Original Research Article

EVALUATION OF EFFICACY OF ULTRASOUND THERAPY AS AN ADJUVANT IN MANAGEMENT OF MYOFASCIAL PAIN: A RANDOMIZED CLINICAL TRIAL

ABSTRACT

Aims: To determine ultrasound therapy as an effective adjuvant for the management of myofascial pain involving masticatory muscles.
Study design:randomized clinical trial study
Place and Duration of Study: Department of oral medicine and radiology, Narayana dental college and hospital between march 2021 to November 2022

Methodology:we included 30 patients (20 females and 10 males; age group >18 years) clinically diagnosed with Myofascial pain who were randomly assigned into two groups each comprising of 15 patients. Group A patients received ultrasound therapy along with tizanidine 2mg twice a day for 14 days while group B patients received tizanidine alone. All the patients were evaluated for maximum inter-incisal distance, tenderness of muscles of mastication on palpation, pain while chewing, and pain during mandibular movements at baseline, 7th and 14th day.

Results:A significant pain reduction and improvement in mouth opening was found in both the groups. However, patients who received both tizanidine and ultrasound therapy had greater relief compared to other group from 7th day to 14th day and the results were statistically significant**.**

Conclusion:: No side effects were observed in Group A during or after ultrasound therapy. As it is a non-invasive therapeutic modality and offers good patient compliance, ultrasound therapy can be used as an effective therapeutic adjuvant for the management of myofascial pain.

Keywords: Ultrasound therapy, Myofascial pain, Temporomandibular disorders, Tizanidine

1. INTRODUCTION

Myofascial pain is a chronic form of muscle pain that originates from Myofascial trigger points in the skeletal muscle. TRPs are small and sensitive areas in a muscle that spontaneously or upon stimulus(compression) can initiate muscle pain and induce referred pain.[1] Myofascial pain is classified as a TMJ dysfunction group I Axis I, according to Research Diagnostic Criteria for TMDs that primarily involves the muscles of mastication.[2]Myofascial pain syndrome is widely prevalent in the general population and its prevalence estimates to be ranging from 9 to 85%.[3] The prevalence of TMDs among patients presenting to dental clinics due to pain ranges from 30 to 93%. The most common signs & symptoms include pain in the orofacial region, muscle tenderness, decreased mandibular motion, and deviation of jaw to the affected side during the opening. Most of the cases of Myofascial pain present with dull, aching pain in pre-auricular region aggravated by mandibular movements which with restricted mouth opening.[4] Management of myofascial pain aims to identify the myofascial trigger points and provide treatment either by eliminating etiology or providing pharmacological/ non- pharmacological therapy, thereby restoring

normal muscle function and relieving pain.[5] A wide number of therapeutic approaches have been tried for the management of myofascial pain. They include pharmacological agents such as muscle relaxants, NSAIDs, and tricyclic antidepressants, occlusal splints, electrotherapy using TENS, behavioral therapy, and physiotherapy using therapeutic ultrasound.[6] Ultrasound is an accepted adjuvant therapeutic modality for pain relief in various diseases. It uses ultrasound vibrations above 16,000 vibrations or 16 Hz with a frequency of 1.0-3.0 MHz range.[7]Therapeutic US have thermal and non-thermal effects which accelerates healing, decreases joint stiffness, and reduces pain and muscle spasm which is directly related to improved mouth opening. Hence, the aim of the study is to evaluate the efficacy of ultrasound therapy in the management of myofascial pain. In the current study, we hypothesized that ultrasound therapy when used as an adjuvant along with conventional pharmacotherapy would be more effective compared to pharmacotherapy used alone.

