Red palm oil supplementation: A feasible diet-based approach to improve the vitamin A status of pregnant women and their infants

M. S. Radhika, P. Bhaskaram, N. Balakrishna, and B. A. Ramalakshmi

Abstract

This double-blinded, randomized, controlled study was designed to study the effect of dietary supplementation with red palm oil during pregnancy on maternal and neonatal vitamin A status. A total of 170 women were recruited at 16 to 24 weeks of gestation and randomly assigned to an experimental group that received red palm oil to supply approximately one recommended dietary amount (RDA) (2,400 µg) of β-carotene or to a control group that received an equivalent volume of groundnut oil. The women received the oils for a period of 8 weeks, starting at 26 to 28 weeks of gestation and extending to 34 to 36 weeks of gestation. The mean postintervention (34 to 36 weeks) levels of serum retinol were 1.20 ± 0.22 (SD) µmol/L (95% CI, 1.15–1.25) in women receiving red palm oil and 0.73 ± 0.15 µmol/L (95% CI, 0.69–0.77) in their infants; these levels were significantly higher than those in women receiving groundnut oil (1.07 ± 0.26 µmol/L; 95% CI, 1.01–1.13; p < .01) and their infants (0.62 ± 0.17 µmol/L; 95% CI, 0.57–0.67; p < .001). A significantly lower proportion of women in the red palm oil group than in the control group had vitamin A deficiency (serum retinol levels < 0.7 µmol/L) after intervention (1.5% vs. 9.7%). The proportion of women having anemia was significantly lower (p < .01) in the red palm oil-supplemented group (80.6%) than in the control group (96.7%). The mean birthweight and gestational age of the infants did not differ significantly between the two groups. An increased risk of low birthweight (p = .003) and preterm delivery (p = .000) was observed with decreasing serum retinol levels in the third trimester of pregnancy. These results show that red palm oil supplementation significantly improved maternal and neonatal vitamin A status and reduced the prevalence of maternal anemia. Maternal vitamin A status in the later part of pregnancy is significantly associated with fetal growth and maturation. Hence red palm oil, a rich source of bioavailable vitamin A, could be used as a diet-based approach for improving vitamin A status in pregnancy.

Key words: India, red palm oil, serum retinol, anemia, pregnant women, infant, birthweight, gestational age

Introduction

Vitamin A deficiency, defined as serum retinol < 0.7 µmol/L, has been recognized for more than two decades as a major public health problem among preschool children in the developing world [1]. However, it is only in recent years that attention has been drawn to the extent and functional significance of vitamin A deficiency during pregnancy. In Southeast Asian countries, where childhood vitamin A deficiency is a significant problem, night-blindness has also been observed in 10% to 20% of women during pregnancy [2]. Studies from India also report a prevalence of night-blindness during pregnancy ranging from 3% to 39% in different parts of the country [3–5]. We have recently reported subclinical vitamin A deficiency in 27% of pregnant women attending prenatal clinics during the later part of pregnancy, which was associated with maternal anemia and preterm delivery [5]. It has also been observed that nearly 80% of newborns have serum retinol < 0.7 µmol/L, and 30% of these breastfed infants continue to have low retinol levels throughout infancy, even after maternal supplementation with vitamin A (a single dose of 200,000 IU within 48 hours after delivery) in the postpartum period [6]. These studies suggest the need for improving the vitamin A status of women during pregnancy as well as that of newborns. Food-based approaches offer feasible, sustainable, and cost-effective strategies that are required to improve the vitamin A content of the routine diets of the population, particularly providing a safe intake of vitamin A during pregnancy. Crude
palm oil is the richest known source of carotenoids, and refined red palm oil has 17,500 mg of β-carotene per 100 g, and 28,000 mg of α-carotene per 100 g for a total of 6,140 retinol equivalents per 100 g. [7] Thus it has the potential for enriching routine diets with carotenoids. The safety, acceptability, and efficacy of red palm oil as a human food have been evaluated in supplementary feeding trials among children and lactating women [8–13]. The present study was conducted with the major objective of investigating the effect of red palm oil supplementation during pregnancy on maternal and neonatal vitamin A status. The effects of supplementation on maternal anemia, birthweight, and gestational age of newborns were also studied.

