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Clinical Study

Spinal manipulation and electrical dry needling as an adjunct to conventional physical therapy in patients with lumbar spinal stenosis: a multi-center randomized clinical trial

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Abstract

BACKGROUND CONTEXT: Nonoperative management of lumbar spinal stenosis (LSS) includes activity modification, medication, injections, and physical therapy. Conventional physical therapy includes a multimodal approach of exercise, manual therapy, and electro-thermal modalities. There is a paucity of evidence supporting the use of spinal manipulation and dry needling as an adjunct to conventional physical therapy in patients with LSS.

PURPOSE: This study aimed to determine the effects of adding thrust spinal manipulation and electrical dry needling to conventional physical therapy in patients with LSS.

STUDY DESIGN/SETTING: Randomized, single-blinded, multi-center, parallel-group clinical trial.

PATIENT SAMPLE: One hundred twenty-eight (n=128) patients with LSS from 12 outpatient clinics in 8 states were recruited over a 34-month period.

OUTCOME MEASURES: The primary outcomes included the Numeric Pain Rating Scale (NPRS) and the Oswestry Disability Index (ODI). Secondary outcomes included the Roland Morris Disability Index (RMDI), Global Rating of Change (GROC), and medication intake. Follow-up assessments were taken at 2 weeks, 6 weeks, and 3 months.

FDA device/drug status: Not applicable.

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METHODS: Patients were randomized to receive either spinal manipulation, electrical dry needling, and conventional physical therapy (MEDNCPT group, n=65) or conventional physical therapy alone (CPT group, n=63).
RESULTS: At 3 months, the MEDNCPT group experienced greater reductions in overall low back, buttock, and leg pain (NPRS: F=5.658; p=.002) and related-disability (ODI: F=9.921; p<.001; RMDI: F=7.263; p<.001) compared to the CPT group. Effect sizes were small at 2 and 6 weeks, and medium at 3 months for the NPRS, ODI, and RMDI. At 3 months, significantly (p=.003) more patients in the MEDNCPT group reported a successful outcome (GROC≥+5) than the CPT group.
CONCLUSION: Patients with LSS who received electrical dry needling and spinal manipulation in addition to impairment-based exercise, manual therapy and electro-thermal modalities experienced greater improvements in low back, buttock and leg pain and related-disability than those receiving exercise, manual therapy, and electro-thermal modalities alone at 3 months, but not at the 2 or 6 week follow-up.

Keywords: Dry needling; Exercise; Lumbar; Mobilization; Spinal manipulation; Stenosis

Introduction

Lumbar spinal stenosis (LSS) is described as the narrowing of space surrounding the neurovascular structures of the spine [1], resulting in pain, cramping, and lower extremity weakness that is worsened with standing, walking, and lumbar extension [2,3]. The estimated prevalence of LSS is 9% among the general population [4], but it is the most common reason for spinal surgeries among patients over 65 years-old in the United States [5,6]. The diagnosis of LSS is typically made via radiologic and clinical findings, and treatment typically includes physical therapy (PT), spinal manipulation, medication, steroid injection, and spinal decompression surgery [1,7]. While medication and injections may provide temporary relief in the early stage of the condition, there is limited evidence supporting either of these treatments for LSS in the long-term [7−9]. Spine surgery has also been shown to have limited long-term satisfaction, however, it does seem to be an effective option in select patients with LSS who do not improve with conservative management [1,7,9]. A number of studies have shown efficacy for conventional PT, including exercise and spinal manipulative therapy [1,10−12], however, the literature to date regarding the efficacy of electrical dry needling (DN) in this patient population is very limited [13,14]. Furthermore, to date, no clinical trials have compared conventional physical therapy (CPT)—ie, nonthrust spinal/extremity mobilization, exercise, and electro-thermal modalities—with CPT plus electrical DN and thrust spinal manipulation (MEDNCPT) in the management of patients with LSS. Therefore, the purpose of this study was to compare the changes in outcomes (pain and disability) in conventional PT (nonthrust spinal/extremity mobilization, exercise and electro-thermal modalities) to conventional PT plus electrical DN and thrust spinal manipulation. We hypothesized that patients in the MEDNCPT group would exhibit greater improvements in pain and related-disability than those patients in the CPT group.

Methods

Study design

This randomized, single-blinded, multicenter, parallel-group trial compared 2 treatment protocols for the management of LSS: thrust spinal manipulation, electrical DN, and conventional PT (MEDNCPT) versus conventional physical therapy (CPT). The current clinical trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) extension for pragmatic clinical trials [15]. The study was approved by the ethics committee at Universidad Rey Juan Carlos, Madrid, Spain, (URJC-DPTO11-2017), and the trial was prospectively registered (ClinicalTrials.gov NCT03167736).

