

# Rapid Magnetic Resonance Imaging vs Radiographs for Patients With Low Back Pain

## A Randomized Controlled Trial

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**A**DVANCES IN MAGNETIC RESONANCE imaging (MRI) have led to faster and therefore less expensive examinations. Several groups, including ours, have reported the development of a rapid MRI examination for the lumbar spine.<sup>1-6</sup> Using rapid MRI early in the care of patients with low back pain might benefit patients by providing a swifter definitive diagnosis, obviating further imaging or referral, and reassuring both patient and physician that there is no serious disease. However, early imaging with rapid MRI risks discovering incidental anatomic findings. In studies of subjects without low back pain, disk herniations are seen in approximately one third,<sup>7-10</sup> disk bulges in half to two thirds,<sup>7,8,10,11</sup> and disk degeneration in

**For editorial comment see p 2863.**

**Context** Faster magnetic resonance imaging (MRI) scanning has made MRI a potential cost-effective replacement for radiographs for patients with low back pain. However, whether rapid MRI scanning results in better patient outcomes than radiographic evaluation or a cost-effective alternative is unknown.

**Objective** To determine the clinical and economic consequences of replacing spine radiographs with rapid MRI for primary care patients.

**Design, Setting, and Patients** Randomized controlled trial of 380 patients aged 18 years or older whose primary physicians had ordered that their low back pain be evaluated by radiographs. The patients were recruited between November 1998 and June 2000 from 1 of 4 imaging centers in the Seattle, Wash, area: a university-based teaching program, a nonuniversity-based teaching program, and 2 private clinics.

**Intervention** Patients were randomly assigned to receive lumbar spine evaluation by rapid MRI or by radiograph.

**Main Outcome Measures** Back-related disability measured by the modified Roland questionnaire. Secondary outcomes included Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), pain, preference scores, satisfaction, and costs.

**Results** At 12 months, primary outcomes of functional disability were obtained from 337 (89%) of the 380 patients enrolled. The mean back-related disability modified Roland score for the 170 patients assigned to the radiograph evaluation group was 8.75 vs 9.34 for the 167 patients assigned the rapid MRI evaluation group (mean difference,  $-0.59$ ; 95% CI,  $-1.69$  to  $0.87$ ). The mean differences in the secondary outcomes were not statistically significant: pain bothersomeness ( $0.07$ ; 95% CI  $-0.88$  to  $1.22$ ), pain frequency ( $0.12$ ; 95% CI,  $-0.69$  to  $1.37$ ), and SF-36 subscales of bodily pain ( $1.25$ ; 95% CI,  $-4.46$  to  $4.96$ ), and physical functioning ( $2.73$ , 95% CI  $-4.09$  to  $6.22$ ). Ten patients in the rapid MRI group vs 4 in the radiograph group had lumbar spine operations (risk difference,  $0.34$ ; 95% CI,  $-0.06$  to  $0.73$ ). The rapid MRI strategy had a mean cost of \$2380 vs \$2059 for the radiograph strategy (mean difference, \$321; 95% CI,  $-1100$  to  $458$ ).

**Conclusions** Rapid MRIs and radiographs resulted in nearly identical outcomes for primary care patients with low back pain. Although physicians and patients preferred the rapid MRI, substituting rapid MRI for radiographic evaluations in the primary care setting may offer little additional benefit to patients, and it may increase the costs of care because of the increased number of spine operations that patients are likely to undergo.

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up to 90% of the scars.<sup>7,10,11</sup> Identifying incidental abnormalities with early MRI might lead to unnecessary interventions that otherwise would not have been performed, potentially resulting in both worse patient outcomes and higher costs.

Because low back pain is extremely common, any change in the diagnostic and treatment approach may have a large impact on health care resources. Spine imaging may detect a wide range of abnormalities, for which a wide range of treatments exists, some of which have only modest evidence of efficacy. Furthermore, the frequent occurrence of incidental findings often makes the true source of symptoms ambiguous. We therefore thought that a randomized trial evaluating treatment decisions, costs, and patient outcomes was the best approach to compare rapid MRI with radiographs as an initial diagnostic imaging test.

