

# 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

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# O bjectives

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- Definitions, Patho-anatomy and Patho-physiology
- Diagnosis, Differential Diagnosis and Treatment
- U of T Spinal Stenosis Study

# Neurogenic Claudication due to Lumbar Spinal Stenosis

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Definitions

Patho-anatomical classification

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

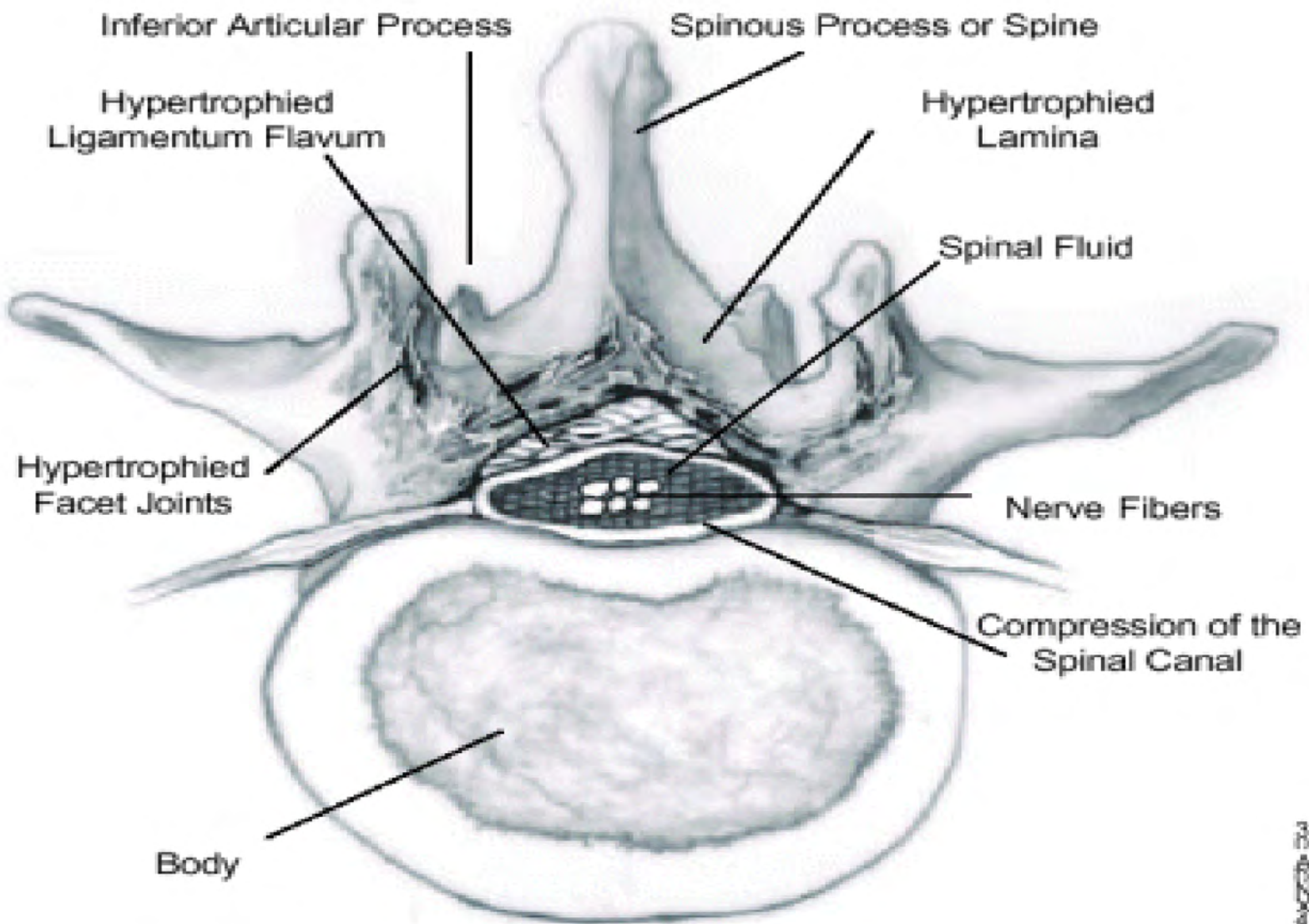
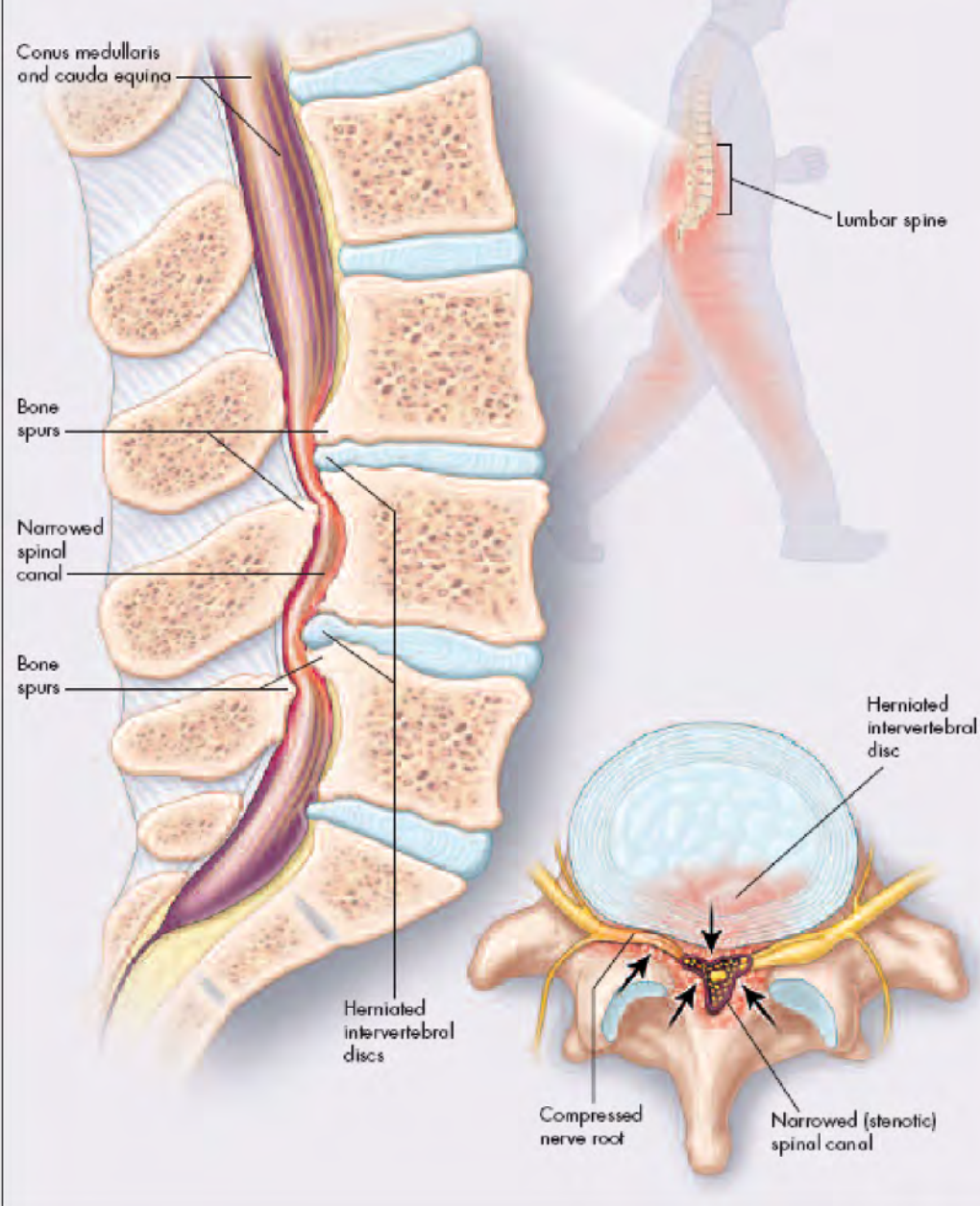


