

# Manual therapy interventions for patients with lumbar spinal stenosis: a systematic review

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## ABSTRACT

**Objective:** The objective of this paper is twofold (1) determine the quality of current available studies regarding the use of manual therapy intervention for the treatment of lumbar spinal stenosis LSS and (2) determine the effectiveness of manual therapy for the treatment of LSS.

**Data sources:** A literature search was conducted using the MEDLINE, CINAHL, PEDro and Cochrane Controlled Trials databases. Clinical trials and observational studies were also included.

**Review methods:** Abstracts of potentially relevant articles were reviewed and screened for inclusion criteria. The quality of the relevant articles after abstract screening was measured against the nineteen item Maastricht-Amsterdam criteria list. Two reviewers independently assessed the relevant articles using these criteria. Overall methodological quality scores and internal validity scores were determined by adding the positive scores from their respective criteria.

**Results:** Thirty-one relevant studies were identified. Twenty of these studies were excluded, leaving eleven studies meeting inclusion criteria for review. Overall methodological quality of the eleven studies was poor. Only one high quality randomized controlled trial (RCT) was identified.

**Conclusion:** Based on this systematic review, preliminary evidence indicates that manual therapy combined with exercise demonstrates potential benefit in the treatment of LSS, but further evidence of effectiveness is needed. **Reiman MP, Harris JY, Cleland JA (2009): Manual therapy interventions for patients with lumbar spinal stenosis: a systematic review. New Zealand Journal of Physiotherapy 37(1) 17-28.**

Key Words: spinal stenosis, lumbar spine, systematic review

## INTRODUCTION

Lumbar spinal stenosis, a focal narrowing of the spinal canal, nerve root canals, or intervertebral foramina (Arnoldi et al., 1976; Penning 1992) is a common and disabling condition in the older adult (Tomkins et al. 2007, Deyo et al. 2005; Weinstein et al. 2006). High depression score has been associated with more severe symptoms, poorer walking capacity and less treatment satisfaction (Katz et al. 1995), as well as poorer postoperative treatment satisfaction (Katz et al. 1999). These physical and mental impairments may continue to increase in prevalence as it has been estimated that approximately 4% of patients visiting their primary care physician and 14% of patients seeking assistance from a specialist for low back pain (LBP) present with LSS (Fanuele et al., 2000; Hart et al., 1995; Long et al., 1996).

Increasing numbers of older adults may further increase the financial and societal burden. Recently it has been demonstrated that spending for lumbar fusion increased more than 500%, from \$75 million to \$482 million over the decade from 1992 to 2003 (Weinstein et al. 2006). Lumbar fusion represents 47% of total spending for back surgery in 2003, compared to 14% in 1992 (Weinstein et al. 2006)

despite the fact that the effectiveness of surgery for LSS as compared with nonsurgical treatment has not been demonstrated in controlled trials (Weinstein et al. 2008). There continues to exist considerable controversy as to the most optimal management strategies for patients with LSS (Ciol et al., 1996; Gibson et al., 1999; Waddell and Gibson 2000).

In addition to the fact that the number of surgical interventions performed for the management of LSS has increased dramatically over the past few decades (Tomkins et al. 2007, Deyo et al. 2005; Weinstein et al. 2006), re-operation rates for patients with LSS range from 5-23% (Chang et al. 2005; Jansson et al. 2005). Adverse events associated with spinal surgery for the treatment of LSS must also be considered and have been reported to include myocardial infarction, wound infections, renal failure, congestive heart failure, cerebrovascular accident, and dural tears (Carreon et al. 2003; Malter et al. 1998; Ragab et al. 2003). It has been proposed that better data on surgical effectiveness is needed as instrumented fusion was found to be very expensive compared with the incremental gain in health outcome (Kuntz et al. 2000). As a result of the aforementioned a trial of

conservative management has been recommended for patients with LSS prior to surgical intervention (Reindl et al. 2003).

Clinical trials specifically examining and reporting on patients with lumbar spinal stenosis who receive conservative measures are rare (AHRQ 2001). The lack of evidence in support of commonly utilized conservative interventions continues to result in a lack of clarity regarding what interventions should be utilized to manage patients with LSS. Manual therapy is an intervention often used by physical therapists, and includes both thrust and non-thrust manipulation. (Guide to Physical Therapist Practice 2003). Despite the fact that manual therapy has been employed by skilled physical therapists since the inception of the profession (Paris 2000), its use for the management of LSS has begun to gain attention in the literature. To date, the use of manual therapy has not been systematically reviewed in an attempt to determine its effectiveness in patients with LSS. The purpose of this study was to systematically review the evidence and make treatment recommendations regarding the use of manual therapy interventions for patients with LSS.

