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Evaluation of Plain Ultrasound Therapy Versus Diclofenac Phonophoresis for the Management of Temporomandibular Joint Disorders

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ABSTRACT

Objective: Temporomandibular joint disorders (TMD) are one of the most common causes of Chronic orofacial pain. Management of TMD includes various invasive and non-invasive methods. The present study was undertaken to compare the efficacy of plain ultrasound therapy and 1% diclofenac gel phonophoresis in the management of TMDs.

Materials and Methods: 50 participants with pain in the TMJ region, falling in Research Diagnostic Criteria (Group I and II) for TMJ disorders and in the age group of 18-40 years were included in the study. Participants were divided into 2 groups by simple randomization. Group A comprised of 25 participants who received plain Ultrasound therapy, while Group B comprised of 25 participants who received Diclofenac gel Phonophoresis. All the study participants were asked to refrain from consuming any other analgesics and muscle relaxants until the completion of six sessions over a period of two weeks. Pre and Post treatment assessment of the participants was carried out using visual analogue scale (VAS) for TMJ pain, Maximum Mouth opening (MMO) and Helkimo clinical dysfunctional Index (HI). Recurrence within a period of 3 months was recorded in both groups.

Results: Intergroup comparisons of VAS, HI and MMO between pre and post treatment were analysed using Independent t-tests. The difference in the mean pre (T1) and post (T2) treatment pain VAS scores and Helkimo index (HI) in both the groups was statistically significant. Group B showed statistically significant reduction in the VAS scores, HI compared to Group A. There was no statistically significant difference in the recurrences among the two groups.

Conclusion: The findings of present pilot study showed that both the methods were effective, however 1% Diclofenac phonophoresis was more effective than plain ultrasound therapy with regard to reduction of pain and functional ability of the TMJ.

Keywords: Temporomandibular joint disorders, Ultrasound therapy, Phonophoresis.

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Introduction

Temporomandibular joint (TMJ) is one of the most complex synovial joint formed by the mandibular condyle and its corresponding temporal cavity. TMJ has a vital role in monitoring the mandibular movements thereby controlling various essential daily tasks such as speech and mastication.[1] Temporomandibular joint disorders (TMD) are one of the most common causes of chronic orofacial pain. According to the American Academy of Orofacial Pain (AAOP), TMD is a collective term given for a number of clinical problems which involve the masticatory muscles, the temporomandibular joints and associated structures.[2] Literature evidence shows that TMD affects approximately 10% to 15% of adult population.[3] The etiology of these disorders is complex and their management includes various invasive and non-invasive methods. Conservative management options for TMD treatment include occlusal therapy, physical therapy, oral pharmacotherapy, orthodontic treatment.[4]

Oral pharmacotherapy is the most commonly used treatment for TMDs. Non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants are the frequently used drugs for pharmacotherapy, but they have significant adverse effects.[5] Physical therapy modalities such as manual therapy, biofeedback, ultrasound therapy and transcutaneous electrical nerve stimulation (TENS) are also widely accepted non-invasive modalities for the management of TMDs.[6] Therapeutic ultrasound utilizes ultrasonic waves with vibrations above 16,000 vibrations/second or 16 Hertz. It is known to increase blood flow, permeability, and promote healing of tissues. It also has the ability to reduce pain and muscle spasms by increasing the extensibility of collagen fibres.[7,8] Phonophoresis is a treatment modality that utilizes ultrasound waves to aid the percutaneous transport of drug molecules to aid in better absorption.[9] Established proofs need to be included in the literature regarding the beneficial effects of phonophoresis in TMDs.

Though there are various non-invasive modalities available in the literature for the management of TMDs, there is a scarcity of literature comparing their efficacy in the management of TMDs. The primary outcome of management of TMDs is pain relief and improved functional ability. Hence, the present study was undertaken to compare the efficacy of plain ultrasound therapy and 1% diclofenac gel phonophoresis in the management of TMDs.

Materials and Methods

Our study was approved by the Institutional Research and Ethical Committee (Certificate No. ABSM/E/123/2021) and followed the principles set forth in the Helsinki Declaration.

