

Session I

# 어떻게 치료하나?

김충효  
강원의대

### Nonsurgical Treatment of spinal stenosis Evidence based recommendations

- 약물치료
- Physical therapy
- Pelvic traction
- Therapeutic Exercise
- Acupuncture ?
- 신경차단과 주사 (척추학, The spine)

### Nonsurgical Treatment of spinal stenosis Ammendolia 2012

- Inclusion criteria
  1. **Clinical symptoms:** back pain radiation to lower limbs or buttocks; fatigue or loss of sensation in the lower limbs aggravated by walking. Persistent pain without progressive neurologic dysfunction. Duration of symptoms and signs for **more than 6 months**.
  2. **Imaging techniques:** spinal canal narrowing, the sagittal diameter of the dural sac being **less than 10 mm** or cross-sectional dural area being less than 75 mm
  3. Clinical signs and symptoms corresponding to segmental radiographic level of stenosis.
- Result
  - **Low quality evidence that prostaglandins, and very low quality evidence that gabapentin or methylcobalamin, improves walking distance.**
  - **Low and very low quality evidence that physical therapy** was no better in improving walking ability compared to no treatment, oral diclofenac plus home exercises, or combined manual therapy and exercise.
  - **Very low quality evidence that epidural injections** improve walking distance up to 2 weeks compared to placebo.
  - **Low- and very low-quality evidence that various direct decompression surgical techniques** show similar significant improvements
- Conclusion
  - **Moderate and high-quality evidence for nonoperative treatment is lacking and thus prohibits recommendations for guiding clinical practice.**

### Nonsurgical Treatment of spinal stenosis Ammendolia 2012

**Four studies with low risk of bias**  
Fulfilled six or more of the 12 criteria, including clearly described and appropriate randomization and allocation concealment, and with no severe flaws.

1. **Matsudaira** The efficacy of prostaglandin E1 derivative in patients with lumbar spinal stenosis. *Spine* 2009
2. **Goren** Efficacy of exercise and ultrasound in patients with lumbar spinal stenosis: a prospective randomized controlled trial. *Clinical Rehabilitation* 2010.
3. **Pua** Treadmill walking with body weight support is no more effective than cycling when added to an exercise program for lumbar spinal stenosis: a randomised controlled trial. *Australian Journal Physiotherapy* 2007
4. **Malmivaara** Surgical or non-operative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine* 2007

### Limaprost vs etodolac Matsudaira 2009

- Randomized, open-label, active-controlled trial was conducted at 4 study sites in Japan
- Inclusion criteria
  - age between 50 and 85 years; presence of both NIC and cauda equina symptoms (at least presence of bilateral numbness in the lower limbs)
  - MRI-confirmed central stenosis with acquired degenerative LSS.
- These outcomes were measured at baseline and then at **week 8** after administration

### Limaprost vs etodolac Matsudaira 2009

- Satisfaction and improving QOL
  - Limaprost was shown superior to etodolac (NSAIDs), not only in terms of quality of life (MOS 36-item SF-36), the primary endpoint, but also in terms of walking distance and patients' subjective assessment of improvement and satisfaction (Genevay 2010)

**Table 2. Primary Efficacy Outcomes: SF-36 Subscale Scores**

SF-36 Subdomains	Limaprost Group (n = 36)		Etodolac Group (n = 32)		Change from Baseline	P*
	Baseline	Wk 9	Baseline	Wk 9		
Physical functioning	58.9 ± 26.0	67.8 ± 18.1	51.7 ± 21.1	57.2 ± 22.4	11.8 ± 14.8	0.01
Role physical	61.2 ± 26.8	72.0 ± 24.5	62.9 ± 24.3	68.4 ± 22.7	11.2 ± 22.0	0.03
Bodily pain	42.2 ± 22.0	58.2 ± 16.7	47.2 ± 23.3	48.2 ± 24.1	13.2 ± 28.8	<0.01
General health	53.5 ± 17.5	62.8 ± 17.8	50.7 ± 17.7	58.4 ± 17.1	4.3 ± 11.2	0.08
Vitality	57.2 ± 22.1	68.2 ± 19.5	48.8 ± 22.4	60.2 ± 24.2	12.2 ± 18.9	0.02
Social functioning	56.2 ± 25.0	70.8 ± 20.1	60.1 ± 22.9	67.2 ± 22.2	10.0 ± 14.0	0.17
Role emotional	60.2 ± 25.0	73.2 ± 20.9	60.8 ± 22.4	62.8 ± 21.9	10.0 ± 16.2	0.07
Mental health	60.2 ± 25.0	72.2 ± 17.2	71.1 ± 23.3	69.8 ± 22.9	8.9 ± 16.0	<0.01

