

# A Prospective Survey of Adverse Events and Treatment Reactions following 34,000 Consultations with Professional Acupuncturists

*Hugh MacPherson, Kate Thomas, Stephen Walters, Mike Fitter*

## Summary

The paper describes the type and frequency of adverse events and transient reactions following consultations with professional acupuncturists. In a postal survey, involving 1848 professional acupuncturists, all of whom were members of the British Acupuncture Council and practising in the UK, details of adverse events and transient reactions following treatment were recorded on standardised self-report forms. A sample size of 30,000 treatments was sought, and piloting indicated that a four-week period was required. Practitioners also provided information on themselves, including age, sex, length of training and years of practice.

A total of 574 practitioners responded, 31% of the total population. These practitioners reported on adverse events and transient reactions associated with 34,407 treatments. No serious adverse events were reported, where these were defined as requiring hospital admission, prolonging hospital stays, permanently disabling, or resulting in death (95% CI: 0 to 1.1 per 10,000 treatments). A total of 43 significant minor adverse events were reported, a rate of 1.3 per 1,000 treatments (95% CI: 0.9 to 1.7). These included severe nausea and actual fainting (12), unexpected, severe and prolonged aggravation of symptoms (7), prolonged and unacceptable pain and bruising (5) and psychological and emotional reactions (4). There were three avoidable events: two patients had needles left in by mistake, and one patient had moxa burns to the skin, also caused by practitioner error. The acupuncturists also recorded 10,920 mild transient reactions occurring in 5136 treatments, 15% (95% CI: 14.6

to 15.3) of the 34,407 total. In terms of local reactions, there were reports of mild bruising (1.7%), pain (1.2%) and bleeding (0.4%). Practitioners reported that patients experienced an aggravation of existing symptoms after 2.8% of treatments. The most common mild transient reactions to treatment were feeling relaxed (11.9%) and feeling energised (6.6%).

In this prospective survey of 34,407 treatments, practitioners reported no serious adverse events. This conclusion was based on data collected from one in three members of the British Acupuncture Council. Given that the whole membership delivers between one and a half and two million treatments a year, this is important evidence on public health and safety. When compared with medication routinely prescribed in primary care, the results suggest that acupuncture is a relatively safe treatment modality.

## Keywords

*Acupuncture, prospective survey, adverse events, safety.*

## Introduction

Recent reports have highlighted the importance of having good evidence on the safety of acupuncture.<sup>1-3</sup> In evaluating the risks associated with acupuncture, much of the existing evidence has been based on individual case reports, which may involve idiosyncratic or unusual cases not necessarily relevant to everyday practice.<sup>4</sup> With the recent House of Lords Report emphasising the public policy issues where there are risks associated with complementary medicine,<sup>3</sup> it is timely to report here on this

Hugh MacPherson  
*research director*  
Foundation for Traditional  
Chinese Medicine, York

Kate Thomas  
*deputy director*  
Medical Care Research  
Unit  
University of Sheffield

Stephen Walters  
*lecturer (medical  
statistics)*  
Sheffield Health  
Economics Group  
University of Sheffield

Mike Fitter  
*research consultant*  
Foundation for Traditional  
Chinese Medicine, York

Correspondence:  
Hugh MacPherson

[hugh@ftcm.org.uk](mailto:hugh@ftcm.org.uk)

prospective survey of adverse events and treatment reactions associated with acupuncture practice in the UK.

While retrospective surveys reporting on adverse events associated with acupuncture have a place in the evidence profile,<sup>5,6</sup> their estimates are weakened because they are based on practitioners remembering past events over a considerable period of time in practice. Better evidence for safety will come from prospective surveys,<sup>7,8</sup> a number of which have been undertaken in other parts of the world. The largest of these prospective surveys are of 140,000 consultations in Czechoslovakia,<sup>9</sup> 28,000 in Taiwan,<sup>10</sup> and 65,000 in Japan.<sup>11</sup>

Recently two prospective surveys have been undertaken in the UK, both of which are reported in full in this issue of *Acupuncture in Medicine*, and both of which have also had a summary of their results published elsewhere.<sup>12,13</sup> White et al based their protocol on achieving a sample size of 30,000 consultations and on surveying members of the British Medical Acupuncture Society and the Acupuncture Association of Chartered Physiotherapists.<sup>12</sup> The survey reported in this paper collected similar data to the Exeter survey, with a similar sample size, but surveyed members of the British Acupuncture Council (BAcC). As the lead body in the UK for professional acupuncturists, the BAcC sets and maintains educational standards based on three-year full time accredited courses, and implements a Code of Practice addressing a range of health and safety issues.

