

LITERATURE REVIEW

Nonoperative Treatment of Lumbar Spinal Stenosis With Neurogenic Claudication

A Systematic Review

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Study Design. Systematic review.

Objective. To systematically review the evidence for the effectiveness of nonoperative treatment of lumbar spinal stenosis with neurogenic claudication.

Summary of Background Data. Neurogenic claudication can significantly impact functional ability, quality of life, and independence in the elderly.

Methods. We searched CENTRAL, MEDLINE, EMBASE, CINAHL, and ICL databases up to January 2011 for randomized controlled trials published in English, in which at least 1 arm provided data on nonoperative treatments. Risk of bias in each study was independently assessed by 2 reviewers using 12 criteria. Quality of the evidence was evaluated using Grades of Recommendations, Assessment, Development, and Evaluation (GRADE).

Results. From the 8635 citations screened, 56 were assessed and 21 trials with 1851 participants were selected. There is very low-quality evidence from 6 trials that calcitonin is no better than placebo or paracetamol, regardless of mode of administration or outcome. From single small trials, there is low-quality evidence that prostaglandins, and very low-quality evidence that gabapentin

or methylcobalamin, improve walking distance. There is very low-quality evidence from a single trial that epidural steroid injections improve pain, function, and quality of life up to 2 weeks compared with home exercise or inpatient physical therapy. There is low-quality evidence from a single trial that exercise is of short-term benefit for leg pain and function compared with no treatment. There is low- and very low-quality evidence from 6 trials that multimodal nonoperative treatment is less effective than indirect or direct surgical decompression with or without fusion.

Conclusion. Moderate- and high-GRADE evidence for nonoperative treatment is lacking and thus prohibiting recommendations to guide clinical practice. Given the expected exponential rise in the prevalence of lumbar spinal stenosis with neurogenic claudication, large high-quality trials are urgently needed.

Key words: neurogenic claudication, lumbar spinal stenosis, systematic review, nonoperative treatment, elderly. **Spine 2012; 37:E609–E616**

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Most patients who seek care for neurogenic claudication are treated nonoperatively.⁷ A course of conservative treatment is also recommended prior to surgical intervention.⁷ However, what constitutes effective conservative or nonoperative treatment is unknown.^{7,8} The purpose of this review is to evaluate the clinical effectiveness of nonoperative treatments of lumbar spinal stenosis with neurogenic claudication systematically.

MATERIALS AND METHODS

Search and Study Selection

An electronic search was performed by an experienced librarian from the Cochrane Back Review Group in CENTRAL (Cochrane Library 2011, issue 1), MEDLINE (1966 to January 2011), EMBASE (1980 to January 2011), CINAHL (1982 to January 2011), and Index to Chiropractic Literature (1985 to January 2011). The terms “spinal stenosis,” “lumbar spinal stenosis,” “neurogenic claudication,” “lumbar radicular pain,” “cauda equina,” and “spondylosis” were combined with a highly sensitive search strategy to identify randomized controlled trials (RCTs).

Studies were included if they were RCTs published in English, at least 1 arm of the trial provided data on effectiveness of a nonoperative treatment, and at least 80% of subjects had neurogenic claudication with lumbar spinal stenosis confirmed by imaging. Neurogenic claudication was defined as buttock or leg pain or aching, numbness, tingling, weakness, or fatigue with or without back pain, precipitated by standing or walking. At least 1 of these outcomes had to be measured: walking ability, pain intensity, function, quality of life, and global improvement. Studies evaluating subjects with radiculopathy due to disc lesions were excluded.

Studies with mixed populations were included only if separate data for subjects with neurogenic claudication due lumbar spinal stenosis were provided.

Two reviewers (C.A. and K.S.) independently screened all titles and abstracts identified by the search strategy. Full text of articles deemed to be potentially relevant was independently assessed by 2 reviewers, who made the final decision for inclusion. A third reviewer was consulted if consensus was not reached.

