University of Toronto Lumbar Spinal Stenosis Study

The Evaluation of Four Novel Self Management Strategies to Improve Walking Ability in Neurogenic Claudication due to Degenerative Lumbar Spinal Stenosis

Carlo Ammendolia, Raja Rampersaud, Pierre Côté, Brian Budgell, Claire Bombardier, Gillian Hawker and U of T Spine Program
Objectives

• Definitions, Patho-anatomy and Patho-physiology

• Diagnosis, Differential Diagnosis and Treatment

• U of T Spinal Stenosis Study
Neurogenic Claudication due to Lumbar Spinal Stenosis

Definitions

Patho-anatomical classification

1. Congenital
2. Spondylolisthesis
3. Iatrogenic
4. Other diseases/metabolic
5. Acquired- degenerative joint/ disc disease
Neurogenic Claudication - Pathobiology

Internal vertebral venous plexuses
Position and Epidural Pressure in LSS

Takahashi et al, Spine 1995
Diagnosis

Diagnostic Criteria- Most useful

- Age > 70
- Age < 60
- Bilateral buttock or leg pain
- No pain when seated
- Symptoms worse standing/walking
- Symptoms improve when bending forward
- Positive Rhomberg / wide stance gait
- Urinary disturbances

Suri et al, JAMA 2010
Differential Diagnosis

- Vascular Claudication
- Osteoarthritis of the Hip (Hip-Spine Syndrome)
- Greater Trochanteric Syndrome
- Diabetic Neuropathy (B12 deficiency)
- Cervical Spinal Stenosis
- Lumbar Disc Herniation

Ammendolia accepted JCCA Mar 2014
## Neurogenic Claudication (LSS) v.s. Lumbar Radiculopathy (LHD)

<table>
<thead>
<tr>
<th></th>
<th>NC</th>
<th>LR</th>
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<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td>&gt; 65</td>
<td>40s</td>
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<tr>
<td><strong>Lumbar flexion</strong></td>
<td>Relief</td>
<td>Worse</td>
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<tr>
<td><strong>Sitting</strong></td>
<td>Relief</td>
<td>Worse</td>
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<tr>
<td><strong>Level</strong></td>
<td>L4-5</td>
<td>L5-S1</td>
</tr>
<tr>
<td><strong>SLR</strong></td>
<td>Negative</td>
<td>Positive</td>
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Suri 2012, Katz 2008, Rainville 2013
Incidence & Prevalence

- Primary care - 3%-4% of LBP patients [Hart 1995]
- Secondary care – 13%-14% LBP patients
- Primary care - 47% of adult patients with leg pain and numbness (mean age 65 yrs for males and 54 yrs in females) [Konno 2007]
Population 65 years and over, Canada, 1971-2051
(percent)

Statistics Canada 2009
Burden

- A leading cause disability & loss independence in elderly [Kalichman 2009]
- Functional limitations > CHF, COPD or SLE [Fanuele 2000]
- Walking limitations > OA hip or OA knee [Winter 2010]
- Most common spine surgery age > 65 [AHCRQ 2001]
- Medicare in US- $1.7 B per year surgical cost alone [Deyo 2010]
# Treatment - Neurogenic Claudication

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effectiveness</th>
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<tbody>
<tr>
<td>Calcitonin</td>
<td>Not likely</td>
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<tr>
<td>NSAIDS, Vit B12, Gabapentin, Prostagladins</td>
<td>?</td>
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<td>Epidural Injections</td>
<td>?</td>
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<tr>
<td>Physical Therapy/ manual therapy</td>
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<td>Multi-modal</td>
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<td>Surgery</td>
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Boot Camp Program Lumbar Spinal Stenosis

- Self management
- Self monitoring
- Flexion exercises
- Strength training
- Manual therapy
- Body re-positioning

Cognitive Behavioural Approach
Emphasis on standing/walking/functional abilities
Boot Camp Program

LUMBAR SPINAL STENOSIS

Dr. Carlo Ammendolia
<table>
<thead>
<tr>
<th>Table for Boot Camp Program for Lumber Spinal Stenosis</th>
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<tbody>
<tr>
<td><strong>Week 1</strong></td>
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<td><strong>1.</strong></td>
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**Version Feb 15 13**

**Avoid back extension activities - that is avoiding your back backwards.**
**All differences in outcomes were both clinically and statistically significant**

Ammendolia submitted JMPT 2014
Animal Models in DLSS
TENS – Neurogenic Claudication

- Lower extremity ischemic pain
- Combination with other treatments
- electroacupuncture
- no RCT of TENS while walking

Lumbar Spinal Stenosis Belt for DLSS
U of T Lumbar Spinal Stenosis Study

Research Questions

1. Can a comprehensive 6 week self management program with workbook, video and pedometer improve walking capacity compared to workbook, video and pedometer alone?