2. MATERIAL AND METHODS

This randomized clinical trial study was carried out in the outpatient department of Oral Medicine and Radiology. A total of 30 adult patients were included for the study of either gender. This study was approved by institutional ethical committee (Ref. No. (IEC/NDCH/2020/P-15). Nature of the study and treatment protocols were explained to the patients. patients with clinically diagnosed cases of myofascial pain according to the RDC for TMDs were enrolled in the study after taking written informed consent forms. Patients were clinically evaluated for signs and symptoms of myofascial pain namely tenderness over muscles of mastication and limited mouth opening. patients fulfilling the RDC for TMDs and willing for participation were included in the study. Patients with Acute Dental Pain, TMJ Arthritis/Internal Derangement, Atypical Facial Pain and Atypical Odontalgia, Neuropathies, Psychiatric disorders, Pain attributable to recent trauma, Migraine and other Vascular Headaches, Sinusitis Patients, Patients with Pain of Auditory Origin and Patients with Artificial Pacemakers were excluded from the study. Patients were randomly divided into Group A and Group B using computer-based randomization. In both the groups, conventional pharmacotherapy was given to all the patients i.e., Tab. Tizanidine 2mg twice a day after food for 14 days. In Group A, in addition to the conventional pharmacotherapy, therapeutic ultrasound wasadministered. During the ultrasound therapy, Acoustic gel was applied to keep the transducer in firm contact with the patient's skin. The transducer was placed on patient's skin over the affected area. The US machine used was Physiogears digital unit ultrasound physiotherapy machine with a frequency of 1MHz and pulse setting of 1:1 for 8 minutes at an intensity of 1W/cm^{2}for each session twice in a week for 2 weeks(figure 1).Both the group of patients were evaluated for following parameters at baseline before the treatment, 7th day and 14th day after treatment.

1. Maximum mouth opening i.e., inter incisal distance without pain.
2.Tenderness on palpation of two or more muscles of mastication were evaluated on Visual Analog Scale as mild, moderate and severe.
3.Pain at rest, pain with mandibular motion, pain on chewing were evaluated on Visual Analog Scale as mild, moderate and severe.

In VAS score 0-3 is taken as mild, 4-6 as moderate 7-10 as severe.

Statistical analysis:

The data obtained was entered in Microsoft Excel spreadsheet 2013 and subjected to statistical analysis with SPSS version 21 to evaluate the significant difference in pain reduction and improvement of mouth opening between group A & group B after the completion of treatment. Mann Whitney U test was used for the comparison of mouth opening between two groups. Fisher exact test was used for the comparison of pain score between two groups from baseline to 7th and 14th day. $P < .05$ was considered as statistically significant.

figure 1: Therapeutic Ultrasound machine

3. RESULTS AND DISCUSSION

Results

The present study consisted of 30 patients clinically diagnosed with myofascial pain of age groups affecting above 18 years of either gender and were randomly assigned into two groups.The mean age of patients in group A & Group B was 41.0±15.15 and 37.5±14.81, respectively. In the study sample, 20 patients were females and 10 were males. In group A 2 (13.3%) were males and 13 (86.7%) were females. In group B, 8 (53.3%) were males, and 7 (46.7%) were females. (Table 1)

The mean ± standard deviation of interincisal mouth opening in both groups individuallybefore and after treatment was statistically significant(*P<.001).* when comparedbetween two groups there was no statistical significance in improvement in mouth opening from baseline to 7th day. But, significant improvement in mouth opening was seen between two groups from 7th day to 14th day(*P<.001).* (Table 2)

The severity of tenderness, pain during mandibular motion, pain while chewing in both the groups individuallybefore and after the treatment was statistically significant (*P<.001)).* when compared between two groups there was no statistical significance in reduction in severity of tenderness, pain during mandibular motion, pain while chewing from baseline to 7th day. However, statistically significant reduction in tenderness, pain during mandibular motion, pain while chewing was seen between two groups from 7th day to 14th day(*P<.05).* (Table 3,4,5)

Table 1: mean age and gender-wise distribution of the study population:

Demographics	**Group A n(%)**	**Group B n(%)**
Males	2(13.3)	8(53.3)
Females	13(86.7)	7(46.7)

