Commentary on “Frenotomy for Tongue-Tie in Newborn Infants”

William McGuire^a Roger Soll^b

^aCentre for Reviews and Dissemination, University of York, York, UK; ^bDivision of Neonatal-Perinatal Medicine, University of Vermont, Burlington, VT, USA

Commentary

Tongue-tie, a short, restrictive lingual frenulum, is reported to occur in up to 1 in 10 newborn infants. Although tongue-tie is usually benign and self-resolving, a persistently tight tongue-tie extending to the tip of the tongue may adversely affect latching and suckling. Suboptimal attachment causing maternal nipple pain and trauma may diminish the chances of successful breastfeeding. Surgical division of the tongue-tie (frenotomy) has been suggested as a simple procedure to improve tongue mobility and support breastfeeding [1, 2]. Concerns exist, however, about the validity of the evidence base and whether early frenotomy is better than simpler measures such as sublingual massage to stretch the frenulum combined with lactation support [3, 4].

The Cochrane review of frenotomy for tongue-tie in newborn infants highlights the key issues that remain if this uncertainty is to be resolved [5]. O’Shea et al. identified five eligible randomised controlled trials, but these were small (302 infant participants in total) and contained various methodological weaknesses that may have biased effect size estimates. Meta-analyses were limited by clinical heterogeneity and selective reporting and did not show any evidence that frenotomy improves the mother-infant dyad breastfeeding technique assessed us-

ing standardised tools: mean difference in the “LATCH” score -0.07 (95% CI -0.63 to 0.48) (Fig. 1). Longer-term breastfeeding success could not be measured, as the trials offered frenotomy to infants in the control arm who still had feeding problems during the early neonatal period. Meta-analysis did show some evidence that frenotomy slightly reduces maternal nipple pain assessed using a 10-point visual analogue pain scale: mean difference -0.74 (95% CI -1.35 to -0.13) (Fig. 2). Awareness of the intervention group to which her infant was assigned, however, may have affected how mothers self-reported this subjective outcome measure if an expectation that frenotomy would be helpful existed.

Given this paucity of applicable trial data, the review authors concluded that a large, pragmatic randomised controlled trial is needed to provide evidence of sufficient validity to inform policy and practice. The “FROSTTIE” trial now being conducted in centres across the UK will enroll 870 infants with breastfeeding difficulties and tongue-tie diagnosed using validated criteria (<https://www.npeu.ox.ac.uk/frosttie>). Infants are allocated randomly to either frenotomy or a sham procedure, and the primary outcome is breastfeeding at 3 months. This trial aims to provide the high-quality evidence needed for mothers and clinicians to make informed, shared decisions about this sometimes distressing treatment dilemma.

Fig. 1. Frenotomy versus control. Infant breastfeeding assessed by the LATCH scale [6, 7].

Fig. 2. Frenotomy versus control. Maternal nipple pain assessed by the visual analogue pain scale [6–8].

Acknowledgment

Cochrane Neonatal Reviews are produced with support from the Vermont Oxford Network, a worldwide collaboration of health professionals dedicated to providing evidence-based care of the

highest quality for newborn infants and their families. Editorial support for Cochrane Neonatal comes from a UK National Institute of Health Research (NIHR) Cochrane Programme Grant (16/114/03).

References

- Obladen M. Much ado about nothing: two millennia of controversy on tongue-tie. *Neonatology*. 2010;97(2):83–9.
- Power RF, Murphy JF. Tongue-tie and frenotomy in infants with breastfeeding difficulties: achieving a balance. *Arch Dis Child*. 2015 May;100(5):489–94.
- National Institute for Health and Clinical Excellence [Internet]. Division of ankyloglossia (tongue-tie) for breastfeeding [NICE Guideline]. 2005 [cited 2018 Nov 1]. Available from: <https://www.nice.org.uk/guidance/ipg149>.
- Rowan-Legg A. Ankyloglossia and breastfeeding. *Paediatr Child Health*. 2015 May;20(4):209–18.
- O'Shea JE, Foster JP, O'Donnell CP, Breathnach D, Jacobs SE, Todd DA, et al. Frenotomy for tongue-tie in newborn infants. *Cochrane Database Syst Rev*. 2017 Mar;3:CD011065.
- Emond A, Ingram J, Johnson D, Plair P, Whitelaw A, Copeland M, et al. Randomised controlled trial of early frenotomy in breastfed infants with mild-moderate tongue-tie. *Arch Dis Child Fetal Neonatal Ed*. 2014;99(3):F189–95.
- Dollberg S, Botzer E, Grunis E, Mimouni FB. Immediate nipple pain relief after frenotomy in breast-fed infants with ankyloglossia: a randomized, prospective study. *J Pediatr Surg*. 2006;41(9):1598–1600.
- Berry J, Griffiths M, Westcott C. A double-blind, randomized, controlled trial of tongue-tie division and its immediate effect on breastfeeding. *Breastfeed Med*. 2012;7(3):189–93.

