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Impact of breastfeeding and/or bottle-feeding on surgical wound dehiscence after cleft lip repair in infants: A systematic review

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'Title page'

Title

Impact of breastfeeding and/or bottle-feeding on surgical wound dehiscence after cleft lip repair in infants: a systematic review

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‘Summary and keywords’

Summary

BACKGROUND: Immediately after cleft lip repair, breastfeeding and bottle-feeding are generally restricted to avoid placing tension on the surgical incision. However, no consensus about feeding methods after cleft lip repair has been reached. The objective of this systematic review was to examine the impact of breastfeeding and/or bottle-feeding on surgical wound dehiscence after cleft lip repair in infants.

MATERIAL AND METHODS: We searched PubMed, CINAHL, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Mednar from October to November 2017. Two reviewers independently assessed eligibility for inclusion and checked critical appraisal of the study quality.

RESULTS: Three randomized controlled trials and two cohort studies involving 342 infants were included in this review. Two cases of surgical wound dehiscence occurred in the control group of alternative feeding. In three of five studies, surgical wound dehiscence did not occur in either the intervention or control group within the first week postoperatively.

CONCLUSIONS: This review showed no increased risk of surgical wound dehiscence in infants with breastfeeding and/or bottle-feeding after cleft lip repair compared with infants with alternative feeding methods. It may not be necessary to restrict breastfeeding and/or bottle-feeding immediately after cleft lip repair.

Key Words: Breastfeeding; Bottle-feeding; Cleft lip; Surgery; Surgical wound dehiscence; Systematic review

'Text'

1. Introduction

Cleft lip and/or palate is a craniofacial anomaly and one of the most common birth defects. The overall worldwide prevalence is 7.9 per 10,000 live births (World Health Organization, 2001). Patients with cleft lip and/or palate usually undergo a combination of surgical procedures, speech therapy, and orthodontic treatment from infancy to young adulthood (Edwards and Costello, 2007).

The first surgery is cleft lip repair. The aim of cleft lip repair is to create contrast between the lip and external nose and provide good muscular continuity across the cleft with no scarring (Peterson-Falzone et al., 2010b). Cleft lip repair is usually performed from 3 to 6 months of age because delaying the surgery decreases the anesthetic risk and allows for growth of the lip structure (Edwards and Costello, 2007).

Infants with cleft lip can generally drink milk from the breast through various feeding techniques (Reilly et al., 2013). In contrast, infants with both cleft lip and palate have difficulty sucking the nipple because of weak intraoral negative pressure (Reid et al., 2006); thus, specially designed nipples are generally used. Although such infants suckle with weakened pressure, these nipples enable them to drink milk by lightly pushing the nipple through the patient's lips (Peterson-Falzone et al., 2010a).

Immediately after cleft lip repair, breastfeeding and bottle-feeding are generally restricted, and alternative feeding methods such as the use of a spoon, cup, or syringe are recommended to avoid placing tension on the surgical incision. The use of a very soft nipple of sufficient size is recommended to provide a dripping milk flow, thus avoiding tension on the operative site (Agrawal and Panda, 2011). Some authors have recommended spoon-feeding patients with cleft lip and/or palate for a certain period of time after cleft lip repair to avoid tension on the surgical site (Peterson-Falzone et al., 2010b). However, other authors have recommended that the feeding method after cleft lip repair should be returned to normal as soon as possible (Gailey, 2016).

A systematic review suggested that alternative feeding methods were associated with less postoperative weight gain in patients than traditional feeding methods (Bessell et al., 2011). Postoperative nutritional intake also influences wound healing (Langemo et al., 2006). After the surgery, feeding takes a longer period of time to complete, and this longer feeding time coupled with weight loss suggests unnecessary energy consumption. Consequently, wound healing may be inhibited or delayed.

No consensus about feeding methods after cleft lip repair has been reached (Peterson-Falzone et al., 2010b). Management of the surgical site after surgical repair of cleft lip and/or palate varies among countries and healthcare centers (Agrawal and Panda, 2010).

A systematic review reported that there was no difference in wound dehiscence between feeding methods after cleft lip repair (Duarte et al., 2016). However, their review has three main limitations. First, the review included an article describing surgical wound dehiscence after palatoplasty and cheiloplasty (Cohen et al., 1992). The influence of feeding methods after cheiloplasty and palatoplasty to the surgical wound should be examined separately because the role of the lips differs from the role of the palate at the time of ingestion. Second, critical appraisal of the study quality was not described. Third, the search period was limited to 1990 through 2015 in spite of the fact that cleft lip repair has been available since the 1950s (Costello and Ruiz, 2012).

