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Bed Rest or Normal Activity for Patients With Acute Low Back Pain

A Randomized Controlled Trial

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Background. The management of common low back pain has two principal objectives: to relieve acute pain and to attempt prevention of transition to chronicity. Several studies have shown the ineffectiveness of prolonged periods of bed rest.

Objective. To compare 4 days of bed rest with continued normal daily activity in acute low back pain, taking into account the type of work (physical or sedentary labor).

Methods. This open, comparative multicenter study enrolled 281 ambulatory patients, ages 18 to 65 years, with low back pain (onset < 72 hours). The subjects did not have pain radiating below the buttocks and did not have work-related injuries. They were randomized into two treatment groups: one instructed to continue normal activity (insofar as the pain allowed), and the other prescribed 4 days of bed rest. After inclusion, patients were seen at three visits: on day 6 or 7, after 1 month, and after 3 months.

Results. On day 6 or 7, pain intensity was similar for both groups, as was the overall judgment of the treatment by patients and physicians. At 1 and 3 months, the groups again had equivalent intensity of back pain, functional disability, and vertebral stiffness. A higher proportion of patients in the bed rest group than in the normal activity group had an initial sick leave (86% *vs* 52%; $P < 0.0001$). This difference was greater for the patients whose work was sedentary.

Conclusions. For patients with acute low back pain, normal activity is at least equivalent to bed rest. The findings of this study indicate that prescriptions for bed rest, and thus for sick leaves, should be limited when the physical demands of the job are similar to those for daily life activities. [Key words: acute low back pain, bed rest, sick leave] **Spine 2002;27:1487–1493**

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Because of its high prevalence, common low back pain is a public health problem in all industrialized countries. The rate of recovery, assessed by return to work, varies only moderately by country, and is on the order of 60% to 70% at 6 weeks and 80% to 90% at 12 weeks.[2] In a cohort of 2342 Quebec workers followed for 3 years, Rossignol et al[15] found that 6% to 7% of their patients developed chronic pain, which represented 68% of the sick leave days and 76% of the workers' compensation costs for this condition. In the same cohort, these authors noted a positive relation between the duration of sick leave associated with the initial episode and the risk of relapse, as well as with the cumulative duration of sick leave associated with relapse.[14] The management of patients with acute low back pain thus has two principal objectives: to relieve the acute pain and to attempt prevention of transition to chronicity.

To optimize the management of low back pain, several countries have developed guidelines based on exhaustive and up-to-date reviews of the literature. The objective of these recommendations is to furnish primary care physicians with a synthesis of the scientific data that will enable them to use the treatment strategies most likely to reduce the risks of chronicity and disability associated with low back pain.[3]

The recommendations concerning bed rest for common acute low back pain have changed over the years.[3] The first guidelines, in 1994, recommended up to 4 days of bed rest, whereas the most recent guidelines, in 2000, advise avoiding bed rest to the extent possible.[1] These recommendations are based on the results of several randomized studies. In 1986, the study by Deyo et al,[5] conducted by primary care physicians in the walk-in clinic of a public hospital, found that the prescription of 2 days rest was equivalent to a prescription of 7 days in terms of pain and function. Moreover, a prescription of 2 days rest was associated with fewer days of sick leave. Nine years later, Malmivaara et al[12] showed that continuation of daily activity to the extent tolerable resulted in a more rapid recovery than either bed rest or back-mobilizing exercises.

Nonetheless, the results of these two principal studies[5,12] did not take into account the kind of work patients did. Therefore, it is difficult to be sure whether the recommendations are equally applicable to patients with sedentary jobs and those performing physical labor.

The goal of the current study was to compare, in a private practice setting, 4 days of bed rest with continuation of normal activity in the treatment of acute low back pain in terms of pain, functional disability, and days of sick leave, taking into account the type of work: physical or sedentary labor.

■ Patients and Methods

This was a randomized, open, comparative multicenter study of two treatment groups: one treated with instructions to continue their normal activity (insofar as the pain allowed), and the other prescribed 4 days of bed rest. The protocol was approved by the local ethics committee (CCPPRB) before enrollment began.

