

A Comprehensive Protocol to Diagnose and Treat Pain of Muscular Origin May Successfully and Reliably Decrease or Eliminate Pain in a Chronic Pain Population

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Abstract

Objective. A comprehensive protocol is presented to identify muscular causes of regional pain syndromes utilizing an electrical stimulus in lieu of palpation, and combining elements of Prolotherapy with trigger point injections.

Methods. One hundred seventy-six consecutive patients were evaluated for the presence of muscle pain by utilizing an electrical stimulus produced by the Muscle Pain Detection Device. The diagnosis of “Muscle Pain Amenable to Injection” (MPAI), rather than trigger points, was made if pain was produced for the duration of the stimulation. If MPAI was found, muscle tendon injections (MTI) were offered to patients along with post-MTI physical therapy, providing neuromuscular electrical stimulation followed by a validated exercise program [1]. A control group, evaluated 1 month prior to their actual consultation/evaluation when muscle pain was identified but not yet treated, was used for comparison.

Results. Forty-five patients who met criteria completed treatment. Patients’ scores on the Brief Pain Inventory decreased an average of 62%; median 70% ($P < 0.001$) for pain severity and 68%; median 85% ($P < 0.001$) for pain interference one month following treatment. These changes were

significantly greater ($P < 0.001$) than those observed in the untreated controls.

Conclusion. A protocol incorporating an easily reproducible electrical stimulus to diagnose a muscle causing pain in a region of the body followed by an injection technique that involves the entirety of the muscle, and post injection restoration of muscle function, can successfully eliminate or significantly reduce regional pain present for years.

Key Words. Muscle Pain; Myofascial Pain Syndrome (MPS); Trigger Points (TrPs); Muscle Pain Amenable to Injection (MPAI); Muscle Tendon Injections (MTI); Low Back Pain; Muscle Pain Detection Device; MPDD

Introduction

The study of pain in the past 40 years has evolved into an important field of scientific inquiry leading to improved understanding of the mechanisms of various painful conditions and the development of commensurate treatment interventions. One potential area of promise however is glaringly overlooked. Muscle involvement in common clinical regional pain syndromes is neither generally studied nor considered as an important source of treatable pain. Many factors have made it difficult to conceptualize muscles as an integral part of the standard of evaluation and treatment protocols. Muscle exercise programs may be effective [1] but are rarely taught in medical training. Even when muscle involvement is considered, approaches to diagnosis and treatment are highly variable, leading to unexplainable results and suboptimal outcomes.

“Myofascial Pain” Lacks Universal Understanding

Varying concepts of myofascial pain [2–12] and oversimplification of the nomenclature are responsible for difficulties in the diagnosis and treatment of muscle pain. According to the core curriculum of the International Association for the Study of Pain, myofascial pain is defined as pain emanating from muscle and connective tissue that causes pain in common clinical regional pain syndromes and “lacks reliable means [for physicians] to identify, categorize, and treat such pain” [13]. Studies of clinicians attempting to identify painful muscles demonstrate poor inter-rater reliability in the identification of myofascial trigger points (TrPs) [14–19]. Clinicians will frequently and mistakenly use the terms, “myofascial trigger point” and “myofascial pain,” interchangeably. “Myofascial trigger

point” is only one of the four various potential etiologies of myofascial pain. The other three suggested etiologies of myofascial pain—deficiency (weakness and or stiffness) spasm, and tension [20]—are not typically appreciated by clinicians, leading to the disregard of critical causes of muscle pain, and the ensuing suboptimal outcomes. These issues collectively have contributed to the absence of muscle pain as a putative source of investigation in published pain treatment guidelines, such as the 2007 Low Back Pain Guidelines from the American Pain Society and the American College of Physicians [21]. The failure to create an agreed methodology for muscle pain assessment and treatment has contributed to the rejection of trigger point injections (TPIs) and sclerosant injections, as recommended treatment options for low back pain [22]. Ignoring muscles facilitates an overemphasis on structural abnormalities demonstrated on imaging and not necessarily identifying the true source of the patient’s pain. Subsequent inappropriate treatments contribute to the \$86 Billion spent in 2005 on neck and back pain in the United States [23].

