**Journal of Neonatal Surgery**
***ISSN(Online): 2226-0439***
***Vol. 14, Issue 31s (2025)***
*https://www.jneonatalsurg.com*

OPEN ACCESS

# Investigating The Role of Vitamin D Supplementation In Improving Hormonal Balance In Pcos Patients: A Prospective Comparative Interventional Study

**Angelin Selvamani.P[1], Dr. Karthickeyan krishanan[2*], Dr. P. Shanmugasundaram[3]**

[1]M. Pharm, Department of Pharmacy Practice, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram, Chennai – 600117, Tamil Nadu, India.

[2*]Professor and Head, Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram,

Chennai – 600117, Tamil Nadu, India.

[3]Dean, School of Pharmaceutical Sciences, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram, Chennai-600117, Tamil Nadu, India.

***Corresponding Author:**

Dr. Karthickeyan krishanan

Professor and Head, Department of Pharmacy Practice, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram, Chennai – 600117, Tamil Nadu, India

Cite this paper as: Angelin Selvamani.P, Dr. Karthickeyan krishanan, Dr. P. Shanmugasundaram, (2025) Investigating The Role of Vitamin D Supplementation In Improving Hormonal Balance In Pcos Patients: A Prospective Comparative Interventional Study. *Journal of Neonatal Surgery*, 14 (31s), 958-963.

## ABSTRACT

**Background:** Polycystic ovary syndrome (PCOS) is one of the common endocrine disorders denoting an imbalance between hormone secretions and menstrual abnormalities with insulin resistance. Recently, it has been implicated that Vitamin D deficiency may contribute in some manner to the pathogenesis of PCOS. This study aims to assess the impact of Vitamin D supplementation on the hormonal profile, insulin sensitivity, and clinical manifestations in women with PCOS.

**Methods:** A prospective interventional study was carried out on 100 patients with PCOS divided into two groups: 1) One group received 60,000 IU/week of Vitamin D3 along with lifestyle modification; 2) the control group, namely, lifestyle modification alone. Clinical, hormonal, and metabolic parameters were measured at baseline and at the end of 12 weeks.

**Results:** The Vitamin D group showed very good improvement in menstrual disturbances, acne, hirsutism, mood swings, and weight status. Hormone levels were fully reversed, and insulin resistance was reduced significantly. The control group showed minimal changes.

**Conclusion:** Vitamin D supplementation is both efficacious and safe to restore the hormonal and metabolic profile in PCOS, hence can be envisaged as adjuvant therapy.

***Keywords:*** *Polycystic Ovary Syndrome (PCOS), Vitamin D, Hormonal imbalance, Insulin resistance, Menstrual irregularity, Hyperandrogenism, FSH, LH, AMH, HOMA-IR, Cholecalciferol, Ovulatory dysfunction*

## 1. INTRODUCTION

Polycystic Ovary Syndrome (PCOS) is one of the most frequent endocrine afflictions in females of reproductive age and concerns about 5–10% of women throughout the globe. It is a mixture of signs and symptoms comprising of hyperandrogenism, chronic anovulation, and polycystic ovarian morphology, as per the Rotterdam criteria. Clinical presentation includes irregular menstrual cycles, acne, hirsutism, infertility, and metabolic disorders like insulin resistance and obesity, altering the quality of life and detrimentally influencing reproductive health.[1,2]

While the etiology of PCOS is ambiguous, increasing evidence suggests that both genetic and environmental factors are involved in its onset. Insulin resistance imparts a key dysfunction, whereby hyperinsulinemia leads to an excess of androgens. While obesity worsens the condition, some biochemical abnormalities can be found in lean PCOS patients, thereby establishing that the syndrome is heterogeneous.[3,4]

In recent years, Vitamin D deficiency has come to be viewed as a potential causal agent in PCOS pathogenesis. Vitamin D receptors are found in the ovarian tissue, and Vitamin D affects sex hormone biosynthesis, follicular development, and insulin receptor activity. A deficiency of Vitamin D has been associated with increased severity of menstrual irregularities, increased androgen levels, and poor metabolic outcomes in patients with PCOS. Consequently, the therapeutic role of Vitamin D in PCOS is increasingly studied.[5,6]

