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Variation in eligibility criteria from studies of radiculopathy due to a herniated disc and of neurogenic claudication due to lumbar spinal stenosis: A structured literature review

S. Genevay, MD[1,3], **S.J. Atlas, MD MPH**[2], and **J.N. Katz, MD MSc**[3]

[1] Division of Rheumatology, University Hospitals of Geneva, Switzerland [2] General Medicine Division, Massachusetts General Hospital, Boston MA, USA [3] Department of Orthopaedic Surgery and Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Harvard Medical, Boston MA, USA

Abstract

Study Design—A structured literature review.

Summary of the Background Data—Widely recognized classification criteria for rheumatologic disorders have resulted in well-defined patient populations for clinical investigation.

Objectives—We sought to determine whether similar criteria were needed for back pain disorders by examining variability in eligibility criteria in published studies

Methods—Studies involving radiculopathy due to lumbar herniated disc (HD) and for neurogenic claudication due to lumbar spinal stenosis (LSS) were identified. Randomized controlled trials published between January 1, 2006 and October 1, 2008 in select peer reviewed journals were retrieved, their eligibility criteria were identified and categorized.

Results—Twelve eligible HD studies were identified. Thirteen unique categories of eligibility criteria were identified with a mean of 3.9 (+/−2.0) and a range from 0 to 8 categories per study. More categories were present for studies that included nonsurgical (5.6 +/− 2.5) treatment for studies with only surgical treatment (2.6 +/− 1.7) p= 0.04). Seven LSS studies met eligibility criteria, and 9 unique categories were identified. A mean of 5.0 (+/−2.2) categories with a range from 2 to 7 was used per study.

Conclusion—Wide variation in the number and type of eligibility criteria from randomized clinical trials of well defined back pain syndromes was identified. These results support the need for developing and disseminating international classification criteria for these clinical conditions.

Keywords

Radiculopathy; Herniated disc; Neurogenic claudication; Lumbar spine stenosis; Eligibility criteria

Correspondence to: Dr Stéphane Genevay Division of Rheumatology University Hospitals of Geneva 26 Av Beau-Séjour 1211 Geneva 14, Switzerland Phone: 0041 22 382 36 78 Fax: 0041 22 382 35 35 stephane.genevay@hcuge.ch.

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INTRODUCTION

The last two decades have witnessed an explosion of controlled trials involving a wide range of low back pain conditions. Prior to this, there were few high quality randomized controlled trials of common back pain treatments. Well conducted meta-analyses of low back pain treatments routinely concluded that reliable data were too sparse to draw firm conclusions [1-4].

Immense improvements in the quality and quantity of research have taken place in recent years. Major randomized controlled trials have been conducted and published in highly rated peer reviewed journals [5-7]. It is tempting to imagine that high quality meta-analyses with well grounded, clear conclusions for many low back conditions and treatments are just a few years off.

In contrast with many rheumatological conditions, such as rheumatoid arthritis 8 or complex regional pain syndrome 9, the literature on low back pain disorders has developed without widely recognized diagnostic and classification criteria. The development of internationally recognized classification criteria for rheumatological disorders has contributed to their pathophysiologic understanding and the development of new therapeutic targets 10. Classification criteria are also critical for conducting clinical trials, epidemiologic studies and other clinical investigations. The use of established classification criteria ensures recruitment of a more clinically homogeneous sample of subjects [10]. Imprecise definitions of specific spinal conditions may have clinical consequences as physicians attempt to apply the results from trials with potentially different patient populations to their own patients. To document and address the potential impact of different case definitions, we examined variation in eligibility criteria in recently published studies for two seemingly well defined back pain syndromes, radiculopathy arising from a lumbar herniated disc (HD) and neurogenic claudication due to lumbar spinal stenosis (LSS). Our goals were to document variability in classification of the same entities across studies and to identify possible classification criteria for future evaluation.

