

ONLINE FIRST

Effect of MRI on Treatment Results or Decision Making in Patients With Lumbosacral Radiculopathy Referred for Epidural Steroid Injections

A Multicenter, Randomized Controlled Trial

Steven P. Cohen, MD; Anita Gupta, DO, PharmD; Scott A. Strassels, PhD, PharmD; Paul J. Christo, MD, MBA; Michael A. Erdek, MD; Scott R. Griffith, MD; Connie Kurihara, RN; Chester C. Buckenmaier III, MD; David Cornblath, MD; To-Nhu Vu, MD, PharmD

Background: Studies have shown that radiologic imaging does not improve outcomes in most patients with back pain, though guidelines endorse it before epidural steroid injections (ESIs). The objective of this study was to determine whether magnetic resonance imaging (MRI) improves outcomes or affects decision making in patients with lumbosacral radiculopathy referred for ESI.

Methods: In this multicenter randomized study, the treating physician in group 1 patients was blinded to the MRI results, while the physician for group 2 patients decided on treatment after reviewing the MRI findings. In group 1 subjects, an independent physician proposed a treatment plan after reviewing the MRI, which was compared with the treatment the patient received.

Results: Slightly lower leg pain scores were noted in group 2 at 1 month compared with MRI-blinded patients in group 1 (mean scores, 3.6 vs 4.4) ($P = .12$). No differences were observed in pain scores or function at 3 months. Overall, the

proportion of patients who experienced a positive outcome was similar at all time points (35.4% at 3 months in group 1 vs 40.7% in group 2). Among subjects in group 1 who received a different injection than that proposed by the independent physician, scores for both leg pain (4.8 vs 2.4) ($P = .01$) and function (38.7 vs 28.2) ($P = .04$) were inferior to patients whose injection correlated with imaging. Collectively, 6.8% of patients did not (group 2) or would not have (group 1) received an ESI after the MRI was reviewed.

Conclusion: Magnetic resonance imaging does not improve outcomes in patients who are clinical candidates for ESI and has only a minor effect on decision making.

Trial Registration: ClinicalTrials.gov Identifier: NCT00826124

Arch Intern Med.

Published online December 12, 2011.

doi:10.1001/archinternmed.2011.593

LOWER BACK PAIN (LBP) IS THE number 1 cause of disability in the world, and 1 of the top 3 reasons people seek medical attention.¹ Estimates on the lifetime prevalence of LBP generally range between 50% and 80%, with recent studies suggesting that upwards of 30% will experience persistence or frequent recurrences.² According to some sources, the total annual cost of LBP approaches \$100 billion in the United States alone.³

See Invited Commentary at end of article

One factor contributing to the rising economic cost of this epidemic is the burgeoning use of indiscriminate imaging. Despite several studies demonstrating that advanced

radiologic testing does not improve outcomes in patients with LBP, with or without radicular symptoms,⁴⁻⁷ the use of magnetic resonance imaging (MRI) in this context continues to soar.⁸ Moreover, indiscriminate use of MRI has been shown to account for at least some of the increasing rate of spine surgery.⁹ The American College of Physicians recommends MRI only in the presence of serious or progressive neurological deficits, when a serious underlying condition is suspected, or when considering surgery or epidural steroid injections (ESI).¹⁰ Guidelines endorsed by the American College of Occupational and Environmental Medicine recommend MRI only in the presence of focal neurologic symptoms that persist for at least 6 weeks and are not trending toward improvement.¹¹

The lack of unequivocal guidelines on the use of MRI before ESI is somewhat unexpected, considering that ESI is the most frequently performed procedure in pain clin-

Author Affiliations are listed at the end of this article.

ics throughout the United States.¹² Studies conducted in patients with chronic spinal pain have found that between one-third and one-half of cases are primarily neuropathic.^{13,14} Yet no study has examined the effects of MRI in patients referred for ESI. To determine the utility of MRI in patients who clinically merit ESI, we conducted a study to determine (1) whether MRI use improves outcomes in patients with clinical symptoms of sciatica and (2) whether MRI use affects decision making.

METHODS

RECRUITMENT AND SELECTION CRITERIA

Permission to conduct this study was granted by the internal review boards of Johns Hopkins Medical Institutions, Walter Reed Army Medical Center (now Walter Reed National Military Medical Center), University of Pennsylvania, and WellSpan Health. Patients were recruited from the pain clinics and primary care practices at participating institutions. Inclusion criteria were age greater than 18 years; signs and symptoms of lumbosacral radiculopathy clinically warranting ESI; leg pain as great or greater than back pain; and agreement to receive an ESI regardless of MRI results. To ensure blinding, patients had to either have had an MRI within the past year ($n=99$) or, for those without an MRI, with an MRI more than 1 year old, or with new neurologic symptoms warranting repeated imaging ($n=33$), agree to undergo an MRI that might or might not be viewed by the evaluating physician.

Excluded from participation were patients who had previous back surgery, duration of pain greater than 4 years, treatment with an ESI within the past 2 years, serious neurologic deficit, and/or serious psychiatric disease. For the subset of patients who knew their MRI findings, divulging this information to the treating doctor was also grounds for exclusion.

A power analysis conducted with a sequential analysis for 2 looks using the O'Brien-Fleming procedure for multiple testing boundaries determined that 130 patients were needed to have an 80% chance to detect a 1-point difference in numerical rating scale (NRS) leg pain scores between groups, assuming comparable baseline scores and an SD of 1.9.

RANDOMIZATION AND BLINDING

A total of 132 patients were randomized in blocks of 26 via a computer-generated randomization table. Group 1 subjects all received ESIs, with the type (eg, interlaminar or transforaminal) and level determined solely by history and physical examination findings (ie, the treating physician was blinded to the MRI). In group 2, the physician determined treatment based on clinical findings and imaging results. In these patients, the treating physician could elect not to perform an ESI if the MRI finding was noncorroborative. In this scenario, the patient exited the study because the alternative treatment (eg, surgical referral, rehabilitation program) and follow-up could not be standardized.

Since the decision to perform an ESI in group 1 subjects was rendered without regard to MRI results, to gauge whether the MRI affected decision making and to ensure safety, a physician privy to the patient's clinical and MRI findings who was unaware of the epidural they received independently reviewed the MRI to confirm that no warning signs (eg, metastases) existed, as well as to determine a theoretical treatment plan based on the conglomeration of diagnostic information. This judgment could be to perform the same procedure as the treating physician, perform an ESI at a different level (ie, if imaging and symptoms were nonconcordant), or to perform a

different treatment altogether, which could occur if the MRI revealed no disease that could account for the radicular symptoms. Patients and the evaluating physicians were blinded to treatment allocation.

