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Original Contribution

Comparison of intravenous NSAIDs and trigger point injection for low back pain in ED: A prospective randomized study

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ABSTRACT

Introduction: Low back pain (LBP) is a common complaint originating from muscles
Myofascial pain syndrome (MPS) is mainly associated with trigger points (TrP) in the muscle tissue. We compared the intravenously administered non-steroidal anti-inflammatory drug (NSAID) and trigger point injection (TPI) in the treatment of LBP patients admitted to the emergency department due to pain caused by TrPs.
Material and method: After randomization, NSAID was administered intravenously in group 1 and TPIs were performed as specified by Travell and Simons in group 2. The TrPs were identified with the anamnesis and physical examination
Demographic characteristics and vital signs of the patients were recorded. Pain scores were measured with the Visual Analogue Scale (VAS) at admission; and in minutes 5, 10, 15, 30, and 60.
Results: There were 32 patients in group 1 and 22 patients in group 2. The demographics, vital signs, and pain scores at admission were not statistically significantly different between the groups. The pain scores decreased significantly in the TPI group. During the 60 min' follow-up period, the mean VAS pain score decreased by 0.41 ± 1.30 in the TPI group and by 2.59 ± 2.37 in the NSAID group ($p < 0.001$). Respond the treatment was significantly higher group TPI than Group NSAID (21/22 vs 20/32 respectively, $p = 0.008$).
Conclusion: In this small randomized study with several methodological limitations, TPI was superior to the intravenous NSAIDs in the treatment of acute LBP due to TrPs. TPI can be used in the emergency departments for the acute treatment of LBP in selected patients.

1. Introduction

Acute or chronic pain results in a remarkable burden for mankind from the clinical, economic, and social aspects. The most common cause of physician visits is the pain. Pain caused extra burden in the patients and their families; including opioid use and dependence, depression, poor social relationships and economic costs [1]. The feeling of pain is, in fact, one of the control mechanisms of the body. Pain transmits the information about the presence of injuries in the body tissues to the brain, allowing for awareness. This is a protective mechanism essentially [2].

Low back pain (LBP) is a common and expensive medical condition. LBP rarely refers to a serious disorder. The annual prevalence of low back pain in the US is estimated between 15% and 20% and its lifetime prevalence is over 60% [3]. LBP is one of the most common causes of admission to emergency departments (ED) [4,5]. LBP related accounts for approximately 2.5% of ED visits [6,7]. However the prevalence and analgesic management of LPB in the ED is still unclear [8].

Myofascial pain syndrome (MPS) is an uncommon cause of musculoskeletal pain. MPS is a neuromuscular disorder characterized by localized muscle tenderness and often manifests with pain in the back, shoulders, lower back; and tension-type headaches. The origin of the MPS is the presence of a hyperalgesic spot in the form of a painful band and it is called as a trigger point. A trigger point (TrP) is defined as a sensitivity felt at deeper levels in the musculoskeletal tissue, causing pain in the zone of reference, which is the region of pain associated with the TrP. The TrPs are localized only in the muscles and myofascial trigger points (MTrPs) are a common source of (regional) pain in patients presenting with

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musculoskeletal pain, with a lifetime prevalence of up to 85% in the general population [9]. The pain is usually localized in the TrP, and referred to the surroundings. The main objective in the treatment of MPS is to break the pain cycle by eliminating the trigger points. Currently, several therapies are available for treating myofascial trigger points; including massaging, stretching, dry needle injections, electrical stimulation, cold laser treatment, and ultrasound [10]. An insufficient treatment of pain will cause a significant socioeconomic burden, as well as, a reduction in the quality of lives of the affected individuals.

In our study, we aimed to compare the intravenously administered nonsteroidal anti-inflammatory drug (NSAID) treatment versus trigger point injection (TPI) in patients admitted to the emergency department due to pain caused by an LBP with TrPs.

