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Comparative study on effectiveness of myofascial release technique along with ultrasound therapy V/S myofascial release technique along with transcutaneous electrical nerve stimulation in the fibromyalgia neck patients

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Abstract

Introduction: Fibromyalgia is a chronic pain syndrome characterized by wide spread musculoskeletal pain with multiple symptoms which include fatigue, sleep disturbance, cognitive dysfunction and psychological distress. It is one of the most common chronic pain conditions in the world. It has prevalence rate of 2% in the world population, and it's found 1% to 4.9% in women population, 0% to 2.9% in men population. There are many aetiologies fibromyalgia such as Diet, Viral, Occupation, Seasonal, Environmental, Post traumatic stress disorder, Psychological and Cognitive behavioural factors are most common. Neck pain is one of the symptoms that experience with fibromyalgia.

Aim: To compare the effect Myofascial Release technique along with Ultrasound Versus Myofascial Release technique along with Transcutaneous Electrical Nerve Stimulation in the Fibromyalgia Neck patients.

Materials and Methods: This was a Randomised Control study. A total of 60 patients were divided into two groups of 30 each. Group A patients treated with Ultrasound along with MFR and Group B patients treated with TENS along with MFR and outcome measures were collected on day 1, at the end of 2nd week and at the end of 3rd week. Data from study were analysed using the statistical package SPSS 21.0 (SPSS Inc., Chicago, IL) and level of significance was set at $p < 0.05$.

Results: Group B shows the mean of VAS is 7.6 (SD 1.10) at day 1 which was reduced to mean of 4.2 (SD 0.88) at the end of 2nd week and this was further reduced to mean 1.93 (SD 0.78). ($p < 0.05$) in group B compared to group A patients. The group B shows the range of motion of Cervical flexion and extension where the mean of the patients in group B was 24.6 (SD 4.13) on day 1, which was increased to a mean of 29.16 (SD 3.73) at the end of Week 2, which was further increased to a mean of 34.83 (SD 4.25) at the end of week 3. The group B shows the range of motion of Cervical Lateral flexion right and left where the mean of the patients in group B was 24.6 (SD 4.13) on day 1, which was increased to a mean of 29.16 (SD 3.73) at the end of Week 2, which was further increased to a mean of 34.83 (SD 4.25) at the end of week 3. The group B shows an increase in the range of motion of Cervical rotation right and left where the mean of the patients in group B was 29.5 (SD 4.22) on day 1, which was increased to a mean of 34.66 (SD 4.13) at the end of Week 2, which was further increased to a mean of 47.66 (SD 5.37) at the end of week 3. The group B shows the RFIQ mean of 123.9 (SD 14.27) on day 1 which was decreased to mean of 93.16 (SD 12.92) at the end of week 2, which was further decreased to mean of 64.33 (SD 15.47) at the end of week 3 with statistically significant difference $p < 0.05$.

Conclusion: The present study showed Transcutaneous Electrical Nerve Stimulation along with Myofascial Release had shown superior sensitivity in increasing the Cervical Range of motion, reducing the pain and increasing the overall impact.

Keywords: Fibromyalgia, transcutaneous electrical nerve stimulation, myofascial release, ultrasound, range of motion, visual analogue scale

Introduction

The word fibromyalgia comes from the Latin word, the fibrous tissue (fibro) and the Greek ones for muscle (myo) and pain (algia) ^[1].

Fibromyalgia is a chronic pain syndrome characterized by wide spread musculoskeletal pain with multiple symptoms which include fatigue, sleep disturbance, cognitive dysfunction and psychological distress. It is one of the most common chronic pain conditions in the world. It has prevalence rate of 2% in the world population, and it's found 1% to 4.9% in women population, 0% to 2.9% in men population [2].

A common finding in chronic pain syndromes is central sensitization, which is defined as an increased responsiveness of the central nervous system to a variety of stimuli (e.g., pressure, temperature, light, and medication). This central hyper excitability causes hyperalgesia, allodynia, and referred pain across multiple spinal segments which in turn result in chronic widespread pain and decreased tolerance to sensory input of the musculoskeletal system. Further fibromyalgia systemically caused by the dysregulation, neurologic, immunologic, endocrinologic and enteric organ systems [3].