METHODS

We performed a structured literature review using PubMed to identify potential clinical studies of radiculopathy due to a lumbar herniated disc and neurogenic claudication due to lumbar spinal stenosis. Two independent literature searches were conducted by one author (SG). Search terms on radiculopathy due to HD included: sciatica, lumbar radiculopathy, and lumbar disc herniation. Search term on neurogenic claudication due to LSS included: degenerative lumbar stenosis, lumbar spinal stenosis, neurogenic claudication and intermittent claudication. We focused exclusively on randomized controlled trials comparing two treatments because strict eligibility criteria are particularly important for such studies. Studies that included mixed pathological conditions were excluded. For both conditions, additional search criteria included: 1) age 19 or older and 2) English literature. As methodology in back pain literature has been said to have recently improved, the search was also restricted to manuscript published between January 1, 2006 and October 1 2008. We augmented the electronic search by including studies from the reference lists of retrieved papers. To specifically identify high quality clinical trials, the literature search was limited to publications from journals with an impact factor of at least 1. To avoid duplication we excluded secondary analyses of previously published studies if the parent study met eligibility criteria for this analysis.

Data abstraction from eligible studies involved reviewing the Methods sections to identify inclusion and exclusion criteria. Eligibility criteria were then extracted and classified into one of the following four groups: a) demographic characteristics; b) symptoms; c) physical examination signs; d) and investigative procedures. Categories were identified and classified

within each of these four broad groups. Eligibility criteria that were not directly related to the diagnosis of the underlying clinical condition but rather related to the design of the study (e.g. symptom duration, failure of previous treatments, history of previous surgery, etc.), or to the treatment provided (e.g. allergies to studied medication, specific contraindications to the procedure, etc.) were excluded. The entire selection process was reviewed with a second author (JK). Discrepancies and ambiguities were discussed and consensus was achieved.

Analyses

Eligible studies were classified into 3 treatment categories: surgical treatment only, surgical versus nonsurgical treatment, and nonsurgical treatment only (Table 1 and 2). For each clinical condition, the number of studies (mean, median, and range) reporting each identified criteria were reported. Reported criteria across studies were also compared. Unpaired t-tests for unequal variance were used to assess differences between groups.

RESUTS

Radiculopathy due to Herniated Disc

The literature search on radiculopathy due to HD retrieved 56 references. One additional study was identified by checking reference lists of the retrieved studies. After reviewing the abstracts of these 57 studies, 43 were excluded because they did not meet inclusion criteria. Two more were discarded after reviewing the entire article. Discrepancies between SG and JK arose on 3 occasions and were resolved by reanalyzing the Methods section of the specific study. The Methods section of each of the remaining 12 studies underwent review to identify eligibility criteria.

Thirteen unique categories were identified that accounted for all identified diagnostic related criteria (Table 1). No category was assigned to the demographic characteristic group. Five related to clinical symptoms: 1) presence of accompanying back pain; 2) leg pain greater than back pain; 3) characteristic of leg pain (radicular/sciatic/dermatome distribution); 4) pattern of pain radiation (anterior thigh, below the knee) and 5) pain on Valsalva manoeuvre. Three categories referred to clinical examination: 1) nerve root irritation sign (straight leg raise test [L5 or S1] or femoral stretch test [L3 or L4], contralateral straight leg raise test); 2) presence of neurological deficit; and 3) neurological deficit corresponding to pain pattern. Four categories related to investigations: 1) herniated disc on imaging; 2) herniated disc on imaging corresponding (level + side) with clinical observation; 3) specification of the kind of HD included/excluded (protrusion, extrusion, sequestration, foraminal, etc.) and 4) electromyographic findings. The final category, specification of nerve roots included, could not be specifically attributed to a specific group.

The mean number of diagnostic categories identified per study was 3.9 (standard deviation 2.0, median 4, range 0 to 8). Trials comparing surgery and nonsurgical treatments used more eligibility categories (5.6 +/− 2.5) than trials only comparing surgical techniques (2.8 +/− 1.7). Trials only comparing nonsurgical treatments had a mean of 4.3 (+/− 1.9) categories cited per article. Studies comparing only surgical techniques used fewer criteria than studies involving at least one nonsurgical treatment (2.8 +/−1.7 vs. 4.8 +/− 1.9, p=0.04).

