Association of deleterious sucking habits with the occurrence of otitis in newborns, infants, preschool children, and children: a systematic review protocol

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ABSTRACT

Objective: The objective of this review is to determine whether deleterious sucking habits contribute to otitis in newborns, infants, preschool children, and children.

Introduction: Otitis is one of the most prevalent diseases in infants. Diverse studies have suggested that deleterious sucking habits, such as pacifier use, bottle-feeding, and finger-sucking, may be risk factors for the development of otitis in young individuals.

Inclusion criteria: This systematic review will include observational studies in which the association between deleterious sucking habits and otitis was assessed in newborns, infants, preschool children, and children. Studies will compare caregiver reporting of sucking habits in this population to those with no deleterious sucking habits or those who exclusively breastfeed. The primary outcome will be the presence of otitis.

Methods: The searches will be carried out in six electronic databases, and gray literature will also be screened. A three-step search strategy will be used, with no date or language restrictions. Studies whose full text meets the eligibility criteria will be included in the systematic review. Study screening and selection, critical appraisal, and data extraction will be performed by two independent reviewers. The Grading of Recommendations, Assessment, Development and Evaluation approach will be used to assess the certainty of the evidence. Meta-analysis will be performed if there is relative homogeneity among included studies.

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Keywords: bottle-feeding; finger-sucking; infant; otitis; pacifiers

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Introduction

Otitis is characterized by inflammation of the outer, middle, or inner ear. It is a highly prevalent disease in childhood, and may affect around 90% of children up to two years of age.[1] Otitis can result from exacerbated allergies, infections caused by viruses and bacteria, or diseases caused by fungi.[2] There are different types of otitis, with otitis media being the most common. Otitis media is one of the main reasons for the prescription of antibiotics and visits to the physician by infants.[3]

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Otitis media with effusion (OME) is characterized by the presence of secretion in the middle ear with no signs or symptoms of infection or acute inflammation[4]; for this reason, it is difficult to diagnose.[4,5] Data show that one-third of infants experience at least one episode of OME before they turn one year old.[5] This type of otitis media can cause sequelae in hearing, impairing children's speech and cognition.[6,7] Acute otitis media (AOM) is characterized by viral and/or bacterial infection of the middle ear with simultaneous signs and symptoms, such as otalgia, otorrhea, fever, and irritability.[4] One study concluded that 62.4% of children younger than one year experienced at least one episode of AOM.[8] Recurrent acute otitis media is a subtype of AOM. This subtype, which is defined as three or more

episodes of AOM within six months, affects around 15% of children.[9]

A plethora of studies describes the risk factors associated with the occurrence of otitis media in children. Some of these factors are environmental and modifiable,[10,11] including deleterious sucking habits, such as the use of pacifiers, bottle-feeding, and finger-sucking. Deleterious sucking habits can cause malocclusion and changes in dentofacial structures. Many studies have shown an association between pacifier use and finger-sucking with anterior open bite and posterior crossbite.[12,13] Despite the known impairments caused by pacifiers, they are still widely used during childhood[14] because of their hypothesized capacity to prevent sudden infant death syndrome (SIDS),[15] among other reasons. However, a systematic review of randomized controlled trials showed that there is insufficient evidence to support or refute the role of pacifiers in preventing SIDS.[16] Like pacifier use, bottle-feeding is common.[14] Bottles are used as a complementary feeding method, usually to offer water, teas, formula, and human or non-human milk to babies.[14,17] A higher prevalence of bottle-feeding is associated with low maternal age and mothers working away from home.[17,18]

The mechanism that can explain the association of sucking habits with otitis is related to the increased reflux of nasopharyngeal secretions to the middle ear due to the negative pressure caused by suction.[19] Moreover, changes in dental structures caused by sucking may promote dysfunctions in the Eustachian tube.[19] Studies have shown that children who used a pacifier were more likely to develop recurrent AOM.[20-22] Bottle-feeding at night also has been associated with the development of AOM in 80% of children.[11] Authors have suggested that supine or semi-upright positions during feeding may lead to aspiration of milk into the middle ear cavity, resulting in blockages that may increase the incidence of otitis media.[23,24] Sucking habits also act indirectly by reducing breastfeeding, which has been reported as a major protective factor against otitis.[8] However, few studies have described the strict relationship between decreased breastfeeding and the use of pacifiers and bottle-feeding.[14,25]

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and *JBI Evidence Synthesis* was conducted, and no current or in-progress systematic reviews on the association between deleterious sucking habits and the occurrence of otitis in children were identified. Because otitis is a highly prevalent disease, and deleterious oral habits are common in infancy, it is important to investigate whether these habits predispose the occurrence of otitis. Thus, the aim of this systematic review will be to determine whether deleterious sucking habits contribute to otitis in newborns, infants, preschool children, and children.

Review question

Are deleterious sucking habits associated with the occurrence of otitis in children?

Inclusion criteria

Participants

This systematic review will include studies on newborns (first 28 days after birth), infants (one to 23 months of age), preschool children (two to five years of age), and children (six to 12 years of age) who have deleterious sucking habits. Studies including individuals older than 12 years will be excluded.