**Table 5. Secondary Efficacy Outcomes: Neurogenic Intermittent Claudication (NIC) Distance**

Distance	Limaprost Group (n = 34)		Etodolac Group (n = 32)		P*
	Baseline	Wk 9	Baseline	Wk 9	
Distance	112.0 ± 41.0	112.0 ± 41.0	112.0 ± 41.0	112.0 ± 41.0	<0.01
Change from Baseline	0.0	0.0	0.0	0.0	<0.01

### Limaprost vs etodolac Matsudaira 2009

- LBP and claudication
  - A trend towards less leg pain but no difference in back pain was observed in the limaprost group
- Adverse event
  - 1 participant: hot flashes /flushing and anorexia a few days after administration
  - 2 : stomach discomfort at the start of administration and 4 weeks after administration

**Table 4. Secondary Efficacy Outcomes: Low Back Pain, Leg Pain, and Leg Numbness**

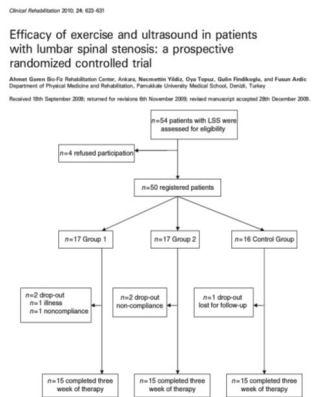
Outcome	Severity	Limaprost Group (n = 34)		Etodolac Group (n = 32)		P*
		Baseline	Wk 9	Baseline	Wk 9	
Low back pain	None	6	7	4	7	0.77
	Slight	1	8	5	5	
	Mild	8	9	6	6	
	Moderate	16	7	11	9	
	Strong	3	2	4	3	
Leg pain	None	0	1	2	2	0.08
	Slight	2	2	4	3	
	Mild	1	10	5	8	
	Moderate	19	8	13	11	
	Strong	9	4	7	7	
Leg numbness	None	1	1	3	2	<0.01
	Slight	0	3	0	0	
	Mild	3	8	0	0	
	Moderate	5	10	4	2	
	Strong	15	9	14	17	

### Other Medical treatment (The spine)

- Acetaminophen
  - Initial medication is recommended, S/E: liver toxicity
- NSAIDs
  - S/E: Short term: GI problem, Long term: Renal problem
  - S/E: COX-2 inhibitor: cardiac
- Narcotics or muscle relaxant
  - only short term use
  - S/E: Fall-activity restriction
- Amitriptyline/imipramine
  - Anticholinergic S/E: cardio, orthostatic hypotension, confusion, weight gain, dry mouth, urinary retention, constipation
- Gabapentin
  - S/E: Dizziness, fatigue, drowsiness, ataxia, peripheral edema, tremor
  - Sexual dysfunction, toxicity in renal impairment

### Efficacy of exercise and ultrasound Goren 2010

- Participants were randomized to the ultrasound plus exercise group (group 1, n=17), sham ultrasound plus exercise group (group 2, n=17) or no treatment/no exercise group (control, n=16)
- Stretching and strengthening exercises for lumbar, abdominal, leg muscles as well as low-intensity cycling exercises were given as therapeutic exercises.
- Ultrasound was applied with 1 mHz, 1.5W/cm2 intensity, in continuous mode on the back muscle for 10 minutes in group 1 while ultrasound on/off mode was applied in group 2.