The objective of this systematic review was to examine the impact of breastfeeding and/or bottle-feeding on surgical wound dehiscence after cleft lip repair in infants. Our proposed systematic review will contribute to a better understanding of this topic and identify areas for further research. If breastfeeding and/or bottle-feeding can be recommended immediately after cleft lip repair, infants may experience less stress and crying and placing less tension on the wound than with alternative feeding methods. Breastfeeding and/or bottle-feeding should result in more weight gain, facilitating wound healing.

2. Material and methods

This systematic review was conducted in accordance with the JBI methodology for systematic review of effectiveness evidence (Tufanaru et al., 2017). This

review was conducted in accordance with an *a priori* protocol (Matsunaka et al., 2015).

2.1. Inclusion criteria

2.1.1. Participants

This review considered studies that included infants who underwent cleft lip repair. The review excluded studies involving patients who underwent cleft palate repair.

2.1.2. Intervention

This review considered studies that evaluated the impact of the same feeding method (breastfeeding and/or bottle-feeding) as that used preoperatively on surgical wound dehiscence after cleft lip repair in infants.

2.1.3. Comparator

This review considered studies that compared the intervention to alternative feeding methods (spoon-, cup-, or syringe-feeding).

2.1.4. Outcomes

This review considered studies that included the following outcome measure: incidence of surgical wound dehiscence ascertained by health professionals or researchers within the first week after the surgery because wound dehiscence manifests within the first week after surgery (Shetty and Bertolami, 2012). Secondary outcomes included wound healing complications and weight gain. Healing complications such as swelling, bleeding, and infection were ascertained by health professionals or researchers, and weight gain was measured by health professionals or researchers.

2.1.5. Types of studies

This review considered any type of experimental study design, including randomized controlled trials (RCTs), for feeding interventions after cleft lip repair. If RCTs were not available, other research designs such as quasi-RCTs or cohort

studies were considered for inclusion. Studies published in English and Japanese from 1950 to 2017 were considered for inclusion in this review.

2.2. Search strategy

We utilized the following databases to identify both published and unpublished studies: PubMed, CINAHL, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Mednar. The latest search date was from October to November 2017. Keywords and MeSH terms such as mouth abnormalities, bottle feeding, breast feeding, feeding behavior, feeding methods, infant nutritional physiological phenomena, spoon or sput or syring or cup or cups feeding were used for the search.

2.3. Study selection

Following the search, all identified citations were loaded into RefWorks and duplicates removed. Titles and abstracts were screened by two independent reviewers for assessment against the inclusion criteria for the review. The full text of potentially eligible studies was retrieved and assessed in detail against the inclusion criteria by two independent reviewers. The details of studies that met the inclusion criteria were imported into the Joanna Briggs Institute's System for the Unified Management, Assessment and Review of Information (The Joanna Briggs Institute, 2017). Full text studies that did not meet the inclusion criteria were excluded. Any disagreements that arose between the reviewers were resolved through discussion or by a third reviewer.

2.4. Assessment of methodological quality

Eligible studies were critically appraised by two independent reviewers at the study level using standardized critical appraisal instruments for experimental and quasi-experimental studies from the Joanna Briggs Institute (The Joanna Briggs Institute, 2016). Any disagreements that arose between the reviewers were resolved through discussion or by a third reviewer. In RCTs/pseudo-RCTs, the most important type of bias is selection bias (Tufanaru et al., 2017). The highest-priority criterion for the included studies was truly random assignment to the treatment groups (Q1). If this was negative or unclear, we considered identical treatment of the groups other than for the intervention (Q7) as the second priority

because tension on the surgical wound (Peterson-Falzone et al., 2010b) and a clean wound (Nagy and Mommaerts, 2011) influence wound healing after cleft lip repair. The highest-priority criterion for cohort studies was whether the follow-up was complete, and if not, whether the reasons for loss to follow-up were described and explored (Q9); this is because follow-up of the greatest possible percentage of people is important in a cohort study (Tufanaru et al., 2017).

3. Results

3.1. Study inclusion

Details of the study selection, including results specific to PubMed, CINAHL, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), and Mednar, were presented in Figure 1. In total, 1458 studies were screened for matching with the inclusion criteria. Of these 1458 records, 267 duplicates were removed, leaving 1191 records. Of these, 1178 records were excluded for the following reasons after checking the year of publication and language by reading the title and abstract: 16 records were published prior to 1950. Five records were not published in English or Japanese. The patients in 848 records did not have cleft lip and/or palate; these patients had birth defects such as tongue-tie or Pierre Robin sequence (n = 116), pregnancy (n = 80), and cancer (n = 65). The number of records dealing with cleft lip and/or palate was 322. Further, 309 records were excluded for the following reasons: feeding methods irrelevant to the operations (n = 58), patients with cleft palate who did not need cleft lip repair (n = 43), and treatment of cleft lip and/or palate (n = 35). 13 papers were retained for full-text assessment. Of these, eight papers were excluded because they did not meet the inclusion criteria. Five studies were included for the methodological quality assessment. These five studies (Weatherley-White et al., 1987; Darzi et al., 1996; Skinner et al., 1997; Assunção et al., 2005; Augsornwan et al., 2013) met the inclusion criteria and were included in the review. They comprised three RCTs and two cohort studies involving 342 infants who underwent cleft lip repair.