Figure 1:  
Lumbar Spinal Stenosis (LSS)



1.5T MSHMR02

A

MSH

Ex: 12570

AXIAL FRFSE PD/T2

1957 Jun 18 M 805 492 452 MSH

Se: 5/8

Acc: 001274014

Im: 33/58

2008 Apr 24

Ax: 1113.7

Acq Tm: 00:16:34

256 x 224

R

L

ET: 12

TR: 4266.7

TE: 23.6

8CTL456

4.0thk/0.5sp

Id:DCM / Lin:DCM / Id:ID

W:1445 L:722

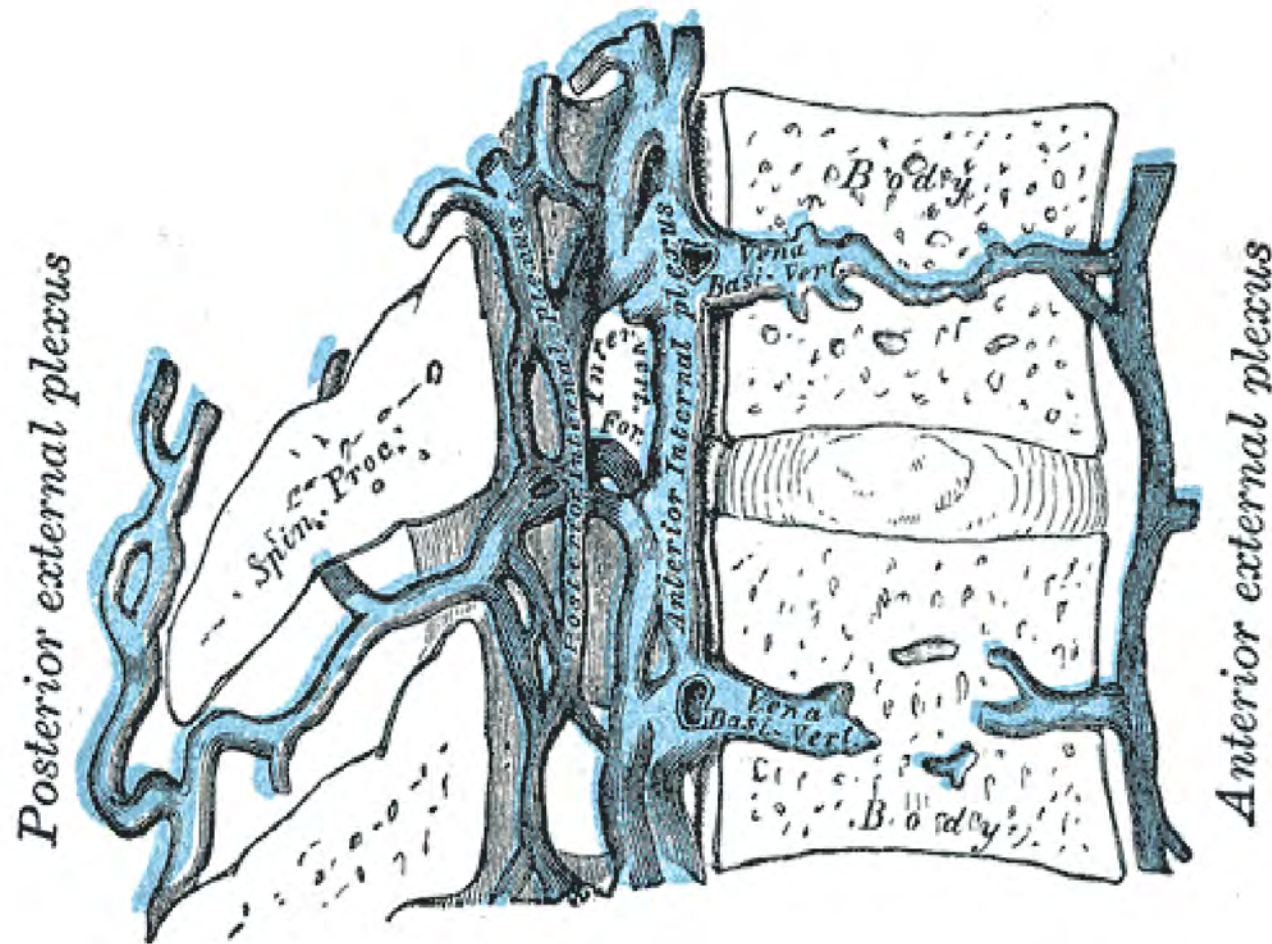
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DFOV: 20.0 x 20.0cm

