

Complementary and alternative medicine - facts and figures (Part I)

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Abstract

Background: Complementary and alternative medical practices are flourishing despite the current fast pace of scientific research and discovery. Traditional practices combine with newer philosophies to make up the vast spectrum that constitute this phenomenon.

Objectives: To describe homeopathy and acupuncture, proposed mechanisms of action, present scientific research to prove or disprove their efficacy and discuss safety issues.

Method: Studies, reviews and meta-analyses dealing with this subject were researched from various publications to present evidence for or against the efficacy of complementary and alternative medicine.

Results: Recent rigorous studies on acupuncture and homeopathy show no results beyond what is attributable to placebo effect.

Conclusion: Complementary and alternative medical practices should be researched for efficacy and safety by the same standards used in conventional medicine.

Introduction

Complementary and alternative medicine (CAM) constitutes a broad spectrum of therapeutic and diagnostic disciplines that exist largely outside conventional health care institutions. Common to most CAM systems is a focus on individualizing treatment and being holistic, whilst recognizing the spiritual nature of each individual. However, claims about efficacy often lack scientific evidence and have often been disproved during testing. The United States National Science Foundation has defined CAM as “all treatments that have not been proven effective using scientific methods” (National Science Foundation, 2001). Many practices form part of historical

or cultural traditions rather than being based on scientific principles, e.g. Chinese and herbal medicine.

Definition

Complementary medicine refers to practices which are used together with conventional medicine e.g. acupuncture used with conventional pain relief. **Alternative** medicine includes practices used in place of conventional practices, while **integrated** medicine is defined as conventional medicine combined with CAM practices that are safe and show some evidence of efficacy (National Centre for Complementary and Alternative Medicine, 2011). CAM practitioners refer to conventional medicine as **allopathic** medicine.

Prevalence of Use

CAM is very popular in both developed and less developed countries and use seems to be increasing: in 1997, CAM practitioners were visited by 627 million Americans, 200 million more than in 1990. Use of conventional medicine remained unchanged (Eisenberg et al, 1993, 1998).

In 2002, the most common therapies used by Americans were herbal medicines (19%), deep breathing (12%), meditation (8%), chiropractic (8%), yoga (5%), massage (5%) and diet-based therapies (4%). Use was more common in the more educated sector, women and higher income groups (Barnes, 2004). Users also tended to be more obese, to suffer from depression or chronic illness and to be a member of a religious organisation. A study carried out in England during 2005 gave similar results (Hunt, 2010).

CAM is also often incorporated into palliative care, where its use has always been more acceptable than in other fields of medicine as long as the treatments were safe and provided additional support. It “took for granted the necessity of placing patient values and lifestyle habits at the core of any design and delivery of quality care at the end of life”. (Kellehear, 2003)

Key Words

Complementary and alternative medicine, homeopathy, acupuncture, research, evidence-based, placebo effect

Use in developing countries is mainly driven by tradition and a lack of resources to buy more expensive conventional medicine; traditional or alternative remedies make up 80% of therapies used. Overall, over one third of the population in developing nations has no access to conventional drugs. (WHO, 2005)

The popularity of alternative therapy in Malta has not been assessed, but articles in the press, slots on television programs and advertising show that there is no lack of interest in the subject.

Classification

Complementary and alternative medicine methods can be very different in their origins and practice, being variously based on traditional medicine, spiritual beliefs or novel approaches to healing.

The National Centre for Complementary and Alternative Medicine (NCCAM) in America has classified CAM into five major groups (National Centre for Complementary and Alternative Medicine, 2008), with some overlap:

- 1 **Whole medical systems:** overlaps more than one group; e.g. Traditional Chinese medicine, Naturopathy and Homeopathy.
- 2 **Mind-body medicine:** explores the interconnection between the mind, body, and spirit e.g. meditation, yoga, hypnotherapy, tai chi and even prayer.
- 3 **Biology-based practices:** are based on natural products such as herbs and food.
- 4 **Manipulative and body-based practices:** consist of therapies involving manipulation and movement of body parts e.g. chiropractic and osteopathic manipulation, and massage therapy.
- 5 **Energy medicine:** a domain that deals with putative and verifiable energy fields:
 - **Biofield therapies** are based on supposed energy fields surrounding and penetrating the body. No evidence supports their existence.
 - **Bioelectromagnetic-based therapies** use electromagnetic fields such as pulsed fields, alternating-current, or direct-current in an unconventional way.

