

Original Article

## Evaluating the impact of Vitamin D deficiency on analgesic use in primary dysmenorrhoea: A correlation study

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### ABSTRACT

**Objectives:** The study aimed to determine the relationship between serum Vitamin D levels and primary dysmenorrhoea severity, as well as the efficacy of Vitamin D3 supplementation in reducing the concurrent use of analgesics in women with primary dysmenorrhoea.

**Materials and Methods:** For 8 weeks, 65 participants with primary dysmenorrhoea and a Vitamin D insufficiency aged 14–40 received Vitamin D3 supplements once a week. The level of serum Vitamin D was measured at baseline and after 8 weeks. In this study, the Working ability, intensity, location, days of pain, dysmenorrhoea (WaLIDD) score for the severity of dysmenorrhoea and the use of analgesic medicine was assessed at baseline, 4 weeks and 8 weeks.

**Results:** Eight weeks after starting the Vitamin D3 supplementation, serum Vitamin D levels increased significantly from  $19.13 \pm 5.86$  ng/mL to  $41.65 \pm 8.85$  ng/mL ( $P < 0.001$ ). At 8 weeks, the WaLIDD score, which gauges the severity of dysmenorrhoea, significantly improved ( $9.92 \pm 1.49$ – $6.54 \pm 1.54$ ;  $P < 0.001$ ) after the intervention. Moreover, the amount of analgesic medications required for each menstrual cycle was significantly reduced after 8 weeks ( $3.86 \pm 1.56$  at  $0.85 \pm 1.46$  at 8 weeks;  $P < 0.001$ ). However, there was no significant correlation seen in relation to serum Vitamin D levels and pain thresholds.

**Conclusion:** In the final analysis, the overall favourable outcomes indicate that Vitamin D therapy may serve as a supportive treatment for primary dysmenorrhoea.

**Keywords:** Analgesic use, Correlation study, Primary dysmenorrhoea, Vitamin D deficiency

### INTRODUCTION

Primary dysmenorrhoea, characterised by debilitating menstrual cramps in the absence of underlying pelvic pathology, represents a significant public health concern affecting a substantial proportion of the female population. Global prevalence estimates range from 16% to 91%, with peak incidence occurring during adolescence and young adulthood.<sup>[1]</sup> These severe cramps demonstrably disrupt daily life, impacting school, work and overall well-being.<sup>[2]</sup>

Conventionally, management of primary dysmenorrhoea has primarily relied on pharmacological interventions, particularly non-steroidal anti-inflammatory drugs (NSAIDs). While these medications offer effective pain relief, concerns regarding their potential side effects, particularly with prolonged or high-dose use, necessitate exploration of alternative strategies.<sup>[3]</sup>

Gastrointestinal distress, cardiovascular complications and renal dysfunction are some of the documented adverse effects associated with NSAIDs. Consequently, there is growing interest in investigating non-pharmacological approaches for managing dysmenorrhoea.<sup>[4]</sup>

Recent studies have indicated that Vitamin D may have a possible impact on reducing menstrual pain. The presence of Vitamin D receptors within the female reproductive system, including the endometrium and ovaries, suggests a plausible connection between Vitamin D status and menstrual function. The anti-inflammatory properties of Vitamin D, which are mediated by decreased cytokine levels such as IL-6 and TNF- $\mu$  and by reducing the generation of prostaglandins, may be the mechanism by which it treats primary dysmenorrhoea.<sup>[5]</sup>

Several compelling lines of evidence suggest a potential link between the severity of primary dysmenorrhoea and Vitamin D insufficiency. Epidemiological studies have documented a higher prevalence of Vitamin D deficiency amongst women experiencing severe dysmenorrhoea compared to those with milder symptoms.<sup>[6]</sup> Mechanistically, Vitamin D is believed to exert its pain-relieving effect through various pathways. One proposed mechanism involves the regulation of prostaglandin synthesis. Prostaglandins, cytokines, and tumour necrosis factor (TNF) mediators involved in uterine muscle contractions and inflammation contribute to menstrual pain.<sup>[5]</sup> Several research studies have indicated that Vitamin D inhibits the synthesis of certain prostaglandins, cytokines and TNF, potentially offering a biological explanation for its potential analgesic effect in dysmenorrhoea.<sup>[7]</sup>

