. This is in accordance with our prespecified inclusion criteria for analysis.

Excluded studies

We have excluded two studies from the review (Collins 2004; Howard 2003). One study (Collins 2004) compared use of bottles and pacifiers versus cup feeding in preterm breastfeeding infants who wanted to breastfeed their infant. The other excluded study (Howard 2003) compared the effect of early versus late pacifier use in term infants on duration of breastfeeding. For further information, *see*Characteristics of excluded studies.

Risk of bias in included studies

All three included studies employed computerised central randomisation. The method of allocation concealment was 'adequate' in two studies (Jenik 2009; Kramer 2001). These two studies used consecutively numbered, opaque sealed envelopes but in one of the trials (Schubiger 1997) the method of concealment was 'unclear', as it reported use of sealed envelopes but did not state whether these were sequentially numbered. Two studies reported blinding of research nurse and outcome assessors (Jenik 2009; Kramer 2001). In both studies blinding of the care-giver was not mentioned. It would not be feasible to blind participants to the intervention. One study did not mention whether there was any blinding. Overall, the dropout rate was less than 10% from both arms, i.e. 4.9% versus 4.5% in Jenik 2009, 9.3% versus 7.1% in Kramer 2001 respectively. However, in Schubiger 1997, the total dropout rate was 45% versus 10.5% which did not satisfy our prespecified inclusion criteria for analysis. We detected no selective reporting or other potential source of bias in any of the included studies.

Effects of interventions

Primary outcomes

We included two out of three RCTs enrolling 1302 healthy full-term breastfeeding infants for analysis (Jenik 2009; Kramer 2001). Both of the trials contributed to at least one of the primary outcomes, i.e. proportion of infants partially or exclusively breastfed at three and four months of age. Comparison between pacifier use (intervention) and no pacifier use (control) revealed that there was no significant difference in the proportion of infants exclusively breastfed at three months (risk ratio (RR) 1.00; 95% confidence interval (CI) 0.95 to 1.06, two studies, 1228 babies (Analysis 1.1)) and at four months of age (RR 0.99; 95% CI 0.92 to 1.06, one study, 970 babies (Analysis 1.2)). There was also no significant difference in the proportion of infants partially breastfed at three months (RR 1.00; 95%; CI 0.97 to 1.02, two studies, 1228 babies (Analysis 1.3)), or at four months (RR 1.01; 95% CI 0.98 to 1.03, one study, 970 babies (Analysis 1.4)). Thus, pacifier use in full-term breastfeeding infants after birth or after the establishment of lactation did not significantly affect the prevalence or duration of exclusive or partial breastfeeding up to the age of four months.

None of the included studies reported data on the other primary outcomes, i.e. mean duration of partial or exclusive breastfeeding.

Secondary outcomes

None of the included studies reported data on any of our prespecified secondary outcomes: rate of breastfeeding difficulties (mastitis, cracked nipples, breast engorgement); infant's health (dental malocclusion, otitis media, oral candidiasis; sudden infant death syndrome); maternal satisfaction and level of confidence in parenting; or mean episode/frequency of infant crying and fussing per day.

Discusión *available in* English | **Español**

Esta revisión indica que, en las madres sumamente motivadas, el uso de chupetes no se asoció con una reducción de la tasa ni la duración de la lactancia materna exclusiva o parcial, independientemente de si el chupete se introdujo antes o después de que la lactancia se hubiera establecido.

