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Efecto de los métodos de alimentación postoperatoria en pacientes con fisura labio máximo palatina: revisión sistemática y metanálisis. / Effect of postoperative feeding methods in patients with cleft lip and palate: A systematic review and meta-analysis

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EFFECT OF POSTOPERATIVE FEEDING METHODS IN PATIENTS WITH CLEFT LIP AND PALATE: A SYSTEMATIC REVIEW AND META-ANALYSIS

EFFECTO DE LOS MÉTODOS DE ALIMENTACIÓN POSTOPERATORIA EN PACIENTES CON FISURA LABIOMAXILOPALATINA: REVISIÓN SISTEMÁTICA Y METANÁLISIS

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ABSTRACT

Objective: To evaluate the effect of postoperative feeding methods (i.e., breast, bottle, cup, spoon, syringe, or others, alone or in any combination) on body weight and surgical wound dehiscence in infants with cleft lip and/or palate (CLP).

Design: Systematic review and meta-analysis of randomized and controlled clinical trials. Searches were conducted in *PUBMED*, *Cochrane CENTRAL*, *Web of Science* and *EMBASE* from inception to June 2023. Certainty of evidence was assessed using the *GRADE* approach.

Results: Four randomized clinical trials involving 359 infants were included. It remains uncertain whether breastfeeding or bottle-feeding compared with spoon feeding results in improved body weight (MD: 0.13 kg; 95 % CI = -0.64 to 0.91; $p = 0.74$; very low certainty). Feeding via cup, spoon, or syringe may result in little to no difference in wound dehiscence (RR: 1.47; 95 % CI = 0.24 to 9.14; $p = 0.68$; low certainty).

Conclusions: Given the overall low and very low certainty of evidence, well-designed clinical trials with adequate sample sizes are required to determine the true effect of postoperative feeding methods in infants with CLP.

Keywords: Cleft lip, cleft palate, postoperative feeding, wound dehiscence, infant nutrition.

RESUMEN

Objetivo: Evaluar el efecto de los métodos de alimentación postoperatoria (es decir, pecho, mamadera, vaso, cuchara, jeringa u otros, solos o en cualquier combinación) sobre el peso corporal y la dehiscencia de la herida quirúrgica en lactantes con fisura labial y/o palatina (FLP).

Diseño: Revisión sistemática y metanálisis de ensayos clínicos aleatorizados y controlados. Las búsquedas se realizaron en PUBMED, Cochrane CENTRAL, Web of Science y EMBASE desde su inicio hasta junio de 2023. La certeza de la evidencia se evaluó utilizando el enfoque GRADE.

Resultados: Se incluyeron cuatro ensayos clínicos aleatorizados que involucraron a 359 lactantes. Persiste la incertidumbre sobre si la lactancia materna o la alimentación con mamadera, en comparación con la alimentación con cuchara, producen una mejora en el peso corporal (DM: 0,13 kg; IC 95 %: -0,64 a 0,91; $p = 0,74$; certeza muy baja). La alimentación mediante vaso, cuchara o jeringa puede generar poca o ninguna diferencia en la dehiscencia de la herida quirúrgica (RR: 1,47; IC 95 %: 0,24 a 9,14; $p = 0,68$; certeza baja).

Conclusiones: Dada la certeza global baja y muy baja de la evidencia disponible, se requieren ensayos clínicos bien diseñados y con tamaños muestrales adecuados para determinar el verdadero efecto de los métodos de alimentación postoperatoria en lactantes con FLP.

Palabras clave: Fisura labial, fisura palatina, alimentación postoperatoria, dehiscencia de la herida, nutrición infantil.

