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Original Article

Maternal and Neonatal Benefits of Prophylactic Administration of Vitamin K Before Elective Cesarean Section; A Randomized Control Trial

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Abstract

Background: The importance of Vitamin K is well known for its hemostasis role. It is an essential cofactor that synthesizes and activates vitamin K-dependent coagulation factors; prothrombin II, VII, IX, and X. Also, vitamin K controls proteins C and S in the liver **Aim of work:** We aimed to assess the efficacy of prenatal prophylactic maternal vitamin k administration in decreasing blood loss during and after elective cesarean section (CS) and its effects on neonatal outcomes. **Patients and methods:** A clinical trial included 200 pregnant women planned for elective CS, were randomized into two equal groups. The study group included 100 women who received vitamin K (10 mg) intramuscularly once daily for three days before elective CS, while the control group included 100 women who did not have vitamin K before CS. Maternal PT, PC, APTT, and hematocrit were evaluated pre-and postoperatively. Maternal blood loss during CS was assessed by counting the soaked gauzes. Vitamin K levels in the umbilical cord, neonatal APGAR score, and the neonatal PT and PC were measured. **Results:** Postoperative PT and APTT of women in the vitamin K group were shorter than the control group ($p<0.001$). Also, women's postoperative PC and hematocrit in the vitamin K group were higher than that of the control group ($p<0.001$). Neonates who received vitamin K had significantly shorter PT, higher PC, and less bleeding than the control group ($p<0.001$). Cord blood vitamin K levels in the group who received vitamin K were considerably higher than in the controls ($p<0.001$). **Conclusions:** Administration of prophylactic vitamin K had a beneficial effect on maternal bleeding tendency but to somewhat added no value in neonates as both PT and PC values were within normal despite of significant differences in both groups.

Key words: Vitamin K; bleeding; elective cesarean section; neonatal hemorrhage.

Introduction

The importance of Vitamin K is well known for its hemostasis role. Vitamin K is one of the fat-soluble vitamins. It is an essential cofactor that synthesizes and activates vitamin K-dependent coagulation factors; prothrombin II, VII, IX, and X. Also, vitamin K controls proteins C and S in the liver [1, 2]. In addition, it is involved in calcium homeostasis, tissue renewal, and cell growth control [3]. Vitamin K also exhibits a biological protective activity against oxidative stress and inflammation in the brain and neurological system [4]. Thus, vitamin K deficiency, although it is extremely rare among the adult population, may be harmful to pregnant women and their newborns, leading to hemorrhage [5, 6].

Studies usually investigated the importance of vitamin K through unfavorable outcomes of its deficiency, especially bleeding complications. Neonates have reduced vitamin K stores at birth due to deficient placental transfer. This is enhanced by vitamin K deficiency in breast milk leading to higher proteins induced in lack of vitamin K in breastfed neonates [1, 7].

Vitamin K deficiency may be risky for pregnant women as well as their newborns, causing hemorrhage as prothrombin needs vitamin K for blood coagulation. When there is a decrease in prothrombin level, there is also an associated slow in blood clotting, and severe bleeding in mothers or neonates is expected [8].

Diagnosis of vitamin K deficiency should be considered when prothrombin time (PT) is prolonged while both platelets count and fibrinogen levels are normal. Thus, the most practical confirmatory test is restoring normal PT by vitamin K supplementation. Evaluation of sufficient t women with vitamin K levels in pregnan more than three weeks of eating disorders may develop fetal intracranial hemorrhage (ICH) as a result of maternal [9] subclinical vitamin K deficiency Anorexia nervosa, bulimia

‹inflammatory bowel disease ‹nervosa cystic fibrosis, chronic kidney disease are examples ofeating disorders causing vitamin K insufficiency states [10].

Aim of the Work: This study aimed to assess the efficacy of prenatal prophylactic maternal vitamin K administration in decreasing blood loss during and after elective cesarean section (CS) and its effects on neonatal outcomes.