Los "Diez Pasos para la Lactancia Materna Exitosa" de la Organización Mundial de la Salud son guías valiosas para los hospitales. Algunas recomendaciones, sin embargo, se basan en estudios observacionales. El uso del chupete es una práctica frecuente en muchas poblaciones y por lo tanto, sin pruebas científicas sólidas de su repercusión sobre la duración de la lactancia materna, esta recomendación debe ser revisada. El mecanismo propuesto para la relación entre la reducción de la lactancia materna y el uso de chupetes es que cuando los lactantes utilizan chupetes tienden a succionar menos de la mama, por lo que el suministro de leche se reduce y posteriormente fracasa. Esta revisión contradice el resultado de un metanálisis de 31 estudios transversales y de cohortes (Karabulut 2009) donde participaron varios miles de lactantes que informó que el uso de chupetes se asoció con una disminución de la duración de cualquier lactancia materna y de la lactancia exclusiva antes de los seis meses de vida (CR 2,02, IC del 95%: 1,62 a 2,51 y CR 2,76, IC del 95%: 2,08 a 3,7; respectivamente).

La presente revisión consiste en dos ECAs multicéntricos que incluyeron seis hospitales terciarios de dos países diferentes, con 1 302 participantes. El riesgo de sesgo de los estudios incluidos era generalmente bajo. Sin embargo, no se encontró heterogeneidad significativa entre los estudios. Ambos ensayos mostraron de forma consistente que el uso de chupetes no afectó significativamente la duración de la lactancia materna. Todos los efectos resumidos obtenidos en los resultados estuvieron de forma consistente entre 0,99 y 1,01 y los IC del 95% fueron estrechos. Varios factores podrían afectar la duración de la lactancia materna como la edad materna, la educación, la posición social y el contacto madre-lactante sin restricción, así como factores psicosociales como la intención materna de lactar, la autoeficacia, la confianza en la lactancia materna y la experiencia anterior con la lactancia materna (Kronborg 2004; Righard 1998). La comparación de las características iniciales de los participantes en ambos ensayos incluidos no mostró diferencias significativas en cuanto a la edad materna, la educación, la posición social ni la paridad. Las madres que participaron en estos ensayos estaban sumamente motivadas a continuar la lactancia materna. Jenik 2009 sólo incluyó madres que habían establecido con éxito la lactancia materna después de dos semanas, mientras que en el estudio Kramer 2001 participaron madres después del parto pero antes de que se hubiera establecido la lactancia. Por lo

tanto, la presente revisión concluye que el uso de chupetes antes o después de que la lactancia materna se haya establecido no afecta la duración de la misma cuando las madres están motivadas a lactar a sus lactantes. Sin embargo, es posible que el resultado de esta revisión no se aplique a las madres que están menos motivadas o que no tienen deseos de lactar a sus lactantes por más tiempo.

Los dos estudios de la revisión también informaron que una proporción de parejas madre-lactante del ensayo no cumplió la recomendación a la cual se asignaron al azar. Esta tasa de incumplimiento no es sorprendente en una población con antecedentes culturales diversos. Las situaciones de la vida real, como el llanto infantil intenso y las preferencias del recién nacido, pueden haber influido en el uso de los chupetes. Este resultado es compatible con el análisis de intención de tratar, lo que indica que la recomendación del uso de un chupete en una población similar no influye en el éxito ni en la duración de la lactancia materna. Kramer 2001 no informó diferencias significativas en la frecuencia media de comportamiento de llanto y agitación por día entre los lactantes que usaron chupete y los que no lo usaron a las seis y nueve semanas de vida. Sin embargo, el estudio no contribuyó con datos suficientes para permitir el análisis de este resultado.

Esta revisión no pudo evaluar ninguna de las medidas de resultado secundarias (efecto del uso de chupetes sobre las dificultades para la lactancia materna enfrentadas por las madres y el efecto del chupete sobre la salud de los lactantes a largo plazo, p.ej. maloclusión dental, otitis media, caries dental y síndrome de muerte súbita del lactante). Por lo tanto, para responder estas preguntas se recomienda un ECA que evalúe estos efectos.

