

The Somatic Connection

“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 *The Journal of the American Osteopathic Association (JAOA)* strives to chronicle the significant increase in published research on manipulative methods and treatments in the United States and the renewed interest in manual medicine internationally, especially in Europe.

To submit scientific reports for possible inclusion in “The Somatic Connection,” readers are encouraged to contact *JAOA* Associate Editor Michael A. Seffinger, DO (mseffingerdo@osteopathic.org), or *JAOA* Editorial Advisory Board Member Hollis H. King, DO, PhD (hollis.king@famned.wisc.edu).

Yoga vs Usual Care for Chronic Low Back Pain

Tilbrook HE, Cox H, Hewitt CE, et al. Yoga for chronic low back pain: a randomized trial. *Ann Intern Med.* 2011;155(9):569-578.

During the past 20 years, there has been a documented increase in the use of complementary and alternative medicine. Yoga, along with osteopathic manipulative medicine, has been depicted as a form of complementary and alternative medicine in integrative medicine awareness surveys. Many small studies have documented the positive effects of yoga on chronic or recurrent back pain; however, such studies have had various limitations. After completing a review of the literature on yoga research, investigators in the United Kingdom conducted a parallel-group, randomized controlled trial in which a 12-week yoga class was offered to adults. The objective of this trial was to compare the efficacy of yoga vs the efficacy of “usual care” for the management of chronic and recurrent low back pain.

Participants were chosen from a group of 1093 individuals who were recruited through database searches of 39 general medical practices and through advertisements placed in local media.

Participants who were identified through database searches had visited a general medical practice office for low back pain during the 18 months prior to recruitment. All participants were aged between 18 and 65 years, with most being women aged between 45 and 65 years. The average duration of participant back pain was 10 years, and 77% of participants had back pain at the time of recruitment. The 313 participants were randomly allocated to 1 of 2 groups: a usual care group (n=157) or a yoga group (n=156). The median age of participants was 46.4 years in the usual care group and 47.2 years in the yoga group. This number of participants met the requirements of a power analysis to detect an effect size of 0.39.

Participants assigned to the yoga group were required to attend one 75-minute yoga class per week for 12 weeks. Researchers selected a total of 12 experienced yoga instructors to teach the classes. Two yoga instructors were assigned to teach each yoga class series, with 1 instructor serving as the teacher and the other providing backup. Twice during treatment, the yoga instructors who were providing backup reported on those who were teaching to ensure treatment fidelity. In an attempt to achieve uniformity in teaching, all instructors were required

to teach the same form of yoga, in accordance with class plans outlined in the teacher's manual. The pose descriptions and sequences were included in a separate students' manual that was given to the study participants at the first class.

The Roland-Morris Disability Questionnaire (RMDQ), a questionnaire that measures activities of daily life affected by back pain, was completed by participants at baseline, 3 months (ie, at the end of the yoga intervention), 6 months, and 12 months.

Analysis of the usual care group and the yoga group was planned in advance by an independent steering committee. Analyses were conducted according to randomized treatment assignment and were completed without regard for adherence to protocol. Analyses were conducted by comparing the changes in RMDQ scores from baseline between groups during the course of the trial. The statistician was blinded to group assignment.

The RMDQ scores showed that the yoga group had better back function than the usual care group at 3 months (after completion of the 12-week yoga course), 6 months, and 12 months. At the assessment performed at 3 months, the adjusted mean RMDQ score was 2.17 points lower for participants in the yoga group. A Forrest plot was used to compare the RMDQ changes noted in the yoga group at 3 months with the changes noted at 3 months in previously published studies assessing various other treatments for low back pain. The Forrest plot indicated that yoga was superior to exercise, manipulation, manipulation and exercise, cognitive behavioral therapy, and 6 sessions (but not 24 sessions) of treatment with use of the Alexander technique.

In the UK BEAM (United Kingdom Back Pain Exercise and Manipulation) trial,¹ the type of manipulation used was a combination of techniques used by the British physiotherapy, chiropractic, and osteopathic professions. Participants in the UK BEAM trial¹ received manipulation for 6 weeks followed by exercise for 6 weeks or they received manipulation alone for 6 weeks.

