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Assessment of Pain in the Osteoarthritis Knee following Vitamin D3 supplementation using NRS 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 score in the patients with Osteoarthritis 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. Pain assessment using Numerical Rating Scale (NRS Score) was assessed in both groups at 3 mo,6mo and 1 year .

Results

While baseline NRS Score was comparable in controls in comparison to cases at baseline (6.0 [3.0, 6.5] vs. 6.0 [4.0, 6.0]; P=0.766); at 3 mo,6 mo and 1 year follow up there was a significant improvement in pain score as compared to controls. The values of controls vs cases at 3 months (5.0 (4.0, 6.0) vs 6.0 (4.0, 8.0)); P=0.029, 6 months (4.0 [3.0, 4.0] vs. 6.0 [4.0, 6.0];P<0.0001), and 12 months (2.5 [2.0, 4.0] vs. 5.0 [3.75, 8.0]; P<0.0001), showed P value <0.05 in cases as compared to controls.

Conclusion

Vitamin D3 supplementation is effective in improvement in NRS (Numerical Rating Scale) in patients with Osteoarthritis knee.

Key Words : Knee, Numerical Rating Scale, Osteoarthritis, 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 particularly pronounced for cardiovascular 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].

As we know Vitamin D3 receptor (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].

Whether there is improvement in pain scores in OA Knee patients is a matter of debate. In the present study we have assessed improvement

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in pain in Osteoarthritis Knee patients following Vitamin D3 supplementation using Numerical Rating Scale.

II. PATIENTS AND METHODS

This prospective, double-blind, 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 (Fig.1).

Outcome Assessment

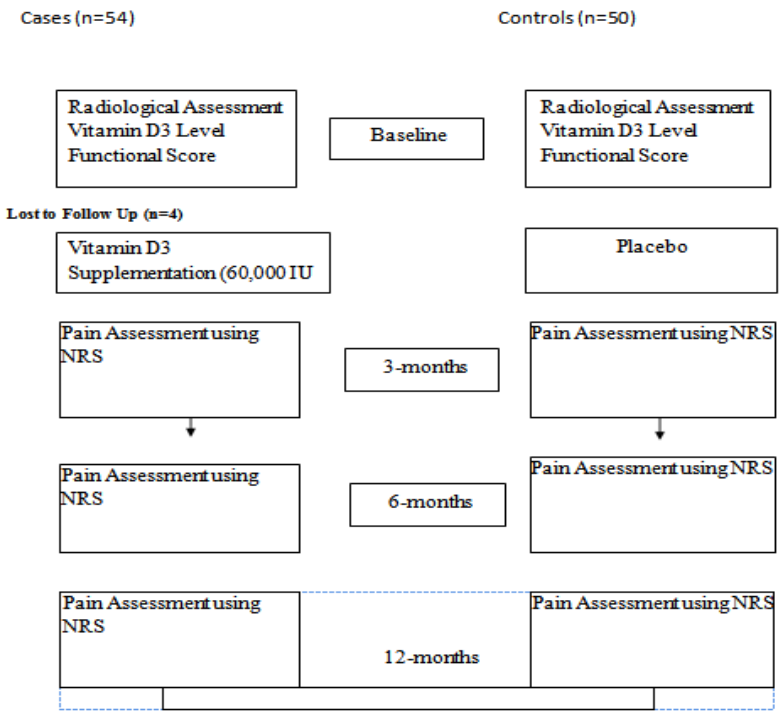
Pain related to Osteoarthritis Knee was assessed using Numerical Rating Scale(NRS)

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). 41% of the patients had bilateral knee osteoarthritis while 30% of the patients had right knee osteoarthritis. Type of knee osteoarthritis was comparable between controls and cases (P=0.971). 4 cases were lost to follow up from case group. Assessment by NRS in both groups was done at baseline, 3 months, 6 months and 1 year. Our study observed baseline NRS Score comparable in controls in comparison to cases at baseline (6.0 [3.0, 6.5] vs. 6.0 [4.0, 6.0]; P=0.766). At 3 months (5.0 [4.0, 6.0] vs. 6.0 [4.0, 8.0]; P=0.029), 6 months (4.0 [3.0, 4.0] vs. 6.0 [4.0, 6.0]; P<0.0001), and 12 months (2.5 [2.0, 4.0] vs. 5.0 [3.75, 8.0]; P<0.0001), NRS Score in cases were significantly lower in comparison to controls(Table 1 & Fig. 2).



