

Efficacy of Tens Therapy, Therapeutic Ultrasound and Stabilization Splint as an Adjuvant to Pharmacotherapy for Temporomandibular Disorders

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Abstract

➤ Introduction:

Temporomandibular disorders also known as temporomandibular joint pain dysfunction syndrome. TMD does not fit neatly into any one etiologic category since the pathophysiology is poorly understood and it represents a range of distinct disorders with multifactorial etiology. TMD accounts for the majority of pathology of the of the TMJ and it is the second most cause of orofacial pain after dental pain.

➤ Aim:

To assess the efficacy of TENS therapy, Therapeutic ultrasound and Stabilization splint as an adjuvant to pharmacotherapy for temporomandibular disorders.

➤ Materials and Methods:

After ethical clearance from institution, a study was conducted on 30 adult patients to evaluate the efficacy of TENS therapy, therapeutic ultrasound, stabilization splint as an adjuvant to pharmacotherapy for Temporomandibular disorders. Group A (10 patient): TENS therapy + pharmacotherapy (patient with Tab.Myosone 50mg BD) Group B (10 patient): Therapeutic Ultrasound + pharmacotherapy (patient with Tab.Myosone 50mg BD) Group C (10 patient): Splint therapy + pharmacotherapy (patient with Tab.Myosone 50mg BD)

➤ Results:

TENS therapy (3.9) showed better results in reducing the muscle and joint pain with a statistically significant difference when compared with Therapeutic ultrasound therapy (4.5) and splint modality(6.0).

➤ Conclusion:

The observations from the present study justify the use of TENS therapy as well as Therapeutic ultrasound therapy in the management of TMD.

Keywords:- Temporomandibular disorder, temporomandibular joint, transcutaneous electric nerve stimulation, Therapeutic ultrasound, Stabilization splint, Helkimo Dysfunction Index (HDI), Visual analog scale(VAS).

I. INTRODUCTION

Temporomandibular disorders also known as temporomandibular joint pain dysfunction syndrome. TMD does not fit neatly into any one etiologic category since the pathophysiology is poorly understood and it represents a range of distinct disorders with multifactorial etiology. TMD accounts for the majority of pathology of the of the TMJ and it is the second most cause of orofacial pain after dental pain. ^(1,2)

Helkimo Dysfunction Index (HDI) is one of the effective aid for diagnosis of severity of TMDs on the basis of clinical examination.⁽³⁾ In literature, there are many successful treatment modalities reported, including stabilization splint, therapeutic ultrasound, TENS therapy and pharmacological interventions.

TENS is a non-invasive intervention that turn-on a neural network system to decrease intensity of pain by actuating descending inhibitory system. TENS works by a phenomenon called "gate control theory". These are multiple receptors in the periphery - pain, vibration, temperature, etc. - All of which transmit information to brain via spinal cord. It is safe, nonintellectual method. ^(4,6,9)

Therapeutic ultrasound (Th US) is a non-invasive method that have intensity and frequency in between 1 to 3.5 and 1 to 3 MHz. It is used to accelerate healing process, reduce localized spasm, ease pain and enhance the impart power of collagen fibers. Mechanism of this therapeutic based on enhancing power of blood flow, alteration in nerve and cell membrane function that reduce inflammatory condition. ^(4,5,8)

The pharmacological modality with TMD patient is usually empirical. In this study, the most commonly used drug is muscle relaxant that is Tab.Myosone of 50mg dosage for two times in a day.⁽¹⁰⁾

According to literature, the stabilization splint is one of the different modality for the treatment of TMDs.⁽⁷⁾

II. AIM

To assess the efficacy of TENS therapy, Therapeutic ultrasound and Stabilization splint as an adjuvant to pharmacotherapy for temporomandibular disorders.

