Critical Review:
Can bottle feeding help manage feeding difficulties in newborns with a cleft lip and/or palate and improve their nutritional gain and anthropometric measurements during infancy?

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The following literature review examined evidence to determine whether bottle-feeding methods are able to improve the feeding difficulties that newborns with craniofacial abnormalities experience. The craniofacial abnormalities of focus are cleft lip and/or palate. The research studies identified described randomized controlled trial designs, single group time series designs, and mixed method research procedures. Overall, findings suggest that assisted bottle-feeding approaches are able to facilitate improved feeding that was associated with nutritional growth in infants with cleft lip and/or palate; however, the success may depend on the type and severity of the cleft, along with parental feeding education and clinical support provided.

Introduction

Clefts to the lip and/or palate are types of craniofacial abnormalities that arise during embryonic development within the first trimester of pregnancy. As a result of the insufficient closure and fusion that takes place between the developing structures of the lips, nose, and hard and soft palates, infants are born with open gaps of different severities in these anatomical facial regions. Between 2004 and 2006, it was estimated that approximately 10 out of every 10,000 newborns in the United States were born with a cleft lip with or without a cleft palate. In comparison, 6 out of every 10,000 infants are estimated to be born with an isolated cleft palate (National Institute of Dental and Craniofacial Research, 2014).

Parents will often express initial concern about their child's cosmetic differences and the surgical procedures needed to repair the open cleft. However, one of the first major complications that needs to be addressed is in the domain of feeding. Breast feeding is often desired for infants, but this form of nursing is commonly unsuccessful for newborns whose clefts extend beyond just the lip (Reilly, Reid, Skeat, Cahir, Mei & Bunik, 2013). Depending on the location and the extent of the open cleft, infants can experience difficulty latching onto nipples, in addition to achieving and maintaining a negative intra-oral pressure required for suction generation during both breast and standard bottle feeding (Miller, 2011). Research has suggested that poor feeding abilities puts infants with these forms of craniofacial abnormalities at an increased risk for undernourishment, limited physical growth, and longer feeding times for food consumption (Clarren, Anderson, & Wolf, 1987; Miller, 2011). Other feeding complications include excessive fatigue for the infant, and poor control over the liquid bolus leading to nasal regurgitation, choking, and aspiration (Clarren et al., 1987). Therefore, feeding assessments and determining alternative methods for food consumption are critical with the first few days post-natal for nutritional gain and development.

Both Mizuno, Ueda, Kani, and Kawamura (2002) as well as Reid, Reilly and Kilpatrick (2006) found that compression style bottles and modified nipples can help to overcome the absent or reduced suction pressure that these infants are able to generate, thus improving feeding abilities. This could suggest that certain types of assistive bottle feeding approaches could be used to supplement breast feeding difficulties in newborns with cleft lip and/or palate.

Objectives

The objective of this paper is to critically evaluate a series of research findings to determine whether bottle-feeding methods are successful in overcoming feeding difficulties newborns with cleft lip and/or palate experience. Specifically, does bottle-feeding facilitate nutritional gain and manage anthropometric measurements in this population to avoid failure to thrive?

Methods

Search Strategy: A search strategy was employed in the following computerized search engines to locate the studies included in the current critical analysis: Google Scholar, PubMed, Scholars Portal, ScienceDirect, and Sage Journals. Studies were limited to those written in the English language and published between 1990 and 2015. The following key words were also used to narrow the results returned in the database search:

[("cleft lip" OR "cleft palate") AND "bottle feeding" AND "management"]
[("cleft lip" OR "cleft palate") AND "bottle feeding" AND "weight gain" OR "anthropometric"]

Selection Criteria: Studies that met the following inclusion criteria were selected for review: evaluation of feeding through a bottle method of delivery, a participant population limited to infants born with cleft lip and/or palate, and study initiation or completion prior to surgical repair to close the cleft. With the inclusion criteria applied, four studies were selected/identified.

Data Collection: Two of the studies selected implemented a between-groups randomized control trial (RCT) design. Another study carried out a single group time series design, and finally a mixed methods research design was also selected and included in the review.

Results

Randomized Clinical Trial Designs:

Randomized controlled trial studies are considered to be the gold standard for research designs. When participants are randomly assigned to a devised treatment group, this helps to control for predetermined researcher bias based on participant characteristics, and more strongly validates findings and outcomes as resulting from the treatment received itself (Sullivan, 2011).