Methods

The present study was a prospective randomized, case-controlled clinical trial to assess the efficacy of prophylactic maternal vitamin K administration before elective CS in decreasing maternal blood loss and its effects on neonatal outcomes. It included 200 pregnant women admitted for elective CS at Gynecology and Obstetrics Department, Minia University Hospital, from July to October 2021.

The primary outcome was to study the effect of prenatal vitamin K administration on the maternal coagulation profile, including the prothrombin time (PT), the prothrombin concentration (PC), and the activated partial thromboplastin time (APTT). In addition to study its effect on the neonatal coagulation profile (PT and PC). The secondary outcome was to measure the amount of blood loss during the delivery by CS.

The study followed CONSORT recommendations. Two hundred women were included in the study after fulfilling the inclusion criteria: age ranges from 18-35 years, singleton pregnancy with gestational age between 37-42 weeks, and no obstetric or medical complications. Women were excluded if they had thromboembolic complications or were on anti-coagulant, anti-epileptic, or long-term antibiotics. Women with obstetric and medical complications or with anomalous fetuses were also excluded (Figure 1).

All recruited women before CS underwent careful history taking, general and obstetric examination including

obstetric ultrasonography, and laboratory investigations such as complete blood count (CBC), PT, PC, and APTT. They were randomized into two equal groups; each group comprised one hundred pregnant women. Blinding of the study procedures was not possible because the two selected treatment modalities were entirely distinct. Group allocation was predetermined and concealed by placement in numbered opaque sealed envelopes. These envelopes were kept in the operative theater and drawn in consecutive order. Pregnant women of group I (the study group -vitamin K group) received vitamin K (1 ml of Amri K®) intramuscularly once daily for three days before the elective CS. The pregnant women of group II (control group) did not receive vitamin K before the elective CS.

During the elective CS, the blood loss during the operation was measured by counting the soaked gauzes with blood by visual estimation, which is the most common method to estimate intraoperative blood loss. However, it is not the most accurate. In this method, three different sizes of surgical gauze (10 × 10 cm, 30 × 30 cm, and 45 × 45 cm) are commonly used, but in our study, we used 30 × 30 cm for easy blood loss calculation [11, 12].

Sample Size: We calculated sample sizes of 79 in group one and 79 in group two to achieve 80% power to detect a difference between the group proportions of 0.114 to assess the effect of prenatal vitamin K administration on neonatal bleeding. The proportion in group one (the treatment group) is assumed to be 0.139 under the null hypothesis and 0.025 under the alternative hypothesis. The proportion in group two (the control group) is 0.139. The statistical test used is the two-sided Z test with pooled variance. The significance level of the test was targeted at 0.05. The sample size was increased by 25% to allow for dropout. Therefore, the sample size needed in each group is 100 patients.

Ethical considerations

The study was approved by the Research Ethics Committee of the Council, Faculty of Medicine, Minia University. The study was registered at ClinicalTrials.gov on 30/07/2021under registration number NCT04984083. Written consent was obtained from all the women included in the study.

Clinical Trial registration: It was first registered at ClinicalTrials.gov on 30/07/2021 with registration number NCT04984083

Informed consent: All participants gave their consent after being informed of the study's objective and design, and they were given the option to leave the study at any time.

Availability of data and materials: The data that support the findings of this study are available from Minia Maternity and Children University Hospital, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request after permission from Minia University Hospital for Obstetrics, Gynecology and Pediatrics.

Statistical analysis

Data were analyzed by Statistical Package for the Social Sciences "SPSS" v. 25. Normally distributed quantitative variables were expressed in the form of mean ± standard deviation (SD). Qualitative variables were expressed in the form of numbers and percentages. We used the independent samples t-test for the normally distributed variables and the Chi-Square test for the qualitative variables to compare both groups. P-value was assumed significant if less than 0.05.

