Trigger Point Injection for Myofascial Pain Syndrome of the Low Back: A Partially Blinded Three-Arm Randomized Controlled Trial

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Study objective: Low back pain is a common complaint in the emergency department (ED), often attributed to myofascial pain syndrome. Prior studies demonstrate trigger point injection efficacy in the ED in various body distributions, but only one has specifically assessed myofascial low back pain, and none have evaluated functional outcomes. The purpose of this study was to compare the efficacy of trigger point injections and standard therapy compared with standard therapy alone.

Methods: In this partially blinded, 3-arm randomized controlled trial, we randomized adults with low back pain and clinically identified trigger points to receive either standard therapy alone or a trigger point injection consisting of bupivacaine or normal saline solution with standard therapy. The primary outcome was change in pain at 30 to 60 minutes measured on a 10 cm visual analog scale. Secondary outcomes included changes in the Modified Oswestry Disability Index score at 30 to 60 minutes. Tertiary outcomes included change in pain on visual analog scale and Modified Oswestry Disability Index score at 60 to 72 hours compared with baseline.

Results: We randomized 180 participants (60 per cohort) into 3 arms. All treatment arms demonstrated pain reduction at 30 minutes. Compared with standard therapy alone, pain reduction at 30 to 60 minutes was 0.55 (95% confidence interval [CI] −0.19 to 1.28) for bupivacaine and 0.71 (95% CI 0.00 to 1.43) for normal saline solution. We found no difference among groups for pain or functional outcomes. No serious adverse events occurred.

Conclusion: We found no improvement with trigger point injections over standard therapy alone. [Ann Emerg Med. 2025;■:1-10.]

Please see page XX for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

Acute low back pain is a common emergency department (ED) complaint, accounting for 4.4% of worldwide ED presentations and $100 billion per year for treatment.[1–5] Ninety percent of low back pain is mechanical and improves significantly within 6 weeks.[6,7] A subset of patients have pain defined by myofascial pain syndrome.

Myofascial pain syndrome results from localized muscle fiber hyperactivity and muscle ischemia, creating the syndrome-defining trigger point that precipitates a regional, nondermatomal referred pain.[8–12] These hyperirritable foci are associated with a taut band of muscle, which is painful on palpation and may elicit an involuntary jump response.[9,11,13,14]

Although no consensus exists on treatment of low back pain in the ED, therapy often consists of a combination of acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxers, and topical anesthetics.[6,8] Nonpharmacologic outpatient therapy includes rest, ice, heat, physical therapy, and the McKenzie stretches.[6,15] Trigger point deactivation through injection of liquids, dry

Editor's Capsule Summary

What is already known on this topic

Trigger point injections are widely used to treat muscular pain.

What question this study addressed

In emergency department adults with low back pain, do trigger point injections of either bupivacaine or normal saline solution improve on standard therapy alone?

What this study adds to our knowledge

In this randomized controlled trial of 180 patients, there were no differences between groups in pain reduction, functional status, or adverse events.

How this is relevant to clinical practice

Trigger point injections do not appear helpful for lower back pain.

needling, stretch and spray techniques, and positional release have been used for both acute and chronic myofascial pain in various body regions.

Prior literature suggests trigger point injection efficacy for managing myofascial pain within minutes to hours, depending on the injectate, but demonstrated equivalence with other medications by time of discharge.[8,16–20] Few of these studies were in the ED or specifically evaluated myofascial low back pain.[8,9,17–21] Of those studies performed in the ED, the most relevant study by Kocak et al[16] demonstrated better pain improvement for trigger point injections in the low back as compared to intravenous NSAIDs in an ED setting. Several other studies demonstrated efficacy of trigger point injections in an ED setting, but location of identified trigger points was heterogeneous and did not specifically address myofascial low back pain.[8,18,19]

Only 2 studies evaluated pain after discharge and demonstrated efficacy at 48 and 24 hours, respectively.[21,22] No ED study to date has evaluated functional status after trigger point injection at an interval pertinent to ED care, although a prior study at a physical therapy hospital demonstrated improvement at 1-month post-injection compared to medications and exercise.[23]

Importance

Our study seeks to evaluate trigger point injection efficacy for pain control and functional improvement in myofascial low back pain in the ED and to assess whether these effects persist after discharge at a time frame relevant to the ED. Efficacy of trigger points in managing myofascial low back pain would give physicians an additional nonopioid tool to manage low back pain in the ED while potentially improving functional outcomes after care in the ED.

Goals of This Investigation

In this study, we aimed to assess efficacy of trigger point injection for low back pain in the ED. We hypothesized that trigger point injections with bupivacaine in combination with standard therapy are superior to both standard therapy alone or with trigger point injection with normal saline solution.

