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Original article

Design and feasibility of a randomized clinical trial to evaluate the effect of vertical traction in patients with a lumbar radicular syndrome

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SUMMARY. **The effect of lumbar traction in patients with a lumbar radicular syndrome has been evaluated by many different studies. The results of these studies are often in contradictory. As yet no research has been carried out into the effect of lumbar traction in a vertical position. The advantage of this type of traction is that there is no friction produced, and it can be carried out at home. Therefore, a pilot and feasibility study was performed to study the additional effect of traction therapy on bed rest patients with a radicular syndrome who were being principally managed with bed rest.**

Patients were all incident cases selected between January and May 1996 aged between 18 and 61 years old from six general practices and one hospital department of neurology. After screening for in- and exclusion criteria, patients were randomly assigned to either 1. the bed rest group or 2. the bed rest plus traction group. Traction consisted of vertical traction applied at home for at least 3 hours a day with a maximum of six applications a day. Outcome measures included 1. improvement on the Roland Disability Questionnaire (RDQ), 2. improvement on a 10-point rating scale, registered in a pain diary for leg and back pain separately, 3. global perceived recovery measured on a seven-point rating scale (all three were measured after 3 weeks) and 4. physical examination that was measured after 2 weeks (Schöberscore, Lasègues test, crossed Lasègues test).

Sixteen patients were included in the study and randomized into two treatment groups. The two treatment groups were, despite small differences, similar regarding most base-line characteristics. The traction group showed slightly more improvement on the RDQ (difference: 2.2), the mean pain reduction in the leg (difference: 2.0) and Lasègues test (67% vs 38%). In addition more patients in the traction group reported complete recovery or much improved status regarding their back pain compared to the bed rest only group.

The main problem found in this study was patient recruitment, which was lower than expected. Furthermore, seven patients experienced some problems with the traction belt. In five of these seven cases this problem was very easily solved. One patient, however, hyperventilated and had to refrain from traction.

This study indicated a potential small beneficial and short-term effect of traction therapy in addition to bed rest in patients with a radicular syndrome. Since the study was a pilot and feasibility study no conclusion can be drawn concerning the efficacy of vertical traction. The authors recommend that a larger study should be conducted with some changes in the protocol to evaluate the effect of this therapy in patients suffering from a lumbar radicular syndrome.

INTRODUCTION

Low back pain is a common disorder. Approximately 80% of all adults will experience an episode of low back pain in their lives (Fast 1988; Jensen et al. 1994; van der Heijden et al. 1995; Faas et al. 1996). Most cases of low back pain are non-specific, and only 5–10% of all cases are due to a specific cause such as nerve root compression, m. Bechterew, malignancies etc (Faas et al. 1996). A common theory is that non-specific low back pain is correlated with the stressing of discs, joints, nerves and muscles (Weber et al. 1993; Faas et al. 1996). Until recently it has not been possible to classify non-specific low back pain reliably in relation to an affected structure (Beurskens 1996; Faas et al. 1996). Fortunately, the

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prognosis is in most cases favourable. Ninety-five per cent of all cases recover within a period of 3 months (Faas et al. 1996). After recovery, however, 50–80% of the cases experience a relapse within one year (Faas et al. 1996).

Radicular syndrome is a frequently occurring associated disorder of low back pain (Saal & Saal 1989; Shvartzman et al. 1992; Beurskens 1996; Faas et al. 1996). In this article radicular syndrome is defined as low back pain radiating below the knee together with at least two of the following complaints: immobility of the lumbar spine, positive Lasègue's sign, sensitivity disorders, loss of strength or reflex disorders.

The incidence of radicular syndrome in The Netherlands is estimated to be five per 1000 registered patients (in general practice) per year (Faas et al. 1996; Smeele et al. 1996). It is often due to a herniated intervertebral disc. However, many non-symptomatic herniated discs can be found in healthy subjects (Jensen et al. 1994; Smeele et al. 1996). It is also possible that patients recover from the syndrome while the herniated disc is still present. Therefore, an additional irritation of the nerve root is probably necessary for the development of sciatic symptoms (Weber 1994; CBO 1995; Smeele et al. 1996).

