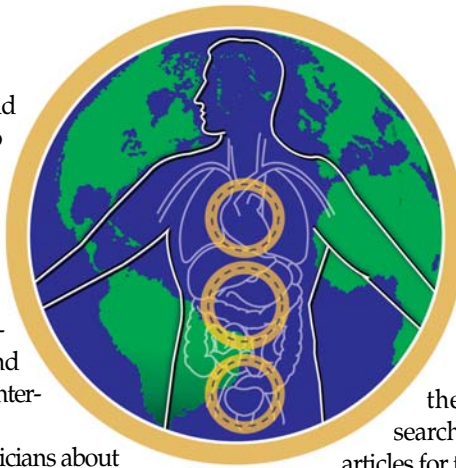


"The Somatic Connection" highlights and summarizes important contributions to the growing body of literature on the musculoskeletal system's role in health and disease. This section of *JAOA—The Journal of the American Osteopathic Association* strives to chronicle the significant increase in published research on manipulative methods in the United States and the renewed interest in manual medicine internationally, especially in Europe.

Designed to inform osteopathic physicians about significant musculoskeletal research being published in journals other than the *JAOA*, "The Somatic Connection" gives special attention to research articles directly related to the tenets and principles of osteopathic medicine.



Some research articles featured in "The Somatic Connection" may focus on tests of the efficacy of manipulative methods in a variety of clinical situations. Other articles may focus on other aspects of the musculoskeletal system, including the mechanism of chronic pain and interventions other than spinal manipulation.

To identify research articles to feature, the editors of "The Somatic Connection" search multiple electronic databases and assess articles for their scientific validity. To submit scientific reports for possible inclusion in "The Somatic Connection," readers are encouraged to contact section editors *JAOA* Associate Editor Felix J. Rogers, DO (fjrogers@aol.com), or Michael A. Seffinger, DO (mseffinger@westernu.edu).

OMT Improves Outcomes in Children With Recurrent Acute Otitis Media

Current clinical practice guidelines for the clinical management of recurrent acute otitis media (AOM) in children recommend judicious use of antibiotics and surgical placement of tympanostomy tubes when effusion persists. In addition to providing conventional medical care, osteopathic physicians have long used osteopathic manipulative treatment (OMT) to treat somatic dysfunction related to recurrent AOM.

This study was a multisite, prospective, randomized controlled trial that evaluated the efficacy of OMT as an adjuvant therapy in routine pediatric care for patients with AOM aged 6 months to 6 years. Study inclusion criteria specified that potential subjects must have had a documented diagnosis of recurrent AOM with symptoms clear for at least 2 weeks between episodes and either three episodes of AOM in the previous 6 months or four episodes in the previous year. In addition, exclusion criteria specified that potential subjects could not be current candidates for surgical intervention. Potential subjects were also excluded from study if they had immunologic or chromosomal anomalies, congenital malformation of the head, prior manual therapy, or previous otorhinolaryngologic surgery. Outcomes measured at regularly scheduled intervals during the 6-month study period were antibiotic use, AOM episodes, audiometry, behavior, surgical intervention, and tympanometry.

The OMT procedures used were chosen at the discretion of the treating physician, each of whom was an American-trained DO and an experienced OMT instructor. The entire body, including the head, was included in osteopathic evaluation and manipulative treatment. Initially, patients were given weekly treatments of 15 to 25 minutes' duration for 3 weeks. Treatment frequency then tapered downward to

biweekly treatments for 6 weeks, and finally monthly treatments for 3 months.

Seventy-six patients were enrolled and randomly assigned in a 60:40 ratio to either a standard care only group (n=45) or a standard care with adjuvant OMT group (n=31). As expected, twice as many patients in the control group dropped out of the study (13 vs 6). Fifty-seven patients (control, 32; OMT, 25) completed the study protocol. At each study site, an allopathic pediatrician managed standard care protocols and was blinded to group assignment and study outcomes. Osteopathic physicians providing adjuvant OMT were blinded to patient clinical course.

Adjusting for the baseline frequency before study entry, OMT 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 (1 vs 8 procedures; $P=.03$), and more mean surgery-free months (6 vs 5.25 months; $P=.01$). Baseline and final tympanograms obtained by the audiologist showed an increased frequency of more normal tympanogram types in the OMT 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.

