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Review

Int J Clin Pediatr. 2024;13(1):1-7

Minimizing Risk Associated With Vitamin K Deficiency Bleeding During Ankyloglossia Release of Infants

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Abstract

The practice of releasing restrictive oral frenula, more commonly known as tongue or lip ties has increased markedly in recent years. Providers who perform release of restrictive frenula include otolaryngologists, pediatricians, family practitioners, dentists, and nurse practitioners. It has been documented in the literature that training and protocols vary among providers regarding diagnosis, education, and auxiliary care. In this post-coronavirus disease 2019 (COVID-19) world, resistance to vaccinations of newborns may also lead to resistance to administration of vitamin K immediately after delivery. Vitamin K deficiency bleeding (VKDB) is a potentially fatal sequela of ankyloglossia release if vitamin K has not been administered to the infant. This paper focuses on and proposes a protocol to mitigate or eliminate the risk of VKDB during infant tongue tie release based on the standards of care established by the American Academy of Pediatrics and the College of Family Physicians of Canada and the principle of *primum non nocere* (first, do no harm), one of the principal precepts of the Hippocratic Oath.

Keywords: Ankyloglossia; Tongue tie release; Vitamin K deficiency bleeding

Introduction and History

The practice of releasing restrictive oral frenula, more commonly known as tongue or lip ties has increased markedly in recent years. The release of such oral restrictions reportedly increased by 834% in the USA between 1997 and 2012 [1]. A study in British Columbia, Canada, reported an increase of 89% between the years of 2004 and 2013 [2]. Based on the literature, the incidence of ankyloglossia in the newborn ranges from 4% to 12.8%. Ricke et al reported an incidence of 4.2% in his studies [3]. Hogan et al reported an incidence of 10.7% [4]. Ballard et al reported an incidence of 3.2% in hospital inpatients and 12.8% in outpatients [5]. More concerns with tongue-tie surgery have been noticed as breastfeeding has become more prevalent [3, 5-12]. Mosby's Dental Dictionary defines a frenectomy as "the surgical detachment or excision of a frenum from its attachment…also called a frenotomy" [13]. The newborn nursery at Lucile Packard Children's Hospital of Stanford University defines frenotomy (also known as frenulotomy or frenulectomy) as "…the procedure in which the lingual frenum is cut. It is done when the frenulum seems unusually short or tight (ankyloglossia or 'tongue-tie'). In the newborn nursery, frenotomy is indicated when the abnormal frenulum is impairing the infant's ability to breastfeed" [14]. Providers who perform release of restrictive frenula include otolaryngologists, pediatricians, family practitioners, dentists, and nurse practitioners. It has been documented in the literature that training and protocols vary among providers regarding diagnosis, education, and auxiliary care [15-18].

Due to the increased number of frenectomies, this paper focuses on and proposes a protocol to mitigate or eliminate the risk of vitamin K deficiency bleeding (VKDB) during infant tongue tie release based on the standards of care established by the American Academy of Pediatrics and the College of Family Physicians of Canada [19-22] and the principle of *primum non nocere* (first, do no harm), one of the principal precepts of the Hippocratic Oath.

Risks of Ankyloglossia Release

While risks are low when performing a frenectomy, some adverse postoperative sequelae may occur which may result in suboptimal outcomes, and could in some cases be serious, or even fatal. Medical sequelae include pain, suboptimal to no improvement in breastfeeding, ranula, swelling, damage to salivary glands, infected sublingual hematoma, edema, oral

Manuscript submitted November 24, 2023, accepted March 1, 2024
Published online April 9, 2024

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doi: https://doi.org/10.14740/ijcp526

aversion, trauma to the baby and mother, increased length of hospitalization when care is associated with their birth admission, and bleeding. Financial burdens to the family may also occur [23-28]. The International Journal of Pediatric Otorhinolaryngology [29] published a case report and a systematic review of complications after tongue-tie release.