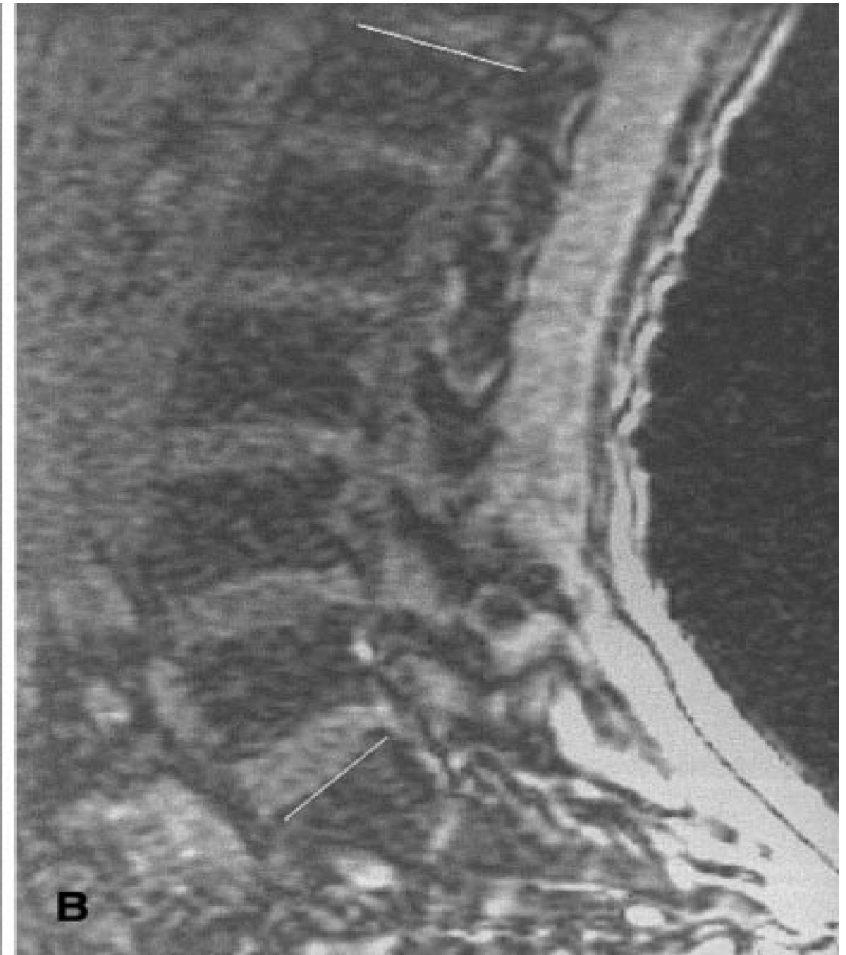
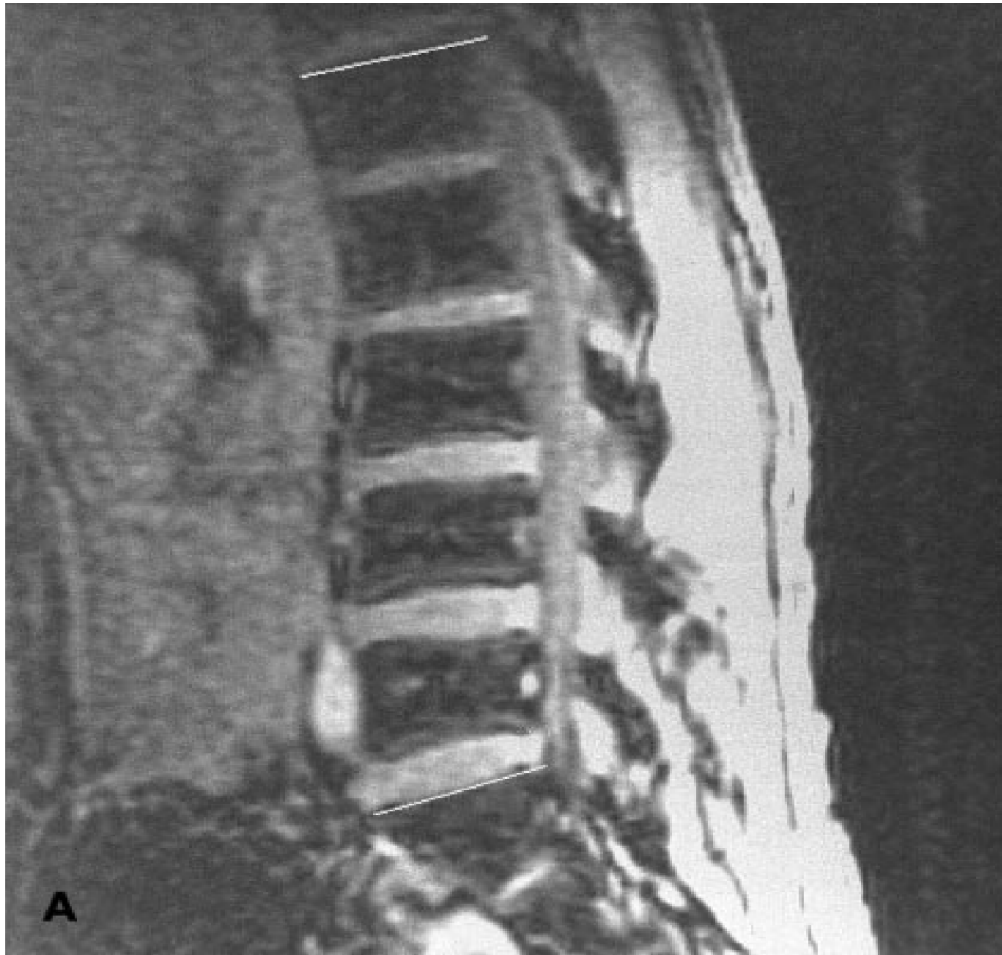




