Acupuncture in the Treatment of Headache: A Traditional Explanation of an Ancient Art

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Background.—Over the past 4000 years, acupuncture has survived the test of time. Recent scientific studies posit acupuncture is an effective intervention for back and joint pain and headache, including migraine.
Methods.—The process of acupuncture is explained, including the role of Qi, the integration of Yang and Yin, the 5 elements, the 8 trigrams, and the metaphors that help the acupuncturist understand the patient, interpret symptoms, and determine acupuncture points in the meridians used to prevent or treat disease. A case study is presented from 3 perspectives: allopathic, traditional acupuncture, and Western acupuncture.
Results.—Selected acupuncture studies in headache are reviewed. The safety of acupuncture is discussed as well as the challenges in conducting clinical studies of acupuncture.

Key words: acupuncture, alternative medicine

Acupuncture is one of the oldest and most enduring healing practices in the world. Its origins can be traced back over 4000 years.[1,2] While modern medical science promotes the thirst for "new science," acupuncture values human experience as the cornerstone for health and the key for preventing and treating disease, and it is gaining in scientific stature and growing in popularity. In the United States, it is used by more than 3.1 million Americans per year.[3] Studies are beginning to generate explanations for acupuncture that create bridges with scientific thought.

BRIEF HISTORY OF ACUPUNCTURE

The origin of acupuncture remains obscure. It has been suggested that ancient Chinese doctors observed that soldiers pierced by arrows in battle recovered not only from their wounds, but also from a preexisting disease. These insights possibly led to the earliest developments of acupuncture. Stone and bone shards from the Neolithic period have been found and presumed to have been used for acupuncture needling. This suggests that acupuncture was practiced during or shortly after the Stone Age.[4] The earliest written record of acupuncture is found in the "*Yellow Emperor's Classic of Internal Medicine*" dating to about 200 BC.[5] This ancient text represents the earliest published foundation of acupuncture and Traditional Chinese Medicine.

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Headache

From China, the practice of acupuncture was carried to Japan, Korea, and South East Asia. There is evidence that it may have been practiced in Europe as early as the Bronze Age. Missionaries are presumed to have brought acupuncture to the West, and a Navy surgeon, Franklin Bache, published the first reports of the use of acupuncture for back pain in 1826.[6]

In China, the Communist Revolution nearly destroyed the practice of acupuncture and discounted it as unscientific. Chairman Mao later reversed this position, recognized acupuncture as a "national treasure," and promoted its exploration and understanding. During and after President Richard Nixon's visit to China in 1972, the world became transfixed by stories and demonstrations of surgery being done on fully awake patients with analgesia provided by acupuncture. While these demonstrations were later partially discredited, they impressed the Western world, including the scientific community.[7] Today acupuncture is commonly used worldwide, particularly for back and joint pain and headache. Although Western culture may not understand how acupuncture works, it has been used by over 6% of the US population.[8]

DEFINING ACUPUNCTURE

Acupuncture is defined in the modern scientific era as a "collection of procedures involving penetration of the skin to stimulate certain points of the body to prevent or treat disease."[1] Acupuncture is a component of classical Chinese Medicine and is considered to be a form of complementary medicine. Yet more accurately, acupuncture entails a medical methodology and philosophy that integrates and manipulates the complex interactions of a human organism with its internal and external environment in a manner that promotes harmony and health.

Several clinical studies demonstrated the validity of acupuncture as an effective therapeutic intervention for migraine and tension-type headache.[9-11] However, its efficacy remains controversial, and unfortunately some consider its benefit to be largely a placebo response.[12] While not a panacea, acupuncture demonstrates the importance of incorporating an understanding of the patient into the treatment of symptoms. This fact is supported by recent scientific and evidence-based observations.[13]

UNDERSTANDING THE FUNDAMENTALS OF ACUPUNCTURE

Acupuncture is a component of Traditional Chinese Medicine. Inherent in Chinese Medicine is a conceptual foundation of Qi

