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Acupuncture for Improving Chronic Back Pain, Osteoarthritis and Headache

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Abstract

Objective—To conduct a critical review of the literature on acupuncture for chronic back pain, osteoarthritis and headache.

Methods—Review of meta-analyses, systematic reviews and some well-conducted, recent studies.

Results—Overall, acupuncture appears superior to no treatment or usual care for persons with chronic back pain, osteoarthritis, or headache. However, these findings vary depending on the specific outcome and the follow-up period. The magnitude of the effect varies, but is consistent with a small to moderate effect size in most cases. Moreover, acupuncture is not clearly superior to sham acupuncture, although the latter is a controversial control group. Acupuncture has a favorable safety profile, with relatively few side effects and serious ones quite rare. Limited evidence suggests that acupuncture is a cost effective treatment.

Conclusions—The evidence suggests that acupuncture is a reasonable therapeutic option, but not the clear therapy of choice for any of these conditions. Acupuncture may be especially valuable for patients who prefer it to other options or are concerned about using analgesic medications.

Introduction

Chronic pain is the most common reason for using complementary and alternative medical therapies (1). While a variety of biological, physical and mind-body CAM therapies have been used for these conditions, the focus herein is on the use of acupuncture for three common and costly pain conditions: chronic back pain, osteoarthritis, and headache.

Although acupuncture use is relatively uncommon among Americans, with 4.1% having reported ever use and 1.1% indicating recent use, pain is one of the most common reasons for its use (2,3). Among a national sample of recent acupuncture users, 34% reported use for back pain, 16% for joint pain or stiffness and 9% for severe headaches or migraine (2). Sherman (3) found that back symptoms, headache, and knee pain were among the most common symptoms treated by acupuncturists in 2 US states.

Because this report is designed to assist physicians in understanding the role that acupuncture might play in pain relief, our review of evidence emphasizes the results of the most recent reviews and any large, well-designed studies published since then. Over the last decade, a number of large, rigorously designed studies have been conducted on acupuncture for chronic pain in the United States and Europe (4–11). However, most of these do not evaluate acupuncture as it is actually practiced. Therefore, to assist the reader in placing the findings in

a practical context, a summary is presented of the most important complexities in practice of acupuncture and how key elements of the design of acupuncture studies impact the findings.

Acupuncture in the US: Practice patterns

In the United States, acupuncture is typically delivered by non-physician providers who are trained in acupuncture and possibly, herbal medicine. Such providers are licensed or regulated in 43 states (12). In addition, more than 3,000 physicians and an unknown number of chiropractors are believed to practice acupuncture (13,14).

Non-physician acupuncturists commonly practice acupuncture using a non-Western conceptual framework, most commonly the principles of Traditional Chinese Medicine. Hallmarks of this framework include: a variety of East Asian medicine diagnoses are found among patients with a single biomedical diagnosis; treatments, including specific acupuncture points, are customized to the individual patient based their East Asian diagnoses and, sometimes, symptom profiles; substantial variability exists in needling techniques and point prescriptions; besides acupuncture needles, treatments typically include other therapeutic elements, such as heat, East Asian massage, herbs, and/or lifestyle advice (3). For example, in a study of the treatment of chronic back pain, Sherman (15) reported that Traditional Chinese medical treatments most commonly included acupuncture needling of the body with elicitation of *de qi*, the dull, achy sensation believed by acupuncturists to be important for ensuring therapeutic benefits. Needling was typically supplemented with heat (i.e., nmoxibustion or heat lamps), East Asian massage, herbs and/or cupping as well as self care recommendations. While some acupuncture point locations are more commonly needled than others for patients with back pain, a review of texts used in US acupuncture schools revealed recommendations of over 100 distinct acupuncture points by at least one text for this condition.

A nationwide survey conducted by Kalauokalani (16) found that physician acupuncturists most commonly used trigger point acupuncture or electrical stimulation for back pain, but also frequently used other medical treatments, such as referrals to physical therapy or massage. In a survey of graduates of one training program for physician acupuncturists, Yeh (17) found that physician acupuncturists preferred to use Japanese acupuncture.

