

Complementary and alternative medical therapies

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Current Opinion in Neurology 2008, 21:184–189

Purpose of review

Complementary and alternative medical therapies include herbs, acupuncture, and mind–body therapies. This review highlights the findings of recently published studies of complementary and alternative medical therapies and epilepsy, and provides an update of the US Food and Drug Administration's role in regulating herbal products.

Recent findings

Complementary and alternative medical therapies are often tried by patients with epilepsy, frequently without physician knowledge. Many modalities have been evaluated in patients with epilepsy, though methodological issues preclude any firm conclusions of efficacy or safety. Some herbal medicines have been shown experimentally to have mechanisms of action relevant to epilepsy and promising actions in animal models.

Summary

There is currently a paucity of credible evidence to support the use of complementary and alternative medical therapies in patients with epilepsy. Herbal medicines traditionally used for epilepsy and compounds isolated from them, as well as other herbal medicines and their constituent compounds that have been shown experimentally to have mechanisms of action relevant to epilepsy, should undergo further preclinical evaluation with a view towards clinical development under the new US Food and Drug Administration guidelines. Additional studies of other, nonherbal complementary and alternative medical therapies are also warranted based on anecdotal observations or pilot studies that suggest a favorable risk–benefit ratio.

Keywords

acupuncture, complementary and alternative therapy, epilepsy, herbal medicine, mind–body therapy

Curr Opin Neurol 21:184–189
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1350-7540

Introduction

Despite an expanded array of antiepileptic drugs (AEDs), improvements in and increased availability of brain surgery, and aggressive worldwide campaigns to narrow the diagnosis and treatment gaps, a significant proportion of patients treated for epilepsy continue to have seizures or troublesome AED-related side effects [1], and millions of people with epilepsy around the world have no access to modern treatments [2].

Patients treated for chronic medical conditions, such as epilepsy, and especially those with ongoing symptoms, such as seizures or medication-related side effects, often turn to complementary and alternative medical (CAM) therapies for relief, preferring 'natural' treatments to 'artificial' or 'synthetic' drugs, believing that 'natural' treatments are better and safer, and valuing the increased self-management afforded by their relationships with alternative healthcare providers. Likewise, people with epilepsy or other chronic disorders who live in regions of the world where geographic, economic, cultural, social or

religious factors present barriers to accessing modern medical treatments generally receive CAM therapies as their primary healthcare, or in association with medicine (e.g. AEDs) [3–6].

The National Center of Complementary and Alternative Medicine at the National Institutes of Health (NIH) defines CAM therapies as those healthcare and medical practices that are not currently an integral part of conventional medicine, and consequently are not typically taught in the standard curricula of Western (e.g. American) medical schools. CAM therapies include herbal medicines as part of traditional Chinese medicine (TCM; which also features acupuncture), Ayurveda, and other healthcare systems; homeopathy; mind–body therapies, such as yoga, prayer and therapeutic touch; other 'natural' substances, including high-dose vitamins and dietary supplements; special diets; movement, manipulation and massage therapies, including reflexology, massage, osteopathy, chiropractic, Reiki and Qigong; and electromagnetic forces.

This review starts with the scope of use of CAM therapies for epilepsy, describes those CAM therapies that have been evaluated for epilepsy in recent publications, highlights the findings, and concludes with an overview of related regulatory developments. Interested readers are referred to other sources that provide greater detail, particularly on specific therapies and safety considerations [7[•],8–14,15[•]].

Scope of use of complementary and alternative medical therapies in epilepsy

This section analyses the use of CAM therapies in developed and developing countries.

Developed countries

Up to 40% of patients attending epilepsy centers in developed countries take or have taken herbal medicines or dietary supplements, and the majority may not inform their physicians [16–18]. Products most often taken include ginseng, St John's Wort, melatonin, ginkgo biloba, garlic, soy, kava and black cohosh [17,18], suggesting that some usage was intended for epilepsy-related symptoms or comorbidities such as memory disturbance (ginkgo) and depression (St John's Wort). Likewise, ginkgo biloba was the most common herbal product identified in a survey of herbal use among residents of American nursing homes, including residents with a diagnosis of epilepsy, raising the potential for herbal-related adverse effects such as increased seizure frequency [19[•]].

Liow and colleagues [20] assessed usage of and perceptions about a variety of CAM therapies among 228 adult patients with epilepsy in the midwestern US using a 25-item survey. Thirty-nine per cent of the sample reported using CAM therapies, including 25% whose use was specifically for seizure control. The most common forms of CAM were herbs/dietary supplements, prayer/spirituality, 'mega' vitamins, chiropractic care and stress management.

Developing countries

The choice and use of CAM therapies by persons with epilepsy in developing countries, including those who subsequently move to industrialized countries, are influenced by existing traditional systems of healthcare, educational level, and prevailing cultural beliefs, such as that epilepsy results from evil spirits or sins of a past life [21–26]. For example, Carod-Artal and Vazquez-Cabrera [27[•]] collected information from several different groups of shamans and medicine men in Central and South America about the epilepsy-related beliefs among their people. One group believed that epilepsy turned the affected person into a witch and was caused by an attack suffered by the animal spirit who accompanies the person, after a fight between the spirits who serve the

forces of good and evil. Other groups thought it was due to the revenge of the armadillo spirit killed by a huntsman or a witchcraft that enters into the nose and the head, as a wind. Treatments consisted of roots kneaded and diluted in water, a ritual animal sacrifice and dried insect infusions and bird's blood.

