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EFFECTIVENESS OF VITAMIN D OPTIMIZATION AS AN ADJUNCT TO STANDARD ANALGESIC THERAPY IN ADULTS WITH POST-VIRAL ARTHRALGIA PRESENTING TO FAMILY MEDICINE CLINICS: A RANDOMIZED CONTROLLED TRIAL.

Dr. Shariq Nawab[*1], Dr. Fatima Jehangir[2], Dr. Momina Mazhar Ali Khilji[3], Dr. Ambrina Qavi[4], Dr. Uroosh Tariq Khanzada[5], Dr Rukhsana Rashid[6]

[*1, 4,5,6]Resident, Department of Family Medicine, Ziauddin University Hospital
[2]Head of Department Family Medicine, Ziauddin University Hospital
[3]*Resident Internal Medicine Jinnah Postgraduate Medical Center (JPMC)*

[*1]drrukhsanakk@hotmail.com [2]shariqnawabpak@gmail.com, [3]a_qavi@yahoo.com, [4]urooshkhanzada@gmail.com

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Corresponding Author: *
Dr. Shariq Nawab

Abstract

Introduction: *The complaint of post-viral arthralgia is a new condition in family medicine and is frequently seen after COVID-19, dengue, and chikungunya-like illness.*

Objective: *The effectiveness of vitamin D optimization as an adjunct to the standard analgesic therapy in reducing the severity of pain among adults who have post-viral arthralgia and vitamin D insufficiency attending family medicine clinics.*

Methods: *This was a randomized controlled trial that was carried out over six months in the Family Medicine Outpatient Department, Tertiary Care Teaching Hospital. The study participants were 140 adults with post-viral arthralgia and serum 25-hydroxyvitamin D <30 ng/mL who were enrolled using non-probability consecutive sampling and randomly divided into two equal groups. Group A was given oral cholecalciferol 50,000 IU per week for 8 weeks along with the standard therapy, and Group B was given only the standard therapy. The analysis of the data was performed with SPSS version 27.0.*

Results: *There were no differences in baseline characteristics between groups ($p>0.05$). At 8 weeks, Group A showed a significantly greater reduction in mean pain score than Group B (mean reduction 4.1 ± 1.4 vs 2.5 ± 1.3, $p<0.001$), along with lower Brief Pain Inventory interference scores and lower analgesic requirement. The 25-hydroxyvitamin D level rose significantly more in Group A ($p<0.001$), and adverse effects were mild and similar between groups ($p=0.30$).*

Conclusion: *In vitamin-D-deficient adults with post-viral arthralgia, vitamin D optimization in addition to regular analgesic treatment is able to substantially decrease the severity of arthralgia and enhance functional outcomes.*

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INTRDOCUTION

Persistent joint pain after an acute viral illness is referred to as post-viral arthralgia (PVA), and is a more common presentation in family medicine and primary care clinics. Post-infection symptoms of pain, stiffness, fatigue, and decreased functional capacity are common and often persistent for weeks or months after the acute infection has been resolved, creating a significant burden on outpatient services and patient quality of life (1). Musculoskeletal symptoms after COVID-19 have been well reported, and the prevalence of joint pain has varied widely between 2% and 65% in different populations and with different follow-up periods (2). Chikungunya infection is also known to cause a prolonged and intense arthralgia, and the World Health Organization reported that the joint pain can last for weeks, months, or even years following the acute phase of the illness (3).

Common symptoms are fever and diffuse body pain, and the choice of an appropriate, safe analgesic is important: the Centers for Disease Control and Prevention (CDC) recommends paracetamol/acetaminophen and advises against the use of NSAIDs such as aspirin and ibuprofen because of the potential for bleeding in suspected dengue (4). Vitamin D deficiency is common in all South Asian populations and has been associated with non-specific musculoskeletal pain, muscle weakness, fatigue, and delayed recovery from illness (5). Due to its physiological actions on immunity and musculoskeletal health, vitamin D has been of interest for therapeutic use in pain conditions, but there is inconsistent evidence in this area. A Cochrane review did not show a consistent benefit of vitamin D supplementation for chronic painful conditions as a whole, but did indicate that more research is needed to establish if benefits are limited to people who are vitamin-D deficient and what dose or time period may be needed to see benefits (6).

