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Efficacy of Extracorporeal Shockwave Therapy versus Corticosteroid Injection in Patients with Myofascial Pain Syndrome: A Prospective Study

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ABSTRACT

Background: Myofascial pain syndrome (MPS) is a musculoskeletal disorder, that results from trigger points, which are small, taut skeletal muscle and fascia.

Objective: To compare the efficacy of Extracorporeal Shock Wave Therapy (ESWT) versus corticosteroid injection in the treatment of patients with MPS of the upper trapezius muscle.

Patients and Methods: This prospective randomized study included fifty patients with MPS who were randomly divided equally into two groups. The active myofascial trigger points (MTrPs) in the upper trapezius were identified. Group 1 patients received ESWT 3 times at one-week intervals and group 2 patients received one injection of corticosteroids. The visual analog scale (VAS), Neck Disability Index (NDI), and pain pressure threshold (PPT) assessed the outcomes.

Results: VAS scores were 7.24±1.01, 3.72 ±1.43 and 2.44±1.36 at baseline, week-4 and -8 respectively in group1; while were 7.16±1.03, 5.76 ±1.16 and 5.24±1.48 at baseline, week-4 and -8 respectively in group2. NDI scores were 11±2.63, 7.92±2.63 and 6.52±2.66 at baseline, week-4, and -8 respectively in group1, whereas were 11.16±2.36, 8.72±2.37 and 7.64±2.66 at baseline, week-4 and -8 respectively in group2. PPT scores were 2.81±0.70 at baseline, and 4.64 ±1.03 and 5.54±1.1 at week-4 and week-8 in group1, while, in group2 the scores were 2.89±0.71, 3.92 ±0.81 and 4.08±0.92 at baseline and week-4 and -8 respectively. VAS, NDI, and PPT pre- and post-treatment results showed statistically significant improvements in both groups, P <0.001.

Conclusion: ESWT and corticosteroid injection considerably reduced pain intensity, physical impairment, and MTrP sensitivity to pressure in patients with MPS. ESWT was more effective in the reduction of pain and MTrPs sensitivity to pressure.

Keywords: Myofascial pain syndrome, ESWT, Corticosteroid injection, NDI, PPT.

INTRODUCTION

Myofascial pain syndrome (MPS) could affect as many as 85% of people in general, with an estimated prevalence of 46%, at some point in their lives. MPS is a primary source of persistent musculoskeletal pain [(1,2)]. The trapezius, a muscle that is sometimes neglected as a cause of temporal and cervicogenic headaches, is likely the muscle most impacted by the pain, which is mostly felt in the neck, lumbar, and shoulder areas [(3,4)]. One of the primary reasons for missed employment, medical appointments, and disability benefits is MPS [(5)].

The name "myofascial" was created since the pathophysiology of MPS includes various soft tissue components of the myofascial unit, such as the superficial fascia and deep fascia, in addition to its primary muscle origin [(6)]. Myofascial trigger points (MTrPs), which are described as hyperirritable sites inside a tight band of skeletal muscle or fascia, play a key role in the pathogenesis of MPS. Upon palpation, these locations can cause recognizable soreness, referred pain, and motor or autonomic symptoms [(7)].

Traditional MPS treatments include medication (such as NSAIDs, steroids, tricyclic antidepressants, vasodilators, or oral skeletal muscle), injectable therapy (such as local anesthetic injections into trigger points with or without corticosteroids or "dry" needling"), physical therapy, and behavioral modification [(8)].

Extracorporeal Shock Wave Therapy (ESWT) has also been steadily employed to treat musculoskeletal illnesses, and more recently, its application has broadened the range of MPS therapy options [(9-12)].

High-pressure air is used to create mechanical energy in high-intensity shockwave treatment. This energy moves through the tissues as a longitudinal wave. It induces micro-functional and micro-structural changes that help in revascularization and encourages tissue regeneration. According to reports, it can help with MPS, calcifying tendonitis, and plantar fasciitis discomfort [(13)].

Although therapeutic options vary, there is no clinical evidence to guide the treatment response and several studies have been conducted to demonstrate the effectiveness of different treatments in reducing pain in patients with MPS. Therefore, we conducted this prospective study to compare the efficacy of ESWT versus corticosteroid injection in the treatment of patients with MPS of the upper trapezius muscle.

