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INTERNATIONAL JOURNAL OF CURRENT RESEARCH

International Journal of Current Research Vol. 11, Issue, 12, pp.8987-8992, December, 2019

DOI: https://doi.org/10.24941/ijcr.37582.12.2019

RESEARCH ARTICLE

COMPARATIVE EVALUATION OF EFFICACY OF ULTRASOUND THERAPY AND LOW LEVEL LASER THERAPY IN TEMPOROMANDIBULAR DISORDER PATIENTS – A RANDOMIZED CLINICAL TRIAL

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ARTICLE INFO	ABSTRACT
Article History: Received 24 th September, 2019 Received in revised form 28 th October, 2019 Accepted 25 th November, 2019 Published online 31 st December, 2019	Aim: To compare the effectiveness of Ultrasound therapy and low level laser therapy in the treatment of temporomandibular joint disorders. Objectives: To compare the pretreatment and post-treatment pain intensity (VAS score); pretreatment and post-treatment mouth opening (measured as interincisal distance) in selected TMD patients treated with therapeutic ultrasound (USG) and Low level laser therapy (LLLT). Materials and Methods: A total 26 patients were selected as per inclusion criteria. Patients were divided into two groups. 13 patients in each group. Group I was treated with USG and Group II were treated with LLLT. Pain intensity was assessed according to VAS in each session. Inter incisal opening were checked by using verniercaliper before and after the treatment.
Key Words:	Results: Mean improvement in VAS in group I was 77.85 (SD- 9.272) and in group II was 69.77 (SD- 12.5575) and the difference in both the group was not statistically significant. Mean improvement in interincisal opening 1.31
Temporomandibular Joint Disorders, Ultrasound Therapy, Low Level Laser Therapy, Mouth Opening, Pain.	(SD- 1.1091) in group I was and in group II was 2.62 (SD- 0.9592) and the difference in both the group was statistically significant. P< 0.005 was considered as statistically significant. Conclusion: Both USG and LLLT found to be beneficial in patients with TMDs and as per mean score LLLT gives better pain relief.
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Citation: Dr. Pragati Bramhe, Dr. Ajay Bhoosreddy, Dr. Chetan Bhadage, Dr. Prutha Rathod and Dr. Prajakta Chaudhari. 2019. "Comparative evaluation of efficacy of ultrasound therapy and low level laser therapy in temporomandibular disorder patients – a randomized clinical trial.", International Journal of Current Research, 11, (12), 8987-

INTRODUCTION

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The Temporomandibular joint is located just anterior to the external auditory meatus, consists superiorly of the temporalis bone and inferiorly of the mandible, contains an intraarticular disk within the joint capsule, and its contractile tissues are the muscles of mastication. The temporomandibular joint (TMJ) has long since been established as a source of pathology but did not become a central focus of research until the 1980s (Shaffer et al., 2014). Temporomandibular disorders (TMD) Include conditions affecting the, temporomandibular joint (TMJ), masticatory musculature and associated structures. A temporomandibular disorder affects more than 25% of the general population (Mehmet Ucar, 2014; Rezazadeh, 2017; Melissa Thiemikato, 2006). Etiologic factors is currently known to be multifactorial (Melissa Thiemikato, 2006). TMD etiology include the presence of parafunctional habits, trauma, stress, and emotional, systemic, hereditary, and occlusal factors (Rezazadeh, 2017; Melissa Thiemikato, 2006). The joint sounds, limited mouth opening, and muscle and joint tenderness are the most common signs and symptoms of TMD (Mehmet Ucar, 2014).

**Corresponding author:* Pragati Bramhe, PG student, MGV's KBH Dental College and Hospital The cause of pain in the orofacial region that does not take its origin from dental arches is mostly the TMD (Ayyildiz, 2015). In the community 40% to 75% of healthy individuals point out at least one sign and 33% observed at least one symptom of TMD (Ayyildiz, 2015; Liebert, 20166,7) The most affected anatomical structures of the TMJ from these diseases are posterior attachments, collateral ligaments, and periarticular tissues (capsule, synovium, and temporomandibular joint ligaments) (Ayyildiz, 2015) Various studious reported that Diagnosis and evaluation of TMD is generally based on Research diagnostic criteria for temporomandibular disorders (RDC/ TMD); clinical examination, history, and other methods such as questionnaires, clinical examination (Rezazadeh et al., 2017). As it has multifactorial etiology (Puri, 2015) different treatment modalities are used to treat the TMDs (Grieder, 1971) including physical therapy, acupuncture, exercises, massages, thermal therapy, electric stimulation (TENS), ultrasound, and low level laser (Melissa Thiemikato, 2006; Zawawi, 2012; Narayanan, 2017) have been used. Although both surgical non-surgical treatments are employed to manage TMD, the non-surgical route is the first choice of treatment (Narayanan, 2017). Therapeutic ultrasound (USG) is a noninvasive therapeutic method which accelerates healing, decrease joint stiffness, alleviate pain, increase the