MacPherson (18) reported that acupuncturists included a variety of therapeutic elements beyond needling in their back pain treatments. These included building a therapeutic relationship, which was believed to serve as a basis for successful results from treatment, individualizing the treatment to the patient's condition, and actively involving the patient in their recovery by assisting them to make appropriate lifestyle and behavior changes. The plethora of treatments falling under the rubric of acupuncture, coupled with lack of knowledge regarding the optimal number and spacing of treatments, has made achieving consensus about the optimal design of treatment regimens in therapeutic studies of acupuncture difficult. Thus, it is hard to know when adequate acupuncture has been provided in a trial or how representative trial treatment(s) are of care for patients in the community.

“Non-responders” to acupuncture

Clinicians should be aware that acupuncturists anecdotally report that roughly 15 to 30% of persons with pain conditions are “non-responders” to acupuncture. A similar phenomenon is seen in laboratory rats that are given electroacupuncture (19). These animals have been found to have higher levels of the cholecystokinin octapeptide, a molecule that acts as an anti-opioid and has been shown experimentally to attenuate electroacupuncture analgesia (19).

Controversies in the design of acupuncture studies

In addition to the challenges in defining appropriate and representative treatments for acupuncture studies, even more controversy exists about appropriate comparison groups. While researchers have typically used a variety of “misplaced” and/or “shallow needling” needling control groups, the lack of clarity on the active ingredient(s) of acupuncture (e.g., stimulation of an acupuncture point, needle insertion *per se*, depth of insertion, the synergy of a variety of treatments delivered by acupuncturists) and the variability in practice has made it impossible to engender consensus regarding the most appropriate type of “sham” or “placebo” acupuncture controls. For example, apart from the wide variability in needle locations and depth of insertion used when treating patients with pain, some styles of acupuncture include non-insertive needling as part of their practice (20). Thus, needling controls and even non-insertive controls could be considered inappropriate comparison groups. Moreover, some researchers argue that acupuncture is part of a holistic system of care, rather than being needle insertion *per se* (21). In that view, the decision to investigate needling efficacy is misguided because it does not yield useful information about the benefits of acupuncture. Thus, the reader should be cautioned that the acupuncture research community has not reached consensus about the interpretation of findings from patients receiving “sham” acupuncture.

For pain conditions, acupuncture is typically compared with no treatment (a wait list control that typically allows use of medications), with some sort of “sham” physical treatment (usually, but not always, needle insertion), or with another medical treatment, which could include a complementary or biomedical therapy. Sometimes acupuncture is studied as an adjunct to another type of medical care. Clearly, using each of these comparison groups answers different questions. Typically, information from few trials is available to answer each of these questions. Further obstructing firm conclusions from many studies is the clinical importance of multiple outcomes (e.g., functional status, pain levels, ‘global outcomes’, reduction in medication use) for each of these conditions and the importance of multiple follow-up periods (e.g., just after treatment, several months post-treatment, 6 months to over a year after treatment). Because few studies measure all important outcomes at all relevant follow-up periods, the findings across various comparisons are often inconsistent.

Chronic Back Pain

Back pain is one of the most common health problems in developed countries. More than 50% of adults are bothered by back pain each year (22) and 70% to 80% of adults are afflicted by it at some time in their lives (23). Moreover, back pain may persist substantially longer than previously thought. In a recent study of persons with a new episode of back pain, about a third of patients still have back symptoms a year after their episode began (24). Once back pain becomes chronic, it appears to persist (25).

Back pain is the most costly ailment of working-age adults, with an estimated \$26 billion spent annually in the U.S. on the direct costs of personal medical care for back pain (26) and an estimated \$19.8 billion lost because of back-related lost worker productivity (27). Despite a vast array of treatments, both conventional and complementary, no clear consensus exists on how to treat this problem (28,29). Eisenberg (30) found that most people with back problems considered complementary and alternative medical care to be superior to conventional care for back pain.

Although acupuncture appears to confer benefits as an adjunctive treatment to usual medical care for persons with back pain, it is neither superior to sham acupuncture, massage or chiropractic (31). One study found it superior to guideline driven best conventional care (11). Acupuncture is also a safe treatment and appears to be cost effective.

