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Botanical Agents for the Treatment of Obesity, Lipid Abnormalities, and Metabolic Syndrome

By Bridget S. Bongaard, MD, FACP

Dr. Bongaard is a Fellow in Integrative Medicine at the University of Arizona, Program in Integrative Medicine, in Tucson; she reports no consultant, stockholder, speaker's bureau, research, or other financial relationships to this field of study.

IT IS ESTIMATED THAT MORE THAN ONE BILLION ADULTS WORLDWIDE are overweight.¹ More than 60% of all Americans are now obese, and 47 million people have the metabolic syndrome (increased waist-to-hip ratio, hyperglycemia, insulin resistance, hypertension, and dyslipidemia). In underdeveloped countries, the incidence of obesity is also rising as they experience the same phenomenon of a continuous decrease in energy expenditure from physical activity and an increase in caloric intake.

Complicating the problem is that attempts at weight loss are rarely successful, and compliance with exercise or other weight-management programs is notoriously poor, indicating a need for safe and effective therapeutic options.² Even a modest 5% loss of body weight significantly decreases the risk of developing diabetes and cardiovascular disease.³

Obesity is tightly linked to major public health problems such as: Type 2 diabetes, dyslipidemias, hypertension, sleep apnea, and an increased inflammatory milieu in the body, which may contribute to the development of cancers. The incidence of osteoarthritis secondary to degeneration of weight-bearing joints increases with the progression of obesity as well. These conditions lead to substantial complications and suffering, as well as to strain on respective national health care budgets.

Definition of Obesity

Healthy normal body weight for a person is defined clinically as having a measured body mass index (BMI) of 18.5-24.9 kg/m². Currently, 34% of the U.S. population is overweight with a BMI of 25-29.9 kg/m², while 31% is obese at a BMI of > 30 kg/m².² Morbid obesity is defined as having a BMI > 40 kg/m². A child is defined as being severely obese if his or her BMI meets or exceeds the 99th

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percentile for age,² as the usual definition of BMI/morbid obesity is not relevant for children between ages 2 and 19.

Pathophysiology of Obesity

The location of the obesity is just as important as the determination of total weight, as central obesity (located around the waist area) is much more deleterious than fat deposits on the hips or upper arms. This central deposition of fat is associated with insulin resistance, which then leads to postprandial hyperinsulinemia, elevated blood glucose levels, and the eventual development of Type 2 diabetes. The insulin-resistant, hyperinsulinemic state also creates dyslipidemia due to abnormal lipase activity leading to the development of elevated serum free fatty acids and subsequent oxidative changes of LDL, with reduction in the production of the cardioprotective HDL component. The oxidation of LDL to a small dense lipoprotein particle is known to induce atherogenic cardiovascular changes. Obesity contributes to oxidative stress throughout the body. Oxidative stress in accumulated fat is one of the underlying causes of dysregulation of adipocytokines and development of metabolic syndrome.⁴

Botanically Based Agents for Treatment of Obesity-induced Risk Factors

Hoodia gordonii, a centrally acting anorectic agent

Though widely used in the nutraceutical market for appetite suppression, clinical trial research on *Hoodia*

gordonii is not available to date. Most of the existing research details the mechanism of action of this succulent plant native to sub-Saharan Africa's Kalahari Desert. It is used traditionally by the San, an indigenous tribe, for appetite suppression to reduce hunger in times of famine.

Research indicates that the active ingredient in hoodia is a sterol glycoside called P57, which acts on receptors deep within the brain. When injected into rats' third ventricle a 40-60% reduction in 24-hour food intake is noted.⁵ This was suspected to occur in response to changes in ATP governing mechanisms, as it was found that the ATP levels increased by 50-150% in the hypothalamic nuclei following administration of hoodia. The hypothalamus plays a critical role in running the body's homeostatic mechanism of thirst and temperature, as well as appetite, hence hoodia's anorectic effect.

Recommendations regarding the use of hoodia for the treatment of overweight and obesity must wait until sound clinical trials have been performed. To date, no published randomized controlled studies employing hoodia for weight loss exist; there are also no adequate guidelines for assessing a possible effective dose, inadequate understanding of how P57 affects other medications, and no research assessing potential side effects from usage in humans.

Phaseolus vulgaris extract, a starch neutralizer

Overconsumption of rapidly absorbed carbohydrates is frequently associated with obesity. Starch blockers could promote weight loss by inhibiting or retarding the degradation of ingested complex carbohydrates. The mechanism behind potential weight loss with use of the extract appears to be inhibition of α -amylase. With the reduced activity of α -amylase, the splitting of complex carbohydrates into simple absorbable sugars is decreased, thereby reducing the availability of carbohydrate-derived calories. By delaying the absorption of the carbohydrates in the upper gastrointestinal tract and shifting it to the colon, there is a decrease in the postprandial insulin response, which in turn leads to lesser fat accumulation.¹

Two well-performed clinical studies exist assessing the use of white bean extract (*Phaseolus vulgaris*). The first study by Udani et al utilized a cohort of 27 subjects with a BMI of 30-43 kg/m², taking 1,500 mg of white bean extract (Phase 2™) in the setting of a 100-200 g complex carbohydrate-restricted diet over eight weeks.³ The randomized, double-blind, placebo-controlled study excluded subjects with eating, endocrine, gastrointestinal, neuralgic, cardiac, renal, hepatic, or substance abuse disorders. The primary outcome measurements were weight loss and triglyceride levels. Secondary outcomes

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of percentage body fat, energy level, appetite control, hunger, HbA1c, total cholesterol, and change in waist and hip measurements were also examined.

The group utilizing Phase 2 lost an average of 3.79 lbs, while the placebo group averaged a 1.65 lbs weight loss, a statistically significant difference. Triglyceride levels showed a positive reduction in the active vs. control group, decreasing on average by 26.3 mg/dL. No adverse events were noted. The study was limited by small sample size, but provides a framework upon which future research can take place. The study is important in that it suggests that 1,500 mg of *P. vulgaris* extract taken after two daily carbohydrate-rich meals could not only prevent the absorption of digested complex carbohydrate calories and promote weight loss, but also potentially reduce cardiovascular morbidity by significantly decreasing the hypertriglyceridemia present in the obese cohort.