<Insert Figure 1 here>

3.2. Methodological quality

Two independent reviews were performed to critically appraise the five studies regarding their methodological quality using the JBI appraisal checklists (The Joanna Briggs Institute, 2016). The results indicated that all five studies were appropriate for inclusion in the review.

3.3. Methodological quality of RCTs (Table 1)

Darzi et al. (1996) used random assignment of treatment methods. The infants' mothers chose a numbered slip of paper from a well-shuffled box containing 20 slips for each group. However, the allocation method and assessor blinding were not described. The treatment groups were similar at baseline because the authors reported that there was no significant difference between the two groups. The treatment groups were treated identically other than the feeding strategies, although two surgical techniques of cleft lip repair were used. The postoperative care, such as the use of antibiotics and arm restraints, was the same in each group. Follow-up was complete because the number of patients reported in the Methods section accorded with the number of patients reported in the Results section. Deviation from the allocated groups was not reported. The outcomes were assessed by the surgeon who repaired the lips. Student's unpaired t-test was used in the statistical analyses.

Assunção et al. (2005) did not describe the allocation method or assessor blinding. The authors described the characteristics of both groups and indicated that the treatment groups were similar at baseline. All patients were surgically treated with the same cleft lip repair technique, received analgesics on the first postoperative day, and were given water followed by milk after recovery from anesthesia. The surgical wounds of only 30 patients were described despite the fact that 45 patients were initially recruited; therefore, it appears that 15 patients dropped out of the study. The issue of incomplete follow-up was not discussed. Deviation from the allocated groups was not reported. The contents and timing of the outcome evaluation were reported. However, the assessors and evaluation methods were not described. Fisher's exact test was used in the statistical analyses.

Augsornwan et al. (2013) used random assignment of treatment methods. The patients were allocated using computer-generated blocks of eight

randomizations. The allocation schedule was concealed until the end of the trial in one study. However, the authors did not state whether assessor blinding was performed. The treatment groups were similar at baseline, and the characteristics of both groups were described. All patients received the same standard of nursing care. Follow-up was complete in two studies because the number of patients reported in the Methods section accorded with the number of patients reported in the Results section. Deviation from the allocated groups was not reported. The Z-test was used in the statistical analyses.

All three studies met the criteria for assessment of methodological quality. However, their overall methodological quality was low because blinding was not achieved and the sample sizes were small. The patients were not blinded to the treatment allocation because infant patients did not understand the difference in feeding methods after surgery. Nurses (Augsornwan et al., 2013) or physicians (Darzi et al., 1996) assessed the outcomes. They presumably understood the allocation of the participants, although the studies did not describe assessor blinding. One study (Assunção et al., 2005) did not report who assessed the outcomes. Sample sizes were small; $n = 30$ (Assunção et al., 2005), $n = 192$ (Augsornwan et al., 2013) and $n = 40$ (Darzi et al., 1996).

<Insert Table 1 here>

3.4. Methodological quality of cohort studies (Table 2)

Weatherley-White et al. (1987) examined whether breastfeeding in the early postoperative period would harm the cleft lip repair in six-week follow-up study. The infants' mothers were offered the opportunity to select the feeding method (breastfeeding or cup-feeding) after cleft lip repair. The characteristics of the two groups were not described. The authors did not mention how the outcomes were measured or whether adjustment was performed for confounding factors. However, the six-week follow-up was complete, and appropriate statistical analysis was used.

Skinner et al. (1997) designed a study to identify complications (e.g., dehiscence) related to the type of feeding strategy (cup-feeding or bottle-feeding) in a six-week follow-up study. A doctor recommended that the caregivers perform cup-feeding, and before cleft lip repair, a speech-language pathologist/oral-motor

feeding specialist demonstrated the feeding guidelines for postoperative cup-feeding. After the surgery, however, 40 infants underwent cup-feeding and two underwent bottle-feeding. The characteristics of the two groups were not described. The duration of exposure to cup feeding varied from two to six weeks after the surgery. However, the six-week follow-up was complete, and appropriate statistical analysis was used.

