Survey of Adverse Events Following Acupuncture (SAFA): A Prospective Study of 32,000 Consultations

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Summary

Acupuncture is increasingly used, so it is important to establish whether its benefits outweigh its risks. Numerous case reports of adverse events show that acupuncture is not free of risk, but accurate data from prospective investigations is scarce. A prospective survey was undertaken using intensive event monitoring. Forms were developed for reporting minor events each month and significant events as they occurred. The sample size was calculated to identify any adverse events that occurred more frequently than once in 10,000 consultations. Acupuncturists were recruited from two professional organisations in the UK. Seventy-eight acupuncturists, all doctors or physiotherapists, reported a total of 2178 events occurring in 31,822 consultations, an incidence of 684 per 10,000 consultations. The most common minor adverse events were bleeding, needling pain, and aggravation of symptoms; aggravation was followed by resolution of symptoms in 70% of cases. There were 43 significant minor adverse events reported, a rate of 14 per 10,000, of which 13 (30%) interfered with daily activities. One patient suffered a seizure (probably reflex anoxic) during acupuncture, but no adverse event was classified as serious. Avoidable events included forgotten patients, needles left in patients, cellulitis and moxa burns. In conclusion, the incidence of adverse events following acupuncture performed by doctors and physiotherapists can be classified as minimal; some avoidable events do occur. Acupuncture seems, in skilled hands, one of the safer forms of medical intervention.

Keywords

Acupuncture, prospective survey, adverse events, safety.

Introduction

Acupuncture is being increasingly used to treat a variety of conditions. In one population from which samples were surveyed on two occasions, in 1993 and again in 1999, the use of acupuncture rose from 6% to 10%.[1] There is also an increasing amount of evidence in some conditions that acupuncture is effective;[2] however, as with all medical treatments, we need to be sure that the benefits of acupuncture outweigh its risks. Although acupuncture is commonly perceived as safe, case reports have associated the treatment with serious adverse events and even death.[3-5] But case reports cannot give reliable information on how common or rare these adverse events are. The only way to establish the incidence of adverse events is through prospective investigations.

Nine prospective surveys have been reported.[6] Their results are inconsistent, for several reasons. Some are limited in what they report: a survey of 140,000 acupuncture treatments at the Faculty Hospital, Brno over 10 years reported two cases of pneumothorax and two of fractured needle, but otherwise noted the incidence only of haematoma and fainting.[7] Others, such as the survey of 3,535 acupuncture treatments in Germany,[8] are too small to give reliable information on relatively rare events. Others use varieties of acupuncture that are different from that used in the west: for instance, a six-year prospective survey of 65,482 treatments in Japan, where acupuncture needles are usually

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inserted very superficially, recorded only 94 adverse events.[9] No prospective investigation had been conducted in the UK prior to this survey.

Our aim was to use the method of intensive event monitoring to ascertain the incidence of adverse events related to acupuncture treatment as currently practised in the UK by doctors and physiotherapists.[10] This study has already been reported in abbreviated form,[11] together with a similar survey from the Foundation for Traditional Chinese Medicine.[12]

Participants and Methods

Definition

We defined an adverse event as 'any ill-effect, no matter how small, that is unintended and non-therapeutic'.[13] This definition was used both in order to identify events that occurred through error but were not reactions to acupuncture, and in order to include minor events such as bleeding, not just serious events, even when these may have been an expected consequence of needling. We decided not to record unintended beneficial or pleasant events.[14]

Volunteers

Acupuncture practitioners were recruited for this study through publication of the protocol as a journal article in the professional publications,[13] and notices in the journals of the British Medical Acupuncture Society (BMAS) and the Acupuncture Association of Chartered Physiotherapists (AACP). The two organisations had approximately 2750 members in total at that time. During April 1998 each acupuncturist who had volunteered to participate was sent the forms, a reminder sheet with brief instructions about completing and returning the forms and contact telephone numbers in case of difficulty, self addressed envelopes and a covering letter.

