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Special Issue: Acupuncture

Acupuncture for Arthritis

By Sharon L. Kolasinski, MD, FACP, FACR

ACUPUNCTURE HAS BEEN IN USE AS AN ANALGESIC FOR CENTURIES and its application to the treatment of arthritis pain remains a frequent one. In the 1970s, President Nixon's overtures to China led indirectly to the introduction of many aspects of traditional Chinese medicine into the popular consciousness, if not into mainstream medical practice. Since then, acupuncture has become one of the most widely accepted of the traditional methods and continues to grow in availability. Its use in the treatment of depression,[1] postoperative dental pain,[2] nausea,[3] and fibromyalgia[4] has recently been reviewed.

Mechanism of Action

Understanding the mechanism of action of acupuncture depends to some extent on the background and assumptions of who is offering the explanation. In traditional Chinese medicine, the mechanism is thought to involve alterations in the flow of *qi* by the placement of acupuncture needles in well-defined locations on the skin. This interpretation of the mechanism of action assumes that *qi*, or vital energy, flows along routes, or meridians, throughout the body and that the flow is disrupted by illness. *(See sidebar "Glossary of Selected Acupuncture Terms.")* The imbalance in the flow of *qi* can then be restored by the insertion of the needles, with resultant improvement in health.

If one assumes a Western pathophysiologic model, the most frequently cited mechanism of action for the analgesic properties of acupuncture involves inducing endogenous opioid production or altering pain neurotransmitter release.[5,6] Experimental evidence shows that some of acupuncture's analgesic effects in dental pain can be blocked by naloxone, substantiating the argument that opioid production occurs with the use of acupuncture.[7] The use of oral narcotics along with acupuncture improves upon the pain relief provided by acupuncture alone.[8] Stimulation by acupuncture needles also may stimulate the hypothalamus and pituitary gland, altering neurotransmitter and neurohormone secretion and central and peripheral blood flow.[5]

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INSIDE

Methodological Difficulties

The appropriate choice of a placebo in acupuncture research continues to make interpretation of controlled trials problematic *(see Table 1)*. Since the mechanism of action is incompletely understood, it remains difficult to know what the most reliable placebo would be. Some of the effects of acupuncture appear to be nonspecific and may be induced by sham acupuncture as well. Furthermore, blinding of both patients and investigators remains difficult to accomplish. This dilemma has led to a variety of creative solutions, including the development of devices that permit skin contact without penetration by an acupuncture needle. The acupuncturist may be blinded using some of these devices as well. Studies using these methodological innovations are in progress.

NIH Position

In 1998, the National Institutes of Health (NIH) convened a Consensus Development Panel to provide "a responsible assessment of the use and effectiveness of acupuncture to treat a variety of conditions." The panel reviewed thousands of publications from 1970 to 1997. They concluded that there was "a paucity of high-quality research assessing the efficacy of acupuncture" and that there are numerous problems with interpretation of the available literature. These include difficulties with study design, sample size, and controls. However, they concluded that areas in which acupuncture "may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program" include tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, and carpal tunnel syndrome.

Table 1

Methodological challenges of acupuncture studies[23,24]

- Appropriate and adequate treatment (a sufficient number of points stimulated per treatment, adequate frequency and duration, adding extra stimulation of acupoints using electroacupuncture or moxibustion, and fixed regimens stimulating predetermined acupoints vs. individualized treatments);
- Appropriate comparison groups;
- Blinding of patients and practitioners (although the latter of which is impossible, assessors blinded to treatment group can be used for objective measures);
- Adequate sample sizes;
- Adequate assessment of outcomes (validated subjective and objective measures); and
- Adequate duration of trial and follow-up.

Clinical Studies: Osteoarthritis

One of the earliest studies to assess the role of acupuncture in the treatment of osteoarthritis (OA) pain was published in the *New England Journal of Medicine* in 1975.[9] In this study, 40 patients with OA of the hip, knee, spine, or hands were randomly assigned to receive acupuncture or placement of acupuncture needles on sites contiguous to actual acupuncture points. Each patient received a total of eight treatments. All those undergoing acupuncture were said to experience *de qi*, the sensation of numbness, tingling, or heaviness frequently reported by treated patients, and all those undergoing sham acupuncture, reportedly, did not. Subjective and unvalidated outcome measures were used to assess patient response. Subjects improved, regardless of treatment, according to physicians' evaluations of joint tenderness and joint range of motion and in patients' own evaluations of pain and mobility. The authors concluded that they could demonstrate no difference between acupuncture and the problematic placebo used.

A review of additional randomized, controlled trials for OA symptoms has shown no difference between

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acupuncture and sham acupuncture. However, none of these studies have been sufficiently powered to detect a difference between actual and sham intervention. Furthermore, in each study, both groups improved, underscoring the point that any needle puncture may evoke an analgesic response.[10]

One study used delayed vs. immediate acupuncture in a group of 32 Danish patients severely affected by OA.[11] Participants were drawn from those subjects awaiting total knee replacement. Half were randomly assigned to receive acupuncture treatments twice weekly for three weeks; the other half were treated in the same manner eight weeks later. Outcome measures included standard tests of function, such as walking and climbing stairs, as well as a visual analog scale (VAS) assessment of pain. Patients undergoing acupuncture experienced significant reductions in VAS scores and use of non-steroidal anti-inflammatory drugs (NSAIDs). Participants who experienced benefit were invited to continue to receive acupuncture treatments. Of the 22 who did derive benefit and received continued treatment, seven decided to forego surgery.

A more recent study used a similar design to assess not only response to therapy but also the demographic and medical characteristics of patients that might predict response.[12] The investigators assessed 74 patients during eight weeks of twice weekly treatment. Acupuncture reduced pain at week 4, week 8, and week 12, four weeks after completion of the treatment. No patient experienced an adverse effect. The effectiveness of acupuncture was not correlated with any demographic factor assessed, including age and sex. The severity of symptoms at baseline was predicted by the duration of disease; however, patients across the spectrum of disease severity benefited from acupuncture. Similarly, medical comorbidity did not reduce the effectiveness of acupuncture for analgesia in patients in this study. The investigators did find that the least symptomatic patients were most likely to return to a near-normal level of function and report the absence of chronic pain.

