health technology assessment

EXECUTIVE SUMMARY

ROUTINE NEONATAL VITAMIN K ADMINISTRATION AT BIRTH

HEALTH TECHNOLOGY ASSESSMENT UNIT
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HDN (Haemorrhagic disease of newborn) was first described in 1894, and only in 1940 was its relationship with vitamin K deficiency documented. Currently the preferred term for HDN is 'Vitamin K Deficiency Bleeding' (VKDB). Vitamin K is an anti-hemorrhagic factor that is capable of correcting clotting defects caused by obstructive jaundice and other biliary diseases in humans. HDN is an acquired coagulopathy secondary to reduction of Vit K- dependent coagulation factors below haemostatic levels. It is characterized by prolonged prothrombin time with normal fibrinogen and platelet count and elevated levels of Proteins Induced by Vitamin K Absence-II(PIVKA-II). The coagulopathy and/or clinical bleeding can be corrected early within 30-120 minutes by Vit K administration parenterally.

The causes of VKDB can either be primary (idiopathic) , usually associated with exclusive breastfeeding, or secondary to underlying disorders like diseases causing cholestasis, malabsorption or due to drugs. The condition can be classified according to the age of onset - early (first 24 hours), classical (first week of life) or late (after day 8 until 6 months age).
Vitamin K prophylaxis is required to prevent VKDB, and is administered intramuscularly at birth at a dosage of 1 mg. In the absence of vitamin K prophylaxis the incidence of classical VKDB has been reported to vary between 0.4% to 1.7%. When routine administration of parenteral Vit K was introduced to newborns, VKDB cases ceased. The objective of this assessment is to determine the effectiveness, safety and cost implication of routine administration of vitamin K at birth.

The main concern was the association between IM vitamin K and leukemia raised in a study in England. However, subsequent studies showed that there is sufficient evidence to refute the carcinogenic risk of parenteral vitamin K.

From this assessment, it can be concluded that there is sufficient evidence on the safety of vitamin K. With respect to effectiveness there is sufficient evidence to support vitamin K in preventing VKDB. A selective policy of vitamin K administration after screening is not appropriate since relatively high incidence of both classic and late VKDB occurred without prophylaxis. The evidence on a comparison of parenteral with intramuscular route of administration appears inconclusive, however there is sufficient evidence to show that oral regimens are effective. In relation to starting oral regimen, ethnical and geographical differences in vitamin K metabolism and absorption, incidence of underlying disease, breastfeeding patterns and uptake would need to be considered. In the area of cost implications, there is insufficient evidence, although there is some evidence that it is cost effective.
It is recommended that an intramuscular dose of vitamin K be given to all newborns at birth as prophylaxis to prevent VKDB