Results

Following CONSORT guidelines, 279 women were assessed for eligibility, and only 200 women who were included and randomized into two equal groups. Concerning their demographic data, the mean age was 27.86 ± 5.24 (years), and the mean gestational age at delivery was

37.91 ± 0.55 (weeks). Both groups showed no significant differences regarding maternal age, gestational age at delivery and neonatal weight and sex (Table 1).

When comparing both groups regarding the maternal clinical and laboratory findings, there were no significant differences in pre-operative laboratory data (PT, PC, APTT, Hematocrit). On the other hand, postoperative PT and APTT of women in the vitamin K group were shorter than the control group (P<0.001 and 0.003, respectively) (Figure 2). Women's postoperative PC and hematocrit in the vitamin K group were higher than the control group (P<0.001 and 0.006, respectively) (Figure 3). Furthermore, we observed during the elective CS that the number of soaked gauzes and the amount of blood (in cc) in the vitamin K group were less than that of the control group (P<0.001) (Table 2).

Regarding the neonatal clinical and laboratory data, the neonates of the study group who received prophylactic vitamin K had significantly shorter PT, higher PC, less tendency for bleeding than the control group (P<0.001, <0.001, and 0.043, respectively). In addition, the cord blood vitamin K level in the vitamin K group increased significantly than the control group (P<0.001) (Figure 4). However, there was no significant difference between both groups regarding the APGAR score (Table 3). Four neonates in the control group presented with bleeding during the first month follow up; 2 neonates presented with GIT bleeding, one presented with ICH, and the last one presented with umbilical cord bleeding. All four neonates had prolonged PT and low PC%.

Discussion

Assessment of efficacy and safety of vitamin K regimens during pregnancy may help to improve maternal and newborn outcomes. Antenatal administration of vitamin K for pregnant women may significantly improve maternal and neonatal outcomes via

improving prothrombin and partial thromboplastin activities. Furthermore, it improves factor VII deficiency in megaloblastic anemia of pregnancy with thrombocytopenia [13].

The present study included 200 pregnant women admitted for elective CS, aimed to assess the efficacy of prophylactic maternal vitamin K administration before CS in decreasing maternal blood loss and improving neonatal outcomes. The participating women were randomized into two equal groups; each group comprised 100 women; the study group (vitamin K group) included 100 women who received vitamin K (1 ml) intramuscularly once daily for three days before CS, while the control group included 100 women who did not receive the vitamin K before CS.

In our study, there were no significant differences between both groups in maternal and neonatal demographic data, including maternal age, gestational age, neonatal weight, and sex. We recorded insignificant differences between the two groups (regarding maternal pre-operative PT, PC, APTT, and hematocrit value while we recorded significant differences in their postoperative levels. In addition, there was a significant decrease in the hematocrit values in the control group than in the vitamin K group. The amount of blood loss measured by the number of soaked gauzes was remarkably lower in the vitamin K group than in the control group.

Regarding the neonatal effect of vitamin K supplementation, there was no significant beneficial effect on either 5 min or 10 min APGAR score. On the contrary, the neonatal PT was significantly prolonged in the control group than the vit k group. In addition, the neonatal PC was significantly higher in the vitamin K group than in the control group. Obviously, vitamin K levels in the umbilical cord were significantly higher in the vitamin K group than in the control group ($P<0.001$). We reported no neonatal bleeding in the vitamin K group, while we reported four cases (4%) with

neonatal bleeding in the control group, which made a significant difference between both groups (P=0.043).

A comparative study by *Anai et al.* investigated the effect of maternal intranatal vitamin K supplementation and its reflection on neonatal vitamin K levels. On their fifth day of birth, two groups of infants were assessed for uncarboxylated prothrombin and Normotest; study group: their mothers took vitamin K 10 mg/day orally for at least ten days before labor and control group: their mothers did not take vitamin K. They found vitamin K effectiveness depends on the given dose and how soon women gave birth. There was a significant difference between vitamin K levels in both groups as the mean level was 59.6 ± 10.1% (range 38.9–84.4) in the study group while it was 53.4 ± 9.9% (range 16.3–89.9) in the control group (P <.001). According to Normotest results, vitamin K can cross the placental barrier and activate coagulation factors until the fifth day of life [14].