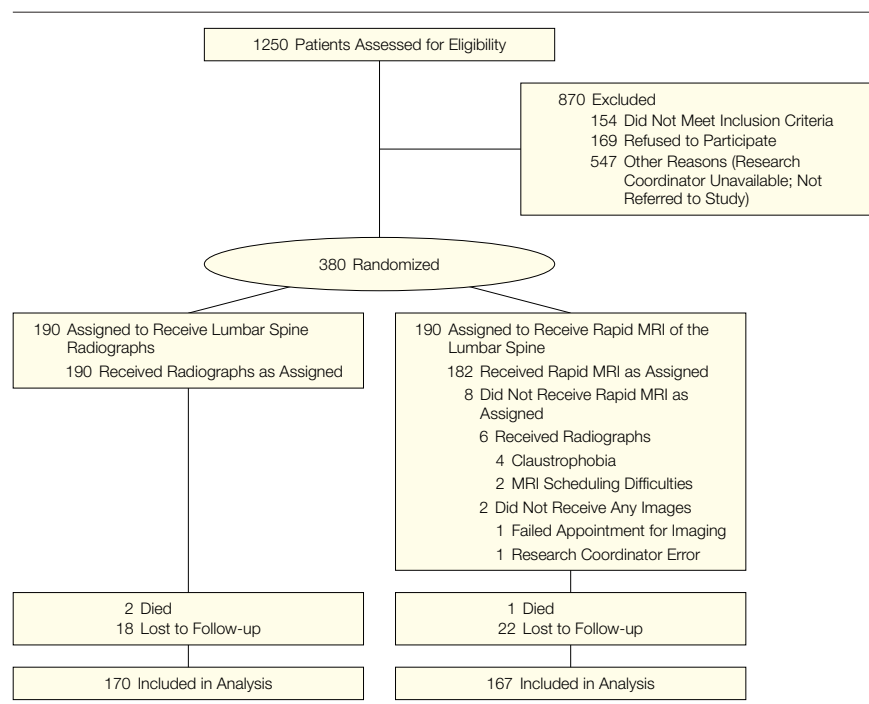
## METHODS

### Study Population

We recruited patients with low back pain from 4 imaging centers in western Washington State: a university outpatient clinic; a private, nonprofit teaching hospital; a private, for-profit, multispecialty clinic with on-site radiology; and a private, for-profit, free-standing imaging center. We identified potential patients when their physicians ordered radiographs of the lumbar spine. We targeted general internal medicine and family practice physicians, but we also enrolled patients visiting medical and surgical subspecialty physicians for an initial presentation of back pain. Eligible patients had low back pain with or without radiating leg pain, no lumbar surgery for 1 year prior to enrollment, no history of acute external trauma, no metallic implants in the lumbar spine (eg, Harrington rods or pedicle screws), and no contraindications for MRI. We also required that patients have a telephone, be at least age 18 years, not be pregnant, and speak English.

Of 1250 patients seen with low back pain at the recruiting clinics between November 1998 and June 2000, 547 did

**Figure 1.** Study Flow Chart



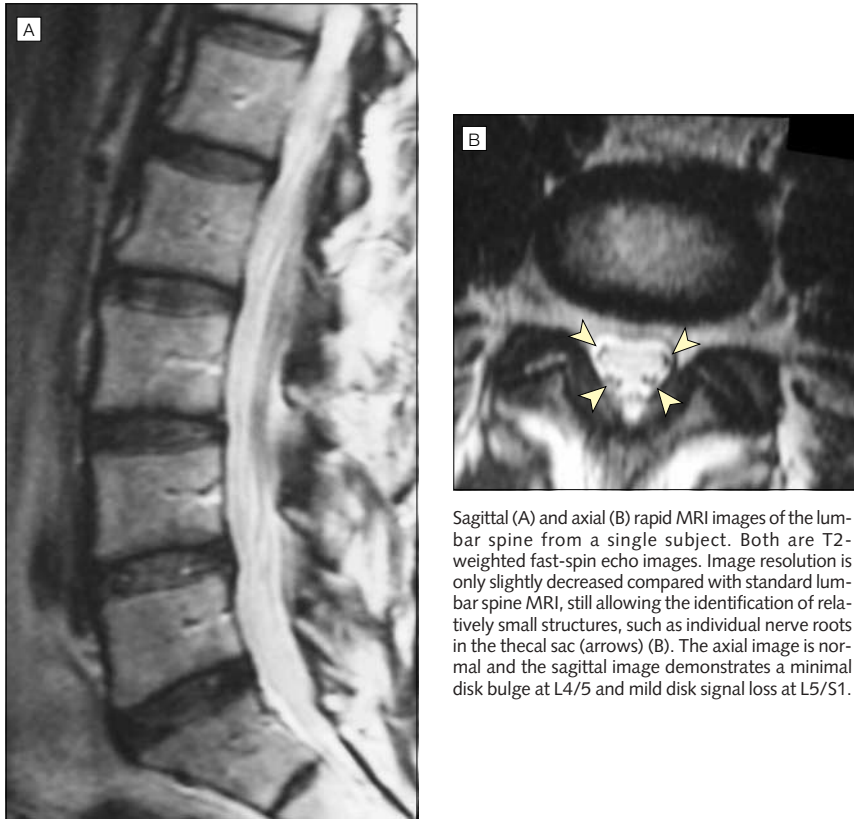
not participate because either the research coordinator was not available to enroll the patient or the primary physician decided not to refer the patient to the study (FIGURE 1). Of the 703 remaining patients, 154 did not meet inclusion criteria and 169 refused to participate, leaving 380 who enrolled.

The study was approved by the institutional review boards and radiation safety committees of the participating institutions. All patients gave written informed consent.

