

LACK OF EFFECTIVENESS OF BED REST FOR SCIATICA

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ABSTRACT

Background and Methods Bed rest is widely advocated for sciatica, but its effectiveness has not been established. To study the effectiveness of bed rest in patients with a lumbosacral radicular syndrome of sufficient severity to justify treatment with bed rest for two weeks, we randomly assigned 183 subjects to either bed rest or watchful waiting for this period. The primary outcome measures were the investigator's and patient's global assessments of improvement after 2 and 12 weeks, and the secondary outcome measures were changes in functional status and in pain scores (after 2, 3, and 12 weeks), absenteeism from work, and the need for surgical intervention. Neither the investigators who assessed the outcomes nor those involved in data entry and analysis were aware of the patients' treatment assignments.

Results After two weeks, 64 of the 92 patients in the bed-rest group (70 percent) reported improvement, as compared with 59 of the 91 patients in the control (watchful-waiting) group (65 percent) (adjusted odds ratio for improvement in the bed-rest group, 1.2; 95 percent confidence interval, 0.6 to 2.3). After 12 weeks, 87 percent of the patients in both groups reported improvement. The results of assessments of the intensity of pain, the bothersomeness of symptoms, and functional status revealed no significant differences between the two groups. The extent of absenteeism from work and rates of surgical intervention were similar in the two groups.

Conclusions Among patients with symptoms and signs of a lumbosacral radicular syndrome, bed rest is not a more effective therapy than watchful waiting. (N Engl J Med 1999;340:418-23.)

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THE condition of patients with sciatica usually improves over time.^{1,2} Several conservative therapies have been proposed for this disorder, with bed rest as a mainstay. For low back pain, bed rest has traditionally been considered effective, although there are few objective data to support this view,³ and in recent years evidence of the ineffectiveness of bed rest for patients with low back pain has accumulated.⁴⁻⁶ Although bed rest continues to be widely used to treat sciatica,⁷ evidence from a randomized, controlled trial has been lacking. We conducted a randomized, controlled, blinded trial of the efficacy of two weeks

of bed rest (frequently advocated in the Netherlands⁷) for the treatment of sciatica.

METHODS

Selection of Patients

Between February 1995 and December 1996, 50 general practitioners in Maastricht and surrounding villages referred patients who presented with back pain radiating into one leg below the gluteal fold to the neurology department of Maastricht University Hospital. Patients were eligible for the study if the intensity of pain was sufficient to justify two weeks of bed rest as therapy. Patients were excluded if they had previously undergone spinal surgery, were pregnant, had pending workers' compensation claims, were unavailable for follow-up (i.e., planned to move), or had severe coexisting illnesses. The general practitioners were also asked to register eligible patients who were not referred. Within two days of referral, all patients had a history taken and underwent a physical examination and magnetic resonance imaging (MRI) of the lumbar spine. The MRI consisted of T₁-weighted sagittal and transverse images, sagittal proton-density and T₂-weighted images, and coronal-oblique magnetic resonance radiology. The assessment of the images focused on nerve-root compression. The investigators then confirmed that the patients met the selection criteria and applied two further criteria for eligibility. First, the patients had to have sciatica (as indicated by at least two of the following symptoms and signs: radicular pain distribution; increased leg pain on coughing, sneezing, or straining; decreased muscle strength; sensory loss; reflex loss; or a positive straight-leg-raising test). Second, they could not have an indication for immediate surgical intervention (morphine-dependent intractable pain, a rapidly progressing paresis of short duration, or a cauda equina syndrome). The study was approved by the institutional review board of Maastricht University Hospital, and all the patients provided written informed consent.

A research nurse assigned patients to either bed rest or watchful waiting according to a randomization schedule, balanced in blocks of 10, that was constructed with use of a computer-generated random-number table. (The watchful-waiting group served as the control group.) After randomization, the nurse provided the patients with written instructions and a diary. The patients were asked to record the total number of hours of bed rest (including rest at night), the degree of pain (on a visual-analogue scale), and their functional status daily in this diary.