The results of this study will contribute to debates on the relative safety of acupuncture. Comparisons can be made not only between this survey and the results of White et al,<sup>12</sup> but also between this and other surveys in other parts of the world and in different clinical contexts. In addition, it is possible to estimate acupuncture's safety record alongside that of non-steroidal anti-inflammatory drugs, a comparable intervention for chronic pain. It is hoped that the assessments of risk associated with acupuncture are germane to debates on statutory regulation of professional

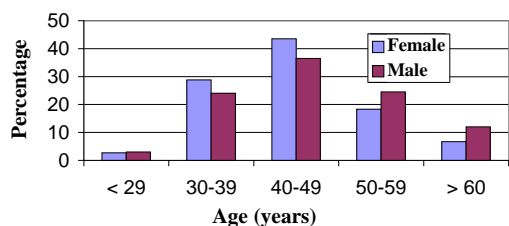
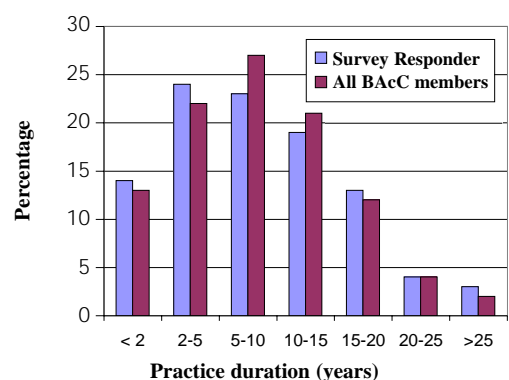
acupuncturists, a recommendation of the House of Lords.<sup>3</sup>

### **Methods**

All 1,848 UK based members of the BAcC were invited by the Foundation for Traditional Chinese Medicine to participate in the survey. Data on sex, duration in practice and place of training of the practitioners who agreed to participate was compared with that of the whole membership to gauge whether or not the sample was representative.

In calculating the required sample size, we followed White et al<sup>7</sup> in using Hanley's Rule of Threes.<sup>14</sup> This states that to have a 95% probability that no serious event occurs in  $n$  treatments, a survey sample size needs to be three times  $n$ . On this basis, we chose a sample size of 30,000 treatments, and if no serious event was reported in this sample, then we could estimate with a 95% probability that no serious event would occur in a sample of 10,000 treatments. A pilot survey showed that 30% of practitioners were willing to complete the questionnaire, each practitioner reporting on approximately 60 treatments. Accordingly, a four-week reporting period was calculated to be required, with a target of 500 practitioners reporting on events associated with 30,000 treatments. To help with the response rate, a decision was made to keep practitioners' reports anonymous.

Practitioners were provided with a standardised self-reporting booklet, modelled on White et al,<sup>12</sup> with some modifications. Practitioners were asked to record 'significant' adverse events on the yellow pages within the booklet, each entitled Significant Adverse Event Report, much like the Yellow Card of the UK Committee of Safety of Medicines. The word significant was used in the survey to help practitioners decide whether an adverse event was one that warranted more investigation. In the standardised booklet, a 'significant adverse event' was defined as any event that was 'unusual, novel, dangerous, significantly inconvenient, or requiring further information'. Other details of an event were requested, including the date and description of the

**Table 1 Clustering bar chart of age by sex of participating acupuncturists****Table 2 Relationship of survey responders to BAAC membership in regards to practice duration**

event, assessment of severity (on a scale of 1= 'mild' to 5= 'severe'), attribution to acupuncture (on a scale of 1 = 'not sure' to 5 = 'definite'), outcome of the event, and the reason that the patient was attending for treatment. Details were also asked about the acupuncture provided, including the differential diagnosis and treatment methods (needle locations, depths of insertion, needle techniques and any auxiliary interventions, etc.) Where relevant, medical history and current medication was also recorded. Practitioners were also asked about what useful advice they may have for others, and what changes to procedures they would suggest.

In a separate part of the booklet, practitioners were asked to record mild transient reactions to treatment, within one or more of three categories. First there were systemic reactions, spontaneously described by patients, including feeling energised, hungry, tired, relaxed, drowsy, dizzy, faint, nauseous, pain not at the site of needling, and heavy sweating. Secondly there were aggravations

to symptoms following acupuncture, (details of which were asked of patients by their practitioners at subsequent treatments) where such aggravations were of existing symptoms that may or may not have been followed by an improvement. Thirdly, there were local (i.e. non systemic) reactions at the site of needling, including bruising, bleeding (for more than 10 seconds) and local pain (such as nerve pain). The survey was structured so that more than one reaction (symptom) could be reported for each treatment (event). At the end of the 4-week period, practitioners summed up the totals of all mild transient reactions to treatment and also provided the total number of treatments they had delivered.