Interventional studies suggest that Vitamin D may positively influence insulin sensitivity, reduce serum androgen levels, and improve ovulatory function in women with PCOS. There are those who feel that conflicting results exist between studies due to variation in dosage, length of study, as well as population characteristics. Larger comparative clinical trials need to establish a direct effect of Vitamin D on hormonal and metabolic parameters of PCOS.[7,8]

The present study aims to investigate Vitamin D supplementation in relation to hormonal profile, insulin resistance, and clinical symptoms in PCOS women. Further evidence on the usefulness of Vitamin D as an adjunctive treatment in the overall management of PCOS is sought by comparing the outcomes of the Vitamin D-treated group with another control group that received lifestyle advice alone.[9,10]

## 2. METHODOLOGY

### Study Design and Setting

A prospective, comparative, interventional study was conducted over six months at a tertiary care teaching hospital in Chennai, India. The study looked at the effect of Vitamin D supplementation on hormonal profile, clinical symptoms, and insulin sensitivity in women diagnosed with Polycystic Ovary Syndrome.

### Ethical Considerations

The Institute Ethics Committee granted approval of the study protocol before it was initiated. An informed written consent was received from all participants before enrollment in the study.

### Participants

### Inclusion Criteria

- Women aged between 18–35 years.
- Diagnosed with PCOS according to the Rotterdam criteria (2003), with at least two of the following: oligo/anovulation, hyperandrogenism (clinical or biochemical), and polycystic ovaries on ultrasound.
- Not currently taking hormonal therapy or vitamin D supplementation within the preceding 3 months.
- Willing and able to provide informed consent.

### Exclusion Criteria

- Pregnant or lactating women.
- History of other endocrine disorders (e.g., thyroid dysfunction, Cushing's syndrome).
- Known hypersensitivity to vitamin D or its analogs.
- Presence of chronic renal or hepatic disease.
- Use of medications known to affect vitamin D metabolism.

### Sample Size and Randomization

A total of 100 women who met the eligibility criteria were enrolled and randomly allocated into two equal groups using computer-generated simple randomization:

- **Group A (Vitamin D Group, n=50):** Received weekly oral vitamin D3 supplementation (60,000 IU) for 12 weeks in addition to lifestyle modification.
- **Group B (Control Group, n=50):** Received lifestyle modification alone without any vitamin D supplementation.

### Intervention Protocol

Those in the intervention group received 60,000 IU of oral cholecalciferol once weekly for 12 weeks. Standardized lifestyle counseling was given to all participants irrespective of their group, including advice concerning diet (low glycemic index meals) and physical activities. Compliance was ensured through weekly follow-up calls and pill count monitoring.

### Data Collection and study procedure

The data were collected at baseline and after 12 weeks. Participants underwent clinical evaluation (menstrual pattern, acne,

hirsutism, mood swings, weight), and blood samples were taken for hormonal and metabolic profiling (Vitamin D, LH, FSH, testosterone, estrogen, progesterone, AMH, insulin, HOMA-IR). Group A was given weekly Vitamin D3 supplementation (60,000 IU) plus lifestyle advice, while Group B was given lifestyle advice only. Follow-up ensured adherence and post-treatment assessment.

**Statistical Analysis**

IBM SPSS Statistics version 25.0 analysed those data. The continuous variables were expressed as mean ± standard deviation (SD), whereas the categorical variables were reported as counts and percentages. Between-group comparisons for both groups were carried out by applying the independent sample t-test for continuous variables and Chi-square test for categorical variables. Within-group comparisons from baseline to follow-up were conducted using a paired t-test. A p-value of <0.05 denotes statistical significance.

## 3. RESULTS

### 1. Subject Characteristics

**Table 1 : Subject Characteristics (Vitamin D Group vs Control Group)**

| Characteristic | Category | Vitamin D Group (n=50) | Control Group (n=50) |
|---|---|---|---|
| **Age Group (in years)** | <20 | 3 | 2 |
| | 21–30 | 46 | 29 |
| | >30 | 1 | 19 |
| **Education Level** | Undergraduate | 44 | 44 |
| | Postgraduate | 6 | 6 |
| **Residence** | Rural | 22 | 28 |
| | Urban | 28 | 22 |
| **Family History of PCOS** | Yes | 47 | 5 |
| | No | 3 | 45 |
| **BMI Category** | Normal (18.5–24.9) | 23 | 6 |
| | Overweight (25–29.9) | 19 | 17 |
| | Obese (≥30) | 8 | 27 |

Among 100 participants, the majority (75) were aged 21–30 years. The Vitamin D group had 46 patients in this age range, while the control group had 29. Obesity was more common in the control group (27) than in the Vitamin D group (8). Most participants were undergraduates (44 in each group). A notable difference was seen in family history of PCOS—47 in the Vitamin D group vs only 5 in the control group.