<Insert Table 2 here>

3.5. Characteristics of included studies (Table 3 and Table 4)

<Insert Table 3 and Table 4 here>

3.5.1. Sample size and participants

Cleft lip repair in these five studies (Weatherley-White et al., 1987; Darzi et al., 1996; Skinner et al., 1997; Assunção et al., 2005; Augsornwan et al., 2013) was performed from 3 to 13 months after birth. In two studies (Weatherley-White et al., 1987; Skinner et al., 1997), infants with other multiple anomalies were excluded. The first published study was conducted in 1983 (Weatherley-White et al., 1987), the second oldest study was conducted from 1991 to 1995 (Skinner et al., 1997) and a more recent study was conducted from 2010 to 2013 (Augsornwan et al., 2013). Two other studies (Darzi et al., 1996; Assunção et al., 2005) did not report the study period. The total number of participants was 342, with the sample size ranging from 30 (Assunção et al., 2005) to 192 (Augsornwan et al., 2013). Only one study (Augsornwan et al., 2013) calculated the sample size.

3.5.2. Intervention and comparators

In this review, particular focus was placed on the impact of the same feeding methods (breastfeeding and/or bottle-feeding) used both preoperatively and postoperatively. This feeding method was compared with alternative feeding methods (spoon-, cup-, or syringe-feeding) performed postoperatively in terms of its impact on surgical wound dehiscence. The feeding methods included in the intervention and comparison groups differed among studies. When the intervention was bottle-feeding, the comparator was spoon-feeding (Assunção et

al., 2005) or cup-feeding (Skinner et al., 1997). When the intervention was breastfeeding, the comparator was spoon-feeding (Darzi et al., 1996) or cup/syringe-feeding (Weatherley-White et al., 1987). When the intervention was breastfeeding/bottle-feeding, the comparator was spoon/syringe-feeding (Augsornwan et al., 2013).

3.5.3. Outcomes

The five studies (Weatherley-White et al., 1987; Darzi et al., 1996; Skinner et al., 1997; Assunção et al., 2005; Augsornwan et al., 2013) included surgical wound dehiscence as a primary outcome. The intervals between the surgery and evaluation of wound dehiscence varied among studies, ranging from immediately postoperatively (Assunção et al., 2005; Augsornwan et al., 2013) to 7 to 13 months postoperatively (Darzi et al., 1996). Surgical wound dehiscence, swelling, bleeding, and infection were visually inspected immediately postoperatively, the first day postoperatively, and 30 days postoperatively (Assunção et al., 2005). In one study, surgical wound dehiscence, swelling, bleeding, and infection were measured by a registered nurse who was well-trained in wound assessment using a surgical wound evaluation form immediately postoperatively, the first day postoperatively, and two weeks postoperatively (Augsornwan et al., 2013). In the other study, surgical wound dehiscence and scarring were assessed by the surgeon who repaired the lips with a follow-up period of 7 to 13 months after surgery (Darzi et al., 1996). The other three assessors did not describe who the assessors were, and the follow-up period for surgical wound dehiscence was six weeks postoperatively in one study and three months (Weatherley-White et al., 1987) in the other study.

Two studies (Assunção et al., 2005; Augsornwan et al., 2013) included wound healing complications such as swelling, bleeding, and infection as outcomes. Two studies (Darzi et al., 1996; Weatherley-White et al., 1987) included weight gain.

3.6. Review findings

3.6.1. Surgical wound dehiscence (Table 5)

No wound dehiscence associated with any type of feeding method developed in either the intervention or control group among all 342 infants in the five studies

within the first week postoperatively (Weatherley-White et al., 1987; Darzi et al., 1996; Skinner et al., 1997; Assunção et al., 2005; Augsornwan et al., 2013). Two cases of dehiscence (Weatherley-White et al., 1987; Darzi et al., 1996) occurred in the alternative feeding group within the first week after surgery. In one study, an accidental fall occurred on the third postoperative day, resulting in wound dehiscence (Darzi et al., 1996); the other study (Weatherley-White et al., 1987) did not provide the reason for the partial dehiscence.

Two further cases of wound dehiscence at two weeks postoperatively were reported, and both were in the control group. One case of partial lip dehiscence resulted from an accidental fall (Augsornwan et al., 2013). Another case of mild dehiscence at the right nostril was noted in a patient with failure to thrive and respiratory difficulties, but the allocation of this infant was not mentioned (Skinner et al., 1997).

3.6.2. Wound healing complications such as swelling, bleeding, and infection (Table 5)

Wound complications reported in the two studies showed no statistically significant differences between the two feeding method groups on the first postoperative day (Assunção et al., 2005; Augsornwan et al., 2013). Bleeding immediately after the surgery was reported in one bottle-fed infant in the study by Assunção et al. (2005) and in five breast/bottle-fed and two spoon/syringe-fed infants in the study by Augsornwan et al. (2013). However, no case of bleeding was reported after the first postoperative day in these two studies (Assunção et al., 2005; Augsornwan et al., 2013). No case of infection was observed in the study by Assunção et al. (2005) within 30 days postoperatively, and two cases of infection were reported in spoon-/syringe-fed infants on the 14th day after surgery in the study by Augsornwan et al. (2013).

