Evaluation of outcome measures for neurogenic claudication

A patient-centered approach

John D. Markman, MD
Jennifer S. Gewandter,
PhD, MPH
Maria E. Frazer, BS,
CCRC
Christine Pittman, MPH
Xueya Cai, PhD
Kushang V. Patel, PhD,
MPH
Babak S. Jahromi, MD,
PhD
Robert H. Dworkin, PhD
Laurie B. Burke, MPH
John T. Farrar, MD, PhD

Correspondence to
Dr. Markman:
john_markman@urmc.rochester.
edu

ABSTRACT

Objectives: To determine whether patients with neurogenic claudication associated with lumbar spinal stenosis would prefer a treatment that makes it possible for them to walk farther or walk with less pain; to examine associations between this treatment preference and patient-reported and in-clinic treadmill testing measures of walking ability and walking-associated pain.

Methods: In this cross-sectional study, 269 patients with neurogenic claudication were asked to report their pain intensity when walking, complete the Swiss Spinal Stenosis Questionnaire, rank their outcome preferences for treatment, and undergo standardized treadmill testing, including measures of final pain rating and time to first pain of moderate intensity (T_{first}). Descriptive statistics were used to characterize patient preferences for treatment outcome. Associations between self-report questionnaires and standardized treadmill testing outcomes were evaluated using Spearman correlations.

Results: Seventy-nine percent of patients expressed a preference for treatment that allowed them to walk with less pain. Preference for reduced pain was associated with higher pain during daily walking, along with a shorter T_{first} and higher final pain severity on treadmill testing. In contrast, patient preference for treatment outcome was not associated with self-reported measures of daily walking capacity or walking distance on the treadmill.

Conclusions: A majority of patients with neurogenic claudication prioritized walking with reduced pain over walking farther. Reduction in pain while walking may therefore constitute a sufficient patient-focused treatment outcome for the majority of these patients. These results have implications for clinical trial design and assessment of treatment efficacy in neurogenic claudication. **Neurology® 2015;85:1250-1256**

GLOSSARY

NRS = numeric rating scale; **PRO** = patient-reported outcome; **SSS** = Swiss Spinal Stenosis; **T_{first}** = time to first moderate pain intensity.

There is unanimous agreement that an analgesic medication should relieve pain to be considered effective.¹ However, there is still debate whether decreased pain in the absence of increased physical function provides sufficient benefit to warrant use of analgesic therapy.² The debate over the need for efficacy on both analgesic and physical function outcomes is especially pertinent to chronic low back pain syndromes, which are the most common indication for analgesic therapy³ and the leading cause of disability worldwide.⁴

Neurogenic claudication associated with lumbar spinal stenosis is a highly prevalent chronic low back and lower extremity pain syndrome in older adults that is associated with impaired mobility in seniors.⁵⁻⁷ There is a major unmet need for nonsurgical therapy for neurogenic claudication.^{8,9} Because advanced imaging techniques that characterize anatomical stenosis are not specific or sensitive for the experience of evoked pain, patient report of symptoms is the cornerstone of analgesic efficacy assessment.¹⁰ Pain-related activity limitation with standing and walking is the clinical hallmark of neurogenic claudication.¹¹ As such, patients with neurogenic

From the Department of Neurosurgery, Translational Pain Research Program (J.D.M., M.E.F., C.P., B.S.J.), and Departments of Anesthesiology (J.S.G., R.H.D.) and Biostatistics and Computational Biology (X.C.), University of Rochester School of Medicine and Dentistry, NY; Department of Anesthesiology and Pain Medicine (K.V.P.), University of Washington, Seattle; LORA Group, LLC (L.B.B.), Royal Oak, MD; and Department of Biostatistics and Epidemiology (J.T.F.), University of Pennsylvania, Philadelphia.

Go to Neurology.org for full disclosures. Funding information and disclosures deemed relevant by the authors, if any, are provided at the end of the article.

claudication could prioritize improvements in physical function as much as or more than reductions in pain intensity. If patients prioritize reduced pain over increased physical function, or at least find decreased pain in the absence of enhanced physical function a sufficiently successful treatment outcome, denying access to analgesic benefit, even in the absence of functional improvement, could be considered an unsatisfactory clinical outcome.