Possible Etiologies of Myofascial Pain are not Fully Recognized by Clinicians

Myofascial pain can be caused by various etiologies. However, the current community standard of establishing the diagnosis is limited to only palpating the putative muscle causing regional pain and identifying any TrPs. The standard treatment is to give TPIs to the putative muscle, injecting into a discrete area that includes only the TrPs and associated taut bands. The evaluation of TrPs without a complete assessment of muscle conditioning leads to unexplainable variability in treatment outcomes because diagnoses are confounded when clinicians fail to consider weakness, stiffness, spasm, or tension as a primary source of pain [24]. Therefore, even if the putative muscle is correctly identified and injected, failure to acknowledge, and/or appropriately treat pain from these other causes of myofascial pain may leave the patient with persistent discomfort and clinically unchanged.

Limits of Palpation as a Diagnostic Tool

Palpation alone used to detect areas of muscle pain introduces two confounding variables: First, varying amounts of pressure may be applied diminishing the reliability of the examination. Pressure-recording devices have been introduced to determine more accurately the amount of applied pressure necessary to elicit discomfort in the patient [25,26]. However, the accuracy of these devices is compromised because examiner preconceptions have been reported to influence the assessment [27]. Second, palpation to elicit a subjective experience of pain is done in a sedentary muscle. Most functional muscle pain is experienced with muscle activity vs rest. Therefore, an examination of a resting muscle is likely to be less accurate in determining the source of the muscle pain, frequently identifying a referred pain pattern, compared with an examination utilizing movement of discrete muscles [28,29].

New Approach to Diagnosis and Treatment of Myofascial Pain

It has been shown in humans with delayed onset muscle soreness that the presence of hardness in the muscle or muscular tendonous junction does not correlate with the presence of muscle hyperalgesia [30]. An unpublished observational study comparing traditional palpation with external electric stimulation of putative muscles demonstrated that among nearly 50% of the evaluated patients, the tenderness and taut band in the trapezius muscle was actually secondary to the primary source of pain in an adjacent muscle, which when injected eliminated the pain and taut band in the trapezius (data available upon request).

Since a patient is unable to isolate and move just one muscle, an electrical device was developed that can stimulate individual muscles to identify the involvement of one or more that are suspected as the source of pain in a clinical regional pain syndrome. We postulate that externally induced contraction of the putative muscle in the painful region produces pain by two means: 1) Muscle fiber contraction stimulating the density of sensitized nociceptors in the muscle-tendon and bony-tendon attachments, and 2) Stimulation of sensitized nociceptors in the muscle belly through deformation of the area where sensitized nociceptors in TrPs are located. The present study was conducted to test a new standardized evaluation and treatment algorithm that we believe accurately identifies and effectively treats pain from muscle involvement in common clinical regional pain syndromes.

Methods

Study Description and Patients

This nonrandomized, nonblinded, controlled study was designed to evaluate the effectiveness of a novel protocol for the diagnosis and treatment of myofascial pain. The study population was drawn from a pool of 176 consecutive patients seeking relief from a variety of chronic painful conditions at the lead author’s (N.M.) pain practice. All patients were evaluated by the senior author (N.M.), a board certified pain medicine specialist, using a structured physical examination to detect potential muscle involvement as the cause of their pain syndromes. When muscle involvement was confirmed using the Muscle Pain Detection Device (MPDD) and the evaluation protocol suggested that injections were indicated, the muscle was identified as a “Muscle Pain Amenable to Injection” (MPAI), as opposed to “trigger point pain.” Patients diagnosed with MPAI and without exclusionary criteria (see below) were offered treatment. This treatment consisted of muscle tendon injections (MTIs), followed by a structured physical therapy protocol that includes a validated set of exercises. Patients were excluded from the study if they had a concurrent physical diagnosis (including morbid obesity, severe deconditioning, Parkinson’s disease, severe peripheral neuropathy or significant psychological co-morbidities) that discouraged aggressive treatment of

A Comprehensive Muscle Algorithm

the muscle pain. A control group was drawn from a pool of 79 patients using the same inclusion and exclusion criteria as in the treatment group of patients. The control group patients completed the Brief Pain Inventory (BPI) survey by mail or by phone at one month prior to their actual initial consultations, at which time they were retested with the BPI, now 1 month later, and assessed for MPAI. Informed consent was given for all procedures that patients received.

Structured Physical Examination

All 176 patients in the study pool and the 18 controls received a structured physical examination that consisted of the Kraus–Weber (KW) test for key trunk muscle strength and flexibility, Kraus examination protocol for neck and shoulder range of movement, neurological examination, standard palpation for muscle tenderness and resilience, and evaluation with the MPDD (SPOC, Inc. Stamford, CT), a hand-held biomedical device that locates muscle pain (the device picture is available to view in the supporting information link provided online only). Palpation for tenderness and resilience was performed only to identify presumptive sources of muscle pain, but the diagnosis of MPAI was only made with the MPDD.