The prognosis of patients with a radicular syndrome is worse than the prognosis of patients with non-specific low back pain, but is still favourable. More than 80% of patients with a radicular syndrome can successfully be treated with conservative care (Smeele et al. 1996). These patients usually recover within 10–12 weeks (Shvartzman et al. 1992).

Many different treatment modalities are used in the treatment of a radicular syndrome. In general the treatments can be divided into conservative and invasive treatments.

In most cases conservative therapy is the treatment of first choice. One of the most frequently used treatments is bed rest, which aims to reduce the pain and decrease intradiscal pressure (Fast 1988; Smeele et al. 1996). The effectiveness of bed rest, however, has not yet been thoroughly tested. Also, the optimum duration of bed rest has been under debate. In a review article, Fast concluded that in patients with a radicular syndrome a period of 10–14 days bedrest should be prescribed (Fast 1988). However, another study indicated that a period of 1 week was enough (Weber et al. 1993). Most authors consider 2 weeks of bed rest to be a good compromise, providing enough rest for the patient to recover from the inflammatory reaction on the one hand, and to restrict the patient's inactivity on the other hand (Bell & Rothman 1984).

Another prescribed conservative treatment is lumbar traction. In The Netherlands, patients receive traction therapy in approximately 7% of the annual 21 million physical therapy sessions (Groenewegen et al. 1989; van der Heijden et al. 1995). However, this includes all traction therapies. No precise information is available about the amount of traction therapy prescribed in patients suffering from low back pain or radicular syndrome (Groenewegen et al. 1989).

There are many different traction modalities available. Most of them are applied with the patient in a horizontal position with the traction force working in a horizontal direction. In this position, however, the main counterforce is the friction between the body and the support-surface, which is absent in vertical traction (Kane et al. 1985; van der Heijden et al. 1995). Another possible advantage of vertical traction is that it can be applied at home for more frequent and lengthier periods, thereby increasing the dosage of traction.

Rationale of traction therapy

Different mechanisms are proposed to explain the rationale of traction therapy. In all these explanations the increase of the intervertebral disc space is a central feature (Lehman & Brunnes 1958; Weber 1973; van der Heijden et al. 1990, 1995). This increase possibly has two main consequences. Firstly, it has been assumed that with the increase of the intervertebral disc space the nerve roots may be decompressed (Weber 1973; van der Heijden et al. 1990). It has been suggested that, because of the increase of the intravertebral disc space, the intradiscal pressure may decrease and the nucleus pulposus may slide back into the intervertebral disc space spontaneously (Weber 1973; van der Heijden et al. 1990). Because lying in a horizontal position also decreases the intradiscal pressure, traction might have a beneficial additional effect on bed rest therapy (Fast 1988).

A second proposed mechanism is the relaxation of the back musculature. The activity of the lumbar musculature decreases significantly in healthy people after only 7 minutes of traction (Weber 1973; van der Heijden et al. 1990). However, this could not be confirmed by Letchuman et al. (1993). The minimal force needed for relaxation of the muscles has yet to be established. However, it has been established that a force of 25% of the total body weight is the minimum force needed to overcome the counterforces, such as friction with the table and widening of the disc space, in horizontal traction (van der Heijden et al. 1990).

Delordosis of the lumbar spine (van der Heijden et al. 1990; Beurskens 1996), a combination of distraction and gliding of the facet joints (Onel et al. 1989; van der Heijden et al. 1990; Beurskens 1996) and stretching of the spinal ligaments (Onel et al. 1989; Beurskens 1996) are other proposed mechanisms.

Little research has been carried out to investigate these mechanisms. However, an increase of the intervertebral height posteriorally was seen in three studies investigating the physical effects of traction (Lehmann & Brunner 1958; Kane et al. 1985; Onel et al. 1989).

Given the postulated working mechanisms of traction therapy, beneficial effects, if any, are most likely to be expected in patients with a radicular syndrome.

