

## REVIEW ARTICLES

### WHAT ROLE FOR THE PACIFIER IN ACUTE OTITIS MEDIA RISK?

#### QUAL O PAPEL DA CHUPETA NO RISCO DE OTITE MÉDIA AGUDA?

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#### ABSTRACT

**Introduction:** Sucking reflex is acknowledged as a comforting mechanism for infants. When used for short periods of time, it is considered a healthy habit. Acute otitis media is one of the most frequent infections in pediatric age and has been associated with pacifier misuse.

**Objectives:** To review available evidence regarding the association between pacifier use in the first years of life and otitis media risk.

**Methods:** A literature search was conducted on several databases using MeSH terms “otitis” and “pacifiers” for guidelines, systematic reviews, randomized controlled trials, and observational studies over the last 20 years. SORT scale of the American Family Physician was used to evaluate evidence levels.

**Results:** A total of 56 articles were retrieved, of which four guidelines, one systematic review, and one original article were selected. According to guidelines, there is no reason to discourage pacifier use, as it can be particularly beneficial in the first six months of life. Afterwards, pacifier use should be limited to moments of falling asleep. Its use should also be avoided in infants with chronic or recurrent otitis media. The systematic review established pacifier use as a risk factor for recurrent acute otitis media (RAOM) which is susceptible to intervention. In the observational study, a statistically significant association was found between pacifier use and RAOM risk.

**Conclusions:** Pacifier use should not be actively discouraged in the first semester of life, as it can have beneficial effects for children (SORT A). Afterwards, its use should be discontinued due to increased otitis risk (SORT A).

**Keywords:** child; otitis; pacifier; review

#### RESUMO

**Introdução:** O reflexo de sucção é reconhecido como um mecanismo de conforto usado pelo lactente. A utilização de chupeta é considerada benéfica quando efetuada por curtos períodos de tempo. A otite média aguda é uma das infeções mais frequentes em idade pediátrica e tem sido associada ao uso indevido deste objeto.

**Objetivos:** Rever a evidência científica publicada sobre a associação entre utilização de chupeta nos primeiros anos de vida e risco de otite.

**Metodologia:** Foi efetuada uma revisão da literatura em várias bases de dados utilizando os termos MeSH “otitis” e “pacifiers”, tendo sido pesquisadas orientações, revisões sistemáticas, ensaios clínicos aleatorizados e estudos observacionais publicados nos últimos 20 anos. Foi utilizada a escala SORT da *American Family Physician* para avaliar os níveis de evidência.

**Resultados:** No total, foram identificados 56 artigos, dos quais foram selecionadas quatro orientações, uma revisão sistemática e um artigo original. De acordo com as orientações, não existe motivo para desencorajar o uso de chupeta, que pode ter efeitos protetores nos pequenos lactentes. A sua utilização deve ser descontinuada a partir do segundo semestre de vida, limitando-a aos momentos de adormecer,

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e deve ser evitada em crianças com antecedentes de otite. A revisão sistemática estabeleceu o uso de chupeta como fator de risco para otite média aguda recorrente (OMAR) passível de intervenção. O estudo observacional encontrou uma associação estatisticamente significativa entre o uso de chupeta e risco de OMAR.

**Conclusões:** O uso de chupeta não deve ser desencorajado no primeiro semestre de vida, pois pode ter efeitos benéficos para as crianças (SORT A). A partir do segundo semestre, o seu uso deve ser descontinuado devido ao risco crescente de otite média aguda (SORT A).

**Palavras-chave:** criança; otite; chupeta; revisão

## INTRODUCTION

Nonnutritive sucking is a natural reflex for newborns and babies and is recognized as a comforting mechanism. Pacifier has been used as a method for fulfilling this innate desire. When used for short periods of time, it is considered a healthy routine; however, its prolonged use is detrimental.<sup>1</sup>

Historically, pacifiers were considered beneficial until the early 1900s, when an anti-pacifier movement spread concerns about their use leading to poor hygiene and indulgent behavior.<sup>2</sup> Although nearly 80% of children in Western countries use pacifiers, the benefit of its use is not duly established at present.<sup>3</sup>