The patients in the bed-rest group were instructed to stay in the supine or lateral recumbent position with one pillow under the head for two weeks. They were permitted to get out of bed to use the toilet and to bathe. The patients in the control group were instructed to be up and about whenever possible but to avoid straining the back or provoking pain. They were allowed to go to work, but bed rest was not prohibited. After being examined at two weeks, the patients were referred to either a general practitioner or a specialist for usual care, which ranged from ad-

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vice to resume normal activities to surgery, but in all cases they were advised against bed rest. The patients were seen again by an investigator after 12 weeks.

The patients were allowed to take acetaminophen (1000 mg three times a day) for pain, supplemented by codeine (10 to 40 mg six times a day) or naproxen (500 mg three times a day) when necessary. Temazepam (10 mg once daily) was prescribed for insomnia. Patients were asked to record any other treatments they used for radicular symptoms, although these were discouraged.

Study Procedures and Outcome Measures

The patients were repeatedly instructed to conceal their treatment assignment from the investigator who assessed their outcomes. In addition, the patient's care giver was unaware of the treatment-group assignments except in the cases of a few patients whose group assignment and outcome were thought to be helpful to the care giver in planning further management. Data were entered and analyzed by personnel who had no knowledge of the group assignments. The MRIs were evaluated by a single investigator who was unaware of the treatment-group assignments. Patients, care givers, and the investigator who assessed the outcomes were unaware of the results of the MRI studies.

After the two-week treatment period, all patients returned to the clinic. They were asked by a single investigator, who was unaware of their treatment-group assignments, whether there was any improvement in their condition. The investigator also recorded his own perception of the degree of improvement since the history taking and physical examination were conducted, using the same scale. At the follow-up visit after 12 weeks, both the patients' and the investigator's perceptions of whether there was improvement were recorded; these served as the primary outcome measures in the trial.

The secondary outcome measures were the rates of absenteeism from work, further evaluation by a specialist (initiated by the evaluating investigator, who was unaware of the patients' treatment assignments), and surgical procedures during the first six months. On visual-analogue scales, the patients scored the bothersomeness of their chief symptom and the intensity of pain in the leg and low back at follow-up visits at 2 and 12 weeks and at home after 3 weeks. Differences in the qualitative description of pain were assessed at 2 and 12 weeks with the McGill Pain Questionnaire,⁸ in which patients choose words that best describe the pain they are experiencing, generating a total pain index. The completed questionnaires were checked by the blinded investigator. A modified Roland Disability Scale^{9,10} and the revised Oswestry Low Back Pain Questionnaire,¹¹ completed by the patients at 3 and 12 weeks, were used to evaluate functional status.¹² A single investigator saw the patients at all follow-up visits.

Statistical Analysis

The results were analyzed according to the intention-to-treat principle.¹³ The primary outcomes were compared in two-sided chi-square tests. Changes in scores on visual-analogue scales and questionnaires were compared with use of two-sided Mann-Whitney U tests.¹⁴ Absenteeism from work and the length of time to surgical intervention in each group were compared with use of Kaplan-Meier curves and log-rank tests.¹⁴

Subsequently, the data were analyzed in a logistic-regression model¹⁵ with adjustment for the following: age, sex, visual-analogue score for the investigator's assessment of the severity of disease and the patient's assessment of the bothersomeness of the chief symptom, presence or absence of nerve-root compression on the MRI, presence or absence of paresis, duration of disease, and presence or absence of a history of sciatica. Interaction terms for the last four covariates and the treatment group were added to enable us to investigate modification of the effect of treatment. For the secondary outcome measures, linear regression¹⁴ and Cox regression¹⁶ (for absenteeism from work) were used. A number of covariates defined a posteriori (e.g., age as a continuous variable, degree of pain in the leg on a visual-analogue scale, results of a

test of straight-leg raising, job status, and education level) were investigated as possible confounders. For each treatment group a logistic model was constructed to investigate whether the likelihood of improvement could be predicted by the number of hours of bed rest.