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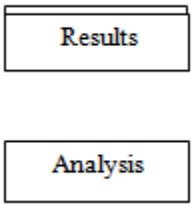

Fig 1 Flow chart showing conduction of study

Table 1 : Comparison of NRS Score between case and controls (n=100)

	Cases (n=50	**Controls (n=50)**	**P Value**
Baseline	6.0 [4.0, 6.0]	6.0 [3.0, 6.5]	0.766
3 Months	5.0 [4.0, 6.0]	6.0 [4.0, 8.0]	0.029
6 Months	4.0 [3.0, 4.0]	6.0 [4.0, 6.0]	<0.0001
12 Months	2.5 [2.0, 4.0]	5.0 [3.75, 8.0]	<0.0001

Data expressed as median [IQR]; Mann-Whitney U test

IV. DISCUSSION

So far research on the role of vitamin D in improving pain score in Knee Osteoarthritis is inconclusive. Literature has shown many studies analyzing effect of Vitamin D3 supplementation on improvement in pain score in Knee OA patients. Sanghi et al studied whether treatment with vitamin D3 would (1) reduce knee pain (WOMAC and VAS), (2) improve function (WOMAC) and (3) change levels of relevant biochemical markers in patients with knee OA with vitamin D3 insufficiency.

Thisrandomizedcontrolledpilottrialprospectivelyenrolled107patientswithkneeOA with vitamin D3 insufficiency (25(OH)D ≤ 50 nmol/L) to receive oral vitamin D3 or placebo. The primary outcome measures were pain and function, and the secondary were biochemical markers. At baseline, the two groups were comparable. The patients were followed for 1 year. At 12 months, knee pain had decreased in the vitamin D3 groupbymean-0.26(95%CI,-2.82to-1.43)onVASand-0.55(95%CI,-0.07to1.02) ontheWOMAC,whereasintheplacebogroup,itincreasedbymean0.13(95%CI,-0.03 to 0.29) on the VAS and 1.16 (95% CI, 0.82 to 1.49) on the WOMAC (effectsize = 0.37 and 0.78). Likewise, 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). There were 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, although they recommend a long-term study to determine whether these changes are clinically important and whether they will be sustained with time. Further studies with long-term radiologic evaluations are needed[7].

