

The safety of acupuncture – evidence from the UK

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Abstract

Background Patients are attracted to acupuncture partly by its reputation for having low risks. The safety of acupuncture should be established by positive evidence.

Methods Two prospective surveys were conducted among different groups of professionals in the UK, including doctors, physiotherapists and practitioners primarily trained in acupuncture. Participants monitored adverse events over a defined period of time, and reported minor and significant events on purpose designed forms.

Results A total of 652 acupuncturists reported 6733 adverse reactions including tiredness in 66 229 patients, an adverse event rate of 10.2%. The most common events were tiredness (3%) bleeding or bruising (3%), aggravation of symptoms (2%) and pain at the needling site (1%). There were no serious adverse events. A total of 86 (0.1%) of the treatments was associated with an event that the practitioner judged to be significant though without persistent consequences for the patient's health.

Conclusion The risks associated with acupuncture can be classified as negligible, and acupuncture is a very safe treatment in the hands of competent practitioners.

Keywords

Acupuncture, adverse event, prospective survey.

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Introduction

Acupuncture is increasingly popular with patients, because it is seen as attractive both for its effectiveness and its low risk.¹ However, in principle any treatment that can have an effect can also have an adverse effect.² Therefore it is necessary to provide positive evidence of the safety of acupuncture.

The particular major risks that acupuncture carries are the risk of traumatic injury to an internal organ, especially the pleura, by needle penetration;³ and the risk of causing bacterial infections in deep structures, though this seems to be small, probably because the needle tip is too small to carry a sufficient inoculum of infected material from the skin.⁴ Historically, acupuncture carried the risk of transmitting blood borne infection from one patient to another, but this risk is eliminated with the single-use disposable needles, which are in routine use in all parts of the world. Minor risks are thought to be fairly common, and include such problems as bleeding and worsening of symptoms.³

Case reports in the scientific literature provide

some information about the diversity of adverse events, but not their frequency. The usual way to obtain an estimate of the frequency of adverse events is to conduct prospective surveys specifically for the purpose. This article describes two such surveys conducted among practitioners with different professional backgrounds in the UK, that have been previously reported.⁵⁻⁸

Methods

Two prospective studies were conducted in the UK, with the aim of determining the incidence of adverse events associated with acupuncture practice. The surveys used similar methodology, known as intensive event monitoring in which practitioners are recruited and trained to observe and report any adverse events that occur over a particular defined period.

The terms 'adverse reaction', 'side-effect' and 'complication' used in research into the safety of pharmaceutical agents do not cover the problem of practitioner error. Therefore the term 'adverse event' (AE), borrowed from the world of surgical safety

and hospital incidents, is more appropriate in acupuncture.^{9,10} We defined an adverse event as ‘any untoward occurrence that presents during or after treatment with acupuncture’. A ‘serious’ AE is one that ‘results in death, requires hospital admission or prolongation of existing hospital stay, results in persistent or significant disability/incapacity,² or is life threatening’.^{2,11}

Since pneumothorax is the most common serious adverse event with acupuncture,³ we planned the sample size in order to determine whether the incidence of pneumothorax was less than 1:10 000, with 95% confidence. Using Hanley’s rule of threes,¹² we calculated the intended sample size for each study as 30 000 consultations. Neither study had the resources to collect data on the number of actual needle insertions.

In the SAFA (Survey of Adverse events Following Acupuncture) study, 78 medically trained staff including doctors and physiotherapists, who mainly practise acupuncture alongside conventional therapy, were recruited to collect data over 21 months. Practitioners had the option to remain anonymous if they wished, a feature designed to improve recruitment and the accuracy of reporting. In the York study, 574 health care personnel trained primarily as traditional acupuncture practitioners (who may or may not practise other therapies including Chinese herbs or, in a few cases, conventional treatments) were recruited to collect data over one month.