Studies in which drugs were used as a control found mixed results. In a group of 32 patients with OA of the hip, knee, or shoulder, weekly acupuncture provided superior analgesia to the NSAID piroxicam, after the initial two weeks.[13] The superiority of acupuncture persisted over the entire eight-week trial. In a group of 58 knee OA patients who were allowed to continue their NSAID, those receiving acupuncture experienced significant improvement in self-reported pain and disability.[14] However, in a report on 44 cervical spine OA patients, acupuncture was not better than diazepam in the relief of pain.[15]

A systematic, best-evidence analysis of the literature on acupuncture for OA of the knee from 1966 to 1999 recently was published.[16] Seven randomized trials that did not include electroacupuncture, thermal stimulation, or digital pressure were surveyed. The trials included

Glossary of Selected Acupuncture Terms

Acupuncture
An ancient Chinese health practice that involves puncturing the skin with hair-thin needles at particular locations, called acupuncture points, on the patient's body. Acupuncture is believed to help reduce pain or change a body function. Sometimes the needles are twirled, given a slight electric charge (see electroacupuncture), or warmed (see moxibustion).

Electroacupuncture
A variation of traditional acupuncture treatment in which acupuncture or needle points are stimulated electrically.

Meridians
A traditional Chinese medicine term for the pathways throughout the body for the flow of *qi*, or vital energy, accessed through acupuncture points.

Moxibustion
The use of dried herbs in acupuncture. Compressed herbs are placed in contact with acupuncture needles and burned. This method is believed to be more effective at treating some health conditions than acupuncture needles alone.

Qi
(Pronounced "chee.") The Chinese term for vital energy or life force.

Traditional Chinese Medicine
An ancient system of medicine and health care that is based on the concept of balanced *qi*, or vital energy, that flows throughout the body. Components of traditional Chinese medicine include herbal and nutritional therapy, restorative physical exercises, meditation, acupuncture, acupressure, and remedial massage.

Yang
The Chinese concept of positive energy and forces in the universe and human body. Acupuncture is believed to remove yang imbalances and bring the body into balance.

Yin
The Chinese concept of negative energy and forces in the universe and human body. Acupuncture is believed to remove yin imbalances and bring the body into balance.

Source: The National Institutes of Health. Available at: http://nccam.nih.gov/fcp/factsheets/acupuncture/acupuncture.htm#glossary. Accessed March 13, 2002.

393 patients. Based on the quality of the trials, the authors concluded that there was strong evidence that acupuncture was more effective than sham acupuncture for OA knee pain, but that evidence was inconclusive for assessing effect on function. In trials that compared acupuncture with usual treatment or being on a waiting list, however, the evidence was found only to be limited and indicated that acupuncture was superior since these trials were of lower quality. The results of this analysis favored acupuncture more strongly than had the review the previous year,[10] but included only two of the same studies as the previous review and used more systematic criteria for study selection and analysis.

Clinical Studies: Rheumatoid Arthritis

Studies of patients with rheumatoid arthritis (RA) are considerably less compelling than are those of patients with OA. The first published study to address the use of acupuncture in RA appeared in abstract form in 1973.[17] The study used insertion of needles at sites adjacent to traditionally defined points at superficial depths without "the traditional twirling" as the placebo control. Four of 10 patients subjectively improved over a period of 10 weeks, during which time patients received acupuncture treatment, and then were crossed over to receive "inappropriate" acupuncture. Physical findings improved in only one patient; two patients' findings progressed and seven were unchanged.

Results were better in a randomized, controlled trial of 10 RA patients with bilateral knee involvement. Subjects received acupuncture treatment on one knee and sham acupuncture on the other. In each patient, analgesia was superior in the acupuncture-treated knee. Interestingly, the sham-treated knee experienced a reduction in pain for an average of 10 hours, while the acupuncture-treated knee averaged 1-3 months of pain relief.[18] However, these and most subsequent studies of RA patients are too small and poorly designed to make statistically valid observations about the utility of acupuncture in this disease.[10,19]

A recent well-designed, randomized, placebo-controlled (using a needle introducer, but no needle, placed at the same acupuncture site as the treatment group) study prospectively crossed over 56 RA patients between treatment and placebo.[20] Validated and disease-specific outcome measures were chosen that reflected

Acupuncture Regulations in the United States

As the acceptance of acupuncture in the United States grows, the need for guidelines and regulations governing these practitioners becomes imperative. Two national organizations are responsible for certifying practitioners and ensuring that acupuncture training and practice meet minimum standards for safety.

The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) developed a national certification process to ensure safety and competency in practicing acupuncture. The following requirements must be met before non-physicians may become nationally board-certified in acupuncture:[1]

- Graduation from a full-time acupuncture program (minimum 1,725 hours entry-level education, with at least 1,000 didactic hours and 500 clinical hours) or completion of an apprenticeship (4,000 contact hours over a three- to six-year period, five years' experience prior to apprenticeship, and minimum of 500 acupuncture visits per year by no fewer than 100 different patients).
- Successful completion of NCCAOM-approved clean needle technique course.
- Passing score on both written and practical licensing exams.

The Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM) is recognized by the U.S. Department of Education and the Council on Higher Education Accreditation to accredit professional acupuncture programs.[2] Thirty-four U.S. programs are accredited currently, and seven programs are candidates for accreditation.

In the United States, regulation of physician acupuncture practice varies among states. Although some states require certification or licensure, many states do not have such requirements for physicians.[3] In most states, health care professionals holding a license in an established medical field may complete an acupuncture training course and apply to their professional board for recognition of this therapy within their scope of practice. ❖

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pain and inflammation. However, only a single point bilaterally, Liver 3 (Li3), was used for treatment over a five-week period. This point was chosen because of its known ability to induce a significant endogenous endorphin response and prior work that suggested analgesic efficacy for headache. This well-conducted trial showed no analgesic or anti-inflammatory benefit to this application of Li3 needling. The authors noted the difference between OA and RA trial results and wondered if they might be explained on the basis of substantial differences in disease pathophysiology.

