Chinese Medicine and Your Practice

Annual Review in Family Medicine
December 10th, 2015

Sanjay Reddy
Goals of Session

- Overview of Chinese Medicine
- Botanicals in the United States
- Acupuncture for clinicians
Chinese Medicine in brief

- Nei Jing written 1-3rd century BCE
- Flourished Ming Dynasty (1368-1644 AD)
- New York Times 1971 → Popularity in USA
- Increasingly used, 3 million 2007
Chinese Medicine Concepts

- Rooted in Taoism and Confucianism
- Person inseparable from nature
- Based on concept of harmony
- Disease inseparable from person
Chinese Medicine Components

- Diet
- Physical activity (Tai Chi, Qi Gong)
- Herbs
- Acupuncture
- Tui Na
- Gua Sha
Herbs- Botanical Medicine

Old as people (probably)

In the United States, the use of botanicals has increased significantly over the past two decades.

In the USA annual total cost of more than $4 billion!
Herbal Usage

2012 National Health Institute Survey:
- 23.6% of American adults have used herbs/dietary supplements

A lot of our patients use them, less talk about it\(^1\)
- Recent study of oncologists showed less than half discuss herbs with their patients

Dietary Supplement and Health Education Act ‘94

- Classifies vitamins, minerals, botanicals, and amino acids as nutritional or dietary supplements

- Supplements can be marketed *without proof* of safety or efficacy

- No claims allowed to treat or cure
Manufacturers can make "structure and function" claims

- Ex. saw palmetto can be marketed to support urinary tract health but not to treat benign prostatic hyperplasia.

FDA must first prove that a botanical preparation **unsafe**!

- Opposite of medications
FDA Steps in More

2007: manufacturers must evaluate the identity, purity, strength, and composition of their products and report all serious adverse events.

2010: greatly increased inspections of botanical sellers to ensure adherence to good manufacturing practices.
Safety Concerns

- Adulterated like crazy
  - Heavy Metals
  - Pesticides
  - Poisons
  - Prescription drugs
  - Things I don’t even know about
How to Advise Patients

- There’s a lot of adulterated products
- Discuss with their providers what they are taking
- Review tested products/quality
- In general, few botanicals have been studied for safety in pregnancy
Most Used Natural Products by U.S. Children

- 1.1% Fish oil/omega 3/DHA, EPA fatty acids
- 0.7% Melatonin
- 0.5% Probiotics/Prebiotics
- 0.4% Echinacea
- 0.1% Garlic supplements
- 0.1% Combination herb pills
- 0.1% Ginseng
- 0.1% Glucosamine and/or chondroitin
- 0.1% Cranberry (pills or capsules)
Use of Complementary Health Approaches in the U.S.
National Health Interview Survey (NHIS)

Most Used Natural Products by U.S. Adults

7.8%  Fish oil/omega 3/DHA, EPA fatty acids
2.6%  Glucosamine and/or chondroitin
1.6%  Probiotics/Prebiotics
1.3%  Melatonin
1.3%  Coenzyme Q10
0.9%  Echinacea
0.8%  Cranberry ( pills or capsules)
0.8%  Garlic supplements
0.7%  Ginseng
0.7%  Ginkgo biloba
Resources for Clinicians

Resources for busy clinicians:

– Natural Medicines Comprehensive Database (www.naturaldatabase.com) and Natural Standard (www.naturalstandard.com).

Third-party testing: www.consumerlab.com

– 2-3$/mo, consumer products

University of Maryland and Sloan:

– https://umm.edu/health/medical/altmed/treatment/herbal-medicine
Use of Complementary Health Approaches in the U.S.
National Health Interview Survey (NHIS)

0.7% of U.S. adults (1.8 million) used ginseng

- 7.8% Fish oil/Omega-3 fatty acids
- 2.6% Glucosamine and/or chondroitin
- 1.6% Probiotics/Prebiotics
- 1.3% Melatonin
- 1.3% Coenzyme Q10
- 0.9% Echinacea
- 0.8% Cranberry (pills or capsules)
- 0.8% Garlic supplements
- 0.7% Ginseng
- 0.7% Ginkgo biloba

## Purported Ginseng Uses

<table>
<thead>
<tr>
<th>Good evidence in humans</th>
<th>Not so good</th>
</tr>
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<tbody>
<tr>
<td>Cancer Related Fatigue</td>
<td>Prevent Cancer</td>
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- Good evidence in humans:
  - Cancer Related Fatigue
  - Glucose lowering
  - Cognitive function (early data)
  - Decreasing URI/colds (some evidence)

