EFFECT OF TRIGGER POINT INJECTION VS ULTRASONIC THERAPY VS TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION IN REHABILITATION OF CERVICAL AND PERI-SCAPULAR MYOFASCIAL PAIN SYNDROME- A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

BACKGROUND

Myofascial Pain Syndrome (MPS) is a major cause of musculoskeletal pain in the shoulder neck region in modern era, originating from Myofascial Trigger Points (MTrPs) in skeletal muscle, either alone or in combination with other pain generators.

The objectives of this study were- 1. to compare the efficacy and outcome of 3 different treatment modalities namely ultrasound therapy (UST), transcutaneous electrical nerve stimulation (TENS) and steroid mixed with local anaesthetics injection to trigger points, in the clinical outcome of MPS and 2. to propose steps for early rehabilitation after identifying area needing clinical research.

MATERIALS AND METHODS

Based on the Travell and Simon's criteria, 109 patients diagnosed to have MPS in the cervical and peri scapular region were recruited for this study. They were randomly divided into 3 groups. Group A received ultrasound therapy (UST), group B received transcutaneous electrical nerve stimulation (TENS) and group C received depot form of steroid (Triamcinolone 20 mg) injection with local anaesthetics (lidocaine 2%) at trigger points (TPI). All patients also received therapeutic exercises (Stretching exercises of trapezius muscle, strain/ counter strain exercise of cervical and upper back), hot packs application and tablet amitriptyline (10 mg) daily at night for 6 weeks. They were followed up after initial visit, at 2nd week, 6th week, 12th week and at 24th week. Pain and result of the treatment were assessed with visual analogue scale (VAS) scores, number of trigger points, index of MTrPs and neck disability index (NDI) questionnaire method.

RESULTS

Pain scores improved in the patients of all the 3 groups, in the early visits but gradually worsened in later visits. Group C showed significant improvement (p value <0.01) in the pain scores by VAS scale and other scores like number of trigger points, MTrP index score and neck disability index score as compared to group A and B. But no group could show significant improvement in outcome measures at long term follow up.

CONCLUSION

MPS can be effectively managed by TPI. UST and TENS are also approved methods of treatment, but their efficacy is not as remarkable as TPI. But the improvements were sustained for a short term only.

KEY WORDS

MPS: Myofascial Pain Syndrome, MTrPs: Myofascial Trigger Points, UST: Ultrasound Therapy, TENS: Transcutaneous Electrical Nerve Stimulation, TPI: Trigger Point Injection, LTR: Local Twitch Response.

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BACKGROUND

Myofascial pain syndrome is one of the causes of neck pain characterised by MTrPs, found in taut band of muscle bellies. They are small and sensitive foci in muscle that spontaneously or upon compression, cause pain to a distal region, known as referred pain zone along with local twitch response.

MPS has a high prevalence among individuals with regional pain complaints to the extent of 30%. In general orthopaedic clinic, 21% of all patients are due to MPS.[1] The wide varieties of effective management techniques are available with indication of clinical usefulness of each.[2] It includes manual therapies i.e. stretching, trigger point pressure relief, therapeutic exercises, Physical modalities i.e. thermotherapy, transcutaneous electrical nerve stimulation (TENS) or needling which can be dry or with use of steroids or anaesthetics or botulinum toxin. This study was a humble attempt to compare the roles and efficacy of different physical modalities and local infiltration of steroid at trigger points in cervical and peri-scapular myofascial pain syndrome.

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Objectives of The Study

1. To compare the efficacy and outcome of three different treatment variation like ultrasound therapy (UST), transcutaneous electrical nerve stimulation (TENS) and local steroid injection to trigger points in the clinical outcome of Myofascial pain syndrome and
2. To propose steps for early rehabilitation and identify the area needing further clinical research.

MATERIALS AND METHODS

The study design used was a prospective, single-centred, parallel designed, randomized clinical trial which was reviewed and approved by Research Evaluation committee and the institutional Ethical Committee. Information was given comprehensively, both orally and in written form in their own language, to the patients. Written informed consent was obtained prior to their inclusion. The trial was initiated by the investigators and funded by an internal hospital grant. No drug or medical company had any involvement in drug supply, trial conduct or manuscript review. Since the duration of the study was less. The number of patients were taken for convenience.