Searching via MEDLINE, EMBASE and Scopus, 47 major complications were found in 34 patients. The complications included: hypovolemic shock, acute airway obstruction, apnea, and Ludwig's angina. Documentation of cases of excessive hemorrhage post procedure varies from study to study. In a review of complications following lingual frenectomy, Varadan et al noted that 3% to 8% of cases result in bleeding during or after frenectomy [30]. Hale et al noted bleeding as a complication of infant frenotomy in 19% of cases [31].

Three cases from the literature are summarized here. Kim et al [32] described a case of delayed hemorrhage leading to hypovolemic shock post-surgery. A 6-week-old healthy baby presented to a dental office for release of a tongue-tie and a maxillary anterior lip tie. Both ties were released with a diode laser. On postoperative day (POD) 2, the mother noted blood-tinged sputum, but no active bleeding. On POD 5, the mother noted bloodstains on the infant's bed and shirt with blood clots in the mouth. The patient was brought to the emergency department. At admission, the patient's blood pressure was 50/35 mm Hg, with a heart rate of 217, and initial hemoglobin of 117 g/L. White blood cell (WBC), hematocrit, international normalized ratio (INR), and partial thromboplastin time (PTT) levels were all within normal limits, but venous blood gas pH was 7.2, and lactate was 7.2 mmol/L. Based on these laboratory values, a diagnosis of hypovolemic shock was made. A 2.5-cm blood clot was found at the operative site, with no active bleeding. When the clot was suctioned, a 1.5-cm raw surgical site extended from the lingual frenum to the left floor of the mouth. The site was cauterized with silver nitrate, and clindamycin was given postoperatively prophylactically for 5 days.

Tracy et al [33] discuss two cases of hypovolemic shock following labial and lingual frenectomy. The first case describes a 13-month-old female who received both lingual and maxillary anterior labial frenectomy. She experienced no bleeding after the procedure, but at 19 h post-surgery was found limp and unresponsive at home with blood-stained bed linens. Emergency Medical Services providers observed tachycardia, tachypnea, hypotension, pallor, and lethargy. Cardiopulmonary resuscitation was administered with the return of spontaneous respirations, and she received a transfusion of one unit of packed red blood cells (PRBC) upon admission to the hospital. She had no family history of bleeding disorders, and she tested negative for coagulopathies. The second case describes a 4-year-old male who underwent a lingual frenectomy performed with scissors and silver nitrate for hemostasis without complication. After multiple episodes of bleeding beginning on POD 2, he was ultimately admitted to the hospital on day 8, where he received a transfusion, and was taken to the operating room for control of hemorrhage. Arterial bleeding was noted at the surgical site, which was treated by suction electrocautery and over-sewing of the surgical site.

Vitamin K Refusal

Though the cases described above are rare, they do occur; and with the marked increase in surgical frenum release, the possibility of more frequent cases must be considered. Though none of the above cases were directly linked to VKDB, the Tennessee Department of Health (TDH) and Centers for Disease Control and Prevention (CDC) investigated vitamin K refusal among parents in 2013 after learning of four cases of VKDB associated with prophylaxis refusal [34]. Marcewicz et al reported that chart reviews were conducted at Nashville-area hospitals for 2011 - 2013 and Tennessee birthing centers for 2013 to identify parents who had refused injectable vitamin K for their infants. At hospitals, 3.0% of infants did not receive injectable vitamin K due to parental refusal, but at birthing centers 31% of infants did not receive injectable vitamin K [35]. In his PubMed search for the frequency of and reasons for refusal of intramuscular vitamin K, Loyal et al noted that the frequency of refusal of intramuscular vitamin K by parents ranged from 0% to 3.2% in US hospitals, up to 14.5% in home births, and up to 31.0% in birthing centers [36]. The possibility of more adverse sequelae post-frenectomy as a result of vitamin K deficiency must be considered, when one looks at the significant increase in the number of frenectomy cases being performed. Another consideration is the recent politicization of vaccines. The past 2 years during the coronavirus disease 2019 (COVID-19) pandemic has seen a great deal of skepticism regarding vaccination efforts against COVID-19. Sahni et al studied a cohort of 282,378 children. They noted that children whose parents had refused vitamin K were more than 14 times as likely not to have received the recommended vaccinations by age 15 months than were those who received the vitamin K. They noted that midwife-assisted deliveries were more associated with vitamin K refusal. Planned home deliveries and deliveries at birth centers were also more likely to result in vitamin K refusal [37]. Schmidt et al noted a 239% increase in Google searches of home birth information during the COVID-19 pandemic when compared with pre-pandemic search levels [38]. Noddin et al completed a retrospective study of over 300,000 births, with 50.26% pre-pandemic and 49.73% during the pandemic. Principal findings included a 30% increase in home births during the pandemic [39]. Other similar studies [40, 41] have also reported significant increases in home births during the pandemic. This statistically significant increase in home births combined with the increase in vitamin K refusal has the potential to lead to devastating consequences if these infants undergo surgical procedures such as frenectomy.

