Complementary medicine: evidence base, competence to practice and regulation

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ABSTRACT – This paper describes the current status and evidence base for acupuncture, homeopathy, herbal and manipulative medicine, as well as the regulatory framework within which these therapies are provided. It also explores the present role of the Royal College of Physicians’ Subcommittee on Complementary and Alternative Medicine (CAM) in relation to these developments. A number of CAM professions have encouraged the Royal College of Physicians Subcommittee to act as a reference point for their discussions with the conventional medical profession and the subcommittee believes that they are able to fulfil this function.

KEY WORDS: acupuncture, alternative medicine, chiropractic, complementary medicine, herbal medicine, homeopathy, osteopathy, regulation, safety

Introduction

Forty-seven percent of people in the UK have a history of lifetime use of complementary and alternative medicine (CAM) use and 10% use some form of CAM each year. At least 10% of hospital physicians also use CAM as part of their clinical practice. This level of apparent interest and use demands a considered and rational response from the Royal College of Physicians. The College has been involved in discussions with the CAM professions for the last three years. This resulted in the current Subcommittee on CAM and an international conference in January 2001 involving both the College and the National Institute of Health in the USA. The Department of Health responded to the recent House of Lords Select Committee Report on CAM by initiating and funding a research capacity building exercise over the next five years and working with interested professional organisations to enable and inform the debate on integrating CAM into clinical practice based on evidence, continuing professional development and appropriate statutory regulation for medically and non-medically qualified CAM practitioners, be they self-regulated or currently unregulated. It also hopes to act as a visible and informed point of contact for the organisations representing non-medically qualified practitioners.

Acupuncture

Background

Traditional Chinese acupuncture has ancient origins, perhaps as far back as the twenty-first century BC, although acupuncture-like techniques probably originated much earlier, approximately 5,200 years ago, as Ötzi the Tyrolean Ice Man’s tattoos suggest. An elaborate philosophical and medical system evolved, and needles were used to influence the flow of vital energy or ‘Qi’ via ‘meridians’ or ‘channels’. Acupuncture is now used in medicine as a technique informed by neurophysiological principles following an orthodox diagnosis.

Neurophysiological mechanisms

Acupuncture for pain works through Aδ nerve stimulation to give analgesia via local release of enkephalins at the same segmental level as the needle is inserted. In addition, heterosegmental analgesia is obtained via ascending spinothalamic and spinoreticular pathways, multiple central connections and descending inhibitory spinal pathways that use serotonin and noradrenaline as neurotransmitters. The sustained effects of acupuncture may be due to genetic up-regulation of pain inhibitory systems, with increased production of precursors such as preprodynorphin and preprometenkephalin. Acupuncture has widespread autonomic effects, eg the normalisation of gastric motility. Bowsher, White and Pomeranz review the neurophysiology in greater depth.

Does it work?

Acupuncture trial methodology has problems. The issues are complex and involve the use of appropriate
placebos, as well as many other aspects of trial design. Needling trigger points (TrPs) is particularly effective in the treatment of pain. Acupuncture is also used for many non-painful conditions.

Positive clinical trial evidence, based on systematic reviews and meta-analyses of acupuncture trials is available in experimental pain, nausea and vomiting, dental pain and headache. The efficacy of acupuncture treatment in back pain is less clear, with one positive systematic review, one neutral, and one negative review. Inconclusive evidence exists for stroke, asthma and neck pain so far, and negative evidence for weight loss and smoking cessation. However, the effect size of acupuncture in smoking cessation trials is similar to that of nicotine patches. Acupuncture is currently used in at least 84% of pain clinics in the UK and in primary care for multiple pain and non-pain symptoms.

Is it safe?
Although serious side effects can occur with acupuncture, they are rare. They include infection, damage to tissue, eg pneumothorax, and problems due to migration of broken or embedded needle fragments. However, an orthodox Western diagnosis is essential before starting treatment as acupuncture can potentially mask the signs and symptoms of cancer.

Cost effectiveness
Economic evaluation of acupuncture is currently based on limited evidence. Myers has demonstrated savings in drugs bills using acupuncture in primary care, and Lindall has determined the cost savings of running a dedicated acupuncture clinic, again in general practice. Christensen and Tillu both helped patients with knee osteoarthritis using acupuncture to such a degree that they voluntarily left waiting lists for knee replacement. In successive years, Ross dramatically reduced referrals to rheumatologists and physiotherapists from primary care with implied cost savings.

