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COMPARISON OF EFFICACY OF OZONE INJECTION AND DRY NEEDLING IN MYOFASCIAL PAIN SYNDROME INVOLVING TRAPEZIUS; A RANDOMISED CONTROL TRIAL

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ABSTRACT

Background: Myofascial pain syndrome (MPS) is a common musculoskeletal disorder characterized by presences of multiple myofascial trigger points (MTrPs). In this study, we aim to evaluate and compare the efficacy and safety of ozone in MPS with those of the widely used dry needling. Methods: This randomised controlled trial was conducted from 16/12/2019 to 15/12/2020, involving 42 patients with confirmed diagnosis of MPS. They were randomised into two groups using simple randomization by sealed envelope method. One group received dry-needling (DN) (n= 21) and the other received ozone-injection (OI) (n=21). Both interventions were performed once per week for three weeks. The patients were examined 4 weeks after the last injection. Results: Males: females= 24:18. There were no significant differences in the baseline parameters. Four parameters were studied: Numerical pain scale (NPS), Neck disability index (NDI), Tissue imaging score with ultrasonography (TIS) and range of motion- Lateral neck flexion (LNF) angle. Both groups showed a statistically significant decrease in all four parameters after the intervention. When both groups were compared for post-intervention outcomes, significant differences were observed in NPS (pvalue= 0.047) and NDI (p-value= 0.024). The difference in the reduction of the TIS and LNF was comparable in both groups and was not statistically significant (p-value= 0.329 and 0.134 respectively). Conclusions: Both dry needling and ozone injection are effective modalities for the treatment of myofascial pain syndrome. Ozone injection showed significant additional benefits. A comparative study with large cohort is recommended to determine if one method is better than the other

Key words: Myofascial pain, chronic pain.

INTRODUCTION

Myofascial pain syndrome (MPS) is a non-inflammatory condition of musculoskeletal origin, associated with pain and muscle stiffness. The prevalence of MPS ranges from 30% to 46% in specialised pain clinics, and up to 15% in general clinics ¹. It is characterised by the presence of hyperirritable, palpable nodules in skeletal muscle fibres called myofascial trigger points (MTrP), which are a cardinal feature of MPS ^{1, 2}. These trigger points appear in muscle end

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plates due to excessive release of acetylcholine from repeated injuries. Persistent contraction leads to a cascade of biochemical responses, including the release of vasoactive components and inflammatory factors (viz: bradykinin, substance P). This in turn contributes to localised muscle pain and further neuroplastic changes in central nervous system ³. It has also been suggested that neurogenic inflammation after central sensitization, could give rise to MTrP loci in the absence of peripheral muscle injury.

The Trapezius is one of the most affected muscles, with MTrPs observed in up to 93% of individuals with neck pain ⁴. In addition to MPS, MTrPs in trapezius are also associated with tension type headache, sleep disturbances and chronic neck pain ⁵. Increased nocturnal trapezius muscle activity is seen in chronic neck pain patients with sleep disturbances ⁶. Treatment of muscle pain is vital in improving sleep quality in such patients. The MTrPs are found in taut bands within muscles, which demonstrate a local twitch response following a rapid snapping stimulus or insertion of a needle ^{7, 8}. Repeated trauma, muscular overload, psychological stress, and systemic pathologies can lead to the development of taut bands in which latent MTrPs can appear. Mechanical stress and similar stimuli can lead to activation and development of symptoms ⁹.

The diagnosis of MPS is mostly clinical, and relies on eliciting a detailed history with a thorough physical examination to identify the MTrPs. Well established clinical tools like Travell and Simons' criteria help in diagnosis of MPS ¹⁰. However, there are ongoing efforts to standardize these ^{11, 12, 13}. Newer evolving methods, including ultrasound imaging (USI), elastomyography, and magnetic resonance elastography, have shown promise in this regard. The combination of USI with elastography localises hypoechoic, elliptical, and focal areas that correspond to palpable trigger point nodule ¹⁴.