MATERIALS AND METHODS

Study Design and Setting

This single-center, partially double-blinded, randomized controlled trial received approval from the Madigan Institutional Review Board (protocol #220042) and was registered with clinicaltrials.gov #NCT04704297 prior to study initiation. The study took place at a US ED at an academic military hospital with an annual census of 60,000. It serves active-duty military members and families, retirees, Veterans Affairs patients, and civilian trauma patients. Enrollment spanned from January 2021 to February 2024. We designed and conducted our study per the CONSORT criteria.[24]

Selection of Participants

Triage nurses identified a convenience sample of potential study participants presenting for low back pain when study investigators were present for enrollment. Investigators were available when working clinically and clinically managed the patients. Sixteen trained study investigators, including residents, attendings, and physician assistants, screened and assessed identified patients for inclusion and exclusion criteria per the case report forms and enrolled qualifying participants after trigger point identification (Appendix E1, Appendix E2, available online at http://www.annemergmed.com). Investigators provided patients with study documentation (Appendix E2). The senior investigator instructed all investigators in trigger point identification and injection at onboarding.

We included English-speaking adults in the ED presenting for low back pain, defined as pain between the lower angle of the scapula and gluteal muscles and an identifiable trigger point. A trigger point was defined as having at least 2 of 3 criteria: a taut band of muscle, muscle

tenderness on palpation, and referred pain elicited by palpation. We defined an acute exacerbation of chronic low back pain as at least a 1.5 cm increase from baseline pain based on our expected effect size.

To protect participants, we excluded patients with allergies or contraindications to study medications, pregnancy (per urine pregnancy test collected during triage for biologically female participants), new focal neurologic deficit, current anticoagulation, overlying cellulitis, febrile illness, an alternative identifiable pain cause, and participants unable to provide informed consent. We also excluded soldiers wounded in combat, individuals in student status, and prisoners. To ensure treatment of myofascial pain, we excluded participants with sciatica, known active malignancy, identifiable spinal or hip fractures, spinal or hip surgery in the last 6 months, fibromyalgia, rheumatoid arthritis, or ankylosing spondylitis. Participants recently treated with trigger point injections were also excluded.

Interventions

Institutional statisticians created a computer-generated randomization that allocated patients to 1 of 3 treatment arms in permuted blocks of 9. Arm one, standard therapy alone, included 30 mg of intramuscular ketorolac and 975 mg of oral acetaminophen in the ED. We discharged participants with 400 mg Ibuprofen and 650 mg acetaminophen every 4 hours, 10 mg of cyclobenzaprine before bed, and instructions on heat therapy and the McKenzie back exercises.[25–28] Arm 2 included standard therapy plus trigger point injections of 0.5% bupivacaine (bupivacaine). Arm 3 included standard therapy alone plus trigger point injections with normal saline solution.

We double-blinded trigger point injection arms to participant and provider, but standard therapy alone was unblinded. For ethical reasons, there was no placebo arm. We blinded pharmacists and statisticians to outcomes until data collection was complete.

Research pharmacists premade injectates and refrigerated them in a badge-controlled medication room. We created identification cards in resealable bags denoting the participant number and whether treatment was standard therapy or standard therapy plus trigger point injection. In trigger point injection arms, pharmacists placed 4 prefilled syringes with either 2 mL of 0.5% bupivacaine or normal saline solution. Injectates were indistinguishable. On enrollment, investigators retrieved the next numbered bag. Investigators marked the cards with patient identification stickers in case unblinding was necessary.

Investigators administered trigger point injections using 27-gauge, 1.25-inches needles simultaneously with standard therapy. Nurses delivered standard therapy medications, and investigators administered up to 4 trigger point injections in 2 mL aliquots depending on trigger point quantity per investigator discretion. After 30 to 60 minutes, the investigator reassessed pain on the visual analog scale (VAS) and functional score on the Modified Oswestry Disability Index (MODI), a validated, low back pain patient-centered functional score (Appendix E1).[29] The MODI asks 10 questions about function ranked on a Likert scale from 0 to 5, with 5 representing the greatest disability. Its product represents percentage-disability.[30]

Investigators assessed side effects, and both participant and investigator guessed the treatment arm in trigger point arms. If participants deemed their pain not adequately controlled, investigators ordered additional medications. We discharged all patients with standard therapy medications, instructions on heat therapy and McKenzie stretches, and the follow-up questionnaire (Appendix E3, available online at http://www.annemergmed.com). At 60 to 72 hours, any available investigator contacted the participant by phone and interviewed them using the case report form regarding pain, disability, side effects, medication/intervention compliance, and willingness to undergo future trigger point injections.

To ensure follow-up, we used an office communication application to post participant enrollment, investigator availability to perform follow-up, and confirmation of follow-up. We considered participants unable to be reached after 3 calls within the 12-hour time frame as lost to follow-up. We included participants requiring additional ED analgesia in the intention-to-treat analysis but removed them from per protocol analysis. The senior investigator reviewed and entered all data at least quarterly and withdrew participants with data collection errors.

