

**ACUPUNCTURE: REVIEW AND ANALYSIS OF  
REPORTS ON CONTROLLED CLINICAL TRIALS**



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# Introduction

## Background

Over its 2500 years of development, a wealth of experience has accumulated in the practice of acupuncture, attesting to the wide range of diseases and conditions that can be effectively treated with this approach. Unlike many other traditional methods of treatment, which tend to be specific to their national or cultural context, acupuncture has been used throughout the world, particularly since the 1970s. In recognition of the increasing worldwide interest in the subject, the World Health Organization (WHO) conducted a symposium on acupuncture in June 1979 in Beijing, China. Physicians practising acupuncture in different countries were invited to identify the conditions that might benefit from this therapy. The participants drew up a list of 43 suitable diseases. However, this list of indications was not based on formal clinical trials conducted in a rigorous scientific manner, and its credibility has been questioned.

The past two decades have seen extensive studies on acupuncture, and great efforts have been made to conduct controlled clinical trials that include the use of “sham” acupuncture or “placebo” acupuncture controls. Although still limited in number because of the difficulties of carrying out such trials, convincing reports, based on sound research methodology, have been published. In addition, experimental investigations on the mechanism of acupuncture have been carried out. This research, while aimed chiefly at answering how acupuncture works, may also provide evidence in support of its effectiveness.

In 1991, a progress report on traditional medicine and modern health care was submitted by the Director-General of WHO to the Forty-fourth World Health Assembly.<sup>1</sup> The report pointed out that in countries where acupuncture forms part of the cultural heritage, its use in an integrated approach to modern and traditional medicine presents no difficulty. However, in countries where modern Western medicine is the foundation of health care, the ethical use of acupuncture requires objective evidence of its efficacy under controlled clinical conditions.

In 1996, a draft report on the clinical practice of acupuncture was reviewed at the WHO Consultation on Acupuncture held in Cervia, Italy. The participants recommended that WHO should revise the report, focusing on data from controlled clinical trials. This publication is the outcome of that process.

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<sup>1</sup> *Traditional medicine and modern health care. Progress report by the Director-General.* Geneva, World Health Organization, 1991 (unpublished document A44/10).

## Objectives

The objective of this publication is to provide a review and analysis of controlled clinical trials of acupuncture therapy, as reported in the current literature, with a view to strengthening and promoting the appropriate use of acupuncture in health care systems throughout the world. Information on the therapeutic mechanisms of acupuncture has also been incorporated.

Since the methodology of clinical research on acupuncture is still under debate, it is very difficult to evaluate acupuncture practice by any generally accepted measure. This review is limited to controlled clinical trials that were published up to 1998 (and early 1999 for some journals), in the hope that the conclusions will prove more acceptable. Such trials have only been performed for a limited number of diseases or disorders. This should not be taken to mean, however, that acupuncture treatment of diseases or disorders not mentioned here is excluded.

## Use of the publication

This publication is intended to facilitate research on and the evaluation and application of acupuncture. It is hoped that it will provide a useful resource for researchers, health care providers, national health authorities and the general public.

It must be emphasized that the list of diseases, symptoms or conditions covered here is based on collected reports of clinical trials, using the descriptions given in those reports. Only national health authorities can determine the diseases, symptoms and conditions for which acupuncture treatment can be recommended.

The data in the reports analysed were not always clearly recorded. We have made every effort to interpret them accurately, in some cases maintaining the original wording in the text and summary table presented here. Research on traditional medicine, including acupuncture is by no means easy. However, researchers should be encouraged to ensure the highest possible standards of study design and reporting in future research in order to improve the evidence base in this field.

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# 1. General considerations

## 1.1 Definition

Acupuncture literally means to puncture with a needle. However, the application of needles is often used in combination with moxibustion—the burning on or over the skin of selected herbs—and may also involve the application of other kinds of stimulation to certain points. In this publication the term “acupuncture” is used in its broad sense to include traditional body needling, moxibustion, electric acupuncture (electro-acupuncture), laser acupuncture (photo-acupuncture), microsystem acupuncture such as ear (auricular), face, hand and scalp acupuncture, and acupressure (the application of pressure at selected sites).

## 1.2 Need for evaluation

Acupuncture originated in China many centuries ago and soon spread to Japan, the Korean peninsula and elsewhere in Asia. Acupuncture is widely used in health care systems in the countries of this region; it is officially recognized by governments and well received by the general public.

Although acupuncture was introduced to Europe as long ago as the early seventeenth century, scepticism about its effectiveness continues to exist in countries where modern Western medicine is the foundation of health care, especially in those where acupuncture has not yet been widely practised. People question whether acupuncture has a true therapeutic effect, or whether it works merely through the placebo effect, the power of suggestion, or the enthusiasm with which patients wish for a cure. There is therefore a need for scientific studies that evaluate the effectiveness of acupuncture under controlled clinical conditions.

This publication reviews selected studies on controlled clinical trials. Some of these studies have provided incontrovertible scientific evidence that acupuncture is more successful than placebo treatments in certain conditions. For example, the proportion of chronic pain relieved by acupuncture is generally in the range 55–85%, which compares favourably with that of potent drugs (morphine helps in 70% of cases) and far outweighs the placebo effect (30–35%) (1–3). In addition, the mechanisms of acupuncture analgesia have been studied extensively since the late 1970s, revealing the role of neural and humoral factors.

## 1.3 Evaluation methodology

Unlike the evaluation of a new drug, controlled clinical trials of acupuncture are extremely difficult to conduct, particularly if they have to be blind in design and the acupuncture has to be compared with a placebo. Various “sham” or “placebo” acupuncture procedures have been designed, but they are not easy to perform in countries such as China where acupuncture is widely used. In these countries, most patients know a great deal about acupuncture, including the special sensation that should be felt after insertion or during manipulation of the needle. Moreover, acupuncturists consider these procedures unethical because they are already convinced that acupuncture is effective. In fact, most of the

placebo-controlled clinical trials have been undertaken in countries where there is scepticism about acupuncture, as well as considerable interest.

A more practical way to evaluate the therapeutic effect of acupuncture is to compare it with the effect of conventional therapy through randomized controlled trials or group studies, provided that the disease conditions before treatment are comparable across the groups, with outcome studies developed for all patients.

