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Research Report

The Efficacy of Traction for Back and Neck Pain: A Systematic, Blinded Review of Randomized Clinical Trial Methods

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Background and Purpose. *The purpose of this study was to conduct a systematic analysis of the literature to assess the efficacy of traction for patients with neck or back pain.* ***Subjects.*** *For this purpose, randomized clinical trials comparing traction with other treatments were selected.* ***Methods.*** *A computer-aided search of the literature was conducted for relevant articles, followed by blinded assessment of the methods of the studies. The main outcome measures were (1) scoring for quality of the designated conduct of studies (based on a methodological checklist with four main categories: study population, interventions, measurement of effect, and data presentation) and the main conclusions of author(s) with regard to traction and (2) calculation of confidence intervals and power of the studies.* ***Results.*** *Only three studies scored more than 50 points (maximum score= 100 points), suggesting that most of the selected studies were of poor quality. None of these three studies showed favorable results for traction. Only four studies, of which one scored more than 50 points, had an acceptable power ($1-\beta > 80\%$).* ***Conclusion and Discussion.*** *The available reports of studies on the efficacy of traction for back and neck pain do not allow clear conclusions due to the methodological flaws in their design and conduct. Most studies lacked power ($1-\beta$) due to small sample sizes. To date, no conclusions can be drawn about whether a specific traction modality for back or neck pain is effective, or more efficacious than other treatments. There are no clear indications, however, that traction is an ineffective therapy for back and neck pain. Further trials are needed in which much more attention should be paid to proper design and conduct, as well as to clear descriptions of crucial methodological features and results. [van der Heijden GJMG, Beurskens AJHM, Koes BW, et al. The efficacy of traction for back and neck pain: a systematic, blinded review of randomized clinical trial methods. Phys Ther. 1995; 75:93–104.]*

Key Words: *Back pain, Blinded review, Neck pain, Physical therapy, Randomized controlled trials, Traction.*

Back pain and neck pain are common in western industrialized countries. Approximately 80% of all people will have one or more episodes of back pain in the course of their lives, and about 50% will have one or more episodes of neck pain.[1–3] The majority of all episodes of back and neck pain disappear within a few months, often with the help of rest, analgesics, and home exercises.[4] Only in about 5% of all cases do back and neck pain last for more than 3 months.[1] The recurrence rate of back and neck pain is high; approximately 60% of all episodes are followed by a relapse.[2,3] Little is known about the relevant prognostic features of back and neck pain. Prognoses seem to worsen with the occurrence of radiating pain and with increasing number of relapses.[5–8] Although back and neck pain are the most frequent disorders of the musculoskeletal system in general practice, there is no consensus about the management of these conditions. The efficacy of primary care treatment

(including physical therapy) for back and neck pain remains questionable.[1,4,9–17] General practitioners in the Netherlands often refer patients with back and neck pain for physical therapy. The majority of these patients complain of persistent pain.[18] In these cases, traction is one of the possible treatment modalities. In the Netherlands, patients receive traction treatment in approximately 7% of the annual 21 million physical therapy sessions, often in combination with other treatments.[18–20] Doubt exists, however, whether traction is a beneficial treatment modality for back and neck pain.[4]

Lumbar traction is applied with a harness (with self-adhesive strapping) that is put around the lower rib cage and the iliac crest. A head halter sling is used for cervical traction. The duration and level of exerted traction can be varied in a continuous or intermittent mode.[21–24] Of the different traction techniques, manual traction (ie, traction exerted by the therapist, using the patient's head, arms, or legs) and motorized traction (ie, traction exerted by a motorized pulley) are most often used, whereas inverted suspension (ie, traction exerted by gravitational forces, through the body weight of the patient) and bed-rest traction (ie, traction is exerted by a pulley and weights) are only occasionally used.

During application of traction, muscle tension, skin stretch, and intra-abdominal pressure should be taken into account as counterforces. Friction between the body and the support surface is the main counterforce during application of traction on a table or in bed. This friction can be reduced by using a split tabletop with ball bearings and by altering the angle of pull.[25,26]

The rationale for traction is based on mechanical and reflex mechanisms.[21–24] Spinal elongation through an increase of intervertebral space and relaxation of spinal muscles is assumed to be the most important of the proposed mechanisms by which traction could be effective.[27–31] Because spinal elongation as the proposed specific effect is not expected to occur below a traction force of 25% of the total body weight,[26,32,33] a traction force below this weight is sometimes denoted as a sham treatment or placebo. The proposed mechanisms of traction, however, have not been supported by sufficient research. Furthermore, it is not very likely that an annular tear would disappear through traction, or that a protruded or prolapsed nucleus of an intervertebral disk could be reduced and stabilized within the annulus by spinal elongation.[29,33] To date, there is little clarity about the mechanism by which traction could be effective.

No systematic research has been performed into the adverse effects of traction.[34] Some case reports[22,35] suggest that there is some danger of adverse effects in heavy traction (eg, lumbar traction with forces exceeding 50% of the total body weight) or in cervical traction with forces exceeding 50% of the weight of the head (ie, approximately 4% of the total body weight). It has been theorized that traction in cases of medial or distal protrusion of the nerve root might increase nerve impingement.[36] Other risks described for traction concern increased blood pressure and respiratory constraints due to traction harness, and temporomandibular joint strain due to the head sling.[21,35,37–42]

The question addressed in this review is whether different traction modalities for back and neck pain have been shown to be clinically effective through published research (ie, have a causal relation with clinical improvement). Randomized clinical trials (RCTs) are considered to be the best design for control of validity (ie, absence of systematic error) and precision (ie, absence of random error).