## Neurogenic Claudication - Pathobiology

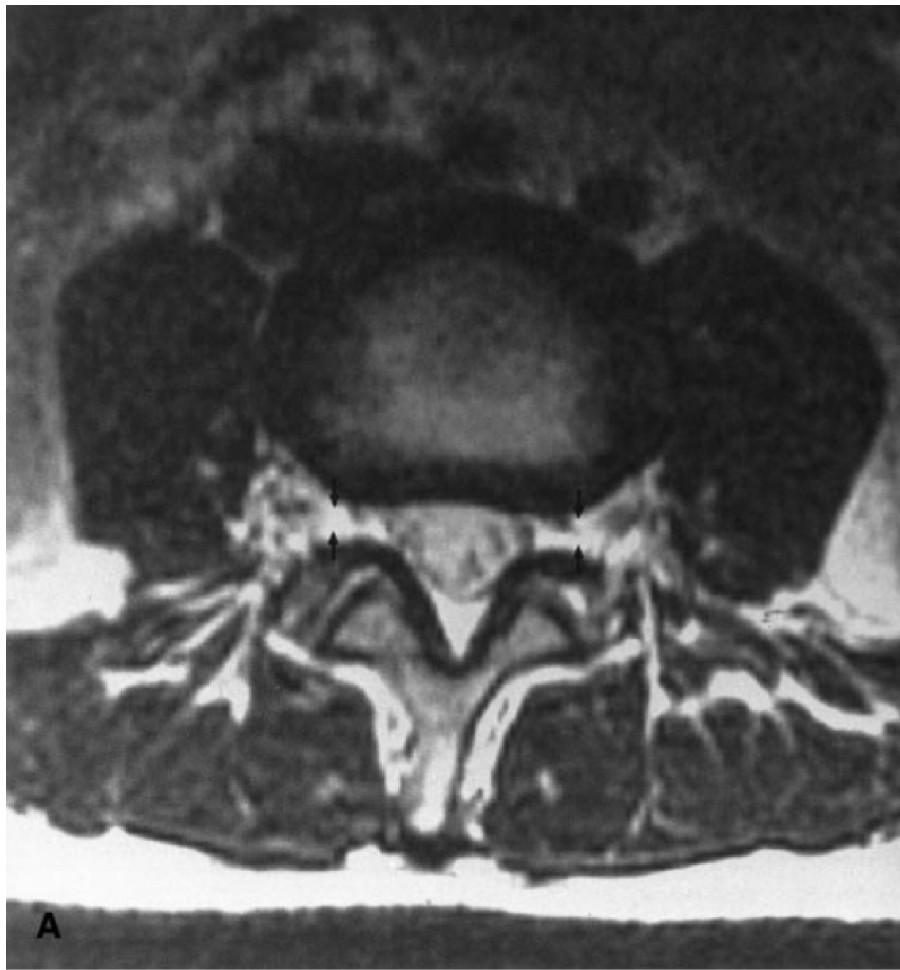


Internal vertebral venous plexuses



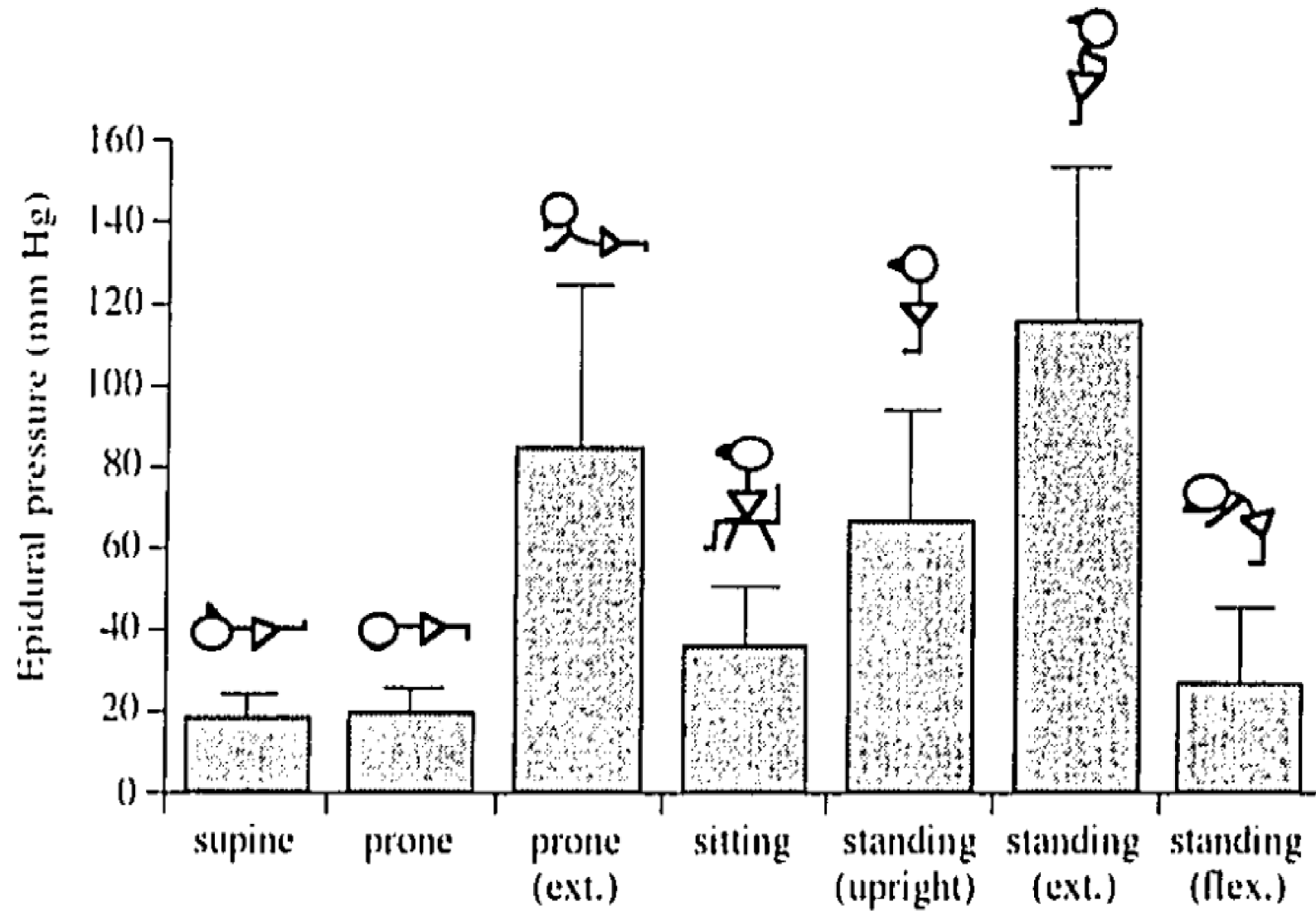
Chung et al Skeletal Radiol 2000





Chung et al Skeletal Radiol 2000

## Position and Epidural Pressure in LSS



Takahashi et al, Spine 1995

# Diagnosis

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## 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

# Differential Diagnosis

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

