Acute Low Back Pain and Radiculopathy: MR Imaging Findings and Their Prognostic Role and Effect on Outcome[1]

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Published online
10.1148/radiol.2372041509
Radiology 2005; 237:597–604

Abbreviations:
CI = confidence interval
LBP = low back pain

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Authors stated no financial relationship to disclose.

Author contributions:
Guarantor of integrity of entire study, M.T.M.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, M.T.M., M.N.B., P.N.G., E.C.B.; clinical studies, M.T.M., M.N.B., P.N.G.; statistical analysis, M.T.M., N.A.O.; and manuscript editing, M.T.M., N.A.O., J.S.R., P.N.G., D.J.M., E.C.B.

PURPOSE: To prospectively determine in patients with acute low back pain (LBP) or radiculopathy, the magnetic resonance (MR) imaging findings, prognostic role of these findings, and effect of diagnostic information on outcome.

MATERIALS AND METHODS: Institutional review board approval and informed consent were obtained. This study was HIPAA compliant. A total of 246 patients with acute-onset LBP or radiculopathy were randomized to either the early information arm of the study, with MR results provided within 48 hours, or the second arm of the study, where both patients and physicians were blinded to MR results, unless this information was critical to patient care. Patients underwent 6 weeks of conservative care. Roland function scoring, visual pain analog, Short Form 36 health status survey, self-efficacy scoring, and a fear avoidance questionnaire were completed at presentation; at 2-, 4-, 6-, and 8-week follow-up; and at 6-, 12-, and 24-month follow-up. A second MR imaging examination was performed at 6-week follow-up. Multivariate logistic regression analysis was used to determine which imaging and nonimaging variables can be used to predict improvement in Roland function and patient satisfaction. The χ^2 test and repeated-measures analysis of variance were used to compare outcome of blinded and unblinded patients.

RESULTS: Herniation was identified in 60% ($n = 147$) of patients at the initial examination. The prevalence of herniations in patients with LBP (57%) ($n = 85$) and those with radiculopathy (65%) ($n = 62$) were similar ($P = .217$), although patients with radiculopathy were more likely to have stenosis and nerve root compression ($P < .006$). There was no relationship between herniation type, size, and behavior over time with outcome. An improvement of 50% or more in Roland function score at 6-week follow-up occurred 2.7 times as often among patients with a herniation at baseline ($P = .003$). Improvement at 6-week follow-up was similar in unblinded (60%) ($n = 55$) and blinded (67%) ($n = 57$) patients ($P = .397$). Self-efficacy, fear avoidance beliefs, and the Short Form 36 subscales were similar for blinded and unblinded patients.

CONCLUSION: In typical patients with LBP or radiculopathy, MR imaging does not appear to have measurable value in terms of planning conservative care. Patient knowledge of imaging findings does not alter outcome and is associated with a lesser sense of well-being.

Intervention in patients with a disease requires that the intervention be more beneficial, safer, and cost-effective compared with the untreated natural history. Intervention should occur after accurate diagnosis and consideration of prognostic findings. In today's environment, there is rapid access and substantial use of imaging tests to improve diagnostic accuracy. This is a two-edged sword. While current diagnostic imaging technology enables remarkably detailed anatomic assessment, there is also the potential for identification of incidental findings. These incidental findings fall into two main groups: The first is findings that are morphologically abnormal but not responsible for the symptoms. The second is findings that are abnormal and possibly related to symptoms but not relevant to

clinical decision making and outcome. Incidental findings might lead to additional testing and the potential for unnecessary interventions, increased cost of care, and possibly worse outcomes.

This dilemma is particularly important in patients with low back pain (LBP) with or without radiculopathy. The natural history of LBP is not clearly understood, and there is little consensus, either within or among specialties, on the use or prognostic value of imaging findings for patients with back pain (1). The diagnostic evaluation depends heavily on the individual physician, his or her specialty, and patient socioeconomics, as well as the patient's symptoms (1,2). The long- and short-term morbidity and costs associated with LBP with or without radiculopathy are substantial. Predicting which patients will do poorly from the large affected population is difficult.

In practice, the major decision that confronts clinicians is whether the condition will respond to conservative care or whether a more invasive intervention such as surgery is appropriate. Methods to prospectively determine which patients do well with conservative care would be of great value. Conversely, similar methods might help identify patients undergoing prolonged conservative care who require more aggressive therapy (eg, surgery). This would save the cost of lost work, medical expenses, and personal discomfort.

The role of diagnostic imaging in patients with back pain is an important one in today's health care environment. Previous studies have demonstrated a high prevalence of morphologic abnormalities in both symptomatic and asymptomatic individuals (3,4). The importance of these findings, the relevance of their changes over time, and their relationship to symptoms or effect on therapeutic decision making is not fully understood. In patients with acute LBP and radiculopathy, the basis of and recommendations for the most effective use of diagnostic imaging have been based on retrospective reviews or meta-analyses and are not specific for advanced imaging modalities or subjected to a prospective randomized approach.