### Efficacy of exercise and ultrasound Goren 2010

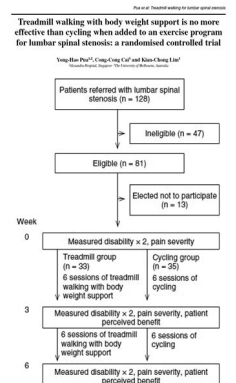
- A statistically significant improvement is found in all of the post-treatment parameters in group 1 and group 2, except for the leg pain parameter in group 1.
- leg pain score and Oswestry Disability Index score were significantly lower in both treatment groups at the end of the treatment compared with the control group.
- In addition, it was detected that the consumption of analgesics in group 1 was statistically lower than that in the control group

**Table 2. Comparison of clinical characteristics of patients in groups**

	Group 1 (n=17)	Group 2 (n=17)	Control (n=16)	P-value*
<b>Pain - visual analogue scale</b>				
Pre-treat	5.53 ± 1.96	6.20 ± 2.00	5.26 ± 2.26	0.605
Post-treat	2.22 ± 1.29	4.50 ± 2.28	4.66 ± 2.90	0.104
Change	-3.31 ± 3.02	-1.68 ± 2.88	-0.61 ± 1.68	P=0.285
<b>Leg pain</b>				
Pre-treat	5.80 ± 2.90	6.33 ± 3.23	6.45 ± 2.80	0.584
Post-treat	4.53 ± 2.98	5.98 ± 3.02	7.13 ± 3.04	0.006*
Change	-1.47 ± 3.02	-2.47 ± 3.75	0.52 ± 1.59	P=0.194
<b>Disability - Oswestry Disability Index</b>				
Pre-treat	25.80 ± 7.50	26.90 ± 10.19	22.20 ± 8.60	0.090
Post-treat	21.50 ± 9.30	19.10 ± 8.00	28.60 ± 9.20	0.034*
Change	-3.94 ± 7.20	-7.80 ± 10.20	-3.60 ± 11.66	P=0.366
<b>Functional capacity - treadmill test</b>				
Pre-treat	548.60 ± 266.10	421.96 ± 364.30	412.10 ± 269.20	0.479
Post-treat	628.90 ± 460.20	526.90 ± 356.40	346.90 ± 213.40	0.099
Change	94.30 ± 173.90	114.94 ± 212.40	-65.10 ± 158.87	P=0.162
<b>Time to the first symptoms</b>				
Pre-treat	136.33 ± 93.40	159.70 ± 96.50	89.60 ± 91.96	0.946
Post-treat	212.20 ± 211.75	241.40 ± 196.90	183.10 ± 244.00	0.987
Change	156.55 ± 159.00	121.70 ± 102.71	93.50 ± 252.19	P=0.807
<b>Using analgesic - paracetamol tablet</b>				
Pre-treat	8.33 ± 15.10	16.00 ± 22.47	39.60 ± 27.75	0.046*

### Treadmill walking with body weight support vs cycling Pua 2009

- RCT was conducted at the physiotherapy outpatient clinic of a large tertiary institution in Singapore
- Participants in both groups received intervention twice a week for the next 6 weeks, for a total of 12 sessions.
- Drop out
  - Twelve participants (18%) did not complete the Week 3 measurements.
  - Twenty-one participants (29%) did not complete the Week 6 measurements.
  - There were 25 participants in all (37%) who did not attend on at least one measurement occasion.



### Treadmill walking with body weight support vs cycling Pua 2009

- No difference between groups in the overall reduction in disability. When the groups were combined, they reduced their disability on both measures over time ( $p < 0.001$ ).
- At 3 weeks, the treadmill group perceived a benefit two thirds as often as the cycling group; and at 6 weeks, half as often as the cycling group
- The number needed to treat for participants in the treadmill group to perceive a benefit greater than that perceived by the cycling group was -21 at 3 weeks and -8 at 6 weeks

**Treadmill walking with body weight support is no more effective than cycling when added to an exercise program for lumbar spinal stenosis: a randomised controlled trial**

Yong-Ho Pua<sup>1,2</sup>, Chung-Feng Lin<sup>3</sup> and Kuan-Feng Lin<sup>4</sup>

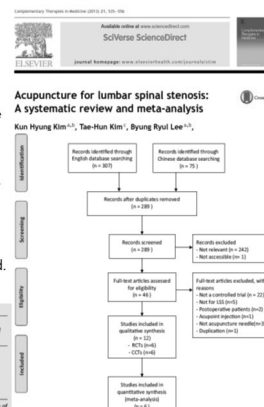
Table 1. Number of participants (%) in each group who reported an improvement, odds ratio (95% CI) and numbers needed to treat (NNT) for difference between groups for those categorised as response.

