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ORIGINAL RESEARCH

Effects of Diagnostic Information, Per Se, on Patient Outcomes in Acute Radiculopathy and Low Back Pain

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BACKGROUND AND PURPOSE: We conducted a prospective randomized study of patients with acute low back pain and/or radiculopathy to assess the effect of knowledge of diagnostic findings on clinical outcome. The practice of ordering spinal imaging, perhaps unintentionally, includes a large number of patients for whom the imaging test is performed for purposes of reassurance or because of patient expectations. If this rationale is valid, one would expect to see a measurable effect from diagnostic information, per se.

MATERIALS AND METHODS: A total of 246 patients with acute (<3 weeks) low back pain (LBP) and/or radiculopathy (150 LBP and 96 radiculopathy patients) were recruited. Patients were randomized using a stratified block design with equal allocation to either the unblinded group (MR imaging results provided within 48 hours) or the blinded group (both patient and physician blinded to MR imaging results.) After the initial MR imaging, patients followed 6 weeks of conservative management. Roland function, visual pain analog, absenteeism, Short Form (SF)-36 Health Status Survey, self-efficacy scores, and Fear Avoidance Questionnaire were completed at presentation; 2, 4, 6, and 8 weeks; and 6, 12, and 24 months. Improvement of Roland score by 50% or more and patient satisfaction assessed by Cherkin symptom satisfaction measure were considered a positive outcome.

RESULTS: Clinical outcome at 6 weeks was similar for unblinded and blinded patients. Self-efficacy, fear avoidance beliefs, and the SF-36 subscales were similar over time for blinded and unblinded patients, except for the general health subscale on the SF-36. General health of the blinded group improved more than for the unblinded group ($P = .008$).

CONCLUSIONS: Patient knowledge of imaging findings do not alter outcome and are associated with a lesser sense of well-being.

SPINE

ORIGINAL RESEARCH

Traditionally, the role of diagnostic imaging has been to provide accurate anatomic or physiologic information and, perhaps most importantly, to affect the therapeutic decision-making process. It has also been suggested that a diagnostic test may play a role in reducing patient anxiety and in providing reassurance both to the patient and the treating physician. There is at least one prospective randomized, controlled study in the literature involving patients with nonspecific chest pain supporting that diagnostic tests have a psychologically mediated effect.[1]

Clearly the ordering practice of spinal imaging, perhaps unintentionally, includes a large number of patients for whom the imaging test is performed for purposes of reassurance or because of patient expectations. If this rationale is valid, one would expect to see a measurable effect from diagnostic information, per se. In a recent study, we sought to examine the prognostic value of MR imaging findings in a population of patients with low back pain (LBP) or radiculopathy.[2] As part of this study design, we attempted to determine whether there was a measurable effect on patients from the knowledge of imaging findings and whether this knowledge had an impact on outcome. Although it might seem obvious to some that diagnostic information, per se, may have a measurable effect, it is reasonable to test this expectation and to identify whether it is positive, negative, or neutral relative to patient outcome, separate from the potential placebo effect of having had the examination itself. This article is a more in-depth analysis of this effect in patients with LBP or radiculopathy.

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Methods and Materials

Study Population

This prospective study was conducted with institutional review board approval from July 1998 and December 2002. Written informed consent was obtained from patients before enrollment. The study was Health Insurance Portability and Accountability Act (HIPAA)-compliant based on follow-up of subjects after HIPAA went into effect. Patients with acute-onset (<3 weeks) of LBP and/or radiculopathy who met the inclusion and exclusion criteria were recruited from the Center for the Spine, primary care units and regional satellites, and the emergency department of the Cleveland Clinic Foundation.[2] The treating physician performed the initial physical examination. A total of 246 patients (150 LBP and 96 radiculopathy patients) underwent MR imaging at presentation and constitute our study sample. Overall, there were 104 men and 142 women, with mean age of 43.0 years (SD = 10.4 years). There were 172 whites, 64 African Americans, 3 Asians, 2 Hispanics, and 5 patients of unspecified race. Among LBP patients, 41% were men, and the mean age was 42.7 years. For the radiculopathy patients, 45% were men, with a mean age of 43.7 years.

