Vitamin K1 Injection &Vitamin K Deficiency Bleeding (VKDB) Informed Consent

What is Vitamin K?

Vitamin K is a fat-soluble vitamin that comes in two forms. The main type is called phylloquinone (Vitamin K1), found in green leafy vegetables like collard greens, kale, and spinach which makes up about 90% of vitamin K in our bodies (Dekker, 2015). The other type, menaquinones (Vitamin K2), are found in some animal foods and fermented foods. Menaquinones can also be produced by bacteria in the human body within the gastrointestinal (GI) tract. Vitamin K is known as the clotting vitamin. The body needs vitamin K to make certain proteins in the liver that cause blood to clot. These proteins are called clotting factors. Without vitamin K, the liver could not produce clotting factors II, VII, IX, and X, and blood would not clot causing bleeding concerns (Dekker, 2015).

Why are newborns different?

Babies don't have much vitamin K when they are born and won't have a good supply of vitamin K until they are close to six months old. This is because vitamin K does not cross the placenta and breast milk has very low levels of vitamin K. They are also born without the GI tract bacteria that can help produce vitamin K2. Without enough vitamin K, babies cannot make the substances used to form clots, called clotting factors.

Unless there are genetic components their clotting abilities are assumed normal and just need to be activated with vitamin K. When bleeding happens because of low levels of vitamin K, this is called “vitamin K deficiency bleeding” or VKDB (Dekker, 2015). It was commonly believed that traumatic births caused more likelihood for VKDB in newborns, but all newborns are at risk equally, no recent evidence supporting the theory that infants born with instrumental help, or by Cesarean, are at higher risk for Vitamin K deficiency bleeding (Dekker, 2015).

What is Vitamin K Deficiency Bleeding (VKDB)?

A baby who does not have enough Vitamin K can start to bleed suddenly, without warning and no other correlations have been found to cause this besides not receiving the vitamin K shot within 6 hours from birth and exclusive breastfeeding due to low levels passed on. Vitamin K deficiency bleeding can be *idiopathic* or *secondary*. Idiopathic VKDB means that the cause is unknown. Secondary VKDB means that the baby has an underlying disorder such as gallbladder disease, cystic fibrosis, or medication side effects (Dekker, 2015). VKDB can begin early (within the first 24 hours of life), classically (within 2-7 days of life), and late-onset (after the first week of life, usually 3-8 weeks later). Early VKDB is usually caused by birthers taking medications that interfere with vitamin K such as seizure or tuberculosis medications. Classical is the most common and happens when vitamin K levels are lowest in the baby. Late VKDA is often first discovered by bleeding in the brain and is primarily found in breastfed infants who did not get the vitamin K vaccine. This one is the most dangerous and often undiagnosed.

Statistical risks of VKDB in newborns:

Classical VKDB bleeding that occurs in the first week of life is more common than late VKDB sitting at about 440 out of 100,000 newborns (Dekker, 2015). When infants do not receive any Vitamin K at birth, statistics show that 4.4 to 7.2 infants out of 100,000 will develop late VKDB. When infants receive 1 mg of oral Vitamin K at least three times during infancy (typically at birth, one week, and four weeks), about 2.6 infants out of 100,000 will develop late VKDB (Dekker, 2015). When infants receive 2 mg of oral Vitamin K at least three times during infancy (at birth, 4 to 6 days, and 4 to 6 weeks) or 2 mg of oral Vitamin K after birth and 1 mg of oral Vitamin K every week for three months, somewhere between 0 to 0.9 infants out of 100,000 will develop late VKDB (Dekker, 2015). When infants receive the Vitamin K shot at birth, anywhere from 0 to 0.4 infants per 100,000 get late VKDB. The shot doesn't prevent every case of late VKDB, but most countries report incidence rates of zero or close to zero (Dekker, 2015). The mortality rate for late VKDB is approximately 20%. One study that looked at 131 cases around the world found an overall death rate of 14%. Of the surviving infants, about 40% had long-term brain damage (Dekker, 2015).