Because of the difficulty of ruling out the placebo effect, a comparative study with no treatment as the control may not be convincing in the evaluation of acupuncture practice. Retrospective surveys, in which the effect of acupuncture therapy is compared with past treatments, may not be of significance either, particularly if they have not been well designed. Non-comparative studies are certainly of little significance, particularly when acupuncture is used for the treatment of a self-limited disease. However, if rapid improvement can be achieved in the treatment of a long-standing, chronic disease, or if there is definite improvement in a disease that is generally recognized as intractable to conventional treatment, the effect of acupuncture should be viewed in a more favourable light, even when a well-designed, controlled study has not been carried out.

Another difficulty in evaluating acupuncture practice is that the therapeutic effect depends greatly on the proficiency of the acupuncturists—their ability and skill in selecting and locating the acupuncture points and in manipulating the needles. This may partly explain the disparities or inconsistencies in the results reported by different authors, even when their studies were carried out on equally sound methodological bases.

Evaluating acupuncture practice and arriving at generally accepted conclusions is no easy task, therefore. While effectiveness is doubtless of the utmost importance, other factors, including safety, cost, availability and the condition of local health services must also be considered. Given the same effectiveness, these other factors may lead to different evaluations of acupuncture in different countries and areas. However, conclusions are needed that apply to worldwide use, particularly for countries and areas where proper development of acupuncture practice would bring a great deal of benefit. Evaluations should not therefore be confined to those diseases for which modern conventional treatments are inadequate or ineffective.

Because of the success of surgical procedures carried out under acupuncture analgesia, the treatment of pain with acupuncture has been extensively studied. For other conditions often treated with acupuncture, there are fewer reports that have adequate methodology.

## 1.4 Safety

Generally speaking, acupuncture treatment is safe if it is performed properly by a well-trained practitioner. Unlike many drugs, it is non-toxic, and adverse reactions are minimal. This is probably one of the chief reasons why acupuncture is so popular in the treatment of chronic pain in many countries. As mentioned previously, acupuncture is comparable with morphine preparations in its effectiveness against chronic pain, but without the adverse effects of morphine, such as dependency.

Even if the effect of acupuncture therapy is less potent than that of conventional treatments, acupuncture may still be worth considering because of the toxicity or adverse effects of conventional treatments. For example, there are reports of controlled clinical trials showing that acupuncture is effective in the treatment of rheumatoid arthritis (4–6), although not as potent as corticosteroids. Because,

unlike corticosteroids, acupuncture treatment, does not cause serious side-effects, it seems reasonable to use acupuncture for treating this condition, despite the difference in effectiveness.

## 1.5 Availability and practicability

The availability and practicability of acupuncture are also important factors to consider. The advantages of acupuncture are that it is simple, convenient and has few contraindications. Although the success rate of acupuncture therapy in treating kidney stones, for example, is confirmed by comparative studies with other therapies (7), it is by no means as high as that of surgical intervention. However, acupuncture treatment of kidney stones is still worth recommending because of its simplicity, which makes it more acceptable to patients.

There are also instances where acupuncture is not more practicable than conventional therapy. For example, the effectiveness of acupuncture treatment of acute bacillary dysentery has been shown to be comparable with that of furazolidone (8–10), but this is of rather academic significance because oral administration of furazolidone or other antidysenteric drugs is more convenient.

The conditions of the health service in a given country or area should also be considered in evaluating acupuncture practice. In developing countries, where medical personnel and medicines are still lacking, the need for acupuncture may be considerable and urgent; proper use of this simple and economic therapy could benefit a large number of patients. On the other hand, in developed countries, where the health system is well established, with sophisticated technology, adequate personnel and a well-equipped infrastructure, acupuncture might be considered to be of great value in only a limited number of conditions. It could still serve as a valuable alternative treatment for many diseases or conditions for which modern conventional treatments are unsuccessful. It is also valuable in situations where the patient is frightened of the potential risks or adverse effects of modern conventional treatments. In fact, in some developed countries, the diseases for which patients seek help from acupuncturists tend to be beyond the scope of orthodox medicine.

## 1.6 Studies on therapeutic mechanisms

Clinical evaluations indicate whether the therapy works; research on the mechanisms involved indicates how it works and can also provide important information on efficacy. Knowing that acupuncture is effective and why makes the practitioner confident in its use, and also allows the technique to be used in a more appropriate way.

The clinical evaluation may precede studies on the mechanisms, or vice versa. For acupuncture, in most instances the clinical effect has been tested first. Use of the technique may then be further expanded on the basis of the results of research on the mechanisms. For example, experimental studies of the effect of acupuncture on white blood cells led to a successful trial of the treatment of leukopenia caused by chemotherapy.

To date, modern scientific research studies have revealed the following actions of acupuncture:

- inducing analgesia
- protecting the body against infections
- regulating various physiological functions.

In reality, the first two actions can also be attributed to the regulation of physiological functions. The therapeutic effects of acupuncture are thus brought about through its regulatory actions on various systems, so that it can be regarded as a nonspecific therapy with a broad spectrum of indications, particularly helpful in functional disorders. Although it is often used as a symptomatic treatment (for pain, for instance), in many cases it actually acts on one of the pathogenic links of a disease.

Although different acupuncture points and manipulations may have an effect through different actions, the most important factor that influences the direction of action is the condition of the patient. Numerous examples reveal that the regulatory action of acupuncture is bi-directional. Acupuncture lowers the blood pressure in patients with hypertension and elevates it in patients with hypotension; increases gastric secretion in patients with hypoacidity, and decreases it in patients with hyperacidity; and normalizes intestinal motility under X-ray observation in patients with either spastic colitis or intestinal hypotonia (11). Therefore, acupuncture itself seldom makes the condition worse. In most instances, the main danger of its inappropriate application is neglecting the proper conventional treatment.