Table 2

Incidence of adverse effects of acupuncture[21]

Adverse Effect	Prevalence
Needle pain	1-45%
Tiredness	2-41%
Bleeding	0.03-38%
Feeling faint/syncope	0-0.3%
Relaxation	~ 86%
Pneumothorax	rare
Cardiac tamponade	rare

Adverse Effects

Adverse effects of acupuncture are rare. The NIH Consensus Panel concluded that "the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used" for the conditions it studied.[5]

The most comprehensive systematic review of prospective studies addressing acupuncture studies to date concurs that serious complications are rare.[21] *(See Table 2.)* However, if pain at the insertion site, bleeding, and a sense of fatigue are considered adverse effects, then minor side effects may be considerable, each sometimes occurring in more than 40% of patients.

The most frequently reported serious complication is pneumothorax, of which approximately 90 cases have been described, two of which were fatal. Of note, one patient treated with acupuncture for OA of the knee developed soft-tissue infection in the calf with *Mycobacterium chelonae*.[22] The Food and Drug Administration mandates the use of single-use, disposable needles.

Contraindications

Acupuncture treatment has been observed to stimulate uterine contractions and pregnant patients should not be treated. Those with valvular heart disease should avoid insertion of semi-permanent needles. Patients with a bleeding diathesis and those on anticoagulants should avoid acupuncture because of the bleeding risk. Those with implantable cardiac devices, including pacemakers and defibrillators, and those with epilepsy should avoid electroacupuncture. Patients with infectious diseases, including skin infections, should forego acupuncture as well.

Conclusion

Acupuncture appears to be an effective analgesic for the pain of osteoarthritis, but has less support in the literature for effectiveness in treating pain of rheumatoid arthritis. Pain relief in osteoarthritis may be additive to that already provided by medications such as NSAIDs and narcotics, making acupuncture a useful adjunctive therapy in this condition. Side effects are likely to be minimal.

Recommendation

Acupuncture is an option for the treatment of osteoarthritis pain. It may be used alone or in combination with other interventions in a comprehensive management plan. It may be used in both early and late disease. Patients seeking care by acupuncturists should be aware that practitioners are licensed in most states. Information is available regarding physicians practicing acupuncture from the American Academy of Medical Acupuncture (http://www.medicalacupuncture.org). *(See sidebar "Acupuncture Regulations in the United States" for more information about certification.)*

The role of acupuncture for the management of inflammatory arthritis, such as rheumatoid arthritis, is less clear. It is unlikely to have anti-inflammatory effects, based on the available clinical data, and should be used only as an adjunctive analgesic. Inflammatory arthritis treatment requires specific and intensive use of medications. ❖

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Acupuncture for the Treatment of Addiction

By Robert J. Nardino, MD, FACP

ACUPUNCTURE WAS POPULARIZED IN THE WESTERN world after a *New York Times* reporter travelling with President Nixon's entourage in China described his experience with acupuncture as anesthesia for an emergency surgical procedure. It was soon afterward that a patient of a Hong Kong neurosurgeon reported relief from opium withdrawal symptoms after acupuncture anesthesia.

The surgeon, Dr. H. L. Wen, went on to attempt acupuncture on other addicted patients and reported his findings in the mid-1970s.[1] The most popular protocol was developed over years of use at Lincoln Hospital in the South Bronx, NY. Currently, many drug-treatment programs use acupuncture for management of drug addiction, particularly for drug addictions that have no highly effective treatment, such as cocaine addiction.

Traditional Use

Acupuncture is a therapeutic modality that has been used for thousands of years. Although texts of traditional Chinese medicine refer to its use in a wide variety of afflictions, they do not make reference to its use for addictive disorders.

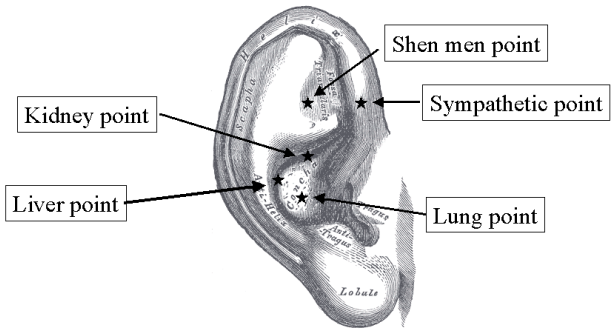
Mechanism of Action

More so than other complementary therapies, there has been significant investigation into the mechanism of acupuncture.

Beta-endorphin levels, which play a role in pain control, were observed to rise in the brain tissue of mice when acupuncture was used to counteract the effect of naloxone-induced opiate withdrawal.[2] Ulett and colleagues demonstrated that the withdrawal-preventive

Figure

The five National Acupuncture Detoxification Association addiction points



Source: Illustration reprinted with permission. *Gray's Anatomy of the Human Body*. 20th ed. New York: Bartleby.com; 2000.

effect of electroacupuncture could be transferred to a second animal by infusing cerebrospinal fluid (CSF) from the animal receiving acupuncture. They also were able to prevent acupuncture-induced anesthesia by administering anti-endorphin antibodies.[3] Continued investigation of the physiologic effects of acupuncture implicates stimulation of kappa-opioid receptors in the spinal cord.[4] Andersson and Lundeberg have reported that the physiologic effects of acupuncture mimic those of vigorous exercise, including the release of endorphins and inhibition of the sympathetic system at the level of the hypothalamus.[5]

On the other hand, a study by Clement-Jones et al in heroin addicts showed that plasma endorphin and enkephalin levels did not change despite suppression of symptoms with acupuncture, although increased levels of CSF met-enkephalin were associated with successful acupuncture.[6] Cortisol, adrenocorticotropic hormone, and cyclic adenosine monophosphate levels were reduced after auricular electroacupuncture.[7]

Despite all of this work, there is still disagreement about the exact mechanism.

Technique

Early use of acupuncture for addiction focused on the lung point *(see Figure)*. Later, the shen men relaxation point was added. Most studies employ auricular acupuncture according to the National Acupuncture Detoxification Association (NADA) protocol, which specifies needle insertion in five regions, with the sympathetic, liver, and kidney added.