# Neurogenic Claudication (LSS) v.s. Lumbar Radiculopathy (LHD)

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	NC	LR
Demographics	> 65	40s
Lumbar flexion	Relief	Worse
Sitting	Relief	Worse
Level	L4-5	L5-S1
SLR	Negative	Positive

Suri 2012, Katz 2008, Rainville 2013



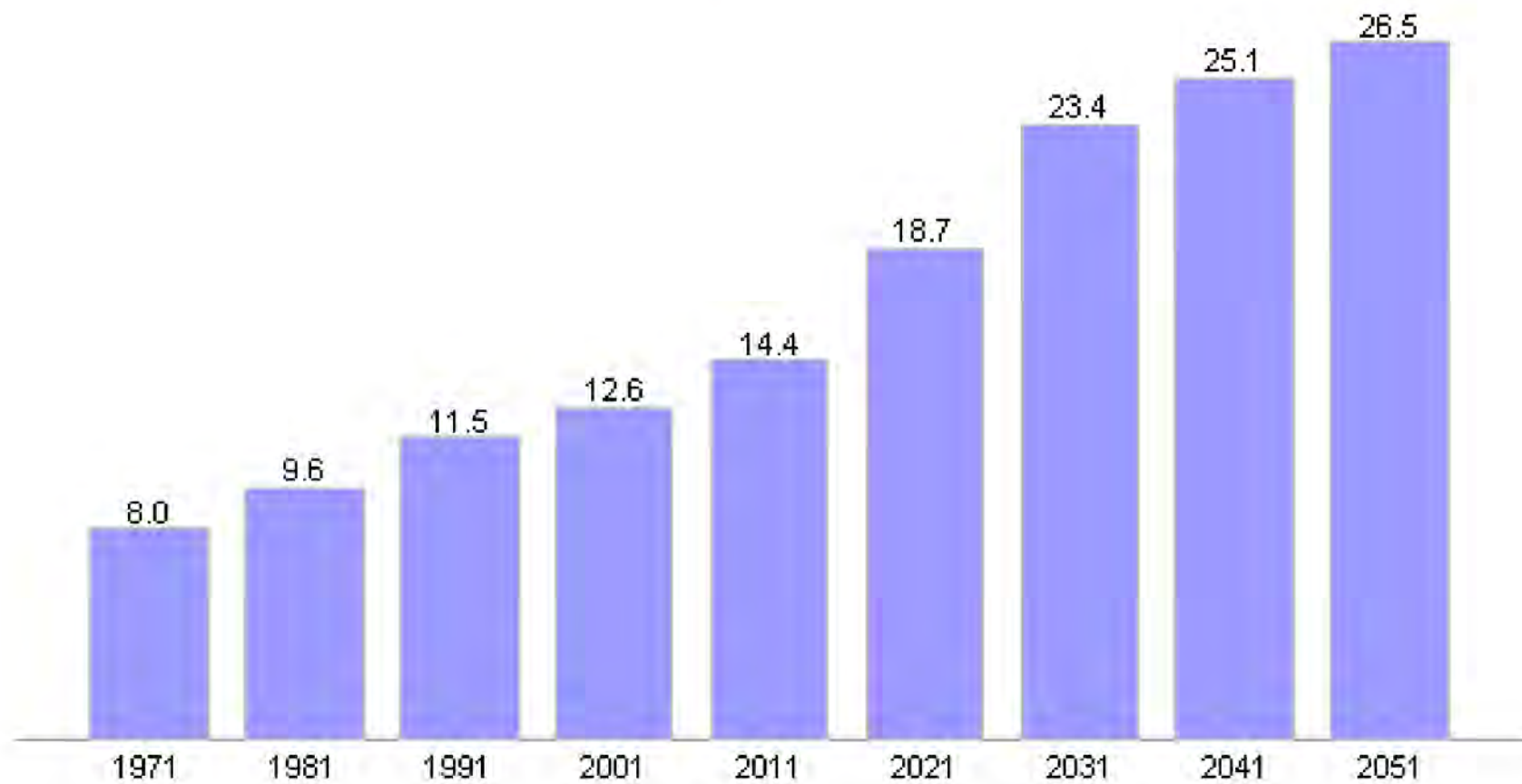
# Incidence & Prevalence

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- 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