BACKGROUND

Cleft lip and palate (CLP) is a congenital anomaly characterized by incomplete fusion of the lip and/or palate during embryogenesis¹. Infants with CLP commonly experience feeding difficulties due to impaired oral suction and altered anatomy². Although various surgical techniques exist for CLP repair³, postoperative feeding protocols differ considerably among centers, and there is no consensus regarding the optimal approach^{4,5}. Alternative feeding strategies, such as cup, spoon, or syringe feeding, have been suggested to reduce stress on the surgical site by minimizing negative intraoral pressure^{6,7}. However, these methods may be challenging for infants accustomed to breast or bottle feeding, potentially contributing to inadequate postoperative nutritional intake and weight loss^{8,9}. This review aimed to determine the impact of postoperative feeding methods on body weight and wound dehiscence in infants undergoing cleft lip and/or palate repair.

METHODS

Protocol development

This systematic review followed the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0)¹⁰ and adhered to PRISMA guidelines¹¹. The protocol was registered in PROSPERO (CRD42024602387).

Selection criteria

Inclusion criteria

Types of studies: Randomized clinical trials or controlled clinical trials.

Participants: Infants with non-syndromic cleft lip, cleft palate, or cleft lip and palate.

Interventions: Breastfeeding, bottle feeding, cup feeding, spoon feeding, syringe feeding, or other feeding methods.

Comparators: Any of the above interventions compared with each other.

Outcomes: Postoperative body weight and surgical wound dehiscence.

- Body weight: Mean difference between weight at the time of surgery and at follow-up, or percent increase compared with weight on the day of surgery.
- Wound dehiscence: Clinical evaluation of the surgical wound at follow-up.

Exclusion criteria

Non-randomized studies, narrative reviews, case reports, letters to the editor.

Search strategy

In June of 2023, a search of the available literature was conducted in the following databases through their online portals: *PUBMED*, *Cochrane CENTRAL*, *Web of Science* and *EMBASE*. For each of these options, the advanced search tool was used with the following terms: cleft lip, cleft palate, cleft lip and palate AND feeding. Each term was investigated and adjusted according to the syntax of each specific database. No date or language restrictions were applied.

Selection of studies

Two previously trained reviewers performed an independent title and abstract screening of the search results, following the inclusion and exclusion criteria once established. Disagreements were solved by consensus or with a third reviewer. Afterward, two reviewers independently conducted the full-text screening; disagreements were also sorted out by agreement or, if not possible, with a third author. For this process, Microsoft Excel was used. Finally, the references of the selected articles were reviewed to identify other possible studies to be included in the review.

Data extraction and management

Using a data extraction table created in Microsoft Excel, the necessary background information for the purpose of this review was completed independently by two reviewers. Extracted data included first author and year of publication, study design, patients, interventions, outcomes, risk of bias assessment.

Assessment of risk of bias in included studies

For randomized clinical trials, the risk of bias was assessed with the Cochrane Collaboration Risk of Bias Tool ROB I¹². The evaluation of all the domains of this tool (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias) was followed by the instructions of the Cochrane Handbook. The evaluation was done by two reviewers independently from the complete reading of the articles. All disagreements were discussed and resolved by consensus to classify the paper as low, high, or unclear risk of bias.

Data analysis

The treatment effect measures used to assess the outcome of each study were: for continuous data, the mean difference and their respective 95 % confidence intervals and percent increase; for categorical variables, risk ratio with 95 % confidence intervals.

Assessment of study heterogeneity

The chi-square test was used to determine the presence of statistical heterogeneity, a 0,1 significance level was used. Quantification of the inconsistency was made by the statistical I^2 test, following the Cochrane recommendations¹³. Clinical heterogeneity was assessed considering the patients characteristics, environment and intervention, consulted with experts. Methodological heterogeneity was assessed by the Risk of Bias Tool's domains¹⁰.

Data synthesis

A meta-analysis for the outcomes using a random effect model available on RevMan 5.4 was performed¹⁴. The decision to pool data in a meta-analysis was based on data available on results.

The *GRADE* approach was used to assess the certainty of evidence (confidence in the effect estimators) for each outcome, thorough evaluation of the study design, assessment of limitations (risk of bias, inconsistency, indirectness, imprecision, and publication bias) was realized. Evidence certainty was classified in 4 levels: high, moderate, low, very low¹⁵.