Risk of Bias Assessment and Data Analysis

Two reviewers independently assessed methodological risk of bias and performed data extraction. Safety data (intervention adverse effects and/or complications) when available were also collected. Risk of bias was assessed using the 12-item criteria recommended by the Cochrane Back Review Group.⁹ Discrepancies in risk of bias scoring and data extraction were discussed during a consensus meeting.

Low risk of bias was defined as fulfilling 6 or more of the 12 criteria, including clearly described and appropriate randomization (item A) and allocation concealment (item B) and with no severe flaws. A severe flaw was defined *a priori* as a serious methodological deficiency not captured by the

12-item criteria that significantly increases the risk of bias, such as very high dropout or crossover rates.

For each comparison, outcomes were analyzed according to these follow-up periods: immediate (up to 1 wk), short-term (between 1 wk and 3 mo), intermediate (between 3 mo and 1 yr), and long-term (1 yr or longer). Outcome data were pooled and meta-analyses were performed when trials were judged to be sufficiently both clinically and statistically homogeneous.

Data Synthesis

The quality of the evidence for each outcome and for each comparison was evaluated using Grades of Recommendations, Assessment, Development, and Evaluation (GRADE).^{9,10} The overall quality of the evidence is based on performance against 5 domains: (1) risk of bias, (2) consistency of findings, (3) directness comparisons, (4) precision, and (5) other considerations such as selective reporting.

The quality of the evidence starts at high when there are consistent findings among at least 75% of RCTs with no limitations of the study design; consistent, direct, and precise data; and no known or suspected publication bias. It reduces a level for each domain not met. Treatment effects between comparators (more effective, less effective, or no difference) were based on statistically significant differences in outcomes.

High-quality evidence: All 5 domains are met; further research is very unlikely to change the confidence in the estimate of effect.

Moderate-quality evidence: One of the domains is not met; further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate.

Low-quality evidence: Two domains are not met; further research is very likely to have an important impact in the confidence of the estimate of effect and is likely to change the estimate.

Very low evidence: Three or more domains are not met; there is great uncertainty about the estimate of effect.

Evidence provided by a single small trial was considered to be both inconsistent and imprecise and thus provide “low” or “very low” quality evidence, depending on whether it was assessed as having a low or high risk of bias, respectively, and there were no other limitations.

RESULTS

Selection and Description of Included Trials

Among the 8635 titles and abstracts screened, 56 full publications were selected for full review. This resulted in 21 RCTs that met the inclusion criteria and were included in the review (Figure 1). Supplemental Table 1 (see Supplemental Digital Content 1, <http://links.lww.com/BRS/A585>) describes the characteristics of the included trials. A total of 1851 participants (926 men and 925 women) were randomized to 1 of 23 comparison groups. Nineteen trials were conducted at tertiary care centers and 2 at medical/rehabilitation clinics.^{11,12} The mean age of participants was more than 50 years in all but 2

trials in which the mean age was just less than 50 years.^{13,14} The duration of symptoms varied considerably among the studies, with a mean range of 12 weeks to 15 years. Follow-up periods also varied significantly. Three^{13,14,20} of the 4 studies evaluating epidural injections provided follow-up data up to a week after the injections, whereas all studies comparing multimodal nonoperative care with surgery^{21,22-25} provided long-term follow-up (at least 2 yr) outcome data.

Risk of Bias of Included Studies

Both the median and mean number of criteria met was 6 of 12 (range of 3–9) (Table 1). Although 13 studies met 6 or more, only 4 studies were considered to have low risk of bias.^{11,15,22,26} Among the remaining 9 studies that met 6 or more criteria, 7 failed to explicitly describe and/or use appropriate randomization procedure, allocation concealment, or both,^{12-14,20,25,27,28} and 2 had severe flaws^{23,24} due to high crossover rates, which made the intention-to-treat analyses uninterpretable. Other common risk of bias included failure to blind the participants receiving the intervention or control,^{11,12,15-25,29} failure to blind the treating health care provider,^{11,12,15-25,29} selective reporting, which meant data were not available,^{15,16,18,29-31} and a lack of reporting of cointerventions (all trials).

