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Original Articles

The Efficacy of Chiropractic Manipulation for Back Pain: Blinded Review of Relevant Randomized Clinical Trials

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ABSTRACT

Objective: To assess the efficacy of chiropractic for patients with back pain.

Data Sources: Randomized clinical trials (RCTs) on spinal manipulation were identified with a *Medline* search (1966–1990), by citation tracking, and by manual examination of the relevant chiropractic reference systems [*Chiropractic Research Archives Collection* and *Index to Chiropractic Literature*]. [Indexing terms, *Medline*: backache, musculoskeletal diseases, manipulation, osteopathy or chiropractic in combination with evaluation studies, outcome and process assessment, prospective studies, comparative studies, clinical trials or double blind method. Indexing terms, *Chiropractic Research Archives Collection*: backache therapy-chiropractic, clinical trials, cost benefit analysis, evaluation studies—chiropractic, manipulation—spinal, prospective studies, sciatica-therapy. Indexing terms, *Index to Chiropractic Literature*: backache therapy, clinical trials, cost benefit analysis, intervertebral disc displacement-therapy.]

Study Selection: All RCTs involving chiropractors as therapists. To find additional evidence from nonchiropractic RCTs, chiropractic standards similar to the type of treatment used in nonchiropractic trials were deter-

mined by a panel of blinded chiropractors.

Data Extraction: Review by two blinded reviewers independently, using a list of methodological criteria, each of which was attached to a weight. The maximum was set at 100 points.

Data Synthesis: We identified five chiropractic RCTs. No similarity to chiropractic standards could be detected in any of the nonchiropractic RCTs. No chiropractic RCT had a methodological score of more than 50 points. The authors of four of the trials report favorable results for chiropractic, while one refrains from drawing conclusions. The results of the chiropractic RCTs differed on the timing of maximal effect as well as on the subgroups showing the best treatment results.

Conclusions: Although the small number of chiropractic RCTs and the poor general methodological quality precludes the drawing of strong conclusions, chiropractic seems to be an effective treatment of back pain. However, more studies with a better research methodology are clearly still needed. (*J Manipulative Physiol Ther* 1992; 15:487–494).

Key Indexing Terms: Chiropractic, Clinical Trials, Low Back Pain.

INTRODUCTION

The acceptance of chiropractic by the general public, other health care suppliers, third party payers and na-

tional governments has been growing recently (1). The demand for scientific proof of the efficacy of chiropractic manipulation is often linked to the question of full acceptance of the profession (2, 3). The chiropractic profession has participated in several national investigations [e.g., in New Zealand (4), Sweden (5) and U.S. Government-sponsored workshops (6, 7)]. For a long time, patient-related chiropractic research has consisted of (large) case series (8, 9) and retrospective Workmen's Compensation studies (10). Because these types of uncontrolled studies have major methodological flaws (11–14), there is a growing demand for randomized clinical trials (RCTs). A number of RCTs on the efficacy of various techniques of manipulation for low

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back and neck pain have been performed. Several reviews written by chiropractors (8, 9, 15–17) or other experts (5, 18–21) have tried to summarize the results of these RCTs.

Clearly, it is preferable that RCTs involving chiropractors as therapists be used to determine the efficacy of chiropractic therapy. However, the number of non-chiropractic RCTs in this field still far exceeds the number of chiropractic RCTs. RCTs incorporating manipulative regimens with a similarity to chiropractic standards might be used as additional evidence for the efficacy of chiropractic care. Identification of such RCTs should preferably be done by members of the profession itself. However, it is possible that the assessment of the degree of similarity will be biased by knowledge of the outcome of the RCT at issue.

Besides this problem of the generalizability (external validity) of results of the available RCTs to chiropractic practice, there is the problem of internal validity: do the design, conduct and reporting of the study fully justify the author's conclusions? In chiropractic research, there is a growing awareness of the importance of methodological quality. Brunarski (8), Leboeuf (22) and Klinoski and Leboeuf (23), for instance, appraised chiropractic literature by means of a methodological checklist.

To put it simply, the efficacy of chiropractic in the treatment of low back and neck pain has to be determined from RCTs with chiropractors as therapists or nonchiropractic RCTs incorporating techniques which are similar to chiropractic manipulation. In addition, most attention should be paid to the RCTs with the highest methodological quality.

