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# Efficacy of Traction for Nonspecific Low Back Pain: 12-Week and 6-Month Results of a Randomized Clinical Trial

[Traction]

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## Outline

## Graphics



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# Abstract^


Study Design. A randomized clinical trial.

Objectives. To assess the efficacy of motorized continuous traction for low back pain.

Summary of Background Data. The available studies on the efficacy of lumbar traction do not allow clear conclusions because of severe methodologic flaws. The current trial aimed to overcome these shortcomings.

Methods. Patients with at least 6 weeks of nonspecific low back pain were selected. High-dose traction was compared with sham (or low-dose) traction. Sham traction was given with a specially developed brace that becomes tighter in the back during traction. This was experienced as if real traction were exerted. The patients and the outcome assessor were unaware of treatment allocation. Outcome measures were: patient's global perceived effect, severity of main complaints, functional status, pain, range of motion, work absence, and medical treatment. Results for the outcome measures at 12 weeks and 6 months after randomization are presented.

Results. One hundred and fifty-one patients were randomly allocated to one of the two treatment methods. Intention-to-treat analysis of the 12-week and 6-month results showed no statistically significant differences between the groups on all outcome measures; all 95% confidence intervals included the value zero. The number of patients lost to follow-up study was very low. Other analyses showed the same results.

Conclusions. Most common flaws of earlier studies on traction therapy could be overcome. This trial did not support the claim that traction is efficacious for patients with low back pain.


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Epidemiologic studies have indicated that approximately 80% of the population experiences low back pain (LBP).[9,15] In spite of the large amount of research in this field, it is not possible to classify LBP patients in a reproducible and valid way. Because of the enormous ambiguity involved in the diagnosis of low back pain, it is difficult to make a distinction between patients with disc, facet joint, or muscular problems.[7,8,22] There is no consensus about the management of nonspecific LBP. The efficacy of many physiotherapeutic interventions remains questionable.[16,27] One of the treatment

options is traction, often combined with other treatment modalities (*e.g.*, massage, exercises, electrotherapy, or heat).[1]

Fourteen randomized clinical trials (RCTs) about the efficacy of different lumbar traction modalities were traced in the literature before June 1992.[10] These studies do not allow clear conclusions because of methodologic flaws, such as poor prognostic comparability at baseline and lack of blinding of patients and outcome assessors. Three recent randomized clinical trials published after June 1992 did not change the conclusions of the review.[17-19]

In a pilot study of 25 individuals, it was possible to avoid the most common flaws.[11] The recovery rate after 5 weeks in the high-dose traction group was 64%, and in the low-dose (sham) traction it was 34%. In view of these substantial effects, it was decided that a larger trial with 150 patients should be conducted.

The available literature is not clear on the working mechanisms by which continuous lumbar traction could be effective. Supposed mechanical effects of traction are vertebral distraction and widening of the intervertebral foramen.[5,6,20,24] These mechanisms suggest short-term rather than long-term effects.[26,28] A certain amount of traction force is necessary to achieve separation of the vertebrae and widening of intervertebral foramina, and a part of the force is needed to overcome muscle contraction, spinal curvatures, ligamentous resistance, and friction of the body on the tabletop and of the machinery.[13,14,21] Lumbar traction forces that are less than 20% of the total body weight using a split table to overcome friction of the body on the tabletop can be regarded as sham (or low-dose) traction. To reach sufficient contrast with sham traction, a traction force 35-50% of the total body weight was chosen for the real traction.

# Methods^

**Study Design.** The effects of continuous motorized lumbar traction and of sham traction on the magnitude of recovery were compared in patients with persistent nonspecific LBP for 5 weeks, 12 weeks, and 6 months after randomization. The 5-week follow-up evaluation was included to detect short-term effects. The 12-week and 6-month follow-up evaluations were included to detect longer-term effects. This article presents the results of the 12-week and 6-month follow-up evaluations. The short-term effects are reported elsewhere.[3] The Medical Ethics Committee of the University of Limburg and the University Hospital Maastricht in the Netherlands approved the study protocol. An elaborate description of the study design has been published previously.[2]

**Patient Selection and Randomization.** Physiotherapists in 10 practices and six general practitioners recruited and selected the patients. An experienced research physiotherapist (AJK) checked the inclusion and exclusion criteria. He gave information about the goal of the study and the chance of receiving the sham traction. After receiving a letter that included this information, the patients signed their informed consent. Patients were selected if they had experienced nonspecific LBP for at least 6 weeks, if they were at least 18 years old, and if they had never had any form of lumbar traction

treatment before. Nonspecific was defined as having no evidence of underlying diseases or anatomic abnormalities (*e.g.*, malignancy, osteoporosis). Further, patients were excluded if their condition had improved significantly during the previous 2 weeks. Subsequently, patients were blindly and randomly allocated to high-dose or low-dose traction based on a computer-generated list of random numbers. Duration of LBP symptoms (less than or longer than 6 months) and physiotherapy practice (n = 10) were prestratified.