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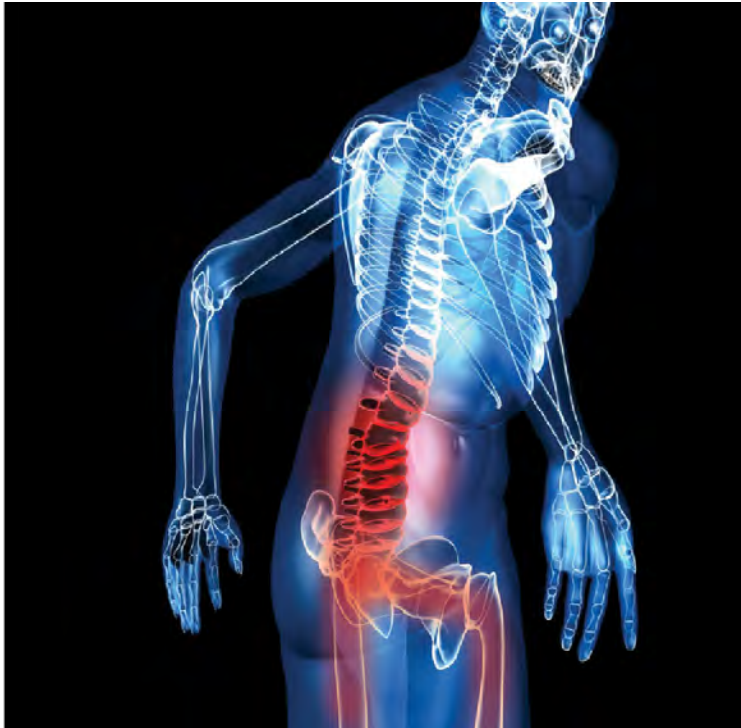
- A leading cause disability & loss independence in elderly [Kalichman 2009]
- Functional limitations > CHF, COPD or SLE [Fanuele 2000]
- Walking limitations > OA hip or OA knee [Winter 2010]
- Most common spine surgery age > 65 [AHCRQ 2001]
- Medicare in US- \$1.7 B per year surgical cost alone [Deyo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

# Treatment- Neurogenic Claudication

Intervention	Effectiveness
Calcitonin	Not likely
NSAIDS, Vit B12, Gabapentin, Prostagladins	?
Epidural Injections	?
Physical Therapy/ manual therapy	?
Multi-modal	?
Surgery	?

Ammendolia et al Spine 2012, Ammendolia et al Cochrane Library 2013,  
Ammendolia et al Euro Spine J 2014

# 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**

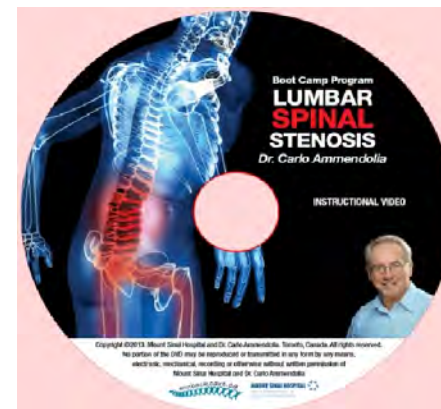


# Boot Camp Program

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Boot Camp Program  
**LUMBAR  
SPINAL  
STENOSIS**  
*Dr. Carlo Ammendolia*





Version 6	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
1. Stationary Bike - leaning forward	___ min	___ min	___ min	___ min	___ min	___ min
Lying on Back						
2. Knee to chest stretch	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
Right then left	repeat	repeat	repeat	repeat	repeat	repeat
3. Knee to opposite chest	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
Right then left	repeat	repeat	repeat	repeat	repeat	repeat
4. Double knee to chest	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
5. Pelvic tilt	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
6. Nordic hamstring (leg then foot)	Repeat to	Repeat to	Repeat to	Repeat to	Repeat to	Repeat to
Right then left	max lift	max lift	max lift	max lift	max lift	max lift
7. Pelvic tilt	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
8. W sit ups	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
Lying on Side						
9. Side sit ups-knees bent	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
Right then left	repeat	repeat	repeat	repeat	repeat	repeat
10. Side leg lifts - elevate-move forward and back	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
Right then left	repeat	repeat	repeat	repeat	repeat	repeat
11. Quadriceps stretch- Gray foot or lower leg and pull toward buttock- right and left	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
Lying on stomach with large pillow under pelvis						
12. Back leg extensions- lift on inches. Right then left	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
13. Torso extensions-lift on inches	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
Sitting						
14. Sit -stand from chair	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
15. Sit forward, grasp ankles and pull downward	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
Standing						
16. Standing pelvic tilt	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
17. Groin stretch- place foot on chair and lean forward-right and left	hold ___	hold ___	hold ___	hold ___	hold ___	hold ___
	repeat	repeat	repeat	repeat	repeat	repeat
Walking						
18. Graduated walking with pelvic tilt	___ steps	___ steps	___ steps	___ steps	___ steps	___ steps