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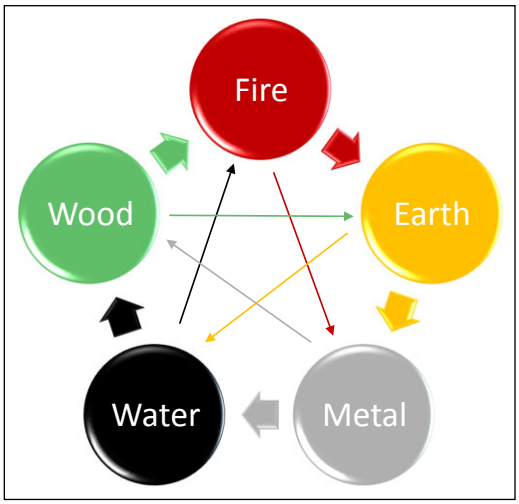

Fig 1.—The five elements. Adapted from Kaptchuk TJ. *The Web That Has No Weaver*. New York: McGraw Hill, 2000; 437–445.

or Chi (pronounced "Chee"), which is a transmutable energy that connects all that is known.[14] Qi is the life force of existence and transmutes or supports the changes of energy and matter.

In humans, there are 3 basic types of Qi: Original Qi (hereditary), Grain Qi (derived from digesting food), and Natural Air Qi (extracted from the air through breathing).[15] These energies are presumed to flow through 12 meridians or channels of the body. The meridians are also connected by an additional 8 "curious meridians" that together generate a web of transmutable energetic flow throughout the body.[16]

From Qi, the concept of Yang and Yin is generated representing 2 polar opposites that are used to explain worldly and human interactions. From an acupuncture perspective, a healthy human being has a balance of Yang and Yin. Imbalances or disharmonies of Yang and Yin are capable of producing symptoms and, if unattended, diseases. Imbalances can be described broadly as deficiency, stagnation, or rebellion.[14] The ultimate goal of acupuncture is not necessarily to defeat disease, but to reestablish the harmonious flow of Qi, which ensures health.

Yang is represented by the sun, incorporating energy, masculinity, and power. By contrast, Yin represents the shade, embodying damp, Earth, female, and potential. Neither Yang nor Yin can exist without the other, and each must always contain an interaction with the other. Together, Yang and Yin provide a model that organizes the flow and creative potential of Qi. In traditional Chinese acupuncture (TCA), this organization is represented as 5 elements: fire, earth, water, metal, and wood (Fig. 1).[17]

These metaphors are used to establish the relationships of virtually all human observations about the world. For example, fire is summer, earth is harvest, metal is autumn, water is winter, and wood is spring. These elements become a never-ending stream of metaphors to describe relationships of nature and human function (see the Table). Thus, winter equates to the emotion of fear, spring, to anger as in determination and anticipation, summer, to joy, harvest, to sympathy, and autumn, to sadness. The interactions of the 5 elements can be used to interpret such qualities as color, taste, and voice. They also describe qualities of personality. Fire is bold, extraverted, and enthusiastic. Earth is grounded, steady, and stable. Water is flowing, yielding yet persistent, and adaptable. Wood is flexible, strong, and confident. Metal is organized and durable. Each element describes negative qualities of personality as well. An acupuncturist will use these metaphors to understand the patient and interpret his or

Table.—The Five Element Relationships

	Fire (Summer)	Earth (Harvest)	Metal (Autumn)	Water (Winter)	Wood (Spring)
Positive traits	Bold	Grounded	Courageous	Adaptable	Flexible
	Energetic	Loyal	Disciplined	Determined	Strong
	Enthusiastic	Predictable	Durable	Flowing	Confident
	Expressive	Stable	Moral	Persistent	Kind
	Extroverted	Steady	Organized	Resourceful	Understanding
	Polite	Trusting	Spiritual	Yielding	Organized
Negative Traits	Anxious	Interfering	Destructive	Indecisive	Inflexible
	Manipulative	Meddler	Introverted	Plotting	Intolerant
	Restlessness	Miserly	Merciless	Self-centered	Prejudiced
	Unfeeling	Obstinate	Unkind	Trickiness	Stubborn
Yin Organ	Heart	Spleen	Lung	Kidney	Liver
Yang Organ	Small Intestine	Stomach	Large Intestine	Urinary bladder	Gallbladder
Emotion	Anxiety	Worry	Grief/Sadness	Fear	Anger
Virtue	Joy	Equanimity	Courage	Wisdom	Kindness

her symptoms. From this understanding of the 5 elements, a traditional acupuncture practitioner will determine the points in meridians to treat a symptom experienced by a specific patient.