III. OBJECTIVES

- To evaluate effectiveness of listed treatment modalities on TMD Patients.
 - TENS therapy with Pharmacological Modality.
 - Therapeutic ultrasound with Pharmacological Modality.
 - Stabilization splint with Pharmacological Modality.
- To evaluate the severity of TMD on clinical basis through Helkimo dysfunction index as a subjective method.

IV. METHODOLOGY

- **Place of study:** Department of Oral Medicine in a Dental College and Research centre.
- **Study design:** Randomized comparative study.
- **Study population:** Adult of age group 18 to 70 years. Reporting to outpatient Department of a Dental College.
- **Sample size:** Sample size calculated for each group is 10
 - Group A: Adult receiving TENS therapy with pharmacotherapy.
 - Group B: Adult receiving Therapeutic ultrasound with pharmacotherapy.
 - Group C: Adults receiving stabilization splint with pharmacotherapy.
 - Total sample size: 30
- **Duration of study:** 3 months.
- **Selection criteria:**
 - **Inclusion criteria:**
 - ✓ Subjects who consent to participate in the study.
 - ✓ Dentulous patients who have sign and symptoms of TMD.
 - ✓ Participants who were in 18 to 70 years.
 - **Exclusion Criteria:**
 - ✓ Patients who had surgery in TMJ region.
 - ✓ Patients below 18years and above 70 years.
 - ✓ Patients on steroids and sedative drugs.
 - ✓ Medically compromised patients.
- **Methods of diagnostic measurement:** Clinical examination using Helkimo dysfunction index⁽³⁾. Patients that have five following symptoms.

- Discomfort of mandibular movement.
- Muscle pain.
- TMJ impairment.
- Tender on movement of the mandible.
- Tender on palpation of TMJ.

➤ **Method of study:** After obtaining the appropriate permission from institutional ethics committee, a study was conducted on 30 adult patients to evaluate the efficacy of TENS therapy, therapeutic ultrasound, stabilization splint as an adjuvant to pharmacotherapy. Each subject should give his/her written consent for participating in this study.

➤ Pharmacological modality:

Group A (10 patients): TENS therapy + pharmacotherapy (patient with Tab.Myosone 50mg twice daily)

Group B (10 patients): Therapeutic Ultrasound + pharmacotherapy (patient with Tab.Myosone 50mg twice daily)

Group C (10 patients): Splint therapy + pharmacotherapy (patient with Tab.Myosone 50mg twice daily)

Data collection procedure will be as follows:

Adults in age group of 18 to 70 years reporting to outpatient department of a Dental College were selected for study. Adult with absence of any systemic and developmental disorders fulfilling the inclusion criteria would be selected randomly.

The study was conducted in three to four visits.

First Dental Visit:

- Adults reporting to outpatient department were assessed, with age 18 to 70 years.
- The patients who meet the inclusion criteria should enter into the study.
- Helkimo dysfunction index was applied and those coming under the criteria of this index were considered eligible for study.
- Eligible subjects were provided with informed consent document.

The patients were randomly divided into three equal groups, 10 patients each.

Group A: 10 subjects were treated in TENS therapy with pharmacotherapy. The parameters would make before therapy, 1st day, 7th day, 14th day, and 21st day and after Tens Therapy.

Group B: 10 subjects were treated in Therapeutic ultrasound with pharmacotherapy. The parameters would make before therapy, 1st day, 7th day, 14th day, 21st day and after Therapeutic ultrasound.

Group C: Ten subjects were treated by stabilization splint with pharmacotherapy. The parameters would make before Stabilization Splint, 1st week, 3rd weeks, and 3rd month after Stabilization Splint.

❖ *Second, Third and Fourth Dental Visit:*

On follow up visits the intensity of pain that patient is suffering from would measure on VAS.

❖ *TENS Therapy:*

The subjects in the TENS were administered TENS therapy using BiotronixCombi machine (The power was 20 W, with a maximum frequency of 3MHz and intensity ranging from 2 to 6 vibrations/sec),⁽¹⁶⁾ each therapeutic session lasted for approximately 15 to 20 minutes, once in a week for a period of four consecutive weeks. According to patient comfort level intensity of device should be adjustable.

