

Association of Feeding Evaluation With Frenotomy Rates in Infants With Breastfeeding Difficulties

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IMPORTANCE Inpatient surgical release of lingual frenulums rose 10-fold between 1997 and 2012 despite insufficient evidence that frenotomy for ankyloglossia is associated with improvements in breastfeeding. Clear indications for surgical release remain murky, and best practice guidelines have yet to be developed.

OBJECTIVE To determine whether infants referred for frenotomy to treat breastfeeding difficulties should undergo procedures after comprehensive feeding examination, during which the primary cause of feeding issues was identified, and targeted intervention was provided.

DESIGN, SETTING, AND PARTICIPANTS This observational quality improvement study followed mother-infant dyads between March and December of 2018 who were referred to our tertiary care center for difficulty with breastfeeding. All infants underwent a comprehensive feeding evaluation by speech and language pathologists who examined the infants' ability to breastfeed prior to a surgical consultation for initial frenotomy. Data analysis was performed between January 2019 and May 2019.

INTERVENTIONS A multidisciplinary feeding evaluation that examined infants' oral structure and function and their ability to breastfeed and that offered techniques for mothers to address any feeding difficulties prior to surgical intervention was developed. Infants either found success in feeding and weight gain through this program or underwent procedures.

MAIN OUTCOMES AND MEASURES The primary outcome was the percentage of frenotomy procedures following implementation of a multidisciplinary feeding team evaluation. The secondary outcome was the percentage of infants referred for lingual frenotomy who later had either combined lingual and labial frenotomy or labial frenotomy alone.

RESULTS Included in the study were 115 patients (median age, 34 days [interquartile range, 19-56 days], 68 (59%) were male) referred for surgical division of the lingual frenum. Following the development of a program with feeding examination with a pediatric speech and language pathologist, 72 (62.6%) patients subsequently did not undergo surgical procedures. Although all of the referrals were for lingual frenotomy, 10 (8.7%) underwent labial frenotomy alone and 32 (27.8%) underwent both labial and lingual frenotomy.

CONCLUSIONS AND RELEVANCE The majority of patients referred for ankyloglossia may benefit from alternative intervention strategies following comprehensive feeding evaluation. Close collaboration and formation of multidisciplinary teams are imperative for treating these children.

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JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2019.1696
Published online July 11, 2019.

Both the American Academy of Pediatrics and the World Health Organization have affirmed breastfeeding as the preferred method of infant feeding.¹⁻³ With more mothers now wanting and expecting to breastfeed, there is an increased pressure by clinicians to diagnose the cause of any feeding difficulties. In recent years, both the diagnosis of ankyloglossia and the use of lingual frenotomy have substantially increased.^{4,5} An analysis of the Kids' Inpatient Database in the United States found an estimated increase in inpatient frenotomies alone, rising from 1279 in 1997 to 12 406 in 2012 under a stable birth rate.⁴

Unfortunately, there is a lack of evidence to support the direct association of frenotomy with improved breastfeeding. A recent systematic review concluded that there was low to insufficient evidence that frenotomy for ankyloglossia was associated with mother-reported improvements in breastfeeding.⁴ A 2017 Cochrane review concluded that frenotomy reduced breastfeeding mothers' nipple pain in the short term, but there was no consistent positive effect on infant breastfeeding.⁶ Such lack of evidence regarding the efficacy of frenotomy calls into question its inherent value in the treatment of breastfeeding difficulties.

Multiple studies and systematic reviews have emphasized the importance of carefully selecting infants who may benefit from frenotomy to avoid unnecessary procedures.⁷⁻¹⁰ Sources also cite the importance of feeding evaluation by either a lactation consultant or speech pathologist prior to frenectomy.^{10,11} However, there is varied belief in restrictions of ankyloglossia, with a minority of surveyed pediatricians (10%) and otolaryngologists (30%) believing that ankyloglossia commonly affects feeding, while 69% of surveyed lactation consultants believed that it frequently causes breastfeeding problems.¹² Therefore, specialized and comprehensive feeding evaluations appear to be paramount in the evaluation of breastfeeding infants prior to frenotomy.