The second study from Celleno et al again was a randomized, double-blinded, placebo-controlled study looking at the impact of a dietary supplement containing 445 mg of *P. vulgaris* extract (Phase 2) in a 30-day trial of 60 overweight volunteers whose weight had been stable for six months.¹ The study cohort followed a carbohydrate-rich 2,000-2,200 calorie diet. Outcome measurements of body weight, BMI, fat mass, adipose tissue thickness, waist/hip/thigh circumferences, and lean body mass were examined.

The group receiving the Phase 2 compound had much greater loss of body weight (-2.93 kg), fat mass (-2.4 kg), adipose tissue thickness (-4.2 mm), and decreased waist, hip, and thigh circumference with a barely significant loss in lean body mass ($P < 0.05$) over the 30-day period. Again, no adverse effects were noted during the trial. One observation made by the study authors was that scale weight loss may not reflect reduction of specific fat compartments. Results of the study showed that body fat, rather than lean body mass, was reduced. BMI is known to relate closely to fat mass more than scale weight alone, and in this study's subjects BMI was reduced from $25.9 \pm 2.0 \text{ kg/m}^2$ to $24.9 \pm 1.9 \text{ kg/m}^2$.

***Cissus quadrangularis*, reducing obesity-induced oxidative stress**

This medicinal and culinary succulent native to India and Africa has been used for centuries by traditional Ayurvedic healers to treat bone fractures, stomach ailments, and digestive problems, as well as ear and eye diseases. It is also an edible vegetable naturally containing high amounts of vitamin C, vitamin A, and calcium. Phytochemical analysis revealed high contents of anabolic steroidal substances as well.⁴ The effects of anabolic steroids on physical performance are unclear. Well

controlled, double-blind studies have rendered conflicting results. Almost all studies have failed to show a beneficial effect on maximal oxygen consumption or endurance capacity.

As increasing obesity places the individual at progressive risk for oxidative stress and sequelae of cardiovascular disease, Type 2 diabetes, and inflammatory state-mediated diseases, it appears imperative that antioxidant therapy be utilized to stabilize the tissues against the oxidative stress. These compounds are abundant in fruits and vegetables, but also are present in *Cissus quadrangularis*.

A recent study examined the effect of *C. quadrangularis* on obesity, obesity-induced oxidative stress, and treatment of the metabolic syndrome. Oben et al performed a double-blind, placebo-controlled investigation of the antioxidant and weight-loss properties of two compounds containing *C. quadrangularis*.⁴ The methodology utilized both a pure standardized extract preparation of 300 mg of *C. quadrangularis* (CQR-300) taken once a day, and a formulated product (CORE 1,028 mg daily) containing *C. quadrangularis* 7.5 mg, ChromeMate[®] (niacin-bound chromium concentrate) 0.15 mg, green tea extract (40% polyphenols, 22% EGCG, 40% caffeine) 100 mg, selenium 0.06 mg, soy albumin 50 mg, vitamin B₆ 50 mg, vitamin B₁₂ 0.05 mg, and folic acid 0.04 mg. The participants were 168 overweight individuals with BMIs ranging from 25 kg/m² to 48.7 kg/m² (weight 70.6-142 kg).

Patients were randomized to five study arms of 6-8 weeks duration, utilizing placebo with a 2,100 kcal diet, and the two separate compounds with and without dietary restriction. Anthropomorphic measurements and blood sampling for analysis of plasma thiobarbituric acid reactive substances (TBARS) formation (measuring lipid peroxidation) and carbonyls (marker for oxidative injury), and the ability to scavenge free radicals were ascertained in all groups. Measurements of lipid profile, fasting plasma glucose, plasma serotonin levels, and plasma creatinine were evaluated simultaneously.

High plasma concentration of TBARS and carbonyl compounds were present in study participants, and were significantly reduced after treatment. CORE formula elicited the larger response compared to CQR-300. There was also a significant reduction of weight and BMI in the obese patients. In the CORE group there was an 8.5% change in weight and a reduction in BMI from 37 kg/m² to 33 kg/m². This was comparable to observed weight loss using orlistat for six months or one year and sibutramine for one year. A substantial increase in HDL (from 38 mg/dL to 55 mg/dL) and decrease in LDL (from 116 mg/dL to 78 mg/dL) were also noted. An

increase in serotonin was found and was believed to have a positive effect on mood. It is possible this serotonergic impact could help reduce binge-eating behaviors, but further study is needed. An increase in creatinine concentrations was identified and paralleled an increase in lean muscle mass, and likely a reduction in total body fat. Serum glucose levels were also reduced. As there was a significant improvement in the lipid profiles, blood sugar, and serotonin profiles of the participants, and an increase in antioxidant and free radical scavenging properties, it was suggested that CQR-300 as well as CORE could have applications as potential treatment for metabolic as well as other physiological complications in which there is an increase in oxidative stress.

Conclusion

The research on the botanical preparations discussed in this article utilized small patient samples, thus the results may not be generalizable; however, they do seem to point to the possibility of using white bean extract and the cissus products for weight loss and reduction of linked disease morbidity. More studies are clearly warranted.

Recommendation

Over the counter weight-loss agents should be analyzed carefully before purchase and consumption. Inherent quality issues may arise from efforts to protect species such as hoodia, and may lead to the substitution of other phytochemicals or the dilution of the purported active compound, limiting any potential therapeutic effectiveness. Adequate research may not be available, such as in the case of hoodia, to determine potentially effective dose, duration of treatment, contraindications, or side effect profile. A wide variety of weight loss compounds are available over the counter, and they can be expensive as well as ineffective.