❖ *Therapeutic Ultrasound Therapy:*

The subjects in the Therapeutic ultrasound therapy were administered Therapeutic ultrasound therapy using BiotronixCombi machine (The power was 20 W, with a maximum frequency of 1 MHz and intensity ranging from 2 to 6 vibrations/sec), each therapeutic session lasted for approximately 15 to 20 minutes, once in a week for a period of four consecutive weeks. According to patient comfort level intensity of device should be adjustable.

❖ *Stabilization Splint:*

Normally, the patient wears the hard splint only at night time. Ideal thickness of splint starts from 2mm to 3mm and adjusted at every visit on the basis of surface point.⁽¹³⁾

❖ *Pharmacotherapy:*

The pharmacological modality with TMD patient is usually empirical. In this study, the most commonly used drug is muscle relaxant that is Tab.Myosone of 50mg dosage for two times in a day.(low dose and less side effect when compare to others) It is a centrally acting muscle relaxant and produce effect by binding to specific inhibitory neurotransmitter receptor sites in the brain and spinal cord that are activated by GABA. This regulated the blood supply to the muscles.

All the patients were evaluated for masticatory muscle tenderness and TMJ pain on VAS starting score from 0 (no pain at all) to 10 (the worst pain imaginable) was carried out. Parameters were recorded at pre-treatment visit, during, and after every treatment session.

V. STATISTICAL DATA ANALYSIS:

- The inter-group statistical comparison of distribution of categorical variables is done using Chi-Square test.
- The inter-group statistical comparison of means of continuous variables is done using analysis of variance (ANOVA) technique
- The intra-group statistical comparison of means of continuous variables is done using
- Paired t test. All results are shown in tabular as well as graphical format to visualize the statistically significant difference more clearly.

VI. RESULTS

| Group Code | Description | No. of cases | % of cases |
|------------|--|--------------|------------|
| Group A | TENS Therapy + Pharmacotherapy | 10 | 33.3 |
| Group B | Therapeutic Ultrasound + Pharmacotherapy | 10 | 33.3 |
| Group C | Stabilization Splint + Pharmacotherapy | 10 | 33.3 |
| | Total | 30 | 100.0 |

Table 1:- The distribution sample size studied across three study groups.