VKDB

Vitamin K modulates blood clotting, as it is responsible for activating clotting factors II, VII, IX and X. Newborns chronically have low vitamin K levels because only small amounts pass through the placenta. Vitamin K is produced by bacteria in the intestines. Since a neonate's gut is sterile, they have fewer endogenous stores of vitamin K. Breast milk is known to contain very low levels of vitamin K; thus, neonates receive

little during breastfeeding. Therefore, breast-fed neonates are at risk for elongated vitamin K deficiency [42-45].

VKDB is associated 90% of the time with exclusively breast-fed babies and is approximately twice as likely in males as females [46]. An increase in the manifestation of VKDB, previously known as hemorrhagic disease of the newborn (HDNB), has recently drawn attention [47]. This surge correlates well with the recent phenomenon of parental refusal of the normally administered intramuscularly (IM) dose of vitamin K immediately following delivery [48].

VKDB has been categorized in the literature into three presentations: early, classic, and late. Early VKDB usually occurs during the first 24 h. It is most frequently linked to maternal medications, such as anti-epileptics (barbiturates, carbamazepine, and phenytoin), anti-tuberculosis (rifampicin, isoniazid) and select antibiotics (cephalosporins), as well as anti-coagulants (warfarin and coumadin) [49-51]. Without vitamin K administration, babies whose mothers had taken these drugs during pregnancy have a 6-12% chance of developing VKDB [52]. Classic VKDB is observed on days 2 through 7 [49]. Infants with classic VKDB typically present with bruising, oozing from injection sites, and/or bleeding around their umbilicus. Tragically they may experience intracranial and intra-abdominal hemorrhaging [49, 51]. Classic VKDB has been almost eliminated with the administration of IM vitamin K at birth [53, 54]. Statistical variance is observed in the literature, with the prevalence ranging from 0-1.5% [55, 56]. Early and classic VKDB occur more often than late VKDB, affecting from 1 in 60 to 1 in 250 babies [57, 58].

Late VKDB is characterized as having a typical onset from week 2 to 6 months but can be up to 1 year of age. It occurs primarily in breast-fed babies, and results from low vitamin K ingestion and low absorption secondary to hepatobiliary disease, such as cholestasis [44, 49, 50]. The condition is quite serious and can result in gastrointestinal bleeds and intracranial hemorrhage in 50% of affected babies [49, 50]. Late VKDB is known for a high risk of morbidity and mortality; however, there is insufficient evidence that a 1 mg IM dose will reduce the chance of developing late VKDB [53]. The incidence of late VKDB ranges from 1/14,000 to 1/25,000 [57-59]. The American Academy of Pediatrics (AAP) recommends administration of 0.5 to 1 mg of vitamin K IM to all newborns [20, 21]. The Canadian Pediatric Society (CPS) recommends the IM formulation yet allows for an alternative oral dosing of 2 mg within 6 h of delivery, another 2 mg dose at 24 weeks and a third dose at 6 - 8 weeks [50]; however, they instruct physicians to advise patients that oral vitamin K is less effective than IM.