Prescribed pharmacologic agents are readily available for the treatment of obesity. Serotonergic agents, noradrenergic agents, and lipase inhibitors, while effective, are expensive, and can have serious side effects such as valvular heart disease, hypertension, seizures, sexual dysfunction, and fecal incontinence, all for a minimal amount of weight loss.⁵ It is hoped that quality research continues to illuminate and expand the possible safe alternatives currently available to tackle the obesity epidemic in the United States and globally. ❖

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Tai Chi to Prevent Falls Among the Elderly

By Dónal P. O'Mathúna, PhD

PART 1 OF A SERIES ON TAI CHI: FALLS AS PRIMARY OUTCOME

Dr. O'Mathúna is a lecturer in Health Care Ethics, School of Nursing, Dublin City University, Ireland; he reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

AROUND THE WORLD, THE PROPORTION OF THOSE WHO are elderly (> 65 years of age) is growing and their life expectancy is increasing.¹ Between one-third and one-half of elderly people fall each year, with those living in long-term care facilities having a higher incidence of falls than community dwellers.² Although only about 20% of those falls require medical attention, and less than 10% result in fractures, less serious falls can be painful and reduce functionality. A fall can also lead to fear of further falling, although many elderly are afraid of falling even if they have not had an injurious fall. Approximately half of the elderly living in the community report experiencing fear of falling, which can lead to a debilitating spiral of loss of confidence, reduced physical activity and social involvement, further frailty, falling, and loss of independence.³

Effective fall prevention programs are therefore crucial to improving and maintaining health among the elderly. Several approaches have been examined, with tai chi (also called tai chi chuan) developing a significant reputation as a low-impact method of reducing the incidence of falls. Classes in its slow, graceful movements are commonly offered in many settings, including wellness programs and residential centers. Such classes also bring social benefits, but it can be practiced individually in almost any

location. Its effectiveness is also being investigated actively, with several new studies published in 2007 alone. Part 1 will review the evidence from clinical studies of tai chi that directly measured the frequency of falls. Part 2 will review other studies that measured outcomes associated with falls, such as balance or fear of falling.

Background

Tai chi literally means “supreme ultimate power.” Originally developed to provide general physical fitness for the martial arts, it was influenced by Chinese Taoism and Buddhism. As such, it is believed to balance the flow of life energy (chi) within the body and promote healthy living.⁴ In the West, it has been modified to make the movements easier to learn and practice in shorter periods of time.⁴ Five major styles of tai chi have developed, with the Yang form being the most popular. The Chinese government made tai chi compulsory in many colleges and universities, promoting it as a national cultural activity and leading to millions of Chinese people practicing tai chi regularly.⁵

All forms of tai chi involve meditation, breathing exercises, and slow, graceful movements. Many of these represent animal and bird movements, as reflected in their names: “white crane spreads wings,” “golden rooster stands on one leg,” and “ride the tiger.”⁵ Each session is composed of a series of specific postures combined into one long exercise. The movements are all considered circular with each session being viewed as one continuous, integrated circle. Sessions vary considerably from one another. For example, the traditional Yang style has 108 postures while simplified styles can have as few as six.¹ Sessions can last anywhere from 10 minutes to more than an hour.

Mechanism of Action

The traditional explanation within TCM for how tai chi promotes health is by restoring a balanced flow of chi. Chi is a nonphysical “life energy” that is believed to pervade everything, with illness arising when its flow is hindered or imbalanced. Tai chi as practiced in Western society is a gentle form of exercise and “moving meditation.”⁴ The movements are believed to improve balance, flexibility, fitness, and muscle strength, also leading to greater confidence and less fear of falling. The activity may also lead to general health benefits, which further reduce the risk of disability and falls.

Clinical Studies

Since the early 1990s, more than 30 studies have examined the effectiveness of tai chi for improving balance, muscle strength, or flexibility.¹ Differing research designs involving participants of different ages and abili-

ty have led to conflicting conclusions. Three systematic reviews were published between 2003 and 2004, and all found only one randomized controlled trial (RCT) of tai chi where the primary outcome measure was incidence of falls among the elderly.⁶ A number of other studies used secondary outcome measures like balance and muscle strength, which can be predictors of risk of falling.⁷ The latter will be reviewed in a subsequent article.

The one RCT mentioned above was published in 1996 and republished in 2003 when named the best research paper from the 1990s by the American Geriatrics Society.⁶ Two hundred participants older than age 70 (average, 76 years) were randomly assigned to one of three groups: tai chi, computerized balance training, or a discussion group instructed not to change exercise activities. The tai chi subjects met with an instructor twice a week for approximately 20 minutes, and were encouraged to practice tai chi on their own twice daily for 15 minutes. The latter was not monitored. Outcomes were measured at baseline, after 15 weeks of training, and upon follow-up at four months by blinded assessors. The number of falls and fear of falling were substantially reduced in the group practicing tai chi, but not in the two other groups. After adjusting for all fall risk factors, tai chi reduced the risk of falls by 47.5%.

In a more recent RCT, 256 physically inactive people older than 70 years living in the Oregon area were recruited to participate.⁸ Subjects were randomly assigned to attend a one-hour class in either tai chi or stretching exercises. The classes met three times weekly for six months. Falls were recorded in a diary along with any resulting injuries. Both groups showed reductions in falls, but the reduction was significantly greater in the tai chi group ($P = 0.007$). Over the six months, the proportion of those falling in the tai chi group fell by 55%. Follow-up assessment occurred six months after the end of the study and the group differences remained significant ($P < 0.001$). The tai chi group also showed significantly better improvements than controls in balance, walk speed, and fear of falling ($P < 0.001$).

Most tai chi research focusing on the elderly involves those living in the community; however, falls occur more frequently in residential facilities and are more likely to lead to serious injuries. One study enrolled 110 nursing home residents older than 65 years (average, 84.7 years).⁹ Participants were randomly assigned to either control, an exercise regimen, or tai chi. All received educational instruction on improving the quality of residential life, though not specifically on fall prevention. The exercise group received an individualized program involving a treadmill, exercise bicycle, and weight lifting. Structured sessions were held three times weekly. The tai

chi group met three times weekly and also received instruction on various methods to reduce fear of falling. All but 11 participants were followed for 24 months before the study ended. There were no significant differences between any of the groups for number of falls or time to first fall. Adherence to the two regimens was poor, with adherence to tai chi being significantly worse than the general exercise program (24% vs. 56%; $P < 0.001$). No statistical differences were found in numbers of falls between those who adhered and those who didn't. The researchers noted that the participants in this study were older and frailer than in most other studies.

