Manual medicine diversity: research pitfalls and the emerging medical paradigm

ERIC A. MEIN, MD; PHILIP E. GREENMAN, DO; DAVID L. MCMILLIN, MA; DOUGLAS G. RICHARDS, PhD; CARL D. NELSON, DC

Recent studies published in leading medical journals have concluded that chiropractic treatment is not particularly helpful for relieving asthma and migraine symptoms because even though study participants showed notable improvement in symptoms, those subjects who received sham manual medicine treatments also showed improvement. Yet the sham treatment received by control groups in these studies is reminiscent in many ways of traditional osteopathic manipulation. This seems to represent not only a failure to recognize the value of many manual medicine techniques but also an ignorance of the broad spectrum of manual medicine techniques used by various practitioners, from osteopathic physicians to physical therapists. Such blind spots compromise research methodology with regard to manual medicine studies, which could, in turn, diminish the role of manual medicine in clinical practice. Osteopathic manipulative treatment provides an excellent model for recognizing and integrating the full range of manual medicine techniques into research and clinical applications because of the wide range of techniques employed. The potential exists for these techniques to contribute much to medical research and clinical practice—provided that osteopathic physicians and other manual medicine practitioners work to alleviate ignorance about the efficacy of various forms of manipulation.

(Key words: osteopathic manipulative treatment, chiropractic, research design, alternative medicine)

Manual medicine covers a broad spectrum of techniques, including soft tissue treatment and high-velocity low-amplitude (HVLA) thrusting. In osteopathic terminology, these and many other manual medicine techniques as a whole are commonly referred to as osteopathic manipulative treatment (OMT).1

Dr Mein is medical director at Meridian Institute, Virginia Beach, Virginia, where Mr McMillin is program director, Dr Richards is director of research, and Dr Nelson is a clinical researcher. Dr Greenman is professor emeritus at Michigan State University College of Osteopathic Medicine, East Lansing, Mich. Correspondence to Eric A. Mein, MD, Meridian Institute, 1853 Old Donation Parkway, Suite 1, Virginia Beach, VA 23454. E-mail: meridian@meridianinstitute.com

Although many osteopathic physicians take the variety of techniques for granted because of the rich heritage of their profession, there remains ignorance of manual medicine diversity in the healthcare community at large, and this has led to serious shortcomings in current research methodology with regard to manipulation. Consequently, the role of manual medicine in the emerging medical paradigm is uncertain.

Healthcare services that use manual medicine include osteopathic medicine, chiropractic, physical therapy, and massage therapy. Specific types of practitioners often rely more often on certain techniques or sets of techniques than do other practitioners (for example, long-lever techniques with osteopathic physicians, HVLA adjustments with chiropractors), but there remains considerable diversity within manual medicine-oriented professions and significant overlap between them. However, the research literature often fails to reflect this diversity. For example, one recent study of treatments for low back pain refers simply to “chiropractic” in the abstract and throughout most of the article, as if a general set of modalities were being applied (the article only noted briefly that side-posture, HVLA adjustments were the only chiropractic modality used).2

Early osteopathic physicians used a variety of articular and nonarticular approaches to achieve their goal of normalizing blood flow. They used general mobilizations (the osteopathic "general treatment"), long- and short-lever manipulations of the entire musculoskeletal system, strain-counterstrain, and specific pressures ("stimulation" and "inhibition") to influence and regulate sympathetic nervous system functions. Also, drainage techniques were part of commonly accepted practice.3

Early chiropractors, with the goal of normalizing nerve function by reducing the vertebral subluxation, were somewhat more limited in their approach, relying primarily on HVLA thrusts. As time has passed, chiropractors have added considerably to their body of therapeutic applications, broadening their range of manual articular techniques; adding manual reflex and muscle relaxation techniques; and incorporating nonmanual therapeutic modalities, such as electrical and thermal modes of therapy, bracing, casts, support, traction, and nutritional counseling—all of which have been beneficial. However, in their research approach to demonstrate the validity of manual medicine, chiropractors have focused almost entirely on the HVLA spinal adjustment, ignoring the diversity of other manual techniques with claims of effectiveness.4

Problematic research methodology

Two well-publicized studies reported in leading medical journals illustrate the potential methodologic problems associ-
cavitation occurred."  

nontherapeutic contacts, with adequate 

tolerance; low-velocity impulses "in all these 

berance"; and (6) applying low-ampli-

ders; (2) "turning the subject's head from 

the spine, paraspinal muscles, and shoul-

tissue massage and gentle palpation" to 

standard HVLA technique used by a wide 

joints followed by high-velocity low-

"manual contact with spinal or pelvic 

childhood asthma, conducted by Balon 

manner to a traditional general osteopathic 

controlled treatment bears a marked similari-

of this widely publicized study.  

