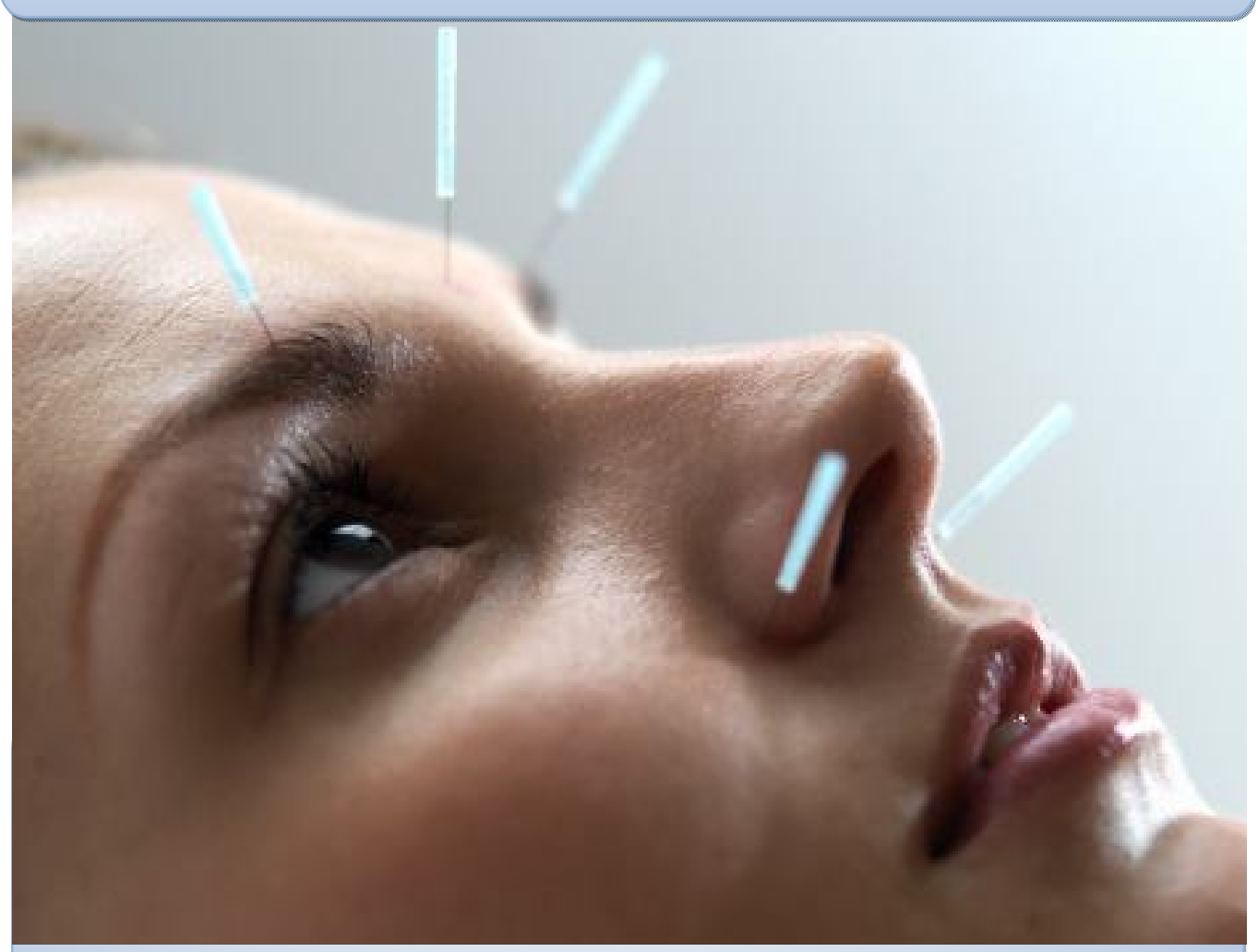
Literary review compilation on Traditional Chinese Medicine



Intended audience: General public and practitioners

Compiled by the AQTN team

www.Association.Quebec.AQTN.ca

Acronyms

ACEi	Angiotensin-converting enzyme inhibitors
ADR	Adverse drug reaction
AES	American Epilepsy Society
AMI	Acute myocardial infarction
ARB	Angiotensin receptor blockers
ASD	Autism spectrum disorders
BDNF	Brain-derived neurotrophic factor
BPW	Blood pressure waveform
CABG	Coronary artery bypass graft
CDH	Chronic daily headache (CDH)
CKD	Chronic kidney disease
cLBP	Chronic low back pain
CP	Cerebral palsy
DHRs	Drug hypersensitivity reactions
DSHEA	Dietary Supplement and Health Education Act
EEGs	Electroencephalograms
fMRI	functional magnetic resonance imaging
IC	Intermittent claudication
ISCMR	International Society for Complementary Medicine Research
MBM	Mind/body medicine
MCMIA	Modernized Chinese Medicine International Association
MD	Mean difference (Statistics)
MEG	Magnetoelectroencephalography
NCCAM	National Center for Complementary and Alternative Medicine
NGF	Nerve growth factor
PAD	Peripheral artery disease
PMS	Premenstrual syndrome
QCP	Quality control program
RA	Rheumatoid arthritis
RCTs	Randomised controlled trial
RR	Relative risk (statistics)
SBO	Small bowel obstruction
SLE	Systemic lupus erythematosus
SUD	Sudden unexpected death in epilepsy
TNF	Tumor necrosis factor
TCM	Traditional chinese medicine
WIM	Western Integrative Medicine
WM	Western Medicine

Definitions

The conceptual foundation of TCM is entirely different from that of western medicine. This has important implications when it comes to controlled randomized trials. As a result, there are considerable difficulties in comparing the two; a great deal of TCM has no anatomical basis.

Acupuncture -- a treatment originating from traditional Chinese medicine. It consists of the stimulation of defined points on the skin. It involves inserting fine needles into specific points on the skin or applying various other techniques to the acupuncture points to bring about healing.

Qi -- Energy that is considered the capacity of life to transform and maintain itself. It is responsible for transformation and movement. 'Qi' also refers to the vital substances comprising the human body and the physiological functions of viscera and bowels, channels and collaterals. It maintains life activities and reflects the resistance of the human body. Deficiency of 'qi' allows the invasion of exogenous pathogenic wind.

Qi stagnation -- Normal movement of Qi is impaired and the smooth flow of Qi is impeded in a particular organ, meridian, or other part of the body. A primary symptom of Qi stagnation is distention and/or soreness or pain.

Kidney Qi deficiency -- In Chinese medicine, the kidneys (which do not have the same function as in biomedicine) serve as the body's reservoir of Qi. A deficiency of Kidney Qi reflects an overall depletion of the body's energy and will manifest itself in a broad range of symptoms that may include frequent urination, chronic lower back pain, and weakness in the lower back, sore knees, and diminished libido.

Blood stagnation -- In Chinese medicine, Blood is the red fluid flowing through the vessels and meridians and a condensed form of Qi. Blood stagnation occurs when the Blood is unable to follow 4smoothly through the channels. The primary sign of Stagnant Blood is a stabbing pain.

Yin deficiency -- In Chinese medicine, there is emphasis on maintaining a harmonious balance between the opposite qualities of Yin and Yang. When the balance between these qualities is disturbed, disharmony will result. If Yin is deficient or weakened, heat will arise because the Yin is unable to control the warming Yang energies and cool the body properly. Common symptoms of Yin deficiency include insomnia, night sweats, flushed cheeks, dry mouth, and restlessness.

De Qi -- A characteristic sensation of a dull ache, numbness, or tingling that may be felt after an acupuncture needle is inserted through the skin. The sensation thought to indicate the "arrival

of Qi" is generally felt at the site of needling, along the course of the meridian needled, or in the surrounding tissues.

Moxibustion -- A technique of applying heat to specific sites on or near the surface of the body by burning dried mugwort plant (Artemisia vulgaris).

Channel points -- Acupuncture points or other tender spots that are located on one of the 14 regular meridians.

Traditional Chinese Medicine questioning -- Often called the Asking Examination or Asking Diagnosis, these traditional questions elicit information from the patient about the sensations of hot or cold, quality and location of pain, medical history, perspiration, headaches and dizziness, urination and stool, thirst, appetite and tastes, sleep, and for women, gynecologic concerns. Sample TCM questions are: "Do you prefer your drinks hot or cold?" "Have you noticed changes in bowel or bladder activity?"

Urinary Bladder meridian -- The meridian that extends from the head, down the back approximately 2" lateral to the midline parallel on either side of the spine, down the back of the leg, and to the foot.

Cupping -- Using a small glass or cup to induce a vacuum on the skin surface to increase local circulation and to remove excess cold and damp.

Blood -- Fluid form of Qi that circulates throughout the body.

Visual inspection -- Includes direct observation of the patient's "spiritual quality" as represented by posture, expressions, skin color.

Voice analysis -- Listening to the patient's voice quality (ie, pitch and tone).

Warming needle -- A technique wherein moxa (either loose moxa or a portion of a moxa stick) is placed on the handle of the acupuncture needle and then ignited. In this manner, the moxa both warms the skin and is "drawn into the channel" (on which the acupoint is located) through the needle.

Sources of data for this literary review

All relevant search results were included in a list compiled in July 2013.

Cochrane Library – 33 articles
http://www.thecochranelibrary.com/

Searching title, abstract and keywords for: "traditional chinese medicine"

Medscape – 33 articles
http://www.medscape.com/

Search terms included "traditional Chinese medicine"

Pub Med – 32 articles
http://www.ncbi.nlm.nih.gov/

Search term "traditional chinese medicine" TCM massage has 37 results and was used.

Search term "Traditional Chinese medicine" TCM has almost 3000 results.

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Introduction

AQTN[1] is a regulatory body in Québec for select natural therapies with no provincial oversight. We are particularly interested in the efficacy and especially the dangers of the therapeutic modalities we license. This is in line with one of our mandate's which is to protect the public. Protecting the Quebec public in the context of the literature may take the form of refusing applications that do not correspond to the scope of practice as we have them defined using the literature. While applicants can still apply with other associations, this simply provides our group of therapists with added credibility.

While acupuncture is regulated in Quebec, Traditional Chinese medicine (TCM) is not. Some Canadian provinces do regulate TCM. It's most common forms are herbal therapies and acupuncture, but other forms include moxibustion, cupping, massage, mind–body therapy, meditative practices such as Qigong and Tai Chi, and dietary therapy. Influenced by Taoist and Buddhist philosophy, TCM encompasses a complex, holistic model of the body.

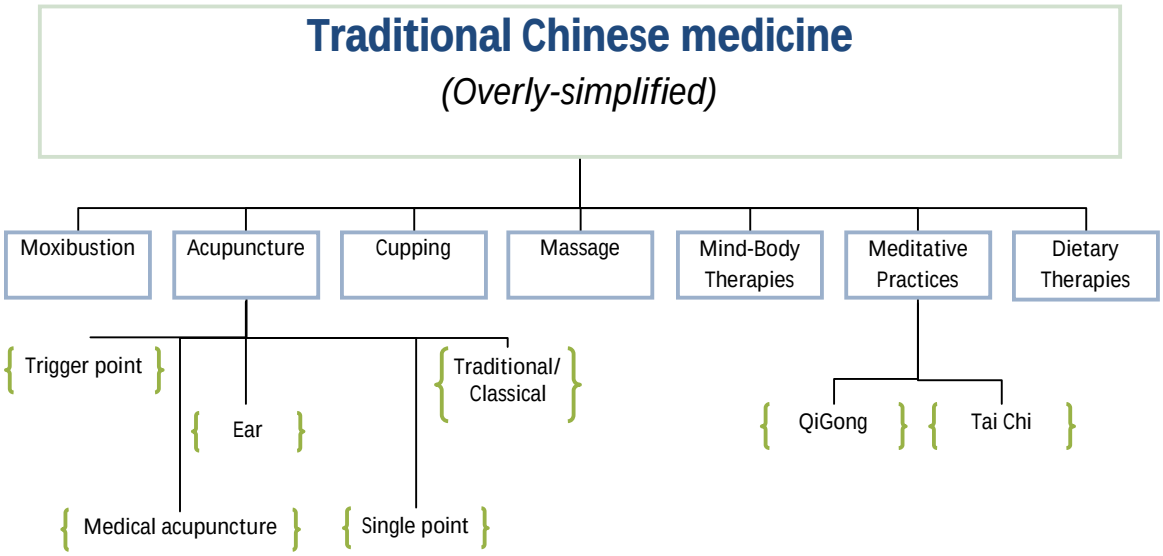
Training in the United States involves 3 or 4 years of full-time courses. It includes herbalism, massage, dietary therapy, and acupuncture and exercise programs. Most schools provide 500 hours or more of Western medial science. There is a range of styles of acupuncture, such as traditional, classical, and auricular.

TCM works around five solid organs–heart, liver, spleen, lung, and kidney and six hollow viscera–large and small intestine, urinary bladder, stomach, gall bladder, and 'triple burners'. These 'structures' are connected by conduits and vessels with 'qi' (energy) and blood circulating through them. There is lacking research of equivalent counterparts in conventional Western medicine for Qi.

A person is considered to be in good health if every 'structure' is functioning in harmony with the other 'structures' in the body and with the surrounding environment.

TCM establishes a diagnosis of the individual, contrary to Western medicine which typically does so on the disease. TCM utilizes a process called '*syndrome identification*', whereby the practitioner makes a dynamic conceptualization of the individual's situation and comes up with a '*pathophysiologic status*' , the type of disharmony for the individual; this status is called 'zheng' or 'syndrome'.

[1] Alliance québécoise des thérapeutes naturels, also Association québécoise des thérapeutes naturels www.aqtn.ca



WHY A LITERARY REVIEW ON TRADITIONAL CHINESE MEDICINE?

A comprehensive literary review of Traditional Chinese medicine will help AQTN better understand its position in the Quebec market as well as help us promote the aspects of TCM that hold the most promise for clients. This document may also serve as an information source for the growing number of people suffering from illness or afflictions who wish to learn more about the benefits of TCM.

Acupuncture is just one element of traditional Chinese medicine being used to treat fatigue, nausea, insomnia, diarrhea, menstrual problems, and HIV-related peripheral neuropathy. Acupuncturists also treat a wide range of conditions, including musculoskeletal problems (usually back, neck, and shoulder), general body symptoms, neurological problems such as headaches, and psychological complaints, especially anxiety and depression. TCM is also used to treat chronic pain, gastrointestinal disorders, cancer as well chronic stress, to name a few specific conditions.

Traditional Chinese medicine has been used to treat mental health disorders, including schizophrenia, for more than 2000 years. Chinese herbs in the literature may have antipsychotic properties when used in a Western biomedical context.

The key word employed here is "*treat*"; not cure. Furthermore, the underlying premise of the preceding paragraphs is that acupuncture or TCM can treat the named conditions. It implies that treating schizophrenia with TCM is effective, that it has an impact. This has yet to be proven.

Treating a condition is NOT synonymous with effectiveness.

The two are completely and entirely different issues.

Reasons cited for using complementary alternative medicine (CAM) in a broader context include having more control over pain; having fewer side effects; increased sense of safety and lower costs compared to conventional medicine. When people run out of options with Western medicine, as is often the case with chronic diseases and illnesses that have no known cure, we see an increasing trend in our society to look beyond conventional medicine, looking for answers to health problems within alternative medicine. People are increasingly turning to CAM.

According the literature, TCM is the most commonly used form of CAM worldwide. It is estimated that 70% of the world's population uses medicinal herbs. This is true largely because TCM is prevalent in China, with its estimated 1.3 billion people.

In Quebec, at the time of this writing, acupuncture is taught at one single College[2]. Some acupuncturists are medical doctors by training in Quebec. They may prescribe interventions for a wide range of illnesses, often in combination with food, nutrition and lifestyle changes. They may also recommend yoga, meditation, Traditional Chinese medicine, acupuncture, massage and the most common would probably be the use of pharmaceutical drugs. All of these help patients cope with diseases, in different ways.

AQTN is acutely aware that client satisfaction is different from effective therapy.

To find answers we must turn to the literature.

METHODOLOGY USED

We used three of the most important free online databases including Cochrane, PubMed and Medline, and ran searches using the keywords: "Traditional Chinese medicine". We then proceeded to review all the search results in the literature. We extracted excerpts to create the supporting arguments found in this document, which makes up the bulk of this text. This is why we consider this literary review on Traditional Chinese medicine a compilation.

[2] http://www.crosemont.qc.ca/admission-programmes/formations-techniques/acupuncture

IS ANYTHING LEFT TO PROVE?

The resounding answer is yes, plenty - despite thousands of years of use. The most frequent recurring remark in the literature for TCM is "*Large, high quality, randomized controlled trials are needed*", and "*further research is required*". The explanation is quite simple. Aside from the fact that most clinical studies mention this, the use of Western models for scientific studies is lacking in the majority of studies, because they were not done in the West. Virtually none of the results are conclusive. The broad consensus that more research and better controlled trials are required stems from a prolific issue of low quality studies, a lack of rigor and paucity in methodology. This is because most clinical trials on TCM are done in China. Their study models lack randomized controlled trials - the gold standard in Western clinical research.

Because TCM is holistic and conceptual, it identifies and treats syndromes rather than diseases. It is difficult to compare TCM approaches with Western ones because their entire model and treatment course is different. We might as well be comparing apples and oranges. As we will see, using Western medicine in combination with certain TCM approaches may provide benefits; although more research is needed as already noted.

TCM has both advocates and critics in the scientific literary community. While praised by some physicians, it is deemed quackery by others. Most authors and physicians converge on the value of proper diet via food and nutrition. Yoga, meditation and in many cases massage also is generally accepted as offering some therapeutic value[3]. Concerning herbal medicine, one physician pointed out that most supplements are ineffective unless you have a deficiency in the first place.

Pharmaceutical companies have been known to aggressively study the herbal medicine used in TCM. They proceed to extract and synthesize key molecules. They then go on to patent them and use it certain prescription drugs. These multi-billion dollar valued companies are listed on the stock-markets. They do not share their findings to protect shareholders' interests. The scientific community is slowly trying to carry out, in a fragmented way, what pharmaceuticals already know. According to the literature, there is little collaboration between different research centers, each competing for funding.

What pharmaceutical companies achieve is steady and uniform dosage, with low or no impurities, measured by PPM[4]. Herb and plant extracts invariably have different dosages[5]. For this reason the TCM practitioner must meet every few weeks with the client to adjust the dosage of the herbal remedy. This actually fosters a stronger relationship between the therapist and client, which increases the amount of advice for lifestyle changes and general *personalized* advice.

[3] AQTN has dedicated an entire literary review to massage alone, given its prominent use in North American. It is available at www.AQTN.ca
[4] Parts per million
[5] Quantity of sunlight, quantity of rain, minerals in earth, etc.

Did you know? Aspirin, one of the wonder drugs of the 21st century, comes from the bark of the Willow tree. It is now synthesized in laboratories, of course, but knowledge of its properties and its use goes back thousands of years. At least one clinical trial compared Nao-an capsule with aspirin for the primary prevention of stroke in people at high risk, with Nao-an being superior for stroke. Further research is required, especially given that widespread use of aspirin.

FROM STONES TO NEEDLES - A BRIEF HISTORY

Acupuncture originated in China, and has a long history of use in both China and Japan. It involves the insertion of fine needles into different parts of the body to correct the imbalance of energy in the body.

The literary source with the largest timeline outlier suggests it may date back as far as 200 000 – 300 000 BC, based on bone needles and bamboo shafts thought to be acupuncture tools.

By most other accounts, TCM dates back only several thousand years. It is rooted in the ancient philosophy of Taoism. Westernized medical application of acupuncture involves the use of acupuncture using trigger points, segmental points and commonly used formula points. This variation actually originated very recently, in the 19th century in Europe and America, according to certain articles in the literature.

The development of needle tools in ancient China evolved via a series of incremental changes, such as:

- From stone through to bamboo, to bone, to ceramic to metal materials ;
- From rough to delicate manufacture ;
- From multiple uses of a single one to diversified structure and shapes with different functions.

The stone needle can be divided into three categories according to it's different forms and functions. Conical-tip stone needles for pricking, e. g. lithostyle, coup de poing and stone arrowhead etc.; sickle-shaped needle stone for cutting, e. g. stone knife, stone sickle, stone adze and stone chisel etc; spear-shaped stone needle for both cutting and pricking, e. g. stone spear, stone sword, jade (stone) spear etc. From the usage cases recorded in the ancient literature, the conical-tip stone needle for pricking ought to be the most used of the ancient stone needles.

Modern day Western TCM practitioners use disposable needles. It is interesting to note that in the literature there is no consensus on the optimal duration of needling for acupuncture. Should the acupuncturist needle for 30 seconds, 90 seconds or 10 minutes? One would expect this question to have an answer with a range for optimal use, but it seems this is not the case.

This is particularly important given that many of the clinical studies in the literature attempt to compare "true" acupuncture and "sham" acupuncture. What they found in many instances is that both led to patients doing markedly better than doing nothing. This means that the actual location of the needle (or sham needle), at least in these studies, is markedly less important than the fact that they believed they were receiving a therapy. In other words, acupuncture exhibits some placebo effect properties. This is not to say acupuncture is a placebo. It means acupuncture has placebo component – as does a typical consultation in North America with a physician who prescribes medication for a migraine, also having a placebo component.

TCM advocates would be quick to point out it is almost impossible to truly create a randomized controlled trial with blinded participants. This is also problematic for massage and reflexology (but not so for homeopathy). How do you trick a person into believing they're are getting a massage when they are not, or tricking a person into believe they are receiving acupuncture when they are not? It's much easier to do with pills than therapy.

We found one study where individualized TCM treatments were consistent with molecular imaging technologies. In other words, expensive modern Western imaging devices found different types of cellular responses to treatments.

On Qi and Meridians

Qi and meridians are foreign concepts to Western medicine because they have no anatomical basis. Meridians cannot be examined via a biopsy, and the Qi that circulates in the blood cannot be measured – they are conceptual.

While they do not exist in any physical form, meridians have their specific locations along the body. If you ask ten TCM practitioners to press on point SP20 for the spleen, they will likely all identify the same location. This is like asking medical doctors or anyone else to identify the femur bone, it's mapped out and we can expect to see consistency in the answers.

As a complete system of healthcare, it has its own unique theories of anatomy, diagnosis, health, and treatment. There is little development on the neurological front, as the role of the brain is a relatively recent notion.

Acupuncture has evolved

There are a range of styles of acupuncture including:

- Traditional/classical acupuncture;
- Auricular acupuncture involves the use of the ear to make a diagnosis and subsequent needling to points on the ear.
- Trigger point acupuncture;
- Single point acupuncture;

- Medical acupuncture may involve the application of acupuncture based on the principles of neurophysiology and anatomy, rather than TCM principles and philosophy.

Traditional Chinese medicine and classical acupuncture are based on theoretical concepts of Yin and Yang and the Five Elements and explain disease and physiological function.

WESTERN SOCIETY AND TCM SOCIETY

We have thus far seen various forms of criticism of Traditional Chinese medicine. To shift perspectives, let's compare stereotypes. We correctly take for granted that Western medicine offers the most advanced and specialized medical care available in the world, even as it continues to advance and evolve as more studies and evidence is added to the literature.

Western medicine's populace

Characterized with chronic obesity, high prescription medication use, diabetes type II and depression, to name but a few complications.

East Asia / TCM populace

Characterized with less prescription medication than the West, Tai Chi, frequent meditation and physical and mental balance, healthier diets but also with a higher prevalence of poverty.

The question begs to be asked, in which society do we see healthier lifestyles? On the one hand, the Western world has the most advanced medical knowledge and most sophisticated machines, while the developing countries do not. Western medicine's knowledge is very advanced concerning vitamins, diets, proper lifestyle choices and healthy foods, however somehow this knowledge does not translate into common practice among the actual people - there is a disconnect, also referred to in the literature as a schism.

Traditional Chinese medicine is accepted as mainstream throughout East Asia, routinely practiced in hospitals in China. It is much closer to a way of living, including the actual Chinese diet. In the West, advances in molecular biology and carcinogenesis lead to the development and approval of new oral anticancer agents, which is great. But this then shifts the responsibility and power to maintain health from the doctor to the patient instead of a supervised clinical setting, which isn't as great. It seems pharmaceuticals are cashing in on the doctor's lack of time for prolonged emphatic discussions with their patients, and with patients who may feel there are fighting the battle in relative isolation.

What we see, in fact, is that In America, as in Canada, the relationship of the citizen with a medical doctor is on a need-basis. Many Quebecers do not have a family doctor. In contrast, TCM offers a stronger relationship and more frequent consultations. This in turn enhances lifestyle changes – preventative measures to illness. Western physicians are just as aware of the importance of lifestyle changes, but the health care structure and political framework in which they exercise their duties as doctors has created a deep divide.

EPIGENETICS

Epigenetics refers to the impact of our environment on how our genes express themselves. While our DNA does not change[6], how we live our lives affects gene expression. Specifically, things like stress, sugar intake, fatty foods and our daily activities all influence gene expression. Lifestyle changes are basically a strategy for managing risk. Nothing we can do will prevent cancer or a stroke, but we can augment or reduce the risk significantly through our lifestyle choices.

Epigenetics is extremely relevant to TCM as it has infiltrated the lifestyles of millions - while Western medicine's guidelines have not incorporated the daily lifestyles of many. Everyone who lives long enough would theoretically eventually develop both cancer and Alzheimer's; we can only try to push its incidence further into the future.

Ninety-nine percent (99%) of government-approved TCM formulas examined in one large study are epigenome and micro-RNA[7] interacting. This epigenetic information cannot yet be used to predict herb–drug interactions, although further investigation is underway. This means, placebo effect withstanding, that herbs have anatomical influences. The main problem with herbs is inconsistent doses, which TCM remedies via frequent visits and adjustments.

[6] DNA changes through mutations all the time, but these cells are quickly destroyed in healthy people.
[7] http://en.wikipedia.org/wiki/MicroRNA

CONDITIONS IN WHICH THERE IS NO EVIDENCE FOR TCM BENEFITS

Here is a list of clinical trials in which there was no evidence of efficacy. Please note that each clinical trial typically evaluates a single condition and a single method of TCM. The following are therefore globalized answers. There is no evidence for the following:

- Epilepsy ;
- Bleeding from haemorrhoids ;
- Rheum offiandle on chronic kidney disease ;
- Small bowel obstruction ;
- Autistic spectrum disorder ;
- Depression ;
- G. lucidum for cancer ;
- Ginkgo biloba on peripheral arterial disease ;
- Ginkgo biloba is the same as placebo on higher bleeding risk.

In each of the following examples, effectiveness refers to research where evidence is weak and more studies must be conducted, not to actual proven effectiveness. It portrays the most promising venues for future research on the health impacts of TCM.

CONDITIONS IN WHICH THERE IS EVIDENCE FOR TCM BENEFITS WHEN USED IN COMBINATION WITH WESTERN MEDICINE

- We see benefits in terms of mental state, global functioning and decrease of adverse effects ;
- Limited (although some) evidence for Schizophrenia ;
- Miscarriage ;
- Improve disease-free survival in patients with colorectal cancer. The longer the exposure to TCM therapy, the better the outcome | Yet another study showed no statistical difference ;

- Reduced frequency of blood transfusions and the number of clinical visits for certain rare cancers; speculation that TCM enhances sensitivity of chemotherapy; boosting its hematopoietic effects, strengthening the immune system ;
- Prednisone combined with ginsenosides can increase the clinical effective rate and improve the clinical symptoms of SLE patients ;
- Use of nonsteroidal anti-inflammatory drugs (NSAIDs) declined linearly over TCM visits 1-16; Among the heaviest NSAID users, the researchers observed a short-term reduction in NSAID use that was sustained as TCM visits became less frequent. There was no indication that pain reduction during TCM treatment was influenced by drug use ;
- TCM therapies appear to be effective for treating fibromyalgia. Further rigorous trials are warranted because of insufficient methodological rigor in the included trials ;
- Hypnosis and acupuncture seem to create a synergy. Together the effect is greater than the sum of its parts ;
- Adjunct antiemetic for surgery and chemotherapy ;
- Decrease of side effects of certain western medicine.

CONDITIONS IN WHICH THERE IS EVIDENCE OF TCM EFFICACY

- Acupuncture and heat compression for reducing menstrual pain in the treatment of primary dysmenorrhoea, compared to NSAIDs and the oral contraceptive pill ;
- Needle acupuncture associated with an improvement in the areas of communication, linguistic ability, cognitive function and global functioning in autism spectrum disorder ;
- Decoction Jingqianping granule increased rate of recovery from PMS symptoms ;
- Chuanxiong: Nao-capsule reduced incidence of stroke versus aspirin ;
- Grapefruit and peel of some citrus fruits (used in herbs) ;
- St John's wort can reduce plasma concentrations of CYP3A4, statins ;
- TCM has better efficacy than some antiobesity drugs, with fewer side effects ;
- Oral ingestion of decoction of ten herbs – significantly more effective : dermatology ;
- Atopic dermatitis ;
- TCM provided significantly greater short-term (8-week) chronic facial pain relief ;

- Migraine and chronic head ache ;
- Decreasing hot flashes in peri- and postmenopausal women ;
- Chronic low back pain, shoulder pain ;
- Shigyaku-san for palmoplanter hidrosis, improves symptoms such as sweat volume and skin temperature ;
- Ginseng (Panax ginseng) for sexual dysfunction (delaying ejaculation) ;
- Black cohosh and foods that contain phytoestrogens show promise for the treatment of menopausal symptoms ;
- Meditation on blood pressure and cardiovascular system ;
- Herbs & botanicals on epilepsy treatment ;
- Vomiting ;
- Depression ;
- Bell's palsy ;
- Dysmenorrhea ;
- Arthritis of the knee.

RISKS INVOLVED

Some patients do not tolerate acupuncture either because of a needle phobia or the inability to remain in a comfortable position for treatment. Septic or extremely weakened patients, and those who are uncooperative because of delusions, hallucinations, or paranoia, are likewise unsuitable. Local infections such as cellulitis or loss of skin integrity from burns or ulcerations may preclude certain local treatments.

Electro acupuncture should not be applied over the heart or brain or in the region of an implanted electrical device such as a pacemaker or a medication pump. Hemophiliacs and others with severe bleeding disorders should be excluded from acupuncture treatment.

There are various concerns regarding adverse events, especially with regards to the herbal remedies aspect of TCM. Herbs are regarded as food products, such as grapefruit peel,

cranberry, garlic, ginseng, licorice or citrus fruits. As a result, the quality of these products are not monitored, regulated or controlled in the same vein as conventional drugs.

A rule of thumb regarding the interaction of herbs and prescription drugs is that drugs with a narrow therapeutic index[8] are more prone to drug adverse effects accompanied by herb use.

Specific examples:

- Kava may cause liver toxicity and ephedra and Ginko biloba may precipitate seizures;
- Allergic reaction and Chinese herbal nephropathy (kidney damage).

Literary studies suggest that few patients disclose their history of herbal and CAM use to physicians. While in most cases there is no clinical significance, the interaction can also be fatal.

Concluding remarks

TCM, although holistic and largely conceptual, has some very strong supporters. The World Health Organization and the White House Commission on complementary alternative medicine both agree that more clinical trials need to be carried out to establish degree of the efficacy of TCM.

In a more global healthcare marketplace, the convergence of Western medicine and TCM modalities may lead to higher patient satisfaction and more cost-effective treatments.

The scientific community is still establishing the strength and validity of TCM. Evidence is mounting that some of the products and practices have measurable clinical benefits. TCM will clearly never replace Western medicine, but some of its practice may become integrated if more positive studies are produced, creating the effect of pushing of TCM into Western medicine.

Western medicine will continue to improve and evolve. Incorporation of TCM holds great promises, but can only be accomplished when proper clinical trials are conducted.

We need to mobilize and connect TCM practitioners who are already working with the public to establish record-keeping in order to increase the quantity and quality of evidence. The ideal place for this might just be North America, particularly with physicians trained in acupuncture, and a centralized database to collect data, such as the WHO or IN-CAM, to cite only two.

TCM, at this stage, is still lacking the “proof” needed to integrate into Western medicine.

[8] http://en.wikipedia.org/wiki/Therapeutic_index

COCHRANE LIBRARY – 33 ARTICLES REVIEWED

TCM FOR EPILEPSY

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006454.pub2/abstract

There is no strong evidence for the use of traditional Chinese medicine as a treatment for epilepsy.

TCM HERBS FOR STOPPING BLEEDING FROM HAEMORRHOIDS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006791.pub2/abstract

TCMHs might be effective for this illness and provide an alternative therapeutic measure. However, our primary research for this review showed that there was no strong evidence concerning the effectiveness of TCMHs in stopping bleeding from haemorrhoids.

TCM HERBS FOR THE TREATMENT OF IDIOPATHIC CHRONIC FATIGUE AND CHRONIC FATIGUE SYNDROME

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006348.pub2/abstract

Chronic fatigue is increasingly common. Conventional medical care is limited in treating chronic fatigue, leading some patients to use traditional Chinese medicine therapies, including herbal medicine.

However, no studies that met all inclusion criteria were identified.

CHINESE HERBAL MEDICINE FOR SCHIZOPHRENIA

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003444.pub2/abstract

Antipsychotic medication is the mainstay of treatment for people with schizophrenia, and although effective, still leaves some people with distressing symptoms and/or disabling adverse effects. Safer and more effective health care interventions are needed.
Traditional Chinese medicine has been used to treat mental health disorders, including schizophrenia, for more than 2000 years. Chinese herbs may also have antipsychotic properties when used in a Western biomedical context. In this review we sought and found trials relevant to the effects of both approaches for schizophrenia. Traditional Chinese medicine methodology has been evaluated for schizophrenia, but the one included study was too limited in terms of sample size and study length to guide good practice. However, this pioneering study does show that TCM can be evaluated for its efficacy for people with schizophrenia , and should encourage trialists to undertake further, more comprehensive trials in this area.

The results of these six trials suggest that using Chinese herbs alone for psychotic symptoms may not be indicated, but if used in conjunction with Western antipsychotic drugs, they may be beneficial in terms of mental state, global functioning and decrease of adverse effects.

RHEUM OFFICINALE (A TRADITIONAL CHINESE MEDICINE) FOR CHRONIC KIDNEY DISEASE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008000.pub2/abstract

Chronic kidney disease (CKD) is a major public health issue worldwide. Standard therapies to delay CKD progression include dietary protein restriction and administration of angiotensin-converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARB) to help control blood pressure and confer additional renoprotective effects. Despite such interventions, CKD incidence and mortality rates continue to increase. *Rheum officinale* (Da Huang) a medicinal herb used widely in China to treat CKD has been reported to offer a range of pharmacological properties that may delay disease progression.

We found no high quality evidence to indicate that treatment with *Rheum officinale* can improve CKD or delay its progression. *Rheum officinale* was not found to cause any serious health problems in patients with CKD. Well-designed randomised controlled studies are needed to provide robust, high quality evidence to assess if there are benefits from *Rheum officinale* for people with CKD.

ORAL TRADITIONAL CHINESE MEDICATION FOR ADHESIVE SMALL BOWEL OBSTRUCTION

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008836.pub2/abstract

Five randomised trials involving 664 participants were analysed. Five different herbal medicines were tested in these trials, including Huo-Xue-Tong-Fu decoction, Xiao-Cheng-Qi-Tang decoction, a combination of Xiao-Cheng-Qi-Tang and Si-Jun-Zi-Tang decoctions, Chang-Nian-Lian-Song-Jie-Tang decoction, and Fufang-Da-Cheng-Qi-Tang decoction.
SBO is one of the most common emergent complications of general surgery. Intra-abdominal adhesions are the most frequent complication of abdominal surgery. SBO due to postoperative intra-abdominal adhesions is associated with a high rate of rehospitalisation and huge costs. Thus, non-operative management is preferred. Chinese herbal medicine is frequently used to treat adhesive SBO in China. This review examined five randomised trials with five different Chinese herbal medicines, involving a total of 664 participants. All trials were conducted and published in China. None of the trials mentioned adverse effects. The methodological limitations

in these studies are quite obvious, and any conclusions based on their results should be made with caution. This systematic review did not find sufficient evidence to support the objective efficacy and safety of TCM for adhesive SBO patients. Further high-quality trials evaluating oral TCM for adhesive SBO are urgently needed.