<Insert Table 5 here>

3.6.3. Weight gain

Weight gain in the postoperative period was reported in two studies (Weatherley-White et al., 1987; Darzi et al., 1996). Infants in the breastfeeding group tended to gain more weight than those in the spoon-feeding group at three

weeks postoperatively, although the difference did not reach statistical significance ($P > 0.10$) (Darzi et al., 1996). At six weeks after surgery, the mean weight of infants in the breastfeeding group was significantly higher than that of infants in the spoon-feeding group (6.35 ± 0.48 and 5.88 ± 0.37 kg, respectively; t value = 3.36, $P < 0.01$).

The results of the above-mentioned studies were supported by Weatherley-White et al. (1987). They found that infants in the breastfeeding group had gained an average of 28% of their preoperative weight at 1 month postoperatively, while infants in the cup-/syringe-feeding group had gained an average of only 17% during the same period. At three months, infants in the breastfeeding group had gained an average of 67% compared with their preoperative weight, and infants in the cup-/syringe-feeding group had gained 43%. However, the authors did not report the results of a statistical analysis.

4. Discussion

This systematic review examined the impact of the postoperative feeding method on surgical wound dehiscence after cleft lip repair in infants. Surgical wound dehiscence related to the feeding strategy did not occur in any infants. Two cases of dehiscence unrelated to the feeding method occurred in the alternative feeding group within the first week after surgery (Weatherley-White et al., 1987; Darzi et al., 1996). The postoperative feeding method was not associated with any secondary outcomes such as swelling, bleeding, and infection. Our results suggest that continuation of breastfeeding or bottle-feeding after cleft lip repair is unlikely to influence the surgical wound.

The incidence of surgical wound dehiscence is rare despite the fact that surgical wound dehiscence has been regarded as a typical complication after cleft lip and/or palate repair, followed by pyrexia (Zhang et al., 2014). In one case series, postsurgical complications occurred in 11 of 2100 infants who underwent surgical cleft lip and/or palate repair during a 7-year period (Zhang et al., 2014). The incidence of dehiscence after cleft lip repair is 1.3% (Kantar et al., 2018). Surgical wound dehiscence results from tissue failure rather than improper suturing technique (Shetty and Bertolami, 2012), which suggests the importance of avoiding tension on the surgical wound after cleft lip repair.

In our review, two cases of accidental falls occurred in the control group (Darzi et al., 1996; Augsornwan et al., 2013). After cleft lip repair, infants are likely to experience not only a change in their feeding method but also the use of elbow restraints (Nagy and Mommaerts, 2011) and restriction of pacifier sucking (Barsi et al., 2013). Distress caused by alternative feeding methods, the use of elbow restraints, or restriction of pacifier use may have increased the risk of accidental falls in these two infants after cleft lip repair. After cleft lip repair, efforts should be made to both minimize crying to avoid tension on the surgical wound (Peterson-Falzone et al., 2010b) and to maintain a clean wound (Nagy and Mommaerts, 2011). Our study suggests that preventing accidental falls from the infant's bed is important to avoid tension on the surgical wound. Accidental injuries, including those at home care settings, require investigation in future studies.

None of the five studies in our review mentioned any policy that either restricted or allowed the use of a pacifier or elbow restraints during the study period. In a randomized trial (n = 94) conducted to test the effects of a policy that restricted arm restraints on surgical complications following cleft lip or palate repair, no differences were found in adverse outcomes such as postoperative fistulae between the intervention group and control group (Huth et al., 2013). Additionally, 79% of the infants used their thumb or fingers and/or a pacifier, the use of which had no impact on the occurrence of adverse outcomes. Contrary to the theory of avoiding pressure on the surgical site, adult patients who have undergone hip or knee replacement are rehabilitated to walk on the day of surgery (Husted, 2012) despite the fact that considerable pressure is exerted on the surgical site. Thus, the current wound management protocols for cleft lip repair should be reconsidered, although larger studies are needed to confirm the findings reported by Huth et al (2013).

Another wound healing complication following cleft lip repair is scarring or laterality of the lips. However, our literature search revealed only one study (Darzi et al., 1996) that examined scarring. Cleft lip repair is performed to achieve an aesthetic appearance (Peterson-Falzone et al., 2010a). Long-term follow-up is necessary to investigate these outcomes, which are influenced by the surgical methods used and the development of the muscles around the lips; thus, it is

difficult to conduct a study with these outcomes. However, it is important to examine the impact of postoperative feeding methods on scarring or laterality of the lips.