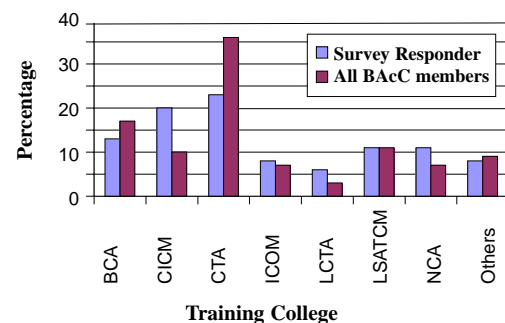
Finally, practitioners completed questions on themselves and their approach to acupuncture. These included questions on age, sex, practice duration, where trained, length of training, professional memberships, and where they worked. In terms of practice style, details were requested on average number of needles used per session, whether practitioners generally aimed to attain '*de qi*', methods of sterilisation and utilisation of auxiliary modalities of treatment. Practitioners were also asked whether they would be interested in taking part in a follow-up study exploring the patient's perspective on treatment reactions and adverse events.

## Results

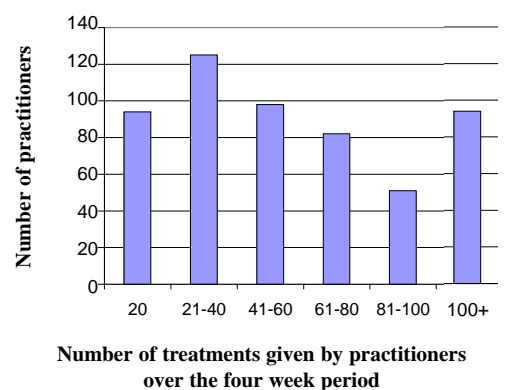
### Survey responders.

Of the 1848 practitioners, 574 responded to the survey, a response rate of 31%. Of these, 35% were male and 65% female, similar to the 40% male and 60% female membership of the BAAC as a whole.<sup>15</sup> The average age of the practitioners was 44.8 years (range 23 to 79, standard deviation 9 years). A cluster bar chart of responders' age by gender is presented in Table 1. In terms of practice duration and where the practitioner trained, Tables 2 and 3 show the distribution of the survey responders compared with the membership as a whole.<sup>15</sup> Overall, the survey sample was sufficiently representative of the membership for re-weighting of the primary data to be unnecessary.

**Table 3 Comparison between the survey responders and BacC members as a whole in regard to where they trained**



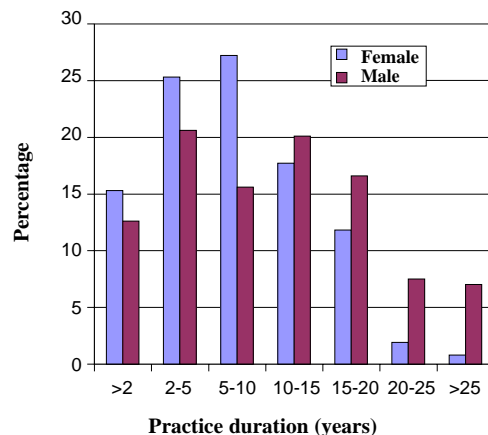
**Table 5 Cluster bar chart of practitioners by number of treatments over the 4 week period**



A cluster bar chart of gender by duration in practice is presented in Table 4, showing a preponderance of men in practice for the longer durations, and women for the shorter durations. In terms of the length of initial professional training, 11% of the survey practitioners trained for between 1 and 2 years, 75% trained for 3 years and 14% trained for between 4 and 6 years. On average 25% of practitioners used 1 to 5 needles per treatment, 52% used 5 to 10 needles and 22% used 11 to 20 needles. Attaining '*de qi*' was an aim for 87% of practitioners. While all practitioners were members of the BAcC, one was also a member of the British Medical Acupuncture Society.

The total number of treatments delivered over the four-week period by all responders was 34,407, exceeding the target set. Practitioners delivered on average 60

**Table 4 Cluster bar chart of sex by duration practising as an acupuncturist**



treatments over the period. Table 5 presents the distribution of treatments per practitioner over the period.

#### *Serious adverse events*

A total of 43 events were reported on the yellow forms labelled 'Significant Adverse Event Report'. Of these, none was classified as serious, where a serious adverse event is defined as one that requires hospital admission, prolongs hospital stays, is permanently disabling or results in death.<sup>16,17</sup> This is statistically consistent, given Hanley's Rule of Threes with 95% confidence, with an underlying serious adverse event rate of between 0 and 1.1 per 10,000 treatments.