Treatment Options:

The main treatment for VKDB is to give the infant Vitamin K. When an infant with VKDB receives a shot of Vitamin K1, this will usually slow or stop the bleeding within 20-30 minutes. However, if bleeding happens in the brain, the infant may already have brain damage by the time the shot is given. Other treatments that have been used in infants with late VKDB include blood and plasma transfusions, brain surgery to remove the accumulated blood, and giving anti-seizure medicines (Dekker, 2015).

Vitamin K Supplementation After Birth

There are two main options for giving your newborn vitamin K supplementation. There is the vitamin K1 injection commonly known under many different brand names such as Phylloquinone, Phytonadione, AquaMEPHYTON, Mephyton, and Konakion. There are **two vitamin K1 injections**. One is **preservative free** meaning it does not contain benzyl alcohol while the **standard Vitamin K1** shot does contain it.

The alternative is **oral vitamin K1** supplementation with drops you can administer on your own over the course of 12 weeks. This looks like 4 drops (2 mg) on the day of birth, and then 2 drops (1 mg) once a week for 12 weeks. found online at Amazon.com from Biotics Research. The supplement is called "Bio-K-Mulsion 1oz" and must be purchased usually a week or two before 37 weeks since the date of birth is unknown and it must begin at birth to be effective. This is the only oral vitamin K option approved for newborns but it is not FDA regulated. Research suggests that a properly followed oral regimen of 2 mg of Vitamin K1 is very effective, however, each family's compliance with the schedule may leave room for less effective rates if not properly administered. The main concern with using oral Vitamin K is that it may not work as well for infants with undiagnosed gallbladder problems.

Delayed cord clamping raises iron levels because cord blood is rich in iron. In contrast, cord blood has extremely low levels of Vitamin K1 (<.05 micrograms per Liter), meaning that delayed cord clamping while beneficial for iron is not a treatment for VKDB or prevention method as it provides too low of levels of vitamin K.

Here is the Vitamin K1 injection

(*Vitamin K Injection*, n.d.)

Here is the Vitamin K1 Oral

(Corporation, B. R., n.d.)

Pro vs. Con to Each Treatment Method

The benefits to vitamin K1 injection are that it is a one-time very effective dose that doesn't require any more effort. The delayed-release mechanism as the vitamin is stored in the thigh muscle and released into the baby's bloodstream over the following several months, protecting against both classic AND late Vitamin K deficiency bleeding (Dekker, 2015). This method is absorbed better than oral vitamin K and all ingredients are non-toxic. When the injection is given the chances of VKDB are near zero without other underlying causes existing. The downsides are any injection can lead to site irritation and redness, but this is rare and it almost never leads to any intervention. Injections can also cause pain, which can be minimized by nursing the baby during the shot (Dekker, 2015).

The benefit of oral Vitamin K1 is that there is no shot to the baby, and it can be administered by the parents themselves which some families prefer. It is more preventative of VKDB than no treatment at all even if not all doses are administered. Downsides could be that administering something orally to a newborn can be challenging and they could spit it up or doses could be forgotten or missed leading to less effective doses. This method is less effective than an injection of vitamin K1. There could be gallbladder issues underlying that are undiagnosed making this method unusable by the infant.

_____ **Please initial** stating you fully understand all risks and benefits to VKDB and all treatment options offered. You had opportunities to ask questions and do research of your own as desired prior to making this decision, and you accept full responsibility for your choices.

Vitamin K1 Informed Choices

_____ I choose the Vitamin K1 intramuscular (IM) injection to be administered to the baby after birth.

_____ I choose the preservative-free Vitamin K1 IM injection to be administered to the baby after birth and accept responsibility to pay a $25.00 out-of-pocket cost insurance doesn't cover.

_____ I choose to self-administer the oral Vitamin K drops to the baby in the 12 week protocol and will bring these to my 36 prenatal visit to ensure the proper drops are prepared and purchased.

_____ I choose to decline all forms of Vitamin K supplementation and understand the risks of VKDB.

Client Signature: X _____ Date: _____

Print Name: _____

Midwife Signature: X_____ Date: _____

Print Name: _____

References

Corporation, B. R. (n.d.). *Biotics Research*. https://www.bioticsresearch.com/

Dekker, R. (2019, April 9). *Evidence Based Birth, Evidence on: The vitamin K shot in newborns.* https://evidencebasedbirth.com/evidence-for-the-vitamin-k-shot-in-newborns/

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