Evidence of Effect of Interventions

Nineteen of the 23 comparisons were examined in a single trial, most with small sample sizes. It was possible to combine data only from 2 trials for 1 outcome in a meta-analysis^{22,24} (Table 2). Heterogeneity in source population, intervention, and outcomes instruments precluded pooling of data of other trials. Supplemental Table 2 (see Supplemental Digital

Content 2, <http://links.lww.com/BRS/A586>) summarizes the quality of the evidence for the outcomes for each comparison. The results below are reported on the basis of statistically significant differences between comparators for each outcome.

Calcitonin

There is very low-quality evidence from 6 trials^{16,17,27,28,30,31} (N = 231) that calcitonin is no better than placebo or paracetamol regardless of mode of administration or outcome assessed. Adverse effects of the calcitonin injections were reported as minor (nausea and rash) and were experienced among 40%¹⁶ to 89%³⁰ of the subjects.

Oral Medication

There is low-quality evidence based on 1 trial¹⁵ (N = 79) that prostaglandins improve walking distance and leg pain in the short-term compared with etodolac (a nonsteroidal anti-inflammatory drug [NSAID]), with 5% of subjects in both groups reporting gastrointestinal upset.

A small trial evaluating gabapentin¹⁹ (N = 55) provided very low-quality evidence for improved walking distance and pain intensity compared with placebo in the intermediate and long-term follow-up periods. This trial reported that some subjects randomized to the gabapentin group (no data specified) experienced mild to moderate drowsiness and/or dizziness.

There is very low-quality evidence from 1 trial¹⁸ (N = 152) that methylcobalamin (vitamin B₁₂) plus conservative care improves walking distance in the intermediate and long-term follow-up compared with conservative treatment alone. There were no reported adverse effects for methylcobalamin.

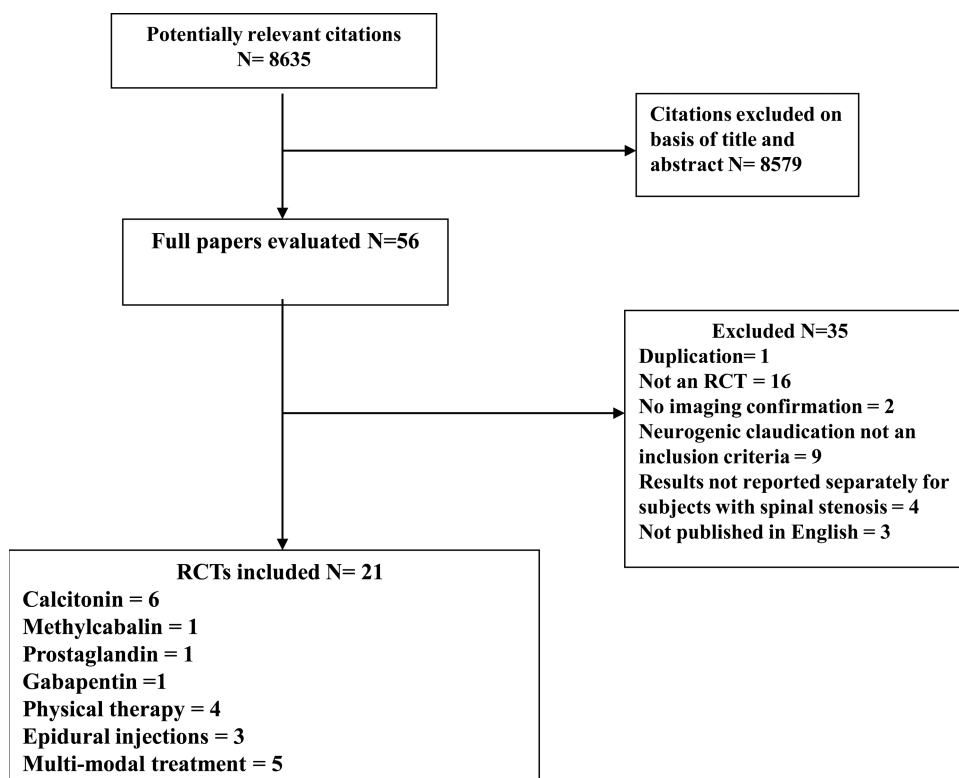


Figure 1. Selection process of included articles. RCT indicates randomized controlled trial.

