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INSIDE

Acupuncture for the Treatment of Depression

By Yoon-Hang Kim, MD, MPH, DABMA

DEPRESSION IS A COMMON, CHRONIC, AND COSTLY MEDICAL CONDITION. The World Health Organization identified major depression as the fourth leading cause of worldwide disease in 1990, resulting in more disability than either ischemic heart disease or cerebrovascular disease.[1] In the United States, depression's impact on disability is comparable to that of heart disease.[2] In addition, depression is associated with a heightened incidence of physical symptoms, such as pain and increased functional impairment.[3] Furthermore, post-myocardial infarction depression is an independent risk factor for increased mortality.[4]

The effectiveness and side effects of selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs) are well-documented. However, one of the potential side effects appears to be the possibility of increased suicide risk in select populations; this possibility currently is being investigated.[5]

The use of complementary and alternative medicine (CAM) for depression has been well documented by Kessler et al.[6] Their findings suggest that CAM therapies are used more frequently than conventional therapies by people with self-defined anxiety attacks and people with severe depression. The efficacy of CAM modalities have been evaluated in a review by Jorm et al, which includes a brief section on acupuncture.[7] The use of acupuncture within psychiatry has been described in a textbook by Flaws and Lake.[8] Another text by Schnyer and Allen describes issues in conducting research on the use of acupuncture to treat depression.[9]

Mechanism of Action

Acupuncture is probably the most thoroughly researched modality in complementary and alternative medicine.[10] It is widely believed that acupuncture stimulates small diameter nerves in muscles, sending impulses to the spinal cord, midbrain, and pituitary, and results in the release of neurotransmitters such as monoamines and endorphins.[10]

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Endorphins are part of the mechanism for the acupuncture pathway. The discovery of naloxone, an endorphin antagonist, helped to elucidate the role of endorphins with acupuncture. Naloxone was shown to block acupuncture analgesia in human volunteers in a randomized, double-blind study.[11] A subsequent study reproduced these results displaying a dose-response curve for naloxone, and found that increasing doses produced increasing blockade.[12]

More importantly for the treatment of depression, monoamines such as serotonin and norepinephrine appear to be involved in acupuncture. Microinjection of serotonin antagonists has been shown to block the effects of acupuncture.[13] A similar study using microinjection of a norepinephrine antagonist has also been shown to block the effect of acupuncture.[14] Sprott et al demonstrated the rise of serum serotonin during acupuncture treatments.[15] Another recent study demonstrated characterization of serotonin receptor subtypes involved in modulation of electrical acupuncture.[16]

The monoamines' involvement in the acupuncture pathway provides possible mechanisms by which acupuncture might be effective in treating monoamine-mediated conditions, including depression and anxiety. In addition, a recent study reported that acupuncture treatments result in increased nocturnal melatonin secretion, reducing both insomnia and anxiety.[17]

In 1975, Riederer et al conducted a human trial demonstrating that needling of specific acupuncture points results in changes in norepinephrine levels measured in blood and urine.[18]

In the 1980s, Han investigated the effects of electroacupuncture on serotonin and norepinephrine.[19] The findings demonstrated that electroacupuncture accelerates the synthesis and release of serotonin and norepinephrine in the central nervous system. Furthermore, Fanqiang et al reported that plasma norepinephrine concentrations were significantly elevated in depressed patients who improved following a six-week course of electro-acupuncture; in contrast, the non-responding patients did not show significant changes in serum norepinephrine levels.[20]

Clinical Trials

In 1985, Luo et al conducted a clinical trial comparing the efficacy of acupuncture for treating depression vs. amitriptyline.[21] The 47 patients were randomly assigned to two groups. One group received electric acupuncture at Bai Hui and Yintang acupuncture points for one hour per day, six days a week, for five weeks. The control group received amitriptyline. The results demonstrated that electric acupuncture was as effective as amitriptyline for treating depression. In addition, electric acupuncture was found to be more effective for treating anxiety without the side effects of drug treatment.

Luo et al reported the results from a repeat trial with 241 patients in 1990. The results were similar to the earlier study: Acupuncture was found to be as effective as amitriptyline for treating depression and more effective for treating anxiety.[22]

In 1994, Yang et al reported the results of a clinical trial comparing the effects of acupuncture and amitriptyline.[23] In contrast to the two previous studies by Luo et al where only two acupuncture points were utilized, Yang et al explored the use of traditional acupuncture taking into account the presenting traditional Chinese medicine diagnoses. The findings were similar to the earlier two trials conducted by Luo et al where acupuncture treatment was found to be as effective as amitriptyline for the treatment of depression and more effective for treating anxiety.