The Autonomic Nervous System (ANS) and immune system is responsible for the nonrestorative sleep, pain, fatigue, and cognitive/mood symptoms in FM. Muscle pain is characterized as the major symptom of FMS, often described by patients as "aching or burning" regardless of physical activity. Other symptoms or associated problems which occur with various reports of frequencies, that can also be affect function. Neck pain is one of the symptoms that experience with fibromyalgia [4].

According to the American College of Rheumatology, fibromyalgia is defined as a history of pain in all four quadrants of the body lasting more than 3 months. Pain in all four quadrants means that pain in both right and left sides, as well as above and below the waist. American College of Rheumatology described 18 characteristic tender points on the body that are associated with fibromyalgia in order to be diagnosed with fibromyalgia, a patient must have 11 or more tender points [5].

Pathophysiology and the neuroscience behind the patients are the most effective method of reducing pain symptoms in Fibromyalgia of neck patients [6].

Transcutaneous Electrical Nerve Stimulation (TENS) is shown to be effective for several pain conditions such as, chronic musculoskeletal pain, osteoarthritis, and any postoperative incisional pain. According to the current research, TENS is the one treatment aimed to reduce central excitability [7]. TENS application was being applied at minimal intensities that caused a tingling sensation over tender points. It is a "non-pharmacological" treatment for pain that is inexpensive, safe, and easy to use. In most of the Prior studies showed that the TENS utilizes opioid receptors both spinally and supra-spinally to produce inhibition of nociceptive dorsal horn neurons which reduce the excitatory neurotransmitter release and reduce hyperalgesia [8]. TENS produces this effect by activating central inhibitory pathways that involve the periaqueductal gray and the rostral ventromedial medulla and the spinal cord. Thus, TENS reduces central sensitization and central excitability by increased central inhibition and decreased central excitability. Ultrasound therapy has been found to reduce musculoskeletal pain levels in fibromyalgia patients [9]. Ultrasound therapy is a technique widely used to treat pain and stiffness, involving the use of an ultrasound probe and a transmission coupling gel. The probe is used to sweep over the areas of the body that are known to be painful or stiff, emitting waves which pass through the skin which causes the local soft tissues to vibrate. The vibrations caused by the probe then increase levels of

haemoglobin, a molecule that shuttles oxygen to the body's cells and tissues, as well as tissue temperature which improves blood circulation through tissues [10].

Ultrasound therapy increases blood flow through tissues, removing waste products which can cause muscle pain, stiffness and inflammation. In addition to the above, increased blood flow is also known for oxygenating the body's tissues, which is a huge plus for fibromyalgia sufferers; poor tissue oxygenation is known to worsen symptoms [11].

Myofascial Release (MFR) technics focus on relaxing the deep tissue of the patient body to provide effective pain relief. It is a combination of manual traction and prolonged assisted stretching manoeuvres designed to break up fascial adhesions. MFR reduce the tension in muscles with secondary to increase the blood circulation, pain relief, and increased mobility by inducing segmental and suprasegmental reflex. Stimulation of the mechano-receptors by MFR may also close the "pain gate" via pre- and post-synaptic inhibition. Moreover, it has been found to induce release of endogenous opiates [12].

The purpose of MFR is to break down scar tissue, relax the muscle, myo fascia and restore good posture [13].

Pain status of fibromyalgia of neck patients will be measured by VAS scale. Range of motion of cervical will be measured by universal goniometer. Measuring the functions, overall impact and symptoms by Revised fibromyalgia impact questioner.

The main objective of this study was to compare the effect Myofascial Release technique along with Ultrasound Versus Myofascial Release technique along with Transcutaneous Electrical Nerve Stimulation in the Fibromyalgia Neck patients.

Null hypothesis: There will be no significant difference in Ultra Sound Therapy along with Myo Fascial Release vs Transcutaneous Electrical Nerve Stimulation along with Myo Fascial Release on the Fibromyalgia neck pain patients.

Alternative hypothesis: There will be significant difference in Ultra Sound Therapy along with Myo Fascial Release vs Transcutaneous Electrical Nerve Stimulation along with Myo Fascial Release on the Fibromyalgia neck pain patients.

