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Efficacy of Lumbar Traction: A Randomised Clinical Trial

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Key Words

Randomised clinical trial, traction, low back pain.

Summary

This pilot study for a randomised clinical trial compares the effect of high-dose continuous lumbar traction and low-dose continuous lumbar traction on the magnitude and rate of recovery for patients with low back pain. A motorised traction force of 44% of the body weight was applied in the treatment group ($n=13$) and of 19% in the control group ($n=12$). Both groups were comparable before randomised treatment allocation. The patients were blinded successfully. The results for most outcome measures favoured high dose traction, treatment *versus* control group: 64% *v* 34% at five weeks, and 45% *v* 25% at nine weeks. These results are clinically substantial but do not reach statistical significance (95% confidence intervals include zero). Due to the small number of patients this study lacks power, therefore the 95% confidence intervals are very wide. With 50 patients in each group the 95% confidence intervals at five weeks would have excluded zero.

Introduction

Back pain is very common in Western industrialised countries. Approximately 80% of all people will suffer from one or more episodes of back pain in the course of their active life (Frymoyer, 1988; Kelsey and White, 1980; Kelsey, 1982). In most cases no underlying disease can be established and the causes of the complaints remain unknown, but the majority of all episodes of back pain disappear within a few months, often with the help of rest, analgesics, and home exercises. Only a small proportion (about 5%) suffer for more than three months (Frymoyer, 1988). The recurrence rate of back pain is high: approximately 60% of all episodes are followed by a relapse (Kelsey and White, 1980; Kelsey, 1982). Little is known about the relevant prognostic

indicators for relapse and chronicity. The prognosis seems to worsen with the occurrence of radiating pain and with increasing duration and recurrence rate (Hull, 1982; Roland, 1983; Pedersen, 1981; Turk and Flor, 1984). Although back pain is the most frequently presented disorder of the musculoskeletal system in general practice, there is no consensus about its management. The efficacy of therapeutic interventions for back pain, including physiotherapy, still remains questionable (Frymoyer, 1988; Quintet and Hadler, 1979; Rose, 1979; Bell and Rothman, 1984; Koes *et al*, 1991a, b; Grahame, 1980; Deyo, 1983; Spitzer *et al*, 1987).

General practitioners in the Netherlands often refer patients with persistent complaints of the musculoskeletal system for physiotherapy. Approximately 41% of these are patients with persistent low back pain (Grundemeijer and Brouwer, 1989). In these cases traction is one of the possible treatment options. In the Netherlands patients receive motorised lumbar (or cervical) traction treatment in approximately 7% of the annual 21 million physiotherapy sessions, often combined with other treatment modalities (eg massage, exercises, ultrasound, electrotherapy or heat) (Groenewegen *et al*, 1989; Beckerman *et al*, 1993).

Of all the traction modalities (motorised, manual, bedrest, pulley-weight, gravitational, suspension, inverted) motorised and manual lumbar traction are most frequently applied (Harris, 1976). Traction is exerted by two canvas harnesses (with Velcro strapping). One is put around the lower rib cage and the other around the iliac crest (Harris, 1976; Saunders, 1983; Geiringer *et al*, 1988). The duration and magnitude of force exerted during motorised lumbar traction (ie the traction is exerted by a motorised pulley) can be varied in a continuous or intermittent mode (Harris, 1976; Saunders, 1983; Geiringer *et al*, 1988; Swezey, 1983). With the patient lying on the traction table, the friction of the body on the table provides the main counterforce during traction (Saunders, 1983; Geiringer, Kincaid and Rechtien, 1988). In lumbar traction in a horizontal plane, these counterforces can be reduced by as much as 85% by using a friction free tabletop (Youel, 1967; Judovich and Nobel, 1957). In applying traction force, counterforces depending

on the angle of pull and on the patient's position also must be taken into account, as well as lumbar muscle tension, lumbar skin stretch and abdominal pressure (Harris, 1976; Saunders, 1983; Geiringer *et al*, 1988; Youel, 1967; Judovich and Nobel, 1957).

