

# Comparison of Classification-Based Physical Therapy With Therapy Based on Clinical Practice Guidelines for Patients with Acute Low Back Pain

## A Randomized Clinical Trial

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**Study Design.** A randomized clinical trial was conducted.

**Objective.** To compare the effectiveness of classification-based physical therapy with that of therapy based on clinical practice guidelines for patients with acute, work-related low back pain.

**Summary of Background Data.** Clinical practice guidelines recommend minimal intervention during the first few weeks after acute low back injury. However, studies supporting this recommendation have not attempted to identify which patients are likely to respond to particular interventions.

**Methods.** For this study, 78 subjects with work-related low back pain of less than 3 weeks duration were randomized to receive therapy based on a classification system that attempts to match patients to specific interventions or therapy based on the Agency for Health Care Policy and Research guidelines. The subjects were followed for 1 year. Outcomes included the impairment index, Oswestry scale, SF-36 component scores, satisfaction, medical costs, and return to work status.

**Results.** After adjustment for baseline factors, subjects receiving classification-based therapy showed greater change on the Oswestry ( $P = 0.023$ ) and the SF-36 physical component ( $P = 0.029$ ) after 4 weeks. Patient satisfaction was greater ( $P = 0.006$ ) and return to full-duty work status more likely ( $P = 0.017$ ) after 4 weeks in the classification-based group. After 1 year, there was a trend toward reduced Oswestry scores in the classification-based group ( $P = 0.063$ ). Median total medical costs for 1 year after injury were \$1003.68 for the guideline-based group and \$774.00 for the classification-based group ( $P = 0.13$ ).

**Conclusions.** For patients with acute, work-related low back pain, the use of a classification-based approach resulted in improved disability and return to work status after 4 weeks, as compared with therapy based on clinical practice guidelines. Further research is needed on the

optimal timing and methods of intervention for patients with acute low back pain. [Key words: classification, clinical practice guidelines, low back pain, physical therapy, return to work] **Spine 2003;28:1363–1372**

The 1-year prevalence for an episode of acute low back pain (LBP) has been estimated to be reach 65%.<sup>1,2</sup> Many individuals suffering an acute episode of LBP will not completely recover, as was previously believed.<sup>3,4</sup> Despite its prevalence and the risk for progression to chronic or recurrent LBP, evidence for effective treatment strategies for acute LBP is generally lacking. The interventions most often used by physical therapists in the treatment of patients with acute LBP include exercise, mobilization–manipulation, and to a lesser extent, traction.<sup>5,6</sup> However, these interventions are not strongly supported by evidence. Various forms of exercise therapy, including flexion and extension exercises, have not proved to be any more effective than other active or inactive interventions.<sup>7</sup> Findings have not consistently shown spinal manipulation to be more effective than other interventions for patients with acute LBP.<sup>8</sup> Little research has been performed on the effectiveness of spinal traction for acute LBP. However, studies on patients with chronic LBP have not supported its use.<sup>9,10</sup>

The lack of research evidence for many common treatments for individuals with acute LBP has been reflected in clinical practice guidelines published in recent years.<sup>11–16</sup> These guidelines generally have emphasized an approach of watchful waiting rather than specific interventions during the initial 4 to 6 weeks after the onset of LBP. The guidelines published by the Agency for Health Care Policy and Research (AHCPR) in the United States are consistent with this approach, recommending that health care providers provide assurance to patients with acute LBP and advise them to remain active within the limits of pain as long as there is no evidence of underlying serious pathology.<sup>13</sup> Exercise recommendations during the first 4 weeks after onset consist of low-stress aerobic activity, with referral for specific interventions recommended only after 4 weeks.<sup>13</sup>

One explanation offered for the inability to identify effective treatments for patients with acute LBP is the lack of success in defining subgroups of patients who are most likely to respond to a specific treatment approach.<sup>17–19</sup> Because of the difficulty in grouping pa-

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Funded by a Clinical Research Center grant from the Foundation for Physical Therapy.

Acknowledgment date: May 17, 2001. First revision date: August 9, 2001. Second revision date: October 25, 2001. Acceptance date: November 27, 2002.

The submitted manuscript does not contain information about medical devices or drugs.

Foundation funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this article.

