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Medical Acupuncture—A Review

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Editor's Note—*Medical acupuncture is acupuncture that has been successfully incorporated into medical or allied health practices in Western countries. It is derived from Asian and European sources of acupuncture and is practiced in both pure and hybrid forms.*[1] *Medical acupuncture is the complementary discipline most commonly integrated into medical practice. The biomedical viewpoint that relies on quantitative measurement and objective technology is very different from the Chinese medicine assertion that, "contemplation and reflection on sensory perception and ordinary appearances are sufficient to understand the human condition, including health and illness."*[2]

The basic idea of medical acupuncture is to combine our understanding of neuroanatomy and pain physiology with the basic tenets of Eastern thought and the concept of a subtle circulation network of a vivifying source known as qi (pronounced chee). Medical acupuncture is the therapeutic insertion of solid needles in various combinations and patterns based on traditional concepts such as qi and yin/yang, on neuroanatomical and segmental distribution, or a combination of the two.

Variation in acupuncture technique and concepts is not confined to the West. China, Japan, and Korea each developed a distinct version of acupuncture with multiple approaches. Japanese acupuncture is often more superficial than that practiced as part of traditional Chinese medicine (TCM). European interpretation of the original Chinese writings gave way to the energetic concept with further variation by the British and French. Somatotopic representations of the body are used in 3 specialized systems of acupuncture developed in France (auriculotherapy—or ear acupuncture), Korea (Korean hand acupuncture), and Japan (scalp acupuncture). Medical acupuncture allows for all of these systems to be integrated into the knowledge gained from the biomedical training of medical school. The approach also emphasizes choosing acupuncture points based on Western understanding of trigger points, scientific discoveries on mechanism of action, and more formulaic approaches to point location.[3,4]

History

The first codification of acupuncture as part of East Asian medicine was sometime in the first or second century BC. The *Huang Di Nei Jing* (*Inner Classic of the Yellow Emperor*) discussed acupuncture in terms of keeping the body in harmonious balance internally and with regard to the external environment. The *Nan Jing* (*Classic of Difficult Issues*) advanced the theories of points and channels and etiology and treatment of illness in the second century AD. The *Zhen Jiu Da Cheng* (*Great Compendium of Acupuncture and Moxibustion*), published in 1601, synthesized many classical texts that preexisted the time period. It was the primary source of acupuncture information in Europe in the 17th-20th centuries after its translation into Latin by various missionaries and scholar-diplomats.[1] The continual codevelopment of acupuncture and

biomedical sciences in Europe during the later 20th century influenced what we know as medical acupuncture today.

Recent American interest in acupuncture dates back to James Reston's 1971 *New York Times* article discussing his acupuncture-assisted postsurgical pain management during the Nixon visit. As doors opened to China, so did more information and positive reports from Westerners. Work by Pomeranz[5] and others in the late 1970s elucidated some of the physiologic mechanisms of acupuncture and fueled acceptance by Western practitioners and the public. Two landmark events in the 1990s further legitimized acupuncture as a viable medical system. In 1996, the FDA removed the experimental tag and approved the acupuncture needle for routine use,[9] and in 1997, an NIH consensus conference on acupuncture determined that there was scientific evidence of efficacy in some clinical situations.[10]

Today, acupuncture is the most widely accepted form of complementary and alternative medicine (CAM) recommended by physicians.[6] It is also popular with the American public. Eisenberg showed that American spending on CAM treatments increased from $13 billion in 1990 to $27 billion in 1997.[7,8] With an estimated 629 visits to CAM practitioners, acupuncture and other CAM treatments are big business.

Theory

In acupuncture, the models of health and disease are presented in terms of man's harmony or disharmony within himself and as a microcosm in the macrocosm of the universe. Thus illness develops as the individual loses balance or harmony between yin and yang affecting the flow of this vivifying life essence or energy called qi. The ability to handle external forces like wind, cold, heat, dampness, and dryness determines whether illness results.

Yin is associated with female, cold, wet, soft, and interior. Yang is associated with male, heat, dryness, excessiveness, and exterior. Acute illnesses are often associated with yang excesses and chronic conditions are often associated with yin deficiencies. Qi is the connecting force through which the disharmony of yin and yang may be corrected with acupuncture. Qi regulates spiritual, emotional, mental, and physical balance. Think of qi as the water flowing through rivers and tributaries. The yin and yang affect the composition of the water and whether the body erects dams or blockages to the flow.