A serious risk of frenotomy is the out-of-pocket expense for the family. Unfortunately, there is much variation related to clinicians performing a frenotomy, with dental professionals, pediatric otolaryngologists, and neonatologists providing this service with often-unpredictable cost and coverage by medical insurance. Frenotomy cost is high, with 1 study citing a surgical fee of \$850 for lingual frenotomy.¹³ This same study also found that performing a lingual frenotomy under general anesthesia included extra costs that consisted of an anesthesia fee of \$500 to \$900 and hospital charges ranging from \$500 to \$8000. Furthermore, when dental professionals perform these procedures, costs are often not submitted to medical insurance. This creates a financial burden for new parents as they expand their families.

The primary goal of this quality improvement study was to develop a sustainable and reproducible quality initiative to develop a multidisciplinary assessment and therapeutic strategy program for infants who otherwise were being sent directly for surgical intervention for ankyloglossia. This study supports a movement in the literature toward the role of multidisciplinary assessment of infants with ankyloglossia and feeding difficulties and supports the need to ensure careful selection of infants who may benefit from lingual frenotomy.¹⁴

Key Points

Question Can a comprehensive feeding assessment providing targeted interventions for infants referred for frenotomy to treat breastfeeding difficulties reduce the percentage of procedures required?

Findings This quality improvement study of 115 infants referred for frenotomy evaluates a program of feeding examination by a pediatric speech and language pathologist; 72 (62.6%) of the infants in the program subsequently were not recommended for procedures.

Meaning Many patients referred for surgical treatment of ankyloglossia were not recommended for procedures following comprehensive feeding assessment; close collaboration and formation of multidisciplinary teams are imperative for treating these children.

Our primary outcome was to examine how often procedures for feeding difficulties were determined to be unnecessary by the multidisciplinary team after comprehensive feeding evaluation of infants referred for frenotomy. Our secondary outcome was difference in procedure type desired by the referring specialist from the type recommended by our multidisciplinary team.

Methods

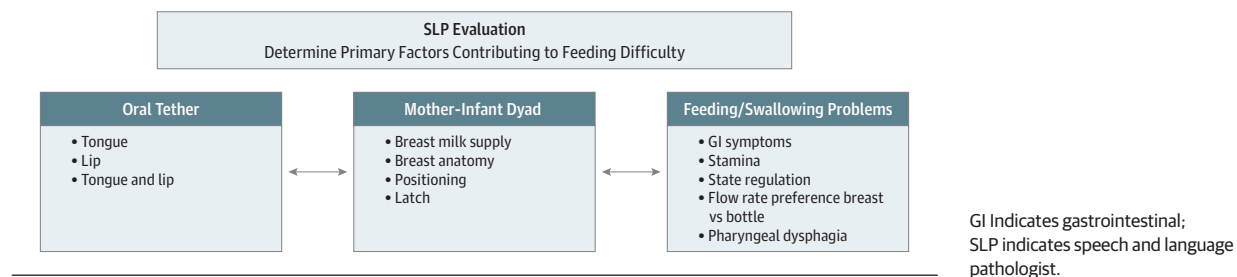
Participant Enrollment

Study patients were recruited from all mother-infant dyads that were referred to our tertiary care center for feeding difficulty and evaluation for initial frenotomy between March and December of 2018. For context, in the 6 months prior to the study, the senior author (C.J.Hartnick) performed either a tongue release or tongue-tie/lip release on more than 95% of patients referred for lingual frenotomy. These infants underwent evaluation by outside lactation consultants and were recommended for ankyloglossia release. These infants were referred either by pediatricians or lactation consultants directly. The Massachusetts Eye and Ear Infirmary review board waived the need for ethics approval and informed patient consent because this study was conducted as a patient care improvement initiative. When surgical intervention was performed, informed consent was obtained from the parents of patients, and office-based procedures were performed.

