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Re: Expanding acupuncture's role

My name is Matthew Bauer, L.Ac. and I am President of the Non-Profit Acupuncture Now Foundation. Our mission is to educate the public, policymakers, and healthcare professionals about the practice of acupuncture by providing accurate information about acupuncture best practices. We appreciate the opportunity to provide input on the important subject of how an expanded role of acupuncture services can improve the health and well-being of Minnesotans.

While a great deal of attention is being placed on the health risks pain medications and especially opioid medication can cause, we urge you to consider that acupuncture offers a unique combination of virtues that makes it a logical alternative to many classes of drugs and especially opioids.

There have been two landmark studies, one conducted in Germany(1) and paid for by their insurance industry the second in the U.S. (2) and funded by a grant from the National Institutes of Health, that both found acupuncture to be roughly twice as effective as "conventional care" for the treatment of chronic low back pain. The "conventional care" these studies referred to include the use of pain medications, especially opioid medications, and chronic low back pain is the leading condition for which those medications are prescribed.

Consider the following from a recent study published in the British Journal of Medicine(3):

"In the United States, opioid prescription for low back pain has increased, and opioids are now the most commonly prescribed drug class. More than half of regular opioid users report back pain."

And this from a 2007 Cochrane Database systematic review on opioid studies(4):

"Based on our results, the benefits of opioids in clinical practice for the long-term management of chronic LBP remains questionable."

And then this quote from a CDC publication “Prescription Drug Overdose-Understanding the Epidemic”(5):

“In recent years, there has been a dramatic increase in the acceptance and use of prescription opioids for the treatment of chronic, non-cancer pain, such as back pain or osteoarthritis.” “People who take prescription painkillers can become addicted with just one prescription. Once addicted, it can be hard to stop.”

In many instances where acupuncture may be authorized for use within an official treatment guideline whether of a governmental agency or a medical insurer, it is often relegated to the role of a possible alternative only after conventional therapy has already been tried. Taken together, these studies should be seen as a call to action to expand the role of acupuncture:

1. A single prescription of an opioid medication can lead to addiction.
2. Opioid use for chronic back pain has dramatically increased in the U.S. over the past several years.
3. Studies show opioids to be of limited effectiveness in the treatment of chronic pain.
4. Acupuncture has shown itself to be twice as effective as conventional care for the most common condition for which opioids are prescribed.

Physicians take an oath to “First, do no harm.” Acupuncture is clearly safer than conventional therapy in a wide range of conditions and, should be not only “allowed” as a down-the-line alternative in limited cases but encouraged as a first-line therapy in many cases.

Putting Acupuncture Research into Perspective

One might wonder if research shows acupuncture to be as effective or, as in the case of chronic low back pain, up to twice as effective as drug dominated conventional care, why is it not being seen a slam dunk to replace drug therapy as a first-choice? One reason is because there are no for-profit business interests pushing for this but another is undoubtedly due to a lack of perspective regarding acupuncture research.

A popular trend in acupuncture research has been to try to include a control arm that is similar to a placebo control in drug trials. “Sham” acupuncture involves a range of different approaches to use points that are not believed to be effective for the condition under study and compare that to “real” or verum acupuncture using points believed to be effective. Unfortunately, it is our belief that many of these studies were of poor quality in two major categories; the methodological rigor of the study design/implementation and the level of acupuncture expertise employed. Many of the studies that had a higher level of methodological rigor were done by those with expertise in that area but not in the clinical application of acupuncture. Those studies tend to find little if any difference between real and sham acupuncture. Many studies done by those with expertise in the clinical application of acupuncture did not have a high level of knowledge in study design or, in the case of some of the studies done in the Far East, were mainly concerned with answering questions about a therapy already accepted and in widespread use rather than questions exploring if a new therapy now under consideration was valid or not. Most of those studies show real acupuncture clearly outperforming sham.