With the proposed unified accreditation of graduate medical education programs under the Accreditation Council for Graduate Medical Education, it is important to think about how osteopathic manipulative medicine is categorized and how it compares with the other therapies in its perceived class. A recent article in *The DO*, titled "'Self-OMT': Yoga Boosts Patients' Structure and Function, DOs Say,"² discusses a possible synergy between yoga and osteopathic manipulative treatment in treatment schemes. Further studies assessing osteopathic manipulative treatment and yoga may enhance our understanding of the capacities of current therapies.

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Yoga vs Stretching and Use of a Self-Care Book for Chronic Low Back Pain

Sherman KJ, Cherkin DC, Wellman RD, et al. A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain. *Arch Intern Med*. 2011;171(22):2019-2026. doi:10.1001/archinternmed.2011.524

Chronic low back pain is a common reason for visits to a physician's office. Despite the socioeconomic repercussions of such pain, consistent, highly effective treatment options are lacking. Several stud-

ies suggest that yoga may help decrease chronic low back pain. However, many people equate the pain relief derived from yoga as equivalent to that derived from basic stretching. In this study, the National Institutes of Health supported a randomized controlled trial of yoga, conventional stretching, and use of a self-care book for the management of chronic low back pain, to determine whether yoga is more effective than the other 2 treatment modalities. The researchers hypothesized that the mental component of yoga could enhance its physical benefits, making it more effective than both conventional stretching and use of a self-care book.

A total of 228 adults were recruited to participate in this 3-arm, parallel-group, stratified controlled trial. Patients were randomly assigned (in a 2:2:1 ratio) to 12 weekly classes of either yoga (n=92) or conventional stretching (n=91), or to use of a self-care book (n=45). Primary outcomes were measured using the Roland-Morris Disability Questionnaire (RMDQ) and a self-rating of pain bothersomeness. Participants were assessed at baseline and at 6, 12, and 26 weeks after randomization. The primary criterion for study participation was the presence of nonspecific chronic low back pain. Individuals excluded from the trial were those whose back pain was attributed to a specific cause (eg, spondylolisthesis), was potentially secondary to an underlying medical condition (eg, pregnancy), was complex (eg, required previous back surgery), was rated as less than 3 on the 11-point bothersomeness scale at screening, and was not chronic (defined as pain lasting <3 months). Also excluded were persons with severe disease, those for whom yoga was contraindicated, and those with any form of mental illness.

A research assistant randomly assigned participants to each recruitment cohort after baseline interviews were completed. Treatment assignments were generated by a statistician and were then embedded in the computer-assisted telephone interviewing program so they could not be accessed by study staff prior to randomization.

Yoga was taught by using a protocol that the team of researchers had used in a previous trial.¹ The style of yoga taught was viniyoga, an approach “that adapts the various means and methods of practice to the unique condition, needs and interests of each individual.”² A series of 12 standardized, weekly 75-minute yoga and stretching classes were held in group health facilities. The classes used 17 simple postures (with variations and adaptations); 5 to 11 of these postures were practiced in each class. The classes also involved breath work and guided meditation. Experienced registered yoga instructors led the classes. The stretching classes, which were also adapted from those used in a previous trial,¹ included aerobic exercise, 10 strength exercises, and 12 stretches led by a licensed physical therapist. The self-care book provided to participants was *The Back Pain Helpbook*.³

Primary outcomes were analyzed using regression analysis with general estimating equations. After adjustment for baseline values, the 12-week outcomes for the yoga group were better than those for the self-care group, with a mean difference in function of -2.5 (95% confidence interval [CI], -3.7 to -1.3; $P<.001$) and a mean difference in symptoms of -1.1 (95% CI, -1.7 to -0.4; $P<.001$). At 26 weeks, function in the yoga group remained superior to that in the self-care group, with a mean difference of -1.8 (95% CI, -3.1 to -0.5; $P<.001$). At no point in time was yoga superior to conventional stretching exercises.