RESULTS

Search findings and study characteristics

A total of 2,650 studies were identified, selecting a total of 56 studies that potentially met the selection criteria. Once the studies were selected, 25 were eliminated due to duplicates between databases. The resulting 31 studies were searched both physically and

digitally for full reading; however, it was not possible to obtain the full text of 9 of them, nor could the authors be contacted¹⁶⁻²⁴. A set of 22 articles was reviewed by two reviewers independently, reading the complete text according to the selection criteria. A total of 4 articles were ultimately included in this review for analysis. A flow diagram following the recommendations of the *PRISMA* Statement was used to illustrate the results of the study selection for this review (Figure 1).

Description of the studies

The four selected studies correspond to randomized clinical trials²⁵⁻²⁸. One study was conducted in Thailand²⁵, one in Korea²⁶, one in India²⁷, and one at the Craniofacial Anomalies Rehabilitation Hospital in Brazil²⁸.

The total population consisted of 359 infants, of whom 85 underwent cheiloplasty^{27,28}, 82 underwent palatoplasty²⁶, and 192 underwent both procedures²⁵. No distinction was made by sex. Infants with cleft lip, cleft palate, or cleft lip and palate were included, while patients with associated syndromes were excluded.

The mean age at surgery varied between groups depending on the cleft type and the criteria of each center and surgeon. After cleft repair surgery, groups were formed according to the postoperative feeding method: breastfeeding, conventional bottle feeding, cup feeding, spoon feeding, or syringe feeding. These groups were compared according to the outcomes measured.

Postoperative body weight, expressed as mean weight difference or percentage gain, and surgical wound dehiscence were assessed at the time of surgery and at follow-up, which varied across studies from 30 days to 2 months (Table I).

Risk of bias

The risk of bias assessment for the randomized controlled trials is presented in Figure 2. Of the four trials evaluated²⁵⁻²⁸, none were classified as “low risk” across all domains.

Overall, insufficient information was reported in the domains of random sequence generation, allocation concealment, and blinding of participants and personnel, indicating potential selection and performance bias. In contrast, the assessments for blinding of outcome assessors, incomplete outcome data, and selective reporting were mostly favorable. Sensitivity analysis was not performed because none of the included studies were judged to have a high risk of bias in any domain.

Effects of interventions

A summary of the findings is presented in Table II.

Outcome body weight

The forest plot of the meta-analysis for body weight is shown in *Figure 3*. This outcome was assessed in two randomized clinical trials^{27,28}, which evaluated postoperative weight at 30 days²⁷ and six weeks²⁸ in a total of 85 infants with cleft lip aged 3 to 13 months. It is uncertain whether breast or bottle feeding improves postoperative body weight compared with spoon feeding (MD: 0.13 kg; 95 % CI -0.64 to 0.91; $p = 0.74$; very low-certainty evidence).

In one of the included studies²⁶, the data required for inclusion in the meta-analysis (mean, SD, and sample size) were not reported; instead, outcomes were presented as percentage weight gain. The comparison of bottle feeding versus spoon, cup, or syringe feeding after cleft palate surgery showed weight gain in both groups, with no statistically significant differences at the first ($p = 0.47$) or second postoperative month ($p = 0.33$). Weight gain was 6.4 % versus 5.1 %, respectively, in the first month, and 10.3 % versus 9.3 % in the second month²⁶.

Outcome surgical wound dehiscence

The forest plot of the meta-analysis for surgical wound dehiscence is shown in *Figure 4*. This outcome was assessed in four randomized clinical trials²⁵⁻²⁸ at different postoperative time points, including after the first meal²⁵, on the first postoperative day^{25,28}, during the first six days²⁶, at 14 days²⁵, and at 30 days²⁸. One study did not report the specific timing of assessment²⁷. In total, 359 infants aged 3 to 13 months with cleft lip and/or palate were included. Feeding through a cup, spoon, or syringe may result in little to no difference in the occurrence of wound dehiscence compared with breastfeeding or bottle feeding (RR: 1.47; 95 % CI 0.24 to 9.14; $p = 0.68$; low-certainty evidence).