Uncertainty surrounds the precise effect of Vitamin D status on the use of analgesics in this situation, despite mounting evidence linking Vitamin D insufficiency to dysmenorrhoea. The relationship between Vitamin D levels and pain intensity is the main focus of current research. The potential effects of a Vitamin D deficiency on the frequency of analgesics used by women experiencing primary dysmenorrhoea are, however, not well understood.

This correlation study looked into any possible links between Vitamin D insufficiency and analgesic use in females with primary dysmenorrhoea in an effort to address this knowledge gap.

## MATERIALS AND METHODS

### Study design and setting

This prospective, open-label, interventional study was conducted from February 2023 to January 2024 at the department of pharmacology in collaboration with the department of obstetrics and gynaecology.

Prior to research beginning, the Biomedical Research Ethics Committee of Pt. B. D Sharma PGIMS, Rohtak (No. BREC/22/TH/Pharma-02) approved the study in accordance with ethical criteria. The most recent amendments to the Declaration of Helsinki and the guidelines for good clinical practice were followed throughout the conduct of this investigation. Every person who was enrolled provided written informed consent, or in the case of minors, assent. Patient confidentiality was ensured throughout the research process.

Females aged 14–40 years experiencing painful menstruation for at least four consecutive cycles (3–7 days' duration) with serum Vitamin D3 levels <30 ng/mL (per Endocrine Society guidelines)<sup>[8]</sup> were included. Patients with secondary dysmenorrhoea, specific medical conditions, on-going treatment regimens or allergies to the study medication were excluded.

Enrolled individuals were given a 60,000 IU Vitamin D3 sachet with milk when their menstrual cycle started weekly for 8 weeks. In addition, a combination of mefenamic acid (250 mg) and dicyclomine hydrochloride (10 mg) tablets was prescribed for use as needed for pain relief, with a maximum of one dose every 6 h for 8 weeks. The number of analgesic tablets used per day was recorded.

### Data collection and study instruments

#### *Baseline assessment-demographic and medical history*

Along with demographic data, thorough medical and gynaecological information was collected.

#### *Menstrual history*

A thorough menstrual history was captured, including characteristics of menstrual cycles.

#### *Vitamin D3 levels*

Serum Vitamin D3 levels were evaluated at baseline and after 8 weeks. Serum 25-hydroxyvitamin D [25(OH)D] levels were estimated using a commercially available enzyme-linked immunosorbent assay kit (Calbiotech, USA) according to the manufacturer's instructions. Absorbance was measured at 450 nm, and concentrations were calculated using a standard curve derived from known calibrators.

#### *Diagnosis of dysmenorrhoea*

The WaLIDD score was used to diagnose dysmenorrhoea.<sup>[9]</sup> This score assesses: Pain location, Pain intensity, Duration of pain, Impact on activity.

Each component of the WaLIDD score is assigned a value between 0 and 3, yielding a total score between 0 and 12. Higher scores indicate greater dysmenorrhoea severity, while

lower scores signify improvement. Notably, this score has not been used till now in any study of this kind. As it tells us about multiple parameters of dysmenorrhoea in a single score, it could serve as an effective tool for evaluating patient improvements following Vitamin D3 supplementation.

All the patients were assessed for improvement in the WaLIDD score for the drug response at baseline, 4 weeks, and 8 weeks. Elevation of serum Vitamin D levels was also compared to baseline after 8 weeks, and its association with a decline in WaLIDD score.

