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Bundesärztekammer  
Arbeitskreis „Wiss. Bewertung  
der Osteopathie“  
Federführender  
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### Wissenschaftliche Bewertung der Osteopathie

Sehr geehrter Herr Professor Haas,

wie in Ihrem Schreiben vom 12.07.2007 angefordert, übermittele ich Ihnen nachfolgend die gewünschte Ausarbeitung für das Gutachten zur wissenschaftlichen Bewertung der Osteopathie.

In Vorbereitung eines Gutachtens zur wissenschaftlichen Bewertung der Osteopathie sollte eine Literatursuche zur möglichst umfangreichen Erfassung bereit stehender, relevanter Artikel durchgeführt werden. Dabei wurde eine inhaltliche Unterteilung in a) parietale, b) viszerale und c) cranio-sacrale Osteopathie angestrebt.

### Hintergrund

Dem musste zunächst eine Definition und Klärung der Begrifflichkeiten vorangestellt werden.

In den USA gilt die Osteopathie als medizinischer Ansatz, der die Rolle des muskuloskeletalen Systems für Gesundheit bzw. Krankheit betont. *Doctors of Osteopathy* (D. O.s) sind ihren schulmedizinischen Kollegen gleichgestellt; daneben werden außerdem *Chiropractors* unterschieden (American Osteopathic Association).

Im deutschen Raum gestaltet sich das Auffinden einer einheitlichen Definition schwieriger. So findet sich im Roche Medizin Lexikon (online) lediglich der Eintrag „Chirotherapie“. Die

Begriffe „manuelle Medizin“, „Manualtherapie“, „Osteopathie“ und „Chiropraktik“ werden hier synonym gebraucht.

Manipulative Techniken finden sowohl im Rahmen der Osteopathischen Medizin als auch im Rahmen der Manuellen Medizin Anwendung.

Die Deutsche Gesellschaft für Osteopathische Medizin (DGOM) definiert Osteopathische Medizin wie folgt:

*Osteopathische Medizin beinhaltet eine umfassende manuelle Diagnostik und Therapie von Fehlfunktionen im Bewegungssystem, den inneren Organen und am Nervensystem. Im Zentrum der Therapie steht nicht die Behandlung einer Krankheit an sich, sondern immer die individuelle Situation bei einem Patienten. Im Mittelpunkt stehen die Selbstheilungskräfte des Patienten. Jeder Körper hat eine starke Kraft zur Gesundheit in sich. Der Osteopathische Arzt regt diese Kräfte an und fördert damit die Selbstheilung.*

(Quelle: Internet-Referenz I)

Die Formulierung des ersten Satzes dieser Definition birgt die Interpretationsmöglichkeit, die MM als einen Teil der OM zu betrachten. Dies wiederum gilt jedoch nicht als einheitliche Auffassung. So beantwortete J. Buchmann bereits 2002 die Frage, was ein „osteopathisch ausgebildeter Arzt, nachdem er eine Diagnose gestellt hat“ mache, mit folgender Aussage: „Er legt spezifisch Hand an und behandelt mit manuellen Techniken Funktionsstörungen beweglicher Strukturen des menschlichen Körpers“ und warf damit wiederum die Frage auf „Wo ist der Unterschied zur manuellen Medizin?“. Offensichtlich ist eine inhaltlich-konzeptionelle Differenzierung der Begriffe OM und MM bisher nicht ohne weiteres möglich. Buchmann stellt zudem fest, dass die drei Bereiche parietale, viszerale und kraniosakrale Osteopathie durchaus unabhängig voneinander existieren und dass insbesondere einzelne Techniken der Osteopathie eine Bereicherung der MM darstellen.

Dvorak et al. (2001) stellen u. a. Gemeinsamkeiten und Unterschiede bzgl. diagnostischer Maßnahmen, welche sowohl MM, OM und in Chiropraktik genutzt werden, vor. Dabei fällt auf, dass immerhin sieben der ausgewählten fünfzehn manuellen Techniken in allen drei Bereichen zur Standardprozedur gehören.

Verschiedene Verbände (wie die Deutsche Gesellschaft für Physikalische Medizin und Rehabilitation e.V., der Berufsverband der Rehabilitationsärzte Deutschlands e.V., die Gesellschaft für Manuelle Wirbelsäulen- und Extremitätenbehandlung (MWE), die Schweizer Gesellschaft für Manuelle Medizin, das Europäische Forum für Manuelle Medizin (EFOMM) und die Ärztevereinigung für Manuelle Medizin – Ärzteseminar Berlin (ÄMM) e.V.) betrachten die Osteopathie heute als Bestandteil *und* Erweiterung der MM. Eine strikte Abkoppelung scheint hier somit nicht im Vordergrund zu stehen. Dennoch ist es für die Bewertung vorhandener Literatur essentiell, eine einheitliche Klärung der Begrifflichkeiten zu finden.

Um trotz der beschriebenen Unklarheiten eine erste Sichtung relevanter Literatur vornehmen zu können, wurden einige Schlagwörter für die Suche festgelegt, welche im weiteren Verlauf benannt werden.

**Methodik**

Die primäre Literaturrecherche wurde in elektronischen Datenbanken durchgeführt. Dabei lag der Schwerpunkt auf der Recherche in *PubMed*, der frei zugänglichen Online-Datenbank der *U.S. National Library of Medicine*. *PubMed* erlaubt unter anderem den Zugriff auf die Datenbank *MEDLINE*, in der alle Einträge nach so genannten *Medical Subject Headings (MeSH)* indiziert werden. Hierbei handelt es sich um deskriptive Titel/ Überschriften, die aufgrund ihrer hierarchischen Anordnung eine Suche auf unterschiedlich spezifischen Ebenen erlauben.

Ziel war es, diejenigen Artikel zu identifizieren, welche Wirksamkeit und Effizienz osteopathischer Behandlungsformen thematisieren. Zunächst wurde der eher unspezifische Suchbegriff „osteopathy“ in der *MeSH-Database* verwendet (Tab. 1, #1). Drei von 28 *MeSH-Kategorien* schienen als Basis der weiteren Recherche geeignet.

Tabelle 1: Ergebnisse Suchbegriff: „osteopathy“, MeSH-Datenbank

Search	Most Recent Queries	Time	Result
#1	Search <b>osteopathy</b>	03:28:26	<u>28</u>

(aktualisierte Suche 05.11.07)

Einordnung der relevanten Kategorien/ Begriffe (*MeSH-Terms*)

(1) All MeSH Categories

Biological Sciences Category

Health Occupations

Medicine

***Osteopathic Medicine***

(2a) All MeSH Categories

Analytical, Diagnostic and Therapeutic Techniques and Equipment Category

Therapeutics

Complementary Therapies

Musculoskeletal Manipulations

***Manipulation, Osteopathic***

(2b) All MeSH Categories

Analytical, Diagnostic and Therapeutic Techniques and Equipment Category

Therapeutics

Musculoskeletal Manipulations

***Manipulation, Osteopathic***

(3) All MeSH Categories

Biological Sciences Category

Health Occupations

***Chiropractic***

Die gefundenen, osteopathisch relevanten *MeSH-Terms* dienten im Folgenden als Suchbegriffe in der PubMed-Datenbank. Es wurden Einträge gesucht, die in mindestens einer der drei Kategorien verzeichnet waren; deshalb wurden die Begriffe mit dem *boolean operator* „OR“ verknüpft. Insgesamt fanden sich für diese Begriffe 4806 Einträge.

Tabelle 2: Ergebnisse der Suche relevanter MeSH-Terms in PubMed-Datenbank

Search	Most Recent Queries	Time	Result
#2	Search ("Osteopathic Medicine"[Mesh] OR "Manipulation, Osteopathic"[Mesh]) OR "Chiropractic"[Mesh]	04:38:51	<u>4806</u>

(aktualisierte Suche 05.11.07)

Diese zunächst grobe, aber klare Struktur wurde eingesetzt, um möglichst viele osteopathisch relevante Einträge zu erfassen und den so genannten *retrieval bias* – das Nicht-Auffinden relevanter publizierter Literatur – gering zu halten. Darüber hinaus wurden grundsätzlich keine Einschränkungen bezüglich der Sprache oder des Erscheinungsjahres der Einträge vorgenommen. Somit wurde zunächst die gesamte Literatur seit Beginn der Indizierung bis einschließlich November 2007 geprüft.

In der nachstehenden Tabelle wird die Zahl der Ergebnisse bei einfacher, unverknüpfter Suche präsentiert.

Tabelle 3: „einfache“ Suche

Search	Most Recent Queries	Time	Result
#10	Search <b>craniosacral</b>	04:40:25	<u>41</u>
#9	Search <b>visceral</b>	04:40:17	<u>34037</u>
#8	Search <b>parietal</b>	04:40:10	<u>33551</u>
#7	Search <b>"evidence based"</b>	04:40:04	<u>38202</u>
#6	Search <b>efficiency</b>	04:39:51	<u>151363</u>
#5	Search <b>effectivity</b>	04:39:43	<u>1327</u>
#4	Search <b>effect</b>	04:39:26	<u>1675262</u>
#3	Search <b>"clinical effect"</b>	04:39:15	<u>4209</u>
#2	Search <b>("Osteopathic Medicine"[Mesh] OR "Manipulation, Osteopathic"[Mesh]) OR "Chiropractic"[Mesh]</b>	04:38:51	<u>4806</u>

(aktualisierte Suche 05.11.07)

In der folgenden Übersicht ist das Fließschema der weiteren Suchbegriffe abgebildet. Die einzelnen Terme wurden mittels des *boolean operator* „AND“ absteigend kombiniert; die blau unterlegten Zahlen geben die Anzahl der jeweils gefundenen Einträge an.

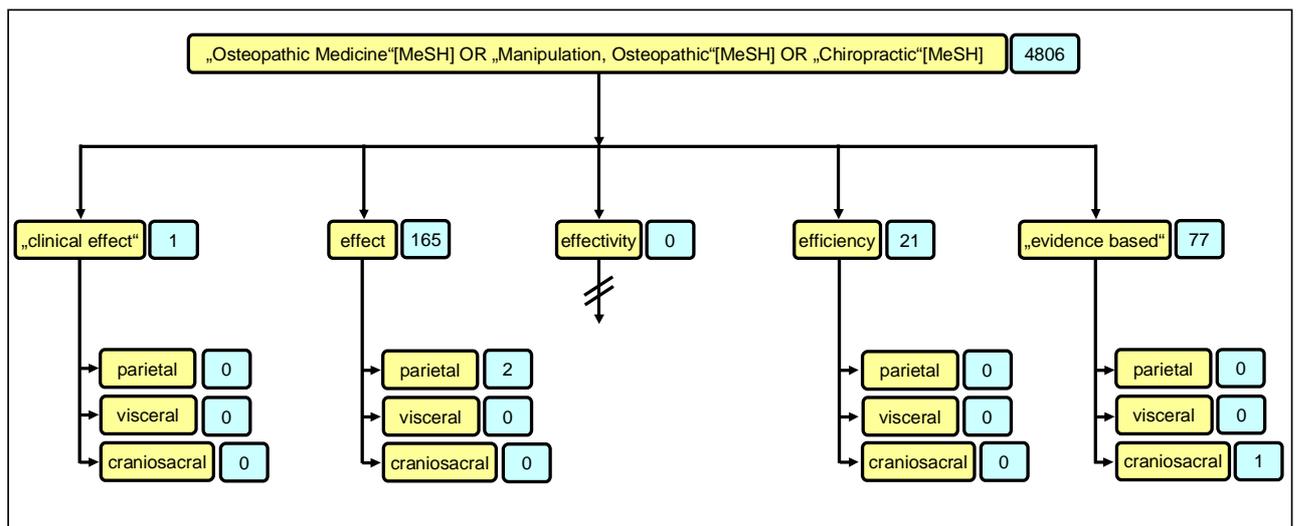


Abb. 1: Fließschema/ Suchstrategie

Tabelle 4 sowie das oben stehende Fließschema zeigen, dass beispielsweise 21 Einträge sowohl in einer der 3 MeSH-Kategorien verzeichnet sind als auch den Begriff „*efficiency*“ aufweisen.

Tabelle 4: Ergebnisse der Suche kombinierter Begriffe

Search	Most Recent Queries	Time	Result
#27	Search #2 AND #7 AND #10	05:04:05	<u>1</u>
#26	Search #2 AND #7 AND #9	05:04:01	<u>0</u>
#25	Search #2 AND #7 AND #8	05:03:57	<u>0</u>
#24	Search #2 AND #7	05:03:48	<u>77</u>
#23	Search #2 AND #6 AND #10	05:03:39	<u>0</u>
#22	Search #2 AND #6 AND #9	05:03:35	<u>0</u>
#21	Search #2 AND #6 AND #8	05:03:31	<u>0</u>
#20	Search #2 AND #6	05:03:24	<u>21</u>
#19	Search #2 AND #5	05:03:17	<u>0</u>
#18	Search #2 AND #4 AND #10	05:03:11	<u>0</u>
#17	Search #2 AND #4 AND #9	05:03:06	<u>0</u>
#16	Search #2 AND #4 AND #8	05:02:58	<u>2</u>
#15	Search #2 AND #4	05:02:48	<u>165</u>
#14	Search #2 AND #3 AND #10	05:02:28	<u>0</u>
#13	Search #2 AND #3 AND #9	05:02:24	<u>0</u>
#12	Search #2 AND #3 AND #8	05:02:19	<u>0</u>
#11	Search #2 AND #3	05:02:07	<u>1</u>

(aktualisierte Suche 05.11.07)

Da in PubMed schwerpunktmäßig U.S.-amerikanische Journals vertreten und europäische Zeitschriften eher unterrepräsentiert sind, wurde eine zweite elektronische Datenbank zur Recherche herangezogen – die *Cochrane Library*.