No single diagnostic eligibility category was used in all the studies (Table 3). The most commonly used categories were “radicular pattern of radiation” and “HD on imaging” (each 13/19, 68%). Congruence between pain pattern of radiation and HD on imaging were less commonly used (each 6/19, 32%), while congruence between pain pattern and neurological deficit were each used only twice (11%). There was additional variation in the definition used within a category. For example when the category “specification of nerve roots included” was used the number of defined nerve roots ranged from 1 11 (S1) to 6 12 (from L1 to S1). The

definition of the straight leg raise test varied in 2 ways: a) the kind of triggered pain (i.e. any leg pain versus radicular pain) and b) the degree of minimal/maximal angle for the test to be positive.

Neurogenic claudication due to Spinal Stenosis

The search for studies of neurogenic claudication due to LSS retrieved 20 citations. Eleven were excluded after reviewing the abstract, and an additional 2 were excluded after reviewing the entire paper. The remaining 7 eligible studies underwent review to identify eligibility criteria.

Nine unique categories were identified that accounted for all identified diagnostic related criteria (Table 2). One category was demographic: age limitation (usually older than 50). Three categories related to clinical symptoms: 1) presence of accompanying back/buttock/ lumbopelvic pain; 2) characteristics of radiating pain (neurogenic claudication / radicular pain); 3) definition of neurogenic claudication (symptoms restricted to pain or include fatigue and sensory loss: factors that made it worse; factors that ease the symptoms). No category was assigned to the clinical examination group. Four categories related to investigations: 1) radiological confirmation of stenosis; 2) explicit description of radiological stenosis (e.g. minimal sagittal diameter); 3) correlation between symptoms and level of radiological stenosis; 4) specific inclusion or exclusion of some other radiological findings (e.g. degenerative spondylolisthesis, instability). The final category could not be specifically attributed to a specific group: exclusion of other spinal (congenital stenosis) or non spinal problems (e.g. vascular, articular or neurogenic).

The mean number of criteria per study was 5.0 (+/−2.2), (median 6, range 2 to 7). No differences were noticed between surgical, nonsurgical and mixed studies (means between 5 and 5.5). On average more categories were used in trials of neurogenic claudication (mean of 5 crtieria used per paper of the 9 possible criteria; 57%) compared to trials on radiculopathy (mean of 3.9 criteria of a possible 13; 28%), p 0.02.

The presence of imaging findings consistent with lumbar stenosis was used in all studies, while the presence of neurogenic claudication was used in 5/7 (71%) studies. The definition of neurogenic claudication varied considerably across studies (e.g. “fatigue or loss of sensation in the lower limbs aggravated by walking” 13 and “sitting as a better position for symptom severity than standing or walking” 14.) Some studies included pain located in the buttock area as a possible radiation pain likely to have claudicating pattern 13,14. This allows the inclusion of patients who would be ineligible in studies adhering to the classical definition of lumbar pain (i.e. pain located between the 12th costal margin and the buttock folds 15). Detailed radiological definition of LSS was provided in 4/7 (57%) studies. In addition, the definition of radiological LSS varied among studies. Some mentioned dural sac compression [16], while others referred to precise measurement of the lumbar canal 17. Congruence between radiating pain pattern and the radiological level of stenosis was mentioned once. Of note, some radiological findings such as degenerative spondylolisthesis are mentioned in the list of exclusion criteria 18 in some studies while they are specifically mentioned as being included in others 13.