Population Studied. The study, conducted by 54 investigators, both rheumatologists and general practitioners, enrolled ambulatory patients, ages 18 to 65 years, who had acute low back pain or a painful recent episode of chronic low back pain (in the past 72 hours) with spontaneous lumbar pain rated at least 40 mm on a 100-mm visual analog scale (VAS). All patients with pain radiating below the buttocks were excluded. Current work status was neither an inclusion nor an exclusion criterion. To be enrolled in the study, patients had to accept randomization (*i.e.,* the possibility that they might be allocated to either group).

Exclusion criteria specified compressive, posttraumatic, inflammatory, infectious, or tumoral lumbar disease as well as low back pain resulting from an occupational accident. Each participant provided written informed consent.

Study Procedure. After inclusion, patients had at least three visits over 3 months: on day 6 or 7, after 1 month, and after 3 months. They were asked to record in a notebook provided at the initial consultation (day 1) the time they spent in bed each day from day 1 through day 6 or 7.

Description of and Allocation to Treatment. Randomization was centralized and stratified according to the patient's type of work (none, physical, sedentary). Accordingly, at the first visit, each investigator verified eligibility criteria, explained the study, obtained written informed consent for participation, and called the coordinating center to process the randomization (computer-generated the numbers) and be informed of the treatment allocation.

Patients in the bed rest group were advised by their practitioner to stay in bed except for personal care and eating. The mean time spent in bed was not to be less than 16 of every 24 hours, and all activity, including housework and occupational duties, were forbidden for the first four study days. Patients in the activity group were advised to continue normal daily activities, insofar as the pain allowed. The mean time spent in bed was not to exceed 12 of every 24 hours during the first 4 days (night rest included).

Whatever the allocation group, all the subjects received the same medication during the first 4 days: 1 g of paracetamol three times per day and 8 mg of a muscle relaxant, thiocolchicoside, two times per day. Nonsteroidal antiinflammatory treatment was authorized during the study in the case of real need. Any analgesic or muscle relaxant treatment other than the study treatment was forbidden during the first week. Local or systemic corticoids and local treatments such as massage, physical therapy, vertebral manipulations, or braces were forbidden throughout the 3 months of the trial.

Assessment Criteria. All assessment criteria were recorded on day 6 or 7, after 1 month, and after 3 months by the patient's treating physician, who was also the investigator. The principal efficacy criterion was back pain on day 6 or 7, as assessed on a 10-cm visual analog scale (VAS) whose anchors were "no pain" and "extreme unbearable pain." At each evaluation visit, the physician asked the patient provide a VAS rating of his or her mean pain during the 24 hours preceding the visit.

The secondary criteria were back pain, as assessed on VAS at 1 month and at 3 months, functional disability on day 6 or 7, at 1 month, and at 3 months, as assessed by the Eifel index (a French translation of the Rolland–Morris index),[4] and the number of sick leave days taken between day 6 and 1 month, and between day 6 and 3 months. The investigator, on the basis of information requested at each consultation, recorded the inclusive dates of any sick leaves. The number of sick leave days was the difference between the inclusion date and the return-to-work date. In the case of additional sick leave during the study, the total number of sick leaves was calculated.

Also studied on day 6 or 7, after 1 month, and after 3 months was the intensity of vertebral stiffness, as assessed by Schober's test, which the literature shows to be valid and reliable.[7,11] The Schober drawing was provided to the investigators to ensure the sufficient quality of the measure. A global assessment of the treatment effect by the patient (investigator inquiry) and by the investigator (self-report) was recorded at day 6 or 7 on a 5-point scale as much worse, worse, stable, improved, or much improved. The percentage of patients with one or more intercurrent episodes of low back pain was recorded, as was the percentage of patients requiring NSAID treatment or other treatment measures and the actual number of days bed rest and sick leave between day 1 and day 5. Adverse events were spontaneously reported by the patient or observed by the investigator and recorded during each consultation.

Statistical Analysis.

Calculation of the Number of Subjects. For this equivalence study, the investigators calculated the number of patients necessary to determine that the VAS on day 6 or 7 was not higher for the patients to whom normal activity was recommended than for those treated with 4 days of bed rest.

