BREASTFEEDING MEDICINE
Volume 2, Number 4, 2007

DOI: 10.1089/bfm.2007.9984

ABM Protocols

ABM Clinical Protocol #17: Guidelines for Breastfeeding Infants with Cleft Lip, Cleft Palate, or Cleft Lip and Palate

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A central goal of the Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.

BACKGROUND

Definitions and incidence of cleft lip and/or palate

When a cleft lip (CL) occurs, the lip is not contiguous, and when a cleft palate (CP) occurs, there is communication between the oral and nasal cavities.[1] Clefts can range in severity from a simple notch in the upper lip to a complete opening in the lip extending into the floor of the nasal cavity and involving the alveolus to the incisive foramen.[2] Unilateral clefts of the lip are twice as likely to be on the left-hand side as the right.[3] Similarly, a CP may involve just the soft palate or extend partially or completely through the hard and soft palates.[1] In a CP, the alveolus remains intact. A CP may be submucous and not immediately detected if there are subtle or no corresponding clinical signs or symptoms.[1]

The worldwide prevalence of a cleft lip and/or palate (CL/P) ranges from 0.8 to 2.7 cases per 1000 live births.[4] There are differences in incidence rates across racial groups, with the lowest reported incidence among African–American populations (approximately 0.5 per 1000)[5,6] and Caucasian populations (approximately one per 1000 births),[4] and higher incidence among Native American (approximately 3.5 per 1000),[7,8] and Asian populations (approximately 1.7 per 1000).[9]

Although reports vary considerably, it is estimated that out of the total number of infants with a CL/P, approximately 50% have a combined cleft lip and palate (CLP), while 30% have an isolated CP, and 20% an isolated CL; a CL extending to include the alveolus occurs in approximately 5% of cases.[10] Clefts are usually unilateral; however, in approximately 10% of cases, clefts are bilateral.[11]

Breastfeeding and CL/P

In these guidelines, *breastfeeding* refers to direct placement of baby to the breast for feeding and *breastmilk feeding* refers to delivery of breastmilk to baby via bottle, cup, spoon, or any other means except breast. Babies use both suction and compression to breastfeed successfully. The ability to generate suction is necessary for attachment to the breast, mainte-

nance of a stable feeding position and, together with the let down reflex, milk extraction. Normally when feeding, a baby's lips flange firmly against the areola, sealing the oral cavity anteriorly. The soft palate rises up and back to contact the pharyngeal walls and seal the oral cavity posteriorly. As the tongue and jaw drop during sucking the oral cavity increases in size and suction is generated drawing milk from the breast.[12] Compression occurs when the baby presses the breast between the tongue and jaw. Suction and compression help milk transfer delivery during breastfeeding.[13–15]

There is a relationship between the size of oral pressures generated during feeding and the size/type of cleft[16] and maturity of the baby. For example, babies with a CL are more likely to breastfeed than those with a CP or CLP.[17] Some babies with small clefts of the soft palate generate suction[18] but others with larger clefts of the soft and/or hard palate may not generate suction.[18–20] Newborns and premature babies generate lower suction pressures compared to older babies.[16,21,22] Babies with a CP or CLP have difficulty creating suction[20,23] because the oral cavity cannot be adequately separated from the nasal cavity during feeding. A cleft which interferes with suction (or compression) has the potential to impact on breastfeeding.

The literature describing breastfeeding outcomes in a CL/P is limited,[24] anecdotal, and often contradictory. Furthermore, the populations studied have not been well described in terms of the size, location, and type (unilateral, bilateral) of the cleft, thus affecting interpretation and usefulness of data.

Aim

To develop evidence-based guidelines for breastfeeding babies with clefts.

