Guidelines for case reports of adverse events related to acupuncture

Elmar Peuker, Timm Filler

Summary
Numerous case reports of adverse events of acupuncture have been published, mostly in journals which are not related to acupuncture. The authors usually have no training in acupuncture. In principle, case reports on adverse events are of value as an aid for learning. They can only achieve this effect if useful information is provided. In the case of acupuncture related adverse events and complications, basic information about the patient and the therapist as well as the treated acupuncture points and topographical regions and the needling technique are desirable. This article offers suggestions on what details should be included in a case report on adverse events related to acupuncture.

Keywords
Case report, adverse event, complication, acupuncture, pneumothorax

Introduction
Reporting of adverse events can lead to improved safety in several ways: new – or previously unrecognised – hazards can be identified from even a small number of case reports. An analysis of many reports can reveal trends and hazards that require attention and lead to recommended ‘best practice’ for all to follow.

Reports of one’s own incidents probably often remain unpublished because of time pressure, fear of punishment, or lack of any perceived benefit. Shame and fear of liability, loss of reputation, and peer disapproval are other particularly strong disincentives. In contrast, the reporting of complications which were caused by others seems to be easier as it does not bring such disadvantages. Moreover, it seems that case reports are more readily published if the adverse event relates to complementary or alternative therapies.

Numerous case reports of adverse events show that acupuncture is not free of risk, though accurate data from prospective investigations are scarce. However, to achieve any learning benefit from case reports beyond mere anecdotal entertainment, certain details of information must be reported. This article aims to give guidance on how to write case reports on adverse events associated with acupuncture. As an example, the case reports on pneumothorax which have been published in the scientific literature so far are analysed concerning their content of relevant information.

Case reports on pneumothorax associated with acupuncture
In the last 30 years, 34 reports of individual cases of pneumothorax due to or associated with acupuncture have been published in Medline-listed journals. This figure does not include the cases which have been published in retrospective reviews or prospective studies on adverse events of acupuncture. None of the case reports has been published in a journal related to acupuncture. Most were written up by members of the respective emergency departments (circa 35%) or chest physicians (20%). Other specialists involved as authors include radiologists, thoracic surgeons, family physicians, and pathologists. None of the authors declares his or her qualification in acupuncture, and it seems likely that none of the authors has received any training in acupuncture.

Most articles contain basic information about the patients (age, sex). However, more details on the physical constitution in terms of height, weight, and BMI would be useful.

The medical history of the patients is described in sufficient detail in only about half of the articles. In the case of pneumothorax, it would
be useful to be given information about known pulmonary diseases (emphysema, bulla, bleb formation, etc), and previous investigations (eg x-ray film, computed tomography). In all case reports, the reason why the patients received acupuncture should be stated in Western medical terms. The diagnosis and treatment of the pneumothoraces is described in adequate detail by most of the authors.

The location of the needle sites used is generally given in terms of topography, so it is often difficult to be sure which precise acupuncture points have been treated. Some examples from the respective case reports will illustrate this (see Table 1). Some authors omit even the surface anatomy and just state that acupuncture was performed. Cantan et al report a case of bilateral pneumothorax and cardiac tamponade after acupuncture. Unfortunately, neither the relevant acupuncture points nor surface anatomy are described.

Surface anatomy has some value, although the exact acupuncture points can only be guessed. It would be more useful to state the needleling depth and direction. Unfortunately none of the case reports provide this.