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Jump to: **estudios excluidos** | **referencias adicionales**

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Characteristics of studies

Characteristics of included studies [ordered by study ID]

Jump to: **excluded studies**

Jenik 2009

Methods	A multicentre, non-inferiority, RCT. The randomisation was carried out centrally with consecutively numbered, sealed, opaque envelopes containing random generated numbers constructed by an independent statistician.
Participants	1021 mothers highly motivated to breastfeed their term newborns of birthweight 2500g or more and who regained weight by 15 days postpartum, were assigned to offer or not to offer pacifiers as part of the advice given on how to comfort crying infants. Mothers with breast problems that could interfere with breastfeeding were not included in the study.
Interventions	The group offered pacifiers (n = 528) received a package containing 6 silicone pacifiers and a written guide for parents. They were also informed that other pacifiers could be use according to their preference. The group that were not offered pacifier use (n = 493) received a guide with other alternatives for comforting a crying baby. At the 3-month assessment, complete data for 499 mother-infants pairs in the group offered pacifiers and 471 in the group not offered pacifiers were available for the main outcome analysis.
Outcomes	Primary outcomes: the prevalence of exclusive breastfeeding at 3 months. Secondary outcomes: prevalence of exclusive and any breastfeeding at specified ages and duration of any breastfeeding.
Notes	The study was carried out at 5 tertiary centres in Argentina.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	It is reported that the randomisation was carried out centrally with random generation conducted by an independent statistician.

Allocation concealment (selection bias)	Low risk	Consecutively numbered, sealed opaque envelopes were used to conceal a randomly generated assignment. A series of 500 envelopes was given to research assistants at each participating hospital with instructions to open the envelopes in numerical sequence and to assign the dyads to the corresponding group.
Blinding (performance bias and detection bias) All Outcomes	Low risk	The outcome assessors were 'blinded to the group assignment' but there was no mention of whether the researchers were blinded to the group assignment. Participant blinding was not feasible.
Incomplete outcome data (attrition bias) All outcomes	Low risk	4.9% (26/528) participants in offer pacifier group and 4.5% (22/493) in the non-offer pacifier group were lost to follow-up due to various reasons.
Selective reporting (reporting bias)	Low risk	None detected.
Other bias	Low risk	None detected.

Kramer 2001

Methods	Double-blinded RCT.
Participants	A total of 281 healthy breastfeeding women and their healthy term singleton infants.
Interventions	Participants were randomly allocated to 1 of 2 counselling interventions provided by a research nurse trained in lactation counselling. A basic breastfeeding promotion package was included in both the intervention and control groups. The intervention group (n = 140) were 'asked to avoid pacifiers when the infant cried or fussed' and suggested alternative ways to provide comfort. The control group (n = 141) 'all options were discussed for calming an infant' including pacifier use .
Outcomes	Mothers was asked to complete a validated behaviour diary on 3 consecutive days, at 4, 6 and 9 weeks of age. Study mothers were interviewed at 3 months. Primary outcome measures: rate of early weaning at 3 months, 72 hour infant behaviour logs detailing frequency and duration of crying and fussing and pacifier use at 4, 6, 9 weeks.
Notes	The trial was carried out from January 1998 to August 1999 on women giving birth at the Royal Victoria Hospital, a McGill University-affiliatted maternity hospital in Montreal, Quebec.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Randomization within each stratum was accomplished using computer-generated random numbers in blocks of 4'. 'Women were stratified by parity and if multiparous according to whether they had breastfed previously.'
Allocation concealment (selection bias)	Low risk	'The assigned allocation was contained in an opaque envelope opened by a research nurse after the consent was obtained'.
Blinding (performance bias and detection bias) All Outcomes	Low risk	'Study mothers were interviewed at 3 months by a research assistant who was blinded to the intervention status of the mother.'
Incomplete outcome data (attrition bias) All outcomes	Low risk	8.2% (23/281) participants, i.e. 13/140 from pacifier avoidance group, 10/141 from pacifier advised group lost to follow-up and did not complete the trial.
Selective reporting (reporting bias)	Low risk	None detected.
Other bias	Low risk	None detected.

