Effect of TENS Versus Placebo on Walking Capacity in Patients With Lumbar Spinal Stenosis: A Protocol for a Randomized Controlled Trial

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Abstract

Background: Lumbar spinal stenosis (LSS) is a growing health problem and a leading cause of disability and loss of independence in older adults. It is usually caused by age-related degenerative narrowing of the spinal canals leading to compression and ischemia of the spinal nerves and symptoms of neurogenic claudication. Limited walking ability is the dominant functional impairment caused by LSS. Animal studies suggest increased blood flow to the spinal nerves and spinal cord with superficial paraspinal electrical stimulation. The purpose of this study is to assess the effectiveness of paraspinal transcutaneous electrical nerve stimulation (TENS) applied while walking on walking ability in patients with LSS.

Methods/Design: We propose to conduct a 2-arm double-blinded (participant and assessor) randomized controlled trial. We will recruit individuals who have limited walking ability due to degenerative LSS from hospital specialists, community physicians, and chiropractors located in the city of Toronto, Canada. Eligible consenting participants will be randomly assigned to either paraspinal TENS or placebo paraspinal TENS applied while walking. The primary outcome will be walking distance measured during a single self-paced walking test. We will calculate the differences in proportions among participants in both groups who achieve at least a 30% improvement in walking distance from baseline using Pearson χ^2 test with 95% confidence intervals.

Discussion: Effective nonoperative interventions for LSS are unknown. Interventions that can improve blood flow to the spinal nerves while walking may increase walking ability in this population. Transcutaneous electrical nerve stimulation is a low-cost intervention that may have the potential to achieve this objective. To our knowledge, this study will be the first clinical trial to assess the effects of TENS on walking ability of patients with LSS.

Trial Registration: ClinicalTrials.gov ID: NCT02592642 (J Chiropr Med 2016;15:197-203)

Key Indexing Terms: *Randomized controlled trial; Spinal stenosis; Intermittent claudication; Transcutaneous electrical nerve stimulation; Walking; Clinical protocol*

Introduction

Lumbar spinal stenosis (LSS) is often caused by age-related degenerative narrowing (stenosis) of the central and lateral spinal canals leading to compression and ischemia of the spinal nerves (neuroischemia).[1] Lumbar spinal stenosis is a leading cause of pain, disability, and loss of independence in older adults.[2] The prevalence and economic burden of LSS are growing exponentially

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because of the aging population. Limited walking ability is the dominant functional impairment due to LSS.[3] Those afflicted have greater walking limitations than individuals with knee or hip osteoarthritis[4] and greater functional limitations than those with congestive heart failure, chronic obstructive lung disease, or systemic lupus erythematosis.[2] The clinical syndrome of LSS is known as neurogenic claudication. It is characterized by bilateral or unilateral buttock and lower extremity pain, heaviness, numbness, tingling, or weakness precipitated by walking and standing and relieved by sitting and bending forward.[3,5] Claudication symptoms are believed to arise because of ischemia of the spinal nerves secondary to venous congestion within the spinal canals.[6,7] This is plausible based on the rapid symptom reduction with sitting and stooping forward. Standing and walking postures increase both the lumbar lordosis and axial load that leads to further narrowing of the canals.[8–10] A narrowed spinal canal impairs venous return and leads to engorgement of the venous plexus.[6] Engorgement of the venous plexus blocks the flow of cerebral spinal fluid within the epidural space, leading to further congestion.[6] Venous and cerebral spinal fluid congestion increases with time standing or walking and eventually compromises arterial perfusion and leads to hypoxia of the spinal nerves and symptoms of claudication.[6] Sitting and/or stooping forward increases the canal size, relieves epidural pressure, and restores blood flow to the spinal nerves.[10]

Nonoperative treatments aimed at a reduction of spinal congestion and/or increase in blood flow to the spinal nerves while walking may improve symptoms of neurogenic claudication. Recent evidence from animal models suggests that transcutaneous electrical nerve stimulation (TENS) to specific dermatomes results in a significant increase in blood flow to somatotopically linked spinal cord segments.[11] Other animal models demonstrate an increase in blood flow to the lumbar spinal cord and cauda equina with electrical stimulation of the sciatic nerve.[12]