INJECTIONS

All injections were performed using fluoroscopic guidance. The arbiter of treatment in all cases was the treating physician, but in accordance with clinical practice, patients with unilateral symptoms usually received transforaminal epidural delivery, while those with bilateral symptoms underwent interlaminar injections. Transforaminal injections were accomplished by inserting 22-gauge spinal needles at 45° angles or greater into the targeted foramina, with correct position confirmed by contrast injection. After the attending physician was satisfied with placement, a 3-mL solution containing 60 mg of depo-methylprednisolone, 1 mL of bupivacaine, 0.25%, and 0.5 mL of saline was injected.

Interlaminar ESIs were performed using the loss-of-resistance technique, with placement also confirmed by contrast injection. After the physician was satisfied with contrast spread, 4 mL of a solution containing 60 mg of depo-methylprednisolone, 1 mL of bupivacaine, 0.25%, and 1.5 mL of saline was administered.

FOLLOW-UP AND DATA COLLECTION

Baseline data were collected prior to the first injection. In addition to demographic data, clinical information included duration of pain; average NRS leg and back scores over the past week; analgesic use, duration of symptoms; an Oswestry disability index (ODI)¹⁵ score (version 2.0, MODEMS); and for group 1 patients, any discrepancy between the procedure performed by the blinded treating physician and the theoretical treatment rendered by the unblinded reviewer. After the first procedure, subjects were scheduled for a repeat ESI 2 weeks later. However, patients who obtained excellent relief after the first injection could elect to forego a second injection. In between the first injection and final follow-up visit, no patient received additional therapeutic interventions.

The first follow-up visit occurred 1 month after the second injection by a physician blinded to treatment allocation. In addition to updates in baseline parameters, other categories recorded were medication reduction,¹⁶ global perceived effect (GPE),¹⁶ and adverse effects. The primary outcome measure was leg pain score at 1 month. A composite successful outcome was predetermined to be a 2-point or greater decrease in leg pain score¹⁷ coupled with a positive GPE to the extent that the patient was able to forego additional interventions.

All patients who experienced a positive categorical outcome at their 1-month visit returned to the clinic for 3-month follow-ups, whereas those with a negative outcome exited the study to receive alternative treatments. This paradigm was followed for ethical reasons, and is consistent with recent clinical trials evaluating ESIs and other injections.^{16,18-20}

We conducted an as-treated analysis in which only actual data garnered from follow-up visits were analyzed because there is no pharmacologic basis for patients who failed to obtain relief at 1 month to improve at 3 months secondary to a treatment effect. In addition, we performed an intention-to-treat analysis in which the last recorded data were carried over in treatment failures.

STATISTICAL ANALYSIS

Statistical analyses were conducted using Stata/MP 11.2 (StataCorp LP). The distribution of continuous variables was assessed by examining histograms. For variables that were nor-

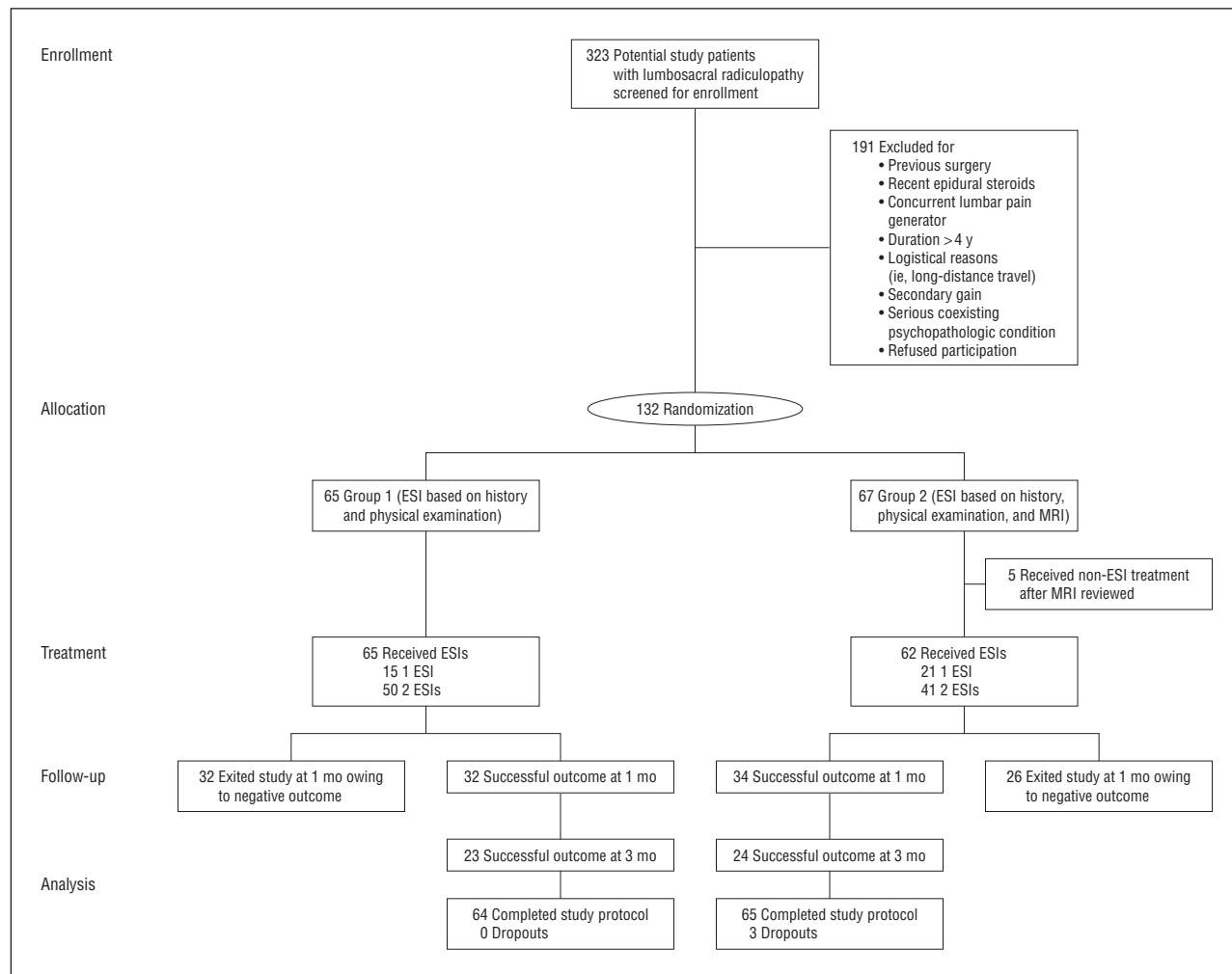


Figure 1. CONSORT flowchart showing progression of study subjects. CONSORT indicates Consolidated Standards of Reporting Trials; ESI, epidural steroid injection; MRI, magnetic resonance imaging.

mally distributed, *t* tests with an assumption of unequal variances were used to test a null hypothesis of no difference, while non-normally distributed variables were assessed using the Wilcoxon rank-sum test. Categorical variables were assessed using the χ^2 test or the Fisher exact test.