Measurements

Investigators used case report forms to record participants' baseline characteristics, evaluate inclusion and exclusion criteria, confirm a reliable phone number, and assess medications taken prior to arrival. Participants identified their pain duration from <4 weeks (acute), 5 to 12 weeks (subacute), or more than 12 weeks (chronic).[31] Participants identified their baseline and present low back pain on a 10 cm VAS followed by the MODI (Appendices E1 and E2).

Investigators recorded the number of trigger point injections administered. Participants evaluated their pain and functional score at 30 to 60 minutes post injection on a new VAS and MODI, recorded side effects, and additional

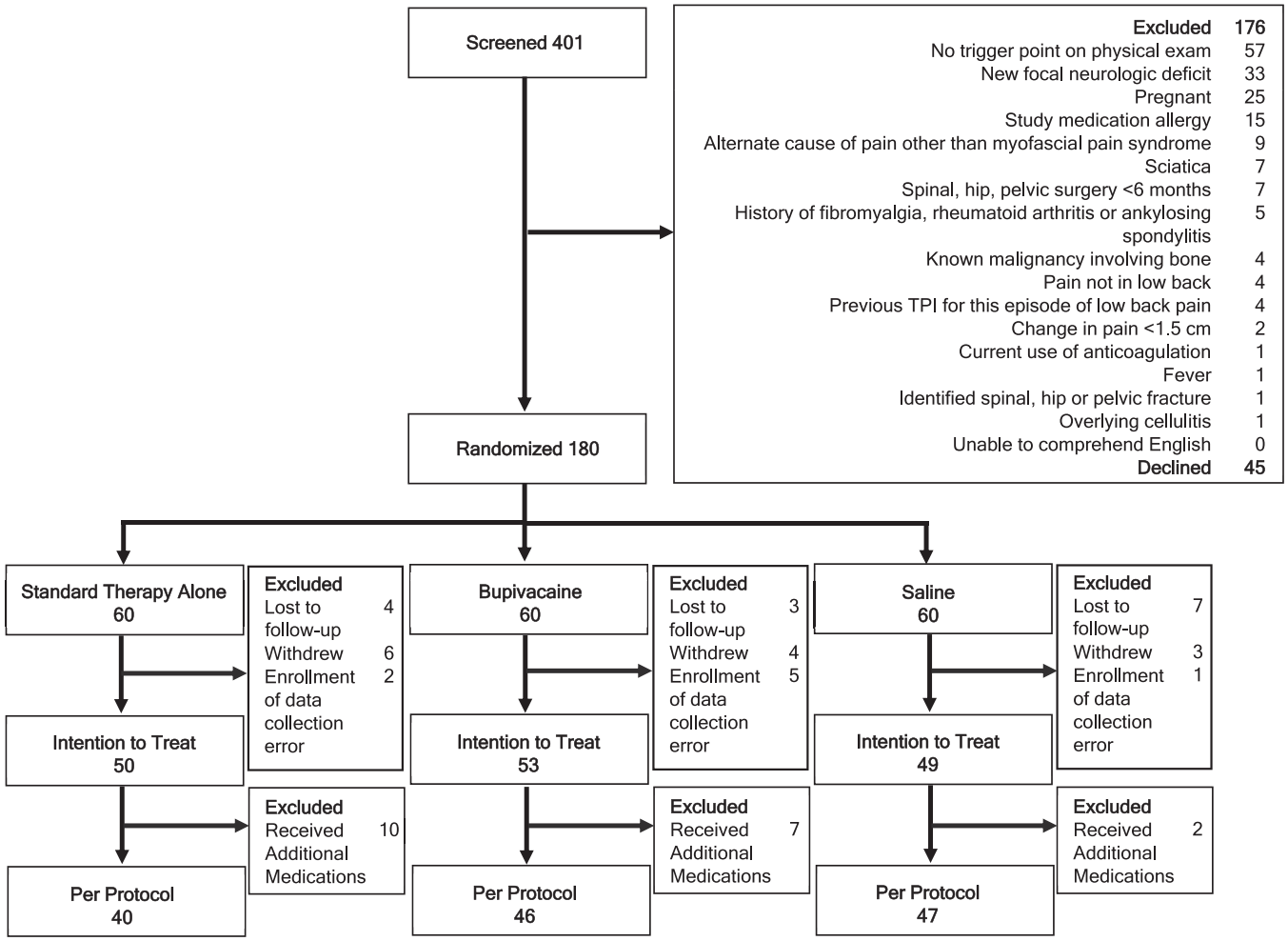

Figure 1. Study recruitment schematic. *TPI*, trigger point injection.

pain medication administration. We assessed and recorded blinding of the trigger point arms for participants and investigators before discharge. We collected reassessment data on the data collection case report form.