Another study by *Motohara et al.* showed a significant elevation of cord blood levels in women who took vitamin K antenatally compared to women who did not take vitamin K antenatally [15]. On the other hand, *Shearer et al.* mentioned in their review that some researchers believe in a notion of the placental barrier to Vitamin K (phylloquinone) as the average maternal/neonatal cord's Vitamin K concentration gradient is within 20:1 to 40:1, and they suggest no effect to maternal vitamin K supplementation [16].

Shahrook et al. performed a meta-analysis to evaluate the effect of supplementing pregnant women with vitamin K, even alone or put together with other nutrients. Researchers meta-analyzed neonatal bleeding (RR 1.16, 95% CI 0.59-2.29; P=0.67) and maternal plasma vitamin K (mean difference 2.46, 95% CI 0.98-3.93; P=0.001). They revealed that many outcomes were not assessed, such as perinatal death,

maternal bleeding, and healthcare utilization. In particular, newborns were included when vitamin K was significantly efficient, e.g., serum vitamin K (maternal and neonatal) and maternal breast milk [8].

Few trials found adverse neonatal morbidities. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) evidence was very low for neonatal bleeding, neonatal jaundice, maternal plasma vitamin K. Also, Adaramodu and Venyo stated that the use of vitamin K in higher doses in late pregnancy and labour may increase the risks of neonatal hemolytic anemia, hyper-bilirubinaemia, and kernicterus [17].

Although the intervention was advantageous for maternal vitamin K, neonatal bleeding and other outcomes are still doubtful. There was a significant difference between vitamin K and control groups concerning neonatal plasma vitamin K. Neonatal cord vitamin K levels recorded significant group differences between vitamin K and placebo groups (43.2 pg/ml vs. <20 pg/ml, P<0.01). Vitamin K levels were significantly higher in cord plasma intervention samples [8]. According to their review, although vitamin K supplementation improved maternal plasma vitamin K status, it exhibited no advantages for reducing neonatal bleeding. Antenatal vitamin K brought beneficial effects for many other outcomes, e.g., cord serum vitamin K, maternal-newborn vitamin K-dependent factors, breast milk vitamin K [8]. Vitamin K levels in maternal sera and in cord sera showed a significant correlation, with a large gradient (mostly < one-tenth) [15]. Also, vitamin K in the supplemented cord sera was reported to be very fading, 2.5 times below the lower normal adult range, 60 times fewer than the equal maternal values [18]. Although levels of vitamin K were high in maternal sera, it remained non-detectable (<20 pg/ml) for placebo mothers and cord samples [15]. Thus, researchers

suggested that the placental barrier is an important consideration for vitamin K transportation to newborns. Its levels were significantly higher in treated women than in control women. In addition, neonatal cord vitamin K concentration was also significantly higher in treated women [8].

Assessing maternal plasma vitamin K levels at delivery revealed a significant increase in treated women. Therefore, vitamin K supplementation was suggested to enhance maternal osteocalcin carboxylation, including newborns, especially since women's vitamin K levels are dropped during the third trimester. They concluded that vitamin K supplementation reflects a hugely significant improvement in blood coagulation factors in mother and newborn [8]. Elalfy et al. stated that Vitamin K prophylaxis at birth and even to mothers at imminent risk of preterm labour is mandatory. Also, El-Ganzoury et al. recommended antenatal vitamin K administration for pregnant women at imminent risk of preterm labour to prevent early- onset vitamin K deficiency bleeding [19, 20]. Pregnant women with cystic fibrosis, celiac disease, or consuming anticonvulsant drugs are advised to have VK either 2 or 4 weeks before delivery [8].