After enrollment, patients completed questionnaires focused on pain and functional status and were then randomly assigned to undergo radiograph or a rapid MRI of the lumbar spine. The random allocation scheme used a computer-generated block design with block sizes varying between 4 and 8 and stratified by site. Research assistants were not involved in generating the sequence and were unaware of the block randomization scheme. Group assignments were placed in opaque sealed envelopes that were opened by the research assistants after completing baseline questionnaires.

The number of radiographic views was left up to the ordering clinician although we excluded patients if the physician had ordered flexion or extension views or special views of the sacroiliac joints. There were 161 patients who had anteroposterior and lateral views only, 9 who had additional views (such as oblique), and 11 for whom the number of views was not available. Although we attempted to schedule patients randomized to rapid MRI on the day of enrollment, when that could not occur, we scheduled them within a week. Most MRI scans were conducted on systems with a field strength of 1.5 T (n=136), with the rest scanned at either 0.3 or 0.35 T (n=46), reflecting real-world variation in imaging equipment. The pulse sequences used for the rapid MRI were sagittal and axial T2-weighted fast spin echo images whose total acquisition time was approximately 2 minutes on a 1.5-T scanner (FIGURE 2).

Radiologists interpreted images as part of their normal workflow. Preliminary reports were faxed or personally delivered to the referring clinician.

**Figure 2.** Rapid Magnetic Resonance Images of the Lumbar Spine

Sagittal (A) and axial (B) rapid MRI images of the lumbar spine from a single subject. Both are T2-weighted fast-spin echo images. Image resolution is only slightly decreased compared with standard lumbar spine MRI, still allowing the identification of relatively small structures, such as individual nerve roots in the thecal sac (arrows) (B). The axial image is normal and the sagittal image demonstrates a minimal disk bulge at L4/5 and mild disk signal loss at L5/S1.

### Outcome Measures

The primary outcome measure was the modified Roland back pain disability scale,<sup>12,13</sup> conducted 12 months after randomization, testing the hypothesis that rapid MRI would result in better 12-month scores than radiograph. The modified Roland Scale is a 23-item functional status scale that focuses on how back pain affects common daily activities, with higher scores indicating worse function. Patrick et al<sup>13</sup> showed high internal consistency, validity, and responsiveness of this scale in a sciatica cohort, with an effect size of  $-1.6$  (the score change for improved patients divided by the SD at baseline).

Secondary outcome measures included back pain frequency and bothersomeness; the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), version 1; days of reduced or lost work; patient satisfaction with care; and reassurance and preference

scores. The pain frequency and bothersomeness indices are symptom scales that measure the frequency and bothersomeness of pain on a 24-point scale.<sup>13,14</sup> Patients rate 4 separate symptoms on a 1-to-6 scale: (1) leg pain; (2) numbness or tingling in the leg, foot, or groin; (3) weakness in leg or foot; and (4) back or leg pain while sitting. Scores are summed to create the symptom score, with higher scores indicating worse symptoms. The SF-36 is a highly reliable and valid generic measure of health-related quality of life.<sup>15-18</sup> We measured patient satisfaction using a modified version of the 11-item Deyo-Diehl patient satisfaction questionnaire.<sup>19</sup> We deleted a question that asked if patients thought they should have an imaging study and added 2 questions about reassurance that patients attributed to the imaging study.

Patient-elicited preference scores were measured with interactive soft-

ware, U-titer II.<sup>20</sup> Preference scores aim to combine all aspects of quality of life in 1 summary score anchored at 0 (death) and 1 (perfect health). As an introduction to the preference assessment, we asked patients to use the time trade-off technique<sup>21</sup> to value the theoretical health states of monocular and binocular (complete) blindness. We then asked patients to value their current health state using the time trade-off technique and rating scale methods. We excluded from subsequent preference score analysis patients who rated binocular blindness as a better health state than monocular blindness. All measures except for the time trade-off technique had been previously validated for patients with low back pain.<sup>13</sup>

We contacted patients by telephone or mail 1, 3, 6, and 9 months after randomization. At 12 months, we asked patients to return to the clinic to undergo a brief physical examination, repeat the preference scores assessment, and answer the outcome questionnaires. We collected the primary outcome measure, the modified Roland Scale, at months 3, 6, and 12. We measured patient satisfaction at months 1, 3, and 12. We obtained rating scale and time trade-off technique measures only at baseline and month 12. We administered all other outcome questionnaires at baseline and months 3 and 12.

Research assistants collecting outcome data were blinded to patient allocation but were asked at the end of each interview to which group they thought the patient had been assigned on a 5-point scale ("definitely x-ray" to "definitely MRI"). We considered them unblinded if they reported that they were "definitely" or "probably" aware of the patient's true randomized assignment.