Evidence is starting to emerge that studies done with higher methodological rigor used a suboptimal “dosage” of acupuncture – employing far fewer treatments than needed to give the real acupuncture a chance to be most effective and/or they used personal with very limited training in acupuncture to carry-out the therapy. Remarkably, there currently are no standards for researchers to follow in study designs for establishing an effective dosage or for the training needed for those performing acupuncture in these trials. The Acupuncture Now Foundation is in the process of calling for and helping to develop those standards. Most Western researchers that carry-out reviews of acupuncture studies will omit those with poor methodological designs but do not omit those with poor clinical protocol designs. This has caused there to be a tendency in these reviews to find that both sham and real acupuncture are clinically effective but that it did not appear to matter where the needles are placed and so it may not be necessary to employ acupuncture specialists utilizing the complex traditional theories in systems like Traditional Chinese Medicine.

The Evidence Map of Acupuncture study recently completed for the Veterans Administration by their Evidence-based Synthesis Program, is a prime example of well-intended but poorly conceived research on the subject of acupuncture. Those researchers made the all-to common mistake of confusing effectiveness with efficacy. While it appears that they classified the evidence of acupuncture’s effectiveness for different conditions into 4 levels from weakest “evidence of no effect” to strongest “evidence of a positive effect” those categories were in fact reflective of how real acupuncture outperformed sham acupuncture in the studies chosen for their review.

Policymakers looking at the evidence for acupuncture’s clinical effectiveness should not make the mistake the V.A. researchers did by focusing on how far above sham acupuncture real acupuncture fares in some studies. The bottom-line for policymakers should be the risk to benefit ratio. Even if a good deal of acupuncture’s clinical effectiveness is not dependent on following traditional acupuncture theories, acupuncture is effective and far safer than conventional care in many instances. Acupuncture was clinically effective in every condition in the V.A.’s Evidence Map. It was just that for some conditions, the “real” acupuncture did not consistently outperform the “sham”.

While the so-called “real” (verum) acupuncture did not significantly outperform the so-called “sham” acupuncture in the German and U.S. chronic low back pain studies, we believe this was due to under-treating with acupuncture, i.e. an inadequate “dosage”. Several recent studies have found the frequency and duration of acupuncture plays a major role in its effectiveness. We believe if the acupuncture done in those studies two studies we cite had been done at the appropriate dosage, the “real” acupuncture would have been THREE times more effective than conventional care as that is what experienced Acupuncturists see in practice. A large randomized controlled trial published in The Lancet(6) found that acetaminophen, the most frequently used pain medication in the world, is no more effective than a placebo for managing acute lower back pain and it is known to cause serious side-effects. Given the seriousness of the opioid epidemic, the fact that the world’s most popular pain medication may not outperform placebo, and the call for exploring safer alternatives, we see no reason to hold back on acupuncture; the safer and more effective alternative, just because some questions remain about its exact mode of action. We urge a serious effort to explore an expansion in the use of acupuncture services and stand ready to assist policymakers to answer the questions needed to make that happen.

Thank you,

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References:

1). Haake M, Müller HH, Schade-Brittinger C, et al. German acupuncture trials (GERAC) for chronic low back pain. Arch Intern Med. 2007;167(17):1892-1898. At 6 months, positive response rate was 47.6% in the real acupuncture group, 44.2% in the sham acupuncture group, and 27.4% in the conventional therapy group.

2). Cherkin D, Sherman K, Avins A, et al. A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain. Arch Intern Med. 2009;169(9):858-866 At eight weeks, mean dysfunction scores for the first three groups (individualized acupuncture, standardized acupuncture, simulated acupuncture) were 4.5, 4.5, and 4.4 points compared to 2.1 points for conventional care. Symptoms improved by 1.6 to 1.9 points in the first three groups and 0.7 in the conventional care group.