TABLE 1. Risk of Bias Assessment for Studies on Nonoperative Treatment of Lumbar Spinal Stenosis With Neurogenic Claudication

Authors	A	B	C	D	E	F	G	H	I	J	K	L	Total
<i>Calcitonin</i>													
Eskola et al ^{B0}	?	?	+	+	+	?	+	-	?	?	?	+	5
Podichetty et al ²⁷	?	?	+	+	+	-	+	-	+	?	?	+	6
Porter and Hibbert ¹⁶	?	?	-	?	?	+	+	?	-	?	+	+	4
Porter and Miller ³¹	?	?	+	?	?	-	+	+	?	?	?	+	4
Sahin et al ¹⁷	?	?	-	-	+	-	?	+	+	?	?	+	4
Tafazal et al ²⁸	?	?	+	+	+	+	+	+	-	?	?	+	7
<i>Methylcobalamin</i>													
Waikakul and Waikakul ¹⁸	-	?	-	-	+	+	+	?	+	?	?	+	5
<i>Prostaglandin</i>													
Matsudaira et al ¹⁵	+	+	-	-	+	+	+	?	+	?	?	+	7*
<i>Gabapentin</i>													
Yaksi et al ¹⁹	?	?	-	-	-	?	+	+	?	?	?	+	3
<i>Physical therapy</i>													
Goren et al ¹¹	+	+	-	-	+	+	-	+	+	?	?	+	7*
Koc et al ²⁹	?	?	-	-	+	+	+	-	+	?	?	+	5
Pua et al ²⁶	+	+	-	-	+	-	+	+	+	?	-	+	7*
Whitman et al ¹²	+	?	-	-	+	+	+	+	+	?	?	+	7
<i>Epidural injections</i>													
Cuckler et al ¹³	?	?	+	+	+	+	+	+	+	?	+	+	9
Fukusaki et al ²⁰	?	?	?	?	+	+	+	+	+	?	+	+	7
Zahaar ¹⁴	?	?	+	?	+	+	+	+	+	-	?	-	6
<i>Multimodal nonoperative care</i>													
Zucherman et al ²⁵ ; Zucherman et al ⁴⁴ ; Hsu and colleague ⁴⁵	?	+	-	-	+	±	±	+	+	?	+	+	6++
Amundsen et al ²¹	+	?	-	-	-	+	+	+	-	?	-	?	4
Malmivaara et al ²²	+	+	-	-	+	+	+	+	+	?	?	+	8*
Weinstein et al ²³ ; Weinstein et al ⁴⁶	+	+	-	-	+	±	+	+	?	?	-	+	6+‡,§
Weinstein et al ²⁴ ; Weinstein et al ⁴⁷	+	+	-	-	+	-	+	+	?	?	-	+	6§

A to L indicate the following questions—A: Was the method of randomization adequate? B: Was the treatment allocation concealed? C: Was the patient blinded to the intervention? D: Was the care provider blinded to the intervention? E: Was the outcome assessor blinded to the intervention? F: Was the dropout rate described and acceptable? G: Were all randomized participants analyzed in the group to which they were allocated? H: Are reports of the study free of suggestion of selective outcome reporting? I: Were the groups similar at baseline regarding the most important prognostic indicators? J: Were cointerventions avoided or similar? K: Was the compliance acceptable in all groups? L: Was the timing of the outcome assessment similar in all groups? +, yes; -, no; ?, unclear.

*Low risk of bias if 6 or more items met including valid randomization and treatment allocation techniques and no severe flaws.

‡Two-year follow-up dropout rate 30%, 1 year <20%; intention to treat inconsistent at 2-year f/u.