The study was carried out in the Orofacial Pain Clinic of a private dental hospital in India. The present randomised control study comprised of 50 participants in the age group of 18-40 years, who reported with complaint of pain in the TMJ region. All patients were evaluated by two trained Oral Medicine and Radiology specialists with more than 10 years of clinical experience. Panoramic radiograph and TMJ views were taken to evaluate degenerative changes in the TMJ. Participants with degenerative changes such as flattening, surface erosions, Ely cyst, sclerosis, osteophytes, and loose joint body in panoramic radiograph and TMJ view were excluded from the study. All the relevant data was recorded in the study proforma. Any contradictions that arose in the evaluation of research topics were resolved by discussing among the two specialists.

TMJ disorders were evaluated according to the Research Diagnostic Criteria (RDC/TMD)[10] in the study. The Research Diagnostic Criteria (RDC) categorise TMD into 3 groups. They are as follows: [10]

Group I: Muscle disorders
a) Myofascial pain
b) Myofascial pain with limited opening,
Group II: Disc Displacements (DD)
a) DD with reduction
b) DD without reduction with limited opening
c) DD without reduction without limited opening,
Group III: Other common Joint disorders:
a) Arthralgia
b) Osteoarthritis
c) Osteoarthrosis

Participants with a history of TMJ pain for more than 3 months, participants falling in Research Diagnostic Criteria Group I and II for TMJ disorders were included in the study. The exclusion criteria for the study consisted of the following:

- Participants with history of recent trauma, open facial wounds, cardiac pacemakers, metal implants in the craniofacial region.
- Participants with a history of systemic disorders and syndromes
- Participants with pure arthrogenic pain (RDC/TMD Group III), patients with known disease such as rheumatoid arthritis, ankylosing spondylitis, systemic lupus, gout, reactive arthritis, fibromyalgia
- Participants with features of degenerative diseases such as flattening, surface erosions, Ely cyst, sclerosis, osteophytes, and loose joint body in the panoramic radiograph and TMJ views.
- Participants with associated odontogenic pain.
- Participants who had been previously treated with ultrasound therapy without any clinical improvement were also excluded from the study.

Study sample size calculation

Based on Standard deviation of 0.86 in group I, Standard deviation of 1.21 in group II, Mean difference of 1.22, Effect size is 1.17874396135266, Alpha Error is 0.5(%), Power 90% for two sides test the required sample size per group is 25.[11] This was calculated using Master software version 2.

Study participants who fulfilled the inclusion criteria and were willing to take part in the study were explained about the study procedures in detail and written informed consent was obtained before commencement of the intervention. Participants were categorized into 2 groups based on simple random sampling by independent postgraduate residents. Group A comprised of 25 participants who received plain Ultrasound therapy, while Group B comprised of 25 participants who received 1% Diclofenac gel (Voveran® Emulgel®) Phonophoresis. All the study participants were asked to refrain from consuming any other analgesics and muscle relaxants until the completion of six sessions.

Electroson–709 (Techno med Electronics) ultrasound device was used for performing the ultrasound therapy and phonophoresis. The pre-auricular skin of the affected TMJ region was cleansed prior to the therapy. A layer of Ultrasound gel was evenly spread over the transducer head and the application was done on Continuous mode in slow circular motions with a frequency of 1 MHz, intensity of 1.3 W/cm² for 10 minutes for one session. Three such sessions weekly for a period of 2 weeks was given. For the phonophoresis group (Group B), Ultrasound gel along with 1% Diclofenac gel (in the ratio of 1:1) was spread evenly over the transducer head and the application was done using the same parameters and duration. Figure 1 shows ultrasound device and clinical application procedure. During each follow up visit, patients were asked about compliance with the instruction to refrain from consuming any other analgesics and muscle relaxants and response were recorded. All the study participants were informed to report if they experience any adverse effects pertaining to the treatment provided.

The visual analogue scale (VAS) and Helkimo dysfunctional clinical index were used before and after every treatment session to monitor changes in intensity of pain and efficacy of the treatment.

The participants were assessed in terms of TMJ Pain, Maximum Mouth opening, Helkimo clinical dysfunctional Index and recurrence within a period of 3 months. Pain was measured using VAS in a 0-to-10-point scale. VAS was used to assess subjective ratings of the subject's pain intensity.

Maximum Mouth opening (MMO) was measured as using a calibrated vernier calliper with 1mm precision and the inter incisal distance was noted. Helkimo clinical dysfunction index (HI) was recorded based on the clinical examination of TMJ.

Helkimo clinical dysfunction index (HI) has the following signs for assessment: limited movement, limitation of TMJ

movement, muscle pain, TMJ pain and pain during jaw movements. Patients were given a score of 0 points for absence of symptoms, 1 point for mild pain or dysfunction, and 5 points for severe pain or dysfunction.[12-14]

The pre and post treatment assessments were performed by oral physicians who were blinded about the intervention provided to the subject.