Objectives

In this article two branches of CAM, acupuncture and homeopathy, will be described and scientific research presented to provide evidence, if any, for their efficacy. Possible mechanisms for apparent effect and safety issues will be discussed.

Method

Articles, studies and meta-analyses regarding acupuncture and homeopathy were researched in various medical publications to present relevant evidence for or against their efficacy. Other studies researched related to safety issues and prevalence of use.

Acupuncture

Acupuncture is a 2000 year old branch of Traditional Chinese Medicine (TCM) in which different types of needles are inserted into specific points in the body to promote general health or treat various conditions, with an emphasis on pain relief. Diseases are attributed to disturbances in the metaphysical force known as *qi* (“vital energy”), imbalance of yin and yang, and the five elements: earth, water, fire, wood and metal (Wiseman and Ellis, 1996). No force corresponding to *qi* (or yin and yang) has been found in physical science or human physiology (Singh and Ernst, 2008). Dissection was forbidden and knowledge of internal anatomy was very limited. The location of the 12 meridians were probably based on the number of rivers flowing through the ancient Chinese empire, and the 365 acupuncture points were originally derived from Chinese astrological calculations and do not correspond to any anatomical structure (Lu, Needham and Lo, 2002).

In TCM, there are four diagnostic methods: inspection, auscultation and olfaction, inquiring, and palpation (Cheng, Deng and Cheng, 1987)

- **Inspection** focuses on the face and tongue.
- **Auscultation and olfaction:** listening for particular sounds (such as wheezing) and noting body odor.
- **Inquiring** focuses on: chills and fever, perspiration, appetite, thirst and taste, defecation and urination, pain, sleep and menses.
- **Palpation** includes feeling the body for tender points, and palpation of radial pulses.

Diagnosis relies primarily on examination of the tongue and pulse. The surface of the tongue is believed to contain a map of the entire body, and while teeth marks on one part of the tongue might indicate a problem with the heart, teeth marks on another part might indicate a problem with the liver (Maciocia, 1995). Three superficial and three deep pulses at different locations on the radial artery of each arm are postulated to correspond to twelve internal organs (Wright and Eisenberg, 1995).

Evidence for Acupuncture

Several indications for acupuncture have been reviewed:

A. Pain

The British Medical Journal published a review in 2009 of the highest quality clinical trials of acupuncture in the treatment of pain, which reported “a small analgesic effect of acupuncture was found, which seems to lack clinical relevance and cannot be clearly distinguished from bias” (Madsen, Gotzsche and Hrobjartsson, 2009). In 2011, a review of fifty seven systematic reviews of the topic, published in the journal of the International Association for the Study of Pain found that there is “little truly convincing evidence that acupuncture is effective in reducing pain” (Ernst, Lee and Choi, 2011).

Isolated studies have shown moderately favourable results when acupuncture is used alone or in combination with conventional therapies for neck and back pain. However, conducting research on low back pain is unusually problematic because of the **nocebo** effect. Many patients may have become disillusioned by conventional care – which in itself can be relatively ineffective – and have low expectations for it. Therefore, conventional care groups may not be an adequate scientific control, further inflating the apparent effectiveness of acupuncture (O’Connell, 2009).

A study done in 2005 showed that patients with chronic daily headache treated with acupuncture in addition to conventional therapy, responded 3.7 times better than controls (Coeytaux et al., 2005). Limitations included lack of blinding and of sham control. Several other trials have indicated that migraine patients benefit from acupuncture, although the correct placement of needles seems to be less relevant than supposed (Linde et al., 2009).

B. Nausea and vomiting

Stimulation of acupuncture point P6 (located on the underside of the forearm, several finger-widths from the wrist) is believed to relieve nausea. A Cochrane Review published in 2009 concluded that both penetrative and non-penetrative stimulation of the P6 acupuncture point had an effect approximately equal to that of preventive antiemetic drugs for postoperative nausea and vomiting (PONV), although only 10% of the studies had adequate information on patient blinding (Lee and Fan, 2009). An earlier Cochrane Review had concluded that electroacupuncture can be helpful in the treatment

of chemotherapy-induced vomiting, but more trials were needed to test their effectiveness versus modern antiemetic medication (Ezzo et al., 2006).