Various methods ranging from exercise to physical interventions have been used to treat MPS. Physical methods include transcutaneous electrical stimulation, infrared, ultrasound, manual pressure massage, acupuncture, anaesthetic injections, and dry needling (DN) ¹⁵. In DN, a thin filamentous needle is inserted into the MTrP muscle. Modulation of regional bradykinin, calcitonin gene-related peptide, and substance P levels is the proposed mechanism of action of DN ¹⁶. However, the validity of this hypothesis remains unclear. Recently, increasing evidence supports the role of ozone injection (OI) in the management of musculoskeletal disorders. Ozone can improve tissue oxygenation, inhibit inflammatory mediators by downregulating tumour necrosis factor (TNF) and TNFR2, and induce a moderate analgesic effect through phosphodiesteraseA2 blockage ¹⁷. Ozone in low concentrations, ozone is an activator of enzymatic scavenger systems (catalase, glutathione peroxidase, and superoxide dismutase), and hence, is known to prevent free radical damage in muscles ¹¹. In this study, we aimed to evaluate and compare the efficacy and safety of ozone in MPS with those of the widely used DN.

SUBJECTS AND METHODS

This randomised controlled trial was conducted at the ESI Institute of Pain Management, Sealdah, Kolkata, India from 16/12/2019 to 15/12/2020. Approval was obtained from the Institutional Ethical Committee (IEC/IRB No- 002/ 2019-20) and written informed consent was obtained from all the patients. The study was registered at CTRI (CTRI/2020/04/024561). Forty-two patients with a confirmed MPS diagnosis were included in this study (Table 1). They were randomised into two groups by alternatively assigning odd numbers to one group and even numbers to the other, with one group receiving DN (n= 21) and the other group receiving

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ozone (n=21). Both interventions were performed once per week for three weeks. The patients were examined four weeks after the last injection, and the parameters were noted (Table 2).

METHODOLOGY

Trigger points (TP) were identified by manual palpation, and the most painful point was identified in those with two or more TP. Ultrasonography of the trapezius on the affected side was performed and the findings were noted. The MTrP site was marked, and its distance from anatomical landmarks was measured in possible cases where the marker was washed off. With the patient in the prone position and sterile precautions, the point was grabbed between the thumb and index fingers. A 24-gauge, 1.25-inch needle was used in all patients. In the Oz group, 8 cc of oxygen/ozone gas was injected into the affected MTrP at a concentration of 15 μ g/mL (Waterhouse Medical Ozone Generator, number 0023GWP). In the DN group, the needle was inserted into the MTrP and withdrawn from subcutaneous tissue (Trigger Point Dry Needling method) for 5-8 minutes. This was repeated in different directions to frustrate the point.

Statistical analysis:

For sample size calculation, reduction in pain score and NDI percentage were regarded as the primary outcome measures. It was estimated that 21 subjects would be required per group, with 80% power and a 5% probability of type 1 error using the formula $N = (Z \alpha/2) 2 *P(1-P)/d 2$ (where, $Z \alpha/2$ is the critical value of the standard normal distribution at $\alpha/2$ level of significance). Data were summarised using descriptive statistics, mainly mean and standard deviation for numerical variables and counts and percentages of categorical variables. Numerical variables were compared between groups using student's independent sample and paired t-tests. The chi-square test & analysis of variance were employed for intergroup comparison and analysis of categorical variables, and statistical significance was set at p<0.05.

RESULTS

All 42 patients were included in the final analysis. This study included 24 males and 18 females. Mean weight of patients was 67.12 kg and mean BMI was 22.5. In 31 patients, right side of the body was affected, while in 11 patients left side was affected. The demographic features and baseline parameters are presented in Table 3. There were no statistically significant differences in baseline parameters between the groups.