The role of diagnostic imaging can be understood only if we understand the morphologic natural history, prognostic value of the findings, and effect of this diagnostic information on the physician's and patient's decision to select therapy. In view of the frequency and substantial effect of this disorder, we sought to prospectively determine the type of magnetic resonance (MR) imaging findings, the prognostic role of these findings, and the effect of diagnostic information on outcome in patients with acute LBP or radiculopathy.

TABLE 1
Inclusion and Exclusion Criteria for LBP and Radiculopathy

Inclusion or Exclusion Status and Condition	Criteria
Inclusion	
Radiculopathy	Leg pain greater than back pain in a radicular distribution
	Duration of symptoms of less than 3 weeks
	Age of 18–65 years
	Positive findings (reproduction of radicular symptoms) at nerve tension test (ie, straight leg raise or bowstring)
LBP	Back pain 50% worse than leg pain
	Duration of symptoms of less than 3 weeks
	Age of 18–65 years
	Negative findings at nerve tension test
Exclusion	Clinical features suggestive of cauda equina syndrome (ie, bilateral leg weakness, saddle anesthesia, bowel and/or bladder dysfunction)
	Polyradiculopathy
	Leg and/or back pain in the previous 6 mo
	Substantial hip and/or knee arthritis
	History of blunt trauma
	Previous lower back surgery
	Diabetes with neuropathy
	Other medical conditions, such as heart disease, diabetes, renal disease, gastric and/or duodenal ulcers, or hypertension, if of sufficient severity to contraindicate components of nonsurgical therapy
	Concurrent disorders, such as substantial osteoporosis, known intraabdominal or pelvic conditions associated with referred LBP
	Contraindications to MR imaging, such as pregnancy, claustrophobia, metal fragments, pacemakers, and allergies to contrast media
	Oral or parenteral corticosteroid use in the past month
	Ongoing litigation
	Inability to return for scheduled visits and/or complete patient questionnaire

MATERIALS AND METHODS

Our prospective study was conducted between July 1998 and December 2002 with institutional review board approval. Written informed consent was obtained from patients prior to enrollment. Our study was compliant with the Health Insurance Portability and Accountability Act on the basis of follow-up of subjects after this act went into effect.

Study Population

Patients with acute onset (<3 weeks) LBP or radiculopathy were recruited from the Cleveland Clinic Spine Institute (Cleveland, Ohio), primary care units, regional satellites, and the emergency department of the Cleveland Clinic Foundation (Cleveland, Ohio). The treating physician performed the initial physical examination. Inclusion and exclusion criteria are summarized in Table 1. A total of 246 patients (150 patients with LBP and 96 patients with radiculopathy) underwent an MR imaging examination at presentation, and these patients constitute our study sample. Overall, there were 104 men and 142 women, with a mean age of 43 years ± 10.4 (standard deviation). There were 172 white, 64 black, three Asian, and two Hispanic patients; five patients did not specify their race. Among the patients with LBP, 41% (n = 61) were men, with a mean age of 42.7 years. Among the patients with radiculopathy, 45% (n = 43) were men, with a mean age of 43.7 years.

Subjects completed the following health questionnaires: Roland scale, visual pain analog, number of sick days, the Short Form 36 health status survey, self-efficacy scores, and a fear avoidance questionnaire. A second baseline physical examination was performed by a nurse clinician with 2 years of experience examining patients with back pain. Subjects were then randomized by using a stratified block design, with equal allocation to either the early information arm (ie, MR imaging results provided to referring physician and patient within 48 hours) or the blinded arm (ie, both patient and physician were blinded to MR imaging results, unless this informa-

tion was critical to patient care). The variables we stratified when randomizing patients were age, sex, race, type of pain (LBP or radiculopathy), and referral source. We used a standardized form to convey the diagnostic information to the unblinded arm. At enrollment, patients in both arms were counseled on the benign nature of LBP and radiculopathy. After the initial MR imaging examination, patients were enrolled in 6 weeks of conservative care. If, during these 6 weeks, a patient in the blinded arm developed progressive motor loss and/or bowel or bladder symptoms, the patient and physician were unblinded to MR results.

Outcome Measures

Roland function, visual pain analog, absenteeism, Short Form 36 health status survey, self-efficacy scores, and fear avoidance questionnaires were completed at presentation; at 2-, 4-, 6-, and 8-week follow-up; and again at 6-, 12-, and 24-month follow-up. The percentage improvement in patient function (as measured with Roland score [5]) from presentation to 6 weeks after presentation was measured. Improvement of 50% or more was considered a positive outcome; improvement of less than 50% or plans for surgery were considered negative outcomes. Patient satisfaction was assessed with a symptom satisfaction measure (6). At 6 weeks after presentation, satisfaction described as "very pleased" or better was considered a positive outcome. At the end of the study, patients were contact by telephone by a research assistant and asked about their work status and any surgery or other treatment they had undergone.