Auch hier wurde zunächst in der MeSH-Datenbank nach „*osteopathy*“ gesucht; als geeigneter MeSH-Term wird „*Osteopathic Medicine*“ ausgegeben. Mit diesem Begriff wurde die Cochrane Library durchsucht, was insgesamt 18 Ergebnisse brachte. Zwei der Einträge sind Cochrane Reviews, 12 sind kontrollierte Studien und weitere vier Einträge fanden sich in der NHS Economic Evaluation Database, welche v. a. Informationen über die Kosteneffizienz von Behandlungsformen bereithält.

Hand search und Refrenzzeitschriften sind geplant, konnten im Zeitrahmen nicht vollständig durchgeführt werden.

Da es Zielstellung war, insbesondere Wirksamkeits- und Effizienzstudien zu betrachten, wurden von den insgesamt 285 Treffern Medikamentenstudien, Reliabilitäts- und Validitätsstudien bezüglich osteopathischer Untersuchungen, grundlagenbezogene sowie

berufspolitisch orientierte Artikel, Leserbriefe, Editorials, Pilotstudien, Kasuistiken und selbstverständlich auch Doppelseinträge von der weiteren Betrachtung ausgeschlossen. Die übrig gebliebenen Artikel wurden zunächst danach beurteilt, ob sie von Relevanz sind in Hinblick auf die Zielstellung des geplanten Gutachtens. Anschließend erfolgte – sofern Zugriff auf ausreichend Informationen bestand – eine Einordnung auf Stufen der Evidenz. Dabei wurde derjenigen Evidenz-Hierarchie gefolgt, wie sie auch auf den Internet-Seiten des Cochrane-Zentrums publiziert ist (Tab. 5) – wohl wissend, dass sich diese Einteilung „auf die grundsätzliche Eignung eines Studiendesigns, durch Vermeidung systematischer Fehler (Bias) zu validen Ergebnissen zu kommen“ (Internet-Referenz II) bezieht und „v. a. eine historische Bedeutung“ (Internet-Referenz III) hat.

Tabelle 5: Evidenz-Hierarchie

Stufe	Evidenz-Typ
Ia	wenigstens ein systematischer Review auf der Basis methodisch hochwertiger kontrollierter, randomisierter Studien (RCTs)
Ib	wenigstens ein ausreichend großer, methodisch hochwertiger RCT
IIa	wenigstens eine hochwertige Studie ohne Randomisierung
IIb	wenigstens eine hochwertige Studie eines anderen Typs quasi-experimenteller Studien
III	mehr als eine methodisch hochwertige nichtexperimentelle Studie
IV	Meinungen und Überzeugungen von angesehenen Autoritäten (aus klinischer Erfahrung); Expertenkommissionen; beschreibende Studien

Insgesamt fanden sich somit **62** als thematisch relevant zu bezeichnende Einträge, welche also tatsächlich die Wirksamkeit und Effizienz osteopathischer Behandlungsformen thematisieren. Hiervon konnten **16** der Evidenzklasse Ia zugeordnet werden. Zudem erfüllen weitere **16** Artikel die Kriterien der Evidenzklasse Ib. Die restlichen **30** Einträge zählen entweder zu den Kategorien II-IV oder können aufgrund unzureichender Informationen nicht eindeutig klassifiziert werden. Es muss allerdings betont werden, dass eine ernsthafte Bewertung nur nach umfassender Lektüre der einzelnen Artikel vorgenommen werden sollte, was im vorliegenden Fall aufgrund begrenzter Zugriffsmöglichkeiten und v. a. wegen des großen zeitlichen und personellen Aufwandes nicht realisierbar war. Darüber hinaus wird in jüngerer Vergangenheit mehr und mehr auf das neue „GRADE-System“ der GRADE Working Group verwiesen (Internet-Referenz IV), welches eine Verbesserung und Vereinheitlichung bisheriger Klassifikationssysteme anstrebt.

Wie eingangs festgehalten, stellt die Tatsache, dass manualmedizinische und osteopathische Konzepte mal synonym gebraucht werden und mal eines dem anderen untergeordnet wird bzw. umgekehrt, die momentan größte Schwierigkeit für die Beantwortung der Frage nach der Wirksamkeit und Effizienz osteopathischer Medizin dar.

Die Problematik äußert sich bereits darin, dass mit dem MeSH-Term „*Osteopathic Medicine*“ in der *Cochrane Library* gefundene Einträge teilweise von „manual therapy“, „osteopathic manipulative treatment“, „manipulative technique“, „manipulative treatment“, „chiropractic“, „manipulation“, „spinal manipulation“ und weiteren Bezeichnungen handeln, so dass – zumindest augenscheinlich – keine einheitliche Definition zugrunde liegt.

Darüber hinaus setzt eine Bewertung vorhandener Literatur im Allgemeinen eine äußerst umfangreiche Literaturrecherche – auch in anderen Datenbanken als den hier aufgeführten – sowie eine zusätzliche Handsuche voraus. Die Sichtung und Bewertung sollte von unabhängigen Reviewern vorgenommen werden. Zudem verlangen Aussagen über die Wirksamkeit bestimmter Therapien durchaus statistische, also Metaanalysen. In der Regel wird eine solch anspruchsvolle Arbeit von mindestens zwei Vollzeitkräften in einem Zeitraum von zwei bis drei Jahren absolviert. Es wird empfohlen, ein systematisches Review erstellen zu lassen und dabei eine Zusammenarbeit mit dem Cochrane Zentrum anzustreben.

## Literatur

- Internet-Referenz I: <http://www.dgom.info/>
- Internet-Referenzen II und III: [http://www.cochrane.de/de/comment\\_gradesys.htm](http://www.cochrane.de/de/comment_gradesys.htm)
- Internet-Referenz IV: <http://www.gradeworkinggroup.org/>
- Buchmann, J. (2002). Manuelle Medizin und Osteopathie in Deutschland oder Was ist Neues an der Osteopathie?. *Man Med* 40; 235-237
- Dvorak, J. et al. (2001). Manuelle Medizin, Chiropraktik, Osteopathie. *Man Med Osteopath Med* 39; 66-71
- Osteopathie als Bestandteil und Erweiterung der Manuellen Medizin – Position zur Osteopathie. *Man Med* 45; 345-346

## Liste relevanter Literatur

### Cochrane Reviews

1. Rongen, F. M. and A. P. Verhagen (2000). "Whiplash: een systematische review naarde effectiviteit van manuele therapie bij patienten na een whiplashtrauma (Whiplash: a systematic review of the efficacy of manual therapy in patients with whiplash) (Structured abstract)." *Nederlands Tijdschrift voor Fysiotherapie* 110(2): 41-47.
2. Schwerla, F., K. Hass Degg, et al. (1999). "Evaluierung und kritische Bewertung von in der europaischen Literatur roffentlichten, osteopathischen Studien im klinischen Bereich und im Bereich der Grundlagenforschung [Evaluation and critical review of clinical and fundamental research studies on osteopathy published in the European literature] (Provisional record)." *Forschende Komplementarmedizin* 6(6): 302-310.

### Clinical Trials

3. Boesler, D., M. Warner, et al. (1993). "Efficacy of high-velocity low-amplitude manipulative technique in subjects with low-back pain during menstrual cramping." *The Journal of the American Osteopathic Association* 93(2): 203-8, 213-4.

Previous studies have shown that dysmenorrhea produces low-back pain and an electromyographic (EMG) pattern typical of trauma-induced low-back pain. To determine the effects of high-velocity low-amplitude osteopathic manipulative treatment (OMT) on this type of low-back pain, 12 dysmenorrheic subjects were assigned to a group receiving OMT or to a group not receiving OMT (or both). Eight subjects participated in both groups, the other four being equally distributed between groups. Osteopathic manipulative treatment significantly decreased EMG activity during extension of the lumbar spinae erector muscles and abolished the spontaneous EMG activity. These EMG changes coincided with the patient's report of alleviated low-back pain and menstrual cramping. Osteopathic manipulative treatment did not change the creatinine kinase, lactate dehydrogenase or lactate-dehydrogenase isoenzyme activity, or myoglobin concentration.

**4. Mills, M. V., C. E. Henley, et al. (2003). "The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media." *Archives of pediatrics & adolescent medicine* 157(9): 861-6.**

OBJECTIVE: To study effects of osteopathic manipulative treatment as an adjuvant therapy to routine pediatric care in children with recurrent acute otitis media (AOM).

STUDY DESIGN: Patients 6 months to 6 years old with 3 episodes of AOM in the previous 6 months, or 4 in the previous year, who were not already surgical candidates were placed randomly into 2 groups: one receiving routine pediatric care, the other receiving routine care plus osteopathic manipulative treatment. Both groups received an equal number of study encounters to monitor behavior and obtain tympanograms. Clinical status was monitored with review of pediatric records. The pediatrician was blinded to patient group and study outcomes, and the osteopathic physician was blinded to patient clinical course.

MAIN OUTCOME MEASURES: We monitored frequency of episodes of AOM, antibiotic use, surgical interventions, various behaviors, and tympanometric and audiometric performance.

RESULTS: A total of 57 patients, 25 intervention patients and 32 control patients, met criteria and completed the study. Adjusting for the baseline frequency before study entry, intervention patients had fewer episodes of AOM (mean group difference per month, -0.14 [95% confidence interval, -0.27 to 0.00];  $P = .04$ ), fewer surgical procedures (intervention patients, 1; control patients, 8;  $P = .03$ ), and more mean surgery-free months (intervention patients, 6.00; control patients, 5.25;  $P = .01$ ). Baseline and final tympanograms obtained by the audiologist showed an increased frequency of more normal tympanogram types in the intervention group, with an adjusted mean group difference of 0.55 (95% confidence interval, 0.08 to 1.02;  $P = .02$ ). No adverse reactions were reported.

CONCLUSIONS: The results of this study suggest a potential benefit of osteopathic manipulative treatment as adjuvant therapy in children with recurrent AOM; it may prevent or decrease surgical intervention or antibiotic overuse.

**5. Noll, D. R., J. H. Shores, et al. (2000). "Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia." *The Journal of the American Osteopathic Association* 100(12): 776-82.**

While osteopathic manipulative treatment (OMT) is thought to be beneficial for patients with pneumonia, there have been few clinical trials--especially in the elderly. The authors' pilot study suggested that duration of intravenous antibiotic use and length of hospital stay were promising measures of outcome. Therefore, a larger randomized controlled study was conducted. Elderly patients hospitalized with acute pneumonia were recruited and randomly placed into two groups: 28 in the treatment group and 30 in the control group. The treatment group received a standardized OMT protocol, while the control group received a light touch protocol. There was no statistical difference between groups for age, sex, or simplified acute physiology scores. The treatment group had a significantly shorter duration of intravenous antibiotic treatment and a shorter hospital stay.

**6. Sucher, B. M. (1994). "Palpatory diagnosis and manipulative management of carpal tunnel syndrome." *The Journal of the American Osteopathic Association* 94(8): 647-63.**

Carpal tunnel syndrome was studied by use of supplemental palpatory diagnosis in 20 abnormal wrists. Restriction in motion at the carpal tunnel was quantified with a rating system. All wrists with carpal tunnel syndrome revealed at least moderate restriction to motion, as compared with only mild or no restriction in 20 wrists in normal, symptom-free subjects. Several participants (16 abnormal wrists) underwent osteopathic manipulative treatment, including a new "opponens roll" maneuver, and self-stretching, or a similar treatment accomplished by use of a self-treatment appliance. In those treated, palpatory restriction decreased into the normal range, often before symptoms decreased. Improvement in nerve conduction studies usually followed within 1 to 3 months. Palpatory diagnosis is a useful adjunctive method of assessing patient status in carpal tunnel syndrome and helpful in prognosticating outcome. The modified manipulative technique described for the treatment of mild to moderate carpal tunnel syndrome may be effective in more severe cases.

**7. Williams, N. H., R. T. Edwards, et al. (2004). "Cost-utility analysis of osteopathy in primary care: results from a pragmatic randomized controlled trial." *Family practice* 21(6): 643-50.**

**BACKGROUND:** Spinal pain is common and costly to health services and society. Management guidelines have encouraged primary care referral for spinal manipulation, but the evidence base is weak. More economic evaluations alongside pragmatic trials have been recommended.

**OBJECTIVE:** Our aim was to assess the cost-utility of a practice-based osteopathy clinic for subacute spinal pain.

**METHODS:** A cost-utility analysis was performed alongside a pragmatic single-centre randomized controlled trial in a primary care osteopathy clinic accepting referrals from 14 neighbouring practices in North West Wales. Patients with back pain of 2-12 weeks duration were randomly allocated to treatment with osteopathy plus usual GP care or usual GP care alone. Costs were measured from a National Health Service (NHS) perspective. All primary and secondary health care interventions recorded in GP notes were collected for the study period. We calculated quality adjusted life year (QALY) gains based on EQ-5D responses from patients in the trial, and then cost per QALY ratios. Confidence intervals (CIs) were estimated using non-parametric bootstrapping.