Age (mean ±SD)	41.0±15.15	37.5±14.81

Table 2: Intergroup comparison of mouth opening b/w group A and group B

Intervals	Groups	Mean ±SD	Mean difference	Mean % change	*P*-value
Baseline	Group A	27.13±3.11	1.33±4.0	4.9	0.224(NS)
	Group B	28.46±3.15			
7^{th} day	Group A	32.53±2.85	1.67±3.9	5.1	0.136(NS)
	Group B	30.86±2.92			
14^{th} day	Group A	38.4±2.09	4.8±2.8	12.5	<0.001*
	Group B	33.6±2.26			

Table 3: Intergroup comparison of tenderness on palpation of muscles of mastication betweenGroup A & Group B

Intervals	**Severity of pain**		Groups		Fisher exact test
			Group A	Group B	
Base line	severe	N	15	15	----
		%	100.0%	100.0%	
7^{th} day	moderate	N	14	13	x^2:0.37 p=0.543(NS)
		%	93.3%	86.7%	
	severe	N	1	2	
		%	6.7%	13.3%	
14^{th} day	mild	N	14	6	x^2:9.6 p=0.002*
		%	93.3%	40.0%	
	moderate	N	1	9	
		%	6.7%	60.0%	

Table 4: Intergroup comparison of pain during mandibular movement between group A and groupB

Intervals	Severity of pain		Groups		Fisher exact test
			Group A	Group B	
Baseline	severe	N	15	15	-----
		%	100.0%	100.0%	
7^{TH} DAY	mild	N	2	0	x^2:2.143 p=0.143(NS)
		%	13.3%	0.0%	
	moderate	N	13	15	
		%	86.7%	100.0%	
14^{TH} DAY	mild	N	14	9	x^2:4.658 p=0.003*
		%	93.3%	60.0%	

	moderate	N	1	6	
		%	6.7%	40.0%	

Table 5: intergroup comparison of pain while chewing between Group A & Group B

Groups	Severity of pain		Visits			Fisher exact test
			Base line	7th day	14th day	
Group A	mild	N	0	1	14	x^2:78.8 p=<0.001*
		%	0.0%	6.7%	93.3%	
	moderate	N	0	14	1	
		%	0.0%	93.3%	6.7%	
	severe	N	15	0	0	
		%	100.0%	0.0%	0.0%	
Group B	mild	N	0	0	6	x^2:47.50 p=<0.001*
		%	0.0%	0.0%	40.0%	
	moderate	N	0	13	9	
		%	0.0%	86.7%	60.0%	
	severe	N	15	2	0	
		%	100.0%	13.3%	0.0%	

Discussion

Myofascial Pain is the pain that originates from myofascial TRPs in the skeletal muscles. It is characterized by regional muscle pain, described as dull or achy and is a frequent cause of persistent regional pain in neck region, shoulder region and orofacial region.[8] Multiple factors can cause myofascial pain that includes psychological stress, trauma, imbalanced occlusion, and para-functional habits like bruxism, clenching. Signs & symptoms include pain in orofacial region aggravated by mandibular movements, muscle tenderness, decreased mandibular motion and deviation of the jaw to the affected side during the opening.

Diagnosis of myofascial pain includes recording the patient's history, signs & symptoms and conducting thorough examinations. Muscles of mastication should be palpated. Myofascial pain should be diagnosed according to classification by research diagnostic criteria on TMDs.

Management aims to identify the underlying cause and provide treatment by either eliminating etiology or pharmacological/nonpharmacological therapy, thereby restoring normal muscle function. Grieder et al. concluded that ultrasound therapy will be more effective when used as an adjuvant compared to when it is used alone.[9] In present study, we hypothesized that ultrasound therapy when used as an adjuvant along with accepted conservative therapy would provide better outcomes when compared to conservative treatment used alone. In control group Tizanidine is the chosen as drug of choice because of its advantages such as therapeutic effect even at low doses and reported fewer side effects.