Since its therapeutic actions are achieved by mobilization of the organism's own potential, acupuncture does not produce adverse effects, as do many drug therapies. For example, when release of hydrocortisone plays an important role in the production of a therapeutic effect, the doses of this substance released by acupuncture are small and finely regulated, thereby avoiding the side-effects of hydrocortisone chemotherapy (12). On the other hand—and for the same reason—acupuncture has limitations. Even under conditions where acupuncture is indicated, it may not work if the mobilization of the individual's potential is not adequate for recovery.

## 1.7 Selection of clinical trial reports

In recent decades, numerous clinical trials have been reported; however, only formally published articles that meet one of the following criteria are included in this review:

- randomized controlled trials (mostly with sham acupuncture or conventional therapy as control) with an adequate number of patients observed;
- nonrandomized controlled clinical trials (mostly group comparisons) with an adequate number of patients observed and comparable conditions in the various groups prior to treatment.

In many published placebo-controlled trials, sham acupuncture was carried out by needling at incorrect, theoretically irrelevant sites. Such a control really only offers information about the most effective sites of needling, not about the specific effects of acupuncture (13). Positive results from such trials, which revealed that genuine acupuncture is superior to sham acupuncture with statistical significance, provide evidence showing the effectiveness of acupuncture treatment. On the other hand, negative results from such trials, in which both the genuine and sham acupuncture showed considerable therapeutic effects with no significant difference between them, can hardly be taken as evidence negating the effectiveness of acupuncture. In the latter case, especially in treatment of pain, most authors could only draw the conclusion that additional control studies were needed. Therefore, these reports are generally not included in this review.

The reports are first reviewed by groups of conditions for which acupuncture therapy is given (section 2). The clinical conditions covered have then been classified into four categories (section 3):

1. Diseases, symptoms or conditions for which acupuncture has been proved—through controlled trials—to be an effective treatment.
2. Diseases, symptoms or conditions for which the therapeutic effect of acupuncture has been shown, but for which further proof is needed.
3. Diseases, symptoms or conditions for which there are only individual controlled trials reporting some therapeutic effects, but for which acupuncture is worth trying because treatment by conventional and other therapies is difficult.
4. Diseases, symptoms or conditions in which acupuncture may be tried provided the practitioner has special modern medical knowledge and adequate monitoring equipment.

Section 4 provides a tabulated summary of the controlled clinical trials reviewed, giving information on the number of subjects, the study design, the type of acupuncture applied, the controls used and the results obtained.



## 2. Review of clinical trial reports

### 2.1 Pain

The effectiveness of acupuncture analgesia has already been established in controlled clinical studies. As mentioned previously, acupuncture analgesia works better than a placebo for most kinds of pain, and its effective rate in the treatment of chronic pain is comparable with that of morphine. In addition, numerous laboratory studies have provided further evidence of the efficacy of acupuncture's analgesic action as well as an explanation of the mechanism involved. In fact, the excellent analgesic effects of acupuncture have stimulated research on pain.

Because of the side-effects of long-term drug therapy for pain and the risks of dependence, acupuncture analgesia can be regarded as the method of choice for treating many chronically painful conditions.

The analgesic effect of acupuncture has also been reported for the relief of eye pain due to subconjunctival injection (14), local pain after extubation in children (15), and pain in thromboangiitis obliterans (16).

#### 2.1.1 Head and face

The use of acupuncture for treating chronic pain of the head and face has been studied extensively. For tension headache, migraine and other kinds of headache due to a variety of causes, acupuncture has performed favourably in trials comparing it with standard therapy, sham acupuncture, or mock transcutaneous electrical nerve stimulation (TENS) (17–27). The results suggest that acupuncture could play a significant role in treating such conditions.

Chronic facial pain, including craniomandibular disorders of muscular origin, also responds well to acupuncture treatments (28–31). The effect of acupuncture is comparable with that of stomatognathic treatments for temporomandibular joint pain and dysfunction. Acupuncture may be useful as complementary therapy for this condition, as the two treatments probably have a different basis of action (2, 32).

#### 2.1.2 Locomotor system

Chronically painful conditions of the locomotor system accompanied by restricted movements of the joints are often treated with acupuncture if surgical intervention is not necessary. Acupuncture not only alleviates pain, it also reduces muscle spasm, thereby increasing mobility. Joint damage often results from muscle malfunction, and many patients complain of arthralgia before any changes are demonstrable by X-ray. In these cases, acupuncture may bring about a permanent cure. Controlled studies on common diseases and conditions in this category have been reported by different authors, with favourable results for acupuncture treatments compared with standard therapy, delayed-treatment

controls, control needling, mock TENS, or other sham acupuncture techniques. The conditions concerned include cervical spondylitis or neck pain due to other causes (33–37), peri-arthritis of the shoulder (38, 39) fibromyalgia (40), fasciitis (41), epicondylitis (tennis elbow) (42–44), low back pain (45–49), sciatica (50–53), osteoarthritis with knee pain (54–56), and radicular and pseudoradicular pain syndromes (57). In some reports, comparison was made between standard care and acupuncture as an adjunct to standard care. The conclusion from one such randomized controlled trial was that acupuncture is an effective and judicious adjunct to conventional care for patients with osteoarthritis of the knee (58).

Rheumatoid arthritis is a systemic disease with extra-articular manifestations in most patients. In this disease, dysfunction of the immune system plays a major role, which explains the extra-articular and articular features. Acupuncture is beneficial in the treatment of rheumatoid arthritis (4–6). While acupuncture may not improve the damage that has been done to the joints, successful pain relief has been verified in the majority of controlled studies (58). The action of acupuncture on inflammation and the dysfunctional immune system is also beneficial (5, 59).

### **2.1.3 Gout**

In a randomized controlled trial, blood-pricking acupuncture was compared with conventional medication (allopurinol). The acupuncture group showed greater improvement than the allopurinol group. In addition, a similar reduction of uric acid levels in the blood and urine of both groups was noted (60). Plum-blossom needling (acupuncture using plum-blossom needles), together with cupping (the application to the skin of cups which are then depressurized), has been recommended for treating gouty arthritis (61).