Feeding Evaluation

Following the initiation of our multidisciplinary approach, mother-infant dyads would first undergo a formal feeding evaluation by a pediatric speech and language pathologist about 3 to 14 days prior to consultation with the pediatric otolaryngology department. Mothers were encouraged to bring their infants hungry to the feeding examination so that a full oral feeding could be evaluated. Speech and language pathology (SLP) clinicians used certain instruments in their comprehensive feeding assessment. This was a standardized examination applied to all patients. Instruments included the Kotlow

Figure 1. Primary Causes of Feeding Difficulties With Trialed Interventions



Lip Tether Score, the Kotlow Tongue Tether Score,¹⁵ the Bristol Breastfeeding Assessment Tool (BBAT),¹⁶ a visual analogue scale for pain associated with breastfeeding,¹⁷ the Worry subscale of the Feeding Swallow Impact Survey (FSIS),¹⁸ the Breastfeeding Self-efficacy Scale-Short Form,¹⁹ and the Hazelbaker Assessment Tool.²⁰ The FSIS and the BBAT were used as measures in assessment of change in feeding difficulty. Our examination included clinical assessment of nonnutritive and nutritive sucking and latch and suck-swallow-breathe coordination. Assessment also included examination of oral structures and function for latching, nutritive and nonnutritive sucking, suck-swallow-breathe coordination, initiation and maintenance of the breast and/or bottle-feeding, and observation of the mother-infant dyad. Maternal and infant history as well as presence or absence of weight gain concerns were also noted for each patient.

Program Interventions

After comprehensive evaluation, the primary cause of the feeding difficulty was explored, and interventions were trialed during the oral feeding (Figure 1). Patients were recommended for frenotomy if functional impairments were assessed to be related to lip- or tongue-tie. Functional impairments of the lip most commonly included incomplete seal, shallow latch, decreased flange, and/or anterior spillage. Functional impairment of the tongue was determined by reduced range of motion (as reflected on the Hazelbaker Assessment tool), tongue clicking, loss of seal, and/or creased or misshapen nipples after feeding. A primary aim of the assessment was to determine if these observations were related to tethered oral tissue or another cause. While we did use physical characteristics of the labial and lingual frenulums for classification purposes, these findings were always interpreted in the context of restriction of function.

If patients were not determined to be surgical candidates after the initial feeding evaluation by an SLP, we attempted to identify the primary cause of feeding difficulty and implement interventions to improve the perceived primary causes (Figure 1). If sleep state regulation was determined to be the primary issue (with the baby falling asleep and transitioned to a nonnutritive sucking pattern causing maternal nipple pain/injury/prolonged feeding), interventions included arousal actions such as applying a wet facecloth or tapping the infant's foot. Hunger state regulation issues were encountered if the baby was too hungry while trying to suckle the breast with reduced patience for correct latch. If breastfeeding latch was the

primary issue, interventions included maternal instruction on ways to attain deep latch. The following interventions were administered as appropriate: positioning and stimulation to promote slight head hyperextension and wide jaw excursion (eg, nipple-to-nose alignment, appropriate support without restricting head range of motion, adequate trunk and extremity support, tactile cues to nose and lip, maternal support of breast). This was frequently paired with instruction to the mother and techniques to promote adequate infant feeding state. If volume or rate of breast-milk flow (tongue clicking, gulping, or pulling off the nipple) appeared to be the primary issue, modifications included the following strategies to slow the flow of milk: placing the mother in a supine position (gravity to slow flow), expressing milk prior to breastfeeding, and/or placing the mother and baby in a side lying position. If previously-diagnosed reflux appeared to be the primary issue (eg, arching, pulling off nipple), verbal reassurance to continue gastroesophageal reflux disease medication treatment was provided. In the case of parental anxiety and heightened breastfeeding concerns, when feeding evaluation revealed that no intervention was needed, we provided reassurance and general feeding instructions.