Participants

Consecutive individuals with LSS from 12 outpatient PT clinics across the United States were screened for eligibility criteria and recruited over a 34-month period (June 2017−March 2020). For patients to be eligible, they had to be ≥50 years-old and meet the following criteria: [11] (1) Symptoms of neurogenic claudication (pain in the buttock, thigh, or leg during ambulation that improves with rest) or radicular leg symptoms with associated neurological deficits on physical examination for at least 12 weeks and (2) confirmatory imaging (ie, magnetic resonance imaging, computed tomography, myelography, ultrasound, or radiographic images of either central [ie, spinal canal] or lateral [ie, foraminal] lumbar stenosis at one or more levels in the lumbar spine).

Patients were excluded if any of the following criteria were present: (1) potential contraindications to manual therapy (eg, severe hypertension, infection, ankylosing spondylitis, neoplasm, uncontrolled diabetes, peripheral neuropathy, heart disease, stroke chronic ischemia, edema, severe varicosities, tumor, metabolic disease, prolonged

steroid use, fracture, rheumatoid arthritis, osteoporosis, severe vascular disease, malignancy, etc.); (2) severe vascular, pulmonary, or coronary artery disease limiting participation in exercise, to include walking; (3) severe degenerative stenosis with intractable pain and progressive neurological dysfunction; (5) lumbar stenosis not caused by degeneration; (6) radiographic evidence of instability, degenerative spondylolisthesis, fracture, or scoliosis of more than 15°; (7) a diagnosis of lumbar disc herniation in the last 12 months; (8) previous surgery for lumbar stenosis or instability (eg, prior lumbar fusion, lumbar microdiscectomy, lumbar foraminotomy, lumbar laminectomy, etc.); (9) psychiatric disorder or cognitive impairment; and (10) pregnancy.

Examination procedure

All patients provided demographic information and completed several self-report measures followed by a standardized history and physical examination at baseline. During the physical examination, each evaluating clinician assessed the following items to help confirm the diagnosis of LSS: (1) leg symptoms that increase with walking and decrease with leaning forward on a shopping cart and/or sitting [16,17]; and (2) increased pain with lumbar extension that improves with lumbar flexion [16,17].

Treating therapists

Twelve physical therapists (mean age, 38.3 years, SD 9.3) participated in the screening/evaluation and treatment of patients in this study. They had an average of 10.2 (SD 7.2) years of clinical experience, and all had completed a 54-hour postgraduate certification program that included practical training in DN and spinal manipulation for LSS. The physical therapists were fellows-in-training in the APTA-accredited American Academy of Manipulative Therapy Fellowship in Orthopaedic Manual PT postgraduate program. As such, they received advanced clinical training in the diagnosis and treatment of LSS. Similar to previous studies [18,19], all participating physical therapists were required to study a manual of standard operating procedures and participate in a 6-hour training session with the principal investigator to ensure standardization of examinations, outcome assessments, and treatment procedures.

Randomization and blinding

Following baseline examination, patients were randomly assigned to either the MEDNCPT or the CPT group. Similar to previous trials [18–20], concealed allocation was conducted using a computer-generated randomized table of numbers created by a statistician who was not otherwise involved in the trial and did not participate in analysis or interpretation of the results. Individual and sequentially numbered index cards with the random assignment were prepared for each of the data collection sites. The index cards were folded and placed in sealed opaque envelopes. Blinded to the baseline examination, the treating therapist opened the envelope and proceeded with treatment according to the group assignment. Patients were instructed not to discuss the treatment procedure received with the examining clinician. The examining clinician remained blinded to the patient's treatment group assignment at all times. However, based on the nature of the interventions, it was not possible to blind patients or treating therapists.

Interventions

All participants received 8 to 12 treatment sessions at a frequency of 2 times per week for up to 6 weeks. However, fewer treatment sessions could be delivered if symptom resolution occurred sooner. Participants in both groups received exercise, manual therapy, and electro-thermal modalities, which are widely considered key components or 'conventional' in the conservative management of patients with LSS [21,22]. Treatment included 8 to 15 minutes of impairment-based strengthening/stretching exercises targeting the lumbopelvic region, to include Williams flexion exercises [10,23] and/or stationary bike cycling [24]. Flexion-based exercises and stationary cycling is advocated for this patient population to improve core strength, posture, and cardiovascular performance while limiting structural narrowing of the spinal cord [25,26]. The exercise program was taught by an experienced physical therapist during the first treatment session and supervised on subsequent sessions. Exercises were progressed according to the symptoms and tolerance of each patient. A detailed description of the exercise program is provided in Supplementary Materials 1.