Complementary and alternative medical therapies used for epilepsy

This section examines CAM therapies used for epilepsy.

Herbal medicines

Herbal medicines have been used to treat convulsive seizures for thousands of years, often as a major component of well established systems of healthcare such as TCM [28–30], Korean traditional medicine [31], and Ayurveda, a medical system and a science of life that is believed to have originated in India 6000 years BC [32].

TCM practitioners usually prescribe combinations of herbal medicines [33]. Over 130 herbal medicines used singly or in combinations for the treatment of epilepsy in the Far East have been reported in English or an Asian language [15[•],34[•]], which as of March 2005 consisted of three randomized controlled trials, five nonrandomized controlled trials, six case control studies and 57 observational studies including case reports [35]. Only one clinical study could be identified since 2005 in the English literature [36]. These clinical trials are generally difficult to interpret because of methodological issues in study design, inadequate powering, insufficient categorization of seizure types and epilepsy syndromes, questionable choices of outcome measures and statistical methods, and lack of characterization of the herbal medicines used for active interventions, as further discussed below.

The most frequently used herbal medicines in the published epilepsy literature from the Far East are *Pinella ternate*, *Arisaema japonicum*, *Acorus calamus*, *Gastrodia elata*, *Buthus martensii*, *Poria cocos*, *Bombyx bartriticatus*, *Citrus reticulata*, *Uncaria rhynchophylla*, *Glycyrrhiza glabra*, *Salivae miltiorrhizae*, *Scolopendra subspinipes*, *Bupleurum falcatum*, *Succinum*, *Paeonia albiflora*, *Panax ginseng*, *Perichaeta communissima* and *Curcuma longa* [15[•]].

Ayurvedic practitioners advise people with epilepsy to adopt specific lifestyle and dietary practices, and to take herbal preparations, the most common being Brahmira-sayan, Brahmighritham, Ashwagandha, old pure desi ghee, daily fresh juice of brahmi with honey, and powdered root of wild asparagus with milk. Other Ayurvedic herbal medicines include *Acacia arabica*, *Acorus calamus*, *Bacoppa monnieri*, *Clitorea turuataea*, *Celastrus panniculata*, *Convolvulus pluricaulis*, *Embllica officinalis*, *Mukta pishiti*, *Whithania somnifera*, and *Vaca brahmi yoga* [15[•],37].

In-vivo and in-vitro studies of many of these herbal medicines have evaluated their effects in animal models of epilepsy and mechanisms of action on neurons or in hippocampal slice preparations, and suggest that some possess anticonvulsant and neuroprotective properties. Interpretation of these results, however, is often limited by inconsistent descriptions of the methods used to authenticate the source plants, produce extractions and fractions, characterize the active ingredients and conduct the evaluations [15[•]]. More recent investigations have attempted to address these limitations [38–40,41^{••}]. For example, Khan *et al.* [42] studied the effects of *Bacopa monnieri* extract, a traditional Ayurvedic therapy, on glutamate receptor binding and NMDA R1 gene expression in the hippocampus of pilocarpine-induced epileptic rats. Unlike many other papers, this report describes the source of the plant material as well as the authentication and extraction methods. Further, voucher specimens were prepared and stored, allowing for further characterization of the plant materials or repeat laboratory studies.

The most common strategy for selecting herbal medicines for laboratory or clinical studies has been to choose those products that have a historical tradition of use as treatments for seizures. A recent paper [43[•]] suggests an alternative approach based on epidemiology. Salih and Mustafa noted that the prevalence of epilepsy among school children of Khartoum Province, Sudan, was lower compared with that of Europe and North America. They further observed that *Vicia faba* (broad beans) is a major food item for these children, much more so than for populations away from the Nile River. They therefore speculated that the constituents of *Vicia faba* have anticonvulsant properties. Consistent with this hypothesis, they reported that an extract of *Vicia faba* effectively reduced seizures in the mouse strychnine model.

Acupuncture

Acupuncture is another major component of TCM that has been used for people with epilepsy throughout the centuries, usually in conjunction with herbs [44]. Acupuncture appears to have anticonvulsant effects in a variety of animal models [45,46].

While various theories have been advanced to account for the putative anticonvulsant effects of acupuncture, including involvement of the vagus nerve and its central connections [47], demonstration of efficacy in patients is largely limited to open series or case reports. A recent Cochrane review identified only three randomized trials published in any language through June 2005, including two in China and one in Norway [48[•]]. The adult trial, which utilized the acupuncture points known as LR3, LI4, GV20 and one or two other points based on individual diagnoses [49] found no evidence that

acupuncture reduced seizure frequency or duration of seizure-free periods significantly more than sham acupuncture. Based on methodological limitations such as inadequate description of randomization and blinding procedures, the authors of the Cochrane review concluded that neither one of the remaining two studies, both in children, provided evidence of clinical benefit. An additional, more recent literature review also found no evidence to support the use of acupuncture in patients with epilepsy [50].