### Economic Analysis

We tracked societal resource use with patient diaries and medical and billing record reviews. Record abstraction documented the name, dose, route, frequency, and duration of each drug prescription. For office visits, tests and

procedures, we recorded current procedural terminology codes.<sup>22</sup> From inpatient records, we identified the relevant diagnosis related group and *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes for surgery, radiology, anesthesiology, and pathology. To track surgeries, we queried the Washington State Comprehensive Hospital Abstract Reporting System.

We supplemented record abstraction with a resource utilization questionnaire that patients completed every 3 months. This included (1) office visits to conventional or alternative health care practitioners (2) drug use, including over-the-counter medications; (3) hospitalizations; (4) patient time spent obtaining health care for back pain; and (5) transportation, home care, and other expenses incurred while seeking health care. To avoid double counting, we examined each questionnaire entry and excluded those already in the medical record abstraction. We imputed missing values for drug dose and duration by the relevant modal and mean values, respectively. We excluded resources unrelated to back pain.

We used the federal upper limit and average wholesale price to estimate the unit cost of generic and branded drugs, respectively.<sup>23</sup> The cost of over-the-counter drugs was based on prices from a nationwide pharmacy.<sup>24</sup> We used Medicare local fee schedules<sup>25-27</sup> to estimate the cost of ambulatory care. Services not covered by Medicare were valued using reimbursements from a Washington state health insurance plan.<sup>28</sup> We used the Medicare prospective payment system<sup>29</sup> to value inpatient facility costs, supplemented with reimbursements for surgeon, radiologist, anesthesiologist, and pathologist.

We conducted a microcosting exercise based on a time-motion study to estimate the cost of rapid MRI and radiographs.<sup>30</sup> In brief, the time-motion study tracked radiologist, technologist, and patient imaging room time, for a series of patients receiving rapid MRI or radiograph for low back pain. We

multiplied staff time by relevant compensation rates. Equipment time was valued using the amortized capital cost of equipment, room construction, and maintenance plus consumable and overhead costs. All costs were in year 2001 values.

We classified patients as either (1) in the labor force (eg, full-time or part-time worker), (2) in the nonlabor force (eg, homemaker, retired, or receiving disability compensation), or (3) in the nonproductive labor force (eg, unemployed). We multiplied the number of hours spent seeking treatment for back pain by the age, sex, and labor-type specific mean earnings per hour in the United States in 2001.<sup>31,32</sup>

### Statistical Analysis

We compared baseline demographic characteristics, clinical findings, symptoms, and functional status of patients allocated to the 2 study groups by calculating means and SDs or frequencies and proportions. For the primary outcome variable, the 12-month modified Roland score, we used analysis of covariance to compare the diagnostic groups controlling for baseline Roland score and recruitment site. Using an intention-to-treat strategy, we used the Mann-Whitney *U* test for ordinal variables and the  $\chi^2$  or Fisher exact test for dichotomous variables. We did not adjust for multiple comparisons over time or between different outcome measures. Analyses were performed with SPSS<sup>33</sup> or SAS<sup>34</sup> software. Statistical tests were 2-sided with  $P < .05$  being considered statistically significant.

A 2-point difference on the modified Roland Scale is likely the smallest clinically important difference.<sup>13</sup> In order to detect a clinically important difference with 80% power, and a 2-tailed  $\alpha$  level of .05, we calculated a final target sample size of 314, based on pilot data (pooled variance, 40) for the modified Roland scale.<sup>5</sup> Anticipating a 15% drop-out rate, our recruitment goal was 372.

Because of concern that 11 patients referred by orthopedic surgeons were systematically different from the rest of the cohort, we performed the main

analyses with and without these patients. There was no important difference between the results, so we report only results for the entire cohort.

We performed an incremental cost-effectiveness analysis from the societal perspective. We used bootstrap analyses<sup>35</sup> with 5000 iterations to derive a 95% confidence interval (CI) for total costs and cost-effectiveness.

## RESULTS

We enrolled 380 patients. The characteristics of the radiograph and rapid MRI groups were similar at baseline (TABLE 1), although the rapid MRI group was slightly more likely to have comorbidities and to be receiving or applying for disability compensation. The most common comorbid conditions were osteoarthritis ( $n = 112$ ), hypertension ( $n = 106$ ), and depression ( $n = 90$ ).

There were 187 patients referred by general internal medicine or family practice physicians, 131 by rheumatologists, 38 by physical medicine and rehabilitation specialists, 11 by orthopedic specialists, and 13 by other provider types. There were 109 primary care physicians, with a mean of 3.5 patients referred per physician.

Six patients randomized to undergo rapid MRI instead received radiographs (4 due to claustrophobia and 2 because of scheduling difficulties). Two additional patients randomized to the rapid MRI group did not undergo MRI scan (1 due to a coordinating error, and 1 who failed to return for the diagnostic scan). All patients randomized to the radiograph group underwent radiographs (Figure 1).

