

ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

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Chiropractic for Low Back Pain

By Felise Milan, MD

THE LIFETIME PREVALENCE OF LOW BACK PAIN IN INDUSTRIALIZED nations is 70%.¹ More than one-third of those afflicted with low back pain seek care from a health care provider.² Low back pain is the second most common reason for office visits to primary care providers and the most common reason for visits to orthopedists, neurosurgeons, and occupational medicine physicians.³ This results in 17.4 million visits to physicians per year with an estimated cost of \$190 million per year.⁴

Low Back Pain in Women

Although some reports suggest an equal incidence of low back pain in men and women,⁵ others have found that women are at greater risk for low back pain.¹ Risk of low back pain in women is associated with older age, smoking, parity, and occupational factors.¹ One study in the Netherlands found a 26% prevalence of low back pain in women who worked in nursing homes, with frequent recurrences over a year.⁶ In older women, there is an especially strong association between back symptoms and functional limitations. One study found more than half of functional limitations were attributable to back symptoms in older women.⁷

There has been some exploration of the role of female sex hormones and their influence on joint laxity in women.¹ Although there is not a clear causative mechanism in humans, there is some evidence from animal models that estrogen interacts with articular cartilage.¹ Increased pelvic laxity during pregnancy has been demonstrated and prevalence of low back pain during pregnancy was 49-67% in one study.¹ Another study found 68.5% of pregnant women reporting low back pain and 58% reporting sleep disturbance and impaired daily living secondary to low back pain.⁸ Although low back pain is prevalent in pregnancy and the postpartum period, the relationship between epidural anesthesia and low back pain remains controversial.⁹

No difference in the incidence of low back pain has been found in women taking oral contraceptives (OCPs),¹⁰ but postmenopausal women who took OCPs in the past may be at increased risk for low

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back pain.¹¹ In one study of more than 7,000 older women, postmenopausal estrogen use was associated with increased rates of low back pain. This association was stronger in current hormone replacement therapy users and independent of vertebral fractures.¹

Chiropractic: Background Information

Spinal manipulation as a technique for treating musculoskeletal pain has been documented as far back as ancient China and Greece. The profession of chiropractic was developed in 1895 by Daniel David Palmer, a grocer and magnetic healer in Davenport, Iowa. Chiropractic (Greek for done by hand) was founded on the principle that joint dysfunction and misalignment of the spine may play a significant role in health and disease. Spinal manipulation, therefore, can correct these problems and facilitate the return of health and equilibrium. Early in its history, the profession experienced a theological split between two factions. The "straight" chiropractors insisted on remaining true to the original theories proposed by Palmer, while the "mixers" felt that it was more realistic to incorporate other theories of health and disease, such as infection, which were being adopted by the scientific

community of the time. This lack of uniformity within the field continues today.¹²

There are 17 accredited colleges of chiropractic in the United States with a total of 2,000 graduates per year. Two years of college is required for admission and the five-year curriculum requires 4,000 hours of basic science instruction and 1,000 hours of clinical internship for graduation. The National Board of Chiropractic Examiners administers a three-part licensing exam. Most states also require a practical exam for state licensure.¹³ All 50 states require licensure, but individual states vary with regard to their permitted scope of practice. For example, all states allow a spine-focused history and physical exam, X-rays, and spinal manipulation, and 90% also permit a more general history and physical, health advice, and ordering tests (ranging from blood work to CT scans). It is advisable for any physician to find out from his/her own state's licensing body what his/her state allows.

Chiropractic: Efficacy Data for Low Back Pain

The literature for chiropractic undoubtedly has been the most scrutinized of all the complementary and alternative medicine fields. Chiropractic research has faced the same challenge as other therapies that involve strong doctor-patient interactions and hands-on and individualized therapy with criticism of its methodology. An expert panel assembled for the RAND Corp. critically reviewed the literature on the efficacy of spinal manipulation for acute and chronic low back pain, neck pain, and headache. Although several of the studies had poor research design, the consensus of the panel was that for acute, uncomplicated low back pain, spinal manipulation hastens recovery and decreases work time lost. Its long-term effect either in preventing chronic low back pain or a recurrence of acute low back pain is unknown at present.¹⁴ Two more recent reviews concluded that there was limited evidence to suggest that spinal manipulation is better than placebo, physical therapy, and exercise in the treatment of acute low back pain.^{15,16} These same authors, however, felt that there was strong evidence of efficacy in the treatment of chronic low back pain.