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**Table 1. Treatment Classifications Used for the Classification-Based Group<sup>18,22,30</sup>**

Classification	Examination Findings	Treatment
Mobilization		
Sacroiliac pattern	Unilateral symptoms without signs of nerve root compression, positive findings for sacroiliac region dysfunction (pelvic asymmetry, standing and seated flexion tests)	Joint mobilization or manipulation techniques and spinal active range of motion exercises
Lumbar pattern	Unilateral symptoms without signs of nerve root compression, asymmetrical restrictions of lumbar side-bending motion, lumbar segmental hypomobility.	Joint mobilization or manipulation techniques and spinal active range of motion exercises
Specific exercise		
Flexion pattern	Patient preference for sitting versus standing, centralization with lumbar flexion motions.	Lumbar flexion exercises, avoidance of extension activities
Extension pattern	Patient preference for standing versus sitting, centralization with lumbar extension motions.	Lumbar extension exercises, avoidance of flexion activities
Immobilization	Frequent previous episodes, positive response to prior manipulation or bracing as treatment, presence of "instability catch" or lumbar segmental hypermobility	Trunk strengthening and stabilization exercises
Traction	Radicular signs present, unable to centralize with movements, may have lateral shift deformity	Mechanical or auto-traction

tients on the basis of pathoanatomic mechanisms,<sup>20,21</sup> attempts have been made to develop classification systems based on findings from the clinical examination.<sup>22-26</sup> Delitto *et al*<sup>22</sup> developed a treatment-based classification system for patients with acute LBP. This system uses information from the clinical examination and patient self-reports of pain (pain scale and pain diagram) and disability (modified Oswestry questionnaire) to classify the patient into one of four treatment categories; immobilization, mobilization (sacroiliac or lumbar), specific exercise (flexion, extension, or lateral shift correction), or traction. The cluster of signs and symptoms used to categorize the patient and the associated treatment approaches are presented in Table 1.

Classification systems for patients with acute LBP need to be evidence based, and the identification of subgroups of patients with LBP has been specified as a research priority.<sup>27</sup> Many of the tests currently used to identify subgroups of patients have not been validated, and little research has investigated the outcomes of therapy based on a classification approach. Preliminary evidence exists for one category in the classification system (mobilization) based on two pilot studies,<sup>28,29</sup> and the system has been found to have adequate interrater reliability.<sup>30</sup> No studies so far have compared a classification-based approach, in which patients are categorized and treated using a specific intervention, with an approach based on the current evidence recommending a more general initial approach for all patients during the first 4 weeks. The purpose of this study was to compare the effectiveness and medical costs of a classification approach to the rehabilitation of persons who have acute, work-related LBP with an approach based on clinical practice guidelines.

## ■ Materials and Methods

**Subjects.** This study was conducted at five Employee Health Services outpatient clinics at the University of Pittsburgh Medical Center (UPMC). The enrollment period was from August 1997 through August 1999. Physical therapy was provided in

one of nine facilities. One or two therapists were trained in the study procedures at each facility. The study was approved by the institutional review board at the University of Pittsburgh. Patients with work-related LBP of less than 3 weeks duration and of sufficient severity to necessitate modification of work duties were identified by the occupational medicine physician. Eligible patients were referred to a research assistant, who obtained their written informed consent and conducted the baseline examination including the completion of self-report measures and a clinical examination. Patients were excluded from participation if they did not require any work modifications, had a history of surgery to the lumbosacral region, were pregnant, or had any "red flags" of potentially serious conditions (*i.e.*, tumor, fracture, infection, cauda equina syndrome) as specified by the AHCPR guidelines.<sup>13</sup> Individuals with sciatica or a history of LBP were included in the study.

**Treatment.** After confirmation of eligibility and completion of the baseline examination, the subjects were randomly assigned to receive treatment based on either clinical practice guidelines,<sup>13-16</sup> or the classification scheme described by Delitto *et al*.<sup>22,30</sup> A computer-generated randomization list was used by an office assistant to make the group assignment. The research assistant and the occupational medicine physician were blinded to the group assignment.

As advocated by clinical practice guidelines, all the subjects were reassured by the occupational medicine physician that most patients with LBP recover quickly and were encouraged to remain as active as possible. All the subjects were referred to physical therapy, which began within 1 week of randomization. The subjects assigned to the guideline-based group received treatments based on the recommendations of clinical practice guidelines including low-stress aerobic exercise (treadmill walking or stationary cycling) and general muscle reconditioning exercises after 2 weeks. The subjects also received advice to remain as active as possible within the limits of their pain. They were reminded that most persons with LBP return to full work capacity.

The subjects assigned to the classification-based group were examined by the treating physical therapist and placed into one of four treatment classifications on the basis of their signs and symptoms (Table 1). The treatment received was specific to the classification assignment of the subject. The subjects in the

classification group were reevaluated at the beginning of each therapy session. The reevaluation consisted of lumbar range of motion and special tests required for classification (Table 1). If the patient's signs and symptoms changed, resulting in a new classification, the treatment was altered to match the new classification. Thus, a key distinction between the two treatment groups was the allowance for reassessment and adjustment of the treatment program on the basis of changes in signs and symptoms in the classification group, as compared with a consistent, guideline-based approach. All the subjects were scheduled for two or three therapy sessions per week and reassessed by the occupational medicine physician on a weekly or bi-weekly basis. Therapy charts were reviewed by one of the investigators periodically to ensure therapist compliance with the study protocols. Discharge from physical therapy occurred at the discretion of the occupational medicine physician.

