Research Article

Impact of Vitamin D3 Supplementation on Health-Related Quality of Life in Women with Primary Dysmenorrhea and Vitamin D Deficiency: A Secondary Analysis

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ABSTRACT

Background: Primary dysmenorrhea (PD) is widely prevalent gynaecological disorder that substantially impairs health-related quality of life (HRQoL). While studies have demonstrated a relationship between Vitamin D deficiency and heightened menstrual pain, there is limited evidence regarding the influence of Vitamin D3 supplementation on multiple domains of HRQoL in women with dysmenorrhea.

Objectives: To assess effect of Vitamin D3 supplementation on HRQoL in women presenting with primary dysmenorrhea and concurrent Vitamin D deficiency.

Materials and Methods: This study presents secondary analysis of HRQoL data from prospective interventional clinical trial registered with Clinical Trials Registry- India. A total of 65 women between 14 and 40 years of age, diagnosed with primary dysmenorrhea and having serum Vitamin D levels below 30 ng/mL, were administered oral Vitamin D3 at 60,000 IU weekly over eight-week period. HRQoL was evaluated by employing Short Form-36 (SF-36) questionnaire at baseline, four weeks, and eight weeks. Secondary outcome measures included pain intensity via Visual Analogue Scale (VAS), menstrual blood loss via Pictorial Blood Loss Assessment Chart (PBLAC), and safety monitoring throughout study period.

Results: Significant improvements were documented across all eight SF-36 domains at both four-week and eight-week assessments relative to baseline ($P < 0.001$). Mean serum Vitamin D levels rose from 19.13 ± 5.86 ng/mL to 41.65 ± 8.85 ng/mL following supplementation ($P < 0.001$). VAS pain scores declined markedly, whereas menstrual blood loss measured by PBLAC did not change significantly.

Conclusion: Vitamin D3 supplementation significantly improved HRQoL in women with primary dysmenorrhea and Vitamin D deficiency, with benefits extending beyond pain reduction alone.

Keywords: Primary dysmenorrhea; Vitamin D deficiency; Health-related quality of life; Vitamin D3; SF-36.

1. INTRODUCTION

Primary dysmenorrhea (PD) ranks among the most frequently encountered gynaecological problems in adolescent and young adult women [1]. Global prevalence estimates reported in the literature span a broad range, from approximately 16% to as high as 91%, with younger age groups demonstrating disproportionately elevated rates [2]. Within India, population-based data suggest that PD affects between 50% and 87.8% of menstruating women [3].

Clinically, PD manifests as recurring, cramp-like lower abdominal pain coinciding with menstruation in the absence of any detectable pelvic organic pathology [4]. Beyond this defining physical symptom, the condition exerts a broad negative influence encompassing diminished academic performance, reduced workplace productivity, psychological distress,

and restricted participation in social activities [5, 6, 7].

The growing recognition of health-related quality of life (HRQoL) as a meaningful clinical endpoint in gynaecological research underscores its relevance in PD. The condition impairs multiple functional domains including physical capacity, energy, emotional regulation, and interpersonal relationships making comprehensive outcome measurement essential in any therapeutic evaluation [8].

Non-steroidal anti-inflammatory drugs (NSAIDs) represent the cornerstone of pharmacological treatment for PD owing to their prostaglandin-mediated mechanism of action. However, their use is frequently limited by adverse gastrointestinal effects, which prompt a proportion of affected women to discontinue therapy or seek alternative interventions [9, 10].

