Research

Effectiveness of Vitamin D along with Splint therapy in the Vit D deficient patients with Temporomandibular disorder-A Randomized, double-blind, placebo-controlled clinical trial

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Abstract

Aim: The purpose of this study is to comparatively evaluate the Vitamin D supplementation and stabilization splint therapy in patients exhibiting temporomandibular disorders (TMD).

Settings and Design The study design was double-blinded, parallel-group, randomized and placebo-controlled trial conducted in patients with low Vitamin D and TMDs, which were allocated to two groups, Study group S + D (Stabilization splint with Vitamin D supplementation) and Control Group S (Stabilization Splint with placebo drug).

Subjects and Methods: Thirty-six participants of 18–45 years of age gap with Vitamin D deficiency and TMD were included in the study. Preoperative values of Vitamin D levels in ng/ml, comfort mouth opening (CMO) in mm, maximum mouth opening (MMO) in mm, temporomandibular joint (TMJ) tenderness (grading 0–3), Visual analog scale score (VAS Score 0–10 cm), and total energy (TE) integral values of both left and right TMJ's in Hertz (Hz) were recorded using joint vibration analysis All the values of CMO, MMO, TMJ Tenderness and VAS were recorded at each follow-up at 1st week, 1st month, 2nd month, and 3rd month, respectively. Postoperative Vitamin D levels and TE of both TMJs were recorded at end of 3 months.

Statistical Analysis Used: For intergroup comparison, Mann–Whitney *U*-test and Pearson Chi-square tests were done. For Intragroup comparison, Wilcoxon signed rank test was used for comparison.

Results: In Intergroup comparison, a significant difference was seen in CMO, VAS score and MMO ($P < 0.05$) but not among mean values of TE of right and left TMJ, and Vitamin D levels ($P < 0.05$). In both groups, there were significant statistical variations in CMO, VAS score, MMO, and TE integral before and after treatment in the right and left TMJs ($P < 0.05$).

Conclusions: The study concludes centric stabilization splint helps in improving symptoms of TMD patients and Vitamin D supplementation provided faster relief in those cases.

Keywords: 1, 25 dihydroxy 20 epi Vitamin D_3, joint vibration, occlusal splint, temporomandibular disorders

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INTRODUCTION

The temporomandibular joint (TMJ) and its associated neuromuscular system are the two fundamental components of the temporomandibular system. The American Academy of Orofacial Pain broadly classifies temporomandibular disorders (TMD) into myogenous or muscle-related TMD, and arthrogenous or joint-related TMD.[1] The clinical features of TMD include pain in the temporomandibular region or muscles of mastication; radiation of pain to the face, behind the eyes, shoulder, neck and/or back; headaches and dizziness; tinnitus or ear-ache; clicking, locking or deviation of jaw; restricted jaw opening; clenching of teeth; and sensitivity of apparently healthy teeth without any oral disease. The most common symptom for which patients seek medical attention is pain in the associating region.[2] Patients with TMD who do not experience pain, may complain of popping, clicking and crepitus sounds, at the TMJ during joint movement. TMD has a multifactorial etiology. Several theories, including mechanical displacement, biomedical, trauma, osteoarthritis, muscle theory, neuromuscular, psycho-physiological and psychosocial theory, have been proposed to explain the etiology of TMD.[3] The factors can be classified as predisposing factors, initiating factors and perpetuating. Predisposing factors increases the risk of developing TMD such as genetic factors. Initiating factors like trauma are acute reasons for TMD and at last, perpetuating factors are those factors which delay the healing process. Among perpetuating factors, systemic mineral or vitamin deficiency plays an important role. Vitamin D deficiency has been associated with poor muscle strength and poor physical performance. Recently, it has been linked with TMJ Disorders.[4] Thus, it can be either a predisposing or perpetuating factor in manifestation of TMJ Disorder. Vitamin D supplementation in patients who had deficiency, should improve symptoms of TMD.[4] The most effective treatment for TMJ issues necessitates a thorough diagnostic examination using research diagnostic criteria/TMD (RDC/TMD). Along with RDC/TMD, an objective method such as evaluating joint vibrations using joint vibration analysis (JVA) can provide to be a very useful and significant diagnostic tool by reducing the chance of individual bias. An ideal therapeutic approach for TMD should focus on ameliorating the main signs and symptoms of this condition. Conservative management for TMD includes medication, occlusal splints, physiotherapy, interventions based on cognitive-behavioral approaches, and self-management strategies.[5] Despite its advantages, evidence for the comparative effectiveness of surgical and conservative intervention to reduce short-term pain in atherogenic TMD is still controversial and inconclusive.[5] The definitive treatment for TMD is to reinstate a normal disc-condyle relationship. For this, we usually use centric stabilization splint.[5] The centric stabilization splint has been reported to resolve myogenic pain, restricted mouth opening, and TMDs. Stabilizing splints help in stabilizing physiologically static and dynamic occlusion, relax the tensed masticatory muscles, and reduce the physiological stress in joint structures. The multimodal treatment plan of combined Vitamin D supplementation and Splint therapy can be implemented in TMD patients to evaluate their response. There is a lack of knowledge in associating Vitamin D with splint therapy in improving the comfort and quality of life in patients exhibiting TMD. The effectiveness of Vitamin D has not yet been established as a supplementary treatment in TMD. Thus, the null hypothesis of this study is that there is no significant difference in combining Vitamin D supplementation along with Splint therapy in patients exhibiting TMD.