The study was conducted on recruited patients attaining outpatient department in Physical medicine and Rehabilitation department in a city-based government tertiary hospital at Kolkata, India. Duration of this study was 16 months from December 2012 to May 2014. Total 120 patients were recruited in this study; among them 40 patients were included in each three groups. Patients was determined after reviewing various journals analysis.[3,4,5]

Subjects who fulfilled the Inclusion criteria was 1) Age between 18 and 60 years, 2) Trigger points in the neck & shoulder region, which disturb normal daily activities for at least 3 months, 3) Reproduction of patient's pain by palpation of trigger points, 4) The number of trigger points was less than 10. Subjects were excluded from the trial if they were 1) Cervical disc herniation or cervical spine fracture or any other bony abnormalities (Congenital or traumatic), 2) Pregnant, breastfeeding or women planning conception during the study, 3) Poorly controlled Diabetes mellitus, 4) Bleeding diathesis, local or systemic infection & allergy to anaesthetic agents, insensitive skin or other dermatological diseases, 5) Malignancy, local infection, mechanical implants etc., 6) any hereditary deficiencies. Randomization was done by selecting computer generated random number tables.

Total number of patients included in our study is 109 out of 120 patients. From group A 36, group B 34 and group C 39 patients was missing after first visit. [Fig. 1]

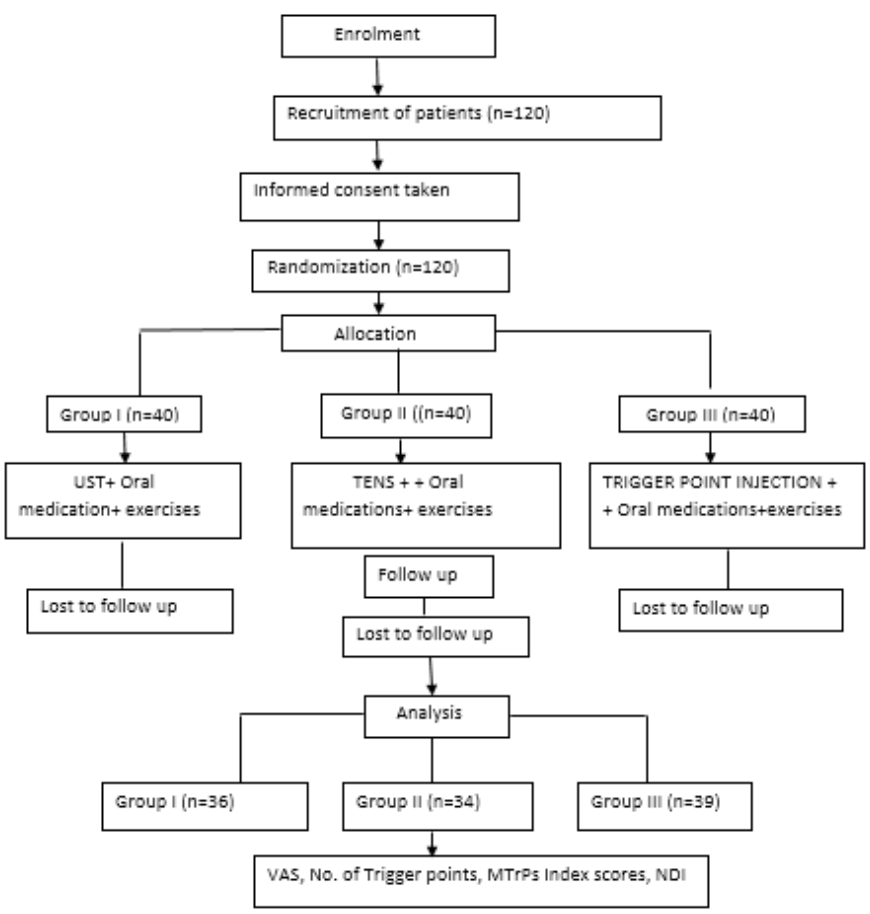

Figure 1. Consort Flow Diagram

Group A

Allocated patients received Ultrasonic therapy (Continuous mode, frequency – 1 MHz, intensity- 1.5 W/cm^2). Total given dose varied depending on how many MTrPs found with treatment time of each trigger point of 5 minutes for 14 days.[6] Therapeutic exercises (Spray and Stretch technique to

manually release trigger points and home exercise program), superficial heat application and concomitant oral medications was received along with the trial.

