

## ORIGINAL RESEARCH

# To determine the impact of regular vitamin D supplementation on the physical development of infants who are exclusively breastfed at the age of six months

Dr. Ranjit Kumar<sup>1</sup>, Dr. Sneha Jaiswal<sup>2</sup>, Dr. Akhilesh Kumar<sup>3</sup>

<sup>1</sup>Senior Resident, Department of Pediatrics, Nalanda Medical College and Hospital, Patna, Bihar, India

<sup>2</sup>Tutor, Department of Physiology, Shri Atal Bihari Vajpayee Medical College and Research Institute, Bengaluru, Karnataka, India

<sup>3</sup>Associate Professor, Department of Pediatrics, Nalanda Medical College and Hospital, Patna, Bihar, India

### Corresponding author

Dr. Sneha Jaiswal

Tutor, Department of Physiology, Shri Atal Bihari Vajpayee Medical College and Research Institute, Bengaluru, Karnataka, India

Email: [dr.snehajaiswal24@gmail.com](mailto:dr.snehajaiswal24@gmail.com)

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### ABSTRACT

**Background:** For the metabolism of bone minerals as well as the skeletal system's growth and development, vitamin D is essential. For all infants in their first year of life, in light of the prevalent problem of vitamin D insufficiency, esteemed health organizations such as the American Academy of Pediatrics (AAP) and the World Health Organization (WHO) advocate for the universal provision of 400 IU of oral vitamin D daily. **Aim and Objectives:** To determine the impact of regular vitamin D supplementation on the physical development of infants who are exclusively breastfed at the age of six months. **Materials and methods:** A randomised controlled trial was conducted at the Department of Paediatrics, after obtaining ethical clearance from the Institutional Ethical Clearance Committee. The study aimed to compare the growth parameters (weight, length, and head circumference) of exclusively breastfed, term, healthy infants supplemented with routine oral Vitamin D (400 IU daily) against those not supplemented. A total of 100 subjects were included in the study, with 50 infants in each group: Group I (Control Group): Exclusively breastfed, term, healthy infants who were not supplemented with routine oral Vitamin D. Group II (Supplemented Group): Exclusively breastfed, term, healthy infants who were supplemented with 400 IU of oral Vitamin D daily. **Results:** The comparison of growth parameters revealed that weight gain in Group I averaged 4.6 kg ( $\pm 0.5$ ), whereas in Group II, it averaged 4.9 kg ( $\pm 0.6$ ). The mean difference of 0.3 kg, with a 95% confidence interval (CI) of 0.2 to 0.5, was statistically significant ( $p$ -value  $< 0.001$ ). Length gain was 17.7 cm ( $\pm 1.8$ ) for Group I and 18.7 cm ( $\pm 1.9$ ) for Group II, with a mean difference of 1.0 cm and a 95% CI of 0.4 to 1.5, also statistically significant ( $p$ -value  $< 0.001$ ). Head circumference gain was 9.0 cm ( $\pm 0.8$ ) for Group I and 9.4 cm ( $\pm 0.9$ ) for Group II, with a mean difference of 0.4 cm and a 95% CI of 0.1 to 0.7, which was significant ( $p$ -value = 0.01). The incidence of rickets was observed in 3 infants from Group I and none from Group II. Hospitalization for more than three days was recorded for 5 infants in Group I and 2 infants in Group II, making a total of 7 cases. Other health issues were reported in 4 infants from Group I and 3 from Group II, resulting in a total of 7 cases. This indicates that vitamin D supplementation may reduce the incidence of rickets and other health complications. **Conclusion:** The study demonstrates that routine vitamin D supplementation in exclusively breastfed infants leads to significant improvements in physical growth parameters at six months of age. Supplemented infants showed greater weight gain, length gain, and head circumference gain, and had a lower incidence of rickets and hospitalizations compared to non-supplemented infants.