**Outcomes.** Outcome measures included a clinical examination and completion of a battery of self-report measures. Both components were assessed at the baseline examination, then weekly for 4 weeks. Self-report measures were completed by mail after 6 months and 1 year. Telephone interviews were conducted at 6 months and 1 year to assess work status. Outcome measures were collected by a research assistant who was blind to the patient's group assignment. The clinical examination provided data for computing the physical impairment index. A 0- to 7-point scale of physical impairment resulting from to LBP was calculated from the range-of-motion and trunk-strength tests, as described by Waddell *et al.*<sup>31</sup>

The self-report measures included an 11-item pain scale asking the subject to rate his or her pain between 0 (no pain) and 10 (worst imaginable pain). The modified Oswestry questionnaire<sup>32</sup> was used to assess functional disability resulting from LBP. The Oswestry is a 10-item, 100-point scale, with higher numbers indicating greater disability.<sup>33</sup> The modified version replaces the sex life item with an employment-homemaking item because of poor compliance with the former. The modified Oswestry has been proved reliable, valid, and sensitive to change.<sup>32</sup>

The Medical Outcomes Survey Short Form (SF-36) was used to assess general health status. The SF-36 measures eight dimensions of health: general health perceptions, physical function, physical role, bodily pain, social functioning, mental health, emotional role, and vitality.<sup>34</sup> The eight scales may be combined into two summary scores, the physical component summary (PCS) and the mental component summary (MCS), which are norm-referenced to a general U.S. population with a mean of 50 and standard deviation of 10.<sup>34,35</sup> The SF-36 has well-established psychometric properties for the general population<sup>35</sup> and individuals with LBP.<sup>36</sup>

Depressive symptoms were assessed with the Center for Epidemiological Studies Depression Scale (CES-CD), a 20-item scale designed for use in community-dwelling adults.<sup>37</sup> Each item is scored on a scale of 0 to 3, for a total possible score from 0 to 60. Higher numbers indicate greater severity of depressive symptoms. The CES-CD has been tested in general samples and in populations with psychiatric diagnoses, and has shown adequate reliability and discriminative validity.<sup>38,39</sup>

Fear-avoidance beliefs were assessed through the Fear Avoidance Beliefs Questionnaire (FABQ) described by Waddell *et al.*<sup>40</sup> The FABQ has 16 items, each scored 0 to 6, with higher numbers indicating increased levels of fear-avoidance beliefs. Two subscales within the FABQ have been identified: a 7-item

work subscale (score range, 0–42) and a 4-item physical activity subscale (score range, 0–24). Previous studies among patients with chronic LBP found the FABQ work subscale to be predictive of disability and work loss.<sup>40–42</sup> Klenerman *et al.*<sup>43</sup> found fear-avoidance variables to be predictive of future disability in patients with acute LBP.

The work status of the subjects was assessed after 4 weeks and recorded as either “returned to work without restrictions” or “continued work restrictions.” Each subject was asked to rate the overall change in his or her low back condition since the beginning of physical therapy treatment using a 15-point rating scale. The choices ranged from –7 (a very great deal worse) to 0 (about the same) to +7 (a very great deal better), with intermittent descriptors of worsening and improving assigned values ranging, respectively, from –1 to –6 and +1 to +6.<sup>44</sup> Work status and the number of additional days of work missed because of LBP after the initial return to work were assessed after 1 year. Total medical costs related to the LBP episode over a 1-year period after the baseline evaluation including the costs of physical therapy, physician and specialist visits, diagnostic imaging, and any additional therapeutic procedures were recorded from the databases of the UPMC Employee Health Services.

**Statistical Analysis.** Baseline variables were summarized for descriptive purposes using means and standard deviations for continuous measures and percentages for categorical measures. Independent sample *t* tests and  $\chi^2$  tests were used to compare baseline measures between treatment groups. Lilliefors tests for normality were used to test the hypothesis that outcome measures (Oswestry, MCS, PCS, impairment index, patient satisfaction, and medical costs) were normally distributed.<sup>45</sup> The null hypothesis of normality was retained for all variables except change in impairment, patient satisfaction, and medical costs. Change in impairment and patient satisfaction was compared between groups using the Mann-Whitney *U* test. Total medical costs and costs for physical therapy were compared between groups using a two-sample Kolmogorov-Smirnov test to assess the null hypothesis that the two samples possessed the same distribution.<sup>45</sup>

The Oswestry, PCS, and MCS were analyzed as continuous variables with separate analyzes of covariance. Potentially important predictor variables (the baseline score for the dependent variable, the F0ABQ work subscale score, and the CES-CD depression score) were used as covariates. Categorical outcomes (return to work, patient satisfaction) were compared using a  $\chi^2$  test of significance. All significance tests were two-tailed, with an alpha of 0.05 indicating significance. All outcome data were analyzed according to the intention to treat. The most recent follow-up scores were substituted when available for missing data at the 4-week and 1-year follow-up assessments. It was estimated that a sample size of 37 subjects per group would be needed to detect a difference of 10 points on the Oswestry questionnaire at 80% power with a two-tailed hypothesis and an alpha level of 0.05.