TONGXINLUO (TONG XIN LUO) CAPSULE FOR UNSTABLE ANGINA PECTORIS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004474.pub2/abstract

Tongxinluo, in capsule form, is a traditional Chinese medicine which consists of herbs and insects. Traditionally it has been thought to have clinical benefits for patients with angina, including the reduction of the occurrence of acute myocardial infarction (AMI), and complications of some types of heart surgery. Some studies also suggest a possible benefit in reducing the frequency and severity of angina attacks and improving symptoms. However, none of these individual studies have been reviewed systematically.

The review authors systematically reviewed evidence from 18 randomised controlled trials for the benefit of tongxinluo with or without other treatments, including routine care or placebo, for patients with unstable angina. All the trials were conducted in China. The total number of participants was 1413, ranging in age from 25 to 88 years. Most studies randomised patients to receive tongxinluo with conventional medication or conventional medications alone.
There was some evidence from seven studies that tongxinluo improved the electrocardiogram (ECG) changes indicating ischaemia and reduced the number of people with no improvement or worsening of ECG (six studies). Some improvement in angina symptoms (10 studies) and reduced numbers of people showing no improvement or worsening of symptoms were apparent with tongxinluo. Tongxinluo appeared to be as effective as isosorbide mononitrate in three studies. A few cases of slight gastrointestinal discomfort were reported after giving tongxinluo in seven studies and three cases of breaking of tiny blood vessels under the skin (ecchymosis) in one study.

The evidence suggested possible benefits relating to a range of outcomes among patients with unstable angina but all the studies were of poor quality and neither blinding nor allocation concealment were used. This makes it impossible to reach firm conclusions about the benefit of this treatment. Large, high quality, randomised controlled trials are needed to confirm the possible benefit of tongxinluo for unstable angina and to suggest appropriate future use of this herbal medicine.

ACUPUNCTURE FOR AUTISM SPECTRUM DISORDERS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007849.pub2/abstract

Autism spectrum disorders (ASD) are lifelong disorders of development. People with ASD have particular difficulties with social interaction and communication and they lack flexibility in their thinking and behavior. No cure is currently available but interventions may improve symptoms. Acupuncture involves using needles or pressure on specific areas of the body and is an important therapeutic method in Traditional Chinese Medicine. It is also being used more and more in countries in the west for a range of ailments. Acupuncture has been considered as a possible intervention to improve ASD symptoms, but it has not been thoroughly evaluated to see if it works and is safe.

We wanted to evaluate the effectiveness and safety of acupuncture for ASD by systematically reviewing all studies of acupuncture for ASD where people were randomly allocated to a treatment or control group (placebo, sham or no treatment), i.e. randomized controlled trials (RCTs). We searched through 15 databases, most recently in September 2010, and read over the titles and abstracts to make sure we identified everything relevant. We found10 RCTs to include in this review. These studies, which were carried out in Hong Kong, mainland China and Egypt, involved 390 children aged between three and 18 years.
Two studies compared needle acupuncture with sham acupuncture and found no difference in core autistic features. Results did suggest that needle acupuncture might be associated with improvement in other areas of communication and linguistic ability, cognitive function and global functioning.

Six studies compared needle acupuncture plus conventional treatment with conventional treatment alone. They used a range of tools to measure core autistic features and most could not show that acupuncture led to improvement in these. One trial did report, though, that needle acupuncture led to an improvement in scores on Autism Behavior Checklist. There was no evidence for improvement due to acupuncture on communication and linguistic ability but it might be beneficial for cognitive function and global functioning.
Two studies compared acupressure plus conventional treatment with conventional treatment alone and found no difference in core autistic features, although acupressure seemed to improve some aspects of the secondary outcomes.
Problems that were noted by parents of study participants included crying due to fear or pain, bleeding, sleep disturbance and increased hyperactivity. It is unclear if these were due to the acupuncture treatment. Half of the trials reported some negative effects but did not report how often or how severe these were and sometimes the problems occurred in both the treatment and control groups. None of the studies used measures of quality of life.
Overall, acupuncture did not seem to be effective in improving core features of ASD but it might have improved certain developmental and functioning outcomes, at least in the short term.

There are problems with assessing acupuncture due to the quality of the evidence. There were a small number of studies and they were all conducted with children. Moreover, there is a high likelihood that they may have been biased due to the methods used not being rigorous enough, the wide variety in the people and interventions in the studies, the inconsistent and imprecise reporting of results and the large number of analyses carried out, which make it more likely a significant result will be found just by chance.

In conclusion, current evidence does not support the use of acupuncture for the treatment of ASD. We need high quality trials of larger size and longer follow-up as the evidence base at present has many limitations.

CHINESE HERBAL MEDICINE FOR PRIMARY DYSMENORRHOEA

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005288.pub3/abstract

Dysmenorrhoea is a very common complaint that refers to painful menstrual cramps in abdomen. Primary dysmenorrhoea refers to pain of an unknown cause (i.e. no medical condition is identified). Nonsteroidal anti-inflammatory drugs or the contraceptive pill have been used successfully for treatment but more women are looking for non-drug therapies. Chinese herbal medicine has been used for centuries in China and it is currently used in public hospitals in China for the treatment of primary dysmenorrhoea. The review found promising evidence for the use of Chinese herbal medicine in reducing menstrual pain in the treatment of primary dysmenorrhoea, compared to conventional medicine such as NSAIDs and the oral contraceptive pill, acupuncture and heat compression. No significant adverse effects were identified in this review. However the findings should be interpreted with caution due to the generally low methodological quality of the included studies.

ACUPUNCTURE FOR CHRONIC ASTHMA

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000008.pub2/abstract

Acupuncture has traditionally been used to treat asthma in China and is used increasingly for this purpose internationally.

Acupuncture is a treatment originating from traditional Chinese medicine. It consists of the stimulation of defined points on the skin (mostly by insertion of needles). The objective of this review was to assess whether there is evidence from randomised controlled trials that asthma patients benefit from acupuncture. The studies included in the review were of variable quality and had inconsistent results. Future research should concentrate on establishing whether there is a non-specific component of acupuncture which benefits recipients of treatment. There should be an assessment not merely of placebo treatment, but also of 'no treatment' as well.

There is insufficient evidence to make recommendations about the value of acupuncture as a treatment for asthma based on current evidence.

CHINESE MEDICINAL HERBS FOR SORE THROAT

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004877.pub3/abstract

Sore throat is a widespread acute respiratory tract illness which affects all age groups. In China, many Chinese herbal medicines are used to treat this illness. Because the majority of clinical research into traditional Chinese medicine (TCM) as a treatment for sore throat failed to meet world standards of clinical research reporting, the authors could not recommend any preparation or formulation for clinical use in the previous published version.

In this updated review, we included a total of 12 studies (including five new studies), involving 1954 participants. Six Chinese herbal medicines may facilitate the improvement of symptoms and increase the rate of recovery. Two studies separately reported one case of diarrhoea and one case of mild nausea; two trials reported no adverse events in the treatment group; and other studies did not report any adverse events. We identified ten studies as being of poor methodological quality and only two studies as being of medium methodological quality. Chinese medicinal herbs may be the treatment choice for sore throat, but we cannot recommend any particular preparation or formulation over another as we did not find any well-designed studies to provide strong evidence to conclusively support or reject the use of Chinese traditional herbal medicines in the treatment of sore throat. Enhancing the quality of research into Chinese medicinal herbs for sore throat is imperative, and stronger evidence from high quality, randomised controlled trials (RCTs) are needed.

CHINESE HERBAL MEDICINE FOR PREMENSTRUAL SYNDROME

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006414.pub2/abstract

Herbal medicines are sometimes used for treating premenstrual syndrome (PMS). However, the effectiveness of this type of therapy has not be rigorously evaluated in randomised controlled trials.

The authors identified two trials that evaluated herbal medicines in PMS. One of these was a higher quality study that tested the traditional Chinese medicine decoction Jingqianping granule. This was shown to increase the rate of recovery from PMS symptoms. Because the formula for this herbal medicine was provided by the trialists themselves, the review authors recommend further trials to ensure that the results are reproducible with other formulations. Strong evidence in support of other herbal formulae for the treatment of PMS is currently lacking.

ACUPUNCTURE FOR SLOWING THE PROGRESSION OF MYOPIA IN CHILDREN AND ADOLESCENTS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007842.pub2/abstract

Myopia, also called near-sightedness or short-sightedness, is one of the most commonly occurring eye problems in children and adolescents. Early detection and treatment of initial myopia is associated with better outcomes of visual improvement and correction. Myopia is usually managed by wearing glasses and/or contact lenses. It is common practice for traditional Chinese medicine practitioners to use acupuncture for the treatment of myopia. Acupuncture is the stimulation of acupuncture points by needle insertion, acupressure, surface electrical and laser stimulation. This review aimed to assess the effectiveness and safety of acupuncture in slowing the progression of myopia in children and adolescents. We included two studies conducted in Taiwan with a total of 131 school children and did not combine the results as the two trials assessed different outcomes. One study found no significant difference in changes in the length of the eyes. Both studies found several children experienced mild pain while pressing and dropped out. The included studies in this review were unable to provide evidence of the effect of acupuncture for slowing the progression of myopia. More trials should be conducted where acupuncture is compared to placebo, other types of acupuncture are investigated, compliance with treatment for at least six months is explored and axial length elongation of the eye should be for at least one year.

ACUPUNCTURE FOR BELL'S PALSY

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002914.pub5/abstract

Bell's palsy or idiopathic facial palsy is the most common disorder affecting the facial nerves and results in weakness or paralysis on one side of the face. The paralysis causes distortion of the face and interferes with normal functions, such as closing the eye and eating. It is thought to be caused by inflammation of the facial nerve.

According to Traditional Chinese Medicine, facial paralysis is known as 'deviated mouth'. It was attributed to 'wind' by past dynasties. 'Qi' refers to the vital substances comprising the human body and the physiological functions of viscera and bowels, channels and collaterals. It maintains life activities and reflects the resistance of the human body. Deficiency of 'qi' allows the invasion of exogenous pathogenic wind. Acupuncture is part of Traditional Chinese Medicine and dates back thousands of years. It involves inserting fine needles into specific points on the skin or applying various other techniques to the acupuncture points to bring about healing. In Bell's palsy, acupuncture treatment might have numerous beneficial effects. This review aimed to review systematically all randomised controlled trials and controlled clinical trials, which examined the effectiveness of acupuncture by needle insertion for Bell's palsy. Six studies including a total of 537 participants met the inclusion criteria. Five studies used acupuncture

while the other used acupuncture combined with drugs. No trials reported on the outcomes specified for this review. Harmful side effects were not reported in any of the trials. Poor quality caused by flaws in study design or reporting (including uncertain method of randomisation, allocation concealment and blinding) and clinical differences between trials prevented reliable conclusions about the efficacy of acupuncture. More research with high quality trials is needed.

INTERVENTIONS FOR PEMPHIGUS VULGARIS AND PEMPHIGUS FOLIACEUS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006263.pub2/abstract

This review of clinical trials aimed to find out which is the most effective and safest treatment option for pemphigus vulgaris and pemphigus foliaceus.

Pemphigus vulgaris and pemphigus foliaceus are rare diseases characterised by fragile blisters and sores on the skin and mucosa. They are auto-immune diseases which are caused by the body making an antibody against the person's own skin. These diseases are chronic and are not currently curable. Pemphigus vulgaris and foliaceus are managed with drugs which suppress the immune system. The aim of treatment is to suppress blister formation. Systemic glucocorticoids are the cornerstone of management in pemphigus, however adjuvant immunosuppressive and anti-inflammatory agents are commonly used. There are many treatments available, however it is not known which is the most effective or safest treatment option, or which is the best combination.

This review included data from 11 clinical trials involving 404 participants. The studies had very small numbers of participants, so can provide only limited information. Ten different active treatments were studied, including prednisolone, pulsed oral dexamethasone, azathioprine, cyclophosphamide, cyclosporine, dapsone, mycophenolate, plasma exchange, topical epidermal growth factor and traditional Chinese medicine.

This review found insufficient information to conclude which is the most effective and safest treatment plan. We found that mycophenolate mofetil appears to be more effective than azathioprine in controlling disease, although no difference was seen in remission. We found that taking azathioprine and cyclophosphamide decreased the amount of glucocorticoids required. Topical epidermal growth factor decreased time required for lesions to heal by 6 days (median). We found no difference in withdrawal due to adverse events in any study, although differing adverse event profiles were observed for each intervention. We were not able to conclude which treatments are superior overall.

Multiple treatments are available for pemphigus vulgaris and pemphigus foliaceus and there is a variation in dosage plan and combination of drugs used, which makes choice of treatment schedule complex. In addition, response to treatment can vary between individuals. Treatments need to be chosen after careful consideration of the potential benefits and side effects, in the context of the individual's other medical conditions. This review found insufficient information to conclude which is the most effective and safest treatment regimen. Further studies are required to determine the optimal treatment regimen, especially to assess the optimal glucocorticoid dose, the role of adjuvant immunosuppressive medications, and long-term adverse events to improve harm:benefit analyses.

ACUPUNCTURE FOR DEPRESSION

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004046.pub3/abstract

Depression is widely experienced in our communities. In clinical depression, people report a lack of interest in life and activities which they otherwise normally enjoy. This can be accompanied by other symptoms including weight loss, over-eating, feelings of uselessness, sleep disturbance, self neglect and social withdrawal, insomnia or hypersomnia (sleeping too much), loss of energy, low self esteem and poor concentration.

Acupuncture has a long history of use in China and Japan. Traditional Chinese medicine theory describes a state of health maintained by a balance of energy in the body. Acupuncture involves the insertion of fine needles into different parts of the body to correct the imbalance of energy in the body. There are a range of styles of acupuncture from traditional/classical acupuncture, auricular acupuncture, trigger point acupuncture, and single point acupuncture. Traditional Chinese Medicine (TCM) and Classical Acupuncture are based on theoretical concepts of Yin and Yang and the Five Elements and explain disease and physiological function. A westernised medical application of acupuncture involves the use of acupuncture using trigger points, segmental points and commonly used formula points. Medical acupuncture may involve the application of acupuncture based on the principles of neurophysiology and anatomy, rather than TCM principles and philosophy. Auricular therapy involves the use of the ear to make a diagnosis and subsequent needling to points on the ear.

There are studies indicating a preference for treatment with self-help and complementary therapies for depression. Thirty trials, and 2812 participants were included in the review and meta-analysis, however there was insufficient evidence that acupuncture can assist with the management of depression.

CHINESE HERBAL MEDICINES FOR TREATING PRE-ECLAMPSIA

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005126.pub2/abstract

Pre-eclampsia is a condition in pregnancy involving high blood pressure and protein in the urine (proteinuria) after 20 weeks of pregnancy. Most women with mild pre-eclampsia give birth without problems. However, severe pre-eclampsia can cause major problems with the liver, blood clotting etc, and some women go on to have fits (eclampsia). This can lead very occasionally to serious complications, and possibly to a life-threatening situation for both the mother and her baby. Chinese herbal medicines might help to protect vulnerable organs like the liver and kidneys, and so these remedies may help with pre-eclampsia. Traditional Chinese medicine (TCM) incorporates concepts of cause, diagnosis and treatment. Typical treatment in TCM is Chinese herbal remedies based on one or several herbs that come from natural plants. Their selection is often based on the individual and presence of TCM symptoms. The prescribed herbs are combined by a distinctive method to form the prescription. In recent decades, TCM has sometimes been integrated with Western medicine to incorporate its therapeutic concepts. Not all Chinese herbal medicines are free of risk, and there are concerns regarding adverse events; for example, allergic reaction and Chinese herbal nephropathy (kidney damage).

The authors searched for controlled trials that randomly assigned women with pre-eclampsia, toxaemia or pregnancy-induced hypertension to treatment with Chinese herbal medicines (or integrated Western medicine with Chinese herbal medicines) or a control treatment. The control treatment could be a placebo, no treatment or a Western medicine. The authors identified no trials that were suitable for inclusion and so the efficacy and safety of Chinese herbal medicines for treating pre-eclampsia remains unclear. Although the authors identified 45 studies, none of the trials reported adequate methodology to be classified as randomised controlled trials.

CHINESE HERBAL MEDICINES FOR THREATENED MISCARRIAGE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008510.pub2/abstract

Miscarriage or spontaneous abortion is the loss of a pregnancy without medical or mechanical means before completion of the 20th week of gestation. The fetus is not sufficiently developed to have been able to survive outside the mother's womb. Threatened miscarriage is a very common in early pregnancy. Most threatened miscarriages occur in the first 12 weeks of pregnancy and become evident as vaginal bleeding, abdominal and low back pain that persist for days or weeks. So far, therapies have limited effectiveness in preventing early pregnancy loss due to threatened miscarriage. Chinese herbal medicines are a part of Traditional Chinese Medicines and are made up of products from plants and some animal and mineral substances. They have become very popular and are commonly used as an alternative treatment for threatened miscarriage.

This review compared the therapeutic effects of Chinese herbal medicines with other pharmaceutical agents. Among the 44 included randomised trials involving 5100 participants, all from China, no trial used placebo or bed rest as a control intervention. Twenty trials used a common prescription of Shou Tai Pill as a basic formula, while the other 24 trials used other formulae. The Western medicines included tocolytic drugs such as salbutamol and magnesium sulfate, hormonal supplementation with human chorionic gonadotrophin or progesterone and supportive supplements including vitamin E and folic acid. Five trials followed 550 women until after 28 weeks of gestation and delivery and showed that combined Chinese herbal and Western medicines were more effective than Western medicines alone in the treatment of threatened miscarriage. The remaining studies looked at the immediate effects of treatment. Combined treatment was more effective than Western medicines in preventing inevitable miscarriage so that the pregnancy continued. Many of the trials did not report on side effects during treatment or throughout continuing pregnancy and birth. Chinese medicine practitioners slightly modify the classical prescriptions depending on the individual women's clinical presentations. All the trials had poor methodological quality. In conclusion, there is a lack of evidence from randomised controlled trials on the effectiveness of Chinese herbal medicines for the treatment of threatened miscarriage and to determine if Chinese herbal medicines alone are more beneficial than Western medicines alone for threatened miscarriage.

ACUPUNCTURE FOR MUMPS IN CHILDREN

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008400.pub2/abstract

Mumps is an acute, viral illness transmitted by respiratory droplets and saliva. A number of studies published in China have suggested that acupuncture is beneficial for children with mumps but the literature reporting the benefits or harms of acupuncture for mumps has not been systematically reviewed.

Acupuncture has been used to treat children with mumps for hundreds of years in China. Benefits attributed to acupuncture include decreased swelling and pain, and shortening of the disease duration. According to traditional Chinese medicine, health is achieved by maintaining an uninterrupted flow of Qi, or energy, along 14 meridians. Mumps is caused by 'wind warmth evil' (epidemic heat) and 'pyretic toxicity' accumulated in Shaoyang and Yangming meridians, thus the flow of Qi, sputum and 'heat evil' stagnate in and around the ears and the cheeks. Acupuncture can help expel 'wind warmth evil', clear pathogenic heat, remove toxic substances, act as an anti-inflammatory, alleviate pain and re-establish the normal flow of Qi, thus restoring internal balance.

Although acupuncture has been widely used in China for children with mumps and quite a number of trials claiming to be randomised controlled trials have been published, we identified only one study with 239 participants that met our inclusion criteria. The study results suggest that acupuncture may be beneficial in improving swelling and pain of the parotid gland and returning the body temperature to normal. However, the included study is of low methodological quality and did not report adverse effects and long-term follow-up. Therefore, we could not draw any definite conclusions about the efficacy and safety of acupuncture for children with mumps.

ACUPUNCTURE FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN CHILDREN AND ADOLESCENTS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007839.pub2/abstract

Attention Deficit Hyperactivity Disorder (ADHD) is a common childhood psychiatric disorder with features of inattention, hyperactivity and impulsivity. In general, effective treatment for ADHD relies on comprehensive therapy. Acupuncture is a complementary and alternative medicine (CAM) therapy that seems to have few side effects.

Being considered a relatively simple, inexpensive and safe treatment compared to other conventional interventions, acupuncture is used widely in oriental countries. According to the basic theory of Traditional Chinese Medicine (TCM), ADHD is caused by 'liver yang overactive', 'effulgent gallbladder fire', 'heart-spleen qi deficiency', 'non-interaction of heart and kidney' and 'yin-yang disharmony'. Thus, ADHD in children presents as clinical symptoms of over-activity, restlessness, recklessness, impoliteness and stubbornness. 'Yin-yang' and 'Qi-xue' are very important concepts in TCM. In a meridian system, the main interpretation of 'yin' and 'yang' is symmetry and balance. Acupuncture could help keep internal yin and yang in balance. It is also believed in TCM theory that acupuncture can strengthen the vital essence of the human body, which is called 'Qi' in China, and remove the blockage of channels. Qi could move between yin and yang to coordinate them in harmony so as to make an amiable, stable and peaceful internal environment.

Acupuncture is increasingly practiced as a therapeutic intervention in Western countries. However, it remains uncertain whether the existing evidence is strong enough to justify the use of acupuncture as a treatment for ADHD.

No trials were included in this review. The review authors concluded that there is inadequate evidence to draw any conclusions about the efficacy or safety of acupuncture for ADHD in children and adolescents. There is an urgent need for further large scale, multicenter, randomised, controlled, double-blinded studies of acupuncture with standardized evaluation of outcomes for ADHD in children and adolescents.

No studies met the inclusion criteria for this review.

ACUPUNCTURE FOR DYSPHAGIA IN ACUTE STROKE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006076.pub2/abstract

Only one trial of 66 participants was included. In the acupuncture group, 12 out of 34 participants recovered to normal feeding (35.3%). In the control group, seven out of 32 participants recovered to normal feeding (21.9%). The relative risk of recovery was 1.61 with a 95% confidence interval of 0.73 to 3.58. No statistical significance was detected.

Better designed clinical trials are needed to prove whether acupuncture is effective for treating swallowing difficulties in patients with stroke. Patients who have swallowing difficulties (dysphagia) as a result of their stroke are less likely to survive and be free of disability than stroke patients who can swallow normally. Acupuncture is commonly used to treat this complication in traditional Chinese medicine practice. We systematically reviewed currently available evidence for the use of acupuncture in treating swallowing difficulties after acute stroke. Only one small randomised controlled trial was identified, involving 66 participants, which did not provide clear evidence of benefit from adding acupuncture to standard Western medical treatment. Considering the small sample size and methodological imperfections, there is insufficient evidence to determine the effectiveness of acupuncture. More research is needed.

CHUANXIONG-TYPE PREPARATIONS FOR ACUTE ISCHEMIC STROKE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005569.pub2/abstract

Stroke is a common disorder. It is due either to blockage of an artery in the brain or to bleeding in the brain. Chuanxiong is a Traditional Chinese Medicine. It is widely used in China for the treatment of patients with stroke. Two poor quality trials involving 161 participants were included in this review. The authors did not find any strong evidence about its effects. Well-designed and conducted trials will be needed to provide reliable evidence to show whether this intervention does more good than harm.

CHINESE HERBAL MEDICINE IN THE TREATMENT OF ECTOPIC PREGNANCY

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006224.pub3/abstract

We have not found any well-designed trials investigating Chinese herbal medicines in the treatment of ectopic pregnancy. We cannot support or refute any CHM preparation for clinical use on the basis of evidence from randomised controlled trials.

TONGXINLUO CAPSULE FOR ACUTE STROKE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004584.pub2/abstract

Traditional Chinese medicine is often used to treat patients with acute ischaemic stroke. The authors undertook a systematic review of the potential benefits and safety of tongxinluo capsule used for the treatment of patients with acute ischaemic stroke. Two relevant studies with a total of 232 participants were identified, but they did not provide reliable evidence about the effects of this treatment. Larger-scale high quality randomised controlled trials (RCTs) are needed to determine the effects of tongxinluo capsule in patients with stroke.

CHINESE HERBAL MEDICINE FOR CHRONIC NECK PAIN DUE TO CERVICAL DEGENERATIVE DISC DISEASE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006556.pub2/abstract

Significance of the review

Degenerative changes of the cervical spine are quite common and can cause severe neck pain, impairment and decreased quality of life. Degenerative disc disease of the cervical spine can result in severe pain, instability and radiculopathy (pain spreading down the arms and into the head), myelopathy (spasticity and weakness of arms or hands, which may include "numb and clumsy" hands) or both. Chinese oral and topical herbal medicines are being used to treat many neck disorders. Some have been tested in clinical trials.

Description of the trials

Two Chinese oral herbal medications were tested in three randomized controlled trials that included 701 adults with chronic neck pain with radicular signs or symptoms or myelopathy. One oral herbal medication was compared with Mobicox (non-steroidal anti-inflammatory medication) and Methycobal (drug to reduce numbness, tingling in the arms), and the other (Compound Qishe Tablet) with placebo and Jingfukang. A topical herbal medicine (Compound Extractum Nucis Vomicae) was compared with Diclofenac Diethylamine Emulgel (non-steroidal anti-inflammatory medication).

Findings

Oral herbal medications may reduce neck pain more than placebo and Jingfukang. A topical herbal medicine (Compound Extractum Nucis Vomicae) also relieved neck pain in the short term (four weeks), but the trail had a high risk of bias.

Limitations

All four included studies were in Chinese and two of these studies were unpublished. Half of the trials had a low risk of bias, but they only tested the effects of short term use (up to eight weeks). The size of the studies was small. There is a need for trials with adequate numbers of participants that address the long-term efficacy or effectiveness of Chinese herbal medicine compared to placebo.

Conclusion

For chronic neck pain with or without radicular symptoms, there is low quality evidence that Compound Qishe Tablet is more effective than placebo for pain relief, measured at the end of the treatment. However, the size of the studies was small and the effect was measured in the short-term. Further research is very likely to change both the effect size and our confidence in the results. There is a need for trials with adequate numbers of participants that address long-term efficacy or effectiveness of herbal medicine compared to placebo.

ACUPUNCTURE AND ELECTROACUPUNCTURE FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003788.pub2/abstract

Although the results of the study on electroacupuncture show that electroacupuncture may be beneficial to reduce symptomatic knee pain in patients with RA 24 hours and 4 months post treatment, the reviewers concluded that the poor quality of the trial, including the small sample size preclude its recommendation. The reviewers further conclude that acupuncture has no effect on ESR, CRP, pain, patient's global assessment, number of swollen joints, number of tender joints, general health, disease activity and reduction of analgesics. These conclusions are limited by methodological considerations such as the type of acupuncture (acupuncture vs electroacupuncture), the site of intervention, the low number of clinical trials and the small sample size of the included studies.

CHUANXIONG PREPARATIONS FOR PREVENTING STROKE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006765.pub2/abstract

Stroke is a major healthcare problem. It is one of the leading causes of death and serious long-term disability. Prevention of stroke is considered to be an important strategy. Some Traditional Chinese Medicines are used to try and prevent stroke because evidence suggests that they can improve blood circulation, dilate blood vessels, lower blood pressure, inhibit thrombosis, regulate lipid metabolism and other functions. We looked for evidence on the effects of Chuanxiong, a treatment widely used in China to treat and prevent stroke.

We found three trials that tested treatments based on Chuanxiong. One trial compared Nao-an capsule with aspirin for the primary prevention of stroke in people at high risk. This trial found that Nao-an capsule reduced the incidence of stroke. It may, therefore, be a choice for the primary prevention of stroke. However the design of the trial means that the results may have been affected by the way people were selected to take part in the study, and by potential conflicts of interest of the researchers.Two further trials were identified but they were of low quality and their evidence was weak. Further good quality research is required.

CHINESE MEDICINAL HERBS FOR MUMPS

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008578.pub2/abstract

Mumps (epidemic parotitis) is an infection caused by the multiplication of the mumps virus in the upper respiratory tract. It can range from a mild upper respiratory disease to serious

complications. Herbal medicines have been used in traditional Chinese medicine (TCM) as the main therapy to prevent and treat mumps for thousands of years. Many Chinese physicians believe that Chinese medicinal herbs are effective in alleviating symptoms and reducing the duration of mumps.

The review authors did not find any randomised controlled trials which provided reliable evidence for the effectiveness and safety of Chinese medicinal herbs for mumps. Although no trials were included, the authors reviewed the studies and found no reports of adverse events with Chinese medicinal herbs as a treatment for mumps. High-quality trials are needed to answer these questions.

AYURVEDIC MEDICINE FOR SCHIZOPHRENIA

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006867/abstract

Ayurvedic medicine has been used to treat mental health problems since1000 BC.

Ayurvedic medicine was developed in India over 3000 years ago and is the oldest medical system to have survived until the present time. It sees each individual as having a unique mind-body constitution and set of life circumstances. It is similar to traditional Chinese medicine in believing that matter and energy are the same thing. Treatment in an ayurvedic system is holistic, involving natural medicine, massage, diet and the regulation of lifestyle. Ayurveda has been used for the treatment of schizophrenia, a serious long-term mental health condition, since its formulation (c1000 BCE) although nowadays Western-style medication using antipsychotics and hospital treatment are also used.

This review examines randomised controlled trials which compare aspects of ayurvedic medicine with the use of antipsychotics for people with schizophrenia. All trials took place in India and were for 12 weeks or less. When the ayurvedic herbs brahmyadiyoga and tagara were compared to placebo (2 trials) there was no significant difference between the two groups in acceptability of treatment or overall improvement. The brahmyadiyoga group did, however, show some improvement when assessed ayurvedically (a combination of assessing aspects of the mind, decision, orientation, memory and habit, and looking for the absence of symptoms of illness). When these two herbs were compared to groups of people taking the antipsychotic, chlorpromazine, again there was no difference in acceptability of treatment, but in one of the two trials there was an improvement in mental state in those taking chlorpromazine. There was also a trial comparing an ayurvedic package (of herbs and other treatment) to chlorpromazine, and although both treatments were acceptable, the rest of the data were not able to be used. Brahmyadiyoga and tagara tended to have vomiting and nausea as an adverse effect, while chlorpromazine caused people to be sleepy. It may be possible that ayurvedic treatments could be used as adjuncts to antipsychotic medication. A new larger trial comparing ayurvedic herb(s) alone, chlorpromazine alone and both together would answer this question.

ACANTHOPANAX FOR ACUTE ISCHAEMIC STROKE

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007032.pub2/abstract

Most strokes take place when a blood clot blocks a blood vessel leading to the brain. Without a proper blood supply, the brain quickly suffers damage, which can be permanent. The damage from a stroke can cause arm or leg weakness, or difficulties with language or vision. Data from some experimental and human studies have suggested acanthopanax, a traditional Chinese medicine, may be beneficial for people with acute ischaemic stroke. It has been used in China for many years to treat stroke. To obtain a reliable assessment of the effects of acanthopanax in acute ischaemic stroke, we reviewed data from 13 studies involving 962 participants. The quality of the trials was poor, and there was not enough evidence to support the routine use of acanthopanax in the treatment of acute ischaemic stroke. More high-quality trials are needed.

GANODERMA LUCIDUM (REISHI MUSHROOM) FOR CANCER TREATMENT

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007731.pub2/abstract

Our review did not find sufficient evidence to justify the use of *G. lucidum* as a first-line treatment for cancer. It remains uncertain whether *G. lucidum* helps prolong long-term cancer survival. However, *G. lucidum* could be administered as an alternative adjunct to conventional treatment in consideration of its potential of enhancing tumour response and stimulating host immunity. G. lucidum was generally well tolerated by most participants with only a scattered number of minor adverse events. No major toxicity was observed across the studies. Although there were few reports of harmful effect of *G. lucidum*, the use of its extract should be judicious, especially after thorough consideration of cost-benefit and patient preference. Future studies should put emphasis on the improvement in methodological quality and further clinical research on the effect of *G. lucidum* on cancer long-term survival are needed. An update to this review will be performed every two years.

GINKGO BILOBA FOR INTERMITTENT CLAUDICATION

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006888.pub3/abstract

Ginkgo biloba for people with leg pain while walking (intermittent claudication)

The main symptom of peripheral arterial disease (PAD) is leg pain in one or both calves while walking. Typically, this pain occurs during walking and is relieved by a short period of rest. This clinical phenomenon is called intermittent claudication (IC). Peripheral arterial disease is caused by progressive narrowing of the arteries in one or both legs and is a manifestation of systematic atherosclerosis, possibly leading to cardiovascular events. Conservative treatment consists of treatment for cardiovascular risk factors and symptomatic relief by exercise therapy and pharmacological treatments. One of the pharmacotherapeutical options is Ginkgo biloba extract, which is derived from the leaves of the Ginkgo biloba tree and has been used in traditional Chinese medicine for centuries. It is a vasoactive agent which is believed to have a

positive effect on walking ability in patients with PAD. This review shows that people using Ginkgo biloba could walk 64.5 metres further, which was a non-significant difference compared with the placebo group. Overall, there is no evidence that Ginkgo biloba has a clinically significant benefit for patients with PAD.

MEDSCAPE 33 ARTICLES REVIEWED

Search: "traditional chinese medicine" TCM yields 35 results (June 2013)

ESTABLISHING THE EFFICACY OF TRADITIONAL CHINESE MEDICINE

http://www.medscape.com/viewarticle/553037

Traditional Chinese medicine (TCM) is the most commonly used of all the CAM disciplines, and, according to Rao *et al*.,[4] of the 60-90% of patients with arthritis who have used CAM, most used TCM. Although the use of and interest in TCM is not an indication that TCM is effective, it does show that patients with rheumatic diseases, and perhaps the physicians who treat them, are looking for alternative therapeutic options. Western medicine has not provided satisfactory treatment for all rheumatic diseases, and it is essential that rheumatologists know about TCM in order to better serve their patients.

To understand the issues surrounding the use of TCM, it is essential to realize that it is a comprehensive conceptual system that is very different from the Western reductionist and mechanistic approach to diseases. TCM works around five solid organs–heart, liver, spleen, lung, and kidneyand six hollow viscera–large and small intestine, urinary bladder, stomach, gall bladder, and 'triple burners'. These 'structures' are connected by conduits and vessels with 'qi' (energy) and blood circulating through them. This system is a concept of how the body functions, and the 'structures' are not actual anatomical structures as in Western medicine. The 'qi' and blood are vital substances of life; the function of the solid organs is to store these substances, and the hollow viscera act as reservoirs to regulate the circulation of these substances. TCM is a holistic approach, and emphasizes the importance of keeping all the structures functioning harmoniously. A person is considered to be in good health if every 'structure' is functioning in harmony with the other 'structures' in the body and with the surrounding environment.

To diagnose a condition or disease using Western medicine, the patient's history, physical findings, and test results are used, and treatment is devised according to the patient's symptoms or the root cause of the problem. TCM establishes a diagnosis of the individual rather than the disease, and uses a process called 'syndrome identification', whereby the practitioner makes a dynamic conceptualization of the individual's situation and comes up with a 'pathophysiologic status' (the type of disharmony) for the individual; this status is called 'zheng' or 'syndrome'. The therapeutics used to restore the harmony within the host and between the host and their environment are determined by the identified 'syndrome'. The theory of TCM

diagnosis and management has not been elucidated in Western scientific terms, but the TCM 'syndrome identification' process seems to work. Although it is important to understand the theory of TCM, as I think there is a scientific explanation behind it, we should firstly establish whether or not TCM has an impact on patients.

Ideally, all medicine should be rigorously tested,[5] and both the WHO Traditional Medicine Strategy and the White House Commission on Complementary and Alternative Medicine Policy suggest that clinical trials should be carried out to establish the efficacy of CAM. Physicians will, therefore, have to take on the responsibility of conducting these clinical trials. In Western medicine, randomized, controlled trials are the gold standard of rigor in clinical research, and they are designed to determine the efficacy of treatments, where end points can be reduced to one or a few objectives. The randomized, controlled trial design, however, has distinct limitations when applied to TCM, because TCM is holistic and conceptual, and it identifies and treats 'syndromes' rather than diseases. The assessment of the efficacy of TCM tends to use multiple, interactive measures, and its outcomes tend to depend on whether harmony is restored or not, which makes measurement difficult. These differences between Western medicine and TCM indicate that alternative strategies must be developed for the evaluation of TCM.