Participants also received 8 to 15 minutes of impairment-based manual therapy, which was an eclectic approach consisting of techniques described by Maitland [27], Greenman [28], and Whitman et al [10,29]. Both lumbar/hip nonthrust joint mobilizations and stretching have been found to be beneficial in this patient population [16,26,30] to improve intersegmental and nerve root mobility along with trunk and hip motion [22]. Nonthrust mobilizations and stretches were graded according to impairments and pain tolerance of each patient. In addition, participants received 15 minutes of electro-thermal modalities. Superficial heat has been shown to improve strength and flexibility in patients with chronic low back pain [31], and a recent clinical trial found interferential electro-therapy improved pain perception and disability in patients with chronic low back pain better than massage, mobilization, and soft-tissue treatment [32]. In addition, all patients were given a detailed home exercise program designed to increase strength, flexibility, and walking tolerance as described in the Supplementary Materials 2.

In addition to conventional PT, patients allocated to the MEDNCPT group received electrical DN at a frequency of

2 sessions per week for up to 6 weeks using a standardized protocol of 28 mandatory needle points for 20 minutes [33]. Needles targeted the paraspinal muscles over the lumbar spine and sacrum as well as the gluteus medius and minimus muscles, bilaterally. Clinicians were also permitted to needle the quadratus lumborum and piriformis muscles along with peri-neural targets including the sciatic, tibial, and common peroneal nerves consistent with the symptom presentation in the lower extremity. Details regarding needle size, insertion site, angulation, depth, anatomical target, manipulation [12,41,34–36], and electric stimulation parmeters [37,38] are summarized in Supplementary Materials 3.

Patients in the MEDNCPT group also received at least one treatment that included high-velocity, low amplitude thrust spinal manipulation targeting the middle and lower lumbar spine (ie, L2-S1), as described in previously published studies [10,39,40]. A detailed description of the thrust spinal manipulation techniques used can be found in Supplementary Materials 4. Selection of the spinal segments to target was left to the discretion of the treating therapist and was based on the combination of the patient symptoms and manual examination. If no audible popping or cracking sound was heard on the first attempt, the therapist attempted a second manipulation. A maximum of 2 attempts were performed on each patient, which is consistent with previous studies [20,41]. Clinicians were told to expect multiple audible cavitations as a result of the manipulation [42–46].

Outcome measures

The primary outcomes included the Numeric Pain Rating Scale (NPRS) [47–53] and Oswestry Disability Index (ODI) [53–58]. Secondary outcome measures included the Roland Morris Disability Index (RMDI) [52,59–63], the Global Rating of Change (GROC) [64], and medication intake. Outcomes were collected at baseline, 2 weeks, 6 weeks, and 3 months. A detailed description of each outcome measure and its psychometric properties are listed in the Supplementary Materials 5.

Treatment side effects

Patients were asked to report adverse events during the study [18,19]. Adverse events were defined as a sequelae of 1-week duration with any symptom perceived as distressing and unacceptable to the patient that required further treatment [65]. The treating therapists and patients in the group that received DN as part of their treatment were instructed to pay particular attention to the presence of ecchymosis and postneedling soreness.

Sample size determination

The sample size calculations were based on detecting a between-group medium effect size of 0.50 on the main outcome (overall low back, buttock, and leg pain intensity as measured by the NPRS) at 3 months, using a 1-tailed test, an alpha level (α) of 0.05, and, a desired power (β) of 80%. The estimated sample size was calculated to be at least 64 participants per group. Anticipating a 10% loss to follow-up, we aimed to recruit 70 participants per group.

Statistical analysis

Statistical analysis was performed using SPSS software, version 28.0 (Chicago, IL, USA), and it was conducted according to intention-to-treat analysis. Little's Missing Completely at Random test [66] was used to determine if missing data points associated with dropouts were missing at random or missing for systematic reasons. Intention-to-treat analysis was performed by using expectation-maximization whereby missing data was computed using regression equations.

The effects of treatment on the pain (NPRS) and related-disability (ODI and RMDI) were each examined with a 2-by-4 mixed model analysis of covariance (ANCOVA) with treatment group (CPT vs MEDNCPT) as the between-subjects factor, time (baseline, 2 weeks, 6 weeks, and 3 months) as the within-subjects factor, and adjusted for baseline data (ie, age, height, weight, and duration of symptoms) for evaluating between-group differences. Separate ANCOVAs were performed for the NPRS, ODI, and RMDI as the dependent variable. For each ANCOVA, the main hypothesis of interest was the 2-way interaction (group by time) with a Bonferroni-corrected alpha of 0.0125 (4 time points).