METHODS Study design. This article reports the results from a cross-sectional research study utilizing data that were collected as part of clinical practice from patients with lumbar spinal stenosis that assesses patients' preferences for treatment outcomes as well as self-reported pain and physical function in daily life and treadmill walking-induced pain and walking performance.

Standard protocol approvals, registrations, and patient consents. This study was approved by the University of Rochester Research Subjects Review Board. It was a retrospective chart review of data from routine clinical assessment forms and therefore did not require patient consent.

Participants. Patients who were undergoing initial evaluation for lumbar stenosis by the senior author (J.D.M.), a board-certified neurologist, or a board-certified neurosurgeon faculty colleague affiliated with the Neuromedicine Pain Management Center at the University of Rochester between 2008 and 2014 were included in the initial sample. Patients who reported exercise-induced lower back or extremity pain, numbness, heaviness, or vague discomfort that was relieved by sitting, squatting, or forward flexion posturing for a minimum of 3 months were further evaluated as part of our usual clinical care including a treadmill test and standard battery of questionnaires. Treadmill tests and standardized questionnaires were administered by trained clinical coordinating staff using a standardized protocol. Neurogenic claudication was confirmed by requiring patients to report (1) a resting pain level of <4 out of 10 on a 0 to 10 numeric rating scale (NRS) (0 = no pain, 10 = pain as bad as you can imagine), and (2) a pain level of ≥ 4 out of 10 on the NRS within 15 minutes of walking on the treadmill. Patients reporting acute musculoskeletal injury unrelated to their baseline low back and leg pain, comorbid medical problems affecting their gait that would preclude treadmill testing (e.g., parkinsonism), or comorbid problems that would alter their walking capacity (e.g., shortness of breath, clinical findings of lower extremity vascular disease [e.g., abnormal distal pulse]) were excluded or rescheduled for another visit if the problem was reversible.

Assessments. Clinical variables. Age and sex were captured from the medical charts. Medication use was self-reported at the time of the treadmill test. For pain location, patients were asked to identify the areas where they experience walking-induced pain, and the clinical coordinator categorized the locations into the following groups: lower back, upper legs, lower legs, buttocks, hips, and/or feet. Any area other than lower back was considered "lower extremity" in these data.

Treatment outcome preference. Participants were asked, "Which of the following results of a possible treatment is more important to you?" (1) a treatment that allows you to walk farther or (2) a treatment that allows you to walk with less pain.

Patient-reported assessments of walking capacity in everyday life. Patients completed the Swiss Spinal Stenosis (SSS) physical function subscale that includes questions pertaining to how far patients can walk and where they have been able to walk (e.g., outdoors, in the house on a flat surface, to the bedroom or bathroom). The SSS physical function subscale has demonstrated construct validity when compared with other self-report measures of function in patients with lumbar spinal stenosis.¹² One of the questions included "How far can you walk before needing to rest: (1) more than 2 miles; (2) more than 2 blocks, but less than 2 miles; (3) more than 50 ft, but less than 2 blocks; (4) less than 50 ft?" (note that a lower score indicates better walking capacity).

Patient-reported assessment of pain intensity when walking in everyday life. Patients were asked, on a 0 to 10 NRS, "what is the highest level of pain you experience when walking?"

Clinic-based treadmill assessment of walking ability and associated pain intensity. Patients sat for 15 minutes before treadmill assessment or until their pain was ≤ 3 out of 10, whichever came first. Patients then walked on a 0° incline at 1.2 mph or 0.6 mph if they were unable to walk at 1.2 mph. They were instructed to walk with an upright posture and were not permitted to lean forward or lean on the handrails. They were, however, allowed to lightly touch the handrails if they felt off balance. The time display on the treadmill was obstructed from the patients' view. Patients were asked to report their pain intensity on the 0 to 10 NRS at 30-second intervals. The examination was stopped after 15 minutes or when the patients reached the level of discomfort that would make them stop walking in everyday life. The time when the patient reported a rating of ≥ 4 for leg or back pain on the NRS was designated as T_{first} (i.e., the time to first reported pain of moderate intensity). Pain intensity at 15 minutes or when the patient decided to stop walking, whichever came first (i.e., pain intensity at final), and total distance walked on the treadmill were also recorded.

