Double-Blind Clinical Efficacy Study of Pulsed Phonophoresis on Perceived Pain Associated With Symptomatic Tendinitis

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The purpose of this study was to determine the clinical efficacy of dexamethasone-lidocaine (DX-L) phonophoresis on perceived pain associated with symptomatic tendinitis. Twenty-four subjects were randomly assigned to a DX-L or placebo phoresis group. All subjects received strengthening, stretching, and cryotherapy. Five double-blind sessions were administered over a 5- to 10-day period, with 24 to 48 hr between sessions. Perceived pain was quantified using a visual perceived pain scale (VPPS) and a punctate tenderness gauge (PTG). Data were collected before stretching, strengthening, and DX-L/placebo phoresis treatments, 1 min after treatment, and 10 min after cryotherapy. There were no significant differences for VPPS or PTG between groups. There was a significant difference between treatment sessions, regardless of group or test, and there were significant decreases in perceived pain between Tests 1 and 3 and between Treatment Sessions 1 and 5. It was concluded that stretching, strengthening, and cryotherapy significantly decreased the levels of perceived pain associated with symptomatic tendinitis regardless of whether the subjects received phonophoresis.

Tendinitis is a common inflammatory condition that is caused by overuse, resulting in repetitive microtrauma that leads to tendon disruption and degeneration (2, 17). The most common treatment techniques used to decrease the inflammation and pain associated with tendinitis are ice, soft tissue strengthening and stretching, manual techniques, and prescription medications (4, 37). Clinicians commonly combine these techniques in treating tendinitis.

Applying ice decreases acute inflammation by decreasing tissue metabolism and blood flow. Ice also decreases nerve conduction velocity, allowing a greater pain threshold (33, 37). Decreasing the tissue temperature of a structure while...
maintaining the tissue stretch may increase overall tissue elasticity, thus creating a stronger tissue (35). Conductive cooling via ice bag application is a convenient and effective method for subcutaneous tissue cooling (40).

Soft tissue strengthening and stretching are typically incorporated into the treatment protocol for tendinitis, with the target tissue being the entire muscle–tendon–bone unit (19). Strengthening and stretching techniques used early in the treatment of tendon injuries counteract the potential destructive biomechanical and mechanical changes resulting from the inflammation (19). Applying a parallel force to the tendon results in an orderly arrangement of the collagen fiber bundles and increases the tensile strength and range of motion (ROM) of the tissue (19, 35, 40). Eccentric and concentric training over a 7-week conditioning period increases isometric muscle tension (28). The combination of eccentric strengthening and static stretching has been shown to be effective in prevention and rehabilitation of tendinitis (13, 20).

Prescription medications may also be used to treat tendinitis. The medications may be nonsteroidal (NSAIDs) or steroidal anti-inflammatory drugs. These medications are administered orally, topically, or transdermally (e.g., percutaneous injections, iontophoresis, phonophoresis). Percutaneous injections deliver fluids through the skin and into the subcutaneous tissue via a syringe (6, 43). Anti-inflammatory drugs inhibit the synthesis of prosteoglandins to decrease the inflammation and pain of tendinitis (6, 43). However, NSAID and steroidal injections have numerous contraindications and adverse side effects (6, 20, 26, 41, 43).

Phoresing is a safe, noninvasive alternative to injections. Iontophoresis uses an uninterrupted direct current via an active electrode containing an ion solution (3, 33, 37). However, soft tissue burns are a potential adverse side effect of iontophoresis (37). To date, no research exists relative to the efficacy of iontophoresis treatment for symptomatic tendinitis. Phonophoresis involves the use of ultrasound as a transmission vehicle to drive topical medications through the skin into the subcutaneous tissue (37). Ultrasound is an acoustic device that utilizes mechanical vibrations at frequencies greater than 10,000 Hz to produce thermal and nonthermal effects (10). Ultrasound energy increases cell and skin tissue permeability, allowing the medication to enter the cell and produce an anti-inflammatory effect (22). The thermal, continuous mode of ultrasound increases nerve conduction velocity, increases blood flow, and produces a mild inflammatory reaction (21). These effects are unfavorable in the treatment of tendinitis. The nonthermal, pulsed mode of ultrasound phonophoresis increases tissue permeability without the increased blood flow that could carry the medication away from the affected area (9, 10, 21). Pulsed ultrasound phonophoresis produces favorable anti-inflammatory effects with minimal risk to the patient (10, 21, 38). Pulsed ultrasound phonophoresis has been shown to be an effective treatment for bursitis and myositis (8, 11, 22, 27). Further research is necessary to determine its efficacy in reducing the inflammation and pain associated with tendinitis (11, 33). The purpose of this study was to investigate the influence of pulsed phonophoresis with dexamethasone and lidocaine (DX-L) as a treatment modality for symptomatic tendinitis.
Methods