#Dropout rate <20% at 1 year, >20% at 4 years.

§Severe flaw due to high crossover rates.

Physical Therapy

Four trials evaluated various physical therapy interventions, each of which included some form of exercise.^{11,12,26,29} None

of the trials demonstrated improved walking ability. There is low-quality evidence from 1 small trial¹¹ (N = 45) that exercise is better than no treatment for leg pain and function

TABLE 2. GRADE for Direct Decompression +/- Fusion Versus Multimodal Nonoperative Care for Oswestry Disability Index

Quality Assessment					Summary of Findings			
					No. of Patients		Effect	
No. of Studies	Risk of Bias	Consistency	Directness	Precision	Direct Decompression	Multimodal Nonoperative	Mean Difference (95% Confidence Interval)	
ODI at 6 mo								
2—Malmivaara et al ²² ; Weinstein et al ²⁴	High†	No	Yes	No	170	179	-3.66 (-10.12, 2.80)	+000
ODI at 12 mo								
2—Malmivaara et al ²² ; Weinstein et al ²⁴	High†	No	Yes	No	170	170	-6.18 (-15.03, 2.66)	+000
ODI at 24 mo								
2—Malmivaara et al ²² ; Weinstein et al ²⁴	High†	Yes	Yes	No	158	157	-4.43 (-7.91, -0.96)	+000

*GRADE evidence: +000, very low-quality evidence.
†Severe flaw because of high crossovers in Weinstein et al.²⁴
ODI indicates Oswestry Disability Index.

in the short term. Another small trial²⁶ (N = 68) provided low-quality evidence that unweighted treadmill walking is no better than stationary cycling in the short term regardless of outcome. The other 2 trials provided very low-quality evidence for all outcomes. One trial²⁹ (N = 29) demonstrated that inpatient physical therapy improved pain intensity, function, and quality of life in the short term compared with a home exercise program plus oral diclofenac. The other trial¹² (N = 68) showed short-term global improvement using a combination of manual therapy, exercise, and unweighted treadmill walking compared with flexion exercises, walking, and sham ultrasound. Among the physical therapy trials, 1 reported a mild increase in symptoms with exercises²⁶ and in another, 1 patient developed angina pectoris.²⁹

Epidural Injections

All 4 trials^{13,14,20,29} evaluating epidural injections provided very low-quality evidence for all outcomes. One trial²⁰ (N = 53) comparing translaminar epidural block injections, with or without steroids, with placebo showed improved walking distance only immediately after the injection. Another small trial²⁹ (N = 29), evaluating intralaminar epidural steroid injection plus epidural block compared with home exercise or inpatient physical therapy, demonstrated improvements in pain intensity, function, and quality of life at 2 weeks' follow-up. One trial evaluating caudal¹⁴ (N = 30) and another translaminar¹³ (N = 37) epidural steroid injections showed no difference in global improvement compared with placebo injections.

Two trials did not mention adverse events,^{13,14} whereas the other 2 trials^{20,29} reported no complications after the injections.

Multimodal Nonoperative Treatment

There were 5 trials²¹⁻²⁵ that compared multimodal nonoperative care with indirect or direct surgical decompression. In general, multimodal nonoperative treatment was used to simulate usual nonoperative care in the community and varied considerably within and across the trials. Nonoperative treatments included orthosis, rehabilitation, physical therapy, exercise, NSAIDs, analgesics, education, heat and cold applications, transeletrical nerve stimulation, ultrasound, and epidural injections. Details on the frequency or duration of nonoperative care were lacking.

There is very low-quality evidence from 1 trial²⁵ (N = 191) that indirect decompression using interspinous spacers (X-Stop, St. Francis Medical Technologies, Concord, CA) with or without grade 1 spondylolisthesis provides long-term global improvement and improved quality of life compared with multimodal nonoperative care. No complications were reported for subjects receiving nonoperative care. Complications were reported in 11% of subjects undergoing interspinous spacer implants; these included spinous process fracture, coronary ischemia, respiratory distress, hematoma, and death due to pulmonary edema.