PATIENTS AND METHODS

Patients

This prospective randomized study compares the effectiveness of shockwave therapy against corticosteroid injection for patients with MPS of the upper trapezius muscle. Fifty patients were recruited at the Rheumatology, Rehabilitation, and Physical medicine outpatient clinic of Benha University hospitals. Patients who agreed to participate were asked

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general questions about their age, the duration of their pain, the medications they were currently taking, and the average intensity of their pain over the preceding week before their participation in the study was blinded. Two physiatrists diagnosed MPS in the upper trapezius muscle using Simon's criteria [14]. This describes a clearly defined, painful, hypersensitive, palpable nodule inside a taut band of the upper trapezius muscle; a typically referred pain pattern with pain starting within 3 months and pain linked to the ipsilateral shoulder and neck with a visual analog scale (VAS) score of 4 or above.

Exclusion criteria included taking anticoagulant medication, taking an antiplatelet agent within 3 days of the study's start, getting a trigger point injection in the same area within 3 months of the study, being diagnosed with fibromyalgia syndrome or cervical radiculopathy, having a history of cervical or shoulder surgery, being obese, with a body mass index of 27.5 or higher, and having any other medical or psychological illness.

Two equal groups of patients were randomly assigned. ESWT and a local steroid injection were conducted in group 1 (n=25) and group 2 (n=25), respectively **(Fig 1).**