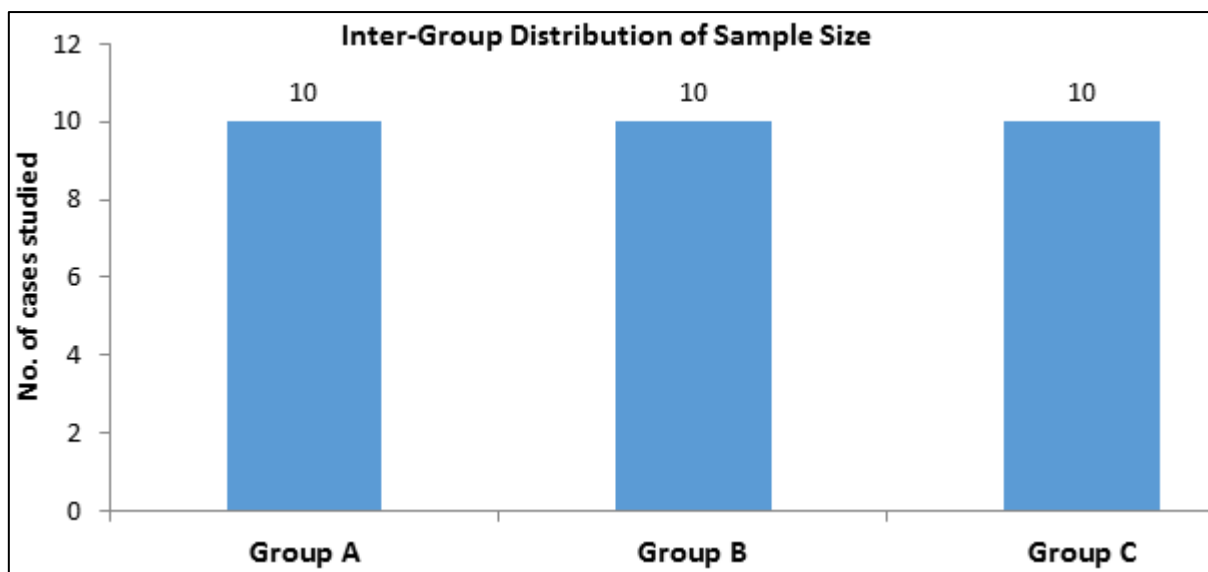


Fig 1:- The distribution sample size studied across three study groups.

| Age (years) | Group A (n=10) | | Group B (n=10) | | Group C (n=10) | | P-value (Inter-Group) | | |
|-------------|----------------|-------|----------------|------|----------------|-------|-----------------------|---------------------|---------------------|
| | Mean | SD | Mean | SD | Mean | SD | Group A v Group B | Group A v Group C | Group B v Group C |
| Age (years) | 26.40 | 12.38 | 31.70 | 8.03 | 32.70 | 14.61 | 0.995 ^{NS} | 0.751 ^{NS} | 0.999 ^{NS} |

Table 2:- Inter-Group Comparison of mean age.

A. Inter-Group Comparison of mean age:

The mean ± SD of age of cases studied in Group A, Group B and Group C was 26.40 ± 12.38 years, 31.70 ± 8.03 years and 32.70 ± 14.61 years respectively. The minimum – maximum age range in Group A, Group B and

Group C was 19 – 60 years, 23 – 45 years and 20 – 67 years respectively.

Distribution of mean age of cases studied did not show any statistical significant difference across three study groups (P-value>0.05 for all).