Main Outcome Measures

The measurement of pain severity and interference with movement was assessed by the administration of the BPI [31,32]. The BPI assesses severity of pain and interference in normal movement as two dependent variables. The numerical results of the four severity questions were averaged to determine a “Severity Score” and the first seven interference questions were averaged to determine an “Interference Score.” The BPI was administered to all patients in the study pool by the office manager at three time points: 1) initial visit, 2) last day of treatment, and 3) 1 month following the last day of treatment in person or by USPS mail.

Diagnosis of Myofascial Pain

See Figure 1.

For a detailed discussion of the evaluation technique including the KW test, see the supporting information link (provided online only).

Treatment Protocols

Injection Technique—Muscle Tendon Injections

See Figure 2.

For a detailed discussion of the injection technique, see the supporting information link (provided online only).

Patients who have MPAI diagnosed and no contraindications to MTI are injected in one or two muscles each day for a total of 1–5 muscles each week. The choice of which

muscle to inject first is made according to the patient’s complaint of their worst pain in a region coupled with the degree of discomfort experienced with the MPDD. Proximal and/or superficial muscles are injected prior to deep and/or distal muscles. Patients who travel long distances may receive multiple muscle injections (more than one muscle a day) in order to finish the treatment as quickly as possible and decrease the costs of food and lodging. Patients are reevaluated with the MPDD prior to each MTI to ensure that all previously identified muscles still test positive for MPAI.

Post Injection Physical Therapy

See Figure 3.

For more detailed discussion of the post injection physical therapy including the Kraus exercises, see the supporting information link (provided online only).

Statistical Methods

Treated and withdrawn groups were compared on baseline and treatment variables with chi-square tests (for nominal and yes/no variables) and either *t*-tests or Mann–Whitney *U*’s for numeric variables. The numeric variables are generally presented as mean (median) range, as many were quite non-normal in distribution. Within-group changes were analyzed with Wilcoxon tests. The control subjects only had data at baseline and one month later. Within group changes for this group were also analyzed with Wilcoxon tests. Mean changes were compared between controls and treated subjects with a Mann–Whitney *U*-test.

Results

Patient Characteristics

Of the 176 patients in the study pool, 106 patients were excluded because of the following reasons: 1) no primary muscle pain ($n = 43$); 2) primary muscle pain with MPAI was present, but patients had a concurrent physical diagnosis ($n = 25$) that included morbid obesity, severe deconditioning, Parkinson’s disease and severe peripheral neuropathy, or significant psychological co-morbidities; and 3) primary muscle pain with MPAI was present, but patients refused suggested treatment ($n = 38$). Of the remaining 70 patients that began treatment, 45 patients (64.3%) completed the treatment and 25 patients (35.7%) chose to withdraw from the treatment program. As shown in Table 1, the average age of patients in the withdrawn group (51.3 years) was slightly older than the patients who completed treatment (44.7 years; $P = 0.06$), but there were few other differences. About half of the patients in the treatment group (58%) and withdrawn group (48%) were female, and both groups had a wide range of ages (age 12–76 years) and a wide range of duration of symptoms, with a median of 6 years of pain for both groups.

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I. Kraus-Weber Test → Pass – No weakness or stiffness in key postural muscles
 → Fail – Weakness and/or stiffness in key postural muscles

↓
 (suggest administration of Kraus exercises)

II. Muscle Pain Detection Device applied to suspected muscles – used on initial consult and prior to each Muscle-Tendon Injections