Statistical Analysis

The data obtained were tabulated and expressed in mean ± standard deviation. Statistical analysis was performed using Statistical Package for the Social Sciences - Version 21 (SPSS Inc., Chicago, IL, USA). Intra-group differences for pain between pre-treatment and post treatment were analysed using Wilcoxon rank test, while intergroup comparisons of VAS, HI and MMO between pre and post treatment were analysed using independent t-tests. Chi square test was used to compare the recurrences among the groups. P value< 0.05 was considered to be statistically significant.

Results

The study constituted of 50 subjects, 25 participants in group A and 25 participants in group B. Out of which 17 were males and 33 were females. Group A had 10 males and 15 females and Group B had 7 males and 18 females. Minimum age of the participants was 18 years and maximum age was 40 years. Demographic details of the study participants were given in Table 1. The mean age of the study participants in group A was 29.32±9.8 years and in Group B was a 29.84±11.28 year.

Group A participants received plain Ultrasound therapy and Group B participants who received 1% Diclofenac gel phonophoresis. None of the study participants reported adverse effects pertaining to the treatment provided.

Subjective pain assessment by VAS showed decreased pain after treatment provided in both the groups. There was a statistically significant difference in mean pre (T1) and post (T2) treatment in both the groups (p<0.001) (Table 2). The pretreatment VAS in Group A and Group B was 7.24 and 7.76, while it reduced to 2.80 & 1.56 respectively post treatment. There was statistically significant reduction in the VAS (T2-T1) in Group B when compared to Group A (p=0.001) (Table 3, Figure 2).

Helkimo Dysfunctional Index was recorded in both groups before and after treatment sessions. There was a statistically significant difference between mean pre (T1) and post (T2) treatment in both the groups (p<0.001) (Table 2). The pretreatment HI in Group A and Group B was 5.28&5.84, while it reduced to 2.28 and 1.84 respectively post treatment. There was statistically significant reduction in the HI (T2-T1) in Group B when compared to Group A (p=0.027) (Table 3, Figure 3).

Maximum Mouth Opening was recorded in all study participants pre and post treatment. The pre-treatment MMO in Group A and Group B was 40.04 & 39.6, while it reduced to 42.76 & 43.32 respectively post treatment. There was a statistically significant difference between the mean pre (T1) and post (T2) treatment in both the groups (p<0.001) (Table 2). There was statistically significant increase in the maximum mouth opening (T2-T1) in Group B when compared to Group A (p = 0.005) (Table 3, Figure 4).

The participants were followed up for a period of 3 months after the intervention for the recurrence of the pain and functional limitation of the TMJ. Four (16%) participants in Group A and one (4%) subject in Group B reported with recurrence. But there was no statistically significant difference in the recurrences among the two groups (P value 0.157). Comparison of recurrence among both the groups shown in Table 4.

Table 1: Demographic details of the participants included in the study

	Group – A Ultrasound Therapy	Group – B Diclofenac Phonophoresis
Number (n)	25	25
Age (in years)	Minimum = 19 Maximum = 39 Mean = 29.32	Minimum = 18 Maximum = 40 Mean = 29.84
Gender n (%)	Males = 10 (40%) Females = 15 (60%)	Males = 7 (28%) Females = 18 (72%)

Table 2: Intra group Comparison between two groups

T2-T1		Group	Mean	Std. Deviation	P value *
VAS	A	Pre (T1)	7.24	1.899	< 0.001
		Post (T2)	2.80	1.500	
	B	Pre (T1)	7.76	1.090	< 0.001
		Post (T2)	1.56	1.083	
HI	A	Pre (T1)	5.28	1.620	< 0.001
		Post (T2)	2.28	1.242	
	B	Pre (T1)	5.84	1.434	< 0.001
		Post (T2)	1.84	1.027	
MMO	A	Pre (T1)	40.04	2.776	< 0.001
		Post (T2)	42.76	3.031	
	B	Pre (T1)	39.60	3.175	< 0.001
		Post (T2)	43.32	2.982	

VAS : visual analogue scale , MMO: Maximum Mouth opening , HI: Helkimo clinical dysfunctional Index , * : symbol represents statistically significant value

Table 3: Inter group Comparison between two groups

T2-T1	Group	Mean	Std. Deviation	P value *
VAS	A	4.44	1.635	0.001
	B	6.20	1.848	
HI	A	3.00	1.154	0.027
	B	4.00	1.870	
MMO	A	2.72	1.027	0.005
	B	3.72	1.061	

Table 4: Comparison of recurrence among both the groups

	Group – A Ultrasound Therapy	Group – B Diclofenac Phonophoresis	P value
Recurrence within 3 months n (%)	4 (16%)	1 (4%)	0.157

Figure 1: Clinical image showing instrumentation (A,B) and application procedure(C).