Over the past 15 years, an increasing number of studies evaluating TCM have been published in Western scientific journals; however, most of the research has not involved collaboration between Western and TCM scientists, and thus has failed to address the fundamental concepts of TCM. English taxonomies of diseases do not correspond with TCM classifications, and the measures of efficacy derived from Western views of disease do not assess the goals of TCM. It is important to incorporate the concepts of both Western medicine and TCM into research protocols. Establishing collaboration between Western medicine and TCM is a major challenge, because communication between the TCM and Western medicine practitioners rarely occurs.
These limitations of research could be overcome by creating a new strategy to evaluate the effect of TCM on rheumatic and musculoskeletal disorders. A collaboration between clinical scientists trained in TCM and those trained in Western medicine should be organized; patients attending a TCM clinic of their own free will should be evaluated, diagnosed, and managed by TCM practitioners according to the TCM principles. Every patient should also be seen by a rheumatologist to establish the Western medical diagnosis. The rheumatologist should not be involved in the treatment or management of the patients. Detailed clinical records according to TCM concepts and standards should be kept. Since each patient will have a Western medical diagnosis, their progress and outcome can be monitored using established Western medicine methods by independent assessors. This model is a form of open, long-term, observational clinical study assessing the effect of TCM on patients with rheumatic disorders; however, it will not assess the TCM diagnoses. This model will generate high-quality, patient-oriented, level 3

evidence according to Ebell and colleagues[6] of the efficacy of TCM. This strategy would also foster communication between TCM and Western medicine practitioners, and could lead to improved TCM services.

THERANOSTICS MEETS TRADITIONAL CHINESE MEDICINE

http://www.medscape.com/viewarticle/777312

Herbal medicines have long been used for a variety of ailments in Asian countries and have become more popular worldwide over the last two decades.[1,2] It has been reported by the WHO that approximately 70% of the world's population currently uses medicinal herbs as complementary or alternative medicine.[1,3] There is a general belief by the public that herbal medicines are safe because of their natural origin, and consumers often take these products without consulting or informing their regular healthcare providers.[4] However, all herbal medicines are actually a combination of potentially biologically active compounds possessing various inherent pharmacological activities, and as the metabolism of these compounds usually occurs by the same mechanisms as that of drugs, there is considerable potential for the interaction between herbal components and drugs.[5] Herbal supplements are often used concomitantly with conventional drugs, especially in the elderly or those with chronic disease who are likely to be treated with multiple drugs, raising the increased risk of drug–herb interactions (DHIs) with potentially serious consequences, particularly for those drugs with very narrow therapeutic indices.[2,6–8] This article aims to provide an update on the mechanisms and evidence of DHIs and discusses the rational prediction of clinically important DHIs.

Pharmacokinetic Mechanisms

Pharmacokinetic DHIs arise from effects on absorption, interference in distribution pattern and changes or competition in the metabolic and excretory pathways.[1,4,13] The underlying mechanisms of pharmacokinetic DHIs often involve the inhibition or induction of intestinal and/or hepatic drug metabolizing enzymes, particularly the cytochrome P450 (CYP) enzymes and the drug transporters.[14–16]

CYP Enzymes. Most herbal medicine constituents undergo Phase I and/or II metabolism, yielding inactive or active metabolites. The CYP enzymes are usually considered the most important Phase I drug metabolizing enzymes and are responsible for the oxidative metabolism of over 90% of prescribed drugs.[14,17] The inhibition of CYP enzymes by herbal medicines may result in enhanced systemic exposure of drugs leading to increased toxicity, while induction of CYP enzymes could result in reduced drug concentrations leading to subtherapeutic plasma levels of the drugs with reduced drug efficacy or even treatment failure as possible clinical consequences.[18]

The CYP3A enzyme group constitutes the largest amount of CYP enzymes and is highly expressed, not only in the liver but also in the small intestine. The CYP3A enzymes account for approximately 30% of hepatic CYP activity and more than 70% of intestinal CYP activity.[19] Many pharmacokinetic DHIs have occurred through the inhibition or induction of CYP3A enzymes by herbs or natural substances, with grapefruit juice (*Citrus paradise*) and St John's wort (*Hypericum perforatum*) being two well-known examples.[11,12]

Grapefruit and other citrus fruit juices are not regarded as herbs, although the peel of some citrus fruits is used in traditional Chinese medicine (TCM), but these products have provided convincing evidence of a mechanism of how natural substances can influence drug disposition. Grapefruit juice contains the furanocoumarin 6'7'-dihydroxybergamottin and the flavonoids naringenin and naringin, which produce a mechanism-based irreversible inactivation of intestinal CYP3A4, resulting in reduced presystemic metabolism and increased oral bioavailability of drugs, which are metabolized through this pathway, as originally demonstrated with felodipine.[20–22] The effect seems to be confined to intestinal CYP3A4/5, but it has been proposed that very large doses of grapefruit juice could also inhibit hepatic CYP3A4.[23]

St John's wort is one of the most popular herbal medicines used for mild depression and insomnia. It has been shown that St John's wort can reduce the plasma concentrations of CYP3A4 substrates including cyclosporine, some statins, indinavir, warfarin, amitriptyline, tacrolimus and oral contraceptives[24–27] by increasing intestinal and hepatic CYP3A4 activity through activation of the nuclear receptor, pregnane X receptor (PXR).[25,28] In addition, some of the interactions may be partly mediated by its inducing effect on the intestinal transporter P-glycoprotein (P-gp: gene *ABCB1*), thereby attenuating the systemic exposure and efficacy of various drugs. Hyperforin, but not hypericin, appears to be the key activator of PXR, resulting in the induction of CYP enzymes and P-gp, and St John's wort extracts with low hyperforin content do not result in clinically relevant interactions.[9]

Many herbal medicines, including those used in TCM, have been reported to influence the activity of CYP enzymes in *in vitro* studies, but the clinical relevance of these effects remain uncertain (Table 1). Danshen (*Salvia miltiorrhiza*), dong quai or danggui (*Angelica sinensis*), echinacea (*Echinacea purpurea*), ginkgo (*Ginkgo biloba*), goldenseal (*Hydrastis canadensis*), green tea (*Camellia sinensis*) and milk thistle (*Sylibum marianum*) have all been shown to inhibit various CYP enzymes *in vitro* and to interact with some substrate drugs in humans, in some but not all studies (Table 1).

However, data from the *in vitro* and *in vivo* studies on some herbs are inconsistent, suggesting the value of *in vitro–in vivo* extrapolation may be limited in studying some DHIs. Typically, *in vitro* studies use single components and high concentrations, and these effects may be

modulated by poor systemic bioavailability and/or protein binding of active components *in vivo*. Furthermore, many *in vitro* studies use hepatic microsomes, which do not detect induction of metabolizing enzymes but only inhibition, whereas many herbs may possess both inducing and inhibitory effects on drug metabolizing enzymes, although *in vitro* studies can provide fundamental mechanistic information.[5] It is also worth noting that as herbs are regarded as food products, the quality of these products are not as adequately controlled or regulated as conventional drugs are. It is known that many factors could influence the composition of an extract, for example, its geographic origin, the stage of growth of the plant, harvest and post-harvest treatments, and so on;[4] therefore, the components of the herbal products are highly variable, and the induction and inhibition effects may vary between different batches of herbal products.

A very recent study evaluated the potential for DHIs of 50 single-herbal preparations used in TCM on CYP3A4 activity determined by the metabolism of testosterone to 6β-hydroxytestosterone in human liver microsomes.[29] The study showed that huang qin (*Scutellaria baicalensis*), mu dan pi (*Paeonia suffruticosa*), ji shiee terng (*Spatholobus suberectus*) and huang qi (*Astragalus membranaceus*) significantly inhibited the CYP3A4 activity, whereas xi yi hua (*Magnolia biondii*) had a moderate inhibitory effect on the activity of CYP3A4 in human liver microsomes. Further animal studies demonstrated a substantial increase of the systemic exposure to midazolam in rats treated with huang qi, mu dan pi and ji shiee terng with the area under the plasma concentration time curve (AUC) increased by 1.8-fold to threefold, but these increases were not statistically significant, probably due to the small sample size and large variability of CYP activity in rats.

Several herbs have been reported to activate PXR and induce CYP3A expression in cell lines,[30] including kava (*Piper methysticum*),[31] tian xian (a TCM anticancer herbal formula)[32] and ginkgo (*G. biloba*),[33] but the clinical significance of these interactions has not been studied systematically. Some herbs have been reported to exhibit both inhibition and induction of CYPs in *in vitro* studies, which is probably related to different concentrations of the constituents within different formulations of a natural product. For example, *in vitro* studies have shown that *G. biloba* extract inhibited the major human CYPs, particularly CYP2C9.[34,35] The standardized EGb761 *G. biloba* extract containing 24% flavonoids, 6% terpenoids and 0.5–1% organic acids was found to strongly inhibit CYP2C9 (Ki = 14 ± 4 μg/ml), and to a lesser extent, CYP1A2 (Ki = 106 ± 24 μg/ml), CYP2E1 (Ki = 127 ± 42 μg/ml) and CYP3A4 (Ki = 155 ± 43 μg/ml) with the terpenoidic fraction inhibiting only CYP2C9 (Ki = 15 ± 6 μg/ml) and the flavonoidic fraction of EGb761 showing high inhibition of CYP2C9, CYP1A2, CYP2E1 and CYP3A4 (Ki between 4.9 and 55 μg/ml).[35]

Another *in vitro* study investigated the effect of *G. biloba* extract and some of its chemical constituents (terpene trilactones and flavonols, which account for ~30% of the chemical constituents in *G. biloba* extract) on the *in vitro* catalytic activity of CYP2B6 as assessed by the bupropion hydroxylation assay with recombinant enzyme and hepatic microsomes.[36] Enzyme kinetic analysis indicated that *G. biloba* extract competitively inhibited hepatic microsomal CYP2B6-catalyzed bupropion hydroxylation (apparent Ki was 162 ± 14 μg/ml) with its flavonol aglycones being responsible for the inhibition of CYP2B6 catalytic activity, whereas the bilobalide, ginkgolides A, B, C and J and a monoglycoside and a diglycoside of kaempferol, quercetin and isorhamnetin had no effect on the hepatic microsomal bupropion hydroxylation. Interestingly, animal studies showed that feeding *G. biloba* extract or EGb761 to rats for 10–28 days markedly increased the concentration of hepatic CYP, the expression of various CYP mRNAs and the activity of some enzymes, including CYP2B1/2 and CYP3A1, and altered the metabolism of endogenous steroids at high doses (0.5% w/w or 100 mg/kg) but not at a lower dose (10 mg/kg),[37–39] while in human subjects, no effect on the urinary steroid profile was observed after intake of EGb761 240-mg daily for 4 weeks.[38]

It has been identified that bilobalide in *G. biloba* extract is a major substance inducing several hepatic CYPs including CYP1A1/2, 2B, 2C9, 2E1 and 3A in mice using a dose of 1000 mg/kg for 5 days[40] and is responsible for the attenuated anticoagulant action of warfarin through induction of hepatic CYPs, particularly CYP2C9.[41] However, in contrast to these rat studies, reports of *G. biloba* extract–drug interactions in clinical studies are inconsistent; some showed *G. biloba* extract (280–360 mg daily for 12–28 days) significantly reduced the drug levels of the CYP2C19 probe omeprazole,[42] the CYP2C9 probe tolbutamide and the CYP3A4 probe midazolam,[43] but many studies showed no interactions.[44–46] The inconsistent results between different clinical studies may be related to the dose, particularly of bilobalide, in the product and period of -treatment with *G. biloba* extract.

Uridine-diphospho-glucoronosyl-transferases. The CYP hydrophilic conversions of xenobiotics usually make herbal compounds more susceptible to Phase II conjugative reactions, such as glucuronidation catalyzed by various uridine-diphospho-glucoronosyl-transferases (UGTs) and sulfation by sulfotransferases, generally producing molecules more amenable to biliary or renal excretion.[16,47] Glucuronidation represents the major Phase II reaction and one of the most essential detoxification pathways in humans. However, unlike the CYP-mediated DHIs, which have been extensively investigated in various studies, herbal medicine metabolism mediated by UGT enzymes and the effects of herbal extracts on UGT enzymes have not been adequately studied.[47,48] It is known that many flavonoids (e.g., quercetin and kaempferol) are substrates for UGT enzymes, and inhibitory effects of herbal extracts on UGT enzymes have been reported in some *in vitro* studies; therefore, for substrates metabolized mainly through glucuronidation, DHIs may occur through this pathway.[49] Although *in vitro* studies revealed that many

commonly used herbal extracts rich in flvavonoid compounds, for example, cranberry (*Vaccinium macrocarpon*), echinacea, ginko, green tea, hawthorn (*Crataegus oxyacantha*), milk thistle, St John's wort and soy isoflavones, are substrates and inhibitors of UGT enzymes,[47,50,51] some animal studies showed an inducible effect of certain herbs on UGT enzymes with increased glucuronidation of substrate drugs observed as summarized recently by Mohamed and Frye.[47]

The data on the clinical relevance of these effects is still lacking, however, and there are only three published clinical studies investigating the effects of herbal extracts (garlic [*Allium - sativum*], ginseng and milk thistle) on the pharmacokinetics of drugs metabolized primarily by UGT enzymes, and all the three studies showed no significant interactions.[52–54] Further clinical studies are warranted to characterize the glucuronidation of herbal medicines and to determine the clinical significance of the potential interactions between herbs and the UGT substrate drugs.

Lee *et al.* reported that ginseng extracts significantly induced the activity of NAD(P)H dehydrogenase (quinone 1), a Phase II enzyme, in Hepa1c1c7 cells with polyacetylenes being the most active components.[55] Clinical studies are needed to verify whether ginseng extracts and components are bioavailable and induce cytoprotective enzymes in humans.

Drug Transporters. Drug transporters, in particular, the members of the ATP-binding cassette (ABC) and solute carrier (SLC) superfamilies, play significant roles in the absorption, distribution and elimination of many drugs. Certain herbs that interfere with drug transport may be associated with altered pharmacokinetics and efficacy of the substrate drugs.[56,57] Studies have shown that flavonoids found in fruit juices, vegetables, tea and herbal products could inhibit multiple ABC efflux transporters, including ABCB1, ABCC2 and ABCG2,[58,59] as well as the influx SLCO transporters.[60–62]

The efflux transporter P-gp (also called MDR1, gene *ABCB1*), which shares many common substrates and inhibitors with CYP3A enzymes,[63] is expressed at high levels in the apical membrane of the enterocytes in the intestine and thus limits the absorption of many drugs. Inhibition or induction of P-gp by herbal medicines can result in elevated or reduced drug concentrations, respectively.[64–69] As with CYP3A4, the induction of P-gp appears to be regulated by the nuclear receptor PXR. St John's wort is known to induce P-gp, and long-term consumption of St John's wort resulted in a significant decrease in the oral bioavailability of talinolol, a substrate for P-gp, associated with induction of intestinal MDR1 mRNA and P-gp in healthy volunteers.[66]

Some fruit juices, such as grapefruit juice, pomelo juice (*Citrus maxima*), orange juice (*Citrus sinesis*) and apple juice (*Malus domestica*), have been shown to inhibit P-gp in *in vitro* studies and thus may enhance oral drug bioavailability by reducing intestinal efflux transport.[13] Interestingly, recent *in vivo* studies showed that grapefruit juice, orange juice and apple juice all markedly reduced the systemic exposure to the renin-inhibiting antihypertensive drug aliskiren (a substrate of SLCO2B1, P-gp and CYP3A4) to a similar magnitude (peak plasma concentration by ~80% and AUC by ~60%),[70,71] and the mechanism of these interactions was considered to be related to the inhibition of the SLCO2B1-mediated uptake of aliskiren in the small intestine by these fruit juices. These studies suggested that the fruit juices are clinically important inhibitors of SLCO2B1.

Alteration of Gastrointestinal Function. Besides interactions through influence on the drug-metabolizing enzymes and drug transporters, herbal medicines may alter the absorption of concomitantly administered drugs through physical and biological interactions, for example, changes in the gastrointestinal pH, altered gastrointestinal motility and formation of insoluble herb–drug complexes in the GI tract.[1,13] Herbal-induced diarrhea can result in a shorter transit time of the drug along the GI tract and thus lead to decreased drug absorption. Anthranoid-containing plants – cassia (*Cassia senna*), cascara (*Rhamnus purshiana*), rhubarb (*Rheum officinale*), soluble fibers, ginkgo leaf extract containing flavonoids and terpenoids, ginger (*Zingiber officinale*) and kava are known to increase gastrointestinal motility and may alter the absorption and pharmacokinetics of drugs taken concomitantly.[1,13]

Pharmacodynamic Mechanisms

Herbal products contain multiple pharmacologically active phytochemicals and DHIs can occur through the additive, synergistic or antagonistic actions of herbal products with conventional medications as a result of affinities for common receptor sites or similar actions through different mechanisms.[1,72] These interactions may lead to increased or decreased pharmacodynamic outcomes and may sometimes induce severe consequences.[2,73] One of the major and clinically significant pharmacodynamic DHIs involves interactions between certain herbs with antiplatelet and/or anticoagulant therapies, for example, warfarin, which is discussed in detail in the section on 'Anticoagulant/antiplatelet drug & herb interactions'. With St John's wort, which is widely used for depressive disorders, hyperforin is known to inhibit the reuptake of several brain neurotransmitters, including 5-hydroxytryptamine (5-HT; serotonin) dopamine and noradrenaline and is believed to be the bioactive substance responsible for the antidepressant activity of St John's wort.[1,74] Pharmacodynamic interactions may occur when St John's wort is coadministered with drugs that enhance 5-HT signaling in the brain (e.g., sertraline and paroxetine).[1,74]

Pharmacogenetics of DHIs

Genetic variants in drug-metabolizing enzymes, transporters and drug targets may affect their activity for different substrates, and thus may influence DHIs.[11,12] The concentrations of the herbal extract and the drug may determine the degree of DHI and therefore polymorphisms in drug-metabolizing enzymes and drug transporters that alter the systemic exposure to the substrate drugs or active components of herbs may affect the risk of interaction. On the other hand, when a drug has more than one metabolic pathway which is reduced or inhibited due to a poor metabolizer genotype or an inhibitor of the enzyme, an alternate pathway will be used for the metabolism of the drug, but this pathway may be more susceptible to interactions with other drugs or herbs. However, clinical evidence of this mechanism in DHIs is still lacking. The pharmacogenetic/pharmacogenomic approach may help to identify some interactions, which may be more pronounced or only occur in specific groups of subjects based on their genetic background. Table 2 provides some references for clinical evidence of the implication of pharmacogenetics in DHIs. These pharmacogenetic studies examined the impact of polymorphisms in CYP enzymes, drug transporters or genes involved in the pharmacodynamic pathways of the drug on DHIs, but there appear to be no reports as yet on the effect of UGT polymorphisms on DHIs. The US FDA has recently updated the Guideline for Industry for conducting drug interaction studies, and one of the major revisions is that in addition to CYPs, UGTs should also be considered if this pathway contributes to 25% of the metabolism of the drug under evaluation.[201] Therefore, future pharmacogenetic studies are required to investigate the role of UGT polymorphisms on DHIs mediated by UGTs.

Epigenetics of DHIs

Epigenetics refers to functionally relevant modifications to the genome that do not involve a change in the nucleotide sequence, and the epigenetic mechanisms in mammalian cells usually involve methylation of CG dinucleotides, post-translational modifications of histone proteins and RNA interference.[75] Hsieh *et al*. tested the role of epigenetics in TCM through chemical–protein interactions by searching 3294 TCMs containing 48,491 chemicals and found that nearly 30% of the TCMs are potentially affecting the epigenomes and miRNA expression of human cells and 99% of government-approved TCM formulas examined are epigenome and miRNA interacting.[75] However, whether this epigenetic information can be used in predicting herb–drug interactions remains unclear at present and warrants further investigation.

Anticoagulant/Antiplatelet DHIs

Drugs with anticoagulant or antiplatelet activity (e.g., warfarin, and aspirin) were frequently implicated in DHIs.[78–80] Some herbs can potentially increase the risk of spontaneous bleeding or augment the anticoagulant effects of warfarin, and these interactions can result from a combination of factors, such as intrinsic anticoagulant and antiplatelet properties of the herbs and effects on the pharmacokinetics of warfarin.[81] According to the Natural Medicines

Comprehensive Database, approximately 180 dietary supplements have the potential to interact with warfarin, and more than 120 may interact with antiplatelet drugs, for example, aspirin, clopidogrel and dipyridamole.[80]

It has been reported that St John's wort significantly induced the apparent clearance of both S- and R-warfarin by 29% (95% CI: 16–46%) and 23% (95% CI: 11–37%), respectively, which in turn resulted in a significant reduction in the pharmacological effect of rac-warfarin in healthy subjects.[82] St John's wort also significantly reduced blood levels of digoxin in healthy subjects, and this interaction was dependent on the dose of the active component hyperforin.[83] These studies suggested that coadministration of St John's wort with warfarin or digoxin may result in treatment failure.

More than 60 herbal remedies have been identified with antiplatelet, anticoagulant or coagulating ability, and the bioactive compounds include polyphenols, taxanes, coumarins, saponins, fucoidans and polysaccharides, but most information relies on *in vitro* assays.[78] It has been shown that ginkgo has clinically relevant antiplatelet activity, and consumption of ginkgo has been reported to be associated with bleeding episodes; therefore, the concurrent use of ginkgo with antiplatelet, anticoagulant or antithrombotic agents may increase the risk of bleeding.[2] In healthy subjects, coadministration of ginkgo with cilostazol or clopidogrel did not enhance antiplatelet activity compared with the individual agents alone, but ginkgo potentiated the bleeding time prolongation effect of cilostazol.[84] However, ginkgo at recommended doses does not significantly affect clotting status, the pharmacokinetics or pharmacodynamics of warfarin in healthy subjects,[44] and a meta-analysis did not support a higher bleeding risk associated with standardized *G. biloba* leaf extracts alone compared with placebo treatment.[85] A recent retrospective population-based study performed in Taiwan showed that the combination of ginkgo with antiplatelet or anticoagulants had no significant correlation to the risk of hemorrhage.[86]

Danshen has also been found to affect hemostasis in several ways, including inhibition of platelet aggregation, interference with the extrinsic blood coagulation, antithrombin III-like activity and promotion of fibrinolytic activity. There were several published case reports of gross overanticoagulation and bleeding complications in patients receiving chronic warfarin therapy who also took danshen, and it is likely that some constituents of danshen inhibit the metabolism of warfarin through CYP2C9.[2,87]

Several other herbs can also potentiate the risk of bleeding such as cranberry (*Vaccinium macrocarpon*), dong quai, garlic (*A. sativum*), ginseng (*Panax ginseng*) and licorice (*Glycyrrhiza glabra*).[2,88] Chan *et al.* reported that the patients with nonvalvular atrial fibrillation treated with

warfarin who consumed common herbs at least four-times per week had suboptimal anticoagulation control with warfarin compared with infrequent users.[89]

HIV Medications & Herb Interactions

Herbal medicines are commonly used in patients with HIV/AIDS, particularly in Africa and Asia.[90] Patients who use antiretroviral agents and herbal medicines concomitantly are at increased risk of experiencing clinically significant DHIs with most of the interactions involving pharmacokinetic mechanisms as all of the currently marketed protease inhibitors and non-nucleoside reverse transcriptase inhibitors are substrates for P-gp and/or are extensively metabolized via the CYP enzymes. Several clinical studies and case reports involving pharmacokinetic interactions of herbs with antiretroviral agents have been described.[90,91]

St John's wort 300-mg (standardized to 0.3% hypericin) daily for 14 days significantly reduced the $AUC_{0–8\ h}$ of indinavir by 57% and decreased the extrapolated 8-h indinavir trough plasma concentration by 81% in healthy subjects.[92] A case study in five HIV-positive patients showed that chronic use of St John's wort resulted in an increased clearance of 35% ($p = 0.02$), thus leading to a decreased exposure to nevirapine.[93] Garlic has been considered to have immune modulatory, antioxidant, antimicrobial and lipid-lowering properties and has been frequently used in patients with HIV/AIDs for enhancement of the immune system. It has been shown that administration of a garlic product for 20 days significantly reduced the steady-state mean $AUC_{0–8\ h}$ of saquinavir by 51%, trough levels at 8 h after dosing by 49%, and the mean maximum concentrations (C_{max}) by 54% compared with baseline without garlic.[94] After the 10-day washout period, the AUC, trough and C_{max} values returned to 60–70% of their values at baseline. This interaction is probably through the inducing effect of garlic on P-gp rather than CYP3A4 as garlic has been found to induce human intestinal P-gp but had no effect on intestinal and hepatic CYP3A4.[95] However, short-term use of garlic over 4 days did not significantly alter the single-dose pharmacokinetics of ritonavir in healthy volunteers.[96] Interestingly, severe gastrointestinal toxicity after starting ritonavir therapy has been reported by two HIV-infected patients who were also taking garlic supplements for a long period of time, and this has been considered to be related to the inhibition effect of ritonavir on the metabolism of garlic or ritonavir potentiated the toxic effects of garlic on the intestinal tract leading to this side effect.[97] However, these assumptions have not been confirmed.

E. purpurea 500-mg, three-times per day for 28 days significantly induced CYP3A activity using midazolam as the probe, but it did not alter lopinavir–ritonavir exposure in healthy subjects, probably due to the potent CYP3A inhibitory effect of ritonavir.[98] In another study in 15 HIV-infected patients receiving darunavir–ritonavir (600/100-mg twice daily) for at least 4 weeks, *E. purpurea* 500 mg, four-times per day for 14 days did not affect the overall darunavir or ritonavir pharmacokinetics, but individual patients did show a small decrease in darunavir concentrations with the geometric mean ratios of darunavir coadministered with echinacea relative to that for

darunavir alone for C_{min} (the concentration at the end of the dosing interval) of 0.84 (90% CI: 0.63–1.12), for 0.90 $AUC_{0–12\ h}$ (90% CI: 0.74–1.10) and for C_{max} of 0.98 (90% CI: 0.82–1.16). Although no dose adjustment is required, monitoring darunavir concentrations on an individual basis is advised in this setting.[99]

Anticancer DHIs

Herbal medicines and TCM are increasingly used by cancer patients worldwide in conjunction with chemotherapy treatment for the anticancer properties and supportive care properties attributed to some herbs.[100,101] There are increasing numbers of reports on the interaction of herbal medicines with anticancer agents, but these are mostly limited to *in vitro* rather than clinical studies. The clinical significance and potential mechanisms of herbal interactions with anticancer drugs has been the subject of several recent reviews.[100–104] Many anticancer DHIs occurred through pharmacokinetic modulations which involved mainly induction or inhibition of the CYP enzymes and P-gp.[101,104]

In an unblinded, randomized crossover study in five cancer patients, treatment with St John's wort at 900 mg per day for 18 days decreased the plasma levels of the active metabolite of irinotecan, SN-38, by 42% (95% CI: 14–70%), and consequently, the degree of the adverse effect of myelosuppression was substantially worse in the absence of St John's wort.[105] In healthy subjects, treatment with St John's wort 300 mg, three-times daily for 2 weeks significantly increased imatinib clearance by 43% and decreased the $AUC_{0–\infty}$ of imatinib by 30%. The elimination half-life of imatinib (12.8 vs 9.0 h) and C_{max} (2.2 μg/ml vs 1.8 μg/ml) were also significantly decreased.[106] Similar results were reported in another study in healthy subjects with the median $AUC_{0–\infty}$, C_{max} and the half-life of imatinib being reduced by 32, 29 and 21%, respectively, by treatment with St John's wort.[107] These data indicate that St John's wort increases imatinib clearance by inducing the expression of CYP3A4.

Cox *et al*. investigated the effect of garlic supplementation (600 mg, twice daily for 12 days) on the pharmacokinetics of docetaxel (a substrate of CYP3A4 and CYP3A5) in ten women with metastatic breast cancer treated with docetaxel for 3 out of 4 weeks.[108] They found that although garlic did not significantly affect the disposition of docetaxel in the subjects overall, the mean AUC ratio between day 1 and 15 was substantially higher in three individuals with the *CYP3A5**1A/*1A genotype compared with that in the six individuals carrying the *CYP3A5**3C/*3C genotype (3.74 vs 1.02), although this difference was not statistically significant. This result suggested that garlic supplementation may influence the pharmacokinetics of docetaxel in a *CYP3A5* genotype-dependent manner, but further research is clearly required to verify this result and assess its clinical implications.

Immunosuppressant & Herb Interactions

Pharmacokinetic DHIs have compromised the safety and efficacy of the key immunosuppressive drugs in renal transplant patients.[109] The two natural products, grapefruit juice and St John's wort, are known to modify the bioavailability of cyclosporine and tacrolimus, immunosuppressive drugs widely used in the prevention of organ allograft rejection.[109–111]

The interaction caused by St John's wort was first described by Breidenbach *et al*. when they observed a drop in cyclosporine blood trough levels by a mean of 47% (range: 33–62%) in 30 patients with kidney grafts after self-medication with St John's wort,[112] and this resulted in a gradual increase in cyclosporine dosage by a mean of 46% (range: 15–115%). With discontinuation of St John's wort in these patients, cyclosporine blood levels increased markedly by a mean of 187% (range: 84–292%). No patient was reported to have any permanent consequences as a result. However, acute organ rejection in transplant patients due to a metabolic interaction of St John's wort and cyclosporine has been described in several case reports.[113]

Grapefruit juice significantly increased the bioavailability of cyclosporine with AUC and C_{max} increase by 55 and 35%, respectively, in healthy subjects, primarily through P-gp inhibition (rather than CYP3A4 inhibition).[114] In nine patients with autoimmune diseases stabilized on a dosage of cyclosporine, grapefruit juice produced significant increases in systemic exposure to cyclosporine and metabolite with one patient developing significant neurological side effects associated with a 68.9 and 214% increase in trough cyclosporine and metabolite concentrations, respectively, during grapefruit juice coadministration.[115] Clinical studies in renal transplant recipients also showed that grapefruit juice induced a moderate, but significant, increase in the systemic exposure of cyclosporine.[116,117]

Antidepressants & Herb Interactions

Antidepressant drugs have high potential for clinically significant interactions with St John's wort, as St John's wort itself is consumed by patients for depression, and these interactions can be through pharmacokinetic or pharmacodynamic mechanisms.[26,27] A pharmacokinetic interaction between St John's wort and amitriptyline has been reported with St John's wort significantly decreasing the steady-state AUC of amitriptyline by 22% and nortriptyline by 41% in 12 patients undergoing amitriptyline treatment.[118] Pharmacodynamic interactions have been reported when St John's wort was coadministered with several antidepressants such as nefazodone, paroxetine, sertaline and venlafaxine in some cases with serotonin syndromes being observed probably due to additive effect on 5-HT accumulation and signaling.[74] Concurrent use of grapefruit juice for 1 week increased mean serum sertraline levels in five patients with depression with the mean (±SD) serum sertraline trough levels increased significantly from 13.7 ± 4.9 μg/l before to 20.2 ± 4.4 μg/l ($p = 0.047$) after administration of

grapefruit juice, but larger studies are warranted to substantiate the clinical significance of this - finding.[119]

Other Clinically Relevant DHIs

St John's wort has been shown to interact in a clinically relevant manner with a number of other conventional drugs mostly via these pharmacokinetic mechanisms. These have included increases in the apparent clearance of oral contraceptives leading to breakthrough bleeding and unplanned pregnancies; it reduces the systemic exposure and the lipid-lowering efficacy of statins and influences the safety and efficacy of various drugs acting on the CNS (e.g., anesthetics, the anxyolityc drugs alprazolam, midazolam, quazepam and buspirone, the anti-epileptic drugs mephenytoin, drugs for addicted patients, such as methadone and bupropion, the centrally acting muscle relaxant chlorzoxazone and the antitussive drug dextromethorphan).[27,74]

Grapefruit juice significantly increases the bioavailability of many prescription drugs, for example, felodipine, midazolam, talinolol and statins, mainly through its mechanism-based inhibition of CYP3A4.[13,110] Administration with grapefruit juice increased the plasma levels of the acid and lactone of atorvastatin, lovastatin and simvastatin by 2.5–7-fold and 3.3–16-fold, respectively, and thus may increase the risk of statin-induced myopathy, although no clinical cases appear to have been described.[120–122] Therefore, the use of these statins concomitantly with large quantities of grapefruit juice (>1 quart daily) should be avoided, particularly for lovastatin and simvastatin which usually have very low bioavailability (<5%).

Identifying the Population at Risk of Altered Drug Efficacy or Clearance by Herb Use

As an expensive immunosuppressant, tacrolimus in long-term use is costly, thus calcium channel blockers with CYP3A inhibitory effects such as diltiazem, which increase tacrolimus concentrations and decrease tacrolimus maintenance dosage requirement, have been widely used as tacrolimus-sparing agents in clinical practice. A similar dose- and cost-saving approach has been used with cyclosporine and diltiazem for over two decades in some countries, although there was initial skepticism among some physicians that the interaction would produce consistent effects in such a critical situation.[123] An effect of the *ABCB1* G2677T/A polymorphism and haplotypes but not *CYP3A5**3 genotype was found on cyclosporine concentrations in Chinese renal transplant patients cotreated with diltiazem in one study,[124] but another study found the concentration-to-dose ratios for tacrolimus taken with diltiazem but not for cyclosporine were influenced by *CYP3A5**3 genotype in Asian renal transplant recipients.[125] Moreover, Li *et al*. found that the tacrolimus-sparing effect of diltiazem was very limited in subjects with the *CYP3A5* nonexpresser genotype *CYP3A5**3.[126] They suggested that an algorithm-predicted dosing schedule with the *CYP3A5* genotype-guided tacrolimus–diltiazem combination would be cost saving because of reduced tacrolimus maintenance dosage in the

patients identified as *CYP3A5* expressers and would also reduce adverse effects of tacrolimus by improving the accuracy of the initial dose of tacrolimus and dose adjustments.
Similar conclusions may be drawn from studies with the herbal medicine *Schisandra sphenanthera* extract (Wuweizi – also used in TCM from *Schisandra chinensis*) since it has been found to significantly increase the oral bioavailability of tacrolimus, both in rats and healthy volunteers,[127,128] and a cell-based *in vitro* study confirmed that the potential mechanism was the inhibitory effects of *S. sphenanthera* extract on P-gp-mediated efflux and CYP3A-mediated metabolism of tacrolimus.[127] Wuzhi tablet (a preparation of ethanolic herb extract of *S. sphenanthera*, registration number in China: Z20025766) has been prescribed concurrently with tacrolimus in China for transplant patients. Studies in rats have also shown that Wuzhi tablets have a pharmacokinetic interaction with paclitaxel when it is given orally and to a lesser extent when given intravenously.[129] To our knowledge, there are no published reports on whether the interactions of *S. sphenanthera* with tacrolimus or paclitaxel are influenced by the common polymorphisms in *CYP3A5* or *ABCB1*.

Conversely as mentioned above, St John's wort should be avoided in patients taking tacrolimus due to its inductive effects on tacrolimus metabolism associated with the risk of organ rejection as evidenced by pharmacokinetic interaction studies in healthy volunteers and renal transplant patients.[130,131] However, the study in transplant patients also identified that St John's wort did not result in a pharmacokinetic interaction with mycophenolic acid.[131] Likewise, whether the interaction of St John's wort and tacrolimus is dependent on *CYP3A5* or *ABCB1* genotype has not been reported as far as we are aware.