A sample of 246 patients provided a power of 90% for rating the treatments equivalent if the upper limit of the 90% confidence interval for the difference in the VAS on day 6 or 7 was less than 7.5 mm, with a standard deviation estimated at 20 mm and the real difference between the two groups estimated as zero.[10] In all, a sample of 272 patients was required to take into account a 10% dropout rate.

Intention-to-Treat Analysis. A per treatment analysis would have introduced a bias in favor of the treatment hypothesis being tested because it would have excluded the patients who had not complied with the bed rest period (essentially those doing best in the rest group and worst in the normal activity group). Accordingly, the principal analysis was an intention-to-treat analysis.

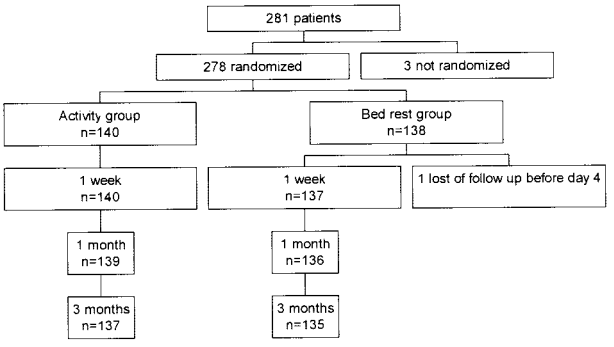

Figure 1. Trial profile.

Methods of Analysis. The confidence intervals (CI) of the differences between the two groups were calculated for the variables studied: 90% CI for the VAS on day 6 or 7. The two treatments were considered equivalent if the upper limit of the confidence interval was less than 7.5 mm, with a one-tailed α risk of 5%.

To maintain a global α risk for the other criteria (because of the multiplicity of confidence intervals), two-sided 97.5% CIs (corresponding to one-sided 98.75% CIs) were constructed, again with a 7.5 mm limit for the VAS at 1 month and at 3 months. Two-sided 99% CIs, corresponding to one-sided 99.5% CIs, were calculated for the other criteria, without any test. The CIs were calculated after adjustment for the baseline levels of the variables and for the VAS after further adjustment for the history of low back pain.

Multiple regression models were used to determine the factors associated, or not, with the initial prescribed sick days and with the cumulative sick days. Square root transformation of the number of sick days was used to normalize the distributions. Models that attempted to explain the initial prescribed sick days (dependent variable) were used to explore the initial pain, the type of work (physical or sedentary), the randomization group, and the interaction between randomization group and type of work. Models trying to explain the cumulative sick days (dependent variable) were used to explore the duration of initial prescription, the type of work, and the randomization group.

Results

Population Studied

In all, 281 patients were included in the two treatment groups. Four were excluded from the intention-to-treat analysis: one lost to follow-up evaluation and three not randomized (allocation by the practitioner without calling the randomization center). The intention-to-treat analysis included 277 patients: 137 in the bed rest group and 140 in the normal activity group. Assessment involved 275 patients at 1 month and 275 patients at 3 months (Figure 1).

During the recruitment period, a special registry collected information about the 634 subjects with low back pain who were not included in the trial. The most frequent reasons for noninclusion were impossibility of sick leave (refused randomization) (23%), refusal to consent (17%), low back pain present longer than 72 hours (15%), patient considered by the physician incapable of following the protocol (9.5%), patient not in trial age group (6%).

Patients' Characteristics

Table 1 summarizes the subjects' demographic and clinical characteristics. The two groups were comparable for most of the variables at inclusion. The intensity of low back pain on the VAS was 63.3 ± 11.3 in the bed rest group and 62.3 ± 12.1 in the normal activity group. A history of acute low back pain was more frequent in the

Table 1. Demographic and Clinical Characteristics of Patients at Inclusion

	Bed Rest Group (n = 138)	Normal Activity Group (n = 140)	*P*
Age (years)	43.6 ± 12.3	43.8 ± 11.8	0.910*
Men (%)	51.4	42.9	0.186†
Occupational status (%)			
Working	70.3	67.9	
Physical demands	41.3	40.0	
Sedentary	29.0	27.9	0.919†
Not working	29.7	32.1	
History of acute low back pain (%)	63.8	55.7	0.181†
Duration of current episode (%)			
0 day	13.0	10.7	
1 day	60.1	47.1	0.04†
2 days	25.4	37.1	
3 days	1.4	5.0	
Bed rest since beginning of the episode (%)			
Yes	14.5	17.1	0.623†
No	85.5	82.9	
Intensity of pain VAS 0–100 mm (range)	63.2 ± 11.3 (41–89)	62.3 ± 12.1 (43–95)	0.300*
Functional disability Eifel 0–24 (range)	13.1 ± 4.5 (3–22)	12.6 ± 4.2 (3–24)	0.276*
Schober test (mm)‡	25.3 ± 12.4	28.4 ± 12.0	0.033*