There are numerous human studies demonstrating significant reduction in laboratory-induced ischemic pain in the lower and upper extremities with the application of superficial TENS vs a placebo TENS.[13–17] A recent pilot study of 12 patients with limited walking ability due to neurogenic claudication and 13 age-matched controls demonstrated that 5 minutes of superficial electrical stimulation of the tibial nerve before a walk test significantly improved walking distance.[18] The authors speculated that the nerve stimulation improves blood flow and oxygenation to the spinal nerves of the cauda equina. At present, there are no randomized controlled trials (RCTs) evaluating the effectiveness of TENS applied while walking to patients with neurogenic claudication due to LSS.

The purpose of this article is to describe a protocol for a randomized controlled trial comparing the effectiveness of TENS in improving walking capacity among individuals with neurogenic claudication. Specifically, we propose to compare the change in walking capacity from baseline when using active superficial paraspinal TENS vs placebo superficial paraspinal TENS applied while walking. We hypothesize that paraspinal TENS used while walking will be more effective in improving walking capacity than placebo TENS.

Methods

Design

We will conduct a 2-arm double-blinded (participant and assessor) single-session RCT (Fig 1). A single session means that the intervention and the assessment of walking ability will occur at the same time in a single session. This will be a nested study within a larger RCT.[19]

Study Setting and Source Population

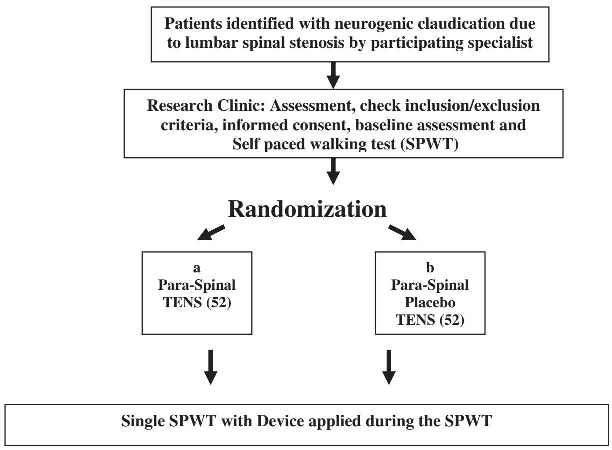
Eligible participants are individuals who consult with specialists (orthopedists, neurosurgeons, rheumatologists, neurologists, or physiatrists), family physicians, or chiropractors for symptoms suggestive of neurogenic claudication at 1 of 7 hospitals and several community clinics in Toronto, Canada, and the surrounding area.

Recruitment

Participating physicians and chiropractors will identify potential participants using an eligibility checklist (Fig 2). Eligible potential participants will be given a pamphlet outlining information concerning the study and providing contact information for the trial coordinator. Interested and potentially eligible participants will be asked to contact the trial coordinator directly. Pamphlets will also be available in patient waiting rooms of participating hospital clinics and community clinics. Similar information will be advertised in local newspapers to enhance recruitment. The trial coordinator will provide details about the study and answer questions by phone. The coordinator will confirm eligibility including age, duration of symptoms, and self-reported walking ability. Walking ability will be assessed by the participants' response to the question "Are you able to walk continuously for 30 minutes without aids or without stopping to rest or stooping forward to alleviate your symptoms?" Self-reported walking ability has been shown to be highly correlated (r = 0.80) to the Self-Paced Walk Test (SPWT).[20] Only interested participants who respond "No" and meet the other inclusion/exclusion criteria will be given an appointment for an intake assessment at the study site (at Mount Sinai Hospital in Toronto, Canada).

Eligibility Criteria

At the intake assessment, potential participants will be assessed by a licensed practitioner. The assessment will confirm eligibility (Fig 2) and will include a history,



* SPWT = Self Paced Walking Test

Fig 1. *Process of recruitment, randomization, and outcomes assessment. TENS, transcutaneous electrical nerve stimulation.*

physical examination, and a review of imaging results provided by the referring specialist. Following the assessment, eligible and willing participants will be asked by the research coordinator to provide informed written consent to participate in the study. Consenting participants will be asked to complete a baseline questionnaire and a short physical performance battery[21] and perform a 30-minute SPWT[20] (Fig 3).