In present study myofascial pain patients having an age group above 18 years were included. This is similar to the age range patterns in myofascial pain stated by Fouda et al.[10]and Shewta RK et al.[11] In other studies conducted by, Nidhi Mishra et al.[12] and Roopika Handa et al.[13] the age range is reported to be from 18-50 years.Sanyukta Khairnar et al.[14]stated that myofascial pain is seen in age groups between 25-45 years. In the current

study, the female predominance of 66.7% is observed. These results are in accordance with the previous studies done by Ramesh et al.[15] with 83.3%, Venkatesh G Naikmasur et al.[16] with 60%, Roopika Handa et al. with 70% and Shalu rai et al.[17] with 62% female predominance. However, these findings are not in similarity with Rashmi Kiran Ekka et al.[18]with 57% male predominance. The reason for female predominance may be attributed to increased stress levels in females. A study by Beaton et al. observed no significant gender differences.[19]

In present study, either of the groups showed significant increase in mouth opening from baseline to 7th and 7th to 14th day. The percentage of mean change in mouth opening between the groups i.e., Group A & Group B at baseline, 7 th day and 14th day was 4.9% and 5.1% and 12.5 %. There is no statistically significant difference in improvement of interincisal mouth opening between two groups from baseline to 7th day. But patients receiving both ultrasound therapy and Tizanidine showed significant difference in improvement of interincisal mouth opening from 7 th day to 14th day. The increase in mouth opening may be due to its thermal and mechanical effects on the tissues which include increase in local metabolism, increase in blood flow and also removes inflammatory mediators and prevent accumulation of these mediators at pain site. Ultrasound therapy accelerates healing, increases extensibility of collagen fibers, decrease the stiffness of joints, provide relief of pain, and reduces the muscle spasm.

A study conducted by fouda et al. found statistically significant differences in mouth opening from baseline to 2, 4, 6 follow up days between the patients receiving Intra articular injection in the upper compartment of joint space with 5 ml of SoluMedrol. And ultrasound therapy. Increase in mouth opening is seen within 6 days of ultrasound therapy which may be due to frequency of treatment in alternate days. The increase in mouth opening may be due to thermal effects of ultrasound therapy which causes reduction in muscle spasm, and increase in extensibility of collagen fibers and thereby improved the mouth opening. A study by Shalu rai at al. concluded that there was a significant increase in mouth opening in both groups receiving ultrasound (three times every 2 weeks for 12 weeks). and TENS therapy. But there was no statistical significance seen in improvement of interincisal mouth opening when compared between two groups before and after the completion of treatment.

However, these findings are not in accordance in a study conducted by Sanyukta Khairnar et al. It was evident that patients who received low-level laser therapy had statistically significant improvement in mouth opening when compared to ultrasound therapy. This may be because of the biochemical effect of LASER light that stimulates to produce VEGF & converts AMP into nitric oxide, which in turn improves vessel growth thereby, resulting in pain reduction and subsequent increase in mouth opening may be seen.

In the current study, there is statistically significant reduction of tenderness on palpation in either of the groups from baseline to 7th day and from 7th day to 14th day. There is no significant difference in reduction of tenderness on palpation b/w Group A & Group B from baseline to 7th day. However, Group A showed significant reduction of pain on tenderness on palpation is seen from 7th to 14th day.

The decrease in tenderness observed in Group A might be attributed to its thermal & mechanical effects on the tissues which include increase in local metabolism, increase in blood flow and also removes inflammatory mediators and prevent accumulation of these mediators at pain site. US therapy accelerates healing, increases extensibility of collagen fibers, decreases stiffness of joints, provide relief of pain, and hence reduces muscle spasm thereby increases the mouth opening.

A study conducted by Richa Jain et al. found statistically significant differences in tenderness on palpation at baseline to 6,11& 16 follow up days between the patients receiving both conventional and ultrasound therapy (frequency of 1 MHz and continuous setting at 1:1 for 6 min each session.) pain relief in therapeutic ultrasound may attributed to removal of inflammatory mediators by increase in the blood flow, changes in nerve

conduction, or altered cell membrane permeability which decreases inflammation. A study by Nidhi Mishra et al. concluded that there was statistically significant reduction in tenderness of masseter and temporalis muscle before and after the completion of treatment in patients receiving ultrasound therapy (Frequency of 1 MHz and pulse setting at 1:1 for 8 min each session).

