Routine Administration of Vitamin K_1 Prophylaxis to the Newborn

Practice Resource for Health-Care Providers

October 2023

Perinatal Services BC
Provincial Health Services Authority

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Note

The information attached is the summary of the position statement and the recommendations from the recent CPS evidence-based guideline for routine intramuscular administration of Vitamin K_1 prophylaxis to the newborn*: cps.ca/en/documents/position/vitamin-k-prophylaxis-in-newborns

*Permission to reprint recommendations granted by the Canadian Paediatric Society on April 25, 2016.

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Summary

Vitamin K deficiency bleeding or VKDB (formerly known as hemorrhagic disease of the newborn or HDNB) is significant bleeding which results from the newborn's inability to sufficiently activate vitamin K-dependent coagulation factors because of a relative endogenous and exogenous deficiency of vitamin K.[1]

There are three types of VKDB:

1. Early onset VKDB, which appears within the first 24 hours of life, is associated with maternal medications that interfere with vitamin K metabolism. These include some anticonvulsants, cephalosporins, tuberculostatics and anticoagulants.
2. Classic VKDB appears within the first week of life, but is rarely seen after the administration of vitamin K.
3. Late VKDB appears within three to eight weeks of age and is associated with inadequate intake of vitamin K (exclusive breastfeeding without vitamin K prophylaxis) or malabsorption. The incidence of late VKDB has increased in countries that implemented oral vitamin K rather than intramuscular administration.

There are three methods of Vitamin K_1 administration: intramuscular, oral and intravenous. The Canadian Paediatric Society (2018)[2] and the American Academy of Pediatrics (2009)[3] recommend the intramuscular route of vitamin K administration. The intramuscular route of Vitamin K_1 has been the preferred method in North America due to its efficacy and high compliance rate. The incidence of late VKDB when Vitamin K_1 is administered orally is 1.4 to 6.4/100,000 versus 0.25 to 3.2/100,000 when intramuscularly.[2, 4]

It is important to note that the administration of Vitamin K_1 by intramuscular injection does not provide complete protection, especially in breast fed infants whose oral intake of vitamin K is low.[2] The Canadian Paediatric Society (2018)[2] recommends considering additional doses of Vitamin K_1 to infants at high risk for VKDB, for example, infants who fail to thrive, have liver disease or have long term diarrhea.

A 1992 study[5] in the British Medical Journal reported a link between intramuscular Vitamin K_1 and childhood cancer and caused great concern, especially in Europe. This led some countries to change practice and administer Vitamin K_1 orally rather than the standard intramuscular route. Those countries showed an increase in late VKDB of the newborn. Since then, the CPS[2], AAP[3] and Zipursky[4] reported several case-controlled studies that have found no evidence to suggest that intramuscular Vitamin K_1 causes childhood cancer.

Oral administration may be a harm-reduction alternative in cases where parents refuse intramuscular administration.[1, 2, 6] Parents may make this choice for various reasons. Some of those reasons include:

- To protect their infant from pain associated with intramuscular injection,
- They have an opinion that the injection is unnecessary,
- A desire to minimize their infant's exposure to 'toxins'.

To lessen pain associated with intramuscular injections, encourage skin to skin 10 to 15 minutes before the injection and/or breastfeeding during the injection. For infants who are unable to breastfeed, and have non-nutritive sucking (NNS) as part of their care, NNS may be used. Parents may encourage infant to suck on their clean finger.

The intravenous route for less than 1500 grams premature or ill infants is preferred by some providers in tertiary centers. This route may not fully protect against late VKDB.

Recommendations

1. To prevent early VKDB (which occurs within the first 24 hours of life), administer Vitamin K_1 to expectant mothers who take drugs that impair vitamin K metabolism.

2. Administer Vitamin K_1 within the first 6 hours after birth following initial stabilization of the newborn and an appropriate opportunity for maternal (family) — infant interaction.

3. Administer Vitamin K_1 as a single intramuscular dose of:
   - 0.5 mg if birth weight is 1500 grams or less
   - 1 mg if birth weight is greater than 1500 grams

4. For infants whose parents refuse an intramuscular injection, three 2 mg oral doses of Vitamin K_1 are recommended at:
   - the time of the first feeding
   - repeated at 2 to 4 weeks and
   - again at 6 to 8 weeks of age

   Oral prophylaxis is contraindicated in infants who are ill, on antibiotics, have cholestasis or diarrhea.