In addition, Yang and Yin are associated with different body organs and each dictate specific energetic qualities to a person and the body's physiological function. Hollow organs such as the stomach, bladder, gall bladder, large and small intestine are considered Yang organs, while solid organs such as the kidney, spleen, heart, lung, and liver are Yin organs. Each Yang organ is paired with a Yin organ, and the flow of Qi can be initiated when the needles are inserted to create an energetic imbalance causing Qi to flow between paired meridians.

The 5 elements can also be translated into 8 trigrams that further refine and interpret the interactions of Yang and Yin (Fig. 2). Each element and trigram has an associated element (trigram) it nurtures (for example, wood nurtures fire and water nurtures wood), and each element is also paired to an element or trigram that controls the influence of its counterpart. In acupuncture, the individual patient is assigned an element or trigram based on history taking, and the symptom is also assigned an element or trigram as well. Interactions between assigned elements or trigrams are manipulated by the practitioner and used to define specific meridians and, indirectly, specific acupuncture points available for treatment. This yields an individualized treatment plan for a specific patient to treat a specific symptom. In acupuncture rarely does the practitioner seek pathology as a "cause" of disease, but instead looks to the patient and symptoms as expressing disharmony in Qi.

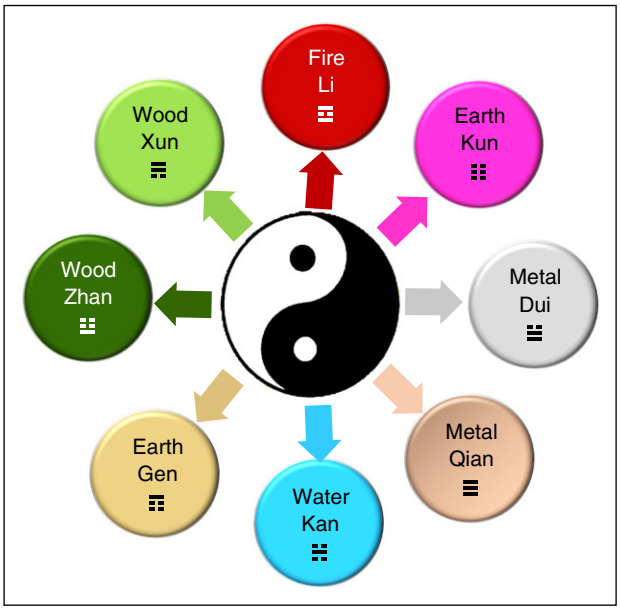

Fig 2.—Eight trigrams with corresponding elements. Adapted from Kaptchuk TJ. *The Web That Has No Weaver*. New York: McGraw Hill, 2000; 215–234.

A significant differentiation between TCA and Western medicine is that in acupuncture, the human body is not divided into silos or distinct body systems. While meridians are named as organs, these organs represent organizational principals of human functions more than distinct physical structure. For example, the stomach and spleen are paired organs reflecting the element Earth. While stomach prepares food by breaking it into its components for digestion and assimilation, it would also be the organ to "digest" emotional stagnation into its components for assimilation as well. The spleen is responsible for blood, which, in turn, is responsible for transporting nutrients to the body. In acupuncture, there is no such thing as a neurological system, an endocrine system, a psychiatric system, etc. Even the concept of disease is quite different. While Western medicine dwells on pathological factors threatening and altering human physiology in a detrimental manner to "cause" disease, in TCA, the viewpoint is about disruptive impedance to the flow of Qi that is reflected by the patient's symptoms.