Both groups showed a statistically significant decrease in all four parameters after the intervention (Table 4). When both groups were compared for post-intervention outcomes, significant differences were observed in NPS and NDI scores (Table 5). The difference in the reduction of the TIS and LNF was comparable in both groups and was not statistically significant.

Table 1: Inclusion & exclusion criteria

Inclusion criteria	Exclusion criteria			
Age 18–60 years	History of cervical radiculopathy or			
	degenerative condition			
Symptoms beyond 3 months with	Surgery or trauma to the neck during last year			
conservative treatment, including				
physiotherapy & medications.				

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Presence of active trigger points in the upper	Previous injection for MPS during last 6		
trapezius muscles (at least one)	months		
Presence of at least one taut band on	Confirmed diagnosis of cognitive disorders,		
palpation	fibromyalgia, rheumatoid arthritis,		
	hypothyroidism or diabetes mellitus		
NRS score 6 & above			

Table 2: Parameters studied

Sl	Parameter observed	Comment/ Description		
No		-		
1	Numerical pain scale (NPS)	Severity of pain		
2	Range of motion- Lateral neck flexion (LNF) angle	Measured using goniometry as the maximum angle the neck can bent laterally on both sides.		
3	Neck disability index (NDI)	 Self-reported 10-point neck pain questionnaire including severity of pain, its impact on sleeping, driving, etc. Responses are scored from 0-5. Total score out of a maximum 50 is noted as percentage. Higher NDI indicates more disability 		
4	Ultrasounography- imaging score (TIS)	 Grayscale & vibration sonography with colour doppler study of affected upper trapezius TIS, ranging from 0 (normal, uniform echogenicity & stiffness) to 2 (abnormal structure, multiple focal hypoechoic & stiffnodules) is assigned 		

Table 3: Baseline parameters

Parameter		Total	DN group	Ozone group	p-value
					(student's t test)
Sex	Female	18 (47.6%)	10 (42.8%)	8 (38%)	0.291
	Male	24 (52.4%)	11 (57.2%)	13 (62%)	0.407
Age		37.68 +/- 7.42	37.42 +/- 7.43	37.57 +/- 1.61	0.313
NPS		7.54 +/- 0.91	7.48 +/- 0.92	7.62 +/- 0.92	0.461
NDI		53.42 +/- 8.22	54.01 +/- 7.77	52.81 +/- 8.80	0.216
TIS		1.59 +/- 0.49	1.57 +/- 0.50	1.62 +/- 0.49	0.60
LNF		33.01 +/- 3.26	32.72 +/- 3.29	33.31 +/- 3.29	0.327

(NPS- Numerical pain scale, NDI- Neck disability index , TIS- Tissue imaging score, LNF-Lateral neck flexion angle)

Table 4: Intragroup comparison before & after intervention

Paramete	Dry Needling group			Ozone group		
r	Before	After	p-	Before	After	p-
	interventio n	interventio n	value	interventio	interventio	value

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			(Paire d t-			(Paire d t-
			test)			test)
NPS	7.48 +/- 0.92	1.67 +/- 0.48	< 0.001	7.62 +/- 0.92	1.24 +/- 0.70	< 0.001
NDI	54.01 +/-	15.22 +/-	< 0.001	52.81 +/-	12.81 +/-	< 0.001
	7.77	3.74		8.80	3.03	
TIS	1.57 +/- 0.50	0.38 +/- 0.49	< 0.001	1.62 +/- 0.49	0.24 +/- 0.43	< 0.001
LNF	32.72 +/-	34.07 +/-	< 0.001	33.31 +/-	35.54 +/-	< 0.001
	3.29	2.92		3.29	2.63	

(NPS- Numerical pain scale, NDI- Neck disability index, TIS- Tissue imaging score, LNF-Lateral neck flexion angle)