The authors recommend a larger study be conducted. In addition, they conclude that there is a potential benefit of OMT as adjuvant therapy in children with recurrent AOM; it may prevent or decrease surgical intervention or antibiotic overuse. —M.A.S.

Mills MV, Henley CE, Barnes LL, Carreiro JE, Degenhardt BF. The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media. *Arch Pediatr Adolesc Med*. 2003;157:861-866. Available at: <http://archpedi.ama-assn.org/cgi/content/full/157/9/861>. Accessed November 13, 2006.

THE SOMATIC CONNECTION

Lumbar Manipulation Alters Lower Extremity Perfusion: A Pilot Study

Randomized clinical trials have demonstrated the efficacy of spinal manipulative treatment in the therapeutic management of low back pain. Cigarette smoking is known to cause a decrease in cutaneous peripheral blood perfusion. The objective of this pilot study was to determine the effect of spinal manipulation, as provided by British-trained osteopaths, on peripheral cutaneous blood flow in smokers vs nonsmokers. The authors report on the effects of lumbosacral spinal unilateral high-velocity low-amplitude thrust (HVLTAT) on cutaneous blood flow in the lumbar 5 (L5) dermatome using transcutaneous laser Doppler flowmetry.

Twenty healthy men (age range, 18 to 38 years; body mass index range, 20.1 and 25 kg/m²) were recruited for study by random selection from a student cohort. Subjects were assigned to one of two groups: group 1, nonsmokers (n=14), and group 2, smokers (n=6). Subjects in group 2 smoked between one and five cigarettes daily but were not otherwise different from subjects in group 1. Each subject underwent sham manipulation before receiving spinal manipulation, allowing subjects to act as their own control subjects. A transcutaneous laser Doppler flowmetry probe (1 mm radius) was applied to the dorsum of the foot at the L5 dermatome and distal to the second tarsometatarsal joints, intentionally avoiding the superficial venous arch and the dorsalis pedis artery. Subjects were given 10 minutes to acclimate to the examination room and to their positioning on the treatment table. Environmental parameters were kept constant for the duration of the procedure.

Sham manipulation involved researchers leading subjects through a side-lying lumbar roll setup without follow-through. Each subject received HVLTAT treatment once, and cavitation status was recorded.

Twelve nonsmoking subjects who received HVLTAT treatment showed a significant increase ($P<.001$) in blood perfusion ipsilaterally and contralaterally. Conversely, six smokers responded with a significant decrease in blood flow ipsilaterally ($P<.001$) and contralaterally ($P<.001$) after treatment with HVLTAT. No relationship was observed between the number of cigarettes smoked per day and the decrease in cutaneous blood flow. The posttreatment increase in blood perfusion continued to be evident 1 hour after the start of recording in one randomly selected subject.

No correlation was found between blood perfusion and the following objective measures: blood pressure or heart rate; tendon reflexes; history of regular physical activity; use of herbal remedies; subject-reported comfort levels during HVLTAT treatment; assessed dysfunctions at the level of L5; the side of HVLTAT; subject's age, height, weight, and calculated body mass index; and number and location of cavitations.

The authors conclude that lumbosacral spinal manipulation results in an increase in cutaneous blood flow in nonsmokers, and that it has the opposite effect in smokers. Further studies are required to confirm these findings, and more knowledge is needed regarding the specific neurophysiologic effects of spinal manipulation. —M.A.S.

Karason AB, Drysdale IP. Somatovisceral response following osteopathic HVLTAT: a pilot study on the effect of unilateral lumbosacral high-velocity low-amplitude thrust technique on the cutaneous blood flow in the lower limb. *J Manipulative Physiol Ther.* 2003;26:220–225.



Cranial OMT Affects Sleep and Sympathetic Nervous System

Patients report a sense of relaxation and drowsiness during and after the clinical use of the osteopathic manipulative procedure known as compression of the fourth [cerebral] ventricle, or CV-4. With the patient in a supine position, the physician holds the patient's primary respiratory mechanism in its extension phase of motion until the still point is obtained. This study investigated the effects of the CV-4 procedure on sleep latency (time to sleep onset after lying down), sleep duration, and sympathetic nerve activity in healthy human subjects. A randomized block design with repeated measures was used in a controlled laboratory environment at

an American osteopathic medical school.