**RESULTS:** Osteopathy plus usual GP care was more effective but resulted in more health care costs than usual GP care alone. The point estimate of the incremental cost per QALY ratio was 3560 pounds (80% CI 542 pounds-77,100 pounds). Sensitivity analysis examining spine-related costs alone and total costs excluding outliers resulted in lower cost per QALY ratios.

**CONCLUSION:** A primary care osteopathy clinic may be a cost-effective addition to usual GP care, but this conclusion was subject to considerable random error. Rigorous multi-centre studies are needed to assess the generalizability of this approach.

## Economic Evaluations

8. Haas, M., R. Sharma, et al. (2005). "Cost-effectiveness of medical and chiropractic care for acute and chronic low back pain (Structured abstract)." *Journal of Manipulative and Physiological Therapeutics* 28(8): 555-563.
9. Maniadakis, N. and A. Gray (2000). "The economic burden of back pain in the UK (Provisional record)." *Pain* 84(1): 95-103.
10. Pincus, T. and S. Newman (2001). "Recall bias, pain, depression and cost in back pain patients (Provisional record)." *British Journal of Clinical Psychology* 40(2): 143-156.

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## PubMed

11. Yong-Hing, K. (1994). "Sacro-iliac joint pain: etiology and conservative treatment." *Chir Organi Mov* 79(1): 35-45.

Orthopedic surgeons use many modalities in conservative treatment of low back pain (LBP) and sacroiliac pain (SIP) but few have been studied with randomized controlled trials. We have been studying the physiological effects of manipulation on joints and the clinical effect on patients. Manipulation is different from other forms of manual therapy. Quantitative sacroiliac scintigraphy and three clinical tests in patients with unilateral pain and tenderness over the SI joint suggest sacroiliac joint syndrome is a clinical entity. The iliac and sacral surfaces of the sacroiliac joint develop differently. Although this statement need further study it seems that manipulations may play a role in the treatment of LBP and SIP.

12. Assendelft, W. J., B. W. Koes, et al. (1992). "The efficacy of chiropractic manipulation for back pain: blinded review of relevant randomized clinical trials." *J Manipulative Physiol Ther* 15(8): 487-94.

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 determined 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.

**13. Berkson, D. L. (1991). "Osteoarthritis, chiropractic, and nutrition: osteoarthritis considered as a natural part of a three stage subluxation complex: its reversibility: its relevance and treatability by chiropractic and nutritional correlates." Med Hypotheses 36(4): 356-67.**

It is proposed that chiropractic and nutritional treatment contribute to the amelioration and perhaps reversal of osteoarthritis (OA). It is further proposed that the chiropractic manipulative thrust, is in effect, treating dysfunctional bio-mechanics of joints, affecting positive cartilaginous change. The pathophysiology and multifactorial causes of OA are reviewed. New interpretations of the literature surrounding OA are discussed which offer arguments for OA's treatment and reversal through chiropractic manipulation and nutritional support. Presented is a new model of the chiropractic concept of subluxation (abnormal joint complex resulting in fixation or decrease in normal range of motion) and the chiropractic manipulative thrust. The associated histologic correlates are also discussed. A review of the literature of anti-inflammatory and muscle/joint complex supportive nutrients appropriate for OA is presented. Finally, a complete treatment protocol for OA is summarized.

**14. Bronfort, G., W. J. Assendelft, et al. (2001). "Efficacy of spinal manipulation for chronic headache: a systematic review." J Manipulative Physiol Ther 24(7): 457-66.**

**BACKGROUND:** Chronic headache is a prevalent condition with substantial socioeconomic impact. Complementary or alternative therapies are increasingly being used by patients to treat headache pain, and spinal manipulative therapy (SMT) is among the most common of these.

**OBJECTIVE:** To assess the efficacy/effectiveness of SMT for chronic headache through a systematic review of randomized clinical trials.

**STUDY SELECTION:** Randomized clinical trials on chronic headache (tension, migraine and cervicogenic) were included in the review if they compared SMT with other interventions or placebo. The trials had to have at least 1 patient-rated outcome measure such as pain severity, frequency, duration, improvement, use of analgesics, disability, or quality of life. Studies were identified through a comprehensive search of MEDLINE (1966-1998) and EMBASE (1974-1998). Additionally, all available data from the Cumulative Index of Nursing and Allied Health Literature, the Chiropractic Research Archives Collection, and the Manual, Alternative, and Natural

Therapies Information System were used, as well as material gathered through the citation tracking, and hand searching of non-indexed chiropractic, osteopathic, and manual medicine journals.

DATA EXTRACTION: Information about outcome measures, interventions and effect sizes was used to evaluate treatment efficacy. Levels of evidence were determined by a classification system incorporating study validity and statistical significance of study results. Two authors independently extracted data and performed methodological scoring of selected trials.

DATA SYNTHESIS: Nine trials involving 683 patients with chronic headache were included. The methodological quality (validity) scores ranged from 21 to 87 (100-point scale). The trials were too heterogeneous in terms of patient clinical characteristic, control groups, and outcome measures to warrant statistical pooling. Based on predefined criteria, there is moderate evidence that SMT has short-term efficacy similar to amitriptyline in the prophylactic treatment of chronic tension-type headache and migraine. SMT does not appear to improve outcomes when added to soft-tissue massage for episodic tension-type headache. There is moderate evidence that SMT is more efficacious than massage for cervicogenic headache. Sensitivity analyses showed that the results and the overall study conclusions remained the same even when substantial changes in the prespecified assumptions/rules regarding the evidence determination were applied.

CONCLUSIONS: SMT appears to have a better effect than massage for cervicogenic headache. It also appears that SMT has an effect comparable to commonly used first-line prophylactic prescription medications for tension-type headache and migraine headache. This conclusion rests upon a few trials of adequate methodological quality. Before any firm conclusions can be drawn, further testing should be done in rigorously designed, executed, and analyzed trials with follow-up periods of sufficient length.

**15. Cassidy, J. D., A. A. Lopes, et al. (1992). "The immediate effect of manipulation versus mobilization on pain and range of motion in the cervical spine: a randomized controlled trial." J Manipulative Physiol Ther 15(9): 570-5.**

OBJECTIVE: The main objective of this study is to compare the immediate results of manipulation to mobilization in neck pain patients.

DESIGN: The patients were compared in a randomized controlled trial without long-term follow-up.

SETTING: The study was conducted at an outpatient teaching clinic on primary and referred patients.

PATIENTS: One hundred consecutive outpatients suffering from unilateral neck pain with referral into the trapezius muscle were studied. Fifty-two subjects were manipulated and 48 subjects were mobilized. The mean (SD) age was 34.5 (13.0) yr for the manipulated group and 37.7 (12.5) yr for the mobilized group. Sixteen subjects had neck pain for less than 1 wk, 34 subjects had pain for between 1 wk and 6 mo and 50 subjects had pain for more than 6 mo. Seventy-eight subjects had a past history of neck pain. Thirty-one subjects had been involved in an injurious motor vehicle accident and 28 subjects had other types of minor trauma to the neck. There were no significant differences between the two treatment groups with respect to history of neck pain or level of disability as measured by the Pain Disability Index.

INTERVENTION: The patients received either a single rotational manipulation (high-velocity, low-amplitude thrust) or mobilization in the form of muscle energy technique.

MAIN OUTCOME MEASURES: Prior to and immediately after the treatments, cervical spine range of motion was recorded in three planes, and pain intensity was rated on the 101-point numerical rating scale (NRS-101). Both pre- and post-test measurements were conducted in a blinded fashion.

RESULTS: The results show that both treatments increase range of motion, but manipulation has a significantly greater effect on pain intensity. Eighty-five percent of the manipulated patients and 69% of the mobilized patients

reported pain improvement immediately after treatment. However, the decrease in pain intensity was more than 1.5 times greater in the manipulated group ( $p = .05$ ).

CONCLUSION: This study demonstrates that a single manipulation is more effective than mobilization in decreasing pain in patients with mechanical neck pain. Both treatments increase range of motion in the neck to a similar degree. Further studies are required to determine any long-term benefits of manipulation for mechanical neck pain.

**16. Curtis, P. (1988). "Spinal manipulation: does it work?" *Occup Med* 3(1): 31-44.**

This article reviews the value of spinal manipulation in treating low back pain. Although there is still little evidence by which to judge this form of treatment, there is speculation that manipulation exerts a powerful placebo effect in producing a specific but short-term benefit.

**17. Duncan, B., L. Barton, et al. (2004). "Parental perceptions of the therapeutic effect from osteopathic manipulation or acupuncture in children with spastic cerebral palsy." *Clin Pediatr (Phila)* 43(4): 349-53.**

Fifty children were involved in a randomized, controlled trial to evaluate the effectiveness of either osteopathic manipulation or acupuncture as a 6-month therapeutic adjunct for children with spastic cerebral palsy. Exit interviews were used to obtain parental perceptions and form the basis of this report. Only 2 of 17 parents reported positive gains while their child was in a wait-list control period but all 17 reported gains while in the treatment phase of the study. Ninety-six percent (48 of 50) of the parents reported some improvement while their child was receiving treatments but the gains varied from child to child. The most frequent gains were seen in improvement in the use of arms or legs (61% and 68%) and more restful sleep (39% and 68%) in the osteopathic and the acupuncture groups, respectively. Improvement in mood and improved bowel function were also very common benefits noted by the parents in both groups.

**18. Eisenhart, A. W., T. J. Gaeta, et al. (2003). "Osteopathic manipulative treatment in the emergency department for patients with acute ankle injuries." *J Am Osteopath Assoc* 103(9): 417-21.**

STUDY OBJECTIVE: The purpose of this study was to evaluate the efficacy of osteopathic manipulative treatment (OMT) as administered in the emergency department (ED) for the treatment of patients with acute ankle injuries.

METHODS: Patients aged 18 years and older with unilateral ankle sprains were randomly assigned either to an OMT study group or a control group. Independent outcome variables included edema, range of motion (ROM), and pain. Both groups received the current standard of care for ankle sprains and were instructed to return for a follow-up examination. Patients in the OMT study group also received one session of OMT from an osteopathic physician.

RESULTS: Patients in the OMT study group had a statistically significant ( $F = 5.92$ ,  $P = .02$ ) improvement in edema and pain and a trend toward increased ROM immediately following intervention with OMT. Although at follow-up both study groups demonstrated significant improvement, patients in the OMT study group had a statistically significant improvement in ROM when compared with patients in the control group.

CONCLUSIONS: Data clearly demonstrate that a single session of OMT in the ED can have a significant effect in the management of acute ankle injuries.

**19. Figar, S. and L. Krausova (1964). "[Plethysmographic Study of the Effect of Manipulation Therapy in Vertebrogenic Syndromes]." Cesk Neurol 27: 246-50.**

**20. Frymann, V. M., R. E. Carney, et al. (1992). "Effect of osteopathic medical management on neurologic development in children." J Am Osteopath Assoc 92(6): 729-44.**

For 3 years, children between 18 months and 12 years of age with and without recognized neurologic deficits were studied at the Osteopathic Center for Children. Their response to 6 to 12 osteopathic manipulative treatments directed to all areas of impaired inherent physiologic motion was estimated from changes in three sensory and three motor areas of performance. Houle's Profile of Development was used to compare neurologic with chronologic age and rate of development, and scores were age-adjusted. Results in children after treatment were compared with those following a waiting period without treatment. Neurologic performance significantly improved after treatment in children with diagnosed neurologic problems and to a lesser degree in children with medical or structural diagnoses. The advances in neurologic development continued over a several months' interval. The results support the use of osteopathic manipulative treatment as part of pediatric healthcare based on osteopathic medical philosophy and principles.

**21. Greenspan, J. and J. Melchior (1966). "The effect of osteopathic manipulative treatment on the resistance of rats to stressful situations." J Am Osteopath Assoc 65(11): 1205-9.**

**22. Gross, A. R., P. D. Aker, et al. (1996). "Conservative management of mechanical neck disorders. A systematic overview and meta-analysis." Online J Curr Clin Trials Doc No 200-201: [34457 words; 185 paragraphs].**

OBJECTIVE: This overview reports the efficacy of conservative treatments (drug therapy, manual therapy, patient education, physical medicine modalities) in reducing pain in adults with mechanical neck disorders.

METHODS: Computerized bibliographic database searches from 1985 to December 1993, information requests from authors, and bibliography screenings were used to identify published and unpublished research. Applying strict criteria, two investigators independently reviewed the blinded articles. Each selected trial was evaluated independently for methodologic quality.

RESULTS: Twenty-four randomized controlled trials (RCTs) and eight before-after studies met our selection criteria. Twenty RCTs rated moderately strong or better in terms of methodologic quality. Five trials using manual therapy in combination with other treatments were clinically similar, were statistically not heterogeneous ( $p = 0.98$ ), and were combined to yield an effect size of  $-0.6$  (95% CI:  $-0.9, -0.4$ ), equivalent to a 16 point improvement on a 100 point pain scale. Four RCTs using physical medicine modalities were combined using the inverse chi-square method: two using electromagnetic therapy produced a significant reduction in pain ( $p < 0.01$ ); and two using laser therapy did not differ significantly from a placebo ( $p = 0.63$ ). Little or no scientific evidence exists for other therapies, including such commonly used treatments as medication, rest and exercise.