Brine et al. (1994) carried out a between groups randomized clinical trial (RCT) design to compare how efficient two different methods of bottle feeding (standard/rigid bottles and compression bottles) were at facilitating growth in infants born with facial clefts. Thirty-one infants with cleft lip and/or palates were randomly assigned to one of two bottle feeding methods. Twenty-two of these participating infants also used palatal obturators to cover their more extensive palatal clefts, and these infants were evenly distributed across the feeding groups. All parents were educated on appropriate infant positioning during feeding. Outcome anthropometric measurements (weight, body length, head circumference, tricep and subscapular skinfold measures, and mid-arm circumference) were recorded for these infants. An ANOVA statistical analysis was computed to compare the different growth outcomes in each bottle-feeding group. Brine et al. (1994) concluded that both bottle types were equally efficient in facilitating appropriate amounts of formula consumption for nutritional gain and physical growth.

A clear research question and detailed study inclusion criteria was given, including infant weight at birth. It was also specified that additional malformations, syndromes, and medical conditions were absent in participating infants. This increased our confidence that the feeding behaviours and growth outcomes obtained were associated with the success of the bottle feeding method and not other predisposing factors. However, the sample size was small.

The methodology of the study was complete, and detailed descriptions of the bottle/nipple types, feeding positioning and instructions were outlined. The randomization of infants into bottle feeding groups also ensured that an equal representation of cleft types were in both groups, thus increasing the validity and efficiency of the particular bottle type and associated growth outcomes. Equal distribution of palatal obturator use in both bottle feeding groups was also a strong control to ensure feeding success and growth outcomes were related to the bottle type, also increasing the validity and reliability of the results.

Overall, the Brine et al. (1994) study provided level one evidence with compelling results supporting that bottle-feeding approaches can manage the feeding difficulties in newborns with cleft-lip and/or palate, which is important for clinical applications. They were able to address their clinical question and further suggest that parent training and education is crucial to augment bottle-feeding success for this population of infants.

In a later study, **Shaw et al. (1999)** also evaluated how successful two different methods of bottle feeding were at facilitating nutritional gain and physical growth in infants with cleft lip and/or palate. Using a between groups randomized clinical trial design, ninety-nine infants were randomly assigned to nurse from either a standard/rigid bottle or from a compression bottle, and were monitored for changes in weight, head circumference, and overall body length. Parents were provided with feeding instruction and bottle-fed their child in the assigned treatment group. Findings revealed that both rigid and compression bottle types contributed to nutritional growth and weight gain in all infants, however, rigid bottles often required additional modifications to meet the feeding capabilities and characteristics of the infant. Shaw et al. (1999) also suggested that infants with cleft lip and/or palate can be bottle fed successfully without the aid of a palatal appliance.

These researchers conducted a two-sample t-test from anthropometric data obtained from the Manchester Growth Study in Bannister's (1985) thesis, to ensure that the sample size of ninety-nine infants in the current study was adequate. A randomization procedure (permuted blocks) was also used, which ensured that there would be a relatively equal number of infants with certain cleft severity representations in each feeding treatment method. This reduced the bias of one bottle feeding treatment appearing to be more reliable clinically, due to an over or under representation of a

certain cleft type. Appropriate one-way ANOVA statistical analyses were completed, in addition to an analysis of covariance to adjust for growth limitations due to premature birth instead of the bottle feeding method. This further controlled for infant prognostic factors that these researches did not consider during entry into the study, and increases study reliability. Researcher bias was not controlled for, which these authors also identified as a limitation for themselves. The health care visitor, who collected measurements on the three anthropometric growth variables in the study, was cognisant of the bottle feeding method group and feeding modifications that each infant was receiving. Although the researchers concluded that both bottle-feeding methods were successful at facilitating growth in cleft-infants, they did not compare anthropometric data to standardized norms or to the growth data of a non-cleft control group. This would have further increased the strength of these results. Feeding difficulties was also said to have improved for the infants compared to the pre-trial period, however, the specific feeding difficulties.