The future
In the UK, over 4,000 doctors, physiotherapists and other healthcare professionals using acupuncture are already regulated by statute, but there are also at least 2,000 professional acupuncture practitioners who are currently self-regulated but in the process of seeking statutory regulation as recommended by the House of Lords Select Committee, plus countless completely unregulated practitioners. It is noteworthy that the House of Lords Report makes a distinction between 'Acupuncture' (in Group 1 which it chooses to regulate) and Traditional Chinese Medicine (TCM) including an energetic diagnosis (in Group 3a) which it dismisses.

Herbal medicine

Background
Herbal medicine is among the most ancient forms of treatment known to man and the medicinal use of plants is common to all cultures and peoples of the world.

Does it work?
Despite a growing worldwide interest in herbal medicines, there has been relatively little high-quality research into the efficacy of herbal medicines, perhaps because they are difficult to exploit commercially. Since herbs often rely for their effect on a multiplicity of chemical constituents, which may have a synergistic or buffering effect, a plant which looks promising may fail to yield any effective isolated single active chemicals. Also, unlike conventional medicines, prescriptions are prepared individually to suit a particular need. For example, St John’s Wort may be marketed to treat mild to moderate depression but herbalists often combine this with various remedies, eg Lemon balm (Melissa officinalis) for anxiety and depression, with Wild oat (Avena sativa) and/or Ginseng (Panax ginseng) for neurasthenia. Although there are relatively few randomised trials evaluating herbal medicine, nevertheless Western herbal medicine has an extensive evidence base, to be found in several peer-reviewed journals. EXTRACT, a dedicated herbal medicine database developed at the University of Exeter, contains systematic reviews, meta-analyses of randomised controlled trials and textbook summaries.

A large body of research exists for Chinese herbal medicine (CHM), most of it carried out in China. The majority of these studies take the form of collected case histories and clinical outcome studies. However, controlled trials (in particular comparing the effectiveness of CHM with placebo or with pharmaceutical drugs) have increasingly become the norm.

Are herbs safe?
Herbal medicines contain a multiplicity of chemical constituents, some of which may cause adverse effects. Such effects may also be caused by contaminants present in herbs such as heavy metals, or by misidentification of a herb. There is also a potential for herb–drug interactions, eg St John’s Wort may interact with indinavir, warfarin, cyclosporin, digoxin, theophylline and possibly oral contraceptives. This interaction appears to be mediated via the cytochrome P450 metabolising enzyme system in the liver.

In the context of the number of consultations, incidences of herbal adverse events are infrequent. A five-year study (1991–6) into adverse events involving traditional medicines and food supplements by the National Poisons Unit received 1,297 enquiries but found genuine adverse effects in just 38 instances.

The UK Medicines Control Agency (MCA) has recently published a report which states, ‘in general most herbal products are unlikely to pose a significant threat to human health.’
The professional herbal associations in the UK are now running a yellow card Adverse Event Scheme with the MCA.

**The future**

The European Herbal Practitioners Association (EHPA), founded in 1993, comprises the majority of herbal organisations representing the 2,000 UK practitioners and has a growing membership throughout the EU. Its work over the last decade enabled the Government to set up in early 2002 the independently chaired Herbal Medicine Regulatory Working Group (HMRWG) charged with publishing proposals for the state registration of herbalists. The HMRWG together with the MCA is also engaged in drawing up and publishing for public discussion, new measures regarding the legal arrangements for the one-to-one prescription of herbal medicines.

**Homeopathy**

**Background**

Homeopathy (also spelt homoeopathy) is a system of therapeutics based on the idea of ‘treating like with like’ (*similia similibus curentur*). It originated in the last decade of the eighteenth century in the work of the German physician, Dr Samuel Hahnemann. He experimented on himself, taking a dose of Cinchona bark (the source of quinine), and developed intermittent fevers, similar to the fever it was used to treat. Homeopathic medicines are prepared by a process of serial dilution in steps of 1:10 or 1:100 (denoted x and c respectively), with succussion (vigorous shaking) at each step. The dilution most frequently sold over the counter in pharmacies is 6c, which is a $10^{-12}$ dilution of the original ‘mother tincture’. It is likely that a 6c dilution will contain a few molecules of the initial substance, but much higher dilutions, such as the 30c ($10^{-60}$) probably do not contain any of the starting substance. A large number of homeopathic medicines have been described but about 200 are in regular use. Around 60% are of plant origin, the remainder mostly of animal origin, minerals and chemical salts and disease products. In prescribing such treatment, the homeopath will enquire not just about the symptoms and signs of the disease, but also about ‘constitutional’ factors peculiar to the patient (rather than the disease) including their psychological state, environmental reactions and body habitus.

Despite its apparent implausibility, homeopathy is among the most popular forms of CAM, with an estimated 470,000 regular users in the UK, and sales growing by around 12% annually.1 Because homeopathic treatment is individualised, several meta-analyses have focused on single medical conditions. They support the effectiveness of homeopathic treatment in hayfever32, post-operative ileus33 and rheumatism34, but not asthma35 or other single conditions.