RECOMMENDATIONS

Summary of recommendations for clinical practice

Based on the reviewed evidence, the following recommendations are made:

1. As these infants are prone to otitis media, mothers should be encouraged to provide the protective benefits of breastmilk. Evidence suggests that breastfeeding protects against otitis media in this population.[25,26] Additionally, there is speculative information regarding possible benefits of breastfeeding versus bottle feeding on the development of the oral cavity. Education of both parents before and after delivery on risks of formula versus breastmilk and potential feeding difficulties and their management may be particularly important. These families may benefit from peer support from other breastfeeding families with infants with a CL/P, found through family associations such as Wide Smiles, in addition to routine referral for breastfeeding support groups.
2. Babies with a CL/P should be evaluated for breastfeeding on an individual basis. In particular, it is important to take into account the size and location of the baby's CL and/or CP, as well as the mother's wishes, previous experience with breastfeeding, and supports. There is moderate evidence to suggest that infants with CL are able to generate suction,[23] and descriptive reports suggest that these infants are often able to breastfeed successfully.[27] There is moderate evidence that infants with a CP or CLP have difficulty generating suction[18,20] and have inefficient sucking patterns[19] compared to normal infants. The success rates for breastfeeding infants with a CP or CLP are observed to be lower than for infants with a CL or no cleft.[17,27,28]
3. As in normal breastfeeding, knowledgeable support is important. Mothers who wish to breastfeed should be given immediate access to a lactation advisor to assist with positioning, management of milk supply, and expressing milk for supplemental feeds.
4. Mothers should be counselled about likely breastfeeding success. Where direct breastfeeding is unlikely to be the sole feeding method, the need for breastmilk feeding and, when appropriate, possible delayed transitioning to breastfeeding should be discussed.
5. Breastmilk feeding (via cup, spoon, bottle, etc.) should be promoted in preference to formula feeding. In these circumstances,

assistance with hand expression/pumping breastmilk should commence on day 1.

6. Monitoring of a baby's hydration and weight gain may be important while a feeding method is being established. If inadequate, supplemental feeding should be implemented or increased. (See ABM Protocol #3: Hospital Guidelines for the Use of Supplementary Feedings.)
7. Modification to breastfeeding positions may increase the efficiency and effectiveness of breastfeeding. Positioning recommendations that have been recommended on the basis of weak evidence (clinical experience or expert opinion), and should be evaluated for success are:
   a. For infants with CL:
      i. The infant should be held so that the cleft lip is orientated toward the top of the breast[29,30] [e.g., an infant with a (R) CL may feed more efficiently in a "Madonna" position at the right breast and a "football/twin style" position at the left breast];
      ii. The mother may occlude the CL with her thumb or finger[7,31,32] and/or support the infant's cheeks to decrease the width of the cleft and increase closure around the nipple;[33]
      iii. For bilateral CL, a "face-on" straddle position may be more effective than other breastfeeding positions.[30]
   b. For infants with a CP or CLP:
      i. Positioning should be semi-upright to reduce nasal regurgitation, and reflux of breastmilk into the Eustachian tubes;[30,32,34–40]
      ii. A "football hold"/twin position (body of infant directed away from the mother, rather than across the mother's lap, and with the infants shoulders higher than its body) may be more effective than a traditional Madonna position;[29]
      iii. For infants with a CP it may also be useful to position the breast toward the "greater segment"—the side of the palate which has the most intact bone.[29] This may facilitate better compression and stop the nipple being pushed into the cleft site;[41]
      iv. Some experts suggest supporting the infant's chin to stabilize the jaw during sucking[32] and/or supporting the breast so that it remains in the infant's mouth;[33,37,42]
      v. If the cleft is large, some experts suggest that the breast be tipped downward to stop the nipple being pushed into the cleft;[29]
      vi. Mothers may need to manually express breastmilk into the baby's mouth to compensate for absent suction and compression and to stimulate the letdown reflex.[42–44]
8. If a prosthesis is used for orthopedic alignment prior to surgery, caution should be used in advising parents to use such devices to facilitate breastfeeding, as there is strong evidence that they do not significantly increase feeding efficiency or effectiveness.[45,46]
9. Evidence suggests that breastfeeding can commence/recommence immediately following CL repair,[47,48] and 1 day after CP repair without complication to the wound.[47]
10. Assessment of the potential for breastfeeding of infants with a CL/P as part of a syndrome/sequence should be made on a case-by-case basis, taking into account the additional features of the syndrome that may impact on breastfeeding success.

