A cumulative review of the range and incidence of significant adverse events associated with acupuncture

Adrian White

Abstract

Objective To summarise the range and frequency of significant adverse events associated with acupuncture in order to provide evidence on which to base continuing efforts to improve the safety of acupuncture practice.

Methods Searches were conducted of computerised databases, previous reviews of case reports, population surveys, prospective surveys of acupuncture practice and relevant sections of textbooks for primary and secondary reports to indicate the range of significant adverse events associated with acupuncture. Data from prospective surveys of acupuncture were combined to estimate the incidence of serious adverse events.

Results A total of 715 adverse events was included. There were 90 primary reports of trauma, and 186 secondary reports; the most common were pneumothorax and injury to the central nervous system. Infection accounted for 204 primary reports and 91 secondary reports. Over 60% of these cases were hepatitis B. The next most common infection was of the external ear, as a complication of auricular acupuncture. The 144 miscellaneous events mainly comprised seizures and drowsiness judged severe enough to cause a traffic hazard. There were 12 primary reports of deaths. According to the evidence from 12 prospective studies which surveyed more than a million treatments, the risk of a serious adverse event with acupuncture is estimated to be 0.05 per 10 000 treatments, and 0.55 per 10 000 individual patients.

Conclusions The risk of serious events occurring in association with acupuncture is very low, below that of many common medical treatments. The range of adverse events reported is wide and some events, specifically trauma and some episodes of infection, are likely to be avoidable.

Keywords Acupuncture, risk, safety, adverse events, survey.

Introduction

One significant recent development in medical practice is the introduction of clinical governance, the system through which NHS organisations are accountable for continuously improving the quality of the services they provide and safeguarding high standards of care.1 Much discussion on governance has focussed on the use of evidence for making decisions on the effectiveness of treatments, but evidence should also provide the basis of safe practice. A literature review of the adverse events associated with acupuncture should be regarded as a positive aid to making acupuncture safer for patients, and not as a criticism of the acupuncture profession or of the use of acupuncture in clinical practice.

There are a number of methods for reporting and investigating the safety of medical procedures,2 at least seven of which have been used for assessing the risks associated with acupuncture. The first and most straightforward is the primary case report, an anecdotal description of the event by someone who was involved: these reports are often of limited use, because they are open to bias in reporting and publication; they may be difficult to identify as they may not be indexed in databases, and they may be difficult to retrieve from obscure journals. In addition, the description of the acupuncture in case reports is often limited,3 and the attribution of the event to the acupuncture
needle is often not established for certain. Secondly, voluntary organised reporting relies on practitioners reporting events to permanent schemes, such as the Yellow Card scheme for reactions to drugs and herbs in the UK. Thirdly, intensive event monitoring is the term used to describe a survey using volunteers who collect data for a defined period, such as the SAFA study. Fourthly, a record review involves hand-searching patient notes on discharge, which is reliable but expensive. Fifthly, a cohort study follows a group of patients over time to establish adverse events with acupuncture and identify the risk factors, though no examples can be found. Sixthly, case-control studies identify patients who have a particular complication such as hepatitis or HIV, and their exposure to acupuncture is compared with matched patients who do not have the condition. Seventhly, population surveys can be conducted, for example of patients, or practitioners, though these have the usual limitations of poor response and biased reporting because of inaccurate recall.

It is often uncertain whether a specific event can be correctly attributed to acupuncture. For example, pneumothorax may happen spontaneously, so when a case occurs after acupuncture treatment it is likely to be blamed on the acupuncture, though this may sometimes be incorrect. However, if we are clear that the purpose of reviewing the risks of acupuncture is to improve safety for patients, then it is sensible to be over-inclusive so as not to miss the opportunity to learn a lesson. A similar argument applies to the decision to include a death from asthma in reviews, as the event was associated indirectly with acupuncture practice though not directly with needling. This approach has been challenged, but governance of acupuncture practice clearly has to cover the skill of clinical judgement and the knowledge of orthodox management of medical conditions, as well as the skills necessary to treat patients with needles. The same arguments were applied in the inclusion of an example of delayed diagnosis.