While 1 mg of vitamin K IM is widely used to reduce or prevent the incidence of early and classic forms of VKDB, insufficient evidence exists on the efficacy of reducing the late form. Also, it is unknown if the IM form and supplemental oral formulations increase efficacy [42, 44, 47, 54]. Due to the high morbidity and mortality, IM prophylaxis is recommended for all neonates for early, classic and late forms [22, 44, 57].

Vitamin K deficiency is diagnosed by an INR of 4, or normal platelet count and fibrinogen levels with a prothrombin time (PT) that is four times the control values. Administration of intramuscular vitamin K results in the clotting factors II, VII, IX and X returning to normal levels [42, 46, 49, 57, 60].

Parental refusal of the administration of IM vitamin K to newborns has become a public health concern. As discussed earlier, four cases of VKDB presented in Nashville, Tennessee (USA) in 2013. In all four infants, the parents had refused vitamin K prophylaxis [34]. Parental anxiety about IM vitamin K administration may partly be due to concerns about developing cancer secondary to the IM formulation [61-63]. The original formulation from 1960 contained adjuvants such as propylene glycol and phenol, which has been shown to promote tumors in mice [64]. Subsequent studies failed to establish a relationship between intramuscular vitamin K and childhood cancer [65-68]. The updated mixed micellar preparation is comprised of phosphatidylcholine and glycolic acid [64].

Vitamin K supplementation in mothers has not been shown to be effective in eliminating VKDB in babies [69]. Also, studies show the oral formulations are not as effective as the IM form [66]. Multiple oral doses are more effective than a single oral dose, but compliance is often poor [60, 70].

Data are available on circumcision, another frequently performed early elective surgical procedure, which includes the risk of possible hemorrhage. It has been noted that excessive bleeding occurs in 1% of cases [71, 72]. Practitioners can reduce the risk of VKDB bleeding by a vitamin K injection after birth [73, 74].

It is imperative that providers engaging in any surgical procedure be aware that bleeding disorders can reveal themselves even with no family history of any bleeding abnormalities. For example, hemophilia presents as a primary spontaneous mutation in at least 30% of cases when there is no known family history [42].

Responsibilities of Ankyloglossia Team Members

Every member of the Ankyloglossia Care Team functions within complex multifaceted roles. We each assess and intervene, all within our own unique scope of practice, while we are also held accountable to high ethical guidelines. Our actions must be navigated by non-malfeasance and research-based practices. Additionally, health care providers are educators purely as part of our role in the structure of society. Critically important to note is that when caring for pediatric clients, when our patients are minors, unable to grant informed consent or agree to take risks for themselves, we are held to an even heightened level of standards.

Ethical Points to Consider

Ethically, we are obligated to honestly and transparently share the information we possess, as we eliminate or strive to mitigate unnecessary risks. Performing an ankyloglossia release or revision without appropriate vitamin K IM prophylaxis may result in both unnecessary and unacceptable risks, either for excessive or uncontrollable bleeding, potential hospitalization, or even death. Therefore, in the authors' opinions, vitamin K

IM ethically must be required preoperatively.

The greatest responsibility of discussing postoperative bleeding risks falls upon the professional who performs the frenectomy. These health care practitioners serve in what many families consider the apex role of influence with respect to the frenectomy procedure within the Ankyloglossia Care Team. Therefore, he or she possesses the highest ethical obligation to support the entire care team, including the patient's pediatrician, in explaining the importance of intramuscular vitamin K in the prevention of VKDB.