Materials and Methods

This was a Randomised Control study. The study duration for data collection was 12 months, April 2020 to April 2021. Chit method in simple random sampling method was used. IEC approval was done by the Institutional ethical committee (Ref No. KIPT/07/F/19-20 Dated 14/04/2020.) and informed consent was signed by all the patients participated in the study.

Sample size calculation

$$n = 2 \times \frac{\left(\frac{Z_{\alpha/2} + Z_{\beta}}{d_1 - d_2}\right)^2 \times SD^2}{1}$$

$Z_{\alpha/2}$ = Type I error (5%) = 1.96

Z_{β} = Type II error (20%) = 0.84 (power of the study = 80%)

SD = Standard deviation = 0.9 (From literature)

$d_1 - d_2$ = difference between the mean = 1.2

$$n = 2 \times \frac{(1.96 + 0.84)^2 \times 1.2^2}{0.9^2}$$

$$= 2 \times \frac{7.84 \times 1.44}{0.81} = 26.31 \approx 30$$

Total Sample Size, N=60(2*30)

Inclusion criteria: Patients with the age group between 35 - 50 years, both male and female subjects, subjects showing score from 5 to 10 on VAS and duration of illness more than three months.

Exclusion Criteria: Uncontrolled blood pressure or diabetes, neuropathic pain at or around neck condition, cardiac pacemakers, Malignancy near neck region, Any Metal Implants in and around the neck, Thrombosis., Radiculopathy, Spinal cord injury patients, Open wounds and skin allergies at the site of treatment, Congenital malformation of spine

Outcome measures

Pain status, Range of Motion, Function, Overall Impact and Symptoms were measured by using Visual Analogue Scale, Universal Goniometer and Revised Fibromyalgia Impact Questionnaire. Questionnaire are available as a free tool on the internet and the scales were not modified by the researcher in the present study. The outcome measures were taken on the day before commencing the treatment, at the end of the 2nd week and finally at the end of the 3rd week after the treatment. The study was a hospital center based comparative follow up from day 1 to week 3. Sample for the study comprised of 60 Fibromyalgia neck patients aged between 35 to 50 selected by simple random sampling method. Samples of the study comprised of fibromyalgia neck patients at Kempegowda Institute of Medical Sciences. The study was conducted, and outcome measures (VAS, Range of motion and Overall impact) were collected on day 1, at the end of 2nd week and at the end of 3rd week. The study samples were selected based on inclusion and exclusion criteria. A total of 60 patients were divided into two groups of 30 each. Group A patients were given Ultrasound therapy of Frequency 1MHz, Intensity 1.5 W/cm², Mode: Continues mode, Durations of 6-8 min and Technique by Direct contact method followed by Myofascial release for Gross Stretch of the Posterior Cervical Musculature, Cranial Base Release and Sternocleidomastoid release. Group B patients were given Transcutaneous Electrical Nerve Stimulation of Frequency 50 – 80 Hz, Pulse duration 50 – 100 m sec, Amplitude 10 – 30 mA and durations

15 minutes followed by Myofascial release. All the subjects were given physiotherapy treatment for five visits per week for three weeks.

Statistical Analysis

Data was analysed using the statistical package Statistical Package for Social Science (SPSS) version 21.0 (Chicago, IL) and level of significance was set at $p < 0.05$. Descriptive statistics was performed to find out the mean and standard deviation of the respective groups. Normality of the test was assessed using Shapiro Wilkins test. Inferential statistics was done by using ANOVA test followed by post hoc analysis to find out the statistical significance within the groups. Independent t test was used between the groups to find out the significance.

Results

Group A participant's mean age is 42.7 and 43.06 is of Group B. The standard deviation of group A was 4.77 and 5.59 is of group B. T test analysis showed statistical non significance hence the groups are comparable. ($p > 0.05$).

Table 1: Age Comparison

	MEAN	SD
Group A	42.7	4.77
Group B	43.06	5.59
P Value (T Test)	0.76	

Group A consists of 40% male (12) and 60% females (18). Group B includes 36.6 % males (11) and 63.4% females (19)

Table 2: Gender Comparison

		Number	Percentage
Group A	Male	12	40
	Female	18	60
Group B	Male	11	36.6
	Female	19	63.4

Statistical analysis using ANOVA and Posthoc test within the groups showed significant reduction in VAS scale from PRE – WEEK 3 in Group A and Group B. Posthoc analysis also showed significant difference at all pair group comparisons ($P < 0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (75.6% vs 65.8%) compared to Group A.