Much research has been carried out to study the effects of horizontal traction. Six randomized controlled trials (RCTs) evaluating the effect of traction in non-specific low back pain resulted in contradictory outcomes. Most of them were of poor methodological quality or lacked power (van der Heijden et al. 1990; van der Heijden et al. 1995). However, given the available evidence, including the most recently published high quality RCT, it may be concluded that for patients with non-specific low back pain traction therapy is not efficacious (Beurskens 1996).

The six RCTs using patients with sciatica also showed contradictory results. One study showed that traction had significantly better short term results than rest and a corset (Larsson et al. 1980). Although one study (Mathews et al. 1975) showed a slight, non-significant, benefit of traction, none of the other RCTs could confirm this result (Weber 1973; Coxhead et al. 1981; Weber et al. 1984).

No RCTs have yet been carried out to study the effect of vertical traction. The authors of this paper performed a feasibility study to evaluate the additional effect of vertical traction on bed rest management in patients with lumbar radicular syndrome. In this paper the short term results of the study are presented.

The aspects of the practical feasibility in which the authors were interested focused on:

- the selection procedure, including the number of eligible patients and the patients' willingness to participate
- the practical implications of traction at home
- the effect measurement.

METHODS

Selection of patients

Incident cases of lumbar radicular syndrome, diagnosed by their general practitioner or neurologist, were recruited from six general practices and one hospital department of neurology in the period from January 1996 to May 1996. The patients were included if they were aged between 18–60 years, had backpain radiating below the knee and were prescribed bed rest by their physician for at least 1 and a maximum of 2 weeks. They also had to have at least two of the following neurological signs: loss of sensitivity in one or two dermatomes (L_4–S_1), paralysis in the musculature of the lower extremities, provocation of the leg symptoms with increased pressure such as coughing or sneezing, a positive Lasègue's sign and asymmetry of the lower limb references (Table 1).

As a measurement of the immobility of the lumbar spine the Schöberscore was determined. A horizontal line was drawn between the two superior posterior iliac spines. Exactly in the middle of this line a point 15 cm above the line was marked on the lumbar spine.

Table 1. Selection criteria observer

History taking
complaints about sensitivity in one or two dermatomes (L_4–S_1)
complaints about reduction of strength
provocation of the leg symptoms with increased pressure
Physical examination
immobility of the lumbar spine
dermatologic disorder in L_4, L_5 or S_1
paresis:
m. extensor hallucis longus
mm. peronei
m. tibialis anterior
mm. triceps surae
m. quadriceps femoris
m. iliopsoas
mm. glutei
mm. hamstrings
Lasègue's tests
the normal Lasègue's sign
the crossed Lasègue's sign
asymmetry of reflexes
knee jerk
ankle jerk

The patient then bent forwards maximally. The Schöberscore was recorded as the number of centimeters in lengthening that occurred during the movement. For the Lasègue's test the patient lay horizontally. The test was regarded as positive when raising of the leg provoked radiating pain in the same leg. The crossed Lasègue's test was regarded as positive when raising of the non-affected leg provoked radiating pain in the affected leg. The angle between the leg and the supporting horizontal surface on which the tests were performed was also noted, using three categories: <30 degrees, <60 degrees and, <90 degrees (van den Hoogen 1996).

The skin sensitivity was tested in the dermatomes L_4, L_5 and S_1. Sensitivity was tested by comparing the two legs.

Two reflexes were tested: the knee jerk and the ankle jerk. The reflexes were noted according to the following score: –2 = absent; –1 = hard to generate; 0 = normal; 1 = lively; 2 = clonus.

In testing paresis of the two legs were compared. The extent of the paresis was expressed in a number ranging from 5 (normal strength) to 0 (no contraction). The strength was tested in the following muscle groups: extensor hallucis longus, peronei, tibialis anterior, triceps surae, quadriceps femoris, iliopsoas, glutei and the hamstrings.