Diagnostic Imaging Protocol and Image Interpretation

The diagnostic imaging protocol consisted of an MR examination of the lumbar spine at presentation and at 6-week follow-up performed with a 1.5-T MR imager standardized in the following fashion: *(a)* T1-weighted sagittal images were obtained with the following parameters: repetition time (msec)/echo time (msec), 500/12; matrix, 192 × 256; three signal averages; sequence time, 4 minutes 20 seconds). *(b)* T1-weighted transverse images were obtained with the following parameters: (600/12; matrix, 192 × 256; three signal averages; sequence time, 4 minutes and 40 seconds). *(c)* T2-weighted sagittal and transverse fast spin-echo images were obtained with the following parameters: 5000/120; matrix, 192 × 256; three signal averages; sequence time, 4 minutes 42 seconds.

MR studies of patients in the early information arm were interpreted by the radiologist on duty at the time of the examination, and this routine interpretation was made available to the treating physician and patient. Eight neuroradiologists were involved in this interpretation (including M.T.M. and J.S.R.). The MR studies of patients in the "blinded arm" were reviewed within 24 hours by one of the authors (M.T.M.) for important abnormalities, such as infection or neoplasm, that required immediate treatment. The information from this review was not made available to the patient or treating physician unless it was believed that a serious consequence would result if treatment was delayed.

In a retrospective review, three independent radiologists (J.S.R., M.N.B., and P.N.G., with 15, 20, and 10 years of spinal MR experience, respectively) were blinded to clinical information and the temporal sequence used, and they recorded the presence or absence of altered morphology with use of nomenclature and classification of lumbar disk abnormalities, as described in a consensus paper (7). The presence and type of disk herniation and level of nerve root impingement were noted. Other morphologic characteristics assessed include central canal and foraminal stenosis, free fragments, anular tears, spondylolisthesis, endplate changes, and facet disease.

Treatment Algorithm

The therapeutic plan for each patient was determined at the time of the clinical visit (ie, before the MR examination). The treatment algorithm was part of a multidisciplinary consensus guideline approach, which emphasized conservative care and was used to develop consistency across the institution. This included advice to patients to avoid bed rest and continue their daily routines as actively as possible, as permitted by their pain. Antiinflammatory drug therapy, analgesics, and muscle relaxants were to be used as needed. All patients were referred for physical therapy evaluation in patient education. These guidelines are in line with recommendations of the Agency for Health Care Policy and Research.

Statistical Methods

With 246 total patients (150 patients with LBP and 96 with radiculopathy), we estimated that a difference of 0.20 in the prevalence rate of herniated disks between patients with LBP and radiculopathy could be detected with 85% power (two-tailed test with type I error rate, 5%); a difference of 0.25 in the probability of a positive outcome at 6-week follow-up between patients with and patients without herniation could be detected with 92% power; and a difference of five to 10 points on the Short Form 36 subscales between blinded and unblinded patients could be detected with 80% power. All patients who gave informed consent and underwent baseline MR imaging were included in statistical analysis.

The majority opinion of the three radiologists (M.N.B., J.S.R., and P.N.G.) in classifying disk level as normal, protruding, or extruding, and in classifying stenosis as normal or mild, moderate, or severe was used in the statistical analysis. Consensus of two neuroradiologists (M.T.M. and J.S.R.) was used, as needed. Interreader agreement was assessed with κ statistics.

We defined agreement between the level of the herniation on MR images and the patient's origin of radiculopathy if the MR finding matched the reported level of pain or was one level below. For patients with radiculopathy who had multiple herniations, the level with the most severe nerve root compression was used in the analysis. κ Statistics were calculated for the level and side of pain.

Demographics, signs, and symptoms at baseline were compared with MR imaging findings for various populations (eg, patients with LBP vs those with radiculopathy; patients blinded to findings vs those unblinded to findings) with analysis of variance, Wilcoxon two-sample test, Kruskall-Wallis test, or χ^2 test, as appropriate. A P value of .05 was considered to indicate a statistically significant difference.

Outcome data at 6-week follow-up were not available for all patients. Thus, for those patients with data at 4- and/or 8-week follow-up but without data at 6-week follow-up (n = 20), we inferred patient outcome on the basis of results at 4- and/or 8-week follow-up. Prognostic variables, both nonimaging (age, sex, race, pain distribution [ie, LBP vs radiculopathy], Quebec Task Force classification [8], which is based on initial signs and symptoms, baseline score, and absenteeism at presentation) and imaging variables (presence vs absence of herniation, severe stenosis, and nerve root compression at initial MR), along with their interactions, were included in several

multivariable logistic regression analyses to determine whether imaging data can be used to predict patient outcome beyond the prediction ability provided by nonimaging data.

Roland scores at 1- and 2-year follow-up were compared in patients with and without herniation at presentation; adjustments for race, sex, and pain distribution (ie, patients with LBP vs those with radiculopathy) were made with linear regression on ranked variables (9).