At the 60 to 72-hour assessment, investigators surveyed participants by telephone on their pain and function with the VAS and MODI, respectively. Investigators surveyed participants about the same items in the 30 to 60-minute assessment plus yes or no questions about interest in future trigger point injections and treatment compliance.

Investigators stored case report forms in a locked filing cabinet and entered them into an Excel (version 2308; Microsoft; Redmond, WA) file manually. The research monitor reviewed 10% of case report forms and Excel data for errors.

Outcomes

Our primary outcome aimed to determine which treatment is superior at 30 to 60 minutes. Our predetermined standard for superiority was a decrease in pain from baseline (ΔVAS) of 1.5 cm or more than the other treatment arms.[16] Our secondary outcome was the change in MODI score (ΔMODI) at 30 to 60 minutes. Data regarding a clinically significant change in MODI was unavailable at time of protocol development. We selected a 10% change as significant in absence of data. Tertiary outcomes include ΔVAS and ΔMODI at 60 to 72 hours with identical superiority thresholds.

Analysis

Primary outcome analysis compared the ΔVAS between groups at 30 to 60 minutes. We performed 2-sided testing for superiority due to multiple treatment arms. Our sample size estimate assumed an α=.025, given a Bonferroni correction and a β=0.20. We assumed a standard deviation (SD) of 2.44 based on previous studies with expected minimum effect size of 1.5 cm on a VAS, producing a sample size of 51.[16]

Table 1. Patient demographics data.

Characteristic	Standard Therapy Alone N = 50	Bupivacaine N = 53	Saline Solution N = 49
Age (y) (Mean [95% CI]) Median	(38 [13]) 35	(34 [13]) 31	(33 [12]) 30
Sex			
Male n, (%)	38 (76)	40 (75)	38 (78)
Female n, (%)	12 (24)	13 (25)	11 (22)
Type of injury			
None, n, (%)	35 (70)	36 (68)	39 (80)
Exercise related n, (%)	2 (4.0)	3 (5.7)	1 (2.0)
Lifting injury n, (%)	9 (18)	9 (17)	6 (12)
Army Combat Fitness Test other than lifting n, (%)	0 (0)	1 (1.9)	0 (0)
MVC n, (%)	2 (4.0)	0 (0)	1 (2.0)
Other injury n, (%)	2 (4.0)	4 (7.5)	2 (4.1)
Deployment related			
No n, (%)	41 (82)	44 (85)	42 (86)
Duration of pain n, (%)			
0-4 wk n, (%)	36 (72)	37 (70)	33 (67)
5-12 wk n, (%)	0 (0)	3 (5.7)	2 (4.1)
>12 wk n, (%)	14 (28)	13 (25)	14 (29)
Current pain management			
None n, (%)	18 (36)	22 (42)	17 (35)
NSAID n, (%)	18 (36)	16 (31)	14 (29)
Acetaminophen n, (%)	6 (12)	3 (5.8)	10 / (20)
Nonbenzodiazepine muscle Relaxant n, (%)	4 (8.0)	7 (13)	2 (4.1)
Benzodiazepine muscle relaxant n, (%)	0 (0)	0 (0)	1 (2.0)
Narcotics n, (%)	1 (2.0)	1 (1.9)	2 (4.1)
Physical therapy n, (%)	1 (2.0)	1 (1.9)	2 (4.1)
Chiropractic therapy n, (%)	0 (0)	1 (1.9)	0 (0)
Home stretching n, (%)	1 (2.0)	0 (0)	0 (0)
Heat therapy n, (%)	0 (0)	1 (1.9)	0 (0)
Ice therapy n, (%)	1 (2.0)	0 (0)	1 (2.0)
No. of trigger point injections			
0 n, (%)	49 (98)	0 (0)	0 (0)
1 n, (%)	0 (0)	1 (1.9)	3 (6.1)
2 n, (%)	0 (0)	4 (7.5)	3 (6.1)
3 n, (%)	0 (0)	11 (21)	10 (20)
4 n, (%)	1 (2.0)	37 (70)	33 (67)
Additional medications			
Yes n, (%)	10 (20)	7 (13)	3 (6.3)
No n, (%)	40 (80)	46 (87)	45 (94)
Side effects at 30 min			
None n, (%)	49 (98)	41 (77)	44 (90)
Bleeding from trigger point injection*	0 (0)	3 (5.7)	3 (6.1)
Soreness from trigger point injection n, (%)	1 (2.0)	6 (11)	2 (4.1)
Allergic reaction n, (%)	0 (0)	1 (1.9)	0 (0)
Other reaction†	0 (0)	2 (3.8)	0 (0)
Taking medications as directed			
Yes n, (%)	47 (94)	50 (94)	44 (90)
Performing stretches as directed			
Yes n, (%)	45 (90)	42 (79)	34 (69)
Warm heat as directed			
Yes n, (%)	37 (74)	35 (66)	28 (57)
If received trigger point injection, would get again			
Yes n, (%)	N/A	39 (74)	38 (78)

MVC, motor vehicle crash.
*All controlled by adhesive bandage.
†Drowsiness and vasovagal response.

