

Research Protocol

Feeding Interventions among Cleft Lip/ Palate Infants - A Systematic Review Protocol

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Background: The Indian subcontinent is one of the world's most densely populated regions, with cleft birth rates ranging between 27,000 and 33,000 per year. Most of the time, these babies are unable to breastfeed, but it is still possible to try. There is a distinct lack of understanding regarding various techniques and breastfeeding positions, not only among the masses, but also among clinicians. There is currently no information in the Indian literature regarding the therapeutic efficacy of these procedures, and the patient is ultimately the sufferer. Here we have attempted to classify the various feeding interventions in use for feeding among children having cleft lip and cleft palate on the basis of the literature.

Methods: Searches were undertaken in PubMed, CINAHL, Web of Science, Cochrane database, PsycINFO, Scopus, Maternity and Infant care, AMED for primary research studies that report on feeding interventions/ feeding techniques/ feeding methods, and challenges faced by mothers/ caretakers/ health personnel. This systematic review will include all research available in the English language that report on the feeding interventions, feeding strategies, feeding methods, and challenges faced by parents/ mothers/ health personnel to feed cleft babies. A narrative synthesis will be done for every population-intervention-context triad distinguished by study design.

Discussion: This systematic review will include classification and explanation of research comparing pre-and postoperative feeding procedures for children with diverse forms of cleft lip and/ or palate, with the aim of preparing parents as well as clinicians for the challenging work of feeding children having cleft lip and cleft palate.

Systematic Review Registration: PROSPERO CRD42020208437

Keywords: Cleft Palate, Cleft Lip, Swallowing Disorders, Feeding Interventions, Breastfeeding

Background of the Review

Cleft lip and palate (CLP) are usual birth defects that affect

the lip, palate, or both,^{1,2} and are caused by problems during the embryonic facial fusion process.³ It affects around one out of every 700 newborns due to abnormalities in the



main and/ or secondary palate development.^{4,5} The Indian subcontinent is one of the world's most densely populated regions, with cleft birth rates ranging between 27,000 and 33,000 per year.⁶

Feeding these babies is a huge concern for parents, and it has been observed that children with a cleft, unlike children without a cleft, have delayed growth. Feeding difficulties have been well documented in such children. Failure to create sufficiently negative intraoral pressure while suctioning is the main cause.⁷

Nausea, uncontrolled air intake, tiredness, congestion, tiresome extended feeds, repeated burping, and pain for the mother are all problems associated with feeding in these infants. Poor protection of airway while swallowing can have dire suggestions for respiratory condition of the infant, as repeated aspiration during feeding can cause chronic respiratory disease, lung damage, and pneumonia.⁸

Surgery is the only way to cure CLP fully. Lip repair is recommended between the ages of 3 and 6 months and palate repair between the ages of 9 and 12.^{9,10} In order to ensure the process of cleft repair, the infant must have adequate nutrition, which includes healthy weight gain along with no health complications and the ability to obtain anaesthetics safely.¹¹ Various suggestions and equipment are advocated for feeding babies with clefts in order to combat decreased weight for height. Until having surgery for the lip or the palate, the baby can be provided all the eating's advantages, such as attachment with the mother, enough nutrition for growth by making some changes to feeding methods and positioning.¹²

Feeding recommendations after cleft lip repair can be very different. Suction avoidance is generally recommended till six weeks from the date of procedure.¹³ This divergence is much greater after palatoplasty, and some centres have adopted protocols prohibiting the use of bottles and nipples for a duration of approximately one month.¹⁴

In a prospective randomised study, Darzi et al. discovered that beginning postoperative breastfeeding soon post cleft lip repair is healthy, supports better weight gain at 6 weeks after surgery, and is more cost-efficient as compared to spoon-feeding.¹⁵

Feeding Interventions

Breast milk has various advantages over formula milk, such as the fact that breast milk contains antibodies from the mother, which aid in infection prevention, cause reduced trouble to mucous membranes, is found at body temperature, and requires no sterilisation beforehand.