Pacifiers have multiple benefits, including analgesic effects, shorter preterm infant hospitalizations, and lower risk of sudden infant death syndrome (SIDS).<sup>4-6</sup> Pacifier has been recommended for pain relief in newborns and infants undergoing minor Emergency Department procedures, such as heel sticks, immunization, and venipuncture.<sup>4</sup> The benefits of its use are also documented in preterm infants regarding an improved earlier transition from enteral to bottle feeding.<sup>7</sup> The American Academy of Pediatrics guidelines suggest offering infants pacifiers at the onset of sleep to reduce SIDS risk.<sup>6</sup> Although the exact mechanism underlying reduction in SIDS rates is not fully understood, pacifier use may decrease the likelihood of rolling into prone position, increase arousal, and maintain airway patency. It also decreases gastroesophageal reflux and resulting sleep apnea.<sup>8</sup>

Potential complications of pacifier use include negative impact on breastfeeding, dental malocclusion, and otitis media and are more frequent with prolonged use. Pacifier use may be associated with early breast weaning or be a marker of breastfeeding difficulties; therefore, it should be avoided until breastfeeding is well established (usually by the age of one month).<sup>9,10</sup>

Although adverse dental effects may occur after the age of two years, they are more significant after the age of four. Therefore, pacifier use should be discouraged after this age.<sup>11,12</sup>

Acute otitis media (AOM) is one of the most frequent infections in pediatric age and has been associated with pacifier use. Although pacifier use does not increase the risk of respiratory infections, the

mechanism by which it predisposes to AOM is not understood.<sup>13</sup> A direct association has been reported between pacifier use frequency and AOM risk, with the main theory suggesting a pressure equilibrium alteration between the middle ear cavity and nasopharynx, with Eustachian tube function impairment.

The aim of this study was to review available evidence regarding an association between pacifier use in the first years of life and otitis media risk.

## METHODS

A literature search was conducted in February 2019 on several databases using the MeSH terms “otitis” and “pacifiers”. Searched databases included the National Guideline Clearinghouse, the National Health Service (NHS) Electronic Library, Cochrane Library, Database of Abstracts of Reviews of Effectiveness (DARE), Bandolier, Canadian Medical Association, the Portuguese Health Authority (DGS) database, and PubMed.

Retrieved publication types included guidelines, systematic reviews (SR) and meta-analyses (MA), randomized controlled trials (RCT), and observational studies published over the last 20 years in Portuguese, English, or Spanish language. Articles were selected if meeting the following criteria: a) population: children up to five years old; b) exposure: pacifier use; c) comparison: no pacifier use; and d) outcome: presence of AOM or recurrent otitis. Studies were excluded if not meeting inclusion criteria, diverging from the study purpose, representing duplicates, or having been included in a MA or SR.

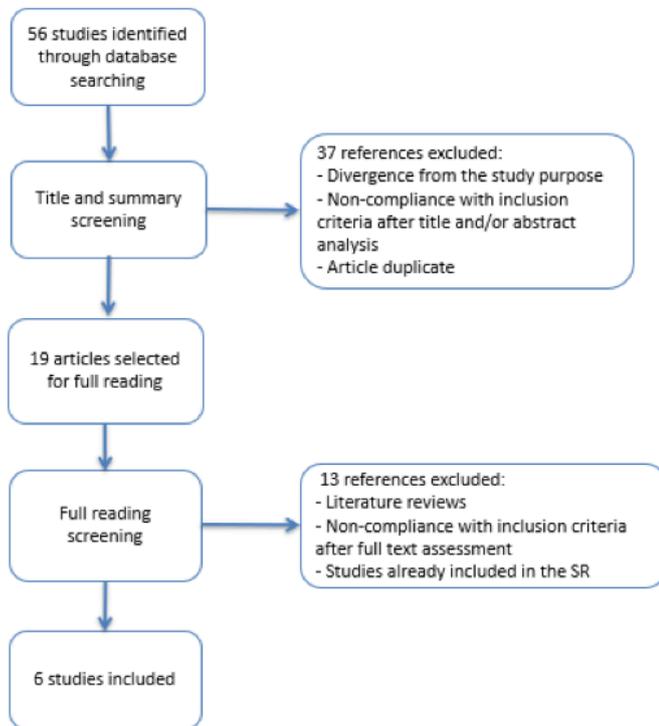
The Strength of Recommendation Taxonomy (SORT) scale of the American Family Physician was used to assign evidence levels (EL) and assess the strength of recommendations (SR).