Treatment recommendations and compliance with recommendations were compared with χ^2 tests in patients who were unblinded and in those who were blinded. The χ^2 tests were used to compare outcome at 6-week follow-up in patients who were unblinded and in those who were blinded. Repeated measures analysis of variance was used to compare patients who were unblinded and those who were blinded for differences in self-efficacy scores, fear-avoidance belief, and the eight subscales of Short Form 36. Adjusted *P* values were calculated to control the family error rate (10).

TABLE 2
Comparison of Patients with LBP and Radiculopathy at Presentation

Characteristic	Patients with LBP	Patients with Radiculopathy	*P* Value
Mean age (y)*	42.7 ± 10.6	43.7 ± 10.1	.468
No. of men	61 (40.7)	43 (44.8)	.523
No. of minorities	39 (26.2)	34 (35.4)	.123
No. of patients with myotomal weakness	7 (4.7)	60 (66.7)	<.001
No. of patients with sensory abnormality	5 (3.3)	75 (78.1)	<.001
Reflex loss	6 (4.0)	10 (10.8)	.039
Roland score*	12.5 ± 5.6	14.3 ± 5.2	.017
Average pain score*	5.1 ± 2.1	5.6 ± 1.4	.035
Worst pain score*	8.3 ± 2.0	8.9 ± 1.2	.037

Note.—Data in parentheses are percentages.
* Data are mean ± standard deviation.

TABLE 3
MR Imaging Findings at Presentation

MR Imaging Finding	No. of Patients with LBP	No. of Patients with Radiculopathy	*P* Value
Degenerative disk disease			
Normal	65 (43.3)	34 (35.4)	.126
One protrusion	40 (26.7)	20 (20.8)	
One extrusion	14 (9.3)	17 (17.7)	
Multiple herniations	31 (20.7)	25 (26.0)	
Stenosis			
Normal or mild at all levels	124 (82.7)	67 (69.8)	.006
Moderate at one level	16 (10.7)	8 (8.3)	
Severe at one level	5 (3.3)	12 (12.5)	
Multiple levels	5 (3.3)	9 (9.4)	
Nerve root compression			
None	110 (73.3)	52 (54.2)	<.001
Mild or moderate	36 (24.0)	22 (22.9)	
Severe	4 (2.7)	22 (22.9)	

Note.—Data in parentheses are percentages.

RESULTS

MR Findings in Patients with LBP and Radiculopathy

Patients with LBP and radiculopathy were similar in age, sex, and race (Table 2), but they differed in regard to their symptoms. Patients with radiculopathy presented more frequently with sensory abnormalities, myotomal weakness, and tendon reflex loss, and they were experiencing more pain and loss of function.

All three readers agreed about the degenerative disk disease findings in 79% (n = 1359) of levels; two of three readers agreed in 20% (n = 342) of levels, and three readers disagreed in 1% of levels (n = 15) (κ = 0.61); these 15 levels were classified with a consensus reading. All three readers agreed about the stenosis findings in 86% (n = 1473) of levels, two of three readers agreed in 13% (n = 216), and the three readers disagreed in 1% (n = 27) (κ = 0.41); these levels were classified with a consensus reading.

The degenerative disk disease findings on MR images at presentation were not significantly different for patients with LBP and those with radiculopathy. In our study, 27% (n = 40) of patients with LBP and 21% (n = 20) of patients with radiculopathy had one protrusion; 9% (n = 14) of patients with LBP and 18% (n = 17) of patients with radiculopathy had a single extrusion; 21% (n = 31) of patients with LBP and 26% (n = 25) of patients with radiculopathy had multiple herniations (P = .126) (Table 3). The prevalence rate of herniations was 57% (n = 85) (95% confidence interval [CI]: 0.49, 0.65) for patients with LBP and 65% (n = 62) (95% CI: 0.55, 0.74) for patients with radiculopathy (P = .217).

Patients with radiculopathy were more likely to have stenosis, especially severe stenosis, than patients with only LBP (P = .006) (Table 3). The prevalence rate of severe stenosis was 5% (95% CI: 0.0, 0.08) in patients with LBP and 19% (95% CI: 0.11, 0.27) in patients with radiculopathy (P < .001). Nerve root compression was mild or moderate in 23% (n = 22) of patients with radiculopathy compared with 24% (n = 36) of patients with LBP and severe in 23% (n = 22) of patients with radiculopathy compared with 3% (n = 4) of patients with LBP (P < .001).

The level of herniation on the MR images agreed with the patient's origin of radiculopathy in 85% (n = 82) of patients (κ = 0.75). Similarly, the side of herniation on MR images agreed with the side of radicular pain in 79% (n = 76) of patients (κ = 0.55).

There was no relationship between the number or extent of herniations and patient signs (ie, myotomal weakness, sensory or reflex abnormality, distribution of pain) or symptoms (ie, intensity of pain) at presentation. There was no relationship between the type of symptoms at presentation (patients with LBP vs patients with radiculopathy) and the level of herniation; however, male patients (n = 50, 48%) were more likely to have an extrusion or multiple herniations than were female patients (n = 37, 26%) (P = .004). Also, patients with herniation had higher Roland scores (ie, worse function) (mean Roland score, 14.0) than did patients without herniation (mean Roland score, 12.0; P = .023) at baseline.