Subjects completed several health questionnaires, including the Roland function, visual pain analog, number of sick days, SF-36 Health Status Survey, self-efficacy scores (SESs), and Fear Avoidance

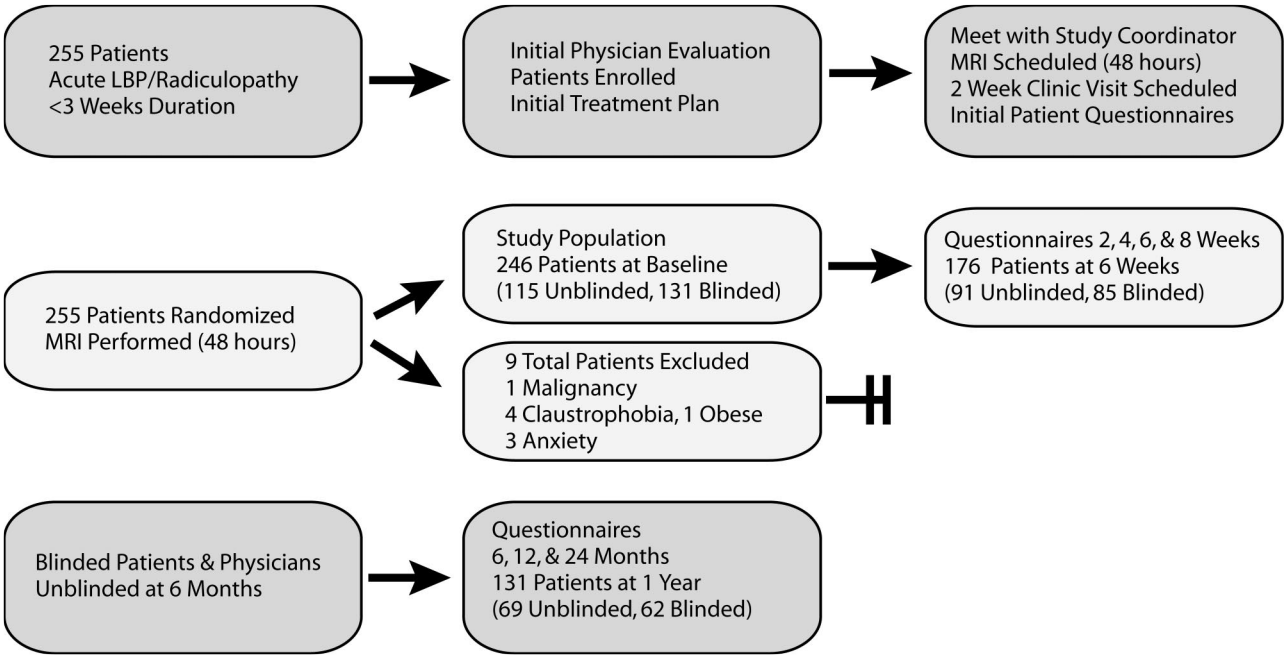

Fig 1. Flow chart of study algorithm. Major stages of the study are highlighted, as well as the number of patients in the blinded and unblinded groups in each stage.

Questionnaire (FAQ). A second baseline physical examination was performed by the study coordinator, a nurse clinician with 2 years of experience examining patients with back pain. Subjects were then randomly assigned by using a stratified block design with equal allocation to either the early information arm (ie, MR results provided within 48 hours) or the blinded arm (ie, both patient and physician blinded to MR results unless the information was critical to patient management). The variables that we stratified when randomly assigning patients were age, sex, race, type of pain (LBP or radiculopathy), and referral source. The study coordinator maintained a randomization notebook and identified the appropriate stratum for the patient. The study coordinator then removed the next concealed envelope for that stratum, which contained the group assignment. A standardized form was used 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, patients followed 6 weeks of conservative management. However, the initial treatment plan was devised by the physician before the MR to avoid influence by the diagnostic information in the MR. If, during these 6 weeks, a patient in the blinded arm developed progressive motor loss and/or bowel or bladder symptoms, then the patient and physician were unblinded to the MR results. Regardless of how blinded patients were progressing clinically, all of the blinded patients and physicians were told the MR examination results 6 months after presentation. Blinding adherence rate was not assessed. Please see Fig 1 for a flow chart of the study algorithm.