Therefore, we decided to ask a blinded panel of chiropractors to assess the similarity to chiropractic treatment of the regimens of manipulation that were used in the available RCTs. Subsequently, we reviewed the RCTs thus identified and assessed their methodological quality by using a standardized set of criteria.

METHODS

RCTs on spinal manipulation were identified with a *Medline* search (1966–1990), by citation tracking and by manual examination of the relevant chiropractic reference systems [*Chiropractic Research Archive Collection* (24) and *Index to Chiropractic Literature* (25)]. RCTs involving study subjects suffering from low back and neck pain were selected if the treatment included manipulation or mobilization of the spine. Additional interventions were allowed. RCTs with chiropractors as therapists were identified and will be discussed separately.

To enable blind judgment of additional RCTs with methods of manipulation similar to chiropractic, the full description of the manipulative treatment as given in the "Methods" section was typed on a separate form by one of the authors (W.A.). The description included the method of manipulation or mobilization, the (maximal) frequency, treatment intervals and the relevant references as far as they were presented in the article. The actual profession of the therapist was not given on the form. To reduce recognition of "classic" RCTs, we added descriptions from textbooks (e.g., Maitland, Cyriax) and journals (e.g., *Journal of Manipulative and Physiological Therapeutics*). Subsequently, a panel of four experienced Dutch chiropractors (appointed by the Netherlands Chiropractors Association) assessed the similarity of these descriptions to chiropractic standards on a 6-point scale, ranging from "almost certainly not similar" to "almost certainly similar." They had to reach a consensus on this rating. They were not allowed to consult any reference books or articles. The discussion was not to be directed toward the source of the description, only the actual content of the description could be discussed. Similarly, at a separate meeting, three Dutch manual therapists, who were delegated by their professional organization (*Nederlandse Vereniging voor Manuele Therapie*), assessed the description from the RCTs as well.

The articles, blinded for author(s), journal and outcome, were assessed by two blinded reviewers independently. A standardized list of methodological criteria was used (Table 1) (26). In a subsequent meeting, the reviewers discussed instances where they did not initially agree. For the (few) instances where no consensus was reached, a third blinded reviewer made the final decision.

The criteria are based on generally accepted principles of intervention research (27, 28). To each criterion, a weight is attached. The maximum score was set at 100 points for each study. The assessment resulted in a hierarchical list in which higher scores indicate studies with a better methodology.

RESULTS

Thirty-five different RCTs were identified: 30 on low back pain (29–58) and 5 on neck pain (59–63). Five of them, all on low back pain, involved chiropractors as therapists (29–33). No chiropractic RCTs on neck pain could be identified.

The total time necessary for assessment of the blinded method descriptions by the chiropractors was 3.5 hours. In their opinion, most descriptions contained only very limited information regarding the exact method of ma-

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TABLE 1. Criteria list for the methodological assessment of randomized clinical trials of manipulation for back and neck pain

Criteria	Weight	
Study population	(30)	
A Homogeneity	2	of patients at main moment of effect measurement for the main outcome measure, divided by all randomized patients times 100.
B Comparability of relevant baseline characteristics	5	
C Randomization procedure adequate	4	F Smallest group immediately after randomization.
D Drop-outs described for each study group separately	3	G Manipulative treatment protocolized and described (5 points). All reference treatments protocolized and described (5 points).
E <20% loss to follow-up	2	H Comparison with an existing treatment modality.
<10% loss to follow-up	2	I Other physical therapy modalities or medical interventions are avoided in the design of the study (except analgesics, advice on posture or use at home of heat, rest or a routine exercise scheme).
F >50 subjects in the smallest group	6	J Comparison with a placebo therapy.
>100 subjects in the smallest group	6	K Mentioning of qualified education and/or experience of the manipulative therapist(s).
Interventions	(30)	L Placebo controlled: attempt for blinding (3 points), blinding evaluated and fully successful (2 points). Pragmatic study: patients fully naive (3 points), or time restriction (no manipulative treatment for at least 1 yr) (2 points), naiveness evaluated and fully successful: 2 points.
G Interventions protocolized and described	10	M Use (measured and reported) of: pain, global measure of improvement, functional status (activities of daily living), spinal mobility, medical consumption (2 points each).
H Pragmatic study	5	N Each blinded measurement mentioned under criterion M earns 2 points.
I Cointerventions avoided	5	O Moment of measurement during or just after treatment (3 points). Moment of measurement 6 months or longer (2 points).
J Placebo controlled	5	P Intention-to-treat analysis when loss to follow-up is less than 10%: all randomized patients for most important outcome measures, and on the most important moments of effect measurement minus missing values, irrespective of noncompliance and cointerventions. When loss to follow-up > 10%: intention-to-treat as well as an alternative analysis which accounts for missing values.
K Mentioning good qualification of manipulative therapist	5	Q For most important outcome measures, and on the most important moments of effect measurement. In the case of (semi)continuous variables: presentation of the mean or median with standard error or percentiles.
Effect	(30)	
L Patients blinded	5	
M Outcome measures relevant	10	
N Blinded outcome assessments	10	
O Follow-up period adequate	5	
Data presentation and analysis	(10)	
P Adequate analysis	5	
Q Frequencies of most important outcome presented for each treatment group	5	
<u>Operationalization of the criteria</u>		
Each criterium must be applied independently of the other criteria.		
A Description of inclusion and exclusion criteria (1 point). Restriction to a homogeneous study population (1 point).		
B Comparability for: duration of complaints, value of outcome measures, age, recurrence status and radiating complaints (1 point each).		
C Randomization procedure described (2 points). Randomization procedure which excludes bias (e.g., sealed envelopes) (2 points).		
D Information from which group and with reason for withdrawal.		
E Loss to follow-up: all randomized patients minus the number		