In order to aid recruitment, acupuncturists were invited to report anonymously using a code if they wished, and were not asked to provide personal details at the outset. At the end of the study, acupuncturists were asked to state their age, gender, whether doctor or physiotherapist, hours of training and years of practice in acupuncture.

Survey forms

Two forms were developed in collaboration with representatives of the BMAS, the AACP and the British Acupuncture Council. Both forms were piloted for one month by one of us (SH) and three other acupuncturists, leading to minor changes to improve the clarity of definitions of terms as well as easier use of the forms.

On the first form, the 'Monthly Return of Minor Events' (Form A), acupuncturists were asked to record for each month the number of consultations in which acupuncture was used, together with the number of adverse events classified under specific headings:

i. Bleeding, more than 10 seconds; or any bruise/haematoma
ii. Any relevant history associated with the above minor bleeding, such as drug or condition (aspirin, NSAID, other)
iii. Feeling faint (if actually fainted, complete Form B)
iv. Heavy sweating during treatment (state age and gender of patient)
v. Other minor problems during treatment (describe, e.g. needling pain)
vi. Minor problems and reactions after treatment (e.g. nausea)
vii. Aggravation of symptoms after treatment (also consider Form B)
viii. Excessive drowsiness after treatment (if hazardous, Form B)

For each event, a vertical mark was to be placed in the appropriate box. Respondents were not asked to make any explicit assessment of causality. Some practitioners regard aggravation or drowsiness as a part of the response to treatment (the 'healing crisis'), and not as unintended 'adverse' events. Therefore, if a patient later improved substantially, respondents were instructed to convert the relevant mark in the box to an asterisk.

The second form, the 'Significant Event

Table 1 **Details of 58 of the 78 practitioners involved in the survey**

Age, mean year (range)	47 (27-71)
Sex	Male 29 (50%) Female 29 (50%)
Occupation	Doctor 36 (61%) Physiotherapist 23 (39%)
Acupuncture training	<24 h: 3 (6%) 25 to 100 h: 20 (37%) > 100 h: 31 (57%)
Duration of practice	0-2 y: 1 (2%) 3-5 y: 15 (27%) 5-10 y: 20 (36%) >10 y: 19 (35%)

Report' (Form B), was developed from the 'Yellow Form' (Committee on Safety of Medicines) for reporting adverse drug events. Respondents were asked to complete relevant parts of the form in order to record any event that was 'unusual, novel, dangerous, significantly inconvenient or requiring further information'. Examples were provided, which included needling problems (broken or forgotten needle, moxa burns), systemic effects (faint, convulsion, drowsiness causing hazard e.g. on the road, severe nausea) and symptoms (unexpected or prolonged aggravation). Spaces were provided for the patient's date of birth, sex, description of event, date of onset, outcome details of acupuncture, and the condition being treated. In addition, respondents were asked to assess the degree of certainty that the event was the result of acupuncture (unsure / fairly sure / certain), and state whether the patient received subsequent acupuncture treatment, and if so whether the event recurred. Details of other simultaneous treatments, both physical and pharmacological, were requested, together with relevant medical history and known allergies. Respondents were asked to state any changes to procedures that they intended to make as a result of the occurrence.

Sample size

The sample size was calculated in order to identify, with 95% confidence, any adverse event that occurred once in 10,000 consultations, which, according to one authority,[15] represents 'minimal risk' for serious events such as pneumothorax.[3] Using Hanley's rule of threes,[16] we calculated that this requires a sample of 30,000 consultations. Estimates were calculated with the acupuncturist, not the consultation, as the primary sampling unit.