#### *Significant minor adverse events*

We class the 43 events discussed above as significant minor adverse events. The most common were severe nausea and actual fainting, with the related symptoms of severe dizziness, heavy sweating and vomiting (14), unexpected, severe and prolonged aggravations of existing symptoms (7), prolonged and unacceptable local pain and bruising (5), and psychological and emotional reactions (4). The significant minor adverse event rate is calculated to be 1.3 per 1,000 (95% CI: 0.9 to 1.7). A complete list is at Table 6.

Three of the 43 significant minor adverse events involved what could be called avoidable events. For two patients, needles were left in place inadvertently by the practitioners: in one case a

**Table 6 Significant minor adverse events associated with 34,407 acupuncture treatments**

Significant minor adverse events	Number of occurrences	Descriptions
Severe nausea, actual fainting, severe dizziness, heavy sweating and vomiting	12	5 cases of severe nausea (2 with feeling faint, sweating and dizziness, 1 started next day and lasted several days, and 1 started four days later with angina and nose bleeds), 4 fainted (2 with nausea and dizziness), 1 severe dizziness and feeling faint, 1 heavy sweating and slight needle shock, and 1 vomiting after treatment
Unexpected, severe and prolonged aggravation of existing symptoms	7	1 difficulty walking the next day because of stiff painful legs, 1 increase in shoulder pain for 20 minutes, 1 neck and shoulder pain increase for 1 week, 1 morning sickness worsened, 1 diarrhoea in patient with colitis, 1 constipation in patient with irritable bowel, and 1 temporary aggravation of neck pain
Prolonged and unacceptable pain and bruising	5	3 local pain at site of needling, 2 heavy bruising
Psychological and emotional reactions	4	1 emotional outburst and anger at practitioners, 1 feeling of panic with sensation of heat and sweatiness, 1 intense emotional release, feeling manic, relaxed, rage and confusion, and 1 depression with anxiety
Avoidable errors	3	2 forgotten needles, and 1 moxibustion burns at two points
Miscellaneous symptoms	10	1 haematuria next day, 1 headache next day, 1 unwell, tired, sore throat, breathless and achy, 1 knee went weak and couldn't stand on it, 1 very tired next day, 1 felt sick and exhausted, 1 severe drowsiness, 1 tiredness next day with 10 hours of diarrhoea, 1 skin rash after taking herbs, and 1 rash developed on abdomen a few days after treatment
Unspecified	2	
<b>Total</b>	<b>43</b>	

patient was turned over on the couch before two needles in the ankles (at BL60) were discovered to have been left in by mistake; and in the other case the patient discovered on the way home that a needle hadn't been removed from her neck at GB20. For another patient, moxa-on-the-needle was used at two buttock points, (GB30 and the Extra Point Tinzhong nearby) resulting in two burns to the skin, almost certainly because the needles were too short, such that the burning moxa was too close to the patient's body. All three of these events would have been avoided by good practice.

There were also ten miscellaneous adverse events, with potentially the most worrying being a haematuria, which occurred once, the day after treatment. The practitioner described the patient as a 'stocky' man and inserted needles in points in the limbs and in BL23 to a depth of one centimetre. At this point, needle insertion would

need to be to a depth of at least four centimetres for the needle tip to reach the kidney in a slim adult.

#### *Mild transient reactions to treatment*

In the standardised booklet, practitioners reported a total of 10,920 mild transient reactions to treatment. These were reported to have occurred during or after 5136 treatments. Given the total of 34,407 treatments covered in the survey, these events occurred in 15% (95% CI: 14.6 to 15.3) of treatments. A summary of the nature of these reactions is reported in Table 7. The first of the three categories of mild transient reactions to treatment, systemic reactions, made up the largest percentage, with the most frequently reported being 'feeling relaxed', which occurred in 4098 (11.9%) treatments, and 'feeling energised', which occurred in 2267 (6.6%). Other systemic reactions included tiredness in 903 (2.6%) treatments,