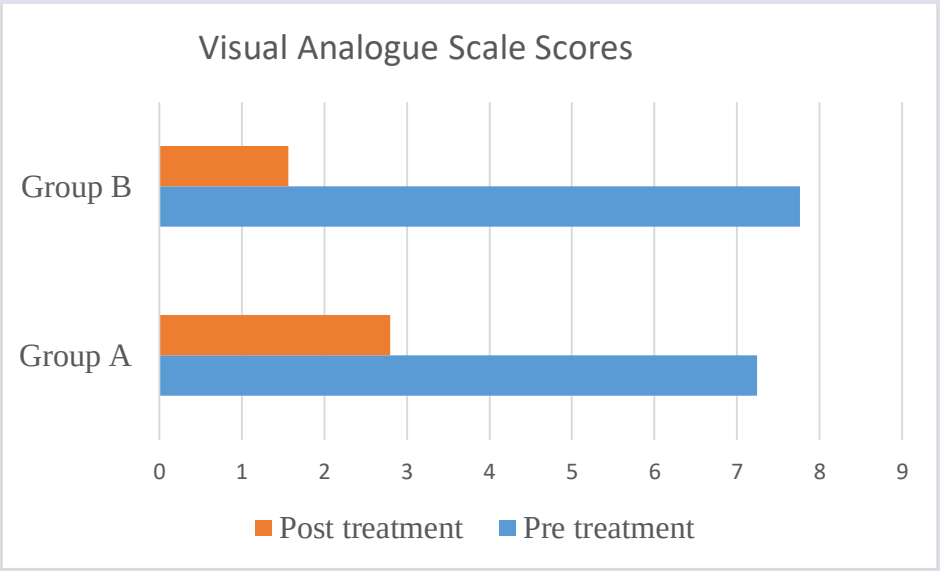

Figure 2: Mean Pre and Post treatment VAS score of both the groups

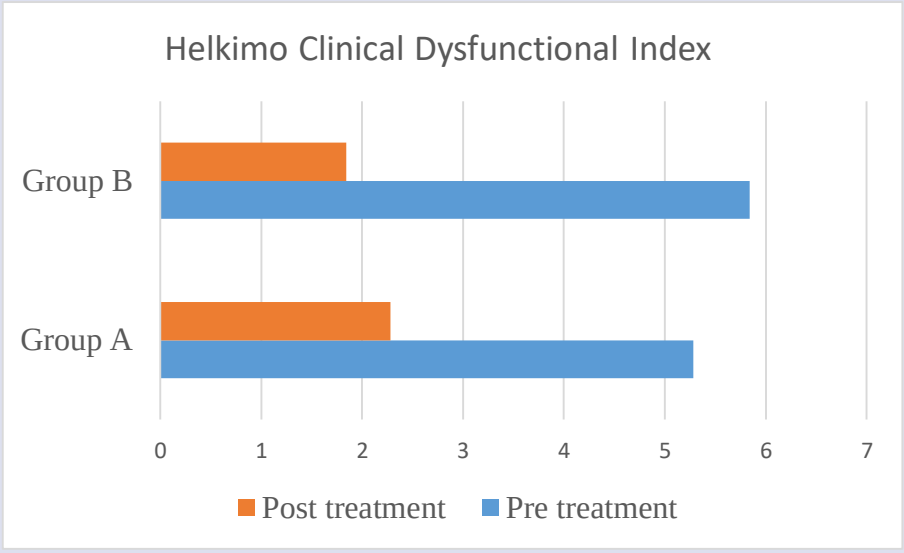

Figure 3: Mean Pre and Post treatment HI value of both the groups.