extendibility of collagen fibers, and reduce muscle spasm (Atef Abd, 2014; Rai, 2016). Ultrasound can be defined as sound wave or pressure wave with a frequency above the limit of the human hearing range (16 to 20 kHz). The unit of ultrasound is the Hertz or cycles per second. Therapeutic ultrasound is used in medicine and physiotherapy which uses frequency between 1 and 3 MHz and intensities of 0.1 to 2.0 W/cm² (Nghiem Doan, 1999). Different studies used LLLT for TMD management (Rezazadeh, 2017). Low Level Laser Therapy (LLLT) is used in different fields of medicine. A potential noninvasive treatment for TMJ pain is low-level laser treatment (LLLT) (Emshoff, 2008). It reduces histamine, Prostaglandin inhibitors (PGE2) (Ambra Petrucci, 2011) and substance P which are inflammatory mediators (Paulo César, 2016) of pain in the posterior horn of the spinal cord. Therefore, this paper aimed to compare the effectiveness of the recent advances like USG therapy and low level laser therapy in the temporomandibular disorders patients for reducing pain and improvement in mouth opening.

MATERIALS AND METHODS

The present randomized clinical trial is a prospective in-vivo study conducted on patients with temporomandibular joint pain and reduced mouth opening at the outpatient Department of Oral Medicine and Radiology after obtaining approval from the institutional ethical committee. Every participant included was explained in detail about the study/ procedures performed. Subject's verbal and written informed consent in the language he/she understands was taken. A total of 26 patients were included in the study visiting the Department of Oral Medicine and Radiology, in our dental institution. Patients were randomly selected and proportionally divided into two groups, namely Group 1 (USG) and Group 2(LLLT) by enveloped sealed method.

Inclusion Criteria

- Patients willing to participate in the study and sign the written consent.
- Patients clinically diagnosed with TMD.
- Patients > 18 years of age.
- Patient with no history of surgery in TMJ region.

Exclusion Criteria

- Patients with other orofacial pain conditions.
- Patients who recived other TMD treatments within last 3 months.
- Patients with neurological and psychiatric disorders.
- Pain attributable to recent trauma, dental surgery, metabolic disorders, vascular disorders and neoplasia.
- Patients who have treated with USG and Low level laser therapy previously.

METHODOLOGY

- Detailed customized case history was taken.
- Clinical assessment of TMD patients was done on the basis of RDC/ TMD.
- Pain and mouth opening was evaluated at baseline and on 2nd, 4th and 6th day. Patient was assessed at baseline and on 0th, 2nd, 4th, 6th day for pain and for improvement

in mouth opening patient was assesses at baseline and on 0^{th} and 6^{th} day of followup.

- Pain intensity was recorded as per visual analog scale (VAS) score [0-100], where 0 – means no pain and 100
 means most severe pain⁽¹²⁾.
- All the patients fulfilling the inclusion criteria were included in the study. A total of 26 patients completed the study. Patients were divided into two groups
- Group 1 Patients receiving USG therapy,
- Group 2 Patients receiving LLLT.

Group 1- Patient was asked to sit normal and relax all the muscles. Solidstate Therapeutic Ultrasound machine was used in the present study manufactured by Umesh Electromedical Company in Mumbai. The Ultrasound transmission scan care gel was applied in he temporomandibular region round circular motion and Pulsed ultrasound at a frequency of 1 MHz, with pulse repetition rate of 120 Hz, and intensity of 1 W/cm2 was applied to the patientsfor 5 min/session at 0, 2nd, 4th, 6th day.Patients were assessed at baseline and on 0, 2nd, 4th, 6thday. Group 2-For Low level laser therapy groupDIODE LASER UNIT [Biolase[®], USA] was applied on the posterior and anterior aspect of the joint, as well as the trigger points. Patient was asked to sit at normal position by keeping all the muscles in relax position.Biolase laser was used in Non contact mode with wavelength of 940 nmfor 2.5 min/session at 0, 2nd, 4th, 6th day respectively. Energy intensity was adjusted to 5 j/cm2 using the output power of 200 mw for 2.5 minutes.Patients were assessed at baseline and on 0, 6th day. Pain score was assessed by Visual analog scale at baseline and on 0, 2^{nd} , 4^{th} and 6th day of followup and improvement in mouth opening was assessed by divider and scale at 0 and 6th day of followup. Vas score was measured from 0 - 100 where o is no pain and 100 is the pain as worst as possible.