DISCUSSION

This study documented a high level of variation in diagnostic eligibility criteria for randomized controlled trials involving treatments for radiculopathy due to HD and for lumbar stenosis due to LSS. There was wide variation in the number of criteria used within each study and few criteria were used consistently across studies. These findings support our hypothesis that even for spine conditions that are thought to be well characterized, there is no single, standardized case definition used in the research literature. In addition, differences were found within

defined categories, such as the number of nerve roots included or the definition used for the straight leg raise test in the case of radiculopathy or the definition of radiological stenosis for neurogenic claudication.

Some of the categories that were created from our analysis such as “pattern of radiation” (e.g. anterior thigh, below the knee) and “specification of the nerve root included” may appear similar; the precision added by the second proposition was however considered to be crucial, justifying the separation, especially in reference to the L4 nerve root. Pain from the L4 nerve root may radiate below the knee, but the clinical assessment of L4 nerve root requires quadriceps testing for deficit and the femoral stretch test, rather than the straight leg raise test. Some discrepancies were noted in studies where eligibility criteria included pain below the knee and clinical examination related to L5 and S1 nerve root without mentioning the appropriate neurological testing for L4 nerve root [19].

In the absence of widely accepted diagnostic eligibility criteria, each group of authors devised their own construct. This makes generalizing findings across studies and to routine clinical practice a challenge. At a time when other musculoskeletal diseases are considering revision of well established sets of criteria [20,21], the absence of diagnostic and/or classification criteria in the field of low back pain should be considered a major focus for international organizations and clinical investigators. We suggest this process should differentiate among several needs. For epidemiological studies, broad criteria are needed and we suggest they should exclusively rely on symptoms that can be elicited from patients as part of survey research. For clinical studies however, the focus should be put on achieving more homogenous populations. For studies in the primary care setting involving patients with acute symptoms, the addition of clinical findings would be appropriate. Finally, for most clinical trials involving treatments, confirmatory investigative findings from imaging studies or electrodiagnostic tests are needed.

A number of important limitations may limit the interpretation of our results. A broader literature search criteria would have likely retrieved more diagnostic eligibility criteria. However it would also have included a large proportion of studies without any eligibility criteria [22]. We believe that finding wide variation in diagnostic eligibility criteria in recent randomized controlled trials published in high quality journals (defined as journals with higher impact factor) strengthens our conclusions. We also could have examined more spine conditions to generalize our findings across a broader range of disorders. However, focusing on two common and presumably well defined conditions, radiculopathy due to a herniated disc and neurogenic claudication due to lumbar spinal stenosis, supports the need for similar efforts for non-specific low back pain disorders as well. Some discrepancies were noted between the two reviewers in term of article selection (3 times) and in term of number of eligibility criteria (5 times). The vast majority were related to imprecision within the abstract. These discrepancies were generally resolved after considering the full text of the article. However, in some cases, imprecise or inconsistent reporting in the Methods section required subjective decisions by the reviewers. Excluding these few criteria would not alter our general findings.

In conclusion, we identified wide variation in diagnostic eligibility criteria for studies of radiculopathy due to HD and for neurogenic claudication due to LSS. These findings support efforts to convene a multidisciplinary, international effort to propose validated classification criteria for these conditions.

Key points (3-5)

- As distinct from many other musculoskeletal diseases, no widely accepted classification criteria have been developed for low back pain conditions.

- A high degree of variability in eligibility criteria was found in studies of radiculopathy due to disc herniation and of neurogenic claudication due to spinal stenosis.
- This lack of uniformity will impair the quality of knowledge of these conditions by compromising the capacity to compare studies.
- For both conditions, there is an urgent need for validated classification criteria.
- Criteria retrieved through this structured literature search could be used as a basis for the development of sets of criteria.

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Table 1

Eligible Randomized Control Studies of Radiculopathy due to Disc Herniation.

