

# Clinical Research on Acupuncture: Part 1. What Have Reviews of the Efficacy and Safety of Acupuncture Told Us So Far?

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## ABSTRACT

**Overview and methods:** This paper discusses those medical conditions in which clinical trials of acupuncture have been conducted, and where meta-analyses or systematic reviews have been published. It focuses on the general conclusions of these reviews by further examining official reviews conducted in the United States, United Kingdom, Europe, and Canada each of which examined available systematic reviews. While all reviews agree that the methodological rigor of acupuncture clinical trials has generally been poor and that higher quality clinical trials are necessary, this has not completely hampered the interpretation of the results of these clinical trials. In some conditions the evidence of efficacy has clearly reached a sufficient critical mass from enough well-designed studies to draw clear conclusions; for the rest, the evidence is difficult to clearly interpret. This paper also examines conclusions from the same international reviews on the safety and adverse effects of acupuncture. Here, conclusions are more easily drawn and there is good agreement about the safety of acupuncture.

**Results and conclusions:** General international agreement has emerged that acupuncture appears to be effective for postoperative dental pain, postoperative nausea and vomiting, and chemotherapy-related nausea and vomiting. For migraine, low-back pain, and temporomandibular disorders the results are considered positive by some and difficult to interpret by others. For a number of conditions such as fibromyalgia, osteoarthritis of the knee, and tennis elbow the evidence is considered promising, but more and better quality research is needed. For conditions such as chronic pain, neck pain, asthma, and drug addiction the evidence is considered inconclusive and difficult to interpret. For smoking cessation, tinnitus, and weight loss the evidence is usually regarded as negative. Reviews have concluded that while not free from serious adverse events, they are rare and that acupuncture is a relatively safe procedure.

## INTRODUCTION

In recent years acupuncture has received a lot of attention in peer-reviewed journals and through several national reviews such as the British Medical Association report (BMA, 2000) and the National Institutes of Health (NIH) consensus Conference (1998). Hundreds of clinical trials of acupuncture have been conducted in the West since the early 1970s.

Starting as early as the mid-1970s, a number of reviews of these clinical trials of acupuncture have been performed. Many of these have been less formal or not systematic, presenting summaries of the literature with some discussion (Anonymous, 2001; Bensoussan and Myers, 1996; Birch, 2001, 2002; Birch et al., 1996; Brewington et al., 1994; Cherkin et al., 2003; Culliton and Kirusek, 1996; Diehl, 1999, 2002; Ernst, 1996b; Ewies and Olah, 2002; Ezzo et

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al., 2001b; Fargas-Babjak, 2001; Filshie and White, 1998; Hammerschlag and Morris, 1997; Hester, 1998; Jobst, 1996, 2002; Jorm et al., 2002; Leake and Broderick, 1998; Lewith and Vincent, 1996; Linde et al., 2002; Lytle, 1993; Manias et al., 2000; Marcus, 1998; Mayer, 2000; McLellan et al., 1993; McMillan, 1998; Naeser, 1996, 2002; Paola and Arnold, 2003; Parfitt, 1996; Pomeranz, 1998; Rabinstein and Shulman, 2003; Richardson and Vincent, 1986; Schnyer and Allen, 2002; Smith and Butler-Arkow, 2002; Steurer-Stey et al., 2002; Taub, 1975; Tureanu and Tureanu, 2002; Vincent, 1993; Vincent and Richardson, 1987). Some have also been reviews of multiple therapies including acupuncture for specific health problems, usually with only small data sets related to acupuncture, and thus no clear conclusions (Brennan et al., 2002; Crossley et al., 2001; Ernst, 2000; Ernst et al., 1998; Gabriel and Bombadier, 1989; Gerritsen et al., 2002; Holdcraft et al., 2003; Johannson et al., 2002; Kjellman et al., 1999; Kronenberg and Fugh-Berman, 2002; Pan et al., 2000; Puett and Griffin, 2002; Sim and Adams, 2002; Smith et al., 2003; Vernon et al., 1999; Volmink et al., 1996; Willemsen et al., 2003).

More than 45 systematic reviews or meta-analyses of acupuncture have been conducted to date. The first systematic reviews and meta-analyses of acupuncture clinical trials started appearing in the late 1980s (Patel et al., 1989; ter Riet et al., 1989a, 1989b, 1989c, 1989d, 1989e, 1989f, 1989g, 1989h) and early 1990s (Kleijnen et al., 1991; ter Riet et al., 1990a, 1990b). Most of these reviews were systematic analyses of the quality of the studies that they examined rather than analyses of the efficacy of acupuncture.