Group B

Local heat application, therapeutic exercises, oral medication and transcutaneous electrical nerve stimulation (TENS) (Pulsed mode, frequency – 70-80 Hz, 100-110 microsecond duration) maximum of 14 sessions varied depending on the number of MTrPs with 20 minutes each trigger point per session for 2 weeks.[7]

Group C

Patients received local trigger point injection (TPI) of 0.5 ml of triamcinolone acetonide depot preparation (40 mg) and diluted with (0.25%) lidocaine without adrenalin (Total 2 ml) along with superficial heat application, therapeutic exercises, oral medication. Each session of TPI was given once per week for a total of 2 weeks.[1] All three groups received Hot Packs at 75^0C for 20 minutes and Active Stretching exercises, [8] along with use of vapo-coolant spray(Spray and Stretch technique to manually release trigger points) and home exercise program and low dose tab Amitriptyline (10 mg),[4] along with proposed treatment (UST, TENS or Trigger point injection).

Trial Regimen and Procedures

All patients were fully informed of the possible adverse effects of different physical modalities and trigger point injection and other medications were used in the trial prior to participation.

Exercise Protocol

The home training programme for the neck exercises focused on strength and mobility for the neck and shoulder region. The programme also included stretching of the involved muscle after hot pack application. Subjects in all three groups were instructed to do stretching exercises of trapezius muscle according to involvement followed by neck isometric exercises.[3]

Spray and Stretch Technique to Manually Release Trigger Points[9]

The patient neck is side bended in sitting position, i.e. head toward the opposite side shoulder with the subject in position for stretch the first sweep of jet stream of vaporized coolant spray applied before any stretch pressure is applied in parallel sweeps in one direction over the entire length of the muscle in direction of referred pain pattern from 15 cm away from skin with not more than 2 or 3 sweeps, the therapist simultaneously stretches the involved muscle.[10] Home exercises were advised to continue for total treatment session.[9]

Hot Packs[8]

Standardized hot pack was used and applied for 20 minutes over the shoulder as to cover the upper trapezius muscle in supine lying position before starting the session.

Ultrasound Therapy (UST)

All the patients of group A are being treated with ultrasound therapy. A calibrated ultrasound machine was used for treatment purpose. Ultrasound probe was applied with circular motion that completes one circle in 2 sec with tight circle enough to produce a small overlap of circle with the trigger point in center of the circle. The parameters were 1.5 watt/cm^2 at 3 MHz, continuous mode for 5 minutes at each trigger points per session. Total given dose varied depending on how many MTrPs found with treatment time of each trigger point of 5 minutes for 14 days.[6]

Transcutaneous Electrical Nerve Stimulation (TENS)

Group B patients are being treated with transcutaneous electrical nerve stimulation (TENS) therapy. After skin exposure, the negative electrode of TENS unit was placed on the trigger point of the trapezius muscle, and the positive electrode was placed in the direction of long axis of same dermatome of that muscle.[11] The current was applied at a pulse mode, frequency of 70-80 Hz and duration 100 – 110 μs; the intensity was set at a level that each subject could feel but that was not strong enough to induce muscle contraction. The current was applied for 25 minutes at each trigger point.

Trigger Point Injection Procedure

All the patients of group C are being treated with trigger point injection.[12]

Pre-Injection

Iincreased bleeding tendencies should be explored before injection. Capillary haemorrhage augments post injection soreness and leads to unsightly ecchymosis.[13] Patients should refrain from daily aspirin dosing for at least three days before injection to avoid increased bleeding. While the patient was in a sitting position, the trigger point area was determined, and the skin was cleaned with an appropriate antiseptic solution. Local injections were performed according to the technique previously described by Travell and Simons.[13] When a trigger point (MTrP) was located and the overlying skin was cleansed with alcohol, the point was immobilized between the thumb and index finger or index and middle finger. Using sterile technique, 21-gauge, 2-inch needle then was inserted 1 to 2 cm away from the MTrP, so that the needle could be advanced into the MTrP at an acute angle of 30° to the skin. To ensure that the needle was not within a blood vessel, the plunger was withdrawn before injection. A small amount (0.2 mL) of anaesthetic was injected when the needle encountered a tiny sensitive locus when a LTR response was elicited and then withdrawn. 1 to 2 ml of solution containing depot preparation of triamcinolone acetonide (20 mg) with 0.25% lignocaine without adrenaline was injected. The needle then was withdrawn to the level of the subcutaneous tissue and redirected in all direction and was repeated according to number of trigger points.[14,15]

Data Collection

The primary outcome was measured using following outcome measures and documented at initial and subsequent visits-

1. Assessment of subjective pain intensity measured using visual analogue scale (VAS) between 0 and 10.

participants were asked to rate their average pain during the last 24 hours out of 10, with 0 representing no pain and 10 representing the worse pain imaginable.[16]

2. Physician palpated the number of trigger points at each visit (MTrPs).[16,17]
3. Index score of MTrPs: After palpating the MTrPs, marked the size, consistency and tenderness, using a score from 0 to 3.
   0: indicating increased consistency but where palpation produced no pain
   1: increased consistency but patient indicating only pain after being asked
   2: increased consistency and the patient spontaneously expressed pain
   3: increased consistency and the patient withdrew from palpation (jump sign).