**Methods**

**Study population and selection of sample**

A randomized clinical trial of red palm oil supplementation was conducted in pregnant women attending the outpatient department of Niloufer Hospital, Hyderabad, India, between January 2001 and March 2002. A sample size of 43 in each group was required to detect a difference of 0.17 µmol/L (5 µg/dl) in serum retinol of the infants at birth between the control and experimental groups, with a significance level of \( p < .05 \), and a power of 80% using a mean of 0.63 ± 0.28 (SD) µmol/L in the cord blood, as reported in our earlier study [5]. In this study, more women than required (a total of 170) were recruited to account for an assumed dropout rate of 35% to 40%. Only women who were willing to have a follow-up every two weeks and who resided in the city area were chosen for the study. Women with recurrent pregnancy loss or earlier preterm delivery and those with diabetes, hypertension, or any other metabolic disorder were excluded. All the women were recruited between 16 and 24 weeks of gestation as confirmed by ultrasound examination. Each woman was given a serial identification number at recruitment. The women received a detailed explanation of the study, and written informed consent was obtained. Ethical approval for the study was obtained from the institutional ethical committee, the scientific advisory committee, and the Indian Council of Medical Research.

**Experimental design**

The women were randomly allocated to experimental and control groups. The supplements (CAROTINO molecular-distilled red palm oil provided by Global Palm Products, Malaysia, and groundnut oil obtained from the local market in Hyderabad) were coded as A and B. The serial identification number given at recruitment was used for random allocation of the women to one of the two supplementation groups.

The women in the experimental group received red palm oil providing 2,173 to 2,307 µg of β-carotene per day with a dosage schedule of one sachet per day (8 ml), which provided 91% to 96% of the daily requirement of vitamin A in pregnancy, i.e., 2,400 µg of β-carotene [14]. The women in the control group received one sachet of groundnut oil (8 ml). Both the red palm oil and the groundnut oil were packed and supplied in identical-appearing sachets and placed in identical-appearing boxes. A person not involved in the study did the coding, and the boxes were labeled with one of the two letter codes and handed over to the investigators. A set of 15 sachets from each box was further packed in larger polyethylene bags. A field assistant using the list of assigned random numbers and codes labeled each polyethylene bag used for dispensing the supplements with the identification number of the woman and the supplement code. Supplementation was given for a period of 8 weeks starting from 26 to 28 weeks of gestation up to 34 to 36 weeks of gestation. Enough supplements for two weeks were dispensed by the field investigator once every 15 days to the women. The women were instructed to consume the contents of one sachet with food in one sitting each day.

A detailed clinical anthropometric and obstetric examination was conducted in all the women at baseline and every 2 weeks up to 36 weeks and thereafter every week until delivery. All the women received iron-folate tablets (60 mg of iron and 500 µg of folic acid) for 100 days and routine prenatal care. The gestational age of the infant was calculated from the date of the last menstrual period and confirmed by developmental criteria at birth [15]. Infants born before 37 weeks of gestation as a result of spontaneous onset of labor were considered preterm.

**Anthropometric studies**

The mother’s height and changes in her weight were measured up to delivery. The mother’s weight was measured within 48 hours after delivery, and her body mass index (the weight in kilograms divided by the square of the height in meters) was calculated. The infant’s weight was measured to an accuracy of 10 g with a Seca lever-activated weighing balance within one hour after birth. Birthweights under 2,500 g were considered low birthweights.

**Dietary survey**

Dietary surveys by the oral questionnaire method (24-hour dietary recall) were conducted on every second woman at recruitment, using the standardized cups developed by the National Institute of Nutrition, Hyderabad [16]. The dietary intakes obtained from the standardized cups were converted into quantities.
of raw food ingredients, and the vitamin A content was computed from food-composition tables [17].