Qi can be disrupted by stagnation, excess, or rebellion. Stagnations and deficiencies are generally represented by whole body symptoms such as lethargy, fatigue, or depression, and treated by tonification or stimulation. Stagnation, observed as body pain especially in the extremities, is treated by dispersion of Qi. Rebellious Qi occurs when Qi is flowing in the wrong direction and produces such paradoxical symptoms as vomiting or mania. While allopathic physicians would view the co-occurrence of unilateral throbbing headache, nausea, photophobia, and phonophobia as the syndrome of migraine, to the traditional acupuncturist, they are a series of symptoms that illustrate levels of disruptions of Qi.

Yang and Yin meridians provide layers of energy that protect the integrity of the body and encompass health. Symptoms (disease) occur when these layers are penetrated and Qi is disrupted. Acute disruptions, such as the flu or some forms of episodic headache, generally reflect superficial disruptions of Yang meridians, but these disruptions have the potential to become more pervasive and involve Yin meridians as symptoms become chronic. For example, the acute attack or exacerbation of a migraine may be viewed as a superficial (self-limited) disruption of Qi, while the chronic nature of migraine would be understood as involving a deeper disturbance reflected in several meridians of both Yang and Yin energy. In general, diseases of Yang origin are more likely to be acute, while diseases of Yin origin are more likely to be chronic.

Paramount to traditional acupuncture as a therapeutic tool is an understanding that both the "symptom" and the "person" are interacting to produce the symptom or "disease." In other words, disease is a personalized process as is its treatment with acupuncture. Each acupuncture point governs a unique domain or influence on the person being treated and selecting the right points for the right person, and the disease is the basis of treatment. While in Western medical thinking one would consider an infectious disease as being characterized by a specific organism with susceptibility to specific antibiotics, a traditional

acupuncturist would not necessarily consider the infecting organism, but instead would consider the symptoms being observed and the uniqueness of the person with the infection. Characteristics such as location, quality of the symptom, a person's specific physical, personal, or family traits all help determine acupuncture treatment needs. In acupuncture, there are no direct ties to a specific pathophysiological process that produces the disease. In traditional acupuncture, there are no treatment algorithms that apply to everyone, even if they experience the same symptoms or syndrome.

This concept has been intuitively understood by brilliant clinicians such as Hippocrates and William Osler. Hippocrates is reported to have said, "It is more important to know what sort of person has a disease than to know what sort of disease a person has." And Osler has been quoted as stating, "The good physician treats the disease; the great physician treats the patient who has the disease." Recently, however, the scientific study of the human genome has brought back this concept and the potential to meaningfully individualize medical treatment.

TREATMENT IN ACUPUNCTURE

There are over 2000 acupuncture points on the human body, and defining which of these points should be needled to treat a specific patient with a specific disease is a daunting challenge even for a seasoned practitioner. In fact, most practitioners use only a limited number of points to treat patients.

The traditional process of determining treatment need begins with taking a history, using the metaphors provided by the 5 elements as a guide to understand the patient and his or her symptoms. Once the interactions between the 5 elements are determined, the practitioner uses needling to nurture or inhibit the perceived imbalance to relieve symptoms and restore health. For example, wood increases or nurtures fire, while water dampens or inhibits fire. These elements become metaphors for interactions in health, disease, and life itself. Through these elements, specific symptoms and diseases are understood along with the unique traits and characteristics of the person with the symptom or disease. Each element is associated with a season, taste, color, and sense. Literally all qualities of human experience can be classified into the 5-element schema.

THE PROCEDURE OF ACUPUNCTURE

The location and properties of acupuncture points and meridians are difficult to define in specific physiological or anatomical terms. They are often considered to be in close proximity to nervous or vascular structures under the skin. When a needle is placed into acupuncture points, there is often a "grabbing of the needle" by the acupuncture point that is referred to as a "take." This has been considered to be a response of the neuromuscular bundle to needling. By turning or twirling the needle, a deep, uncomfortable sensation often occurs that stops when the needle is no longer manipulated. This feeling is considered the Qi energy being brought to the needle. Once the needles are properly placed, there is very little discomfort noted by the patient. Commonly during treatment some of the needles are stimulated by electrical current. Traditionally, needles are stimulated by moxibustion or manual manipulation, and these techniques are commonly used alone or in conjunction with electrical stimulation.