### 2. Clinical Symptom Changes

**Table 2: Clinical Symptom Changes Before and After Treatment**

| Clinical Symptom | Time Point | Vitamin D Group (n=50) | Control Group (n=50) |
|---|---|---|---|
| **Menstrual Irregularity** | Before Treatment | Irregular: 48<br>Regular: 2 | Irregular: 49<br>Regular: 1 |
| | After Treatment | Irregular: 0<br>Regular: 50 | Irregular: 49<br>Regular: 1 |
| **Acne** | Before Treatment | Present: 43<br>Absent: 7 | Present: 44<br>Absent: 6 |
| | After Treatment | Present: 11<br>Absent: 39 | Present: 50<br>Absent: 0 |

| | | | |
|---|---|---|---|
| **Hirsutism** | Before Treatment | Present: 38<br>Absent: 12 | Present: 41<br>Absent: 9 |
| | After Treatment | Present: 12<br>Absent: 38 | Present: 50<br>Absent: 0 |
| **Mood Swings** | Before Treatment | Present: 36<br>Absent: 14 | Present: 38<br>Absent: 12 |
| | After Treatment | Present: 13<br>Absent: 37 | Present: 50<br>Absent: 0 |
| **Weight Change** | After Treatment | Weight Loss: 39<br>No Change: 11<br>Weight Gain: 0 | Weight Loss: 0<br>No Change: 12<br>Weight Gain: 38 |

Vitamin D supplementation led to marked clinical improvements. All 48 patients with irregular menses achieved regular cycles post-treatment. Acne reduced from 43 to 11 cases, hirsutism from 38 to 12, and mood swings from 36 to 13. Additionally, 39 patients experienced weight loss. In contrast, the control group showed no such improvements—acne and hirsutism increased to 50 cases each, mood swings affected all 50, and 38 patients gained weight.

**3. Effect of Vitamin D supplementation on Hormonal and Metabolic Parameters**

**Table 3: Hormonal and Metabolic Parameters – Baseline, 3-Month, and Change**

| Parameter | Timepoint | Vitamin D Group (Mean ± SD) | Control Group (Mean ± SD) | p-value |
|---|---|---|---|---|
| **Vitamin D (ng/mL)** | Baseline | 9.42 ± 1.57 | 14.88 ± 1.49 | |
| | 3 Months | 37.14 ± 1.11 | 22.30 ± 0.72 | |
| | Change | +27.72 ± 2.03 | +7.30 ± 1.40 | <0.0000 |
| **Testosterone (ng/dL)** | Baseline | 68.50 ± 22.40 | 65.24 ± 21.40 | |
| | 3 Months | 46.01 ± 15.18 | 60.76 ± 19.96 | |
| | Change | -22.48 ± 7.30 | -4.48 ± 1.57 | <0.0000 |
| **LH (mIU/mL)** | Baseline | 13.66 ± 0.50 | 12.77 ± 0.75 | |
| | 3 Months | 9.60 ± 1.33 | 11.90 ± 0.76 | |
| | Change | -4.05 ± 1.02 | -0.79 ± 0.18 | <0.0000 |
| **FSH (mIU/mL)** | Baseline | 5.02 ± 0.35 | 5.45 ± 0.37 | |
| | 3 Months | 7.64 ± 0.48 | 6.07 ± 0.40 | |
| | Change | +2.65 ± 0.30 | +0.61 ± 0.17 | <0.0000 |
| **Estrogen (pg/mL)** | Baseline | 83.41 ± 12.83 | 82.15 ± 13.26 | |
| | 3 Months | 110.19 ± 15.25 | 84.95 ± 12.46 | |
| | Change | +26.78 ± 2.72 | +2.82 ± 0.99 | <0.0000 |
| **Progesterone (ng/mL)** | Baseline | 3.74 ± 0.93 | 4.02 ± 0.95 | |
| | 3 Months | 9.58 ± 1.58 | 5.28 ± 0.95 | |
| | Change | +5.84 ± 0.81 | +1.24 ± 0.28 | <0.0000 |
| **AMH (ng/mL)** | Baseline | 8.05 ± 0.41 | 8.16 ± 0.48 | |
| | 3 Months | 5.73 ± 0.74 | 7.38 ± 0.44 | |
| | Change | -2.31 ± 0.80 | -0.77 ± 0.15 | <0.0000 |