There is very low-quality evidence based on intention-to-treat analysis among randomized subjects from 1 trial²³ (N = 304) that direct surgical decompression with or without fusion for spondylolisthesis is no better than multimodal nonoperative care for all outcomes assessed. At 2-year follow-up, about 40% of subjects crossed over in either direction.

One trial²² (N = 94) provided low-quality evidence that direct surgical decompression improves back and leg pain but not walking ability compared with nonoperative care

at 6 months and 2 years. The intention-to-treat analysis in another trial²⁴ (N = 289) with a high crossover rate (51% of subjects assigned to nonoperative care received surgery) provided very low-quality evidence that surgical decompression improves bodily pain at 2 years but not 4 years compared with nonoperative treatment. A meta-analysis was performed for 1 outcome, the Oswestry Disability Index among randomized subjects in 2 trials,^{22,24} and showed borderline improvement at 24 months compared with nonoperative care (Table 2).

Perioperative complication rates reported for direct decompression with or without fusion ranged from 5.4% to 14%, with dural tears being the most commonly reported. Postoperative complications ranged from 8.2% to 18% of subjects and included pulmonary edema, peridural hematoma, and sepsis.

DISCUSSION

Neurogenic claudication is an important and growing cause of disability in the elderly. The purpose of this review was to evaluate the effectiveness of nonoperative treatments. Our findings suggest that the current evidence is of low and very low quality. This prohibits the ability to make any conclusions about effective nonoperative treatment and suggests that future research is very likely to have an important impact on our confidence of the estimates of the effect and is likely to change the estimates found in our review.

We found low- or very low-quality evidence from single and generally small trials that gabapentin, methylcobalamin, and prostaglandins may improve walking distance. Walking distance was also improved after the use of translaminar epidural block injections with or without steroids but only immediately after the injection. Benefits beyond 2 weeks were not seen with epidural injections regardless of dose, mode of administration, or outcome. Despite the lack of evidence, 25% of all epidural injections are administered for symptoms of lumbar spinal stenosis and their use is growing.⁸ Calcitonin failed to show any benefit, whether administered by injection or nasal spray.

Physical therapy is a recommended treatment of neurogenic claudication; however, current evidence has not established its role. What constitutes physical therapy varied considerably among the trials. A common denominator was exercise. Exercise was of short-term benefit for leg pain and function compared with no treatment, but it is uncertain what the important components of an exercise program are and whether supervised exercise is more effective than a home-based program.

Among the nonoperative trials that reported statistically significant differences in outcomes, the effect sizes were small and unlikely of clinical significance.

Larger effect sizes were seen favoring indirect decompression using interspinous spacers (X-Stop)²⁵ and direct decompression with or without fusion²² compared with multimodal nonoperative treatment. However, the nonoperative care used in the surgical trials varied significantly, was typically unstructured, and often consisted of failed therapy (surgical protocol required patients to have failed conservative care prior to surgery).

The relationship between symptoms of neurogenic claudication (lower extremity pain numbness, tingling, burning, weakness, and heaviness) and standing or walking ability is unknown. This review found that subjects who reported significantly improved back and leg pain,^{22,29} back pain-related disability,^{11,22} and global improvement^{12,29} did not have corresponding improvement in their ability to walk. This could be explained in part by the way walking ability was evaluated. The Treadmill Walking Test was used in a third of trials measuring walking distance. However, the Treadmill Walking Test has been found to underestimate walking ability,³² and patients often refuse to walk on a treadmill because of their fear of falling.¹² More valid methods of assessing walking ability include the Self Pace Walking Test³² and the Shuttle Walk Test.³³

Considerable variation in eligibility criteria exists among trials evaluating interventions for lumbar spinal stenosis with neurogenic claudication.³⁴ This presents challenges with the selection, synthesis, and interpretation of the evidence for effective interventions for this population. A set of internationally agreed-upon diagnostic criteria for neurogenic claudication due to lumbar spinal stenosis is needed.