Outcome Measures

Roland function, visual pain analog scale (VPAS), absenteeism, SF-36 Health Status Survey, SESs, and FAQ questionnaires were completed at presentation; 2, 4, 6, and 8 weeks; and 6, 12, and 24 months. The percentage of improvement in patient function (as measured by the Roland score) from presentation to 6 weeks postpresentation was measured. Improvement by 50% or more was considered a positive outcome; improvement less than 50% or plans for surgery were considered a negative outcome. Patient satisfaction was assessed by a symptom satisfaction measure.[3] At 6 weeks postpresentation, satisfaction described as "very pleased" or better was considered a positive outcome. At the end of the study, patients were phoned 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 study of the lumbar spine at presentation and 6 weeks, performed on a 1.5T magnet standardized in the following fashion: 1) T1-weighted sagittal images (500/12 ms, TR/TE); matrix 192 × 256, 3 averages, sequence time 4 minutes and 20 seconds; 2) T1-weighted axial images (600/12 ms, TR/TE), matrix 192 × 256, 3 averages, sequence time 4 minutes and 40 seconds; and 3) T2-weighted sagittal and axial fast spin-echo images (5000/120 ms, TR/TE), matrix 192 × 256, 3 averages, sequence time 4 minutes and 42 seconds.

The MR studies of the patients in the unblinded arm were interpreted by the radiologist on duty at the time of the study, and this routine interpretation was made available to the treating physician and patient. There were 8 neuroradiologists who were involved in this interpretation, 2 of whom were involved in the study (M.T.M. and J.S.R.). The MR studies of the patients in the blinded arm were reviewed within 24 hours by one of the authors (M.T.M.) for significant abnormalities needing immediate treatment, such as infection or neoplasm. The information from this review was not made available to the treating physician and patient unless it was felt that a serious consequence would result if treatment was delayed. In our study, MR imaging examination of one blinded patient was positive for malignancy. This patient and his physician were unblinded per study protocol. In addition, 8 patients could not undergo MR imaging due to severe claustrophobia (4), obese body habitus (1), or refusal due to anxiety of having the MR imaging performed (3). None of these patients were included in the study population.

In a retrospective review, 3 independent radiologists (J.S.R., M.N.B-Z., and P.N.G. with 15, 20, and 10 years of spinal MR experience, respectively), blinded to the clinical information and temporal sequence, recorded the presence or absence of altered morphology using nomenclature and classification of lumbar disk pathology de-

scribed in a recent consensus article.[4] 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, annular tears, spondylolisthesis, endplate changes, and facet disease. Majority opinion of the 3 radiologists was used to classify each disk level as normal, protrusion, or extrusion and to classify stenosis as normal/mild, moderate, and severe.

Treatment Algorithm

The therapeutic plan for each patient was determined at the time of the clinical visit (ie, before the MR study). The treatment algorithm was part of a multidisciplinary consensus guideline approach, which emphasized conservative management and was used to develop consistency across the institution. This included advice to the patient to avoid bed rest and continue their daily routines as actively as possible as permitted by their pain. Anti-inflammatory drug therapy, analgesics, and muscle relaxants were to be used as needed. All of the patients were referred for physical therapy evaluation in patient education. These guidelines are in line with the recommendation contained in "Agency for Health Care Policy and Research Clinical Practice Guideline 14: Acute Low Back Problem in Adults."

Statistical Methods

All of the patients who signed informed consent and completed the baseline MR (excluding 1 patient initially allocated to the blinded arm but found to have malignancy) were included in the statistical analysis. With 246 patients (131 blinded and 115 unblinded), it was determined that a difference of 5 points on the SF-36 could be detected with 80% power and 5% type I error rate between the blinded and unblinded patient groups. Demographics, signs, and symptoms at baseline and MR imaging findings were compared for various populations (eg, LBP versus radiculopathy patients and blinded versus unblinded patients) by using analysis of variance (ANOVA), Wilcoxon 2-sample test, Kruskal Wallis test, or χ^2 test, as appropriate. Intention-to-treat principle was used for entire statistical analysis of the article. A significance level of .05 was used.

Outcome data at 6 weeks were not available for all of the patients. Thus, for those patients with data at 4 and/or 8 weeks but without data at 6 weeks ($n = 20$), we inferred the patients' outcome based on their results at 4 and/or 8 weeks. For example, if the patient reported more than a 50% improvement at 4 weeks, then we inferred that the patient was a success at 6 weeks. If the patient reported less than a 50% improvement at 8 weeks, then we inferred that the patient was not a success at 6 weeks.