3). Opioids for low back pain

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Back pain affects most adults, causes disability for some, and is a common reason for seeking healthcare. In the United States, opioid prescription for low back pain has increased, and opioids are now the most commonly prescribed drug class. More than half of regular opioid users report back pain. Rates of opioid prescribing in the US and Canada are two to three times higher than in most European countries. The analgesic efficacy of opioids for acute back pain is inferred from evidence in other acute pain conditions. Opioids do not seem to expedite return to work in injured workers or improve functional outcomes of acute back pain in primary care. For chronic back pain, systematic reviews find scant evidence of efficacy. Randomized controlled trials have high dropout rates, brief duration (four months or less), and highly selected patients. Opioids seem to have short term analgesic efficacy for chronic back pain, but benefits for function are less clear. The magnitude of pain relief across chronic non-cancer pain conditions is about 30%. Given the brevity of randomized controlled trials, the long term effectiveness and safety of opioids are unknown. Loss of long term efficacy could result from drug tolerance and emergence of hyperalgesia. Complications of opioid use include addiction and overdose related mortality, which have risen in parallel with prescription rates. Common short term side effects are constipation, nausea, sedation, and increased risk of falls and fractures. Longer term side effects may include depression and sexual dysfunction. Screening for high risk patients, treatment agreements, and urine testing have not reduced overall rates of opioid prescribing, misuse, or overdose. Newer strategies for reducing risks include more selective prescription of opioids and lower doses; use of prescription monitoring programs; avoidance of co-prescription with sedative hypnotics; and reformulations that make drugs more difficult to snort, smoke, or inject.

4). Cochrane Database Syst Rev. 2007 Jul 18;(3):CD004959.

Opioids for chronic low-back pain.

Deshpande A1, Furlan A, Mailis-Gagnon A, Atlas S, Turk D.

Despite concerns surrounding the use of opioids for long-term management of chronic LBP, there remain few high-quality trials assessing their efficacy. The trials in this review, although achieving high internal validity scores, were characterized by a lack of generalizability, inadequate description of study populations, poor intention-to treat analysis, and limited interpretation of functional improvement. Based on our results, the benefits of opioids in clinical practice for the long-term management of chronic LBP remains questionable. Therefore, further high-quality studies that more closely simulate clinical practice are needed to assess the usefulness, and potential risks, of opioids for individuals with chronic LBP.

5.) CDC Publication Prescription Drug Overdose-Understanding the Epidemic

Prescription Painkiller Abuse, Overdose, and Death

A big part of the overdose problem results from prescription painkillers called opioids. These prescription painkillers can be used to treat moderate-to-severe pain and are often prescribed following a surgery, injury, or for health conditions such as cancer. In recent years, there has been a dramatic increase in the acceptance and use of prescription opioids for the treatment of chronic, non-cancer pain, such as back pain or osteoarthritis. The most common drugs involved in prescription overdose deaths include:

Hydrocodone (e.g., Vicodin)

Oxycodone (e.g., OxyContin)

Oxymorphone (e.g., Opana)

Methadone (especially when prescribed for pain)

Prescription painkiller overdose deaths also often involve benzodiazepines. People who take prescription painkillers can become addicted with just one prescription. Once addicted, it can be hard to stop. In 2013, nearly two million Americans abused prescription painkillers. Each day, almost 7,000 people are treated in emergency departments for using these drugs in a manner other than as directed.

Taking too many prescription painkillers can stop a person's breathing—leading to death.

The Solutions

Safe Prescribing Practices

Problematic prescribing practices are a leading contributor to epidemic. Safe and informed prescribing practices and instituting sensible prescribing guidelines can help stop it.

State Policies

Cities and states across the country have taken steps to improve painkiller prescribing and prevent prescription misuse, abuse, and overdose. These efforts include regulating pain clinics, using systems to identify fraudulent prescriptions, and improving access to naloxone—the antidote to opioid overdose. Additionally, states can take steps to improve prescribing practices in public insurance programs, like Medicaid or Workers Compensation programs.

Prescription Drug Monitoring Programs

Use of state prescription drug monitoring programs gives health care providers information to improve patient safety and protect patients. At the same time, they preserve patient access to safe and effective pain treatment.

6). [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60805-9/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60805-9/abstract)

Our findings suggest that regular or as-needed dosing with paracetamol does not affect recovery time compared with placebo in low-back pain, and question the universal endorsement of paracetamol in this patient group.