Sham or control acupuncture is much less standardized. Acupuncture points are based on the traditional Chinese medicine concept of the flow of *qi*. Because there is uncertainty about the mechanism of *qi*, it could be difficult to discern whether needling at non-acupuncture points lacks a physiological effect. However, to assess what could be a substantial placebo effect, it would appear to be important for control patients to receive sham acupuncture. There is ongoing research to better define active vs. control auricular acupuncture points.[8]

Clinical Studies

Alcohol. A 1990 meta-analysis by Ter Riet et al on acupuncture for addiction included two studies of alcohol-dependent patients. Although results seemed to favor treatment with acupuncture, the quality of the studies was poor: There was a lack of randomization in one study and an unacceptably high drop-out rate in the other.[9] A subsequent randomized study of 56 alcoholics receiving acupuncture vs. sham acupuncture or standard care showed no benefit in terms of several outcome measures, although one-third of the patients also had addiction to other substances.[10] Sapir-Weise et al reported a study of 72 alcoholics who were randomized to acupuncture or sham acupuncture; no significant difference in craving or drinking days was found.[11]

Overall, the data do not support the use of acupuncture for the treatment of alcohol dependence.

Cocaine. Acupuncture is used widely in cocaine treatment centers across the United States because the response to conventional treatment generally is poor. However, quality data are limited.

Bullock et al concurrently studied two groups with different controls.[12] The first group of 236 patients in residential treatment was randomized to acupuncture at three auricular points vs. sham acupuncture or standard treatment. The second group of 202 ambulatory patients was randomized to acupuncture at five points for a varying duration of treatment. They found no significant differences in abstinence between acupuncture and control groups or between the different acupuncture regimens.

Another study by Avants et al was more promising.[13] It reported the effectiveness of acupuncture on 82 cocaine-dependent patients who were receiving methadone maintenance. Patients were randomly assigned to receive acupuncture, sham acupuncture, or a relaxation control (passive imagery and music) with no needling. The acupuncture group received a variant of the NADA protocol, with only four points needled (lung, shen men, sympathetic, and liver). Patients received treatments five times per week over an eight-week period, with screening for cocaine use three times weekly.

The experimental group was more likely to submit cocaine-free urine samples; however, only 46% of the patients in the acupuncture group completed the eight-

Table

Adverse events attributed to acupuncture

Type of Event	Example	Number of Absolute Events	
		White et al[19] (31,822 patients)	MacPherson et al[20] (34,407 patients)*
Administration problem	Needle lost or forgotten	7	2
Application site problem	Cellulitis; needle allergy; needle site pain	7	6
Cardiovascular	Fainting	6	5
Gastrointestinal	Nausea; vomiting	3	6
General problems	Drowsiness; disorientation; lethargy; rash	7	9
Neuropsychological	Anxiety/panic; headache; paresthesia; seizure; slurred speech	8	5
Renal	Hematuria	—	1
Exacerbation of symptoms	Back pain; fibromyalgia; shoulder pain; migraine	5	7

* Two adverse events in the MacPherson survey were unspecified.

week treatment course. Nevertheless, intention-to-treat analysis showed a significant improvement in abstinence when acupuncture was compared with relaxation therapy and, when compared with sham acupuncture, the difference just reached significance.

A recently published randomized, multicenter trial similarly investigated auricular acupuncture as compared with needling of non-acupuncture sites or relaxation therapy.[14] Six centers throughout the United States enrolled 620 patients. Treatments were offered five times per week for eight weeks. There was a high drop-out rate in all three treatment arms (45%). The main outcome measure was detection of cocaine metabolites by urine toxicology. In the intention-to-treat analysis, an overall modest reduction in cocaine use was seen, but there was no difference between acupuncture and the two control conditions. A limitation of the study may be that in an effort to be rigorous in design of the study, the treatment context may have differed from that used in practice.

The existing data do not confirm efficacy for treatment of cocaine addiction; further evaluation may be warranted to determine if acupuncture adds benefit to a program of psychosocial intervention.

Nicotine. The best summary of the evidence for acupuncture as a technique for smoking cessation comes from the Cochrane Collaboration.[15] Only studies that randomized patients to acupuncture vs. sham acupuncture, another intervention, or no intervention were selected. A total of 18 studies met the criteria for inclusion. When acupuncture was compared to sham acupuncture, the odds ratio for the outcome of abstinence at six months was 1.38 (95% confidence interval [CI] 0.90-2.11) and at 12 months was 1.02 (95% CI 0.72-1.43), indicative of no effect. Likewise, there was no benefit compared to other interventions.

Despite widespread use, there is little evidence to support the use of acupuncture for smoking cessation.

Opiates. The Ter Riet meta-analysis reviewed five studies of acupuncture for heroin addiction, none of which were randomized.[9] Since then, Washburn randomized 100 heroin addicts to acupuncture or sham acupuncture.[16] Acupuncture patients attended the clinic more days than the control patients and stayed in treatment longer. Unfortunately, this study also suffered from a very high drop-out rate.

In another non-randomized study, Russell et al examined auricular acupuncture as an adjunct to substance abuse treatment in chronic repeat offenders.[17] They followed 37 patients for 180 days looking at the endpoints of program retention, new arrests, drug-positive urine, and number of days to progress from entry level to secondary level of treatment. They used historical controls as the comparison, and found significantly improved program retention, although the impact diminished with time (30 days best, decreased over 30-day intervals until non-significant at 180 days). The other endpoints were better in the treatment cohort but did not reach statistical significance.

Finally, a retrospective study of patients seeking substance abuse treatment in Boston compared those who received acupuncture with those who participated in a residential program.[18] The acupuncture group was less likely to require detoxification at six months, with an odds ratio of 0.71 (95% CI 0.53-0.95). However, the retrospective nature of the study allows for differences between the two groups, most importantly in regard to motivation to remain abstinent.

Overall, the data in support the use of acupuncture for treatment of heroin addiction are weak. A larger, well-designed RCT may clarify its efficacy.

Adverse Effects

Until recently, there has been a scarcity of data concerning the safety of acupuncture. Three *British Medical Journal* studies have improved this circumstance, although voluntary reporting and inclusion of only licensed acupuncturists may have produced under-reporting in both of these surveys.