A Korean study involved two long-term care facilities, which were randomly assigned to be the tai chi or control site.² Sixty-eight fall-prone residents participated, 29 in the tai chi site and 30 in the control. Sun-style tai chi classes were taught three times per week for 35 minutes for 12 weeks while the control site received no exercise intervention. During the 12 weeks, falls were reported by nine people in the tai chi group and 15 in the control, but the difference was not statistically significant. Those using tai chi had increased confidence that they could avoid falling, while the control group's score fell ($P < 0.001$). Outcomes for muscle strength, flexibility, balance, and mobility were significantly better in the tai chi group compared to control ($P < 0.001$).

A small number of other RCTs have examined the impact of tai chi on other outcomes regarded as indicators of risk of falling. These included recent studies on balance and stability, muscle strength, and fear of falling.^{3,10} Although the quality of earlier studies in this area was viewed as problematic, recent studies have been designed more rigorously and generally favor the tai chi group over control. These types of studies will be reviewed in detail in Part 2.

Adverse Effects

No adverse effects of tai chi were reported in the literature examined.

Conclusion

The number of tai chi RCTs involving the elderly has grown, but remains small. In general, that evidence supports tai chi as a program to reduce falls in those living in the community. Other trials measuring risk factors for falls also found evidence favoring tai chi. Although tai chi is practiced in many different ways, most studies use instructor-led sessions meeting three times a week for 30-60 minutes. The gentle nature of tai chi makes it particularly suited for elderly adults, but studies involving nursing home residents found tai chi no better than control. Modified versions of tai chi are being developed to

accommodate frailer people.¹¹ Whether the benefits of tai chi result from exercise more generally, or the unique combination of exercise, meditation, and breathing, remains unclear. One study found that elderly men who participated regularly in tai chi or golf had similar stability and joint movement as young men, and significantly better scores than elderly men who did not exercise.¹²

Recommendation

The evidence supports the use of tai chi to help prevent falls in elderly people living in the community. They may also reap the benefits of other physiological, psychological, and social interactions that accompany tai chi. As tai chi programs vary considerably in duration and rigor, the precise nature of the exercise should be understood before participating. All adults, especially the elderly, who are considering starting such a program should seek out medical advice to ensure they are physically ready to do so. People should remain alert to symptoms that could indicate overexertion. Keeping such cautions in mind, regular practice of tai chi may provide the elderly with protection against falls. ❖

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Effectiveness of Acupuncture for Treating Asthma

By Yoon Hang Kim, MD, MPH,
and Jeanne Bowers

Dr. Kim is the director of Georgia Integrative Medicine in Atlanta, and Ms. Bowers is completing a master's degree in psychology at the University of West Georgia in Carrollton. They report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

IN THE UNITED STATES, ASTHMA RESULTS IN MORE THAN 1.5 million emergency room visits, approximately 500,000 hospitalizations, and more than 5,000 deaths annually. Approximately 15 million Americans have asthma, and the cost of conventional medical treatment for asthma is in excess of \$6 billion annually.¹

The pathophysiology of asthma is complex and involves at least the following components: 1) airway inflammation, 2) intermittent airflow obstruction, and 3) bronchial hyper-responsiveness. Inflammation in asthma may be acute, subacute, or chronic, and the presence of airway edema and mucus secretion contributes to airflow obstruction and bronchial reactivity. In addition, varying degrees of mononuclear cell and eosinophil infiltration, epithelial desquamation, smooth muscle hyperplasia, and airway remodeling occur. The primary focus of recent pharmaceutical advances in the treatment of asthma has thus been targeted at modulation of inflammation. Great strides have been made, but prevalence of the disease continues to grow, and concerns about complications from treatment still exist. As such, the search for effective therapies continues.

In the past two decades, acupuncture has grown in popularity in the United States. The report from a Consensus Development Conference on Acupuncture held at the National Institutes of Health (NIH) in 1997 stated

that acupuncture is being “widely” practiced—by thousands of physicians, dentists, acupuncturists, and other practitioners—for relief or prevention of pain and for various other health conditions.² According to the 2002 National Health Interview Survey—the largest and most comprehensive survey of complementary and alternative medicine (CAM) use by American adults to date—an estimated 8.2 million U.S. adults have used acupuncture, and an estimated 2.1 million U.S. adults had used acupuncture in the previous year.³

In 2003, a comprehensive review of acupuncture for pediatric asthma was published in this newsletter.⁴ The present article will provide an update of recent developments, specifically regarding the theoretical plausibility of the mechanism behind acupuncture for treatment of asthma, and new clinical trials that explore the potential effectiveness of acupuncture in this setting.

Mechanism of Acupuncture for Treating Asthma

The Chinese medical view of acupuncture is that it enhances the harmony of the bioenergy, or life force, called qi. Stimulation of acupuncture points is believed to activate the bioenergy and balance disharmony, resulting in resolution of symptoms. In addition to acupuncture points, there are energy channels (known as meridians) for each organ including lung energy. In traditional Chinese medicine, asthma is considered a complex illness involving deficiencies of kidney organ bioenergy governing vitality and lung bioenergy governing harmony.

Mechanisms relevant to the role of acupuncture for treatment of asthma appear to involve modulation of the inflammatory cascade.⁵ Jeong et al investigated the regulatory effect of cytokine production in asthma patients treated with Korean hand acupuncture.⁶ Interleukin-6 (IL-6) is a pro-inflammatory cytokine secreted by T cells and macrophages to stimulate immune response. Plasma levels of IL-6 were lowered after acupuncture treatment compared to pretreatment levels.