All baseline measurements were carried out before randomization. Blinding of the patients was, of course, not possible. However, the observer, who was an experienced physiotherapist, was blind to the allocated treatment of the patients.

Patients with radicular syndrome due to specific underlying diseases (e.g. cauda syndrome, malignancies, traumas, etc.) or anatomical abnormalities (e.g. trunk-obesity, etc.) were excluded. In addition, patients

Table 2. Exclusion criteria

Underlying diseases:
malignancy
the complaints are due to a severe trauma
problems with micturition (possible cauda syndrome)
operated on the back within the last 6 months
Contraindications for traction:
disorders of the heart
disorders of the lungs
tightness of the chest at exertion or at night
abnormality of the trunk, trunk obesity
hypertrophy of the liver, other disorders of the liver
disorders of the kidneys
disorders of the pancreas
severe disorders of the blood
pregnancy
treatment with anti-coagulants

were excluded if they were suffering from a disease, which constituted a contraindication for traction therapy, such as respiratory diseases (Table 2).

The treating physician referred the patient to the study coordinator. The coordinator first screened the patient regarding the exclusion criteria (Table 2). If, according to the coordinator, the patient could be included in the trial, an appointment was made with the observer who checked the patient on the criteria listed in Table 1.

Eligible patients, who consented to participate, were randomly assigned to either bed rest and traction, or bed rest alone by the coordinator. The patients were randomized in blocks of six. The randomization was performed by opening sequentially numbered sealed opaque envelopes that contained the prerandomized treatment code.

Interventions

The bed rest intervention (in both groups) was prescribed for at least 1 and a maximum of 2 weeks by the treating physician. Toilet visits were allowed, but the patients had to register in a diary the number of times they got out of bed. In order to equalize the number of times the patients had to get out of bed in both groups, traction patients were asked to combine a toilet visit with a traction session.

Traction therapy consisted of a vertical traction in addition to the bed rest therapy. In the traction device the patient hung in a vertical position (Fig. 1). The device consisted of a metal frame and a synthetic belt, which was applied around the chest. Patients, who received traction devices at home, could apply the devices themselves without assistance, so therefore they could apply the traction therapy at home at their convenience. On the first day of their bed rest period the patients received an instruction regarding the use of the traction device. The prescription was for four times 45 minutes, or six times 30 minutes.

Physical therapy was not allowed during the intervention period. If the patient's attending physician insisted on physical therapy, the therapist was allowed to give instructions concerning the best way to use the back only. Furthermore, the following agreements were made with the cooperating physicians regarding the patients' medication. If the physician wished to prescribe pain medication, an analgesic was prescribed first. If necessary (in case of severe pain) NSAIDs could be prescribed. If the effect of the NSAID was not sufficient, the physician could add diazepam®, or they could then change the NSAID for an alternative NSAID.