### Safety assessment of Vitamin D3 supplementation

Active monitoring of adverse drug events (ADEs) was implemented throughout the study. A predefined ADE reporting form, based on known potential side effects of Vitamin D3, was utilised to actively monitor for adverse events. Patients were instructed to report any and all adverse experiences encountered during the study, with specific inquiries made at the 4-week and 8-week follow-up visits.

### Sample size calculation

With the 95% confidence interval probability taken into account, the sample size of 61 participants was determined by reviewing prior research.<sup>[10]</sup> The proportion of subjects achieving pain resolution was 54.6% (0.546), calculated based on the findings outlined by Lama *et al.*<sup>[11]</sup> This estimate was associated with a precision of 12.5% (0.125) and a Type I error rate ( $\alpha$ ) of 5% (0.05). As a result of this, this study comprised a minimum of 65 patients.

### Statistical analysis

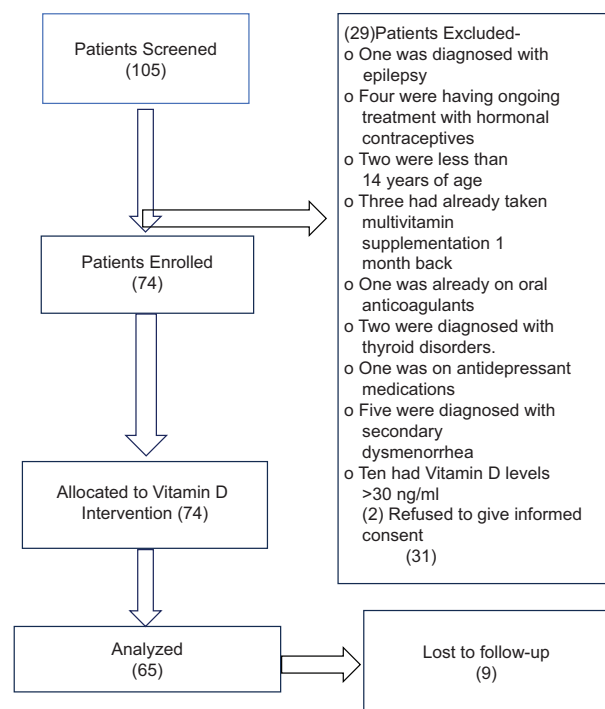
Data were entered into a Microsoft Excel spreadsheet after being coded. A combination of descriptive and inferential techniques was used in statistical analysis:

#### Descriptive statistics

For continuous variables with a normal distribution, means and standard deviations were employed. For continuous data that were not normally distributed, medians and interquartile ranges were used. Frequencies and percentages were used to represent categorical variables.

#### Inferential statistics

Associations between categorical variables were evaluated using the Chi-squared test. Associations between continuous and categorical variables were investigated by a paired *t*-test (two categories). For assessing the strength of linear relationships between two continuous variables, Pearson's correlation coefficient was used when the data were normally



**Figure 1:** Flow diagram showing the recruitment and selection of study participants.

**Table 1:** Demographic and baseline characteristics of study population.

Characteristics	Mean±SD
Age (Years)	24.25±6.33
Weight (kg)	57.49±12.84
BMI (kg/sqm)	22.21±4.47
Marital status	Number of cases
Married (%)	19 (29.23)
Unmarried (%)	46 (70.76)
Age at menarche in years	13.20±1.33
Days of menstruation	4.98±1.37
Duration of the menstrual cycle in days	27.96±3.14
Serum Vitamin D levels (ng/mL)	19.13±5.86
WaLIDD score	9.92±1.49
Number of Analgesics required	3.86±1.56
All values are expressed as Mean±SD population. BMI: Body mass index, SD: Standard deviation	

distributed. A threshold of  $p \leq 0.05$  was established for statistical significance.

## RESULTS

A total of 105 patients with dysmenorrhea were screened as per predefined inclusion and exclusion criteria. Thirty-one

were excluded due to conditions such as epilepsy, thyroid disorders, secondary dysmenorrhea, concurrent medications, or refusal to consent. The remaining patients received Vitamin D3 supplementation (60,000 IU weekly for 8 weeks). Nine patients were lost to follow-up, and 65 completed the study and were included in the final analysis [Figure 1].