Treatment recommendations and compliance with recommendations were compared for unblinded and blinded patients by using χ^2 tests. χ^2 tests were used to compare outcome at 6 weeks for blinded versus unblinded patients. Repeated-measures ANOVA was used to compare unblinded and blinded patients for differences in SESs, fear-avoidance belief, and the 8 subscales of the SF-36. With 246 total patients (150 LBP and 96 radiculopathy), we estimated that a difference of 5-10 points on the SF-36 subscales between blinded and unblinded patients could be detected with 80% power. Adjusted *P* values were calculated to control the family-wise error rate.

Results

Demographics, Signs, and Symptoms at Baseline and MR Findings

The 246 patients forming the study population were randomly assigned with 131 patients (55 LBP and 76 radiculopathy) allocated to the blinded population and 115 (41 LBP and 74 radiculopathy) allocated to the unblinded population. There were no statistically significant differences in demographics, absenteeism, intensity of pain, or general health (GH) in the 2 arms at baseline, though Roland scores tended to be higher for the unblinded arm (mean = 14) than the blinded arm (mean = 12; $P = .054$; Table 1).

Table 1: Comparison of unblinded and blinded patients at baseline

Variable	Unblinded	Blinded	Unadjusted *P*
No. of patients (%)	131 (53.3%)	115 (46.7%)	
Mean age	42.8 (SD = 10.3)	43.3 (SD = 10.6)	.733
No. of women (%)	79 (55.6%)	63 (44.4%)	.382
No. of people of color (%)	40 (54.8%)	33 (45.2%)	.732
Mean years of education	14.5 (SD = 2.9)	15.0 (SD = 2.7)	.087
Mean no. of sick days	2.4 (SD = 4.1)	2.4 (SD = 4.2)	.682
No. with radiculopathy (%)	76 (58.0%)	74 (49.3%)	.310
Mean Roland score	13.9 (SD = 5.2)	12.4 (SD = 5.8)	.054
Mean VPAS for average pain	5.3 (SD = 1.8)	5.2 (SD = 2.0)	.867
Mean VPAS for worst pain	8.8 (SD = 1.4)	8.3 (SD = 2.1)	.180
Mean self-efficacy pain	55.4 (SD = 21.7)	59.3 (SD = 22.9)	.165
Mean self-efficacy other	60.5 (SD = 21.6)	64.2 (SD = 21.0)	.186
Mean FAQ physical activity	17.0 (SD = 5.8)	17.4 (SD = 5.5)	.517
Mean FAQ work	14.4 (SD = 10.9)	14.4 (SD = 10.8)	.975
Mean SF-36: PF	45.3 (SD = 25.1)	47.6 (SD = 26.5)	.517
Mean SF-36: RP	17.4 (SD = 30.7)	22.8 (SD = 35.1)	.287
Mean SF-36: BP	28.9 (SD = 30.7)	33.7 (SD = 21.5)	.093
Mean SF-36: GH	73.4 (SD = 18.3)	74.7 (SD = 16.1)	.723
Mean SF-36: VT	41.5 (SD = 22.0)	46.9 (SD = 20.2)	.032
Mean SF-36: SF	57.4 (SD = 32.5)	62.5 (SD = 30.3)	.252
Mean SF-36: RE	74.9 (SD = 38.7)	77.3 (SD = 35.7)	.904
Mean SF-36: MH	75.7 (SD = 20.4)	78.3 (SD = 16.3)	.698

Note:—SD indicates standard deviation; VPAS, visual pain analog scale; FAQ, fear avoidance questionnaire; SF, short form; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

Treatment recommendations for unblinded and blinded patients were remarkably similar: 87% (92 of 106) of unblinded patients were prescribed nonsteroidal anti-inflammatory drugs (NSAIDS) versus 88% (80 of 91) of blinded patients, 81% (78 of 96) of unblinded patients were prescribed analgesics versus 76% (76 of 88) of blinded patients, 43% (45 of 104) of unblinded patients were prescribed other medications versus 51% (47 of 92) of blinded patients, and 71% (69 of 97) of unblinded patients were prescribed physical therapy versus 73% (64 of 88) of blinded patients ($P \geq .193$). Patient compliance with treatment recommendations was also similar for unblinded and blinded patients: 71% (65 of 92) of unblinded patients were compliant with prescribed NSAIDS versus 74% (59 of 80) of blinded patients, 55% (43 of 78) of unblinded patients were compliant with prescribed analgesics versus 60% (40 of 67) of blinded patients, 38% of unblinded (17 of 45) and blinded (18 of 47) patients were complaint with other prescribed medications, and 71% (49 of 69) of unblinded patients were compliant with physical therapy versus 75% (48 of 64) of blinded patients ($P \geq .318$).