Objectives

The current study aims at giving a diagnosis-based treatment plan to patients with TMD along with Vitamin D deficiency. The purpose of this study is to comparatively evaluate the role/effectiveness of Vitamin D supplementation along with stabilization splint therapy in the treatment of patients exhibiting TMDs. The diagnosis was based on both clinical symptoms using RDC/TMD and JVA.

SUBJECTS AND STUDY DESIGN

This was a double-blind, randomized, parallel-group, and placebo-controlled clinical trial carried out at the Department of Prosthodontics in Maulana Azad Institute of Dental Sciences, New Delhi.

Ethics

The Institutional Ethical Committee approved the study with informed consent was taken for each patient. For reference, Ethical Committee Number is MAIDS/Ethical committee/2016/3273.

Controlled trial registration

The trial was registered in Clinical Trial Registry under ICMR. The protocol (CTRI Number: CTRI/2020/10/028748), can be accessed through the following link: http://ctri.nic.in/Clinicaltrials/pdf_generate.php?trialid = 47731andEncHid = andmodid= andcompid=%27,%2747731det%27.

Inclusion and exclusion criteria

Inclusion criteria

Patient's age ranging from 18 to 45 years (both included) were included in our study. Patients were

recruited irrespective of sex, religion, caste, or socioeconomic status. RDC/TMD classification among Axis 1 with Group II patients were selected which was further verified using JVA[6] whose Vitamin D levels were <30 ng/ml[7] and were fully dentate or at least had sufficient occlusal stops, no more than two posterior teeth missing in each quadrant (excluding third molars) were selected.

Exclusion criteria

Completely edentulous patients or patients with no posterior occlusal stops were excluded from the study. Patents having reduced mouth opening or patients who had undergone previous treatment with occlusal appliances were also excluded from the study. Patients undergoing Orthodontic treatment and patients with pain because of systemic disease (e.g., rheumatoid arthritis, etc.) were also excluded from the study.

Sample size

The sample size was kept in accordance to the study done by Mazzetto *et al*.[8] in 2007 who evaluated the effect of low intensity laser application in TMD's. The sample size was calculated using formulae of comparison of two independent means with α set at 0.05 and β at 0.2. A minimum number of 16 patients per group were to be needed to obtain a significant difference in the treatment and control group. It was decided to keep a sample size of 20 participants per group (including 25% of drop out). Thirty-six participants completed the study with dropout of 4 participants (2 from each group).

Study procedures

Step 1: Screening of patients

Proper informed consent was taken from the patient. After he/she gave consent, then only the enrollment of the participant in the study was done. Preoperative blood tests were done for Vitamin D levels. Patients with levels <30 ng/ml and TMD and who come under our inclusion criteria were included in the study [Figure 1]. For randomization, random number table sequence generated by SPSS Statistics for Windows, version 26.0(SPSS Inc., Chicago, III., USA) and was used to allocate patients in study group S + D and control group S. The participants with even number in table were selected for study group S + D and participants with odd number were selected for control group S. For randomization concealment, participants in study group were given Vitamin D supplements in sealed envelope and control group participants were given placebo drug in sealed envelope. Patients who were excluded from study were also given appropriate treatment for TMD.