Reference	Treatments	Quoted Definition from "Materials and Methods"	Eligibility Criteria *												Total
			1	2	3	4	5	6	7	8	9	10	11	12	13	
Studies of different surgical techniques																
Ruetten S. Spine 2008 [12]	full-endoscopic v. microsurgical discectomy	"Patients with clinically-symptomatic disc herniation… The indication for surgery was defined according to present-day standards based on radicular pain symptoms and existing neurologic deficits… L5–S1 level … L4–L5 … L3–L4 … L2–L3 … L1–L2 were included"			+		+			+						3
Ryang YM Neurosurgery 2008 [23]	microsurgical discectomy v. minimal access trocar microdiscectomy	"…were included: …2) typical monoradicular symptoms attributable to the involved lumbar segment with predominant sciatica compared to less severe lower back pain … Exclusion criteria consisted of …, or signs of spinal canal stenosis on computed tomography or magnetic resonance imaging and neurogenic claudication… intra- and extraforaminal far lateral disc herniation"	+	+	+									+		4
Brock M. Eur. Spine J. 2008 [24]	subperiosteal versus transmuscular microdiscectomy:	"…scheduled for first time lumbar microdiscectomy were enrolled in the study… Patients in which the disc herniation was combined with a relevant lateral recess stenosis requiring substantial facet joint drilling were also excluded."														0
Righesso O Neurosurgery 2007 [25]	open v. microendoscopic discectomy	"Patients with sciatica caused by herniated lumbar discs … the presence of a posterolateral herniated lumbar disc observed on magnetic resonance imaging scans … The exclusion criteria were as follows: …, foraminal or extraforaminal disc herniations, spondylolisthesis…"			+							+		+		3
Ozer AF Neurosurgery 2006 [26]	microlumbar discectomy with preservation of the LF versus classic microlumbar discectomy	"… symptoms of radiculopathy; magnetic resonance imaging (MRI) findings correlated with clinical picture; single-level (L5–S1), unilateral herniated disc; …. The exclusion criteria were multilevel, far lateral, or bilateral disc herniation; significant degenerative spinal disorder; scoliosis; …"			+		+					+	+	+		5
Katayama Y J Spinal Disord Tech. 2006 [26]	Macro Discectomy and Micro Discectomy	"…patients underwent primary surgery for lumbar disc herniation…. The affected segments being: L2-L3 …, L3-L4 … L4-L5 … L5-S1…"					+									1
Arts MP BMC musculoskelet disors. 2006 [27]	microendoscopic discectomy or conventional discectomy	"Inclusion: … radicular pain … Disc herniation confirmed MRI… unilateral disc herniation larger than 1/3 of the spinal canal diameter or unilateral disc herniation less than 1/3 of the spinal canal diameter with concomitant lateral recess stenosis or sequestration."			+							+		+		3
Aminmansour B Spine 2006 [28]	Per operative high-dose steroids versus placebo	"Patients with a single-level herniated lumbar disc at L4–L5 or L5–S1 were included, and those with a history of neurogenic claudication, gastrointestinal bleeding, or magnetic resonance imaging findings consistent with concomitant central or lateral canal stenosis were excluded."					+					+				2