2. Can paraspinal TENS while walking improve walking capacity compared to placebo TENS?

3. Can the stenosis belt worn while walking improve walking capacity compared to sham belt?
U of T Lumbar Spinal Stenosis Study

Study Design

• *Two RCTs nested within a larger Pragmatic RCT*

Source Population

• Patients from U of T hospitals specialists
• > 50 yrs, NC with imaging confirm DLSS
• *Walk > 20m < 30 minutes unassisted*
• *Able to perform mild-moderate exercise*
U of T Lumbar Spinal Stenosis Study

Exclusion criteria

• Intractable pain and progressive neurological dysfunction
• Lumbar spinal stenosis not caused by degeneration
• Lumbar herniated disc diagnosed during the last 12 months
• Previous back surgery for lumbar spinal stenosis
• Ankylosing spondylitis, neoplasm, infection or metabolic disease
• Claudication due to vascular disease
• Severe osteoarthritis of lower extremities causing limited walking ability
• Neurologic disease causing impaired function of the lower limbs, including diabetes
• Psychiatric disorders and/or cognitively impaired
U of T Lumbar Spinal Stenosis Study

Main Study - Intervention

- standardized boot camp program with workbook, video and pedometer
- administered by chiropractor 2xw-6w with booster session at 4 weeks

Main Study – Control

- one session with chiropractor plus workbook, video and pedometer
Secondary Studies - Interventions

a) **TENS paraspinal** - 65-100 Hz modulated over 3-second intervals with a pulse width of 100-200 usec, intensity approximately 3mA

b) Stenosis belt inflated firmly over sacrum prior to walk test

Secondary Studies – Controls

a) Placebo TENS – over quads with 5 sec stim every 15 seconds

b) **sham belt- stenosis belt inflated over lumbar spine**
U of T Lumbar Spinal Stenosis Study

Main Outcome

- Self Paced Walking Test
  - gold standard with high validity in NC
  - high test-retest reliability (ICC = 0.98)
  - simulates real life walking
  - distance and time to termination
  - MCID unknown- will use 30%

Tomkins 2009, Tomkins 2011
<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline</th>
<th>6 Weeks</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
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<tr>
<td>Socio-demographic characteristics</td>
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<tr>
<td>Duration of symptoms (back or leg)</td>
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<td>Dominant pain (back or leg)</td>
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<td>Co-Morbidity Disease Index</td>
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<tr>
<td>Self Paced Walking Test</td>
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<tr>
<td>Claudication Questionnaire (ZCQ) Symptom and Functional scales</td>
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<tr>
<td>Oswestry Disability index (ODI) and ODI walk</td>
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<td>Numerical rating scale for back pain</td>
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<td>Numerical rating scale for leg pain</td>
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<td>x</td>
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<td>36-item short-form health survey (V2)</td>
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<td>Center for Epidemiological Studies-Depression Scale (CES-D)</td>
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<td>Co-interventions and compliance</td>
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Statistics

Sample Size

• Used a MCID of 30% or more improvement in walking distance

• Estimate of 30% difference in proportions btw Groups, a power of 0.8, an alpha of 0.05 and drop-out rate of 20%, a minimum of 52 participants per group is estimated to be required to achieve significance using a two-tailed t-test for two independent proportions
Statistics

Primary Analysis

• Intention to treat analysis
• Difference in proportions meeting MCID using chi squared tests with 95% CI
• Logistic regression models and GEE methods to control for confounding and baseline differences
Patients identified with neurogenic claudication due to lumbar spinal stenosis by participating specialist

Assessment, check inclusion/exclusion criteria, informed consent, baseline assessment and self paced walking test (SPWT)

Randomization

Group 1 (52)
6 week Training Program: Plus Instructional Workbook, Video & Pedometer and 4 week booster session

Group 2 (52)
Single Session Plus Workbook, video and pedometer

6w, 3m, 6 m and 12 m follow up
Secondary Studies Flow

Assessment, check inclusion/exclusion criteria, informed consent, baseline assessment and self paced walking test (SPWT)

Randomization

A
Para-Spinal TENS (26)

B
Para-Spinal Placebo TENS (26)

C
Stenosis Belt (26)

D
Sham Stenosis Belt (26)

Day 1 Single SPWT with Device applied during the SPWT

(A and B) Randomization (C and D)

C
Stenosis Belt (26)

D
Sham Stenosis Belt (26)

A
Para-Spinal TENS (26)

B
Para-Spinal Placebo TENS (26)

Day 2 Single SPWT with Device applied during the SPWT

After 2 weeks participants begin assigned treatment Group 1 or Group 2
Recruitment

University of Toronto

- Spine Program Faculty (orthopedic and neurosurgery)
- Rheumatologists
- Physiatrists
- Neurologists

Study Pamphlet with contact information
Carlo Ammendolia

Contact info:
cammendolia@mtsinai.on.ca

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