In both cases, all minor events observed that could be associated with acupuncture were reported on special forms developed for the purpose and modified after piloting. Respondents were not asked to try to judge whether acupuncture was the direct cause of the event or not. The wording and layout of the York data form encouraged the reporting of events that might be considered positive, such as feeling energised or relaxed. In addition, any events that the practitioner considered were ‘unusual, novel, dangerous, significantly inconvenient or requiring further information’ were reported individually on a different form, as they occurred. The use of a wider definition than ‘serious’ event was intended to provide richer information on the kind of event that was more troublesome than ‘minor’ and yet did not meet the strict definition of ‘serious’.

The data were analysed descriptively.

Results

The adverse events occurring during the relevant periods of 1998 to 2000 were reported. In the SAFA study, a total of 2178 events were reported in 31 822 consultations (7%), and in the York study 4528 events in 34 407 treatments (13%). The difference is likely to be explained at least partly by the additional option provided on the forms used in the York study to record mild symptoms such as tiredness that were spontaneously reported by patients. The total presented here does not include patient reports of feeling relaxed (12%) or feeling energised (7%), which are side effects of treatment though not adverse.

The most frequently reported adverse events are present in Table 1. The commonest events reported were feeling tired, and bleeding (lasting more than 10

Table 1 Incidence of the most common adverse events reported in two prospective surveys of over 66 000 treatments with acupuncture

Event	SAFA study (%)	York study (%)	Overall* (%)
feeling tired	NR	3	3
bleeding/haematoma	3	2	3
aggravation	1	3	2
needling pain	1	1	1
drowsiness	0.3	1.1	0.7
dizziness	NR	0.6	0.6
feeling faint	0.3	0.2	0.3
nauseated	NR	0.3	0.3
sweating	0.01	0.2	0.2
stuck/bent needle	0.1	NR	0.1
headache	0.01	NR	0.01

*overall estimate from the available data

NR = event not reported individually

Table 2 Significant events reported in over 32 000 consultations in the SAFA study

Event	number
neurological or psychiatric problems	8
needle or patient forgotten	7
infection, blister, allergy or pain at needling site	7
drowsiness, disorientation, lethargy	7
fainting	6
significant exacerbation of symptoms	5
severe nausea or vomiting	3

Table 3 Significant events reported in over 34 000 consultations in the York study

Event	number
severe nausea or dizziness, fainting, heavy sweating, vomiting	12
severe or prolonged aggravation of symptoms	7
prolonged pain and bruising	5
psychological and emotional reactions	4
avoidable errors (forgotten needles, moxa burn)	3
miscellaneous including haematuria, headache, influenza-like symptoms, fatigue and skin rash	10
no details available	2

seconds) or haematoma, followed by aggravation of symptoms and needling pain. Seventy percent of patients who experienced an aggravation of symptoms were reported as subsequently improved. A range of other minor events occurred less frequently than these.

There was no adverse event reported in either study that met the standard definition of 'serious'. A total of 86 significant events were reported in the two studies, about 0.1% of treatment episodes (Tables 2 and 3). Probably the most dramatic of these was a reflex anoxic seizure: none produced any lasting adverse events. Some avoidable events occurred, included forgotten patients, forgotten needles and moxa burns.

There was no evidence from either study that practitioners with less experience reported higher adverse events. In the York study, practitioners who treated more patients per week were significantly less likely to report all adverse events with the exception of feeling faint and bleeding. Practitioners who were older and male were more likely to report lower rates. In the SAFA study, reporting rates for different practitioners ranged from 0% to 89.6%, (the latter involving only 77 consultations and including a much higher rate of bleeding than average), with no association with duration of training or clinical experience, number of consultations per month, or gender of the practitioner.

Discussion

No serious adverse events were reported in more than 66 000 acupuncture treatments given by 652 acupuncturists in various health professions in the UK. Patients may expect to experience minor events,

including tiredness, in about 10% of consultations with acupuncture, of which the most common will be tiredness, bleeding, exacerbation of symptoms and needling pain.