Reference	Treatments	Quoted Definition from "Materials and Methods"	Eligibility Criteria *													Total
			1	2	3	4	5	6	7	8	9	10	11	12	13	
Hoogland T Spine 2006 [29]	Endoscopic Discectomy versus same + chymopapain	"Inclusion criteria were: (1) primarily radicular pain; (2) magnetic resonance imaging (MRI) or computed tomography proven disc herniation corresponding to the neurologic findings; (3) a clear nerve-root tension sign with a straight leg raising sign of less than 45, or a positive neurologic finding in terms of an absent knee or ankle reflex, corresponding dermatomal numbness or weakness of quadriceps, foot-toe-dorsiflexors or triceps-weakness."			+				+	+		+	+			5
Studies of surgery versus nonsurgical treatment																
Peul, WC NEJM 2007 [7]	Surgery v. Prolonged nonsurgical treatment	"… had a radiologically confirmed disk herniation, and had received a diagnosis from an attending neurologist of an incapacitating lumbosacral radicular syndrome … Correlation of magnetic resonance imaging (MRI) findings with symptoms was registered by the neurosurgeon."			+							+	+			3
Weinstein JN JAMA 2006 [30]	Surgery v. nonsurgical treatment	"Criteria at enrollment were radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) and evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise–positive between 30° and 70° or positive femoral tension sign) or a corresponding neurologic deficit (asymmetrical depressed reflex, decreased sensation in a dermatomal distribution, or weakness in a myotomal distribution). Additionally all participants [had] … advanced vertebral imaging showing disk herniation (protrusion, extrusion, or sequestered fragment) at a level and side corresponding to the clinical symptoms." Exclusion criteria… scoliosis…, segmental instability."			+	+			+	+	+	+	+	+		8
Osterman H Spine 2006 [31]	microdiscectomy v. nonsurgical treatment	"Consultation because of sciatica…radiating pain below the knee with clinical findings suggestive of nerve root compression…. 2) a CT finding of intervertebral disc extrusion or sequester, and 3) at least one specific physical finding (a positive straight leg raising test <70°, muscle weakness, altered deep tendon reflex or a dermatomal sensory change). Exclusion criteria were 1) previous back surgery, 2) spondylolisthesis, 3) symptomatic spinal stenosis,"			+	+			+	+		+		+		6
Studiess of different nonsurgical treatments																
Friedman BW Spine 2008 [32]	Corticosteroid v. placebo	"Low back pain … [and] positive result on a straight leg raise test [defined] as pain radiating below the knee when either leg was raised to an angle between 30° and 70°…"	+						+							2
Luijsterburg PAJ Eur. Spine J. 2008 [33]	GP care v. GP care + physical therapy	"Inclusion criteria: Radiating (pain) complaints in the leg below the knee…Presence of one of the following symptoms. More pain on coughing, sneezing or straining. Decreased muscle strength in the leg. Sensory deficits in the leg. Decreased reflex activity in the leg. Positive straight leg raising test."				+		+	+	+						4

Reference	Treatments	Quoted Definition from "Materials and Methods"	Eligibility Criteria *													Total
			1	2	3	4	5	6	7	8	9	10	11	12	13	
Ackerman WE Anesth Analg. 2007 [11]	3 different epidural steroid injection	"…had radicular pain consistent with S1dermatomal distribution. The diagnosis of [corresponding] disk herniations was then documented by magnetic resonance imaging and electromyographic evidence of [corresponding] nerve root involvement."			+		+					+			+	4
Gallucci M Radiology 2007[34]	Steroid and Oxygen-Ozone versus Steroid	"Lumbar disc herniation (L3-L4 … L4-L5 … L5-S1) and…monoradicular pain, lumbar disk herniation on CT or MR images, herniation site congruous with the neurologic level."			+		+					+	+			4
Khoromi S Pain 2007 [19]	Morphine, Nortriptiyine, both or placebo	"Evidence of lumbar radiculopathy, including pain in one or both buttocks or legs … and at least one of the following a)Sharp and shooting pain below the knee; b) Pain evoked by straight leg raising to 60 degrees or less; c)Decreased or absent ankle reflex; d) Weakness of muscles below the knee. e) Sensory loss in L5/S1 distribution; f) Electromyographic evidence for L4, L5, or S1 root denervation; g) Imaging (MRI, CT/myelogram) evidence of nerve root compression in the lower lumbar region"			+	+			+	+		+			+	6
Korhonen T Spine 2006 [35]	Infliximab v. placebo	"… unilateral sciatic pain in conjunction with a magnetic resonance imaging (MRI)-confirmed disc herniation concordant with the symptoms and signs of radicular pain. …[and] neural entrapment (straight leg raising [SLR] <=60°)"			+				+			+	+			4
Finckh A Spine 2006 [36]	Methylprednisolone v. placebo	"… pain radiating below the knee, with or without concomitant low back pain, and signs of radicular irritation, such as a positive straight leg raising test (Lasegue test) or a neurologic deficit (motor, sensory, or reflex deficit). …corroborated by computerized tomography or magnetic resonance imaging showing the presence of a herniated disc at a site that corresponds to the clinical presentation."	+			+			+	+		+	+			6