**Table 7 Mild transient reactions associated with 34,407 treatments**

Type of Mild Transient Reaction to Treatment	No. of reactions	Rate /100trt	95% CI for rate	
			Lower	Upper
<b>Systemic Mild Transient Reactions to Treatment</b>				
Feeling relaxed	4098	11.9	11.6	12.3
Feeling energised	2267	6.6	6.3	6.9
Feeling tired	903	2.6	2.5	2.8
Feeling drowsy	368	1.1	1.0	1.2
Dizzy	211	0.6	0.5	0.7
Hungry	189	0.5	0.5	0.6
Pain (not at needle site)	177	0.5	0.4	0.6
Nauseous	97	0.3	0.2	0.3
Sweating	78	0.2	0.2	0.3
Feeling faint	73	0.2	0.2	0.3
<b>Aggravations of Existing Symptoms</b>				
Transient aggravation of existing symptoms followed by an improvement	830	2.4	2.3	2.6
Mild aggravation of existing symptoms, not followed by an improvement	136	0.4	0.3	0.5
<b>Local Mild Transient Reactions to Treatment</b>				
Bruising	587	1.7	1.6	1.8
Pain (at needle site)	422	1.2	1.1	1.3
Bleeding	126	0.4	0.3	0.4
<b>Other Mild Transient Reactions to Treatment</b>				
	288	0.8	0.7	0.9

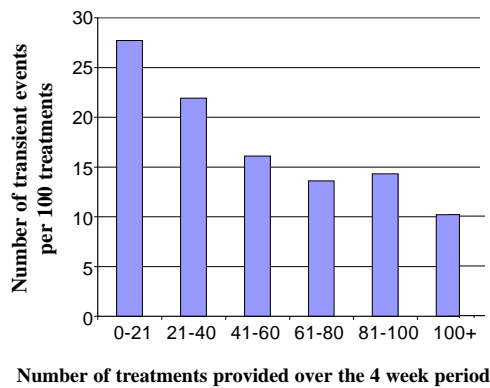
drowsiness in 368 (1.1%), dizziness in 211 (0.6%), nausea in 78 (0.3%) and feeling faint (but not actually fainting) in 73 (0.2%). The second category of mild transient reactions, aggravations of existing symptoms, were reported to have occurred in 966 (2.8%) treatments, and following 830 (2.4%) of these aggravations there was a resulting improvement to symptoms. The third category of mild transient reactions, local reactions at the site of needling, included reports of local pain (i.e. nerve pain not just *de qi*) in 422 (1.2%) treatments, bruising in 587 (1.7%) and bleeding (for more than 10 seconds) in 126 (0.4%).

In a univariate logistic regression analysis on the practitioner variables, the primary correlates with the mild transient reaction rate were assessed. Through an analysis of the data, the odds of a mild transient reaction being reported were found to be significantly associated with age, sex, practice duration, length of training and number of treatments (all  $p < 0.0005$ ). Multivariate analysis to assess for possible confounding between age, sex and practice duration as variables showed that age and sex, but not practice duration, independently affected the reporting rate of mild transient reactions ( $p < 0.002$ ). Male practitioners had an odds ratio of 0.73 (95% CI: 0.69 to 0.78)

compared with female practitioners, of recording a mild transient event, after allowing for age. Similarly, the odds of recording a mild transient event reduced by a factor of 0.994 (95% CI: 0.990 to 0.998) for every year increase in age, after allowing for the sex of the responder. In other words, male and older practitioners reported fewer mild transient reactions to treatment.

The rate at which practitioners reported mild transient events, an event being one or more symptoms associated with a single treatment, for every 100 treatments, is reported in Table 8. For every 1 unit (i.e. 20 treatments) increase in the number of treatments provided over the four week period, the odds of a mild transient event being reported reduces by a factor of 0.81 (95% CI 0.80 to 0.83). In other words, the larger the number of treatments given over the four weeks, the fewer the number of mild transient events recorded. For each individual type of reaction, a separate analysis was undertaken to establish if there was a significant association with the number of treatments given. At a significance of  $p < 0.0005$  an association was found for the following mild transient reactions: feeling energised, tired, relaxed, drowsy, dizzy and nauseous, sweating, temporary aggravations followed by an

Table 8 Transient event reporting rate



improvement, bruising and local pain. A less significant association ( $p < 0.05$ ) was found for mild aggravations (not followed by an improvement). No significant association with number of treatments was found for feeling faint and bleeding (for more than 10 seconds).

### Discussion

The study suggests that professional acupuncturists are committed to monitoring their safety record. It is encouraging that 574 (31%) members of the BAAC were motivated to complete the standardised self-report booklet over a four-week period. It is a credit to the profession that one in three members participated, given the complexity of the documentation and the potential for exposing one's safety record, either as an individual or as a profession. In this context it is known that not all professional associations are willing to co-operate in such surveys, as has been the experience in Germany (Peuker 2001, personal communication). Apart from this survey and that of White et al,<sup>12</sup> all previous large scale prospective surveys have been based within hospital or acupuncture teaching clinics.<sup>9-11</sup> As such, the two prospective surveys reported in this issue are breaking new ground.