The more than 2000 acupuncture points on the human body connect through 12 primary and 8 extra channels called meridians. Half of the channels are yin and half of the channels are yang. The principal meridians are associated with metaphorical organ systems that have influence over regions and functions of the body. Six organs are solid, parenchymal, energy producing, yin organs, and 6 are hollow, substance transporting, yang organs. Each yin organ is paired with a yang organ. For example, the kidney meridian (yin) and its coupled yang bladder meridian has influence over joints, spine, hair, hearing, marrow, and overall well being as well as parts of the genitourinary system. Similarly, each lower extremity yin principal meridian is synergistic with an upper extremity yin principal meridian to complete the flow through the body (*see Figure 1*). These channels provide the main tributaries for the flowing qi. The extra meridians (often called extraordinary or curious meridians) create connections between the principal meridians and are used in complex conditions of imbalances within multiple acupuncture organ system spheres of influence. Figure 2 shows an example of how the meridians course along the body.

Tendinomuscular meridians are a group of points that are regionally based and serve as an interface between the individual and the external environment. Those points are commonly used for acute strains and sprains. Shu and mu points are acupuncture points associated with each of the 12 organs to allow for direct access to organ energy. Distinct meridians connect the external body to the internal organs and allow the organ energy to circulate through the body. These meridians are used for deeper organ pathology types of syndromes like kidney stones, interstitial cystitis, and laryngitis. Figure 3 schematically depicts how these various meridian systems interact.

Diagnosis in acupuncture involves determining the level of the manifestation of the disorder through the identification of symptoms associated with yin and yang, excess and deficiency, organ influences, and the 5 elements of earth, metal, fire, wood, and water. Each different acupuncture system follows its own paradigm of how to choose appropriate points for treatment. Acupuncture energetics[3] derives from the European interpretation of the Chinese classics and involves combining energy movement through the channels with local focusing treatment. TCM is the most common system practiced by nonphysicians. This is linked with herbal prescribing and is based on the 8 principles that take into account yin/yang, hot/cold, and excess/deficiency. It is most effective with internal medicine type problems.[11] Five-element acupuncture, popularized in Great Britain, is best for problems of a psycho-emotional or

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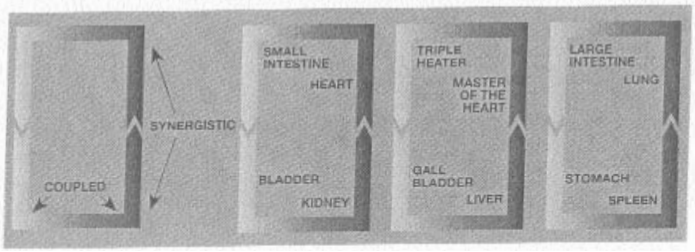
Figure 1. Schematic Illustration of the Coupled and Synergistic Organ-Named Principal Meridians



From: Helms JM. *Acupuncture Energetics: A Clinical Approach for Physicians*. Berkeley, Calif: Medical Acupuncture Publishers; 1995.

psychosocial nature. The somatotopic reflex systems of the ear, hand, and scalp are often used on conjunction with traditional body acupuncture. They also are effective in modifying neurological problems that aren't well suited to traditional acupuncture. Auriculotherapy is the type most often used in treatment of addiction problems.

Basic Science

There is a substantial body of data supported by more than 100 scientific papers that the pain-relieving aspects of acupuncture are in part mediated by endogenous monoamines and neuropeptides that are activated by the needle. Opioids are released into the system as identified by reversal with naloxone and transfer of effect to another animal via cerebral spinal fluid transfusions.[5,12] Dale points out that acupuncture points are enhanced conductors of electromagnetic signals. Stimulating acupuncture points increases the relay capability of the electromagnetic signals that may direct flow of immune cells and other neurohormones to the injured area.[13] Recently, Joos et al reported that acupuncture as an adjunct to conventional asthma therapy had significant immune modulating effects.[14]

Figure 4 is a schematic representation of how electroacupuncture may stimulate the neurohumoral response and result in analgesia. Electroacupuncture stimulates high-threshold, small-diameter nerves. These send messages to the spinal cord and activate spinal cord, brain stem, and hypothalamic neurons that trigger endogenous opioid production. Endorphins, enkephalins, and adrenocorticotropic hormones, are all produced in this manner. Variation in electricity frequency results in production of different neuropeptides.[5] Functional MRI studies and PET scans have also demonstrated changes in brain areas associated with pain and sensory pathways when studying acupuncture vs. sham-controlled treatments.[2]