RESULTS

BASELINE CHARACTERISTICS

A total of 323 patients referred or scheduled for ESI were screened for inclusion; 191 were excluded for various reasons, resulting in an enrollment of 132. Among the 67 patients enrolled in group 2, 5 did not receive an ESI after the treating physician reviewed the MRI results (7%), leaving a total of 127 patients who received an ESI (**Figure 1**). The 5 patients who did not receive an ESI were excluded from analysis because their subsequent treatment and follow-up could not be standardized. Ninety-one patients underwent transforaminal ESIs for predominantly unilateral pain (72%). Two patients were lost to follow-up.

Baseline demographic and clinical characteristics were comparable between groups and are listed in **Table 1**. The mean (SD) age for all subjects was 52.0 (15.0) years,

and the mean (SD) duration of pain was 1.5 (1.4) years. Fifty-seven percent of subjects were women, and 34% were taking opioids. Preprocedure leg pain scores and functional capacity findings demonstrated moderate to severe dysfunction, averaging 6.6 (1.9) on the NRS pain scale and 44.5 (16.9) on ODI.

TREATMENT GROUP OUTCOMES

As-Treated Analysis

Outcomes stratified by primary treatment group are listed in **Table 2**. Mean (SD) leg pain scores (3.6 [2.9] vs 4.4 [2.8]) ($P = .12$) and back pain scores (4.0 [2.9] vs 4.6 [2.8]) ($P = .21$) were slightly lower at 1-month follow-up in group 2 patients, although none of these values reached statistical significance. By 3 months after the procedure, the differences between treatment groups had narrowed even further. No observed differences were noted for ODI scores at any time point.

A higher percentage of group 2 patients were able to reduce their analgesic consumption at 1 month (53% vs 40%) ($P = .02$) but not by 3 months (57% vs 56%). A slightly higher proportion of subjects obtaining a positive GPE at 1 month (69% vs 55%) ($P = .12$) and 3 months

Table 1. Baseline Demographic and Clinical Characteristics by Study Group^a

Characteristic	MRI-Blinded (n=65)	MRI (n=67)	P Value
Age, mean (SD) (range), y	53.2 (16.8) (20-96)	50.8 (13.1) (24-78)	.36
Sex			
Male	29 (45)	28 (42)	.74
Female	36 (55)	39 (58)	
Duration of pain, mean (SD) (range), y	1.6 (1.3) (0.1-5.0)	1.5 (1.5) (0.1-8.0)	.74
Baseline ODI score, mean (SD) (range)	45.0 (18.3) (10-84)	44.0 (15.5) (8-78)	.73
Baseline NRS leg pain intensity, mean (SD) (range)	6.7 (1.9) (3-10)	6.6 (1.8) (3-10)	.70
Baseline NRS back pain intensity, mean (SD) (range)	6.1 (2.7) (0-10)	6.1 (2.3) (0-10)	.72
Opioid use			
No	45 (69)	42 (63)	.43
Yes	20 (31)	25 (37)	
Injection type			
Transforaminal epidural	50 (77)	41 (61)	.03
Interlaminar epidural	15 (23)	21 (31)	
Nonepidural	0 (0)	3 (4)	
None	0 (0)	2 (3)	
Epidural injections	(n=65)	(n=62)	
1 ^b	15 (23)	21 (34)	.18
2	50 (77)	41 (66)	

Abbreviations: MRI, magnetic resonance imaging; NRS, numerical rating scale (0-10); ODI, Oswestry disability index.¹⁵

^aUnless otherwise indicated, data are reported as number (percentage) of patients.

^bIncludes patients who received only 1 injection owing to either excellent response or worsening symptoms.

Table 2. Outcomes Stratified by Primary Treatment Group

Variable	MRI-Blinded (n=65)	MRI (n=67)	P Value
NRS at 1 mo, mean (SD) (range)			
Leg pain	4.4 (2.8) (0-10) (n=65)	3.6 (2.9) (0-10) (n=61) ^a	.12
Back pain	4.6 (2.8) (0-10) (n=65)	4.0 (2.9) (0-10) (n=61) ^a	.21
NRS at 3 mo, mean (SD) (range)			
Leg pain	3.0 (3.0) (0-9) (n=32)	2.7 (2.8) (0-10) (n=32)	.77
Back Pain	3.5 (3.1) (0-10) (n=32)	3.2 (2.8) (0-9) (n=32)	.81
ODI at 1 mo, mean (SD) (range)	34.9 (20.4) (0-80) (n=65)	34.8 (17.2) (2-72) (n=61)	.98
ODI at 3-mo, mean (SD) (range)	30.6 (17.1) (2-56) (n=32)	29.7 (14.8) (6-58) (n=32)	.79
Positive GPE at 1 mo, No. (%) (95% CI)	36 (55) (43-68) (n=65)	42 (69) (57-81) (n=61)	.12
Positive GPE at 3 mo, ^b No. (%) (95% CI)	24 (40) (28-52) (n=60)	26 (53) (31-59) (n=49)	.17
Medication reduction at 1 mo, ^c No. (%) (95% CI)	14 (27) (15-39) (n=52)	26 (48) (35-62) (n=54)	.02
Medication reduction at 3 mo, ^c No. (%) (95% CI)	14 (56) (37-76) (n=25)	17 (57) (39-74) (n=30)	.96
Overall success, ^d No. (%) (95% CI)			
None	32 (49) (37-61) (n=65)	26 (43) (30-55) (n=61) ^a	.46
At 1 mo only ^e	10 (15) (7-24) (n=65)	11 (18) (8-28) (n=61)	.69
At 3 mo	23 (35) (24-47) (n=65)	24 (41) (28-53) (n=59) ^f	.54

Abbreviations: ESI, epidural steroid injection; GPE, global perceived effect; MRI, magnetic resonance imaging; NRS, numerical rating scale; ODI, Oswestry disability index.¹⁵

^aExcludes 5 patients who did not receive ESIs after reviewing their MRI and 1 patient lost to follow-up before first visit.

^bNegative GPE at 1 month carried over to 3 months.

^cMedication reduction defined as cessation of nonopioid analgesic or a greater than 20% decrease in opioid use.