## **METHOD**

### **Types of participants**

Studies were considered only if they included patients diagnosed with LSS or symptoms consistent with LSS. These symptoms would typically include postural dependent symptoms (e.g. pain worse with extension and ambulation, relieved with flexion and sitting), progressive aching pain in mid lower back, possible unilateral or bilateral lower extremity symptoms (including neurogenic claudication) and potential lower extremity myotomal and dermatomal changes. Trials that included patients with acute, chronic or general LBP of non-specific nature; as well as subjects with other diagnosis of LBP were excluded.

### **Types of intervention**

Trials in which at least one of the treatments administered was a type of manual therapy, including thrust and/or non-thrust manipulation, massage or other manual treatments were included. Studies involving techniques where there was no manual contact between the clinician and the subject were excluded. Multi-modal interventions, including use of stretching and strengthening exercises, ultrasound, and joint protection home instructions, were included if the treatment program involved a component of manual therapy. Interventions including any form of manual therapy that were used in a comparison between conservative and surgical treatment of LSS were also included in the study.

### **Types of outcome measures**

To be eligible for this review, outcome measures had to include at least one of the following: pain

intensity scales, region specific disability scales (Oswestry Disability Index [ODI] or the Roland Morris disability scale), functional performance scales (6 minute walk test, treadmill walk test, etc.), or a global rating of perceived outcome.

## **Types of studies**

Both randomized clinical trials (RCT) and observational studies (non-randomized clinical trials, cohort studies, case series and case studies) were included due to the an expected low volume of evidence available on this topic.

## **Search of literature**

Multiple bibliographic databases were searched during October to November 2007. The following electronic databases were searched: MEDLINE using PubMed (1966-2007), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1983-2007), Physiotherapy Evidence Database (PEDro), and the Cochrane Controlled Trials Register in the Cochrane Library (latest edition). This is the search strategy recommended by the Cochrane Collaboration (van Tulder, et al. 1997). The MEDLINE search terms used in the search strategy are detailed in table 1. We also hand searched the reference lists of articles selected for this review to determine if other articles of relevance could be identified.

## **Study selection**

One reviewer (MR) performed the database searches and reviewed the title and abstracts. If it was determined the article might meet the inclusion criteria from the description of the diagnosis, patient symptoms, or manual therapy interventions utilized, the full text articles were obtained and selection criteria applied. See Figure 1 for the flow chart illustrating the reasoning for inclusion/exclusion of articles. Two authors of articles on this topic were contacted by e-mail to see if they were aware of any other relevant sources of information. No other studies of relevance to this review were identified.

**Table 1: MEDLINE search terms**

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Intervention terms: [physical therapy OR rehabilitation OR massage OR joint mobilization OR joint manipulation OR manual therapy OR stretching OR conservative treatments OR therapy]

Condition terms: [spinal stenosis OR lumbar spinal stenosis OR lumbar spine]

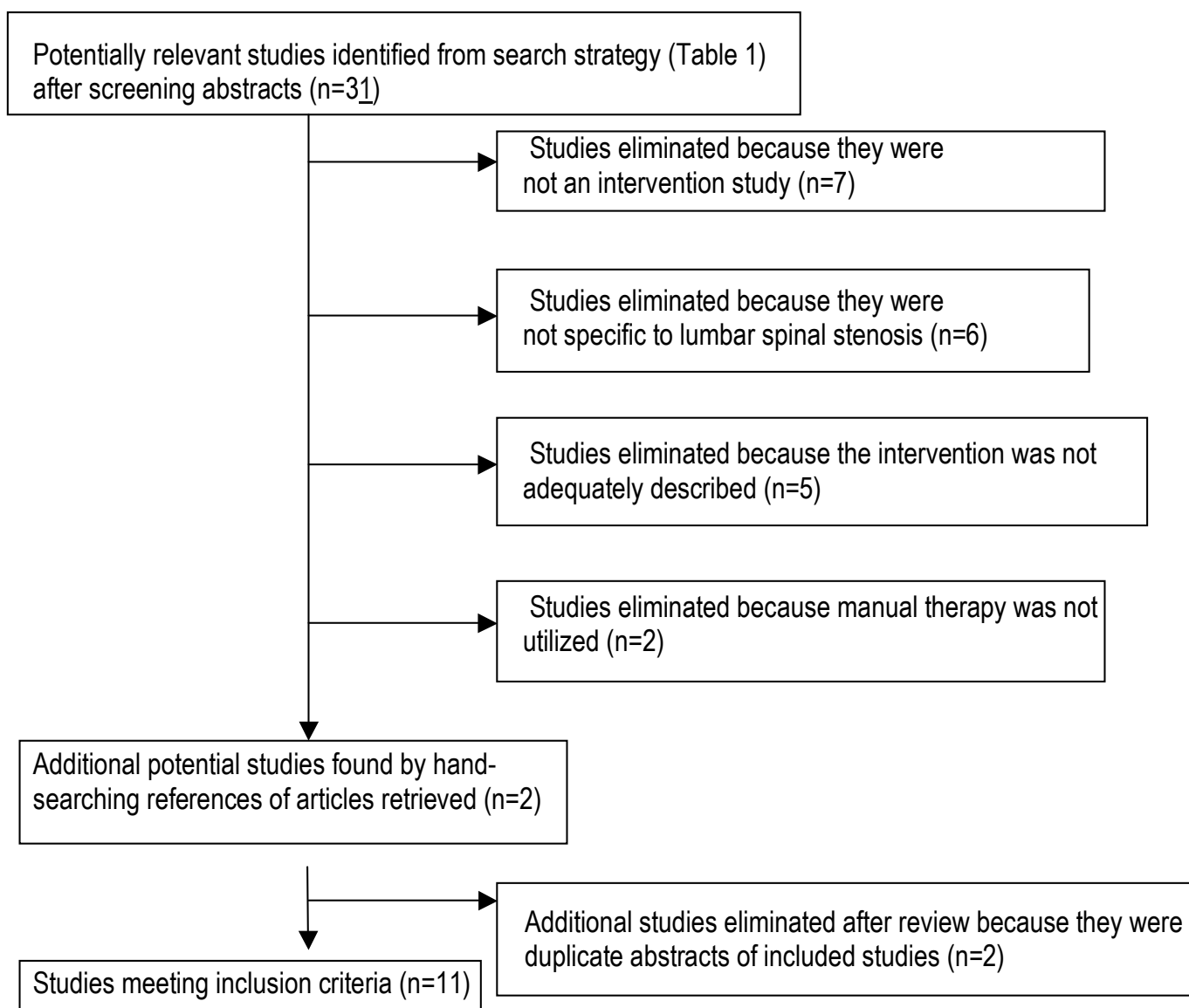
Limiting terms: method of study [clinical trial, meta-analysis, practice guideline, randomized controlled trial, review, case reports, journal article, multicenter study]; English language only; All Adult: 19+ years; Humans