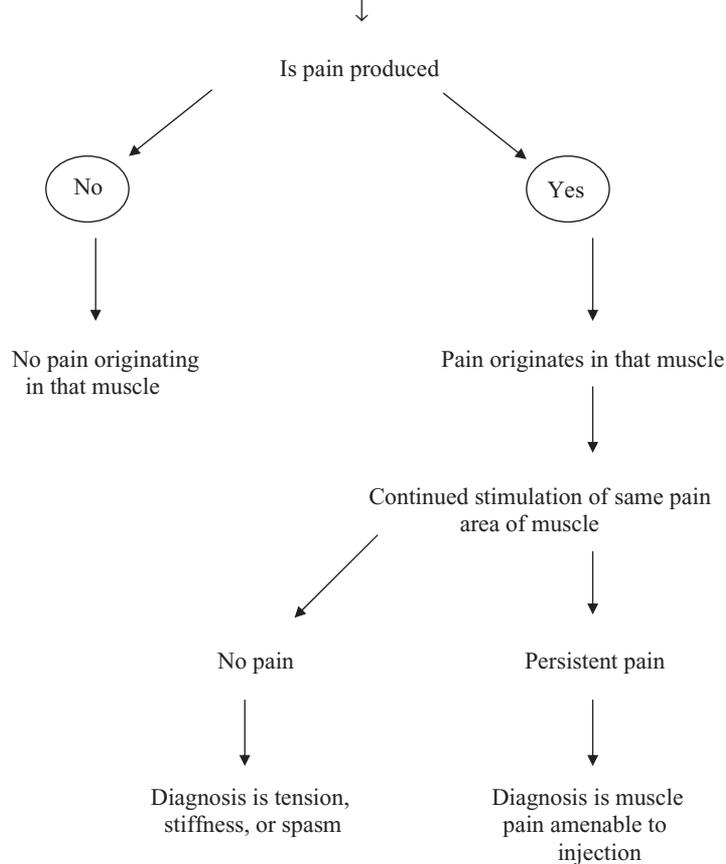


Figure 1 Muscle pain evaluation algorithm.

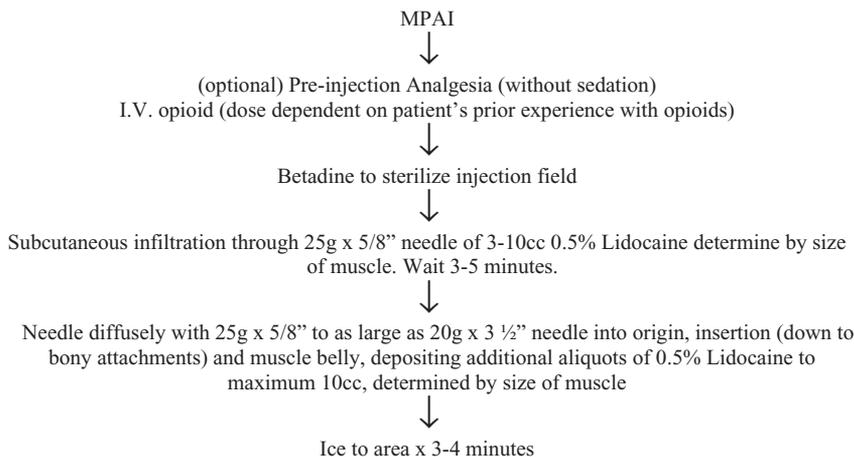


Figure 2 Muscle pain amenable to injection protocol.

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To each injected muscle for 3 consecutive post injection days:
Rhythmic Sinusoidal Wave Neuromuscular Electrical Stimulation, 2 seconds on 2 seconds off, to
a visible contraction with Ice x 20 minutes



First seven lower body exercises or eight upper body exercises

Figure 3 Post injection physical therapy protocol.

Patients Who Received Treatment

In the patients who completed treatment (Completers), the only gross neurological abnormality was a diminished lower extremity reflex in two patients. The vast majority of all patients reported pain for more than 1 year, with only two patients who completed treatment having pain duration of 3 months or less. Of the patients who withdrew, one patient had hyperreflexia of the lower extremities, and one patient had pain for 3 months or less. As shown in Table 1, some patients in both groups had undergone previous treatments, including TPIs. About 1/3 of both groups had evidence of depression. The withdrawn group had nonsignificantly higher rates of all prior diagnoses and treatments.

Discontinued Treatment

Patients in the withdrawn group were verbally asked for their primary reason for not continuing treatment and reported the following reasons: lack of time or distance from the pain center (n = 8); diagnosed with more urgent, prominent health condition (n = 7); felt the treatment was not working (n = 4); financial concerns prevented them from continuing the treatment (n = 3); elected to try another

form of treatment rather than finish the prescribed treatment (n = 2); noncompliant with the post injection protocol (n = 1). Patients who chose to discontinue treatment were not reevaluated. At the beginning of treatment, all patients were informed in a written instruction sheet that "pain may not be relieved until all muscles that were identified as MPAL are injected, and treatment is completed." There were two patients with neurological abnormalities in the group of 38 patients who refused the suggested treatment. One patient had neurologic impairment of an arm and shoulder due to a car accident and one patient had diminished reflexes in one leg following a microdiscectomy. Pain duration was 14.8 years (median 13.5) with a range of 1.5 months to 51 years, with one patient having pain for less than 3 months. Similar to the treatment group and the withdrawn group, about 1/3 of the patients who chose not to have treatment had evidence of depression.