## ■ Results

For this study, 78 subjects were recruited as participants. Of these participants, 38% were women, 50% had a history of activity-limiting LBP, and 18% had symptoms extending below the knee. The mean age was  $37.4 \pm 10.4$  years, and mean duration of symptoms was  $5.5 \pm$



**Table 2. Baseline Characteristics of the Subjects**

Characteristic	Guideline Group (n = 37)	Classification Group (n = 41)
Age (y)	39.1 (10.3)	35.9 (10.3)
Gender (number of female subjects)	11 (30%)	19 (46%)
Prior history LBP (% with no prior history)*	17 (47%)	22 (54%)
Symptoms extending below the knee	5 (14%)	9 (22%)
Occupational group†		
Patient-care provider (%)	6 (16%)	17 (42%)
Other manual laborer (%)	27 (73%)	23 (56%)
Non-manual labor (%)	4 (11%)	1 (2%)
Duration of current episode (median days)*‡	4	3
Pain rating	6.8 (1.8)	6.5 (1.7)
CES-D depression score	12.8 (8.2)	13.4 (6.9)
Fear-avoidance beliefs about work	29.1 (8.6)	27.2 (8.8)
Physical impairment index (median)*‡	5	4
Oswestry disability score	42.8 (16.1)	42.9 (15.7)
SF-36 physical component score*	29.5 (7.7)	29.7 (8.0)
SF-36 mental health component score*	53.5 (9.8)	51.4 (8.6)
Classification group*		
Mobilization	15 (42%)	20 (49%)
Specific exercise	10 (28%)	13 (32%)
Immobilization	10 (28%)	4 (10%)
Traction	1 (3%)	4 (10%)

Values are means and (standard deviations) unless otherwise indicated.

\* One subject in the guideline group had missing data, n = 36 for the guideline group in this comparison.

† The only statistically significant difference between the treatment groups was for occupational group ( $P = 0.027$ ).

‡ Values given are medians due to non-normal data distribution.

4.6 days. Occupationally, 23 subjects (30%) were employed within the UPMC and directly involved in patient care (e.g., RN, LPN, nurse's aide, patient transport), 50 subjects (64%) had occupations involving regular manual labor but not directly related to patient care, and 5 subjects (6%) had occupations that did not involve regular manual labor. During randomization, 37 subjects

were assigned to the guideline-based group, and 41 to the classification-based group. The baseline characteristics of subjects in each group are presented in Table 2. The only significant baseline difference between the groups was the occupational distribution ( $\chi^2 = 7.2$ ;  $P = 0.027$ ). The classification-based group had a greater proportion of subjects employed in patient care positions, whereas the guideline-based group had a greater proportion of individuals involved in other manual labor occupations. Both the patient care and manual labor groups tended to involve moderate to heavy physical job demands. The overall percentage of patients with sedentary jobs was low, and did not differ statistically between the two groups. However, the differences in occupational grouping may have been a confounding variable for the analysis.

Characteristics of the treatments for both groups are described in Table 3. Two subjects in the guideline-based group did not attend any therapy sessions. Of the remaining 76 subjects, 15 (20%) were noncompliant with therapy, attending fewer than 50% of scheduled appointments. The proportion of noncompliant subjects did not differ between groups. Noncompliant and non-attending subjects were included in the data analysis, in keeping with the intention to treat. The subjects in both treatment groups attended a median of five therapy sessions. There were no differences between groups in the number of therapy sessions attended during the initial 4-week study period, or during the 1-year period after admission to the study (Table 3).