Three patients (2 with radiculopathy and 1 with only LBP) underwent surgery within 12 weeks of presentation. The 2 patients with radicular symptoms were randomly assigned to the blinded group. The first of these patients had a large extrusion at L5 to S1. Findings were unblinded at 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 that was significantly larger on a subsequent MR study. 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 baseline MR study, which was unchanged in appearance on a second MR study. This patient underwent surgery 1 week after the second MR examination. Six additional patients underwent surgery 4–34 months (mean 16 months) after enrollment. These patients were openly unblinded per the study protocol and were not subsequently involved in further follow-up questionnaires.

All 3 of the readers agreed about the degenerative disk disease findings in 79% of levels, 2 of 3 readers in 20%, and 3 readers disagreed in 1% (15 levels). Two neuroradiologists reread these 15 levels together and classified them by consensus. All 3 of the readers agreed about the stenosis findings in 86% of levels, 2 of 3 readers in 13%, and the 3 readers disagreed in 1% (27 levels), which was resolved by consensus.

The prevalence rate of herniations was similar for patients who presented with LBP or radiculopathy: 57% (95% confidence interval [CI]: 0.49–0.65) for LBP patients ($n = 85$) and 65% (95% CI: 0.55–0.74) for patients with radiculopathy ($n = 62$) ($P = .217$). Twenty-seven percent ($n = 40$) of patients with LBP and 21% ($n = 20$) of patients with radiculopathy had 1 protrusion; 9% ($n = 14$) of patients with LBP and 18% ($n = 17$) of patients with radiculopathy had 1 extrusion; 21% ($n = 31$) of patients with LBP and 26% ($n = 25$) of patients with radiculopathy had multiple herniations ($P = .126$). 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 was severe in 23% ($n = 22$) of patients with radiculopathy compared with 3% ($n = 4$) of patients with LBP ($P = .001$). Patients with radiculopathy were more likely to have stenosis than patients with LBP only ($P = .006$).

The prevalence of herniations in the blinded and unblinded groups was also similar: 61% (70 of 115) of blinded patients versus 59% (77 of 131) unblinded patients ($P = .739$). There was no statistically significant difference in the prevalence of severe stenosis in the blinded and unblinded groups: 11% (13 of 115) of blinded patients had severe stenosis versus 9% (12 of 131) of unblinded patients ($P = .579$).

Value of Information, Per Se

There was no significant difference in the primary outcomes of the 2 groups at each interval (Tables 2 and 3). However, there was a slight trend at 6 weeks for blinded patients to have more positive outcomes. Sixty percent of unblinded patients experienced a 50% improvement in Roland function compared with 67% of blinded patients ($P = .397$). Twenty-three percent of unblinded patients were satisfied with their symptoms at 6 weeks compared with 31% of blinded patients ($P = .207$). Of note, the Roland score was slightly higher in the unblinded population at each interval.

Similarly, there was no statistically significant difference for nearly all of the secondary outcome measures. A trend was seen for blinded patients to have a slightly lower VPAS at each interval. Self-efficacy, fear-avoidance beliefs, and the SF-36 subscales (physical functioning, role physical, bodily pain, GH, vitality, social functioning, role emotional, and mental health) were similar over time for blinded and unblinded patients, except for the GH subscale on the SF-36. Although the blinded and unblinded groups had similar scores at baseline (means of 74.7 and 73.4 for blinded and unblinded groups), the mean GH score of the blinded group improved more (by 2.5, 4.1, and 6.0 points at 2, 4, and 6 weeks, respectively) than for the unblinded group (0.4, 1.3, and 4.2, respectively; $P = .008$). At the 1-year interval, the unblinded GH score 70.2 (SD = 24.7) remained lower than the blinded GH score 75.2 (SD = 18.2) but was not statistically different (Fig 2).