We present a critical review of the available RCTs about the effectiveness of traction for back and neck pain. Although RCTs potentially provide the most valid and precise results, flaws in their design and conduct can result in overestimation or underestimation of treatment effects, and consequently can lead to false-positive or false-negative conclusions. Therefore, we will place strong emphasis on the quality of the methods of the studies selected for review.

Method

We traced relevant study reports by means of a MEDLINE literature search (1966–1992, using the following Medical Subject Headings terms or free-text words: traction, therapeutic use, not fractures, musculoskeletal diseases, joint diseases, spinal diseases, neck, backache, cervical, adverse effects, comparative studies, evaluation studies, outcome and process assessment, physical therapy, epidemiology, statistics, science), as well as an EMBASE literature search (1974–1992, using the following key words: physiotherapy, traction, not fractures, musculoskeletal diseases, joint diseases, spinal diseases, neck, back, major clinical studies, placebo, randomization, double-blind procedure, review). In addition, a number of relevant journals not

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Table 1. *Criteria List for a Methodological Assessment of Randomized Clinical Trials of Traction Treatment for Low Back and Neck Pain*

Criteria[a]	Weight
Study population (n=40)	
A—Homogeneity	2
B—Comparability of prognoses at baseline	10
C—Adequate randomization procedure	4
D—Dropouts described for each treatment group separately	4
E—Loss to follow-up described for each treatment group separately	8
F—Study size	12
Interventions (n=20)	
G—Explicit description of experimental treatment(s)	5
H—Explicit description of control treatment(s)	5
I—Cointerventions avoided (or comparable)	6
J—Study type	4
Measurement of effect (n=30)	
K—Patients blinded	6
L—Relevant outcome measures	10
M—Blinded outcome measurement	10
N—Duration of follow-up	4
Data presentation (n=10)	
O—Intention-to-treat analysis	5
P—Data presented for most important outcome measures	5

[a]Each criterion must be applied independently of the other criteria. A—Description of inclusion criteria (1 point); restriction to a prognostically homogeneous study population (1 point). B—Prognostic comparability of study groups after randomization for duration of the complaint; baseline score for main outcome measure, age, number of relapses, radiating complaints (2 points each). C—Randomization procedure explicitly described (2 points); randomization procedure excludes bias (according to blinded reviewers) (2 points). D—Number of patients who withdraw (dropouts) given for each group without reasons for withdrawal (1 point); no dropouts or number of patients for each group with reasons for withdrawal (4 points). E—Loss to follow-up: all randomized patients minus the number of patients at the main moment of measurement for the most important outcome measure, as a proportion of all randomized patients. If less than 20% loss to follow-up in one of the groups: 4 points; if less than 10% loss to follow-up in one of the groups: 8 points. F—Smallest group after randomization: 75 subjects (12 points), 50 subjects (8 points), 25 subjects (4 points). G—Traction treatment explicitly described: modality, application mode, weight, duration, and frequency (or number) of sessions (1 point each). H—Reference treatment explicitly described: modality/type, application mode, measure of applied intensity, and frequency (or number) of sessions (1 point each). I—Other medical treatment or physical therapy modalities avoided (6 points) or comparable between groups (2 points). J—Placebo or other than placebo as reference treatment (2 points); both (4 points). K—Attempt at patient blinding or naive patient (3 points); blinding evaluated and successful (3 points). L—Outcome measures reported: global estimate of improvement, pain, functional status (activities of daily living), spinal mobility, use of drugs and/or other medical consumption (2 points each). M—Blinded measurement of criterion L outcome measures (2 points each). N—Outcome measurement immediately after last treatment (2 points) and after 6 months or longer (2 points), or both (4 points). O—If loss to follow-up is less than 10%: analysis for all randomized patients irrespective of noncompliance (5 points), or, if loss to follow-up is more than 10%: alternative analysis that accounts for missing values (5 points). P—Presentation of frequencies or mean and standard deviation or median and quartiles for main outcome measures at main moment of effect measurement (5 points).

indexed in these two databases were screened, as well as the *Index to Chiropractic Literature* (1980–1992) and the *Physiotherapy Index* (1986–1992). To be included in the review, a study had to meet the following criteria: (1) A random procedure was used for treatment allocation, (2) included patients had back or neck pain, (3) one of the treatment regimens had to include a traction technique (additional care was allowed), (4) clinically relevant outcome measures were used (eg, global estimate of improvement, pain, mobility, functional status), and (5) results were published before June 1992. Abstracts, unpublished studies, and studies with alternate treatment allocation were excluded.

The quality of design and conduct of the selected studies were assessed according to generally accepted methodological principles of intervention research.[43–45] These methodological principles are grouped into four categories: (1) study population, (2) interventions, (3) measurement of effect, and (4) data presentation. These four categories comprise 16 criteria (Tab. 1, A–P), which have been further divided to create a 49-item checklist. Every checklist item is given a certain weight that relates to its possible contribution to validity and precision. A study can earn a maximum methodology score of 100 points. Similar lists have been used in reviews about the efficacy of various interventions.[12,13,16,46–48] For this blinded review, we adapted the items relating to clinical relevance to back and neck pain and traction (criteria A, B, G, and L). The methodological principles are briefly explained here in the order they are presented in Table 1.