Exposure

This systematic review will include studies in which caregivers reported the presence of deleterious sucking habits, such as pacifier use, bottle-feeding, or finger-sucking in newborns, infants, preschool children, and children.

Comparator

In this systematic review, the comparators will be newborns, infants, preschool children, and children with no deleterious sucking habits as well as newborns, infants, preschool children, and children with exclusive breastfeeding.

Outcome

The primary outcome will be otitis in newborns, infants, preschool children, and children. Otitis will be assessed according to location (externa, media, interna) and type (acute [with signs or symptoms of inflammation], with effusion [without signs or symptoms of inflammation], or recurrent [three or more episodes of acute otitis within six months]). The secondary outcome will be malocclusion among the individuals assessed. The presence or absence of anterior open bite and posterior crossbite will be assessed.

Types of studies

This systematic review will consider observational studies (cohort studies, case-control studies, and cross-sectional studies) assessing the association between otitis and deleterious sucking habits in newborns, infants, preschool children, and children.

Methods

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of etiology and risk.[26] A protocol was registered in PROSPERO (CRD42020197162).

Search strategy

The search strategy will be conducted according to the *JBI Manual for Evidence Synthesis*.[26] The strategy will aim to identify both published and unpublished studies. An initial limited search of MEDLINE (PubMed) was conducted as a pilot test to identify articles on the topic. The words relevant to the topic in the titles and abstracts [Text Words] of relevant articles, and the indexing terms [MeSH Terms] used to describe the articles were used to develop a full search strategy for MEDLINE (PubMed; Appendix I). The search strategy, including all identified keywords and indexing terms, will be adapted for each included information source. The reference lists of all studies selected for inclusion will be screened for additional studies. Databases will be consulted from their inception date until the date of the search. There will be no language or date restrictions on the included articles.

Computerized searches will be carried out in six electronic databases: Web of Science, Cochrane Central Register of Controlled Trials (Cochrane Library), LILACS, Scopus (Elsevier), MEDLINE (PubMed), and Embase. A gray literature search will be performed using Google Scholar, OpenGrey, National Institute for Health and Care Excellence, and ProQuest Dissertations and Theses. In gray literature sources, except for ProQuest Dissertations and Theses, the searches will be restricted to the first 300 hits.[27] Manual searches will be carried out using the reference lists of the included studies. The searches will be updated shortly before the final analyses.

Study selection

All retrieved references will be exported to EndNote Web (Clarivate Analytics, PA, USA) and duplicates removed. The studies will be selected by two independent reviewers, who will assess the titles/abstracts of the retrieved references and examine the data. Following a pilot test, titles/abstracts will then be screened by two independent reviewers for assessment against the inclusion criteria for the systematic review. Authors of articles will be contacted to request missing or additional data for clarification, where required. Studies whose titles/abstracts provide information that clearly fulfills the eligibility criteria will be included. For studies whose titles/abstracts do not contain sufficient information for a decision on inclusion/exclusion, the full texts will be retrieved. Studies whose full texts fulfill the eligibility criteria will be included. Any disagreements that arise between the two reviewers at each stage of the study selection process will be resolved with a third reviewer.

Citation details of included studies will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia).[28] The results of the search and study selection and inclusion process will be reported in full in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.[29]

Assessment of methodological quality

The assessment of methodological quality will be performed using the JBI critical appraisal checklist for analytical cross-sectional studies, the JBI critical appraisal checklist for case-control studies, and the JBI critical appraisal checklist for cohort studies.[26]

In each study, three ratings will be assigned to the items: Yes (high methodological quality), No (low methodological quality), or Unclear. Two reviewers will independently assess the methodological quality of the included studies. Any disagreements that arise between the reviewers will be resolved with a third reviewer. All studies, regardless of the results of their methodological quality, will undergo data extraction and synthesis (where possible). The results of critical appraisal will be reported in a table with an accompanying narrative.

Data extraction

All included studies will undergo data extraction. The data will be extracted using the standardized JBI data extraction tool.[26] The extracted data will include the last name of the first author, year of publication, journal, country where the study was conducted,

sample size, age of individuals (mean and standard deviation), ethnicity of individuals, deleterious sucking habits evaluated, otitis according to location and type, and the main results about the association between deleterious sucking habits and the occurrence of otitis. Two reviewers will extract data independently. Any disagreements that arise between the reviewers will be resolved with a third reviewer.

Data synthesis

A narrative synthesis of the studies depicting the extracted data will be provided in textual and tabular format. The possibility of data aggregation in meta-analyses will be assessed. To evaluate whether meta-analyses are feasible, the characteristics of the included studies, their degree of methodological homogeneity, and the interpretation of the results will be assessed.[26] If possible, meta-analyses will be conducted and the statistical heterogeneity will be examined. If the value of the I^2 statistic is equal to or higher than 40%, the random effects model will be used. If the value of the I^2 statistic is lower than 40%, the fixed effects model will be used.[30] RevMan software (Copenhagen, The Nordic Cochrane Centre, Cochrane) will be used. For meta-analysis with high statistical heterogeneity, sensitivity analysis will be performed, removing estimates of studies one at a time, reassessing the calculations, and checking the influence of the estimates of each study.