**Biochemical analysis**

Hemoglobin and serum retinol were measured in the maternal blood at baseline (2 ml of venous blood), at 26 to 28 weeks, at 34 to 36 weeks, and in the cord blood after delivery. Serum retinol was determined by reverse-phase high-performance liquid chromatography (HPLC) following the method of Bieri et al. [18], and the hemoglobin concentration was determined by the cyanmethemoglobin method of Dacie and Lewis [19]. A hemoglobin level under 110 g/L was considered to indicate anemia, according to the World Health Organization (WHO) criteria [20], and a serum retinol level under 0.7 µmol/L was considered to indicate vitamin A deficiency, according to the cutoff for pregnant women defined by the authors in an earlier study [5].

**Surveillance**

A trained field investigator visited each of the recruited women at home every week. If the woman was not available, an attempt at a second visit, and, if required, a third visit was made within the next two days. If the attempts at visitation failed, the reason for the nonavailability of the woman was recorded. The field investigator conducted surprise checks to ensure compliance with the supplement intake. Side effects, such as nausea and vomiting, were recorded. Women who failed to come for follow-up on their own were brought to the hospital from their homes by the field investigator.

**Data management**

The maternal data of each woman at recruitment, 26 to 28 weeks of gestation, and 34 to 36 weeks of gestation and the data for both the mother and her infant at delivery were entered by the tabulator using the FoxPro database, version 2.5, on a personal computer. The printout was manually checked, and entry errors were corrected.

**Statistical analysis**

Descriptive statistics, which included geometric means, prevalence rates, and 95% confidence intervals in the two groups, were computed, and the differences were tested by Student’s t-test and the normal curve proportion test (Z test) using the SPSS/PC statistical package (version 10.0). The paired t-test was used to calculate the net increase in serum retinol and hemoglobin concentrations from preintervention (26 to 28 weeks) to postintervention (34 to 36 weeks) within the same group. Analysis of covariance (ANCOVA) was used to adjust the mean values of dependent variables. Stepwise logistic regression analysis was performed to test the association of various independent maternal factors with the dependent variables birthweight (values of 1 for birthweight < 2,500 g and 0 for birthweight ≥ 2,500 g were assigned in the regression model) and gestational age of the infant (values of 1 for gestational age < 37 weeks and 0 for gestational age ≥ 37 weeks were assigned). The independent variables included in the model were age, maternal education, family income, family size, parity, postintervention serum retinol and hemoglobin values, individual weight gain from 26 to 28 weeks until delivery, and experimental group (values of 1 for the control and 0 for the red palm oil group were assigned). Values are expressed as means ± SD with 95% confidence intervals (CI) or percentages.

The flow of participants through each stage of the randomized trial is described in the flow chart (fig. 1).

**Results**

**Baseline characteristics of the women at recruitment and at 16 to 24 weeks of gestation**

The socioeconomic status, mean age (years), parity, mean height (centimeters), and mean weight were comparable between the two groups. The mean dietary intakes of vitamin A were 352.0 ± 414.6 µg/day (95% CI, 214.6–489.3 µg/day) in the red palm oil group and 289.2 ± 255.5 µg/day (95% CI, 208.0–370.5 µg/day) in the control group; the difference between the groups was not statistically significant. The mean serum retinol was comparable in the two groups, whereas the mean hemoglobin concentration was significantly higher in the red palm oil group (98.0 ± 13.2 g/L; 95% CI, 94.5–101.5 g/L) than in the control group (89.2 ± 11.7 g/L; 95% CI, 84.9–93.5 g/L; p < .01) (table 1).