Imaging results for the 2 groups are summarized in TABLE 2. In the rapid MRI group, disk findings and facet degeneration were common: 35 patients (20%) had moderate or severe central spinal stenosis and 31 (17%) had lateral recess stenosis. Only 13 (7%) of patients had nerve root impingement and 9 (5%) had compression fractures. In the radiograph group, disk-space height loss and facet degeneration were also common, and 24 (13%) had compression fractures. The scans or x-ray films

**Table 1.** Baseline Characteristics\*

Characteristics	Radiograph (n = 190)	Rapid MRI (n = 190)	Total (n = 380)
<b>Demographics</b>			
Age, average (SD), y	51.9 (14.3)	54.5 (14.9)	53.2 (14.7)
Body mass index, average (SD)†	28.5 (5.86)	28.9 (6.06)	28.7 (5.96)
Women	104 (55)‡	107 (56)	211 (56)
<b>Race or ethnicity</b>			
White	153 (81)	158 (83)	311 (82)
Black	23 (12)	18 (10)	41 (11)
Other	19 (10)	21 (11)	40 (11)
<b>Marital status, married or living with another</b>			
≤High school	49 (26)	47 (25)	96 (25)
<b>General health history</b>			
Cigarette smoking	28 (15)	27 (14)	55 (15)
Alcohol use to relieve pain	27 (14)	26 (14)	53 (14)
Any comorbidity	137 (72)	154 (81)	291 (77)
Unemployed, disabled, or on leave‡	29 (15)	26 (13)	55 (15)
Depressed	48 (26)	42 (22)	90 (24)
<b>Recruitment site</b>			
1	73 (38)	75 (39)	148 (39)
2	30 (16)	30 (16)	60 (16)
3	46 (24)	46 (24)	92 (24)
4	41 (22)	39 (21)	80 (21)
General internal medicine or family practice provider group	97 (51)	90 (47)	187 (49)
<b>Previous episodes of low back pain</b>			
Continuous pain	64 (34)	70 (37)	134 (35)
>5 Episodes	71 (38)	78 (41)	149 (39)
1-5 Episodes	41 (22)	33 (17)	74 (20)
None previously	13 (7)	9 (5)	22 (6)
Previous operation on back	12 (6)	11 (6)	23 (6)
Use of pain medications	162 (86)	151 (80)	313 (83)
Pain travels into leg	124 (69)	131 (71)	255 (70)
Pain travels below knee	80 (44)	83 (45)	163 (45)
Receiving or plan to apply for Social Security, worker's compensation, or disability insurance due to back‡	12 (6)	26 (14)	38 (10)

Abbreviation: MRI, magnetic resonance imaging.

\*Numbers for each analysis vary slightly due to missing values. Data are presented as numbers (percentage) unless otherwise indicated.

†Body mass index is calculated as weight in kilograms divided by the square of height in meters.

‡The disability compensation variable included patients who were already receiving or applying for workman's compensation, social security disability, or private disability.

**Table 2.** Imaging Result

	No. (%)	
	Radiograph (n = 181)	Rapid MRI (n = 178)
Disk herniation	...	58 (33)
Disk bulge	...	106 (60)
Disk signal loss	...	113 (63)
Disk space height loss	110 (61)	81 (45)
Nerve root impingement	...	13 (7)
Facet degeneration	61 (34)	102 (52)
Central spinal stenosis	...	35 (20)
Lateral recess stenosis	...	31 (17)
Compression fracture	24 (13)	9 (5)
Metastases or infection	0	0

Abbreviations: MRI, magnetic resonance imaging; ellipses, radiographs are unable to detect.

baseline Roland Scale scores of 16.0 vs 12.9 for those who completed the study (12.9; 95% CI of difference, 1.13-4.96;  $P = .002$ ). But baseline scores were quite similar between groups among those who dropped out (16.4 rapid MRI vs 15.6 radiograph; 95% CI of the difference,  $-4.27$  to  $2.70$ ;  $P = .65$ ). Those who dropped out had more comorbid conditions than those who did not (2.4 vs 1.6; 95% CI of the difference, 0.34 to 1.31;  $P = .002$ ). There were no significant differences between those lost to follow-up and those contacted with respect to age; sex; and smoking, depression, body mass index, or disability compensation status. There were no important adverse events in either group. Because of an administrative error, only two thirds of patients completed the Roland Scale that was administered at 3 months.

### Pain and Functional Outcomes

After adjusting for baseline modified Roland score and study site, the 12-month Roland Scale score in the radiograph group was 8.75 vs 9.34 in rapid MRI group, which did not represent a clinically or statistically significant difference (mean difference  $-0.59$ ; 95% CI  $-1.69$  to  $0.87$ ;  $P = .53$ ). Although modified Roland scores were more than 2 points lower at 2 sites compared with the other 2 sites, this difference was not statistically significant when adjusted for baseline scores. The range of observed Roland scores, SF-36 subscale scores, pain indices scores, and disability days were also similar between groups.