A funnel plot will also be created using RevMan software. The Egger test will be used to analyze the asymmetry of the graph in meta-analyses of continuous outcomes. For dichotomous outcomes, the Harbord test will be used.[30] Subgroup analyses will be performed considering data from methodologically homogeneous studies, studies with the same design, and those assessing similar outcomes. Different subgroups based on frequency of habit, intensity of habit, duration of habit, type of sucking habit (pacifier, bottle-feeding, or finger-sucking), and age group (newborn, infant, preschool children, or children) will be analyzed. If other factors are identified during the study, these will be analyzed as well.

Tests of interaction between groups will be employed. The prevalence ratio (number of individuals with the outcome and total number of individuals assessed), odds ratio/relative risk, and confidence interval will be extracted. For data on prevalence, meta-analysis of dichotomous outcomes will be performed. For odds ratio/relative risk, the generic inverse variance will be used. Data on odds ratio/relative risk along with the standard error will be aggregated. The standard error will be obtained applying the following formula: standard error = (upper bound of confidence interval – lower bound of confidence interval) / 3.92.[30]

Assessing certainty in the findings

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for assessing the certainty of the evidence will be followed.[31] Certainty assessment and a Summary of Findings will be created using GRADEpro GDT (McMaster University, ON, Canada). The certainty assessment will include the number of studies, study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias. The Summary of Findings will present the following information, where appropriate: number of individuals with exposure, number of individuals without exposure (control), absolute risk with confidence interval, or relative risk with confidence interval. Data on the certainty assessment and the Summary of Findings will be presented in a table. According to these criteria, the certainty of the evidence will be rated as follows: high, moderate, low, or very low. The outcome reported in the certainty of evidence will be as follows: otitis (externa, media, interna, acute, recurrent, and with effusion).

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Appendix I: Search strategy

MEDLINE (PubMed)
Search conducted in July 2, 2020

Search	Strategy employed	Records retrieved
#1	child[MeSH Terms] OR children[Text Word] OR "preschool child"[MeSH Terms] OR "preschool children"[Text Word] OR infant[MeSH Terms] OR infants[Text Word] OR childhood[Text Word] OR toddler[Text Word] OR toddlers[Text Word] OR preschool[Text Word] OR preschoolers[Text Word] OR schoolchild[Text Word] OR "school child"[Text Word] OR schoolchildren[Text Word] OR "school children"[Text Word] OR kid[Text Word] OR kids[Text Word] OR newborn[MeSH Terms] OR newborns[Text Word] OR youth[Text Word] OR youths[Text Word] OR pediatric[Text Word] OR pediatrics[MeSH Terms] OR paediatric[Text Word] OR paediatrics[Text Word] OR pedodontic[Text Word] OR pedodontics[Text Word]	4,552,092
#2	pacifier[Text Word] OR pacifiers[MeSH Terms] OR dummy[Text Word] OR dummies[Text Word] OR soother[Text Word] OR soothers[Text Word] OR bottlefeed[Text Word] OR "bottle feed"[Text Word] OR bottle-feed[Text Word] OR bottlefeeding[Text Word] OR "bottle feeding"[MeSH Terms] OR bottle-feeding[Text Word] OR bottlefed[Text Word] OR "bottle fed"[Text Word] OR bottle-fed[Text Word] OR "nursing bottle"[Text Word] OR "nursing bottles"[Text Word] OR fingersucking[MeSH Terms] OR "finger sucking"[Text Word] OR finger-sucking[Text Word] OR thumbsucking[Text Word] OR "thumb sucking"[Text Word] OR thumb-sucking[Text Word] OR "deleterious habit"[Text Word] OR "deleterious habits"[Text Word] OR "deleterious oral habit"[Text Word] OR "deleterious oral habits"[Text Word] OR "deleterious sucking habit"[Text Word] OR "deleterious sucking habits"[Text Word] OR "sucking habit"[Text Word] OR "sucking habits"[Text Word] OR "nonnutritive sucking habit"[Text Word] OR "nonnutritive sucking habits"[Text Word] OR "non nutritive sucking habit"[Text Word] OR "non nutritive sucking habits"[Text Word] OR "non-nutritive sucking habit"[Text Word] OR "non-nutritive sucking habits"[Text Word] OR "breast feeding"[MeSH Terms] OR "breastfeeding"[Text Word] breast-feeding[Text Word] OR breastfeed[Text Word] OR "breast feed"[Text Word] OR breast-feed[Text Word] OR breastfed[Text Word] OR "breast fed"[Text Word] OR breast-fed[Text Word] OR weaning[Text Word] OR "sucking behavior"[Text Word] OR "sucking behaviors"[Text Word] OR "feeding behavior"[Text Word] OR "feeding behaviors"[Text Word]	181,854
#3	otitis[MeSH Terms] OR "ear inflammation"[Text Word] OR "ear infection"[Text Word] OR otitides[Text Word]	36,815
#4	#1 AND #2 AND #3	308