The study investigated 2 additional measures of clinical improvement: a 30% improvement from baseline,⁴ which indicated minimal improvement, and a 50% improvement from baseline, which indicated substantial improvement. Both 52% of the yoga group and 56% of the stretching group demonstrated clinical improvement of at least 50% on the RMDQ, whereas only 23% of the self-care group had substantial clinical improvement. At 26 weeks, both yoga and stretching had produced substantial benefits compared with that of self-care. However,

according to this study, stretching resulted in substantial improvements in the self-rating of pain bothersomeness.

The authors of this article concluded that although yoga was not more effective than conventional stretching, it was more effective than a self-care book. In both the yoga group and the stretching group, use of pain medications decreased from the levels noted at baseline. The results of this study conflict with those of other studies that highlight yoga as being substantially more effective than an exercise regimen and other treatment modalities for the management of low back pain.⁵ To assess this difference, the yoga protocol used in this study would need to be compared with other standardized yoga protocols. To gain a greater depth of understanding of the conclusions from the present study, one would need to create a randomized controlled study that compared the stretching protocol and the viniyoga protocol with other standardized yoga protocols that have produced a substantial reduction in low back pain. In the future, specific standardized yoga protocols may be shown to have different effects. The aspects of sequencing yoga postures involve many theories of order and action. It may be the case that not all yoga sequences are equivalent when it comes to treating patients with low back pain. This may also hold true for osteopathic manipulative procedures.

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Yoga vs Home-Based Exercise for Chronic Neck Pain

Cramer H, Lauche R, Hohman C, et al. Randomized-controlled trial comparing yoga and home-based exercise for chronic neck pain. *Clin J Pain.* 2013;29(3):216-223.

Chronic neck pain has become a significant public health issue, with an average lifetime prevalence of just less than 50%.¹ In a study examining national expenditure trends related to back and neck pain, Martin et al² estimated that individuals with spinal problems incurred nearly \$86 billion in related health expenditures in 2005, whereas those with cancer and diabetes had related health expenditures of \$89 billion and approximately \$98 billion, respectively. Researchers have investigated the myriad benefits that exercise provides to physical and psychological health, as well as how improving these factors can contribute to the reduction and management of musculoskeletal pain.^{3,4} Interest in yoga as a form of exercise to relieve pain associated with musculoskeletal disorders is growing; however, more evidence-based research is needed to prove the efficacy of yoga vs more traditional exercise regimens. In Resolution H-257 (A/2004—Osteopathic Manipulative Treatment of the Cervical Spine), the American Osteopathic Association rec-

ommends the use of osteopathic manipulative treatment (OMT) for cervical spine somatic dysfunction. The most reliable cardinal finding that supports the diagnosis of somatic dysfunction is tenderness upon palpation. Although it has yet to be determined how yoga measures up to OMT as a treatment modality for chronic neck pain related to somatic dysfunction, or whether it should be recommended as an adjunct to OMT, it would be important to know if yoga relieved tenderness to palpation, at least, and eventually determine if it relieves somatic dysfunction with or without OMT. To assess whether yoga alleviated physical (pressure pain) and subjective findings related to chronic neck pain, researchers from the Department of Internal and Integrative Medicine at the University of Duisburg-Essen in Essen, Germany, conducted a randomized controlled trial on the effects of a 9-week yoga intervention.

Patients were included in this study if they were aged between 18 and 60 years, had nonspecific neck pain for at least 5 days per week during the previous 3 months, and had a mean neck pain intensity of at least 40 mm on a 100-mm visual analog scale (with 0 mm indicating no pain and 100 mm indicating the worst pain imaginable). Patients were excluded from study participation if they had inflammatory rheumatic disease, active oncologic disease, affective disorder, addiction, or psychosis; if they had recently undergone invasive spinal procedures; or if they were pregnant. They were also excluded if they could not practice yoga; if they had practiced yoga within the previous 12 weeks; or if they had started a new treatment for their neck pain in the previous month or were planning to start one during the next 9 weeks. Researchers completed screening of 227 participants by telephone, using the aforementioned criteria, and 51 patients qualified for and completed the study.