The current treatment of post-viral arthralgia in family medicine is largely symptomatic, including reassurance, paracetamol, topical or oral NSAID where appropriate, hydration, and gradual return to activity (7). Yet a significant percentage of patients still have pain and functional limitation that exceeds the time of recovery, and there is a need for easy-to-use adjunct strategies that are appropriate for outpatient practice. Vitamin D deficiency correction is an inexpensive and viable intervention in primary care, as testing and supplementation are both commonplace. However, uncontrolled high-dose supplementation is not without risk, as hypercalcemia, nephrolithiasis, renal injury, and cardiac arrhythmias are all possible side effects of excessive vitamin D intake (8). Supervised dosing regimens, such as 50,000 IU weekly for 8 weeks, have been recommended as safe and effective ways to correct deficiency in adults without exceeding recommended treatment guidelines (9).

The idea of adding micronutrients to routine symptomatic treatment is aligned with a growing trend in primary care to focus on modifiable physiological factors contributing to chronic symptoms in addition to symptomatic treatment alone (10). The potential use of vitamin D as an adjunctive treatment for post-viral arthralgia is a clinically relevant and practical research question, given the ease of vitamin D testing and treatment in the outpatient family medicine setting (11). Validated, reproducible tools are needed to assess pain in these trials. In clinical research, the Numeric Pain Rating Scale (NPRS) is a widely used, simple, reliable instrument used to quantify pain intensity, and the Brief Pain Inventory (BPI) is a validated measure of the functional interference pain causes to daily activities, mood, and sleep (12,13). The standardized tools enable meaningful comparisons of treatment effect between arms of the intervention.

Randomized controlled trials are the strongest design to determine causal treatment effects, provided that they are randomized appropriately and, if possible, blinded to reduce selection and confounding bias (14). To further minimize the likelihood of imbalance in heterogeneous populations (e.g., patients recovering from different viral infections) between comparison groups, stratified randomization should be used to allocate patients to groups, with stratification based on the presence or absence of viral illness and baseline pain severity. Family physicians have a unique opportunity to treat post-viral arthralgia, as they are most likely to have the continuity of

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care and access to the outpatient diagnostic and therapeutic resources necessary to identify early vitamin D deficiency and to correct it under their own supervision without specialist referral (16).

Therefore, it may be useful to evaluate a structured, protocol-driven approach to vitamin D optimization in this context to guide routine primary care practice and to prevent unnecessary referral for uncomplicated post-viral musculoskeletal complaints (17). This study aimed to assess the effectiveness of supervised vitamin D optimization, in addition to standard analgesic therapy, to achieve greater pain relief and functional improvement than standard therapy alone, given the high prevalence of post-viral arthralgia in the recent past in the region for COVID-19, dengue, and chikungunya-like illness, and the biological plausibility of vitamin D as a modifiable factor in musculoskeletal pain (18).

The deficiency threshold used in this study (<30 ng/mL) and the 50,000 IU weekly regimen follow the 2011 Endocrine Society guideline for the treatment of vitamin D deficiency. The 2024 Endocrine Society guideline, which updates and replaces the 2011 guideline, suggests against routine 25(OH)D testing and does not define an optimal target 25(OH)D level; however, its recommendations apply explicitly to generally healthy individuals without an established indication for vitamin D testing or treatment. As the participants in this study were symptomatic, with a clinical indication and biochemically confirmed deficiency, they fall outside the scope of the 2024 recommendations, and the 2011 deficiency-treatment thresholds remain applicable. It is also noted that the Institute of Medicine (IOM/NAM) considers a 25(OH)D level of ≥20 ng/mL adequate; the Endocrine Society threshold was adopted here because the cohort was symptomatic with a clinical indication for treatment.

Objective: The aim of this study was to assess the effectiveness of vitamin D optimization in addition to the conventional analgesic treatment in reducing pain severity and functional outcome among adults who presented to family medicine outpatient clinics with post-viral arthralgia and vitamin D insufficiency.