Vitamin D insufficiency is highly prevalent in India, estimated to affect 50% to 94% of the population, with a predominance among females, yet it frequently goes unrecognized and untreated [11]. Natural dietary sources contribute relatively little to overall vitamin D intake because only a limited number of foods contain appreciable amounts of the vitamin. Vitamin D3 is primarily found in animal-derived foods including fatty fish, cod liver oil, and egg yolks whereas Vitamin D2 is present in fungi such as mushrooms and yeast following exposure to sunlight or ultraviolet radiation; but dietary intake alone is often insufficient to correct vitamin D deficiency, particularly in populations with limited sun exposure [12]. Vitamin D receptors are expressed in both the endometrium and myometrium, and the vitamin exerts well-established anti-inflammatory and immunomodulatory actions. Mechanistically, it modulates prostaglandin synthesis and suppresses pro-inflammatory cytokine production, pathways directly implicated in menstrual pain [13]. Vitamin D_3 supplementation may improve health-related quality of life by enhancing musculoskeletal function, modulating immune and inflammatory responses, and supporting neurological and psychological health, thereby improving physical functioning and overall well-being [14]. Several observational and interventional studies have demonstrated an association between Vitamin D insufficiency and worsening dysmenorrhea severity [15].

This research team previously investigated the association between deficiency of Vitamin D and analgesic consumption patterns in women with PD enrolled in a registered clinical trial [16]. However, the specific impact of Vitamin D3 supplementation on full spectrum of HRQoL outcomes within that cohort has not been individually examined.

Given the clinical importance of HRQoL as a patient-centred outcome measure, the present study aimed to comprehensively evaluate how Vitamin D3 supplementation influences HRQoL in women experiencing primary dysmenorrhea and concurrent deficiency of Vitamin D.

2. Subjects and Methods

Study Design

This paper constitutes a secondary analysis of HRQoL outcomes derived from a prospective, single-arm interventional clinical trial registered with the Clinical Registry of India (CTRI/2023/01/049144). Primary clinical findings from this cohort, including pain-related outcomes, have been reported in a prior publication [16].

Study Setting and Participants

The trial was conducted jointly by the Department of Pharmacology and the Department of Obstetrics and Gynaecology at a tertiary-level academic medical institution. Before the initiation of participant enrolment, the study protocol was reviewed and approved by the Institutional Ethics Committee (No. BREC/22/ TH/Pharma-02).

Eligible participants were women aged 14 to 40 years who fulfilled the clinical criteria for primary dysmenorrhea, had serum Vitamin D concentrations below 30 ng/mL, and demonstrated regular menstrual cycles. Informed written consent was acquired from all participants (and from a parent or guardian in the case of minors). Women were excluded if they had secondary causes of dysmenorrhea, were currently using hormonal therapies, had documented pelvic pathology, suffered from

chronic systemic illnesses, or were pregnant or lactating.

Intervention

All enrolled participants received Vitamin D3 sachet containing 60,000 IU weekly for a total duration of 8 weeks with a glass of milk on the first day of the menstrual cycle. All the patients received the commercial preparation of the study medicines which were available in the hospital/market. The same brand and formulations were used throughout the study. Treatment adherence was monitored through scheduled follow-up consultations at the end of 4 weeks and 8 weeks along with telephonic reminders between visits [17].

Outcome Measures

Primary Outcome

HRQoL was the primary outcome of this analysis, measured by means of the validated Short Form-36 (SF-36) questionnaire at baseline, four weeks, and eight weeks. The SF-36 comprises eight subscales and two composite summary scores (Physical Component and Mental Component). All scores are standardized on a 0 to 100 scale, with greater values implying improved health status. The physical dimension encompasses subscales for physical functioning, role constraints associated with bodily pain, physical health and general health perception. Social functioning, mental well-being, role restrictions resulting from emotional health and vitality are all part of mental health dimension [18].

Secondary Outcomes

Pain intensity was evaluated using the Visual Analogue Scale (VAS) — a 100-mm horizontal scale anchored at 'no pain' and 'worst imaginable pain' — at baseline, four weeks, and eight weeks [19]. We also assessed the effect of Vitamin D3 supplementation on blood loss during menstruation by utilizing Pictorial Blood Loss Assessment Chart (PBLAC) at baseline, four weeks and 8 weeks [20]. Serum Vitamin D concentrations were determined at baseline and again after eight weeks of follow-up. Adverse drug events (ADEs) were actively monitored at each visit throughout the study.