^dSuccessful procedure defined as a 2-point decrease in leg pain or greater coupled with positive GPE.

^eIncludes patients with a successful procedure who dropped out for surgical or other interventional treatment for back pain or weakness.

^fExcludes subjects with a successful outcome at 1 month who dropped out before 3 months.

(53% vs 40%) ($P=.17$) was observed in group 2 patients. However, no differences in overall success rates between treatment groups were found at any time point.

Intention-to-Treat Analysis

We conducted intention-to-treat analysis to permit study patients for whom ESI failed to provide relief to

pursue other treatments without having the results of those treatments affect our findings. When the final data points in 1-month treatment failures were carried over to 3 months, mean (SD) leg pain scores in groups 1 and 2 were 4.6 (3.0) and 4.3 (3.0), respectively ($P=.53$). Back pain scores also failed to reach significance, averaging 4.7 (3.0) and 4.0 (3.0) in the 2 respective groups ($P=.23$).

Table 3. Outcomes Stratified by Whether MRI Influenced Treatment Plan

Outcome	MRI Group + MRI-Blinded Patients for Whom MRI Did Not Affect Treatment Plan (n=104) ^a	MRI-Blinded Patients Who Received Different Injection Than That Proposed by Physician Privy to MRI and Examination Findings (n=22)	P Value
NRS at 1 mo, mean (SD) (range)	(n=104)	(n=22)	
Leg pain	3.9 (2.9) (0-10)	4.3 (2.7) (0-10)	.59
Back pain	4.1 (2.9) (0-10)	5.2 (2.5) (0-10)	.10
NRS at 3-mo, mean (SD) (range)	(n=52)	(n=12)	
Leg pain	2.4 (2.7) (0-10)	4.8 (3.2) (0-9)	.01
Back pain	3.1 (2.7) (0-9)	4.3 (3.8) (0-10)	.40
ODI, mean (SD) (range)			
1 mo	34.7 (18.9) (0-78) (n=104)	35.4 (19.1) (4-80) (n=22)	.87
3 mo ^b	28.2 (15.5) (2-58) (n=52)	38.7 (15.5) (6-56) (n=12)	.04
Positive GPE			
1 mo, No. (%) (95% CI)	65 (63) (53-72) (n=104)	13 (59) (39-80) (n=22)	.77
3 mo, No. (%) (95% CI)	44 (50) (39-61) (n=88)	6 (29) (11-52) (n=21)	.08
Medication reduction ^c			
1 mo, No. (%) (95% CI)	36 (41) (31-52) (n=88)	4 (22) (6-48) (n=18)	.14
3 mo, No. (%) (95% CI)	26 (59) (43-74) (n=44)	5 (45) (17-77) (n=11)	.51
Overall success, ^d No. (%) (95% CI)	(n=110)	(n=22)	
None	48 (46) (37-56) (n=104)	10 (45) (25-66) (n=22)	.95
1 mo only ^e	14 (14) (7-20) (n=104)	7 (32) (12-51) (n=22)	.06
3 mo	42 (41) (32-51) (n=102) ^f	5 (23) (5-40) (n=22)	.12

Abbreviations: ESI, epidural steroid injection; GPE, global perceived effect; MRI, magnetic resonance, imaging; NRS, numerical rating scale; ODI, Oswestry disability index.¹⁵

^aExcludes 5 patients who did not receive ESIs after their MRIs were reviewed and 1 patient lost to follow-up before first visit.

^bNegative GPE at 1 month carried over to 3 months.

^cMedication reduction defined as cessation of nonopioid analgesic or 20% or greater decrease in opioid use.

^dSuccessful procedure defined as a 2-point decrease in leg pain or greater coupled with positive GPE.

^eIncludes patients with a successful procedure who dropped out to undergo surgical or other interventional treatment for back pain or weakness.

^fExcludes 2 additional patients with a positive 1-month outcome who dropped out before 3-month follow-up.

OUTCOMES STRATIFIED BY WHETHER MRI USE INFLUENCED TREATMENT DECISION

We set out to determine whether a subset of patients whose clinical presentation differed from their imaging results might have benefitted from reviewing their MRI. To do this, we compared group 1 patients who received a different ESI than that recommended by the independent evaluating physician who viewed the MRI findings (n=22) with the rest of the subjects who received treatment concordant with both clinical symptoms and MRI findings (ie, all group 2 patients plus the group 1 patients for whom the independent physician recommended the same injection as the treating physician) (**Table 3**). In this analysis, we found that those subjects whose injection(s) corresponded to their condition fared better than those whose condition was noted to be at a different level than that of the injection they received. Mean (SD) leg pain (2.4 [2.7] vs 4.8 [3.2]) (P=.01) and ODI scores (28.2 [15.5] vs 38.7 [15.5]) (P=.04) were both lower at 3-month follow-up in participants who received anatomically correct ESIs compared with those whose procedures were performed at a level corresponding to clinical presentation but not to radiologic findings. The proportion in the anatomically correct ESI group who reported a positive GPE was also higher at 3 months (50% vs 29%) (P=.08). Overall, 41% of those who received an ESI corresponding to

both clinical presentation and MRI findings reported a positive categorical outcome at 3 months, which favorably compared with the 23% positive outcome in cases where the injection was inconsistent with MRI findings (P=.12).

FACTORS ASSOCIATED WITH TREATMENT SUCCESS

Table 4 and **Table 5** list factors associated with treatment success. While no demographic or clinical variable attained statistical significance, trends were found in which older mean (SD) age (54.6 [14.0] vs 50.6 [15.4] years) (P=.13) higher baseline leg pain (6.9 [2.0] vs 6.4 [1.7]) (P=.12), and higher ODI score (47.6 [16.8] vs 42.8 [17.0]) (P=.13) were associated with a successful procedure (Tables 4). Controlling for potential confounding factors did not change the results of either the primary or secondary (whether having an injection different than that decided by the doctor who viewed the MRI affected outcome) analyses (Table 5). In multivariable analysis, those with an ODI score of 40 or higher were twice as likely to experience a positive outcome at 1 month than were those with less severe disability (odds ratio [OR], 2.02; 95% CI, 0.86-4.95), while being female was associated with a 43% increased risk for treatment failure (OR, 0.57; 95% CI, 0.25-1.29).

