Functional outcome in the patients with Osteoarthritis Knee following Vitamin D3 supplementation using KOOS score

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ABSTRACT: Objective . OA is the most common articular disease of the developed world and a leading cause of chronic disability . Vitamin D supplementation has been known to improve pain and knee function in patients with Knee OA. The aim of this study was to evaluate effectiveness of vitamin D supplements in improving pain and function in the patients with OA Knee.

Methods: 104 patients with OA Knee who fulfilled inclusion criteria and consented to participate were enrolled for study. Patients of OA Knee were blinded and randomized to receive either Tab Vit D3 or identical placebo tablet. Vitamin D3 Tab was administered in a dose of 60000U/Week for 3 months in 12 doses while placebo tablets with identical dosing schedule were used for control group. The patients who received Vitamin D3 tablets were allocated to Case group (n=54) while those receiving identical placebo tablets were grouped as controls (n=50). 4 patients from case group were lost to follow up. Functional outcome score (KOOS score) was assessed in both groups of 50 each at 3 mo,6mo and 1 year.

Results: While baseline KOOS Score were comparable in case and controls [38.0 (31.50, 60.0)] vs 34.0 (32.0, 64.0), P= 0.657], there was significant improvement in follow up scores in case group vs controls at 3 mo,6mo and 1 year follow up **Conclusion:** Vitamin D3 supplementation is effective in improvement in KOOS (The Knee Injury and Osteoarthritis Outcome Score) in patients with osteoarthritis knee.

Key Words: Osteoarthritis, Knee, Vitamin D3

I. INTRODUCTION

Osteoarthritis (OA) is one of the most prevalent conditions resulting to disability particularly in the elderly population. OA is the most common articular disease of the developed

world and a leading cause of chronic disability, mostly as a consequence of the knee OA and/or hip OA[1]. The economic costs of OA are high, including those related to treatment, for those individuals and their families who must adapt their lives and homes to the disease, and those due to lost work productivity [2].

Patients with OA are at a higher risk of death compared with the general population. History of diabetes, cancer, or cardiovascular disease and the presence of walking disability are major risk factors. Excess mortality is observed for all diseases with specific causes of death but is pronounced for cardiovascular particularly complications. Knee OA is more important not only for its high prevalence rate compared with other types of OA but also for its presentation at earlier age groups particularly in younger age groups of obese women. The incidence of knee OA increases by age and further increase with longer lifetime and higher average weight of the population [3].

Pain and other symptoms of OA may have a profound effect on quality of life affecting both physical function and psychological parameters. Patients with knee osteoarthritis tend to increase their physical limitations, pain and functionality restriction with disease progression[4].

Vitamin D3 and its receptor (VDR) play an important role in bone metabolism, in response to the immune system, cancer and osteoarthritis. VDR has an important function in regulating calcium metabolism and cellular function in bones. There is evidence from a number of epidemiological studies suggesting that low dietary intake of vitamin D3 and low serum 25-OH-D3 levels are associated with increased radiological progression of knee OA [5],[6].

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Whether there is improvement in functional outcome in OA Knee patients is a matter of debate. Hence the present study was aimed at assessing functional outcome of Osteoarthritis Knee patients following Vitamin D3 supplementation using KOOS Score (The Knee Injury and Osteoarthritis Outcome Score).

II. PATIENTS AND METHODS

double-blind, This prospective, randomized controlled study was conducted at outpatient department (OPD) of a teritiary care institute over a period of one year (2018-19). The patients with osteoarthritis knee having vitamin D3 levels <40 ng/ml and following ACR criteria were enrolled in the study while patients receiving daily supplementation of Vitamin D3, Calcium, and drugs interacting with effects of Vitamin D3, use of steroids, patients undergoing surgery during the study, patients having diseases including lymphoma, sarcoidosis, tuberculosis, hyperparathyroidism, malabsorption disorders, GFR<30, history of inflammatory joint disease, and pregnancy, and not willing to participate were excluded.

A total of 104 patients were randomized to two groups (Case n=54,Controls n=50) to

receive either Tab Vit D3 preparation or an identical looking placebo .Vit D3 supplementation was provided to case group in the form of 60000 U weekly X 3 mo in 12 doses., and controls were provided with identical looking placebo tablets.

Outcome Assessment

Knee function assessment was measured in the form of Knee injury and Osteoarthritis Outcome Score (KOOS) at 3, 6 and 12 months.

Statistical Analysis

Data were expressed as frequency, percentage, median, and interquartile range (IQR). Normality of data was assessed using Shapiro Wilk test. Categorical variables were compared using Chi square test. Skewed data were compared using Mann Whitney U test. P value <0.05 was considered significant. Statistical analysis was performed using SPSS v21.