To evaluate the effects of Iyengar yoga vs a home-based exercise program as an intervention for chronic nonspecific neck pain, researchers randomly assigned the 51 patients to either a yoga group (n=25) or a home-based exercise group (n=26)

(ie, the active control group). All patients completed psychosocial questionnaires and had physiological measurements obtained at baseline. Present pain was the primary outcome measure and was assessed on a 100-mm visual analog scale. Subjective secondary outcome measures, including pain on motion, functional disability, and health-related quality of life, were assessed using a 100-mm visual analog scale, the Neck Disability Index, and the Short Form-36 Health Survey questionnaire, respectively. Objective secondary outcome measures included cervical range of motion, proprioceptive acuity, and the pressure pain threshold.

The participants who were assigned to the yoga group were taught Iyengar yoga postures that targeted the muscles of the neck and shoulder region. Iyengar yoga is a style of yoga that includes variations of classical yoga postures, with emphasis given to proper postural alignment and the use of props to help maintain such alignment. For 9 weeks, the yoga group practiced Iyengar yoga in weekly 90-minute sessions led by a certified Iyengar yoga instructor. An individual who had a master's degree in psychology and who specialized in working with patients with chronic pain was also present to assist the instructor. In addition to their weekly yoga sessions, patients were required to practice yoga at home for 10 minutes per day and to record daily home practice times in a log. In contrast, participants in the home-based exercise group received self-care exercise manuals. They were also expected to practice at home for 10 minutes per day and keep detailed records of their activity. Patients in both groups were instructed to maintain their usual pain management regimens.

An investigator blinded to group allocation repeated all physiological measurements at week 9 (after the yoga intervention). At baseline, sociodemographic variables and neck pain characteristics did not differ between the 2 groups; however, after the yoga intervention, the yoga group reported significantly less neck pain intensity than did the

home-based exercise group, with a mean between-group difference of -13.9 mm (95% confidence interval, -26.4 mm to -1.4 mm; $P=.03$). Moreover, the yoga group demonstrated decreased functional disability and clinically significant improvement in several parameters on the Short-Form-36 Health Survey questionnaire, including mental health and bodily pain. The yoga group also exhibited significantly better results for the physiologic secondary outcome measures, greatly outperforming their counterparts in the home-based exercise group.

The authors of this study concluded that Iyengar yoga provided more pain relief for patients with chronic nonspecific neck pain than did home-based exercise. Furthermore, as illustrated by the physiologic measurements of chronic neck pain, yoga seemed to help improve the functional status of the cervical musculature. Some limitations of this study include the inability to blind patients to treatment group allocation and the lack of an instructor-guided experience for the home-based exercise group. Future studies might incorporate a physical therapist experienced in training patients with chronic musculoskeletal disorders, as well as examine the effects of Iyengar yoga in a long-term follow-up of patients. More and more studies are demonstrating the effect that yoga can have on the alleviation of musculoskeletal pain. Some studies may even suggest that yoga is a more effective modality than OMT. For osteopathic physicians, the question now becomes: Should yoga be considered an adjunct therapy to OMT?

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Yoga for Chronic Neck Pain: A 12-Month Follow-Up

Cramer H, Lauche R, Hohmann C, Langhorst J, Dobos G. Yoga for chronic neck pain: a 12-month follow-up [published online ahead of print February 6, 2013]. *Pain Medicine*. doi:10.1111/pme.12053.

Between 50% and 70% of individuals have neck or shoulder pain at least once in their lives.^{1,2} According to some sources, neck pain is one of the most common reasons that complementary and alternative medicine is pursued. The current understanding is that individuals who are healthy and have a physically active lifestyle are less likely to have chronic pain, but little information exists regarding the type of therapy that might provide moderate mobilization for someone who is in pain. Yoga, a form of complementary and alternative medicine therapy and exercise that has roots in ancient Indian spiritual practices, has been thought to help control chronic pain. According to a study published in 2004, 20% of yoga practitioners use yoga techniques for control of spinal pain.³

Researchers from the Department of Internal and Integrative Medicine at the University of Duisburg-Essen in Essen, Germany, conducted a randomized controlled trial in which the effects of a 9-week yoga intervention for alleviation of chronic nonspecific neck pain were assessed.⁴ The research-

ers found that patients assigned to a yoga group had improvements in pain, functional disability, and mental quality of life, compared with patients assigned to a control group.⁴ In this study, the results of a 12-month follow-up of data from the aforementioned study of Iyengar yoga are reported.