Category	Week 3		Week 6	
	Groups	Difference between groups	Groups	Difference between groups
Improved (number)	5 (7)	0.86 (-0.6 to 2.4)	8 (13)	0.50 (-0.17 to 1.18)
OR (95% CI)	(0.25)	(0.18 to 2.4)	(0.25)	(0.17 to 1.48)
NNT (95% CI)	(20)	(1.2 to 1.9)	(20)	(1.1 to 2.0)
Ability to walk (number)	8 (11)	0.66 (-0.16 to 1.48)	12 (19)	0.41 (-0.2 to 1.02)
OR (95% CI)	(0.21)	(0.23 to 2.3)	(0.25)	(0.18 to 2.98)
NNT (95% CI)	(15)	(1.2 to 2.2)	(15)	(1.2 to 2.4)

Abbreviations: CI, confidence interval; OR, odds ratio; NNT, number needed to treat.

### Acupuncture for lumbar spinal stenosis: Kim 2013

- All RCTs had generally high or uncertain risk of bias
  - No studies reported whether allocation concealment was attempted.
  - All studies had high risk of performance bias due to the unblinded nature of open comparison and did not report whether the outcome assessors were blinded.
  - Four RCTs did not mention whether dropout or loss of follow-up occurred during the study
  - No studies provided information about any discrepancy between the original trial protocol and the reported results or trial registration number.
- No placebo or sham-controlled RCTs or RCTs comparing acupuncture with conventional non-surgical or surgical treatments were found.



**Table 4. Risk of bias of included RCTs.**

Study	Random sequence generation	Allocation concealment	Participant blinding	Assessor blinding	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Chen (2009) <sup>13</sup>	Low	Unclear	High	Unclear	Low	Unclear	Low
Kim (2011) <sup>12</sup>	Low	Unclear	High	Unclear	Low	Unclear	Low
Kou (2011) <sup>14</sup>	Low	Unclear	High	Unclear	Low	Unclear	Low
Lu (2012) <sup>15</sup>	Low	Unclear	High	Unclear	Low	Unclear	Low

### Acupuncture for lumbar spinal stenosis: Kim 2013

**Table 2. Summary characteristics of included RCTs.**

First author (year)	Sample size	Interventions	Outcomes (follow-up periods)	Comments
Chen (2009) <sup>13</sup>	(1) 60 (30/30)	Electroacupuncture plus biofeedback therapy versus electroacupuncture alone. Once daily for 20 days	Response rate (post-treatment)	Significantly favored combined treatments
Ji (2011) <sup>14</sup>	(1) 126 (64/62)	Manual acupuncture plus oral herbal decoction versus manual acupuncture alone. Once daily for 10 days	(1) Response rate (post-treatment) (2) Average lumbar assessment scores (post-treatment)	Both outcomes significantly favored combined treatments
Kou (2011) <sup>14</sup>	(1) 154 (77/77)	Manual acupuncture with warm-dredging techniques versus manual acupuncture with simple insertion. Once daily for 20 days	(1) Response rate (post-treatment) (2) Pain VAS for back and leg (up to 6 months) (3) Overall assessment scores (up to 6 months) (4) Spinal function scores (up to 6 months) (5) Quality of life scores (up to 6 months)	All outcomes other than response rate significantly favored augmented acupuncture with warm-dredging techniques
Lu (2012) <sup>15</sup>	(1) 60 (30/30)	Manual acupuncture with warm-promoting techniques versus manual acupuncture with simple insertion. Once daily for 20 days	(1) Response rate (2) Overall assessment scores (up to 6 months) (3) Spinal function scores (up to 6 months) (4) Quality of life scores (up to 6 months)	All outcomes significantly favored augmented acupuncture other than response rate, overall assessment scores at post-treatment, and spinal function scores at 6-month follow-up
Chen (2011) <sup>12</sup>	(1) 120 (30/30/30)	Manual or Electroacupuncture including BL32 stimulation versus those without BL32 stimulation. Once daily for 30 days	(1) Response rate (post-treatment) (2) Overall assessment scores (post-treatment)	All outcomes significantly favored acupuncture with BL32 stimulation
Lu (2012) <sup>15</sup>	(1) 62 (32/30)	Manual acupuncture with thick silver needle insertion on BL32 plus warm-needle techniques versus warm-needle techniques alone. Twice a week for 5 weeks	(1) Response rate (post-treatment) (2) Spinal function scores (post-treatment)	All outcomes significantly favored silver needle insertion on BL32

RCT, Randomised controlled trial; VAS, visual analogue scale.