On the other hand, a study by *Pacifici et al.* examined cord blood samples at delivery for PT, APTT, factor II, and protein C activity, and antigen levels. There were no significant differences for PT, APTT, factor II, and protein C in newborns of mothers treated by vitamin K antenatally versus mothers who did not. Thus, they suggested no significant effect of antenatal vitamin K maternal supply before 32 weeks gestation on fetal levels of vitamin K-dependent coagulation factors [21].

Since 1961 the American Academy of Pediatrics has recommended a single intramuscular dose of 0.5-1 mg of vitamin K for all neonates to prevent vitamin K deficiency bleeding [22]. In addition, NICE guidelines stated that

vitamin K can prevent hemorrhagic disease of the newborn, and routine administration of 1 mg intramuscular vitamin K to all newborns has been recommended [23].

Conclusions

We concluded that antenatal vitamin K had a significant effect on reducing intraoperative maternal bleeding but to somewhat added no value in neonates as both PT and PC values were within normal despite of significant differences in both PT and Pc. The human diet has changed markedly during the last decades, causing deficient vitamin K deposit levels in the human body. Thus, we recommend the administration of vitamin K before elective CS.

We have some limitations in our study as it was not blinded. we only included healthy mothers with no bleeding tendency, chronic diseases, or drug intake.

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Author's contributions

EK, RA, and HH designed, supervised the study. EK, RA, K.E., BT, and HH conducted the study. RA and EK helped to perform the statistical analysis and drafted the manuscript**.** All authors have read and approved the manuscript.

Conflict of interest

The authors declare that they have no competing interests.

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Table (1) Maternal and neonatal demographic data

Item	Vitamin K group	Control group	P-value
Maternal Age (year)	27.91 ± 5.30	27.81 ± 5.20	0.893
Gestational Age (wks)	37.87 ± 0.51	37.94 ± 0.60	0.373
Neonatal Weight (kg)	2.84 ± 0.46	2.89 ± 0.48	0.460
Neonatal Sex - **Males** - **Females**	 48 (48.00%) 52 (52.00%)	 53 (53.00%) 47 (47.00%)	0.479

Table (2) Maternal clinical and laboratory data

Item	Study group	Control group	P-value
Pre-operative PT (sec)	12.42 ± 0.70	12.39 ± 0.71	0.772
Post-operative PT (sec)	11.53 ± 0.74	12.51 ± 0.79	<0.001*
Change in PT (sec)	-0.89 ± 0.14	0.12 ± 0.23	<0.001*
Pre-operative PC %	86.38 ± 7.42	85.61 ± 8.10	0.484
Post-operative PC %	88.77 ± 7.20	84.02 ± 8.12	<0.001*
Change in PC %	2.39 ± 1.90	-1.59 ± 1.13	<0.001*
Pre-operative APTT (sec)	27.03 ± 2.13	26.66 ± 2.77	0.291
Post-operative APTT (sec)	26.58 ± 2.20	27.67 ± 2.83	0.003*
Change in APTT	-0.45 ± 0.50	1.01 ± 0.81	<0.001*
Pre-operative Hematocrit	37.10 ± 2.58	37.34 ± 3.02	0.547
Post-operative Hematocrit	36.10 ± 2.75	34.93 ± 3.14	0.006*
Change in Hematocrit	-1.00 ± 0.79	-2.41 ± 1.14	<0.001*
Number of soaked gauzes	4.03 ± 0.17	5.47 ± 1.11	<0.001*
Amount of blood (cc)	339 ± 33.38	485 ± 117.16	<0.001*

***Significant**

Table (3) Neonatal clinical and laboratory data

Item	Vitamin K group	Control group	P-value
APGAR after 5 min	7.07 ± 0.81	7.04 ± 0.82	0.794
APGAR after 10 min	9.52 ± 0.52	9.51 ± 0.54	0.894
Neonatal PT (sec)	11.81 ± 1.12	12.64 ± 0.87	<0.001*
Neonatal PC %	87.40 ± 8.32	78.40 ± 8.90	<0.001*
Vit K in umbilical cord	0.10 ± 0.06	0.01 ± 0.01	<0.001*
Cases of Bleeding	0 (0.00%)	4 (4.00%)	0.043*