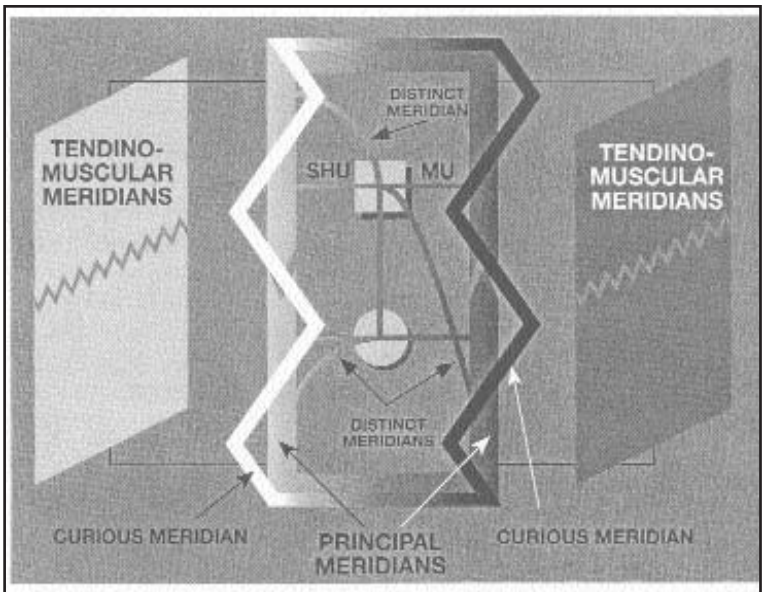
Education and Training

The increased demand for acupuncture drives a natural increase in education and training requirements. Wetzel et al summarized the state of medical school education in the United States.[15] Their 1998 article found that 64% of US medical schools had elective courses on CAM or included the topic as part of required courses. Two medical residency programs, 1 in general internal medicine[16] 1 one in physical medicine and rehabilitation[17] described their efforts to expose their residents to CAM. Both include experiential and didactic programs in acupuncture that are designed to peak the residents' interest and familiarization with CAM, but not meet specific training requirements that will result in independent practice following completion of the residency program.

Forty-nine of the 50 states and the District of Columbia (DC) have laws or rules and regulations regarding the practice of acupuncture. Thirty-three states and DC have statues enabling nonphysician acupuncturists to practice with varying degrees of supervision or independence. In most cases, the nonphysician must graduate from an approved 3- or 4-year acupuncture or TCM school and pass a certification exam given by the national Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) or the National Commission for the Certification of Acupuncturists (NCCA).[18] The curriculum is usually defined by accreditation standards of the National Accreditation Commission of Schools and Colleges of Acupuncture and Oriental Medicine (NACSCAOM).

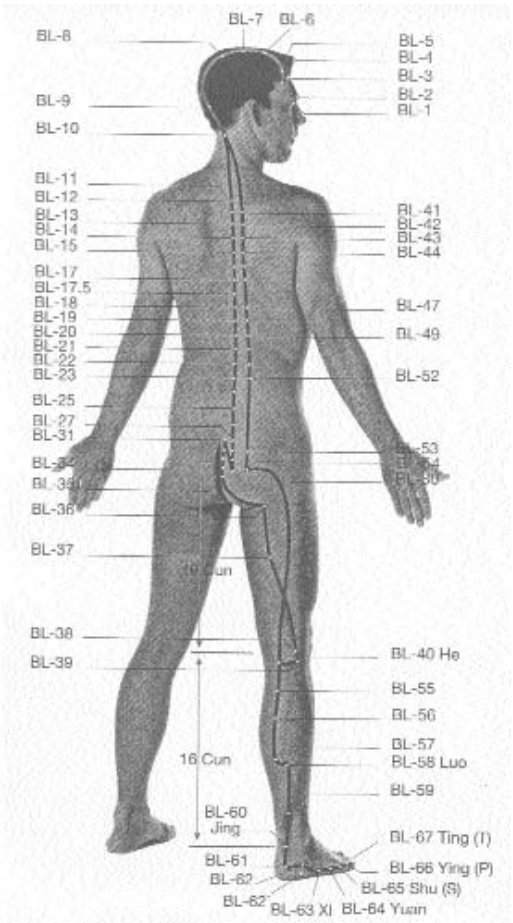
In most states, acupuncture falls within the scope of the physician's license. There are a growing number of states that require additional training in acupuncture before granting a license, certificate, or registration to physicians. The additional training requirement ranges from "adequate training" in Nevada to passing the NCCAOM exam in Hawaii and Montana. Most other states require category 1 continuing medical education (CME) instruction of 100-300 hours.[17] No formal curriculum is mandated for physician training. Typical CME training programs may include acupuncture theory in terms of TCM, acupuncture energetics, 5 phases theory, auriculotherapy, musculoskeletal/neuroanatomic models, and other less used paradigms. Point location, patient assessment, treatment planning, and manual skills are often included.[17]

Figure 2. Course and Points Along the Bladder Principal Meridian



From Helms JM. *Acupuncture Energetics: A Clinical Approach for Physicians*. Berkeley, Calif: Medical Acupuncture Publishers; 1995.

Figure 3. Schematic Representation of the Acupuncture Meridians and their Relationship to One Another



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The American Academy of Medical Acupuncture (AAMA) represents the education, legislation and professional interests of physicians who are well trained in acupuncture. Full membership requires the physician to have completed 220 hours of formal acupuncture training and 2 years of clinical experience following the training.[19] These requirements are based on recommendations of the World Health Organization (WHO) for physician acupuncture training via the World Federation of Acupuncture and Moxibustion Societies (WFAS). After developing a recommended curriculum for physician training, the AAMA founded the American Board of Medical Acupuncture in 2000. To date, 242 physicians have met the training and practice requirements and passed the certification exam to become board certified in medical acupuncture.