confounding of the studies do not allow us to draw such 

accurate conclusion should have been 

favorable outcomes could have resulted from chance or placebo 

effects, a reasonable person might also 

justifiably conclude that various forms 

The active treatment consisted of 

most commonly to the sacrum or iliac 

and use of β-agonists decreased and the 

depicted to be indicative that the subjects in 

OMT could be used in treatment of 

mons of the researchers, it would seem 

omitted; and (6) applying low-ampli-

ture have noted.  

spinal manipulation to usual medical care pro-

manipulation does not seem to have a 

the design and outcome of 

the functional differences between 

the groups. The conclusion was that 

"the addition of chiropractic spinal 

from two 

able affect attitudes toward all types of 

practitioners. The problem is that while 

sbe indicative of the diversity of 

ominal medicine options from a variety of health-

ratory conditions, particularly by 

Kuchera and Kuchera.  

The methodology limitations of the study by Balon 

and others with regard to manual 

Kuchera and coworkers responded that they 

were unconvinced by the evidence sup-

supporting the efficacy of their "simulated 

treatment."  

The results as reported by the re-

searchers were "Symptoms of asthma 

and use of β-agonists decreased and the 

quality of life increased in both groups, 

without significant differences between 

The conclusion was that 

"the addition of chiropractic spinal 

manipulation to usual medical care pro-

vided no benefit."  

Thus, the conclusion suggests an 

apparent failure of chiropractic to address 

systemic dysfunction, such as asthma. Although technically this conclusion is 

limited to HVLA spinal adjustments, the 

fallout will, for all practical purpose, probably 

affect attitudes toward all types of 

manual medicine and manual medicine 

practitioners. The problem is that while 

the study is widely perceived as indicating a failure of manual medicine for the treatment 

of systemic dysfunction, it may 

indeed be indicative that the subjects in 

both groups benefited—but from two 

distinct forms of manual medicine. 

Ignorance of the diversity and validity of the full spec-

trum of manual therapy applications con-

founds the issue.  

One research is desper-

ately needed—research which seriously 

considers the full spectrum of manual 

medicine options from a variety of health-

care professions. 

Developing an appropriate research 

methodology is a challenge. Consideration 

must be given not only to the diversity of 

potentially effective manual techniques, 

but also to the difficulty of identifying a sim-

ulated treatment with no physical effects. 

Even light stroking of the skin may have 

significant effects on physiology. 

In contrast to randomized clinical trials of drugs, 

double-blind methodology is not possible 

with manual medicine research; the ther-

apist is always aware of the technique 

being applied. Even blinding patients is 

problematic, particularly if they have pre-

vious exposure to manual techniques. 

Rather than a treatment/placebo com-

parison, perhaps the only possible com-
The diversity of manual medicine techniques provides a variety of approaches that could have significant cost-saving potential. This is particularly true for simple regulatory techniques, as contrasted with corrective techniques. For example, inhibitive pressure and thoracic lymphatic pump applications can be easily adapted for application by lay persons and therapists.

In a study on labor pain during contractions of gravid uterus at term, lumbar inhibitory pressure was shown to be effective in reducing pain in a group of 175 women. This simple technique was applied by husbands and other family members, as well as by nurses and physicians. "Since back pressure in a high percentage of cases was administered by the husband, this suggests that training of husbands in the proper technique would minimize staff time required in labor and delivery, as well as the need for medication."

Also, thoracic lymphatic pumping (TLP) has been shown to be at least as effective as incentive spirometry in preventing atelectasis in patients who have undergone cholecystectomy. In addition to its treatment efficacy, the authors noted that TLP costs were lower than those for incentive spirometry and that "the TLP treatment costs could be further reduced by training a respiratory therapist to administer the treatment."

There is historical precedent for involving lay persons and therapists in the less technical manual therapy applications. The early osteopathic physicians recognized a hierarchy of expertise with regard to technique. One early osteopathic textbook was specifically written with the lower end of this hierarchy in mind. In the preface to the second edition of his book, Eduard Goetz acknowledged the accessibility of simple manual medicine applications when he wrote, "The mere reading of the book cannot possibly result in one's becoming a full fledged osteopath. The intention is simply to impart sufficient knowledge of the mode of procedure to enable the careful reader to apply the treatment in his home in case of emergency and until such a time as a regular practicing osteopath can be called in should that be found necessary." (For those interested in the work of Goetz and other early osteopathic physicians, some of their texts are now available on the Early American Manual Therapy Website at www.meridianinstitute.com.)