Statistical Analysis: Unpaired T- test is applied to compare both groups having 13 patients each at 24 degrees of freedom and 95% confidence level. Similarly, after calculating increase in interincisal distance in both the groups G1, unpaired t- test is applied at 24 degrees of freedom and 95% confidence level separately. The data were analyzed using SPSS software (version 14.0) and descriptive statistics was obtained.

RESULTS

In Group I, the mean age of the subjects was 34.93 years (standard deviation [SD] ± 12.57), Group II was 32 years (± 10.174)[Table-1]. In Group I, out of 13 patients, there were 7 female (60%) and 6 male (40%), in Group II, 9 female (76.7%) and 4 male (23.30%)[Table-2]. The Mean \pm SD VAS score for pretreatment (baseline) in Group I was 95 \pm 39.27.

Table 1. Age wise distribution of patients

Group	$Mean \pm SD$	
Group1 (USG)	34.93±12.57	
Group2(LLLT)	32±10.174	

 Table 2. Gender wise distribution of patients

Sex	Groups		
	Group1	Group 2	
Female	7	9	
Male	6	4	
Total	13	13	

 Table 3. Comparison of Pretreatment And Post-Treatment Mean±Sd of Vas

 In Usg and Lllt Groups Using Unpaired T- Test

	VAS SCORE		
	BASELINE(PRETREATMENT)	6 TH DAY (POST TREATMENT)	PVALUE(P<0.005)
GROUP I	95 ± 39.27	28±1.1	0.004
GROUP II	92±29.45	15±1.1	0.001

 Table 4. Comparison of pretreatment and post-treatment mean± sd of interincisal opening in usg and lllt groups using unpaired t- test

	INTERINCISAL OPENING			
	BASELINE (Pretreatment)	6 th DAY(Post-treatment)	PVALUE (P<0.005)	
GROUP- I	11.2 ± 9.1	15.2 ± 7.6		0.058
GROUP- II	7.7 ± 9.3	25.7 ± 12.2		0.004

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	Groups	Mean mprovement	SD	S.E	T-value	P-Value
						(<0.005)
VAS Score	Group1	77.85	9.272	4.329	1.8656	0.07437
	Group2	69.77	12.5575			

Table 6. Comparison of improvement in interincisal opening in usg and lllt groups

	Groups	Mean Improvement	SD	S.E	T-value	P-Value
						(<0.005)
Interincisal distance	Group1	1.31	1.1091	0.4123	-3.2127	0.0037
	Group2	2.62	0.9592			

The Mean±SD VAS score in Group I for post treatment (6th day) was 28±1.1. This difference is found statistically significant. The Mean±SD VAS score for pretreatment (baseline) in Group II was 92±29.45. The Mean±SD VAS score in Group II for post treatment (6th day) was 15±1.1. Similarly, this difference is found statistically significant. [Table- 3]. The Mean±S Dpretreatment (Baseline) score of interincisal opening in Group I was 11.2 ± 9.1 . The Mean \pm SD score in Group I for post treatment (6^{th} day) was 15.2 \pm 7.6 this difference is not statistically significant, thus there is less improvement in mouth opening in group I. Also The Mean±SD pretreatment (Baseline) score of interincisal opening in GroupII was 7.7 ± 9.3 . The Mean±SD score in Group II for post treatment (6th day) was $25.7\pm$ 12.2 this difference is statistically significant [Table-4]. The mean \pm SD of the VAS score in group 1 is 77.85 (SD 9.272) and Mean \pm SD of VAS score in group 2 is 69.77 (SD 12.5575) [Table- 5]. This difference is not significant statistically. Thus we can conclude that the improvement in pain (VAS score) in both these groups is similar. The VAS score recorded for reduction in pain does not show any significant difference in average pain reduction for both the groups, but there is significant increment in mean interincisal distance of the patient treated with LLLT as compared to those treated with USG. The mean \pm SD of the increase in interincisal distance in group 1 is 1.31 (SD 1.1091) and that of group 2 is 2.62 (SD 0.9592) [Table- 6].

DISCUSSION

Treatment plan for TMD should not only be determined by the disorder but more importantly by the individual's needs ⁽¹¹⁾. Different therapeutic modalities that have been used for the treatment of TMDs results in similar improvements in pain and dysfunction, care should be taken with regard to the use of invasive and other irreversible treatments, particularly in the initial management of TMD patients.