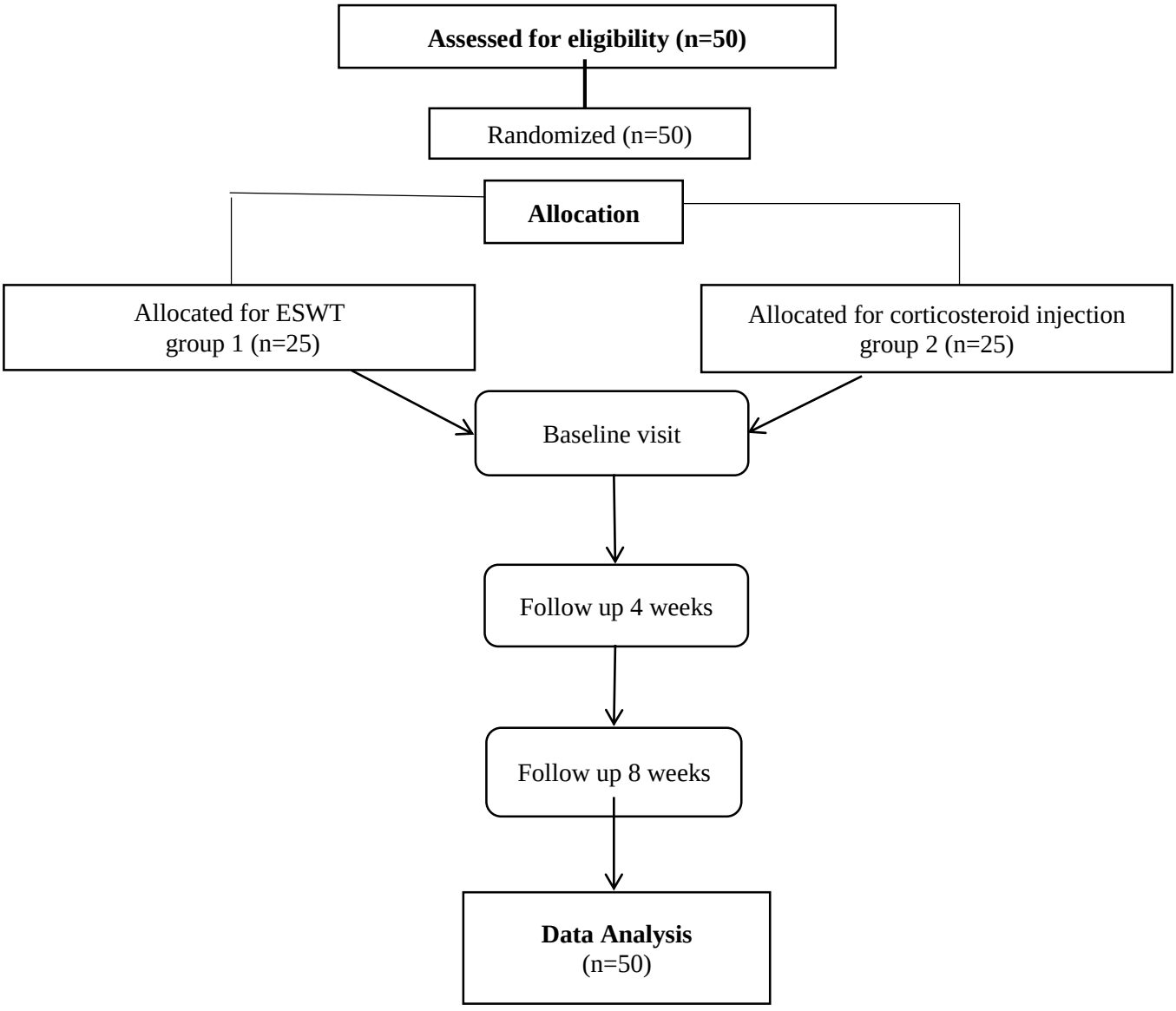

Fig. (1): Flow chart of the patients.

Interventions

For ESWT treatment, patients were subjected to a total of 1,500 shock waves each treatment session at a rate of 240 waves per minute, with a low energy flux density (EFD) of 0.10 mJ/mm^2 per minute, delivered three times with a one-week gap between sessions utilizing the Pagani Hc SWT377 (total of 4,500 shock waves). Treatment was administered by concentrating on the area where a muscle twitching response or referred pain should be induced by carefully adjusting the placement of the targeted probe.

When receiving a corticosteroid injection, patients sat in an upright, comfortable position. Palpation and pen marking was used to identify the active myofascial trigger point that was the most agonizing. Steroids (triamcinolone 40 mg) were injected once after the skin had been cleaned with the appropriate antiseptic.

Outcome measurement

An objective observer unfamiliar with the treatment plan carried out clinical follow-up evaluations during hospital visits at the baseline, 4 weeks, and 8 weeks following the final therapy. The VAS, NDI, and PPT were used to assess the outcomes.

A VAS, which has a straight line of 10 cm, and numbers set in a gradual and rising sequence, with point 0 (left) representing no pain and point 10 (right) representing the worst pain the patient could imagine, was used to assess pain intensity. Each patient was told to mark the location that most accurately captured the severity of her/his suffering. The distance between the zero point and the mark made by the patient, which represented the degree of pain the patient was experiencing at the time of the assessment, was then quantified by the researchers in centimeters [15, 16].

The NDI survey questionnaire, which is the most popular tool for evaluating cervical spine abnormalities, was used to assess the degree of physical disability. NDI was initially established to determine the degree of limitations in everyday activities experienced by individuals with significant cervical pain, particularly for those who had whiplash injuries [16]. NDI is composed of 10 questionnaires; 7 of them asses functional activity, while 2 questionnaires assess symptoms, and one to asses concentration. By summing the results from each question, the final NDI score was calculated. A functional impairment related to cervical anomalies was suggested by a higher NDI score. The original creator, Vernon, suggested categorizing the scores from 0 to 50 as follows: 4 or below = no disability, 5 to 14 = mild disability, 15 to 24 = moderate impairment, 25 to 34 = severe disability, and 35 or more = total disability [17].

The pain pressure threshold (PPT) is the lowest pressure (kg/cm2) at which pain or discomfort is produced. An analog algometer, a force gauge, and a rubber disc with a 1 cm2 surface area were used to measure PPT. The rubber tip was positioned on the dominant upper trapezius muscle 9 cm lateral to the C7 spinous process (which is congruent with the upper trapezius' motor point) with the shaft of the algometer vertical to the surface being studied [18]. The pressure was then gradually raised by about 0.1 kg/cm2 until the PPT was reached.

Based on prior studies [19,20,21], we determined that a 50% reduction in VAS, a 4kg/cm^2 increase in PPT, and a 30% reduction in NDI would be clinically significant in this study.

Patients were asked to sign if they need any analgesic or anti-inflammatory medicine, and we included this information in their ambulant files. The outcome characteristics were noted before the initiation of therapy (baseline), as well as following the therapy sessions at weeks 4 and 8.

Ethical consent

The study complied with the Helsinki Declaration and was approved by the ethical committee of Benha University. Before being enrolled, all patients gave their signed, informed consent.