Patients with severe stenosis were significantly older (mean age, 48.1 years vs 42.5 years; P = .011), experienced more

TABLE 4
Change in MR Findings at 6-week Follow-up

Finding	No. of Patients with LBP	No. of Patients with Radiculopathy	*P* Value
Degenerative disk disease			
Normal at baseline			
Unchanged	41 (91.1)	22 (84.6)	.453
New herniation	4 (8.9)	4 (15.4)	
Herniation at baseline			
Unchanged	46 (69.6)	25 (54.3)	.064
New and/or enlarged	10 (15.2)	5 (10.9)	
Reduced or gone	10 (15.2)	16 (34.8)	
Nerve root compression			
Normal at baseline			
Unchanged	74 (91.4)	37 (97.4)	.434
New compression	7 (8.6)	1 (2.6)	
Compression at baseline			
Unchanged	21 (70.0)	18 (52.9)	.358
New and/or worse	4 (13.3)	6 (17.7)	
Reduced or gone	5 (16.7)	10 (29.4)	
No 6-wk MR imaging	39	24	. . .

Note.—Data in parentheses are percentages.

pain (mean visual pain analog score, 6.1 vs 5.2; $P = .009$), and were more likely to have myotomal weakness (50% [$n = 12$] vs 26% [$n = 56$], $P = .012$) than patients without severe stenosis. Nerve root compression was significantly related to patient signs at presentation, with myotomal weakness, sensory and reflex abnormalities, and radicular pain being significantly more common among patients with nerve root compression; patient pain intensity and function were not associated with nerve root compression.

Of the 246 patients, 183 (74%) underwent a second MR examination (Table 4). Of these patients, 15 (13%) had a new or enlarged herniation at 6-week follow-up. Herniations at presentation were reduced in size or completely resolved in 15% ($n = 10$) of patients with LBP and 35% ($n = 16$) of patients with radiculopathy ($P = .064$). Nerve root compression was less severe in 17% ($n = 5$) of patients with LBP and 29% ($n = 10$) of patients with radiculopathy ($P = .358$).

Prognostic Role of MR

Three patients (two with radiculopathy and one with only LBP) underwent surgery within 12 weeks of presentation. The two patients with radicular symptoms were randomly assigned to the blinded group. The first of these patients had a large extrusion at L5-S1 (Roland score, 18). Findings were unblinded because of clinical request, and this patient underwent surgery 7 days after the first MR imaging examination. The second patient had a right paracentral protrusion on the first MR study (Roland score, 19) that was significantly larger on the second MR study (Roland score, 19). This patient underwent surgery 12 weeks after enrollment. The patient with LBP who underwent surgery was randomly assigned to the unblinded group. This patient had a large central extrusion at the L4-5 level on the first MR study (Roland score, 18), which was unchanged in appearance on the second MR study (Roland score, 11). This patient underwent surgery 1 week after the second MR examination. Six additional patients underwent surgery 4–34 months (mean, 16 months) after enrollment.

Improvement in Roland function from baseline to 6-week follow-up could be calculated for 176 patients. An additional 20 patients had outcome data at 4- and/or 8-week follow-up, which were used to infer outcome at 6-week follow-up. Overall, 122 of 196 patients (62.2%) reported an improvement at 6-week follow-up. Of 121 patients with herniation, 86 (71.1%) improved, compared with 36 (48.0%) of 75 patients without herniation. Of 46 patients with stenosis, 28 (60.9%) improved, compared with 94 (62.7%) of 150 patients without stenosis. Of 70 patients with nerve root compression, 46 (65.7%) improved, compared with 76 (60.3%) of 126 patients without nerve root compression.

In a multivariable analysis of both imaging and nonimaging variables, improvement in Roland function occurred 2.7 times as often among patients with herniation at baseline than among patients without herniation ($P = .003$); the distribution of pain at presentation (ie, LBP vs radiculopathy) was not significant ($P = .059$) (model 1, Table 5). Similarly, the Quebec Task Force classification ($P = .102$) (model 2, Table 5), severe stenosis ($P = .096$) (model 3, Table 5), and nerve root compression ($P = .460$) (model 4, Table 5) were not significant predictors of outcome. Race was the only other variable that was statistically significant in all models: improvement in Roland function occurred 3.2 times more often in white patients than in other patients (model 1, Table 5). In the patients with herniation, there was no relationship between the number or extent of herniations, level, behavior over time, patient signs or symptoms, and outcome.