### Table 1

<table>
<thead>
<tr>
<th>Author’s description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘…insertion of a posterior paraspinal acupuncture needle…’  3</td>
<td>Most likely a point of the inner branch of the bladder meridian is described. Alternatively, the Huatuojiaji points could be involved</td>
</tr>
<tr>
<td>‘…needles were inserted into three sites around the shoulder…’  1</td>
<td>The latter acupuncture point could be ST12</td>
</tr>
<tr>
<td>‘…paravertebral insertion of acupuncture needles…’  1</td>
<td>These could be Bladder meridian points</td>
</tr>
<tr>
<td>‘…the needles were positioned in the upper arms, the left paraspinal area and the posterior aspect of the neck.’  1</td>
<td>The ‘left paraspinal region’ suggests the stomach or the kidney meridian, the ‘posterior aspect of the back’ includes more than 20 potential acupuncture points</td>
</tr>
<tr>
<td>‘…multiple needle insertions at her back…’  3</td>
<td>No useful information is provided here</td>
</tr>
<tr>
<td>‘…acupuncture needles were placed in the right second intercostal space anteriorly…’ 4</td>
<td>This description points either to KI25 or to ST15</td>
</tr>
<tr>
<td>‘…over the posterior deltoid and above the lateral third of the clavicle…’  3</td>
<td>The second description is appropriate for ST12</td>
</tr>
<tr>
<td>‘…two needles were inserted immediately above the clavicles…’  3</td>
<td>These acupuncture points could have been ST11 and ST12</td>
</tr>
<tr>
<td>‘…the first (set of needles) into the anterior chest below the medial ends of the clavicles, and the third and fifth intercostal spaces parasternally on both sides and the second posteriorly over the scapula and laterally to the fourth, fifth, and sixth thoracic vertebrae over both lungs…’  3</td>
<td>The first set describes KI 22, 24, and 27. The second set suggests BL14-16 (paravertebral) and points of the small intestine (SI13-14) or the triple energizer (TE15) meridian, as well as GB21 (over the scapula)</td>
</tr>
<tr>
<td>‘Needles were inserted into the anterior chest…’  3</td>
<td>No useful information is provided here</td>
</tr>
<tr>
<td>‘…multidomed spinal acupuncture...’  3</td>
<td>This specification includes governor vessel, bladder meridian, and Huatuojiaji points</td>
</tr>
<tr>
<td>‘…needles were inserted in the second left intercostal space on the anterior aspect of the chest wall…insertion of one needle into the supravacicular fossa…’  3</td>
<td>KI22, ST18, or LV14 could be involved</td>
</tr>
<tr>
<td>‘…a needle was inserted in the second left intercostal space on the anterior aspect of the chest wall…insertion of one needle into the supravacicular fossa…’  3</td>
<td>The first description suggests BL11 to 16 and BL41 to 44, the second to KI 27</td>
</tr>
<tr>
<td>‘…she went to an acupuncturist who inserted standard acupuncture needles bilaterally in the tissues of her upper back…’  3</td>
<td>The first description points to KI 25 the second to ST11 or ST12</td>
</tr>
<tr>
<td>‘…needles being placed across the upper back and both shoulders…’  7</td>
<td>No useful information is provided here</td>
</tr>
<tr>
<td>‘…following acupuncture to the spine and bilateral paraspinal regions along the region of the fourth ribs…’  8</td>
<td>Most likely BL13 and 14 had been treated in this case</td>
</tr>
<tr>
<td>‘…to the upper thoracic bilateral paraspinal regions…’  8</td>
<td>Probably points of the bladder meridian or Huatuojiaji points have been used</td>
</tr>
</tbody>
</table>
reports on acupuncture related pneumothorax provides these details. However, it should be recognised that only the acupuncturist and, to some extent, the patient can give this information.

The position of the patient during treatment would be useful information, as well - but is not given in any of the articles analysed. Moreover, none of the authors includes further details on the treatment, eg whether blankets were used, if the needle was stimulated, etc.

The indication for acupuncture treatment is specified in most case reports in orthodox medical terms, but some even lack information about the indication for acupuncture (eg Ritter et al).9 Only rarely are data provided about the equipment used (eg type of needle, length, material).