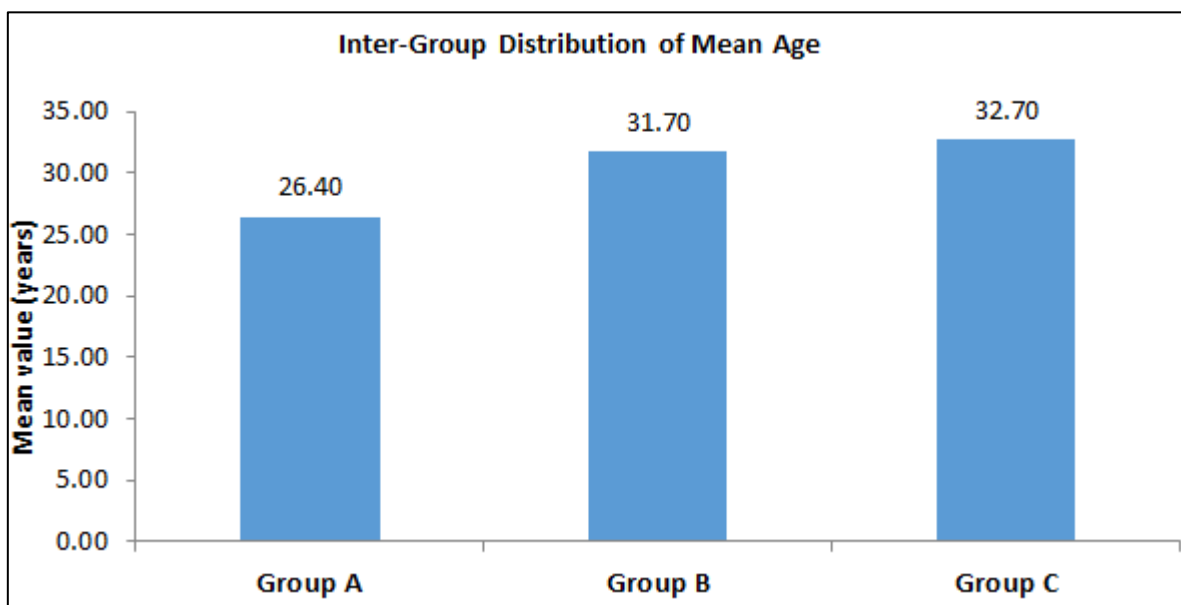


Fig 2:- Inter-Group Comparison of mean age.

B. Inter-Group Comparison of distribution of gender:

10 cases studied in Group A, 5 (50.0%) were male and 5 (50.0%) were female. Of 10 cases studied in Group B, 2 (20.0%) were male and 8 (80.0%) were female. Of 10 cases

studied in Group C, 7 (70.0%) were male and 3 (30.0%) were female. Distribution of sex of cases studied did not show any statistical significant difference across three study groups (P-value>0.05 for all).

| Sex | Group A (n=10) | | Group B (n=10) | | Group C (n=10) | | P-value (Inter-Group) | | |
|--------------|----------------|--------------|----------------|--------------|----------------|--------------|-----------------------|---------------------|---------------------|
| | n | % | n | % | n | % | Group A v Group B | Group A v Group C | Group B v Group C |
| Male | 5 | 50.0 | 2 | 20.0 | 7 | 70.0 | 0.350 ^{NS} | 0.650 ^{NS} | 0.070 ^{NS} |
| Female | 5 | 50.0 | 8 | 80.0 | 3 | 30.0 | | | |
| Total | 10 | 100.0 | 10 | 100.0 | 10 | 100.0 | | | |

Table 3:- Inter-Group Comparison of distribution of gender of cases studied.