**How it may work**

The ‘Benveniste Affair’ erupted in 1988, when the immunologist Jacques Benveniste published, in *Nature*, a paper claiming to have detected effects of an immunoglobulin at ultramolecular dilution, using the human basophil degranulation test.36 This led to a fierce debate, and Benveniste's results appear not to be reproducible.37 However, in 1999 a multi-centre experiment using a related method showed positive results.38 The leading current hypothesis on the action of ultramolecular dilutions is the ‘information medicine’ hypothesis: ‘water is capable of storing information relating to substances with which it has previously been in contact, and subsequently transmitting this information to pre-sensitised biosystems.’ The process is thought to be mediated by structural modifications of water, analogous to the storage of information by magnetic media. Such information is retained in physical, rather than chemical, form.39

**Is it safe?**

Homeopathy appears to be very safe,40 which is an important motivating factor amongst its patients. The alternative of homeopathy is one of the reasons frequently cited by parents who do not wish their children to be immunised.41 Some non-medical practitioners claim that homeopathy is an effective substitute for immunisation. There is no evidence that this is so. The Faculty of Homeopathy supports the Department of Health immunisation guidelines and provides an information sheet for parents.

**Homeopathy, homeopathic practitioners and the NHS**

Homeopathic practice is essentially unregulated in the UK: anyone can describe her/himself as a homeopath. Doctors therefore cannot refer, only delegate, the care of their patients to non-medically qualified homeopathic practitioners, retaining at least some of the liability for any untoward event. Uniquely among CAM therapies, homeopathy has a recognised specialist training body (which admits registered health professionals only) – the Faculty of Homeopathy, which issues the diplomas of Fellow, Member and Licensed Associate (FFHom, MFHom, LFHom), and has five dedicated NHS secondary care centres. These centres are staffed by doctors and referrals to them can be made in the normal way. Most of them offer a range of CAM therapies, not exclusively homeopathy. Homeopathic medicines are licensed or registered by the MCA, and are NHS-prescribable in the normal way.

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1. Linde et al, which included all placebo-controlled trials of homeopathy, concluded that homeopathy’s clinical effects are not attributable solely to placebo;29 however, homeopathy was not clearly efficacious for any single medical condition. Two further meta-analyses of homeopathy came to broadly similar conclusions.30,31
The manipulative therapies

Background

Osteopathy and chiropractic established themselves in the USA in the late nineteenth century. Andrew Taylor Still founded osteopathy in 1874 and Daniel David Palmer founded chiropractic some twenty years later. They and their followers were practical people who sought workable solutions to the healthcare problems of a rapidly expanding nation, where conventional medicine and surgery were seldom easily available and offered few safe and effective treatments. In this pioneering and entrepreneurial new society, homeopathy, herbalism, various forms of ‘nature cure’ and ‘magnetic healing’ thrived as popular alternatives. Osteopathy and chiropractic appealed because of their apparently common-sense notions of mechanical holism, and their emphasis on health maintenance. Both approaches rapidly evolved into formalised systems of professional healthcare with their own training schools, and by the early twentieth century their practitioners competed increasingly with mainstream medics.

Early thinking in osteopathy and chiropractic shared the notion that the neuromuscular and nervous systems have a prime importance in maintaining health. Traditionally, osteopathy has placed greater emphasis on the role of the entire neuromuscular apparatus, whereas chiropractic considered the CNS and autonomic nervous systems as prime integrators of physiological processes. Today, only extreme traditionalists are confined by these theories and most practitioners have been heavily influenced by twentieth century scientific and behavioural research. While both chiropractors and osteopaths use manual methods, including spinal manipulation to treat musculoskeletal pain and dysfunction, a minority who remain wedded to the original idea (that neuromuscular dysfunction is fundamental in triggering or maintaining other diseases) also use these methods as wide-ranging adjunctive approaches to healthcare of many conditions. However, the overwhelming application of spinal manipulation is by osteopaths, chiropractors and a small proportion of the physiotherapy profession, for musculoskeletal disorders.

Does it work?

A recent large and authoritative systematic review of the relative effectiveness of interventions that included spinal manipulation for patients with low back pain identified 38 randomised trials of sufficiently high quality to have their outcomes converted into measures of pain and disability.

For acute back pain (duration of less than six weeks), manipulated groups had substantially and significantly better outcomes than traction, corsets, bed rest, home care, topical gel, no treatment or massage and modestly better outcomes than physical therapy with exercise. They also had apparently large, but non-significant, advantages over sham treatment. They had only modest (and non-significant) benefits over back schools, and ‘conventional’ GP care with analgesics.