MATERIALS AND METHODS

Study Design: An open-label randomized controlled trial.

Study Setting: Family Medicine outpatient department of a tertiary care teaching hospital, Pakistan.

Study Duration: Total time of about 6 months, including recruitment, 8 weeks of follow-up for each participant, and analysis of data.

Sample Size: A total of 140 participants (70 per group) was calculated to detect a clinically meaningful difference of approximately one point on the Numeric Pain Rating Scale (NPRS) between the two groups, with 80% power and a 5% level of significance, allowing for the expected loss to follow-up. The minimal clinically important difference of approximately one point was based on Farrar et al. (19).

Sampling Technique: Non-probability consecutive sampling was used to enroll eligible patients, who were subsequently randomized using a computer-generated random sequence.

Inclusion Criteria: Adults aged 18–60 years who had recently suffered from a viral illness (COVID-19, dengue or chikungunya-like illness) within 4–12 weeks prior, with joint pain lasting for at least 2 weeks after the acute illness and who had a baseline NPRS score ≥4 and a blood serum 25-hydroxyvitamin D level <30 ng/mL were included, provided they gave informed consent.

Exclusion Criteria: Exclusion criteria included patients with pre-existing inflammatory or autoimmune arthritis, chronic widespread pain syndromes, joint trauma or septic arthritis, unstable dengue with warning signs, chronic kidney disease, hypercalcemia, current use of high-dose vitamin D or immunosuppressive therapy, pregnancy or lactation, and malaria-positive cases.

METHODS

Demographic and clinical data were collected on a structured proforma, after approval from the institutional ethical review committee and written informed consent, and eligible participants were randomly assigned to two groups with a computer-generated random sequence, stratified by type of preceding viral illness and baseline pain severity. In addition to the standard therapy, group A was given oral cholecalciferol (vitamin D3) 50,000 IU

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per week for 8 weeks under medical supervision. Standard therapy was used in group B. Both groups received standard treatment, including patient education, hydration, and optimization of sleep, graded activity, paracetamol as a first-line analgesic, and topical and/or oral non-steroidal anti-inflammatory drugs, when clinically appropriate and not contraindicated by the presence of active bleeding risk from dengue.

Participants were followed at weeks 2, 4, and 8, with pain score, functional interference, analgesic use, compliance, and adverse effects recorded at each visit. At week 8, serum 25-hydroxyvitamin D, calcium, and creatinine were re-evaluated. Mean change in the NPRS score from baseline to week 8 was the primary outcome. Secondary outcomes were Brief Pain Inventory interference score change, analgesic requirement, serum 25-hydroxyvitamin D level change, and adverse effect frequency. The data were entered and analyzed with SPSS version 27.0 (IBM Corp., Armonk, NY, USA). The quantitative variables were presented as mean ± standard deviation, and were compared between groups using an independent sample t-test. Frequency and percentage were used to express categorical variables and compared with the chi-square test. Repeated measures analysis of variance was used to analyze the within-group changes over time. A p-value of <0.05 was deemed statistically significant. The analyses were conducted on an intention-to-treat basis.

RESULTS

140 individuals were enrolled in the study, 70 in each group. The two groups were well randomized with respect to baseline demographic and clinical data, which were similar (p>0.05 for all comparisons) (Table 1).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants (n = 140)

Variable	Group A (Vitamin D + Standard) n = 70	Group B (Standard Alone) n = 70	p-value
Age, years, mean ± SD	34.9 ± 9.6	34.3 ± 10.1	0.71
Gender – Male, n (%)	31 (44.3)	29 (41.4)	0.73
Gender – Female, n (%)	39 (55.7)	41 (58.6)	0.73
BMI, kg/m², mean ± SD	25.8 ± 3.4	26.1 ± 3.6	0.61
Preceding illness – COVID-19, n (%)	29 (41.4)	28 (40.0)	0.86
Preceding illness – Dengue, n (%)	26 (37.1)	27 (38.6)	0.86
Preceding illness – Chikungunya-like, n (%)	15 (21.4)	15 (21.4)	0.86
Baseline NPRS pain score, mean ± SD	6.2 ± 1.3	6.1 ± 1.4	0.68
Baseline BPI interference score, mean ± SD	5.9 ± 1.6	5.8 ± 1.5	0.72
Baseline serum 25(OH)D, ng/mL, mean ± SD	18.4 ± 5.2	18.9 ± 5.0	0.55