nipulation, the (maximal) frequency of treatments and the intervals between the treatment. In general, the four chiropractors had no difficulty in reaching a consensus.

The panel of Dutch chiropractors concluded that two of the RCTs included a treatment regimen similar to chiropractic (Table 2). Both turned out to be executed by a chiropractor (32, 33). They thought that 29 had used techniques that were "absolutely not similar," three "probably not similar, and two "maybe not similar" [among which was one chiropractic RCT (30)], and from three RCTs, the description was not sufficient [a total of 39 descriptions, because two studies (34, 35) used one form and one study (29) used two forms of mobilization as reference treatment]. The two chiropractic studies which were rated "description not sufficient" (29, 31) did not contain enough information to make a final decision, but were expected to be chiropractic by the panel.

The chiropractic trials had scores of 48, 37, 33, 30 and 20 (Table 3), indicating a rather poor methodological quality.

Reading Table 3 in a vertical direction shows that the most prevalent methodological problems concern: the lack of a proper description of drop-outs (D); the small size of the study population (F); an inadequate protocolization and description of the interventions (G); the lack of blinded or naive patients (L, N); and an improper data-analysis (P). The recently published British Medical Research Council (MRC) trial (29) is the highest ranking chiropractic trial. The methodological shortcomings of this trial have been discussed in detail in the *Journal of Manipulative and Physiological Therapeutics* recently (64).

The results of the chiropractic RCTs were not consistent (Table 4). Three studies reported a rapid improvement with chiropractic manipulation (30, 31, 33),

while the MRC trial (29) did not find any advantage of chiropractic during the first 6 wk. Postacchini et al. (31) reported positive results for acute patients only, while Waagen et al. (30) and Meade et al. (29) reported favorable outcomes especially for chronic patients. Only two of the chiropractic RCTs reported long-term results (>3 months after randomization): the MRC study (29) reported increasingly favorable results for chiropractic compared to physiotherapy throughout follow-up, while Postacchini et al. (31) found no advantage of chiropractic over other treatments at 6 months. Bronfort (32) refrained from drawing conclusions because of a small sample size.

DISCUSSION

Thirty-five RCTs on the efficacy of spinal manipulation for back and neck pain were identified; only five of them appear to be chiropractic. At present, there are a number of chiropractic RCTs on low back pain in the preparation, execution or reporting phase [e.g.,

McGregor et al. (65), Pope et al. (66), Waagen et al. (67), Bronfort et al. (68), Jochumsen (69)]. It is surprising that there is only one recently completed chiropractic RCT on neck pain (Lopes et al. (70), since after back pain, neck pain is the second most prevalent complaint in chiropractic practice (71, 72). This trial only reports on the immediate effects of a single manipulation vs. a single series of mobilization. Since a final assessment of methodological quality and the results can only be made when a study is published, these RCTs on low back and neck pain cannot be discussed yet, although preliminary reports on some of them seem to be promising.