Table 4. Clinical and Demographic Characteristics Stratified by Success at 3-Month Follow-up^a

Characteristic	Negative Outcome (n=77)	Positive Outcome (n=47)	P Value
Age, mean (SD) (range), y	50.7 (15.4) (20-96)	54.6 (14.0) (25-81)	.13
Sex, No. (%)			.69
Male	31 (41)	21 (45)	
Female	46 (59)	26 (55)	
Type of injection, No. (%)			.53
Transforaminal	54 (70)	35 (74)	
Interlaminar	23 (30)	12 (26)	
Duration of pain, mean (SD) (range), y	1.5 (1.4) (0.1-8.0)	1.6 (1.3) (0.1-5.0)	.55
Opioid use, No. (%)			.48
No	52 (68)	29 (62)	
Yes	25 (32)	18 (38)	
Baseline ODI, mean (SD) (range)	43.0 (17.0) (8-84)	47.6 (16.8) (10-84)	.13
Baseline NRS pain intensity, mean (SD) (range)			
Leg	6.4 (1.7) (3-10)	6.9 (2.0) (3-10)	.12
Back	6.2 (2.3) (0-10)	5.9 (2.9) (0-10)	.58

Abbreviations: NRS, numerical rating scale (0-10); ODI, Oswestry disability index.¹⁵

^aExcludes 5 patients in the MRI group who did not receive an injection plus 3 patients lost to follow-up.

Table 5. Characteristics Associated With Outcome in Multivariable Analysis^a

Characteristic	Univariable OR (95% CI)	P Value	Multivariable OR (95% CI)	P Value
Age, centered at mean ^b	1.01 (0.99-1.04)	.27	1.01 (0.98-1.04)	.41
Female ^c	0.62 (0.30-1.26)	.18	0.57 (0.25-1.29)	.18
Duration of pain >2 y ^c	1.33 (0.63-2.81)	.45	1.51 (0.64-3.56)	.34
Study center ^c				
Walter Reed	1.19 (0.30-4.76)	.81	0.90 (0.18-4.55)	.90
Penn	1.08 (0.36-3.29)	.89	0.79 (0.21-2.89)	.72
WellSpan	1.21 (0.49-3.00)	.68	1.20 (0.42-3.58)	.73
Opioid use ^c	0.81 (0.39-1.69)	.57	0.91 (0.41-2.03)	.82
Baseline leg pain >7/10 ^c	0.82 (0.41-1.66)	.59	1.11 (0.45-2.76)	.82
Baseline back pain >7/10 ^c	0.65 (0.32-1.32)	.23	0.60 (0.23-1.56)	.30
Baseline ODI >40 ^c	1.44 (0.71-2.92)	.31	2.02 (0.86-4.75)	.11
Interlaminar ESI ^c	1.20 (0.55-2.60)	.65	1.27 (0.52-3.06)	.51
MRI group ^c	1.30 (0.64-2.62)	.47	1.40 (0.60-3.23)	.44
MRI-blinded patients who received different injection ^d	0.89 (0.35-2.24)	.81	1.21 (0.39-3.76)	.73

Abbreviations: ESI, epidural steroid injection; GPE, global perceived effect; MRI, magnetic resonance imaging; NRS, numerical rating scale; ODI, Oswestry disability index¹⁵; OR, odds ratio.

^aSuccessful outcome defined as greater than a 2-point decrease in leg pain score coupled with positive GPE at 1-month follow-up.

^bThe OR for age is interpreted as the contribution for each additional year above the reference age of 52.1 years.

^cBaseline covariates are male, duration of pain <2 years, treatment at Johns Hopkins, no opioids, baseline pain scores <7, baseline ODI <40, transforaminal injection, and blinded MRI.

^dFor MRI-blinded patients who received a different injection than that proposed by the independent physician privy to the MRI findings, the reference was the MRI group and MRI-blinded patients who received the same injection as that proposed by the independent physician.

MRI AFFECT ON DECISION MAKING

Two methods were used to determine whether MRI affected decision making. The first compared the injection performed by the blinded physician to that recommended by the independent evaluator privy to imaging results in group 1 subjects; the second identified how many patients in group 2 (who would have received an ESI had clinical findings alone been used) did not receive an ESI after the treating physician viewed the MRI results. In group 1 patients, the independent evaluator decided on the same ESI as the blinded treating doctor in 66% of cases. In 82% of the other 22 cases (n=18), the independent evaluator believed that a different ESI was warranted, with a nonepidural injection recom-

mended in only 4 cases. In no case was noninjection therapy decided on (**Figure 2**).

In group 2 patients, the treating physician opted not to perform an ESI after reviewing the MRI in 5 cases (7%). Three of these patients received a nonepidural injection, while 2 were treated with pharmacotherapy. Within 6 months of treatment, 3 of these patients ended up receiving an ESI anyway. No patients in either group had a "red flag" condition, which would have precluded them from receiving an ESI.

COMPLICATIONS

Three patients experienced worsening of pain that resulted in them refusing a second injection or seeking fur-

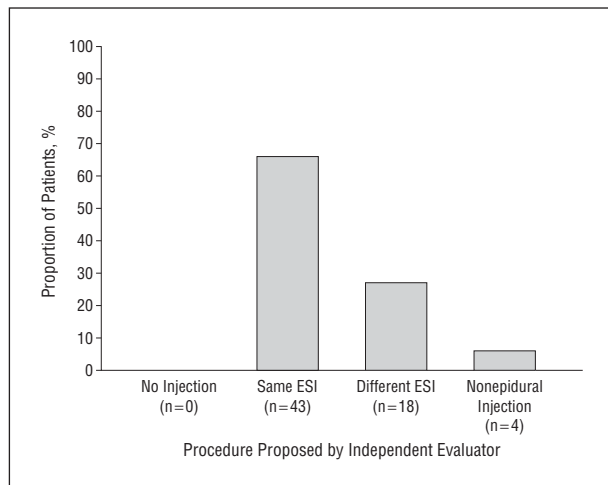


Figure 2. Differences in treatment plans for group 1 patients between the blinded treating physician and independent evaluator privy to the magnetic resonance imaging (MRI) findings. ESI, epidural steroid injection.

ther medical attention. None constituted a new neurologic complaint. One man experienced unstable angina 1 week after his first ESI, while another developed an arrhythmia within a week.

COMMENT

The main finding in this study was that the use of imaging failed to improve outcomes in patients who presented to an interventional pain clinic with clinical signs of lumbosacral radiculopathy. In group 1 patients, the independent physician privy to both MRI and clinical findings decided on a different treatment than did the treating physician who was blinded to imaging results 66% of the time. However, in over 80% of cases, this difference was limited to performing either a different type of ESI (ie, transforaminal instead of interlaminar) or performing the same type of ESI at a different level. In none of the cases did the independent evaluator elect not to perform an injection. In the 5 group 2 patients for whom the treating physician decided not to perform an ESI, none obtained significant benefit from the alternative treatment.