The average rate of improvement in each group during treatment was illustrated by a graph showing daily visual-analogue scores for pain. The rates were calculated for each patient as the regression slope of the visual-analogue score plotted against the day for days 1 through 14 and compared with use of a two-sided t-test.

RESULTS

Of the 338 patients referred to us by the general practitioners, 227 were considered eligible, of whom 44 declined to participate in the study. Of the 183 patients who entered the study, 1 in each group did not return after two weeks; both reported improvement. After 12 weeks, seven patients in each group had been lost to follow-up. Their base-line characteristics and success rates after two weeks were similar to those of the 167 remaining patients. Twelve patients in the bed-rest group and 10 in the control group did not undergo MRI. The base-line characteristics of the two groups (Table 1) were similar except that the patients in the bed-rest group had less leg pain as measured on the visual-analogue scale ($P=0.03$).

After 2 and 12 weeks, there were no significant differences between the groups in the primary outcome measures (Table 2). The logistic-regression analysis also showed no significant differences between the groups after adjustment for base-line differences in age, sex, duration of disease, nerve-root compression on MRI, paresis, history of sciatica, the investigator's global assessment, or the patient's assessment of the bothersomeness of the chief symptom (mostly leg pain). In addition, none of the covariates defined a posteriori (e.g., job status and degree of pain in the leg on the visual-analogue scale) were significant.

There were no significant differences between the groups in any of the secondary outcome measures after 2 and 12 weeks (Table 3). Seventeen percent of the patients in the bed-rest group and 19 percent of those in the control group eventually required discectomy. Forty percent of the patients in both groups required further consultation with a specialist. Of 21 patients in the control group who had muscle paresis, 2 had recovered after 2 weeks and an additional 12 had recovered after 12 weeks. Of the 13 patients in the bed-rest group who had paresis, 4 had recovered after 2 weeks and an additional 4 had recovered after 12 weeks. Paresis developed during the study in four patients in the control group and two in the bed-rest group.

The duration of leg pain and the presence or absence of paresis or of nerve-root compression on MRI did not affect the primary or secondary outcomes in either group. Among the patients with a

TABLE 1. BASE-LINE CHARACTERISTICS OF THE PATIENTS WITH SCIATICA IN THE BED-REST AND CONTROL GROUPS.*

CHARACTERISTIC†	BED REST (N=92)	CONTROL (N=91)
Age (yr)	44±12	48±12
Male sex (%)	51	61
Median duration of pain (days)	16	15
Any previous episode of pain in the leg (%)	31	35
Satisfaction score	4±1	4±1
Score on visual-analogue scale		
Chief symptom	85±16	87±16
Pain in the leg‡	62±22	68±21
Pain in the back	49±30	45±33
Score on McGill Pain Questionnaire	19±10	20±11
Score on revised Roland Disability Scale	5.5±3.9	5.2±3.8
Score on Oswestry Low Back Pain Questionnaire	27±10	29±8
Paresis (%)	13	21
Sensory loss (%)	38	39
Reflex differences (%)		
Ankle tendon	18	19
Knee tendon	3	8
Positive straight-leg-raising test (%)	67	64
Intermediate or high education level (%)	56	56
Employed (%)	55	57
Definite clinical diagnosis of sciatica (%)	77	80
Nerve-root compression on MRI§	49	60

*Plus-minus values are means ±SD.