### **2.1.4 Biliary and renal colic**

Acupuncture is suitable for treating acute pain, provided the relief of pain will not mask the correct diagnosis, for which other treatments may be needed. Biliary and renal colic are two conditions for which acupuncture can be used not only as an analgesic but also as an antispasmodic. In controlled studies on biliary colic (62–64) and renal colic (7, 65, 66), acupuncture appears to have advantages over conventional drug treatments (such as intramuscular injection of atropine, pethidine, anisodamine (a Chinese medicine structurally related to atropine, isolated from *Anisodus tanguticus*), bucinnazine (also known as buciperazine) or a metamizole–camylofin combination). It provides a better analgesic effect in a shorter time, without side-effects. In addition, acupuncture is effective for relieving abdominal colic, whether it occurs in acute gastroenteritis or is due to gastrointestinal spasm (67).

### **2.1.5 Traumatic or postoperative pain**

For traumas such as sprains, acupuncture is not only useful for relieving pain without the risk of drug dependence, but may also hasten recovery by improving local circulation (68–70). Acupuncture analgesia to relieve postoperative pain is well recognized and has been confirmed in controlled studies (71–76). The first successful operation under acupuncture analgesia was a tonsillectomy. This was, in fact, inspired by the success of acupuncture in relieving post-tonsillectomy pain. Post-tonsillectomy acupuncture was re-evaluated in a controlled study in 1990, which not only showed prompt alleviation of throat pain, but also reduction in salivation and promotion of healing in the operative wound (76).



### 2.1.6 Dentistry

Acupuncture has been widely used in dentistry. There are reports of randomized controlled trials on the analgesic effect of acupuncture for postoperative pain from various dental procedures, including tooth extraction (77–78), pulp devitalization (79), and acute apical periodontitis (80). According to a systematic review of papers on the use of acupuncture in dentistry published between 1966 and 1996, 11 out of 15 randomized controlled studies with blind controls, appropriate statistics and sufficient follow-up showed standard acupuncture to be more effective than a placebo or sham acupuncture. It was therefore concluded that acupuncture should be considered a reasonable alternative or supplement to current dental practice as an analgesic (81). Its use in the treatment of temporomandibular dysfunction was also supported in these studies.

### 2.1.7 Childbirth

In childbirth, acupuncture analgesia is useful for relieving labour pain and can significantly reduce the duration of labour (82). In the case of weakened uterine contractions, acupuncture increases the activity of the uterus. Episiotomy and subsequent suturing of the perineum can also be carried out with acupuncture analgesia. In addition, the avoidance of narcotics is advantageous for newborn infants.

### 2.1.8 Surgery

Acupuncture analgesia has the following advantages in surgical operations. It is a very safe procedure compared with drug anaesthesia; no death has ever been reported from acupuncture analgesia. There is no adverse effect on physiological functions, whereas general anaesthesia often interferes with respiration and blood pressure, for example. There are fewer of the postoperative complications that sometimes occur after general anaesthesia, such as nausea, urinary retention, constipation, and respiratory infections. The patient remains conscious and able to talk with the medical team during the operation so that injury of the facial and recurrent laryngeal nerve can be avoided. However, remaining conscious may be a disadvantage if the patient cannot tolerate the emotional stress of the procedure.

While the benefits of acupuncture analgesia are many, the disadvantages must also be considered. The use of acupuncture is more time-consuming and in many cases may fail to bring about complete analgesia. It is often not suitable for abdominal surgery because suppression of visceral pain and muscle relaxation may be inadequate. It is not suitable in children because few children will tolerate the needling and keep still during major surgery. Also, the surgeon must be quick and deft, so that the operation can be finished before the patient develops tolerance to the needling.

In conclusion, acupuncture analgesia as an anaesthetic for surgical procedures is indicated in selected patients who show a good response to needling in the preoperative trial, particularly when they may be a poor surgical risk under conventional general anaesthesia. The use of adjuvant drugs to potentiate the effect of the acupuncture treatment is preferred. Acupuncture can also be used in combination with general anaesthesia to reduce the dosage of anaesthetic agents (83).

## 2.2 Infections

Acupuncture has been reported to be effective for treating acute bacillary dysentery (8–10). Its effect is comparable with that of conventional medicines such as furazolidone, but the use of acupuncture in the first line of defence against this disease is not practicable—daily performance of needling procedures is much more complicated than administering oral drug therapy. However, when no antidysenteric agent is available or the patient is allergic to antidysenteric agents, acupuncture may occasionally be used.

The results of research on the effects of acupuncture treatments that stimulate the immune system suggest that acupuncture may be of use in conjunction with other medical therapies for treating infections (84).

The effect of acupuncture on the immune system has been tested in hepatitis B virus carriers. In a comparative study, acupuncture–moxibustion is apparently superior to herbal medications in producing hepatitis B e core antibodies and reducing hepatitis B surface antigen (85). For epidemic haemorrhagic fever, compared with steroid and supportive treatments, moxibustion shortened the period of oliguria and promoted the reduction of kidney swelling (86).

Acupuncture may be useful in treating pertussis (whooping cough), by relieving cough as well as promoting a cure (87).

## 2.3 Neurological disorders

In the neurological field, headaches, migraines and neuralgia are the common painful conditions treated with acupuncture. Strokes and their sequelae are another major indication for acupuncture. Early treatment of paresis after stroke has proved highly effective.

Because improvement in the effects of stroke also occurs naturally, there has been some doubt about the contribution of acupuncture. In recent years, however, a number of controlled clinical evaluations have been undertaken in stroke patients. For example, in randomized controlled studies, acupuncture treatment of hemiplegia due to cerebral infarction gave better results than conventional medication (88–93) and physiotherapy (94, 95). There were also beneficial effects when acupuncture was used as a complement to rehabilitation (96–98).

In one study, patients with ischaemic cerebrovascular disease treated with acupuncture were compared with patients treated with conventional drugs. Nerve function, as evaluated by electroencephalographic map and somatosensory evoked potential, showed a much more marked improvement in the patients treated with acupuncture (89). This has been further confirmed by experimental studies. In the laboratory, a rat model of reversible middle cerebral artery occlusion was used. The somatosensory evoked potential recorded before and after the occlusion showed that electric acupuncture markedly promoted the recovery of the amplitude of the P1–N1 wave (to 58.6% in the electric acupuncture group in contrast to 25.5% in the control group after 7 days) (93). In addition, recent clinical studies suggest that the effectiveness of acupuncture therapy can be further promoted by using temporal acupuncture (99, 100).