Table 1 summarises the baseline demographic and clinical characteristics of the study population.

### Improvement in serum Vitamin D levels

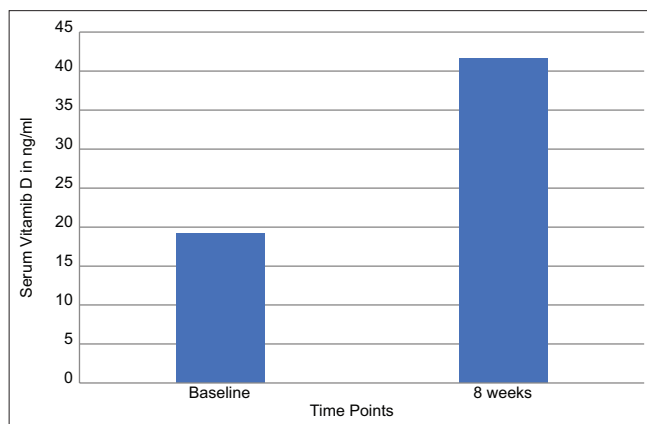
The rise in serum Vitamin D levels was highly statistically significant when compared to the baseline at 8 weeks ( $P < 0.001$ ) [Figure 2].

### Improvement in WaLIDD score

The decrease in the WaLIDD score was highly statistically significant when compared to the baseline ( $P < 0.001$ ) [Table 2].

### Correlation analysis

Vitamin D levels and WaLIDD scores improved, but no significant correlation was found [Table 3].



**Figure 2:** Improvement in serum Vitamin D levels (ng/mL) at 8 weeks compared to baseline ( $P < 0.001$ ).

**Table 2:** Effect of Vitamin D3 intervention on WaLIDD score in primary dysmenorrhoea.

WaLIDD score	Mean±SD	P-value* (Comparison with baseline)
Baseline	9.92±1.49	-
4 weeks	8.17±1.29	<0.001
8 weeks	6.54±1.54	<0.001

Each value is represented as mean±SD population. Paired *t*-test used. SD: Standard deviation. \* Probability value.

### Analgesic medication use

The number of analgesic medications required per menstrual cycle significantly decreased after Vitamin D3 supplementation [Table 4].

### Safety assessment

Adverse events were reported by 18.46% ( $P > 0.05$ ) of participants. The most common events were nausea/vomiting, constipation, anorexia and abdominal pain. No serious adverse events were observed [Figure 3].

### DISCUSSION

The role of Vitamin D deficiency in inducing or aggravating the symptoms of primary dysmenorrhoea has been explored by some studies. Vitamin D may have anti-inflammatory properties that help treat dysmenorrhoea by reducing the generation of prostaglandins, cytokines such as interleukin 6 and TNF. A potential positive impact of Vitamin D on uterine pathophysiology is possible due to the widespread expression of the Vitamin D receptor, the expression of the mitochondrial cytochrome P450 enzyme 25(OH)D3-1 $\alpha$ -hydroxylase, which catalyses the synthesis of D3 from its precursor 25(OH)D, and the fact that Vitamin D reduces the synthesis of PGs, thereby being effective in reducing menstrual pain.<sup>[6]</sup>

The results of the study point to a direct link between the use of analgesics and Vitamin D insufficiency in primary dysmenorrhoea. An 8-week intervention's significant increase in serum Vitamin D levels shows the supplementation