Analysis

Every three months reports were returned in reply-paid envelopes to the Department of Complementary Medicine, University of Exeter, for analysis. Data were entered into an Excel spreadsheet by a secretary, with all questions of interpretation being decided by the first author. Since the data were skewed, with extreme values, bias-corrected confidence intervals for mean incidences were computed using bootstrapping procedure 'bs' on estimates from the function 'svyratio' in Intercooled Stata version 6.0 with 10,000 replications.[17;18] This modelled the clustering by acupuncturist.

Acupuncturists reporting high individual rates of adverse events were contacted by letter during the analysis period in a search for explanations.

Results

Data were collected over 21 months (June 1998 to February 2000) from 78 acupuncturists working in 76 centres throughout the UK. Thirteen respondents chose to remain anonymous. In total, 883 monthly reports covering 31,822 consultations were received (median 318, range 5 to 1911 per acupuncturist). Twenty-two respondents (28%) returned 20 or 21 reports, and 45 (58%) returned 10 or more reports. Four reports had to be excluded from the analysis (two with no reporter details, two apparent duplicates). Background personal and practice information was provided by 59 (76%) of the acupuncturists and is shown in Table 1.

Overall, 2178 events were reported, an incidence of 684 per 10,000 consultations. Fourteen respondents (18%) reported no adverse events in a total of 1130 consultations. Table 2 lists the seven most common events reported (all those

Table 2 **Summary of the minor adverse events reported by 78 acupuncturists**

Event	***Cases reported***	***Mean Incidence per 10,000 consultations (95% CI)***	***Number (%) of acupuncturists reporting none***	***Extreme values reported by individual practitioners***[†] (rate per 10,000 consultations)
Bleeding or haematoma	982	310 (160 to 590)	19 (25)	2610, 5320
Needling pain	364	110 (48 to 247)	42 (55)	1880, 2400
Aggravation	306[‡]	96 (43 to 178)	42 (55)	9900, 1140
Faintness	93	29 (22 to 37)	35 (46)	1400, 1600
Drowsiness after treatment	93	29 (16 to 49)	48 (63)	5300, 2000[§]
Stuck or bent needle	40	13 (0 to 42)	73 (96)	2900
Headache	34	11 (6 to 18)	58 (76)	3500, 4000
Sweating	33	10 (6 to 16)	60 (79)	2900, 3300

[†] *Values based on fewer than 5 consultations have been omitted*

[‡] *Of whom 70% reported subsequent improvement in presenting complaint*

[§] *Based on 5 consultations only*

Table 3 **Significant minor events reported by 78 doctors and physiotherapists in 31,822 acupuncture consultations**

Event	***Number reported***
Administration problems	
Needle lost or forgotten	5
Patient forgotten in treatment room	2
Application site problems	
Cellulitis after treatment of oedematous leg*	1
Blister following moxibustion	1
Needle allergy	2
Needle-site pain* (one case lasted 2 weeks)	3
Cardiovascular problems	
Fainting	6
Gastrointestinal problems	
Nausea**	2
Vomiting	1
Patient fell asleep during treatment	1
Drowsiness** (one case lasted 1 day; one case lasted 1 week)	2
Disorientation* (one case lasted 1 hour; one case lasted 1 day)	2
Lethargy*	2
Neurological and psychiatric problems	
Anxiety & panic** (one episode lasted 60 hours)	2
Euphoria	1
Headache for 3 days	2
Hyperaesthesiae with numbness for 3 days*	1
Seizure shortly after insertion of needles* (probably reflex anoxic)	1
Slurred speech	1
Exacerbation of symptoms	
Back pain, fibromyalgia*, shoulder pain*, vomiting*, migraine*	5
Total	**43**

** Event led to reduction in daily activities; each asterisk indicates one patient.*

with an incidence of 10:10,000 or more). The most common event was bleeding (including haematoma) which occurred on 982 occasions. In 75% of these cases, no information was given on relevant drugs being taken; in 18% of cases the report stated no drug taken, and in about 5% patients were reported to be taking nonsteroidal anti-inflammatory drugs (NSAIDs) or aspirin. The range of incidence of bleeding for individual practitioners varied between zero and 53%.