Medical cost data were available for all 78 subjects from the UPMC Employee Health database. Cost data for physical therapy could not be separated from total medical costs for five subjects (4 in the classification-

**Table 3. Physical Therapy Treatments**

Characteristic	Guideline Group (n = 37)	Classification Group (n = 41)	Significance
Number of subjects not attending any therapy sessions	2 (5%)	0	
Number of therapy appointments during initial 4 weeks			
Mean (SD)	5.7 (3.6)	5.4 (3.1)	
Median	5	5	0.47*
Range	0–12	1–9	
Number of therapy appointments during 1 year period			
Mean (SD)	6.7 (5.5)	6.2 (4.2)	
Median	6	5	0.45*
Range	0–18	1–21	
Number of subjects who did not attend >50% of scheduled therapy appointments	9 (26%)	6 (15%)	0.23†
Number of subjects attending therapy beyond the initial 4 weeks	6 (17%)	4 (10%)	0.37†
Cost of therapy treatments during 1 year period			
Mean (SD)	\$682.23 (647.44)	\$604.47 (549.63)	
Median	\$599.00	\$465.70	0.08‡
Range	\$0.0–3583.06	\$96.58–1830.08	
Total medical costs incurred during 1 year period:			
Mean (SD)	\$1160.24 (1002.89)	\$883.37 (826.92)	
Median	\$1003.68	\$774.00	0.13‡
Range	\$190.00–5966.06	\$221.92–2841.00	

\* Significance tested with Mann-Whitney  $U$  test due to non-normal distribution of data.

† Significance tested with  $\chi^2$  test.

‡ Significance tested with two-sample Kolmogorov-Smirnov test to test the null hypothesis that the two samples possessed the same distribution.

**Table 4. Distribution of Subjects Incurring High/Low Medical Costs**

	Guideline Group (n = 37)	Classification Group (n = 41)
Number of subjects incurring high costs	13	7
Number of subjects incurring low costs	24	34

$\chi^2$  test:  $P = 0.068$ .  
Relative risk: 2.1 (0.92, 4.6).  
Number needed to treat: 5.5 (2.7, infinity).

based group and 1 in the guideline-based group). For these five subjects, the cost of physical therapy was estimated from the average cost per visit for the other study subjects who attended the same therapy clinic in the same calendar year. The Kolmogorov–Smirnov test failed to reject the hypothesis that the distribution of cost data was the same between treatment groups for either the cost of physical therapy ( $P = 0.08$ ) or total medical costs ( $P = 0.13$ ) over a 1-year period. Exclusion of the two patients in the guideline-group who did not attend any therapy from the analysis of therapy costs resulted in a statistically significant result ( $P = 0.047$ ), indicating that the distribution of costs differed between groups, with the costs for the classification-based group showing a smaller median value (\$465.70) than the costs for the guideline-based group (\$616.00).

Similar to the findings of others,<sup>46,47</sup> cost data showed a negatively skewed distribution, with 25% (20 subjects) accounting for 51% of the total medical costs. Of the 20 subjects incurring high medical costs, 13 were in the guideline-based group and 7 in the classification-based group (Table 4). The relative risk of incurring high costs for subjects in the guideline-based group was 2.1, as compared with the risk in the classification-based group. The number needed to treat calculated from the group

proportions was 5.5, indicating that an additional 6 subjects would need to be treated with classification-based therapy to avoid one additional subject incurring high medical costs.

Eleven subjects (14%) did not complete the 4-week follow-up evaluation (5 guideline-based and six classification-based subjects). Each of these subjects was contacted for follow-up evaluation, but chose not to return for reassessment. An additional three subjects had 2-week follow-up data for the Oswestry, and six subjects had 2-week data for the physical impairment index. At the time of the 1-year follow-up assessment, 51 subjects (65%; 27 guideline-based and 24 classification-based subjects) completed the self-report outcome measures. When available, 6-month or 4-week data were substituted for subjects with missing data. The 1-year phone interview was completed by 67 patients (86%; 32 guideline-based and 35 classification-based subjects).

Outcomes at 4 weeks showed statistically significant differences in change in the Oswestry and PCS scores favoring the classification-based therapy group (Table 5). Change in the MCS, adjusted for the baseline variables, approached statistical significance ( $P = 0.052$ ) and also favored the classification-based group. The classification-based group had a higher median satisfaction score ( $P = 0.006$ ). There were no differences between the groups in physical impairment changes ( $P = 0.18$ ). After 1 year, differences between groups for the PCS or MCS change scores were no longer significant. Changes in the Oswestry score continued to favor the classification-based group, with the adjusted scores approaching statistical significance ( $P = 0.063$ ).