When considering the relatively low level of expertise required to perform deep friction massage and soft-tissue techniques, such as those used as control treatments in the previously discussed asthma and tension headache studies, one wonders if there might be a role for family members or massage therapists in treating conditions like asthma and headache. Theoretically, the physician could become an educator, trainer, and supervisor of the treatment regimen for a singular condition with the increased emphasis on home health and cost-effectiveness, this could be a workable model in the new medical paradigm—so long as issues of training and safety are addressed.

Osteopathic medicine is now presented with the opportunity to contribute to the broader emerging medical paradigm with regard to research into manual medicine and clinical applications of manual techniques. Osteopathic physicians are in an excellent position to shape the new paradigm, but they also face the danger of sitting quietly on the sidelines while others determine the role of manual medicine in the evolving healthcare system.

References
Case report

Digoxin toxicity in a 26-year-old woman taking a herbal dietary supplement

MICHAEL E. SCHEINOST, DO, PhD

Herbal dietary supplements are often considered by patients to be safe and free from side effects. The case described here shows digoxin toxicity in a patient taking a dietary supplement not normally considered to contain digoxin. In addition to highlighting the risks of herbal supplements, this case also demonstrates the concept that digoxin equivalents are not picked up by the standard digoxin assay. (Key words: digoxin, dietary supplements)

Use of herbs as dietary supplements has become common in the United States. According to a 1997 survey, 12.1% of the households interviewed were using herbal medicines. The out-of-pocket expense for these medicines was estimated at $5.1 billion. Unfortunately, many people do not know the possible side effects of these treatments. Too often, patients perceive that because herbal medications are “natural,” they are therefore safe to take without fear of side effects.

This case presents an otherwise healthy young female who was taking an herbal supplement for emotional stress. She came to the emergency department because of chest pain, and subsequently became bradycardic and hypotensive. The patient was then found to have an elevated digoxin level.

Report of case

A 26-year-old woman presented to the emergency department via ambulance with chest pain of approximately 7 hours' duration. The patient was a topless dancer who started having the chest pain while at work. The pain was described as a shooting pain that was “in her ribs” on the left side. She went home after work and continued to have pain, and it eventually became severe enough that she decided to visit the hospital.

She had no known drug allergies. The patient’s only medication was birth control pills. Her past medical history was negative, and her past surgical history was negative. The social history was significant in that the patient reported tobacco use (1 pack/day) and reported that she had ingested four alcoholic drinks over the course of her shift at work. The patient denied use of illicit drugs. Review of systems was noncontributory.

Physical examination was significant only for chest pain, which was reproducible to palpation over the left chest, superior to the breast, and approaching the left sternal border. The patient's heart exhibited regular rate and rhythm without murmur. Her lungs were clear to auscultation. Vital signs included temperature, 98.6°F; respirations, 16 breaths/min; heart rate, 76 beats/min; and blood pressure, 112/59 mm Hg. The rest of the examination was unremarkable.

In the emergency department, the patient was given oxygen via nasal canula, and she was placed on a cardiac monitor—according to standard chest pain protocol. During the course of monitoring, her heart rate dropped to 39 beats/min and her blood pressure dropped.


17. Guthrie RA. Lumbar inhibitory pressure for lumbar myalgia during contractions of the gravid uterus at term. JAOA 1980;80:264-266.

to 59/36 mm Hg. The monitor showed an absence of P waves (Figure 1). The patient was placed in Trendelenburg’s position and infused with normal saline. Before a 12-lead EKG could be obtained, the patient’s heart rate and blood pressure returned to original baseline. Cardiac laboratory results and urine drug screen results were normal with the exception of a digoxin level of 0.9 ng/mL (normal therapeutic range, 0.5 to 2.0 ng/mL).

Further discussion with the patient revealed that she had been under a great deal of stress recently and that she had been taking an herbal dietary supplement that contained skullcap herb (Scutellaria lateriflora), wood betony herb (Pedicularis canadensis), black cohosh root (Cimicifuga racemosa), hops flowers (Humulus lupulus), valerian root (Valeriana officinalis), and cayenne pepper fruit (Capsicum annuum). She denied taking any more than the indicated dosage of one to two capsules three times a day. Poison control center personnel suggested that the herbs in the patient’s supplement could cause bradycardia and hypotension. The recommendation was to observe the patient, provide supportive care, and to instruct her to stop taking the medication. The patient was admitted to telemetry for 24-hour observation. She was discharged in normal sinus rhythm and was lost to subsequent follow-up after this time.