* Mann-Whitney test
† Fisher's exact test
‡ Schober test (mm): difference in the distance measured during erect standing and forward flexing.
VAS = visual analog scale.

Table 2. Intention-to-Treat Assessments of Patients in the Bed Rest and Normal Activity Groups at Day 6 or 7

	Bed Rest Group (n = 137)	Normal Activity Group (n = 140)	Difference Between Groups	Confidence Interval
Intensity of pain VAS (0–100 mm)*	28.05 ± 1.74	23.99 ± 1.70	−4.05	90% −8.06 to −0.04
Functional disability Eifel (0–24)†	7.37 ± 0.41	6.34 ± 0.41	−1.02	99% −2.55 to 0.50
Schober test (mm)‡§	37.7 ± 0.94	38.1 ± 0.92	0.41	99% −2.55 to 0.50
NSAID treatment n (%)	2 (1.5)	7 (5)		

* Adjustment for the initial VAS value and back history
† Adjustment for the initial Eifel index value
‡ Adjustment for the initial Schober test value
§ Schober test (mm): difference in the distance measured during erect standing and forward flexing
VAS = visual analog scale

bed rest group, but not significantly so. Pain had developed slightly more recently among the patients in the bed rest group, and the they were stiffer than those in the normal activity group. Most of the patients who worked were employed by others (93.7%) rather than self-employed or professional.

Compliance

The prescribed treatment was followed by 95 patients (72%) in the bed rest group (mean duration of bed rest at least 16 hours daily for 4 days), as compared with 122 (89.7%) of those in the normal activity group (mean duration of bed rest 12 or fewer hours daily for 4 days) ($P < 0.001$). The mean number of actual days of bed rest was 3.0 ± 1.5 in the bed rest group and 0.1 ± 0.4 in the normal activity group. The mean number of hours of bed rest during the 4 days was 17.9 in the bed rest group and 9.9 in the activity group (night rest included). The groups did not differ in compliance with the drug treatment. Overall, 80% complied, with duration of treatment ranging from 3 to 5 days.

Assessment at 1 Week

On day 6 or 7, the pain intensity measured on the VAS was similar for the two groups. The multiple linear analysis that included pain at inclusion, history of low back pain, and type of work activity showed that pain on day 6 or 7 was influenced by the first two factors. The values for the other criteria (functional disability and vertebral stiffness) were similar in both groups (Table 2).

When the patients' overall judgment of this treatment was examined, 78.8% of the patients in the bed rest group and 85% of those in the normal activity group considered that their condition had improved (OR, 1.522; 99% CI, 0.674–3.453). Similar results were noted for the investigators' overall judgment of the treatment: 80.3% *versus* 87.9%, respectively (OR, 1.776; 99% CI, 0.747–4.223)]. Recourse to NSAID treatment was necessary for 1.5% of the bed rest patients and 5% of the normal activity group.

Assessment at 1 and 3 Months

Intensity of back pain again was equivalent in the two groups. The groups also were similar in terms of functional disability and vertebral stiffness at 1 month, and again at 3 months (Tables 3 and 4). Between day 7 and 3 months, one or more episodes of intercurrent low back pain were observed in 36 patients in the bed rest group (26.l3%) and in 35 patients in the normal activity group (25%). The duration of relapse was comparable in this subset of patients for each group.