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## **Methodological quality**

The methodological quality of each article was rated using the Maastricht-Amsterdam criteria list (van Tulder et al., 1997). It consists of 19 items that can be rated individually using one of three options: 'yes/no/don't know' (Table 2). The overall methodological quality score (overall QS) is determined by adding up all of the 'yes' ratings, with

Figure 1: Flow chart illustrating the literature search.



a maximum score of nineteen. Items that refer to internal validity include criteria B, E, F, G, H, I, J, L, N, P (van Tulder et al., 1997). External validity is evaluated with the descriptive criteria (A, C, D, K, M), while the remaining two items (O, Q) are statistical criteria.

An internal validity score (IVS) was also given by adding the positive scores for internal validity items (van Tulder et al., 1997; Peeters et al., 2001; Verhagen et al., 2002). A score of greater than 50% for the study on overall QS or IVS was considered of acceptable validity (Verhagen et al. 2002).

**DATA ABSTRACTION**

Two reviewers (MR and JH) independently read, examined, and extracted the necessary key data in the appropriate categories: characteristics of patients (age, gender and diagnosis), treatments utilized, outcome measures assessed, and the results of the respective studies. Any disagreements related to differences in interpretation of the criteria were resolved with both authors reviewing the article a second time and additional discussion.

Table 2: The criteria list from the Cochrane Back Review Group\*

A	Were the eligibility criteria specified?
B. 1	Was a method of randomization performed?
B. 2	Was the treatment allocation concealed?
C.	Were the groups similar at baseline?
D.	Were the experimental and control interventions explicitly described?
E.	Was the care provider blinded to the intervention?
F.	Were the co-interventions avoided or comparable?
G.	Was the compliance acceptable in all groups?
H.	Was the patient blinded to the intervention?
I.	Was the outcome assessor blinded to the intervention?
J.	Were outcome measures relevant?
K.	Were adverse effects described?
L.	Was the withdrawal/drop-out rate described and acceptable?
M. 1	Was a short-term follow-up measurement performed?
M. 2	Was a long-term follow-up measurement performed?
N.	Was the timing of the outcome assessment in both groups comparable?
O.	Was the sample size for each group described?
P.	Did the analysis include an intention-to-treat analysis?
Q.	Were point estimates and measures of variability presented for the primary outcome measures?

\*van Tulder et al., 1997

## Analysis

Qualitative analysis was achieved by attributing levels that rate the scientific evidence (van Tulder et al., 2003).

- Level 1: Strong evidence – provided by generally consistent findings in multiple higher quality RCTs.
- Level 2: Moderate evidence – provided by generally consistent findings in one higher quality RCT and one or more lower quality RCTs.
- Level 3: Limited evidence – provided by generally consistent findings in one or more lower quality RCTs.
- Level 4: No evidence – if there were no RCTs or if the results were conflicting.

Higher quality trials were those scoring 50% or more for the IVS (van Tulder, et al. 1997; Verhagen et al., 2002).

Generally consistent findings were defined as 75% or more of the studies having statistically significant findings in the same direction (Verhagen et al., 2002).

## RESULTS

Thirty-one trials were identified using various MEDLINE search strategies. These were reviewed and eleven articles satisfied the eligibility criteria. Searching the reference lists of these articles and other databases did not identify any further trials. The reasons for ineligibility of articles are listed in Figure 1, and the articles that were not eligible for this systematic review are listed in the appendix.