Table 2: Comparison of unblinded and blinded patients at 6 weeks

Variable	Unblinded	Blinded	Unadjusted *P*
Mean Roland score	6.1 (SD = 5.48)	5.1 (SD = 5.50)	.099
No. with 50% Roland score improvement (%)	55 (60.4%)	57 (67.1%)	.397
Mean VPAS for average pain	3.5 (SD = 2.70)	2.96 (SD = 2.71)	.179
No. with 50% VPAS improvement (%)	43 (48.3%)	44 (53.7%)	.529
Mean no. of sick days	0.6 (SD = 2.2)	0.8 (SD = 2.3)	.743
No. with 0 sick days (%)	12 (14.0%)	12 (15.0%)	.677
Mean self-efficacy pain	72.2 (SD = 21.8)	72.5 (SD = 24.1)	.639
Mean self-efficacy other	73.6 (SD = 19.2)	74.8 (SD = 21.3)	.400
Mean FAQ physical activity	13.8 (SD = 6.4)	13.4 (SD = 6.3)	.698
Mean FAQ work	12.1 (SD = 11.3)	10.8 (SD = 10.6)	.457
Mean SF-36: PF	69.0 (SD = 22.3)	76.0 (SD = 24.7)	.010
Mean SF-36: RP	60.5 (SD = 41.3)	70.2 (SD = 39.5)	.112
Mean SF-36: BP	56.5 (SD = 22.7)	65.0 (SD = 24.4)	.041
Mean SF-36: GH	77.6 (SD = 19.4)	80.7 (SD = 15.5)	.360
Mean SF-36: VT	58.3 (SD = 21.4)	63.1 (SD = 20.0)	.157
Mean SF-36: SF	85.3 (SD = 21.7)	86.0 (SD = 20.6)	.886
Mean SF-36: RE	77.5 (SD = 36.7)	84.8 (SD = 29.8)	.246
Mean SF-36: MH	69.4 (SD = 21.0)	78.7 (SD = 20.2)	.001

Note:—SD indicates standard deviation; VPAS, visual pain analog scale; FAQ, fear avoidance questionnaire; SF, short form; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

Discussion

Given the number of abnormalities seen on MR imaging in both symptomatic and asymptomatic patients,[5-7] it is not surprising that blinded and unblinded patients with LBP and radiculopathy undergoing the same conservative treatment had no difference in primary clinical outcomes in our study. A slight trend was seen, however, for blinded patients to have more improvement of function (50% increase in Roland score from baseline) and more satisfaction with their symptoms at 6 weeks. Secondary outcomes were also similar over time, with the exception of the GH subscale of the SF-36.

The SF-36 health survey is a self-assessment of 8 health concepts most affected by disease and treatment and has been fre-

Table 3: Comparison of unblinded and blinded patients at 1 year

Variable	Unblinded	Blinded	Unadjusted *P*
Mean Roland score	4.9 (SD = 5.3)	4.2 (SD = 5.3)	.386
Mean VPAS for average pain	2.9 (SD = 2.4)	2.8 (SD = 2.8)	.407
Mean VPAS for worst pain	4.5 (SD = 3.1)	3.9 (SD = 3.3)	.221
Mean no. of sick days	0.27 (SD = 0.85)	0.34 (SD = 3.3)	.493
Mean self-efficacy pain	72.0 (SD = 23.6)	73.9 (SD = 21.8)	.749
Mean self-efficacy other	75.7 (SD = 21.6)	76.9 (SD = 9.9)	.810
Mean FAQ physical activity	13.3 (SD = 7.0)	13.9 (SD = 6.5)	.589
Mean FAQ work	11.2 (SD = 10.5)	11.7 (SD = 9.9)	.770
Mean SF-36: PF	75.0 (SD = 25.4)	75.7 (SD = 24.2)	.903
Mean SF-36: RP	72.5 (SD = 38.3)	73.5 (SD = 40.8)	.607
Mean SF-36: BP	64.1 (SD = 26.5)	64.7 (SD = 26.8)	.888
Mean SF-36: GH	70.2 (SD = 24.7)	75.2 (SD = 18.2)	.461
Mean SF-36: VT	58.9 (SD = 22.1)	62.4 (SD = 21.7)	.362
Mean SF-36: SF	85.9 (SD = 24.9)	86.7 (SD = 22.8)	.980
Mean SF-36: RE	83.1 (SD = 33.1)	87.4 (SD = 28.0)	.665
Mean SF-36: MH	74.3 (SD = 20.2)	81.0 (SD = 16.7)	.032*

Note:—SD indicates standard deviation; VPAS, visual pain analog scale; FAQ, fear avoidance questionnaire; SF, short form; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.
* The *P* value for mental health, after adjusting for the multiple comparisons, was >.05, not statistically significant.