In 1998, Allen et al published results of a pilot trial involving 33 female outpatients who met criteria for major depression and were assigned to one of three groups: acupuncture treatment specific for depression; a non-specific treatment using valid acupuncture points;

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and a no-treatment group of patients who were placed on a wait list.[24] They reported that 64% of patients who received acupuncture treatments specific for depression showed full remission and improved significantly more than women in the non-specific treatment group. However, no statistical differences were shown between the depression-specific treatment group and the no-treatment group. The full-scale trial was recently completed and results should be soon available.

In 1999, Roscheke et al studied the effect of adding acupuncture to antidepressant medication. They assigned 70 inpatients to three groups: acupuncture plus antidepressant, sham acupuncture plus antidepressant, and antidepressant.[25] The results showed that the addition of acupuncture resulted in a significantly better clinical response than antidepressants alone. However, there was no difference between the true acupuncture and sham acupuncture groups.

In 2000, Eich et al published results of a trial in which 43 subjects received either acupuncture or sham acupuncture for the treatment of depression.[26] They concluded that acupuncture was significantly more effective than sham acupuncture after 10 treatments but not after five treatments.

Adverse Effects/Safety

The safety of acupuncture is well documented. Ernst and White conducted a systematic review to determine the incidence of adverse events associated with acupuncture.[27] The most common adverse events were needle pain (1-45%) from treatments, tiredness (2-41%), and bleeding (0.03-38%). Feelings of faintness and syncope were uncommon, with an incidence of 0-0.3%. Pneumothorax was rare, occurring only twice in nearly a quarter of a million treatments.

Conclusion

A significant amount of information exists on the effectiveness of acupuncture for treating depression. The chain of evidence, from neurotransmitter involvement to clinical trials, supports biological plausibility and efficacy. Further studies comparing acupuncture to newer antidepressant agents are needed, however.

Recommendation

Depression is a prevalent medical problem with huge social, economical, and medical implications. Given the low risk of side effects, a trial of acupuncture can be considered a potentially useful option for some patients with depression, including those with mild-to-moderate anxiety/depression, patients experiencing significant adverse reactions to medications, and patients who have not yet achieved optimal benefit from conventional treatments. ❖

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Gymnema sylvestre for the Treatment of Diabetes—How Sweet It Isn't

By Jay Udani, MD, and Mary L. Hardy, MD

BECAUSE THE AYURVEDIC HERB *GYMNEMA SYLVESTRE* IS becoming an increasingly popular ingredient in diabetes and weight-loss formulas, it is advisable that health care providers familiarize themselves with its uses and properties.

A venerable history supports the use of this herb for diabetes. Classical Ayurvedic texts recognize a condition similar to diabetes and identify a specific remedy, gymnema, referred to as the "sugar destroyer." *(See sidebar on p. 29 for more information on Ayurvedic philosophy.)* This common woody climbing vine has been used for centuries in Indian traditional medicine to treat "honey urine," or what conventional Western medicine calls diabetes, a disease that has been diagnosed in Ayurveda for more than 2,000 years. In fact the concordance between the Ayurvedic diagnosis of madhu meha and the Western disease of diabetes is so close that Ayurveda recognizes both a congenital type of this disease and an acquired type, which correspond to our Type 1 and Type 2 diabetes.[1]

Gymnema or gurmar, to use its common Hindi name, means sugar destroyer, because it was noted that chewing the fresh leaves temporarily destroyed the taste of sugar in the mouth. Traditional uses for a decoction (water-based extraction process that involves boiling the plant material) of the leaves include the reduction of sugar in the urine, as a remedy for fever and cough, as a uterine tonic, cardiotonic, diuretic, or laxative, and to treat other urinary disorders.[2-4] There have even been references for use of the root in the treatment of snakebite.[4,5]

However, since first studied by the British in India during the 19th century, modern herbal medicine has focused on the use of the gymnema leaf to decrease blood sugar. According to a recent review, gymnema is the herb most frequently studied in human clinical trials of diabetes, either as a single agent or in traditional Ayurvedic formulas.[1] Additional information from phytochemical research and animal trials has elucidated a unique set of mechanisms for controlling blood sugar. These data plus a number of clinical trials, largely conducted in India, provide the supportive evidence for gymnema's use as a hypoglycemic agent.