Study Population

A prognostic homogeneous study population can be recruited if trial participation is restricted to a subgroup of patients with identical treatment susceptibility and prognoses. Randomization is used to exclude patients' treatment preferences, and therapists must be excluded during allocation of the interventions compared. In addition, randomization scatters confounders (ie, known and unknown determinants for prognosis and treatment susceptibility) over the groups, thereby creating prognostically comparable groups.

When prognostic subgroups can be specified, stratified randomization can further improve the prognostic comparability of groups. Restriction, stratifica-

tion, and randomization, however, do not guarantee prognostically comparable groups in the case of small studies. Therefore, large studies in general provide more valid and more precise results than smaller studies.

Refusal to participate after enrollment, or attrition either during the treatment phase (dropouts) or at follow-up (loss to follow-up), can be due to a variety of causes. Validity, however, is only threatened when attrition is related to prognostic incomparability or to the success or failure of allocated interventions. Therefore, details about attrition rates are essential for evaluation of trial results.

Interventions

The contrast between interventions can be ascertained if the proposed specific treatment components of the interventions within groups can be standardized. The validity of this contrast is further improved if nonspecific treatment components (eg, attention and bedside manners), additional care, and cointerventions can be standardized for all patients. In addition, group differences in compliance can also obfuscate the intervention contrast.

Measurement of Effect

Treatment preferences of patient, therapist, and outcome assessor can give rise to biased effect measurement. Blinding for the nature of assigned interventions, therefore, is needed for unbiased outcome measurement. In explanatory trials, in which specific effects of interventions or their components are studied by comparison with a placebo, the blinding of patients and therapists is often done via use of a placebo. Because blinding can be jeopardized, therefore, ascertainment of blinding should be evaluated and reported. In management studies, in which two or more usual treatment modalities are compared, the blinding of patients and therapists is difficult to achieve. In such studies, blinding can be ensured, in part, by selection of patients who have no previous experience with the interventions. Furthermore, the participation of a blinded observer, coupled with the exclusion of the influence of the patients' opinion, is needed for the unbiased evaluation of treatment effects in management studies.

Data Presentation

Flaws in the design and conduct of a study can give rise to biased results that will lead to underestimation or overestimation of the effects of the compared interventions. Consequently, the results, whether statistically significant or not, will lead to false-positive or false-negative conclusions. Therefore, methodological shortcomings (eg, prognostic incomparability of groups, partial blinding or absence of blinding, poor compliance, the number of dropouts and loss to follow-up) must be reported, preferably for each group. Sometimes these methodological shortcomings can be corrected during data analysis.

The selected reports were blinded for author(s), journal, and results by the first author (GJMGH). The methodological quality of the reported studies was assessed, via the checklist, by two of the authors (BWK, WJJA). In a subsequent meeting, these two authors (still blinded) reached consensus on every checklist item they disagreed about. The assessment resulted in a methodological score for each study. This process enabled us to make a hierarchical list on the basis of methodological quality. We labeled the outcome of a study "positive" if the authors of the report concluded that there was a difference in effect between the compared treatments in favor of at least one of the traction modalities applied. The outcome of a study was labeled "negative" if the authors of the report concluded that there was no difference between the compared treatments, or that there was a difference in effect in favor of one or more reference treatments.

Results

We found 21 papers,[49–69] reporting 24 studies, that met the four conditions for inclusion in the blinded review. Three studies about the efficacy of lumbar traction[49–51] were excluded from the blinded review because the patients receiving the traction regimen could not be identified. In addition, comparison of the reports revealed that some studies[52–57] were reported in more than one article. Table 2 presents 17 RCTs (3 on cervical traction and 14 on lumbar traction) in hierarchical order based on their methodological scores.

Initially, the two blinded reviewers agreed on more than 80% of all checklist items. After a consensus meeting (still blinded), there was agreement in all instances. The discrepant scores were found mainly to be due to reading errors. Of the studies reported in more than one article, the reports with the lower scores did not reveal additional or different information.

Table 2 shows the wide range in method scores (range=23–68). Only 3 RCTs (2 lumbar traction, 1 cervical traction) scored more than 50 points. These 3 RCTs showed no favorable effects of traction on pain, mobility, functional status, or other symptoms and complaints. Among the remaining 14 studies, only 4 showed positive results according to the authors of the reports (3 lumbar traction,[60–62] 1 cervical traction[63]). In total, only 5 RCTs (2 cervical traction, 3 lumbar traction) scored more than 40 points, indicating the poor overall methodological quality of most of the studies.

Common methodological flaws concerned incomparability of prognosis at baseline (criterion B), insufficient description of randomization procedure (criterion C), small sample size (criterion F), incomparability of cointerventions (criterion I), no attempts to blind patients (criterion K), and no attempts to blind outcome measurement or failure to include a blinded assessor (criterion M). Blinding of the therapists was not reported for any of the studies. Despite some incomplete information, the studies reported were methodologically sound with respect to restriction to a homogeneous population (criterion A), little loss to follow-up (criterion E), sufficient de-

Table 2. *Randomized Trials of the Efficacy of Traction for Back and Neck Pain in Order of Method Score*