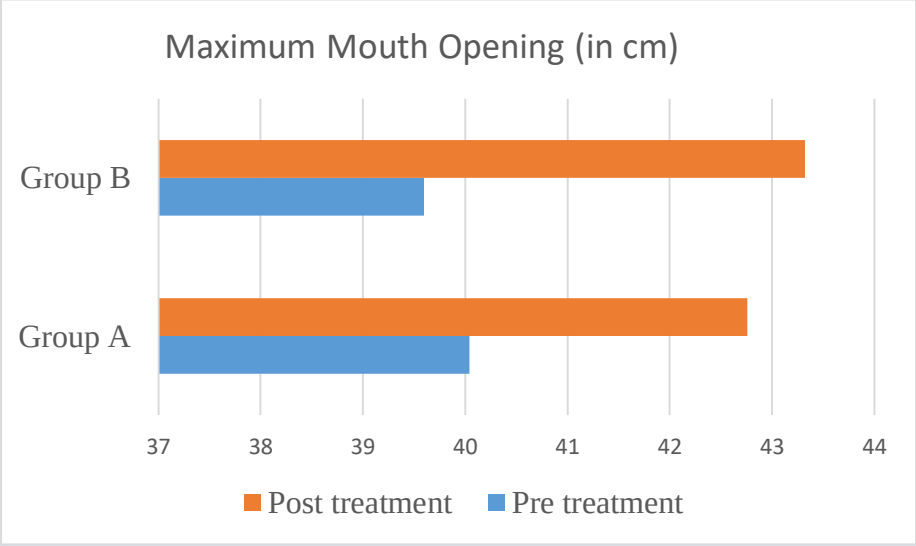

Figure 4: Mean Pre and Post treatment Maximum Mouth Opening of both the groups.

Discussion

Temporomandibular joint disorders may present with various signs and symptoms such as pain, joint noises, deviation of the jaw, limitation in the range of motion etc. Present study involved patients reporting with TMDs within the age range of 18-40 years. In the present study, the mean age of participants with TMDs was 29.5 years. A Study by Sachdeva *et al*. also found TMD to be more prevalent in the age group of 17–26 years of age.[14] Literature evidences show that the peak incidence of TMDs occur in the age group of 20-40 years.[3] We observed a female predilection in our study that can be attributed to behavioural, hormonal, and constitutional variations in females. Various studies have reported female predilection of TMDs, similar to our study.[14-17]

Pain is the foremost problem associated with TMD and it is the major reason for patients to seek medical care for TMDs.[3] The primary aim in the management of any TMD is to provide pain relief and to improve the functional ability.[18]

A systematic review assessed the efficacy of topical interventions in pain reduction and other secondary outcomes associated with TMD and reported that evidence is insufficient to support the use of topical nonsteroidal anti-inflammatory drug (NSAIDs) and capsaicin, Threraflex-TMJ, bee venom, Ping On, and cannabidiol. They recommended additional studies to validate the results.[19]

Ultrasound therapy can aid in the alleviation of pain and serve as a delivery medium for topical drugs. There are various advantages of application of ultrasound therapy in the management of TMDs, such as the lack of invasiveness and elimination of the systemic administration. It is also well tolerated by the patients, which makes ultrasound a versatile tool in the management of various musculoskeletal conditions.[20] Hence the present study used Ultrasound therapy for management of TMDs. Various drugs such as anti-

inflammatory drugs, corticosteroids such as hydrocortisone, dexamethasone, salicylates, anesthetics such as lidocaine, can be delivered percutaneously by the application of Ultrasound.[21] Diclofenac gel was used in the present study for phonophoresis.

A recent report stated that phonophoresis is a valued modality in physiotherapy, which has diverse applications and has demonstrated clinical efficacy in various musculoskeletal and inflammatory conditions. They listed various patents available related to phonophoresis in their report.[22]

Assessment of pain and pain related disability is of paramount importance in evaluation of TMD patients.[23] In our study, we evaluated the efficacy of treatment by assessing the pain, clinical dysfunction and MMO. Pain is a subjective sensation experienced by the patient. There are various qualitative and quantitative methods to assess pain.[24] A systematic review by Hjermstad *et al*[25] recommended the use of unidimensional pain scales for the assessment of pain intensity. This includes the Numerical Rating Scale, Verbal Rating Scale and Visual Analogue Scale (VAS).[25] In our study, we evaluated the pain intensity using VAS, which is easy to record and a comparable method to assess the pain. Various other studies have also used VAS for measurement of TMJ related pain.[25-28] Assessment of dysfunction associated with TMD is another important factor that has been evaluated. Helkimo Clinical Dysfunction Index is a simple, swift and a reliable method to assess the limitation of motion, pain and joint function. According to Alonso-Royo *et al*., Helkimo Clinical Dysfunction Index is a suitable and valid diagnostic method for temporomandibular joint disorders.[29]