Allocation and Randomization to Treatment Groups

All participants will be randomly allocated to either paraspinal TENS or paraspinal placebo TENS. The randomization sequence will be prepared by the study biostatistician ahead of recruitment using a computerized random numbers table (NQuery Advisor 7.0[22]). The biostatistician will provide the trial coordinator with sequentially numbered sealed opaque envelopes that will contain treatment allocation. The study biostatistician will not be involved in the selection, treatment, or follow-up of participants.

Interventions and Controls

All participants will return within 1 week from the baseline assessment for the intervention.

1. Paraspinal TENS: Participants randomized to this subgroup will have disposable self-adhesive electrical pads (Blue Sensor P, Ambu A/S, Denmark) applied over the paraspinal musculature from L3 to S1 by a licensed practitioner. The electrodes will be connected to a TENS machine (NeuroTrac TENS from Verity Medical Ltd [UK]) which will be worn by the subject concealed within a waist pouch. The TENS will be programmed for a frequency of 65-100 Hz modulated over 3-second intervals with a pulse width of 100-200 μsec, and turned on 2 minutes before the start and during the SPWT. Current intensity will be set to the level of comfort of the patient, approximately 3 mA in pilot experiments, and below the level causing muscle twitch.
2. Paraspinal transient placebo TENS: Participants randomized to this subgroup will have disposable self-adhesive electrical pads (Blue Sensor P, Ambu A/S, Denmark) applied over the paraspinal muscular from L3 to S1 by a licensed practitioner. The electrodes will be connected to a TENS machine (NeuroTrac TENS from Verity Medical Ltd [UK]) which will be worn by the subject concealed within a waist pouch. The TENS will be programmed using a transient placebo frequency and intensity according to the protocol of Rakel et al,[23] that is, the unit active for the first 30 seconds then ramping down to zero stimulus over 15 seconds and worn from 2 minutes before the start and during the SPWT.

Blinding

Participants will perform a single SPWT while wearing their assigned device. All SPWTs will be performed and recorded by blinded assessors. Blinding will be achieved by having participants wear hospital gowns and concealing TENS units within zippered waist pouches. Participants will be instructed not to communicate with the assessor beyond answering questions that are part of the self-paced walking test. The licensed practitioner will be nearby during the assessment should the participant experience any discomfort or difficulties related to the wearing the device. Every effort will be made to ensure that the assessor does not become unblinded during the assessment.

Outcomes

Primary Outcome

Objective Walking Capacity. Walking capacity will be assessed using the SPWT. The test requires subjects to walk on a level surface without support at their own pace until forced to stop due to symptoms of LSS or a time limit of 30 minutes.[24] *Test termination* will be defined as a complete stop of 3 seconds. A blinded assessor will follow 1 m behind the subject, without conversing, with a distance instrument (Lufkin Pro-Series Model PSMW38) and stopwatch. Distance walked and time to test termination will be recorded. The SPWT is considered the criterion standard with high validity for assessing walking capacity in this population because it directly observes walking ability under conditions representative of a real-world setting.[20,25] It has high test-retest reliability (intraclass correlation coefficient = 0.98).[24] The minimal clinically

Inclusion criteria

1. Age greater or equal to 50 years
2. Clinical symptoms of back and/or radiating lower limb or buttock pain; fatigue or loss of sensation in the lower limbs aggravated by walking and/or standing and relieved by sitting.
3. Intermittent or persistent pain without progressive neurological dysfunction
4. Duration of symptoms and signs for more than 3 months
5. Imaging confirmed spinal canal narrowing using MRI, CT scan, myelography or ultrasound
6. Clinical signs and symptoms corresponding to segmental level of narrowing identified by imaging
7. Patients with degenerative spondylolisthesis are included
8. Not considered to be a surgical candidate (in the next 12 months) or patient unwilling to have surgery
9. Able to perform mild-moderate exercise
10. Able to walk without assistive devices for at least 20 metres and less than 30 minutes continuously
11. Able to give written informed consent and complete interviews and questionnaires in English.