Identifying the Population at Risk of Drug Adverse Effects by Herb Use

Drug adverse effects due to DHIs are often difficult to identify because other causes of adverse events cannot always be excluded. Drugs with a narrow therapeutic index are more prone to drug adverse effects accompanied by herb use, leading to the potential of mild, moderate-to-severe or even lethal clinical consequences. DHIs related to cardiovascular medications, anti-coagulants, oral hypoglycemic agents, psychiatric medications, laxatives and medications for HIV infection have been described in some recently published reviews which citied common herbal supplements and DHIs that produce adverse effects.[2,132] These interactions involved both pharmacokinetic and pharmacodynamic mechanisms. However, the clinical relevance of DHIs has seldom been verified because of the lack of discern between theoretical and actual clinical safety risks.[133] Despite the lack of definitive clinical data, doctor–patient communication and education on DHIs and the potential dangers should not be omitted, and disclosure of the use of complementary and alternative medicines by patients to their physicians and pharmacists should be encouraged.

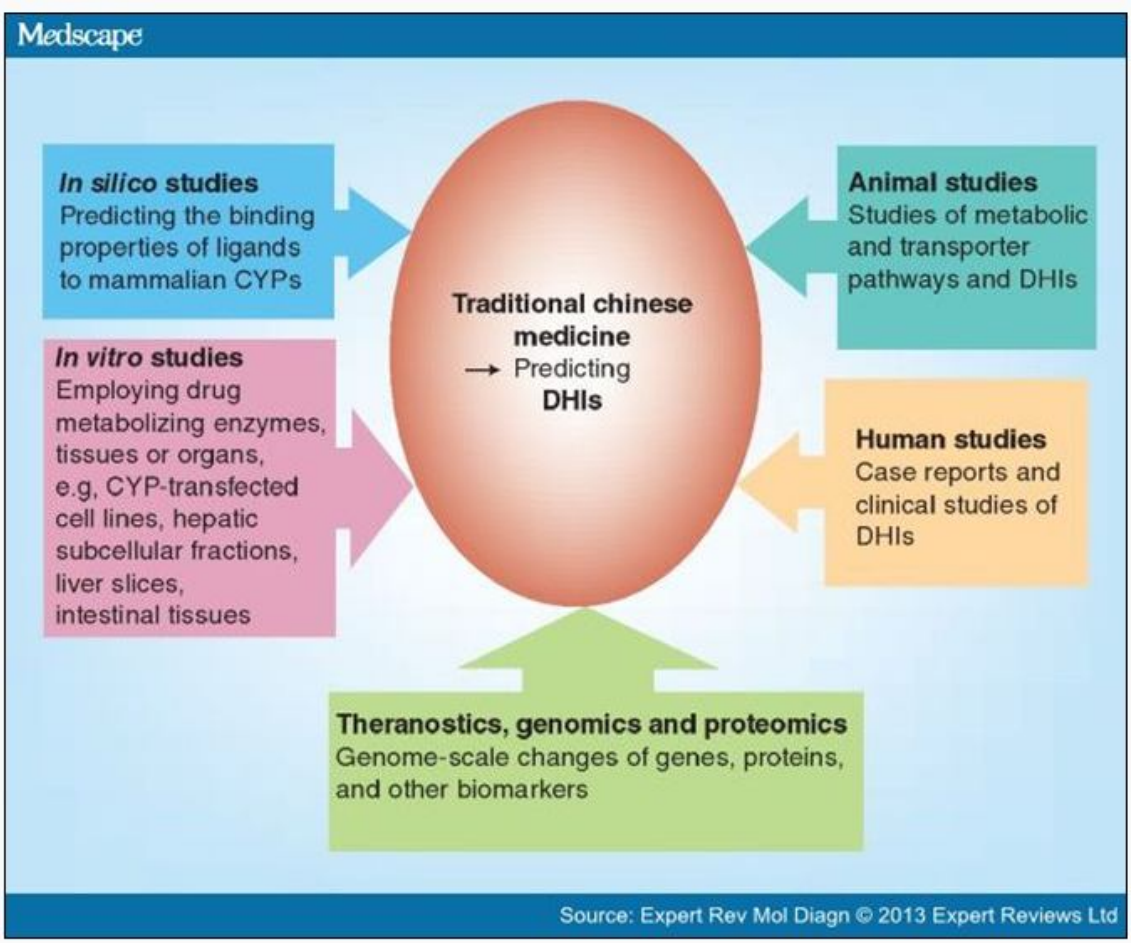


Figure 1.

Methods for identifying drug–herb interactions.

CYP: Cytochrome P450; DHI: Drug–herbal interaction.

Theranostics Approaches to Predicting DHIs

Both *in vitro* and *in vivo* studies to examine potential DHIs are frequently reported, and the approaches to evaluating DHIs have been assessed in several recent systematic reviews (Figure 1).[1,74] Based on a structured assessment procedure of drug–drug interaction, Fasinu *et al*. divided the evidence for DHIs for clinical risk assessment into different levels according to the approaches involved.[1] Clinical evidence for DHIs has also been categorized into several levels.[74] The higher the level is, the more reliable the evidence for a DHI becomes, and the more likely it is for the DHIs with clinical relevance to be predicted. It was accepted that well-documented case series or case reports with the absence of other explaining factors and controlled pharmacokinetics interaction studies in humans would be a comparatively reliable evidence for clinically relevant DHIs, whereas the studies based on structure–activity

relationship analysis, or those conducted using an *in vitro* platform or in animals would be less likely to be extrapolated to human studies (Table 1).

Controlled pharmacokinetic interaction studies are usually conducted in healthy volunteers rather than in patients, unless one of the drugs involved is particularly toxic, and this may have some impact on the clinical implications of the findings. The impact of pharmacogenetics and pharmacogenomics could be simultaneously taken into account by recruiting volunteers with different genotypes or haplotypes of specific genes relevant to the drugs involved (Table 2). However, whether the degree of change in the pharmacokinetics from a DHI would have a significant impact on clinical response has seldom been confirmed.

Ideally, DHIs identified by case reports, confirmed by clinical pharmacokinetic and pharmacodynamic studies and mechanistically explained by *in vitro* and animal studies would have the most definitive evidence. At the same time, the complex nature of herbal products should be considered, and the main active components or extracts of the herbal medicine used in DHI studies should be well established and quantified. It would not be possible to predict DHIs with actual clinical relevance based on the conclusions drawn from the mass of published studies lacking such information, not to mention applying theranostics to this area to attempt to avoid potential clinical risk.

Expert Commentary

It is a common finding that few patients disclose their history of herbal and complimentary medicine consumption to their physicians. Although in most cases, there will be no clinical significance, concomitant use of herbs and conventional drugs may present with untoward events. Patients, physicians and pharmacists should be equipped with appropriate knowledge of potential DHIs as well as related policies and regulations. Researchers are encouraged to undertake prospective randomized clinical studies to assess DHIs, and use meta-analysis of prospective clinical studies to make their conclusions more relevant to the real clinical situation.

Since 1994, the Dietary Supplement Health and Education Act, serious adverse event reporting and good manufacturing practices for dietary supplements, has provided a regulatory framework to deal with adverse effects and DHIs in the USA, although there are challenges in establishing standardization for the dietary supplement industry. Moreover, herbal medicine providers, academics and the pharmaceutical and herbal medicine industries should all be informed of the potential clinical relevance of DHIs. Theranostics tools, especially emerging technologies (e.g., pharmacogenomics) to detect individual susceptibility in DHIs, should be extensively employed to provide effective translation of new scientific discoveries into safe and effective medical products. Nevertheless, there is still a long way to go before herbal supplements can be safely and efficiently used in clinical practice to avoid any potential DHI.

Five-year View

Considering the theranostics techniques currently available and the present level of knowledge about the mechanisms of DHIs, there is the potential to develop this area very rapidly in the next 5 years. The major pharmaceutical companies are well aware of the implications of DHIs and are beginning to consider these in the process of new drug development. As the pathways for drug metabolism and disposition are mostly identified at an early stage of drug development, many of the important drug–drug interactions and DHIs can be predicted. Furthermore, there has been considerable interest in identifying novel therapeutic agents from natural materials, and many herbal medicines have been subjected to rapid throughput screening to identify new candidate drugs with particular pharmacological actions. Such techniques could also identify the potential for DHIs with herbal compounds, but unfortunately, these results are unlikely to be publicized because of commercial pressures.

Smaller scale studies are performed in some academic centers, and the results from these will be made public, resulting in progress in identifying clinically important DHIs. However, translation from *in vitro* models to human studies is often difficult because of a lack of funding and lack of systematic coordination between academic investigators. Much of the work been carried out at at present is fragmented with little collaboration between different centers. This could be improved if funding bodies and regulatory agencies encouraged a systematic coordinated approach between centers using *in silico*, *in vitro*, animal and human studies to identify DHIs, but this is unlikely to occur. It seems unlikely that any major new DHI resulting in serious toxicity will be identified with the drugs in current use, but considering the large variation between individuals in the response to many drugs, which is partly related to genetic variation, there is considerable scope to develop the beneficial effects of DHIs to produce more reliable responses in individuals using theranostics techniques. This is exemplified by the combined use of tacrolimus with *S. sphenanthera* as described above. This cost-saving combination may well have a pharmacogenetic component and as this has only been described quite recently,[127] there is considerable scope for other herb–drug combinations to be developed for various beneficial effects.

Overall, we predict that there will be considerable progress in this field in the next 5 years, and the majority of significantly harmful DHIs will have been identified and will be potentially avoidable. Some of these are likely to have a pharmacogenetic component, and genotyping individual patients may help to improve these safety considerations. However, it is most unlikely that all of the important DHIs will be identified within the next 5 years, or indeed over a much longer period, considering the vast number of herbal materials used in TCM and other herbal medicines. A coordinated effort involving pharmaceutical companies, academic researchers, funding bodies and regulatory agencies is needed to facilitate this work and advance this important area of theranostics.

THE PATIENT WITH THOSE EMBARRASSING PLAQUES

http://www.medscape.com/viewarticle/777678

Traditional Chinese Medicine (TCM)

The literature on other CAM therapies for psoriasis remains elusive, often limited to small uncontrolled studies involving ingredients or formulations not easily replicable outside the study settings. One such example, which comes from traditional Chinese medicine (TCM), is an herbal preparation called "Wong-tong-hua-yu." A randomized controlled trial conducted at a single center compared this formulation, administered by an experienced TCM physician, with methotrexate and placebo groups.[16] The trial included 61 patients who stopped topical corticosteroids, phototherapy, and other systemic medications 4 weeks before the intervention; vitamin D analogs, keratolytics, and coal tar were permitted. Oral methotrexate was associated with a 74% improvement in PASI score after 6 months. Improvements with TCM and placebo were 15% and 32%, respectively. The authors were unable to find any effect of TCM in this study.

Another preparation, a combination of *Radix scutellariae* and *Cortex phellodendri* in petroleum jelly, called Pulian cream, was tested over 4 weeks in a randomized controlled study with 108 patients with psoriasis vulgaris.[17] The Pulian ointment was associated with an effective rate of 84% compared with a rate of 51% for placebo, with similar improvements in PASI score and lesion scores for erythema, size, and itching. However, the ointment had a sticky, greasy consistency and deep color, contaminating clothes (like coal tar does), and was not acceptable among patients. The authors proposed that the *Radix scutellariae* component in this ointment may inhibit skin cell proliferation by blocking the cell cycle of fibroblasts with additional anti-inflammatory effects and proposed development of future preparations that may be more acceptable to patients. However, efficacy remains to be proven.
Auricular acupuncture, another TCM approach, falls into a similar not-yet-proven category.[18]

ACUPUNCTURE TREATMENT OF PHANTOM LIMB PAIN AND PHANTOM LIMB SENSATION IN A PRIMARY CARE SETTING

http://www.medscape.com/viewarticle/781572

Acupuncture has previously been reported to be of benefit in PLP and PLS,[6,7] although the total numbers of patients included in these reports were low. Most recently, Bradbrook needled the asymptomatic intact limb in three patients in a rehabilitation clinic for patients with lower limb amputation.[8] It was this short series which provided the inspiration for considering acupuncture as a treatment option for the patient described in this report but, in contrast to the cases described by Bradbrook, all of which involved lower limb amputations, the patient in this report underwent amputation of his upper limb.

There appears to be little consensus on the optimal duration of needling to obtain the optimal effect from acupuncture sessions, with needling time often influenced by personal preference. There are schools of thought suggesting that brief periods of needling are effective.[9] Needling time during the first session was short at 3 min due to the marked *de qi* effect. Since the symptomatic response at the first session was good, subsequent sessions were limited to a maximum of 5 min needling time each session. This worked well for this patient, as the sessions were fitted into busy general practice surgeries running on a 10 min appointment system. There is little flexibility within such a system to allow dedicated acupuncture sessions with longer appointment slots, and there is minimal scope for arranging sessions more frequently than once weekly.

The patient and GP had developed a good therapeutic relationship over a number of years, and the patient had had a good response from acupuncture some years previously for an unrelated problem. This previous experience may have influenced his agreement to the idea of undergoing acupuncture of his intact limb for PLP and PLS.

As acupuncture was used as an early intervention with the first session being only 13 weeks after surgery, the good response may be due to the fact that PLP and PLS had not become established in this patient.

In this particular case the patient derived considerable benefit from short sessions of acupuncture. This benefit was commented on when he attended a secondary care pain control clinic which was unaware that he was having acupuncture in primary care. The clinic letter noted a dramatic improvement in his symptoms to the extent that the patient no longer had any pain whatsoever in his phantom limb.

Even 5 months after the end of his acupuncture sessions he remained free of PLP, his PLS was continuing to improve and his perception of his right arm was that it was shortening. His VAS scores for PLP had fallen from 73 at the first session of acupuncture to 0 at review 3 weeks after ending the acupuncture sessions and 0 again on further review 19 weeks after the end of acupuncture. The VAS scores for PLS were 94 at the start, 30 on review 3 weeks after the end of acupuncture and 7 on further review 19 weeks after the end of acupuncture. This may represent the continued effect of the acupuncture or may have represented continued healing after his amputation. Only time will tell how long this benefit will last. It will be interesting to see what his PLP and PLS VAS scores will be over the next 12–18 months.

TRADITIONAL CHINESE MEDICINE APPEARS USEFUL FOR OBESITY

http://www.medscape.com/viewarticle/762306

April 19, 2012 — Traditional Chinese medicine (TCM), including acupuncture and Chinese herbal medicine, has better efficacy than placebo and lifestyle interventions and similar efficacy to antiobesity drugs, with fewer side effects, according to the findings of a systemic review.

Yi Sui, from the Chinese University of Hong Kong, in Shatin, Hong Kong, China, and colleagues published their findings in the May 2012 issue of *Obesity Reviews*.

Although TCM is used frequently in clinical practice, the authors noted that its efficacy has not been thoroughly researched by using international standards. "Many systematic reviews in this

area do not include clinical trials conducted in China, especially those using traditional Chinese herbal recipes," the authors write. "Most authors also do not evaluate the rationale, safety and relapse of weight gain in these reviews."

The authors identified 96 randomized trials conducted within and outside China that compared TCM with a control group: 49 evaluating Chinese herbal medicine, 44 on acupuncture, and 3 evaluating a combination of these treatments. Through use of a randomized effect model, the efficacy of Chinese herbal medicine against obesity was found to be similar to that of the antiobesity agents fenfluramine and metformin among 9 clinical trials (pooled risk ratio [RR], 1.11; 95% confidence interval [CI], 0.96 - 1.28), although heterogeneity was observed (I^2 = 82%) because of the small number of studies and small sample sizes and effects.
The authors included participants in the accepted studies irrespective of age, sex, and obesity status and excluded pregnant and lactating women, patients with serious medical conditions, and those with secondary obesity. Additionally, the authors excluded preclinical studies, case reports, and self-control and nonrandomized trials. The primary outcomes measured were changes in body weight, body mass index (BMI), waist and hip circumference, and body fat percentage.

Among 15 trials of acupuncture, acupuncture treatment resulted in greater weight loss than did no-treatment sham operation, co-interventions, and lifestyle modification, as indicated by a pooled RR of 2.14 (95% CI, 1.58 - 2.90) in favor of acupuncture; heterogeneity (I^2 = 88%) was noted because of the small number of studies and small sample sizes and effects. Among 11 trials that compared acupuncture with western drugs, including sibutramine, fenfluramine, and orlistat, acupuncture exhibited greater efficacy (pooled RR, 1.14; 95% CI, 1.03 - 1.25), with heterogeneity (I^2 = 76%) due, again, to the small number of studies and small sample sizes and effects.

When analyzed according to the mean difference in body weight reduction, both Chinese herbal medicine (body weight reduction, 2.93 kg; 95% CI, 1.81 - 4.05 kg; BMI reduction, 1.36 kg/m^2; 95% CI, 0.89 - 1.82 kg/m^2) and acupuncture (body weight reduction, 1.85 kg; 95% CI, 1.03 - 2.67 kg; BMI reduction, 1.42 kg/m^2; 95% CI, 0.63 - 2.20 kg/m^2) were associated with greater efficacy compared with controls. In addition, relapse of weight gain was more common in the control groups than in the Chinese herbal medicine or acupuncture treatment groups.
The adverse effects of Chinese herbal medicine and acupuncture were generally mild. The most common were gastrointestinal symptoms for both Chinese herbal medicine and acupuncture, and local skin reactions for those receiving acupuncture treatments.
The limitations of the review included the use of different herbal formulations within and outside China, the lower methodologic quality of studies conducted within China, and the incomplete citation tracking of some studies.

Overall, the findings indicate the efficacy and tolerability of TCM, including Chinese herbal medicine and acupuncture. "Given the large unmet needs of obesity, these findings may form the basis for selection of intervention strategies in future randomized clinical trials," the authors write. "The combined use of Western principles of scientific inquiry and the holistic approach of Chinese medicine may provide a vital new dimension in our pursuit of control and prevention of chronic diseases, such as obesity and diabetes."

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ADJUNCT CHINESE MEDICINE BOOSTS COLORECTAL CANCER SURVIVAL

http://www.medscape.com/viewarticle/772680

October 16, 2012 — Combining traditional Chinese medicine (TCM) with conventional treatment can improve disease-free survival in patients with colorectal cancer, according to a new study. In addition, the longer the exposure to TCM therapy, the better the outcome.

These results of a trial of 312 patients conducted in China were presented here at the 9th International Conference of the Society for Integrative Oncology.

The 2-year rate of recurrence and metastasis was lower in those who were exposed to TCM than in those who were not, reported lead author Dr. Yu Fei Yang, from Xiyuan Hospital, China Academy of Chinese Medical Sciences, in Beijing.

Whether patients can benefit from longer-term TCM treatment needs to be verified with further research, said Dr. Yang.

TCM dates back several thousand years and is rooted in the ancient philosophy of Taoism. It is a complete system of healthcare with its own unique theories of anatomy, diagnosis, health, and treatment. The most common forms are herbal therapies and acupuncture, but other forms are moxibustion, cupping, massage, mind–body therapy, and dietary therapy. Currently, many hospitals and clinics in China use TCM in conjunction with Western therapies. According to the National Center for Complementary and Alternative Medicine, it is estimated that 3.1 million adults used acupuncture in the United States in 2006.

Dr. Yang explained that she and her colleagues have been assessing the use of TCM in conjunction with conventional medicine for the treatment of colorectal cancer since 1997. They believe that TCM might play an active role in the postoperative management of the disease.

Statistically Significant After Stratification

In this study, Dr. Yang and colleagues evaluated the ability of TCM in patients with stage II and III postoperative colorectal cancer to reduce the risk for recurrence and metastasis.

In this retrospective/prospective cohort study, 312 patients who had undergone radical surgery from April 2007 to February 2009 were recruited from 8 hospitals in China. All patients received adjuvant chemotherapy, radiotherapy, and follow-up visits in accordance with National Comprehensive Cancer Network guidelines. In this group, 167 patients had colon cancer and 145 had rectal cancer; median age was 57.24 years.

The patients were divided into 3 different groups, according to the length of time they were exposed to TCM and the intensity the intervention: high exposure (n = 138), low exposure (n = 70), and nonexposure (n = 104).

"High exposure meant that the therapy lasted for at least 1 year," said Dr. Yang, although the specific TCM treatments administered were not discussed in her presentation.
In the high-exposure group, 12 patients were lost to follow-up and 70 experienced disease recurrence and metastasis. The 2-year rate of disease recurrence and metastasis was lower in the high-exposure group than in the low- and nonexposure groups (14.49% vs 22.86% vs 22.12%).

The difference between the patients who were treated with TCM and those who were not was not statistically significant (*P* = .149). However, Dr. Yang noted that when the groups "were stratified by confounders," there was a significant difference between the high-exposure group and the nonexposure group.

On multivariate analyses, 2-year disease-free survival was higher in the high-exposure group than in the low-exposure group (odds ratio [OR], 2.174; 95% confidence interval [CI], 1.057 to 4.469; *P* = .035) and the nonexposure group (OR, 0.320; 95% CI, 0.124 to 0.826; *P* = .019). However, the difference between the high-exposure and low-exposure groups still did not reach statistical significance.

This study was funded by the Ministry of Science and Technology of the People's Republic of China, and the National Research Centre of Complementary and Alternative Medicine of Norway.

CHINESE MEDICINE ENHANCES THERAPY IN RARE CANCER

http://www.medscape.com/viewarticle/772883

ALBUQUERQUE, New Mexico — In a patient with Waldenström's macroglobulinemia, traditional Chinese medicine (TCM), which consists of herbal formulas and acupuncture, enhanced conventional treatment and improved quality of life.

The integration of TCM into the treatment regimen also dramatically reduced the frequency of blood transfusions and the number of clinic visits.

Even though this is only 1 case, the results are "really interesting," said lead author Amy Matecki, MD, from Alta Bates Summit Medical Center in Oakland, California. The case study was presented here at the 9th International Conference of the Society for Integrative Oncology.

In the year before the patient began using TCM, he was treated with multiple transfusions. He received 23 units of platelets and 74 units of red blood cells (RBCs) in 61 clinic visits.

After 2 years of TCM, he only needed 2 units of platelets and 22 units of RBCs, and the number of clinic visits dropped to 11.

Dr. Matecki, who is trained in Western medicine and TCM, told *Medscape Medical News* that the patient was referred to her as a last resort. "His disease was progressing despite conventional treatments, and there really were no other options for him," she said. "The next step was hospice, so he really felt that he had nothing to lose by trying Chinese medicine."

Waldenström's macroglobulinemia, also known as lymphoplasmacytic lymphoma, is relatively rare; there are about 1500 cases diagnosed each year in the United States. It is an indolent and progressive lymphoproliferative disease that shares clinical characteristics with indolent types of non-Hodgkin's lymphoma, and is characterized by high levels of immunoglobulin M, elevated serum viscosity, and the presence of a lymphoplasmacytic infiltrate in the bone marrow.

Because of the involvement of bone marrow, more than 70% of patients have stage IV disease at the time of their diagnosis, although about one third are asymptomatic.

Dr. Matecki and colleagues speculate that TCM helps by enhancing the sensitivity of chemotherapy, boosting its hematopoietic effects, and strengthening the immune system.

The 51-year-old man, who was diagnosed in early 2002, had become dependent on transfusions. From December 2007 to February 2010, several herbal formulas and acupuncture treatments were integrated into his regular regimen of 9 cycles of rituximab (*Rituxan*), 1 cycle of cyclophosphamide plus prednisone, platelet and RBC transfusions, and pegfilgrastim/filgrastim (*Neulasta*/*Neupogen*) injections as needed. He was closely monitored and received weekly or biweekly blood draws.

Improved Blood Count, Decreased Transfusions

In the 2 years that he was receiving TCM, his platelet and RBC counts improved, he required fewer transfusions and clinic visits, and his quality of life improved, explained Dr. Matecki.

Treatment and Results by Year

Variables	2007	2008	2009
No. of office visits	61	45	11
Platelet count ($\times 10^3/\mu L$)	4	21	63
No. of platelet transfusions	23	9	2

Hemoglobin level (g/dL)	7.80	8.00	8.38
No. of RBC transfusions	74	41	22

Despite this improvement, the patient eventually succumbed to his disease. Waldenström's macroglobulinemia is generally incurable, and survival patterns vary. This patient had very advanced disease when he began TCM, and he suffered from the effects of multiple transfusions over a sustained period of time, Dr. Matecki noted.

However, the patient and his wife "were very appreciative that his quality of life improved so much during his treatment with Chinese medicine," said Dr. Matecki. "They were able to travel and do things that he had been too sick for before that."

Begin Sooner?

The patient might have survived longer if he had started TCM earlier or when the initial diagnosis was made, Dr. Matecki said. "It is very hard to even begin to design research" because cancer patients are often referred to me as a last resort, when nothing is working anymore," she explained.

Despite it being an uncommon condition, Dr. Matecki is currently treating another patient with Waldenström's macroglobulinemia. The woman is in her 60s and was diagnosed about 8 years ago. Her disease is not as advanced as the previous patient's. She has been receiving TCM treatments for about 3 years.

So far, the patient is doing well, and Dr. Matecki is working closely with her oncologist. "She had needed chemotherapy every year, but since starting the Chinese medicine, she has gone for more than 2 years without it," said Dr. Matecki. "She hasn't needed transfusions either."

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COMPLEMENTARY AND ALTERNATIVE MEDICINE IN DERMATOLOGY

http://www.medscape.com/viewarticle/769258

According to survey data, 35–69% of patients with skin disease have used complementary and alternative medicine (CAM) in their lifetime. A literature search on this subject reveals a number of studies on the efficacy of CAM treatment for dermatologic conditions, as well as a number of articles showing the growing prevalence of CAM use amongst patients suffering from these conditions. Given the consensus amongst these articles that dermatologists require increased education on CAM, this paper presents an overview of some of the most widely used systems of alternative medicine to serve as a tool for practicing dermatologists. Specifically, the history and theory behind psychocutaneous therapies, traditional Chinese medicine (including

acupuncture), homeopathy, and Ayurvedic medicine will be described, along with current evidence for their efficacy and reports of their adverse effects. The authors conclude that more evidence and better studies are needed for each of the major CAM modalities before they may be considered as independent therapeutic options. Moreover, given the shortage of evidence supporting the efficacy and safety of CAM, dermatologists should obtain a thorough history of CAM use from their patients. In general, ingestible substances including most homeopathic, Ayurvedic, and traditional Chinese medicine herbal formulations that are not US FDA regulated should be viewed with caution as they may cause severe adverse effects such as arsenicosis and hepatotoxicity. On the other hand, less invasive techniques such as acupuncture and psychocutaneous therapiesmay be more acceptable given their low-risk profile. Ultimately, until the availability of more sound data, these treatments should primarily be used in combination with conventional treatment and rarely independently.

Introduction

According to survey data, 35–69% of patients with skin disease have used complementary and alternative medicine (CAM) in their lifetime.[1] A 2009 study found that 49.4% of patients with skin problems had used CAM within the previous year, and 6% had used it specifically for their skin disease.[2] A literature search finds a number of studies on the efficacy of herbal and non-pharmacologic CAM treatments for dermatologic conditions, as well as a number of articles revealing the growing prevalence of CAM use amongst patients with these conditions. Given the consensus amongst these articles that dermatologists require increased education on CAM, this paper presents an overview of some of the most widely used systems of alternative medicine amongst dermatologic patients, to serve as a tool for practicing dermatologists. As CAM represents a vast and constantly evolving field, a discussion of all potential alternative therapies is beyond the scope of this paper. Specifically, we focus on the history and theory behind psychocutaneous therapies, traditional Chinese medicine (including acupuncture), homeopathy, and Ayurvedic medicine, along with current evidence for their efficacy and reports of their adverse effects.

4. Traditional Chinese Medicine (TCM)

Traditional chinese medicine (TCM) originated in China roughly 5000 years ago and is accepted as mainstream throughout East Asia.[27] Influenced by Taoist and Buddhist philosophy, TCM encompasses a complex, holistic model of the body and a wide variety of traditional therapies, from herbal remedies to acupuncture, dietary therapy, massage, and meditative practices such as Qigong and Tai Chi.

TCM views the body as a constellation of dynamic forces called Qi, which flow through the body in a pattern of channels, or meridians, which form the basis of needle placement in

acupuncture.[27] When the flow of energy becomes deranged by pathology, forces become congested in certain areas and deficient in others, and thus form the basis of illness in TCM. Acupuncture, considered a way of relieving this congestion, originated in China and possibly dates as far back as 200 000–300 000 BC based on bone needles and bamboo shafts thought to be acupuncture tools.[28]

TCM divides the body into internal and external, and classifies dermatology as external. Texts dating back to the 2nd century BC describe urticaria as an excess of Yin causing fluid obstruction in the skin, reminiscent of histologic dermal edema. Eczema is considered an excess of "wind heat" or "damp heat," likely corresponding to chronic and acute eczema, respectively.[28]

4.1 TCM in Dermatology

Studies on TCM, mainly from China, are relatively more numerous than on other CAM modalities. An article by Koo and Desai[29] provides a comprehensive overview of TCM efficacy, focusing on studies requiring translation from the Chinese literature. The article describes the best-known clinical trial of TCM, a double-blind, placebo-controlled study of atopic dermatitis in London. Oral ingestion of a decoction of ten herbs was compared with a false formulation. The true TCM mixture was significantly more effective, resulting in a decrease in erythema by 91.4% and in affected surface area by 85.7% (compared with 10.6% and 17.3%, respectively, for placebo). The article also discusses phototherapeutic Chinese herbs, including *Radix angelicae dahuricae* and *pubescentis*, which combine with DNA in a manner similar to psoralen plus UVA (PUVA). When administered with UVA, results were comparable to PUVA, with fewer adverse effects, although some reports described lens changes with long-term use.[29] A well known herb, green tea extract, was given before and after PUVA treatment and was shown to prevent early photochemical damage.

A Cochrane review of TCM treatments of atopic dermatitis selected four studies looking at the efficacy of Zemaphyte® (Phytopharm Plc, Cambridge, UK), a collection of ten Chinese herbs. All showed an overall reduction in erythema and surface damage; however, the authors concluded that all four studies were poorly reported and larger-scale, better-designed trials are required.[30] A study of soybean extract, rich in isoflavones, demonstrated its potential as a novel anti-photoaging ingredient. The study found *in vitro* inhibition of UVB-induced cell death and *in vivo* reduction of erythema and epidermal thickness.[31]

On the other hand, some studies have failed to demonstrate TCM efficacy compared with conventional treatment. A recent RCT of methotrexate 10mg weekly versusTCMversus placebo for moderate to severe plaque psoriasis showed a 73.9% improvement in Psoriasis Area and Severity Index (PASI) scores at 6 months for the methotrexate group, 15.1% in the TCM group, and 32% in the placebo group, demonstrating a significant difference between the methotrexate

group and the other two groups, but no significant difference between placebo and TCM.[32] A commonly expressed limitation in many studies on CAM, however, is that CAM treatments cannot be fairly compared with Western medication in clinical trials either because of a difference in treatment formulation (decoction vs pill), an inability to include non-pharmacologic treatments such as yoga and meditation into the study design, or because treatment individualization in CAM contradicts the need for standardization in clinical trials. The aforementioned study illustrates this limitation in that, in order to standardize the treatment, the TCM formulation was made into a pill, not the traditional decoction, and this may have affected its efficacy.

While these therapies appear to have some benefit, they are not without adverse effects, and they have been reported to cause reversible hepatic enzyme elevation. A few reports describe fatal fulminant hepatitis.[33] Arsenicosis with prolonged use of certain TCMs is described as well.[34] Fixed drug eruption has been described due to ma huang,[35] containing pseudoephedrine, while allergic contact dermatitis has been described from topical therapies with peanut and sesame oil.[36]

Acupuncture represents one of the most mainstream CAM treatment modalities. There is evidence for its efficacy in both acute and chronic urticaria, with studies showing a 90% and 30–50% resolution of lesions compared with placebo, respectively.[37] Moreover, recent studies show that acupuncture may help relieve pain associated with herpes zoster and post-herpetic neuralgia.[38] Evidence for its use in psoriasis is equivocal. One double-blind, randomized study found true acupuncture was no more effective than placebo.[39] However, an open-label study found that 52 out of 61 psoriasis patients reported some improvement after acupuncture.[40]
Serious adverse effects are rare; one study estimated their incidence as 0.55 per 10 000 individual acupuncture patients. This is considered 'very low' risk – lower than that of many common medical treatments. While adverse effects include vasovagal events and local infections, reported serious events included pneumothorax, spinal cord injury, and hepatitis B infection.[41]

5. Ayurveda

Originating more than 5000 years ago, Ayurveda is an ancient Indian system of healing that literally means 'the science of life' in Sanskrit. It views the body, mind, and soul holistically.[42] Charaka, the father of Ayurveda, divided the skin into six layers. The outermost layer reflects complexion and serves as a mirror of internal health, while the innermost layer reflects skin firmness and is disturbed in aging.

Illness in Ayurveda is defined as an imbalance of the normal ratio of *doshas,* or humors, and treatment is aimed at correcting this balance. This concept of body constitution represents a

defining feature, wherein each individual is composed of a unique ratio of the three doshas.[42] Vata controls the body's nervous system and movement, pitta controls digestion and metabolism, and kapha is responsible for lubrication and strength.[43]

In one commonly used treatment approach, Ayurvedic therapy follows the principle that opposites balance and so cure each other, in contrast to the homeopathic Law of Similars. Other specific approaches are used as well and the decision about how to treat is based on the disease aswell as the patient profile. Thus, treatments are considered unique to each patient. In addition to herbal medications, Ayurvedic treatment regimens often include diet and lifestyle changes, oil massages, and evacuative procedures. As mentioned earlier, clinical trials based on Western research methodology tend not to incorporate these latter therapies and this omission, considered a disruption of the holistic approach, is often cited as a study limitation that may influence the results.

5.1 Ayurveda in Dermatology

Very fewtrials of trueAyurvedic preparations exist. One study from India compared four different oral formulations with placebo for the treatment of acne in 66 patients. The study showed a 60% decrease in lesion count in the group treated with Sunder Vati tablets. These were composed of the fruit *Phyllanthus emblica*, an immunomodulator rich in vitamin C; *Embelia ribes*, another fruit with antibacterial activity against *Escherichia coli* and *Staphylococcus aureus*; *Holarrhena antidysenterica*, a bark with astringent qualities; and *Zingiber officinale* (ginger), a rhizome with anti-inflammatory activity.[44]

Several studies demonstrate efficacy of curcumin in psoriasis. Curcumin is the active ingredient in turmeric root, a plant in the ginger family (*Curcuma longa*) commonly used in Ayurvedic medications and Asian cooking. This polyphenol, responsible for the yellow color of turmeric, has multiple effects on cellular processes, including the downregulation of kinases, activation of transcription factors, and inhibition of tumor growth. The root has shown chemoprotective effects against various cancers, including gastrointestinal, colon, lung, breast, and skin. In one study, an ethanol extract of turmeric applied topically to external cutaneous neoplasms (actinic keratoses, superficial spreading basal cell carcinomas, and genital warts) resulted in remarkable symptomatic relief, including decreased size and pain.[45] Another study evaluated anti-psoriatic effects by measuring phosphorylase kinase activity. The highest levels were found in patients with active psoriasis, followed by those treated with a topical vitamin D^3 analog (calcipotriol), then topical curcumin, and finally those without psoriasis, suggesting superior efficacy of curcumin to vitamin D^3 analogs.[46] Curcumin has shown very few adverse effects, even in doses as high as 12 g a day for 3 months.[47]

Areview article onCAMuse in psoriasis describes a study of neem tree bark (*Azadirachta indica*). Commonly used in Ayurveda, its active ingredient is a potent prostaglandin synthesis inhibitor. Fifty patients were treated with topical 5% crude coal tar and 3%salicylic acid in a petrolatum base nightly and one capsule of placebo or neem extract three times daily. After 12 weeks, the neem group demonstrated significantly better PASI scores.[48,49] Another study showed improvement in wound healing by two out of five topical Ayurvedic preparations as compared with the control. The study evaluated tensile strength, hydroxyproline content, and wound contraction using an incision and excision model. The preparations included clarified butter and flaxseed oil, which contain high amounts of essential fatty acids, as well as ingredients rich in zinc and vitamin C. On all parameters, the two formulations showed statistically significant benefit compared with the other creams and the control.[50]

Despite the scarcity of studies, the few that exist appear to demonstrate efficacy. Still, Ayurveda is not without risk. Metals, including arsenic and mercury, may be found in certain formulations. While medications from a reputable and governmentregulated source in India might be safe, thosemanufactured in the US are not regulated under the FDA. Therefore, clinicians must be aware of these products, their origin, and their ingredients.