Statistical analyses. The sample size was determined based on the available patient records, as this was a retrospective study. Descriptive statistics were used to assess the number of participants who preferred a treatment that would decrease their pain while walking vs those who preferred a treatment that would allow them to walk farther. Scores for walking capacity and pain intensity measures were compared between these 2 groups using the Wilcoxon rank sum test. Multivariable logistic regression models were applied to assess the relationship between patient preference and (1) walking capacity and (2) pain intensity measures after adjustment for age and sex. Associations between walking capacity and pain intensity measures were assessed using Spearman correlations. If a variable was missing for a patient, the patient was excluded from the analyses involving that variable. The sex and age of the participants who did and did not answer the preference question were compared to evaluate the possible effects of missing data. A p value <0.05 was considered significant for all comparisons. Adjustments in α were not made for multiple comparisons because many of the analyses are considered hypothesis-generating.

RESULTS In total, 470 patients with lumbar spinal stenosis were evaluated for the first time at the Neuromedicine Pain Center using our standardized clinical protocol between 2008 and 2014. Of those patients, 142 reported pain ≥ 4 out of 10 at rest and 59 did not report pain induced by walking, and therefore were excluded. Thus, 269 participants with neurogenic claudication were evaluated for this study (figure).

The median age of the participants was 69 years and 55% were male. The majority of patients reported pain symptoms in their back and lower extremities (69%); 57 (22%) reported symptoms only in their lower extremities and 26 (10%) reported having only lower back pain (table 1). Of the patients with neurogenic claudication, 221 answered the question pertaining to their preference to walk with less pain or to walk farther. The participants who did not answer the preference question were similar in age and sex to those who did answer it (median age 70 vs 69 years and 59% vs 54% male). Of those 221 patients, 175 (79%) reported they would prefer a treatment that allowed them to walk with less pain to a treatment that would allow them to walk farther. When only patients who had no pain at rest ($n = 111$) were analyzed, the results were similar, with 72% of patients preferring a treatment that would allow them to walk with less pain.

Participants who reported that they preferred to walk with less pain reported higher pain when asked about the highest pain they experience when walking in their everyday life compared with those who preferred a treatment that would allow them to walk farther (median 0–10 NRS: 8.5 vs 7.5, $p = 0.002$). In addition, they had a shorter T_{first} during the treadmill test (median: 1.5 vs 2.5 minutes, $p = 0.01$) and reported a higher pain severity at the end of the treadmill test (median 0–10 NRS: 7 vs 6, $p = 0.02$) (table 1). In contrast, there were no significant differences between the treatment outcome preference groups on any of the walking capacity measures that were investigated, including (1) the SSS physical function subscale

(median: 2.6 vs 2.6, $p = 0.54$), (2) the distance they reported they could walk in their everyday life (median [arbitrary units]: 3.0 vs 3.0, $p = 0.92$), and (3) the distance walked on the treadmill (median: 170 vs 193 m, $p = 0.24$) (table 1). After adjusting for participants' age and sex in the multivariable logistic regression models, the relationships of treatment outcome preference with (1) the highest pain when walking in everyday life and (2) the pain rating at the end of the treadmill test were still significant (table 2). However, the T_{first} was no longer significantly associated with the outcome preference (table 2). A list of Spearman correlations between different measures can be found in table 3.

DISCUSSION A considerable majority (79%) of the patients with neurogenic claudication in this sample preferred a treatment that would decrease their pain when walking over one that would allow them to walk farther. These data suggest that a reduction in pain intensity, even in the absence of concurrent improvement in physical function, is an important treatment outcome for most individuals with lumbar stenosis and neurogenic claudication. Considering that expert consensus groups¹³ and the US Food and Drug Administration¹⁴ prioritize patient input when identifying meaningful outcomes, data such as these should be weighted heavily in the ongoing discussions about the need for functional criteria in addition to reduction in pain for analgesic regulatory approval. Although for many patients the pain they experience when walking is the limiting factor in the distance they choose to walk, these results suggest that pain relief would serve as a necessary and sufficient primary endpoint in clinical trials using a patient-centered treatment approach. Understanding patients' treatment priorities is of critical importance because clinical trials in chronic low back pain study populations have become the most common development path for novel analgesic medications since 2011.^{15–18}