Avoid back extension activities - that is arching your back backwards



Effective July 1st, 2010

Chiropractic fees

Initial Assessment	\$100
Subsequent visit	\$50
Re-assessment	\$75













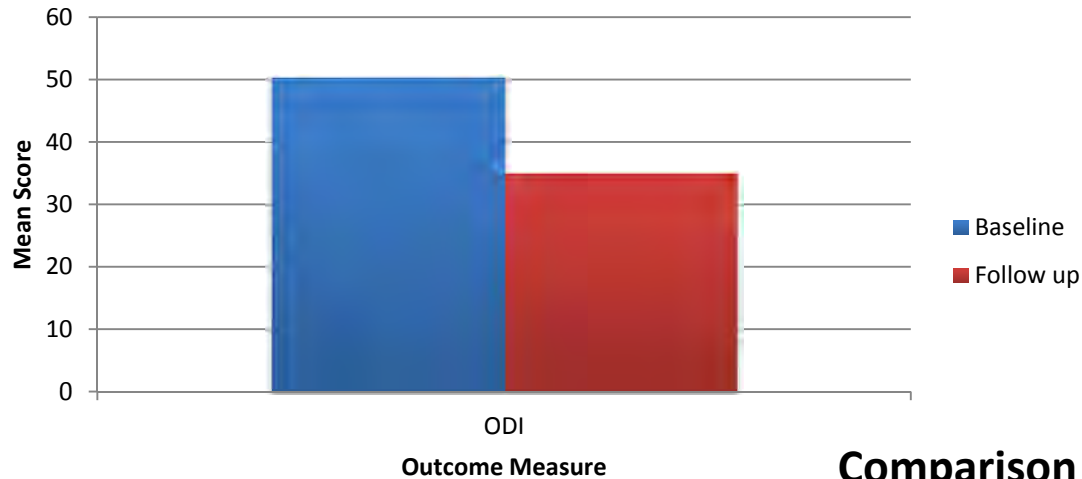






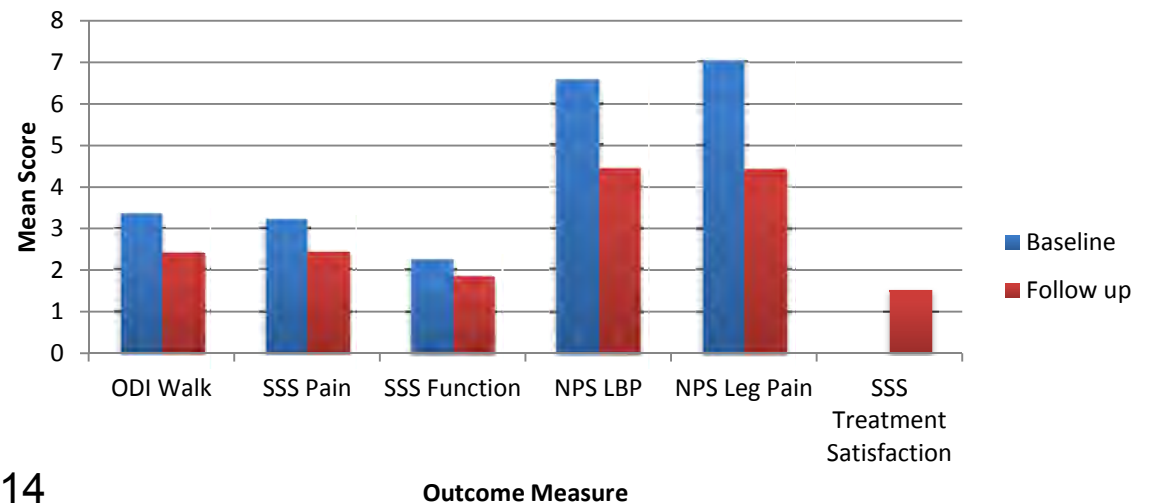
# Retrospective Study

## Comparison of Outcome Measures at Baseline and 6-week Follow Up



**\*\*All differences in outcomes were both clinically and statistically significant**

## Comparison of Outcome Measures at Baseline and 6-week Follow Up





# Animal Models in DLSS



# TENS – Neurogenic Claudication

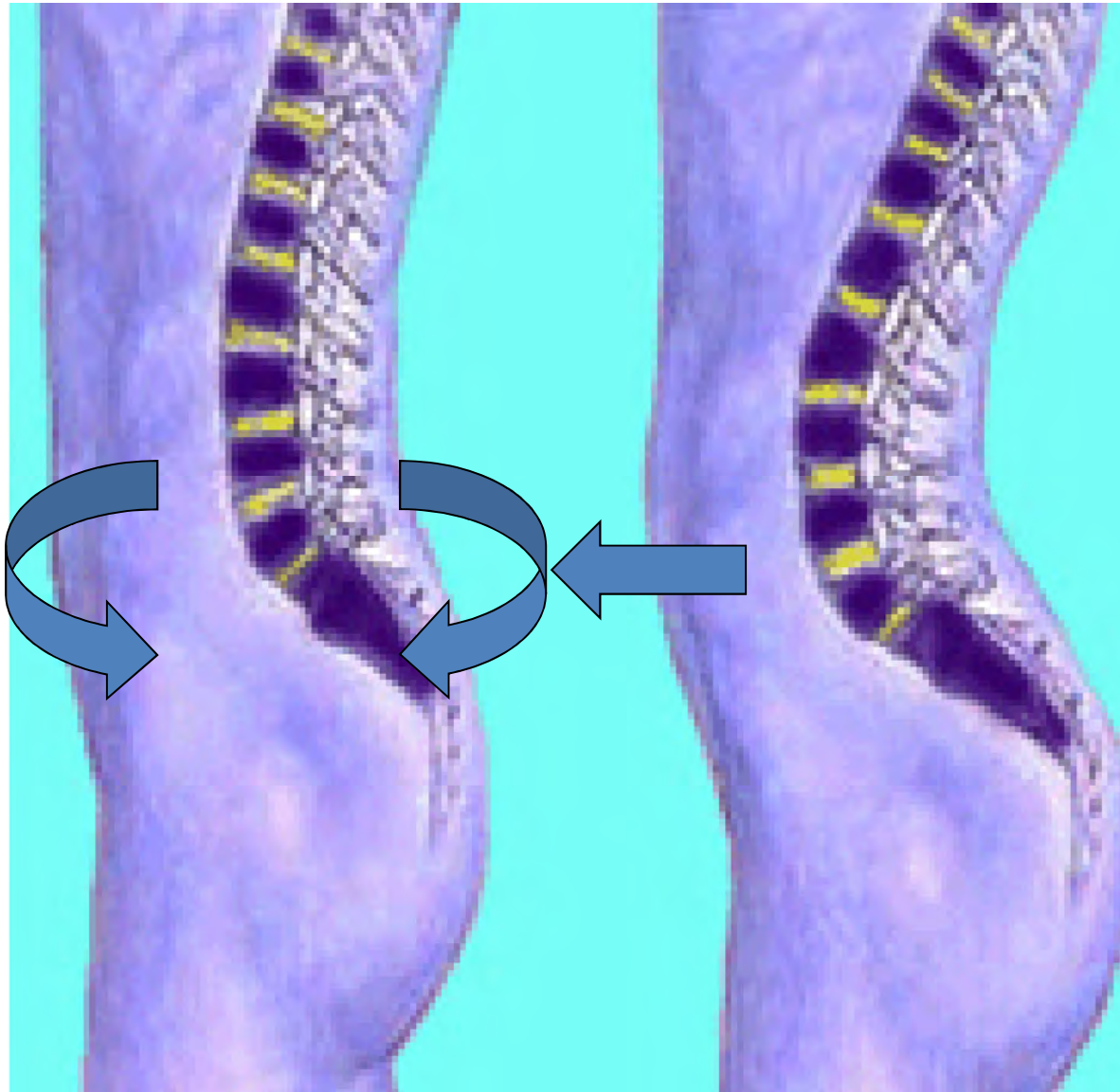
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- Lower extremity ischemic pain
- Combination with other treatments
- electroacupuncture
- no RCT of TENS while walking