Our panel of Dutch chiropractors was not able to detect a clear similarity with chiropractic manipulation among the 30 nonchiropractic studies, so these studies seem to shed little light on the efficacy of chiropractic.

In contrast, Dutch manual therapists identified themselves to a much greater extent with the methods of manipulation used in published RCTs (Table 2). Dutch manual therapy as represented in the panel is taught to physiotherapists and physicians in a post-initial part-time curriculum. The colleges offering this curriculum are not explicitly connected to a specific international mainstream in manipulation, but various influences seem to have been assimilated to mutual different levels (73). This might be the explanation for the large difference between Dutch chiropractors and manual therapists in the assessment of the techniques used in these RCTs to their own profession.

In addition, the descriptions taken from the methods paragraphs only contained information on the manipulative treatment given. There was no reference to the diagnosis of the patient, the profession of the therapist, the actual skills of the therapist in manipulation, the accuracy of diagnosis and the additional advice provided to the patient. For the members of the panel, it was only possible to judge the manipulative technique on the basis of the often very limited information provided by the authors of the article on the RCT.

The low methodological scores indicate that there are

TABLE 2. Comparison of the judgment of Dutch chiropractors (NCA^a) and Dutch-trained manual therapists (NVMT^b) about similarity of the description of manipulative technique in RCTs compared to chiropractic standards

Judgment (corresponding percentage of similarity)	Number of studies (chiropractic studies)	
	NCA	NVMT
Almost certainly similar (95%)	0 (0)	15 (2)
Probably similar (80%)	2 (2)	5 (1)
Maybe similar (60%)	0 (0)	3 (0)
Maybe not similar (40%)	2 (1)	1 (0)
Probably not similar (20%)	3 (0)	5 (0)
Almost certainly not similar (5%)	29 (0)	10 (2)
Description not sufficient	3 (2)	0 (0)
Total	39 ^c (5)	39 ^c (5)

^a NCA = Nederlandse Chiropractoren Associatie (Netherlands Chiropractors Association).

^b NVMT = Nederlandse Vereniging voor Manuele Therapie (Dutch Society for Manual Therapy).

^c Thirty-nine descriptions from 35 RCTs, because additional descriptions from two studies (48, 49) using mobilization as reference treatment and one study (42) using two different manipulation/mobilization regimes as reference treatment were included as well.

TABLE 3. Hierarchical list of methodological quality of randomized trials on the efficacy of chiropractic for back pain [adapted from Koes et al. (26)]

Author	Reference no.	Methodological Criteria																	Total score
		A 2	B 5	C 4	D 3	E 4	F 12	G 10	H 5	I 5	J 5	K 5	L 5	M 10	N 10	O 5	P 5	Q 5	
Back pain trials																			
Meade	29	—	4	4	—	2	12	—	5	—	—	5	—	6	—	5	—	5	48
Waagen	30	1	2	—	—	—	—	5	5	5	—	5	5	4	2	3	—	—	37
Postacchini	31	—	2	—	—	2	—	—	5	5	5	5	—	4	—	5	—	—	33
Bronfort	32	1	2	—	—	2	—	—	5	—	—	5	3	2	—	5	—	5	30
Rupert	33	1	1	—	—	—	—	—	—	—	5	5	3	2	—	3	—	—	20

TABLE 4. Randomized clinical trials on efficacy of chiropractic for back pain

Author	n ^a	Methodological score	Patient sampling	Indication	Manipulative treatment	Control treatment
Meade, 1990 (29)	741	48	Patients from 11 centers consisting of chiropractic clinics and hospital outpatient departments (G.B.)	Patients with acute and chronic low back pain, with or without radiation; nerve root not affected	Standardized chiropractic technique	Physiotherapy including Maitland mobilization/manipulation, Cyriax manipulation, traction and exercises
Waagen, 1986 (30)	29	37	Patients from clinic of chiropractic college (U.S.)	Chronic low back pain (>3 w); intensity mild to moderate	Chiropractic full-spine adjustments	Sham adjustment using minimal force and paraspinal soft tissue massage
Postacchini, 1988 (31)	459	33	Patients from 2 low back clinics (Italy)	5 different groups: IA = acute (<4 w)/no radiation; IB = chronic (>8)/no radiation; IC = chronic with acute episode; IIA = acute with radiation; IIB = chronic with radiation	Standardized chiropractic technique	1. NSAID (diclofenac) 2. Physiotherapy (massage, infrared or short wave) 3. Placebo (antiedema gel) 4. Bedrest (6-8 days) 5. Low back school
Bronfort, 1989 (32)	10	30	Patients from several medical practices (Denmark)	Low back pain of various duration with or without radiation	Chiropractic procedures: low amplitude/high velocity	Medical treatment including analgesics, injections, bedrest and/or physiotherapy
Rupert, 1985 (33)	155	20	Patients from 3 hospitals (Egypt)	Low back or leg pain and/or restriction in lumbar range of motion	Specific short lever manipulations	1. Sham manipulation consisting of touching and palpating 2. Drugs and bedrest