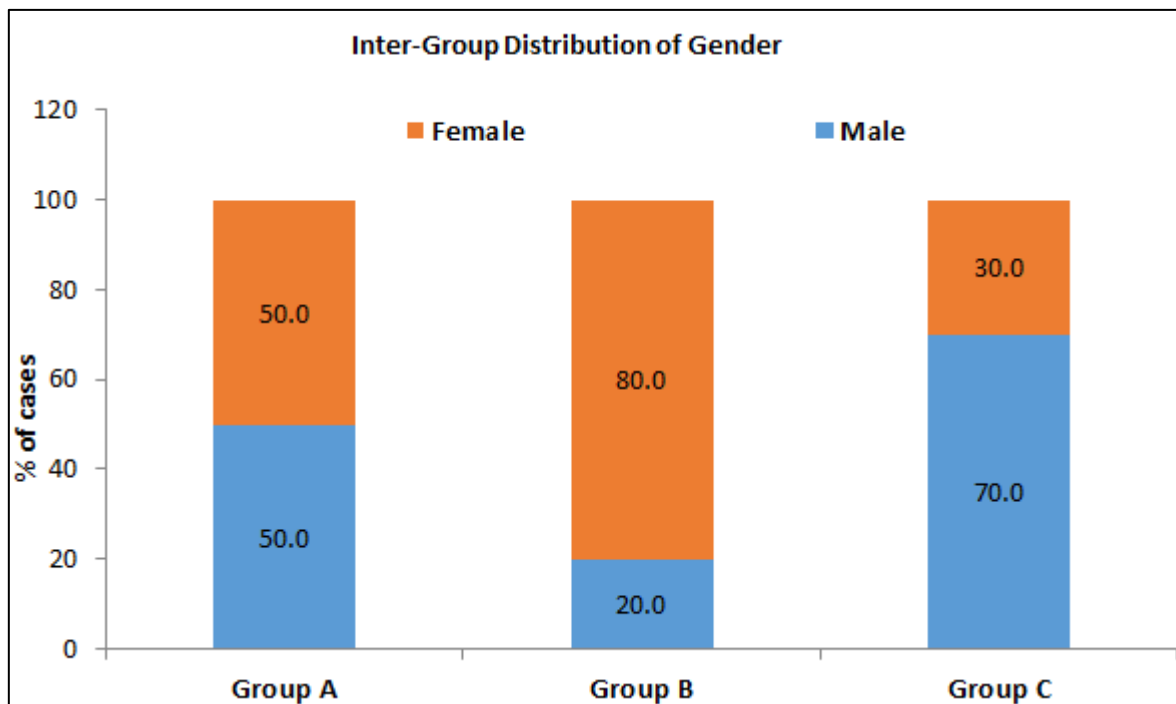


Fig 3:- Inter-Group Comparison of distribution of Gender of cases studied.

C. Inter-Group Comparison of mean Pain Score:

The mean ± SD of pre-intervention pain score of cases studied in Group A, Group B and Group C was 8.30 ± 0.67, 8.50 ± 0.97 and 8.20 ± 0.42 respectively. Distribution of mean pre-intervention pain score among the cases studied did not show any statistical significant difference across three study groups (P-value>0.05 for all).

The mean ± SD of post-intervention pain score of cases studied in Group A, Group B and Group C was 3.90 ± 0.99, 4.50 ± 0.97 and 6.00 ± 0.82 respectively. Distribution of mean post-intervention pain score among the cases studied is significantly higher in Group C compared to Groups A and B (P-value<0.05 for all). Distribution of mean post-intervention pain score among the cases studied did not differ significantly between Groups A and B (P-value>0.05).

The mean ± SD of % post-intervention change in pain score at among the cases studied in Group A, Group B and Group C was 52.76%, 46.53%, 26.94% respectively.

Distribution of mean post-intervention % change in pain score among the cases studied is significantly higher in Group A compared to Groups B and C (P-value<0.05 for all). Distribution of mean post-intervention % change in pain score among the cases studied did not differ significantly between Groups A and B (P-value>0.05).

D. Intra-Group Comparison of mean Pain Score:

In Group A, distribution of mean post-intervention pain score is significantly lower (improved) compared to mean pre-intervention pain score (P-value<0.001).

In Group B, distribution of mean post-intervention pain score is significantly lower (improved) compared to mean pre-intervention pain score (P-value<0.001).

In Group C, distribution of mean post-intervention pain score is significantly lower (improved) compared to mean pre-intervention pain score (P-value<0.001).

| Pain Score (VAS) | Group A (n=10) | | Group B (n=10) | | Group C (n=10) | | P-value (Inter-Group) | | |
|-----------------------|----------------------|------|----------------------|------|----------------------|------|-----------------------|----------------------|----------------------|
| | Mean | SD | Mean | SD | Mean | SD | Group A v Group B | Group A v Group C | Group B v Group C |
| Pre-intervention | 8.30 | 0.67 | 8.50 | 0.97 | 8.20 | 0.42 | 0.999 ^{NS} | 0.999 ^{NS} | 0.999 ^{NS} |
| Post-intervention | 3.90 | 0.99 | 4.50 | 0.97 | 6.00 | 0.82 | 0.483 ^{NS} | 0.001 ^{***} | 0.004 ^{**} |
| % Change | 52.76% | -- | 46.53% | -- | 26.94% | -- | 0.639 ^{NS} | 0.001 ^{***} | 0.001 ^{***} |
| P-value (Intra-Group) | | | | | | | | | |
| Pre v Post | 0.001 ^{***} | | 0.001 ^{***} | | 0.001 ^{***} | | | | |

Table 4:- Inter-Group Comparison of mean pain score (VAS).