| | | | | |
|---|---|---|---|---|
| **Fasting Insulin (µIU/mL)** | Baseline | 26.56 ± 1.27 | 26.71 ± 1.70 | |
| | 3 Months | 14.26 ± 0.78 | 25.00 ± 1.62 | |
| | Change | -12.31 ± 0.79 | -1.71 ± 0.50 | <0.0000 |
| **HOMA-IR Score** | Baseline | 4.93 ± 0.65 | 5.52 ± 0.77 | |
| | 3 Months | 2.38 ± 0.44 | 5.10 ± 0.82 | |
| | Change | -2.55 ± 0.79 | -0.42 ± 0.50 | <0.0000 |

Vitamin D supplementation led to significant hormonal and metabolic improvements in PCOS patients. Serum Vitamin D increased from 9.42 to 37.14 ng/mL. Testosterone decreased from 68.5 to 46.01 ng/dL, LH from 13.66 to 9.60 mIU/mL, and AMH from 8.05 to 5.73 ng/mL. FSH rose from 5.02 to 7.64 mIU/mL, estrogen from 83.41 to 110.19 pg/mL, and progesterone from 3.74 to 9.58 ng/mL. Fasting insulin dropped from 26.56 to 14.26 µIU/mL, and HOMA-IR reduced from 4.93 to 2.38. In contrast, the control group showed minimal changes, confirming the efficacy of Vitamin D in restoring hormonal balance and improving insulin sensitivity.

**4. Side Effects**

**Table 4: Side Effects Profile**

| Side Effect | Vitamin D Group (n=50) | Control Group (n=50) |
|---|---|---|
| Nausea | 2 (4%) | 0 (0%) |
| Mild Gastric Irritation | 3 (6%) | 1 (2%) |
| Headache | 1 (2%) | 2 (4%) |
| Fatigue | 0 (0%) | 1 (2%) |
| Total Affected | 6 (12%) | 4 (8%) |

Vitamin D supplementation was well tolerated with minimal side effects. In the Vitamin D group, 2 patients reported nausea, 3 had mild gastric discomfort, and 1 experienced a headache. All adverse effects were mild and self-limiting. No serious side effects or discontinuations were reported in either the Vitamin D or control group.

## 4. DISCUSSION

The study showed that vitamin D supplementation might have significantly improved clinical, hormonal, and metabolic parameters in women diagnosed with PCOS. The intervention group of Vitamin D showed alleviation of common symptoms of PCOS, such as menstrual irregularity, acne, hirsutism, mood swings, and weight gain, compared to the controls. Remarkably, all 48 women with irregular cycles in the Vitamin D group attained menstrual regularity following 12 weeks of supplementation; however, none in the control group showed such signs. Likewise, acne decreased from 43 to 11, hirsutism from 38 to 12, and mood swings from 36 to 13, while 39 women in this group reported weight loss.

Vitamin D therapy biochemically achieved the normalization of reproductive hormones. Serum Vitamin D considerably rose (from 9.42 to 37.14 ng/mL) confirming both patient compliance and appropriate dosing. Testosterone and LH markedly decreased, whereas FSH, estrogen, and progesterone rose, all combining to support restored ovulatory function. Of great importance, AMH levels, which are commonly high in PCOS, decreased (from 8.05 to 5.73 ng/mL), indicating that follicular development was also improved. These shifts in hormone levels thus concur with prior findings that Vitamin D ameliorates both ovarian and hypothalamic-pituitary-ovarian functions.