The acupuncture needle is generally a tapered needle that separates the tissue rather than cuts it. It is often constructed of a fine metal needle wrapped at one end with different metal. The two metals exchange electrons when inserted into a salt bath (the body) and hence generate a tiny electrical current. The depth of inserting the needle is variable, depending on the point being needled and the practitioner. Likewise, the number of points being needled varies considerably among practitioners, but generally between 10 and 25 needled points. The amount of time needles stay in place is generally 20 to 30 minutes, but may vary. These factors underscore some of the challenges of studying the effectiveness of acupuncture in allopathic clinical trials.

WESTERN MEDICAL ACUPUNCTURE (WMA)

There have been increasing and ongoing efforts to explain traditional acupuncture in terms that are more palatable to modern science. This effort was championed in the 1970s by Felix Mann, a well-known British acupuncturist who abandoned traditional explanations of acupuncture points, Yin and Yang, and Qi.[18] WMA attempts to explain acupuncture in anatomical and physiological terms that rest on evidence-based clinical trials. WMA promotes acupuncture as part of conventional rather than alternative medicine.

WMA emphasizes the role of acupuncture in stimulating the nervous system to produce antidromic axonal reflexes and neuromodulation of both the peripheral and central nervous system.[19] Studies using this methodology demonstrated that acupuncture has an effect on production of endorphins, serotonin, and gamma-aminobutyric acid (GABA) in the central nervous system, and fMRI studies have demonstrated changes in the limbic system.[20,21] This suggests that peripheral acupoints (WMA terminology for points needled in the periphery) result in activation of the representative correspondence of that point in the central nervous system. These mechanisms provide common ground for acupuncture and allopathic medicine to exist harmoniously, but it may also overlook important distinctions of these fundamentally distinct paradigms of healing arts.

CASE STUDY

MN is a 27-year-old woman with a 12-year history of recurrent throbbing headaches that are interfering with her daily life. She is not experiencing a headache at the time of her visit. She is conservatively dressed and wears little jewelry other than her

wedding ring. She is reserved, slightly overweight, articulate, and has a curious frailty in her mannerisms. Initially she is anxious, but this improves as the interview goes on. Despite subdued lighting in the exam room, she wears dark sunglasses for the first 15 minutes, and even after the glasses are removed, she avoids eye contact and is cautious and measured in her answers to questions. Her appearance and demeanor communicate a sense of fatigue and defeat.

Her headaches are usually left sided, but can be on the right or occasionally bilateral. The headache is worsened by activity, and the pain intensity is moderate to severe. The pain is described as a hot, searing, throbbing pain. Nausea and rarely vomiting accompany the headache as does significant sensitivity to light and sound. Headaches generally last 24 to 48 hours and are followed by a day of fatigue and tiredness, and an inability to sleep soundly. These episodes occur 4 to 6 times per month. She is missing work 1 to 2 days per month. Menses worsens her headaches. Stress and weather changes are also triggers for her headaches. Over-the-counter (OTC) non-steroidals lessen, but do not stop the headache. The medicine also upsets her stomach, so she is only using it once or twice a week. She is otherwise healthy except for recent weight gain and a history of recurrent urinary tract infections. She takes no other medications. She has noted no recent change in her headache symptoms.

ASSESSMENT FROM AN ALLOPATHIC PHYSICIAN VIEWPOINT

After obtaining her history, I conduct medical and neurological examinations primarily oriented to rule out occult pathology. After concluding that the examinations are normal, except for a body mass index (BMI) of 30, I am not compelled to order an imaging study, but if I did, it would be to rule out underlying pathology.