CONCLUSIONS: Within the limits of methodologic quality, the best available evidence supports the use of manual therapies in combination with other treatments for short-term relief of neck pain. There is some support for the use of electromagnetic therapy and against the use of laser therapy. In general, other interventions have not been studied in enough detail adequately to assess efficacy or effectiveness. This overview provides the foundation for an evidence-based approach to practice. More robust design and methodology should be used in future research, in particular, the use of valid and reliable outcomes measures.

**23. Guiney, P. A., R. Chou, et al. (2005). "Effects of osteopathic manipulative treatment on pediatric patients with asthma: a randomized controlled trial." J Am Osteopath Assoc 105(1): 7-12.**

Asthma is a common chronic condition that has long plagued the pediatric patient population. Asthma in children can cause excessive school absenteeism, hospitalizations, and even death. Osteopathic manipulative treatment (OMT) is an underutilized noninvasive treatment method for patients with asthma. The use of OMT may help decrease mortality and morbidity rates among this patient group. The authors conducted a randomized controlled trial attempting to demonstrate the therapeutic relevance of OMT in the pediatric asthma population. With a confidence level of 95%, results for the OMT group showed a statistically significant improvement of 7 L per minute to 9 L per minute for peak expiratory flow rates. These results suggest that OMT has a therapeutic effect among this patient population. The authors suggest that more clinical trials are required to better demonstrate the effectiveness of OMT in patients with asthma.

**24. Haldeman, S., P. Carey, et al. (2002). "Clinical perceptions of the risk of vertebral artery dissection after cervical manipulation: the effect of referral bias." Spine J 2(5): 334-42.**

BACKGROUND CONTEXT: The growing recognition of cervical manipulation as a treatment of neck pain and cervicogenic headaches has led to increased interest in potential complications that may result from this treatment approach. Recent surveys have reported that many neurologists will encounter cases of vertebral artery dissection that occur at various times after cervical manipulation, whereas most practitioners of spinal manipulation are of the opinion that these events are extremely rare. We asked the question whether these differences in perception could be explained in part by referral or selection bias.

PURPOSE: To assess the effect of referral bias on the differences in perceived incidence of vertebral artery dissection after cervical manipulation between neurologists and chiropractors in Canada.

STUDY DESIGN: This study was a retrospective review of cases where neurological symptoms consistent with cerebrovascular ischemia were reported by chiropractors in Canada.

METHODS: An analysis of data from a chiropractic malpractice insurance carrier (Canadian Chiropractic Protective Association [CCPA]) and results of a survey of chiropractors was performed to determine the likelihood that a vertebral artery dissection after cervical manipulation would be reported to practicing chiropractors. This was compared with the likelihood that a neurologist would be made aware of such a complication.

RESULTS: For the 10-year period 1988 to 1997, there were 23 cases of vertebral artery dissection after cervical manipulation reported to the CCPA that represents 85% of practicing chiropractors in Canada. Based on the survey, an estimated 134,466,765 cervical manipulations were performed during this 10-year period. This gave a calculated rate of vertebral artery dissection after manipulation of 1:5,846,381 cervical manipulations. Based on

the number of practicing chiropractors and neurologists during the period of this study, 1 of every 48 chiropractors and one of every two neurologists would have been made aware of a vascular complication from cervical manipulation that was reported to the CCPA during their practice lifetime.

CONCLUSIONS: The perceived risk after cervical manipulation by chiropractors and neurologists is related to the probability that a practitioner will be made aware of such an incident. The difference in the number of chiropractors (approximately 3,840 in 1997) and neurologists (approximately 4,000 in 1997) in active practice and the fact that each patient who has a stroke after manipulation will likely be seen by only one chiropractor but by three or more neurologists partly explains the difference in experience and the perception of risk of these two professions. This selection or referral bias is important in shaping the clinical opinions of the various disciplines and distorts discussion on the true incidence of these complications of cervical manipulation. The nature of this study, however, describes the likelihood that a clinician will be made aware of such an event and cannot be interpreted as describing the actual risk of stroke after manipulation.

**25. Hawk, C., R. Khorsan, et al. (2007). "Chiropractic care for nonmusculoskeletal conditions: a systematic review with implications for whole systems research." J Altern Complement Med 13(5): 491-512.**

OBJECTIVES: (1) To evaluate the evidence on the effect of chiropractic care, rather than spinal manipulation only, on patients with nonmusculoskeletal conditions; and (2) to identify shortcomings in the evidence base on this topic, from a Whole Systems Research perspective.

DESIGN: Systematic review.

METHODS: Databases included were PubMed, Ovid, Mantis, Index to Chiropractic Literature, and CINAHL. Search restrictions were human subjects, peer-reviewed journal, English language, and publication before May 2005. All randomized controlled trials (RCTs) were evaluated using the Scottish Intercollegiate Guidelines Network (SIGN) and Jadad checklists; a checklist developed from the CONSORT (Consolidated Standards of Reporting Trials) guidelines; and one developed by the authors to evaluate studies in terms of Whole Systems Research (WSR) considerations.

RESULTS: The search yielded 179 papers addressing 50 different nonmusculoskeletal conditions. There were 122 case reports or case series, 47 experimental designs, including 14 RCTs, 9 systematic reviews, and 1 a large cohort study. The 14 RCTs addressed 10 conditions. Six RCTs were rated "high" on the 3 conventional checklists; one of these 6 was rated "high" in terms of WSR considerations.

CONCLUSIONS: (1) Adverse effects should be routinely reported. For the few studies that did report, adverse effects of spinal manipulation for all ages and conditions were rare, transient, and not severe. (2) Evidence from controlled studies and usual practice supports chiropractic care (the entire clinical encounter) as providing benefit to patients with asthma, cervicogenic vertigo, and infantile colic. Evidence was promising for potential benefit of manual procedures for children with otitis media and elderly patients with pneumonia. (3) The RCT design is not necessarily incompatible with WSR. RCTs could improve generalizability by basing protocols on usual practice. (4) Case reports could contribute more to WSR by increasing their emphasis on patient characteristics and patient-based outcomes. (5) Chiropractic investigators, practitioners, and funding agencies should increase their attention to observational designs.

**26. Hawk, C., R. L. Rupert, et al. (2006). "Comparison of bioenergetic synchronization technique and customary chiropractic care for older adults with chronic musculoskeletal pain." J Manipulative Physiol Ther 29(7): 540-9.**

**OBJECTIVE:** The aim of the study was to compare the clinical outcomes of 2 approaches to chiropractic care for patients with chronic musculoskeletal pain. Included were the approach most commonly used by doctors of chiropractic (diversified technique spinal manipulation) and a nonmanipulative mind-body approach (Bioenergetic Synchronization Technique). This clinical experiment tested the null hypothesis that there is no clinically or statistically significant difference in effect between the 2 approaches.

**METHODS:** The study was conducted in the research clinic of the Parker College of Chiropractic. Patients were initially recruited by contacting a previously developed pool used for studies related to fall prevention in the elderly. Eighty-one patients (74 females; median age, 66 years) were enrolled and 78 (96%) completed the study. The primary end point was the end of a 3-week nontreatment interval after a 4-week treatment period. An intention-to-treat analysis was used; all patients who completed assessments were included whether or not they were compliant with the treatment protocol. A sample size of 55 per group was estimated to be necessary to detect a clinically significant (6-point) between-group difference in the Pain Disability Index (PDI). The primary outcome, the mean between-group difference between PDI scores at visit 1 and the exit visit, was tested with a 2-tailed t test for independent samples.

**RESULTS:** Mean improvements in the PDI from visit 1 to the exit visit were 6.9 points in the Bioenergetic Synchronization Technique group (n = 40) and 6.4 in the diversified technique group (n = 38); the between-groups difference was not statistically or clinically significant (95% confidence interval, -4.7 to 5.8).

**CONCLUSIONS:** For this particular group of patients, both groups demonstrated similar improvement scores on the PDI; the study's null hypothesis was not rejected.

**27. Hebert, J. and J. P. Boucher (1998). "Effect of manual segmental vibration on neuromuscular excitability." J Manipulative Physiol Ther 21(8): 528-33.**

**OBJECTIVE:** To measure the effects of manual segmental vibration (MSV) on motoneuron pool excitability.

**METHODS:** Seven healthy subjects were tested under five conditions: pretest, upholding static knee position (USKP), MSV, posttest 1 and posttest 2. Each test lasted 2 min, and a 2-min rest was given between pretest, USKP and MSV, whereas the last two tests were consecutive. Cutaneous pressure and vibration frequency were stabilized through training periods. The effects of MSV on motoneuron excitability were investigated by measuring the H-reflex peak-to-peak amplitude.

**MEASURES:** The H-reflex and M response were taken from the medial gastrocnemius electromyogram and elicited every 7 sec by a 1 ms square wave pulses to the tibial nerve. Fifteen trials were recorded for each condition. Stimulation intensity was set at 10% (+/- 2.5%) of Mmax stimulus.

**RESULTS:** Repeated-measures analysis of variance comparing conditions revealed no significant differences in M response [ $F(4,24) = 2.37, p > .05, \beta = .35$ ]. H-reflex comparisons revealed significant differences [ $F(4,24) = 30.39, p < .05, \beta = .01$ ] between conditions. Duncan post hoc analysis showed that MSV produced the greatest inhibition (decreases 95%) and USKP also elicited a significant inhibition (decreases 41%).

**CONCLUSIONS:** The inhibition may be the result of the following mechanisms: the reflex inhibition, the implication of cutaneous afferences and the higher control mechanism. Because MSV produces a reduction in neuromuscular excitability, it could also play a role in predisposing the system for changes to occur and therefore be used as an adjunct for other therapeutic applications.

**28. Hirayama, F., Y. Kageyama, et al. (2003). "The effect of postoperative ataralgesia by manual therapy after pulmonary resection." *Man Ther* 8(1): 42-5.**

Muscle therapy, a form of manual therapy, was applied to control pain persisting for more than 1 week following posterolateral thoracotomy, and its efficacy for the alleviation of pain was investigated. Eight patients who underwent posterolateral thoracotomy and lung resection for cancer (n=7) or emphysema (n=1) received manual therapy to incised muscles and the muscles inserting into the ribs in the affected area for an average of 17 days postoperatively. Pressure-friction and stretching techniques were used. Treatment was continued until the intensity of the pressure-friction technique reached a level at which the patient complained of pain and a decrease in muscle tone was detected. Treatment was performed once a week for 3 weeks. Pain severity was measured using a visual analog scale (VAS) (0-10). Before the first treatment, the VAS was set at 10, and changes of the score were observed before and after the treatment as well as over time. After three sessions, all patients showed a decrease in pain from 10 to an average of 1.9 (range 1.3-2.6).

**29. Jordan, A., T. Bendix, et al. (1998). "Intensive training, physiotherapy, or manipulation for patients with chronic neck pain. A prospective, single-blinded, randomized clinical trial." *Spine* 23(3): 311-8; discussion 319.**

STUDY DESIGN: A randomized, prospective clinical study was conducted that included 119 patients with chronic neck pain of greater than 3 months' duration.

OBJECTIVES: To compare the relative effectiveness of intensive training of the cervical musculature, a physiotherapy treatment regimen, and chiropractic treatment on this patient group.

SUMMARY OF BACKGROUND DATA: There are only a few studies involving chronic neck pain patients representative of those seeking care in primary health care centers. Mobilization techniques and intensive training have been shown to be useful, but cervical manipulation has not been assessed. Clinical results involving these commonly used therapies have not been compared.

METHODS: A total of 167 consecutive patients were screened. One hundred nineteen patients were admitted to the study and were randomized according to Taves' minimization principles. Primary outcome measures included self-reported pain, disability, medication use, patients' perceived effect, and physician's global assessment. Patients were assessed at enrollment and at completion of the study. Postal questionnaires were used to carry out 4- and 12-month follow-up assessments. Secondary outcome measures included active range of motion of the cervical spine as well as strength and endurance measurements of the cervical musculature. These measurements were carried out at enrollment and completion of the study.

RESULTS: A total of 88% of the patients completed the study. Of these, 97% completed the 4-month questionnaire and 93% the 12-month questionnaire. Patients from all three groups demonstrated significant improvements regarding self-reported pain and disability on completion of the study. Improvements were maintained throughout the follow-up period. Medication use was also significantly reduced in all groups. There was, however, no significant difference between groups at any assessment period. Physician's and patients' assessments were also positive, and again group scores were essentially equal. Patients who underwent intensive training demonstrated significantly greater endurance levels at the completion of treatment.

CONCLUSIONS: There was no clinical difference between the three treatments. All three treatment interventions demonstrated meaningful improvement in all primary effect parameters. Improvements were maintained at 4- and 12-month follow-up. However, whether this was a result of the treatments or simply a result of time is unknown. Future studies will be necessary to delineate ideal treatment strategies.