### Study characteristics

Of the eleven included studies, one was a randomized clinical trial, six were non-randomised cohort studies, two were case series and two were single case studies. The only RCT (Whitman et al., 2006) compared two groups with both groups treated conservatively. The group allocated to the manual therapy arm received exercises addressing specified physical impairments and body weight supported treadmill walking as well as manual physical therapy techniques addressing the thoracic and lumbar spine, pelvis and lower extremities. The comparison group received lumbar flexion exercises, treadmill walking, and sub-therapeutic ultrasound. Four studies compared surgical to conservative interventions (Atlas et al., 1996, 2000, 2005, Athiviraham and Yen 2007); however, none used a randomized design. These four studies found that surgical intervention results were generally greater than conservative, but the degree of difference between the two groups decreased over time. At 8-10 years after intervention Atlas et al (2005) reported the two groups had relatively equal outcomes (table 3).

## Methodological quality

Table 4 details the methodological assessment of the eleven included studies. The scores from the two reviewers (MR and JH) were within three points for every article.

The overall methodological quality of the eleven studies was poor (see Table 4). Insufficient information regarding methodological items, or non-randomized study design, result in lower scores for the majority of studies. Only one study (Whitman et al., 2006) scored 50% or more on the overall methodological QS or IVS. This was the only study that included adequate information on the internal validity items (B1, B2, E, F, G, H and I). Therefore, Whitman et al (2006) was the only study demonstrating acceptable validity (van Tulder et al 1997; Peeters et al 2001; Verhagen et al 2002).

The most common reasons for low internal validity scores were non-randomized study design, groups non-equivalent at baseline, and lack of information regarding contamination by co-interventions (table 4). Insufficient information was often provided about co-interventions (F) and compliance with interventions (G). Blinding of the patient is often impossible in physical therapy trials, and for this reason was not commonly seen in the included studies.

Intervention types (type of intervention, intensity, duration, number and frequency of sessions [D]) were generally not well described for most studies, except on those single and small cohort type studies and the trial by Whitman et al (2006). Initial group characteristics (C) and adverse effects (K) were also either not often described or difficult to ascertain. This may affect the external validity of the studies.

Many of the studies used inadequate descriptions of manual therapy interventions. In the only RCT identified (Whitman et al 2006) the specific manual therapy techniques utilized in this study were not adequately described in the text; however, accompanying video clips with audio descriptions were available on the publishing journal's website describing some of the more commonly used interventions in the study.

Several studies that adequately described the manual therapy interventions implemented (Creighton et al 2006; Whitman et al 2003; Snow et al 2001; Dupriest et al 1993) were of low level evidence due to study design. All of the aforementioned studies recruited 6 or fewer subjects and did not include a comparison group. The fact that there were multiple 'don't know' scores was due to the fact that occasionally the studies provided inadequate details to ascertain if the criteria were actually satisfied. Even after individual and collaborative scoring and discussion by the two reviewers the study description was still not clear enough to more definitively score.

Statistical information was also relatively poor. Point estimates and measures of variability (Q) were described for only six of the eleven studies