Statistical Analysis

Data were systematically recorded and organized in Microsoft Excel for analysis. Continuous parameters were expressed as mean ± standard deviation (SD), and categorical measures were summarized as absolute frequencies with corresponding percentages. Given the within-subject, repeated-measures design of the study, changes in continuous outcomes — including serum Vitamin D levels, SF-36 subscale scores, VAS scores, and PBLAC scores were analysed using paired t-test to compare baseline and follow-up values. Categorical measures, such as the occurrence of adverse events, were analysed by employing Chi-square test. A two-tailed P-value of ≤ 0.05 was deemed statistically significant.

3. Results

All 65 enrolled participants completed the study. The mean age of the cohort was 24.25 ± 6.33 years, consistent with the reproductive age group. Serum Vitamin D deficiency was confirmed in every participant at baseline. Demographic and baseline clinical characteristics are summarised in Table 1.

Table 1: Baseline demographic and clinical characteristics of the study population

Primary Outcome: Health-Related Quality of Life

Characteristic	Mean ± SD / n (%)
Age (years)	24.25 ± 6.33
Weight (kg)	57.49 ± 12.84
Marital status — Married	19 (29.23%)
Marital status — Unmarried	46 (70.76%)
Age at menarche (years)	13.20 ± 1.33
Duration of menstruation (days)	4.98 ± 1.37
Menstrual cycle length (days)	27.96 ± 3.14
Serum Vitamin D (ng/mL)	19.13 ± 5.86
VAS score	84.32 ± 8.69
PBLAC score	55.97 ± 11.89
SF-36: Physical Function	55.7 ± 9.37
SF-36: Physical Role	50.63 ± 9.03
SF-36: Emotional Role	37.89 ± 6.94
SF-36: Bodily Pain	66.85 ± 7.93
SF-36: Social Function	69.74 ± 9.21
SF-36: Emotional Well-being	57.32 ± 8.68
SF-36: Energy/Fatigue	48.98 ± 8.90
SF-36: General Health	58.35 ± 8.03

Vitamin D3 supplementation produced significant and progressive improvements across all eight SF-36 domains at both follow-up time points. These changes were consistent across the physical and mental health dimensions and are detailed in Table 2.

Table 2: Change in SF-36 domain scores following Vitamin D3 supplementation in women with primary dysmenorrhea

SF-36 Domain	Time Point	Mean ± SD	P-value vs. Baseline
Physical Function	Baseline	55.7 ± 9.37	—
	4 weeks	62.89 ± 9.09	< 0.001
	8 weeks	69.01 ± 11.94	< 0.001
Physical Role	Baseline	50.63 ± 9.03	—
	4 weeks	57.76 ± 10.04	< 0.001
	8 weeks	64.38 ± 11.20	< 0.001
Emotional Role	Baseline	37.89 ± 6.94	—
	4 weeks	44.21 ± 8.07	< 0.001
	8 weeks	49.15 ± 10.06	< 0.001
Bodily Pain	Baseline	66.85 ± 7.93	—
	4 weeks	57.25 ± 9.58	< 0.001
	8 weeks	50.65 ± 10.42	< 0.001
Social Function	Baseline	69.74 ± 9.21	—
	4 weeks	75.05 ± 8.36	< 0.001
	8 weeks	78.51 ± 8.97	< 0.001
Emotional Well-being	Baseline	57.32 ± 8.68	—
	4 weeks	61.01 ± 8.77	< 0.001
	8 weeks	65.56 ± 10.34	< 0.001
Energy/Fatigue	Baseline	48.98 ± 8.90	—
	4 weeks	54.17 ± 9.52	< 0.001
	8 weeks	60.78 ± 10.65	< 0.001
General Health	Baseline	58.35 ± 8.03	—
	4 weeks	62.89 ± 8.58	< 0.001
	8 weeks	67.29 ± 8.66	< 0.001

**All values expressed as Mean ± SD. Statistical comparison performed using the paired t-test*

Improvements were observed uniformly across all domains - Physical Function, Physical Role, Emotional Role, Bodily Pain, Social Function, Emotional Well-being, Energy/Fatigue, and General Health. The magnitude of benefit was greater at eight weeks than at four weeks, indicating a cumulative and sustained response to Vitamin D3 repletion. Both physical and mental health components demonstrated parallel and consistent enhancement.

