

# Treatment of Acute Low Back Pain in Wisconsin: Results of the State Medical Society's Medical Outcomes Research Project

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## ABSTRACT

**Background:** Acute low back pain is the fifth most common reason for physician visits. Multiple treatment options are available, but not all physicians and patients are satisfied with the results. This study evaluated treatment outcomes from patients' perspectives using standardized measures.

**Methods:** 368 patients with acute low back pain were enrolled in the study. Only 128 participants (35%) completed all 4 health outcome questionnaires (administered at baseline, 6 weeks, 3 months, and 1 year).

**Results:** Most participants reported improved health at 1-year follow-up, with the most significant gains achieved by 3 months. However, 40% were not satisfied with their outcome. Patients with radicular low back pain scored lower on health outcome measures than patients without radicular symptoms.

**Conclusion:** A sizeable percentage of patients with acute low back pain progress to chronic pain despite therapeutic intervention. Patients with radiculopathy may require nonstandard treatment to avoid unfavorable outcomes.

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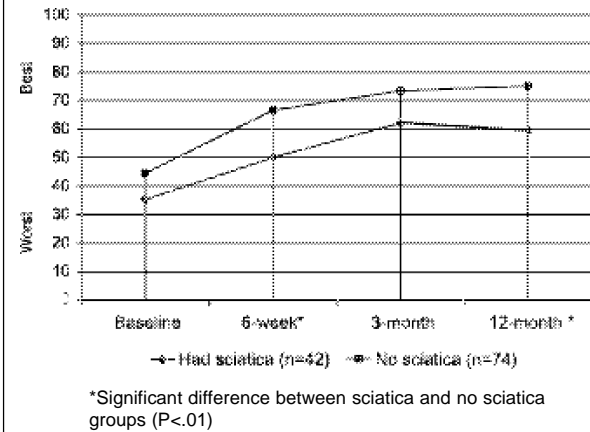
## INTRODUCTION

Acute low back pain is the fifth most common reason for all physician visits.<sup>1</sup> Low back pain is the most common chronic pain condition among patients seen by primary care physicians.<sup>2</sup> The annual incidence of back pain in the United States is 30% to 60%, and low back pain is the most common cause of disability in people under age 45. As many as 80% of Americans will be functionally limited by back pain at some time during their lives.<sup>1</sup> An on-line search of the MEDLINE literature database failed to reveal any prior studies documenting the incidence or prevalence of acute low back pain in Wisconsin.

In 1994 the Agency for Health Care Policy and Research (AHCPR, recently renamed the Agency for Healthcare Research and Quality) published a clinical practice guideline for the treatment of acute low back problems in adults. A 23-member multidisciplinary panel reviewed several thousand scientific articles on the clinical and scientific aspects of low back pain, and based their consensus on those studies that were most methodologically sound. Even so, it is interesting to note that the majority of their recommendations were based on "limited research-based evidence" (defined as at least one adequate scientific study meeting minimal formal criteria for methodology). The essential "take home message" of the AHCPR guidelines can be summarized as follows:

In the absence of 'red flags' [e.g. a history of prior cancer, unexplained weight loss, history of trauma, immunosuppression, recent infection, IV drug use, saddle anesthesia, bladder dysfunction, and/or progressive neurologic deficit involving the lower limbs], neither routine nor special testing is required in the first month of symptoms for either [sciatica or non-specific low back pain]. Most of these patients

**Figure 1. Physical Health & Pain Scale**



will recover spontaneously from their activity limitations within one month. (p. 2)