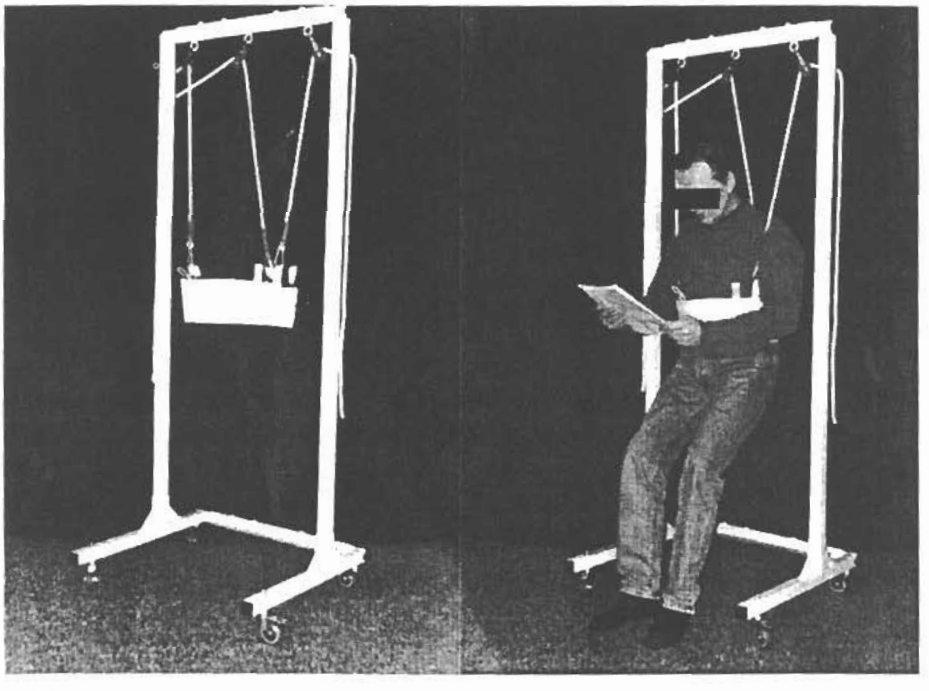

Fig. 1

Finally, the physician was allowed to prescribe an opiate. The patients were asked to register in a diary the drugs that they had used.

Effect measurement

For measuring the short term effects of vertical traction, all patients were examined by the observer at baseline and at 2 weeks follow-up, which for all patients was the maximum time period for bed rest. At a 3-week follow-up appointment the patient was seen by the study coordinator.

Four outcome measures were recorded:

1. improvement on the Roland Disability Questionnaire (RDQ) (Roland & Morris 1983), measured after 3 weeks by the coordinator
2. mean pain score measured by a pain diary (filled in by the patient for 3 weeks) using a 10-point rating scale, for pain in the leg as well as for the pain in the back
3. global perceived recovery rated by the patient on an ordinal seven-point scale ranging from completely recovered to worse than before, measured after 2 weeks by the observer
4. physical examination after 2 weeks by the observer.

The global perceived recovery was assessed by the patients themselves and focused on perceived recovery in general and on back pain and leg pain separately.

The same protocol prescribed at the baseline measurements for the physical examination were used to measure the Schöberscore and Lasègue's tests after 2 weeks. Patients were classified as being improved when they improved by one point on a four point scale: 1 = positive at $<30°$, 2 = positive at $<60°$, 3 = positive at $<90°$ and 4 = negative.

RESULTS

In the period January 1996 – May 1996, 18 patients were referred by their treating physician. One patient had no radiating pain below the knee and had to be excluded. Another patient refused to participate. Eventually 16 patients entered this study, of which eight were randomly assigned to each treatment group.

The two treatment groups were similar regarding most of the demographic and clinical baseline characteristics (Table 3). The Schöberscore was somewhat higher in the traction group. In the bed rest group two patients had received physical therapy for the present episode, but in both cases the therapy had ended before the patients were included in the study. In the bed rest group there were also more patients with reflex asymmetry of the achilles tendon.

In the traction group two patients had received back surgery in the past, but none of the bed rest patients had received back surgery. Two patients in the traction group had unequal knee jerks versus none of the bed rest patients. Although there were some slight differences between the groups, it can be concluded that, in general, the groups were more or less comparable regarding most prognostic indicators.

Table 3. Comparability of treatment groups with respect to distribution of prognostic variables at baseline

Characteristics	Bed rest and traction	Bed rest
No. of patients	8	8
no. hospitalized	3	3
Mean age (SD)	43.3 (9.0)	39.8 (8.8)
Gender (no. males)	7	5
Onset of complaints		
sudden (no.)	5	3
Use of painkillers (no. yes)	8	6
Radiation in the foot	5	6
Previous therapy during this episode	3	3
bed rest	3	1
physical therapy	0	2
No. of previous episodes	6	6
7–10	3	0
more than 10	1	1
Back surgery in past	2	0
No. of persons with paid jobs	7	7
No. of persons with paresis	7	5
No. of persons with sensitivity asymmetry	6	5
No. of persons with patellar-reflex asymmetry	2	0
No. of persons with achilles-reflex asymmetry	1	6
Schöberscore (sd) (cm)	3.5 (2.2)	2.6 (0.8)
Positive Lasègue score	6	8
Positive crossed Lasègue score	2	2
Mean pain score (back) on a 10 point rating scale (sd)	6.6 (2.0)	5.3 (2.7)
Mean pain score (leg) on a 10 point rating scale (sd)	7.4 (1.2)	7.3 (1.0)
Roland disability score* (sd)	18.1 (1.8)	18.5 (2.1)

*Roland disability score ranges from 0 to 24.