Walsh 1995, Seenan 2002, Inone 2008

# Lumbar Spinal Stenosis Belt for DLSS



# U of T Lumbar Spinal Stenosis Study

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## 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

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## 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

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## 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

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## 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*



# U of T Lumbar Spinal Stenosis Study

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## 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

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## 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*

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

# Statistics

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## 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

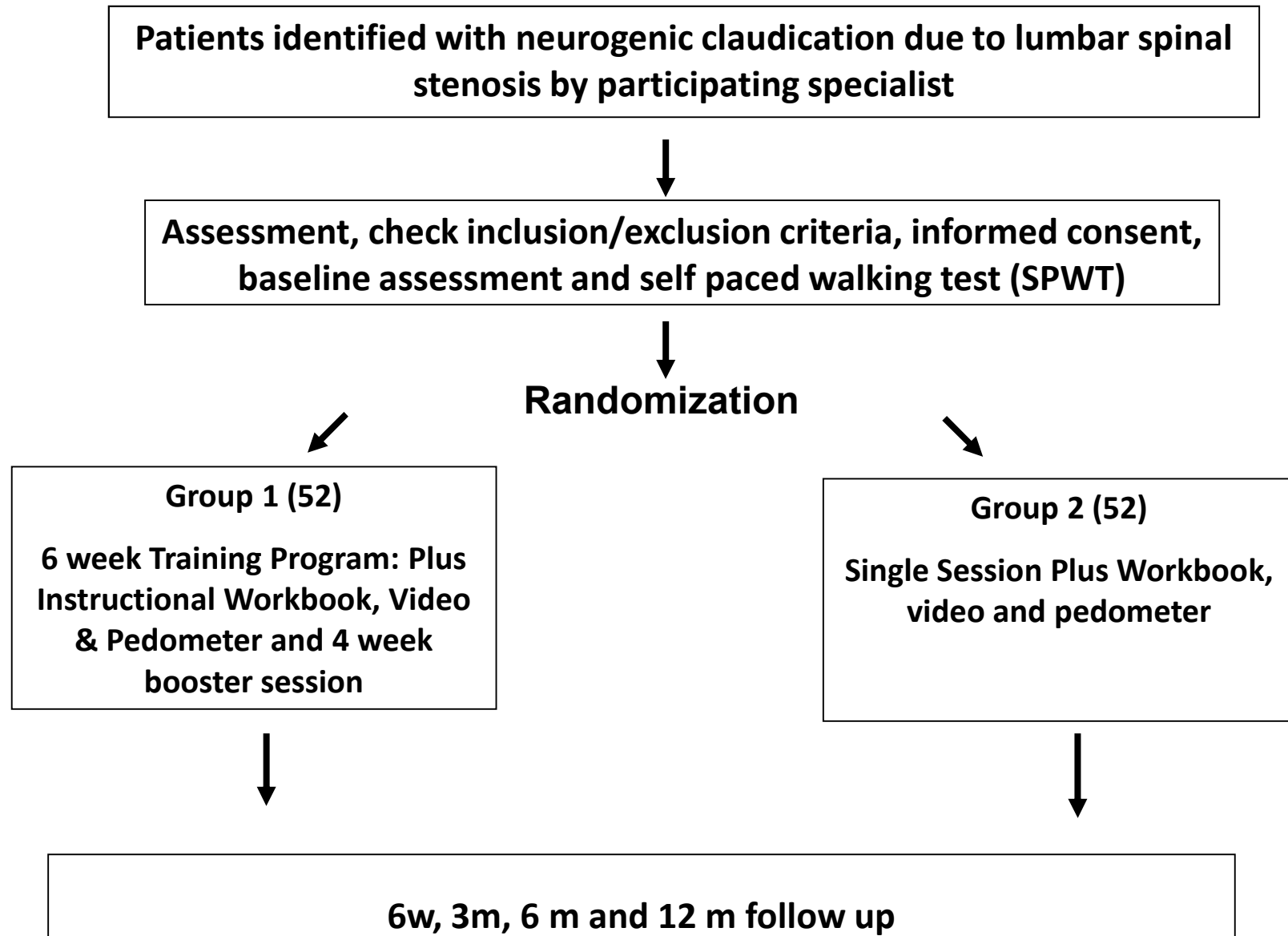
# Statistics

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## 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

## Primary Study Flow



## 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

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## University of Toronto

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

Study Pamphlet with contact information

# Carlo Ammendolia



Contact info:  
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