III. RESULTS

Among cases (n=54) and age , sex matched controls(n=50) grading of knee OA was comparable (P>0.05) (Table 1).

Table 1: Age and Sex Distribution Cases and Controls

	Cases (n=54)	Controls (n=50)	P value
Age (years)	47.50 [38.75, 55.00]	49.38 [42.0, 57.25]	0.205
Sex (M:F), n	13:37	10:40	0.476
Type of knee OA			0.971
Bilateral	24	21	
Left	15	14	
Right	15	15	

4 cases were lost to follow up from case group. Assessment by KOOS score in both groups was done at 3 months,6 months and 1 year. While baseline KOOS Scores were comparable in case and control group [38.0 (31.50, 60.0)] vs 34.0

(32.0, 64.0), P= 0.657] , there was significant improvement in cases (received Vit D3 supplementation) as compared to controls (who received placebo); at 3 mo,6mo and 1 year follow up [Table2,Fig. 1]

Table 2: Comparison of KOOS Score between Cases and Controls

	Cases	Controls	P Value
Baseline	38.0 [31.50, 60.0]	34.0 [32.0, 64.0]	0.657
3 Months	43.0 [36.0, 62.0]	31.50 [26.0, 58.0]	< 0.0001
6 Months	46.0 [41.5, 65.25]	26.50 [21.0, 52.25]	< 0.0001
12 Months	49.5 [43.0, 68.25]	24.0 [16.75, 50.0]	< 0.0001

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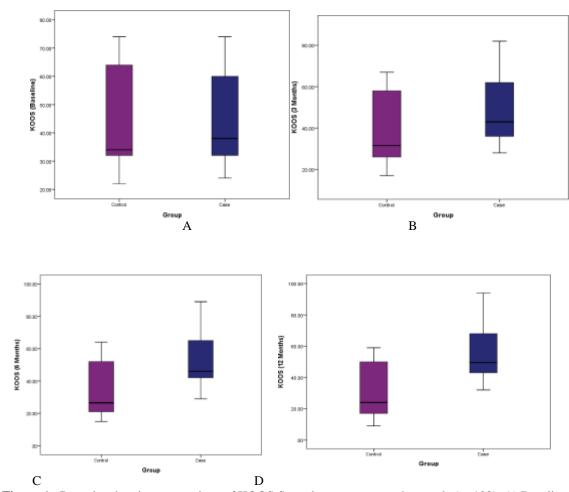


Figure 1: Box plot showing comparison of KOOS Score between case and controls (n=100). A) Baseline; B) 3 Months, C) 6 Months, and D) 12 Months

IV. DISCUSSION

So far research on the role of vitamin D in improving outcomes in KOA is inconclusive Literature has shown many studies analyzing effect of Vitamin D3 supplementation on functional outcome in Knee OA patients.

In a study by Sanghi et al it was observed that in patients with Vitamin D3 supplementation , knee function improved in the vitamin D3 group by mean -1.36 (95% CI, -1.87 to -0.85) over the placebo group which had a mean 0.69 (95% CI, 0.03 to 1.41; effect size = 0.06). This was accompanied by significant biochemical changes in serum total calcium, 25(OH)D and alkaline phosphatase. The results above suggested there was a small but statistically significant clinical benefit to vitamin D3 treatment in patients with knee OA[7].

On the contrary Zbehlik et al studied functional outcome in Knee OA following Vitamin D3 supplementation in a discrete subset of patients with higher age and BMI \geq 30 kg/m². This study did

not show a difference in functional progression of KOA between older adults with obesity who took vitamin D supplements at baseline and those who did not, which could be due to less bioavailability of Vit D3 and hence requirement of high doses of Vitamin D3 or higher grades of OA Knee in the study It could be a reason for not improvement in KOOS functional scale in their study [8].

While the present study has shown that vitamin D3 supplementation was effective in improved functional outcome of knee OA patients in terms of KOOS score. While baseline KOOS Scores were comparable in case and control group [38.0 (31.50, 60.0)] vs 34.0 (32.0, 64.0), P= 0.657] , there was significant improvement in cases (received Vit D3 supplementation) as compared to controls (who received placebo); at 3 mo,6mo and 1 year followup

V. LIMITATIONS

The present study has few limitations.



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- Different dose and duration effects of vitamin D3 supplements have not been considered in current study
- Safety of vitamin D3 supplements have not been studied thoroughly nor cohort event reporting of adverse effects of the supplements has been performed.
- Sample size is small. A large sample size is required for tangible outcomes.

VI. CONCLUSION

Vitamin D3 supplementation in the dose 60000 U weekly X 3 mo in 12 doses is effective in improvement in functional outcome of the patients with OA Knees. KOOS score is a useful tool in assessing functional status of patients with Knee Osteoarthritis

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