Inevitably, there are limitations to the accuracy and reliability of these results, including possible errors in identifying and classifying the events, and bias in reporting them. This is a universal problem with measuring adverse events.² These studies do not provide data on the rates of adverse events per needle insertion, nor per patient. There also could be some doubt about the generalisability of the results to the professions as a whole, as the respondents were self-selected and may not be representative. There is evidence of very different rates of reporting of events by different practitioners, and it is not clear whether this represents genuine differences in frequency with different techniques or populations of patients, or whether it can be explained simply by different standards of reporting. Clearly there are also differences that arise from the precise wording of the survey forms, such as the different reporting rates in these studies for mild events such as feeling tired or energised. Nevertheless, these are the best data within the resources available, and the rates reported here are in general agreement with those found in other studies.¹³

Some events can be seen as unpredictable and therefore unavoidable, such as the seizure in one patient shortly after inserting needles. This is presumably explained by the sensitivity of this patient's nervous system to stimulation with a needle. It is commonly recognised clinically that patients differ in their response to needling.

Other events described here are clearly avoidable, such as forgetting patients in treatment rooms, forgetting to remove needles from patients, and moxa burns. As is true of all professions, performance can be improved. Lessons learned by practitioners in one of these surveys were included in the report.⁸ The recent increase in literature on the safety of acupuncture has focused attention on the needs for safe practice to be addressed in both foundation and continuing training,¹⁴ and the need to establish safe systems of practice from the start of a professional career.¹⁵

There have now been several prospective studies of acupuncture in which the incidence of adverse events has been reported systematically and more or

Table 4 Cumulative review of serious adverse events associated with acupuncture in prospective surveys by practitioners

First author, year	number of treatments	serious adverse events
Umlauf, 1988 ¹⁶	139 988	pneumothorax 2 broken needle 2
Chen, 1990 ¹⁷	28 285	0
Melchart 1994/5 ¹⁸	*15 763	0
Melchart, 1998 ¹⁹	1 198	0
Yamashita, 1999 ²⁰	65 482	0
Yong, 1999 ²¹	12 172	0
Ernst, 2000 ²²	3 535	0
Yamashita, 2000 ²³	1 441	0
MacPherson, 2001 ⁶	34 407	0
White, 2001 ⁸	31 822	0
Odsberg, 2001 ²⁴	9 277	0
Melchart, 2004 ²⁵	97 733	pneumothorax 2
Linde, 2006 ²⁶	>4 000 000	pneumothorax 3 asthma attack 1 depression with suicidal thoughts 1
totals	4 441 103	11

*estimated at 10.5 treatments per patient

less rigorously. The incidence of serious adverse events reported in these studies is presented in Table 4. These studies were conducted in a variety of countries and a range of settings within those countries. The largest studies represent a significant proportion of physicians practising acupuncture in their everyday clinics in Germany. It is clear that the overall rate of serious adverse events is very low indeed, less than three per million treatments, and much lower than the risk attached to many conventional medical treatments.²⁷ According to one authoritative source, the risk of major adverse events from acupuncture can be classified as negligible.²⁸

In particular, the safety of acupuncture treatment for osteoarthritis can be favourably compared with that of non-steroidal anti-inflammatory drugs. About 2% of patients using these drugs will be hospitalised each year for gastrointestinal haemorrhage,²⁹ amounting to one in every 2823 prescriptions in elderly patients.³⁰ About 12% of these people will die, and it has been estimated that haemorrhage caused by NSAIDs are the cause of death in about 2000 people in the UK each year.³¹

Patients should be provided with information on the risks of acupuncture before giving consent to treatment. While the precise details and method of

presentation will vary according to the circumstances and the needs of individual patients, as a minimum they should be informed of the risks of drowsiness (particularly in relation to driving), of minor bleeding or bruising, of pain during needling, of aggravation of symptoms, and of fainting.³²

In conclusion, acupuncture is a very safe intervention in the hands of competent practitioners.

Summary points

Prospective surveys can be used to determine the rate of adverse events of treatment

In two surveys, 652 acupuncturists recorded side effects of acupuncture in 66 229 patients

There were no serious side effects

Tiredness, minor bleeding, aggravation of symptoms and needling pain were the most common events in no more than 3% of patients

Acupuncture is very safe in the hands of competent practitioners

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