The U.S. Agency for Health Care Policy and Research¹⁷ and its British equivalent, the Clinical Standards Advisory Group,¹⁸ both have suggested that spinal manipulation is better documented as an effective treatment for acute mechanical low back pain than any other except nonsteroidal anti-inflammatory drugs (NSAIDs).

A recent meta-analysis of 39 randomized controlled trials (n = 5,486) compared spinal manipulative therapy to sham therapy, therapies considered ineffective

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(traction, bed rest, corset, home care, topical gel, and diathermy), and therapies conventionally advocated (physical therapy, exercise, back school, care by general practitioners, and analgesics).¹⁹ The authors found that spinal manipulative therapy (SMT) was more effective than either sham or ineffective therapies in relieving

short-term pain for both acute and chronic low back pain. For chronic low back pain, SMT was more effective for relieving short- and long-term pain as well as improving short-term function. (See Figures 1 and 2.) SMT was equally as effective as all therapies conventionally advocated on all outcome measures.¹⁹

Use of Chiropractic in the United States

By Felise Milan, MD

WITH 60,000 PRACTICING CHIROPRACTORS, THEY COMPRISE the third-largest group of health care providers in the United States after physicians and dentists. It is the largest and fastest-growing group of complementary and alternative medicine (CAM) providers in the United States, and its ranks are projected to nearly double by 2010. One in three persons with low back pain sees a chiropractor, amounting to 190 million patient visits per year. This figure has doubled in the past 15-20 years.¹ Most patients self-refer with only 3% of patients being referred by MDs. Most insurance carriers, including Medicare, cover chiropractic. Some plans now require a referral from a MD for coverage of the service. Several studies have attempted to determine what makes some patients with back pain seek chiropractic instead of or in addition to conventional medical care. Results have been inconsistent²⁻⁴ except for the finding that chiropractic use is associated with having insurance that covers the service or having no health insurance at all.^{3,4}

A national telephone survey conducted in 1997 (n = 2,055) showed that 29% of those interviewed used some type of CAM therapy to treat back and neck pain, 25% used CAM in addition to a conventional provider, and 34% used neither.⁵ Chiropractic was the most commonly reported CAM therapy used at 20%.⁶ Women were more likely than men to use CAM providers to treat neck or back pain. In this same sample, conventional practitioners were perceived by 27% to have been "very helpful" in treating their neck or back pain while chiropractors were rated as very helpful in 62% of cases.⁶

Several randomized controlled and observational trials have examined patient satisfaction with chiropractic vs. medical care for low back pain. They have consistently found that patients prefer chiropractic care to care by physicians.^{4,7-11} Satisfaction levels are better or similar to those reported by patients receiving care for low back pain from physical therapists.^{9,12}

A large randomized controlled trial (UCLA Low Back Pain Study) examined what factors accounted for the difference in satisfaction between chiropractic and medical patients with low back pain.⁹ In their cohort of 672 patients, satisfaction was significantly greater in the patients randomized to receive chiropractic care (P < 0.001). The difference

in satisfaction was accounted for almost entirely by the patients' reports of having received an explanation of treatment and self-care advice. This finding is not surprising when you consider that 85% of patients with isolated low back pain are not given a precise pathoanatomical diagnosis within the conventional medical framework.¹³ ♦

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Figure 1**Spinal manipulative therapy for acute low back pain compared to sham, ineffective therapies¹⁹**

	Clinically significant improvement	Statistically significant improvement
Short-term pain	+	+
Long-term pain	-	-
Short-term function	+	-

Figure 2**Spinal manipulative therapy for chronic low back pain compared to sham, ineffective therapies¹⁹**

	Clinically significant improvement	Statistically significant improvement
Short-term pain	+	+
Long-term pain	+	+
Short-term function	+	+

Table 1**What to ask a chiropractor**

- What therapies do you incorporate into your practice?
- Do you prescribe any supplements? If so, what kind?
- Do you believe in the usefulness of “maintenance therapy”? Do you recommend it for your patients?
- What problems do you feel comfortable treating? What would be a welcomed referral?

There has been some work recently to develop²⁰ and validate²¹ a clinical prediction rule to identify which patients with low back pain are the most likely to benefit from spinal manipulation. Although having a clinical prediction rule potentially would be useful, it has been studied in a military population with physical therapists administering a standardized manipulation therapy,²¹ making it difficult to generalize the results to the general population receiving individualized SMT from chiropractors.