**Table 3: Characteristics of studies meeting the review criteria.**

Authors	Participants	Interventions	Outcome measures	Results	Comments
<b>Randomized clinical trials:</b>					
Whitman et al (2006)	58 patients with LSS; 29 in flexion exercise and walking group (mean age 70.0 (7.2) years; 17 females; 29 in manual therapy group (mean age 68.9 (8.7) years	Patients randomized into two groups: flexion exercise and walking group (FExWG)(n=29) and manual physical therapy, exercise, and walking group (MPExWG) (n=29). Treatment for the FExWG group included lumbar flexion exercises, performance of a progressive treadmill walking program, and sub-therapeutic ultrasound. Treatment for the MPExWG received manual physical therapy to the thoracic and lumbar spine, pelvis and lower extremities, as well as specific exercises to address impairments in mobility, strength, and/or coordination, including instruction in the same flexion exercises as prescribed for the FExWG group	Perceived recovery with a global rating of change, Modified Oswestry Disability Index (OSW), treadmill walking test, numeric pain rating scale, SSS satisfaction subscale	A greater proportion of patients receiving MPExWG reported recovery at 6 weeks compared with those receiving FExWG (P=0.0015). Improvements in disability, satisfaction, and treadmill walking tests favored the MPExWG at all follow-ups (6 weeks and 1 year).	RCT with multiple objective measures. Blinding to group allocation and treatment. Multi-modal approach. Adequate sample size.
<b>Observational or descriptive studies:</b>					
Atlas et al (1996)	148 patients recruited from Orthopedic surgeons and Neurosurgeons from throughout Maine with diagnosed LSS. 81 patients treated surgically (mean age 67.6 (range 30-87) years; 67 nonsurgical patients (mean age 65.3 (range 22-89) years.	Surgical patients: 71 had laminectomy, 7 had open discectomy only and 3 had fusion and laminectomy. Therapy patients: bed rest (28.6%), back exercises (39.3%), traction (3.6%), corset or brace (14.3%), TENS (14.3%), physical therapy (23.2%), spinal manipulation (23.2%), other alternative therapies (5.4%), epidural steroids (18.2%), and narcotic analgesic use in past week (20.7%)	Baseline interviews and follow-up mail interviews at 3, 6, and 12 months. Stenosis frequency index, Roland scale, SF-36, Quality of life and satisfaction surveys.	Surgical patients (77.4%) were significantly better than nonsurgical (41.8%) of patients (P < 0.001). Surgical patients were also significantly better on the Roland scale and SF-36 (P<0.001).	Prospective cohort design with objective outcome measures comparing a surgical and nonsurgical group. Not randomized. No blinding. Multi-modal approach surgical and nonsurgical. Large sample size in both groups.
Atlas et al (2000)	119 remaining patients from original study; 67 surgically treated and 52 treated nonsurgically (mean ages, etc. not given).	See Atlas et al (1996)	See Atlas et al (1996)	70% of the surgically treated and 52% of the nonsurgically treated patients reported that their predominant symptom, either back or leg pain, was better (P=0.04). Patient satisfaction with quality of life nonsignificantly favored the surgical group (P=0.16)	See Atlas et al (1996); less difference between surgical and nonsurgical groups compared to initial study.
Atlas et al (2005)	105 patients alive after 10 years (67.7% survival rate); 56 patients of the initially treated surgically and 41 of the initially treated nonsurgically.	See Atlas et al (1996)	See Atlas et al (1996)	A similar percentage of surgical and nonsurgical patients reported that their low back pain was improved (53% vs. 50%, P=0.8), their predominant symptom (either back or leg pain was improved (54% vs. 42%, P=0.3), and they were satisfied with their current status (55% vs. 49%, P=0.5).	See Atlas et al (1996); even less difference between surgical and nonsurgical groups compared to initial study.

**Table 3: (continued)**

Authors	Participants	Interventions	Outcome measures	Results	Comments
Athiviraham et al (2007)	125 consecutive patients with clinical and radiographic LSS. Surgery without fusion patients (n=49) average age of 63 years; surgery with fusion (n=39) average age 70 years; nonsurgical patients (n=24) average age of 69 years.	Surgery with or without fusion; nonsurgical treatments most frequently used included physical therapy, weight reduction, back braces, spinal manipulation, analgesics, muscle relaxants, anti-inflammatory medication, or epidural steroids.	Roland-Morris Questionnaire (RM), subjective outcome analyses (patient rating of worse, same, or better).	At 2 years follow-up, the average improvement in Roland-Morris score in decompression only, decompression with fusion, and nonsurgical groups were 6.9, 6.1, and 1.2, respectively. Percentage of patients who were better, worse, or the same: decompression only (63.3%, 4.1%, and 32.7% respectively); decompression with fusion (61.5%, 2.6%, and 35.9% respectively); and nonsurgical (25.0%, 12.5%, and 62.5% respectively).	Prognostic cohort study. Not randomized. No blinding. Surgical vs. nonsurgical comparison with large sample sizes. No measures of variability.
Creighton et al (2006)	6 subjects diagnosed with LSS and neurogenic claudication (ages: 82, 71, 52, 64, 72, and 81 years).	Low and high velocity translatoric manipulations of T1-T9 and L1-L3, and two lumbar flexion exercises.	Treadmill walking time, Oswestry Disability Index (ODI), McGill Pain Questionnaire scores, thoracolumbar flexion mobility.	All 6 subjects demonstrated improvements in treadmill walking test prior to neurogenic claudication (range: 1 min 34 sec to 26 min); in ODI (range: 7.5% to 64.7%); and in McGill questionnaire scores (range: 25% to 57%). All 5 subjects that were measured demonstrated improvement in thoracolumbar flexion mobility.	Case series study design. Objective measures. No blinding. No measures of variability.
Murphy et al (2006)	55 patients (19 males and 36 females) with mean age of 65.2 (range 32 to 80) years.	Distraction manipulation in prone on adjustable table, neural mobilization, "cat and camel" exercises, "nerve flossing" exercises, some patients also had mobilization and/or stabilization exercises.	RM, numerical rating scale (NRS); patients were also asked to rate their perceived percentage improvement	Mean patient-rated percentage improvement from baseline to end of treatment was 65.1%. The mean improvement in disability from baseline of the end of treatment was 5.1 points. The mean improvement in "on average" pain intensity was 1.6 points. The mean improvement in "at worst" pain was 3.1 points.	Observational study (consecutive patients). No blinding. Manual therapy approach with supplemental exercises. Objective outcome measures.
Simotas et al (2000)	49 patients meeting radiographic and clinical criteria for LSS. Non-operative treatment initiated on all patients; at 3 years following treatment, 9 of the 49 patients had undergone surgical intervention. Nonoperative patients (n=40) average age 72 (range 53-87) years, operative patients (n=9) average age 67 (range 58-80) years. 13 nonoperative patients were male and 2 operative patients were male.	Surgical intervention was not specifically described. Non-surgical intervention consisted of bed rest (6 patients), corset (9), acupuncture (29), TENS (2), manipulation (2), physical therapy (47), and epidural steroid injection (39).	Global outcome score, RM, overall rating of daily anxiety and depression levels, motor score to assess motor strength of lower extremities, numerical pain rating scale, functional survey.	Improvement and function scores for nonoperated patients were significantly improved (P<0.001 for pain on average, frequency of pain, pain in back or buttocks, and pain in leg or foot. 32% improved in walking distance and frequency (P<0.229 and P<0.259 respectively).	Descriptive study with disparity of numbers in each group due to design of study. Objective measures used. No blinding for outcome assessment.