**Compliance**

Of the 170 women enrolled in the study, 23 were not available for supplementation, while 18 dropped out after initiating supplementation. Of the 18 women who did not complete full supplementation, 5 in the red palm oil and 7 in the control group emigrated, and 2 in the red palm oil and 4 in the control group withdrew consent to continue the supplement because of either vomiting or nausea. Sixty-four women in the red palm oil and 58 in the control group delivered in the hospital where the neonatal measurements could be recorded. All of the characteristics of the women who dropped out, including age, parity, height, body weight, hemoglobin, and serum retinol, were comparable to those of the compliant cohort within their respective groups during the preintervention period at 26 to 28 weeks.
weeks of gestation, suggesting that the results from the compliant group were unbiased. Maternal anthropometric and biochemical data from only those women who completed the full eight weeks of supplementation (67 women receiving red palm oil and 62 in the control group) and pregnancy outcome data from 64

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**TABLE 1. Baseline characteristics of the women at 16 to 24 weeks of gestation**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Red palm oil (n = 67)</th>
<th>Control (n = 62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal education (yr)</td>
<td>5.3 ± 4.60 (4.2–6.5)</td>
<td>5.1 ± 4.45 (4.0–6.2)</td>
</tr>
<tr>
<td>Family income (Rs)</td>
<td>3,062.7 ± 1,957.41 (2,585.2–3,540.1)</td>
<td>2,724.2 ± 1,856.11 (2,252.8–3,195.6)</td>
</tr>
<tr>
<td>Family size (no.)</td>
<td>4.4 ± 2.86 (3.7–5.1)</td>
<td>4.1 ± 1.76 (3.6–4.5)</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>21.5 ± 2.74 (20.9–22.2)</td>
<td>21.6 ± 2.78 (20.9–22.3)</td>
</tr>
<tr>
<td>Parity</td>
<td>0.57 ± 0.72 (0.4–0.7)</td>
<td>0.66 ± 0.68 (0.5–0.8)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>152.3 ± 6.70 (150.6–153.9)</td>
<td>151.3 ± 6.25 (149.7–152.9)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>46.5 ± 6.81 (44.5–48.5)</td>
<td>44.5 ± 5.31 (42.8–46.1)</td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>100.4 ± 4.69 (99.0–101.8)</td>
<td>100.0 ± 3.16 (99.0–101.0)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>69.6 ± 4.19 (68.3–70.8)</td>
<td>69.0 ± 3.00 (68.1–70.0)</td>
</tr>
<tr>
<td>Hemoglobin (g/L)</td>
<td>98.0 ± 13.2 (94.5–101.5)</td>
<td>89.2 ± 11.7** (84.9–93.5)</td>
</tr>
<tr>
<td>Serum retinol (µmol/L)</td>
<td>1.24 ± 0.24 (1.17–1.31)</td>
<td>1.20 ± 0.31 (1.10–1.30)</td>
</tr>
</tbody>
</table>

*a. Values are means ± SD (95% CI).

b. Rs. 50 = US$1.

**p < .01 for the difference between the two groups.
and 58 members of the red palm oil and the control groups, respectively, were included in the final analysis. Because one maternal blood sample from the red palm oil group and three from the control group were clotted, hemoglobin could be analyzed in only 66 pairs from the red palm oil group and 59 pairs from the control group. Cord blood could be collected from 57 members of the red palm oil group and 50 members of the control group.

The acceptability of red palm oil by the pregnant women was above 90%. Reports of minor side effects, such as nausea and vomiting, were comparable in the red palm oil (6%) and control (8.9%) groups.

Serum retinol and hemoglobin profile during pregnancy and in the newborn

There was a significant decline in the mean values of serum retinol and hemoglobin at 26 to 28 weeks from the respective values at recruitment, whereas there was a subsequent significant rise by 34 to 36 weeks in both groups (figs. 2 and 3). The mean cord blood retinol level was 0.73 ± 0.15 µmol/L (95% CI, 0.69–0.77 µmol/L) in the red palm oil group and 0.62 ± 0.17 µmol/L (95% CI, 0.57–0.67 µmol/L) in the control group, which was about 50% of the respective maternal third trimester value in each of the groups. The mean hemoglobin values were higher than the respective maternal third trimester values: 123.4 ± 18.96 g/L (95% CI, 119.0–129.0 g/L) and 124.4 ± 16.69 g/L (95% CI, 119.6–129.1 g/L) in the red palm oil and control groups, respectively.