Constituents

A number of constituents have been isolated from this plant since the first chemical studies were reported at the end of the 19th century. The gymnemic acids, which were first isolated by Hooper in 1889, appear to be the most important constituents for lowering blood sugar.[2] These exist in the plant in a complex mixture of at least nine closely related compounds, with the major component being identified as gymnemic acid A1.[3,6,7]

The "sugar destroying effect" of gymnema, on the other hand (affecting taste), is related to a polypeptide, gurmarin, which consists of 35 amino acids.[3] The best-studied extract of gymnema, GS4, contains both the triterpene sapinoids (the gymnemic acids) as well as the polypeptide, gurmarin.

Philosophy of Ayurveda

Ayurveda (Sanskrit for "knowledge of life") is a comprehensive system of traditional health care that emphasizes the relationship among body, mind, and spirit. Originating in India roughly 3,000 years ago, Ayurveda seeks to restore an individual's innate harmony. Primary Ayurvedic treatments include diet, exercise, meditation, herbs, massage, exposure to sunlight, and controlled breathing. It is a functional system of health care, more akin to traditional Chinese medicine than to conventional Western medicine.

According to the principles of Ayurveda, the five basic elements (ether, air, fire, water, and earth) combine with each other and manifest themselves in the human body as three humors or doshas, the essential energetic essence of a person, known as vata, pitta, and kapha. The doshas govern all biological, psychological, and pathophysiological functions in the body, mind, and consciousness. It is an imbalance of these doshas that leads to illness, and Ayurveda seeks to bring the doshas back into harmony.

Humans are endowed at birth with one of seven different body types, depending on which dosha, or combination of the three basic doshas, dominates. A person's dosha or personal body type (or energetic essence) is expressed both physically and emotionally; for example, a person with a vata-dominant body type will have a thin frame and an insecure temperament. The Ayurvedic physician takes body type and imbalances among the doshas into consideration when treating a patient, requiring individualized prescriptions. Classical formulas have been described for certain conditions and may contain as many as seven herbs as well as minerals or even metals.

The Ayurvedic diagnosis of madhu meha is the result of a multi-factorial disease process. The cause may be inherited at birth or result as the outcome of a series of environmental and behavioral influences. Finally, the imbalance which results in this urinary disorder may be in any of the three vatas, but an excess of kapha is most often implicated and usually carries the best prognosis. A traditional Ayurvedic formula for this condition would contain herbs and/or minerals, which would resolve the underlying disorder and restore balance to the doshas. Therefore, gymnema would rarely be given as a single herb, but rather as part of a formula.

Pharmacokinetics/Mechanism of Action

Indian physicians are strong proponents of the efficacy of gymnema for diabetic patients, and the evidence suggests that this herb can lower blood sugar. Various preparations have been tested clinically including fresh leaves (chewed), dried leaf powder, water-based decoctions, a standardized extract (GS4), and multi-herbal formulas containing minerals and other herbs in addition to gymnema.[1] Several pharmacologic actions of gymnema contribute to this herb's hypoglycemic effects.

Although animals with normal blood sugar are largely unaffected,[8-10] gymnema has been shown to cause increased insulin release from isolated islet cells as well as from animals with an intact pancreas.[11,12] However, the pancreas is not essential for gymnema's action as it can still normalize blood sugar in animals without any remaining beta-cell function.[11] Actions of the herb have been identified that involve the liver and a variety of hepatic enzymes that regulate glucose production and storage, which favors glucose uptake from blood into cells.[13] Some evidence exists for a reduction in absorption of glucose from the small intestine,[14] and results of some animal trials have even suggested that gymnema may protect the pancreas from toxins and promote beta-cell regeneration.[11,15] These last two actions have not been studied or observed in humans. An additional concern in people with diabetes is dyslipidemia. Gymnema also has been shown to increase fecal excretion of cholesterol but not bile acids in rats.[16]

The most unique action of gymnema involves its ability to decrease the perception of sweet taste. Traditionally, after chewing the fresh leaf, it was noted that the sense of sweetness was decreased for up to two hours. Bitter tastes also are obscured but not other taste sensations such as salty, pungent, acidic, or astringent.[17] The constituents that are most responsible for this effect are the gymnemic acids and gurmarin. This effect is achieved by a direct action on the chordae tympani or sensory efferent nerves responsible for transmitting the sweet perception.[18] This may be a clinically significant effect. Subjects who were previously exposed to a gymnema solution ate fewer total calories when offered ad libitum access to typical junk food. The effect was attributed to the change in sweet sensation and accompanying decrease in appetite caused by gymnema.[19]

Clinical Trials: Diabetes

Human clinical trials studying the effectiveness of gymnema on Type 1 and 2 diabetes mellitus are limited and most are flawed in their methodology. The number of eligible studies is further limited by the fact that many gymnema trials use proprietary multiple herb

combinations. The following five studies described are single herb trials of gymnema.

