Vitamin K for the Prevention of Bleeding in Newborns: Oral Vitamin K as an Alternative

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Oral Vitamin K as an Alternative

Oral vitamin K administration would appear to offer several advantages for routine VKDB prophylaxis. In addition to the concerns raised about a link with childhood cancer, other disadvantages with IM administration include the trauma and complications associated with this route of administration (hematoma, vessel or nerve injury, abscess, or osteomyelitis) and the higher cost of therapy.[1,2,4-6]

It is clear that oral administration of vitamin K produces adequate serum concentrations for the prevention of classic VKDB.[11,18] While no oral liquid preparation is available in the United States, the injectable product has been found to be safe and effective when given by the oral route.[19,20] In a retrospective review of 23,228 infants at the University of Missouri given a single dose of vitamin K via nasogastric tube after birth, no cases of classic VKDB were identified over the period from 1967 to 1993.[20]

Unfortunately, the rise in the use of oral vitamin K prophylaxis has led to an increase in reports of late VKDB. A single oral dose does not typically provide the sustained elevation in serum vitamin K concentrations needed to prevent late bleeding. While most infants are receiving adequate vitamin K through breastmilk or formula after a week of life, some still have relatively low stores due to inadequate intake or hepatic dysfunction. A multidose regimen, typically three 1 or 2 mg doses given over the first two months, is used in many countries to provide prophylaxis against late VKDB.[1,2,4-6,18]

Several countries currently use an alternative mixed micellar preparation of vitamin K (Konakion MM®; Roche) for multidose oral prophylaxis. This formulation appears to provide greater absorption than traditional preparations and may make oral administration more effective. It is currently under investigation in the United States. In 1998, Greer and colleagues compared 2 mg doses of Konakion MM® given at birth and repeated at 7 and 30 days of life in 79 infants with standard IM dosing (a single 1 mg injection at birth) in 77 infants at two Wisconsin hospitals.[21] At three months, patients receiving the oral preparation had significantly higher serum vitamin K concentrations than the patients receiving the IM dose. No patients in either group experienced late VKDB. There were no significant differences in prothrombin times (INR values) between the groups. Uncarboxylated prothrombin (PIVKA II) values were

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elevated in three of the 77 IM patients at 56 days, but none of the 79 infants given the new oral product. The authors concluded that the mixed micellar preparation is a safe and effective alternative to traditional IM vitamin K administration. It should be noted, however, that this product is currently administered in the United Kingdom by health care providers, rather than parents, making it a considerably more expensive alternative.

Although there have been several studies which support the efficacy of oral three-dose regimens in controlled settings, there is now a significant number of reports of treatment failures in clinical practice.[22-24] Zipursky recently summarized a number of large scale surveillance studies highlighting a growing incidence of late VKDB in infants treated with oral vitamin K.[25] von Kries, Hachmeister, and Gobel recently reported treatment failures in Germany, with late VKDB occurring at a rate of 1.8 per 100,000 live births despite the use of three 2 mg doses of the mixed micellar preparation.[23,26] A similar failure rate was reported in Australia, where the recommendation for prophylaxis subsequently returned to IM administration. Switzerland reported the highest failure rate with 3.6 cases per 100,000 live births, using only two doses of the mixed micellar preparation.[23]

In the United States, the American Academy of Pediatrics formed a task force to examine the data regarding oral versus IM vitamin K dosing.[27] Based on the rise in treatment failures in countries switching to oral prophylaxis, the participants concluded that IM administration should remain the treatment of choice for VKDB prevention. It should be kept in mind, however, that no method of prevention is without fail. Although new surveillance data from Australia, where IM dosing is once again standard, and Denmark have not identified any late VKDB,[18,23] there has recently been a report following IM dosing in Italy.[28]

It has been suggested that longer regimens of oral vitamin K would prevent late VKDB while avoiding the concerns with IM use.[24] In 1992, The Netherlands adopted a regimen of 1 mg oral vitamin K at birth, followed by daily doses of 25 mcg from 1 week to 3 months of age in breastfed infants.[29] Surveillance data collected on infants receiving this regimen have revealed no cases of late VKDB.[23] Another alternative regimen now used in Switzerland consists of weekly 1 mg oral doses for two or three months with the Konakion MM® preparation.[30] The primary disadvantages of these methods are the reliance on parent compliance and the increased cost. In addition, oral administration is still hindered by unreliable intake in infants and poor absorption in infants with undiagnosed cholestasis.[1]

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