Nonphysician acupuncturists believe that their lengthy in-depth training in TCM make them the best-suited professionals to practice acupuncture. Physicians believe that medical acupuncture's blend of Eastern and biomedical Western training make them the best acupuncture providers. The following quote from Niemtzow's article on integrating complementary disciplines into the oncology clinic demonstrates both the benefit of combining Eastern and Western paradigms as well as the responsibility to maintain a certain standard of care: "the Western physician [acupuncturist] must meet acceptable practices. For example, I would not treat a bacterial pharyngitis with acupuncture but rather would use the appropriate antibiotic. If a painful sore throat could not be controlled with analgesic medication, then the use of acupuncture as adjunctive therapy is justified and acceptable."[20]

Safety

When acupuncturists are appropriately trained, significant adverse events are rare. It is difficult to introduce long-lasting adverse physiologic/energetic effects with one or two acupuncture treatments, but adverse events due to introduction of a needle into the body are possible. The most severe adverse reactions associated with acupuncture include pneumothorax, spinal cord injury, and hepatitis B infection. Most of these serious events were retrospectively reported in Japan and China and were due to broken or purposefully embedded needles. Yamashita[21] attributes this to poor training programs in Japan.

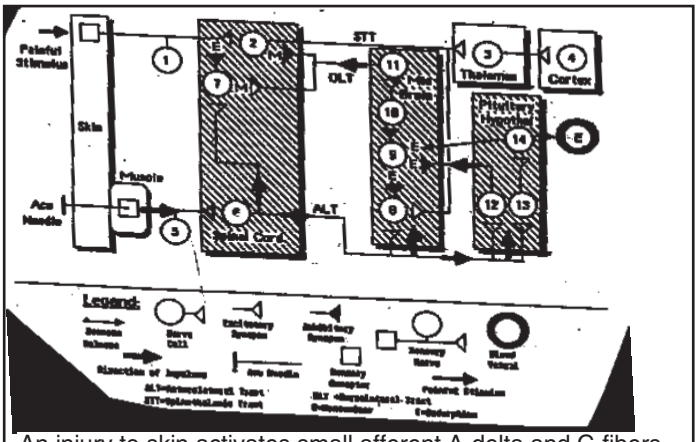
In the United States and Great Britain, prospective studies identified 2 cases of pneumothorax out of 250,000 treatments[22] and no incidence of spinal cord injury. Hepatitis B infection has not been reported with the use of sterile disposable acupuncture needles. When carefully performed, acupuncture involving the chest wall for asthma and coronary obstructive pulmonary disease (COPD) is safe without significant risk of pneumothorax.[23] In separate prospective reviews of medical acupuncturists and nonphysician providers, White et al[24] and MacPherson et al[25] reported minor adverse events occurred in 1.3-1.4 per thousand treatments. These include nausea and fainting, prolonged aggravation of the presenting complaint, significant pain and bruising, and psycho-emotional reactions. In a few instances, provider error contributed to problems like needles left in patients and burns from using the burning herb Moxibustion. Fifteen percent of patients reported transient reactions such as feeling relaxed or energized. None of these adverse events required hospitalization or unscheduled office visits.

One case of a possible wound infection to a total knee arthroplasty (TKA) following acupuncture was reported.[26] However, a follow-up survey to medical acupuncturists in the AAMA identified no other incidence of wound infection to total joint patients following nearly 8000 acupuncture treatments. Since the acupuncture infection rate was less than the expected TKA postsurgical infection rate, Braverman and Prieto concluded that the infection was most likely coincidental and not due to the acupuncture. The combined data from prospective and retrospective studies and case reports confirm that acupuncture is safe in the hands of trained providers.

Indications and Efficacy

In the United States, acupuncture has its greatest success and acceptance in the treatment of musculoskeletal pain. Problems such as acute sprains and strains are most easily treated, while chronic pain patients make up the largest numbers of patients seeking acupuncture from American physicians.[27] Table 1 lists general indications for acupuncture as adapted from the AAMA web site[19] and the WHO.[28] Most of these indi-

Figure 4. Schematic Representation of the Neurologic Effects of Acupuncture with Low Frequency High Intensity Stimulation