Another asthma study investigated the effect of acupuncture on immunoglobulins and reported decreased IgE levels ($P < 0.01$).⁷ In a murine model of ulcerative colitis, electroacupuncture was shown to down-regulate serum TNF- α , levels of which correlate well with severity of symptoms.⁸

Despite these data, more basic science research needs to be performed to elucidate the role of acupuncture in modulating inflammation.

Systematic Reviews

Four systematic reviews of the use of acupuncture for treating asthma have been published. The first was performed by Kleijnen et al in 1991.⁹ The authors

reviewed 13 trials, which were evaluated against 18 pre-defined methodological criteria and scored out of 100. Only eight studies scored above 50 and no paper scored above 72, leading the authors to conclude that no recommendations could be made due to the poor quality of the trials. A similar conclusion was reached in the review carried out by Linde et al in 2001 as a part of the Cochrane Collaboration.¹⁰ This review involved rigorous criteria; only seven of 21 studies met the inclusion criteria. Martin et al conducted another systematic review and meta-analysis of 11 RCTs, again finding insufficient sound data exist on which to make firm conclusions.¹¹ Thus, all three of these reviews proposed that there was no conclusive evidence that acupuncture has a significant effect on the course of asthma; however, there was also no evidence that acupuncture is ineffective. Some of the problems pointed out by the three systematic reviews include heterogeneity of acupuncture techniques, outcome measures, and controls. The studies have also been small: The median sample size was 25 and the largest RCT had only 39 participants.

In 2004, the Cochrane Collaboration published an updated review of acupuncture for chronic asthma that included 11 studies meeting their inclusion criteria.¹² These trials (n = 324) of variable quality found that acupuncture had no significant effect on pulmonary function or global assessment of well-being, but the reviewers noted that some studies reported significant positive changes in daily symptoms, reductions in medication use, and improved quality of life. The authors concluded that there was not enough evidence to make recommendations about the value of acupuncture in asthma treatment.

Randomized Control Trials Published after 2004

In 2005, Zhang et al randomly divided 90 asthma patients into two groups: an acupuncture treatment group and a control group receiving sham acupuncture.¹³ The study found that both groups showed an improvement in pulmonary functions, but differences between groups were not statistically significant.

Another study was performed by Cai et al in 2005 comparing two specific acupuncture points in 200 patients with acute exacerbations of asthma.¹⁴ Patients were randomly divided into two groups: one group treated at the acupuncture point Qingchuan and the other group treated at the acupuncture point Dingchuan. Although Dingchuan is a standard acupuncture point located on paraspinal muscles on the level of the T1 spinous process and is traditionally used to calm acute asthma, the point Qingchuan is not a described point and the authors did not reply to communication asking for the location of Qingchuan. The authors concluded that

the total effective rate for the Qingchuan treatment group was 92% vs. 81% for the Dingchuan treatment group ($P < 0.01$). One limitation of this study is that it did not employ a sham acupuncture group, which measures non-specific effects of needling.

In 2006, Zhang conducted a clinical trial with 104 patients divided into two groups: a control group receiving usual conventional treatment for asthma and an acupuncture treatment group.¹⁵ After six months, the acupuncture treatment group reported a reduced incidence of asthmatic attacks ($P < 0.05$). Again, this study was limited at least by lack of a sham acupuncture control group, and the effects reported may have been due to non-specific effects of needling.

The above three publications were published in Chinese with English abstracts only. Requests to the principle investigator of each study for clarification of the study design and results have gone unanswered. Thus, no firm conclusions can be drawn from their stated results.

Stockert et al conducted a randomized controlled trial combining laser acupuncture and probiotics in school age children with asthma.¹⁶ The small study involved 17 children who were divided into laser acupuncture and probiotics vs. sham laser acupuncture and placebo. The study concluded that there was no significant effect from the combination therapy on quality of life, FEV₁, or medication changes.

Mehl-Madrona et al explored the possibility of synergy between acupuncture and craniosacral therapy on clinical outcomes in adults with asthma.¹⁷ Results of this study suggest no synergy between the two modalities.

Despite addition of trials with larger numbers of participants coming from China, the state of evidence in clinical trials has not changed. The research trials still have weaknesses pointed out in the systematic review. However, there are some positive points in strengthening the biological plausibility of acupuncture for treating asthma through modulation of inflammation, the same way many asthma medications work.

Adverse Effects

In experienced hands acupuncture is a safe practice. In the United States, only sterile, single-use surgical grade stainless steel needles are permitted to be inserted into acupuncture points. The most common complaints involve local bleeding, transient pain during needle insertion, nausea, syncope, and mild disorientation.^{18,19} The treatment of asthma with acupuncture may result in pneumothorax as documented in early case studies,²⁰ though this is a rare event, with but two reported cases in nearly a quarter of a million treatments.²¹

Conclusion

Despite some advances in understanding the biological plausibility of acupuncture's mechanism of action on the inflammatory cascade, the level of clinical research support is insufficient. An interesting trend is that acupuncture is being combined with other modalities. Treatment of chronic asthma with acupuncture to assess impact on quality of life and need for rescue medication would be a welcomed clinical trial.

Recommendation

Although acupuncture is a widely used CAM therapy in the United States, the evidence in support of its use for asthma is inconclusive due to inadequate data. Until there is clear evidence for the benefit of acupuncture in treating asthma, acupuncture should play at most a complementary role to proven management therapies. ❖

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CME Questions

CME Instructions: Physicians participate in this continuing medical education program by reading the articles, using the provided references for further research, and studying the CME questions. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity, participants must complete the evaluation form provided at the end of each semester (June and December) and return it in the reply envelope provided to receive a credit letter. When an evaluation form is received, a credit letter will be mailed to the participant.

After completing the program, physicians will be able to:

- a. present evidence-based clinical analyses of commonly used alternative therapies;
- b. make informed, evidence-based recommendations to clinicians about whether to consider using such therapies in practice; and
- c. describe and critique the objectives, methods, results and conclusions of useful, current, peer-reviewed clinical studies in alternative medicine as published in the scientific literature.