Finally, considerations and clinical patterns were investigated with the goal of identifying the primary underlying contributor to the feeding issues and administering interventions to improve the oral feeding. For example, tongue clicking was often the likely result of a tight frenulum or an infant's attempt at milk volume control owing to a high flow rate. Pulling off of the breast was sometimes seen in the setting of lip tether impacting the lip flange or ankyloglossia, but gastroesophageal reflux disease and general gastrointestinal discomfort were also considered as possibilities. Pain with breastfeeding or injury to the nipple was not always considered a consequence of a challenged mother-infant dyad but rather incorporated as a possible cause of such challenges. One or multiple strategies were offered to mothers and administered over a period of 3 to 14 days prior to surgical consultation.

The surgical consultation considered the efficacy of any intervention recommended in the clinical feeding examination. Surgical evaluation then focused heavily on the mother's history in determining whether nonsurgical intervention would be a valid strategy. A focused head and neck examination was performed to compare with findings from the functional assessment and previous examination.

When surgical intervention was performed, a small amount of topical anesthetic was applied to the surgical site(s) using a

Table 1. Demographic Characteristics of the Study Infants

| | Intervention | |
|--------------------|-------------------|-----------------------|
| | Surgical (n = 43) | Non-Surgical (n = 72) |
| Gender | | |
| Male | 28 | 40 |
| Female | 15 | 32 |
| Age, mean (IQR), d | 35.8 (5-139) | 48.7 (5-197) |

Abbreviation: IQR, interquartile range.

cotton swab. Of note, while the authors acknowledge the risk of methemoglobinemia, we consulted with our clinical pharmacist prior to the initiation of the study on the use of topical anesthetics in infants and were met with reassurances on its safe use in small quantities in this age group. A bipolar cautery was used to perform the frenotomy procedure at the appropriate anatomical location, taking care to avoid Wharton ducts in the case of a lingual frenotomy. No suture closure was performed in either case. Infants were returned to their mothers and encouraged to breastfeed immediately if appropriate. No postprocedural stretching exercises were specifically advised. Mothers of patients were encouraged to follow up in 2 weeks with SLP clinicians for a follow-up feeding evaluation.

Statistical Analysis

Data were collected prospectively, and study data were collected and managed using REDCap electronic data capture tools managed by Massachusetts Eye and Ear Infirmary.²¹

Continuous variables are reported using median and interquartile ranges (IQRs). Categorical data are presented as frequency counts and percentages. Unpaired *t* tests were used to compare means between study populations. The Fisher exact test was used to compare categorical variables. *P* ≤ .05 was considered to be statistically significant. Statistical analyses were performed with GraphPad Prism, version 6.0. Data analysis was performed between January 2019 and May 2019.

Results

A total of 115 patients presented to our clinic after referral for frenotomy within the study period. The median age at the time of initial feeding evaluation was 34 days (IQR, 19-56 days). The majority (68; 59%) of infants were male (Table 1). The median length of follow-up after intervention (surgical or nonsurgical) was 14 (IQR, 11-23) days. Ninety-eight (85%) patients had Kotlow lip and tongue classes as well as Hazelbaker scores recorded, and 87 (76%) patients had BBAT scores recorded. The findings are summarized in Table 2.

Of the 115 initial referrals for frenotomy, 43 (37.4%) patients were recommended for a procedure by our multidisciplinary team (Figure 2), and 72 patients (62.6%) were not recommended for surgical intervention. There was no significant difference in sex or median age at presentation among those who underwent vs did not undergo a procedure. Ten patients underwent labial frenotomy only, 32 underwent both labial frenotomy and lingual frenotomy, and 1 underwent lingual frenotomy alone.