Schubiger 1997

Methods	Multicentre prospective randomised trial (from 10 centres).
Participants	A total of 602 healthy full-term infants (> 37 weeks of gestation, birthweight 2750 g to 4200 g) of mothers who intended to stay in the hospital for 5 days postpartum and planned to breastfeed for more than 3 months.

Interventions	UNICEF group (n = 294): 'bottles, teats and pacifiers were strictly forbidden'; 'supplements if medically indicated were administered by cup or spoon'. Standard group (n = 308): 'pacifiers were offered to all infants without restriction. Supplements were conventionally offered by bottle after breastfeeding'. In both groups, the fluid supplements during the first few days consisted of a 10% dextrin-maltose solution. Fluid supplements were considered to be medically indicated in the following situations: babies agitated or screaming after breastfeeding; signs of dehydration (no urine output over 4 hours after day 1); symptoms of hypoglycaemia with blood glucose < 2 mmol/l. In the standard group fluids were more liberally offered. About 180 participants in the UNICEF group and 291 participants in the standard group completed the protocol. Almost 40% of the participants in the UNICEF group violated protocol during the first 5 days in the hospital. Upon discharge from the hospital, it was left to the mothers of both groups to decide whether to use a pacifier and/or bottle.
Outcomes	Incidence of breastfeeding at day 5, and at 2, 4, 6 months, proportion of fully or partially breastfeeding on day 5, sucking behaviour (good, mediocre, insufficient), incidence of fever, incidence of phototherapy. Questionaires administered to mothers at 2, 4, and 6 months were used to collect breastfeeding outcomes after hospital discharge.
Notes	Study conducted in Switzerland. Results were reported in 2 separate publications with slight differences in the presentation of results. This study however was not included for analysis due to high attrition bias (almost 40% loss of participants in the intervention group) due to protocol violation in the first weeks of the study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centrally randomised, method of sequence generation not reported.
Allocation concealment (selection bias)	Unclear risk	Sealed protocol forms distributed to each centre but it is not reported whether they were consecutively numbered or whether opaque envelopes were used.
Blinding (performance bias and detection bias) All Outcomes	Unclear risk	There is no mention of blinding of researchers or outcomes assessors. Blinding of participants would not be feasible.

Incomplete outcome data (attrition bias) All outcomes	High risk	About 38% (114/294) of the participants in the UNICEF group were excluded due to protocol violation in the first week, i.e. mother requested a bottle (19), mother requested a pacifier (70), failed to spoon/cup feed (9), early discharge (6) and other reasons (10); leaving 180 participants in the UNICEF group. Similarly, in the control group 5.5% (n = 17) participants were excluded due to early discharge and other reasons. Subsequently there was a 6% (36/602) loss to follow-up (UNICEF 23, Standard 13).
Selective reporting (reporting bias)	Low risk	None detected.
Other bias	Low risk	None detected.

RCT: randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

Jump to: **included studies**

Study	Reason for exclusion
Collins 2004	This RCT aimed to determine the effect of artificial teats and cup on breastfeeding in preterm infants and not term infants, our prespecified inclusion criteria.
Howard 2003	This RCT evaluated the effect of bottle feeding and pacifier use versus cup feeding and pacifier use in breastfeeding infants. Infants in both the intervention and the control group used pacifiers and hence there is no comparison between pacifier use and non pacifier use in breastfeeding infants.