## RESULTS

Article selection flow is depicted on **Figure 1**. Search strategy retrieved 56 articles, six of which met pre-defined inclusion criteria and were included in the analysis: one original article, one systematic review, and four guidelines.

Mohamed Salah *et al* published a retrospective study in 2013 analysing risk factors for recurrent AOM (RAOM). RAOM was defined as three or more AOM episodes over a six-month period. The study included 340 infants below the age of two years diagnosed with RAOM, 73 (21.5%) of which were pacifier users. Data was collected from parent-fulfilled hospital charts documenting children's medical history. In the study, RAOM was shown to have a statistically significant association with pacifier use ( $p < 0.005$ ). Pacifier-using children showed a higher RAOM recurrence rate (mean  $\pm$  standard deviation [SD] =  $5.8 \pm 1.8$ ) compared with non-pacifier-using children (mean  $\pm$  SD =  $5.1 \pm 1.6$ ). Early recurrence was defined as evidence of AOM signs and symptoms one month after initial improvement and treatment failure was defined as acute infection persistence or

worsening for up to one week following initial treatment. The authors found no statistically significant association between pacifier use and early recurrence or treatment failure ( $p > 0.05$ ).<sup>14</sup>



**Figure 1** - Study selection flow during the review process. SR, systematic review

The systematic review by Lubianca Neto *et al* analysed evidence about modifiable risk factors for AOM and RAOM in children. In this study, RAOM was defined as three or more AOM episodes during a six-month period or at least four AOM episodes during 12 months. The authors searched MEDLINE for studies published from January 1966 to July 2005 using no language restriction and the descriptors “acute otitis media/risk factors” and included three observational studies, one MA, and one RCT addressing pacifier use as a risk factor for otitis media in infants.<sup>15</sup> In one study, pacifier use was significantly associated with AOM development from the sixth to the ninth months of life ( $p < 0.05$ ) and showed a strong trend towards statistical significance in the period from nine to twelve months ( $p = 0.056$ ).<sup>16</sup> According to Niemela *et al*, pacifier use was significantly associated with otitis media (relative risk [RR] 1.48,  $p = 0.01$ , 95% confidence interval [CI] 1.08–2.02).<sup>17</sup> In a prospective study, the same authors investigated a group of 845 children and concluded that pacifier use increased the annual incidence of AOM and was responsible for 25% of AOM cases.<sup>13</sup> In the MA by Uhari *et al*, pacifier use increased AOM relative risk by 24% (RR 1.24; 95% CI 1.06–1.46).<sup>18</sup> In the RCT conducted by Niemela *et al*, study intervention consisted in parental counselling regarding pacifier use, with parents advised not to use

pacifier in children after the age of six months. At the end of the study, AOM prevalence in the intervention group decreased 29%. Children consistently not using pacifier in both intervention and placebo groups displayed 33% less AOM episodes. These results suggest that restricted pacifier use, limited to falling asleep moments, has the potential to reduce AOM risk and that its use should be limited to the first ten months of life, when sucking need is more pronounced and AOM risk is lower (EL 2).<sup>3</sup>

The expert panel responsible for the Italian Guidelines for AOM management recommends that infants should reduce pacifier use to the minimum (SORT A).<sup>19</sup> Experts base their recommendation on two studies: the previously described SR from Lubianca Neto *et al* and the cohort study from Rovers *et al*.<sup>15,20</sup> The last was performed as part of the Utrecht Health Project, which followed 495 children aged between zero and four years between 2000 and 2005. Parents filled a baseline questionnaire regarding pacifier use and potential confounders and AOM was diagnosed by general practitioners. Overall, 35% of pacifier-using children and 32% of non-pacifier-using children developed at least one AOM episode and 16% and 11% developed recurrent AOM (defined as three or more AOM episodes during the study period), respectively. The adjusted odds ratio (OR) for the correlation between pacifier use and AOM and recurrent AOM was 1.3 (95% CI 0.9–1.9) and 1.9 (95% CI 1.1–3.2), respectively.<sup>20</sup>

The Canadian Pediatric Society guidelines acknowledge pacifier use as a risk factor for otitis media, although other factors are implicated in the condition’s pathogenesis.<sup>21</sup> The risk is proportional to use duration and frequency. Therefore, infants and children with chronic or recurrent otitis media should have a limited pacifier use (SORT A).<sup>21</sup> One study showed that pacifiers were free of the major otitis media-causing pathogens and almost 50% of recently used pacifiers were uncontaminated.<sup>22</sup> In another study, pacifier sucking was reported in 40% of 601 children with chronic otitis media requiring tympanostomy tubes in Toronto, Ontario.<sup>23</sup>