   If the infant vomits or regurgitates the dose within one hour of administration, the oral dose should be repeated.[7]

   An appropriate oral form of Vitamin K_1 has not been licensed in North America. The injectable form of Vitamin K_1 is currently being used for oral administration.

5. Consider the possibility of vitamin K deficiency for any bleeding that occurs during the first six months of life. Consider consultation or referral as appropriate. Institute appropriate therapy with Vitamin K_1 when required.

6. Consider administering further doses of Vitamin K_1 to infants at high risk of VKDB, identified as those who fail to thrive, have liver disease or have long term diarrhea.

Family education is imperative. Promote awareness among families of the risks of late VKDB (including the 50% chance of an intracranial hemorrhage with late VKDB) associated with inadequate vitamin K prophylaxis with the current oral dosage regimens, particularly for newborns who are breastfed. Inform parents of the importance of the follow-up doses. (Refer to Appendix for family handout).

References

1. Schulte R, Jordan LC, Morad A, Naftel RP, Wellons III JC, Sidonio R. (2014) Rise in Late Onset Vitamin K Deficiency Bleeding in Young Infants Because of Omission or Refusal of Prophylaxis at Birth. Pediatr Neurol 2014; 50: 564-568

2. Canadian Paediatric Society. 2018. Guidelines for Vitamin K prophylaxis in newborns: A joint statement with the College of Family Physicians of Canada https://cps.ca/en/documents/position/vitamin-k-prophylaxis-in-newborns

3. American Academy of Pediatrics. (2003 – reaffirmed May 2009). Controversies concerning Vitamin K and the newborn. Pediatrics, 112(1), 191-192.

4. Zipursky, A. (1999). Prevention of Vitamin K deficiency bleeding in newborns. British Journal of Haematology, 104, 430-437.

5. Golding, J., Greenwood, R., Birmingham, K., Mott, M. (1992). Childhood cancer, intramuscular Vitamin K, and pethidine given during labour. British Medical Journal, 307, 89-91.

6. Eventov-Friedman S1, Vinograd O, Ben-Haim M, Penso S, Bar-Oz B, Zisk-Rony RY. (2013). Parents' Knowledge and Perceptions Regarding Vitamin K Prophylaxis in Newborns. J Pediatr Hematol Oncol;35:409–413.

7. NHMRC (National Health and Medical Research Council – Australian Government) (2010). Joint statement and recommendations on Vitamin K administration to newborn infants to prevent vitamin K deficiency bleeding in infancy – October 2010 (the Joint Statement). Canberra AU.

Appendix: Family handout

https://caringforkids.cps.ca/handouts/pregnancy-and-babies/vitamin-k-for-newborns

Vitamin K for newborns

What is vitamin K?

Our bodies need vitamin K to form clots and to stop bleeding. We get vitamin K from the foods we eat, such as green leafy vegetables, fish, meat, and eggs.

Why does my newborn need vitamin K?

Babies are born with a very small amount of vitamin K. Not having enough can cause bleeding that doesn't stop because there isn't enough vitamin K to form a clot. The bleeding can happen inside or outside of the body – including the brain – at any time up to 6 months of age.

How is vitamin K given to babies?

There are two ways newborns can receive vitamin K:

- A single injection in the thigh within 6 hours of birth, or
- 3 doses by mouth—one at baby's first feeding, another at 2 to 4 weeks of age, and another at 6 to 8 weeks of age. Your baby must receive all 3 doses.

The Canadian Paediatric Society recommends that doctors give newborns vitamin K by injection.

Giving vitamin K by mouth is not as effective as by injection. Vitamin K is not absorbed as well when given by mouth and does not last as long. Babies who get vitamin K by mouth have a higher risk of later developing vitamin K deficiency. This can cause bleeding, which can happen between 2 weeks and 6 months of age.

Is the vitamin K injection safe?

Yes, the vitamin K shot is very safe. There are no side effects. There may be some redness, swelling, or pain at the injection site.

Can't my baby get vitamin K from my breast milk?

Breast milk contains very low amounts of vitamin K, so babies who only breastfeed will not get enough. Even formula-fed babies have very low levels of vitamin K for several days.

What about the injection pain? My baby is so little!

To reduce pain from the injection, hold your baby during the vitamin K shot. You can also try breastfeeding at the same time to comfort your baby.

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