Recommendations for future research

The most pressing issue for healthcare professionals working with mothers who wish to breastfeed their infants with a CL/P is the lack of evidence on which to base clinical decisions. Well-designed, data-driven investigations which document feeding success rates, management strategies, and outcomes for infants with CL/P are imperative. Furthermore, investigators must clearly describe their sample of infants and intervention techniques so that the research outcomes are able to be generalized.

ACKNOWLEDGMENT

Supported in part by a grant from the Maternal and Child Health Bureau, Department of Health and Human Services.

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ABM protocols expire five years from the date of publication. Evidence-based revisions are made within five years or sooner if there are significant changes in the evidence.

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APPENDIX I: FREQUENTY ASKED QUESTIONS

Breastfeeding infants with cleft lip, cleft palate, or cleft lip and palate

Except where noted, the literature reviewed relates to infants with nonsyndromic clefts of the lip and/or palate.

1. Can infants with a cleft lip (CL) breastfeed successfully?
There is no strong evidence with regard to breastfeeding of infants with a CL. There was moderate (Level II-2) evidence that babies with a CL create suction during feeding.[18,23] Descriptive (Level III) studies have demonstrated successful breastfeeding at rates approaching the normal population.[27] Expert opinion (Level III) suggests that infants with CL may find breastfeeding relatively more easy than bottle feeding because the breast tissue molds to the cleft and occludes the defect more successfully than an artificial nipple.[34,49–52] Expert opinion suggests that modifications to positioning can facilitate breastfeeding for these infants.[7,29–33]

2. Can infants with a cleft palate (CP) breastfeed successfully?
There is no strong evidence with regard to breastfeeding infants with a CP. There was moderate evidence (Level II-2) that infants with a CP do not create suction when bottle feeding,[18,20,23] although infants with clefts of the soft palate may be able to create suction.[16,18] Descriptive studies indicate that breastfeeding success for infants with CP is much lower than for infants with a CL.[27,28] There was weak evidence (Level III, expert opinion) to suggest that partial breastfeeding (with supplementation) can be achieved,[35,36,51,53,54] and that the size and location of the cleft are determining factors for breastfeeding success.[31,40,43,55] As with infants with CL, modifications to positioning are reported to increase breastfeeding success (Level III, expert opinion).[30,32,34–40]

3. Can infants with a cleft lip and palate (CLP) breastfeed successfully?
There is no strong evidence with regard to breastfeeding infants with a CLP. There was moderate (Level II-2) evidence that infants with a CLP are unable to create suction when measured using a bottle,[16,18,23] and moderate to weak evidence that infants with CLP are sometimes able to breastfeed successfully.[51,56,57] Descriptive studies suggest breastfeeding success rates ranging from 0–40%.[27,28,58] Modifications to positioning to increase breastfeeding success are recommended by experts (Level III).[29,30,32,34–40,42–44]

4. Is there evidence to guide assessment and management of breastfeeding in infants with CL/P?
Aside from strong evidence regarding the use of palatal obturators (considered separately), there was moderate evidence (Level II-3) that lactation education is important to facilitate feeding efficiency in infants with a CL/P.[59] The remaining evidence is weak (Level III, expert opinion) and focuses on (a) areas for monitoring, and (b) recommendations for supplementation.