Two studies published after the Cochrane review period present illustrative methodological issues. In one [51], five courses of acupuncture treatment were given to 98 patients said to have ‘Jacksonian epilepsy’ and 52 were said to have a ‘markedly effective’ outcome. In the other study [52], 100 patients with ‘general paroxysmal epilepsy’ were randomized either to catgut implantation into selected acupuncture points or valproate (VPA); the ‘total effective’ was 94% in the catgut-treated patients compared with 82% in the VPA-treated patients.

Psychological therapies and mind–body techniques

Psychological therapies and mind–body techniques encompass a variety of methods appropriate for children [53] and adults, including behavioral inhibition of symptoms at seizure onset [54], cognitive–behavior therapy [55], relaxation techniques such as yoga and related meditative techniques [56,57], and neurofeedback [58,59]. Evaluating these treatments in double-blinded, randomized, controlled trials is generally not feasible, and while small open or pilot studies may suggest a therapeutic effect, evidence from large, randomized studies is either negative or not available. For example, the most recent Cochrane reviews on psychological therapies [60] and yoga [61] found no conclusive evidence of benefit in patients with epilepsy. Nevertheless, investigators continue to conduct open trials, which usually are interpreted to show therapeutic effects without side effects [62].

Homeopathy

The modern-day father of homeopathy was Samuel Hahnemann (1755–1843), who proposed that ‘like should be cured with like’, meaning that homeopathic preparations to treat patients’ symptoms should include plant or animal products that cause similar symptoms when given to healthy volunteers [63], and which are then serially diluted and vigorously shaken before being taken by patients [64].

Homeopathic medicines are taken by patients with epilepsy [3], though critics maintain there are no incremental benefits of homeopathy in excess of a placebo effect [65]. Interestingly, a homeopathic preparation of *Belladonna* was recently shown in an uncontrolled study

to reduce tonic-clonic seizures in 10 of 10 dogs with idiopathic epilepsy as reported by their owners [66].

Regulation of herbal medicines and recent developments

Herbal medicines in the US are regulated by the 1994 Dietary Supplement and Health Education Act, which defines a dietary supplement as a product taken by mouth that contains a dietary ingredient intended to supplement the diet, including herbs or other botanicals. Manufacturers of herbal products cannot claim they are effective against a specific disease or medical condition, such as epilepsy, nor are they currently required to produce herbal products using 'good manufacturing practice' (GMP) standards, as is the case for pharmaceutical products. Patients are generally unaware of the resulting wide variability in consistency, potency, and per-capsule quantity of herbal products from lot to lot – even from bottle to bottle – of the same product.

Two recent developments are changing the role of the US Food and Drug Administration (FDA) in overseeing the manufacturing and labeling of herbal products. First, in June 2007, the FDA issued its final rule entitled 'current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements' (<http://www.fda.gov/ohrms/dockets/98fr/cf0441.pdf>) that will significantly tighten manufacturing standards, thereby improving the quality and consistency of herbal products. Second, the FDA is now reviewing the safety and efficacy of complex herbal preparations for their approval for specific indications. The first such approval, in late 2006, was for a special extract of green tea that the FDA approved as a topical treatment of genital warts caused by the human papilloma virus. This new mechanism opens up the possibility that herbal extracts could be developed as potential FDA-approved treatments for epilepsy.

Conclusion

CAM therapies are heterogeneous in nature and are often tried by patients with epilepsy without the knowledge of their physicians, and despite the lack of well controlled trials to support their use and the possibility of adverse effects [7^o,67]. Therefore, neurologists need to ask their patients with epilepsy whether they use CAM therapies, especially herbal products, evaluate the associated possible risks with regard to seizure exacerbation and pharmacokinetic and pharmacodynamic interactions with AEDs, and advise their patients accordingly.

Nonetheless, herbal medicines with a tradition of use for epilepsy and compounds isolated from them, as well as

other herbal medicines and their constituent compounds that have been shown experimentally to have mechanisms of action relevant to epilepsy, should be further evaluated in animal models of epilepsy and moved into clinical development when feasible to assess for efficacy, safety and tolerability, using procedures that are consistent with the new FDA approval mechanism for herbal products [15^o,68,69]. Additionally, more studies of pharmacokinetic and pharmacodynamic interactions between AEDs and herbal products are needed.

Additional studies of other, nonherbal CAM therapies, such as acupuncture and mind-body techniques, are also warranted based on anecdotal observations or pilot studies that suggest a favorable risk-benefit ratio; however, methodological limitations will likely continue to impede their evaluation in the foreseeable future unless novel approaches to clinical study design and conduct are implemented [70].

Acknowledgement

This work was supported by grants from the Epilepsy Therapy Project, the Epilepsy Research Foundation and the American Epilepsy Society.

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Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 216).

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