Impact of intervention in the mother

Serum retinol

The mean postintervention serum retinol was significantly higher in the red palm oil group (1.20 ± 0.22 µmol/L; 95% CI, 1.15–1.25 µmol/L) than the control group (1.07 ± 0.26 µmol/L; 95% CI, 1.01–1.13 µmol/L). The mean individual increase from preintervention to postintervention was significantly higher in the red palm oil group (0.30 ± 0.16 µmol/L; 95% CI, 0.23–0.34 µmol/L) than in the control group (0.14 ± 0.14 µmol/L; 95% CI, 0.11–0.18 µmol/L; p < .01) (table 2).

The pre- and postintervention proportions of women having serum retinol levels below 0.7 µmol/L were compared in the two groups (fig. 4). Since the proportion of women with vitamin A deficiency was similar in the two groups at the preintervention time point, the data were pooled and compared with the postintervention proportions of each of the two groups. There was a reduction of 15.6% in the prevalence of vitamin A deficiency among women with red palm oil supplementation. In the control group, there was a nonsignificant drop of 7.9% in the prevalence of vitamin A deficiency. At the end of the intervention, the red palm oil group had a significant reduction in the prevalence of vitamin A deficiency as compared with the control group.

Hemoglobin

The mean hemoglobin level was comparable in the two groups of women in both the preintervention (26 to 28 weeks of gestation) and the postintervention (34 to 36 weeks of gestation) periods after adjustment for the initial differences at baseline. The mean individual rise in the hemoglobin level from the preintervention to the postintervention period was also comparable in the two groups (table 2). The proportion of women with anemia was significantly lower in the red palm oil group than in the control group after intervention (80.6% vs. 96.7%; p < .01) (fig. 4).
**Maternal weight**

The mean gain in maternal body weight from the presupplementation period (26 to 28 weeks of gestation) until delivery was comparable in the red palm oil group (4.05 ± 2.58 kg; 95% CI, 3.42–4.69 kg) and the control group (3.83 ± 2.24 kg; 95% CI, 3.26–4.41 kg) (table 2).

**Impact of intervention in the newborn**

**Serum retinol**

The mean cord blood retinol level was higher in the red palm oil group (0.73 ± 0.15 µmol/L; 95% CI, 0.69–0.77 µmol/L) than in the control group (0.62 ± 0.17 µmol/L; 95% CI, 0.57–0.67 µmol/L; p < .001) (table 3).

**Hemoglobin**

The mean cord blood hemoglobin was comparable in the two groups: 123.4 ± 18.96 g/L (95% CI, 119.0–129.0 g/L) in the red palm oil group and 124.4 ± 16.69 g/L (95% CI, 119.6–129.1 g/L) in the control group (table 3).

**Birthweight and gestational age**

The mean birthweight and gestational age of the infants were similar in the two groups: 2,747 ± 505.20 g (95% CI, 2,621–2,873 g) and 2,666 ± 493.14 g (95% CI, 2,537–2,796 g) and 38.7 ± 2.57 weeks (95% CI, 38.1–39.4 weeks) in the control group. The mean birthweights were similar in the two groups even after adjustment for gestational age of the infant at birth. The proportions of low birthweight and preterm infants were also similar in the two groups (table 3).