Patients with higher pain levels may find severe pain to be a worse experience than walking limitations, causing them to prioritize decreased pain over increased physical function. In addition, patients may prioritize analgesia over functional benefit because they appreciate how many other contextual factors—other than pain intensity—influence how far they are able to walk, such as fatigue, motivation, comorbid medical problems, or the availability of a caregiver. Many patients report clinically that pain is only one of multiple factors that can affect their function; therefore, their expectations of an analgesic medication or decompressive surgery may be limited to pain reduction alone. Preference studies similar to this one, however, should be conducted in other

Figure Patient sample flow diagram

LSS = lumbar spinal stenosis.

Table 1 Patient characteristics according to treatment outcome preference

Characteristic	Total (N = 269)	Prefer pain relief (n = 175)	Prefer increased function (n = 46)	p Value ^a
Age, y	69 (60, 76)	68 (61, 76)	69 (60, 79)	0.800
Sex, male	147 (55)	90 (51)	29 (63)	0.185
Medications^b				
Opioids	22 (8)	11 (6)	2 (4)	1.000
Anticonvulsants	7 (2.6)	4 (2)	2 (4)	0.607
Muscle relaxants	1 (0.3)	1 (0.5)	0 (0)	1.000
Analgesics (e.g., NSAIDs)	33 (12)	19 (11)	3 (7)	0.580
Location of pain				
Lower back only	26 (10)	21 (12)	2 (4)	0.177
Lower back and lower extremity	181 (69)	123 (70)	26 (57)	0.081
Lower extremity only	57 (22)	18 (10)	30 (65)	0.002 ^c
Pain-related measures				
T _{first} , min	1.5 (0.5, 3.5)	1.5 (0.5, 3)	2.5 (1.0, 4.5)	0.014 ^c
Pain intensity at final	6.3 (5, 8)	7 (5.5, 8)	6 (5, 7)	0.002 ^c
PRO worst pain intensity when walking	8 (7, 9)	8.5 (7.5, 9.5)	7.5 (5, 8.1)	0.021 ^c
Function-related measures				
SSS physical function	2.6 (2.2, 3)	2.6 (2.2, 3)	2.6 (2.2, 2.8)	0.536
PRO how far can walk	3 (2, 3)	3 (2, 3.3)	3 (2, 4)	0.918
Total distance walked, m	179 (91, 483)	170 (86, 483)	193 (123, 419)	0.239

Abbreviations: NSAID = nonsteroidal anti-inflammatory drug; PRO = patient-reported outcome; SSS = Swiss Spinal Stenosis; T_{first} = time to first moderate pain intensity.

Data represent median (interquartile range) or n (%).

^aThe p values represent Wilcoxon sign ranked tests for continuous variables and Fisher exact test for categorical variables for comparing the preference groups.

^bValues represent the number and percentage of patients who reported taking a medication in each class at the time of their treadmill test visit.

^cHighlights p values < 0.05.

evoked chronic pain conditions, especially those in which activity avoidance is one reasonable strategy to limit induced pain.

Patients expressing a priority for functional improvement reported lower pain on the measures we investigated, but similar physical function and walking capacity (table 1). The highest correlation between outcomes was between the patient-reported outcome (PRO) question that asks how far a patient can walk and the SSS physical function score ($\rho = 0.596$). This result is not surprising considering that the PRO *distance-can-walk* question is included in the SSS physical function subscale. Both of the patient-reported walking capacity assessments (i.e., the single item *distance-can-walk* question and the SSS physical function score) were only moderately correlated with the total distance walked on the treadmill ($\rho = -0.361$, $p < 0.0001$, and $\rho = -0.443$, $p < 0.0001$, respectively [note that these correlations are negative because a lower score indicates ability to walk farther on the single item question and better function on the SSS physical function subscale]). These

data suggest that self-report measures of function focused on walking ability may reflect other constructs than walking capacity alone. These moderate correlations between PRO measures of walking capacity in everyday life and treadmill tests of walking capacity are consistent with the view that self-reported and performance-based measures assess different aspects of physical function that can provide complementary information.^{19–21,23}