Secondary Outcomes

Effect on Pain Intensity (VAS)

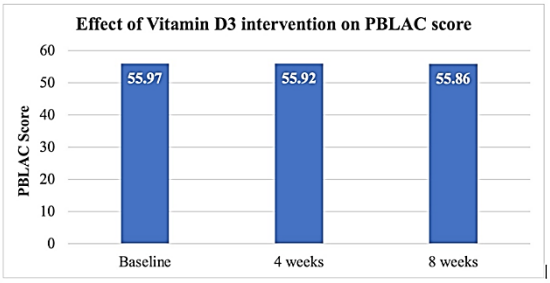
Table 3: Effect of Vitamin D3 supplementation on VAS pain scores in primary dysmenorrhea.

VAS Score	Mean ± SD	P-value vs. Baseline
Baseline	**84.32 ± 8.69**	**—**
4 weeks	**70.37 ± 10.25**	**< 0.001**
8 weeks	**57.60 ± 13.25**	**< 0.001**

**All values expressed as Mean ± SD. Paired t-test used.*

A progressive and statistically significant decline in VAS pain scores was noted at the end of four and eight weeks relative to baseline ($P < 0.001$), as shown in Table 3. This trajectory of pain reduction is consistent with a beneficial modulatory effect of Vitamin D3 on dysmenorrhea-associated pain pathways.

Effect on Menstrual Blood Loss (PBLAC)



**All values are expressed as Mean ± SD population.*

** Paired -T test used*

Figure 1: Effect of Vitamin D3 intervention on PBLAC score in Primary Dysmenorrhea

PBLAC scores remained essentially stable across the three time points (Baseline: 55.97 ± 11.89; 4 weeks: 55.92; 8 weeks: 55.86), with no statistically significant change from baseline to study completion. [Figure 1] These data suggest that Vitamin D3 supplementation does not meaningfully alter menstrual blood volume in women with primary dysmenorrhea.

Serum Vitamin D Levels

Table 4: Change in serum Vitamin D levels following supplementation

Measurement	Baseline (ng/mL)	8 Weeks (ng/mL)	P-value
Serum Vitamin D	19.13 ± 5.86	41.65 ± 8.85	< 0.001

**All values expressed as Mean ± SD. Paired t-test used.*

Serum Vitamin D concentrations more than doubled from baseline to eight weeks, as shown in Table 4, a change that was highly statistically significant ($P < 0.001$). This confirms successful repletion of Vitamin D status and establishes a biological basis for the observed clinical improvements.

Safety Assessment

No serious adverse drug events were documented throughout the study. At the four-week assessment, 20% of participants (n = 12) reported mild adverse events, predominantly nausea, vomiting, constipation, anorexia, and epigastric discomfort. By eight weeks, the frequency of adverse events had declined to 13.84% (n = 8), with constipation being the most common complaint. All events were transient and self-limiting, and none necessitated treatment withdrawal.

4. Discussion

Primary dysmenorrhea imposes a substantial burden on women's quality of life, affecting not only physical functioning but also academic and occupational performance, mental health, sleep quality, and the ability to engage in social activities [5, 7]. A notable subset of women discontinued NSAIDs or oral contraceptives due to adverse effects or personal contraindications, generating demand for well-tolerated therapeutic alternatives, including micronutrient-based interventions [10, 11].

Vitamin D has surfaced as a compelling candidate in this context, given its capacity to suppress pro-inflammatory mediators such as interleukin-6 and tumour necrosis factor-alpha, and to inhibit prostaglandin biosynthesis [13]. These anti-inflammatory mechanisms plausibly account for both the symptomatic relief and the HRQoL improvements observed in the current study. Supplementation with Vitamin D3 in the present cohort yielded a consistent and statistically significant improvement in all SF-36 domains, accompanied by meaningful reductions in pain intensity.