A review of studies about prevention of PONV in the first 24 hours, done in 2008, concluded that despite three of the ten studies found to have statistically significant evidence that acupuncture could prevent PONV, comparison was limited by the use of varied methodologies (different patient groups, different ways of stimulating the P6 point, timing of application of pressure and whether a general anaesthetic was used). It was concluded that “due to the lack of robust studies, [this review] found that neither acupressure nor acupuncture was effective in preventing or managing PONV in adults” (Abraham, 2008). Further study was warranted as more recent, better quality studies, offered more negative results.

C. Fertility and childbirth

In TCM, problems with fertility, pregnancy and childbirth are attributed to difficulty with the flow of qi through various meridians (Singh and Ernst, 2008).

While a 2008 Cochrane review of randomized controlled trials (RCT) of in vitro fertilisation and acupuncture showed an increase in live birth rate (Cheong, Hung Yu Ng and Ledger, 2007), a different review article published in 2010 found that there was no evidence acupuncture improved pregnancy rates (El-Toukhy and Khalaf, 2009). One of the limitations of earlier trials was the small number of women included.

D. Other conditions

The Danish Knowledge and Research Center for Alternative Medicines has evaluated the results of reviews by the Cochrane Collaboration regarding acupuncture and found that “...no solid evidence exists to determine the effectiveness of the treatments. The reviews point out that many of the studies suffer from methodological defects and shortcomings ... thus most of the overall conclusions are uncertain.” (Danish Knowledge and Research Center for Alternative Medicines, 2011)

This applies to the following conditions, among others: chronic asthma, Bell’s palsy, cocaine dependence, depression, drug detoxification, primary dysmenorrhea, menopausal symptoms, epilepsy, fibromyalgia, glaucoma, insomnia, irritable bowel syndrome, induction of childbirth, rheumatoid arthritis, schizophrenia, smoking cessation, acute stroke and vascular dementia.

Possible mechanisms for apparent effect

The placebo effect is thought to play a major role in the mechanism of action of acupuncture (Singh and Ernst, 2008). It is defined as a “physiological effect caused by a substance or procedure that is objectively without specific activity for the condition being treated”. No difference to clinical effect is demonstrated whether needles are inserted at acupuncture points or elsewhere. “Sham” acupuncture controls include insertion of needles at nonacupuncture points and the use of telescoping needles (Marcus and McCullough, 2009).

Sham and conventional acupuncture both provided significant analgesia compared with no treatment. However, there was little or no difference in the relief experienced by the two acupuncture groups where most participants could not distinguish between them (Assefi et al., 2005). The roles of belief in the procedure and expectations of relief were demonstrated in several trials.

When the skin is actually punctured, endorphin release, stimulation of the peripheral nervous system, and pain mediation through the effects of other neuropeptides are postulated to be the most likely explanations for the effects of acupuncture (Sun, Gan, Dubose and Habib, 2008).

Safety Issues

Acupuncture is considered to be safe when administered by well-trained practitioners using sterile needles. However it is an invasive procedure and rare adverse effects have been reported, the majority of which were minor e.g. slight haemorrhage, haematoma and dizziness (Ernst, Strzyz and Hagmeister, 2003; Ernst, Lee and Choi, 2011). More serious consequences included bacterial infections, nerve injuries and hepatitis B (Woo, Lin, Lau and Yuen, 2010), kidney damage, haemopericardium and even reports of pneumothorax leading to fatality (Ernst, 2010).

As with other types of CAM, the use of acupuncture may delay diagnosis or treatment of conditions for which conventional medicine has a better treatment record, potentially worsening patient outcomes; this is defined as opportunity cost. Patients’ resources may also be used up on ineffective procedures.

Homeopathy

Classical homeopathy is defined as a system of medical treatment based on the use of minute quantities of remedies that in larger doses produce effects similar to those of the disease being treated (“**law of similars**”). This

alternative therapy was conceived by a German physician called Samuel Hahnemann in 1796 in response to the highly dangerous practices performed by conventional doctors at that time, including administering mercury emetics, applying leeches and bloodletting. He came up with the theory that “like is cured by like” after he discovered that cinchona, a tree bark used for treating malaria, gave him chills and fever similar to that produced by the illness. He proceeded to test many substances on himself and on his friends and family (“**provings**”), ascribing solutions of the substances to different diseases and conditions according to the side-effects produced. He also theorised that highly diluted preparations should cure these diseases, the more dilute the solution, the stronger the resulting remedy – “**Law of Infinitesimals**”. This is an unproven assertion and not a true law of nature based on the scientific method (Maddox, Randi and Stewart, 1998).

