COMPARATIVE STUDY OF ORAL VERSUS INJECTABLE VITAMIN K IN NEONATES

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ABSTRACT

One hundred term exclusively breast fed babies weighing more than 2.5 kg were evaluated to determine the efficacy of various modes and doses of Vitamin K to prevent hemorrhagic disease of newborn (HDN). The babies were grouped into four categories of 25 each: Group A–1 mg Vitamin K intramuscular (Menadione sodium disulphite) at birth; Group B–0.5 mg Vitamin K intramuscular ; Group C–1 mg Vitamin K orally, and Group D–no Vitamin K. The prothrombin index was estimated in all babies between 36-72 hours of age. The results revealed a prothrombin index in Groups A, B, C and D as 94.98 ± 7.64%, 95.08 ± 9.91%, 92.51 ± 10.10% and 80.39 ± 15.90%, respectively. The differences between Groups A, B and C were insignificant. However, Group D, prothrombin index was significantly reduced as compared with the other three groups. It is, therefore, concluded that oral Vitamin K is as effective as injectable Vitamin K and its usage is recommended in our country to reduce complications and costs of parenteral therapy.

Key words: *Vitamin K, Prothrombin time, Prothrombin index, Hemorrhagic disease of newborn (HDN).*

With the increased emphasis on exclusive breast feeding all over the world and because of the biological handicap of the newborn regarding liver immaturity and absence of bacterial flora in the gut(1,2) it is likely that the incidence of hemorrhagic disease of the newborn (HDN) may increase unless adequate Vitamin K prophylaxis is given at birth.

Prophylactic administration of Vitamin K to high risk babies is undisputed but there have been considerable controversies regarding its routine use in normal newborns(1,3). The American Academy of Pediatrics has recommended that Vitamin K be given as a single parenteral dose of 0.5-1 mg or an oral dose of 2 mg to the newborn infant(3). At our hospital, routinely 1 mg Vitamin K is given intramuscularly to all newborns. The present study was undertaken to evaluate the efficacy of oral water soluble Vitamin K preparation (menadione sodium disulphite)(4) versus injectable Vitamin K in preventing HDN in the neonates.

Material and Methods

This prospective study was done at the postnatal wards of T.N. Medical College and B.Y.L. Nair hospital, Bombay. It included 100 term, normally delivered, exclusively breast fed babies above 2.5 kg who were randomly grouped into 4 categories of 25 each: Group A–babies received 1 mg Vitamin K intramuscularly; Group B–0.5 mg Vitamin K intramuscularly; Group C–

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Received for publication: March 18, 1991;
Accepted: February 6, 1992

1 mg Vitamin K orally and Group D–no Vitamin K. The Vitamin K preparation used was menadione sodium bisulphite.

Oral or injectable Vitamin K was given immediately after birth. Blood samples for prothrombin time by Quick's one stage method(5) were collected between 36-72 hours. The prothrombin index was calculated as a percentage of prothrombin time of control.

In Group D, Vitamin K 1 mg intramuscular was given after blood sample for prothrombin time was collected. All the above relevant data was recorded in prestructured proforma. The statistical test used was analysis of variance (ANOVA) using the 'F' distribution.

Results

The birthweight of the babies in all groups ranged between 2.7 to 3 kg which were comparable and the sex distribution (M : F) in Group A, B, C, D was 15 : 10, 19 : 6, 11 : 14 and 14 : 11, respectively. The prothrombin index in Groups A, B, C, D was 94.8 ± 7.7, 95.0 ± 9.9, 92.5 ± 10.19, 80.4 ± 15.9, respectively (*Fig.*), *i.e.,* the prothrombin index was nearly identical in Groups A, B and C but was significantly lowered in Group D (at 5% level of significance). No neonate suffered from HDN and no baby in Group C (Oral Vitamin K group) had any side effects.

Discussion

HDN is a potentially serious condition in the neonate resulting from the transient deficiencies of Vitamin K dependant factors(6-8). Vitamin K is necessary for the modification and activation of coagulation proteins namely factors II, VII, IX and X(1,9). The normal full term infant is born with levels of Vitamin K dependant clotting

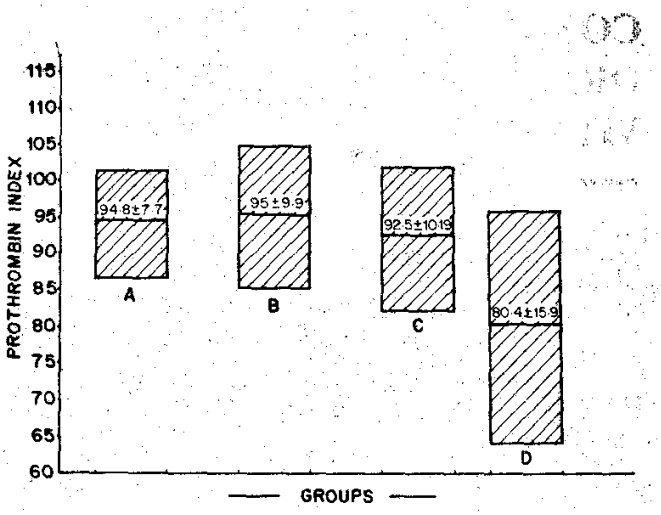

Fig. Average prothrombin index in various groups. Group A = 94.8 ± 7.7, Group B = 95 ± 9.9, Group C = 92.5 ± 10.19, and Group D = 80.4 ± 15.9.

factors that are low by adult standards (upto 50%)(1,4,9). The levels further decrease rapidly reaching a nadir at 48-72 hours of life especially in breast fed infants. This physiological postnatal decrease may in a few infants result in HDN(10-12). Various studies have shown normal prothrombin time ranging from 14.5 ± 1.0 sec(10) to 17.5 ± 3.2 sec(9) in the newborn infant.

Many reports in literature have shown that oral Vitamin is as effective as injectable in preventing HDN(13,14). O'Connor and Addiego showed in their study that oral Vitamin K caused a significant fall in the prothrombin time(4). Also, Ishii and Uedo showed the same by using thrombo test(15). Similarly, Dunn(16) documented only one case of HDN when 31,000 infants were given oral Vitamin K. Earlier Indian studies have also proved efficacy of oral Vitamin K(12,17,18).

The present study revealed that prothrombin index was almost identical in Groups A, B and C except in Group D. Thus, 1 mg oral and 0.5 mg intramuscular Vitamin K were as effective as 1 mg Vita-

min K intramuscular (A *vs* B, B *vs* C, A *vs* C were statistically insignificant). Further analysis showed that prothrombin index was significantly decreased and prothrombin time was markedly prolonged in Group D babies (where no Vitamin K was given), as compared to other groups but not enough to increase the risk of bleeding.

Thus, our study conclusively proved that oral water soluble menadione sodium disulphite is as effective as injectable Vitamin K in preventing HDN and should be routinely given to all full term neonates. Besides, the oral preparation is cost effective, reduces the complications and pain of an injection and requires no expertise to administer it.

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