JPPT | Commentary

Injectable Vitamin K Dosing in Extremely-Low Birth Weight Infants

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The American Academy of Pediatrics (AAP) recommends Vitamin K prophylaxis to all newborns irrespective of their gestational age.[1] The recommended dose of Vitamin K for infants less than 1500 g is 0.3 to 0.5 mg/kg. The commercially manufactured Vitamin K is available as a single-use 1 mg/0.5 mL concentration. Dosage forms include an ampule, vial (manufactured by Hospira, Inc, Lake Forest, IL), or a prefilled syringe (Prefilled Syringe with safety device (Saf-T-Jet) International Medication Systems, Ltd, South El Monte, CA, An Amphastar Pharmaceuticals Company; See Supplemental Figure). The advantage of the prefilled syringe is that it eliminates the handling and cracking of the neck of the glass ampules and the use of extra filter needles. It is dispensed in a ready-to-use formulation, which minimizes the chances of dispensing and administration errors. However, the potential problem encountered with the single-use prefilled syringes is the need to draw the calculated dose in mL for extremely-low birth weight (ELBW) infants (<1000 g). The final volume in mL using a dose of 0.5 mg/kg for ELBW infants would be less than 0.25 mL (Table). The possible solution to this problem is to draw the needed amount using a separate tuberculin 1 mL syringe.

However, this practice has the potential for errors and patient safety (Figure).[2]

There is no available evidence of Vitamin K toxicity in ELBW infants. Costakos et al[3] reported serum Vitamin K of over 500 times higher than fasting adult concentrations on day 10 of life in the preterm infant with no documented side effects after Vitamin K administration. They concluded that a lower initial prophylactic dose (of 0.3 mg/kg Vitamin K) is warranted for infants with a birth weight of 1000 g or less. Interestingly, they had only 7 infants in the 0.5 mg/kg group with a mean gestational age of 27.3 ± 2.9 weeks and a birth weight of 1.08 ± 0.47 kg.

A single dose of 0.3 mg/kg ± 0.1 mg/kg dose of intravenous (IV) Vitamin K has been shown to achieve plasma concentrations at 24 and 120 hours similar to that achieved by oral (PO) or intramuscular (IM) doses of 1.5 mg.[4,5] Ardell et al[6] reported significantly lower plasma concentrations of Vitamin K in the 0.2 mg IM group as compared with the 0.5 mg IM group at 5 days of life, while on day 25, Vitamin K plasma concentrations in the 0.2 mg IM group and the 0.5 mg IM groups were not significantly different.[7] Therefore, a dose of 0.5 mg would be adequate.

Table. The Final Dose in mL Using AAP 0.5 mg/kg Dose for Infants Weighing ≤ 1000 g

Weight (kg)	Dose (0.5 mg/kg)	Dose in mL (1 mg per 0.5 mL)
1	1 × 0.5 = 0.5 mg	0.5 × 0.5 = 0.25 mL
0.9	0.9 × 0.5 = 0.45 mg	0.45 × 0.5 = 0.22 mL
0.8	0.8 × 0.5 = 0.4 mg	0.4 × 0.5 = 0.2 mL
0.7	0.7 × 0.5 = 0.35 mg	0.35 × 0.5 = 0.17 mL
0.6	0.6 × 0.5 = 0.3 mg	0.3 × 0.5 = 0.15 mL
0.5	0.5 × 0.5 = 0.25 mg	0.25 × 0.5 = 0.12 mL
0.4	0.4 × 0.5 = 0.2 mg	0.2 × 0.5 = 0.1 mL
0.3	0.3 × 0.5 = 0.15 mg	0.15 × 0.5 = 0.07 mL

Most ELBW infants receive parenteral Vitamin K in total parenteral nutrition (TPN) within the first 24 hours of life. The multivitamin infusion (MVI) used in customized pediatric TPN contains Vitamin K 0.2 mg/5 mL. Thus, dosing from the preparation would provide 1.5 mL (0.06 mg) for infants < 1 kg and 3.25 mL (0.13 mg) for infants 1 to 3 kg. This dose of parental Vitamin K should be adequate to protect against Vitamin K deficiency bleeding (VKDB) in preterm infants. Although, we did not find any studies specifically describing simultaneous use of Vitamin K in TPN and IM Vitamin K, the question is: as almost all EBLW infants receive TPN containing adequate Vitamin K during the first 24 hours of life, would it be safe to hold IM Vitamin K in these infants? This will save extra use of Vitamin K, increase patient safety, and eliminate a painful procedure.

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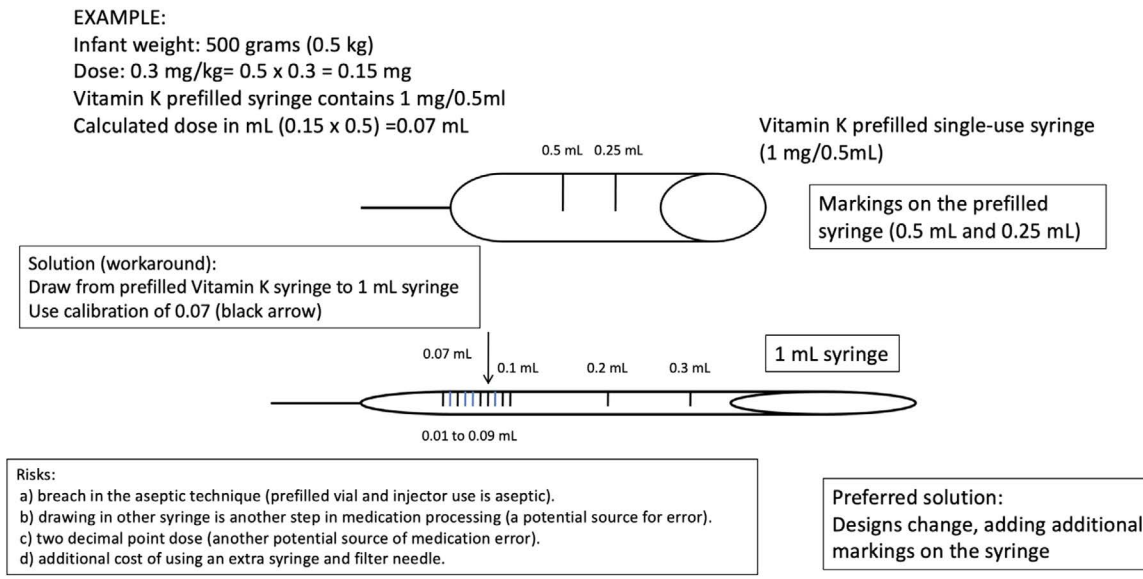
Figure.



In the meantime, we suggest to use a fixed dose of Vitamin K rather than weight based dose, that is, infants < 1 kg would receive 0.5 mg and infants > 1 kg would receive 1 mg. There is a need for a design change in the single-use prefilled syringe preparations to be used for these infants.

Article Information

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