The Figure shows median Roland scores from baseline to 2-year follow-up for patients with radiculopathy and those with LBP with and without herniation at baseline. Although patients with herniation had significantly higher Roland scores at baseline, they had significantly lower scores at 1-year follow-up (median Roland score, 1.0 and 1.5 for patients with radiculopathy and patients with LBP, respectively) compared with patients without herniation (median Roland score, 3.0 and 5.5 for patients with radiculopathy and patients with LBP, respectively; $P = .008$, $n = 131$). The trend was similar at 2-year follow-up, but it was not statistically significant ($P = .083$, $n = 114$).

Overall, 27% ($n = 48$) of patients were satisfied with their current symptoms at 6-week follow-up. No variable was predictive of patient satisfaction at 6-week follow-up.

Value of Information per Se

A total of 131 patients were randomized to the blinded arm, and 115 were randomized to the unblinded arm. There were no statistically significant differences in demographics, absenteeism, intensity of pain, or general health in the two arms at baseline analysis, although Roland scores tended to be higher in the unblinded arm (mean Roland score, 14) than in the blinded arm (mean Roland score, 12) ($P = .054$). Treatment recommendations and compliance for unblinded and blinded patients were remarkably similar.

Outcome at 6-week follow-up was similar for blinded and unblinded patients. We found that 60% ($n = 55$) of unblinded patients experienced a 50% improvement in Roland function, com-

pared with 67% (n = 57) of blinded patients (P = .397). We found 23% (n = 21) of unblinded patients were satisfied with their condition at 6-week follow-up, compared with 31% (n = 26) of blinded patients (P = .207).

Self-efficacy, fear-avoidance beliefs, and the Short Form 36 subscales were similar over time for blinded and unblinded patients, except for the general health subscale on Short Form 36. While the blinded and unblinded groups have similar scores at baseline analysis (mean score, 74.7 and 73.4 for blinded and unblinded groups, respectively), the mean general health score improved more for the blinded group (by 2.5, 4.1, and 6.0 points at 2-, 4-, and 6-week follow-up, respectively) than for the unblinded group (0.4, 1.3, and 4.2, respectively; P = .008).

TABLE 5
Multivariable Results for Improvement in Roland Function

Model No. and Predictor	Odds Ratio Estimate	95% CI	*P* Value
1			
Race	3.20	1.58, 6.48	.001
Sex	0.53	0.27, 1.02	.058
Pain distribution: LBP or radiculopathy	1.88	0.98, 3.62	.059
Herniation at baseline	2.67	1.40, 5.10	.003
2			
Race	3.56	1.64, 7.71	.001
Sex	0.52	0.25, 1.07	.076
Absenteeism	1.74	0.86, 3.51	.123
Quebec Task Force Classification			
1 vs 4	0.70	0.28, 1.79	.102
2 or 3 vs 4	1.84	0.60, 5.66	
Herniation at baseline	2.59	1.28, 5.24	.008
3			
Race	3.27	1.60, 6.69	.001
Sex	0.52	0.27, 1.01	.054
Pain distribution: LBP or radiculopathy	1.69	0.86, 3.31	.125
Herniation at baseline	2.92	1.51, 5.64	.002
Severe stenosis at baseline	0.42	0.15, 1.17	.096
4			
Race	3.09	1.55, 6.16	.001
Sex	0.47	0.25, 0.90	.022
Pain distribution: LBP or radiculopathy	1.78	0.93, 3.45	.083
Nerve root compression present at baseline	1.29	0.66, 2.50	.460

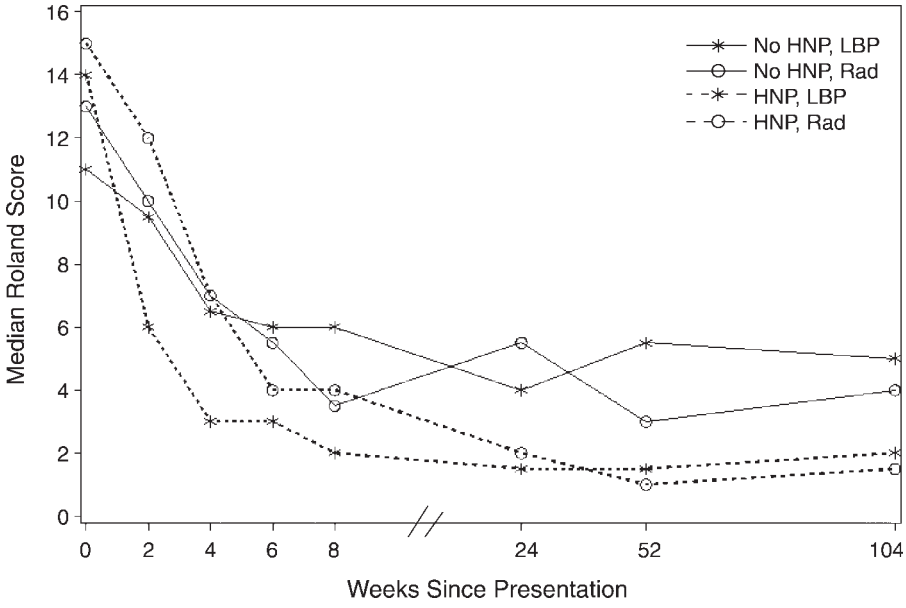
Note.—Data are based on findings in 196 patients. Variables considered in other multivariable models (which are not shown) did not reach statistical significance. These include age (P = .842), Roland score at baseline (P = .826), randomization arm (P = .376), and various interactions ($P \geq$ .236).