6. Conclusions

Asummary of theCAMmodalities discussed in this reviewis provided in Table I.

The prevalence of CAM use amongst patients with skin disease makes it a subject worth reviewing for the practicing dermatologist, both for exposure to available therapeutic options and for awareness about toxicity. However, a literature search on this topic reveals that more evidence and better studies are needed for each of the major CAM modalities. Given the current level of evidence, these treatments should primarily be used in combination with conventional treatment and rarely independently, particularly in severe or life-threatening conditions. Moreover, the dermatologist must weigh the known risks and benefits of a certain drug or treatment. For example, in light of inconsistent evidence, ingestible substances such as homeopathic, Ayurvedic, and TCM herbal formulations that are not FDA regulated should be viewed with caution as they may cause severe adverse effects such as arsenicosis and hepatotoxicity. On the other hand, the evidence threshold for pursuing less invasive techniques such as acupuncture and psychotherapies may be lower, given their lower risk profile. The goal for future studies will be to better address the holistic CAM perspective by incorporating the entirety of these modalities' therapeutic regimens, including prescribed diet and lifestyle changes, yoga, meditation, and individualization of treatment in order to more accurately conduct comparative clinical trials. Evidence from this type of study would hopefully provide a sounder platform for the discussion about how best to integrate Western medicine and CAM.

All in all, CAM represents interesting and relatively uncharted territory within medicine, and further investigation may help define its role within dermatology.

INTEGRATIVE MEDICINE USE UP, BUT OUTCOMES STILL UNCERTAIN

http://www.medscape.com/viewarticle/758725

February 15, 2012 — In a survey of US medical centers using integrative medicine, 75% reported success using integrative practices to treat chronic pain, with more than half reporting positive results in the areas of gastrointestinal conditions, depression, anxiety, cancer, and chronic stress, according to a report released today by the Bravewell Collaborative.

The Bravewell Collaborative "support[s] the advancement of integrative medicine by creating and translating emerging knowledge into broad practice," according to its Web site. In the report, the collaborative defines integrative medicine as "an approach to care that puts the patient at the center and addresses the full range of physical, emotional, mental, social, spiritual and environmental influences that affect a person's health."

The survey, *Integrative Medicine in America: How Integrative Medicine Is Being Practiced in Clinical Centers Across the United States*, involved 29 integrative medicine centers (9 of them in the Bravewell Clinical Network) at many leading medical institutions, including the Cleveland Clinic in Ohio; Duke University in Durham, North Carolina; the Mayo Clinic in Rochester, Minnesota; Stanford University in California; and the M.D. Anderson Cancer Center in Houston, Texas. These institutions provided a range of services including adult, geriatric, adolescent, obstetric-gynecologic, pediatric, and end-of-life care. The most frequently prescribed interventions, often in combination, were food and nutrition, supplements, yoga, meditation, traditional Chinese medicine (TCM) and acupuncture, massage, and pharmaceuticals.

Report coauthor Constance Pechura, PhD, senior advisor at the Bravewell Collaborative, said, during a telephone briefing on the release of the report that 29 centers were chosen from about 60 candidate integrative medicine centers (about 50 of them in an integrative medicine academic consortium). Coauthor Donald Abrams, MD, professor of clinical medicine and a consultant at the Osher Center for Integrative Medicine at the University of California, San Francisco, said the 29 centers were chosen based on their leadership, having been in operation for more than 3 years, having a significant patient volume, and having "contributed to the field." He told *Medscape Medical News* during the telephone briefing that, "[i]n fact, we were looking at some of the best centers, but I do think it's probably generalizable to certainly other centers in the academic consortium."

Conditions Treated With Best Success

During the briefing, Dr. Abrams said, "We were not measuring outcomes. We were asking the center directors and the clinical directors to give us their impressions of where they were having success."

The survey results were not necessarily objective measurements and did not compare institutions practicing integrative medicine with those that took a more conventional approach to providing care. Some of the reported measurements were mainly physician observation notes, patient comments and satisfaction surveys, assessment forms, biomarkers, and electronic medical record captures.

Furthermore, the measures of success were not uniform across the institutions surveyed. The report notes that patient satisfaction was "measured in a variety of ways, the most common being surveys created by the centers themselves," and that "with the exception of data derived from clinical trials, most of the centers stated that, although they do capture patient outcomes data, they did not have the staff and financial resources to collect and analyze it." The report suggests that analysis of these data should be a priority for future funding and could provide valuable information on treatment efficacy. It also says that future research at integrative medicine centers should focus on measures of cost and cost-effectiveness of treatments for specific conditions.

Dr. Abrams noted that most of the data came from surveys sent to directors of the 29 centers, asking about conditions treated. The respondents were asked to rate the 5 conditions out of 20 listed for which they were having the most clinical success. He said the determination of clinical success was left up to each center. More than half the institutional respondents listed the same 5 conditions: chronic pain (75%), gastrointestinal disorders (59%), depression and anxiety (55%), cancer (52%), and stress (52%).

Dr. Abrams, an oncologist, noted that techniques such as mind–body interventions, nutritional support, acupuncture, exercise, and massage therapies helped patients with cancer cope with the disease, manage their survivorship, and often helped relieve treatment-related adverse effects.

All of these same interventions, plus nutritional supplements, botanicals, and meditation, were often used in some combination for many of the conditions treated. "There's a lot of similarity as to what each center uses as far as integrative interventions for each condition," he said.

Models of Care

Report coauthor Sheldon Lewis said during the briefing that the survey looked at 3 models of how integrative care is being delivered," and we found that these are not mutually exclusive." The most common model is consultative care, in which care is delivered in consultation with a patient's primary care or specialist provider; this method is used by 90% of the surveyed centers. The second model is comprehensive care (62%) for a specific condition, in which the integrative practitioner is the point person who coordinates the care for that condition. The

third model is primary care (45%), which is the overall care of a person's health by a physician or nurse practitioner.

Cardiologist Mimi Guarneri, MD, from the Scripps Center for Integrative Medicine in San Diego, California, discussed a model of comprehensive cardiovascular care, describing her evolution from being an interventional cardiologist to taking an approach addressing "all the underlying issues for cardiovascular disease" to prevent it in the first place. She told *Medscape Medical News* that "none of this was taught to me in medical school. Things like nutrition...the role of depression and stress, physical activity, and so on are key to cardiovascular health, to brain health, to cancer prevention, and so on."

Taken as a whole, the report delineates how some major medical centers are practicing integrative medicine now, but it is short on solid measures of patient outcomes or cost-effectiveness. In this regard, Benjamin Kligler, MD, vice chair of the Department of Integrative Medicine at Beth Israel Medical Center, associate professor of Family and Social Medicine at Albert Einstein College of Medicine, and research director of the Continuum Center for Health and Healing, all in New York City, reiterated the goals of the survey, saying it was not an effectiveness outcomes study.

"This study was much more in the vein of health services information or utilization information than it is in effectiveness," he said to *Medscape Medical News*. However, he pointed out that Bravewell is also sponsoring a project called BraveNet, a practice-based research network that is carrying out effectiveness studies based on comparative effectiveness, and not randomized clinical trials.

Is Integrative Medicine "Little More Than Quackery?"

Steven L. Salzberg, PhD, professor of medicine and biostatistics in the McKusick-Nathans Institute of Genetic Medicine at Johns Hopkins University School of Medicine in Baltimore, Maryland, commented to *Medscape Medical News* about the survey and report. "It looks like a report that is simply trying to boost integrative medicine, which the Bravewell Collaborative funds a lot of integrative medicine programs, so they're basically boosting the things that they fund...something they call integrative medicine," he said. "But that is really a marketing term, and I would emphasize that strongly. That is a cover for a number of practices that are highly questionable and have no science to back them up — that don't actually help patients."

He continued, "It's little more than quackery, a lot of it. They are one of the leading groups doing it, and have money to back them up. There's lots of integrative medicine being practiced; therefore, the implication, which is the false part, is that therefore it must be good, must be valuable, must be giving people some benefit. But, of course, they're funding it, so it's spreading because there's money coming from groups like theirs that gets people to set up integrative

medicine centers, and then they go around and say, 'Oh, look, there's more integrative medicine centers now than there used to be, so there must be something to it.' It's a completely circular argument."

Dr. Salzberg also objects to integrative medicine touting itself as "personalized" to the individual patient's situation, with the implication that traditional practices are not. "Any good physician looks at the whole patient...that's what good medical care is all about." He also cites treatments based on the relatively new field of genomic analysis as very personalized, "but we're doing it scientifically."

He calls integrative "just a buzz word" that includes some practices that are legitimate, but also some he says are not. "By putting them all under the same umbrella...they're [supposedly] all legitimate. But that isn't true. It's a logical fallacy, but it's an argumentative strategy that they use here, and that's used many times," Dr. Salzberg said.

He faulted the report for not saying "a single thing about the effectiveness of the treatments. All that really matters: Is the treatment they're giving effective or not?" He also objected to the authors' considering all the interventions in aggregate. In his opinion, some treatments are valid, such as food/nutrition, yoga, meditation, and massage. However, "there's a lot of data, especially recent data, showing that almost all supplements are ineffective unless you have a deficiency," he said.

By grouping 34 different interventions together in the survey, he said, one cannot tell which ones are effective.

Pharmaceuticals are "just conventional medicine," he said. "And then they throw in something which is just complete quackery in the middle," referring to TCM and acupuncture. He noted that all recent studies of acupuncture showed it is no better than placebo, and that the positive studies have been too small or poorly designed, in his opinion.

In conventional medicine, practices that are proven not to work are discarded. "The difference with pseudoscience is that they ignore the evidence, and they continue to practice and make excuses for why the studies didn't come out the way they wanted to come out," he explained. "The well-done studies are uniformly negative when they look at most of these modalities."
He said that in his view as a scientist, "if you're going to go do a survey about any medical practice, you want to see whether it's effective. That should be the first question, not how many people are using it, but how many people are getting benefit." A lot of the growth in the practice of integrative medicine "is driven by the fact that if you make money available," medical

centers will pick up on it, Dr. Salzberg said, and furthermore, "these centers themselves do a lot of marketing, and people respond to marketing."

In a self-selected population such as patients going to integrative medicine practitioners, patients probably respond to the time and attention they receive, and so report high levels of satisfaction. Also, many conditions wax and wane, and patients often seek care when symptoms are at their worst, such as chronic pain. They may attribute relief of symptoms to the intervention, when in fact, symptoms may often subside on their own, Dr. Salzberg said.

Elaborate Placebo?

David Gorski, MD, PhD, associate professor of surgery at Wayne State University School of Medicine and the Breast Multidisciplinary Team Leader at the Karmanos Cancer Institute in Detroit, Michigan, told *Medscape Medical News* that the Bravewell report is "very credulous" and "totally buys into what we like to call the bait-and-switch of [complementary and alternative medicine], which is where they rebrand various things that should be science-based medicine as being somehow alternative."

He said that "there is nothing alternative" about food and nutrition; that yoga is exercise, so it is a lifestyle intervention; that meditation is relaxation; and that massage feels good — none of which he objects to — but he agrees with Dr. Salzberg that modalities such as TCM and acupuncture get "mixed in there."

Dr. Gorski referred to a lot of complementary and alternative medicine as "elaborate placebo, and we all know that placebo effects are strengthened when there is belief and trust in the practitioner, and that's certainly what a lot of this seems to boil down to.... They don't have good health outcome measures...I noticed that a lot of what they tracked as outcomes was patient satisfaction."

He said integrative medicine should be held to the same standards, using the same methods, as conventional medicine. Asked whether there should be a formal discipline of integrative medicine, he responded emphatically, "Absolutely not. It's a false dichotomy.... We already should be integrating things that are shown to be effective in clinical trials without having to have a special category for it.

IS IT TIME FOR HEADACHE MEDICINE TO COMPLEMENT "CONVENTION" WITH ALTERNATIVE PRACTICES?

http://www.medscape.com/viewarticle/746812

What are headache sufferers and their healthcare providers to do? There are so many aspects of diagnosis and care to consider. For the sufferer, important issues may include stress and/or anxiety related to pain and its treatment, including the expense, availability, effectiveness, tolerability, and safety of the treatment(s) provided. For both, there are communication issues, 1-way or 2-way, as between sufferers and family, friends, strangers (Internet), or healthcare providers; the last is often the least thorough. Most exchanges are well-meaning … but good intentions do not necessarily ensure a positive result

Paradigm shifts, according to Thomas Kuhn, are scientific revolutions that happen non-linearly due to the inability to solve a problem sufficiently with current scientific concepts.[1,20] WIM represents a paradigm shift in the practice of headache medicine which seems warranted today to improve the management of chronic daily headache … if not for all headache disorders. As the application of WIM is beyond the capability of any single provider, a team approach will be required to accomplish such treatment most effectively.

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POPULAR USE OF TRADITIONAL CHINESE MEDICINE IN HIV PATIENTS IN THE HAART ERA

http://www.medscape.com/viewarticle/579102

We set out to explore the pattern of TCM use by ethnic Chinese HIV patients. Hong Kong is uniquely positioned for such a study in light of the high proportion of Chinese patients, access to TCM and TCM practitioners, superimposed on the pre-existing western health care system. HAART has become a standard of HIV treatment in the territory since the mid-nineties, enabling the impacts of TCM use to be studied.

A self-administered anonymised questionnaire survey was administered to eligible patients. The respondents were asked to complete it while waiting for/after consultation at the Centre in confidence. Questions in the survey covered the following areas:(a) report of TCM use, (b) general beliefs and perception about TCM; (c) association of TCM use with HAART, and (d) sources of advice on TCM. TCM use was defined as the consumption of recipes as prescribed by TCM practitioners, products perceived to be TCM in nature and purchased over the counter (OTC) or provided by other people, like friends or relatives. This relatively loose definition was used in order to capture all potentially relevant information as well as the perception of

individuals.The questionnaires were coded and additional information was retrieved from the clinical information system, with the consent of the patients: latest clinical staging (CDC, 1992); CD4 and viral load readings.

A research nurse presented all interested patients during the study period with an explanation of the study, a consent form,and the self-administered questionnaire for completion.

The survey was conducted over a four-week period in July and August 2005. Eighty-two patients were recruited, accounting for 36.4% of all patients attending the clinic in the same period of time. The results of 76 successfully completed questionnaires were finally available for analysis. There was no significant difference between the age, viral load and CD4 counts between recruited patients and those who had not been recruited (results not shown).

Patients who had used TCM were classified as *Infrequent* or *Common Users*. *Infrequent Users* were those that reported using any 1 or more types of TCM only 1-2 times in the preceding 6 months, such as patients who had sampled one form of TCM but had not used it habitually. The more frequent users and those taking TCM regularly were classified as *Common Users*. Using this criteria, 11 (14.5%) were *Infrequent* TCM Users and 33 (43.4%) were *Common Users* (the two did not add up to 45 because of one missing entry). There's no difference in age, duration of illness and HAART between the two groups.

Comparing between TCM and western medicine, a majority (58/75, 77.3%) believed that the latter was more effective in treating major illnesses; whereas opinion on minor illness was split. Overall, many believed TCM to be useful for supporting the maintenance of health (56/75, 74.7%). In the event of a minor medical problem, many (33/76, 43.4%) preferred to see only western doctor, or not seeking any advice (27/76, 35.5%) instead of consulting a TCM practitioner in the first place (4/76, 5.3%).

This is the first study addressing the use of TCM in a Chinese population on HAART, showing that the practice was common. The main indication was general health maintenance, and/or treatment for minor illness, rather than specifically for HIV/AIDS. A good variety of TCM products were used, many of which might not actually be considered medicinal in nature in Chinese communities. The difference in the definition of TCM and the perception of patients about what constituted TCM could have affected the reported frequency in this and other study. Lingzhi, for example, is commonly used to improve health status, prolong life or sometimes as a tonic (Jong & Birmingham, 1992). Herbal tea was widely used for treating common cold or other minor ailments, and was the most common TCM product consumed in our study. The ready access to these products and the customary use in families probably explain their popularity. More than half of our TCM users did not consult any TCM practitioners upon their consumption.

Over-the-counter TCM was actually preferred by patients. Although the use of TCM was common among those who have developed AIDS, further study is needed to explore the relationship between TCM use and severity of the illness.

HIGHLIGHTS OF THE INTERNATIONAL CONFERENCE AND EXHIBITION OF THE MODERNIZATION OF TRADITIONAL CHINESE MEDICINE AND HEALTH PRODUCTS

http://www.medscape.com/viewarticle/511877

As a "western" rheumatologist attending this meeting, there is increasing awareness that a large proportion (perhaps a majority) of our patients are using nutritional supplements including herbs. Some health insurance providers even pay for the cost of such supplements.[1] However, most western physicians remain largely unaware of the use of these medications (supplements) by their patients, as well as their potential efficacy or their toxicity when combined with other herbs or with western medications.

As a specific example of differences between western and TCM, we will review RA as a diagnostic category. Although criteria for RA are considered "well defined" in western medicine, RA does not clearly fit into a specific TCM classification based on concepts of "ying," "yang," and "qi."

The conceptual foundation of TCM is entirely different from that of western medicine. Also, mixtures of herbs are frequently adjusted (often every 2 weeks) based on the ongoing assessment of the TCM practitioner.

Many patients in China and in the United States use herbal medicines (which I call "nutriceuticals" to indicate their regulation as food supplements) as an adjunct to their western medication regimens.[2,3] The nutriceuticals historically were classified as "benign," "intermediate," or "potentially toxic" in the original herbal compendium that was written over 1000 years ago.[4] Virtually all of the herbs used as nutriceuticals are considered as benign. However, any single component (such as ginseng) may have different content in a given preparation based on the location of growth, time of harvest, and method of extraction.[5,6] Because these substances are herbal, they may be subject to contamination by heavy metals and pesticides, and there may be problems with sterility.[5,6] Additionally, unfortunately, we may also encounter problems associated with adulteration of the herbs by unscrupulous manufacturers who may add other compounds such as cortisone, phenylbutazone, or aminopyrine before selling the herb as a "pill." This problem is distinct from the intrinsic cortisone-like activity found in some herbs. The speakers emphasized that any unregulated

industry, such as that of nutriceuticals, will have its share of unscrupulous manufacturers, and that many preparations sold overseas as "herbal medications" are being prescribed by individuals (both Chinese and non-Chinese) with minimal training in either herbal medicine or traditional Chinese medicine in general.

Several pharmaceutical companies have begun marketing standardized preparations of herbal extracts. While these newer products provide a much higher grade and relatively "predictable" response that physicians can recommend to their patients, they paradoxically raise a number of controversial issues for patients who want a "natural product." For these patients, it is not clear whether these products represent herbs or are actually new pharmaceutical agents. Thus, for the pure herbalists, these extracts and pharmaceutical productions may be regarded as "drugs" because they do not use the entire plant with all of its constituents.[4,17] An additional challenge to standardization and use is the "misuse" of herbal medications, as exemplified by the recent removal from market of ephedra. This herbal extract was used for treatment of asthma in TCM rather than the higher doses used in the west for weight reduction.[4,17] Despite these challenges, this pharmacologic approach to standardization and the development of databases may ultimately answer questions about relative efficacy and safety.

Professors CS Lau and U. Chau Leung reviewed the philosophical orientation of users of TCM in Hong Kong and in the United States. They noted that users of TCM are generally not dissatisfied with conventional "Western" medicine, but find alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life.[15]

Additional sessions of the meeting were devoted to acupuncture. This is a source of frustration to the western rheumatologist, who does not recognize an anatomic basis for use of acupuncture that is intended to "unblock channels where energy is trapped." Thus, we have a paradox. Many western physicians have patients (or family members) who enthusiastically embrace acupuncture for pain relief. However, they have little in the way of positive randomized, double-blind control trials. This has led western physicians to suggest that the entire response is a "placebo" effect. Prof. Wolfgang Weidenhammer of the University of Koblenz (Germany) reported that acupuncture using traditionally targeted points was not superior to minimal acupuncture that scrupulously avoided the traditional points. However, outcomes derived by both "true" acupuncture and "sham" acupuncture appeared to be markedly better than doing nothing (placebo). This failure of acupuncture in "double" blind trials has been previously reviewed in the US literature by Kaptchuk.[36] Nevertheless, the use of acupuncture has a persuasive appeal as judged by the number of patients who pay "out of pocket" for these treatments and thus express their satisfaction.[10]

Part of the schism between western physicians and their patients involves the concept that herbs are natural, while western medications are "drugs" and thereby less safe and less natural. Acupuncture is an example of this schism where randomized trials do not show efficacy but the practice of acupuncture is becoming increasingly popular. Most western rheumatologists feel "why not give acupuncture a try, it is a safe placebo." Indeed, the perception of "wellness" in the brain resulting from acupuncture may lead to beneficial changes in endogenous transmitters of pain.[36] The interest in acupuncture has led to recent studies using functional MRI of the brain and the abolition of acupuncture effect with opioid antagonists suggests that humility toward these methods is still warranted. Before we dismiss the value of acupuncture as a placebo, it is certainly worth looking at the placebo curve in virtually all drugs approved for RA by the FDA. The key may be the qi of the acupuncturist, the quality of the physician-patient relationship in terms of trust, or simply the act of the physician being a "witness" or "facilitator" to help the patient cope with the illness. All of these "interventions" may be at least as important as the medications we prescribe to ultimately help the patient function more optimally. Perhaps, it is timely to re-visit the history of western medicine, that we come from a 200-year-old tradition of use of heavy metals (arsenic), herbs, and blood letting.[7]

As an observer, I was impressed with the parallel of TCM with the role of "prayer" or religion in healing. Certainly, the role of coping with illness has played a key role in the western Judeo-Christian society. At a minimum, the doctor- patient relationship has an inherent therapeutic value and this certainly plays a role in both western and TCM. However, the therapeutic value of prayer is difficult to validate in a randomized control trial, but it remains a very important response to the illness of a relative. Thus, it seems that TCM has a kindred philosophical system of Confucianism and Taoism. The diagnosis in TCM is based on the precept that sensory perceptions and ordinary appearances are sufficient to understand the human condition, including health and illness.

TCM approach to help western physicians unfamiliar with the historical framework better understand TCM. The concept of TCM have been recently reviewed in the western literature.[36-38]

Yin. *Yin* is associated with cold, darkness, being stationary, passiveness, receptivity, tranquility, and quiescence.[39]

Yang. *Yang* is associated with heat, light, stimulation, excess, assertiveness, dominance, movement, arousal, and dynamic potential.[39]

In TCM, these complementary opposites are successively intertwined for additional levels of descriptive refinement. A simple example is dampness. It has the *yin* qualities of cold, wet, soft,

and lingering and also the *yang* qualities of excessiveness, dominance, heaviness, and "inexhaustible abundance." TCM suggests that dampness is easy to recognize and that it applies to "psychological, ecological, and even moral as well as corporeal phenomena." Some damp signs point to imbalance, or "bad weather," for example, weeping eczema, edema, "slippery" pulse, heaviness in digestion, indecision, clinging, or being helpful to others at the expense of oneself. Some dampness is an essential component of a healthy state of being, for example, smooth skin, normal secretions and excretions, being imperturbable when threatened, generosity, and patience.

In addition to a general synthesis, *yin* and *yang* and their climatic subcategories are used to interpret specific "subregions" of a person's health. These subregions can be different from a person's general meteorological pattern and can create overlapping domains of *yin* and *yang* (for example, *yins* within *yangs*) that are as complex as multiple, intersecting circles. Both for the overview pattern and for the subregions, no single sign is conclusive; the overall context defines the parts. Heaviness in digestion or generosity might be "wind" if it appeared in a different configuration of signs. Unlike western medicine, in which signs and symptoms are used analytically to isolate an underlying mechanism, East Asian medicine seeks to discern a qualitative image in the overall gestalt or regions of a person's signs and behaviors. Whereas biomedicine aspires toward the scientific and dimensionally measurable quantitative, East Asian medicine emphasizes a *human-centered* approach of artistic impressions and sensitivities. If TCM resembles anything in the West, it would be the pre-scientific but rational Greek humoral medical system, which also perceived health status in such images of weather as phlegmatic (cold-moist) and choleric (hot-dry).

Qi. In TCM, *Qi* is the "life force" that is similar to the ancient Greek notion of pneuma, and takes on a myriad of forms. The concept of *qi* for the Chinese provides a rationale for explaining positive healing energy. Whether qi is some kind of "real" quantitative energy in the western sense (akin to 19th century vitalist life-force) or an internal "energy pathway" is assumed in classic Asian thought. In addition, the target of treatment in TCM is the state of the body's "disharmony," any imbalance in *yin-yang* and its connecting *qi*. There has been increasing recognition of benefit in chronic disease by non-medicinal methods such as tai chi and yoga.

An analogy is the weather report. Large scientific computers have difficulty predicting weather patterns with certainty more than a few days in advance, but on a particular day, it is clear that it is raining. Thus, western medicine is the long-range diagnosis and TCM is the daily weather report. Some conditions such as RA have a daily status detected by TCM but the different goal of western medicine is long-term forecasting. The example of RA indicates the difficulty that western medicine will have in evaluating results of TCM studies and developing a uniform policy

for credentialing TCM practitioners or therapy.[45] Thus, the immediate goal is to use traditional medications in a western style randomized trial.

TRADITIONAL ACUPUNCTURE IN MIGRAINE: A CONTROLLED, RANDOMIZED STUDY

http://www.medscape.com/viewarticle/572382

Objective: To check the effectiveness of a true acupuncture treatment according to traditional Chinese medicine (TCM) in migraine without aura, comparing it to a standard mock acupuncture protocol, an accurate mock acupuncture healing ritual, and untreated controls.

Migraine prevalence is high and affects a high rate of adults in the productive phase of their life, causing significant disability and loss of daily activities, with relevant social and economic costs.[1–4] Furthermore, the majority of patients suffering from migraine report tension-type symptoms.[5–8] Despite the continuous progress in diagnosis and pharmacologic treatment of migraine, the outcome is still below the expectations: as a result, acupuncture and other non pharmacologic treatments have been increasingly advocated and used in western countries. In 1998 the NIH stated that acupuncture could be a useful adjunct treatment or an acceptable alternative in several disturbances, including headache,[9] while a recent study reported that some 12% of patients attending a neurology outpatient clinic had already tried acupuncture and 73% would be willing to do it.[10]

Recently, 3 studies with these features have been published,[16–18] 2 of them conclude that acupuncture provides persisting, relevant clinical benefits and health-related quality of life at a small additional cost, suggesting that an increase of acupuncture services in UK should be considered. The third study reports some effectiveness of both true and sham acupuncture at short-term follow-up (12 weeks), when compared to waiting list controls, but no difference between true and sham acupuncture; this gives rise to some concern about the specificity of acupoint selection, at least at a short-term outcome.

Acupuncture involves several specific problems related to research methods, including the problem of placebo (sham acupuncture is far from being a real placebo) and appropriate acupoint selection (see[19] as a review). As far as migraine is concerned, none of the published reviews properly addresses the problem of acupoint selection,[19,20] apart from the Cochrane review. A large variability of treatments was present in the studies quoted in the published systematic reviews, most of which seemed inappropriate according to traditional Chinese medicine (TCM).[20] As the acupoint selection is often skipped, the low level of evidence of acupuncture effectiveness might partly depend on inappropriate treatment,which might have a key role for efficacy (likewise the use of different drugs in Western medicine).

Acupuncture Treatment.—Since the Western picture of migraine does not clash with TCM classification of headache, all the patients were clinically evaluated according to the TCM syndrome differentiation and classified into the following, so called, internal or external syndromes:[23–26] (1) exogenous wind-cold attack; (2) exogenous wind-heat attack; (3) exogenous wind-dampness attack; (4) excess of liver yang; (5) obstruction of the middle jiao due to damp-phlegm; (6) deficiency of kidney essence; (7) stagnation of Qi and blood. Each type of syndrome was treated with a specific acupoint selection according to TCM (Table 1), as suggested by Liu Gongwan (Tianjin College of Traditional Chinese Medicine, personal communication); the acupoints were defined according to the WHO standard acupuncture nomenclature.
Twice a week, all the patients were submitted to 2 courses of 10 acupuncture applications each, with a 1-week rest between the 2 courses. Acupuncture was performed with single-use stainless steel filiform needles (according to Chinese manufacturing standards), 25 or 40 mm long and with a Ø of 0.30 mm.

Headache is a major public health problem, due to its high prevalence. Despite the great progress in pharmacologic treatment, many patients do not achieve optimal control, or do so only at the expense of unacceptable side-effects. As a result, an increasing use of behavioral as well as non-conventional therapies has occurred in the past 2 decades: acupuncture has been reported to be used by 19% of patients and is perceived as the most effective non-conventional treatment.[27] Similar data have been reported in migraine,[10] where about 12% of patients attending a neurology outpatient clinic reported that they had already tried acupuncture and 73% would be willing to try it. A recent review provides the rationale for traditional acupuncture indication in headache.[28]

Given its proven mechanisms in analgesia,[28,37,38] acupuncture might provide long-lasting relief in headache with a substantial lack of side effects. The wealth of available data strongly support the value of acupuncture for the prevention of headache,[11–15] but evidence still remains weak; a major source of weakness seems to be the bias introduced by variability of study designs and acupoint selection.

As far as acupoint selection is concerned, it is so variable in the published studies, as to prevent any evaluation of effectiveness.[19,20] Sometimes the authors do not even mention the acupoints they have chosen,[17,18] or only partially report them.[16]

Among TCM syndromes, the so-called “excess of Liver yang” and “deficiency of Kidney essence” seem to be the ones closer to Western migraine, since they imply throbbing pain, vomiting, and/or worsening with physical activity.[26] These 2 syndromes were found in nearly 50% of cases in our series, while the remaining ones probably reflected the coexistence of migraine and tension-type symptoms, indicating different acupuncture treatments.

The transient effects observed in group RMA can therefore be assigned to a placebo effect, although the limit between a simple placebo and a true effect may not be so well defined. In fact, one cannot easily rule out that the closer physician-patient relationship yielded by the TCM approach might positively affect the treatment, through an iatroplacebogenesis rather than a simple placebo.[39]

We do believe that acupoint selection plays a key role for effectiveness, and we are to face TCM in the process of acupuncture validation. It is the "true" acupuncture, with an enormous store of tradition and empirical knowledge, trickled out over 2,000 years of practice and still routinely used in Chinese hospitals. Western medicine and TCM are 2 deeply different worlds with different paradigms, which seem incompatible at a first glance. A correct approach to TCM has strong epistemological implications, but this cannot prevent us from trying to build a bridge between the 2, which is essential for acupuncture understanding.

A Randomized, Controlled Pilot Study of Acupuncture Treatment for Menopausal Hot Flashes

http://www.medscape.com/viewarticle/583598

Objective: To investigate the feasibility of conducting a randomized trial of the effect of acupuncture in decreasing hot flashes in peri- and postmenopausal women.

Conclusions: These results suggest either that there is a strong placebo effect or that both traditional and sham acupuncture significantly reduce hot flash frequency.
Participants assigned to acupuncture (both TCM and sham) were seen twice a week for 8 weeks (a total of 16 treatment sessions) by a trained acupuncturist. Study staff who administered questionnaires were blinded to which form of acupuncture that the women received. All study participants were instructed not to take hormonal medications or initiate other treatments for their hot flashes during treatment. All study participants (including those in the UC group) were paid $10 for each clinic visit (baseline, mid-treatment, and end of treatment). Those who completed all three visits were paid an additional $20.

Sterile, single-use, Vinco 34-gauge, 1-inch (0.22 x 25 mm) and 30-gauge, 1.5-inch (0.30 x 40 mm) needles were used. Needles were inserted through the skin to a depth of from 0.5 to 3 cm based on anatomical location. Acupuncturists attempted to achieve a *de Qi* sensation upon insertion of acupuncture needles (a sensation of soreness, numbness, heaviness, or distention around the needled acupuncture point), whenever possible. The duration of each treatment was approximately 30 minutes: 20 minutes for anterior points and 10 minutes for posterior points.

Conclusions

In this three-arm randomized trial of acupuncture for menopausal hot flashes, both TA and SA produced a significant decrease in hot flashes compared with a no-treatment, UC group. Whether this result was due to the effectiveness of sham needling or a placebo effect could not be determined.

THE REALITY OF "TRADITIONAL CHINESE" MEDICINES

http://www.medscape.com/viewarticle/541341

TCM developed in a tradition of an authoritarian culture. Independent thinking and argument were discouraged. A tradition of objective science did not develop.[2]

Diseases were not described. Symptoms and physical characteristics were related only to natural elements and the cosmos. Ideas conformed to those of the emperor and state. TCM contained no concept of physiology, biochemistry, organ function, heredity, or infectious disease. Tongue and pulse diagnoses were essentially random; therapies based on them were useless -- accepted on authority, not proved.[3]

What made TCM therapies appear effective? A collection of nonspecific psychological mechanisms, now known to be sources of error: misdirection, counterirritation (in the case of acupuncture and moxibustion), suggestion, and compliance demand. These observational errors and treater-subject interactions resulted in erroneous post hoc conclusions. Error was compounded by inability to identify error itself or to detect long-term effects. Conditioning and reinforcement, amplified by social pressures, created patient satisfaction and appearance of therapeutic success.[4]

New anthropological findings and China scholars' re-evaluation indicate that acupuncture descended from various informal techniques, not formalized until the 19th and 20th centuries, largely by Europeans[5,6] and in China by the cultural revolution. TCM is not highly regarded by modern Chinese physicians, as 85% or more of medicine there is scientific, and TCM is utilized through self-referral.[7]

TCM advocates in Western countries alternately propose that acupuncture effects have other scientific explanations, but unless they can prove that it has real effects and does not work through these nonspecific mechanisms that can apply to any method, their claims remain unverified and probably erroneous.
That's my opinion. I'm Dr. Wallace Sampson of the *MedGenMed* Editorial Board.

READERS' RESPONSES AND AUTHOR'S REPLY TO "THE REALITY OF 'TRADITIONAL CHINESE' MEDICINES"

http://www.medscape.com/viewarticle/548353

The point is that medical science along with other sciences did not develop at the same rate in China as they did in Euro-America because of cultural-political reasons. In addition, some modern forms of TCM were developed not in China, but in Europe and North America. One major organization of acupuncture occurred in France in the 19th and 20th centuries during waves of popularity in Europe. Ear acupuncture was an invention of a French physician in the 1920s-1930s. The last significant formal reorganization occurred in post World War II China, politically influenced by the Marxist state and the Cultural Revolution.

A series of heated questions & answers by polarized views is presented. View article for full details.

ACUPUNCTURE FOR CHRONIC LOW BACK PAIN: DIAGNOSIS AND TREATMENT PATTERNS AMONG ACUPUNCTURISTS EVALUATING THE SAME PATIENT

http://www.medscape.com/viewarticle/410779

Methods. Seven office-based acupuncturists practicing Traditional Chinese Medicine evaluated the same patient with chronic low back pain and provided data regarding principal assessment techniques, diagnoses, and therapeutic recommendations.

Results. A high diagnostic agreement existed among 5 of 7 acupuncturists. However, recommended treatments included varying numbers and locations of acupuncture points. Recommendations varied between 5 and 14 points requiring 7 to 26 needles, since many points were intended for bilateral application. Of 28 acupuncture points selected, only 4 (14%) were prescribed by two or more acupuncturists. Most recommended various forms of adjuvant heat.

Conclusions. Seven acupuncturists agreed considerably in the diagnoses for the same patient with chronic low back pain, but treatment recommendations varied substantially. Clinicians and researchers must recognize treatment recommendation variations and the challenges they present for study design and interpretation.