Subjects

Twenty-four athletes diagnosed with tendinitis of the shoulder \( n = 13 \), biceps \( n = 1 \), triceps \( n = 1 \), and knee \( n = 9 \) volunteered to participate. Subjects \( 17 \) male and 7 female, ages 18 to 25 years) were randomly divided into two groups: treatment and placebo. Subjects were randomly distributed with respect to gender and injury. Each subject read and signed an informed consent in accordance with the Institutional Review Board.

Instrumentation

Coupling Mediums. The medicated phonophoresis coupling medium consisted of 0.75-mg pulverized dexamethasone (DX) tablets, 2% viscous lidocaine, and 480 ml of blue Aquasonic 100 gel (Parker Laboratories, Inc., Orange, NJ). The placebo phonophoresis coupling medium consisted of the Aquasonic 100 gel only. Both the medicated and placebo phonophoresis coupling mediums were identical in color, odor, and viscosity to ensure a double-blind treatment protocol.

Ultrasound Unit. The Dynatron 150 ultrasound unit, Model DRF 100 (Dynatronics Corp., Salt Lake City, UT) was used for all aspects of data collection. The ultrasound applicator head had an effective radiating area of 5 cm², a beam nonuniformity ratio of 6.0, a frequency of 3 MHz, and duty cycles of 20, 50, and 100%. The unit was equipped with a digital treatment timer to control the duration of treatment.

Visual Perception Pain Scale (VPPS). The VPPS is a variation of the visual analogue scale developed by Melzack (32). It consists of a 10-cm line with endpoints of no pain/soreness (0) and extreme pain/soreness (10 cm). This device has been effectively used by researchers to assess muscle soreness (11, 18, 24).

Punctate Tenderness Gauge (PTG). The PTG (Technical Products Co., Caldwell, NJ) was used to assess point tenderness of the affected tendon. The PTG is a 2-mm metal probe, 9.5 mm in length, which is attached to a metal cylinder 12 mm in length. The pressure of the probe is controlled by a spring-loaded strain gauge; a small rubber ring indicates the tolerated pressure in ounces. A 1-cm closed-cell foam stopper was fastened to the end of the 2-mm probe in order to reliably reproduce tissue palpation. Previous researchers have used this device effectively (12, 24, 31).

Procedures

The primary investigator (C.E.P.) performed all measurements, administered all treatments, and recorded all data. Five treatments were administered via a double-blind protocol within a 5- to 10-day period, with 24 to 48 hr between treatment sessions. The only difference between the treatment group \( n = 12 \) and the control group \( n = 12 \) was that the treatment group received pulsed phonophoresis with a DX-L gel and the control group received pulsed ultrasound with Aquasonic gel
only. Both groups participated in exercise programs for the participants’ respective pathologies. This research design was selected because the subjects involved were all collegiate athletes, and withholding all treatment or just addressing the symptoms of the injury would have been unethical.

Test 1. Subjects were asked to place a vertical line on the VPPS relative to their immediate level of perceived pain. This mark was measured from the left endpoint (no pain = 0, extreme pain = 10) to the nearest 0.1 cm. PTG testing was always performed after VPPS testing. The most painful site on the involved tendon was identified via palpation, and a permanent marker was used to label this point. The PTG was positioned directly over this tender site and pressure was slowly applied to the point at which a sensation of discomfort changed to pain. This value was recorded in ounces.