Outcome measurements

Outcome measurements were divided in two categories. Firstly the measurements focusing on the complaints of the patient (Table 4), and secondly the measurements that were obtained from the physical examination (Table 5).

The mean improvement on the RDQ, measured at 3 week follow-up, was somewhat higher in the traction group (3.6) than in the bed rest group (1.4) (Table 4).

Furthermore, the patients kept a diary in which they scored their pain every day on a 10-point rating scale. The mean daily pain scores for each group are graphically presented for the back and leg pain separately (Figs 2 and 3). These graphics show that the leg pain in the traction group increased and subsequently decreased and finally ended about two points lower compared with the score of the bed rest group. For back pain, however, no difference can be seen in the two groups.

Table 4. Outcome measurements. Improvement and difference between treatment groups with 95% confidence interval (CI)

Outcome measure	Bed rest and traction ($n = 8$)	Bed rest ($n = 8$)	Difference	95% CI
Improvement on the Roland disability questionnaire after 3 weeks	3.6	1.4	2.2	−1.57; 5.97
Mean pain reduction on a 10 point rating scale, measured after 3 weeks (leg)	3.0	1.0	2.0	−1.99; 3.99
Mean pain reduction on a 10 point rating scale, measured after 3 weeks (back)	3.1	3.0	0.1	−2.56; 2.84
Global perceived recovery after 2 weeks				
In general	1	0	–	–
recovered	4	4	–	–
strongly improved	2	1	–	–
little improved	1	2	–	–
no change	0	0	–	–
little worse	0	1	–	–
much worse	0	0	–	–
worse than ever				
back pain	2	1	–	–
recovered	4	2	–	–
strongly improved	0	2	–	–
little improved	2	3	–	–
no change	0	0	–	–
little worse	0	0	–	–
much worse	0	0	–	–
worse than ever				
leg pain	1	1	–	–
recovered	3	3	–	–
strongly improved	2	2	–	–
little improved	1	1	–	–
no change	1	0	–	–
little worse	0	1	–	–
much worse	0	0	–	–
worse than ever				

Table 5. Improvement in physical measurements after 2 weeks

Outcome measure	Bed rest and traction	Bed rest	Difference	95% CI
Improvement on Schöberscore (cm)[1]	0.61	1.39	0.78	1.19; 2.76
No. of patients improved on Lasègue's sign(%)[2,3]	4 (67)	3 (38)	–	–
No. of patients improved on crossed Lasègue's sign(%)[2,4]	2 (100)	2 (100)	–	–

[1]In both groups one patient is missing.
[2]Only the patients who were positive in those tests at baseline. A patient is classified as being improved when he went one point up on a four-point scale.
[3]($n = 6$ traction group; $n = 8$ bed rest group).
[4]($n = 2$ traction group; $n = 2$ bed rest group).

The mean pain reduction in the leg measured on a 10-point rating scale was somewhat higher in the traction group (3.0) than in the bed rest group (1.0) (Table 4). None of the differences were statistically significant on the conventional 5% level (using Wilcoxon's test). No difference between the two groups was found in the mean pain reduction concerning back pain.

In the traction group more patients ($n = 6$ vs $n = 3$ in the control group) indicated that they were completely recovered or strongly improved concerning their back pain. There were no differences regarding global perceived recovery in general or concerning their leg pain (Table 4).

Regarding the outcome measurements obtained from the physical examinations more patients in the traction group (4 out of 6) compared to the bed rest group (3 out of 8) improved on Lasègue's test. The improvement on the Schöberscore was the same in both groups.