Comparative studies have shown acupuncture treatments to be as effective for treating hemiplegia due to cerebral haemorrhage as for that due to cerebral infarction. Since early treatment with physiotherapy is unsatisfactory, it is advisable to use acupuncture as the primary treatment. Even in hemiplegia of long duration, remarkable improvements can often be achieved. Hemiplegia due to other causes, such as brain surgery, can also be improved by acupuncture

(101). Aphasia caused by acute cerebrovascular disorders can also be treated with acupuncture (102).

Although acupuncture is effective for many painful conditions, there are only a few reports on post-herpetic neuralgia. Two of them were based on randomized clinical trials and provided completely opposite results (103, 104). Evaluation of acupuncture in the treatment of this painful condition therefore awaits further study.

Peripheral nervous disorders are often treated with acupuncture. For example, good effects for Bell's palsy have been reported in randomized controlled trials (105, 106). Facial spasm is another peripheral nervous disorder for which acupuncture treatment may be indicated. For this condition it has been shown that wrist-ankle acupuncture is significantly better than traditional body acupuncture (107).

Coma is a serious condition that can hardly be cured by acupuncture alone, but in a comparative study of two groups of patients with similar levels of coma, a significantly greater number of patients in the acupuncture group had a 50% or greater neurological recovery than those in the control group. This suggests that it is reasonable to incorporate acupuncture along with other therapeutic and supportive measures in the treatment of the comatose patient (108).

Insomnia can also be treated successfully with acupuncture. In randomized control trials, both auricular acupressure and auricular acupuncture had a hypnotic effect (109, 110).

## 2.4 Respiratory disorders

Acupuncture is often used in treating respiratory disorders. Allergic rhinitis is one of the major indications. In controlled studies, it has been shown that acupuncture is more effective than antihistamine drugs in the treatment of allergic rhinitis (111–115). Acupuncture's lack of side-effects is a distinct advantage in treating this condition; however, its protective effect against allergen-provoked rhinitis has not been verified (116).

The acute symptoms of tonsillitis can be effectively relieved with acupuncture (117). Since there is no information about the incidence of complications secondary to tonsillitis treated with acupuncture, in clinical practice antibiotic therapy should still be considered the treatment of choice for acute tonsillitis. For sore throats from other causes, acupuncture treatment provides definite benefits, in contrast to a placebo and acupuncture refusal (118).

Although there are conflicting results from controlled trials in treating bronchial asthma with acupuncture, the majority of the reports suggest that acupuncture is effective (119–123) and that the effect is related to the points used (122). While bronchial asthma is not cured by acupuncture, it may be substantially relieved, at least for short periods of time. The success rates quoted in the literature are 60–70%. Acupuncture has a limited role in treating acute asthmatic attacks since it is a weak bronchodilator, but it may serve as a prophylactic measure over the long term. Controlled trials have shown that acupuncture brings about modest improvement in objective parameters, with significant subjective improvement (124). Prospective randomized single-blind studies of the effects of real and sham acupuncture on exercise-induced and metacholine-induced asthma revealed that real acupuncture provided better protection than did sham acupuncture (119), but it failed to modulate the bronchial hyperreactivity to histamine (125). Corticosteroid-dependent bronchial asthma may respond better to acupuncture treatment than other types: the required dosage of corticosteroids gradually decreases during the first weeks of acupuncture treatment (126). Acupuncture

may also provide symptomatic improvement in the late stages of bronchial asthma, where there are complications of disabling breathlessness due to impaired lung function (127).

## 2.5 Digestive disorders

Epigastric pain is a common symptom in diseases of the stomach, including peptic ulcer, acute and chronic gastritis, and gastric spasm. Acupuncture provides satisfactory relief of epigastric pain—significantly better than injections of anisodamine or morphine plus atropine, as shown in randomized controlled trials (128, 129). For gastrointestinal spasm, acupuncture is also superior to injections of atropine (130), and for gastrokinetic disturbances, the effectiveness of acupuncture is comparable with that of conventional medicine (domperidone) (131).

Another common symptom of digestive disorders is nausea and vomiting. This can be due to a disordered function of the stomach, but it is more often a symptom or sign of generalized disorders. Morning sickness, postoperative vomiting, and nausea and vomiting related to chemotherapy are frequently encountered clinically. In all these conditions, acupuncture at point *nèiguān* (PC6) seems to have a specific antiemetic effect. A recent systematic review of trials using acupuncture for antiemesis showed that 11 of 12 randomized placebo-controlled trials, involving nearly 2000 patients, supported this effect. The reviewed papers showed consistent results across different investigators, different groups of patients, and different forms of acupuncture stimulation (132).

Irritable colon syndrome and chronic ulcerative colitis are often difficult to treat with conventional medication. For these diseases, acupuncture may serve as a complementary or alternative therapeutic measure (133, 134).

Because of its analgesic effect, acupuncture can be used in endoscopic examinations, e.g. in colonoscopy. It has been reported that the effect of acupuncture to relieve pain and discomfort during the examination is comparable with that of scopolamine or pethidine with fewer side-effects (135, 136).

There has been extensive research on the effect of acupuncture on the digestive system, with extensive data showing its influence on the physiology of the gastrointestinal tract, including acid secretion, motility, neurohormonal changes and changes in sensory thresholds. Many of the neuroanatomic pathways of these effects have been identified in animal models (137).

Acupuncture shows good analgesic and antispasmodic effects on the biliary tract and, as indicated previously, can be recommended for treatment of biliary colic (62–64). It also has a cholagogic action, which has been demonstrated in experimental studies. In the treatment of biliary colic due to gallstones, acupuncture is not only effective for relieving the colicky pain, but is also useful for expelling the stones. Satisfactory results were reported when electric acupuncture was used in combination with oral administration of magnesium sulfate (138). Acupuncture treatment is also worth trying for chronic cholecystitis, even if there is acute exacerbation (139).

## 2.6 Blood disorders

Among various blood disorders, leukopenia is the most suitable for acupuncture treatment. In controlled studies, acupuncture has been shown to be more

effective than batilol and/or cysteine phenylacetate in the treatment of leukopenia due to chemotherapy (140–142) or benzene intoxication (143, 144).