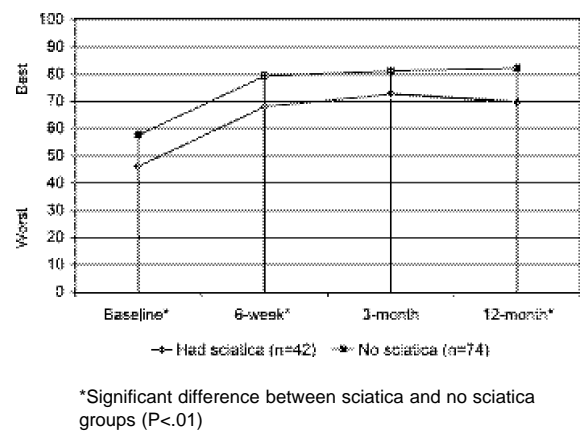
The working hypothesis of the State Medical Society of Wisconsin's Low Back Pain Study Group was that despite the AHCPR guidelines, the management of low back pain continues to vary widely and in ways that cannot be explained on the basis of patient differences or upon known efficacy of the different methods of care.<sup>4</sup> This variation in treatment methods affects patient outcomes in terms of functional status, quality of life, employment status, and satisfaction with the medical care received. Indeed, as suggested above, the benefits of most of the methods of care for acute low back pain remain relatively unproven. We proposed that outcomes measurement and research, based upon information given by patients about the end results of their care, would provide valid indicators showing which care is best. It was furthermore our hope that these "best care" approaches would permit practitioners who routinely care for patients with low back pain to improve their own practices. Unfortunately, due to inadequacies of the survey instrument that became evident only after the study was underway, the existing data do not permit us to make conclusions as to the optimal treatments for different low back conditions. However, we remain convinced that there is no better way to evaluate and improve the quality of our practices than to determine the real outcome of what we do, as perceived by our patients.

## METHODS

### Study Design

The study design was a prospective cohort survey of patients in Wisconsin with acute low back pain.

**Figure 2. Pain & Disability Scale**



### Participants and Procedure

Data were collected from patients at 14 sites throughout Wisconsin between March 1999 and March 2000. Taken together, these 14 sites served both rural and urban areas, and included both primary care and tertiary care facilities. Study sites identified patients between the ages of 18 and 65, who presented with complaints of low back pain of less than 6 weeks duration. Using continuous open enrollment, patients were identified when they called for an appointment or after they arrived at the medical facility. Walk-in patients were eligible, and every attempt was made to identify and recruit walk-in patients with acute low back pain. The project was designed to allow any willing physician in Wisconsin to participate. However, there was no requirement that all physicians from each participating office or clinic participate in the study. Recruitment of physicians was via the State Medical Society of Wisconsin (SMS). There was no patient or physician compensation for participating in the study.

Although specific personnel varied by site, in general a staff person at each study site identified eligible patients and invited them to participate in the study. Study participation involved completing a survey at the time of the initial physician visit and then at 6 weeks, 3 months and 1 year following the baseline survey. Patients were informed that their participation in the study was voluntary and that the data from the surveys would be coded in such a way that when analyzed in aggregate by the SMS no individual would be identifiable. Only the study sites knew patients' identities. Study sites transferred blinded survey data to the SMS for data entry and analysis. The Marshfield Clinic Institutional Review Board

**Table 1. SF-36 Scores by Survey Period (Scoring: 0 = Worst Health to 100 = Best Health)**

Outcome	Baseline survey	6 week survey	3 month survey	12 month survey	Normative scores for US Population **
	mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)
Physical Functioning	58.5* (28.3)	74.4* (25.7)	77.8* (25.9)	78.6 (24.7)	84.2 (23.3)
Role Physical	29.4* (38.1)	54.6* (44.7)	68.7* (41.3)	68.3* (41.0)	81.0 (34.0)
Bodily Pain	34.0* (20.5)	57.2* (24.7)	63.1* (23.5)	62.0* (24.6)	75.2 (23.7)
General Health	68.9 (18.0)	70.0 (16.6)	69.1 (18.1)	68.0 (17.9)	72.0 (20.3)
Vitality	51.6* (20.7)	56.4 (20.8)	57.2 (20.9)	58.6 (21.4)	60.9 (21.0)
Social Functioning	67.8* (25.8)	76.9* (25.2)	81.3 (23.9)	81.9 (24.9)	83.3 (22.7)
Role Emotional	82.8 (32.8)	86.6 (29.5)	85.3 (31.3)	88.1* (28.1)	81.3 (33.0)
Mental Health	73.5 (16.1)	75.1 (16.8)	76.2 (17.7)	77.0 (17.1)	74.7 (18.1)
Physical Component Summary	33.8* (9.8)	42.3* (11.2)	45.1* (11.3)	44.4* (10.7)	50.0 (10.0)
Mental Component Summary	53.2* (8.9)	52.3* (8.7)	51.9 (9.2)	52.8* (8.8)	50.0 (10.0)