A case series of eight Type 2 diabetic patients given 10 mg of dried *Gymnema sylvestre* leaf powder for 21 days found a statistically significant reduction in fasting blood glucose of 50.5 mg/dL and reduction in two-hour post-prandial blood glucose levels of 40.5 mg/dL at 21 days ($P < 0.05$) as compared with the same patients prior to treatment with gymnema.[20] The study also found a non-significant increase in body weight of 0.9 kg in the subjects during this same 21-day period. There was no comparison group for this trial.

The same author published a controlled clinical trial in 1992 involving three research arms: Sixteen healthy volunteers received gymnema, and 43 Type 2 diabetic patients received either gymnema or tolbutamide (an oral hypoglycemic agent at a typical therapeutic dose) for a total of 21 days.[21] The patients were not assigned to groups randomly and neither the patients nor the investigators were blinded. The non-diabetic patients experienced a significant reduction in fasting blood sugar (FBS, from 80.8 mg/dL to 71.6 mg/dL) at day 7. The diabetic patients in the gymnema treated arm experienced significant reductions in both FBS (152 mg/dL to 133 mg/dL) and post-prandial blood sugar (PPBS, 215 mg/dL to 142 mg/dL) at 21 days. The diabetic patients in the tolbutamide treatment arm also showed significant reductions in both FBS and PPBS at day 7, but not at day 14. Decreases also were reported in total cholesterol for both diabetic and non-diabetic patients (284 mg/dL to 244 mg/dL and 217 mg/dL to 200 mg/dL, respectively). P values were not provided for this short, non-randomized study.

A longer controlled clinical trial followed 47 Type 2 patients for 20 months.[15] Each patient was already utilizing oral hypoglycemic agents and was stable on their medications with incomplete control. For half of the patients, their usual treatment continued. For the other half, 400 mg/d of GS4, a specific extract of gymnema, was added to their usual regimen. The average HBA1C in the GS4 group fell from 12% to 8.5%; FBS decreased as well from 174 mg/dL to 124 mg/dL; total cholesterol and triglycerides improved from 260 mg/dL to 231 mg/dL and from 170 mg/dL to 140 mg/dL, respectively. All results were significant at the $P < 0.001$ level. In the GS4 treatment group 23% of these patients were able to stop all hypoglycemic agents except for the gymnema. There are several cautions in interpreting this study. The patients were not allocated randomly to treatment groups and there were differences in fasting glucose at baseline. They were however fairly well matched for weight and body mass index (BMI).

In a small, short-term study, 10 healthy volunteers and six patients with Type 2 diabetes were given 2 g of an aqueous decoction of the shade-dried leaves of gymnema three times per day.[22] Significant reductions in both FBS and PPBS were demonstrated. After 10 days, significant reductions were seen in the FBS of both normal (80.2 mg/dL to 69.2 mg/dL; $P < 0.05$) and Type 2 (135.7 mg/dL to 110.7 mg/dL, $P < 0.02$) patients. Significant reductions were also demonstrated in 30-minute PPBS (220 mg/dL to 180.7 mg/dL, $P < 0.05$) and two-hour PPBS (152.7 mg/dL to 121.1 mg/dL, $P < 0.01$) in the Type 2 group.

Only one study evaluated the effectiveness of gymnema in Type 1 diabetics ($n = 63$, 8-30 years old).[23] Thirty-seven patients continued on their usual and customary care while 27 insulin-dependent patients added 400 mg/d of gymnema to their usual insulin regimen for eight months. The average insulin requirement in the supplemented group decreased from 60 uNPH/d to 45 uNPH/d. All gymnema patients experienced at least one episode of hypoglycemia that prompted decreases in their insulin dosages. Unfortunately, 40% of the patients dropped out before the end of the study due to persistent hypoglycemia in one patient and logistical difficulty with follow-up for the remainder.

As a group these trials are very suggestive of a positive effect for gymnema on blood sugar in both Type 1 and Type 2 diabetics. This coupled with the positive effect demonstrated on blood lipids is especially encouraging given the propensity for diabetic patients to have dyslipidemias. However, these trials have limitations in design and analysis typical of preliminary data. Well designed, larger clinical trials should be undertaken to confirm the effects seen in the trials from India.