Chi squared ($\chi 2$) tests were used to compare self-perceived improvement with the GROC and changes in medication intake. To enable comparison of between-group effect sizes, standardized mean differences were calculated by dividing mean score differences between groups by the pooled standard deviation. Number needed to treat (NNT) and 95% confidence intervals (CI) were also calculated at the 3-month follow-up using each definition for a successful outcome.

Results

Between June 2017 and March 2020, 352 consecutive patients with LSS were screened for eligibility (Fig. 1). One hundred and twenty-eight (36.4%) satisfied all the inclusion criteria, agreed to participate, and were randomly allocated into the MEDNCPT (n=65) group or the CPT (n=63) group. Randomization resulted in similar baseline characteristics for all variables (Table 1). The reasons for ineligibility are found in Fig. 1, which provides a flow diagram of patient recruitment and retention. There was no significant difference (p=.268) between the mean number of completed treatment sessions for the MEDNCPT group (mean: 11.4) and the CPT group (mean: 11.1). Twelve therapists from 12 outpatient PT clinics each treated 18, 16, 15, 15, 12, 12, 10, 9, 8, 6, 5, and 2 patients, respectively; furthermore, each of

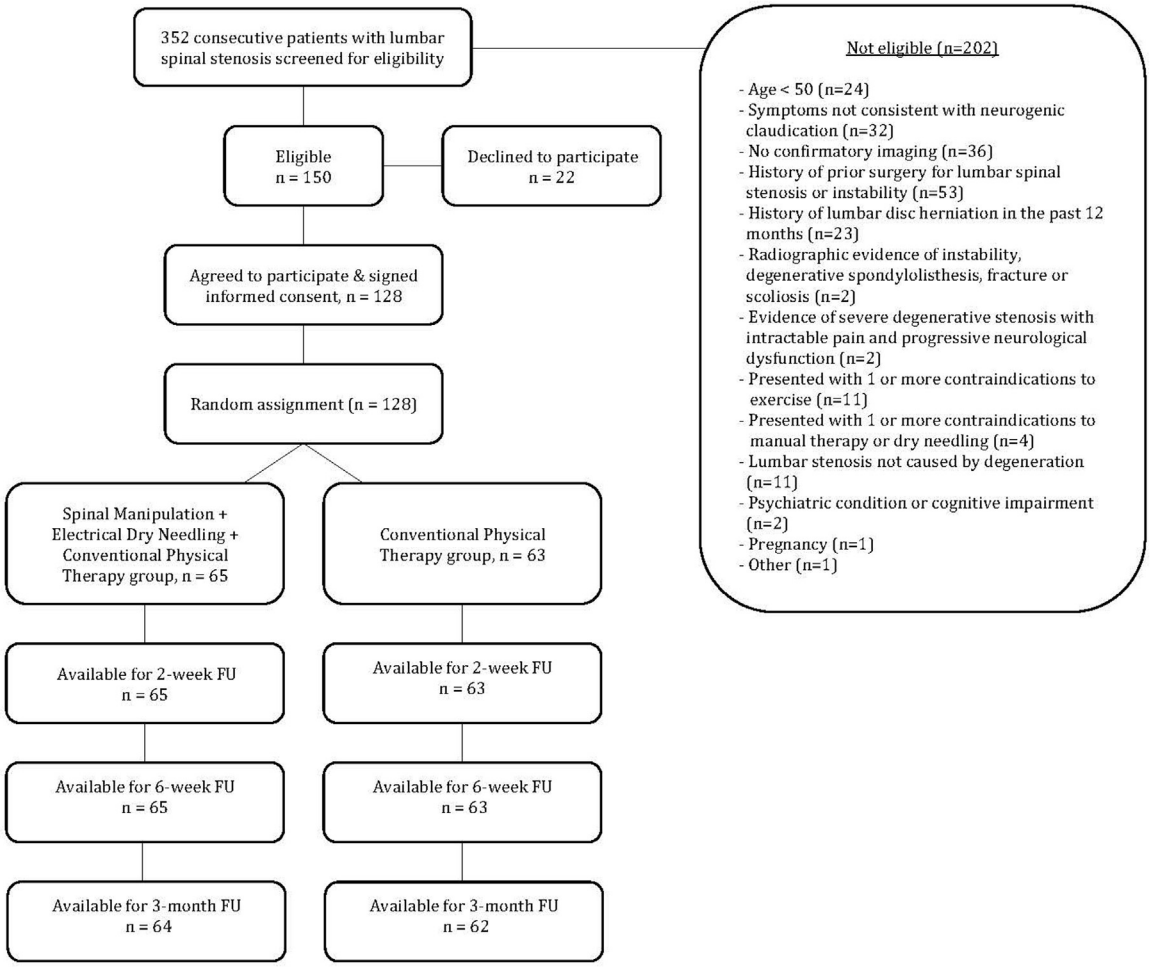

Fig. 1. CONSORT flow diagram of patient recruitment and retention.