\* indicates a significant difference between LBP study population mean score and US population mean score (P<.01)  
 \*\*Source: Ware JE. SF-36 Health Survey: Manual & Interpretation Guide. Boston, MA: New England Medical Center, 1993.

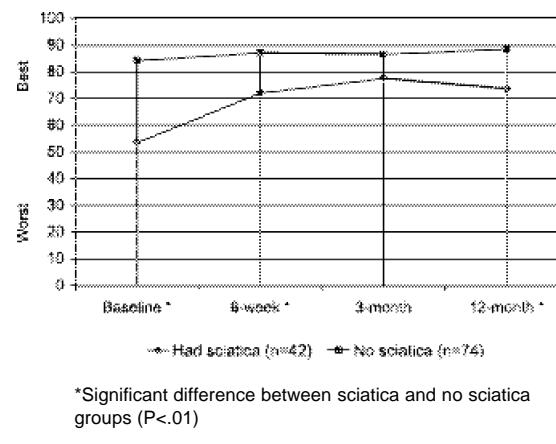
approved the research protocol. Patients who agreed to participate in the study were asked to give written informed consent.

The baseline patient survey was completed, if at all possible, before the patient saw the physician. After the patient encounter, the attending physician rated the patient's symptom severity on the Physician Survey. In addition, the physician was asked to classify the patient's symptoms according to the system devised by Nachemson and Andersson and subsequently extended by the Quebec Task Force on Spinal Disorders.<sup>5</sup> Information about the primary and secondary ICD-9 diagnosis codes and the CPT procedure code(s) for any corresponding treatment administered was also requested. After the appointment, the patient completed the Patient Satisfaction Survey.<sup>6</sup> Each site mailed follow-up surveys to participants at 6 weeks, 3 months, and 12 months.

### Measures

The Lumbar Spine Questionnaire of the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) was used for data collection.<sup>7</sup> The MODEMS program was designed to permit musculoskeletal caregivers to assess the outcomes of treatment for most patient populations and conditions. The Lumbar Spine Questionnaire was designed specifically and validated for use with patients presenting with conditions affecting the lumbar portion of the spine.<sup>8</sup> The questionnaire includes sections on demographics, history, general health status, comorbidities, expectations, and joint-related

**Figure 3. Neurogenic Symptoms Scale**



pain and function. In a study designed to test the reliability and validity of the instrument, test-retest reliability and internal reliability coefficients ranged from 0.85 to 0.97. The Pain and Disability and Neurogenic Symptoms subscales discriminated among patients judged successful by their physicians after surgery.<sup>8</sup> There are baseline and follow-up versions of the questionnaire.

### Comorbidities

Information on patient comorbidities was collected. The questionnaire inquired as to a history of and treatment for several conditions, including heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, anemia or other blood disease, cancer, depression,