We displayed primary, secondary, and tertiary results as means with SDs in a box plot. Outcomes were reported per intention-to-treat and per protocol analysis. Per precedent, we treated our ordinal VAS data as continuous for ease of understanding.[32,33] Demographic data were reported with descriptive statistics. We performed ad hoc testing to assess effect size, measuring the difference in means between trigger point injection arms and standard therapy alone.

RESULTS

Characteristics of Study Subjects

We excluded similar numbers from each group due to withdrawal, loss to follow-up, additional medication requirements, or data collection errors, leaving similar numbers in the intention-to-treat group. Standard therapy alone, however, had more exclusions than either trigger point arm (Figure 1).

Demographics, baseline pain levels, incidence of preceding injury, and pain duration for each group were similar, suggesting adequate randomization. Most participants were men. There was a bimodal distribution of acute and chronic pain. The 30 to 60-minute evaluation demonstrated increased additional medication

requirements in standard therapy alone compared with either trigger point injection arm. The bupivacaine arm incurred more side effects; however, no side effects required further care. After discharge, the standard therapy alone arm reported greater compliance with discharge medications, stretching, and the use of heat (Table 1).

Main Results

Our primary outcome, ΔVAS per intention-to-treat analysis at 30 to 60-minute reassessment, demonstrated improvement in all groups at all reassessment times without significant differences (Figure 2, Table 2). Compared with standard therapy alone, pain reduction at 30 to 60 minutes was 0.55 (95% confidence interval [CI] −0.19 to 1.28) for bupivacaine and 0.71 (95% CI 0.00 to 1.43) for normal saline solution. Comparison with standard therapy alone at 60 to 72 hours of reassessment yielded a reduction of 0.45 (95% CI -1.11 to 0.20) for bupivacaine and 0.09 (95% CI −0.79 to 0.62) for normal saline solution (Table 3).

ΔMODI per intention-to-treat analysis demonstrated improvement without significant differences in all groups at all reassessment times (Figure 3, Table 2). ΔMODI per intention-to-treat analysis also demonstrated improvement in all groups but no difference between groups (Figure 3). At 30 to 60-minute reassessment, the difference in ΔMODI compared with standard therapy alone was 9.44 (95% CI 3.93 to 14.96) for bupivacaine and 5.18 (95% CI −0.08 to 10.45) for normal saline solution. At 60 to 72 hours of reassessment, the difference in ΔMODI compared with standard therapy alone was −1.47 (95% CI −8.51 to 5.57) for bupivacaine and 0.42 (95% CI −6.07 to 6.92) for normal saline solution (Table 3).

Twenty-one percent of participants and 26% of the investigators correctly guessed their treatment arm during assessment of blinding. Per protocol analysis, the results did not demonstrate any superiority in any outcomes.

LIMITATIONS

Several factors limit the generalizability of our study, including that it is a single-center trial at a military hospital with a disproportionately younger and male population with higher incidence of low back pain.[34,35] Additionally, our study excluded multiple populations, which may limit applicability to other EDs. Other factors may have