the 12 therapists treated approximately an equal proportion of patients in each group. In total, 126 of the 128 patients completed all outcome measures through 3 months (98% follow-up). Of the 2 patients that failed to complete the outcome measures at the 3-month follow-up, one was from the CPT group and one was from the MEDNCPT group

Table 1
Baseline characteristics by treatment assignment

Baseline variable	Conventional physical therapy (n=63)	Manipulation + electrical dry needling + conventional physical therapy (n=65)
Gender (male/female)	24 / 39	33 / 32
Age (y)	67.9±9.9	65.6±10.4
Weight (kg)	81.1±16.8	87.9±17.7
Height (cm)	167.6±9.6	169.8±9.6
Duration of symptoms (y)	3.7±4.6	4.6±5.2
Number of treatment sessions	11.1±1.5	11.4±1.4
Medication intake (n [%])		
Not at all	10 (15.9%)	9 (13.8%)
Once a wk	7 (11.1%)	5 (7.7%)
Once every couple of days	5 (7.9%)	18 (27.7%)
Once or twice a day	31 (49.2%)	22 (33.8%)
Three or more times a day	10 (15.9%)	11 (16.9%)
Overall low back, buttock and leg pain intensity (NPRS, 0−10)	5.7±1.9	6.1±1.9
Oswestry Disability Index (ODI, 0−50)	20.8±7.0	21.1±8.0
Roland Morris Disability Index (RMDI, 0−24)	10.2±4.6	10.8±5.1

Table 2
Within-group and between-group mean scores by randomized treatment assignment

Outcomes	Timeline scores: mean ± SD (95% CI) Within-group change scores: mean (95% CI)		Between-group differences: Mean (95% CI)
	Conventional physical therapy (n=63)	Spinal manipulation + electrical dry needling + conventional physical therapy (n=65)	
	Overall low back, buttock and leg pain intensity (NPRS 0-10)		
Baseline	5.7±1.9 (5.2, 6.1)	6.1±1.9 (5.6, 6.5)	
2 wk	4.3±2.0 (3.8, 4.8)	3.8±1.8 (3.4, 4.3)	
Change baseline → 2 wk	-1.4 (−1.8, −1.0)	-2.2 (−2.7, −1.7)	−0.8 (−1.5, −0.2); SMD=0.45; p=.012
6 wk	3.2±2.0 (2.6, 3.7)	2.5±2.0 (2.0, 2.9)	
Change baseline → 6 wk	−2.5 (−3.0, −2.0)	−3.6 (−4.1, −3.0)	−1.1 (−1.8, −0.3); SMD=0.49; p=.006
3 mo	3.3±2.1 (2.8, 3.8)	2.4±2.1 (1.9, 3.0)	
Change baseline → 3 mo	−2.4 (−2.9, −1.8)	−3.6 (−4.2, −2.9)	−1.3 (−2.1, −0.4); SMD=0.53; p=.003
	Oswestry Disability Index (ODI 0-50)		
Baseline	20.8±7.0 (19.0, 22.5)	21.1±8.0 (19.1, 23.1)	
2 wk	16.0±7.2 (14.2, 17.9)	15.1±7.5 (13.2, 17.0)	
Change baseline → 2 wk	−4.7 (−6.1, −3.4)	−6.0 (−7.1, −4.9)	−1.3 (−3.0, 0.5); SMD=0.26; p=.150
6 wk	13.3±9.2 (10.9, 15.6)	10.7±7.9 (8.7, 12.6)	
Change baseline → 6 wk	−7.5 (−9.3, −5.7)	−10.4 (−12.1, −8.8)	−2.9 (−5.4, −0.5); SMD=0.42; p=.019
3 mo	13.7±8.9 (11.4, 15.9)	9.1±7.6 (7.1, 10.9)	
Change baseline → 3 mo	−7.1 (-9.0, -5.3)	−12.0 (−13.8, −10.3)	−4.9 (−7.4, −2.4); SMD=0.68; p<.001
	Roland Morris Disability Index (RMDI 0-24))		
Baseline	10.2±4.6 (9.0, 11.3)	10.8±5.1 (9.5, 12.1)	
2 wk	7.9±4.9 (6.7, 9.2)	7.0±4.5 (5.9, 8.1)	
Change baseline → 2 wk	−2.2 (−3.1, −1.4)	−3.8 (−4.7, −2.8)	−1.6 (−2.8, −0.3); SMD=0.43; p=.017
6 wk	5.6±4.7 (4.4, 6.8)	4.4±4.5 (3.3, 5.6)	
Change baseline → 6 wk	−4.6 (−5.6, −3.6)	−6.4 (−7.5, −5.2)	−1.8 (−3.3, −0.2); SMD=0.40; p=.026
3 mo	6.0±4.8 (4.8, 7.2)	3.9±3.8 (3.0, 4.9)	
Change baseline → 3 mo	−4.2 (-5.2, -3.1)	−6.9 (−8.1, −5.6)	−2.7 (−4.3, −1.1); SMD=0.58; p<.001

(Fig. 1). None of the participants in either group reported receiving other interventions during the study.

