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## SPECIAL ARTICLE

### HOW MANY DAYS OF BED REST FOR ACUTE LOW BACK PAIN?

#### A Randomized Clinical Trial

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**Abstract** Bed rest is usually recommended for acute low back pain. Although the optimal duration of bed rest is uncertain, a given prescription may directly affect the number of days lost from work or other activities. In a randomized trial, we compared the consequences of recommending two days of bed rest (Group I) with those of recommending seven days (Group II).

The subjects were 203 walk-in patients with mechanical low back pain; 78 percent had acute pain (≤30 days), and none had marked neurologic deficits. Follow-up data were obtained at three weeks (93 percent) and three months (88 percent). Although compliance with the recommenda-

tion of bed rest was variable, patients randomly assigned to Group I missed 45 percent fewer days of work than those assigned to Group II (3.1 vs. 5.6 days,  $P = 0.01$ ), and no differences were observed in other functional, physiologic, or perceived outcomes.

For many patients without neuromotor deficits, clinicians may be able to recommend two days of bed rest rather than longer periods, without any perceptible difference in clinical outcome. If widely applied, this policy might substantially reduce absenteeism from work and the resulting indirect costs of low back pain for both patients and employers. (*N Engl J Med* 1986; 315:1064-70.)

IN many large industrial settings, low back pain is second only to upper respiratory infection as a cause of absence from work.<sup>1</sup> It is estimated that 1400 days of work per 1000 workers are lost annually in the United States because of back pain, and perhaps more in Great Britain.<sup>2</sup> Much of this lost productivity may be related to bed rest, the most commonly recommended treatment for low back pain, as well as to the illness itself.

Most observers agree that the prognosis of acute low back pain is good, regardless of the specific treatments applied.<sup>2,3</sup> There is also agreement that bed rest

is a mainstay of therapy,<sup>1,3,4</sup> although objective data to support its efficacy are meager.<sup>5</sup> In addition, the optimal duration of bed rest remains uncertain. Published treatment schedules, although vague, often mention periods of one to two weeks.<sup>3,4,6</sup> Whatever the particular prescription, it may directly affect the number of days lost from work or other activities.

Information about the usual duration of symptoms or functional limitation might help to guide recommendations for bed rest, but data on the natural history of low back pain are also fragmentary. In a study of army recruits randomly assigned to bed rest or continued ambulation, the mean interval for return to full activity was 6.6 days in the bed-rest group and 11.8 days in the ambulatory group.<sup>4</sup> In a study that did not include uniform bed-rest recommendations, however, most patients lost fewer than three days from their usual activities.<sup>7</sup> On the basis of expert opinion and published data, then, reasonable bed-rest recommendations may range from less than three days to two weeks. Although shorter treatments may reduce the amount of time lost from work or other usual activi-

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ties, there may be a minimum below which recovery is delayed.

This study was therefore designed to determine whether two days of bed rest could be confidently recommended for selected patients rather than longer periods (seven days), without loss of therapeutic benefit. In addition, we sought to determine whether this strategy would reduce work absenteeism.

## METHODS

### Patient Selection and Evaluation

All patients presented with a chief symptom of low back pain at the busy walk-in clinic of a public hospital between March 1982 and August 1984. In this setting, most patients have acute pain or exacerbations of chronic pain and are not receiving ongoing care from a specialist. Potential subjects were evaluated by resident physicians from the departments of medicine, surgery, and family practice, with faculty supervision. The examining physician completed a standardized form containing 65 items relating to the patient's history and physical examination, adapted from previous studies of low back pain.<sup>6,7</sup>

In an effort to assemble a group with uncomplicated mechanical back pain, we excluded patients who were pregnant, were under 18 years of age, had pain located above T12, were receiving steroids or anticoagulants, were seeking disability compensation, or had alcohol or drug abuse, a history of cancer, possible cauda equina syndrome, a temperature  $\geq 37.8^{\circ}\text{C}$ , rectal bleeding, disabling comorbidity, or probable urinary tract disease. Patients who were planning to move out of town and those who were inaccessible by telephone were also excluded. Lumbar-spine films were made in patients over the age of 50, whereas radiography was used selectively in patients under 50. A urinalysis and determination of the hematocrit and the erythrocyte-sedimentation rate were ordered for all subjects to screen for urinary tract or systemic disease. Patients with any duration of pain were accepted, though most had acute pain. Although we intended to exclude patients with even minor neuro-motor deficits, 11 subjects with equivocal or minor deficits were randomized. These deficits included weak toe dorsiflexion, asymmetric ankle jerks, and difficulty with heel or toe walking. Three additional subjects had stable postoperative neurologic deficits.