Clinical Trials: Weight Loss

Gymnema was included as an ingredient in a weight-loss formula tested in 60 moderately obese subjects.[24] The subjects were randomly allotted to one of three groups and received three times a day before meals either 4,667 mg of a highly bioavailable hydroxycitric acid (HCA-SX), the same amount of HCA-SX combined with 4 mg of niacin-bound chromium and 400 mg of a standardized gymnema extract (containing 25% gymnemic acid), or placebo. All subjects were instructed to eat a 2,000 cal/d diet and exercise regularly. The trial lasted eight weeks and outcomes measured included weight, BMI, and lipids. Both groups taking HCA-SX recorded a decrease in their BMI of 5-6% and the placebo group did not change. Total cholesterol, LDL, and triglycerides decreased for both HCA-SX groups. There was however no difference in response between

the two HCA-SX groups, so the effects observed cannot be primarily attributed to the added gymnema. Blood sugar levels were not reported for this trial.

Adverse Reactions/Contraindications

To date, no adverse reactions or toxicities have been associated with the use of gymnema other than hypoglycemia. None of the clinical trials reviewed above reported any side effects. Gymnema may have a temporary blocking effect on the tongue for sweet taste if the leaves are chewed or a gymnema preparation is held in the mouth, but again, this is considered part of its therapeutic properties. Because of the likelihood that gymnema will decrease blood sugar, it should be used with caution in any person already using a hypoglycemic agent.

Dosage and Formulation

Gymnema is most often available in the form of a dried extract of the leaves. It is usually standardized to 25% gymnemic acid. The dose most often advised, according to a survey of internet sellers, is 400 mg three times per day before meals. This standardization and dose corresponds with the GS4 extract studied in many of the Indian trials. However, a wide array of choices is available including extracts standardized to 75% gymnemic acid, dried unstandardized leaves, and tea.

Conclusion

Gymnema is an herb with more than 2,000 years of recorded use, and it has been prized for at least that long for its hypoglycemic properties. Clinical evidence to date is suggestive of therapeutic benefit, but studies are small and have methodological limits. However, each clinical trial of gymnema reported to date demonstrates a positive effect on the blood sugars of both Type 1 and Type 2 diabetic patients. Many, but not all of the trials also showed a positive effect on blood lipids.

There is no evidence to date for its efficacy in weight loss.

Recommendation

Gymnema may have a place as an adjunct in the treatment of diabetes that does not require medication or as a novel aid to modify taste and limit sweet consumption. If the patient and/or the provider decide to use this in combination with conventional medication, careful monitoring is necessary to ensure that the dose is adjusted to prevent hypoglycemia. ❖

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Complementary and Alternative Therapies and End-of-Life Care

PART 2 OF A SERIES ON END-OF-LIFE CARE

By Lynn Keegan, RN, PhD, HNC, FAAN

As discussed in part 1 of this series on end-of-life care, achieving a peaceful and comfortable death for patients must be a priority.[1] Complementary and alternative (CAM) therapies could help in this regard. Specific imagery scripts, ritual exercises, massage therapy, and guided imagery are examples of CAM therapies available to support this mission. A patient with terminal illness and pain could receive not only medication for pain control, but also could be offered therapies such as blending breaths and co-meditation, healing touch, acupuncture/acupressure, or soothing aromatherapy. *[See Part 1 of this series in the February 2005 issue of* Alternative Medicine Alert *for a discussion of end-of-life suffering, efficacy of CAM at end of life, pain management and end-of-life care, hypnosis, and music therapy.]* Toward the end of life (EOL), palliative care should generally increase in line with increasing symptoms and other problems.

Fortunately, there is increasing recognition of the importance of delivering high-quality symptomatic care and support near EOL.[2] This article will examine the roles acupuncture and massage can play at this pivotal stage of life.

Acupuncture

Many practitioners and researchers recommend traditional Chinese medical therapies for the supportive care of cancer patients, and believe that the holistic approach of traditional Chinese medicine (TCM) may be integrated into conventional Western medicine to supplement the current biomedical model.[3]

Acupuncture use for cancer patients has been recommended by the American Cancer Society (ACS) for the treatment of cancer and treatment-related symptoms. Pain, nausea, breathlessness, vasomotor symptoms, and limb edema have all been found to respond to this treatment modality. In addition, the immunomodulatory effects of acupuncture, both via the release of pituitary beta-endorphin and ACTH, as well as the alleviation of patient stress through relief of symptoms, may be anti-carcinogenic.[4]

Studies support the belief that acupuncture is effective in pain relief in terminally ill patients. A French investigation in a pain-management unit examined the efficacy of auricular acupuncture in decreasing pain intensity in cancer patients.[5] Treatment effectiveness was based on the absolute decrease in pain intensity measured two months after randomization of 90 patients using a visual analog scale (VAS). Pain intensity decreased by 36% at two months from baseline in the group receiving acupuncture; there was little change (2%) for patients receiving placebo ($P < 0.0001$).

