

Original Research

Validity of a Sham Dry Needling Technique on a Healthy Population

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Background

Various methods of sham procedures have been used in controlled trials evaluating dry needling efficacy although few have performed validation studies of the sham procedure.

Hypothesis/Purpose

The purpose of this study was to examine the validity of a sham dry needling technique on healthy, active subjects.

Study Design

Validation study

Methods

Runners capable of completing a half-marathon or marathon race and were randomized to receive true (using an introducer and needle) or sham (using an introducer and fixed, blunted needle) dry needling. Blinded subjects were asked to identify if they received sham or true dry needling following the procedure. Proportions of those who correctly identified their needling were also examined on the basis of past experience of receiving dry needling.

Results

Fifty-three participants were included in this study, with 25 receiving the true dry needling procedure and 28 receiving the sham. Of those who had received dry needling in the past (n = 16), 11 (68.8%) correctly identified their respective groups. For those who had not previously received dry needling (n = 37), 13 (35.1%) accurately identified their group. Most importantly, 94.1% of dry needling-naïve participants were unable to identify they received the sham procedure (p < 0.001).

Conclusions

This study shows that a fixed needle in an introducer tube is a simple, inexpensive, effective sham procedure in patients who have never received dry needling before. This technique may be useful for randomized controlled trials in the future.

Levels of Evidence

2

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INTRODUCTION

Trigger point dry needling is a procedure in which a thin needle is inserted through the skin into the underlying muscle, directly into trigger points (TrPs), taut bands of muscle assumed to be responsible for pain, muscle dysfunction, and biomechanical alterations.¹ It is becoming more commonly used as a treatment modality for a variety of musculoskeletal conditions including myofascial trigger point pain, migraine, and chronic pain.¹ It has recently gained traction in the sports medicine realm for injury prevention,² strength gains,^{3,4} and sports injury treatment;⁵⁻⁷ however, the literature to date consists of many case reports and has not demonstrated definitive evidence of its efficacy.

One of the challenges in evaluating TrP dry needling efficacy in controlled trials is establishing an adequate method to account for a subject's placebo response. Blinding is essential in these studies to accurately determine therapeutic effect and to decrease bias effects on outcomes. Without adequate blinding, therapeutic effect can be overestimated.⁸ Furthermore, the simple insertion of a needle into the skin (often called superficial dry needling) may have an effect.⁹⁻¹¹ As is the case with several physical interventions such as acupuncture,^{12,13} massage (usually use an alternative therapy as placebo^{14,15}) and surgery,¹⁶ participants are not easily blinded to intervention with TrP dry needling. Given the nature of the therapy, participants can feel the needle puncture, and may have site soreness or bleeding after TrP dry needling.¹⁷

A valid control is therefore necessary to attempt to establish cause and effect from TrP dry needling. A variety of attempts at providing adequate control conditions have been attempted. Using a contralateral side as a control has been described,¹⁸ but TrP dry needling on one side has been demonstrated to have ipsilateral and contralateral effects.¹⁹⁻²¹ Others have used "false" dry needling as a control technique, such as needling at the incorrect location or depth,²²⁻²⁴ but insertion of a needle at any point may carry some form of pain control, likely from descending inhibition²⁵ thus confounding results.^{21,26} To counteract these limitations, several attempts have been made at creating sham dry needles²⁷⁻³¹ including specialized retractable needles³² and using a blunted needle.^{28,29,31} Other studies have used a tube sheath without a needle as a sham.^{27,33} Many dry needling and acupuncture studies have not assessed the validity of the sham intervention,⁸ however of those that did assess validity, a blunted needle was shown to be a reasonable sham intervention.^{26,31} The purpose of this study was to evaluate perception of sham TrP dry needling in healthy subjects both naïve and experienced in TrP dry needling, using a fixed needle as a sham intervention, to evaluate success of blinding of subjects to a TrP dry needling intervention.

METHODS

SUBJECTS

Subjects were recruited as part of a separate study,³⁴ including only marathon and half-marathon runners. Exclusion criteria included runners under 18 years of age, those with

acute or chronic skin breakdown in the area of needling (such as abrasions, infection, chafing, etc.), inability to complete the half- or full marathon, and inability or unwillingness to complete questionnaires. Potential participants received email notifications prior to the 2018 Salt Lake City Marathon describing the study. A block randomization schedule was used prior to the study to place each consecutive subject into a real or sham dry needling group, as outlined below.