Eligible subjects were interviewed by a research assistant, and written informed consent was obtained. All activities were approved by the institutional review board of the University of Texas Health Science Center at San Antonio. Personal and demographic data were collected with a standard questionnaire, and the Sickness Impact Profile was administered. The latter is a comprehensive health-status questionnaire that we have validated for use in patients with low back pain.<sup>8,9</sup> It contains two principal subscales, the Physical Dimension and the Psychosocial Dimension. All questionnaires were available in English or Spanish.<sup>10</sup> Eligibility was established, and base-line questionnaires were completed before treatment assignments were made.

### Prognostic Stratification and Assignment

The study sample was stratified according to the number of prior episodes (zero to one and more than one) and according to work status (employed and unemployed), since these factors are thought to have prognostic importance.<sup>11-13</sup> After giving consent and completing base-line questionnaires, subjects were randomly assigned to receive bed-rest recommendations (two days or seven days) in sealed envelopes. Random assignment was performed in blocks of four to ensure approximately equal numbers in each bed-rest group, and it was done separately for each stratum. The sequence was determined with use of a random-number table.

A subgroup of subjects who were judged to have a very low risk of systemic disease were simultaneously randomly assigned to undergo or not undergo lumbar-spine radiography, so that the effect on patient satisfaction and reassurance could be examined. However, there was no significant interaction between bed-rest and radio-

graphic-examination strategies with regard to any of the outcomes reported here, and this report concerns only bed rest.

### Compliance

Since compliance with bed-rest recommendations is often poor, we attempted to ascertain the actual number of days spent resting in bed. We did this by asking an unthreatening question ("Many people have difficulty staying in bed for long periods of time. How many days were you able to spend in complete bed rest?"). Since this was a test of two clinical strategies (intention to treat) rather than a study to establish the biologic efficacy of bed rest, we thought that some variation in compliance would not defeat the purpose of the study.

### Co-interventions

All patients were advised to avoid heavy lifting for one week after returning to work. Uniform recommendations regarding local application of heat, exercise, and weight loss were given to each subject in writing. Although clinic physicians were given latitude to tailor drug therapy individually, we expected the random assignment process to result in similar therapy for the two groups overall. We recorded all therapy prescribed at the index visit, and at the follow-up visit each subject was questioned about any other treatments he or she might have received.

### Follow-up and Outcome Assessment

Follow-up appointments were scheduled for all patients three weeks and three months after the initial visit. We anticipated difficulty in achieving follow-up, because many patients were indigent, with unstable housing circumstances, transportation problems, or difficulty in arranging leave from work. With rapid improvement in symptoms, many patients might also have lacked motivation to return. Therefore, subjects were reminded of each visit by mail or telephone, and a \$10 reimbursement was offered for each follow-up appointment kept. When subjects did not keep the follow-up appointments, several efforts were made to obtain telephone interviews, and if they were unsuccessful, a questionnaire was mailed.

Outcome assessments were grouped in four main categories: (1) functional status, which included the reported number of days absent from work and days of limited activity, time of resumption of normal activities, and the Sickness Impact Profile score; (2) patient and clinician perceptions, which included the patient's self-rated improvement as assessed on a six-point ordinal scale (1 = pain entirely gone, 6 = much worse), a clinician's rating on an identical scale, and the patient's satisfaction with the medical care for this illness (the satisfaction scale was adapted from Greenfield et al.<sup>6</sup> and was validated among the early subjects in our study<sup>14</sup>); (3) symptoms and signs, which included the number of days of pain, the degree to which the straight leg could be raised on the more limited side, spinal flexion, as assessed by the distance from finger tips to floor on maximal forward flexion, and the persistence or appearance of any neurologic deficit; and (4) the use of services, which included the reported number of inpatient hospital days during the follow-up interval, and the use of services outside the study institution.

The physical examination and the clinician's rating were carried out and the patient's self-rating was elicited by a specially trained nurse practitioner or a physician who was blinded to study-group assignment. The standardized questionnaires (the Sickness Impact Profile and the satisfaction scale) and the remaining individual questions were administered by a research assistant who was not blinded to treatment assignment but was trained to administer the questionnaires in a standard manner.

