Incidence of adverse effects during acupuncture therapy—a multicentre survey

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SUMMARY. Introduction: Acupuncture is frequently used to treat chronic pain syndromes or other chronic diseases. Several hundred reports have been published of life-threatening adverse events after acupuncture. The aim of our study was to assess the adverse effects of acupuncture during a normal treatment routine. Methods: Thirteen general practitioners and outpatient clinics and 16 other practitioners were included in a questionnaire survey in Germany. Patient gender and age, indications for and method of treatment, and adverse effects were documented by the therapists. Results: Four hundred and nine patients receiving 3535 acupuncture treatment were included. Adverse effects were observed in 402 treatments (11.4%) in 153 different patients. The main side effects were slight haemorrhage (2.9%), haematoma (2.2%), dizziness (1%) and other systemic symptoms (2.7%). Other side effects mentioned (all below 1%) were fainting, nausea, prolonged DeQi effect (paraesthesia) and increase of pain. In one case, aphasia was reported lasting 1 h after acupuncture. Conclusion: Acupuncture has adverse effects, like any therapeutic approach. If it is used according to established safety rules and carefully at appropriate anatomic regions, it is a safe treatment method.

INTRODUCTION

Acupuncture is one of several therapies that comprise traditional Chinese medicine. In Western medicine, acupuncture is frequently used to treat chronic pain syndromes or other chronic diseases. It has been claimed that acupuncture has no adverse effects.1 Complementary therapy methods are recommended as ‘natural’, and this term is often used as a synonym for ‘harmless’ or without adverse effects.2 However, since the 1970s there have been several hundred reports about life-threatening adverse effects occurring in relation to acupuncture.3,4 There have been few attempts to quantify these complications. In the meantime, several systematic studies using different methods of assessment have been published.5-10

The issue is complicated by a great variability in acupuncture methods from country to country. In Japan, the use of permanent needling methods, which may cause serious complications, was more frequent than in Europe. Some adverse effects are more typical of ear acupuncture (e.g. local infections) rather than body acupuncture. Particular adverse effects are inherent with associated techniques; for example, moxa therapy (burning a cone or cigar of moxa close to the skin or in contact with an acupuncture needle) may cause burns.

The aim of our study was to assess the adverse effects of acupuncture during a normal treatment routine (i.e. the insertion of about 10-15 needles) in daily practice. In addition, potential correlating factors were examined for their possible role in increasing the risk of adverse effects.

MATERIAL AND METHODS

The acupuncture patients treated by 13 general practitioners and outpatient clinics and by 16 other practitioners in Berlin, Germany, were observed. The Berlin list of physicians was used to identify
physicians using acupuncture, and other practitioners were identified with the help of a local telephone register. Those who mentioned acupuncture as treatment method were included. No additional information regarding their acupuncture training and experience were requested.

Two questionnaires were used. On the first was documented the patient’s gender and age, the indication for acupuncture treatment, the acupuncture points and treatment method and any accompanying illnesses. The second was used to documenting adverse effects after every treatment session. A checklist was provided which mentioned haemorrhage, haematoma, infections, neurological abnormalities, fainting, vestibular symptoms, nausea, prolonged DeQi effect and increase of pain. Free space was provided to record other observed adverse effects. All therapists asked their patients with standardised open questions: during therapy, “How do you feel now?”; and before every subsequent therapy, “How did you feel after the last acupuncture therapy?”.

Questionnaires were completed by the therapists. Prolonged DeQi effect was defined as paraesthesiae and/or muscle weakness lasting more than 1h after treatment. The therapists were asked to document ‘possible septic syndrome’ if fever and/or hypotension were observed in combination with local infection at one or more points that had been needled. Informed consent of patients for an ‘observational study on acupuncture effects’ was obtained. The study procedures were reviewed by the data security commissioner of the local government.

### Table 1: Adverse effects reported (number of treatments and number of patients)

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Number of treatments</th>
<th>Treatments (%)</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>313</td>
<td>256</td>
<td></td>
</tr>
<tr>
<td>With adverse effect</td>
<td>102</td>
<td>11.4</td>
<td>153</td>
</tr>
<tr>
<td>Small haemorrhage</td>
<td>194</td>
<td>2.9</td>
<td>54</td>
</tr>
<tr>
<td>Haematoma</td>
<td>79</td>
<td>2.2</td>
<td>49</td>
</tr>
<tr>
<td>Dizziness</td>
<td>36</td>
<td>1.0</td>
<td>23</td>
</tr>
<tr>
<td>Fainting</td>
<td>5</td>
<td>0.1</td>
<td>3</td>
</tr>
<tr>
<td>Nausea</td>
<td>7</td>
<td>0.2</td>
<td>5</td>
</tr>
<tr>
<td>Other systemic symptoms</td>
<td>97</td>
<td>2.7</td>
<td>32</td>
</tr>
<tr>
<td>Prolonged DeQi effect</td>
<td>17</td>
<td>0.5</td>
<td>6</td>
</tr>
<tr>
<td>Pain while needle is in place</td>
<td>33</td>
<td>0.9</td>
<td>22</td>
</tr>
<tr>
<td>Pain after needle was removed</td>
<td>13</td>
<td>0.4</td>
<td>11</td>
</tr>
<tr>
<td>Other adverse effects</td>
<td>96</td>
<td>2.7</td>
<td>41</td>
</tr>
</tbody>
</table>