Safety

One of the myths about chiropractic is that spinal manipulation, especially cervical, is actually dangerous. In fact, the estimated risk of a major complication from cervical spine manipulation is 6.39 per 10 million

manipulations and 1 per 100 million manipulations for lumbar spine manipulation.²² This compares quite favorably to the other forms of therapy for the same conditions. The rate of serious complications for spinal surgeries is 15.6 per 1,000 surgeries and 3.2 per 1,000 subjects for NSAIDs.²² Although serious complications from manipulation of the lumbar spine are exceedingly rare, there has been much concern about case reports of vertebral artery stroke attributed to cervical spine manipulation. The incidence of this has been estimated to anywhere from 1 in 0.5 million to 1 in 5.85 million cervical manipulations.^{23,24} The rarity of vertebral artery stroke makes this association very difficult to study.

Contraindications to manipulative therapy include severe rheumatoid arthritis with ligamentous laxity, bleeding disorders or anticoagulation therapy, and conditions that render the bony structures susceptible to trauma such as acute fractures, bone tumors, and severe osteoporosis. It is not unusual for patients to report benign effects from manipulation such as increase in symptoms, myalgias, and fatigue. These effects usually are transient and need not prohibit further manipulation treatments.

Clinical Practice

As mentioned above, the field of chiropractic is not unified in the philosophies that it promotes. This manifests itself in varying practice styles and practices among different chiropractors. Before making a chiropractic referral, it is useful to find out what you and your patient can expect from the practitioner. (*See Table 1.*) Some chiropractors limit their practice to spinal manipulation, and others may use any variety of other therapeutic interventions including exercise, dietary changes, and dietary and nutritional supplements. Some promote the idea of routine spinal manipulation on an ongoing basis (maintenance therapy), while others believe it is inappropriate and focus on successfully treating the presenting problem. Some tout the use of chiropractic for any and all physical problems, but others use it almost exclusively for musculoskeletal problems and perhaps for other problems for which chiropractic has been proven efficacious.

Conclusion/Recommendation

Spinal manipulative therapy is safe and as effective as any of the more conventional therapies that routinely are recommended for the treatment of low back pain. Patient satisfaction with chiropractic for the treatment of low back pain is consistently higher than for patients who visit physicians. (*See “Use of Chiropractic in the United States” on page 19.*) This may be explained by

the relative inadequacy of the explanation that physicians are able to provide and paucity of self-care advice provided compared to chiropractors. It also may be due, in many patients, to an actual improvement in their pain and function. In the future, it may be clearer which patients are likely to benefit from chiropractic. As fears of additional adverse effects from analgesics (NSAIDs and COX-2 inhibitors) commonly used for low back pain increase, chiropractic should be considered as an attractive alternative for patients with this very common complaint. ❖

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Thyroid Function and Soy: The Good, the Bad and the Not-so-ugly!

Source: Bruce B, et al. Isoflavone supplements do not affect thyroid function in iodine-replete postmenopausal women. *J Med Food* 2003; 6:309-316.

Abstract: Despite the safety review conducted by the U.S. Food and Drug Administration in the process of awarding a health claim for the cholesterol-lowering properties of soy protein, concerns about the possible goitrogenic effects of

soybean isoflavones persist. Concerns are based primarily on in vitro research, animal studies, and older reports of goiter in infants fed soy formula not fortified with iodine. In a randomized, double-blind, placebo-controlled study, the authors investigated the effect on thyroid function of a daily supplement containing 90 mg/d (aglycone weight) of total isoflavones vs. placebo in 38 postmenopausal women, ages 64-83 years, who were not on hormone replacement therapy. Serum thyroid-stimulating hormone (TSH), thyroxine (T4), and triiodothyronine (T3) were measured at baseline and after 90 and 180 days. In the supplement group, at baseline and six months, TSH (micro U/mL), T4 (nM), and T3 (nM) levels (mean \pm SE) were 3.00 ± 0.44 , 149.00 ± 5.04 , and 1.53 ± 0.13 , respectively, and 3.49 ± 0.52 , 154.52 ± 2.09 , and 1.78 ± 0.12 , respectively. In the control group, levels at baseline and at six months were 3.35 ± 0.51 , 145.39 ± 6.69 , and 1.55 ± 0.18 , respectively, and 3.63 ± 0.57 , 153.77 ± 6.64 , and 1.75 ± 0.10 , respectively. Intragroup differences for all three measures were statistically indistinguishable at six months, and levels were similar between the isoflavone supplement and placebo groups at each measurement. These results indicate that in this group of healthy iodine-replete subjects, soy isoflavones do not adversely affect thyroid function.