Considering that our patients generally favored a treatment that allows them to walk with less pain over one that allows them to walk farther, it is important to identify the outcome measure that can most validly measure pain when walking for clinical trials of analgesic treatments for neurogenic claudication. Asking patients to rate their highest pain when walking in everyday life was relatively moderately correlated ($\rho = 0.304$, $p < 0.0001$) with the final pain rating on the treadmill test (i.e., the point at which the patient decided to stop walking or after 15 minutes, whichever came first). The T_{first}, however, was less well correlated with pain intensity at final

Table 2 Multivariable logistic regression models of treatment outcome preference predicted by age, sex, and pain measures

	OR (95% CI)	p Value
Time to first model		
Age, per 1-y increment	1.00 (0.98, 1.03)	0.843
Sex, M vs F	1.65 (0.85, 3.30)	0.145
T _{first} per 1-min increment	1.10 (0.98, 1.23)	0.100
Pain at final model		
Age, per 1-y increment	1.00 (0.98, 1.03)	0.998
Sex, M vs F	1.58 (0.80, 3.19)	0.186
Pain at completion of treadmill test	0.83 (0.70, 0.98)	0.026 ^a
PRO highest pain with walking model		0.026
Age	0.28 (0.96, 1.03)	0.532
Sex, M vs F	1.96 (0.75, 5.70)	0.186
PRO highest pain when walking	0.02 (0.42, 0.78)	0.0006 ^a

Abbreviations: CI = confidence interval; OR = odds ratio; PRO = patient-reported outcome; T_{first} = Time to first moderate pain intensity.

ORs represent the odds of preferring a treatment outcome that reduces pain while walking (over an outcome of walking farther) for every unit change in the predictor variable (i.e., 1 year of age, 1 point on the pain numeric rating scale, or 1 minute for T_{first}).

^aHighlights p values < 0.05.

($\rho = -0.242$, $p = 0.0008$) or worst pain when walking in everyday life ($\rho = -0.068$, $p = 0.418$). This lower correlation suggests that some patients have increased determination to walk farther than others might at the same pain level. Outcomes that assess the patients' highest pain when walking in everyday life or pain intensity when they decide to stop the treadmill test will likely have increased variability because of differences in patients' levels of pain resilience. This variability in an individual's worst pain scores with walking may have a negative impact on the ability of the measure to detect change over time and to be responsive to a treatment effect. However, if administered in a standardized manner, T_{first} will

likely have less variability due to differences in pain resilience and therefore may be more responsive to change than outcomes that are affected by pain resilience. These hypotheses, however, need to be tested in future studies.

A possible advantage of the treadmill test is that like other experimental induced-pain tests, it limits patient recall bias and focuses the patient's attention on the type of pain being studied. Neurogenic claudication is a unique chronic pain condition because the symptom pattern is very specific and only occurs when induced by walking or prolonged standing. Thus, an experimental model (i.e., the treadmill test) that specifically induces this type of pain can help focus the patients' attention solely on the symptoms of neurogenic claudication and decrease the variability in pain ratings that are introduced by varied pain resilience and activity levels that occur in everyday life. However, it does limit the assessment to 1 day, which may not be representative of the patient's general pain condition. These pain measurement challenges associated with neurogenic claudication highlight why it is important to assess treatment efficacy in this population separately with a syndrome-specific pain outcome measure.

A few limitations of this study need to be acknowledged. First, because for many patients with neurogenic claudication, pain often limits how far they choose to walk, it could be argued that in order to walk farther, patients would first have to walk with less pain and therefore the question cannot sufficiently dissect patient preference. Even if patients chose the option to walk with less pain because they believed this would allow them to walk farther, these results suggest that walking with less pain is a sufficient outcome for treatment success from the patient perspective. Future studies should challenge patients with specific pain

Table 3 Spearman correlations between pairs of outcome measures

	SSS physical function	PRO highest pain with walking	PRO distance can walk	Pain at final	T _{first}	Total distance walked
SSS physical function	1					
PRO highest pain with walking	0.337 ^a	1				
PRO distance can walk	0.596 ^a	0.275 ^b	1			
Pain at final	0.305 ^a	0.304 ^a	0.274 ^a	1		
T _{first}	-0.341 ^a	-0.068	-0.246 ^a	-0.242 ^a	1	
Total distance walked	-0.361 ^a	-0.139	-0.443 ^a	-0.245 ^a	0.595 ^a	1

Abbreviations: PRO = patient-reported outcome; SSS = Swiss Spinal Stenosis Questionnaire; T_{first} = time to first moderate pain intensity.