Authors	Score for Methods Criteria[a]																	Indication	Radiating Pain Included	Neurologic Deficit	Authors' Overall Conclusion
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Total				
	2	10	4	4	8	12	5	5	6	4	6	10	10	4	5	5	100				
van der Heijden et al[58]	1	8	4	4	8	—	5	5	6	2	6	6	6	2	5	5	73	Chronic low back pain	—	Excluded	Negative
Matthews et al[52]	1	4	—	4	8	8	5	5	2	2	—	4	—	4	5	—	52	Acute low back pain	—	—	Negative
Goldie and Landquist[59]	2	4	—	4	8	—	5	5	2	2	—	4	4	2	5	5	52	Chronic cervical pain	Brachialgia	—	Negative
Weber[56]	2	—	—	4	4	4	5	5	2	2	—	6	4	2	5	—	45	Prolapsed lumbar disk	Sciatica	Included	Negative
British Association of Physical Medicine[64]	1	—	—	1	4	8	3	3	—	4	—	6	2	4	5	—	41	Cervical pain	Brachialgia	—	Negative
Reust et al[65]	1	4	—	4	—	—	5	5	2	4	3	4	—	2	5	—	39	Low back pain	Sciatica	—	Negative
Larsson et al[60]	1	8	—	4	8	4	1	2	2	2	—	2	—	2	—	—	36	Acute low back pain	—	Excluded	Positive
Zylbergold and Piper[63]	1	4	—	—	—	4	5	5	2	2	—	4	2	2	5	—	36	Subacute cervical pain	Brachialgia	—	Positive
Ljunggren et al[57]	2	—	—	—	8	—	3	4	2	2	—	4	2	4	5	—	36	Prolapsed lumbar disk	Sciatica	Included	Negative
Coxhead et al[69]	1	—	—	—	8	12	2	1	2	2	—	4	—	2	—	—	34	Acute low back pain	Sciatica	—	Negative
Walker et al[66]	—	2	2	—	4	—	4	4	—	2	3	4	2	2	5	—	34	Acute low back pain	Sciatica	—	Negative
Pal et al[67]	—	6	—	4	8	—	2	3	—	2	3	2	2	2	—	—	34	Acute low back pain	Sciatica	—	Negative
Weber et al[54]	2	—	—	—	8	—	4	4	2	2	—	2	2	2	5	—	33	Prolapsed lumbar disk	Sciatica	Included	Negative
Weber et al[54]	2	—	—	—	8	—	1	2	2	2	—	2	2	2	5	—	28	Prolapsed lumbar disk	Sciatica	Included	Negative
Lidström and Zachrisson[61]	1	2	—	—	—	—	5	4	—	2	—	2	2	2	5	—	25	Chronic low back pain	Sciatica	—	Positive
Matthews and Hickling[68]	2	—	—	—	8	—	1	2	2	2	—	2	2	2	—	—	23	Low back pain	—	—	Negative
Bihaug[62]	1	2	—	—	4	—	3	2	—	2	—	2	—	2	5	—	23	Chronic low back pain	—	—	Positive

[a]See Tab. 1 footnote for description of criteria. Dash=criterion not fulfilled or incomplete, or no information given.

scription of traction modalities and reference intervention(s) (criteria G and H), and adequate data presented on the most important outcome measures (criterion P).

Recalculation of the weighted and unweighted method scores for the 16 criteria (A-P) and the 49 checklist items provides a sensitivity analysis of the checklist and the distribution of weights. The results of these recalculations (Tab. 3) revealed only minor differences in the hierarchical order of the studies, and the three best studies and the four worst studies remained so. In between, the sequence varied

Table 3. *Sensitivity Analysis of Scoring System*

Authors	Weighted Scores (Maximum Score=100 Points)		Unweighted Scores (Maximum Score=16 Criteria)			Unweighted Method (Maximum Score=49 Items)		
	Rank	% Score	Rank	Score	% Score	Rank	Score	% Score
van der Heijden et al[58]	1	73%	1	15	94%	1	33	67%
Matthews et al[52]	2	52%	3	12	75%	2	26	53%
Goldie and Landquist[59]	2	52%	2	13	81%	3	25	51%
Weber[56]	4	45%	3	12	75%	3	25	51%
British Association of Physical Medicine[64]	5	41%	5	11	69%	7	19	39%
Reust et al[65]	6	39%	5	11	69%	5	22	45%
Larsson et al[60]	7	36%	5	11	69%	10	18	37%
Weber et al[54]	7	36%	10	10	63%	7	19	39%
Ljunggren et al[57]	7	36%	10	10	63%	7	19	39%
Coxhead et al[69]	10	34%	14	9	56%	13	16	33%
Walker et al[66]	10	34%	5	11	69%	10	18	37%
Pal et al[67]	10	34%	10	10	63%	12	17	35%
Zylbergold and Piper[63]	13	33%	5	11	69%	6	21	43%
Weber et al[54]	14	28%	10	10	63%	16	13	27%
Lidström and Zachrisson[61]	15	25%	14	9	56%	13	16	33%
Matthews and Hickling[68]	16	23%	14	9	56%	13	16	33%
Bihaug[62]	16	23%	14	9	56%	17	12	25%

little. These recalculations show the robustness of the scoring system.

Table 4 presents a description of the details of the three RCTs[59,63,64] that compared cervical traction techniques with different control treatments. The method score of one study[59] exceeded 50 points, and one study[63] showed positive results according to the authors of the report. Information about the standardization of traction treatment was incomplete for all three studies. Goldie and Landquist[59] excluded additional care in their study. The other two studies[63,64] used additional care, but only Zylbergold and Piper[63] applied it in a standardized way for all patients.