At 3 months, after adjusting for baseline scores and site, the mean modified Roland score for the rapid MRI group was 10.4 vs 8.6 in the radiograph group (95% CI of the difference,  $-3.47$  to  $-0.19$ ;  $P = .03$ ), but this difference narrowed and was no longer significant at 12 months (TABLE 3).

Both groups had significant and clinically important improvement over time on many measures, with most of this improvement occurring within the first 3 months. However, there were no significant differences between groups in

showed no evidence of infection, tumor, or inflammatory spondylitis among any of the patients.

The coordinators collecting follow-up data were successfully blinded to 82% of the patients at 12 months. At 12 months, 337 (89%) of 380 patients had completed the modified Roland scale, but the rate at the sites ranged from 73% to 96%. Among those assigned to the rapid MRI group, 167 (88%) of 190 (95% CI, 0.84-0.93) and 170 (89%) of 190 assigned to the radiograph group (95% CI, 0.85-0.94) completed the study ( $P = 0.73$ ). Those lost to follow-up had

SF-36 scores, pain scores, or days lost from work.

Although there was no significant difference in overall patient satisfaction scores between groups, satisfaction was associated with the degree of reassurance patients received from the MRI scans. At months 1, 3, and 12, the overall satisfaction score had a positive correlation with the degree of self-reported reassurance that patients had received from the MRI scan results (Pearson correlation coefficients ranging from 0.55-0.59,  $P < .001$  for all 3 times). Patients consistently rated reassurance from the MRI scan results higher than for the radiographic results, but only by a half point on a 5-point scale. When asked simply if they were reassured by the results of the diagnostic test, 58% of patients in the radiograph group responded affirmatively at 12 months compared with 74% of those in the rapid MRI group ( $P = .002$ ). Reassurance due to the diagnostic test did not decrease over time.

The time trade-off technique preference scores were significantly higher in the rapid MRI group at 12 months after adjusting for baseline scores (mean

difference  $-0.03$ ; 95% CI of the difference,  $-0.12$  to  $-1.02$ ;  $P = .005$ ). However this improvement correlated only weakly with other quality-of-life measures and patient reassurance.

### Use of Medical Services

Patients initially randomized to undergo radiograph were more likely to be referred for a conventional MRI scan in the year following randomization (TABLE 4). Conversely, patients randomized to undergo rapid MRI had more subsequent radiographs of the lumbar spine or pelvis although the economic impact was small due to their low cost. There were 131 specialist consultations after randomization to rapid MRI compared with 90 radiographs. In contrast, patients in the radiograph group had approximately twice the total number of physical therapy, acupuncture, massage, or osteopathic and chiropractic manipulation appointments as patients randomized to undergo rapid MRI. This finding was consistent for treatments likely to be initiated by the physician (eg, physical therapy) and those more likely to be patient initiated (eg, acupuncture).

Ten patients (6%) randomized to undergo rapid MRI had lumbar spine surgery within 1 year compared with 4 patients (2%) in the radiograph group (risk difference, 0.34;  $P = .09$ ). The mean time from enrollment to surgery was greater, but not significantly, in the rapid MRI group (138 vs 97 days,  $P = .31$ ). Patients who underwent surgery had similar clinical and demographic characteristics compared with nonsurgically treated patients at baseline. The respective mean scores for the 14 patients who had surgery vs the remaining patients who did not were not significantly different: 14.4 vs 13.2, Roland score ( $P = .46$ ); 13.2 vs 11.9, pain frequency ( $P = .33$ ); and 11.9 vs 12.3, pain bothersomeness ( $P = .74$ ). Pain radiating into 1 leg was more common among surgical patients (69%) than the others (46%,  $P = .08$ ).

The MRI scan results most predictive of future surgery were those that detected either a disk herniation or central stenosis, observed in 8 (80%) of 10 patients who had surgery vs 69 (41%) of 168 patients who did not have surgery (Figure 2). However, 69 (90%) of 77 patients with herniations or central ste-

**Table 3.** Change in Functional Status and Satisfaction Measures From Baseline to 12 Months

Variables	Baseline		12 Months		Difference (95% CI)†
	Radiograph (n = 190)	Rapid MRI (n = 190)	Radiograph (n = 170)	Rapid MRI (n = 170)	
Modified Roland Score, 0-23 point scale*	12.81	13.63	8.75	9.34	-0.59 (-1.69 to 0.87)
SF-36, 0-100 scale					
Bodily pain	36.04	33.15	52.59	51.34	1.25 (-4.46 to 4.96)
Physical functioning	51.38	47.78	63.77	61.04	2.73 (-4.09 to 6.22)
Role-physical	29.61	23.71	50.15	42.75	7.40 (-3.77 to 12.53)
Pain indices, pain in past week, 4- to 24-point scale					
Pain-bothersomeness*	11.66	12.06	9.75	9.68	0.07 (-0.88 to 1.22)
Pain-frequency*	11.68	12.12	10.21	10.09	0.12 (-0.69 to 1.37)
Disability days, past 4 wk					
Lost work*	2.31	2.94	1.26	1.57	-0.30 (-0.92 to 1.15)
Limited activity*	10.68	12.26	5.38	5.60	-0.22 (-1.69 to 1.84)
Bed*	2.38	2.08	1.31	1.04	0.28 (-0.38 to 1.00)
Time trade-off	0.78	0.75	0.83	0.86	-0.03 (-1.12 to -0.02)
Rating scale	0.70	0.70	0.74	0.75	-0.02 (-0.05 to 0.02)
Patient satisfaction, 11-point scale‡	8.02	8.36	7.34	7.04	0.30 (-0.42 to 0.99)
Patient reassurance, 5-point scale‡	2.59	2.93	2.50	3.18	-0.68 (-1.00 to -0.35)