32. Although more research is needed, the following botanical preparations may be of possible benefit for weight loss and reduction of linked disease morbidity except:

- a. cissus products.
- b. hoodia.
- c. white bean extract.

33. Evidence from controlled trials of tai chi for falls among the elderly can be summarized as finding that:

- a. Tai chi can be recommended to reduce falls among some elderly populations.
- b. There is no evidence that tai chi may reduce the risk of falls.
- c. Tai chi should not be recommended for any elderly adult.
- d. All of the above

34. Evidence of a benefit from tai has been most clearly demonstrated in which of the following groups?

- a. All elderly adults
- b. Those who are relatively frail and weak
- c. Those who are mobile and living in the community
- d. Those who live in nursing homes and other residential facilities

35. At this time, if used at all, acupuncture should be considered at most a complementary role to proven asthma management therapies.

- a. True
- b. False

Answers: 32. b, 33. a, 34. c, 35. a.

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Clinical Briefs

With Comments from Russell H. Greenfield, MD

Dr. Greenfield is Clinical Assistant Professor, School of Medicine, University of North Carolina, Chapel Hill, NC; and Visiting Assistant Professor, University of Arizona, College of Medicine, Tucson, AZ.

Heaven Scent? Aromatherapy Massage for Cancer Anxiety

Source: Wilkinson SM, et al. Effectiveness of aromatherapy massage in the management of anxiety and depression in patients with cancer: A multicenter randomized controlled trial. *J Clin Oncol* 2007;25:532-539.

Goal: To determine if aromatherapy massage (AM), when added to usual supportive care (USC) for people with cancer experiencing anxiety and depression, is more effective than USC alone.

Study design: Ten-week pragmatic, two-armed, randomized, controlled trial.

Subjects: Patients with cancer who were referred to complementary therapy services for treatment of anxiety and depression (n = 288, of whom 221 completed at least some of the final assessment) recruited from four U.K. National Health Service cancer centers and one hospice.

Methods: Twelve participating massage therapists agreed upon a treatment protocol that included 20 essential oils, specific massage strokes, timings, and overall style, with individual treatments chosen from these protocols to meet the unique needs of subjects. Participants with DSM-IV criteria for anxiety and depression were randomly allocated to

receive either USC + AM, or USC alone. USC consisted of access to psychological support services. Those randomized to massage received one-hour sessions of AM once a week for four weeks in addition to USC. Demographic, clinical, and socioeconomic data were collected at baseline, and interview and questionnaire data were collected at baseline, and six and 12 weeks later. The primary outcome of interest was change in anxiety and/or depression between "full case and borderline and noncase, or between borderline and noncase" at trial's end. Secondary outcomes included change in clinical anxiety and/or depression at six weeks post-randomization, change in self-reported anxiety at six and 10 weeks post-randomization, change in self-reported depression at six and 10 weeks post-randomization, and change in self-reported fatigue, pain, nausea and vomiting, and global quality of life at six and 10 weeks post-randomization. Twelve participants at each center were asked to complete pre- and post-AM session questionnaires to evaluate immediate effects of AM.

Results: At baseline, 38% (109) of subjects were deemed to have borderline anxiety and/or depression, and 62% (179) as having case anxiety and/or depression. Of the 144 people assigned to AM + USC, 86% received 2-4 ses-

sions of AM. At six weeks post-randomization, 55% of subjects had experienced improvement in their clinical anxiety and/or depression, with more in the USC + AM group showing improvement than in the USC alone group. The greatest improvement was noted for symptoms of anxiety and borderline depression. At 10 weeks post-randomization, 63% of subjects had experienced improvement in anxiety and/or depression, but no objective difference was identified between those in the USC + AM group and the USC group. Subjects using psychotropic medications at baseline were less likely to experience symptom improvement. At both six and 10 weeks post-randomization, those who received AM reported a significant improvement in self-reported anxiety; there was, however, no significant difference between groups with respect to self-reported symptoms of depression. In addition, no differences between the two arms were noted for any secondary outcome measures. A total of 57 subjects completed pre- and post-AM session State Anxiety Inventory questionnaires, showing a mean improvement of 13.9.

Conclusion: AM acutely improves clinical anxiety and/or mild depression in cancer patients, with objective benefits from four weekly one-hour sessions persisting for two weeks beyond the last

treatment. Subjective benefit endures significantly beyond objective symptom improvement. AM appears to be most effective for amelioration of anxiety.

Study strengths: Degree to which consensus of diagnosis assured; testing for researcher bias; sample size; duration of follow-up; intention-to-treat analysis; range of clinical presentations (subjects with early and advanced cancers entered into study); combination of standardized outcome measures, patient self-report, and structured interviews; autonomy of therapists (approximating real-world application).

Study weaknesses: Frequency of intervention (a single one-hour massage per week); only people referred for complementary therapy services were enrolled in the trial; not all assessments took place in person; incomplete blinding; significant amount of missing data requiring multiple imputation (the authors state that “nonmissing data at the two outcome assessment points were not representative of the patients randomly selected”); suboptimal recruitment; significant attrition, mainly due to poor health; don’t know if any subjects received AM outside of protocol.

Of note: AM is commonly offered within cancer centers, and is very popular among people with cancer; patients generally perceive AM in a positive light, feeling that it offers subjective therapeutic benefit; only cancer patients with an expected survival of more than three months were included in the present trial; cancer patients who had been prescribed psychotropic medication or received psychological counseling within three months of baseline assessment were excluded from participating; the majority of participants were female, and > 50% had breast cancer (almost half had advanced cancer, and two-thirds were receiving chemotherapy and/or radiation therapy); subjects randomized to USC only were offered a course of AM at the end of the trial; diagnostic assessments were tape recorded, and consensus meetings held regularly to assure both quality and consistency of diagnostic rating; most assessments took place in face-to-face meetings within clinics, but 50

occurred by phone and 12 at subjects’ homes; participants were from a wide variety of socioeconomic backgrounds; participants were recruited over a period of approximately 3.5 years (yielding an average of 82 patients per year).