■ Comments by Mary Hardy, MD

IN 1999, THE U.S. FOOD AND DRUG ADMINISTRATION designated soy protein as a heart-healthy food because of its positive effects on lipids¹ (*The Good*). However, persistent concerns have been raised about the negative effect of soy isoflavones on thyroid function (*The Bad*). A recent clinical trial has provided evidence that these concerns are not clinically significant (*The Not-so-ugly*) and that deserves to be considered in more detail, given the large number of women with decreased thyroid function and the increasing use of soy foods and supplements.

In vitro studies have shown that genistein and daidzein, the two principle isoflavones in soy, interfere with enzymatic reactions catalyzed by thyroid peroxidase (TPO) that are essential to the production of thyroid hormone.² In animal studies, inhibitory effects on TPO are demonstrated by soy isoflavones in a dose-dependent fashion, and goiter is more common in rats fed a soy diet, especially if they are iodine-deficient.³ However, effects on other aspects of thyroid function, such as thyroid hormone levels and weight of the gland, were not affected.

Early concerns were raised regarding soy and thyroid function in humans, when a cluster of cases of goiter was reported in infants fed soy formula exclusively. This problem was addressed by adding iodine to formulas and no cases since have been reported.⁴ However, a study of hypercholesterolemic women reactivated concern.⁵ These women were fed 40 g of soy with either high (90 mg) or low (56 mg) doses of isoflavones per day for six months. Lipids, steroid hormone levels, and thyroid

hormone levels were measured at three and six months. Small effects on thyroid hormone were measured, but the clinical effects of these changes were not known.

To address these persistent concerns, Bruce and her colleagues performed a randomized, double-blind, placebo-controlled trial of the effects of 90 mg/d of isoflavones on thyroid function in postmenopausal women.⁴ Women were recruited from an ongoing study examining the effect of soy isoflavones on bone density. For this nested study, women must not have a history of breast cancer and currently could not be taking hormone replacement. To ensure an adequate level of iodine, all subjects were given a multivitamin with 150 mcg/d of iodine. Women currently taking thyroid medication were allowed to enroll in the trial; presumably, their conditions were stable before entry into the study. All but one of the recruited women were Caucasian.

After randomization, 42 women were given either an undistinguishable placebo or an isoflavone supplement. This intervention was unusually well-characterized in the article. Each tablet contained 50 mg of isoflavones (30 mg aglycone by weight) in the ratios of 1.3:1.0:0.3 for the glycosides genistin, daidzin, and glycitin. The saponin, protein, and fat content also were reported. This dose was chosen to represent a higher daily dose of isoflavones than was consumed even in the typical Asian diet and is equivalent to approximately 9-12 ounces of tofu. Subjects were instructed to limit soy-containing foods to one serving per week. Blood for thyroid function was drawn at three and six months.

Of the initial 42 subjects, 38 completed the trial. Withdrawals were not related to adverse reactions to the intervention. At six months, there were no statistical differences between groups based on serum levels on TSH, T4, and T3. Isoflavone levels were similar between groups demonstrating equivalent compliance with the study protocol.

This trial is very significant in addressing the lingering concerns regarding the effect of soy isoflavones on thyroid function. As long as women have a normal iodine level, which is easy to ensure with supplementation if dietary sources are not adequate, there should be no concern about clinically significant effects on thyroid hormone levels or function. Happily, we can encourage our patients to use heart-healthy soy foods and supplements without concern for their thyroids. ❖

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CE Objectives

After reading *Alternative Therapies in Women's Health*, the health care professional will be able to:

1. evaluate alternative medicine and complementary therapies for women's health concerns;
2. identify risks and interactions associated with alternative therapies;
3. discuss alternative medicine options with patients; and
4. offer guidance to patients based on latest science and clinical studies regarding alternative and complementary therapies.

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CE/CME Questions

11. In one study, what percent of pregnant women reported experiencing low back pain?
 - a. 26%
 - b. 58%
 - c. 68.5%
 - d. 70%
12. All 50 states allow chiropractors to include in their permitted scope of practice all of the following *except*:
 - a. general health advice.
 - b. spine-focused history and physical exam.
 - c. spinal manipulation.
 - d. X-rays.
13. A meta-analysis of 39 trials and more than 5,000 subjects found that spinal manipulative therapy was more effective than either sham or ineffective therapies in relieving short-term pain for both acute and chronic low back pain.
 - a. True
 - b. False
14. A recent trial in postmenopausal women found that as long as women have a normal iodine level, which is easy to ensure with supplementation if dietary sources are not adequate, there should be no concern about clinically significant effects of soy isoflavones on thyroid hormone levels or function.
 - a. True
 - b. False

Answers: 11. c, 12. a, 13. a, 14. a.