Duration of Sick Leaves

The investigators determined the need for sick leave and its duration on a case-by-case basis. The frequency and duration of sick leaves were analyzed in the subgroup of

Table 3. Intention-to-Treat Assessments of Patients in the Bed Rest and Normal Activity Groups at 1 Month

	Bed Rest Group (n = 136)	Normal Activity Group (n = 139)	Difference Between Groups	Confidence Interval
Intensity of pain VAS (0–100 mm)*	13.68 ± 1.56	10.19 ± 1.51	−3.49	97.5% −2.55 to 0.50
Functional disability Eifel (0–24)†	3.30 ± 0.34	2.47 ± 0.34	−0.82	99% −2.55 to 0.50
Schober test (mm)‡§	41.34 ± 0.95	42.52 ± 0.94	1.18	99% −2.55 to 0.50

* Adjustment for the initial VAS value and back history
† Adjustment for the initial Eifel index value
‡ Adjustment for the initial Schober test value
§ Schober test (mm): difference in the distance measured during erect standing and forward flexing
VAS = visual analog scale

Table 4. Intention-to-Treat Assessments of Patients in the Bed Rest and Normal Activity Groups at 3 Months

	Bed Rest Group (n = 135)	Normal Activity Group (n = 137)	Difference Between Groups	Confidence Interval
Intensity of pain VAS (0–100 mm)*	9.82 ± 1.50	6.49 ± 1.45	−3.34	97.5% −2.55 to 0.50
Functional disability Eifel (0–24)†	2.33 ± 0.29	1.78 ± 0.29	−0.55	99% −2.55 to 0.50
Schober test (mm)‡§	42.55 ± 0.93	45.04 ± 0.93	2.49	99% −2.55 to 0.50

* Adjustment for the initial VAS value and back history
† Adjustment for the initial Eifel index value
‡ Adjustment for the initial Schober test value
§ Schober test (mm): difference in the distance measured during erect standing and forward flexing
VAS = visual analog scale

the intention-to-treat population of employees with a complete 3-month follow-up evaluation (Table 5). This subgroup comprised 171 patients: 88 in the bed rest group and 83 in the normal activity group. At inclusion, the characteristics of each group in this subpopulation were similar to those of the total intention-to-treat population, as were their drug treatments during the study.

A higher proportion of the bed rest group than of the normal activity group had an initial sick leave (86% *vs* 52%; $P < 0.0001$, Fisher's exact test). For the two groups, the median initial duration was 5 days and 3 days, respectively. A multiple regression analysis of the factors associated with the initial prescription of sick leave showed an interaction between the randomization group and the type of work (physical or sedentary; $P = 0.0131$). That is, the difference in prescription rates between the two treatment groups was much greater for patients whose work was sedentary. Of the subjects whose work involved physical labor, 94% of those in the bed rest group had sick leave prescribed, as compared with 69% in the normal activity group. For sedentary labor, the values were 76% in the bed rest group and 25% in the normal activity group. Sick leave prescriptions were not associated with the initial level of pain.

A further analysis of the total duration of the sick leaves from day 1 to day 90 showed that this duration depended solely on the initial prescription ($P = 0.0165$). It did not depend on the treatment group or on the physical or sedentary nature of the work.

■ Discussion

This study shows that continuing normal activity with acute low back pain is equivalent to bed rest for the principal criterion (*i.e,* for back pain assessed by a VAS on day 6 or 7, as well as at 1 and 3 months). The results for the secondary criteria (functional disability and vertebral stiffness) were similar for the two groups. This is consistent with most studies on this subject.[5,6,8,9,12,13,16,17] The trial of Wiesel et al[19] was the only study whose results favored bed rest, but because its setting was in the military, these results cannot be applied to a general population.

Table 5. Sick Leave by Treatment Group and Physical or Sedentary Nature of Occupational Activity

	Physical Occupational Activity		Sedentary Occupational Activity	
	Bed Rest (n = 51)*	Activity (n = 51)*	Bed Rest (n = 37)*	Activity (n = 32)*
Initial prescription‡				
n (%)†	48 (94.1)	35 (68.6)	28 (75.7)	8 (25.0)
Median days‖	6	5	5	0
Sick leave between days 1§ and 90				
n (%)†	48 (94.1)	36 (70.6)	29 (78.4)	9 (28.1)
Median days‖	7	7	6	0
Sick leave between days 1 and 5				
n (%)†	48 (94.1)	35 (68.6)	28 (75.7)	8 (25.0)
Median days‖	5	5	5	0
Sick leave between days 6 and 14				
n (%)†	31 (60.8)	29 (56.9)	20 (54.1)	3 (9.4)
Median days‖	2	2	1	0
Sick leave between days 15 and 90				
n (%)†	9 (17.7)	7 (13.7)	5 (7.3)	0 (0)
Median days‖	0	0	0	0