After 4 weeks, 15 subjects (42%) in the guideline-based group and 7 subjects (17%) in the classification-based group continued to have work restrictions (Tables 6 and 7). The relative risk of persistent work restrictions

**Table 5. Four-Week Outcomes**

Variable	Baseline (n)	Four-Week (n)	Mean Within-Group Change (SD)	Between-Group Difference (95% CI)	<i>P</i> Value	Adj. <i>P</i> Value*
Modified Oswestry						
Guideline-based group	42.8 (37)	32.4 (32)	11.6 (18.1)			
Classification-based group	42.9 (41)	21.4 (38)	22.5 (19.3)	10.9 (1.9, 19.9)	0.018	0.023
SF-36: PCS						
Guideline-based group	29.5 (36)	36.8 (32)	−8.0 (11.3)			
Classification-based group	29.7 (41)	43.0 (35)	−13.6 (9.3)	5.6 (0.6, 10.7)	0.030	0.029
SF-36: MCS						
Guideline-based group	53.5 (36)	50.6 (32)	3.5 (8.5)			
Classification-based group	51.4 (41)	52.2 (35)	−2.1 (7.4)	5.7 (1.8, 9.5)	0.005	0.052
Physical impairment†						
Guideline-based group	5 (36)	4 (33)	2			
Classification-based group	4 (41)	2 (40)	2	1 (0, 2)	0.18	
Patient satisfaction‡						
Guideline-based group		11 (30)				
Classification-based group		13 (33)		2 (1, 3)	0.006	

\* The *P* values were adjusted for baseline levels of the dependent variable, depressive symptoms, and fear-avoidance beliefs about work.

† Physical impairment was measured on a 0–7 scale with higher numbers indicating greater levels of impairment. Values presented are medians and significance was tested with a Mann–Whitney *U* test.

‡ Patient satisfaction was measured on a 0–15 scale with higher values indicating greater levels of satisfaction. Values presented are medians and significance was tested with a Mann–Whitney *U* test.

**Table 6. One-Year Outcomes**

Variable	Baseline (n)	One-Year (n)	Mean Within-Group Change (SD)	Between-Group Difference (95% CI)	P Value	Adj. P Value*
Modified Oswestry						
Guideline-based group	42.8 (37)	25.8 (35)	17.4 (20.6)			
Classification-based group	42.9 (41)	17.4 (39)	26.4 (16.9)	9.0 (0.30, 17.7)	0.044	0.063
SF-36: PCS						
Guideline-based group	29.5 (36)	40.7 (34)	-12.0 (12.8)			
Classification-based group	29.7 (41)	45.0 (35)	-15.6 (10.7)	3.6 (-2.1, 9.3)	0.21	0.20
SF-36: MCS						
Guideline-based group	53.5 (36)	51.3 (34)	2.9 (11.2)			
Classification-based group	51.4 (41)	50.8 (35)	-0.74 (9.6)	3.6 (-1.4, 8.7)	0.15	0.82

\* The P values were adjusted for baseline levels of the dependent variable, depressive symptoms, and fear-avoidance beliefs about work.

after 4 weeks for subjects in the guideline-based group was 2.4 times that for subjects in the classification-based group. The number needed to treat was 4.1, indicating that approximately four additional subjects would need to be treated with classification-based therapy to prevent one additional subject from having persistent work restrictions. After 1 year, two subjects (1 in the guideline-based group and one in the classification-based group) remained off work entirely. Two subjects, both in the guideline-based group, continued to require restrictions to work duties (restricted lifting capacity) after 1 year. During the year after the initial injury, 17 subjects (11 in guideline group and 6 in the classification group) missed at least 1 day of work because of LBP after the 4-week therapy period (Table 8). The relative risk of missing additional work because of LBP for subjects in the guideline-based group was two times that for subjects in the classification-based group. The number needed to treat was approximately six subjects.

## Discussion

Current research evidence has led to the recommendation that general activity within the limitations of pain is the best initial management for patients with acute LBP, and more specific interventions are not indicated during the first 4 to 6 weeks of management.<sup>7,12,13,48</sup> The recently published report of the International Paris Task Force on Back Pain summarized the evidence for patients with acute LBP by stating, "It appears that the key to success is physical activity itself (*i.e.*, activity of any form) rather than any specific activity."<sup>12</sup> Some clinical guidelines do recommend manipulation as an option for pain relief in the acute stage.<sup>11,13,14</sup> However, no attempt

is made to select particular patients most likely to respond to the treatment. This study sought to match specific treatments to patients presenting with certain clusters of signs and symptoms, and to permit therapists to adapt the treatment as the patient's presentation changed. The classification criteria for each treatment group were based on published data, clinical experience, and pilot data suggesting the existence of more homogeneous subsets of patients with acute LBP who can be identified reliably, whose prognosis may differ, and who may respond more favorably to an intervention specific to their presentation.<sup>22,28-30,49-51</sup>

With the classification system used in this study, the patient is placed into one of four classifications, each with its own treatment approach. Patients with signs and symptoms that suggest movement restrictions of the lumbar of sacroiliac region are treated with joint mobilization-manipulation techniques and range of motion exercises. Patients exhibiting the centralization phenomenon during lumbar range of motion testing are treated with the specific exercises (flexion or extension) that promote centralization of symptoms. The centralization phenomenon has been identified as an important clinical finding,<sup>52-54</sup> and exercises that promote centralization may improve outcomes in these patients. Numerous findings from the patient's history or physical examination (*e.g.*, frequent previous episodes with minimal perturbations, "instability catch") reportedly are associated with clinical instability,<sup>55,56</sup> and patients with these findings are treated with a trunk strengthening and stabilization exercise program.