In 1996 the Cochrane Collaboration agreed to establish a field for reviewing trials of complementary medicine (Berman, 1997). After the establishment of a complementary medicine field within the Cochrane Collaboration, the guidelines and methods of conducting meta-analyses and systematic reviews of acupuncture became more standardized. A number of systematic reviews of acupuncture have been undertaken for a range of different health problems many of which followed the Cochrane Collaboration guidelines (Ashenden et al., 1997; Berman et al., 1999; Buchbinder et al., 2002; Casimiro et al., 2002; Ernst, 1997a, 1997b; Ernst et al., 2002; Ernst, Pittler, 1998; Ernst, White, 1996, 1998, 1999; Ezzo et al., 2000, 2001; Fernandez et al., 2002; Lautenschlager, 1997; Law, Tang, 1995; Lee, Done, 1999; Linde et al., 1996, 2000; Longworth and McCarthy, 1997; Martin et al., 2002; Melchart et al., 1999; Park et al., 2000, 2001; Proctor et al., 2002; Rosted, 1998; Smith et al., 2000; Strauss, 1999; Sze et al., 2002; van Tulder et al., 1999; Vickers, 1996; White and Ernst, 1999b; White et al., 1999, 2002; Young, Jewell, 2002).

In addition to these attempts at summarizing the scientific knowledge on the efficacy of acupuncture in systematic reviews, various government bodies, professional bodies, and government-sponsored research groups have undertaken official reviews and summaries of the literature (Alpert, 1996; British Medicine Association, 2000; Ernst,

1999a; Linde et al., 2001; Monckton et al., 1998; NIH Consensus Conference Acupuncture, 1998; Tait et al., 2002; Vickers, 2001; Vickers et al., 2002). Some of these have been more descriptive summaries of the literature and some more formal reviews.

A number of reviews and discussions of the safety of acupuncture have been published since the early 1980s (Alpert, 1996; American Medical Association, 1981; Bensoussan, Myers, 1996; BMA, 2000; Ernst, 1995, 1996a, 1999b; Ernst and White, 1997a; Lao, 1996; Lao et al., 2003; Lytle, 1993; Monckton et al., 1998; NIH Consensus Conference. Acupuncture, 1998; Norheim, 1996; Rampes and James, 1995; Rampes and Peuker, 1999; Rosted, 1996; Tait et al., 2002; Vickers, 2001; Vickers et al., 2002; Vincent, 2001). In recent years several surveys of adverse events of acupuncture have been published (Abbot et al., 1996; Bensoussan and Myers, 1996; Chen et al., 1990; MacPherson et al., 2001; Norheim and Fonnebo, 1995, 1996; Oldsberg et al., 2001; Umlauf, 1988; White et al., 1996, 1997, 2001a; Yamashita et al., 1998, 1999, 2000). Additionally, a number of authors have discussed problems with reports of adverse events from acupuncture and difficulties interpreting them (British Medical Association, 2000; Ernst and White, 1997b, 2000; Jonas, 1996; MacPherson, 1999a, 1999b; Margolin et al., 1997; Mills, 1996; Monckton et al., 1998; Peuker et al., 1999; Rotchford, 2000, 2001; Sena, 1999; White and Ernst, 1999a; Yamashita and Tsukayama, 1999a). Among these problems are confusion with the definitions of acupuncture, establishing causality of adverse events, and proper reporting of adverse events.

A number of articles have been published discussing clinical research methods in acupuncture trials (Birch, 2003; Birch et al., 2002; Hammerschlag, 1998; Hopwood, Lewith, 2003; Lao et al., 2001; Lewith and Vincent, 1996; Margolin et al., 1998; Sherman and Cherkin, 2003; Vincent and Lewith, 1995; White et al., 2001). Part 2 of this article develops a list of criteria that need to be attended to when conducting controlled clinical trials of acupuncture. The discussions of these criteria identify many problems that arise when attempting clinical trials of acupuncture, systematically presenting them in relation to the methods involved with proposed solutions for each (Birch, 2004). The reader is referred there for an overview of research methods and problems. Research problems in acupuncture trials often make it difficult to draw clear conclusions about efficacy of acupuncture from those trials or in systematic reviews. This is apparent in the conclusions of many reviews.