Main Outcome: Pain Severity and Interference Scores

Completers

Individual BPI scores for severity at initial consultation, completion of treatment, and 1-month follow up are

Table 1 Statistical analyses

N	Treated 45	Withdrawn 25	Control 18
Age (y) ^a	44.7 (44) 12–71	51.32 (52) 26–76 ^{*d}	51.61 (51) 20–79 ^{*d}
Pain duration (y) ^a	9.2 (6) 0.1–37	8.34 (6) 0.25–30 ^{NS,b}	18.97 (18.7) 1.7–37 ^{**b}
Sex: N (% female)	26 (58%)	12 (48%) ^{NS}	11 (61%) ^{NS}
Length of treatment (weeks)	2.1 (2) 1–8	1.8 (1) 1–7 ^{**b}	N/A
Prior back surgery	7 (15.5%)	6 (24%) ^{NS}	7 (39%) [*]
Prev Dx Herniated disk	8 (17.8%)	7 (28%) ^{NS}	4 (22%) ^{NS}
Prev. Treatment with epidural steroids or facet blocks	14 (31.1%)	11 (44%) ^{NS}	10 (56%) [*]
Prior trigger point tx	4 (8.9%)	3 (12%) ^{NS}	1 (6%) ^{NS}
Depression ^c	13 (28.9%)	9 (36%) ^{NS}	7 (39%) ^{NS}
# Muscles identified with MPAL	6.7 (4.5) 1–35	7.1 (6) 1–27 ^{NS,b}	7.1 (6) 2–27 ^{NS,b}
# Muscles treated	5.6 (4) 1–31	4.6 (3) 1–18 ^{NS,b}	N/A
Pain location			
Upper body only	11 (24%)	4 (16%) ^{NS}	1 (6%) ^{NS}
Lower body only	24 (53%)	11 (44%)	11 (61%)
Both locations	10 (22%)	10 (40%)	6 (33%)

* $P \leq 0.10$ vs treated; ** $P \leq 0.01$ vs treated. All others, $P > 0.10$.

^a Numeric variables are shown as mean (median) range.

^b Mann–Whitney U -test (those without a letter are chi-square, uncorrected or Yates corrected as appropriate).

^c Suffered with or medicated for.

^d Unpaired t -test.

NS = nonsignificantly different from treated.

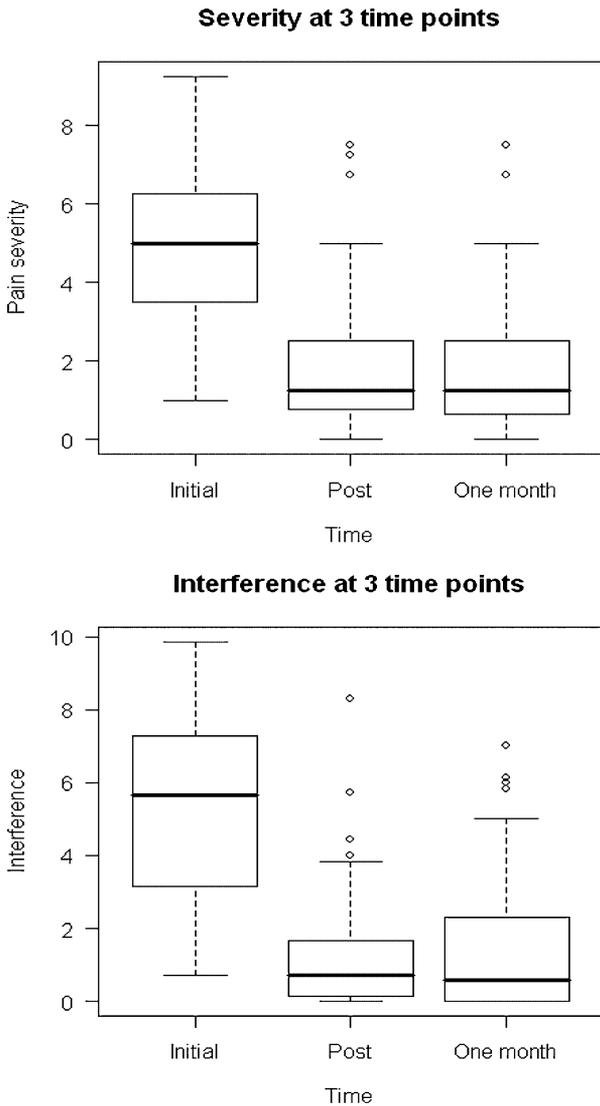


Figure 4 Severity and interference at three times points in 45 patients who completed treatment. Each plots shows the median (dark bar), 75th and 25th percentile (top and bottom of box) and the range. $P < 0.001$ for post and one month vs initial (baseline) on each measure.