RCT: randomised controlled trial

Data and analyses

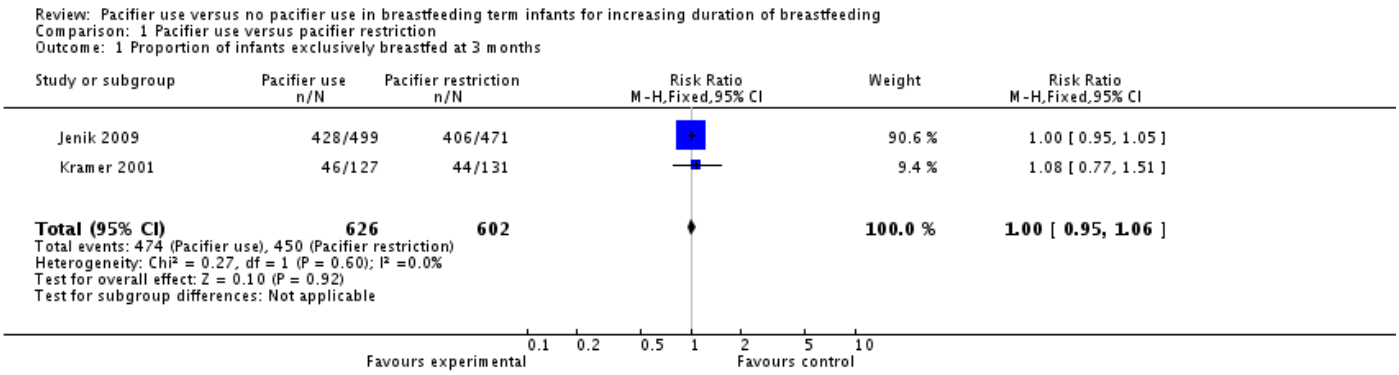
Comparison 1. Pacifier use versus pacifier restriction **Open in table viewer**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion of infants exclusively breastfed at 3 months Show forest plot	2	1228	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.95, 1.06]

Analysis 1.1

Open in figure viewer | Download as PowerPoint

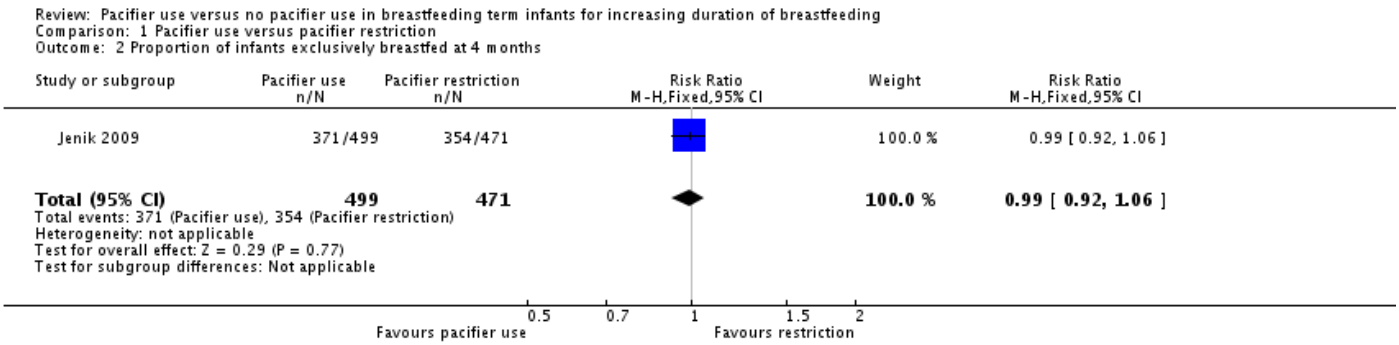


Comparison 1 Pacifier use versus pacifier restriction, Outcome 1 Proportion of infants exclusively breastfed at 3 months.

2 Proportion of infants exclusively breastfed at 4 months Show forest plot	1	970	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.92, 1.06]

Analysis 1.2

Open in figure viewer | Download as PowerPoint



Comparison 1 Pacifier use versus pacifier restriction, Outcome 2 Proportion of infants exclusively breastfed at 4 months.