A standard "consent for surgery" mentions the risk of unforeseen or unavoidable bleeding, but in no way releases the frenectomy provider from the obligation to take reasonable precautions to prevent VKDB. The provider may be considered specifically negligent for performing an elective procedure without requiring prior administration of IM vitamin K, because that specific intervention has a known proven effect in reducing the risk of VKDB.

Additionally, herein we believe that providers who offer an option to sign a waiver or an additional consent form or a specific release omitting IM vitamin K or allowing for the substitution with an oral form of vitamin K gives the impression that the provider believes the oral form to be as efficacious as the IM form, or that taking on these risks is acceptable. Therefore, we do not recommend the use of any such documents.

Proposal of the Authors: Best Practice Considerations

The authors of this report, based on both the previously mentioned standard of care recommended by the American Academy of Pediatrics, and the lack of evidence of any therapeutically equivalent alternatives to intramuscular vitamin K prophylaxis in protection from early, classic, or late VKDB herein propose all providers of elective frenulum release or revision should require intramuscular vitamin K prophylaxis prior to performing any surgical procedure on patients under 6 months of age.

We propose the question of vitamin K IM status should be addressed prior to the scheduled date of any elective procedure. Neglecting to inquire about this detail before bringing the family into the provider's office adds undue stress to an already complex situation. Initial omission of vitamin K will not negate eventual release, as vitamin K IM can be obtained via the patients' primary care physicians prior to an appointment with a release provider.

We must emphasize once again that oral vitamin K has not been proven to provide the same therapeutic prevention of VKDB as vitamin K administered via the IM route. Therefore, we draw to your attention our specific recommendation that vitamin K must be administered via the intramuscular route.

Legal Considerations

Finally, no recommendation would be complete without a brief discussion of the legal considerations regarding the recommendation. Though none of the authors are attorneys, we feel it incumbent upon ourselves to briefly discuss the literature regarding standard of care and clinical practice guidelines (CPGs). For more concise advice, the reader is strongly urged to consult with a malpractice attorney or hospital legal counsel. Remember that standard of care is not a medical term, it is a legal term. In the past, standard of care was discussed as standard of care in the community where one practiced. In the past few decades, due to the widespread availability of online journals and online continuing education, standard of care is now thought of as nationwide, rather than community wide. Standard of care is now the same whether one practices in an urban, suburban or rural setting.

Vitamin K prophylaxis has been standard of care in the USA since the American Academy of Pediatrics Committee on Nutrition recommended it in 1961 [75]. The CPS also recommends IM injection and instructs physicians to advise patients that oral vitamin K is less effective than IM [76]. We earlier discussed that the provider may be considered specifically negligent for performing an elective procedure without requiring prior administration of IM vitamin K, because that specific intervention has a known proven effect in reducing the risk of VKDB.

Moffett et al [77] discuss the association between CPGs and standard of care. They state that the guidelines "may be used as learned treatises…to suggest physician deviance from the document as deviance from the standard of care". They further state that CPGs "are being used more frequently in court cases as support for the standard of care". Kelly et al state "the courts now use CPGs as shorthand for the standard of care in making malpractice determinations" [78]. Performing an ankyloglossia release without prior IM vitamin K injection could possibly be construed as a violation of standard of care, as well as negligence.

Health care providers are responsible to always model best practice, among not only our immediate colleagues, but also when counseling the families we serve. Families trust us to constantly advocate for the highest of safety standards for everyone we have under our care. We must strive to deserve that trust.

Acknowledgments

None to declare.

Financial Disclosure

There is no financial interest from any source for this paper. This paper was not funded by any person or organization.

Conflict of Interest

All of the authors deny any conflict of interest.

Author Contributions

All of the authors have contributed equally to the preparation

and review of this paper. More specifically: Ms. Funston wrote the sections on Ankyloglossia Team functioning and best practices. Dr. Convissar researched the references, added the case histories and wrote the section on legal considerations. Dr. Morse wrote the section on VKDB. Dr. Abramczyk wrote the remainder of the paper.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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