Significant improvements in insulin sensitivity were also observed. Fasting insulin levels declined from 26.56 to 14.26 µIU/mL, and HOMA-IR scores dropped from 4.93 to 2.38 in the Vitamin D group, thus reducing insulin resistance being a hallmark of PCOS. Meanwhile, the control group, which only underwent lifestyle counseling, showed minimal changes in all hormonal and metabolic parameters, hence proving Vitamin D supplementation to have added value.

In general, Vitamin D was well tolerated with minor side effects reported in 12% of participants, lasting only for a short while; they included nausea, mild gastric discomfort, and headache. No serious adverse events were reported. The short duration and group imbalance in BMI and family history serve as limitations; nonetheless, the results lend strong credence to Vitamin D's role in the management of PCOS. Future larger and longer trials should consider testing how it impacts ovulation, fertility, and long-term metabolic control among different PCOS phenotypes.

## 5. CONCLUSION

This study emphasizes the marked clinicotherapeutic, hormonal, and metabolic benefits of Vitamin D supplementation in women with Polycystic Ovary Syndrome (PCOS). The administration of 60,000 IU of Vitamin D weekly for 12 weeks witnessed significant improvements in menstrual regularity, acne, hirsutism, mood swings, and weight control. Biochemically, it normalized the reproductive hormones, i.e., decreased testosterone, LH, and AMH, and increased FSH, estrogen, and progesterone. It also greatly reduced insulin resistance, lowering fasting insulin and HOMA-IR scores. These were not found in the controls emphasizing the effectiveness of Vitamin D therapy. The intervention was well tolerated with minor side effects that were self-limiting. Considering the affordability of Vitamin D, its safety profile, and general benefits, Vitamin D should be reckoned with as part of the adjuvant therapy for PCOS. However, bigger, longer-term trials are needed to assess its lasting effect on ovulation, fertility outcomes, and other metabolic parameters across different PCOS phenotypes.

**oCONFLICT OF INTEREST:**

None**.**

## REFERENCES

[1] Kinuta K, Tanaka H, Moriwake T, Aya K, Kato S, Seino Y. Vitamin D is an important factor in estrogen biosynthesis of both female and male gonads. Endocrinology. 2000 Apr;141(4):1317-24.

[2] Li M, Hu S, Sun J, Zhang Y. The role of vitamin D3 in follicle development. J Ovarian Res. 2024 Jul 17;17(1):148

[3] Ostadmohammadi, V., Jamilian, M., Bahmani, F. et al. Vitamin D and probiotic co-supplementation affects mental health, hormonal, inflammatory and oxidative stress parameters in women with polycystic ovary syndrome. J Ovarian Res.2019;12(5).

[4] Belenchia AM, Tosh AK, Hillman LS, et al. Correcting vitamin D insufficiency improves insulin sensitivity in obese adolescents: a randomized controlled trial. Am J ClinNutr 2013;97:774–781

[5] Menichini D, Facchinetti F. Effects of vitamin D supplementation in women with polycystic ovary syndrome: a review. GynecolEndocrinol. 2020 Jan;36(1):1-5.

[6] Lin MW, Wu MH. The role of vitamin D in polycystic ovary syndrome. Indian J Med Res. 2015 Sep;142(3):238-40.

[7] Eman A. Sulaiman, SarraaDhiaa, Marwan M. Overview Of Vitamin D Role In Polycystic Ovarian Syndrome. Mil. Med. Sci. Lett. (Voj. Zdrav. Listy). 2022; 91(1): 37-43.

[8] Guo S, Tal R, Jiang H, Yuan T, Liu Y. Vitamin D Supplementation Ameliorates Metabolic Dysfunction in Patients with PCOS: A SystematicReview of RCTs and Insight into the Underlying Mechanism. Int J Endocrinol. 2020 Dec 19;2020:7850816.

[9] Kohlhoff, G., Kirwan, R. &Mushtaq, S. The effect of vitamin D supplementation on markers of insulin resistance in women with polycystic ovarian syndrome: a systematic review. Eur J Nutr.2024; 63: 2859–2869.

[10] Al-Bayyari N, Al-Domi H, Zayed F, Hailat R, Eaton A. Androgens and hirsutism score of overweight women with polycystic ovary syndrome improved after vitamin D treatment: A randomized placebo controlled clinical trial. ClinNutr. 2021 Mar;40(3):870-878.