## EFFICACY

Table 1 lists by condition the different meta-analyses and systematic reviews that have been conducted. For some such as chronic pain and asthma, there have been several reviews. In some areas later reviews were updates by the same au-

TABLE 1. SYSTEMATIC REVIEWS AND META-ANALYSES OF ACUPUNCTURE

<i>Condition</i>	<i>Authors/year</i>	<i>Number studies included</i>	<i>Conclusions of authors</i>
Chronic pain	Patel et al., 1989	14 RCT	Inconclusive, poor methodology, but results greater than predicted by chance
	—ter Riet et al., 1989c	32 RCT, 5 CCT	Inconclusive, poor methodology
	—ter Riet et al., 1990a	51 RCT	Inconclusive, poor methodology
	Ezzo et al., 2000	51 RCT	Limited evidence vs wait list, otherwise inconclusive, poor methodology
Low-back + neck pain	—ter Riet et al., 1989a	16 RCT, 6 CCT	Inconclusive, poor methodology
	Smith et al., 2000	13 RCT	Negative
Low-back pain	Ernst and White 1998	12 RCT	Somewhat positive, but poor methodology
	van Tulder et al., 1999	11 RCT	Inconclusive/negative, poor methodology
	Strauss, 1999	4 RCT	Inconclusive, poor methodology
	Ernst et al., 2002	12 RCT	“Collectively these data imply that acupuncture is superior to various control interventions”
Pregnancy pelvic/back pain	Young and Jewell, 2002	1 RCT	“Acupuncture may reduce back and pelvic pain,” but insufficient evidence
Neck pain	White and Ernst, 1999b	14 RCT	Inconclusive, poor methodology
Fibromyalgia	Berman et al., 1999	3 RCT + 4 Coh	Somewhat positive, but still insufficient number studies
Osteoarthritis—general knee	Ernst, 1997a	10 RCT 3 CCT	Inconclusive, poor methodology
	Ezzo et al., 2001	7 RCT	Somewhat positive, poor methodology
	Fernandez et al., 2002	4 RCT	“Currently insufficient evidence to recommend acupuncture”
Inflammatory rheumatic disease	ter Riet et al., 1989b	1 RCT, 2 CCT	Inconclusive, poor methodology
	Lautenschlager, 1997	2 RCT 7 CT 9 Coh	Inconclusive/negative, poor methodology
	Casimiro et al., 2002	2 RCT	Inconclusive/negative, poor methodology
Tennis elbow	Buchbinder et al., 2002	4 RCT	“Insufficient evidence to either support or refute the use of acupuncture”
Sciatica, disc problems	Longworth and McCarthy, 1997	1 RCT, 6 CCT, 31 UCT	Poor methodology, suggestively positive
Headache	ter Riet et al., 1989d	7 RCT, 3 CCT	Inconclusive, poor methodology
	Melchart et al., 1999	22 RCT	Somewhat positive vs. sham, inconclusive vs. standard care
Temporomandibular disorder/facial pain	ter Riet et al., 1989e	2 RCT	Inconclusive, poor methodology
	Ernst and White, 1999	3 RCT	Positive
	Rosted, 1998	8 RCT	Somewhat positive
Acute dental pain	Ernst and Pittler, 1998	11 RCT 5 CCT	Positive
	Rosted, 1998	7 RCT	Positive
Dysmenorrhea	Proctor et al., 2002	2 RCT	Insufficient but suggestive evidence
Asthma	ter Riet et al., 1989f	8 RCT, 4 CCT	Inconclusive, poor methodology
	Kleijnen et al., 1991	13 RCT	Inconclusive
	Linde et al., 1996	15 RCT	Inconclusive
	Linde et al., 2000	7 RCT	Inconclusive
	Martin et al., 2002	11 RCT	Negative, poor methodology
	Ernst and White, 1996	5 RCT, 1 CCT	Promising/inconclusive
Stroke rehabilitation	Park et al., 2001	9 RCT	Promising findings but inconclusive
	Sze et al., 2002	14 RCT	No effect on motor recovery, some effect on disability, poor methodology
Drug addiction	ter Riet et al., 1989h	1 RCT, 5 CCT	Inconclusive, poor methodology
Smoking cessation	ter Riet et al., 1990b	14 RCT, 8 CCT	Inconclusive
	ter Riet et al., 1989g	14 RCT, 2 CCT	Inconclusive, poor methodology
	Law and Tang, 1995	8 RCT	Negative
	Ashenden et al., 1997	9 RCT	Promising, but methodological problems
	White et al., 1999	14 RCT	Negative/inconclusive
	White and Rampes et al. 2002	22 RCT	Negative
	Vickers, 1996	28 RCT 5 CCT (all)	Positive
Nausea/vomiting—postop + chemo-related	Lee, Done, 1999	19 RCT (post-op)	Positive
Tinnitus	Park et al., 2000	6 RCT	Inconclusive
Weight reduction	Ernst, 1997b	4 RCT	Negative/inconclusive

RCT, randomized controlled trial; CCT, controlled trial, Coh, cohort study; UCT, uncontrolled trial; post op, postoperative; chemo-related, chemotherapy-related.

thors such as for asthma and low-back pain (Linde et al., 1996, 2000; Ernst and White, 1998; Ernst et al., 2002). In some reviews there were only as few as one controlled clinical trial that could be included (Young and Jewell, 2002).