Twenty healthy volunteers (12 men, 8 women; age range, 22 to 35 years) were randomly assigned to three study arms: control (no treatment), sham manipulative treatment (simple touch), and CV-4. In 11 subjects, sleep latency was assessed during each procedure using electroencephalography at occipital (O1 and O2) and central sites (C3 and C4); electro-oculography, right horizontal or oblique, left horizontal or oblique, and vertical; and mental/submental electromyography. In the remaining nine subjects, efferent muscle sympathetic nerve activity (MSNA) was measured using standard microneurographic techniques in the peroneal nerve in one leg. Heart rate was measured with standard limb-lead electrocardiography. Arterial blood pressure was measured noninvasively with photoplethysmography at the finger. Subjects were blinded as to which trial was sham manipulative treatment or CV-4. The same osteopathic physician provided both inter-

ventions as appropriate to group assignments. Sleep onset was defined as either three epochs of stage 1 non-rapid eye movement sleep or one epoch of stage 2 non-rapid eye movement sleep as scored by an independent sleep expert who was blinded to group assignments. Sleep latency was measured as the time to sleep onset from the time when lights in the examination room were turned off after subjects were instructed to "Please lie quietly, keep your eyes closed, and try to fall asleep."

Because the still point is achieved only by application of the CV-4 and not by touch alone or in non-touched control subjects, the time from pretreatment still point to treatment still point was measured and the same time frame was then compared with measured values in the control and manipulative treatment groups. Sleep latency was significantly decreased ($P < .05$), and length of time asleep was increased in both intervention groups. The change in MSNA at pretreatment still point vs treatment still point was significantly different ($P < .05$) when compared with time-matched control and manipulative treatment interventions. Muscle sympathetic nerve activity during treatment still point was decreased when compared with pretreatment still point MSNA ($P < .01$). Time-matched MSNA measurements were not different for control and manipulative treatment groups ($P > .05$).

This study is the first to demonstrate that cranial manipulation, specifically the CV-4 technique, can alter sleep latency and directly measured muscle sympathetic nerve activity in healthy humans. —M.A.S.

Cutler MJ, Holland BS, Stupski BA, Gamber RG, Smith ML. Cranial manipulation can alter sleep latency and sympathetic nerve activity in humans: a pilot study. *J Altern Complement Med*. 2005;11:103–108.

Effects of Cranial OMT Consistent Among DOs

Objective measures of physiologic change from osteopathic manipulative treatment (OMT) have included blood pressure and heart rate variability, cannabimimetic effects, electroencephalographic change, radiographic evidence, skin-resistance testing, and sympathetic nerve activity. The authors report on the effect of a cranial OMT procedure called compression of the fourth [cerebral] ventricle, or CV-4, on low-frequency oscillations in cutaneous blood flow velocity as measured by transcutaneous laser Doppler flowmetry (LDF). Each biologic process has its own biorhythm or rhythmic fluctuation. The oscillations of these biorhythms can be measured by various devices, including LDF. Computer software and LDF technology allow researchers to discern various frequencies of body rhythms (ie, other than the directly measured cutaneous blood flow) that may be affected by OMT. The CV-4 procedure has previously been shown to affect the low-frequency component of blood flow velocity measurements, but not the higher frequency components (eg, respiratory or cardiac fluctuations). In other unrelated studies, CV-4 has also been shown to decrease sleep latency (brain electronic rhythmic fluctuations)

and sympathetic nerve activity (sympathetic nerve rhythmic fluctuations).

This study was conducted at the annual American Academy of Osteopathy Convocation in Colorado Springs, Colo, March 18 to 19, 2004. Twenty-eight DOs and 26 healthy adult subjects participated. The LDF consists of a fiber optic probe that rests on the skin surface of subjects' foreheads. The probe has two optic fibers, one that sends laser light into the subcutaneous capillaries while the other transfers the reflected light from passing hemoglobin molecules to a photo detector for electronic processing. The Doppler effect is used to calculate blood flow velocity and display this number on a standard scale. Physicians were asked to verbally cue investigators when initiating the CV-4 procedure, when the subject's inherent motion was palpably minimized (ie, the still point was achieved), and again when that motion had resumed. The LDF measurements were compared with resting measures in both pretreatment "control" and posttreatment response. Sham treatment was not used.