Patients for the original study were recruited through a local newspaper. Participants were aged between 18 and 60 years, had nonspecific neck pain for at least 5 days per week during the past 3 months, and had a mean neck pain intensity of at least 40 mm on a 100-mm visual analog scale (with 0 mm denoting no pain and 100 mm denoting the worst pain imaginable). Exclusion criteria included psychiatric problems, addiction, a specific diagnosis of neck pain, active oncologic disease, inflammatory rheumatic disease, pregnancy, disability precluding yoga practice, invasive spinal treatment performed within the past 4 weeks, spinal surgery performed during the previous 12 months, and yoga practiced during the previous 12 weeks.

In this 2-arm, randomized controlled clinical trial with long-term follow-up, participants were randomly assigned to a yoga group or a control group after completing the first baseline assessment session. The control group was provided with a self-care exercise manual designed by a large statutory German health insurance company. One week later, the yoga group started their 9-week yoga intervention. The Iyengar style of yoga, known for its accessibility, focus on precise alignment, and use of props to prevent straining and achieve perfect alignment, was used in the intervention.⁴ The 9-week program was taught by a certified Iyengar yoga instructor who received assistance from an individual with a master's degree in psychology who specialized in working with patients with chronic pain. Participants in the yoga group practiced Iyengar yoga in weekly 90-minute sessions, and they were also asked to practice at home for 10 minutes each day. When the intervention was complete, both the yoga group and the control group were reassessed. The

control group then began its own 9-week yoga intervention. Twelve months after completion of the yoga intervention, both study groups participated in a final assessment.

The outcomes that were measured included neck-related disability (assessed by the neck disability index [NDI], with sum scores ranging from 0 to 100, and with higher values indicating greater disability), health-related quality of life (assessed by the Short-Form 36 Health Survey questionnaire, which evaluates both the general mental and general physical state), overall improvement (assessed on a basic 5-point scale), and intervention adherence (based on the number of minutes that yoga was practiced during the past month). Binary logistic regression analysis was performed to assess possible predictors for obtaining clinically important (30%) reductions or clinically substantial (50%) reductions in pain intensity. Included in the regression analysis were the number of yoga courses attended, regular yoga practice during the past 12 months, and the number of minutes practiced weekly during the past 4 weeks.

Of the 51 participants in the original study, 36 completed 12-month follow-up. From baseline to the 12-month follow-up, the mean (standard deviation [SD]) changes noted were as follows: pain intensity improved from 48.81 (17.71) mm to 32.31 (20.68) mm ($P<.001$), the NDI decreased from 25.26 (9.02) to 19.49 (11.52) ($P=.001$), and bodily pain improved from 49.37 (12.40) to 59.26 (17.57) ($P=.005$). Improvements in pain intensity were predicted on the basis of the number of minutes that yoga was practiced each week during the past 4 weeks ($r^2=0.12$; $P=.028$), and improvements in neck-related disability ($r^2=0.24$; $P=.001$) and bodily pain ($r^2=0.26$; $P=.006$) were predicted by regular yoga practice during the past 12 months. Generic disability did not decrease significantly. Twenty-four patients (68.6%) considered their health to be at least somewhat improved.

Although this study indicates that patients had reduced neck pain and decreased disability for at

least 12 months after completion of the yoga intervention, improvement in pain intensity was correlated with continued practice of yoga. Continuing to practice yoga therefore seems to be the most accurate predictor of long-term efficacy and relief from pain. Two limitations of the present study are that it comprised mostly well-educated women and that it was small in size, which may limit the generalizability of its findings to the entire population of patients with chronic neck pain.

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Section Editor's Note: The following 3 reviews share a theme and were selected to appear in this installment of "The Somatic Connection" because they report a possible benefit of manual therapy and osteopathic manipulative therapy in the treatment of patients with visceral disorders. Osteopathic manipulative treatment has been proven effective in the management of chronic low back pain and is accepted as a beneficial treatment for musculoskeletal disorders in general. In addition, according to the osteopathic tenet of the structure-function relationship, application of osteopathic manipulative treatment has a positive impact on physiological functions and shows benefit

in the treatment of systemic disorders (King HH, Jänig W, Patterson MM, eds. *The Science and Clinical Application of Manual Therapy.* Edinburgh, Scotland: Churchill Livingstone/Elsevier; 2011:301-312.). These 3 studies were also selected because they represent the research of international practitioners of osteopathy and other manual therapy professions, which is relevant to osteopathic medical research on applicable techniques and outcome measurements.