The same guidelines state that pacifier use is a significant risk factor for AOM, based on the previously described prospective study of children in day care centers and in the MA of otitis media risk factors.<sup>13,18</sup> One survey to parents of children aged 12 months or younger also found an otitis media risk twice as high in pacifier users.<sup>24</sup> This study was limited by the definition of pacifier use to more than five hours per day and by parental reporting reliability. A similar study also based on parental reporting found a higher otitis media prevalence in pacifier users (OR 1.20).<sup>16</sup>

The joint recommendations of the American Academy of Family Physicians/American Academy of Pediatrics are based on the previous studies by Niemela, Uhari, and Rovers.<sup>3,18,20</sup> These guidelines recommend reducing or stopping pacifier use in the second six months of life to reduce otitis media risk (SORT B).<sup>7,25</sup>

In 2014, the Portuguese Health Authority (DGS) issued recommendations about AOM diagnosis and treatment in pediatric age, with pacifier use identified as one of the risk factors for AOM in healthy children.<sup>26</sup>

## OBSERVATIONAL STUDY

Reference	Population	Intervention	Results	EL
Salah M, <i>et al</i> (2013)	Infants below the age of 2 years with RAOM  (n=340)	Data collected from hospital charts.  Analysis of risk factors with potential impact on RAOM prognosis, including age, prematurity, URTIs, breastfeeding duration, pacifier use, etc.	RAOM showed a statistically significant association with pacifier use ( $p < 0.005$ ). Pacifier-using infants showed a higher recurrence rate (mean $\pm$ SD = $5.8 \pm 1.8$ ) compared with non-pacifier-using infants (mean $\pm$ SD = $5.1 \pm 1.6$ ). No statistically significant association was found between pacifier use and early recurrence or treatment failure ( $p > 0.05$ ).	2 EL, evidence level; RAOM, recurrent acute otitis media; SD, standard deviation; URTI, upper respiratory tract infection

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## SYSTEMATIC REVIEW

Reference	Studies included	Conclusions	EL
Lubianca N, <i>et al</i> (2006)	- 3 observational studies (n=3158) - 1 meta-analysis (2 observational studies; n=4287) - 1 randomized controlled trial (n=484)	- Pacifier use increased children's AOM episode number. - Pacifier use was significantly associated with AOM from 6 to 9 months and showed a trend towards significance from 9 to 12 months ( $p = 0.56$ ). - AOM risk was 24% higher in pacifier users (RR 1.24, 95% CI 1.06–1.46). - Parental counselling reduced pacifier use and AOM incidence by 29%.	2

AOM, acute otitis media; EL, evidence level

## GUIDELINES

Reference	Results	Sort
Canadian Pediatric Society	Infants and children with chronic or recurrent otitis media should have a restricted pacifier use	A
American Academy of Family Physicians	Pacifier use should be stopped or limited in the second six months of life to reduce otitis media risk	B
Italian guidelines	Pacifier use should be reduced to a minimum	A
Portuguese Health Authority	Risk factors for AOM development in healthy children are: (...)pacifier use	B

## DISCUSSION

One of the concerns associated with pacifier commonly expressed by parents is how long it can be used without harm to the infant. This review aimed to address this question using the most up-to-date information and evidence-based medical publications.

One of this study's limitations is the fact that the systematic review included was based on a limited number of studies, all of which with more than ten years. Most included studies had an observational and retrospective design, allowing only to establish associations and not causality relations. On the other hand, data was based on parental reporting, which is subject to memory bias and not as accurate as physician reporting. Another study limitation is the acknowledgment that pacifier use is not the only factor implicated in AOM development, with other factors potentially involved. The role of pacifier in AOM development seems to be proportional to the time and frequency of use.

Given these facts, further studies are required to draw more robust conclusions about this subject.

## CONCLUSION

Given available evidence, pacifier use should not be actively discouraged in the first six months of life, as it can have beneficial effects (SORT A). Nevertheless, it should be avoided until breastfeeding is well established. Following the second six months of life, pacifier use should be discontinued due to the higher risk of AOM (SORT A).

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Received for publication: 07.06.2019

Accepted in revised form: 09.12.2019