Table 5 presents a concise description of the details of the seven RCTs[54,56,58,65–68] that compared lumbar traction techniques with placebo traction. Four of these studies[56,58,65,68] were concerned with continuous motorized traction, two studies[54,66] were concerned with autotraction, and one study[67] was concerned with continuous bed traction. Only one study[58] had a method score exceeding 50 points, and none showed positive results according to the authors of the reports. In three studies,[54,66,68] the information about the standardization of the traction treatment was incomplete. In two studies,[65,66] additional care was used, but only Reust et al[65] applied it in a standardized way for all patients. The remaining five studies excluded additional care.

Table 6 summarizes the details of the seven RCTs[52,54,57,60–62,69] that compared different lumbar traction techniques or lumbar traction with heat, corset, exercises, massage, and rest. Three of these studies[57,60,62] were concerned with autotraction, two studies[54,57] were concerned with manual traction, two studies[61,69] were concerned with intermittent motorized traction, and one study[52] dealt with continuous motorized traction. The method score of only one negative study[52] exceeded 50 points, whereas positive results were reported for three studies[60–62] with lower method scores. Information about the standardization of the traction treatment was incomplete in five studies.[52,54,57,62,69]

In Table 7, the studies are once again ordered by their method scores. For this table, we calculated the power ($1-\beta$) and the 90% confidence interval (90% CI) for the differences in success rates of the compared interventions of each study. When a 90% CI excludes zero, there is no significant difference with accepting a 10% chance of a Type I error (alpha=10%).[70] The power ($1-\beta$) was calculated for detecting a 30% difference with the reported success rates in the reference groups, because this was the difference in success rate of the study with the highest method score. Power indicates the chance of missing a true significant difference in success rates (ie, a Type II error) and is acceptable when it exceeds 80% (β=20%).[71] Apart from the assumed clinically relevant effect size (ie, 30%), power depends on the number of patients per group (sample size). Therefore, most of the comparisons shown in Table 7 lack power due to small sample sizes.

In one study,[61] the calculated 90% CI was negative and excluded zero; therefore, the published results favored the control treatment. In three studies that were concerned with lumbar traction[60,62,65] and in two studies that were concerned with cervical traction,[59,63] the 90% CI was positive and excluded zero. In only one of these studies[59] did the method score exceed 50 points. Our power calculations showed that this study also reached an acceptable power ($1-\beta$ of >80%). Although two other studies with significant results[60,61] reached an acceptable power, their method scores did not exceed 50 points.

Table 4. *Cervical Traction*

Authors	Traction Modality (No. of Randomized Patients)	Conservative Treatment or Placebo (No. of Randomized Patients)	Method Score	Reported Results[a] (Ratio of Improved Patients)	Authors' Conclusions
Goldie and Landquist[59]	(i) Intermittent motorized traction, (11.34–18.14 kg) 25–40 lb (n=26)	(ii) Isometric exercises (n=24) (iii) No intervention (n=23)	52	PGE at 3 wk: (i) 17/26, (ii) 17/24, (iii) 7/23	No significant difference
British Association of Physical Medicine[64]	(i) Continuous motorized traction, hot packs, and mobilizing exercises (n=114)	(ii) Sham traction (positioning exercises) (n=114) (iii) Collar (n=120) (iv) Placebo (detuned, ultrashort waves) (n=66) (v) Placebo (analgesics) (n=52)	41	PGE at 4 wk: (i) 24/114, (ii) 26/114, (iii) 29/120, (iv) 14/66, (v) 8/52	No significant difference
Zylbergold and Piper[63]	(i) Continuous motorized traction, 25 lb, hot packs, neck school, mobilizing and isometric exercises (n=25) (ii) Intermittent motorized traction, 25 lb, hot packs, neck school, mobilizing and isometric exercises (n=25) (iii) Manual traction, hot packs, neck school, mobilizing and isometric exercises (n=25)	(iv) Hot packs, neck school, mobilizing and isometric exercises (n=25)	36	CGE at 6 wk ($\bar{X}\pm$SD for pain score): (i) 1.3±1.0, (ii) 1.5±0.8, (iii) 1.0±1.1, (iv) 0.9±1.2	Significant difference; only motorized traction is effective

[a]CGE=clinician's global estimate of improvement, PGE=patient's global estimate of improvement.

Discussion and Conclusions

Studies could only earn points if a report provided the necessary details that met with the methodological requirements. The standard of 100 points is probably not easy to reach in this area of intervention research, but it is disappointing to find that the methodological quality of the available RCTs on traction is so low. In some instances, a more informative report might have revealed additional flaws in the design or conduct of the studies included in this review.

Study Population

Biased treatment assignment could not be excluded for most studies because the reports provided insufficient information about how and by whom the randomization procedure was carried out. A statement about the "at random" division of subjects over intervention groups is no guarantee that all selected patients had the same chance to be assigned to any of the groups.

Although most studies proved methodologically sound with respect to prognostic homogeneity of the selected population, they hardly included a sufficient number of patients (sample size). Prognostic comparability of groups after randomization was impeded by these small sample sizes. In addition, few authors reported adequate information about dropouts and loss to follow-up.

Intervention

Because forces exerted during inverted suspension and manual traction are limited by total body weight and the strength of the patient or therapist, these modalities cannot necessarily be standardized. In contrast, forces exerted during motorized traction and bed-rest traction can be standardized. Occasionally, however, traction modalities and control intervention(s) seemed sufficiently standardized. Additional care and cointerventions were not standardized or poorly standardized. Compliance was only reported occasionally and therefore, in the case of unequal distribution, may have affected the intended intervention contrast.