   An index score[16] was made from the sum of the scores at each treatment session. The total number of MTrPs and index scores was used as effect variables.
4. Functional disability was assessed with neck disability Index (NDI) items score range from 0 to 5, higher score indicated greater disability.[18,19]

Statistical Analysis

Statistical analysis was done by SPSS version 15 for analysing the collected data. Results on continuous measurements are presented as mean ± SD and results on categorical measurements are presented in number. Student's 't' test was used for comparison of continuous data between two groups. Proportions were analysed by the use of the Chi-square test or Fisher's test. Results were considered statistically significant if $p < 0.05$, highly significant if $p < 0.001$ and not significant if $p > 0.05$

RESULTS

Demographic Characteristics

Incidence of MPS was more in males than females. In group A, incidence among females and males were 72.2% and 27.8%, in group B, 76.5% and 23.5% and in group C, it was 87.2% and 12.8%. P values of comparison between group A and B was 0.684, group A and C was 0.106 and between group B and C was 0.233. In this study, mean age of presentation was 32.8±7.308 in group A, 36.26± 10.387 in group B and 35.36 ±10.449 in group C. VAS scores for pain intensity measurement was significantly improved after treatment at visit 2 in all the groups but more profoundly in group C with P value <0.001 when compared with visit 1. Mean of number of trigger points and Index score of MTrPs were decreased in subsequent visits (p value <0.001) compared to initial visit [Table 3, 4]. Statistically significant improvement seen in NDI on 2nd visit onward with p value <0.001 compared to initial visit; but 4th and 5th visit scores were again increased. P value of VAS scores, Number of trigger points, MTrP index score and in NDI in different visits (Between A, B and C Groups) were showed significant improvement in post treatment visits with p value <0.001 for all 3 groups. But trigger point injection was superior than other 2 groups [Refer Table 3, 4, 5, 6].

Group	N	Mean	Std. Error of Mean	Median	Std. Deviation	Quartiles	
						Lower	Upper
A	36	32.83	1.218	32	7.308	28	36
B	34	36.26	1.781	35.5	10.387	29	43.25
C	39	35.36	1.673	32	10.449	28	45

Table 1. Age Distribution

	A vs B	A vs C	B vs C
p Value	0.113	0.233	0.712

Table 1

Sex	Variables	Group				p Value		
		A	B	C	Total	A VS. B	A VS. C	B VS. C
Female	Number	26	26	34	86	0.684	0.106	0.233
	%	72.2	76.5	87.2	78.9			
Male	Number	10	8	5	23			
	%	27.8	23.5	12.8	21.1			
Total		**36 (100)**	**34 (100)**	**39 (100)**	**109 (100)**			

Table 2. Gender Distribution: Comparison of Categorical Variables Between Three Groups (A, B and C)

	Group			p Value		
	UST	TENS	Trigger Point Inj.			
	Mean ± Std. Deviation	Mean ± Std. Deviation	Mean ± Std. Deviation	A VS. B	A VS. C	B VS. C
VAS Visit 1	7.25 ± 0.91	7.26 ± 0.9	7.38 ± 0.91	0.946	0.523	0.573
VAS Visit 2	3.06 ± 1.31	3.26 ± 1.08	1.59 ± 0.5	0.470	<0.001	<0.001
VAS Visit 3	3.69 ± 1.26	4.32 ± 0.84	1.87 ± 0.73	0.017	<0.001	<0.001

VAS Visit 4	4.81 ± 1.31	5 ± 1.04	2.64 ± 0.99	0.495	<0.001	<0.001
VAS Visit 5	5.94 ± 1.22	6.15 ± 1.13	4.13 ± 1.22	0.474	<0.001	<0.001
p Value Visit 1 vs. Visit 2	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 3	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 4	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 5	<0.001	<0.001	<0.001			

Table 3. Comparison of Numerical Variables and p Values VAS Scores Between Different Visits and Between the Three Groups