Author	Main outcome measures	Follow-up measurements	Results
Meade 1990 (29)	Oswestry back pain questionnaire, SLR, lumbar flexion	Weekly first 6 wk, 6 months, 1 yr, ^b 2 yr, ^b 3 yr ^b	Chiropractic treatment more effective on Oswestry scale, especially for patients with chronic and severe pain; no differences after 6 wk, increasing difference throughout follow-up period. From main secondary outcome measures only right SLR significantly larger in chiropractic group
Waagen, 1986 (30)	Objective index consisting of: SLR lumbar flexion, extension and lateral bending; VAS for pain	2 wk	Significant greater improvement on objective index and VAS; results considered preliminary because of small sample size
Postacchini, 1988 (31)	Total index consisting of: pain, functional status, fingertip-distance, strength abdominal and back muscles, SLR, pressure pain spinous processes	3 wk, 2 months, 6 months	Best results at 3 wk in acute patients (IA and IIA) with chiropractic treatment; at long term and for other indications (chronic or chronic with acute episode; IB, IC and IIB) no superiority over other (placebo) treatments
Bronfort, 1989 (32)	Patient's and observers' blinded assessment of improvement; percentage of patients with symptoms	1 month, 3 months, 6 months	Patient's assessment of improvement more positive in chiropractic patients; other outcomes no differences; no conclusions because of small sample size
Rupert, 1985 (33)	VAS for pain; fingertip-floor distance; SLR	On the 8 consecutive visits (3 visits/wk)	Greater pain reduction in chiropractic patients compared to the other 2 treatments; more immediate relief for chronic patients and patients under age 40; no reporting of results of fingertip-floor distance and SLR

^a n = number of randomized patients.

^b Follow-up periods of 1, 2 and 3 yr not completed by a part of the patients.

VAS = visual analogue scale; SLR = straight leg raising.

severe methodological shortcomings in all chiropractic RCTs. This low methodological quality is a general problem in RCTs on spinal manipulation (26). There seems to be no difference in methodological scores between chiropractic and nonchiropractic RCTs (26).

The highest ranking chiropractic trial [Meade et al. (29)] is among the methodological "best" RCTs of spinal manipulation. Most methodological problems are avoidable, but some seem to be inherent to studies on spinal manipulation. One of the major problems is

the blinding of the patients. The first safeguard should be the choice of naive patients only, as done in some chiropractic RCTs (30, 32, 33). The success of blinding should be evaluated carefully in studies using sham manipulation for the reference group. The study of Waagen et al. (30) offers a good example of this. In studies using another treatment modality for the reference group, blinding is impossible and naivety of the patients has to be accepted as a substitute.

The results of the chiropractic RCTs were not consistent; they differed both on time of maximal effect and on subgroups showing best treatment results. When compared to the nonchiropractic RCTs, there are no main differences in outcome. Of the 30 nonchiropractic RCTs, 29 report short-term results: 16 positive, 3 positive only in a subgroup and 10 negative (26). In addition, 13 nonchiropractic RCTs mentioned long-term results: 2 positive, 10 negative and 1 positive only for a subgroup (26).

CONCLUSION

Although the small number of chiropractic RCTs and the poor general methodological quality preclude the drawing of strong conclusions, chiropractic seems to be an effective treatment of back pain. However, studies with a better research methodology are clearly needed. Special attention should be paid to the way in which duration of the complaints (and other prognostic factors) modify the effect of manipulation, since this is one of the main points of controversy. In addition, more effort should be made to establish long-term follow-up, because lasting improvement will be the most convincing in the estimation of cost-effectiveness (29).

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