**Table 2.** Sciatica and Health Status Scores - Mean (SD)

Scale	Description	Scores for patients with ...	Baseline	6-week	3-month	12-month
Physical Health & Pain		All 4 surveys & Dx info (n=116)	41.3 (24.7)	60.7 (29.0) *	69.5 (27.6) *	69.4 (27.0)
		No Sciatica (n=74)	44.6 (25.1)	66.7 (26.8) **	73.5 (24.5)	75.2 (23.5) **
		Sciatica (n=42)	35.4 (23.2)	50.1 (30.0)	62.3 (31.5)	59.5 (29.8)
Pain & Disability		All 4 surveys & Dx info (n=116)	53.5 (20.2)	75.2 (20.7) *	78.2 (19.4)	77.8 (20.4)
		No Sciatica (n=74)	57.7 (19.5) **	79.4 (17.3) **	81.3 (16.3)	82.3 (17.1) **
		Sciatica (n=42)	46.1 (19.3)	68.2 (24.0)	72.6 (23.1)	69.8 (23.3)
Neurogenic Symptoms		All 4 surveys & Dx info (n=116)	73.2 (28.9)	81.7 (24.5) *	83.4 (22.1)	83.2 (22.9)
		No Sciatica (n=74)	84.3 (20.8) **	87.2 (19.9) **	86.7 (21.3)	88.7 (18.1) **
		Sciatica (n=42)	53.6 (31.0)	72.1 (28.8)	77.6 (22.4)	73.7 (27.3)

Higher scores indicate better health  
 \*Significant difference from previous survey (P<.01)  
 \*\*Significant difference between sciatica and no sciatica groups (P<.01)

osteoarthritis-degenerative arthritis, and rheumatoid arthritis.

## HEALTH STATUS

### *SF-36 General Health Status*

The Short Form (SF)-36 (included as part of the MODEMS instrument) was used to measure general health-related quality of life.<sup>9</sup> The SF-36 includes 36 questions that are used to provide a common metric that is useful for comparing patients with health problems to the general population. The 36 questions are scored into 8 scales: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH). Two component summaries, the Physical Component Summary (PCS) and the Mental Component Summary (MCS), are computed from the 8 scales following a standard formula.<sup>10</sup> Scores for all scales range from 0 to 100, with higher scores indicating better health.

## LOW BACK RELATED HEALTH STATUS

### *Radicular Low Back Pain*

Patients were considered to have radicular low back pain (“sciatica”) if the appropriate ICD-9 code was specified, or if the patient’s symptoms were coded on the Physician Survey as “pain plus radiation to extremity (proximally or distally)” or “pain plus lower limb-neurologic signs.” Pain without radiation was considered indicative of non-radicular low back pain.

### *Physical Health and Pain*

The MODEMS Physical Health and Pain scale is the average of the 3 SF-36 physical health scales (Physical Functioning, Role Physical, and Bodily Pain). Scale

scores range from 0 to 100, with higher scores indicating better health.

### *Pain and Disability*

The MODEMS Pain and Disability scale is derived from patient responses to questions examining whether they had experienced low back and/or buttock pain and had trouble performing daily activities during the preceding week. Examples of daily activities include getting dressed, lifting, walking and running, sitting, standing, sleeping, social and recreational life, traveling, and sexual activity. Pain and Disability scale scores range from 0 to 100, with higher scores indicating better health (i.e. freedom from pain and disability).

### *Neurogenic Symptoms*

The MODEMS Neurogenic Symptoms scale is derived from responses to whether the patient suffered from or was bothered by leg pain, numbness/tingling in leg and/or foot, or weakness in leg and/or foot in the past week. Neurogenic Symptoms scale scores range from 0 to 100, with higher scores indicating better health (i.e. freedom from neurogenic symptoms).

## PATIENT SATISFACTION

### *Symptom Severity*

Symptom severity as perceived by the patient was measured by the following question and response choices: “Compared to when you last completed the questionnaire, is your musculoskeletal condition: much better now, somewhat better now, about the same, somewhat worse now, or much worse now?”

### *Satisfaction with Symptoms*

Satisfaction with Symptoms was measured by the following question, “If you had to spend the rest of

your life with the symptoms you have right now, how would you feel about it?" Responses were measured using a 5-point Likert scale ranging from "very dissatisfied" (1) to "very satisfied" (5).