Severity of Irritable Bowel Syndrome Symptoms Is Reduced by Osteopathy

Florance B-M, Frin G, Dainese R, et al. Osteopathy improves the severity of irritable bowel syndrome: a pilot randomized sham-controlled study. *Eur J Gastroenterol Hepatol.* 2012;24(8):944-949.

Irritable bowel syndrome (IBS) affects 10% to 20% of the adult and adolescent population,¹ but conventional IBS treatments offer minimal clinical benefit. Alternative treatments, including acupuncture, meditation, and herbal medicine, have therefore been attractive treatment options for some patients with IBS.² Osteopathy, with its focus on the interrelationship of structure and function, is an appealing alternative treatment for functional gastrointestinal disorders such as IBS. To assess the effect of osteopathy on the severity of IBS, researchers from the Department of Gastroenterology at the Centre Hospitalier Universitaire de Nice in Nice, France, conducted a single-blind, randomized sham-controlled trial in which 2 sessions of standardized osteopathy were assessed.

A total of 30 patients (23 women and 7 men) who met Rome III criteria for IBS were eligible to participate in the study. All patients had IBS symptoms (eg, abdominal pain, discomfort, changes in stool frequency) that were present more than 25% of the time, as measured by patient-recorded data in daily diaries of abdominal and stool symptoms. Criteria for exclusion from the study were celiac disease, inflammatory bowel diseases, lactose intolerance, severe depression and anxiety, thyroid and renal dysfunction, and rheumatologic disease

or symptoms. Patients who either were familiar with osteopathy, had previously been treated with osteopathy, or both, were also excluded. Selected patients were randomly assigned (in a 2:1 ratio) to receive either osteopathy (ie, the treatment group [n=20]) or sham osteopathy (ie, the control group [n=10]).

Patients in the treatment group received two 60-minute sessions of osteopathy that were provided at a 7-day interval. An examination occurred at the start of each session, which I interpret as meaning that the osteopathic maneuvers were individualized to each patient. A standardized osteopathic procedure was provided by the same osteopath. The procedure involved both direct and indirect manipulation directed at the vertebral column, although specific spinal levels were not mentioned. At the end of each session, visceral osteopathy was performed to improve the interconnections between the motions of all organs. The sham procedure performed on patients in the control group involved gentle massage of the spine and abdomen. Follow-up data were collected from both patient groups at day 28 of the study.

At baseline, no statistically significant differences were noted between the treatment group and the control group with regard to demographic characteristics or IBS symptoms. At day 7 (the day when the second session of osteopathy or sham osteopathy was applied), the treatment group had a statistically significant reduction in the IBS severity score ($P=.01$) and a statistically significant improvement in quality of life ($P=.03$), compared with the control group. However, no significant differences were noted at the 28-day follow-up evaluation. An equal reduction in depression and anxiety scores was noted in both patient groups. Stool frequency and consistency were unchanged in both groups.

The authors of this article acknowledged that the small sample size of their study may have underpowered results related to bowel habits. They also expressed uncertainty that the benefits of oste-

opathy and sham osteopathy, compared with “usual care,” stemmed from the interaction between the osteopath and the patients with IBS. The authors concluded that osteopathy has a clinical advantage over sham osteopathy in alleviating symptom severity and improving quality of life in patients with IBS, but they also acknowledged that their study did not evaluate the possible benefit of osteopathy provided in multiple treatment doses over an extended period.

In my experience, IBS symptoms can be virtually eliminated in patients with IBS, when osteopathic manipulative treatment is provided over an extended period of years. The authors speculated that the effect of osteopathic manipulative treatment on the autonomic nervous system was the likely mechanism of action in producing improvements in bowel function. I believe that this speculation is correct but limited, because the osteopathy described in this article did not include upper cervical manipulation, which, in my experience, may improve parasympathetic nervous system function in the gastrointestinal system via cranial nerve X.

