

COMPARISON OF ROPIVACAINE ALONE VS ROPIVACAINE WITH METHYLPREDNISOLONE INJECTION AS A TREATMENT OF TRIGGER POINTS FOR MYOFASCIAL PAIN: A SUPERIORITY RANDOMIZED CLINICAL TRIAL

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Abstract: Soft tissue rheumatism, known as myofascial pain syndrome (MPS), is typified by taut bands, transferred pain that is distinct, sensory alterations that occur, and a local twitch response. It is also connected with trigger points in one or more muscles. The purpose of the research is to evaluate the effects of injections of Ropivacaine alone vs. Ropivacaine with methylprednisolone in decreasing pain in people in our community who have myofascial pain caused by trigger points. The design of this study was a randomized controlled trial. This study was carried out from July 2022 to August 2023. The research comprised 50 individuals (27 females and 23 males) diagnosed with MPS who came to our clinic. Using online randomization software, the patients were randomly divided into two groups. Group B got a mixture of 0.25% Ropivacaine & 10mg methylprednisolone in 3ml normal saline at each trigger point, whereas Group A received 3ml of 0.25% Ropivacaine. Dry needling of trigger sites was done in both groups. Patients were assessed at two, four, and eight weeks of intervention. The patients' pre-treatment assessment measures showed no statistically significant differences. After 4 and 8 weeks of assessment, Group B NRS pain and BDI scores showed statistically significant improvements compared to pre-treatment results (p<0.05). NRS and BDI scores were reduced in group A compared to their pretreatment values, but that was not clinically significant. Results of our study showed that there was a statistically significant difference between both groups in terms of pain, stress, and anxiety after the intervention. Ropivacaine with methylprednisolone gave better results than Ropivacaine alone in reducing pain and anxiety among the study population.

Keywords: Local anesthetic, Local injection, Myofascial pain syndrome, Ropivacaine

Introduction

Soft tissue rheumatism, known as myofascial pain syndrome (MPS), is typified by taut bands, transferred pain that is distinct, sensory alterations that occur, and a local twitch response (Ottem, 2016). It is also connected with trigger points in one or more muscles. Most patients experience stiffness, discomfort, weakness, restricted movement, and autonomic problems or exhibit a clinical manifestation of these (JAIN et al., 2021; Plaut, 2022).

The goal of treatment is to reduce discomfort, guarantee enough muscular strength and proper posture, and get rid of the things causing the problem. The main objective is to release the tight bands and deactivate the trigger points. Numerous therapeutic approaches include exercise, acupuncture, stretch and spray techniques, rehabilitation, nonsteroidal anti-inflammatory medications (NSAIDs), and patient counseling (Alshammari et al., 2023; Bodine, 2023). One of the best ways to treat MPS is by Trigger point injection. It has been proven helpful in reducing pain and spasms in the muscles and can induce the development of fibrous scars on trigger sites (Shah et al., 2015).

Injections of botulinum toxin, steroids, saline, local anesthetic, and dry needling are examples of local injections (Appasamy et al., 2022; de Abreu Venancio et al., 2009; Yilmaz et al., 2021). The most popular applications are dry needling and local anesthetic injection. Different outcomes have been found in research using both approaches (Navarro-Santana et al., 2022).

The purpose of this study was to evaluate the effects on pain and depression in MPS patients of two different local anesthetic injection strategies: Ropivacaine alone and Ropivacaine combined with methylprednisolone.

Methodology

This research used a randomized controlled trial design. The time frame for this study was July 2022–August 2023. The study included 50 patients with MPS diagnoses (40 females and ten males) who came to our clinic. Before the assignment, informed permission was sought from the participants both orally and in writing.

Between July 2022 and August 2023, 50 patients with MPS were included in the trial in our facility. Travell and Simons' criteria for establishing a clinical diagnosis of MPS were used. Travell and Simons set five primary and three minor diagnostic criteria.

Essential requirements were: 1. Localized spontaneous pain; 2. Sudden pain or altered sensation due to trigger points in a specific referred pain location; 3. Palpable tight bands in the muscles; 4. Incredibly tender areas along the taut bands; and 5. A measurable decrease in range of motion. Minor criteria were: 1. palpating the taut bands to reproduce the pain and changed sensations; 2. transverse snapping palpation or needle insertion into the taut bands to induce a local twitch response; and 3. pain alleviation

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1

following stretching or injection of the taut bands A minimum of one minor and five main criteria are required for the diagnosis of MPS. Individuals with concurrent fibromyalgia, cervical radiculopathy, thoracic outlet syndrome, cervical spondyloarthropathy, shoulder abnormalities, rheumatological conditions, or malignant illnesses were not allowed to participate in the study. After meeting these requirements, each patient was assigned randomly by removing a sealed envelope that included details regarding the treatment to be given.