The mean (SD) length of treatment was 4.43 (2.22) minutes. The most consistent and significant change in blood flow velocity oscillations was at the 0.1 Hz frequency (ie, the baro or Traube-Hering wave). These low-frequency oscillations are manifestations of autonomic vascular regulation. An analysis of variance established significant differences between groups (ie, pretreatment, during CV-4, and posttreatment) at both the 0.08 Hz ($P = .041$) and 0.1 Hz ($P = .000$) low frequencies, but not at the higher, cardiac cycle-related frequencies or at very low temperature regulation-related frequencies (0.02 Hz). Amplitude of the 0.1 Hz frequency decreased during CV-4 and was dampened or eliminated at the still point. Posttreatment measures of the 0.1 Hz oscillation were significantly amplified ($P = .011$) when compared with pretreatment control and CV-4 measures.

The authors conclude that CV-4 has quantifiable physiologic effects on low-frequency oscillations of blood flow velocity as measured by the transcutaneous LDF. This research model enables researchers to objectively ascertain when the procedure was in use, whether a still point was reached, and whether a physiologic effect was obtained. The potential health benefit of these physiologic changes induced by CV-4 has yet to be investigated. —M.A.S.

Nelson K, Sergueef N, Glonek T. The effect of an alternative medical procedure upon low-frequency oscillations in cutaneous blood flow velocity. *J Manipulative Physiol Ther*. 2006;29:626–636.

Editor's note: Please see the authors' recent contribution to *JAOA—The Journal of the American Osteopathic Association*:

Nelson K, Sergueef N, Glonek T. Recording the rate of the cranial rhythmic impulse. *J Am Osteopath Assoc*. 2006;106:337–341. Available at: <http://www.jaoa.org/cgi/content/full/106/6/337>. Accessed November 20, 2006.

THE SOMATIC CONNECTION

Spinal Manipulation and Exercise: An Efficacious and Cost-Effective Option for Patients With Low Back Pain

Back pain in working adults is a significant economic problem in industrialized nations. This study was conducted in the United Kingdom, where socialized medicine pays for standard medical care as well as spinal manipulation provided by physical therapists and registered osteopaths or chiropractors. Manual treatment services are also offered in the private sector. In 2003, there were about 5000 manipulative physiotherapists, 3200 registered osteopaths, and 2100 registered chiropractors in the United Kingdom.

The study assessed the efficacy and cost-effectiveness of adding two commonly used treatment modalities to standard medical care for patients with low back pain: exercise classes and spinal manipulation, individually and combined, as compared with “best care” in general practice” alone. The best care control model encourages “active management” of back pain: exercise, back reeducation with the assistance of a self-care book, and the use of nonsteroidal analgesics for pain control.



The exercise intervention model requires an initial assessment and up to nine classes within 12 weeks. An original spinal manipulation model was used, however. This study is the first pragmatic randomized clinical trial to combine the work of manipulative physiotherapists with that of registered osteopaths and chiropractors. Developed by consensus with representatives from each of these three professional groups, the study's protocols for spinal manipulation were provided in eight sessions during 12 weeks. Although practitioners could use a variety of manual treatment techniques from the consensus protocol, they were expected to provide at least one high-velocity thrust procedure during the study period.

The combined treatment model consisted of 6 weeks of spinal manipulation followed by 6 weeks of exercise. Study subjects were randomly assigned to one of the four study groups. In addition, those receiving spinal manipulation were randomly assigned between study sites (ie, private vs National Health Service sites).

One hundred eighty-one general practices and 63 community care providers at 14 centers across the United Kingdom participated in this study, enrolling 1334 patients, of whom 1287 (96%) completed study protocols. Primary outcome measures were healthcare costs, quality adjusted life years (QALYs), and cost per QALY at 12 months.

Within 1 year, mean treatment costs relative to “best care” were £195 (approximately \$368 as of November 16, 2006; €279; 95% confidence interval [CI], £85 to £308 or \$161 to \$582) for manipulation, £140 (\$264; CI, £3 to £278 or \$6 to \$525) for exercise, and £125 (\$236; CI, £21 to £228 or \$40 to \$431) for combined treatment. At 12 months, spinal manipulation, exercise classes, and manipulation followed by exercise all increased QALYs more than did best care. The authors concluded that spinal manipulation for back pain is a cost-effective addition to best care practices.