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Manual Therapy May Benefit Women With Primary Dysmenorrhea

Molins-Cubero S, Boscá-Gandía JJ, Rus-Martínez MA. Assessment of low back and pelvic pain after applying the pelvis global manipulation technique in patients with primary dysmenorrhea: a pilot study. *Eur J Ost Clin Rel Res*. 2012;7(1):29-38

Primary dysmenorrhea is a gynecologic condition that affects 40% to 70% of women of childbearing age. Pain in the lower abdomen, followed by low back pain and pelvic pain, is the symptom most frequently associated with the disorder. Researchers in Spain conducted a double-blind, randomized controlled trial to assess the efficacy of a global pelvic manipulation (GPM) technique in improving low back and pelvic pain in women with primary dysmenorrhea.

Women with primary dysmenorrhea diagnosed by a gynecologist were identified through searches of medical records at the principal investigator's clinic. Inclusion criteria were age between 18 and 40 years and a history of regular menstruation. Exclusion criteria were the presence of secondary dysmenorrhea or any gynecologic pathology other than primary dysmenorrhea, use of an intrauterine device, previous gynecologic interventions, contraindications to GPM, osteopathic therapy received within 2 months of initiation of the trial, and a fear of either blood tests or GPM. The 20 patients who were selected for the study were randomly assigned to an experimental group (n=10) or a control group (n=10).

Outcome measures were the intensity of low back pain and pelvic pain, as well as the pressure pain threshold (PPT) in the left and right sacroiliac joints (SIJs) of the posterior superior iliac spine. Because the researchers' review of the literature suggested that chemical modulators of pain might be related to primary dysmenorrhea and might be affected by manual therapy, the researchers also performed tests to determine blood levels of serotonin

and catecholamines (dopamine, noradrenaline, and adrenaline).

On day 1 of their menstrual cycle, patients reported to the clinic to undergo a series of assessments and procedures. Pain intensity was assessed on a 100-mm visual analog scale (VAS), and the PPT of the SIJs was determined using a pressure algometer. A blood sample was obtained, an experienced osteopath then applied the GPM technique to each patient in the experimental group, and a placebo or sham procedure was applied to each patient in the control group. A second set of VAS and PPT measurements was then obtained, and at 30 minutes after application of the GPM technique or sham procedure, a second blood sample was obtained.

Both the GPM technique and the sham procedure took 2 minutes to perform. The experimental group received 1 bilateral application of the GPM technique, which was administered to each SIJ and the lumbosacral joint area. The GPM technique, which was applied to each side of the pelvis, was described as a thrust technique that affects, or gaps, both the SIJs and the lumbosacral joints. No illustrations of the GPM technique were included in the article. However, a high-velocity, low-amplitude (HVLA) manipulation for sacral torsion somatic dysfunction that may be similar to the procedure described in this article is illustrated in the *Outline of Osteopathic Manipulative Procedures: The Kimbly Manual 2006 (Updated 2008)*.¹ Application of the sham procedure to the control group consisted of the osteopath placing a hand on the hypogastric region just above the pubic symphysis.

The experimental group had a statistically significant improvement in postintervention measurements of the PPT for both SIJs, compared with the control group. No statistically significant differences between preintervention and postintervention assessments were noted for any of the other outcomes.

The authors discussed the limitations of their study. They acknowledged that patient ingestion of nonsteroidal anti-inflammatory drugs could have

influenced the pain measurements obtained at baseline. One possible way to avoid this potential bias would have been to enforce exclusion of patients from the study if they ingested nonsteroidal anti-inflammatory drugs on the day before study initiation. The authors also explained that, because of the effects of circadian rhythm on catecholamine and serotonin levels, controlling the measurements of these biomarkers was difficult and could have been affected by such factors as unreported patient stress. I believe the authors should have acknowledged that their study involved only 1 brief intervention and speculated on the possible effects of applications involving multiple interventions.

Despite the limitations of this study, I believe that the degree of pain reduction achieved in such a small number of patients, as measured with PPT algometry, suggests that the application of just 1 set of bilateral GPM procedures is an effective intervention and merits further study.