All the case reports in this series take it as self-evident that the adverse events described are caused by acupuncture, because of the time course of the events. In the adverse event literature, it appears that not only is there a tendency to readily accept that the association is synonymous with causation, but often no attempt is made to establish whether there is a genuine association between the ‘error’ and the outcome.16

Edwards defines an adverse event as an ‘adverse outcome that occurs while a patient is taking a drug, but [that] is not or not necessarily attributable to it’. Applied to acupuncture, this definition states that not all adverse events are necessarily acupuncture-related and that it is not always possible to ascribe causality. Moreover, authors should differentiate between ‘caused by’, ie adverse effect of’, and negligence. In case of traumatic events, a reliable knowledge of both anatomy and acupuncture is necessary to assess this point.18

For acupuncture, most clinicians can make a reasonable judgement on the basis of timing and plausibility. Based on a well known scheme for the causality assessment of suspected adverse drug reactions,9 we propose the following categorisation of adverse events of acupuncture:

- **Certain** - an adverse event that occurs in a plausible time relation to acupuncture, and that cannot be explained by concurrent diseases or other treatment approaches
- **Possible** - an adverse event that occurs in a reasonable time relation to acupuncture, and that is unlikely to be attributed to concurrent diseases or other treatment approaches
- **Unlikely** - an adverse event with a temporal relation to acupuncture that makes a causal relation improbable, and in which concurrent diseases or other treatment approaches provide plausible explanations
- **Unclassified** (ie more information awaited) - an adverse event, reported as an adverse reaction, about which more data are essential for a proper assessment or the additional data are being examined
- **Unclassifiable** (ie more information not available) - a report suggesting an adverse reaction that cannot be judged, because information is insufficient or contradictory and cannot be supplemented or verified.

**Discussion**

We suggest a list of what should be included in a case report about adverse events related to acupuncture (see Table 2). To the best of our knowledge, no guideline or standard has been previously published in the scientific literature on quality criteria for case reports on adverse events.

Although case reports cannot give reliable information on how common or rare adverse events are, collecting adverse events has two purposes: suggesting the approximate level of risk, and encouraging a discussion of procedural changes that might maximise patient safety. Case reports on adverse events therefore can have a major value as an aid for learning. Thompson et al state that cases are good as a means of learning because people enjoy learning through stories.23 A good case report brings the different parts together into a coherent narrative.

These positive aspects should not obscure the fact that most of the case reports on adverse events associated with complementary therapies do not provide enough useful information for learning, but seem to serve mainly as entertainment. It remains obscure why respectable medical journals should publish case reports on acupuncture which
do not fit simple quality criteria; it is not too difficult to believe that it is because these reports imply criticism of complementary therapies.

Reference List


Table 2 Check-list of items that should be included in a case report of an adverse event related to acupuncture

<table>
<thead>
<tr>
<th>Category</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture expertise</td>
<td>Statement of the author's training in, and working knowledge of, acupuncture. If the author does not possess a sufficient expert knowledge, did he seek advice from a fully trained acupuncturist? Declaration of the profession and the level of education of the acupuncturist who is assumed to have caused an incident. This might include a short description of the acupuncture training programs in the respective country and the years of practice</td>
</tr>
<tr>
<td>Description of patient</td>
<td>Basic information about the patient, including sex, weight, and height or body mass index Information about previous diagnoses, current illnesses and treatments Predisposing and risk factors concerning the acupuncture treatment (eg immunosuppression, bleeding tendency) Actual complaints which led to acupuncture (indication for treatment; Western and traditional view, if applicable)</td>
</tr>
<tr>
<td>The acupuncture</td>
<td>Relevant information on treatment, using the STRICTA criteria Acupuncture rationale (style of acupuncture, rationale for treatment) Treatment regime (number of treatment sessions, frequency of treatment) Co-interventions Acupuncture points treated and topographical data Needling details (eg needling depth and direction, needle retention time, needle type) Position of the patient during treatment Special features of the treatment (blankets used, stimulation, cupping…)</td>
</tr>
<tr>
<td>The adverse event</td>
<td>Description of adverse event and chronology of its development Diagnosis and treatment of the adverse event Outcome</td>
</tr>
<tr>
<td>Discussion</td>
<td>Discussion in the context of the scientific literature, eg in what ways is the reported case different from those previously reported? Does it emphasize earlier conclusions? Appraisal of the attribution of the adverse event to acupuncture (certain, probable, possible, unlikely, unclassified, unclassifiable) Error discussion, including suggestions for ways other practitioners can avoid this adverse event in the future</td>
</tr>
</tbody>
</table>


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