The 90% CI (Tab. 7) of a comparison of cervical traction with no treatment excluded zero, and its power was sufficient.[59] The method score of this study was 51 points. In situations, however, in which a desired treatment is withheld from the control group, expectation bias and disappointment of patients will easily lead to an overestimation of the effect of traction, and thus to false-positive conclusions. Remarkably, the confidence interval of another study[63] with the same flaw

Table 5. *Lumbar Traction Compared With Placebo*

Authors	Traction Modality (No. of Randomized Patients)	Placebo (No. of Randomized Patients)	Method Score	Reported Results[a] (Ratio of Improved Patients)	Authors' Conclusions
van der Heijden et al[58]	(i) Continuous motorized traction (n=13), 30%–50% of body weight	(ii) "Continuous motorized traction" (n=12), 0%–25% of body weight	73	PGE at 5 wk: (i) 7/11, (ii) 4/12 PGE at 9 wk: (i) 5/11, (ii) 3/12	No significant difference
Weber[56]	(i) Continuous motorized traction, 40–70 kg (n=44)	(ii) "Autotraction," 10 kg (n=44)	45	PGE at 1 wk: (i) 19/43, (ii) 16/44	No significant difference
Reust et al[65]	(i) Continuous motorized traction, 15–50 kg, analgesics, bed rest, hot packs, and massage (n=20) (ii) Continuous motorized traction, 5–15 kg, analgesics, bed rest, hot packs, and massage (n=22)	(iii) "Continuous motorized traction," <5 kg, analgesics, bed rest, hot packs, and massage (n=18)	39	PGE at 2 wk: (i) 19/20, (ii) 16/22, (iii) 10/18	No significant difference
Walker et al[66]	(i) Autotraction, 40–70 kg, analgesics, and back school (n=17)	(ii) "Autotraction," <10 kg, analgesics, and back school (n=12)	34	CGE at 1 wk: (i) 4/17, (ii) 2/12	No significant difference
Pal et al[67]	(i) Continuous bed traction, 5–8 kg (n=24)	(ii) "Continuous bed traction," 1–2 kg (n=15)	34	PGE at 3 wk (mean improvement in pain [VAS]: (i) 45 cm, (ii) 47 cm	No significant difference
Weber et al[54]	(i) Autotraction (n=21)	(ii) "Autotraction" (n=23)	33	CGE at 2 wk: (i) 5/21, (ii) 5/23	No significant difference
Matthews and Hickling[68]	(i) Continuous motorized traction, >45 kg (n=13)	(ii) "Continuous motorized traction," 9 kg (n=14)	23	PGE at 3 wk (mean improvement in pain [VAS]): (i) 29%, (ii) 19%	No significant difference

[a]CGE=clinician's global estimate of improvement, PGE=patient's global estimate of improvement, VAS=visual analog scale (standard deviation not reported).

also excluded zero (ie, was statistically significant). A credible placebo can prevent this type of bias. In this context, it is remarkable that the confidence intervals of the studies that used sham traction as the control treatment always included zero (ie, were not statistically significant).

Measurement of Effect

In the selected trials, hardly any attempts at blinding patients, therapists, and outcome measurements were reported. Only occasionally were long-term effects reported.

Little is known about valid and precise outcome measures that are also sensitive for clinically important changes. In addition, because the relevance of outcome measures is mainly determined by the research question, it is not possible to define in general which outcome measures are relevant. Nevertheless, in day-to-day practice, clinically relevant outcome measures, such as a global measure of improvement, pain, spinal mobility, or functional status, are preferred. That is because they correspond with complaints most often heard as reasons for encounter or referral. Only a few authors, however, reported on more than two of these clinically relevant outcome measures.

Data Presentation

The aim of treatment is a desired treatment outcome that concerns an expected minimal effect size at relevant moments of measurement for predetermined relevant outcome measures. Before mounting an RCT, this desired treatment outcome is also important for calculation of the sample size. None of the authors in our review, however, reported a desired treatment outcome, or the anticipated sample size. For our calculations of 90% CI and power, we used a 30% improvement in the global estimation of the patient or clinician as a relevant outcome measure. We propose it as a clinically relevant measure that is easy to apply in clinical trials and in day-to-day practice. Although confidence intervals and power were only reported occasionally, the presentation of results was sufficient. However, an alternative analysis accounting for