DISCUSSION

In this study, patients with radiculopathy and LBP had similar degenerative disk disease findings on MR images at presentation and similar outcome at 6-week follow-up. There were significant morphologic changes in the appearance of disk herniations over time, but no prognostic behavioral or morphologic changes were identified on MR images that would alter patient care. In fact, the presence of a herniation on MR images was a positive prognostic finding. Patient knowledge of imaging findings did not alter outcome, and knowledge of findings was associated with a lesser sense of well-being.

The purpose of diagnostic imaging is twofold: The first purpose is to provide accurate anatomic information. The second, and perhaps most important, purpose is to affect the therapeutic decision-making process (11). The relevance of an imaging finding requires knowledge relative to the spectrum of changes, prevalence, importance, and behavior of change with time.

Some information about the imaging history of herniated disk disease is available. Multiple studies, in which CT or MR imaging were used, have shown that the size of a disk herniation, especially large ones, can reduce dramatically in patients undergoing conservative care (12–15). In general, these studies were not rigidly controlled, and radiologists were not able to determine if the appearance or change was clinically important and whether it correlated with a favorable outcome. Data from a pilot study of 25 patients (16) with acute radiculopathy indicated that there were no characteristics of disk herniation that were prognostic (ie, size, location, type, enhancement, or behavior over time). In this study (16), 72% of patients had herniations at presentation, one-third of these herniations regressed in size or disappeared at 6-week follow-up, and two-thirds regressed or disappeared at 6-month follow-up. In this study, (16) 15% of herniations in the LBP group and 35% of herniations in the ra-



Graph shows that patients with LBP and patients with radiculopathy *(Rad)* who also have disk herniation at presentation improved more than patients who do not have herniation. Patients with herniation at presentation experienced better function at 1- and 2-year follow-up than did patients without herniation. *HNP* = herniation of nucleus pulposus.

diculopathy group were reduced or had disappeared at 6-week follow-up.

Any study in which the prognostic value of morphologic changes is assessed will be confounded by the high prevalence of morphologic change in the asymptomatic population. Wiesel et al (17) used CT to evaluate 52 patients with no history of back trouble. Irrespective of age, findings were abnormal in 35%. Boden et al (4) evaluated 67 individuals who never had low back pain with MR imaging. Of the patients who were younger than 60 years of age, 20% had a herniated nucleus pulposus, and one had spinal stenosis. In patients older than 60 years of age, images were abnormal in 57%; 37% of the subjects had a herniated nucleus pulposus, and 21% had spinal stenosis. Jensen et al (3) evaluated 98 asymptomatic patients with MR imaging. They found that 52% of asymptomatic subjects had a bulge at at least one level, 27% had a protrusion, and 1% had an extrusion. In a 7-year follow-up of patients in the study of Boden et al (4), the findings of MR imaging were not predictive of the development or duration of LBP (18).

In this study of symptomatic patients, the prevalence of disk herniations in patients with LBP and the prevalence in those with radiculopathy at presentation were similar. There was a higher prevalence of herniations (ie, 57% in patients with LBP and 65% in patients with radiculopathy) than that in reported asymptomatic patients (ie, 20%–28% prevalence). Patients with radiculopathy were more likely to have an extrusion and nerve root compression, but there was no correlation between the severity of disease seen on MR images and patient function and pain. Disks characterized as extruded showed a trend toward more improvement in both groups. The type, size, and location of herniation at presentation and changes in herniation size and type over time did not correlate with outcome. Patients with evidence of herniation at presentation showed greater improvement in Roland scores than did patients without herniation at presentation, irrespective of whether they presented with LBP or radiculopathy.

Regarding the second role of a diagnostic test (ie, its effect on therapeutic decision making), MR imaging did not have additive value over clinical assessment. In this study, no prognostic sign that might alter treatment versus clinical assessment alone was identified. Size and type of disk herniation and location and presence of nerve root compression, which were important in terms of morphologic alteration, were not related to patient outcome. A previous study by Caragee and Kim (19) also suggested that qualitative morphologic features of herniated disks have not proved helpful in the prediction of outcome in patients with LBP and sciatica. In a cohort of 135 patients who were followed up for more than 2 years, demographic and clinical features appeared useful in the prediction of outcome of nonsurgical treatment, whereas morphometric features of disk herniation and the spinal canal were much more powerful predictors of surgical outcome. The only important prognostic sign noted in our study was the presence of disk herniation. A multivariable analysis of both imaging and nonimaging variables demonstrated improvement in Roland function occurred twice as often among patients with herniation at baseline than among patients without herniation ($P = .003$). Given its positive nature, its identification should not alter clinical care.