**Interventions.** All patients were treated with similar traction apparatus (Eltrac, DIMEC Delft Instruments, the Netherlands). Both intervention groups were treated 12 times in 5 weeks for 20 minutes per session. After the inclusion of a patient into the trial, the treating physiotherapist received a sealed envelope that contained the treatment code. At the first treatment session, he opened the envelope containing the treatment code and therefore was not blinded for the assigned treatment.

As the patient lay down on the traction table in the semi-fowler position, braces were attached around the iliac crest and the lower thoracic cage. After unlocking the sliding tabletop, the physiotherapist increased the traction force. In the traction group, the force was increased until the patient indicated that the tolerance for pulling was reached, with a minimum traction force of 35% and a maximum of 50% of the total body weight. In the sham group, the force was increased slowly until the patient indicated that he felt little pulling, with a maximum traction force of 20% of the total body weight. Patients received sham traction with a special brace around the iliac crest that became tighter in the back during treatment. This was experienced as if traction were being exerted. In this way, it was expected that the patients would feel the pulling earlier, and that the traction force in the sham group could be restricted to a minimum.

The patients were allowed to continue taking the pain medication they had used before entry into the study, *i.e.*, nonnarcotic analgesics or nonsteroidal anti-inflammatory drugs. Other cointerventions were not allowed during the treatment period. The patients were asked to take no pain medication during the 24 hours before the effect measurement. After the treatment period, the treating physiotherapists and research physiotherapist asked the patients to restrict further treatment as much as possible.

**Outcome Measurements and Follow-up Study.** The 12-week evaluation included a physical examination. At the 6-month follow-up evaluation, the patients were asked to complete a postal questionnaire. The primary outcome measures were: 1) global impression of the perceived effect (recovery) rated by the patient on a 7-point scale and 2) the severity of the three main complaints. At baseline, the patients selected their three main complaints in a standardized way: each patient selected three activities he performed frequently, which he perceived as important in his daily life, and which LBP made difficult for him. The severity of these main symptoms were rated on a 100-mm visual analog scale.

Secondary outcome measures were: 1) functional status measured with the Roland Disability Questionnaire,[25] 2) pain (100-mm visual analog scale), 3) severity of LBP as evaluated by the research physiotherapist indicated on an 11-point scale after a standardized interview and physical

examination, 4) range of motion of the spine measured with the inclinometer EDI 320-CYBEX (Cybex, Division of Lumex Inc., Ronkonkoma, NY; degrees), 5) activities of daily life disability (100-mm visual analog scale), 6) work absence in days, and 7) additional treatments sought by the patient during the follow-up period (medical consumption) recorded by questionnaires. Medical consumption is an important outcome measure for long-term follow-up evaluation. Therefore, special attention is paid to describing the results of this outcome measure in this report. The research physiotherapist (AJK) who conducted almost all outcome measurements was blinded for treatment allocation. During periods in which the research physiotherapist was on holiday, another research physiotherapist (AJB) performed the blinded outcome measurements. To minimize interobserver variation, the two observers were trained in performing the measurements in a standardized way.

**Data Analysis.** The researcher (AJB) who analyzed the data was blinded for treatment allocation until all decisions were made about cut-off points and protocol deviations. She also was blinded during the primary analyses.

The primary statistical analysis was carried out according to the "intention-to-treat" principle: all patients, including those who withdrew from treatment and those with poor compliance, remained in the group to which they had been randomly assigned. Besides this, a "per protocol" analysis was performed that is restricted to a group of patients in which everything went the way it was planned. The results of the per-protocol analysis should be interpreted with caution. Patients who dropped out or had a low compliance may differ from the other patients in the intervention groups. Therefore the groups may become prognostically incomparable, leading to a biased estimate of the treatment effect. The similar results for the intention-to-treat and per-protocol analyses indicate that patients who dropped out and those with low compliance had not affected the validity of the results. Patients were excluded from the per-protocol analysis if they: 1) withdrew during the treatment period, 2) were treated with inadequate traction forces (too low or too high), 3) received cointerventions during the 5-week treatment period, or 4) received medical treatment after the 5-week treatment period.

All data analyses were done with SPSS statistical software (SPSS Inc., Chicago, IL).[23] For the outcome measures that also were recorded at baseline, the differences between the post-treatment and the baseline scores were computed for each individual and were compared between the two groups. For the outcome measures without baseline information (*e.g.*, global perceived effect and medical treatment), only the posttreatment scores of the two groups could be compared. Group differences and two-sided 95% confidence intervals were calculated for all outcomes. One-way analysis of covariance was used to estimate group differences adjusted for differences at baseline of important prognostic indicators, cointerventions, degree of compliance, use of regular pain medication, and strata of randomization.