For chronic back pain, interventions that included spinal manipulation were shown to confer substantial and significant improvement over traction, corsets, bed rest, home care, topical gel, no treatment and massage, and moderate, but non-significant advantage over sham treatment. For chronic back pain, these groups were generally no more (but no less) effective than back schools, conventional GP care with analgesics and physical therapy with exercise.

In general, this large review found that the long-term outcomes in these comparisons were only modestly poorer than the short-term ones. Therefore, while spinal manipulation has been found to be as good as, or better than, the interventions to which it has been compared for acute back pain in this and other reviews, these reflect less advantage in chronic back conditions. However, preliminary results of one randomised trial of manipulation, which is the largest ever undertaken, show that a defined manipulation ‘package of care’ for chronic back pain by a cross-disciplinary group of manipulation practitioners was slightly but significantly more effective than best evidence-based GP care in terms of reducing disability. The results of this trial in terms of pain reduction are still awaited.

There is emerging evidence, following the same general pattern, for manipulation for neck pain, although this is currently insufficient to support as full a review as for back pain. The amount and quality of the evidence in headache is modest and in other conditions it is poor. There is no evidence that spinal manipulation used by any professional group is better than any other manipulative technique, ie osteopaths do not get better outcomes than chiropractors.

Is it safe?

Acknowledged contraindications to spinal manipulation include severe osteoporosis, malignant, infective or inflammatory spinal disease. Caution is advised in spinal manipulation of elderly patients, patients with bleeding disorders and those who have an aversion to touch, dissociative tendencies and psychotic illness.

The commonest adverse events following manipulation are transient discomfort or brief exacerbation of symptoms in around half of patients. Despite warnings in the medical literature, more serious adverse events are very rare but include arterial damage and cerebrovascular accidents following cervical manipulation in between 1:400,000 and 3–6 in 10 million procedures. These appear to be limited mostly to dissection of the vertebral or carotid arteries, which may present as neck pain or headache in the under-45s and already be in progress when patients present. To date, there is no good evidence of causation, since the only existing case-control study did not control for pre-existing stroke risk factors. Cauda equina injury after lumbar manipulation is even more rare (calculated average of 1 in 100 million manipulations). Some authors have criticised chiropractors’ overuse of X-rays. However, with current evidence-based guidance for the management of back pain and recent EU legislation, recent audits of chiropractic practice by the General Chiropractic Council have...
found a considerable drop in their use. Currently, X-rays are mainly used to rule out serious underlying pathology or to help to explain chronicity.

Current and future status in the UK and USA

In the USA, the early clashes between medicine and osteopathy over theory, practice and professional territory are now long over. Osteopathic medical training in the USA now produces practitioners who enter the mainstream as conventional doctors with little knowledge of manipulation. Recently, as a consequence of more positive evidence, chiropractors have been widely recognised by US State authorities and medical insurance companies.

Osteopathy arrived in London in the 1920s; from there it reached France. In the UK especially, almost all those who popularised and practiced osteopathy and chiropractic have been non-medically qualified. Increasingly, though, doctors consider such practitioners as colleagues with specialist knowledge and skills in treating the musculoskeletal system. Four-year degree level training programmes, high standard professional regulation, peer-reviewed clinical research and conventional medicine’s own poor track record of success with musculoskeletal dysfunction have all contributed to this convergence. The osteopaths were regulated by an Act of Parliament in 1993 and subsequently the General Osteopathic and the General Chiropractic Councils were established. Only those registered with these Councils, and subject to its revalidation programmes, can use the titles of osteopath and chiropractor.

A growing number of primary care trusts are making manipulative therapies available. In some areas, this entails new community-based clinics which include osteopaths or chiropractors. Many physiotherapists are trained to use manipulative skills and a number of physiotherapy departments now include osteopaths.

Conclusion

The House of Lords Select Committee was particularly concerned with the regulation and public safety of acupuncture and herbal medicine. The relevant professional bodies are represented on the Royal College of Physicians Subcommittee and are involved in the debate concerning the recognition of herbalists, herbal medicine and acupuncture. The Prince of Wales’s Foundation for Integrated Health and the Department of Health have jointly approached neutral chairmen for both these regulatory bodies. It is intended that these bodies will define an appropriate mechanism for the regulation of herbalists and acupuncturists over the next year, in discussion with the relevant professional organisations, both medical and non-medical. The Subcommittee intends to propose further academic conferences at the Royal College of Physicians in order to help raise the quality and quantity of scientific research in this area. We hope that initiatives such as the Department of Health’s investment in research capacity will help to rectify the current lack of evidence of efficacy and the consequent ill-informed debate that often surrounds the issues raised by CAM practice.

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References

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