3 Proportion of infants partially breastfed at 3 months Show forest plot	2	1228	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.97, 1.02]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size

Analysis 1.3

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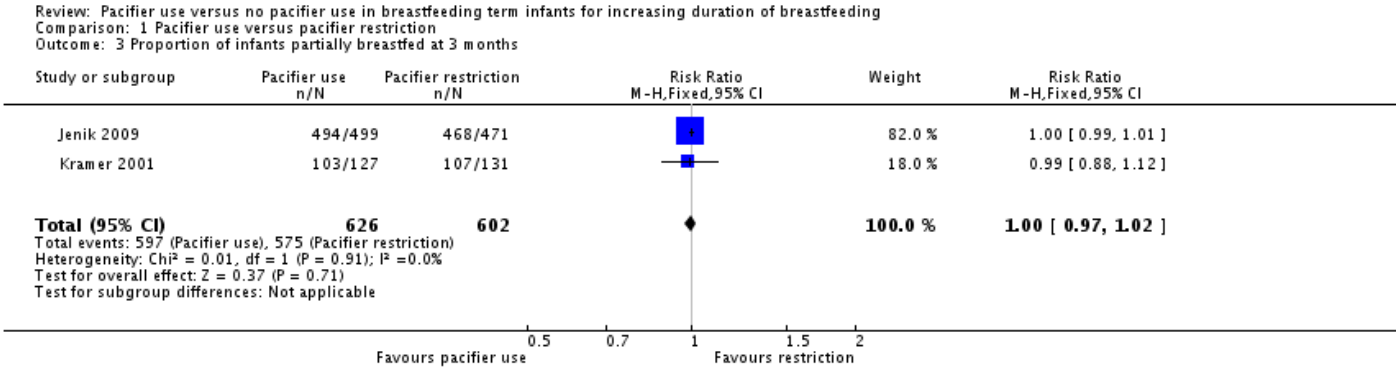
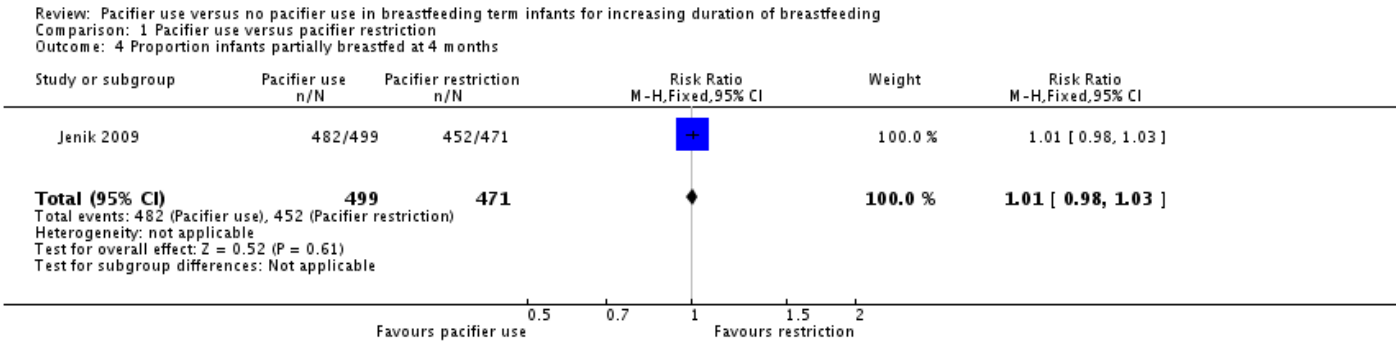


Comparison 1 Pacifier use versus pacifier restriction, Outcome 3 Proportion of infants partially breastfed at 3 months.

4 Proportion infants partially breastfed at 4 months Show forest plot	1	970	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.98, 1.03]

Analysis 1.4

Open in figure viewer | Download as PowerPoint



Comparison 1 Pacifier use versus pacifier restriction, Outcome 4 Proportion infants partially breastfed at 4 months.