DISCUSSION

The overall estimate derived from the meta-analysis of the randomized clinical trials indicates that there is no statistically or clinically meaningful difference between the feeding groups (breast and/or bottle feeding versus spoon, syringe, or cup feeding) for either outcome. The relative risk for surgical wound dehiscence was 1.47 (95 % CI 0.24-9.14), showing no clear benefit of one feeding method over another. The certainty of the evidence for this outcome was rated as low due to concerns related to risk of bias and imprecision. For postoperative body weight, the mean difference was 0.13 kg (95 % CI -0.64 to 0.91), again demonstrating no advantage for either intervention, with the certainty of evidence rated as very low because of methodological limitations and substantial heterogeneity ($I^2 = 78\%$).

Heterogeneity varied considerably depending on the outcome evaluated. Studies assessing surgical dehiscence showed no observable heterogeneity ($I^2 = 0\%$), as reflected by the overlapping confidence intervals across trials. In contrast, postoperative body weight exhibited high heterogeneity ($I^2 = 78\%$), likely attributable to differences in patient age (3-13 months), follow-up periods, surgical techniques, study settings, and baseline nutritional status.

Regarding the broader postoperative impact of feeding methods, one study reported that infants fed with a spoon required analgesia, sedation, and intravenous fluids more

frequently and for longer periods compared with those who were breastfed²⁷. Consistent with these findings, Weatherley-White et al. first advocated for breastfeeding after cleft lip repair, reporting shorter hospital stays and faster transitions from intravenous to oral feeding among breastfed infants²⁹. Other studies similarly indicate that breastfeeding or bottle feeding does not adversely affect surgical outcomes nor increase the risk of complications such as wound dehiscence or fistula formation, suggesting that these methods may be safely implemented when appropriate³⁰. Additionally, breastfeeding may confer benefits beyond nutritional adequacy, including enhanced comfort and reduced irritability, as infants fed by spoon or syringe have been shown to cry more frequently during feeding²⁴. Importantly, the act of sucking itself contributes to infant soothing and emotional regulation³¹.

To our knowledge, no previous systematic reviews have evaluated postoperative body weight in infants with cleft conditions according to feeding method. Previous work has focused primarily on the preoperative period or has not clearly differentiated between pre- and postoperative outcomes. A major strength of this review is its systematic approach and use of meta-analysis, which allow for rigorous synthesis of the available evidence and increase precision in estimating the effects of the feeding methods examined.

The main limitations of this review are related to the quality of the available evidence for addressing the clinical question. A lack of high-quality studies has been identified, which was revealed only through a systematic review and subsequent evaluation of the quality of the evidence. This analysis also highlights knowledge gaps in the field, identifying topics with limited information that could be addressed in future research. In addition, given that most patients in the total pool were lip repair cases, the review sample size may be underpowered to detect significant differences in dehiscence rates. However, an inherent limitation is that, although a review brings together the results of multiple studies and provides a more comprehensive and robust view of a topic, its validity directly depends on the methodological quality of the included studies.

CONCLUSIONS

The effect of postoperative feeding methods on postoperative body weight in infants with cleft lip and/or palate remains uncertain, reflecting very low certainty of the available evidence. Feeding via cup, spoon, or syringe may result in little to no difference in surgical wound dehiscence compared with breastfeeding or bottle feeding, based on low-certainty evidence. Well-designed randomized controlled trials with adequate sample sizes are needed to determine the true effect of postoperative feeding methods on clinically relevant outcomes.

REQUIRED DISCLOSURES

Ethical Statement

This study is a systematic review and meta-analysis that synthesizes data already published in peer-reviewed sources. No new human participants were recruited, and no identifiable individual data were collected. Therefore, ethical approval from an institutional review board or ethics committee was not applicable.