Table 2. Anatomical Classifications on Presentation

| Classification/Score | Patients, No. (%) |
|--|-------------------|
| Kotlow Lip Class | |
| Class 1 | 0 |
| Class 2 | 4 (4) |
| Class 3 | 57 (58) |
| Class 4 | 37 (38) |
| Kotlow Tongue Class | |
| Class 1 | 1 (1) |
| Class 2 | 22 (22) |
| Class 3 | 56 (57) |
| Class 4 | 20 (20) |
| Total patients, No. (% of total study participants) ^a | 98 (85) |
| Hazelbaker Functional Assessment, median (IQR) | 12 (9-14) |
| Bristol Breastfeeding Assessment Tool, median (IQR) | 5 (4-7) |

Abbreviations: IQR, interquartile range.

^a This metric represents the total number of patients in the study who had Kotlow Lip and Tongue Class scores before undergoing the comprehensive feeding evaluation.

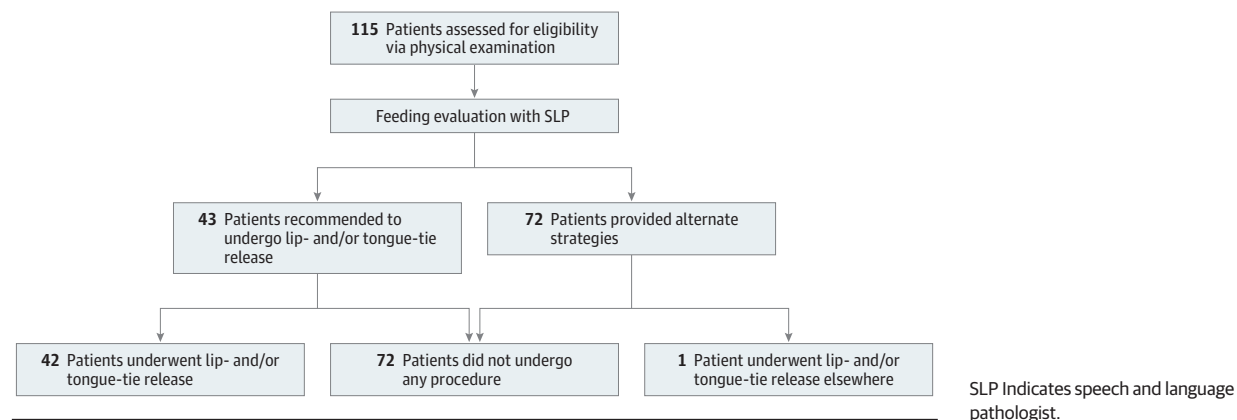
Discussion

The primary goal of the present study was to evaluate a sustainable and replicable multidisciplinary approach to frenotomy evaluation to improve the quality of care delivered to patients. The rising frenotomy rate taken with the substantial pressure on new mothers for successful and exclusive breastfeeding were deeply concerning and prompted our group to change our practice patterns. This initiative fostered an opportunity for critical reflection on past management of these infants, recognizing that the current evidence did not allow us to engage in objectively informative discussions with parents.

Reports of initiatives to reduce frenotomy intervention rate are scarce in the literature. One study conducted in New Zealand reported a marked reduction in frenotomy rate after the introduction of a multilevel education pathway on breastfeeding difficulties and ankyloglossia.¹⁴ This study emphasized the need for a multidisciplinary assessment of infants with ankyloglossia and feeding difficulties and supports the need for collaborative work to ensure careful selection of infants who may benefit from lingual frenotomy. Taken with our findings, the results point to a clear need for the implementation of such initiatives for multidisciplinary collaboration for quality improvement in the area of ankyloglossia evaluation and feeding challenges in infants.