Abbreviations: MRI, magnetic resonance imaging; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey.

\*A higher score indicates worse health.

†Confidence interval (CI) from analysis of covariance analysis adjusting for baseline score and study site.

‡Measured at months 1 and 12.

nosis did not have surgery and 12 (92%) of 13 patients with nerve root impingement did not have surgery. Because of the higher surgical rate, the mean cost of surgery, averaged across all patients, was higher for patients randomized to undergo rapid MRI (\$417) than patients randomized to undergo radiograph (\$156,  $P=.09$ ).

### Costs of Care

The mean cost of health care services was higher among patients randomized to undergo rapid MRI than radiograph (\$2121 vs \$1651, respectively), primarily due to more inpatient admissions (Table 4). This difference was not statistically significant (mean difference -\$470; 95% CI, -\$1044 to \$105;  $P=.11$ ).

Patients in the radiograph arm reported more hours spent attending health care appointments (mean difference 5.3 hours), reflecting their greater use of physical and other manual therapies. Similarly, patients randomized to radiograph reported higher out-of-pocket expenses than those randomized to MRI. In total, the societal cost in the year following rapid MRI was 16% higher (\$2380) than lumbar radiograph (\$2059) but not statistically significantly (-\$321; 95% CI, -\$1100 to \$458;  $P=.42$ ).

FIGURE 3 shows the likely range for the cost-effectiveness of rapid MRI. The mean estimate suggests that rapid MRI is more costly and associated with clinically equivalent outcomes. However, there is wide variation around this mean estimate as represented by the 5000

bootstrap replicates in the scatter plot. The CI around the incremental cost-effectiveness ratio is undefined due to the non-negligible probability that cost-effectiveness for the entire population lies in any 1 of the quadrants in Figure 3. Thus, the economic effect of replacing radiographs with rapid MRI in this setting remains ambiguous.

### COMMENT

Replacing lumbar spine radiographs with a rapid MRI scan in primary care patients resulted in no long-term difference in disability, pain, or general health status. There was a preference among both patients and physicians for the rapid MRI scan, but there may be a higher surgical rate among patients undergoing MRI scan, and overall soci-

**Table 4.** Costs Associated With Care (n = 365)

Variables	Radiograph (n = 185)		Rapid MRI (n = 180)		Difference (95% CI)	P Value
	Frequency	Mean Cost Per Patient, \$	Frequency	Mean Cost Per Patient, \$		
Initial imaging	185	44	180	124	-80 (NA)	
Drugs						
Cox-2 inhibitors	41	103	39	112	-8 (-68 to 51)	.78
Other NSAIDs	99	87	108	68	19 (-31 to 69)	.45
Opioid analgesics	46	67	46	70	-3 (-86 to 79)	.94
Anticonvulsants	26	100	14	42	58 (-4 to 120)	.07
Other drugs	116	94	117	218*	-124 (-292 to 44)	.14
Visits and procedures						
MR imaging of spine	40	140	16	61	78 (19 to 138)	.01
Radiography of spine	29	7	51	12	-5 (-10 to -0)	.04
CT +/- myelogram of spine	9	22	3	7	15 (-5 to 34)	.14
Nuclear medicine	14	34	8	15	18 (-7 to 44)	.16
Injections of spine	72	28	90	37	-9 (-32 to 13)	.43
Physical medicine†	1462	180	676	94	86 (23 to 150)	.008
Spine manipulation	314	56	276	51	5 (-37 to 47)	.80
Laboratory tests	560	50	505	44	7 (-14 to 28)	.54
Evaluation and management	648	180	682	209	-29 (-77 to 19)	.24
Consultations	90	65	131	97	-32 (-67 to 3)	.07
Other	371	127	289	159	-32 (-123 to 59)	.49
Inpatient						
Lumbar spine surgery	4	156	10	417	-261 (-560 to 37)	.09
Other inpatient	2‡	112	6§	284	-172 (-468 to 123)	.25
Total health care costs		1651		2121	-470 (-1044 to 105)	.11
Time cost of subsequent care, h	18.2	342	12.9	212	130 (-35 to 295)	.12
Out of pocket expenses		86		29	57 (11 to 102)	.02
Total societal costs		2059		2380	-321 (-1100 to 458)	.42

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging; NSAIDs, nonsteroidal anti-inflammatory drugs.