PERSONNEL AND PROCEDURES

Two practitioners completed the TrP dry needling sessions – one sports medicine physician with five years of dry needling experience and one physical therapist with two years of dry needling experience. This was performed immediately following the aforementioned race, within an hour of completing the race. Subjects were placed in a prone position initially. Alcohol wipes were used on the bilateral calves to sterilize the test area. Based on the subject's randomization, the practitioner used either the real or sham dry needle on each lateral and medial soleus muscle. The patient was then placed supine on the table, and the process was repeated for the vastus medialis and vastus lateralis muscles. This allowed for a total of eight locations, four on each lower extremity. These sites were chosen due to common clinical complaints seen in the running population. The same treatment group (sham or true TrP dry needling) was used for all muscles on each subject. Subjects were not allowed to watch the procedure (heads remained on the table). Subjects could not see the needles being removed from packaging. All subjects were told that some patients feel a sharp feeling during the procedure. All subjects were also aware that they may receive either real or sham dry needling, but were not told what sham dry needling entailed. Subjects reported on their experience two days after the procedure, which allowed for adequate time for TrP dry needling soreness to set in,³⁵ which is a common side effect of the procedure. They were given three possible responses: "I definitely had the real dry needling," "I definitely had the sham (placebo) dry needling", or "I am not sure if I had the real or sham dry needling." This is in line with the study by Park et al.,³² who reported their findings in a similar manner.

TRUE TRIGGER POINT DRY NEEDLING PROCEDURE

For subjects who underwent true TrP dry needling, the gloved practitioner opened a new package and placed the 0.25 x 40 solid-bore filiform (solid, not hollow) needle into the introducer tube. The tube was placed on the patient's leg and the needle was tapped to insert the needle quickly into the skin; the needle remained, and the tube was removed. The practitioner then moved the needle deeper and aimed for a taut band of muscle, with the goal of eliciting a local twitch response (LTR) in the area. A local twitch response is a complex reflex that has been associated with pain relief.^{36,37} Repeated passes were made with the needle until a LTR was obtained and repeated until no further LTRs occurred in that area (a "pistoning" technique). If no LTR was obtained after 10 passes, the needle was withdrawn.

Table 1: Subject demographics.

| Variable | Dry needling | |
|--------------------------------------|----------------------|----------------------|
| | Sham (n = 28, 52.8%) | True (n = 25, 47.2%) |
| Gender [frequency (%)] | Male | 8 (28.6) |
| | Female | 20 (71.4) |
| Race [frequency (%)] | Marathon | 7 (25.0) |
| | Half-marathon | 21 (75.0) |
| Age | 41.9 (12.5) | 42.7 (11.8) |
| Height (cm) | 168.4 (6.4) | 173.6 (8.8) |
| Weight (kg) | 68.9 (13.7) | 72.3 (14.1) |
| Body mass index (kg/m ²) | 24.3 (4.6) | 23.8 (3.5) |

Values are mean (SD) unless specified otherwise

Only single-use, sterile needles were used. Manual pressure was used if bleeding was noted (which occurs in approximately 16% of patients¹⁷).

SHAM DRY NEEDLING PROCEDURE

A sham needle/introducer was created to allow for an identical-appearing needle and introducer, but without inserting the needle (Figure 1). Prior to the study, a single needle was removed, and its sharp point was first cut off around 5 mm proximal to the tip. The shortened needle was blunted for safety and then glued into the introducer with clear glue (cyanoacrylate) so it appeared like a normal dry needle (with the thicker end slightly protruding from the introducer). These sham needles thus had no sharp tip protruding, the needle could not be removed from the introducer, and thus the needle never contacted the skin. The practitioner would hold one of these needles in the same manner they would hold a true dry needle, and would place it on the patient's skin. They would tap it identically, but as the needle was glued in, no needle would penetrate the skin. Subjects would still feel the introducer pressed hard against their skin however, similar to a prior sham-controlled study.²⁷ The practitioner would then proceed to gently manipulate the introducer/needle apparatus on the skin, in the same location, for approximately thirty seconds at each location, which matched our approximate clinical time for performing this procedure with the true method. In between patients, the sham needles were placed in 70% isopropyl alcohol to ensure sterility.