Breastfeeding or bottle-feeding is also more beneficial for weight gain than alternative feeding methods during the first several weeks postoperatively (Weatherley-White et al., 1987; Darzi et al., 1996), although the evidence level is low. Assunção et al. (2005) reported that 21.7% of infants who were given milk by a spoon on the first day after cleft lip repair resisted feeding by crying and/or moving the head laterally, while all infants who had been fed by the nipple used preoperatively accepted feeding without a major observable response. In another study, infants who were breastfed or bottle-fed after the repair were reportedly more relaxed than spoon-fed or syringe-fed infants (Augsornwan et al., 2013). These two studies show that infants treated with an alternative feeding method tend to be distressed and seem to have a difficulty in drinking a sufficient amount of milk (Assunção et al., 2005; Augsornwan et al., 2013). As a result, breastfed or bottle-fed infants are likely to gain more weight than infants on alternative feeding methods. It is recommended that postoperative feeding return to normal as soon as possible to maintain adequate nutrition intake (Redford-Badwal et al., 2003).

The methodological quality of the five studies (Weatherley-White et al., 1987; Darzi et al., 1996; Skinner et al., 1997; Assunção et al., 2005; Augsornwan et al., 2013) included in this systematic review was low because blinding was not achieved and the sample size was small. The infants could not be blinded because they received treatment. Assessor blinding was not described in the reviewed studies. However, lack of blinding is unlikely to have affected the assessment of primary outcomes because the incidence of wound dehiscence related to the feeding methods was zero for both groups. Additionally, weight gain is an objective measurement, and it is difficult to conceive that the individuals who weighed the infants knew the infants' feeding method and that this knowledge subsequently affected the weight measurement.

5. Conclusions

The data of the studies included in this review suggest no increased risk of surgical wound dehiscence after cleft lip repair in infants who continue to be breastfed or bottle-fed when compared with infants fed with alternative methods. Although the evidence level is low, the incidence of the primary outcome associated with the feeding method itself was very low. Breastfeeding and/or bottle-feeding may be preferable to alternative feeding methods because infants can maintain milk intake after the surgery.

5.1. Recommendations for practice

We suggest that breastfeeding and/or bottle-feeding may be safe for the surgical wound region immediately after cleft lip repair in infants when proper care is delivered, such as preventing tension on the patients' lip caused by crying or accidental falls. The five studies included in this systematic review suggested that breastfeeding and/or bottle-feeding immediately after the surgery is unlikely to cause surgical wound dehiscence and seem to be more beneficial for weight gain than alternative feeding methods such as spoon-, cup-, or syringe-feeding after the surgery. It may not be necessary to restrict breastfeeding or bottle-feeding immediately after cleft lip repair.

5.2. Recommendations for research

The quality of all five studies reviewed was low. However, we do not recommend a larger RCT to pursue this topic for the following reasons. First, the incidence of wound dehiscence related to the feeding method was very low (0% in 342 cases). Second, adverse outcomes such as accidental falls only occurred in the control group, possibly due to the increased stress related to the alternative feeding methods. Third, infants who were breastfed or bottle-fed tended to gain more weight than those fed with alternative methods. Alternative feeding methods after cleft lip repair have offered no benefit to date, and it may be unethical to conduct a further study because of the potentially increased risk of accidental falls. We recommend that the incidence of surgical wound dehiscence following cleft lip repair should be treated as a sentinel event to be reported and examined.

Wound healing complications associated with cleft lip repair include scarring or laterality of the lips. However, our literature search revealed only one study (Darzi et al., 1996) that included scarring as an outcome. It is important to examine the

impact of postoperative feeding methods on these complications because cleft lip repair is performed to obtain an aesthetic appearance.

‘Acknowledgements and conflict of interest statement’

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Declaration of Conflicting Interests

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'Tables'