2. Material and method

2.1. Study design and setting

All patients were informed about the study and its procedures, and informed consents on paper were collected from the agreeing volunteers before their inclusion in the study. The study was approved by the Ethics Committee at Ataturk University Faculty of Medicine. Our study was conducted in the emergency department at Ataturk University, Faculty of Medicine between 01.04.2018 and 30.10.2018. The patients presenting to the emergency department with the complaint of LBP, who had trigger points as the cause of pain, were included in the study and divided into two groups. A total of 80 patients were planned to be included in each group. The Patients were allocated to two groups; NSAID and TPIs groups.

2.2. Patients

The patients presenting to the ED with the complaint of LBP were considered eligible for the study. First, we investigated the presence of active TrPs in the previously identified muscles including the deep lumbar paraspinal muscles, the left and right quadratus lumborum muscles; and the left and right gluteus medius muscles. Delphi consensus criteria; consisting of a taut band, hypersensitive spot, and referred pain; were used for the active diagnosis of active TrPs [11]. According to these criteria, TrPs were identified based on the clinical findings and the characteristics of pain emerging upon exerting a pressure of 2 kg/cm^2 onto the suspected area and by comparing the elicited findings with the corresponding contralateral site. The pressure pain threshold of TrP was measured with a handheld mechanical pressure algometer. Palpating the active TrPs by exerting a constant pressure on them deeply by a fingertip, will cause a change in the characteristics of pain felt at the referred area (an increase or reduction in the intensity) and cause it to be referred further in the zone of reference. This phenomenon can be observed immediately or occur after a few seconds. In this way, the zone of reference is determined. The patient may sometimes react to the palpation. This is called as the "jump sign", which is manifested by several behavioral reactions including retraction of the head, grimace, wrinkling the forehead, or a verbal response. These findings help to identify the TrPs.

Inclusion Criteria

- Age > 18
- The patient should present to the emergency department with the complaint of LBP
- LBP should have a recent time of onset (duration of LBP should not be over 48 h)
- At least one TrP should be identified as the cause of the pain.

Exclusion Criteria

- LBP should not be associated with an organic cause
- Chronic illnesses including hypertension, diabetes mellitus, coronary artery disease, chronic pulmonary diseases, thyroid diseases, inflammatory rheumatic diseases, muscular diseases or lupus.
- Fibromyalgia
- Lumbar radiculopathies, lumbar disc herniations, degenerative joint diseases
- Individuals being allergic to local anesthetics or dexketoprofen
- The individuals to whom trigger point injections were applied
- Individuals with bleeding disorders
- Patients taking medications which increase the risk of bleeding
- A history of surgery on the neck or shoulders
- Pregnant patients
- Patients with cognitive impairments or psychiatric disorders
- Oral or topical use of NSAIDs
- A history of a gastrointestinal bleeding
- Patients with cancer
- Patients receiving physical therapy (in the last 6 months)

The patients were assigned to two groups randomly by means of the random allocation software (RAS). Gender was not taken into account during the randomization because it was not a factor that could affect patients' response to the treatment. The patients were planned to be allocated to two groups; NSAID and TPIs groups.

2.2.1. Injection procedure

TPIs were performed in compliance with the technique described by Travell ve Simons [12,13]. While the patient was lying in the prone position, TrPs were identified and the skin was cleaned with an appropriate antiseptic solution (Betadine). During the injections, 22 gauge 1.25-in. needles were used. The trigger point was stabilized between the thumb and forefinger. Then, the needle was inserted vertically into the skin and advanced until it reached the trigger point. After ensuring a negative aspiration, the local anesthetic (2% lidocaine, 2.5 cc from 100 mg-5 cc of ampoule with 2.5 cc saline mixture) was injected in small amounts to the identified point. Then the same point was needled several times. All injections were performed by the same physician. Trigger point injections were performed by experienced and trained professionals. Local twitch response was obtained for all patients in whom TPIs were performed. Local twitch response was defined "a transient contraction of a group of tense muscle (taut band) that traverses a trigger point. The contraction of the fibers is in the response to stimulation of the same trigger point or sometimes of a nearby trigger points. The injection site was then compressed for approximately 2 min to ensure hemostasis. Group 1 received 50 mg dexketoprofen in 100 cc isotonic solution over a period of 5 min.