In the present study, participants in both the groups showed considerable reduction in pain and dysfunction along with improvement in mouth opening. Rai *et al*. found ultrasound therapy to be effective in reducing TMD associated myofascial pain.[7] Various other studies have also found ultrasound to be beneficial in the management of pain and in improving mouth opening, similar to our findings.[4,7,30]

[27] Topical applications of drugs can induce allergic reactions in hypersensitive individuals; hence a skin testing is mandatory before phonophoresis. Our patients did not report any adverse reactions. Apart from NSAIDs, corticosteroids can also be safely administered using phonophoresis for the management of TMDs.[28]

The main goal of management of TMJ disorders is alleviation of pain. The pain associated with TMD is proportional to the deterioration of functional ability of the joint.[33] Hence, effective management of pain can reduce the dysfunction associated with TMDs. Though ultrasound therapy and phonophoresis are effective in the symptomatic management of TMDs, we noted recurrence in 16% of participants in the therapeutic ultrasound group and in 4% of participants in the phonophoresis group. Though the symptomatic recurrence is less in the phonophoresis group, it was not statistically significant. The variations in the recurrences observed may be attributed to the multifactorial nature of the disorder. Wieckiewicz M *et al* mentioned that though physical therapy modalities are considered as the primary therapeutic choice for the management of TMD pain, the treatment should also be directed towards the elimination

Ultrasound waves penetrate the tissues and produce vibrations at the molecular level generating thermal energy. The local increase in thermal energy aids in vasodilatation, alteration of cellular permeability and promotion of cellular metabolism. This results in utilization of inflammatory mediators, yielding pain relief and decrease in joint stiffness which in turn leads to increase in mouth opening and reduced joint dysfunction.[31]

We used 1% diclofenac gel in conjugation with ultrasound to provide phonophoresis. There are various drugs that have been used to as analgesic for TMD phonophoresis. Fernandez-Cuadros *et al*. in their study used 10% diclofenac, while Vijayalakshmi *et al* and Ramakrishnan et al. used aceclofenac.[11,27,32] In our study, there was a significant decrease in the post treatment VAS and dysfunctional index, with improved mouth opening when compared to the baseline in the phonophoresis group. Vijayalakshmi *et al*. in their clinical trial, reported improved mean maximum mouth opening with reduction in scores of VAS and Helkimo dysfunction index in aceclofenac phonophoresis group as compared to topical application of acelcofenac.[32] Our study results are in collaboration with Ramakrishnan *et al*. study which reported aceclofenac phonophoresis to be superior to plain ultrasound therapy in pain management of TMDs.[11]

The improved efficacy of diclofenac phonophoresis group can be attributed to the anti-inflammatory and analgesic effect of the NSAID that contributes in the reduction of inflammation of the joint.[26] Since, Diclofenac is not metabolized in the skin; it can be transported transdermally with the aid of ultrasound. Phonophoresis can provide a safe absorption of the drug without the need for oral administration which may be accompanied by various adverse effects. It can also serve as a painless, non-invasive substitute to injections for the management of inflammatory musculoskeletal conditions.[21,26-27] Our finding is also in accordance with a study by Fernandez-Cuadros *et al*. who reported diclofenac phonophoresis to be effective in the management of TMDs.

of possible etiology to achieve long term results without recurrences.[34]

Limitations of the present study was unequal gender distribution in both the groups. Due to randomization equal gender distribution in two study groups was not considered in the present study.

Conclusions

Therapeutic ultrasound and Phonophoresis are effective physical therapy modalities for the management of temporomandibular joint disorders. Present study results showed that 1% Diclofenac phonophoresis was more effective than plain ultrasound therapy in terms of reduction of pain and improving the functional ability of the TMJ. Though our study results emphasize the superiority of Diclofenac phonophoresis over plain therapeutic ultrasound in the management of temporomandibular joint disorders, further large-scale studies comparing the efficacy of phonophoresis using drugs for the management of TMDs have to be undertaken.

Conflicting interests

The authors declare no conflicts of interest

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Ethic approval

Our study was approved by the Institutional Research and Ethical Committee (Certificate No. ABSM/E/123/2021) and was performed abiding the principles set forth in the Helsinki Declaration.

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