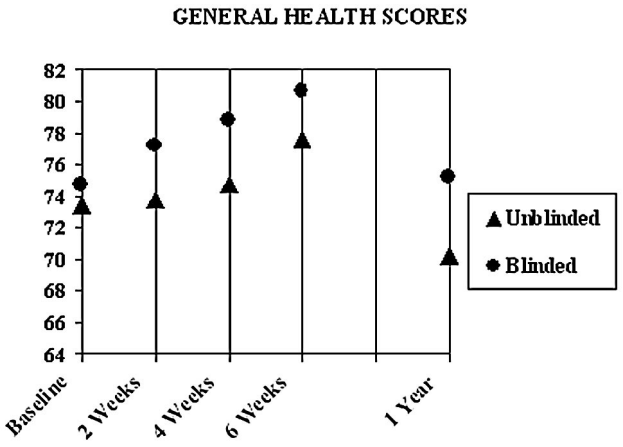

Fig 2. GH scores of unblinded and blinded patients at baseline; 2, 4, and 6 weeks; and 1 year.

quently used to estimate disease burden in cases of arthritis, depression, diabetes, hypertension, and back pain.[8] These health concepts: physical functioning, role-physical, bodily pain, general vitality, social functioning, role-emotional, and mental health, are categorized into physical and mental health components. This segregation is clinically important because scales that load "highest on the physical component are most responsive to treatments that change physical morbidity, whereas scales loading highest on the mental health component respond most to drugs and therapies that target mental health."[8] Most subscales fall strictly under physical or mental health components, whereas the GH subscale has correlations with both components.

Blinded patients in our study had more improvement in the mean GH subscale score at 2, 4, and 6 weeks. Although both blinded and unblinded GH scores decreased at 1 year, the blinded score remained slightly above baseline, whereas the unblinded score dropped 3.2 points below baseline. These findings would seem to imply that unblinded patients not only perceived their own health to be poor and had a lesser sense of well-being than blinded patients but may have had a poorer response to treatment directed at both physical and mental health. Moreover, although the difference only involved a single SF-36 subscale, this was still probably clinically significant, because the GH subscale is one of the most precise in the SF-36 health survey. The GH subscale defines "the widest range of health states and therefore usually produce[s] the least skewed score distribution."[8]

Although the GH score for blinded patients improved more at the 2-, 4-, and 6-week intervals than the unblinded patients and remained higher overall at 1 year, it can only be postulated why the blinded patient's scores did not continue to improve between 6 weeks and 1 year and actually decreased in a fashion similar to the unblinded patient's scores. Between 6 weeks and 1 year, the blinded patients saw a decrease of 5.5 points from 80.7 to 75.2 in their GH score. Unblinded patients' score fell from 6 weeks (77.4) to 1 year (70.2). This would seem to indicate that between 6 weeks and 1 year some common factor(s) affected both the blinded and unblinded populations. Due to the lack of uniform treatment of all of the patients after the initial 6 weeks of conservative treatment, no direct correlation can be reliably found between any 1 variable and the drop in the GH score at 1 year. However, the fact that blinded patients, as well as their physicians, were told the MR imaging results 6 months after the test should be considered. The knowledge of diagnostic findings may have had a negative effect on blinded patients at 1 year and may explain why unblinded patients did not see the same degree of improvement in their scores at 2, 4, and 6 weeks as blinded patients.

It is not surprising that patients who are informed that they have degenerative changes of the spine might develop a sense of lesser well-being, and this illustrates the adverse effects of labeling a patient based on diagnostic findings rather than clinical symptoms. This negative psychological effect could easily be forgiven if MR imaging was generally accepted to have a dynamic role in guiding patient management. However, the prognostic role of MR imaging in acute LBP and radiculopathy is still being debated without a clear consensus within or among specialties.[9-17] Jarvik et al[18] further found no measurable difference in comparing conventional radiographs and rapid MR imaging in low back patients except for a potentially higher rate of surgery in those undergoing MR imaging without an apparent benefit to patients and a needless increase in costs.