Table 6. *Lumbar Traction Compared With Conservative Treatment*

Authors	Traction Modality (No. of Randomized Patients)	Conservative Treatment (No. of Randomized Patients)	Method Score	Reported Results[a] (Ratio of Improved Patients)	Authors' Conclusions
Matthews et al[52]	(i) Continuous motorized traction, >25% of body weight, maximum 61 kg (n=83)	(ii) Infrared heat (n=60)	52	PGE at 2 wk: (i) 40/77, (ii) 27/54	No significant difference
Larsson et al[60]	(i) Autotraction and corset (n=41)	(ii) Corset (n=41)	36	PGE at 1 wk: (i) 17/41, (ii) 2/41 PGE at 3 wk: (i) 20/41, (ii) 8/41 PGE at 3 mo: (i) 19/41, (ii) 24/41	Significant difference after 1 wk and 3 wk, not after 3 mo
Ljunggren et al[57]	(i) Autotraction and back school (n=26) (ii) Manual traction and back school (n=23)		36	CGE at 1 wk: (i) 5/26, (ii) 8/23 CGE at 2 wk: (i) 5/26, (ii) 7/23	No significant difference
Coxhead et al[69]	(i) Intermittent motorized traction alone or with exercises, manipulation, or corset (n=161)	(ii) No intervention or exercises, manipulation, or corset (n=161)	34	PGE at 4 wk: (i) 117/143, (ii) 110/149	No significant difference
Weber et al[54]	(i) Manual traction (n=24)	(ii) Isometric exercises (n=26)	28	CGE at 2 wk: (i) 10/21, (ii) 10/23	No significant difference
Lidström and Zachrisson[61]	(i) Intermittent motorized traction, 58–95 kg, and isometric abdominal exercises (n=21)	(ii) Hot packs and rest (n=20) (iii) Hot packs, massage, and mobilizing	25	PGE at 3 wk: (i) 10/21, (ii) 18/20, (iii) 14/21	Significant difference only after 3 wk
Bihaug[62]	(i) Autotraction (n=21)	(ii) Isometric abdominal exercises (n=21)	23	PGE at last session: (i) 5/21, (ii) 2/21 PGE at 1 mo: (i) 12/21, (ii) 5/21 PGE at 3 mo: (i) 16/21, (ii) 12/21	Significant difference only after 1 mo

[a]CGE=clinician's global estimate of improvement, PGE=patient's global estimate of improvement.

shortcomings that occurred was never reported.

The criteria we used to assess the available RCTs are based on generally accepted requirements for high methodological quality in intervention research. We do not pretend that our methodological checklist is exhaustive. Because the data in Table 2 show that criteria B (prognostic comparability), D (dropouts described), F (study size), L (relevant outcome measures), M (blinding of outcome measurement), and P (data presentation) contribute most to the discriminative character of the checklist, we believe that our rating system can be used to distinguish methodologically sound studies from those that are not.

We did not pool the results of the studies statistically for two reasons: (1) All studies used different protocols for selection, intervention, and effect measurements; and (2) we prefer not to pool data from studies with high and low methodological quality.

Possible disagreement among independent readers might give rise to conflicting conclusions. This disagreement can be reduced by standardization of the scoring system. Our conclusions are based on methods scoring by two independent assessors with our 49-item checklist. Concordance of their scores was high, and differences were mainly based on reading errors. Blinding of both assessors for results, conclusions, and journal identification was used to prevent occurrence of reviewer bias. In addition, both assessors were not involved in the design or conduct of any of the selected studies.

The weights given to the criteria were chosen arbitrarily, but were assumed to reflect their relative importance for validity and precision. Readers may wish to assign different weights and calculate their own method scores. The sensitivity analysis, however, confirmed the robustness of the methodological scoring system. This analysis revealed that the hierarchical order was not severely affected by discarding weighting factors or by the use of either the 49 checklist items or the 16 criteria. In addition, Shekelle et al[72]

Table 7. *Power Based on 30% Difference in Success Rates Between Groups Based on the Respective Success Rates in the Control Groups and 90% Confidence Intervals (90% CI), Both for the Reported Main Outcome Measures, at the Main Moment(s) of Measurement*