Table 3: (continued)

Authors	Participants	Interventions	Outcome measures	Results	Comments
Whitman et al (2003)	3 retired military patients all reporting LBP and lower extremity (LE) symptoms aggravated by standing upright and walking; detailed information regarding patient is listed; 81 year old male suffering from worsening LBP and right LE symptoms; 63 year old male with episodic, worsening LBP of 45 year duration and intermittent LE symptoms; 71 year old male with history of worsening intermittent dull ache in left buttock and intermittent dull achy symptoms into left LE.	Supine iliopsoas stretch, prone hip posterior to anterior mobilization, prone rectus femoris stretch, lumbar rotation mobilization/manipulation in neutral, caudal glide to hip joint in flexion, unilateral posterior to anterior lumbar spine mobilization.	Posture, SLR and ROM measurements, reflexes and strength measures, OSW, global rating of change, patient assessment of overall functional status, modified Spinal Stenosis Scale.	All 3 patients demonstrated substantial positive changes that were sustained up to 18 months. OSW score improvement ranged from 66% to 95% of their baseline scores by discharge and 33% to 82% at 18 months.	A case series of 3 patients with treatment individualized plan of care for each respective patient. Detailed description of manual therapy interventions utilized. Objective outcome measures utilized. No measures of variability (3 patients).
Snow et al (2001)	A single 78 year old male with low back pain and severe bilateral leg pains. Severe degenerative changes noted with magnetic resonance imaging.	Flexion-distraction manipulation of the lumbar spine. No other treatments or modalities were used.	10 point verbal rating scale, verbal rating of improvement.	Decreased frequency and intensity of leg symptoms and a resolution of LBP that were maintained at a 5 month follow up visit.	Single case study. Limited objective measure. No point estimates or measures of variability (single case).
Dupriest et al (1993)	A single 76 year old male with chief complaint of LBP and left LE pain with MRI confirmed LSS.	Flexion-distraction manipulation of the lumbar spine to the L4-5 and L5-S1 levels. Manual stretching of the thoracolumbar fascia, including tissue massage; exercises consisting of double knee to chest, iliopsoas stretches, quadriceps stretches, hamstring stretches, calf stretches, pelvic tilt, bridging, stationary bicycling and progressive ambulation; ultrasound, heel lift on the right, and modification of patients activities of daily living.	Lumbar flexion and extension ROM and visual analog pain scale.	Visual analog pain rating was 0, improved lumbar ROM for extension and flexion, resolved analgia.	Single case study. Limited objective measure. No point estimates or measures of variability (single case).

(Whitman et al 2006; Atlas et al 1996, 2000, 2005; Murphy et al 2006; Simotas et al 2000).

### Treatment recommendation

The varying levels of evidence relating to manual therapy interventions for LSS are described in table 5. It is our recommendation that there is currently Level 2 evidence to support including manual therapy interventions in combination with other physiotherapy interventions for the treatment of LSS, on the basis of one high quality RCT and several lower quality (non RCT) studies. We found no RCT evidence directly comparing manual therapy with other interventions, placebo or no treatment. Although some studies are of low (Level 4) quality and present high risk of bias, the evidence generally supports the utilization of various manual therapy techniques in the management of patients with LSS.

### DISCUSSION

This systematic review demonstrates a lack of high quality evidence regarding the utilization of manual therapy in the treatment of LSS. We identified only one RCT, comparing two physiotherapy treatment approaches with no control group. Due to the lack of studies with acceptable validity, and because the quality of the available research regarding manual therapy and its effectiveness on LSS patients is generally poor, it is difficult to make clear conclusions. This review found preliminary evidence for the utilization of manual therapy and exercise intervention for patients with LSS, although it is apparent that there is a need for future investigation on this topic. The findings of this review are consistent with a recent best-practice clinical guideline recommending that use of physical therapy and exercise may be potentially beneficial in certain subgroups of patients for controlling symptoms of LSS with neurogenic claudication (Watters et al 2008).