### Sample Size

We used the sample-size calculations of Greenland et al., which were made for a study comparing several treatments for low back pain on the basis of data from previous trials of physical therapy.<sup>15</sup> Their calculations were made for a six-point scale of improvement

nearly identical to ours, with use of variance estimates from the earlier trials and with the assumption that group differences of about 0.5 point would be the smallest clinically important difference. They estimated that about 150 subjects per treatment group would be necessary to achieve a statistical power of 0.90, and about 100 subjects to achieve a power of 0.80 ( $\alpha = 0.05$ ). Though our goal was to achieve the larger number, time, financial constraints, and the number of exclusions limited us to approximately 100 per group.

### Statistical Analysis

Analysis of variance in the subgroup randomly assigned to both bed-rest and radiography strategies suggested that there was no interaction between these interventions. We therefore combined all subjects assigned to two days of bed rest and all subjects assigned to seven days of bed rest. We then performed analyses of variance using the follow-up Sickness Impact Profile score, patient self-rating, and satisfaction score as the dependent variables. The independent variables included bed-rest group and the stratifying variables (number of prior episodes and initial employment status). For analyses of the Sickness Impact Profile and its subscales, base-line values were entered as covariates.

Because there was no significant interaction between the three independent variables in any analysis, we also performed univariate analyses for each outcome measure, using two-sided t-tests and chi-square tests with Yates' correction. Because many outcome variables had skewed distributions or were not true interval scales, we also used the nonparametric Mann-Whitney U-test for ordinal variables. Levels of significance were virtually the same with parametric or nonparametric tests, and the results of the parametric tests are reported here. The Statistical Package for the Social Sciences was used for all analyses.<sup>16</sup>

## RESULTS

### Derivation of Study Sample

A total of 450 eligible subjects were identified. Of these, 247 declined participation; the reason most often cited was unwillingness to comply with bed rest, to miss work, or to keep the necessary follow-up appointments. The eligible subjects who declined were very similar as a group to those who enrolled, with regard to mean age, sex distribution, spinal flexion, straight-leg raising, duration of pain, number of prior episodes, and prior surgery ( $P > 0.1$  for every comparison).

A total of 203 patients were randomly assigned. Two days of bed rest was recommended for 101 patients (Group I), and seven days for 102 (Group II). Follow-up information was obtained three weeks later for 189 of these subjects (93 percent). Eleven subjects were lost from Group I, and three were lost from Group II. One patient asked to be dropped from the study without explanation; we were unable to contact the remaining 13 patients for follow-up. Those who were lost to follow-up differed from the remaining subjects in having a significantly shorter mean duration of pain before entry, having substantially lower Sickness Impact Profile scores, and being more likely to be employed. Thus, they appeared to be somewhat less severely ill or functionally impaired than subjects for whom follow-up was obtained. For 11 subjects, only a telephone interview was possible; a follow-up visit (allowing physical examination and completion of the Sickness Impact Profile) was obtained for 178 (88 per-

cent). At three months, an interview was obtained for 179 subjects (88 percent).

### Patients' Characteristics

Demographic and clinical characteristics of the subjects for whom follow-up was available are shown in Table 1. The educational level was significantly different in the two groups ( $P = 0.03$ ), but for all the other variables listed, differences were not significant ( $P > 0.1$ ). Eighty-two percent of the subjects were Hispanic, and there were no significant differences in ethnic distribution between the groups. In addition, the self-rated severity of pain on a four-point scale was nearly identical in the two groups: 86 percent of Group I rated their pain as "extremely" or "somewhat" severe, as compared with 88 percent of Group II.

Only 67 subjects were employed at the time of study enrollment. Many patients (61) were housewives. Among those employed on entry into the study, the occupations most frequently cited were building-trade worker (9 subjects), maintenance or janitorial worker (8), restaurant worker (7), hospital employee (7), heavy laborer (7), and housemaid (6).

### Compliance with Bed Rest

In each group there was substantial variation in the actual durations of bed rest as reported by the patients (Fig. 1). The modal durations of bed rest for the two groups were two and seven days, respectively, but the means were 2.3 days for Group I and 3.9 days for Group II. Compliance with the seven-day recommendation was especially limited: 73 of the 99 subjects (74 percent) reported less than seven days of actual bed rest. Nonetheless, the group differences were significant ( $P < 0.0001$ ) whether assessed by parametric or nonparametric tests.

