Dry Needling Versus Cortisone Injection in the Treatment of Greater Trochanteric Pain Syndrome: A Noninferiority Randomized Clinical Trial

Greater trochanteric pain syndrome (GTPS) is the current terminology for what used to be called greater trochanteric or subgluteal bursitis. Characterized by chronic, intermittent pain accompanied by tenderness to palpation overlying the lateral aspect of the hip, GTPS is estimated to affect 10% to 25% of the general population. The incidence has been reported to be higher in women and patients with coexisting low back pain, osteoarthritis, iliotibial band tenderness, and obesity. The change in nomenclature was due to findings that, in most cases, contractile tissues, not the bursa, are injured, and that inflammation is often not involved. Greater trochanteric pain syndrome may include a number of disorders involving the lateral hip, such as bursitis, gluteal tears, external coxa saltans (snapping hip), and trigger points in contractile tissue crossing the hip.

Cortisone injection into the lateral hip has traditionally been the accepted treatment for this condition. Because the medical community agrees that the etiology of GTPS is not necessarily the bursa around the greater trochanter, injecting the bursa with a steroid is not as beneficial as once thought. Furthermore, corticosteroid injections pose potential concern for providers and patients. The adverse effects of steroid injections are poorly quantified, but clinically significant adverse side effects, such as osteonecrosis, osteomyelitis, hallucinations, and death, have been documented. Dry needling (DN), whereby filament needles are used to stimulate functional tissue, is recognized as a safe and effective treatment for pain.

STUDY DESIGN: Prospective, randomized, partially blinded.

BACKGROUND: Greater trochanteric pain syndrome (GTPS) is the current terminology for what used to be called greater trochanteric or subgluteal bursitis. Cortisone (corticosteroid) injection into the lateral hip has traditionally been the accepted treatment for this condition; however, the effectiveness of injecting the bursa with steroids is increasingly being questioned. An equally effective treatment with fewer adverse side effects would be beneficial.

OBJECTIVE: To investigate whether administration of dry needling (DN) is noninferior to cortisone injection in reducing lateral hip pain and improving function in patients with GTPS.

METHODS: Forty-three participants (50 hips observed), all with GTPS, were randomly assigned to a group receiving cortisone injection or DN. Treatments were administered over 6 weeks, and clinical outcomes were collected at baseline and at 1, 3, and 6 weeks. The primary outcome measure was the numeric pain-rating scale (0-10). The secondary outcome measure was the Patient-Specific Functional Scale (0-10). Medication intake for pain was collected as a tertiary outcome.

RESULTS: Baseline characteristics were similar between groups. A noninferiority test for a repeated-measures design for pain and averaged function scores at 6 weeks (with a noninferiority margin of 1.5 for both outcomes) indicated noninferiority of DN versus cortisone injection (both, P<.01). Medication usage (P = .74) was not different between groups at the same time point. No adverse side effects were reported.

CONCLUSION: Cortisone injections for GTPS did not provide greater pain relief or reduction in functional limitations than DN. Our data suggest that DN is a noninferior treatment alternative to cortisone injections in this patient population.


KEY WORDS: glucocorticoid injection, hip pain, methylprednisolone acetate, trigger point dry needling, trochanteric bursitis
sensitive loci (trigger points) in the muscles, has shown potential in treating soft tissue injury and neuromyofascial pain with minimal risks.\textsuperscript{7,10,16,23-25,28,30,45}

Evidence suggests that analgesic injection is not superior to DN in other regions of the body.\textsuperscript{17,21,46} Therefore, it is possible that cortisone injection for GTPS is not superior to DN. If DN is equally or more effective in treating GTPS than cortisone injection, then effective patient care could be delivered without subjecting patients to the harmful effects of steroids. This would not only avoid any detrimental effects of steroids in these patients, but would also provide an equally effective alternative treatment for individuals with contraindications to steroid injection and for those who do not respond positively to cortisone injection.

The purpose of this study was to explore whether administration of DN is equally effective as cortisone injection in reducing lateral hip pain and improving function in patients with GTPS. We hypothesized that there would be no difference between DN and cortisone injection in reducing lateral hip pain and improving function in this patient population.