# Results^

## Study Sample^

From June 1993 to December 1994, 243 patients were invited for an appointment with the research

physiotherapist to check their eligibility for this study based on inclusion and exclusion criteria. Of these, 92 patients (38%) were excluded. The most common reasons for exclusion were: not enough motivation (n = 24; *i.e.*, no time, chance of sham traction) or less than 6 weeks of LBP (n = 16). Finally, 151 patients signed informed consent; of these, 130 patients were selected by physiotherapists, and 21 were selected by general practitioners. The patients were randomly allocated to treatment groups: 77 patients to traction and 74 to sham traction. Of the 151 patients, 150 patients completed the 12-week follow-up evaluation and 148 completed the 6-month follow-up evaluation. After 12 weeks, one patient in the sham group went to work abroad and was lost to follow-up study. In addition, four patients failed to attend the 12-week visit for physical measurement by the research assistant. They returned the completed questionnaires by post, however, and therefore could be included in those analyses for outcome measures for which their data were not missing. After 6 months, three patients did not return the questionnaires: the patient who went to work abroad and two patients who moved without leaving their forwarding addresses.

The two treatment groups were similar in most of the demographic and clinical baseline characteristics (Table 1). The traction group contained a few more patients with pain radiating below the knee, previous treatment, and previous LBP. Conversely, the median number of previous LBP episodes was higher in the sham traction group.

Table 1. Comparability of Treatment Groups With Respect to Distribution of Prognostic Variables

## Compliance and Blinding^

The average traction force was 42 ± 5% of the total body weight in the traction group and 15 ± 4% in the sham group. The average traction force was calculated from the individual average traction force (percentage of the total body weight) from all treatment sessions. Eight patients in the traction group received a traction force that was less than 35% of the body weight. The forces in the traction group ranged from 27-50%, and those in the sham group ranged from 3-20%. During the treatment period, eight patients (four in each group) withdrew from treatment. Directly after the 5-week period of traction treatment, the patients were asked to guess their treatment allocation. The traction was not unmasked systematically; only 6% of the patients in the sham group and 1% in the traction group thought that they had received sham traction.[3]

## Outcomes^

Tables 2 and 3 show the 12-week and 6-month results, respectively, of the intention-to-treat analyses of outcome measures. Both the traction and sham traction groups improved, but the differences between the groups were very small for all outcome measures at both measuring points. All confidence intervals for the differences between groups included the value zero, which means that they were not statistically significant at the 5% level (two-sided test).

Table 2. Intention-to-Treat Analysis at 12 Weeks: Improvement and Difference Between Intervention Groups With 95% Confidence Interval (CI)

Table 3. Intention-to-Treat Analysis at 6 Months: Improvement and Difference Between Intervention Groups With 95% Confidence Interval (CI)

The ratings of the global perceived effect on a 7-point scale were dichotomized into improved (completely recovered and much improved) and not improved (slightly improved, not changed, slightly worsened, much worsened, and vastly worsened). After 12 weeks, 50% of the patients in the traction group and 48% in the sham group had recovered completely or were much improved. After 6 months, these percentages were 47% and 44%, respectively.

The patients were asked to select their three main complaints at baseline, but some patients (5%) could identify only two complaints. For that reason, only the scores of the first two main complaints were evaluated. Both groups showed a clear improvement on their two main complaints, but there was no difference between the groups.

Given the mechanical rationale, a positive effect of high-dose traction (> 35% body weight) was expected compared with that of low-dose traction (< 20% body weight). To evaluate whether the choice of the cutoff points influenced the results, the traction force was plotted against the global perceived effect (Figure 1). There appeared to be no relation at all between global perceived effect and the percentage traction force applied. In other words, the effect of traction did not depend on the amount of traction force.

Figure 1. Percentage traction force of body weight (20% = maximum for sham traction; 35% = minimum for traction) *versus* global perceived effect (1 = completely recovered; 7 = vastly worsened). There is no correlation between traction force applied and effect. Reproduced with permission from Beurskens AJHM, Vet HCW de, Köke AJH, et al. Efficacy of traction for nonspecific low back pain: A randomized clinical trial. Lancet, 1995;346:1596-600. Copyright by the Lancet Ltd. 1995.[3]

Adjustments in the analysis of covariance for baseline differences, use of regular pain medication, and the use of covariables for strata of randomization only slightly changed the estimates (and confidence intervals) of the group differences. Therefore, only the unadjusted data are presented. The results of the per-protocol analysis were similar to the results of the intention-to-treat analysis: there was no difference in outcome measures between the traction and the sham traction groups.

