

## Vitamin D Supplementation Potentiates the Clinical Benefits of Metformin and Pioglitazone in Indian Women with Polycystic Ovary Syndrome

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**Abstract :** Accumulating evidence suggests that Vitamin D deficiency (VDD) might at least contribute to the metabolic comorbidities in PCOS. Hence, we aimed to study the effect of vitamin D supplementation in co-prescription with insulin sensitizers like metformin and pioglitazone on clinical, hormonal and metabolic parameters in women with PCOS. In this open label randomized, controlled trial a total of 120 women with PCOS diagnosis (AE-PCOS 2009 Criteria) were assigned to four treatment groups (n= 30 in each): group I (metformin 1 gm/day in combination with cholecalciferol 4000 IU/day), group II (pioglitazone 30 mg/day in combination with cholecalciferol 4000 IU/day), group III (metformin 1 gm /day) and group IV (pioglitazone 30 mg/day). Vitamin D supplementation was given as 60,000 units every two weeks for 24 weeks. All the subjects were routinely evaluated for clinical, biochemical, hormonal and insulin sensitivity parameters in addition to various safety parameters especially serum calcium levels at baseline and after 24 weeks of the treatment. Our results indicate that 95.5% of PCOS women were vitamin D deficient at baseline. Serum 25 (OH) D levels increased significantly ( $p < 0.001$ ) in groups I and II without any adverse effects after 24 weeks of oral administration of 4000 IU cholecalciferol daily. However, serum 25 (OH) D levels remained unchanged in group III and IV. By six months, number of menstrual cycles per year increased whereas Ferriman-Gallwey score, serum total testosterone and HOMA-IR decreased significantly ( $P < 0.001$ ) in the treatment groups supplemented with cholecalciferol as compared to those treated either drug alone. No significant beneficial changes were observed on weight, BMI, blood pressure, glucose tolerance and serum lipids in any of the groups supplemented with cholecalciferol. We conclude that daily dose of 4000 IU cholecalciferol might be a useful adjunct in complex treatment of PCOS with fewer adverse events. Furthermore, pioglitazone and cholecalciferol combination seems to be marginally better although there was no statistical significance.

**Keywords :** PCOS, vitamin D supplementation, insulin resistance, spironolactone, metformin, pioglitazone

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