#### *Treatment Expectations Met*

Patients were asked about the results they expected from treatment in the following areas: relief from symptoms to: do more everyday activities, sleep more comfortably, go back to their usual job, exercise and do recreational activities, prevent future disability. The baseline survey contained the following question, "What results do you expect from treatment?" Responses were measured for each area using a 5-point Likert scale ranging from "not at all likely" (1) to "extremely likely" (5). Follow-up surveys contained the following question, "Are the results of your treatment what you expected?" Responses were measured using a 5-point Likert scale ranging from "definitely yes" (1) to "definitely not" (5). Both baseline and follow-up questionnaires contained the response option of "not applicable."

#### *Satisfaction with Treatment Choice*

Satisfaction with treatment choice was measured by the following question, "If you could go back in time and make the decisions again would you choose the same treatment for your musculoskeletal condition/problem?" Responses were measured using 5-point Likert scale ranging from "definitely yes" (1) to "definitely not" (5).

#### *Satisfaction with Health Care Provider*

Patients' satisfaction with their health care provider was measured by patients' responses to the following question, "Would you recommend the person you saw to family or friends?" Responses were measured using a 4-point Likert scale ranging from "definitely not" (1) to "definitely yes" (4). Satisfaction was measured at baseline and 12-month follow-up only.

#### *Statistical Methods*

Where applicable, an analysis of variance (ANOVA) was performed on the data prior to analyzing individual effects in order to control for Type I error. In addition, given the exploratory nature of the study, several specific comparisons were of interest, so an alpha level of 0.01 was chosen for these analyses.

## RESULTS

#### *Demographics*

Of the 368 patients who completed baseline surveys, 35% (128) completed all three follow-up surveys. Only those 128 patients who completed all four sur-

veys were included in the present analysis. Patients who completed all four surveys were significantly older than patients who did not complete all four surveys, but the groups did not differ in terms of gender. Patients who completed all four surveys did not differ from patients who did not complete all four surveys on health status scores at baseline (SF-36 Physical Component Summary, Physical Health and Pain, Neurogenic Symptoms, Pain and Disability). The average age of the 128 participants at baseline was 43.2 years (SD 10.9), and 57% were male. Ninety-eight percent of patients were white, 75% were married, and 77% were working. Seventy percent of patients were overweight or obese (BMI  $\geq$  25).

#### *Comorbidities*

Fifty-two percent of patients reported having at least one comorbidity, and 14% of patients reported that at least one comorbidity limited their level of activity. The most common comorbidities were arthritis (13%) and high blood pressure (12%).

## HEALTH STATUS

#### *SF-36 General Health Status*

Compared to normative scores for the US Population, patient scores on the SF-36 Physical Component Summary were lower (indicating worse health) across all survey periods (Table 1). Conversely, higher scores (suggesting better health) were noted on the Mental Component Summary across the four questionnaires, with the exception of the 3-month follow-up where there was no significant difference when compared to US population scores.

In general, Physical Component Summary scores improved over the survey periods. By comparison, the Mental Component Summary scores did not change significantly over the survey period. Significant differences in the Physical Component Summary scores occurred between baseline and the 6-week follow-up and between the 6-week and 3-month follow-ups. There were no significant differences between the 3-month and 12-month scores on any of the SF-36 scales.

#### *Physician-Coded Radicular Symptoms and Health Status*

Physician-coded symptom information was available for 116 of the 128 patients who completed all four surveys. Of the 116 patients, 42 (36%) had radicular symptoms and 74 (64%) had no symptoms suggestive of sciatica. Table 2 shows means and standard deviations for health status measures related to low

back pain for the 116 patients with physician-coded symptom information. Asterisks indicate measures with significant ( $P < .01$ ) differences.

#### *Physical Health and Pain*

In general, Physical Health and Pain scores improved over survey periods. More specific analysis indicated that those differences were significant between baseline and 6-week follow-up and between the 6-week and 3-month follow-ups. However, the difference between the 3-month and 12-month follow-ups was not statistically significant.