Breast, spoon, bottle, or cup feeding, or a variation of these, may be selected with breastfeeding advice about how to position the infant correctly. Considering the fact that

breastfeeding a baby with a cleft palate can be challenging, the mother may feed it by expressing it and giving it to the baby via a bottle.¹⁶

Feeding Intervention for Babies with Cleft Lip

While feeding is not a primary issue for babies with cleft lips, they do need some adjustments in feeding positioning. An adjusted football technique or the straddle position may be beneficial in case the cleft is unilateral. The process may be made easier for the baby by tucking the cleft into the breast tissue using this approach and location.¹⁷

Increasing the infant's cheek defence reduces the cleft's width and improves sealing around the nipples. The baby should be kept upright in all feeding positions to allow the milk to move down and reduce the risk of choking.

The obvious difficulty faced in creating an airtight seal surrounding the nipple makes breastfeeding harder for infants with bilateral cleft lips. It is suggested that mothers should use the 'dancer hand pose'. The baby may be provided with some help in the process of pressing the nipple and areola by the gums by sliding the hand forward keeping it under the breast, supporting it using three fingers in place of four, and creating a U-shape by the forefinger and thumb so that the chin of the infant can be cradled.

In case breastfeeding is not adequate in spite of taking all the measures, specially designed bottles can be used to ensure that the baby receives an adequate amount of nutrition.

Feeding Intervention for Infants having Cleft of the Soft Palate

An infant having a cleft lip or cleft soft palate might be able to breastfeed with proper positioning, much like infants with cleft lip. Supplemental feeds from specifically crafted bottles with expressed breast milk may be needed in some cases.

Feeding Intervention for Infants having Cleft Lip/ Soft/ Hard Palate

Such infants often have no capacity to breastfeed, but it is still possible to try. If breastfeeding fails to produce the desired results, bottle feeding may be needed. There are a variety of specially made feeding bottles available, including the Haberman feeder, Pigeon bottle, and Mead-Johnson cleft palate nurses bottle.

These bottles are made of smooth, squeezable plastic that allows milk to be drawn from the bottle with minimal pressure. A long nipple with a cut in the shape of 'Y' made in the tip is advised to be rubbed against the tongue.¹⁸ The position must be kept upright. The baby's head should be kept in one hand and the other hand should hold the bottle. It's a good idea to experiment with these squeeze bottles first with water to see how they function so that it

can be figured out that how hard and how much the bottle should be pressed to obtain a regular flow.

Not only among the general public but also among clinicians, there is a dearth of information regarding specifically made squeezable bottles and nipples, as well as various techniques and positions of feeding. The therapeutic effectiveness of these procedures is currently unknown in the Indian literature, and the patient is essentially the sufferer. Counselling and instructions regarding proper feeding techniques should be given to the mothers/ caretakers as required. If the parents are unable to obey these guidelines, feeding obturators with instructions about how to keep them clean may be recommended.⁸

Ms Julie Reid published a study of feeding procedures for children with cleft palate in 2004 that looked at fifty-five articles and found that there were a variety of interventions for babies with isolated cleft conditions, along with prompt feeding and nutrition education, and supported feeding approaches. She also elaborated the dearth of proof that was either moderate or strong, emphasising the importance of ongoing clinical review of feeding processes for babies with cleft palates.

This systematic review has been presented with an objective to explore and describe pre- and postoperative research analysing the numerous feeding strategies for infants with various forms of cleft lip and/ or palate, in order to prepare parents and clinicians for the challenging work of feeding infants having cleft lip and/ or palate.

Aim

To come up with awareness and cognizance, via collection, summary, and analysis of results from various kinds of research done regarding different feeding interventions in use for feeding babies having cleft lip and/ or cleft palate.

Specific Objectives

- To identify feeding interventions used for babies having unoperated cleft lip and/ or palate
- To identify feeding interventions used for babies after surgery done to repair cleft lip, palate or both
- To determine the challenges faced by health professionals (doctors and nurses) while educating the parents/ caretakers regarding feeding techniques for children with cleft

Materials and Method

Study Design

This systematic review and meta-synthesis is in accordance with the PRISMA guidelines (PRISMA Checklist), and follows Lucas et al.'s framework¹⁹ and comprises four steps:

Step 1: Data will be collected from, and independent review of, published literature that will meet the objective of the

review, accompanied by an organised and well-planned study of available articles.

Step 2: Identification and isolation of evolving concepts from the results of individual articles by making sure precision and ingenuity of the final outcome in order to gather them together to draw out comprehensive themes.