After 8 weeks, the participants in Group A had a significantly lower pain score than those in Group B. The mean Numeric Pain Rating Scale score at week 8 was 2.1 ± 1.2 in Group A and 3.6 ± 1.5 in Group B (p<0.001); and the mean reduction from baseline was 4.1 ± 1.4 points in Group A versus 2.5 ± 1.3 points in Group B (p<0.001). Patients in Group A reported a

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clinically meaningful decrease of ≥2 points in pain compared to Group B (82.9% vs 55.7%, p<0.001). Analgesic consumption was converted to a paracetamol-equivalent Defined Daily Dose (DDD) using WHO ATC/DDD reference values (paracetamol DDD = 3 g/day oral; ibuprofen DDD = 1.2 g/day oral; other NSAIDs converted using their respective WHO DDD values), allowing paracetamol and NSAID use to be expressed on a single comparable scale rather than as a raw tablet count. The 25-hydroxyvitamin D level was significantly higher in Group A (mean 34.7 ± 6.1 ng/mL at week 8) than in Group B (mean 21.3 ± 5.4 ng/mL, p<0.001). The incidence of adverse effects, such as mild nausea and constipation, was similar in both groups (8.6% versus 4.3%, p=0.30), and none of them were severe enough to require intervention, including no hypercalcemia or renal impairment (Table 2).

Table 2. Comparison of Pain, Functional, and Biochemical Outcomes at Eight Weeks

Outcome at Week 8	Group A (n = 70)	Group B (n = 70)	p-value
Mean NPRS pain score, mean ± SD	2.1 ± 1.2	3.6 ± 1.5	<0.001
Mean reduction in NPRS from baseline	4.1 ± 1.4	2.5 ± 1.3	<0.001
Patients achieving ≥2-point NPRS reduction, n (%)	58 (82.9)	39 (55.7)	<0.001
Mean BPI interference score, mean ± SD	2.4 ± 1.3	3.9 ± 1.6	<0.001
Serum 25(OH)D at week 8, ng/mL, mean ± SD	34.7 ± 6.1	21.3 ± 5.4	<0.001
Paracetamol-equivalent analgesic dose, DDD/week, mean ± SD	1.9 ± 0.8	3.1 ± 1.1	<0.001
Adverse effects reported, n (%)	6 (8.6)	3 (4.3)	0.30

Within each group, the trend of pain scores across follow-up visits was progressive for both groups, with Group A having a consistently greater decrease from week 2 onwards than Group B, and the difference between groups being statistically significant at each follow-up time point after baseline (Table 3).

Table 3. Mean Numeric Pain Rating Scale Score Across Follow-Up Visits

Follow-up Visit	Group A mean ± SD	Group B mean ± SD	p-value
Baseline	6.2 ± 1.3	6.1 ± 1.4	0.68
Week 2	4.6 ± 1.3	5.3 ± 1.4	0.002
Week 4	3.2 ± 1.3	4.4 ± 1.4	<0.001
Week 8	2.1 ± 1.2	3.6 ± 1.5	<0.001

Figure 1. Comparison of Mean Numeric Pain Rating Scale Scores Between Group A and Group B at Baseline, Week 2, Week 4, and Week 8

The line graph shows the changes in pain levels for both groups over the 8-week follow-up. Both groups had a gradual reduction in pain scores, and Group A consistently and gradually had a better improvement in pain scores from week 2 onwards,

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with a significant difference between the two groups at week 8, indicating the additional benefit of vitamin D optimization in addition to standard therapy.