Exclusion criteria

1. Severe degenerative stenosis with intractable pain and progressive neurological dysfunction
2. Lumbar spinal stenosis not caused by degeneration
3. Lumbar herniated disc diagnosed during the last 12 months
4. Previous back surgery for lumbar spinal stenosis or instability
5. Underlying spinal disorder such as ankylosing spondylitis, neoplasm, infection or metabolic disease
6. Intermittent claudication due to vascular disease
7. Severe osteoarthrosis or arthritis of lower extremities causing limited walking ability
8. Neurologic disease causing impaired function of the lower limbs, including diabetes
9. Psychiatric disorders and /or cognitively impaired

Fig 2. *Inclusion and exclusion criteria. CT, computed tomography; MRI, magnetic resonance imaging.*

important difference (MCID) in walking distance in this population is unknown.

Statistical Issues

Sample Size

We have estimated the sample size for the primary outcome of objective walking capacity based on an estimate of the difference in the proportion of participants who achieve an MCID in walking distance from baseline. Because the MCID for the SPWT is unknown, we will estimate it to be an improvement in walking distance from baseline of 30% or more. We estimate that a total of 30% of participants will achieve the estimated MCID in the paraspinal TENS placebo group and 60% in the paraspinal TENS group. Based on an estimate of 30% difference in proportions, a power of 0.8, an α of .05, and an estimated dropout rate of 20%, a minimum of 52 participants per group is estimated to be required to achieve significance using a 2-tailed t test for 2 independent proportions.[26]

Statistical Analysis

Baseline status of treatment groups will be compared using 2-tailed independent-samples t tests, χ^2 tests of independence, and Mann-Whitney U tests as indicated. Our analyses will be based on the "intention to treat" principle.

Measures
Socio-demographic characteristics
Duration of symptoms (back or leg)
Dominant pain (back or leg)
Co-Morbidity Disease Index
Self-Paced Walking Test
Zurich Claudication Questionnaire (ZCQ)
Symptom and Functional scales
Oswestry Disability index (ODI) and ODI walk
Numerical rating scale for back pain
Numerical rating scale for leg pain
36-item short-form health survey (V2)
Center for Epidemiological Studies-Depression Scale (CES-D)
Short Physical Performance Battery (SPPB)
Falls Efficacy Scale (FES)

Fig 3. *Measures collected at baseline.*

We will analyze the primary outcome (SPWT) by calculating the differences in proportions meeting the MCID between the 2 groups using Pearson χ^2 test with 95% confidence intervals (CIs). We will also calculate the relative risk with 95% CIs among participants in both groups who achieve the MCID. To control for potential confounding (sex, education, perceived health status, dominant leg or back pain, and hospital), logistic regression models and generalized estimation equation methods will be used.[27] These models will control for baseline differences not balanced by randomization.

Protection of Human Subjects and Assessment of Safety

Protection of Human Subjects

The study protocol has been approved by the Mount Sinai Hospital (Toronto, Canada) Research Ethics Board (certificate number 14-0020). This proposed trial has been registered with ClinicalTrials.gov ID: NCT02592642.

Adverse Events

We will measure the presence of adverse events that may be associated with each intervention during the SPWT. We will define *adverse event* as an unintended sign or symptom of the intervention. These include significant increase in back and/or lower extremity pain, numbness, tingling, tiredness, or claudication symptoms beyond those normally experienced when walking. We will compute the incidence (95% CI) of each adverse event listed above. The total number of participants will be used as the denominator. Any adverse event that is life threatening or associated with significant disability will be reported to the Mount Sinai Hospital Ethics Review Board.

Data Management

Data will be entered electronically using a pretested tablet. Deidentified data will be stored electronically using a secure data warehouse. A random set of 20% of the data will be evaluated for accuracy. No data monitoring committee will be necessary because of the low risk of harm and because the intervention and assessment will be performed once at the same time with no other follow-up assessments.