**30. Keller, T. S. and C. J. Colloca (2000). "Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: a comparative clinical trial." J Manipulative Physiol Ther 23(9): 585-95.**

**OBJECTIVE:** The objective of this study was to determine whether mechanical force, manually-assisted (MFMA) spinal manipulative therapy (SMT) affects paraspinal muscle strength as assessed through use of surface electromyography (sEMG).

**DESIGN:** Prospective clinical trial comparing sEMG output in 1 active treatment group and 2 control groups.

**SETTING:** Outpatient chiropractic clinic, Phoenix, AZ. **SUBJECTS:** Forty subjects with low back pain (LBP) participated in the study. Twenty patients with LBP (9 females and 11 males with a mean age of 35 years and 51 years, respectively) and 20 age- and sex-matched sham-SMT/control LBP subjects (10 females and 10 males with a mean age of 40 years and 52 years, respectively) were assessed.

**METHODS:** Twenty consecutive patients with LBP (SMT treatment group) performed maximum voluntary contraction (MVC) isometric trunk extensions while lying prone on a treatment table. Surface, linear-enveloped sEMG was recorded from the erector spinae musculature at L3 and L5 during a trunk extension procedure. Patients were then assessed through use of the Activator Methods Chiropractic Technique protocol, during which time they were treated through use of MFMA SMT. The MFMA SMT treatment was followed by a dynamic stiffness and algometry assessment, after which a second or post-MVC isometric trunk extension and sEMG assessment were performed. Another 20 consecutive subjects with LBP were assigned to one of two other groups, a sham-SMT group and a control group. The sham-SMT group underwent the same experimental protocol with the exception that the subjects received a sham-MFMA SMT and dynamic stiffness assessment. The control group subjects received no SMT treatment, stiffness assessment, or algometry assessment intervention. Within-group analysis of MVC sEMG output (pre-SMT vs post-SMT sEMG output) and across-group analysis of MVC sEMG output ratio (post-SMT sEMG/pre-SMT sEMG output) during MVC was performed through use of a paired observations t test (POTT) and a robust analysis of variance (RANOVA), respectively.

**MAIN OUTCOME MEASURES:** Surface, linear-enveloped EMG recordings during isometric MVC trunk extension were used as the primary outcome measure.

**RESULTS:** Nineteen of the 20 patients in the SMT treatment group showed a positive increase in sEMG output during MVC (range, -9.7% to 66.8%) after the active MFMA SMT treatment and stiffness assessment. The SMT treatment group showed a significant (POTT,  $P < 0.001$ ) increase in erector spinae muscle sEMG output (21% increase in comparison with pre-SMT levels) during MVC isometric trunk extension trials. There were no significant changes in pre-SMT vs post-SMT MVC sEMG output for the sham-SMT (5.8% increase) and control (3.9% increase) groups. Moreover, the sEMG output ratio of the SMT treatment group was significantly greater (robust analysis of variance,  $P = 0.05$ ) than either that of the sham-SMT group or that of the control group.

**CONCLUSIONS:** The results of this preliminary clinical trial demonstrated that MFMA SMT results in a significant increase in sEMG erector spinae isometric MVC muscle output. These findings indicate that altered muscle function may be a potential short-term therapeutic effect of MFMA SMT, and they form a basis for a randomized, controlled clinical trial to further investigate acute and long-term changes in low back function.

**31. Koes, B. W., W. J. Assendelft, et al. (1996). "Spinal manipulation for low back pain. An updated systematic review of randomized clinical trials." Spine 21(24): 2860-71; discussion 2872-3.**

STUDY DESIGN: Systematic review of randomized clinical trials.

OBJECTIVES: To assess the efficacy of spinal manipulation for patients with low back pain.

SUMMARY OF BACKGROUND DATA: The management of low back pain remains controversial. Spinal manipulation is a widely used treatment option for low back pain. Recently issued clinical guidelines suggest that spinal manipulation may be effective for patients with acute low back pain.

METHODS: A computer-aided search for published papers was conducted, and the methods of the studies identified were assessed. Scores were assigned for quality of methods (based on four main categories: study population, interventions, measurement of effect, and data presentation and analysis), the conclusion of authors regarding spinal manipulation, and the results based on the main outcome measure.

RESULTS: Thirty-six randomized clinical trials comparing spinal manipulation with other treatments were identified. The highest score of a trial was 60 points (maximum score was set at 100 points), indicating that most were of poor quality. Nineteen studies (53%) showed favorable results for manipulation. In addition, five studies (14%) reported positive results in one or more subgroups only. Among the five studies with 50-60 points, three were positive, and two were positive only for a subgroup of the study population. Eleven trials compared manipulation with some placebo therapy, with inconsistent results. There appeared to be no clear relation between the methodologic score and the overall outcome of the studies. Twelve trials included patients with acute low back pain only. Of these, five reported positive results, four reported negative results, and three reported positive results in a subgroup of the study population only. There were eight trials comparing manipulation with other conservative treatment modalities, focusing on patients with subacute or chronic low back pain. Of these, five reported positive results, two reported negative results, and in one study no conclusion was presented. There were only 16 studies that included an effect measurement of at least 3 months. In only six of these do the authors report positive effects of manipulation.

CONCLUSIONS: The efficacy of spinal manipulation for patients with acute or chronic low back pain has not been demonstrated with sound randomized clinical trials. There certainly are indications that manipulation might be effective in some subgroups of patients with low back pain. These impressions justify additional research efforts on this topic. Methodologic quality remains a critical aspect that should be dealt with in future studies.

**32. Koes, B. W., W. J. Assendelft, et al. (1991). "Spinal manipulation and mobilisation for back and neck pain: a blinded review." Bmj 303(6813): 1298-303.**

OBJECTIVE--To assess the efficacy of spinal manipulation for patients with back or neck pain.

DESIGN--Computer aided search for published papers and blinded assessment of the methods of the studies.

SUBJECTS--35 randomised clinical trials comparing spinal manipulation with other treatments.

MAIN OUTCOME MEASURES--Score for quality of methods (based on four main categories: study population, interventions, measurement of effect, and data presentation and analysis) and main conclusion of author(s) with regard to spinal manipulation.

RESULTS--No trial scored 60 or more points (maximum score 100) suggesting that most were of poor quality. Eighteen studies (51%) showed favourable results for manipulation. In addition, five studies (14%) reported positive results in one or more subgroups. Of the four studies with 50-60 points, one reported that manipulation was better, two reported that manipulation was better in only a subgroup, and one reported that manipulation was

no better or worse than reference treatment. Eight trials attempted to compare manipulation with some placebo, with inconsistent results.

CONCLUSIONS--Although some results are promising, the efficacy of manipulation has not been convincingly shown. Further trials are needed, but much more attention should be paid to the methods of study.

**33. Koes, B. W., L. M. Bouter, et al. (1993). "A randomized clinical trial of manual therapy and physiotherapy for persistent back and neck complaints: subgroup analysis and relationship between outcome measures." J Manipulative Physiol Ther 16(4): 211-9.**

OBJECTIVE: To study the efficacy of manual therapy and physiotherapy in subgroups of patients with persistent back and neck complaints. The second objective was to determine the correlation between three important outcome measures used in this trial.

DESIGN: Randomized clinical trial (subgroup analysis).

SETTING: Primary health care in the Netherlands.

PATIENTS: Two hundred fifty-six patients with nonspecific back and neck complaints of at least 6 wk duration who had not received physiotherapy or manual therapy in the past 2 yr.

INTERVENTIONS: At the discretion of the manual therapists, physiotherapists and general practitioners. Physiotherapy consisted of exercises, massage and physical therapy (heat, electrotherapy, ultrasound, shortwave diathermy). Manual therapy consisted of manipulation and mobilization of the spine. Treatment by the general practitioner consisted of drugs (e.g., analgesics), advice about posture, home exercises and (bed)rest. Placebo treatment consisted of detuned shortwave diathermy (10 min) and detuned ultrasound (10 min).

MAIN OUTCOME MEASURES: Changes in severity of the main complaint and limitation of physical functioning measured on 10-point scales by a blinded research assistant and global perceived effect measured on a 6-point scale by the patients.

RESULTS: Improvement in the main complaint was larger with manual therapy (4.3) than with physiotherapy (2.5) for patients with chronic conditions (duration complaint of 1 yr or longer). Also, improvement in the main complaint was larger with manual therapy (5.5) than with physiotherapy (4.0) for patients younger than 40 yr (both were measured after 12-mo follow-up). Labeling of patients by the treating manual therapists as "suitable" or "not suitable" for treatment with manual therapy did not predict differences in outcomes. Generally, there was a moderate to strong correlation between the three outcome measures, although a considerable number of patients gave a relatively low score for perceived benefit, while the research assistant gave a high improvement score for the main complaint and physical functioning.

CONCLUSIONS: The subgroup analysis suggests better results of manual therapy compared to physiotherapy in chronic patients (duration of present complaints of 1 yr or longer) and in patients younger than 40 yr old. Differences for other subgroups were less clear. The explorative findings of these subgroup analyses have to be investigated in future research.

**34. Lantz, C. A. and J. Chen (2001). "Effect of chiropractic intervention on small scoliotic curves in younger subjects: a time-series cohort design." J Manipulative Physiol Ther 24(6): 385-93.**

BACKGROUND: Chiropractors have long claimed to affect scoliotic curves, and case studies abound reporting on successful outcomes. No clinical trials exist, however, that evaluate chiropractic's effectiveness in the management of scoliotic curves.

OBJECTIVE: To assess the effectiveness of chiropractic intervention in the management of adolescent idiopathic scoliosis in curves less than 20 degrees. DESIGN: Cohort time-series trial with all subjects electing chiropractic care. Entry-level Cobb angle was compared with postmanagement curve.

METHODS: Forty-two subjects completed the program of chiropractic intervention. Age range at entry was 6 to 12 years, and patients were included if their entry-level x-ray films revealed curves of 6 degrees to 20 degrees. Participants had adjustments performed for 1 year before follow-up. Full-spine osseous adjustments were the major form of intervention, but heel lifts and postural and lifestyle counseling were used as well.

RESULTS: There was no discernable effect on the severity of the curves as a function of age, initial curve severity, frequency of care, or attending physician.

CONCLUSION: Full-spine chiropractic adjustments with heel lifts and postural and lifestyle counseling are not effective in reducing the severity of scoliotic curves.

**35. Leach, R. A. (1983). "An evaluation of the effect of chiropractic manipulative therapy on hypolordosis of the cervical spine." J Manipulative Physiol Ther 6(1): 17-23.**

Cervical curve depth (CCD) was radiographically evaluated in 35 patients who presented with cervical hypolordosis or kyphosis (CH/K). Of these, one group of 20 patients received chiropractic manipulative therapy (CMT) for the purpose of correcting the disorder. A second group of nine patients received both CMT and an orthopedic cervical pillow for in home correction of the CH/K. A control group of six patients received CMT which was not intended to correct the CH/K. The purpose of the study was to determine the efficacy of CMT in the correction of CH/K. Analysis of the data indicated that CMT is significantly effective in the treatment of CH/K. There was a mean improvement of 4.55 degrees ( $p$  less than 0.01) in the group receiving only CMT, as assessed by CCD radiographic analysis. There was also significant improvement of 2.22 degrees ( $p$  less than 0.05) in the group receiving both CMT and orthopedic cervical pillow therapy. The findings lend support to fundamental chiropractic tenets such as that spinal manipulation is beneficial in correcting biomechanical disorders of the spine. Specifically, the study documents the role of chiropractic care in the correction of CH/K as may result from postural, musculoligamentous, or traumatic etiology such as the so-called "whiplash" injury.

**36. Lehman, G. J., H. Vernon, et al. (2001). "Effects of a mechanical pain stimulus on erector spinae activity before and after a spinal manipulation in patients with back pain: a preliminary investigation." J Manipulative Physiol Ther 24(6): 402-6.**

BACKGROUND: Several recent studies in animal models of spinal pain have shown changes in sensory processing and in reflex muscular responses. One group of researchers reported consistent electromyographic responses in the paraspinal muscles of healthy men after spinal manipulation, and they speculated that such responses may underlie some of the observed clinical effects of spinal manipulation (namely, reduction in pain and muscular hypertonicity). OBJECTIVES: To determine whether a painful mechanical stimulus applied above a

spinous process influences paraspinal electromyographic amplitude and whether this response is modulated by a spinal manipulation.

**STUDY DESIGN:** Analytic cohort with a convenience sample in a research clinic.

**METHODS:** Seventeen subjects with back pain (9 men and 8 women) were recruited. Electromyographic signals were recorded from the paraspinal musculature during the following procedures before and after manipulation: quiet stance and prone during the application of a mechanical pain stimulus. A 2-way repeated-measures analysis of variance was used to compare the effect of the force application on electromyographic amplitude. A second 2-way repeated-measures analysis of variance investigated whether the muscular response to a painful stimulus at either segment was influenced by the manipulative procedure.

**RESULTS:** A statistically significant increase in bilateral electromyographic activity was observed at the painful motion segment; however, no such statistical increase occurred at the segment that was not painful. It appears that manipulation results in a decrease in bilateral local electromyographic activity in the painful motion segment during the application of the mechanical stimulus; however, a statistically significant decrease was not found in the control segment. It was also found that while the subjects were quietly standing, the left erector spinae at a painful segment was the only muscle group to show significant differences before and after manipulation.