	Group			p Value		
	UST	TENS	Trigger Point INJ			
	Mean ± Std. Deviation	Mean ± Std. Deviation	Mean ± Std. Deviation	A VS. B	A VS. C	B VS. C
No. of Trigger Points Visit 1	3.53 ± 0.94	3.59 ± 0.99	3.85 ± 1.16	0.794	0.198	0.314
No. of Trigger Points Visit 2	2.5 ± 1.06	2.85 ± 0.82	1.97 ± 0.9	0.125	0.023	<0.001
No. of Trigger Points Visit 3	2.61 ± 1.02	2.88 ± 0.81	2 ± 0.89	0.224	0.007	<0.001
No. of Trigger Points Visit 4	2.86 ± 1.05	3.12 ± 0.98	2.15 ± 0.88	0.294	0.002	<0.001
No. of Trigger Points Visit 5	2.94 ± 0.96	3.38 ± 1.02	2.72 ± 0.97	0.067	0.313	0.006
p Value Visit 1 vs. Visit 2	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 3	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 4	<0.001	<0.001	<0.001			
p Value Visit 1 vs. Visit 5	<0.001	0.017	<0.001			

Table 4. Comparison of Numerical Variables and p Values of Number of Trigger Points Between Different Visits and Between the Three Groups

	Group			p Value		
	UST	TENS	Trigger Point Inj.			
	Mean ± Std. Deviation	Mean ± Std. Deviation	Mean ± Std. Deviation	A VS. B	A VS. C	B VS. C
MTrPs Index Score Visit 1	8.11 ± 2.72	8.65 ± 2.53	9.33 ± 2.6	0.398	0.050	0.259
MTrPs Index Score Visit 2	3.86 ± 1.76	4.65 ± 1.94	2.77 ± 1.29	0.080	0.003	<0.001
MTrPs Index Score Visit 3	4.22 ± 1.61	5.38 ± 1.83	3 ± 1.36	0.006	0.001	<0.001
MTrPs Index Score Visit 4	5.14 ± 2.19	6.29 ± 2.1	3.46 ± 1.54	0.028	<0.001	<0.001
MTrPs Index Score Visit 5	6.22 ± 2.4	7.38 ± 2.39	5 ± 2	0.047	0.019	<0.001
P Value Visit 1 vs. Visit 2	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 3	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 4	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 5	<0.001	<0.001	<0.001			

Table 5. Comparison of Numerical Variables and p Value of MTrPs Index Score Between Three Different Groups and Different Visits

	Group			p Value		
	UST	TENS	Trigger Point Inj.			
	Mean ± Std. Deviation	Mean ± Std. Deviation	Mean ± Std. Deviation	A VS. B	A VS. C	B VS. C
Neck Disability Index (NDI) Score VISIT 1	48.99 ± 7.64	49.6 ± 7.98	49.72 ± 7.59	0.746	0.683	0.951
Neck Disability Index (NDI) Score VISIT 2	17.03 ± 7.31	21.53 ± 9.34	10.29 ± 4.58	0.028	<0.001	<0.001
Neck Disability Index (NDI) Score VISIT 3	21.59 ± 8.35	28.62 ± 9.03	11.36 ± 5.02	0.001	<0.001	<0.001
Neck Disability Index (NDI) Score VISIT 4	29.93 ± 9.92	33.71 ± 9.05	15.26 ± 5.28	0.102	<0.001	<0.001
Neck Disability Index (NDI) Score VISIT 5	37.76 ± 11.03	42.44 ± 8.09	27.32 ± 9.41	0.048	<0.001	<0.001
P Value Visit 1 vs. Visit 2	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 3	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 4	<0.001	<0.001	<0.001			
P Value Visit 1 vs. Visit 5	<0.001	<0.001	<0.001			

Table 6. Comparison of Numerical Variables and p Values of Neck Disability Index (NDI) Score Between Different Visits and Between the Three Groups

DISCUSSION

In current medical practice Myofascial Pain Syndrome has becoming a real rehabilitation challenge in our society. Multiple treatment options are available now in the hands of clinicians preclude any standardized management, which can be practiced for every patient of MPS. This clinical trial aimed to compare the efficacy of three treatment approaches for MPS. Here, Incidence among females was more than males, mostly were desk job sedentary worker. Friction et al[20] and Drewes et al[21] were also found female predominance than male. According to SK Severino et al, some hormonal changes attributing to MPS in females and pain was reported to