An injury to skin activates small afferent A-delta and C-fibers (1) which synapse on the spinothalamic tract (STT) in the spinal cord (2) to the thalamus (3) and cortex (4). Dark triangles are excitatory synapses, and white are inhibitory. Acupuncture needle activates small afferent nerve in muscle (5) which goes through the anterolateral tract (ALT) cell (6) to the spinal cord, midbrain, an pituitary-hypothalamus (PH) complex. In the spinal cord an endorphogenic cell (7) releases enkephalin or dynorphin which causes presynaptic inhibition of cell 1. Cell 6 ascends ALT to midbrain and disinhibits cell 10 via 8 and 9 enkephalin release. This activates the raphe nucleus through cell 11 and provides for postsynaptic inhibition of cell 2 and presynaptic inhibition of cell 1 via monoamine release in the spinal cord. Activation of the PH generates circulatory B-endorphin and ACTH resulting in cortisol release from the adrenal cortex possibly explaining the anti-inflammatory effects. (Adapted from: Pomeranz B, Stuz G, eds. *Scientific Basis of Acupuncture*. New York, NY: Springer-Verlag; 1989).

cations are supported by text books or at least one journal article. However, the state of acupuncture research is poor but improving and definitive conclusions based on research findings are rare.

The 1997 National Institutes of Health Consensus Development Panel on Acupuncture[10] concluded that clear evidence existed to support acupuncture efficacy in postoperative and chemotherapy induced nausea and vomiting and in postoperative dental pain. They cited other situations in which acupuncture may be useful as an adjunct treatment or an acceptable alternative: addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.

The biggest problem in evaluating scientific efficacy data is that many studies provide equivocal results due to flaws in design, small sample size, and the inherent difficulty in the use of controls such as placebo and sham acupuncture. Other problems with randomized controlled trials (RCTs) include testing of poorly defined illness with imprecise outcomes, heterogeneous study groups (eg, all types of back or neck pain), and inadequate follow-up. Acupuncture RCTs are also subject to bias due to the difficulty in blinding both the acupuncturists and the patients. Sham techniques that include needle insertion in nonacupuncture points don't remove the potential positive physiologic effects of needle insertion itself. Finally, the training and experience of the researcher, or lack thereof, may affect the appropriateness of the treatment arm of a particular study.

Acupuncture RCTs range from single point treatment protocols[29-31] to set programmatic treatments based on Western diagnoses[32,33] to individualized treatments determined by the acupuncturist based on an Eastern diagnosis (eg, kidney yin deficiency).[34] Each of the different types of RCTs represent variations in the practice of acupuncture. However, that technique variation makes it difficult to consolidate results into systematic reviews and determine whether "acupuncture" is effective or ineffective for a particular pathological condition. Rather, the studies show that various treatment protocols within acupuncture are effective or ineffective against a particular (sometimes not well-defined) disease process. From a Western perspective, it would be like studying the effect of penicillin therapy on a group of patients with viral or bacterial pneumonia and concluding that antibiotics are ineffective in the treatment of pneumonia. Another problem is the lack of agreement on the adequacy of an acupuncture treatment in terms of frequency and duration of treatments. To use the pneumonia analogy, insufficient dosages of the antibiotic would likely result in poor outcome results.

The problems above help explain why many of the systematic reviews and meta-analyses on acupuncture result in contradictory and inconclusive results.[11] Nonetheless, they are used by the medical community and insurance industry to determine whether acupuncture is effective and should be covered as a benefit by third-party insurers. A summary of some of the more recent RCTs and systematic reviews follows.

The study often quoted as supporting acupuncture for the treatment of depression is a good example of small sample size leading to possibly faulty conclusions that get permeated in the literature. Allen concluded that acupuncture was helpful in treating unipolar depression when more than half of the eleven subjects showed significant improvement in symptoms.[35] No larger study is available for comparison.

Two areas where recent RCTs and systemic reviews consistently show a lack of efficacy for acupuncture are stroke and tinnitus. Two recent RCTs were negative for acupuncture efficacy in stroke when compared to Transcutaneous Nerve Stimulation[36] and placebo.[37] Additionally a 2001 systematic review by Park et al[38] found that the best-constructed RCT was the most negative toward acupuncture efficacy. Likewise, a systematic review of acupuncture for tinnitus found that none of the blinded studies demonstrated improvement.[39]

The 2 areas best studied with consistent positive results for acupuncture are its effect on emesis and dental pain. Vickers' systematic review on emesis[40] found that every study that used the acupuncture point Pericardium-6 had a positive outcome on emesis of all causes. Two recent RCTs demonstrate specific efficacy in the treatment of chemotherapy induced emesis[41] and hyperemesis gravidarum.[29] Dental pain studies are summarized in a systematic review by Ernst and Pittler[42] which found that 12 of 16 studies had a positive effect of acupuncture.