**CONCLUSION:** This study suggests that motion segments identified as a problem in subjects with chronic low back pain have an exaggerated local muscular response to a painful stimulus compared with that observed in problem segments. In addition, spinal manipulation appears to attenuate the electromyographic response to a painful stimulus.

**37. Licciardone, J. C., A. K. Brimhall, et al. (2005). "Osteopathic manipulative treatment for low back pain: a systematic review and meta-analysis of randomized controlled trials." BMC Musculoskelet Disord 6: 43.**

**BACKGROUND:** Osteopathic manipulative treatment (OMT) is a distinctive modality commonly used by osteopathic physicians to complement their conventional treatment of musculoskeletal disorders. Previous reviews and meta-analyses of spinal manipulation for low back pain have not specifically addressed OMT and generally have focused on spinal manipulation as an alternative to conventional treatment. The purpose of this study was to assess the efficacy of OMT as a complementary treatment for low back pain.

**METHODS:** Computerized bibliographic searches of MEDLINE, EMBASE, MANTIS, OSTMED, and the Cochrane Central Register of Controlled Trials were supplemented with additional database and manual searches of the literature. Six trials, involving eight OMT vs control treatment comparisons, were included because they were randomized controlled trials of OMT that involved blinded assessment of low back pain in ambulatory settings. Data on trial methodology, OMT and control treatments, and low back pain outcomes were abstracted by two independent reviewers. Effect sizes were computed using Cohen's d statistic and meta-analysis results were weighted by the inverse variance of individual comparisons. In addition to the overall meta-analysis, stratified meta-analyses were performed according to control treatment, country where the trial was conducted, and duration of follow-up. Sensitivity analyses were performed for both the overall and stratified meta-analyses.

**RESULTS:** Overall, OMT significantly reduced low back pain (effect size, -0.30; 95% confidence interval, -0.47 - -0.13;  $P = .001$ ). Stratified analyses demonstrated significant pain reductions in trials of OMT vs active treatment or placebo control and OMT vs no treatment control. There were significant pain reductions with OMT regardless of whether trials were performed in the United Kingdom or the United States. Significant pain reductions were also observed during short-, intermediate-, and long-term follow-up.

CONCLUSION: OMT significantly reduces low back pain. The level of pain reduction is greater than expected from placebo effects alone and persists for at least three months. Additional research is warranted to elucidate mechanistically how OMT exerts its effects, to determine if OMT benefits are long lasting, and to assess the cost-effectiveness of OMT as a complementary treatment for low back pain.

**38. Meade, T. W., S. Dyer, et al. (1995). "Randomised comparison of chiropractic and hospital outpatient management for low back pain: results from extended follow up." Bmj 311(7001): 349-51.**

OBJECTIVE--To compare the effectiveness over three years of chiropractic and hospital outpatient management for low back pain.

DESIGN--Randomised allocation of patients to chiropractic or hospital outpatient management.

SETTING--Chiropractic clinics and hospital outpatient departments within reasonable travelling distance of each other in 11 centres.

SUBJECTS--741 men and women aged 18-64 years with low back pain in whom manipulation was not contraindicated.

OUTCOME MEASURES--Change in total Oswestry questionnaire score and in score for pain and patient satisfaction with allocated treatment.

RESULTS--According to total Oswestry scores improvement in all patients at three years was about 29% more in those treated by chiropractors than in those treated by the hospitals. The beneficial effect of chiropractic on pain was particularly clear. Those treated by chiropractors had more further treatments for back pain after the completion of trial treatment. Among both those initially referred from chiropractors and from hospitals more rated chiropractic helpful at three years than hospital management.

CONCLUSIONS--At three years the results confirm the findings of an earlier report that when chiropractic or hospital therapists treat patients with low back pain as they would in day to day practice those treated by chiropractic derive more benefit and long term satisfaction than those treated by hospitals.

**39. Nilsson, N., H. W. Christensen, et al. (1996). "Lasting changes in passive range motion after spinal manipulation: a randomized, blind, controlled trial." J Manipulative Physiol Ther 19(3): 165-8.**

PURPOSE: To study whether a 3-wk series of spinal manipulation has any lasting effect on passive cervical range of motion.

DESIGN: Randomized, controlled trial with a blind observer.

SETTING: Ambulatory outpatient facility in an independent National Health Service funded chiropractic research institution.

PARTICIPANTS: Thirty-nine headache sufferers who, on entering the study, displayed objectively decreased passive cervical range of motion. These subjects were recruited from 400 headache sufferers who responded to newspaper advertisements.

INTERVENTION: Half of the group received high-velocity, low-amplitude cervical manipulation twice a week for 3 wk. The other half received low-level laser in the upper cervical region and deep friction massage in the lower cervical/upper thoracic region, also twice a week for 3 wk.

MAIN OUTCOME MEASURE: Goniometrically assessed passive range of motion of the cervical spine.

RESULTS: Although passive cervical range of motion increased in both groups during the trial period, there were no statistically significant differences between the two groups 1 wk after the last treatment.

CONCLUSION: It seems that any changes in passive range of motion after spinal manipulation are of a temporary nature.

**40. Nilsson, N., H. W. Christensen, et al. (1997). "The effect of spinal manipulation in the treatment of cervicogenic headache." J Manipulative Physiol Ther 20(5): 326-30.**

PURPOSE: To study whether the isolated intervention of high-speed, low-amplitude spinal manipulation in the cervical spine has any effect on cervicogenic headache.

DESIGN: Prospective randomized controlled trial with a blinded observer.

SETTING: Ambulatory outpatient facility in an independent research institution.

PARTICIPANTS: Fifty-three subjects suffering from frequent headaches who fulfilled the International Headache Society criteria for cervicogenic headache (excluding radiological criteria). These subjects were recruited from 450 headache sufferers who responded to newspaper advertisements.

INTERVENTION: After randomization, 28 of the group received high-velocity, low-amplitude cervical manipulation twice a week for 3 wk. The remaining 25 received low-level laser in the upper cervical region and deep friction massage (including trigger points) in the lower cervical/upper thoracic region, also twice a week for 3 wk.

MAIN OUTCOME MEASURES: The change from week 1 to week 5 in analgesic use per day, in headache intensity per episode and in number of headache hours per day, as registered in a headache diary.

RESULTS: The use of analgesics decreased by 36% in the manipulation group, but was unchanged in the soft-tissue group; this difference was statistically significant ( $p = .04$ , chi 2 for trend). The number of headache hours per day decreased by 69% in the manipulation group, compared with 37% in the soft-tissue group; this was significant at  $p = .03$  (Mann-Whitney). Finally, headache intensity per episode decreased by 36% in the manipulation group, compared with 17% in the soft-tissue group; this was significant at  $p = .04$  (Mann-Whitney).

CONCLUSION: Spinal manipulation has a significant positive effect in cases of cervicogenic headache.

**41. Peterson, K. B. (1997). "The effects of spinal manipulation on the intensity of emotional arousal in phobic subjects exposed to a threat stimulus: a randomized, controlled, double-blind clinical trial." J Manipulative Physiol Ther 20(9): 602-6.**

OBJECTIVE: To determine the effect of spinal manipulation upon the intensity of emotional arousal in phobic subjects exposed to a threat stimulus.

DESIGN: Randomized, controlled, double-blind clinical trial.

SETTING: Community college campus.

SUBJECTS: Eighteen phobic community college student volunteers randomized into treatment and control groups.

INTERVENTION: Visual analog scale (VAS) and pulse rates were obtained in response to the subjects' viewing their phobogenic stimulus. Spinal manipulation was performed while the subjects experienced emotional responses. Manual muscle testing was utilized to ascertain the associated spinal segments and involved emotion.

RESULTS: Data were analyzed using analysis of variance for a repeated measures experimental design and Least Significant Differences (LSDs) for mean comparisons. Baseline, preintervention and postintervention pulse rates were not statistically different for the control and treatment groups ( $p = .0807$ ). VAS postintervention mean for the spinal manipulation group was significantly lower than the control means ( $p = .05$ ) and from its corresponding preintervention mean ( $p = .001$ ).

CONCLUSION: Spinal manipulation significantly decreased the intensity of emotional arousal reported by phobic subjects. The mechanism for this effect is not known.

**42. Plaugher, G. (1993). "The effect of spinal manipulation on pain and prostaglandin levels in women with primary dysmenorrhea." J Manipulative Physiol Ther 16(3): 199-201.**

**43. Senstad, O., C. Leboeuf-Yde, et al. (1996). "Side-effects of chiropractic spinal manipulation: types frequency, discomfort and course." Scand J Prim Health Care 14(1): 50-3.**

OBJECTIVE--To make a preliminary appraisal of the types of unpleasant reactions reported by patients after spinal manipulation and to estimate their frequency.

STUDY DESIGN--Standardized interview data collected in a longitudinal survey.

METHOD--Ten chiropractors collected data on all unpleasant reactions that were reported after a maximum of six visits by ten consecutive patients per chiropractor, with the use of a questionnaire that contained mainly closed-ended questions.

RESULTS--Following 368 treatments in 95 patients, some type of side-effect was reported after 1/3 of treatments. Local or radiating symptoms were most commonly reported (23%). No alarming events were reported. Ninety percent of all reactions were graded by the patients as moderate or slight. They commenced on the day of therapy in 87% of cases, and had disappeared within 24 hours in 83%.

CONCLUSION--Results from this preliminary study indicate that reactions to spinal manipulation may be relatively common but benign in nature and of short duration. No estimate could be made of rare or serious side-effects.

**44. Shekelle, P. G., A. H. Adams, et al. (1992). "Spinal manipulation for low-back pain." Ann Intern Med 117(7): 590-8.**

PURPOSE: To review the use, complications, and efficacy of spinal manipulation as a treatment for low-back pain.

DATA IDENTIFICATION: Articles were identified through a MEDLINE search, review of articles' bibliographies, and advice from expert orthopedists and chiropractors.

STUDY SELECTION: All studies reporting use and complications of spinal manipulation and all controlled trials of the efficacy of spinal manipulation were analyzed. Fifty-eight articles, including 25 controlled trials, were retrieved.

DATA ANALYSIS: Data on the use and complications of spinal manipulation were summarized. Controlled trials of efficacy were critically appraised for study quality. Data from nine studies were combined using the confidence profile method of meta-analysis to estimate the effect of spinal manipulation on patients' pain and functional outcomes.

RESULTS OF DATA SYNTHESIS: Chiropractors provide most of the manipulative therapy used in the United States for patients with low-back pain. Serious complications of lumbar manipulation, including paraplegia and death, have been reported. Although the occurrence rate of these complications is unknown, it is probably low. For patients with uncomplicated, acute low-back pain, the difference in probability of recovery at 3 weeks favoring treatment with spinal manipulation is 0.17 (for example, increase in recovery from 50% to 67%; 95% probability limits of estimate, 0.07 to 0.28). For patients with low-back pain and sciatic nerve irritation, the difference in probabilities of recovery at 4 weeks is 0.098 (probability limits, -0.016 to 0.209).

CONCLUSIONS: Spinal manipulation is of short-term benefit in some patients, particularly those with uncomplicated, acute low-back pain. Data are insufficient concerning the efficacy of spinal manipulation for chronic low-back pain.

**45. Skargren, E. I., P. G. Carlsson, et al. (1998). "One-year follow-up comparison of the cost and effectiveness of chiropractic and physiotherapy as primary management for back pain. Subgroup analysis, recurrence, and additional health care utilization." Spine 23(17): 1875-83; discussion 1884.**

STUDY DESIGN: A randomized trial was conducted in which patients with back and neck pain, visiting a general practitioner, were allocated to chiropractic or physiotherapy.

OBJECTIVES: To compare outcome and costs of chiropractic and physiotherapy as primary treatment for patients with back and neck pain, with special reference to subgroups, recurrence rate, and additional health care use at follow-up evaluation 12 months after treatment.

SUMMARY OF BACKGROUND DATA: Earlier studies on the effect of spinal manipulation have shown inconsistent results. Mostly they include only short-term follow-up periods, and few cost-effectiveness analyses have been made.

METHODS: A group of 323 patients aged 18-60 years who had no contraindications to manipulation and who had not been treated within the previous month were included. Outcome measures were changes in Oswestry scores, pain intensity, and general health; recurrence rate; and direct and indirect costs.

RESULTS: No differences were detected in health improvement, costs, or recurrence rate between the two groups. According to Oswestry score, chiropractic was more favorable for patients with a current pain episode of less than 1 week (5%) and physiotherapy for patients with a current pain episode of greater than 1 month (6.8%). Nearly 60% of the patients reported two or more recurrences. More patients in the chiropractic group (59%) than in the physiotherapy group (41%) sought additional health care. Costs varied considerably among individuals and subgroups; the direct costs were lower for physiotherapy in a few subgroups.

CONCLUSIONS: Effectiveness and costs of chiropractic or physiotherapy as primary treatment were similar for the total population, but some differences were seen according to subgroups. Back problems often recurred, and additional health care was common. Implications of the result are that treatment policy and clinical decision models must consider subgroups and that the problem often is recurrent. Models must be implemented and tested.

**46. Straub, W. F., M. P. Spino, et al. (2001). "The effect of chiropractic care on jet lag of Finnish junior elite athletes." J Manipulative Physiol Ther 24(3): 191-8.**

OBJECTIVE: To determine the effect of chiropractic care on jet lag in Finnish junior elite athletes.