It is not easy to produce a definition for the ‘risks’ of acupuncture, or to find a terminology and classification system that is sensible and meets different needs. The term ‘adverse events’ is preferred for acupuncture because it includes cases that are caused by practitioner error as well as the side-effects of treatment – which terms like ‘adverse reactions’ and ‘side-effects’ do not. The severity of the event needs to be classified. Many events are mild and self-limiting, and their main significance is simply that patients should be warned to expect them. Terminology such as ‘harmful or significantly unpleasant’ have been suggested to try to classify those events such as infection which require further treatment or have other consequences for the patient. The term ‘significant event’ was also suggested in order to indicate those events that are ‘unusual, novel, dangerous, significantly inconvenient or requiring further information’. Examples of significant events included needling problems (broken or forgotten needle, moxa burns), systemic effects (faint, convulsion, drowsiness causing hazard eg on the road, severe nausea) and symptoms (unexpected or prolonged aggravation). A ‘serious’ adverse event is clearly defined by its consequences: it ‘results in death, requires hospital admission or prolongation of existing hospital stay, results in persistent or significant disability or incapacity, or is life threatening’. Adverse events may also be classified in two other ways: firstly, those that are inherent in the acupuncture (unavoidable), those due to technical error (avoidable) and those due to lack of medical knowledge (‘indirect’ risk), and secondly traumatic, infectious, and miscellaneous.

Writers on acupuncture were not reluctant to discuss its risks as long as 30 years ago. More recently, surveys of the literature have been systematic and several have been published in journal articles in English. These are summarised in Table 1. This paper is an attempt to update and aggregate the available literature, to determine both the range of significant adverse events and the frequency of serious adverse events associated with acupuncture practice.

Methods
It is not easy to conduct a search for reports of adverse events that is both systematic and comprehensive. Reports are not systematically indexed in computerised databases, due both to the lack of use of keywords for adverse events, and to the reporting of many anecdotes in the correspondence sections of journals, which may
Therefore this article is not a report of a single systematic search, but forms a comprehensive review which formed part of a doctoral thesis. Searches of specific databases were performed systematically for previous reports, and reprints of articles accumulated as they became available from colleagues or libraries in the years 1994 to 2003. Finally, the list of adverse events was systematically updated in July 2004 by a search of PubMed for the years 2002-2004, using the keyword 'acupuncture' combined with 'adverse event' or 'effect', 'injury', 'infection', and each of the major event headings which were found in the course of the project (see Table 2).

Data were extracted from all available types of publication including case reports, reviews of the literature, population surveys, prospective surveys of acupuncture practice, and textbooks that had been cited in case reports or otherwise come to the author's attention. Reports of adverse events were classified as 'primary' if written by a clinician who had dealt with the case, and as 'secondary' if written by another author. Examples of secondary reports include data from two retrospective population surveys of practitioners or patients. Secondary reports like these are clearly less reliable than primary reports since they are subject to recall bias, and may include double reporting of a single incident. They are therefore reported separately here. Not all original case reports were available for this review, because of limited resources, but cases were accepted as primary if they were clearly summarised in a literature review and if the title was available with English translation in a computerised database. Following these criteria, two reviews of Eastern cases were included as secondary reports. In two literature reviews, numbers of patients were given who had adverse events in various categories, without citing all the original reports. These events were included as numbers in the list of secondary reports, but only the excess over the number of primary reports from other sources, to avoid double counting. Reference lists were cross-checked to ensure no case was counted twice.

The analysis of the range of events includes 'significant events'. These were defined pragmatically, to include events which would need further specific intervention such as antibiotics, or would interfere with the patient's normal life for at least the remainder of the day. For example, reports were not included of needle allergy, argyria, bleeding, bruising, Koebner phenomenon, and petechiae, but seizures and skin infections were included. Post needling pain was not included because of the difficulty in judging from the report whether it was significant or not. Drowsiness was not included systematically (but see Results section for severe drowsiness). When an event covered two categories such as cardiac tamponade and pneumothorax, it was classified according to the more medically urgent problem, in this example tamponade.