Patients were divided into two groups, Group A and Group B. Group B got a mixture of 0.25% Ropivacaine & 10mg methylprednisolone in 3ml normal saline at each trigger point. In contrast, Group A got 3ml of 0.25% Ropivacaine. Dry needling was done in patients of both groups. Patients were assessed at two weeks, four weeks, and eight weeks of intervention via telephonic calls. Over the palpable trigger points, needles were introduced into the skin and advanced deeply into the taut bands. It's acknowledged that the right place for a hand is where the local twitch reaction or pain reproduction occurs. Then, the appropriate medicine was inserted through the needle into trigger points. Myo relaxants and non-steroidal anti-inflammatory drug use were prohibited for the participants. Every patient had evaluations four times: before the start of the treatment regimen, two weeks after it concluded, four weeks after it was finished, and eight weeks after it ended. Every patient was instructed to utilize the numerical pain rating scale (0-10). Assessments of TPI-provided pain reduction, measured using the standard 0-10 NRS (numerical rating scale), and the Beck Depression Inventory (BDI) were used to assess depression and anxiety among participants

Using NRS, pain was assessed; endpoints 0 and 10 represented no pain and the most significant possible pain, respectively. A 21-item self-report tool called the Beck Depression Inventory (BDI) evaluates affective, cognitive, and physical symptoms of depression. Each twenty-one item has four possible answers, each with a score between 0 and 3, where 0 denotes the least depressed condition and

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three the most. Patients are asked to select the alternate statement that best describes their circumstances for the last two weeks. The overall result falls between 0 and 63. More excellent overall scores correspond to more severe symptoms of depression. Hisli et al. conducted the Turkish validity and reliability assessment of the BDI. In MPS, the BDI is used to evaluate mood. Categorical variables are specified as percentages, while continuous variables are expressed as the mean \pm SD. Where applicable, the Mann-Whitney U test or the student t-test is employed to compare continuous variables. The threshold for statistical significance was p<0.05. For all statistical computations, SPSS version 21 was utilized.

Results

Randomization was used to place 50 patients into Group A (n = 25) and Group B (n = 25). Following an 8-week followup period, all 25 patients from group A and 25 from group B completed the trial. Table 1 provides a summary of the patient demographics details.

Most of the study population was predominantly female. The mean age in group A was 39.57 ± 11.93 , while in group B, it was 38.24 ± 13.41 .majority of the population was married, as shown in Table 1. Pretreatment Groups' NRS and BDI scores were comparable (Table 2).

Table 3 shows the effectiveness of intervention in both groups. There was a significant difference in the NRS and BDI scores among group B people at two, four, and eight weeks of analysis. NRS and BDI scores were reduced in group A As compared to their pretreatment values, but that was not clinically significant, as shown by their respective *p*-values in Table 3.

The adverse event profile showed no statistically significant difference among both groups. Ten individuals in Group B and 12 individuals in Group A felt a burning sensation. Three people in Group B and four in Group A appreciated nausea.

| Table 1. Demographic details | | | | | | |
|------------------------------|-----------|----------------|---------|----------------|------------------|--|
| Variable | Group A | | Group B | | <i>p</i> - value | |
| | Ν | Percentage (%) | Ν | Percentage (%) | | |
| Age (mean \pm SD) | 39.57±11. | 39.57±11.93 | | | 0.25 | |
| Sex | | | | | | |
| Male | 4 | 16 | 6 | 24 | | |
| Female | 21 | 84 | 19 | 76 | | |
| Socioeconomic status | | | | | 0.085 | |
| Low | 8 | 32 | 10 | 40 | | |
| High | 17 | 68 | 15 | 60 | | |
| Occupation | | | | | 0.18 | |
| Active working/student | 16 | 64 | 14 | 56 | | |
| Not active working | 9 | 36 | 11 | 44 | | |
| Marital status | | | | | 0.32 | |
| Married | 17 | 68 | 19 | 76 | | |
| Single/divorced | 8 | 32 | 6 | 24 | | |

Table 1: Demographic details

Table 2 Comparison of the groups' pre-treatment BDI and VAS ratings during the day and at night

| Variable | Group B | Group A | <i>p</i> -value |
|------------------------------|------------------|-------------|-----------------|
| Pre-treatment daytime NRS | 68.71±18.27 | 69.54±18.85 | 0.28 |
| Pre-treatment night-time NRS | 48.25±24.89 | 47.24±27.54 | 0.15 |
| Pre-treatment BDI | 11.82 ± 9.40 | 12.92±8.25 | 0.23 |

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| Fable 3 | Treatment | effectiveness | in tl | he second, | fourth, | and eighth | weeks |
|---------|-----------|---------------|-------|------------|---------|------------|-------|
| | | | | | | | |

| Variable | Pre-treatment | 2 nd week | <i>p</i> -value | 4 th week | P value | Eight week | <i>p</i> -value |
|----------------|----------------------|----------------------|-----------------|----------------------|---------|-------------|-----------------|
| | Group B | | | | | | |
| NRS Pain score | 68.71±18.27 | 25.85±16.82 | < 0.001 | 23.26±17.26 | < 0.001 | 24.95±17.26 | < 0.001 |
| BDI score | 11.82 ± 9.40 | 6.85 ± 8.44 | < 0.001 | 7.28±9.12 | < 0.001 | 7.24±9.21 | < 0.001 |
| | Group A | | | | | | |
| NRS Pain score | 69.54±18.85 | 47.25±17.25 | 0.21 | 46.15±19.94 | 0.14 | 46.85±18.24 | 0.85 |
| BDI score | 12.92 ± 8.25 | 10.22±9.55 | 0.067 | $10.85{\pm}10.84$ | 0.65 | 11.75±11.54 | 0.27 |