White et al presented survey data from 78 physicians and physiotherapists in Great Britain who performed acupuncture.[19] During 32,000 encounters, 43 events considered significant were reported *(see Table)*; in addition, 2,135 minor events (predominantly minor bleeding and needling pain) also were reported.

MacPherson audited all 1,848 members of the British Acupuncture Council to report adverse events during a four-week interval in 2000.[20] Among 574 acupuncturists participating, 43 adverse events were documented from 34,407 encounters *(see Table)*, as well as 10,920 mild transient reactions.

Indeed, Ernst reviewed all of the adverse events reported worldwide in 1998 and noted just 11 serious complications, including fatal streptococcal myositis, acupuncture-induced angina, pneumothorax, and other infectious complications.[21]

In the setting of clinical trials, not only for addiction but also for a wide variety of medical problems, acupuncture is uniformly safe. The reports of White and MacPherson indicate event rates that are very low and compare very favorably with medication side effects; however, patients should be aware of a small potential for serious complications.

Conclusion

Although acupuncture is widely available through numerous treatment programs, there is a paucity of well-executed randomized, controlled trials studying its effect in the treatment of addiction. The best-designed studies do not favor the use of acupuncture.

There appear to be two major methodological obstacles. First is the difficulty in selecting the control intervention. Sham acupuncture remains a poorly defined entity. Second is the difficulty of encouraging this population of patients to remain active study participants—studies consistently suffer from high drop-out rates.

At the present time, the available evidence does not support acupuncture for nicotine or alcohol addiction. The data for heroin need strengthening. Promising initial results in cocaine-addicted patients are in conflict with the negative results of a recent large multicenter trial.

Recommendation

In the hands of experienced practitioners, acupuncture generally is a safe procedure. Because of this, and because response to conventional treatment is poor, further study is warranted for acupuncture as an adjunct to the treatment of patients addicted to cocaine and opiates. Clinical use of acupuncture outside of clinical trials is not recommended. ❖

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Acupuncture for Urinary Incontinence in Women

By Christine Dehlendorf and Nassim Assefi, MD

URINARY INCONTINENCE AFFLICTS 17-55% OF OLDER women and 12-42% of middle age women,[1] causing a significant deterioration of quality of life, including emotional disturbances, social isolation,[2] and increased risk of placement in long-term care facilities.[3] It also presents a major cost burden to the U.S. health care system, estimated in the range of $26.3 billion for both direct and indirect costs.[4]

Although conventional treatments often are effective, they fail a significant number of women. Many therapies are associated with unacceptable side effects, and pelvic floor exercises are dependent on patient motivation and ability to contract the muscle groups voluntarily. Furthermore, conservative treatment has decreased effectiveness with increasing age.[5]

Acupuncture has long been used to treat disorders of the urinary tract and increasingly is being investigated as both an adjunctive and first-line therapy for all three types of incontinence in women.

Description

Genuine stress incontinence (GSI) describes an involuntary loss of urine during physical exertion, whereas urge incontinence (UI) is an irritative bladder syndrome that is associated with dysuria, frequency, and urgency. Mixed incontinence, any combination of the preceding two types, is the third major form of incontinence in women.

Conventional Treatment

Conventional treatment for GSI consists of pelvic floor exercises with or without biofeedback, hormone replacement therapy, surgery, and the use of devices such as vaginal cones. UI generally is treated with bladder re-training with or without medication. Newer approaches to the treatment of both types of incontinence include transcutaneous electrical stimulation,[6,7] as well as direct neuromodulation of the sacral nerve roots.[8]

Mechanism of Action

The understanding of the physiologic basis of acupuncture in urinary conditions remains rudimentary. In GSI, acupuncture has been suggested to have a role in afferent nerve stimulation, producing reflex contraction of the muscles contributing to urethral closure.[9,10] A second proposed mechanism is that of improved vascularization to the pelvic floor, resulting in improved competence of the urethral sphincter mechanism.[9] Controlled studies have shown an increase in urethral pressure following acupuncture.[10,11]

With respect to UI, one proposed mechanism relates to acupuncture's effect in increasing cerebrospinal fluid levels of endogenous opiates.[12,13] Enkephalins have been shown to inhibit in vitro detrusor muscle contraction,[14] and the pontine micturition center is under tonic inhibition by enkephalins.[15] Furthermore, intravenous naloxone has been associated with decreased bladder capacity, compliance, and stability, as well as decreased urethral closure pressure in urodynamic studies.[16] A second hypothesis suggests that acupuncture may function in a manner similar to electrical stimulation, which influences neuronal pathways for detrusor inhibition.[17]

Table

Results of clinical trials of acupuncture and urinary incontinence

Study	Design	Incontinence	Patients	Objective Results	Subjective Results
Bergström et al[9]	Prospective, no control	Urge and mixed	15	+	+
Huitian et al[10]	RCT vs. placebo	Stress	60	+/-	N/A
Chang[17]	RCT vs. placebo	Urge	52	+/-	+
Preiner et al[19]	Prospective, no control	Stress	17	-	+
Kelleher et al[21]	RCT vs. medication	Urge	39	+/-	+/-
Philp et al[22]	Prospective, no control	Urge	16	+/-	+
Pigne et al[23]	Prospective, no control	Urge	16	+	N/A

Finally, the periurethral muscle contractions associated with acupuncture itself could contribute to reflex inhibition of the detrusor muscle.[18]

Clinical Trials

Literature searches of Pubmed, Cochrane registry, Biosis, CINAHL, and AMED, with key words "urine," "urinary," "incontinence," and "acupuncture," supplemented by hand-searched citations, revealed nine relevant studies.

For UI, there were two randomized controlled trials (RCTs) of acupuncture, three non-controlled studies, and two poorly designed studies that provided some support for the use of acupuncture.

For GSI alone, two studies were found. One abstract reported a study of 17 women with GSI, showing significant improvement in subjective quality-of-life variables up to six months after treatment, but no improvement in bladder capacity or leakage.[19] One randomized controlled study of 60 women with stress incontinence showed improvement in maximal pressure of the urethra and urethral length, but not in the 2-second flow rate of urine.[10] *(See Table.)*

In 1988, Chang conducted a RCT of 52 female outpatients without urinary tract infections who complained of frequency, urgency, and dysuria.[17] The study group received one acupuncture treatment at a point traditionally used in the treatment of urinary tract disorders, Spleen 6 (Sp6), while the control group received treatment at a point generally used for the treatment of gastrointestinal disease, Stomach 36 (St36).