The survey reported here has some specific limitations. In particular, generalising to the whole population of professional acupuncturists can only be done with caution. In this study we have

analysed the responding practitioners' sex, how long they had been in practice and where they trained. By comparing this sample with the data for the population of the BAAC as a whole, it is reasonably representative, i.e. sufficiently representative to not warrant a statistical re-weighting of data in compensation. There remains the potential criticism, however, that it is possible that only the 'good' acupuncturists participated, and therefore the results may be skewed towards underestimating the risks associated with acupuncture treatment.

A further limitation of this survey is that the reporting practitioners, in taking a subjective view of what happened in their self-reporting, may have omitted reactions and events. Such omissions could be either conscious or unconscious. To illustrate this point, it has been shown that the busier practitioners in this survey reported fewer mild transient events per treatment (see Table 8). Despite further analysis of the data, it is uncertain whether this effect was because the busier practitioners noticed the reactions of their patients less, gave less weight to the reporting of these reactions, or had patients who actually experienced fewer reactions. While these factors may have contributed to the generally lower levels of reporting of mild transient reactions by busier practitioners, there is evidence, in the case of two reactions, feeling faint and bleeding (for more than 10 seconds), that there was no significant drop off in recording levels as practitioners got busier. The reason for this may be that bleeding and feeling faint are relatively noticeable reactions, difficult for any practitioner to ignore. This suggests that there was no under-reporting of noticeable reactions from busier practitioners. On this basis one could argue that busier practitioners were unlikely to be under-reporting significant adverse reactions.

The most important finding from this survey is that there were no serious adverse events associated with 34,407 treatments provided by professional acupuncturists. Following Hanley's Rule of Threes,<sup>14</sup> we estimate that, with 95% confidence, the underlying serious adverse event

lies between 0 and 1.1 per 10,000 treatment episodes. This outcome parallels the prospective survey of White et al which was based on 32,000 treatments by physicians and physiotherapists.<sup>12</sup> The similarity between the two surveys is all the more striking when comparing the number of significant adverse events reported. In both prospective surveys, 43 significant adverse events were reported, none of them 'serious'. The surveys used very similar standardised self-reporting forms and the same definition of what constituted a 'significant adverse event', which makes the results directly comparable. Interestingly, the prospective survey of Yamashita et al reported 94 minor adverse events associated with 65,482 treatments,<sup>11</sup> a rate of 1.4 per 1,000 treatments, very similar to the 1.3 (95% CI: 0.9 to 1.7) of this survey.

In comparing acupuncture's safety to the record of drug-related adverse events, a comparison can be made with non-steroidal anti-inflammatory drugs (NSAIDs), which, when taken for at least two months, cause 1 in 1,200 patients to die from gastrointestinal complications.<sup>18</sup> Some 20 million prescriptions for this group of drugs are taken in the UK every year, resulting in between 3,500 and 12,000 hospital admissions.<sup>17</sup> Estimates of non-steroidal drug related deaths range from 2000 to 2,500 a year in the UK.<sup>18;19</sup> If one acupuncture treatment is equated with one prescription of this group of drugs, or even with one week of medication, then the evidence from this survey of acupuncture practitioners suggests that the adverse event rate associated with acupuncture may be orders of magnitude lower than that associated with NSAIDs.

Some adverse events are avoidable, for example those caused by errors in administering acupuncture and moxibustion. This is a category of adverse events that Yamashita et al argued should be identified separately as cases of 'negligence'.<sup>20</sup> In this survey such errors included failure to remove needles in two patients and moxa burns in another patient, an error rate of 0.0001%. These errors can be compared with those reported in other prospective surveys. For

example, Yamashita et al reported 27 cases of failure to remove needles and seven burn injuries from moxa,<sup>11</sup> an error rate of 0.05%. Because these patients were being treated in a teaching clinic, the authors of this study interpret their higher rate of forgotten needles as possibly being due to often having a different therapist removing the needles from the one who inserted them. This is highly unlikely to be the case in our sample.

In terms of study design, one of the main differences between this survey and that of White et al<sup>12</sup> was the range of mild transient reactions that were listed in the self-report documentation. In this survey a decision was made to explore what could be called 'positive' reactions to treatment, such as 'feeling relaxed' and 'feeling energised'. There was an explicit intention in this study to draw out the wider range of reactions that occur spontaneously following acupuncture. As a result a far higher incidence of mild transient reactions was reported in this survey, namely 10,920 reactions reported in 5136 treatments (i.e. 15% of the 34,407 treatments). In the survey by White et al,<sup>12</sup> which did not specifically ask about 'positive' treatment reactions, practitioners reported 2139 minor events (i.e. 7% of the 31,822 treatments).