One of the first systematic reviews of acupuncture trials

of chronic pain was a meta-analysis done by Patel et al in 1989.[43] They reported that acupuncture was efficacious in the treatment of chronic pain. However, the majority of their included studies consisted of unblinded trials with small sample sizes totaling 720 in 14 studies. The few placebo trials in their summary had negative results. More recent systematic reviews were inconclusive or mostly negative.[44,45] When considering chronic neck and back pain, the systematic reviews[46-48] are again inconclusive. Two recent RCTs also show conflicting results when considered together. Leibing et al[49] studied programmatic acupuncture treatments (everyone got the same treatment) for chronic low back pain vs. sham acupuncture and Physical Therapy, and found that acupuncture was better than both. On the other hand, Cherkin et al[34] published a well-designed study comparing acupuncture to therapeutic massage and self-care education for chronic low back pain. That study was relatively unique in that the acupuncture arm allowed the TCM acupuncturist to select an individualized treatment plan for each patient. Cherkin et al concluded that therapeutic massage was better than acupuncture.

The last illustrative set of examples comes from the studies on hip and knee osteoarthritis (OA). Most studies demonstrate positive efficacy for acupuncture.[11,32,33,50-52] What sets these studies apart is that they follow a sequence that first identifies a successful treatment protocol and then refines it. Berman's initial studies[32,52] confirmed that acupuncture works in knee OA. The next group of studies identified the timing of treatment in regards to the disease course[50] (the earlier the better) and the amount of treatment necessary for effect—unilateral treatment was as good as bilateral treatment.[51] The success of the research methodology in knee OA serves as a model of how rigorous Western scientific methodology may yet provide answers regarding the efficacy of acupuncture.

Table. Acupuncture Indications According to the American Academy of Medical Acupuncture

* *Items with an asterisk are also included in the World Health Organization list of acupuncture indications.*

- Acute and chronic pain control*
- Post-traumatic and postoperative ileus *
- Muscle spasms, tremors, tics, contractures*
- Paresthesiae *
- Anxiety, fright, panic*
- Drug detoxification *
- Neuralgias (trigemnial, Herpes Zoster, postherpetic, other)
- Seventh nerve palsy Sequelae of CVA's (aphasia, hemiplegia)*
- Certain functional gastro-intestinal disorders (nausea and vomiting, esophageal spasm, hyperacidity, irritable bowel, etc)*
- Headache, vertigo (Meniere's), tinnitus*
- Phantom pain
- Frozen shoulder*
- Cervical and lumbar spine syndromes*
- Plantar fasciitis*
- Arthritis/arthrosis*
- Bursitis, tendonitis, carpal tunnel syndrome*
- Sprains and contusions*
- In fractures, assisting in pain-control, edema, and enhancing healing process, Temporo-mandibular joint derangement, bruxism*
- Dysmenorrhea, pelvic pain*
- Insomnia*
- Anorexia
- Atypical chest pain (negative work-up)
- Idiopathic palpitations, sinus tachychardia
- Allergic sinusitis*
- Persistent hiccups*
- Selected dermatoses (urticaria, pruritus, eczema, psoriasis)
- Constipation, diarrhea*
- Urinary incontinence, retention (neurogenic, spastic, adverse drug effect)*
- Abdominal distention/flatulence*
- Severe hyperthermia
- Cough with contraindications for narcotics
- Acupuncture anesthesia for high-risk patients, or patients with previous adverse responses to anesthetics

Adapted from: Conditions for which Medical Acupuncture May Be Indicated in a Hospital Setting, 2001 [on-line]. American Academy of Medical Acupuncture, Los Angeles California; http://www.medicalacupuncture.com/acu_info/hospconds.html

Treatment

The initial evaluation and course of treatment differ based on whether the acupuncturist combines Western biomedical paradigms and treatment with the Eastern acupuncture paradigms. The physician acupuncturist practicing medical acupuncture will often use a combination of both. Therefore, the initial evaluation will include a history and physical exam that identifies signs and symptoms related to both paradigms. For example, the patient with an S-1 radiculopathy would not only have the classic symptoms and signs of dropped reflexes and sciatica, but he may also have signs and symptoms associated with kidney and bladder yin/yang imbalance or qi blockage. The acupuncture treatment may vary based on a neuroanatomic vs. TCM approach, but nonsteroidal anti-inflammatory drugs (NSAIDs) or other medications may be used as well. Other referral models have a physician taking care of the patient from a Western perspective and referring to a nonphysician acupuncturist outside of or connected with the practice.

Acupuncture treatments are usually weekly but sometimes are more frequent for acute conditions. Once the effectiveness of a treatment lasts a full week, the treatments are scheduled further apart. As the response stabilizes for longer periods of time, the treatments are spread out further until a determination is made whether to stop or go to periodic maintenance visits. Chronic conditions usually require maintenance visits every 2-3 months. The number of needles in a treatment ranges from 1 to 20 depending on whether the treatment is bilateral and which acupuncture method is used. Electrical stimulation is added to the nee-

dles in most medical acupuncture treatments. Heated Moxibustion is also used in some treatments. A typical initial visit will last more than an hour with follow-up treatment visits lasting 30-60 minutes.