SUBJECTS: Fifteen Finnish junior elite athletes.

METHODS: Through use of a table of random numbers, each athlete was assigned by sex to one of 3 groups: chiropractic adjustment, sham adjustment, or control. As needed, the chiropractic adjustment group athletes (n = 5) were adjusted on a daily basis by licensed chiropractors using a toggle/recoil procedure. The sham adjustment group athletes (n = 5) received sham adjustments on a daily basis by licensed chiropractors. The control group athletes (n = 5) were not adjusted or sham-adjusted but participated in all test protocols. Sleep, jet lag, chiropractic, and mood data (the last acquired through use of the Profile of Mood States) were collected on a daily basis for 18 consecutive days.

RESULTS: Repeated-measures analyses of variance (3 x 2) of total mood disturbance scores and heart rate variables indicated that there were no significant (.05 level) between-group differences. Sleep data were analyzed through use of a 3 x 2, repeated-measures multivariate analysis of variance. Pillai's trace indicated that there were no between-group differences. Self-assessment of jet lag by participants after traveling to Georgia and after returning to Finland showed no between-group differences.

CONCLUSIONS: It was concluded that chiropractic care did not reduce the effects of jet lag.

**47. Sucher, B. M., R. N. Hinrichs, et al. (2005). "Manipulative treatment of carpal tunnel syndrome: biomechanical and osteopathic intervention to increase the length of the transverse carpal ligament: part 2. Effect of sex differences and manipulative "priming"." J Am Osteopath Assoc 105(3): 135-43.**

As a theoretical basis for treatment of carpal tunnel syndrome (CTS) and expanding upon part 1 of this study, the authors investigated the effects of static loading (weights) and dynamic loading (osteopathic manipulation [OM]) on 20 cadaver limbs (10 male, 10 female). This larger study group allowed for comparative analysis of results by sex and reversal of sequencing for testing protocols. In static loading, 10-newton loads were applied to metal pins inserted into carpal bones. In dynamic loading, the OM maneuvers used were those currently used in clinical settings to treat patients with CTS. Transverse carpal ligament (TCL) response was observed by measuring changes in the width of the transverse carpal arch (TCA) with three-dimensional video analysis and precision calipers. Results demonstrated maximal TCL elongation of 13% (3.7 mm) with a residual elongation after recovery of 9% (2.6 mm) from weight loads in the female cadaver limbs, compared to less than 1 mm as noted in part 1, which used lower weight loads and combined results from both sexes. Favorable responses to all interventions were more significant among female cadaver limbs. Higher weight loads also caused more linear translatory motion through the metal pins, resulting in TCA widening equal to 63% of the increases occurring at skin level, compared to only 38% with lower loads. When OM was performed first, it led to greater widening of the TCA and lengthening of the TCL during the weight loading that followed. Both methods hold promise to favorably impact the course of management of CTS, particularly in women.

**48. Torstensen, T. A. (1996). "[Effect of physical therapy and chiropractic]." Tidsskr Nor Laegeforen 116(14): 1717; author reply 1718.**

**49. Vernon, H. T. (1995). "The effectiveness of chiropractic manipulation in the treatment of headache: an exploration in the literature." J Manipulative Physiol Ther 18(9): 611-17.**

OBJECTIVE: To review the literature on outcome studies of chiropractic/manipulation for tension-type and migraine headaches.

DESIGN: Qualitative literature review.

RESULTS: Of nine studies of manipulation for tension-type headaches that reported quantitative outcomes, four were randomized clinical trials and five were case series designs. These studies reported on 729 subjects, 613 of whom received manipulation. Outcomes ranged from good to excellent. Manipulation seems to be better than no treatment, some types of mobilization and ice, and it seems to be equivalent to amitriptyline but with greater durability of effect than this medication. Of three studies on migraine, only one was a randomized clinical trial. These studies reported on 202 subjects, 156 of whom received manipulation. The outcomes ranged from fair to very good.

CONCLUSION: A modest body of clinical studies exists dealing with the effect of manipulation and headache. The overall results are encouraging, even if not quite supportive in the case of tension-type headache. Further studies in this area are definitely warranted, particularly well-controlled studies in migraine.

**50. Walsh, M. J. and B. I. Polus (1999). "A randomized, placebo-controlled clinical trial on the efficacy of chiropractic therapy on premenstrual syndrome." J Manipulative Physiol Ther 22(9): 582-5.**

OBJECTIVE: To evaluate the efficacy of chiropractic therapy on the treatment of symptoms associated with premenstrual syndrome.

DESIGN: A prospective, randomized, placebo-controlled, crossover clinical trial.

SETTING: Multicenter private clinics. SUBJECTS: Twenty-five subjects with diagnosed premenstrual syndrome (with a Moos premenstrual syndrome questionnaire plus daily symptom monitoring).

INTERVENTION: After randomization, 16 of the subjects received high-velocity, low-amplitude spinal manipulation plus soft tissue therapy 2 to 3 times in the week before menses for at least 3 cycles. The remaining 9 subjects received a placebo treatment with a spring-loaded adjusting instrument wound down for minimum force. After a 1-cycle washout, the 2 groups changed over.

OUTCOME MEASURE: Daily rating of symptom level, comparing total scores for premenstrual week with baseline for treatment and placebo phases. DATA ANALYSIS: The data were analyzed with paired Student t tests and Wilcoxon signed rank tests, with the statistical significance set at  $P < .05$ .

RESULTS: There was a significant decrease in scores after treatment compared with baseline scores ( $P = .00001$ ) and a statistically significant decrease in scores for the treatment phase compared with the placebo ( $P = .006$ ). For group 1 ( $n = 16$ ), there was a significant decrease in scores after treatment compared with baseline scores ( $P = .0001$ ) and a statistically significant decrease in scores for the treatment phase compared with the placebo ( $P = .041$ ). For group 2 ( $n = 9$ ), there was a significant decrease in scores during treatment compared with the baseline ( $P = .01$ ); however, there was no difference at the  $P = .05$  level between treatment and placebo scores.

CONCLUSIONS: Within the limitations of the study, the results support the hypothesis that the symptoms associated with PMS can generally be reduced by chiropractic treatment consisting of adjustments and soft-tissue therapy. However, the role of a placebo effect needs further elucidation, given that the group receiving the placebo first, although improving over the baseline, showed no further improvement when they had actual treatment.

**51. Klein, P. (1998). "[Osteopathy and chiropractic]." Rev Med Brux 19(4): A283-9.**

Osteopathy and chiropractic represent two challenging domains with a specific degree of multiplicity and complexity. This makes a complete appraisal difficult and impossible to appreciate in one single analysis. These disciplines exist since more than one century. An hermeneutic approach permits to understand their genesis but indicates also the nonsense of trying to transfer and apply earliest principles nowadays. It seems that most, but not all, practicing clinicians take into account recent developments in physiology, biomechanics and pathophysiology. Clinical studies and especially their meta-analyses on base of precise criteria permit to clarify the indications, therapeutic efficiency as well as socio-economic advantages. The meta-analyses point also at the poor quality of most clinical studies even if in the last years an improvement can be noted. Fundamental studies exist in both domains revealing interesting information that have permitted to reject several preconceived ideas and to clarify others. Research topics as the morphology of the intervertebral disk before and after application of a manipulative technique are discussed. Results of experimental determination of global and segmental amplitudes in the cervical and in the lumbar spine during a manipulation in healthy subjects are reported. Finally the necessity but also the difficulties inherent to research studies in osteopathy and in chiropractic will be discussed.

**52. Licciardone, J. C., S. T. Stoll, et al. (2004). "A randomized controlled trial of osteopathic manipulative treatment following knee or hip arthroplasty." J Am Osteopath Assoc 104(5): 193-202.**

CONTEXT: Preliminary study results suggest that osteopathic manipulative treatment (OMT) may reduce pain, improve ambulation, and increase rehabilitation efficiency in patients undergoing knee or hip arthroplasty.

OBJECTIVE: To determine the efficacy of OMT in patients who recently underwent surgery for knee or hip osteoarthritis or for a hip fracture.

DESIGN: Randomized controlled trial involving hospital and postdischarge phases.

SETTING: Hospital-based acute rehabilitation unit.

PATIENTS: A total of 42 women and 18 men who were hospitalized between October 1998 and August 1999.

INTERVENTION: Patients were randomly assigned to groups that received either OMT or sham treatment in addition to standard care. Manipulation was individualized and performed according to study guidelines regarding frequency, duration, and technique.

MAIN OUTCOME MEASURES: Changes in Functional Independence Measure (FIM) scores and in daily analgesic use during the rehabilitation unit stay; length of stay; rehabilitation efficiency--defined as the FIM total score change per rehabilitation unit day; and changes in Medical Outcomes Study Short Form-36 scores from rehabilitation unit admission to 4 weeks after discharge.

RESULTS: Of 19 primary outcome measures, the only significant difference between groups was decreased rehabilitation efficiency with OMT (2.0 vs 2.6 FIM total score points per day;  $P = .01$ ). Stratified analyses demonstrated that poorer OMT outcomes were confined to patients with osteoarthritis who underwent total knee arthroplasty (length of stay, 15.0 vs 8.3 days;  $P = .004$ ; rehabilitation efficiency, 2.1 vs 3.4 FIM total score points per day;  $P < .001$ ).

CONCLUSION: The OMT protocol used does not appear to be efficacious in this hospital rehabilitation population.

**53. Conlin, A., S. Bhogal, et al. (2005). "Treatment of whiplash-associated disorders--part I: Non-invasive interventions." *Pain Res Manag* 10(1): 21-32.**

BACKGROUND: A whiplash-associated disorder (WAD) is an injury due to an acceleration-deceleration mechanism at the neck. WAD represents a very common and costly condition, both economically and socially. In 1995, the Quebec Task Force published a report that contained evidence-based recommendations regarding the treatment of WAD based on studies completed before 1993 and consensus-based recommendations.

OBJECTIVE: The objective of the present article--the first installment of a two-part series on interventions for WAD--is to provide a systematic review of the literature published between January 1993 and July 2003 on noninvasive interventions for WAD using meta-analytical techniques.

METHODS OF THE REVIEW: Three medical literature databases were searched for identification of all studies on the treatment of WAD. Randomized controlled trials (RCTs) and epidemiological studies were categorized by treatment modality and analyzed by outcome measure. The methodological quality of the RCTs was assessed. When possible, pooled analyses of the RCTs were completed for meta-analyses of the data. The results of all the studies were compiled and systematically reviewed.

RESULTS: Studies were categorized as exercise alone, multimodal intervention with exercise, mobilization, strength training, pulsed magnetic field treatment and chiropractic manipulation. A total of eight RCTs and 10 non-RCTs were evaluated. The mean score of methodological quality of the RCTs was five out of 10. Pooled analyses were completed across all treatment modalities and outcome measures. The outcomes of each study were summarized in tables.

CONCLUSIONS: There exists consistent evidence (published in two RCTs) in support of mobilization as an effective noninvasive intervention for acute WAD. Two RCTs also reported consistent evidence that exercise alone does not improve range of motion in patients with acute WAD. One RCT reported improvements in pain and range of motion in patients with WAD of undefined duration who underwent pulsed electromagnetic field treatment. Conflicting evidence in two RCTs exists regarding the effectiveness of multimodal intervention with exercise. Limited evidence, in the form of three non-RCTs, exists in support of chiropractic manipulation. Future research should be directed toward clarifying the role of exercise and manipulation in the treatment of WAD, and supporting or refuting the benefit of pulsed electromagnetic field treatment. Mobilization is recommended for the treatment of pain and compromised cervical range of motion in the acute WAD patient.

**54. Gamber, R., S. Holland, et al. (2005). "Cost-effective osteopathic manipulative medicine: a literature review of cost-effectiveness analyses for osteopathic manipulative treatment." *J Am Osteopath Assoc* 105(8): 357-67.**

Despite the value that osteopathic manipulative medicine (OMM) may offer to healthcare consumers in a managed care, evidence-based healthcare system, very little research has been published on the cost-effectiveness of osteopathic manipulative treatment compared with other treatment modalities. The authors searched MEDLINE and OSTMED for English-language articles published between January 1966 and June 2002 using the key terms cost-effectiveness, osteopathic medicine, workers' compensation, hospital length of stay, healthcare providers, and manipulative medicine. The authors then extended their search by reviewing the reference lists provided in the articles initially identified as relevant by these databases. The purpose, methods, findings, and conclusions of each study were evaluated for how the cost-effectiveness of OMM was analyzed.

The authors conclude that the osteopathic medical profession needs to conduct and publish research that is consistent with current practices in the conventional medical literature.

**55. Gerster, J. C. (2000). "[Medical treatment of low back pain according to evidence-based medicine]." *Schweiz Rundsch Med Prax* 89(15): 619-23.**

Results of therapy of low back pain with drugs (NSAIDs), locally injected corticosteroids, active physical therapy, back school and chiropractic are assessed according to "Evidence Based Medicine". The assessment after a trial period of therapy is difficult because clinical symptoms and signs of low back pain are non specific. There is no good correlation of clinical signs with the radiological images. The therapy is empiric since controlled randomized clinical studies have until now not shown that drugs, corticosteroids (epidural or intra facet-joint injections), back school, chiropractic or physical therapy give results better than with placebo.