†The satisfaction score was the patient's level of satisfaction with his or her current status as indicated on a scale from 0 to 10 (0 denoted not satisfied and 10 very satisfied). Patients indicated the bothersomeness of their chief symptom and the intensity of pain in the leg and back on a visual-analogue scale, on a line with 0 representing the least pain or least bothersomeness and 100 the most. The McGill Pain Questionnaire is a standardized and validated questionnaire that measures the intensity of pain as well as the emotional and sensory aspects of pain by scoring the words patients use to describe their pain. Scores range from 0 to 63, with higher scores indicating more distressing pain. The revised Roland Disability Scale is a questionnaire that measures functional status in patients with pain in the leg or back. Scores range from 0 to 23, with higher scores indicating better functional status. The Oswestry Low Back Pain Questionnaire measures functional status. Scores range from 0 to 50, with higher scores indicating worse functional status. Paresis was defined as decreased muscle strength in any of the major muscle groups in the leg; sensory loss as hypalgesia tested by pin prick or hypoesthesia tested by light touch; and reflex differences as differences between the affected and the unaffected leg. The straight-leg-raising test was positive if the observer noted any increase of typically dermatomal pain when the leg was raised. There were three missing scores for the Roland Disability Scale and Oswestry Low Back Pain Questionnaire and one for the visual-analogue scale for the chief symptom in each group.

‡P=0.03 for the comparison between groups.

§Twelve patients in the bed-rest group and 10 in the control group did not undergo MRI.

history of sciatica, the proportion of patients who had any improvement was higher in the bed-rest group than in the control group (adjusted odds ratio for any improvement, 4.5; 95 percent confidence interval, 1.4 to 15.1). Among the patients without prior sciatica, this rate was lower in the bed-rest group than in the control group (adjusted odds ratio, 0.6; 95 percent confidence interval, 0.2 to 1.3).

TABLE 2. PRIMARY OUTCOMES AMONG THE PATIENTS IN THE BED-REST AND CONTROL GROUPS.

TIME AND OUTCOME MEASURE	BED REST (N=92)	CONTROL (N=91)	ADJUSTED ODDS RATIO (95% CI)*
% of patients			
At 2 weeks			
Patient's assessment			
Any improvement	70	65	1.2 (0.6–2.3)
Great improvement	37	35	1.1 (0.6–2.0)
Investigator's assessment			
Any improvement	73	65	1.4 (0.6–2.6)
Great improvement	17	21	0.7 (0.3–2.0)
At 12 weeks			
Patient's assessment			
Improvement	87	87	1.0 (0.4–2.9)
Investigator's assessment			
Improvement	86	89	0.6 (0.2–1.7)

*Odds ratios have been adjusted for age, sex, visual-analogue scores for the investigator's assessment of the severity of disease and the patient's assessment of the bothersomeness of the chief symptom, the presence or absence of nerve-root compression on the MRI, the presence or absence of paresis, duration of disease, and the history with respect to sciatica. The control group served as the reference group in all comparisons. CI denotes confidence interval.

The proportions of patients with great improvement and the changes in secondary outcome measures in the patients with a history of sciatica and those without prior sciatica, however, did not differ significantly in either group. At 12 weeks, no interaction was found between the history with respect to sciatica and the type of treatment.

At base line and during treatment, leg pain was slightly less intense in the bed-rest group (Fig. 1). The changes over time in the two groups were not significantly different (P=0.45 for the comparison of the slopes of the visual-analogue scores).

The investigator who assessed the outcomes reported that blinding was unsuccessful in 10 of the 183 cases (5 patients in each group); his assessment of the treatment assignment was correct in 9 of these cases. This investigator became aware of the MRI findings in three patients before the first assessment of outcome.

According to the patients' diaries, those assigned to the bed-rest group were in bed for a mean (±SD) of 21±4 hours daily, as compared with 10±4 hours for the patients in the control group. The most common reasons for not complying with the treatment instructions on a particular day were "resolution of complaints" (5 percent in the bed-rest group and 4 percent in the control group), "incompatibility with work" (20 percent and 10 percent), and "it didn't work" (12 percent and 9 percent). The number of hours of bed rest had no relation to the likelihood of improvement in either group.