Approximately 70% of nonphysician acupuncturists practice alone or in acupuncture groups; 30% work in multidisciplinary settings, usually in association with other alternative providers.[2] Most physician acupuncturists are primary care providers in private practice and treat about 25% of their patients with acupuncture. Few do medical acupuncture exclusively. The two most common nonprimary care specialties are anesthesiology and physiatry. Endorsement or use of other complementary methods such as manual medicine, herbal medicine, and supplements are common.[27] Third-party reimbursement varies by locale with different fees and rules between physician and nonphysician acupuncturists. Insurance coverage is more common in the western states, though most patients still pay out of pocket for acupuncture.[7,8]

The AAMA has a list on their web site of medical acupuncturists who accept referrals.[19] Nonphysician acupuncturists maintain referral lists on a web site maintained by TCM providers.[53]

Conclusion

Acupuncture is an ancient medical system originating in China and spread around the world. Medical acupuncture is the incorporation of Western biomedical knowledge into Eastern medical paradigms. Scientific data confirm that acupuncture is effective for some medical conditions. The data are inconclusive for others. Two thousand years of history merit continued evaluation of acupuncture as an efficacious paradigm for medical treatment in the 21st century. It is likely here to stay.

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Physician CME Questions

1. Which of the following best describes medical acupuncture?
   a. Acupuncture performed by physicians
   b. Acupuncture performed by doctors of oriental medicine
   c. Acupuncture incorporated into Western medical practice
   d. Acupuncture in which the needles are treated with medication prior to insertion

2. Which of the following is true about acupuncture?
   a. Its origins date back several thousand years.
   b. There is more than one acupuncture paradigm in existence today.
   c. There is an accepted scientific basis for some of the effects of acupuncture.
   d. Acupuncture is not well understood from a Western perspective.
   e. All of the above

3. Which of the following is a yang organ?
   a. Kidney
   b. Bladder
   c. Heart
   d. Spleen
   e. Lung

4. The 1997 landmark event that legitimized acupuncture in the United States was the:
   a. NIH Consensus Conference on Acupunture.
   b. World Health Organization International Symposium.
   c. FDA regulation regarding acupuncture needle safety and infection prevention.
   d. James Reston's visit to China.

In Future Issues:

Management of Migraine—James R. Couch, MD, PhD

PHARMACOLOGY WATCH

Study Concludes Premarketing Drug Trials Underpowered

The phrase: "Never be the first to prescribe a new drug" may be sage advice, according to a new study. More than 10% of new drugs (56 of 548) approved between 1975 and 1999 were withdrawn from the market or given black box warnings indicating serious side effects. Half of the withdrawals occurred in the first 2 years of the drug's introduction while half of the black box warnings occurred within the first 7 years. A recent study concluded that premarketing drug trials may be underpowered to detect serious adverse drug reactions, and that many drugs have limited postmarketing follow-up. It is only after the use of these medications is expanded to large numbers of patients that trends are discovered. This study suggests that the FDA should consider raising its threshold for approving new drugs, especially when safe and effective therapies already exist. They also suggest that clinicians should be wary of new drugs and should immediately report adverse drug reactions to Medwatch, the FDA's adverse drug reporting program (*JAMA*. 2002;287:2215-2220). In an accompanying editorial, physicians from the FDA said that many of the warnings were the result of ongoing clinical studies such as the Cardiac Arrhythmia Suppression Trial. In general the FDA's evaluation process is improving. They do however agree that physicians should carefully contemplate prescribing a new drug—especially when safe alternatives are available (*JAMA*. 2002;287:2274-2275).

Sildenafil to Receive Competition

Sildenafil (Viagra-Pfizer) may soon be in for some tough competition as Lilly's tadalafil (Cialis) nears approval. The drug has received an approvable letter from the FDA for the treatment of erectile dysfunction and needs only completion of additional clinical pharmacology studies, manufacturing inspections, and finalization of labeling to receive approval. Tadalafil is reported to have a quicker onset of action than sildenafil. Lilly, which is marketing the drug in partnership with Seattle-based Icos pharmaceuticals, feels that a 2003 launch is likely.

New Thrombolytic Therapy Study

Patients with pulseless electrical activity do not benefit from thrombolytic therapy, according to a new study. A total of 233 patients with cardiac arrest and pulseless electoral activity were randomized to receive tissue plasminogen activator or placebo along with CPR. The proportion of patients returned a spontaneous circulation of 21.4% in the t-PA group vs. 23.3% in the placebo group (P = 0.85; 95% confidence interval, -12.6-8.8). The basis of study was assumption that coronary thrombosis or pulmonary thromboembolism are common causes of acute cardiac arrest and pulseless electrical activity. The study, however, found no benefit of fibrinolyis with t-PA in these patients (*N Engl J Med*. 2002;346:1522-1528).