increase during second week of menstrual period.[22] Anette Kaergaard et al[23] assessed the occurrence of two restrictively defined neck-shoulder disorders among sewing machine operators among 243 patients where job involves monotonous, highly repetitive tasks performed in a sitting working posture with upper back curve and head bent over the sewing machine. Es Rachlin[24] said, occupational or recreational activities that produce repetitive stress on a specific muscle or muscle group commonly cause chronic stress in muscle fibres, leading to trigger points due to improper body mechanics. The primary goal of management for MPS is to break the vicious cycle of pain through elimination of trigger points. A multi-disciplinary approach is required in managing MPS. [25] Physical therapy, exercise, ischemic compression, heat, stretch and spray technique, local injections with local anaesthetics, steroid or dry needling and pharmacological treatment are all used for management of MTrPs.[16,24,25] Anthony H. Wheeler,[26] Frost et al [27] proved trigger point injection is one of the most effective methods[26] for treatment of MPS. It is performed by different means as dry needling or local anaesthetics, steroids etc. In this study the trigger point injection was superior to ultrasound therapy or TENS in the treatment of cervical and peri-scapular MPS for short term pain relief. Tablet Amitriptyline (10 mg) is also used here. The 6-week and 1-year effectiveness of low dose amitriptyline (10-30 mg) showed a significant reduction of pain scores.[4] NDI score was used in outcome measure which proved greater disability reduction with group C patients in our trial. J Sarrafzadeh et al [28] and Majlesi and Unalan [29] have proved effectiveness of UST in management of MPS. Eriksson et al [30] stated burst TENS were more effective than conventional one. Group A and B patients have shown significant improvement in all parameters in 2nd, 3rd, 4th and 5th visit with p value <0.001 as compared to 1st visit. From the mean value of each visit, it is observed that, more improvement occurred at post treatment 1st and 2nd visit, but 3rd visit onwards, improvement was less than immediate previous visits. In other words, although the patients got significant relief from their painful condition after treatment with UST or TENS, but this improvement was more marked up to 2 to 6 weeks from the treatment. Chuen-Ru Hou et al[5] proposed that TENS alone is not useful treating modality for MTrPs; it can be used as a secondary technique when combined with other therapeutic exercises to increase cervical ROM. Cold spray and release of taut bands by stretching was helpful for pain relief in our study. TM Cummings [31] and J C King et al [32] stated that trigger point injection is one of the most effective methods among other managements. TA Garvey et al [33] used four different types: lidocaine, lidocaine combined with a steroid, acupuncture, and vapo-coolant spray with acupressure for trigger point management. Results indicated that therapy without injected medication (63% improvement rate) was as effective as therapy with drug injection (42% improvement rate).[35] Needling technique actually break contraction knots suggested by Simon[13] and ultimately disrupt vicious cycle. Ay S et al also used local anaesthetic injection (2 ml lidocaine of 1%) and dry injection on trigger points. No significant differences were observed between the groups ($p > 0.05$).[34] Summarizing the effect of trigger point injection with lidocaine combined with steroid, in this present study, group C showed that VAS Scores decreased significantly in 2nd, 3rd and 4th visits. (Refer Table no 2, 3, 4, 5, Figure 1). Lignocaine was acted as short term pain relief [35] and steroid played as anti-inflammatory agent by aborting upregulation of arachidonic acid pathway.[36] In our study, when we compared the improvement of VAS scores, number of trigger points and index scores of trigger points and NDI between different groups, improvement with trigger point injection was greater than UST and TENS group. Effectiveness of UST and TENS is more or less similar in our trial. Although UST, TENS and TPI have proven effectiveness in management of MPS but TPI was preferred because improvement was more than UST and TENS. But it has to be admitted that regardless of the mode of treatment be it UST or TENS or TPI, satisfactory relief from the pain of cervical and peri-scapular MPS is short lived, mainly up to 6 weeks. Long term effectiveness (up to 24 weeks/ 6 months) is not much pronounced albeit a significant improvement statistically.

Limitations

Limitation was the effect of treatment duration. Long term treatment sessions may be necessary to prolong the benefit. Another limitation was less number of participant recruitment. Further randomised controlled trials are needed to validate the safety and effectiveness of multiple treatment sessions by trigger point injection therapy.

CONCLUSION

Single injection at trigger point or use of other physical modalities for small period of time is not helpful enough and only gives short term relief. Multiple treatment sessions may be required to prolong the effectiveness of the treatment modality long term. The efficacy of the treatment is more significant up to 6 weeks (p value <0.001). In long term follow up (24 weeks), no treatment options, among the three groups in our study, could prove their effectiveness.

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