Manheimer et al (32) performed a meta-analysis on 22 trials of acupuncture for chronic back pain published before September 2004. Although the largest and newest trials were not included in this analysis, they found that in the short term, acupuncture was statistically and clinically superior to sham acupuncture (standardized mean difference = 0.58, 95% CI=0.36–0.80; 4 trials with 343 patients) and no additional treatment (standardized mean difference = 0.69, 95% CI=0.4–0.98; 8 trials with 586 patients). They concluded that insufficient data existed to draw conclusions about acupuncture's short term effectiveness compared with most other treatments. Finally, they noted that their results were preliminary, there was lots of heterogeneity in the trials and the publication of results from ongoing major trials would have a major effect on the evidence.

Ammendolia (31) performed the most recent systematic review of acupuncture needling for chronic back pain, including studies published through July 2006. They included 19 trials (median = 60 patients per study and 4998 patients total; range = 20 to 3093 patients/study), most of which included needle acupuncture only. The review compared acupuncture to no treatment (3 trials), to sham acupuncture (7 trials), to other therapies (4 trials) and as an adjunctive treatment to other care (7 trials). They evaluated improvements in both pain and functional status over a variety of time periods: immediately after treatment (< 1 week), and in the short (up to 3 months), intermediate (3 to 12 months) and longer term (> 1 year). Immediately after treatment, three trials found acupuncture appears more effective than no treatment in improving pain relief and functional status.

Acupuncture was rarely superior to sham acupuncture for pain relief (i.e., in one of six trials immediately post-treatment, in two of three trials for short term outcomes and in none of four trials with intermediate outcomes and in the one trial with long-term outcomes). Functional status among persons receiving acupuncture and sham acupuncture was similar at short-term follow-ups.

Among four trials comparing acupuncture to other treatments, massage proved superior to acupuncture in reducing pain and improving functional status at 1 year, chiropractic proved superior to acupuncture in reducing pain and improving functional status in the short term, and the two studies comparing acupuncture and TENS were inconsistent.

Acupuncture was evaluated as an adjunctive treatment in seven trials. The primary treatments were exercise (2 trials), usual or standard care (3 trials), physiotherapy (1 trial), and orthopedic care (1 trial). In all trials for virtually all follow-up periods, those receiving adjunctive acupuncture did better than the others.

One additional large trial (n=1162) has been published since then (11). This trial also found acupuncture clearly superior to guideline driven best conventional care, but not superior to sham acupuncture, for at least 6 months. Nearly twice as many people receiving acupuncture or sham acupuncture showed clinically relevant response as in the conventional care group. While some studies have shown that persons receiving acupuncture who are optimistic about its effectiveness do better than others (33,34), other studies have not (4).

Acupuncture appears to be a relatively safe treatment for persons with back pain, with only 6 – 8% of over 13,000 such patients reporting side effects in 12 trials and one large observational study (10,31,35). Most of the side effects were minor (e.g., increased back pain, drowsiness, dizziness, local bleeding). No deaths, permanent disability or hospitalizations were reported. This adverse event profile is similar to that of some large prospective studies evaluating the safety of acupuncture in routine practice (36–38).

Both of the trials of acupuncture for back pain that included cost-effectiveness analyses found costs were greater in the acupuncture group than in usual care as a result of the cost of

acupuncture (10,39). However, those costs were relatively modest and the average incremental gains per quality adjusted life year were substantially lower than internationally accepted thresholds for cost-effectiveness. Authors of both studies concluded that acupuncture is a cost-effective intervention for back pain.

Osteoarthritis

Arthritis is the most common cause of disability in older Americans (40), with osteoarthritis being the most common type and knee osteoarthritis being a major cause of osteoarthritis related impairment (41). Because arthritis cannot be cured, the goal of both conventional and complementary therapy is pain control and improvement in function while avoiding the toxic effects of medications (42), including non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen (43). Complementary therapies, including acupuncture, are often used for patients with osteoarthritis (44,45).

Acupuncture typically appears superior to usual care or wait list controls for persons with osteoarthritis (46–48). However, it was not better than “advice and exercise” in one large recent trial (49). Overall, while acupuncture is statistically superior to sham acupuncture, the magnitude of the difference is clinically unimportant.