## 2.7 Urogenital disorders

Urinary retention due to functional disorders, with no organic obstruction, is often treated with acupuncture. For postpartum or postoperative urinary retention, successful micturition usually occurs immediately after one session of needling (66, 145). It is probably for this reason that controlled studies on this subject have been neglected. However, there has been a report of a randomized controlled trial on traumatic retention of urine, a condition more complicated than postpartum or postoperative retention. In this trial, the efficacy of acupuncture was remarkably superior to that of intramuscular injection of neostigmine bromide (146).

Acupuncture is not only useful for relieving renal colic, but also for expelling urinary stones (if they are not too large), because it dilates the ureter. Satisfactory results have been obtained in comparisons with conventional medication (7), but it is better to use acupuncture as a complementary measure in conjunction with medication or lithotripsy.

Sexual disorders are often treated with acupuncture, but conclusive results based on methodologically sound clinical studies are still lacking. Acupuncture was shown to be more effective than placebo in the treatment of non-organic male sexual dysfunction, but the improvement was not statistically significant (147). In another randomized controlled trial, acupuncture had a better effect than the control in the treatment of defective ejaculation (no ejaculation during intercourse) (148).

Acupuncture may also be helpful to patients with chronic prostatitis. As shown in a randomized controlled trial, acupuncture was superior to oral sulfamethoxazole in relieving symptoms and improving sexual function (149).

In women, it has been shown that acupuncture can lower urethral pressure and relieve urethral syndrome (150, 151). Acupuncture has also been successfully used as a prophylaxis against recurrent lower urinary tract infections (152).

## 2.8 Gynaecological and obstetric disorders

Primary dysmenorrhoea, a painful condition, is one of the major indications for acupuncture in the field of gynaecological disorders. The beneficial effect of acupuncture on this condition has been repeatedly reported in controlled trials (153, 154). Acupuncture relieves pain and also regulates the motility of the uterus to facilitate menstrual discharge and further alleviate the pain.

Premenstrual syndrome is characterized by cyclical mood changes and is a common condition in women of fertile age. Acupuncture seems to be helpful to patients with this syndrome. In a controlled study, the majority of the patients receiving acupuncture gained relief from symptoms and no recurrence in the six-month follow-up (155).

Although acupuncture was reported to be effective in the treatment of female anovular infertility (156), no methodologically sound, controlled trials have been reported. However, the mechanism of acupuncture in regulating abnormal function of the hypothalamic–pituitary–ovarian axis has been demonstrated in experimental studies. The data suggest that electric acupuncture with relative

specificity of acupuncture points could influence some genetic expression in the brain, thereby normalizing the secretion of certain hormones, such as gonadotropin-releasing hormone, luteinizing hormone and estradiol (157). Acupuncture is also worth trying in the treatment of female infertility due to inflammatory obstruction of the fallopian tubes, where it seems to be superior to conventional therapy with intrauterine injection of gentamicin, chymotrypsin and dexamethasone (158).

Acupuncture in pregnant women should be undertaken with care. Needling at some points (namely, on the abdomen and lumbosacral region), as well as strong stimulation of certain distant points, such as *hégǔ* (LI4), *sānyīnjiāo* (SP6) and *zhìyīn* (BL67), may cause miscarriage. However, this action is useful if induction of labour is desired, such as in prolonged pregnancy; the effect is comparable with that of oxytocin by intravenous drip (159–161).

In early pregnancy, acupuncture at the upper limb points can be used for the prevention and treatment of morning sickness. The efficacy of acupressure at *nèiguān* (PC6) has been reported repeatedly in placebo-controlled studies (13, 162, 163). In order to prevent miscarriage induced by needling, acupressure is recommended for the treatment of morning sickness.

Various methods of acupuncture, such as pressure at ear points and moxibustion at *zhìyīn* (BL67) or *zúlínqí* (GB41), have been used to correct abnormal fetal position during the last three months of pregnancy. The success rates in groups treated with these methods were much higher than the occurrence of spontaneous version or in groups treated with knee-chest position or moxibustion at non-classical points (164–167).

Acupuncture stimulates milk secretion after childbirth and can be used to treat deficient lactation due to mental lability or depression. It has been observed that acupuncture elevates the blood prolactin level in women with deficient milk secretion after childbirth; in the majority of cases, lactation starts as the blood prolactin level increases (168). The clinical use of acupuncture to promote lactation has also been demonstrated in a randomized controlled study (169).

## 2.9 Cardiovascular disorders

Acupuncture is suitable for treating primary hypotension (170, 171) and early essential hypertension (172–176). It has been reported that the influence of acupuncture on hypertension might be related to its regulatory effect on the level of serum nitrogen monoxide (177). For primary hypotension, acupuncture seems to be more effective than general tonics. For mild and moderate essential hypertension, the hypotensive effect of acupuncture is much more potent than that of placebos and is comparable with that of certain conventional hypotensive agents. In addition, acupuncture is often effective for relieving subjective symptoms, and it has no side-effects.

Encouraging results have been reported for a number of controlled studies on the treatment of heart disease with acupuncture, particularly in psychosomatic heart disorders, such as cardiac neurosis (178). In coronary heart disease, acupuncture has been shown by various authors to be effective in relieving angina pectoris. Its beneficial influence has been demonstrated during coronary arteriography. Cardiological, neurophysiological and psychological observations, made in mutually independent studies, indicated that acupuncture improved the working capacity of the heart in patients with angina pectoris and activated autoregulatory cardiovascular mechanisms in healthy persons (179). In controlled studies, acupuncture has provided significantly greater improvement in symptoms and cardiac work capacity than either placebo (180–182) or conventional medication, such as glyceryl trinitrate (183, 184). Dilation of the

coronary artery during acupuncture has been shown to be comparable with that observed during intracatheter injection of isosorbide dinitrate (185). In addition, acupuncture has a beneficial effect on the left ventricular function of patients with coronary heart disease, and is also more effective than nifedipine and isosorbide dinitrate (186). *Nèiguān* (PC6) is the point most commonly used for treating cardiac disorders. The beneficial effect of acupuncture at this point has been demonstrated by serial equilibrium radionuclide angiography (187). Acupuncture also produces haemorrhheological improvement (188).