Thirty-nine patients assigned to the MEDNCPT (60.0%) experienced postneedling muscle soreness and 23 (35.4%) experienced mild bruising (ecchymosis) which resolved within 48 hours and 2 to 4 days, respectively. One patient (1.5%) in the MEDNCPT group reported drowsiness, headache and/or nausea, which spontaneously resolved within several hours. No major adverse events were reported in the MEDNCPT group.

Adjusting for baseline outcomes, the mixed-model ANCOVA revealed a significant group-by-time interaction for the primary outcome of overall low back, buttock, and leg pain intensity (NPRS: F=5.658; p=.002, Table 2). Patients in the MEDNCPT group experienced greater reductions in overall low back, buttock, and leg pain intensity at 2 weeks (Δ -0.8; 95%CI: −1.5, −0.2; p=.012), 6 weeks (Δ -1.1; 95%CI: −1.8, −0.3; p=.006) and 3 months (Δ -1.3; 95%CI: −2.1, −0.4; p=.003) than those in the CPT group (Fig. 2). For the primary outcome (overall low back, buttock, and leg pain intensity), between-group effect sizes for the NPRS were small at 2 weeks (SMD: 0.45; 95%CI: 0.10, 0.80), small at 6 weeks (SMD: 0.49; 95%CI: 0.14, 0.84), and medium at 3 months (SMD: 0.53; 95%CI: 0.18, 0.89) after the first treatment session in favor of the MEDNCPT group.

The intention-to-treat analysis also revealed a significant group-by-time interaction for related-disability (ODI: F=9.921; p<.001, Fig. 3) in favour of the MEDNCPT group (Table 2). For disability (ODI), between-group effect sizes

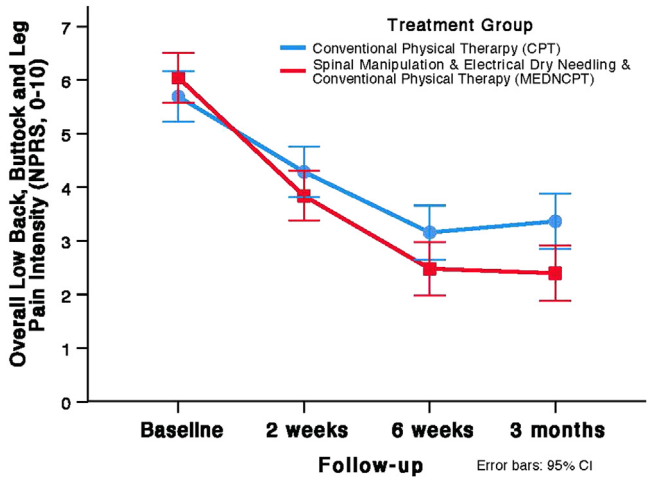

Fig. 2. Evolution of the Numeric Pain Rating Scale throughout the course of the study.

were small at 2 weeks (SMD: 0.26; 95%CI: 0.09, 0.60), small at 6 weeks (SMD: 0.42; 95%CI: 0.07, 0.77), and medium at 3 months (SMD: 0.68; 95%CI: 0.33, 1.04) in favor of the MEDNCPT group.

There was a significant group-by-time interaction for the secondary outcome measure of related-disability (RMDI: F=7.263; p<.001) in favour of the MEDNCPT group (Table 2, Fig. 4). Between-group effect sizes for disability (RMDI) were small at 2 weeks (SMD: 0.43; 95%CI: 0.08, 0.78), small at 6 weeks (SMD: 0.40; 95%CI: 0.05, 0.75), and medium at 3 months (SMD: 0.58; 95%CI: 0.23, 0.94)