Phonophoresis/Ultrasound Treatment. Ultrasound frequency was 3.0 MHz since the target tissues were less than 2–3 cm below the skin surface (21, 33). The intensity was 1.0 W/cm² at a 20% duty cycle for 5 min (10, 21, 33, 39). These parameters were selected to ensure that a nonthermal phonophoresis treatment would be administered. Based on the formula developed by Draper et al. (16) for a 3-MHz frequency, these parameters should yield less than a 0.6°C increase in tissue temperature.

To test the supraspinatus tendon, the subject was seated in a position of 70° of shoulder abduction and 10° of hyperextension, with the elbow comfortably flexed and the forearm resting in neutral. This position allowed optimal blood flow to the supraspinatus tendon (29).

To test the biceps and triceps tendons, the subject was seated with 0° of shoulder abduction, 0° of extension, and 10° of external rotation. The elbow was flexed to 90° with the forearm resting in neutral. This position allowed ease of palpation of the long tendon of the biceps through the intertubercular groove of the humerus (25) and of the common triceps tendon insertion onto the olecranon process of the ulna (5).

To test the infrapatellar and suprapatellar tendons, the subject was seated with the knee supported at 15° of flexion. This position allowed for optimal tendon palpation via relaxation of the surrounding musculature (5).

Test 2. VPPS and PTG measurements were taken 1 minute after the DX-L/placebo phonophoresis treatment. A new VPPS was used for each test.

Strengthening and Stretching Exercises. Strengthening exercises included two to three sets of 10 repetitions and were completed in accordance with each subject’s capabilities (2). Progressive resistance was provided via dumbbell weights. All stretching exercises were held for 30–40 s each (2).

Supraspinatus tendinitis exercises included shoulder abduction, flexion, external rotation in 70° of abduction and flexion, and abduction with internal rotation. Anterior capsular stretching was performed with the arm abducted to 70° and externally rotated in a doorway. The 70° angle was selected to avoid impingement, which occurs when the greater tuberosity of the humerus is forced against the
anterior-inferior acromial surface at 90° of abduction (29). Posterior capsule stretching was performed using the uninvolved hand to distract the involved arm across the chest (i.e., horizontal adduction).

Biceps tendinitis exercises included shoulder abduction to 90°, triceps extensions, horizontal abduction, and shoulder external rotation. Anterior and posterior capsular stretches were identical to those performed for supraspinatus tendinitis. In addition, wrist flexion and extension stretches were performed using the uninvolved hand to apply the passive stretch at the end of the ROM.

Infrapatellar and suprapatellar tendinitis exercises included straight leg raises into hip abduction, adduction, and flexion. Terminal knee extensions were performed through the last 15° of knee extension using an inclined board. Subjects performed a standard quadriceps stretch by using the ipsilateral hand to pull the foot posteriorly into knee flexion.

At the conclusion of the exercise routine, ice was applied to the injured tendon for 15 min.

Test 3. VPPS and PTG measurements were taken once again 10 min after the ice application. This time interval was allowed to permit the tissue temperature to recover.

Data Analysis

VPPS and PTG data were recorded three times (i.e., Tests 1, 2, and 3) throughout a total of five treatment sessions. Two $2 \times 5 \times 3$ ANOVAs with repeated measures were used to analyze the dependent variable of perceived pain ($p < .05$). The Biomedical Data Program Statistical Software was used for data analyses (15). Tukey post hoc tests (7) were performed when significant main effects were revealed to determine where differences occurred.