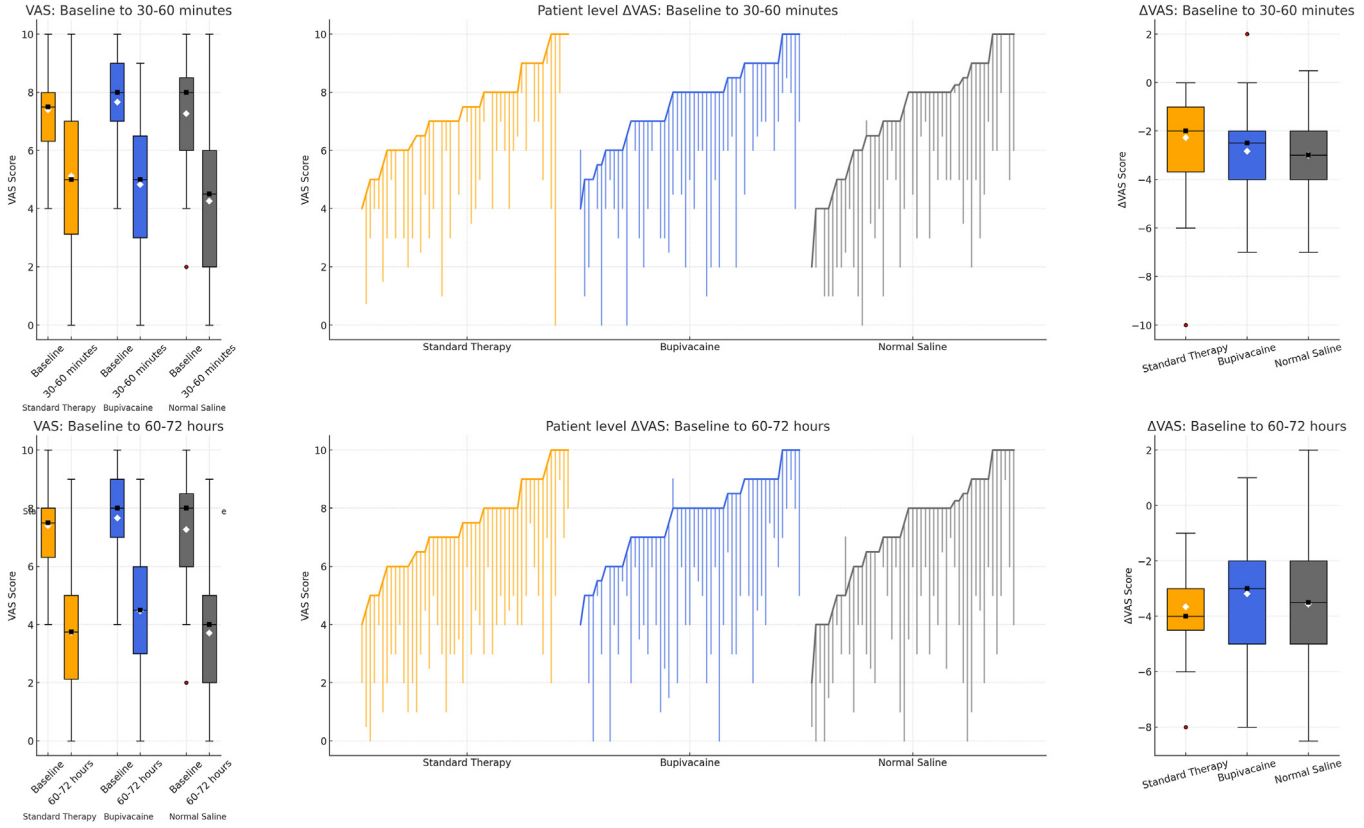

Figure 2. The left graph demonstrates raw VAS of treatment arms from baseline to 30-60 minutes and 60-72 hours respectively. The right graph denotes ΔVAS for treatment arms with the line indicating the baseline VAS. Black boxes represent means, white boxes represent medians, and red boxes represent outliers.

Table 2. ΔVAS and Δ MODI means from baseline at 30-60-minute reassessment and 60-72-hour reassessment.

ΔVAS from Baseline (Mean [95% Confidence Interval])	30-60-Min Reassessment	60-72-H Reassessment
Standard therapy alone	2.28 (1.72-2.84)	3.67 (3.27-4.06)
Bupivacaine	2.83 (2.31-3.38)	3.19 (2.63-3.75)
Normal saline solution	3.01 (2.50-3.52)	3.56 (2.93-4.19)
ΔMODI from Baseline (Mean [95% Confidence Interval])	**30-60-Min Reassessment**	**60-72-H Reassessment**
Standard therapy alone	8.16 (4.35-11.98)	19.54 (14.83-24.26)
Bupivacaine	17.73 (13.27-22.19)	17.95 (12.14-23.78)
Normal saline solution	13.43 (9.31-17.54)	19.95 (14.87-25.03)

introduced biases. Convenience sampling may have introduced risk of selection bias. Investigators performed all assessments and interventions, which increases risk of social desirability bias; however, one might expect these biases to favor treatment arms.

We did not have a placebo arm due to ethical concerns about not treating patients. This necessitated a standard therapy in all arms, which may have masked trigger point injection superiority over standard therapy alone or placebo.[35,36] Lack of blinding in the standard therapy alone arm may have also introduced bias; however, it would likely favor the trigger point injection arms. Our study, for practical reasons, also lacks testing for inter-rater reliability. Investigators did have training and instructions on the paperwork, but we cannot rule out misidentification of trigger points.

Our study did include patients with both acute and chronic pain. We considered the possibility that pathophysiologic differences between acute and chronic pain may have obscured treatment effect in one of these subgroups.[37] Further subgroup analysis may be appropriate in future studies. Another limit to our study is that it was underpowered, with exception of the bupivacaine intention-to-treat arm, limiting definitive conclusions from this study.

Other study limitations include minor baseline differences between groups; however, we suspect these played little role in group outcomes (Table 1). The unblinded nature of standard therapy alone, coupled with nonprotocolized additional medication administration, may account for the greater need for additional medications in that arm. Lastly, data collection during COVID may have affected our results, as well as an overall decreased census and patient characteristics may have varied.