However, use of frenotomy to treat difficulties with breastfeeding in infants remains a controversial topic. This is owing to lack of quality evidence in the literature, as some have argued that randomized clinical trials may involve risk of suboptimal breastfeeding for those not undergoing frenotomy.²² However, the present study may provide a feasible solution, offering a study arm involving multidisciplinary evaluation with more nonsurgical options that may be ethically acceptable. It is our hope that the evidence presented here offers a

Figure 2. Flowchart of the Outcome of Evaluations Using the Multidisciplinary Strategy Among Infants Referred for Frenotomy



basis for larger longitudinal studies to better investigate the utility of multidisciplinary initiatives.

While upper-lip tether and ankyloglossia are assessed and managed in multiple settings by various specialties, it is important to provide a comprehensive and collaborative feeding assessment to determine the primary cause of feeding issues and whether labial frenotomy and/or lingual frenotomy would be appropriate interventions. In the present study, infants underwent initial feeding evaluation by a pediatric speech and language pathologist. Our institution was particularly suited to undertake such a multidisciplinary evaluation, because we already have in place an aerodigestive multidisciplinary clinic involving both pediatric otolaryngology and pediatric SLP clinicians. However, it is important to note that lactation consultants as well as occupational therapists also commonly evaluate infants and young children for these issues and are often critical members of the care team for these patients.

The overwhelming majority of the study patients were referred for tongue release alone. Following comprehensive feeding evaluation, the primary cause was determined to be related to lip tether, tongue tether, both, or a feeding issue. Of the infants who were determined to be surgical candidates, it was recommended that they be treated with labial and/or lingual frenotomy. Perhaps, through comprehensive feeding evaluation, the factors contributing to breastfeeding challenges were better determined, and those infants thought to need tongue release were better diagnosed as having lip tether and/or ankyloglossia or administered alternative feeding techniques. Furthermore, when the cause of restriction was unclear, discussion was had with parents, who most often opted to undergo concurrent procedures rather than to stage them.

Since interventions were administered in the home environment following initial feeding evaluation, surgical consultation was maximized and resources used most wisely be-

cause surgical consults were only done with infants to whom surgical intervention was deemed necessary by the multidisciplinary team. In some instances, surgical consultation was avoided altogether as mothers found success with new techniques recommended at the initial feeding consultation. This scenario highlights the utility of our multidisciplinary approach in avoiding potentially harmful procedures for these infants and maximizing the quality of care delivered.

Limitations

Limitations of the study include a relatively short length of follow-up as well as a small number of patients undergoing intervention. Since our interventions were often implemented at varying points in the study (conservative first followed by surgical), the varied length of follow-up likely led to higher unknown success rate in our surgical group. Finally, given the multifactorial causes of breastfeeding difficulties in the mother-infant dyads in the present study, analysis of contributing cause was limited and did not allow for further investigation to create a more comprehensive protocol for feeding assessment.

Conclusions

This study applied a multidisciplinary approach to frenotomy evaluation, using nonsurgical intervention at the recommendation of a pediatric speech and language pathologist prior to surgical consultation. We were successful in reducing the number of procedures recommended for these infants. This evidence can be used to objectively inform parents on expectations when considering appropriate intervention in the setting of a comprehensive, multidisciplinary evaluation for frenotomy.

ARTICLE INFORMATION

Accepted for Publication: May 20, 2019.

Published Online: July 11, 2019.
doi:10.1001/jamaoto.2019.1696

Author Contributions: Dr Caloway had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Hersh, Baars, Diercks,

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Acquisition, analysis, or interpretation of data: Caloway, Hersh, Baars, Sally, Diercks.

Drafting of the manuscript: Caloway, Baars, Hartnick.

Critical revision of the manuscript for important intellectual content: Hersh, Baars, Sally, Diercks. *Statistical analysis:* Caloway. *Administrative, technical, or material support:* Baars, Hartnick. *Study supervision:* Hersh, Diercks, Hartnick.

Conflict of Interest Disclosures: Dr Hersh reported a salary from the Massachusetts General Hospital. No other disclosures were reported.

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