Informed Consent / Patient Consent

No new patients were enrolled, and no original clinical data were obtained for this review. As this study relies solely on previously published data, patient consent was not applicable.

Compliance With Ethical Standards

This research was conducted in accordance with the ethical principles of the Declaration of Helsinki and with the journal's ethical requirements for secondary data analyses.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

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Figure 1. PRISMA 2020 flow diagram for systematic reviews describing study selection.

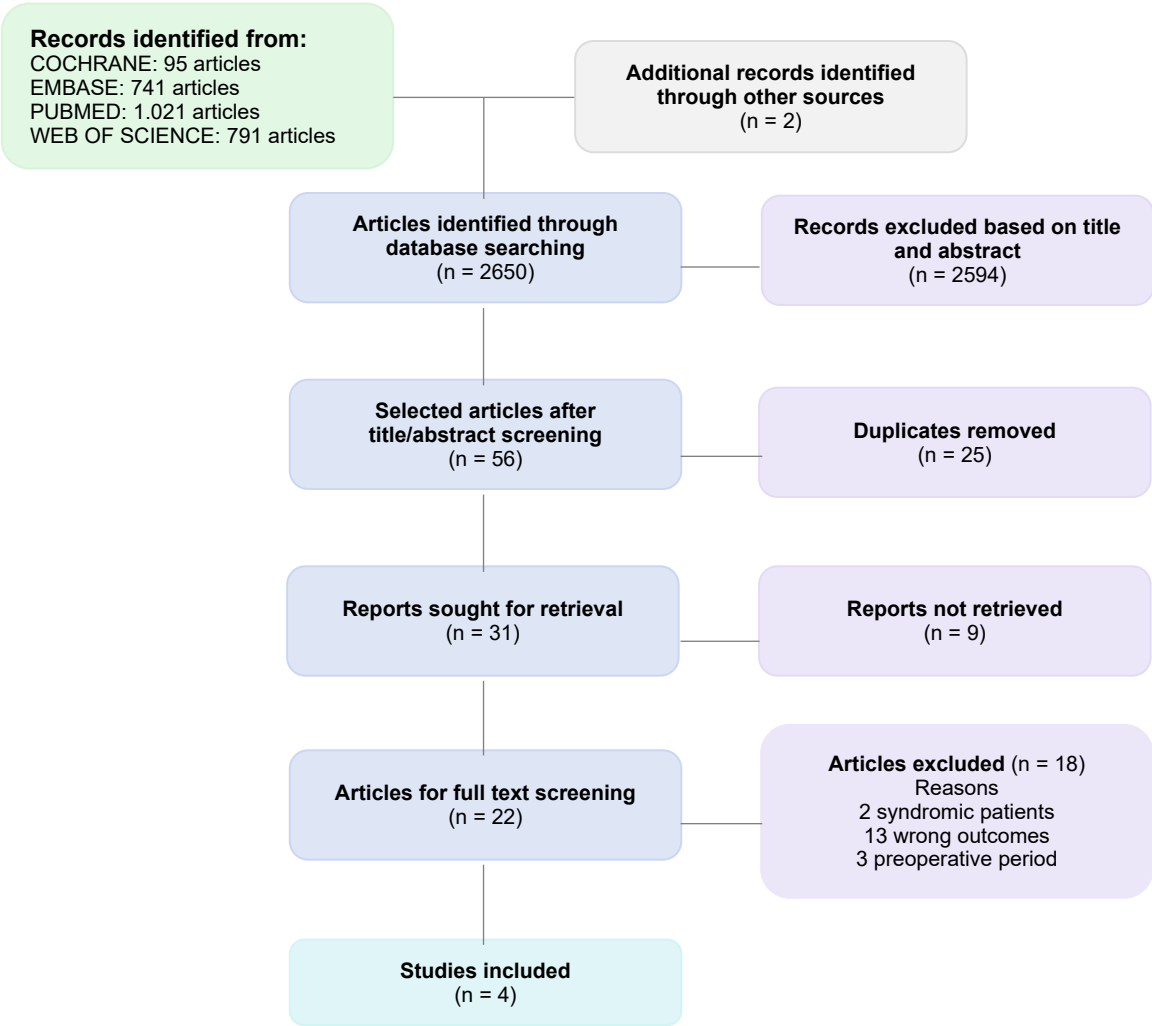


Table I. Demographic and clinical characteristics of the studies included in the review.

Study	Design	Country	n	Age	Cleft type	Clinical characteristics	Interventions		Outcomes	Follow up
Augsornwan, 2013	RCT	Thailand	192	4.3 months (mean)	CLP	Patients with non-syndromic cleft lip and palate undergoing cheiloplasty	Bottle feeding (n = 96)	Spoon or syringe feeding (n = 96)	Surgical dehiscence, surgical wound assessment, parent's satisfaction	Bottle feeding (n = 96)
Kim et al., 2009	RCT	Korea	82	7.9 months	CP - CLP	Patients with non-syndromic cleft palate undergoing palatoplasty.	Bottle feeding (n = 42)	Spoon, cup or syringe feeding (n = 40)	Postoperative body weight, surgical dehiscence, oral intake, sedative use, complications	Bottle feeding (n = 42)
Guedes Alcoforado et al., 2004	RCT	Brazil	45	3-13 months	CL	Patients with cleft lip undergoing cleft lip closure surgery between 3 and 13 months of age	Bottle feeding (n = N.R)	Spoon feeding (n = N.R)	Postoperative body weight, surgical dehiscence, surgical wound evaluation, anthropometric values, diet, laboratory tests	Bottle feeding (n = N.R)
Darzi et al., 1996	RCT	India	40	4.4 months	CL	Patients with cleft lip without other associated clefts between 3 and 6 months of age	Breast feeding (n = 20)	Spoon feeding (n = 20)	Postoperative body weight, surgical dehiscence, surgical wound assessment, cost and hospital stay	Breast feeding (n = 20)