**56. Giles, L. G. (2001). "Evidence-based clinical guidelines submitted to the Australian National Health and Medical Research Council for the management of acute low back pain: a critical review." *J Manipulative Physiol Ther* 24(2): 131-9.**

**57. Gross, A. R., P. D. Aker, et al. (1996). "Conservative management of mechanical neck disorders. A systematic overview and meta-analysis." *Online J Curr Clin Trials Doc No 200-201: [34457 words; 185 paragraphs]*.**

OBJECTIVE: This overview reports the efficacy of conservative treatments (drug therapy, manual therapy, patient education, physical medicine modalities) in reducing pain in adults with mechanical neck disorders. METHODS: Computerized bibliographic database searches from 1985 to December 1993, information requests from authors, and bibliography screenings were used to identify published and unpublished research. Applying strict criteria, two investigators independently reviewed the blinded articles. Each selected trial was evaluated independently for methodologic quality. RESULTS: Twenty-four randomized controlled trials (RCTs) and eight before-after studies met our selection criteria. Twenty RCTs rated moderately strong or better in terms of methodologic quality. Five trials using manual therapy in combination with other treatments were clinically similar, were statistically not heterogeneous ( $p = 0.98$ ), and were combined to yield an effect size of -0.6 (95% CI: -0.9, -0.4), equivalent to a 16 point improvement on a 100 point pain scale. Four RCTs using physical medicine modalities were combined using the inverse chi-square method: two using electromagnetic therapy produced a significant reduction in pain ( $p < 0.01$ ); and two using laser therapy did not differ significantly from a placebo ( $p = 0.63$ ). Little or no scientific evidence exists for other therapies, including such commonly used treatments as medication, rest and exercise. CONCLUSIONS: Within the limits of methodologic quality, the best available evidence supports the use of manual therapies in combination with other treatments for short-term relief of neck pain. There is some support for the use of electromagnetic therapy and against the use of laser therapy. In general, other interventions have not been studied in enough detail adequately to assess efficacy or effectiveness. This overview provides the foundation for an evidence-based approach to practice. More robust design and methodology should be used in future research, in particular, the use of valid and reliable outcomes measures.

**58. Hawk, C., R. Khorsan, et al. (2007). "Chiropractic care for nonmusculoskeletal conditions: a systematic review with implications for whole systems research." J Altern Complement Med 13(5): 491-512.**

OBJECTIVES: (1) To evaluate the evidence on the effect of chiropractic care, rather than spinal manipulation only, on patients with nonmusculoskeletal conditions; and (2) to identify shortcomings in the evidence base on this topic, from a Whole Systems Research perspective. DESIGN: Systematic review. METHODS: Databases included were PubMed, Ovid, Mantis, Index to Chiropractic Literature, and CINAHL. Search restrictions were human subjects, peer-reviewed journal, English language, and publication before May 2005. All randomized controlled trials (RCTs) were evaluated using the Scottish Intercollegiate Guidelines Network (SIGN) and Jadad checklists; a checklist developed from the CONSORT (Consolidated Standards of Reporting Trials) guidelines; and one developed by the authors to evaluate studies in terms of Whole Systems Research (WSR) considerations. RESULTS: The search yielded 179 papers addressing 50 different nonmusculoskeletal conditions. There were 122 case reports or case series, 47 experimental designs, including 14 RCTs, 9 systematic reviews, and 1 a large cohort study. The 14 RCTs addressed 10 conditions. Six RCTs were rated "high" on the 3 conventional checklists; one of these 6 was rated "high" in terms of WSR considerations. CONCLUSIONS: (1) Adverse effects should be routinely reported. For the few studies that did report, adverse effects of spinal manipulation for all ages and conditions were rare, transient, and not severe. (2) Evidence from controlled studies and usual practice supports chiropractic care (the entire clinical encounter) as providing benefit to patients with asthma, cervicogenic vertigo, and infantile colic. Evidence was promising for potential benefit of manual procedures for children with otitis media and elderly patients with pneumonia. (3) The RCT design is not necessarily incompatible with WSR. RCTs could improve generalizability by basing protocols on usual practice. (4) Case reports could contribute more to WSR by increasing their emphasis on patient characteristics and patient-based outcomes. (5) Chiropractic investigators, practitioners, and funding agencies should increase their attention to observational designs.

**59. LaBrot, T. M. (2006). "Evaluating chiropractic care/records." Lippincotts Case Manag 11(2): 67-70.**

**60. Mertz, J. A. (2000). "Chiropractic care for children can help." Arch Pediatr Adolesc Med 154(10): 1062-3.**

**61. Pistolese, R. A. (2000). "In defense of pediatric chiropractic care." Arch Pediatr Adolesc Med 154(10): 1063.**

**62. Rosner, A. L. (2001). "Evidence-based clinical guidelines for the management of acute low back pain: response to the guidelines prepared for the Australian Medical Health and Research Council." J Manipulative Physiol Ther 24(3): 214-20.**

**Cost-effective Osteopathic Manipulative Medicine: A Literature Review of Cost-effectiveness Analyses for Osteopathic Manipulative Treatment**

**Gamber et al., 2005**

- Mangel an Kosten-Effektivitäts-Analysen bzgl. der Osteopathischen Manipulativen Medizin (OMM) in den USA
- manuelle Therapie wird in unterschiedlichen Professionen eingesetzt; Osteopathische Manipulative Therapie (OMT) beschreibt diejenigen Techniken, welche von DOs zur Behandlung muskuloskeletaler und anderer Beschwerden eingesetzt wird
- in den USA besteht somit ein Unterschied zw. OMT und anderen Formen manueller Therapie, wie zum Bsp. Chiropraktik
- bisher in osteopathisch orientierter Literatur nur wenige Studien, die zudem indirekte Kostenmessungen einschließen → Anlass für diese systematische Übersicht
- wichtige Betrachtungen sind u. a., ob prospektive Kostenfragen gestellt und ob die Quelle der Kostendaten genau definiert wurde
- Standards für Kostenanalysen erfordern unbedingt die Erfassung der Alternativkosten von Ressourcen, die durch Gesundheitsdienste bereitgestellt werden; aber auch die solch indirekter Kosten wie Kosten durch Patiententransporte, Arbeitszeitverluste u. ä.
- **Methoden:**
  - *Datenbanken:* OSTMED; MEDLINE
  - *Schlagwörter:* cost-effectiveness, osteopathic medicine, workers' compensation, hospital length of stay, healthcare providers, manipulative medicine
  - *Analyse:* Zweck, Methode, Ergebnisse, Schlussfolgerungen
  - *Einschluss:* peer-reviewed und nicht-peer-reviewed sowie Regierungsberichte; nur Artikel, die die Kosten von OMM mit Standard-Versorgung vergleichen
- **allg. Ergebnisse:**
  - 16 Artikel gefunden (11 peer-reviewed) + 4 Regierungsberichte
  - Analyse direkter Kosten und so genannter indirekter „proxy variables“ (i. S. v. stellvertretende Variablen, z. B. Länge des Krankenhausaufenthaltes)
  - jeweils 3 Gruppen/ Anbieter unterschieden:
  - Chiropractors (C) vs. Allopathic Physicians (AP) vs. Osteopathic Physicians (OP)
  - Tab. 1: Ergebnis-Übersicht
- **Hinweise aus Studien mit direkten Kostenvariablen:**
  - 1.) 2 Artikel mit gewissen methodischen Einschränkungen, siehe S. 361
    - OP: niedrigste totale und durchschnittl. Kosten sowie niedrigste durchschnittl. Entschädigungskosten pro Anspruchsberechtigtem; durchschnittl. kürzeste Dauer des Entschädigungszeitraums
    - C: bessere Behandlungsergebnisse als OP, aber höhere Kosten
  - 2.) 3 Regierungsberichte, auch mit gewissen methodischen Einschränkungen, siehe S. 362
    - C: höchste durchschnittl. Kosten pro Anspruchsberechtigtem; OP: niedrigste durchschnittl. Kosten pro Anspruchsberechtigtem
    - AP: höchste durchschnittl. Kosten pro Anspruchsberechtigtem; OP: niedrigste durchschnittl. Kosten pro Anspruchsberechtigtem

- Kosten pro Service: AP > OP > C

- **Hinweise aus Studien mit indirekten Kostenvariablen:**

- 1.) 2 Studien zu: cost of „lost work time“ and provider services

- Standardbehandlung: deutlich höhere Kosten pro Patient als bei Standardbehandlung plus OMM
- AP höchste Kosten, gefolgt von OP und C

- 2.) 3 Studien zu: „imputed cost variables“

- OP: geringster Arbeitsumfang und direkter Patientenkontakt im Vgl. zu den anderen Anbietern
- OMT → 68% der Befragten erlebten deutliche bis komplette Schmerzbefreiung, 86% berichten, dass ihr Bedarf an physikalischer Therapie dadurch abnahm, 73% benötigen nach OMT keine Medikation mehr
- OMT-Patienten benötigten auch weniger Medikamente und physikalische Therapie als Patienten mit Standardbehandlung

- 3.) 4 Studien zu „length of hospital stay“; z. T. keine Schlussfolgerung möglich; keine Aussagen über tatsächliche Kosten

- 67 Diagnosegruppen; bei 16% dieser Gruppen blieben OMT-Patienten mehr als 1 Tag kürzer im Krankenhaus
- OMT-Patienten haben signifikant kürzere Krankenhaus-Aufenthalte
- Krankenhaus-Aufenthalt sowie mittlere Dauer der Antibiotika-Einnahme im KH war bei OMT-Patienten kürzer

- 4.) 4 Studien im ambulanten Setting; Kosten assoziiert mit frühen Diagnosen und Behandlungen potentiell chronischer Erkrankungen

- im Vgl. zu Patienten einer Referenzgruppe des SF-36 haben OPM-Patienten höhere Schmerzen, niedrigere Lebensqualität und höhere Werte bzgl. der Schwere physischer Einschränkungen; keine Hinweise wie es nach OMT aussah (!)
- signifikante Schmerzverringering nach OMT
- weitere Informationen dazu S. 365 (teilweise diffus)

- **Diskussion:**

- Kritik: Studien, die direkte Kosten erfassten, nutzten lediglich den Aspekt Versicherungszahlungen an Behandlungsanbieter; andere Studien, die positive Ergebnisse für die OMM fanden, beriefen sich teilweise auf unvollständige Daten oder definierten ebenfalls keine direkten Kostenvariablen
- Kostendaten sollten generell erhoben werden
- mögliche Ergebnisse von Kosteneffektivitäts-Studien lassen sich wie folgt zusammenfassen:

cost	outcome		
	worse	same	better
lower	ambiguous	more efficient	more efficient
same	less efficient	ambiguous	more efficient
higher	less efficient	less efficient	ambiguous

**Zusammenfassung:**

1. Der Begriff der Osteopathie ist unklar und differiert stark im internationalen Vergleich. Es besteht für die Osteopathie, wie auch für die gesamte Manuelle Medizin kein einheitliches methodisches und begriffliches Fundament.
2. Bei osteopathischen Methoden handelt es sich überwiegend um besondere Techniken der Manuellen Medizin. Diese sind bei funktionellen Störungen des Bewegungssystems breit und sicher anwendbar. Da diese Indikationen eine erhebliche Inzidenz und einen erheblichen ökonomischen Impact für die Volkswirtschaften haben, wäre eine breit anzuwendende und nebenwirkungsarme Methode potentiell von großen medizinischen und volkswirtschaftlichen Nutzen.
3. National, wie international ist die Anbieterlandschaft durch die Existenz von zahlreichen Schulen und Gesellschaften zersplittert.
4. Dies erschwert erheblich die Bewertung der Methodik, da unterschiedliche Begriffe, Umfänge der Intervention bis zu den Differenzen in den einzelnen Techniken einen notwendigen Vergleich kaum ermöglichen.
5. Die Evidenzbasis für die Effizienz und Kosten-Effektivität der manualmedizinischen Methoden, insbesondere die der Osteopathie ist unzureichend.
6. Die Häufigkeitsverteilung der publizierten Arbeiten zu diesem Thema ist deutlich zu Ungunsten der höheren Evidenzstufen verschoben.
7. Vergleiche zwischen den einzelnen Studien sind aufgrund der Unvergleichbarkeit der methodischen Güte, der Indikationen, der Interventionen und der Outcomes kaum möglich.
8. Datenpooling oder Erstellung einer Meta-Analyse war nicht möglich.
9. Eine erhebliche Anstrengung ist notwendig zur Schaffung einer gemeinsamen begrifflichen Basis, Abstimmung der neurophysiologischen Wirkmechanismen, der Definierung der Gemeinsamkeiten und Besonderheiten der Interventionen innerhalb und zwischen der einzelnen Schulen der Manuellen Medizin sowie Durchführung

hochwertiger Studien zur konkludenten Bestimmung der Effizienz und Kosten-Effektivität manualmedizinischer, also auch osteopathischer Therapiemethoden.

10. Die Bewältigung dieser Aufgaben scheint nur durch internationale Harmonisierung und gemeinsame Anstrengung aller Beteiligten, inklusive der wissenschaftlichen Fachgesellschaften, der Berufsverbände, der Schulen, der Träger der Sozialsysteme und der Politik möglich zu sein.

Mit freundlichen Grüßen

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