**METHODS**

**Participants**

Participants (N = 43) were all patients treated by providers within the orthopaedic department of the Baylor Scott & White Health, Roney Bone and Joint Institute between May 2013 and July 2015. There were 21 participants in the DN group and 22 in the cortisone injection group, and a total of 50 hips observed. Participant demographics are reported in TABLE 1. The study was approved by the Institutional Review Board of Baylor Scott & White Health. All subjects provided informed consent prior to study enrollment and their rights were protected. The trial was registered at www.clinicaltrials.gov (NCT02639039).

Inclusion criteria were being 18 years of age or older, having lateral hip pain (pain anywhere from the iliac crest to the mid iliotibial band), and having an active e-mail account. Exclusion criteria were low back pain associated with hip pain, motor and/or sensory impairment consistent with radiculopathy, active infection or malignancy of the hip, connective tissue disease, lack of proficiency in spoken English, and pregnancy.

**Randomization/Blinding**

The patients were randomized in blocks to either the DN or cortisone injection treatment (n = 10 per block). The block randomization was used to reduce the variability between treatment groups and to reduce bias.\textsuperscript{18} The randomization schedule was provided by a biostatistician, performed using SAS Version 9.2 (SAS Institute Inc, Cary, NC). Once the patient consented to participate in the study, he or she was allocated to either the DN or cortisone injection group, according to the randomization scheme provided by the biostatistician to an independent study research coordinator, to provide allocation concealment. The independent study research coordinator was not blinded to group allocation.

Patients were not told which treatment they would receive, and were instructed to schedule treatment with a specific provider. Despite not being told which group they were in, patients could identify their group allocation and therefore were not blinded.

**Participant Flow**

The study protocol was approved for recruitment of 50 subjects (25 per group). At one point during data collection, 2 subjects withdrew from the DN group, and a request for site enrollment of an additional 2 subjects was approved by the Institutional Review Board. The group assignment of subjects continued according to the original allocation list, and once the cortisone injection group was assigned its final subject, the subsequent subjects were allocated to the DN group, the group from which the previous subjects withdrew.

**Outcome Measures**

The numeric pain-rating scale (0-10) and Patient-Specific Functional Scale (PSFS; 0-10) at 6 weeks following initial treatment were the primary and secondary outcome measures, respectively. The PSFS metric allows patients to identify up to 5 tasks that are most limited by a specific body part (in this study, the hip). The patient assigned a score to each task he or she designated, ranging from 0 (unable to perform activity) to 10 (able

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Demographic and Baseline Characteristics*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Variable</strong></td>
<td><strong>Dry Needling(^1)</strong></td>
</tr>
<tr>
<td>Number of hips treated, n (%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>17 (80.9)</td>
</tr>
<tr>
<td>2</td>
<td>4 (19.1)</td>
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<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (9.5)</td>
</tr>
<tr>
<td>Female</td>
<td>19 (90.5)</td>
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<tr>
<td>Side treated, n (%)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>11 (44.0)</td>
</tr>
<tr>
<td>Left</td>
<td>14 (56.0)</td>
</tr>
<tr>
<td>Age, y</td>
<td>61.3 ± 16.5</td>
</tr>
<tr>
<td>Body mass index, kg/m(^2)</td>
<td>31.0 ± 6.4</td>
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</tbody>
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*Values are mean ± SD unless otherwise indicated.
\(^1\)n = 21 patients, 25 hips.
\(^2\)n = 22 patients, 25 hips.
to perform activity at the same level as before injury or problem). The final score was weighted, and the weights were calculated as the number of times the repeated function appeared, divided by the total number of functions the patient listed.

Medication intake for pain in the involved hip, sex, age, and body mass index were collected as covariables.

**Time Frame for Measurements**

Measurements were taken at baseline (within 24 hours prior to initial treatment) and at 1, 3, and 6 weeks after initial treatment. Data were collected at the initial and follow-up appointments or by email. The outcome scales were explained and collected by a third-party research coordinator. Instructions for answering the scales were read to the patient at every data-collection period.

**Treatment Groups**

**Dry Needling** Treatment was initiated during the first visit. Exact location of needle insertion and number of penetrations within the region of the involved posterolateral hip were determined by the treating therapist. The DN procedure is outlined in TABLE 2. All patients in this group were treated by the same investigator, who was certified in DN, had 17 years of clinical practice experience, and 4 years of experience in DN. The number of follow-up visits within 6 weeks of initiation of study treatment was determined by the therapist. Dry needling was the only form of treatment administered.