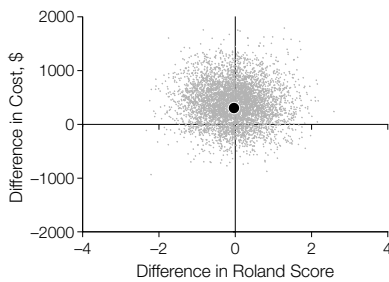
\*Both patients who were taking entanercept were in the rapid MRI group; excluding these 2 patients reduces this number to 116.

†Includes: physiotherapy, acupuncture, massage, and therapeutic ultrasound.

‡1 Hip replacement, 1 cholecystectomy. Both were conceivably related to low back pain.

§1 Hip replacement, 1 renal lithotripsy, 1 biopsy of rib, 1 implantation of epidural catheter, 2 admissions for medical management of back pain. All conceivably related to low back pain.

**Figure 3.** Cost-effectiveness Results of Rapid Magnetic Resonance Imaging (MRI) vs Radiograph



The black circle indicates the mean cost of \$321 and change in Roland Score of 0.04 difference between rapid MRI and radiograph observed in the trial. Difference was calculated by subtracting mean values in the radiograph group from mean values in the MRI group. The gray points represent the 5000 replicates of the bootstrap procedure.

etal costs may be higher as well. A major impetus for this work was the concern that substituting radiographs with rapid MRI scans would result in worse patient outcomes because incidental abnormalities would foster increased interventions and unnecessary morbidity. Our study suggests that substituting rapid MRI scan for radiographs is likely safe but may in fact result in more specialist consultations and operations. Despite the higher rate of surgery, average outcomes were not better among those in the rapid MRI group.

The use of MRI scan instead of radiographs as the initial imaging for low back pain has become more common. McNally et al<sup>6</sup> substituted a limited MRI scan for radiographs for 1042 patients with at least 6 weeks of low back pain.<sup>6</sup> They concluded that MRI scans detect a greater number of abnormalities, having discovered neoplasms in 17 (1.6%), more than double the percentage observed in a primary care population.<sup>36</sup> In fact, their cohort was mostly not a primary care population, with only 40% having been referred by general practitioners. Nevertheless, they have incorporated limited use of MRI into their routine practice, using it instead of radiographs for patients without radiculopathy and more than 6 weeks of low back pain.

The equivalency of patient outcomes in our study provides some reassurance that the policy advocated by McNally et al is not harmful to patients. However, it is worrisome that in our study more patients in the rapid MRI group had back operations than patients in the radiograph group. In general, the rapid MRI group had more specialist physician consultations while the radiograph group had more manual and physical therapy consultations. The difference in health care service costs was not statistically significant between the rapid MRI and radiograph groups. However, the observed difference in mean health services cost (\$470) suggests that routine use of rapid MRI has the potential to increase costs for patients with low back pain without a measurable benefit in pain or functional status. This observed increase in surgical costs may be off-set, to some extent, by lower costs for services such as physical therapy and chiropractor visits, as well as lower future diagnostic imaging costs.

Our results are concordant with trials examining similar issues. Kendrick et al<sup>37,38</sup> reported the results of a randomized controlled trial of radiograph vs no-imaging for primary care patients with low back pain.<sup>37,38</sup> There were no differences in outcomes after 9 months except for higher patient satisfaction in the radiograph group. However costs were also higher in that group. These results parallel our study despite the use of different technologies. The reassurance value provided by a diagnostic test is a well-recognized phenomenon that may have an effect on patient outcomes.<sup>39</sup> However, in low back pain, our data suggest that improvement in measures of reassurance and satisfaction do not result in measurable improvements in functional status or health-related quality of life.

Recruiting patients from both academic and private practice settings improves the generalizability of our results. A potential spectrum bias does exist because patients with more bothersome back pain might have been motivated to enroll in order to obtain a free

MRI scan. However the pain and disability scores of our cohort are comparable with other back pain studies.<sup>13</sup>

Given the current evidence, it is difficult to make strong recommendations regarding the use of rapid MRI for patients with low back pain. On the one hand, it does not appear that rapid MRI causes harm or greatly increases costs, and it provides more reassuring information for both patients and physicians. On the other hand, patient symptoms and functional outcomes are not, on average, improved by using MRI scan as the first imaging test. Rapid MRI has the potential to increase the number of back operations without an apparent benefit to patients and perhaps to increase costs. If the use of rapid MRI scans disseminates widely and surgical complications are more common than we observed, the consequences could be detrimental. In this setting, a cautious approach is probably most prudent, and we recommend that rapid MRI not become the first imaging test for primary care patients with back pain until its consequences for surgical rates and costs are better defined.

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**Study supervision:** Jarvik.

**Economic analysis:** Hollingworth.

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