Original Article

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Efficacy of Oral Vitamin K Compared to Injectable Vitamin K in Neonates

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Abstract

Introduction: According to guidelines of American Association of Pediatrics and Indian Association of Pediatrics, Vitamin K is routinely given immediately after delivery.

Aim of Study: This is a comparative study to evaluate the efficacy of oral Vitamin K and parenteral Vitamin K.

Materials and Methods: 150 breastfed infants weighing more than 2.5 kg were evaluated to find out the efficacy of different routes of administration of Vitamin K to prevent hemorrhagic disease of newborn. The babies were grouped into three. Group A was given 1 mg of Vitamin K intramuscular; Group B, 2 mg of Vitamin K orally; and Group C no Vitamin K. The prothrombin index was estimated in all babies.

Results: The prothrombin index was 94.98 ± 7.64%, 95.08 ± 9.91%, and 80.39 ± 15.9%, respectively, among the three groups. The difference between Group A and B were insignificant ($P < 0.01$). However, in Group C, prothrombin index was reduced significantly as compared with other two groups ($P < 0.001$).

Conclusion: Oral Vitamin K is as effective as intramuscular Vitamin K and its usage can be recommended in our country to reduce complications and cost of parenteral therapy.

Key words: Hemorrhagic disease of newborn, Prothrombin index, Prothrombin time, Vitamin K

INTRODUCTION

Exclusive breastfeeding is recommended for all newborns and breast milk is a poor source of Vitamin K. Vitamin K is necessary for the modification and activation of coagulation factors namely II, VII, IX, and X. A newborn baby has poor bacterial flora which can synthesize Vitamin K.[1,2] So, universally Vitamin K prophylaxis is recommended. Hemorrhagic disease of newborn (HDN) may be markedly reduced in the future since more and more mothers accept the recommendation of exclusive breastfeeding.

Unfortunately, there are not many studies regarding the efficacy of oral Vitamin K in our country to recommend oral Vitamin K as prophylaxis for HDN. The American Academy of Pediatrics has recommended that Vitamin K is given as a single parenteral dose of 0.5 mg to 1 mg or an oral dose of 2 mg for the newborn infant.[3]

Mallik *et al.* done a study on the comparative efficacy of oral and injection Vitamin K and showed that oral Vitamin K is equally effective in preventing HDN.[4] The present study was undertaken to evaluate the efficacy of oral Vitamin K preparation (menadione sodium bisulfite vs. injectable Vitamin K in preventing HDN in neonates.

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MATERIALS AND METHODS

This prospective study was done in the post-natal wards of Kannur Medical College, Anjarakkandi, Kannur district, Kerala. It included 150 exclusively breastfed term neonates without any complications of delivery including birth asphyxia. Pre-term babies, small for gestational age babies, and babies with asphyxia and immediate neonatal problems were excluded from the study. After taking the informed

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consent from the parents, the neonates were randomly grouped into three categories. Group A included those babies who received 1 mg of intramuscular Vitamin K, Group B received 2 mg of oral Vitamin K, and Group C received no Vitamin K. The Vitamin K preparation used was menadione sodium bisulfite. Oral or injectable Vitamin K was given immediately after birth. Blood samples for prothrombin time by quicks one stage method[5] were collected, and relevant data were recorded in pre-structured proforma.

Statistical Analysis

Statistical analysis is with the help of SPSS version 11. Data are analyzed by unpaired Student's *t*-test. $P < 0.05$ is considered significant.

RESULTS

The number of neonates studied was 150. The neonates were divided into three groups of 50 each. The mean weight of all neonates was 2.96 ± 0.35 kg. The birth weight of the babies in all groups ranged between 2.6 and 3.5 kg which was comparable and the sex distribution (M: F) in Group A, B, and C was 28:22, 26:24, and 25:25, respectively, i.e. the prothrombin index was nearly identical in Group A and B but was significantly lowered in Group C (at 5.5 level of significance).

Prothrombin index difference was not statistically significant among injectable Vitamin K and oral Vitamin K ($P < 0.01$), but the difference was significant between injectable Vitamin K and control group ($P < 0.0001$) and between oral Vitamin K and control group ($P < 0.0001$). Even though there was statistical significance between the control group and Vitamin K group but none of the babies in all the three groups have not developed any HDN clinically (Tables 1-3).

Table 1: Gender distribution of the study population

Group	Male	Female	Total
A	28	22	50
B	26	24	50
C	25	25	50

Table 2: Mean weight distribution of the study population

Group	Weight (mean)	SD
A	2.91	0.25
B	3.12	0.40
C	2.85	0.20

SD: Standard deviation

Table 3: Distribution of prothrombin index in study group and control group

Group	Prothrombin index (mean)	SD
A	94.98	7.64
B	95.08	9.91
C	80.39	15.9

SD: Standard deviation

DISCUSSION

HDN is a potentially serious condition in the neonate resulting from transient deficiency of Vitamin K-dependent factors.[6-8] The normal full term neonate is born with levels of Vitamin K dependent clotting factors that are low by adult standards (up to 50%). The levels further decrease rapidly reaching at a peak at 48-72 h especially in breastfed infants. This physiological post-natal decrease in a few infants results in HDN.[9-11] Various studies have shown normal prothrombin time ranging from 14.5 ± 1 s[9] to 17.5 ± 3.2 s[12] in the newborn infant.

Many reports in the literature have shown that oral Vitamin K is as effective as injectable Vitamin K in preventing HDN.[13-15] O'Connor and Addiego showed in their study that oral Vitamin K caused a significant fall in the prothrombin time.[4] Furthermore, Ishii and Uedo showed the same using thrombo test.[16] Similarly, Dunn[17] documented only one case of HDN when 31,000 infants were given oral Vitamin K. Earlier Indian studies also proved efficacy of oral Vitamin K.[11,17,18]

The present study revealed that prothrombin index was almost identical in Group A and B but not in Group C. Thus, 1 mg of intramuscular Vitamin K is as effective as 2 mg of oral Vitamin K. Further analysis has showed that prothrombin index was significantly decreased and prothrombin time was markedly prolonged in Group C (where no Vitamin K was given) as comparable to other groups but not enough to increase the risk of bleeding.[19,20]

CONCLUSION

Oral Vitamin K is as effective as injectable Vitamin K. Oral Vitamin K is cheap and affordable. This can be practiced in resource-poor setup.

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