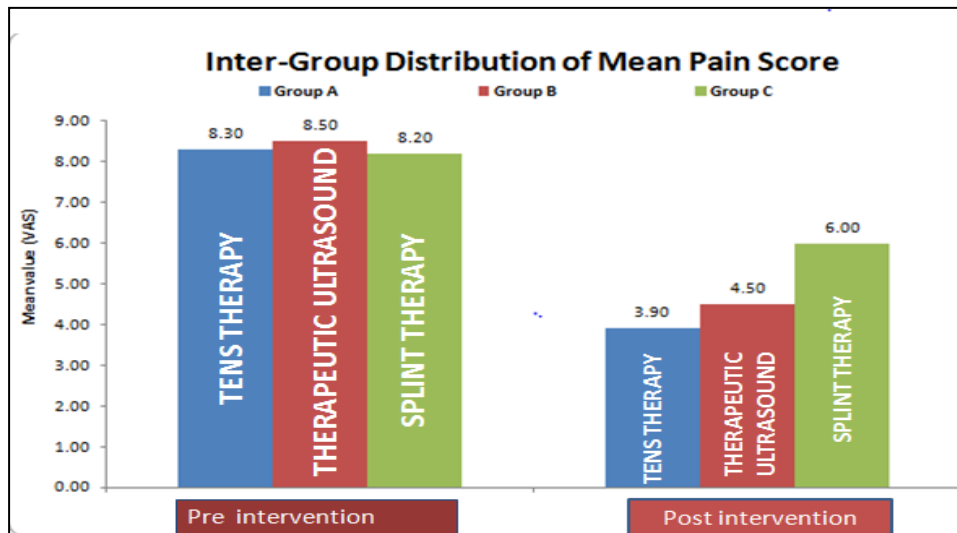


Fig 4:- Inter-Group Comparison of mean pain score (VAS).

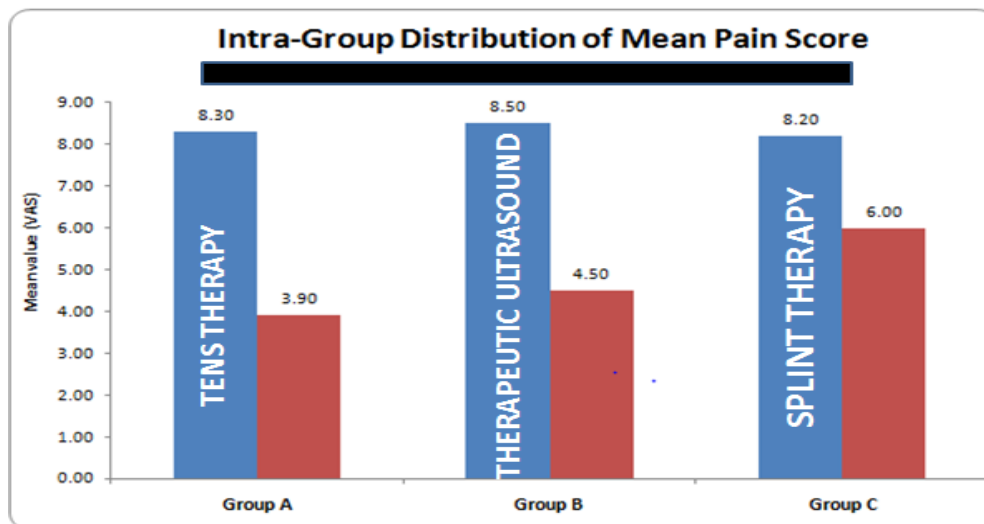


Fig 5:- Intra-Group Comparison of mean pain score (VAS).