***Significant**

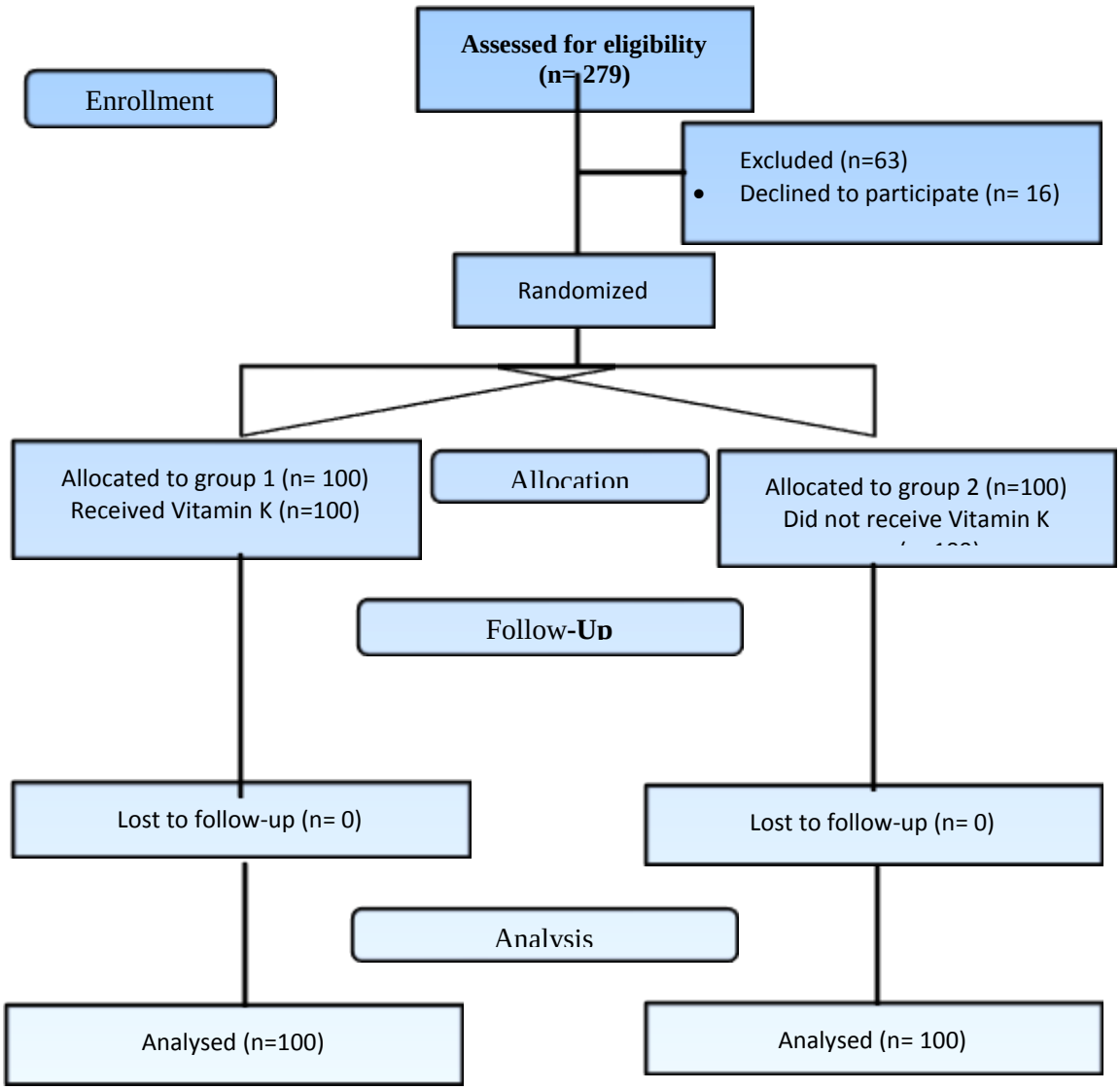