## Medical Consumption^

The number of additional treatments sought by the patient between baseline and the 12-week follow-up evaluation in the traction group was higher than in the sham group (34% *vs.* 25%; Table 2). After 6 months, however, the number of treatments was similar for both groups; 45% of the patients in the traction group and 42% in the sham group had at least one additional treatment (Table 3).

The number of additional treatments provides no information about the content of the treatments. It is, therefore, important to look to the types of treatments patients received. Table 4 presents the cumulative number of medical consumption at follow-up evaluation. The types of treatments for LBP diverged during the 6-month follow-up period, but were not remarkably different for the two groups. Some patients had more than one type of treatment (*e.g.*, medication and physiotherapy).

Table 4. Cumulative Number of Medical Consumption at Follow-up

When many patients have additional treatments, it is not possible to separate effects of traction and other treatments. Only four patients had another form of treatment in addition to traction during the 5-week intervention period. The additional treatments sought by the patients occurred mainly between 5 weeks and 6 months after randomization. Therefore, at the 5-week follow-up evaluation, the pure effect of traction was assessed. To evaluate which patients had treatments, the relation between global perceived effect assessed after 5-week traction treatment and medical consumption at the 6-month follow-up evaluation was studied (Figure 2). Because high-dose traction and sham traction did not differ in terms of the effect of traction, only the relation with global perceived effect for the whole study population was shown. None of the nine patients who rated themselves as recovered after the traction treatment had an additional treatment during the 6-month follow-up period (Figure 2). However, 20 (33%) of the 61 patients who were significantly recovered after 5 weeks had one or more treatments in the follow-up period. The majority of the patients who rated themselves as slightly improved, not changed, or deteriorated received additional treatment for LBP.

Figure 2. Additional treatment at the 6-month follow-up evaluation across global perceived effect assessed after the 5-week traction treatment.

# Discussion^

Supposed rationales of traction are based on mechanical effects. These mechanisms suggest that short-term rather than long-term effects can be expected.[26,28] Until now, the rationales offered no explanations for long-term effects of traction. The 5-week results showed no statistically significant

differences between the intervention groups.[3] After the 12-week and 6-month follow-up periods, there were also no statistically significant differences between traction and sham traction treatment on all outcome measures.

The number of patients who had some kind of additional treatment for their LBP during the follow-up period was compared between the two intervention groups (high-dose traction vs. sham traction). Additional treatment after the 5-week intervention period was regarded as an outcome measure and not as a protocol deviation. The underlying assumption was that patients will turn to other therapies when the allocated therapy is no longer effective or not effective enough. In this trial, the types of additional treatments during the follow-up period were divergent, and the numbers were relatively high, but not remarkably different, for the two groups. When the number of patients with additional treatments is high, the results of the other outcome measures are difficult to interpret; it is no longer clear to what extent the effect can be attributed to traction therapy or to the other treatment. One third of the patients who rated themselves as much improved after the 5-week traction treatment had additional treatment for LBP within 6 months. This is an indication that the improvement was only temporary or not satisfactory enough for the patient.

The number of recurrences is considered to be an important outcome measure in long-term follow-up of intervention trials for LBP. In the design of this trial, the number of recurrences was intended to serve as an outcome measure for long-term follow-up evaluation.[2] Recurrences were recorded by means of patient questionnaires at 12-week and 6-month follow-up evaluations. During the follow-up, however, it appeared to be very difficult for patients to identify and recall accurately the beginning and end of periods with LBP and the number of these periods. Thus, because of recall bias, the answers of the patients were almost certainly imprecise and probably not valid. For this reason, it was decided not to use the data on recurrences in the analysis.

To ascertain the number and duration of recurrences precisely, more frequent measurements are necessary, *e.g.*, with short telephone interviews monthly.[12] It seems quite likely that there is a correlation between recurrences and medical treatments. The fact that patients who had totally recovered had no additional treatment indicates that these patients probably had no recurrences.

A serious form of bias may occur when patients are lost to follow-up evaluation. Patients who did not show up for their follow-up measurement might be a select group of patients in which therapy was very successful or unsuccessful. Frequently, as patients become more ill and symptomatic, they will be incapable of completing a questionnaire or unwilling to do so.[7] Large numbers of patients lost to follow-up often are overlooked as a serious source of bias for evaluating the effect of a therapy.[4] At each contact, the research physiotherapist explained to the patients that it was very important for them to take part in the effect measurements and to fill out the questionnaires to record whether their condition improved. Great effort was put forth to get in touch (by phone or post) with patients who did not respond. As a result, the number of patients lost to follow-up was limited, and the data set was very complete, which made the analyses simple and clear.

In this trial it was possible to remain close to the original design of this study. Thereby, most common flaws in previous studies on traction therapy could be overcome. The results of this trial did not support the claim that traction is efficacious for patients with low back pain.

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