Comments
Use of herbal dietary supplements in the United States has become a multibillion dollar industry.1 Because many of these products are listed as dietary supplements, no US Food and Drug Administration controls are exerted over the quality or quantity of herbs in any given product. Patients tend to see such products as harmless supplements and therefore rarely inform their physicians of herbal supplement use, unless specifically asked about such use. In this case, the patient was taking an herbal supplement to help relieve her stress—as the product name suggested the supplement would do. The only warning on the product label was one

### Table
Digoxin-like “Factors” in Selected Herbs

<table>
<thead>
<tr>
<th>Herb</th>
<th>NKA*</th>
<th>RIA†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cayenne</td>
<td>4.85</td>
<td>0.004</td>
</tr>
<tr>
<td>Hops</td>
<td>2.51</td>
<td>0.013</td>
</tr>
<tr>
<td>Skullcap</td>
<td>1.84</td>
<td>0.014</td>
</tr>
<tr>
<td>Wood Betony</td>
<td>0.656</td>
<td>0.008</td>
</tr>
<tr>
<td>Valerian</td>
<td>0.579</td>
<td>0.006</td>
</tr>
<tr>
<td>Black Cohosh</td>
<td>0.555</td>
<td>0.013</td>
</tr>
</tbody>
</table>

*NKA = inhibition of Na, K-ATPase ouabain binding.
†RIA = cross-reactivity to digoxin antibody in radioimmunoassay.
Adapted from Longerich et al.2

Figure 1.
Emergency room monitor strips.
that stated, “Do not drive or operate machinery while using this product, as drowsiness may result.”

Longerich and colleagues showed that many of the herbs used in teas contain digoxin-like “factors.” Like digoxin, these “factors” are cardioglycoside compounds, and they exert the same effect on the myocardium as does digoxin. Table 1 lists the digoxin activity equivalents for the herbs in the supplement described in this case study. Note that there is a difference between the amounts of digoxin-like “factors” measured by the two methods. This suggests that while the measured amount of “digoxin” in this patient was 0.9 ng/mL, the effective amount of digoxin-like “factors” in the blood may have been much higher.

Digoxin antibody immunoassays only detect those digoxin-like compounds with a chemical structure similar enough to digoxin to bind to the antibody. Such tests do not detect compounds with enough difference in the structure to avoid binding, but which still exhibit significant cardioglycoside activity. This activity is measured by the ouabain Na,K-ATPase binding assay that detects those compounds, which will exert an effect on the digoxin receptor on the myocardium. The assay works by detecting the ability of compounds to displace radio-labeled ouabain from Na,K-ATPase and comparing it to the ability of digoxin to displace the ouabain from the Na,K-ATPase (the site of action for digoxin in the body). While the patient denied taking any more pills than was suggested on the label, actual amounts consumed cannot be verified.

The product the patient had taken was not available for further analysis. Therefore, we could evaluate neither the precise amounts of the specified herbs nor contamination of the product with other herbs. Over the past several years, some herbal supplements have come under increased scrutiny as a result of patient illnesses. A recent report describes digoxin toxicity in two patients taking an herbal supplement for cleansing of the bowel. The shipment of plantain used in the supplement was shown to be contaminated with Digitalis lanata. A number of other plants, including oleander (Nerium oleander, a cause of accidental poisoning in children), have been shown to contain cardiac glycosides. Furthermore, an analysis of traditional Chinese medicines in California showed that 32% contained undeclared compounds.

This case serves to remind us, as physicians, of the importance of discussing alternative medicines with patients. Our patients take a wide variety of herbal medications, including saw palmetto (Serenoa repens or Sabal serrulata) for prostate problems, ginkgo (Ginkgo biloba) for dementia and memory problems, echinacea (Echinacea purpurea or Echinacea angustifolia) for immunostimulation, pleurisy root (Asclepias tuberosa, which also contains high quantities of digoxin-like compounds) for asthma, and so on. Furthermore, many patients take combination products that contain several different herbal compounds. All of these kinds of herbal supplements can potentially interact with medications that patients may be taking.

Depending on the reliability of the source of the herbs, these supplements also may be contaminated with other plants that are not intended to be in the product. Such contamination can significantly interfere with treatments we may be giving outpatients. Such contamination also means the patient may be unknowingly receiving medicinal substances that they do not need or want, such as digoxin or digoxin-like factors. We must remember to ask our patients not just what medicines they are taking, but also what dietary supplements they may be using.

References