In the main subgroup analysis, greater benefit was noted in patients who received ESIs consistent with both MRI and clinical findings compared with those who received an ESI different from what the independent evaluating physician recommended after reviewing the MRI. While one interpretation of this finding is that the MRI could have improved outcomes in these patients, an equally plausible explanation is that treatment was more likely to fail in these patients regardless of the intervention they received because their symptoms were inconsonant with their disease. Previous studies have demonstrated a high rate of abnormal findings, including disc protrusions and annular tears, in asymptomatic volunteers.^{21,22} Studies have also found a positive correlation between pain relief following ESI and the degree of spinal stenosis, suggesting that individuals who have minimal abnormality at the dermatomal level(s) corresponding to their symptoms might benefit less from ESIs.²³

Our findings are consistent with other studies evaluating the effect of early advanced imaging on the management of neuropathic back pain. Modic et al⁶ evaluated the effects of MRI on 246 patients with acute (<3 weeks) LBP treated conservatively, 39% of whom had radicular symptoms. At 6-week follow-up, no differences in outcomes were noted between those patients whose physician was routinely notified of the results and those whose physician was notified only if “clinically indicated.” A similar study of 782 patients by Gilbert et al⁷ found that early imaging afforded only slight benefit but did not influence management. Our study differs from these in that our patients all presented with sciatica; all were referred for ESIs; and all received MRIs, although only an independent evaluator viewed the images in group 1.

There are several reasons why an MRI might not improve outcomes in patients with sciatica. First, imaging studies conducted in asymptomatic volunteers consistently show a high rate of abnormal findings,^{21,22} which minimizes the likelihood that an MRI would be used as grounds to preclude an injection. Second, systematic reviews have shown that ESIs provide benefit to only a subset of people, so that a comparative effectiveness study with liberal inclusion criteria might fail to detect a difference.^{24,25}

Third, even when ESIs are performed at a level different from the main site of the abnormality, the injectate will most likely still reach the affected area.^{26,27} Even under ideal circumstances, the utility of performing an injection at the site of the imaging abnormality remains unknown. This is illustrated by a study finding that ESI administered at the level above the affected nerve root resulted in superior outcomes to those administered at the same level as the abnormality.²⁸ This phenomenon is probably attributable not only to the extensive segmental spread that occurs with a single ESI, but also to the fact that the steroid dose typically used is much higher than what is necessary.²⁹

Nevertheless, the trend toward superiority in the MRI group for the primary outcome measure at 1 month leaves open the possibility that obtaining an MRI might improve short-term outcomes in a minority of individuals or affect treatment decisions unrelated to the performance of ESIs. Whereas most experts generally acknowledge that ESIs can provide short-term benefit, with respect to the intermediate-term efficacy of ESI, systematic reviews are mixed in their conclusions.^{30,31}

There are several limitations to this study. First, our population consisted of patients who were referred to an interventional pain clinic, some of whom had already tried conservative therapies without relief. Hence, these patients may have been less likely to respond to any treatment. Second, because this was not a primary efficacy study, we did not include a control group that received noninterventional therapy. It is currently not clear whether ESIs are more effective than conservative therapy, and in some patients, noninterventional treatments may be preferable as a first-line treatment option.

Third, our study was under-powered to detect any difference in red flag indicators, which is one of the main reasons for obtaining an MRI. Even if one elects not to routinely order advanced imaging before an ESI, prudence dictates that imaging be performed for those pa-

tients at high risk for serious disease, such as elderly patients or those with a personal or strong family history of cancer. Magnetic resonance imaging remains the reference standard for ruling out serious causes of back pain that can be missed by examination.

Fourth, because there is considerable variability in treatment decisions even when all data are reviewed, one cannot necessarily attribute differences in treatment plans solely to the use of MRI. Fifth, and perhaps most importantly, failing to observe patients for whom treatment failed for longer than 1 month may limit long-term extrapolation, as our intention-to-treat analysis did not account for the vagaries of LBP. A final caution is that these results should not be extrapolated to the cervical spine, which may be associated with a higher risk for complications.³²

In conclusion, our results suggest that although MRI may have a minor affect on decision making, it is unlikely to avert a procedure, diminish complications, or improve outcomes. Considering how frequently ESIs are performed, not routinely ordering an MRI before a lumbosacral ESI may save significant time and resources.

Accepted for Publication: September 24, 2011.

Published Online: December 12, 2011. doi:10.1001/archinternmed.2011.593

Author Affiliations: Departments of Anesthesiology and Critical Care Medicine (Drs Cohen, Christo, and Erdek) and Neurology (Dr Cornblath), Johns Hopkins School of Medicine, Baltimore, Maryland; Department of Anesthesiology, Uniformed Services University of the Health Sciences, Bethesda, Maryland (Dr Cohen); Pain Management Division, Anesthesia Service (Drs Cohen, Griffith, and Buckenmaier), and Pain Treatment Center (Ms Kurihara), Department of Surgery, Walter Reed National Military Medical Center, Bethesda; Department of Anesthesiology, University of Pennsylvania School of Medicine, Philadelphia (Dr Gupta); Division of Pharmacy Practice, University of Texas at Austin (Dr Strassels); Defense and Veterans Pain Management Initiative, Rockville, Maryland (Dr Buckenmaier); and WellSpan Interventional Pain Management, York Hospital, York, Pennsylvania (Dr Vu).

Correspondence: Steven P. Cohen, MD, 550 N Broadway, Suite 301, Baltimore, MD 21029 (scohen40@jhmi.edu).

Author Contributions: Dr Cohen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. **Study concept and design:** Cohen and Cornblath. **Acquisition of data:** Cohen, Christo, Erdek, Kurihara, Buckenmaier, and Cornblath. **Analysis and interpretation of data:** Cohen, Gupta, Strassels, and Griffith. **Drafting of the manuscript:** Cohen and Strassels. **Critical revision of the manuscript for important intellectual content:** Gupta, Strassels, Christo, Erdek, Griffith, Kurihara, Buckenmaier, Cornblath, and Cornblath. **Statistical analysis:** Gupta and Strassels. **Administrative, technical, and material support:** Gupta, Griffith, Kurihara, Buckenmaier, Cornblath, and Vu. **Study supervision:** Cohen, Christo, Erdek, and Griffith. **Recruitment and treatment:** Vu.

Financial Disclosure: None reported.

Funding/Support: This work was funded in part by a Congressional grant from the John P. Murtha Neuroscience

and Pain Institute, Johnstown, PA (through the Defense and Veterans Pain Management Initiative, Rockville, MD).