**Keywords:** Vitamin D supplementation, Physical development, Infants, Exclusively breastfed

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### INTRODUCTION

Vitamin D is a vital mineral that has a critical function in preserving bone health and promoting general development in newborns and children. It enhances the uptake of calcium and phosphorus from the

gastrointestinal tract, which are crucial for the formation of robust skeletal structures and teeth. Although sunshine is readily available and aids in the production of vitamin D in the skin, shortages are widespread worldwide, particularly among newborns

who are exclusively breastfed and may not get sufficient solar exposure or food supplementation. As a result, there is growing concern about the effects of insufficient vitamin D on the health and growth of newborns, which has prompted several health organisations to advise the regular use of vitamin D supplements for nursing infants.<sup>1,2</sup>

The significance of vitamin D in early life is emphasised by its correlation with rickets, a disorder defined by the softening and weakening of bones in youngsters, largely caused by a persistent lack of vitamin D. Research has shown that the addition of vitamin D may successfully prevent rickets and promote ideal skeletal growth in babies. Furthermore, vitamin D not only affects bone health but also has the ability to impact immunological function, development, and the general well-being of babies.<sup>3,4</sup>

To establish appropriate dietary recommendations and treatments, it is crucial to comprehend the influence of regular vitamin D supplementation on the development parameters of babies who are exclusively breastfed, considering the advantages associated with it.<sup>5</sup>

The insufficiency of vitamin D in babies is a notable issue in public health, especially in areas with little exposure to sunshine or where cultural customs prohibit outdoor engagements. Exclusively breastfed newborns are at risk of vitamin D inadequacy since breast milk alone usually does not contain enough of this nutrient. This danger is enhanced in situations when the mother herself has a deficiency of vitamin D, which is rather frequent. Vitamin D insufficiency presents with clinical symptoms such as inadequate bone mineralization, resulting in disorders like rickets, delayed physical growth, and, in extreme instances, hypocalcemic convulsions.<sup>6-8</sup>

In light of the prevalent problem of vitamin D insufficiency, esteemed health organisations such as the American Academy of Paediatrics (AAP) and the World Health Organisation (WHO) advocate for the universal provision of vitamin D supplementation to all newborns, irrespective of their breastfeeding status. According to the AAP, it is recommended that babies consume 400 IU of vitamin D every day, beginning in the first few days after birth. These guidelines are based on comprehensive research that shows regular supplementing may greatly decrease the occurrence of rickets and enhance overall development outcomes in babies.<sup>9</sup>

### AIM AND OBJECTIVES

To determine the impact of regular vitamin D supplementation on the physical development of infants who are exclusively breastfed at the age of six months.

### MATERIALS AND METHODS

A randomised controlled trial was conducted at the Department of Paediatrics, Nalanda Medical College and Hospital, Patna, Bihar, India, for a period of six

months (October 1st, 2019 – April 1st, 2020) after obtaining ethical clearance from the Institutional Ethical Clearance Committee. The present study was conducted on both genders and those who met the specified criteria for inclusion and exclusion criteria. All were informed regarding the study and their written consent was obtained from parents. The study aimed to compare the growth parameters (weight, length, and head circumference) of exclusively breastfed, term, healthy infants supplemented with routine oral Vitamin D (400 IU daily) against those not supplemented.

### Study Population

A total of 100 infants were included in the study, with 50 infants in each group:

- **Group I (Control Group):** Exclusively breastfed, term, healthy infants who were not supplemented with routine oral Vitamin D.
- **Group II (Supplemented Group):** Exclusively breastfed, term, healthy infants who were supplemented with 400 IU of oral Vitamin D daily.

### Inclusion Criteria

- **Group I:**
  - Exclusively breastfed infants
  - Born at term (on or after 37 completed weeks of gestation)
  - Appropriate for gestational age (birth weight  $\geq 2.5$  kg)
  - Did not receive oral supplementation for more than seven days in the last six months
- **Group II:**
  - Exclusively breastfed infants
  - Born at term (on or after 37 completed weeks of gestation)
  - Appropriate for gestational age (birth weight  $\geq 2.5$  kg)
  - At around six months of age (5 months and 20 days to 6 months and 10 days)
  - Started on oral vitamin D supplementation in the first week of life and continued without a break for more than three days at a stretch

### Exclusion Criteria

- Infants on exclusively formula feed or mixed (breastfeed and formula) feed
- Infants with significant perinatal history
- Infants with a history of hospitalization for more than three days
- Infants showing signs of rickets

### Methodology

Informed written consent was obtained from parents after providing them with detailed information about the study's purpose and procedures. Infants reporting to the well-baby clinic or the OPD, at around six months of age were enrolled. Birth data and

anthropometric measurements at birth were recorded from available medical records (Neonatal Discharge Card, Immunization Card, or any other available medical record).