### Co-interventions

At three weeks, there were no significant or substantial differences between the randomized groups in the proportion of subjects receiving the following co-interventions: muscle-relaxant drugs, nonsteroidal anti-inflammatory drugs, both muscle relaxants and nonsteroidal anti-inflammatory drugs, narcotic analgesics, hospital admission, referral to a specialist, physical therapy, additional drugs after the index visit, or care from sources outside the study institution.

### Three-Week Outcomes

Results for each outcome variable are shown in Table 2. Among the patients who were employed at the time of study entry, those randomly assigned to two days of bed rest missed substantially less work than those assigned to seven days. The difference in the mean number of days absent was 2.5, which was statistically significant ( $P = 0.01$ ).

None of the other outcome variables showed significant or substantial differences between groups. On the

basis of prior investigation,<sup>15,17</sup> we believed that group differences of 0.5 point on the self-rating scale or 3.0 points on the Sickness Impact Profile would represent the smallest clinically discernible differences in pain and function. The actual differences observed were considerably smaller. When scores for the Sickness Impact Profile and its main subscales (Physical and Psychosocial Dimensions) were analyzed with the base-line values as covariates, there were still no significant differences between bed-rest groups. The slight differences observed in some outcome measures favored one group in some cases and the other in other cases, so that there was no apparent trend favoring one group.

The bed-rest main effect was not significant in any of the multivariate analyses, nor was employment status. The number of prior episodes did prove to be a significant correlate of self-rated improvement ( $P = 0.02$ ). There was no significant interaction, however, between the three independent variables (bed-rest group, previous episodes, and employment status) with regard to the outcomes of patients' self-ratings, Sickness Impact Profile scores, and satisfaction.

We also examined the proportion of patients in each group who reported any degree of improvement on the self-rating scale. Seventy-five percent of Group I reported improvement, as compared with 78 percent of

Group II — a nonsignificant difference. We also compared the proportion of subjects in each group who had at least a three-point improvement in Sickness Impact Profile score. Again, the groups were very similar: 53 percent of Group I had such an improvement, as compared with 57 percent of Group II ( $P = 0.67$ ).

Because of the wide variation in bed-rest compliance, it might be argued that our study was not a fair test of the effects of two as compared with seven days of bed rest. Although we believe the analysis of the intact randomized groups to be the most valid, we also compared outcomes for compliant patients only. For this purpose, we included only the 68 subjects in Group I who reported one to three days of bed rest and only the 38 subjects in Group II who reported five to eight days of bed rest. As expected, there was an even larger difference in the mean number of days absent from work (3.9), and the number of days of limited activity favored the two-day group. Even among these compliant subjects, there was no advantage for the group with longer bed rest in any of the remaining outcome variables.

Although we tried to exclude subjects with neurologic deficits, there was a substantial proportion (42 percent) with symptoms suggestive of sciatic irritation, defined as the presence of two or more of the following three findings: (1) pain or numbness radiating below the waist, (2) pain increased with cough or sneeze, and (3) inability to raise a straight leg 60°. Because patients with sciatica might possibly require longer bed rest, we analyzed the results in the subset with symptoms of sciatic irritation. Even in this subgroup, patients assigned to two days of bed rest had significantly fewer days of limited activity and of absence from work than those assigned to seven days. Again, there was no significant advantage for the seven-day group in any of the other outcome variables. Among the 11 patients with possible neuromotor deficits at entry, only 2 (one in each group) had persistent deficits at follow-up, and both were substantially improved.

Because the 14 patients who dropped out of the study appeared less severely ill than those who remained in the study, we might expect their outcomes to have been better than average. Nonetheless, we examined our primary outcomes, making unlikely assumptions that heavily favored the seven-day group. We assumed that none of the drop-

Table 1. Demographic and Clinical Characteristics of Study Subjects at the Time of Random Assignment.\*