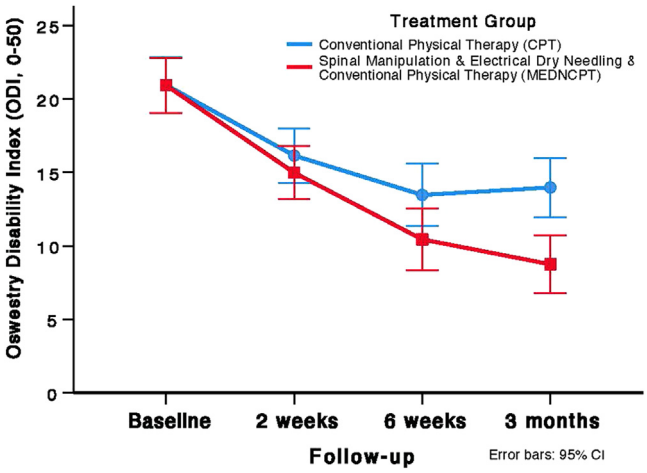

Fig. 3. Evolution of the Oswestry Disability Index throughout the course of the study.

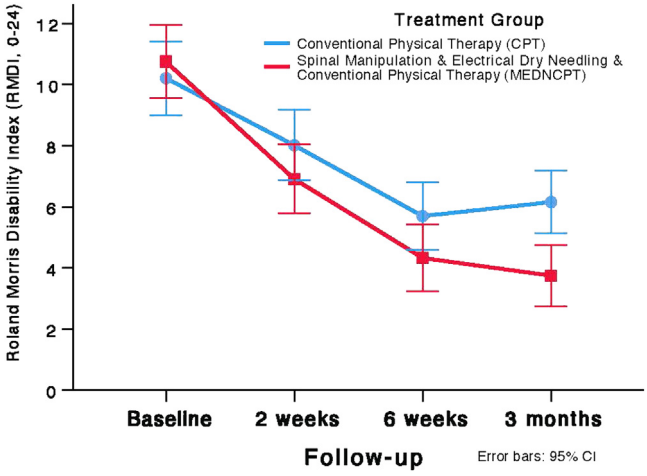

Fig. 4. Evolution of the Roland Morris Disability Questionnaire throughout the course of the study.

after the first treatment session in favor of the MEDNCPT group.

Based on the cut-off score of ≥+5 on the GROC, significantly (X^2=9.0901; p=.003) more patients (n= 46, 71%) within the MEDNCPT group achieved a successful outcome compared to the CPT group (n=28, 44%) at 3 months follow-up (Table 3). Therefore, based on the cut-off score of ≥+5 on the GROC, the NNT was 3.8 (95%CI 2.3, 10.2) in favor of the MEDNCPT group at 3-month follow-up. Likewise, based on a 50% improvement from baseline to 3 months in overall low back, buttock, and leg pain intensity on the NPRS, the NNT was 4.9 (95%CI 2.7, 30.6) in favor of the MEDNCPT group at 3-month follow-up. Significantly (X^2=4.5612; p=.033) more patients in the MEDNCPT group (n=27, 42%) completely stopped taking medication for their low back, buttock, and/or leg pain compared to the CPT group (n=15, 24%) at the 3-month follow-up.

Discussion

In patients with LSS, the addition of electrical DN and spinal manipulation to conventional PT resulted in greater improvements in pain (NPRS) and related-disability (ODI and RMDI) at 3 months (Table 2). While the between-group difference in the ODI (4.9 points; 95%CI −7.4, −2.4) fell within the range of the MCID in patients with LSS [53], the NPRS (1.3 points; 95%CI −2.1, −0.4) and the RMDI (2.7 points; 95%CI −4.3, −1.4) were not within the range of MCID scores for LSS [52] and low back pain [61–63], respectively.

It seems, there is no clear consensus when comparing surgical versus nonsurgical management of patients with LSS over exercise for LSS [67]. However, the literature suggests that PT may reduce the need for surgery secondary to LSS [11]. Similar to previous studies using a multimodal treatment approach, the combination of exercise, manual therapy, and electro-thermal modalities in the CPT group resulted in improved function in patients with LSS [10,29,68].

Although Herman et al [69] considers the use of manipulation (and mobilization) inappropriate for patients with LSS, the chiropractic literature reports some evidence for using spinal manipulation, particularly techniques that incorporate both lumbar flexion and distraction [70,71]. Notably, following the use of manipulation and/or mobilization in patients with LSS, Whitman et al [29] reported significant improvements in disability, symptoms, and function that were maintained for up to 18 months.

Table 3
Self-perceived improvement measured with the Global Rating of Change (GROC) in both groups [n (%)]

Global rating of change (GROC, -7 to +7)	Conventional physical therapy (n=63)	Manipulation + electrical dry needling + conventional physical therapy (n=65)
	3 mo after the first treatment session	
Small changes (+2 / +3)	5 (7.9%) / 11 (17.5%)	2 (3.1%) / 5 (7.7%)
Moderate changes (+4 / +5)	8 (12.7%) / 9 (14.3%)	7 (10.8%) / 15 (23.1%)
Large changes (+6 / +7)	9 (14.3%) / 10 (15.9%)	10 (15.4%) / 21 (32.3%)

GROC: (−7=a very great deal worse; to +7=a very great deal better). Successful outcome: ≥+5 (quite a bit better).