* Eligibility criteria include: 1- Presence of accompanying back pain. 2-Leg pain greater than back pain. 3-Characteristic of leg pain (radicular/sciatic/dermatome distribution) 5-Pattern of irradiation (anterior thigh, below the knee). 6-Specification of nerve roots included. 6-Positive Valsalva manoeuvre. 7-Nerve root irritation sign (straight leg raise test [L5 or S1] or femoral stretch test [L3 or L4], reverse straight leg raise test). 8-Neurological deficit. 9-Neurological deficit corresponding to pain pattern. 10-Herniated disc on imaging. 11-Herniated disc on imaging corresponding (level + side) with clinical observation. 12-Specification of the kind of HD included/excluded (protrusion, extrusion, sequestration, foraminal,). 13-Electromyographic findings

Table 2

Eligible Randomized Control Studies of Neurogenic Claudication due to Lumbar Spinal Stenosis.

Reference	Treatments	Quoted Definition from the "Materials and Methods"	Eligibility Criteria*									Total
			1	2	3	4	5	6	7	8	9	
Studies of different surgical techniques												
Cavuşoğlu H Eur. Spine J. 2007 [16]	unilateral laminotomy versus unilateral laminectomy	"(1) symptoms of neurogenic claudication referable to the lumbar spine (claudicant or radicular symptoms brought on either by walking or by prolonged standing, relieved by sitting or the flexed position, in the absence of vascular or neuropathic pathology), (2) radiological/neuroimaging evidence of degenerative lumbar stenosis (neurologic compression by hypertrophied (infolded) ligamentum flavum, osteophytic facet joints, and annular bulging), …(4) the absence of associated pathology such as instability, inflammation or malignancy,…. Patients presenting with mild degenerative spondylolisthesis were not excluded."			+	+	+	+		+	+	6
Hallett A Spine 2007 [37]	Foraminotomy v. foraminotomy + PLIF v. foraminotomoy + TLIF	"…had both 1) single-level degenerative disc disease and 2) evidence of associated foraminal stenosis. All the patients had suffered from some backache over the preceding 5 years, yet this was not the main presenting feature… All patients complained of unilateral or bilateral leg pain with or without positive nerve root tension signs, associated muscle weakness, and/or sensory loss… Plain radiographs and MR images were obtained in all subjects to diagnose intraforaminal or extraforaminal nerve root compromise, in association with single-level degenerative disc disease. Patients were excluded if they had 1) degenerative spondylolisthesis of Grade II or greater at the level of the degenerative disc or at an adjacent level, 2) vertebral translocation in excess of 1 cm, 3) disc space narrowing of greater than 50% proximal or distal to the level of proposed fusion,…"		+			+			+		3
Surgery vs. nonsurgical treatment												
Weinstein JN NEJM 2008 [18]	Surgery versus nonsurgical treatment	"… history of neurogenic claudication or radicular leg symptoms … and confirmatory cross-sectional imaging showing lumbar spinal stenosis at one or more levels; Patients with degenerative spondylolisthesis … [and} patients with lumbar instability (which was defined as translation of more than 4 mm or 10 degrees of angular motion between flexion and extension on upright lateral radiographs) were excluded."			+		+			+		3
Malmivaara A Spine 2007 [13]	Nonsurgical versus surgery	"… back pain radiation to lower limbs or buttocks; fatigue or loss of sensation in the lower limbs aggravated by walking… [and] spinal canal narrowing, the sagittal diameter of the dural sac being less than 10 mm2, or the planimetrically assessed cross-sectional dural area being less than 75 mm2. …. [and] signs and symptoms corresponding to segmental radiographic level of stenosis. The following conditions did not prevent inclusion: radiographic instability of the lumbar spine, degenerative spondylolisthesis, Patients…were ineligible in the case of spinal stenosis not caused by degeneration; spondylolysis and spondylolytic spondylolisthesis; lumbar herniated disc …: an other spinal disorder…; intermittent claudication due to atherosclerosis; severe osteoarthrosis or arthritis causing dysfunction of the lower limbs; neurologic disease causing impaired function of the lower limbs…"		+		+	+	+	+	+	+	7
Studies of different nonsurgical treatments												
Yaksi A Spine 2007 [38]	Gabapentin versus placebo	"… symptoms of [neurogenic intermittent claudication] … and diagnosed with [lumbar spinal stenosis] based on radiologic studies."			+		+					2