Literature Review

Little is known about the mechanism by which traction could be effective. The rationale for using lumbar traction is based on mechanical and neuroreflectory mechanisms (Harris, 1976; Saunders, 1983; Geiringer *et al*, 1988). However, there is no clear scientific evidence favouring any of the proposed mechanisms. It is not very likely that an annular tear would disappear through traction, or that a protruded or prolapsed nucleus of an intervertebral disc could be retracted and stabilised within the annulus by spinal elongation (Gillström *et al*, 1985; Ljunggren Eldvik, 1986). Spinal elongation due to intervertebral widening is likely to occur with a traction force above but not below 25% of the total body weight (Colachis and Strohm, 1969). With lumbar traction forces below 25% of the total body weight relaxation of spinal muscles are usually assumed to play an important role (Gillström *et al*, 1985; Onel *et al*, 1989; Reilly *et al*, 1979; Hood *et al*, 1981; Murphy, 1991). However, so far credible empirical evidence for this mechanism is lacking.

No systematic research has been performed into the adverse effects of traction (Eie and Khristiansen, 1962). Only a few case reports are available, which suggest that there is some danger in lumbar traction forces exceeding 50% of the total body weight (Saunders, 1983; Quain and Tecklin, 1985; Yates, 1972). Other risks described for lumbar traction are respiratory constraints due to the traction harness or increased blood pressure during inverted positional traction (Haskvitz and Hanten, 1986; Kand *et al*, 1985; Plocher, 1982; Balogun *et al*, 1990; Hood *et al*, 1981; Twomey, 1985). Furthermore, it has been theorised that traction in cases of medial or distal protrusion of the nerve root might increase nerve impingement (Rahlman, 1987).

The efficacy of lumbar traction should preferably be evaluated in randomised clinical trials (RCTs – Pocock, 1991; Bloch, 1987; Meinert, 1986). Until now 16 RCTs about the effectiveness of lumbar traction or a specific modality thereof have been published (Heijden *et al*, 1995). However, most of these studies are very small, and they all suffer from severe methodological flaws. The most common methodological flaws concern poor prognostic comparability at baseline; lack of information about the randomisation procedure; incomparability of the co-interventions; and lack

of blinding of the patients during treatment and during outcome assessment. These flaws hamper valid conclusions about the effectiveness of lumbar traction (Heijden *et al*, 1995). There has been no evidence for any specific effect of traction. On the other hand, there are no clear indications that lumbar traction is an ineffective therapy as well (Heijden *et al*, 1995). In this article we present the design and results of an RCT. It is a small scale pilot study (Heijden, 1990; 1991) which tries to prevent the methodological flaws from earlier studies (Heijden *et al*, 1995).

Methods

Study Design

This randomised clinical trial compares the effect of high and low-dose (or sham) motorised continuous lumbar traction on the magnitude and rate of recovery for patients with low back pain. The study protocol has been approved by the Medical Ethics Committee of the University of Limburg and the University Hospital Maastricht. The study has been conducted in the department of physiotherapy in that hospital. Figure 1 shows the design of the study.

Tx = Start of selection procedure
 T0 = Randomisation after documentation of prognostic status and baseline measures
 Treatment phase: 4 weeks, 3 sessions of 20 minutes per week
 T5 = Effect measurement 5 weeks after T0
 T9 = Effect measurement 9 weeks after T0

Fig 1

Enrolment

Patients between 25 and 65 years of age were enrolled if they suffered from persistent non-specific low back pain and/or sciatica, and had no experience with traction treatment. *Non-specific* meant that no evidence was available for underlying systemic disease or anatomical abnormalities, and *persistent* meant for at least three months.

Informed Consent and Randomisation

Before treatment allocation with sealed envelopes, the eligibility criteria were checked (table 1), written informed consent was obtained and prognostic indicators and baseline status of the effect measures was documented. The sealed envelopes contained a code for either high or low dose lumbar traction and were prepared by an

independent person from a list with random numbers. The treating physiotherapist opened the envelope at the first treatment session, and therefore was not blinded for the assigned treatment. This procedure ensured blinding of both patients and researchers who selected patients.

Table 1: Eligibility criteria

Inclusion

Between 25 and 65 years of age
Low back pain for 3 months or longer
Never before treated with traction
No other treatment
Fluent in the Dutch language

Exclusion

Inguinal hernia
Pregnancy
Cardiovascular disorder
Respiratory disorder
Spastic hemiplegia
Malignancy
(Previous) prolapse of nucleus pulposus
Pain or numbness on coughing or sneezing
Spondylolysis/spondylolisthesis
Hemilumbarisation/hemisacralisation
Congenital hip dysplasia
Bechterew syndrome
Scheuermann syndrome
Ehlers Danlos syndrome
Osteoporosis
Previous fracture, operation or subluxation in thoracic, pelvic, lumbar, or hip region
Local acute infection
5 cm or more difference in leg length