DISCUSSION

Trigger point injections have been used and studied largely in the setting of physical therapy and rehabilitation clinics, but only recently in the ED setting.[8,11,12,16–18,21] Many studies demonstrate efficacy of trigger points for myofascial low back pain; however, most studies were small.[19] The only comparably sized study demonstrated efficacy of trigger point injections within 15 minutes, but pain levels equivocated with standard care by ED discharge.[18] This study also included neck pain injections, which may have different pain management characteristics.[18] One smaller study demonstrated superiority of trigger point injections for low back pain in the ED setting over NSAIDs but did not include functional outcomes.[16] To our knowledge, our study is the largest study to exclusively evaluate trigger point injections for myofascial low back pain and the only study to evaluate functional outcomes at a time frame clinically relevant to ED care.

Our study contradicts some prior studies. Although all groups had improved ΔVAS over time, none of the groups demonstrated superiority to the others at any time frame. The addition of trigger point injections did not add additional pain improvement regardless of injectate.

Table 3. Effect size between trigger point injection arms compared with standard therapy alone at 30-60-minute reassessment and 60-72-hour reassessment.

Effect Size Between Mean ΔVAS of Trigger Point Injection Arm and Mean ΔVAS Standard Therapy Alone	30-60-Min Reassessment (Mean [95% Confidence Interval])	60-72-H Reassessment (Mean [95% Confidence Interval])
Mean ΔVAS bupivacaine—mean ΔVAS standard therapy alone	0.56 (−0.23 to 1.33)	0.48 (−0.21 to 1.17)
Mean ΔVAS normal saline solution—mean ΔVAS standard therapy alone	0.73 (−0.02 to 1.48)	0.11 (−0.85 to 0.63)
Effect Size Between Mean ΔMODI of Trigger Point Injection Arm and Mean ΔVAS Standard Therapy Alone	**30-60-Min Reassessment (Mean [95% Confidence Interval])**	**60-72-H Reassessment (Mean [95% Confidence Interval])**
Mean ΔMODI bupivacaine—mean ΔMODI standard therapy alone	9.57 (3.77-15.37)	1.68 (−8.98 to 5.82)
Mean ΔMODI normal saline solution—mean ΔMODI standard therapy alone	5.27 (−0.27 to 10.81)	0.31 (−6.43 to 7.25)