In addition to a prognostic role, it has been suggested that a diagnostic test may have a role in reducing patient anxiety and providing reassurance, both to the patient and to the treating physician. There is at least one prospective randomized controlled report (20) that suggests diagnostic tests have a psychologically mediated effect. That study involved patients with nonspecific chest pain. In our study, the knowledge of diagnostic imaging findings did not have an effect on outcome, and it may even be counterproductive. Given the prevalence of abnormal morphologic findings in both the symptomatic and asymptomatic populations, it is not surprising that patients who are informed they have degenerative changes of the spine might develop a sense of "less well-being" than those who are not told of such findings.

The cause of symptoms in patients with pure LBP is diverse, and there is often ambiguity in the diagnosis (21). In general, the course of back pain seems to be characterized by variability and change rather than by predictability and stability (22). Traditionally, patients with LBP have been evaluated only with clinical assessment alone or in conjunction with conventional radiographs. Agency for Health Care Policy and Research clinical practice guidelines for acute low back problems in adults, which were published in 1994, suggest that in the absence of signs and symptoms that suggest tumors or infection, acute imaging does not affect patient care. This conservative approach differs from the currently more common approach that liberally uses advanced imaging techniques driven by easy access and physician or patient expectations, thus resulting in earlier and more imaging intervention. The use of MR imaging, either as a complete examination or as a truncated rapid imaging technique, as a replacement for conventional radiography has become common (23,24). Defense of this approach may be related to an attempt to exclude differential considerations, such as neoplasms and infections. In one patient who was enrolled in our study, the MR study demonstrated diffuse replacement of the marrow, which was consistent with metastatic disease. While the diagnosis was initially suggested by MR imaging findings, the patient's immediate clinical course was such that the diagnosis would have been made readily. In a study of 1042 patients with LBP, McNally et al (24) found a prevalence of neoplasms in 1.7% of patients. This prevalence was much higher than that in previous studies (23). Notwithstanding this consideration, the increased use of imaging has occurred in the absence of well-controlled studies to identify findings that can be reliably used to guide therapy or if their use alters outcome. To this point, a study by Jarvik et al (23) comparing conventional radiography and rapid MR imaging in patients with LBP found no measurable differences between the two groups, with the exception of higher costs and a potentially higher rate of surgery in patients who underwent the latter. In the current study, there were no specific findings in patients with LBP that should alter clinical care. This study suggests substantial ambiguity regarding the importance of diagnostic imaging findings.

Radiculopathy exists in a subgroup of patients and accounts for only about 1% of patients with acute LBP (25). Multiple authors (26–28) suggest that an imaging examination is indicated in the evaluation of a patient with sciatica when *(a)* true radicular symptoms are present, *(b)* there is evidence of nerve root irritation at physical examination (ie, positive straight leg raise test), and *(c)* the condition of the patient has failed to improve after 4–6 weeks of conservative care. Earlier imaging is considered appropriate if clinical features raise concern regarding malignant or infectious causes of the symptoms or if neurologic findings worsen during observation. These recommendations are based on several studies of successful nonsurgical treatment of sciatica (13,15,29–35). Thus, imaging is recommended only for the remaining minority of patients with persistent signs and symptoms who are believed to be

candidates for surgery or in whom diagnostic uncertainty remains. Even in this setting, the surgical outcome is more dependent on surgical findings than on imaging findings (36).

There are several reports (37,38) that suggest surgical treatment in appropriate individuals with radicular symptoms has a clear short-term advantage over nonsurgical treatment, with more rapid relief of symptoms. This claim is supported by the following evidence: Patients with herniated disks that are treated surgically have better short-term outcomes than do patients treated with conservative care (38). The earlier surgery is performed, the better patient outcome will be (39). Surgery is cost-effective when compared with conservative care (40). Hence, the use of imaging earlier in the course of acute radiculopathy has been proposed to aid in the identification of patients whose health is unlikely to improve with conservative care. Unfortunately, this study failed to reveal an imaging finding that would make this distinction.

A limitation of this study was that 20% ($n = 50$) of the enrolled patients were lost to follow-up, and a disproportionate number of patients were minorities. It should be noted, however, that the MR findings of patients with a known outcome did not differ from the MR findings of patients with an unknown outcome.

In typical patients with LBP or radiculopathy, MR imaging does not appear to have a measurable value in terms of planning conservative care. Given the potential for confounding information, the act of imaging may have a deleterious effect in terms of unnecessary patient therapy or unnecessary worry and concern on the part of patients relative to misconceptions regarding the seriousness of degenerative change. Whether a patient is a potential candidate for surgery is a clinical decision that should be based on signs and symptoms. Once a patient is deemed a potential candidate for surgery, imaging is an important preoperative tool in establishing appropriateness and planning any subsequent surgery.

Acknowledgments: In addition to the authors, study personnel consisted of Grace M. Cheah, RN, and Karen Justi, RN (Cleveland Clinic Foundation, Cleveland, Ohio).

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