**Cortisone Injection** Treatment was carried out during the first visit. Exact location and technique of injection within the region of the involved greater trochanter were determined by the provider. Injection prescription and technique are outlined in TABLE 3. Injections were performed by 1 of 3 orthopaedic surgeons or by 1 of 2 physician assistants. The number of follow-up visits within 6 weeks of initiation of study treatment was determined by the provider. Cortisone injection was the only form of treatment administered.

**Sample-Size Determination**

The goal of this study was to investigate the use of DN as a noninferior alternative to cortisone injection, with pain as the primary outcome. A 2-sample t test for noninferiority was used, with a noninferiority margin of 1.5, a standard deviation of 2, and a true difference of zero.1,3,4,6,7,8,9,20,22

For the PSFS, it was assumed that a difference of 3 units was of clinical significance.1,8,9,20,22 The sample size was calculated for a significance level of .05 and 80% power. The resulting sample size was 23 observations (hips) per arm. Assuming a dropout of 5%, the target sample size was 25 observations (hips) per arm. These calculations were done with PASS 13 (NCSS, LLC, Kaysville, UT).

**Data Analysis**

Descriptive statistics are reported for baseline characteristics and demograph-
**TABLE 1**

| Function | Averaged and weighted PSFS scores between the 2 groups did not differ at 6 weeks. The mixed-effects model using time and treatment as covariates indicated that time was statistically significant (P < .01), but not treatment (P = .63). Sex and age were considered in the model, but were not significant (both, P = .17), so were not included in the final model. The noninferiority test with a 1.5 noninferior margin from the mixed model found DN to not be inferior to cortisone injection, with a difference of 0.2 (95% CI: −0.57, 0.96; P < .01). The maximum difference in function scores of −1.3 ± 2.5 was observed between the groups at 1 week (FIGURE 2).

**Medication Intake**

Medication intake for pain associated with the involved hip did not differ between the 2 groups at 6 weeks (P = .74) or at any other time (P = .19 at 1 week; P = .11 at 3 weeks).

**Details of Functional Deficits**

While analysis of the nature of functional limitations was not an aim of this study,

**RESULTS**

**Baseline Characteristics and Demographics**

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**FIGURE 1**

Average pain scores by group over time. Abbreviation: VAS, visual analog scale.

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we did characterize the functional limitations as listed by the subjects (FIGURE 3). Due to the variability in possible answers inherent to this metric, we stratified functions into 7 categories: locomotion, closed chain, lying on the involved side, lying on the uninvolved side, sitting, other, and bending over.

Adverse Effects
No adverse effects were observed by the clinicians or reported by any of the subjects for either group. The typical side effects associated with needle penetration/injection, such as temporary pain, bruising, and posttreatment soreness, were not documented as adverse effects.

DISCUSSION
Greater trochanteric pain syndrome is a fairly common condition that encompasses a number of potential etiologies. Historically, the clinical presentation of GTPS was attributed to bursitis and often treated with cortisone injection. More recent evidence has indicated pathology/dysfunction of other structures of the posterolateral hip/pelvis and led to other interventions. In this study, we sought to explore whether DN, which does not involve pharmaceutical administration, would result in clinical outcomes that were not inferior to those of cortisone injection and DN in patients with GTPS. Our results indicated that there was no inferiority in the clinical outcomes of pain and function between cortisone injection and DN in patients with GTPS. This study is the first to directly compare these 2 treatments for GTPS.