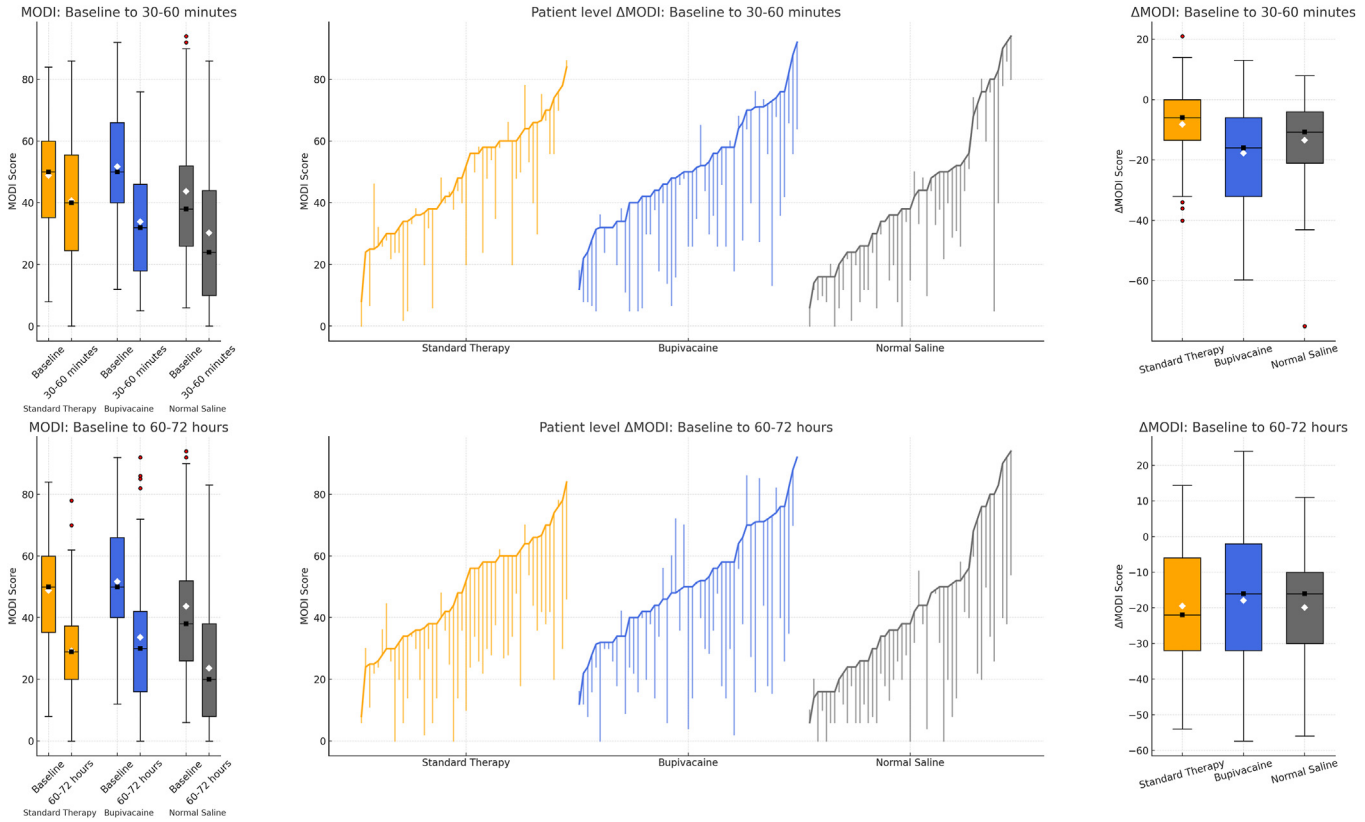

Figure 3. The left graph demonstrates raw MODI of treatment arms from baseline to 30-60 minutes and 60-72 hours respectively. The right graph denotes ΔMODI for treatment arms and the line denotes the baseline MODI. Black boxes represent means, white boxes represent medians and red boxes represent outliers.

ΔMODI likewise demonstrated improvement in all groups over time without superiority of any group at any time frame.

We considered 3 possible explanations. First, that trigger point injections may not be effective; however, this contradicts prior studies demonstrating efficacy of trigger point injections.[8,16,18] Second, this may suggest that no therapy modifies myofascial pain in the low back beyond a certain threshold and that there is a ceiling beyond which treatment will not further modify pain. Third, it is possible that trigger point injections may work earlier than standard therapy but equivocate with the onset of standard medication in approximately 30 minutes.[18]

The trigger point injection groups required less rescue pain medication but did have a higher incidence of side effects. None of these side effects required further treatment or modification of the intervention. This study suggests improvement with standard therapy; however, lack of placebo control tempers this finding. Additional trials with fewer standard therapy medications may better elucidate whether trigger point injections contribute to pain relief of myofascial low back pain.

This study also sought to compare local anesthetic versus normal saline solution as the injectate. Although prior studies suggest equivalence of injectates, our study was unable to comment on the superiority of different injectates. The possibility of a ceiling effect from standard therapy alone prevents conclusion of equivalence or superiority of these injectates based on this study.[17,38]

Our study also evaluated functional outcome as a secondary outcome with clinical significance of the ΔMODI prespecified as 10%. We deemed this a clinically significant difference and used it to define superiority. To our knowledge, we are the first group to evaluate functional outcomes beyond ED care, which is relevant for both patient discharge and to prevent bounce-backs. Similar to pain improvement, no group established superiority at either reassessment. We acknowledge that the effect size measurement of bupivacaine at 30 to 60-minute reassessment was significant but realistically is not clinically significant. This, too, may represent a functional ceiling effect after treatment. These pain and functional improvements over time may simply display the natural history of myofascial low back pain.

Although our study was negative, it does raise interesting avenues for further research. This study showed that trigger point injections, in addition to a regimen of oral pain medications and adjunctive measures such as stretching or moist heat, likely do not add additional relief for myofascial low back pain. This suggests that patients capable of taking standard therapy medications may not benefit from trigger point injections. Further studies would be necessary to determine if trigger point injections have a role in patients unable to take these medications.

We conclude that in this study, no treatment arm demonstrated superiority regarding change in pain or functional status at 30 to 60 minutes or 60 to 72 hours. In the population studied, there appears to be little role for trigger point injections for low back pain when concurrently treated with appropriate standard therapy. Future research may be useful to determine whether certain subgroups may benefit from trigger point injections for low back pain.

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Author contributions: ML and TO conceived the study, designed the trial, and worked the study through the IRB process. CW served as the faculty adviser and subject matter expert during the initial IRB process and aided in initial study design. JO was the senior author, study coordinator, data manager, and recruited patients. VND and HWP participated in study design, randomization and execution of medication blinding, and data analysis. KC served as the study monitor, revised the IRB protocol, and helped with manuscript revision. MA provided statistical advice, aided in study refinement and manuscript revisions. JS aided with statistical advice, data analysis and manuscript writing (figures). HAB, PC, MSP, RSD, CAD, NCD, MWG, AMH, BLJ, MJK, TJM, NN, BTS, and NDW were all responsible for patient recruitment, intervention execution follow-up and participated in IRB and manuscript revision. All team members were involved in data analysis. ML, JO, and TO drafted the manuscript, and all authors contributed substantially to its revision. ML takes responsibility for the paper as a whole.

Data sharing statement: The entire deidentified data set, data dictionary, and analytic code for this investigation are available as of November 2024 at https://clinicaltrials.gov #NCT04704297.

All authors attest to meeting the four ICMJE.org authorship criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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