VII. DISCUSSION

TMJ is combination of hard tissue, muscular system and neural system. If these systems or anyone of them get affected can cause TMD which includes complaints of muscle impairment, impaired movement of mandible, TMJ impairment, tenderness on palpation and occlusal derangement. (1, 2, 11)

This study comprised of distribution of gender of cases studied did not show any statistical significant difference across three study groups this was in accordance with Beaton RD et al., and Patil S et al., did not observe any statistical significant difference in their studies.^(16,17) In contrast to this Shahanavas M et al., Dworkin SF et al., Rai S et al., did observe statistical significant difference of gender in their studies^(4, 18, 19). In the present study, distribution of age of cases studies did not differ

significantly across three study groups. In contrast to this Moger G et al., Juniper RP et al., Shanavas M et al., and Riden DK et al, did observe majority of the subjects were in third and fourth decades of life.^(18, 20, 21, 22)

In the present study, the patients in the TENS group (3.9), showed a significant reduction from pre-treatment to last visit, with respect to muscles of mastication tenderness and TMJ pain. Many previous studies in the literature reported the effectiveness of TENS therapy in reducing pain and discomfort of TMD patients.⁽¹⁴⁾ Singh H et al. conduct a study and found that TENS therapy showed significant difference in reducing pain.⁽¹²⁾ Moger G et al., conduct study and observed efficacy of TENS therapy in reducing muscular and chronic pain and enhancement of opening the mouth.⁽²⁰⁾ S.R Patil et al, conduct a study and justified the effect of TENS therapy as well as HE therapy in the management of TMD.⁽²³⁾

In the present study, the patients in the therapeutic ultrasound therapy (4.5) group showed better results in reducing the muscle and joint with a statistically significant difference when compared with splint modality (6.0). Rai S et al, conduct a study and found therapeutic ultrasound showed subjectively better for treatment of TMD.⁽⁴⁾ Handa R et al, showed therapeutic ultrasound therapy serve as a vigorous and self-sufficient therapeutic modality in TMDs.⁽⁵⁾ And one more literature showed ultrasound therapy is more effective in reducing pain in TMDs than TENS by k kirupa et all.⁽²⁴⁾ Soni A et all, conduct a study and observed splint therapy is easy, negligible invasive procedure with a less risk complications and significant effective in the patient with TMDs.⁽²⁵⁾ In literature there are several previous studies only on pharmacotherapy modality with long period of time, but the present study revealed short term with different modalities that are TENS therapy, therapeutic ultrasound and stabilization splint as an adjuvant to pharmacotherapy for TMDs.

This study finding confirmed that the TENS therapy with pharmacotherapy (3.9) showed better results in reducing the muscle and joint with a statistical significant difference when compared with Therapeutic ultrasound therapy with pharmacotherapy (4.5) and splint modality with pharmacotherapy (6.0).

VIII. LIMITATION

The limitation of present study was finite sample size and absence of controlled group. Further, protensive studies are affirmed to evaluate the long-term effects of treatment modalities.

IX. CONCLUSION

From the results of this study, we can be concluded that, both TENS and Therapeutic ultrasound therapies were effective in the reduction of masticatory muscle tenderness and joint pain after treatment, but the TENS therapy (3.9) showed better results in reducing the muscle and joint with a statistical significant difference when compared with

Therapeutic ultrasound therapy (4.5) and splint modality (6.0). The observations from the present study justify the effect of TENS therapy as well as Therapeutic ultrasound therapy in the management of TMDs.

A. Patient Consent:

Patients have been provided with adequate explanation about the procedure to be conducted during this research project and all the benefits as well as risk associated with the procedure in the language patient understand. Patients have understood all the information provided. Patients have approved voluntary participation in this research project after understanding the information thoroughly. Patients have decision to participate in this research project is completely voluntary and is not driven by any undue pressure or enticement. He/she fully aware that he/she shall not be receiving any monetary remuneration for participation in this research project. Patients also understand that participation into clinical research project for any incurable or difficult to cure disease may not guarantee cure from the disease.

Patients hereby declare that data/information gathered shall be a proprietary of the institution and the researcher. Thus it can be used for educational and scientific publication purpose.

➤ *Financial support and sponsorship:*
Nil.

➤ *Conflicts of interest:*
There are no conflicts of interest.

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