2.3. Measurement

Age, sex, vital signs (blood pressure, pulse rate, respiratory rate, fever, and oxygen saturation) of the patients who agreed to participate in the study were recorded. The causes of LBP were categorized under three headings, which were sudden movement, lifting an object, and trauma. The means of arrival at the emergency department was categorized as either an ambulance or ambulatory transportation. The patients were asked to score the current intensity of the pain they experienced at several time points, which were the time of admission, minute 5, minute 10, minute 15, minute 30, and minute 60. Visual ana-

log scale (VAS) was used for scoring. Marking of the pain scores on VAS was performed by the patients. A 10-cm Visual Analogue Scale (VAS) was used to score the pain, where 0 indicated the absence of pain and 10 indicated the highest intensity of pain felt ever. After procedure TPI or NSAID administration, VAS scores ≥4 is defined as unresponsive to treatment. Finally, occurrences of any side effects were questioned and the responses of the patients were recorded.

2.4. Statistical analysis

Statistical analyses were performed using SPSS 20 statistical analysis program (IBM). Data are presented as mean, standard deviation, and median; and with the minimum and maximum values, percentages, and numbers. Shapiro-Wilk and Kolmogorov – Smirnov tests were used to evaluate whether the data conformed to a normal distribution. Independent samples *t*-test was used for comparing normally distributed data between two independent groups, and the Mann–Whitney *U* test was used if the data were not normally distributed. Categorical variables were compared using Chi-square and Fisher's exact tests. A p value of <0.05 was considered to be statistically significant.

3. Results

Our study was conducted on patients who presented to the emergency department due to LBP associated with identified TrPs. The patients were allocated to two groups at the time of admission so that a total of 80 individuals would be included in the study with 40 patients in either group. As some patients did not agree to participate in the study or some met with at least one of the exclusion criteria, a total of 54 patients completed the study with 22 (40.7%) patients in the TPI group and 32 (59.3%) patients in the NSAID group. Eligible patients for this study were analysed for the primary outcomes and reshown in the CONSORT flow diagram (Fig. 1).

Table 1
Demographic details of patients.

	Group NSAID (n = 32)	Group TPI (n = 22)	p
Age	40.94 ± 13.18	45.14 ± 13.03	0.253*
Sex (M/F)	17/15	14/8	0.577γ
Duration of back pain (hours)	9.03 ± 8.38	6.27 ± 6.16	0.296*

Values are presented as number or mean ± standard deviation, TPI: Trigger Point Injection, NSAID: nonsteroidal anti-inflammatory drug.
* p > 0.05 Independent sample *t*-test

The examination of the causes associated with the presenting complaints of the study patients revealed that the most frequent cause of the emergency department visit was trauma (20 patients, 37%). The trauma resulting in LBP most commonly resulted either from an abrupt, shock-like movement in 17 (31.5%) patients or emerged after lifting a heavy object in 17 patients (31.5%). Five patients were transported to the emergency department with 112 emergency-call ambulances. All participating patients completed the study. No patients developed any side effects during the study.