Practical feasibility and compliance of intervention

The biggest problem with this study was the recruitment of patients, which was much lower than expected. From the six general practitioners approximately two patients per month were obtained, and from the hospital approximately four a month. The recruitment from the hospital started in April 1996. Eventually 16 patients participated whereas the

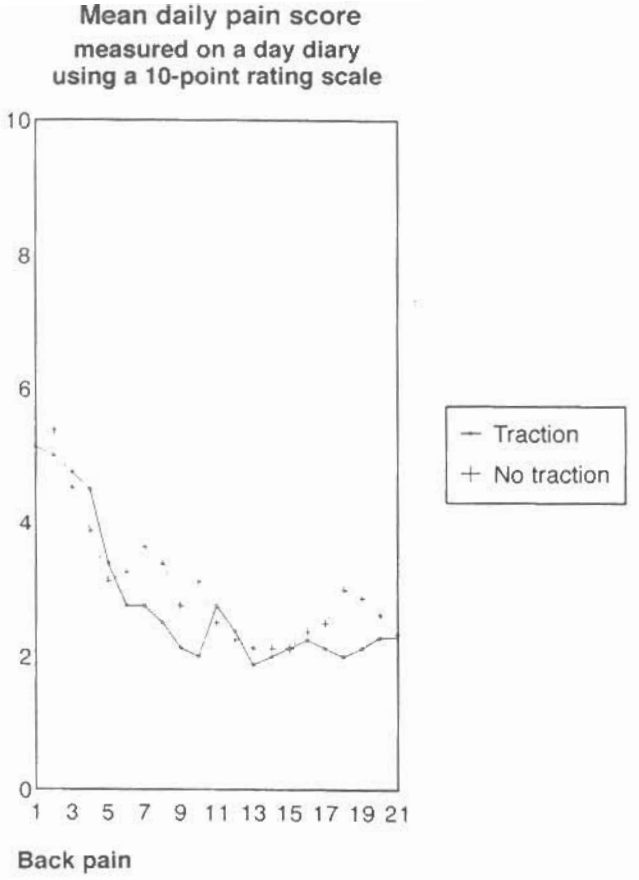

Fig. 2

researchers had expected that about 30 patients could be recruited in this period.

Table 6 provides information about the compliance and the implementations of the traction therapy. The duration of the bed rest period was somewhat longer than prescribed and was somewhat longer in the bed rest group (mean 16.9 days) than in the traction group (mean 15.4 days). Furthermore, the traction patients got out of bed more often (6.4 times) than the bed rest patients (3.0 times). On average the patients used the traction device five times a day for 34 minutes. This means that in general the patients in the traction group followed the traction protocol very well.

Table 6. Compliance

	Bed rest and traction	Bed rest
Number of days of bed rest (mean, sd)	15.4 (2.9)	16.9 (2.1)
Number of times out of bed per day (mean, sd)[1]	6.4 (0.5)	3.0 (0.4)
Number of times traction per day (mean, sd)[1]	4.9 (0.5)	–
Minutes of traction per session (mean, sd)[1]	34.1 (2.12)	–
Withdrew from traction	1	–

[1]Until day 14.

One patient had to stop traction before the end of the therapy period because of hyperventilation complaints. Other transitional complaints about the traction mainly concerned discomfort from the traction belt ($n=6$). These kinds of complaints were corrected by the traction supplier who checked the belt and gave extra instructions about how to fasten the belt around the chest. After correction five of the six patients no longer had any complaints from the belt. No other complaints were noted by the patients.

The blinding of the observers did not work well. The traction device was too big to hide in most situations. Therefore, the observer could see the device when he visited the patients. In the hospital it was even worse because the observer there had to visit the department of neurology every day for the treatment of his other patients (not included in the study). Therefore he saw which patient received traction therapy when he visited.