The mechanism by which DN is effective in pain reduction and improved function is not fully understood, but researchers have discovered biochemical, neurologic, vascular, and clinical changes effected through this technique. Shah and Gilliams found significantly elevated levels of inflammatory and pain biochemicals (P < .01) and lower pH (P < .02) in the blood surrounding active trigger points in the upper trapezius muscle when compared with subjects with latent or no trigger points in the upper trapezius. Following DN, subjects with active trigger points had significantly lower levels of substance P and calcitonin gene-related peptide (P < .02), both of which are chemicals associated with pain. Simons et al recorded end-plate noise at myofascial trigger points (MTrPs), which was significantly elevated compared with sites outside of the MTrP but within the end plate. One MTrP (experimental) site and 2 non-MTrP (control) sites were identified in 11 muscles in 10 subjects. One of the control sites was within the end plate but outside of the trigger point. The other control site was a taut band, outside of the end plate. End-plate noise without spikes was recorded in all 11 MTrPs, 4 of the control sites within the end plate (P = .024), and none of the control sites outside of the end plate (P < .001). These data indicate consistently increased motor excitability of MTrPs. Ge et al measured lower H-reflex thresholds (P < .001) and higher amplitudes (P < .001) in MTrPs than in non-MTrPs in 13 of 13 subjects, indicating elevated gain in the anterior motor horn and increased spindle excitability of the segments coinciding with the MTrPs. These findings offer more evidence of discrete elevated motor activity within the muscle, but also a spinal segmental etiology. In keeping with this finding of segmental excitability associated with MTrPs, Srbely et al demonstrated an immediate increase in pressure pain threshold in the infraspinatus (P < .015), but not the gluteus medius muscles, of subjects following 1 session of trigger point DN to an active MTrP in the supraspinatus. Furthermore, Skorupska et al reported vasodilation in the region of referred pain in 16 subjects who underwent DN for subacute sciatic pain, suggesting sympathetic nervous activity in the myofascial pain mechanism. Data such as these have bolstered the theory originally put forth by Simons et al and expounded upon by Gerwin et al that MTrPs are discrete painful loci in the muscles due to altered motor end-plate activity, leading to tonic fiber contraction, local ischemia, myofiber injury, and biochemical imbalance.

Other studies have reported good improvement in pain and function when the
active MTrP was treated and when remote latent MTrPs, not necessarily in the same neurologic segment, were treated. In a randomized controlled trial, Fernández-Carnerro et al reported pain-free jaw opening range of motion (P < .001) and decreased pressure pain threshold in the masseter (P < .001) and mandibular condyle (P < .001) after 2 sessions of DN, 7 days apart. In a randomized controlled trial of 41 patients with a whiplash diagnosis, 20 were treated with DN to active MTrPs and 21 underwent sham treatment with blunted needles to these same points. At the end of the 6-week trial, significantly more patients who were treated with DN had stopped taking analgesics (P = .04). In a study by Tsai et al, 35 patients with unilateral active MTrPs in the trapezius were randomly divided into a DN group (n = 17), whose participants received DN into a latent MTrP in the ipsilateral extensor carpi radialis brevis muscle, and a sham group (n = 18), whose participants received a sham DN procedure into the ipsilateral extensor carpi radialis brevis. After a single treatment, the DN group demonstrated significantly decreased pain (P < .05), increased pressure pain threshold in the trapezius (P < .05), and increased cervical range of motion (P < .05) compared with the sham group.

Decreased pain and improved function following steroid injections in patients with GTPS have also been reported. In an uncontrolled study, Ege Rasmussen and Fano injected 36 hips in 33 patients with methylprednisolone or triamcinolone hexacetonide, interchangeably. After 1 to 3 injections, patients reported excellent results in 25 hips and improvement in 11 hips. Shbeeb and Matteson randomly allocated 75 patients with a diagnosis of trochanteric bursitis to receive 1 of 3 conventional doses of betamethasone sodium phosphate/betamethasone acetate suspension. In 20, 32, and 22 patients, injections of 6, 12, and 24 mg of betamethasone, respectively, mixed with 4 cm³ of 1% lidocaine, were administered. Patients completed a functional questionnaire and visual analog scale for pain at 1, 6, and 26 weeks postinjection. The only significant finding was that patients treated with the highest dosage of betamethasone were more likely to experience pain relief when compared with lower doses (P < .012). In an uncontrolled study, Brinks et al studied 120 participants and divided them into 2 groups: patients who took oral analgesics as needed (control group) and those who received an injection containing 40 mg of triamcinolone acetate combined with 1% to 2% lidocaine. Patients were then examined at 3- and 12-month follow-up visits, with pain severity at rest and during activity (numeric rating scale, 0-10) and recovery (yes or no total or major recovery) being the primary outcome measures. At 3 months, the 2 groups reported clinically relevant differences in both measures: 55% recovery in the injection group and 34% recovery in the group taking oral analgesics, with a greater decrease in pain severity in the injection group. However, after 12 months, differences between the 2 groups were no longer present, with the injection and oral analgesic groups posting a 61% and 60% recovery, respectively, as well as similar decreases in pain severity.