Table 2 lists global summaries of the literature published since 1996. The first followed a workshop in 1994 by the U.S. Food and Drug Administration (FDA) in order to re-examine the issue of the classification of the acupuncture needle. Afterwards, five papers were submitted to the FDA in support of the safety and efficacy of acupuncture for various health problems (Birch et al., 1996; Culliton and Kiresuk, 1996; Jobst, 1996; Naeser, 1996; Parfitt, 1996). In 1996

the FDA ruled that the acupuncture needle should be reclassified from an experimental device to a class II medical device (Alpert, 1996). However, this was not based on a systematic review of the literature, and no conclusions about efficacy of acupuncture were drawn with this review (Table 2).

Following on the heels of the FDA workshop and its findings, the next examination of the literature was made in the United States in November 1997. This was a 3-day workshop where data was presented to a diverse panel of experts at a U.S. National Institute of Health Consensus Development Conference on Acupuncture (NIH Consensus Confer-

TABLE 2. GLOBAL SUMMARIES OF THE REVIEWS

<i>Review source</i>	<i>Literature</i>	<i>Conclusions</i>	
Alpert, US—Food & Drug Administration (FDA), 1996	Studies and reviews	No conclusions of efficacy drawn, but sees promising results.	Not rigorous analysis
Acupuncture, US—National Institute of Health (NIH) Consensus Conference, 1998	Studies and reviews	Positive acute postsurgical dental pain, nausea + vomiting from chemotherapy and postsurgery. Promising for: drug addiction, stroke rehabilitation, headaches, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low-back pain, carpal tunnel syndrome and asthma. Negative for smoking cessation	Not rigorous analysis
Monckton et al. European commission, (COSTB4), 1998	Studies and reviews	Positive for nausea + vomiting, especially postoperative. Evidence for various painful conditions is not convincing and for asthma the evidence is contradictory. For smoking cessation, the evidence shows that acupuncture is not better than sham. The evidence for stroke rehabilitation is promising.	Not rigorous analysis
British Medical Association (BMA), 2000	Reviews only	Positive for nausea + vomiting, especially postoperative, for back pain, dental pain and migraine. Unclear if effect is more than nonspecific for neck pain and osteoarthritis. Effects for stroke rehabilitation, tension headache, fibromyalgia and temporomandibular joint problems still uncertain. Not superior to sham for smoking cessation or weight loss.	Rigorous analysis
Vickers, UK—National Health Service (NHS) 2001, and Vickers et al. 2002	Reviews only	Positive for postoperative and chemotherapy-related nausea + vomiting in adults and for postoperative dental pain. Unlikely to be effective for obesity, smoking cessation or tinnitus. Unclear for all other conditions.	Rigorous analysis
Tait et al. Canadian/Alberta Health Authorities report, 2002	Reviews only	Positive for dental and TMD pain and nausea/vomiting. Encouraging results for idiopathic headaches and fibromyalgia. Inconclusive for back pain, chronic pain, smoking cessation and asthma. Effectiveness “not supported by the evidence” for tinnitus, stroke rehabilitation, neck pain, addictions and weight reduction.	Rigorous analysis
Ernst, 1999a	Reviews only	Positive for dental pain, low-back pain, nausea/vomiting; inconclusive for experimental pain, neck pain, headache/migraine, osteoarthritis, inflammatory rheumatic diseases, stroke, addictions, asthma; conclusively negative for: smoking cessation, weight loss. Most studies methodologically unsound. Need better research and more money to do it.	Rigorous analysis
Linde et al., 2001	Reviews only	“Apart from postoperative nausea (positive) and smoking cessation (negative)” the reviewers apparently felt unable to make clear conclusions whether acupuncture was effective or not. Significant methodological problems were found and more higher quality research is needed.	Rigorous analysis

TMD, temporomandibular disorder.

ence. Acupuncture, 1998). However, this was not a systematic examination of the literature either. Instead the conference sought consensus among the panel members regarding the different sets of data that were examined. The evidence was considered good for acute dental pain associated with dental extraction, nausea and vomiting after surgery and associated with chemotherapy. The evidence was considered to be promising for the following conditions: drug addiction, stroke rehabilitation, headaches, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low-back pain, carpal tunnel syndrome and asthma, and negative for smoking cessation. The review concluded that more research is needed in all areas.