We knew that: Relieving mild-to-moderate psychological distress for people with cancer is a significant challenge; psychological distress appears to be closely related to symptoms like pain, nausea, and insomnia; prior data have shown that aromatherapy massage may decrease self-reported symptoms of anxiety immediately following treatments; inhaled aromatherapy oils administered without human touch do not appear to have a positive impact on anxiety.

Comments: Significant issues exist that somewhat limit interpretation of the results of this study, but the authors are to be commended for carrying out such a methodologically difficult trial. Troubles like the significant attrition rate, anemic subject recruitment, and missing data are problematic, but challenges like these can only be expected when focusing on such an ill patient population. There are other issues as well. It is unfortunate that recruitment only took place through referral to complementary therapy services, as a significant number of potential subjects may have been missed. Those who were referred for complementary therapy services and who followed through were likely those most open to complementary therapies, and thus may have been more likely to respond favorably to AM. Measured benefit may have been subconsciously inflated because of the face-to-face nature of interviews. In addition, the authors sagely note that improvement in anxiety levels could well have occurred simply due to passage of time beyond that when the dual crises of diagnosis and discussion of necessary treatment first occurred. Beyond all the challenges inherent in such a study, however, results showed that the trajectory of improvement was significantly greater in the AM arm than in the USC group, and that subjective improvements were even more enduring than objective benefits. The results cannot be classified as

definitive, but when considered together with prior data, they suggest that appropriate human touch is an underutilized therapeutic tool.

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I’m OK, You’re OK— Physician Self- Disclosure

Source: McDaniel SH, et al. Physician self-disclosure in primary care visits. Enough about you, what about me? *Arch Intern Med* 2007;167:1321-1326.

Goal: To examine the presence and impact of physician self-disclosure (MD-SD) on patients, the nature and sequence of communication, and the process of care.

Study design: Descriptive study (sequence analysis applied to existing database of patients’ first visits to a selected group of primary care providers).

Subjects: Primary care providers (n = 100) who agreed to complete surveys and have two unannounced, covertly audio-recorded, standardized patient visits (n = 193, data analyzed on 113).

Methods: Standardized patients were intensively trained to portray specific patient roles in a manner indistinguishable from actual patients. Detailed biographies were developed for two middle-aged, Caucasian patient presentations (gastroesophageal reflux disease and medically unexplained symptoms). Each physician was randomly assigned two standardized patients who presented with one or the other malady, one male patient and one female. Initial contact was made by requesting a new patient appointment for a person with “chest pain for a couple of weeks” that appeared to be non-urgent. Each visit was surreptitiously recorded, later transcribed, and reviewed for verbal content and intonation. Two days after the standardized patient visit, practitioners received a faxed inquiry about the interaction to determine whether the doctor correctly identified the person as a standardized patient, and

if their practice style changed in response to their opinion.

Results: Thirty-eight visits (34%) to 32 physicians contained at least one MD-SD, with an average of one MD-SD per self-disclosing physician, and a total of 73 MD-SDs identified. No association was found between the number of MD-SDs and gender, role, or duration of patient visit. Most MD-SDs occurred prior to the physical examination, during history and information gathering, and typically were preceded by patient statements. MD-SDs were related to the patient statement in the majority of instances, but were seldom a response to a direct patient inquiry; rather, it appeared that the physician assumed patient interest in her or his experience. None of the identified MD-SDs were patient-focused. There were but three identifiable instances where the MD-SD was deemed potentially helpful to the patient; in each case the physician mentioned that she or he had the same medical condition as the standardized patient. There were eight MD-SDs that seemed disruptive, in some way detracting from the physician-patient relationship. There was a suggestion that longer MD-SDs tend to be disruptive or at least not helpful.

Conclusion: MD-SDs are common in primary care, are usually not helpful to patients, and may serve to impede development of a healthy patient-practitioner relationship.

Study strengths: Avoidance of potential confounding factors; method of review.

Study weaknesses: A significant number of patient visits (40%) were excluded from analysis because practitioners suspected the standardized patient was not a real patient; assumptions of authors relating to value of specific interactions between patient and practitioner.

Of note: MD-SD, when the practitioner shares personal information and/or experiences, is a controversial topic with a paucity of data despite it being widely perceived as a way to deepen the patient-practitioner relationship; the current analysis is part of a larger study using covert audio recordings of office visits to study patient-centered commu-

nication and health outcomes; prior qualitative evaluation of these data focused on physician responses to ambiguous symptoms, but researchers remarked on the frequency of MD-SDs, which led to the current study; existing studies suggest MD-SDs to be beneficial in a surgeon's office, where they were associated with enhanced patient satisfaction and reports of friendliness and reassurance, while MD-SDs in primary care practices are not helpful, and were associated with low scores on similar scales; researchers were blinded to gender when evaluating transcripts; participating physicians were reimbursed \$400 for their time.

We knew that: Effective communication between patient and health care provider appears to improve health outcomes; doctors may work harder to create connection with a new patient, and may use SD to promote a healing, trusting relationship.

Comments: This article was widely discussed in the lay press, with headlines and video introductions suggesting that doctors should stop talking about themselves. The implication is that health care practitioners are often self-centered, and in the office more concerned with their own daily concerns than with those of their patients.

Aside from the large number of patient-practitioner interactions not evaluated, this is a well-done study. A question for our readers: Have you ever perused a well-done study and disagreed with its conclusions?

The authors rightly state that MD-SDs may take away from important patient concerns, especially in an age where time for supporting the healing relationship between patient and provider is in high demand but often in short supply. The authors note they saw no evidence that MD-SDs help build rapport, and cite examples of discussions that offered no therapeutic benefit. However, many patients prefer to work with a health care provider who creates an equal plane of interaction, and who prudently shares something about themselves if appropriate. Of course a practitioner should not be presumptuous, but provision of excellent health care does not necessarily mean patients cannot know anything about the personal nature of their health care providers. As with all of health care, such decisions need be made on an individualized basis. The authors state that physicians should be empathetic, and fulfill their need to share by speaking with friends, or joining support groups. This reviewer believes physicians are a privileged lot to have people share their stories with us. Those stories often help us on our own paths; in return, we offer expertise in the hope that our patients will be well. We have shared vulnerabilities, often shared dreams. Doctors need not be dissuaded from appropriately, cautiously, and respectfully sharing of themselves, provided that doing so does not interfere with patients' expectations and care.