* Subgroup of the intention-to-treat population of employees with a complete 3-month follow-up evaluation
† Number of patients with at least 1 day of sick leave
‡ Initial prescription means the first sick leave prescription at inclusion.
§ Day 1 means inclusion date
‖ Median duration of the sick leave during the period considered (all patients)

For feasibility reasons, the current investigation was an open study, and the patient's treating physician also was the investigator. Because of this, the assessment of the results might have been biased if the investigating physician had a particular idea concerning the rule of bed rest or activity in the treatment of acute low back pain.

This study was conducted by general practitioners and rheumatologists in private practice. Its aim was to study an occupationally mixed population and obtain results that could be applied to the general population. Because nearly all the patients were employed (93.7%), it was impossible to compare employees with the self-employed or professionals. These results thus cannot be generalized to all patients with low back pain, but only to employees. Because back pain associated with an occupational accident was an exclusion criterion, these results cannot be applied to that population either. The same is true for patients with sciatica.

Back pain before inclusion in the study had been brief, less than 3 days, as required by the inclusion criteria. The patients in the bed rest group had even a significantly shorter duration of pain than the normal activity group, a difference that might have induced bias. The authors doubt this, however. This difference did not seem clinically significant, especially because pain intensity measurements were comparable. The duration of the back pain episode in this study was briefer than in the studies of Deyo et al[5] (7 days for the prolonged rest group as compared with 10 days for the short rest group) and Malmivaara et al[12] (4.5 days).

A balanced distribution between working and nonworking patients, and between physical and sedentary work was ensured by the stratified, centralized randomization. This balance is one advantage of the current study over those previously published on this theme.[5,12] This stratification enabled the observation that the median duration of the initial sick-leave for the patients with physically demanding jobs was similar between the bed rest and normal activity groups. Sick leaves were, however, more often prescribed for patients in the bed rest group (94.1% *vs* 68.6%). The greater frequency of sick leaves in this group is explained by the need for a sick leave to comply with bed rest. Nonetheless, the same trend was observed beyond the 4-day treatment period. Among patients with sedentary jobs, the median duration of the first sick leave was longer in the bed rest group (5 *vs* 0 days). This treatment may thus prolong the duration of the initial episode. These data about sick leaves must nonetheless be interpreted with prudence because these results came only from analysis of the subgroup, which was not the object of a statistical analysis.

Drug treatment was controlled, thereby avoiding bias in the interpretation of the results. Recourse to NSAIDS in the early days of the study was low (1.5% of the bed rest group and 5% of those in the normal activity group). Nonetheless, it should be noted that investigators were advised at the beginning of the study to limit this prescription to the necessary minimum.

Compliance with the drug prescriptions was good in both groups. Compliance with the study treatment (bed rest or normal activity) was significantly better in the normal activity group. This is in accordance with the data of Deyo et al[5] about compliance in the prolonged bed rest group.

From the end of the study treatment (4 days) through 3 months, relapses were not more frequent in the normal activity group. Waddell et al[18] have already pointed out in a systematic review that rapid return to work does not seem to increase the risk of relapse.

The current findings indicate that prescriptions for bed rest, and thus for sick leaves, should be limited when the physical demands of the job are similar to those for daily life activities, in compliance with the recommendations of the Paris Task Force.[1]

In conclusion, the results of this study show that for patients whose acute low back pain is treated with paracetamol and a muscle relaxant, thiocolchicoside, normal activity is at least equivalent to bed rest. The initial prescription for bed rest increased the prescription of sick leave among patients with sedentary jobs. These factors encourage prudence in the management of patients with low back pain, especially when their occupational activity is not physically demanding.

■ Key Points

- This open randomized study compared 4 days of bed rest with continuation of daily activity in patients with acute low back pain.
- At one week, pain intensity, functional disability, and overall judgement were similar for both groups.
- The same results were obtained at 1 and 3 months.

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