Statistical analysis

Version 25.0 of the IBM SPSS program was used to analyze the data (IBM, Armonk, NY, USA). The mean and standard deviation for parametric data were used to represent quantitative data after the Kolmogorov-Smirnov and Shapiro tests for normality. Quantitative data were described using percentages and figures. A Bonferroni pairwise repeated-measures analysis of variance (ANOVA) was carried out for each of the three assessment periods (baseline, 4 weeks, and 8 weeks), for each outcome measure (VAS, PPT, and NDI), and for treatment groups. The modeling of individual and sets of outcome measures for therapy response (between individuals) and assessment time was made possible by this technique (within subjects). To compare the variations between the treatment groups, we further used an independent t-test. P-values less than 0.05 were used to determine statistical significance.

RESULTS

All patients enrolled in the present study finished the corresponding treatment.

This study included 50 patients divided into 2 groups, group 1 received ESWT, and group 2 received a local Corticosteroid injection. Both groups were nearly similar in demographic characteristics, where the mean age ± SD of group 1 patients was 39.44±7.8 while it was 39.96±8.79 in group 2 patients. The majority of patients were females (84% vs 16% males) in group 1 and (80% vs 20 % males) in group 2. There were no significant differences between both groups regarding age, sex, and BMI ($p > 0.05$). The duration of disease in Group 1 was 12.52±7.13 months versus 12.08±7.7 months in Group 2. There was no significant difference

regarding unilateral/bilateral involvement among patients of both groups (p: 0.53). Pretreatment scores were as follows, for group 1: VAS was 7.24±1.01, NDI was 11 ± 2.63 and PPT was 2.81±0.70 while for group 2 VAS was 7.16±1.03, NDI was 11.16 ± 2.36 and PPT was 2.89±0.71. There were no statistically significant differences between the two groups in terms of disease-related characteristics at baseline. In addition, there was no significant difference between patients of both groups regarding the need for medication at baseline assessment (p 0.76) **(Table 1).**

Table (1): Demographic data and baseline disease-related characteristics of the patients

Variable	**Group 1 (n=25)**	**Group 2 (n=25)**	**P**
Age (years), Mean (SD)	39.44±7.8	39.96±8.79	0.83
Sex Female n (%) Male n (%)	 21(84%) 4(16%)	 20(80%) 5(20%)	 0.71
BMI Kg/m, Mean (SD)	27.55±2.24	27.94±2.64	0.58
Duration of symptoms (months), Mean (SD)	12.52±7.13	12.08±7.7	0.83
Site Unilateral n (%) Bilateral n (%)	 19 (76%) 6 (24%)	 17 (68%) 8 (32%)	 0.53
VAS, Mean ±SD	7.24±1.01	7.16±1.03	0.78
NDI, Mean ±SD	11 ± 2.63	11.16 ± 2.36	0.82
PPT, Mean ±SD	2.81±0.70	2.89±0.71	0.68
Need for medication, n (%)	7 (28%)	8 (32%)	0.76

VAS: Visual Analogue Scale, NDI: Neck Disability Index, PPT: Pain Pressure Threshold, The comparison between the two groups was done using an independent t-test; the comparison between sex and the number of patients needing medication was done using a chi-squared test.

Within-group comparisons of outcome measures revealed that at 4 weeks follow-up time-point, group 1 patients experienced a significant improvement in their clinical condition, with a decrease in mean± SD of VAS score from 7.24±1.01 at the first visit to (3.72±1.43 and 2.44±1.36) at 4 weeks and 8 weeks post-treatment, respectively, with mean difference 4.8 (P<0.001).

Additionally, the mean± SD of the NDI score decreased from 11±2.63 at baseline to 7.92±2.63 at 4 weeks post-treatment and 6.52±2.66 at 8 weeks post-treatment, with a mean difference of 4.48 (P<0.001), and the mean±SD PPT score increased from 2.81±0.70 at the first visit to 4.64±1.03 at 4 weeks post-treatment and 5.54±1.1 at 8 weeks post-treatment (P<0.001) **(Table 2).**