© 2019 S. Karger AG, Basel

Cochrane Abstract

Background: Tongue-tie, or ankyloglossia, is a condition whereby the lingual frenulum attaches near the tip of the tongue and may be short, tight and thick. Tongue-tie is present in 4% to 11% of newborn infants. Tongue-tie has been cited as a cause of poor breastfeeding and maternal nipple pain. Frenotomy, which is commonly performed, may correct the restriction to tongue movement and allow more effective breastfeeding with less maternal nipple pain. **Objectives:** To determine whether frenotomy is safe and effective in improving ability to feed orally among infants younger than three months of age with tongue-tie (and problems feeding). Also, to perform subgroup analysis to determine the following. – Severity of tongue-tie before frenotomy as measured by a validated tool (e.g. Hazelbaker Assessment Tool for Lingual Frenulum Function [ATLFF] scores <11; scores ≥11). – Gestational age at birth (<37 weeks' gestation; 37 weeks' gestation and above). – Method of feeding (breast or bottle). – Age at frenotomy (≤10 days of age; >10 days to three months of age). – Severity of feeding difficulty (infants with feeding difficulty affecting weight gain (as assessed by infant's not regaining birth weight by day 14 or falling off centiles); infants with symptomatic feeding difficulty but thriving (greater than birth weight by day 14 and tracking centiles). **Search Methods:** We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase and CINAHL up to January 2017, as well as previous reviews including cross-references, expert informants and journal handsearching. We searched clinical trials databases for ongoing and recently completed trials. We applied no language restrictions. **Selection Criteria:** Randomised, quasi-randomised controlled trials or cluster-randomised trials that compared frenotomy versus no frenotomy or frenotomy versus sham procedure in newborn infants. **Data Collection and Analysis:** Review authors extracted from the reports of clinical trials data regarding clinical outcomes including infant feeding, maternal nipple pain, duration of breastfeed-

ing, cessation of breastfeeding, infant pain, excessive bleeding, infection at the site of frenotomy, ulceration at the site of frenotomy, damage to the tongue and/or submandibular ducts and recurrence of tongue-tie. We used the GRADE approach to assess the quality of evidence. **Main Results:** Five randomised trials met our inclusion criteria ($n = 302$). Three studies objectively measured infant breastfeeding using standardised assessment tools. Pooled analysis of two studies ($n = 155$) showed no change on a 10-point feeding scale following frenotomy (mean difference [MD] -0.1 , 95% confidence interval [CI] -0.6 to 0.5 units on a 10-point feeding scale). A third study ($n = 58$) showed objective improvement on a 12-point feeding scale (MD 3.5 , 95% CI 3.1 to 4.0 units of a 12-point feeding scale). Four studies objectively assessed maternal pain. Pooled analysis of three studies ($n = 212$) based on a 10-point pain scale showed a reduction in maternal pain scores following frenotomy (MD -0.7 , 95% CI -1.4 to -0.1 units on a 10-point pain scale). A fourth study ($n = 58$) also showed a reduction in pain scores on a 50-point pain scale (MD -8.6 , 95% CI -9.4 to -7.8 units on a 50-point pain scale). All studies reported no adverse effects following frenotomy. These studies had serious methodological shortcomings. They included small sample sizes, and only two studies blinded both mothers and assessors; one did not attempt blinding for mothers nor for assessors. All studies offered frenotomy to controls, and most controls underwent the procedure, suggesting lack of equipoise. No study was able to report whether frenotomy led to long-term successful breastfeeding. **Reviewers' Conclusions:** Frenotomy reduced breastfeeding mothers' nipple pain in the short term. Investigators did not find a consistent positive effect on infant breastfeeding. Researchers reported no serious complications, but the total number of infants studied was small. The small number of trials along with methodological shortcomings limits the certainty of these findings. Further randomised controlled trials of high methodological quality are necessary to determine the effects of frenotomy [see Ref. 5.]