Information

DOI:

10.1002/14651858.CD007202.pub2 Check for updates

Database:

Cochrane Database of Systematic Reviews

Version published:

16 March 2011 see what's new

Type:

Intervention

Stage:

Review

Cochrane Editorial Group:

Cochrane Pregnancy and Childbirth Group

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Contributions of authors

Sharifah Halimah is the main author and guarantor for the review. She wrote the first draft of the protocol; provided a clinical and policy perspective as well as providing general advice on the development of the protocol. For the review she assessed studies for inclusion, assessed trial quality and extracted and analysed the data and wrote the review.

Shayesteh Jahanfar provided a input into the protocol development as well as the review. She independently assessed the quality of the trials, extracted and analysed the data. She also wrote the plain language summary of the review.

Mubashir Angolkar provided general comment, proof read the draft of the protocol as well as the review.

Jacqueline Ho provided general comments and advice from the protocol development to the completion of the review. She assessed trial quality where disagreement arose in the decision to include or exclude trials.

Sources of support

Internal sources

- University Kuala Lumpur Royal College of Medicine Perak, Malaysia.

- Penang Medical College, Malaysia.
- Jawaharlal Nehru Medical College Campus, Belgaum, India.
- Ipoh Specialist Hospital, Perak, Malaysia.

External sources

- SEA ORCHID, Malaysia.

Declarations of interest

None known.

Acknowledgements

We would like to acknowledge the contributions of the SEA-ORCHID group and members of the Cochrane Australasian Centre.

As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

What's new

Last assessed as up-to-date: 31 January 2011.

Date	Event	Description
22 December 2011	Feedback has been incorporated	Comments from Simona Di Mario, Adriano Cattaneo, Vittorio Basevi and Nicola Magrini added - see Feedback.

Version history

Title	Stage	Authors	Version	Publication Date
Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding	Review	Sharifah Halimah Jaafar, Jacqueline J Ho, Shayesteh Jahanfar, Mubashir Angolkar	https://doi.org/10.1002/14651858.CD007202.pub4	30 August 2016
Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding	Review	Sharifah Halimah Jaafar, Shayesteh Jahanfar, Mubashir Angolkar, Jacqueline J Ho	https://doi.org/10.1002/14651858.CD007202.pub3	11 July 2012
Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding	Review	Sharifah Halimah Jaafar, Shayesteh Jahanfar, Mubashir Angolkar, Jacqueline J Ho	https://doi.org/10.1002/14651858.CD007202.pub2	16 March 2011
Pacifier use versus no pacifier use in breastfeeding term infants for increasing duration of breastfeeding	Protocol	Halimah Sharifah, Mubashir Angolkar, Shayesteh Jahanfar, Jacqueline J Ho	https://doi.org/10.1002/14651858.CD007202	16 July 2008

Differences between protocol and review

The methods have been updated to reflect the latest *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009) and the Cochrane Pregnancy and Childbirth Group's methodological guidelines.

What's new

Last assessed as up-to-date: 31 January 2011.

Date	Event	Description
22 December 2011	Feedback has been incorporated	Comments from Simona Di Mario, Adriano Cattaneo, Vittorio Basevi and Nicola Magrini added - see Feedback.

Feedback

Di Mario, 6 July 2011

Summary

Pacifier use and breastfeeding [1] is an issue that is highly relevant to health professionals and families, for example this topic was the most accessed among Evidence Updates registrants (http://plus.mcmaster.ca/EvidenceUpdates) and it is relevant to one of the ten steps to successful breastfeeding of the WHO-UNICEF Baby Friendly Hospital Initiative [2].

We believe that this Cochrane review, stating that pacifier does not reduce breastfeeding rates, is severely flawed and biased and therefore should be promptly revised. Here below is our criticism in detail.

The analysis is based only on two randomized controlled trials (RCTs) [3,4]. Validity of the review authors conclusions is limited as they have excluded from the review a third RCT which shows an association between pacifier use and breastfeeding discontinuation at four weeks [5]. The reason for this exclusion is reported as being that both groups were exposed to pacifier. Actually, the intervention group was exposed to pacifier soon after birth while the control group was advised to avoid pacifiers up to five weeks of life of the newborn. Therefore, data comparing breastfeeding practice before five weeks of life could have been appropriately included in the review, or at least commented on.