shown in Figure 4. The mean BPI score for severity at initial consultation was 4.95; median 5.00. After completion of treatment (MTIs and Physical Therapy) the mean BPI severity score had dropped to 2.02; median 1.25 ($P < 0.001$ vs baseline). The mean BPI score for severity at the 1-month follow up was 1.87; median 1.13 (also $P < 0.001$ vs baseline). Comparing completion of treatment with 1-month follow-up, no difference was observed ($P = 1.0$). The mean decrease in BPI severity of all patients was 62%; median 70%.

The distribution of BPI scores for pain Interference at all three time points in the patients who completed treatment

is shown in Figure 5. At initial consultation the mean was 5.28; median 5.67. After completion of treatment (MTIs and Physical Therapy) the mean BPI interference score had dropped to 1.32; median 0.71, at the 1 month follow up the average was 1.57; median 0.57. As we found for severity, both posttest and 1 month were significantly different from baseline ($P < 0.001$ for each), but not from each other ($P = 0.49$). The average decrease in BPI rated pain interference of all patients was 68%; median 85%. As shown in the figure, prior to treatment, over 75% of the patients had values above 3 on severity and likewise on interference, whereas 75% of the patients were below 3 on these variables at post-treatment and 1 month.

Controls

For both severity and interference, there was effectively no average change in the control group (median change on

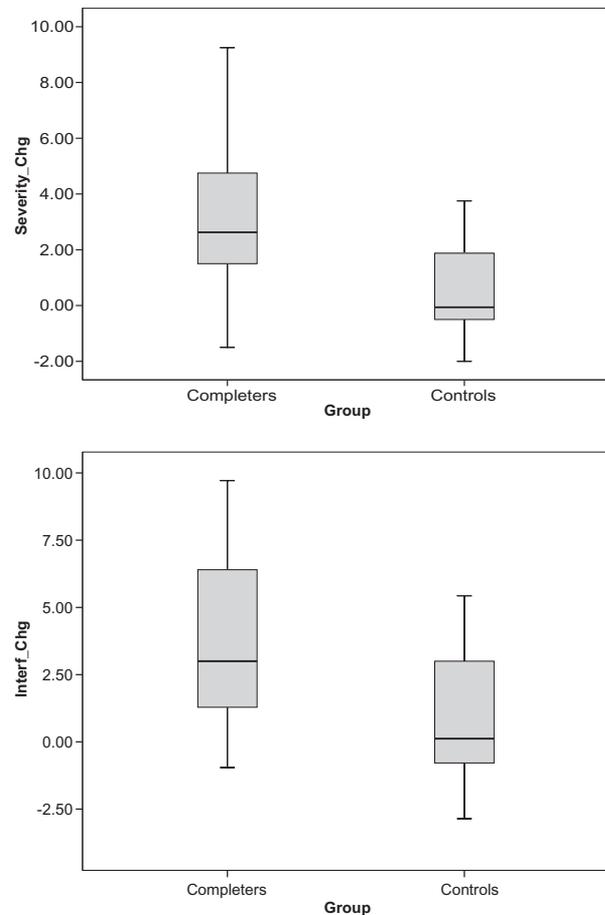


Figure 5 Change in severity pretreatment to 1 month post treatment (in 45 patients who completed treatment) or post evaluation (in the 18 untreated controls). Each figure shows the median (dark bar), 75th and 25th percentiles (top and bottom of box), and the range. $P < 0.001$ between groups on both change measures.

severity was -0.0625 , a slight worsening, while the median change on interference was 0.1214 . Mean changes were positive, but only 0.61 and 0.81 , respectively). Neither change was even close to significant. The 95% confidence interval for the mean change suggests that the maximum plausible mean improvement in untreated controls would be 1.39 on severity and 2.00 on interference.

Completers vs Controls

Median changes on severity and interference in the completer group are both >2.5 (means are >3). Both are highly significant ($P < 0.001$), and both are significantly greater than the changes in the controls ($P < 0.001$). The lower bound of the 95% confidence interval, indicating the minimum plausible mean changes in the completer group are 2.37 for severity and 2.83 for interference. These minimums are greater than the upper end of the 95% confidence interval in the controls—in other words, the 95% confidence intervals are nonoverlapping.