In estimating the incidence of adverse events, case reports are of little value because the denominator (ie the number of patients or number of treatments) is highly speculative. Therefore, only surveys of adverse events were included for this analysis. This estimation refers to serious rather than significant events since that is what most of these surveys report. Other authors report

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**Table 1**  Systematic literature reviews of risks associated with acupuncture

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Literature search up to (year)</th>
<th>Number of events (and/or reports) included</th>
<th>Inclusion restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rampes &amp; James</td>
<td>1993</td>
<td>395(132)</td>
<td></td>
</tr>
<tr>
<td>Norheim</td>
<td>1994</td>
<td>193 (78)</td>
<td></td>
</tr>
<tr>
<td>Rosted</td>
<td>1995</td>
<td>41 (93)</td>
<td>fully detailed cases</td>
</tr>
<tr>
<td>Ernst &amp; White</td>
<td>1996</td>
<td>(56)</td>
<td>life-threatening events</td>
</tr>
<tr>
<td>Peuker et al</td>
<td>1998</td>
<td>50</td>
<td>traumatic events</td>
</tr>
<tr>
<td>Yamashita et al</td>
<td>1999</td>
<td>124 (89)</td>
<td>Japanese literature</td>
</tr>
<tr>
<td>Lao</td>
<td>1999</td>
<td>202 (98)</td>
<td></td>
</tr>
<tr>
<td>Peuker &amp; Gronemeyer</td>
<td>2001</td>
<td>120</td>
<td>traumatic events</td>
</tr>
</tbody>
</table>

Only articles in English and covering more than one year's literature are included.
Table 2 Significant and serious adverse events associated with acupuncture practice: primary reports by clinicians involved in the case, and secondary reports by other authors

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>Primary case reports</th>
<th>Secondary reports*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Number of cases in report, details, and reference</td>
</tr>
<tr>
<td>TRAUMA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pneumothorax</td>
<td>54</td>
<td>1[34,36-39,41-42] 137</td>
</tr>
<tr>
<td>haemothorax</td>
<td>1</td>
<td>1[40]</td>
</tr>
<tr>
<td>heart and pericardium</td>
<td>9</td>
<td>1 cardiac tamponade[33,34,40] 1 penetration[39-42]</td>
</tr>
<tr>
<td>peripheral nerve</td>
<td>3</td>
<td>1[56-58]</td>
</tr>
<tr>
<td>other site</td>
<td>1</td>
<td>1 Baker's cyst[62]</td>
</tr>
<tr>
<td>INFECTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>4</td>
<td>1[64,65]</td>
</tr>
<tr>
<td>auralicular chondritis</td>
<td>14</td>
<td>1[67,68,69,70,71] 4[72]</td>
</tr>
<tr>
<td>endocarditis</td>
<td>6</td>
<td>1[75-78]</td>
</tr>
<tr>
<td>meningitis</td>
<td>1</td>
<td>1[80]</td>
</tr>
<tr>
<td>spinal infection</td>
<td>3</td>
<td>1 epidural[84] 1 epidural[85]</td>
</tr>
<tr>
<td>septicaemia</td>
<td>5</td>
<td>1[87-90] 2[91]</td>
</tr>
<tr>
<td>necrotising fasciitis and toxic shock</td>
<td>3</td>
<td>1[92-94]</td>
</tr>
<tr>
<td>septic arthritis</td>
<td>3</td>
<td>1 glenohumeral[95] 1 knee[96] 1 sacroiliac[97]</td>
</tr>
<tr>
<td>other</td>
<td>4</td>
<td>1 atrial myoxoma[113] 1 infected compartment[114] 1 eyelid[115] 1 osteomyelitis[116]</td>
</tr>
<tr>
<td>herpes zoster reactivation</td>
<td>1</td>
<td>1[118]</td>
</tr>
<tr>
<td>MISCELLANEOUS EVENTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>collapse</td>
<td>4</td>
<td>1[120-123]</td>
</tr>
<tr>
<td>exacerbation of asthma</td>
<td>3</td>
<td>1[124,125]</td>
</tr>
<tr>
<td>other</td>
<td>46</td>
<td>1 regional pain syndrome[137,138] 2 fractured needle[139] 42 dangerously drowsy[140]</td>
</tr>
</tbody>
</table>