In order to avoid unexpected accidents, however, special attention should be paid to the treatment of heart disease. Acupuncturists must be able to differentiate between angina pectoris and acute myocardial infarction.

## 2.10 Psychiatric disorders and mental disturbances

Acupuncture is being increasingly used in psychiatric disorders. The effect of acupuncture on depression (including depressive neurosis and depression following stroke) has been documented repeatedly in controlled studies (189–194). Acupuncture is comparable with amitriptyline in the treatment of depression but has fewer side-effects. In addition, acupuncture has been found to be more effective in depressive patients with decreased excretion of 3-methyl-4-hydroxy-phenylglycol (the principal metabolite of the central neurotransmitter norepinephrine), while amitriptyline is more effective for those with inhibition in the dexamethasone suppression test (192). This suggests that these two therapies work through different mechanisms. There have also been reports that, in controlled trials of schizophrenia treatment, acupuncture might have a better effect than chlorpromazine (194, 195).

Acupuncture (auricular acupressure) is much more effective than psychotherapy in the treatment of competition stress syndrome, and is worth further study (196).

The possible use of auricular acupuncture as a treatment for opium dependence was first noted in 1973 (197). It was found that some of the patients whose postoperative pain was relieved by acupuncture were hiding a dependence on opium. In 1979, a study carried out jointly in Hong Kong and London showed that endorphin concentrations were raised by acupuncture in heroin-dependent persons, resulting in successful suppression of withdrawal symptoms. Since then, acupuncture has been used to treat dependence on a variety of substances. Many substance-abuse programmes use acupuncture as an adjunct to conventional treatment (198). Most of the reports are anecdotal, and while there have been several controlled trials (199–202), the findings have not been consistent. This entire field of research is still at an early stage, holding some promise, but requiring larger-scale and more demanding research studies (198).

Acupuncture treatment has also been used in patients who wish to give up smoking. The conclusions of different researchers are conflicting, however. Some favour acupuncture, while others dismiss its value (203–207). Probably the most convincing results are from randomized controlled trials of passive abstinence, with no suggestion or motivation to stop smoking. The patients were told they would receive acupuncture for other purposes, and they were not asked to stop smoking. A comparison of the effects of auricular acupuncture and body acupuncture was made: 70% of the auricular-acupuncture patients and 11% of those receiving body acupuncture either abstained totally from smoking or reduced the amount of consumption by half. In addition, 72% of the auricular-acupuncture patients experienced disgust at the taste of tobacco (204). However, in contrast, a meta-analysis of seven reports carefully selected from 16 controlled

studies of smoking cessation indicated that acupuncture did not have any greater effect than the placebo (208).

Acupuncture has also been reported to be useful for treating alcohol recidivism. In placebo-controlled trials (with acupuncture at nonspecific points as the control), the patients in the treatment group expressed less need for alcohol than did the control patients. Patients in the treatment group also had fewer drinking episodes and admissions to a detoxification centre (209–211). It is interesting to note that in an experimental study on healthy volunteers, acupuncture diminished clinical alcohol intoxication by increasing the alcohol level in expired air and decreasing blood alcohol levels (212).

## 2.11 Paediatric disorders

Diarrhoea in infants and young children is still a daunting problem worldwide, particularly in developing countries. Acupuncture seems to be worth using, at least as an adjunct to conventional treatments, because it regulates intestinal function and enhances immune response without causing an imbalance in the intestinal flora as do antibiotics (213, 214).

Convulsions due to high fever are not infrequently encountered in infants and young children. In a controlled clinical trial, convulsions stopped two minutes after needling was started, a result superior to that of intramuscular phenobarbital injection (215).

Although the specific treatment for pertussis is antimicrobials, the paroxysmal coughing is usually very distressing. There has been a report that acupuncture could hasten the cure as well as relieving the cough (87).

There are two controlled studies indicating that acupuncture may be of some help in the treatment of Tourette syndrome in children (216, 217).

## 2.12 Disorders of the sense organs

Deaf-mute children were once extensively treated with acupuncture in China, but no methodologically sound reports have ever shown that acupuncture therapy had any real effectiveness. A recent randomized controlled clinical trial on sudden-onset deafness in adults favoured acupuncture treatment (218).

Acupuncture might be useful in the treatment of Ménière disease for relieving symptoms and also for reducing the frequency of attacks. It seems to be more effective than conventional drug therapy (betahistine, nicotinic acid and vitamin B<sub>6</sub>) (219).

Tinnitus is often difficult to treat. Traditionally acupuncture has been believed to be effective for treating tinnitus, but only two randomized controlled clinical trials are available—with inconsistent results (220, 221).

Unexplained earache that is neither primary (due to ear disease) nor secondary (as referred pain), is often regarded as a manifestation of psychogenic disturbances. Acupuncture has been shown to be effective in this kind of earache in a placebo-controlled trial (222).

Acupuncture might be helpful in the treatment of simple epistaxis unassociated with generalized or local disease, but only one report of a randomized controlled clinical trial is available. This report indicates that auricular acupuncture



provides a more satisfactory effect than conventional haemostatic medication (223).

### **2.13 Skin diseases**

In some countries, many skin diseases are customarily treated with acupuncture, but very few controlled studies have been published. In a randomized controlled clinical trial on chloasma, acupuncture had a significantly better effect than vitamins C and E (224).

Some evidence favouring acupuncture treatment of herpes zoster (human (alpha) herpesvirus 3) has been reported. In a randomized controlled trial, laser acupuncture relieved pain and promoted formation of scar tissue much more quickly than treatment with polyinosinic acid (225).

Acupuncture is known to have an antipruritic effect. This has been shown experimentally in volunteers, suggesting that acupuncture could be used in clinical conditions associated with pruritus (226). Acupuncture with dermal needles (seven-star or plum-blossom needles) has traditionally been used in the treatment of neurodermatitis, but confirmation of its effect in a controlled clinical trial was only recently reported (227).

For the treatment of acne vulgaris, acupuncture, particularly ear acupuncture, is worth recommending if the reported therapeutic effects can be further proved (228, 229).