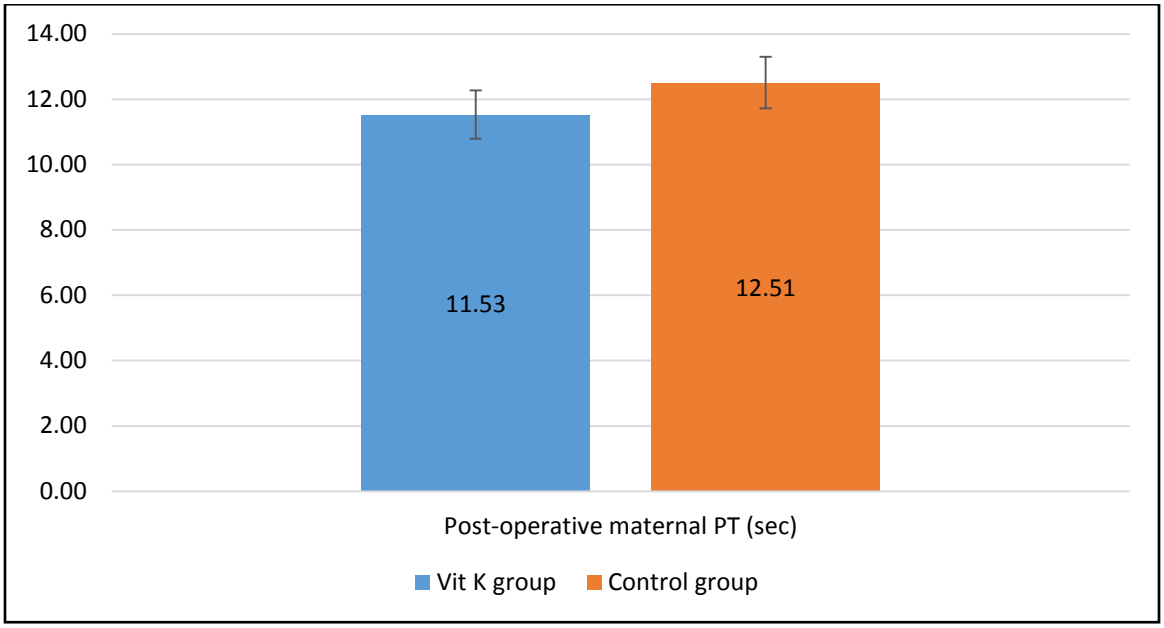