At the conclusion of the examinations, I organize the information into a single syndrome and diagnose her as having episodic migraine without aura. Based on this diagnosis, I prescribe an oral triptan and a non-oral triptan for rescue. Noting the high frequency of attacks, I also prescribe a prophylactic drug. With a BMI of 30, I believe she will benefit from topiramate, which will be titrated up to 100 mg per day. After a discussion of potential adverse events from the medications just prescribed and the value of early intervention with acute therapy, I instruct her to keep a headache and medication diary and give her another appointment in 6 weeks.

ASSESSMENT FROM A TRADITIONAL ACUPUNCTURIST VIEWPOINT

An acupuncturist uses 4 basic tools in the history taking process. These include inspection, auscultation and olfaction, questioning, and palpation. This may include examination of the tongue and the taking of the 3 dimensions of the pulse. These later skills take years to perfect and are less common in the practice of many occidental acupuncture practitioners.

In the initial component of taking this patient's history, I focus on characteristics, such as her appearance, vocal intonations, dress, personality, likes, and dislikes in order to assign an element or trigram that best represents her as a person. From this perspective, I conclude her water element is dominant in her personality though at present is unbalanced, as I consider her to be frozen or weakened in her adaptability. She is withdrawn, inhibited, exercising excessive caution, and is slightly suspicious. The elements and trigrams used in treatment from my analysis of her as a person would be reflected in strengthening water/kidney meridians. This assumption is also supported by her history of frequent urinary tract infections.

The next step is to assess the various disruptive symptoms she is experiencing and assign an element and trigram to these symptom(s). Her throbbing headache of acute onset and burning quality is best represented by the element of fire, which is a disturbance of Yang energy. Her other symptoms would be assessed as well in a similar regard, but their analysis is not included in this discussion.

The interaction of these 2 elements and their representative trigrams (water [the patient] and fire [the symptom]) determine the meridians and elemental energies for treatment. Individual acupuncture points are allocated based on the meridian and specific governing attributes of the acupuncture point.

Her abrupt headache can be interpreted as rebellion of excessive wood feeding fire or weakness of water unable to control fire. Given consideration of her constitution (frozen water), I want to strengthen the influence of water and do this either through tonification or stimulation of acupuncture points in meridians representing metal, which is the element that nurtures water or dispersing the influence of Earth, which is the controlling element of water. The primary focus of her treatment is on acupuncture points in the liver (wood), bladder (water), and spleen (Earth) meridians. These are used to strengthen water, disperse liver, and restore the normal direction to flow of Qi in the head. Elimination of the unwanted symptom of headache may be promoted through the large intestine meridian (for example, Large Intestine 4, which is in the web space between the thumb and index finger). Additional symptoms such as the nausea, vomiting, or photo- or phonophobia would also be addressed in the comprehensive treatment of this patient. The acupuncture treatments are individualized and modified over several weekly or biweekly visits based on her progress and symptom expression. Subsequent sessions would focus on constitutional symptoms such as lethargy, fatigue, and sleep, as well as triggers such as menses. Ultimately, efforts are based on strengthening and restoring the harmonious flow of Qi as prevention for future migraine. This would likely include discussions of diet, biofeedback, and physical activity, and, sometimes, the integration of allopathic medications.

ASSESSMENT FROM THE WESTERN ACUPUNCTURIST VIEWPOINT

History taking follows more of an allopathic approach, and the patient is diagnosed with episodic migraine without aura. Consideration is given to the anatomical location of pain and needles inserted and generally stimulated briskly, with the intention of elevating endorphins and other neuromodulators or activating central inhibition to noxious peripheral inputs. Needle insertion may occur at distant prominent acupuncture points (Large Intestine 4 or Stomach 36). In general, specificity of acupuncture points is not as relevant to the Western acupuncturist as it is to the traditional acupuncturist. In this regard, little attention is paid to acupuncture circuitry, meridians, or Qi.