Pain at final, T_{first}, and total distance walked are outcomes from the treadmill test.

^a $p < 0.0001$.

^b $p = 0.0008$.

function trade-off scenarios (e.g., would you prefer to walk to your mailbox with pain of 2/10 or to your mailbox and down the street with pain of 6/10) to better characterize treatment preference. Our results are based on data from a single tertiary care center and therefore may not be representative of the experiences of all patients with neurogenic claudication. However, our patients were very similar in age to patients admitted to the hospital in the United States and Canada for lumbar spinal stenosis surgery between 2000 and 2009.²²

This study demonstrates that patients with neurogenic claudication associated with lumbar spinal stenosis generally prioritize decreased pain when walking over the ability to walk farther as a treatment outcome. This result should be considered when designing treatment trials for neurogenic claudication and similar studies should be executed for other chronic pain conditions with evoked symptoms to better understand the patient perspective on the relative importance of pain relief vs improved function when evaluating analgesic treatments.

AUTHOR CONTRIBUTIONS

John D. Markman: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval, acquisition of data, statistical analysis, study supervision. Jennifer S. Gewandter: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval, statistical analysis. Maria E. Frazer: drafting/revising the manuscript, study concept or design, accepts responsibility for conduct of research and will give final approval, acquisition of data, study supervision. Christine Pittman: drafting/revising the manuscript, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval, statistical analysis. Xueya Cai: analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval. Kushang V. Patel: drafting/revising the manuscript, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval. Babak S. Jahromi: drafting/revising the manuscript, accepts responsibility for conduct of research and will give final approval. Robert H. Dworkin: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval. Laurie B. Burke: drafting/revising the manuscript, accepts responsibility for conduct of research and will give final approval. John T. Farrar: drafting/revising the manuscript, analysis or interpretation of data, accepts responsibility for conduct of research and will give final approval, statistical analysis.

STUDY FUNDING

No targeted funding reported.

DISCLOSURE

The authors report no disclosures relevant to the manuscript. Go to Neurology.org for full disclosures.

Received March 22, 2015. Accepted in final form June 11, 2015.

REFERENCES

1. US Department of Health and Human Services, Food and Drug Administration. Guidance for Industry: Analgesic Indications: Developing Drug and Biological Products.