Finally, patients with signs of nerve root compression who do not demonstrate centralization during the exam-

**Table 7. Return to Work Status After Four Weeks**

	Guideline Group (n = 36)	Classification Group (n = 41)
No work restrictions	21	34
Continued work restrictions	15	7

$\chi^2$  test:  $P = 0.017$ .

Relative risk: 2.4 (1.1, 5.3).

Number needed to treat: 4.1 (2.3, 19.6).

**Table 8. Additional Missed Work Due to Low Back Pain Over One Year Period**

	Guideline Group (n = 32)	Classification Group (n = 35)
No additional missed work	21	29
Additional work missed due to low back pain	11	6

$\chi^2$  test:  $P = 0.11$ .

Relative risk: 2.0 (0.84, 4.8).

Number needed to treat: 5.8 (1.5, infinity).

ination are treated with spinal traction. More detailed descriptions of the patient classifications have been published elsewhere.<sup>22,30</sup> These four treatment approaches are consistent with those widely used by physical therapists,<sup>5,6,57</sup> yet indications for their application have not been adequately studied. There is some evidence supporting the use of manipulation,<sup>48,58</sup> stabilization exercises,<sup>59</sup> and specific exercises.<sup>60,61</sup> However, when these treatments have been applied in clinical trials without an attempt to decide which patients may respond to particular a treatment, the results are generally equivocal,<sup>62-64</sup> leading to the contention that these treatments offer no benefits beyond what could be achieved by reassurance, encouragement, and general activity.<sup>7,65,66</sup>

The design of this study does not permit any conclusions to be drawn regarding the effectiveness of any of the individual treatments used. In addition, the generalizability of the decision-making criteria used in this study has not been examined. The results however, support the need for further efforts to determine the optimum methods for matching specific treatments to patients with particular clinical presentations.

The classification system used takes into account that patients with acute LBP are expected to demonstrate change in their clinical presentation over the course of treatment. Previous research has shown that treatments administered for LBP by physical therapists vary between patients, as well as within episodes of care, and usually are based on examination findings.<sup>57,67</sup> Whereas clinical practice guidelines appear to prescribe the same treatments for patients throughout an episode of acute LBP (*i.e.*, reassurance, low-stress aerobic exercise, general muscle conditioning), patients in the classification-based group received treatments believed to be specific to the individual's presentation, and therapists were allowed to alter the treatment as the presentation changed. In the authors' experience, patients with LBP frequently change classifications throughout their clinical course, requiring modifications in the treatment used. In this study, the classification-based therapy resulted in better outcomes for disability, return to work, and patient satisfaction after 4 weeks than an approach in which all patients continued to receive treatments advocated by clinical practice guidelines regardless of presentation. Changes in impairment were not significant, which was not unexpected given the dissociation frequently observed between impairment and disability in patients with LBP.<sup>68</sup> The differences in functional recovery as measured by the Oswestry questionnaire persisted for 1 year after the completion of treatment. The results support the effectiveness of a classification approach to physical therapy that seeks to match treatments to the patient's presentation and permits reassessment and revision of treatments as the presentation changes. The design used in this study does not permit conclusions regarding the efficacy of any individual treatment used.

All the subjects in this study had work-related LBP, which can have a negative impact on clinical outcomes.<sup>69</sup>

Despite the potentially worse prognosis, the initial management recommendations in clinical practice guidelines targeting work-related LBP do not differ from those developed for primary care populations.<sup>12,15</sup> Studies have found that individuals not returning to work within the first 4 to 8 weeks after injury are at increased risk for long-term disability,<sup>70</sup> suggesting a need for early, effective interventions in patients with acute, work-related LBP. Furthermore, Loisel *et al*<sup>71</sup> found that individuals with LBP remaining in modified work duties often were unable to resume full work activities, indicating that the goal of treatment should be return to full, not modified, work duty. The current results suggest that a classification-based approach tailoring interventions to the specific presentation of the individual patient is more effective for promoting early return to full duty work status than an approach of encouragement, reassurance, and low-stress aerobic activity.