The breadth of improvement across both physical and mental health dimensions of the SF-36 reinforces the notion that correcting Vitamin D deficiency carries multidimensional benefits beyond analgesia alone. Direct evidence evaluating HRQoL outcomes in PD in relation to Vitamin D remains limited. Zarei *et al.*, previously examined a combined calcium–Vitamin D3 intervention and noted HRQoL improvements; however, inter-group differences failed to reach statistical significance [21].

The present study, by contrast, demonstrated uniform and significant improvement across multiple SF-36 subscales, a discrepancy that may reflect differences in study population characteristics, supplementation regimen, or duration of follow-up. Collectively, these findings provide further support for a clinically meaningful role of Vitamin D3 in HRQoL improvement in PD. The significant attenuation of VAS pain scores observed at both time points adds to a growing body of literature reporting that Vitamin D supplementation reduces dysmenorrhea-related pain [22].

This pain-modulating effect, combined with the parallel HRQoL improvements, strengthens the therapeutic rationale for Vitamin D3 in this population. The marked increase in serum Vitamin D concentrations at eight weeks (from a deficient to a sufficient range) validates the adequacy of the supplementation protocol. Prior investigations have similarly documented normalization of Vitamin D levels with comparable dosing regimens, alongside reductions in dysmenorrhea prevalence and pain severity, lending further confidence to the biological plausibility of the present findings [23, 24]. In contrast to the significant gains in HRQoL and pain scores, menstrual blood loss as quantified by PBLAC showed no significant change, a pattern also reported in previous randomized trials evaluating Vitamin D3 in PD [22].

This dissociation between HRQoL improvement and unchanged menstrual volume implies that the therapeutic effects of Vitamin D3 are predominantly mediated through symptomatic relief mechanisms rather than alterations in menstrual physiology.

The favourable tolerability profile observed - mild, transient adverse events that diminished over time without causing any treatment discontinuation - is consistent with findings from other studies confirming the safety of Vitamin D3 supplementation in women with PD [21, 23, 25].

The present analysis contributes meaningfully to the evolving evidence base for Vitamin D in women's reproductive health by providing a dedicated examination of multidimensional HRQoL outcomes. Unlike prior studies that focused primarily on pain metrics, this work illuminates broader physical, emotional, and social benefits of Vitamin D3 repletion. Given the high prevalence of both Vitamin D deficiency and primary dysmenorrhea, these findings carry practical clinical implications: routine assessment and correction of Vitamin D status could represent a straightforward, safe, and cost-efficient adjunct in the comprehensive management of PD. Nonetheless, the absence of a comparator arm; relatively short follow-up duration; use of paired *t*-tests instead of repeated-

measures ANOVA for repeated assessments constitute limitations, and larger randomized controlled trials with extended follow-up are necessary to establish causality and guide clinical practice.

5. Conclusion

Oral Vitamin D3 supplementation resulted in significant and progressive improvements across all health-related quality of life domains in women with primary dysmenorrhea and concurrent Vitamin D deficiency. These findings indicate that therapeutic correction of Vitamin D insufficiency confers clinical benefits extending well beyond pain reduction, encompassing physical, psychological, and social dimensions of well-being. Given its favourable safety profile and ease of administration, Vitamin D3 represents a promising and practical adjunctive strategy in the holistic management of primary dysmenorrhea. Further large-scale, adequately powered randomized controlled studies are warranted to confirm these observations and delineate the role of Vitamin D3 within the broader therapeutic algorithm for PD.

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Conflict of Interest

None

Funding

None

Ethical Statement

The study was approved by the Biomedical Research Ethics Committee (Approval No. BREC/22/TH/Pharma-02) and registered with the Clinical Trials Registry- India (CTRI/2023/01/049144). The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all participants, with assent obtained from minors where applicable. Particiapnt confidentiality was maintained throughout the study.

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