REVIEW OF SELECTED ACUPUNCTURE STUDIES IN HEADACHE

Perhaps the noblest study on acupuncture for migraine was conducted by Diener et al published in *Lancet Neurology* in 2006.[22] The study was a prospective, randomized, double-blind controlled trial of patients with a diagnosis of migraine using modification of allopathic criteria similar to those of the International Headache Society. Subjects had 2-6 attacks of migraine per month. They were assigned to 1 of 3 study arms: traditional or "verum" acupuncture, sham acupuncture, or standard drug therapy. One thousand two hundred ninety-five patients were screened, and 960 were assigned to a treatment group. However, 125 subjects withdrew immediately after randomization, most because they were not assigned to an acupuncture arm of the study. All subjects recorded their migraine frequency for 1 month prior to randomization to establish their baseline migraine frequency.

Selection of investigators was based on acceptable training standards and active experience in the use of acupuncture in their clinical practice. Investigators were provided an ample list of acupuncture points that could be selected for verum acupuncture and another list of sham points for the sham acupuncture group. Subjects were informed they would be treated by Chinese (verum) or new Western acupuncture and treated with at least 10 sessions over a 6 week period. Electrical stimulation or moxibustion was not permitted, but the needles were manually manipulated several times during treatment.

The primary outcome measure, a reduction of migraine days between baseline and weeks 23-26 for the intent to treat population, showed a statistically significant reduction for migraine days for all 3 arms of the study. There were, however, no statistical differences between groups. Interestingly, an exploratory analysis revealed a significant difference in migraine days at week 26 vs baseline between verum vs sham acupuncture. The verum acupuncture group and the standard therapy group reported a reduction of 2.3 days and 2.7 days, respectively, compared with a reduction of 1.3 days for the sham group ($P = .03$). Subjects achieving a greater than 50% reduction in migraine days were observed in 47% of subjects receiving verum acupuncture vs 39% for sham acupuncture and 40% for standard therapy.

Secondary outcome analysis noted better scores for verum vs standard treatment on patient global assessment and pain-related impairment for subjects using verum acupuncture vs standard therapy. Both verum and sham acupuncture were well tolerated and with few adverse consequences.

The authors concluded all 3 treatments were effective and demonstrated similar efficacy. In the exploratory analysis, verum acupuncture was superior to sham acupuncture. The authors concluded with the argument that "efficacy of a treatment, especially with no adverse events or contraindications, is more important than knowledge of mechanism of action of his particular therapy."

Linde and colleagues have published Cochrane reviews on the use of acupuncture for both tension-type headache and migraine. The most recent migraine review looked at 22 trials with 4419 subjects.[23] Six trials compared acupuncture to routine care for subjects not using preventive pharmacological care. In these studies, subjects receiving acupuncture had fewer headaches. Fourteen studies attempted to compare sham and traditional (true) acupuncture and found no statistical differences between the 2 techniques. The authors note that this is difficult to interpret given many of the challenges discussed previously in this article. Four trials were comparisons of acupuncture to proven prophylactic medications. In these trials, acupuncture provided slightly better efficacy and fewer adverse events. The authors integrating their conclusion with a previous Cochrane review of acupuncture for migraine concluded that there is now consistent evidence "that acupuncture provides additional benefit to treatment of acute migraine only or to routine care." They also suggest acupuncture is at least as good as and possibly slightly better than prophylactic drug treatment and is associated with fewer adverse events.

Cochrane reviews of tension-type headache included 11 trials with 2317 subjects.[9] Two large studies compared acupuncture to treatment of acute headache or routine care only. Both studies found statistically significant benefit in reduction of headache days and pain intensity, at least in short-term evaluations of up to 3 months. Benefits were also observed for true acupuncture over sham. The authors conclude that acupuncture "could be a valuable non-pharmacological tool in patients with frequent, episodic, and chronic tension-type headache."

SAFETY OF ACUPUNCTURE

The safety of acupuncture has been demonstrated in several large studies. While the safety of commonly used pharmacological treatments for acute or preventive treatment of migraine and tension-type headache is reasonably high, it is fair to say that acupuncture offers a level of safety and tolerability that is several magnitudes better than observed with pharmacological interventions. This is particularly true when acupuncture is performed

with sterile surgical grade acupuncture needles. There are occasional reports of vasovagal reactions, increased symptoms requiring treatment, nausea, and sleepiness. Bleeding events are exceedingly rare even in patients taking anticoagulants.[24] This is largely due to the size and design of the modern acupuncture needle. A study in 2001 assessing 34,000 acupuncture treatments in the United Kingdom found no serious adverse events associate with acupuncture.[25] The rate of minor adverse events was between 0 and 1.1 per 10,000 treatments. Even though there are no absolute contraindications to acupuncture, the risks vs benefits of acupuncture should be carefully assessed where the integrity of the skin is weakened, the patient demonstrates serious psychiatric disease, there are implanted electrical devices (with electrical stimulation), and, possibly, pregnancy.