The incidence of feeling faint in this study was 0.22% (n=78). This can be compared with 0.3% in the study of White et al 2001, and 0.2% (when including dizziness) in a Japanese study.<sup>11</sup> These results show a reasonable equivalence, leading us to conclude that a rate of 0.2% to 0.3% is a reliable guide to the incidence of feeling faint following acupuncture.

There has been considerable discussion in the literature about the frequency and significance of aggravations to existing symptoms associated with acupuncture. This effect is much reported by professional acupuncturists, along with an expectation that such aggravations are often followed by a strong improvement in symptoms soon afterwards, indicating an overall positive response to treatment.<sup>8</sup> In Japan this effect is called the 'Menken phenomenon', which Yamashita et al describe as a 'healing crisis'.<sup>11</sup> In their study of patients in a Japanese teaching clinic, practitioners

recorded that 1.1% of sessions resulted in an aggravation of pre-existing symptoms. In this survey we obtained data to explore the frequency of aggravations and the percentage of these that resulted in an improvement. We found that the incidence of aggravations of symptoms was 2.8% (n=966), of which 86% (n=830) subsequently improved. White et al reported that 1% of sessions resulted in an aggravation of symptoms, of which 70% subsequently improved.<sup>12</sup> These two studies are breaking new ground in reporting for the first time data on the rates of improvement after aggravations of existing symptoms. However, the extent that an aggravation influences the overall course of recovery awaits further exploration.

In terms of local mild transient reactions to treatment at or near the site of needling, pain on insertion was recorded at 1.2% (n=422) of sessions, which compares with the study of White et al of 1%.<sup>12</sup> Bleeding for more than 10 seconds after withdrawal of the acupuncture needle occurred in 0.4% (n=126) sessions and bruising 1.7% (n=587). The combined reactions of bleeding and haematoma in White et al showed an incidence of 3%.<sup>12</sup> These results demonstrate a reasonable level of comparability.

The relatively high rate of positive reactions to treatment reported was an important outcome from this study. Reports of 'feeling relaxed' in 11.9% (n= 4098) of treatments and 'feeling energised' in 6.6% (n=2267) are congruent with what many patients experience who attend for acupuncture. This spontaneous reaction tends to occur during or immediately after treatment. A series of interesting questions arise in this context. Do the same patients tend to respond in the same way after each treatment? Do these reactions tend to occur early on in a course of treatment, as suggested by Yamashita et al?<sup>20</sup> Do different types of patients tend to experience different types of reactions? And if so, are there useful predictors, such as for example the diagnostic categories of acupuncture theory? While these questions point towards future avenues of research, the major result here is that a considerable number of treatments result in the patient experiencing a

positive transient reaction, particularly feeling relaxed or energised.

A useful development of this study would be to survey patients and ask for their experience of adverse events following acupuncture. To date there have been no large scale (n>1,000) prospective surveys of patient reporting on adverse events. The evidence from smaller scale surveys,<sup>21</sup> with patients completing standardised questionnaires, is that patients report much higher rates of adverse events. It is possible that either patient questionnaires with suggestive checklists result in an over-estimate, or that practitioner surveys, with their dependence on the practitioner reporting, result in an underestimate of the adverse event rate. To address this issue, the Foundation for Traditional Chinese Medicine is currently undertaking a large scale prospective survey of patients' experiences of adverse events. Surveying patients will provide useful triangulation with the practitioner survey reported here. In addition, it will provide initial data in two further areas of concern; first, errors of omission by the practitioner, for example in not detecting a serious underlying pathology such as cancer and therefore not referring the patient to their primary care practitioner; and secondly, errors involving advice on medication, where practitioners may inappropriately advise their patients to reduce or discontinue medication without realising the consequences. The extent of these concerns is unknown.<sup>2,6</sup> Research in this area also has value in the development of good practice guidelines on appropriate referral, and communication procedures between professional acupuncturists and their patients' primary care practitioners.

### *Conclusion*

The primary result from this prospective survey is that no serious adverse events occurred in the 34,407 reported acupuncture treatments. This result is consistent with, given a 95% probability, an underlying serious adverse event rate of between 0 and 1.1 per 10,000 treatments. A total of 43 significant minor adverse events were reported, a rate of 1.3 per 1,000 (95% CI: 0.9 to

1.7). These events included severe nausea and fainting, aggravations of existing symptoms, local pain and bruising at the site of needling, and psychological and emotional reactions. In addition, practitioners reported that 10,920 mild transient reactions occurred in 5136 of the treatments, i.e. 15% of all treatments (95% CI: 14.6 to 15.3), most of these involving the patient feeling relaxed or energised.