TABLE 3. SECONDARY OUTCOMES AMONG THE PATIENTS IN THE BED-REST AND CONTROL GROUPS.*

OUTCOME MEASURE	BED REST (N=92)	CONTROL (N=91)	P VALUE FOR CHANGE OVER TIME	ADJUSTED DIFFERENCE (95% CI)†
At 2 weeks				
Satisfaction score	6±2	6±2	0.41	-0.1 (-0.6 to 0.3)
Score on visual-analogue scale				
Chief symptom	45±34	49±33	0.74	2.9 (-7.0 to 12.9)
Pain in the leg	36±28	44±27	0.60	2.3 (-5.4 to 10.0)
Pain in the back	30±27	30±28	0.16	1.4 (-6.1 to 8.8)
Score on McGill Pain Questionnaire	13±10	15±11	0.30	1.3 (-1.7 to 4.3)
At 3 weeks				
Score on revised Roland Disability Scale	8.2±6.2	9.2±6.3	0.07	-1.6 (-3.7 to 0.4)
Score on Oswestry Low Back Pain Questionnaire	22±11	20±11	0.34	-2.7 (-1.0 to 6.4)
At 12 weeks				
Satisfaction score	7±2	8±1	0.59	-0.1 (-0.6 to 0.3)
Score on visual-analogue scale				
Chief complaint	20±31	18±28	0.36	-1.4 (-10.2 to 7.5)
Pain in the leg	16±26	14±24	0.06	-1.6 (-9.2 to 6.0)
Pain in the back	19±25	22±27	0.51	5.3 (-2.2 to 12.8)
Score on McGill Pain Questionnaire	8±9	7±8	0.74	-0.6 (-3.3 to 2.1)
Score on revised Roland Disability Scale	15.2±7	15.7±7	0.32	-0.5 (-2.6 to 1.6)
Score on Oswestry Low Back Pain Questionnaire	11±10	11±11	0.29	-0.4 (-3.6 to 2.9)
P VALUE FOR COMPARISON OF SURVIVAL CURVES				
During follow-up				
Further follow-up (%)‡	40	40		
Discectomy (%)‡	17	19	0.93	
Median no. of days of work missed§¶	46	47	0.88	
Work resumed during follow-up (%)¶	71	76	0.91	

*Plus-minus values are means ±SD.

†The values shown are the differences in the scores between the bed-rest group and the control group, with adjustment for base-line score and age, sex, visual-analogue scores for the investigator's assessment of the severity of disease and the patient's assessment of the bothersomeness of the chief symptom, the presence or absence of nerve-root compression on the MRI, the presence or absence of paresis, duration of disease, and the history with respect to sciatica. CI denotes confidence interval.

‡Values are for outcomes during the first six months.

§There were 64 possible work days in the 12-week period.

¶Values are for outcomes during the first three months.

The patients in the bed-rest group, on average, took temazepam once during the two weeks of treatment, as compared with three times for the patients in the control group ($P=0.002$). The rates of use of acetaminophen and codeine were similar in the groups. Notwithstanding the investigators' instructions, several other types of treatment were used. Only for heat treatment was there a difference in the frequency of use; patients in the bed-rest group applied heat twice, on average, as compared with five times in the control group ($P<0.001$).

DISCUSSION

We found no evidence that bed rest is an effective treatment for patients with sciatica. Slight imbalances in the distribution of characteristics that might have affected prognosis were accounted for in the statistical analysis. All planned interventions were carried out according to the schedule. The rate of loss to follow-up was less than 8 percent and was similar in the two groups. The patients in the bed-rest group were out of bed about 3 hours a day, and the patients in the control group about 14 hours a