CHARACTERISTIC	GROUP I (2 DAYS BED REST)	GROUP II (7 DAYS BED REST)
No. of subjects	90	99
Mean age — yr (SEM)	43.3 (1.47)	41.6 (1.51)
Sex (% women)	66	60
Mean education — yr (SEM)	7.4 (0.47)	8.7 (0.40)
Married (%)	52	45
Employed at entry (%)	37	34
First medical visit for back pain (%)	58	53
Median duration of episode (days)†	10.1	7.0
Number with chronic pain (>3 mo)	10	13
Median number of prior episodes†	1.3	1.1
Prior back surgery (%)	2	5
Neurologic deficit (%)	5	7
Nerve-root irritation (%)‡	37	47
X-ray findings (%)		
Radiography not done	30	29
Normal	26	29
Degenerative change	23	22
Other§	21	19
Any comorbidity (%)	58	53
Mean initial SIP score (SEM)¶	19.3 (1.44)	20.4 (1.29)
Mean Physical Dimension score (SEM)	18.1 (1.60)	19.2 (1.26)
Mean Psychosocial Dimension score (SEM)	19.4 (1.80)	21.5 (1.68)

\*None of the differences are statistically significant (by the t-test or chi-square test,  $P > 0.1$ ) except for years of education.

†Because of highly skewed distributions, medians are reported rather than means, and significance was tested by the Mann-Whitney U-test ( $P > 0.7$ ).

‡Nerve-root irritation was defined as including at least two of the following: (1) pain radiating below the waist, (2) pain increased with cough or sneeze, and (3) straight-leg raising of less than 60°.

§"Other" included mild scoliosis, spondylolysis, mild spondylolisthesis, postoperative changes, osteopenia, and congenital anomalies.

¶SIP denotes Sickness Impact Profile; scores range from 0 to 100, with higher scores indicating worse function.

||The Physical and Psychosocial Dimensions are major subscales of the Sickness Impact Profile.

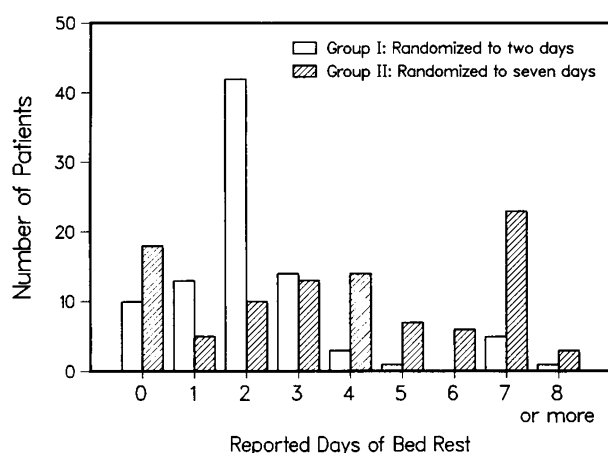


Figure 1. Distribution of Reported Number of Days of Bed Rest for the Two Study Groups.

outs in Group I improved on the self-rating scale but that all the dropouts in Group II rated themselves "much better." We also assumed a five-point deterioration in the Sickness Impact Profile score for Group I dropouts and a five-point improvement for Group II dropouts. Even with these pessimistic assumptions, the group differences in self-rating or functional scores were not significant or clinically important.

Because our early experience raised uncertainty about the validity of the Spanish Sickness Impact Profile,<sup>18</sup> we repeated the analysis using data only from English-speaking subjects ( $n = 132$ ). Again, there were no important differences between the groups except in the number of days absent from work.

### Three-Month Outcomes

After the three-week visit, no significant or important differences were observed in absence from work, number of days of limited activity, number of additional days of bed rest, or self-rated improvement (Table 3). Similarly, there were no significant differences in the number of hospitalizations or in the percentage of subjects seeking care outside the study institution. Only one subject, from the seven-day group, was hospitalized for back pain.

Three-month scores on the Sickness Impact Profile and its two main subscales were not significantly different. When the scores were analyzed with base-line values as covariates, a significant difference in overall score did emerge, fa-

voring the seven-day group. When the subscales were examined, however, the differences were largely confined to the Psychosocial Dimension, among users of the Spanish questionnaire. None of the differences were significant or substantial among the subjects who used the English questionnaire (for whom validity appears greatest<sup>18</sup>) or for the Physical Dimension. Similarly, the reported number of additional days with pain symptoms favored the seven-day group after three months, but variability was great. Although differences were not significant according to parametric tests, they were marginally significant when nonparametric tests were used ( $P = 0.049$ ), with medians of 3.7 days for Group I and 2.1 days for Group II. Nevertheless, differences in the total number of days of pain for the three-month interval were not significantly different, and the advantage for the seven-day group was again largely limited to those using the Spanish questionnaire. In view of the multiple statistical tests used, the fact that other outcomes showed no differences, and the limitation of substantial differences to the subgroup using the Spanish questionnaire, we do not believe that the shorter median duration of pain represents an important advantage of the seven-day approach. We conclude that with longer follow-up, there was no evidence of an increase in absence from work, symptoms, dysfunction, or health care use for the subjects assigned to two days of bed rest.

