



Immediate nipple pain relief after frenotomy in breast-fed infants with ankyloglossia: a randomized, prospective study

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Abstract

Purpose: Ankyloglossia (“tongue-tie”) occurs in nearly 5% of neonates, but its clinical significance relating to breast-feeding difficulties is controversial. We tested the hypothesis that in infants with ankyloglossia referred because of breast-feeding difficulties, frenotomy alleviates the symptoms.

Methods: Twenty-five mothers of healthy infants with ankyloglossia were recruited because of sore nipples. Infants were randomized to either of 2 sequences: (1) frenotomy, breast-feeding, sham, breast-feeding (n = 14) or (2) sham, breast-feeding, frenotomy, breast-feeding (n = 11). The mothers as well as all personnel taking care of the child after each sham or frenotomy procedure were masked as to the study sequence. In every sequence, and after each sham or frenotomy procedure, a standardized latch score and pain score were obtained from the mother.

Results: There was a significant decrease in pain score after frenotomy than after sham ($P = .001$). There was also a nearly significant improvement in latch after the frenotomy in these mothers ($P = .06$).

Conclusion: Frenotomy appears to alleviate nipple pain immediately after frenotomy. We speculate that ankyloglossia plays a significant role in early breast-feeding difficulties, and that frenotomy is an effective therapy for these difficulties.

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Ankyloglossia, also referred to as tongue-tie, is a congenital anomaly of the tongue characterized by short and sometimes anteriorly inserted frenulum. Ankyloglossia occurs in approximately 5% of newborn infants, at a male-to-female ratio of 2.6:1 [1]. The clinical significance of

ankyloglossia is a matter of controversy, particularly as it relates to breast-feeding difficulties; sore nipples [1], poor infant weight gain [2], neonatal dehydration [3], and shortened breast-feeding duration have been reported as possible consequences of ankyloglossia [2,4]. A recent review article on the topic, published under the auspices of the Committee on Breast feeding of the American Academy of Pediatrics, expressed the personal opinion of its author, that frenotomy “is safe and effective” in minimizing breast-feeding difficulties created by symptomatic tongue-tie [5]. A few articles have reported that symptoms of ankyloglossia

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were alleviated by frenotomy (clipping of the frenulum) [1,4,6,7]. In all of them, mothers were fully aware that frenotomy had been performed, which may have introduced a significant bias in favor of frenotomy. The authors of a large, recent study pointed out to this bias as a significant study limitation [7]. We therefore conducted this randomized, prospective, masked clinical trial of frenotomy in ankyloglossia to test the hypothesis that frenotomy alleviates breast-feeding difficulties (nipple pain, inadequate latching, or both) in infants with ankyloglossia.

1. Methods

Institutional review board permission for conducting the study was granted, and written informed parental consent was obtained for each of the participants. We recruited 25 full-term healthy, appropriate-for-gestational age infants aged 1 to 21 days. This number of patients was initially designed as a pilot that would help to calculate sample size of a larger study. All patients had been referred to the lactation clinic at the Lis Maternity Hospital because of nipple pain. On physical examination by a neonatologist, all of these infants were found to have ankyloglossia. Ankyloglossia was defined as the inability of the infant to protrude the tip of the tongue over the lower gum line while the tip was tied to the floor of the mouth by a tight cord of a frenulum, and the tongue became heart-shaped when lifted up [8]. Infants were randomized to either of 2 sequences: (1) frenotomy, followed immediately by breast-feeding, then sham, followed immediately by breast-feeding; ($n = 14$); or (2) sham, followed immediately by breast-feeding, then frenotomy, followed immediately by breast-feeding ($n = 11$). Randomization was by computer-generated random numbers in sealed opaque envelopes. Enrolment was performed by one investigator (EG), allocation sequence by another one (FBM), and frenotomy or sham procedure by either a neonatologist (SD) or a pediatric dentist (EB) who were masked from the evaluation that was performed before and after the procedure by the mother, and recorded by another investigator (EG). All personnel taking care of the child after each sham or frenotomy procedure, as well as the mother, were masked as to whether frenotomy or sham had been performed. In addition, one investigator (EG) was present during breast-feeding that followed the procedure to verify that the mother would not try to examine the mouth floor of the infant before placing it to the breast. Care was taken not to incise any vascular tissue. Careful hemostasis (by applying mild pressure for several seconds to several minutes) was done after each frenotomy to ensure blindness. In all cases, there was minimal blood loss, that is, no more than a drop or two, collected on sterile gauze, and infant crying lasted a few seconds only. In every sequence, and after each sham or frenotomy procedure, a standardized latch score [9] (10 points minimum difficulties) and pain score using a standard visual analogue pain scale [10] (10

points maximum pain) were obtained from the mother by the lactation consultant.