In addition, the two studies included in the review were not designed to answer the clinical question about the effect of pacifier use for healthy full-term newborns whose mothers have initiated breastfeeding and intend to exclusively breastfeed, on the duration of breastfeeding. These two trials assessed the effects on breastfeeding of interventions aimed at reducing the use of pacifiers; they did not assess the effect of pacifiers on breastfeeding. Mothers in the pacifier group used it in 71% of cases, while mothers in not pacifier group used it in 44% of cases (overall rates). Contamination between two treatment arms points to no difference or inconclusive results. Your conclusions of a null effect of pacifier on breastfeeding success based only on two studies with high contamination rate are therefore falsely reassuring.

Major problems of the studies included in the review are insufficiently discussed. The larger of the two included studies (1021 infants out of a total of 1302) [3], has exclusion and inclusion criteria so strict that the population observed is extremely selected, limiting the external validity of the conclusions, which is not even mentioned. For example, participating hospitals had established breastfeeding programs, 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 reported an intention to breastfeed for at least 3 months, not using pacifiers and with lactation well established at the age of 2 weeks were included. 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 communicated a preference in the introduction or not of a pacifier were also excluded. Further evidence that this study assessed an extremely selected population of women is the remarkably high rate of exclusive breastfeeding at three months for both groups (> 85%), much higher than the rate of exclusive breastfeeding at three months

commonly seen in Europe (e.g. 47% in Italy in 2008, and in Sweden ranging between 68% at four months and 79% at two months in 2002) [6,7]. Finally the authors of the study powered the sample to perform an analysis based on intention to treat, but as the trial was non-inferiority, the 'according to protocol' analysis would have been more appropriate [8]. Unfortunately, as the authors admit, the study sample was not sufficiently large to adequately perform this analysis.

The second RCT included in the review also suggests that the null effect of pacifier on breastfeeding could be a false conclusion [4]. As there was a high contamination rate, results are presented based on actual exposure (observational analysis) in addition to the analysis based on randomized groups. This observational analysis showed a significant difference between pacifier users and not users for weaning by 3 months (RR: 1.9; 95%CI: 1.1, 3.3). Although observational studies are not reliable for assessing the association between pacifier use and breastfeeding practice, due to residual confounding and reverse causality, we think that RCTs with low compliance and high contamination, as in this study, cannot provide a valuable answer, especially when no differences among groups are detected. None of these issues were adequately discussed in this Cochrane review.

Finally, we believe that a potentially very relevant conflict of interest in one of the trials included [3] was not mentioned: the authors of the study report as a funding source an association (the International Children Medical Research Association) whose characteristics are unclear, since it is not possible to find any information on it in the web. The only other citation of this association we have traced is a letter by Dr Peter PW Weiss to Pediatrics [9] criticizing a paper that reported a relationship between reduced pacifier use and reduced acute otitis media incidence. Is he maybe the same Peter Weiss, consultant for a manufacturer of pacifiers, that appears in the acknowledgment section of the trial report [3]? A Dr Peter Weiss is also the vice-president (the president is unknown) of the International Children Medical Research Society, which is, maybe, another name of the International Children Medical Research Association, created in Switzerland by a company founded by the same manufacturers of pacifiers. Should this be made clear to the readers of the Cochrane review?

Our view is that these issues raise questions about the validity of the conclusions of this Cochrane review. Considering that Cochrane reviews represent a seal of quality among health professionals and the public, we think that it is responsibility of the Cochrane Collaboration to scrutinize the evidence selection, its critical appraisal and the validity of the conclusions, specially for a hot topic relevant for public health, as is the case for breastfeeding.

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Reply

A reply from the authors will be published as soon as it is available.