The findings in our review are concurrent with other recent systematic reviews evaluating exercise,³⁵ calcitonin,³⁶ epidural injections,³⁷ oral medications,⁸ interspinous spacers,^{38,39} and surgical decompression.^{38,40} However, across these reviews there was variation on how the study population was defined.

The strengths of this review are the inclusion of all nonoperative interventions and the consistent inclusion and exclusion criteria for neurogenic claudication, which included the corroboration of a diagnosis of lumbar spinal stenosis on imaging. The use of these criteria to define the study population increases the likelihood that the presenting symptoms are caused by narrowing of the central or lateral foramina.^{38,40,41} However, a high reliance on imaging alone can lead to an incorrect diagnosis because 20% of asymptomatic individuals older than 60 years have lumbar spinal stenosis on imaging.⁴²

Another strength of this review is the use of rigorous methods recommended by The Cochrane Collaboration, the World Health Organization, and the Cochrane Back Review Group.^{9,43} This included the use of the GRADE method to analyze the quality of the evidence. To our knowledge, this is the first systematic review on this topic to use the GRADE method.

Limitations of this review include the potential for publication bias because only English articles were accepted. The definition of a severe flaw and the criteria used to assess risk of bias (low *vs.* high) were arbitrary and therefore alternative definitions and criteria could have impacted the findings and conclusions of this review.

The lack of high- or moderate-quality evidence found in this review prohibits any recommendations for clinical practice. To resolve this uncertainty, more research is needed with special attention to evidence-based clinical criteria for neurogenic claudication and appropriate and clearly described methods of randomization and allocation concealment. Trials on epidural injections and oral medication should ensure blinding of

all trial participants. Trials on physical interventions (physical therapy, manual therapy, surgery), in which subject blinding and provider blinding are not possible, should ensure that there is independent assessment of outcomes. All trials should use valid measures of walking ability, ensure that follow-up rates are above 80%, provide sufficient data on all primary outcomes, base conclusions on intention-to-treat analysis, and track and report cointerventions. Adequate description of nonoperative treatments is also needed.

CONCLUSION

Lumbar spinal stenosis with neurogenic claudication is an important cause of disability in the elderly. Current evidence for nonoperative care is of low and very low quality and thus prohibits recommendations to guide clinical practice. Given the expected exponential rise in its prevalence, more high-quality research is urgently needed.

sufficient data on all primary outcomes, base conclusions on intention-to-treat analysis, and track and report cointerventions. Adequate description of nonoperative treatments is also needed.

➤ Key Points

- ❑ We identified 21 RCTs including 1851 subjects randomized to 23 different comparisons, in which at least 1 comparison was nonoperative treatment. Nonoperative treatments included calcitonin, epidural injections, oral medications, physical therapy, and multimodal nonoperative care.
- ❑ Only 4 trials had a low risk of bias. There is low-quality evidence that prostaglandins improves walking ability compared with etodolac (NSAID); exercise improves leg pain and function compared with no treatment; unweighted treadmill walking provides similar improvements in pain, function, and walking ability compared with stationary cycling; and direct surgical decompression improves leg pain compared with multimodal nonoperative treatment. There is very low-quality evidence that gabapentin and methylcobalamin improve walking ability compared with placebo and conservative treatment, respectively; calcitonin is no better than placebo or paracetamol; epidural steroid injections improve pain, function, and quality of life up to 2 weeks compared with home exercise or inpatient physical therapy; and indirect surgical decompression (interspinous spacers) improves quality of life and global recovery compared with multimodal nonoperative care.
- ❑ Low- and very low-quality evidence precludes recommendations for clinical practice. Future studies should pay special attention to evidence-based clinical criteria for neurogenic claudication and provide appropriate and clear description of randomization and concealment of treatment allocation. Trials on epidural injections and oral medication should ensure subject, provider, and assessor blinding. Trials on physical therapies and surgery, in which subject blinding and provider blinding are not possible, should ensure that there is independent assessment of outcomes. All trials should include valid measures of walking ability, have high follow-up rates, provide

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