Despite the lack of consensus of the appropriate use of MR imaging in back pain and its potential negative impact, many physicians may still feel that the reassurance that imaging provides to patients, as well as themselves, is invaluable. Kendrick et al[19] found that physicians requested radiography 88% of the time to reassure patients and 78% of the time to reassure themselves in cases of LBP. Although radiography was not associated with improved patient functioning, severity of pain, or overall health status, patients undergoing radiography in this study were more satisfied with their care.

Providing patients with information and an explanation of their pain are perhaps the most cost-effective ways to avoid un-

warranted imaging while satisfying patients' expectation of care. As one study found, the most frequently cited source of dissatisfaction among patients was failure to receive an adequate explanation.[20] Furthermore, those patients who reported an adequate explanation were less likely to request additional diagnostic tests, whereas those who perceived that they did not receive an adequate explanation were less satisfied with their visit and were less likely to want the same doctor.[20] Interestingly, physician time spent with patients did not differ between those receiving an adequate explanation and those who did not. Similarly, LBP patients receiving an education booklet on acute or recurrent LBP showed a statistically significant greater improvement in Roland scale, VPAS, and fear-avoidance beliefs about physical activity.[21] To avoid the potential negative impact that a lack of information or explanation could have on patients' clinical outcomes, all of the patients in our study were counseled on the benign nature of LBP and radiculopathy at enrollment.

Although the primary purpose of our study was to examine the effect of early diagnostic information on clinical outcomes in patients with acute LBP or radiculopathy, it was also our foremost limitation. Because we did not have a third population group that did not undergo an MR imaging to compare with the blinded and unblinded patients who did, we do not know the effect that undergoing the test itself has on patients, and our conclusions can only be about the consequences of knowing the diagnostic information of the MR imaging. Despite this limitation, it is reasonable to test the expectation that knowledge of imaging findings has an impact on outcome and to identify whether it is positive, negative, or neutral relative to patient outcome, separate from the potential placebo effect of having had the examination itself. In this respect, the study by Gilbert et al[22] complements our own. Their study randomly allocated patients with LBP into early and delayed imaging groups. Ultimately, they found that early imaging had no effect on treatment overall but did see improvements in the Aberdeen Low Back Pain score and bodily pain subscale score of the SF-36 in the early imaging population.[22] Although our study addresses the impact of early versus delayed knowledge of imaging findings, the study by Gilbert et al[22] addresses the potential placebo effect of early versus delayed imaging itself.

Because it is not realistic to expect patients to undergo testing without knowledge of the findings, the next question to be addressed in future studies is whether undergoing MR imaging with knowledge of its diagnostic information is better or worse than no test at all. More importantly, if it is found that the therapeutic placebo effect of undergoing MR imaging outweighs the negative impact of knowing its diagnostic information, does this benefit outweigh the harm from potential spine surgeries that MR imaging findings may prompt, the cost of the MR imaging, and the currently unknown long-term psychological effects of being labeled with incidentally found degenerative disease?

Another limitation was our lack of evaluation of patient and physician satisfaction for care received or provided. In retrospect, it would have been interesting to see how blinded and unblinded patients, as well as physicians, differed in satisfaction of care, even with the knowledge that patient care was controlled by the artificial limitations of a study. Lastly, 20% of enrolled patients were lost to questionnaire follow-up, with a disproportionate number being minorities. Despite the loss of minorities, the referring mechanism ensured that the patient population was representative of the different population groups in the northeast Ohio region. Referring facilities included several satellites hospitals located within communities of diverse ethnicity, race, and socioeconomic status. Overall, our study had good representation of whites and African Americans but poor representation of Asian and Hispanic populations.

In summary, it was our experience that patient knowledge of MR imaging findings did not alter primary clinical outcomes in the setting of acute LBP and radiculopathy. However, in one secondary measure of outcome, the GH subscale of the SF-36 health survey, blinded patients saw more improvement at 2, 4, and 6 weeks. These patients perceived their health to be better and had a better sense of well-being. As the debate over the proper use of MR imaging in acute LBP and radiculopathy continues, our findings point to the potential negative psychological impact of labeling patients with disease based on diagnostic findings rather than clinical symptoms, as well as the inappropriate use of MR imaging for the purpose of patient and/or physician reassurance.

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