5. Is there evidence that palatal obturators facilitate breastfeeding success with infants with a CLP or CP?
Breastfeeding outcomes may be affected by the use of feeding plates (which obturate some of the cleft and attempt to "normalize" the oral cavity for feeding)[46] or presurgical orthopedics (prosthesis to reposition the cleft segments prior to surgery). These are collectively referred to as "obturators" for this report. *There was strong (Level I) evidence that obturators do not facilitate feeding or weight gain in breastfed babies with a CLP,*[45] *and that they do not improve the infant's rate of bottle feeding.*[46] There was moderate evidence (Level II-2) obturators do not facilitate suction during bottle feeding.[23] This is because obturators do not facilitate complete closure of the soft palate against the walls of the throat during feeding. Contradictory evidence exists, supporting the use of obturators to facilitate breastfeeding in infants with a CP or CLP, but it is from much weaker sources (Level II-3, and Level III descriptive and case studies, and expert opinion).[29,39,51,53,59–66]

6. Is there evidence for additional benefits of breastfeeding for infants with CL/P compared to the normal population?

A number of moderate to weak (Level II-2 and below) studies exist, with the majority of evidence representing expert opinion (Level III). It is well accepted that breastfeeding and breastmilk feeding conveys positive benefits to both mother and baby. With regard to babies with a CP there was moderate to weak evidence that feeding with breastmilk protects against otitis media in infants with a CP.[25,26] These babies are more prone to otitis media than the general population due to the abnormal soft palate musculature.[26,56] There was moderate to weak evidence that breastmilk can promote intellectual development and school outcomes in babies with clefts.[67,68] Expert opinion (Level III) suggests that antibacterial agents in breastmilk promote postsurgical healing[21,61,69] and reduce irritation of mucosa (compared to artificial formula).[70] Additionally, experts have suggested that breastfeeding facilitates the development of oral facial musculature,[29,61] speech,[29,37,66] bonding,[37,61] and pacifying infants postsurgery.[29,51]

7. Is there evidence to indicate when it is safe to commence/recommence breastfeeding following surgery for lip or palate?

CL repair (cheiloplasty) is generally carried out within a few months of birth[9] and CP repair (palatoplasty) takes place between 6 and 12 months of age. *There are several studies which yield strong evidence to inform this area (Level I to Level II-2).* There is moderate to strong evidence (Levels I and II-2) that it is safe to commence/recommence breastfeeding immediately following CL repair[47,48] and moderate evidence (Level II-2) for initiating breastfeeding 1 day after CP repair.[47] There is strong evidence (Level I) that breastfeeding immediately following surgery is more effective for weight gain, with lower hospital costs, than spoon feeding.[48] Contradictory evidence exists, but it is from weaker sources (Level III, expert opinion) and is divided as to recommendations.[32–34,39,69,71]

8. Is there evidence to indicate whether infants with a CP as part of a syndrome/sequence are able to breastfeed?

There are over 340 syndromes in which CL/P appears.[72] It is beyond the scope of this protocol to review and make recommendations for them all in detail. However, some key data are presented to guide breastfeeding practice. *Moderate to weak evidence suggests that, as well as the cleft, the additional oral facial anomalies associated with these syndromes (e.g., hypotonia, micrognathia, glossoptosis) impact on feeding success.*[73–78] It is important to examine the influence of all anomalies on feeding and design treatment with this in mind.

Method

A systematic review of relevant literature was undertaken. The evidence was sorted and ranked based on scientific rigor using the framework of the U.S. Preventive Services Task Force*, as follows:

I—Strong evidence, as obtained from a randomized controlled trial, or systematic review of RCTs.
II-1—Moderate-strong evidence, for example, obtained from well-designed controlled trials without randomization of subjects.
II-2—Moderate evidence, obtained from cohort or case–control studies.
II-3—Moderate-weak evidence, for example, from multiple time series designs.
III—Weak evidence, based on opinions, clinical experience, descriptive studies, case reports, etc.

*U.S. Preventive Services Task Force Ratings: Strength of Recommendations and Quality of Evidence. Guide to Clinical Preventive Services, Third Edition: Periodic Updates, 2000–2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/3rduspstf/ratings.htm.