### Table 2: Other vegetative effects reported

<table>
<thead>
<tr>
<th>Systemic effect</th>
<th>Number of treatments</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>51</td>
<td>10</td>
</tr>
<tr>
<td>Generalised sweating</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>Feeling of cold</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Isolated sweating of hands</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Increased perspiration</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Feeling of heat</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Tachyphasia</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

### Statistics

Data were processed descriptively. In addition, correlations between adverse effects and gender and age were tested.

Correlations between nominal structured data were processed with Chi-square test or Fisher’s exact test for small numbers. A combination of nominal and metrical structured data was processed by Student’s t-test, or, in case of non-normal distribution, by the Mann–Whitney U-test. Because most patients had several treatments, data analysis was carried out both with numbers of patients and numbers of treatments. Correlations are reported if they exist on both denominators. The level of significance is $P < 0.01$. Because of the exploratory character of the study, significant results are regarded as only a measure of the strength of the association, not a proof.

### Results

The study took place from December 1995 to December 1996 in Berlin, Germany. In all, 409 patients (279 female, 125 male, 5 with no information about gender) receiving 3535 acupuncture treatments were included. Female patients had in average 9.01 treatments, male patients 7.85.

Adverse effects were observed in 402 treatments in 153 patients. Descriptive data of the major events are shown in Table 1, and less frequently observed systemic symptoms are shown in Table 2. In 41
patients (96 treatments), adverse effects were rather unusual or not otherwise classifiable (Table 3). Other effects reported, that only occurred during or after one treatment, included: ‘feeling a acupuncture point on the other arm’ without a needle, an asthma attack, tremor, loss of appetite, aggressive behaviour, grief/crying, weakness in the arms and legs, and aphasia (60 min).

Small haemorrhage and haematoma were often observed together and there exists a correlation with the number of used needles. Small haemorrhage was observed less frequently in female patients. Haematoma were observed less often in young patients, who on the other hand expressed more pain (all $P < 0.01$). Intake of acetyl salicylic acid led to a higher incidence of haemorrhage ($P < 0.05$ for patients, $P < 0.01$ for treatments).

**DISCUSSION**

Adverse effects can be defined in different ways. It is important to distinguish between adverse effects that are significant for the patient and those that are mild or short-lived. Adverse effects that are significant for patients are those that are life threatening (such as pneumothoraces, infections) or otherwise have a big impact (e.g. long-lasting pain, severe pain, or nausea). Other adverse effects are harmless (like small haematoma or slight haemorrhage). Adverse effects must be distinguished from side effects or non-specific effects, such as changes in sleeping pattern or digestion, which occur frequently in acupuncture patients and constitute a therapeutic effect besides the goal of the therapy that is sometimes very welcome. In this study, we tried to identify both potentially dangerous side effects and harmless side effects in order to develop a risk profile based on a higher number of patients and treatments.

The assessment of adverse effects by the therapists themselves contains a high risk of underestimation. A bias can be assumed, leading to falsely low reported numbers. This is especially likely for serious life-threatening adverse effects, like pneumothoraces or other acupuncture-associated trauma, where a therapist might be afraid of possible legal consequences. Other reported side effects, however, might be less likely to suffer this bias. In addition, there may be a selection bias in the centres that participated. Two possibilities can be expected: an increased interest in the study, leading to a higher observation rate and possibly even suggestions to the patient, so that patients are influenced to mention very non-specific feelings that may have no connection to the acupuncture therapy. Such overestimation can only be ruled out by using a control group in a different study design. On the other hand, participating physicians and healers might tend to underestimate adverse effects because of their belief that acupuncture is a safe method. These difficulties are common in observational studies, especially those involving adverse effects, and the reported numbers have to be discussed with caution. In two larger studies, there were lower numbers of adverse effects than in our study, possibly because of our monthly monitoring of the participating centres. On the other hand, a population survey on the use of acupuncture in Norway revealed that 7% of patients reported adverse effects, which corresponds to our numbers. There was no measure to test the accuracy of the questionnaires, however, which might have led to errors in documentation. On the other hand, due to the multicentre character of the study, some of these individual subjective factors might have been eliminated. In addition, we monitored only 3525 treatments, which might be too low a number to establish the incidence rate of adverse effects which are rather rare.