Other events commonly reported were needling pain and aggravation of symptoms. Of those patients whose symptoms were aggravated, the condition subsequently improved in 70%. The incidences of both faintness and drowsiness were 0.3%, and the incidences of stuck or bent needle, headache and sweating were each about 0.1%. The patient's gender was recorded for 27 cases of sweating, 16 being male and 11 female.

Other minor events during treatment reported less frequently included allergic phenomena (18), and flushed cheeks or body warmth (3). Minor events noted after treatment were change in bowel function (3), thirst (8), and heavy legs (1). A further 25 minor cases were unclassified either because no description was provided, or because the event could clearly not be classified as adverse, for example local erythema (10), and one report of 'urge to laugh'.

Forty-three Forms B reporting significant events were completed, a rate of 14 per 10,000 (95% CI 8 to 20), see Table 3. Twenty-eight were judged as 'certainly' caused by acupuncture, ten as 'fairly sure' and five as 'unsure'; 13 (30%) were sufficiently serious to interfere with daily activities. In addition, 48 apparently similar events were reported on the monthly forms A, presumably due to varying interpretations of the term 'significant'. All had cleared within a week except one incident of pain lasting two weeks and one of sensory symptoms lasting several. The avoidable events were either administrative (needles left in patients or lost in hair or clothing, and patients abandoned in the clinic) or application site disorders (cellulitis). Changes to procedures suggested by those reporting the adverse events are listed in Table 4. In addition to these cases reported as significant, two avoidable cases of moxa burns were reported as minor events on Form A.

One patient suffered a seizure occurring during treatment. He was aged 35, presented with back pain, and was treated lying prone. Needles were inserted 1 cm deep in his hands, back muscles and feet. They were not stimulated and did not cause pain. Within a few minutes, the patient developed a strong flexor spasm of the whole body and became unconscious. He remained unconscious for about three minutes after which he recovered complaining of nausea and fatigue. He had bitten his tongue. On further questioning, he gave a history of one previous seizure, for which he was given cardiopulmonary resuscitation, during a painful cystoscopy. He had subsequently donated blood with only a transient feeling of faintness. The diagnosis may have been reflex anoxic seizure.[19]

The adverse event rate (number per 100 consultations) for individual practitioners ranged from 0 to 89.6% (the latter was from 77 consultations, the majority of events being bleeding), with a median value of 4%. There was no evidence of any association between this rate and the duration of acupuncture training or clinical experience, the number of consultations per month, the profession and gender of the practitioner, or the number of monthly reports that were returned.

Discussion

The SAFA study, in which doctors and physiotherapists intensively monitored the adverse events associated with acupuncture, found an overall incidence of events of 684 per 10,000 consultations. The three most common minor events that were reported on Form A (bleeding, aggravation, and pain) each occurred in at least 100 per 10,000 consultations. The reported incidence for a few individual acupuncturists was considerably higher, up to 53% of sessions. Significant minor events occurred at a rate of about 14 per 10,000. Although about 30% of these

interfered with daily activities, none of these events can be classified as 'serious' according to the usual criteria,[10] with a 95% CI of 0 to 1.2 per 10 000. Combining these with the figures from the Foundation for Traditional Chinese Medicine study, the rate of serious adverse events is less than 1 per 66,000 consultations. The incidence of adverse events associated with acupuncture can therefore be classified as 'minimal' according to the standards of one authority, who defines 'minimal risk' as less than 1 per 10,000 for major complications and less than 1,000 per 10,000 for minor events.[15]