- Not so good:
  - Prevent Cancer
  - Athletic Performance
  - Immune Stimulation (animal studies +)
  - Strength and stamina
American Ginseng
*Panax Quinquefolius*

- Like Asian ginseng has ginsenosides
  - Exact mechanism of action unknown

More calming than Asian ginseng

(Asian Ginseng is Panax Ginseng, less robust human evidence)
Ginseng and Cancer Fatigue

364 patients from 40 institutions

≥4 on Cancer Related Fatigue (CRF)
- (0 being none and 10 “as bad as it can be”) for at least 1mo prior to study
- Excluded steroids, opiates, current ginseng or other fatigue agents

Showed American Ginseng 2000mg daily led to a significant difference in 8 weeks for CRF scores.

Ginseng Interactions

- Can induce CYP3A4
- Can antagonize Warfarin’s effects and reduce effectiveness
Ma Huang - *Ephedra sinica*

- TCM: safe for millenia
- Contains ephedrine and pseudoephedrine
- Sold for weight loss in massive doses, often with caffeine
- 2004: banned in USA due to severe and fatal reactions
Last Botany Thoughts

- Using herbs outside of the context they were developed in can be dangerous.
- There seems to be a difference between whole herbs and isolated active ingredients.
- Increasingly studied.
Chinese Medicine View

Part of larger system of Chinese Medicine

Use of needles to access energetic meridians throughout the body

Alterations in energy flow cause disharmony

Disharmony $\rightarrow$ Disease
Western Proposed Mechanisms

Acupuncture points may have unique properties\(^1,2\):
- Denser innervation, tightly packed connective tissue, different receptor distribution

Central opiate receptors (varying types) mediate analgesic effect\(^3\)
- Spinal and supraspinal neurotransmitter release; Narcan can block effects

Local inflammatory mediators\(^4\)

NIH ‘97 Report of Efficacy

- Myofascial Pain
- Headache
- Dental Pain
- Fibromyalgia
- Tennis Elbow
- Osteoarthritis
- Menstrual Cramps
- Carpal Tunnel
- Lower Back Pain

- Nausea
- Asthma
- Stroke Rehab
- Addictions
"The effectiveness of acupuncture analgesia has already been established in controlled clinical studies. As mentioned previously, acupuncture analgesia works better than a placebo for most kinds of pain, and its effective rate in the treatment of chronic pain is comparable with that of morphine. In addition, numerous laboratory studies have provided further evidence of the efficacy of acupuncture’s analgesic action as well as an explanation of the mechanism involved. In fact, the excellent analgesic effects of acupuncture have stimulated research on pain."
“Because of the side-effects of long-term drug therapy for pain and the risks of dependence, acupuncture analgesia can be regarded as the method of choice for treating many chronically painful conditions.”

– Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials
Safety - Many studies

Sample study of German physicians:
- 140 hours of formal acupuncture training
- Only 19% > 350 hours of training
- >95k people with >700k treatments: 6 Major Complications:
  - Exacerbation of Depression
  - Acute HTN Crisis
  - Vasovagal reaction → LOC
  - Asthma attack → HTN and Angina
  - Pneumothorax x2

Table 1. Nonserious Adverse Events of Acupuncture Reported in 97733 Patients

<table>
<thead>
<tr>
<th>Event</th>
<th>No.</th>
<th>% of Total</th>
<th>99% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needling pain</td>
<td>3202</td>
<td>3.28</td>
<td>3.13-3.43</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3114</td>
<td>3.19</td>
<td>3.04-3.34</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1346</td>
<td>1.38</td>
<td>1.28-1.48</td>
</tr>
<tr>
<td>Orthostatic problems</td>
<td>447</td>
<td>0.46</td>
<td>0.40-0.52</td>
</tr>
<tr>
<td>Forgotten needles</td>
<td>242</td>
<td>0.25</td>
<td>0.21-0.29</td>
</tr>
<tr>
<td>Other</td>
<td>674</td>
<td>0.69</td>
<td>0.62-0.76</td>
</tr>
<tr>
<td>Local skin irritation</td>
<td>173</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deterioration of symptoms</td>
<td>118</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any nonserious adverse event</td>
<td>6936</td>
<td>7.10</td>
<td>6.88-7.32</td>
</tr>
</tbody>
</table>
Contraindications