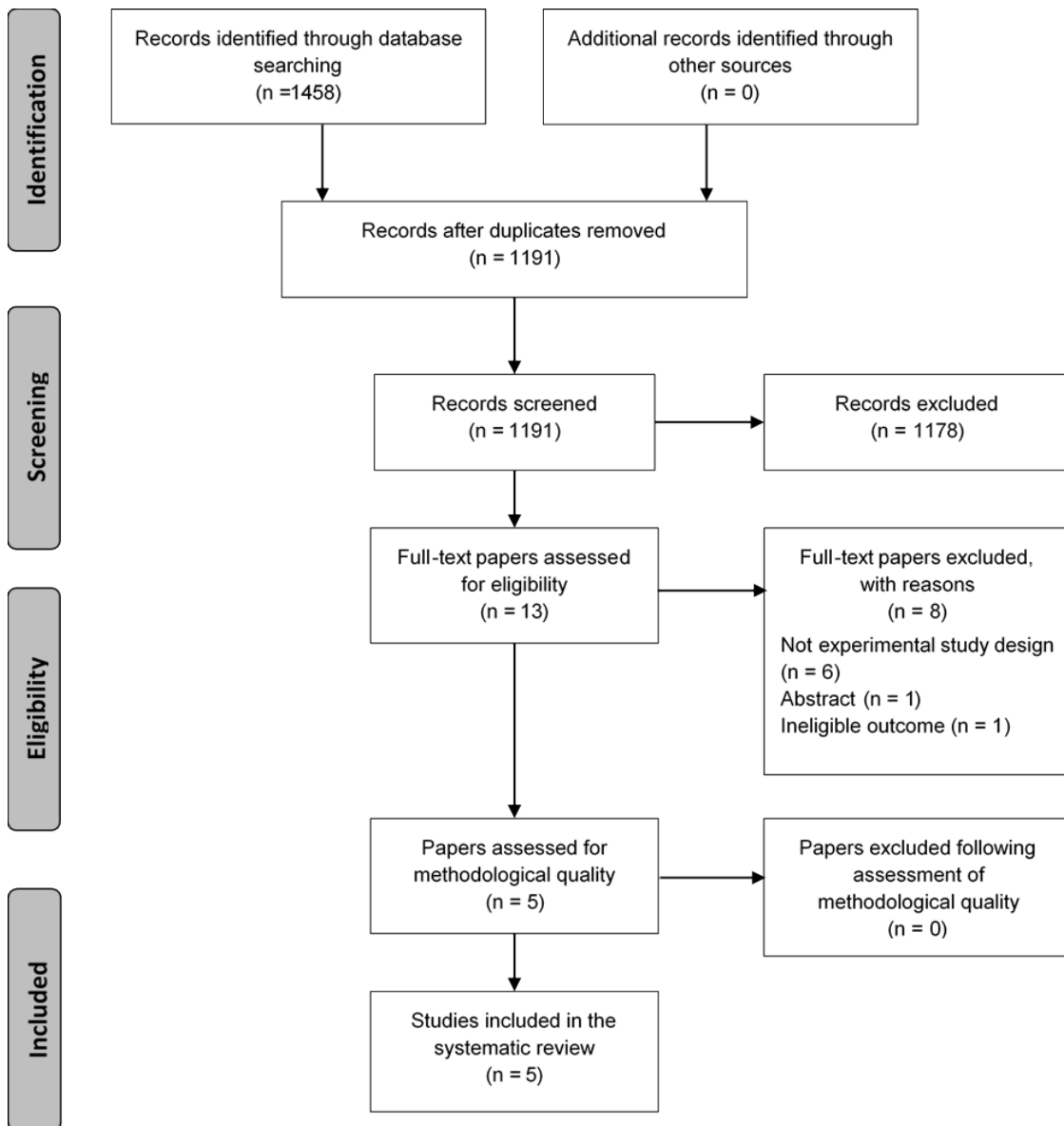


Figure 1: Search results and study selection and inclusion process

Table 1: Critical appraisal results of eligible studies of randomized/pseudo-randomized controlled trials

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13
Darzi MA, et al. (1996)	Y	N	Y	N	N	N	Y	Y	N	Y	Y	Y	Y
Assunção AG, et al. (2005)	U	N	Y	N	N	N	Y	N	N	U	U	Y	Y
Augsornwan D, et al. (2013)	Y	Y	Y	N	N	N	Y	Y	N	Y	Y	Y	Y
Total %	67	33	100	0	0	0	100	67	0	67	67	100	100

Y = Yes, N = No, U = Unclear; JBI critical appraisal checklist for randomized controlled trials: Q1 = Was true randomization used for assignment of participants to treatment groups?; Q2 = Was allocation to treatment groups concealed?; Q3 = Were treatment groups similar at baseline?; Q4 = Were participants blind to treatment assignment?; Q5 = Were those delivering treatment blind to treatment assignment?; Q6 = Were outcome assessors blind to treatment assignment?; Q7 = Were treatment groups treated identically other than the intervention of interest?; Q8 = Was follow-up complete, and if not, were strategies to address incomplete follow-up utilized?; Q9 = Were participants analyzed in the groups to which they were randomized?; Q10 = Were outcomes measured in the same way for treatment groups?; Q11 = Were outcomes measured in a reliable way?; Q12 = Was appropriate statistical analysis used?; Q13 = Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?