A number of literature reviews and meta-analyses consider "acupuncture and DN" as a single category of intervention.[72–74] Despite differences in terminology, philosophy, and theoretical construct, both disciplines use monofilament needles without injectate and incorporate similar techniques [34,75,76]. Notably, "acupuncture/electroacupuncture" and "DN/electrical DN" were considered interchangeable terms in the present study so as to assess the broader literature on the use of monofilament needles for LSS.

While acupuncture is generally recommended in the literature for LSS [77,78], only 1 systematic review on the use of acupuncture for LSS found no conclusive evidence to support its use [36]. Interestingly, 3 studies reported more robust outcomes in patients with LSS. Ahn et al [13] performed fluoroscopically guided transforaminal epidural DN on 34 consecutive patients with LSS and reported significant pre- and postimprovements in pain and disability. Similarly, Inoue performed electroacupuncture at the level of the lumbar spinal nerve roots on 17 patients with LSS and noted significant improvements in walking ability along with reductions in lumbar and lower limb pain/dysaesthesia, lasting beyond 3 months [14]. Collectively, these studies suggest that needling therapies in isolation may have an effect on outcomes in patients with LSS. Unfortunately, these aforementioned studies are difficult to compare and contrast to the current study, as DN was combined with spinal manipulation as an adjunct to other interventions. Furthermore, needle dose (ie, needle depth and stimulation) may be an important consideration when treating patients with LSS [36,79]. While superficial needling may be enough to treat myofascial/trigger point pain [80], patients with LSS may require deeper needle insertions so as to directly stimulate spinal nerve roots and disrupt structures associated with foraminal compression [14,81,82] (eg ligamentous flavum, the interspinous ligaments, and the deep erector spinae muscles) [83]. Additional manual and/or electric needle stimulation may also be warranted in patients with LSS. Adequate needle stimulation has been shown to: (1) increase blood flow [79,84], (2) stimulate nociceptive fibers required to drive opioidergic and nonopioidergic pain reduction [76,85,86], (3) elicit mechanotransduction required to initiate a reparative response [87–89], and (4) activate the anterior middle cingulate cortex, which is considered an important structure for managing chronic pain [90,91]. Given the importance of both the needle depth and stimulation, it is possible that the DN performed in the present study may have been underdosed. Hence, using a different dosage (increased needle depth & increased needle stimulation) with ultrasound guided imaging, could result in enhanced outcomes.

There are a number of limitations associated with this study. First, it did not incorporate a sham-needling comparison group. Nevertheless, verum acupuncture has already been found to be superior to sham acupuncture in patients with chronic low back pain [35,92,93]. Second, the MEDNCPT group received additional treatments compared to the CPT group, which has the potential to introduce bias. However, the goal of the current study was to determine the additive effect of electrical DN and spinal manipulation to more common PT interventions, and in doing so, establish the effect size of the novel interventions when compared to conventional PT [94,95]. Third, the use of separate region specific pain scores (ie, NPRS-back, NPRS-buttock, NPRS-leg) as opposed to a single NPRS used in this study, measuring the "overall" changes in these areas, may have provided more robust data on the effects of treatment in each group. Fourth, the fact that all treating physical therapists were enrolled in the same postgraduate fellowship program introduces some risk of treatment bias. However, such treatment bias is not uncommon in manual therapy trials that require advanced level training or skillsets. Lastly, several of the authors are senior instructors in the postgraduate fellowship program which provides training in spinal manipulation/mobilization, DN, extremity manipulation, extremity mobilization, instrument-assisted soft-tissue mobilization, vestibular rehabilitation, therapeutic exercise, diagnostic ultrasound, and differential diagnosis to licensed physical therapists, osteopaths and, medical doctors.

Conclusion

The results of the current randomized clinical trial demonstrated that patients with LSS who received electrical dry needling and spinal manipulation in addition to exercise, manual therapy, and electro-thermal modalities experienced greater improvements in low back, buttock, and leg pain and disability than those receiving exercise, manual therapy, and electro-thermal modalities alone at 3 months, but not at the 2 or 6-week follow-up. Future studies should consider a direct comparison between DN/spinal manipulation and conventional treatment, as well as the effect of different types of dosages of DN and spinal manipulation in patients with LSS.

Declarations of Competing Interest

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2023.12.002.

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