Homeopathic remedies are prepared by serial dilution of substances, followed by **succussion** or forceful shaking. Substances used include Arsenicum album (arsenic oxide), Natrum muriaticum (table salt), Lachesis muta (the venom of the bushmaster snake) and Thyroidinum (thyroid hormone). Nosodes (Greek *nosos*, disease) are made from diseased or pathological products such as fecal, urinary, and respiratory discharges, blood, and tissue (Bellavite, Conforti, Piasere and Ortolani, 2005). Each dilution followed by succussion is assumed to increase the effectiveness, a process called **potentisation** or **dynamisation**. Dilution often continues until none of the original substance remains, being carried out by factors of ten or a hundred (Ernst, 2005). In fact at 12C or 12 serial dilutions by 1:100, only one molecule of substance may be present in solution. Hahnemann himself preferred to use 30C remedies. The presumed effect of the various dilute remedies is ascribed to “**water memory**”. It is asserted that the water molecules retain a “memory or vibration” of the substances that have been in contact with it even when no more molecules of substance are present, another claim unsupported by scientific evidence (Teixeira, 2007).

Hahnemann believed that disease was caused by **miasms** (e.g. psora or “itch”). If symptoms are suppressed by conventional medication, the cause supposedly goes deeper and begins to manifest itself as diseases of the internal organs. Homeopaths maintain that conventional medicine is ineffective as it treats diseases by directly opposing their symptoms (Ward, 1937).

During a long consultation, homeopaths generally take a detailed history, including questions regarding their patients' physical, mental and emotional states. The complex formula of mental and physical symptoms, including likes, dislikes, innate predispositions and even body type, enables the homeopath to treat the patient by consulting the homeopathic repertory, which is an index of symptoms and associated remedies.

Evidence for Homeopathy

There is a total lack of scientific evidence to support any of the theories of homeopathy, in fact the *Law of Infinitesimals* runs counter to the laws of chemistry and physics (Teixeira, 2007). This idea is inconsistent with the observed dose-response relationships of conventional drugs, confirmed by countless experiments on both animals and humans. Abstract concepts such as quantum entanglement, the theory of relativity and chaos theory have been used to explain how remedies might work, however these speculations often apply concepts incorrectly and are not supported by actual experiments (Shelton, 2004).

The theory of "water memory" is inconsistent with the fact that water molecules would actually have been in contact with millions of different substances throughout their existence, making water an extreme dilution of almost any conceivable substance. According to this interpretation, every imaginable medical condition can be treated by simply drinking water (Milgrom, 2007).

A widely cited 1997 publication concluded that the results of a meta-analysis were not compatible with the hypothesis that "the clinical effects of homeopathy are completely due to placebo" (Linde et al., 1997). After critics pointed out that 68 of the 89 trials included in the meta-analysis were of poor quality, the authors re-examined the same data two years later and concluded that "studies with better methodological quality tended to yield less positive results" (Linde et al., 1999).

In 2002, a review of systematic reviews found that there was no convincing evidence that any homeopathic remedy had better effects than placebo, and usage was not recommended in clinical management (Ernst, 2002). A later meta-analysis, which identified only eight trials that met higher standards for quality, concluded that "homeopathy was only very marginally more effective than placebo" (Shang, 2005). That report was accompanied by an editorial in *The Lancet* entitled "The end of homeopathy" (Lancet, 2005). Despite these analyses demonstrating no clear benefit for homeopathy

beyond a placebo effect (Ernst, 2006), advocates continue to cite the 1997 publication as evidence for homeopathy's efficacy.

Possible mechanisms for apparent effect

The placebo effect is the most widely quoted mechanism by which homeopathy is thought to exert an influence (Ernst, 2007). Belief in the efficacy of homeopathy and confidence and trust in the practitioner would enhance this effect. Veterinary use may seem to contradict the role of the placebo effect but there has been little scientific investigation and current research in the field is generally not of a high enough standard to provide reliable data (Hektoen, 2005). One well-designed study found no effect of homeopathic nosodes in preventing mastitis in cows (Holmes, Cockcroft, Booth and Heath, 2005). Other studies have found that giving animals placebos can play active roles in influencing pet owners to believe in the effectiveness of the treatment when none exists (Hektoen, 2005).