STATISTICAL METHODS

Initial power analysis was based on similar studies,^{26,31} estimating approximately 20 subjects in each group. Descriptive statistics were calculated for subjects' demographics. Proportions of those who correctly identified their needling were compared by past experience of receiving dry needling,

using a two-sample test of proportions. Lastly, the effectiveness of sham needling as a placebo was examined by comparing the proportion of subjects in the sham needling group who were unable to identify which needling they received (either identified that they received real dry needling or were not sure if they received real or sham) to a chance occurrence (= 50%), using an exact binomial test. Statistics were performed with Stata/MP 16.0 for Windows (StataCorp LLC, College Station, TX).

RESULTS

A total of 53 subjects were included in this data analysis. Of those, 28 (52.8%) and 25 (47.2%) received the sham and true TrP dry needling, respectively (Table 1).

The results of dry needling identifications by prior experience of dry needling are summarized in Table 2. Of all subjects, regardless of group assignment, 28 (52.8%) subjects were unsure which group they were in, 24 (45.3%) identified their group appropriately, and 1 (1.9%) was incorrect. Of those who had received dry needling in the past ($n = 16$), 11 (68.8%) correctly identified their respective groups. For those who had not previously received dry needling ($n = 37$), 13 (35.1%) accurately identified their group. The difference in the proportions was statistically significant ($z = 2.26$, $p = 0.024$).

Of the 28 subjects in the sham needling group, 11 subjects had received dry needling in the past, while 17 had not. For those who had previously received dry needling, 7 (63.6%) subjects were able to identify that they received the sham needling. The exact binomial test showed that this proportion was not significantly different from 50.0%, a chance occurrence ($p = 0.549$). Meanwhile, of the dry needling-naïve subjects, only one (5.9%) was able to identify that they received the sham needling. This proportion was significantly lower than 50%, a chance occurrence (5.9% [95% CI, 0 - 17%], $p < 0.01$). Similarly, one (5.9%) dry

Table 2: Dry needling identifications by prior experience of dry needling.

| Prior experience of dry needling | Identification | Dry needling | |
|----------------------------------|--|----------------------|----------------------|
| | | Sham (n = 28, 52.8%) | True (n = 25, 47.2%) |
| Yes (n = 16) | I am not sure if I had the real or sham. | 4 | 1 |
| | I definitely had the sham dry needling. | 7* | 0 |
| | I definitely had the real dry needling. | 0 | 4* |
| No (n = 37) | I am not sure if I had the real or sham. | 15 | 8 |
| | I definitely had the sham dry needling. | 1* | 0 |
| | I definitely had the real dry needling. | 1 | 12* |

Values are frequency.

*Correct identification.

needling-naïve subject felt they had received true TrP dry needling.

DISCUSSION

This study examined the validity of a fixed needle as a sham dry needling procedure. Validating a non-penetrating type of sham procedure as an effective placebo treatment is important as this type of sham procedure is likely more inert than a penetrating sham procedure⁹⁻¹¹ and thus decreases confounding factors caused by superficial needling or “false” dry needling techniques when evaluating dry needling outcomes.¹⁹⁻²¹ The sham technique in this study mimicked dry needling in that the participants felt the introducer tube, but the needle did not penetrate the skin. The sham needling was done in the same location, setting, position, and for approximately the same amount of time as the true TrP dry needling procedure. Subjects were not able to see the procedure being done in either the true or sham dry needling group. Mitchell et al.²⁶ performed a similar study with a blunted needle to examine dry needling-naïve subjects’ view on whether a sham needle penetrated the skin. The needling technique in their study did not, however, include “pistoning” as the practitioners did in our study. To the authors’ knowledge, no study has examined this particular type of sham TrP dry needling procedure.^{12,38} There have been many validation studies examining non-penetrating sham techniques in acupuncture research showing that these can be successful shams, particularly in subjects naïve to acupuncture.^{23,39-42} Of note, even the non-penetrating sham dry needling procedure may have some limited therapeutic effects as trigger point massage and myofascial release are treatments used for myofascial pain, and pistoning a guide tube over a trigger point, may affect the trigger point to a limited extent.