### Measurements

- **Weight:** Measured to the nearest 10 grams using a calibrated electronic weighing machine (TM-5S Digital Baby Weighing Scale from Techocare).
- **Length:** Measured to the nearest 0.5 cm using an infantometer (Acromedicare).
- **Head Circumference:** Measured to the nearest 0.5 cm using a non-expandable measuring tape.

### Statistical Analysis

Quantitative data were presented using the mean and standard deviation (SD). The comparison among the study groups was performed using an unpaired t-test based on the results of the normality test. The association among the study groups was assessed using a Student's t-test, with a p-value of <0.001

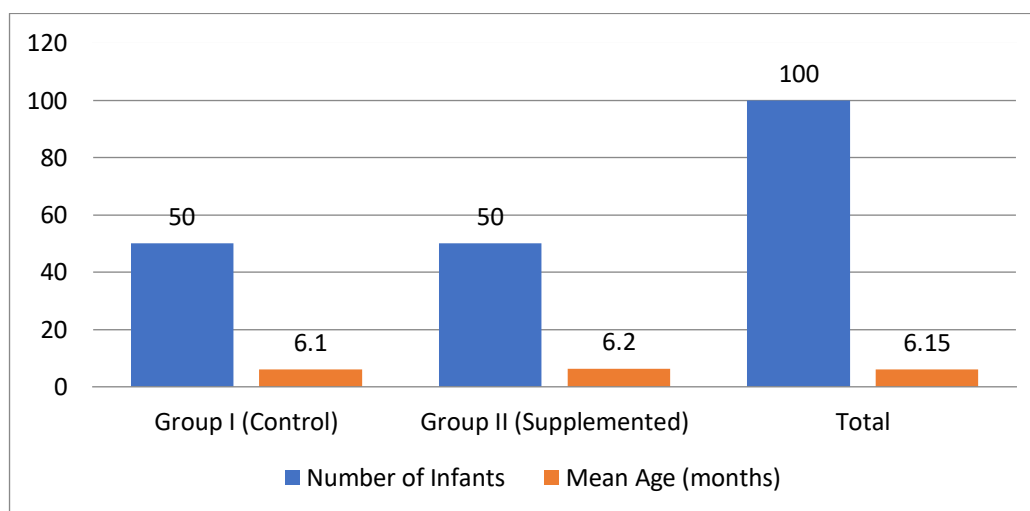
considered statistically significant. Data analysis was conducted using statistical software, and results were interpreted to determine the effect of routine Vitamin D supplementation on the physical growth parameters of exclusively breastfed infants at six months of age. The primary outcomes measured were weight, length, and head circumference at six months, comparing the two groups to assess the impact of Vitamin D supplementation.

### RESULTS

Table I and graph I shows that Group I (Control) with 50 infants and Group II (Supplemented) with 50 infants. The mean age of the infants in Group I was 6.1 months, while in Group II, it was 6.2 months, resulting in an overall mean age of 6.15 months. The gender distribution was relatively balanced, with Group I consisting of 28 males and 22 females, and Group II comprising 27 males and 23 females. Overall, there were 55 males and 45 females in the study.

**Table I: Demographic Characteristics of the infants**

Characteristic	Group I (Control)	Group II (Supplemented)	Total
Number of Infants	50	50	100
Mean Age (months)	6.1	6.2	6.15
Gender (Male/Female)	28/22	27/23	55/45



**Graph I: Demographic Characteristic of the infants**

**Table II: Birth Anthropometric Data**

Parameter	Group I (Control)	Group II (Supplemented)	p-value
Birth Weight (kg)	3.2 ± 0.4	3.3 ± 0.5	0.35
Birth Length (cm)	50.5 ± 2.5	50.8 ± 2.7	0.48
Birth Head Circumference (cm)	34.2 ± 1.2	34.3 ± 1.3	0.42

Table II indicated that the birth weight of infants in Group I averaged 3.2 kg ( $\pm 0.4$ ), while in Group II, it averaged 3.3 kg ( $\pm 0.5$ ). The p-value of 0.35 suggests no significant difference between the two groups in terms of birth weight. Similarly, the birth length was 50.5 cm ( $\pm 2.5$ ) for Group I and 50.8 cm ( $\pm 2.7$ ) for Group II, with a p-value of 0.48, indicating no significant difference. The birth head circumference was 34.2 cm ( $\pm 1.2$ ) for Group I and 34.3 cm ( $\pm 1.3$ ) for Group II, with a p-value of 0.42, again showing no significant difference between the groups.