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Manual Therapy May Benefit Women With Interstitial Cystitis and Pelvic Floor Pain

FitzGerald MP, Payne CK, Lukacz ES, et al; Interstitial Cystitis Collaborative Research Network. Randomized multicenter clinical trial of myofascial physical therapy in women with interstitial cystitis/painful bladder syndrome and pelvic floor tenderness. *J Urol*. 2012;187(6):2113-2118.

Interstitial cystitis/painful bladder syndrome (IC/PBS) is characterized by a highly variable clinical course. Although treatment of patients with this disorder continues to be suboptimal, evidence suggests that myofascial physical therapy (MPT) techniques can provide clinically significant relief of IC/PBS symptoms.¹⁻³ A large group of researchers from academic health centers in North America conducted a single-blind, randomized controlled trial to assess the effectiveness and safety of pelvic floor MPT vs global therapeutic massage (GTM) in women with IC/PBS.

A total of 81 women aged between 18 and 77 years (mean age, 43 years) were recruited at 11 clinical study sites in North America. The majority of patients were white. Inclusion criteria were a clinical diagnosis of IC/PBS and recorded ratings of at least 3 on 0- to 10-point severity scales for bladder pain, frequency, and urgency, for at least 3 months. An additional inclusion requirement was the identification of pelvic floor tenderness during a vaginal examination performed by a physician, followed by confirmation of this finding by a physical therapist. Exclusion criteria included having previously received pelvic floor MPT and not having ever received standard IC/PBS therapy. The 81 patients were randomly allocated to receive MPT (n=39) or GTM (n=42).

To standardize treatment, physical therapists from each site received training at a central location and were certified in the performance of each intervention. Myofascial physical therapy consisted of targeted internal and external tissue manipulation that honed in on the muscles and connective tissues

of the abdomen, pelvic floor, and hip girdle. Global therapeutic massage consisted of a typical program of full-body Western massage. Each patient underwent ten 60-minute treatment interventions during a 12-week period. Patients were blinded to which therapy they received, and physician examiners and data collectors were blinded to the therapy assignment for each patient.

The primary outcome was the proportion of patients who indicated having a moderate or marked improvement in overall symptoms at week 12, as determined by a global response assessment (GRA) that provided 7 response options (markedly worse, moderately worse, slightly worse, same, slightly improved, moderately improved, and markedly improved). Such patients were known as responders, whereas patients who did not provide data on the primary outcome or who withdrew from the study were known as nonresponders. Secondary outcome measures included patient-reported bladder pain, urgency, and frequency ratings on scales of 0 to 10; measurements of urinary frequency and volume obtained from a 24-hour voiding diary; scores on the O'Leary-Sant IC Symptom Index, the O'Leary-Sant IC Problem Index, and the 2000 Female Sexual Functioning Index; and responses to the 12-item Short Form Health Status Questionnaire and the Female Symptom Questionnaire. All outcome measures were determined at baseline and again at 12 weeks (after the series of intervention sessions was completed).

A total of 59% of the patients receiving MPT and 26% of the patients receiving GTM were considered to be GRA responders. Although improvements in secondary outcome measures were noted for patients in both the MPT and GTM groups, no statistically significant differences in such measures were noted between the 2 groups. The fact that the proportion of responders in the MPT group was more than double that of responders in the GTM group led the authors to justify favoring clinical use of MPT for the treatment of IC/PBS and other pelvic pain conditions.

Pain, which was the most common adverse event, occurred at nearly the same rate in both the MPT and GTM groups. Serious adverse events, however, were not recorded. I was gratified that the authors acknowledged viscerosomatic or somatovisceral interactions as the cause of pain (ie, pain that is referred to the low back and pelvis as a result of a primary pelvic visceral abnormality or as a result of a structural injury or abnormality that causes a secondary visceral hypersensitivity).

The authors state that the generalizability of their results may be limited because of the stringent nature of the study's inclusion criteria. They also indicate that it is unknown whether MPT would benefit patients who have symptoms of IC/PBS but have no pelvic floor tenderness. The study does not provide data on either the durability of the benefit received or whether this benefit could be optimized if MPT were provided periodically over a longer, multiple-year period.

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