Patients with radicular symptoms tended to score lower than patients without radicular symptoms across all survey periods on Physical Health and Pain. Those differences between the sciatica and no sciatica groups were largest at the 6-week follow-up and the 12-month follow-up.

#### *Pain and Disability*

In general, Pain and Disability scores improved over survey periods. However, the improvement was largest between baseline and the 6-week follow-up. The difference between the 6-week and 3-month follow-ups was marginally significant ( $P = .011$ ). The difference in Pain and Disability scores between the 3-month and 12-month follow-ups was not statistically significant.

Patients with radicular symptoms tended to score lower than patients without radicular symptoms across all survey periods on the Pain and Disability scale (Figure 2). These differences between the sciatica and no sciatica groups were largest at baseline and at the 6-week and 12-month follow-ups.

#### *Neurogenic Symptoms*

In general, Neurogenic Symptoms scores improved over survey periods. Scores were also generally higher for the no sciatica group (Figure 3). However, these improvements over time and differences between groups were not consistent. Scores in the no sciatica group were generally high and increased only slightly over survey periods. Scores in the sciatica group were generally lower but increased significantly from baseline to the 6-week follow-up. As a result, the difference between the sciatica and no sciatica groups was largest at the baseline time period. The differences, although smaller, continued to be significant at the 6-week follow-up and the 12-month follow-up.

## **PATIENT SATISFACTION**

#### *Symptom Severity*

The number of patients who indicated that their

musculoskeletal condition was much better or somewhat better than the last time they completed the survey was compared across follow-up surveys. At the 6-week follow-up, 76% of patients indicated that their condition was better than at baseline. At the 3-month follow-up, 52% of patients indicated that their condition was better than at the 6-week follow-up. At the 12-month follow-up, 47% of patients indicated that their condition was better than at the 3-month follow-up. At the 12-month follow-up, 15% of patients indicated that their musculoskeletal condition was much or somewhat worse than at the 3-month follow-up.

#### *Satisfaction with Symptoms*

At the 12-month follow-up, 39% of patients responded "very satisfied" or "somewhat satisfied" to the question, "If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?" (compared to 10% at baseline). The percent of patients who responded "somewhat dissatisfied" or "very dissatisfied" decreased from 89% at baseline to 49% at the 12-month follow-up.

#### *Treatment Expectations Met*

Although 83% of patients at baseline expected that relief from symptoms was extremely likely or very likely, only 60% at the 12-month follow-up indicated that this expectation was met.

At 6-week, 3-month, and 12-month follow-ups, higher (better) Physical Component Summary scores and Physical Health and Pain scores were positively correlated with higher scores on Treatment Expectations Met for the same survey period.

#### *Satisfaction with Treatment Choice*

At the 12-month follow-up, 69% of patients responded "definitely yes" or "probably yes" to the question, "If you could go back in time would you choose the same treatment?"

#### *Satisfaction with Health Care Provider*

At baseline, 58% of patients indicated that they would recommend their health care provider to family or friends. At the 12-month follow-up, only 40% indicated that they would make this recommendation.

## **DISCUSSION**

The purpose of this study was to evaluate the outcomes of the treatment for acute low back pain from the patient perspective using a standardized outcome measure over a broad range of Wisconsin physicians. Questionnaires were administered to patients over

the course of a year at points in time considered to be milestones for recovery from low back pain. Our results indicate that although the majority of patients made progress by the 1-year follow-up, only 60% experienced the degree of symptom relief they expected. Furthermore, only 39% of patients indicated they would be satisfied to spend the rest of their lives with their symptoms at 12 months, and only 40% would recommend their health care provider to family or friends. For patients in our study, the most significant gains in physical health were made by the 3-month follow-up. However, at the 3 and even at the 12-month follow-ups, SF-36 physical health scores remained below the national norms. These treatment results fall short of what practitioners should anticipate according to the AHCPR guidelines, which suggest giving patients the expectation of a rapid recovery. However, our data suggest that recovery from an episode of acute low back pain may not to be as rapid or predictable, nor back pain as benign, as the medical community would like it to be.<sup>11,12</sup>