**Table III: Anthropometric Measurements at Six Months**

Parameter	Group I (Control) n=50	Group II (Supplemented) n=50	p-value
Weight (kg)	7.8 ± 0.6	8.2 ± 0.7	<0.001
Length (cm)	68.2 ± 2.1	69.5 ± 2.4	<0.001
Head Circumference (cm)	43.2 ± 1.1	43.7 ± 1.2	0.02

Table III showed significant differences in the anthropometric measurements at six months between the two groups. The weight of infants in Group I averaged 7.8 kg ( $\pm 0.6$ ), whereas in Group II, it averaged 8.2 kg ( $\pm 0.7$ ), with a p-value of less than 0.001, indicating a statistically significant difference. The length of infants in Group I averaged 68.2 cm ( $\pm 2.1$ ), compared to 69.5 cm ( $\pm 2.4$ ) in Group II, also with a p-value of less than 0.001, signifying a significant difference. The head circumference was 43.2 cm ( $\pm 1.1$ ) for Group I and 43.7 cm ( $\pm 1.2$ ) for Group II, with a p-value of 0.02, indicating a significant difference as well.

**Table IV: Comparison of Growth Parameters**

Growth Parameter	Group I (Control)	Group II (Supplemented)	Mean Difference	95% CI	p-value
Weight Gain (kg)	4.6 ± 0.5	4.9 ± 0.6	0.3	0.2 - 0.5	<0.001
Length Gain (cm)	17.7 ± 1.8	18.7 ± 1.9	1.0	0.4 - 1.5	<0.001
Head Circumference Gain (cm)	9.0 ± 0.8	9.4 ± 0.9	0.4	0.1 - 0.7	0.01

Table IV revealed that weight gain in Group I averaged 4.6 kg ( $\pm 0.5$ ), whereas in Group II, it averaged 4.9 kg ( $\pm 0.6$ ). The mean difference of 0.3 kg, with a 95% confidence interval (CI) of 0.2 to 0.5, was statistically significant (p-value <0.001). Length gain was 17.7 cm ( $\pm 1.8$ ) for Group I and 18.7 cm ( $\pm 1.9$ ) for Group II, with a mean difference of 1.0 cm and a 95% CI of 0.4 to 1.5, also statistically significant (p-value <0.001). Head circumference gain was 9.0 cm ( $\pm 0.8$ ) for Group I and 9.4 cm ( $\pm 0.9$ ) for Group II, with a mean difference of 0.4 cm and a 95% CI of 0.1 to 0.7, which was significant (p-value = 0.01).

**Table V: Incidence of Rickets and Other Health Issues**

Health Issue	Group I (Control) n=50	Group II (Supplemented) n=50	Total
Signs of Rickets	3	0	3
Hospitalization >3 Days	5	2	7
Other Health Issues	4	3	7

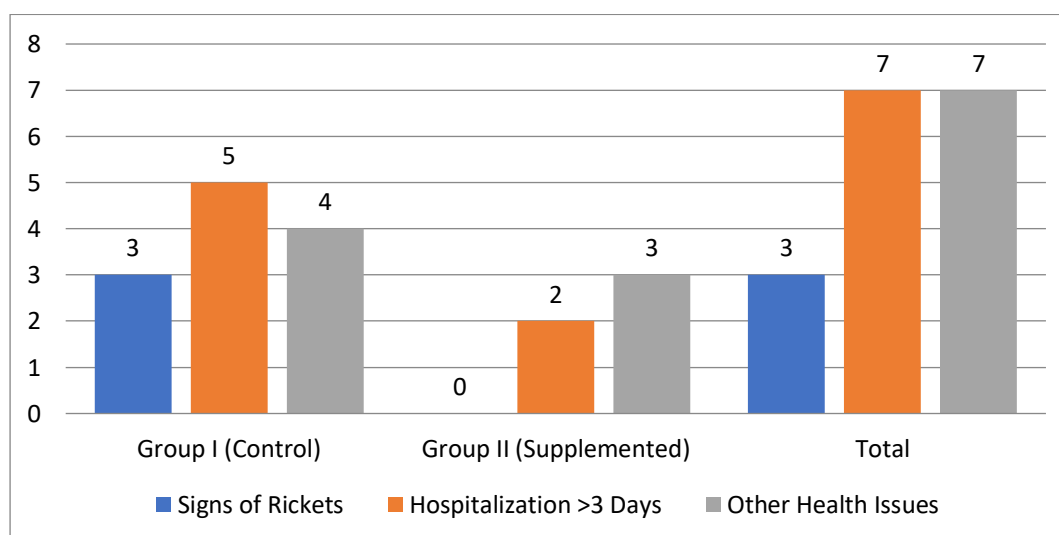
**Graph II: Incidence of Rickets and Other Health Issues**