Consistent with an effectiveness trial, there was not control for what rate of physical therapy used in the first 4 weeks of the study. The decision to continue or discontinue physical therapy was left to the physician, who used data that normally would be used for such decisions (*e.g.*, patient feedback with regard to functional status, input from the physical therapist). The authors believe their approach represents the standard of care practiced in most work-related injury environments, in which physical therapy is used, depending on the functional status and work readiness of the patient. When a patient has reached optimal outcome (low functional disability and return to work), physical therapy is typically discontinued. There also was no control used for the interventions in the period between the completion of the first 4 weeks of treatment and the 1-year follow-up evaluation. The sustained improvement in Oswestry disability scores in the classification-based group, which exceeded the threshold for clinical importance<sup>32</sup> and approached statistical significance ( $P = 0.06$ ) even after 1 year, indicates the potential impact of initial therapy decisions on long-term outcomes.

Clinical practice guidelines<sup>13-16</sup> generally emphasize reassurance and advice to remain active as the most important initial management strategies for patients with LBP. These management strategies would not necessarily require the involvement of a physical therapist. The current authors chose to have patients randomized into the guideline-based group see a physical therapist to reduce the likelihood of a differential placebo effect between the groups. This approach may have inflated the number of therapy appointments and medical costs in the guideline-based group. However, the potential for bias resulting from differences in attention was reduced.

The results of this study must be considered in light of several limitations. The sample size was relatively small, providing adequate power for only the short-term outcomes. The participating therapists were trained to provide both treatment approaches used in this study, and although the number of therapy appointments given to



each group was equal, the potential influence of the therapists cannot be discounted. Although blinding of therapists would not be possible in a study such as this, the potential for bias may have been reduced if therapists had delivered only one treatment or the other. A baseline difference in occupational groupings was found between the two treatment groups, which may have influenced the results. The sample consisted entirely of patients with work-related LBP treated within one system, so the findings may not be directly generalizable to a broader population of patients with acute LBP. The number of potentially eligible patients not participating in this study was not documented, which may further limit the generalizability of the results. Many patients with work-related LBP over the study period did not participate. The most common reasons for nonparticipation appeared to be the lack of a need for work restrictions and refusal by the patient.

### ■ Conclusions

Better short-term outcomes were found for patients with acute, work-related LBP when they were treated using a classification-based approach to physical therapy instead of an approach based on the recommendations of clinical practice guidelines without regard for an individual patient's signs and symptoms. Although the current study examined only one patient population and clinical environment, the authors believe that identifying relevant classifications of patients with LBP will improve clinical outcomes, and will enhance the power of future clinical trials. Further research is needed to define optimum criteria for classifying and treating patients with acute LBP.

### ■ Key Points

- Patients with acute, work-related low back pain treated using a classification-based approach to physical therapy instead of an approach based on the recommendations of clinical practice guidelines showed greater improvement in disability 4 weeks after initiation of treatment.
- Patients treated using a classification-based approach instead of an approach based on clinical practice guidelines were more likely to return to unrestricted work within the first 4 weeks after treatment.
- Patients treated using a classification-based approach instead of an approach based on clinical practice guidelines were more satisfied with their treatment after 4 weeks.
- Treatment using a classification-based approach did not result in increased medical costs, and instead showed a trend toward decreased costs, as compared with an approach based on clinical practice guidelines.

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## ■ Point of View

Stephen L. Gordon

Acute low back pain is one of the most frequently occurring medical conditions. Fortunately, most affected individuals will recover in less than 2 months regardless of what therapeutic intervention is applied. In general, patients are advised to return to normal activity as quickly as pain allows and to avoid complete bed rest. This normally positive outcome does not mean that patients should be denied improved treatment plans when they are practical and cost-effective. Patients may be able to get past the pain and disability stage as quickly as possible and reduce the chance of progressing to a chronic condition.

The current study by Fritz and colleagues compares the effectiveness of a patient-specific, classification-based physical therapy with therapy based on general clinical practice guidelines in a group of patients with acute, work-related low back pain. There is an inherent potential advantage of any treatment that is reasonable and specific to the patient's medical status over treatment based on a one-size-fits-all treatment. The guideline-based treatment group received the same generalized treatment used for all patients. A four-level classification system, pre-

viously described by the authors, defines corresponding exercises and physical methods for each patient-specific category. Periodic reassessment of signs and symptoms allowed the classification and treatment to change during the course of therapy. Although the evaluative process is relatively simple, it may not be practical to reassess with such frequency in normal clinical settings.

A comprehensive battery of outcome questionnaires and assessments was performed at baseline and weekly for 4 weeks. Telephone interviews and self-report questionnaires were completed at 6 months and 1 year. The number of therapy sessions was equal between the two groups. In general, although not all the outcome measures reached statistical significance, the classification-based approach was more effective and cost less throughout the evaluation period than the guideline-based approach. Small sample size, unbalanced patient occupations, a single employment system, and unblinded treatment providers may limit generalization of these outcomes. This is an encouraging study indicating that there may be a better means of applying physical therapy treatment to acute patients with low back pain. Further studies should be conducted to confirm these results.

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