Table 4 Adverse effects comparison among both groups

| Variable | Group B n=25 | Group A n=25 | <i>p</i> -value |
|------------------------|--------------|--------------|-----------------|
| Pain-burning sensation | 10/25 | 12/25 | 0.14 |
| Nausea | 3/25 | 4/25 | 0.24 |
| Dizziness | 2/25 | 3/25 | 0.33 |
| Adverse event | 15/25 | 19/25 | 0.08 |

Discussion

The most prevalent muscle disorder, MPS, is defined by the presence of hyperirritable regions, known as trigger points, identified by tense bands in muscles or fascia and by Pain that is referred from these places. Trigger points inside the taut band cause myofascial pain syndrome symptoms and outcomes. The exact process underlying trigger point development is unknown. The three most significant causes are acknowledged to be stress, injury, and muscular overload. Peripheral muscle nociceptor sensitization and a disruption in the pain-control mechanism were suggested. Pain in trigger areas may be caused by stimulation of locally afferent sensory neurons by decreased ATP and glycogen concentration, higher levels of substance P, acetylcholine, bradykinin, serotonin, prostaglandin, and related enhanced tissue sensitivity (Bourgaize et al., 2018; Money, 2017; Niraj, 2018). The fundamental goal of therapy is to eradicate the trigger point and interrupt the muscle's "spasm-painspasm" cycle. Saline, steroids, botulinum toxin, dry needling, and local anesthetic are utilized for local injections (Hou et al., 2002; Vázquez Delgado et al., 2010). It is uncertain how injection-induced trigger point inactivation works. Nevertheless, depending on the injected material, Simons and Travell have proposed that mechanical damage to muscle fibers and nerve terminals causes an increase in extracellular potassium, depolarization of nerve endings, blocking of central feedback pathways, regional dilution of nerve-sensitizing chemicals, increased vasodilatation, and the development of necrosis in the trigger point area (Simons et al., 1999). The present research aimed to compare the impact of two alternative local anesthetic injection strategies-ropivacaine alone and ropivacaine coupled with methylprednisolone-on pain and depression in individuals with MPS.

Our study is the first to check the impact of Ropivacaine alone and Ropivacaine and methylprednisolone in MPS patients. Not many studies have been done on the use of these medicines as the treatment of MPS. Ropivacaine provides a shorter length of motor blockade. It has a superior safety profile than bupivacaine, although being almost comparable in terms of the onset, quality, and duration of sensory block (Sorathiya et al., 2023). A local anesthetic is typically used for trigger point injections, or the local anesthetic may be combined with a steroid (Li et al., 2022). Because of the steroid's anti-inflammatory properties, it is added (Desai et al., 2013). In our study, there was a statistically significant difference in the pain and depression scores in group B. Group A also had a decrease in pain and anxiety scores, but that difference was not so significant. This result is comparable to previous studies on the effect of bupivacaine, a structural analog of ropivacaine, in research comparing Botulinum A toxin vs. bupivacaine (Graboski et al., 2005). Although there was improvement with each therapy, there was no discernible difference across the groups.

Although it has been demonstrated that injecting a local anesthetic is more effective than injecting saline (Nouged et al., 2019), adding a steroid to the local anesthetic did increase its effectiveness (Appasamy et al., 2022).

Migraine sufferers received an injection of 10 mg of ropivacaine into their myofascial TPs by Garcia-Levia et al. (García-Leiva et al., 2007). Nine patients saw a pain reduction of more than 50%, while 19 patients experienced a decrease of 11%-49%. Eight out of thirty patients with chronic migraines developed episodic migraines after therapy, according to their findings. These results also show that ropivacaine can be used effectively for MPS management, but further research is needed in this aspect. Our findings suggest that ropivacaine with methylprednisolone may be more advantageous for trigger point injections than ropivacaine alone.

Conclusion

The findings of our investigation demonstrated that, following the intervention, there was a statistically significant difference in pain, tension, and anxiety between the two groups. When it came to lowering pain and pressure in the study population, methylprednisolone combined with ropivacaine performed better than ropivacaine alone.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript. Ethics approval and consent to participate Approved by the department Concerned. Consent for publication Approved Funding Not applicable

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Conflict of interest

The authors declared absence of conflict of interest.

Author Contribution

SADAF MUSHTAQ (Fellow)

Study Design, Review of Literature Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript

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Coordination of collaborative efforts. Conception of Study, Final approval of manuscript

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Data entry and analysis & Coordination of collaborative efforts.

KHALID BASHIR (Consultant & HOD) Data acquisition, critical input. ATEEQ UR REHMAN GHAFOOR (Consultant) critical input, Coordination of collaborative efforts.

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