Step 2: Preoperative examination

Preoperative baseline values of inter-incisal comfortable mouth opening (CMO) and maximum mouth opening (MMO) were measured in millimeters. TMJ tenderness was recorded on scale of 0–3 in which, 0 depicted no pain on palpation; score 1 denoted mild pain; score 2 for moderate pain; and 3 for severe pain. Pain score was assessed on a visual analog scale (VAS) of 0–10 cm. Total energy (TE) integral values of TMJs of either side in Hertz (Hz) were obtained by a JVA record.

Step 3: Joint vibration analysis record

JVA sensors (BioJVA™, BioResearch) were placed over the patient's TMJs, and sensor wires were attached to the amplifier [Figure 2]. The patient was trained to get synchronized with metronome (The video instructions how to open and close mouth) on laptop. Both side TMJ vibrations were recorded as the patient followed the metronome of opening and closing movements. During closing, the patient was instructed to make only light contacts. A summary of the procedure was stored in the software provided by BioJVA™ [Figure 3].

Step 4: Bite registration and splint fabrication

Impression of the maxillary and mandibular arch was taken in irreversible hydrocolloid and were poured in Type III Gypsum product. Bite Registration was done at centric relation using VPS material (CADBITE, IVOCLAR). Models were mounted with dental plaster on HANAU Wide-Vue 183-2 articulator using a HANAU Spring bow and the patient's bite registration record. Wax-up of the splint was done using modeling wax. It was processed in clear heat cure resin. Full coverage splint was fabricated covering the entire arch and it fitted the occlusal and incisal surfaces of maxillary or mandibular teeth. The choice of arch was made on clinical condition like remaining tooth in each arch, periodontal support of each arch and the preference of patient was also considered. The thickness of splint ranged between 2 and 3 mm. Splint was retrieved and polished.

Step 5: Vitamin D supplementation

Group S + D patients were given Vitamin D tablets 60,000 IU once a week for 8 weeks. Control group S patients were given placebo drug for the same time period. Vitamin D supplements and placebo drugs were packed in a sealed envelope imprinted with a random table number, which were given to the patients by a third person to ensure double-blinding. This procedure was done along with randomization. The study was double-blinded so that neither the researcher nor the participants were aware, whether the patient was in the study group or control group.