Two national surveys indicate that back pain is among the most common reasons for a visit to an alternative medicine practitioner.[2,3]

This study was part of a larger trial designed to compare the effectiveness of TCM acupuncture, massage, and self-care educational materials for persistent low back pain.[10]

Acupuncturists use a variety of diagnostic assessment techniques that include inspection and palpation. Therapeutic modalities are most likely to include the insertion of needles and application of heat. Assessments are highly individualized, and specific points do not necessarily coincide with the site of the symptoms. There appears to be substantial variability among acupuncturists in the treatments they prescribe. More research is needed to better understand the impact that variability among acupuncturists has on clinical outcomes and on the design and interpretation of effectiveness studies.

ACUPUNCTURE: A CLINICAL REVIEW

http://www.medscape.com/viewarticle/501973

This article summarizes the research base, probable mechanism of actions, and clinical applications of acupuncture. It offers the clinician a deeper understanding of appropriate conditions for which acupuncture may be useful, outlines how to integrate acupuncture into a clinical practice, and describes referral and training issues.

Key principles in traditional Chinese medicine (TCM) are that both wellness and illness result from an imbalance of *yin* and *yang.* Yin refers to the feminine aspect of life: nourishing, lower, cool, deficient, inside, receptive, protective, soft, yielding. Yang is the male counterpoint: hard, dominant, energetic, upper, hot, excessive, outside, creative. The movement between these opposite forces, named *Qi,* is considered to be the essential element in the healing system of TCM. It is best thought of as energy becoming manifest, a vitalistic force that flows ceaselessly through the meridians, or energy channels of the body.

Skeptics maintain that acupuncture has basically a placebo effect, since the acupuncture meridians and their energy or chi (Qi) as described in TCM cannot be directly observed, dissected, or measured with standard anatomic approaches or physiologic instrumentation. The acupoints are located at sites that have a high density of neurovascular structures and are generally between or at the edges of muscle groups.[5] These locations, curiously, are less painful than random needle sticks into a muscle group. An interesting study demonstrating the map of a meridian pathway involved the injection of Technitium99, a radioactive tracer, into both true and sham acupoints.[6] The scan of the injection sites showed random diffusion of the tracer around the sham point but rapid progression of the tracer along the meridian at a rate that was inconsistent with either lymphatic/vascular flow or nerve conduction. Another study demonstrated that needling a point on the lower leg traditionally associated with the eye activated the occipital cortex of the brain as detected by functional magnetic resonance imaging.[7]

Opium addicts who underwent acupuncture analgesia for surgery were noted not to go through narcotic withdrawal compared with similar patients who received conventional anesthesia. This gave birth to the endorphin hypothesis, which has been explored as one of the mechanisms of action of acupuncture. Needling affects cerebrospinal fluid levels of endorphin and enkephalin, and such effects can be blocked by the opiate antagonist naloxone. A number of other imputed mechanisms of action have used the model of the acupuncture needle as an electrode, which activates changes in the ionic milieu of the interstitial fluid, these changes being rapidly conducted along the fascial lamellar planes by the highly conductive electrolyte medium. Because nociceptive stimulation, such as with a transcutaneous electrical nerve stimulation unit, is known to block pain perception, the neurogate theory has also been suggested as a mechanism of action for acupuncture.[8]

The presence of a foreign body (the needle) may act to stimulate vascular and immunomodulatory factors, including locally occurring mediators of inflammation. Measurements of adrenocorticotropic hormone (ACTH) have been demonstrated to be elevated after acupuncture treatments, suggesting that adrenal activation and release of endogenous corticosteroids may also result from acupuncture. Various physics concepts such as quantum physics, electromagnetic force field changes, and wave phenomena have been proffered to explain the nonlocal effects of acupuncture.[9,10]
Dangers))

Some patients do not tolerate acupuncture either because of a needle phobia or the inability to remain in a comfortable position for treatment. Septic or extremely weakened patients, those who are uncooperative because of delusions, hallucinations, or paranoia, are likewise unsuitable. Local infections such as cellulitis or loss of skin integrity from burns or ulcerations may preclude certain local treatments. Electroacupuncture should not be applied over the heart or brain or in the region of an implanted electrical device such as a pacemaker or medication pump. Hemophiliacs and others with severe bleeding disorders should be excluded from acupuncture treatment.[1]

There are approximately 17,000 acupuncturists in the United States, with most having been trained as Oriental Medical Doctors, Doctors of Oriental Medicine, or Licensed Acupuncturists. The National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM) maintains a database of 13,000 practitioners distributed in every state in the United States who have completed their certification process (http://www.nccaom.com).[26]

Training here and abroad is usually a 3- to 4-year process, including all aspects of TCM, which includes not only acupuncture but also herbalism, massage, dietary therapy, and exercise programs such as tai chi and qi gong. The herbalism aspect of these programs is intense, since

TCM formulas are often a mixture of 9 to 12 herbs and other substances meant to balance the system in a complex way. Most schools provide 500 hours or more of Western medical science focusing primarily on identifying conditions, which need referral to a medical doctor, for example, myocardial infarction, cancer, or significant weight loss. They also teach familiarity with biomedical terminology, the referral and consultation process, and the diagnostic and therapeutic tools of Western physicians.

The ancient method of acupuncture has gained significant popularity in our era, particularly among non-Asian populations. Because of its long history of use, safety, and reports of efficacy, more patients select acupuncture as part of their therapeutic plan. Although thorough clinical trials of the reported benefits of acupuncture as well as understanding of its mechanism of action lag behind its widespread use, physicians ought to become familiar with its potential applications for their patients. Some physicians may wish to expand the scope of his or her practice by taking additional training to administer acupuncture. However, even if one does not add this training, knowing how to refer to credible, well-trained acupuncturists and for what indications is increasingly important in the evolving model of integrative medicine, combining the best of both scientific medicine and traditional systems of care.

POTENTIAL SYNERGISM BETWEEN HYPNOSIS AND ACUPUNCTURE -- IS THE WHOLE MORE THAN THE SUM OF ITS PARTS?

http://www.medscape.com/viewarticle/559778

Both hypnosis and acupuncture have gained credibility over the years in their effectiveness for treating various health conditions. Currently, each of these treatments is administered in distinct settings and separate times. That is, even if patients receive both treatments as part of a multidimensional therapeutic program, they would typically receive them separately rather than simultaneously at the same session. This separation however might be undesirable since, at least theoretically, hypnosis and acupuncture could potentially augment each other if administered concomitantly. In this article we outline the rationale for this hypothesis and discuss the potential ramifications of its implementation.

According to traditional Chinese medicine (TCM) theory, certain points on the body are linked together in a network of channels called 'meridians'.[1] The meridians conduct Qi, a vital force that animates all living things. Qi is believed to regulate spiritual, emotional, mental and physical balance. TCM theory asserts that a smooth and adequate flow of Qi defines health and suggests that the various characteristics of Qi are determined by a complex set of interactions between external and internal factors (e.g. genetic predisposition, nutrition, physical and emotional influences).[2] TCM practitioners believe that acupuncture may facilitate normal flow of Qi, thus

maintaining or restoring health to the body and mind. Various forms and styles of acupuncture are used to that end. In the most traditional form, fine needles are inserted into well-defined anatomic locations (acupoints). A typical acupuncture session includes an initial assessment according to which acupoints are selected and needled. Patients usually lie with needles in place for 2030 min.

The mechanisms by which acupuncture elicits its effects are believed to be the result of three factors:[3]

1. 'Specific' physiologicaleffects that are believed to be directly related to the needling of particular acupoints;

2. 'Nonspecific' physiologicaleffects that arise from the micro trauma resulting from piercing the skin, a procedure that has been shown to induce a variety of physiological responses involving the microcirculation, local immune function, and neurally mediated analgesia and

3. 'Nonspecific' psychologicaleffects that arise concomitantly with the treatment and emanate from a variety of sources including, but not limited to, treatment environment, patient expectations, practitioner intention, patient-provider rapport, and the natural history of the condition.[4]

State of relaxation

Following needle insertion, several characteristics associated with light (hypnoidal) hypnotic state such as slow, deeper breathing, progressive feelings of lethargy and relaxation are often observed.[41] It has been postulated that even at this light level of hypnotic state and relaxation, suggestibility is already enhanced.[42] Thus, acupuncture may facilitate a process in which the hypnotic state experience may occur. This may be important for two practical reasons. First, in cases where patients subconsciously display resistance to hypnosis and have a hard time entering a hypnotic state,[43] acupuncture may help to bypass that resistance by facilitating a state of relaxation. Second, it is generally agreed that the deeper the hypnotic state the more suggestible the subject is.[44] Furthermore, certain hypnotic phenomena such as hypnoanalgesia are believed to occur primarily in a deeper hypnotic state.[42] After overcoming the initial resistance and entering hypnotic state, it would be less difficult to deepen that state, for various applications, using the hypno-acupuncture combination. We suggest that the relaxation state that hypno-acupuncture induces may help patients reach and maintain a deep hypnotic state, which is needed for the hypnotic work.

In our experience, the idea of hypno-acupuncture may not only be scientifically plausible, but is also practically feasible. Once inserted, acupuncture needles are usually retained in place for ~2030 min. It is mainly during that relative 'downtime' period that we suggest that patients would enjoy the hypnotic component of hypno-acupuncture. We propose that this time could be utilized to empower patients by providing them with hypnotic suggestions related to their disease condition, the healing power of both hypnosis and acupuncture, and the importance of health and well-being.

Synergism is defined as the 'interaction of discrete agents (as drugs), or conditions such that the total effect is greater than the sum of the individual effects'.[55] Thus, synergism should be distinguished from 'additivity' that, briefly stated, means that each therapeutic constituent contributes to the total effect in accord with its own potency. A typical example of synergism is the deadly combination of alcohol and narcotics, which in most instances is clearly more harmful than either alone.

In conclusion, we present a new hypothesis that suggests synergism between two relatively safe and inexpensive modalitieshypnosis and acupuncture. We call for rigorous testing of that hypothesis through a new line of research that will inform clinical practice guidelines and health policy decision-making regarding the potential integration of hypno-acupuncture into healthcare.

Placebo-Controlled Trials of Chinese Herbal Medicine and Conventional Medicine-Comparative Study

http://www.medscape.com/viewarticle/567456

Background: Chinese herbal medicine (CHM) is increasingly used in the West, but the evidence on its effectiveness is a matter of debate. We compared the characteristics, study quality and results of clinical trials of CHM and conventional medicine

Clinical Evaluation of Perspiration Reducing Effects of a Kampo Formula, Shigyaku-san, on Palmoplantar Hidrosis

http://www.medscape.com/viewarticle/584402

Palmoplantar hidrosis is common in patients who are susceptible to strain on the autonomic nervous system, and stress and mental strain have been proven to produce sweating in this population. It is known that physiological sweating due to exercise is mediated by stimulation of the sudorific center in the hypothalamus, while sweating due to stress is mediated by stimulation of the sudorific center in the frontal area, which causes an increase in autonomic nerve strain that leads to palmoplantar sweating.[1,2]

Patients with palmoplantar hidrosis often present with lower body coldness, purulent blisters, erythema, facial flushing, atopic dermatitis, constipation and menstrual disorders.

In the present study, I evaluated the effects of Shigyaku-san (Sini san, TJ-35: Tsumura & Co., Tokyo, Japan)[3] on sweat volume and skin temperature in patients with palmoplantar hidrosis with such troublesome complications. Shigyaku-san seems to be effective for relieving stagnation of liver Qi and vital energy in traditional Chinese medicine (TCM) theory, leading to an improvement in palmoplantar hidrosis and its accompanying symptoms.

Preparation of Herbs

Shigyaku-san (TJ-35) is composed of 5 g (dry weight/day) Saiko (chai hu, Bupleuri Radix), 4 g Shakuyaku (shao yao, Paeoniae Radix), 2 g Kijitsu (zhi shi, Aurantii Fructus Immaturus) and 1.5 g Kanzo (gan cao, Glycyrrhizae Radix). All herb mixtures were extracted with boiling water and spray-dried to generate granules by adding dextrose.

Shigyaku-san is used to treat conditions in which liver Qi stagnates around the hypochondrium and upper abdomen, inhibiting the spreading of Yang Qi to the extremities. (Yang Qi is the capacity of the body to generate and maintain warmth and circulation.) Coldness of the extremities in spite of warmth of the body is related to the inability of Yang Qi to move outward due to the stagnation of liver Qi. In other words, stagnation of liver Qi is the major causative factor of coldness of the extremities.[15-17]
The administration of Shigyaku-san brought about excellent improvement by resolving the stagnated liver Qi and thereby achieving a smooth body Qi flow.[19] Although warming prescriptions were unable to cure coldness in Case 2 and anti-inflammatory prescriptions for purulent blisters and erythema did not work in Case 1, the administration of Shigyaku-san brought about excellent improvement in the patients' symptoms.

Is Acupuncture a Therapeutic Option for Premature Ejaculation?

http://www.medscape.com/viewarticle/743142

Acupuncture, incorporating traditional Chinese medicine (TCM) as an integral part of its practice and theory, claims to relieve pain, treat infertility, prevent and treat several diseases, and promote general health. However, the use of acupuncture for sexual purposes is not frequent: TCM more often uses ginseng (*Panax ginseng*) roots, taken orally, as aphrodisiacs for sexual dysfunction in men, or tiger or deer penis and rhinoceros horn to enhance male virility. In general, TCM and acupuncture seem more concerned with erection than in the control of ejaculation.

For these reasons, we read with great interest the first randomized, placebo-controlled clinical trial comparing acupuncture with paroxetine (20 mg daily) in men with PE. Sunay *et al*.[3] demonstrated that, although less effective than daily paroxetine, acupuncture had a significantly stronger effect on delaying ejaculation compared with placebo. Mean-rank intravaginal ejaculatory latency time (IELT) was significantly longer in men treated with paroxetine (*P* = 0.001) and acupuncture (*P* = 0.001), than in those who received placebo. The observed increases in IELT with paroxetine, acupuncture, and placebo acupuncture were 82.7, 65.7, and 33.1 s, respectively. The extent of ejaculation delay induced by paroxetine was significantly higher than that of acupuncture (*P* = 0.001).

The authors hypothesized that the observed effectiveness of this revolutionary approach to PE could be due to a central effect of acupuncture on neurotransmitters such as serotonin or endorphins, which are frequently involved in sexual behavior.[5] They assume that PE, at least in its lifelong form, could be due to a serotonin derangement. However, data directly connecting PE with an alteration of serotonin machinery are currently quite scarce, and the main evidence that the serotoninergic system acts as a suppressor of the ejaculatory reflex at the hypothalamic level is that both serotonin reuptake inhibitors (SSRI) and serotonin agonists extend ejaculatory latency.[6] This, unfortunately, is very frequently misinterpreted as the establishment of a causal relationship between PE and serotonin. Is the effectiveness of sildenafil on erectile dysfunction proof that this symptom is due to an "alteration" in type 5 phosphodiesterase? Obviously not.
In line with the recommendations of a recently published guideline,[7] the authors stated that daily SSRI treatments are the first-choice treatment for PE. This is not universally true, as some patients with PE find chronic treatment with an antidepressant excessive.[8] Furthermore, in countries where dapoxetine—a short-acting, non-antidepressant SSRI—is approved by the regulatory agencies, this drug must be considered the first choice for on-demand treatment of PE, as it is good clinical practice to use approved drugs instead of off-label treatments, such as paroxetine, unless doing so is scientifically and clinically justified.[9] At the moment, in the absence of approval from regulatory agencies to use long-acting SSRIs, and without data to support the use of alternative approaches, such as acupuncture, this is the main take-home message for the clinical urologist.

VARIATION ANALYSIS OF SPHYGMOGRAM TO ASSESS CARDIOVASCULAR SYSTEM UNDER MEDITATION

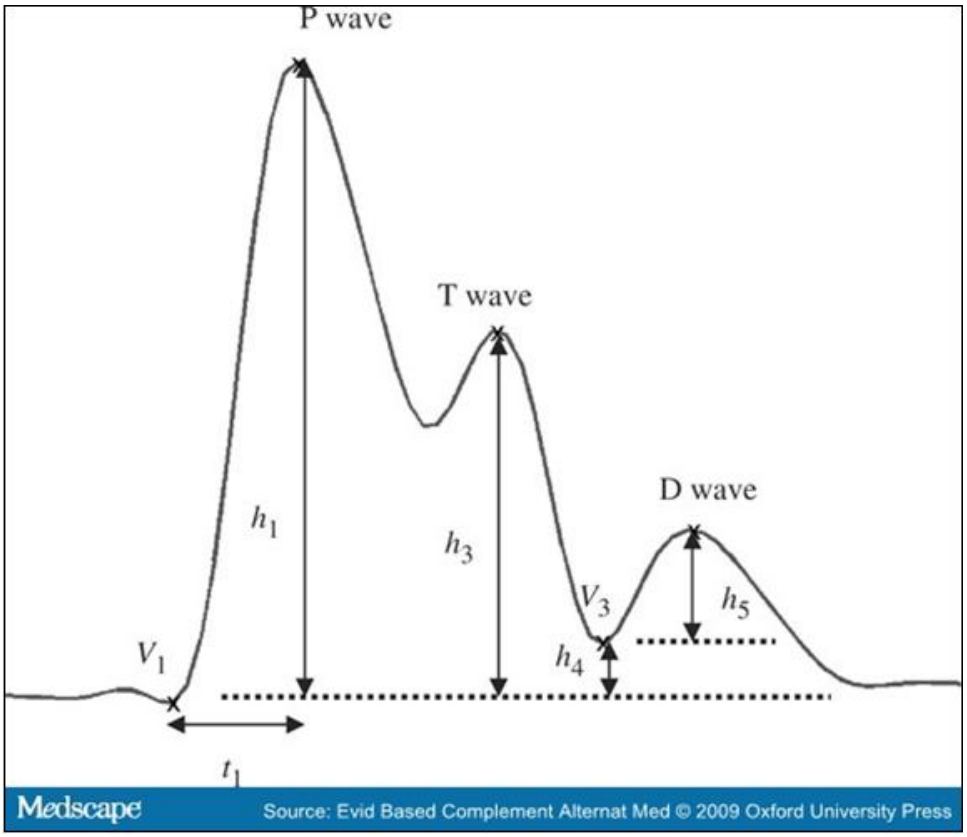
http://www.medscape.com/viewarticle/704717

In this article, we studied how meditation affects the characteristicsof the cardiovascular system, mainly based on blood pressurewaveforms (BPW).

As more clinical evidence supported the benefits of meditationfor health, about fifty years ago researchers began investigatingthe physiologic phenomena of the human body under meditation.Dillbeck *et al.* [8] compared the physiologic differences intwo groups of subjects, one under transcendental meditationand the other at rest. Some research found that the training of transcendental meditation could significantly lower the systolic and diastolic blood pressure of hypertensive persons[9-12].Meditation hereafter became a feasible method to improve hypertension.Hankey,[13] compared Tibetan Buddhist meditation with Transcendental Meditation. He summarized how practicing different meditation techniques influenced hypertension and other physiologic changes.Barnes *et al.* [14] found that, under meditation, total peripheral resistance decreased and they suggested that was why meditation could decrease or control hypertension. To assess how meditation affects the cardiovascular system, this paper presents a quantitative approach to evaluate variations in BPW before and after meditation sessions.

We measured the blood pressure waveforms of twenty Zen-meditation participants and twenty normal, healthy subjects in the same age range as the participants. According to the clinical experience of TCM professionals, we designed a set of parameters that quantify the waveform patterns of BPW.

The BPW prototype of a healthy subject is shown in Fig. 3. The heart pumping mechanism correlating with BPW is illustrated as follows (Fig. 4). The ejection of blood from the left ventricle into the aorta results in the first peak in BPW that is called the Percussion wave (P wave). The height of P wave, h_1 and the fast ejection time of the left ventricle, t_1 is related to the ejection ability of heart and the compliance index of aorta.We define the rising slope of P wave as h_1/t_1. A larger slope indicates a better performance of the heart ejection function and aorta compliance[15]. Thus it is used as a quantitative feature to evaluate the cardiovascular system.


P wave
T wave
D wave
h_1
h_3
h_5
V_3
V_1
h_4
t_1
Medscape
Source: Evid Based Complement Alternat Med © 2009 Oxford University Press

The second peak, called the Tidal wave (T wave), appears when blood hits the artery wall and rebounds. As a result, T wave manifest if the artery possesses excellent elasticity that reflects low peripheral resistance of the circulatory system.On the other hand, an artery with a stiff wall makes the T wave propagate fast according to the Moens-Korteweg equation of wave velocity[16-17]. Accordingly, the T wave will merge with the P wave, which results in a wider P wave. The second parameter, h_3/h_1 where h_3 represents the height of T wave, is utilized to measure the effect of T wave. We thus expect a largeh_3/h_1 for an arterial system with better elasticity. The valley height h_4 reveals the level of peripheral resistance[15,1].As the peripheral resistance increases (decreases), parameterh_4 increases (decreases) as well. The normalized parameter,h_4/h_1 is employed to measure the drift of peripheral resistance.Finally, when the aortic valve is closed, the Dicrotic wave(D wave) is generated. h_5 is the magnitude of D wave and the normalized parameter, h_5/h_1 represents the effect of D wave on arterial system. h_5 will decrease due to a stiff aorta or aortic regurgitation.

The participants were divided into two groups—20 meditationpractitioners and 20 normal, healthy people without any experiencein meditation. In the experimental group, 13 females and 7 maleswith a mean age of 26.6 ± 2.2 years participated. Their experiences in Zen-Buddhist practice span 6.9 ± 3.3 years.The control group comprised 9 females and 11 males with a mean age of 25.2 ± 1.8 years. All the meditation practitioners learned Zen-Buddhist meditation in the Taiwan Zen-Buddhist Association.Only experienced practitioners with more than 3 years of meditation experience were invited.

Why does meditation improve the cardiovascular system? It is possible that in meditation, the meditator devotes attention to breathing, thus reducing dispersive thoughts, brain activity,muscle stress and the influence of the sympathetic system on blood vessels. Consequently, the artery wall becomes more relaxed and elastic. In other words, the blood flow encounters less peripheral resistance and can be more easily transported into organ, tissue, cell, etc. With such a high-efficiency blood transporting system, human health improves.
In modern society, cardiovascular related diseases have become a dominant cause of death for a long time. Meditation provides an alternative mode of health care for conditions that are challenging conventional treatment. At the same time, scientists are urged to develop a scientific approach to the underlying mechanism and how it affects the human life system. More scientific and clinical evidence may inject innovative ideas into mainstream medicine and popular health care practices. According to preliminary results analyzing BPWs, Zen meditation is more effective in improving cardiovascular characteristics than normal relaxation.

HIGHLIGHTS OF THE 2005 JOINT MEETING OF THE AMERICAN EPILEPSY SOCIETY AND THE AMERICAN CLINICAL NEUROPHYSIOLOGY SOCIETY

http://www.medscape.com/viewarticle/522349

Dr. Schachter introduced the concept that herbs and botanicals may represent an economical and effective resource for modern epilepsy treatment. Natural products are contained in more than half of the best-selling US prescription drugs, such as aspirin (willow bark), digitalis (foxglove), galantamine (daffodil bulbs), and paclitaxel (Pacific yew tree bark). Over 100 drugs have been studied in the Far East for the treatment of epilepsy. More than 70% of people with epilepsy use herbs for their general health, and some try to treat their epilepsy with natural products.

Dr. Sucher's studies revealed multiple mechanisms of action, including NMDA antagonism with a non-magnesium-type block, blockade of caspase-8 (an enzyme involved in programmed cell death), and neuroprotective properties. Dr. Sucher suggested that herbal medicines act with low affinity at multiple targets and may be more effective when used in combination.
Of importance, Dr. Elsas stated that botanicals are not without health risks. For example, kava may cause liver toxicity and ephedra and Ginko biloba may precipitate seizures. Dr. Elsas recommended that formal clinical trials need to be conducted to further investigate the use of herbs and botanicals in the treatment of epilepsy, and that compounds should elicit at least a 50% responder rate in order to qualify for further study.

THE PRACTICE OF ACUPUNCTURE: WHO ARE THE PROVIDERS AND WHAT DO THEY DO?

http://www.medscape.com/viewarticle/502754

Purpose: This study provides basic information about the training and practices of licensed acupuncturists.

Methods: Randomly selected licensed acupuncturists in Massachusetts and Washington state were interviewed and asked to record information on 20 consecutive patient visits.

Acupuncturists treated a wide range of conditions, including musculoskeletal problems (usually back, neck, and shoulder) (33% in Massachusetts and 47% in Washington), general body symptoms (12% and 9%, respectively) such as fatigue, neurological problems (10% and 12%, respectively) (eg, headaches), and psychological complaints (10% and 8%, respectively) (especially anxiety and depression). Traditional Chinese medicine (TCM) was the predominant style of acupuncture used in both states (79% and 86%, respectively). Most visits included a

traditional diagnostic assessment (more than 99%), regular body acupuncture (95% and 93%, respectively), and additional treatment modalities (79% and 77%, respectively). These included heat and lifestyle advice (66% and 65%, respectively), most commonly dietary advice and exercise recommendations. Chinese herbs were used in about one third of visits. Although most patients self-referred to acupuncture, about one half received concomitant care from a physician. Acupuncturists rarely communicated with the physicians of their patients who were providing care for the same problem.

More than 75% of acupuncture visits included one or more adjunctive treatments (Table 6). Almost one half of the treatments included the use of heat, usually with a lamp heat or by moxibustion (the burning of the mugwort plant *Artemisia vulgaris* on or just above acupuncture points or meridians), and nearly one third included the prescription of Chinese herbs.
About two thirds of the visits in both states included self-care recommendations, with about 25% including multiple recommendations. Dietary or nutritional counseling from the perspective of Chinese medicine and exercise were the most common recommendations, each occurring in about one third of the visits in both states. Sitting or moving meditation was recommended during 21% of visits in Massachusetts and 14% in Washington.

More than 40 meta-analyses and systematic reviews of the effectiveness of acupuncture for a host of conditions have been published,[31] but nearly all are inconclusive because of the poor quality and small size of the primary studies. Nevertheless, at this point acupuncture appears to hold the most promise as an adjunct antiemetic for surgery and chemotherapy[32] and for the treatment of headache.[33-35] In addition, most studies evaluating acupuncture for temporomandibular disorders,[36] and shoulder pain[37,38] have been positive.
Although results of studies of acupuncture for back and neck pain have been inconsistent,[39-41] there is growing evidence that it might be helpful.[42-45]

LATEST FROM THE LITERATURE IN IBS AND CHRONIC CONSTIPATION: SEPTEMBER 2006

http://www.medscape.com/viewarticle/544018

It is estimated that nearly 35% of all general medical patients use some form of alternative or complementary medicine on a regular basis.[7] The reasons for this are varied (ease, perceived benefits, no requirement for a prescription or office visit), although their dissatisfaction with the currently available Western medications is also frequently cited by these patients. Acupuncture is one of the most common alternative therapies employed by patients, and it is used to treat a variety of disorders, ranging from arthritis to tobacco withdrawal. Its efficacy, however, has been demonstrated in only a few disorders, including postoperative nausea and vomiting and chronic pain.[8] The 2 published studies evaluating the role of acupuncture in IBS were flawed

because one was quite small (n = 7) and did not involve a control group,[9] whereas the other used only a single acupuncture site, which is not considered standard of care in traditional Chinese medicine (TCM).[10]

Schneider and colleagues[11] investigated the role of acupuncture in patients with IBS in a blinded, sham-controlled trial involving 10 treatment sessions over 5 weeks. All patients met Rome II criteria. Approximately 40% of subjects had mixed symptoms of alternating constipation and diarrhea, whereas 40% had IBS with diarrhea predominance. The mean age of all 43 subjects was 47 years, and most were women (77% in the acupuncture group and 81% in the sham group; NS). Acupuncture was performed according to TCM using 8 preselected sites. Sham acupuncture used a blunted needle that did not penetrate the skin; it was performed 2 cm adjacent to the real acupuncture point to avoid the possible confounding effects of acupressure. Seven of the 8 sites were identical, although the midline of the head was excluded in the sham group because this was thought to be technically difficult. Patients were followed using 2 separate validated quality-of-life questionnaires (general quality-of-life questionnaire [SF-36] and functional digestive diseases quality-of-life questionnaire [FDDQL]) and the validated bowel disease questionnaire (BDQ). These questionnaires were given at baseline, at the end of 10 treatment sessions, and 3 months after the last treatment. The study authors reported that quality of life, as measured by the FDDQL, improved in both the acupuncture group (11% improvement) and the sham group (10% improvement), although this small difference was not statistically significant. Subscores for "coping with disease" and "diet," along with the daily activity index, were most improved -- although, again, there was no statistically significant difference between sham and acupuncture groups. SF-36 scores also improved in both groups; but only scores for bodily pain were significantly improved above baseline, and there was no difference between the sham group and the acupuncture group. The study authors concluded that beneficial effects of acupuncture in IBS are likely due to the placebo effect because no benefit could be identified when a properly controlled trial was performed using TCM and a sham acupuncture group. They also performed a power analysis showing that a larger trial involving nearly 600 patients would be required to show any potential benefits.

This study emphasizes the need to objectively study alternative and complementary therapies using well-accepted scientific criteria (ie, blinded, placebo-controlled trials), so that we can accurately and fairly compare these therapies with currently available medical therapies.

Constipation is a highly prevalent condition, affecting up to 15% of adults in the United States.[12] Chronic constipation has been shown to reduce patients' quality of life and impose a significant economic burden on our healthcare system.[13] Although a variety of over-the-counter remedies and prescription medications are available, a recent review article found that many of these treatments are not more effective than placebo.[14] The US Food and Drug Administration-

approved prescription medications for the treatment of constipation include tegaserod, lactulose, PEG 3350, and lubiprostone.[15]

READERS' AND AUTHOR'S RESPONSES TO "WHATEVER HAPPENED TO PLAUSIBILITY AS THE BASIS FOR CLINICAL RESEARCH AND PRACTICE AFTER EBM AND CAM RUSHED IN?"

http://www.medscape.com/viewarticle/557126

In regard to the plausibility of acupuncture, I am disappointed that his opinion disregards a large body of modern investigative literature. Twenty years ago, his attitude was common, and perhaps understandable. However, nowadays PubMed is at our fingertips. A good starting point might be the National Institutes of Health (NIH) acupuncture bibliography, with 2302 references.[2]

The question needs to be asked: What is more important, establishing practical clinical use of whole plant products so that patients can benefit sooner (and inexpensively) or making patients wait years until some active principle can be characterized, and then synthesized and sold at high cost by a pharmaceutical company? A good example of this is the use of dronabinol (*Marinol*) vs crude marijuana extracts. Exactly what overwhelming advantages does dronabinol offer to patients over crude marijuana extracts?

I wish there were indeed "hundreds of clinical trials (RCTs [randomized clinical trials])" investigating promising medicinal plants and their active principles. To my knowledge, there are not, at least not in this country. The failure of our society to adequately investigate and deploy a host of plant-derived medicines is a direct consequence of a healthcare system and society that has placed profits far ahead of the needs of patients. From rheumatoid arthritis[4-6] to gastric ulcers[7,8] to diabetes[9,10] to cancer,[11-13] there are promising plant-derived medicines that are awaiting thorough study. It is not that their efficacy is implausible. It is that they cannot be patented and sold at $5 per pill.

In regard to prayer, the chief issue is not the plausibility of superstition, but rather, how do educated, nonsuperstitious medical professionals work effectively with their devout/superstitious patients, so that such patients may derive comfort or benefit from their own personal beliefs? (As well as prayer, why not "your lucky rabbit's foot"?) Research does suggest that belief systems affect health outcomes.[14,15]

RESPONSE

In the case of traditional Chinese medicine (TCM) and acupuncture, claims are supported by 2 sources of erroneous evidence. Traditional concepts and claims are based on unconfirmed personal observations. To repeat: Traditional medical systems had no method for organized objective observation, no systematic meaningful classification of observations, no method for analyzing information, no method of proving or disproving its accuracy, and no system for resolving conflicts. TCM developed no system of experimentation. Observations were classified along lines of systematic correspondence (similarity of forms, taste, etc) and other primitive methods that bore little to no relation to reality. Therefore, treatment mechanisms and organ functions were imagined or invented, not derived from investigation. Furthermore, interpretations often had to conform to currents of social, ideological beliefs (Q'i, yin/yang, political theory.) The result was a chaotic collection of inaccurate observations and uncorrected errors.

RESPONSE

Acupuncture, a modality against which Dr. Wallace has railed previously, is a good example of a discipline worthy of more, not less scrutiny. Granted, acupuncture treatment can induce placebo effects, and acupuncture is not a science. However, to fail to look beyond these facts, to assume therefore that there is no more to be learned about this complicated field ignores reality. Is all of the observation that predates biomedical research worthless? Were all those centuries of patients and practitioners totally deluded? What of the similarity between acupuncture and trigger point therapy? How does the "acupuncture is bunk" attitude jive with the reality that endorphins were discovered largely because of research on how exactly acupuncture stemmed cravings for opiates? Should we discount the studies in which PET [positron emission tomographic], fMRI [functional magnetic resonance imaging], and SPECT [single-photon emission computed tomographic] scans show precise, site-specific responses in structures of the brains of patients undergoing acupuncture? Although it may be true that acupuncture does not easily lend itself to double-blind, placebo-controlled studies, it might just have more to do with the limitations of this type of research study than acupuncture itself.

RESPONSE:

The PET, fMRI, and SPECT scan studies on acupuncture show evidence of mental activity, not connections of anatomic significance. In other words, they probably are showing the areas of the brain where conscious thinking occurs during an acupuncture experiment. (See the analysis of one such study in Sampson W. Evaluation of a study on the possible validity of acupoints. *Sci Rev Altern Med*. 1998;2:56-57.)

UPDATE IN DRUG ALLERGY: NOVEL DRUGS WITH NOVEL REACTION PATTERNS

http://www.medscape.com/viewarticle/730658

An adverse drug reaction (ADR) is a noxious or unintended reaction to a drug that is administered in standard doses by the proper route for the purpose of prophylaxis, diagnosis, or treatment.[1] Reactions are classified into two major subtypes: type A, which are dose dependent and predictable, and type B, which are not dose dependent and unpredictable. Unpredictable reactions include immune (allergic) or nonimmune drug hypersensitivity reactions (DHRs) and are related to genetic susceptibilities or undefined mechanisms (formally called idiosyncratic and intolerance reactions).[2] A drug allergy is always associated with an immune mechanism for which evidence of drug-specific antibodies or activated T lymphocytes can be shown.[3,4]

In the last few years, many novel drugs have entered clinical practice (i.e. biologic agents) generating novel patterns of DHRs. As old drugs continue to be used, new clinical and biologic techniques enable improvement in the diagnosis of these reactions.
This review summarizes current data in this field. A *MEDLINE* search was performed from January 2009 to April 2010, combining the following terms: ADR, drug allergy or hypersensitivity, epidemiology, mechanism, clinical diagnosis, and in-vitro diagnosis.

Several studies addressing ADRs in specific target populations have been published. In psychiatric patients,[5] psychiatric medications accounted for 48.4% of the ADRs and nonpsychiatric medications for 51.6%. It was also shown that ADRs to antipsychotic medications[6] are frequently misdiagnosed as allergies, which may be much less common than suggested by clinical records. Epidemiologic data in specialized care units show a prevalence of ADRs from 24.2 to 28.4%.[7,8]

According to age groups, ADRs in emergency departments were found to be more frequent in elderly patients, with multiple drug regimens and comorbidities.[9] In children, Tan *et al*.[10] estimated the prevalence of ADRs at 5.4%, with 56.7% of patients reporting an ADR to beta-lactam antibiotics. Interestingly, only 6.9% of the children who experienced an ADR were referred for further investigations. An Italian study[11] found evidence of an association between selected antibacterials, NSAIDs, paracetamol, mucolytics, and measles, mumps and rubella (MMR) vaccination in children suffering from immune thrombocytopenic purpura.