Dissemination Policy. We plan to publish the results in an open access document in a scientific journal and communicate findings to participants via an e-mail newsletter. Public dissemination will also take place through sponsor-initiated publications and multimedia platforms (The Arthritis Society).

Discussion

We propose a protocol for an RCT to assess whether the application of TENS while walking can improve walking ability in patients with LSS. There are no published RCTs assessing TENS while walking for LSS. The rationale for this study is based on the proposed pathophysiology of LSS that symptoms of claudication are due to compromised blood flow to the spinal nerves when walking.[6] Animal studies suggest that improved blood flow to the spinal cord and cauda equina can be achieved with superficial electrical stimulation either at the paraspinal level or to peripheral nerves of the lower limb.[12,11] A recent small case-controlled human study showed improved walking ability with stimulation of the tibial nerve before walking.[18] Because neuroischemia occurs at the spinal level during walking to give rise to claudication, interventions that can improve blood flow to the cauda equina during walking may reduce symptoms and improve walking ability. TENS applied at the paraspinal level while walking may potentially achieve this. If shown to be beneficial, TENS can be a low-cost treatment for some individuals with LSS.

We selected an RCT design because it is the study design of choice when comparing the effectiveness of interventions. This study will be nested within a larger RCT, which is feasible because the TENS interventions to be tested can be performed independently before the start of the larger study without impacting the outcome (walking capacity) of the TENS interventions or the outcomes of the larger study. Walking capacity while using the TENS interventions will be measured in a single session using the SPWT with no other follow-up assessments. Walking capacity will be compared with a baseline SPWT. The SPWT is the current criterion standard for measuring objective walking capacity in LSS because it assesses walking ability in a real-life setting.[24]

At our facility, we have 2 long and wide hallways connected by 2 shorter hallways forming a large rectangular area (140 m long) where participants easily can perform the SPWT.

However, the SPWT has a ceiling effect in that the test measures distance traveled for a maximum of a 30-minute period. For this reason, we will only include participants who are more severely impaired and cannot complete the SPWT during the baseline assessment.

We will implement strict rules preventing the communication regarding participant allocation among participants, research coordinator, and blinded assessors. We will also test whether the blinding of the interventions (active or placebo) was successful by asking participants which intervention (the TENS or the placebo TENS) they believe they received following the completion of the SPWT.

Lumbar spinal stenosis causing neurogenic claudication is a growing problem due to the aging population. In Japan where 25% of the population is older than 65 years, about 12 million people have LSS.[28] In the United States, in the year 2030, it is estimated that 73 million people will be older than 65 years[29] and about 30% will have symptoms of LSS.[30] There is no cure for LSS, and although LSS is the most common reason for surgery in older adults,[31] the vast majority of people with LSS do not have surgery but receive nonsurgical care.[31] However, what constitutes effective nonsurgical treatment is unknown.[32–35] High-quality RCTs are needed to assess nonoperative treatment options both new and existing.

Conclusion

Effective nonoperative interventions for LSS are unknown. Interventions that can improve blood flow to the spinal nerves while walking may increase walking ability in this population. Transcutaneous electrical nerve stimulation is a low-cost intervention that may have the potential to achieve this objective. To our knowledge, this study will be the first clinical trial to assess the effects of TENS on walking ability of patients with LSS.

Funding Sources and Conflicts of Interest

This study was funded by The Arthritis Society (Canada), registration number SOG 13-003. The principal author receives salary support from the Canadian Chiropractic Research Foundation. No conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): C.A.

Design (planned the methods to generate the results): C.A., P.C., C.B., G.H., D.S., B.B., R.R.

Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): C.A., D.S., P.C.

Literature search (performed the literature search): C.A., B.B., D.S.

Writing (responsible for writing a substantive part of the manuscript): C.A., P.C., R.R., D.S., B.B.

Practical Applications

- Effective nonoperative treatments for LSS are unknown.
- At this time, there are no human randomized clinical trials evaluating TENS applied while walking in spinal stenosis.
- Transcutaneous electrical nerve stimulation is a practical low-cost self-management intervention that may improve blood flow to the spinal nerves and reduce symptoms and functional limitations of neurogenic claudication.

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