Physical therapy helps to relieve musculoskeletal pain and to restore normal function (Puri, 2015). Nighemon et al reported several in vitro effects of ultrasound that could revert or prevent the hypoxia, hypovascularity, and hypocellularity observed in osteoradionecrosis. It states that ultrasound induces cell membrane permeability increased by altering sodium and potassium ion gradients. This increased permeability improves gas exchange and promotes healing. Ultrasound decreases inflammation, increases vasodilatation and provides pain relief. So the therapeutic ultrasound is considered as one of the non surgical or non invasive treatment modality (Nghiem Doan, 1999). The mechanism of ultrasound action is based on massage and thermal effect. Thermal effects of ultrasound may include increased blood flow vasodilatation, waste removal, acceleration of lymph flow, and stimulation of metabolism (Atef Abd, 2014). Ceasor et al. (2016) studied efficacy of a Low-Level Laser therapy in patients with Temporomandibular Disorders (TMD). It reduces histamine, Prostaglandin inhibitors (PGE2) and substance P which are inflammatory mediators of pain in the posterior horn of the spinal cord. Metabolic activation, stimulation of the cellular respiratory chain, mainly mitochondria, and increasing vascularization and fibroblast formation have been suggested as playing an important role in LLLT success and thus reduces pain (Paulo César, 2016). LLLT utilizes electromagnetic radiation at a particular wavelength and contributes management of pain, impaired wound healing, and inflammations. Also, LLLT is used clinically for the treatment of TMJ pain (Paulo César, 2016). The mean age of subjects in Group I and in Group II was 34.93 years [Table-1] and and there were female predominance as compared to male [Table 2] in present study which is in accordane with the study given by Rai et al. (2018), Dworkin et al., Isacsson et al. and Jensen et al who reported a female predominance, whereas contrary to this, the observations of Beaton et al. observed lack of any significant gender differences in their study (Atef Abd, 2014).



Graph 1. Age Wise Distribution







Graph 3. Pre-Treatment And Post Treatment Vas Score In Group I And Group II

Kulekcioglu et al. showed that after 15 sessions of LLLT in TMDs with a significant reduction in pain presented either by the laser or by the placebo group, but only the active laser group presented improvements on mouth opening, lateral motion, and number of trigger points (Ayyildiz, 2015). Similarly, in present study boththe mean pretreatment and post-treatment score [Table- 3] using USG and LLLT was statistically significant score for group shows reduction in pain but significant improvement in mouth opening was observed in



Graph 4. Pre-treatment and post- treatment improvement in interincisal opening in mm

LLLT group [Table- 4] Moger et al. (2011). who observed that the pain reduction in the USG group was more than in placebo group, Similar results are found in the present study, as there is reduction in pain found between the two groups (USG and LLLT) the difference between the groups was not statistically significant (P < 0.05) [Table-5]. Rodrigues et al. observed a significant reduction in pain intensity (P < 0.05) before and after TENS application (Atef Abd El Hameed Fouda, 2014). Cetiner et al. (2006) studied the effectiveness of low-level laser therapy (LLLT) in the treatment of myogenic originated temporomandibular disorders (TMD) and conluded that LLLT is appropriate treatment modality for TMDs as it improves the interincisal opening and reduces pain which is similar to the results in our study (Mehmet Ucar, 2014).

Ayyildiz s et al in his study concluded that LLLT is an appropriate treatment for TMD related pain and limited mouth opening and should be considered as an alternative to other methods, which is in accordance with the present study ⁽⁴⁾. In the present study there is significant improvement in mouth opening has been observed in LLLT therapy group as compared to USG group [Table- 6]. The ultrasonic therapy was not alone effective in relieving symptoms but more effective when used as an adjunct to the accepted modalities of therapy (Griederet al., 1971) (Puri, 2015; Narayanan, 2017; Atef Abd El Hameed Fouda, 2014). In the study given by Hameed Fouda et al states that Ultrasound therapy is promising with little or no complications could be used with or without other treatment modalities for compromised patients (Narayanan, 2017).

Conclusion

The results of this study concludes that both the treatment modalities therapeutic ultrasound and low level laser therapy found to be beneficial in pain reductionbut as per mean score Low level laser therapy gives better pain relief and showed improvement in interincisal opening in the patients with TMDs.

Summary

Temporomandibular disorders (TMD) Include conditions affecting the, temporomandibular joint (TMJ), masticatory musculature and associated structures. Diagnosis of TMDs is mainly based on clinical assessment according to classification given by RDC/ TMD. Newer treatment modalities like therapeutic ultrasound and Low Level Laser therapy has been used in the present study for the treatment of pian and improvement in mouth opening in TMD patients.

26 patients with TMD showing symptoms like pain and improvement in mouth opening was included was assessed at baseline and on 0, 2^{nd} , 4^{th} and 6^{th} day of follow up for pain and at baseline, 0, 6^{th} day for improvement in mouth opening. It can be concluded form present study that both the treatment modalities can be used for the treatment of pain but Low level Laser therapy showed significant improvement in mouth opening when compared with therapeutic ultrasound.

Limitations and Scope

There is need for further studies with larger sample size to validate improvement in pain and mouth opening using USG and LLLT in the treatment of temporomandibular disorders.

Conflicts Of Interest: No

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