DISCUSSION

From this study no conclusions can be drawn regarding the effect of vertical traction on lumbar radicular

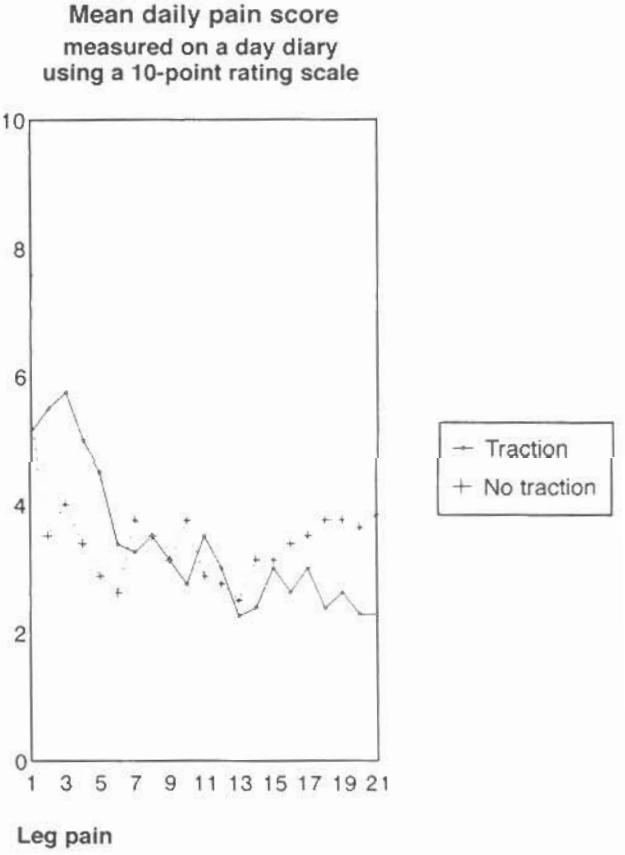

Fig. 3

syndrome. In view of the main rationale for traction, decompression of the nerve root, which leads to relief of the radiating pain (van der Heijden et al. 1990), and the fact that the main improvement of patients with traction therapy in this study occurred in terms of a reduction in leg pain, indicate that vertical traction may have had a beneficial effect. However, more important in this study are the conclusions that can be drawn regarding the practical feasibility of such a study.

It seems contradictory that the results from the mean pain scores indicate that traction therapy was only beneficial for the leg pain where the global perceived recovery indicates that therapy was only beneficial in reducing the back pain. However, the global perceived recovery was measured after 2 weeks, immediately after the bed rest period, and the pain scores were measured after 3 weeks. It may be possible that general mobilization in the third week changed the perception of the patients' pain.

Patients' recruitment in the study was much smaller than expected. The intake from the hospital was relatively higher than the intake from the general practitioners, but was still low. The application of the selection procedures went well, although it may have been more efficient if the whole selection procedure could have been carried out by a single person.

A problem associated with the traction therapy was that in most cases the belt did not fit initially. Many patients initially applied the traction belt at the wrong height and reported discomfort. After a visit of the supplier of the traction devices, most of the problems were solved. Therefore, in any future study, attention must be given to this problem. Perhaps better written instructions for the patients about how to use the belt would be necessary.

Another concern in any future study was the venues for study. In this case the patients were recruited from a hospital as well as from six general practitioners. The number of hospitalized patients was equal in both groups. The authors believe that it would have been best to carry out this study in a hospital setting initially, because in this setting confounding factors are easier to control and the potential number of suitable patients for inclusion in the study is relatively higher than in general practices. However, more hospitals would be needed in order to recruit enough patients in a reasonable time-period.

A further problem is the blinding of the patients and observers. The blinding of the patients was impossible as was known at the start of the study. In the authors' opinion there are no solutions to this problem. The blinding of observers failed in this pilot study, as mentioned earlier in the paper. A solution for this problem may be that the measurements could be carried out by an independent observer and that the patients, still in bed, could be brought to the observer elsewhere in the hospital. In this case, however, it would be necessary for the patient to be instructed repeatedly not to tell the observer which therapy they had received.

In conclusion, the authors recommend that a larger study takes place with some changes in the protocol to evaluate the effect of this type of therapy in patients suffering from a lumbar radicular syndrome.

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