Table 5: Intergroup comparison after intervention

Parameter	Mean	95% confidence interval		p-value
	difference	Lower	Upper	(Intergroup ANOVA)
NPS	0.42 +/- 0.92	0.007	0.850	0.047
NDI	2.40 +/- 4.49	0.359	4.450	0.024
TIS	0.14 +/- 0.65	- 0.155	0.440	0.329
LNF	- 1.47 +/- 4.31	- 3.437	0.494	0.134

(NPS- Numerical pain scale, NDI- Neck disability index, TIS- Tissue imaging score, LNF-Lateral neck flexion angle)

Discussion:

Myofascial pain syndrome is a commonly overlooked entity which not only results in disability but also leads to anxiety and depression in suffering patients ^{11, 18, 19}. The principles of treatment aims to inactivate MTrPs, restore normal muscle function, and correct factors that trigger MTrPs. As numerous treatment options are available, treatment plans should consider individual parameters, lesion site, and disease progression. Dry needling involves the insertion of a solid filiform needle into the MTrP for stimulate it ²⁰. The therapeutic effects of DN have been explained by an integrated hypothesis that involves mechanical and neurophysiological actions ²¹. DN has been shown to be an effective therapy for musculoskeletal disorders, albeit with some studies showing the results lasting only for short periods ²². It is also a well-accepted adjunct for MPS treatment. The therapeutic actions of ozone are attributed to its anti-inflammatory properties. It is also known to increase glucose metabolism in muscles, ameliorate tissue hypoxia, improve erythrocyte activity, and optimise protein metabolism ²³.

Many studies have compared DN and trigger point injections (TrPI), with varying results ^{1, 24, 25}. Studies and systematic reviews have shown that DN alone resulted in improved pain in patients with MPS compared to placebo, although the effect was short- termed ^{26, 27, 28}. Recent studies have observed that DN has an additive effect when combined with physiotherapeutic interventions rather than a single procedure ²⁹. The efficacy of TrPI in MPS is well documented, although no recommendations regarding an ideal injectate have been made ³⁰. Recent meta-analysis showed that TrPI with local anaesthetics and corticosteroids has good short-term pain relief in MPS, while TrPI with platelet-rich plasma and DN fared better in the long term, indicating the variable response to different injectates ^{31, 32}. Conversely, a few trials have shown good long-term pain relief with TrPI with injectates, such as lidocaine & saline ^{33, 34}. Results of our study, using OI as the injectate, showed a similar improvement in symptoms.

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Ozone therapy is a promising minimally invasive intervention with an active role in reducing pain and/or improving functionality in musculoskeletal disorders when used alone or in combination with other modalities ³⁵. However, only a handful of studies have compared the utility of OI to that of other TrPIs. Ozone was shown to significantly improve pain and functional and sonographic parameters compared with corticosteroid infiltration in a study involving chronic plantar fasciitis. However, the effect was slow in onset but longer in duration ³⁶. Similar longevity has been shown in studies using ozone and corticosteroids for carpal tunnel syndrome, with better pain relief and improved functional status ³⁷. In a study comparing DN with lidocaine and ozone TrIP in MPS, all three methods improved the symptoms. However, there was a statistically significant difference in the improvement in pain (visual analogue scale [VAS]), NDI, and PPT, favouring OI and lidocaine ¹. Patients receiving OI showed greater improvement in VAS, PPT, and NDI than those receiving lignocaine, but the difference was not statistically significant. In our study, both DN and OI showed improvement in symptoms; however, OI showed a statistically significant improvement in NPS and NDI, while TIS and LNF were the same for both groups. None of the patients developed local or systemic adverse effects due to the OI. A limitation of our study is the lack of long-term followup, which would have probably resulted in further improvements in the parameters, as seen in other studies.

CONCLUSION

Both dry needling and ozone injection are effective modalities for the treatment of myofascial pain syndrome. Ozone injection showed significant additional benefits. A comparative study with a large cohort is recommended to determine if one method is better than the other.

Disclosure

The authors declare that they have no conflicts of interest. This study received no funding.

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