This study offers moderately strong and compelling results (level 1 evidence) that should be taken into consideration clinically when determining appropriate feeding methods for a cleft infant. Although minimal limitations were present (lack of a blinded assessor during data collection and non-cleft control growth data for comparison), bottle feeding methods were successful for cleft infants, with a particular emphasis on compression bottles for more assistive feeding.

Single Group Time Series Design:

Time series studies focus on a single participant group, where continuous changes in behaviour are monitored for determining treatment success. Participants act as their own control group for monitoring treatment efficiency.

Turner et al. (2001) implemented a single group time series research design to determine whether or not parental feeding education and bottle feeding with or in the absence of palatal obturators would increase increase the amount of formula consumed, decrease nursing time, and improve the overall growth of an infant with craniofacial abnormalities. Eight newborns with a cleft lip and/or palate met inclusion criteria and were recruited for study participation. During the first month of life, all infants were passed through five different phases, where different feeding methods were either added or removed and feeding outcomes of duration, flow rate, and volume consumed were evaluated between each phase (an A, B1, C1, B2, C2 phase design). Additionally, growth patterns related specifically to weight and height of all the infants were followed until their second year of life following study completion. Findings showed that infants were able to consume larger volumes of liquid faster and had typical weight gain patterns when parental education with Haberman bottle use was paired with a palatal obturator, as opposed to use in isolation.

Detailed inclusion criteria for study participants was provided, however the only specified requirements concerning the infants directly was having a cleft to the lip and/or palate and that referral into the study was competed within the first two weeks of life. Turner et al. (2001) did not control for other cognitive, physical, medical, or pharmaceutical factors that could potentially interfere with feeding performances throughout the tasks employed. The sample size was also small. Both of these factors weaken the reliability of the results in terms of generalization to a larger cleft population.

The study methodology and procedures were organized, with well-established descriptions of the different feeding phases that were implemented. Growth data was monitored and recorded by a registered dietician or a dietary technician, which eliminated researcher bias during data collection. Repetition of two of the feeding phases was also a study strength, to ensure the independent variable outcomes of feeding time, flow rate, and volume consumed was consistent and reliable for the infants. However, the different phases of feeding were only implemented up until the first month of age, and a detailed description of how the feeding methods continued, changed, or were monitored until twenty-four months was not provided. Therefore, it cannot be reliably determined that other feeding behaviours and factors did not contribute to infant growth besides the independent variables monitored during the feeding phases, which weakens the study results.

Appropriate data analyses were conducted, including one-way ANOVAS for variable analysis, Tukey tests to ensure phase pairing consistency, and t-tests comparing weight and height to general population norms. Growth data comparison to non-cleft population growth norms acted as a control group to strengthen study results and validity.

Although this study offers level two evidence, the overall results are suggestive due to study limitations in participant inclusion criteria, sample size, and incomplete procedure information following the five feeding phases. On the other hand, the clinical importance of these findings obtained during the phases of feeding are compelling and suggest that bottle feeding paired with palatal obturators and education/training is optimal for infants with cleft lip and/or palate. However, whether these findings would be consistent if the Haberman bottle was substituted for

another bottle type or nipple attachment cannot be concluded or assumed.

Mixed Methods Design:

Mixed method research designs implement a combination of qualitative and quantitative data collection and analysis in a single study.

Martin et al. (2014) conducted a mixed methods research design to investigate and compare how efficient different types of compression bottles were at facilitating weight gain in fifty infants with cleft lip and/or palate. Parental diaries and questionnaires were used for data collection over a six-week period that addressed the frequency and amount that the infants were fed, the time required for consumption, and infant behaviour during and following formula consumption. In addition, weekly weight was documented over the six weeks. Findings revealed that twenty-seven infants achieved typical weight gain patterns, but the remaining infants showed only adequate or deficient weight gain patterns. The authors concluded that successful weight gain in cleft lip and/or palate infants is determined more by the severity and location of the cleft, as opposed to the type of bottle administered for feeding. Infants with unilateral cleft lip and palate were able to gain more weight through bottle feeding compared to those with complete cleft palates in isolation.

The authors of this study provided a clear research question and rationale to support the importance of the study proceedings. The participants recruited displayed a wide range of cleft types, which is a strength considering the different cleft severities that can be observed in this population of infants. However, the overall sample size was small, which reduces how confidently the outcomes obtained from this study can be generalized to a larger cleft population. Participant exclusion criteria was not provided, therefore it cannot be determined if other hereditary, medical, cognitive, or pharmaceutical factors were present to influence feeding and physical development. This should have been controlled to ensure that weight gain outcomes were related to the bottle type, and is thus a weakness in the study procedure.