Other reasons for apparent efficacy could include natural healing, concurrent treatment with conventional medicine and adherence to life-style changes prescribed by the homeopath. Many diseases are cyclical, which would make any improvement attributable to the remedy taken, despite a natural regression towards the mean. Resolution of psychological and psychosomatic disorders can follow a lengthy, caring consultation (Shelton, 2004).

Safety Issues

Whilst most homeopathic remedies have an excellent safety profile, inherent in the fact that they are basically water, there have been instances of unwanted side-effects, secondary to improper preparation or intentional low dilution. Cases of arsenic poisoning have been documented (Chakraborti et al., 2003), as well as instances of anosmia following the use of zinc-containing cold remedies (Barrett, 2003).

Homeopathic drugs are regulated differently by the Food and Drug Administration (FDA) from conventional medications or dietary supplements. Under the provisions of the Food, Drug, and Cosmetic Act of 1938, all homeopathic remedies listed in the homeopathic pharmacopoeia of that time were exempted from tests for efficacy or safety. Remedies can be purchased over the counter and on the Internet as long as they do not claim to treat a serious illness (White Junod, 2001).

Of more concern is the fact that homeopathy users may delay or fail to utilize proper treatment for conditions that are easily cured by conventional medicine. Fatalities have been documented, among them a case of a 3 year-old Italian boy who died of pneumonia in October 2011 after being treated by his homeopath father (The Telegraph, 2011). The resistance of some homeopaths to the use of allopathic medicine can put patients off immunisation (Ernst, 2001) or the use of prophylactic drugs like anti-malarials (Jones 2006), exposing them to serious, often deadly infections. The argument that conventional medicine would “suppress” a disease and drive it deeper into the tissues and organs was used by George Vitoulkas in 1978 to convince his clients to discontinue treatment for syphilis (Birnbaum, Goldschmidt and Buffett, 1999), when it has been proven that treatment with penicillin effects a complete cure in 90% of patients.

Another issue is proper client information. It has been proposed that pharmacists should provide customers with the necessary information about the true nature of homeopathic products, making it obligatory for pharmacy curricula to teach students where unproven systems such as homeopathy depart from evidence-based medicine (Pray, 2006).

Discussion

Despite great advances in science, CAM practices are increasing in popularity. What is the attraction of alternative medicine? Different studies have come up with various reasons. One has cited the low scientific literacy and anti-scientific attitudes prevalent today (Beyerstein, 1999), with a resurgence of new age mysticism. Many people committed to environmentalism and feminism find CAM to be more congruent with their values and beliefs. Chronic illness can create a dissatisfaction with conventional medicine making the more personalized care provided by CAM look more attractive. Unpleasant side-effects caused by pharmaceuticals such as anti-cancer agents can be avoided by using CAM. Financial considerations are an additional factor especially in societies where a lack of a health insurance may mean unattainable conventional healthcare (Astin 1998).

The two CAM practices described in this article have very different origins and postulated mechanisms of action. There is no scientific evidence supporting either system’s philosophy, which is unsurprising considering that acupuncture originated in an ancient unscientific

culture mired in mysticism, while the workings of homeopathy were proposed when science was still in its infancy.

Evidence for efficacy in acupuncture is slightly stronger than for homeopathy. However, several reviews concluded that the placebo effect plays a major role, demonstrated by the fact that sham and actual needling obtained similar results, while varying the position of needle insertion produced no difference in effect. Further research has been recommended because the use of different methodologies makes comparison during reviews difficult.

There are less favourable results for homeopathy. Although earlier poorly designed studies showed some positive findings, later more rigorous trials were markedly less positive.

Safety issues are always important in medical care. Direct serious side-effects are very rare in both practices, although there have been recorded fatalities with acupuncture. A more important issue is **opportunity cost**, when conventional care is replaced by ineffective CAM practices, causing a delay in diagnosis and/or failure to treat serious conditions with proven methods. This may adversely affect outcomes and even cause fatalities.

Conclusion

“The systematic synthesis of evidence is the foundation of all medical discoveries and of good clinical practice.”(Dickersin, Straus and Bero, 2007)

Efficacy and safety of CAM practices should be evaluated by the same standards used to analyse conventional therapies; reliance on anecdotal evidence is not acceptable. Rejection of evidence in favor of traditional beliefs and clinical anecdotes compromises educational standards and clinical practice. Further evidence-based research will determine possible efficacy where controversy still exists.

More education of the general public and the medical profession is required to create more awareness of what really constitutes CAM practices so that informed choices can be made.

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