Discussion

We present for the first time a muscle pain algorithm with a unique combination of features. It incorporates a diagnostic technique that utilizes an electrical stimulus, standardized for each patient, that detects multiple causes of functional muscle pain, a specific injection technique for identified painful muscles diagnosed with MPAL, and an aftercare program which includes specific exercises that have been demonstrated to be effective on patients with back pain.

For relevant physiology of nerve conduction and associated putative mechanism of MPDD effect, please go to the supporting information link (provided online only).

Physical Examination

An important aspect of the examination is the production of pain along the entire course of suspected muscle from origin to insertion in order to unambiguously identify a muscle as a source of pain. A partially blinded randomized controlled validation study has been completed demonstrating that the MPDD is significantly better than palpation in determining a muscle thought to be the source of pain in a region of the body [28]. For MPAL to be diagnosed in a muscle the entire course of the muscle from the origin to insertion must be experienced as painful (tender, aching, or soreness). Sustained pain produced by MPDD in only a portion of the muscle suggests that another muscle is the true source of the pain.

Injection Technique

Our premise is that proper injection technique and aftercare could lead to the elimination of the source of the pain and therefore the need for reinjection. We found that patients' completing our treatment protocol obtained both substantial pain relief and diminished interference in function as measured on the last day of treatment, both of

which persisted at least 1 month, with our treatment protocol. We recognize that a longer follow-up period would be desirable. Of 45 patients, 11 (24.4%) exhibited complete elimination of pain that was present for years. The average duration of pain in 10 of the 11 patients who had complete elimination of pain was 8.9 years, with a range from 1 year to 18 years. The median decrease in pain severity for all patients was 70%, and the median decrease in pain interference was 85%, both highly significant statistically and little changed between the end of treatment and 1 month later.

Changes in a sample of untreated controls were far less, and the difference between completers and controls in change to 1 month was highly statistically significant. Our finding of a decrease in the total number of muscles identified as having MPAL over time in the course of the treatment may be related to central sensitization [33]. The elimination of the most painful muscles may result in diminished centrally facilitated pain and that therefore some of our identified MPALs may be false positives. We believe therefore that the routine re-evaluation prior to each MTI for MPAL is an important part of our protocol.

We postulate that a longer duration of relief is achievable with this approach, vs palpation only, which generally results in transient pain relief. At least one published study used the return of 75% of the pre-injection pain as the dependent time variable in studying TPIs using different injectates [34] and other studies have commented on the need to reinject TrPs [35,36].

Published studies address the specific number of trigger points in a muscle [37], the importance of eliciting a "twitch response" [35], or of thoroughly injecting the "taut band" [38]. Our approach is modeled on that of HK. He had originally thought that injecting TrPs when present could successfully diminish or eliminate muscle pain. He observed that 50% of patients treated with TPIs would repeatedly return with the need for reinjection in the same muscle. He speculated that as the muscle-tendon and bone-tendon attachments had the least blood supply and in animal studies were most prone to rupture, vs the muscle belly, that these areas might also be the source of the recurrent pain pattern. He therefore modified his injection technique so that it always included the origin and the insertion of the identified painful muscle. Gibson et al. [39] reported that the Proximal Tendon Bone Junction and tendon sites are more sensitive and susceptible to sensitization by hypertonic saline than muscle belly. This observation is consistent with our clinical impression of the importance of the tendon bone junction in the course of muscle needling. The injection into the bony attachment of the muscle identified as having MPAL has similarities to prolotherapy injections in which a variety of injectates may be utilized. A sclerosing solution is frequently injected into tendons or ligaments that are found to be painful on palpation with the assumption that the injectate will tighten lax connective tissue or promote healing in damaged tissue. The treatment is always coupled with some form of exercise or spinal manipulation therapy in any of the pub-

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lished studies demonstrating success in relieving pain in a region of the body [40]. We agree that pain does originate in the tendon bone attachments but we suggest that the effect of prolotherapy is based on the placement of the needle into this area rather than the injectate [41].

The utility of exercise in the treatment paradigm makes sense, but prolotherapy (and TPI) protocols that suggest the use of exercise following injections, do not identify which specific exercise are indicated. Varying injectate, as well as exercise protocols may confound outcome data and eliminate the possibility of valid systematic review or meta-analysis.