The next review was a summary from a 6-year study by a pan-European commission established to examine complementary medicine (Monckton et al., 1998). This also was not a systematic examination of the literature. Different panelists each examined data for different complementary therapies. While a broad review of the whole field of complementary medicine, it was limited in terms of how much of the acupuncture literature was examined and how it was assessed, (see Table 2). The evidence was considered positive for nausea and vomiting, especially postoperative; promising for stroke rehabilitation; not convincing for various painful conditions; contradictory for asthma, and no better than sham for smoking cessation.

The next examination was performed on behalf of the British Medical Association (2000). It was a broad review of the field, practice, and status of acupuncture covering five areas: evidence base, safety, education and training, primary care uses, and future developments. The chapter dealing with the efficacy of acupuncture was a rigorous evaluation of the literature, focusing on systematic reviews. While there may have been some problems with this literature review such as controversy over the interpretation of contradictory reviews of back pain (Ernst and White, 1998; Smith et al., 2000; van Tulder et al., 1999) and the interpretation of a review of asthma (Birch, 2001a, 2001b; White and Ernst, 2001), the document drew certain conclusions about the efficacy of acupuncture (see Table 2). The review concluded that the evidence for nausea and vomiting, back pain, dental pain, and migraine is relatively good; unclear if more than nonspecific for neck pain and osteoarthritis; still uncertain for stroke rehabilitation, tension headache, fibromyalgia and temporomandibular joint problems; and not superior to sham for smoking cessation and weight loss.

A research group at the University of York conducted a rigorous evaluation that focused on systematic reviews of the literature on behalf of the U.K. National Health Service (Vickers, 2001; Vickers et al., 2002). The review concluded that acupuncture appears to be effective for postoperative nausea and vomiting, chemotherapy-related nausea and vomiting, and for postoperative dental pain. For obesity, smoking cessation, and tinnitus the data were considered

negative. For most other indications the evidence was seen as insufficient to guide clinical decisions.

A recent review was performed on behalf of various regional health authorities and organizations in Alberta, Canada (Tait et al., 2002) focusing on published systematic reviews (see Table 2). The review concluded that acupuncture appears to be effective for dental and temporomandibular disorder (TMD) pain and nausea and vomiting; encouraging for idiopathic headaches and fibromyalgia; inconclusive for back pain, chronic pain, smoking cessation, and asthma; and efficacy is not supported by the evidence for tinnitus, stroke rehabilitation, neck pain, addictions, and weight reduction.

Table 2 also lists conclusions from other research groups that reviewed the literature (Ernst, 1999a; Linde et al., 2001).

While these broad reviews of the literature have each drawn slightly different conclusions, there is a considerable amount of overlap from these reviews of the efficacy of acupuncture. A comparison of them allows a deeper perspective on the issue of the efficacy of acupuncture for a number of medical conditions. Table 3 lists each condition for which a statement about efficacy was made by seven of the eight reviews in Table 2 (2–8), placing those statements in one of four categories: “acupuncture shown effective,” “acupuncture promising but no conclusions yet,” “unable to interpret and/or contradictory results for acupuncture,” and “acupuncture shown not to be effective.” The seven reviews each made statements about a different number of conditions. This table thus allows an overview of the interpretation of reviews of clinical trials of acupuncture.

One can see in Table 3 that an agreement is emerging for what conditions acupuncture appears to be effective, and for what conditions it appears to be ineffective. All seven reviews from Table 2 suggest that acupuncture has been demonstrated to be effective for postoperative nausea and vomiting in adults provided that the acupuncture is administered prior to the anesthetic. Six of the seven reviews suggest that acupuncture has been demonstrated effective for chemotherapy-related nausea and vomiting; the seventh suggesting that more research is still needed but that the evidence is promising. Five reviews suggest that acupuncture is effective for dental pain, especially postoperative dental pain (tooth extraction); a sixth review suggests that more research is needed; the seventh makes no statement. Six reviews suggest that the evidence for smoking cessation is negative, while the seventh suggests that it is difficult to interpret the results. Three reviews suggest that the evidence for weight loss is negative, two that it is difficult to interpret. Two reviews interpret the evidence that acupuncture is not effective for tinnitus and two that it is difficult to interpret. The evidence for low back pain, migraine and TMD was interpreted as positive by one review each, while one saw the evidence as promising, three difficult to interpret for low-back pain, the evidence for migraines and tension headache was interpreted as promising by two reviews and