A U.S. military hospital study of 123 patients with cancer or symptoms associated with cancer therapy offered acupuncture for potential palliation of their symptoms.[6] A practice-outcome analysis was performed on patients receiving acupuncture therapy. Standard

medical care was continued while patients were receiving acupuncture. Major reasons for referral included pain (53%), xerostomia (32%), hot flashes (6%), and nausea/loss of appetite (6%). Patients had a mean of five acupuncture visits (range 1-9). Most patients (60%) showed at least 30% improvement in their symptoms. About one-third of patients had no change in severity of symptoms.

Many men who undergo castration therapy for prostatic carcinoma have vasomotor symptoms that persist for years. Swedish researchers offered seven men with vasomotor symptoms due to castration therapy acupuncture treatment 30 minutes twice weekly for two weeks and once a week for 10 weeks.[7] Effects on hot flashes were recorded in logbooks. Of the seven subjects, six completed at least 10 weeks of acupuncture therapy and all had a substantial decrease in the number of hot flashes (average 70% after 10 weeks). At three months after the last treatment, the number of hot flashes was 50% lower than before therapy.

British researchers explored the safety and efficacy of acupuncture in 20 patients who were breathless at rest and whose breathlessness was directly related to primary or secondary malignancy.[8] Sternal and LI4 acupuncture points were used. Outcome measures included pulse, respiratory rate, oxygen saturation, and patient-rated VAS of breathlessness, pain, anxiety, and relaxation. At each time point the mean values of the variables were calculated and compared to their pretreatment levels. Fourteen patients (70%) reported marked symptomatic benefit from treatment; there were significant changes in VAS scores of breathlessness, relaxation, and anxiety at least up to six hours post-acupuncture (maximal response at 90 minutes). There was a significant reduction in respiratory rate, which was sustained for 90 minutes post-acupuncture ($P < 0.02$).

Massage

Massage is increasingly used to relieve symptoms in patients with cancer. Four American studies and two British studies document the effectiveness of massage therapy. The Integrative Medicine Service at Memorial Sloan-Kettering Cancer Center in New York conducted a trial with patients reporting symptom severity pre- and post-massage therapy using 0-10 rating scales of pain, fatigue, stress/anxiety, nausea, and depression.[9] Changes in symptom scores and the modifying effects of patient status (inpatient or outpatient) and type of massage were analyzed. Over a three-year period, 1,290 patients were treated. Symptom scores were reduced by approximately 50%, even for patients reporting high baseline scores. Outpatients improved about 10% more than inpatients. Benefits persisted, with outpatients experiencing no return toward baseline scores throughout the 48-hour follow-up.

In a randomized, prospective, two-period, crossover intervention study, researchers tested the effects of therapeutic massage (MT) and healing touch (HT), in comparison to presence alone or standard care, in inducing relaxation and reducing symptoms in 230 subjects with cancer.[10] MT and HT lowered blood pressure, respiratory rate (RR), and heart rate (HR). MT lowered anxiety and HT lowered fatigue, and both lowered total mood disturbance. Pain ratings were lower after MT and HT, with four-week nonsteroidal anti-inflammatory drug use less during MT. There were no effects on nausea. Presence reduced RR and HR but did not differ from standard care on any measure of pain, nausea, mood states, anxiety, or fatigue. The authors concluded that MT and HT are more effective than presence alone or standard care in reducing pain, mood disturbance, and fatigue in patients receiving cancer chemotherapy.

In Britain, aromatherapy massage is a commonly used complementary therapy, and is employed in cancer and palliative care largely to improve quality of life and reduce psychological distress. One systematic review investigated whether aromatherapy and/or massage decreases psychological morbidity, lessens symptom distress and/or improves the quality of life in patients with a diagnosis of cancer.[11] Researchers searched all the primary databases for relevant articles of randomized controlled trials; controlled before and after studies; and interrupted time series studies of aromatherapy and/or massage for patients with cancer that measured changes in patient-reported levels of physical or psychological distress or quality of life using reliable and valid tools. The search strategy retrieved 1,322 references.