The methodology and study protocol was limited in certain areas. Feeding times were recorded by parents and weight gain was monitored on a weekly basis by health visitors, which controlled for researcher bias during data collection. However, the characteristics of the feeding support provided by health care advisors to parents was not outlined, which is important from a clinical application perspective to know what types of compression bottles or clefts require the most support. It cannot be determined what feeding modifications may need to be made related to support, position, and instruction when this information is not provided. Finally, it was not stated what proportion of cleft types were exposed to each compression bottle type.

An appropriate multiple regression analysis was used to determine which variable had the largest impact on facilitating weight gain over the six-week period (the bottle type, the nipple type, or the cleft type). Changes in the standard deviations for weight was compared from birth to week six for each variable.

This study offers level three evidence but provides strong, compelling support that the success of compression bottle-feeding methods depends on the type and severity of the cleft. However, whether or not bottle feeding would improve if positioning during feeding was modified or if bottle feeding was paired with palatal appliances depending on the cleft cannot be determined.

Discussion

The current literature review evaluated whether bottle-feeding approaches manage the feeding difficulties and facilitate nutritional gain and physical growth in newborns with cleft lip and/or palate. Compelling level one clinical evidence was presented by Brine et al. (1994) and Shaw et al. (1999), along with level three evidence by Martin et al. (2014) supporting that both compression and rigid bottle types can promote weight gain and an increase in anthropometric measurements in this population of infants. However, patterns across these findings also suggest that bottle-feeding success and bottle type implemented likely depends on the extent and location of the craniofacial cleft.

The prevalence of feeding difficulties has been found to be as high as seventy-three percent in more severe cases of facial clefts, particularly associated with isolated palatal clefts (Spriestersbach et al., 1973). A 2006 study by Reid and colleagues found that although intra-oral suction generation can be achieved in infants with isolated cleft lips, suction is often reduced in newborns with isolated cleft palates, and completely absent in those with congruent clefts to the lip and palate, while feeding from rigid bottle types. This coincides with Shaw et al. (1999), who found that rigid bottles often required modifications for several newborns in order to achieve feeding success, typical growth outcomes, and nutritional gain. In cases where the extent of the facial cleft is more severe, perhaps assistive compression bottles may be more efficient to promote typical weight gain patterns and overcome failure to thieve, as caregivers can offset a lack of suction generation by physically expressing feeds from bottles.

Furthermore, moderately strong evidence was found for pairing compression bottle use with palatal obturators to facilitate weight gain and physical growth in infants with cleft lip and/or palates (Turner et al., 2001). Palatal obturators not only cover the open structural cleft, but have also been proposed to improve suction generation prior to surgical repair if the palatal extension is made long enough (Kogo et al., 1997). Palatal devices also allow infants to express formula from bottles more efficiently, as the nipple can be compressed between the tongue and the artificial palate even without suction generation (Glass & Wolf, 1999). However, Shaw et al. (1999) and Martin et al. (2014) indicate that typical growth and weight gain patterns can still be achieved without implementing obturators with compression bottles. This continues to support that bottle-feeding success and the need for additional feeding appliances depends on the cleft location and severity.

A diverse representation of cleft types and severities were present in these studies, to evaluate the success of bottle-feeding methods on nutritional gain and physical growth. The results are compelling and clinically relevant towards guiding feeding management; however, their validity and reliability should remain to be interpreted with caution. This is due to occasional study limitations of a lack of assessor blindness, participant exclusion criteria, and smaller sample sizes overall, thus limiting result generalization to a larger cleft population.

Clinical Implications and Conclusion

Feeding difficulties that arise in newborns with cleft lip and/or palate places this population at risk for experiencing malnutrition and failure to thrive. Bottle-feeding management can be appropriate for overcoming these difficulties. Clinicians should be aware that the type and the extent of the craniofacial cleft will often determine which bottle-type to implement along with parental education for appropriate use. Ongoing assessment of a particular bottle-feeding method and monitoring of an infant's corresponding nutritional gain and growth is crucial for determining if modifications or alternative feeding methods are required.

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