The reported incidence of bleeding of 310 per 10,000 treatments in the SAFA study falls between the figures from other surveys, which range from 33 to 3,800.[20;21] It is most similar to the 500 per 10,000 figure of a recent German survey.[8] Aggravations of symptoms (96 per 10,000 in SAFA) have rarely been reported in other surveys, and we have also measured the percentage of 'justified' aggravations, i.e. those that are followed by a resolution of symptoms. Pain on needling (110 per 10,000 in SAFA) has been reported to vary from 20 to 1,300.[20;21] The incidence of fainting was about 2 per 10,000 in this study, which is similar to the figures from surveys in Japan,[9] Singapore,[22] and Germany.[8]

Reliability

The reliability of these findings could have been affected by various factors. Reported incidence may be increased by a low threshold for reporting: acupuncturists may be anxious about adverse effects and meticulously record every slightest event. There is evidence suggesting this from nine identifiable respondents with high incidence rates (table 2) who responded to later enquiry. Two of those with high values for bleeding were reporting every drop of blood, despite instructions on the form. Correcting for this apparent reporting error reduces the incidence of bleeding to about 190 per 10,000 treatments and the overall incidence of adverse events to about 550. At least two respondents with high rates for pain were reporting needle prick or the slightest discomfort, and one used an unusually large number of needles for each treatment. One with high figures for drowsiness was particularly meticulous in questioning patients. The highest incidence of headache reported was due to recurrent headaches in one patient who had noted their association with acupuncture only after several episodes. No particular needle type or style of acupuncture was linked with high individual values, but the high-reporting respondents tended to mention that they treated older patients (who may have a higher likelihood of adverse reactions). Other potential reasons for false high figures include the possibility that incidental events are wrongly attributed to acupuncture, since acupuncturists were not asked to assess causality for minor events (see Methods).

The figures could also be artificially low. Therapists volunteering to participate may be particularly experienced acupuncturists producing atypically low figures. They could also have felt protective towards acupuncture and have an interest in under-reporting problems. Indeed, there is the possibility of someone entering the survey with the intention of proving that acupuncture has no adverse effects and thus under-reporting intentionally (or over-reporting with the opposite intention). Those who start reporting and find a large number of events may subsequently stop reporting. This may have occurred in the case of one respondent who sent a first month's report giving an adverse event rate of 40%, but then submitted no further reports. However, this was a single occurrence, and there is no overall association between the number of report forms returned and the adverse event rate. It appears unlikely that adverse events were frequently missed during treatment in view of the professional status of the respondents, although those occurring after the final treatment session will not normally have been reported. The respondents mostly work in the community as general practitioners or community physiotherapists, so would have been likely to hear of any serious adverse event even if the patient did not return for further treatment.

The methodology in this area is not established and the survey instrument could be improved. For example, we did not include instructions on how to report repeated incidents of an adverse event in the same patient. The question about drugs being taken was poorly answered, probably due to inadequate questionnaire layout. In the section 'Other problems e.g. pain', some who reported a number did not specify the event; it was interpreted as 'pain' by implication if not otherwise labelled. There are inevitably problems persuading busy professionals to follow detailed instructions: some cases of fainting, for example, were reported in the Form A rather than on the Significant Events Form B. There is an inevitable loss of sensitivity in interpreting and classifying complex responses into a single category. Several reports combined nausea and malaise, for example, and from discussion with the participants the severity of the category 'faintness' varied considerably.

Interpretation

Event rates should be interpreted with caution. In particular, we did not ask participants to record the number of patients seen as well as the number of treatments given. Therefore, all rates are per consultation rather than per individual patient. Systemic reactions seem generally more likely to depend on individual predisposition than local events do. The clearest example is the case of seizure during treatment in a patient who was, in retrospect, at risk. The risk of this event in the general population cannot be calculated without knowing the number of patients surveyed; if each patient consulted on average five times, the incidence of seizure estimated from these data would be one case in 6,364 individuals.