The main findings from this study demonstrate that this type of sham dry needling is an effective control for subjects naïve to dry needling. It was far less effective in subjects who had previously experienced dry needling; these subjects more reliably determined whether they received the true or sham needle. Of the participants who were naïve to dry needling, only one was able to correctly identify that they underwent true TrP dry needling. This was equal to the number of dry needling-naïve participants (1) who felt they

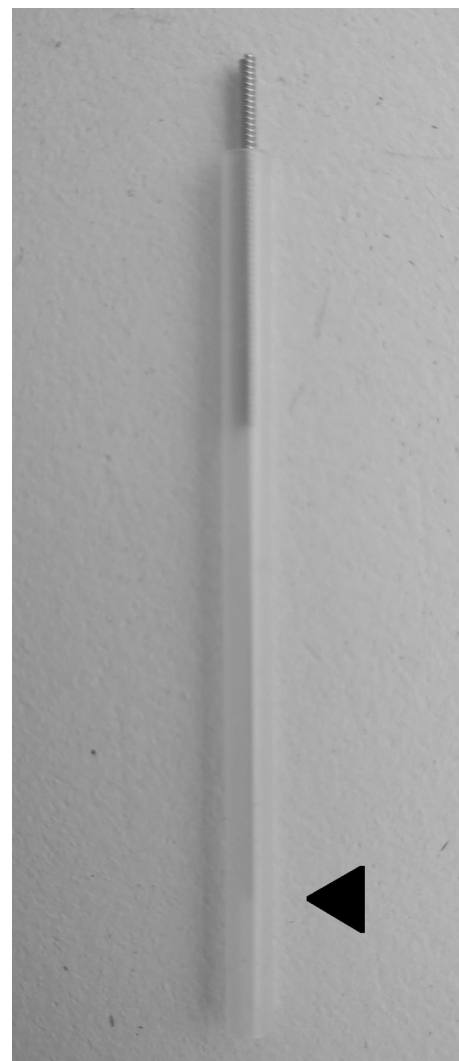


Figure 1: Sham dry needle apparatus. Arrowhead represents tip of needle.

received the true needling when in fact they received the sham. This was likely because the same introducer tube was used as in true TrP dry needling. An introducer tube alone without a needle has been shown to be difficult for participants to distinguish from true needling also using an intro-

ducer tube in other comparison trials.^{26,27,33,43}

The subjects who had prior experience with dry needling were more likely to be able to identify their assigned group. One likely reason was that the sham procedure did not cause the same sensation as what they previously received. Some studies have shown that participants are able to detect a difference in the “sharp” sensation of a needle versus a blunted tip,²⁶ whereas other studies show that subjects detect a “sharp” sensation equally with both blunted and true needle;^{29,31,32} this study did not specifically ask subjects for their definition of the sensation they felt. Some subjects experience secondary symptoms after TrP dry needling such as muscle aches³¹ and they might not necessarily experience this with a sham procedure. This study allowed for time to elapse for delayed-onset soreness, for which subjects who had previously received dry needling may have recognized. Some of the subjects may have received different types of dry needling in the past, perhaps using multiple needles, electrodes or other methods. This sham procedure was meant to mimic dry needling using an introducer tube and repeated passes with the needle to obtain a twitch response. The difference in method alone might have impacted their ability to correctly identify their group. The sham procedure also would not have elicited the twitch response that subjects might have experienced in the past.

This study was primarily limited by the smaller number of participants. Though the study was powered for 20 participants, only 17 naïve subjects were identified. However, it still demonstrated a significant finding. Second, the practitioners could not be blinded to the intervention given the nature of TrP dry needling, which could introduce bias from the practitioners, although blinding practitioners would likely not be feasible in the current study. Third, the technique used by the two practitioners, a physician and a physical therapist, may be different than used by other practitioners and may limit generalizability. For example, this sham method likely will not be usable for practitioners who use electrical stimulation through their needles. This technique used several needle passes, which diminishes electromyographic muscle activity,⁴⁴ and also likely contributes to improved clinical pain relief,^{37,45} but may cause in-

creased soreness initially from tissue trauma. Finally, the participants in this study were half-marathon and marathon runners and thus may not be fully generalizable to patients in other settings. The authors chose endurance runners capable of completing a half-marathon given their homogenous nature and their anecdotally high level of relief from myofascial treatments.

Given the aforementioned limitations, this study contains a number of strengths, in that the participants were blinded to the procedure and the study used an easily-reproducible, inexpensive sham needle technique. This study used a non-penetrating sham technique which could potentially decrease confounding effects of other sham techniques.

CONCLUSION

The results of this study indicate that a fixed needle in an introducer tube is a simple, inexpensive, effective sham procedure in patients who have never received dry needling before. These subjects were less able to identify if they received the sham or true TrP dry needling than the subjects who had experienced dry needling.

CONFLICT OF INTEREST

There are no conflicts of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

ETHICAL APPROVAL

Prior to the study, Institutional Review Board approval was obtained through the authors' home institution (IRB # 108243). All subjects signed written informed consent prior to undergoing study procedures.

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