Table 3: Vas Scale Comparison between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	7.5	5.06	2.56	7.6	4.2	1.93
SD	1.19	1.01	0.85	1.10	0.88	0.78
P Value (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value	0.0001*			0.0001*		
Pre – Week 3 Change (%)	65.8%			75.6%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in FLEXION scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all pair group

comparisons ($p < 0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (41.5% vs 37.2%) compared to Group A

Table 4: Cervical Flexion Comparison between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	24.16	29	33.16	24.6	29.16	34.83
SD	4.16	3.80	3.59	4.13	3.73	4.25
P value (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value	0.0002*			0.0001*		
Pre - Week 3 Change (%)	37.2%			41.5%		

Statistical analysis using ANOVA and Posthoc test within the groups showed significant change in EXTENSION scale from PRE – WEEK 3 in Group A and Group B. Posthoc analysis also showed significant difference at all pair group

comparisons ($p<0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (41.5% vs 37.2%) compared to Group A.

Table 5: Cervical Extension Comparison between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	24.16	29	33.16	24.66	29.16	34.83
Sd	4.16	3.80	3.59	4.13	3.73	4.25
Pvalue (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value (T Test)	0.0001*			0.0001*		
Pre - Week 3 Change (%)	37.2%			41.5%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in LATERAL FLEXION (RIGHT) scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all

pair group comparisons ($p<0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (33.83% vs 32.16%) compared to Group A

Table 6: Cervical Lateral Flexion Comparison (Rt Side) Between Group A And B Patients

	Group A			Group B		
	PRE	Week 2	Week 3	PRE	Week 2	Week 3
Mean	24.16	29	33.16	24.6	29.16	34.83
SD	4.16	3.80	3.59	4.13	3.73	4.25
Pvalue (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value (T Test)	0.0001*			0.0001*		
Pre - Week 3 Change (%)	32.16%			33.83%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in LATERAL FLEXION (LEFT) scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all pair

group comparisons ($p<0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (33.83% vs 32.16%) compared to Group A.

Table 7: Cervical Lateral Flexion Comparison (Lt Side) Between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	24.16	29	33.16	24.6	29.16	34.83
Sd	4.16	3.80	3.59	4.13	3.73	4.25
Pvalue(Anova)	0.0001*			0.0001*		
PRE Vs Week 2 P Value	0.0001*			0.0001*		
PRE Vs Week 3 P Value	0.0001*			0.0001*		
WEEK 2 V Week 3 P Value (T Test)	0.0001*			0.0001*		
Pre - Week 3 Change (%)	33.16%			33.83%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in ROTATION (RIGHT) scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all pair

group comparisons ($p<0.05$) in both group A and Group B. The percentage reduction showed more change with respect to Group B (46.66% vs 44.33%) compared to Group A

Table 8: Cervical Rotation Comparison (Rt Side) Between Group A And B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	35.16	40.16	45.33	29.5	34.66	47.66
Sd	5.16	4.99	5.56	4.22	4.13	5.37
Pvalue(Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value (T Test)	0.0007*			0.0001*		
Pre - Week 3 Change (%)	44.33%			46.66%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in Rotation (Left) scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all pair group

comparisons ($p<0.05$) in both group A and Group B. The percentage reduction showed a more change with respect to Group B (46.66% vs 44.33%) compared to Group A.

Table 9: Cervical Rotation Comparison (Lt Side) Between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	35.16	40.16	45.33	29.5	34.66	47.66
Sd	5.16	4.99	5.56	4.22	4.13	5.37
Pvalue (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value (T Test)	0.0001*			0.0001*		
Pre - Week 3 Change (%)	44.33%			46.66%		

Statistical analysis using ANOVA and Post hoc test within the groups showed significant change in RFIQ scale from PRE – WEEK 3 in Group A and Group B. Post hoc analysis also showed significant difference at all pair group comparisons

($p<0.05$) in both group A and Group B. The percentage reduction showed a more change with respect to Group B (48.1% vs 31.8%) compared to Group A.