Interventions

For every patient at least ten and at most 12 treatment sessions during four consecutive weeks were planned, usually three times a week, with the same physiotherapist from the department of physiotherapy at the University Hospital, Maastricht. To minimise variation in patient instruction between the five participating physiotherapists, a leaflet with patient instruction about low back pain and activities of daily living was given to every patient after randomisation (Heijden *et al*, 1990, 1991). Patients were allowed to continue with their regular pain medication, but other co-interventions (eg injections, massage, exercises, physical modalities) were not allowed. The treatment series could be ended if a patient was free of symptoms before the last session or if the pain increased during two consecutive treatment sessions. All patients were treated with the same traction device (Finntrac-03, Instrumentarium Oy Kojevalmistus – Lamérís Instruments, Utrecht, The Netherlands), which was calibrated before the start of the study. After the patients lay down on the table top in a comfortable position, the canvas traction braces were attached around the iliac crest and the lower thoracic cage.

Since spinal elongation is likely to occur with a traction force above but not below 25% of the total body weight, the minimal intervention contrast was set at a traction force of 5% of the total body weight (treatment *versus* control group: 30% vs 25%). In the treatment group patients were explicitly asked to tell when they felt distinct pulling from the braces. After unlocking the sliding table top, the traction force was slowly increased from 30% of the total body weight until the patient indicated a distinct but tolerable pulling. The maximal force in the treatment group was set at 50% of the total body weight. The patients in the control group were explicitly asked to tell when they felt a little pulling from the braces. After unlocking the sliding table top, the traction force was slowly increased from zero until the patient indicated a little pulling. The maximal force in the control group was set at 25% of the total body weight. In both groups the traction force was held constant during the next 20 minutes. While this procedure guaranteed the minimal intervention contrast of 5%, it also ensured blinding of patients. The maintenance of patient blinding was evaluated five weeks after randomisation.

Outcome Measurement

Five and nine weeks and two years after documenting prognostic status, baseline measurement and randomisation, the blinded patients rated their clinical status. The non-blinded physiotherapist did the same only after five weeks. Recovery (perceived global improvement) was rated on a seven-point ordinal transition scale by the patient and non-blinded physiotherapist. Severity of low back pain yesterday, last night and during effect measurement and severity of physical impairment are rated by the patient and physio-

Table 2: Data collection

	Intake	5 weeks	9 weeks	2 years
Demographic data	X			
Eligibility criteria	X			
Informed consent	X			
Medical history	X			
Randomisation	X			
<i>Patient</i>				
Blinding		X		
Satisfaction		X		
Recovery		X	X	
Low back pain	X	X	X	
Physical impairment	X	X	X	
Functional status	X	X	X	X
Medical consumption				X
Recurrence/relapses				X
<i>Physiotherapist</i>				
Recovery		X		
Low back pain	X	X		
Physical impairment	X	X		

therapist on a 100 millimetre visual analogue scale (VAS, table 2). Functional status was rated by the patient on the Roland Disability Questionnaire (Roland and Morris, 1983) (table 2). In addition, after two years recurrence, medical consumption and functional status were determined by a postal questionnaire.

Recovery (perceived global improvement) is the most sensible outcome measure for both patient and therapist. It is a credible patient tailored measure that probably is more sensitive to change than any other secondary or surrogate measure (Guyatt *et al.*, 1987). The Roland Disability Questionnaire is a multidimensional disability questionnaire for the domain of low back pain. Its 24 yes-no items are derived from the Sickness Impact Profile, and describe prevalent disabilities in the domain of low back pain. The relevance, validity and reproducibility of the Roland Disability Questionnaire (Roland and Morris, 1983; Deyo, 1986, 1988) and the VAS (Sriwatanakul *et al.*, 1983; Revill *et al.*, 1976; Carlsson, 1983) have been tested for the domain of low back pain. In addition, patients rated their satisfaction with the treatment on a VAS. The collected data were analysed with SPSS-X (Anonymus, 1983) and Minitab (Ryan *et al.*, 1980). The calculation of the precision intervals was based on Gardner and Altman (1989). Power calculation was based on Fleiss (1981).

Results

Enrolment and Comparability

Twenty-five patients gave written informed consent and were enrolled in the trial. Of these 19 had already suffered for more than 24 months from persistent low back pain, and 15 also from sciatica. Traction was randomly allocated to 13 patients, sham traction to 12 patients.