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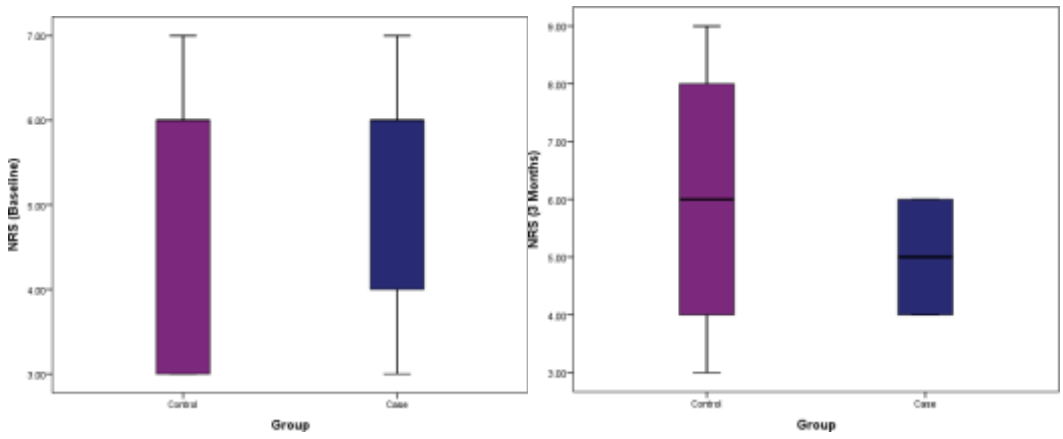
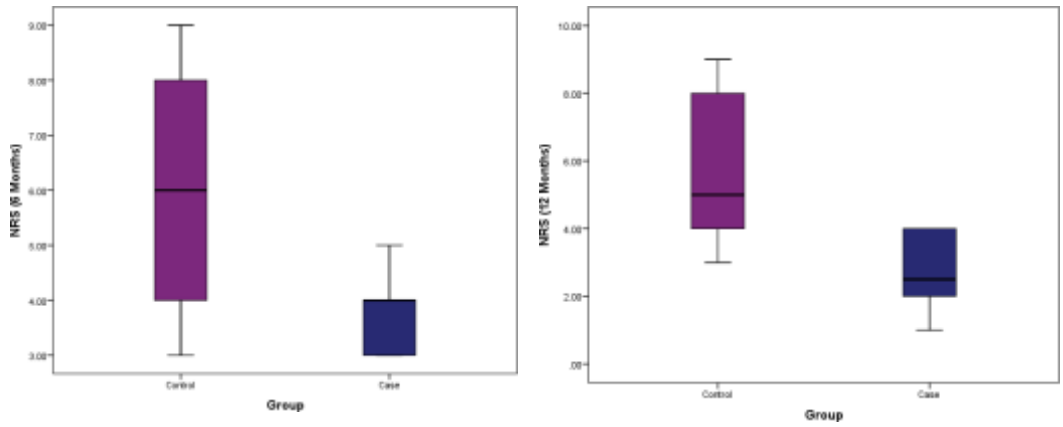


Figure 2 : Box plot showing comparison of NRS Score between case and controls (n=100). A) Baseline; B) 3 Months, C) 6 Months, and D) 12 Months



In another study a two year RCT of 2000 IU/day oral cholecalciferol for patients with vitamin D insufficiency was performed [5]. The primary outcomes were MRI assessed cartilage thickness, radiographic JSN and pain. The population studied had similar baseline concentrations of vitamin D but greater baseline JSW (approximately 5mm vs. 3.5mm). The results demonstrated that despite 63% of patients achieving target concentrations of vitamin D, there were no significant improvements in any of the outcomes.[5]. While the present study has shown that vitamin D3 supplementation was effective in improved functional outcome of knee OA patients in terms of functional scores and pain score (NRS). Our study observed baseline NRS Score comparable in controls in comparison to cases at baseline (6.0 [3.0, 6.5] vs. 6.0 [4.0, 6.0]; P=0.766). We also observed that at 3 months (5.0 [4.0, 6.0] vs. 6.0 [4.0, 8.0]; P=0.029), 6 months (4.0 [3.0, 4.0] vs. 6.0 [4.0, 6.0]; P<0.0001), and 12 months (2.5 [2.0, 4.0] vs. 5.0 [3.75, 8.0]; P<0.0001), NRS Score in cases were significantly lower in comparison to controls. It was observed that vitamin D3 supplementation was effective in improvement in reducing the pain.

V. LIMITATIONS

The study has few limitations like small sample size, not considering different Vitamin D3 doses and their effects, and not incorporating any adverse events reported during study. Multicenteric studies with large sample size would be required to arrive at tangible results.

VI. CONCLUSION

Vitamin D3 supplementation in the dose 60000 U weekly for 3 mo in 12 doses is effective in improvement in functional outcome of the patients with OA Knees. Numerical Rating Scale (NRS) is an effective way to assess pain score in Knee OA patients.

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