Disclaimer: The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

REFERENCES

1. Gatchel RJ, Polatin PB, Noe C, Gardea M, Pulliam C, Thompson J. Treatment- and cost-effectiveness of early intervention for acute low-back pain patients: a one-year prospective study. *J Occup Rehabil.* 2003;13(1):1-9.
2. Henschke N, Maher CG, Refshauge KM, et al. Prognosis in patients with recent onset low back pain in Australian primary care: inception cohort study. *BMJ.* 2008; 337:a171.
3. Crow WT, Willis DR. Estimating cost of care for patients with acute low back pain: a retrospective review of patient records. *J Am Osteopath Assoc.* 2009; 109(4):229-233.
4. Chou R, Fu R, Carrino JA, Deyo RA. Imaging strategies for low-back pain: systematic review and meta-analysis. *Lancet.* 2009;373(9662):463-472.
5. Jarvik JG, Hollingworth W, Martin B, et al. Rapid magnetic resonance imaging vs radiographs for patients with low back pain: a randomized controlled trial. *JAMA.* 2003;289(21):2810-2818.
6. Modic MT, Obuchowski NA, Ross JS, et al. Acute low back pain and radiculopathy: MR imaging findings and their prognostic role and effect on outcome. *Radiology.* 2005;237(2):597-604.
7. Gilbert FJ, Grant AM, Gillan MG, et al; Scottish Back Trial Group. Low back pain: influence of early MR imaging or CT on treatment and outcome—multicenter randomized trial. *Radiology.* 2004;231(2):343-351.
8. Weiner DK, Kim YS, Bonino P, Wang T. Low back pain in older adults: are we utilizing healthcare resources wisely? *Pain Med.* 2006;7(2):143-150.
9. Lurie JD, Birkmeyer NJ, Weinstein JN. Rates of advanced spinal imaging and spine surgery. *Spine (Phila Pa 1976).* 2003;28(6):616-620.
10. Chou R, Qaseem A, Snow V, et al; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007;147(7):478-491.
11. Glass LS, Harris JS, Blais BR, Genovese E. *Occupational Medicine Practice Guidelines: Evaluation and Management of Common Health Problems and Functional Recovery in Workers.* 2nd ed. Elk Grove Village, IL: American College of Occupational and Environmental Medicine (ACOEM); 2007.
12. Manchikanti L. The growth of interventional pain management in the new millennium: a critical analysis of utilization in the medicare population. *Pain Physician.* 2004;7(4):465-482.
13. Freynhagen R, Baron R, Gockel U, Tölle TR. painDETECT: a new screening questionnaire to identify neuropathic components in patients with back pain. *Curr Med Res Opin.* 2006;22(10):1911-1920.
14. Kaki AM, El-Yaski AZ, Youseif E. Identifying neuropathic pain among patients with chronic low-back pain: use of the Leeds Assessment of Neuropathic Symptoms and Signs pain scale. *Reg Anesth Pain Med.* 2005;30(5):422-428.
15. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy.* 1980;66(8):271-273.
16. Cohen SP, Bogduk N, Dragovich A, et al. Randomized, double-blind, placebo-controlled, dose-response, and preclinical safety study of transforaminal epidural etanercept for the treatment of sciatica. *Anesthesiology.* 2009;110(5):1116-1126.
17. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain.* 2001;94(2):149-158.
18. Ackerman WE III, Ahmad M. The efficacy of lumbar epidural steroid injections in patients with lumbar disc herniations. *Anesth Analg.* 2007;104(5):1217-1222.
19. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. *Pain Med.* 2010;11(8):1149-1168.
20. Cohen SP, Strassels SA, Foster L, et al. Comparison of fluoroscopically guided and blind corticosteroid injections for greater trochanteric pain syndrome: multicentre randomised controlled trial. *BMJ.* 2009;338:b1088.
21. Jensen MC, Brant-Zawadzki MN, Obuchowski N, Modic MT, Malkasian D, Ross JS. Magnetic resonance imaging of the lumbar spine in people without back pain. *N Engl J Med.* 1994;331(2):69-73.

22. Jarvik JG, Deyo RA. Diagnostic evaluation of low back pain with emphasis on imaging. *Ann Intern Med.* 2002;137(7):586-597.
23. Kapural L, Mekhail N, Bena J, et al. Value of the magnetic resonance imaging in patients with painful lumbar spinal stenosis (LSS) undergoing lumbar epidural steroid injections. *Clin J Pain.* 2007;23(7):571-575.
24. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976).* 2009;34(10):1078-1093.
25. Airaksinen O, Brox JI, Cedraschi C, et al; COST B13 Working Group on Guidelines for Chronic Low Back Pain. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J.* 2006;15(suppl 2):S192-S300.
26. Botwin KP, Natalicchio J, Hanna A. Fluoroscopic guided lumbar interlaminar epidural injections: a prospective evaluation of epidurography contrast patterns and anatomical review of the epidural space. *Pain Physician.* 2004;7(1):77-80.
27. Botwin KP, Natalicchio J, Brown LA. Epidurography contrast patterns with fluoroscopic guided lumbar transforaminal epidural injections: a prospective evaluation. *Pain Physician.* 2004;7(2):211-215.
28. Jeong HS, Lee JW, Kim SH, Myung JS, Kim JH, Kang HS. Effectiveness of transforaminal epidural steroid injection by using a preganglionic approach: a prospective randomized controlled study. *Radiology.* 2007;245(2):584-590.
29. Owlia MB, Salimzadeh A, Alishiri G, Haghighi A. Comparison of two doses of corticosteroid in epidural steroid injection for lumbar radicular pain. *Singapore Med J.* 2007;48(3):241-245.
30. Armon CA, Argoff CE, Samuels J, Backonja MM; Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: use of epidural steroid injections to treat radicular lumbosacral pain: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology.* 2007;68(10):723-729.
31. Buenaventura RM, Datta S, Abdi S, Smith HS. Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician.* 2009;12(1):233-251.
32. Abbasi A, Malhotra G, Malanga G, Elovic EP, Kahn S. Complications of interlaminar cervical epidural steroid injections: a review of the literature. *Spine (Phila Pa 1976).* 2007;32(19):2144-2151.