TABLE 3. SUMMARIES OF CONCLUSIONS BY CONDITION

<i>Medical condition</i>	<i>Acupuncture shown effective</i>	<i>Acupuncture promising but no conclusions yet</i>	<i>Unable to interpret &amp;/or contradictory results for acupuncture</i>	<i>Acupuncture shown to not be effective</i>
Acute post-surgical dental pain	British Medical Association, 2000; Ernst, 1999a; NIH Consensus Conference. Acupuncture, 1998 Tait et al. 2002, Vickers 2001	Linde et al., 2001		
Postoperative nausea + vomiting	British Medical Association, 2000; Ernst, 1999a; Linde et al., 2001; Monckton et al., 1998; NIH Consensus Conference. Acupuncture, 1998 Tait et al., 2002; Vickers, 2001			
Chemotherapy-related nausea + vomiting	British Medical Association, 2000; Ernst, 1999a; Monckton et al., 1998; Tait et al., 2002; Vickers, 2001	Linde et al., 2001		
Pregnancy-related nausea + vomiting			Linde et al., 2001	
Chronic pain			Monckton et al., 1998; Tait et al., 2002; Vickers, 2001	
Chronic low-back pain	British Medical Association, 2000; Ernst, 1999a;	NIH Consensus Conference. Acupuncture, 1998; Tait et al., 2002	Linde et al., 2001; Tait et al., 2002; Vickers, 2001	
Chronic neck pain			British Medical Association, 2000; Ernst, 1999a; Linde et al., 2001; Tait et al., 2002, Vickers 2001	
Headache	[migraine] British Medical Association, 2000	NIH Consensus Conference. Acupuncture, 1998 Tait et al., 2002	[tension headache] British Medical Association 2000; Ernst, 1999a, Linde et al., 2001; Vickers, 2001	
Temporo-mandibular disorder	Tait et al., British Medical Association, 2002	British Medical Association, 2000; Linde et al., 2001		
Experimental pain			Ernst, 1999a	
Myofascial pain		Acupuncture 1998		
Tennis elbow		Acupuncture 1998		
Carpal tunnel syndrome		Acupuncture 1998		
Fibromyalgia		Acupuncture 1998 BMA 2000, Linde et al. 2001, Taite et al. 2002		
Osteoarthritis + other inflammatory rheumatic problems		Acupuncture 1998	British Medical Association, 2000; Ernst, 1999a; Linde et al., 2001	[rheumatic disease] British Medical Association 2000
Menstrual pain		Acupuncture 1998		
Asthma		Acupuncture 1998	Ernst, 1999a; Linde et al., 2001; Monckton et al., 1998; Tait et al., 2002; Vickers, 2001	British Medical Association 2000
Stroke rehabilitation		Acupuncture 1998. Linde et al., 2001; Monckton et al., 1998	British Medical Association, 2000; Ernst, 1999a; Tait et al., 2002	

(continued)

TABLE 3. SUMMARIES OF CONCLUSIONS BY CONDITION (CONT'D)

<i>Medical condition</i>	<i>Acupuncture shown effective</i>	<i>Acupuncture promising but no conclusions yet</i>	<i>Unable to interpret &amp;/or contradictory results for acupuncture</i>	<i>Acupuncture shown to not be effective</i>
Drug addiction		Acupuncture 1998	Ernst, 1999a; Linde et al., 2001; Tait et al., 2002; Vickers, 2001	
Smoking cessation			Tait et al., 2002	British Medical Association 2000, Ernst 1999a, Linde et al. 2001; NIH Consensus Conference. Acupuncture, 1998; Monckton et al., 1998; Vickers, 2001
Tinnitus			Linde et al., 2001; Tait et al., 2002	British Medical Association 2000, Vickers, 2001
Weight loss			Linde et al., 2001; Tait et al., 2002	British Medical Association 2000, Ernst, 1999a; Vickers, 2001

hard to interpret by four; the evidence for TMD was seen as promising by two reviews. One review saw the evidence for rheumatic disease as negative, while one saw it as promising for osteoarthritis and three difficult to interpret. The evidence is seen as negative for asthma by one review, a conclusion disputed as a misinterpretation of the literature (Birch, 2001a, 2001b; White and Ernst, 2001), promising by one review and difficult to interpret by five reviews.