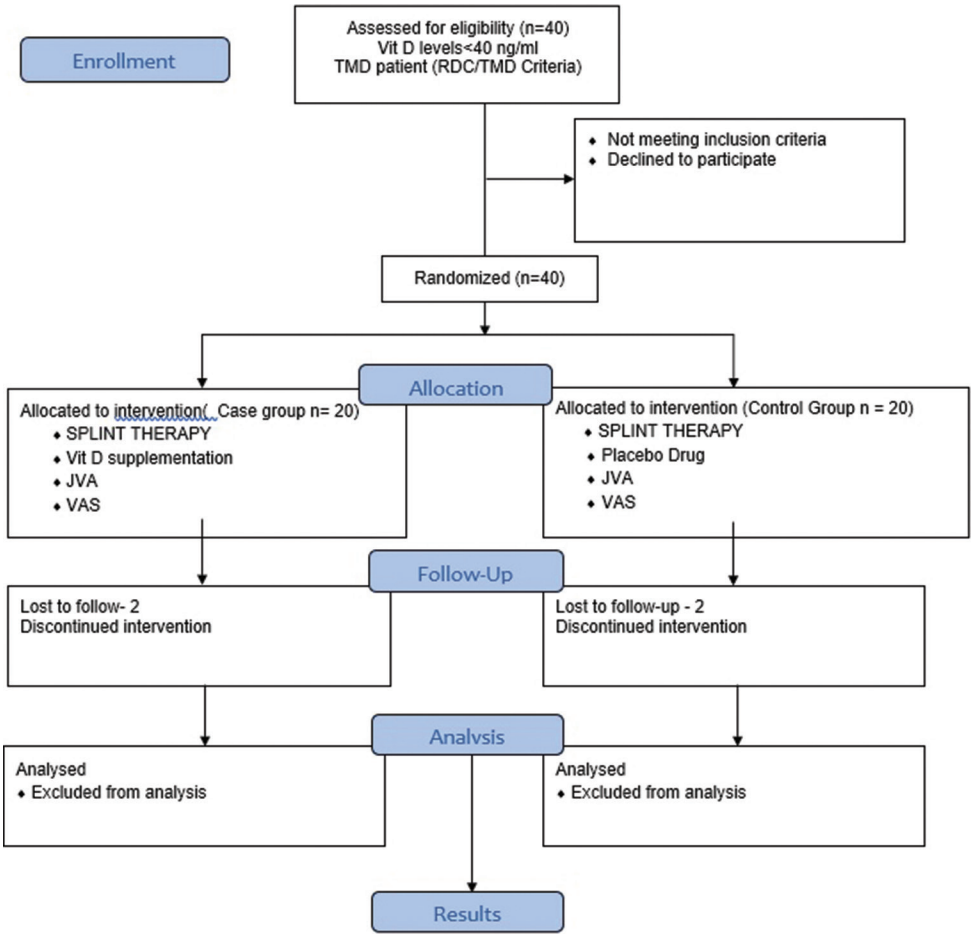

Figure 1: CONSORT flow diagram of trial

Figure 2: Joint vibration analysis sensors placed on temporomandibular joint along with amplifiers

Step 6: Splint insertion and follow-ups

Retention of the splint was checked and occlusal interferences were adjusted using 40 um articulating paper. Uniform contacts were verified in centric and canine-guided occlusion was given in splint. Follow-up done at 1st week, 1st month, 2nd month, and 3rd month after therapy. After the last follow-up, again blood tests were done to determine the Vitamin D levels.

Step 7: Statistical analysis

When the data obtained were under normal distribution, further inter-group and intra-group comparison was done.

Intergroup comparison

MannWhitney *U*-test was used to calculate significant intergroup differences of mean values of CMO, VAS pain score, MMO and TE of right and left TMJs before and after therapeutic intervention. The intergroup comparison of TMJ tenderness was done using Pearson Chi-square test.

Intragroup comparison

Friedman test was used for comparison of change with subsequent follow-up visits within each group. Wilcoxon signed-rank test evaluated the significance of difference in the CMO, VAS pain score, MMO and TE values of right and left TMJs to assess the treatment response and evaluate the improvement in subsequent follow-up.

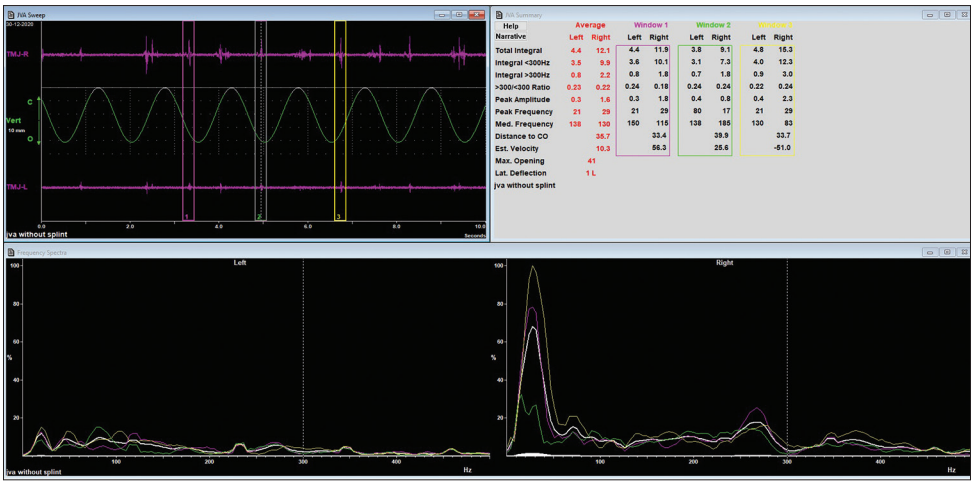

Figure 3: Temporomandibular joint vibrations recorded in the software

RESULTS

After randomization, 18 patients were allocated to each group. Baseline demographic variables of both groups such as CMO, VAS score, MMO, and TMJ tenderness score along with total integral energy (TE) of both the TMJ s are organized in Table 1.

Intergroup comparison

On comparing the mean of CMO, VAS Score, and MMO among two groups between delivery of splint and after 1 month of therapy, significant difference was seen ($P < 0.05$) [Tables 2-4]. Between all follow-ups, there was no significant difference was evident in mean values of TE of right and left TMJ between two groups [Tables 5 and 6]. On comparing means of Vitamin D levels at end of 3 months after therapy, significant difference was seen ($P < 0.05$) among two groups [Table 7].