Authors	Method Score	Compared Groups	Moment of Measurement	No. of Patients	Success Rates	Published Results[a]	90% CI[b]	Power[b]
van der Heijden et al[58]	73	i versus ii	5 wk	11 versus 12	64% versus 34%	NS	30%±33% (NS)	45%
		i versus ii	9 wk	11 versus 12	45% versus 25%	NS	20%±32% (NS)	27%
Matthews et al[52]	52	i versus ii	2 wk	77 versus 54	52% versus 50%	NS	2%±16% (NS)	4%[Pt]
Goldie and Landquist[59]	52	i versus ii	3 wk	26 versus 24	65% versus 71%	NS	6%±22% (NS)	7%[Pt]
		i versus iii	3 wk	26 versus 23	65% versus 30%	S	35%±22% (S)	83%
Weber[56]	45	i versus ii	1 wk	43 versus 44	44% versus 36%	NS	8%±17% (NS)	19%
Coxhead et al[69]	44	i versus ii	4 wk	143 versus 149	82% versus 74%	NS	8%±8% (NS)	51%
British Association of Physical Medicine[64]	41	i versus ii	4 wk	114 versus 114	21% versus 23%	NS	−2%±9% (NS)	10%
		i versus iii	4 wk	114 versus 120	21% versus 24%	NS	−3%±6% (NS)	14%[Pt]
		i versus iv	4 wk	114 versus 66	21% versus 21%	NS	0±10% (NS)	5%
		i versus v	4 wk	114 versus 52	21% versus 16%	NS	5%±11% (NS)	20%
Reust et al[65]	39	ii versus i	2 wk	22 versus 20	73% versus 45%	NS	29%±19% (S)	48%[Pt]
		iii versus i	2 wk	18 versus 20	56% versus 45%	NS	11%±27% (NS)	17%
		ii versus iii	2 wk	22 versus 18	73% versus 56%	NS	18%±25% (NS)	30%
Larsson et al[60]	36	i versus ii	1 wk	41 versus 41	42% versus 5%	S	37%±14% (S)	99%
		i versus ii	3 wk	41 versus 41	49% versus 20%	S	29%±17% (S)	90%
		i versus ii	3 mo	41 versus 41	46% versus 59%	NS	−13%±18% (NS)	33%
Zylbergold and Piper[63]	36	i versus ii	3 wk	25 versus 25	1.3 (1.0) versus 1.5 (0.8)	NS	−0.2±0.4 (NS)	—
		i versus iii	3 wk	25 versus 25	1.3 (1.0) versus 1.0 (1.1)	NS	0.3±0.4 (NS)	—
		i versus iv	3 wk	25 versus 25	1.3 (1.0) versus 0.9 (1.2)	NS	0.3±0.4 (NS)	—
		ii versus iii	3 wk	25 versus 25	1.5 (0.8) versus 1.0 (1.8)	S	0.5±0.4 (S)	—
		ii versus iv	3 wk	25 versus 25	1.5 (0.8) versus 0.9 (1.2)	S	0.6±0.4 (S)	—
		iii versus iv	3 wk	25 versus 25	1.0 (1.1) versus 0.9 (1.2)	NS	0.1±0.3 (NS)	—
Ljunggren et al[57]	36	i versus ii	1 wk	26 versus 23	19% versus 35%	NS	−16%±21% (NS)	25%[Pt]
		i versus ii	2 wk	26 versus 23	19% versus 30%	NS	−11%±20% (NS)	14%[Pt]
Walker et al[66]	34	i versus ii	1 wk	17 versus 12	24% versus 17%	NS	7%±25% (NS)	12%
Weber et al[54]	33	i versus ii	2 wk	21 versus 23	24% versus 22%	NS	2%±21% (NS)	7%
Weber et al[54]	28	i versus ii	2 wk	24 versus 26	48% versus 44%	NS	4%±18% (NS)	5%[Pt]
Lindström and Zachrisson[61]	25	i versus ii	3 wk	21 versus 20	48% versus 90%	S	−42%±21% (S)	91%[Pt]
		i versus iii	3 wk	21 versus 21	48% versus 67%	NS	19%±25% (NS)	25%[Pt]
Bihaug[62]	23	i versus ii	Last treatment	21 versus 21	24% versus 10%	NS	14%±16% (NS)	23%[Pt]
		i versus ii	4 wk	21 versus 21	57% versus 24%	NS	33%±24% (S)	64%[Pt]
		i versus ii	3 mo	21 versus 21	76% versus 57%	NS	19%±17% (S)	27%[Pt]

[a]NS=not significant, S=significant.

[b]Pal et al[65] and Matthews and Hickling[66] reported insufficient data for power and confidence interval calculations; Zylbergold and Piper[61] reported insufficient data for power calculations. [Pt]: $Z_\alpha=1.96$; elsewhere: $Z_\alpha=1.645$ (for placebo or no intervention in control group). Confidence interval calculation: Success rates were calculated using data presented in the reports. Differences between the success rates were calculated for the 95% confidence intervals, using the following equation:

$$(P_i-P_c)\pm Z_\alpha\times\sqrt{[P_i\times(1-P_i)/n_i+P_c\times(1-P_c)/n_c]}$$

Power calculation: A difference in success rate of 30% between intervention groups was considered to be clinically relevant. Power $(1-\beta)$ was calculated using the following equation:

$$Z_\beta=\frac{-Z_\alpha\sqrt{2P(1-P)}+\sqrt{N(P_c-P_i)}}{\sqrt{P_c(1-P_c)+P_i(1-P_i)}}$$

Values of Z_β (standardized normal score for Type II error chance) were converted to β using statistical tables of standard normal distributions. P=mean success rate, P_i=success rate in intervention (traction) group, P_c=success rate in control group, N=mean sample size, n_i=sample size of intervention (traction) group, n_c=sample size of control group, Z_α=standardized normal score for Type I error chance of 5% (=1.96).

validated our rating system in a meta-analysis of spinal manipulation. Their study yielded similar results when our scoring system was compared with that of Chalmers et al.[73]

In meta-analysis, publication bias never can be ruled out completely because relevant studies could have been missed. Its occurrence in studies such as this leads to false-positive conclusions. Publication bias, however, mainly exists for articles that are difficult to publish, because they report trials with small sample sizes and negative results.[74] Because the selected articles mainly report on studies with small samples, the occurrence of publication bias in this research area is not very likely.

Due to the poor methodological quality of the studies we reviewed, it is not possible to formulate a strong and valid judgment about either lumbar traction or cervical traction. So far, there has been no clear-cut information about the mechanism nor evidence for any specific effect of cervical and lumbar traction. There is no conclusive evidence, however, that traction is an ineffective therapy for back and neck pain. In view of the results of this review, it seems advisable to perform new RCTs that focus on the modalities from the three best studies (ie, intermittent motorized cervical traction and continuous motorized lumbar traction). Future studies should avoid the methodological flaws presented, and more attention should be given to the proper execution of the RCTs, as well as to the clear description of the crucial features of their design and results.

In addition, in RCTs priority should be given to the specific effect of traction, that is, comparison of these modalities with a traction placebo (sham or low-dosage traction). To warrant validity in such explanatory studies, the development of a credible traction placebo is very important. When in this respect information for the compared groups differs (eg, during traction, a tolerable but distinct force from the harness must be felt, whereas during a traction placebo, very little pulling from the harness must be felt), the persuasiveness of physical therapists will be crucial.

The available RCTs do not allow conclusions about the effectiveness of cervical or lumbar traction. Therefore, intervention studies do not support the common practical recommendations or clinical guidelines about traction that are mainly based on the rationale of spinal elongation.

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