Thus, there seems to be some general international agreement that acupuncture is effective for dental pain, nausea and vomiting from surgery and chemotherapy and not effective for smoking cessation, tinnitus and weight loss. The evidence for low-back pain, migraine and TMD is sometimes interpreted as positive, sometimes as inconclusive.

For the remainder of the conditions, reviewers have drawn more neutral conclusions. These neutral conclusions are more often that the evidence is promising (e.g., fibromyalgia, tennis elbow, carpal tunnel syndrome, myofascial pain, menstrual pain) and sometimes that the evidence is difficult to interpret (e.g., chronic pain, chronic neck pain, drug addiction). There is a split between reviewers regarding the efficacy of acupuncture in stroke rehabilitation.

## SAFETY

There have been a number of adverse events reported in association with acupuncture treatment. The most serious events such as cardiac tamponade (Halvorsen et al., 1995), punctured organs such as pneumothorax (Ramnarain and Braams, 2002), transmission of disease such as hepatitis (Rampes and James, 1995), are rare but do occur and generally are associated with poorly trained unlicensed acupuncturists (Vickers et al., 2002). Reviewers who have examined these problems have concluded that knowledge of anatomy and proper handling of needles are sufficient to guarantee that these problems will not recur or will be minimized in normal practice (Alpert, 1996, British Medical Association, 2000; Lao et al., 2003; Lytle, 1993; Norheim, 1996; Vickers, 2001). No serious adverse events were found in four recent surveys in Japan, Sweden, and the United Kingdom of 140,229 treatments (MacPherson et al., 2001; Oldsberg et al., 2001; White et al., 2001a; Yamashita et al., 1999). Ernst and White reviewed these and five other surveys and found two cases of pneumothorax in nearly a quarter of a million treatments. From their review they concluded that serious adverse events are rare (Ernst and White, 2001).

Minor adverse events, however, are relatively common and transitory, such as pain on needling, local bleeding or bruising, fainting, fatigue, light-headedness. Two recent U.K. studies found comparable rates of these minor transitory adverse events (MacPherson et al., 2001; White et al., 2001a). In their review of these and seven other similar surveys, Ernst and White (2001) found that, “the most common adverse events were needle pain (1% to 45%) from

TABLE 4. CONCLUSIONS ABOUT ADVERSE EFFECTS AND SAFETY OF ACUPUNCTURE

<i>Review source</i>	<i>Conclusions</i>
Lytle, U.S.—FDA, 1993	“Considering the number of patients treated (estimated 9–12 million treatments per year [in the US]) and the number of needles used per treatment (estimated average of 6–8), ‘there are, however, remarkably few serious complications’ (American Medical Association, 1981).”
Alpert, U.S.—FDA, 1996	“The clinical studies and safety information included in support of these acupuncture petitions report few risks to health associated with the use of acupuncture needles and those that are reported have been clearly identified, documented and characterized. FDA’s own search of the literature supports this finding.”
Lytle, presentation, US—NIH Consensus Conference, 1997	“The present level of information on the low level risks of acupuncture . . . should provide reasonable assurance of safety during use of acupuncture needles.”
Acupuncture, U.S.—NIH Consensus Conference, 1998	“One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions.”
British Medical Association, 2000	“In terms of safety, few major adverse reactions to acupuncture treatment are reported in comparison to adverse reactions to orthodox interventions.” “Many of the injuries can be avoided by ensuring acupuncturists are fully trained in anatomy and physiology, with particular emphasis on teaching the location and depth of the major organs. Even the most basic first aid course has such a component.”
Vickers, UK—NHS, 2001, and Vickers et al., 2002	“Acupuncture appears a relatively safe treatment in the hands of suitably qualified practitioners, with serious adverse events being extremely rare” (2001). And “serious adverse effects including pneumothorax, spinal lesions, and hepatitis B transmission have been reported in the literature, but these are rare and generally associated with poorly trained unlicensed acupuncturists” (2002)
Tait et al. Canadian/Alberta Health Authorities report, 2002	“The studies’ conclusions are consistent in that they found that the rate or incidence of serious adverse events due to acupuncture treatment is low but that they do occur. MacPherson and colleagues stated that the adverse event rate, when compared with primary care drugs, suggests that acupuncture is a relatively safe treatment, and many researchers concur that it is a relatively safe technique.”
Rampes and Peuker 1999	“Previous surveys with differing methodologies indicate that there is a significant but low risk of serious side-effects of acupuncture from 1:10,000 to 1:100,000 (White et al., 1997).” Given the number of practitioners around the world “these figures suggest a very low prevalence of adverse reactions”
Lao et al., 2003	“Declines in adverse reports may suggest that recent practices, such as clean needle techniques and more rigorous acupuncturist training requirements, have reduced the risks associated with the procedure. Therefore, acupuncture performed by trained practitioners using clean needle techniques is a generally safe procedure.”
Prospective surveys, 1999–2001	No serious adverse events were found in a Japanese study of 65,000 treatments (Yamashita et al., 1999), a Swedish study of 9000 treatments (Oldsberg et al., 2001), a U.K. study of 34,407 treatments (MacPherson et al., 2001), and another U.K. study of 31,822 treatments (White et al., 2001a). “Although the incidence of minor adverse events associated with acupuncture may be considerable, serious adverse events are rare” (Ernst and White, 2001).
Incidence of adverse reactions. (from British Medical Association, 2000)	“Norheim and Fonnebo (1996) estimated that for each year of full-time acupuncture practice in Norway, 0.21 complications would arise (complications were classified as mechanical organ injuries, infections, and other adverse effects, not including point-bleeding or small haematomas). Bensoussan and Myers’ Australian study (1996) estimated that the average number of adverse events per year of full-time Traditional Chinese Medicine practice was one every eight months. Umlauf’s (1988) study of acupuncture treatments and found 8.9% (approximately 12,459 treatment) resulted in adverse events (faintness, fainting, haematoma, pneumothorax and retained needles). Considering that the Medicines Control Agency receives approximately 17,000–18,000 U.K. reports of suspected adverse reactions to all medicines each year, of which 35% are serious and 3% are fatal, the incidence of adverse reactions to acupuncture appears relatively low.”