The most consistently found effect of massage or aromatherapy massage was on anxiety. Four trials (207 patients) measuring anxiety detected a reduction post-intervention, with benefits of 19-32% reported. Contradictory evidence exists as to any additional benefit on anxiety conferred by the addition of aromatherapy. The evidence for the impact of massage/aromatherapy on depression was variable. Of the three trials (120 patients) that assessed depression in cancer patients, only one found any significant improvements with therapy. Three studies (117 patients) found a reduction in pain following intervention, and two (71 patients) found a reduction in nausea. The conclusion was that massage and aromatherapy massage confer short-term benefits on psychological well-being, with the effect on anxiety supported by limited evidence. Effects on physical symptoms may also occur. Evidence is mixed

as to whether aromatherapy enhances the effects of massage.

Another study compared the effects of four-week courses of aromatherapy massage and massage alone on physical and psychological symptoms in patients with advanced cancer.[12] Forty-two patients were randomly allocated to receive weekly massages with lavender essential oil and an inert carrier oil (aromatherapy group), an inert carrier oil only (massage group), or no intervention. Outcome measures included a VAS of pain intensity, the Verran and Snyder-Halpern sleep scale, the Hospital Anxiety and Depression scale, and the Rotterdam Symptom Checklist. The investigators were unable to demonstrate any significant long-term benefits of aromatherapy or massage in terms of improving pain control, anxiety, or quality of life. However, sleep scores improved significantly in both the massage and the combined massage (aromatherapy and massage) groups. There also were statistically significant reductions in depression scores in the massage group. In this study of patients with advanced cancer, the addition of lavender essential oil did not appear to increase the beneficial effects of massage. The results suggest that patients with high levels of psychological distress respond best to massage therapy.

Thirty-six oncology inpatients participated in a follow-up pilot study investigating the effects of foot reflexology.[13] Foot reflexology was found to have a positive immediate effect for patients with metastatic cancer who report pain, although there was no statistically significant effect at three hours after intervention or at 24 hours post-intervention.

A quasi-experimental nursing study examined the effects of therapeutic massage on perception of pain, subjective sleep quality, symptom distress, and anxiety in 41 patients in the oncology unit at a large urban medical center.[14] Twenty participants received therapeutic massage and 21 received standard nursing care. The outcome variables were measured on admission and at the end of the first week with several psychological instruments. Mean scores for pain, sleep quality, symptom distress, and anxiety improved from baseline for the subjects who received therapeutic massage; only anxiety improved from baseline for participants in the comparison group. Statistically significant responses were found for pain, symptom distress, and sleep. Sleep improved only slightly for the participants receiving massage, but it deteriorated significantly for those in the control group. The findings support the potential for massage as a therapeutic intervention for cancer patients receiving chemotherapy or radiation therapy.

Conclusion

While the majority of articles cited here address patients with cancer, relief of pain and anxiety is mandatory within any clinical scenario in which a patient suffers. The focus during end-of-life care should be equally spread over treatment, safety issues, and modalities that can enhance an individual's quality of life. Health care professionals have an ethical and legal responsibility to be aware of, and knowledgeable about, any modality that might offer their patient relief from suffering, even if methodologically sound data are wanting.[15] Despite the paucity of controlled trials, there are data to support the use of some CAM modalities in terminally ill patients.[16]

Recommendation

At end of life, uncontrolled pain is often a serious concern. For effective pain management, suitable pharmaceutical agents along with CAM therapies are indicated. In some instances, the CAM therapy alone may offer relief and/or a respite from distressing symptoms. Hypnosis, music, acupuncture, and massage are some of the CAM therapies that promote relaxation and relieve pain, and of these, acupuncture is the only "invasive" therapy. When used appropriately these therapies are safe and generally effective. A variety of symptoms such as pain, nausea, dyspnea, anxiety, or even loneliness should alert the health care provider to consider CAM therapies along with the traditional allopathic regime. Most mind/body therapies can be safely used in even the most earnest circumstances. There comes a time in EOL care when we can and should use all available therapies to make EOL a time of comfort and care. ❖

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Clinical Briefs

With Comments from Russell H. Greenfield, MD

Magnets and Osteoarthritis

Source: Harlow T, et al. Randomised controlled trial of magnetic bracelets for relieving pain in osteoarthritis of the hip and knee. *BMJ* 2004;329:1450-1454.

Goal: To assess effectiveness, or lack thereof, of magnetic bracelets for pain relief in osteoarthritis (OA) of the hip and knee.

Design: Three parallel groups; randomized, placebo-controlled trial.

Subjects: One hundred ninety-four people aged 45-80 years with hip or knee OA recruited from rural general practices in Great Britain who scored at least 8-20 points on the WOMAC A osteoarthritis index.