**Table 3:** Correlation between improvement in serum Vitamin D3 levels and decrease in WaLIDD score.

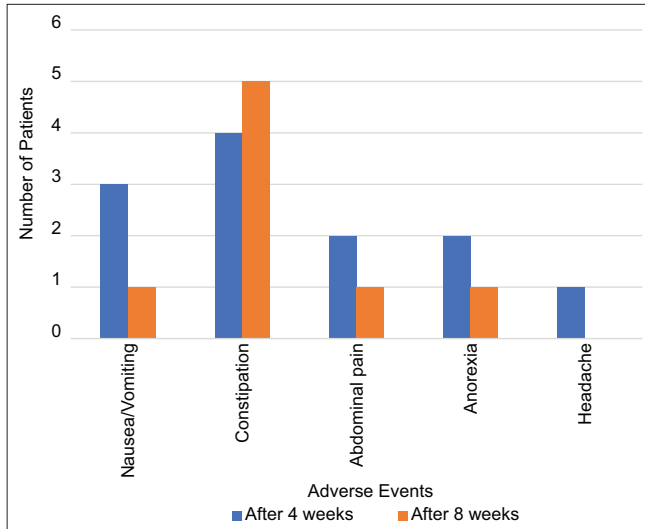
Change in Parameter	Correlation coefficient with change in serum Vitamin D	P-value*
Change in WaLIDD score	0.058	0.647

Pearson correlation test used. \* Probability value.

**Table 4:** Effect of Vitamin D3 intervention on number of analgesic medications required in each cycle.

Number of analgesic medications needed	Mean±SD	P-value* (Comparison with baseline)
Baseline	3.86±1.56	-
4 weeks	2.26±1.39	<0.001
8 weeks	0.85±1.46	<0.001

Each value is represented as Mean±SD population. Paired *t*-test used. SD: Standard deviation. \* Probability value.



**Figure 3:** Safety assessment: Distribution of adverse events at 4 weeks and 8 weeks.

program's effectiveness. This result is consistent with previous research showing that women with primary dysmenorrhoea and insufficient Vitamin D had considerably greater serum Vitamin D levels following Vitamin D3 supplementation.<sup>[12]</sup> Reduced dysmenorrhoea severity and a decreased requirement for analgesics are probably related to this improvement in Vitamin D status.

The WaLIDD score, a validated tool for quantifying dysmenorrhoea pain, showed a marked improvement following administration of supplements of Vitamin D3. The impact of Vitamin D3 on the WaLIDD score has not been investigated in any research so far. Our study represents a pioneering effort in utilising this score to assess the impact of taking supplements of Vitamin D3, potentially advancing our understanding of its influence on dysmenorrhoea symptom improvement. The statistically significant reduction in scores was observed at both 4 and 8 weeks, which suggests a sustained effect of Vitamin D3 intervention. This improvement is consistent with expectations since Vitamin D metabolites influence endometrial receptors to impair biological activity and lower levels of inflammatory cytokines and related contractile factors (PGs).<sup>[7,13]</sup> While similar studies using WaLIDD scores are scarce, the literature supports Vitamin D's efficacy in alleviating dysmenorrhoea symptoms. For instance, Badran GM's and Rahnemaei *et al.*'s research both demonstrated a significant decrease in the duration and intensity of pain with Vitamin D supplementation.<sup>[14,15]</sup> These findings underscore the potential of Vitamin D3 in managing primary dysmenorrhoea, offering relief in pain intensity, discomfort and duration.

The present study demonstrated a significant reduction in the number of analgesic medications required per menstrual cycle

following Vitamin D3 supplementation. This finding aligns with previous research that demonstrated a beneficial link interconnecting Vitamin D supplementation and a reduced requirement for analgesics to treat menstrual cramps. The observed decrease in analgesic usage over time indicates the efficacy of Vitamin D3 in mitigating menstrual pain, thereby reducing the need for pharmacological intervention.