Considering sex as a risk factor, current studies continue to argue in favor of the female sex as a risk factor for developing ADRs.[12–14] It was also found that atopy may be a risk factor for developing sensitization to beta-lactam antibiotics in tertiary hospital nurses.[15]

CAM was defined as natural remedies (origin from herbs, animals, bacterial cultures, minerals, or salts) not excessively processed or refined and which are intended to be used without a prescription for the purpose of self-treatment according to the Medical Products Agency's code of statutes. The study showed that 1.2% of the total reports concerned suspected ADRs were related to 175 different CAM products. The main reactions were urticaria (8.3%), exanthema (7.4%), and contact dermatitis (5.7%). The most reported were purple coneflower (*Echinacea purpurea*) (8.1%), Siberian ginseng (*Eleutherococcus senticosus*), malabar nut (*Adhatoda vasica*) (7.3%), and ginkgo leaf (*Ginkgo biloba*) (6.7%).

Zeng and Jiang[17••] reviewed ADRs induced by traditional Chinese medicine (TCM). Three thousand one hundred twenty-two cases involving 140 different drugs were analyzed. *Herba houttuyniae* and Shuanghuanglian were the most common drugs involved. Most ADRs were cataloged as allergies. One hundred twenty-eight cases (4.1% of the 3122 cases) showed anaphylactic shock, of which most were caused by intravenous injections. Authors concluded that an evaluation system of pharmacology and toxicology should be established and the search for a quality standard of TCM should be strengthened.

Regarding specific drugs, a recent report concerning omalizumab anaphylaxis[18] was established based on the US Food and Drug Administration Adverse Event Reporting System. There were 118 cases consistent with anaphylaxis. Of these, 32 cases were reported after the first dose. Seventy-seven cases were categorized as requiring hospital admission or prolongation, had life-threatening reactions, underwent treatment with epinephrine or corticosteroids, or had omalizumab treatment withheld or discontinued. No deaths were reported. These allergic reactions due to omalizumab underscore a clinical dilemma involving this medication.

Randomized, Controlled Trial of Acupuncture for Chronic Daily Headache

http://www.medscape.com/viewarticle/513075

Background: Approximately 4% of adults experience headaches nearly every day. Nonpharmacologic interventions for frequent headaches may be appropriate because medical management alone is often ineffective.

Objective: To assess the efficacy of acupuncture as an adjunct to medical management for chronic daily headache (CDH).

Methods: We conducted a randomized, controlled trial of 74 patients with CDH that compared medical management provided by neurologists to medical management plus 10 acupuncture

treatments. Primary outcome measures were daily pain severity and headache-related quality of life (QoL).

Results: Patients who received only medical management did not demonstrate improvement in any of the standardized measures. Daily pain severity scores trended downward but did not differ between treatment groups (*P*= .60). Relative to medical management only, medical management plus acupuncture was associated with an improvement of 3.0 points (95% CI, 1.0 to 4.9) on the Headache Impact Test and an increase of 8 or more points on the role limitations due to physical problems, social functioning, and general mental health domains of the Short Form 36 Health Survey. Patients who received acupuncture were 3.7 times more likely (CI, 1.7 to 8.1) to report less suffering from headaches at 6 weeks (absolute risk reduction 46%; number needed to treat 2).

Conclusion: Headache-specialty medical management alone was not associated with improved clinical outcomes among our study population. Supplementing medical management with acupuncture, however, resulted in improvements in health-related QoL and the perception by patients that they suffered less from headaches.

Acupuncture is a promising nonpharmacological treatment for frequent headaches. A recent meta-analysis concluded that acupuncture is more effective than sham acupuncture for the treatment of migraine headaches.[15] Another systematic review identified 27 clinical trials of acupuncture for various headache disorders; of these, 23 were considered "positive," 1 was "negative," and 3 were equivocal.[16] More recently, a randomized clinical trial demonstrated that a series of up to 12 acupuncture treatments was associated with 22 fewer days with headache, 15% less medication use, 25% fewer visits to general practitioners, and 15% fewer work days missed due to illness over 1 year among patients who experienced frequent headaches.[17]

The published literature does little, however, to inform healthcare providers and their patients with CDH about what to expect from a combination of medications and acupuncture. We conducted a randomized clinical trial to determine whether a 6-week course of acupuncture treatments could improve clinical outcomes beyond that which would be expected from medical management alone among patients with CDH.

We randomly allocated study patients to receive either medical management only or medical management plus a series of 10 acupuncture treatments during a 6-week intervention period. All patients received medical management as provided by their personal healthcare providers and by a neurologist at the headache clinic at UNC Hospitals. The headache clinic is staffed by three neurologists with extensive experience in headache management. The headache clinic

neurologists were aware of the trial but did not know which of their patients were participating. Patients were asked not to inform their healthcare providers of their participation in the trial unless necessary for medical reasons and were encouraged to continue taking their medications as directed by their providers.

Patients assigned to the acupuncture group were given their first acupuncture treatment on the day of the baseline evaluation and were scheduled for nine additional acupuncture treatments over the subsequent 6 weeks. All acupuncture treatments were administered by an experienced physician and acupuncturist trained in Traditional Chinese Medicine (TCM) in the People's Republic of China. The study acupuncturist is a Diplomate of the National Certification Commission for Acupuncture and Oriental Medicine. His medical degree was certified by the United States Educational Commission for Foreign Medical Graduates. The study acupuncturist interviewed and examined each patient prior to randomization. He selected the bodily locations in which to insert the acupuncture needles for each patient according to TCM "pattern diagnoses." The acupuncturist also needled tender points at or near the site of maximal headache pain, when indicated. The study acupuncturist reassessed patients at each visit and modified the acupuncture points needled whenever clinically indicated. Up to 30 acupuncture needles were inserted and left in place for approximately 30 minutes at each treatment.

To our knowledge, this is the first randomized clinical trial to evaluate the efficacy of acupuncture as an adjunct to headache-specialty care in the treatment of CDH. Patients whose neurology-specialty medical care was not supplemented with acupuncture failed to demonstrate significant improvement in any of the outcomes assessed upon completion of the 6-week intervention period, with the exception of a weak trend of decreasing daily pain severity. Those who received acupuncture, however, demonstrated improvements in most of the study outcomes, including headache-related QoL, several SF-36 health domains, and Beck Depression Inventory scores. Patients who received acupuncture were also more likely to report a reduction in the perception of suffering from headaches at the end of the intervention period. Acupuncture did not improve subjective daily pain severity, however.

Perhaps, the greatest limitation of this study is that we did not isolate acupuncture, *per se*, as the single, causal variable. Rather, our experimental design evaluated the efficacy of a complex therapeutic package that included acupuncture treatments, the time and attention of an experienced and caring clinician, the credibility of investigators conducting a research study sponsored by the National Institutes of Health, patients' probable hope that an "exotic" treatment approach may help their suffering, and a variety of other factors that may have contributed (positively or negatively) to the outcomes observed.

Additional research is needed to elucidate the extent to which placebo effects associated with acupuncture contribute to clinical benefit, to identify clinical characteristics that predict favorable response to acupuncture, to explore which acupuncture traditions and protocols are most effective for treating the various causes and manifestations of CDH, and to determine whether acupuncture is a cost-effective approach to the treatment of frequent headaches.

COMPLEMENTARY AND ALTERNATIVE MEDICINE USE IN ENGLAND: RESULTS FROM A NATIONAL SURVEY

http://www.medscape.com/viewarticle/730431

Objectives: In many countries, recent data on the use of complementary and alternative medicine (CAM) are available. However, in England, there is a paucity of such data. We sought to determine the prevalence and predictors of CAM use in England.

Results: Data were available for 7630 respondents (household response rate 71%). Lifetime and 12-month prevalence of CAM use were 44.0% and 26.3% respectively; 12.1% had consulted a practitioner in the preceding 12 months. Massage, aromatherapy and acupuncture were the most commonly used therapies. Twenty-nine percent of respondents taking prescription drugs had used CAM in the last 12 months. Women (OR 0.491, 95% CI: 0.419, 0.577), university educated respondents (OR 1.296, 95% CI: 1.088, 1.544), those suffering from anxiety or depression (OR 1.341, 95% CI: 1.074, 1.674), people with poorer mental health (on GHQ: OR 1.062, 95% CI 1.026, 1.100) and lower levels of perceived social support (1.047, 95% CI: 1.008, 1.088), people consuming ≥ 5 portions of fruit and vegetables a day (OR 1.327, 95% CI: 1.124, 1.567) were significantly more likely to use CAM.

Conclusion: Complementary and alternative medicine use in England remains substantial, even amongst those taking prescription drugs. These data serve as a valuable reminder to medical practitioners to ask patients about CAM use and should be routinely collected to facilitate prioritisation of the research agenda in CAM.

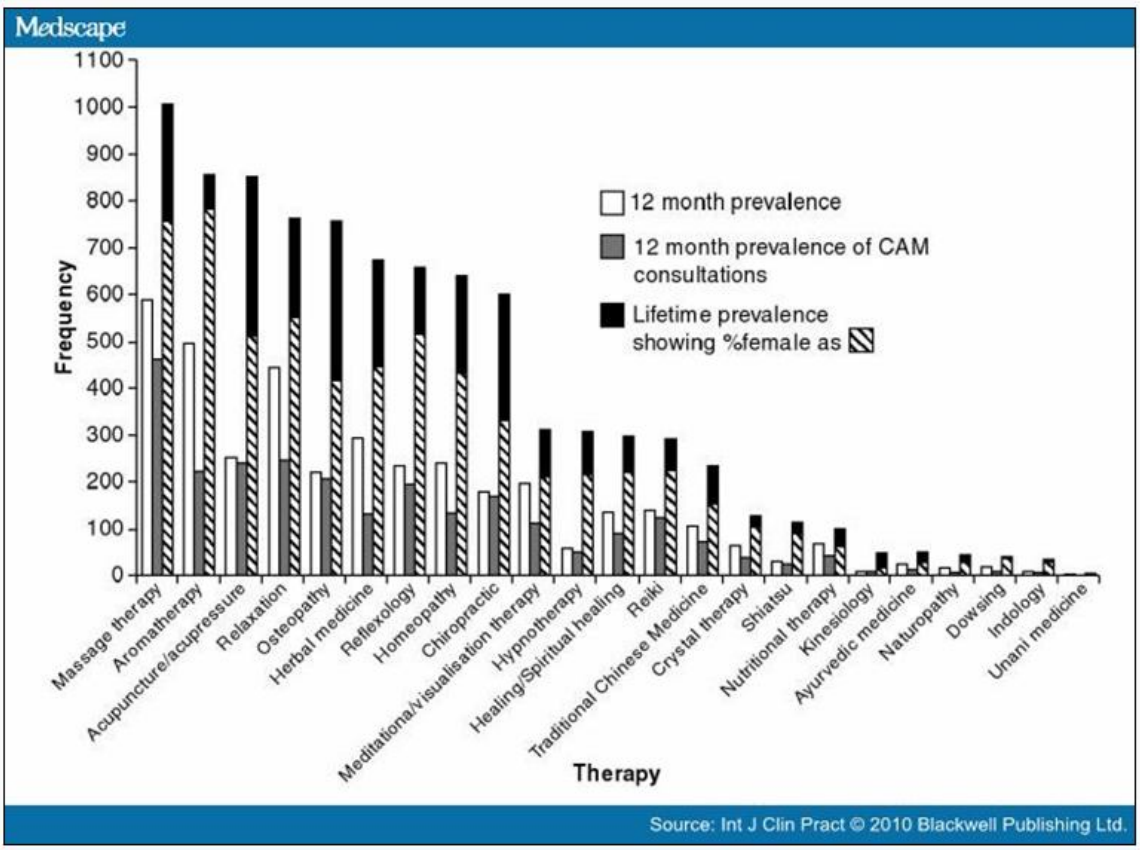


Figure 1.

Prevalence of individual CAM use

Interviews were carried out at 71% of the 7200 approached households, and 89% of those aged 16 years and over in those households were interviewed (*N* = 7630). The socio-demographic characteristics of the sample are presented in Table 1.

Prevalence of CAM Use

The lifetime prevalence of CAM use was 44.0% (*n* = 3355), 12-month prevalence was 26.3% (*n* = 2005), and 12.1% (*n* = 922) had consulted a practitioner in the last 12 months.

Of all CAM modalities, massage had the highest lifetime prevalence of use (13.1%), followed by aromatherapy (11.2%) and acupuncture/acupressure (11.2%), relaxation (10.0%) and osteopathy (9.9%). Twelve-month prevalence follows a similar pattern (Figure 1). Massage therapists were the most frequently visited CAM practitioners (Figure 1). Dowsing had the highest proportion of female users (85%), whereas chiropractic had the highest proportion of male users (44.8%) (Figure 1). Users of osteopathy were older, and users of Unani younger than users of any other CAM.

CI: 1.039, 1.704), have a university education (OR 1.441, 95% CI:1.257, 1.651), work in a professional/managerial role (OR 1.336, 95% CI: 1.169, 1.527), have a household income above the 2005 national average (OR 1.162, 95% CI: 1.010, 1.336) and be in active employment (OR 1.449, 95% CI: 1.263, 1.662). In addition, using CAM was associated with decreasing deprivation (OR 0.748, 95% CI: 0.884, 0.970). Age was not a significant independent predictor of 12-month CAM use (OR 0.997, 95% CI: 0.993, 1.001).

Our regression models suggest that individuals experiencing anxiety, depression or other long standing illnesses, with poorer mental health and with lower levels of perceived social support are more likely than those in good health to use CAM. We also found that CAM is used more by women than men, those with a university education, those in active employment, and those who appear to pursue healthy lifestyles (consuming more than five portions of fruit/vegetables per day and using vitamin supplements) compared with those who do not. This confirms previous research suggesting that individuals who are more likely to select healthy lifestyle choices may also be likely to engage proactively in other self-care behaviours including CAM use, and that less risky health behaviours may be associated with CAM use.[22]

The HSE[9] data show that different CAMs are not used uniformly. For example, osteopathy, chiropractic and acupuncture have the most even gender spread and the mean age of these users is slightly older than the users of other CAM, whereas dowsing, iridology, kinesiology, crystal therapy and reflexology were used predominantly by younger women. This may, in part, be attributable to the referral patterns of health professionals. For example, NHS referrals to osteopathy and chiropractic for back pain treatment may be common, whereas more exotic forms of CAM may be less likely to be endorsed by allopathic health providers and prohibitively costly for many consumers.

These analyses have important limitations. First, all data used were based on self-reports and are thus subject to recall bias, although this may be somewhat mitigated by the use of face-to-face interviews rather than questionnaires. Second, although we account for several variables in our regression models, it is possible that other factors that were not measured may better account for CAM use.

TRENDS IN COMPLEMENTARY/ALTERNATIVE MEDICINE USE BY BREAST CANCER SURVIVORS: COMPARING SURVEY DATA FROM 1998 AND 2005

http://www.medscape.com/viewarticle/560310

Use of complementary and alternative medicine (CAM) by women with breast cancer is often said to be increasing, yet few data exist to confirm this commonly held belief.

The purpose of this paper is to compare overall patterns of CAM use, as well as use of specific products and therapies at two different points in time (1998 vs 2005) by women diagnosed with breast cancer.

Methods: Surveys were mailed to women randomly selected from the Ontario Cancer Registry (Canada) in the spring of 1998 (n = 557) and again in the spring of 2005(n = 877).

Results: The response rates were 76.3% in 1998 and 63% in 2005. In 1998, 66.7% of women reported using either a CAM product/therapy or seeing a CAM therapist at some time in their lives as compared with 81.9% in 2005 (p = 0.0002). Increases were seen in both use of CAM products/therapies (62% in 1998 vs. 70.6% in 2005) and visits to CAM practitioners (39.4% of respondents in 1998 vs 57.4% of respondents in 2005). Women in 2005 reported that 41% used CAM for treating their breast cancer. The most commonly used products and practitioners for treating breast cancer as reported in 2005 were green tea, vitamin E, flaxseed, vitamin C, massage therapists and dietitians/nutritionists.

Conclusion: CAM use (both self-medication with products and visits to CAM practitioners) increased significantly from 1998 to 2005. Now that more than 80% of all women with breast cancer report using CAM (41% in a specific attempt to management their breast cancer), CAM use can no longer be regarded as an "alternative" or unusual approach to managing breast cancer.

In Canadian women, breast cancer is a common malignant neoplasm, with a lifetime risk calculated as 1 in 9.[3] Due to mammographic screening, early detection of disease, and improved therapies, the rate of BC mortality is steadily declining in Canada.[3] Nonetheless, in 2005, it is estimated that 21,600 women were diagnosed and 5,300 women died from this disease.[3] Ontario has the highest incidence of BC cases in Canada, with 8,200 of the 21,600 new cases in 2005.[3]

Many reports suggest that the prevalence of CAM in cancer patients and survivors has been increasing, yet few follow-up studies are available to confirm this.
In addition, the use of different definitions of CAM, and thus different instruments to measure CAM prevalence, makes it difficult to compare studies completed at different points-in-time.

Overall, we found that both the use of CAM products and visits to CAM practitioners by women diagnosed with breast cancer significantly increased from 1998 to 2005. In 2005, 81.9 percent of respondents reported using CAM (41 percent to help manage their breast cancer) compared to

66.7 percent in 1998, suggesting that in 2005 CAM use has become the "norm" in this patient population.

Overall, the biggest increases were seen in the percentage of women seeing bodywork practitioners (including massage therapists, but not chiropractors), TCM practitioners/acupuncturists, homeopaths and "others". This may be related to the fact that massage therapy and acupuncture are two of the CAM practices which are generally the most accepted by the medical profession.[12-15] For example, many physicians use acupuncture in their practices.[16] In addition, given that neither acupuncture nor massage involves taking anything orally, it is likely they are perceived to have fewer potential adverse effects or interactions with conventional cancer treatments than some other CAM therapies. So it is possible that conventional MDs are either recommending these options more often to patients or at least not discouraging patients from using them.

Overall, there was a significant increase in the use of herbal products such as garlic, ginger, ginseng and green tea and special foods/diets. Both green tea and special diets/foods are used by more than 10 percent of all women diagnosed with breast cancer specifically to help manage their breast cancer. A review of the evidence suggests that there may be an overall decreased risk of cancer associated with taking Asian ginseng (*Panax ginseng*), garlic, green tea, soy, and tomatoes but research is extremely preliminary and in some cases contradictory. Also, the minimum dose associated with decreased cancer risk has not been clearly defined for any of the supplements or herbs.[18,19] Although there is evidence that ginger may be useful in the management of chemotherapy-induced nausea, it is not clear exactly what dose or dosing schedule is best. It is also not clear what additional benefits ginger products have over and above conventional anti-nausea medications (fewer adverse effects are claimed).[18,19] There are currently no herbs with significant evidence of efficacy as cancer treatments.[18,19]

INTEGRATIVE MEDICINE: SORTING FACT FROM FICTION

http://www.medscape.com/viewarticle/564560

Acupuncture with 16 systematic reviews in the Cochrane Library (www.cochrane.org) demonstrating efficacy in conditions as diverse as depression, back pain, Bell's palsy, dysmenorrhea, arthritis of the knee,[7] and fibromyalgia.[8]

READERS' AND AUTHOR'S RESPONSES TO "ETHICS AND ANOMALOUS (ALTERNATIVE) MEDICAL PRACTICES"

http://www.medscape.com/viewarticle/544296

I do not believe that one can reasonably state, on the basis of current scientific knowledge, that the practice of alternative/complementary medicine has neither merit nor science behind it. We can argue as to the strength and validity of the studies (issues of representativeness, sample size, selection of endpoints, etc), but the evidence is mounting that some of the products and practices do indeed have measurable clinical benefit.

PUBMED – 32 ARTICLES REVIEWED

THE USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE IN CHRONIC PAIN PATIENTS IN SINGAPORE: A SINGLE-CENTRE STUDY.

http://www.ncbi.nlm.nih.gov/pubmed/23604502

Abstract

INTRODUCTION:

The use of complementary and alternative medicine (CAM) in Singapore for a variety of conditions has been reported to be high. However in Asian chronic pain patients, there is no data on their use of CAM and its perceived benefits.

MATERIALS AND METHODS:

A cross-sectional survey of 210 patients was carried out in Pain Management Centre. Patients were interviewed directly on their use of CAM. The outcomes were prevalence of CAM use, the types of CAM used, the perceived efficacy and factors influencing its use.

RESULTS:

The prevalence of CAM users in chronic pain is 84%. The most common class of CAM is traditional Chinese medicine (68%) the subset of which, acupuncture, was most frequently utilised (49% of patients using CAM). In univariate analyses, ethnicity was significantly linked to CAM use but not gender, age, education level and income (P = 0.027). Specifically for neck pain, it was significant that patients were more likely to see a chiropractor, to use massage, to take take vitamins and ginseng to alleviate their symptoms. With upper limb pain, it was the use of Tui na, massage and seeing a TCM practitioner. For abdominal pain, it was the use of herbal medicines. The majority felt that CAM helped with their pain (72%) although less expressed satisfaction with CAM (64%). Reasons for using CAM included: having more control over their pain; fewer side effects; safety and lower costs compared to conventional medicine.

CONCLUSION:

The use of CAM in chronic pain patients is higher than the general population. Most felt that it improved their pain. As part of multimodal therapy, CAM may have a role in the management of chronic pain.

INTEGRATING TRADITIONAL CHINESE MEDICINE SERVICES IN COMMUNITY HEALTH CENTERS: INSIGHTS INTO UTILIZATION PATTERNS IN THE PEARL RIVER REGION OF CHINA.

http://www.ncbi.nlm.nih.gov/pubmed/23533480

Abstract

In China's healthcare reform, community health centers (CHCs) are designed to take a pivotal role in providing primary care. Whilst about 20% of all outpatient care in China is delivered by the traditional Chinese medicine (TCM) sector, hospitals, instead of CHCs, are major providers. Using current patterns of patient utilization this study aims to inform CHCs on how they may strengthen access to TCM services. Three thousand three hundred and sixty CHC patients from six cities within the urban Pearl Delta Region were enumerated using multistage cluster sampling. Fifty-two percent had visited herbalists within three months with a mean visit frequency of 1.50 times. Herbal treatments, which are cheaper than western medicines, were more popular amongst those who needed to pay out of pocket including the uninsured. Herbal medicines appeared to be an alternative for those who are underinsured. Acupuncturists and massage therapists were visited by smaller proportions, 6.58% and 5.98%, respectively, with a mean three-month visit of 0.27 and 0.26 times. Access was restricted by lack of social insurance coverage. Whilst increasing provision of TCM in CHCs might respond to patient demand, increasing insurance coverage for TCM needs to be evaluated using current evidence on safety and effectiveness.

Figure 1

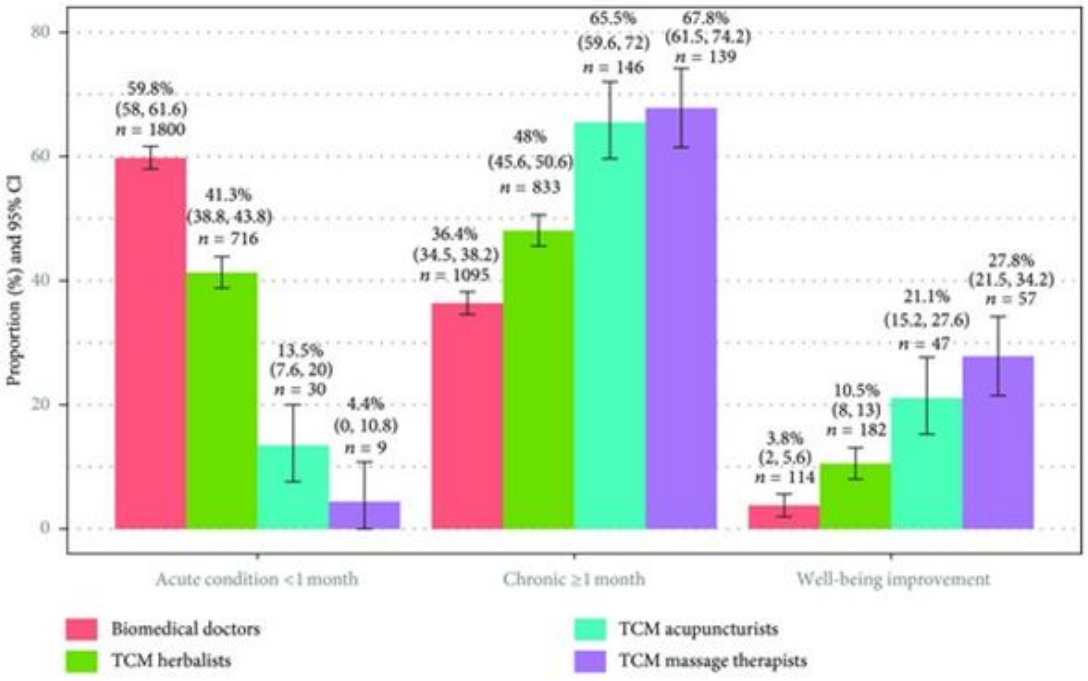
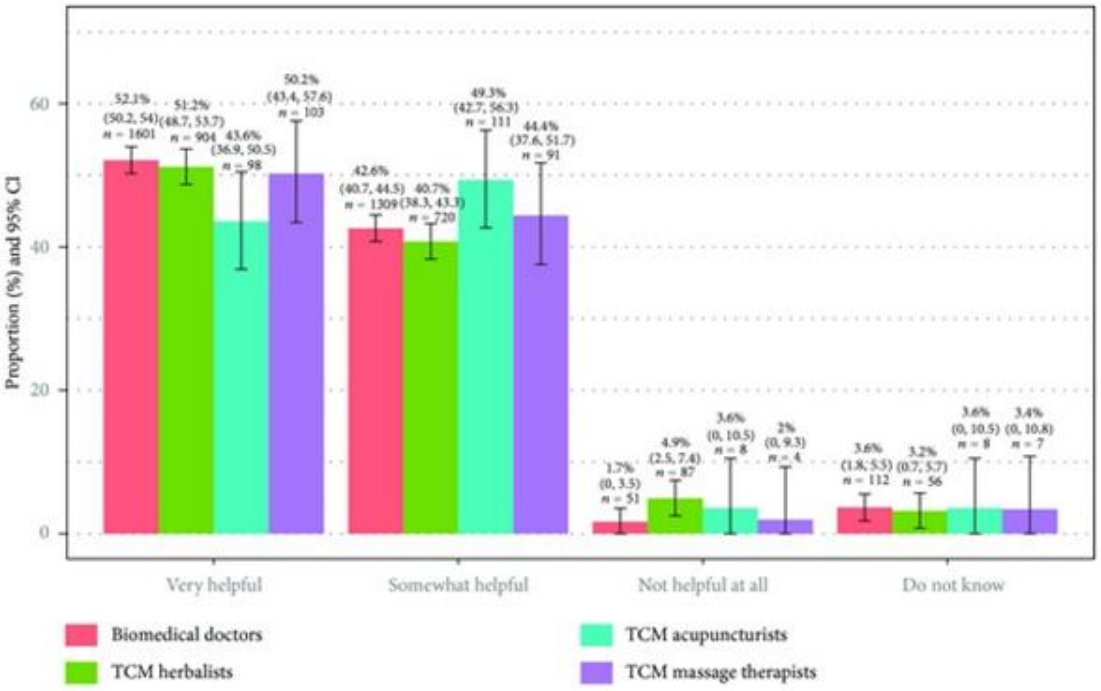


Figure 2



COMPARATIVE EFFECTIVENESS OF TRADITIONAL CHINESE MEDICINE AND PSYCHOSOCIAL CARE IN THE TREATMENT OF TEMPOROMANDIBULAR DISORDERS-ASSOCIATED CHRONIC FACIAL PAIN.

http://www.ncbi.nlm.nih.gov/pubmed/23059454

This dual-site study sought to identify the appropriate role for traditional Chinese medicine (TCM; acupuncture and herbs) in conjunction with a validated psychosocial self-care (SC) intervention for treating chronic temporomandibular disorders (TMD)-associated pain. Participants with Research Diagnostic Criteria for Temporomandibular Disorders-confirmed TMD (n = 168) entered a stepped-care protocol that began with a basic TMD class. At weeks 2 and 10, patients receiving SC whose worst facial pain was above predetermined levels were reallocated by minimization to SC or TCM with experienced practitioners. Characteristic facial pain (CFP: mean of worst pain, average pain when having pain, and current pain; each visual analog scale [VAS] 0-10) was the primary outcome. Social activity interference (VAS 0-10) was a secondary outcome. Patients were monitored for safety. TCM provided significantly greater short-term (8-week) relief than SC (CFP reduction difference, -.60 [standard deviation of the estimate .26], P = .020) and greater reduction in interference with social activities (-.81 [standard deviation of the estimate .33], P = .016). In 2 of 5 treatment trajectory groups, more than two thirds of participants demonstrated clinically meaningful responses (≥30% improvement) in pain interference over 16 weeks. This study provides evidence that TMD patients referred for TCM in a community-based model will receive safe treatment that is likely to provide some short-term pain relief and improved quality of life. Similar designs may also apply to evaluations of other kinds of chronic pain. (ClinicalTrials.gov number NCT00856167).

PERSPECTIVE:

This short-term comparative effectiveness study of chronic facial pain suggests that TCM is safe and frequently efficacious alone or subsequent to standard psychosocial interventions. TCM is widely available throughout North America and may provide clinicians and patients with a reasonable addition or alternative to other forms of therapy.

REDUCTIONS IN PAIN MEDICATION USE ASSOCIATED WITH TRADITIONAL CHINESE MEDICINE FOR CHRONIC PAIN.

http://www.ncbi.nlm.nih.gov/pubmed/23012594

Participants in a randomized trial of traditional Chinese medicine (TCM) for temporomandibular joint dysfunction (TMD) had a linear decline in pain over 16 TCM visits.

OBJECTIVE:

To investigate whether reductions in pain among participants receiving TCM can be explained by increased use of pain medications, or whether use of pain medications also declined in this group.

DESIGN:

One hundred sixty-eight participants with TMD were treated with TCM or enhanced self-care according to a stepped-care design. Those for whom self-care failed were sequentially randomized to further self-care or TCM. This report includes 111 participants during their first 16 TCM visits. The initial 8 visits occurred more than once a week; participants and practitioners determined the frequency of subsequent visits. Outcome measures: Average pain (visual analog scale, range 0-10) and morphine and aspirin dose equivalents.

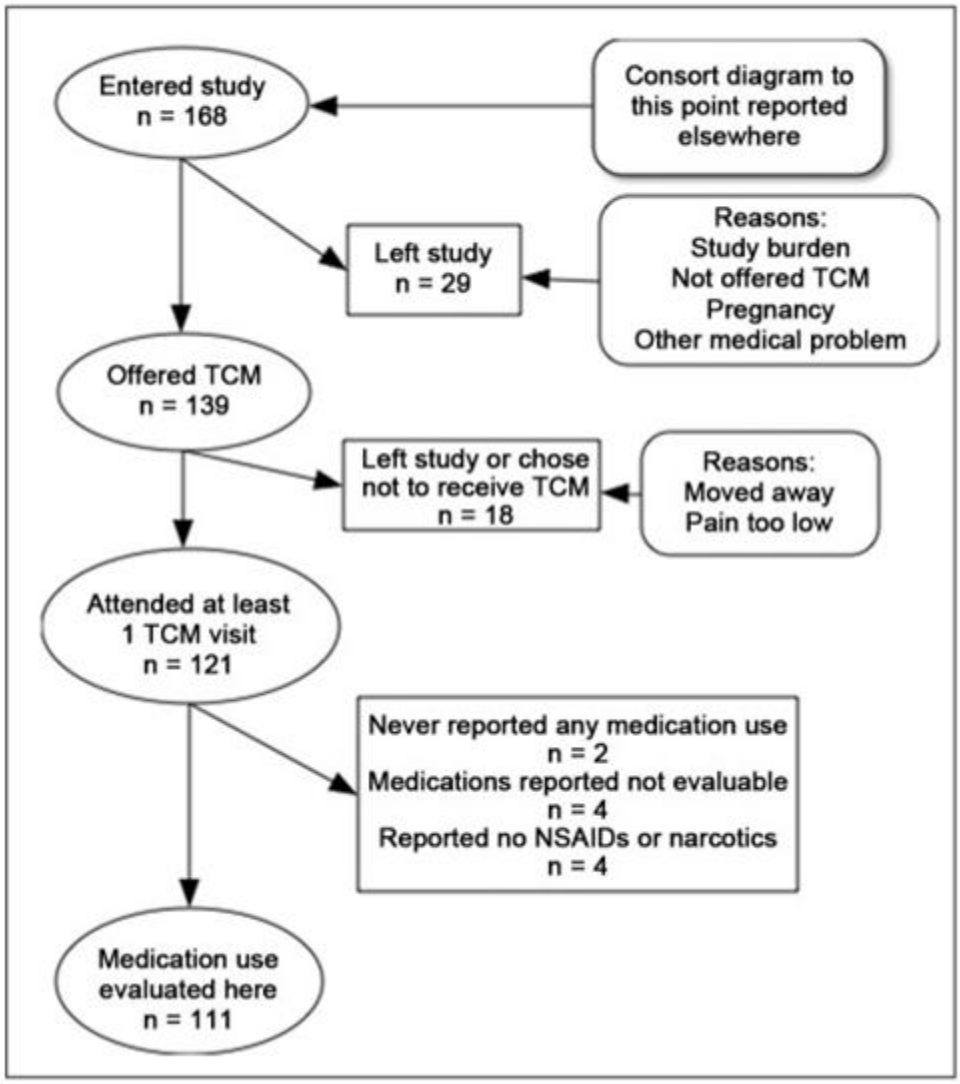
RESULTS:

The sample was 87% women and the average age was 44 ± 13 years. Average pain of narcotics users (n = 21) improved by 2.73 units over 16 visits ($p < 0.001$). Overall narcotics use trended downward until visit 11 (-3.27 doses/week, $p = 0.156$), and then trended upward until week 16 (+4.29 doses/week, $p = 0.264$). Among those using narcotics, use of nonsteroidal anti-inflammatory drugs (NSAIDs) declined linearly over visits 1-16 (-1.94 doses/week, $p = 0.002$). Among the top quartile of NSAID-only users (n = 22), average pain decreased linearly over 16 visits (-1.52 units, $p = 0.036$). Overall NSAID doses/week declined between visits 1 and 7 (-9.95 doses/week, $p < 0.001$) and then remained stable through 16 visits. NSAID use also declined among the third quartile (n = 23) and remained low and stable among the lower half (sorted by total intake) of NSAID users.

CONCLUSIONS:

Among the heaviest NSAID users, we observed a short-term reduction in NSAID use that was sustained as TCM visits became less frequent. There was no indication that pain reduction during TCM treatment was influenced by drug use.

Figure 1



THE WESTERN MODEL OF INTEGRATIVE ONCOLOGY: THE CONTRIBUTION OF CHINESE MEDICINE.

http://www.ncbi.nlm.nih.gov/pubmed/22936317

Western integrative oncology (IO) combines conventional mainstream medicine with complementary and alternative medicine (CAM) for the care of cancer patients. Since it includes patient orientation and the holistic approach of many CAM options, IO offers not only preventive measures, but also a wide spectrum of treatment modalities for all stages of illness, from the acute phases through the rehabilitation period. Many therapeutic methods of IO are supported by scientific evidence, for example, dietary and nutritional counseling, exercise, and mind-body medicine, among others. IO also includes therapeutic interventions of traditional Chinese medicine (TCM). At present acupuncture, qigong, and foot massage play an important

role in the Western care of cancer patients. However, unlike in China, in Western countries herbal remedies are usually only used during those periods in which chemotherapy is not applied in order to avoid herb-drug interactions. Instead, acupuncture is widely used to manage the side-effects that often accompany chemotherapy. This paper focuses on the role of Chinese medicine in Western IO and reviews the scope and limitations of IO in the care of cancer patients today. The future challenges of IO will also be discussed in this paper.