### **2.14 Cancers**

No controlled study has been reported on the efficacy of acupuncture in the treatment of cancer itself. However, acupuncture still has uses in cancer treatments. One is to relieve cancer pain, and the other is to control the adverse reactions to radiotherapy and chemotherapy. For cancer pain, it has been reported that acupuncture provided an immediate analgesic effect similar to that of codeine and pethidine, with a more marked effect after use for two months (230). The effect was comparable with that achieved using the analgesic steps recommended by WHO (231). For radiotherapy and chemotherapy, acupuncture can greatly lessen the adverse reactions in the digestive and nervous systems, as well as providing protection against damage to haematopoiesis (232–237).

### **2.15 Other reports**

Obesity and hyperlipaemia are becoming increasingly important medical issues. If acupuncture could help in reducing body weight and blood lipids, its clinical use could be greatly expanded. Quite a number of reports on this effect have been published, but unfortunately, almost none of them is methodologically sound. There are only two preliminary reports of randomized controlled clinical trials that can be cited here (238, 239), although criticism of the study design cannot be totally avoided.

Acupuncture may be of benefit to patients with non-insulin-dependent diabetes mellitus. Its efficacy has been shown to be superior to that of placebos and comparable with that of tolbutamide (240, 241).

Anisodamine is effective in treating excessive salivation induced by drugs (usually antipsychotics), but acupuncture seems to be more effective (242).

There are also reports on the treatment of Sjögren syndrome (sicca syndrome) (243), Raynaud syndrome (244), Stein–Leventhal syndrome (polycystic ovary syndrome) (244), and Tietze syndrome (costochondritis) (245), which indicate beneficial effects from acupuncture treatment. Since these reports have appeared only in individual papers, confirmation by further study is necessary.





## 3. Diseases and disorders that can be treated with acupuncture

The diseases or disorders for which acupuncture therapy has been tested in controlled clinical trials reported in the recent literature can be classified into four categories as shown below.

**1. Diseases, symptoms or conditions for which acupuncture has been proved—through controlled trials—to be an effective treatment:**

- Adverse reactions to radiotherapy and/or chemotherapy
- Allergic rhinitis (including hay fever)
- Biliary colic
- Depression (including depressive neurosis and depression following stroke)
- Dysentery, acute bacillary
- Dysmenorrhoea, primary
- Epigastralgia, acute (in peptic ulcer, acute and chronic gastritis, and gastrospasm)
- Facial pain (including craniomandibular disorders)
- Headache
- Hypertension, essential
- Hypotension, primary
- Induction of labour
- Knee pain
- Leukopenia
- Low back pain
- Malposition of fetus, correction of
- Morning sickness
- Nausea and vomiting
- Neck pain
- Pain in dentistry (including dental pain and temporomandibular dysfunction)
- Periarthritis of shoulder
- Postoperative pain
- Renal colic
- Rheumatoid arthritis
- Sciatica
- Sprain
- Stroke

Tennis elbow

**2. Diseases, symptoms or conditions for which the therapeutic effect of acupuncture has been shown but for which further proof is needed:**

Abdominal pain (in acute gastroenteritis or due to gastrointestinal spasm)

Acne vulgaris

Alcohol dependence and detoxification

Bell's palsy

Bronchial asthma

Cancer pain

Cardiac neurosis

Cholecystitis, chronic, with acute exacerbation

Cholelithiasis

Competition stress syndrome

Craniocerebral injury, closed

Diabetes mellitus, non-insulin-dependent

Earache

Epidemic haemorrhagic fever

Epistaxis, simple (without generalized or local disease)

Eye pain due to subconjunctival injection

Female infertility

Facial spasm

Female urethral syndrome

Fibromyalgia and fasciitis

Gastrokinetic disturbance

Gouty arthritis

Hepatitis B virus carrier status

Herpes zoster (human (alpha) herpesvirus 3)

Hyperlipaemia

Hypo-ovarianism

Insomnia

Labour pain

Lactation, deficiency

Male sexual dysfunction, non-organic

Ménière disease

Neuralgia, post-herpetic

Neurodermatitis

Obesity

Opium, cocaine and heroin dependence

Osteoarthritis

Pain due to endoscopic examination

Pain in thromboangiitis obliterans

Polycystic ovary syndrome (Stein–Leventhal syndrome)  
Postextubation in children  
Postoperative convalescence  
Premenstrual syndrome  
Prostatitis, chronic  
Pruritus  
Radicular and pseudoradicular pain syndrome  
Raynaud syndrome, primary  
Recurrent lower urinary-tract infection  
Reflex sympathetic dystrophy  
Retention of urine, traumatic  
Schizophrenia  
Sialism, drug-induced  
Sjögren syndrome  
Sore throat (including tonsillitis)  
Spine pain, acute  
Stiff neck  
Temporomandibular joint dysfunction  
Tietze syndrome  
Tobacco dependence  
Tourette syndrome  
Ulcerative colitis, chronic  
Urolithiasis  
Vascular dementia  
Whooping cough (pertussis)

**3. Diseases, symptoms or conditions for which there are only individual controlled trials reporting some therapeutic effects, but for which acupuncture is worth trying because treatment by conventional and other therapies is difficult:**

Chloasma  
Choroidopathy, central serous  
Colour blindness  
Deafness  
Hypophrenia  
Irritable colon syndrome  
Neuropathic bladder in spinal cord injury  
Pulmonary heart disease, chronic  
Small airway obstruction

**4. Diseases, symptoms or conditions for which acupuncture may be tried provided the practitioner has special modern medical knowledge and adequate monitoring equipment:**

Breathlessness in chronic obstructive pulmonary disease  
Coma  
Convulsions in infants  
Coronary heart disease (angina pectoris)  
Diarrhoea in infants and young children  
Encephalitis, viral, in children, late stage  
Paralysis, progressive bulbar and pseudobulbar



## **4. Summary table of controlled clinical trials**

This section provides a tabulated summary of all the controlled clinical trials reviewed for this publication. For each study, information is provided on the author(s), the year of publication, the number of subjects involved, the study design, the type of acupuncture applied, the controls used and the results obtained.