Numerous research investigations have consistently demonstrated that women experiencing primary dysmenorrhoea who take Vitamin D3 supplements report much lower analgesic consumption. For instance, a study by Moini *et al.* found that Vitamin D3 supplementation significantly decreased the number of analgesics required, particularly in the second month of treatment.<sup>[16]</sup> Similarly, Amzajerdi *et al.* reported a significant reduction in Mefenamic acid consumption amongst women receiving Vitamin D3 compared to those receiving a placebo.<sup>[12]</sup>

These findings highlight the potential for Vitamin D3 to be a valuable therapeutic option for women with dysmenorrhoea, offering a non-pharmacological approach to pain management. By reducing reliance on analgesics, Vitamin D3 could potentially minimise the risk of adverse effects associated with long-term NSAID use.

While our study showed significant improvements in several dysmenorrhoea-related outcomes after taking Vitamin D3, we did not detect a significant correlation between Vitamin D levels and changes in the severity of pain or other dysmenorrhoea-related outcomes. This finding aligns with some previous research, such as the study by Rahnemaei *et al.*, which also failed to identify a significant correlation.<sup>[15]</sup> However, our findings differed from those of Moini *et al.*<sup>[16]</sup> may be due to:

- Age range: Our study included a wider range of age groups (14–40 years) compared to Moini *et al.*'s study.<sup>[16]</sup>
- Sample size: Our study had a larger sample size receiving Vitamin D3 treatment.
- Study design: Differences in study design, such as duration of intervention and the specific Vitamin D dosage, may also have contributed to contrasting results.

Adverse events reported after 4 weeks of treatment decreased by the end of the 8-week study. All reported events were mild in severity and resolved without intervention. No participants dropped out due to treatment-related adverse effects.

A literature review identified studies that compared similar treatment regimens for tolerability. In 116 female students who were deficient in Vitamin D levels and had primary dysmenorrhoea, Rahnemaei *et al.* administered 50,000 IU of Vitamin D3 and no adverse effects were observed.<sup>[15]</sup> Bahrami *et al.* also observed no adverse effects in 897 adolescent girls with dysmenorrhoea and premenstrual syndrome who received weekly doses of 50,000 IU cholecalciferol.<sup>[17]</sup>

## Strengths and limitations of the study

### Strengths

Consistent findings, improved dysmenorrhoea symptoms, validated WaLIDD score, a non-pharmacological approach and minimal adverse effects.

### Limitations

The relatively small sample size may limit the ability to generalise the results to a larger population. The study design, which was open-label and lacked a placebo control group, may have introduced biases, such as the placebo effect or participant expectations, which could have influenced the reported outcomes.

### Synopsis

Vitamin D therapy significantly reduced dysmenorrhoea severity ( $P < 0.001$ ), with decreased analgesic use. However, no direct link to pain intensity was found.

### Implications

While the study did not establish a direct correlation between the severity of dysmenorrhoea and Vitamin D status, the notable improvements in pain intensity, analgesic consumption and other clinical outcomes suggest that Vitamin D3 supplementation could be a promising therapeutic approach for women with primary dysmenorrhoea.

## CONCLUSION

The study shows an immediate association between the use of analgesics in primary dysmenorrhoea and Vitamin D insufficiency. Supplementing with Vitamin D significantly lessens the symptoms of dysmenorrhoea, lowers the degree of pain and reduces the need for painkillers. While a consistent direct correlation between Vitamin D levels and pain severity was not found, the overall positive effects of Vitamin D supplementation suggest that it may be a feasible therapeutic option for women with primary dysmenorrhoea. However, to fully understand the intricate connection between Vitamin D and dysmenorrhoea, more investigation is required. Future research should explore larger randomised controlled trials to better assess the long-term effects of Vitamin D supplementation on dysmenorrhoea. In addition, further studies investigating optimal Vitamin D dosing for maximum therapeutic benefit would be a valuable addition. While Vitamin D appears beneficial in reducing analgesic use and alleviating dysmenorrhoea symptoms, more robust evidence is needed before it can be recommended as a standard treatment for this condition.

Name of the registry: Clinical Trials-Registry- India (ICMR-NIMS)

Registration number: CTRI/2023/01/049144 (Registered on: 23 January 2023)

URL of registration: <https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=NzkwNTQ=&Enc=&userName=>

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