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**TABLE 2. Impact of red palm oil intervention on the mother**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Before intervention (26–28 wk)</th>
<th>After intervention (34–36 wk)</th>
<th>Mean increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (g/L)</td>
<td>RPO (n = 66)</td>
<td>86.0 ± 14.09 (82.7–89.4)</td>
<td>99.5 ± 14.44*** (95.9–103.0)</td>
<td>12.8 ± 11.96</td>
</tr>
<tr>
<td></td>
<td>Control (n = 59)</td>
<td>86.4 ± 12.15 (83.3–89.5)</td>
<td>97.9 ± 10.30*** (95.3–100.6)</td>
<td>12.0 ± 11.07***</td>
</tr>
<tr>
<td>Retinol (µmol/L)</td>
<td>RPO (n = 67)</td>
<td>0.90 ± 0.19 (0.85–0.95)</td>
<td>1.20 ± 0.22*** (1.15–1.25)</td>
<td>0.30 ± 0.16*</td>
</tr>
<tr>
<td></td>
<td>Control (n = 62)</td>
<td>0.93 ± 0.23 (0.87–0.99)</td>
<td>1.07 ± 0.26* (1.01–1.13)</td>
<td>0.14 ± 0.14b</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>RPO (n = 67)</td>
<td>49.2 ± 7.24 (47.5–51.0)</td>
<td>53.2 ± 8.75 (51.2–55.3)</td>
<td>4.05 ± 2.58a</td>
</tr>
<tr>
<td></td>
<td>Control (n = 62)</td>
<td>48.0 ± 5.70 (46.5–49.4)</td>
<td>51.8 ± 6.85 (50.1–53.5)</td>
<td>3.83 ± 2.24a</td>
</tr>
</tbody>
</table>

a. Values are means ± SD (95% CI). RPO, Red palm oil. A difference in superscripts indicates a significant difference (p < .01) between the two groups.

* p < .05, *** p < .01 indicate a significant difference within the same group from the preintervention to the postintervention period.

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**TABLE 3. Impact of red palm oil intervention on the newborn**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Red palm oil</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cord retinol (µmol/L)</td>
<td>0.73 ± 0.15*** (0.69–0.77) (n = 57)</td>
<td>0.62 ± 0.17 (0.57–0.67) (n = 50)</td>
</tr>
<tr>
<td>Cord hemoglobin (g/L)</td>
<td>123.4 ± 18.96 (119.0–129.0) (n = 57)</td>
<td>124.4 ± 16.69 (119.6–129.1) (n = 50)</td>
</tr>
<tr>
<td>Mean birthweight (g)</td>
<td>2747 ± 505.20 (2,621–2,873) (n = 64)</td>
<td>2666 ± 493.14 (2,537–2,796) (n = 58)</td>
</tr>
<tr>
<td>% low-birthweight infants (&lt; 2.5 kg)</td>
<td>15.6 (8.7–26.4) (n = 64)</td>
<td>20.7 (12.2–32.8) (n = 58)</td>
</tr>
<tr>
<td>Mean gestational age (wk)</td>
<td>39.2 ± 2.22 (38.6–39.7) (n = 64)</td>
<td>38.7 ± 2.57 (38.1–39.4) (n = 58)</td>
</tr>
<tr>
<td>% preterm infants (&lt; 37 wk)</td>
<td>13.6 (7.4–24.0) (n = 64)</td>
<td>18.6 (10.8–30.4) (n = 58)</td>
</tr>
<tr>
<td>Mean birthweight (g) (after adjustment for gestation)</td>
<td>2720 ± 384.0 (2,625–2,815) (n = 64)</td>
<td>2696 ± 381.0 (2,597–2,796) (n = 58)</td>
</tr>
</tbody>
</table>

a. Values are means ± SD (95% CI).

*** p < .001
When the data were analyzed by stepwise logistic regression to study the association between the dependent variables, birthweight and gestational age of the infant, separately and the independent variables (age, maternal education, family income, family size, parity, individual weight gain from 26 to 28 weeks of gestation until delivery, postintervention serum retinol and hemoglobin values, and experimental group), the risk of low birthweight (odds ratio [OR], 0.857; 95% CI, 0.77–0.95; \( p = .003 \)) and preterm delivery (OR, 0.818; 95% CI, 0.74–0.91; \( p = .000 \)) decreased significantly with increasing serum retinol levels during the third trimester of pregnancy. The risk of low birthweight also decreased significantly with increasing maternal weight gain (OR, 0.687; 95% CI, 0.51–0.93; \( p = .014 \)) and parity (OR, 0.321; 95% CI, 0.12–0.87; \( p = .025 \)) (table 4).