N – number of cases

large clinical trials in which adverse events were specifically recorded as well as the number of treatments (or number of patients and average number of treatments per patient).32;33 These events were included as individual cases, but the trials were not included in estimating the incidence of events since they only involved treatment limited to one specific condition, and do not represent general acupuncture practice. For example, an RCT of acupuncture for knee osteoarthritis would underestimate the risk of pneumothorax in the general clinic. However, one very large trial included treatment of four very different conditions that make up the bulk of normal practice, and therefore was included.34

A number of references was found for adverse events of treatment techniques associated with acupuncture, such as electroacupuncture and moxibustion. These have been reported for interest, but the results are not claimed to be systematic or representative. The Japanese technique of embedding needles (umebari) is excluded as it has already been reviewed,23 and in any case the practice has been discouraged since 1976.21

Results
The literature reviewed includes: a large number of case reports in scientific articles and textbooks which form the basis of the primary reports in Table 2; secondary reports from two population surveys;34 the eight systematic reviews of the literature in Table 1, and updates published as chapters;12 12 prospective surveys listed in Table 3; and one textbook chapter,30 which cites a Chinese article that describes 39 deaths attributed to acupuncture in 26 clinical reports.35

The range of adverse events described in this literature is summarised in Table 2, and amounts to a total of 715 cases. There were 90 primary reports of traumatic injury, and 186 secondary reports. The most common traumatic event was pneumothorax, and the second most frequent event was injury to the central nervous system, with the great majority of the latter arising in the Eastern literature. Infection accounted for 204 primary reports and 91 secondary reports. Over 60% of these cases were hepatitis B. The next most common infection was of the external ear, as a complication of auricular acupuncture. The 61 primary miscellaneous events were dominated by 42 cases of drowsiness judged severe enough to cause a traffic hazard; and the secondary reports by 80 cases of seizure.

All primary reports concerning electroacupuncture that were found described cardiac effects. Angina was reported in two cases,194 in one case EA was blamed for affecting a demand pacemaker,195 and in two cases cardiac arrest occurred in association with EA to the neck.53 Secondary reports describe four deaths from EA, three being from

<table>
<thead>
<tr>
<th>First author, year</th>
<th>Number of patients</th>
<th>Number of treatments</th>
<th>Serious adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umlauf, 1998**</td>
<td>14 340</td>
<td>139 988</td>
<td>pneumothorax, 2</td>
</tr>
<tr>
<td>Chen, 1990**</td>
<td>2855</td>
<td>28 285</td>
<td>0</td>
</tr>
<tr>
<td>Melchart, 1994/5†‡</td>
<td>1507</td>
<td>15 763 *</td>
<td>0</td>
</tr>
<tr>
<td>Melchart, 1998**</td>
<td>121</td>
<td>1198</td>
<td>0</td>
</tr>
<tr>
<td>Yamashita, 1999**</td>
<td>5008</td>
<td>65 482</td>
<td>0</td>
</tr>
<tr>
<td>Yong, 1999**</td>
<td>1128</td>
<td>12 172</td>
<td>0</td>
</tr>
<tr>
<td>Ernst, 2000**</td>
<td>409</td>
<td>3535</td>
<td>0</td>
</tr>
<tr>
<td>Yamashita, 2000**</td>
<td>391</td>
<td>1441</td>
<td>0</td>
</tr>
<tr>
<td>MacPherson, 2001**</td>
<td>-</td>
<td>34 407</td>
<td>0</td>
</tr>
<tr>
<td>White, 2001*</td>
<td>-</td>
<td>31 822</td>
<td>0</td>
</tr>
<tr>
<td>Odberg, 2001*</td>
<td>-</td>
<td>9277</td>
<td>0</td>
</tr>
<tr>
<td>Melchart, 2004**</td>
<td>97 733</td>
<td>763 900 **</td>
<td>pneumothorax, 2</td>
</tr>
<tr>
<td>**</td>
<td></td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>