Both groups were comparable with respect to age, sex, back pain history (first attack, duration of complaints, exacerbation frequency, radiating pain). White collar workers and steady complaints are more frequent in the sham traction group. Except for small differences in the severity of low back pain the previous night and during effect measurement, both groups are also comparable with respect to the baseline state of the effect measures (table 3).

Drop-outs

After randomisation, but before the first treatment session, two patients from the traction group withdrew, and were completely lost to follow up (five and nine weeks and two years). Two other patients (one in each group) withdrew from treatment, but did attend the follow-up appointments. For all four patients the ratings of

Table 3: Comparability of groups

	Traction (N=13)	Sham traction (N=12)
Prognostic status*		
Age	46±8	47±8
Female	46	50
Sick leave	9	17
Workers compensation for IBP	27	33
White collar profession	18	58
Present episode		
Duration		
< 6 months	18	17
> 24 months	82	83
Activity related pain	64	67
Radiating pain	73	58
Pain worst at waking up	60	67
Pain increased since occurrence	64	67
> 2 relapses last year	64	42
First episode of LBP		
Occurrence		
6 to 12 months ago	9	0
12 to 24 months ago	0	8
> 24 months ago	91	91
Previous treatment		
Bedrest	0	33
Medication	73	75
Physiotherapy	82	67
Baseline status of effect measures†		
Patient rating		
Low back pain		
during measurement	47±27	37±23
last night	27±32	34±42
yesterday	50±27	47±24
Physical impairment	45±33	41±37
Functional status	11±6	11±5
Physiotherapist rating		
Low back pain	34±16	42±16
Physical impairment	34±17	45±18

*All variables given in percentages, except age; mean and standard deviation.

†All measures are expressed in means and standard deviations; except functional status, all measures are rated on a 100 mm visual analogue scale (best score 0, worst score 100). Functional status is rated on a 24-item questionnaire (best score 0, worst score 24).

treatment effects by the physiotherapist are missing. After two years in total, three patients were lost to follow up, including the two who withdrew before the first treatment session.

Blinding

Both groups were highly satisfied with their treatment (treatment vs control group: 83 *versus* 80). At five weeks after randomisation only six patients (three in both groups) thought that they were treated with a placebo (table 4). The average traction force was calculated from the individual average traction force (percentage of the total body weight) over all the treatment sessions: treatment group 44% and control group 19%. Since the actual intervention contrast (25%) was much larger than the predetermined minimal

contrast, the likelihood of differences in effect was increased.

Table 4: Comparability of treatments

	Traction (N=13)	Sham traction (N=12)
Patient's opinion: placebo given – n (%)	3 (18)	3 (25)
Treatment satisfaction – median (mean)	83 (82)	80 (69)
Sessions given median (mean)	11 (10)	11 (10)
Traction force – median (mean)	43% (44%)	20% (19%)

*Rated on a 100 mm visual analogue scale (best score 100, worst score 0).

Outcomes

Table 5 shows that at five weeks, four of the 12 patients (34%) in the control group, and seven of the 11 patients (64%) in the treatment group reported that they had completely recovered or were much improved (difference 30% and 95%CI: –9% <> 69%). At nine weeks three of the 12 patients (25%) in the control group, and five of the 11 patients (46%) in the treatment group reported that they were completely recovered or much improved (difference 21% and 95%CI: –18% <> 59%; table 5). The non-blinded physiotherapists agreed with these recovery reports at five weeks for almost all patients (36% vs 60%; difference 24% and 95%CI: –18% to 65%; table 5). If no recovery is assumed (primary effect measure) for the patients lost to follow up this results in smaller rates for the traction group (worst-case analysis): 54% after five weeks and 35% after nine weeks. Subsequently, the differences in recovery rates between the groups decrease (table 5). These outcomes all lack power. The data analysis for the primary effect measure was based on the chi-square test for proportions.

Table 6 shows that at five and nine weeks both groups improved for the secondary effect measures. Except for physical impairment and functional status at five weeks and pain during effect measurement at nine weeks, there was a consistent small difference between the groups in favour of traction, but the 95%CI for differences between the groups always included zero (table 6). There was also a small difference between the groups in favour of traction for the median improvement of low back pain and physical impairment, rated by the non-blinded physiotherapists, but the 95%CI for these differences also included zero (table 6). The data analysis for the secondary effect measures was based on the Mann-Whitney U-test, since these semi-continuous data were not normally distributed.