### Discussion

We observed in this study that giving pregnant women red palm oil as a supplement providing approximately one RDA of \( \beta \)-carotene significantly improved maternal and neonatal vitamin A status. The safety of red palm oil consumption was established by toxicological and nutritional evaluation of the oil by Manorama et al. in the early 1990s [8, 9]. Since then, evidence has been provided for the health benefits of red palm oil, including supporting cardiovascular health in both experimental animals and humans [21, 22], offering antioxidant potential against certain types of cancers in experimental animals [23, 24], and preventing nutritional deficiencies, most promisingly vitamin A deficiency in children [10–12]. However, there are very few studies documenting the efficacy of maternal vitamin A supplementation in pregnancy.

There are conflicting reports on the changes in serum retinol levels at different periods of gestation. Some authors have observed a progressive decline [25–27], whereas others have observed a rise in serum retinol values with advancing gestation [28, 29]. In the present study, we observed a significant decrease in serum retinol near mid-gestation (26 to 28 weeks) compared with the earlier period of pregnancy, which again increased significantly at 34 to 36 weeks in both groups of women. These changes could be attributed to the normal plasma serum retinol volume changes in pregnancy, which reach peak expansion by 24 to 26 weeks. This expansion causes hemodilution, after which there is minimal or no further significant expansion of plasma volume until term, as demonstrated by Lund and Donovan [30].

Supplementary feeding trials in preschool children have shown that daily supplementation with red palm oil in a diet providing 2,400 µg of \( \beta \)-carotene for one month significantly improved serum retinol status [10]. Sivan et al. [12] reported a reduction in the prevalence of Bitot’s spots of 50% and significant improvement in \( \beta \)-carotene levels in preschool children when red palm oil providing 415 µg of \( \beta \)-carotene was administered daily for 10 months. There are several reports indicating beneficial effects of vitamin A supplementation during pregnancy on maternal and neonatal vitamin A status [25, 31, 32]. However, this is not universally accepted, even though daily supplements of up to 10,000 IU per day have been found to have no adverse effects and are recommended by WHO [33].

Food-based approaches to vitamin A supplementation are safe and natural and could be sustainable compared with synthetic vitamin A supplementation, especially during pregnancy. In rural Tanzanian women, maternal supplementation with 1,100 µg of \( \beta \)-carotene from red palm oil daily from the third trimester of pregnancy to the third month postpartum significantly improved maternal plasma and breastmilk \( \beta \)-carotene levels [34]. We demonstrated in this study that dietary supplementation with red palm oil providing 2,173 to 2,307 µg of \( \beta \)-carotene per day for a period of two months significantly improved the vitamin A status of the mother during pregnancy and of the infant at birth. This confirms the bioavailability and efficacy of \( \beta \)-carotene from red palm oil in pregnant women.

We also observed a significantly lower prevalence of maternal anemia at 34 to 36 weeks of gestation in the women receiving red palm oil. It has been consistently shown in both experimental animals and humans that vitamin A is essential for iron mobilization in hemat-

### Table 4. Association of maternal factors with birthweight and gestational age of the infant (logistic regression model)

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Independent variable</th>
<th>Regression coefficient (β)</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight (g)</td>
<td>Serum retinol</td>
<td>−0.155</td>
<td>0.857</td>
<td>0.77–0.95</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>Weight gain</td>
<td>−0.376</td>
<td>0.687</td>
<td>0.51–0.93</td>
<td>.014</td>
</tr>
<tr>
<td></td>
<td>Parity</td>
<td>−1.138</td>
<td>0.321</td>
<td>0.12–0.87</td>
<td>.025</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>Serum retinol</td>
<td>−0.201</td>
<td>0.818</td>
<td>0.74–0.91</td>
<td>.000</td>
</tr>
</tbody>
</table>