Subjectively, 22 patients (84.6%) in the treatment group reported improvement, compared to six (23.1%) in the control group. In the treatment group, the maximum cystometric capacity increased ($P < 0.01$) and the peak urinary flow rate decreased ($P < 0.02$) significantly 30 minutes after acupuncture, while no changes were found in the control group. In addition, six of the eight patients in the treatment group with unstable detrusors achieved stability, compared to one of six in the control group. There were no changes in first sensation to void, residual urine, maximum urethral closure pressure, or voided volume.

A subsequent paper published by Chang and colleagues in 1993 reported the long-term follow-up data (average 66.2 months) for this same study group.[20] Although the study population showed continued symptomatic improvement with repeated acupuncture treatments, when urodynamic studies were performed one week after the most recent treatment, no long-term improvement was found.

The second RCT randomized 20 women with irritative bladder symptoms to receive acupuncture and 19 women to receive conventional pharmacologic therapy with oxybutynin.[21] Following six weekly treatments at multiple acupuncture points, the subjective measures of urgency and frequency were significantly improved in both groups and nocturia was improved in the acupuncture group, but there was no significant improvement in UI in either group. Objectively, significant improvement was found in both groups in detrusor pressure rise on filling. A significant improvement also was seen in the acupuncture group in bladder capacity, but not in the other group. No changes were seen in flow rate, residuals, first sensation, or voiding pressure for either group. The medication group also reported more side effects than the acupuncture group. Three months following the treatment, eight of the 18 women who received acupuncture and were available for follow-up remained symptom-free, with four more continuing to experience partial relief. Seven of the 19 oxybutynin-treated patients were symptom-free.

Three non-controlled studies also addressed the use of acupuncture in UI, including mixed incontinence. A recently published pilot study investigated UI symptoms in 15 elderly women who had failed conventional

treatment.[9] Quality-of-life measures, subjective urge to void, and objective leakage tests were significantly improved up to three months following acupuncture treatment. Another non-controlled study of 16 patients with UI showed symptomatic improvement in 11 patients, with no consistent change in bladder filling curves.[22] Finally, one study of 16 patients with UI that was published only as an abstract found improvement in frequency of micturition, leakage, first desire to void, bladder capacity and compliance, and detrusor instability. [23]

Methodologic Challenges

There are numerous challenges in interpreting acupuncture studies. These include specifying the acupuncture treatment plan (i.e., the number of points stimulated, the type of acupuncture used, and the frequency and duration of treatment), identifying appropriate controls (e.g., acupuncture at presumed non-therapeutic points, non-invasive acupuncture, and mock electro-stimulation units), correlating diagnoses between traditional Chinese medicine and allopathic medicine, and the blinding of patients to the intervention.[24]

In addition, measurement of treatment outcomes is complicated by the time-consuming and potentially invasive nature of objective measures in studies of incontinence. Furthermore, objective measures in UI do not always correlate with patient symptoms.[25]

Adverse Effects

A review of the global acupuncture literature from 1981 to 1994 attempted to identify the adverse effects of acupuncture, and found 193 adverse events with three deaths.[26] The largest risk with acupuncture is infection, including 100 reported cases of hepatitis B/C/non-A-non-B. In all of these cases, the sterilization of needles was inadequate. One case of HIV infection also has been reported, and is presumed to be due to lack of sterilization. Sterilization of needles is not thought to be an issue in the United States where the use of disposable sterile needles is required by the Food and Drug Administration.

Sepsis and endocarditis are reported rarely, as well as one case of death secondary to an asthma attack. Finally, pneumothorax is reported to be the dominant mechanical injury, and is more common in those with pre-existing chronic obstructive pulmonary disease.

With respect to acupuncture for incontinence, only one of the above studies reported side effects.[21] Of the 20 women receiving acupuncture, two complained of discomfort upon insertion of the needles, three noted feeling lightheaded following treatment, four patients reported headache, and four patients experienced drowsiness. Some patients may have experienced multiple side effects.

Conclusion

Reasonable data support a physiologic mechanism for the use of acupuncture for both GSI and UI. However, high-quality clinical trials are scarce. No RCT of acupuncture for GSI was identified. One randomized, placebo-controlled trial of acupuncture for UI showed subjective efficacy, with some objective benefit, and another RCT found some increased subjective and objective efficacy of acupuncture treatment for the same symptoms when compared to standard pharmacologic therapy. Non-controlled reports support the effectiveness of acupuncture in urge and mixed incontinence.

Recommendation

Acupuncture appears to be a promising option for urge incontinence. However, the frequency and duration of treatment, the acupuncture points to use, and potential interactions with pharmacologic therapies have not been elucidated. There are insufficient data to recommend the use of acupuncture in the treatment of genuine stress incontinence. ❖

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In the News

Recall of PC SPES

Consumers should immediately stop using the dietary supplement herbal products PC SPES and SPES because they contain undeclared prescription drug ingredients that could cause serious health effects if not taken under medical supervision. PC SPES and SPES are marketed for prostate health and strengthening the immune system, respectively.

BotanicLab, the Brea, CA-based manufacturer, has voluntarily recalled PC SPES and SPES nationwide.

The California Department of Health Services' (CDHS) Food and Drug Branch conducted a laboratory analysis of the products and found PC SPES contains warfarin and SPES contains alprazolam. PC SPES is available in 60-capsule bottles, and SPES is available in 30-capsule bottles, through mail or telephone order, Internet sales, distributors, retailers, and health care professionals.

Consumers who have unused SPES and PC SPECS capsules should return the product in its original packaging to PC SPES Recall Program, 2900-B Saturn St., Brea, CA 92821, or call (800) 458-5854. CDHS' Food and Drug Branch is continuing to investigate these products and can be reached at (800) 495-3232 for more information. The U.S. Food and Drug Administration is assisting in the investigation and monitoring of the recalls throughout the United States.