Table (2): Outcome measures changes among patients of group 1

	Mean±SD	**Mean diff. (Pre/post)**	**95% CI**		**P-value**
			Lower	Upper	
VAS - Baseline - Week 4 - Week 8	 7.24 ±1.01 3.72 ±1.43 2.44 ±1.36	 4.8	 4.28	 5.32	 - **<0.001** **<0.001**
NDI - Baseline - Week 4 - Week 8	 11±2.63 7.92±2.63 6.52±2.66	 4.48	 3.81	 5.14	 - **<0.001** **<0.001**
PPT - Baseline - Week 4 - Week 8	 2.81 ±0.70 4.64 ±1.03 5.54 ±1.1	 -2.73	 -3.06	 -2.41	 - **<0.001** **<0.001**
Need for medication: - Baseline - Week 8	 7 (28%) 2 (8%)	 -			 0.76

The comparison of outcome measure changes within group 1 was done using the repeated measure ANOVA test; the comparison between changes in the number of patients needing medication was done using the Chi-square test.

Similarly, it was noted that group 2 patients achieved statistically significant improvement in their clinical condition, with a decrease in mean± SD of VAS score from 7.16±1.03 at the first visit to (5.76±1.16, 5.24±1.48) at (4 weeks, 8 weeks post-treatment) respectively with mean difference 1.92 (P<0.001). A drop in the mean± SD of NDI from 11.16±2.36 at baseline to (8.72±2.37, and 7.64±2.66) at (4 weeks, and 8 weeks post-treatment respectively) with a mean difference of 3.52 (P<0.001), and an increase in the mean± SD of PPT score from 2.89± 0.71 at the initial visit to (3.92±0.81, 4.08±0.92) at (4 weeks, and 8 weeks post-treatment respectively) (P<0.001) **(Table 3).**

Table (3): Outcome measures changes among patients of group 2

	Mean±SD	**Mean diff. (Pre/post)**	**95% CI**		**P-value**
			Lower	Upper	
VAS					
- Baseline	7.16 ±1.03				-
- Week 4	5.76 ±1.16	1.92	1.54	2.29	**<0.001**
- Week 8	5.24 ±1.48				**<0.001**
NDI					
- Baseline	11.16±2.36				-
- Week 4	8.72±2.37	3.52	2.99	4.05	**<0.001**
- Week 8	7.64±2.66				**<0.001**
PPT					
- Baseline	2.89 ±0.70				-
- Week 4	3.92 ±0.81	-1.18	-1.4	-1.02	**<0.001**
- Week 8	4.08 ±0.92				**<0.001**
Need for medication:					
- Baseline					
- Week 8	8 (32%) 3 (12%)	-			0.64

The comparison of outcome measure changes within group 2 was done using the repeated measure ANOVA test; the comparison between changes in the number of patients needing medication was done using the Chi-square test.

When comparing the outcome measures between the two groups, it was discovered that group 1 saw statistically significant greater gains in VAS and PPT scores than group 2 (P <0.001), but there was no statistically significant difference between the two groups NDI scores (P > 0.05). The number of patients taking drugs (pain relievers/muscle relaxants) at baseline and after 8 weeks of receiving therapy did not vary in a way that was significantly different between the two groups (P>0.05) (**Table 4 & Fig 2**).

Table (4): Comparison of outcome measures changes between the 2 group

	Group 1	**Group 2**	**p-value**
VAS			
- Week 4	3.72 ±1.43	5.76 ±1.16	**<0.001**
- Week 8	2.44 ±1.36	5.24 ±1.48	**<0.001**
NDI			
- Week 4	7.92±2.63	8.72±2.37	0.26
- Week 8	6.52±2.66	7.64±2.66	0.14
PPT			
- Week 4	4.64 ±1.03	3.92 ±0.81	**0.008**
- Week 8	5.54 ±1.1	4.08 ±0.92	**<0.001**
Change in no. need for medication no (%)	5 (20%)	5 (20%)	1

Comparison between the two groups' changes in outcome measures and the number of patients needing medication was done by using an independent t-test and a Chi-square test, respectively.