A study conducted by Manfredini et al. found a significant difference in pain intensity before & after the completion of treatment in patients receiving Tab Tizanidine 2mg two times a day for 2 weeks.[20] Reduction in pain among Group B patients may be attributed to muscle relaxation which is obtained through the inhibition of spinal and supra-spinal reflexes. Such action seems to be mediated mainly by imidazoline receptors and only partly by a2 adrenergic receptors.

In present study, there is statistically significant difference in decrease in severity of pain during mandibular movements in both groups from baseline to 7th day and from 7th day to 14th day. There is no significant difference in reductionof pain during mandibular movements between two groups from baseline to 7th day. However, in Group A, significant reduction of pain during mandibular movements from 7th to 14th day is seen.

Significant reduction of pain during lateral mandibular movements was achieved by Shalu rai et al. in the patients receiving ultrasound therapy for 12 weeks (three times every 2 weeks). Pain at rest, pain with mandibular motion, and pain while chewing was combinedly evaluated using VAS on a scale of 1-100 for each parameter. In the current study, there is significant reduction of pain while chewing in both groups from baseline to 7th day and from 7th day to 14th day. There is no significant difference in the severity of pain while chewing between the two groups from baseline to 7th day. However, Group A showed significant reduction of pain while chewing from 7th to 14th day. A significant reduction of pain while chewing was observed by Shalu rai et al. in the patients receiving ultrasound therapy for 12 weeks (three times every 2 weeks).

US therapy has its thermal & mechanical effects on the tissues. Dyson suggested that the tissue must reach a temperature of 408C to 458C for minimum of 5 minutes to be therapeutic in nature.[21] ultrasound could increase the tissue temperature at frequency of 1 W/cm2, 1 MHz. Draper et al. measured the increase in muscle temperature during a 10-minute treatment with either 1-MHz or 3-MHz. ultrasound.[22] Thermal effects of ultrasound therapy include increase in local metabolism, increase in blood flow, removal of inflammatory mediators and prevents accumulation of these mediators at site of pain. The non-thermal effects include Cavitation and Acoustic streaming. Cavitation is the physical forces of the sound waves on microenvironmental gases within fluid. Acoustic streaming is the physical forces of the sound waves that provide a driving force capable of displacing ions and small molecules.[23]Combined effects of acoustic streaming and cavitation on cells showed growth retardation of cells, increase in protein synthesis, and membrane alterations and then initiates a cellular recovery response characterized by an increase in protein production.[24]Pain relief in short duration i.e., within 2 weeks by therapeutic ultrasound may be attributed to removal of inflammatory mediators by increase in the blood flow, changes in nerve conduction, or altered cell membrane permeability which decreases inflammation which in turn reduces pain by resolution of inflammation. The present study is the only study that assessed masticatory myofascial pain by considering all parameters such as tenderness on palpation, mouth opening, pain during mandibular motion, and pain while chewing.

4. CONCLUSION

No side effects were observed during or after ultrasound therapy. As it is non-invasive and because of good patient compliance ultrasound therapy can be used as an effective treatment regimen in the management of myofascial pain. To conclude, both groups showed statistically significant improvement in mouth opening and reduction of pain. however, greater improvement is seen in patients who received both ultrasound therapy and tizanidine

than patients who received tizanidine in shorter duration of time from 7th to 14th day. Involving larger sample size and extended period of follow-up are needed to find out the efficacy of ultrasound therapy as an adjuvant in the management of myofascial pain for better improvement of symptoms.

CONSENT

All authors declare that 'written informed consent was obtained from each patient and nature of the study and treatment protocols were explained to the patients.

ETHICAL APPROVAL

This study was approved by institutional ethical committee (Ref. No. (IEC/NDCH/2020/P-15). They were recognized by MH & FW, Govt of India and Dental Council of India.

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ABBREVIATIONS

TMDs-Temporomandibular Disorders; TMJ-Temporomandibular Joint; RDC- Research Diagnostic Criteria; TRPs-Trigger points; TENS-Transcutaneous electric nerve stimulation; NSAIDs- Non-steroidal anti-inflammatory drugs; Th US- Therapeutic ultrasound; VAS- Visual Analog Scale