Results and Discussion

VPPS means and standard deviations for DX-L and placebo phonophoresis treatment groups throughout tests and treatment sessions are presented in Table 1. The ANOVA for VPPS data revealed a significant difference between sessions ($F = 7.38, p < .00$) and between tests ($F = 31.07, p < .00$). PTG means and standard deviations for DX-L and placebo phonophoresis treatment groups are displayed in Table 2. Likewise, the ANOVA for PTG data revealed a significant difference between sessions ($F = 19.47, p < .00$) and between tests ($F = 71.40, p < .00$). VPPS and PTG $F$ values revealed no significant differences ($p < .05$) between DX-L and placebo phonophoresis treatment groups regardless of test or session. Tukey post hoc tests for VPPS and PTG data indicated significant ($p < .05$) decreases in perceived pain between Tests 1 and 3 and Treatment Sessions 1 and 5. VPPS and PTG $F$ values did not reveal any interactions among tests, among treatment groups, or between treatment groups.
The results of this study provide very interesting clinical insights. First we will compare tests within treatment sessions, then compare treatment sessions, and finally look at the overall treatment protocol.

Perceived pain levels did not significantly change between Tests 1 and 2 but did significantly change from Test 1 to Test 3. The VPPS values decreased whereas the PTG values increased from Test 1 to Test 3. At first glance this may appear to
be a contradiction. However, these data are consistent because as pain level declines, the amount of pressure that an individual will tolerate from the PTG increases. Although the plasma half-life of DX is 110 min (1.8 hr) to 210 min (3.5 hr), lidocaine has a biphasic half-life with a distribution phase of approximately 7 min and an elimination phase of 1.5 to 2 hr (42). The total treatment time from Test 1 to Test 2 was 25 to 30 min and from Test 1 to Test 3 was 50 to 55 min. Therefore, we expected that the impacts of lidocaine on perceived pain would be noted by Test 3 of the phonophoresis treatment group. In addition, Test 3 was conducted 10 min after ice application and an anesthetic effect may have remained, whereas the impacts of DX should have been apparent between treatment sessions. The fact that it was not may have been influenced by the exercise program, but Ciccone et al. (11) and Oziomek et al. (36) did not find a significant effect of trolamine-salicylate phonophoresis on delayed-onset muscle soreness (DOMS) either.

Perceived pain measured via VPPS and PTG decreased from the first to the fifth treatment sessions in both treatment groups. However, results were not significant between individual Treatment Sessions 1 and 2, 2 and 3, 3 and 4, 4 and 5, or even 2 to 5 or 1 to 4. Therefore, treatment efficacy (i.e., decreased pain) associated with tendinitis should not be assessed in a period of less than 5 to 10 days.

As previously stated, the results of the present study indicated no significant differences between treatment groups for VPPS and PTG measurements regardless of tests or treatment sessions. These results are in contrast with all but one of the phonophoresis treatment studies performed previously (8, 11, 14, 22, 23, 27, 34). Ciccone et al. (11) also reported no significant difference in DOMS as measured via Visual Analogue Scale (VAS) and ROM between subjects treated with trolamine salicylate phonophoresis and those subjects treated with placebo phonophoresis. Most of the studies that revealed results contrasting with the present study involved the use of rabbits, pigs, and dogs to investigate the capacity of phonophoresis to drive medications through the skin and into the subcutaneous tissues (8, 14, 34). Byl et al. (8) reported significant interactions in collagen deposition following continuous mode DX phonophoresis to pigs at an intensity of 1.5 W/cm². Hydrocortisone (HC) phonophoresis and DX and HC medications administered topically did not significantly impact collagen deposition or cellular activity when compared to placebo phonophoresis. Novak (34) investigated the level of lidocaine concentration in the excised quadriceps muscles of rabbits following phonophoresis and found higher intramuscular concentrations of lidocaine in rabbits treated with continuous 2 W/cm² phonophoresis than those treated with topical lidocaine. Davick et al. (14) investigated the cortisol concentrations in the stratum corneum of dogs and found higher concentrations in dogs treated with 0.5 W/cm² HC phonophoresis for 8 min than placebo phonophoresis. The lower intensity treatment chosen by Davick et al. (14) is considered safer and less irritating to an existing inflammatory state (21, 37). The above studies have proven phonophoresis to be an effective means of driving medication into subcutaneous tissue; however, the higher intensities (1.5–2.0 W/cm²) in a continuous mode may create a thermal reaction, irritating the existing tendinitis and/or burning the skin (33, 37).
Griffin et al. (22) and Kleinkort and Wood (27) investigated the efficacy of cortisol phonophoresis in the treatment of pain associated with bursitis, arthritis, and tendinitis. Griffin et al. (22) administered a 5-min continuous-mode phonophoresis at 1.5 W/cm² with 10% HC to 102 patients. Sixty-eight percent (42/66) of the patients treated with HC reported significant decreases in pain, while only 28% (10/36) of the patients treated with placebo phonophoresis reported significant decreases in pain. Kleinkort and Wood (27) also used a large sample (N = 285) of subjects presenting with tendinitis, bursitis, arthritis, and fasciitis to investigate the efficacy of HC phonophoresis treatment applied at 2.0 W/cm². Eighty percent of those patients treated with 1% HC reported significant decreases in pain, and 94.7% of those subjects treated with 10% HC phonophoresis reported decreases in pain following treatment. The authors concluded that the higher intensity created a thermal effect to allow greater medication penetration secondary to increased cell permeability. In addition, the large sample size of these studies (22, 27) may have been instrumental in obtaining the significant results. The phonophoresis protocol in these studies involved a notably higher intensity than that of the present study. Considering the dosage (min-W/cm²) of all of the studies discussed and the use of continuous versus pulsed phonophoresis, it becomes apparent that the dosage of the present study was considerably lower (1.0 min-W/cm²) than in those studies that reported successful pain reduction (4.0–10.0 min-W/cm²). Perhaps the lower dosage was not adequate to phorese a therapeutic level of medication.