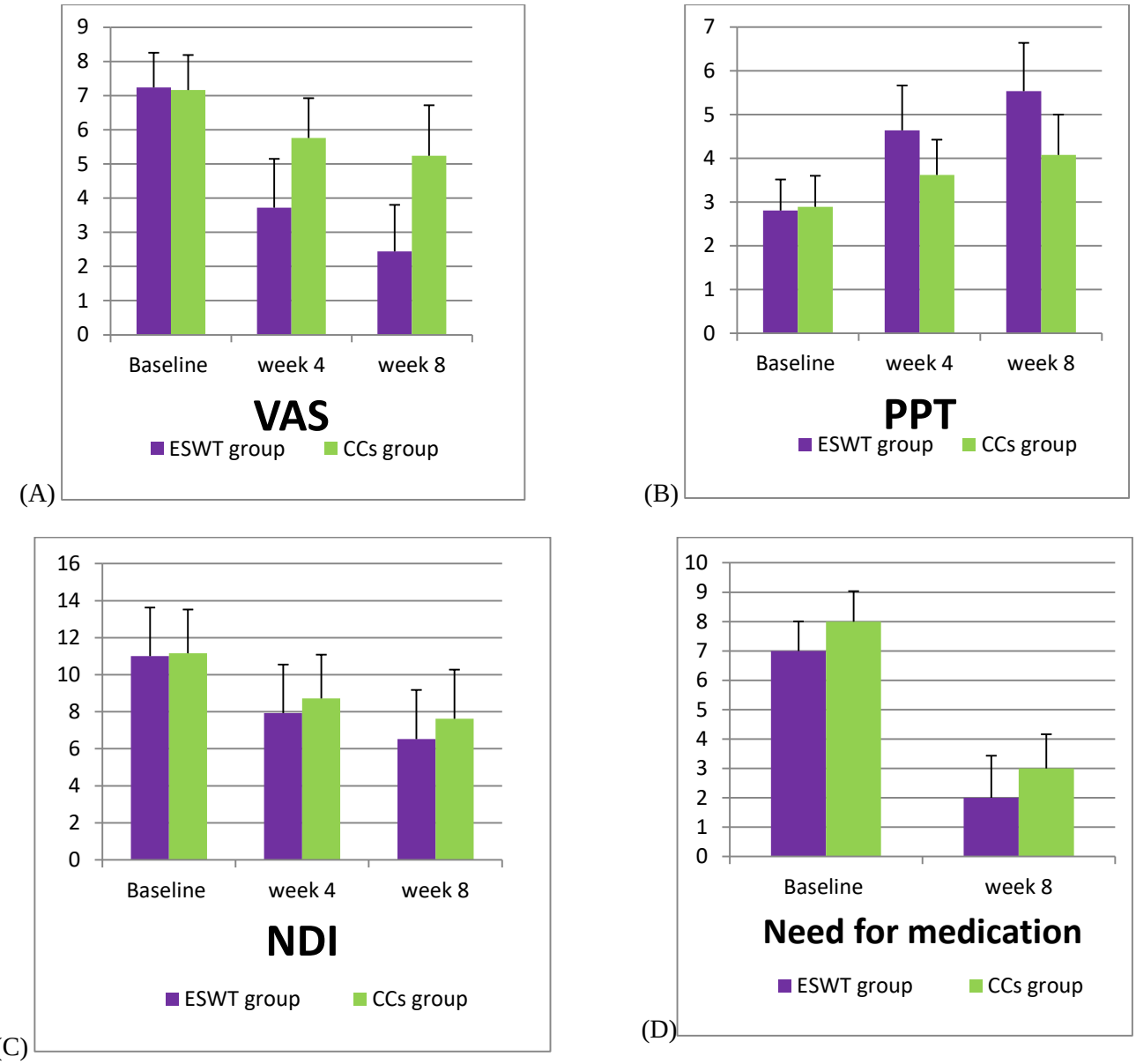

Figure (2): Bar chart showing the comparison of changes in outcome measures and the number of patients needing medication within and between the two groups.

DISCUSSION

The etiology of the MTrP is unclear, and current theories regarding how it is related to MPS are still lacking. As etiologic agents, trauma, muscular overload, and muscle overuse have all been mentioned, with trauma being one of the top possibilities. As a result of tissue injury, noxious substances that bind to, sensitize, and/or activate nociceptors are produced. As a result, signals indicating tissue damage and inflammation are sent, potentially leading to persistent pain states [22].

A variety of therapeutic approaches are available for MPS. These approaches include massage, stretching the affected muscle, transcutaneous electrical stimulation (TENS), ultrasound, acupuncture, dry needling, and injections [2].