In a systematic review of manual and electro acupuncture for peripheral joint osteoarthritis, Kwon (46) found that 10 of 18 trials showed greater pain reduction in acupuncture compared to various control groups. The trials varied widely in the amount of acupuncture provided, with from 5 to 45 total treatments provided (median of 10, mean of 11.8) over 2 to 26 weeks (median of 4, mean of 6.1) and 1 to 5 treatments per week (median of 2, mean of 2.5). They found acupuncture more effective in pain reduction than no treatment (2 trials) or sham controls (3 of 4 trials). White (47) conducted a systematic review of acupuncture for chronic knee pain. They included 13 trials, of which 8 were judged to have provided “adequate acupuncture” and thus, included in a meta-analysis. They found acupuncture superior to sham controls (5 studies with 1334 patients) and to no additional treatment controls (4 studies with 927 patients) in improving function and reducing pain in the short and long term. The effect size of acupuncture for relieving pain in the short-term (of 0.4, or “moderate”) was similar to that in a recent meta-analysis of NSAIDs (50). They believed the evidence was sufficiently robust that acupuncture should be encouraged more widely to relieve knee pain. Manheimer (48) published the most recent systematic review of acupuncture for osteoarthritis, including trials published before February 2007. They included 11 trials in their report and were able to use 9 for a meta-analysis. Several of those were large trials not included in the White (47) review. They found persons receiving acupuncture reported clinical relevant short-term improvements in pain and function compared to those receiving usual care or wait-list controls (standardized mean difference for pain = -0.96 , 95% CI = 1.21 to -0.70 ; standardized mean difference for function = -0.93 , 95% CI = -1.16 to -0.69). Compared to sham controls, acupuncture was related to clinically irrelevant (but statistically significant) short and long term improvements in pain and function. They interpreted the discrepancy in the results as suggesting that the clinically relevant benefits of acupuncture may, in part, be due to placebo or expectation effects.

Since the publication of the Manheimer review, two large trials have been published (49,51). In a trial where all participants were given advice and exercise, persons receiving up to 6 acupuncture treatments over 3 weeks or a similar number of treatments with a non-penetrating sham needles showed no additional pain reduction after treatment, at 6 months or at 12 months (49). In persons awaiting knee replacement surgery, 6 weeks of acupuncture and physiotherapy both led to short term reductions in an osteoarthritis composite score post treatment compared to standardized advice, but such benefits did not persist at 12 weeks follow-up (51).

One acupuncture trial looking at short term relief for osteoarthritis included a cost-effectiveness component (52). Even though acupuncture treatment modestly increased costs in that group compared with usual care, the incremental improvement in quality adjusted life years was considered cost-effective by international standards.

Headache

Among the general adult population in developed countries, approximately 40% of persons report tension-type headache (TTH) (53), 12–18% report migraine (54,55), and 4–6% report chronic daily headache (CDH) (56–58). Given the general lack of efficacy of pharmacological management strategies in the treatment of TTH and CDH and the risks associated with many migraine-specific medications for patients with cardiovascular disease, CAM therapies have the potential to play an important role in the management of primary headache disorders.

Acupuncture appears superior to usual care for persons with TTH(59), migraine (60) or CDH (5,61–64). However, it is not consistently better than sham acupuncture for persons with TTH or migraine.

In 2008, the first Cochrane review of acupuncture for headache was updated and published as separate systematic reviews and meta-analyses examining the effectiveness of acupuncture for the prevention of TTH (59) and migraine (60). The published literature also includes another meta-analysis of sham-acupuncture controlled clinical trials of acupuncture for TTH (65) and three reviews of acupuncture for the treatment of migraine (66–68). There are no systematic reviews of acupuncture trials of acupuncture for chronic daily headache. Each of the five studies that involved patients with either "chronic" or "chronic daily" headache found that acupuncture more effective than no acupuncture, but none compared true acupuncture to a "placebo" acupuncture procedure (5,61–64). No serious adverse events likely to be associated with acupuncture were reported in any of the trials cited above.

Linde et al. (59) recently completed a comprehensive review and meta-analysis of acupuncture for TTH, including 11 trials, representing 2317 patients (median 62, range 10 to 1265). Comparison groups included usual care only, sham acupuncture, and other treatments, including conventional medical management. Compared to no acupuncture, the acupuncture group had statistically and clinically significant improvements at 3–4 months post-randomization in relative risk of improvement (range: 2.68, 11.36), number of headache days (range: 5.4, 9.9), headache intensity (range: 2.9, 4.0), analgesic use, and headache score. Compared to a sham control, statistically significant but clinically questionable improvements at 3–4 months post-randomization were found for fewer outcomes (e.g., response rate, headache days, and analgesic use).