Significantly, a sizable percentage of patients enrolled in our study developed chronic back pain despite physician-directed treatment of their acute symptoms. Care should therefore be taken to prepare patients for managing future flare-ups of back pain and to provide adequate support and strategies for effective patient-directed management of chronic or recurrent back pain.<sup>2</sup> Perhaps future outcomes studies will be able to identify factors predictive of chronic low back pain, thereby enabling these individuals to receive targeted interventions designed to aggressively treat their symptoms in the hope of preventing a chronic pain syndrome.

According to the AHCPR guidelines, the assessment and treatment of patients who have chronic low back pain (defined as symptoms lasting over 3 months) may be quite different than for patients with acute problems. In this study, meaningful comparisons could not be made among the treatments and medications used because it is unclear how patients interpreted the term "episode" when answering the treatment and medication questions. However, the confusion related to this term emphasizes the importance of findings in the current literature that back pain needs to be conceptualized as occurring in phases. A review of long-term outcome studies of primary care patients found that "a recurrent course is far more typical than either an acute or a chronic course and that primary care back pain patients experience chronic phases of back pain more often than

previously believed."<sup>2</sup> Other results of our study, such as patient dissatisfaction, may be secondary to these recurrences.

In addition to symptom duration, radicular symptoms also appear to be an important consideration when treating acute low back pain. In our study, patients diagnosed with radiculopathy or with symptoms suggestive of sciatica reported worse health than patients without radicular symptoms on the main physical health outcome measures. This finding suggests that patients may need to be treated differently when there is potential nerve root involvement, an idea that is inductive. This conclusion is at odds with the AHCPR guidelines, which would favor treating patients with and without radicular symptoms identically for the first 4-6 weeks. Furthermore, our outcomes are less favorable than those previously reported in the literature.<sup>13</sup> It is interesting to note, however, that Carey and colleagues found that patients with sciatica were more likely to develop chronic back pain.<sup>14</sup> Further investigation into the outcome of various treatment approaches for radicular low back pain would therefore seem warranted.

Patient dissatisfaction with symptom relief may explain the finding that only 40% of patients at the 12-month follow-up would recommend their health care provider to family or friends. While we realize that other factors besides relief from symptoms enter into a patient's satisfaction with their treating physician, this figure suggests a generalized patient dissatisfaction with their outcome. This conclusion in turn leads us to ask: "Where do these patients go, and what kind of care do they seek?" The study instrument used in our investigation was not designed to answer this question. Clearly, further research is needed to provide physicians and patients with a better understanding of the optimal treatment of recurrent, episodic low back pain.

The low response rate of this study limits our ability to generalize these findings to other patients with back pain. Although we tried different methods to increase the response rate, it was not possible to significantly improve the percentage of returned questionnaires at most of the designated study sites. While patients who completed all four surveys did not differ in regard to their baseline measures of health status from patients who did not complete all four surveys, whether these two groups would differ in their outcomes at a later point in time is of course uncertain.

The Study Group believes that outcomes research

should not be limited by tradition to tertiary care centers, but should encompass a wider variety of settings including primary care. Unfortunately, current Wisconsin private and group practice settings generally lack the infrastructure to confidently support this kind of undertaking. Our experience tells us that attempts to collect data require significant resources, including funding and dedicated personnel. It appears that outcomes research is not a process that can be reliably left to mail-in questionnaires. A much more structured and funded environment is needed. To make outcomes research across a spectrum of practice settings (as attempted in this study) both logistically and financially feasible will require new procedures or systems of data collection. Lessons learned in the process of this study, along with insights and recommendations for the design of future outcomes research projects, will be the subject of a separate paper that is being prepared.

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