**Table 4: Methodological quality scores in decreasing order of overall quality score.**

	A	B1	B2	C	D	E	F	G	H	I	J	K	L	M1	M2	N	O	P	Q	OQS	IVS
Whitman et al (2006)	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	16	9
Atlas et al (1996)	Y	N	N	N	N	N	DK	Y	N	DK	Y	N	Y	Y	Y	Y	Y	N	Y	9	4
Atlas et al (2000)	Y	N	N	N	N	N	DK	Y	N	DK	Y	N	Y	Y	Y	Y	Y	N	Y	9	4
Atlas et al (2005)	Y	N	N	N	N	N	DK	Y	N	DK	Y	N	Y	Y	Y	Y	Y	N	Y	9	4
Athiviraham et al (2007)	Y	N	N	N	N	N	DK	Y	N	N	Y	Y	Y	N	Y	Y	Y	N	N	6	3
Creighton et al (2006)	Y	N	N	DK	N	N	DK	Y	N	N	Y	N	N	Y	Y	N	N	N	N	5	2
Murphy et al (2006)	Y	N	N	N	N	N	DK	DK	N	DK	Y	Y	DK	Y	Y	N	N	N	Y	5	1
Simotas et al (2000)	Y	N	N	N	N	N	DK	DK	N	DK	Y	N	DK	DK	Y	N	Y	N	Y	5	1
Whitman et al (2003)	Y	N	N	N	N	N	Y	DK	N	N	Y	N	N	Y	Y	N	N	N	N	5	2
Snow et al (2001)	N	N	N	N	N	N	Y	DK	N	N	Y	N	N	Y	Y	N	N	N	N	4	2
Dupriest et al (1993)	N	N	N	N	N	N	DK	DK	N	N	Y	N	N	Y	Y	N	N	N	N	3	1

D/K=don't know; OQS=overall quality score; IVS=internal validity score

A few limitations exist in this systematic review. Firstly, studies published in languages other than English were excluded for this review. This could result in language bias and decrease precision. The

fact that only the first author selected the articles could also result in selection bias. A blinding mechanism of the articles was not implemented as the first author (MR) was also primarily involved

**Table 5: Level of evidence levels for treatment comparisons identified in the review.**

Treatment/Comparison	Strength of Evidence	Comments
Manual physical therapy as a component of conservative intervention (compared with other conservative interventions)	Level 2*	1 RCT and multiple lower quality non-randomized studies. One RCT compared manual therapy, exercises and bodyweight-supported treadmill walking to lumbar flexion exercises, treadmill walking, and sub-therapeutic ultrasound. Manual therapy consisted of techniques to thoracic and lumbar spine, pelvis and lower extremities. Superior improvement in manual therapy group was significant at 6 week and 1 year duration (Whitman et al 2006).  1 Non-randomized observational study (Simotas et al 2000): Spinal manipulation was a component of a multi-modal conservative therapy approach for 2 patients and other conservative interventions for 47 subjects; 9 patients ended up having surgery; remaining 40 patients all demonstrated subjective and objective improvement  3 Case series and 2 single case reports: Spinal distraction manipulation (Murphy et al 2006), spinal low and high velocity translatoric manipulations (Creighton et al 2006) Hip mobilization; spinal mobilization/manipulation (Whitman et al 2003). Improvement in subjective and objective measures. Decreased frequency and intensity of leg symptoms and resolution of LBP maintained at 5 month follow-up in one case following flexion-distraction manipulation on single subject (Snow et al 2001). Spinal manipulation was a component of a multi-modal conservative therapy approach in one case (Dupriest et al 1993).
Spinal manipulation as a component of conservative intervention (compared with surgical intervention)	Level 4	4 non-randomized observational studies of 2 cohorts. (Atlas et al 1996, 2000, 2005) (Athiviraham et al 2007) Spinal manipulation was one of multiple conservative interventions; Only 23.2% of subjects were treated with spinal manipulation and the techniques were therapist dependent (Atlas et al 1996, 2000, 2005); 2 year follow-up favored surgical intervention versus conservative intervention at 10 year follow-up conservative intervention compared favorably with surgical intervention (Athiviraham et al 2007).

\*According to the criteria for the levels of evidence described by van Tulder et al (2003), Level 2 evidence requires one high quality RCT and one or more lower quality RCTs. We awarded a Level 2 rating for the evidence, on the basis of one high quality RCT and accepting generally consistent findings in several non-randomized studies in lieu of one or more lower quality RCTs. The criteria for the levels of evidence described by van Tulder et al (2003) do not cover the situation of one high quality RCT alone.



in article selection and review. Due to minimal and conflicting evidence on consistency of scores, blinding is not seen as a mandatory step in performing a systematic review (van Tulder et al 1997; Jadad et al 1998; Reid and Rivett 2005).