Intragroup comparison

In both groups, there were significant statistical variations in CMO, VAS score, MMO, and TE integral before and after treatment in the right and left TMJs. Between follow-ups, there were significant statistical variations in CMO, VAS score, and MMO [Tables 8-10]. Statistically significant differences were seen between follow-up visits in TE integral of right TMJ in Group CS + D and TE integral of Left TMJ in both the groups [Tables 11 and 12]. Moreover, statistical difference was seen in Vitamin D levels before and after drug therapy in Group CS + D [Table 13].

Graphs were used to show the changes in tenderness grading as therapy progressed [Figures 4 and 5]. In Figure 4, it is depicted that at the time of diagnosis, 11 participants had Grade 3 tenderness and 7 participants had grade 2 tenderness, but at the end of 3 months, 12 participants had grade 1 tenderness and 6 of them had Grade 0 tenderness.

In Figure 5, it is depicted that at the time of diagnosis, 10 participants had Grade 3 tenderness and 8 participants had Grade 2 tenderness, but at the end of 3 months, 10 participants had Grade 1 tenderness and 8 of them had Grade 0 tenderness.

DISCUSSION

This trial was conducted to compare the Vitamin D supplementation and stabilization splint therapy in patients suffering from TMD using both JVA and VAS.

On comparing the mean of CMO, VAS score, and MMO among two groups, statistically significant difference were observed between delivery of splint and after 1 month of therapy which shows significant improvement. Stiesch-Scholz *et al*.[9] stated that increase in active mouth opening of 8.05 mm causes a significant reduction in pain during splint therapy. Pain reduction in group was evident after 1st follow-up where-as in control group, it was seen after 2nd follow up. This difference was significant and is because of Vitamin D supplementation. Hence, the null hypothesis was rejected. In this clinical trial, change in CMO was 2.11 mm for S + D group, 2.01 mm for S group, change in MMO was 3.11 mm for S + D group, 2.8 mm for S group.

Both therapy group patients showed improvement after 1 month of splint delivery and were consistent in both the groups as Stabilization splint therapy was given. Sato *et al*.[10] stated that Stabilization splint therapy gives 13% more successful results than other splints. Similar studies has been performed by Minakuch *et al*.[11] and

Table 1: Baseline characteristics of both group and control group

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
CMO (mm) at time of diagnosis	37.67±4.9 (26-46)	38.61±2.25 (35-43)	0.74
MMO (mm) at time of diagnosis	40.44±4.9 (30-48)	40.67±2.1 (38-44)	0.95
TMJ pain (Scale 0,1,2,3)	2.31±0.502 (2-3)	2.31±0.5 (2-3)	0.31
VAS score (0–9)	7.61±0.6 (6-8)	7.67±0.59 (7-9)	0.78
Serum Vitamin D levels at start (ng/ml)	25.11±1.7 (21.7-28.5)	24.83±1.89 (21.0-28.6)	0.64

*$P<0.05$, based on Chi-square and Mann–Whitney U test. SD: Standard deviation, S + D: Centric stabilization Splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, CMO: Comfortable mouth opening, MMO: Maximum mouth opening, TMJ: Temporomandibular joint, VAS: Visual Analog Scale

Table 2: Mean comparison of comfortable mouth opening

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	37.67±4.9 (26-46)	38.61±2.25 (35-43)	0.742
At 1st week	39.78±4.5 (30-48)	40.06±2.38 (36-44)	0.050*
At 1 month	41.67±3.29 (35-49)	41.78±2.15 (38-46)	0.188
At 2nd month	43.22±3.26 (36-50)	43.00±2.19 (38-48)	0.226
At 3 months	44.39±3.24 (36-50)	44.33±1.94 (40-48)	0.041*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 3: Mean comparison of maximum mouth opening

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	40.44±4.9 (30–48)	40.67±2.1 (38–44)	0.952
At 1st week	43.22±5.18 (36–52)	42.39±2.06 (38–46)	0.031*
At 1 month	44.44±3.05 (40–50)	44.50±2.59 (40–52)	0.379
At 2nd month	46.28±2.84 (41–52)	45.17±1.42 (42–48)	0.040*
At 3 months	47.11±2.61 (41–52)	45.94±1.58 (42–48)	0.076

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 4: Mean comparison for visual analog scale score