1. Silver Spring, MD: Center for Drug Evaluation and Research, Food and Drug Administration; 2014.
2. Franklin GM. Opioids for chronic noncancer pain: a position paper of the American Academy of Neurology. *Neurology* 2014;83:1277–1284.
3. Deyo RA, Von Korff M, Duhrhoop D. Opioids for low back pain. *BMJ* 2015;350:g6380.
4. Murray CJ, Atkinson C, Bhalla K, et al. The state of US health, 1990–2010: burden of diseases, injuries, and risk factors. *JAMA* 2013;310:591–608.
5. Ciol MA, Deyo RA, Howell E, Kreif S. An assessment of surgery for spinal stenosis: time trends, geographic variations, complications, and reoperations. *J Am Geriatr Soc* 1996;44:285–290.
6. Comer CM, Redmond AC, Bird HA, Conaghan PG. Assessment and management of neurogenic claudication associated with lumbar spinal stenosis in a UK primary care musculoskeletal service: a survey of current practice among physiotherapists. *BMC Musculoskelet Disord* 2009;10:121.
7. Whitehurst M, Brown LE, Eidelson SG, D'Angelo A. Functional mobility performance in an elderly population with lumbar spinal stenosis. *Arch Phys Med Rehabil* 2001;82:464–467.
8. Markman JD, Frazer ME, Rast SA, et al. Double-blind, randomized, controlled, crossover trial of pregabalin for neurogenic claudication. *Neurology* 2015;84:265–272.
9. Markman JD, Gewandter JS, Frazer ME, et al. A randomized, double-blind, placebo-controlled cross-over trial of oxymorphone hydrochloride and propoxyphene/acetaminophen combination for the treatment of neurogenic claudication associated with lumbar spinal stenosis. *Spine* 2015;40:684–691.
10. Markman JD, VanWilet H. Spinal root disease: radiculopathy and arachnoiditis. In: Dworkin RD, McArthur JC, Simpson DH, editors. *Neuropathic Pain: Mechanisms, Diagnosis and Treatment*. New York: Oxford University Press, Inc.; 2012.
11. Porter RW. Spinal stenosis and neurogenic claudication. *Spine* 1996;21:2046–2052.
12. Tomkins CC, Battie MC, Hu R. Construct validity of the physical function scale of the Swiss Spinal Stenosis Questionnaire for the measurement of walking capacity. *Spine* 2007;32:1896–1901.
13. Turk DC, Dworkin RH, Burke LB, et al. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations. *Pain* 2006;125:208–215.
14. US Department of Health and Human Services, Food and Drug Administration. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Silver Spring, MD: Center for Drug Evaluation and Research, Food and Drug Administration; 2009.
15. US Department of Health and Human Services, Food and Drug Administration. Exalgo (Hydromorphone ER) NDA 21-217 Medical Review. Silver Spring, MD: US Food and Drug Administration; 2009.
16. US Department of Health and Human Services FDA Opana ER (Oxymorphone ER) NDA 201655 medical review, 2011.
17. US Department of Health and Human Services FDA Butrans (Buprenorphine transdermal system) medical review, 2012.

18. US Department of Health and Human Services FDA Zohydro ER (Hydrocodone bitartrate extended release capsules) medical review, 2012.
19. Sanderson T, Morris M, Calnan M, Richards P, Hewlett S. Patient perspective of measuring treatment efficacy: the rheumatoid arthritis patient priorities for pharmacologic interventions outcomes. *Arthritis Care Res* 2010;62:647–656.
20. Rainville J, Childs LA, Pena EB, et al. Quantification of walking ability in subjects with neurogenic claudication from lumbar spinal stenosis: a comparative study. *Spine J* 2012;12:101–109.
21. Tomkins-Lane CC. Commentary: validity and responsiveness of measures of walking in lumbar spinal stenosis—what are we measuring? *Spine J* 2012;12:110–112.
22. Skolasky RL, Maggard AM, Thorpe RJ Jr, Wegener ST, Riley LH III. United States hospital admissions for lumbar spinal stenosis: racial and ethnic differences, 2000 through 2009. *Spine* 2013;38:2272–2278.
23. Tomkins-Lane CC, Battie MC. Validity and reproducibility of self-report measures of walking capacity in lumbar spinal stenosis. *Spine* 2010;35:2097–2102.

New Payment and Delivery Models

How can you ensure your first value-based contract is a success? Check out the AAN's Top 5 tips to get on the right track!

Link to – <https://www.aan.com/practice/top-five/>

This Week's *Neurology*[®] Podcast

Evaluation of outcome measures for neurogenic claudication: A patient-centered approach (see pg. 1250)

This podcast begins and closes with Dr. Robert Gross, Editor-in-Chief, briefly discussing highlighted articles from the October 6, 2015, issue of *Neurology*. In the second segment, Dr. Ted Burns talks with Dr. John Markman about his paper on a patient-centered approach for evaluation of outcome measures for neurogenic claudication. In our “What’s Trending” feature of the week, Dr. Ted Burns interviews Dr. Robert Gross about the *Neurology* spoke journals. In the next part of the podcast, Dr. Ted Burns focuses his interview with Dr. Steve Ringel on a *Neurology Today*[®] story about the topic of acute flaccid myelitis. Disclosures can be found at Neurology.org.

At Neurology.org, click on “RSS” in the Neurology Podcast box to listen to the most recent podcast and subscribe to the RSS feed.

CME Opportunity: Listen to this week's *Neurology* Podcast and earn 0.5 AMA PRA Category 1 CME Credits[™] by answering the multiple-choice questions in the online Podcast quiz.