Twenty-two trials with a total of 4419 patients (median 42, range 27 to 1715 were included in the review and meta-analysis of acupuncture for migraine trials (60). Findings were similar to those of other reviews on this topic (61,66,67) and the Cochrane TTH review. The pooled relative risk for positive response to acupuncture compared to no acupuncture at 3–4 months after randomization was 2.33 (95% CI: 2.01, 2.69). In these studies, acupuncture was associated with statistically significantly fewer headache days (range: 4.2–12.1), fewer migraine attacks (range: 1.5–2.4), and significantly lower headache scores (range: 2.1–18; pooled standard mean difference: -1.19; 95% CI: -2.12, -0.25). In contrast, when acupuncture was compared to a sham acupuncture control, statistically significant differences were not seen as frequently at the 3–4 months assessment. Exceptions included headache frequency, number of migraine attacks, and migraine days, all of which were improved in the acupuncture study arms, compared to the sham acupuncture control.

Two studies of acupuncture compared to usual care for headache have included a cost-effectiveness analysis (69,70). Both of those studies included persons with either tension headache or migraine. While total costs of treatment were higher for persons receiving acupuncture in both trials, the costs per quality adjusted life year were lower than accepted international thresholds for cost-effectiveness. Both studies concluded that acupuncture was relatively cost-effective for persons with headache.

Summary and Clinical Recommendations

While some large studies of acupuncture for these pain conditions are currently being conducted and others are not yet published, it is unlikely that a plethora of large trials will be conducted in the near future. Thus, clinicians are left with a dilemma regarding the value of acupuncture for three common pain conditions. Acupuncture appears superior to no additional treatment, to usual medical care and, for back pain, to optimal conventional care. However, acupuncture is not superior to other complementary treatments for back pain and confers no additional benefits for persons with osteoarthritis receiving advice and exercise. While acupuncture is typically not clinically superior to sham acupuncture, the lack of a well accepted but physiologically inert “mock acupuncture” control makes this finding difficult to interpret. Nonetheless, for clinicians who believe that proving treatment efficacy requires double-blind, placebo controlled trials, benefits from acupuncture could well be viewed as a placebo therapy (71). Interestingly, both acupuncture and placebo analgesics are at least partially mediated by endogenous opioid release (19). Given the uncertainty raised regarding the value of acupuncture compared with placebo therapy, a pragmatic approach may prove most useful for patients with these conditions.

For back pain, osteoarthritis, and headache, there are few proven monotherapies. Acupuncture features a favorable safety profile and modest (most often for chronic back pain, osteoarthritis) to moderate (most often for headache) benefits on average. A reasonable view of the current evidence would add acupuncture to the therapeutic armamentarium as an option, but not as the clear therapy of choice for any of these conditions. Acupuncture may be especially valuable for patients who prefer it to other options or are concerned about using analgesic medications. Acupuncture might also be useful as part of a multi-therapy package of care for some patients.

Recommendations for Future Research

Some fundamental clinical questions remain for future studies. For each of these conditions, we currently lack information on how many acupuncture treatments need to be provided over what time frame for optimal therapeutic effects. By having this information, we would be able to focus future reviews on those studies that actually provided sufficient treatment. While these conditions are chronic, most studies of acupuncture have lacked follow-up more than several months post-treatment. Longer term follow-up is critical to more completely understand acupuncture’s role in the treatment of these pain conditions. Even though a number of outcomes are important for each of these conditions (e.g., pain and function for back pain), most published studies have focused on a small number of outcomes. Future studies are encouraged to measure the full range of appropriate outcomes for each of these conditions. Some important questions, such as whether acupuncture is more effective among those with more severe pain or among other sub-groups of patients, probably require individual patient level data for meta-analyses using the largest studies. Finally, acupuncture is often delivered as part of a package of care. Some studies should compare a package containing acupuncture with other evidence-based packages to see which, if any, are superior.

While neuroimaging data exist suggesting that acupuncture modulates a network of brain areas (72) and other physiological data suggest that many neurotransmitters are involved in acupuncture’s analgesic effects (19), much remains to be discovered about the physiological

underpinnings of this ancient therapy. As these become better understood, a clearer picture of how to design and deliver optimal clinical treatments may emerge.

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