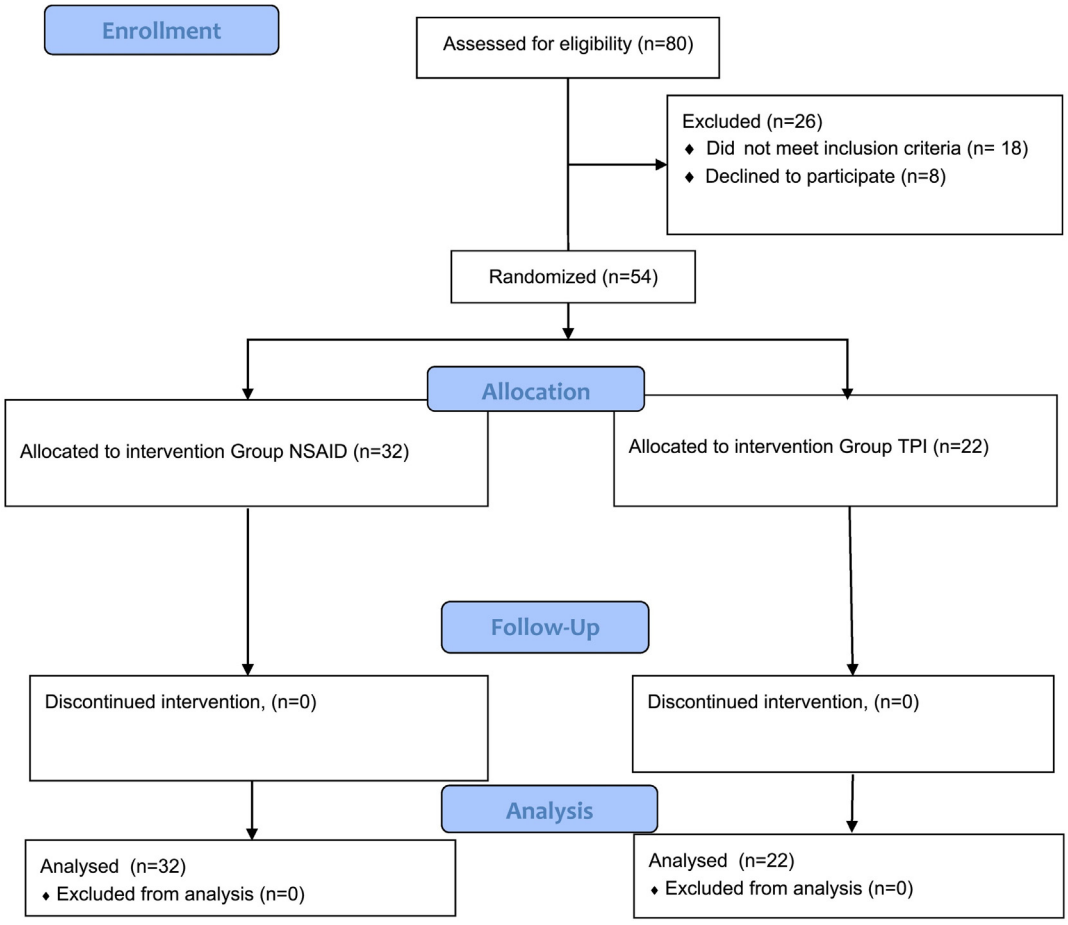

Fig. 1. CONSORT diagram.

Table 2
Pain scores and respond the treatment after procedure.

	Group NSAID (n = 32)	Group TPI (n = 22)	p
VAS 0.	7.22 ± 1.64	7.55 ± 1.68	0.339
VAS 5 min	6.22 ± 2.11	2.77 ± 2.81	<0.0001*
VAS 10 min	5.22 ± 2.41	1.45 ± 2.15	<0.0001*
VAS 15 min	4.25 ± 2.41	0.82 ± 1.71	<0.0001*
VAS 30 min	3.28 ± 2.44	0.55 ± 1.60	<0.0001*
VAS 60 min	2.59 ± 2.37	0.41 ± 1.30	<0.0001*
Respond to treatment (yes/no)	20/12	21/1	0.008[a]

Values are presented as number or mean ± standard deviation, TPI: Trigger Point Injection, NSAID: nonsteroidal anti-inflammatory drug, VAS: Visual Analogue Scale, min: minute, Respond to treatment: After procedure TPI or NSAID administration, VAS scores <4.

* $p < 0.05$ Independent sample *t*-test.

[a] Chi-square.