After two years follow up only one patient in both groups (8%) remained free of symptoms, and ten

Table 5: Success rate for recovery per group* (percentages) with differences between the groups (δ) with 95 confidence intervals for δ (95 CI) and power per contrast

	Traction n	%	Sham traction n	%	δ	95CI	Power
Blinded patient							
<i>Five weeks after randomisation</i>							
Drop-outs excluded	7/11	64	4/12	34	30%	-9%<>69%	45%
Drop-outs included	7/13	54	4/12	34	20%	-18%<>58%	27%
<i>Nine weeks after randomisation</i>							
Drop-outs excluded	5/11	46	3/12	25	21%	-18%<>59%	28%
Drop-outs included	5/13	38	3/12	35	13%	-25%<>51%	7%
Non-blinded physiotherapist							
<i>Five weeks after randomisation</i>							
Drop-outs excluded	6/10	60	4/11	36	24%	18%<>65%	30%
Drop-outs included	6/13	46	4/12	33	13%	-25%<>51%	17%

*Ratings (on a 7-point ordinal transition scale) are dichotomized in *treatment success*: completely recovered and much improved; and *treatment failure*: little improved, unchanged, little worsened, much worsened and vastly worsened.

The 95 confidence intervals are based on the chi-square-test (Minitab).

Table 6: Difference (δ) between the groups for median improvement for secondary outcome measures with 95 confidence interval for δ (95 CI)*

	Traction (N=11) median [†]	Sham traction (N=12) median [†]	δ	95 CI
Blinded patient				
<i>Five weeks after randomisation</i>				
Low back pain				
During measurement	14	16	2	-29<>14
Previous night	3	18	15	-7<>34
Previous day	4	11	7	-10<>22
Physical impairment	16	6	-10	-26<>24
Functional status	2	1	-1	-2<>2
<i>Nine weeks after randomisation</i>				
Low back pain				
During measurement	14	4	-10	-31<>17
Previous night	-3	1	4	-26<>26
Previous day	11	15	4	-21<>17
Physical impairment	1	2	1	-18<>47
Functional status	2	2	0	-3<>5
Non-blinded physiotherapist (n=10)				
<i>Five weeks after randomisation</i>				
Low back pain	13	20	7	-4<>+35
Physical impairment	16	29	13	-4<>+34

* All measures, except functional status, are rated on a 100 mm visual analogue scale (best score 0, worst score 100). Functional status is rated on a 24-item questionnaire (best score 0, worst score 24).

[†] If positive: improvement compared with baseline measurement; if negative: worsened compared with baseline measurement.

[‡] If positive: difference in favour of traction; if negative: difference in favour of sham traction.

The 95 confidence intervals are based on the Mann-Whitney-U-test (Minitab).

patients (92%) suffered from either steady low back pain and/or one or more relapses. There is no difference between the groups in the associated medical consumption.

Discussion

In the design and conduct of our study, we tried to avoid the most prevalent flaws of published studies about the efficacy of lumbar traction. In our opinion we succeeded in this, mainly due to close surveillance of protocol deviations. Although both groups were small, after randomisation they were comparable for the relevant prognostic factors.

Probably because patients were selected who had no experience with traction treatment, an intervention contrast of 25% (on average) was reached with maintenance of patient blinding. Since the differences between the groups for the primary effect measure at five and nine weeks are rather large, traction seemed to be more effective than sham traction. However, these differences failed to reach statistical significance, as the 95% confidence intervals did include zero. The 95% confidence intervals for the differences of the secondary effect measures at five and nine weeks also included zero. Therefore traction did not appear to be more effective than sham traction, both in the short term and long term.

Since the results of this study lack power there is a great chance of missing the true difference between traction and sham traction (β or type II error) (Freiman *et al*, 1978; Detsky and Sackett, 1985). The most important reason for the absence of statistically significant results probably lies in the small size of the study. With 50 patients per group, a similar difference in recovery rates between the groups at five weeks (34% vs 64%) would have reached statistical significance ($\alpha=5\%$) (ie the 95% confidence intervals would exclude zero) (Fleiss, 1981).

Owing to the lack of statistical significant differences in our study, and in view of the lack of power ($1-\beta$) due to the small number of patients, the results probably will lead to false negative conclusions. Therefore, it can be concluded with some caution that traction seems to be more effective than sham traction. In addition to this it can be concluded that only short term effects of traction can be expected, since no differences were found between the groups at two years follow-up were found.

In view of the rather substantial short-term effects, this study is currently being repeated with 150 patients (Beurskens *et al*, 1995).

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