* a. The independent variables included in the model were age, maternal education, income, family size, parity, weight gain from 26–28 weeks until delivery, postintervention serum retinol, postintervention hemoglobin, and experimental group. Codes of 1 for birthweight < 2,500 g and 0 for birthweight > 2,500 g, and 1 for gestational age < 37 weeks and 0 for gestational age > 37 weeks, were assigned in the regression model.
the beneficial effects of supplementation of vitamin A along with iron and folic acid on hemoglobin levels in individuals with anemia have been well established [36, 37]. Suharno et al. reported that administration of 8,000 IU of vitamin A along with 60 mg of iron during pregnancy was more effective in eliminating anemia than administration of iron alone [38]. Similar results were obtained by Muslimatun et al. [39] when vitamin A was administered at weekly doses of 20,000 IU with 120 mg of iron and 500 µg of folic acid. However, Sembra et al. [40] failed to demonstrate any improvement in hemoglobin when only 30 mg of iron and 400 µg of folic acid were administered with 10,000 IU of vitamin A to a group of pregnant women with a high prevalence of anemia. In the present study, the prevalence of anemia was reduced by consumption of enough red palm oil to provide 2,173 to 2,307 µg of β-carotene per day (the RDA of β-carotene for pregnant Indian women is 2,400 µg), together with 60 mg of elemental iron and 500 µg of folic acid. This result suggests that adequate intake of both vitamin A and iron-folate is required to have a beneficial effect in anemic populations. Maternal weight gain during pregnancy was not influenced by red palm oil supplementation.

Reviews by Kramer [41] and Rush [42] indicate that a few intervention trials using dietary supplements resulted in modest increases in maternal weight gain, whereas some others did not have an impact. There is limited evidence from controlled studies of the effects of supplementation with synthetic vitamin A during gestation on pregnancy outcome [27, 31]. In these studies, supplementation significantly improved maternal and neonatal vitamin A status but had no effect on birthweight. Studies from Nepal found a 40% reduction in maternal morbidity in addition to a reduction in the prevalence of maternal vitamin A deficiency (serum retinol < 0.7 µmol/L), but no effect on birthweight [43, 44]. In the present study, because the sample size is adequate to show a difference of 250 g in birthweight (at p < .05 and 80% power), an attempt was made to examine the effect of supplementation with red palm oil as a source of bioavailable vitamin A on the birthweight and gestational age of the infants.

Stepwise logistic regression analysis showed that the risk of low birthweight and preterm delivery significantly decreased with increasing serum retinol levels during the third trimester of pregnancy, irrespective of the group to which the woman was assigned. These results support our earlier observations on the association between low serum retinol levels (< 0.7 µmol/L) during the third trimester of pregnancy and preterm delivery [6]. More research is required to explore the mechanism of the association.

The results obtained in this study show that supplementation with red palm oil as a source of bioavailable vitamin A significantly improves maternal and neonatal vitamin A status, as well as reducing the prevalence of maternal anemia. Hence, red palm oil can be used as a dietary approach to improving the vitamin A status of pregnant women and their infants.

Acknowledgments

We are grateful to Dr. Kamala Krishnaswamy, director of the National Institute of Nutrition (NIN), Hyderabad, for her keen interest in this study. We are thankful to Global Palm Products, Malaysia, for donating the red palm oil and Biological Evans, Hyderabad, for providing the facility for filling and sealing the oil sachets. We extend our thanks to Mr. A. P. Gupta of Biological Evans and Dr. Dinesh Kumar of the NIN for their help in packing the oil in sachets. We also acknowledge the invaluable technical assistance of Mrs. A. Chandrakala Omkar, technical officer, NIN, and the secretarial support of Mr. B. Surya Prakash Goud. The help rendered by Mr. Venkat Raj Reddy, field investigator, is gratefully appreciated.

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