Figure 2. Risk of bias summary: review authors' judgments for each risk of bias domain across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Darzi 1996	+	?	?	+	+	+	+
Guedes 2004	?	?	?	+	?	+	+
Kim 2009	?	?	?	+	+	+	+
Augswornwan 2013	+	+	?	+	+	+	+

Risk of bias

- + Low risk
- ? Unclear
- High risk

Table II. Summary of findings GRADE.

Effect of postoperative feeding methods in patients with cleft lip and palate

Patients or population: 359 patients

Intervention: Spoon, cup or syringe feeding

Comparison: Breast and/or bottle feeding

Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Absolute effect (per 1,000 patients)
Body weight	85 (2 RCTs)	⊕⊕⊕⊕ Very low ^{a,b}	-	MD 0.13 kg higher (0.64 kg lower to 0.91kg higher)
Wound dehiscence	359 (4 RCTs)	⊕⊕⊕⊕ Low ^{c,d}	not estimable	4 fewer per 1,000 (4 fewer to 4 fewer)

**The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

CI: confidence interval; MD: mean difference.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. The certainty of the evidence was downgraded one level due to unclear risk of bias, particularly in the domain of allocation concealment.

b. The certainty of the evidence was downgraded two levels because of very serious inconsistency, reflected in substantial heterogeneity ($I^2 = 78\%$) and wide variation in effect estimates across studies.

c. The certainty of the evidence was downgraded one level for risk of bias, as adherence to the feeding protocols could not be assured in the included studies.

d. The certainty of the evidence was downgraded one level due to imprecision, given the small sample sizes and limited number of events, which reduced confidence in the effect estimates.

Figure 3. Forest plot of the mean difference in postoperative body weight between infants fed with breast and/or bottle feeding versus spoon feeding.