We were unable to match the results of our literature review exactly to the criteria for the levels of evidence described by van Tulder et al (2003). Level 2 evidence requires one high quality RCT and one or more lower quality RCTs, while Level 3 evidence requires generally consistent findings in one or more lower quality RCTs (van Tulder et al 2003). We identified one high quality RCT; however, all of the other studies identified were non-randomized observational studies. We decided to award a Level 2 rating for the evidence, due to finding one high quality RCT, accepting generally consistent findings in several non-randomized studies in lieu of one or more lower quality RCTs. These included 3 case series (Simotas et al 2000; Murphy et al 2006; Creighton et al 2006) and 2 single case reports (Whitman et al 2003; Snow et al 2001) in support of manual therapy. Although there is no precedent in the literature to support the rating of Level 2 evidence for this specific combination of evidence, we did this based on a similar reasoning process as described by Reid and Rivett (2005). It should be recognized that different pooling rules could have resulted in a different level of evidence (Ferreira et al 2002). However, our results are consistent with a recent clinical practice guideline giving a rating of "Good" level of evidence and B level of recommendation for the utilization of both spinal manipulation and exercise therapy as measures of noninvasive interventions in patients with chronic or subacute LBP (Chou et al 2007). Therefore, based on the results of this review, manual therapy could be considered a plausible treatment for LSS, in combination with other physiotherapy interventions including exercise therapies, although the small number of studies available, as well as the poor quality of such studies, does not allow for definitive conclusions.

As we anticipated the paucity of RCTs on this topic, we decided to include non-RCT studies in this systematic review. This inherently resulted in an overall lower level of evidence in the hierarchy of evidence based practice. Case series, single case studies and other studies without comparison groups carry an uncontrollably high risk of bias and therefore cannot test a hypothesis that the interventions studied result in better outcomes than a comparison intervention or no treatment at all. It could be argued that the indirect evidence provided by such studies should have been eliminated from this review. The fact that this review was forced to rely on such low level evidence only further supports the position that the current lack of studies is critical, in this group of patients that will only increase in number with time.

Greater numbers of well designed RCTs on this subject will improve the understanding of the

benefit of manual therapy in LSS patients. Although RCT's are considered the highest level of evidence of efficacy, it must also be taken into account that what is efficacious in randomized clinical trials is not always effective in a real world of day-to-day practice (Westfall et al 2007). This can be relevant with interventions such as manual therapy, which has proven to be an effective intervention for various lumbar spine disorders in non RCT's (Hough et al 2007; Hsieh et al 2002), as well as in RCT's (Aure et al 2003; Lewis et al 2005; Goldby et al 2006). While RCTs are important to confirm whether a new treatment causes an effect, they are unlikely to discover combinations of interventions or practices that are effective and efficient in routine care (Horn and Gassaway 2007). It has also been argued that practice-based research provides the 'laboratory' that will help generate new knowledge and bridge the chasm between current recommended care and future improved care (Westfall et al 2007). Contributions via observational designs can produce valuable clinical evidence that is practical and applicable, especially since the stringent nature of RCT's may limit some of this creative clinical application.

Besides the lack of RCTs and low quality of methodology amongst these studies, another problem that became apparent was the poor description of these trials. As can be seen by the high number of 'don't know' scores in table 4, it was often difficult to surmise if a criterion had been met. The lack of detailed description of the intervention employed in many of the studies makes it difficult not only to repeat the study, but also to implement the same techniques with similar patients.

Several of the studies reviewed involved comparisons between surgical and nonsurgical interventions, which can present tribulations. Comparison of surgical and nonsurgical treatment groups in non-randomized, observational study designs is problematic because of a lack of comparable patient groups and pretreatment data (AHRQ, 2001). There is limited, contradictory evidence on whether patients with moderate pain benefit more from surgery or from conservative care for patients with LSS (AHRQ, 2001). There is a greater lack of comparable data with regards to patients with severe stenosis, as such patients typically receive surgery shortly after the diagnosis, making comparisons more difficult to ascertain (AHRQ, 2001).

## CONCLUSION

We conclude that there are an insufficient number of high quality studies on this topic to confidently determine the role of manual therapy for patients with LSS. This systematic review found that there is currently very limited clinical research of adequate quality on the use of manual therapy for these individuals. While this review demonstrates the potential for manual therapy and exercise intervention in patients with LSS, we

suggest that future research more closely examine not only potential benefits of manual therapy in this type of individual, but whether specific types of manual therapy or multimodal approaches are more beneficial.

#### Key Points

- There is insufficient high-quality evidence regarding the effectiveness of manual therapy for patients with LSS
- There is one high quality trial indicating that manual therapy in combination with exercise therapy and bodyweight-supported treadmill walking is superior to lumbar flexion exercises, treadmill walking and sub-therapeutic ultrasound
- There is some additional low-quality evidence indicating meaningful change in pain and function with the use of manual therapy; however, further research is required to substantiate these results
- There is insufficient research comparing manual therapy with other interventions such as exercise and/or surgical intervention
- There is insufficient evidence regarding the specific patient population most likely to benefit from a manual therapy approach.

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## APPENDIX 1. STUDIES ELIMINATED FROM REVIEW.

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