Table 10: Revised Fibromyalgia Impact Questionnaire Comparison between Group A and B Patients

	Group A			Group B		
	Pre	Week 2	Week 3	Pre	Week 2	Week 3
Mean	166.5	137.5	113.5	123.9	93.166	64.33
Sd	8.80	8.80	8.80	14.27	12.92	15.47
Pvalue (Anova)	0.0001*			0.0001*		
Pre Vs Week 2 P Value	0.0001*			0.0001*		
Pre Vs Week 3 P Value	0.0001*			0.0001*		
Week 2 Vs Week 3 P Value (T Test)	0.0001*			0.0001*		
Pre - Week 3 Change (%)	31.8%			48.1%		

Discussion

At the beginning, 105 patients were evaluated for eligibility to enter the study. Finally, 60 patients were included in the study. The study population, characteristics, samples, age, gender, visual analog scale, range of motion and revised fibromyalgia impact questionnaire. The result of the present study was consistent with previous study which showed that there was specific importance of Transcutaneous electrical nerve stimulation along with Myo fascial release which when implemented on the patients had shown significant improvement in the scores of VAS, Cervical ROM and Revised Fibromyalgia Impact Questionnaires. In present study, null hypothesis was rejected, and alternate hypothesis was accepted.

The mean age in the Group A was 42.7 and 43.06 is of Group B. The standard deviation of Group A was 4.77 and 5.59 is of Group B. Further the present study was supported by Sahin Ozaslan *et al.* (2014) from Turkey conducted a systematic review on Middle age group^[14].

The present study showed significant improvement in VAS between Day 1- Week 3 ($p<0.05$) in group B compared to group A patients. Boonstra *et al.* (2008), conducted a study to

check the reliability and validity of the visual analogue scale (VAS) for disability in patients with chronic musculoskeletal pain. The study concluded that the reliability of the VAS for disability is moderate to good^[15].

The present study showed the Cervical Flexion and Extension range of motion in group B shows significant difference in terms of mean and standard deviation from Day 1 – end of 3rd week ($p<0.05$).

The present study showed the Cervical Lateral flexion right and left range of motion in group B shows significant difference in terms of mean and standard deviation from Day 1 – at the end of 3rd week ($p<0.05$).

The present study showed the Cervical Rotation right and left range of motion in group B shows significant difference in terms of mean and standard deviation from Day 1 – at the end Week 3 ($p<0.05$).

The present study showed that there is significant improvement in the scores of the RFIQ from day 1 and at the end week 3 ($p<0.05$). Further this was supported by Robert M Bennet, *et al.* 2009 Fibromyalgia Research Unit, Oregon Health & Science University where the researcher had reviewed various studies in which the RFIQ was used as a

valid tool [16].

Castro-Sánchez *et al.* found that the MFR was effective in reducing muscle pain in FM. Since MFR more directly targets the proposed peripheral pain generators residing in the fascia. Primary goal of MFR works to change the course of bodily functions, to reset imbalance and progress in a balanced state by relieving fascial restriction thus normalizing health, tension and movement of the body [17]. Dailey DL *et al.* 2013 found that Transcutaneous electrical nerve stimulation reduces pain, fatigue and hyperalgesia while restoring central inhibition in primary fibromyalgia [18]. Kavadar G, *et al.* [2015]. The aim of the study was to assess efficacy of Ultrasound therapy for the treatment of trigger point in myofascial pain syndrome (MPS). The study concluded that Ultrasound therapy treatment is effective on Myofascial syndrome [19].

Limitation(s)

This study was carried out on small sample size. No long term follow up was carried out to assess whether subjects retained the gained improvement after 3 weeks of the intervention due to Covid 19. The age group of the patient limits the study. Practical and time constraints meant that it was unable to measure an even wider range of physical performance measures.

Conclusion

The present study showed significant differences in the outcome measures of Cervical Range of motion, Visual analogue Scale and also the Revised Fibromyalgia Impact Questionnaire in Group A and Group B. There was statically significant difference in the pre and post total scores of group B. The present study also showed that the Transcutaneous Electrical Nerve Stimulation along with Myo Fascial Release had shown superior sensitivity in the percentage wise improvement in the Fibromyalgia neck patients. Hence, we reject the null hypothesis and accept alternate hypothesis that there will be significant difference in effectiveness of Myofascial release technique along with Ultra sound V/S Myo fascial release technique along with TENS in the Fibromyalgia neck patients.

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