* estimated, from mean of other studies (10.5 treatments per patient)
** estimated from stated mean 7.8 treatments per patient
injury to the CNS from cervical needles, and one from cardiac injury from thoracic needles. Five cases of moxibustion burns were found.4;196;197

The incidence of serious adverse events was estimated from the data provided by 12 prospective surveys (Table 3). A total of six serious adverse events (four cases of pneumothorax and two broken needles) occurred in association with 1 107 270 treatments surveyed. In addition, one serious burn was reported which is attributed to moxibustion and not to acupuncture,198 and therefore not included here. According to this evidence, the cumulative world-wide incidence for serious adverse events with acupuncture is estimated to be 0.05 per 10 000 treatments, and the incidence is 0.55 per 10 000 individual patients. The latter represents ‘very low’ risk, which is below that of many common medical treatments.199

The deaths associated with acupuncture found in the course of this work include 12 primary reports, and 39 secondary reports.30 The deaths were not attributed to acupuncture ‘for certain’ in all cases. Of the primary reports, six were traumatic, with four due to pneumothorax38;46;52;70 and two to cardiac tamponade85;89 one of which was a case of an 82 year old woman who gave herself acupuncture with a sewing needle. Five deaths were due to infection, including two from septicaemia,158 and one each from hepatitis,118 pyohaemothorax,166 and toxic shock syndrome.160 The twelfth death was from an acute asthma attack,10 and occurred during treatment with acupuncture but was not due to trauma from the needles. The secondary reports include 13 deaths from pneumothorax, nine from cardiac or aortic injury, eight from injury to the CNS (seven to the medulla, one to the cerebellum), and three from trauma to the liver. One case was reported to have been due to laryngeal spasm, and in five cases no details were available.30 Seven of these secondary reports of deaths stated that the treatment was given by unqualified practitioners, and in some cases needles had been inserted through clothing.

Risks for the acupuncturist seem a priori to be small. The main theoretical risk is needle stick injury causing blood borne infection, and no reported case of this or any other adverse event for practitioners was discovered in the course of this work.

Discussion
A total of 355 primary reports of significant adverse events associated with acupuncture were located. The most common significant events are hepatitis and pneumothorax. An additional 360 secondary reports were found but this figure includes some cases identified in retrospective surveys and is therefore less reliable. From 12 trials in which the adverse events were recorded from more than a million treatments, the rate of serious adverse events is estimated to be 0.05 per 10 000 treatments – and about 0.55 per 10 000 patients undergoing acupuncture treatment. Thus, acupuncture can be said to incur ‘very low’ risk, confirming the conclusion that acupuncture is ‘a very safe intervention in the hands of a competent practitioner’.205

The figures for primary reports are likely to be an underestimate for several reasons: many adverse events will not be recognised as due to acupuncture, for example hepatitis B or C; not all events that are recognised will be reported (as an example of under-reporting, a retrospective survey of neurologists identified 35 serious neurological complications of spinal manipulation, but none had been reported in the scientific literature);206 and, even if an event was reported, it may not have been located by the literature searches. The prospective surveys of acupuncture by practitioners using the methods of voluntary organised reporting, intensive event monitoring or case record review may also underestimate adverse events, though this seems less likely to happen for serious events than for mild or significant events.

Some of the primary reports do not relate to standard acupuncture practice,89 and in some cases the attribution is only at the level of ‘possible’, rather than certain or even probable.23 In reality, however, the risk of underestimation seems to be much higher than the risk of overestimation. In any case, the major point of the primary reports is to indicate the range of events rather then their frequency.