COX-2 Findings Criticized in BMJ

An editorial in the June 1 edition of the *British Medical Journal* severely criticizes the findings of the Celecoxib Long-term Arthritis Safety Study (CLASS) trial (*JAMA*. 2000;284:1247-1255). That study, which was sponsored by, and has been widely publicized by, celecoxib's manufacturer Pharmacia, showed that the COX-2 inhibitor celecoxib, when compared with traditional nonsteroidal anti-inflammatory drugs (NSAIDs), was

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associated with the lower incidence of symptomatic ulcers and ulcer complications. The authors of the editorial argue however that the CLASS data reported in the JAMA article actually referred to the combined analysis of the results of the first 6 months of 2 separate and longer trials, both of which had different protocols, outcomes, and durations. With re-review of the data, almost all ulcer complications in the second half of the trial were in users of celecoxib. Also when the predefined definition of ulcer complications was used, a nonsignificant trend in favor of diclofenac was found. Perhaps more significantly, the *JAMA* paper reported only the first 6 months of data, when data up to 12 months were available to the researchers, at which time the rate of ulcer complications for celecoxib was equal to that of traditional NSAIDs. This editorial points out that the VIGOR trial comparing the upper GI toxicity of rofecoxib and naprosyn in patients with rheumatoid arthritis found an unequivocal benefit for the other COX-2 inhibitor, Rofecoxib and over a traditional NSAID (*N Engl J Med*. 2000;343:1520-1528). The authors point out not only the flaws in the CLASS data, but their disappointment in the use of the data in marketing efforts (*BMJ*. 2002;324:1287-288).

Salmeterol Aids Pulmonary Edema Victims

The beta adrenergic agonist salmeterol helps protect mountaineers against high-altitude pulmonary edema. Beta agonists, along with causing bronchodilation, also facilitate clearance of alveolar fluid in the lung, the primary cause of high-altitude pulmonary edema. In a recent Swiss study, 37 mountain climbers who were subject to pulmonary edema were randomized to receive salmeterol or placebo in a double-blind fashion. After a rapid ascent to 4500 m, 74% of those in the placebo group developed pulmonary edema vs. 33% in the salmeterol group ($P = 0.02$). Subjects in the study were also evaluated for nasal transepithelial potential difference, a marker of transepithelial sodium water transport in the distal airways. The results from susceptible individuals were compared to the results from mountaineers not prone to pulmonary edema. The mountaineers prone to pulmonary edema were found to have a low nasal potential difference value. It is speculated that this may also be the case of patients for prone to pulmonary edema from such conditions as congestive heart failure and acute respiratory distress syndrome. It is suspected that this mechanism may be an appropriate target for therapy with inhaled beta agonists (*N Engl J Med*. 2002;346:1631-1636).

Azithromycin vs. Vitamin C for Bronchitis

Azithromycin is one of the most popular antibiotics for the treatment of upper respiratory tract infections. However, a recent study suggests that it is no more effective than vitamin C in treating acute bronchitis. A total of 230 patients were randomized to receive azithromycin (Zithromax Z-Pack) for 5 days or vitamin C also for 5 days. Patients also received liquid dextromethrophan and albuterol inhalers spacer. After 7 days, 89% of patients in both groups had returned to normal activities. There's no difference in the incidence of adverse effects. Eighty-one percent of patients reported benefit from the albuterol inhaler. The authors conclude that azithromycin is no better than vitamin C in the treatment of acute bronchitis and suggest that similar studies should be done to identify the best treatment for this disorder (*Lancet*. 2002;359:1648-1654).

FDA News

The FDA has approved a new angiotensin II receptor blocker (ARB). Olmesartan medoxomil (Benicar—Forest Laboratories) is a once-a-day ARB that is approved for monotherapy or in combination with another antihypertensive. It will be available in 5-, 10-, and 20-mg tablets. It will be the seventh ARB approved for use in this country.

The Nonprescription Drug Advisory committee for the FDA will soon consider omeprazole (Prilosec) for over-the-counter status. AstraZeneca is proposing an over-the-counter 20 mg dose of omeprazole be taken for 14 days for symptoms of frequent heartburn.

The same committee recently proposed loratidine's (Claritin) switch to OTC for the treatment of urticaria. Final action on loraditine is expected to occur on November 28, 2002.

Drugs receiving expanded indications from the FDA:

Sertraline (Zoloft) has been approved for premenstrual dysphoric disorder, joining its cousin SSRI fluoxetine in having this indication.

QVAR inhaler, a nonfluorocarbon-based beclomethasone inhaler, has been approved for adults and children up to age 12; now the FDA has expanded the indication to children ages 5-11.

The FDA has approved a 35 mg once-a-week dose of residronate (Actonel) for the treatment of osteoporosis. Residronate joins alendronate (Fosamax) with a once-a-week formulation for this indication. ■