- Local infection or tumor
- Severe Neutropenia*
- Pregnancy for certain points
- AICD or Pacemaker for electrical stimulation

Bleeding dyscrasias and anticoagulation not contraindications as needles are small
Evidence for Post-Op

Post-operative Pain, selected study:
– 2008 Meta-Analysis of 15 RCTs:
  ♦ Decreased Pain
  ♦ Decreased opiate consumption and side effects:
    – Nausea
    – Dizziness
    – Sedation
    – Pruritis
    – Urinary retention

Evidence for OA

- OARSI 2010:
  - Acupuncture adjunct for pain and function

- Acupuncture for knee OA- 3 armed trial
  - Acupuncture with etoricoxib statistically significantly superior to sham+med, med alone

- 2010 Cochrane Review:
  - Statistically significant benefits, but some blinding concerns

Acupuncture for Chronic Pain

- Reviewed RCTs and performed an individual patient data meta-analyses
  - Patients receiving acupuncture had significantly less pain than sham controls for back and neck pain, OA and chronic headache

Conclusion: Acupuncture is effective for the treatment of chronic pain.

Labor

180 Nulliparous 20-35yo randomized:
- Acupuncture on EX-B2 or SP6 or control
- VAS recorded in last contraction before intervention, then 30, 60 and 120” after
- Change of ≥3 considered effective
- Significant differences in pain and duration of active phase of labor
- EX-B2 more effective than SP6

Migraines

Recent review including 2009 Cochrane and large trials.

Conclusion: “Acupuncture seems to be at least as effective as conventional drug preventative therapy for migraine and is safe, long lasting, and cost-effective.”

Some Really Great Trials


Is it all positive?

Maybe you read these studies (or many others)....
Chronic Knee Pain- JAMA 2014

- 282 Patients >50yo with mod-sev pain
- Nada vs Needle vs Laser vs Sham Laser
- 12wk and 1y avg Knee Pain and Function

Summary:
- Modest better than nothing at 12wk (not 1y)
- No significant difference from sham

Pain 2011
Is Acupuncture effective for pain?

36 reviews rated as good or excellent:
- 13 (36%) reached a positive or tentatively positive conclusion
- 14 (39%) failed to show effectiveness
- 9 (25%) inconclusive

Conclusion: High-quality reviews show mixed effectiveness of acupuncture for pain.

Why the difference?

Controversial topic

We don’t have a way to measure “qi”

Hard to study in Western paradigm
Expectancy in Real and Sham Electroacupuncture: Does Believing Make It So?

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Correspondence to: Jun J. Mao, MD, MSCE, Perelman School of Medicine at the University of Pennsylvania, 227 Blockley Hall, 423 Guardian Drive, PA 19104 (e-mail: jun.mao@uphs.upenn.edu).

Background

The large placebo effect observed in prior acupuncture trials presents a substantial challenge for investigating the efficacy of acupuncture. We sought to evaluate the relationship between response expectancy, a component of the placebo effect over time, and treatment outcome in real and sham electroacupuncture.

Methods

We analyzed data from a randomized controlled trial of EA and sham acupuncture (SA) for joint pain relief in response to aromatase inhibitors among women with breast cancer. Responders were identified using the Perceived Impression of Change instrument at Week 8 (end of intervention). The Acupuncture Expectancy Scale (AES) was used to measure expectancy four times during the trial. Linear mixed-effects models were used to evaluate the association between expectancy and treatment response.

Results

In the wait list control group, AES remained unchanged over treatment. In the SA group, Baseline AES was significantly higher in responders than nonresponders (15.5 vs 12.1, \( P = .005 \)) and AES did not change over time. In the EA group, Baseline AES scores did not differ between responders and nonresponders (14.8 vs 13.4, \( P = .287 \)), however, AES increased in responders compared with nonresponders over time (\( P = .004 \) for response-time interaction term) with significant difference at the end of trial for responders versus nonresponders.
Expectancy in Real and Sham Electroacupuncture: Does Believing Make it So?

Study by Bauml et al at Penn on 76 pts

Measured AES and randomized to EA, Sham and Waitlist control

In EA, baseline expectancy no different in responders and non-responders!
Final Thoughts

- Acupuncture is safe, cost-effective and efficacious for many conditions
- We don’t understand it well
- Often used outside of original framework
- Therapeutic effect from visit and treatment
Thank you

Any questions, comments, concerns, other things?