To view the recall notice, visit: http://www.botaniclab.com/html/recall.html. ▼

Kava Linked to Liver Toxicity

The Food and Drug Administration (FDA) is investigating whether the use of dietary supplements containing kava (also known as kava kava or *Piper methysticum*) is associated with liver toxicity. To help determine whether there is a problem in the United States, the

FDA is asking that physicians review cases of liver toxicity to determine if any may be related to the use of kava-containing dietary supplements.

Products containing herbal extracts of kava have been implicated in cases of serious liver toxicity in Germany and Switzerland. Approximately 25 reports of hepatic toxicity associated with the use of products containing kava extracts have been reported in these countries. Serious hepatic adverse effects include hepatitis, cirrhosis, and liver failure. At least one patient required a liver transplant. Based on their assessment of the adverse events reported to them, the regulatory authority in Switzerland has prohibited the sale of products containing the kava extract associated with the adverse effects. Last month, the German authorities issued a proposal to remove all kava extract-containing products from the market.

FDA is investigating whether the use of kava-containing dietary supplements in the United States poses similar public health concerns. The agency has received several reports of serious injury allegedly associated with the use of kava-containing dietary supplements, with at least one report of hepatic failure requiring liver transplantation in a previously healthy young female.

Dietary supplements containing kava are promoted for a variety of uses, including relaxation (e.g., to relieve stress, anxiety, and tension), insomnia, and premenstrual syndrome.

Because of the potentially serious nature of these concerns, any cases of hepatic toxicity or other adverse events that may be related to the use of kava-containing dietary supplements should be reported as soon as possible to FDA's MedWatch program by telephone: (800) 332-1088 or through the Internet: http://www.fda.gov/medwatch. ▼

Lipokinetix and Liver Injury

Lipokinetix, distributed by Syntrax Innovations Inc., has been implicated in several cases of serious liver injury. The Food and Drug Administration (FDA) has received reports of at least six persons who developed acute hepatitis and/or liver failure while using Lipokinetix. The injuries reported to FDA occurred in persons between 20 and 32 years of age. No other cause for liver disease was identified. In all cases, no pre-existing medical condition that would predispose the consumer to liver injury was identified. Onset of liver injury was observed between two weeks and three months of starting Lipokinetix.

Lipokinetix has been promoted for weight loss by mimicking exercise and supporting an increased metabolic rate. The product contains norephedrine (also known as phenylpropanolamine or PPA), caffeine, yohimbine, diiodothyronine, and sodium usniate.

FDA has issued a consumer warning advising consumers to stop using this product and to consult their physician if they are experiencing symptoms possibly associated with this product, particularly nausea, weakness or fatigue, fever, abdominal pain, or any change in skin color.

FDA urges physicians to review all cases of hepatitis in order to determine if any may be related to the use of dietary supplements in these patients. Adverse events associated with the use of dietary supplements should be reported as soon as possible to FDA's MedWatch program by telephone: (800) 332-1088 or via the Internet: http://www.fda.gov/medwatch. ▼

Distinguished Lecture Series on CAM

The National Center for Complementary and Alternative Medicine (NCCAM), a component of the National Institutes of Health (NIH), recently announced the launch of the Distinguished Lecture Series on Complementary and Alternative Medicine (CAM).

A national survey revealed that in 1997 more than 42% of the American public used CAM, at a cost of $27 billion per year, which exceeded out-of-pocket spending for all U.S. hospitalizations. In 1998, the Congress established the NCCAM to stimulate, develop, and support research in CAM for the benefit of the public. The NCCAM is an advocate for high-quality science, rigorous, and relevant research, and open and objective inquiry into which CAM practices work, which ones do not, and why. Its overriding mission is to give the American public reliable information about the safety and effectiveness of CAM practices.

The new CAM lecture series offers an opportunity for NIH staff, scientists, and the public to come together to learn about current thinking and research, and engage in constructive dialogue about innovative approaches to integrated disease prevention and management.

The first lecture was given by Stephen E. Straus, MD, director of NCCAM, on March 11. Future lectures will include talks on July 25, by Charles Rosenberg, PhD, professor of the History of Science, and Ernest E. Monrad, Professor in the Social Sciences, Harvard University. On Nov. 7, Arthur Kleinman, MD, professor of Social Anthropology, Harvard University, and Lillian Presley, Professor of Medical Anthropology and Psychiatry, Harvard Medical School, will present a talk.

For more information about this lecture series, visit http://nccam.nih.gov or contact Linda Gaskill by telephone: (301) 984-7191 or email: Linda.Gaskill@matthewsgroup.com. ▼

CME Questions

24. The mechanism of action of acupuncture in treatment of arthritis pain:
a. is completely explained by the production of endogenous opioids.
b. is likely to depend primarily on inhibition of inflammation.
c. is likely to be multifactorial.
d. has been conclusively demonstrated.

25. Acupuncture research has been hindered by:
a. the lack of an appropriate placebo.
b. poor study design.
c. the use of nonstandard outcome measures.
d. All of the above

26. According to the NIH Consensus Panel, acupuncture maybe useful in the treatment of:
a. fibromyalgia.
b. myofascial pain.
c. low back pain.
d. carpal tunnel syndrome.
e. All of the above

27. Acupuncture can be recommended for:
a. primary treatment of rheumatoid arthritis.
b. adjunctive treatment of osteoarthritis.
c. pregnant patients.
d. patients with a bleeding diathesis.

28. Sham acupuncture is best described as:
a. pretending to insert needles.
b. using dull needles.
c. needling points that are not described acupuncture points.
d. None of the above

29. Published evidence supports the use of acupuncture for which of the following?
a. Heroin addiction
b. Cocaine addiction
c. Nicotine addiction
d. Alcohol addiction
e. None of the above

30. Adverse effects of acupuncture include which of the following?
a. Local pain and hemorrhage
b. Pneumothorax
c. Pulmonary embolism
d. Both a and b are correct
e. Both b and c are correct

31. Incontinence is associated with which of the following?
a. Increased admission to long-term care facilities
b. Decreased quality of life
c. Emotional disturbances
d. Social isolation
e. All of the above

32. Acupuncture may be useful in the treatment of incontinence because:
a. there are no other effective treatments for incontinence.
b. surgery is the only effective treatment for incontinence.
c. acupuncture has been shown to be the most effective treatment.
d. conventional treatments are not effective for everyone and may be associated with side effects.