Step 3: Grouping themes to isolate the comprehensive ones and draw out the subthemes to elaborate different interventions used to feed the infants with cleft lip/ palate.

Step 4: Arriving at outcomes from these studies and elaborating them as per all the derived themes and subthemes to project the outcome i.e., different feeding techniques used and challenges faced by health personnel/ caretakers.

Criteria of Studies

Inclusion Criteria

It will include all research studies, available in the English language that report on the feeding interventions, feeding strategies, feeding methods, challenges faced by parents/ mothers/ health personnel to feed these cleft babies.

The PICo (Population, Interest, Context) approach will be utilised to reach the desired aims and hold up the search procedure.

Population (P): This will include the characteristics of the population of interest. The phrases used to recognise Population (P) in this case will include the infants with cleft lip, cleft palate, cleft lip and palate (e.g. 'infant' OR 'infants' AND/ OR 'cleft lip' AND/ OR 'cleft palate').

Interest (I): This will include interest related to a defined event, activity, experience or process. The terms to isolate the Interest (I) will be associated with recognition of the feeding interventions (e.g. 'intervention' or 'interventions' 'OR 'method or methods') for cleft babies.

Context (Co): This will include the context around the topic of interest. The context in this systematic review is the challenges faced by parents/ caretakers/ health personnel. The terms to recognise the Context (Co) will include issues in feeding the infants with cleft.

Exclusion Criteria

Non-English language studies will be excluded.

Search Methods

CINAHL, PsycINFO, Cochrane database, PubMed, Maternity and Infant care, Scopus, Web of Science, AMED will be searched for primary research studies that report on feeding interventions/ feeding techniques/ feeding methods, challenges faced by mother/ caretaker/ health personnel.

Search Terms

- Cleft lip and infant feeding

- Cleft palate and infant feeding
- Cleft palate and feeding efficiency
- Cleft palate and bottle feeding
- Cleft palate and breastfeeding
- Cleft palate and feeding obturators
- Cleft palate and feeding after palatoplasty
- Palatoplasty and feeding
- Cleft palate and infant feeding and challenges
- Cleft palate and infant feeding and education

Methods of Review

Retrieved papers will be reviewed separately as per their title, abstract, and text by two authors independently. Two authors will have to agree on the incorporated articles, and any difference of opinion will be considered and solved by a third reviewer.

Quality Assessment

An updated model of Thomas et al.'s²⁰ 12-point quality assessment criteria checklist will be utilised to evaluate the methodological level of incorporated research since it supports the evaluation of such studies. The tool has various criteria, which if met will be awarded score '1', and if not met, will be awarded '0'. Studies will be evaluated and scores will be awarded. The final scores will be considered as 'weak' (0 to 6), 'moderate' (7 to 9) or 'strong' (10 to 12) based on their methodological status. Studies that score '6' or less will be excluded. Three reviewers will assess the studies independently and will confirm the final score and each study's incorporation for data collection.

Extraction of Data

A tool for data extraction will be used to extract data from included studies. Data will be extracted by two reviewers independently and all dissimilarities between the two early reviews will be discussed and solved by the third reviewer.

Data Analysis

Lucas et al.'s framework will be used for a thematic analysis of the results of all studies.¹⁹ Arguments from each of the studies will be gathered and grouped to create comprehensive topics and sub-topics which will be amalgamated and the outcome will be derived.

Presentation of Results

Supplementary Material

Figures, flowcharts, summary Tables, and the like, will be presented in the final article.

Dissemination of Findings

Findings will be introduced at conferences (national and international) and will be published in a peer-reviewed journal.

Timeline for Review (in months)

- Protocol - 1
- Literature Search - 2
- Quality Appraisal - 2
- Extraction of Data - 2
- Analysis - 2
- Writing up - 3

Delimitations of the Study

- The study is limited to only feeding techniques
- The study has been published in English language only

Authors' Contribution

MD developed the objectives and scope of the review and registered in PROSPERO. Search strategy support was given by MD, DPM, and KD. Suggestions and methodological support along with review were done by DPM. The article was compiled by MD and editing was done by DPM and KD. All the authors have gone through the manuscript and have approved it for publication.

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