It is not possible to use these aggregate figures to calculate the actual risk to a individual patient attending a particular acupuncturist in a given country. Individual patients can be at increased risk, eg if they are immunsuppressed;154 acupuncturists vary greatly in their adverse event rate;154 and
aspects of practice in certain parts of the world seem to put patients at greater risk, such as injury to central nervous tissue in Eastern practice found in the present review.

Having a recognisable qualification in acupuncture is not a guarantee of safe practice. Practitioners' qualifications were not taken into account in performing the present review, and the reporting of the qualifications and experience of practitioners involved in case reports is notoriously poor. Guidelines exist for improving case reports. From the few reports for which information about the practitioner's qualifications was available, it was estimated that about 80% were at the hands of qualified practitioners. The findings of this review are therefore relevant for the clinical governance of qualified practitioners, and its implications could be considered by individual practitioners, professional organisations, acupuncture teachers, and authors of acupuncture text books.

Traumatic lesions seem generally to be due to practitioner error, particularly penetration of the lung, heart or spinal cord, though pseudo-aneurysm and peripheral nerve injury involve some bad luck. Practitioners might want to consider refreshing their knowledge of the surface anatomy of the lungs and reconsider their depth of needling in an annual review.

The infections in the largest group described here were due to transmission by the needle from patient to patient, and Lao pointed out that the incidence of hepatitis has already fallen with the introduction of single use disposable needles. This practice is not yet universal, since HIV transmission is still being reported. There is obviously an increasing risk of hepatitis B or C transmission to the practitioners themselves through needle-stick injury, so they would be wise to review their needle handling procedures from time to time and check their immune status.

Bacterial infections seem most likely to have occurred through the introduction of the patient’s own skin contaminants. Complete sterilisation of the skin is not even possible under surgical conditions, which are totally impracticable for acupuncture practice anyway. The accidental inoculation of external organisms from the practitioner’s hands is unlikely but possible, since in practice acupuncture is a 'clean' rather than a 'sterile' procedure. However, the number of organisms that can be inoculated by a needle tip is likely to be insufficient to result in a clinical infection, which is one probable explanation why infection is so rarely reported after acupuncture. However, practitioners need to remain alert for the possible risk factors, including the site needled (joint spaces, meninges, ears) and the susceptibility of the patient (immunosuppression, heart valve disease).

Some of the miscellaneous events are likely to be unpredictable and therefore unavoidable, one example being reflex anoxic seizure. But the seizures occurring as part of a faint are much more common and these can be prevented by treating patients lying down. Many acupuncture practitioners will have experienced patients whose asthma is exacerbated by acupuncture, and the four significant cases are a reminder of the need to treat patients with this condition extremely cautiously. Severe drowsiness also seems to be an inevitable response to treatment in some patients, and all should be warned not to drive if affected.

In conclusion, the cumulative literature on adverse events associated with acupuncture allows practitioners to give evidence based information to patients about the risks from acupuncture, in order to formulate a risk benefit assessment. Patients can be reassured that there is a very low risk of severe adverse events from receiving acupuncture from a properly trained practitioner. However, significant and serious

Summary points

Evidence of previous adverse events can be used to improve the safety of acupuncture practice. Worldwide, 715 significant or serious adverse events have been reported in association with acupuncture.

Four fifths of cases were due to trauma or infection, in approximately equal numbers.

There were 12 primary reports of deaths, and 39 secondary reports.

The overall risk of acupuncture treatment is classified as 'very low', but the risk for any individual patient may vary with the practitioner.
events do occur, and clinical governance requires practitioners and their professional organisations to take the range and frequency of adverse events seriously in order to make an already safe treatment safer still.

Acknowledgments
I am grateful to Jongbae Park for contacting Dr Luo for further details of secondary reports of deaths from China, and for searching for and translating reports in Chinese.

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