Figure (1) Flowchart of participants in the study



. Figure 2: Post-operative prothrombin time (PT) in both groups

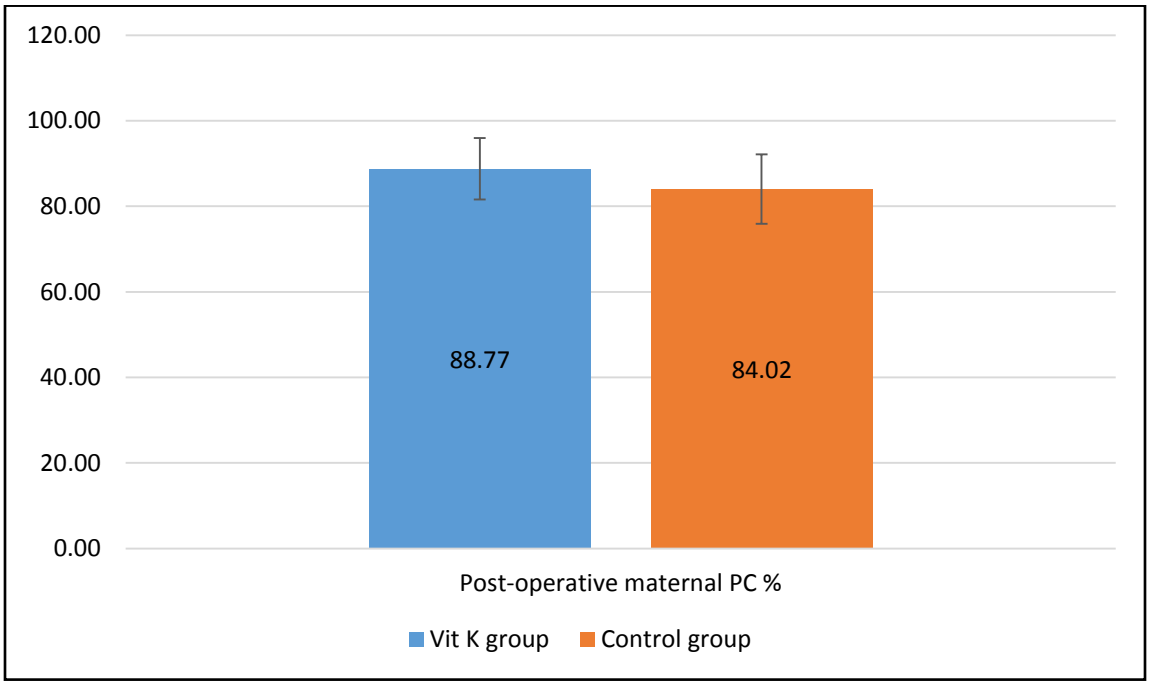


Figure 3: Post-operative prothrombin concentration (PC) in both groups.

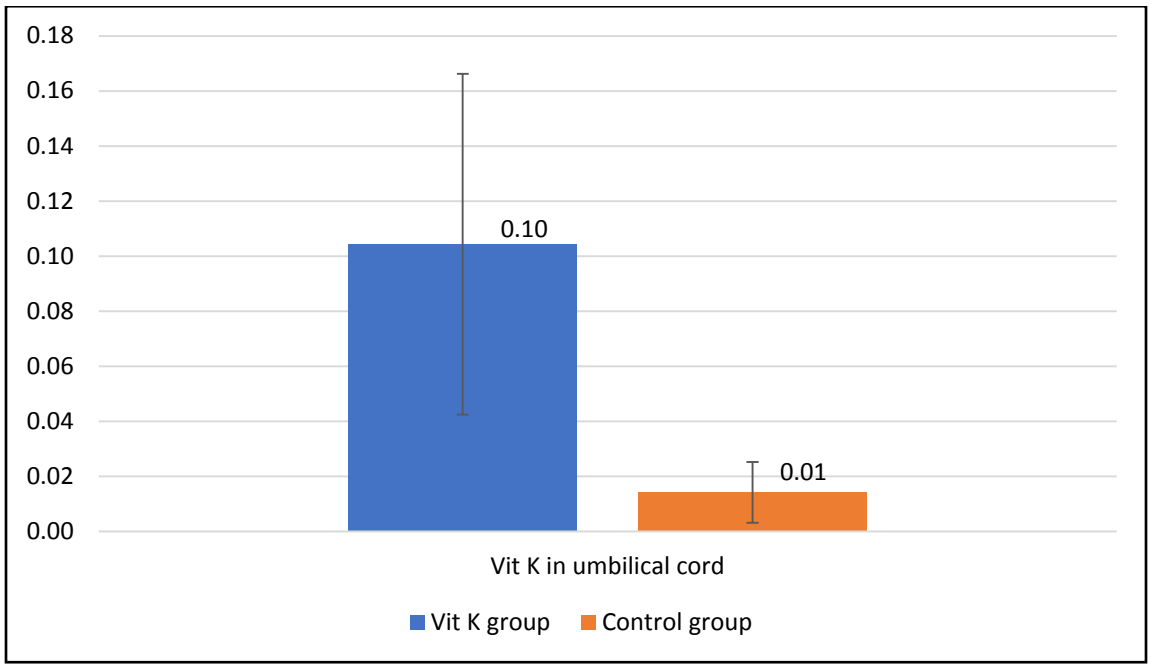


Figure 4: Cord blood vitamin K in both groups.

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