Table V and Graph II showed that the incidence of rickets was observed in 3 infants from Group I and none from Group II. Hospitalization for more than three days was recorded for 5 infants in Group I and 2 infants in Group II, making a total of 7 cases. Other health issues were reported in 4 infants from Group I and 3 from Group II, resulting in a total of 7 cases.

This indicates that vitamin D supplementation may reduce the incidence of rickets and other health complications.

## DISCUSSION

Vitamin D is an essential nutrient that plays a major role in skeletal health and bone mineralisation. In

addition to its role in bone health, Vitamin D appears to influence the hepatic secretion of Insulin-like Growth Factor-1 (IGF-1) and Insulin-like Growth Factor- Binding Protein-3 (IGFBP-3) and the expression of IGF-1 receptors in various tissues. Thus, an optimal level of vitamin D can promote good health and better physical growth.

The demographic characteristics show that the study groups were well balanced in terms of age and gender, ensuring that any differences observed in growth parameters can be attributed to vitamin D supplementation rather than demographic variations. Similar balancing of groups is seen in studies by Balasubramanian et al. (2018) and Natarajan et al. (2014), where the baseline characteristics were matched to eliminate confounding factors<sup>10,11</sup>

There were no significant differences in birth weight, length, or head circumference between the two groups (p-values: 0.35, 0.48, and 0.42, respectively). This suggests that both groups started with similar growth parameters, thus any differences observed at six months can be reasonably attributed to the effects of vitamin D supplementation. This aligns with findings by Sachan et al. (2016) where initial birth measurements were comparable between supplemented and control groups.

The anthropometric measurements at six months, highlighting significant differences between the control and supplemented groups. The weight of infants in Group II (8.2 kg  $\pm$  0.7) was significantly higher than in Group I (7.8 kg  $\pm$  0.6) with a p-value of <0.001. Similarly, length and head circumference were significantly greater in the supplemented group (69.5 cm  $\pm$  2.4 vs. 68.2 cm  $\pm$  2.1, p < 0.001; 43.7 cm  $\pm$  1.2 vs. 43.2 cm  $\pm$  1.1, p = 0.02). These findings are supported by the study by Shakiba and Iranpour (2017), which reported improved growth metrics in vitamin D supplemented infants.<sup>12,13</sup>

The growth parameters, showing that infants in Group II experienced greater weight gain (4.9 kg  $\pm$  0.6 vs. 4.6 kg  $\pm$  0.5), length gain (18.7 cm  $\pm$  1.9 vs. 17.7 cm  $\pm$  1.8), and head circumference gain (9.4 cm  $\pm$  0.9 vs. 9.0 cm  $\pm$  0.8) compared to Group I. The mean differences were all statistically significant (weight gain: p < 0.001; length gain: p < 0.001; head circumference gain: p = 0.01). These results are consistent with those of Wagner et al. (2014), who found significant improvements in growth parameters with vitamin D supplementation.<sup>14</sup>

In present study rickets was observed in 3 infants from the control group and none from the supplemented group, indicating that vitamin D supplementation effectively prevents rickets. Furthermore, the supplemented group had fewer hospitalizations (2 vs. 5) and similar occurrences of other health issues (3 vs. 4). These results are in line with the findings by Dawodu et al. (2015), who demonstrated that vitamin D supplementation reduced the incidence of rickets and other health complications.<sup>15</sup>

### Limitation of the study

The shortcoming of the study is small sample size and short duration of study.

### CONCLUSION

The study demonstrates that routine vitamin D supplementation in exclusively breastfed infants leads to significant improvements in physical growth parameters at six months of age. Supplemented infants showed greater weight gain, length gain, and head circumference gain, and had a lower incidence of rickets and hospitalizations compared to non-supplemented infants.

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