CHALLENGES IN CONDUCTING CLINICAL STUDIES OF ACUPUNCTURE

The gold standard for public health policy in occidental countries is largely determined by evidence generated through randomized, double-blind, placebo-controlled, clinical trials. These trials are structured to differentiate the benefit and risk of a specific variable (molecule) from a placebo for a specific diagnosis. Studies are designed to reduce the number of confounding variables despite the complexity of many diseases or the unfathomable complexity of biological systems.

In traditional acupuncture, it is challenging to construct a randomized double-blinded, placebo-controlled study because there are numerous variables introduced by and inherent to the acupuncture procedure itself. These include depth of penetration of the needles, selection of acupuncture points and meridians being used, type and duration of needling, and skill and blinding of the acupuncturist. In addition, it may be that patients gravitating to acupuncture have unique expectations of medical treatment different from those gravitating to allopathic medicine. Finally, there is the choice of clinical endpoints, such as, altering pathology vs balancing Qi. It is always important to bear in mind that acupuncture is more about prevention than treatment of disease.[26]

It is also difficult to conduct a placebo-controlled study with acupuncture. From research conducted by Western medical acupuncturists, it has become evident that insertion of a needle into the human body can have measurable and profound physiological effects. To account for this fact, numerous acupuncture studies attempt to compare traditional acupuncture not to placebos, but to a "sham" acupuncture procedure. Sham acupuncture is a comparison of traditional acupuncture point needling to needling of points away from known meridians and traditional acupuncture points. These studies rarely compare sham and traditional acupuncture where each patient has individualized acupuncture treatment meaningful to their disease. Instead a group of points are generally selected *a priori* for needling and used as acupuncture treatment without regard to the patient's component of the treatment equation. While this improves scientific integrity of the study, it is contrary to the individualized patient care principle of traditional acupuncture. However, without these procedures, there would be little hope of conducting a properly blinded study.

Results of several acupuncture studies demonstrated the benefit of acupuncture in migraine and tension-type headache, but not necessarily the benefit of traditional acupuncture over "sham" acupuncture. At times, the distinction between "sham" and traditional acupuncture has been lost, and scientific conclusions are made that acupuncture is no better than placebo.[27] This is unfortunate, as this distinction has considerable importance to allopathic headache medicine in attempting to interpret studies of neurotoxins and, perhaps, future injectable therapies. It appears that there is a need to construct new paradigms of study for acupuncture and other needle-based interventions.

CONCLUDING REMARKS

Acupuncture is an ancient art that has endured for over 4000 years. It is a testimony to efforts of ancient healthcare practitioners to understand that symptoms are a reflection of disharmony between a person and the environment. Even though acupuncture is not scalable, it offers an intervention that is less costly, more personalized, and often provides a better cost/benefit ratio than allopathic medicine.[28]

For example, acupuncture for headache provides modest benefit even when measured by contemporary Western medical standards, without the risks imposed by many pharmacological treatments as assessed by randomized, double-blinded, placebo-controlled clinical trials. These results suggest that safe, time-honored efforts to restore health appear to hold their value even when measured by standards developed 4000 years later. It is doubtful that any medical procedure or medication approved through the rigorous regulatory standards for headache will boast of its value 4000 years from now.

To summarize, rather than acupuncture proving its value to allopathic medicine, allopathic medicine needs to learn lessons from acupuncture about integrating the patient into the equation of effective treatment. Acupuncture should be considered as a valuable option in an integrated approach to the treatment of migraine and tension-type headache.

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