The 574 practitioners who participated in this survey comprised one in three members of the BAaC. That such a large percentage of the total membership of a professional association took part is a measure of acupuncturists' commitment to the safety of their patients. Compared with existing evidence on the risks associated with NSAIDs, acupuncture when practised by professional acupuncturists who are members of the BAaC is a relatively safe intervention. Given that the whole membership delivers between one and a half and two million treatments a year, this survey provides important evidence on public health and safety. Further research into the patients' experience of adverse events is merited.

#### Acknowledgements

The authors would like to thank the 574 BAaC practitioners who took part in the survey, the project steering group members Rosy Grandage and Nicola Owen, and the project advisors Alan Bensoussan, Stephen Birch, Alan Breen, Roy Carr-Hill and Adrian White.

#### Reference list

- Ernst E, White A. Acupuncture: safety first. *BMJ* 1997;314(7091):1362.
- British Medical Association. *Acupuncture: efficacy, safety and practice*. Harwood Academic Publishers; 2000.
- House of Lords Select Committee appointed to consider Science and Technology. *Sixth Report: Complementary and Alternative Medicine*. London: The Stationary Office; 2000.
- MacPherson H. Fatal and adverse events from acupuncture: allegation, evidence, and the implications. *J Altern Complement Med* 1999;5(1):47-56.
- Norheim AJ, Fonnebo V. Acupuncture adverse effects are more than occasional case reports: Results from questionnaires among 1135 randomly selected doctors, and 197 acupuncturists. *Complement Ther Med* 1996;4(1):8-13.
- Bensoussan A, Myers SP. *Towards a safer choice: the practice of traditional Chinese medicine in Australia*. Faculty of Health, University of Western Sydney McArthur; 1996.
- White A, Hayhoe S, Ernst E. Survey of adverse events following acupuncture. *Acupunct Med* 1997;15(2):67-70.
- MacPherson H. How safe is acupuncture? Developing the evidence on risk. *J Altern Complement Med* 1999;5(3):223-4.
- Umlauf R. Analysis of the main results of activity of the acupuncture department of Brno hospital. *Acupunct Med* 1988;5(2):16-8.
- Chen FP, Hwang SJ, Lee HP, Yang HY, Chung C. Clinical study of syncope during acupuncture treatment. *Acupunct Electrother Res* 1990;15(2):107-19.
- Yamashita H, Tsukayama H, Tanno Y, Nishijo K. Adverse events in acupuncture and moxibustion treatment: a six-year survey at a national clinic in Japan. *J Altern Complement Med* 1999;5(3):229-36.
- White A, Hayhoe S, Hart A, Ernst E. Adverse events following acupuncture: prospective survey of 32 000 consultations with doctors and physiotherapists. *BMJ* 2001;323(7311):485-6.
- MacPherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34 000 treatments by traditional acupuncturists. *BMJ* 2001;323(7311):486-7.
- Eypasch E, Lefering R, Kum CK, Troidl H. Probability of adverse events that have not yet occurred: a statistical reminder. *BMJ* 1995;311(7005):619-20.
- White E. *Attitudes and profile of members of the British Acupuncture Council*. British Acupuncture Council; 2000. p. 71.
- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA* 1998;279(15):1200-5.
- Moore A, McQuay H. NSAID focus. *Bandolier* 1998;52.
- Tramer MR, Moore RA, Reynolds DJ, McQuay HJ. Quantitative estimation of rare adverse events which follow a biological progression: a new model applied to chronic NSAID use. *Pain* 2000;85(1-2):169-82.
- Blower AL, Brooks A, Fenn GC, Hill A, Pearce MY, Morant S *et al*. Emergency admissions for upper gastrointestinal disease and their relation to NSAID use. *Aliment Pharmacol Ther* 1997;11(2):283-91.
- Yamashita H, Tsukayama H, Hori N, Kimura T, Tanno Y. Incidence of adverse reactions associated with acupuncture. *J Altern Complement Med* 2000;6(4):345-50.
- Ernst E, White AR. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med* 2001;110(6):481-5.



## A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists

Hugh MacPherson, Kate Thomas, Stephen Walters, et al.

*Acupunct Med* 2001 19: 93-102

doi: 10.1136/aim.19.2.93

---

Updated information and services can be found at:

<http://aim.bmj.com/content/19/2/93>

---

### References

*These include:*

Article cited in:

<http://aim.bmj.com/content/19/2/93#related-urls>

### Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

---

### Notes

---

To request permissions go to:

<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:

<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:

<http://group.bmj.com/subscribe/>