DISCUSSION

In the present randomized controlled trial, vitamin D optimization in combination with regular analgesic treatment resulted in a significantly larger reduction in pain severity and functional interference in vitamin-D-deficient adults with post-viral arthralgia than regular analgesic treatment alone. The results are consistent with the biological plausibility that correcting underlying vitamin D deficiency may improve recovery from chronic post-viral musculoskeletal symptoms, especially in populations with a high prevalence of vitamin D deficiency (1). PVA following COVID-19, dengue, and chikungunya-like illness has been emerging as a significant cause of chronic morbidity in primary care populations, as reported previously for COVID-19 (2) and for chikungunya infection (3), which is a well-known cause of prolonged joint pain. The similarity of baseline characteristics of the study groups in the current trial increases the confidence that the observed differences in outcome are due to the treatment and not due to differences in the type of illness or disease severity. Previous evidence on vitamin D supplementation for chronic pain has been mixed, with a Cochrane review finding no overall benefit in a wide range of painful conditions, but suggesting that there is a need for further research specifically in vitamin-D-deficient populations (6). The present results, which are limited to a population of individuals who had been diagnosed with vitamin D insufficiency at baseline and a well-defined post-viral pain phenotype, support the hypothesis that the benefits of supplementation may be limited to those who are vitamin D deficient, a point highlighted in previous reviews (5,6). The marked improvement in Brief Pain Inventory interference scores and reduction in pain in Group A indicates that vitamin D optimization may have a beneficial effect beyond pain intensity alone, on functional domains like general activity, mood, and sleep, which are known to be negatively impacted by chronic post-viral symptoms (12,13).

This overall functional enhancement is clinically significant in family medicine, where restoration of daily function is equally important to patients as is pain reduction. This finding of reduced requirement for analgesics is clinically relevant, as there is continued concern about the choice of safe analgesics in patients recovering from dengue, in which aspirin and non-steroidal anti-inflammatory drugs are contraindicated because of bleeding risk (4). A complementary technique that does not need as many analgesics for pain control without reducing the efficacy of analgesics could be especially beneficial in this subset of patients. The safety profile seen in this trial was good, with no instances of hypercalcemia, renal impairment, or other serious adverse events noted in either group, which aligns with current recommendations for supervised weekly dosing to safely achieve vitamin D sufficiency within recommended upper limits of intake (8,9).

This discovery underlines the importance of vitamin D correction in a supervised and protocol-driven manner, not by high-dose supplementation without supervision, to ensure patient safety in primary care (8). These findings support the larger idea that physiological factors that are potentially modifiable, including micronutrient deficiencies, should be routinely assessed and addressed in the treatment of persistent post-viral symptoms in addition to symptomatic therapies (10,11). Routine vitamin D testing may be a low-cost and accessible option within family medicine practice, and could help identify patients who may require targeted correction, without the need for specialist referral for uncomplicated cases (16,17). These results need to be interpreted with caution due to a number of limitations. Laboratory confirmation of viral illness was not possible in all participants, and the diverse pathogenesis of arthralgia after various viral infections may have contributed to the variability in treatment response (2,3). The subjective nature of pain may be affected by mood, sleep, and psychological factors, which are not fully addressed in this trial.

As an open-label trial, participants and treating physicians were not blinded to group allocation,

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which may have contributed to performance bias. However, the primary and secondary outcomes (NPRS and BPI) were patient-reported and self-administered, limiting the influence of assessor bias on outcome ascertainment. A standardized co-therapy protocol was applied to both groups to further reduce performance bias. Finally, the duration of the eight weeks of follow-up is not enough to assess long-term recurrence or durability of effect (18). The uniformity of the improvement across pain, functional, and biochemical outcomes and the good safety profile make vitamin D optimization as an adjunct measure for post-viral arthralgia highly relevant for the family physician. Additional multicenter studies with more follow-up and laboratory confirmation of viral diagnosis are suggested to confirm these results and optimize dosing regimens for wider clinical use.

Conclusion

This randomized controlled trial showed that vitamin D optimization, along with standard analgesic treatment, could significantly decrease the severity of pain, functional interference, and the need for analgesics in vitamin-D-deficient adults with post-viral arthralgia, without any increase in side effects. The results of this study are in favor of introducing routine vitamin D screening and supervised correction in the management of post-viral arthralgia in patients who have suffered from COVID-19, dengue, and chikungunya-like illness in family medicine. Larger, multicenter trials with longer follow-up are suggested to validate these results and to guide clinical standard practice.

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