Shockwave therapy has been applied to the management of musculoskeletal disorders since the 1980s. Although the exact processes by which it works are unknown, modulatory effects on nitric oxide and vascular growth factors are probably to blame for the reduction of pain and inflammation. It can support angiogenetic factor stimulation and microvascular regeneration, including microcapillary dilatation. Its beneficial effects were mostly seen in soft tissue disorders (fasciitis, tendinitis). In addition to reducing pain in patients with MPS, shockwave therapy also improves motion and increases pain tolerance [23,10].

However, MTrPs injection is still a commonly practiced pain interventional technique for symptom relief in MPS [24]. Bee venom, botulinum toxin, isotonic saline, lidocaine, nonsteroidal anti-inflammatory drugs, serotonin antagonists, and corticosteroids are examples of injectable pharmaceuticals [25].

Our findings demonstrated that all evaluated parameters significantly improved in both groups at follow-up intervals (at week 4 and week 8). The improvement was not only sustained throughout the

follow-up period but also continued to improve at week 8 for all parameters in both groups. In terms of pain intensity and MTrPs sensitivity to pressure, patients who received ESWT improved much more than those who had corticosteroid injection, however, there was no difference between the two groups in terms of reducing physical disability.

In agreement with our results, **Jeon *et al.* [10]** reported that ESWT in patients with MPS in the trapezius muscle is as effective as trigger point injection and TENS for relieving pain and enhancing cervical range of motion.

In a study by **Muller-Ehrenberg and Licht[26]**, ESWT was applied to 30 MPS patients; 95% of the individuals experienced discomfort and typical referred pain throughout the procedure, and the assessment revealed a decrease in pain intensity. They gave two explanations: a reduction in pain caused by a decrease in nonmyelinated fibers in MPS, and an improvement in ischemia as a result of an improvement in the vicious loop of localized muscle contraction and the formation of new blood vessels. Additionally, it was noted that undergoing an ESWT could aid in the diagnosis of MPS by producing both localized and referral pain in addition to a therapeutic reduction in pain.

Although prolonged corticosteroid use has been linked to the occurrence of local muscle and connective tissue damage, it appears to reduce the effects of central and peripheral sensitization [27,28]. Although inflammation plays a role in MPS, steroids play a limited role in trigger point injection. A steroid injection combined with lidocaine reduced injection sensitivity more than dry needling or lidocaine alone in a trial of 45 patients with headache and MPS [29], but it had no impact on general pain or cervical motion after 12 weeks. As a consequence of the corticosteroid's anti-inflammatory properties, the authors observed that a combination injection of lidocaine and corticosteroid decreased post-injection discomfort, local symptoms abated a few days after application and the need for medications.

Based on our previously established objective of clinical significance, Out of 25 patients who received ESWT, 23(92%) achieved a 50% decrease in VAS, 2(8%) achieved a 4 kg/cm2 reduction in PPT, and 20(80%) patients had a 30% decrease in NDI scores. In the same context, 2 (8%) of the 25 patients who received corticosteroid injections experienced a 50% reduction in VAS, and 19 (76%) patients experienced a 30% reduction in NDI scores. Surprisingly, none of the 25 patients who got corticosteroid injections met the clinically meaningful PPT goal.

At the beginning of treatment, 32% of patients who received corticosteroid injections and 28% of patients who underwent ESWT were taking analgesics and muscle relaxants. At follow-up week 8 after therapy, there was no difference between the two groups in the number of patients taking medication.

Our findings contradict those of **Király *et al.* [3],** who investigated the effects of shockwave therapy and low-level laser therapy on patients suffering from MPS. Less than 25% of the patients in their study were taking medication at baseline, and there was a substantial variation between each follow-up visit in terms of the percentage of patients using medication. Additionally, the duration of pharmacotherapy was brief.

Even though ESWT and corticosteroid injection were effective in treating MPS of the upper trapezius, our study had some limitations. Firstly, the small sample size and the female predominance. Another limitation was the short follow-up period, so the long-term efficacy of therapies was not fully assessed. Lastly, lack of a control group to rule out the placebo effect.

CONCLUSION

Both ESWT therapy and corticosteroid injection considerably reduced pain intensity, physical impairment, and MTrP sensitivity to pressure in patients with MPS. Moreover, ESWT was found to be superior in effectiveness concerning the reduction of pain intensity and MTrPs sensitivity to pressure.

Conflict of interest: The authors state they have no potential conflicts of interest.

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