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	7.61±0.6 (6-8)	7.67±0.59 (7-9)	0.783
At 1st week	6.78±0.7 (6-8)	6.72±0.57 (6-8)	0.028*
At 1 month	6.00±1.02 (4-8)	6.00±0.76 (5-8)	0.345
At 2nd month	5.06±0.8 (4-7)	5.33±0.68 (4-7)	0.882
At 3 months	4.06±0.8 (3-5)	4.61±0.69 (3-6)	0.057*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

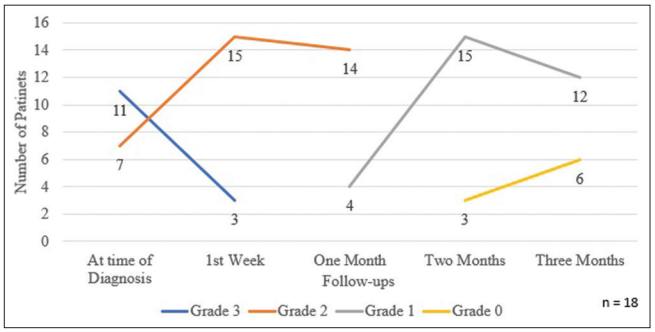

Figure 4: Graphs of how gradation of temporomandibular joint pain on palpation varies in Group S + D

Suvinen and Reade[12] which stated that the stabilization splints have a greater edge above other type of splint design. In this study, stabilization splint therapy was given to both groups keeping in mind the previous quoted literature.

In both the groups, there was a reduction in TMJ tenderness and muscle pain, resulting in increased MMO. This finding is consistent with study of Block *et al*.[13] in which he concluded that after 1 month of occlusal splint therapy, more than 73% of patients experience symptom remission because of correct condyle-disk relationship which alleviates the symptoms and reduce the muscle tenderness resulting in increased MMO.

After analyzing the pain score, S + D group showed the best response to therapy. In our study, the VAS Score decreased from 7.61 to 4.06 in group S + D, and 7.67 to 4.61 in group S. Both the group patients showed improvement in VAS Score in 4–8 weeks of therapy with consistent improvement. Best results were seen between 1st week and end of 3rd month ($P < 0.05$) in both the groups. Ekberg *et al*.[14] found that muscle myalgia decreases significantly after 6 weeks of duration and so does

Table 5: Mean comparison for total integral energy right temporomandibular joint (Hertz)

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	15.22±7.50 (2.3-29.2)	12.41±9.45 (3.9-34.0)	0.171
At 3 months	14.52±7.32 (1.8-28.6)	10.82±6.92 (3.4-28.4)	0.165

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 6: Mean comparison for total integral energy left temporomandibular joint (Hertz)

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	12.32±6.07 (2.3-22)	10.45±9.67 (3.3-39.1)	0.203
At 3 months	10.42±5.45 (2.2-21)	7.29±6.81 (2.0-28)	0.077

*$P<0.05$ significant, $P>0.05$=Insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 7: Mean comparison for serum Vitamin D levels

Characteristics	Mean±SD (minimummaximum)		*P* values between groups*
	Group S + D	Group S	
At time of diagnosis	25.11±1.7 (21.7-28.5)	24.83±1.89 (21.0-28.6)	0.64
At 3 months	33.56±2.79 (27.9-39.1)	26.11±2.08 (21.9-30.2)	0.02*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs, SD: Standard deviation

Table 8: Wilcoxon signed-rank test for comfortable mouth opening

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.512	0.917
P difference between 1st week and 1 month	0.040*	0.037*
P difference between 1 and 2 months	0.069	0.685
P difference between 2 and 3 months	1.000	0.820
P difference between at time of diagnosis and 3 months	0.05*	0.002*

$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 9: Wilcoxon signed-rank test for maximum mouth opening

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.031	0.092
P difference between 1st week and 1 month	0.126	0.018*
P difference between 1 and 2 months	0.023*	0.114
P difference between 2 and 3 months	0.343	0.246
P difference between at time of diagnosis and 3 months	0.023*	0.002*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 10: Wilcoxon signed-rank test for Visual Analog Scale score

Groups	Group S + D	Group S
P difference between at time of Diagnosis and 1st week	0.126	0.352
P difference between 1st week and 1 month	0.140	0.052
P difference between 1 and 2 months	0.020*	0.049*
P difference between 2 and 3 months	0.092	0.102
P difference between at time of diagnosis and 3 months	0.035*	0.032*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

VAS Score because of reduction in muscular myalgia in specifically inferior lateral pterygoid muscle.