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Patient Handout: Healthy Weight

WHETHER YOU WANT TO LOSE WEIGHT OR MAINTAIN A HEALTHY WEIGHT, IT'S IMPORTANT to understand the connection between the energy your body takes in (through the foods you eat and the beverages you drink) and the energy your body uses (through the activities you do). To lose weight, you need to use more calories than you take in. To maintain a healthy weight, you need to balance the calories you use with those you take in.

Want to find out if you are at a healthy weight? Use the Centers for Disease Control and Prevention's (CDC's) Body Mass Index calculator, available at: www.cdc.gov/nccdphp/dnpa/bmi/index.htm.

Getting the Most Nutrition out of Your Calories

There is a right number of calories for you to eat each day. This number depends on your age, activity level, and whether you are trying to gain, maintain, or lose weight. You could use up the entire amount on a few high-calorie foods, but chances are, you won't get the full range of vitamins and nutrients your body needs to be healthy.

Choose the most nutritionally rich foods you can from each food group each day—those packed with vitamins, minerals, fiber, and other nutrients, but lower in calories. Pick foods like fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products more often.

For more information about food choices and appropriate calories, visit the Dietary Guidelines for Americans 2005 (www.health.gov/dietaryguidelines/) and MyPyramid.gov.

Finding Your Balance between Food and Physical Activity

Becoming a healthier you isn't just about eating healthy—it's also about physical activity. Regular physical activity is important for your overall health and fitness. It also helps you control body weight by balancing the calories you take in as food with the calories you expend each day.

Be physically active, at a moderate intensity for at least 30 minutes most days of the week.

Increasing the intensity or the amount of time that you are physically active can have even greater health benefits and may be needed to control body weight. About 60 minutes a day may be needed to prevent weight gain.

Children and teenagers should be physically active 60 minutes every day, or most every day.

Whether you want to lose weight or maintain a healthy weight, it's important to understand the connection between the energy your body takes in (through the foods you eat and the beverages you drink) and the energy your body uses (through the activities you do).

Energy balance is like a scale. To remain in balance, the calories consumed (from foods) must be balanced by the calories used (in physical activity). To lose weight, you need to use more calories than you take in. To maintain a healthy weight, you need to balance the calories you use with those you take in. No matter which results you want, eating a healthy diet and being physically active can help you reach your goal.

Overcoming Barriers to Physical Activity

Given the health benefits of regular physical activity, we might have to ask why two out of three (60%) Americans are not active at recommended levels. There are barriers that

keep Americans from being, or becoming, regularly physically active. Understanding common barriers to physical activity and creating strategies to overcome them may help you make physical activity part of your daily life.

Environmental Barriers

Social environments such as school, work, family, and friends can significantly influence an individual's level of physical activity. However, characteristics of our communities such as the accessibility and location of parks, trails, sidewalks, and recreational centers as well as street design, density of housing, and availability of public transit may play an even greater role in promoting or discouraging an individual's or family's level of physical activity. There are also significant environmental barriers from water and air pollution to crime and dangerous automobile traffic.

To address this, the CDC has initiated the ACES: Active Community Environments Initiative project to promote and support the awareness and development of places where people of all ages and abilities can easily enjoy walking, bicycling, and other forms of recreation.

There are many opportunities within our environment that support physical activities from parks, trails, and sidewalks to recreation and fitness centers. Even malls provide opportunities for fitness walking. Understanding environmental opportunities and barriers that we face in our pursuit of a healthy lifestyle may provide some of the knowledge necessary to promote healthy living. This information may also provide ideas for advocacy and civic participation (visit www.cdc.gov/nccdphp/dnpa/physical/health_professionals/active_environments/aces.htm to learn more).

Personal Barriers

Aside from the many technological advances and conveniences that have made our lives easier and less active, many personal variables, including physiological, behavioral, and psychological factors, may affect our plans to become more physically active. In fact, the 10 most common reasons adults cite for not adopting more physically active lifestyles are:¹

- Do not have enough time to exercise
- Find it inconvenient to exercise
- Lack self-motivation
- Do not find exercise enjoyable
- Find exercise boring
- Lack confidence in their ability to be physically

active (low self-efficacy)

- Fear being injured or have been injured recently
- Lack self-management skills, such as the ability to set personal goals, monitor progress, or reward progress toward such goals
- Lack encouragement, support, or companionship from family and friends
- Do not have parks, sidewalks, bicycle trails, or safe and pleasant walking paths convenient to their homes or offices

Tips for Being More Active

With a little creativity and planning, even the person with the busiest schedule can make room for physical activity. For many, before or after work or meals is often an available time to cycle, walk, or play. Think about your weekly or daily schedule and look for or make opportunities to be more active. Every little bit helps. Consider the following suggestions:

- Walk, cycle, jog, skate, etc., to work, school, the store, or place of worship.
- Park the car farther away from your destination.
- Get on or off the bus several blocks away.
- Take the stairs instead of the elevator or escalator.
- Play with children or pets. If you find it too difficult to be active after work, try it before work.
- Take fitness breaks—walk or do desk exercises—instead of taking cigarette or coffee breaks.
- Perform gardening or home repair activities.
- Avoid labor-saving devices—turn off the self-propel option on your lawn mower or vacuum cleaner.
- Use leg power—take small trips on foot to get your body moving.
- Exercise while watching TV (use hand weights, stationary bicycle/treadmill/stairclimber, or stretch).
- Dance to music.
- Keep a pair of comfortable walking or running shoes in your car and office. You'll be ready for activity wherever you go!
- Make a Saturday morning walk a group habit.
- Walk while doing errands.

Reference

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Source: Centers for Disease Control and Prevention. Available at: www.cdc.gov. Accessed July 17, 2007.

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