Methods: Subjects were randomized to wear for 12 weeks either a standard-strength bipolar magnetic bracelet (170-200 mTesla), a weak magnetic bracelet (21-30 mTesla), or a non-magnetic bracelet (non-magnetic steel washers). Participants were advised they would be receiving either an active or an inactive bracelet. Outcome measures included change in WOMAC scales (A = pain, B = leg stiffness, C = functioning), and a visual analogue scale (VAS) for pain. Data were collected at 0, 4, and 12 weeks. At trial's end all bracelets were returned and tested, and all participants were offered a full-strength magnetic bracelet.

Results: Significant differences were found for WOMAC A and C and VAS pain score with greater improvements seen in the standard magnetic bracelet group than in the non-magnetic bracelet group. No significant difference in 12-week WOMAC B change was detected among the three groups. The average strength of the standard magnets was 186 mTesla, while the non-magnetic bracelets all showed 0 strength. A significant error was identified in the production of the weak magnets (some were stronger than expected).

Conclusions: Magnetic bracelets are effective at relieving pain from OA of the hip and knee as compared with placebo bracelets.

Study strengths: Blinding of participants and providers; testing of the three types of bracelets to assure uniformity of intervention; the few subjects lost to follow-up were evenly spread among the three groups; reported compliance close to 100% during waking hours.

Study weaknesses: Manufacturing error with weak magnets (34 of the weak magnets were actually strong with a mean of 128 mTesla); manner of ascertaining compliance (VAS at 4 and 12 weeks); short duration of trial.

Of note: The majority of participants were Caucasian; there exist significant differences between the strength and types of magnets used therapeutically, as well as the recommended durations of application; the strength of the weak magnets was designed to be enough to appear to be magnetic, but not sufficient to be therapeutic (intended to provide placebo, but the manufacturing error prevented objective assessment of placebo effect); WOMAC B score has been shown to lack specificity; the reduction in WOMAC A and C scores for the active group approximate those previously found with nonsteroidal anti-inflammatory drugs (NSAIDs) and exercise therapy for OA.

We knew that: One in 13 people in the United States has OA; worldwide sales of static magnetic devices in

1999 reached approximately $5 billion; whereas some studies have suggested therapeutic benefit with static magnets (specifically for pain relief), others have not; field strength plays a significant role in potential efficacy, as studies that failed to show a beneficial effect for pain relief used weaker magnets (19-50 mTesla), while those reporting significant pain reduction used magnets with strengths of 47-180 mTesla; although magnetic bracelets can be expensive (as much as $100), the cost compares favorably with that of pain medications and anti-inflammatory agents.

Clinical import: This creative study addresses areas of both need and controversy, namely pain relief for those suffering with OA and the therapeutic use of magnets, respectively.

With regard to the former there can be no doubt, especially in a time when people with OA are desperate to find an effective replacement for the COX-2 inhibitors so rudely taken from them. Skepticism has surrounded the use of magnets, at least among conventionally minded practitioners, in large part due to major methodological flaws in some of the published trials, as well as the widely held perception that the entire idea of magnets as therapeutic aid is groundless.

Nonetheless, our patients utilize magnets, often unbeknownst to us, and perhaps claim benefit from them. Although the data are far from conclusive, this paper provides much needed information we can use both to discuss magnet therapy and guide those who are interested in experiencing it. Identification of readily available product from credible manufacturers, however, remains a challenge.

What to do with this article: Keep a hard copy in your file cabinet. ❖

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 certificate of completion. When an evaluation form is received, a certificate will be mailed to the participant.

7. Importantly for the treatment of depression, both serotonin and norepinephrine appear to be involved in acupuncture.
a. True
b. False

8. Given the low risk for complications, a trial of acupuncture may be considered a potentially useful option for which of the following patient populations?
a. Patients with mild-to-moderate anxiety/depression
b. Patients experiencing significant adverse reactions to medications
c. Patients who have not yet achieved optimal benefit from conventional treatments
d. All of the above

9. Clinical trials of gymnema:
a. have demonstrated a positive effect on blood sugars of Type 1 diabetic patients.
b. have demonstrated a positive effect on blood sugars of Type 2 diabetic patients.
c. do not provide evidence of efficacy in weight loss.
d. All of the above

10. Toward end of life, palliative care should generally increase in line with increasing symptoms and other problems.
a. True
b. False

Answers: 7. a, 8. d, 9. d, 10. a.

In Future Issues:

Tai Chi and Depression

Shark Cartilage and Cancer

Peppermint and IBS

Acupuncture for Fertility