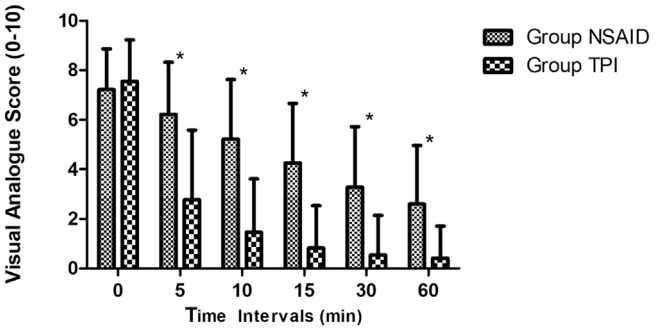

Fig. 2. Pain scores after procedure.

The demographic data and the elapsed time since the onset of pain of the patients are summarized in Table 1. There were no significant changes between the groups.

The mean VAS mean scores of the groups at admission were 7.22 and 7.55, respectively; and there was not a significant association between the groups ($p > 0.05$). A significant difference between the study groups occurred after procedure starting from minute 5 ($p < 0.05$). The pain scores decreased significantly in the TPI group. The patients in the NSAI group also benefited from the treatment, but the trigger point injection group benefited more as observed in all time points of VAS scoring. During the 60 min' follow-up period, the mean VAS pain score decreased by 0.41 ± 1.30 in the TPI group and by 2.59 ± 2.37 in the NSAI group ($p < 0.001$). Respond the treatment was significantly higher group TPI than Group NSAID (21/22 vs 20/32 respectively, $p = 0.008$) The VAS scores and respond the treatment of the study groups are presented in Table 2 and Fig. 2.

4. Discussion

Our study was conducted on LBP patients who presented to the emergency department. Patients presenting to the emergency department due to LBP with TrPs; identified in the deep lumbar paraspinal muscles, right and left quadratus lumborum, and right and left gluteus medius muscles by means of the medical history and physical examination were included in the study. The aim of our study was to investigate the efficacy of trigger point injection in the emergency department. For this purpose, dexketoprofen was selected as the comparator treatment as it was used commonly in the emergency settings for the treatment of pain. The pain scores decreased in the patients staying in the TrP treatment after the first intervention. Our study is the first study in the literature evaluating the efficacy of trigger point injections performed in the emergency department. Our study found that pain intensity decreased statistically significantly in the TPI group. Those reductions in the intensity of pain occurred starting from minute 5, suggesting evidence that TPI can be performed in the emergency departments.

LBP is accompanied with several diagnoses Most LBP is nonspecific origin approximately 90%. Myofascial etiologies are uncommon cause of LBP [14]. However the prevalence of pain due to MPS is still unknown, 78% of these undiagnosed pain is referred to MPS [15]. MPS is associated with hypersensitive spots in a taut band in skeletal muscles [16]. These points are called trigger points [17,18]. Diagnosis and treatment of TrPs in emergency settings is important. The sooner they are diagnosed and treated, the lower number of TrPs will occur resulting in a musculoskeletal pain of lower intensity. Trigger points are actually very common, however, the information about them is limited in the literature. It might be because a diagnosis of a TrPs is usually missed, and the respective patients receive other treatments not allowing the prevention of TrPs from acquiring a chronic character. In daily clinical practice, MPS is often considered as myalgia. MPS patients receiving a misdiagnosis of myalgia often use NSAIDs, which is not a definite treatment. We would like to emphasize particularly this point in our study.

In literature review, TPI can be used in the treatment of renal colic pain and headache in emergency department [19,20]. The physicians working at emergency settings may identify TrPs by means of medical history and physical examination and treat them by applying TPI with proven efficacy to the patients with an emerging pain, which developed after trauma, lifting a heavy object, or following a sudden abrupt movement. Emergency physicians should exercise care for the recognition of this issue. In our study, the control group received an NSAID because TrP associated pain is commonly treated with this group of medications.