33. Kava recently has been linked to:
a. nephrotoxicity.
b. cardiotoxicity.
c. hepatotoxicity.
d. hematotoxicity.
e. All of the above

Clinical Briefs

With Comments from John La Puma, MD, FACP

Acupuncture Theory and Practice

Source: Kaptchuk TJ. Acupuncture: Theory, efficacy, and practice. *Ann Intern Med* 2002; 136:374-383.

TRADITIONALLY, ACUPUNCTURE IS embedded in naturalistic theories that are compatible with Confucianism and Taoism. Such ideas as yin-yang, *qi*, dampness, and wind represent East Asian conceptual frameworks that emphasize the reliability of ordinary, human sensory awareness. Many physicians who practice acupuncture reject such prescientific notions.

Numerous randomized, controlled trials and more than 25 systematic reviews and meta-analyses have evaluated the clinical efficacy of acupuncture. Evidence from these trials indicates that acupuncture is effective for emesis developing after surgery or chemotherapy in adults and for nausea associated with pregnancy. Good evidence exists that acupuncture also is effective for relieving dental pain. For such conditions as chronic pain, back pain, and headache, the data are equivocal or contradictory.

Clinical research on acupuncture poses unique methodologic challenges. Properly performed acupuncture seems to be a safe procedure. Basic-science research provides evidence that begins to offer plausible mechanisms for the presumed physiologic effects of acupuncture.

Multiple research approaches have shown that acupuncture activates endogenous opioid mechanisms. Recent data, obtained by using functional magnetic resonance imaging, suggest that acupuncture has regionally specific, quantifiable effects on relevant brain structures. Acupuncture may stimulate gene expression of neuropeptides. The training and provision of acupuncture care in the United States are rapidly expanding.

Recommendation

The best single scientific review in a first-tier, peer-reviewed medical journal of the state of the art and science of acupuncture. Basic reading for clinicians, though there are no data about reimbursement or malpractice litigation. ❖

Acupuncture and Tennis Elbow

Source: Green S, et al. Acupuncture for lateral elbow pain (Cochrane Review). *Cochrane Database Syst Rev* 2002;(1):CD003527.

THIS REVIEW IS ONE IN A SERIES OF reviews of interventions for lateral elbow pain. Lateral elbow pain, or tennis elbow, is a common condition causing pain in the elbow and forearm and lack of strength and function of the elbow and wrist. Acupuncture has long been used to treat lateral elbow pain in China and in Western countries, practitioners and consumers are increasingly exploring acupuncture as a first-line treatment for musculoskeletal disorders. No previous systematic review of the available evidence has been conducted to determine whether acupuncture is efficacious in the treatment lateral elbow pain.

The effectiveness of acupuncture in the treatment of adults with lateral elbow pain with respect to pain reduction, improvement in function, grip strength, and adverse effects has been studied. A search of MEDLINE, CINAHL, EMBASE, and SCISEARCH and the Cochrane Clinical Trials Register and the Musculoskeletal Review Group's specialist trial database from 1966 to June 2001 used identified keywords and authors to retrieve as many trials as possible.

Two independent reviewers assessed all identified trials against predetermined inclusion criteria. Randomized and pseudo-randomized trials in all languages were included in the review provided they were testing acupuncture compared to placebo or another intervention in adults with lateral elbow pain. Outcomes of interest were pain, function, disability, quality of life, strength, participant satisfaction with treatment, and adverse effect.

For continuous variables, means and standard deviations were extracted or imputed to allow the analysis of weighted mean difference, while for binary data, numbers of events and total population were analyzed and interpreted as relative risks. Trial results were combined only in the absence of clinical and statistical heterogeneity.

Four small, randomized controlled trials were included; due to flaws in study designs (particularly small populations, uncertain allocation concealment, and substantial loss to follow-up) and clinical differences between trials, data from trials could not be combined in a meta-analysis. One randomized controlled trial found that needle acupuncture results in relief of pain for significantly longer than placebo (weighted mean difference = 18.8 hours, 95% confidence interval [CI] 10.1-27.5) and is more likely to result in a 50% or greater reduction in pain after one treatment (relative risk [RR] 0.33, 95% CI 0.16-0.69).

A second randomized controlled trial demonstrated needle acupuncture to be more likely to result in overall participant-reported improvement than placebo in the short term (RR = 0.09 95% CI 0.01-0.64). No significant differences were found in the longer term (after three or 12 months). A randomized controlled trial of laser acupuncture vs. placebo demonstrated no differences between laser acupuncture and placebo with respect to overall benefit. A fourth included trial published in Chinese demonstrated no difference between vitamin B_{12} injection plus acupuncture, and vitamin B_{12} injection alone.

There is insufficient evidence to either support or refute the use of acupuncture (either needle or laser) in the treatment of lateral elbow pain. This review has demonstrated needle acupuncture to be of short-term benefit with respect to pain, but this finding is based on the results of two small trials, the results of which were not able to be combined in meta-analysis. No benefit lasting more than 24 hours following treatment has been demonstrated. No trial assessed or commented on potential adverse effect. Further trials, utilizing appropriate methods and adequate sample sizes, are needed before conclusions can be drawn regarding the effect of acupuncture on tennis elbow.

COMMENT

Acupuncture also is booming at wellness and resort spas, where the youngest still play tennis, and ice their knees before and after games. So now, from the Australasian Cochrane Center at Monash University in Australia comes this excellent assessment of tennis elbow trials.

Alas, a definitive opinion is not forthcoming, other than short-term pain relief seems to result. Which is good enough for those at resorts, but not for the court addict whose nagging elbow pain disables her, and who remains on nonsteroidal anti-inflammatory drugs, and often, glucosamine.

Recommendation

Acupuncture may be tried for short-term pain relief from tennis elbow, but it is not the first tool in the toolbox. ❖

In Future Issues:

Red Clover for Menopausal Symptoms

Fish Oil for High Triglyceride Levels

Ginger for Nausea