Exercise is defined as a “series of movements to promote good physical health.” This definition is problematic in that it allows almost any activity to be defined as an exercise protocol, thus accounting for the wide variety of outcomes achieved through “exercise” [42,43]. In 2007, van Tulder et al. [44] found that of 43 Cochrane-reviewed trials on exercise for the treatment of low back pain, 18 of the trials reported a positive response but only four showed any statistically significant reduction of pain. We believe that the nonspecific nature of the physical therapy programs provided in conjunction with muscle injections contributes to the inconsistent outcomes, even when apparently similar injection techniques are used.

The aftercare we provide is not generic stretching or a choice of techniques, but a structured, rigorous, albeit simple, exercise program performed following passive movement of the injected muscle using a neuromuscular electrical stimulator (NMES). NMES interestingly, following MTIs, reduces discomfort whereas electrical stimulation to the same muscle prior to MTI causes discomfort. We specifically prescribe an exercise program developed on 3,700 patients over the course of 4¹/₂ years and given to 300,000 participants at the YMCA with an 80% success rate in minimizing or eliminating low back pain [1]. The exercises provide relaxation (to address tension), limbering (to address stiffness), and gentle stretching (to address shortened muscles) after the muscle with MPAL is needled, vs a generic instruction to stretch the effected muscle and or do home exercises [30], or the suggestion to do Kraus or McKenzie exercises [42]. Studies discussing the low quality of heterogeneous outcome measures overlook the role of exercising.

Our study does not address the various injectates that are typically utilized in TPIs. We agree with the Cochrane group that there is no significant difference in outcomes when using various injectates and that the needle itself is the critical factor in the various muscle and ligamentous injection techniques [45].

There are a number of limitations in our study. An “intent to treat” model was not used for this analysis, since 1-month data was not obtained for patients who withdrew. An “intent to treat” model would require using an extremely conservative strategy such as last observation carried forward, and would introduce more bias than

simply excluding these patients. We asked why the patients were leaving the study and lack of efficacy was not the typical reason. We assume a patient would be less likely to withdraw if the treatment was wonderfully effective. However, patients are informed in writing that full treatment efficacy is not attained until after the complete course of treatment, and these patients withdrew before completion.

The data are preliminary in that there is no randomized control group or blinded treatment. In addition, a substantial number of subjects withdrew from the treatment group and have no follow-up data. We also note that the diagnostic and treatment protocol incorporates multiple variables, each of which should be investigated for their individual contributions to the overall outcome: The electrical detection device to identify MP and to determine possible etiologies of such pain (MPAL, TrPs, tension, stiffness, and/or spasm as the cause of pain. [We have noted above a successful RCT comparing MPDD to palpation in identifying MPAL]) [28], injections only of muscles identified as containing trigger points vs tension, stiffness or spasm through the use of the electrical device, the muscle injection procedure itself (entire muscle including the origin and insertion down to the bony attachment) and the injectate, 0.5% Lidocaine. The post-injection protocol variables that should be studied for their role in the total outcome are: use of a neuromuscular electrical stimulation to provide a rhythmic contraction and use of a specific structured exercise protocol.

The presented protocol was utilized successfully to avoid surgery in a group of pain patients whose pain was attributed to a variety of nonmuscle diagnoses and for whom surgery was recommended [46].

Conclusion

A protocol has been developed for the identification and treatment of muscle pain, utilizing electrical stimulation for potentially more precise identification of painful muscles, which appears to be successful at reducing and perhaps eliminating muscle based pain. Our data on 176 consecutive patients presenting to a comprehensive pain center indicate that 133 (76%) had MPAL, based on our model of identification of painful muscles with the use of electrical stimulation. It is estimated that 70–85% [21,47] of patients with low back pain have nonspecific low back pain. We suggest that a large percentage of these patients with not only low back pain, but upper back and shoulder pain as well, have a muscular component to their pain [28,29,48]. Although we only specifically address those patients with MPAL as a cause of pain, many of the patients had pain also from weakness stiffness, and tension, which we did not specifically analyze. The study of patients treated at the YMCA suggests that the Kraus exercises are an effective method to address these causes of muscle pain. Randomized controlled studies need to be performed to substantiate the suggested effectiveness of this comprehensive approach.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Physiology of Muscle Nociceptors Related to Effects of MPDD Diagnostic Technique.

Image 1. Muscle pain detection device.

Evaluation Technique.

Injection Technique.

Image 2. Infraspinatus muscle tendon injection protocol.

Post Injection Physical Therapy.

Appendix 1. Kraus-Weber test.

Appendix 2. Instruction sheet for patients receiving muscle tendon injections.

Appendix 3. Kraus-Weber program level 1.

Appendix 4. Kraus-Weber program upper body.

References.

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