CURRENT APPLICATIONS OF MOLECULAR IMAGING AND LUMINESCENCE-BASED TECHNIQUES IN TRADITIONAL CHINESE MEDICINE.

http://www.ncbi.nlm.nih.gov/pubmed/21693174

ETHNOPHARMACOLOGICAL RELEVANCE:

Traditional Chinese medicine (TCM), which is fundamentally different from Western medicine, has been widely investigated using various approaches. Cellular- or molecular-based imaging has been used to investigate and illuminate the various challenges identified and progress made using therapeutic methods in TCM. Insight into the processes of TCM at the cellular and molecular changes and the ability to image these processes will enhance our understanding of various diseases of TCM and will provide new tools to diagnose and treat patients.

MATERIALS AND METHODS:

Various TCM therapies including herbs and formulations, acupuncture and moxibustion, massage, Gua Sha, and diet therapy have been analyzed using positron emission tomography, single photon emission computed tomography, functional magnetic resonance imaging and ultrasound and optical imaging. These imaging tools have kept pace with developments in molecular biology, nuclear medicine, and computer technology.

RESULTS:

We provide an overview of recent developments in demystifying ancient knowledge - like the power of energy flow and blood flow meridians, and serial naturopathies - which are essential to visually and vividly recognize the body using modern technology.

CONCLUSIONS:

In TCM, treatment can be individualized in a holistic or systematic view that is consistent with molecular imaging technologies. Future studies might include using molecular imaging in conjunction with TCM to easily diagnose or monitor patients naturally and noninvasively.

** SEEMS LIKE A MUST READ FULL ARTICLE **

GENERALIZED PROPENSITY SCORE FOR ESTIMATING THE AVERAGE TREATMENT EFFECT OF MULTIPLE TREATMENTS.

http://www.ncbi.nlm.nih.gov/pubmed/21351291

The propensity score method is widely used in clinical studies to estimate the effect of a treatment with two levels on patient's outcomes. However, due to the complexity of many diseases, an effective treatment often involves multiple components. For example, in the practice of Traditional Chinese Medicine (TCM), an effective treatment may include multiple components, e.g. Chinese herbs, acupuncture, and massage therapy. In clinical trials involving TCM, patients could be randomly assigned to either the treatment or control group, but they or their doctors may make different choices about which treatment component to use. As a result, treatment components are not randomly assigned. Rosenbaum and Rubin proposed the propensity score method for binary treatments, and Imbens extended their work to multiple treatments. These authors defined the generalized propensity score as the conditional probability of receiving a particular level of the treatment given the pre-treatment variables. In the present work, we adopted this approach and developed a statistical methodology based on the generalized propensity score in order to estimate treatment effects in the case of multiple treatments. Two methods were discussed and compared: propensity score regression adjustment and propensity score weighting. We used these methods to assess the relative effectiveness of individual treatments in the multiple-treatment IMPACT clinical trial. The results reveal that both methods perform well when the sample size is moderate or large.

EFFICACY OF GINSENOSIDES COMBINED WITH PREDNISONE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

http://www.ncbi.nlm.nih.gov/pubmed/20727331

BACKGROUND:

The side effects of glucocorticoid in treatment of systemic lupus erythematosus (SLE) have been the focus of debate, and our preliminary study indicates that ginsenosides can enhance the efficacy of dexamethasone.

OBJECTIVE:

To observe the effects of ginsenosides combined with prednisone in SLE patients.

DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS:

A total of 60 SLE patients from Department of Rheumatology and Immunology, Changhai Hospital, Second Military Medical University, were randomly divided into treatment group and control group, with 30 patients in each group. Patients in the treatment group were given routine treatment with prednisone plus ginsenosides, while those in the control group were given routine treatment with prednisone plus placebo. They were all treated for 3 months.

MAIN OUTCOME MEASURES:

After three-month treatment, syndrome score in traditional Chinese medicine (TCM), total response rate and symptom improvement rate were measured and evaluated.

RESULTS:

Twenty-eight cases in treatment group and twenty-seven cases in control group were included in analysis. The total response rates in the treatment group and control group were 89.28% and 66.67% respectively, and there was a significant difference between the two groups ($P<0.05$). After treatment, the TCM syndrome scores in the two groups were lower than those before treatment ($P<0.01$), and prednisone plus ginsenosides was better in decreasing the TCM syndrome score than prednisone plus placebo ($P<0.05$). The symptoms were improved in the treatment group as compared with the control group ($P<0.05$).

CONCLUSION:

Prednisone combined with ginsenosides can increase the clinical effective rate and improve the clinical symptoms of SLE patients.

NEUROTROPHINS AND ACUPUNCTURE.

http://www.ncbi.nlm.nih.gov/pubmed/20451467

The aim of this review is to report recent findings and ongoing studies on the effects of acupuncture on endogenous biological mediators, in particular on neurotrophins such as nerve growth factor (NGF) and brain-derived neurotrophic factor (BDNF). Acupuncture is a therapeutic technique and is a part of Traditional Chinese Medicine (TCM). Western descriptions of the clinical efficacy of acupuncture on pain, inflammation, motor dysfunction, mood disorders, and seizures are based on the stimulation of several classes of sensory afferent fibers and the consequent activation of physiological processes similar to those resulting from physical exercise or deep massage. The established research on the neuro-physiological correlates of acupuncture has pointed towards endogenous opioids as the principal biological mediators of the therapeutic actions of this ancient technique. More recently, several classes of molecules, such as neurotransmitters, cytokines and growth factors, have also been identified as possible

mediators for specific acupuncture effects. This review will focus on the links between acupuncture and a class of growth factors known as neurotrophins (NTs), which are the main mediators of neural activity, plasticity and repair following neurodegeneration and/or traumatic injury. A special emphasis will be placed on the work of our laboratory investigating the role of nerve growth factor (NGF), the prototypical member of the neurotrophin family, as a mediator of acupuncture effects in the central nervous system (CNS) and as a modulator of sensory and autonomic activity.

TRADITIONAL CHINESE MEDICINE FOR TREATMENT OF FIBROMYALGIA: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS.

http://www.ncbi.nlm.nih.gov/pubmed/20423209

BACKGROUND: Traditional Chinese Medicine (TCM) is popular for treatment of fibromyalgia (FM) although there is a lack of comprehensive evaluation of current clinical evidence for TCM's therapeutic effect and safety. Objective: To review systematically the beneficial and harmful effects of TCM therapies for FM.

METHODS: We searched six English and Chinese electronic databases for randomized clinical trials (RCTs) on TCM for treatment of FM. Two authors extracted data and assessed the trial quality independently. RevMan 5 software was used for data analyses with an effect estimate presented as mean difference (MD) with a 95% confidence interval (CI).

RESULTS: Twenty-five RCTs were identified with 1516 participants for this review. Seven trials (28%) were evaluated as having a low risk of bias and the remaining trials were identified as being as unclear or having a high risk of bias. Overall, ten trials were eligible for the meta-analysis, and data from remaining 15 trials were synthesized qualitatively. Acupuncture reduced the number of tender points (MD, -3.21; 95% CI -4.23 to -2.11; $p < 0.00001$, $I(2) = 0\%$), and pain scores compared with conventional medications (MD, -1.78; 95% CI, -2.24 to -1.32; $p < 0.00001$; $I(2) = 0\%$). Acupuncture showed no significant effect, with a random-effect model, compared with sham acupuncture (MD, -0.55; 95% CI, -1.35-0.24; $p = 0.17$; $I(2) = 69\%$), on pain reduction. A combination of acupuncture and cupping therapy was better than conventional medications for reducing pain (MD, -1.66; 95% CI, -2.14 to -1.19; $p < 0.00001$; $I(2) = 0\%$), and for improving depression scores with related to FM (MD, -4.92; 95% CI, -6.49 to -3.34; $p < 0.00001$; $I(2) = 32\%$). Other individual trials demonstrated positive effects of Chinese herbal medicine on pain reduction compared with conventional medications. There were no serious adverse effects reported that were related to TCM therapies in these trials.

CONCLUSIONS:

TCM therapies appear to be effective for treating FM. However, further large, rigorously designed trials are warranted because of insufficient methodological rigor in the included trials.

TRADITIONAL CHINESE MEDICINE IN THE TREATMENT OF RHEUMATOID ARTHRITIS: A GENERAL REVIEW.

http://www.ncbi.nlm.nih.gov/pubmed/20204371

Rheumatoid arthritis (RA) is difficult to cure. Many methods have been used for its treatment, among which traditional Chinese medicine (TCM) has been considered as an important strategy. All of the three parts of TCM: Chinese herbs, acupuncture, and massage have been reported with varying degrees of therapeutic effects on RA. Also the mechanism exploration is under process. Many effective ingredients of anti-rheumatic Chinese herbs have been found to inhibit RA development and some of the effective ingredients have been verified. Furthermore, greatly enhanced life quality of RA patients was obtained using acupuncture and massage to relieve pain, expand joint motion and modulate emotion which mainly correlated with the possible modulation of immune system, nerve system, endocrine system, etc. Thus, a systemic review on the therapeutic effect of TCM on RA is necessary. In our paper, the current status of TCM application in the clinic for the therapy of RA was summarized accompanied with the related mechanism exploration using modern test facilities.

PERSPECTIVE ON THE NATIONAL STANDARD STANDARDIZED MANIPULATION OF ACUPUNCTURE AND MOXIBUSTION PART II: SCALP ACUPUNCTURE.

http://www.ncbi.nlm.nih.gov/pubmed/20088422

Major difficulties and problems in composing the national standard Standardized Manipulation of Acupuncture and Moxibustion Part II: Scalp Acupuncture are discussed in this paper. The difficulties, including the importance of standards, selection of terminology, standardization and characteristics of traditional Chinese medicine, instructions of inserting and manipulating needle, basis and science of the standards, are elaborated as well as the further research and improvements are proposed in the present paper.

IMPROVED QUALITY MONITORING OF MULTI-CENTER ACUPUNCTURE CLINICAL TRIALS IN CHINA.

http://www.ncbi.nlm.nih.gov/pubmed/20035630

BACKGROUND: In 2007, the Chinese Science Division of the State Administration of Traditional Chinese Medicine(TCM) convened a special conference to discuss quality control for TCM clinical research. Control and assurance standards were established to guarantee the quality of clinical research. This paper provides practical guidelines for implementing strict and reproducible quality control for acupuncture randomized controlled trials (RCTs).

METHODS: A standard quality control program (QCP) was established to monitor the quality of acupuncture trials. Case report forms were designed; qualified investigators, study personnel and data management personnel were trained. Monitors, who were directly appointed by the project leader, completed the quality control programs. They guaranteed data accuracy and prevented or detected protocol violations. Clinical centers and clinicians were audited, the randomization system of the centers was inspected, and the treatment processes were audited as well. In addition, the case report forms were reviewed for completeness and internal consistency, the eligibility and validity of the patients in the study was verified, and data was monitored for compliance and accuracy.

RESULTS AND DISCUSSION: The monitors complete their reports and submit it to quality assurance and the sponsors. Recommendations and suggestions are made for improving performance. By holding regular meetings to discuss improvements in monitoring standards, the monitors can improve quality and efficiency.

CONCLUSIONS: Supplementing and improving the existed guidelines for quality monitoring will ensure that large multi-center acupuncture clinical trials will be considered as valid and scientifically stringent as pharmaceutical clinical trials. It will also develop academic excellence and further promote the international recognition of acupuncture.

THINKING ABOUT ACUPUNCTURE FOR TREATMENT OF SIMPLE OBESITY

http://www.ncbi.nlm.nih.gov/pubmed/19835127

In the viewpoint of traditional Chinese medicine (TCM), the authors consider that simple obesity is not a disease, which does not fit to be treated according to the models of diagnosis and treatment in TCM. Considering its cause, pathogenesis, syndrome differentiation, principles and methods of treatment, as well as experimental study, etc. , the authors point out that the true effects of acupuncture on weight-loss should be investigated alone and avoid the influence of diet and exercise. Until now, what we have done on the acupuncture for treatment of simple obesity is not sufficient to verify the direct effects of acupuncture for weight-loss. The correct

way for weight-loss is health care including dietary regime and regular life schedule. Comparatively, the treatment as the main choice for weight-loss is not recommended.

NEW EXPLORATION ON THE TYPES AND FORMS OF STONE NEEDLE

http://www.ncbi.nlm.nih.gov/pubmed/19824367

The basic use of stone needles in curing disease is cutting the carbuncles and purulences and pricking and draining off the sores. As a result, the forms of stone needle need to have a sharp cutting edge or slender point. Combining with corresponding unearthed material objects of archeology, the microlithic stone needle of mainly consists of a scraper, tip-like device and stone arrowheads. The stone needle of polished stone implements can be divided into three categories according to different forms and functions, that is conical-tip stone needles for pricking, e. g. lithostyle, coup de poing and stone arrowhead etc. ; sickle-shaped needle stone for cutting, e. g. stone knife, stone sickle, stone adze and stone chisel etc; spear-shaped stone needle for both cutting and pricking, e. g. stone spear, stone sword, jade (stone) spear etc. From the usage cases recorded in the ancient literature, the conical-tip stone needle for pricking ought to be the most used of the ancient stone needles. Use of the stone needle for hot stroking, massage and knocking at the body surface, which was raised by some related scholars, does not belong to the domain of ancient stone needles.

APPLICATION OF DELPHI TECHNIQUE IN IDENTIFICATION OF APPROPRIATE SCREENING QUESTIONS FOR CHRONIC LOW BACK PAIN FROM TRADITIONAL CHINESE MEDICINE EXPERTS' OPINIONS.

http://www.ncbi.nlm.nih.gov/pubmed/19769476

OBJECTIVE: The goal of the present study was to obtain a standard list of traditional Chinese medicine (TCM) symptoms and signs for screening chronic low back pain (cLBP) from a group of experts and to assess agreement and consistency among their opinions on the items of a questionnaire. DESIGN, SETTINGS, AND SUBJECTS: The study design involved three rounds of modified Delphi technique, and it was carried out by 13 experts in orthopedics, massage, and acupuncture working in four hospitals affiliated with Yunnan University of Traditional Chinese Medicine, China.

OUTCOME MEASURES: The outcome was measured on the 5-score Likert-scale self-administered checklists.

RESULTS: A review of eight textbooks identified 12 pain characteristics, 11 associated factors, and 25 physical and tongue diagnostic expressions as important factors in the TCM diagnosis of cLBP. These 48 diagnostic characteristics were rated by 13 experts as "not important" to "very important" on a scale of 1-5. After three rounds of rating, 13 characteristics were eliminated from the list, with the final numbers for each group being 8, 11, and 16, respectively. Seven items based on Western medicine were also added by the experts. The intra-class correlation (ICC) coefficient for agreement among the experts was 0.2 at the end. Intra-rater, between rounds, consecutive pair-wise median kappa values were 0.53 and 0.66. Analysis of variance using items appearing in all three rounds revealed significant effects of expert and group of symptoms and signs ($p < 0.001$) and nonsignificant differences among scores of the same expert in the three rounds ($p = 0.97$). Mean score of physical and tongue expressions was significantly ($p < 0.001$) lower than that of all other groups of symptoms and signs.

CONCLUSIONS: Modern TCM experts have de-emphasized the items on physical and tongue expressions and have adopted instead those from Western medicine. Intra-expert agreement across items was low, and each expert tended to stick to her/his original opinions.

THE ROOT AND DEVELOPMENT OF OTORHINOLARYNGOLOGY IN TRADITIONAL CHINESE MEDICINE.

http://www.ncbi.nlm.nih.gov/pubmed/19597834

There is an increasing trend in society to look beyond conventional medicine to find answers to problems in health. Traditional Chinese medicine (TCM) is one of the most popular alternative, complementary therapies worldwide. It is becoming a popular alternative in otorhinolaryngology where its use in the treatment of sinusitis, tinnitus, deafness and Meniere's disease is growing. Despite the general awareness of TCM, the literature relating specifically to otorhinolaryngology is relatively scarce. In this review, we have traced the origin and development of otorhinolaryngology with respect to TCM and have provided a few interesting insights into otorhinolaryngology, as it used to be practised. Archaeological sources have shown that diseases affecting the ear, nose and throat were of medical concern as early as the 18th century BC. The first practising otorhinolaryngologist can be traced back to the 5th century BC. Acupuncture, moxibustion, herbal therapy and massage were amongst his treatments. Otorhinolaryngology was recognised as a major specialty when formal medical education began in the 7th century AD. Therapeutic measures since then expanded to include exercise, food therapy and surgery. References to using oesophageal speech as a substitute voice generator, the use of copper wire to excise nasal polyps, procedures for removal of sharp foreign bodies in the oropharynx, repair of lacerated trachea and treatment of cancer of lips can be found in

historical notes. In conclusion, from its primitive roots, TCM has developed into a distinct branch of health care system in China today that works alongside Western medicine.

UTILIZATION, COST, PAYMENT, AND PATIENT SATISFACTION OF REHABILITATIVE SERVICES IN SHANDONG, CHINA.

http://www.ncbi.nlm.nih.gov/pubmed/19539394

OBJECTIVES: China's transformation into a market-based and global economy has had dramatic health policy implications on a system that serves roughly 1.3 billion people. This global perspective is resulting in the integration of Traditional Chinese Medicine (TCM) and western medicine for the treatment of an increasing number of morbidities. However, little research has been conducted that examines patient response to this convergence. This study researches the utilization, cost, payment and patient satisfaction with rehabilitative services received in China.

METHODS: A structured questionnaire was administered to 192 patients receiving rehabilitative services in China's Shandong Province.

RESULTS: The most frequently ordered TCM therapies were acupuncture (14.1%) and massage therapy (15.6%). The most frequently ordered western therapies were physical therapy (62.5%) and occupational therapy (6.3%). Physical therapy was considered the most cost-effective service at almost half the cost of acupuncture. Almost 85% of respondents had some form of health insurance and 90% expressed satisfaction with their therapy.

CONCLUSIONS: Healthcare providers should consider offering TCM and western medicine for morbidities requiring rehabilitative services. In a more global healthcare marketplace, the convergence of these two treatment modalities can lead to higher patient satisfaction and more cost-effective treatments.

STUDY ON THE BIOFEEDBACK EFFECT AND SIGNIFICANCE OF GETTING QI IN ACUPUNCTURE

http://www.ncbi.nlm.nih.gov/pubmed/19489495

In this paper, the basic concept of biofeedback therapy and the relationship between getting qi in acupuncture and biofeedback are introduced. Getting qi in acupuncture as a controllable index of biological information feedback between the physician and the patient, meets the

requirement of technique manipulation for biofeedback therapy. Arrival of qi has double regulative effects on the psychological and physiological functions of the patient, and has the effectiveness of the language suggestion and behavior suggestion in correcting the error in cognition of the patient. To take getting qi as an index in treatment of mental disorders conforms to theories of traditional Chinese medicine and is supported by modern medical research achievements, enriching contents and ways of biofeedback therapy and facilitating the development of acupuncture medicine towards biological-psychological-social medicine model.

DELPHI-DERIVED DEVELOPMENT OF A COMMON CORE FOR MEASURING COMPLEMENTARY AND ALTERNATIVE MEDICINE PREVALENCE.

http://www.ncbi.nlm.nih.gov/pubmed/19422299

Assessing complementary and alternative medicine (CAM) use remains difficult due to many problems, not the least of which is defining therapies and modalities that should be considered as CAM. Members of the International Society for Complementary Medicine Research (ISCMR) participated in a Delphi process to identify a core listing of common CAM therapies presently in use in Western countries. Lists of practitioner-based and self-administered CAM were constructed based on previous population-based surveys and ranked by ISCMR researchers by perceived level of importance. A total of 64 (49%) ISCMR members responded to the first round of the Delphi process, and 39 of these (61%) responded during the second round. There was agreement across all geographic regions (United States, United Kingdom, Canada, and Western Europe) for the inclusion of herbal medicine, acupuncture, homeopathy, Traditional Chinese Medicine (TCM), chiropractic, naturopathy, osteopathy, Ayurvedic medicine, and massage therapy in the core practitioner-based CAM list, and for homeopathy products, herbal supplements, TCM products, naturopathic products, and nutritional products in the self-administered list. This Delphi process, along with the existing literature, has demonstrated that (1) separate lists are required to measure practitioner-based and self-administered CAM; (2) timeframes should include both ever use and recent use; (3) researchers should measure and report prevalence estimates for each individual therapy so that direct comparisons can be made across studies, time, and populations; (4) the list of CAM therapies should include a core list and additionally those therapies appropriate to the geographic region, population, and the specific research questions addressed, and (5) intended populations and samples studied should be defined by the researcher so that the generalizability of findings can be assessed. Ultimately, it is important to find out what CAM modality people are using and if they are being helped by these interventions.

ENGLISH TRANSLATION OF THE TITLE OF ANCIENT CHINESE MEDICAL BOOKS AND DOCUMENTS

http://www.ncbi.nlm.nih.gov/pubmed/19213353

The title of a book is, generally, the high concentration of the writer's intention and the theme of content. Translate the title of an ancient Chinese medical book or document accurately and plainly is meaningful for exhibiting the style of the book, also for promoting the international communication of TCM. The principle should be followed is to choose the translating terms accurately to reveal the theme of content and express the cultural connotation of the book perfectly.

THE INVENTION AND IMPROVEMENT OF ANCIENT NEEDLE TOOLS OF TRADITIONAL CHINESE MEDICINE TCM

http://www.ncbi.nlm.nih.gov/pubmed/19141199

The development of needle tools in ancient China underwent a process of from stone through bamboo, bone, ceramic to metal materials, from rough to delicate manufacture, from multiple uses of a single one to diversified structure and shapes with different functions. Making research on the developing history of needle tools from Stone Age to the Ming and Qing dynasties in its materials, craftsmanship and applications can reveal the inventive values.

SERVING BILLIONS: A PILOT STUDY ON CLINICIAN-PERCEIVED EFFICACY OF REHABILITATIVE SERVICES IN CHINA.

http://www.ncbi.nlm.nih.gov/pubmed/18695405

China has the world's largest number of disabled people, and this number is projected to grow. Although there is ample literature on the utilization and efficacy of Western medicine as it pertains to rehabilitation services, there is far less research on the perceived efficacy of traditional Chinese medicine (TCM). A structured questionnaire was designed for a pilot study on TCM and Western medicine used for rehabilitation services in China, their associated charges, and perceived efficacy. A sample of 33 clinicians responded to the questionnaire. The analysis found that clinicians most frequently prescribed Fenbid and Chinese herbs to treat rehabilitation morbidities, and the most common TCM treatments were acupuncture and massage therapy. The average patient charge for each visit for TCM therapy varied from 56 Yuan (dollars 7.30) for Chinese herbal medicine to 12 Yuan (dollars 1.60) for cupping therapy. The most frequently prescribed Western therapies were occupational, physical, and speech. The

average charge for each visit for Western medicine varied from 111 Yuan (dollars 14.60) for physical therapy to 48 Yuan (dollars 6.30) occupational therapy. Clinicians indicated that acupuncture, Chinese herbal medicine, massage, speech, occupational, and physical therapies were "effective" or "highly effective" in treating morbidities requiring rehabilitation services.

COMPARATIVE STUDY ON CHINESE MEDICINE AND WESTERN MEDICINE FOR TREATMENT OF OSTEOARTHRITIS OF THE KNEE IN CAUCASIAN PATIENTS

http://www.ncbi.nlm.nih.gov/pubmed/18630549

OBJECTIVE:

To compare the efficacy, safety and tolerability of different therapies in Caucasian patients with osteoarthritis (QA) of the knee.

METHODS: Seventy-five cases (90 knee joints) of osteoarthritis were randomly divided into 3 groups, western medicine group, traditional Chinese medicine (TCM) group, integrated Chinese and western medicine group. The western medicine group were treated with oral administration of Glucosamine Sulfate, oral administration and external application of non-steroid anti-inflammatory agent, ultrasound physiotherapy, etc. The TCM group were treated with oral administration of J uanbi Decoction, acupuncture and moxibustion, cupping, massage of acupoint and ear acupuncture. The integrated Chinese and western medicine group were treated with oral administration of Glucosamine Sulfate, oral administration and external application of non-steroid anti-inflammatory agent, acupuncture and moxibustion, cupping, massage of acupoint and ear acupuncture. The intensity of knee joint pain on walking, resting and standing, the nocturnal pain, stiffness, the maximum walking distance and the daily living ability were monitored after 30 days, 60 days and 90 days of treatment.

RESULTS: After 90 days of treatment, the integrated Chinese and western medicine group was better than other two groups in improvement of percentages in self pain assessment with visual analog scale (VAS), pain and stiffness measured by WOMAC scale, pain and maximum walking distance measured by Lequesne scale ($P < 0.05$ or $P < 0.01$). There were no significant differences in the therapeutic effects between the TCM group and the western medicine group. All of these three treatments were well tolerated, and no severe adverse events were found.

CONCLUSION: Combined TCM and western medicine treatment has rapid and definite therapeutic effect in reducing pain and improving mobility of knee joints and daily living ability in Caucasian patients of knee osteoarthritis.

TRADITIONAL CHINESE MEDICINE AND KAMPO: A REVIEW FROM THE DISTANT PAST FOR THE FUTURE.

http://www.ncbi.nlm.nih.gov/pubmed/16866016

Traditional Chinese medicine (TCM) is a complete system of healing that developed in China about 3000 years ago, and includes herbal medicine, acupuncture, moxibustion and massage, etc. In recent decades the use of TCM has become more popular in China and throughout the world. Traditional Japanese medicine has been used for 1500 years and includes Kampo-yaku (herbal medicine), acupuncture and acupressure. Kampo is now widely practised in Japan and is fully integrated into the modern health-care system. Kampo is based on TCM but has been adapted to Japanese culture. In this paper we review the history and characteristics of TCM and traditional Japanese medicine, i.e. the selection of traditional Chinese herbal medicine treatments based on differential diagnosis, and treatment formulations specific for the 'Sho' (the patient's symptoms at a given moment) of Japanese Kampo--and look at the prospects for these forms of medicine.

REVIEW OF THE CHINESE MEDICAL APPROACH TO THE MANAGEMENT OF FIBROMYALGIA.

http://www.ncbi.nlm.nih.gov/pubmed/16157057

Traditional Chinese medicine (TCM) has a long history of efficacy in treating chronic illness. TCM views fibromyalgia and related conditions as disorders in the movement of energy (Qi) and body fluids (including blood) in the body and gets excellent treatment results using acupuncture, herbal medicine, massage, diet, and exercise to restore the proper flow of Qi and fluids. This article briefly introduces the TCM model of human physiology and TCM diagnostics and describes the TCM pathophysiology and treatment models for fibromyalgia.

TREATMENT OF 140 CEREBRAL PALSIED CHILDREN WITH A COMBINED METHOD BASED ON TRADITIONAL CHINESE MEDICINE (TCM) AND WESTERN MEDICINE.

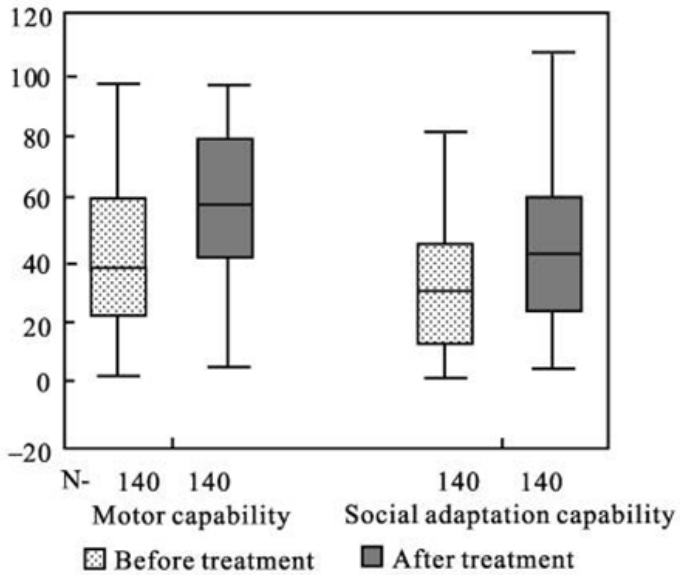
http://www.ncbi.nlm.nih.gov/pubmed/15593394

OBJECTIVE: To observe and evaluate a method that is effective and practical for treatment of cerebral palsied (CP) children in China.

METHOD: The patient's age and disease type and individual specific conditions were considered in choosing therapy methods accordingly: Chinese herbs, acupuncture, auricular seed pressure, point finger pressing, massage, orthopedic hand manipulation, physiotherapy, occupational therapy, language therapy, etc. Meanwhile we created a new CP treatment model that combines hospitalized treatment with family therapy.

RESULTS: The majority of CP patients improved greatly in motor and social adaptation capacities after treatment. Wilcoxon paired rank sum test analysis showed that there were significant differences between the data before and after treatment (P<0.01).

CONCLUSION: This combined therapy method, based on traditional Chinese medicine and western medicine plus family supplemental therapy, is an effective and practical treatment strategy for CP children in China.



INTEGRATING COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) INTO STANDARD HOSPICE AND PALLIATIVE CARE.

http://www.ncbi.nlm.nih.gov/pubmed/12785044

In the United States, there are 629 million visits to complementary and alternative medicine (CAM) providers each year. Many adults appear to value both conventional and CAM approaches. Because of this public interest and promising evidence that CAM relieves suffering and improves quality of life, we established a program of CAM, known as Integrative Palliative Care (IPC), in a US hospice. This paper outlines our strategy of collaborative relationships with

community schools of traditional Chinese medicine (TCM), massage, and harp therapy. It also describes the use of volunteers and small grants and donations to develop and maintain a program of CAM in the hospice setting. The difficulties of research design, problems with tracking outcomes, and the shortcomings of providing therapies with this model are discussed.

THE ROLE OF ALTERNATIVE MEDICINE IN TREATING POSTNATAL DEPRESSION

HTTP://WWW.NCBI.NLM.NIH.GOV/PUBMED/12463609

Postnatal depression is a serious and debilitating condition. Due to the perceived stigma of mental illness, the incidence of it is underreported and many mothers refuse psychiatric help either assuming postnatal depression to be normal or because of the potential consequences of having a psychiatric history. Community practitioners who are in contact with new mothers may welcome additional interventions which can enhance the supportive care they give to these women. This article discusses the evidence for a number of these interventions which mothers may find more acceptable than orthodox treatment. The aim of this article is to highlight the possible role of a number of complementary and alternative medicines as adjuncts or alternative treatments for postnatal depression. The interventions discussed in this article include Ayurvedic medicine, herbalism, homeopathy, aromatherapy, massage, hypnosis and traditional Chinese medicine (TCM). With the exception of TCM and Ayurvedic medicine, these interventions have been supported by the House of Lord's Select Committee on Science and Technology (2000) as having an evidence base. Ayurvedic medicine and TCM have been included in this article however, because a number of clients may be using them as their main system of health care--thereby validating the need for information regarding their efficacy. This article is not exhaustive, nor a licence to practice, but is intended as a resource for practitioners with a sound understanding of postnatal depression and conventional treatments whose clients may reject these approaches and be looking for alternative interventions. The final choice of treatment should be the result of discussion between the health visitor and the client and will depend on considerations such as availability, cost and acceptability of the intervention--this article does not, therefore, suggest a 'best option' approach. In addition, it does not address the professional and legal responsibilities of practitioners since these have been well reviewed by Darley (1995), Mantle (1997), Knape (1998) and Rankin-Box (2001).

COMPLEMENTARY AND ALTERNATIVE MEDICINE FOR MENOPAUSAL SYMPTOMS: A REVIEW OF RANDOMIZED, CONTROLLED TRIALS.

http://www.ncbi.nlm.nih.gov/pubmed/12435217

BACKGROUND:

Women commonly use soy products, herbs, and other complementary and alternative medicine (CAM) therapies for menopausal symptoms. Randomized, controlled trials have evaluated the efficacy and short-term safety of these therapies.

PURPOSE: To review randomized, controlled trials of CAM therapies for menopausal symptoms in order to better inform practice and guide future research.

DATA SOURCES: Searches of MEDLINE for articles published from January 1966 through March 2002, of the Alternative and Complementary Database (AMED) of the British Library for articles published from January 1985 through December 2000, and of the authors' own extensive files. Search terms were hot flash/flush, menopause, and climacteric, combined with phytoestrogens, alternative medicine, herbal medicine, traditional medicine, Traditional Chinese Medicine (TCM), Ayurveda, naturopathy, chiropractic, osteopathy, massage, yoga, relaxation therapy, homeopathy, aromatherapy, and therapeutic touch.

STUDY SELECTION: 29 randomized, controlled clinical trials of CAM therapies for hot flashes and other menopausal symptoms were identified; of these, 12 dealt with soy or soy extracts, 10 with herbs, and 7 with other CAM therapies.

DATA EXTRACTION: Each author extracted information from half of the studies on the number of patients, study design, outcome measures, and results; the other author then checked these results.

DATA SYNTHESIS: Soy seems to have modest benefit for hot flashes, but studies are not conclusive. Isoflavone preparations seem to be less effective than soy foods. Black cohosh may be effective for menopausal symptoms, especially hot flashes, but the lack of adequate long-term safety data (mainly on estrogenic stimulation of the breast or endometrium) precludes recommending long-term use. Single clinical trials have found that dong quai, evening primrose oil, a Chinese herb mixture, vitamin E, and acupuncture do not affect hot flashes; two trials have shown that red clover has no benefit for treating hot flashes.

CONCLUSIONS: Black cohosh and foods that contain phytoestrogens show promise for the treatment of menopausal symptoms. Clinical trials do not support the use of other herbs or CAM therapies. Long-term safety data on individual isoflavones or isoflavone concentrates are not available.

PRICKLY BUSINESS. THE FINER POINTS OF ACUPUNCTURE.

http://www.ncbi.nlm.nih.gov/pubmed/11362204

Acupuncture, which is gaining credibility among the Western medical establishment, is just one element of traditional Chinese medicine (TCM) being used to treat fatigue, nausea, insomnia, diarrhea, menstrual problems, and HIV-related peripheral neuropathy. Acupuncture is often used in combination with exercise massage, meditation, and herbal therapy. Special combinations of Chinese herbs are used to treat HIV-conditions, promote digestion, increase energy, and fight fungal infections. "Enhance", "Resist", and "Combination A", are three such formulas. Another benefit of acupuncture and Chinese herbs is their ability to decrease side effects associated with Western medicine. The growing medical interest in acupuncture is evidenced in the progress of CPCRA 022, a phase II/III trial to study acupuncture alone or in combination with amitriptyline, an anti-depressant, as a treatment for peripheral neuropathy. The National Institutes of Health (NIH) recently awarded the Bastyr University in Seattle, with funds to study alternative therapies. Regardless of outcomes, these studies may encourage other organizations to pursue acupuncture trials.

TRADITIONAL CHINESE MEDICINE (TCM) EXPERT SYSTEM IN POSTPARTUM NURSING.

http://www.ncbi.nlm.nih.gov/pubmed/8591359

The method of TCM treatment is highly appreciated by Chinese people, because it is safe, without side effects, widely applicable, gives good results, and uses natural medicinal herbs. It is an ideal natural cure that will make contributions to the health of patients all over the world. The superiority of TCM nursing and treatment should be brought into full play--it is an active nursing method which deserves recommendation for postpartum nursing. This paper introduces the TCM expert system in postpartum nursing and discusses the features of TCM treatment and nursing by using concepts of modern cybernetics. The human body can be considered a high-level automatic control system in which there are many trans information mediums, for example, neuro-system, humoral-system, meridian system (the response along the channels during acupuncture) etc. They stem from the very long process of evolution. Through the action of them, the body can adapt environments; keep normal metabolism and immunity; and possess the functions of compensation, learning, and self-repair, for example, conditioned reflexes, vaccination, etc. In general, the balancing tendency of dynamic body stays normal homeostate. If the body is ill, then its dynamic balancing tendency will be changed. TCM doctors can make use of remedy, acupuncture, and massage, etc. to regulate the balancing tendency of dynamic body to induce the defending ability itself and recover normal homeostate of body. The TCM nursing expert system in postpartum nursing has been finished. Its working environment must be CCDOS or UCDOS edition 3.0 and above. The hardware environment is PC/286, 386, or 486.