Both groups of patients demonstrated a downgrading of TE value of the right TMJ. Similar results were found for TE value of left TMJ. Statistically significant differences were found between 1st week and end of 3rd month signifying improvement and reduction in both the joints vibrations ($P < 0.05$). Stabilization splints has been proved in reducing TMJ vibrations. Garcia *et al*.[15] noted that the

Table 11: Wilcoxon signed-rank test for total integral energy right temporomandibular joint

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.049*	0.098

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 12: Wilcoxon signed-rank test for total integral energy left temporomandibular joint

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.002*	0.042*

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

Table 13: Wilcoxon signed-rank test for serum Vitamin D levels

Groups	Group S + D	Group S
P difference between at time of diagnosis and 3 months	0.002*	0.08

*$P<0.05$ significant, $P>0.05$ insignificant. S + D: Centric stabilization splint along with Vitamin D supplements, S: Centric stabilization splint along with placebo drugs

vibrations are decreased when mandible is advanced by a mandibular advancement device. Splints causes a forward rotation of the condyle favouring a softer movement during its reduction. In our study, vibrations were decreased in both the groups mostly because of correct condyle-disk relationship permitting softer movements.

Tenderness in TMJ was relieved in both the groups because of stabilization and distribution of forces. Similar studies were found by Kovaleski and De Boever[16] who showed reduction in pain within 2 months of splint therapy.

After analyzing the Vitamin D levels, best response was seen with S + D group, obviously because of 60,000 IU Vitamin D capsules which were given to all the participants in Group S + D. In our study, the Vitamin D levels increased from 25.11 to 33.56 ng/ml and 24.83 to 26.11 ng/ml in group S + D and Group S respectively which was statistically significant ($P < 0.05$). On comparing *P* values between 1st week and end of 3rd month, the difference was significant in group S + D. Park[7] conducted a systematic analysis to see if there was a relation between Vitamin D and osteoarthritis (OA). Vitamin D, according to Park, may help to prevent joint pain. Patients suffering from TMD who have low Vitamin D may benefit from this treatment. Systemic review of Kui *et al*.[17] culminated that the literature is present to link Vitamin D deficiency and TMD but clinical trials or placebo-controlled trials are not there to prove so. Hence, keeping the above statement in mind, this placebo-controlled clinical trial was planned. The current

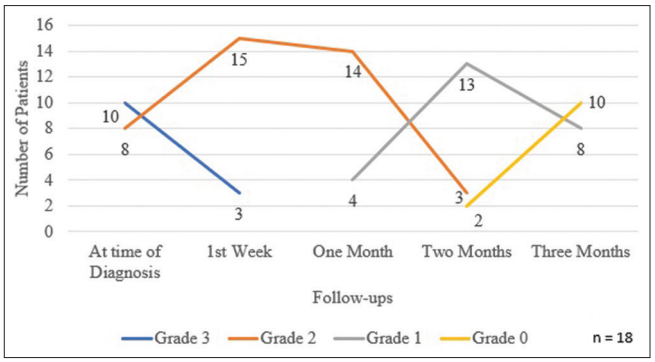

Figure 5: Graphs of how gradation of temporomandibular joint pain on palpation varies in Group S

study had a small sample size, but it was seen that Vitamin D hastens the treatment and gives a quick relief from symptoms of TMD. In future studies, larger sample size and inclusion of more parameters is herewith suggested.

CONCLUSIONS

Following conclusions can be withdrawn from this clinical study:

1. Centric stabilization splint helps in improving mouth opening, reduction in VAS scale, decrease in TEs of both right and left TMJ, and reduction in TMJ tenderness in TMD patients
2. Patients with TMD and Vitamin D deficiency should be supplemented with Vitamin D along with splint therapy to provide faster relief in symptoms.

Acknowledgment

We would like to acknowledge Dr. Vashi, Maulana Azad Institute of Dental Sciences, New Delhi for helping us with the study.

Declaration of patient consent

The authors declare that they have obtained consent from patients. Patients have given their consent for their images and other clinical information to be reported in the journal. Patients understand that their names will not be published and due efforts will be made to conceal their identity but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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