Our findings are consistent with studies comparing injection therapy with some form of DN. de Abreu Venancio et al compared the treatment effects of botulinum injection, lidocaine injection, and DN in 45 patients with headaches who were randomly assigned to 1 of 3 groups. All 3 treatment groups produced significant improvement (P < .05) in pain intensity, duration, and frequency, along with obtaining time and duration of relief. No statistical difference was noted among the groups for any of these outcomes. Hong studied the effects of injection with lidocaine (group 1) versus DN (group 2) into an MTrP within the upper trapezius muscle of 58 patients. Thirty-five patients received lidocaine injection, while 23 received DN. Local twitch response (LTR) was elicited in 26 patients in group 1 and 15 patients in group 2. An LTR was not elicited in 9 patients within group 1 (group 1a) and 8 patients within group 2 (group 2a). Treatment was readministered to these 17 patients according...
to their original group allocation, and LTR was elicited in all. Both groups 1 and 2 significantly improved in pain intensity, pressure pain threshold, and cervical range of motion immediately after 1 treatment (P<0.05). Group 1a reported significant reduction in pain after the initial treatment, but otherwise, groups 1a and 2a did not improve significantly after the first treatment, but did after the second (P<0.05). Hong3 concluded that the elicitation of an LTR is more important than whether one chooses lidocaine or DN for treating MTrPs. Neither of these studies found superior outcomes with the administration of cortisone injection compared with DN.

Ga et al7 did report superior outcomes with the administration of DN compared with cortisone injection. In a single-blinded, randomized study of 39 patients diagnosed with myofascial pain syndrome of one or both upper trapezi, Ga et al7 documented improvement in pain scores, cervical range of motion, pressure pain threshold, and depression for patients receiving lidocaine injection and for those receiving DN, but none of the improvements were statistically significant. As the 3 previously mentioned studies involved treatment to the cervical spine region only, they do not offer direct comparison to outcomes in the hip.

While the literature does address the use of cortisone injection for treatment of GTPS, we found only a case series28 and case report29 describing the effect of DN to treat GTPS. No experimental studies investigating the response of pain or function in patients with GTPS when treated with DN, or studies comparing the effects of DN with those of cortisone injection in patients with GTPS, were found, so no comparison to our data can be made.

This study has limitations. First, a sham DN procedure was not applied, so the degree of partial blinding is questionable. Additionally, because both groups received treatment, we cannot comment on the placebo effect. Second, DN was performed by a single provider, whereas cortisone injection was provided by 1 of 5 possible providers. This presents the issue of inherent variability in the treatment application within the cortisone injection group, but not the DN group. Furthermore, while the sample size was greater than most experimental studies on this topic, a larger sample size would allow smaller CIs. Last, in an effort to control variables, this study did not allow adjunct treatments, and provides evidence for 6-week outcomes only. Whether DN is a sufficient, stand-alone treatment for alleviation of pain and return to normal function in patients with GTPS over the long term is not addressed. Given the nature of suspected etiologies, we recommend experimental investigation of DN in conjunction with neuromuscular re-education over a longer period.

Currently, evidence for DN of the hip in lieu of steroid injection is in its infancy. The current study suggests DN as an effective alternative to cortisone injection, and utilizes a larger sample than most, but further studies are warranted. The potential detrimental side effects of steroid injection, particularly repeated injections, are of concern for patients and providers alike. Furthermore, steroid use is contraindicated in the presence of certain medical conditions, and some patients do not respond positively to cortisone injection. Identification of a noninferior treatment alternative with minimal side effects, such as DN, offers valuable clinical advantages.

CONCLUSION

Cortisone injection to the lateral hip for GTPS did not provide greater pain relief or reduction in functional limitations than DN. The patient demographics in this study were homogeneous between groups, and the sex, age, and body mass index distributions are consistent with previously documented characteristics of patients with GTPS. Our data suggest that DN may be a viable treatment alternative to cortisone injection in this patient population.

KEY POINTS

FINDINGS: Dry needling to the lateral hip for GTPS was not inferior to cortisone injection for the outcomes of pain relief or reduction in functional limitations after 6 weeks.

IMPLICATIONS: Dry needling may be a viable treatment alternative to cortisone injection in this patient population.

CAUTION: Participants were followed for 6 weeks, so the maintenance of, or any further change in, pain or function beyond that time frame was not recorded for either group.

REFERENCES