News Briefs

CAM Should Be Held to Same Standard as Conventional Medicine, Report Says

A new report from the Institute of Medicine of the National Academies calls for conventional medical treatments and complementary and alternative medicine (CAM) treatments to be held to the same standards for demonstrating clinical effectiveness. The same general research principles should be followed in evaluating both types of treatments, although innovative methods

to test some therapies may have to be devised, says the committee that wrote the report.

"Of primary importance to the committee, and underlying all its deliberations, was the question, 'What do patients and health professionals need to know to make good decisions about use of health care interventions, including CAM?'" says committee chair Stuart Bondurant, MD, interim executive vice president for health sciences and executive dean at Georgetown

University Medical Center in Washington, DC. He spoke at a press briefing after the release of the report.

“One answer to that question concerns whether treatments are safe and effective. We recognize that there are extremes of belief about how to judge effectiveness. For some individuals, evidence limited to their own experience or knowledge is all that is necessary to prove that a CAM therapy is effective. For others, no amount of evidence is sufficient. This report will please neither of those extremes.”

The report was written to assist the National Institutes of Health in developing research methods and setting priorities for evaluating products and approaches within CAM. The report also assesses what is known about Americans’ reliance on these therapies: Use of CAM is widespread among the U.S. public, with more than one-third of adults reporting that they have pursued some form of these treatments.

The committee reviewed an extensive collection of relevant literature for the report and heard a series of expert presentations, discussions, and public comments in open meetings, Bondurant says. The committee also established a working liaison group composed of 32 leaders of CAM and conventional medical disciplines and held a number of formal and informal interchanges with these groups.

“The intent of the report is not to medicalize or co-opt CAM but to sustain the existing forms of validated CAM therapies, whether integrated into conventional practices or continued as freestanding approaches,” Bondurant says. The committee urged that great care be taken to test CAM therapies in the ways that they are used, he adds.

With the use of dietary supplements escalating, the committee recommends the testing of CAM therapies to address a lack of consistency and quality in these products. This inconsistency can hinder health professionals’ abilities to guide patients on the use of supplements and researchers’ ability to study them, the committee says. The report calls on Congress to work with stakeholders to amend the regulation of supplements to improve quality control and consumer protections and to create incentives for research on the efficacy of these products.

The committee promotes randomized controlled trials

(RCTs) as the gold standard for providing evidence of efficacy. Other study designs, however, can generate useful information on treatments that do not lend themselves to RCTs. “Observational studies, case control studies, and studies that specifically measure patients’ expectations, emotional states, and other self-healing processes can provide useful data,” the committee notes in a statement. “Some conventional treatments, such as psychotherapy, also have similar characteristics that make them incompatible with RCTs, but they have been successfully evaluated via other methods.”

Since many CAM products and approaches have not undergone formal testing and since resources to conduct research are limited, the report outlined several criteria to help determine which CAM therapies to prioritize for study. These same criteria also apply to as-yet untested conventional treatments, the committee noted. The criteria include the prevalence and severity of the target health condition; existing evidence that the therapy is effective or may have safety issues; the question of whether a plausible biological mechanism exists by which the therapy might work or the likelihood that research will discover a mechanism; and the likelihood that research will yield unambiguous results. Inability to meet any one of the criteria should not necessarily exclude a therapy from consideration, the report says.

The report also discusses the importance of having CAM practitioners involved in research to ensure that research reflects as much as possible the actual ways in which CAM therapies are administered and used, Bondurant says. “We call for more CAM practitioners to be trained in research. Furthermore, practice guidelines for CAM therapies should be developed by CAM practitioners to foster research and quality.

“The committee believes that health care is in the middle of an exciting time of discovery, a time when an evidence-based approach brings opportunities for the incorporation of the best options from all sources of care—both conventional medicine and CAM,” Bondurant says. “The challenge is to avoid parochial bias and to approach each possibility with an appropriate degree of both skepticism and open-mindedness. Only then will it be possible to ensure that informed, reasoned, and knowledge-based decisions are made.” ❖

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