Statistical analyses were conducted using Kruskal-Wallis test. Results are expressed as mean \pm SD. We compared pain and latch scores obtained after the first frenotomy or sham only because after the second procedure, both the mother and the lactation consultant were now aware that frenotomy had been performed (before either the first or the second attempt to breast-feed).

2. Results

The study was successfully completed in 25 infants between December 1, 2001, and September 30, 2004. An additional infant had been excluded because upon breast-feeding, a few drops of blood were seen by the mother at the corner of his mouth, which cancelled blinding. The 25 remaining infants had a mean \pm SD gestational age of 39.8 ± 1.2 weeks and birth weight of 3205 ± 830 g. In only 3 of the infants did the tongue protrude beyond the alveolar ridge, whereas in 22 it did not. Fifteen of the infants had an anterior crease of the tongue. Of the 25 study infants, 4 had a positive family history of ankyloglossia in first-degree relatives (parents and/or siblings). In the 25 mothers who were treated because of pain or nipple trauma, pain score decreased from 7.1 ± 1.9 to 5.3 ± 2.2 after frenotomy ($P = .001$). Concomitantly, there was also a nearly significant increase in latch score, from 6.4 ± 2.3 before frenotomy to 6.8 ± 2.0 after the frenotomy ($P = .06$).

There was no significant side effect of the frenotomy, and bleeding (a few drops) was controlled within seconds in all cases.

3. Discussion

In this prospective randomized masked study, we studied frenotomy or sham in infants with ankyloglossia and maternal nipple pain. We found that after frenotomy, there was an immediate and significant nipple pain relief as judged by a significant decrease in pain score after frenotomy than after sham. We also found a concomitant improvement in infant's latch to the breast in this group.

The design of our study allowed overcoming several biases. As stated in a recent, nonrandomized study, maternal report of feeding difficulties immediately after frenotomy introduces a possible placebo effect [7]. The same is true for the person who is recording the latch score or the pain score.

This is, to the best of our knowledge, the only masked controlled study of the efficacy of frenotomy as treatment of ankyloglossia. Because no scientific data were available, a recent study was published looking at attitudes of medical personnel taking care of newborn infants regarding treatment of ankyloglossia [1]. Messner et al [1] studied responses to a questionnaire from otolaryngologists, pediatricians, speech

therapists, and lactation consultants and found that the significance of ankyloglossia remains controversial both within and between these groups of caregivers.

The pain score decreased (improved) immediately more after frenotomy than after sham, although healing of a sore nipple may take more than 2 weeks [11].

The mechanisms by which ankyloglossia may cause latch and pain difficulties are not known. We speculate that because milk removal involves peristaltic action of the tongue over the lactiferous sinuses, limited tongue movement, as in the case of severe ankyloglossia, may affect milk transfer and may cause friction of the tongue or the gum pads on the nipple instead of on the areolar tissue.

It is believed by some that, most often, ankyloglossia requires no therapy. In *Nelson Textbook of Pediatrics*, it is stated that “a short lingual frenulum (‘tongue-tie’) may be worrisome to parents but only rarely interferes with eating or speech, generally requiring no treatment.” [12]. In contrast, the recent review on the topic, published under the auspices of the Committee on Breast feeding of the American Academy of Paediatrics, concluded that frenotomy “is safe and effective” in minimizing breast-feeding difficulties created by symptomatic tongue-tie [5]. However, although the reported incidence of ankyloglossia is about 4.8%, breast-feeding difficulties are present in only 25% of these infants [1]. Breast-feeding difficulties appear to be significantly more frequent in infants with ankyloglossia than in infants without [1].

Immediately after the procedure, frenotomy does appear to alleviate nipple pain. We speculate that ankyloglossia plays a significant role in early breast-feeding difficulties, and that frenotomy, a safe and simple procedure [8], is effective.

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