When we examined correlates of reported absence from work for the entire three-month follow-up interval using multiple linear regression, study-group

Table 2. Outcomes of the Clinical Trial at Three-Week Follow-up.\*

OUTCOME CATEGORY	SPECIFIC MEASURE	GROUP I (2 DAYS BED REST)	GROUP II (7 DAYS BED REST)	P VALUE†
	No. of subjects	90	99	
Functional status	Days absent from work‡	3.1	5.6	0.01
	Days of limited activity	6.8	7.7	NS
	No. returned to normal activities (%)	58 (67)	62 (65)	NS
	Overall SIP score (follow-up)§	15.7	15.9	NS
	Physical Dimension score¶	11.6	12.4	NS
	Psychosocial Dimension score¶	16.8	16.8	NS
Perceptions	Self-rated improvement	2.7	2.6	NS
	Clinician-rated improvement	2.4	2.2	NS
	Satisfaction with care**	24.3	23.6	NS
Symptoms, signs	Duration of pain (days)	11.2	10.8	NS
	No. with persistent neurologic deficit (%)	1 (1)	1 (1)	NS
	Straight-leg raising (degrees)	89	89	NS
	Spinal flexion (cm from finger to floor)	6.8	6.5	NS
Use of services	Hospital days	0	0	NS
	Sought care elsewhere (%)	2 (2)	7 (7)	NS

\*Values are means unless otherwise indicated.

†NS denotes not significant ( $P > 0.1$ ).

‡Among the 63 patients who were employed when they entered the study.

§SIP denotes Sickness Impact Profile; scores range from 0 to 100, with higher scores indicating worse function.

¶The Physical and Psychosocial Dimensions are major subscales of the Sickness Impact Profile.

||Rated on a six-point scale: 1 = pain entirely gone, 4 = no change, and 6 = much worse.

\*\*Satisfaction was measured on a nine-item scale; scores ranged from 9 to 27, with 27 representing the highest level of satisfaction.

Table 3. Outcomes of the Clinical Trial at Three-Month Follow-up.\*

OUTCOME CATEGORY		GROUP I (2 DAYS BED REST)	GROUP II (7 DAYS BED REST)
No. of subjects		89	90
Functional status	Additional days absent from work†	2.3	2.0
	Additional days of limited activity	6.5	7.7
	Additional days of bed rest	2.3	2.0
	Overall SIP score‡	13.4	11.9
	Physical Dimension score§	10.0	9.2
	Psychosocial Dimension score§	14.8	12.2
Perceptions	Self-rated improvement¶	2.6	2.5
Symptoms	Additional days of pain	18.4	13.3
Use of services	Mean hospital days	0.0	0.10
	Sought care elsewhere (%)	8 (9)	10 (11)

\*Values are means unless otherwise indicated. All questions were about symptoms or limitations occurring after the three-week visit; none of the differences shown are statistically significant (by t-tests or chi-square analysis).

†Among the 61 patients who were employed when they entered the study.

‡SIP denotes Sickness Impact Profile; scores range from 0 to 100, with higher scores indicating worse function.

§The Physical and Psychosocial Dimensions are major subscales of the Sickness Impact Profile.

¶Rated on a six-point scale: 1 = pain entirely gone, 4 = no change, and 6 = much worse.

assignment was highly associated with the number of days lost (fewer days in the two-day group) ( $P = 0.004$ ), whereas base-line variables, such as self-rated pain, duration of pain, prior episodes, spinal flexion, and straight-leg raising, were not. Thus, for patients without neurologic deficits, the physician's therapeutic recommendation may influence the duration of work absence as much as or more than the patient's history and physical examination.

DISCUSSION

We hypothesized that for patients without neurologic deficits, two days of bed rest would be therapeutically similar to seven days, and that absence from work would be reduced. The results of our randomized experimental study support this hypothesis. We believe that for many patients with low back pain and no neuromotor deficits, clinicians can recommend two days of bed rest rather than longer periods. For the patient who appears to have a herniated disk with motor deficits, there is a good biologic rationale for recommending longer periods of bed rest (reduction of intradisk pressure<sup>19</sup>), and this is our practice.