### Acupuncture for lumbar spinal stenosis: Kim 2013

- Current evidence for the use of acupuncture in patients with LSS is limited, due to the scarcity of existing clinical trials and high risk of bias in various aspects, which impedes the reliability of the trials
  - The number of improved patients was significantly higher for acupuncture combined with related therapies or acupuncture with additional stimulation than for acupuncture alone or acupuncture with simple stimulation based on a posttreatment assessment
- None of the included studies provided reports on adverse events.

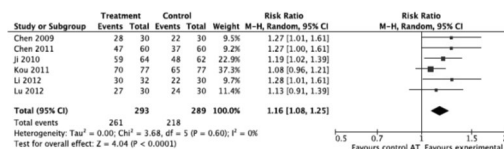


Figure 2. The number of improved patients based on post-treatment assessment. In a study by Chen (2011)<sup>12</sup>, four groups of acupuncture stimulation techniques were merged into two for pairwise comparison between the techniques with BL32 stimulation and the methods without this stimulation.

### Efficacy of acupuncture for degenerative lumbar spinal stenosis: protocol for a randomised sham acupuncture controlled trial Zongshi 2016

**Table 1. Summary of the acupuncture location**

**Open Access**

**BMJ Open Efficacy of acupuncture for degenerative lumbar spinal stenosis: protocol for a randomised sham acupuncture-controlled trial**

Figure 2. Illustration of sham acupuncture.

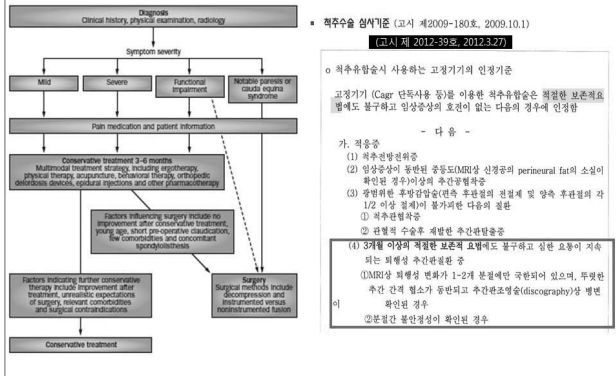
**Table 2. Time of data collection**

Measures	Baseline	Treatment phase (weeks)					Follow-up phase (months)					
		w1	w2	w3	w4	w5	m1	m2	m3	m4	m5	
RMDC	x	x	x	x	x	x	x	x	x	x	x	x
HRQ	x	x	x	x	x	x	x	x	x	x	x	x
SPWT	x	x	x	x	x	x	x	x	x	x	x	x
MSQ	x	x	x	x	x	x	x	x	x	x	x	x

### Surgical treatment vs nonsurgical treatment

- Malmivaara** Surgical or non-operative treatment for lumbar spinal stenosis? A randomized controlled trial. Spine 32 2007
  - Although patients improved over the 2-year follow-up regardless of initial treatment, those undergoing decompressive surgery reported greater improvement regarding leg pain, back pain, and overall disability.
  - The relative benefit of initial surgical treatment diminished over time, but outcomes of surgery remained favorable at 2 years
- Zaina** Surgical versus nonsurgical Treatment for Lumbar Spinal Stenosis spine 41 2016
  - We cannot conclude on the basis of this review whether surgical or nonsurgical treatment is better for individuals with LSS.
  - Nevertheless, we can report on the high rate of effects reported in three of five surgical groups, ranging from 10% to 24%. No side effects were reported for any of the conservative treatment options

## 요추관 협착증 어떻게 치료해야 하나? Siebert 2009



## Take home message

### 요추관 협착증 어떻게 치료해야 하나?

• From three studies with low risk of bias

1. Limaprost vs etodolac Matsudaira 2009

- Superior to etodolac, in terms of quality of life and walking distance
- A trend towards less leg pain but no difference in back pain

2. Efficacy of exercise and ultrasound vs exercise Goren 2010

- Exercise improved QOL, LBP
- US effect? no significant improvement of leg pain, reduced analgesics consumption

3. Treadmill walking with body weight support vs cycling

- Exercise reduced their disability on both measures over time.
- No difference between groups in the overall reduction in disability.

• Acupuncture

- Current evidence for the use of acupuncture in patients with LSS is limited