The authors emphasized that these conclusions hold even if the National Health Service purchased spinal manipulation from the private sector. —M.A.S.

UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ*. 2004;329:1381. Available at: <http://www.bmj.com/cgi/content/full/329/7479/1381>. Accessed November 13, 2006.

Manipulation Improves Outcomes for Patients with Mechanical Neck Pain

Current clinical practice guidelines for the management of mechanical neck disorders recommend a combination of manual treatment and exercise to obtain the best outcomes. However, systematic reviews of the randomized clinical trials (RCTs) on which these recommendations are based noted that RCTs for this application are heterogeneous with regard to methodologic quality, study populations, interventions, reference treatment modalities, and outcomes measured.

They also lack the statistical power to detect clinically relevant differences between interventions. More than half of the studies do not include long-term follow-up.

The authors of this Dutch study conducted a pragmatic RCT to investigate whether general practitioners (GPs) should treat patients with nonspecific neck pain or refer them to physical or manual therapists. Having previously shown in an RCT that manual treatment is more beneficial and cost-effective in the short term (Korthals-de Bos IB et al. Cost effectiveness of physiotherapy, manual therapy, and general practitioner care for neck pain: economic evaluation alongside a randomised controlled trial. *BMJ*. 2003;326:911), the authors conducted a comparison of the relative efficacy of three treatment strategies: GP care (analgesics, counseling, and education), physical therapy (exercise, traction, and massage), and manual therapy (spinal mobilization and exercise).

Researchers recruited 183 patients (age range, 18 to 70 years) from 42 GP offices. Study inclusion criteria speci-



fied that subjects have at least 2 weeks of nonspecific neck pain that was reproducible during active or passive range of motion testing. Patients were excluded from participation in the study if they had previous neck surgery or had received either manual or physical therapy in the previous 6 months. Subjects were randomly assigned to receive treatment for 6 weeks in one of the following three study groups: (1) GP care biweekly, (2) weekly manual therapy, or (3) physical therapy twice weekly—all customary intervals in the Netherlands. After the 6-week intervention, at the discretion of their GPs, patients could receive referrals for an additional intervention.

The primary outcome measures of the study were: perceived recovery, severity of physical dysfunction, pain intensity, and functional disability. Two independent research assistants blinded to treatment allocations conducted the physical examinations. Additional outcome assessments were determined by self-administered patient questionnaires.

At 1 year, the differences between baseline measures and final outcomes data were statistically significant (repeated measures analyses, $P < .001$ to $P = .02$) for all three study groups—except for the Neck Disability Index, which was considered “borderline” ($P = .06$). The highest improvement scores were observed in the manual therapy group for all outcomes at 7 weeks, followed by physical therapy and GP care. The success rate, based on subject-perceived recovery at 13 weeks, was 72% for manual therapy, which was significantly higher than the success rate for continued GP care (42%, $P = .001$), but not significantly higher than physical therapy (59%, $P = .16$). Differences between physical therapy and GP care were slightly short of statistical significance ($P = .06$). At 1 year, success rates were no longer statistically significant among the three study groups.

Short-term results at 7 weeks demonstrated that manual therapy speeded recovery compared with GP care and, to a lesser extent, physical therapy. In the long term, at 1 year, success from GP treatment and physical therapy caught up with the results seen in manual therapy. However, compared with those subjects in the manual therapy group, twice as many patients in the GP and physical therapy groups received co-interventions after the treatment period. This factor may have affected the improvement noted in the long-term outcome measures for patients in those two study groups. As noted, data gathered from this study have demonstrated the cost-effectiveness of manual therapy. —M.A.S.

Hoving JL, de Vet HC, Koes BW, Mameren H, Deville WL, van der Windt DA, et al. Manual therapy, physical therapy, or continued care by the general practitioner for patients with neck pain: long-term results from a pragmatic randomized clinical trial. *Clin J Pain*. 2006;22:370–377.

The good physician treats the disease; the great physician treats the patient who has the disease.

Sir William Osler (1849–1919)