treatments, tiredness (2% to 41%), and bleeding (0.03% to 38%). Feelings of faintness and syncope were uncommon, with an incidence of 0% to 0.3%. Feelings of relaxation were reported by as many as 86% of patients" (Ernst and White, 2001).

Table 4 summarizes conclusions from several of the major reviews of the acupuncture literature discussed in Table 2 and other important reviews. It is clear that the general consensus is that acupuncture is relatively safe, especially when provided by properly trained individuals (Bensoussan and Myers, 1996; British Medical Association, 2000; Ernst and White, 2001; Lao et al., 2003; Lytle, 1993, 2003; NIH Consensus Conference. Acupuncture, 1998; Vickers, 2001; Vickers et al., 2002; Vincent, 2001). The adverse effect rate of acupuncture is lower in comparison to standard conventional treatment (British Medical Association, 2000; NIH Consensus Conference. Acupuncture, 1998).

As a review of published reviews, this paper has several weaknesses. While it provides a global overview of the literature on acupuncture safety and efficacy, it does not necessarily add weight to the findings of the individual reviews. While it clarifies the directions in which the data point, there are a number of areas that are still unclear. The only solution to the current inconsistencies of interpretation of efficacy, for example the contradictory low-back pain reviews (Ernst and White, 1998; Ernst et al., 2002; van Tulder, 1999), is completion of more higher quality trials. Additionally, the approach taken in this review has tended to pool evidence from diverse trial designs, acupuncture versus sham, acupuncture versus standard therapy. Data from these trials are different and further work is necessary to tease the data from these different studies apart.

## CONCLUSIONS

There is now general international agreement that acupuncture is effective for the following conditions: dental pain, postoperative nausea and vomiting and chemotherapy-induced nausea and vomiting. Some conditions are seen to be effective by some and difficult to interpret by others: migraine, low-back pain, and TMD. The evidence is considered to be promising but is generally seen as difficult to interpret because of poor methodology or contradictory results for chronic pain syndromes, neck pain, tension headaches, fibromyalgia, stroke rehabilitation, tennis elbow, carpal tunnel syndrome, osteoarthritis and other rheumatic disease, menstrual pain, asthma, and drug addiction. The evidence is often considered to show that acupuncture is ineffective or not recommended for the following conditions: smoking cessation, tinnitus, and weight loss. But for these conditions some reviewers consider the evidence instead to be difficult to interpret. More better-quality studies are needed if clear conclusions are to be drawn about most of the conditions for which acupuncture is commonly used.

There is general agreement that acupuncture is a relatively safe therapy. While serious adverse events can occur, they are extremely rare and can be avoided with proper training. Minor, transitory adverse events occur more often, but are well tolerated by patients. Overall, the incidence of serious adverse effects from acupuncture is lower than many drugs or other therapeutic procedures used for the same conditions for which acupuncture is used.

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