More than one third of acupuncture patient experience adverse effects while being treated with acupuncture. Most of these are harmless. The most frequent side effects were slight haemorrhage and haematoma. In one Swedish study, 11 of 29 patients had small haematoma, but other studies do not mention the rate for haemorrhage. In our study there was a tendency for the intake of acetyl salicylic acid to lead to a higher incidence of haemorrhage and haematoma. There were no patients on anticoagulation therapy in the study. In our outpatient clinic we observed (before this study) at least two patients with large haematoma after acupuncture while being treated with Vitamin K antagonists. Acupuncture should be used only with caution in these patients and they should be informed about this risk. Some authors recommend not using acupuncture therapy in these patients.

Systemic symptoms, like fatigue, but also wakefulness, dizziness, alterations in digestion and
sleeping habit, were not rare and were also frequently observed in other studies (e.g. References 9,15–19). Because of the subjective nature of those phenomena, they should be tested in a further study because of possible associations with acupuncture point combinations or diagnosis.

In our study, 1.5% of patients reported symptom of prolonged DeQi after needle insertion, a certain feeling of dull pain and paraesthesia lasting about 1 min (or as long as stimulation occurs) is reported by patients. Prolonged DeQi means this effect lasts more than 5 min, up to several hours. Our numbers are lower than reported numbers in a study in which patients were treated for craniomandibular disorders. Despite assumptions of possible nerve damage,9,19,20 we can find no report of permanent neurological symptoms after normal needle acupuncture, nor was it observed in this study. Patients should be informed about this possible effect.

One interesting aspect in this study is those adverse effects which were not seen. No local infection was reported despite the practice of several therapists who used sterile needles without disinfecting the skin before insertion. This is widespread practice among acupuncture practitioners, but has not yet been reported systematically. Hepatitis B infections have been reported in acupuncture patients21 caused by insufficient sterilisation procedures in multiple-use apparatus. There is no evidence, however, that single use needles provide an advantage over multiple-use needles provided the latter are processed according to usual rules for sterilisation (i.e. placed in disinf ecting solution after use, cleaning and inspection for possible needle damage, sterilisation with heat or autoclaving before use). There are several reports of local infections after ear acupuncture.25–27 Despite the negative results of our study we recommend skin disinfection before ear acupuncture because of the poorly nourished nature of ear cartilage. Also, even minor infections in the ear can run a chronic course and can cause major cosmetic effects.9

Despite relatively high prevalence rates for type IV allergic reactions against nickel (12.9%)28 and other metals, and some reports about contact allergies after acupuncture,26–28 we had no report of such skin reactions in our study. This might be because of lack of awareness of such allergic reactions, but considering our patient numbers, we might have expected at least some reported cases. Contact dermatitis due to acupuncture seems to be rare.

Unfortunately, we are not able to answer the very important question of possible acupuncture effects on pregnant patients. Acupuncture effects on oestrogen were observed,30 also possible effects on induction of abortion.31 Most therapists tend to be cautious with this patients and avoid using many acupuncture points32 although observations33 and recently a randomised controlled trial34 did not show any harmful effect on the pregnancy or perinatal outcome.

The incidence of adverse effects in our study is much higher than the numbers reported in an observational study in Japan, with a total number of 55,291 treatments. In that study, only three minor haemorrhages were observed, in contrast to 104 in 5355 treatments in our study. The authors described pain in the puncture region in only two treatments, in contrast to 33 in our study. This difference exists for all reported measures. Possibly, it may arise because of different needling methods, or differing definitions of adverse effects, or more insensitive patients. Compared to our clinical experience with adverse effects, our numbers seem to be adequate.

In difference to 7% of the persons surveyed in a Norwegian study,11 37.4% of our patients described minor adverse effects, a difference which might be explained by the different methods. Our patients were asked after every treatment, whereas in Norheim’s study a random sample of the population was asked if they had been treated with acupuncture at any time in their life. Minor adverse effects might not have been recalled accurately by the participants.

We did not analyse the risk that symptomatic treatment given by acupuncture therapists may cause (potentially fatal) delays in receiving effective therapy. This might be the most dangerous side effect of any complementary treatment method.12,13 Acupuncture treatment is only acceptable after adequate diagnostic procedures. Healers who are not medically qualified should be especially aware of this aspect and the potential for legal consequences. But it is notable that we did not observe any difference in incidence rates of adverse effects between physicians and healers, which suggests careful documentation and treatment by the participating practitioners.

CONCLUSION

Acupuncture is a safe therapy, but has adverse effects like any therapeutic approach. The few serious adverse effects that have been reported to be caused by acupuncture were not observed in our study. Bleeding, haematoma and systemic syndromes are common. It is obligatory to use sterile needles, though skin disinfection might not be mandatory in healthy patients who are not immunosuppressed. The medical history taken before acupuncture treatment should at least include enquiries about bleeding or wound healing disorders, immune deficiencies, possible heart diseases (for risk of bacteraemia), possible pregnancy, intake of medication and existing anatomical abnormalities.

REFERENCES

A multiple survey of incidence of adverse effects during acupuncture therapy