The pathophysiology underlying the emergence of TrPs and the development of the chronicity of the pain associated with the release of a number of mediators due to ischemia. [21-24]. Tissue injury releases the mast cells and leads to the stimulation of the nociceptors. The resulting pain is associated with histamine release leading to vasodilation and edema. The resulting increase in the metabolic rate causes lactic acid synthesis, stimulating the nociceptors [2].

The aim of the treatment is, therefore, to break the "spasm-pain-spasm" cycle in the muscles associated with TrP induced pain, removing the TrPs. Several modalities are employed in the treatment of TrPs including patient education, NSAID medications, physiotherapy, spray and stretch technique, acupuncture, local injections, and workouts. TPI is one of the most effective methods in the treatment of MPS. Local anesthetic agents, saline, steroids, botulinum toxin, and dry needling are applied locally. Of them, the most common ones are the injection of local anesthetics and dry needling. Studies on these two latter modes of treatment report variable results [25]. In our study, local anesthetic agent injection method was used in TPIs as a lower intensity of pain [26,27], as well as the contribution of the local anesthetic effect, was reported after the injections with this method [21,28-31]. A study by Affaitati et al. [21] compared the efficacy of anesthetic agent injections, lidocaine patches, and placebo patches in MPS patients. It was found out that the treatments with lidocaine patches and bupivacaine injections were significantly more beneficial compared to placebo. The reported efficacy of lidocaine patches supports the use of a local anesthetic agent in the treatment in combination with dry needling.

The most common adverse effects of the regular TrP treatments were reported to be bruising, hemorrhage, and pain. As these adverse events were associated with a short-term duration with-

out a need for further treatments, they were categorized as mild. The adverse effects of moderate and severe character (such as fainting, headache, and nausea) occurred at a rate of <0.04% [32]. And also in thoracic region pneumothorax was reported [33]. No adverse effects occurred in our study in none of the study patients. TPIs can be safely applied by the emergency department physicians owing to the remarkably lower frequency of the adverse effects.

The number of studies on the use of NSAIDs for the treatment of TrPs is limited. In our study, the NSAID group also benefited from the treatment. Our study is the first in the literature showing the efficacy of intravenously administered NSAIDs in the treatment of trigger point. It is well known that NSAIDs inhibit the activity of cyclooxygenase, suppressing prostaglandin synthesis from arachidonic acid. The efficacy of NSAIDs observed in our study can be explained by their ability to reduce local prostaglandin synthesis. As the pain is reduced as a result of NSAID use, patients begin to use their muscles more actively. This leads the corresponding muscles to reach the optimum length, and causes the taut bands caused by a reflex relaxation to be resolved; thereby disrupting the vicious contraction-ischemia-contraction cycle. The mechanism of an NSAID treatment for the trigger points can be explained this way.

In the literature various studies were reported for treatment of MPS involving low back pain [28]. This study supports our findings in the sense that TPI treatment is more beneficial.

The use of trigger point injections was reported for the treatment of chronic pain, however, our study evaluated the efficacy of TPI in acute LBP, highlighting its importance. Our study showed that, with the TPI treatment, the pain of the patients was controlled in a shorter period; patients could be discharged from the hospital earlier, return to their daily lives earlier, minimizing the loss of labor productivity and they benefited from a more comfortable mode of treatment.

The main limitation of this study was there was no attempt to determine the reliability/reproducibility of the identification of a trigger point. In study protocol we include only at least one TrP should be identified as the cause of the pain. In addition lumbar radiculopathies, lumbar disc herniations, degenerative joint diseases or chronic low back pains are excluded from study. Patients pain scores were follow-up only 60 min in ED. Long term results are not evaluated according to our study protocol. If long term results were evaluated different results could be obtained. One another limitation of the study is small sample size and selected patients groups (patients with TrP) are included the study. We focused on TrP related LBP so our results are cannot be generalized to all population.

5. Conclusion

In this small randomized study with several methodological limitations, TPI was superior to the intravenously administered NSAID in the acute treatment of LBP caused by trigger points. We believe that the trigger point injection should be a part of the acute treatment of LBP in the selected patient group.

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