The acupuncturists who took part in this survey constituted about 2.5% of the total membership of both participating organisations. It is likely that practitioners who volunteer for this kind of study are particularly enthusiastic, careful and well organised, and may not be totally representative of UK doctors and physiotherapists practising acupuncture. However, some of their characteristics, i.e. their gender and acupuncture workload, do appear representative of their organisations. The sex distribution is similar to that of the societies (doctors: females in sample 28%, in BMAS 33%; physiotherapists: females in sample 90%, in AACP 82%). On average the doctors gave about 26 acupuncture treatments per month, which is very similar to the number given by doctors in other surveys.[23-25] Data on age, training and years of practice are not available in society records, therefore comparisons cannot be made.

Collecting adverse events has two purposes: discovering the level of risk, and encouraging discussion on procedural changes that might maximise patient safety. Several of these adverse events are clearly avoidable, specifically the administrative problems: forgotten patient, forgotten needle, needle left in clothing, needle lost in hair. These events, however, were not reported as causing damage, nor are there any case reports in the literature of a forgotten needle causing any significant injury. Moxa burns, although traditionally regarded as part of the treatment,[26] must be considered an unnecessary and avoidable injury today. Our findings also provide norms as targets for individuals. Acupuncturists may wish to set up a recording scheme for adverse events in line with the Chief Medical Officer's recent report.[27]

Some respondents made suggestions for alteration of practice (Table 4) aimed at reducing the risk of a reported adverse event. It is hoped that these will be discussed by the appropriate professional societies. Nonetheless, it seems that not all the suggestions are totally practical or generally applicable (adequate treatment for neck and shoulder pain, for instance, can be difficult unless the patient is sitting) and several suggestions either imply an overall reduction in treatment intensity, which could affect the success rate for less sensitive patients, or deny patients possible benefit, e.g. in treatment of limb oedema. So practitioners may decide that until strong responders and others at greater risk can be identified prior to treatment, a low level of transient, minor, adverse effects may have be accepted in view of the benefit expected for the

Table 4 **Acupuncturists' recommendations of changes to procedures after the occurrence of significant adverse events, and comments**

Event	***Recommendation / Comment***
Forgotten patient	Provide a reminder for myself and/or an alarm for the patient, every time a patient is left in a side room; reconsider whether to provide acupuncture during surgery hours
Anxiety and panic for 60 hours	Ask about previous anxiety and depression
Tingling and itching on points for 24 hours	Ask about allergies (reported twice)
Fainting	Never treat a patient sitting (reported twice)
Lost needle	Keep guide tubes (to tally with number of needles)
Lost needle	Count them in, count them out!
Drowsiness	Stimulate more lightly first time
Drowsiness	Use fewer points
Aggravation of symptoms, and legs felt numb	"I should have stopped treatment before this as fragile personality"
Cellulitis	Not treat an oedematous limb
Seizure	Ask about previous reactions to medical intervention
Felt spaced out and drove wrong way out of car park	Reinforce usual advice about driving after treatment
Severe headache on 2 occasions	Discontinue if increasing stimulation causes new symptoms. Do not persist in acupuncture it if upsets the patient

majority of patents. This, however, will depend upon the balance of risk to benefit for particular medical problems and forms of acupuncture treatment: a balance that has not been addressed by the SAFA survey, and in general remains to be determined. Nonetheless, reviewing the results of both this and the York survey, Vincent concludes 'while the risk of acupuncture cannot be discounted, it certainly seems, in skilled hands, one of the safer forms of medical intervention.'[28]

These results are relevant to the discussion on what information should be given to patients who are considering acupuncture treatment. It seems unnecessary to provide unsolicited warnings about risks that are minimal, or that might be commonly expected but are trivial; nonetheless, this approach may have to change if challenged under the Human Rights Act 1998.[29] However, if patients ask about risks, this investigation should provide enough information for accurate appraisal. Practitioners may like to keep records to determine where their own practice lies in relation to the level of risk found here.

Conclusion

The risks of adverse events, both minor and major, following acupuncture, can be classified as minimal. Avoidable adverse events do occur and the results of this survey can be used by individual practitioners to audit and improve their own practice.

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Notes