Nachemson has summarized a variety of data suggesting that motion, rather than rest, may be beneficial in healing injured soft tissues and joints.<sup>20</sup> If true, this may explain the apparent lack of benefit for longer periods of bed rest in our study. Although some patients with uncomplicated low back pain may have disk abnormalities, a large number probably have injuries of the muscles, ligaments, and facet joints. For most, a definitive diagnosis is not possible.<sup>21</sup> For such patients, bed rest may offer less benefit than for the patient with disk herniation and neurologic deficits.

The implications of our findings for work absenteeism due to back pain may be substantial. Although there is a wide variation in bed-rest recommendations among clinicians, many recommend approximately a week of bed rest for most patients with acute back

pain. For many such patients, two days of bed rest is probably sufficient. If the recommendation of two days instead of seven were widely applied, our data suggest that work absenteeism might be reduced on the average by 2.5 days per episode of back pain. In our study, this represented a 45 percent reduction in the number of days lost. Although the brief-rest approach may be appropriate only for patients without neurologic deficits, such patients probably constitute a majority of those with acute back pain. Thus, the indirect costs of illness to both patients and employers may be substantially reduced.

Several aspects of the study deserve further comment. First, this

study was conducted in a primary care setting, in which the nature and severity of back problems may differ substantially from those usually seen in specialty practices, such as those of orthopedics and rheumatology. The results are probably most appropriate for application in the primary care setting.

Second, our results should be generalized with some caution. We excluded subjects seeking financial compensation, and a substantial number of subjects refused to participate. Although those who declined were similar to the participants according to many clinical measures, we cannot know how similar their outcomes might have been. Furthermore, our subjects were largely indigent Hispanics, and cultural or financial factors may have influenced our results.

Third, an important limitation of this study is the inability to conduct a truly double-blind trial. Study subjects could not be blinded to their group assignment, and the informed-consent process required that they be aware of the alternative treatment procedure. Because knowledge of both bed-rest alternatives might have influenced patients' expectations and compliance, the use of the pre-randomization design of Zelen<sup>22</sup> was considered, as was that of a consent form that did not make the bed-rest alternatives explicit. In the Zelen design, patients are randomly assigned before consent is sought; those assigned to standard therapy are unaware of the experimental therapy, and consent is not sought from them. However, we did not believe that there was a consensus about the "standard" duration of bed rest to be employed in a pre-randomized scheme. Furthermore, many patients might have been randomly assigned who were overtly unwilling to undergo any bed rest. Even if patients were assigned to a "standard" therapy, the need for informed consent would not be entirely obviated, because of the extensive questionnaires and follow-up visits that exceeded routine care. Since the regimen employed might have important financial conse-

quences for some persons, we (and the institutional review board) thought that fully informed prior consent was preferable for all prospective participants. Whatever design was used to study this problem, patients would know what treatment they received, as they would not in a conventional placebo-controlled drug trial.

Although the standardized questionnaires used for measuring outcomes (the Sickness Impact Profile and the satisfaction scale) were administered by a research assistant who was not blinded to bed-rest assignment, we believe that bias was minimal. The instructions and questionnaires themselves are highly standardized, and the interviewer was not allowed to review the group assignments at the time of follow-up. Other important outcome measures (patients' self-rating, professional rating, and physical examination) were performed or elicited by a completely blinded observer.

Finally, patient compliance with any type of physical treatment, including bed rest, is often limited. Even in a research setting in which patients have given informed consent for participation, most subjects were unable or unwilling to complete seven days of bed rest. Although this limits our conclusions about the biologic value of longer periods of bed rest, it probably reflects actual performance in routine clinical settings. Furthermore, when our analysis was limited to compliant subjects, the conclusions were unchanged. To address the problems of compliance and biologic efficacy with greater certainty would probably require a study involving hospitalization and observed bed rest. Such a strategy would be important for studying patients with neurologic deficits but would perhaps not be feasible for the less severely ill subjects considered here.

Our data support a recent trend toward earlier mobilization of patients with back pain. Not only are brief periods of bed rest apparently safe for selected patients, but they may reduce the potential adverse effects of bed rest, including physical deconditioning. Finally, there are many who believe that an early return to work may help to prevent the emergence of chronic back pain syndromes, with their enormous human and monetary costs.<sup>20</sup>

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