The efficacy of phonophoresis treatment depends on the ultrasound energy that is transmitted through the coupling medium and into the skin and subcutaneous tissue (9). Cameron and Monroe (9) investigated the capacity of various coupling media to transport ultrasound energy through the skin to subcutaneous tissues. Ultrasound was applied under water at intensities of 1.5 W/cm² and quantified with an Ohmic UPM-30 power meter. Results indicated low ultrasound energy transmission rates with 1% and 10% HC powder and with 10% HC cream mixed with an equal weight of ultrasound gel. High (>87%) ultrasound transmission rates were revealed with ultrasound gel, ultrasound lotion, and 0.05% Betamethasone mixed with ultrasound gel. The Betamethasone coupling medium texture, viscosity, and chemical effects resemble the DX coupling medium used in the present study. Therefore, we expected high ultrasound transmission rates in the present study.

All of the subjects in the present study received strengthening, stretching, and ice treatment and reported a decrease in the pain associated with tendinitis regardless of whether they received phonophoresis or placebo phonophoresis treatment. Both of these techniques have been used successfully to treat chronic overuse injuries (1, 13, 19, 28) and pathologies associated with the muscle–tendon unit (40). Previous authors have reported success in treating tendinitis with closed-chain strengthening exercises combined with static stretching (13, 19). Likewise, Almekinders and Almekinders (1) retrospectively studied strengthening, stretching, and NSAID treatment for chronic overuse injuries and found a 71.4% de-
crease in signs and symptoms. All of these findings are consistent with the present study. Unfortunately, no single treatment could be unequivocally identified as the most important treatment modality. One might find more definitive results regarding a hierarchy of modalities for the treatment of tendinitis if the present study was repeated with various combinations of phonophoresis, ultrasound, stretching, strengthening, and cryotherapy and a control group that receives no treatment at all. However, ethical issues surface when treatment is withheld from an injured competitive athlete.

Conclusions

Strengthening, stretching, and cryotherapy decreased the perceived pain associated with tendinitis after 35 to 40 min within 5 to 10 days, regardless of whether phonophoresis or placebo phonophoresis was administered. Without a method of analyzing whether the DX or lidocaine penetrated through the skin to a therapeutic level, we are not able to conclude that the ultrasound was effective in phoresing the medication. Therefore, we have embarked on a phonophoresis study to do precisely that. In a study presently underway, we are looking at the depth of penetration of DX via various phonophoresis dosages. These results are still pending and will be shared in the literature as soon as the study is completed.

References