Spine (Phila Pa 1976). Author manuscript; available in PMC 2011 April 1.

Reference	Treatments	Quoted Definition from the "Materials and Methods"	Eligibility Criteria*									Total
			1	2	3	4	5	6	7	8	9	
Tafazal SI Eur. Spine J. 2007 [17]	Calcitonin versus placebo	"…symptoms of neurogenic claudication and MRI proven lumbar spinal stenosis were enrolled into the study … unilateral or bilateral leg pain made worse by walking and prolonged standing and eased by resting or leaning forwards. Inclusion criteria …Pain including back/leg [and] Standing leg discomfort [and] Weakness, Paraesthesia and absent reflex [and] Age > 50 [and] Radiographic evidence of relative/absolute stenosis- mid sagittal diameter 13 mm or less. Exclusion criteria: …Vascular claudication.. Presence of other neurologic disease including peripheral neuropathy."	+	+	+	+	+	+			+	7
Whitman JM Spine 2006 [14]	2 different physical therapy	"…pain in the lumbopelvic region and lower extremities, ≥50 years of age, MRI findings consistent with LSS (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum , and patient rating of sitting as a better position for symptom severity than standing or walking. Exclusion: history of … lumbar vertebral fractures other than spondylolysis or spondylolisthesis; …signs/symptoms suggestive of potential non benign or pathologic condition as the origin of symptoms."	+	+		+	+	+		+	+	7

*Eligibility criteria are: 1-Age limitation (usually over 50). 2-Presence of accompanying back/buttock/lumbopelvic pain. 3-Characteristics of radiation (neurogenic claudication / radicular pain). 4- Explicit description of neurogenic claudication (symptoms restricted to pain or include fatigue and sensory lost: factors that made it worse; factors that ease the symptoms). 5-Radiological confirmation of stenosis. 6-Definition of radiological stenosis (e.g. minimal sagittal diameter). 7-Correlation between symptoms and level of radiological stenosis. 8-Specific inclusion or exclusion of some other radiological findings (e.g. degenerative spondylolisthesis, instability). 9-Exclusion of other spinal (congenital stenosis) or non spinal problems (e.g. vascular, articular or neurogenic).

Table 3

Classification of diagnostic categories by frequency order of citation from selected studies

	Number of studies citing the diagnostic criterion (in decreasing order of frequency)		
Syndrome	**15-19 studies**	**5-14 studies**	**1-4 studies**
Radiculopathy due to HD		• Characteristic of leg pain • Herniated disc on imaging • Nerve root irritation sign • Neurological deficit • Herniated disc on imaging corresponding (level + side) with clinical observation • Specification of nerve roots included • Precision on the kind of HD included/excluded • Pattern of radiation	• Presence of accompanying back pain. • Electromyographic findings • leg pain > back pain • Positive Valsalva manoeuvre • Neurological deficit corresponding to the pain pattern
	6-7 studies	3-5 studies	1-3 studies
Neurogenic Claudication due to LSS	• Radiological confirmation of stenosis	• Specific inclusion or exclusion of some other radiological findings • Presence of accompanying back/ buttock/lumbopelv ic pain • Characteristics of radiating pain • Explicit definition of neurogenic claudication • Definition of radiological stenosis • Exclusion of other spinal or non spinal problems.	• Correlation between symptoms and level of radiological stenosis • Age limitation