INVITED COMMENTARY

ONLINE FIRST

Imaging and Uncertainty in the Use of Lumbar Epidural Steroid Injections

Low back disorders are extremely common and account for an important (and growing) proportion of medical expenditures.¹ Their prevalence and impact have led to an expanding array of treatments, including spinal injections, implantable devices, and surgical procedures. Over the last 15 years, there has been a dramatic increase in the use of many of these treatments, including epidural steroid injections.² However, wide geographic variations in the use of such injections suggest professional uncertainty as to optimal indications.³ Along with increasing use of these treatments, there has been a rapid increase in the use of advanced spinal imaging.⁴ Despite these trends, overall quality of life for people reporting back pain does not seem to be improving over time.¹

Clinical trials on the efficacy of lumbar epidural steroids have reported inconsistent results. A systematic review commissioned by the American Pain Society concluded that for sciatica or prolapsed lumbar disc with radiculopathy, there is “fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief.”^{5(p1078)} It also concluded that “Evidence on efficacy of epidural injections specifically for spinal stenosis, low back pain without radiculopathy, or failed back surgery syndrome is sparse and inconclusive, but showed no clear benefit.”^{5(p1081-1082)} Nonetheless, it appears that much of the use of epidural steroid injections occurs in these situations of uncertain benefit.²

Given the modest benefits of epidural injections themselves, it may not be surprising that the benefit of imaging prior to injection is hard to demonstrate. Nonetheless, recent radiologic guidelines endorse magnetic resonance imaging (MRI) prior to administration of epidural steroid injections,⁶ and MRI use in this context has become standard of care, regardless of the duration or nature of symptoms. The rationale is that MRI is useful

to rule out “red flag” conditions (eg, tumors, fracture, instability) for which injections would not be safe; to choose the safest level and approach based on anatomy; and to improve outcomes by targeting the injection to the site of pathologic condition.⁷ However, a benefit of imaging on the outcomes of epidural steroid injections has not been established in rigorous studies.

Given the uncertain utility of MRI prior to epidural steroid injection, Cohen et al⁸ designed a study to determine if MRI improved outcomes of such injections for lumbar radiculopathy and if imaging altered treatment decisions. In this randomized trial, every patient underwent an MRI, but in one group, the treating physician was blinded to the results and in the other group, the treating physician used the MRI results to guide the treatment decision and injection approach. The groups demonstrated roughly similar improvements in leg pain, back pain, disability, and perceived treatment effect.

Consistent with earlier studies, 3-month overall treatment success (decreased leg pain and positive global perceived effect) was modest: 35% in the group blinded to MRI, and 41% in the group with MRI results available. Group differences were not statistically significant. However, the group receiving MRI results underwent fewer repeated injections and used less pain medication at 1 month than the group receiving injections by physicians blinded to the MRI results. In the group with MRI results available, physicians decided against epidural injection for a few patients.

In the group blinded to MRI results, an independent physician reviewed patient images and clinical symptoms and determined a treatment plan based on the MRI results. A third of the patients in the blinded group (22 of 67) received an injection different from that recommended by the physician who reviewed MRI findings (ie, different spinal level or approach). Cohen et al⁸ com-

pared the outcomes of these 22 patients to those who received an injection congruent with MRI findings (a total of 104). Patients who received an injection different from the MRI-based recommendation had significantly worse leg pain and disability at 3 months.

There are several potential explanations for the negative overall study results. The authors did not report specific diagnoses, which may have influenced the results. For example, patients with radiculopathy due to multi-level spinal stenosis may be less likely to respond to epidural injections than those with radiculopathy due to a herniated disc. In these situations, MRI may steer a physician toward surgical or other treatment approaches rather than epidural steroid injection. The spread of steroid in the epidural space may minimize the impact of localizing the injection based on MRI results. Though spread may be greater with an interlaminar approach than with a transforaminal approach, even with the transforaminal approach, steroid spread in the epidural space extends at least 1 or 2 spinal levels.⁹ The study was not powered for potentially important secondary outcomes such as obviating epidural injections, minimizing the number of injections, or improving functional status. Finally, of course, it may simply be the case that advanced imaging does not improve the results of epidural steroid injections.

Although the overall results of this study were largely negative, they suggest a small benefit to using MRI to guide epidural steroid injection planning in patients with lumbar radiculopathy. Use of MRI may have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, it seems premature to counsel against guideline recommendations for obtaining MRI prior to consideration of epidural steroid injections.

In the meantime, cost savings and clinical benefit might result from discouraging epidural injections in conditions for which efficacy is unclear, such as spinal stenosis and low back pain without radiculopathy. More prudent patient selection may help offset the costs of obtaining advanced imaging prior to injection for those in whom a treatment benefit is more likely. Other testing strategies may suffice for injection planning, such as the use of lower-cost rapid MRI,¹⁰ facilitated by newer imaging software. Ultimately, we need better data on the efficacy

of epidural steroids for conditions such as spinal stenosis, and on the cost-effectiveness of injections performed with and without MRI.

Janna Friedly, MD

Richard A. Deyo, MD, MPH

Published Online: December 12, 2011. doi:10.1001/archinternmed.2011.581

Author Affiliations: Department of Rehabilitation Medicine, University of Washington, Seattle (Dr Friedly); and Departments of Family Medicine, Medicine, and Public Health and Preventive Medicine, Oregon Health and Science University, Portland (Dr Deyo).

Correspondence: Dr Deyo, Department of Family Medicine, Oregon Health and Science University, 3181 Sam Jackson Park Rd SW, Portland, OR 97239 (deyor@ohsu.edu).

Financial Disclosure: None reported.

Funding/Support: This work was supported in part by grant R01 HS19222-01 from the Agency for Healthcare Research and Quality and by grant 1R01 AR054912 from the National Institute for Arthritis, Musculoskeletal, and Skin Diseases.

1. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299(6):656-664.
2. Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine (Phila Pa 1976)*. 2007;32(16):1754-1760.
3. Friedly J, Chan L, Deyo R. Geographic variation in epidural steroid injection use in Medicare patients. *J Bone Joint Surg Am*. 2008;90(8):1730-1737.
4. Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating chronic back pain: time to back off? *J Am Board Fam Med*. 2009;22(1):62-68.
5. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976)*. 2009;34(10):1078-1093.
6. Chou R, Qaseem A, Owens DK, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Diagnostic imaging for low back pain: advice for high-value health care from the American College of Physicians. *Ann Intern Med*. 2011;154(3):181-189.
7. Maus T. Imaging the back pain patient. *Phys Med Rehabil Clin N Am*. 2010;21(4):725-766.
8. Cohen SP, Gupta A, Strassels SA, et al. Effect of MRI on treatment results or decision making in patients with lumbosacral radiculopathy referred for epidural steroid injections: a multicenter, randomized controlled trial [published online December 12, 2011]. *Arch Intern Med*. doi:10.1001/archinternmed.2011.593.
9. Furman MB, Lee TS, Mehta A, Simon JI, Cano WG. Contrast flow selectivity during transforaminal lumbosacral epidural steroid injections. *Pain Physician*. 2008;11(6):855-861.
10. Gray DT, Hollingworth W, Blackmore CC, et al. Conventional radiography, rapid MR imaging, and conventional MR imaging for low back pain: activity-based costs and reimbursement. *Radiology*. 2003;227(3):669-680.