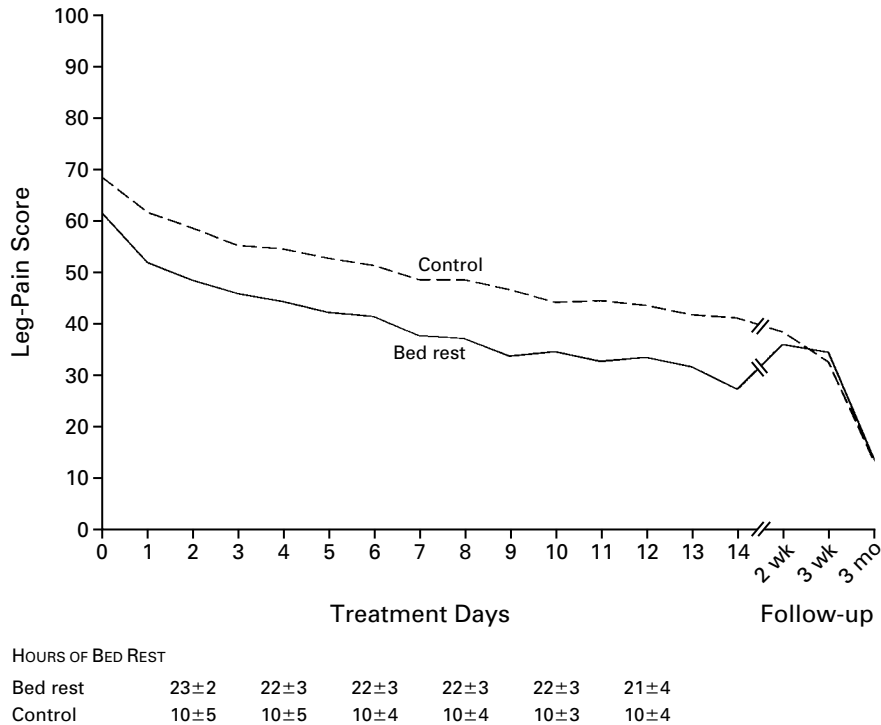


Figure 1. Patients' Scores for Leg Pain on a Visual-Analogue Scale during the First Two Weeks of Treatment for Sciatica and during Follow-up.

Patients in the control group were assigned to watchful waiting. Mean (\pm SD) total hours of bed rest are shown for days 2, 4, 6, 8, 10, and 12. Values were missing for the following numbers of patients in the bed-rest and control groups, respectively: day 2, one and three; day 4, four and four; day 6, three and four; day 8, four and five; day 10, seven and eight; day 12, seven and seven. The values shown for day 0, 2 weeks, 3 weeks, and 3 months were obtained at the clinic. Those for days 1 through 14 were from patients' records of pain scores at home.

day. Within the groups, the number of hours of bed rest was not related to the likelihood of improvement.

We were unable to obtain complete diary entries indicating compliance and pain levels for all the days for 7 patients in the bed-rest group and 11 in the control group. Additional treatments do not seem to have been important in the outcomes. Although blinding was maintained insofar as possible, the patients obviously could not be unaware of their treatment assignments.

All the patients had been seen initially by their primary care physicians for the current episode of sciatica. Though instructed to refer all eligible patients, the physicians may have preferentially referred patients with a more serious and clear presentation of nerve-root involvement, thereby possibly introducing selection bias. The patients who were referred to us but who declined to participate had base-line characteristics very similar to those of the participants.

Previous trials^{4,5} and reviews^{6,17} have addressed the effectiveness of bed rest in patients with low back pain. For patients with sciatica, trials have compared

other therapies with bed rest (an example is Coomes's 1961 comparison of epidural anesthesia with bed rest¹⁸), but the effectiveness of bed rest itself in patients with sciatica has been unclear. Although we found no adverse effects of bed rest, numerous adverse effects, both physical¹⁹⁻²⁷ and psychological,^{28,29} have been reported.

The subgroup analyses had two striking results. First, there were no significant differences in the effectiveness of bed rest between the patients with MRI evidence of nerve-root compression and those without such evidence. Hence, the response to bed rest was not better for patients with demonstrated nerve-root compression. Second, among patients with a history of sciatica, those in the bed-rest group had a higher rate of "any improvement" than those in the control group. If patients had previously had sciatica, their past experience with sciatica and with bed rest might have affected their expectations for the current episode. The outcome categories less susceptible to expectation bias (e.g., "great improvement" in pain and a decrease in the scores on the visual-analogue scale) revealed no interaction be-

tween the history with respect to sciatica and the treatment assignment.

We conclude that the majority of patients with sciatica improve with watchful waiting and that a two-week period of bed rest is not more effective.

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