Table 2: Critical appraisal results of eligible studies of cohort studies

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
Weatherley-White RC, et al. (1987)	N	Y	N	N	N	Y	N	Y	Y	N	Y
Skinner J, et al. (1997)	N	N	N	Y	N	Y	N	Y	Y	N	Y
Total %	0	50	0	50	0	100	0	100	100	0	100

Y = Yes, N = No, U = Unclear; JBI critical appraisal checklist for cohort studies: Q1 = Were the two groups similar and recruited from the same population?; Q2 = Were the exposures measured similarly to assign people to both exposed and unexposed groups?; Q3 = Was the exposure measured in a valid and reliable way?; Q4 = Were confounding factors identified?; Q5 = Were strategies to deal with confounding factors stated?; Q6 = Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?; Q7 = Were the outcomes measured in a valid and reliable way?; Q8 = Was the follow up time reported and sufficient to be long enough for outcomes to occur?; Q9 = Was follow up complete, and if not, were the reasons to loss to follow up described and explored?; Q10 = Were strategies to address incomplete follow up utilized?; Q11 = Was appropriate statistical analysis used?

Table 3: Characteristics of included studies of randomized controlled trials

Study	Country	Participants	Intervention	Comparator	Outcomes	Results
Darzi MA et al. (1996)	India	Infants with cleft lip alone underwent repair at 3 to 6 months of age. Patients with associated cleft palate and those aged >6 months were excluded. (N=40)	Breastfeeding (n=20)	Spoon-feeding (n=20)	1. Surgical wound dehiscence and scarring were assessed by the surgeon who repaired the lips with a follow-up period of 7 to 13 months after surgery. 2. Weight at the time of the operation and at 3 and 6 weeks postoperatively	Only one partial wound dehiscence occurred in a spoon-fed infant who fell from the bed on postoperative day 3. Early postoperative breastfeeding after cleft lip repair is safe, results in more weight gain 6 weeks after surgery (P < 0.01).
Assunção AG et al. (2005)	Brazil	Infants aged 3 to 13 months underwent cleft lip repair. (N=30)	Bottle-feeding (n=13)	Spoon-feeding (n=17)	Surgical wound dehiscence, swelling, bleeding, and infection were visually inspected immediately postoperatively, 1 day postoperatively, and 30 days postoperatively.	No surgical wound dehiscence occurred between bottle-feeding and spoon-feeding.
Augsornwan D et al. (2013)	Thailand	Patients with complete cleft lip or cleft lip and palate aged 3 to 6 months underwent lip repair from 2010 to 2013. Patients with cleft lip and palate and other anomalies were excluded. (N=192)	Breastfeeding/ bottle-feeding (n=96)	Spoon-/syringe-feeding (n=96)	Surgical wound dehiscence, swelling, bleeding, and infection were measured by a registered nurse who was well-trained in wound assessment using a surgical wound evaluation form immediately postoperatively, 1 day postoperatively, and 2 weeks postoperatively.	Surgical wound dehiscence not occur in either the intervention or control group immediately after surgery or 1 day after surgery. An accidental fall resulted in partial lip dehiscence 2 weeks after surgery in the control group.

Table 4: Characteristics of included studies of cohort studies

Study	Country	Participants	Intervention	Comparator	Outcomes	Results
Weatherley-White RC et al. (1987)	United States	All cleft types were included with cleft lip repair in 1983. Infants with severe multiple anomalies or who were aged >6 months at the time of cleft lip repair were excluded. (N=38)	Breastfeeding (n=16)	Cup-/Syringe-feeding (n=22)	1. Surgical wound dehiscence 2. Weight at the time of the operation and at 1 and 3 months postoperatively	Partial dehiscence of the lip occurred on postoperative day 3 in an infant in the cup-/syringe-feeding group. No surgical wound dehiscence occurred in the breastfeeding group. The rate of weight gain was enhanced in the breastfeeding group.
Skinner J et al. (1997)	United States	All cleft types were included with cleft lip repair from 1991 to 1995. (N=42)	Bottle-feeding (n=2)	Cup-feeding (n=40)	Surgical wound dehiscence	A dehiscence was noted in a patient who had a history of failure to thrive and respiratory difficulties, and a mild dehiscence was noted at the right nostril 2 weeks postoperatively when the patient was not nipple-feeding; however, the two dehiscence were not related to the feeding strategies.

Table 5. The incidents of wound healing complications within the first week postoperatively

		Intervention		Comparator	
		The same feeding methods		The alternative feeding methods	
		Events	Total	Events	Total
Surgical wound dehiscence	Darzi MA et al. (1996)	0	20	1	20
	Assunção AG et al. (2005)	0	13	0	17
	Augsornwan D et al. (2013)	0	96	0	96
	Weatherley-White RC et al. (1987)	0	16	1	22
Swelling	Skinner J et al. (1997)	0	2	0	40
	Assunção AG et al. (2005)	4	13	5	17
Beeding	Augsornwan D et al. (2013)	14	96	13	96
	Assunção AG et al. (2005)	0	13	0	17
Infection	Augsornwan D et al. (2013)	0	96	0	96
	Assunção AG et al. (2005)	0	13	0	17